Tips for TIPS

A Three-dimensional Ultrasound based User Interface for the Transjugular Intrahepatic Portosystemic Shunt Procedure

Proefschrift

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Glossary of Acronyms

2D	Two-Dimensional
3D	Three-Dimensional
CT	Computed Tomography
HCI	Human Computer Interaction
HF	Human Factors
HV	Hepatic Vein
IG	Image Guidance
IR	Interventional Radiologist
IVC	Inferior Vena Cava (Hollow Vein)
JV	Jugular Vein
MR	Magnetic Resonance Imaging
PV	Portal Vein
RFA	Radiofrequency Ablation
STW	Stichting voor de Technische Wetenschappen
TIPS	Transjugular Intrahepatic Portosystemic Shunt
UI	User Interface
US	Ultrasound
DSA	Digital Subtraction Angiography
Fluo	Fluoroscopy

..But you obviously puncture in three dimensions, in other words there is one dimension in which you puncture blindly... and because of that you will not always, at the first attempt, arrive in the portal vein. It means that you have to puncture the liver multiple times (to save the life of the patient). In the meantime, those punctures can cause internal bleeding and it will extend the procedure. A prolonged procedure means that the patient is under anaesthesia for a longer time, it also means you will use more X-ray which is harmful for you, the patient and operators.'

[An Interventional Radiologist during an interview, 2011]

Chapter 1: Introduction

1.1 Interventional radiology

Interventional radiology is a medical sub-specialty of radiology. Nearly every organ system can be diagnosed and treated with interventional radiology. During an interventional procedure, interventional radiologists (IRs) make a small incision in the patient's body, into which long, thin instruments are inserted and navigated towards the lesion, for example a tumour, to treat the disease. Depending on the ailment, IRs may apply the endovascular approach by inserting instruments into a shallow blood vessel, then guiding them through the vascular network to the target [JOMI2006]. The vessel's anatomy determines the available routes while navigating the needle inside the body. Alternatively, IRs can also apply the percutaneous approach by sticking through the skin towards a predefined target area [DAFF1999]. During an interventional procedure, IRs navigate instruments through the body and are guided by images from ultrasound (US), computed tomography (CT) and other radiological images. The images are created before or during the procedure. They help IRs to plan, perform and evaluate the diagnostic and therapeutic procedures [DAFF1999].

Interventional radiology has advantages compared to conventional surgery. First, an interventional procedure is less invasive, consequently the number of complications, hospital stays, costs and morbidity are lower than in conventional surgery [DAFF1999; FREU2010]. High-risk patients who should not undergo surgical treatment may be treated with interventional radiology (KAUF2014]). Another advantage is that interventional procedures can be combined with surgery to improve the outcomes of surgical operations. A typical example is the embolization of spinal tumours [OZKA2011]: before the surgery, surgeons may ask IRs to perform an intervention to block the artery of the patient's spinal tumour. As a result, blood loss during surgery may be reduced and a complete resection of the tumour is possible [GEMM2009].

Interventional radiology also has advantages over other minimally invasive procedures, such as laparoscopy. During a minimally invasive procedure [BUZI2010; CALI2013], surgical instruments are inserted through anatomical openings or through the skin into the body cavity. The procedure is facilitated by (a) video camera(s). Where those minimally invasive procedures allow the evaluation and performance of surgery on organs and tissues in the abdominal and thoracic cavities, interventional radiology allows access to structures throughout the whole body [TOBI2013]. Although each procedure has different benefits, in general interventional radiology procedures are less complicated and invasive [MINA2011; KIM2013; ZHU2013].

However, an interventional procedure is not without problems. For example, there is no direct vision of the target area, the conventional image guidance (IG) only presents 2D information, crucial information is often unavailable or inappropriately presented and the IG is often poorly integrated in the workflow [JALO2008; VARG2012; VARG2013]. As a result, the perceptual, cognitive and physical demand on the IRs is high [VARG2012]. The procedures are complex and the quality of a procedure may be affected by errors [JALO2008; CLAS2014]. An example can be found in a typical interventional procedure: the radiofrequency ablation (RFA). The goal of a RFA is treating various tumours and certain internal pain sources. During a RFA, IRs use CT, US or magnetic resonance imaging (MRI) to visualize the target. Based on the information from the IG, IRs estimate the target location and advance a needle towards that location. If the needle is correctly positioned in the target, IRs can ablate it. However, due to the limited IG, IRs often have to first advance the needle before they are able to check its position. Thus, the needle is frequently mispositioned and needs to be adjusted. Multiple modifications are often required, which may introduce new risks [TAKA2012; CLAS2013]. Improving IG systems may prevent errors and therefore provide patients and caregivers with more satisfaction [JALO2008].

The TIPS procedure

The focus of this thesis is to provide an IG user interface (UI) for one of the most technically challenging interventional procedures [FUNA2008], named the transjugular intrahepatic portosystemic shunt (TIPS) procedure. During the TIPS procedure, a shunt is created in the liver to decrease the high blood pressure for patients with portal hypertension [GOYK2010]. Normally, the blood coming from the intestines and spleen flows into the liver via the portal vein (PV), as illustrated in Figure 1. After being filtered by the liver, the blood continues to flow via the liver vein (hepatic vein (HV)) into the hollow vein (vena cava inferior (IVC)) towards the heart. However, some patients suffer from a scarred liver, called liver cirrhosis, which may be caused by alcohol abuse or viral hepatitis [BRAN1974]. Liver cirrhosis causes increased downstream resistance in the PV by impeding the blood flow. In this case, the blood flow through the liver is disrupted, and portal hypertension develops [GOYK2010]. The body responds by producing new veins, named collateral vessels. The collateral vessels let blood flow around the liver and back to the heart. Nevertheless, if this mechanism also fails, the increased pressure in the PV can lead to internal bleeding from the collateral vessels (variceal haemorrhage) and/or can cause an abnormal amount of fluid in the abdomen (refractory ascites). If the condition is not addressed, it is very likely that the patient will die [ELAT2012; LOFF2013]. Thus, both situations are main indications for the TIPS procedure [OWEN2009; GOYK2010; PATI2014].

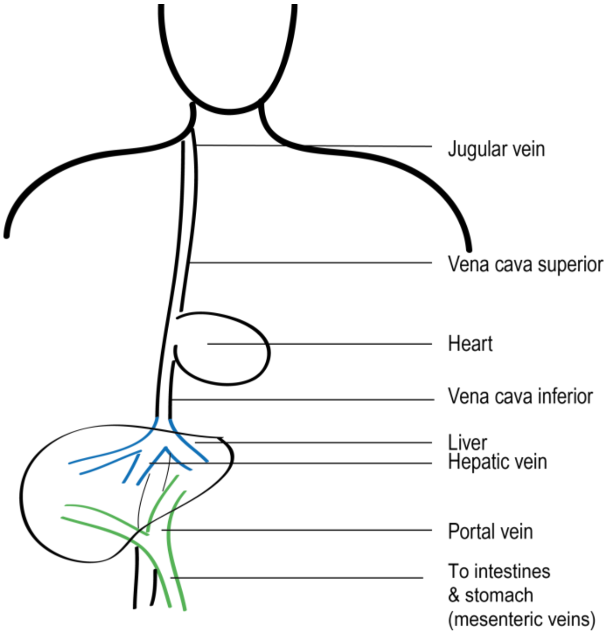


Figure 1: Important human anatomy for TIPS.

IRs navigate instruments from the patient's neck, via the vena cava, into the HV. Via the HV they stick a needle through the liver into the PV. The puncture is referred to as the transhepatic or, as it will be called in this thesis, intrahepatic puncture. Based on the PV access created by the intrahepatic puncture, a stent can be positioned between the HV and PV. The new shunt will bypass blood from the liver to the systemic circulation. The newly created blood flow decreases blood pressure in the portal system [CLARK2008], thus extending the patient's life [BERR2015]. The procedure is complex and has potential risks. For instance, the diverted blood flow may worsen the liver function and increases the risk of the brain swelling (hepatic encephalopathy) [OWEN2009]. However, it is a lifesaving procedure for patients with complications of portal hypertension [BOYV2006; PILI2009].

Several imaging modalities can be used to guide IRs during the TIPS procedure. Currently, the following modalities are often used: 1) pre-operative MR imaging or CT; 2) intra-operative fluoroscopy (Fluo); 3) Fluo in combination with digital subtraction angiography (DSA). The advantages of CT and MR is that they provide detailed anatomic information of the area of study [DAFF1999; HAAG2001], which is why they are often used to plan the procedure. Fluo is applied to help IRs navigate their instruments through the body and to create TIPS [ADAM2009]. This imaging modality enables IRs to select an area of the patient and to visualize the structures of the selected area which are visible under Fluo (radio-opaque structures), such as the instruments. During a procedure, IRs often activate the Fluo by foot in order to free their hands for other tasks. By injecting contrast in the lumen of the veins a DSA can be created. The DSA is used to visualize the contrast filled blood vessels on Fluo [DAFF1999].

Nevertheless, these imaging modalities also have their limitations. First of all, health risks, such as radiation burns or cancer, make X-ray based CT and Fluo harmful for patients, physicians and the environment. Exposure rates are therefore minimized and strictly controlled. Besides, noxious contrast dye has to be used to create the DSA images. The contrast dye may cause life threatening allergic reactions and can worsen kidney conditions. In addition, acquiring CT or MR images are time consuming processes and they can only be conducted before the TIPS procedure. Thus, CT and MR cannot provide real-time information. For Fluo images, the soft tissues cannot be visualized and IRs can only activate Fluo for a short time during the lengthy procedure [LIVI2011] due to its harmful characteristics [SUHOVA2003; FRUSH2004; PICANO2004]. Table 1 summarizes the attributes of those image modalities and their limitations regarding the TIPS procedure.

When acquired?	Pre-operatively	Intra-operatively
Imaging modalities	CT/MR	Fluo and DSA
Contents of images	Provides detailed information of the anatomy Used to plan the procedure	Fluo: see instrument movement DSA: see the location of the -with contrast filled- blood vessels
Limitations	Offline CT uses harmful radiation	Fluo and DSA: not 3D, use harmful radiation Fluo: does not visualize soft tissues DSA: injected contrast only visible under Fluo for a few seconds, contrast is noxious

Table 1: Intrinsic properties of the imaging modalities currently used during the TIPS procedure

1.2 The problem

Even though several imaging modalities are available for the TIPS procedure and these are often helpful, the IG is still recognized as insufficient [SOLO1999; KEW2004]. The insufficient IG is making the three-dimensional (3D) navigation process challenging and risky [ALAS2009], especially when performing the intrahepatic puncture [PILI2009;

ROSE2000]. According to Owen *et al* [OWEN2009] indicating and gaining access to the PV is the most challenging part of the TIPS procedure. Based on previous research [SCAN2008; GABA2011], it was identified that IRs constantly update their knowledge of the needle position in relation to the vascular anatomy by acquiring information from different available images. However, at present information is incomplete and only limited real-time two-dimensional (2D), and the UIs are not ergonomically well-designed [SOLO1999; VARG2012].

As IRs do not see the target when they strive to gain access to the PV [BOYV2006], the puncture is regularly referred to as a blind puncture [FANE2006; ADAM2009]. Multiple punctures are often required, which can cause injury to the patient's body [ADAM2009]. The quote on the introduction of this chapter illustrates this problem. If the IG for the navigation and puncture process can be improved, the TIPS procedure could be less complicated and risky.

1.3 Improve guidance with the use of US

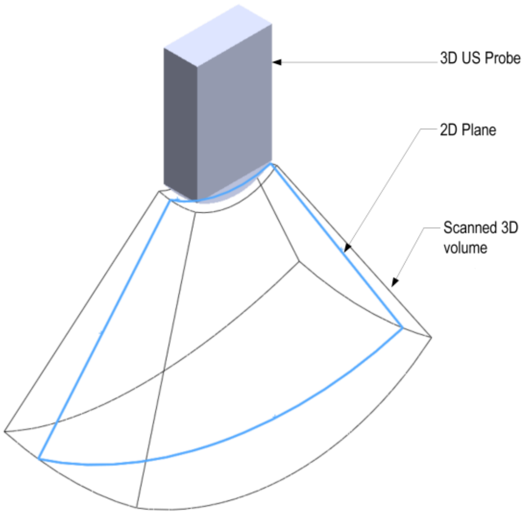


Figure 2. A three-dimensional ultrasound volume (cone), containing a two-dimensional view plane.

To provide IRs with more information during the TIPS procedure, 2D US was introduced as an additional IG aid to CT, Fluo and DSA [e.g., LIVI2011]. In contrast to other imaging modalities, US has the following advantages [NICO2007]. It can 1) be used pre-operatively and intra-operatively; 2) visualize both the anatomy and instruments in real-time and 3) it does not use harmful radiation.

Despite the benefits of 2D US, the effectiveness of 2D US mainly depends on the patient's anatomy [ROSE2000] and the skills of the operating IRs. For example, they have to position and control the US probe to acquire the images [NICO2007]. Rose *et al* [ROSE2010] describes that, as a result, 2D US has limited applicability for guiding the TIPS procedure [ROSE2010]. Due to this, 2D US is not frequently used during the procedure [CARR2006].

3D US is a rather new imaging modality. In contrast to 2D US, interactive 3D US displays clear advantages in guiding the TIPS procedure [ROSE2010] compared to other IG techniques [KIM2001]. For example, it can continuously scan a 3D volume of the body to generate real-time images, such as 2D section planes of the 3D volume (Figure 2), for visualizing both instruments and anatomy [FENST2000; ROSE2000; ROSE2001; OBRU2008; FUKU2012]. Moreover, in the initial research preceding this project, designers, engineers and IRs worked together and found that interactive 3D US has potential for improving TIPS, especially due to its ability of using harmless sound waves to provide real-time information [project proposal]. 3D US will therefore be the basis for the design. However, the current interactive 3D US UI are complex and do not fit IRs' way of working. For instance, a second IR and significant user interventions are required during the procedure to select workable view planes in the 3D volume [OBRU2008; FENS2011].

1.4 The scientific gap

Currently, clear requirements on what elements to integrate in a UI to effectively guide IRs during the TIPS procedure are unavailable. To provide IRs with sufficient spatial information to effectively and efficiently navigate through the body in 3D, the UI should present the end users with the right information at the right moment and in the right way [FREU2007; KERS2013]. Although literature provides some indications of which TIPS UI improvements can be made and how, the required knowledge to simplify a TIPS procedure still needs to be formed, and human factor (HF) principles have rarely been addressed. In the past, many research groups tried to improve the TIPS procedure [e.g., MAUP2005; JOMI2006; ADAM2009, MALE2010, LI2012]. Most of them restricted their focus on one specific aspect of the procedure regarding technical elements, such as testing image registration or system accuracy [KERS2013]. However, clinical needs and operational constraints were not fully reflected in those designs. For instance, arguments regarding different UI elements were hardly found and descriptions of the performance requirements, desired improvements, user characteristics, user needs, the task analysis and other workflow aspects were also omitted. Furthermore, few evaluated the system's effectiveness and efficiency, nor the clinical use to demonstrate the medical needs of the systems. A poorly designed UI may mislead IRs in interpreting the provided information, resulting in wrong decisions or a high stress level that could affect patient survival. As stated by Stüdeli *et al* [STUD2008; STUD2009]: '*the human body as a navigation environment has some specialties and actual surgical navigation systems do not cover the natural human navigation process sufficiently*' [Page318, STUD2009]. In order to improve the IG in TIPS, a deeper understanding of the medical procedure and users' behaviour is required. This is needed to avoid negative consequences caused by using the information system, such as impairment in adoption and user satisfaction [UNER2006]. Furthermore, analysis of IRs' cognitive processes is crucial to design a successful system. Westrenen *et al* [WEST2010] point out that design requirements are based on procedural requirements and cognitive demands, the information provided by the UI must suit the users' cognitive requirements. According to Kushniruk [KUSH2002], designers should understand how physicians process information and how they make decisions. Understanding of these cognitive processes is essential for providing design inputs and evaluating effects in designing healthcare information systems. Besides, Patel *et al* [PATE2001] state that a medical system should be informed by users' cognitive constraints and information process. In short, a medical information system can be improved by addressing the knowledge, memory and strategies used in cognitive activities.

Many researchers are developing computer graphics techniques to visualize medical imaging data [e.g., PREI2014]. Advanced visualization techniques have shown great clinical utility, for instance 3D visualization of a patient's tumour [GOLB2011]. However, this thesis focuses on finding out what types of information are needed in the UI for IRs in the first place. In the future, based on medical image visualization techniques and advanced infrastructure, it is possible to provide the visualization content in a better form. In short, the area of medical image visualization is not within the focus of this thesis, but can be a follow-up of this research.

1.5 Design goal

The goal of this thesis is to design an interactive 3D US based UI for IRs to minimize the number of punctures during the TIPS procedure. To design such a UI, concrete design requirements are needed regarding what information should be presented, and when and how it should be presented. Therefore, the design goal will be supported by the main objective of this thesis: unveil what information should be presented in an interactive 3D ultrasound based UI to minimize the number of punctures during the intrahepatic puncture of the TIPS procedure. For this, this thesis will focus on answering several research questions, namely:

- What is the current TIPS workflow? What are the related challenges? What do IRs need from the IG system? What are indicators to overcome those challenges?
- What are the opportunities of using interactive 3D US to address these challenges?
- What information can be presented on the integrated interactive 3D US based UI to effectively and efficiently guide IRs during TIPS?
- Which information is crucial to integrate in an interactive 3D US based UI to minimize the number of intrahepatic punctures in TIPS?

Based on the acquired knowledge, a Planning-UI and Puncture-UI will be developed. The UIs will be used to answer the final two research questions:

- What information shall be integrated in an interactive 3D US based UI to effectively and efficiently plan the intrahepatic TIPS puncture?
- What information shall be integrated in an interactive 3D US based UI to effectively and efficiently perform the intrahepatic TIPS puncture?

1.6 The approach

This dissertation deals with several research and design challenges. Assessing workflow complications and IRs' requirements and understanding possibilities of interactive 3D US navigation are all examples of these challenges. For this, a series of design approaches and research methods are used in the research.

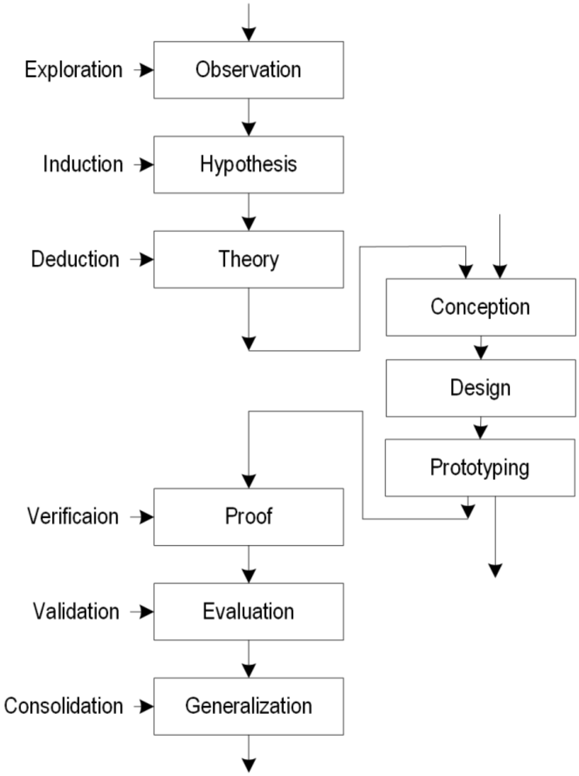


Figure 3. The DIR approach (courtesy of [HORV2007])

First of all, the Design-Inclusive Research (DIR) approach will be used as a framing methodology. DIR allows the systematic blend of the two domains of learning, namely research and design [WANG2002]. It allows the researcher to combine scientific study and designer enquiry in a reliable way [HORV2007] in developing knowledge about how to design an interactive 3D US based UI to minimize the intrahepatic punctures. The DIR consists of three different phases, namely explorative research, creative design and confirmative research, as illustrated in

Figure 3.

DIR is mainly based on conventional design approaches where designers are familiar with the context of the design research [HORV2007]. However, the proposed design research is a multidisciplinary research where multiple stakeholders are engaged and they are not familiar with the other disciplines. Therefore, to accelerate the design process, an iterative process of co-design research will be applied during each of the three phases. The co-design approach is based on the process described by Freudenthal *et al* [FREU2011]. It is applied in order to a) combine the theory and practice through reflection and modification during each cycle of activities and b) maximize innovation in the development of an effective UI. Each iteration is characterized by a cycle of four steps: 1) planning a change; 2) acting to realize the change; 3) observing the process and the consequences of the change and 4) reflecting on the process and its consequences [KEMM2014] as illustrated in
Figure 4.

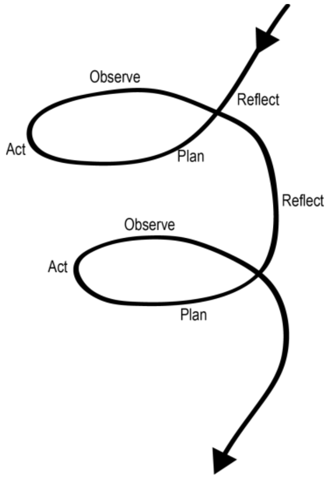


Figure 4. The iterative process of collaborative co-design research.

Applying co-design also means that during the different activities of the iterative process, the author works within a multidisciplinary team where different stakeholders are engaged. The team is committed to collaborate within the workgroup [KLEI2003; DANE2006; FREU2011]. In the design process every team member brings in new expertise to contribute to the solution [KVAN2000], which will support the production of a complete design [FREU2011]. During this research project, co-design will be achieved by having frequent discussions and brainstorming meetings, and by developing and testing prototypes[1] within the team and with invited users. The collaboration among different stakeholders gives the opportunity to quickly, even on-site, fill the knowledge gaps, solve problems and verify design proposals. Using co-designing, knowledge about how to design the UI will be gradually but quickly be collected, generated, verified and validated in each iteration [SPIN2006]. In the design process, nine co-design iterations were performed.

[1] * the term ‘prototype’ refers to the term used in design research [e.g., SAND2014]. In the design research community this term is commonly used for tools which are made to explore a future situation. In this thesis it is thus not a fully functional prototype of a product, but a prototype which represents some aspects of the product. This type of research tool is also named 'mock-up' in other research areas, such as biomedical engineering.

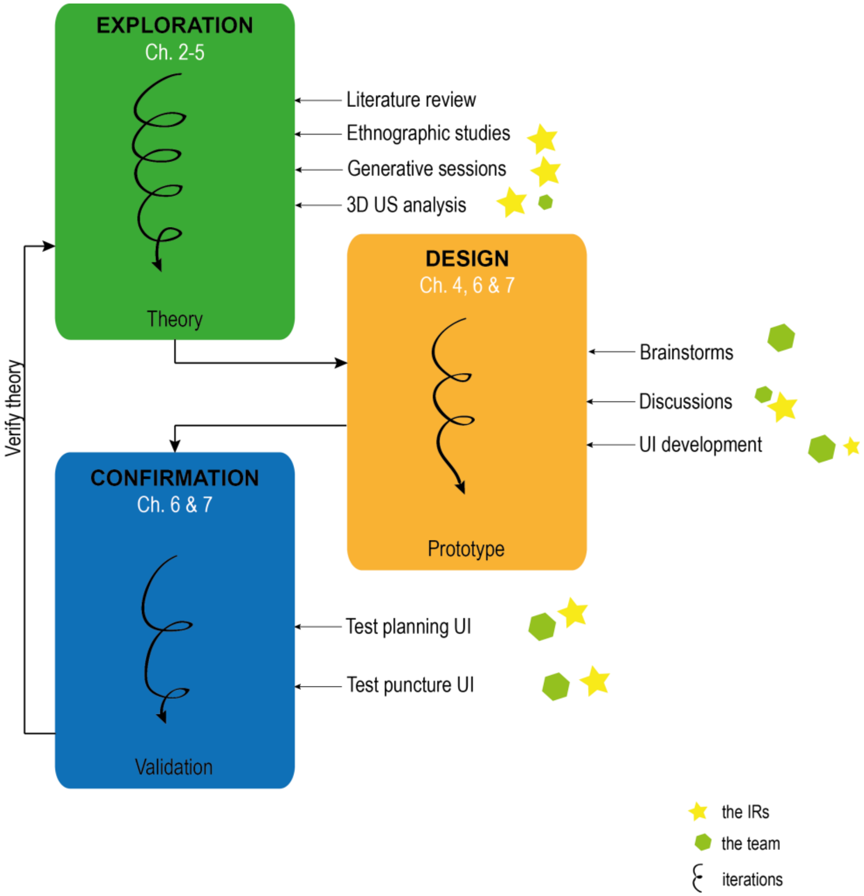


Figure 5. The research phases and nine iterative design processes of this thesis, mainly based on DIR and collaborative co-design.

Methods from user-centred design, user interface design, system ergonomics, and cognitive ergonomics or HF [FREU2010] were also used within the approach. By combining the different research methods the advantages of each could be utilised. Figure 5 illustrates the complete process and related chapters of the thesis. It demonstrates the activities, the intensity of the iterations and the output per exploration, design and evaluation phase, which was described as pre-study, design process and post-study in the DIR research method [HORV2007], respectively. The figure also shows the collaboration with the team (polygon) and IRs (star) and the size indicates the intensity. As a result, information requirements for the interactive 3D US UI could be unveiled and, at the same time, a working prototype was developed.

To minimize the puncture attempts during the TIPS procedure with the new UI (section 1.5), a combination of research activities was used within the proposed approach. These research activities were:

- Explore the procedure and 3D US to systematically reveal aspects such as workflow and 3D US UI requirements with the IRs and the team. This was done in four research actions, by: 1) analysing the literature (literature review); 2) studying the procedure, the users and their context (ethnographic studies); 3) organizing meetings to unveil IRs' tacit knowledge (generative sessions); and 4) using existing 3D US UI's. The goal was to:
  - aggregate and construct knowledge related to the TIPS procedure, the interactive 3D US, UI design;
  - formulate critique of the current understanding;
  - set goals and develop comprehensive theories to solve the research and design problem.
- Design creative solutions with the team and IRs, through 1) brainstorming; 2) discussions; and 3) prototyping. The goal of this phase was to:
  - conceptualize and design UI concepts;
  - prove the feasibility of ideas.
- Confirm research actions by testing the UI's with IRs in a realistic setting, by conducting interviews, questionnaires and observations. This was done to:
  - verify theory;
  - validate findings;
  - examine whether the number of punctures can be minimized.

1.7 The team

As stated before, the author of this dissertation was a member of a multidisciplinary team (Table 2). The team was formed at the beginning of the project. Since the design challenge required understanding of several disciplines, such as hardware, software, design, HF and medicine, the team consists of a total of seven members: two industrial designers (one is the author/leading researcher), two biomedical image technology developers, a computer scientist and two IRs. The team's aim was to decrease the number of interventional challenges by developing an interactive 3D US UI. By doing so, the team wanted to improve the procedure's outcome, for example, by reducing the risks for patients, such as radiation risks; decreasing complications, improving procedural aspects, such as decreasing the number of punctures and by reducing the mortality rate in TIPS. As a result, patients who were not eligible for interventional therapy can be treated due to the reduced risks. Furthermore, the team expected that once the interactive 3D US solution is available for needle interventions, it could also be adapted to other interventional domains, for example vascular interventions, US guided biopsy of prostate cancer, or implantation of radiotherapy beads in brachytherapy.

	Coordinator	Medical details	Workflow	Medical Imaging	Software Design	Human Factors	Human Computer Interaction	User Interface Prototype Design
Industrial design engineer (author/leading researcher)			X-TIPS			X	X - TIPS	X
Industrial design engineer	X							
Computer scientist			X-RFA		X	X	X- RFA	X
Two IRs		X	X					
Two biomedical image technology developers				X				

Table 2. The multidisciplinary team and subdivision of aspects.

Each member had specific relevant expertise and a different task within the group. In addition, a group of IRs and medical product company representatives monitored the team's processes, and the companies provided the team with training and devices, such as a 3D US machine (iU22 with X6-1 probe [PHIL2015]), when required. The project was financed by the foundation of Stichting voor de Technische Wetenschappen (STW) [STW] and Philips® Healthcare [PHIL].

Users, in this case the IRs, played an important role in the multidisciplinary team (star symbol in Figure 5). Kristensson *et al* [KRIST2004] observed that by involving the users, the ideas will be more creative, more highly valued by the users, and implemented more easily. From Rittel *et al* [RITT1973], we can assume that only the users can judge if the solution has a positive or negative effect on the situation. In the proposed research, two IRs joined the team, and several others were asked to help the team if needed. By actively involving the IRs during the nine iterations, the team was able to optimise the solution and evaluate IRs' performance and patient safety quickly [FERR2005; MANZ2009]. Instead of being simply asked "what do you want?" the needs and characteristics of IRs were the focus in each iteration of the design [GOSB2002; MATT2004]. In this research, IRs contributed to each phase of the co-design process: in phase 1) they helped to analyse and redesign the workflow, participated in brainstorming sessions on how to improve the current procedure and provided feedback on concepts; in phase 2) they helped to generate ideas and in phase 3) tested the prototypes.

In the initial research of this project the project goal and application area were defined and a promising modality was chosen. In addition, the project was organized in three work packages: 1) Workflow analysis and user interface design; 2) Integration of pre-operative CT data with interactive 3D US in the interventional scene and 3) Evaluation and validation. Throughout the process, the author mainly focused on aspects 1 and 3.

In the research process, the team initially desired to improve two interventional procedures, namely RFA and TIPS. Halfway through the project, the team decided to primarily focus on the TIPS procedure. The main reasons were that a) towards the end of the project, the TIPS UI was closest to clinical practice; b) it became clear that a UI to improve the TIPS procedure can also be applied in other interventional procedures.

1.8 The structure of the thesis

Following the approach presented in Figure 5, this thesis reports the related activities in eight chapters. Figure 6 illustrated the logical relations among those chapters of the three research phases. Except this chapter, the figure shows:

- *Chapter 2: Literature review* reviews related literature based on the framework of the research. It includes literature research on the TIPS procedure and the solutions of other imaging research groups, unveils current UI solutions and guidelines and identifies what is needed to improve the IG for the TIPS procedure;
- *Chapter 3: TIPS procedure and challenges* presents an overview of the TIPS workflow. It reports the study of the TIPS procedure, medical staff, IRs' navigation process and related challenges. It also identifies opportunities for making the procedure more safe, effective and efficient;
- *Chapter 4: 3D US navigation* investigates limitations of current 3D US and shows what information to present, according to IRs and the researcher, in an interactive 3D US UI to make the imaging modality useful for the TIPS procedure. Concrete examples of preferred view planes per step of the workflow are provided;
- *Chapter 5: Focused TIPS problems and solutions* integrates the knowledge from the previous chapters and presents a strengthened framework of primary improvements needed;
- *Chapter 6: The Planning-UI*, presents the Planning- UI, which is developed for planning the TIPS procedure based on the insights from Chapter 5. Its ability to effectively and efficiently plan an intrahepatic TIPS puncture were tested with five IRs;
- *Chapter 7: The Puncture-UI* presents an interactive 3D US UI to help IRs perform intrahepatic puncture based on the insights from Chapter 5. The effectiveness and efficiency of the UI was evaluated by 28 IRs, based on experiments conducted during a medical conference (CIRSE 2013, www.cirse.org);
- *Chapter 8: Discussion and Conclusion* discusses outcomes of the research. Limitations of the research are presented as well to provide suggestions for future research. Finally, it summarizes the original contributions of this research.

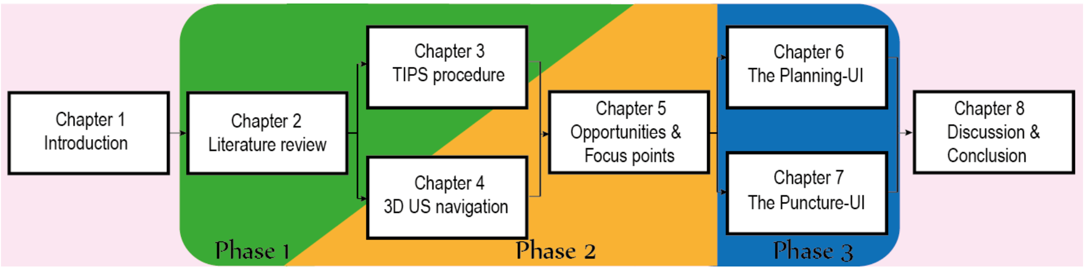


Figure 6. Structure of this thesis.

Chapter 2: Literature review

This chapter presents a review of existing literature to support the study undertaken in this thesis. Centred by the goal of the research: *design a real-time 3D US based UI for IRs to minimize the number of punctures during the TIPS procedure*, section 2.1 first defines a research framework for designing a 3D US based UI for the TIPS procedure. User interface, medicine and medical technology are the three pillars of the research framework. In section 2.2, the review starts by introducing the TIPS procedure. Thereafter the section reveals the disadvantages of the procedure, especially those which are related to IG problems and gaps. Based on the basic understanding about the TIPS procedure, section 2.3 and 2.4 respectively review research on IG solutions and UIs. The chapter ends by giving a brief conclusion on research which should still be conducted to accomplish the design goal.

2.1 The research framework for designing a 3D US UI for the TIPS procedure

In finding an effective way of designing a suitable UI for the TIPS procedure, it was determined that a schematic view, or framework would be useful: a) for defining the relevant topics; b) in structuring the research; c) for guiding the researcher on how to study and design the TIPS UI, and d) for defining relevant design directions. To frame this thesis, the following domains were consulted:

- Medical literature about interventional radiology, the TIPS procedure and other minimally invasive procedures;
- Publications regarding the imaging modalities, to gain understanding of the different IG systems used in interventional radiology (these will be further discussed in Chapter 4);
- Publications about psychology, human computer interaction (HCI) and HF. Psychology literature was reviewed to gain insights on human navigation behaviour, such as navigation processes, navigation guidance, visual navigation information. The other domains were reviewed to learn more about navigation UI solutions and related examples from interventional radiology and other minimal invasive domains, such as laparoscopy. Besides, navigation UIs from other 3D navigation fields, for example gaming and aviation were consulted as well.

The literature search was performed in Google Scholar (www.scholar.google.com), PubMed (www.ncbi.nlm.nih.gov/pubmed), Scopus (www.scopus.com) and Science Direct (www.sciencedirect.com) from December 2010 till February 2015. The first two databases were most frequently used. Examples of search terms used were 'interventional radiology', 'interventional procedures', 'transjugular intrahepatic portosystemic shunt' and 'three-dimensional ultrasound'. The references and citing papers of relevant papers were sometimes consulted as well. Some examples of related journals which were consulted are Radiology; Vascular Interventional Radiology; Medical Image Analysis; Cognition, Technology and Work; International Journal of Human-Computer Interaction; the Journal of the Human Factors and Ergonomics Society. In addition, books, for instance about HF engineering and 3D user interfaces were read as well. Table 3 provides an overview of the framed research domains. In the table, the left column highlights the goal, the corresponding disciplines are listed on the right. Within this framework, knowledge on different domains can be associated and possible solutions and requirements can be unveiled.

Why? – The goal	**What? – The topics**
Guidance…	User interface – Usability: • Human computer interaction • Human Factors • Psychology
…in the TIPS procedure…	Medicine: • The TIPS procedure • Interventional radiology • Minimal invasive surgery
…through 3D US.	Medical technology: • Ultrasound • Fluoroscopy (and angiography) • Computed Tomography • Magnetic resonance imaging

Table 3. Framework for designing a 3D US based UI for TIPS

2.2 The TIPS procedure

The main goal of the TIPS procedure is to divert the blood flow of patients with portal hypertension by creating a permanent shunt in the liver. Before providing a literature review about how this TIPS procedure is performed, an introduction of the TIPS context will be given. Understanding the context provides a basis for understanding the procedure. Besides, the context influences the product limitations and requirements.

2.2.1 The diagnosis and the preparation

As said in *Chapter 1*, the two main indicators for TIPS creation are variceal haemorrhage and/or refractory ascites [PATI2014], as demonstrated in Figure 7. Literature [FUNA2008; POMI2012] emphasizes that when diagnosing the possibility for a TIPS procedure, IRs always closely collaborate with a multidisciplinary team which consists of hepatologists, cardiologists, intensive care specialists and transplant surgeons. The patient is only considered for TIPS if the team agrees that TIPS is the best solution for the patient.

Figure 7. Example of a TIPS patient suffering from refractory ascites, courtesy of [ASCI2014].

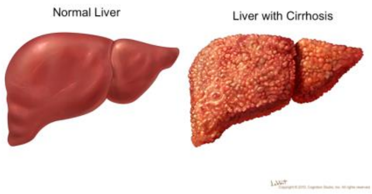


Figure 8. Normal versus cirrhotic liver, courtesy of [GORG2013]

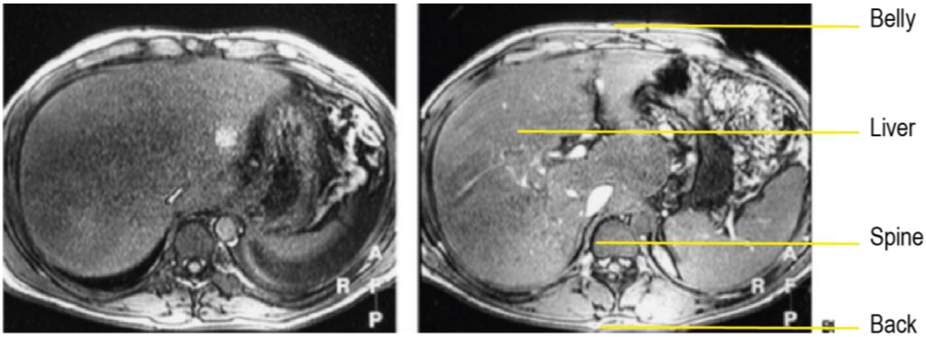


Figure 9. MRs of the liver, two cross sections of the body at a different level, courtesy of [FERR2005]

Based on the advice of the multidisciplinary team, IRs start to plan the TIPS procedure. Liver anatomy can alter drastically among those patients, especially because their livers are often scarred due to liver cirrhosis [SCAN2008] as shown in Figure 8. Hence, before the procedure, IRs carefully study the patient's history in order to gain understanding of the development of the liver [SAXO1997]. Then, IRs assess the current liver status by examining the cross-sectional CT and/or MR images of the liver (Figure 9). They study different aspects such as the anatomy, size, and the anatomical relationships of the veins. Based on a synthesis of the past and current status of the liver, they make an operation plan. Planning is a very important part in the preparation of the TIPS procedure. Literature [SAXO1997; SCAN2008; FERR2008] describe that good planning helps IRs to a) become familiar with the patient's anatomy; b) evaluate the difficulty of the procedure; c) estimate possible outcomes; and c) prepare alternative approaches as the backup plan.

2.2.2 The interventional suite

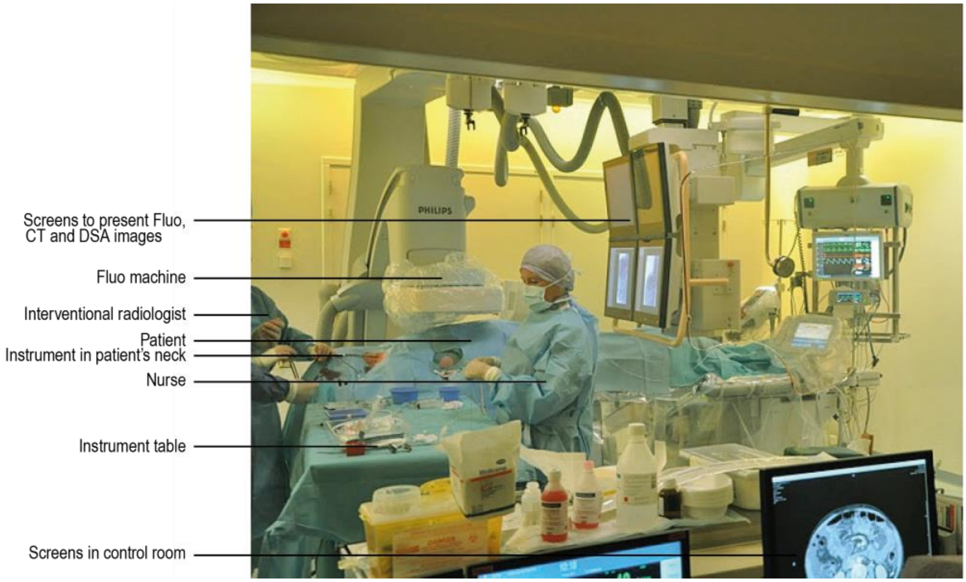
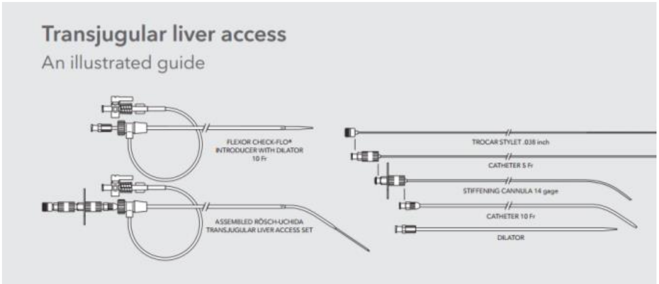


Figure 10. The interventional suite

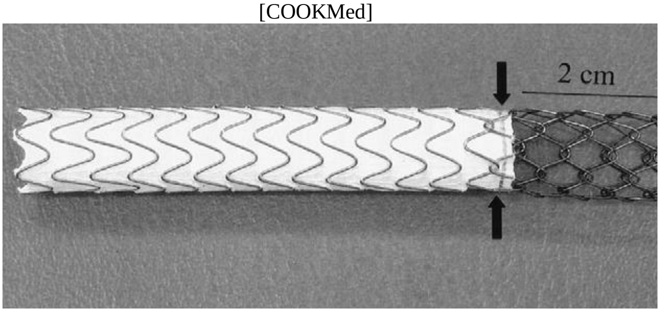
The therapeutic part of the procedure (intra-operative part) is performed in the interventional suite (Figure 10). The interventional suite is divided by leaded glass into two parts:

1. The control room, where supporting staff can control the imaging equipment located in the patient room. They also have access to computers connected to patient files on the hospital's central server and a picture archiving communication system (PACS). This room is protected by the leaded glass and thus the radiation level is very low.
2. The patient room, where the procedure is performed by a team of clinicians. Besides the performing IRs, the team also includes laborant assistants/nurses (these will be called nurses in this thesis), anaesthetists and sometimes additional IRs. Anaesthetists control the patient's pain (e.g., by general anaesthesia [PATI2014]) and monitor the patient [FUNA2008; GABA2011]. This allows IRs to fully concentrate on the procedure. The team is synchronized before the procedure and collaborates during the procedure. Pomier-Layrargues *et al* [POMI2012] emphasized the need for collaboration with highly trained nurses. During the procedure, the team (mainly IRs and nurses) have access to the instruments and the Fluo imaging equipment [SAXO1997; BECK2001]. Examples of instruments, such as catheters, guidewires, needles, balloons and sheaths can be found in Figure 11a. An illustration of the stent, which will be placed inside the patient's liver to create the shunt, can be found in Figure 11b [FUNA2008]. The X-ray based Fluo imaging equipment is often used to visualize the anatomy and instruments inside the patient in real-time. Due to the X-ray usage during the procedure, the medical staff are obliged to wear X-ray protective

clothing. Besides, for hygienic reasons, the patient, medical staff and instruments are all sterilized.



a) The instruments used for TIPS, Rosch-Uchida set, courtesy of [COOKMed]

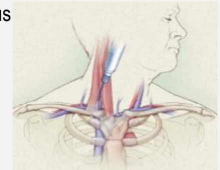
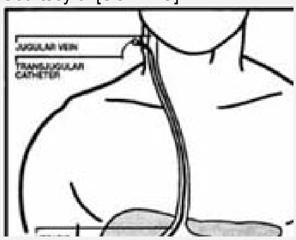
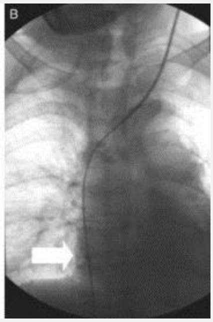
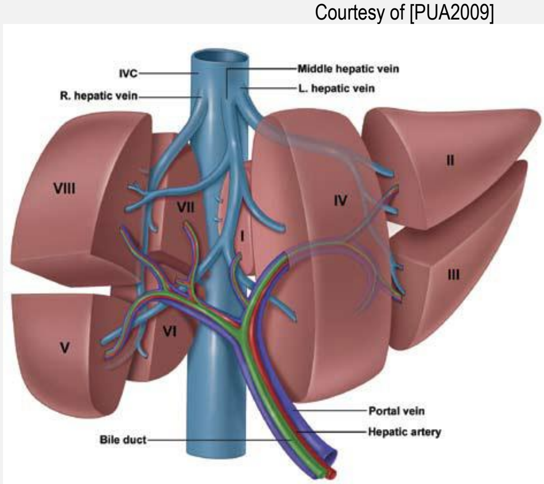
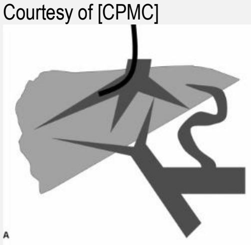


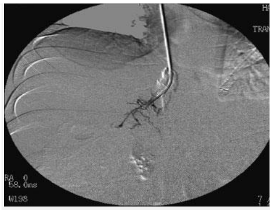
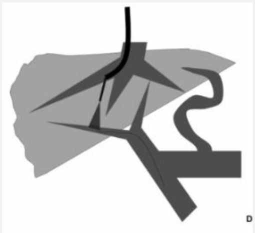
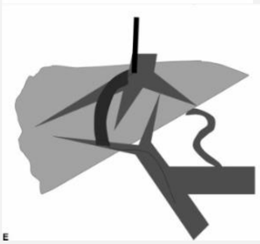
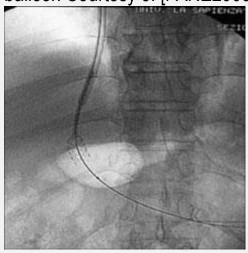
b) The stent-graft: the covered part (white) and uncovered part (2cm, right), courtesy of [HAUS2004]

Figure 11. Instruments and the stent used in the TIPS procedure

2.2.3 The TIPS procedure as described in literature

In the past decades, several IRs have described the TIPS procedure. Some provided an overview of the main procedural tasks [FUNA2008; SAXO1997; ROSC2014; HASK2003] and others described procedure related aspects such as complications [GABA2011], (contra) indications and technical details [FANE2006]. For instance, Funaki [FUNA2008] presented a detailed case study of a TIPS procedure, Clark [CLAR2008] and Fanelli *et al* [FANE2006] illustrated details of different types of instruments used in TIPS regarding their functions and sizes. Based on a summarization of those works, an overview of the steps in the TIPS procedure was generated.

