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The effective dose due to scattered radiation at patients during primary osteosynthesis; a multicenter prospective observational study

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ABSTRACT

Objectives: During osteosynthesis of a fracture patients are exposed to the primary radiation of an X-ray image and scattered (secondary) radiation. The primary objective was to measure the amount of scattered radiation at the thyroid, breast tissue, and gonads of patients undergoing primary osteosynthesis of acute fractures. The secondary objective was to calculate the effective dose caused by scattered radiation.

Methods: In this multicenter prospective observational case series patients undergoing a primary osteosynthesis of an acute fracture of hand/wrist, shoulder, ankle, knee, or hip were included. Three dosimeters were attached to the patient at the level of the thyroid, breast and gonads. Scattered radiation doses were corrected for the average background radiation per hospital per day.

Results: A total of 205 patients were included between March 6, 2017 and June 18, 2018; 49 (24%) had a hand/wrist fracture, 37 (18%) a shoulder fracture, 47 (23%) an ankle fracture, 35 (17%) a knee fracture, and 37 (18%) a hip fracture. In 32–39% of all patients undergoing primary osteosynthesis effective scattered doses was detected. The highest measured median effective dose was 60.43 µSv (P_{25}–P_{75} 33.84–100.76) at the gonads during hip osteosynthesis.

Conclusions: The results of this study show that scattered radiation is detectable in a third of patients undergoing an osteosynthesis. However, both effective doses due to direct radiation and scattered radiation are low.

Advances in knowledge: This is the first study that presents that no radiation protection for patients undergoing an osteosynthesis is necessary.

Introduction

The average individual annual dose of background ionizing radiation for civilians in the Netherlands is estimated at approximately 2.4 millisievert (mSv) [1]. Several studies have been conducted in order to measure the amount of radiation scattered on medical staff during various surgical procedures [2–4]. Based on these studies, medical staff are protected from radiation by wearing lead aprons, lead collars and lead glasses. However clear data is available for medical staff, minimal literature is available about scattered radiation doses absorbed by the patient during surgery. This might be logical since normally the dose of the primary radiation is much higher than the dose from the scattered radiation. However, the effective dose due to the primary radiation on radiation insensitive tissues may be lower, compared with the effective dose due to scattered radiation on radiation sensitive tissues located outside the x-ray beam.

It is known that the higher the cumulative ionizing radiation dose, the greater the risk of developing cancer [5–7]. Therefore, the use of ionising radiation must follow the “ALARA” (as low as reasonable achievable)-principle to ensure the safety of medical staff and patients exposed by irradiation. Deterministic effects and stochastic effects are two types of radiation injuries. Deterministic

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effects are tissue reactions to ionizing radiation and are directly related to the absorbed radiation dose. Deterministic effects increase as the radiation dose increases and could be prevented by ensuring non-exceedance of dose limits. Stochastic effects are based on interference of Deoxyribonucleid acid synthesis by free radicals as a direct consequence of radiation at any dose level [8]. The probability of stochastic effects increase with the dose, but the severity is independent of the dose received [9].

Surgeons routinely implement the ALARA principle, but the emergence of scattered radiation at the patient during osteosynthesis cannot be avoided. Especially for radiation sensitive tissues scattered radiation protection could minimize cancer induction caused hereby. However, the question is whether peroperative protection against scattered radiation for patients is necessary.

The primary aim of this study was to measure the exact amount of scattered radiation at the thyroid, breast tissue, and gonads during primary osteosynthesis. The secondary aim was to calculate the effective dose due to scattered radiation at these anatomic locations. The hypothesis was that patients undergoing primary osteosynthesis would receive a higher effective dose due to scattered radiation on the radiation sensitive tissues than the effective dose due to the primary radiation.

Materials and methods

Study design

A multicenter prospective observational study was conducted between March 6, 2017 and June 18, 2018 in two Dutch hospitals; one academic, level I trauma center and one large regional, level II trauma center. This study was exempted by the Medical Research Ethics Committee of both hospitals. All patients provided written informed consent.

Eligibility criteria

Patients meeting the following criteria were included: 1) acute fracture of hand/wrist, shoulder, ankle, knee, or hip; 2) primary osteosynthesis using intramedullary nails (IM-nails), screws, or plates; 3) age 18 years or older; 4) general or spinal anesthesia; and 5) provision of informed consent by the patient. Patients were excluded if they met any of the following criteria: 1) multiple surgical proceedings needing fluoroscopy in one session (*e.g.*, for additional injuries); 2) surgical procedure performed with patient in prone position; or 3) reoperation.

