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Research article

Cost-effectiveness of [^{18}F]FDG PET/CT in follow-up after thermal ablation in patients with colorectal liver metastases in the Dutch healthcare setting

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ABSTRACT

Introduction: The ESMO and ECIO-ESOI consensus guidelines vary in their recommendations regarding the use of ^{18}F-Fluorodeoxyglucose ([^{18}F]FDG) PET/CT in the follow-up after thermal ablation in patients with colorectal liver metastases. This is partly because studies providing data on long-term benefits of [^{18}F]FDG PET/CT are lacking. Therefore, a simulation model was developed to examine how follow-up with [^{18}F]FDG PET/CT impacts treatment planning, health and cost outcomes.

Methods: For an illustrative Dutch cohort, lifetime health and cost outcomes were simulated to assess the cost-effectiveness of performing a single additional [^{18}F]FDG PET/CT. Patients followed a standard surveillance schedule consisting of three-monthly serum CEA and contrast-enhanced CT, plus [^{18}F]FDG PET/CT 3–4 months after thermal ablation. Therapy could be repeated downstream the care pathway. Quality-of-life and survival estimates were based on disease stage and age. Costs were determined from a healthcare perspective incorporating costs related to diagnostics and treatments. The Consolidated Health Economic Evaluation Reporting Standards were followed.

Results: Health benefits of additional [^{18}F]FDG PET/CT were negligible, incremental QALYs < 0.001, whereas costs increased by €1,277, mainly due to the additional imaging. This lack of health benefits can be explained by the small subset of simulated patients (<5 %) in whom [^{18}F]FDG PET/CT affected treatment planning.

Discussion: Additional [^{18}F]FDG PET/CT 3–4 months after thermal ablation is unlikely to be cost-effective. More research is needed to determine if using [^{18}F]FDG PET/CT in subgroups of patients, or at alternative time points, is cost-effective. This requires collecting more (extensive) follow-up data across multiple centres to reflect heterogeneity between hospitals' clinical practices.

1. Introduction

Colorectal cancer (CRC) introduces a substantial health burden on patients and society due to its relatively high incidence and mortality [1]. In 2020, CRC was the third most commonly diagnosed cancer worldwide, accounting for about 10 % of all new cancer cases [2]. Moreover, CRC was the second leading cause of cancer mortality and accounted for 9.4 % of all cancer-related deaths [2]. Approximately 15–25 % of all patients with CRC history have metastatic disease (mCRC). The liver is the most common and often first site of mCRC. In approximately half of the patients with colorectal liver metastases, the metastatic lesions are confined to the liver. In these cases, locoregional therapy with curative intent results in a 5-year overall survival of approximately 50 % [3,4]. Survival rates remain similar after repeated therapy for recurrent intrahepatic disease [5]. If extrahepatic disease is also identified, systemic therapy with palliative intent is generally

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provided, resulting in a decreased 5-year survival rate of approximately 30–40 % [3,4].

Partial hepatectomy is traditionally the most frequently provided therapy option with curative intent for patients with colorectal liver metastases. However, hepatectomy might result in suboptimal health outcomes in case of complications with unfavourable tumour location, comorbidities and adhesions or post-treatment liver failure due to reduced liver volume. In case of such contraindications, thermal ablation can be an effective and minimally invasive alternative for lesions smaller than 30 mm [6–8]. Thermal ablation leads to lower blood loss and complication rates, shorter hospital stays and reduced costs compared to hepatectomy. Moreover, the disease-free and overall survival rates for thermal ablation are non-inferior compared to hepatectomy for tumours up to 30 mm [9].

In follow-up, potentially unablated residual tumour tissue at the ablation margins, local tumour progression and new intrahepatic or extrahepatic metastatic lesions are biochemically monitored with serum carcinoembryonic antigen (CEA) and radiologically monitored with contrast-enhanced (CE) CT of the thorax-abdomen. In case of inconclusive test results, either additional upper abdominal contrast MRI or percutaneous biopsy of suspicious liver tissue may be performed. However, metastatic lesions at unexpected sites or in morphologically normal tissue might still be overlooked. At the same time, morphological tissue changes in the liver can be misleading due to postinterventional non-malignant changes such as hyperaemia, inflammation and necrosis inside or abutting the ablation zone. ^{18}F-Fluorodeoxyglucose ([^{18}F]FDG) PET/CT can be performed additionally. It provides additional metabolic information, which may enable early detection of residual or recurrent mCRC [10], to facilitate early re-treatment with curative intent.

