The added value of routine radiographs in wrist and ankle fractures

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ISBN 978-94-6361-755-0

Cover design: L. van Kralingen
Lay-out and print: Optima Grafische Communicatie, Rotterdam, the Netherlands | www.ogc.nl

Publicatie van dit proefschrift is mede mogelijk gemaakt door:
Trauma Centrum West, de Stichting ter bevordering van de wetenschap en opleiding van de maatschap heelkunde ZMC, Chipsoft, Erbe Nederland en Bauerfeind.

The added value of routine radiographs in wrist and ankle fractures

Proefschrift

ter verkrijging van
de graad van doctor aan de Universiteit Leiden,
op gezag van rector magnificus prof. dr. ir. H. Bijl,
volgens besluit van het college voor promoties
te verdedigen op woensdag 2 november 2022
klokke 16:15 uur

door

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geboren te Haarlem

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General introduction and outline of the thesis

INTRODUCTION

Epidemiology

Distal radius and ankle fractures are the two most encountered skeletal injuries. Distal radius fractures represent approximately 18% of all fractures worldwide, whereas ankle fractures represent approximately 9% of all fractures.[1, 2] The incidence of distal radius fractures lies between 160 and 320 per 100,000 per annum[3] and between 101 and 187 per 100,000 per annum for ankle fractures.[4, 5] In the Netherlands, with a population around 17 million, 55,000 and 30,000 patients sustain a fracture to their distal radius or ankle, respectively. These incidences are expected to rise in the coming decades because of aging of the population, and an increased participation in athletic activities.[6, 7]

Treatment

Both fractures of the distal radius and the ankle are in close proximity to an articulating joint and can affect its functioning. Anatomical reduction, especially of the joint surface, is critical for optimal recovery and to minimalize the risk of osteoarthritis. Treatment is aimed at optimizing functional recovery. Maintaining anatomical reduction until the fracture is fully healed while reducing the risk of a complication are essential in this recovery process.[8-10]

After a fracture has been adequately reduced, this reduction can be maintained either operatively, by means of internal or external fixation, or nonoperative with use of a cast or brace immobilization. Both treatment options have their associated risk of secondary dislocation and complications. In the Netherlands, operative management is performed in approximately 20% of patients with a distal radius fracture, and approximately 50% of patients with an ankle fracture.[11, 12]

Follow-up

Following the initial treatment, whether it be operative or nonoperative, patients are monitored to examine the healing process. Follow-up in the Netherlands typically consists of outpatient clinic visits, which include routine multi-view x-ray radiography until the fracture has healed. Usually, a patient is discharged following 12-16 weeks of follow-up, which requires four visits (on average) to the outpatient clinic.[13]

Routine radiographs are common practice both for nonoperatively and operatively treated patients worldwide.[7, 13-16] The main reason to obtain follow-up radiographs is to screen for secondary dislocation of the fracture fragments that might lead to incongruity of the joint. Other reasons include monitoring of bone-healing, identification of potential complications, reassurance to patients or to physicians, education of residents, or medicolegal motives.[15]

The current follow-up regimen for ankle and distal radius fractures arose empirically, and was, therefore, not based upon studies with a high level of evidence. Recent publications have debated the usefulness of routine follow-up radiographs in patients with distal radius and ankle fractures.[11, 17-23] These radiographs did, however, add to radiation exposure for patients and cost for the healthcare system.

When a patient with a distal radius fracture shows uncomplicated fracture healing, health-related quality of life is reported to return to its pre-fracture value after 6 months.[24] Patient-reported functional outcomes do not significantly increase after a year.[25, 26] For ankle fractures, patients reported to regain functionality between 6 to 12 months after injury.[27] One study shows that functional outcome does not improve after more than two years of follow-up.[28]

Cost-effectiveness

In the past decades, healthcare costs have risen, mostly due to increased demand for care and aging of the population.[6] As a result, more attention has been directed towards cost-effectiveness. A cost-effectiveness analysis compares the difference in costs between an intervention and a comparator with the difference in effects.[29] Effects are typically expressed as quality-adjusted life-years (QALYs). This generic utility outcome makes it possible to compare costs of interventions to one another. Policymakers can use these data, together with a budget impact analysis, to assess where to allocate funds, or what interventions are worth implementing.

One way to improve cost-effectiveness of clinical practice is to reduce low-value care. The "Choosing Wisely" campaign was initiated in 2012 with the aim to reduce low value care. That is to reduce the use of procedures, treatments and diagnostic tests if there are signs of overuse, potential harm, or significant and unjustifiable costs.[30] Routine radiography during the follow-up of distal radius and ankle fractures might be an example of a diagnostic test with questionable value, i.e., low value care.

Routine radiographs of the distal radius and ankle present a significant burdening to both healthcare and socio-economic systems.[31, 32] In the Netherlands, the cost for obtaining a multi view radiograph is €52.[33] The total amount spent on radiography for distal radius and ankle fractures is estimated to be €19.2 million annually.[*] A reduction in the number of routine radiographs, therefore, could have a significant impact on healthcare expenditures.

In addition to this economic burden, the follow-up regimen encumbers both patients and physicians. Time and effort are wasted by patients traveling to the outpatient clinic, which is additionally cumbersome for those suffering from a reduced mobility as a result of their fracture. It would appear evident that follow-up regimens should, therefore, be diminished if they have no added clinical benefit.

In short, the aim of this thesis was to investigate the effectiveness and cost-effectiveness of routine radiography during follow-up in those with ankle and distal radius fractures.

OUTLINE OF THE THESIS

A systematic review was performed to evaluate the current use as well as the added value of follow-up radiography and the impact of routine radiography on extremity fractures. The results of this review are presented in **Chapter 2.**

To create insight in the current use of routine radiography in standard care, and to determine its impact on the treatment strategy two retrospective studies were conducted. One study on the use of routine radiography in patients with a distal radius fractures was published prior to the onset of this doctorate by a fellow researcher.[11] The second study regarding the use of routine radiography in ankle fracture patients is discussed in detail in **Chapter 3.**

The retrospective design makes both these studies susceptible to bias. In order to provide more definitive evidence, a prospective trial was required: The WARRIOR trial. A multi-center randomized controlled trial with a four-armed design.

One of the arms of the trial was aimed at patients with an ankle fracture. Participants were randomized between the current standard of care routine follow-up regimen and a reduced imaging follow-up regimen. The clinical and functional outcomes for both groups are presented in **Chapter 4.** The results on cost and resource usage, and cost-effectiveness of the intervention are presented in **Chapter 5.**

[*] Based on an annual incidence of 55,000 distal radius fractures, 30,000 ankle fractures and a median number of 4 and 5 radiographs per patient during the treatment of these fractures respectively

The second trial arm concerning patients with a distal radius fracture was similar in setting and design to the ankle fracture arm. Findings and conclusions concerning the functional outcomes of these patients are reported in **Chapter 6**, whereas results on cost-effectiveness are reported in **Chapter 7.**

Finally, for our trials' findings to be incorporated into daily clinical practice, insight on what barriers and facilitators of patients and physicians hinder or aid the implementation these results is required. **Chapter 8** reports on our study into these barriers and facilitators, and by what means and strategies our research finding may best be used by policy makers.

All studies and how to proceed with follow-up radiography are discussed in **chapter 9**. An English summary is given in **Chapter 10.** A Dutch translation and further information of the author are presented in **Chapter 11** and the subsequent **appendices**.

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2

The value of radiography in the follow-up of extremity fractures. A systematic review

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Archives of Orthopaedic and Trauma Surgery. 2018;138:1659–69

ABSTRACT

Background

The added value of routine radiography during the follow-up of extremity fractures is unclear. The aim of the present systematic review was to create an overview of radiography use in extremity fracture care and the consequences of these radiographs for the treatment of patients with these fractures.

Methods

Studies were included if they reported on the use of radiography during the follow-up of extremity fractures and on its influence on the treatment strategy, clinical outcome, or complications. A comprehensive search of electronic databases (i.e., PubMed, Embase, and Cochrane) was performed to identify relevant studies. Methodological quality was assessed with the Newcastle-Ottawa scale for cohort studies. Level of evidence was assessed with use of GRADE. The search, quality appraisal, and data extraction were performed independently by 2 researchers.

Results

Eleven studies were included. All studies were retrospective cohorts. Of these, only 2 used a comparative design. Two of the included studies described fractures of both the upper and lower extremities, 4 studies concerned fractures of the lower extremity only, and 5 studies focused on fractures of the upper extremity. Pooling of data was not performed because of clinical heterogeneity. Eight studies reported on a change in the treatment strategy related to radiography. Percentages ranged from 0 to 2.6%. The overall results indicated that radiographs made during the follow-up of extremity fractures seldom alter the treatment strategy, that the vast majority of follow-up radiographs are made without a clinical indication and that detection of a complication on a radiograph, in the absence of clinical symptoms, is unlikely. All included studies were regarded of a 'very low' level when scored with GRADE.

Conclusions

Based on current literature, the added value of routine radiography during the follow-up of extremity fractures seems limited. Results, however, should be interpreted with care, considering that available evidence is of a low level.

INTRODUCTION

Traumatic skeletal fractures are commonly encountered in healthcare and present a large medical and socio-economic burden.[1, 2] The majority of fractures occur in either the upper or lower extremity. For example, fractures of the wrist, hand and ankle represent roughly 50% of all skeletal fractures.[3] Because of the aging population, the incidence of extremity fractures is expected to increase in the coming decades.[4] Current national and international protocols recommend frequent outpatient clinic visits at which radiographs of the fractured extremity are made. These radiographs can be used to check for (secondary) dislocation, assess bone-healing and provide early detection of complications.[5-8] Other reasons for radiographic imaging include resident education, reassurance of patients, and medicolegal protection.[9] The costs and cost-effectiveness of diagnostic imaging for traumatic skeletal fractures are becoming increasingly important factors in clinical decision-making.[10] Recent studies have assessed routine radiography use in patients with distal radius and ankle fractures. These studies suggested that radiographs made without a clinical indication do not lead to changes in the treatment strategy whilst adding to treatment cost.[11-13] The added value of radiographs for other fractures of the extremities and their consequences for the treatment strategies are still unclear. Therefore, the aim of this review was to analyze studies that examine the influence of follow-up radiography for extremity fractures on the treatment strategy. Specifically, we focused on whether omission of these more or less routine radiographs is associated with a delayed detection of complications and subsequently a possible deteriorated functional outcome.

METHODS

The present systematic review was conducted adhering to the Preferred Reporting Items for Systematic Reviews and Meta-analysis (PRISMA) guidelines.[14] Our methods include a comprehensive search of the literature, independent selection of studies, as well as assessment of the methodologic quality of these studies and extraction of the clinical outcomes by 2 of the authors.

Search Strategy

A comprehensive literature search was conducted in multiple databases (i.e., PubMed, Embase, and the Cochrane library) on October 9, 2017. The search strategies were developed with the guidance of a trained medical librarian and included combinations of different terms and synonyms for effectiveness, radiographs, and both upper and lower extremity fractures. In addition, the reference lists of the selected articles were screened for any other relevant studies not identified in the electronic search. The search was limited to studies published in the English or Dutch language and was aimed at studies on adult, human subjects. The detailed search strategy is presented in Appendix 1.

The search was repeated on July 10, 2018. In total, 385 additional articles were identified and added to the screening process. No additional relevant studies were found, and thus, none were added to the analysis.

Inclusion Criteria

We included studies that described radiographic imaging during the follow-up of fractures of the upper and/or lower extremities. One of the outcome measures had to be either the influence of radiographic imaging on a change in the treatment strategy, the association between radiographic imaging and complications (i.e., a lower number of complications detected, or a delayed detection of a complication because of the omission of radiographs) or a possible relation between the omission of radiographs and clinical outcomes (i.e., because of a possible missed complication) such as: range of motion, a functional outcome score (on a validated test/questionnaire), quality of life (with use of a validated questionnaire), or pain (with use of a validated instrument). Both randomized controlled trials and observational studies were eligible for inclusion. Case reports and small case series (<20 subjects) were not included, as well as studies mainly describing patients with pathologic fractures, open fractures (Gustilo grade II/III), severely injured patients (ISS >16), studies not reporting on the use of radiography in a follow-up setting (but rather in a diagnostic setting), and studies reporting the use of intra-operative control radiographs or their directly post-operative equivalents.

Selection of Studies

After removal of duplicate records, the titles and abstracts of the remaining studies were independently screened by 2 authors with use of the online systematic review tool "Covidence" (www.covidence.org, Veritas Health Innovation Ltd.) Articles selected based on title and abstract were evaluated fully. If it was unclear whether a study met the inclusion criteria or if no abstract was available, but the title suggested relevance, the full text of the article was assessed for eligibility as well. In the case of a dispute, consensus between the 2 reviewers was reached by discussion or by consulting an arbiter, if necessary.

Assessment of Methodological Quality

Methodological quality of the included studies was assessed with the Newcastle-Ottawa scale (NOS) by 2 authors independently. In the case of inconsistent results, consensus between the 2 reviewers was reached by discussion. The Newcastle-Ottawa scale is a frequently used assessment tool for the methodological quality of nonrandomized studies.[15] Separate scales are available for case-control and cohort studies. For the present systematic review, we used the scale that evaluates cohort studies, as none of the included studies were randomized or had a case-control design.

The Newcastle-Ottawa scale assesses the methodological quality of studies on 8 different criteria distributed over 3 domains: selection, comparability, and outcome. It is designed to measure the risk of selection bias, information bias, and confounding. Scoring is performed by allocating points when the criteria are met. A total of 9 points equals a perfect score. The scale for cohort studies is presented in Appendix 2.

Data Extraction and Management

The following study characteristics were extracted: study design, country of origin, fracture location and/or type, number of participants, inclusion and exclusion criteria, participant demographics and study setting, number of (routine) radiographs, outcomes (including changes in the treatment strategy, the number of complications detected on a radiograph, radiographic changes compared with previous imaging or differences in clinical outcome), duration of follow-up, and results. Data extraction was performed by 2 authors independently. In the case of a dispute, consensus between the 2 reviewers was reached by discussion.

Analysis of Results

If the identified studies were clinically homogeneous, a meta-analysis was performed. If the studies were too heterogeneous to pool the data, we performed a descriptive review.

Assessment of Level of Evidence

The GRADE method was used to evaluate the overall quality of the evidence and weigh the recommendations.[16] In GRADE, the levels of evidence are stratified high, moderate, low, and very low. Observational studies are primarily labelled 'low'. A study can gain a 'level' if a large (e.g., RR <0.5) or very large (RR <0.2) effect was found, if there is evidence of a dose-response effect (although this is not applicable to the present systematic review), or if plausible residual bias or confounding would only result in study findings being more distinct. On the other hand, a study might drop a 'level' if there were limitations in the study design and execution and if there was inconsistency, indirectness, imprecision, or publication bias.

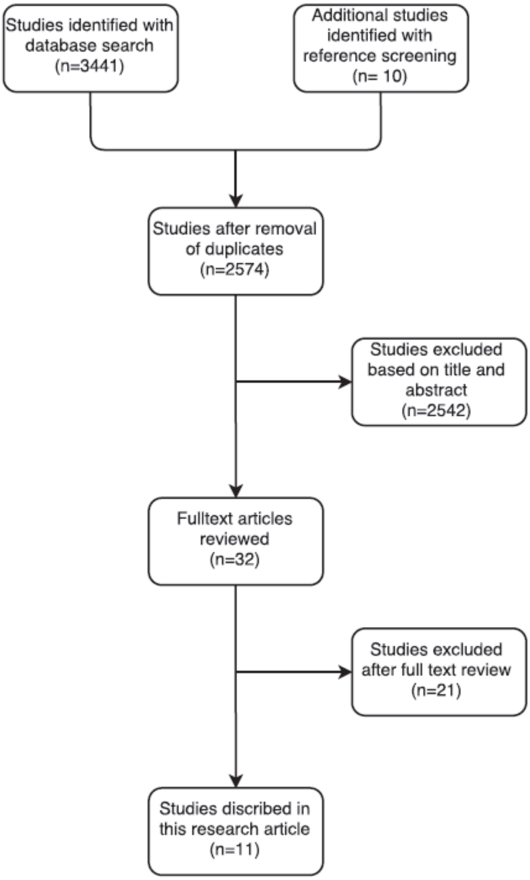

Fig. 1. Flowchart of the article selection process

RESULTS

Search Results

The literature search yielded 2564 unique references. Of these studies, 9 were included. Manual screening of reference lists yielded 2 additional studies. This resulted in 11 unique studies, totaling 4873 participants. The selection process is illustrated in Fig. 1. All studies excluded after full-text review and the reason for exclusion are listed in the Appendix.

Study Characteristics and Overall Results

Two of the included studies described fractures of both the upper and lower extremities.[17, 18] 4 studies concerned fractures of the lower extremity only.[19-22] The remaining 5 studies focused on fractures of the upper extremity.[23-27] The extracted characteristics per study are listed in Table I.

All the included studies used a retrospective cohort design, were conducted in a hospital setting, and evaluated the use of plain radiographs. Two studies compared outcomes between 2 groups (i.e., 1 group with a complete set of radiographs as per protocol, and another group, where some radiographs were omitted). Three of the included studies reported on the number of routine radiographs. Ghattas et al.[18] (92.5%), Weil et al.[23] (86%), and Huffaker et al.[25] (94%) all reported that a large majority of follow-up radiographs is not made for a clinical indication. Three studies mainly focused on complications. They concluded that the detection rate of a complication on a radiograph not made for a clinical indication was low. Similarly, detection rate of complications was not reduced by the omission of routine radiographs. Mean follow-up length within the studies ranged from 9 days to 64 months. For all studies, this was regarded adequate to evaluate the used outcome measures. The outcome measures that were studied and results of the included studies are reported in Table II.

The included articles were clinically too heterogeneous for pooling of data to be meaningful. We therefore chose to describe the results of the individual studies.

Methodological Quality

On the Newcastle-Ottawa scale the included studies earned a total number of 3 to 6 points out of a maximum of 9. For the selection domain, the maximum achieved score was 3 points out of a maximum of 4. As we identified only retrospective studies, none of the studies got a point for item 4: 'demonstration that the outcome of interest was not present at the start of the study'. Schuld et al.,[17] McDonald et al.,[19] and Eastley et al.[26] scored 3 points in the selection domain.

All other studies, with the exception of Robertson et al.,[22] scored 2 points, as there was no nonexposed cohort. None of the studies fulfilled the criteria for comparability, given that none controlled for baseline factors. 6 studies (i.e., McDonald et al.,[19] Ovaska et al.,[20] Kempegowda et al.,[21] Weil et al.,[23] Stone et al.,[24] and Huffaker et al.[25]) scored the maximum number of 3 points for the outcome domain. All other studies scored 2 points, mainly because no statement was made on the adequacy of follow-up. (Table III).

Table I. Characteristics of the studies included in the systematic review

Author	Year	Country	Fracture location and type	No. of participants	Inclusion / Exclusion	Length of follow-up mean (range)	Compared groups
de Beaux	1992	Scotland	Elbow joint	31	incl: patients without a fracture, but with a positive fat pad sign on ED radiographs excl: no FU radiographs, no-show on 2w visit	2 weeks	-
Eastley	2012	UK	Conservatively treated, extra articular, distal radius fracture	138	Incl: hand therapy, grip strength + ROM. excl age <16. Goyrand-Smith fracture, Open fracture. NV symptoms, other ER, no initial or follow-up radiographs, instability/pain at follow-up.	until discharge from physiotherapy	Short (1st x > 2w, n=77) vs Long (1st x <2w, n=61)
Ghattas	2013	USA	All: pelvis, acetabulum, tibia, ankle, clavicle, elbow, hip, wrist, foot, knee, femur, forearm, humerus, scapula.	171 (200 fractures)	incl: acute fracture age<18, time to surgery>2weeks, surgical fixation with implants, radiograph at 1st post-op visit. excl: spine and skull fractures.	24 days (7-61)	-
Huffaker	2014	USA	Distal radius fracture, AO type-A	158 (446 radiographs)	incl: patients with volar locking plate surgery, excl: open fracture, both bone forearm#, skeletal immature, severely injured patients (ISS>16)	4.2 months (1.5-48)	-
Kempegowda	2016	USA	Healed intertrochanteric fracture	465	incl: clinical and radiological consolidation, FU >1Y excl: age<60, pathological fracture, periprosthetic fracture, sec. dislocation, nonunion	81.2 weeks (52-368)	-
McDonald	2014	USA	Operatively treated ankle fracture	1411	incl :surgical fixation excl: open fracture, incomplete charts, no radiography between T+7 and T+120 days	until discharge from clinic	Early (x w 1-3 n=889) vs. Late (x >3w, n=522)

Table I. Characteristics of the studies included in the systematic review (continued)

Author	Year	Country	Fracture location and type	No. of participants	Inclusion / Exclusion	Length of follow-up mean (range)	Compared groups
Ovaska	2016	Finland	Operatively treated ankle fracture	878	incl: age 16+ ORIF of the fracture	64 months	-
Robertson	2000	Scotland	Isolated, closed tibial shaft fracture	53 (343 radiographs)	incl: treated with intramedullary nailing,	no statement. time to union: 24 weeks (10 to 73)	-
Schuld	2016	USA	Non-displaced fracture of hand, wrist, ankle or foot	265 (27 post-splinting X, 179 repeat X at FU)	incl: non-dislocated fracture, plaster immobilization. excl: brace immobilization	9 days (1-135)	-
Stone	2015	USA	Operatively treated distal radius fracture	261 (268 fractures)	excl: skeletal immaturity, absent 2-week radiograph, less than 3 sets of radiographs	12 weeks	-
Weil	2017	NL	Both operatively and conservatively treated distal radius fractures	1042	incl: age >18 excl: absence of FU data, pathologic fracture, open fracture, >1simultaneous fracture of the extremities	no statement	-

Legend for Table I
AO: Arbeitsgemeinschaft für Osteosynthesefragen
ROM: Range Of Motion
FU: Follow-Up
ISS: Injury severity score
ER: Emergency room
ORIF: Open Reduction, Internal Fixation
SD: Standard Deviation

Table II. Measured outcomes and results of included studies outcomes

Author	Relevant measured outcome(s)	Changes in management	Results
de Beaux	change in treatment strategy	0/31 (0%)	6% fractures observed (2 patients), no changes treatment strategy
Eastley	Grip strength, ROM, conversion to operative care	0/61 (0%)	Grip strength / ROM: no difference. no conversion to operative care based on late radiographs.
Ghattas	No. of radiographs per patient, changes from normal postoperative management	3/200 (1.5%)	3/200 changes from normal postoperative management
Huffaker	% clinical findings (changes from expected normal FU), % radiographic findings(hardware or fracture complications), re-intervention, complications	-	0% radiographic complications.
Kempegowda	changes on radiographs obtained after radiological healing had been established. no. of radiographs and clinic visits, complications, costs	-	No. of clinic visits: 2.8, no. of X-rays: 2.6. 98% no changes, 0.7% AVN 0.7% osteoarthritis 0.7% heterotopic ossification
McDonald	complications	-	Complications: early: 62/889 (7.0%) late 31/522(5.9%) *p* = 0.45
Ovaska	change in treatment strategy	3/878 (0.3%)	3/878 changes in treatment strategy based merely on radiographs (0.3%)
Robertson	changes in treatment strategy.	9/343 (2,6%)	9/343 (2,6%) of follow-up radiographs --> change in treatment strategy
Schuld	dislocation on post-splinting radiographs. secondary displacement on repeat radiographs, change in treatment strategy.	0/27 (0%)	no change in treatment strategy based on post-splinting radiographs. 7.8% sec. dislocation. No change in treatment strategy based on repeat radiographs
Stone	change from normal postoperative management, unplanned re-intervention	3/261 (1.1%)	1% unexpected changes in postoperative management (3pt) (secondary dislocation/hardware failure --> re-intervention (all after new trauma)
Weil	changes in treatment strategy.	11/720 (1.5%)	Change in treatment strategy: 22/841radiographs (2.6%). Changes based on routine radiographs: 11/720 (1.5%). 9/11 (1.2%)prolonged cast immobilization, 2/11 (0.2%) conversion to surgery

Legend for Table II
w: weeks
x: Radiograph
ROM: Range Of Motion
FU: Follow-Up

Table III. Scores per category on the Newcastle-Ottawa scale for methodological quality

Author	Selection (max 4 ★)	Comparability (max 2 ★)	Outcome (max 3 ★)
De Beaux	★★	-	★★
Eastley	★★★	-	★★
Ghattas	★★	-	★★
Huffaker	★★	-	★★★
Kempegowda	★★	-	★★★
McDonald	★★★	-	★★★
Ovaska	★★	-	★★★
Robertson	★	-	★★
Schuld	★★★	-	★★
Stone	★★	-	★★★
Weil	★★	-	★★★

Results on Outcome Measures from Individual Studies

Fractures of both the upper and lower extremities

Two studies found no changes in the treatment strategy for post-splinting and post-operative radiographs of both the upper and lower extremities.

Schuld et al.[17] (NOS 5/9) examined the effect of imaging on the treatment of 265 nondisplaced fractures of the hand, wrist, ankle, or foot. They examined the number of dislocations during the splinting procedure on post-splinting radiographs (n=27) and the number of secondary dislocations in patients with follow-up radiographs made at the outpatient clinic (n=179). No changes in management based on post-splinting radiographs were identified. Secondary dislocation was observed in of 7.8% of participants (n=14). The treatment strategy was unaltered in all these patients. Based on these findings, post-splinting radiographs were labelled "likely unnecessary", and the authors stated that repeat imaging in this patient group should be discouraged.

Ghattas et al.[18] (NOS 4/9) assessed the influence of radiographs on the treatment strategy of extremity fractures that were treated with surgical fixation in a retrospective, 2-year cohort. In total, 200 fractures in 171 patients were included. All changes to normal post-operative management (i.e., all procedures or interventions not typically used in the aftercare of that specific fracture) at the initial outpatient clinic visit were identified. Over a mean follow-up period of 24 days (range 7 to 61 days) 3 out of 200 fractures had a change in the treatment strategy. All 3 changes were based on clinical symptoms, rather than on the radiographs. The authors concluded that radiographs at the initial post-operative outpatient clinic visit do not alter the treatment strategy but do pose a financial burden.

Fractures of the lower extremity:

Four studies showed that radiographs of the lower extremity do not change the treatment strategy, do not have an impact on complications, and should not be made if there are no clinical signs of a complication.

McDonald et al.[19] (NOS 6/9) studied the number of complications in relation to the timing of the first post-operative radiograph in a retrospective cohort of 1411 operatively treated ankle fractures. They divided this cohort in 2 groups. The first group had their initial follow-up radiograph taken in the first 3 weeks following surgery; the second received their initial follow-up radiograph more than 3 weeks after the intervention. They observed 62 complications in 889 patients with 'early' radiographs (7.0%), and 31 complications in 522 patients with radiographs solely made more than 3 weeks after surgery (5.9%). This difference was not significant. The researchers concluded that obtaining early routine radiographs (i.e., in the first 3 weeks following surgery) for all patients with an ankle fracture is of questionable benefit.

Ovaska et al.[20] (NOS 5/9) evaluated the number of changes in the treatment strategy based on radiographs made at the first scheduled outpatient clinic visit in a retrospective cohort of 878 patients with an operatively treated ankle fracture. In 3 out of 878 patients (0.3%), a change in the treatment strategy was observed solely based on a routine radiograph. All these changes were adjustments in weight bearing regimen, either after an initially undiagnosed medial malleolus fracture, or after subtle secondary dislocation. The authors concluded that routine radiographs should probably not be made at the first outpatient clinic visit if no clinical signs of a complication are present.

Kempegowda et al.[21] (NOS 5/9) assessed a cohort of 465 patients with healed intertrochanteric fractures with a mean follow-up period of 81 weeks. The main outcome measure was a radiologic change on radiographs made after clinical and radiologic union had already been demonstrated earlier on. On average, patients had 2.8 outpatient clinic visits, and 2.6 radiographs after union had been confirmed. Of these radiographs, 98% did not reveal changes when compared with previous imaging. Three images (0.7%) showed signs of avascular necrosis of the femoral head, 3 showed osteoarthritis of the hip, and 3 revealed heterotopic ossification. The authors concluded that there is a negligible role for radiographs and clinic visits when evidence of clinical and radiographic healing with acceptable alignment of an intertrochanteric fracture is available.

Robertson et al.[22] (NOS 3/9) retrospectively evaluated 53 patients with an isolated tibial shaft fracture that were treated with an intramedullary nail. Out of 343 radiographs made during follow-up, 9 (3%) directly led to a change in clinical management. In 2 patients, radiographs showed union, and the nail was removed. The remaining 7 patients showed signs of delayed union, which gave rise to nail exchange procedures. The authors concluded that serial radiographs are not justified, and that radiographs prior to 10 weeks follow-up should only be made when there is a clinical suspicion of a complication.

Fractures of the upper extremity

Five studies showed that follow-up radiographs of the upper extremity seldom influenced the treatment strategy, should only be made for a clinical indication and that routine radiography can probably be omitted.

Weil et al.[23] (NOS 5/9) evaluated the use of routine radiographs, and the changes in the treatment strategy based on these radiographs, taken after more than 3 weeks of follow-up in a multi-center cohort of 1042 patients with a distal radius fracture. A radiograph was labelled routine if no clinical indication for obtaining it was registered in the medical records. Of the 720 radiographs that complied with these requirements, 11 (1.5%) led to a change in the treatment strategy. In 9 instances, cast immobilization was prolonged, and in 2 instances, the patient was converted to operative treatment. The conclusion of the authors was that routine radiographs after the initial 3 weeks follow-up period seldom influence clinical decision making.

Stone et al.[24] (NOS 5/9) studied radiographs taken 2 weeks after open reduction and internal fixation of distal radius fractures in a retrospective cohort of 261 patients with 268 fractures. They evaluated the number of changes in the treatment strategy as well as the number of re-interventions. At 2 weeks follow-up, 3 changes in management were recorded (1.1%). All these cases involved patients with a loss of reduction or hardware failure after a consecutive trauma to the injured wrist. The authors concluded that for low-energetic, noncomminuted fractures, routine radiographs at 2 weeks could be omitted.

Huffaker et al.[25] (NOS 5/9) evaluated the value of routine postoperative radiographs in AO type A[28] distal radius fractures treated with volar locking plates. They identified 446 post-operative radiographs in a cohort of 158 patients. During follow-up (mean 4.2 months), none of the radiographs showed nonunion, loss of fixation, or a change in alignment. For patients presenting with symptoms (such as neuropathy, signs of infection, pain, or crepitation), radiography was not associated with a higher likelihood of operative intervention. The authors concluded that radiographs, apart from the primary direct post-operative radiograph, should only be made for a clinical indication.

Eastley et al.[26] (NOS 5/9) assessed 137 patients with extra-articular distal radius fractures that were treated nonoperatively. They investigated whether grip strength, clinical deformity, and range of motion were associated with obtaining radiographs after more than 2 weeks of follow-up. The cohort was divided into 2 groups. One that had radiographs taken only in the first 2 weeks ('early' n=77), and another group that had follow-up radiographs beyond this term as well ('late' n=61). No significant differences in grip strength, mean flexion, dorsiflexion, radial deviation, and ulnar deviation were found. There was no conversion to operative care based on late radiographs. The authors concluded that omission of late radiographs in this patient category may have no adverse effects on clinical outcome whilst providing financial benefits.