Procedures

The scattered radiation doses were measured using Thermoluminescence dosimeters type $H_p(10)$ of the Nuclear research and consultancy group ((NRG), Arnhem, The Netherlands). The first dosimeter at the thyroid was placed in the anterior cervical median line near the incisura jugularis. The second dosimeter was attached at breast tissue to the ipsilateral side of the surgical area at the level of costa 5 in the anterior axillary line. The third dosimeter was positioned at the gonads at the level of the pubic symphysis. Dosimeters were positioned with the front towards the patient. These locations were chosen because these organs/tissues are particularly sensitive to radiation [10]. The amount of radiation used during surgery was displayed by the C-arm as dosis area product (DAP), which is the radiation dose times square centimeter (cGy cm [2]). When only a part of the body is exposed to radiation, the effective dose can be calculated. The effective dose is the dose to which the total body should be exposed to generate the same risk as the risk of the dose to the part of the body. The effective radiation dose per location was calculated using the following formula: [11]

$$E\,(\mu Sv) = \Sigma_t W_t n \,.\, F_o n \,.\, H_t$$

where E is the effective dose (μSv), W_t is the tissue weighting factor, F_o is the fraction of the tissue that is irradiated and H_t is the equivalent dose absorbed by tissue t (μSv). The equivalent dose can be calculated from de dose area product by the following formula:

$$H_t = (D_{DAP}/A)\,W_r$$

were D_{DAP} is the dose area product (cGy cm [2]), A is the area of the X-ray beam (cm^2) and W_r is the radiation weighting factor. The radiation weighting factor is equal to 1 for X-rays. To estimate the fraction of the tissue that is irradiated, International commission of radiological protection (ICRP) 70 is used[12]. The fraction of irradiated tissue per fracture are shown in Table 1.

A tissue weighting factor of 0.08 is used for the thyroid, 0.12 for breast tissue, and 0.08 for the gonads [13]. Tissue weighting factor per organ are shown in Table 2.

In order to correct for background radiation, dosimeters were positioned in the operating theaters of both hospitals in such a way that they were only exposed to normal background radiation. Radiation doses were corrected for the average amount of background radiation per hospital per day, calculated from date of reset. Whenever corrected radiation doses were below zero, these values were set to zero since negative radiation doses do not exist.

Data collection

Several variables were collected from the patients' medical files in order to report characteristics per group. Firstly, the intrinsic variables include: 1) age (years); and 2) gender (male or female). Secondly, injury-related variables were collected, including: 1) fracture location (hand/wrist, shoulder, ankle, knee or hip); and 2) affected side (left or right). Thirdly, intervention-related variables were: 1) date of surgery; 2) the surgeon (trauma surgeon or resident); 3) the applied implant (type of IM-nails, number of holes per plate, number of screws per plate, type and number of screws); 4) intervention time (calculated in minutes from entry and departure time at the operation room); 5) position of the patient (supine, lateral position, recliner position, or other); 6) C-arm (registration number, dosis area product (DAP); 7) fluoroscopy time (seconds); and 7) presence of peroperative complications. Thereby, information was recorded with regard to fluoroscopy time and the amount of radiation which the C-arm used. One hospital used three types of C-arms: 1) Ziehm Imaging Vision 2006; 2) Philips BV Pulsera 2010; and 3) Phillips Veradius 2015. The other hospital used four types of C-arms: 1) Siemens Arcadis 3D; 2) Paradius; 3) Philips Veradius; and 4) Philips BV Pulsera.

Sample size calculation

Calculation of the required sample size for the primary analysis was based on a 95% confidence interval and a margin of error of 5% of the mean. The Standard Deviation of scattered radiation dose was estimated to be approximately 15% of the mean based on limited available literature. This projected to a minimal sample size of 175 patients, allocated between five fracture locations.

Statistical analysis

Data were analyzed using the Statistical Package for the Social Sciences (SPSS) version 21.0 (SPSS, Chicago, III., USA). Normality of continuous data was tested with the Shapiro–Wilk test. Missing values were not replaced**.** Descriptive analysis were performed in

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Table 1
Irradiated organs.