Step	Explanation	Illustration	Example of image guidance for IRs
1. Puncture the jugular vein (JV) in the neck;	Through the skin (percutaneous access), IRs gain access into the right internal JV.	 Courtesy of [UCI-EDU]	
2. Catheterize the vena cava (VC)	A guidewire and catheter are advanced through the vena cava superior, the heart, into the IVC.	 Courtesy of [VIA-MED]	 A Fluo image visualizing the guide wire in the VC. Courtesy of [PUA2009]
3. Catheterize the HV	From the IVC, IRs insert the catheter in a branch of the HV. Both Gaba *et al* [GABA2011] and Saxon and Keller [SAXO1993] describe that preferably the right branch of the HV is catheterized, due to its favourable size and position in relation to the PV. The left HV is described as the second best option [SAXO1997].	 Courtesy of [CPMC]  Courtesy of [FUNA2008]	

4. Intrahepatic puncture	A needle is inserted through the catheter and the target PV is punctured to create PV access.	 Courtesy of [FUNA2008]	 Fluo image of the needle puncture in liver parenchyma from HV. Small amount of contrast dye injected to confirm needle position. Courtesy of [FERR2005].
5. Dilate the balloon	A balloon is dilated to create a track in the liver parenchyma.		 Dilation of stent-graft, by dilating a balloon Courtesy of [FANE2006].
6. Place the stent	A metallic and covered stent is inserted and deployed to keep the tract open. The balloon is used again to dilate the stent.	  Courtesy of [FUNA2008]	 Deployment of the stent, Courtesy of [FANE2006].  A deployed stent, visible under Fluo, Courtesy of [FANE2006].

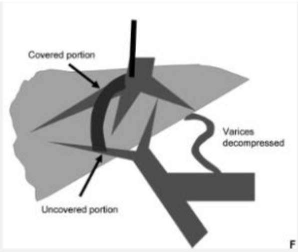
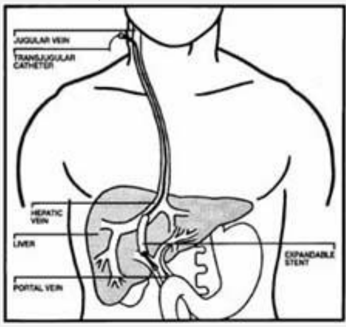
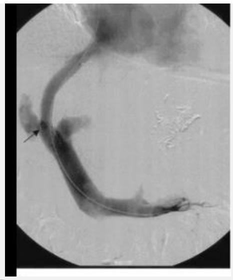
7. The result	The shunt allows a decompression of portal hypertension, since portal blood is now diverted into the systemic circulation.	 Courtesy of [FUNA2008]  Courtesy of [VIA-MED]	 DSA of TIPS: blood flow from PV after TIPS creation (through stent in liver). Arrow indicates covered/non covered part. Courtesy of [HAUS2004].  Completion of TIPS after successful creation of the shunt Courtesy of [FERR2005].

Table 4. Steps in the TIPS procedure based on literature

In addition to the presented steps in the TIPS procedure, some researchers mention more procedural details. For instance, Haskal *et al* [HASK2003] report that both at the beginning and at the end of the procedure, the PV pressure was measured to check the effect of TIPS. Saxon and Keller [SAXO1997] describe that IRs can try to aspirate blood to verify if PV access has been gained. For this, they insert a catheter and slowly withdraw it while suction is applied. If the blood is aspirated, IRs know that access has been gained. In another example, Clark [CLAR2008] described that the parenchymal tract length was measured with a special catheter to estimate the required stent length. These tasks were not described in the other papers, but they indicate that the TIPS procedure involves many other less obvious tasks and the procedure, as it is described now by the different authors, is just the tip of the iceberg and thus still incomplete.

Next to the limited IG from Fluo, literature also indicates other reasons regarding the difficulty of the procedure. Scanlon *et al* [SCAN2008] mention that the TIPS procedure is difficult, because it involves numerous imaging modalities and catheter-based skills. Ferral and Bolbao [FERR2005] describe anatomical challenges that can hamper the standard procedure even further. Variant anatomy and obstruction of the veins (e.g., PV or HV thrombosis) all contribute to anatomical challenges. The difficulties described by Ferral and Bolbao [FERR2005] are: 1) catheterizing, puncturing and visualizing the veins can be hard; 2) extra care is required to avoid critical structures. To be able to perform a procedure with altered anatomy, literature [FREE1993; SAXO1997; FERR2005] suggests using some alternative routes. For example, when the preferred HV is obstructed, the PV can be approached via another HV branch. However, those alternative routes can pose higher risks [FERR2005]. For example, Freedman *et al* [FREE1993] mention that, when a tract between the two veins becomes longer, theoretically it increases risks.

2.2.4 TIPS related disadvantages

This section summarizes literature regarding procedural disadvantages, especially during the blind PV puncture. These disadvantages are:

1. The puncture can cause numerous and even fatal complications [KIM2001; HASK2003]. Non-targeted organ injury, and with that the number of complications, increases when multiple punctures are needed [FREE1993; RIPA2006]. Those puncture related complications are described as the most dangerous [FREE1993; SAXO1997; FERR2005] and as the most feared [RIPA2006]. Table 5 shows examples of puncture related injuries and complications.

PV puncture related injuries, injury of the:	**PV puncture related complications:**
• Liver capsule [FREE1993;PILI2009]	• Bleedings [ROSE2002; ADAM2009]
• Bile duct [FREE1993;GABA2011]	• Infections [OWEN2007;GABA2011]
• Gallbladder [FREE1993;GABA2011]	• Stent occlusion [FREE1993;GABA2011]
• Kidney [FREE1993;GABA2011]	• Worsening of pre-existing portal hypertension [GABA2011]
• Vena cava [FREE1993]	• Morbidity and mortality [COLE1993;PILI2009]
• Hepatic artery [FREE1993]	
• Portal vein [FREE1993;PILI2009]	

Table 5. Examples of puncture related injuries and complications in the TIPS procedure

2. Additional aids are often introduced, but they introduce new risks. Authors suggest aids, such as using ultrasound in addition to the conventional modalities, making a

CO_2 wedged hepatic venogram and placing a percutaneous catheter in the PV, to visualize the PV or the relationship between the HV and the PV. However, an optimal solution was not yet found; the different papers present dissimilar methods of how to visualize the venous anatomy [BOYV2006; OWEN2007; SCAN2007] and the aids are often associated with new complications [RAZA2006; SCAN2007]. Some researchers [SAXO1997] even argue that most additional aids are time consuming and complex, and introduce risk without improving the ability to gain PV access.

3. Only experienced IRs can perform the procedure [ADAM2009], but even for them the procedure is challenging [SCAN2008].
4. The limited IG makes the intrahepatic puncture a blind puncture [ADAM009]. As a result, multiple attempts are often required to access the PV. Kee *et al* [KEE2005] report a mean of 2.6 ± 1.7 punctures for each procedure. Yamaguchi *et al* [YAMA2011] found a mean of 5 punctures (ranges from 1 to 14), based on 11 consecutive cases. Adamus *et al* [ADAM2009] report that experienced IRs gain access within five attempts in only 25 % of the procedures. After comparing the studies, the differences in attempts seem to depend upon several factors, such as differences in experience, patient anatomy and realisation of the procedure. Overall, the blind puncture seems to resemble the game ‘pin the tail on the donkey’, in which children are blindfolded and try to pin a tail on a picture of a donkey. Often, many puncture attempts are needed before the tail is in the right spot.
5. Due to the multiple punctures needed, other risks increase as well. Those risks are related to the high radiation dose, amount of contrast agent and sedation time [MALE2010; ROSE2000].
6. The entire procedure often takes two to three hours, or even up to six hours [KEE2005; YAMA2011; FERR2005]. However, if the first puncture is successful, it can be completed in only one hour, and this would avoid unnecessary risks introduced by excessive PV punctures [FERR2005]. Disadvantages of the considerable procedure time are the high procedural costs, operator fatigue and frustration [BOYV2006; ROSE2000].

It was frequently mentioned that in general the procedure would become safer and more efficient if fewer attempts were needed [FREE1993].

2.2.5 What should be improved in TIPS regarding IG?

Improved visualization support could decrease the number of puncture related disadvantages. Then, the PV access could become substantially easier and more controlled. Literature strongly suggests that, with the current modalities, IRs often do not see the position of their instruments, the veins and surrounding critical structures. As a result, IRs do not see the target position during the puncture. They have to find ways to compensate for this lack of information. Some medical literature proposes (desired) solutions. Table 6 provides an overview of the needs and proposed solutions. The needs and solutions mainly involve improved visualization of anatomy and target.

Needs, based on [SCAL2007; GABA2011; KRAJ2002; RIPA2006; ADAM2009; ROSE2000; SAS1997; SAXS1997; KRAJ2012; FUNA2008]	Proposed solutions, based on [GABA; FREE1993; FUNA2008]
• Have anatomic awareness • Planes which visualize 3D relationships of the existing needle in the HV, the target PV and surrounding critical structures • Be able to aim towards the target • See anatomical positions to distinguish branches • Be able to localize and visualize the target and being aware of catheter's position • Less difficulty when puncturing through cirrhotic livers • Make sure the puncture is completely intrahepatic	• Gain real-time 3D navigation support • Gain real-time 3D tracking support • Gain real-time 3D visualization support • Show 3D images • Have two views of the PV bifurcation • Pay careful attention during the procedure • Use additional techniques (e.g., wedged hepatic venography) • Have a clear understanding of the procedure • Do not panic • Learn from experience • Carefully plan the procedure • Be familiar with radiation projection principles • Improve skills • Improve understanding of the anatomy

Table 6. Examples of needs and proposed solutions, expressed by different authors

The provided solutions primarily describe how IRs can deal with procedural limitations. Clear requests for new and improved visualization support or remarks of what should be improved about the systems were not found. Probably, IRs are not aware of the possibilities and try to make the best of the current situation.

2.3 TIPS needs and solutions according to other IG developers

Based on section 2.2, it is concluded that IRs currently lack real-time 3D information about their instrument position, the liver anatomy and their target. However, concrete suggestions for improving the IG could not be found. The aim of this section is to identify which gaps were already addressed by other IG developers and what solutions they provided.

2.3.1 TIPS gaps addressed regarding IG

Currently, many researchers try to improve the accuracy of the intrahepatic puncture. The researchers [e.g., ADAM2009; PILI2009] had tried to design systems to provide more information about: 1) the PV position; 2) altered anatomy; 3) the needle tract; and 4) the needle path. Their solutions aim to help IRs to work quickly, efficiently and safely and thus to minimize the risk for the patient [JOMI2006]. The presented study outcomes are often related to precision and system accuracy. However, few researchers presented a list of requirements or a detailed motivation of what gaps to address in order to improve the TIPS procedure and why.

Designed TIPS solutions

Two types of solutions have been proposed or implemented in order to improve the IG for TIPS. They are: a) solutions based on existing US visualization techniques from other applications and b) new visualization methods based on currently used X-ray techniques.

A) Existing US visualization techniques from other application areas: existing US techniques have never been used for guidance of the TIPS procedure, but the potential was examined by different researchers. These techniques were:

1. Intravascular ultrasound (IVUS). The IVUS visualizes adjacent tissue organs through a vascular vessel wall. IVUS guidance allows for real-time visualization of the needle tract, improving safety of the procedure [PETE2003; PETE2008; KEW2004] and according to Farsad *et al* [FARS2012], IVUS can be used in cases of PV thrombus or distorted anatomy.
2. 2D US, as an adjunctive and complementary imaging modality (Figure 12), in addition to Fluo [RAZA2006]. It is reported that the puncture was safer and more effective, because the PV was visualized. Nevertheless, a second IR was always needed to operate the US probe to search the workable view plane;
3. 3D US (Figure 13). The 3D US provided guidance information about positions and directions to help IRs to identify specific technical errors or altered anatomy which were encountered in a TIPS procedure, such as obstructed vein [ROSE2000].

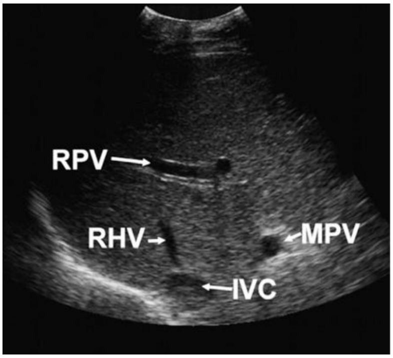


Figure 12: 2D US guidance seeing alignment of the right PV (RPV) near its bifurcation from main PV (MPV) with right HV (RHV) near its junction with IVC [RAZA2006];

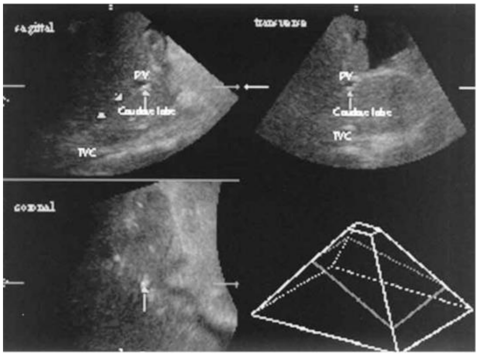


Figure 13: 3D US image obtained after PV access was achieved (3 images from 3 different angles). The needle can be seen as indicated by short arrows, and the PV is indicated by long arrows [ROSE2002].

Technique 1 and 2 could be used for the TIPS procedure, but the disadvantage of US is that it is not easy to visualize anatomical structures with severe ascites and advanced liver cirrhosis [ADAM2009], both are typical TIPS indications. Besides, excessive punctures and punctures outside the liver were still reported [ADAM2009]. Solution 3 is not suitable in its current configuration, because the PV access still required an average of 4.6 needle passes, a second IR was required to manipulate the US probe, and sometimes the operator could not identify the 3D US images with certainty [MALE2010].

B. New visualization methods based on currently used techniques: the new visualization systems:

1. A 3D path from the HV to the PV, planned from two DSAs of the PV, and overlaid onto the Fluo image [ADAM2009]. If desired, the 2D sections of CT or MR acquired before the procedure could be projected on the Fluo image as an overlaid layer.

Then, missed registrations are noticed immediately, and 3D orientations can be provided (anatomic context is given). Tsauo et al [TSAU2014] improved the system by adding a utility to calculate, and thus fit, the angle of the 3D path to the angle of the puncture. As a result, without increasing the procedure's invasiveness, only one needle pass was required to puncture, but the results also showed a rather high failure rate.

2. A 3D image of the PV, created from preoperative CT or MR images [JOMI2006]. Subsequently, the segmented representation of the PV was aligned with two live Fluo images. With the extra information the image helps IRs to visualize the PV as shown in Figure 14a.
3. A rigid pre-operative MR/CT scan synchronized with live Fluo [MALE2010]. It allowed the display of a fused 3D CT DSA to the IRs, together with the real-time Fluo as shown in Figure 14b. According to Maleux et al [MALE2010] and Pilliere et al [PILI2009], rigid registration between pre-operative and intra-operative images may be enough to provide useful IG in clinical practice.
4. A 3D image of the PV, acquired from DSA images. At the same time, a 3D needle track was shown on a Fluo image relative to the 3D image as shown in Figure 14c [MAUP2005].
5. A hybrid cross-sectional DSA image [SZE2006], acquired with a hybrid instrument which facilitates 3D CT reconstruction and combines it with DSA images.
6. A Fluo and MR image was acquired and reconstructed [KEE1999].

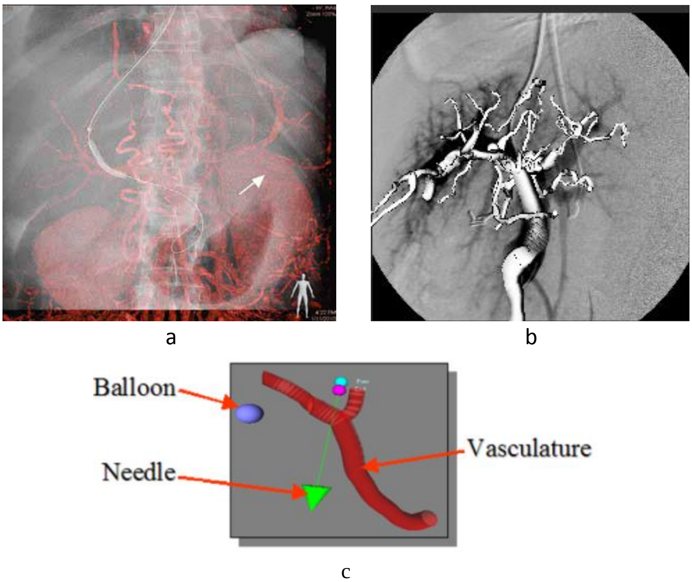


Figure 14. a) A fused visualization of the real-time Fluo stream and the 3D CT angiography [MALE2010]; b) Image of 3D reconstruction and needle direction & position, which could be projected on the Fluo image; [MAUP2005] c); Registration of a 3D on a 2D image [JOMI2006].

Till now, none of proposed solutions clearly shows promising results in terms of functionality and usability. For example, the 3D model of Jomier *et al* [JOMI2006] provides extra information to the IRs, but limitations were found as mentioned by

Maleux *et al* [MALE2010]: '*The feasibility is limited to cases with obvious radiopaque structures within the liver*'. Furthermore, although criteria are still unknown, it is likely that during the implementation, the time-consuming acquisition will probably not fit the busy workflow of the medical staff. Adamus *et al* [ADAM2009] used a 3D path planning tool; in three out of four test cases the method showed promising results. However, according to Maleux *et al*, [MALE2010], important structures were not visualized, and IRs had limited real-time feedback. As a result, injury of these structures may therefore still occur [JOMI2006]. Since no detailed evaluation of solutions 3 and 4 was found, it is hard to evaluate the effectiveness and efficiency. Technique 5 and 6 are still under development to make them available for TIPS [OTZU2005; PILI2009]. Besides, Technique 5 was solely tested on one patient and Technique 6 only on swine.

2.3.2 Imaging modalities used by other research groups to improve TIPS

Currently, Fluo is used as a basic modality to improve the TIPS procedure [ADAM2009; JOMI2006]. So far, literature does not provide a comprehensive comparison of the different TIPS imaging modalities for intra-operative use, including medical and non-medical advantages, bottlenecks and desired improvements. However, it is clear that X-ray is harmful for the patient, physician, society and environment [SUHO2003; FRUSH2004; PICA2004; HEAL2012]. Although TIPS eliminates a potential life-threatening condition [BERR2015] and the used radiation dose is therefore justified [ZWEE1998], repeated exposure to radiation substantially increases health risks. US and MR are modalities without ionizing radiation [DAFF1999; HAAG2001], but somehow, IG developers consider these modalities less often to improve the blind puncture. Also, the use of 3D US has hardly been explored, even though it shows noteworthy potential for guiding the TIPS procedure [ROSE2000].

2.3.3 Additional IG solutions

According to Nagel *et al* [NAGE2005], the interest in navigation systems for interventional radiology is growing continuously, but the application is rather rare compared to, for example, neurosurgery and orthopaedics. Studies that address navigation systems for interventional radiology mainly aim to improve other procedures, such as RFA or liver biopsies [WOOD2005; VARG2013; VILL2014]. Insights from studies of other minimally invasive procedures will be used to discover future IG trends for TIPS. Literature [CLEA2010; LINT2014; NAJM2012] suggests that future navigation systems will use multi-modalities to merge real and virtual worlds and to guide the physician. In addition, several trends are described that will possibly be combined in these mixed reality systems:

1. Registration and fusion, to show pre-operative images and intra-operative images at once. As described by Scanlon *et al* [SCAN2008] and Giesel *et al* [GIES2009], image fusion enables combining two modalities in a single image to show complementary information and to overcome technical difficulties and disadvantages of the different imaging modalities. It is expected that MR-guided systems [NAJM2012] will be used intra-operatively to perform interventions, such as an ablation of the tumours;
2. Needle tracking. Najamaei *et al* [NAJM2012] indicate that the needle and other instruments can be tracked to achieve more accurate navigation. In addition, Varga *et al* [VARG2011] found that path planning can be used in combination with the tracked

needle, to provide additional information about how to navigate along a predefined needle trajectory towards the target;

3. Image segmentation and rendering. Both will be needed to produce a 3D image of the anatomy [VILL2013]. Jalote-Parmar *et al* [JALO2010] found that 3D visualization is useful, for example to understand the 2D US images, identify the target and spatial orientation;
4. Non-rigid registration. Compared to rigid registration which allows translation and rotation of the dataset, non-rigid registration also considers deformations from for example patient movement or breathing. Interventional procedures treating structures in the abdomen often require non-rigid registration [CLEA2010].
5. Intra-operative planning. Najmaei *et al* [NAJM2012] notice that online planning might replace pre-planning to reduce procedural time.

Although each of the aforementioned systems has potential regarding certain aspects, most systems cannot yet be used in clinics. According to Cleary and Peters [CLEA2010], all are still prototypes, and limited clinical trials have been conducted. Also, Kersten-Oertel *et al* [KERS2013] mention that few were developed for commercial use. Literature provides possible reasons on why these systems are still unsuitable: Kersten-Oertel *et al* [KERS2013] argue that some did not take into account the direct clinical needs of the surgeon and daily clinical constraints and those systems were not sufficiently evaluated. In addition, Linte *et al* [LINT2014] state that in spite of the benefits of new equipment, they often have limitations such as incompatibility with standard equipment, requiring extra time for integration and not being cost efficient.

2.4 UI design of IG system for TIPS

This section presents knowledge for designing a UI for 3D guidance. Multiple studies have been conducted [WICK2004; BOWM2004; DJAJ1998; STON2005; DARK1993] regarding the development of a UI. The studies present different guidelines and design principles on how to design a 3D UI and how to stimulate proper decision making, situation awareness or an effective wayfinding process. For instance, Wickens *et al* [WICK2004] provide thirteen principles of UI design and Galitz [GALI2002] present useful techniques and principles to design a UI. The purpose of this section is to understand how to design a useful UI for 3D guidance. First, the section presents the navigation process and cognitive tasks of the IRs. It will provide a deeper understanding of how IRs currently use IG, how they are able to perform an intervention and what they still desire from the future UI of the IG system. Then, the section explains the definitions of a good UI and navigation. Next, it gives an overview of general guidelines relevant to the development of a puncture UI for TIPS. Relevant insights from current guidance visualization UIs in non-medical fields will be explored afterwards to facilitate the UI design. Finally, the section draws a conclusion for further work and the generated insights will help to form preliminary design requirements for the 3D US based UI.

2.4.1 Understand the user of the system

Knowledge regarding the cognitive process of IRs in using the IG system, such as how IRs interact with the IG system and make decisions, is a critical part in the development of medical information systems [PATE2001;VARG2012]. According to Varga *et al* [VARG2012], a deeper understanding of this cognitive process helps researchers foresee which aspects of the intra-operative procedure should be improved. Several authors have described aspects of these cognitive processes. Still, insights are limited and largely come from the field of minimally invasive and conventional surgery. Nevertheless, we expect they are also helpful for interventional radiology, where similar decisions are made. Figure 15 shows an overview of the gained insights and gives an indication of how IRs might be able to plan the procedure, how they orientate and navigate, and what challenges they may encounter.

From the findings in table 15 we can assume that IRs have to deal with many cognitive tasks in order to complete the TIPS procedure. The findings suggest that IRs largely navigate on their mental representation of the real world (mental model), since visual and additional feedback is not always available. A UI is desired which can provide this feedback.

Although some insights were gained now, additional study is still required. TIPS is a complicated procedure, often placing high mental demands on IRs. For instance, Funaki [FUNA2008] mentions that IRs sometimes know that PV access is gained if no resistance is felt after the puncture. Saxon and Keller [SAXO1997] indicate that it is ideal to enter the PV 2-3 cm from the bifurcation in the right branch of the PV. Regarding the same issue, Owen *et al* [OWEN2009] recommend that the needle should advance at least 2 cm from the bifurcation to avoid haemorrhage. All these details contribute to IRs' cognitive processes. Nonetheless, cognitive tasks are hard to unveil from the papers and their exact meaning frequently remains unclear. As a result, it is still not known what information the IRs use, desire or need, or what cognitive tasks they have to perform to complete the main steps of the procedure. Therefore further study is desired.

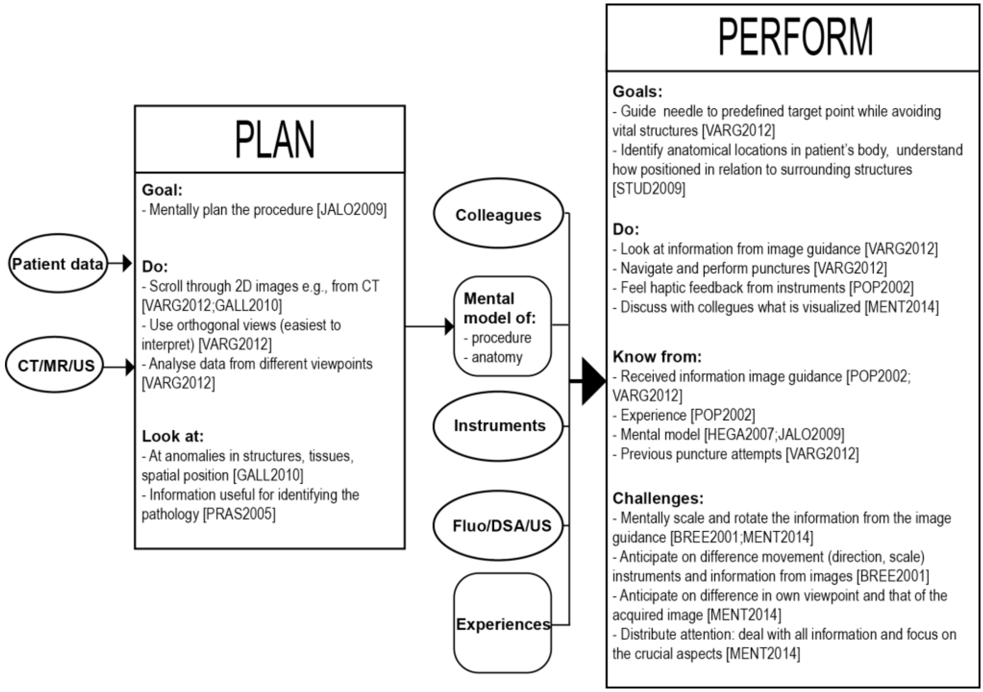


Figure 15. Examples of navigating process and cognitive aspects of operating physicians, based on findings from interventional radiology, laparoscopy and surgery.

2.4.2 How does literature define a 'good UI'?

Literature implicates that a UI is good if it is useful. Stone *et al* [STON2005] describe a good UI as one that is easy to use and to understand, meets the users' needs, and supports users in their required tasks and thus avoids user frustration and dissatisfaction. Bowman *et al* [BOWM2004] define it as easy to use, intuitive and one that meets the users' needs. The above shows that all definitions are rather similar and describe the UI's usability. According to ISO 9241 [ISO 9241-11], usability is referred to as "*the extent to which a product can be used by specified users to achieve specified goals with effectiveness, efficiency and satisfaction in a specified context of use*". Nielsen [NIEL1994] defined usability of a design by five quality components. These components are:

- Learnability: users are able to rapidly accomplish basic tasks in the first time of use;
- Efficiency: once users have learned the design, a high level of productivity is possible;
- Memorability: when users return to the design after a period of time, they have remembered much from the first time use;
- Errors: users make few errors, errors are not severe, and users are able to easily recover from the errors;
- Satisfaction: users like the system because it is pleasant to use.

Based on these definitions, UI designers can determine the usability of a UI by testing it with users and identifying HF design flaws [WICK2004]. Some literature [STON2005, GALI2002] recommends conducting such a usability test as well. This implicates that for TIPS, IRs' needs and tasks have to be supported by the UI and IRs have to be consulted regarding the UI's usability. As indicated in *Chapter 1*, these findings are rather general for the leading researcher and they are very much in line with her opinion. Nonetheless, the insights could apply to every product. The proposed research aims at creating a UI to help IRs to navigate within the patient's body. Navigation in the patient's body is clearly a dominant task of the IR. More concrete insights on navigation aids are thus required.

2.4.3 Definition navigation and wayfinding

To develop a navigation UI, it could be helpful to first define the term navigation. Navigation has many definitions [VOLB2000], in this thesis the definition introduced by Elvins *et al* [ELVI1997]: "*the process of determining and conducting strategy, direction and course with controlling the movement using some aids to achieve a desired goal*" will be adopted.

Bowman *et al* [BOWM2001] subdivide navigation into two tasks, namely 1) the physical task of travelling or motion and 2) the cognitive task of wayfinding. Travel is described as the actual movement from one location to another. The cognitive process of wayfinding involves determining a path through the environment to the desired environment. Elvins *et al* [ELVI1997] describe wayfinding as the most important part of navigation, since it refers to the fundamental components of the navigation process that make up intelligent navigation, namely strategy, direction and course. Ross and Blasch [ROSS2000] indicate that wayfinding is used to spatially orientate and allows to navigate towards the destination. For the TIPS procedure, a UI of the IG system that allows IRs to navigate through the body by supporting them in their wayfinding tasks is thus desired. Therefore, this research project is mainly concerned with the information required to support the wayfinding aspect of navigation.

2.4.4 Guideline to support navigation using a UI

Different aids could be added in the design of the 3D US based UI to support wayfinding during the TIPS procedure. In Table 7 a list of aids to support wayfinding with the UI is provided. For example, distinctive colours could be used to visualize the different veins, or instructions can be provided on how to navigate to the PV, as well as a map of the total anatomy in the patient's liver. All might help IRs to gain spatial knowledge, and stimulate navigation and knowhow to navigate instruments through the human body and to puncture the PV. Although the difference between wayfinding and navigation is conveyed, the terms are often mixed up in literature. Therefore, in the remaining research, the term navigation will be used to express the cognitive task of wayfinding. These aids show how navigation can be supported with the UI. However, what and how information should be visualized remains unclear.

Table 7. Aids to support navigation with the user interface.

Allow the user to…	Why?	How?
Replace memory with visual information [WICK2004]	Memorizing visual information is mentally demanding [STON2005]	
Orient in space [VOLB2000]	To facilitate effective navigation	Show [ROSS2000]: 1) one's location, where one is going to in relation to known landmarks and the target 2) information of the prominent environment features 3) for the user interesting features in the greater surroundings Assist to [ISHI2008]: 1) indicate one's position 2) have understanding of the current position and route from the starting point to the goal 3) execute route [WICK2004]: 1) provide guidance about how to get to a destination 2) facilitate planning 3) help recovery when lost 4) maintain situation awareness 5) avoid mental rotation
Build up [DARK1996;THOR1983; VOLB2000]: - Landmark knowledge: represents shape, size, colour and contextual information for a specific location in an environment; - Procedural knowledge: a series of navigation actions or a particular route from a starting point to an end point, such as distances and turns; - Survey knowledge: allows the traveller to mentally picture a region from a bird's eye view and to navigate with confidence.	To gain spatial knowledge of the environment, support navigation [DARK1996;THOR1983; VOLB2000]:	Use: - landmarks, paths and other elements [LYNC1960; EIVI1997; KIM2005] - a clear image of the environment [LYNC1960] - directional cues [LYNC1960] - a map [WICK2004;KIM2005;PARU2004] or navigation instructions [PARU2004] - entry points in maps [MINO2010] - real-world metaphors or interaction [MINO2010;BOWM2001]
Gain feedback about actions [BOWM2001;DJAJ1998;WICK2004]	To avoid frustration, understand the state of the system, shape performance [BOWM2001;DJAJ1998;GALI2002]	- Provide information without excessive delays [GALI2002] - Match information to speed and flow of human thought [GALI2002]

2.4.5 Additional guidelines

Apart from navigation aids, additional UI guidelines were presented in literature. These insights can also be used in designing a UI for the TIPS procedure. The guidelines which were considered by the author as most relevant are:

- Many authors, for instance, Wickens *et al* and Lynch [WICK2004; LYNC1960], express the needs for designing legible UIs;
- Vinson [VINS1999] and Wickens *et al* [WICK2004] suggest that legible elements should be distinctive and concrete;
- Both Stone *et al* [STON2005] and Wickens *et al* [WICK2004] suggest to present the information in a simple way that users expects and comprehend;
- According to Wickens *et al* [WICK2004], a UI which predicts what will happen can often be quite effective in supporting human performance, since prediction is a difficult cognitive task.

These guidelines seem to be in accordance with the guidelines provided earlier, and all express that the UI has to be easy to use and understand by the users. Next, the importance of choosing a suitable display device was frequently mentioned as well [BOWM2001]. These display devices can be, for example, a virtual UI or augmented reality UI. Furthermore, Bowman *et al* [BOWM2001] emphasize that choosing a suitable input device or interaction technique is desired, since both have a profound effect on the UI's quality. Although the author of this thesis recognizes the importance of these aspects, they are not within the scope of this thesis and will not be researched.

2.4.6 Other UIs

Many visual navigation aids have been developed for non-medical fields, such as gaming, aviation and air traffic control. For instance, Aragon *et al* [ARAG2005] presented an effective airflow hazard visualization system for helicopter pilots to reduce crash rates. The UI represented the position of the helicopter, its direction and the location of the hazard. In the evaluation of their UI they found that pilots preferred a flexible and simple display which only shows the minimal critical information regarding each phase of the flight. In the UI, standard symbols were preferred to avoid confusion and to not distract the pilots from their main tasks. Extensive details, colours, motions and complex shapes were recognized as unhelpful UI elements.

Next, Karikawa *et al* [KARI2011] described the design of a successful visualization tool for air traffic control tasks. To provide support to experts in performing their tasks, the visualization tool presented real-time information about the target, possible risks or boundaries and feedforward information about future scenarios. Azuma *et al* [AZUM2000] also developed a UI for traffic control. The design showed an overview of the current situation, a detailed view of a particular conflict and potential risks. The user was able to select possible solutions to avoid conflicts and was warned if conflicts would still occur. This study also showed that pilots and traffic controllers desired a UI which only shows the crucial information and has minimal clutter and distraction.

The aforementioned applications are similar to the TIPS procedure. They are similar in the aspects of designing a UI for a safety-related application in which large amounts of real-time information are presented in a comprehensive way, but without disturbing the user from his/her main goal, namely to safely complete the procedure. Therefore, the applications give hints for designing a UI for TIPS placement, namely to develop a simple UI which visualizes the current position, critical anatomy and the target and which provides feedforward information about possible risks. This might help IRs in minimizing the TIPS punctures.

2.4.7 A suitable UI for TIPS – information requirements

On top of guidelines and principles to design a suitable UI, many authors recommend basing the design on users' and contextual requirements. For example, Stone *et al* [STON2005] emphasize that how to design a good UI depends on the users' characteristics and needs, tasks, actions and goals. According to Patel *et al* [PATE2001], the design of medical systems should be informed by cognitive constraints that are imposed on the users during their interactions with the information system. To stimulate successful use of information systems, understanding of how IRs process information is crucial. Similar advice is also given by Nagel *et al* and Reason [NAGE2007; REAS2000] about system development in medicine. Nagel *et al* [NAGE2005] concluded that an ideal navigation system must be adapted to the requirements of the IRs and the clinical workflow. Reason [REAS2000] stated that without an in-depth analysis of why errors and near misses occurred, it is impossible to uncover why errors occur and how to avoid them. Furthermore, Volbracht and Domik [VOLB2000] claim that if preferred navigation strategies are not supported, the navigation aids can impair the effectiveness of navigation.

User involvement and testing is recommended to discover users' and context requirements. This is in line with the proposed research approach of this thesis and was recommended by several researchers, even by those who were not from the design field. To illustrate, Galitz [GALI2002] suggests to know and understand the user and to repeatedly test the UI with the user in order to design a UI that reflects users' capabilities and responds to their needs. Both Wickens *et al* [WICK2004] and Bowman *et al* [BOWM2004] advise to apply HF methods and involve the user in the design process in order to identify current design problems and find solutions.

Several methods were mentioned regarding involving users in designing UIs. Bowman *et al* [BOWM2004] describe designing in three phases: requirements gathering (analysis of existing situation, user problems, tasks, user characteristics), design the UI and build prototypes, and evaluate these. Wickens *et al* [WICK2004] also describe the same three phases, but in different terms as front-end analyses, iterative design and testing, and final test and evaluation. Stone *et al* [STON2005] recommend to observe, to interview and to gather information from the user through surveys and questionnaires to set requirements. Furthermore, to involve the user in all design phases and to test the design. The suggested methods are in line with those proposed in Chapter 1 of this thesis.

Overall, by comparing these findings to the TIPS procedure discussed before, it is clear that the existing workflow study in this chapter is not detailed enough to support the UI design. It remains unclear what types of information should be presented to the IRs and when and how it should be presented. User testing is needed to design a suitable UI for TIPS. The general guidelines can trigger inspiration on how to design a 3D UI. However, qualitative research is still needed to discover what information to present in the TIPS UI.

2.5 Conclusion after the literature review: how to continue?

Basic explanations of the TIPS procedure, desired improvements and possible solutions were found in literature. Currently, IRs often lack real-time and 3D information on their instrument position, anatomy and target area, especially during the intrahepatic puncture. Several researchers have presented ways to make the PV puncture more controllable and safe, for example by presenting IRs with a 3D DSA image of the PV. In addition, aids and guidelines of how to design a suitable UI for 3D guidance were collected.

However, to improve the UI for TIPS, current literature cannot provide sufficient insights. In-depth analyses of the total TIPS workflow are missing. TIPS related tasks were discussed only briefly, cognitive tasks hardly researched at all, and visualization needs and possible solutions expressed poorly. Stone *et al* [STON2005] emphasize the need to understand the users, the tasks that users perform with the system and the context in which they use them to design a useful system. Currently, this remains difficult for the TIPS procedure. A complete overview of the procedure, related challenges, needs and requirements is still missing. As a result, it remains challenging to fully understand the TIPS procedure and how the IG can be improved.

A solution to make the PV puncture significantly more efficient and effective was thus not yet found. All proposed solutions have their disadvantages and require further development. At present, many IT systems are used in the healthcare to help physicians provide effective and efficient service; but according to Asan *et al*[ASAN2014], some of them may even introduce risks of hindering physicians' work. Unertl *et al* [UNER2006] claimed that some tools can make the completion of tasks more challenging, decrease efficiency and increase errors. Also according to Linte *et al* [LINT2014], the current design of IG systems result in highly complex infrastructure for the clinical setting, and the information provided may overwhelm or even confuse the user. In many cases the system displays all information and it is up to the user to decide what is relevant and what is not. Little attention is paid to user requirements, HF and other usability aspects of the UI. Often, those conflicts occur due to the fact that the new IT systems do not fit the current way of working [BERG2001] and disconnect between users' and designers' expectations of the system's performance and use [UNER2006]. Also Freudenthal *et al* [FREU2013] emphasize that many developers lack a holistic focus; they look at the system's functionality, but do not take into account the UI's usability. Wickens *et al* [WICK2014] argue that developers should apply HF to make the human interaction with the overall system 1) enhance performance; 2) increase safety and 3) increase user satisfaction. Boivie *et a*l [BOIV2006] mention that HF are regularly taken for granted or involved too late which may lead to poor system implementation.

Next, acquired UI guidelines were interesting, but they provided rather general knowledge. The guidelines involved all UIs and did not reveal specific requirements for designing the UI for TIPS. Besides, most authors recommend studying the UI context and performing usability studies to design a UI for a specific situation.

Many researchers indicate that a detailed workflow analysis can help to design a useful UI. Jalote-Parmar [JALO2009] describes a medical workflow as a sequence of physical and cognitive activities performed by clinicians to complete the medical procedure. In addition, it also incorporates the way people interact with procedures, equipment and other people to realize the tasks. Unertl *et al* [UNER2006] recommend that before designing the UI for a medical device, designers should have a deep understanding of the medical workflow regarding the procedures concerned, in order to stimulate the adoption and acceptance of the new UI. Analysing the medical work may

help designers identify procedural challenges, system requirements and users' needs and behaviours in the earlier stage of system development [KUSH2002; UNERTL2006; FREU2008; JALO2007]. It also allows designers to develop systems which enhance the information needed by physicians for making informed decisions [JALO2009]. Furthermore, workflow analysis can also help designers understand how implementation of a new information system may affect or improve the flow of work [ASAN2014; BAXT2005]. Therefore, further research is required regarding the TIPS workflow and related challenges.
Overall, the review created a basis for designing the UI for TIPS, but did not provide a clear understanding of the TIPS workflow, its related information problems and specific UI requirements. Only elaborate research will allow us to design a useful visual navigation support for TIPS.

Thus the author will:

- Identify current IG problems in TIPS workflow, and discover what information is required and why it is needed;
- Explore the advantages and limitations of CT, MR, Fluo and 2D/3D US to know which has most potential to improve the TIPS puncture and what improvements are needed;
- Go beyond improving technical functions of the IG systems by incorporating the usability aspects in the early stages of design. For instance, an important usability issue is that to support wayfinding in the TIPS procedure, the UI needs to present only the information which is needed in that step, based on the identified crucial information regarding each step of the workflow.

"It is as if you wake up in the dark: you do not turn on the light, but you walk to the toilet and you more or less know where you have to go…. Something similar occurs during the puncture; you somewhat know where you'll have to go."

[An IR, 2011]

Chapter 3: The TIPS workflow

Based on [CUIJ2012a; CUIJ2012b]

The previous chapter provided an overview of the TIPS procedure and the state of the art in improving the IG UI for the TIPS procedure. Based on those findings, it was clear that the understanding of the TIPS workflow is still limited.

In the context of medical fields, a workflow describes different procedural aspects, such as the tasks, the context, and how people utilize information tools [UNER2006]. Workflow analysis may contribute to the design process by revealing the information flow within a procedure and identifying what to improve in different steps [UNER2006].

This chapter presents a detailed description of the TIPS workflow, based on the outcomes of a series of studies. Using information provided by workflow analysis, we are able to understand different challenges in the procedure and identify design opportunities within the 3D US based UI, which could contribute to a more effective and efficient procedure. The chapter is arranged as follows: section 3.1 presents the research methods used in the workflow analysis; section 3.2 lists the identified TIPS workflow; and based on those opportunities, section 3.3 identifies design opportunities and lists requirements for designing an IG UI.

3. 1 Methods

In the presented research, ethnographic studies and generative sessions were used to explore the procedure and related challenges and to understand the TIPS workflow. Based on the outcomes of these studies, a workshop was organised to validate and communicate the findings to the team.

3.1.1 Ethnographic studies for design

Over the past twenty years, ethnographic studies have increasingly been used by designers. The goal of conventional ethnographic studies is to explore the world through the eyes of the users [NARD1997]. Designers share the same goal, but they do not study ethnography with the in-depth and hands-off approach practiced by anthropologists [NARD1997]. Instead, a variety of ethnography-related methods, such as observations, are adapted to study users and their practices in the future products' context. As stated before, only limited aspects of the TIPS workflow were described in the literature, such as technological aspects of the imaging technologies. Using the adapted ethnographic methods in exploring the TIPS procedure allows researchers to look beyond the scope of technological design criteria and to also gain insights into the workflow. According to Freudenthal et al [FREU2013], design researchers can use insights to identify what to focus on or leave out. In addition, Freudenthal *et al* [FREU2013] and Nardi *et al* [NARDI1997] point out that it also helps design researchers to judge the product's potential and to gain development ideas.

Setting
Ethnographic studies were performed from December 2010 until September 2014 in a Dutch hospital. During the study around 50 interventions were observed, of which thirteen were TIPS procedures. Other endovascular procedures, such as radiofrequency ablation, angioplasties and angiographies, were also investigated. The TIPS procedure involves the skills of many other interventional procedures [FUNA2008]. By understanding the goals and actions of those procedures, the actions in TIPS could more easily be recognized and understood. For example, during angioplasties a vein is dilated with a balloon to widen an obstructed artery. In the TIPS procedure, a balloon is inserted as well. Although in this context it is done to dilate the parenchyma tract, the goal is still to widen a passage.

Data collection
Observations during the 50 interventions were noted down. Besides, before, during and after each procedure questions were asked to the available medical staff. Based on the available documentation in the control room, medical protocols of the different procedures were studied as well.

Data analysis
After each TIPS procedure, notes were digitized. With the collected data a preliminary task flow diagram was drawn as a task analysis. Johnson *et al* [JOHN2006] describe a task analysis as the steps which an individual has to make to complete tasks and their reciprocal relations. A task analysis is often performed to identify possible health and safety issues in a workflow analysis [KIRW1992]. Besides the task analysis, remaining questions were noted down and asked during the next observations. This procedure iterated until a satisfied task analysis was achieved.

