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Radiation exposure during direct versus indirect image acquisition during fluoroscopy-controlled internal fixation of a hip fracture: Results of a randomized controlled trial

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ABSTRACT

Background: Intra-operative image acquisition can be obtained indirectly (via verbal request to a technician) or directly (executed at the tableside, by a surgeon stepping on a foot pedal). Direct image acquisition could reduce the exposure time and thus the risk of radiation damage. The aim of this randomized controlled trial was to compare direct surgeon-controlled fluoroscopy with indirect technician-operated fluoroscopy during internal fixation of a hip fracture.

Methods: From March 5, 2014 to August 19, 2015, 100 patients who had sustained a hip fracture that required internal fixation were enrolled. Patients were randomized between direct surgeon-controlled image acquisition using a foot pedal ($n = 52$) and indirect image acquisition by a radiology technician ($n = 48$). The primary outcome measure was the radiation exposure time; secondary outcome measures were the associated effective radiation dose and the dose area product. (DAP)

Results: A total of 96 patients (with a median age of 84 years) were enrolled in this study. Eighty-nine (93%) patients had a pertrochanteric fracture. No statistically significant differences between direct image acquisition and indirect image acquisition were found for overall radiation time, total radiation dose or DAP for the total population. When adjusted for potential confounders, a difference in overall radiation time of 18.50 s (95% CI 2.19; 34.81, $p = 0.027$) was found in favour of indirect image acquisition.

Conclusion: This study showed statistically significantly lower radiation duration using indirect fluoroscopy for the total population and the pertrochanteric fracture subgroup when adjusted for several confounders. No significant effect on radiation dose and DAP was found.

Background

The use of intra-operative fluoroscopy during orthopedic trauma surgery has increased during the last decades. Although risks for both patients and surgeons associated with radiation exposure due to intra-operative fluoroscopy are small, they cannot be neglected. Examples of radiation related health risk are radiation dermatitis, cataract, genetic defects, the induction of cancer, such as basal cell cancer and eventually amputation of fingers [1]. In order to reduce the risk of these adverse effects or radiation, adhering to the ALARA principle (As Low As Reasonably Achievable) is obligatory. Several studies have been designed in order to reduce the radiation exposure. Using an inverted C-arm [2] or a mini C-arm [3] was shown to reduce the radiation dose per unit of time. An alternative approach for preventing radiation-associated adverse effects is to reduce the exposure time [4,5].

Internal fixation of a hip fracture is among the most frequently performed skeletal procedure that uses fluoroscopy-guided positioning of implants. In our clinic, on average 170 patients are treated with a Gamma nail, cancellous screws, or a sliding hip screw annually. These procedures require relatively long fluoroscopy exposure times (mean 3.2 min) [6].

Traditionally, a radiology technician operates the C-arm fluoroscopy image acquisition following a verbal request from the surgeon. Currently, C-arms are also equipped with a remote user interface and foot pedal that is placed at the tableside and can be

Abbreviations: ALARA, As Low As Reasonably Achievable; DAP, dose-area product; Gy, gray; kVp, peak kilovoltage; SD, standard deviation.

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operated directly by the surgeon. Using direct fluoroscopic image acquisition is expected to reduce the radiation exposure time because it avoids a misinterpretation between the surgeon and the technician. The primary objective of this randomized controlled trial was to assess whether the radiation time and the effective exposure radiation during internal fixation of a hip fracture reduces with direct image acquisition.

Patients and methods

Study design and participants

This study was a single center, single-blinded, parallel group randomized controlled trial. All adult patients aged 18 years and older with an X-ray confirmed hip fracture (i.e., collum femoris, pertrochanteric, or subtrochanteric) with planned internal fixation (i.e., cancellous screws, sliding hip screw, gamma nail, or long gamma nail) were included after provision of informed consent. Patients were excluded if they 1) had a pathological fracture; 2) received hemi- or total hip arthroplasty instead of internal fixation; 3) had retained hardware around the affected hip; or 4) had insufficient comprehension of the Dutch language to understand the patient information sheet. The local Medical Research Ethics Committee (Maasstad Hospital, Rotterdam, the Netherlands) has approved the study (reference number 2011/19).