De Beaux et al.[27] (NOS 4/9) evaluated a retrospective cohort of 45 patients with a suspected fracture of the elbow region (depicted by a positive fat pad sign, but the absence of a fracture line on the initial emergency room radiographs). The main research question was if repeat radiography after 2 weeks altered the treatment strategy. At the follow-up moment after 2 weeks, 11 patients failed to attend and 3 had no repeat radiographs made. Of the remaining 31 patients, 29 had normal radiographs, and 2 patients were diagnosed with a nondisplaced fracture of the radial head. No changes were made to the treatment of any participant. The authors concluded that routine follow-up radiography is unnecessary in this patient category.

Level of Evidence

All the included studies are observational, and therefore, the initial level of evidence should be considered 'low'. As the studies are retrospective in nature, the risk of bias was regarded high. As a result, the level of evidence was downgraded to 'very low' for all included studies.

DISCUSSION

In total, we identified 11 retrospective studies that examined the possible relation between radiographic imaging and the treatment strategy. Several studies also described the influence of the omission of radiographs on functional outcome or detection of complications. Unfortunately, these studies were clinically so diverse that it was not possible to pool the data. Based upon the descriptive analysis, it appears that all studies come to essentially the same conclusion. They all suggest that omitting some, or even all, follow-up radiographs of extremity fractures does not have important clinical consequences, such as changes in the treatment strategy, a deterioration of clinical outcomes, or missed complications. From the studies we included in the present systematic review, no distinction could be made between different fracture locations or fracture types. However, all conclusions were based upon retrospective studies, introducing a high risk of bias and confounding. The level of evidence was low, indicating that these results should be interpreted with caution. We did not identify any prospective studies. As a result, studies included in this review should be regarded as the best available evidence at present.

For other indications, such as low back pain,[29] knee osteoarthritis,[30] or following paediatric spinal surgery[31] the added value of routine radiographs are being questioned as well. Apparently, for other indications than extremity fractures, radiographs are also made routinely and without great impact on the treatment strategies. In addition, for direct post-operative check radiographs of, for instance, hip fractures, multiple retrospective studies exist that debate their usefulness or discourage their use.[32-35] A randomized study investigating the usefulness of direct post-operative control radiographs for operatively treated wrist and ankle fractures is currently being conducted by Oehme et al.[36] Routine radiographs might resemble low-value care, and omitting them might lead to increased efficiency for the healthcare system. The American College of Foot and Ankle Surgeons released a consensus statement discouraging the use of routine radiographs to monitor fracture, osteotomy, and arthrodesis healing without a clinical indication in the foot and ankle.[37] However, to date, prospective evidence to support this claim is lacking.

In all studies included in this review, the number of changes in the treatment strategy based on radiography was low. As depicted in Table II, it ranged from 0 to 2.6%. The number of complications detected on a routine radiograph, in the absence of clinical symptoms, was similarly low. Both patients and physicians tend to ascertain value to radiographic confirmation of a favourable recovery. However, this review suggests that findings on a routine radiograph that require a change in the treatment strategy, in the absence of clinical symptoms, are rare. The presence of clinical symptoms could be a good predictor of an unfavorable outcome and might justify the use of radiography to rule out a complication. In the randomized controlled trial, we are currently conducting,[38] reasons to obtain radiographs include: a score higher than 6 on a 0-to-10-points visual analogue scale for pain, a loss in range of motion, neurovascular symptoms, or a successive trauma to the injured limb.

It is clear from our overview that interest in this topic is growing. All but 2 studies were published in the last 6 years, and quality and precision of the studies improved over time.

For example, the older 2 studies contributed just 2% to the total number of participants and scored poorly on the Newcastle-Ottawa scale (3 and 4 points out of 9, respectively). The more recent studies included more participants and, on average, scored higher on the Newcastle-Ottawa scale.

Limitations and Strengths

All studies included in this review had a retrospective design and several other limitations in their study design on the Newcastle-Ottawa scale. All studies but 2 had a non-comparative design, and no statistical testing of outcomes was performed. The risk of bias was high, confounding was likely, and the external validity was limited. This resulted in a 'very low' level of evidence according to GRADE.

Conclusions in systematic reviews are dependent on the quality and design of studies included. The fact that only retrospective studies were identified, and the level of evidence was very low hinders us in making strong recommendations. A second potential limitation was the tool used for assessment of the methodological quality of the included studies. The Newcastle-Ottawa scale is best suited for comparative and prospective nonrandomized studies; therefore, this tool might not deliver the best assessment of risk of bias in the current setup. Finally, we limited our search to English and Dutch; therefore, language bias may affect our conclusions. However, no studies in Dutch were identified by the search strategy, and manual screening of the reference lists of included studies did not yield any references in a language other than English. Consequentially, the chance that language bias played a substantial role in the selection process of the systematic review was deemed low.

A strength of the present study is fact that the percentage of included studies was very low (0.4%). This indicates that our initial search was broad, and as a result, the risk that important publications were missed was low.

CONCLUSION

The added value of routine radiography in extremity fractures appears limited, whilst making these radiographs involves effort and cost. Although this conclusion is based upon results of retrospective studies with all concomitant limitations, some reservation in use of follow-up radiographs for extremity fractures seems justified. We urge physicians to be reticent in ordering follow-up radiographs of lower and upper extremity fractures in the absence of a clear clinical indication. Future research in this topic should focus on the conception of prospective randomized studies. These studies should evaluate the impact of routine radiographic imaging on the treatment strategy and the treatment outcomes of patients with extremity fractures. Conducting such a trial seems feasible and might provide a more solid substantiation of our conclusion.

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2

APPENDICES

Appendix 1: search strategy

PubMed/Cochrane

#1 Reduce frequency Radiography

"Radiography"[Mesh] OR "Radiation"[Mesh] OR Diagnostic X-Ray*[tiab] OR Roentgenograph*[tiab] OR Roentgenogram*[tiab] OR X-Ray Radiolog*[tiab] OR reduced imaging[tiab] OR radiograph*[tiab] OR "diagnostic imaging"[Subheading] OR radiation[tiab] OR (Imaging[tiab] AND (protocol*[tiab] OR "standards"[Subheading] OR standards[tiab] OR guideline*[tiab] OR criteria*[tiab] OR practice*)) **AND** ("Diagnostic Tests, Routine"[Mesh] OR "Unnecessary Procedures/economics"[Mesh] OR "Unnecessary Procedures/epidemiology"[Mesh] OR Reducing[tiab] OR omitt*[tiab] OR omission[tiab] OR frequenc*[tiab] OR decreas*[tiab] OR lessen[tiab] OR restrict*[tiab] OR cut down[tiab] OR routine*[tiab])

#2a bones of upperextremity

(("Upper Extremity"[Mesh] OR Upper Extremit*[tiab] OR Membrum superius[tiab] OR Upper Limb*[tiab] OR "Bones of Upper Extremity"[Mesh] OR arm[tiab] OR arms[tiab] OR brachium*[tiab] OR shoulder[tiab] OR clavic*[tiab] OR collar bone*[tiab] OR scapula*[tiab] OR shoulder blade*[tiab] OR acromion*[tiab] OR coracoid*[tiab] OR glenoid[tiab] OR humerus[tiab] OR humeral[tiab] OR Tuberc*[tiab] OR tuberosity*[tiab] OR trochlea*[tiab] OR epicondy*[tiab] OR condy*[tiab] OR elbow*[tiab] OR ulna*[tiab] OR olecran*[tiab] OR radius[tiab] OR radial[tiab] OR coranoid*[tiab] OR forearm*[tiab] OR Antebrachi*[tiab] OR wrist*[tiab] OR hand[tiab] OR hands[tiab] OR finger*[tiab] OR thumb*[tiab] OR carpus[tiab] OR carpal[tiab] OR scaphoid*[tiab] OR navicular*[tiab] OR triquetra*[tiab] OR Metacarp*[tiab] OR phalanges[tiab] OR phalanx[tiab]) AND ("Fractures, Bone"[Mesh:NoExp] OR "Fracture Healing"[Mesh] OR fracture*[tiab] OR broken bone*[tiab]))

Specific types of upper extremity fractures

"Shoulder Fractures"[Mesh] OR "Humeral Fractures"[Mesh] OR "Ulna Fractures"[Mesh] OR Monteggia*[tiab] OR galeazz*[tiab] OR "essex lopresti"[tiab] OR "Radius Fractures"[Mesh] OR Colles*[tiab] OR boxers fracture*[tiab] OR boxer's fracture*[tiab] OR bankart[tiab] OR hill-sachs[tiab] OR Bennett*[tiab] OR Rolando*[tiab] OR smith's fracture*[tiab] OR Goyrand-Smith's[tiab]

#2b bones of lower extremity

(("Lower Extremity"[Mesh] OR Lower Extremit*[tiab] OR lower limb[tiab] OR membrum inferius[tiab] OR "Bones of Lower Extremity"[Mesh] OR leg bone*[tiab] OR hip fracture*[tiab] OR fracture of the hip[tiab] OR fractures of the hip[tiab] OR Femur*[tiab] OR femoral*[tiab] OR trochanter*[tiab] OR intertrochanter*[tiab] OR subtrochanter*[tiab] OR patella*[tiab] OR knee[tiab] OR knees[tiab] OR kneecap*[tiab] OR tibia*[tiab] OR fibula*[tiab] OR foot bone*[tiab] OR feet bone*[tiab] OR Tarsal*[tiab] OR ankle*[tiab] OR cuneiform*[tiab] OR cuboid*[tiab] OR calcaneus*[tiab] OR heel bone*[tiab] OR metatarsal*[tiab] OR toe bone*[tiab] OR toes bone*[tiab] OR hallux*[tiab] OR hallic*[tiab] OR malleol*[tiab] OR trimall*[tiab] OR bimall*[tiab]) AND ("Fractures, Bone"[Mesh:NoExp] OR "Fracture Healing"[Mesh] OR fracture*[tiab] OR broken bone*[tiab]))

Specific types of lower extremity fractures

"Femoral Fractures"[Mesh] OR "Tibial Fractures"[Mesh] OR "Ankle Fractures"[Mesh] OR maisonneuve*[tiab] OR lisfranc*[tiab] OR segond*[tiab] OR tillaux*[tiab]

#3 QoL/ outcome measurements

"Health Status"[mesh] OR "Quality of Life"[mesh] OR "Treatment Outcome"[mesh] OR "Outcome Assessment (Health Care)"[Mesh] OR "Recovery of Function"[Mesh] OR "Clinical Decision-Making"[Mesh] OR clinical indicat*[tiab] OR clinical impact*[tiab] OR treatment strategy[tiab] OR therapeutic polic*[tiab] OR patient management[tiab] OR management policy[tiab] OR clinical management[tiab] OR recovery[tiab] OR "Health Status"[tiab] OR "Quality of Life"[tiab] OR clinical Outcome*[tiab] OR value[tiab] OR "clinical decision making"[tiab] OR "Quality-Adjusted Life Years"[Mesh] OR (("Life years"[tiab]) AND ("Quality adjusted"[tiab] OR adjusted[tiab] OR Gained [tiab])) OR "QUALY"[tiab] OR "LYG" [tiab] OR "Quality adjusted"[tiab] OR ((change*[tiab] OR changing[tiab]) AND management*[tiab])

#4 Adults only

NOT (("Adolescent"[Mesh] OR "Child"[Mesh] OR "Infant"[Mesh] OR adolescen*[tiab] OR child*[tiab] OR schoolchild*[tiab] OR infant*[tiab] OR girl*[tiab] OR boy*[tiab] OR teen[tiab] OR teens[tiab] OR teenager*[tiab] OR youth*[tiab] OR pediatr*[tiab] OR paediatr*[tiab] OR puber*[tiab]) NOT ("Adult"[Mesh] OR adult*[tiab] OR man[tiab] OR men[tiab] OR woman[tiab] OR women[tiab]))

#5 Publication types/ humans

NOT ("addresses"[Publication Type] OR "biography"[Publication Type] OR "Case Reports" [Publication Type] OR "comment"[Publication Type] OR "directory"[Publication Type] OR "editorial"[Publication Type] OR "festschrift"[Publication Type] OR "interview"[Publication Type] OR "lectures"[Publication Type] OR "legal cases"[Publication Type] OR "legislation"[Publication Type] OR "letter"[Publication Type] OR "news"[Publication Type] OR "newspaper article"[Publication Type] OR "patient education handout"[Publication Type] OR "popular works"[Publication Type] OR "congresses"[Publication Type] OR "consensus development conference"[Publication Type] OR "consensus development conference, nih"[Publication Type] OR "practice guideline"[Publication Type]) NOT ("animals"[MeSH Terms] NOT "humans"[MeSH Terms])

EMBASE.com

#1 Reduce frequency Radiography

'radiography'/exp OR 'radiation'/exp OR Diagnostic X-Ray*:ti,ab OR Roentgenograph*:ti,ab OR Roentgenogram*:ti,ab OR X-Ray Radiolog*:ti,ab OR 'reduced imaging':ti,ab OR radiograph*:ti,ab OR 'diagnostic imaging':ti,ab OR radiation:ti,ab OR (Imaging:ti,ab AND (protocol*:ti,ab OR standards:ti,ab OR guideline*:ti,ab OR criteria*:ti,ab OR practice*)) AND ('diagnostic test'/exp OR 'unnecessary procedure'/exp OR Reducing:ti,ab OR omitt*:ti,ab OR omission:ti,ab OR frequenc*:ti,ab OR decreas*:ti,ab OR lessen:ti,ab OR restrict*:ti,ab OR 'cut down':ti,ab OR routine*:ti,ab)

#2a bones of upperextremity

(('upper limb'/exp OR 'Upper Extremit*':ti,ab OR 'Membrum superius':ti,ab OR 'Upper Limb*':ti,ab OR 'bones of the arm and hand'/exp OR arm:ti,ab OR arms:ti,ab OR brachium*:ti,ab OR shoulder:ti,ab OR clavic*:ti,ab OR 'collar bone*':ti,ab OR scapula*:ti,ab OR 'shoulder blade*':ti,ab OR acromion*:ti,ab OR coracoid*:ti,ab OR glenoid:ti,ab OR humerus:ti,ab OR humeral:ti,ab OR Tuberc*:ti,ab OR tuberosity*:ti,ab OR trochlea*:ti,ab OR epicondy*:ti,ab OR condy*:ti,ab OR elbow*:ti,ab OR ulna*:ti,ab OR olecran*:ti,ab OR radius:ti,ab OR radial:ti,ab OR coranoid*:ti,ab OR forearm*:ti,ab OR Antebrachi*:ti,ab OR wrist*:ti,ab OR hand:ti,ab OR hands:ti,ab OR finger*:ti,ab OR thumb*:ti,ab OR carpus:ti,ab OR carpal:ti,ab OR scaphoid*:ti,ab OR navicular*:ti,ab OR triquetra*:ti,ab OR Metacarp*:ti,ab OR phalanges:ti,ab OR phalanx:ti,ab) AND ('fracture'/de OR 'fracture healing'/exp OR fracture*:ti,ab OR 'broken bone*':ti,ab))

Specific types of upper extremity fractures

'shoulder fracture'/exp OR 'humerus fracture'/exp OR 'ulna fracture'/exp OR Monteggia*:ti,ab OR galeazz*:ti,ab OR 'essex lopresti':ti,ab OR 'radius fracture'/exp OR Colles*:ti,ab OR 'boxers fracture*':ti,ab OR 'boxers fracture*':ti,ab OR bankart:ti,ab OR 'hill-sachs':ti,ab OR Bennett*:ti,ab OR Rolando*:ti,ab OR 'smiths fracture*':ti,ab OR 'Goyrand-Smith*':ti,ab

#2b bones of lower extremity

(('lower limb'/exp OR 'Lower Extremit*':ti,ab OR 'lower limb':ti,ab OR 'membrum inferius':ti,ab OR 'bones of the leg and foot'/exp OR 'leg bone*':ti,ab OR 'hip fracture*':ti,ab OR 'fracture of the hip':ti,ab OR 'fractures of the hip':ti,ab OR Femur*:ti,ab OR femoral*:ti,ab OR trochanter*:ti,ab OR intertrochanter*:ti,ab OR subtrochanter*:ti,ab OR patella*:ti,ab OR knee:ti,ab OR knees:ti,ab OR kneecap*:ti,ab OR tibia*:ti,ab OR fibula*:ti,ab OR 'foot bone*':ti,ab OR 'feet bone*':ti,ab OR Tarsal*:ti,ab OR ankle*:ti,ab OR cuneiform*:ti,ab OR cuboid*:ti,ab OR calcaneus*:ti,ab OR heel bone*:ti,ab OR metatarsal*:ti,ab OR 'toe bone*':ti,ab OR 'toes bone*':ti,ab OR hallux*:ti,ab OR hallic*:ti,ab OR malleol*:ti,ab OR trimall*:ti,ab OR bimall*:ti,ab) AND ('fracture'/de OR 'fracture healing'/exp OR fracture*:ti,ab OR 'broken bone*':ti,ab))

Specific types of lower extremity fractures

'femur fracture'/exp OR 'tibia fracture'/exp OR 'ankle fracture'/exp OR maisonneuve*:ti,ab OR lisfranc*:ti,ab OR segond*:ti,ab OR tillaux*:ti,ab

#3 QoL/ outcome measurements

'health status'/exp OR 'quality of life'/exp OR 'treatment outcome'/exp OR 'outcome assessment'/exp OR 'convalescence'/exp OR 'clinical decision making'/exp OR 'clinical indicat*':ti,ab OR 'clinical impact*':ti,ab OR 'treatment strategy':ti,ab OR 'therapeutic polic*':ti,ab OR 'patient management':ti,ab OR 'management policy':ti,ab OR 'clinical management':ti,ab OR recovery:ti,ab OR 'Health Status':ti,ab OR 'Quality of Life':ti,ab OR 'clinical Outcome*':ti,ab OR value:ti,ab OR 'clinical decision making':ti,ab OR 'quality adjusted life year'/exp OR (('Life years':ti,ab) AND ('Quality adjusted':ti,ab OR adjusted:ti,ab OR gained:ti,ab)) OR 'QUALY':ti,ab OR 'LYG':ti,ab OR 'Quality adjusted':ti,ab OR ((change*:ti,ab OR changing:ti,ab) AND management*:ti,ab)

#4 Adults only

NOT (('juvenile'/exp OR'embryo'/exp OR'fetus'/exp OR adolescen*:ti,ab OR child*:ti,ab OR schoolchild*:ti,ab OR infant*:ti,ab OR girl*:ti,ab OR boy*:ti,ab OR teen:ti,ab OR teens:ti,ab OR teenager*:ti,ab OR youth*:ti,ab OR pediatr*:ti,ab OR paediatr*:ti,ab OR puber*:ti,ab) NOT ('adult'/exp OR adult*:ti,ab OR man:ti,ab OR men:ti,ab OR woman:ti,ab OR women:ti,ab))

#5 Publication types/ humans

PT use EMBASE filters
NOT ('animal'/exp] NOT 'human'/exp)

Appendix 2: Newcastle Ottawa Scale

NEWCASTLE - OTTAWA QUALITY ASSESSMENT SCALE
COHORT STUDIES

Note: A study can be awarded a maximum of one star for each numbered item within the Selection and Outcome categories. A maximum of two stars can be given for Comparability

Selection

1) Representativeness of the exposed cohort
   a) truly representative of the average _______________ (describe) in the community ❋
   b) somewhat representative of the average ______________ in the community ❋
   c) selected group of users eg nurses, volunteers
   d) no description of the derivation of the cohort

2) Selection of the non exposed cohort
   a) drawn from the same community as the exposed cohort ❋
   b) drawn from a different source
   c) no description of the derivation of the non exposed cohort

3) Ascertainment of exposure
   a) secure record (eg surgical records) ❋
   b) structured interview ❋
   c) written self report
   d) no description

4) Demonstration that outcome of interest was not present at start of study
   a) yes ❋
   b) no

Comparability

1) Comparability of cohorts on the basis of the design or analysis
   a) study controls for _____________ (select the most important factor) ❋
   b) study controls for any additional factor ❋ (This criteria could be modified to indicate specific control for a second important factor.)

Outcome

1) Assessment of outcome
   a) independent blind assessment ❋
   b) record linkage ❋
   c) self report
   d) no description

2) Was follow-up long enough for outcomes to occur
   a) yes (select an adequate follow up period for outcome of interest) ❋
   b) no

3) Adequacy of follow up of cohorts
   a) complete follow up - all subjects accounted for ❋
   b) subjects lost to follow up unlikely to introduce bias - small number lost - > ____ % (select an adequate %) follow up, or description provided of those lost) ❋
   c) follow up rate < ____% (select an adequate %) and no description of those lost
   d) no statement

Appendix 3: Excluded articles

Author	Year	Journal	Reason for exclusion
Archdeacon	2015	J Orthop Trauma	Study describing direct postoperative 'check radiography'
Bessette	2017	J Arthroplasty	Study describing patients with an artroplasty, not a fracture
Bhattacharyya	2017	Injury	Study describing a reduction in outpatient clinic visit, not radiography
Chakravarthy	2007	Int J Clin Pract	Study describing direct postoperative 'check radiography'
Chaudhry	2012	J Bone Joint Surg Am	Study describing direct postprocedural 'check radiography'
Ferguson	2015	Injury	Study describing a reduction in outpatient clinic visit, not radiography
Harish	1999	Injury	Study describing direct postprocedural 'check radiography'
Jain	2008	Ann R Coll Surg Engl	Study not reporting on any of the required outcome measures
Johnson	2016	Plast Reconstr Surg	Study describing direct postoperative 'check radiography'
Kurup	2008	Eur J Orthop Surg Traumatol	Study describing direct postoperative 'check radiography'
Michelson	1995	J Trauma	Study not reporting on any of the required outcome measures
Miniaci-Coxhead	2015	Foot Ankle Int	Study describing direct postoperative 'check radiography'
Mohanti	2000	J R Coll Surg Edinb	Study describing direct postoperative 'check radiography'
Moody	2016	J Orthop Trauma	Study not reporting on any of the required outcome measures
Morewood	1987	Br. Med J (Clin Res Ed)	Study with a large percentage (26%) of pediatric patients
O'Shea	2006	J Orthop Surg (Hong Kong)	Study describing direct postoperative 'check radiography'
Pannell	2016	Hand (N Y)	Study without "clinical" cases, solely imaging.
Quinton	1987	J Bone Joint Surg Br	Study describing patients without a fracture.
Stott	2017	J Orthop Trauma	Study describing direct postoperative 'check radiography'
Welsh	1987	Br Med J (Clin Res Ed)	Correspondence with comment on a research article (Morewood 1987)
Westerterp	2013	Eur J Trauma Emerg Surg	Study describing direct postoperative 'check radiography'

3

Routine Follow-up Radiographs for Ankle Fractures Seldom add Value to Clinical Decision-making: A Retrospective, Observational Study

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N.L. Weil
M.F. Termaat
S.M. Rubinstein
M. El Moumni
W.P. Zuidema
J.M. Hoogendoorn
H.G.W.M. van der Meulen
M.W. van Tulder
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The Journal of Foot & Ankle Surgery. 2018;57:957–60

ABSTRACT

Background

Currently, the routine use of radiographs for uncomplicated ankle fractures represents good clinical practice. However, radiographs are associated with waiting time, radiation exposure, and costs. Studies have suggested that radiographs seldom alter the treatment strategy if no clinical indication for the radiograph was present. The objective of the present study was to evaluate the effect of routine radiographs on the treatment strategy during the follow-up period of ankle fractures.

Methods

All patients aged ≥18 years, who had visited 1 of the participating clinics with an eligible ankle fracture in 2012 and with complete follow-up data were included. The data were retrospectively analyzed. The sociodemographic and clinical characteristics and the number of, and indications for, the radiographs taken were collected from the medical records of the participating clinics. We assessed the changes in treatment strategy that were a result of the radiographic findings.

Results

In 528 patients with an ankle fracture, 1174 radiographs were made during the follow-up period. Of these radiographs, 936 (79.7%) were considered routine. Of the routine radiographs taken during the follow-up period, only 11 (1.2%) resulted in changes to the treatment strategy.

Conclusion

Although it is common practice to take radiographs routinely during the follow-up period for ankle fractures, the results from the present study suggest that routine radiographs seldom alter the treatment strategy. This limited clinical relevance should be weighed against the healthcare costs and radiation exposure associated with the use of routine radiographs. For a definitive recommendation, however, the results of our study should be confirmed by a prospective trial, which we are currently conducting.

INTRODUCTION

Routine radiography during outpatient fracture treatment is known to contribute to the increasing costs of healthcare.[1] The cost-effectiveness of diagnostic imaging has become an increasingly important factor in clinical decision-making with healthcare costs increasing globally.[2] Despite this, routine radiographs made during outpatient clinical visits of patients with an ankle fracture are a common worldwide practice.[3, 4] The arguments for routine radiography include monitoring of bone-healing, identification of complications, resident education, reassurance for the physician and patient, and medicolegal motives.[4] Currently, the added value of routine radiographs is under discussion. Several studies examining the value of radiographs immediately after splinting and radiographs taken at the first postoperative outpatient clinic visit have suggested that radiographs without a clear clinical indication (e.g., pain, loss of mobility, or subsequent trauma to the ankle) will not lead to a change in the treatment strategy.[1, 5-10] These radiographs did, however, contribute to additional radiation exposure and unnecessary costs.

In the Netherlands, with a population of 17 million people, the costs of radiographs during the follow-up period for ankle fractures has been ~3 million Euros annually, based on an incidence of 15,000/y and 4 occasions per patient when a radiograph is made, costing €50 each.[11] Considering that the incidence of ankle fractures is expected to increase worldwide in the coming decades because of an aging population,[12] the clinical value of routine radiographs for monitoring fracture healing and delivering good quality care must be established.

We undertook a retrospective cohort study to identify cases in which an outpatient clinic visit during the follow-up of ankle fractures, which included a routine radiograph that led to a change in the treatment strategy. The objective of the present study was to evaluate whether routine radiographs made during the follow-up for patients with an ankle fracture altered the treatment strategy. We hypothesized that routine radiographs during the follow-up of uncomplicated ankle fractures would not alter the treatment strategy.

METHODS

Study Population

We retrospectively analyzed the information from consecutive patients with complete follow-up data available from 4 level 1 trauma centers in the Netherlands, 2 university hospitals and 2 large teaching hospitals. Patients ≥18 years of age with non-Weber[13] type A ankle fractures (unimalleolar, bimalleolar, or trimalleolar fractures with a Lauge-Hansen[14] classification of supination-adduction [SA] 2, supination-external rotation [SE] 2 to 4, pronation-external rotation [PE] 1 to 4, or pronation-abduction [PA] 1 to 3 (14) that had occurred from January 1, 2012 to December 31, 2012 were eligible for inclusion. Distortions and isolated Danis-Weber classification type A fractures (15) were not included. The exclusion criteria were pathologic fractures, open fractures, multiple fractures, and severe injuries (injury severity score ≥16). The follow-up period consisted of the time the patient was receiving treatment at 1 of our affiliated hospitals. No active monitoring was pursued after this period.

Study Procedure

The present investigation was performed in compliance with the current laws and ethical standards in the Netherlands. All data were stored in accordance with Dutch privacy legislation. All participating centers used a follow-up protocol that recommends radiographs at follow-up consultations 1, 2, 6, and 12 weeks after trauma or surgical fixation. The following data were extracted from the medical records: baseline patient characteristics, including age, sex, and American Society of Anesthesiologists score, fracture type according to Lauge-Hansen[14] and Danis-Weber[13] classification schemes, the treatment strategy, the date of trauma and date of discharge from monitoring, the dates, number of, and indications for the radiographic assessments, and whether the initial treatment strategy was changed by the information gathered from the radiographs.

In the present study, the standard set of anteroposterior, lateral, and mortise views was counted as 1 radiographic assessment. The fracture type was classified according to the radiographs taken at the emergency department or, when the patient had first been treated at a different emergency department, during the first consultation visit. A radiograph was considered routine if the physician had not documented the clinical indication for performing the radiograph in the medical record.

A distinction was made between radiographs taken during the first 3 weeks after trauma (defined as the treatment period, during which a treatment strategy was drafted and surgical fixation might be performed) and radiographs taken after the first 3 weeks (defined as the follow-up period, in which the main reasons for taking radiographs were to monitor bone-healing and assess for complications). In the present study, we focused solely on radiographs taken during the follow-up period. The patients were stratified into 2 groups according to the treatment strategy (i.e., operative or nonoperative management).

Statistical Analysis

Descriptive statistics are reported for the baseline characteristics, fracture type, and radiographic characteristics. The outcome values are reported separately for nonoperatively and operatively managed patients. Categorical data were compared with use of a χ^2 test. Continuous data were compared with use of an unpaired *t* test. For all statistical tests, significance was assumed at $p < 0.05$. All analyses were performed with use of SPSS statistics for Windows (version 23; IBM Corp., Armonk, NY).

RESULTS

In the cohort of 601 consecutive patients with an ankle fracture, 73 were excluded by the exclusion criteria. The study group included 528 patients, 238 (45%) males and 290 females (55%). The mean age of all patients was 49.9 ± 19.5 (standard deviation) years. Of the 528 patients, 261 (49%) were managed nonoperatively and 267 (51%) were treated operatively. The baseline characteristics are listed in Table I. The median

Table I. Baseline Characteristics of participants

		Total cohort (n=528)		Nonoperative treatment (n=261)		Operative treatment (n=267)		*p*-value
Male Sex	*n (%)*	238	(45%)	121	(46%)	117	(44%)	0.56
Age	*mean (SD)*	49.9	(19.5)	53.5	(20.5)	46.5	(18.0)	**<0.05**
ASA score	*n (%)*							
	1	281	(53%)	135	(52%)	146	(55%)	0.50
	2	166	(32%)	72	(28%)	94	(35%)	0.06
	3	71	(13%)	48	(18%)	23	(9%)	<0.05
	unknown	10	(2%)	6	(2%)	4	(1%)	0.50
Fracture type	*n (%)*							
	Lauge Hansen SA	7	(1%)	7	(3%)	0	(0%)	<0.05
	Lauge Hansen SE	360	(68%)	198	(76%)	162	(61%)	<0.05
	Lauge Hansen PE	135	(26%)	40	(15%)	95	(36%)	<0.05
	Lauge Hansen PA	15	(3%)	7	(3%)	8	(3%)	0.87
	Posterior malleolar only	10	(2%)	8	(3%)	2	(0.7%)	0.51
	Weber C stress fracture only	1	(0.1%)	1	(0.3%)	0	(0%)	0.31

Legend for table I
SD: Standard deviation;
ASA: American society of Anesthesiologists;
SA: Supination adduction;
SE: Supination exorotation;
PE: Pronation exorotation;
PA: Pronation abduction.
Bold = a significant difference between groups ($p < 0.05$)

follow-up period was 14.1 (range 1.1-133) weeks for all patients. The details regarding the use of radiographs and the influence of the radiographic findings on the treatment strategy are listed in Table II. In the nonoperatively managed patients, 257 radiographs were made during the treatment period (median per patient of 1; range 0 to 3), and 415 radiographs were made during the follow-up period (median 2, range 0 to 6).Of the 415 radiographs taken during the follow-up period, 337 (90%) were scored as routine radiographs. In the operatively managed patients, 364 radiographs (median 1; range 0 to 4) were made during the treatment period, and 759 radiographs (median 3; range 0 to 11) were made during the follow-up period.