3.1.2 Generative sessions
We not only applied ethnographic methods to analyse the workflow, but also used generative research methods [SLEE2005;PREE2007]. Observation methods have been applied to discover what people do and use. Interviews may help designers/engineers to understand what people think. Generative research methods can help in exploring what people feel, know and dream. Sleeswijk Visser *et al* [SLEE2005] report that the generative methods especially help designers to reveal tacit knowledge; to recognize and express nonverbal parts of their expertise. Much of IRs' knowledge is tacit and implicit knowledge. Designers have a totally different professional background, different interests and another way of communicating and absorbing information than IRs. Thus, for IRs, it is hard to discuss and explain the medical procedural knowledge to a designer during the ethnographic interviews. Freudenthal *et al* [FREU2010] found that recognizing what a designer/engineer needs to know appears difficult for physicians, due to different views on what is relevant. Furthermore, the minimally invasive TIPS procedure is difficult to observe. As a consequence, researchers often had difficulties to understand the complex procedure, resulting in ill-formulated questions which hardly provoke useful answers. Generative sessions were applied to overcome those problems.

The design of the generative sessions was based on the insights from Sleeswijk Visser *et al* [SLEE2005] and Meijs *et al* [MEIJ2008]. The individual sessions as described by Meijs *et al* [MEIJ2008] were applied to fit the busy working schedule of IRs. The sensitizing booklet described by Sleeswijk Visser *et al* [SLEE2005] was used as a tool to prepare the IRs for the generative session. For this research, the tools were adjusted to fit the TIPS context and research purpose.

Participants

Six male IRs from three different Dutch and one Belgian hospital participated in the study. Five were IRs, of which three were professors and one was head of the department. One participant was in the final year of his training. Although he was not yet able to independently perform a TIPS procedure, he frequently assisted during TIPS.

Data collection

Six individual generative sessions (60-90 minutes) were organized. One week before the session, the IRs received a sensitizing booklet. The booklet contained four assignments about interventional radiology: 1) introduce yourself; 2) describe an intervention of the previous week along the timeline; 3) describe challenges of the procedure and what helped to overcome the challenges and desired changes; 4) described a procedure which made you proud. Stickers of ambiguous words and images were provided to trigger relevant areas of consideration. The primary aim of the booklets was not to gain specific answers to targeted questions, but rather to prepare the IRs for the session by having parts of their stories prepared from earlier observation and reflection. During the sessions, participants were asked to think of one challenging TIPS procedure and to draw a timeline of that particular procedure (Figure 16). On the timeline they were asked to 1) write down the different TIPS steps; 2) mark the most crucial part of the procedure; 3) note down the difficulties and 4) note down things that helped to overcome those difficulties. The use of drawings and images was stimulated by providing coloured pens and a prepared set of stickers of ambiguous words and images. Subsequently, the participants were asked to discuss their created timeline with the leading researcher. With the participants' consent, the sessions were recorded with a camera or sound recorder.

The moderator

The leading researcher moderated the sessions. The knowledge acquired from the previous studies was used to set a clear goal for the sessions and to become familiar with the medical jargon. The researcher was able to discuss the presented timeline with the participants, since she already obtained sufficient background about TIPS, which helped in having a fruitful conversation.

Data analysis

The recorded sessions were transcribed and analyzed. Quotes relevant to the subject, development goal and research questions were printed and cut out. Each quote was read and clustered to expose patterns. Quotes were grouped together when possible, or new sets were created. Clusters such as the goal of the procedure and complications were easy to define. Quotes such as reasons of challenges and navigation strategies were difficult to cluster: they were not explicitly defined during the interviews, but vaguely described in several sentences. To secure correct placement of the quotes and to provide meaning to the large amount of data, an iterative process of reading and clustering was performed. Furthermore, quotes which could be placed in two groups were reprinted and put in both groups. Finally, an appropriate theme (and subtheme) for each cluster was defined. The main themes were: aim of the procedure, patient, navigation, perceived difficulties.

Updating the task analysis

After analyzing the data from the generative sessions, the leading researcher updated the task analysis which was created after the ethnographic studies. The macro steps of the procedure could be confirmed. Macro steps, or tasks (e.g.,[UNER2006]), are the observable, physical steps of the procedure. In addition, descriptions were added to the task analysis, as well as IRs' perceived challenges and micro steps performed during the procedure. Here, micro steps are the unobservable and elementary actions/questions needed to perform a macro step. In the analysis, notes from the ethnographic studies and literature were consulted when needed.

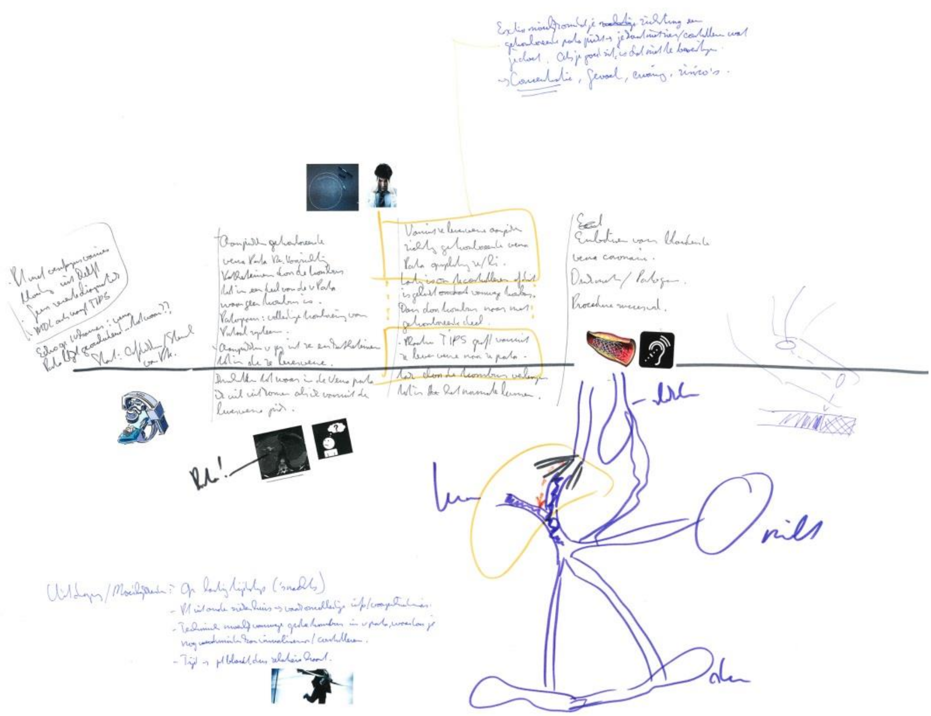


Figure 16. Example of a participant's TIPS timeline, created during the generative session. The figure gives an impression of how words, stickers and drawings were used to describe a TIPS procedure.

3.1.3 Workshop

Based on the outcomes of ethnographic studies and generative sessions, a workshop was organized to validate and communicate the findings and to validate the critical part(s) of the procedure, to prioritize the micro questions and to understand what and how support could be provided for the micro questions.

Before the workshop, the task analysis was visualized on a flipchart. The macro steps for the whole procedure were written in black. The micro tasks for the intrahepatic puncture were listed in green. Questions or doubts regarding the procedure were formulated and noted in red. Finally, different target visualization aids per hospital (e.g., CO_2 wedged hepatic venogram) were shown in blue.

Participants

The participants of the workshop were the members of the multi-disciplinary team.

Data collection

The extended task analysis and a blank paper were hung on the wall (Figure 17). The leading researcher presented and explained all the steps. Team members were allowed to interrupt to ask questions for more elaboration, or to provide comments/ corrections. The leading researcher tried to answer, and the two IRs of the team were consulted when needed. The blank sheet allowed the researcher and IRs to draw and to explain steps in more detail (Figure 17). Missing questions regarding micro steps were added. The workshop was video-taped with a camera recorder (with the participants' consent).

Data analysis

After the workshop, the recordings were analysed and new insights were noted. The task analysis was fine-tuned and the missing steps were finalized.

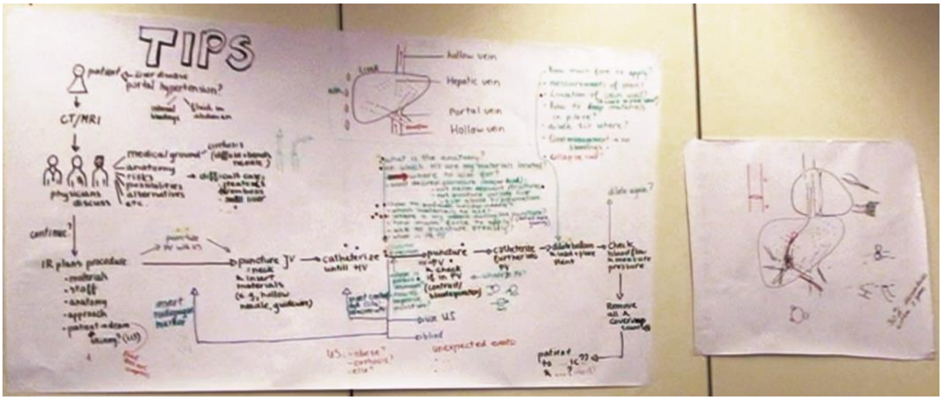


Figure 17. An impression of the workshop materials. Left paper: extended task analysis and flip chart used for workshop, including macro steps, micro steps, doubts, and different target visualization techniques. Right paper: drawing, created by moderator and IRs.

Validation list

The list of macro steps and micro questions was sent to an IR of the team. He was asked to check the list, add comments and to provide input for unclear parts. Based on his feedback, the list was revised and completed. When comments remained unclear or contradictory, the IR was consulted again.

3.2 Results

Outcomes of the research methods contributed to a clear awareness of the procedure's complexity. Apparently, IRs have to perform many physical and mental steps and overcome perceptual challenges before they are able to complete the procedure. This section describes the outcomes of the research as an insight of the TIPS procedure. It first provides a description of the main macro tasks. Then, it discusses the less observable micro steps and provides an overview of the procedure. Finally, the section lists challenges that IRs encounter during the TIPS procedure. We are aware that different hospitals may use different strategies and that deviating cases exist (e.g., extra-hepatic shunt) due to different patient pathology and anatomy.

3.2.1 The macro steps of a TIPS procedure

The IRs described the TIPS procedure as two major parts: the pre-operative phase and the intra-operative phase of the procedure. In the following, macro steps of these two phases are summarized.

A) *Pre-operative phase:* the pre-operative phase precedes the intra-operative phase and involves planning the procedure. This phase is experienced as difficult and time-consuming, but also crucial, since a carefully prepared procedure helps to orientate and anticipate and to limit possible risks. CT or MR and 2D US are available for planning.

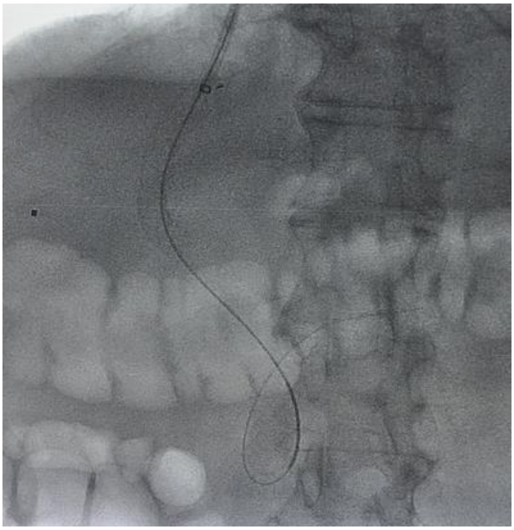
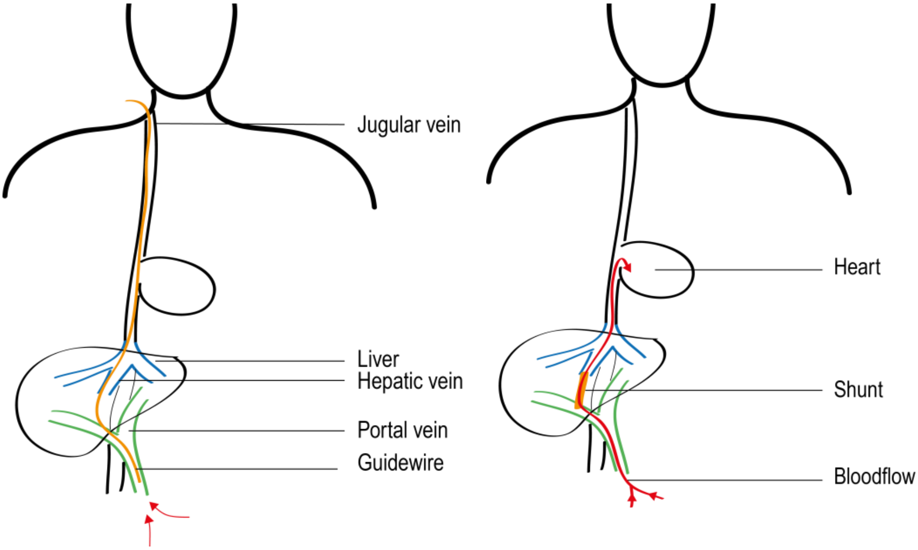


Figure 18. A Fluo image of the procedure; the lungs (upper left white area in the figure), the intestines (horizontal light grey area), the spine (vertical), instruments, such as stent and guidewire (gauze and thin vertical line in middle).

B) *Intra-operative phase*: see Table 8. The table lists IRs' macro steps when performing the procedure. 2D US and Fluo images are often used in the procedure.

Table 8. The intra-operative phase of the procedure

Macro steps	Explanation
1) Puncture the jugular vein (JV) in the neck;	When the patient is fully sedated, IRs locate (by eye or with US) and percutaneously access the JV.
2) Catheterize the HV: • Towards the HV • Into desired branch HV • Position needle in HV	A guidewire and other instruments are inserted and navigated through the patient's blood vessels into a branch of the HV.
3) Intrahepatic Puncture: • Puncture into the PV • Control the puncture/verify access	The guidewire is replaced by a needle, positioned towards the PV, and pushed – over a distance of about 3 cm – through the liver parenchyma, into the PV. This is called the intrahepatic puncture. If PV access is gained, there is a connection between the two veins and IRs can continue. Otherwise, a new attempt is required. Due to insufficient target visualization, PV access often comprises multiple punctures. The six participants described the intrahepatic puncture as the difficult, but most crucial part of the intra-operative procedure; "*To try and puncture the vein is the difficult part of the procedure".* Depending on the number of punctures, the procedure can take one to four, or even up to six hours. IRs mentioned they need to be very concentrated, have confidence, and keep faith in what they are doing.
4) Place Stent: • Catheterize into PV • Insert and inflate balloon • Place stent • Verify the TIPS effect	When access is gained, a stiff wire is placed into the main PV branch to create a work trajectory for other materials (Figure 19a). To enlarge the passage, a balloon is inserted over the wire and inflated between the tract of the HV and PV. Subsequently, IRs insert and deploy a stent between both veins (Figure 18 and Figure 19b). The stent will guide the blood along the tract, so a permanent shunt is created redirecting the blood flow. To verify a decrease of portal hypertension, the new blood flow and porto systemic gradient are checked.
5) Finish off: Remove instruments & cover up	If both the blood flow and the blood pressure improve, the materials are removed, incisions closed and all is finished off by the anesthetists and scrub nurses. Otherwise, the tract is re-dilated to further stimulate the blood flow, or a new stent is introduced to improve the flow.



a b

Figure 19 a) During treatment; a guidewire from the JV to the PV (orange=wire); b) After treatment; blood flows directly from PV, through stent into heart (orange=stent).

3.2.2 General micro navigation cycle of the TIPS procedure

In addition to the macro steps of the TIPS procedure, many micro steps were revealed as well. These steps can also be defined as IRs navigation strategies to perform the procedure. In this section, these micro steps will be presented.

In the procedure, IRs generally 1) decide what to do first; 2) imagine how the navigation will take place; 3) actually perform the action; and 4) check the results. Based on literature [STUD2009; SCHU1999] and these findings, the author can present IRs' navigation process during the TIPS procedure. She used the micro steps per micro navigation cycle to explain each observable action: a macro step. Together, the micro cycles (Figure 20) are used to explain the navigation in the TIPS procedure. In short, the micro cycle involves four navigation phases, namely:

1. Plan - what to do?

2. Do - mentally navigate: how to do it?

3. Act - physically navigate: how to move?

4. Check – check if the goal was reached: where are my instruments?

In this section, a general explanation of the TIPS micro navigation cycles will be given. Subsequently, the micro cycle of each TIPS macro step (see 3.2.1) will be described in detail.

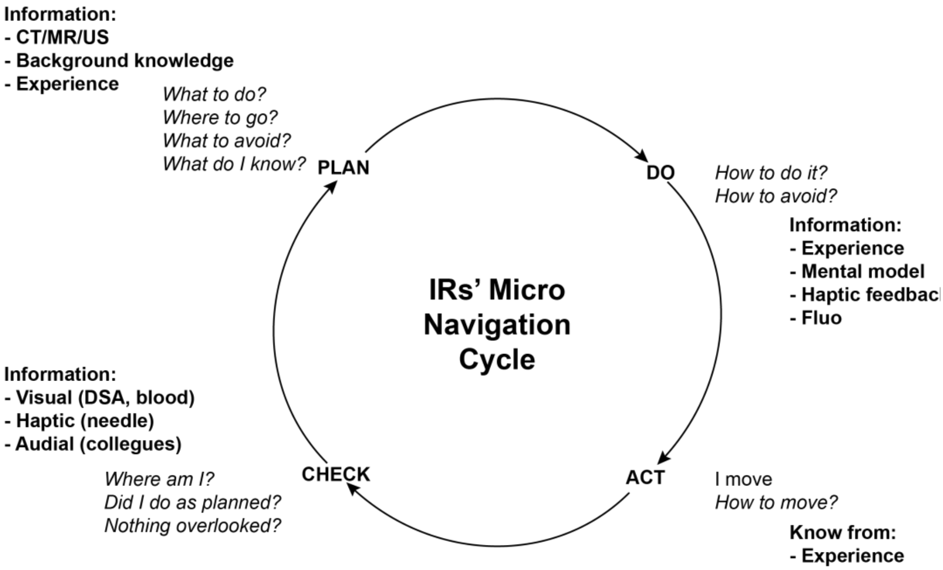


Figure 20. IRs' micro navigation cycle during TIPS, in which the IRs generally start with 'Plan'. The figure shows examples of mental micro questions (italic) and physical micro steps (regular) and information sources (bold). A macro step can be performed by completing a micro cycle. Based on findings and [STUD2009; SCHU1999]

Plan

During the procedure, IRs have a long term and short term plan. IRs have a basic plan of how to perform the procedure for the particular patient. Throughout the procedure, thinking ahead and trying to stick to the basic plan is crucial. Next, IRs also make short term plans on how to perform each subsequent micro step. The short term plan is based on the progress of the procedure.

Throughout the whole procedure, IRs compare the actual data with expectations and constantly evaluate and adopt their plan to decide on how to continue. To plan actions, CT, US, background knowledge and clinical experience are used. CT scans are very informative and thus frequently consulted. They can be used to decide from which branch of the HV to puncture from and to estimate the distance to the PV. A pre-operative US can be used to determine the PV position, to assess PV patency and to determine the presence of ascites. Experience leads to a detailed understanding of the protocol, possible deviations and alternative actions.

From CT scans, US and the background knowledge of standard anatomy and possible deviations, IRs are able to construct a vision or 3D mental model of the anatomy. Especially during the procedure, when real-time 3D information is scarce, the mental model provides anatomical information and helps IRs to plan the next step; to orientate, foresee obstacles, estimate route and to interpret and understand information.

In addition, IRs can inject contrast material to visualize the blood flow within a vein. With the information IRs can check the anatomy and obstructions. The provided information about the veins helps to orientate and plan further actions. Throughout the procedure, the adaptation of the mental model and the plan continue.

Do

To perform an action, IRs should know all the steps of the prescribed protocol in detail. From experience, IRs know each step – and the sequence of steps – very well (as illustrated at the introduction of this chapter). This can be expressed by a statement by an IR during the interview: *"just after the heart, I have to go right"*. When sticking to the standard is impossible, experience can stimulate proper anticipation. Although some IRs doubt the usefulness of landmarks visible on Fluo, landmarks are frequently used as a navigation aid. To illustrate, an IR said during the interview: *"I know that on this image I have to be just under the modic sign of that vertebrae".* It is important that the position of different Fluo images relative to the patient should not have changed to compare different Fluos.

IRs are also able to navigate by sensing the haptic feedback from instruments and combining it with visual feedback. The feedback indicates how to adjust the instruments: 1) no movement, means that instruments got stuck. A guidewire with a small diameter can then be used to pass the obstacle; 2) too rigid or too flexible movements indicate that one should change the instrument's thickness; 3) movement in an undesired direction implies that the instrument's angle should be reshaped, turned or repositioned. Some use haptic feedback when visual feedback is unavailable. Nevertheless, two participants mentioned that they do not trust the subjective and unreliable feedback and they try not to use it.

Due to the insufficient information IRs are sometimes unsure what to do. As a consequence, they perform a probing or systematic search and describe the procedure as a process of trial and error. They constantly anticipate by linking their mental model to the achieved information. For example, based on anatomic relations (e.g., the angle and distance between the HV and PV) they estimate which type of catheter to use, and how to shape or position it. However, the situation and patient's characteristics influence the actual navigation process; therefore, IRs constantly estimate, try and adjust, but continuously consider the possible risks. To illustrate, one IR described to puncture in a certain direction while having strong doubts while doing so, because on the CT a small hepatic artery, and thus a potential risk, was visible. IRs are very aware that each unsuccessful puncture can lead to complications. Not surprisingly, the participants mentioned that lot of confidence is needed to continue. They have to trust themselves, believe that they are making the right choices within the few possibilities they have and need to convince themselves that others will do the same, or neither know what to do best.

Act

IRs pointed out that from experience they gain understanding of instruments' behaviour and how to control it, but only an actual puncture reveals how the needle moves in that particular situation. Overall, three basic ways to manipulate the instruments were identified: 1) manually deform the instruments before use; 2) rotate the instruments; 3) apply force. The IRs control the instruments with their fingers. The instruments are very thin and sensitive to even the smallest finger movements. So, throughout the procedure IRs take care to not accidentally move the fingers or retract instruments before having replaced them by other instruments: otherwise, the acquired position will be lost. Before continuing with the next step, IRs always check their instrument position and if they have gained stable access.

Check results/process

Several checking aids are used to verify actions and check if nothing has been overlooked. One aid is the visual cues from the radio-opaque elements on Fluo or DSA, such as instrument parts, anatomical landmarks (e.g. vertebrae) and contrast material. Their relative position and dynamic behaviour provides valuable information about their location. For example, a needle can move freely when positioned inside the vein, or outside the liver; the needle curls or slips when positioned in a vein; it bends when bumping against the venous wall or hard cirrhotic liver. Vertebrae and other anatomical landmarks are used to re-orientate; by estimating distances in relation to these landmarks. For example, IRs look at the CT to see how a structure is positioned in relation to a vertebra. They trace back the vertebra on Fluo and estimate the structure's position on Fluo to verify instrument positions.

Another visual cue is the visibility of contrast material. As during the planning phase, IRs can inject contrast material to visualize the blood flow within a vein. During the checking phase, the provided information about the veins helps to re-orientate and verify the position. IRs can check the catheter's location within a vein, the blood flow in the stent, or discover a rupture in the vein. Contrast material can be injected manually or automatically by a DSA. The main difference is that a DSA applies higher pressure and a more contrast material. During manual injection, IRs feel a resistance and subtle amounts of contrast can quickly be applied under low pressure. A disadvantage of manual injection is that IRs have to apply the contrast and are thus exposed to radiation. With automatic injection the staff stops the procedure for a while, leave the patient room and activate the machine from the control room. Normally, the contrast material will flow, otherwise there is an occlusion of the catheter because the vein is blocked by thrombosis, the catheter is obstructed, or the contrast is injected in the liver parenchyma. The material can only be applied into a small area providing local and thus limited information; therefore, the bit of information is only useful if IRs are able to interpret what is visualized.

Third, haptic feedback is used as a checking aid. Especially when insufficient visible cues are available, it can provide confirmation and reassurance and gives courage to continue. A catheter provides the best haptic feedback, especially when passing into another anatomical structure (e.g. from liver tissue into the PV).

Last, anaesthetists and surgeons help IRs to verify actions as well. An anaesthetist guards the patient's condition during the intervention. If the blood pressure drops, it might indicate internal bleeding and the anaesthetist will inform the IRs, so they can take action. If the IRs are not able to solve the problem, serious health risks can occur. The patient needs to have lifesaving surgery and is handed over to the surgical department.

3.2.3 Detailed micro navigation cycle, per macro step

By means of the micro navigation cycle, we are able to describe each macro step in more detail. Table 9 presents the micro navigation cycle per macro step. Basically, the table lists specific examples and detailed descriptions of the tools, actions and strategies that IRs use to perform the complex TIPS procedure. It clearly illustrates how complex, elaborate and cumbersome Step 3 – the intrahepatic puncture – is. IRs have to deal with multiple micro questions and focus on many different aspects, such as the haptic feedback and needle behavior, to perform each macro step.

Table 9. The detailed micro navigation cycle per macro step.

	Step 1 Puncture JV	Step 2 – Catheterize HV To HV	 Into the desired branch of the HV	 Position needle in HV
Plan	Puncture the internal JV (preferably the right) percutaneously	Move the instruments from the internal JV towards the HV.	Select the desired branch of the HV and move the catheter into that branch.	Before puncturing, correctly position and angulate the needle in the HV. Instruments should point towards the PV and not accidentally be pushed back into the IVC. To do so, instruments need to be slightly fixated.
Do	Know from experience where the JV is located or how to track the vein on US.	For this step two additional instruments are inserted: 1) a curved catheter, positioned inside the sheath; and 2) a guidewire: a very thin wire with a small curve at the end, positioned inside the catheter. Rotating the bent tip allows for steering and thus to advance the wire into a desired direction. IRs constantly push the catheter over the guidewire till resistance is noticed to provide support and direction to the guidewire. They move both instruments along the lumen of the JV into the VC superior, the right atrium, and along the lumen of the IVC into the HV. The guidewire is constantly used to navigate. Although IRs know from experience where the heart is located in relation to the VC, and feel its resistance, special attention is paid to the Fluo image to assess tool position relative to the features of mediastinal anatomy. After one passed the heart, the HV will be positioned on the right. So, IRs can then navigate the instruments towards the right and advance the instruments into the HV. By entering the HV, the IR will feel an opening through a small loss of resistance.	Based on CT, experience and background knowledge the desired branch of the HV is selected. The right hepatic branch is normally most preferred due to its favourable position. The middle branch is less optimal and the left hepatic branch is only selected when other branches cannot be catheterized. If the instruments do not move into the desired area, IRs use their anatomical knowledge about the patient to compare the direction needed to navigate from current position to the desired branch.	Determining exact instrument position is difficult; therefore, inferring is required for positioning. However, the CT or information from other IG systems is analysed to study the anatomy and to find out at which angle to puncture. In general, the PV is positioned anterior from the IVC. This is checked for the specific patient. Otherwise, an alternative puncture direction is required. Experience helps to predict needle behaviour when exiting the HV. For example, placing the catheter peripherally will lead to a posterior movement, and requires the needle to make a sharp angle to puncture the PV. Placing the catheter close to the heart will cause anterior movement. Consequently, the instruments are placed somewhere in-between those points. To check if instruments are positioned far enough into the HV, attention is paid to the resistance and catheter movement; instruments move freely and little resistance is felt if positioned back into the IVC, but when fixated, much resistance is felt.

Act	Localize the JV through the skin, make a little incision in the neck and insert a large sheath. This sheath is a working channel through which contrast can be given and the catheters, needle and stent can be advanced. It provides stable access to the instruments and is positioned with the tip at the lower border of the right atrium.		Instruments are pushed in a desired direction and pushed forward.	The instruments are retracted, rotated and advanced again when needed.
Check	Aspirate blood to confirm access. Use Fluo to notice the sheath and check the tip's direction and position.	Look at the Fluo and recognize the trajectory: the wire should go to the right of the patient, which is left on the Fluo image, and be positioned just underneath the diaphragm.	To confirm branch position, IRs can check the location: 1) with US; 2) by turning the C-arm of the Fluo: the new viewpoint can help to understand instrument position in 3D; 3) by injecting contrast material.	After repositioning the instruments, the IR re-confirms the position with Fluo. However, only by actually puncturing through the liver the desired instrument position can be identified.

Step 3 – Intrahepatic puncture

Into PV

Plan Puncture from the HV to the PV.

Do IRs estimate instrument location, preferred location, and required puncture force. By combining the information from the IG, the liver size, puncture angles, distances and directions can be determined. IRs juxtaposes visual and haptic feedback and expectations against each other and constantly update their mental model of aspects as current location, preferred location, anatomy, actions to take. An arrow is located at the outer side of the stylet pointing in the same way as the tip. Unless much torsion is applied, the arrow indicates the needle direction. The actual needle movement provides indications of what to do. For example, for needles which got stuck or bend, another needle type, or more force and rotation is required. After an unsuccessful puncture, the needle's end position is analysed and serves as a reference point for the next puncture. IRs can reposition and retract the needle or manually manipulate the instrument's angle (see 'Act'). The puncture was described as a stressful step, because each puncture introduces risks. The target vein is invisible on Fluo, so to succesfully gain access with both instruments (see 'Act'), IRs aim to puncture a little bit further into the PV than where the target is expected. This is generally no problem, as long as the instruments remain inside the liver. However, a puncture outside the liver or into an artery could lead to haemorrhage and should be avoided.

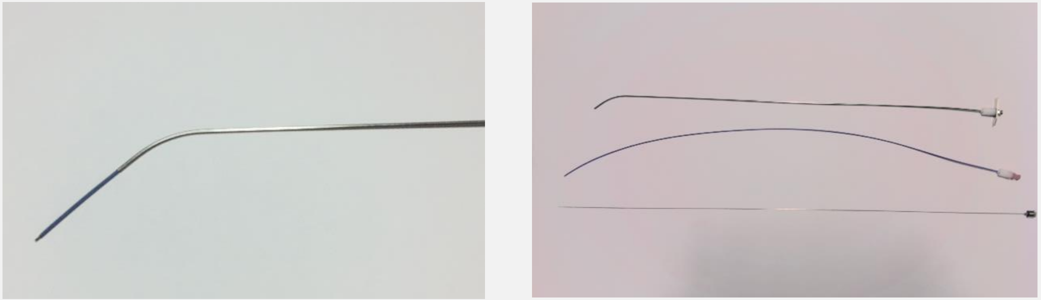


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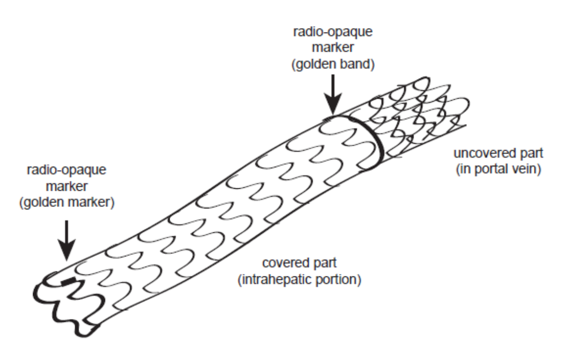
Figure 21. Instruments used for the intrahepatic puncture. a)the sharp needle positioned inside the catheter and large-bore needle; b)the three different instruments used (upper is large-bore needle, middle is flexible catheter, lower is the sharp needle)

Act The catheter is retracted from the sheath and a hollow instrument (rigid outer stylet) is inserted. The stylet is metal and has a blunt bent tip and the shape can be manually adjusted. The guidewire is retracted and replaced by a sharp, flexible needle and a thin, flexible, detachable catheter (Figure 21). The stylet provides direction to the needle and stability to the flexible catheter. When force is applied to the sharp needle, it punctures in the angle directed by the stylet. The arrow on the stylet helps to hold and turn the instruments. After an unsuccessful puncture, one could: 1) slightly retract the sharp needle and puncture again; 2) adjust direction/height of the stylet and puncture again, 3) remove stylet, remodel or use other instruments, and insert and position again. In the latter option the start position might be lost, making the new puncture as challenging as the previous one. The sharp needle, together with the surrounding flexible catheter, will be pushed out of the stylet to puncture into the PV. By pushing them more in or out, one can manipulate the flexibility of the sharp needle from a stiff wire to a firm needle. To puncture from the parenchyma into the PV, the sharp needle and flexible catheter are pushed together, a little bit through the vein. To puncture in a hard cirrhotic liver, a lot of force is needed, but the IRs should avoid the needle moving outside the liver or bending and moving out of the HV, leading to complications.

Check	IRs constantly try to recognise certain landmarks they expect to see or feel. The landmarks are used to update the mental model (e.g., instrument position, orientation). The landmarks on DSA or Fluo help to check instrument location and progress, and to know how to re-orientate after an unsuccessful puncture. IRs look at the vertebrae, ribs, diaphragm, shadow of the liver and intestines and match the information to the mental representation of the anatomy and the needle position. From haptic feedback they recognise structures. For example, the transition from the HV into the parenchyma is difficult to feel, only little resistance is felt. However, cirrhotic livers contain stronger fibrosis near the PV. Cirrhosis and fibrosis can be hard; more resistance is expected near the PV.

		Step 4 – Place Stent	
	Control the puncture/ Verify access	**Catheterize into the portal vein**	**Insert and inflate balloon**
Plan	Verify if PV access was gained	Position the guidewire in the main PV branch, or even into a mesenteric vein, to secure stable access.	Insert and dilate a radio-opaque balloon into the HV-PV tract to create space for the stent.
Do	By experience, IRs know what to do. Again, hepatic feedback can help: fibrosis makes the structure around the PV quite hard and thus a 'snap' can be experienced when entering the PV and resistance is felt when entering the PV back wall. In the vein a loss of resistance can be felt. The feedback not only helps to verify access, but also to estimate how much force should be exerted to do so.	IRs steer the guidewire towards where the PV main branch is suspected and hope to navigate correctly. Normally, the instruments can move freely inside the lumen, but thrombosis can make navigating challenging due to the limited number of distinguishable visual cues and increased resistance. If instruments got stuck, but move again after wrenching, the resistance was indeed caused by thrombus. Otherwise, the wire is hitting the lumen, or an excessive freedom of movement can even indicate a movement outside the liver.	The different consistencies of the vein and the liver parenchyma cause an indentation on the radio-opaque balloon, visible on DSA. The vertebrae are used as a reference to remember the indications points. Based on the indentations and anatomical landmarks, IRs imagine the anatomy and precise location of the veins. The image can be saved and consulted later to estimate the stent length and placement.
Act	When PV access is suspected, the needle will be retracted and the detachable catheter remains. A syringe filled with saline is attached to the outside of the catheter. The plunger is pulled and the catheter is gently retracted to aspirate blood. Contrast could be injected through the catheter as well. When the needle did not puncture inside the PV, IRs just have to try again, and again, and again.	Insert a guidewire through the catheter and then roll the guidewire, move up or down and push a little and constantly advance the catheter over the guidewire when possible. A vein with old thrombus is hard and difficult to puncture; one needs caution not to puncture through the wall. Sometimes instruments get stuck and anticipation is needed; use different instruments, or pull and push the needle.	Retract the guidewire and insert a stiff guidewire through the catheter. The wire functions as a stable work track. Place the balloon catheter over the wire and inflate the balloon to dilate the tract for the stent.
Check	Blood in the syringe indicates that the catheter is inside the PV. The colour of the blood and rate of return are useful to assess whether the needle tip is located in a large or small vessel, in an artery or vein. Also contrast material could be used, to visualize the blood flow in the lumen. However, when no PV access is gained, or when the vein is obstructed by thrombus, the injected contrast will not flow and the DSA will remain black; obstructing the visualization and handicapping IRs. Then IRs must wait until the contrast disappears. This sign can be a huge problem, since no new information can be acquired and the procedure will be delayed. Several alternatives are available for an obstructed vein: 1) try to push the guidewire through the thrombus and into the PV to continue the procedure; 2) visualize instruments and veins on US; 3) Puncture into another branch of the PV from outside the body and inject contrast to visualize the PV; 4) Puncture through the spleen into the splenic vein to inject contrast.	A DSA is generated to check instrument position, blood flow, to re-orientate and plan stent placement.	see– Place stent

	Place stent	Verify TIPS effect and finish off
Plan	Position the stent between the PV and the IVC or HV. It is covered on the HV side and uncovered on the portal side (Figure 22). The covered part should be positioned in the tract consisting of the liver parenchyma and the uncovered mesh inside the PV. .	Verify the effect of the created TIPS by measuring the PV pressure and verifying the new blood flow.
Do:	First, a calibration catheter, containing markers after each centimetre can be inserted to measure the length of the stent. The stent itself is equipped with a radio-opaque marker at the transition of the covered and uncovered part and at the end of the covered part. These indications help to position the stent. The ring is positioned at the transition from the PV to the liver parenchyma. The dilation of the balloon can induce bleeding, especially if IRs have accidently punctured outside the liver before. Unanticipated haemorrhage may be resolved by placing the stent, since the covered part can also cover the bleeding vessel. Therefore, the stent should be placed quickly and IRs are expected to know each step by heart.	1) Generate a DSA to verify stent aspect and position. Based on experience, by looking at the Fluo and by comparing it with previously acquired DSAs, IRs know where to position the catheters and what to look for. The blood should flow from the PV through the shunt into the HV and the IVC. 2) Measure the pressure to verify the stent function. The pressure in the right atrium and the PV system has to be measured and compared. Based on experience and knowledge of the procedure, IRs know how to place the devices. The blood pressure deviation should be below 12 mmHg, preferably around 6mmHg.
Act:	IRs insert the stent deep into the PV and slightly before the desired endpoint. Then they deploy the stent partially and pull until the ring positions towards the opening of the vein. A technician is needed to pull a string and unfold the stent completely. The stent should not move further,  Figure 22. Drawing of the TIPS stent: left the covered part, right the uncovered part because by dilating, the stent may automatically be retracted, but it cannot be pulled forward anymore. After placement the balloon will be inserted again and dilated inside the stent. It was emphasized that stent placement is a simple, but very precise operation which requires cooperation between technicians and IRs. During stent placement, to work fast and with care is important, especially while switching instruments; then, the gained access may not get lost. They cannot pull or reposition the guidewire, and need to constantly check the position on Fluo.	1) IRs insert a catheter deep in the PV, connect the contrast pump to the end of the catheter (outside the patient) and perform a DSA. They analyze the generated image. 2) Attach pressure sensors to the catheter in the PV and the sheath in the right atrium and measure the pressure difference.

Check:	The IRs compare the image of the Fluo, which shows the indication of the balloon, with the Fluo of the stent, which shows the radio-opaque marked ring of the stent. If both are positioned in the same place, the stent is correctly placed at the transition of the PV and parenchyma.	The IRs check the bloodflow on the DSA and the difference in blood pressure. 1) In case of suboptimal position, the stent can be extended with an extra stent. 2) If the pressure difference is too high, IRs dilate the stent again to increase stent diameter and check the pressure again. If the pressure is too low, IRs place an extra stent inside the previously placed stent too further decrease the diameter of the lumen.

3.2.4 An overview of the current TIPS procedure

To summarize all results and present them in one well-arranged overview, a task analysis was drawn as Figure 23. The figure represents the TIPS procedure from the pre-operative phase until the end of the intra-operative phase. For example, it visualizes the main steps, when the different imaging modalities are used and when contrast is injected. The crucial and most complex part of the procedure, the intrahepatic puncture, is marked in red. The dotted loops represent the multiple punctures, which is often needed to gain PV access.

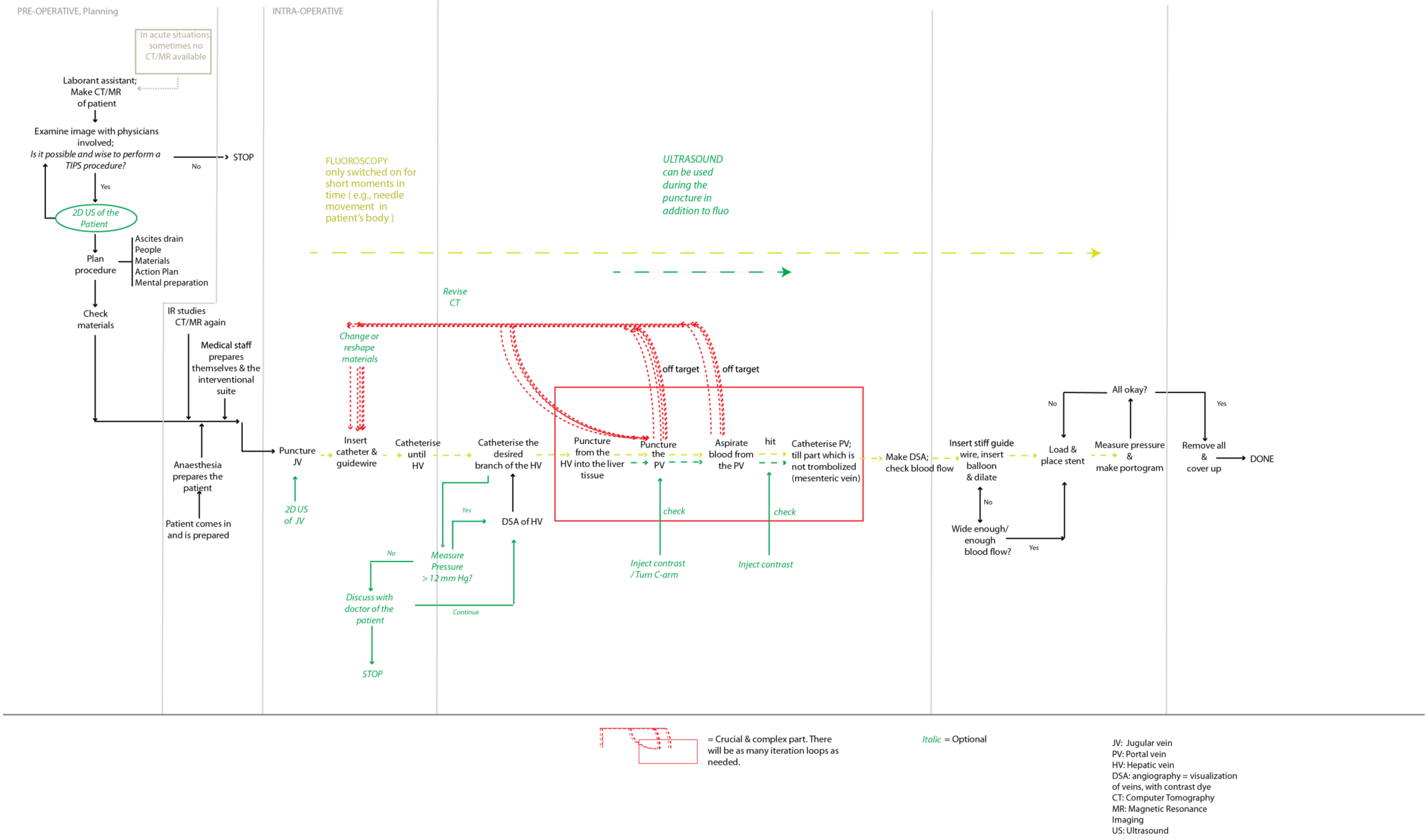


Figure 23. All the macro steps of a TIPS task analysis

3.3 Discussion of the main challenges

During the interviews IRs said that several medical factors could complicate the puncture. First of all, IRs navigate in a liver, which varies anatomically between patients. Furthermore, most TIPS patients have fibrotic livers due to cirrhosis. The fibrosis stiffens the liver which hampers the puncture, and increases the chance that the needle may bend or deviate. As a consequence, the actual puncture options are very limited.

These medical factors pose challenges on IRs' 3D spatial navigation process in the TIPS procedure. Throughout the procedure IRs try to gain information in order to answer mental micro questions, perform micro actions and complete one macro step, such as the intrahepatic puncture. Proper IG could simplify the navigation process by answering those questions in time. However, the current IG provides insufficient guidance, since they mainly show static, 2D feedback information. In the generative session, 64 mental micro questions were disclosed (Table 10). It appears that in 26 out of 64 micro questions IRs can find the proper information to answer the question. For 7 questions only limited information is available and for the remaining 31 questions, no information can be found at all.

IRs mainly miss real-time 3D feedback on exact anatomy and instrument location. This information may help them to control the instrument during a puncture attempt. Currently, visual or haptic information is provided to the IRs, but it is mainly provided after the performed action instead of beforehand. For example, IRs will assess how much force to apply on the needle. However, only by trying they can verify how the needle moves, and whether the right amount of force was applied. During the trial, structures of the liver could be harmed and serious complications may occur. Furthermore, the available information is often indirect and as a result IRs mentioned they are frequently unsure if they interpret information correctly. "*You often ask yourself what you are seeing*", an IR said during the interview.