Randomization and blinding

Eligible patients were informed about the trial while being in the Emergency Department. Patients who signed informed consent were randomly assigned in a 1:1 ratio to surgeon-controlled direct fluoroscopy (i.e., intervention group) or technician-controlled indirect fluoroscopy (i.e., control group). The randomization sequence, with random block sizes, was generated using the Random Allocation Software version 1.0.0 (developed by M. Saghaei, department of Anesthesiology, Ishfahan University of Medical Sciences, Isfahan, Iran). Randomization was done by an independent research assistant, concealing allocation from the recruiting investigator. Patients were blinded for the allocated procedure. Since surgeons would have to employ the C-arm, they could not be blinded. The time interval of radiation and the total radiation dose (the air kerma in mGy), are digitally stored on the C-arm, making outcome assessment unbiased.

Intervention

In the intervention group, the surgeon directly acquired the C-arm fluoroscopy image at the tableside by stepping on a foot pedal. In the control group, image acquisition was done indirectly by a radiology technician acting on a verbal request by the surgeon. In both groups the radiology technician was present in the operating room during the entire operation. The technician controlled the collimator and stored the images. Patients in both groups, were treated following the local hospital protocol. Surgical procedures were performed by an orthopedic trauma surgeon or by a resident-in-training supervised by one of these orthopedic trauma surgeons.

The operating rooms were equipped with a Philips NZS55 fluoroscope, which digitally records the total exposure time, the air kerma (in mGy), and the dose-area product (DAP, in $mGy.m^2$). The DAP meter measures the radiation dose to air, times the area of the X-ray field. The DAP correlates well with the effective dose for patient and surgeon [6]. The C-arm has an Automatic Brightness Control that keeps the brightness of the displayed image at a constant level during examination [7]. The radiation potential (kVp) and tube current (mA) were adjusted automatically depending on the anatomy being examined. It determined the amount of radiation (mGy) per time unit. The overall exposure time and amount of radiation (mGy) were stored automatically and digitally. The overall exposure time included all exposure episodes during surgery, including patient positioning and checking of implant positioning.

Outcome measures and data collection

The primary outcome measure was the overall exposure time. Secondary outcome measures were the effective radiation dosage and the DAP. In addition, the following data were collected: 1) Patient characteristics (i.e., age, gender, height, and weight); 2) Injury characteristics (i.e., affected side and type of fracture); and 3) Operation characteristics (i.e., implant type, surgery by trauma surgeon or resident-in-training, and perioperative complications).

Statistical analysis

A three-month pilot study revealed that the mean exposure time of technician-controlled indirect fluoroscopy was 114.6 s with a standard deviation (SD) of 86 s. Based upon a previous study a reduction of 35–40% was expected [8]. This trial was designed to enrol 100 patients, yielding 80% power to detect 35% exposure time reduction (mean 74, SD 56 s) with a two-sided significance level of 0.05. Sample size calculation was done using the online program DSS Research (www.dssresearch.com/toolkit/sscalc/size.asp).

Data were analyzed using the Statistical Package for the Social Sciences version 21 (SPSS, Chicago, Illinois, USA). Analysis was by intention to treat and all statistical tests were two-sided, with $p < 0.05$ as threshold for statistical significance. Normality of continuous data was tested using the Shapiro-Wilk test. Missing data were not imputed. Subgroup analysis for type of fracture was planned, depending on actual enrolment numbers.

Descriptive analysis was performed in order to report outcome measures and patient, injury, and intervention characteristics in both trial arms. Continuous data were all nonparametric and are reported as medians with percentiles. Categorical data are reported as numbers with frequencies. Statistical significance between the two groups was tested using a Mann–Whitney *U* test (continuous variables) or Chi squared test or Fisher's Exact test (categorical variables).

Next, multiple linear regression analysis was performed in order to model the relationship between different covariates and the exposure time (dependent variable). The group identity (i.e., intervention or control) as well as patient, injury and intervention characteristics that displayed a *p*-value <0.05 in the univariate analyses were added as a covariate. A similar model was made in which the effective radiation dosage and the DAP as dependent variable. Beta values with 95% confidence interval are reported.