Of the 759 radiographs taken during the follow-up period, 563 (74%) were scored as routine radiographs. In the nonoperatively and operatively managed patients, 6 of 337 and 5 of 563 routinely scored radiographs, respectively, resulted in a change in the treatment strategy (Table III).

Table II. Usage of (routine) radiography in the follow-up of ankle fractures.

	Patients (n=528)	**Nonoperative management** (n=261)	**Operative management** (n=267)
Treatment-period:			
No. of radiographs (median, range)	621 (1, 0-4)	257 (1, 0-3)	364 (1, 0-4)
Follow-up-period:			
No. of radiographs (median, range)	1174 (2,0-11)	415 (2, 0-6)	759 (3, 0-11)
No. of routine radiographs	936 (80%)	373 (90%)	563 (74.2%)
No. of radiographs on clinical indication	238 (20%)	42 (10%)	196 (25.8%)
Radiographs leading to a change in treatment strategy	23 (2.0%[a])	8 (1.9%[a])	15 (2.0%[a])
Routine radiographs leading to a change in treatment strategy	11 (1.2%[b])	6 (1.6%[b])	5 (0.9%[b])

Legend for Table II

[a] Radiographs leading to a change in treatment strategy / No. of radiographs in follow-up period.

[b] Routine radiographs leading to a change in treatment strategy / No. of routine radiographs.

Table III. Routine radiographs leading to a change in treatment strategy

Change in treatment strategy:	**Routine radiographs** (n=936)
Total number of changes N(%)	11 (1.2%)
Prolonged cast immobilization (two weeks)	6 (0.6%)
Changed to surgical treatment 3 weeks after trauma	2 (0.2%)
Changed to surgical treatment 6 weeks after trauma	1 (0.1%)
Changed to surgical treatment 5 months after trauma	1 (0.1%)
Cancellation of scheduled implant removal	1 (0.1%)

Cast immobilization was prolonged by 2 weeks for 6 patients, nonoperative management was changed to operative management for 4 patients, and a planned implant removal was canceled for 1 patient because no radiologic consolidation was visible. Of the 4 patients who were scheduled for surgery because of findings from routine radiographs, 2 were assigned to operative management during their second outpatient clinic visit, which was 21 days after the initial trauma. The third patient complained of pain during the first 3 months after the trauma and was referred for physiotherapy. During the next outpatient clinic visit 5 months after the trauma, no complaints were documented; however, the patient was assigned to operative management because no signs of consolidation were seen on the radiographs. The fracture of the fourth patient scheduled for surgery was 2 weeks old before presentation at the emergency department and was initially deemed suitable for nonoperative management. The patient was assigned to surgery during the first outpatient visit 4 weeks later owing to secondary loss of reduction.

In the present cohort, 1174 (65.4%) of the total of 1795 radiographs were taken during the follow-up period. Of these 1174 radiographs, 936 (79.7%) were considered routine. For the general Dutch population, this could mean that 65.4% (€1,962,000) of the total annual radiographic costs of €3 million is spent within the follow-up period. Of these costs, 79.7% (€1,563,714) can be attributed to routine radiography. This indicates that with use of the data found in the present cohort, 52% of all the costs involved in radiography of ankle fractures could potentially be saved by omitting routine radiographs during the follow-up period.

DISCUSSION

We assessed the effect of conducting routine radiographs during the follow-up period on clinical decision-making in a large cohort of patients with ankle fractures. Our results suggest that only a small percentage (1.2%) of routine radiographs made during the follow-up period will lead to changes in patient management, with effort and cost involved in generating these radiographs. Just 2 of 936 radiographs taken during the follow-up period (0.2%) led to surgical fixation based on radiologic findings (i.e., secondary dislocation in 1 patient, and nonunion 1 patient scheduled for surgery). These findings should be considered in light of the increasing healthcare costs and unnecessary exposure to radiation. Although the quantified radiation dose of a single ankle radiograph is low,[15] it is difficult to defend administering even small amounts of ionizing radiation, if the indication to do so is lacking. In addition, each radiograph requires an investment in time from the patient, their companion, and the healthcare professionals involved.

We divided the therapy of our patients into a treatment period and a follow-up period and focused solely on the latter. We did this to diminish any bias that might arise because of differences in fracture-specific, surgeon-specific, or hospital-specific preferences in the early phases of ankle fracture treatment. Previous studies have also focused on routine radiographs taken in later stages of treatment, when protocols are more standardized or have a greater level of adherence[1, 7]. The present results are consistent with previous studies.[1, 4-7] For example, Ghattas et al., Miniaci-Coxhead et al., Ovaska et al., and Harish et al. demonstrated that radiographs taken at the first postoperative clinic visit of patients with various fracture types did not provide any additional clinically relevant information.[1, 6, 8, 9] Eastly et al. studied the effect of radiographs late in the follow-up of distal radius fractures.[7] To the best of our knowledge, to date, no studies have evaluated the use of routine radiographs in the follow-up period of patients with ankle fractures. The present study explored the use of routine radiographs in a large cohort of patients with a non-Weber type A ankle fracture. We choose not to include isolated Danis Weber type A fractures (Lauge-Hansen SA1), because these mainly represent ligamentous injuries, and no radiologic follow-up is recommended for this type of trauma (3). All types of ankle fractures requiring radiologic follow-up (Lauge-Hansen SA 2, SE 2 to 4, PE 1 to 4, and PA 1 to 3) and all treatment strategies (operative and nonoperative management) were included in the present evaluation.

However, the present study had some important limitations. Given its retrospective character, clinically relevant information that might affect fracture healing (e.g., smoking habits[16]) could not be retrieved from the medical records for many patients. Subsequently, the observed number of changes in the treatment strategy might be an underestimation of the assumed effects of these radiographs, because the radiographs can also confirm a correct treatment strategy and acknowledge its continuation. This effect could not be measured in the present study, because this is often not noted in the medical records.

Perhaps even more important is that the clinical indications to generate a radiograph might not always have been properly documented. If no clinical indication was noted in the medical records, a radiograph was considered "routine," potentially leading to an underestimation of the number of radiographs made for a clinical indication. We undertook a crude estimation of the costs of routine radiographs during the follow-up period of ankle fractures. Given the potential underestimation of the number of radiographs made for a clinical indication, these results should be interpreted with care. Second, our analysis does not represent either a cost-effectiveness analysis or a cost-benefit analysis, because the data on the cost associated with a possible gain of health in terms of quality-adjusted life-years or incremental cost differences could not be retrieved from the medical records in the retrospective study design. Similarly, documentation on the continuation of the preset treatment strategy based on the radiographic findings was probably also lacking in many cases. We only considered the documented reasons for a change in the treatment strategy, which created a bias such that the total influence of radiographs on the continuation of the treatment strategy would have been underestimated. Nevertheless, even if we included a certain range of cases in which continuation of the treatment strategy was influenced by routine radiographs, the overall added value of these radiographs would seem overestimated.

In conclusion, although it is common practice to routinely take radiographs during the follow-up period for ankle fractures, the current results suggest that these radiographs seldom influence clinical decision-making and can possibly be omitted. Because of the study limitations, the results of these analyses and the clinical consequences of a reduced imaging protocol should be confirmed in a prospective trial. Our research group is currently conducting a randomized controlled trial in which a group receiving routine radiographs is compared with a group in which radiographs in the follow-up period are made only when deemed necessary. These results could help in weighing the clinical importance of routine radiographs and help establish guidelines for their use in the management of patients with uncomplicated ankle fractures.

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Routine radiography following the initial 2 weeks of follow-up of ankle fracture patients does not have added value. The WARRIOR trial: a multicenter randomized controlled trial

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The Journal of Bone and Joint Surgery. 2020;102:1588-99

ABSTRACT

Background

The clinical consequences of routine follow-up radiographs for patients with ankle fractures are unclear, and their usefulness is disputed. The aim of the present study was to determine if routine radiographs made at weeks 6 and 12 can be omitted without compromising clinical outcomes.

Methods

This multicenter randomized controlled trial with a noninferiority design included 246 patients with an ankle fracture, 153 (62%) of whom received operative management. At 6 and 12 weeks of follow-up, patients in the routine care group (n=128) received routine radiographs whereas patients in the reduced imaging group (n=118) did not. The primary outcome was the Olerud-Molander Ankle Score (OMAS). Secondary outcomes were the American Academy of Orthopaedic Surgeons (AAOS) foot and ankle questionnaire, health-related quality of life (HRQoL) as measured with the EuroQol-5 Dimensions-3 Levels (EQ-5D-3L) and Short Form-36 (SF-36), complications, pain, health perception, self-perceived recovery, the number of radiographs, and the indications for radiographs to be made. The outcomes were assessed at baseline and at 6, 12, 26, and 52 weeks of follow-up. Data were analyzed with use of mixed models.

Results

Reduced imaging was noninferior compared with routine care in terms of the OMAS (difference [β], −0.9; 95% confidence interval [CI], −6.2 to 4.4). AAOS scores, HRQoL, pain, health perception, and self-perceived recovery did not differ between groups. Patients in the reduced imaging group received a median of 4 radiographs, whereas those in the routine care group received a median of 5 radiographs ($p < 0.05$). The rates of complications were similar (27.1% [32 of 118] in the reduced imaging group, compared with 22.7% [29 of 128] in the routine care group, $p = 0.42$). The types of complications were also similar.

Conclusion

Implementation of a reduced imaging protocol following an ankle fracture has no measurable negative effects on functional outcome, pain, and complication rates during the first year of follow-up. The number of follow-up radiographs can be reduced by implementing this protocol.

INTRODUCTION

Ankle fractures are one of the most common skeletal injuries. Approximately 10% of all fractures involve the ankle, and the reported incidence of ankle fractures is between 101 and 187 per 100,000 per year.[1-3] Over the last decade, this incidence has risen because of increasing participation in athletic activities and aging of the population.[4] About half of these fractures are managed operatively because of incongruity of the joint or primary instability.[5] Following ankle fracture treatment, routine radiographic assessment of the ankle is a common practice both for operatively and nonoperatively managed patients worldwide.[4, 6, 7] Screening for incongruity of the joint is a common reason for making follow-up radiographs. Incongruity can lead to uneven joint loading, osteoarthritis, and a poor functional outcome. Other reasons for radiographs include monitoring of bone healing, assessing osteosynthesis material, identifying complications, reassuring the patient and physician, educating residents, and medicolegal motives.[6] Recent studies have debated the usefulness of routine follow-up radiographs for patients with ankle fractures.[8-13] In a previous retrospective study, we found that the treatment strategy was modified in only 11 (1.2%) of 936 instances in which a radiograph was made routinely after >3 weeks of follow-up.[5] This finding suggests that omitting these radiographs does not lead to worse clinical outcomes. However, that analysis was based on data that were collected retrospectively, and, therefore, was subject to various forms of bias that may have influenced the outcomes and conclusions. Therefore, the purpose of the present study was to evaluate whether routine radiography after the initial 2 weeks of follow-up can be omitted without compromising functional and clinical outcomes for patients with ankle fractures.

METHODS

Setting and Design

This research was designed as a multicenter randomized controlled trial (RCT) with a noninferiority design for the primary outcome.[14] The study was performed in 7 hospitals in the Netherlands, including 4 level-I trauma centers, 2 level-II trauma centers, and 1 level-III trauma center. Patients were included between July 2014 and October 2017. Noninferiority trials assess whether an intervention is not worse (noninferior) compared with routine care. If so, other outcomes, such as lower costs, fewer side effects, or improved feasibility, should then be considered.[15] More detailed information, such as study design, can be found in our protocol, which was published prior to the start of patient inclusion.[16] The trial was approved by the Medical Ethics Committee of the Leiden University Medical Center (project number: P14.086). The Consolidated Standards of

Reporting Trials (CONSORT) guidelines for noninferiority trials were followed when reporting our results.[15] The trial was registered in the Netherlands Trial Register (NL4477).

Inclusion Criteria

Patients were eligible if they were ≥18 years of age, had adequate Dutch language understanding, had a closed or Gustilo grade-1 open fracture of the ankle (Lauge-Hansen classification types: supination-adduction [SA] 2, supination-external rotation [SE] 2 to 4, pronation-external rotation [PE] 1 to 4, or pronation-abduction [PA] 1 to 3), and provided written informed consent.[17] Ankle sprains and isolated Danis-Weber type A[18] (Lauge-Hansen SA1) fractures were not eligible for inclusion as radiographic follow-up is not routinely performed in such cases.

Exclusion Criteria

We excluded patients who had a pathological fracture, an open fracture (Gustilo grade 2 or 3), or multiple fractures involving the extremities. Patients deemed unable to comply with follow-up and patients who were assigned to a nonparticipating hospital for treatment or follow-up were also excluded.

Sample-Size Calculation

To demonstrate noninferiority with a power of 0.85 and an alpha of 0.05, 142 participants were necessary on the basis of the margin of noninferiority of 9 points on the Olerud-Molander Ankle Score (OMAS).[19] The sample-size calculation has been described in detail elsewhere.[16] To be able to perform a subgroup analysis for nonoperatively and operatively managed patients, 284 participants had to be included. To account for a 10% rate of loss to follow-up, 312 participants were needed in total.

Randomization

Participants were randomized to either the routine care group or the reduced imaging group in a 1:1 ratio, stratified by hospital and treatment (i.e., operative or nonoperative management). Neither participants nor physicians were blinded.[16]

Routine Care Group

Patients who were randomized to the routine care group received radiographic follow-up according to the local trauma protocol.[7] The first weeks of follow-up were similar for both groups. Follow-up of the routine care group after these initial 2 weeks consisted of outpatient clinic visits that includes a routine radiographic evaluation at 6 and 12 weeks after trauma or operative management. The start of weight-bearing mobilization and the initiation of physical therapy were at the discretion of the treating physician, and additional follow-up evaluations and radiographs could be scheduled at any time.

Reduced Imaging Group

Follow-up in the reduced imaging group was similar to that in the routine care group, except that routine radiographic evaluation was omitted at weeks 6 and 12. Radiographs were made at those intervals only if a clinical indication was present or at the treating physician's discretion. Clinical indications included new trauma involving the affected ankle, a score of >6 on the 0-to-10-point visual analog scale (VAS) for pain, loss of range of motion, or neurovascular symptoms. Clinicians had the discretion to order another radiograph for several reasons. For example, if a specific fracture pattern was regarded as highly unstable, if delayed bone-healing was expected (e.g., because of older age, diabetes mellitus, smoking habits, or osteoporosis), or if the patient wished to have a radiographic examination at the time of follow-up. As in the routine care group, the start of weight-bearing mobilization and the initiation of physical therapy were at the discretion of the treating physician, and additional follow-up evaluations and radiographs could be scheduled at any time.

Primary Outcome Measure

The primary outcome was patient-reported functional outcome according to the OMAS.[19]

Secondary Outcome Measures

Foot and ankle-related disability was assessed with the American Academy of Orthopaedic Surgeons (AAOS) foot and ankle questionnaire for ankle fractures, including the optional AAOS shoe module.[20] Health-related quality of life (HRQoL) was assessed with use of the EuroQol-5 Dimensions-3 Levels (EQ-5D-3L) questionnaire[21] and the Physical Component Summary (PCS) and Mental Component Summary (MCS) scores of the Short Form-36 (SF-36) questionnaire.[22, 23] VAS scores were used to measure pain at rest and when the affected ankle was moved. Overall health status was also scored with use of a VAS. Self-perceived recovery and return of ankle function were scored with use of a 5-point Likert scale. All patient-reported outcomes were gathered at baseline (pre-injury status) and after 6, 12, 26, and 52 weeks of follow-up. Information on the number of radiographs, and reasons to obtain these radiographs were derived from the medical charts. Information on complications, including implant failure, nonunion, malunion, surgical site infections, and chronic pain, was also derived from the medical charts, which were independently reviewed by 2 investigators.

Statistical Analysis

Data were analyzed with use of SPSS Statistics for Windows (version 25; IBM Corp., Armonk, NY). Baseline characteristics were compared with use of descriptive statistics. The Mann-Whitney U test was used to compare the median number of radiographs. The

χ^2 test was used to compare complication rates between groups. Linear mixed models were used to analyze repeated patient-reported outcomes and to handle missing values. The models had a longitudinal 2-level structure in which questionnaires over time were clustered within patients. Differences in outcome in these analyses are reported as the intervention's regression coefficient (difference [β]), with the associated 95% confidence interval (CI). The primary outcome was compared with the noninferiority margin. All secondary outcome measures were analyzed using a superiority design. The analyses were corrected for the patients' pre-injury status and potentially confounding patient characteristics (Table I). Missing values in potential confounders were multiply imputed. For all statistical tests, significance was assumed at $p < 0.05$.

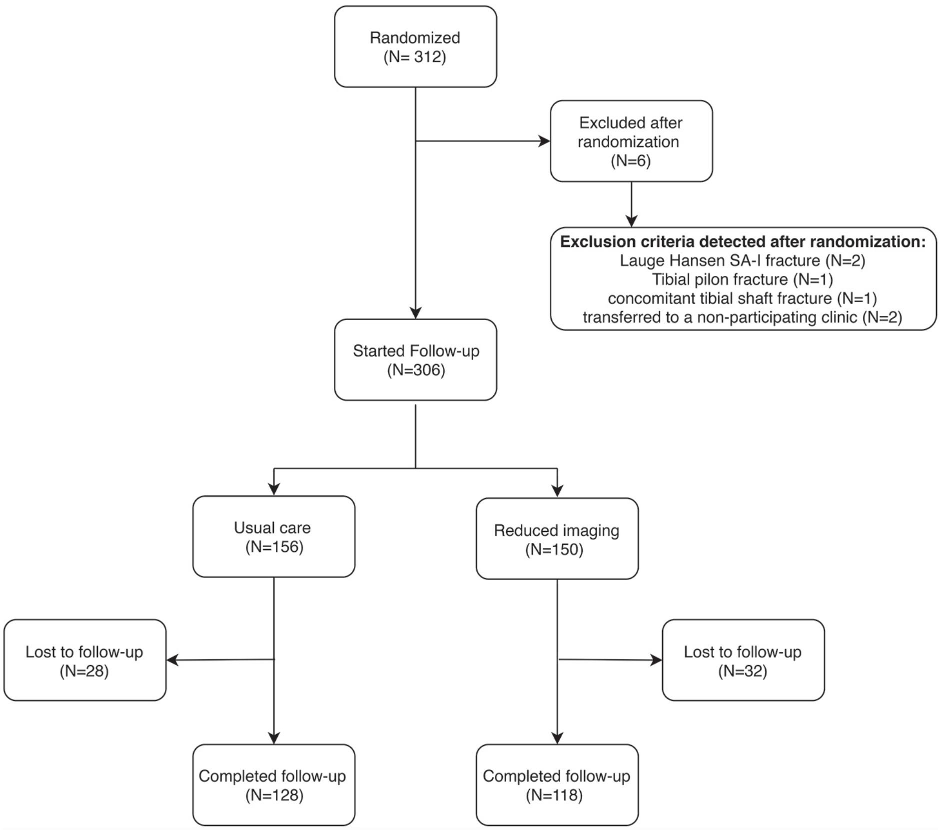

Figure 1. Flowchart of patients.

RESULTS

Participants

In total, 312 eligible patients with an ankle fracture were included in the study. 6 were excluded following randomization, and 60 patients (19.2%) were lost to follow-up because none of the questionnaires were returned during follow-up and therefore no data were available for analysis (Fig. 1). The study group consisted of 246 patients, of whom 128 were randomized to the routine care group and 118 were randomized to the reduced imaging group. No differences were observed in baseline characteristics apart from a higher mean body mass index (BMI) in the reduced imaging group (Table I). Overall, 153

Table I. Patient characteristics by treatment allocation

		Routine care (n=128)		Reduced imaging (n=118)		*p*-value
Male sex,	n (%)	69	(53.9)	58	(48.7)	0.42
Age	mean (SD)	47.7	(18.5)	50.8	(18.2)	0.18
BMI	mean (SD)	25.8	(4.3)	27.3	(6.0)	**0.02**
Alcohol >10 U/week	n (%)	22	(17.2)	16	(13.4)	0.42
Smoking >10/day	n (%)	10	(7.8)	9	(7.6)	0.94
Operative treatment	n (%)	77	(60.2)	76	(64.4)	0.46
Lauge-Hansen classification SA	n (%)	2	(1.6)	2	(1.7)	0.60
SE		94	(73.4)	94	(79.0)	
PA/PE		31	(24.2)	23	(19.3)	
missing		1	(0.8)	0	(0.0)	
Weber classification A	n(%)	2	(1.6)	2	(1.7)	0.49
B		93	(72.7)	94	(79.0)	
C		27	(21.1)	21	(17.6)	
missing		6	(4.7)	2	(1.7)	
Malleolar involvement Uni-	n(%)	66	(51.6)	64	(53.8)	0.79
Bi-		27	(21.1)	21	(17.6)	
Tri-		35	(27.3)	34	(28.6)	
ASA classification 1	n(%)	53	(41.4)	47	(39.5)	0.83
2		60	(46.9)	55	(46.2)	
≥3		15	(11.7)	12	(7.7)	

Legend for Table I:
SD: Standard deviation
SA: Supination-adduction
SE: Supination-external rotation
PA: Pronation-adduction
PE: Pronation-eversion
BMI: Body Mass index
ASA: American Society of Anesthesiologists
Bold = a significant difference between groups (*p* <0.05)

patients (62%) received operative management, including 77 in the routine care group and 76 in the reduced imaging group. In total, 1,096 (89%) of 1,230 questionnaires were completed by the patients in the study group.

Table II: outcome scores per treatment allocation per timepoint, and adjusted differences(β)

	Routine care n=128 median (IQR)	**Reduced imaging** n=118 median (IQR)	**RC vs RI** Adjusted β (95%CI)
OMAS (0-100)			
BL	100 (100-100)	100 (100-100)	-
W6	40 (25-60)	45 (25-65)	-3.3 (-8.4 to 1.9)
W12	65 (45-80)	65 (46-80)	-0.9 (-5.9 to 4.2)
W26	85 (68-95)	80 (65-95)	1.74 (-3.4 to 6.9)
W52	90 (80-100)	90 (80-100)	-0.9 (-6.2 to 4.4)
AAOS (0-100)			
BL	100 (98-100)	100 (98-100)	-
W6	73 (59-82)	76 (63-84)	-2.8 (-6.6 to 1.0)
W12	85 (74-92)	83 (73-92)	1.1 (-2.4 to 4.7)
W26	93 (87-97)	94 (84-98)	0.1 (-3.5 to 3.7)
W52	96 (91-99)	97 (89-100)	0.8 (-2.9 to 4.5)
AAOS shoe (0-100)			
BL	100 (100-100)	100 (75-100)	-
W6	50 (25-100)	50 (25-94)	-2.4 (-113 to 6,5)
W12	60 (37-100)	50 (25-100)	-2.2 (-9.8 to 5.4)
W26	100 (100-100)	80 (43-100)	-4.8 (-12.5 to 2.8)
W52	100 (50-100)	80 (50-80)	0.1 (-7.6 to 7.9)
EQ-5D-3L (0-1)			
BL	1.0 (0.9-1.0)	1.0 (0.84-1.0)	-
W6	0.78 (0.57-0.81)	0.78 (0.65-0.86)	**-0.05 (-0.09 to -0.004)**
W12	0.83 (0.78-1.0)	0.81 (0.78-1.0)	-0.02 (-0.06 to 0.03)
W26	1.0 (0.81-1.0)	0.84 (0.78-1.0)	0.03 (-0.02 to 0.07)
W52	1.0 (0.84-1.0)	1.0 (0.81-1.0)	-0.00 (-0.05 to 0.04)
SF36 PCS (0-100*)			
BL	57.2 (54.8-59.3)	56.9 (52.7-58.9)	-
W6	36.3 (29.6-44.8)	34.8 (28.8-41.7)	0.5 (-1.6 to 2.6)
W12	45.5 (38.5-51.5)	43.2 (36.9-51.1)	0.3 (-1.8 to 2.4)
W26	53.1 (46.9-56.4)	50.8 (41.7-55.6)	1.3 (-0.9 to 3.5)
W52	54.1 (49.1-57.3)	53.5 (47.4-57.0)	0.1 (-2.1 to 2.3)

Table II: outcome scores per treatment allocation per timepoint, and adjusted differences(β) (continued)

	Routine care n=128 median (IQR)	**Reduced imaging** n=118 median (IQR)	**RC vs RI** Adjusted β (95%CI)
SF36 MCS (0-100*)			
BL	53.8 (48.1-58.5)	54.1 (48.3-56.5)	-
W6	53.5 (44.2-58.9)	53.3 (45.1-41.7)	-0.6 (-2.6 to 1.5)
W12	55.0 (49.8-60.1)	56.8 (47.9-60.1)	-0.2 (-2.2 to 1.9)
W26	54.7 (49.1-58.3)	55.6 (50.3-59.1)	-1.0 (-3.2 to 1.1)
W52	54.3 (49.3-58.5)	55.6 (50.3-58.3)	-0.4 (-2.6 to 1.7)
pain rest (0-10)			
BL	0.0 (0.0-1.0)	0.0 (0.0-1.0)	-
W6	1.0 (0.3-2.9)	1.0 (0.0-2.3	0.3 (-0.1 to 0.8)
W12	1.0 (0.0-2.0)	1.0 (0.0-2.0)	-0.0 (-0.5 to 0.4)
W26	0.4 (0.0-1.2)	0.5 (0.0-2.0)	0.2 (-0.2 to 0.7)
W52	0.5 (0.0-1.0)	0.1 (0.0-1.0)	0.1 (-0.4 to 0.5)
pain movement (0-10)			
BL	0.0 (0.0-1.0)	0.1 (0.0-1.0)	-
W6	3.0 (2.0-5.0)	2.5 (1.0-4.8)	0.4 (-0.1 to 1.0)
W12	2.0 (1.0-3.2)	2.0 (1.0-4.0)	-0.2 (-0.7 to 0.4)
W26	1.0 (0.1-2.0)	1.0 (0.1-2.0)	0.1 (-0,5 to 0.7)
W52	1.0 (0.0-1.9)	1.0 (0.0-2.0)	-0.0 (-0.6 to 0.6)
Health status (0-10)			
BL	8.2 (7.5-9.0)	8.0 (7.0-9.0)	-
W6	8.0 (6.8-9.0)	7.5 (7.0-8.8)	-0.1 (-0.5 to 0.4)
W12	8.0 (7.0-9.0)	8.0 (7.0-8.0)	0.0 (-0.5 to 0.5)
W26	8.0 (7.3-9.0)	8.0 (7.0-8.8)	0,4 (-0,0 to 0,9)
W52	8.0 (7.1-9.0)	8.0 (7.0-9.0)	0,1 (-0.4 to 0.6)
***Recovered (1-5)*‡**			
W6	3.0 (3.0-4.0)	3.0 (3.0-4.0)	0.1 (-0.1 to 0.3)
W12	4.0 (4.0-4.0)	4.0 (3.0-4.0)	0.1 (-0.1 to 0.3)
W26	4.0 (4.0-4.0)	4.0 (4.0-4.0)	0.0 (-0.2 to 0.2)
W52	4.0 (4.0-5.0)	4.0 (4.0-5.0)	0.2 (-0.1 to 0.4)
***Regained function (1-5)*‡**			
W6	2.0 (1.0-3.0)	2.0 (1.0-3.0)	-0.1 (-0.4 to 0.1)
W12	4.0 (2.0-4.0)	3.0 (2.0-4.0)	0.1 (-0.1 to 0.4)
W26	4.0 (3.3-4.0)	4.0 (3.0-5.0)	0.1 (-0.2 to 0.3)
W52	4.0 (4.0-5.0)	4.0 (4.0-5.0)	0.0 (-0.2 to 0.3)

Legend Table II
*: 50 = average score
‡: Higher = better
Bold = a significant difference between groups (p <0.05)

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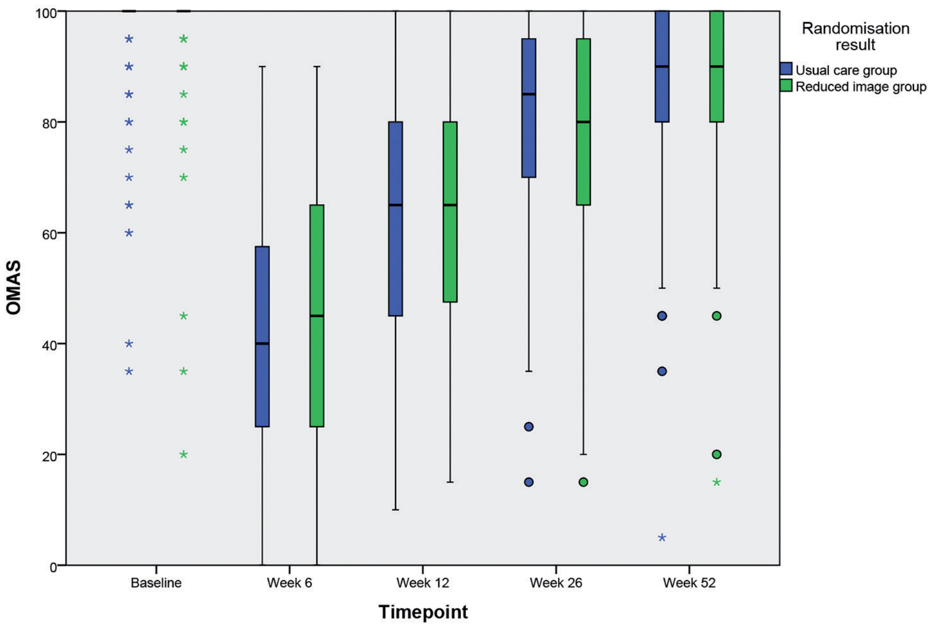

Figure 2: Box plot of OMAS over time. Horizontal line in box = median, top and bottom of box = interquartile range, whiskers = 1.5 times the interquartile range, circles = outliers, and asterisks = extreme outliers

Primary Outcome

The difference in the OMAS between groups was within the margin of noninferiority at all time points (Table II). At 52 weeks, the OMAS for the reduced imaging group (median, 90; interquartile range [IQR], 80 to 100) was noninferior in comparison with that for the routine care group (median, 90; IQR, 80 to 100) (Fig. 2). The difference in the OMAS and its 95% CI were within the margin of noninferiority of 9 points (β, –0.9; 95% CI –6.2 to 4.4).