Clinical practice guidelines from the European Society for Medical Oncology (ESMO) and the European Conference on Interventional Oncology and European Society of Oncological Imaging (ECIO-ESOI) provide different consensus-based recommendations for the use of [^{18}F]FDG PET/CT [11–13]. ESMO does not consider current evidence strong enough to advise the standard use of [^{18}F]FDG PET/CT [12,13]. Their recommendations suggest that [^{18}F]FDG PET/CT may be useful in identifying potentially resectable metastases, but no significant change in patient management can be expected. In contrast, ECIO-ESOI recommendations suggest that [^{18}F]FDG PET/CT can be especially useful for early detection of local tumour progression in the liver, resulting in considerable changes in patient management [11]. This suggestion is supported by a recent Dutch *meta*-analysis that reported a change in management in 54 % of patients if using [^{18}F]FDG PET/CT [14]. Although this percentage is highly uncertain due to the inclusion of small studies (with populations <20 patients) and old studies (published before 2008) [15,16], the use of [^{18}F]FDG PET/CT might become cost-effective when it more frequently would improve patient management. Such a frequent change in management due to [^{18}F]FDG PET/CT was reported in studies focussing on an Australian cohort [17]. Reported changes in management included all types of treatment shifts between surgical procedures and chemotherapy regimens. The observed treatment shifts were classified as a change from curative to palliative management intent in approximately 20 % of patients, and vice versa, a change from palliative to curative management intent in no more than 15 % of patients. However, since these studies have a limited follow-up duration, the long-term health effects, survival benefits, and cost consequences of [^{18}F]FDG PET/CT remain unclear. Therefore, a simulation model has been developed to study how follow-up with [^{18}F]FDG PET/CT impacts treatment planning, long-term health and cost outcomes.

In an illustrative Dutch cohort, lifetime health and cost outcomes were evaluated to assess the cost-effectiveness of adding a single [^{18}F]FDG PET/CT to follow-up 3–4 months after thermal ablation of colorectal liver metastases, compared to standard clinical practice (no additional [^{18}F]FDG PET/CT). This study aimed to explore whether adding [^{18}F]FDG PET/CT allows early re-treatment and results in (i) improved health outcomes as early re-treatment may prevent patients from reaching a palliative phase of disease and (ii) reduced treatment costs as early re-treatment may prevent using more expensive medication and performing open abdominal surgeries.

2. Methods

2.1. Model design

A discrete event simulation was developed to reflect the complex dynamics of clinical practice [18]. The model structure is provided in Fig. 1. All simulated patients enter the model immediately after diagnosis of colorectal liver metastases and undergo thermal ablation with curative intent. A subgroup of patients receive neoadjuvant chemotherapy before thermal ablation. Following the standardisation of terminology and reporting criteria for outcomes of image-guided tumour ablation [19], all patients are monitored and sub-grouped for residual tumours, local tumour progression and new intrahepatic or extrahepatic metastatic lesions (3–4 months after thermal ablation). In case of suspected residual or recurrent mCRC, patients are directly referred for downstream therapy. Based on the extent of intrahepatic and extrahepatic disease recurrence, medical history and general patient characteristics such as the clinical condition and age of the patient, re-treatment with curative intent, systemic therapy with palliative intent or best supportive care has been provided. It is worth noting that therapy selection has always been a decision of the multidisciplinary review board meeting. In case of no suspected recurrent disease, patients receive a watchful waiting management. Patients in watchful waiting follow a surveillance schedule consisting of three-monthly serum CEA and CECT scans during years 1–2 and six-monthly serum CEA and CECT scans during years 3–5. After five years of active surveillance, patients are no longer periodically followed up in the Netherlands.

2.2. Model parameters

Model parameters were defined by parametric distributions describing variations at a patient or group level. Distributions were based on a retrospective multidisciplinary evaluation of imaging (>100 scans) and therapy in 48 patients. Ethical approval was obtained from the local medical ethical committee. Informed consent was waived for the retrospective data gathering. All patients gave informed consent for thermal ablation. A literature search was performed to collect evidence on health-related utilities, survival and care pathway-related costs. Also, long-term follow-up data including the risk of disease recurrences and disease-free survival rates were collected from the literature. A full description of the evidence and data sources used for simulation is reported in the Supplementary Material.