Results

Patient, injury and operation characteristics

Between March 5, 2014 and August 19, 2015, 421 consecutive patients with a hip fracture who required surgery were screened for eligibility, of whom 100 were included. Of the included patients, 52 patients were assigned to the intervention group and 48 to the control group (Fig. 1). All patients received the allocated fluoroscopy. Two patients in each group were lost to follow-up; one patient (with a collum femoris fracture) in the control group withdrew consent, and for the other three patients the radiation details were not stored on the C-arm. The remaining 96 patients, with a median age of 84 years, were included in the analysis. Seventy-three (76%) patients were female and the right side was fractured in 43 (45%) patients. Eighty-nine (93%) patients had a

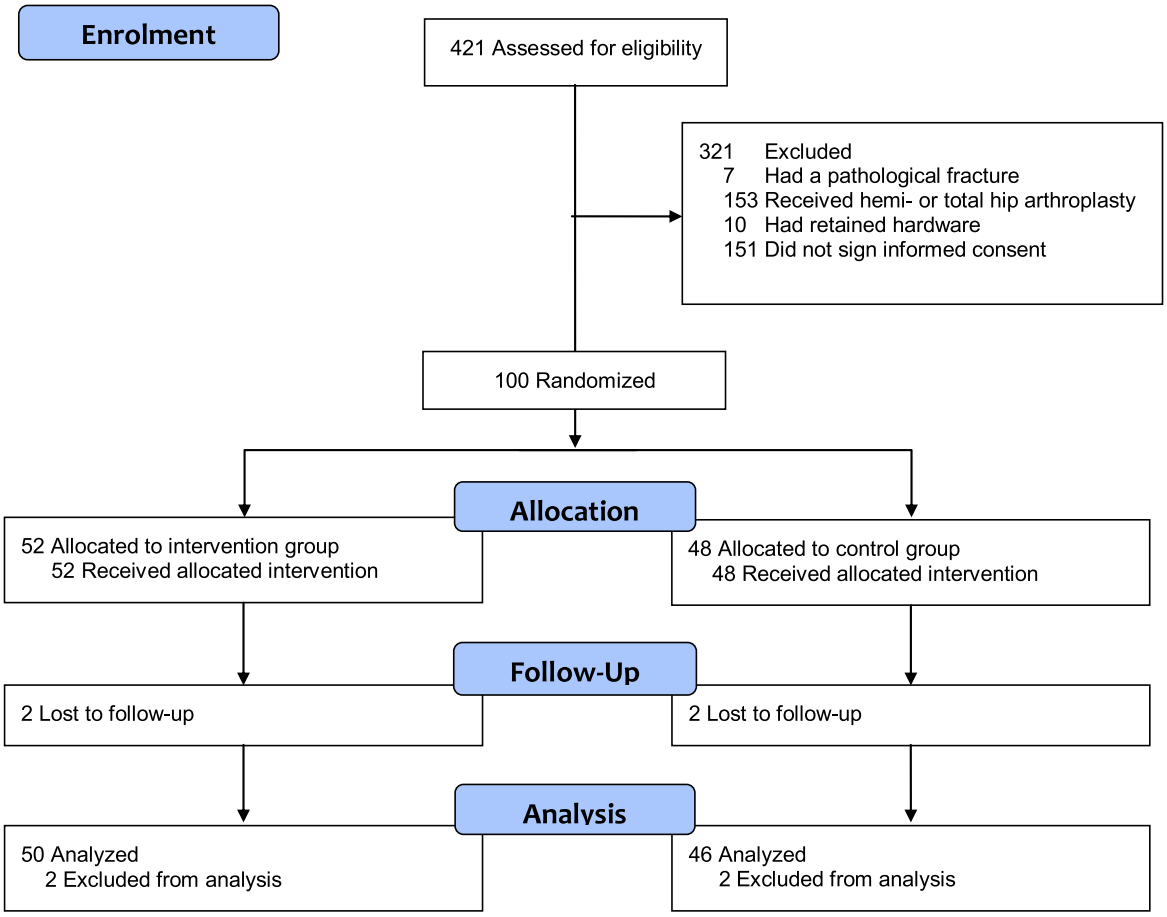

Fig. 1. Flow chart of the study.

pertrochanteric fracture, and treatment was done with a gamma nail or long gamma nail in 61 (64%) and 32 (33%) patients, respectively. Of the pertrochanteric fractures, 36 (40%) patients had an A1 fracture subtype, 37 (42%) an A2 fracture subtype, and 16 (18%) an A3 fracture subtype. The median operation time was 74 min. Only two preoperative complications occurred, both in the control group; one patient developed a superficial wound infection, for which antibiotic treatment was started, and one patient had significant blood loss (700 mL), for which a Redon drain was placed after surgery.