Secondary Outcomes

At 52 weeks, the patient-perceived functional status of the injured ankle was comparable between the groups according to the AAOS foot and ankle questionnaire (β, 0.8; 95% CI, –2.9 to 4.5) (Table II). Scores per time point were similar in both groups (Fig. 3). The scores for the AAOS shoe questionnaire were comparable as well (Table II). No differences between the groups were found at week 52 in terms of HRQoL. The EQ-5D-3L scores were similar at 52 weeks (β, –0.00; 95% CI, –0.05 to 0.04) and at all other individual time points except for week 6, at which the EQ-5D-3L scores for the reduced imaging group were significantly higher than those for the routine care group (β, –0.05; 95% CI, –0.09 to –0.004) (Fig. 4, Table II). Neither the PCS and MCS scores of the SF-36 questionnaire nor pain were inferior in the reduced imaging group as compared with the routine

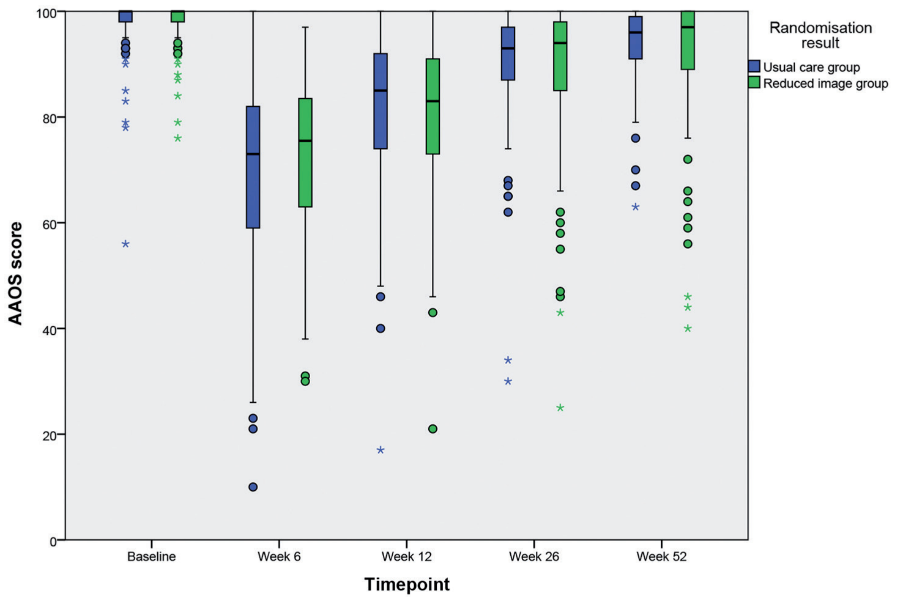

Figure 3: Box plot of AAOS ankle scores over time. Horizontal line in box = median, top and bottom of box = interquartile range, whiskers = 1.5 times the interquartile range, circles = outliers, and asterisks = extreme outliers

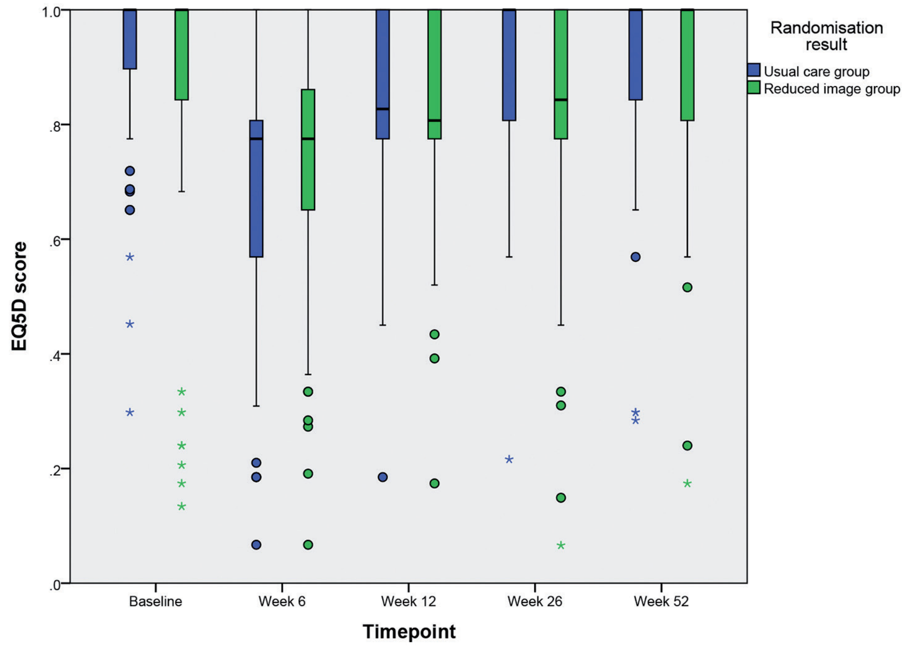

Figure 4: Box plot of EQ-5D-3L scores over time. Horizontal line in box = median, top and bottom of box = interquartile range, whiskers = 1.5 times the interquartile range, circles = outliers, and asterisks = extreme outliers

care group at any time point (Figs. 5 and 6, Table II). Both groups had similar scores for median health status at week 52 (β, 0.1; 95% CI, −0.4 to 0.6), median self-perceived recovery at week 52 (β, 0.2; 95% CI, −0.1 to 0.4), and return of ankle function (β, 0.0; 95% CI, −0.2 to 0.3) (Table II). Complications did not occur more often in the reduced imaging group (27.1% [32/118]) than in the routine care group (22.7% [29/128], $p = 0.42$). Specific types of complications were also equally common (Table III).

Radiographs

During treatment of all patients, 1,204 sets of 3-view radiographs were made (Table IV). Patients in the routine care group received a median of 5 radiographs (IQR, 4 to 6 radiographs) during the entire treatment period, which was significantly higher than the number in the reduced imaging group (median, 4 radiographs; IQR, 3 to 5 radiographs) ($p < 0.05$). More radiographs were made to assess bone-healing in the routine care group in comparison with the reduced imaging group (295 [43%] versus 181 [35%], $p < 0.05$). More radiographs were made to assess a painful ankle in the reduced imaging group than in the routine care group (14 [2.7%] versus 9 [1.3%], $p < 0.05$). A significantly lower percentage of patients in the reduced imaging group had a radiograph made after 2 weeks when compared with patients in the routine care group (77 [65%] versus 105 [82%], $p < 0.05$).

Subgroup Analyses

The OMAS at week 52 for the reduced imaging group were noninferior to those for the routine care group within the subgroups of operatively treated and nonoperatively treated patients (see Appendix). For nonoperatively treated patients, all patient-reported secondary outcome measures were comparable at all time points and for the entire follow-up period, apart from the SF36 MCS score at 6 weeks, which was higher for the routine care group (see Appendix). For operatively treated patients, the AAOS score, EQ-5D-3L score, and SF36 MCS score were higher for the reduced imaging group than for the routine care group at 6 weeks. In contrast, pain at rest and self-perceived recovery were lower for the reduced imaging group at 6 weeks. All other outcome measures showed similar results in the routine care and reduced imaging groups at all time points (see Appendix).

Per-Protocol Analysis

A per-protocol analysis was performed to assess the influence of protocol violations. This analysis resulted in outcomes like the main analysis. Reduced imaging was noninferior to routine care for the OMAS at week 52 (β, −0.5; 95% CI, −7.5 to 6.6) (see Appendix).

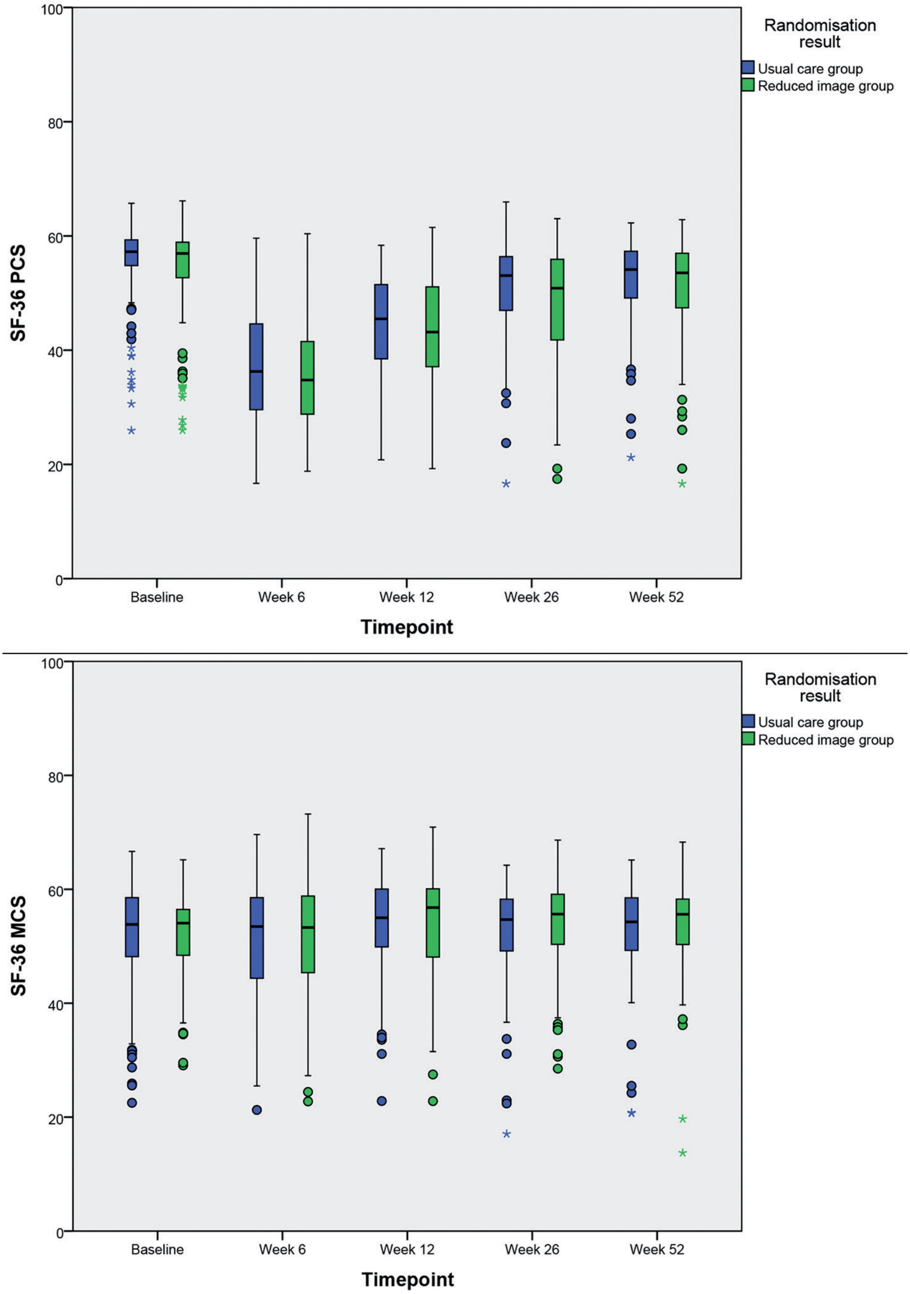

Figure 5: Box plots of SF-36 PCS and MCS over time. Horizontal line in box = median, top and bottom of box = interquartile range, whiskers = 1.5 times the interquartile range, circles = outliers, and asterisks = extreme outliers

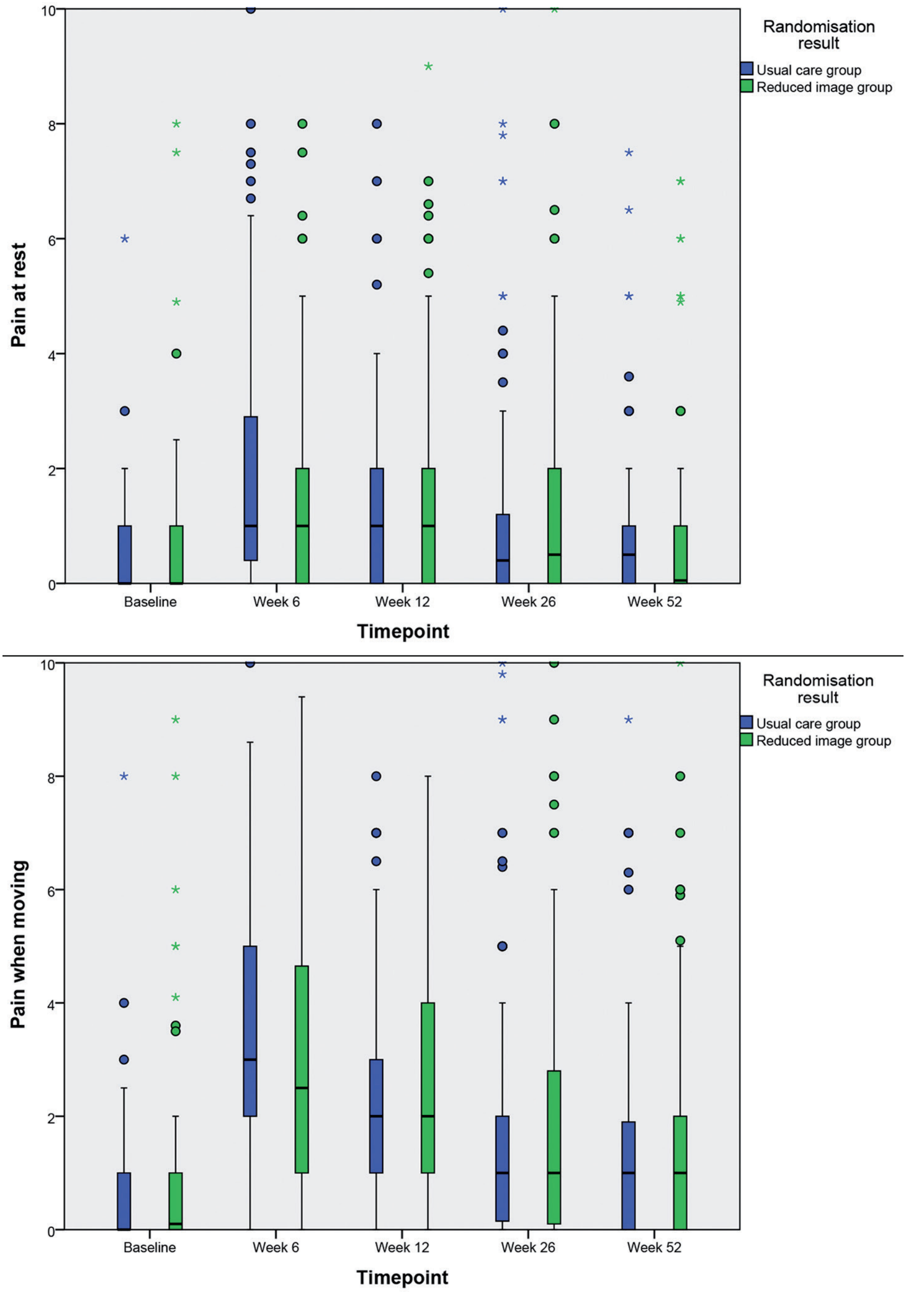

Figure 6: Box plots of VAS for pain at rest and when moving over time. Horizontal line in box = median, top and bottom of box = interquartile range, whiskers = 1.5 times the interquartile range, circles = outliers, and asterisks = extreme outliers

Table III. Complications

Complication:	Routine care (n=128)	Reduced imaging (n=118)	*p*-value
Nonunion	2	3	0.59
Malunion	3	1	0.35
Surgical site infection	7	10	0.35
Failure of fixation	3	1	0.35
Neurological	5	2	0.30
Osteoarthritis	0	3	NA
Hardware Complaints	3	7	0.15
Talar osteonecrosis	2	0	NA
Chronic pain	4	5	0.64
Total	**29 (22.7%)**	**32 (27.1%)**	**0.42**

Table IV. Radiographs and indications

	Routine Care (n=128)	Reduced Imaging (n=118)	*p*-value
Number of radiographs	681	523	
Radiographs per patient, median (IQR)	5 (4-6)	4 (3-5)	**<0.05**
Radiograph after two weeks follow-up, N (%)	105 (84.3)	77 (65.3)	**<0.05**
***Indication,** N (%)*			
Fracture	136 (20)	118 (22.6)	0.3
Dislocation	488 (71.7)	356 (68.1)	0.2
Consolidation	295 (43.3)	181 (34.6)	**<0.05**
Routine	5 (0.7)	1 (0.2)	0.2
Pain	9 (1.3)	14 (2.7)	**<0.05**
Impaired function	1 (0.1)	0 (0)	0.4
Evaluate hardware	134 (19.7)	101 (19.3)	1.0
Before implant removal	11 (1.6)	9 (1.7)	0.9
Suspected complication	11 (1.6)	9 (1.7)	0.9
Unknown	3 (0.4)	1 (0.2)	0.5

Bold = a significant difference between groups (p <0.05)

DISCUSSION

This large, multicenter RCT demonstrates that routine radiographs that are made after the first 2 weeks of follow-up do not affect outcomes in the first 12 months for patients with ankle fractures. Omitting routine radiographs led to a significant decrease of 1 radiograph per patient (median), whereas other outcomes such as functional status, HRQoL, pain levels, and complications were comparable. The decrease in the number of radiographs could provide a cost-saving opportunity.[8] For example, the cost for 1 radiograph (3 views) in the Netherlands is €52. With the incidence of 30,000 ankle fractures per annum, the cost saving potential in the Netherlands would add up to €1.5 million annually while leading to a small (0.003-mSv) reduction in ionizing radiation per patient.[24] These findings are consistent with those of previous retrospective studies that have suggested that routine follow-up radiographs have limited added value for patients with ankle fractures. Harish et al. [9], McDonald et al.,[12] Ovaska et al.,[11] Ghattas et al.,[8] and Miniaci-Coxhead et al.,[10] all concluded that routine radiographs made at the first postoperative outpatient clinic visit were of little value. Schuld et al. [13] reported a similar result for radiographs made after splinting nonoperatively managed fractures. In our previous retrospective cohort study of 528 participants,[5] we found that routine follow-up radiographs seldom influenced the treatment strategy.

The present study had some limitations. The number of protocol violations, especially in the reduced imaging group, was high. In the reduced imaging group, the protocol was followed for 59 (50%) of 118 patients. Of these, 51 patients had no radiographs at weeks 6 and 12 and 8 patients had a radiograph for which an indication was registered. The fact that protocol violations were more common in the reduced imaging group is in contrast with our previous randomized trial concerning reduced imaging in the follow-up period after wrist fractures.[25] In that study, protocol violations occurred mainly in the routine care group when a radiograph was not made at week 6 or 12. This finding might indicate that physicians put more value on follow-up radiographs for patients with an ankle fracture than for those with a distal radius fracture. This finding is in accordance with our retrospective studies,[5, 26] in which radiographs were more frequently made after >2 weeks of follow-up for patients with an ankle fracture[5] as compared with those with a distal radius fractures.[26] The high number of protocol violations also might be related to the possibility that clinical indications for radiographs were not recorded in the medical file. To determine whether these protocol violations influenced our results, a per-protocol analysis was conducted. As the per-protocol analysis showed results like the main analysis, we concluded that protocol violations did not introduce bias.

A second limitation might be related to performance bias as participants and physicians were not blinded to the treatment allocation. Because of the nature of the intervention, blinding of physicians was not possible and blinding of patients was impractical.

A third limitation is related to the high number of outcome measures and multiple time points at which data were collected. Multiple testing might have introduced a type-I error. We found some significant differences between the routine care group and the reduced imaging group at 6 weeks, particularly in the subgroup analyses. These differences are unlikely to be a result of the intervention as follow-up was similar for both groups up until that time point. All significant differences that were found were inconsistent over time and presumably represented random findings. Fourth, as the minimum clinically important difference for the OMAS is unknown, the margin of noninferiority was set at 9 points. This value was based on the minimum clinically important difference for the Disabilities of the Arm, Shoulder and Hand (DASH) score, which we used in a similar study for patients with distal radius fractures.[25] Importantly, our margin of noninferiority is consistent with other trials involving the OMAS such as the Ankle Injury Management (AIM) trial[27] and the Routine versus On DEmand removal Of the syndesmotic screw (RODEO) trial.[28] As the present trial was only powered to demonstrate noninferiority for the OMAS but not for the complication rate, it was possibly underpowered to detect a clinically relevant difference in adverse events such as malunions. Our previous retrospective study showed that conversion to operative care based on a routine radiograph was rare (0.2%).[5] This leads to a high number needed to treat. Whether this is justified in local healthcare and legal systems is up to policymakers and physicians. The study was performed in compliance with the published research protocol, thereby decreasing the risk of selective outcome reporting bias.[29]

In conclusion, this study demonstrates that omitting routine follow-up radiographs for patients with ankle fractures does not negatively affect outcomes or increase the risk of complications in the first 12 months of follow-up in comparison with routine care.

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APPENDICES

Appendix 1: Outcome scores per treatment allocation per timepoint, and adjusted differences(β) for the nonoperatively treated subgroup

	Routine care n=128 median (IQR)	**Reduced imaging** n=118 median (IQR)	**RC vs RI** Adjusted β (95%CI)
OMAS (0-100)			
BL	100 (90-100)	100 (100-100)	-
W6	50 (35-65)	55 (30-70)	1.9 (-6.3 to 10.1)
W12	70 (60-85)	75 (60-85)	1.2 (-6.9 to 9.3)
W26	90 (75-100)	90 (76-100)	5.3 (-2.9 to 13.4)
W52	95 (85-100)	100 (85-100)	2.7 (-5.9 to 11.2)
AAOS (0-100)			
BL	100 (98-100)	100 (99-100)	-
W6	77 (62-87)	76 (63-82)	3.8 (-1.6 to 9.1)
W12	89 (83-95)	86 (75-94)	5.0 (-0.3 to 10.2)
W26	96 (90-99)	98 (93-100)	2.4 (-3.1 to 7.8)
W52	95 (95-100)	99 (96-100)	2.5 (-3.1 to 8.0)
AAOS shoe (0-100)			
BL	100 (81-100)	100 (88-100)	-
W6	38 (25-100)	29 (25-100)	5.4 (-7.0 to 17.8)
W12	64 (50-100)	50 (33-100)	-1.4 (-12.0 to 9.1)
W26	100 (50-100)	100 (50-100)	-3.6 (-15.2 to 8.0)
W52	100 (62-100)	80 (55-100)	8.9 (-2.6 to 20.4)
EQ-5D-3L (0-1)			
BL	1.0 (0.85-1.0)	1.0 (0.84-1.0)	-
W6	0.78 (0.65-0.86)	0.78 (0.78-0.86)	-0.01 (-0.08 to 0.05)
W12	0.85 (0.78-1.0)	0.84 (0.78-1.0)	-0.01 (-0.07 to 0.06)
W26	1.0 (0.84-1.0)	1.0 (0.81-1.0)	0.02 (-0.05 to 0.09)
W52	1.0 (0.89-1.0)	1.0 (0.84-1.0)	0.01 (-0.06 to 0.09)
SF36 PCS (0-100*)			
BL	57.0 (52.8-59.3)	56.7 (53.4-58.7)	-
W6	38.7 (32.1-48.1)	36.3 (30.5-42.2)	2.6 (-0.6 to 5.9)
W12	49.9 (39.6-54.7)	47.9 (39.5-53.6)	0.8 (-2.6 to 4.1)
W26	55.2 (49.2-58.4)	52.9 (49.3-57.2)	2.7 (-0.8 to 6.1)
W52	54.7 (50.7-58.0)	54.6 (50.4-57.3)	1.6 (-2.0 to 5.1)

Appendix 1 (continued)

	Routine care n=128 median (IQR)	**Reduced imaging** n=118 median (IQR)	**RC vs RI** Adjusted β (95%CI)
SF36 MCS (0-100*)			
BL	52.8 (46.4-59.2)	54.2 (48.6-56.6)	-
W6	54.0 (46.9-60.3)	51.4 (44.2-59.1)	**3.6 (0.1 to 5.6)**
W12	56.0 (53.4-60.7)	58.1 (45.3-60.1)	2.2 (-1.0 to 5.3)
W26	54.0 (48.9-59.2)	55.5 (49.8-58.6)	-0.4 (-3.6 to 2.9)
W52	52.6 (48.8-58.0)	56.4 (50.8-58.5)	-0.3 (-3.6 to 3.1)
pain rest (0-10)			
BL	0.0 (0.0-1.0)	0.0 (0.0-1.0)	-
W6	1.0 (0.4-2.0)	1.7 (0.4-4.0)	-0.4 (-1.2 to 0.4)
W12	1.0 (0.0-1.8)	0.1 (0.0-1.5)	-0.0 (-0.8 to 0.8)
W26	0.0 (0.0-1.0)	0.0 (0.0-1.7)	0.0 (-0.8 to 0.8)
W52	0.0 (0.0-1.0)	0.0 (0.0-1.0)	-0.0 (-0.8 to 0.8)
pain movement (0-10)			
BL	0.0 (0.0-1.0)	0.0 (0.0-1.0)	-
W6	3.1 (2.0-5.3)	3.7 (1.0-5.0)	0.2 (-0.6 to 1.1)
W12	1.4 (1.0-2.9)	2.0 (0.5-4.2)	-0.4 (-1.2 to 0.5)
W26	1.0 (0.0-1.2)	0.4 (0.0-2.0)	0.2 (-0.7 to 1.1)
W52	0.2 (0.0-1.0)	0.0 (0.0-1.0)	0.1 (-0.8 to 1.1)
Health status (0-10)			
BL	8.9 (7.6-9.1)	8.0(7.0-9.0)	-
W6	8.0 (7.0-9.0)	7.2 (7.0-8.0)	0.2 (-0.5 to 1.0)
W12	8.0 (7.0-9.0)	8.0 (7.0-8.4)	-0.1 (-0.8 to 0.7)
W26	8.1 (7.0-9.0)	8.0 (7.0-9.0)	0.5 (-0.3 to 1.2)
W52	8.0 (7.0-9.0)	8.0 (6.8-9.0)	0.4 (-0.4 to 1.2)
Recovered (1-5)‡			
W6	3 (3-4)	3 (3-4)	0.1 (-0.2 to 0.4)
W12	4 (4-4)	4 (4-4)	0.2 (-0.1 to 0.5)
W26	4 (4-5)	4 (4-5)	0.1 (-0.3 to 0.4)
W52	5 (4-5)	5 (4-5)	0.2 (-0.1 to 0.5)
Regained function (1-5)‡			
W6	2 (2-3)	2 (2-3)	0.1 (-0.4 to 0.5)
W12	4 (3-4)	4 (3-4)	0.3 (-0.1 to 0.7)
W26	4 (4-5)	5 (4-5)	0.0 (-0.4 to 0.5)
W52	5 (4-5)	5 (4-5)	0.1 (-0.4 to 0.5)

Legend Appendix 1
*: 50 = average score
‡: Higher = better
Bold = a significant difference between groups ($p < 0.05$)

Appendix 2: Outcome scores per treatment allocation per timepoint, and adjusted differences(β) for the operatively treated subgroup

	Routine care n=128 median (IQR)	Reduced imaging n=118 median (IQR)	RC vs RI Adjusted β (95%CI)
OMAS (0-100)			
BL	100 (100-100)	100 (100-100)	-
W6	35 (24-55)	43 (25-60)	-5.4 (-12.1 to 1.3)
W12	60 (40-75)	55 (45-75)	1.5 (-7.9 to 5.0)
W26	80 (63-90)	78 (55-90)	0.5 (-6.1 to 7.0)
W52	85 (78-100)	85 (75-100)	-2.1 (-8.9 to 4.6)
AAOS (0-100)			
BL	100 (98-100)	100 (95-100)	-
W6	70 (55-82)	74 (63-88)	**-6.0 (-11.3 to -0.8)**
W12	80 (72-91)	80 (71-89)	0.0 (-4.6 to 4.7)
W26	92 (94-96)	90 (78-96)	0.0 (-4.7 to 4.8)
W52	94 (90-98)	96 (86-98)	1.1 (-3.7 to 5.8)
AAOS shoe (0-100)			
BL	100 (100-100)	100 (71-100)	-
W6	50 (25-100)	50 (25-100)	-5.8 (-17.8 to 6.1)
W12	50 (33-100)	50 (25-100)	-2.6 (-12.8 to 7.5)
W26	75 (40-100)	71 (40-100)	-6.1 (-16.0 to 3.7)
W52	100 (50-100)	88 (50-100)	-3.8 (-13.8 to 6.3)
EQ-5D-3L (0-1)			
BL	1.0 (1.0-1.0)	1.0 (0.84-1.0)	-
W6	0.69 (0.52-0.78)	0.78 (0.59-0.85)	**-0.07 (-0.1 to -0.0)**
W12	0.81 (0.78-0.89)	0.81 (0.78-0.89)	-0.02 (-0.1 to 0.0)
W26	0.90 (0.79-1.0)	0.84 (0.76-1.0)	0.03 (-0.0 to 0.1)
W52	1.0 (0.83-1.0)	0.93 (0.81-1.0)	-0.01 (-0.1 to 0.0)
SF36 PCS (0-100*)			
BL	57.7 (55.3 -59.2)	57.1 (52.2 -59.1)	-
W6	34.2 (28.9-40.1)	34.5 (28.1-38.6)	-0.5 (-3.1 to 2.2
W12	44.3 (37.6-50.2)	40.4 (35.6-49.7)	0.2 (-1.2 to 1.5)
W26	51.6 (46.1-54.9)	48.7 (39.5-54.3)	0.8 (-0.6 to 2.2)
W52	53.7 (48.6-56.5)	53.3 (46.0-56.7)	-0.2 (-2.9 to 2.6)
SF36 MCS (0-100*)			
BL	54.0 (48.8-58.2)	54.0 (47.5-56.5)	-
W6	51.3 (42.8-58.0)	53.6 (47.6-58.9)	-**2.6 (-5.3 to -0.0)**
W12	52.6 (49.5-59.9)	56.1 (49.4-60.1)	-1.1 (-3.7 to 1.6)
W26	55.3 (49.6-58.3)	55.7 (50.3-59.2)	-1.2 (-3.9 to 1.5)
W52	55.6 (50.6-58.9)	54.5 (49.3-57.5)	-0.3 (-1.7 to 1.1)

Appendix 2 (continued)

	Routine care n=128 median (IQR)	**Reduced imaging** n=118 median (IQR)	**RC vs RI** Adjusted β (95%CI)
pain rest (0-10)			
BL	0.0 (0.0-1.0)	0.2 (0.0-1.0)	-
W6	1.2 (0.2-3.0)	1.0 (0.0-2.0)	**0.8 (0.3 to 1.4)**
W12	1.0 (0.2-2.0)	1.0 (0.0-2.0)	0.0 (-0.6 to 0.6)
W26	1.0 (0.0-2.0)	1.0 (0.0-2.0)	0.5 (-0.1 to 1.0)
W52	0.7 (0.0-1.5)	0.5 (0.0-1.4)	0.2 (-0.4 to 0.8)
pain movement (0-10)			
BL	0,1 (0,0-1,0)	0,2 (0,0-1,0)	-
W6	3.0 (2.0-5.0)	2.0 (1.0-4.0)	0.5 (-0.1 to 1.2)
W12	2.1 (1.0-3.7)	2.0 (1.0-4.0)	-0.0 (-0.7 to 0.7)
W26	2.0 (0.5-3.0)	1.0 (0.7-3.2)	0.2 (-0,5 to 0.8)
W52	1.0 (0.5-2.1)	1.0 (0.6-2.4)	-0.1 (-0.8 to 0.6)
Health status (0-10)			
BL	8.0 (7.0-9.0)	8.0 (7.0-9.0)	-
W6	8.0 (6.0-9.0)	7.5 (6.9-9.0)	-0.1 (-0.7 to 0.4)
W12	8.0 (6.8-8.8)	7.9 (6.5-8.0)	0.2 (-0.4 to 0.7)
W26	8.0 (7.5-9.0)	8.0 (6.5-8.5)	0.5 (-0.0 to 1.1)
W52	8.0 (7.6-9.0)	8.0 (7.0-8.7)	0.1 (-0.5 to 0.7)
Recovered (1-5)‡			
W6	3 (3-4)	3 (2-4)	**0.2 (0.0 to 0.3)**
W12	4 (3-4)	3 (3-4)	0.1 (-0.1 to 0.4)
W26	4 (4-4)	4 (4-4)	0.0 (-0.3 to 0.3)
W52	4 (4-5)	4 (4-5)	0.1 (-0.1 to 0.4)
Regained function (1-5)‡			
W6	2 (1-2)	2 (1-3)	-0.2 (-0.6 to 0.1)
W12	3 (2-4)	3 (2-4)	0.0 (-0.3 to 0.4)
W26	4 (3-4)	4 (3-4)	0.1 (-0.3 to 0.4)
W52	4 (4-4)	4 (4-5)	0.0 (-0.3 to 0.4)