2.2.1. Individual patient data

Patient, imaging procedures and therapy characteristics were obtained from individual patient data (IPD) by retrospective data extraction from the Leiden University Medical Centre's electronic patient database. Therapy-related complication rates were retrospectively determined based on estimates from the Dutch Hepato Biliary Audit. Data on imaging results were derived from a multidisciplinary assessment (double-readings) of [^{18}F]FDG PET/CT and CECT thorax-abdomen. In case of inconclusive test results, either additional upper abdominal contrast MRI or percutaneous biopsy of suspicious liver tissue is performed. All diagnostic assessments were categorised into a set of competing events used for simulation: no metastatic lesions observed, intrahepatic metastatic lesions only and extrahepatic metastatic lesions. We distinguished between intrahepatic and extrahepatic disease because this affects treatment planning and thereby patients' survival and costs.

2.2.2. Survival data

Survival rates were determined based on the recurrent disease stage

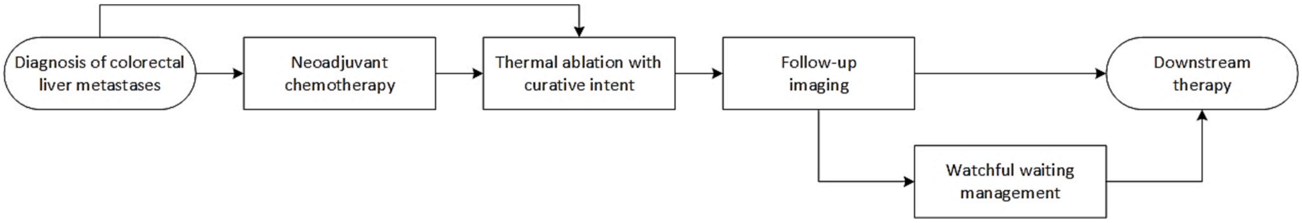

Fig. 1. A graphical representation of the model structure All patients undergo thermal ablation with curative intent. A subgroup of patients receive neoadjuvant chemotherapy. All patients receive follow-up imaging 3–4 months after thermal ablation. In case of suspected residual or recurrent metastatic colorectal cancer, patients undergo downstream therapy. Therapy selection is always a decision of the multidisciplinary review board meeting. In case of no suspected metastatic lesions, patients receive a watchful waiting management.

and the therapy provided, the time spent in watchful waiting and the patient's age. Therapy-dependent survival rates were based on published survival data from a phase III randomised controlled trial (EORTC #40983) for resectable disease in which 63 % of all patients died at a median follow-up of 8.5 years [20] and from a phase II randomised controlled trial (EORTC #40004) for unresectable disease in which 77 % of all patients died at a median follow-up of 9.7 years [21]. Age-dependent background mortality rates were based on Dutch demographic data from 2018 to 2022 from Statistics Netherlands [22].

2.2.3. *Utility and cost data*

Health-related quality-of-life was based on published Dutch EQ-5D evidence from the literature [23]. Quality-adjusted life years (QALYs) were calculated by the discounted sum of utilities over the lifetime time horizon. Costs were determined from a healthcare perspective incorporating the costs related to diagnostics and treatments. Costs were estimated utilising the tariffs included in the Dutch system of diagnosis-treatment combinations. Costs of complications were estimated by incorporating the costs of prolonged hospitalisation and revision surgeries. Imaging costs were derived from Leiden University Medical Centre reference tariffs with an effective date of July 1, 2022. Following the Dutch guideline for health economic evaluations, a discount rate of 1.5 % for health outcomes and 3.0 % for costs were applied [24].

2.3. *Simulation*

The diagnostic accuracies of [^{18}F]FDG PET/CT and CECT thorax-abdomen, and subsequent treatment planning were validated with medical specialists to ensure model face validity [25]. The expert panel consisted of two nuclear physicians and two radiologists specialised in abdominal examinations, an interventional radiologist, a surgeon specialised in abdominal oncology, and a medical oncologist. Study results were reported as the costs per QALY gained in an incremental cost-effectiveness plane. The cost-effectiveness acceptability curve was used to visualise the probability that adding [^{18}F]FDG PET/CT to follow-up was cost-effective. Additionally, the net monetary benefit was calculated by subtracting the incremental costs from the incremental QALYs times the willingness-to-pay (WTP) threshold. In the Netherlands, a WTP threshold of €80,000 per QALY is recommended by the Dutch Healthcare Institute for conditions with a severe disease burden [24]. The consequences of parameter uncertainty were assessed with probabilistic analysis using 2,500 Monte Carlo samples and simulating 10,000 patients per sample. In the Supplementary Material, boxplots show the uncertainty in the costs and QALYs as a function of the number of patients, to demonstrate that sufficient patients were simulated to obtain stable results [18]. For all simulation analyses, R Statistical Software (version 4.2.1) was used [26] (applying R packages 'simmer' [27] and 'survHE' [28]). This study is reported according to the Consolidated Health Economic Evaluation Reporting Standards (CHEERS) [29].