Figure 24 illustrates what information is needed during the procedure and what is currently available. When answers to mental micro questions are unavailable, IRs are forced to make decisions solely based on their anatomical and procedural knowledge, with all its adverse implications. In the interviews and generative sessions, IRs frequently mentioned "..*estimate*.." and "…*reconstruct in our head*". Besides, the information provided after the action only indicates if the action was successful or not, and provides marginal guidance for the next attempt. IRs uses "*You do not know exactly where to go, it is 'God save me from troubles' and try as often as needed*."; "*it is trial and error*" to describe their actions. In reality, the limited amount of information normally leads to multiple attempts to puncture the target vein, increasing the procedural time and the number of risks. When complications occur, IRs are expected to consider alternatives, and "*to be prepared to solve those complications*." However, the shortage of information makes it challenging to solve those complications. Overall, the procedure is experienced as a procedure which is stressful and difficult. IRs describe the physical and mental workload as: "*It* [multiple punctures] *will make me sweat.*" "…*manup.*"

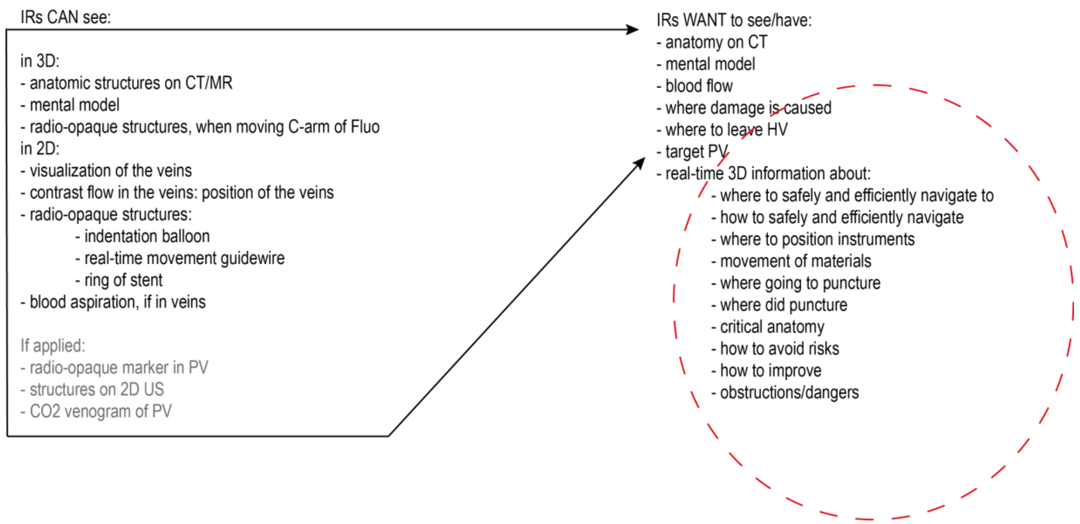


Figure 24 Examples of information which is provided during the TIPS procedure and which IRs currently miss (in the dashed line circle).

3.4 The dream TIPS procedure

Based on the gained insights, a dream scenario for the TIPS procedure was created (Figure 25). In this dream scenario, interactive 3D US is used as an IG system to improve the intrahepatic puncture. The dream scenario illustrates the possible effect of implementing interactive 3D US during the TIPS procedure. Core differences with the current procedure, presented in section 3.2.4, are that in the dream procedure, the PV can accessed at once (no red loops anymore) and that less X-ray and contrast is used. Basically, performing the intrahepatic puncture will no longer be a complex procedure. As a result, it becomes more effective, efficient and safe. The dream scenario will be used by the leading author as an inspiration for the remaining research.

3.5 Conclusion

TIPS placement is a complex procedure in which four major macro steps, 64 specific mental micro steps and 23 general micro steps were distinguished. Among those macro steps, the intrahepatic puncture is described as challenging, since minimal information is available to navigate towards the target. As a result, many puncture attempts are made before IRs gain access to the PV. Currently, a lot of experience, mental effort and patience is needed to complete the procedure. As a conclusion, the required information of the future UI should be provided for each and every macro and micro step, at the desired moment and in the desired way, to help the IRs decrease the cognitive workload and simplify the intrahepatic puncture.

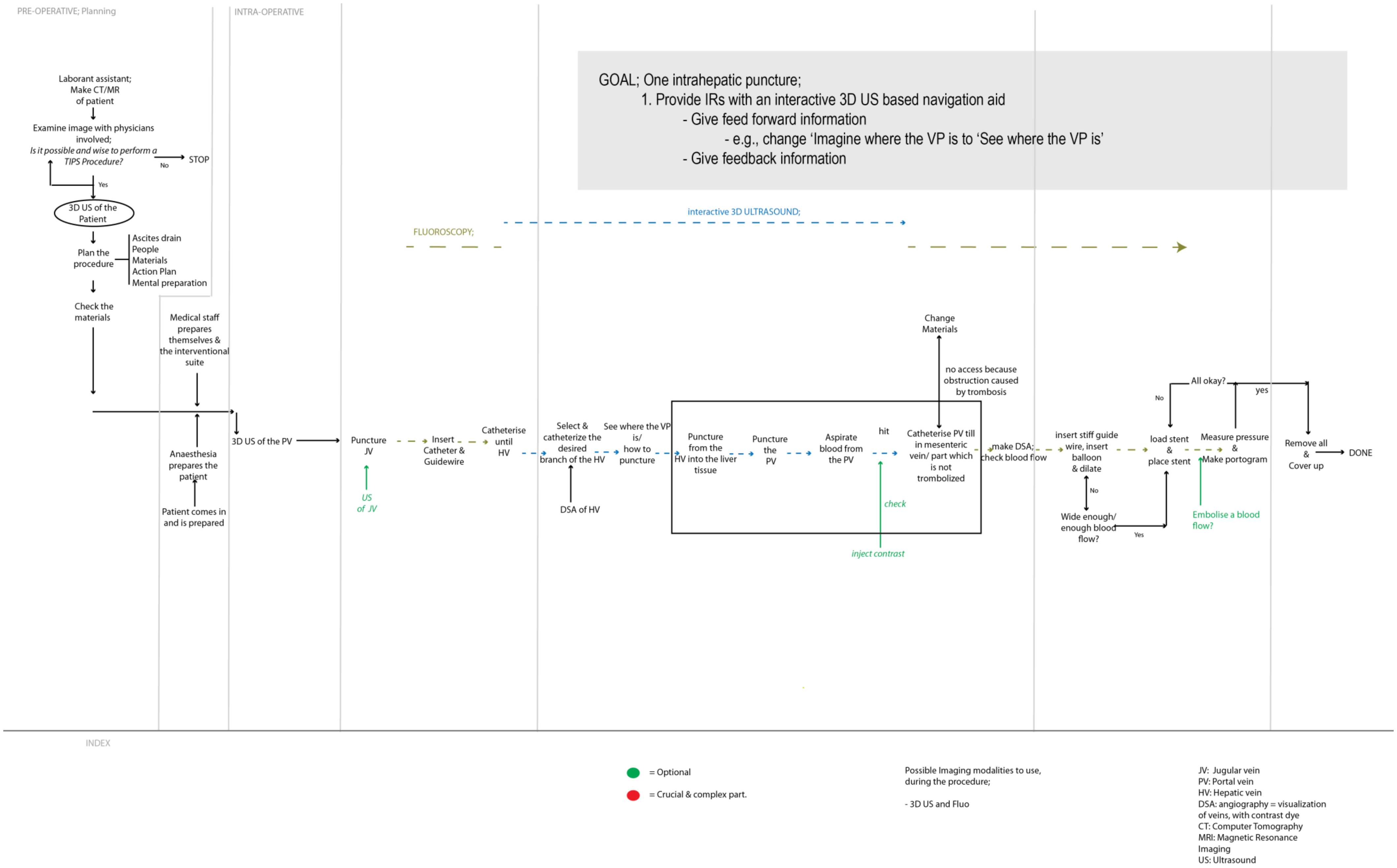


Figure 25. The dream TIPS procedure, based on interactive 3D US guidance: one successful puncture, so less loops and harmful radiation from Fluo. Note that, compared to the current task analysis, it is not optional anymore to measure the pressure before the puncture, as this is only possible if risky visualization aids are used (e.g. placement of catheter in PV)

Table 10 Intraoperative mental micro questions, found during the generative sessions

Macro step/Task	**Micro question**	**Information:**				**Remarks**
		Given?	*System*	*Other*	*Feed-forward/ Feed-back*	
Puncture JV	1. Where to puncture the JV?	Yes	US		FF	Either use US or background knowledge
	2. Punctured the JV?	Yes	BA/US		FB/FF	
To the HV	3. Do I not harm structures? (e.g. heart)	Limited	Fluo		FB	Some haptic information and instrument movement on Fluo
	4. Did not harm the structures (e.g. heart, catch the needle in the IVC)	Yes		An-Pa Drain	FB	- Anesthetist will tell IRs if blood rate drops - Bleedings afterwards - Blood in ascites drain
Into desired branch HV	5. Is the guide wire in the HV?	Yes	CD/Fluo		FB	Know from: -The direction in which the instruments move - Visualizing the veins under DSA with CD
	6. Is the guide wire/catheter in the desired branch of the HV?	No	Fluo			When the C-arm of the Fluo machine is changed: know from experience and estimation if correct.
Position needle in HV	7. Where is the target vein positioned in 2D?	IA, limited			FF	If an additional visualization aid (e.g., CO_2, US, or a radiopaque catheter in the PV) was used
	8. Where is the target vein positioned in 3D?	IA, limited			FF	If a radiopaque marker was used, the 3D position can be required by rotation of the C-arm.
	9. What is the best place to puncture the PV?	No				Only based on estimation.
	10. What is the desired catheter direction?	IA, limited				Can be estimated when additional visualization aids were used. Otherwise, only clear afterwards, when access to PV is gained
	11. Which curve or angle is needed in my catheter to arrive correctly at the target point?	IA, limited			FB	Can be estimated if aid to visualize PV is used/ the c-arm is rotated for 3D information. Otherwise, based on estimation, experience, and trial & error and only clear afterwards, when PV access is gained.
Intrahepatic puncture	12. What is the position of the needle relative to the target vein?	IA, limited			FB	2D position known when using PV visualization tools. Turning the C-arm, shows 3D position

	13. What is the real-time 3D position of materials compared to veins, environment of veins and structures?	No				
	14. How much force should be applied on the needle?	Yes		Pa & Fluo Ha + CT	FB	- Anticipate on severity of cirrhosis - The needle bends/curves, pops away, shoots through, or complications occur (harm to patient)
	15. Do I puncture in a fluent line, without a kink?	Yes	DSA	DSA	FB	- Angle of needle to PV axis - DSA when stent is placed
	16. How do I control the needle?	Yes		Pa, RM		- Position of supporting needle - Anticipate on respiration
	17. Will I sufficiently control the needle to safely puncture the PV (e.g. no resistance from cirrhosis)?	No		An-Pa, Ha	FB	Feedback from the needle, or anesthetist will tell if blood rate drops.
	18. How will the needle move, during each puncture?	No				Estimate by experience
	19. Will I not puncture outside the liver?	No				Estimation
	20. Where is the cirrhosis in the liver?	Yes			FB&FF	-Resistance on the needle -CT
	21. Do I puncture the PV 1-3 cm above the PV bifurcation?	Limited	DSA		FB	
Control the puncture/verify access	22. Why did I not puncture the PV?	No				Guess
	23. Only punctured liver tissue? Did I not harm other structures in and outside the liver?	Yes		An-Pa Hapt Drain	FB	- Materials: shoot away -Anesthetist will tell the IR if blood rate of the patient drops, or later complication of the patient -Blood in ascites drain
	24. How/where is the patient damaged?	Yes	CD& DSA& OR		FB	Complications afterwards, contrast dye to find a leak, and to repair damage. If it is serious and leak cannot be found; surgeon will operate the patient and tell the IR what happened
	25. Did I puncture inside the PV?	Yes	DSA, CD & BA	An-Pa & Ha	FB	Feel resistance, blood aspiration, contrast dye - DSA with CD to see anatomy/PV
	26. Did I puncture on the edge of PV?	No				Guess
	27. Did I puncture the PV in front, or at the back?	IA: yes	Rm on Fluo		FB	Information is available if a catheter is positioned in the PV
	28. How can I improve my puncture?	No				Estimation and background knowledge

	29. Do I puncture the PV wall in a perpendicular line?	No				
	30. Did I not puncture the PV with too much force?	Yes		An-Pa	FB	A rupture in the PV: -Contrast dye leaks -Blood pressure drops
Catheterize into PV	31. What is the most suitable guide wire/catheter?	Yes		Ha DSA	FB	Feel resistance; cannot get in
	32. How to find my way through the PV?	Yes	DSA SA		FB	- Feel resistance - See movement of guide wire on DSA - Expert experience
	33. How do I get my catheter over the guide wire if it gets stuck?	No				-Trial & error - Change materials
	34. How far to insert the catheter in the PV?		RM, DSA CD		FB	See anatomy PV on DSA
Insert and inflate balloon	35. How much force is needed for balloon?	Yes	PG &RM		FB &FF	-Read pressure from dilation pump -Form of balloon on X-ray
	36. Is there no bleeding after dilating the balloon?	Limited		An-Pa Drain		Sometimes from an ascites drain or instability of the patient
	37. Where is the opening between the PV (or HV) and the liver parenchyma?		Fluo			-A notch in the balloon filled with contrast dye -Resistance on balloon
	38. Did I inflate the whole tract between the PV to the HV with the balloon?	Yes	RM		FB	Imprint in balloon; tells where the wall of the vein is
Place Stent	39. What are the required measurements of my stent?	Yes	CT &RM & DSA		FF	HV to atrium/IVC
	40. Is the stent correctly placed between PV and HV? a. Is the stent inside the PV? b. Is the stent inside the IVC?	Yes	RM		FF	Radiopaque markers in wall of veins & of stent change in configuration of distal part of stent while retracing stent to intended position
	41. Is only the covered part of the stent in contact with the liver parenchyma?	Yes	DSA		FB	Change in configuration of distal part of stent while retracing stent to intended position
General	42. What is the anatomy of the patient in 3D, before the procedure?	Yes	CT			
	43. What is the anatomy of the patient in real-time 3D?	No				
	44. What is the safest route? E.g., in case of large tumour?	No	CT			CT will help to plan
	45. Where are the materials located in the body?	Limited	CD & RM	Ha		E.g. sometimes unsure in which HV
	46. Are my materials really positioned in a vein?	Limited	CD			Not possible if e.g. the vein is full of thrombus
	47. In which direction is the material going in 2D (e.g. needle)?	Yes	RM		FB	Needles are moving on Fluo
	48. In which direction is the material going in 3D (e.g. needle)?	No				
	49. How much is the image from e.g. the Fluo delayed?	No				Experience

	50. How do I match the movement of the materials with the delay of the image?	No				Experience
	51. What is the exact anatomy of a vein?	Limited	CD			Not possible if the vein is full of thrombus
	52. How to position the X-ray in an informative way?	No		La		
	53. Do I not inject too much contrast dye?	Yes		An-Pa		Allergic reaction of patient's renal function
	54. Do I not use too much X-ray?	No		Pa		Radiation burns on patient and interventional radiologist
	55. How long is the patient under anaesthesia?	Yes		An		
	56. Did my materials get stuck?	Yes				Haptic information
	57. When materials get stuck, how do I still get access?	No				Estimation and experience: The materials can get stuck through tiny veins, blocked veins, liver cirrhosis, breakdown of material
	58. Which materials do I have to use?	No				Experience and haptic information
	59. How to position/turn/shape the materials to create the desired angle?	No				- See movement on X-ray, learn from other IRs, and know if goal was accomplished. - Previous experience procedure
	60. How far do I have to retract my materials (if gained access to PV)?	No				- Estimate - Haptic - Guidewire position
	61. How far do I have to turn my materials?	No				Estimate
	62. What comes next?	No				Experience and wait
	63. How to improve/ what to do if something happens?	No				Analysis afterwards
	64. Do I not oversee things?	No				
	Legend IA: If applicable	Fluo: Fluoroscopy: DSA: Angiography CD: Contrast Dye RM: Radiopaque Marker CT: Computer Tomography US: Ultrasound BA: Blood Aspiration			La: Laboratory assistant An: Anesthetist Pa: Patient Ha: Haptic feedback from materials Pg: Pressure gauge OR: Surgeon in operating room Drain: Ascites drain in abdomen patient	

“*The main advantage of US is that you get real-time information…. During the procedure you will be certain of your performed actions at an earlier stage*”.

[An IR, see results in section 4.2.2]

Chapter 4: Navigation using 3D US

[Based on CUIJ2013a]

In the previous chapter the TIPS workflow and related challenges were presented. This chapter explores the opportunities of using 3D US to overcome these challenges. In addition, this chapter identifies what elements are needed to develop an interactive 3D US based UI for effective and efficient navigation during TIPS. In section 4.1, 3D US is compared to the other TIPS imaging modalities to demonstrate the potential of using interactive 3D US. In section 4.2, 3D US is used during the TIPS procedure to identify its possibilities and constraints for TIPS. Then, in section 4.3 the preferred US information for the workflow is revealed step by step, and in section 4.4, additional 3D US based UI requirements and ideas are provided.

4.1 Interactive 3D US and other imaging modalities

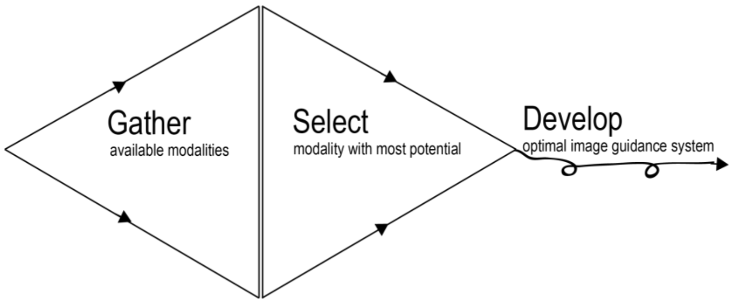


Figure 26. Research approach to select imaging modality for essential information and minimal development risks.

Currently, a comprehensive comparison of the different existing TIPS imaging modalities is not yet available. As stated in *chapter 2*, other researchers mainly use X-ray to improve the TIPS procedure. However, Freudenthal *et al* [FREU2007] argue that comparing the different technical solutions to various criteria is necessary to support innovation. Therefore, in this section the possible TIPS imaging modalities, namely MR, CT, 2D US and 3D US and Fluo, will be compared. Each modality will be compared based on a broad range of criteria to show why interactive 3D US has potential to improve the intrahepatic puncture in the long term. This approach is illustrated in Figure 26.

4.1.1 Methods

A list has been created to compare the different imaging modalities to medical and non-medical aspects in a structured way. The aspects were clustered in three categories: clinical utility, availability and sustainability. The categories were chosen because IRs need access to the modality and to be able to use it within the TIPS context. For instance, sustainability was included in the comparison to make sure IRs are able to use the modality in the long term. The aspects within each category were defined, based on literature, the understanding gained of the author, and the input of an IR in the team on what is important in an imaging modality. The insights from the methods of *Chapter 3* were used to map the different characteristics of the TIPS imaging modalities. Additional literature was reviewed as well. The remaining, unanswered criteria, such as easy to use, were evaluated with IRs' feedback. In addition, trends and advances in cognitive system engineering and imaging technology were adopted from literature.

4.1.2 Results

Table 11 presents the comparison of CT, MR, Fluo, 2D US and 3D US. It appears that, for the TIPS procedure, 3D US has the most advantages compared to other imaging modalities. Below, the main findings per imaging modality will be provided.

CT generates contiguous tomographic 2D images of the patient [FENS2011] providing superlative anatomic detail [HAAG2001]. The image set allows IRs to reconstruct a mental 3D representation of patient's anatomy. The images are made pre-operatively to plan the TIPS procedure and are used intra-operatively to extract actual detailed information about the anatomy and to estimate puncture direction. Disadvantages are that the images consist of 'old' information. Besides, CT is expensive and the second largest source of ionizing radiation, after natural sources [FRUS2004].

MR displays structures similarly to CT [DAFF1999], but normally allows better distinction of soft tissue [JALO2009]. Advantages of MR are freedom in section plane selection and no ionizing radiation [DAFF1999]. MR is less commonly used, since MR is more sensitive for artifacts (e.g., metal, pulsation) and acquisition of images is time-consuming and more expensive comparing to other image modalities [HERF2009; JALO2009].

Fluo uses continuous X-rays through a body part to make real-time 2D projections of the desired area. Mainly radio-opaque elements (needle etc.) are presented on a 2D screen [e.g., DAFF1999]. With a foot control pedal, Fluo can be easily activated, which allows IRs to use their hands for controlling instruments. However, soft tissue is hardly visible [ROSE2000] and the high radiation dose also restricts the usage of Fluo. To acquire spatial orientation in the 2D Fluo images, IRs rely on matching the Fluo images to the pre-operative CT images and their background knowledge in their mental model.

In **2D US**, information of the internal organs is generated by positioning a hand-held transducer on the patient's skin. The transducer transmits acoustic waves into the body [ORTI2012] and 2D image planes are created based on the reflected US waves. The planes have a limited field of view. To acquire sufficient 3D information, IRs position the transducer at different angles and mentally assemble the data. 2D US is cheap, harmless and has the ability of quickly generating images. This allows IRs to see valuable information in real-time [OBRU2009; HERF2009; ORTI2012]. On the other hand, the inefficient acquisition, anatomical constraints (e.g., bone creates acoustic shadows) [ROSE2000], penetration limitations [ORTI2012] and a lack of context [ORTI2012], make the use of 2D US challenging. This is especially true in TIPS since patients often have ascites and cirrhosis [ADAM2009]. These create a poor echogenicity and therefore it is hard to distinguish different structures. Besides, next to the operating IR, an additional IR is needed, during the intervention, to control the probe and acquire valuable information [ADAM2009]. This makes the image acquisition process inefficient and operator-dependent [FENS2002; FENS2011; ORTI2012]. Close collaboration and clear communication between the two IRs are needed, which makes the use of 2D US during the procedure challenging as well.

In **3D US**, 2D planes are created as a section plane of a volume and displayed on the UI. Any slice in the 3D US cone can be calculated, allowing the display of any desired plane [FENS2011; ROSE2000]. According to Rose *et al* [ROSE2000], 3D US provides positional and directional information and identifies specific technical errors or altered anatomy. The modality improves understanding of 3D relationships [ROSE2001], overcomes operator dependency [FENS2000], and, according to Rose *et al*, is "*theoretically free from the most anatomic 2D US constraints and provides planes impossible to view with 2D*" [ROSE2000]. Recently, 3D US systems have the capacity to show real-time 3D images. Real-time 3D US allows the IR to accurately monitor [FENS2002], measure, and manipulate the location of an inserted needle and anatomy in 3D [FENS2000; OBRU2008]. However, the UI is complex and does not fit the current therapeutic workflow [FENS2000; OBRU2008].

Contrast agents are used to visualize the lumen of blood vessels on Fluo. The dye is extremely noxious for patients: it can cause renal failure and sometimes even life-threatening allergic reactions [DAFF1999]. Therefore, IRs have to constantly consider if contrast can actually be used [FREU2007]. In some cases, it cannot [ROSE2000] since it significantly diminishing the usefulness of Fluo. Contrast dye can also be used to intensify the MR, CT or US image [DAFF1999], but the amount needed then is less.

Desired user interface for TIPS

Jalote-Parmar [JALO2009] claims that to benefit the IRs, the future visualization system UI should be intuitive and user-friendly, and information needs to conform to experts' decision making strategies. In TIPS, IRs wish to see planes which visualize the 3D relationship of the exiting needle in the HV, the target PV and surrounding critical structures [ADAM2009; ROSE2000]. Based on *Chapter 3*, we know that the required information should be provided for each macro and micro step in real-time, at the desired moment and in the desired way, without increasing the cognitive load. Finally, the UI-interaction should be intuitive, fast [FENS2011] and accessible (as Table 2).

In the near future, advances in medical technology (as discussed in Chapter 2) could solve some of the current disadvantages of each imaging modality. For example, to enhance perception and comprehension of critical information, the future UI could integrate information of different imaging modalities with registration and segmentation tools [FENS2011; JALO2010]. The information can be filtered to only visualize desired elements. However, the probability that a proper TIPS visualization system can be created varies per imaging modality. To illustrate, we will discuss the required UI changes per imaging modality.

Currently, **CT** and **MR** are reliable imaging modalities in which structures can easily be distinguished, but both imaging modalities are used pre-operatively. It will be unlikely that they become available intra-operatively, mainly due to the limited intra-operative workspace. In addition, to improve the CT's UI, the UI has to allow IRs to see automatically generated (oblique) slices, which are desired by the IRs, show less extensive information and do not require IRs to scroll through the whole dataset. More importantly, information needs to become real-time which is impossible in the current setup. Besides, the needle may cause artefacts. To improve the MR's UI, information has to become real-time and less extensive as well. However, the magnetic character of MR will then hinder the procedure, since special MR compatible instruments are required.

Clearly, two possible TIPS imaging modalities can be used intra-operatively: Fluo and US. For **Fluo**, the UI also has to constantly visualize the HV and PV. Besides, IRs need to be able to constantly achieve real-time information from two directions. To achieve this, two Fluo images need to be generated from two different locations at once.

This requires a double dose of radiation. However, the permitted maximal radiation dose does not allow this. The desired **US** UI should present information without artefacts, regardless of patient characteristics and contact of the probe with the patient's skin. The information has to provide less focused information, but instead provide more overview of the body (i.e. depth, surrounding structures). Furthermore, to make US usable for TIPS workflow, probe control needs to be effortless and the user interaction with the UI minimized.

4.1.3 Conclusion

The results illustrate that for choosing the most suitable imaging modality, a developer has to consider different criteria, such as availability, but also the realizable UI changes. The results also show that each imaging modality provides unique information, but has its shortcomings. IRs therefore combine different imaging modalities to obtain the necessary information. Overall, the interactive 3D US UI needs least technical changes and thus the development will be less time-consuming. Information is already 3D and real-time, US allows sufficient workspace and the UI improvements do not require an increase of radiation, or contrast dye, or considerable changes in materials.

4.1.4 Implications

Interactive 3D US is a promising imaging modality to guide the IRs during the blind puncture and to improve the navigation process. By fusing, i.e. combining desired data from other imaging modalities, such as available CT, visualization barriers will be minimized while acquisition of extra (harmful) data is unnecessary. This could minimize the impact on health and cost. Nevertheless, cognitive requirements need to be uncovered first, to decrease the complex control of the imaging modality and make it more intuitive. IRs should be able to acquire and interpret the image in an effective and efficient way for IRs, for each step of the workflow and for each situation, without requiring an extra IR and without increasing the cognitive load.

Table 11. Comparison of TIPS imaging modalities used for the intrahepatic puncture (see endnote)

	MR	**CT**	**2D US/3D US**	**Fluo**
Clinical utility				
Achieved pre- or intraoperative?	Pre-operatively	Pre-operatively	Intra-operatively (sometimes both)	Intra-operatively
Real-time	No	No [DIGI2012]	**Yes** [ORTI2012]	Yes, but short moments
Details of bony structures	Medium [JALO2009]	**Good** [JALO2009]	Poor [JALO2009]	**Good** [DAFF1999]
Details of soft tissue	**Good** [JALO2009]	Medium [JALO2009]	**Good** [FALL2010]	No [FALL2010]
Details of veins	Medium	Medium, with contrast	**Good**	Good, with contrast
Hand-controlled transducer	**No**	**No**	Yes [ORTI2012;FENS2011]	**No**
Field of view	**Wide** [JALO2009]	**Wide** [JALO2009]	Small [FALL2010]**,** limited penetration [ORTI2012]	**Wide**
3D information	**Yes** [FENS2011]	**Yes** [FENS2011]	2DUS No, **3D yes** [JALO2009]	No [DAFF1999]
Visualize any plane without moving the patient	**Yes: any plane** [JALO2009]	No [JALO2009]; axial & transverse [DAFF1999]	2D: not any plane. **3D theoretically does** [ROSE2000]]	Limited [ROSE2000]
Quality depending on operator (objective and reproducible)	**Medium**	**Medium**	2D: Yes, **3D: Medium**	**Medium**
Easy to use for reference	**Yes, on screen.**	**Yes, on screen.**	No; manually control	**Yes, on screen.**
Easy to generate	No: time-consuming [JALO2009]	Medium, limited scans. IR needs to leave the examination room [DIGI2012]	**Yes**; easily accessible, but much experience required [DAFF1999]	**Yes;** fast [DAFF1999], but toxic: limited Fluo time applicable/ careful use, leave examination room, wear protections
Easy to learn	Medium	**Yes**	Difficult [ORTI2012]*	**Yes**
Trust in system (deviations)	**High**	**High**	Medium	Low
Patient comfort	Low	Medium	**Ok**	**Ok**
Availability				
Relative costs (device & scan)	Very high [HERF2009]	High	**Low** [ORTI2012;SUHO2003]	**Low** [DAFF1999]
Portability device	No	No	**Yes** [ORTI2012]	Yes, portable devices are available, but more heavy and cumbersome than US.
Quickly available for/during TIPS	No	Medium	**Yes**	**Yes**
Time to complete scan (minutes)	30 [JALO2009]	**5** [JALO2009]	**5**	**5**
Mean time imaging modality used (minutes)	30	5	Less than Fluo	38.7 [MILL2003]

Require harmful ionizing radiation	**No** (magnets & radiofrequent waves) [DAFF1999]	Low Dose [SUHO2003]	**No** (soundwaves) [ORTI2012]	High Dose [MILL2003]
Possible life expectancy reduction	**No** [SUHO2003]	Yes [SUHO2003]	**No** [SUHO2003]	Yes [SUHO2003]
Risks from imaging modality	**Unknown****, but screen patient for contra-indications.	Low [DIGI2012] risk of cancer [FRUSH2004] [HERF2009]	**Unknown** [ORTI2012]	Low [DIGI2012]: radiation injury skin patient [MILL2003], cancer risk physician [HERF2009]
Usable for child/pregnant [e.g.,15]	**Yes**	Last option	**Yes**	Last option
Risks from contrast-dye: dye basis	Low: Gd	Medium: I	**No:** N + NaCl	Medium: I/ CO_2 [DAFF1999; ADAM2009]
Mean amount of dye used for TIPS	Unknown	80 ml	25 + 5 ml	200 ml
Sustainability^				
Specific critical materials (apart from basic electronics) [17]	He, Al, N, magnets (often Nb, Ti, Cu)[ROMA2013]	Be, Al, Si, W, Re, Cu, B, Xe, Pb [ROMA2013;SPRA2013;COUR2011]	**Pb, Zr, Ti** [SHUN2007]	Ti, Al, Na, Cs, I, Sb, Zn, Cd, S, Ag, W, Re [SPRA2013; WANG2000; COUR2011]
Risk for resources scarcity	Unknown	Unknown	Unknown	Unknown
Energy consumption	High	Medium	**Low**	**Low**
Biohazard impact	**No** [SUHO2003]	Yes [SUHO2003]	**No** [SUHO2003]	Yes [SUHO2003]
Other				
	**Valuable for diagnosing abnormalities. Unusable when metal in patient [JALO2009]	Detects subtle difference tissue Need contrast dye to see soft tissue [JALO2009]	* Bone and air can decrease visualization [JALO2009;DAFF1999]Images lack context	
Total number of listed advantages compared to other imaging modalities (**bold**=the most advantageous per criteria**)**	13	9	2D US:16, **3D US: 19**	12

^Note that, although limited information on sustainability is available, results imply that US is the most sustainable. More awareness and actions are needed to avoid such serious problems in the future.

4.2 Usability aspects of an existing interactive 3D US based UI during TIPS

In the previous section, the benefits of using interactive 3D US during the TIPS procedure were already presented. Nevertheless, no thorough usability study was conducted yet on how to actually improve the UI to fit the therapeutic TIPS workflow. Due to the novelty of the 3D US technology, literature does not provide the information requirements of a 3D US UI during the TIPS procedure. However, the opinions and experiences which IRs currently have regarding an existing interactive 3D US UI can be helpful in designing an effective and efficient UI for the TIPS procedure in the future. Therefore, in this section, IRs' opinion regarding the information providence of an existing 3D US UI will be analyzed to identify the advantages, possibilities and constraints of using an interactive 3D US UI during TIPS. With these insights the team can design a UI that fulfils the requirements of IRs.

4.2.1 Methods

Getting familiar with real-time 3D US

To gain the IRs' opinion, the research team has to be able to operate the 3D US machine and present available information. Currently, IRs do not use 3D US during TIPS and are thus unfamiliar with the controls. So, before continuing with determining the usability of information, the research team has to be able to make the US information available for IRs. Therefore, the team organised training in which they could use a 3D US machine. They used the Philips 3D US machine (the iU22 with X6-1 probe, see Figure 27).

Trainings

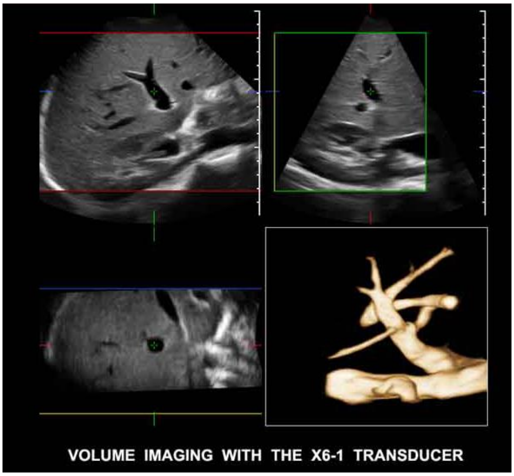
Five training sessions were conducted. The sessions were as follows:

1. A representative of the manufacturer explained the functionality of their real-time 3D US machine to the team. The training of approximately 90 minutes took place in a hospital intervention room. The team asked questions if functions were unclear and the leading researcher made notes during the explanation.
2. Three members of the team (the leading researcher, the computer specialist and one of the IRs) used the interactive 3D US machine themselves. The IR first used the US by placing the probe on the phantom and exploring all the different functions. Actions were explained to the others, the interpretation of the images was explained and possible frustrations were expressed. The others made notes and both asked the IR questions when desired. Subsequently, the leading researcher and the computer specialist explored the use of the US and tried to repeat the IR's previous actions. In other words, they performed actions, such as activating the interactive 3D US menu, generating real-time 3D US images of the phantom (see the example in Figure 28a) and using the scroll buttons to scroll through each of the four images. The IR provided help if the control was difficult or when functions remained unclear. After some exploration with the UI, the IR handed out a needle and the other two explored how to insert a needle towards a lesion in the phantom, under US guidance. The IR gave tips when needed. The session was videotaped and pictures were made for future reference (see Figure 28b).
3. Each of the three team members used the US machine to visualize the abdomen of a fellow researcher. Mainly the liver was visualized, but also the kidneys, the heart and stomach.

4. To further explore the use of the machine and to refresh their memories, the three members practised the US use once more on a liver phantom. Remaining questions and unclear functions were noted down. The leading researcher compiled the answers and remaining questions from the three researchers.
5. As a final action, a second trainer from Philips explained the remaining questions and unclear functions to the multidisciplinary team.

As results of the training, the team had gained deeper understanding of the functioning and control of a real-time 3D US. Some limitations of the UI and usability problems could already be identified.

a) The iU22 machine of Philips



b) An example of the 3D US UI, showing three 2D images of the liver (grey images), from three directions (axial, sagittal, coronal) and a volume rendered image from (lower right in right image)

Figure 27. Philips iU22 3D US, courtesy of [PHIL]

a) The leading researcher is pressing buttons in the interactive 3D US menu

b) The four images of the interactive 3D US UI when visualizing the phantom.

Figure 28. An impression of training number 2

The usability test
After the training, the usability test was prepared. Together with an IR of the team, the leading researcher selected seven steps of the TIPS procedure. The selection was based on the following criteria: 1) additional IG is desired for that step; 2) the addition of the 3D US might provide added value; 3) the procedure could be stopped during that step, to look at the information from the machine's UI. Based on these criteria, the following steps were selected:

1. VCI into HV : to know how to catheterize from the IVC into the HV.
2. Branch HV : after HV catheterization, to verify if positioned in the desired branch
3. HV into PV : to predict the trajectory to puncture from the HV into the PV
4. In PV : after PV puncture, prior to dilation: to verify position in the PV
5. Dilatation : after dilatation: to verify if the whole trajectory was dilated
6. Length stent : after PV catheterization, prior to stent deployment; measure stent length
7. Verify stent : after stent deployment/expansion to assess stent location & blood flow

For these steps, IRs were asked to test the information from the interactive 3D US machine during a TIPS procedure. This was done as described below.:

Materials for the test
- 3D US machine (Philips iU22 with X6-1 probe)
- Task analysis
- Seven interruption steps: the seven steps of the workflow where information from the real-time 3D US machine could be shown
- Plastic tape
- Plastic to cover and sterilize the machine
- Video camera
- Notebook and pen

Materials for the follow-up meeting
- Audio recorder
- Notebook and pen
- Laptop with a compilation of the recorded test
- A list of questions accompanying the recorded test
- Questionnaire (see Table 12)

Preparation
The IR, who had been involved in the interactive 3D US training and the selection of the seven interruption steps was asked to help to perform the test. He was familiar with the TIPS procedure and with using 2D US. He had gained experience from the 3D US training with the information and the control of the interactive 3D US machine. As a result, the IR was able to control the US probe during the test when required.

Protocol
On a paper (Figure 30, at the end of this chapter), the TIPS workflow was visualized in black. In red, the seven interruption steps were indicated. During these steps we desired to briefly stop the IRs actions and ask them to look at the 3D US UI to give feedback on the visualized information from the UI. Furthermore, the steps for which using the information from the US UI was optional were marked in green. These were: prior to preparing and draping, and for the JV puncture. These steps are not the most challenging

parts of the procedure, but the IR and leading researcher felt that IRs might benefit from using 3D US during these steps, or the US information could help IRs in becoming familiar with the new imaging modality. In addition to the workflow paper, the seven interruption steps were also listed on a separate paper. This was done to provide the IRs with a clear overview of the steps.

Participants
IRs of three different hospitals in the Netherlands and Belgium participated in the test. To compare different outcomes, each IR used the imaging modality once during a TIPS procedure. To also include the learning effect, one participant used the device three times. Each participant was used to using a different additional aid to visualize the target PV; one is normally placing a percutaneous catheter in the PV, another is using 2D US, the third is injecting CO_2.
First, a pilot study was conducted with an IR who was used to place a percutaneous catheter. The main purpose was to test the questionnaire, the test setup during the procedure, the workflow and to become familiar with using the US machine during the procedure. After the pilot study some small improvements were made: questions in the questionnaire were adjusted; due to space limitations and the minimal added benefit, one camera was used for the test instead of two. In the original test setup, an additional camera was filming the whole procedure.

Test setup
The fellow researcher (the IR) generated the US images during the TIPS procedure. He could also interrupt the procedure during the seven steps to remind the participant to look at the machine's UI and to provide feedback.

Before the test
The purpose of the test was explained to the participants as well as the task analysis. Meanwhile, the medical staff was able to prepare the patient and the procedure as desired. The participants were requested to perform the procedure as usual, but to stop for a while and look at the 3D US UI during the interruption steps and to provide feedback about the UI and the provided information. It was emphasized that to avoid unnecessary procedural risks, the participant was always allowed to continue the procedure if needed.

Then, in addition to the basic procedural set-up, the machine was positioned next to the patient and the fellow researcher was standing with the US machine at the height of the patient's liver. The machine and the probe were sterilized with plastic.

The video camera was positioned behind the participant. In that way it would not hinder the medical staff, but could still capture the presented information from the 3D US UI. The leading researcher was standing in the operator room to operate the camera and listen to the feedback given, or in the control room to ask input from other staff members. An example of the test setup can be seen in Figure 29.

Figure 29. The test setup. Picture taken from the side of the patient's head. From left to right: the Fluo machine, the fellow researcher, the 3D US machine and instrument table (below the machine), the participating IR, the nurse.

The test

When applicable, the fellow researcher tried to visualize the needle and desired structures on 3D US during each interruption step and asked the participant to briefly stop and look at the UI. Participants were asked to briefly explain which information was visualized, useful, and missing but desired. If requested, the generator explained or changed the image. After the procedure the participants were asked to provide feedback about the test. The first two tests with the IR who used the US three times went as described above. However, the third time the fellow researcher was not available and therefore, the IR had to generate the US images himself, with the assistance of the leading researcher and the nurses.

Video analysis

Within two weeks after the test, the leading researcher analysed the video records and notes and interviewed all participants. She interviewed them about parts in which they had a) expressed positive or negative remarks towards the 3D US information (e.g., "*you can see where you have to go*"), the control and workflow,; b) raised questions regarding vague visualization (e.g., "I suppose this is the portal vein?"); c) expressed unclear comments. During the one-to-one interview, the accompanying video fragments were shown when requested. In general, the following was discussed:

- Overall experience
- Experienced/observed challenges and frustrations
- Added value of the 3D US information
- Experienced certainty per step
- Experienced trust in the imaging modality
- Information gap
- Usability of the machine's UI
- Integration with the workflow: useful/problematic.

After the discussion, participants were asked to fill in a questionnaire (see questions in Table 12). The interviews were voice recorded.

Data analysis
The recorded interview was transcribed. The transcripts and additional test notes, relevant to the subject, design goal and research questions, were printed and cut out and clustered to expose patterns. The data were grouped when possible. To secure correct placement and to provide meaning to the large amount of data, an iterative process of multiple readings and clustering was performed. During this iterative process quotes were constantly re-ordered, allocated, or sub clustered until no further changes were needed. Finally an appropriate theme or subtheme was defined for each cluster. The main themes were: current benefit, potential benefit, unclear added value, frustration current planes, preferred planes, frustration current control, preferred control, workflow, orientation, learning curve. The output of the questionnaires was collated in a table (Table 12).

4.2.2 Results

All but P2 did actually use the interactive 3D US during the TIPS procedure. Despite his good intentions, P2 did not even want to use the 3D US UI after an initial attempt. The participant was very experienced with using 2D US during TIPS and found the 3D US image quality so poor that he would rather only use 2D US. The test results are presented below.

Current benefit and limitations
Table 12 shows that interactive 3D US was said to define HV position, verify PV access and estimate trajectory length (two out of four times 'yes', Table 12). Nevertheless, some IRs had gained additional information. With US P1 could quickly confirm if instruments were positioned in the PV ('yes' in Table 12). For P3 3D US added information in the needle progress ('yes' in Table 12): *"it improved sight on the liver tissue between the cannula and target".* P3 used CO_2 and seems to have gained more profit from the US than P1, who used a percutaneous catheter in the PV (Table 12, question 5).
During the interviews, the two participants claimed to have gained more information from the real-time 3D US during the intrahepatic puncture:

- One participant said that the US information helped him to estimate the distance between the right HV and the PV;
- The other better knew where to go: "*you can see during the puncture that it goes into the porta, or just underneath it*";
- It was also mentioned that the PV's position became clearer;
- One participant mentioned that he was able to better evaluate the liver parenchyma between the HV and PV. As a result, he could verify that the needle was positioned intrahepatic and that a safe continuation of the procedure was possible.

P3 became more certain about the end result of the procedure (Table 12, questions 3 and 4). P1-III said that interactive 3D US did not make him more certain about the end result, but more certain about the steps in between. He explained that in the end, IRs will always know if the procedure has been successfully completed. The difference is that when using US, IRs will be increasingly certain of the success of each step, therefore it is possible to make adjustments. He said: "*the main advantage of US is that you get real-time information…. During the procedure you will be certain of your performed actions at an earlier stage*". He described that with Fluo one often has to find alternative ways, such as aspiring blood, to get the information needed to continue. This will cost time.

Participants said that they did not fully trust the new information after first use. They did not always understand what was visualized and thus did not find real-time 3D

US very useful yet. One participant said "*we had to really try to find the added value of US at this moment*". This is also illustrated in Table 12 question 2 (P3 and P1-I). The main reasons given were:

- The poor image quality, which was described as "*granulated*" or "*spread out*";
- The limited usability of the planes, since not all elements were presented in one plane.

As a consequence, participants said they had to constantly search for suitable planes, the IRs had to estimate what was visualized and a lot of effort was required to analyse and understand the presented information. The instruments' location in relation to the structures was also described as unclear. IRs were never really convinced of what they saw, instead they could only suspect it. For example, one participant mentioned that he was not certain if the needle was inside the PV or not. Another participant said that he saw the needle tip, but did not see its direction. Therefore, he knew where the needle was located, but how to continue remained unclear.

In addition, participants had difficulties to understand how the images were positioned in relation to the patient's body. A participant mentioned that this was because interactive 3D US is able to visualize planes and thus information from a different angle, which cannot be acquired with conventional 2D US. The IR was unfamiliar with these new planes and did not immediately recognize what was visualized. IRs mainly looked at the axial plane, with which they are familiar, sometimes they used it as a guideline to recognize elements in the sagittal plane as well. The coronal plane was hardly used, IRs believed that this was because extracting that information was challenging and the added value remained unclear. The other IR mentioned that IRs might have difficulties to spatially orientate, because US only visualizes a specific part of the whole body and planes are thus visualized without the context. It was mentioned that the UI did not communicate well what was visualized and the relation between the different 2D planes and the anatomy. This made it hard to know which part of the body was visualized. Another reasons mentioned was that hand-eye coordination is missing, because a second person is holding the probe and generating US data.

Table 12 The outcomes of the questionnaire, filled in by the three participants (P1, P2 and P3).