Legend Appendix 2
*: 50 = average score
‡: Higher = better
Bold = a significant difference between groups (*p* <0.05)

Appendix 3: Outcome scores per treatment allocation per timepoint, and adjusted differences(β) for the per-protocol analysis

	Routine care n=128 median (IQR)	**Reduced imaging** n=118 median (IQR)	**RC vs RI** Adjusted β (95%CI)
OMAS (0-100)			
BL	100 (100-100)	100 (100-100)	-
W6	40 (25-55)	55 (38-70)	**-9.4 (-16.2 to -2.6)**
W12	65 (45-75)	70 (55-85)	-6.8 (-13.5 to 0.01)
W26	80 (65-90)	85 (70-100)	-0.2 (-7.0 to 6.5)
W52	85 (80-100)	90 (80-100)	-0.5 (-7.5 to 6.6)
AAOS (0-100)			
BL	100 (99-100)	99 (97-100)	-
W6	74 (59-81)	78 (66-87)	**-7.9 (-12.9 to -2.9)**
W12	83 (74-92)	85 (75-94)	-3.5 (-8.3 to 1.3)
W26	92 (84-96)	96 (88-99)	-2.8 (-7.7 to 2.0)
W52	95 (90-99)	99 (93-100)	-1.5 (-6.4 to 3.3)
AAOS shoe (0-100)			
BL	100 (100-100)	100 (95-100)	-
W6	33 (25-100)	50 (25-100)	-9.0 (-19.8 to 1.8)
W12	50 (33-81)	60 (33-100)	-8.6 (-18.6 to 1.4)
W26	67 (40-100)	100 (58-100)	**-15.9 (-26.1 to -5.6)**
W52	75 (50-100)	100 (52.5-100)	-6.7 (-16.8 to 3.4)
EQ-5D-3L (0-1)			
BL	1.0 (0.89-1.0)	1.0 (0.81-1.0)	-
W6	0.69 (0.52-0.78)	0.78 (0.72-0.86)	**-0.09 (-0.16 to -0.04)**
W12	0.81 (0.78-0.97)	0.84 (0.78-1.0)	-0.03 (-0.10 to 0.03)
W26	0.89 (0.81-1.0)	0.89 (0.75-1.0)	0.01 (-0.05 to 0.07)
W52	1.0 (0.84-1.0)	1.0 (0.81-1.0)	0.03 (-0.04 to 0.09)
SF36 PCS (0-100*)			
BL	58.3 (55.0-59.3)	57.0 (49.8-59.6)	-
W6	35.3 (28.5-42.6)	37.2 (30.0-43.3)	-1.1 (-3.9 to 1.7)
W12	44.8 (38.1-51.6)	45.6 (37.4-53.3)	0.9 (-0.6 to 2.4)
W26	51.5 (46.0-55.4)	51.3 (42.5-56.1)	0.5 (-2.5 to 3.4)
W52	53.8(49.1-57.2)	53.4 (48.8-57.1)	0.4 (-2.6 to 3.4)
SF36 MCS (0-100*)			
BL	53.8 (48.8-58.6)	52.0 (45.1-55.5)	-
W6	52.3 (44.0-58.4)	53.0 (43.3-57.3)	-0.2 (-2.8 to 2.4)
W12	55.5 (49.6-60.7)	56.2 (45.3-60.1)	0.5 (-2.2 to 3.2)
W26	55.7 (49.5-58.4)	54.3 (49.4-58.5)	0.1 (-2.6 to 2.8)
W52	54.4 (49.4-59.3)	54.5 (48-8-57.7)	**1.7 (0.3 to 3.1)**

Appendix 3 (continued)

	Routine care n=128 median (IQR)	**Reduced imaging** n=118 median (IQR)	**RC vs RI** Adjusted β (95%CI)
pain rest (0-10)			
BL	0.0 (0.0-1.0)	0.0 (0.0-1.0)	-
W6	1.4 (0.3-2.9)	1.0 (0.0-2.3)	0.2 (-0.4 to 0.8)
W12	1.0 (0.1-2.0)	0.9 (0.0-1.4)	0.1 (-0.6 to 0.7)
W26	1.0 (0.0-2.0)	0.2 (0.0-2.0)	0.3 (-0.3 to 1.0)
W52	0.6 (0.0-1.2)	0.0 (0.0-1.0)	0.2 (-0.5 to 0.8)
pain movement (0-10)			
BL	0.0 (0.0-1.0)	0.1 (0.0-1.0)	-
W6	3.1 (2.0-5.0)	2.5 (1.1-4.3)	0.5 (-0.3 to 1.2)
W12	2.0 (1.0-3.9)	1.5 (0.6-4.0)	0.2 (-0.5 to 1.0)
W26	1.2 (0.4-3.0)	1.0 (0.0-3.0)	0.3 (-0.5 to 1.0)
W52	1.0 (0.5-2.0)	0.9 (0.0-1.7)	0.2 (-0.5 to 0.9)
Health status (0-10)			
BL	8.5 (7.5-9.0)	8.0 (7.0-9.0)	-
W6	8.0 (6.5-9.0)	7.3 (6.8-8.2)	0.2 (-0.1 to 0.4)
W12	8.0 (7.0-9.0)	7.5 (6.6-8.0)	**0.6 (0.02 to 1.2)**
W26	8.0 (7.2-9.0)	8.0 (7.0-8.9)	0.4 (-0.2 to 1.0)
W52	8.0 (7.2-9.0)	8.0 (6.0-9.0)	0.4 (-0.2 to 1.0)
Recovered (1-5) ‡)			
W6	3 (3-4)	3 (3-4)	-0.0 (-0.3 to 0.2)
W12	4 (3-4)	4 (4-4)	-0.0 (-0.3 to 0.2)
W26	4 (4-4)	4 (4-5)	-0.1 (-0.4 to 0.2)
W52	4 (4-5)	5 (4-5)	0.1 (-0.2 to 0.4)
Regained function (1-5) ‡			
W6	2 (1-3)	2.5 (2-3)	**-0.4 (-0.8 to -0.1)**
W12	3 (2-4)	4 (3-4)	-0.1 (-0.4 to 0.3)
W26	4 (3-4)	4 (4-5)	-0.0 (-0.4 to 0.3)
W52	4 (4-5)	5 (4-5)	-0.2 (-0.5 to 0.2)

Legend Appendix 3
*****: 50 = average score
‡: Higher = better
Bold = a significant difference between groups (p <0.05)

5

Reduction of routine use of radiography in patients with ankle fractures leads to lower costs and has no impact on clinical outcome: an economic evaluation

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BMC Health Services Research. 2020;20:893-905

ABSTRACT

Objective

To evaluate the cost-effectiveness of a reduction in the number of routine radiographs during the follow-up of patients with ankle fractures.

Methods

We performed an economic evaluation alongside the multicentre, randomized WARRIOR trial. Participants were randomized to a reduced imaging follow-up protocol (i.e., radiographs at weeks 6 and 12 follow-up made only for a clinical indication) or routine care (i.e., routine radiography made at weeks 6 and 12). The Olerud-Molander Ankle Score (OMAS) was used to assess ankle function and the EuroQol-5 Dimensions-3 Levels (EQ-5D-3L) was used to estimate quality-adjusted life-years (QALYs). Costs and resource use were assessed with use of self-reported questionnaires and medical records and analysed from a societal perspective. Multiple imputation was used for missing data, and data were analysed with use of seemingly unrelated regression analysis and bootstrapping.

Results

In total, 246 patients had data available for analysis (reduced imaging=118; routine care=128). Fewer radiographs were made in the reduced imaging group (median=4) compared with the routine care group (median=5). Functional outcome was comparable for both groups. The difference in QALYs was –0.008 (95% confidence interval [CI], –0.06 to 0.04) and the difference in OMAS was 0.73 (95% CI, –5.29 to 6.76). Imaging costs were lower for the reduced imaging group (–€48; 95% CI, –€72 to –€25). All other cost categories did not statistically differ between the groups. The probability of the reduced imaging protocol being cost-effectiveness was 0.45 at a willingness to pay of €20,000 per QALY.

Conclusions

Reducing the number of routine follow-up radiographs has a low probability of being cost-effective compared with routine care. Functional outcome, health-related quality of life and societal costs were comparable for both groups, whereas imaging costs were marginally lower for the reduced imaging group. Given this, a reduced imaging follow-up protocol for those with routine ankle fractures can be followed without sacrificing quality of care and may result in reduced costs.

INTRODUCTION

Ankle fractures are common and account for about 9% of all fractures in the UK.[1] The incidence of ankle fractures around the world is reported to lie between 71 and 187 per 100,000 persons per year and has risen over the last decade as a result of aging of the population and increased participation in athletic activities.[2-5] Routine imaging during the follow-up of ankle fractures is associated with relatively high healthcare costs.[6, 7] Healthcare costs are expected to rise in coming decades.[8] This has led to an increased interest in the effectiveness of imaging in clinical decision-making.[9-12] Despite increased costs, both national and international trauma protocols dictate that routine radiographs should be made at regular intervals during the follow-up of patients with an ankle fracture, although there is little scientific evidence to support this position.[4, 13, 14] For both nonoperatively and operatively managed patients, it is recommended that 4 outpatient clinic visits including radiographs, are to be conducted after a follow-up of 1, 2, 6, and 12 weeks.[13] The goal of these radiographs is to monitor the position of the fracture fragments, the position of fixation material, the alignment of the joint, and the bone-healing process.

In the Netherlands, with a population of over 17 million, approximately €5 million is spent annually on radiography for patients with ankle fractures. This estimate is based on an incidence of 30,000 per annum,[15] with 3 to 4 follow-up radiographs,[16] at a cost of €50 per radiograph.[17] Various studies have questioned the value of routine radiographs made at the first outpatient clinic visit and at intermediate-to-late follow-up (i.e., after the initial 3 weeks) of operatively managed ankle fractures.[18, 19] A recent retrospective analysis, involving a cohort of 528 patients with an ankle fracture, demonstrated that as few as 1.2% (11/928) of routine radiographs made after 3 weeks of follow-up led to a change in the treatment strategy.[16] These results suggest that current imaging protocols for the follow-up of ankle fracture patients might not be cost-effective.

METHODS

Aim

The aim of the present study was to evaluate the cost-effectiveness of a protocol with reduced numbers of routine radiographs during the follow-up of ankle fractures, in comparison with the current routine care.

Setting and Design

This economic evaluation was conducted alongside a multicentre, randomized controlled trial (RCT). The methods of this trial, including its sample size calculation, are described in detail elsewhere.[20] 7 hospitals in the Netherlands participated in the study, including 3 university hospitals and 4 large teaching hospitals. Patients were enrolled between July 2014 and October 2017.

Both a cost-effectiveness and cost-utility analysis were performed from a societal perspective. The time horizon of the economic evaluation was 12 months. Consolidated Health Economic Evaluation Reporting Standards (CHEERS) guidelines were followed in preparing this report.[21, 22]

Inclusion and Exclusion Criteria

Patients could participate in the study if they provided written informed consent, were over 18 years of age, had a fracture of the ankle (Lauge Hansen classification types supination-adduction 2, supination-external rotation 2 to 4, pronation-external rotation 1 to 4, or pronation-abduction 1 to 3),[23] and were able to independently complete the Dutch questionnaires. Distortions or isolated Danis-Weber type A fractures[24] were not included. Exclusion criteria were the presence of fractures to multiple extremities, pathologic, or open fractures (Gustilo grades 2 and 3). If patients were deemed unable to comply with follow-up they were also excluded.

Randomization

Patients were informed about the study both verbally and by means of an information letter. All participants had to provide written informed consent. Participants were randomized by means of computerised allocation, with use of an online registration and randomization program (ProMISe; Project Manager Internet Server; https://www.msbi.nl/promise-/ProMISe.aspx)

Participants were assigned in a 1:1 ratio to either the intervention group or the control group. Randomization was carried out with use of a stratified, randomly varying block design (each block size containing 2 to 6 allocations). The tables were internally pregenerated within the secure data management system stratified by hospital and the initial treatment strategy.

Control Group – Routine Care

Patients randomized to the routine care group were monitored at the outpatient clinic and received routine follow-up radiographs at 1, 2, 6, and 12 weeks of follow-up.

Additional follow-up moments with or without the use of radiographs could be scheduled at any time if deemed necessary by the treating physician.

Intervention Group – Reduced Imaging

In the reduced imaging group, radiographs were routinely made after 1 and 2 weeks. Radiographs could be made later in the follow-up if a specific clinical indication was present or could be made at the discretion of the treating physician. Reasons for doing so included an additional trauma to the affected ankle, a pain score of 6 or higher on a 11-point Numerical Rating Scale (NRS), a decrease in Range-Of-Motion (ROM), or neurovascular abnormalities. Motivations to make additional radiographs were required to be logged in the medical file. Aside from the modified imaging protocol at follow-up, all aspects of treatment and follow-up were similar for both groups.

Outcome measures

Measurements at baseline included potential confounders,[25] such as age, sex, medical history, smoking habits, alcohol intake, functional status, health-related quality of life (HRQoL), and socioeconomic status. Follow-up questionnaires assessing the patients' clinical outcomes as well as their resource use were administered after 6, 12, 26, and 52 weeks. The questionnaires could be completed either online or by post. The recall period of these questionnaires varied from 6 weeks at the follow-up moment at week 6 to 26 weeks at the follow-up moment at week 52.

Functional status of the affected ankle was evaluated with use of the Olerud-Molander Ankle Score (OMAS). This is a 9-item questionnaire assessing both pain and disability related to the affected ankle. The OMAS was calculated for all of the measurement points separately, ranging from 0 to 100 with a score of 100 equalling no pain or disability.[26] HRQoL was assessed with use of the Dutch version of the EuroQol-5 Dimensions-3 Levels (EQ-5D-3L). At baseline, participants were asked to complete the EQ-5D-3L for their health state just prior to their trauma. At all other time points, they were asked to consider their current health status. Utility scores per time point were estimated with use of the Dutch EQ-5D-3L tariff.[27, 28] Quality-adjusted life-years (QALYs) per patient were estimated with use of linear interpolation of the utility scores for the different time points. As the patients' utility score right after the trauma was not available (i.e., the patients' "true" baseline utility score), we assumed their utility score at baseline to be equal to the score at 6 weeks of follow-up.

Cost measures

Resource use questionnaires were used to measure the patients' use of primary and secondary healthcare, medication, informal care, as well as their levels of unpaid productivity losses, absenteeism, and presenteeism. Costs of the intervention (i.e., costs for the radiographs) were gathered from electronic patient records. Primary healthcare use included the patients' number of general practitioner consultations, visits to a company medical officer, physiotherapy treatments, and visits to other specialised therapists. All these visits were required to be associated with the ankle fracture. Information on the use of secondary healthcare services was gathered from electronic patient records and included admissions to hospital, nursing home or rehabilitation centre, outpatient clinic visits, all imaging other than plain radiographs (e.g., CT- or MRI-scans of the ankle), and re-operations. These services also included the initial admission right after the trauma occurred and the primary intervention if applicable. All healthcare costs were valued according to Dutch standard costs[29] or, if unavailable, tariffs. Medication costs were calculated as costs-per-day for each medication, which was based upon the standard dosage per day and unit prices of the Royal Dutch Society of Pharmacy.[30] Total medication costs were calculated by multiplying this cost per day with the total days of use. If the duration was not specified, we assumed patients used a certain medication during the complete recall period. Unpaid productivity losses (i.e., volunteer work, caregiving, or domestic activities patients could not perform because of their fracture) and informal care (i.e., care provided by relatives, friends, or volunteers) were valued at €14.13 per hour, a shadow price that is recommended by the Dutch National Healthcare Institute.[29] Absenteeism was defined as the number of days of absence because of the ankle fracture. The Friction Cost Approach was used to value absenteeism, which assumes that costs are limited to the time it takes to replace an absent worker (in the Netherlands: 12 weeks).[29] The participants' number of presenteeism days were estimated by multiplying the number of days worked (i.e., workable days – sickness absence days) by a self-reported score reflecting their productivity level when they were present at work ranging from 0 (equalling no productivity) to 10 (equalling full productivity). Days of absenteeism and presenteeism were valued with use of gender-specific price weights.[29] The trial's follow-up was 12 months and discounting of costs and effects was, therefore, not necessary. All costs were converted to Euros 2016 with the help of consumer price indices.[31]

Statistical Analysis

Analyses were performed in accordance with the intention-to-treat principle. Missing data were multiply imputed with use of STATA (Version 12 SE, Stata Corp, College station, TX). The imputation model included utility scores, the OMAS, and all available cost values at baseline, 6, 12, 26, and 52 weeks as well as the baseline variables fracture classification, Body-Mass-Index (BMI), American Society of Anaesthesiologists (ASA) classification, smoking habits, alcohol intake, hospital, age, sex, randomization result, and whether the fracture was managed operatively or nonoperatively. These baseline variables were added because they were regarded as possible confounders, because they differed between groups at baseline, and/or because they were predictive of the 'missingness' of data. 5 complete datasets were generated in order for the loss-of-efficiency to be lower than 5%.[32] Each dataset was analysed separately, and estimates were pooled with use of Rubin's rules. This method takes into account both imputation variability within each dataset, as well as imputation variability between the separate datasets.[32] Seemingly unrelated regression analyses (SUR) were used to estimate total cost differences (ΔC) and effect differences (ΔE). The advantage of SUR is that ΔC and ΔE are modelled simultaneously so that their possible correlation can be accounted for.[33] For the OMAS, the patients' follow-up scores at week 52 were used as dependent variable. For total costs and QALYs, the patients' total costs and QALYs during follow-up were used as dependent variable, respectively. Analyses of the OMAS were adjusted for the patients' baseline OMAS and other possible confounders measured at baseline (Table I). In contrast to the recommendation of Manca et al.,[34] we decided not to adjust QALYs for baseline utility scores, as a "true" utility score was lacking in the current study. That is, the baseline utility value in the present study described the patients' utility value prior to their fracture, instead of right after their fracture. The incremental cost-effectiveness ratio (ICER) was estimated by dividing the cost difference by the effect difference (ΔC/ΔE). To estimate the uncertainty around the ICER and to estimate 95% confidence interval (95% CI) surrounding the cost differences, bias-corrected and accelerated bootstrapping was performed with 5,000 replications. For all 5,000 replications the cost and effect pairs were plotted on a cost-effectiveness plane to graphically illustrate the uncertainty surrounding the ICER.[35] A summary measure of the joint uncertainty surrounding costs and effects was provided by constructing cost-effectiveness acceptability curves (CEACs). These curves give an indication of the probability that the reduced imaging protocol for ankle fractures is cost-effective for a range of willingness to pay values. CEACs were pooled with use of a combination of Rubin's rules and the incremental net monetary benefit approach. For all statistical tests, significance was assumed at $p < 0.05$.

Sensitivity Analyses

A total of 6 sensitivity analyses were planned. In the first sensitivity analysis, only data of participants with complete data were used (SA1). The second sensitivity analysis (SA2) made use of the measured utility score at baseline (prior to the fracture), instead of the value derived from the utility score at 6 weeks. The third sensitivity analysis (SA3) used the Human Capital Approach to calculate productivity losses instead of the Friction Cost Approach. The Human Capital Approach assumes that productivity losses occur during the complete period of absence instead of being limited to the friction period. For the fourth sensitivity analysis (SA4), costs were assessed from a healthcare perspective. A healthcare perspective regards only costs accruing to the formal Dutch healthcare system, meaning that costs of informal care, absenteeism, presenteeism, and unpaid productivity losses were disregarded. The fifth (SA5) and sixth sensitivity analysis (SA6) only included patients with either a nonoperative or an operative management, respectively.

RESULTS

Participants

We enrolled 312 participants in the study (Fig. 1). 6 were excluded after randomization, because an exclusion criterion was present that was not identified before randomization (Fig. 1). Of the remaining 306 participants, 156 were randomized to routine care and 150 to reduced imaging. In total, 60 patients, 28 in the routine care group (18%) and 32 in the reduced imaging group (21%) did not return any of the follow-up questionnaires

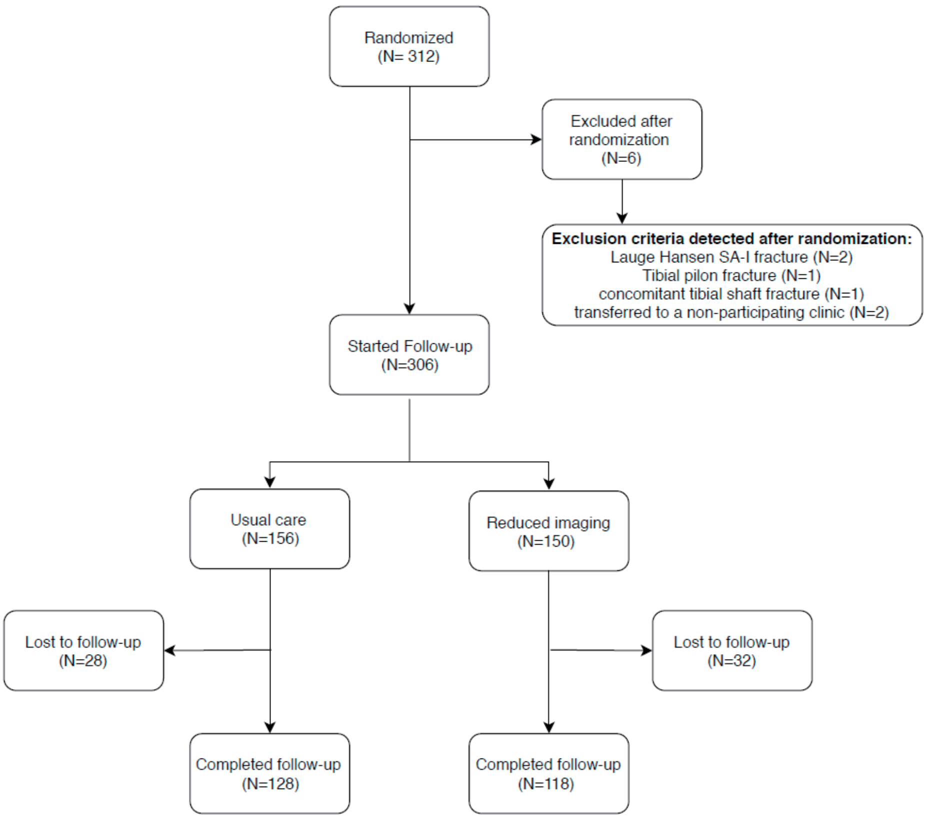

Figure 1. Flowchart of participants

and were lost to follow-up. Thus, 246 participants were included in the analysis (128 in the routine care group and 118 in the reduced imaging group).

Aside from a higher mean BMI for the reduced imaging group, no meaningful differences were observed between groups at baseline (Table I). Surgery was performed in 60% of participants in the routine care group (77/128) and in 65% of participants in the reduced imaging group (76/118). Out of a total of 1,230 (246*5) baseline and follow-up questionnaires, 1,096 were returned by the participants (89%).

Table I. Patient characteristics by treatment allocation

		Routine care (n=128)		Reduced imaging (n=118)		*p*-value
Male sex,	n (%)	69	(53.9)	58	(48.7)	0.42
Age	mean (SD)	47.7	(18.5)	50.8	(18.2)	0.18
BMI	mean (SD)	25.8	(4.3)	27.3	(6.0)	**0.02**
Alcohol >10 U/week	n (%)	22	(17.2)	16	(13.4)	0.42
Smoking >10/day	n (%)	10	(7.8)	9	(7.6)	0.94
Operative treatment	n (%)	77	(60.2)	76	(64.4)	0.46
Lauge-Hansen classification SA	n (%)	2	(1.6)	2	(1.7)	0.60
SE		94	(73.4)	94	(79.0)	
PA/PE		31	(24.2)	23	(19.3)	
missing		1	(0.8)	0	(0.0)	
Weber classification A	n(%)	2	(1.6)	2	(1.7)	0.49
B		93	(72.7)	94	(79.0)	
C		27	(21.1)	21	(17.6)	
missing		6	(4.7)	2	(1.7)	
Malleolar involvement Uni-	n(%)	66	(51.6)	64	(53.8)	0.79
Bi-		27	(21.1)	21	(17.6)	
Tri-		35	(27.3)	34	(28.6)	
ASA classification 1	n(%)	53	(41.4)	47	(39.5)	0.83
2		60	(46.9)	55	(46.2)	
≥3		15	(11.7)	12	(7.7)	

Legend for Table I:
SD: Standard deviation
SA: Supination-adduction
SE: Supination-external rotation
PA: Pronation-adduction
PE: Pronation-eversion
BMI: Body Mass index
ASA: American Society of Anesthesiologists
Bold = a significant difference between groups (p <0.05)

5

Effects

There was no significant difference in the OMAS (0.73; 95% CI, −5.3 to 6.8) and QALYs (−0.008; 95% CI, −0.04 to 0.03) between groups. An overview of the patients' OMAS and EQ-5D-3L score per follow-up moment can be found in the Appendix.

Costs and Use of Resources

As a result of the intervention, patients randomized to the reduced imaging group had fewer radiographs taken of their ankle fracture than patients randomized to routine care, equalling a median number of radiographs of 4 (Interquartile Range [IQR] 3 to 5) for the reduced imaging group versus a median of 5 (IQR 4 to 6) for the routine care group. This resulted in a significant reduction in imaging costs in favour of the reduced imaging group (−€48 per patient; 95% CI, −72 to −25). All other costs, including total societal costs, were not significantly different between groups (Table II).

Table II. Mean cost (in euros) per participant in the intervention and control group and mean cost differences between groups during follow-up

Cost category	Routine care (n=128) mean (SEM)		Reduced imaging (n=118) mean (SEM)		Cost difference (β) adjusted mean (95%CI)	
Intervention	266	(9)	222	(9)	**-48**	**(-72 to -25)**
Primary care	967	(154)	1266	(387)	137	(-277 to 1018)
Secondary care	7435	(971)	7803	(1176)	-169	(-2230 to 2178)
Medication	36	(9)	27	(7)	-8	(-27 to 12)
Informal care	671	(121)	647	(131)	-46	(-373 to 262)
Absenteeism	976	(212)	1218	(312)	306	(-373 to 1109)
Presenteeism	4903	(627)	4373	(605)	-29	(-1503 to 1408)
Unpaid productivity loss	789	(152)	757	(184)	-12	(-437 to 427)
Total	16046	(1419)	16314	(1741)	130	(-2975 to 3723)

Legend
Bold = a significant difference between groups (p <0.05)

Cost-effectiveness

For QALYs, the intervention was dominated by the control, based on a cost difference (ΔC) of €131 and an effect difference (ΔE) of −0.008 QALY. The ICER for functional outcome was 178, based on the same ΔC of €131 and a ΔE of 0.73 points on the OMAS (Table III). The CE-plane for QALYs shows that the cost-effect pairs were scattered across all 4 quadrants of the CE-plane (Fig. 2). The CEAC in Fig. 3 indicates that if decision-makers are willing to pay €20,000 per QALY gained, the probability of reduced imaging being cost-effectiveness compared with routine care was 0.45. This probability reduced with increasing values of willingness to pay to about 0.37 at a willingness to pay of €80,000

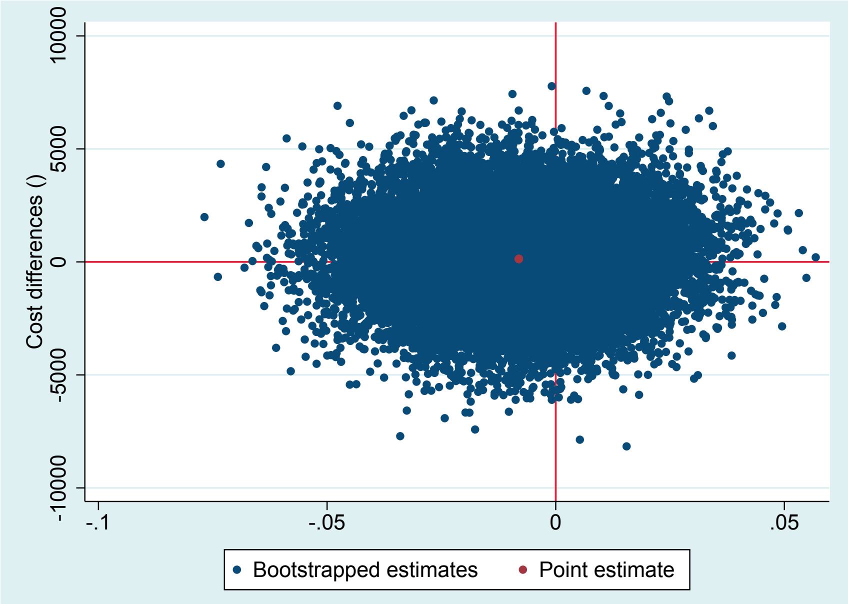

Figure 2. Cost-effectiveness plane for QALYs representing the results from the 5000 bootstrapped replications, and the point estimate.. Higher on the Y-axis corresponds to costlier than routine care, more right on the X-axis corresponds to more effective than routine care.

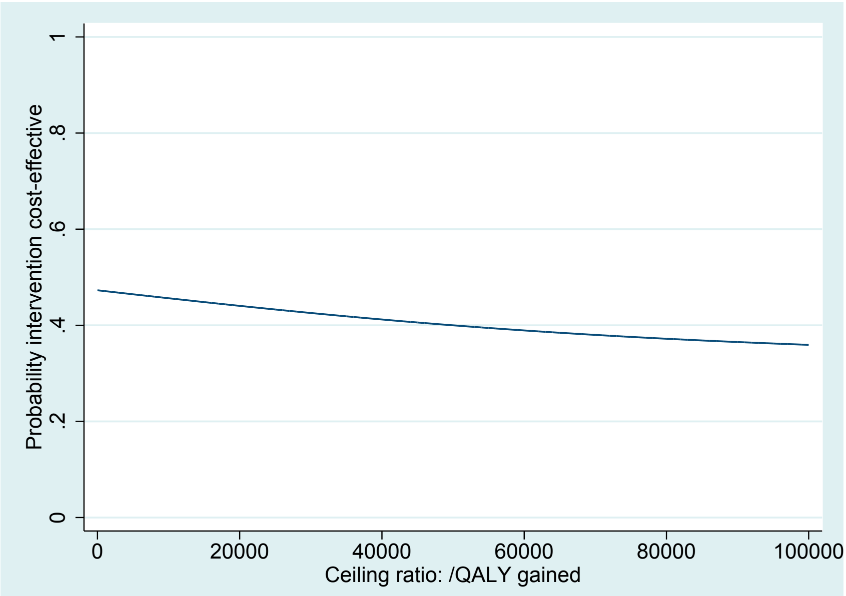

Figure 3. Cost-effectiveness acceptability curve for QALYs, showing the probability of the intervention being cost effective at a certain willingness to pay value per QALY.