Randomization resulted in similar patient, injury, and operation characteristics in the two groups (Table 1). Since 93% of patients had a pertrochanteric fracture, a subgroup analysis was performed for this group. Similar as in the overall population, patient, injury, and intervention characteristics were similar in the two groups (Table 2).

Outcome

Radiation data are shown in Table 3. In the overall study population, the median overall radiation time was 53 s, with a total radiation dose of 3.5 mGy and a DAP of 0.0572 mGy.m^2. In the subgroup of pertrochanteric fractures, the median overall radiation time was 53 s, with a total radiation dose of 3.5 mGy and a DAP of 0.0572 mGy.m^2. Univariate analysis revealed no statistically significant differences between the intervention and control groups both in the overall and the subgroup analysis.

In the total study population, linear regression analysis revealed no statistically significant effect of direct image acquisition on the radiation time (beta 11.51; $p = 0.144$; Table 4). However, when adjusted for potential confounders, the difference in overall radiation time of 18.50 (95% CI 2.19; 34.81, $p = 0.027$) was found in favour of indirect image acquisition. For the subgroup of pertrochanteric fractures, the adjusted beta (20.28; $p = 0.014$) showed a significant effect of the use of direct image acquisition on the radiation time, whereas the unadjusted beta was not (17.61; $p = 0.239$). Despite this significant effect on radiation time, no effect of direct image acquisition on radiation dose or DAP was found in the unadjusted nor in the adjusted analysis.

Discussion

This study is as far as we know the first randomized controlled trial assessing the effects of surgeon-controlled C-arm versus radiology technician-controlled C-arm operation on radiation time, radiation dose, and DAP in patients with a hip fracture treated with internal fixation. No significant differences in overall radiation time, total radiation dose, and DAP were found in the univariate analysis. After adjusting for confounders, a statistically significant difference was found in favor of indirect fluoroscopy for the total study population (18.50 s) as well as for the pertrochanteric subpopulation (20.28 s).

The ALARA principle emphasizes the relevance to minimize the emitted radiation. In response, the mobile C-arm with intraoperative fluoroscopy has increasingly been used during surgery over the last years. Radiation exposure during orthopaedic surgery is inevitable for the surgeon and patient. However with awareness for the fluoroscopy time and implementation of the ALARA principle, radiation dose is reduced in the last decades. Because of this, the radiation dose of one hip fracture surgery (3.5 mGy) in our

Table 1
Characteristics for the intervention and control group in the total study population.

Parameter	Total population ($N=96$)	Intervention group ($N=50$)	Control group ($N=46$)	p-value
Age at surgery (years)	84 (74–89)	84 (75–89)	84 (74–88)	0.600
Female gender	73 (76%)	41 (82%)	32 (70%)	0.231
Height (m)[a]	1.63 (1.58–1.70)	1.65 (1.57–1.70)	1.63 (1.58–1.73)	0.893
Weight (kg)[b]	62 (55–77)	60 (54–71)	64 (57–80)	0.152
BMI (kg/m^2)[c]	23.4 (20.8–25.8)	22.3 (19.7–26.4)	24.1 (22.0–26.1)	0.065
Fracture type				
Pertrochanteric	89 (93%)	47 (94%)	42 (91%)	0.707
Subrochanteric	7 (7%)	3 (6%)	4 (9%)	
Right side affected	43 (45%)	25 (50%)	18 (39%)	0.311
Implant				
Gamma nail	61 (64%)	33 (66%)	28 (61%)	0.704
Long gamma nail	32 (33%)	15 (30%)	17 (37%)	
Sliding hip screw	3 (3%)	2 (4%)	1 (2%)	
Operation time (minutes)	74 (63–90)	74 (72–92)	74 (60–82)	0.228
Surgeon				
Resident-in-training	84 (88%)	43 (86%)	41 (89%)	0.762
Surgeon	12 (12%)	7 (14%)	5 (11%)	
Peroperative complications	2 (2%)	0 (0%)	2 (4%)	0.227