3. Results

3.1. *Simulated treatment planning and survival outcomes*

Re-treatment with curative intent was an option in 81 % of the patients with radiologically observed intrahepatic disease 3–4 months after thermal ablation. In comparison, re-treatment with curative intent was an option in only 39 % of the patients with also radiologically observed extrahepatic disease, when remaining extrahepatic lesions generally involved solitary pulmonary lesions which then could be treated locally. The expected overall survival in patients who could be re-treated with curative intent was similar to patients being (radiologically) disease-free 3–4 months after thermal ablation (166 versus 181 months). However, the expected overall survival of patients who were not eligible for re-treatment with curative intent decreased substantially to 54 months. The simulated additional proportion of patients who could be re-treated with curative intent if adding a single [^{18}F]FDG PET/CT to standard clinical practice was marginal (treatment shift in <5 % of patients with recurrent mCRC).

3.2. *Simulated cost-effectiveness outcomes*

Adding a single [^{18}F]FDG PET/CT to standard clinical practice 3–4 months after thermal ablation, resulted in a negligible difference in life expectancy (7.02 versus 6.98 years) and QALYs (4.204 versus 4.203, incremental QALYs <0.001)) compared to standard practice alone. A small increase of €1,277 in the expected costs was observed (€17,567 versus €16,290), mainly due to the additional imaging. The corresponding net monetary benefit was –€1,229 (Table 1). The incremental cost-effectiveness plane shows the simulated outcomes and uncertainty (Fig. 2). In the Supplementary Material, the cost-effectiveness acceptability curve shows that additional [^{18}F]FDG PET/CT has an approximately 5 % chance of being cost-effective for the considered WTP threshold of €80,000 per QALY.

4. Discussion

Since additional [^{18}F]FDG PET/CT 3–4 months after thermal ablation of colorectal liver metastases did not result in a considerable treatment shift, health outcomes did also not improve substantially. The

Table 1
Expected cost-effectiveness outcomes.

	Costs	Life expectancy	QALYs	Net monetary benefit
Standard clinical practice	€16,290	6,98 years	4,203	−€1,229
Standard clinical practice + additional [^{18}F] FDG PET/CT	€17,567	7,02 years	4,204	
Difference	€1,277	0,04	<0,001	