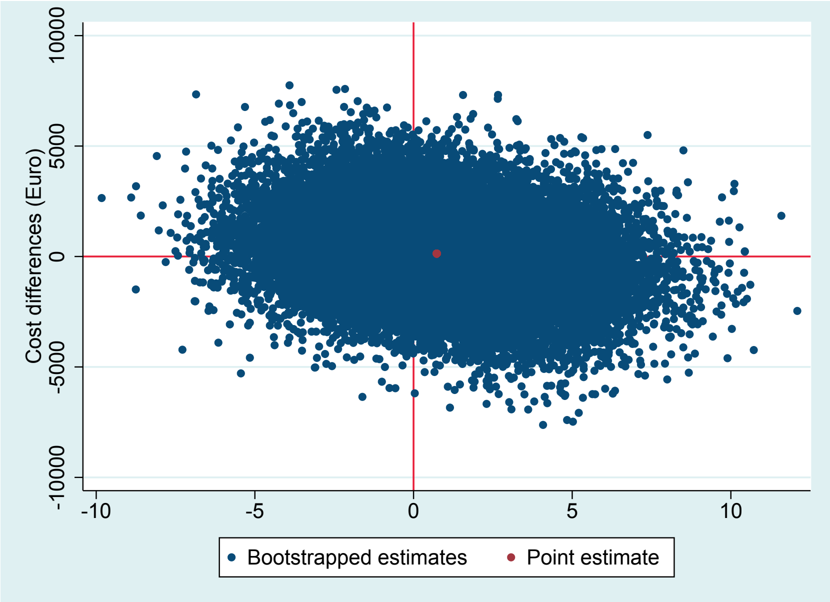

Figure 4. Cost-effectiveness plane for the OMAS, representing the results from the 5000 bootstrapped replications, and the point estimate. Higher on the Y-axis corresponds to costlier than control, more right on the X axis corresponds to more effective than control.

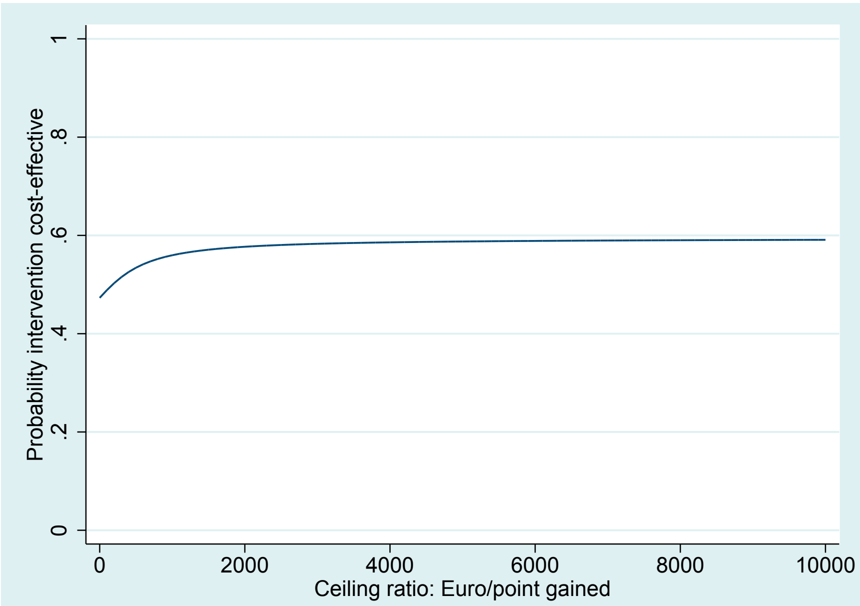

Figure 5. Cost-effectiveness acceptability curve for the OMAS, showing the probability of the intervention being cost effective at a certain willingness to pay value per point increase of the OMAS.

per QALY. The CE-plane for the OMAS also shows that the cost-effect pairs were scattered across all 4 quadrants of the CE-plane (Fig. 4). For the OMAS, the CEAC indicates that if decision-makers are not willing to pay anything per point improvement, the probability of reduced imaging being cost-effectiveness compared with routine care was 0.47. This probability increased with increasing values of willingness to pay to about 0.59 at a willingness to pay of €5,000 per point improvement (Fig. 5).

Sensitivity Analyses

In total, 6 sensitivity analyses (SA) were performed. Outcomes of the sensitivity analyses demonstrated many similarities with those of the main analysis (Table III). Except for SA6, differences in QALYs were in favour of the routine care group. Cost per category for the nonoperatively and operatively treated subgroup are reported separately in the Appendix. Except for SA5, the OMAS was higher for the reduced imaging group than for the routine care group and except for SA4 and SA5, total costs were higher for the reduced imaging group. However, all these differences in costs and effects were not significant. It is important to note that the relatively large differences in ICERs between the main analysis and some of the sensitivity analyses were because of small between-group differences in QALYs and the OMAS.

DISCUSSION

The reduced imaging follow-up protocol resulted in a significant decrease in the number of radiographs as well as the associated cost compared with routine care. Other cost categories, including total healthcare costs and total societal costs, did not statistically differ between groups. Furthermore, no significant differences were found between groups for QALYs and the OMAS. This indicates that functional outcome and HRQoL were unaffected by reducing the number of radiographs performed at 6 and 12 weeks of follow-up. The probability of the reduced imaging protocol being cost-effective compared with routine care was relatively low (0.45) at a willingness to pay threshold of €20,000 per QALY. In the Netherlands, this is deemed an acceptable cost-per-QALY for interventions for diseases/disorders with a relatively low disease burden.[36] For the OMAS, it is currently unknown how much decision-makers are willing to pay per unit of effect gained, so it is not possible to draw any firm conclusions for this outcome. Sensitivity analyses confirm these findings. Literature on the (cost-)effectiveness of omitting routine extremity radiography is scarce. This is discussed in our retrospective review[37] and has been confirmed by researchers investigating the usefulness of an additional shoulder radiograph.[38] Results from the present study, however, were consistent with results from our study which examined the cost-effectiveness of reduced imaging in

Table III: Differences in pooled mean costs and effects, incremental cost-effectiveness ratios, and the distribution of incremental cost-effect pairs around the quadrants of the cost-effectiveness planes for reduced imaging compared to routine care

	Routine care	Reduced imaging	Outcome measure	ΔC € (95% CI)	ΔE Points (95% CI)	ICER €/point	Distribution CE-plane (%)			
							NE	SE	SW	NW
Main analysis	128	118	QALYs (Range: 0 - 1)	131 (-3039 to 3928)	-0.008 (-0.04 to 0.03)	-16198	17.4	14.4	32.1	36.0
			OMAS (Range: 0 – 100)	131 (-3039 to 3928)	0.73 (-5.29 to 6.76)	178	21.4	31.8	15.0	25.8
SA1 *– Complete cases*	29	23	QALYs (Range: 0 - 1)	1242 (-7949 to 6447)	-0.014 (-0.06 to 0.04)	-86988	46.0	7.5	10.9	35.6
			OMAS (Range: 0 – 100)	1242 (-7949 to 6447)	3.04 (-5.82 to 11.89)	409	70.1	16.2	2.8	10.8
SA2 *– QALY 1 VS QALY 2*	128	118	QALYs (Range: 0 - 1)	131 (-3039 to 3947)	-0.013 (-0.05 to 0.02)	-10394	8.3	15.9	30.8	45.0
SA3 *– Human capital approach*	128	118	QALYs (Range: 0 - 1)	383 (-2900 to 4365)	-0.008 (-0.04 to 0.03)	-47311	19.2	13.2	29.8	39.9
			OMAS (Range: 0 – 100)	383 (-2900 to 4365)	0.73 (-5.29 to 6.75)	527	30.6	28.9	13.2	27.4
SA4 *– Healthcare perspective*	128	118	QALYs (Range: 0 - 1)	-89 (-2386 to 3287)	-0.008 (-0.04 to 0.03)	11052	14.3	17.2	36.4	32.1
			OMAS (Range: 0 – 100)	-89 (-2386 to 3287)	0.73 (-5.29 to 6.75)	-121	23.6	36.2	17.4	22.8
SA5 – *Conservative treatment*	51	41	QALYs (Range: 0 - 1)	-2425 (-9691 to 1223)	-0.03 (-0.09 to 0.02)	74883	3.7	8.1	66.2	22.0
			OMAS (Range: 0 – 100)	-2425 (-9691 to 1223)	-1.60 (-10.49 to 7.30)	1519	6.2	28.5	45.5	19.8
SA6 – *Operative treatment*	77	77	QALYs (Range: 0 - 1)	1432 (-3007 to 6706)	0.001 (-0.04 to 0.04)	1504404	39.0	15.5	14.7	30.9
			OMAS (Range: 0 – 100)	1432 (-3007 to 6706)	1.51 (-5.07 to 8.08)	951	50.6	24.7	4.3	20.4

Legend for Table III:
SA: Sensitivity analysis
QALYs: Quality Adjusted Life Years
OMAS: Olerud and Molander Ankle Score
ΔC: Difference in cost
ΔE: Difference in effect
ICER: Incremental Cost Effectiveness Ratio
CE-plane: Cost Effectiveness plane.
NE: North east part of the CE-plane (representing an intervention that is more costly, but more effective)
SE: South east part of the CE-plane (representing an intervention that is cheaper, and more effective)
SW: South west part of the CE-plane (representing an intervention that is cheaper, but less effective)
NW: North west part of the CE-plane (representing an intervention that is both more costly and less effective)

distal radius fractures.[39] In that study we also saw no difference in functional outcome, but a significant reduction in cost for radiographic imaging for the reduced imaging group.

Strengths and Limitations

This economic evaluation was performed alongside a pragmatic RCT. Therefore, our results are likely to have a high internal validity, while their external validity is improved by the pragmatic nature of the trial. Of course, the present study has limitations as do all studies. First, the sample size calculation was based upon a margin of noninferiority[40] for the OMAS, rather than a meaningful difference in societal costs or QALYs. Wide confidence intervals surrounding the aggregate and disaggregate cost differences suggest that the study was underpowered to detect a meaningful difference in cost between groups. This is common for economic evaluations as powering to detect a meaningful difference in societal costs would have required many more participants. This would have been neither feasible nor ethical. Second, the number of radiographs omitted was lower than anticipated. This was because of a high number of protocol violations for the reduced imaging group. The protocol was adhered to (i.e., no routine radiograph made at both 6 as well as 12 weeks of follow-up) in just 59 of 118 participants (50%) in this group. We have reported on this in more detail in an earlier report.[41] Third, self-reported questionnaires were used to query the effect, and some costs. These questionnaires had a maximum recall period of 26 weeks, which might have introduced recall bias. However, as the recall period was similar for both groups, we assume that if present, this bias was similar for both groups. Fourth, 79% (195/246) of the participants had at least 1 missing item on at least 1 of the questionnaires. The number of participants with complete cost and effect data was 242 at baseline (100%), 227 at week 6 (92%), 216 at week 12 (88%), 206 at week 26 (84%), and 201 at week 52 (82%). Multiple imputation was used to deal with missing data. In an economic evaluation, multiple imputation is considered the gold-standard for dealing with missing data.[32] Moreover, a sensitivity analysis with use of data of complete cases showed similar results as the main analysis, i.e., no significant differences between groups for costs, the OMAS, and QALYs. Finally, the patients' EQ-5D-3L health status directly following the fracture was not assessed. It was only assessed prior to the fracture and at the various follow-up measurement points. To deal with this issue, we assumed the patients' EQ-5D-3L health state at week 6 to be representative for the complete period between the occurrence of the fracture and the follow-up moment at week 6 and used this value for calculating QALYs. We opted for this strategy, instead of using their pre-injury EQ-5D-3L health state, as most patients would have had a cast, or nonweightbearing mobilisation during these 6 weeks. We do not expect this to have biased our outcomes, as a sensitivity analysis with use of the patients' EQ-5D-3L health state before the occurrence of the fracture showed similar results as the main analysis.

CONCLUSION

Reducing the number of routine follow-up radiographs (on average 1 per patient) has a relatively low probability of being cost-effective compared with routine care. However, functional outcome, HRQoL, and societal costs were comparable for both groups whereas imaging costs were lower for the reduced imaging group. In the light of these findings and the potential for further reduction of the number of routine follow-up radiographs in daily clinical ankle fracture care, we advise a reduced imaging follow-up protocol for patients with ankle fracture.

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APPENDICES

Appendix 1: outcome scores per treatment allocation per time point.

		Routine care n=128 Median (IQR)	Reduced imaging n=118 Median (IQR)
OMAS	*BL*	100 (100-100)	100 (100-100)
	W6	40 (25-60)	45 (25-65)
	W12	65 (45-80)	65 (46-80)
	W26	85 (68-95)	80 (65-95)
	W52	90 (80-100)	90 (80-100)
EQ-5D	*BL*	1.0 (0.9-1.0)	1.0 (0.84-1.0)
	W6	0.78 (0.57-0.81)	0.78 (0.65-0.86)
	W12	0.83 (0.78-1.0)	0.81 (0.78-1.0)
	W26	1.0 (0.81-1.0)	0.84 (0.78-1.0)
	W52	1.0 (0.84-1.0)	1.0 (0.81-1.0)

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Appendix 2: Mean cost (in euros) per operatively treated participant in the reduced imaging and routine care group, and mean cost differences between groups during follow-up

Cost category	Routine care n=128 mean (SEM)	Reduced imaging n=118 mean (SEM)	Cost difference (β) mean (95%CI)
Intervention	264 (11)	231 (12)	**-40 (-71 to -11)**
Primary care	1110 (161)	1575 (589)	101 (-476 to 1470)
Secondary care	10064 (908)	11469 (1679)	249 (-2733 to 3775)
Medication	35 (10)	32 (11)	-5 (-33 to 26)
Informal care	747 (143)	824 (202)	33 (-384 to 516)
Absenteeism	923 (256)	1335 (443)	551 (-335 to 1746)
Presenteeism	5451 (794)	5012 (885)	257 (-1618 to 2301)
Unpaid productivity loss	753 (175)	1058 (284)	287 (-278 to 980)
Total	**19346 (1330)**	**21536 (2420)**	**1432 (-2596 to 6998)**

Legend for appendix 2
Bold = a significant difference between groups ($p < 0.05$)

Appendix 3: Mean cost (in euros) per nonoperatively treated participant in the reduced imaging and routine care group, and mean cost differences between groups during follow-up

Cost category	Routine care n=128 mean (SEM)	Reduced imaging n=118 mean (SEM)	Cost difference (β) mean (95%CI)
Intervention	271 (17)	205 (13)	**-54 (-96 to -16)**
Primary care	752 (259)	708 (177)	63 (-448 to 564)
Secondary care	3465 (1936)	1169 (272)	-1194 (-5891 to 574)
Medication	37 (14)	18 (7)	-13 (-39 to 6)
Informal care	557 (203)	328 (135)	-161 (-728 to 145)
Absenteeism	1058 (384)	1006 (510)	-42 (-1119 to 1213)
Presenteeism	4076 (949)	3217 (957)	-405 (-2838 to 1613)
Unpaid productivity loss	846 (278)	214 (88)	**-619 (-1524 to -175)**
Total	11063 (2665)	6865 (1267)	-2425 (-9471 to 1162)

Legend for appendix 3
Bold = a significant difference between groups (p <0.05)

6

Omitting Routine Radiography of Traumatic Distal Radial Fractures After the Initial 2 Weeks of Follow-up Does Not Affect Outcomes

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The Journal of Bone and Joint Surgery. 2019;101:1342-50

ABSTRACT

Background

Routine radiography in the follow-up of distal radius fractures is common practice, although its usefulness is disputed. The aim of the present study was to determine whether the number of radiographs during follow-up can be reduced without resulting in worse outcomes.

Methods

In this multicenter, prospective, randomized controlled trial with a noninferiority design, patients ≥18 years of age with a distal radius fracture could participate. They were randomized between a regimen with routine radiographs at 6 and 12 weeks of follow-up (routine care) and a regimen without routine radiographs at these time points (reduced imaging). Randomization was performed with use of an online registration and randomization program. The primary outcome was the Disabilities of the Arm, Shoulder, and Hand (DASH) score. Secondary outcomes included the Patient-Rated Wrist/Hand Evaluation (PRWHE) score, health-related quality of life measured with the EuroQol-5 Dimensions-3 Levels (EQ-5D-3L) questionnaire, pain measured with a 1-to-10-points visual analog scale, and complications. Outcomes were assessed at baseline and after 6, 12, 26, and 52 weeks of follow-up. Data were analyzed with use of mixed models. Neither the patients nor the health-care providers were blinded.

Results

Three hundred and eighty-six patients were randomized, and 326 of them were ultimately included in the analysis. The DASH scores were comparable between the routine care group (n=166) and the reduced imaging group (n=160) at all time points as well as overall. The adjusted difference (β) in the DASH scores was 1.5 (95% confidence interval [CI], −1.8 to 4.8). There was also no difference between the groups with respect to the overall PRWHE score (β, 1.4; 95% CI, −2.4 to 5.2), EQ-5D-3L score (β, −0.02; 95% CI, −0.05 to 0.01), pain at rest (β, 0.1; 95% CI, −0.2 to 0.5), or pain when moving (β, 0.3; 95% CI, −0.1 to 0.8). The complication rate was similar in the reduced imaging group (11.3%) and the routine care group (11.4%). Fewer radiographs were made for the participants in the reduced imaging group (median 3, versus 4; $p < 0.05$).

Conclusions

The present study shows that omitting routine radiography after the initial 2 weeks of follow-up for patients with a distal radius fracture does not affect patient-reported outcomes or the risk of complications compared with routine care.

INTRODUCTION

Distal radius fractures are the most commonly encountered fractures in trauma patients, with an incidence of 160 to 320 per 100,000 patients annually, and they account for 18% of all fractures.[1-3] Because of the aging population, the incidence is expected to increase in the coming decades.[4] In a previous study, 238 (23%) of 1,042 distal radius fractures required operative management because of primary instability, inadequate reduction, or failure of nonoperative management.[5]

The main criteria for adequate reduction are restoration of the articular congruity, radial height, radial inclination, and volar tilt.[6] Incongruity of the joint or displacement of the fracture fragments can lead to uneven joint loading, osteoarthritis, and a poor functional outcome.[6] These parameters are assessed on conventional radiographs. Resolution of soft-tissue swelling and poor cast application leave patients at risk for secondary fracture displacement.[7] One concern about distal radius fractures is secondary loss of reduction in the early phase of treatment, and this can be evaluated with conventional imaging. In the Netherlands, the most common window for operative intervention is judged to be within 2 weeks following trauma, after which early consolidation might complicate the ability to achieve success with operative management. Routine radiography to detect displacement in this period might therefore be justified. However, existing trauma protocols prescribe regular radiographs and clinical assessments, aimed at monitoring the bone-healing process and functional clinical outcome, after this 2-week period.[8-10] Several studies demonstrated that radiographs are often made routinely during follow-up of distal radius fractures without a clinical indication and that they seldom alter the treatment strategy.[5, 11-13] These findings suggest that making fewer radiographs in the follow-up of distal radius fractures does not lead to worse outcomes.

The aim of the present study was to determine whether a modification of the radiographic follow-up protocol for patients with a distal radius fracture is possible with no worse outcomes in comparison with routine care.

METHODS

Design and Setting

The study design, which was described in detail elsewhere prior to patient inclusion,[14] was a multicenter randomized controlled trial with a noninferiority design.[15] It was performed in 4 level-I trauma centers in the Netherlands. A noninferiority trial evaluates whether a new intervention is not worse (noninferior) compared with routine care.

Other benefits (e.g., fewer side effects, lower costs, or improved feasibility) may then favor the implementation of the new intervention.[16] The trial was registered in the Netherlands Trial Registry (NTR4610), and a description of the trial was published before the onset of patient enrollment.[14] The present study was approved by the Medical Ethics Committee of the Leiden University Medical Centre on behalf of all 4 participating hospitals (protocol no. P14.086). The results of the present study are reported following the Consolidated Standards of Reporting Trials (CONSORT) guidelines for noninferiority trials.[17]

Inclusion Criteria

Patients were eligible for inclusion if (1) they had a fracture of the distal part of the radius (AO/OTA classification type 2R3-A, B, or C),[18] (2) were ≥18 years of age, (3) had sufficient understanding of the Dutch language to complete follow-up questionnaires, and (4) provided written informed consent.

Exclusion Criteria

Patients were excluded if they met at least 1 of the following criteria: (1) pathologic fracture, (2) open fracture (Gustilo grade 2 or 3), and (3) multiple fractures in the extremities. They were also excluded when they were not able to comply with follow-up or had been referred for follow-up in a hospital not participating in the present trial.

Sample-Size Calculation

As described elsewhere,[14] 70 participants were necessary to demonstrate noninferiority (power 0.85; alpha 0.05) based on a margin of noninferiority of 9 points on the Disabilities of the Arm, Shoulder, and Hand (DASH) questionnaire.[17] To enable subgroup analysis for treatment (i.e., nonoperative or operative) 350 participants with a distal radius fractures were needed on the basis of an empirical treatment ratio of 1:4. When accounting for a 10% loss to follow-up, a total of 385 participants needed to be recruited.

Randomization

As described in more detail elsewhere,[14] all participants were randomly assigned in a 1:1 ratio to either the current imaging protocol (routine care group) or an imaging protocol with a reduced number of routine radiographs (reduced imaging group) stratified by hospital and the treatment strategy. Patients and health-care providers were not blinded to group assignment.

Routine Care

Participants randomized to routine care received follow-up and imaging in accordance with our current trauma protocol,[10] which prescribes outpatient clinic consultations as well as routine radiographic evaluations at 1, 2, 6, and 12 weeks following injury or surgery. Additional outpatient clinic consultations or radiographs could be scheduled at any time during follow-up by the treating physician if deemed necessary.

Reduced Imaging

Participants randomized to reduced imaging initially received similar follow-up: outpatient clinic consultations and radiographic evaluation up to 2 weeks after injury or operative fixation. However, no routine radiographs were made after the initial 2 weeks. After the initial 2 weeks of follow-up radiographs could still be made if there was a clinical indication for them, including new trauma to the wrist, a pain score of >6 on a 0-to-10-point visual analog scale (VAS), a decreased range of motion, or the presence of neurovascular symptoms. As was the case for participants in the routine care group, additional radiographs or follow-up visits could be scheduled by the treating physician if deemed necessary, including for reasons not listed above. The clinical indication for ordering radiographs after 2 weeks had to be recorded in the medical records.

Primary Outcome Measure

The primary outcome was functional status measured with use of the validated Dutch version of the DASH questionnaire.[19]

Secondary Outcome Measures

Wrist pain and disability in activities of daily living were measured with use of the overall score on the Patient-Rated Wrist/Hand Evaluation (PRWHE).[20, 21] Pain intensity at rest and when moving the involved limb was measured with a VAS. Self-reported health perception was also scored with a VAS. Health-related quality of life (HRQoL) was measured with use of the EuroQol-5 Dimensions-3 Levels (EQ-5D-3L),[22] and physical and mental component summary (PCS and MCS) scores derived from the Short Form-36 (SF-36) questionnaire[23, 24]. All patient-reported outcomes were measured at baseline (i.e., the recalled preinjury status) and 6, 12, 26, and 52 weeks after the injury or surgery.

The range of motion of the wrist (flexion, extension, pronation, and supination) was measured at 6 and 12 weeks of follow-up. Complications, including surgical site infection, nonunion, malunion, and implant failure, were extracted from the medical records.

Statistical Analysis

All data analyses were performed with use of SPSS statistical software (version 23; IBM corp. Armonk, NY). Descriptive statistics were used to compare baseline measures between groups. The median numbers of radiographs were compared with use of a 2-independent-samples test, and the mean ranges of motion were compared with use of an independent-samples *t* test. The complication rate was compared between both groups with use of a χ^2 test. Outcome measures retrieved from the questionnaires had a repeated-measures data structure. To analyze these data, and to deal with missing data, linear mixed model analyses were used with a 2-level structure (i.e., questionnaires were clustered within participants). All results are displayed as a regression coefficient for the intervention, with the corresponding 95% confidence interval (CI). All analyses were carried out as both a "crude analysis" (corrected only for the participants' own baseline measurement) and an "adjusted analysis" (also corrected for all possible confounders including the patient demographics reported in Table I). Analyses were performed to compare results at all individual follow-up times, as well as to compare the overall outcomes. The overall outcome is a weighted number representing the total follow-up period. It considers the mean score over the first 6 weeks (equaling the score at week 6), weighted 6 times; the mean score for weeks 6 to 12, calculated using scores at weeks 6 and 12, weighted 6 times; the mean score for weeks 12 to 26, calculated using scores at weeks 12 and 26, weighted 14 times; and the mean score for weeks 26 to 52, calculated using scores at weeks 26 and 52, weighted 26 times.

To prevent case dropping when a value for a possible confounder was not available, missing values in the used correction factors were multiply imputed. The imputation model was constructed following guidelines drafted by White et al.[25] Five different databases were drafted and were pooled with use of Rubin's rules.[25] For all statistical tests, significance was assumed at $p < 0.05$.

RESULTS

Participants

From July 2014 until August 2016, 386 participants were included in the study. Six were excluded after randomization, and 54 (14.2%) of the remaining 380 were lost to follow-up (Fig. 1) because they did not return a single questionnaire during follow-up. The analyzed group consisted of 326 participants, 166 of whom were randomized to the routine care group and 160 of whom were randomized to the reduced imaging group. Baseline characteristics are listed in Table I, and none differed significantly between the groups. The fracture of 41 participants (13%) required operative management: 21 in the routine care group and 20 in the reduced imaging group. Closed reduction was performed in 109 participants: 54 in the routine care group and 55 in the reduced imaging group.

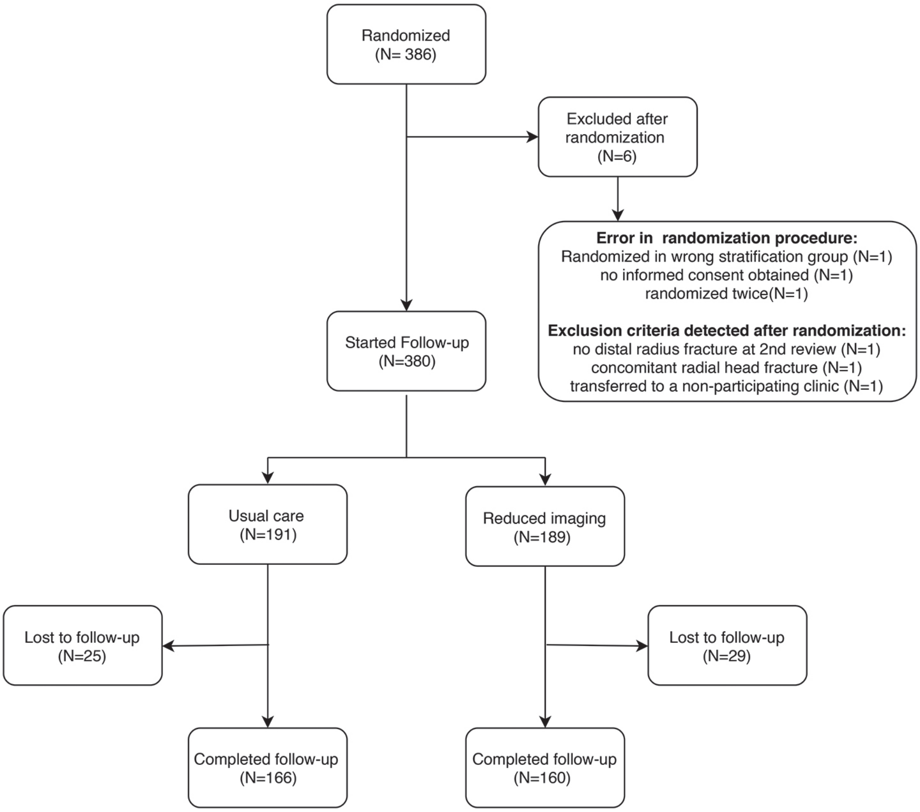

Figure 1. Flowchart of patients.

Primary Outcome

The DASH scores did not differ significantly between the groups at any time point (Fig. 2). The overall DASH scores were similar for both groups, with a median of 12 (Inter Quartile Range [IQR], 3 to 33) in the routine care group and 9.5 (IQR, 2 to 27) in the reduced imaging group. The adjusted regression coefficient (or adjusted difference [β]) for routine care compared with reduced imaging was 1.5 (95% CI, −1.8 to 4.8), indicating that during the entire follow-up function measured with the DASH was on average 1.5 points worse in the routine care group than in the reduced imaging group (Table II).

Secondary Outcomes

The overall functional status of the affected wrist assessed with the PRWHE questionnaire was comparable between the groups (β, 1.4; 95% CI, −2.4 to 5.2) (Table II). The scores at each time point were also not worse in the reduced imaging group (Fig. 3). No differences between groups were found when evaluating HRQoL.

