

The cost of screening radiographs after stable fracture fixation

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Background: Currently up to 58% of Canadian surgeons would forego screening radiographs after stable fracture fixation. It is therefore expected that reducing screening radiographs will be well accepted, provided that patient safety is not compromised, resulting in a cost reduction. The study objective was to measure the savings of a simplified radiographic protocol for well-fixed fractures and establish feasibility for a noninferiority trial that proves patient safety.

Methods: Patients were randomized after fixation. The control group received screening radiographs immediately after fixation and at 2 weeks. The experimental group received radiographs only when clinically indicated. At 6 weeks all patients received radiographs. The cost of imaging, time spent in clinic and patient satisfaction was measured. A blinded reviewer documented adverse events, either detected or missed.

Results: Of the 90 patients screened, 39 were randomized and 26 had complete follow-up. The mean cost of radiographs over the first 6 weeks was \$44.51 (95% confidence interval [CI] 38.64–50.38) per patient in the experimental group, and \$129.23 (95% CI 120.23–138.23) in the control group ($p < 0.001$). The mean time spent in clinic at 2 weeks was 46 min (95% CI 32–60) per patient for the experimental group and 68 min (95% CI 55–81) for the control group ($p = 0.018$). Two complications occurred in the experimental group. Both were detected clinically and did not qualify as missed events.

Conclusion: Implementing a simplified radiography protocol after stable fracture fixation saves time and money. Additionally, no adverse events were missed with the study protocol. Recommendations are made toward a noninferiority trial to establish protocol safety.

Contexte : À l'heure actuelle, jusqu'à 58 % des chirurgiens canadiens renonceraient aux radiographies de contrôle après la fixation d'une fracture stable. On s'attend donc à ce qu'une réduction du nombre de radiographies de contrôle soit bien acceptée, à la condition que la sécurité des patients ne soit pas compromise, et à ce que cela contribue à diminuer les coûts. Les objectifs de l'étude étaient de mesurer les économies générées par un protocole radiographique simplifié pour les fractures bien fixées et d'établir la faisabilité d'un essai de non-infériorité visant à confirmer que la sécurité des patients n'est pas compromise.

Méthodes : L'assignation aléatoire des patients s'est faite après la fixation. Le groupe témoin était soumis à une radiographie de contrôle immédiatement après l'intervention, et 2 semaines plus tard. Dans le groupe expérimental, les radiographies étaient faites uniquement lorsqu'elles étaient cliniquement indiquées. Au bout de 6 semaines, tous les patients étaient soumis à une radiographie. Le coût de l'imagerie, le temps passé à la clinique et la satisfaction des patients ont été mesurés. Un examinateur a documenté à l'aveugle les effets indésirables détectés ou passés inaperçus.

Résultats : Parmi les 90 patients pressentis pour la sélection, 39 ont été assignés aléatoirement et 26 ont fait l'objet du suivi complet. Le coût moyen des radiographies pour les 6 premières semaines a été de 44,51 \$ (intervalle de confiance [IC] de 95 % 38,64–50,38) par patient dans le groupe expérimental, et de 129,23 \$ (IC de 95 % 120,23–138,23) dans le groupe témoin ($p < 0,001$). Le temps passé à la clinique pour la radiographie après 2 semaines a été de 46 minutes (IC de 95 % 32–60) par patient dans le groupe expérimental, et de 68 minutes (IC de 95 % 55–81) dans le groupe témoin ($p = 0,018$). Deux complications sont survenues dans le groupe expérimental. Les deux ont été détectées à l'examen clinique et ne répondaient pas aux critères d'événements passés inaperçus.

Conclusion : L'application d'un protocole radiographique simplifié après fixation d'une fracture stable permet d'épargner du temps et de l'argent. De plus, aucun effet indésirable n'est passé inaperçu avec le protocole expérimental. Nous recommandons la conduite d'un essai de non-infériorité afin d'en confirmer la sécurité.

A recent survey¹ noted that anywhere from 31% to 49% of Canadian orthopedic surgeons do not acquire screening or check radiographs in the first 6 weeks after fracture fixation. The numbers vary depending on the type of fracture and fixation construct as well as on the timing of the radiograph. When asked, many of those who do screen with radiographs said they would consider a change in practice.¹ Such a change is further supported by a review of the literature. There is a paucity of studies that reported screening with imaging successfully led to a change in patient management.²⁻¹¹ A change in clinical practice therefore appears reasonable and would likely produce savings for both patients and the health care system. The magnitude of savings and ultimately the safety of a modified postfracture fixation protocol for acquiring radiographs remain unknown and are worth investigating.

A simplified postoperative radiography protocol for fracture patients may therefore exclude screening radiographs, but include obtaining radiographs when warranted by the surgeon's examination and clinical judgment. The objective of this study was to compare the savings, both in terms of cost and time, of a simplified postfracture fixation radiography protocol, which asks surgeons to base their requests for radiographs on their clinical examinations. The secondary objective was to calculate the sample size required for a noninferiority study to establish the safety of such a protocol. I hypothesized that using a simplified protocol would save money and time and that the sample size for a non-inferiority trial would be large given the expectation of a low adverse event rate.