	Irradiated organs Skin	Bone surface	Lung	Red bone marrow	Bladder	Colon
Hand/wrist (*N* = 49)	2%	1%	–	–	–	–
Shoulder (*N* = 37)	5%	1%	5%	2%	–	–
Ankle (*N* = 47)	4%	3%	–	–	–	–
Knee (*N* = 35)	5%	2%	–	–	–	–
Hip (*N* = 37)	10%	6%	–	9%	5%	5%

Per fracture data are presented as the estimated percentage of the irradiated organ based on the ICRP 70 [12].
ICRP, International commission of radiological protection.

Table 2
Tissue weighting factor per organ.

Organ	Tissue weighting factor
Skin	0.01
Bone surface	0.01
Bladder	0.04
Lung	0.12
Red bone marrow	0.12
Colon	0.12
Remainder	0.12

Tissue weighting factor per organ according to the ICRP 103 [10].
ICRP, International commission of radiological protection.

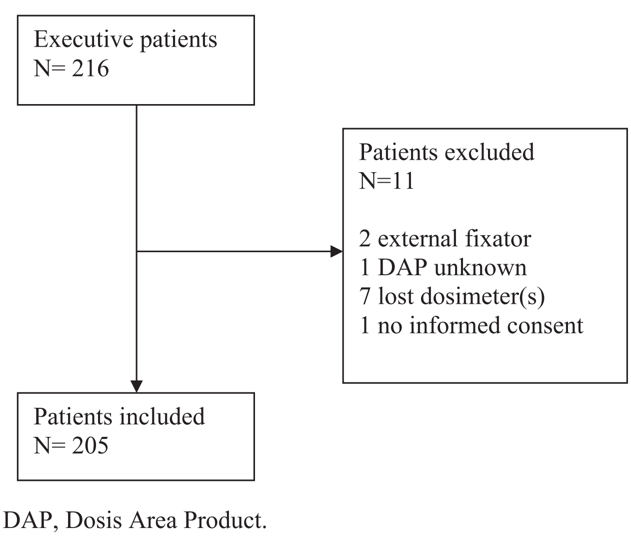

Fig. 1. Flowchart of the study.

order to report patient characteristics, operation characteristics and effective doses due to scattered radiation. Median and percentiles (non-parametric data) were reported for continuous data. Numbers and frequencies were reported for categorical data.

Results

Patient characteristics

During the study period 216 patients were invited for participation of this study of which 11 were excluded (of which one patient did not want to participate in this study), resulting in a total of 205 included patients (Fig. 1). Patient characteristics are shown in Table 3. The median age was 53 years (P_{25}–P_{75} 38–68). This study included 49 (24%) hand/wrist fractures, 37 (18%) shoulder fractures, 47 (23%) ankle fractures, 35 (17%) knee fractures, and 37 (18%) hip fractures.

Table 3
Patient characteristics.

Variable	Total population (*N* = 205)
Male	118 (57.6%)
Age (years)	55 (38–68)
Fractures and locations	
Hand/wrist	49 (24%)
Antebrachii: 22	2 (4%)
Distal radius: 2R3	22 (45%)
(Meta)carpals/phalanges: 77–78	25 (51%)
Shoulder	37 (18%)
Clavicle: 15	20 (54%)
Proximal humerus: 11	15 (41%)
Midshaft humerus: 12	2 (5%)
Ankle	47 (23%)
Tibial shaft: 42-A	7 (15%)
Ankle luxation fracture: 44B-C	2 (4%)
Distal fibula, type Weber C: 44-C	3 (6%)
Distal fibula, type Weber B: 44-B	17 (36%)
Trimalleolar fracture: 44-B3	5 (11%)
Bimalleolar fracture: 44-A2	3 (6%)
Medial malleolus: 44-A	1 (2%)
Calcaneus: 82	2 (4%)
Maisonneuve: 44-C3	3 (4%)
Metatarsal bone: 87	3 (6%)
Lisfranc: 87	2 (4%)
Knee	35 (17%)
Distal femur: 33	7 (20%)
Proximal tibia: 41	21 (60%)
Patella: 34	7 (20%)
Hip	37 (18%)
Intracapsular/extracapsular neck: 31	15 (41%)
Pertrochanteric femur: 31	19 (51%)
Subtrochanteric femur: 31	3 (8%)

Data are shown as fracture: AO classification, median (P_{25}-P_{75}) or as number (%).

Operation characteristics

Operation characteristics are shown in Table 4. The median overall operating time was 92 min (P_{25}–P_{75} 68–131), the median fluoroscopy time was 41 s (P_{25}–P_{75} 18–79), and the median DAP was 19 cGy cm^2 (P_{25}–P_{75} 5–58). During osteosynthesis of the knee and hip the median DAPs were 33 (16–51) and 252 (114–398) cGy cm^2, respectively.