Questions	**P1-I**	**P1-II**	**P1-III**	**P2**	**P3**
1. How much do you trust the information you receive during a conventional TIPS procedure? (scale 1-10)	8	8	7	n/a	7
2. How much do you trust the information, if you get additional information from interactive 3D US? (scale 1-10)	8	8,5	8,5	n/a	4
3. How certain were you about the TIPS result, when you also had interactive 3D US information? (scale 1-10)	8	8	8,5	n/a	8
4. How certain would you have been about the TIPS result, if this extra information from the interactive 3D US would not have been available? (scale 1-10)	8	8	8,5	n/a	7
5. With interactive 3D US, I am more certain of:					
Where the desired HV branch is located:	no	no	yes	n/a	yes
Where the needle is puncturing to	no	no	no	n/a	yes
If I am in the PV	no	yes	no	n/a	yes
If the guidewire is positioned (far enough) in the PV	no	no	yes	n/a	no
What the trajectory length is	no	yes	no	n/a	yes
How the stent is positioned	no	no	no	n/a	no
6. Do you think using interactive 3D US could help you to perform a procedure?	yes	yes	yes	n/a	yes
7. How many punctures did you need?	5	3	1	??	7-10

Potential benefit

Although the way in which 3D US information is currently presented was described as "*miles away from the ideal scenario*" and "*not intuitive*", participants saw the potential of using interactive 3D US during the TIPS procedure. It was said that now the device mainly visualizes the instrument's position, but that interactive 3D US has potential to enhance the guidance and simplify several steps of the procedure. According to the IRs these steps are:

1. During the HV catheterization. It was mentioned that IRs now mainly know from CT how the branches of the HV are positioned, which can make the catheterization difficult. IRs recognized that US can visualize the different branches and thus simplify HV catheterization.

2. Positioning the catheter in the HV. 3D US could help to confirm if the target is positioned outside or inside the liver. An IR mentioned that conventional X-ray IG systems cannot visualize such details. Currently, only a bleeding will notify IRs if the puncture was extrahepatic. It was recognized that interactive 3D US can show the target position before and during puncture and could therefore decrease the number of punctures and risks of bleeding and prevent complications.

3. The intrahepatic puncture. By visualizing all vital elements, IRs are able to estimate how to bend the needle in the desired direction before the puncture, how to puncture towards the target point and how PV access was gained. IRs expected that those estimations will help them save time and effort in verifying the needle's location and repositioning it.

4. Measure stent length. Currently, the required length is estimated or an extra catheter is inserted to define the length. To measure the length, it was emphasized that US should at least be able to visualize the PV entree point and the trajectory to the existence of the IVC.

5. After stent placement: to control the position and unfolding of the stent. However, it was said that this is only possible with a clear US image, meaning that there is no air in the stent and the stent and its transition from the covered and uncovered part are shown in relation to the PV and liver parenchyma. Currently, the ring of the stent and thus the transition was not visible on US. One participant expected that US would never replace the step to verify stent position, because DSA visualizes the flow in the stent very well and in a convenient way.

For the remaining steps, participants said that interactive 3D US could possibly replace Fluo, but it would not provide additional benefits, since sufficient information is already provided by Fluo to realize the steps.

IRs also recognized that interactive 3D US has potential to eliminate the risks from current visualization aids, to reduce procedural time and as a result decrease the level of risks. This is also illustrated in Table 12 question 1-4 and 6. IRs emphasized that this imaging modality is capable of visualizing the needle, the veins and the trajectory in 3D.

Preferred planes

IRs prefer an image quality which allows them to distinguish all important structures and to immediately recognize what is visualized. Participants desired to see the instruments, the target point and all structures in between in real-time, but also the progress, what to do and where to puncture. Furthermore, they said that during HV or PV catheterization, the longitudinal direction of the vein should be represented, as well as the spatial position of the instruments in relation to that vein. For the intrahepatic puncture, one requires to see how to puncture, such as anterior or posterior, the progress of the needle, the target PV, and the trajectory in-between. All preferred elements could be visualized in a 2D plane. An additional 2D plane, perpendicular to the first plane, is required to establish 3D spatial relations. One IR described this second plane as a plane which is angulating around the needle trajectory. He said that this would allow IRs to see all the structures around the needle and its trajectory. In addition, a 3D US view of the veins and the instruments was highly appreciated. It was also recommended to use extra indications and aids to show what is visualized on the UI, but also to guide the IR towards the target point.

Workflow and control

Two IRs mentioned that the current interactive 3D US control is burdensome, not intuitive and time consuming. It was said that an extra IR is required to generate the US data, images are too small, since there is a small 20 inch screen consisting of four even smaller planes, and they had constant difficulties in finding the desired plane. A participant described that they need a system that automatically visualizes the suitable plane(s) and in which performing IRs can easily manipulate the planes instead. He thought that a probe holder might work, as long as it can be sterilized and can be controlled by the operating IR. Nevertheless, one participant worried that the many wires of the device and the echogenic character of the patient may still hinder the clinical feasibility.

Learning curve

Participants noticed they need to adapt to the information from the interactive 3D US, especially to recognize structures in cirrhotic livers. Participants thought that they need both time and experience to become familiar with the 3D US UI, to recognize images, gained from the UI, and be able to judge the true value of 3D US. They said that to let go of the conventional method and to instead see the benefit of using interactive 3D US was difficult. However, all mentioned their inexperience with interactive 3D US. They said that the related difficulty of knowing what to expect and recognize could have influenced the outcome. All were used to Fluo (and DSA) or 2D US. One IR noticed that for the conventional imaging modalities the possibilities and values are well known. Participants said that for 3D US they had to first look at the 2D US or DSA image to recognize structures, and subsequently try to recognize those structures on the provided US planes. One IR addressed the issue that during the procedure there is only limited time for this, because the procedure cannot be delayed. P1, who used the US three times, said that the first time he found it hard to know what to see and expect from the UI, but when using it for the second time that day, he noticed that recognizing structures became easier and he was more aware of possible benefits and potentials. However, it took another year before he used the 3D US for the third time. At that time he noted that using the device was difficult again, as if he were using it for the first time. He emphasized that US has potential to improve TIPS, but more experience is needed for IRs to be able to use the device during the procedure.

4.2.3 Discussion of the benefits and desired improvements

Overall, the potential of interactive 3D US was recognized by all participants. They acknowledged that interactive 3D US might simplify the procedure in the future, as well as decrease procedural time and procedural risks. Currently, the UI mainly visualizes real-time 3D information about the HV, the target PV, the needle position, trajectory length and liver tissue. Sometimes information about the needle advancement is available as well. The interactive 3D US could possibly be used to improve the HV catheterization, the intrahepatic puncture and to estimate the stent length.

However, IRs were not impressed by the current added value of using 3D US during the TIPS procedure and the UI needs further improvement. IRs found it difficult to know what to focus on, what to expect and what to see. They had to concentrate and force themselves to look at the UI and discover additional information. For example, the needle was hardly visible and IRs had to make an effort to discriminate the needle from the vessel's wall. This suggests that using the UI was mentally demanding and time consuming. As a result, IRs were sometimes impatient and had to be asked repeatedly to freeze the procedure and to closely exam the 3D US information. As been said, due to the poor image quality, P2 did not even use the 3D US UI. In the future, acquiring real-time 3D information needs to be less cumbersome and the information well visible.

The examples indicate that the initial learning process was not optimal, but that the usefulness of the UI might increase by experience. Extensive learning may indeed allow IRs to recognize the added value of using 3D US during the TIPS procedure. However, considerable time and effort has to be invested in learning how to use the UI during TIPS. This would be unrealistic since the tight agenda of IRs may prevent them from doing so. Instead, by improving the UI and decreasing the learning curve, the chance that IRs will actually use the UI and recognize its added value will probably be higher.

Based on the findings we can suggest the following improvements for making interactive 3D US suitable for the TIPS procedure:

- Vision:
  - Clearly communicate what information is visualized in the planes;
  - Communicate the added value of the information per step of the workflow;
  - Provide orientation support to recognize anatomical relations;
  - Make the needle and other instruments distinguishable from the anatomy;
  - Improve the image quality to at least 2D US quality;
  - Show two suitable US planes, together they can visualize real-time 3D information;
  - Visualize the instrument in each plane, target point and structures in between;
  - Present a 3D view of the veins.
- Control and workflow:
  - Allow minimal physical interaction with the UI;
  - Allow performing IRs to control the probe and UI;
  - Adjust screen size and other aspects to improve visualization of information;
  - Minimize the number of wires.

Additional testing might lead to more in-depth understanding of the added values of using interactive 3D US during the TIPS procedure. Before the test, IRs recognized the workflow and the interruption steps. However, during the test they mainly used the UI during the first four interruption steps. The information from the interactive 3D US UI was hardly used for the steps of dilating the balloon, measuring stent length and verifying stent location. Possible reasons might be that IRs were too occupied and stressed to look at the UI at that moment and that air hampers the visualization of the stent. Next, during test P1-III, the fellow researcher was unavailable and so the participant had to generate the US images by himself. The IR did not use the device during step 3 'HV into PV' and step 5 'Dilation'. Reasons mentioned were that he did not expect to see much and that he did not want to lose his needle position. Again, procedural stress was observed as a factor as well. For the described test cases, the added value of using interactive 3D US during those steps remains undefined. All illustrates that IRs were not always aware of the benefits and possibilities of using interactive 3D US during the TIPS procedure. It also underlines that it was hard for IRs to use the device during the procedure. All participants expressed the need to use the device more often for providing more valuable feedback.

The leading researcher recognizes those test limitations, but believes that sufficient insights into the advantages, constraints and potential of using interactive 3D US during the TIPS procedure have been gained. The tests were sometimes chaotic: a new device was implemented during the procedure and IRs had to make time to look at the UI and provide feedback. By using the device more frequently participants could become more confident with using the device, and additional insight could be gained. However, it became clear that interactive 3D US is likely to improve the intrahepatic puncture and could replace current IG systems for other steps of the procedure. To do so, the usability of the device should become intuitive and fit the workflow.

4.2.4 Conclusion

Although interactive 3D US has potential, it is not yet valuable in the current setup. Considerable usability improvements are needed to allow easy information assessment when using interactive 3D US during the TIPS procedure. IRs had limited experience of using the interactive 3D US, and additional benefits will probably be recognized more easily. Nevertheless, an UI is highly desired, which communicates what information is visualized and which visualizes the target, the instrument position and direction and critical anatomy in real-time 3D. Overall, all participants acknowledged that interactive 3D US has potential to make the TIPS procedure more efficient and effective.

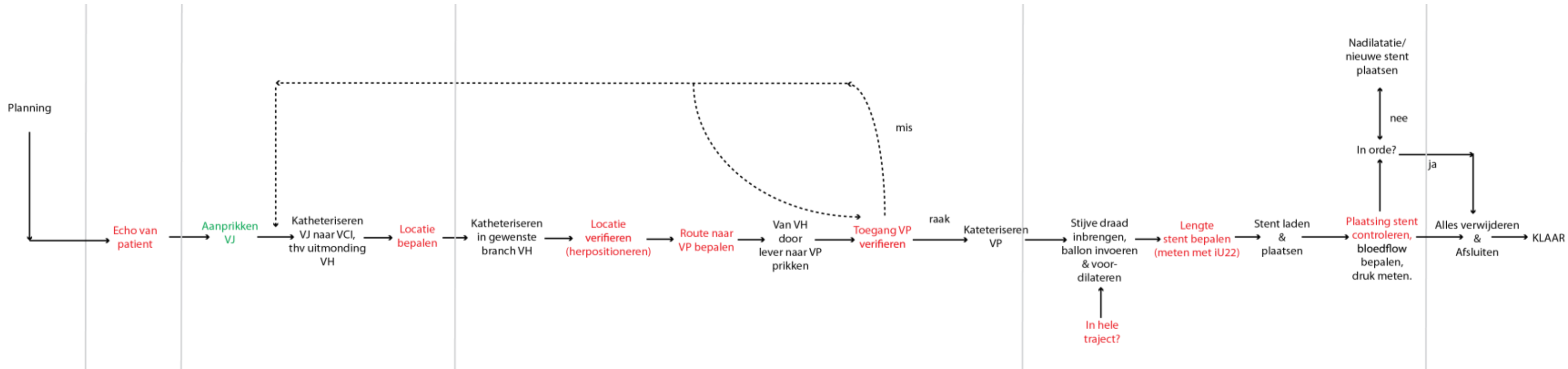


Figure 30. Simplification of the workflow, used during the 3D US during TIPS test. It shows where the IRs have to (red) or could (green) stop the procedure and look at the 3D US UI (in Dutch).

4.3 Preferred information per step of the TIPS procedure

Till now, understanding of the workflow, IRs' needs, 3D US UI requirements and possible solutions was gained. However, concrete comprehension of what, when and how to visualize information on each US plane is still lacking. This is because using an interactive 3D US UI for TIPS procedure is new to IRs. They might find it challenging to envision, generate or communicate what an ideal US plane should look like. Nevertheless, the leading researcher wanted to evoke IRs to express these needs. She desired to have an aid for IRs which could help them to express their information needs per step of the procedure. One way to create a plane is by defining three points in a space. Based on the previous research of this thesis, we know that IRs have certain points per step, such as the target point, which they prefer to see. So, by allowing IRs to define three of these points in a 3D US volume, a 2D plane can be generated. A prototype was created to allow this selection principle and a study was set up to allow IRs to use the prototype and create the planes. The aim of this study was to discover IRs' tacit knowledge in order to generate interactive 3D US plane requirements and solutions.

4.3.1 Method and materials

The following methods were used for the plane selection test:

3D US dataset

A 3D US dataset was generated. The X6-1 probe was positioned below the flat bone in the centre of the chest (subxiphoidal to the body). The place was selected because it allowed the visualization of the IVC, the HV and the PV. The dataset was saved and transferred to a laptop.

Macro steps

Based on the findings from section 4.2, four - instead of seven - macro steps were defined which could potentially benefit from using the real-time 3D US. These are: 1) navigating from the IVC into the HV; 2) catheterizing the desired branch of the HV; 3) puncturing from the HV into the PV; 4) catheterizing the PV. Step three, the intrahepatic puncture, can actually be divided in two; a) the puncture from HV to PV and b) verify access. Nevertheless, IRs often consider both as the intrahepatic puncture, and the leading researcher therefore decided to communicate these as such.

User Interface

The software developer developed the prototype in MeVisLab© 2.2.1 [MEVI]. The prototype's UI consisted of two parts: 1) A left window (Figure 31, left) which showed a 2D axial plane from the acquired 3D dataset. The mouse and arrow keys –pointing up and down- allowed to axially scroll through different 2D planes of the 3D dataset. By clicking in the left image, IRs could select three random points in the dataset. If desired, those points could be deleted at once by pressing the delete button, or one by one, by clicking on the point. 2) A right window (Figure 31, right) visualized the plane containing the three points. The optimal plane was automatically generated from the points selected in the left window.

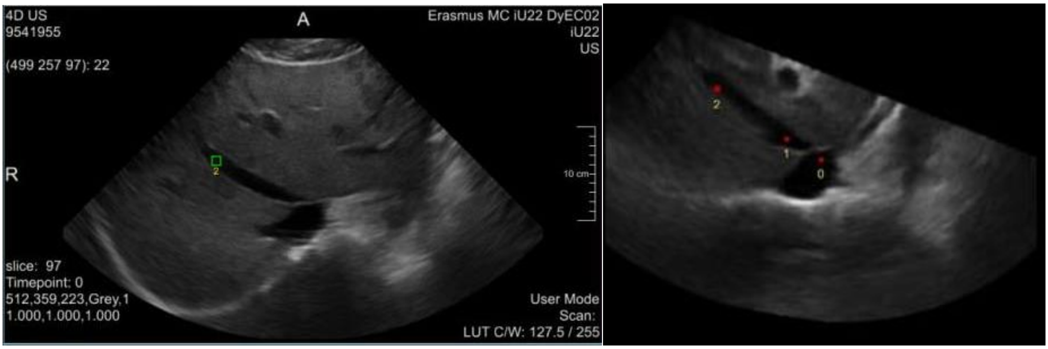


Figure 31. The plane selection user interface. Left: scroll through dataset and select three points. Point 2 was placed in the HV. Visible is the edge of the liver (light grey line), blood or cut through of the HV (long stretched black line) and the IVC (black hole right from the hepatic vein). Right: from three selected points, the suitable plane was generated. Visible is the cut through (in black) of the IVC (point 0), the HV (the line with point 1 and point 2) and a cut through of the PV (upper circle).

Test protocol and experimental task

Before the test, a pilot was conducted by an IR of the team to validate the test setup and protocols. Then, three male IRs were asked to perform the test individually. Two were experienced in performing the procedure and one in assisting it. The participants were positioned in front of a laptop and a list of macro steps, discussed previously, was shown to them. The diagram allowed them to know for which procedural steps desired planes had to be generated. The leading researcher explained that the goal was to generate the optimal plane for each of the four steps and to find out what elements are crucial for each particular step. Next, the use of the UI was explained. IRs were invited to browse through the dataset, select three crucial points and generate their optimal plane for each of the four macro steps. They were asked if the plane was the optimal one for that particular step and why the plane was useful. When desired, corrections could be made by deleting the desired points. The plane which was appointed as most useful was saved. During the interviews, notes were taken about argumentations concerning the selected points, generated planes, corrections, desired planes. After the sessions, a document was created for each step for each IR and contained: 1) which points were selected; 2) the images of the accompanying plane(s); and 3) the participant's comments. Then, the IRs' findings were clustered to find coherence between the outcomes. Similarities and differences were defined to gain a clear understanding of what the crucial elements and optimal planes are. These insights were used as input for UI design.

4.3.2 US Planes for TIPS

During the plane selection test, the participating IRs agreed that IG improvements are most preferred for the intrahepatic puncture. Therefore, more attention was paid to this step. However, concrete information needs were still provided for all macro steps:

Planning: Choosing optimal 3D needle trajectory

IRs' main technical concern is not how, but to safely puncture in the PV. Thus, pre-operative plane planning was recommended to define the desired puncture area in the PV, and then the desired HV branch and exit area. Based on these selections, an effective needle trajectory can be defined, accompanying planes can be generated and visualized intra-operatively.

Intra-operative part: What elements do IRs desire to see?
The IRs desired to have sufficient information when navigating; this means that, per macro step, the whole instrument route has to be visualized in one plane and in real-time. So, for each step the start and end points should constantly be visualized, as well as the instrument location in relation to these points. A description of the required elements per selected macro step is presented below. Since the US images were not generated during an actual procedure, the instruments are not visible in the images.

- Step 1. IVC-HV: To select which HV to enter, visualize the IVC with the middle, the right and sometimes the left HV branch in one plane (Figure 33a). This will assist IRs in selecting a suitable branch and to steer towards it. Once a branch is chosen, IRs desire to see a longitudinal selection of the IVC and the entry point of the desired HV branch (as Figure 33 b). Such an image would visualize where the vein and desired branch are located, and thus at which level to navigate the catheter aside to enter the HV. Moreover, an IR said he desires to see the transverse plane as well (Figure 33 c), it shows if instruments are stuck in the IVC, or actually enter the HV (black dot in Figure 33 c).
- Step 2. HV: To catheterize the HV, visualize the instruments in relation to the HV; starting from the IVC towards the HV exit point from which to puncture through the liver into the PV. A central lumen line could help to accomplish this.
- Step 3. HV into PV: visualize the instruments, the HV exit point, the PV target area, and PV target point (Figure 32). An additional plane has to constantly visualize the needle tip and target point in one plane.
- Step 4. In the PV: visualize how instruments are located when PV access is gained and the whole PV branch to see how to catheterize towards the bifurcation. Again, a central lumen line could be used.

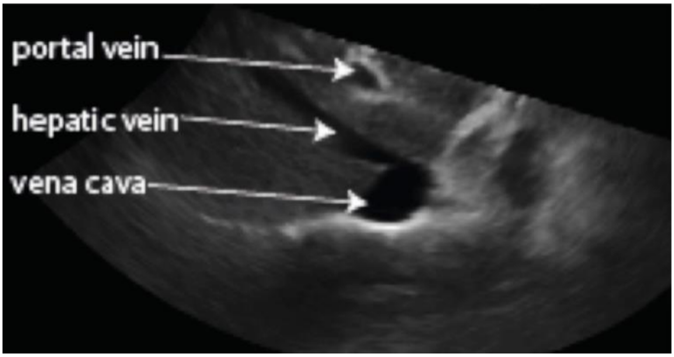
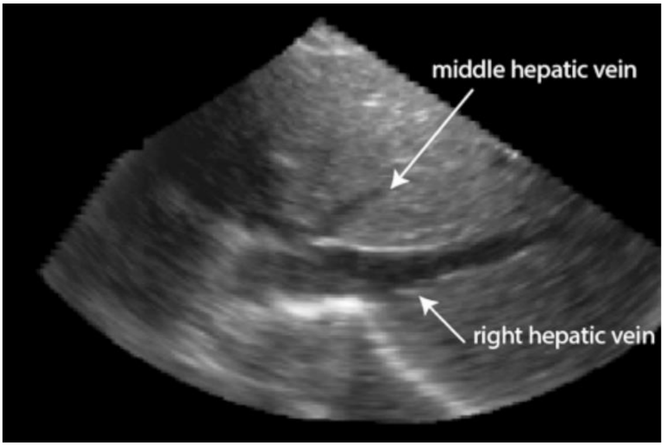


Figure 32. Desired plane for PV puncture, showing the target PV and the selected HV.

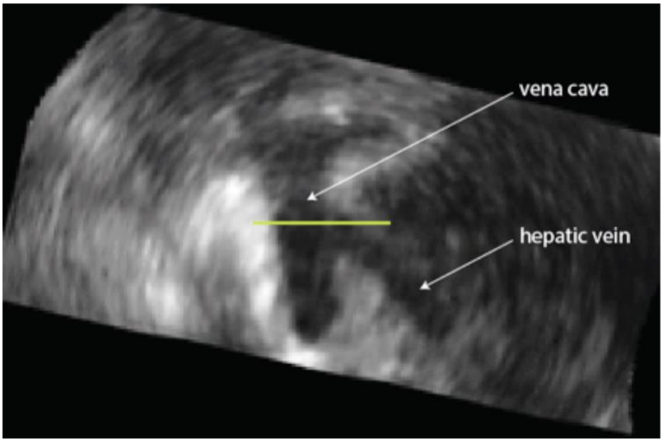
Overall, a UI which allows IRs to generate and visualize the described planes per step of the procedure is highly appreciated.

4.3.3 Interpretation and conclusion

The test was effective in making IRs' information needs concrete. The results illustrate: a) what types of information are needed; and b) how to present them. IRs mainly expressed that they desire to see a) for positioning the needle towards the target PV: the longitudinal and cross-section of the HV and b) for puncturing the PV: the longitudinal view of the HV, the target PV and the cross section of both the HV and PV. Based on these findings, a UI can be created and evaluated.



a



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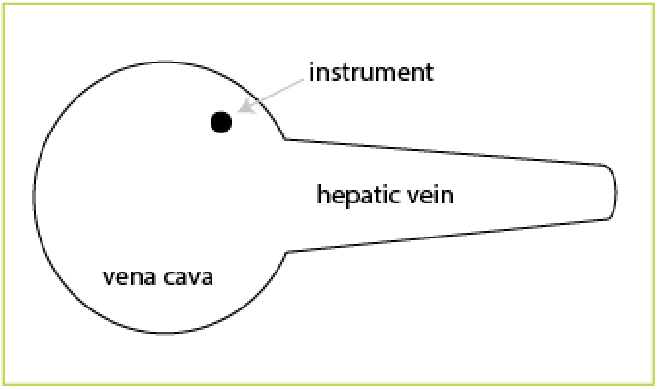


c

Figure 33. Desired planes for catheterisation: a) the axial plane of the HV branches; b) the longitudinal and c) the transverse plane showing IVC and HV.

4.4 Additional 3D US UI requirements and ideas

In c*hapter 3* and *4*, much new data were generated regarding the 3D US UI for TIPS. Therefore, this section gives an overview of the most desired improvements and lists requirements and accompanying ideas. The data were found during the training, real-time 3D US test, plane selection test and brainstorming sessions, but also during informal discussions with IRs throughout the ideation phase. Apart from the already required insights, these additional requirements and ideas could also be used to improve the UI for the TIPS procedure.

Additional requirements and ideas

Additional UI requirements and ideas are:

- Points of reference (Figure 35a); at all times, IRs wants to know which part of the body is visualized on the 2D planes and the relations between the different planes. Thus, communicating the relation between the 2D plane and the 3D US volume, and between the 3D volume and the human body, is necessary. For example, a body marker indicating the position of the US probe, a representation of the 3D US volume with a visualization of the presented 2D US planes in relation to the volume. The macro steps can be represented as well, to help IRs recognize what is visualized on the 2D US planes.
- A planning device (Figure 35b) to analyse a CT/ US pre-operatively, plan a route and create preferred US planes. During the procedure, the real-time plane representation will be presented.
- A tool to calculate correct stent measurements (Figure 35b), this helps to choose a suitable stent.
- Additional landmarks to communicate what is visualized in the image, or to indicate desired areas. The landmarks provide IRs certainty and assistance during the navigation process. Examples are: an indication of PV and HV branches (Figure 36), how far to place the catheter inside the HV, or of the target area in the PV.
- More intuitive and less cumbersome interactions with the UI, since current UI is too complex and demanding. Currently the UI does not fit the therapeutic workflow in which IRs need to be able to quickly adjust the views, with little effort and without needing their hands and losing a lot of time. For example, a probe holder and voice control could help. In addition, the participants desire to scroll, zoom, and turn in the planes and 3D view.
- A 3D reconstruction of the venous anatomy could support in determining and defining the navigation process. To choose a desired trajectory, a 3D reconstruction of possible needle trajectories in relation to the veins is also preferred (Figure 37).
- An orientation support. There is a strong need for spatial orientation support when using a 3D US UI. Currently, US is only able to show information of approximately 20 centimetres in depth and thus only visualizes a specific area within the body. This makes spatial orientation challenging. Therefore, the following orientation aids are preferred: 1) recognizable plane orientation. IRs were not always familiar with the

presented 2D views within the 3D volume, since, as illustrated in Figure 2, the 2D section view of the 3D US data is not necessarily similarly positioned as the US probe. Thus, to allow IRs to identify the visualized anatomy, easy recognition of the plane orientation is desired. For example, the planes could be presented as the conventional position of a liver US, such as intercostal. 2) Recognizable plane-anatomy relations. Again, IRs expressed the need to use reference points to recognize plane-anatomy relations (Figure 35). In Figure 34, an improved understanding of UI elements is represented.

- Plane thickness control: since each 2D US plane only provides information of one layer, one participant mentioned that he desires to control the US planes' thickness. By presenting a stack of combined layers, the amount of information presented at once will increase, showing more details of the vein and instruments.
- It was challenging to orientate within the system. Therefore, users have to be able to know how to navigate within the system. Improvements involve decreasing the number of system settings, and adding useful landmarks.

Next to the findings from the previous sections, it is also desired to take into account all above mentioned UI improvements in the design of a new US UI for TIPS.

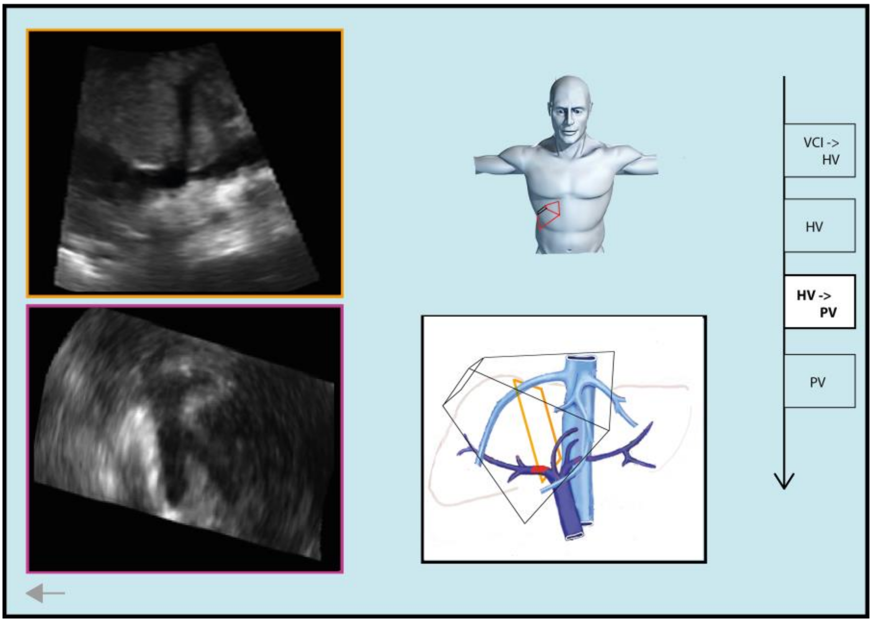
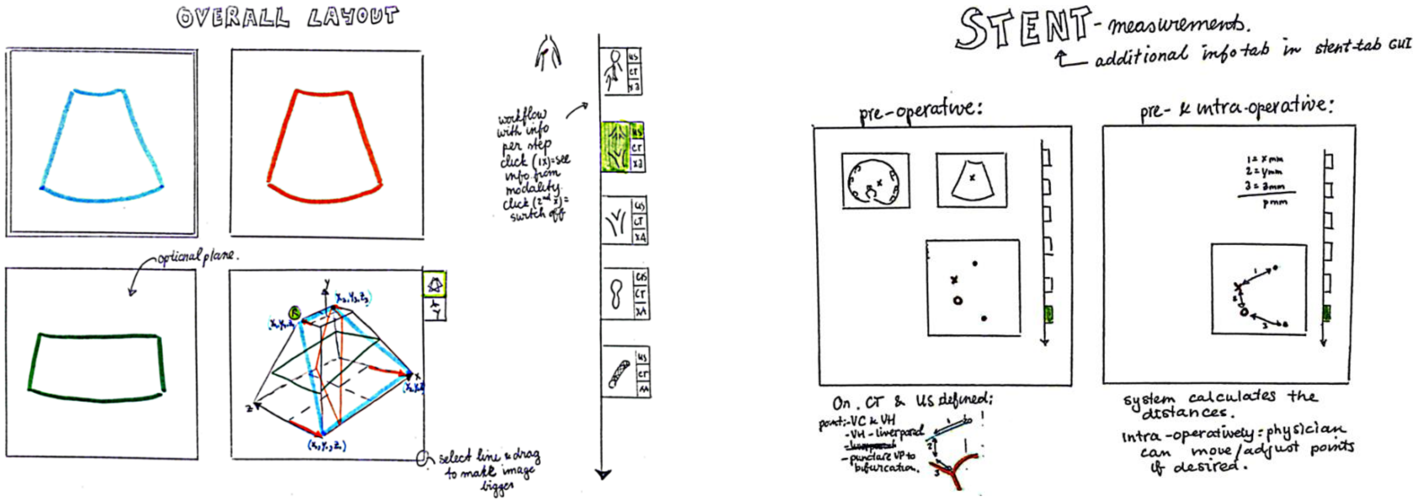


Figure 34. Elements needed in the overall screen; 1) the workflow step, with the current step in white; 2) two 2D US planes; 3) a body marker with probe and cone position; 4) a 3D representation of the veins, the target area (red), the cone, the plane(s).



a b

Figure 35. Preliminary ideas: a) the overall UI; b) the Planning-UI, to indicate landmarks and calculate stent measurements.

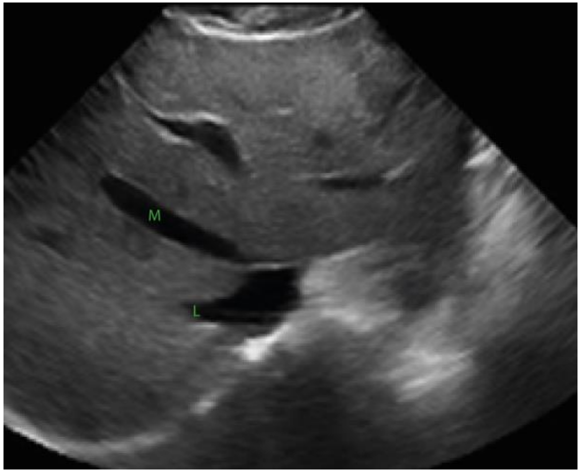


Figure 36. Example of landmarks, indicating the visualized HV (M= middle, L= left)

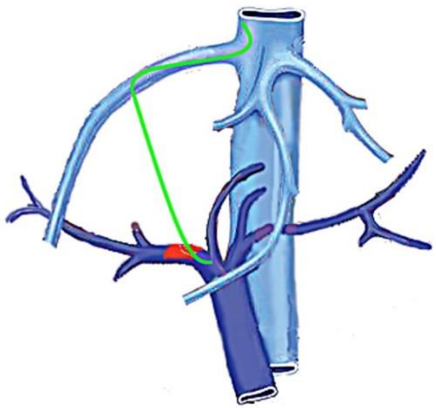


Figure 37. A 3D needle trajectory; visualization of the anatomy and needle trajectory between the IVC, HV (light blue) and target area (red) in the PV (dark blue).

Chapter 5: Prioritize & focus

Based on [CUIJ2013b]

In the previous chapters a considerable amount of data were gathered about the TIPS procedure, interactive 3D US and the UI requirements. The author chose to prioritize the data to know what to address first. As mentioned by Freudenthal *et al* [FREU2008], improving one part first and gradually expanding the improvements allows medical professionals to steer the system in the desired direction. Prioritizing steps allows for creating an IG system which provides the required support. Prioritization could prevent developers from just building a fancy technological solution which is incomplete, or has functions which are superfluous. Therefore, to set focus for the UI development, the aim of this chapter is to integrate what was learned so far, to strengthen the theoretical framework for the UI development. Section 5.1 presents the used prioritizing methods, section 5.2 lists the selected micro questions, which are those which contribute significantly to a successful TIPS placement, and names the crucial UI improvements. Section 5.3 provides a conclusion.

5.1 Methods

From previous studies, the leading researcher had gained a deeper understanding on what could be developed first to improve the intrahepatic puncture. However, to avoid being biased and verify thoughts, she consulted the team's members and additional IRs to prioritize the findings. Experts from different disciplines have their own perspectives, priorities and visions about what to focus on first. Their support allowed the leading researcher to have a thorough view of the possibilities and needs when prioritising the gained insights from *Chapter 3 and 4*. The experts' expertise was consulted as follows:

- The team's opinion was consulted by means of a workshop and discussions. During the workshop of *Chapter 3*, after missing micro steps were added, the team was asked to define the macro steps or micro questions which primarily require improvements. Then, the team discussed the outcomes. The results helped the leading researcher to validate and prioritize those micro questions.
- The prioritized micro questions were verified by an IR of the team. The generated knowledge from *Chapter 3 and 4* and the outcomes of the workshop allowed the leading researcher to create a list of prioritized micro questions. This subset was chosen with the idea that support can be provided for performing the intrahepatic puncture and without changing the whole procedure. For final improvements, the list was sent, together with the original, complete list of micro questions (see Chapter 3) to an IR of the team. The IR reviewed both lists, and after a discussion between both the IR and the leading researcher the list was revised. Questions were deleted or rephrased when they were too general, or not seen as urgent enough. Furthermore, somewhat repetitive questions were combined into one question and questions were rephrased when they were found unclear. The IR could not think of additional questions to add to the list.
- In addition, several informal discussions were held with the team and two additional IRs. During the discussions the focus points were validated and possible solutions for the micro questions were discussed. It helped to prioritize the findings of *chapter 4*

and to generate a list of crucial UI improvements. Mainly findings which were related to the UI, US and TIPS and which could contribute to improving the intrahepatic puncture were listed. The solutions were listed if a) the team thought we were able to improve them during this project; b) IRs emphasized that these findings were crucial; c) the findings had been mentioned more than once by different IRs; d) the leading researcher found that the findings were feasible and contributed to the aim of the research: making intrahepatic puncture more efficient and effective.

5.2 Framework

The new UI will influence the procedure most by making the puncture more efficient and effective. This macro step is the step for which information is limited and additional guidance is highly appreciated. Especially the IRs emphasised the need to only improve this distinct part of the procedure and leave most of the intervention unchanged, at least for now. The remaining steps can still be conducted in the conventional way. Future research may see how much improvement can be gained from applying IG in the other steps.

5.2.1 Micro steps

To improve the intrahepatic puncture, the micro question(s) of the steps *(3) Intrahepatic puncture* and *(4) Control the intrahepatic puncture* and *General* should be improved first. Table 13 (column 2; relevant micro questions) shows that to do so, for 18 of the 64 previously defined micro questions help is urgently needed. For five questions, information is available, but can be improved or made more easily available (column 3 and 4). For the remaining 13, little no or information is currently provided to IRs. This makes answering them and completing the macro steps very challenging.

5.2.2 UI improvements

The crucial UI improvements to support the micro questions are:

1. A Puncture-UI: During the procedure, a UI can visualize **two 2D planes** which help to perform the intrahepatic puncture. The planes visualize landmarks, all critical **anatomical details**, such as the target PV and a preferred **needle trajectory** in real-time. For more information, see section 4. 3. Preferably, the locations and movement of the catheter and needle are visualized in **real-time**. If they are not visible under US, they can be tracked (e.g., by electromagnetic tracking) or redeveloped to make **instruments real-time visible** under US. In addition, a **3D view** of the veins can be added to show the anatomy in 3D. Finally, to tune the planes and to re-plan the procedure, a UI which allows IRs to always interact with the planes is highly desired.

2. A Planning-UI: As 3D US allows to define any **free planes** within the 3D cone, the **Planning-UI** allows IRs to pre-operatively plan the procedure by assigning navigation **landmarks** in the UI, choosing a suitable needle trajectory and visualizing the accompanying planes. The trajectory, related planes and a 3D view of the veins could be visualized on the UI of the IG system. Preferably, the veins and trajectory distances are also presented. **US, CT** or a **registered image** of both could be available to provide all those details.

By taking care of the following, IRs might be able to interact well with the UIs:

3. Orientation aids, which are:

   a. In the main menu: a body marker, the macro steps;

    b. In the 3D view: the 3D US cone, the US probe, 2D plane indicators and direction indicators such as right and head;
    c. In the 2D planes: coloured contour indicating the 2D plane.
4. Intra-operative workflow alterations: to visualize desired **planes**, an option is to not control the 3D US probe manually by an additional IR, but alternatively by a probe holder. Furthermore, if the planes are not generated by hand movements, but calculated in the US cone, visualization of planes might become less operator dependent. The operating IR is able to control what is visualized and to completely focus on the procedure, instead of needing to acquire suitable information.

5.2.3 Overview per micro step

Table 13 presents an overview of required UI improvements per prioritized micro question. The keywords in the column 'Possible improvement' are based on the description of 5.2.2. (bold).

Technical possibilities to create the solutions are already available, making the creation of the innovative solutions highly feasible. For example, automatic registration between real-time 3D US and pre-operative CT can be achieved successfully [NAM2012]. Besides, registration of 3D US volumes to intra-operatively visualize the planned US planes is also possible [SCHN2012]. The option to track instruments on 3D US has already been investigated for other interventional procedures [CHAT2013] and we thus expect that applying this in TIPS will be possible as well.

5.3 Conclusion

The results show that the intrahepatic puncture could become more effective and efficient if IRs are provided with two different UIs in different phases of the TIPS procedure. Based on the provided framework, the interactive 3D US UI can be built. Thus, a Planning-UI and a Puncture-UI will be developed in the project. In the Planning-UI, IRs can load a 3D US scan and the CT images of the patient. They can choose a preferred needle trajectory and prepare the 2D US planes they would like to see during the procedure. Based on the Planning-UI, the US system will show where to position and fixate the probe during the procedure. Then, the Puncture-UI shows a 3D view of the veins and the generated 2D US planes. The images will visualize the anatomy and needle trajectory in real-time, from two directions. Based on the presented information, IRs can navigate towards the target PV. In addition, orientation aids will communicate the relations among the probe, the patient's body, the 3D view and the 2D US views.

Table 13. The selected critical micro questions of TIPS and desired improvements per micro question. These micro questions, as a complete set, should be supported most urgently.

Macro step/task	Relevant Micro question	Information available to IR?	Additional remarks (not mentioned in Table 10)	Possible improvement, e.g.;
1. Navigate from JV to HV				
2. Catheterize the HV				
3.Intrahepatic puncture (puncture from HV to PV)	8. Where is the target vein positioned in 3D?	Limited		Free plane, landmarks, 3D view
	9. What is the position of the needle relative to PV?	Limited		Free plane, real-time instruments, landmarks, real-time details anatomy, trajectory
	10. What is the real-time 3D position of materials compared to veins, environment of veins, structures?	No		Free plane, real-time instruments, landmarks, trajectory, real-time details anatomy, 3D view
	11. What is the best place to puncture the PV?	No		Free plane , landmarks, details anatomy, planning- UI
	12. What is the desired catheter shape and direction to arrive correctly at the target point??	Limited		Trajectory
	14. How much force should be applied on the needle?	Yes		Trajectory, landmarks, real-time details anatomy, real-time instruments
	15. Do I puncture in a fluent line, without a kink?	Yes		Trajectory, real-time instruments, 3D view, Planning-UI
	17. Will I sufficiently control the needle when puncturing to the PV?	Limited	- Before procedure: see cirrhosis on CT. - During procedure: needle movement visible on fluoroscopy provides feedback on actual density and needle behavior. - Anesthetist will tell if blood rate drops. - Blood in ascites drain After first puncture, acquired knowledge will help to estimate needle behavior.	Trajectory, real-time anatomy, real-time instruments.
	18. How will the needle move, during each puncture?	No		Real-time instruments
	19. Will I not puncture outside the liver?	No		Trajectory, free plane, real-time anatomy, added landmarks

	20. Will/ did I not cause collateral damage?	Yes		Trajectory, real-time instruments, landmarks, real-time anatomy, 3D view
	22. How to handle complications? Note: not thoroughly researched. Possible questions are: Where is the damage? How to repair the damage?	Yes		Real-time instruments, free plane.
4.Control the intrahepatic puncture	23. Did I puncture inside the PV?	Yes		Free plane, real-time anatomy, real-time instruments
	24. Did I puncture on the edge of PV?	No		Free plane, real-time anatomy, real-time instruments
	26. Do I puncture the PV 1-3 cm above the PV bifurcation?	No		Real-time instruments, landmarks, trajectory
	27. Why did I not puncture the PV?	No		Free plane, trajectory
	28. How can I improve my puncture?	No		Free plane, trajectory
5. Catheterize the PV				
Place stent etc.				
General	44. What is the safest route? E.g., in case of large tumour?	No		Free plane, trajectory, landmarks, real-time anatomy, 3D view, Planning-UI.

“I think it helps to create a valuable understanding of how to plan the procedure”
[feedback from an IR on the Planning-UI, 2014, see section 6.3]

Chapter 6: The Planning-UI

Based on [CUIJ2015b]

Up till now, a theory has been formed on what TIPS improvements are needed and why. In Chapter 6 and 7, the leading researcher uses this theory for designing and IRs evaluate the design. Based on the evaluation results, we are able to validate our findings and find new insights on how to further improve the interactive 3D US for the TIPS procedure.

The aim of this chapter is to develop an interactive 3D US based UI for effective and efficient pre-operative planning of the intrahepatic puncture. First, section 6.1 gives a brief overview on why a Planning-UI is desired and what information is needed for planning TIPS. Then, section 6.2 presents the methods and materials used to build and evaluate the Planning-UI. Section 6.3 shows the test results and finally, section 6.4 draws conclusions and recommendations for the Planning-UI.

6.1 The design of a Planning-UI

Following the findings of Chapter 2, 4 and 5, it became clear that a Planning-UI is desired to improve the intrahepatic puncture. It allows IRs to load the available CT or MR images and the generated 3D US images. Subsequently, the Planning-UI helps IRs to create and save the desired 2D US planes during the pre-operative phase of the procedure. During the intra-operative phase, interactive 3D US can be used and the saved planes from the pre-operative phase can be used as view planes to navigate in real-time. Combined with information on the preferred needle trajectory, which is also acquired in the planning phase, these intra-operative 2D US planes will show IRs the desired information to gain access to the PV, such as the target point. The predefined information allows IRs to focus on the procedure and the patient during the intra-operative phase. Instead of finding the suitable view planes, IRs can immediately acquire the desired information from the UI.

In addition, a planning-UI will help IRs to mentally plan the procedure. It allows IRs to see the patient's anatomy and possible needle trajectories in 3D. Furthermore, IRs are able to interact with the images and explore different target points. This could help them to become familiar with the anatomy, anatomical constraints, risks, puncture possibilities and distances before the procedure is carried out. Based on that information, IRs are able to select a desired needle trajectory and roughly estimate what to expect during the procedure. Overall, a Planning-UI has potential to make the procedure more efficient and effective. It allows IRs to visualize their actions, not to imagine the actions and their effects.

6.1.1 What to visualize in the Planning-UI and why?

The insights from Chapter 2, 4 and 5 were used to design the Planning-UI. For example, from the literature review it became clear that the UI should provide users with an overview of the situation and detailed information about current locations of anatomy and instruments. In addition, it appeared from previous studies that IRs define where they want to puncture the PV, what is the safest route to arrive at the target point and where they then could start to puncture. Based on their plan, they decide how to position and bend the needle and how to navigate it towards the target point in the PV. They try to gain information to (mentally) visualize the navigation process. From Chapter 5 it became clear that the Planning-UI preferably shows (fused) information acquired by US, CT and a 3D view of the veins. It is also desired to be able to define landmarks, the needle trajectory and show the 2D section planes of the 3D US which visualize these elements.