METHODS

Randomization for this study occurred after fracture fixation, allowing patients to be screened in the operating room at the time of their procedure. Surgeons were asked to consider inclusion and exclusion criteria and record these on the screening form (Appendix 1, available at canjsurg.ca). The inclusion and exclusion criteria are listed in Table 1. The simplified protocol was not meant to be restrictive for surgeons and patients. To this end, surgeons were allowed to exclude patients who had just completed fracture fixation and in whom screening radiographs were warranted based on suboptimal quality of the construct or bone. Surgeons were also allowed to exclude patients with factors not accounted for in the exclusion criteria. A research assistant collected the screening form daily, and patients were approached once they had fully recovered from the anesthetic for consent to participate and for randomization. Randomization was completed using a computerized random number generator in blocks of 10.

Based on a prospective database maintained by the group of surgeons, it was estimated that 100 patients with the fracture types listed in Table 1 would be available for inclusion

into the study over a 6-month period. The study and research support staff were therefore funded for 6 months.

Once enrolled patients were randomized to the control group or the experimental group. Patients in the control group received screening radiographs in hospital on the first or second day after surgery, at the 2-week follow-up visit in clinic and at the 6-week follow-up visit in clinic. The 2- and 6-week visits are typical follow-up times at our institution. Patients in the experimental group did not receive screening radiographs on the first or second day after surgery nor at the 2-week follow-up visit in clinic. They received screening radiographs at the 6-week follow-up visit. At each time point, surgeons were asked what they noted on the radiographs, if anything, and whether a change in patient management was implemented. Importantly, for the simplified protocol group, surgeons were permitted to obtain radiographs, but were asked what clinical findings directed them to request the radiographs. These questions were asked on the study follow-up forms (Appendix 1).

To measure the cost of imaging for the 2 groups, the actual cost of each specific set of images acquired over the study period was tabulated and totaled. The average cost, including materials and labour, per set of images for the fracture types included was \$41.19 CAD at the time of the study. The individual cost per radiograph for each fracture type is listed in Table 2.

To measure the time associated with obtaining screening versus indicated radiographs, time in hospital and time in clinic were tabulated. Time in hospital was measured from the time the patient left the operating room, which is part of the computerized record maintained by the operating room circulating nurse, to the time the patient left the ward, which is noted by the ward nurse in the patient chart. Time in clinic was measured from the time the research assistant recorded when the patient presented to the clinic clerk to

Table 1. Inclusion and exclusion criteria

Inclusion criteria	<ul style="list-style-type: none"> • Mid-shaft femur fracture treated with intramedullary nailing • Mid-shaft tibia fracture treated with intramedullary nailing • Forearm fractures treated with standard compression technique • One or both bones fractured • Simple fracture or presence of single butterfly fragment treated with lag screw • Humeral shaft fractures treated with standard compression technique • Ankle fractures treated with standard compression technique • Clavicle fractures treated with standard compression technique • Olecranon fractures treated with standard compression
Exclusion criteria	<ul style="list-style-type: none"> • Age < 18 yr, or open growth plates • Multiple fractures • History of osteoporosis or osteopenia • Age > 50 yr • Dialysis patients • Surgeon feels patient should be excluded

the time the patient finished the encounter and presented once again to the clerk to obtain the next appointment.

To record adverse events that were either identified or missed by the screening radiographs, the following definitions were used. Controls in whom a surgeon identified a radiographic finding that led to a change in management noted on the follow-up form (Appendix 1) were deemed to have experienced a major event appreciated through the use of screening radiographs. Those cases where findings were identified on the radiograph, but did not require a change in management were deemed minor events. Patients in the experimental group in whom a radiographic change was identified on the final 6-week radiograph compared with the intraoperative fluoroscopy image were deemed to have experienced major events when accompanied by a complication or a change in management noted at the 6-week follow-up. Cases when a complication or a change in management was not noted or required were deemed minor events. Patients in the experimental group for whom surgeons were led to acquire a radiograph owing to clinical concerns are discussed in the results section.

Patient satisfaction was measured using the University of Leeds satisfaction survey, which was administered at the 2-week clinic visit (Appendix 1). This survey was designed for the outpatient setting in a musculoskeletal clinic (rheumatology clinic) and has previously demonstrated both reliability and internal stability.¹² It was provided to both the control and experimental groups at the beginning of their visit. Satisfaction scores were compared between the 2 groups.

RESULTS

Of the 90 patients screened for the study, 39 consented to participate in the study and were randomized to the control or experimental group. The distribution of fracture type among study patients is illustrated in Table 3. Between 30 and 36 of the patients had data available for analysis for the immediate, in-hospital time point and for the 2-week time point. Twenty-six patients had data available for the 6-week time point. Patients in whom data were lacking for the 2- and 6-week time points had missed the designated window of time for those follow-up visits. Table 4 lists patient data available at each time point.