Categorical variables are presented as numbers (%) and tested with a Chi squared or Fisher's exact test. Continuous values are expressed as median (P_{25}–P_{75}) and tested with a Mann–Whitney U test. mGy, milliGray; DAP, Dose area product.
[a] Data missing for 4 patients in the intervention group and 8 in the control group.
[b] Data missing for 1 patients in the intervention group and 2 in the control group.
[c] Data missing for 5 patients in the intervention group and 8 in the control group.

Table 2
Characteristics for the intervention and control group in the subgroup of patients with a pertrochanteric fracture.

Parameter	Total population ($N=89$)	Intervention group ($N=47$)	Control group ($N=42$)	p-value
Age at surgery (years)	84 (74–89)	84 (73–90)	84 (74–88)	0.675
Female gender	68 (76%)	38 (81%)	30 (71%)	0.327
Height (m)[a]	1.63 (1.58–1.70)	1.65 (1.57–1.70)	1.61 (1.58–1.70)	0.642
Weight (kg)[b]	62 (55–77)	60 (54–73)	63 (56–78)	0.251
BMI (kg/m^2)[c]	23.3 (20.8–25.7)	22.3 (19.5–25.4)	24.0 (21.9–25.8)	0.094
Right side affected	41 (46%)	24 (51%)	17 (41%)	0.395
Fracture class				
A1	36 (40%)	21 (45%)	15 (36%)	0.688
A2	37 (42%)	18 (38%)	19 (45%)	
A3	16 (18%)	8 (17%)	8 (19%)	
Implant				
Gamma nail	60 (67%)	32 (68%)	28 (67%)	0.852
Long gamma nail	26 (29%)	13 (28%)	13 (31%)	
Sliding hip screw	3 (3%)	2 (4%)	1 (2%)	
Operation time (minutes)	74 (61–89)	74 (72–90)	75 (60–82)	0.309
Surgeon				
Resident-in-training	77 (87%)	40 (85%)	37 (88%)	0.763
Surgeon	12 (14%)	7 (15%)	5 (12%)	
Peroperative complications	1 (1%)	0 (0%)	1 (2%)	0.472

Categorical variables are presented as numbers (%) and tested with a Chi squared or Fisher's exact test. Continuous values are expressed as median (P_{25}-P_{75}) and tested with a Mann–Whitney U test. mGy, milliGray; DAP, Dose area product.
[a] Data missing for 3 patients in the intervention group and 7 in the control group.
[b] Data missing for 1 patients in the intervention group and 2 in the control group.
[c] Data missing for 4 patients in the intervention group and 7 in the control group.

Table 3
Radiation in the intervention and control group, both in the total study population and in the subgroup of patients with a pertrochanteric fracture, treated with a gamma nail, long gamma nail or sliding hip screw.

Parameter	Total population	Intervention group	Control group	p-value
Total study population	$N=96$	$N=50$	$N=46$	p-value
Radiation time (seconds)	53.0 (39.5–81.8)	55.5 (40.5–89.3)	50.5 (39.0–68.8)	0.245
Radiation dose (mGy)	3.5 (1.9–6.5)	3.6 (2.2–7.0)	3.4 (1.8–5.9)	0.369
DAP ($mGy.m^2$)	0.0572 (0.0278–0.0991)	0.0585 (0.0359–0.1035)	0.0522 (0.0242–0.0911)	0.328
Pertrochanteric fractures	$N=89$	$N=47$	$N=42$	p-value
Radiation time (seconds)	53.0 (41.0–74.5)	57.0 (46.0–89.0)	49.0 (39.0–65.8)	0.072
Radiation dose (mGy)	3.5 (2.1–6.2)	3.8 (2.3–7.3)	3.3 (1.8–4.9)	0.136
DAP ($mGy.m^2$)	0.0572 (0.0290–0.0972)	0.0590 (0.0367–0.1111)	0.0502 (0.0242–0.0743)	0.128

Data are expressed as median (P_{25}-P_{75}) and tested with a Mann–Whitney U test.
mGy, milliGray; DAP, Dose area product.