An original Planning-UI was designed to intuitively assist IRs' planning process. The basic design ideas are as follows:

- IRs can load a set of 2D CT/MR images and the 3D US image (which is a set of 2D US images) in the UI. These 2D images show detailed 2D anatomical information (e.g., about the veins and liver anatomy). IRs then select a target point and target area in the PV and an exit point in the HV. A target area is useful, as literature in Chapter 2 indicated that IRs can safely puncture in a 2-3 cm area around PV bifurcation;
- Based on the loaded US (or CT) images, the system will automatically create a 3D view of the segmented HV, PV and IVC. This 3D view will visualize the vessel anatomy in 3D and the effect of IRs' planning actions and can help IRs to orientate. Currently, IRs have to reconstruct a mental 3D representation of the anatomy, which is mentally demanding and often inaccurate;
- Different needles can be used to puncture the PV, therefore the system will ask IRs to define the preferred needle. Based on this information, the system can define a suitable trajectory;
- An IR in the team said that the trajectory should be as short and as straight as possible. Based on both trajectory criteria and the selections mentioned above, the system will present possible needle trajectories. The IRs see the possibilities in the 3D view and could judge the risks, feasibility and other aspects. They will be able rotate the view, zoom in and out, and thus really see the trajectory in relation to the liver anatomy. In addition, the UI will provide the distances between a) the IVC and HV exit point; b) the HV exit point and the PV entry point, and c) the PV entry point and PV bifurcation point. From Chapter 4 we can assume that the distances help IRs to judge the trajectory and estimate the stent's length;
- IRs will be able to select their preferred trajectory. Based on the selection, 2D US planes are generated which visualize the exit point, entry point, needle trajectory and anatomy (as described in section 4.3). Those planes contain information that IRs need during the puncture. Based on the information, IRs can decide how to bend the needle and how to navigate towards the PV.

Based on the insights from Chapter 2 on designing UIs, the design of the Planning-UI follows minimalist principles [WICK2004; AZUM2000], e.g. by only presenting crucial information. In this way, the UI will not overload the IRs with information. For example, the UI will:

- Only show the required information per task (e.g., 2D US images);
- Use a minimal number of colours, texts and text fonts. The UI will only use these variables to clarify what is visualized or what should be done;
- Present the most important information in the middle (from left to right) and less important information on the sides;
- Only use basic and crucial interactions with the screen, such as click, zoom, scroll, move.

Next, the leading researcher wants IRs to use the UI to explore different options, such as target points, trajectories, and thus to evaluate different possibilities. However, IRs must not lose the overview of the tasks to be performed when using the UI. Therefore, the UI will visualize which tasks have already been performed and which are still to come. IRs can only perform the next task after completing the current one.

6.1.2 How the Planning-UI is designed

Based on these design requirements, an original planning-UI was designed and implemented using MeVisLab© 2.2.1 [MEVI]. A transversal acquired 3D US dataset of a volunteering team member was loaded into the UI. Due to safety concerns, CT images of the volunteer were unavailable.

The segmented 3D images of the HV and PV are visualized on the right side of the UI (Figure 38). On the left an axial 2D US plane is presented. The designed mouse HCI allows IRs to: a) scroll through the dataset in the axial direction; b) zoom or rotate the segmented images and c) to select points by double clicking. Deselecting points is possible by double clicking on another area in the US image. Alterations made in one screen/plane are automatically shown in the other screen/plane as well.

To plan the procedure, IRs have to complete seven tasks. These tasks are needed to allow the UI to generate the needle trajectories and present the intra-operative 2D US images. First, each task is sequentially listed in grey in a vertical taskbar on the right of the 3D view. During the planning, uncompleted tasks remain grey, while current or completed tasks turn white. An instruction window in the centre of the screen provides briefs for each task. IRs have to confirm that they read the brief by clicking the OK button. The OK button and position of the instruction window are designed to avoid that IRs may overlook the instructions. If IRs overlooked what to do, they could click the HELP button at the upper right of the UI and the instruction would appear again. Just below the 3D view, a RESET button is positioned on the right and an UNDO and REDO button on the left. These buttons allow IRs to redo or undo changes in the 3D view or to reset the view to as it was at the start. Only after selecting the NEXT button, in the upmost lower right hand corner of the UI, IRs will be able to continue with the next step. This would avoid IRs making changes without noticing.

Overall, the seven tasks are:

1. Select the preferred entry point (Figure 38), select the preferred target area and click NEXT. In this prototype selecting a target point was only possible in a predefined part of the PV. When selected, the system automatically creates a box with the point as the centre. The box selects an area of 4cm in the vein and its width and height encloses the total diameter of the vein. At each side of the length of the box an extended line is visualized. IRs are able to use the mouse to click on one of the lines and to drag the line in the longitudinal direction. As a result, IRs are able to adjust the length of the box and thus the target area;
2. Select a point in the bifurcation and near the target point and click NEXT; users can click any random point, as long as it is near the bifurcation and near the already selected point. This step was required to allow the system to create a needle trajectory (after step 5).
3. Select a preferred HV and click NEXT (Figure 39); by double clicking on a part of a HV branch in the 2D US image, the whole branch of the HV was selected;
4. Select a point in the IVC near the selected HV and click NEXT; this task was needed for the same reason as described in step 2;
5. Select a needle and click NEXT; the UI presented the option to select Type A 150 degrees or Type B 145 degrees. The type had to represent the different bore needles which can be used during the TIPS procedure;

6. Select an appropriate needle trajectory and click NEXT (Figure 40); Although it was not the goal of this thesis, a first attempt for the possible needle trajectories was made. In the future, a suitable form still has to be found. For now, the system calculates and presents three possible needle trajectories, based on the previous selections. The upper part of the UI shows three tabs representing the number, for example trajectory 1. IRs can view each trajectory in the 3D image. In the top of the 3D view, several numbers are represented: the angle IVC-HV-PV, the angle HV-PV-bifurcation, the total length and the length HV-PV. These numbers might help IRs to judge the length of the needle trajectory, the required puncture angle and stent length. It could help IRs to decide what the most suitable trajectory would be. Here, the NEXT button is replaced by a button representing the number which is currently selected, such as select option 3. This allows IRs to make a well-considered choice;
7. Based on the generated view planes, adjust or click NEXT when satisfied (Figure 41); After selecting a trajectory, IRs can view the trajectory on the 2D US images. One image shows the longitudinal section of the veins and the other shows the cross section of the veins.

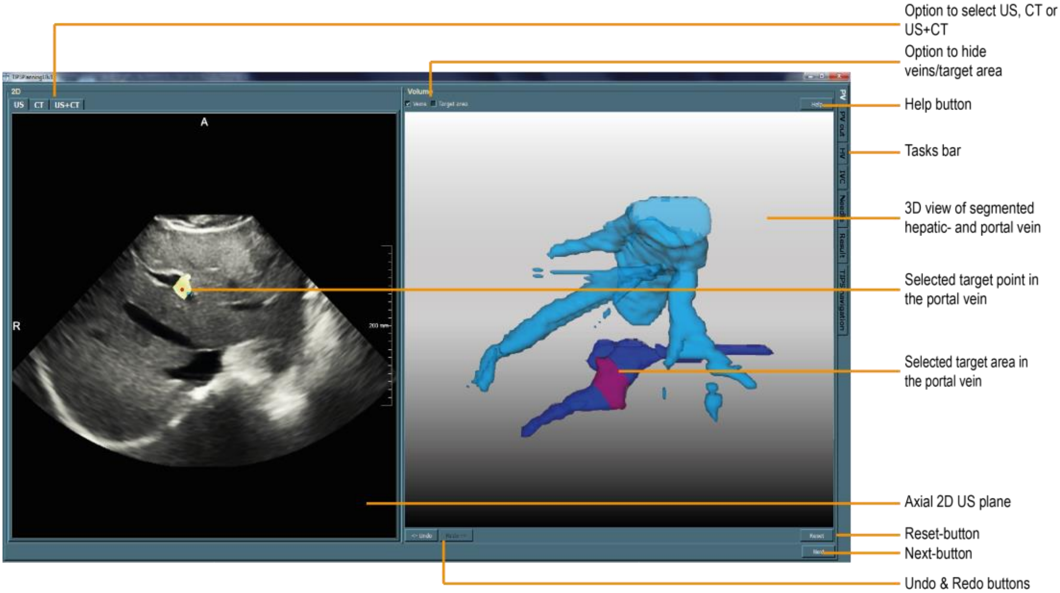


Figure 38. The design of the Planning-UI: showing an example of a selected target point and area in the PV.

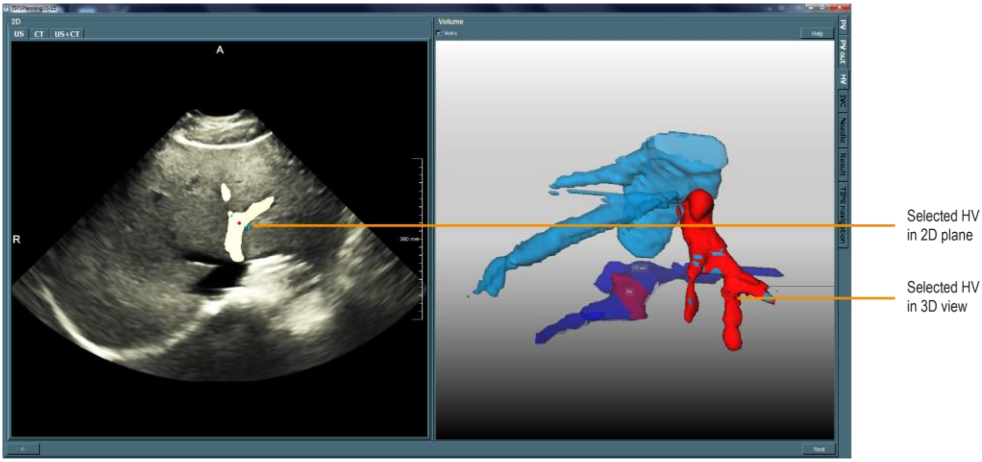


Figure 39. An example of the Planning-UI in which a desired branch of the HV is selected.

Figure 40. An example of a needle trajectory, which the system has created based on the selections

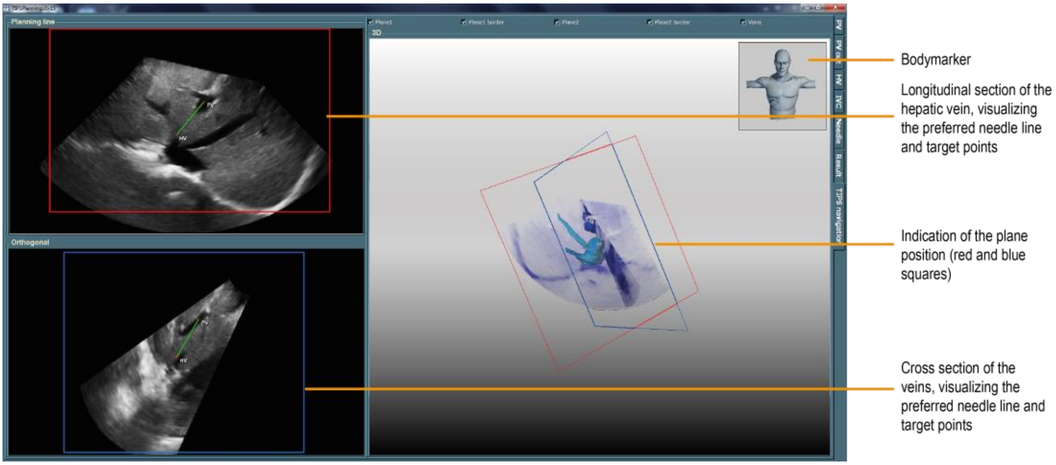


Figure 41. An example of the created 2D US planes, which could be shown during the intrahepatic puncture. The planes visualize the HV, the target point in the PV and the preferred needle trajectory from two directions, together creating 3D information.

6.2 Method and Materials:

A test was designed to assess the usability of the UI which concerns the planning of the intrahepatic puncture.

6.2.1 Materials

The following materials were used:

- A laptop showing the Planning-UI;
- A computer mouse;
- A video recorder;
- Questionnaire;
- Three random post cards, representing the current, the new and the ideal Planning-UI;
- Pen and paper.

6.2.2 Method

Five IRs participated in the test. The IRs were asked to sit in front of the UI and think aloud during the test. Then, the basic goal and functionality of the UI and the aim of the test were explained. When applicable, questions were answered. Then, the participating IRs could start to complete the seven steps and thus to plan and select a desired trajectory and view the created planes. Afterwards, the IRs were asked to fill in a questionnaire by ranking from 1 (disagree) to 7 (agree), if:
a) The planning interface is easy to use;
b) The planning tasks are mentally demanding;
c) The planning method will help them in performing a TIPS procedure;
d) The planning method helps me more than the current planning method;
e) The planning method helps to make the intrahepatic puncture less challenging;
f) I would like to use this new UI to plan a TIPS procedure.
IRs were asked to motivate their answers. Subsequently, they received the three cards and had to place them in order according to personal preference. Afterwards, they could motivate their choice and provide additional feedback. A video recorder was used to record the whole session.

6.2.3. Data analysis

The video recordings were analysed and the results were organized in six categories: added benefit, required improvements, possible improvements, general feedback, learning curve, other procedures.

6.3 Results

Below, the results are presented.

6.3.1 Added benefit

All IRs said they were seriously interested in the UI. Three participants already expressed their desire to clinically test the UI: "when do you think you could come [to the clinic] with a laptop?" (P1); "Yes, I think it is a very nice thing, when will we test it on a patient?" (P2). And "I would also like to, at the proper time, put it into practice" (P4).

The possibility to view and interact with 3D digital information was appreciated. IRs said it made it easier to understand the anatomy, distances, possibilities and constraints and to select the proper trajectory. One IR mentioned that the 3D view provides more insight than currently available. The option to adjust and thus to play with the points and trajectory was valued. Another IR said that the UI also enables him to estimate the puncture's possibilities and their complexities. One IR mentioned that the UI might help IRs to select the correct stent length. Some participants recognized that the UI could make the current procedure less invasive and complex; it could replace the risky and complex visualization aids such as a percutaneous PV puncture or 2D US. However, one IR remarked that the UI should be easy to use. Two IRs said it was too early to claim that the UI will help them to plan and perform the puncture.

6.3.2 Required improvements

During the test, the main criticism related to the limitation of the US dataset. According to one IR, the acquired US volume was limited in visualizing the whole PV. Furthermore, IRs remarked that the leading researcher had misinterpreted the dataset and incorrectly segmented the PV branches. As a result, they found that the 3D US volume was imperfect and the segmentation incomplete. The participants were only able to select a target point in these falsely segmented vessels. Therefore, the test was characterized as unrealistic.

All participants felt that more support was needed for orientation in relation to the anatomy. The main reason given was that the presented images were not acquired by the participants themselves. Therefore, to allow identification of the US images, the need for a CT, body marker and representation of the 2D US planes in the 3D view were expressed.

Participants appreciated the option to visualize and choose a trajectory, but some complained that the suggested needle trajectories were unsuitable options. The IRs said that a) the angles from the IVC- HV-PV or the angle HV-PV-PV bifurcation were to sharp, because the HV exit point or PV entry point was positioned too far inside the veins ("*too lateral*" and "*too periphera*l"); or b) the software connected all points and did not take the anatomy into account (Figure 40). As a result, the trajectory could go out of the IVC and via the abdomen into the HV. Suggestions for a suitable trajectory were provided:

1. One IR said that for an ideal trajectory the trajectory should be based on the anatomy of the veins. The system should know that IRs always navigate from the JV towards the IVC and desire to enter the main branch of the PV via the HV. He described that the only undefined points are the HV exit point and PV entry point. He said that IRs can then be consulted to define, at least, the target point. One IR wished that the HV exit point was reconstructed based on the position of the target point.
2. Various IRs expressed that they desire a system that suggests a smooth and spacious intrahepatic curve. It was said that it is preferred if the HV exit point and PV entry point are positioned as close as possible to the centre of the body and straight above each other.

This allows IRs to puncture as straight as possible, without having to make sharp angles. However, an extremely central trajectory is undesired as well, since the chance of creating an extrahepatic puncture or shunt will then be high. One participant described the process of choosing a trajectory and said to define the 1) HV which is positioned closest to the target point; 2) exit point near the PV, perpendicular to the target point in the PV, so the point which will lead to the smoothest trajectory. This will make the puncture less challenging; 3) shortest distance from HV exit point to PV entry point. It was said that a short distance through the liver parenchyma will decrease the chance that, in time, thrombosis will be formed inside the stent, which can obstruct the blood flow.

3. In addition, it was desired to include the needle possibilities as well. IRs mentioned that sharp angles in the trajectory will complicate the puncture. It will make catheterization difficult and the stent position crooked.

It was said that of all criteria, having a smooth needle trajectory is often the most important of all.

6.3.3 Possible improvements

Although the possibility to select an area in the PV was appreciated, improvements are still needed. Three participants expressed the preference to select the area on US instead. The main reason given is that the US provides detailed and up to date information. Next, a participant desired to see the vessels in the 3D view while adjusting the target area. In the current design, the vessels had to be hidden, before it was possible to change the size of the target area. Another participant found the box, or rectangular selection tool, confusing. A third IR preferred to only see a representation of the target area in the vein, not the box. Furthermore, one participant noticed that the system takes into account all points within the defined target area. He noticed that IRs are first asked to define a target point. He therefore suggested that the system should be able to calculate a trajectory based on that single point. The UI can visualize the target area, but not use it to define the trajectory.

Different preferences also were expressed for the task of selecting a HV branch. One participant preferred to select a point in the HV to define the preferred trajectory. He said that the real-time visual feedback from the UI will simplify making a proper choice. Two others did not find it a problem to select the whole HV and let the system calculate an appropriate exit point, as long as the point is well chosen. Another participant prefers to see all options and thus to not select any HV branch at all. He wants to let the system calculate a trajectory for each branch, visualize each option on the UI and let IRs choose the preferred trajectory. The main reason given was that there is just one optimal trajectory per branch: the one with the smoothest puncture line. Therefore, only one trajectory per branch should be visualized.

Furthermore, the window in which the participants were asked to identify the preferred needle type was described as unclear. Some IRs appreciated that the needle's possibilities were taken into account, but instead of selecting a needle three participants wanted to get feedback of how to bend the bore needle in order to reach the desired target point. They said the difference between the bore needles is not the manufactured angle, but the way IRs bend it to puncture the target vein. To avoid kinking, three IRs said they bend the bore needle just underneath the existing angle. They prefer the UI to visualize how to bend the bore needle to puncture as desired.

In addition, three participants discussed the usefulness of the presented distances. They found the following distances useful: a) distance from HV exit point and PV entry point, to measure the covered stent length needed; b) distance from PV entry point to IVC, to determine the total stent length. The following angles were recognized as useful as well, in order to estimate the flow of the stent: IVC-HV-PV and HV-PV -PV bifurcation. To decide the length of the covered part one participant emphasized that the HV-PV length should be the length between the venal walls, not the middle of both veins. The UI should clearly communicate that. The total length from PV bifurcation to IVC and the length PV to PV bifurcation were regarded as less useful.

One participant argued that the system should also provide aid for rare, but most difficult cases. He described the following cases and solutions: 1) when the HV branches are obstructed (due to Budd-Chiari, obstruction of the HVs caused by blood clots). In this case, the UI should provide the option to puncture from the IVC directly into the PV; 2) due to solidification, the PV cannot be punctured. Here, IRs have to puncture outside the liver, in the collaterals. Currently, IRs have troubles visualizing and thus finding those collaterals. If the UI can show these, IRs can define a target point and a trajectory, and it will benefit the whole procedure.

Although all participants appreciated the presented intra-operative 2D US images, some mentioned that the position of each plane should be correct and consistent. One IR explained that the most obvious way to do so is to present them as acquired during 2D US. This means a) to show transversal images: start form the lower part of the patient, in which the left of the image is the right side of the patient (like on CT); or b) to show sagittal images: start from the right side of the patient. The left side is thus the upper part of the patient (cranial).

Two IRs expressed their wish to use the UI to plan the view planes for additional steps as well. They expressed the need to receive information on how far to catheterize in the HV and how to position the needle. The leading researcher explained the idea of presenting the selected US planes for multiple steps (see chapter 4.3). As a result it will be possible to also see how to turn the instruments, and where to puncture through the vein. Generally, both participants appreciated the idea and underlined the added value.

One participant emphasized that additional anatomical information, such as how far the IVC reaches into the diaphragm or atrium, should be available. He described that serious risks will occur if IRs puncture above the diaphragm and in the atrium, or if the stent enters the atrium. By showing the length of the IVC, IRs are able to predict possibilities. However, where the liver begins and ends was defined as less interesting.

Two participants mentioned that the current UI considers the veins to be static. In reality, the veins deform during the puncture, mainly the HV. It was expected that the deformation will influence the puncture as well. According to the IRs, the HV especially deforms when force is needed, to bend the instruments or to catheterize them far inside the HV. Therefore, it would be appreciated if the system takes into account the deformable character of the veins. For example, if the anatomy does not allow a puncture in a smooth line, the UI can visualize alternative trajectories which require slight anatomical alterations.

Finally, some minor remarks were given about desired additions and alterations. Two IRs found the task of selecting a point in the bifurcation unclear and one even said this function should be deleted. One participant desired a 3D view that solely visualizes the cone, segmented vessels and a representation of the 2D US planes' positions. It was also mentioned that the RESET-button was positioned too close to the next button, which could cause mistakes. Next to US, four IRs said they would like the UI to visualize the CT as well. They said that the CT will add information and add certainty in identifying what is visualized.

6.3.4 General feedback

Two participants emphasized the importance of using real-time information during the puncture. One argued that he was familiar with testing virtual techniques and found that IRs prefer to see their needle in real-time, using actual visual feedback. The main reasons given were that IRs trust that information and it is valuable to see the real-time movement from the preferred direction. In addition, it was also said that it will simplify the procedure. Another participant mentioned that interactions between the points selected in the 2D planes and represented on the segmented view should exactly correspond, otherwise IRs will not trust the system and no longer use it.

Participants recognized that the future UI could help to visualize all veins. It was mentioned that the HV is now poorly visualized on CT. IRs said that the Planning-UI could help to visualize the veins in 3D and to plan a proper trajectory. Two IRs said that the generated images will help to visualize the PV in real-time and in a noninvasive way. Furthermore, they expected that less experience will be needed when using information from 3D US than when using 2D US. One participant said that the current UI could possibly help to already estimate distances and locations *"Well, it is very useful to accurately estimate beforehand."*

Nevertheless, additional concerns were communicated. Two IRs wanted bigger 2D US planes, mainly to be able to use them intra-operatively. Finally, one IR said that during the procedure, the performing IRs should be able to manipulate and interact with images themselves, without needing extra assistance. It was also mentioned that US does not always visualize the anatomy clearly, therefore an additional feature indicating how far to puncture before reaching the target would be highly appreciated. In addition, one participant said that the UI helped to gain proper understanding of the anatomy and puncture, but that the current way of planning is also satisfying, because it is what IRs are familiar with and what they can anticipate.

6.3.6 Other procedures

One participant indicated that the UI could possibly be used for other procedures as well, such as for a tumour ablation, biopsy or aortic endoprosthesis (treatment of enlarged aorta). It was even recognized that it could lead to new procedures.

6.4 Interpretations

All participating IRs were enthusiastic about the Planning-UI and recognized its potential. The UI could make 3D information easier to comprehend and the current procedure less invasive and complex. However, improvements are needed to provide significant added value during the TIPS procedure. From all the acquired feedback, the leading researcher mainly suggests to improve the aspects which were mentioned by multiple participants and aspects which she considered as feasible and in line with the insights gathered from the previous chapters. As a result, the main recommendations for the Planning-UI are to: 1) add CT images; 2) add orientation aids and 3) optimise the possible trajectories. Next, IRs wish to have more useful US volumes and segmentations. However, in reality, the medical staff will be able to generate the images themselves and segmentation will be done automatically. This feedback is therefore not considered as a desired UI improvement. Some IRs also expressed the need to visualize the veins as flexible, instead of static veins. Technically, this is over challenging and it is expected that IRs will already benefit significantly from a Planning-UI which presents static veins. Therefore, this improvement will be of less priority.

Although not all participants were convinced that the Planning-UI will simplify the planning phase and improve the procedural outcome, test results show that it could provide advantages. With the Planning-UI we provide IRs a tool to view and interact with 3D digital information which is currently mentally constructed based on scrolling through CT images. As a result, we expect that the main advantage will be to verify actions. For example, IRs will see if the needle trajectory will really be as short as expected. This will probably make IRs more secure and the procedure more effective and efficient. The US data was acquired from a healthy volunteer and not from a patient suffering from liver cirrhosis. Additional testing is needed to plan the procedure with datasets of cirrhotic livers.

6.5 Conclusion

In this chapter, the Planning-UI was implemented and tested with five IRs. Test results indicate that the Planning-UI provides valuable 3D visualization support to plan the intrahepatic TIPS puncture. Although still a prototype, the IRs appreciated the possibility to view and interact with 3D digital information of the patient's anatomy. However, improvements are still needed. Main improvements involve the design of a proper orientation support, the integration of CT and the possibility to gain suitable trajectory options. Recommendations will be summarized in chapter 8.

"You can now [by using the Planning-UI] see where the needle is heading to: the puncture is not blind anymore"

[Feedback of an IR after the Puncture-UI test, 2013, see section 7.3]

Chapter 7: Puncture- UI

Based on [CUIJ2014; CUIJ2015a]

In *Chapter 6*, a Planning-UI was implemented and evaluated. The development of the Planning-UI was mainly based on the findings from Chapter 3, 4 and 5. In this chapter, those findings are also used for the development of the interactive 3D US Puncture-UI. This UI is designed to actually guide IRs during the intrahepatic puncture. The aim of this chapter is thus to develop and test an interactive 3D US based UI for an effective and efficient puncture during the TIPS procedure. In this chapter, section 7.1 presents the information needed for the puncture and the Puncture-UI design. Section 7.2 shows the test set-up and section 7.3 presents the UI evaluation results. Section 7.4 discusses these results and provides key recommendations for a future Puncture-UI. Section 7.5 draws a brief conclusion.

7.1 The Design of the Puncture-UI

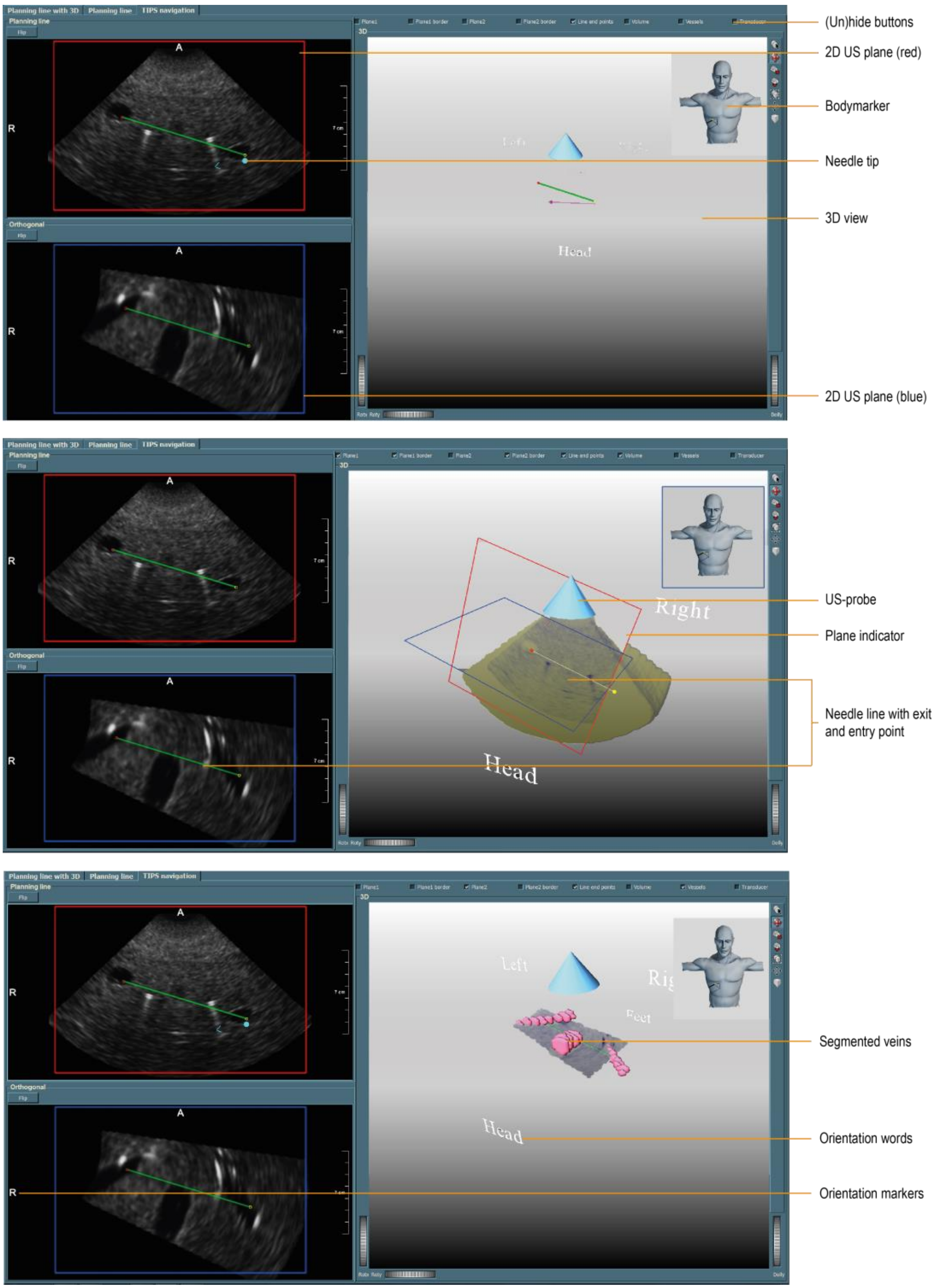
In Chapter 4 and 5 it was stated that the Puncture-UI has to visualize the target PV, exit point in the HV, needle trajectory, the needle movement and the critical anatomical details in-between the exit and target point. Information should be shown from two directions (the longitudinal view of the HV and the target PV and its perpendicular plane) and in real-time. In addition, the relation among the probe's position, the 3D US cone and the 2D planes need to be clearly expressed. Insights regarding the UI revealed in Chapter 2 can also be used for designing the UI. Examples are to use landmarks to facilitate navigation, use minimalistic design principles and communicate how a user can get to a destination. Based on these insights and requirement, the Puncture-UI was designed.

7.1.1 The basic design

The Planning-UI shows the selected 2D US planes to present real-time information. The system knows the 3D US probe position in relation to the body, and the plane position in relation to the 3D volume position. In that way, real-time information about the procedure can be acquired automatically.

During the different procedural steps, IRs will see the accompanying planned images. Interaction with the images is only required if the IRs needs to change the trajectory. As said, it is outside the scope of this project to study what interaction device could best be used. However, the interaction will be sterile, intuitive and fit the medical workflow.

In practice, the instruments will deliver force on the vessels during the puncture. Therefore, the generated intra-operative images might deviate from the already planned images. Although the exact impact of the vessels has to be researched in future work, the team expects that the difference will be minimal because the patient's liver is often full of cirrhosis, thus the mechanical properties of the liver is very hard. During the puncture, the US will show the real-time information about the puncture, but the planned exit and entry point will not deviate much, since 1) the movement of the complete liver is compensated by the system; 2) the internal deformation of the liver caused by the instruments is minimal due to the reason stated above.



Planning line with 3D
Planning line
TIPS navigation
Orthogonal
A
R
3D
Left
Right
Head
Feet
(Un)hide buttons
2D US plane (red)
Bodymarker
Needle tip
3D view
2D US plane (blue)
US-probe
Plane indicator
Needle line with exit and entry point
Segmented veins
Orientation words
Orientation markers

Figure 42. The Puncture-UI design. The figure presents the UI in which different elements are (un)hidden. Each representation shows the 3D image (right); longitudinal US image (upper-left); axial US image (lower-left).

7.1.2 Features of the Puncture-UI

Five different elements are represented in the Puncture-UI, these are (see Figure 42):

1) BodyMarker: the bodymarker is a representation of the human body. The bodymarker shows the position of the US probe and US cone in relation to the body. The position automatically changes with the probe position.

2) 3D view: The 3D view allows IRs to determine the 3D position of the probe, needle and 2D US planes in relation to the veins. It could help IRs to 3D position all presented information in relation to each other and the veins. IRs are able to interact with the 3D view by scrolling, zooming or rotating the view. The 3D view displays:

- the HV, PV and IVC (automatically segmented from US or CT);
- the preferred needle trajectory: to show how to get to the target;
- the actual needle position: to show where the needle is;
- the actual needle direction: to provide feedforward information;
- the position of the probe and 3D US volume: to know which body part is visualized;
- words indicating where the head, feet, left side of the body and right side of the body are located: these will help IRs to orientate;
- an indication of the original, and probably the most suitable, position of the 2D US planes in relation to the veins. The indication shows what part of the anatomy is visualized on the 2D US planes and allows IRs to always go back to this position;
- an indication of the actual position of the 2D US planes in relation to the veins. The indication can differ from the original position if IRs changed the plane position;
- buttons to hide elements described above: these allow IRs to personalize settings.

3)*2D US plane* 1 (with red indicator, see Figure 42): This 2D US plane provides real-time and detailed information of the anatomy (e.g., the position of the veins, the liver edge), the needle, the preferred puncture line and actual puncture line in 2D real-time. The plane provides the IRs with detailed information on how to navigate towards the target point. A red square around the plane is visualized to be able to trace back the plane location on the 3D view. In addition, indication markers, such as head, left, describe how the plane is positioned in the patient's body. The indications will help the IRs to orientate.

4)*2D US plane* 2 (with blue indicator, see Figure 42): Like the 2D US plane described above, the blue marked 2D US plane visualizes elements such as the anatomy in 2D real-time. The main difference to the previous 2D US plane is that this section plane is perpendicular to plane 1. Together, the two 2D US planes provide information from two different directions.

5)*Taskbar* (not visualized in Figure 42) showing for which step of the procedure the planes are visualized. The taskbar will help IRs to understand the information in the currently presented planes.

7.2 Validate the usefulness of the Puncture-UI

In order to validate the Puncture-UI, the UI was implemented in MeVisLab© 2.2.1. Subsequently, a puncture test was prepared and performed. Below, a more detailed description of the test is provided.

7.2.1 Preparation test

In parallel to the UI development, the test was prepared and a phantom was manufactured. This was done in collaboration with the multidisciplinary team, the material department of Erasmus medical centre, the 3D echocardiography and image processing group of the biomedical engineering department and a liver phantom expert [CHMA2013]. After frequently consulting the different experts, the test was prepared as follows:

Phantom

Two test setups had to be built to efficiently test with two IRs at once. Therefore, two identical liver phantoms were manufactured for the present study (see Figure 43). Three hollow tunnels inside the phantom represented two PV branches and a HV branch. The liver parenchyma was imitated by candle gel [CHMA2013].

To real-time guide the IRs when puncturing in the phantom, the interactive 3D US data of the phantom had to be integrated in the UI. However, using the real-time 3D US modality during the test was impossible. Therefore, image registration and electromagnetic (EM) tracking was used as an alternative to track the needle and to real-time visualize the needle movement on the UI. Two different needle lines were generated by defining an exit point in the HV and an entry point in the PV. Each was positioned in a different PV branch, but in line with the needle's angle, so that the puncture could actually be realised.

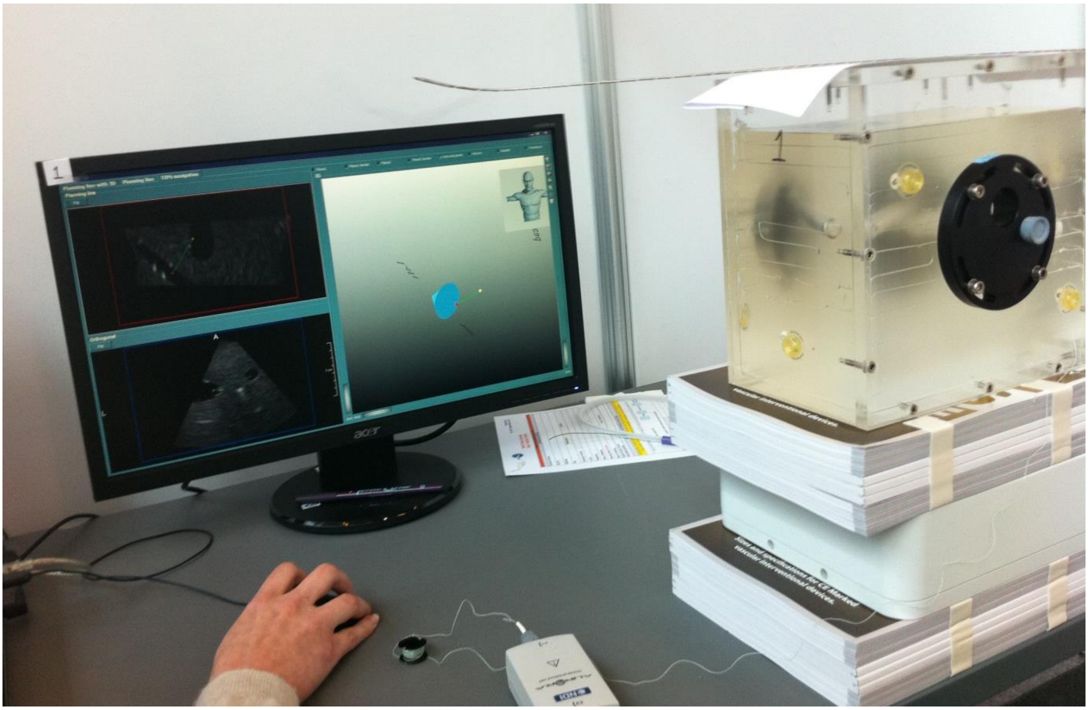


Figure 43. The Puncture-UI test setup: the UI (left), the liver phantom (right) and the tracked needle (on top of the phantom).

Materials

Materials were collected, these were:

- Phantom
- Laptop with MeVisLab
- Cook RUPS-100, 14 G/51.5cm needle
- Aurora EM tracker
- Aurora 6DOF Probe, Straight Tips, Standard
- Aurora Micro 6D sensor, 610059
- 6 CT markers (CT/MR Pinpoint Multimodality #128, Beekley)
- Computer monitor, 24 inch
- Towel
- Tape
- Questionnaire
- NASA-Task Load Index (TLX) [HART2006]
- Video camera
- Pen

Pilot

Before the test an IR who was not familiar with the project was invited to pilot test the working system. The IR was asked to take the tracked needle and to puncture in the phantom from the HV exit point into the PV entry point, while using the displayed information on the Puncture-UI to guide him during the puncture. He was asked to think aloud while doing so and to provide feedback about the UI and the test setup. The generated insights were used to further improve the UI. After improvements were made, the participant was asked again to test the system and to verify those improvements.

7.2.2 The test

The test consisted out of three parts: 1) the introductory part; 2) the puncture part; 3) the evaluation part. During the introductory part, participants were asked:

a) For their professional affiliation: IR, trainee, other;
b) if they had ever performed a TIPS and, if they had, how many times a year;
c) to identify the most challenging part in performing or assisting TIPS;
d) what visualization technique their hospital was using during TIPS;
e) if they used US and, if they did, how often;
f) if they were confident in using US and why.

Subsequently, they could use the UI as IG system and perform the puncture as indicated on the UI. In addition, they were asked to express when they thought the puncture was successful. The IRs had to puncture twice, namely for the two different puncture lines. The number of punctures needed to achieve a successful puncture was counted and the coordinates of the two successful punctures were saved.

Finally, participants were asked a) to fill in a NASA TLX questionnaire; and b) to grade, on a scale from 1-10, if they thought that this new visualization method could improve the intrahepatic puncture; c) whether they would use this method if they had the opportunity to use it to perform an intrahepatic puncture; d) if they did foresee problems using the UI; and e) to provide additional feedback.

7.2.3 Analysis

The video recordings were analysed and the data was documented. Six tables were created containing all the acquired information per participant. The tables were: Intro, No of Punctures, NASA, Final Questions, Extra Feedback. In addition, a document with observation remarks was created. The data were compared and evaluated. In addition, graphs were created of all the punctures in relation to the exit point, target point and target vein. Per phantom and per each of both punctures, a graph was generated of the longitudinal view of the target vein, and of the intersection of the vein. For both, a coordinate system with its origin in the target point was integrated in the graph to analyse the exact puncture positions. In addition, the data from the NASA TLX questionnaire will be summarized and shown in a chart.

7.3 Results

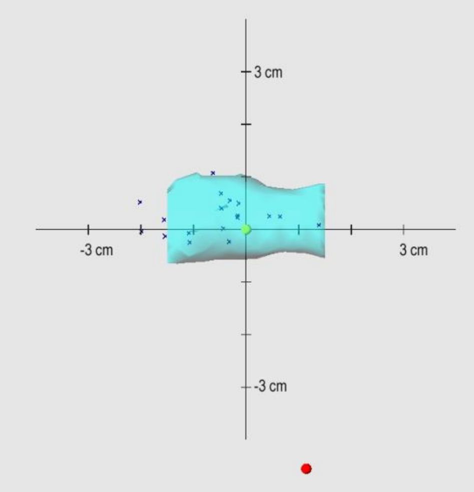
19 IRs and 9 trainees, from 14 nationalities and with various TIPS experience levels, participated in our test (Table 14). One participant had only observed a TIPS placement, 11 had assisted and 14 had performed TIPS. All but two had experience with using 2D US and most used it during the TIPS placement, in addition to Fluo. They mainly used US because it is a safe and real-time imaging modality to visualize anatomy and needle movement. Nearly all participants described the intrahepatic puncture as the most challenging part of the procedure. Additional parts mentioned were using the instruments, finding the PV, maintaining access to the PV, and catheterizing the PV.

Table 14. Characteristics participants

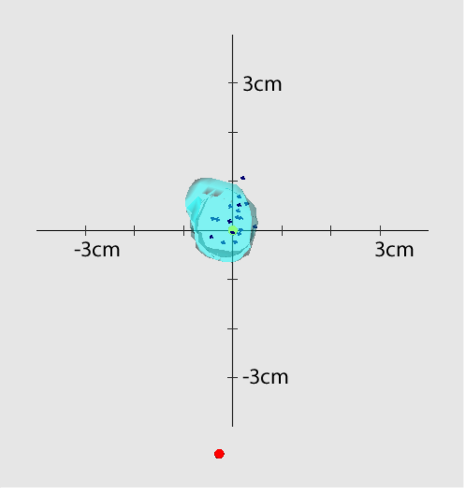
	Number
Trainees	9
IRs	19
TIPS: performed/assisted/observed	14/11/1
Performed procedures a year	
1-5	6
5-10	3
10+	5
Used US	
Yes	26
Every day	18
Used visualization, next to Fluo	
CO_2	2
2D US	11
Marker PV	3
Blind	10

Table 15 Quantitative test results

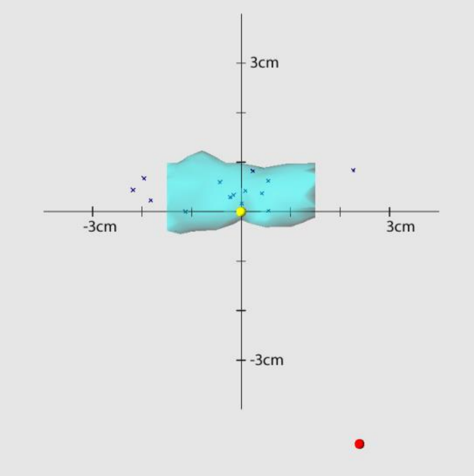
	Puncture 1	**Puncture 2**
Number of punctures needed		
one	25	23
two	2	2
three	-	1
unknown	1	2
In target vein (rest unknown)	27	25
Close to target point (<2cm)	27	22
Far from target point (<4cm)	-	3
Median grade UI (scale 1-10)	8	
Want to use the UI	All (if improved)	
Use in addition/instead	14/12	
Make puncture less challenging		
yes	20	
no	1	
unknown	7	



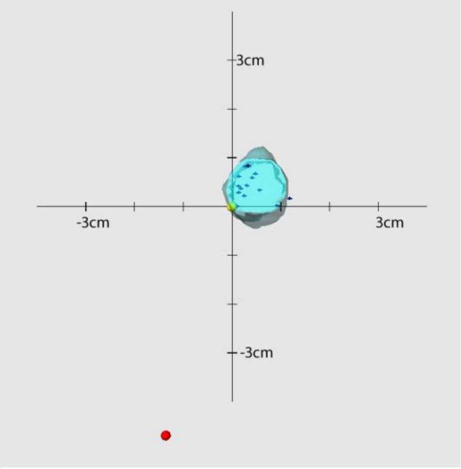
Phantom 1, puncture 1 (a)



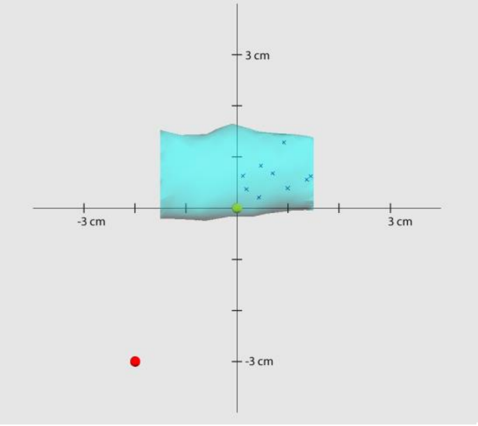
Phantom 1, puncture 1 (b)

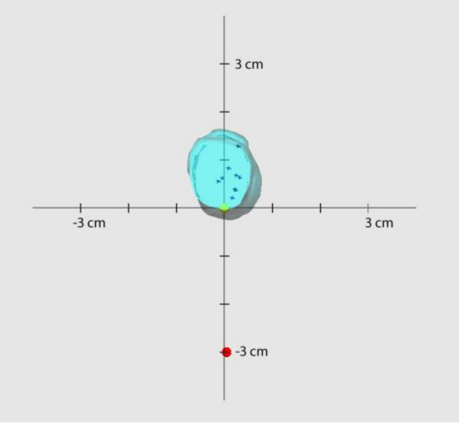


Phantom 1, puncture 2 (a)

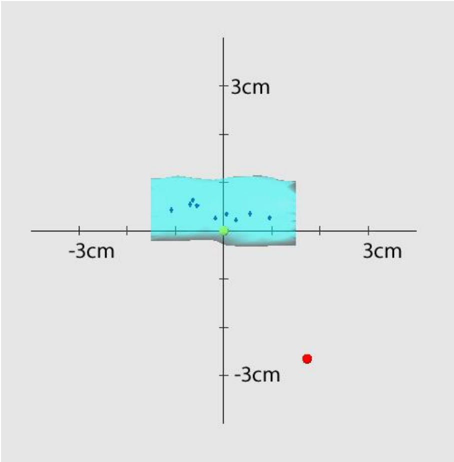


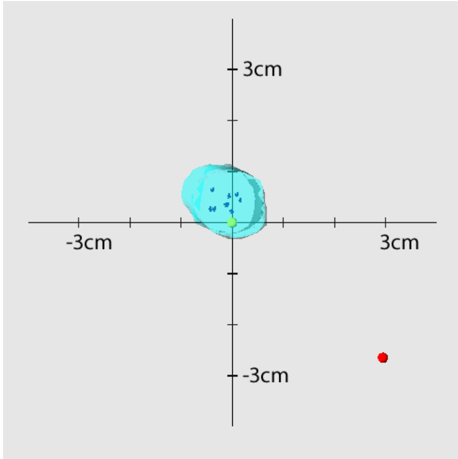
Phantom 1, puncture 2 (b)





Phantom 2, puncture 1 (a) Phantom 2, puncture 1 (b)





Phantom 2, puncture 2 (a) Phantom 2, puncture 2 (b)

Figure 44. Per puncture, the puncture points (blue crosses) in the portal vein (light blue) in relation to the exit point (red dot) and entry point (yellow dot). a) the longitudinal view of the vein and b) the transection of the vein

A shown in Table 15, all participants punctured in the target vein (Table 15); most very close (max 2cm) to the planned entry point, three rather far from the point (max 4cm) (Figure 44). Although three punctured slightly (max 3mm) through the lumen of the target vein ((Figure 44): Phantom 1, puncture 1 (a)), it is recognized as an accepted tactic during TIPS and categorized as secure access. For four punctures, the coordinates are missing. In 48 of 56 trials one puncture was needed to successfully puncture the target vein. Two puncture attempts were only needed on four occasions, and three puncture attempts were required once. For three trials, the number of punctures was unknown. Not only trainees, but also some experienced IRs had to puncture more than once.