Table 2. Cost of radiographs in Manitoba, including material and labour, by anatomic location

Anatomic part	Cost, Canadian dollars (materials and interpretation)
Femur	41.70
Tibia and fibula	41.39
Radius and ulna (forearm)	43.00
Humerus	36.44
Ankle (3 views)	41.39
Clavicle	43.01
Olecranon	41.39

Table 3. Patients enrolled, by anatomic location of fracture

Anatomic location of fracture	No. of patients
Femur shaft	5
Tibia shaft	2
Ankle	16
Humerus shaft	1
Forearm	7
Clavicle shaft	3
Olecranon	5

There was a difference in mean cost of radiographs. The cost was \$44.51 (95% confidence interval [CI] 38.64–50.38) in the experimental group, and \$129.23 (95% CI 120.23–138.23) in the control group ($p < 0.001$). There was also a difference in the mean time in clinic at 2 weeks. Patients in the experimental group spent 46 min in clinic (95% CI 32–60), while those in the control group spent 68 min (95% CI 55–81, $p = 0.018$). There was no difference between the groups in the time spent in hospital immediately after surgery, in the time spent in clinic at 6 weeks, or in patient satisfaction measured in clinic (Table 4).

There were no major events missed in the experimental group by eliminating screening radiographs. There were no major events identified in the control group by using screening radiographs. Two complications occurred, both in the experimental group. These were diagnosed based on patient presentation and clinical findings and did not qualify as events as they were not missed. One patient with olecranon fracture fixation reported pain at the 2-week mark, which prompted radiographs. Early heterotrophic ossification was identified. One patient with an olecranon fracture had a repeat major trauma event within the first 6 weeks after surgery and presented with substantial pain and swelling, which prompted radiographs. Loss of fixation was identified and revised surgically.

These results were used to estimate the sample size for a noninferiority trial that would satisfactorily support the safety of omitting screening radiographs as described in this protocol. There were no major events missed. For the calculation, a low major event rate of 2%, which is close to zero, is proposed for convenience. It is also assumed that tolerance would be close to zero for missing a statistical difference between groups. As such, a 2% difference at most is proposed as acceptable classification as “no difference” in the analysis. Therefore, estimating a major event rate of 2% and accepting a no more than 2% difference as “no difference,” the sample size required for a noninferiority trial would be 1212 (power = 0.80, $\alpha = 0.05$).

DISCUSSION

The present study measured cost savings of 65% and time savings of 30% through the reduction of screening

Table 4. Comparison of results for the experimental and control groups

Result	Group; mean (95% CI) or no.		p value*
	Experimental group	Control group	
Cost of radiographs over first 6 wk (n = 26), Canadian dollars	44.51 (38.64–50.38)	129.23 (120.23–138.23)	< 0.001
Time in clinic at 2-week follow-up (n = 36), min	46 (32–60)	68 (55–81)	0.018
Time in clinic at 6-week follow-up (n = 26), min	69 (55–84)	61 (47–74)	0.38
Time to hospital discharge (n = 35), h	53 (27–78)	92 (43–141)	0.22
Patient satisfaction score (n = 30)	3.0 (2.8–3.1)	2.8 (2.6–3.0)	0.12
No. minor missed events (no change in management required; n = 26)	2	0	$\chi^2 = 0.8586$
No. major missed events (change in management required; n = 26)	0	0	

CI = confidence interval.
*Unless indicated otherwise.

radiographs after fracture fixation. Screening radiographs are still broadly used by orthopedic surgeons, and as such, the projected savings would be considerable. While the average cost per radiograph is \$41.19 in Manitoba, this appears to be representative of the cost in a sample of other provinces. The average cost per radiograph when considering Manitoba, Saskatchewan, Alberta, British Columbia and Ontario, is very similar at \$39.21 (Appendix 1). As such, study findings appear applicable to other parts of Canada.

Limitations

Although randomized and prospective, the present study was small. The projection for patients available for enrolment was accurate; however, fewer patients consented to participate than anticipated, despite the noninvasive nature of the study. Although there is no clear reason for the low enrolment rate, enrolling patients postoperatively is a departure from other studies in our centre. This is the only potential cause identified for low enrolment. The study sample was further limited by the imposition of strict time windows for the 2- and 6-week follow-up visits, which were missed by a number of patients.

CONCLUSION

A noninferiority trial to identify the safety of omitting early screening radiographs would require a large number of patients and, therefore, substantial funding and likely multi-centre involvement. Nevertheless, based on the present study, the collection of data is expected to be simple, as there are few data points of interest. Additionally, the duration of follow-up in the present study was brief compared with most prospective studies. The rigidity of the timing for patient follow-up significantly decreased the sample size for this study. Increasing the follow-up windows would rectify this issue. Additionally, screening and enrolling patients preoperatively may increase participation. Although this is not entirely clear, the protocol would not suffer if changed accordingly. Finally, the literature suggests that hip fractures and distal radius fractures

could also be included in the protocol.²⁻⁵ As such, opening the study to more fracture types would not only increase the sample size, but also the generalizability of findings. Taking all this together, it appears possible to complete a noninferiority trial to speak to the safety of the protocol and to provide definitive proof supporting a change in practice.

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Competing interests: None declared.

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