Effective dose due to direct radiation

Effective dose as a result of direct radiation per location and fracture are shown in Table 5. Effective doses as a result of direct radiation for hand/wrist, shoulder and ankle osteosynthesis were 0.05, 2.82 and 0.17 µSv, respectively. For knee and hip osteosynthesis these effective doses were 0.55and 123.87 µSv, respectively. The overall effective dose due to direct radiation is not shown in Table 5, because it would be based on varying effective doses due to direct radiation in five different types of surgery.

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Table 4
Operation characteristics.

Variable	Operation time (minutes)	Fluoroscopy time (seconds)	DAP (cGy•cm^2)
Overall (N = 205)	92 (68–131)	41 (18–79)	19 (5–58)
Hand/wrist (N = 49)	76 (53–93)	34 (17–68)	7 (3–14)
Shoulder (N = 37)	112 (101–148)	17 (5–31)	13 (2–37)
Ankle (N = 47)	76 (60–109)	33 (17–56)	10 (4–30)
Knee (N = 35)	129 (81–175)	56 (28–87)	33 (16–51)
Hip (N = 37)	84 (67–130)	59 (48–115)	252 (114–398)

Data are shown as median (P_{25}-P_{75}).
DAP, Dosis Area Product; cGy, centigray; cm^2, square centimeter.

Table 5
Effective dose.

	Effective dose due to direct radiation (µSv)	Effective dose due to scattered radiation (µSv) per location		
		Thyroid	Breast tissue	Gonads
Overall (N = 205)	–	65 (32%) 3.73 (1.44–10.62)	77 (38%) 6.23 (2.45–25.63)	79 (39%)13.58 (3.45–55.10)
Hand/wrist (N = 49)	0.05	7 (14%) 3.25 (2.23–5.10)	12 (25%) 3.74 (1.59–6.99)	11 (22%) 1.73 (0.63–4.25)
Shoulder (N = 37)	2.82	18 (49%) 4.42 (2.18–9.08)	15 (41%) 4.10 (1.21–18.45)	9 (24%) 1.45 (0.60–5.99)
Ankle (N = 47)	0.17	14 (30%) 2.43 (1.01–6.24)	12 (26%) 2.45 (0.65–6.48)	14 (30%) 5.16 (3.66–6.14)
Knee (N = 35)	0.55	10 (29%) 12.9 (2.29–28.93)	11 (31%) 14.55 (0.73–41.55)	12 (34%) 24.06 (7.31–47.07)
Hip (N = 37)	123.87	16 (43%) 7.49 (1.37–42.16)	27 (73%) 22.58 (13.73–55.10)	33 (89%) 60.43 (33.84–100.76)

Corrected effective radiation dose per location is shown as number (%) of patients in whom radiation was detected. For these patients, the median (P_{25}–P_{75}) effective radiation dose (µSv) is provided in the second line.
The overall effective dose due to direct radiation is not shown, because it would be based on very varying effective doses due to direct radiation in five different types of surgery.
µSv, microsievert.

Effective dose due to scattered radiation per location

Effective dose as a result of scattered radiation per location and fracture are shown in Table 5. Effective doses due to scattered radiation above zero were measured in 65/205 (32%) patients at the thyroid, 77/205 (38%) at breast tissue and 79/205 (39%) at the gonads. The overall effective dose due to scattered radiation for patients in whom radiation was detected, was 3.73 µSv (P_{25}–P_{75} 1.44–10.62) at the thyroid, 6.23 µSv (P_{25}–P_{75} 2.45–25.63) at the breast tissue, and 13.58 µSv (P_{25}–P_{75} 3.45–55.10) at the gonads.

During osteosynthesis of hand/wrist and shoulder effective dose due to scattered radiation at the thyroid were 3.25 (P_{25}–P_{75} 2.23–5.10) and 4.42 µSv (P_{25}–P_{75} 2.18–9.08), respectively. In addition, for ankle, knee and hip osteosynthesis effective doses due to scattered radiation were 2.43 (P_{25}–P_{75} 1.01–6.24), 12.9 (P_{25}–P_{75} 2.29–28.93) and 7.49 µSv (P_{25}–P_{75} 1.37–42.16) respectively. At breast tissue effective doses were 3.74 µSv (P_{25}–P_{75} 1.59–6.99) for hand/wrist fractures, 4.10 µSv (P_{25}–P_{75} 1.21–18.45) for shoulder fractures and 2.45 µSv (P_{25}–P_{75} 0.65–6.48) for ankle fractures. During osteosynthesis of the hand/wrist, shoulder and ankle effective dose due to scattered radiation at the gonads were 1.73 (P_{25}–P_{75} 0.63–4.25), 1.45 (P_{25}–P_{75} 0.60–5.99) and 5.16 µSv (P_{25}–P_{75} 3.66–6.14), respectively. Additionally, during osteosynthesis of the hip effective dose due to scattered radiation at the gonads was 60.43 µSv (P_{25}–P_{75} 33.84–100.76).