The information presented in the UI was well received and the median grade given for the overall UI was an 8 out of 10 (Table 15). Comments such as *"..a promising technique..", ".. great potential.."*, "*This would be better than what I now use for puncture*" were not unusual. All participants said that they would use this UI during an intrahepatic puncture if they had the opportunity. According to the fourteen participants who would possibly use the UI in addition to the current UI (Table 15), Fluo is still needed for the other steps of the procedure. Three participants indicated that they will first use the UI in addition to Fluo and only if successful, they will replace Fluo where possible. Participants said they appreciated the availability of visual feedback about the puncture; instead of making an educated guess the UI allowed them to control and adjust movements and to see the instruments in relation to the target vein (see quote on page 100). A very experienced IR even said that the puncture was easy and encourages to perform more TIPS procedures. Another participant also complimented that using the UI did not feel special, but easy. Overall, participants predicted that by using the UI, the procedure will remain difficult, but become less challenging and more secure, accurate and guided.

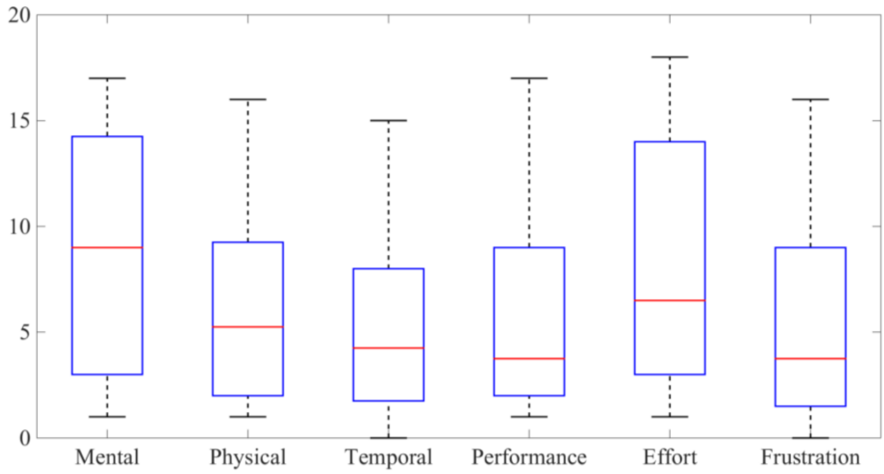


Figure 45. Results of the Task Load Index with on the vertical axis: rating scale and horizontal axis the workload subscales. The red lines represent the median score per subscale, the upper horizontal lines indicate the maximum score and the lower horizontal lines indicate the minimum score.

Figure 45 shows the results of the NASA TLX questionnaire. The task load of the UI is relatively low: the median score for mental load was a 9 and for performance a 3.75. Nevertheless, participating IRs often had trouble to spatially orientate the information and to understand what was visualized. Overall, the 3D view was used to orientate, the longitudinal plane was used to catheterize and then the axial plane was used to puncture. Considerable time and effort was needed to mentally and physically orientate before being able to use the UI and to puncture. Often, IRs had to find the relations between the images. Indicators communicating directions, such as head, in the 3D view were frequently described as unclear. The direction indicators did not change with the plane position. As a result questions such as: "what is what?" were frequently asked. Furthermore, the rectangles, representing the 2D planes within the 3D view, did not move along while scrolling through the dataset. As a result, each participant had to determine the relation between the three planes and adjust the settings to orientate. Three participants explicitly said they want to set the images as if they navigate from head to toe: head is down, right is right, while three IRs preferred to set the images as on DSA, such as head is up, right is left.

During the navigation process participants sometimes got disorientated. This mainly occurred when the needle was off-plane and thus not visualized. Some participants had trouble in getting the needle exactly in plane on both 2D US planes at the same time. Six participants mentioned that they had trouble in knowing on which of the three images to focus.

Furthermore, in the UI, the dots and the arrow representing the needle were often described as confusing and unintuitive. Even though the meaning was explained beforehand, participants still thought that the actual location of the needle was not at the origin of the arrow, but the arrow itself. Due to the confusion, some participants stopped the puncture before the target was reached. Additional feedback given was that the transparency of the US cone should increase, the edges of the liver represented, and the 3D view represented in 3D.

Seven participants describe the possible learning effect and said that once used to the system, using the system will be rather easy: "*…get used to it, then you will be very fast*". On average, the participants performed the second puncture faster, and the number of questions about the orientation dropped significantly.
In addition to current UI problems, participants could also foresee future UI problems, which were mainly related to generating the US data. They were concerned about the UI's usefulness when dealing with patient movement and breathing, the acoustic window of US, breath-hold, alternative TIPS procedures and needing a second IR to acquire the data during the procedure. The reliability of the whole system, the costs of the UI or for needing an echo genetic needle, the availability of proper training and the time needed and complexity to plan the planes and lines were other concerns that IRs mentioned. One participant stated that integrating the UI should be compatible with the current workflow. Seven participants raised questions about the user interaction. They argued that using the UI can be challenging if an extra IR is needed to generate the US volume and if interaction with the planes is cumbersome.

Most participants wish to have constant feedback from the 2D US images about the instrument location. It was emphasized that the needle should always be visualized, otherwise complications could occur. This feedback was mainly given by participants with less TIPS-experience. In addition, it was expressed that the needle representation should be improved, preferably by visualizing the used needle instead of a graphical illustration. Other preferred improvements concern the poor consistency of the plane orientation, unavailable CT scans, unclear communicated orientation per image, and the cumbersome plane interaction.

Finally, some participants commented on the unrealistic test setup. The main points of criticism were that the UI did not involve tissue movement, real patient anatomy, or real-time 3D US data. The test setup did not take into account the needle possibilities in relation to the anatomy. To perform a puncture, IRs therefore had to manipulate the needle in an extreme and unrealistic way.

7.4 Discussion

The quantitative and qualitative data showed promising results. The test showed that the new UI provides valuable visualization support to perform the intrahepatic puncture during the TIPS procedure. IRs were very impressed and satisfied with the UI. The UI provides real-time 3D feedback and effective navigation support to perform the puncture in a more controlled way. Based on these findings we expect that the UI can decrease the number of puncture attempts, procedure time and risks in the future.

The results from the NASA TLX questionnaire seem promising, although the test did not involve a real, and thus particularly stressful, situation. A test in which IRs will experience stress, such as in vivo, is thus recommended. Nevertheless, this was the first time participants were acquainted with the UI and we therefore presume that with some training, the amount of effort and mental demand will decrease. The TLX results sometimes differ per participant. For example, one participant graded his performance with a 17 (very bad), where others gave grades below 5 (very good). Remarkably, the participant punctured very well and gave positive feedback about the UI and even said that we do not have to improve anything. This suggests that the questionnaire was sometimes confusing and IRs did not always fill it in correctly.

Although the Puncture-UI was appreciated, the results indicate that IRs had to put effort into accomplishing the goal. For some the task was mentally demanding. This is also reflected in the TLX score for mental load, which was the highest of all scores. Key reason might be that some IRs had problems in locating and positioning the needle in relation to the presented images. Probably, this is caused by two UI issues. First, when a participant changed the position of the 2D planes or 3D view, the UI did not automatically reset the alterations made. Consequently, the next participant did not start with a basic and recognizable position of the 3D view, but with a confusing one in which the different images were not aligned. As a result, participants were frequently confused. UI improvements are needed to avoid this confusion. Secondly, the needle was only visible when it was exactly in plane. To visualize the needle on both 2D planes at the same time was challenging, but would be desirable.

While it is recommended to improve these two main issues, it remains questionable if visualizing the needle's position will improve the UI's usability. During the test, it was mainly the less experienced IRs that had trouble when using the Puncture-UI. Experienced IRs easily got the needle in plane. Possibly the less experienced IRs have to gain more practice at any rate to understand anatomical relationships. Improving the UI may not significantly help them.

Although successful, the Puncture-UI was still an imitation of a real-life situation. Only the movement of the instrument was shown in real-time, not the actual US data. Time, and thus the efficiency, was not recorded as a dependent measure. Design improvements and elaborate testing such as in vivo are needed. In future research, the UI should be further developed based on participants' feedback and tested in a more real-life setup, for example by using an improved phantom and real-time 3D US acquisition to involve breathing and with real patient anatomy.

7.5 Conclusion

Overall, our findings strongly suggest that the 3D US UI will be a promising technique to support IRs sufficiently to perform the intrahepatic puncture of a TIPS procedure with increased effectiveness and satisfaction. The main recommendations are to 1) show the needle at all times; 2) have a consistent and meaningful plane position; 3) communicate the position of each view plane and the relation between planes more clearly. These recommendations will be included in Chapter 8.

Chapter 8: Discussion and Conclusion

This chapter aims to summarize the outcomes of the research, reflect on the design process and provide an overview of the main contributions of this thesis. Section 8.1 provides a reflection on the old and new workflow. Section 8.2 discusses the advantages and limitations of the UI. Sections 8.3 critically reflects on the findings in the design process and section 8.4 presents the main contributions of this thesis. Finally, section 8.4 lists the recommendations.

8.1 Reflection on the old and new workflow

In literature, an overview of the TIPS procedure and a description of the complete workflow was unavailable. In Chapter 3 these deliverables are provided. They help to answer the research question *What is the current TIPS workflow?* and reflects on the question *What are the related challenges?* Based on the current workflow, the chapter also describes an ideal scenario.

Basically, a TIPS procedure involves many macro and micro steps to puncture in the PV and create a stent in the liver. During the process IRs are provided with a limited amount of information. This thesis showed that the information lacking in those steps is mainly observable at the micro level, which makes it difficult to answer the micro questions of the procedure and thus to perform the macro steps. Although IRs are provided with visual cues and haptic feedback, information is often two-dimensional, not real-time, unavailable, unreliable or extremely difficult to interpret. As a consequence, a lot of experience is needed to recognize and understand the information and to predict what has happened and how to continue. However, even for experienced IRs correct decision making remains difficult. IRs constantly juxtapose the available information with their background knowledge and clinical experience to evaluate the situation. Although information does not have to be complete, during the TIPS procedure information is often insufficient to make decisions. A trial and error approach is therefore inevitable which may result in a lengthy procedure and/or even unnecessary complications. This is especially true for the intrahepatic puncture: IRs do not see the target vein, making the navigation process difficult. They therefore have to perform a blind puncture, which often results in many attempts. In addition, the patient specific anatomical characteristics may hamper the navigation process even more. In short, IRs miss real-time 3D information on exact anatomy and instrument location, and 3D feedforward information on where to puncture and how to control the instrument to perform another puncture attempt.

The described challenges can help to answer *What do IRs need from the IG system?* All implicate that the new UI has to help IRs to be aware of the current situation. Regarding the question *What are indicators to overcome those challenges?* the answer is that the UI has to support IRs decision-making, and thus should provide IRs with the information required for answering 18 of these micro questions (Table 16). Examples of the questions are: Where is the target vein positioned in 3D? What is the best place to puncture the PV? By providing sufficient information for all 18 micro questions, the IR will be able to perform the intrahepatic puncture in a more effective and efficient manner.

Based on Jalote-Parmar et al [JALO2007], we point out that the desired information should be provided: 1) for each micro question; 2) when the IR is confronted with the question; 3) in a way that meets the IRs' cognitive and visual requirements.

Table 16 A list of how the UI can support IRs in performing the macro steps.

Information from the UI	**Steps taken by the user**		
	Micro question	*Micro action*	*Macro task*
• Visualize the target vein • Show critical anatomy • …	• Where is the target vein positioned in 3D? • What is the best place to puncture the PV? • …	• Position the needle • …	• Perform the intrahepatic puncture • …

Several research groups tried to improve the IG for the puncture. However, these IG systems only answer a few of the required micro questions. For example, Adamus *et al* [ADAM2009] aimed to guide the puncture from HV to PV. They used two 2D projections to create 3D path planning on Fluo. The solution helps to answer questions as "What is the position of the needle relative to PV?" and "What is the best place to puncture the PV?" However, according to Maleux *et al* [MALE2010] the solution does not include essential anatomical information and therefore injury may still occur. This indicates that this solution is incomplete since questions such as "What is the 3D position of materials in relation to veins, environment of veins, structures?" and "Will/did I not cause collateral damage?" remain. The same happens in other researchers' work [e.g., MAUP2005]. For example, these do not support the micro question "What is the best place to puncture the PV?" These examples confirm that providing support for all 18 micro questions is essential in order to facilitate an effective puncture, fast recovery after an unsuccessful puncture, and to safeguard patient safety. The findings of this thesis could help research groups to make TIPS IG solutions more complete.

Limitations of the workflow

These are limitations of the presented workflow:

- Hospital focus: The presented workflow is based on the current state of hospitals in the Netherlands and Belgium. The unveiled macro and micro steps are thus also based on this model and do not represent all hospitals worldwide. Thus, there may be future additions. However, the presented research sets a basis, allowing future researchers to efficiently study the procedure in more detail. In the future, they can for example add more loops, tasks and exact manipulation details.
- Restricted level of detail: The presented workflow is not as detailed as workflow or task analyses in the field of system engineering or human factors. However, the level of detail is high in comparison to the medical field and is sufficient to fulfil the requirements of this thesis.
- User focus: During the studies the author defined the IRs as the users, since they have to gain sufficient information from the UI of the IG system to perform the procedure. The author is aware of the fact that multiple other users can be defined as well, such as nurses, technical support staff and cleaners. However, these users are not the users of the information of the 3D US UI and therefore not defined as such.

- Intervention focus: The workflow study covered the whole intervention which involves the part in which IRs deal with the IG systems. For that reason, the study did not include the post-operative part. However, in the future, supplementary research could be conducted involving multiple users and post-operative processes, as it may be interesting for researchers who study the workflow in an operation theatre.

8.2 The new UI

Findings of chapter 4 show that interactive 3D US has the most potential to help IRs in the navigation and puncture process of the TIPS procedure. Chapter 4 addressed the question "*What are the opportunities of interactive 3D US to address the challenges?*" and mainly showed that interactive 3D US is technically able to generate 3D real-time images of the anatomy and instrument simultaneously.

However, to improve the complex navigation process, UI improvements are desired. Chapter 5 specifies that mainly the liver anatomy, target point and real-time needle movement can be defined as "*What is crucial information to integrate in an interactive 3D US based UI to minimize the number of intrahepatic punctures?*" In Chapter 4, the leading researcher found the answer to "*What information to present on the integrated interactive 3D US based UI to effectively and efficiently guide IRs during TIPS?*" The information can be described through three basic UI elements:

1) two 2D perpendicular US planes of the 3D US dataset which show the IRs:
  a) the real-time liver anatomy from two different directions;
  b) the target point or area in the target vein;
  c) a possible needle trajectory which indicates a suitable path for performing the puncture;
  d) the real-time needle movement in relation to the preferred puncture line;
2) a 3D image of the anatomy;
3) aids which communicate how to position the presented information.

The information can be provided by means of a UI which facilitates IRs to plan and perform the intrahepatic puncture. The Planning-UI shows the liver anatomy on US, CT and 3D images. It allows IRs to study the anatomy and trajectory in 3D, place landmarks to plan where to puncture, find a suitable way to navigate towards the target, and to interact with the anatomy and trajectory in order to know what to expect during the puncture. Additional elements regarding the question "*What information shall be integrated in an interactive 3D US based UI to effectively and efficiently plan the intrahepatic TIPS puncture?*" can be found in Chapter 6.

The research question "*What information shall be integrated in an interactive 3D US based UI to effectively and efficiently perform the intrahepatic TIPS puncture?*" is reflected in Chapter 7. Basically, the Puncture-UI shows the needle trajectory, the preferred exit point and entry point on two US planes from two different directions and in 3D. In addition, it helps the IRs to spatially orientate the instruments within the body. As a result, the Puncture-UI delivers real-time 3D feedback and effective navigation support to navigate towards the target and perform the puncture in a more controlled manner.

Based on the gained insights of this thesis, the two UIs were created and tested. IRs were impressed by the prototypes, and the test results showed that both UIs have potential to make the intrahepatic puncture more effective and efficient. Using both UIs could save time on interpreting information, decrease the number of puncture attempts, procedure time and risks in the future and with that decrease the amount of stress.

The leading researcher only focused on one way of improving the intrahepatic puncture; she therefore does not rule out the possibility that there are many more options to minimize the number of TIPS punctures. Nevertheless, all described insights of Chapter 4,5,6 and 7 contributed to meet the main objective, which was to *unveil what information should be presented in an interactive 3D ultrasound based UI to minimize the number of punctures during the intrahepatic puncture of the TIPS procedure*.

Limitations of the UIs

The UIs seem promising in improving the intrahepatic puncture, and the leading researcher is convinced that sufficient aspects were addressed to demonstrate the working system. However, in future research additional features could be addressed by developers to create a suitable UI, such as: a) the position of the different planes; b) the registering of the planes from the Planning-UI to the real-time patient anatomy, to get the same planes on the Puncture-UI, c) suitable interaction devices to intuitively interact with the UIs, d) an intuitive way to visualize the needle position in the 2D US planes. If implemented, these features will make the functions of the UIs complete and will thus influence IRs' decisions to use or not use the UI.

Another UI limitation is that not all micro questions can be solved by improving the IG alone. For example, IRs want to get the full control of the needle, but the current instruments impede this. This suggests that a new IG system will benefit the navigation process, but additional instrument improvements could benefit the procedure even more. Redesigning additional aids was not the thesis project. However, we trust other research teams will develop this idea further.

Due to the limitations, the Puncture-UI will not yet be used to replace Fluo and the dream procedure as presented in Figure 25 in Chapter 3, as it cannot be realized now. By now using the Planning-UI to plan the procedure and the Puncture-UIs in addition to Fluo, the author already expects procedural improvements, such as less complex and fewer punctures. Figure 46 visualizes the expected current improvements. See section 8.4 on what could still be done to realize the dream procedure, as presented in Figure 25 Chapter 3.

8.3 Reflection on the research approach

This thesis provides a detailed overview of the TIPS workflow and possible solutions. The insights in the context, the procedural tasks, navigation strategies and related challenges were gained to integrate HF principles in the early stage of a design process [WICK2004, KUIJ2010]. As similarly mentioned by Savo *et al* [SALV2012], the data helped to set requirements, allowing to plan, focus and evaluate new developments and, as noted by Varga *et al* [VARG2012], to identify challenging parts of the procedure and to know where to provide extra support or workflow redesign.

8.3.1 Overall experience of the leading researcher

Most likely, the insights could not have been acquired without performing participatory research methods in a co-design approach. To illustrate, at the start of the project, the leading researcher read the TIPS literature and observed interventions. However, understanding the TIPS procedure remained challenging and concrete requirements were hard to discover. After applying co-design methods, the procedure and related information needs became explicit and concrete and with that, the team was able to set specific UI requirements. Task analysis of observable processes, but also of unobservable processes and cognition were of assistance to understand which information is missing and which aspects of the UI could be improved. However, the requirements could only be discovered by observing and interacting with IRs multiple times. Time and effort are needed to get to the heart of the problem for the complex TIPS procedure.

The leading researcher finds that co-design would not have been possible without first analysing the current situation. The analysis made her a respected partner during discussions and interviews and allowed to confer deeper level problems and solutions; it improved the efficiency and accelerated the development process.

In addition, by applying co-design in all phases of the development process, the IRs also generated fruitful ideas, such as a tool to calculate correct stent measurements. This substantially contributed to translating the requirements into fruitful design ideas.

Overall, the considerable insights contributed to the development of an effective UI. Extensive data was gained on the problem, requirements and possible solutions. The thorough understanding of the current and desired state made it rather easy for the leading researcher to combine the data and to design two effective UIs.

One of the most unique aspects of our co-design approach was the close collaboration within the team. Together with IRs, the engineers first thoroughly analysed the medical context, the users, the procedure and the problems. When a basic understanding had been gained, the IR researcher was hired and all team members were ready to start with generating ideas. If the IR would have started earlier in the process, we expect that the collaboration would have been less intense and fruitful; more time would have been spent on explaining basics to the engineers, which is probably less stimulating and efficient. Furthermore, instead of starting his own medical experiments in parallel, we were able to develop and test together. All of these facilitated effective collaboration.

Throughout the research project, several engineers questioned why our team analysed the whole TIPS procedure and not just focused on the intrahepatic puncture. Although, the puncture was already defined as the most complex step in the introduction, we chose to not research this macro step alone. There are several reasons for this extensive analysis. First of all, we did not want to overlook important micro questions. With the complete list of 64 micro questions we were able to judge whether to leave out any micro questions and if so, which. Secondly, we wanted to let IRs indicate the focus for system improvement. They know best for which parts of the procedure support is most essential. Furthermore, the analysis provides in-depth understanding of the whole procedure (e.g. actions, concerns, materials) and small steps. Having a holistic view of the small steps and gradually improving them (e.g. by constant checks), suits the common approach in medicine [FREU2008].

8.3.2 Experiences with the used methods

Although several methods were used and needed for this thesis, the generative method in particular revealed the missing information for the current IG. The method helped both the leading researcher and the participating IRs to obtain an improved understanding of the procedure and of IRs' cognition. This is probably not only because the participating IRs had to present their experiences, but also because the setup of the generative session; IRs were not restricted by specific questions, but invited to have an open, facilitated discussion, in which they were free to express their opinion. Besides, IRs' output served as an input for the researcher, and could immediately raise new questions. The ethnographic methods used became more effective after the session than they were before: observations were easier to follow and more detailed questions could be asked. Overall, the generative sessions worked as a catalyst, raising the researcher's understanding of the procedure. As a result the communication between her and the IRs became more effective. We are convinced that the improved understanding facilitated the communication with the IRs, but also amongst IRs, and contributed to a more efficient end result in which an IG system is developed that meets the IRs' wishes in function and use.

It is worth mentioning that discovering all information at once was impossible. Each time IRs described new and more specific TIPS aspects, it generated new insights and questions for the researcher. Multiple conversations and observations were required to collect all fragments and to combine them into a whole. At the end, a comprehensive workflow was presented, which contributes to an improved understanding of the procedure, users, challenges, desired improvements and medical literature.

The 3D US training sessions were useful in experiencing the difficulties of using 3D US and in understanding and recognizing the US images. Although such collaborative training appears to be fairly unusual, it helped to understand each other's way of thinking, questioning, and working and to have fruitful discussions on UI requirements. For example, the engineers of the team were able to experience what actions IRs have to take to puncture.

The plane selection test accelerated the design process. During the test, IRs could express their wishes and expectations, but they even went beyond the given task and provided other solutions, such as the sectional view along a curve. They did not provide these before and were not asked to, but expressed their needs and ideas spontaneously. By using the tool, we were able to create a useful UI together, and thus to again co-design with the IRs. Apparently IRs are willing to help in creating an intuitive device, but need an effective aid to trigger them.

Creating prototypes also appeared to be useful during the evaluation phase. The prototypes allowed the leading researcher to have a proof of concept before the UIs will actually be built and tested. By physically testing the UIs during the evaluation phase, ideas become more concrete and this allowed IRs to test the ideas' feasibility. Providing feedback seemed to become easier and it made the IRs more enthusiastic and willing to co-operate, because they were able to really use a working prototype and get a sense of possible future improvements. The prototypes also facilitated the communication within the team by making everyone understand what is needed to make the working UIs, such as automatic segmentation and realtime-3D US. IG research groups do use prototypes, but they rarely perform usability testing [e.g., ADAM2009] or test in an incorrect manner [e.g., HANU2007]. To illustrate, Hanumara *et al* [HANU2007] only asked the physicians on the research team to tell if the new prototype was an improvement compared to the previous one. They did not ask unbiased physicians to test the new prototype and provide thorough feedback. During our research, usability testing was key, and unprejudiced IRs were frequently asked to test designs and to provide as much feedback about the design as desired.

8.3.3 Limitations of the used methods

The following are limitations of the used methods not already covered under workflow limitations:

- The UIs' usability was tested, but it was not compared to a current UI in a real TIPS procedure. The UIs were not integrated in the TIPS workflow and the Puncture-UI test was just an imitation of a real-life situation. Only the movement of the instrument was shown in real-time, not the actual US data. Also, time was not recorded as an independent measure. Qualitative evaluations were conducted, in which insights about the procedure and UI requirements were formed. However, quantitative evaluations, such as comparing the number of punctures during the TIPS procedure while using and not using the UIs, remain scarce. Therefore, the outcomes cannot yet be compared to the outcomes of the current procedure. By performing quantitative research and test clear hypotheses, the significant effect of the UIs on the intrahepatic puncture can be tested.
- The UIs were tested by many IRs. However, it was tested for only one scenario: the standard TIPS procedure, and participants had clear vision of the anatomy on US. In real life, there is a great variability in patient anatomy and TIPS procedures. Therefore, it remains uncertain if the UIs will also contribute in improving the exceptional, but often most difficult, cases. Time and elaborate testing will tell if the UI can also be used to improve these cases.

8.4 Contribution of this thesis

The design goal of this thesis was *to design an interactive 3D US based UI for IRs to minimize the number of punctures during the TIPS procedure*. In this thesis, an aid was created which allows IRs to see the target vein and needle movement in real-time instead of performing a blind puncture. The aid is non-invasive and does not use harmful radiation. Results of Chapter 7 imply that with the new aid, not a mean of three or five (range1-14, see Chapter 2) but a mean of one (range 1-3) punctures are needed to gain access to the PV. In addition, all IRs expressed positive experiences while using it. Based on these outcomes, we can assume that the design goal was accomplished. However, more evaluations from different aspects (see limitations and recommendations) are needed to fully prove the effect of this assumption.

8.5 Recommendations for future research and design

In future research, more elaborate testing and further UI development are recommended.

In detail, it is recommended to:

- Make adjustments to the Planning-UI: mainly to allow IRs to acquire a realistic needle trajectory at all times, to generate and load a 3D US and CT dataset, to be able to spatially orientate when using the UI.
- Make adjustments to the Puncture-UI: mainly to allow IRs to always see their needle and to spatially orientate. If elements could not be generated by US alone, the elements from other modalities will be integrated in the UI as well.

- Integrate both UIs so that IRs can first plan and then perform the puncture on the same UI.
- Improve the image quality from both updating frequency and resolution points of view. When testing the currently available 3D US machine during TIPS, some IRs complained about the poor image quality of 3D US.
- Improve visibility by presenting each plane on one screen and have another screen with the overview of all. IRs now have problems with identifying different structures in the small planes, because all planes are presented on one screen.

For research, it is recommended to:

- Research ways to use the UIs during the pre-operative and intra-operative phase and explore additional HCI devices. There are more effective ways to visualize the anatomy in 3D (e.g., holograph) and improve the spatial understanding of the anatomy, or to interact with the UI (e.g. eye movement, foot control) to make the UI more intuitive.
- Explore the visibility of the needle and other instruments on US. IRs want to see the instruments in real-time. If the instruments are poorly visualized, the instruments have to be adjusted to make them more echogenic or even to be tracked.
- Test how to position and fixate the US probe at exactly the same position as for the Planning-UI to generate the desired US volume and US planes during the procedure. For now, the leading researcher assumed that a probe holder would suffice, but the validity of this assumption is not verified.
- Perform additional testing with quantitative measure. The design of the UI was largely based on IRs' opinions. We can assume that the insights were in agreement, since many of these findings, such as the need for proper orientation support and to see the target in real-time, were mentioned by different IRs during different studies. These insights were considered as sufficient to use them as a basic input for the design. The limitation is that only few quantitative measurements were obtained. When testing in a more real-life setup and integrating the UIs in the TIPS workflow, for example with real-time 3D US acquisition (e.g., to involve breathing), real patient anatomy and stress, the real effect of using the 3D US based UI during TIPS can be validated and that allows researchers to prove the actual effect of implementing the UIs.

Although this thesis focuses on the TIPS procedure, the gained insights and basic design aspects could be used for other purposes as well, e.g. to improve interventions such as a biopsy or RFA. As stated in Chapter 1, these procedures resemble parts of the TIPS procedure, such as to safely puncture the target. Basic elements of both UIs, such as visualizing the target and needle in real-time 3D, could assist IRs to do so. Next, the workflow analysis allowed the leading researcher to create an overview of the tasks and to describe the IRs' navigation cycles. By mapping the procedure in such an ordered and accessible way, IG developers, but also TIPS instrument and other developers, can now understand the procedure. Furthermore, it could help IRs to explain the procedure and its protocol, for example to IRs and assisting nurses in training. The overview could allow managers and engineers to discover unproductive parts and optimize the procedure. Finally, the methods used in this thesis could inspire developers of complex systems on how to integrate HF in the development process to develop useful systems.

Although an interactive 3D US based UI was designed, the UI design can also be integrated in using other imaging modalities. The team is convinced that interactive 3D US is the most suitable modality for the TIPS procedure and possibly for other procedures as well. Basic UI elements, such as the target point, could also be selected and shown on UIs of other modalities, such as Fluo, given that IRs can see the real-time 3D anatomy and needle movement.

Overall, this thesis provides insights for designing a 3D US based UI which supports IRs to perform the intrahepatic puncture with increased effectiveness, efficiency and satisfaction. Compared to other interventions, the TIPS procedure appears to be very ambitious and complex, and lacking guidance. Additional IG is required, especially for the intrahepatic puncture. This thesis shows what information is needed and how it can be presented to make the puncture effective and efficient. It provides medical developers with a sound overview of the workflow, related challenges and requirements, IG limitations and possible solutions. The studies illustrate: a) why information is needed; b) when information is needed; c) what types of information are needed; and d) how to present the information. The detailed analysis is essential to develop medical systems that enhance performance and increase safety and user satisfaction. Based on the insights a Planning-UI and Puncture-UI was created and its usability was tested. Studies showed that IRs wish to prepare the procedure and, without much physical and mental effort, to see the critical anatomy, their instruments, the target and the preferred navigation line in real-time and in 3D. The basic understanding of what information IRs need to successfully navigate within the patient's body can be used for creating UIs for other interventions as well.

In addition, this thesis provides examples of using co-design methods to develop the UI of complex medical procedures. With co-design methods, obtaining useful information and solutions can become easy and effective. By involving the end-users in all phases of the design process, the number of innovative and promising ideas increases. The methods allow research teams to make medical systems for safe, comfortable and effective human use.

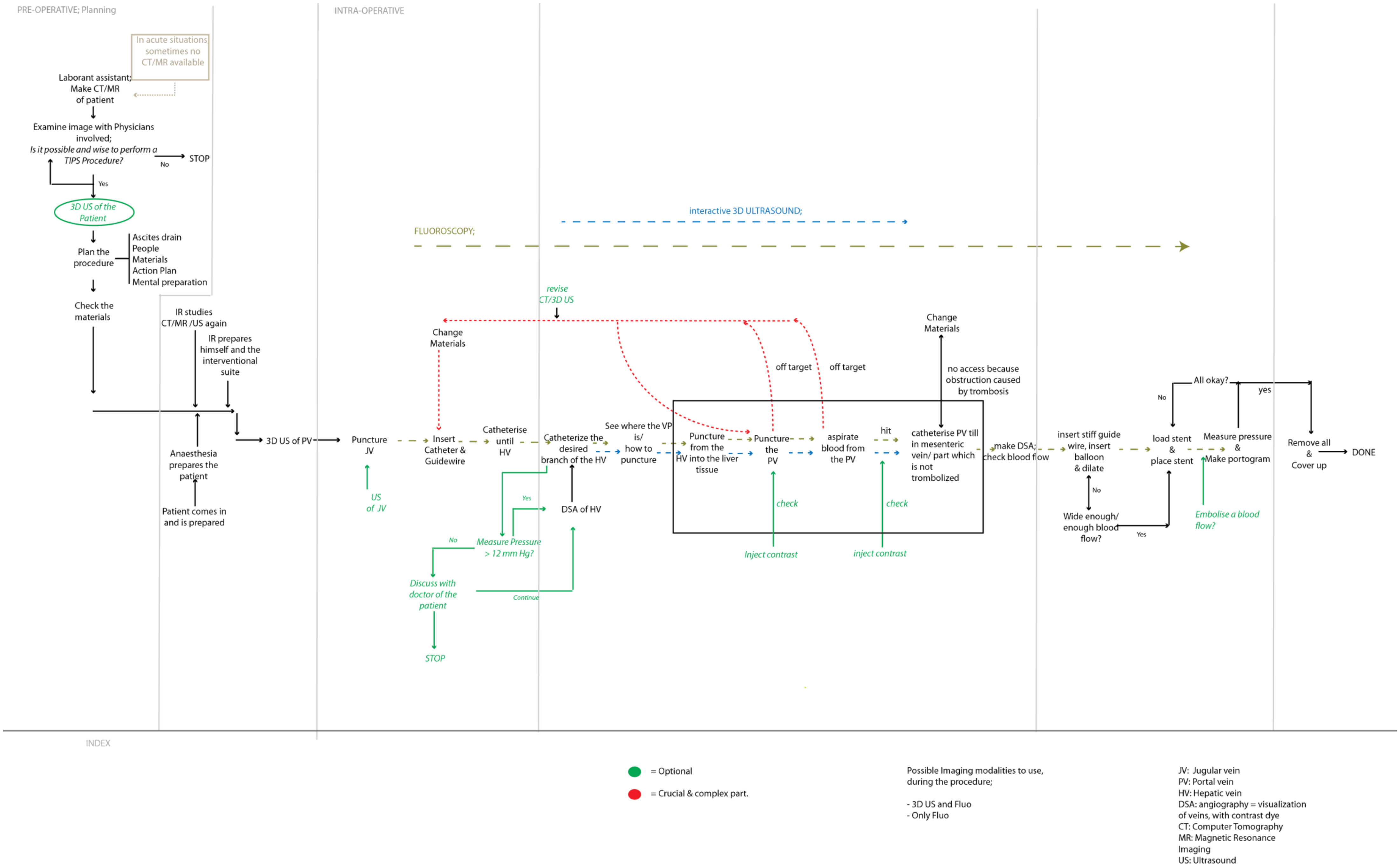


Figure 46. The macro steps of the TIPS procedure, when using the new UIs.

Summary

The transjugular intrahepatic portosystemic shunt (TIPS) procedure is one of the most technically challenging procedures in interventional radiology. The procedure is usually performed for patients with a high blood pressure in their portal vein (PV), also known as portal hypertension. During the procedure, interventional radiologists (IRs) insert and then navigate very thin and long instruments through a little incision in the patient's neck and through the blood vessels to create a shunt in the patient's liver. The shunt bypasses the blood flow from the PV into the hepatic vein (HV) or inferior vena cava. The shunt will help to decrease the portal hypertension.

Among the different steps of the TIPS procedure, the most difficult one is to puncture through the liver to gain access to the PV. This is often referred to as the intrahepatic puncture. The puncture is crucial for creating the shunt.

The difficulty of the puncture lies in the limited availability of real-time three-dimensional (3D) information about the anatomy and instruments during the puncture. IRs usually use the images from different X-ray imaging modalities to navigate, such as computed tomography (CT) in the pre-operative or planning phase and two-dimensional (2D) fluoroscopy during the intra-operative phase. The CT images do not visualize real-time information; the fluoroscopic 2D images do visualize the instruments, but not the soft tissues such as the liver. Besides, the use of X-ray raises safety concerns about both the patient and the clinicians which restricts the use of these images. Due to the limited information, the puncture is frequently described as a blind puncture. To perform the puncture, IRs mainly rely on their own experiences and have to proceed through trial and error. As a result, IRs often need to puncture multiple times. Those multiple punctures prolong the procedure and may cause complications, therefore only experienced IRs are allowed to perform this procedure.

To gain a better view of the anatomy and the instrument during the puncture, researchers and IRs introduced additional visualization aids. These aids, such as injecting CO_2 to visualize the PV, can be used along with the conventional modalities. However, these methods have their limitations and can add risks.

In the past decade, advancements in medical technology have made the usage of 3D ultrasound (US) available for interventional radiology. 3D US is regarded as harmless and can generate real-time 3D images of both instruments and anatomy. However, the user interfaces (UI) of current 3D US machines are complicated and do not meet IRs' expectations. The goal of this research is *to design a real-time 3D US based UI for IRs to minimize the number of punctures during the TIPS procedure*. To support this goal, the main objective of this thesis was to discover what information should be presented in an interactive 3D US based UI to minimize the number of intrahepatic punctures in the TIPS procedure.

Throughout the research, the author worked within a multidisciplinary team to investigate different aspects regarding designing a UI for the TIPS procedure. The team consisted of industrial designers, software engineers, biomedical imaging engineers and IRs.

Before it was possible to design the GI, understanding of the procedure, IRs' navigation strategies, procedural challenges, missing information, 3D US possibilities and desired GI improvements was needed. In literature only very limited information of this kind was available. As the leading researcher in UI design, the author performed several studies to collate this information. She completed literature reviews, field

research of the procedure, tested a current 3D US machine and communicated with IRs with different mock-ups and a prototype. As a result, the author was able to create an overview of the TIPS procedure, identify the related challenges and UI needs, and investigate the possibilities of using 3D US technology to improve the procedure.

It was found that during the TIPS procedure, IRs mainly miss information to perform the elementary cognitive actions. Subsequently, there is limited possibility to create and maintain proper situation awareness, to predict the consequence of actions, and to learn from previous attempts. The desired UI provides IRs with real-time 3D information about the critical anatomy, the target, and the position and direction of the instrument. This information can be presented in 2D planes which display: a) for HV catheterization, the target in the PV and the longitudinal section of the HV; and b) for the intrahepatic puncture, the target PV position and the longitudinal view of the HV and the cross section of both veins, visualizing the exit point in the HV and the target point in the PV.

Based on these findings, two UIs were designed: the Planning-UI and the Puncture-UI. The Planning-UI allows IRs to pre-operatively visualize: a) the CT images, b) a 3D volumetric representation of the HV and PV and c) different section planes of the US volume. With the UI, IRs can see the anatomy, anatomical constraints, risks and anatomical distances. IRs can select possible target points and with these the system can generate potential needle trajectories. Based on the provided elements, IRs can set concrete expectations and plan the procedure. In addition, they can generate suitable 2D US planes for the intrahepatic puncture. The Puncture-UI design was based on these generated 2D planes. The Puncture-UI can be used to guide IRs during the intrahepatic puncture process. As the view planes are specified by IRs themselves, this UI is able to provide IRs with the desired real-time 3D information to perform the puncture.

The UIs were tested with, for the medical world, a large number and great variety of IRs. Due to this, it was possible to discover many essential GI requirements in the early development phase. The Planning-UI was tested with five IRs from three different Dutch hospitals. The results of the Planning-UI test showed that it provides IRs with valuable 3D visualization support to plan the procedure. The test participants said they also appreciated the Planning-UI, since it allowed them to view and interact with 3D information of the patient's anatomy. Next, the Puncture-UI was tested with 28 IRs of 14 different nationalities. The results of the Puncture-UI test showed that the UI provided the participating IRs with real-time 3D feedback and navigation support to perform the puncture in a more effective and efficient manner. Participants mentioned that they mainly appreciated the availability of visual feedback about the puncture, which allows them to see their actions. Currently, the UIs are only tested for a variety in skills and experience, but not patient anatomy. Future research is recommended to make the UIs useful for these cases as well.

However, it was possible to design 3D US based UIs which show IRs the necessary 3D real-time information to perform the intrahepatic puncture. Based on experiment results and IRs' feedback, we expect that those UIs will contribute to a more effective and efficient TIPS procedure, because IRs do not have to perform a blind puncture anymore, but instead see the target and needle movement in real-time. The UI helps IRs to decrease the number of puncture attempts, shorten the lengthy procedure and reduce potential risks. In the end, the procedure will achieve a higher level of satisfaction for the patient, the care givers and the organization.

Samenvatting

De transjugular intrahepatic portosystemic shunt (TIPS)-procedure is technisch gezien een van de meest complexe procedures binnen de interventieradiologie. De procedure wordt voornamelijk uitgevoerd bij patiënten met een hoge bloeddruk in de poortader (PA), oftewel portale hypertensie. Tijdens de procedure maken interventieradiologen (hierna: radiologen) een incisie in de halsader, en navigeren zij vervolgens met dunne, lange instrumenten via de aders naar de lever, om daar een doorgang in te maken. De doorgang moet het bloed van de PA omleiden naar de leverader (LA), zodat het vervolgens weg kan stromen naar het hart. Deze doorgang zal zorgen voor een vermindering van de portale hypertensie.

Om een doorgang te kunnen realiseren, moet eerst de meest gecompliceerde stap van de procedure worden uitgevoerd: de intrahepatische punctie. Tijdens de intrahepatische punctie prikt de radioloog door de lever in de PA. Hierdoor ontstaat een verbinding tussen de LA en de PA en kan een doorgang gerealiseerd worden.

Een gebrek aan realtime driedimensionale (3D) informatie over de anatomie en de instrumenten maakt de intrahepatische punctie zeer ingewikkeld. Om radiologen te ondersteunen tijdens dit navigatieproces, gebruiken zij nu voornamelijk de 2D beelden van twee, op röntgenstralen gebaseerde, beeldmodaliteiten: computed tomografie (CT) en fluoroscopie (Fluo). Radiologen gebruiken CT in de pre-operatieve fase voor het plannen van de procedure en Fluo tijdens de intra-operatieve fase om te navigeren. De Fluo-beelden visualiseren de instrumenten, maar niet de zachte weefsels, zoals de lever. Daarnaast is het gebruik van röntgenstralen schadelijk voor de patiënt en clinici. Daarom wordt het gebruik beperkt. Vanwege het gebrek aan informatie wordt de punctie vaak beschreven als een blinde punctie. Momenteel vertrouwen radiologen vooral op hun ervaring en moeten ze vaak eerst handelen voordat ze de nodige informatie krijgen. Er zijn dan ook vaak meerdere puncties nodig voordat er daadwerkelijk in de PA wordt geprikt. Deze onnodige puncties verlengen de procedure, vergroten de kans op complicaties en zorgen ervoor dat alleen zeer ervaren radiologen in staat zijn om de TIPS-procedure uit te voeren.

Naast de al beschikbare apparatuur, kunnen radiologen ervoor kiezen om extra visualisatiehulpmiddelen te gebruiken om de PA in beeld te krijgen, zoals de injectie van CO_2. Deze methoden hebben echter ook hun beperkingen en extra risico's.

De vooruitgang in medische technologie heeft het gebruik van de 3D echo mogelijk gemaakt. 3D echo wordt beschouwd als niet schadelijk voor de gezondheid en kan realtime 3D-beelden genereren van zowel de instrumenten als de anatomie. Het grote nadeel is dat de gebruikersinterfaces (GIs) van de huidige 3D echomachines complex zijn en niet aansluiten bij de verwachtingen van radiologen. Het ontwerpdoel van dit onderzoek is dan ook om *een op realtime 3D echo gebaseerde GI te ontwerpen voor radiologen, waardoor het aantal puncties tijdens de TIPS-procedure verminderd kan worden*. Om dit doel te verwezenlijken, is het van belang om te weten welke informatie gevisualiseerd moet worden in een op 3D echo gebaseerde GI.

Tijdens het onderzoek was de auteur onderdeel van een multidisciplinair team. Het team bestond uit industrieel ontwerpers, een software-ingenieur, biomedische beeldingenieurs en radiologen. Samen konden zij ervoor zorgen dat de verschillende GI ontwerpaspecten onderzocht konden worden.