Table I. Patient characteristics by treatment allocation

		Routine care (n=166)		Reduced imaging (n=160)		*p*-value
Male sex,	n (%)	39	(23.5)	39	(24.4)	0.9
Age	mean (SD)	56.7	(18.2)	56.8	(17.7)	1.0
BMI	mean (SD)	25.0	(4.5)	24.9	(5.0)	0.9
Alcohol >10 U/week	n (%)	18	(10.8)	9	(5.6)	0.1
Smoking >10/day	n (%)	8	(4.8)	7	(4.4)	0.9
Operative treatment	n (%)	21	(12.7)	20	(12.5)	1.0
Closed reduction	n (%)	54	(32.5)	55	(34.4)	0.7
Fracture of dominant wrist	n(%)	63	(38.0)	65	(40.6)	0.6
AO classification A	n(%)	106	(63.9)	113	(70.6)	0.2
B		18	(10.8)	17	(10.6)	1.0
C		42	(25.3)	30	(18.8)	0.2
ASA classification 1	n(%)	67	(40.4)	76	(47.5)	0.2
2		82	(49.4)	68	(42.5)	0.2
≥3		12	(7.2)	12	(7.5)	0.9
missing		5	(3.0)	4	(2.5)	0.8

Legend for table I:
SD: Standard deviation
BMI: Body Mass index
AO: Arbeitsgemeinschaft für Osteosynthesefragen
ASA: American Society of Anesthesiologists

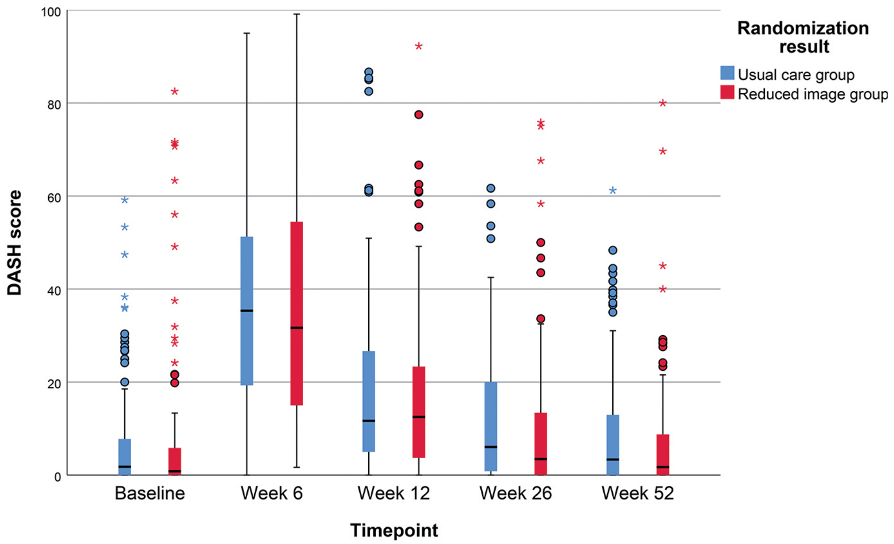

Figure 2: Box plot of DASH scores over time. Horizontal line in box = median, top and bottom of box = interquartile range, whiskers = 1.5 times the interquartile range, circles = outliers, and asterisks = extreme outliers

Table II. Overall outcome scores per treatment allocation, and adjusted regression coefficients

	Routine care (n=166) Median (IQR)	**Reduced imaging** (n=160) Median (IQR)	**RC vs RI** Adjusted β (95% CI)
DASH *0-100, Lower is better*	12(3-33)	9.5 (2-27)	1.5 (-1.8 to 4.8)
PRWHE *0-100, Lower is better*	18 (5-40)	14 (3-38)	1.4 (-2.4 to 5.2)
EQ-5D *0-1*	0.84 (0.73-1.0)	0.84 (0.80-1.0)	-0.02 (-0.05 to 0.01)
SF36 PCS *0-100, 50 = average*	48.7 (41.8-54.4)	50.6 (42.9-56.3)	-0.3 (-1.4 to 0.8)
SF36 MCS *0-100, 50 = average*	54.0 (46.7-58.2)	54.3 (49.3-58.4)	-0.9 (-2.2 to 0.3)
VAS pain rest *0-10*	0.4 (0.0-2.0)	0.2 (0.0-1.4)	0.1 (-0.2 to 0.5)
VAS pain movement *0-10*	2.0 (0.5-4.0)	1.1 (0.0-3.0)	0.3 (-0.1 to 0.8)
VAS Health status *0-10*	8.0 (6.5-9.0)	8.0 (7.0-9.0)	-0.2 (-0.5 to 0.1)
Recovered *1-5, higher = better*	4 (4-4)	4 (4-5)	0.1 (-0.2 to 0.1)
Function *1-5, higher = better*	4 (3-4)	4 (3-5)	-0.1 (-0.3 to 0.1)

Legend for table II:
CI: Confidence interval
IQR: Inter Quartile Range
RC: Routine Care
RI: Reduced imaging
SD: Standard deviation

Participants in the reduced imaging group had comparable EQ-5D-3L scores, both overall (β, −0.02; 95% CI, −0.05 to 0.01) (Table II), and at all individual time points, including at baseline (Fig. 4). The SF-36 PCS and MCS scores over time are presented in Figure 5. Neither score was worse in the reduced imaging group than in the routine care group at any time point or overall (Table II). Pain scores were comparable at all time points, except for the pain score during movement at 26 weeks (Fig. 6), which was significantly higher for the routine care group. Median overall pain scores demonstrated no difference between the routine care group and the reduced imaging group (Table II). The overall range of motion of the affected wrist also did not differ between the groups (see Appendix).

Complications were not encountered more frequently in the reduced imaging group (11.3%, 18 of 160) than in the routine care group (11.4%, 19 of 166). Specific complications were also equally common (Table III).

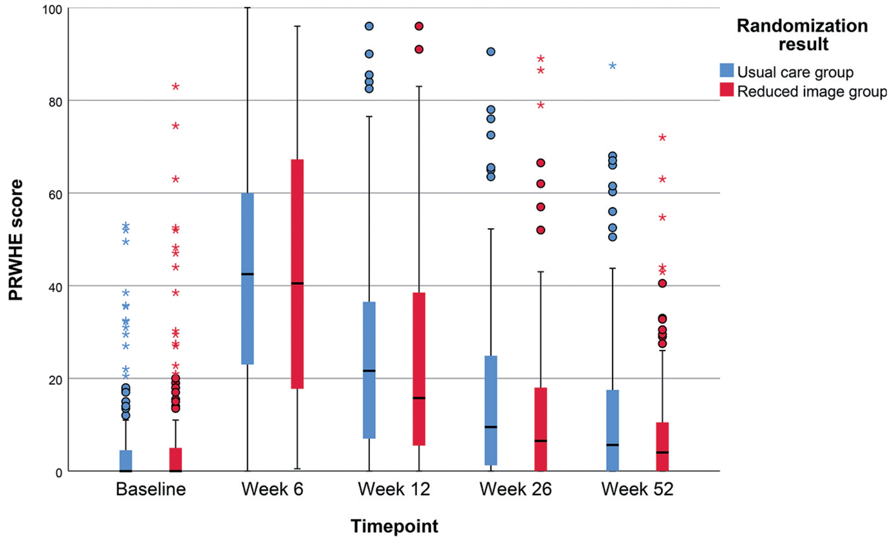

Figure 3: Box plot of PRWHE scores over time. Horizontal line in box = median, top and bottom of box = interquartile range, whiskers = 1.5 times the interquartile range, circles = outliers, and asterisks = extreme outliers

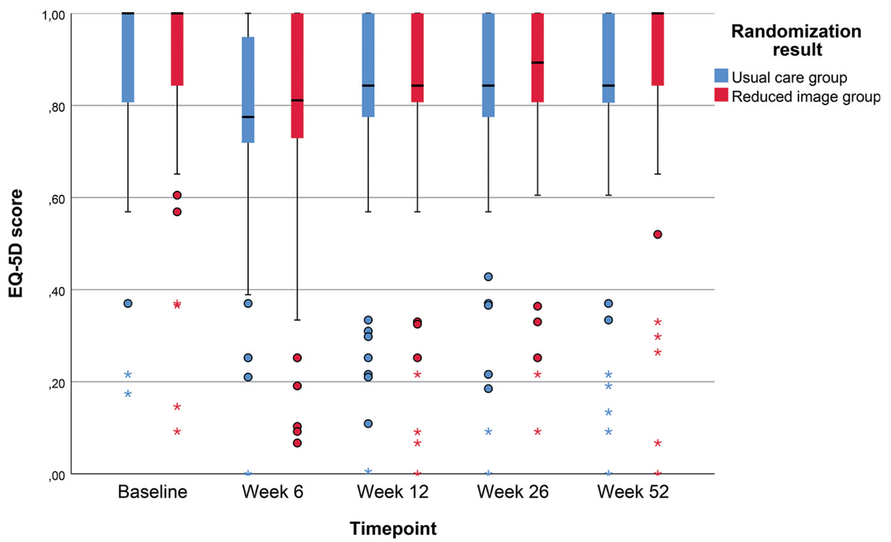

Figure 4: Box plot of EQ-5D-3L scores over time. Horizontal line in box = median, top and bottom of box = interquartile range, whiskers = 1.5 times the interquartile range, circles = outliers, and asterisks = extreme outliers

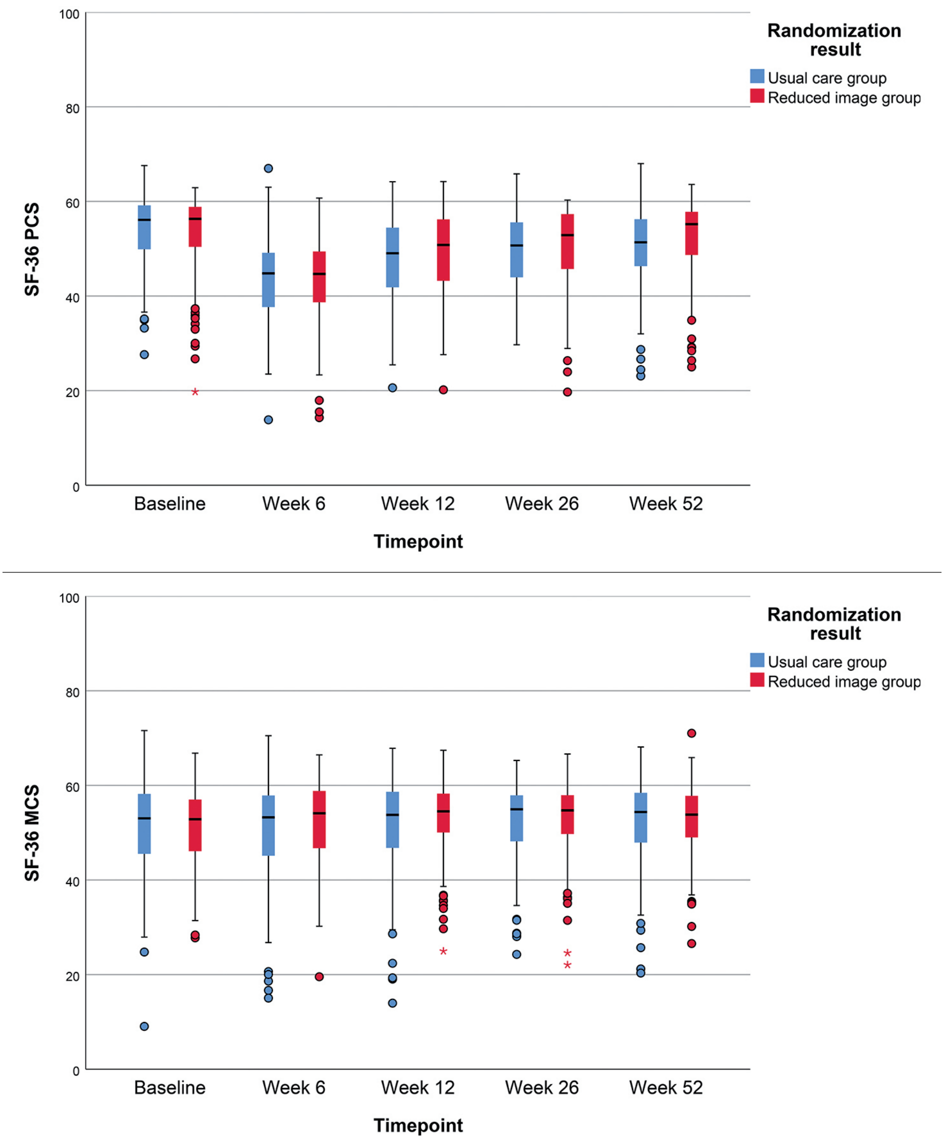

Figure 5: Box plots of PCS and MCS scores of the SF-36 questionnaire over time. Horizontal line in box = median, top and bottom of box = interquartile range, whiskers = 1.5 times the interquartile range, circles = outliers, and asterisks = extreme outliers

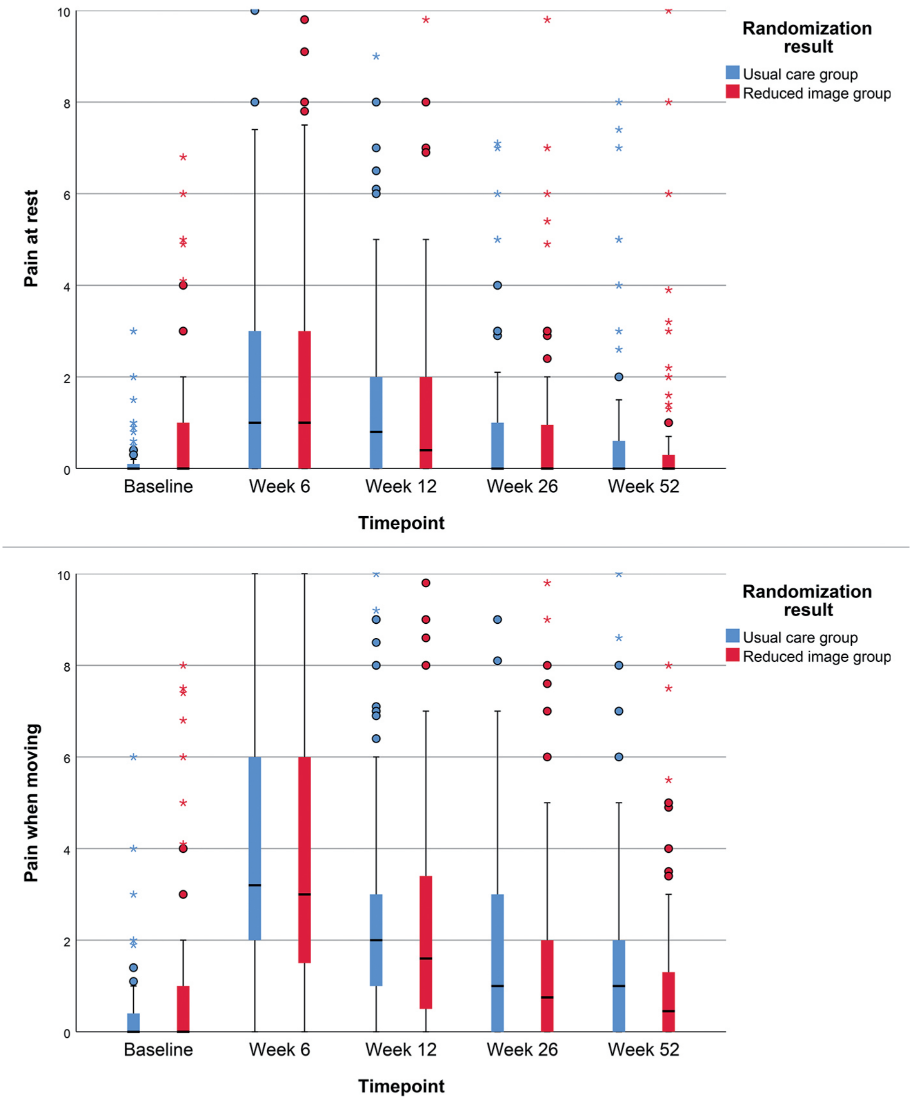

Figure 6: Box plots of pain scores over time. Horizontal line in box = median, top and bottom of box = interquartile range, whiskers = 1.5 times the interquartile range, circles = outliers, and asterisks = extreme outliers

Radiographs

In total, 1,234 sets of radiographs were made in the treatment of the participants, with a median of 4 in the routine care group and 3 in the reduced imaging group (p <0.05). Radiographs were made after more than 2 weeks of follow-up for 140 (84%) of the 166 patients in the routine care group and 27 (17%) of the 160 patients in the reduced imaging group. The reasons for obtaining radiographs are described in Table IV. The percentage of radiographs made to detect a fracture was higher for the reduced imaging group. This was because of a lower overall number of radiographs (but a similar sample size) in that group; the total number of radiographs made to detect a fracture was comparable between the 2 groups. In the routine care group, more radiographs were made to detect consolidation, and more were labeled "routine" than in the reduced imaging group.

Table III. Complications by treatment allocation

Complication:	**Routine care** (n=166)	**Reduced imaging** (n=160)
Non union	3	2
Mal union	2	3
Surgical site infection	0	0
Failure of fixation	1	2
Carpal tunnel syndrome	4	1
Complex regional pain syndrome	5	6
Refracture after second trauma	1	2
Implant related symptoms	1	1
Neurapraxia	1	1
Secondary dislocation	1	0
Total	**19 (11.4%)**	**18 (11.3%)**

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Table IV. Numbers of and indications for radiographs by treatment allocation

	Routine Care (n=166)	**Reduced Imaging** (n=160)	**P-value**
Number of radiographs	706	528	
Radiographs per patient *median (IQR)*	4 (3-6)	3 (2-4)	**<0.05**
Radiograph >2-wk of follow-up *n (%)*	140 (84.3)	27 (16.9)	**<0.05**
Indication for the radiograph *n (%)*			
Fracture	162 (22.9)	161 (30.5)	**<0.05**
Dislocation	480 (68.0)	355 (67.2)	0.8
Consolidation	319 (45.2)	157 (31.4)	**<0.05**
Routine	27 (3.8)	0 (0.0)	**<0.05**
Pain	20 (2.8)	20 (3.8)	0.4
Impaired function	5 (0.7)	5 (0.9)	0.6
Evaluate hardware	38 (5.4)	28 (5.3)	1.0
Unknown	3 (0.4)	2 (0.4)	0.9
Other	9 (1.3)	14 (2.7)	0.1

Legend for table IV
IQR: Inter Quartile Range
SD: Standard deviation
Bold = a significant difference between groups (p <0.05)

DISCUSSION

This multicenter randomized controlled trial shows that omitting routine radiographs after the initial 2 weeks of follow-up of distal radius fractures does not affect clinical outcomes. Functional outcome, HRQoL and pain levels were comparable between groups. Additionally, the omission of routine radiographs did not lead to a higher number of complications. Omission of routine radiographs after 2 weeks reduced the median number of radiographs by 1. The main difference was found in the number of radiographs made to detect hard callus formation, which was less frequently confirmed radiographically in the reduced imaging group, without a negative effect on functional outcome. This provides a cost saving opportunity for the health-care system,[26] and a small (0.002-mSv) dose reduction in ionizing radiation.[27] In the Netherlands, a set of radiographs of the wrist costs €52.[28] The reduction of the median by 1 radiograph per patient would therefore lead to a cost savings of €52 per patient. With an incidence of 55,000 per year,[1] the annual cost savings in the Netherlands would be nearly €3 million.

Our results were comparable with those in previous retrospective studies. In a retrospective cohort of 1,042 patients with a distal radius fracture, Weil et al.[5] demonstrated that changes in the treatment strategy are rarely (1.5%) based on a routine radiograph. Stone et al.[29] reported a similarly low rate of unexpected changes in management (1.1%), in a cohort of 268 patients with an operatively managed distal radius fracture. Huffaker et al.[30] reported finding no complications on 446 follow-up radiographs of the wrist for patients with an AO/OTA type- 2R3-A[18] fracture. Eastley et al.[12] demonstrated that patients with a nonoperatively treated AO/OTA type-2R3-A fracture who had radiographs made beyond 2 weeks after trauma did not have better grip strength or range of motion than patients who did not have these routine radiographs. Additionally, nonoperative management was never converted to operative management based on a late radiograph.

The present study had limitations. First, the adherence to the study protocol was poor, especially in the routine care group. This might indicate that physicians were already deviating from the routine care protocol, despite the lack of evidence-based validation for doing so. Ninety-seven (58.4%) of the 166 patients randomized to routine care received the prescribed follow-up regimen. The fact that many of the patients in the routine care group did not receive all radiographs prescribed after 2 weeks may explain why a lower number of radiographs were omitted in the reduced imaging group than initially expected. Second, we were unable to perform the intended subgroup analysis of operatively treated patients because the rate of operative management was lower than predicted based on data from a retrospective cohort treated in the same hospitals in 2012.[5] Operative management had dropped from 23% in that study to 13% in the inclusion period of the present study. As a result, we included only 41 (59%) of the 70 operatively managed participants needed for adequate power to test noninferiority claims. This subgroup analysis would therefore have been underpowered.[31] Third, whether a fracture was considered malunited was at the discretion of the treating physician, perhaps rendering this parameter less reliable and hindering comparison with other studies.

A strength of the present study is that the trial protocol was registered in a public trials' registry before the onset of patient enrollment. We were able to perform the current study adhering to this protocol, minimizing the risk of publication bias and selective outcome reporting bias.[32]

In conclusion, the present study shows that omitting routine radiographs after the initial 2 weeks of follow-up for patients with a distal radius fracture does not affect patient-reported outcomes or the risk of complications compared with such results for patients receiving routine care.

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APPENDIX

Appendix 1. Range of motion per timepoint, per treatment allocation, and difference (β)

	Rourtine care Mean ± SD	**Reduced imaging** Mean ± SD	**UC vs RI,** β (95%CI)
Palmar flexion – Dorsal flexion			
Week 6	82 ± 44 (n=82)	97 ± 45 (n=86)	**-15 (-26 to -3)**
Week 12	107 ± 36 (n=107)	117 ± 35 (n=85)	-10 (-21 to 1)
Week 26	119 ± 23 (n=30)	115 ± 36 (n=15)	5 (-16 to 26
Week 52	123 ± 27) (n=6)	113 ± 39 (n=2)	1 (-49 to 51)
Pronation – Supination			
Week 6	139 ± 46 (n=64)	146 ± 44 (n=75)	-7 (-18 to 4)
Week 12	157 ± 31 (n=101)	161 ± 31 (n=80)	-4 (-14 to 6)
Week 26	164 ± 22 (n=29)	155 ± 37 (n=14)	9 (-10 to 28)
Week 52	175 ± 12 (n=6)	155 ± 7 (n=2)	30 (-14 to 74)

Legend for appendix 1.
SD: Standard deviation
Bold = a significant difference between groups (p <0.05)

7

Is reduction of routine radiograph use in patients with distal radius fractures cost-effective? Analysis of data from the multicenter, randomized controlled WARRIOR trial

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BMJ Open 2020;10:e035370

ABSTRACT

Objective

To assess the cost-effectiveness of a reduced imaging follow-up protocol of patients with a distal radius fracture compared with routine care.

Methods

An economical evaluation was conducted alongside a multicenter randomized controlled trial. Three hundred and forty-three Patients were randomized to either routine care (routine radiography at 1, 2, 6, and 12 weeks) or a reduced imaging strategy (radiographs at 6 and 12 weeks only for a clinical indication). Functional outcome was assessed with use of the Disabilities of the Arm, Shoulder, and Hand (DASH) questionnaire and quality-adjusted life-years (QALYs) with use of the EuroQol-5 Dimensions-3 Levels. Costs were measured with use of self-reported questionnaires and medical records and were analyzed from a societal perspective. Multiple imputation, seemingly unrelated regression analysis, and bootstrapping were used to analyze the data.

Results

Clinical overall outcomes of both groups were comparable. The difference in DASH scores was −2.03 (95% confidence interval [CI], −4.83 to 0.77) and the difference in QALYs was 0.025 (95% CI, −0.01 to 0.06). Patients in the reduced imaging group received on average 3.3 ± 1.9 (standard deviation) radiographs compared with 4.2 ± 1.9 in the routine care group. Costs for radiographic imaging were significantly lower for the reduced imaging group than for the routine care group (€−48 per patient; 95% CI, −68 to −27). There was no difference in total costs between groups (€−401 per patient; 95% CI, −2,453 to 1,251). The incremental cost-effectiveness ratio (ICER) for QALYs was −15,872. The ICER for the DASH was 198. The probability of reduced imaging being cost-effective compared with routine care ranged from 0.8 to 0.9 at a willingness to pays of €20,000/QALY to €80,000/QALY.

Conclusions

Implementing a reduced imaging follow-up strategy for patients with a distal radius fracture has a high probability of being cost-effective for QALYs, without decreasing functional outcome. We, therefore, recommend imaging only when clinically indicated.

INTRODUCTION

Fractures of the distal radius are common. The reported incidence of a distal radius fracture varies between 160 and 320 per 100,000 patients per year, accounting for 18% of all fractures.[1-3] This incidence is expected to increase as a result of aging of the population.[4] Both nonoperative and operative management aims at restoring joint congruity, radial height, radial inclination, and volar tilt.[5] Approximately, 23% of all distal radius fractures require operative management.[6] Reasons for surgery include primary instability, failed closed reduction, and secondary loss of reduction during nonoperative management. Trauma protocols recommend that radiographs are made routinely during follow-up of all patients with a distal radius fracture.[7] For nonoperatively treated patients, having radiographs made is recommended after 1, 2, and 6 weeks. For operatively treated patients, the same radiographic follow-up regimen is recommended, including an additional radiograph at 12 weeks.[7] In the Dutch population, representing approximately 17 million people, €8 million is spent annually on radiographs for patients with a distal radius fracture, based on an incidence of 55,000 per annum[1], with three follow-up radiographs,[6] at a cost of €50 per radiograph.[8]

Studies have evaluated the clinical value of routine radiographs made immediately following surgery and after the initial 3 weeks of operatively and nonoperatively treated distal radius fractures.[6, 9-11] These findings suggest that the health benefits of the current imaging protocols might not be worth their associated costs. In other words, current imaging protocols do not seem to be cost-effective. The objective of this economic evaluation was to assess the cost-effectiveness of a reduced imaging follow-up protocol for patients with a distal radius fracture compared with routine care.

METHODS

Setting and Design

This economic evaluation was conducted alongside a multicenter, randomized controlled trial, which is described in detail elsewhere.[12] The protocol was published before the onset of patient enrolment. International guidelines were followed in drafting this manuscript.[13, 14] Four level-I trauma centers in the Netherlands participated in the study. Patients were enrolled between July 2014 and August 2016. The primary clinical outcomes of the trial were published in 2019.[15]

Inclusion and Exclusion criteria

Patients were included if (1) they provided written informed consent, (2) were ≥18 years of age, (3) had a fracture of the distal part of the radius (AO/OTA classification type 2R3-A, B, or C),[16] and (4) were able to independently complete Dutch questionnaires. Exclusion criteria were the presence of fractures to multiple extremities, a pathological fracture or an open fracture (Gustilo grade 2 or 3). Patients were also excluded if they were deemed unable to comply with follow-up.

Randomization

Patients were informed about the study both verbally and in writing during their first visit to the emergency department or outpatient clinic. After obtaining written informed consent, patients were randomized with use of the online randomization and registration program (ProMISe; https://www.msbi.nl/promise/ProMISe.aspx). Patients were assigned in a 1:1 ratio stratified by center and treatment strategy (i.e., nonoperative or operative), with use of randomly varying blocks (2 to 6). Randomization tables were pre-generated within ProMISe.

Control group – Routine care

In accordance with current protocols,[7] patients allocated to routine care were monitored in the outpatient clinic with the use of routine follow-up radiographs. Radiographs were taken at 1, 2, 6, and 12 weeks following trauma for nonoperatively treated patients or following surgery. Additional follow-up moments and radiographs could be ordered by the treating physician if deemed necessary.

Intervention Group – Reduced Imaging

In the reduced imaging group, radiographs were made after 1 and 2 weeks. Additional radiographs were only made if a clinical indication was present or at the discretion of the treating physician. Reasons for a protocol deviation were noted in the medical files. Additional clinical follow-up moments, with or without radiographs, could be scheduled at any time if deemed necessary.

Outcome Measures

At baseline, participants reported functional status and quality of life just prior to when the fracture occurred. Patient demographics such as age, sex, dominant wrist, smoking habits, alcohol intake, socioeconomic status, and previous medical history were queried. Follow-up was conducted at 6, 12, 26, and 52 weeks following trauma. Functional outcome was measured with use of the 30-item validated Dutch version of the Disabilities of the Arm, Shoulder, and Hand (DASH) questionnaire.[17, 18] DASH scores range from 0 to 100, with lower scores representing a better functional status.

Health-related quality of life (HRQoL) was measured with use of the EuroQol-5 Dimensions-3 Levels (EQ-5D-3L). Utility scores were calculated with use of the Dutch tariff.[19, 20] Quality-adjusted life-years (QALYs) were calculated with use of the area under the curve approach.[21] The baseline score we assessed was the utility score prior to the occurrence of the fracture, instead of the utility score immediately following the fracture, which would have resulted in an overestimation of the average utility during the first 6 weeks of follow-up. The average utility score for the first 6 weeks of follow-up, therefore, was assumed to equal the utility score measured at 6 weeks of follow-up.

Cost Measures

The number of radiographs was collected from the medical records. Intervention costs were calculated with use of Dutch standard costs.[22] All other costs were measured with use of self-reported questionnaires. Primary healthcare costs included costs for general practitioner visits, visits to an occupational physician, physiotherapy sessions, and visits to other specialized therapists. Secondary healthcare costs included hospital admissions, outpatient clinic visits, radiographic imaging other than plain radiographs, costs of a possible reoperation, and admissions to a nursing home or rehabilitation center. Primary and secondary healthcare costs were valued with use of Dutch standard costs,[22] or tariffs if unavailable. Medication costs were valued with use of unit prices of the Royal Dutch Society of Pharmacy.[23] Informal care (e.g., care provided by relatives, friends or volunteers) and unpaid productivity losses (e.g., volunteer work, caregiving or domestic activities) were valued at €14.13 per hour.[22] Absenteeism was defined as the number of days absent from work because of the distal radius fracture. The friction cost approach was used to value absenteeism (friction period: 12 weeks).[22] Presenteeism (i.e., reduced productivity while at work) was measured with use of the WHO Health and Work Performance Questionnaire.[24] Absenteeism and presenteeism were valued with use of gender-specific price weights.[22] All costs were converted to Euros 2016.[25] Follow-up was 12 months and therefore we did not discount costs and effects.

Statistical Analysis

Missing data were imputed with use of the MICE algorithm in STATA (Version 12). The imputation model included all available cost and effect measure values, variables differing between groups at baseline as well as variables predicting the 'missingness' of data. Five datasets were constructed to ensure a loss of efficiency of <5%.[26] We analyzed each dataset separately, after which estimates were pooled with use of Rubin's rules.[26] Costs and effects were estimated with use of linear regression analysis, adjusted for baseline values and possible confounders. Seemingly unrelated regression analysis was performed to estimate the differences in costs and effects, and to account for their possible correlation.[27] The incremental cost-effectiveness ratio (ICER) was calculated by dividing the difference in costs by the difference in effect. Uncertainty surrounding the ICER and 95% CI for costs was estimated with use of bias-corrected and accelerated bootstrapping (5,000 replications). Uncertainty around the ICER was graphically illustrated with use of cost-effectiveness planes (CE planes).[21] A summary measure of the joint uncertainty surrounding costs and effects was provided with use of cost-effectiveness acceptability curves (CEACs). These curves give an indication of the possibility that reduced imaging is cost-effective compared with routine care, at different values of willingness to pay.

Sensitivity Analyses

Six sensitivity analyses were planned: (1) a complete-case analysis (SA1); (2) the measured EQ-5D-3L score at baseline (i.e., prior to the fracture) was used for estimating the average utility value during the first 6 weeks of follow-up (SA2); (3) the Human Capital Approach was used to calculate productivity losses instead of the Friction Cost Approach (SA3);[28] (4) costs were calculated from a healthcare perspective (SA4); (5) only patients with nonoperative management were included (SA5); and (6) only patients with operative management were included (SA6). In a post-hoc sensitivity analysis, we excluded the costs of unpaid productivity losses (SA7). This was done because of a very low response rate for this cost category (5.2%).

RESULTS

Participants

In total, 386 patients were enrolled in the study (Fig. 1). Of them, 3 were excluded because of an error in the randomization procedure and 3 were excluded because an exclusion criterium was discovered after randomization had occurred. Additionally, 39 patients did not return any of the questionnaires, including baseline, and were thus lost to follow-up. Of the remaining 341 patients, 169 were randomized to reduced imaging and 172 to routine care. Forty-one patients (12%) received operative management. In total, 337 participants (99%) returned their baseline questionnaire. Respectively, 304 (89%), 289 (85%), 272 (80%), and 264 (77%) participants returned their week 6, week 12, week 26, and week 52 questionnaires. In total, 86 patients had no missing values on any of the outcomes. At baseline, there were no significant differences in patient demographics between the groups (Table I).