Table 4
Unadjusted and adjusted effect of direct versus indirect fluoroscopy on radiation time, radiation dose, and DAP.

	Unadjusted analysis		Adjusted analysis[a]	
	Beta (95% CI)	*p*-value	Beta (95% CI)	*p*-value
Total study population ($N = 96$)				
Radiation time (seconds)	11.51 (−4.02; 27.04)	0.144	18.50 (2.19; 34.81)	**0.027**
Radiation dose (mGy)	0.28 (−1.50; 2.07)	0.753	1.01 (−0.83; 2.85)	0.277
DAP (mGy.m^2)	0.005 (−0.02; 0.04)	0.716	0.01 (−0.02; 0.05)	0.382
Pertrochanteric fractures ($N = 89$)				
Radiation time (seconds)	17.61 (2.35; 32.86)	0.239	20.28 (4.18; 36.38)	**0.014**
Radiation dose (mGy)	0.81 (−1.01; 2.63)	0.229	1.14 (−0.73; 3.00)	0.229
DAP (mGy.m^2)	0.01 (−0.02; 0.04)	0.425	0.02 (−0.02; 0.05)	0.344

mGy, milligray; DAP, Dose area product.
Male gender, fracture at right side, absence of preoperative complications, and control group were used as reference groups.
The two results are bold because they are significant (<0.05). Its easier for the reader to identify the significant results. If its is not possible it can be corrected without bold marks.
[a] Adjusted beta was corrected for gender, BMI, affected side, operation duration, and occurrence of preoperative complications.

study is comparable with three times a chest X-ray or one transatlantic flight [9].

In search for even further reduction of exposure time, direct image acquisition has been suggested because it would avoid a verbal delay between the surgeon and the technician. Indeed, an earlier study on the use of the C-arm during orthopedic surgery showed that the mean exposure duration reduced from 65 to 35 s ($p < 0.05$) if the surgeon instead of the technician controls the C-arm [6]. As promising as this sound, the types of procedures were not specified in this earlier study and as a result it is unclear whether differences between both groups might have introduced bias. Another study has shown that Cardiologist-operated fluoroscopy and image acquisition during routine coronary angiography also reduces the patient radiation exposure compared with radiographer-operated procedures [10].

However, this study does not confirm these results for internal fixation for hip fracture surgery. This difference can be explained by several reasons. Firstly, if a surgeon is in control of the C-arm and the threshold to request an image disappears, a side effect could be that the surgeon obtains more images using direct fluoroscopy.

Secondly, the average time of fluoroscopy exposure during surgery is relatively short in this study compared with existing literature (53 s vs. 3.2 min) [6], therefore significant differences between direct and indirect fluoroscopy are probably harder to identify.

This study has some limitations. First is the type of fractures in this study, where all hip fractures treated with osteosynthesis and hence requiring fluoroscopy were included. The majority of this study however, describes pertrochanteric fractures. The second limitation was the size of the study population. Since there was a statistically significant difference in radiation time after correction for possible confounders, it was expected to also show this difference for radiation dose and DAP. The current study, however, does not show these results. Should the study be repeated, basing the study on difference in radiation dose or DAP seems justified. And although only significant in radiation duration after adjusting for several cofounders, it seems better that the radiology technician controls the fluoroscopy during surgery.

This study showed statistically significantly lower radiation duration using indirect technician-controlled fluoroscopy for the total population and the pertrochanteric fracture subgroup when adjusted for several confounders although no significant effects on total radiation dose or DAP were found. If we want to reduce the radiation dose even further, more research on differences in radiation dose or DAP for direct and indirect fluoroscopy is needed.

Declaration of Competing Interest

The authors of this manuscript declare no relationships with any companies, whose products or services may be related to the subject matter of the article.

Supplementary material

Supplementary material associated with this article can be found, in the online version, at doi:10.1016/j.injury.2019.09.035.

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