Voordat het mogelijk was om een GI te ontwerpen, was er eerst meer kennis nodig over de procedure, huidige navigatiemethoden tijdens de procedure, informatiegebreken, informatiebehoeften, de mogelijkheden van 3D echo en gewenste verbeteringen. Deze inzichten werden nauwelijks beschreven in de literatuur. Als hoofdonderzoeker van het GI-ontwerp, voerde de auteur studies uit om deze informatie te verzamelen. Zij voerde literatuur- en veldonderzoeken uit, testte met radiologen een huidige 3D echomachine en communiceerde met radiologen haar ideeën door middel van testmodellen en prototypen. Hierdoor was zij in staat om een overzicht van de procedurele stappen te maken, inzicht te krijgen in het navigatieproces van de radiologen, de procedurele problemen en informatietekortkomingen in kaart te brengen, GI-eisen op te stellen en eventuele mogelijkheden van het gebruik van 3D echo voor de TIPS-procedure te onderzoeken.

Uit de resultaten bleek dat radiologen vooral de ruimtelijke informatie missen om de elementaire cognitieve acties van de procedure uit te kunnen voeren. Hierdoor is het lastig voor radiologen om zich tijdens de procedure voldoende bewust te worden van de situatie en dit te blijven, maar ook om consequenties van acties te kunnen voorspellen en te kunnen leren van precederende pogingen. De gewenste GI voorziet radiologen dan ook van realtime 3D informatie betreffende kritieke anatomie, het doelwit, en de positie en richting van de instrumenten. Deze informatie kan gevisualiseerd worden voor: a) het katheteriseren van de LA; door met 2D echo de longitudinale LA-richting te laten zien, en b) de intrahepatische punctie; door met echo het doelwit in de PA, de longitudinale richting van de LA en een dwarsdoorsnede van beide vaten te laten zien, met het vertrekpunt in de LA en het doelwit in de PA.

Gebaseerd op deze bevindingen zijn een planning-GI en een punctie-GI ontworpen. De planning-GI laat het volgende zien: a) de CT-beelden, b) een 3D volumetrische weergave van de LA en PA en c) verschillende 2D sectievlakken uit het echovolume. Het systeem laat radiologen mogelijke doelwitten selecteren, waarmee het systeem potentiële punctietrajecten kan genereren. Door de mogelijke punctietrajecten, de anatomie, anatomische afstanden en beperkingen in kaart te brengen, maakt de GI het voor de radiologen mogelijk om punctiemogelijkheden te evalueren, concrete procedurele verwachtingen te scheppen en potentiële risico's van de procedure te voorzien. Tot slot kunnen radiologen op basis van een gekozen traject geschikte 2D echovlakken genereren voor de intrahepatische punctie. Het ontwerp van de punctie-GI was vervolgens gebaseerd op deze 2D vlakken. De punctie-GI kan gebruikt worden tijdens de daadwerkelijke punctie. Omdat de vlakken gespecificeerd zijn door de radiologen zelf, is het in staat om radiologen tijdens de punctie van de nodige realtime 3D informatie te voorzien.

De GIs zijn getest met een, voor de medische wereld, aanzienlijke hoeveelheid en variëteit aan radiologen. Hierdoor is het beter mogelijk om de diverse ontwerpeisen vroegtijdig te achterhalen en mee te nemen in het ontwerp. De planning-GI is getest met vijf radiologen van drie verschillende ziekenhuizen. In de planning-GI vonden zij waardevolle 3D informatie om de procedure te kunnen plannen. Daarnaast gaven zij aan dat zij de planning-GI waardeerden, omdat het hen de mogelijkheid gaf om de anatomie van de patiënt in 3D te kunnen zien en ermee te interacteren. 28 Radiologen uit 14 verschillende landen hebben de punctie-GI getest. Uit de resultaten bleek dat de participanten van de GI bruikbare realtime 3D informatie kregen, om de punctie op een effectieve en efficiënte manier uit te kunnen voeren. Participanten zeiden vooral te waarderen dat ze tijdens de procedure konden zien wat ze deden. Momenteel zijn de GIs vooral getest op een variatie aan vaardigheden en ervaring, maar nog niet op een variatie aan patiëntanatomie. Vervolgstudie is nodig om de GIs ook voor de verschillende TIPS-patiënten bruikbaar te maken.

Het was mogelijk om 3D echogeleide GIs te ontwikkelen die tijdens de intrahepatische punctie de radiologen van cruciale realtime 3D informatie kunnen voorzien. Op basis van de testresultaten kan worden aangenomen dat beide GIs zullen bijdragen aan een efficiëntere en effectievere TIPS-procedure, omdat radiologen nu niet meer blind hoeven te prikken, maar hun doel zien en tevens zien waar de naald naartoe beweegt. In de toekomst kunnen de GIs de radiologen mogelijk helpen om het aantal puncties te verminderen, de procedure te verkorten en het aantal risico's te reduceren. Dit zal leiden tot een hogere graad van tevredenheid bij patiënt, zorgverlener en organisator.

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References

[ADAM2009]Adamus R, Pfister M, Loose RWR (2009) Enhancing Transjugular Intrahepatic Portosystemic Shunt puncture by Using Three-Dimensional Path Planning Based on the Back Projection of Two Two-Dimensional Portographs, Radiology, 251:543–547.

[ALAS2009] Alastair JM, Starr PA, Larson PS (2009) Software Requirements for Interventional MR in Restorative and Functional Neurosurgery, Neurosurgery clinics of North America, 20(2): 179-186

[ARAG2005] Aragon CR, Hearst MA (2005) Improving Aviation Safety with Information Visualization: a Flight Simulation Study, Special Interest Group on Computer–Human Interaction, SIGCHI: 441-450

[ASAN2014] Asan O, Chiou E, Montague E, (2014), Quantitative Ethnographic Study of Physician Workflow and Interactions With Electronic Health Record Systems, International Journal of Industrial Ergonomics

[AVIS1999] Avision D, Lau F, Myers M, Nielsen PA, (1999) Action Research, Communication of the ACM, 42(1)

[AZUM2000] Azuma R, Neely H, Daily M, Geiss R (2000) Visualization tools for free flight air-traffic management, IEEE Computer Graphics and Applications, 20(5):32-36.

[BECK2001] Becker GJ (2001) The future of interventional radiology, Radiology 220(2):281-292

[BERG2001] Berg M, (2001), Implementing Information Systems in Health Care Organizations: Myths and Challenges, Intational Journal of Medical Information 64: 143-156

[BERR2015] Berry K, Lerrigo R, Liou IW, Ioannou GN (2015) Association between Transjugular Intrahepatic Portosystemic Shunt and Survival in Patients with Cirrhosis, Clinical Gastroenterology and Hepatology, I*n Press*

[BOIV2006] Boivie I, Gulliksen J, Göransson B (2006) The Lonesome Cowboy: A study of the Usability Designer Role in Systems Development. Interacting with Computers 18:601–634

[BORT2012] Borton C, Tidy C, Bonsal A, 19-04-2012, Ascites, retrieved December 1, 2014 from www.patient.co.uk/doctor/ascites

[BOWM2001] Bowman DA, Kruijff E, LaViola, Jr JJ, Poupyrev I, (2001) An Introduction to 3D User interface Design, Teleoperators and Virual Environments, 10(1):96-108

[BOWM2004] Bowman, DA., Kruijff E., LaViola Jr JJ., Poupyrev I (2004) 3D user interfaces: theory and practice, Addison-Wesley

[BOYV2006] Boyvat F, Aytekin C, Harman A, Ozin Y (2006) Transjugular Intrahepatic Portosystemic Shunt Creation in Budd-Chiari Syndrome: Percutaneous Ultrasound-Guided Direct Simultaneous Puncture of the Portal Vein and Vena Cava. Cardiovascular Interventional Radiology, 29:857–61

[BRAN1974] Brandt KH van der HM. (1974) Capita Selecta; Herkenning en behandeling van Portale Hypertensie. Ned. T. Geneeskunde 118

[BUZI2010] Buzink S, (2010) Improving patient Safety in Image-Based Procedures, PhD Thesis, Delft, ISBN: 9789461130211

[CALI2013] Calise F, Migliaccio C (2013) Minimally Invasive Surgery of the Liver: an Update, Minimally Invasive Surgery of the Liver, Springer 9-14

[CARR2006] Carr CE, Tuite CM, Soulen MC, Shlansky-Goldberg RD, Clark TW, Mondschein JI, Trerotola SO (2006) Role of ultrasound surveillance of transjugular intrahepatic portosystemic shunts in the covered stent era, Journal of vascular and interventional radiology, 17(8): 1297-1305

[CHAR1997] Charitos D (1997) Designing Space in Virtual Environment for Aiding

Wayfinding Behaviour, UK Virtual Reality SIG Conference, Brunel University

[CHAT2013] Chatelain P, Krupa A, Marchal M, 2013, "Real-time needle detection and tracking using a visually servoed 3D ultrasound probe," ICRA, Karlsruhe, Germany

[CHMA2013]Chmarra MK, Hansen R, Marvik R, Lango T (2013), Multimodal phantom of liver tissue, Multimodal Phantom of Liver Tissue. PLoS ONE 8(5)

[CLAR2008] Clark TWI (2008) Stepwise Placement of a Transjugular Intrahepatic Portosystemic Shunt Endograft, Techniques in vascular and interventional radiology, 11: 208–211.

[CLAS2014] Clasen S, Rempp H, Hoffman R., Graf H., Pereira P L., Claussen C.D., (2014) Image-Guided Radiofrequency Ablation of Hepato Cellular Carcinoma (HCC): Is MR Guidance More Effective than CT Guidance?, European Journal of Radiology, 83: 111-116

[CLEA2010] Cleary K., Peters, TM (2010) Image-guided interventions: technology review and clinical applications, Annual review of biomedical engineering, 12: 119-142

[COLE1993] Cole E, Darcy D, Freedman M, Purdum P, Posner MP (1993) Complicatios of Transjugular Portosystemic Shunt: A comprehensive Review, Radiographics, 1185-1210

[COOK] Cook Medical, Transjugular Liver Access, An illustrated guide, retrieved January 28, 2015 from https://www.cookmedical.com/data/resources/productReferences/IR-BM-RUPSP-EN-201210.pdf

[COUR2011] Court, P. (2011). Study Into the Feasibility of Protecting and Recovering Critical Raw Materials through Infrastructure Development in the South East of England European Pathway to Zero Waste.

[CPMC] Liver Cancer (Hepatocellular Carcinoma) Diagnosis and Treatment, Sutter Health CPMC, Retrieved January 28, 2015 from http://www.cpmc.org/advanced/liver/patients/topics/liver-cancer-proficle.html

[CUIJ2012a] Cuijpers CF, Moelker A, Varga E, et al. (2012) Improving IG in Interventional Radiology : Information Lack in TransjugularIintrahepatic Portosystemic Shunt, Conference on Human Decision-Making and Manual Control (EAM), Braunschweig: 143–149

[CUIJ2012b] Cuijpers CF, Moelker A., Varga E, Stappers PJ, Freudenthal A (2012) Addressing information gaps in interventional radiology – TIPS procedures, International Conference of the Society for Medical Innovation and Technology' (SMIT), Barcelona

[CUIJ2013a] Cuijpers CF, Klink C, Stappers PJ, Freudenthal A (2013) "Comparing IG Systems to Improve Complex Navigation in Medicine, International Federation of Automatic Control Conference, Las Vegas, USA

[CUIJ2013b] Cuijpers CF, Klink C, Stappers PJ (2013) Cognitive Task Analysis and Prioritization to Improve IG of TIPS, Procedeedings of Design of Medical Devices Conference, Delft, the Netherlands

[CUIJ2014] Cuijpers CF, Varga E, Klink C, Banerjee J, Stappers PJ, Freudenthal A (2014), A real-time three-dimensional ultrasound user interface for TIPS: Preliminary results, Computer Assisted Radiology and Surgery (CARS), Fukuoka, Japan

[CUIJ2015a] Cuijpers CF, Varga E, Klink C, Banerjee J, Stappers PJ (2015), A real-time three-dimensional ultrasound user interface for TIPS: Preliminary results, Dutch Biomedical engineering conference (BME), Egmond, the Netherlands

[CUIJ2015b] Cuijpers CF, Varga E, Klink C, Stappers PJ, Song Y (2015) Real-time three-dimensional ultrasound user interface for TIPS planning: a case study, European congress of radiology (ECR), Vienna, Austria

[DAFF1999] Daffner H.R. (1999). Clinical Radiology; The Essentials, 2, 49–72

[DANE2006] Danesi F, Gardan N, Gardan Y, 2006, Collaborative Design: from Concept to Application, Proceedings of the Geometric Modeling and Imaging – New Trends

[DARK1993] Darken RP, Sibert JL (1993) A toolset for navigation in virtual environments, Proceedings of the 6th annual ACM symposium on User interface software and technology :157-165.

[DE1997] De RK, Pal NR, Pal SK (1997) Feature Analysis: Neural Network and Fuzzy set Theoretic Approaches, Pattern Recognition, 30(10):1579-1590

[DIGI2012] DiGiacinto D, Bagley J, Garrison M (2012). Comparison of Endobronchial Ultrasound and Computed Tomography With Fluoroscopy in the Guidance of Lung Cancer Biopsies: A Literature Review, Journal of Diagnostic Medical Sonography, 28(5):224–230

[DJAJ1998] Djajadiningrat JP (1998) Cubby:what you see is where you act. Interlacing the display and manipulation spaces, Dissertation, Industrial Design Engineering, Delft

[ELAT2012] El Atrache M, Abdouljoud M, Sharma S, Abbass AA, Yoshida A, Kim D, Kazimi M, Moonka D, Brown K, (2012), Transjugular Intrahepatic Portosystemic Shunt Following Liver Transplantation: Can Outcomes be Predicted? Clinical transplantation, 26(4): 657-661

[ELVI1997] Elvins T, Nadeau D, Kirsch D (1997) Wordlets—3D Thumbnails for Wayfinding in Virtual Environments, Proceedings of the 10th annual ACM symposium on User interface software and technology, ACM.

[FALL2010] Fallavollita, P, Karim Aghaloo, Z, Burdette, E C, Song, D Y, Abolmaesumi, P, Fichtinger, G (2010) Registration between ultrasound and fluoroscopy or CT in prostate brachytherapy. Med.Phys., 37(6): 2749

[FANE2006] Fanelli F, Salvatori FM, Corona M, et al (2006) Stent Graft in TIPS: Technical and Procedural Aspects. La Radiologia medica 111:709–23

[FARS2012] Farsad K, Fuss C, Kolbeck KJ, et al (2012), Transjugular intrahepatic Portosystemic Shunt Creation Using Intravascular Ultrasound Guidance, Journal of Vassaxoular and Interventional radiology, 23(12): 1594-1602

[FENS2000] Fenster, A, Downey, DB (2000). Three-dimensional ultrasound imaging. PMB, 2: 457–75.

[FENS2002] Fenster A, Surry K, Smith W, Gill J, Downey, DB (2002) 3D ultrasound imaging: applications in imageguided therapy and biopsy. CG, 26(4): 557–568.

[FENS2011] Fenster, A., Parraga, G., & Bax, J. (2011). Three-dimensional Ultrasound Scanning. Interface focus, 1(4): 503-519.

[FERR2005] Ferral H, Bolbao JI (2005) The Difficult Transjugular Intrahepatic Portosystemic Shunt: Alternative Techniques and “Tips” to Successful Shunt Creation, Seminars in Interventional Radiology, 22(4):300

[FREE1993] Freedman AM, Sanyal AJ, Tisnado J, Cole PE, Shiffman ML et al (1993) Complications of Transjugular Intrahepatic Portosystemic Shunt: A Comprehensive Review, RadioGraphics, 13:1185-1210

[FREU2007] Freudenthal A, Pattynama PMT (2007) What’s in a Surgeon's Mind? Learning for Performing Treatments and Operating Equipment. New Technology Frontiers in MinimallyIinvasive Therapies. Lupiens Biomedical Publications: 112–121

[FREU2008] Freudenthal A, Stüdeli TP., Sojar V, van der Linden E, Pattynama PMT (2008) Workflow Development to Allow Early User Guidance of Emerging Image Guidance Technologies, International Conference, Healthcare Systems, Ergonomics and Patient Safety, Strasbourg, France

[FREU2010] Freudenthal A, Stüdeli T, Lamata P, Samset E (2010) Collaborative Co-design of Emerging Multi-technologies for Surgery. Journal of Biomedical Informatics, 44(2):198-215

[FREU2013] Freudenthal A, Geer van der MJF, Stappers PJ, Pattynama PMT (2013) Radical co-design for Earliest Design Stage of Complex Biomedical Information Systems. Journal of Design Research 11 (1): 1-38.

[FRUSH2004] Frush DP., Applegate K (2004) Computed tomography and radiation: understanding the issues, Journal of the

American College of Radiology, 1(2): 113–119

[FUKU2012] Fukuda H, Ito R, Ohto M, et al (2012) US-CT 3D dual imaging by mutual display of the same sections for depicting minor changes in hepatocellular carcinoma, European Journal of Radiology, 81(9): 2014–2019

[FUNA2008] Funaki B (2008) Transjugular Intrahepatic Portosystemic Shunt, Seminars in interventional radiology, 1:168–174.

[GABA2011] Gaba RC, Khiatani VL, Knuttinen MG, Omene BO, Carrillo TC, Bui JT, Owens CA, (2011) Comprehensive review of TIPS Technical Complications and How to Avoid them, Vascular and Interventional Radiology, 196: 675-685

[GALI2002] Galitz WO (2002) The Essential Guide to User Interface Design, An Intorduction to GUI Design Principles and Techniques, John Wiley & Sons (2), ISBN:0-471-084646

[GEMM2009] Gemmette JJ, Ansari SA, McHugh J, et al (2009) Embolization of Vascular Tumors of the Head and Neck, Neuroimaging Clinics of North America, 19: 181-189

[GOLB2011] Golby AJ, Kindlmann G, Norton I, Yarmarkovich A, Pieper S, Kikinis R, Interactive diffusion tensor tractography visualization for neurosurgical planning, Neurosurgery, Feb. 2011, 68(2):496-505

[GORG2013] Gorgos L, Marrazzo J (2013) Counseling the Patient with Hepatitis C Infection, University of Washington, retrieved January 1, 2015 from http://depts.washington.edu/hepstudy/healthed/counselingHepC/discussion.html

[GOSB2002] Gosbee J (2002) Human factors engineering and patient safety, Quality and Safety in Health Care, 11(4): 352-354

[GOYK2010] Goykhman Y, Ben-Haim M, Rosen G, et al. (2010) Transjugular Intrahepatic Portosystemic Shunt: Current Indications, Patient Selection and Results. Israel Medical Association Journal, 12:687–691

[HAAG2001] Haaga, JR (2001). Radiation dose management: weighing risk versus benefit, American Journal of Roentgenology, 177(2): 289–291

[HANU2007] Hanumara NC, Walsh CJ, Slocum AH, Gupta R, Shepard JA (2007) Human factors design for intuitive operation of low-cost, image-guided, tele-robotic biopsy assistant, Conference of the IEEE EMBS

[HART2006] Hart, SG (2006) NASA-task load index (NASA-TLX); 20 years later. In Proceedings of the human factors and ergonomics society annual meeting, Vol. 50(9):904-908

[HASK2003] Haskal ZJ, Martin L, Cardella JF, et al. (2003) Transjugular Intrahepatic Portosystemic Shunts, Journal of Vascular Interventional Radiology: 265–270

[HASS2004] Hassoun Z, Pomier-Layrargues G, (2004) The Transjugular Intrahepatic Portosystemic Shunt in the Treatment of Portal Hypertension, European Journal of Gastoenterology & Hepatology 16: 1-4

[HAUS2004] Hausegger KA, Karnel F, Georgieva B, et al. (2004) Transjugular Intrahepatic Portosystemic Shunt Creation with the Viatorr Expanded Polytetrafluoroethylene – Covered Stent-Graft, Journal of Vascular Interventional Radiology

[HEAL2012] Health Council of the Netherlands (2012) Childhood leukaemia and environmental factors, HCN: 2012-2033

[HERF2009] Herfarth, H. (2009) The risk of radiation and choice of imaging, Falk Symposium: 41–42

[HEGA2007] Hegarthy M, Keehner M, Cohen C, et al (2007) The Role of Spatial Cognition in Medicine: Applications for Selecting and Training Professionals, Applied Spatial Cognition, Allan, Mahwah, NJ, Erlbaum

[HORV2007] Horváth I, (2007) Comparison of Three Methodological Approaches of Design Research, International Conference on Engineering Design, France 7:28-31

[HOWA2001] Howard, M.H., Nelson, R.C., Paulson, E.K., Kliewer, M.A., and Sheafor, D.H. (2001) An Electronic Device for Needle Placement during Sonographically Guided Percutaneous Intervention, Radiology, 218: 905-911.

[ISHI2008]Ishikawa T, Fujiware H, Imai O, Okabe A (2008) Wayfinding with a GPS-based Mobile Navigation System: A Comparison with Maps and Direct Experience, Journal of Environmental Psychology, 28:74-82

[ISO9241-11] ISO 9241 (1998) Ergonomic Requirements for Office Work with Visual Display Terminals Part 11, Guidance on Usability

[JALO2007] Jalote-Parmar A, Pattynama PMT, de Ridder H, Goossens RHM, Freudenthal A, Samset E, Surgical Workflow Analysis: Indentifying User Requirements for Surgical Information Systems, Meeting Diversity in Ergonomics: 229-241

[JALO2008] Jalote-Parmar A, Badke-Schaub P (2008) Workflow Integration Matrix: a Framework to Support the Development of Surgical Information Systems, Design studies 29: 338-368

[JALO2009] Jalote-Parmar A (2009), Workflow Driven Decision Support Systems: a Case of an Intra-operative Visualization System for Surgeons, Thesis, Technical University of Delft, Delft

[JALO2010] Jalote-Parmar A, Badke-Schaub P, Ali W, Samset E (2010) Cognitive Processes as Integrative Component for Developing Expert Decision-making Systems: a Workflow Centered Framework, Journal of Biomedical Informatics, 43: 60-74

[JOHN2006] Johnson S, Healey A, Evans J, Murphy M, Crawshaw M, Gould D (2006) Physical and cognitive task analysis in interventional radiology, Clinical radiology, 61(1): 97-103.

[JOMI2006] Jomier J, Bullitt E, Van Horn M, et al. (2006) 3D/2D Model-to-image Registration Applied to TIPS Surgery, Medical Image Computing and Computer-assisted Intervention, 9: 662–9

[KARI2011] Karikawa D, Aoama H, Takahashi M, Furuta K, Wakabayashi T, Kitamura M (2011) A Visualization Tool of En Route aAir Traffic Control Tasks for Describing Controller's Proactive Management of Traffic Situations, Cognition Technology and Work, 15:207-218

[KAUF2014] Kaufman J, Lee M, (2014) Vascular and Interventional Radiology - The Requesites, Amsterdam, the Netherlands, Elsevier Sauners (2), ISBN: 978-0-323-04584-1

[KEE2005] Kee ST, Ganguly A, Daniel BL et al. (2005) MR-guided transjugular intrahepatic portosystemic shunt creation with use of a hybrid radiography/MR system." Journal of vascular and interventional radiology 16(2): 227-234

[KEMM2014]Kemmis S, McTaggart R, Nixon R (2014) The Action Research Planner: Doing Critical Participatory Action Research, Springer, ISBN 978-981-4560-67-2

[KERS2013] Kersten-Oertel M, Jannin P, Louis Collins D (2013) The state of the art of visualization in mixed reality image guided surgery, Computer Medical Imaging and Graphics, 37(2): 98-112

[KEW2004] Kew J, Davies RP (2004) Intravascular Ultrasound in TIPS, Cardiovascular and Interventional Radiology, 27(1): 38-41

[KIM2001] Kim JK, Yun W, Kim JW, Joo Y U, Park JG (2001) Extrahepatic Portal Vein Tear with Intraperitoneal Hemorrhage During TIPS. Cardiovascular Interventional Radiology, 24:436–437

[KIM2013] Kim CY, Engstrom, Horvath J, Suhocki P, Smith TP, (2013), Percutaneous Primary Jejunostomy Tubes Inserted Using Fluoroscopic Guidance: Comparison to Laparoscopically Inserted Jejunostomy Tubes, Journal of vascular and interventional radiology, 2(4): 57-58

[KIRW1992] Kirwan B, Ainsworth LK (1992) A guide to task analysis, Basingstoke, UK: Taylor and Francis Ltd

[KRIS2004] Kristensson P, Gustafsson A, Archer T (2004) Harnessing the Creative Potential Among Users, Journal Product Innovation Management, 21: 4-14

[KLEI2003] Klein M, Sayama H, Faratin P, Bar-Yam Y (2003) The Dynamics of Collaborative Design: Insights from Complex Systems and Negotiation Research, Concurrent Engineering, 11(3): 201–9.

[KRAJ2002] Krajina A, Lojik M, Chovanec V, Raupach J, Hulek P (2002) Wedged Hepatic

Venography for Targeting the Portal Vein During TIPS: Comparison of Carbon Dioxide and Iodinated Contrast Agents, Cardiovascular and Interventional Radiology 25(3):171-175

[KRAJ2012] Krajina A, Hulek P, Fejfar T, Valek V (2012) Quality IMprovement Guidelines for Transjugular Intrahepatic Portosystemic Shunt (TIPS), Cardiovascular Interventional Radiology, 35: 1295-1300

[KUIJ2010] Kuijk van J (2010) Managing Product Usability: 59–66

[KUSH2002] Kushniruk A, (2002) Evaluation in the Design of Health Information Systems: Applications of Approaches Emerging from Usability Engineering, Computers in Biology and Medicine, 32: 141-149

[KVAN2000] Kvan T, (2000) Collaboration Design: What is it? Automation in Construction, 9(4): 409-415

[LI2012] Li K, Tang Z, Liu GJ, Zhang SX (2012) Three-dimensional reconstruction of paracentesis approach in transjugular intrahepatic portosystemic shunt, Anatomical science international, 87: 71-79

[LINT2014] Linte CA, Yaniv Z (2014) When change happens: computer assistance and image guidance for minimally invasive therapy, Healthcare Technology Letters, 1(1): 2-5

[LIVI2011] Livingstone RS, Keshava SN, (2011) Technical note: Reduction of Radiation Dose Using Ultrasound Guidance during Transjugular Intrahepatic Portosystemic Shunt Procedure, Indian Journal of Radiology and Imaging 21(1): 13-14

[LOFF2013] Loffroy R, Estivalet L, Cherblanc V et al (2013), Transjugular Intrahepatic Portosystemic Shunt for the Management of Acute Variceal Hemorrhage, World Journal of Gastroentrerology, 19(37): 6131-6143

[LYNC1960] Lynch K (1960) The Image of the City, MIT Press, 11, ISBN 0262120046

[MALE2010] Maleux, G., Vaninbroukx J, Heye S, Zuurmond K, Radaelli A (2010) Superimposition of Pre-treatment CTA and Live Fluoroscopy for Targeting the Portal Vein in TIPS : a Case Report. Medicamundi 54:28–31.

[MANZ2009] Manzey D, Stefan R, Schulze-kissing D, Dietz A (2009) Image-guided Navigation : the Surgeon’s Perspective on Performance Consequences and Human Factors issues, International Journal Medical Robotics, 297–308.

[MATT2004] Matthing J, Sande´n B, Edvardsson B (2004)“New service development: learning from and with customers”, International Journal of Service Industry Management, 15(5) 479-498

[MAUP2005] Maupu D, Horn MHV, Weeks S, Bullit E (2005) 3D Stereo Interactive Visualization for the TIPS Procedure, North: 1-10

[MEIJ2008] Meijs F, Freudenthal A, Walsum T Van, Pattynama P (2008) Cognitive Processing Research as the Starting Point for Designing IG in Interventions. Interface, 1–10

[MELL2003] Melles M, Freudenthal A (2003) Next Generation Equipment in the Intensive Care Unit: Data Collection for Design Guidelines, Conference on Human Decision-Making and Manual Control, Linkoping: 65–73

[MEVI] MeVisLab© 2.2.1 retrieved from http://www.mevislab.de/.

[MILL2003] Miller DL, Balter S, Cole PE, (2003), Radiation Doses in Interventional Radiology Procedures: the RAD-IR Study, Part II skin dose, Journal of Vascular and Interventional Radiology, 14: 977-990

[MINA2011] Minami Y, Kudo M, (2011) Radiofrequency Ablation of Hepatocellular Carcinoma: A literature review, International Journal of Hepatology, 2011

[MINO2010] Minocha S, Reeves AJ (2010) Design of learning spaces in 3D virtual worlds: An empirical investigation of Second Life, Learning, Media and Technology, 35(2):111-137

[NAGE2005] Nagel M, Schmidt G, Petzold R, Kalender WA (2005) A navigation system for minimally invasive CT-guided interventions, Medical Image Computing and Computer-Assisted Intervention–MICCAI 2005: 33-40

[NAJM2012] Najmaei N, Mostafavi K, Shahbazi S, Azizian M, (2012) Image-guided Techniques in Renal and Hepatic Interventions, the Interventional Journal of Medical Robotics and Computer Assisted Surgery, 9:379-395

[NAM2012] Nam WH, Kang DG, Lee D, Lee JY, Ra JB (2012) Automatic Registration between 3D Intra-opertative Ultrasound and Pre-operative CT Images of the Liver Based on Robust Edge Matching, Physics in Medicine and Biology, 57: 69-91

[NARD1997] Nardi B (1997) The Use of Ethnographic Methods in Design and Evaluation. Handbook of Human-Computer Interaction II, Amsterdam, 361–366

[NICO2007] Nicolaou S, Talsky A, Khashoggi K, Venu V (2007) Ultrasound-guided Interventional Radiology in Critical Care, Critical Care Medicine, 35:186-197

[NIEL1994] Nielsen J (1994) Usability Engineering, Morgan Kaufmann Publishers, ISBN 0-12-518406-9

[OBRU2008] Obruchkov, S (2008). The Technology and Performance of 4D Ultrasound, Critical Reviews™ in Biomedical Engineering, 36(4)

[ORTI2012] Ortiz SH, Chiu T, Fox MD (2012). Ultrasound image enhancement: A review. BSPCl, 7(5): 419–428.

[OWEN2009] Owen A, Stanley A, Vijayananthan A, Moss J (2009) The Transjugular Intrahepatic Portosystemic Shunt (TIPS). Clinical radiology, 64: 664–74.

[OZKA2011] Ozkan E, Gupta S, Embolization of Spinal Tumors: Vascular Anatomy, Indications, and Techniques, Techniques in vascular and interventional radiology, 14(3): 129-140

[OZTU2005] Ozturk C, Guttman M, McVeigh ER, Lederman RJ (2005) Magnetic Resonance Imaging–guided Vascular Interventions. Topics in magnetic resonance imaging: TMRI, 16(5): 369.

[PARU2004] Parush A, Berman D (2004) Navigation and orientation in 3D user interfaces: the impact of navigation aids and landmarks, International journal of human-computer studies, 61(3): 375-395

[PATE2001] Patel VL, Arocha JF, Kaufman DR (2001) A Primer on Aspects of Cognition for Medical Informatics, Journal of the American Medical Informatics Association, 8(4): 324-343

[PATI2014] Patidar KR, Sydnor M, Sanyal AJ (2014), Transjugular Intrahepatic Portosystemic Shunt, Clinics in liver disease, 18(4): 853-876

[PAUL2005] Paul P, Fleig O, Jannin P,(2005), Augmented Virtuality Based on Stereoscopic Reconstruction in Multimodal Image-guided Neurosurgery: Methods and Performance Evaluation, IEEE trans. Medical Imaging, 24(11): 1500-1511

[PHIL] Philips Healthcare b.v., http://www.medical.philips.com/

[PHIL2015] Philips iU22 ultrasound system with X6-1 probe, retrieved February 6, 2015 from http://www.healthcare.philips.com/nl_nl/products/ultrasound/systems/iu22/

[PICANO2004] Picano, E (2004). Sustainability of medical imaging, British Medical Journal, 328(7439): 578–80

[PILI2009] Piliere G, Van Horn MH, Dixon R, et al. (2009) Vessel Target Location Estimation during the TIPS Procedure. Medical Image Analysis, 13(5): 19–29

[POGU2006] Pogue BW, Patterson MS (2006) Review of Tissue Simulating Phantoms for Optical Spectroscopy, Imaging and Dosimetry. Journal of Biomedical Optics, 11(4)

[POMI1996] Pomier-Layrargues G (1996) TIPS and Hepatic Encephalopathy. Seminars in Liver Disease; 16:315–320

[POMI2012] Pomier-Layrargues G, Bouchard L, Lafortune M, Bissonnette J, Guérette D., Perreault P (2012) The transjugular intrahepatic portosystemic shunt in the treatment of portal hypertension: current status. International journal of hepatology

[PREE2007] Preece J, Sharp H, Rogers Y (2007) Interaction Design: Beyond Human-Computer Interaction. John Wiley & Sons

[PREI2013] Preim B, Botha C (2013) Visual Computing for Medicine: Theory, Algorithms, and Applications, Newnes, ISBN-13: 978-0124158733

[PUA2009] Pua U (2009), Radiographic Features of Malpositioning of a Hemodialysis Catheter in the Azygos Vein, American journal of kidney diseases, 55(2): 395-398

[RAZA2006] Raza SA, Walser E, Hernandez A, Chen K, Marroquin S (2006) Transhepatic Puncture of Portal and Hepatic Veins for TIPS using a single-needle pass under Sonographic Guidance, American Journal of Roentgenology, 187(1): 87-91

[REAS2000] Reason J (2000) Human error: models and management, British Medical Journal,320(7237):768-770

[RIPA2006] Ripamonti R, Ferral H, Alonzo M, Patel NH, (2006), Transjugular Intrahepatic portosystemic Shunt-related Complications and Practical Solutions, Seminars in Interventional Radiology, 23(2): 165-176

[RITT1973] Rittel HJW, Webber MM (1973) Dilemmas in a general theory of planning, Policy Science, 4:155-169

[ROMA2013] Romanowski P, CAT Scanner, How Products are made, retrieved April 15, 2014, from http://www.madehow.com/Volume-3/CATScanner.html#b

[ROSC2014] Rösch J, Keller FS, Kaufman JA, (2014) Tranjugular Intrahepatic Portosystemic Shunt: TIPS, PanVascular Medicine, 1-17

[ROSE2000] Rose SC, Pretorius DH, Nelson TR, et al. (2000) Adjunctive 3D US for Achieving Portal Vein Access during Transjugular Intrahepatic Portosystemic Shunt Procedures 1, Journal Vascular and Interventional Radiology,11:611–621

[ROSE2000] Rose SC, Pretorius DH, Nelson T R, et al (2000) Adjunctive 3D US for Achieving Transjugular Intrahepatic Portosystemic Shunt Procedures 1,Society of CardioVascular and Interventional Radiology, 11:611–21.

[ROSS2000] Ross DA, Blasch BB (2000) Wearable interfaces for orientation and wayfinding, Proceedings of the fourth international ACM conference on Assistive technologies:193-200

[SALV2012] Salvendy G (2012) Handbook of Human Factors and Ergonomics, John Wiley and Sons 978-04705283894

[SAND2004] Sandom C, Harvey R (2004) Human Factors for Engineers, The Institute of Engineering and Technology, ISBN 0863413293

[SAND2014] Sanders EBN, Stappers PJ (2014). Probes, toolkits and prototypes: three approaches to making in codesigning. *CoDesign*, *10*(1): 5-14

[SAXO1997] Saxon RR, Keller FS (1997) Technical Aspects of Accessing the portal vein during the TIPS procedure, Journal of Vascular and Interventional Radiology

[SCAN2008] Scanlon T, Ryu RK, (2008) Portal Vein Imaging and Access for Transjugular Intrahepatic Portosystemic Shunts, Techiques in Vascular and Interventional Radiology, 11: 217-224

[SCHN2012] Schneider JR, Perrin DP, Vasilyev NV et al (2012) Real-time Image-based Rigid Registration of Three-dimensional Ultrasound, Medical Image Analysis, 16: 402-414

[SCHU1999] Schufeldt H, Dunlap G, Bauer B (1999) Piloting and Dead Reckoning. Naval Institute Press, 4:1–176

[SHEW1939] Shewhart WA (1939) Statistical Method from the Viewpoint of Quality Control, New york, Dover

[SHUN2007] Shung KK, Cannata JM, Zhou QF (2007) Piezoelectric materials for high frequency medical imaging applications: A review. J Electroceram, 19(1): 141–147

[SLEE2005] Sleeswijk Visser F, Stappers PJ, Van der Lugt R, Sanders EB-N (2005) Contextmapping: experiences from practice. CoDesign 1(2):119–149

[SOLO1999] Solomon SB, Magee C, Acker DE, Venbrux A (1999) TIPS placement in Swine, Guided by Electromagnetic Real-Time Needle Tips Localization Displayed on Previously Acquires 3-D CT, CardioVascular and Interventional Radiology 22:411-414

[SPRA2013] Sprawls, P, X-Ray production, retrieved April 15, 2014 from http://www.sprawls.org/ppmi2/XRAYPRO/

[STON2005] Stone D, Jarrett C, Woodroffe M, Minocha (2005) User Interface Design and Evaluation, Morgan Kaufman, ISBN 0-12-088436-4

[STUD2008] Stüdeli T (2008) Surgical navigation during Minimally Invasive Procedures. Minimally Invasive Technology and Nanosystems for Diagnosis and Therapies. Lupiensis Biomedical Public., Italy: 1–9

[STUD2008] Studeli T, Kalkofen D, Risholm P, et al (2008) Visualization Tool for Improved Accuracy in Needle Placement during Percutaneous Radio-Frequency Ablation of Tumors, Medical Imaging. International Society for Optics and Photonics

[STUD2009] Stüdeli T (2009) Surgical Wayfinding and Navigation Processes in the Human Body. Cognitive processing 10(2): 316–318

[STW] Stichting technische wetenschappen, http://www.stw.nl/

[SUHO2003] Suhova, A., Chubuchny, V., Picano, E. (2003). Principle of responsibility in medical imaging. ISS, 39(2), 205–12

[TAKA2012] Takaki H., Yamakado K., Nakatsuka A., Yamada T., Shiraki K., Takei Y., Takeda K (2012) Frequency of and Risk Factors for Complications after Lover Radiofrequency Ablation under CT Fluoroscopic Guidance in 1500 Sessions: Single-center Experience, Vascular and Interventional Radiology, 200(5)

[TOBI2013] Tobias KM, Johnston SA (2013) Veterinary Surgery: Small Animal: 2-Volume Set. Elsevier Health Sciences

[TORN1983] Thorndyke PW, Goldin SE (1983) Spatial Learning and Reasoning Skill in Spatial Orientation: Theory, Research and Application, HL Pick and LP Acredolo Editors, Plenum Press, New York 195-217

[TSAU2014] Tsauo J, Luo X, Ye L, Li X (2014). Three-Dimensional Path Planning Software-Assisted Transjugular Intrahepatic Portosystemic Shunt: A Technical Modification, Cardiovascular and interventional radiology: 1-5

[UCI-EDU] Central line procedures, University of California Irvine, retrieved January 28, 2015 from, http://www.anesthesiology.uci.edu/clinical_centralline.shtml

[UNER2006] Unertl KM, Weinger MB, Johnson KB (2006) Applying Direct Observation to Model Workflow and Assess Adoption, American medical Informatics Association

[VARG2011] Varga E, Freudenthal A (2011) Allowing free exploration of radiology images with tangible interaction devices to improve patient safety, Proceedings of the International Conference on Healthcare Systems Ergonomics and Patient Safety (HEPS) :268-272

[VARG2013] Varga E, Pattynama PMT, Freudenthal A (2013) Manipulation of mental models of anatomy in interventional radiology and its consequences for design of human–computer interaction, Cognition, Technology & Work, 15(4): 457-473

[VIA-MED] Transjugular intrahepatic portosystemic shunt, retrieved February 28, 2015 from http://www.via-med.com/int_TransjugularIntrahepaticPortosystemicShunt.html

[VILL2014] Villard PF, Vidal FP, Ap Cenydd L et al (2014) Interventional Radiology Virtual Simulator for Liver Biopsy, International Journal of Computer Assisted Radiology and Surgery, 9(2): 255-267

[VINS1999] Vinson NG (1999) Design guidelines for landmarks to support navigation in virtual environments, Proceedings of the SIGCHI conference on Human Factors in Computing Systems: 278-285

[VOLB2000] Volbracht S, Domik G, (2000), Developing Effective Navigation Techniques in Virtual Environments, Paderborn

[WANG2000] Wang J, Blackburn,TJ (2000). The AAPM/RSNA physics tutorial for residents: X-ray image intensifiers for fluoroscopy, RG, 20(5): 1471–1477

[WANG2002] Wang Z, He WP, Zhang DH., Cai MH, Yu SH (2002) Creative Design

Research of Product Appearance Based on Human-machine Interaction and Interface. Journal of Materials Processing Technology, 129:545-550

[WEST2010] Westrenen F (2010) Cognitive Work Analysis and the Design of User Interfaces, Cognition Technology & Work, 13(1):31-42

[WICK2004] Wickens CD, Lee JD, Liu Y, Gordon Becker SE (2004) An Introduction to Human Factors Engineering, Pearson Education International (2)

[WOOD2005] Wood, BJ., Zhang H, Durrani A, et al (2005) Navigation with electromagnetic tracking for interventional radiology procedures: a feasibility study, Journal of vascular and interventional radiology, 16(4): 493-505

[YAMA2011] Yamagami T, Tanaka O, Yoshimatsu R et al (2011) Hepatic artery-targeting guidewire technique during transjugular intrahepatic portosystemic shunt, The British Journal of Radiology, 84(1000:315-318

[ZHU2013] Zhu YP, NI JJ, Chen RB, Matro E, Xu XW, Li XW, Hu HJ, Mou YP, (2013) Successful Interventional Radiology Management of Postoperative Complications of Laparoscopic Distal Pancreatectomy, World J Gasttroenterol, 19(45): 8453-8458

[ZWEER1998] Zweers D, Geleijns J, Aarts NJM, Hardam LJ, Lameris JS, Schultz FW (1998). Patient and staff radiation dose in fluoroscopy-guided TIPS procedures and dose reduction, using dedicated fluoroscopy exposure settings. BJR, 71, 672–676

The Author

Cecile Cuijpers was born 17th November 1983 in Bandung, Indonesia. She studied Industrial Design Engineering at the Delft University of Technology, the Netherlands. In addition, she had the opportunity to study at the National University of Singapore for six months and explored non-design related subjects such as gender studies, Japanese studies and the Indonesian language.

During her master Design for Interaction, she specialized in Medical Design. Her graduation project was for the KLM (Royal Dutch Airlines) Health Services and the KLM Engineering and Maintenance Department. The assignment was to design a device for the assembly of the Low Pressure Turbine (a part of the airplane's engine) to reduce the lower back problems of the mechanics. During this project, she worked in close collaboration with the end-user. She designed a device which the mechanics are using today.

During her PhD research she made an effort to improve the image guidance in interventional radiology and developed a three-dimensional ultrasound based user interface. Within the project, she had to: 1) bridge the gap between engineers and interventional radiologists by focussing on workflow, HF, IRs' cognition, interface design, and 2) focus on on improving one of the most challenging radiological interventions, namely the Transjugular Intrahepatic Portosystemic Shunt (TIPS) procedure.

Ms Cuijpers's interest is in improving healthcare through improving the usability of products and workflow. Her research interest involves, but is not limited to, HF engineering, workflow analysis and integration, user-centred design, design for complex workspaces and cognitive ergonomics. After her PhD she will continue her work as Clinical Scientist Workflow and Usability XR-I at Philips Healthcare in Best, the Netherlands.

Author’s Publications

Cuijpers CF, Moelker A, Varga E, Stappers PJ, Freudenthal A (2012) Improving image guidance in Interventional Radiology : Information Lack in Transjugular Intrahepatic Portosystemic Shunt, Conference on Human Decision-Making and Manual Control (EAM), Braunschweig, Germany: 143–149

Cuijpers CF, Moelker A, Varga E, Stappers PJ, Freudenthal A (2012) Addressing information gaps in interventional radiology – TIPS procedures, International Conference of the Society for Medical Innovation and Technology’ (SMIT), Barcelona, Spain

Cuijpers CF, Klink C, Stappers PJ, Freudenthal A (2013) Comparing IG Systems to Improve Complex Navigation in Medicine, International Federation of Automatic Control Conference (IFAC), Las Vegas, USA

Cuijpers CF, Klink C, Stappers PJ (2013) Cognitive Task Analysis and Prioritization to Improve image guidance of TIPS, Procedeedings of Design of Medical Devices Conference (DMD), Delft, the Netherlands

Cuijpers CF, Varga E, Klink C, Banerjee J, Stappers PJ, Freudenthal A (2014), A real-time three-dimensional ultrasound user interface for TIPS: Preliminary results, Computer Assisted Radiology and Surgery (CARS), Fukuoka, Japan

Cuijpers CF, Varga E, Klink C, Banerjee J, Stappers PJ, Song Y (2015), A real-time three-dimensional ultrasound user interface for TIPS: Preliminary results, Dutch Biomedical engineering conference (BME), Egmond, the Netherlands

Cuijpers CF, Varga E, Klink C, Stappers PJ, Song Y (2015) Real-time three-dimensional ultrasound user interface for TIPS planning: a case study, European congress of radiology (ECR), Vienna, Austria

Cuijpers CF, Klink C, Varga E, Banerjee J., Stappers PJ, Song Y, A 3D ultrasound based user interface for intrahepatic puncture in Transjugular Intrahepatic Portosystemic Shunt Procedures. Submitted for the Journal of CardioVascular and Interventional Radiology