Discussion

This multicenter observational study aimed to measure the amount of scattered radiation doses and to calculate the effective doses due to scattered radiation at the thyroid, breast tissue, and gonads during primary osteosynthesis. The highest scattered radiation doses were measured at the gonads during knee and hip osteosynthesis. The highest median DAP was measured during osteosynthesis of the hip.

The reduction of scattered radiation by wearing protective shields by personnel applying radiation during interventional procedures is widely proven. Although, the consequent influence of scattered radiation on tissue damage is known, it remains unknown if patients need radiation protection peroperatively.

Scattered radiation could increase the risk of developing cancer, especially in radiation sensitive tissues if these doses exceed the maximum radiation dose limits [5–7]. This study presented in 32, 38, and 39% effective scattered doses at the thyroid, breast tissue and gonads, respectively. The highest measured median effective dose found was 60.43 µSv (0.06 mSv) at the gonads during osteosynthesis of the hip. The ICRP indicated a list of threshold doses for short-term exposures at various organs and tissues. These results showed no deterministic effects would be expected below a short term radiation dose of 100 mSv [10]. The ICRP showed that the annual natural background radiation dose is approximately 2.4 mSv [1]. So, the maximum median effective dose of 0.06 mSv is 40 times less than the annual natural background radiation and no deterministic effects are to be expected. In addition, the clinical relevance of a maximum effective dose of 0.06 mSv at the gonads during primary osteosynthesis is debatable.

Although the effective dose due to scattered radiation is in some cases comparable with the effective dose due to the primary radiation, both are so low that no deterministic effects are to be expected and the extra risk on cancer is neglectable.

In patients undergoing more than one osteosynthesis per year the risk of tissue damage will increase, since stochastic effects can occur by any radiation dose level [9]. Thereby, patients do also receive (scattered) radiation due to pre-operative and post-operative radiographs and CT scans.

The lifetime value for an average person is a 5% risk increase in fatal cancer after a whole body dose of 1 Sv [14]. Besides, a statistically significant increase in cancer will not occur in patients exposed to radiation doses of less than 0.05 Sv. Maximum effective dose due to direct radiation was 123.87 µSv (1.23 10^{-4} Sv)during hip osteosynthesis. Since this direct radiation dose is low, no significant increased risk in developing cancer will occur during primary osteosynthesis due to direct radiation nor due to scattered radiation.

Several potential limitations of this study should also be addressed. First, in both hospitals different types of C-arms were used. It is possible that the amount of scattered radiation differs per emitted radiation dose, based on the fact that the energy spectrum could differ per system. Second, the settings of each C-arm were adjusted by the radiographer. As a consequence differences within the emitted radiation cannot be ruled out. Third, every patient was positioned by the preferences of the surgeon. As a result the distance of the dosimeter to the fluoroscopy position differs. It is a fact that the scattered radiation intensity depends on the distance from the dosimeter to the X-ray beam, however this study did not measure the distance from the dosimeter to the X-ray beam. Although these limitations may have introduced some variation in the scattered radiation doses, it mimics the variation in clinical practice and may thus make the results more generalizable.

Conclusion

In summary, this study presented overall effective dose due to scattered radiation of 3.73 µSv (P_{25}–P_{75} 1.44–10.62) at the thyroid, 6.23 µSv (P_{25}–P_{75} 2.45–25.63) at breast tissue and 13.58 µSv (P_{25}–P_{75} 3.45–55.10) at the gonads during primary osteosynthesis. The highest scattered effective radiation dose were 60.43 µSv (P_{25}–P_{75} 33.84–100.76) at the gonads during osteosynthesis of the hip. The results of this study show that scattered radiation is detectable in a third of patients undergoing an osteosynthesis. However, both effective doses due to direct radiation and due to scattered radiation are well below the thresholds for deterministic effects and will not significantly increase the risk of developing cancer.

Declarations of Competing Interest

None.

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