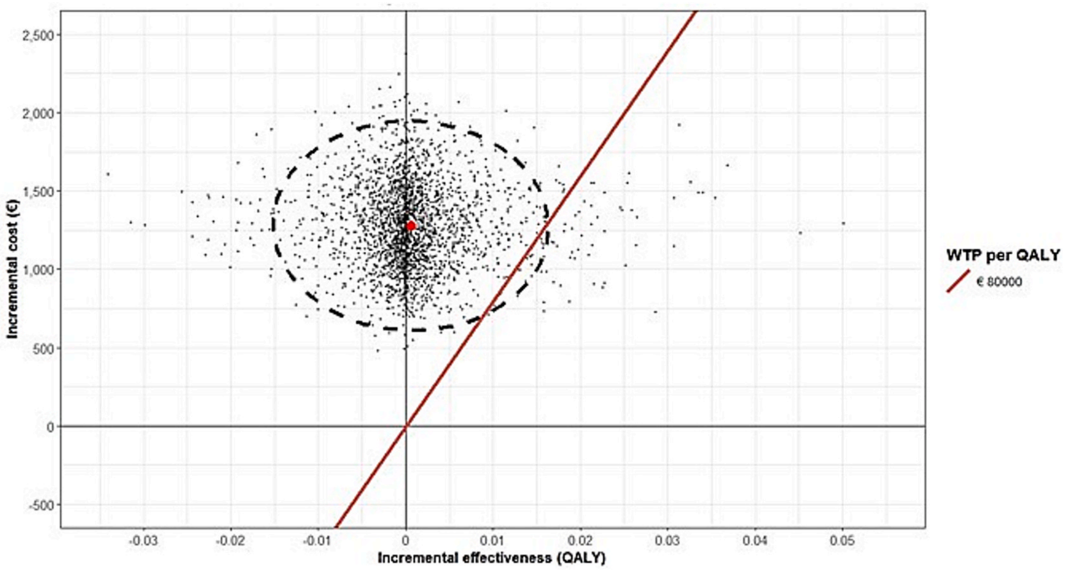

Fig. 2. Incremental cost-effectiveness plane The red line depicts the WTP threshold of €80.000 per QALY. The ellipse depicts the 95 % confidence interval of the outcomes. *Abbreviations*: QALY, quality-adjusted life year. WTP, willingness-to-pay.

expected cost increase did not support the hypothesis that additional costs of [^{18}F]FDG PET/CT could be offset by reduced downstream treatment costs. Therefore, additional [^{18}F]FDG PET/CT 3–4 months after thermal ablation is unlikely to be cost-effective, compared to standard clinical practice, in the Dutch healthcare setting.

This cost-effectiveness study was conducted based on the idea that additional [^{18}F]FDG PET/CT 3–4 months after thermal ablation allows early re-treatment and improves therapy outcomes in patients with recurrent mCRC. However, clinical practices vary widely between hospitals because of different pre-defined time points, frequency (e.g., single or repeated [^{18}F]FDG PET/CT) and interval of [^{18}F]FDG PET/CT scans, or the conventional imaging used (CECT or MRI). In a recent multicentre trial in Europe [30], the value of repeated six-monthly [^{18}F] FDG PET/CT in mCRC patients undergoing local treatment with curative intent was evaluated. Costs increased without decreasing treatment failure rates in the [^{18}F]FDG PET/CT arm. The authors described that the control group was already receiving an intensive follow-up and any additional improvement by [^{18}F]FDG PET/CT would be small and hard to detect. In contrast, treatment shifts in 15–20 % of patients, as observed in the Australian cohort [17], make cost-effectiveness of [^{18}F] FDG PET/CT more likely.

Current combined evidence demonstrates that health benefits from follow-up with [^{18}F]FDG PET/CT are debatable. Hospital surveillance schedules are generally more intensive during the first three years after therapy than at later time points, but no consensus exists on the optimal surveillance interval [31,32]. Advanced ablation systems, anaesthesia and breath-hold techniques, real-time image guidance, and the introduction of pre-ablation and post-ablation image registration for more objective identification of small ablation margins have improved clinical outcomes over the last years [33]. Such improvements may decrease the risk of tumour recurrences, thereby reducing the value of intensive follow-up procedures. Consequently, results from this study cannot directly be generalised to other countries, or hospitals, in which different ablation and follow-up procedures are practised.

This cost-effectiveness study has certain limitations. First, incorporating sequential therapy lines with different follow-up strategies and their impact on cost and health outcomes while considering the downstream consequences of patients' therapy history, would require an unrealistic number of model structural assumptions. Therefore, aggregated cost and health estimates across downstream therapy lines were used. Second, imaging results were derived from double-readings of [^{18}F]FDG PET/CT and CECT scans, while only a single-reading is performed in daily clinical practice. A second observer could correct erroneous observations made by the first observer. The interobserver variability in CECT assessments is generally rather high [34], suggesting that double-readings especially lead to overestimation of the diagnostic accuracy of CECT. A complicating factor in research on tumour recurrences after oncological interventions is the lack of a gold standard, making validation of imaging results very challenging. In this study, additional upper abdominal contrast MRI was performed in 25 % of patients. Histopathology of suspicious liver tissue was only available in four patients. Therefore, the decisions of the multidisciplinary review board meeting were generally based on (sequential) imaging. Out of necessity, we assumed in our analysis that these decisions were correct.

Furthermore, the integration of advanced software and artificial intelligence (AI) tools demonstrate great potential for improving the lesion detectability of [^{18}F]FDG PET/CT, by providing a greater depth of diagnostic information from automated organ segmentation and combinatorial analysis of multiple diagnostic parameters [35]. Particularly, AI-driven image analysis can enhance the detection of subtle metabolic changes over time, enabling early detection of disease recurrence [36]. This could support timely decision-making. The current simulation model does not incorporate such additional AI-driven diagnostic insights from [^{18}F]FDG PET/CT that could positively impact treatment outcomes, but could be updated to include these in the future. It may be challenging for current HTA methods, however, to keep pace with accelerating AI-driven innovations. Simulation models may quickly become outdated as AI tools and algorithms improve [37]. To remain relevant, future modelling efforts should focus on adaptability by developing models that can be continuously updated, and reflect broad aspects of value, in response to rapidly evolving diagnostic AI tools and real-time data integration [38].

Finally, prognostic factors should be weighted critically to restrict retreatment with curative intent to those patients who will likely benefit. Prognostic factors that are expected to be meaningful include the age and clinical condition of patients, primary CRC site, primary tumour stage, mutational status, disease-free duration, synchronous or metachronous metastases, number of metastases, spread to lymph nodes, maximum size of metastases, bilateral liver disease, serum CEA level and extrahepatic disease spread [5]. This cost-effectiveness analysis does not distinguish between subgroups of patients with favourable and unfavourable prognostic information, but the value of [^{18}F]FDG PET/CT will vary between subgroups of patients. [^{18}F]FDG PET/CT may play a critical role in clinically relevant patient stratification, but clinical evidence is currently lacking for appropriate subgroup analyses. Stratification by age may be particularly valuable, as recent European data [39,40] suggest a significant decrease in the median age at diagnosis for metastatic colorectal cancer. This trend highlights the potential value of tailoring imaging strategies to evolving patient demographics.

In conclusion, adding [^{18}F]FDG PET/CT to standard clinical practice 3–4 months after thermal ablation with curative intent in patients with colorectal liver metastases is unlikely to be cost-effective, given the current (but limited) evidence. Larger longitudinal studies are needed to determine whether the use of [^{18}F]FDG PET/CT in subgroups of patients, or at alternative time points, may be cost-effective. This requires the collection of more (extensive) follow-up data, preferably across multiple centres to allow reflection of heterogeneity between hospitals regarding standard clinical practice.

Data statement

The datasets generated and/or analysed during the current study are available in the supplementary material. Software codes on which the conclusions of our paper rely are available upon reasonable substantiated request.

Author contributions

All authors contributed to the study's conception and design. Material preparation, data collection and analysis were performed by Sietse van Mossel and Okker Bijlstra. The first draft of the manuscript was written by Sietse van Mossel and all authors commented on previous versions of the manuscript. All authors read and approved the final manuscript.

CRediT authorship contribution statement

S. van Mossel: Writing – review & editing, Visualization, Software, Methodology, Formal analysis, Conceptualization, Writing – original draft, Validation, Project administration, Investigation, Data curation. **O.D. Bijlstra:** Writing – review & editing, Project administration, Data curation, Validation, Investigation, Conceptualization. **F.A. van Delft:** Conceptualization, Formal analysis, Investigation, Methodology, Software, Writing – review & editing. **B. Boekestijn:** Writing – review & editing, Resources, Validation, Conceptualization. **M.C. Burgmans:** Validation, Resources, Investigation, Writing – review & editing, Supervision, Methodology, Conceptualization. **P. Hendriks:** Validation, Conceptualization, Writing – review & editing, Resources. **E. Kapiteijn:** Validation, Conceptualization, Writing – review & editing, Resources. **J. S.D. Mieog:** Conceptualization, Resources, Validation, Writing – review & editing. **E.L. van Persijn van Meerten:** Validation, Writing – review & editing, Resources, Conceptualization, Investigation. **D.D.D. Rietbergen:** Writing – review & editing, Resources, Conceptualization, Validation, Investigation. **S.Shahbazi Feshtali:** Validation, Investigation, Writing – review & editing, Resources, Conceptualization. **R.J. Swijnenburg:** Validation, Conceptualization, Writing – review & editing, Resources. **L.F. de Geus-Oei:** Writing – review & editing, Supervision, Methodology, Conceptualization, Validation, Resources, Investigation. **H. Koffijberg:** Writing – review & editing, Supervision, Methodology, Formal analysis, Validation, Software, Investigation, Conceptualization.

Ethics approval

Ethical approval was obtained from the local medical ethical committee. Informed consent was waived for the retrospective data gathering. All patients gave informed consent for thermal ablation.

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Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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Appendix A. Supplementary material

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