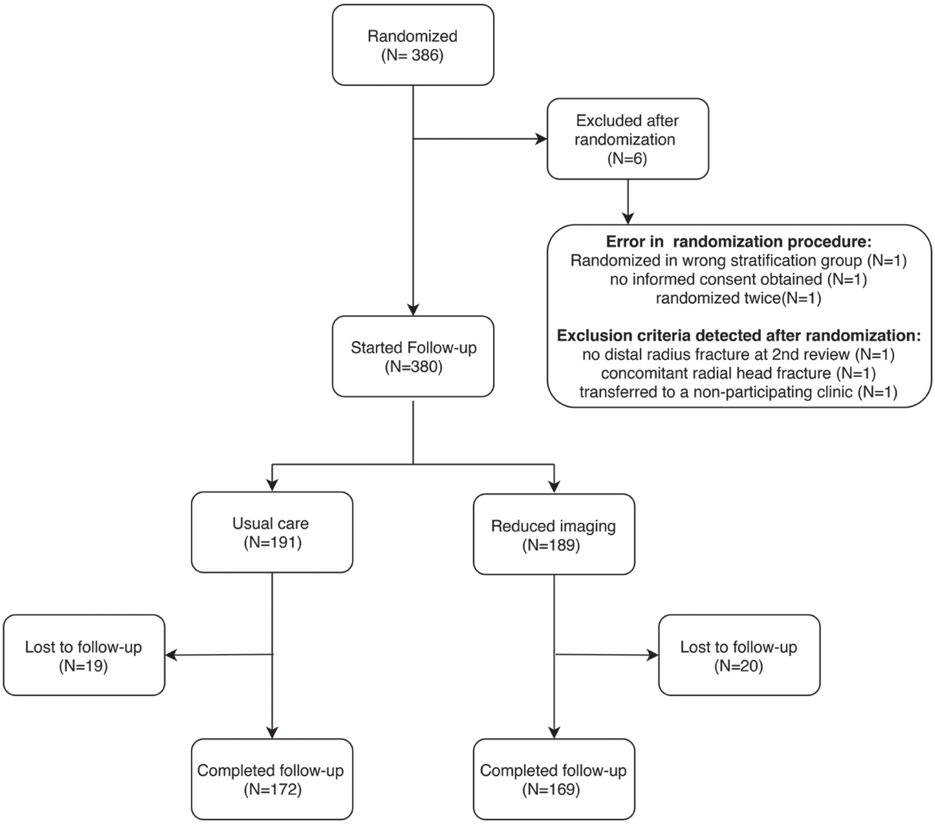

Figure 1. Flowchart of patients.

Effects

The difference between the reduced imaging and routine care group was –2.03 points for DASH (95% CI, –4.83 to 0.77) and 0.025 for QALYs (95% CI, –0.01 to 0.06).

Costs and Use of Resources

Participants in the reduced imaging group received on average 3.3 ± 1.9 radiographs, while participants in the routine care group received on average 4.2 ± 1.9 radiographs. This resulted in significantly lower costs for the intervention in the reduced imaging group (€–48 per patient; 95% CI, –68 to –27). Participants randomized to reduced imaging, however, had significantly higher costs for unpaid productivity losses than in the routine care group (€144 per patient; 95% CI, 30 to 284). All other disaggregate and aggregate costs (€–401; 95% CI, –2453 to 1251) were not significantly different between the groups. (Table II)

Table I. Patient characteristics by treatment allocation

		Routine care (n=166)		Reduced imaging (n=160)		*p*-value
Male sex,	n (%)	39	(23.5)	39	(24.4)	0.9
Age	mean (SD)	56.7	(18.2)	56.8	(17.7)	1.0
BMI	mean (SD)	25.0	(4.5)	24.9	(5.0)	0.9
Alcohol >10 U/week	n (%)	18	(10.8)	9	(5.6)	0.1
Smoking >10/day	n (%)	8	(4.8)	7	(4.4)	0.9
Operative treatment	n (%)	21	(12.7)	20	(12.5)	1.0
Closed reduction	n (%)	54	(32.5)	55	(34.4)	0.7
Fracture of dominant wrist	n(%)	63	(38.0)	65	(40.6)	0.6
AO classification A	n(%)	106	(63.9)	113	(70.6)	0.2
B		18	(10.8)	17	(10.6)	1.0
C		42	(25.3)	30	(18.8)	0.2
ASA classification 1	n(%)	67	(40.4)	76	(47.5)	0.2
2		82	(49.4)	68	(42.5)	0.2
≥3		12	(7.2)	12	(7.5)	0.9
missing		5	(3.0)	4	(2.5)	0.8

Legend for table I:
SD: Standard deviation
BMI: Body Mass index
AO: Arbeitsgemeinschaft für Osteosynthesefragen
ASA: American Society of Anesthesiologists

Table II. Mean cost (in euros) per participant in the intervention and control group and mean cost differences between groups during follow-up

Cost category	Routine care (n=128) mean (SEM)		Reduced imaging (n=118) mean (SEM)		Cost difference (β) adjusted mean (95%CI)	
Intervention	164	(7)	212	(7)	**-48**	**(-68 to -27)**
Primary care	555	(90)	547	(85)	13	(-237 to 223)
Secondary care	661	(123)	949	(410)	-294	(-2371 to 225)
Medication	17	(4)	25	(7)	-9	(-26 to 3)
Informal care	301	(135)	141	(39)	170	(0 to 535)
Absenteeism	532	(185)	627	(174)	-109	(-557 to 349)
Presenteeism	3017	(472)	3426	(613)	-269	(-1531 to 878)
Unpaid productivity loss	246	(61)	104	(35)	144	(30 to 284)
Total	5491	(633)	6033	(783)	-401	(-2453to 1251)

Legend
Bold = a significant difference between groups (*p* <0.05)

Cost-effectiveness

Reduced imaging was dominant over routine care. The CE plane shows that most of the bootstrapped cost-effect pairs were in the south-east quadrant, indicating that reduced imaging had lower total costs and was more effective than routine care (Fig. 2). The CEAC indicates that the maximum probability that reduced imaging was cost-effective compared with routine care was 0.88 (Fig. 3) and was achieved at a willingness to pay of €1,100 to improve functional outcome by 1 point on the 0–100 points DASH score. The ICER for HRQoL was −15,872. The CE plane again shows that most cost-effect pairs were in the south-east quadrant (Fig. 4). The probability of cost-effectiveness of reduced imaging was 0.8 at a willingness to pay of €20,000/QALY, increasing to 0.9 at a willingness to pay of €80,000/QALY (Fig. 5).

Sensitivity Analyses

Results of the sensitivity analyses are presented in Table III. SA6 (only including operatively treated patients) is not reported because a much smaller than expected percentage of participants (12%, 41/341) underwent surgery. This analysis was, therefore, underpowered. SA1 (complete cases only) showed larger differences in both costs and effects. To determine if response bias potentially influenced our results, we compared the baseline characteristics of respondents with complete and incomplete data. Respondents with complete data were more likely to consume over 10 units of alcohol a week, were slightly older (59 vs 55 years), and more frequently had an American Society of Anesthesiologists (ASA) score of "1" as opposed to an ASA score of "2" (respectively, 50% versus 42% and 38% versus 49%) in comparison to respondents with incomplete data (Table IV). Thus, nonresponse may have slightly biased the results of SA1, making the results of the main analysis (for which data were multiply imputed) more valid. SA5 (only including nonoperatively treated patients) and SA7 (excluding unpaid productivity costs) showed larger societal cost savings in the reduced imaging group. The results of all other sensitivity analyses were comparable with the main analysis.

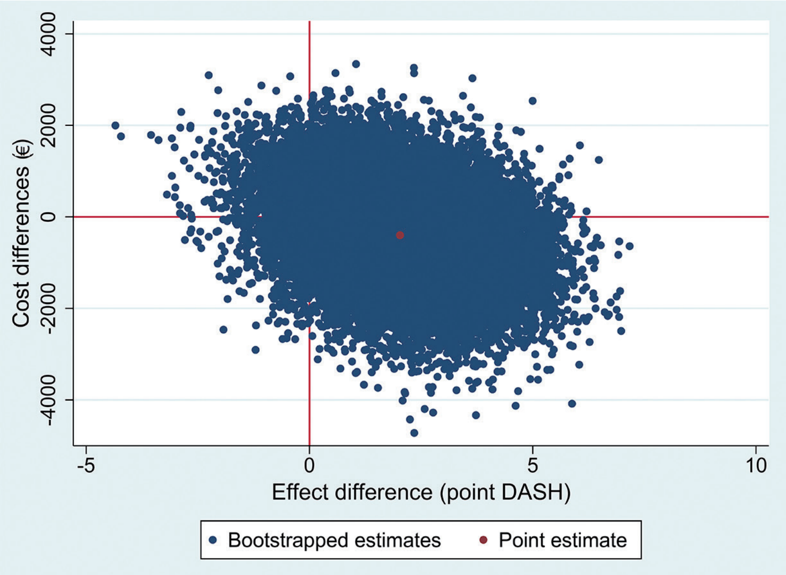

Figure 2. Cost-effectiveness plane for DASH, representing the results from the 5000 bootstrapped replications, and the point estimate. Higher on the Y-axis corresponds to costlier than control, more right on the X axis corresponds to more effective than control.

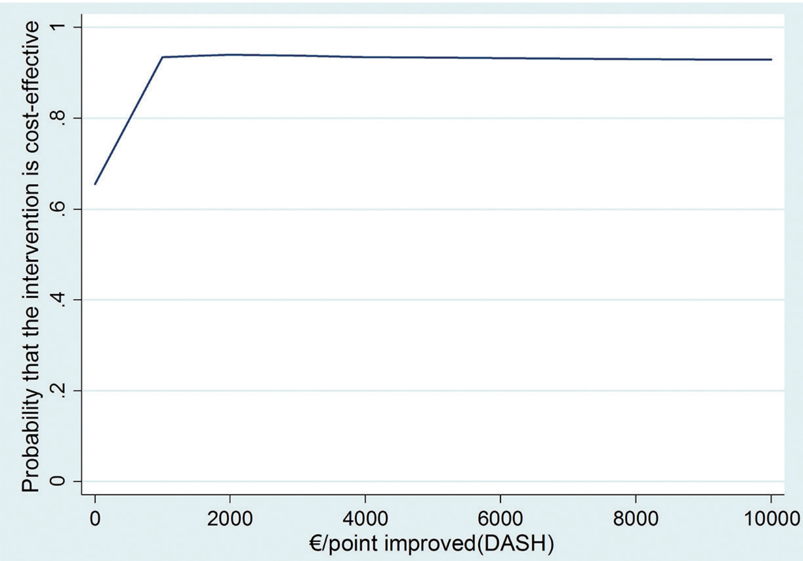

Figure 3. Cost-effectiveness acceptability curve for DASH, showing the probability of the intervention being cost-effective at a certain willingness to pay value per point DASH.

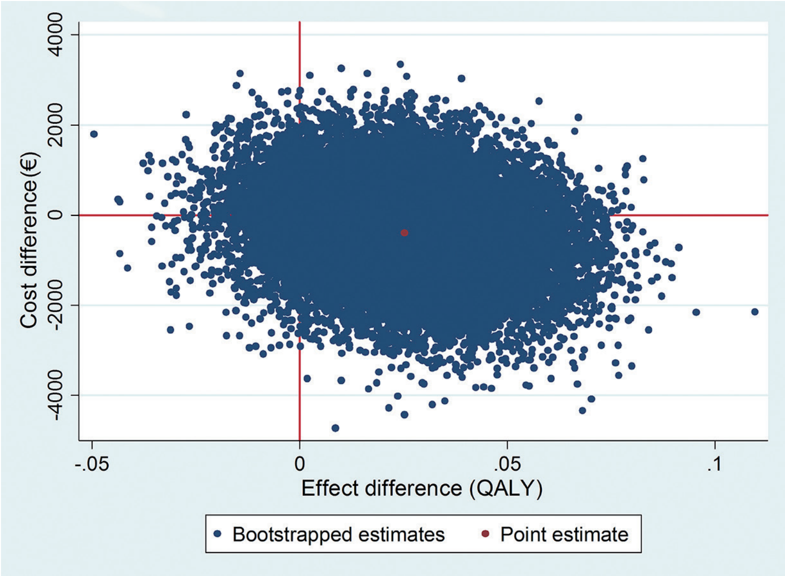

Figure 4. Cost-effectiveness plane for QALYs, representing the results from the 5000 bootstrapped replications, and the point estimate. Higher on the Y-axis corresponds to costlier than control, more right on the X axis corresponds to more effective than control.

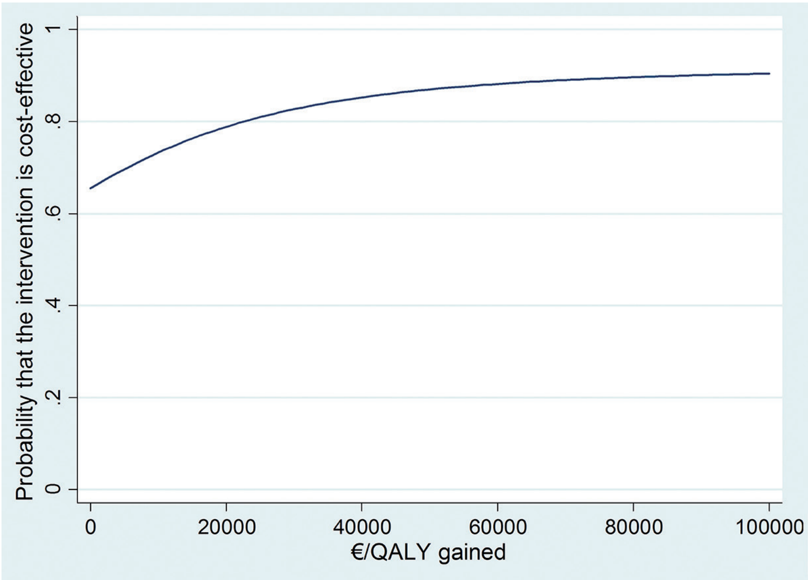

Figure 5. Cost-effectiveness acceptability curve for QALYs, showing the probability of the intervention being cost-effective at a certain willingness to pay value per QALY.

Table III: Differences in pooled mean costs and effects, incremental cost-effectiveness ratios, and the distribution of incremental cost-effect pairs around the quadrants of the cost-effectiveness planes for reduced imaging compared to routine care

	Routine care	Reduced imaging	Outcome measure	ΔC € (95% CI)	ΔE Points (95% CI)	ICER €/point	**Distribution CE-plane** (%)			
							NE	SE	SW	NW
Main analysis	169	172	QALYs (Range: 0 - 1)	-401 (-2393 to 1310)	0.025 (-0.01 to 0.06)	-15872	31.4	60.7	3.8	3.8
			DASH (Range: 0 – 100)	-401 (-2393 to 1310)	-2.03 (-4.83 to 0.77)	198	30.9	60.4	3.4	5.1
SA1 *– Complete cases*	49	37	QALYs (Range: 0 - 1)	-1184 (-4128 to 1207)	0.071 (0.02 to 0.13)	-16914	28.9	70.7	0.2	0.2
			DASH (Range: 0 – 100)	-1184 (-4128 to 1207)	-3.8 (-9.1 to 1.4)	312	25.0	68.3	2.6	4.1
SA2 *– QALY 1 VS QALY 2*	169	172	QALYs (Range: 0 - 1)	-401 (-2393 to 1310)	0.025 (-0.01 to 0.06)	-16180	31.5	60.7	4.0	3.8
SA3 *– Human capital approach*	169	172	QALYs (Range: 0 - 1)	-360 (-2369 to 1385)	0.025 (-0.01 to 0.06)	-14271	32.9	59.4	3.7	3.9
			DASH (Range: 0 – 100)	-360 (-2369 to 1385)	-2.03 (-4.82 to 0.76)	178	32.4	60.1	3.0	4.5
SA4 *– Healthcare perspective*	169	172	QALYs (Range: 0 - 1)	-338 (-2289 to 292)	0.025 (-0.01 to 0.06)	-13377	26.9	65.5	4.3	3.3
			DASH (Range: 0 – 100)	-338 (-2289 to 292)	-2.03 (-4.82 to 0.76)	167	27.0	65.7	4.2	3.2
SA5 – *Conservative treatment*	149	151	QALYs (Range: 0 - 1)	-602 (-2695 to 1137)	-0.018 (-0.02 to 0.06)	-33528	21.8	60.7	10.5	6.9
			DASH (Range: 0 – 100)	-602 (-2695 to 1137)	-1.30 (-4.28 to 1.67)	462	20.0	61.0	10.3	8.7
SA7 – *no unpaid productivity*	169	172	QALYs (Range: 0 - 1)	-545 (-2514 to 1119)	0.025 (-0.01 to 0.61)	-21597	26.4	65.9	4.4	3.3
			DASH (Range: 0 – 100)	-545 (-2514 to 1119)	-2.03 (-4.82 to 0.76)	269	25.8	66.7	3.6	3.9

Legend for Table III:
SA: Sensitivity analysis
QALYs: Quality Adjusted Life Years
DASH: Disabilities of Arm Shoulder, and Hand
ΔC: Difference in cost
ΔE: Difference in effect
ICER: Incremental Cost Effectiveness Ratio
CE-plane: Cost Effectiveness plane.
NE: North east part of the CE-plane (representing an intervention that is more costly, but more effective)
SE: South east part of the CE-plane (representing an intervention that is cheaper, and more effective)
SW: South west part of the CE-plane (representing an intervention that is cheaper, but less effective)
NW: North west part of the CE-plane (representing an intervention that is both more costly and less effective)

Table IV. Patient characteristics of complete cases versus incomplete cases.

		Complete cases (n=86)		Incomplete cases (n=225)	
Male sex,	n (%)	21	(24.4)	61	(23.9)
Age	mean (SD)	59.1	(16.1)	55.6	(18.5)
BMI	mean (SD)	25.5	(4.8)	24.6	(4.7)
Alcohol >10 U/week	n (%)	12	(14.0)	16	(6.5)
Smoking >10/day	n (%)	2	(2.3)	13	(5.3)
Operative treatment	n (%)	11	(12.8)	30	(11.8)
Fracture of dominant wrist	n(%)	36	(41.9)	99	(41.3)
AO classification A	n(%)	52	(60.5)	177	(69.4)
B		11	(12.8)	26	(10.2)
C		23	(26.7)	51	(20.0)
missing		0	(0)	1	(0.4)
ASA classification 1	n(%)	43	(50.0)	106	(41.5)
2		33	(38.4)	126	(49.4)
≥3		10	(11.6)	14	(5.4)
missing		0	(0)	9	(3.5)

Legend for table IV:
SD: Standard deviation
BMI: Body Mass index
AO: Arbeitsgemeinschaft für Osteosynthesefragen
ASA: American Society of Anesthesiologists

DISCUSSION

The use of a reduced imaging protocol led to significantly lower costs per patient for radiographic imaging (€–49; 95% CI, –68 to –27) than routine care in the follow-up of patients with a distal radius fracture. The reduction in the number of radiographs also led to a small (0.003-mSv) dose reduction of ionizing radiation. Clinical outcomes were comparable. The number of QALYs showed no significant difference between the groups. The difference of 0.025 was smaller than the minimal important difference of 0.04 (US algorithm) or 0.08 (UK algorithm).[29] The reduced imaging group was noninferior for DASH scores as both the calculated difference, as well as the 95% CI were within than the margin of noninferiority of 9.[15, 30] Costs for unpaid productivity losses were significantly higher for the reduced imaging group. This difference was most distinct in the first 6 weeks. This is not likely to be a result of the intervention, as follow-up was similar for both groups until this point. Moreover, unpaid productivity costs were reported in very few of the returned questionnaires (5.2%, 76/1461). This low response rate may have introduced bias. We, therefore, decided to perform an additional sensitivity analysis, in which we disregarded this uncertain cost category. This showed an increase in ICER for both QALYs and DASH, leading to a more favorable result for the reduced imaging group in comparison to the main analysis. This indicates that bias might have played a role in the main analysis.

Other cost categories and total societal costs did not differ between groups. As CIs were rather wide for total societal costs, we assume that the study might be underpowered to detect a meaningful difference in aggregate costs between the groups. This is because of the sample size calculation of the primary trial, which was aimed at demonstrating noninferiority for the DASH.[15]

For both HRQoL and upper extremity function, the maximum probability of reduced imaging being cost-effective compared with routine care is relatively high. For HRQoL, the probability that reduced imaging is cost-effective compared with routine care was 0.8 at a willingness to pay of €20,000/QALY, which is deemed acceptable in the Netherlands.[31] Based on these results, we consider reduced imaging cost-effective for QALYs. As a willingness to pay threshold is lacking for functional outcome, we cannot draw any conclusions about cost-effectiveness. However, functional outcome seems unaffected by the intervention.[15]

Strengths and Limitations

These results are based on a large, multicenter randomized study; therefore, the results may be considered generalizable to similar populations as ours.[21] For other settings or regions than the one studied, generalizability may be lower. Additionally, the use of seemingly unrelated regression analyses of the cost and effect differences can be considered a strength because this method diminished the influence of a possible correlation between effects and costs.[27] This study, however, had some limitations. First, effect measures and some cost measures were gathered through questionnaires with a maximum recall period of 26 weeks, therefore potentially introducing recall bias. However, the recall period was similar in both groups, and therefore, this is likely to be nondirectional. A second limitation may have been introduced through missing data. That is, in 75% (255/341) of the patients, one or more cost and/or effect measure items were missing from one of the follow-up moments. This limitation was dealt with using multiple imputation. This is considered the gold standard in dealing with missing data in economic evaluations, as it deals with uncertainty about the missing data by the creation of multiple imputed data sets.[26] Moreover, a sensitivity analysis showed no noteworthy difference in ICER values when only the 86 cases with complete data were analyzed. A third limitation concerns the fact that we used the estimated value for the EQ-5D-3L utility score in the first 6 weeks. We used this because we asked participants for their utility score prior to the fracture instead of the utility score immediately following the fracture. As a result, the measured utility score would have overestimated the patients' functionality in the first 6 weeks following the trauma. The utility score at week 6 was deemed to be a more accurate reflection of the patients' actual utility during the first 6 weeks, as most patients were immobilized in a cast for 4–6 weeks. We do not expect this estimation to have biased our results because a sensitivity analysis utilizing the measured values for the baseline utility score showed similar results as the main analysis.

CONCLUSION

Implementing a reduced imaging protocol in the follow-up of distal radius fractures has a high probability of being cost-effective. Moreover, reduced imaging did not lead to a decreased functional outcome for patients with a distal radius fracture. We, therefore, recommend imaging when clinically indicated and not according to a rigid protocol.

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Reduction of routine radiographs in the follow-up of distal radius and ankle fractures: Barriers and facilitators perceived by orthopedic trauma surgeons

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Journal of Evaluation in Clinical Practice. 2019;25:265–274.

ABSTRACT

Background

Studies suggest that routine radiographs during follow-up of distal radius and ankle fractures result in increased radiation exposure and healthcare costs, without influencing the treatment strategy. Encouraging clinicians to omit these routine radiographs is challenging and little is known about barriers and facilitators that influence this omission. Therefore, the present study aims to identify barriers and facilitators among orthopedic trauma surgeons that might prove valuable towards the design of a deimplementation strategy.

Methods

A mixed-method approach was used. First, interviews were conducted with orthopedic trauma surgeons and patients (n=16). Subsequently, a questionnaire was developed. This questionnaire was presented to 228 orthopedic trauma surgeons in the Netherlands. Regression analyses were performed in order to identify which variables were independently associated to the decision to stop performing routine radiographs 6 and 12 weeks after trauma if proven not effective in a large randomized controlled trial.

Results

In total, 130 (57%) respondents completed the questionnaire. Of these, 71% indicated they would stop ordering routine radiographs if they were proven not effective. Three facilitators were independent predictors for the intention to omit routine radiographs: This will "lead to lower healthcare costs" (Odds Ratio [OR], 5.38 for distal radius fractures and 4.38 for ankle fractures), the need for "incorporation in the regional protocol" (OR, 3.66 and 2.66 for distal radius fractures and ankle fractures respectively), and this will "result in time savings for the patient" (OR, 4.84 for ankle fractures).

Conclusions

We identified three facilitators that could provide backing for a deimplementation strategy aimed at a reduction of routine radiographs for patients with distal radius and ankle fractures.

INTRODUCTION

Over the past decade, the reduction of low-value care has become progressively more important to increase the overall quality of healthcare. One of the driving forces behind this change is the "Choosing Wisely" campaign, which started in 2012 in the United States. Choosing Wisely is committed to reducing the use of diagnostic tests, treatments, and procedures if there is evidence of overuse, potential harm, or significant and unjustifiable costs.[1] Routine radiography in the post-acute follow-up of distal radius and ankle fractures (i.e., after an initial follow-up period of 4 weeks) is an example of diagnostic imaging with questionable value.[2, 3] Distal radius and ankle fractures are common for all ages. The incidence rate is approximately 70 to 160 per 100,000 persons for distal radius fractures and 187 per 100,000 persons for ankle fractures[4-9]. Because of aging of the population, incidence rates are expected to increase over the coming decades.[10] Patients with these fractures present a significant burden to the healthcare system. In order to allow for optimal functional recovery, both nonoperative and operative management aim to optimize and maintain anatomical reduction until fracture healing occurs.[11-13]

Radiographs are used to monitor the position of the fracture fragments or the osteosynthesis material, the alignment of the joint, and the bone-healing process during the initial phase of follow-up (i.e., the first 3 months). Additional reasons for the use of radiographs include reassurance of the physician and/or patient, and medicolegal motives.[14] The frequency and timing of routine radiographs are empirically based. National and international protocols recommend two to four radiographs during the initial phase of follow-up. Typical moments for radiographs in both ankle and distal radius fracture treatment are 1, 2, 6, and 12 weeks after trauma or operative fixation.[15-18] Studies that have evaluated the value of radiographs made directly after splinting and radiographs taken at the first postoperative outpatient clinic visit after a distal radius fracture suggest that these radiographs do not lead to changes in the treatment strategy if they were ordered without a clear clinical indication.[14, 19, 20] A prospective randomized controlled trial: "the WARRIOR-trial", is currently conducted to confirm the safety and cost-effectiveness of omitting routine follow-up radiographs at 6 and 12 weeks among patients with distal radius or ankle fractures.[21] If the WARRIOR-trial confirms that omitting ("de-implementing") follow-up radiographs without a clear clinical indication is safe and cost-effective, this may lay a foundation for a change in the radiographic follow-up of wrist and ankle fractures. Radiographs taken without a clear clinical indication can then be added to the list of low-value diagnostic tests that can be consulted at the Choosing Wisely website (www.choosingwisely.org).

When performing a clinical trial, research on how to implement possible findings is an important step. Previous studies have shown that solely publishing trial results that demonstrate the redundancy of a certain treatment or test, or simply publishing Choosing Wisely recommendations, did not typically lead to an abandonment of low-value care.[22-24] To actually change practice, a strategy is needed to address barriers and facilitators to the change.[25, 26] Currently, detailed insight in barriers and facilitators influencing orthopedic trauma surgeons to adopt a suggested change in follow-up protocol of distal radius and ankle fractures is lacking. Therefore, the present study aims to identify the specific barriers and facilitators among orthopedic trauma surgeons for reducing the use of routine radiographs during follow-up of distal radius and ankle fractures. We achieved to identify several independently associated facilitators influencing the reduction of routine radiography during follow-up of distal radius and ankle fractures.

METHODS

Setting and Design

In this cross-sectional survey, orthopedic trauma surgeons in the Netherlands were invited to complete an Internet-based questionnaire. The Medical Ethics Committee of the Leiden University Medical Center approved the study (protocol number P14.214).

Questionnaire development

To explore potential barriers and facilitators for the de-implementation of routine radiographs during follow-up of distal radius and ankle fractures, semi-structured interviews were performed with 10 healthcare professionals (orthopedic trauma surgeons) and with 6 patients (3 with a distal radius fracture and 3 with an ankle fracture). Purposive sampling of healthcare professionals was applied to obtain contrasting views and identify all potentially relevant barriers and facilitators. To increase generalizability orthopedic trauma surgeons from different regions in the Netherlands, working in university and nonuniversity hospitals were selected. For practical reasons, only patients treated at a single university hospital were asked to participate. They were contacted during their first outpatient clinic visit or by phone in the week following their first visit.

The frameworks of Grol and Wensing,[27] and Cabana[28] were used to compose the questions of the semi-structured interviews. In both frameworks, barriers and facilitators for behavioral change are grouped in several domains (i.e., the innovation itself, the individual professional, the patient, the social context, the organizational context, and the economic and political context). In addition to the barriers and facilitators, the professionals were asked about their current follow-up protocol for distal radius and ankle fractures. This was done because current usage of radiography might influence the willingness to adopt a protocol using less routine radiography. Both the professionals and the patients were asked for their opinion about a protocol prescribing radiographs at 6 and 12 weeks only on clinical indication. The interviews were audiotaped, transcribed, and saved anonymously. Subsequently, the transcribed interviews were qualitatively analyzed. Two researchers independently marked potential barriers and facilitators. In case of discrepancies, a third researcher was consulted. The qualitative analysis was executed with use of the software package ATLAS.ti (ATLAS.ti Scientific Software Development GmBH, Berlin, Germany). A total of 11 barriers and 15 facilitators were identified during the semi-structured interviews. Five items were on the professional level, 10 on the patient level, 6 on the organizational level, and 5 on the level of the external environment. No items were identified on the level of innovation or social context. These items were used for the Internet-based questionnaire for the orthopedic trauma surgeons.

The Questionnaire

The first part of the questionnaire included questions about demographic characteristics such as age, gender, and years of work experience. In addition, questions were included about the follow-up protocol for distal radius and ankle fractures currently used by the respondents and the number of patients with a distal radius or ankle fracture they treat annually. The second part of the questionnaire consisted of 26 items covering barriers and facilitators identified from the interviews. The orthopedic trauma surgeons were asked to what extent they agreed with each barrier or facilitator. Answers could be given on a 4-point Likert scale with options being: "totally disagree", "partially disagree", "partially agree", and "totally agree". The third part included questions about the intention to stop performing routine radiographs if these were proven not to be clinically effective in the WARRIOR-trial. Four response options were given: (a) no; (b) yes, for both distal radius and ankle fractures; (c) yes, but only for distal radius fractures; and (d) yes, but only for ankle fractures.

In a pilot, two local orthopedic trauma surgeons filled out the questionnaire to test the comprehensibility of the questions and the response categories. No changes to the initial questionnaire were deemed necessary after this assessment.

Population

The developed Internet-based questionnaire was sent to all surgeons registered with the Dutch Trauma Association (n=236). Nonresponders received 4 reminders at 1, 3, 4, and 5 weeks after the first invitation

Statistical Analysis

Data from all respondents who completed the survey were included in the analyses. Descriptive statistics were used to describe baseline characteristics of the respondents and to report the answers to the barrier and facilitator items of the questionnaire. The data from the questions concerning barriers and facilitators were dichotomized into "disagree" (grouping the answering categories "totally disagree" and "partly disagree") and "agree" (grouping "totally agree" and "partly agree") because of little observations in some cells. The values of some baseline characteristics were also dichotomized: The number of years of work experience was dichotomized into "0 to 10 years" and ">10 years". The annual number of treated patients was dichotomized into "0 to 50 patients" and ">50 patients".

Two groups of respondents were defined: the surgeons who indicated that they intended to stop performing routine radiographic imaging at 6 and 12 weeks after trauma or operative fixation if proven not clinically effective (hereafter referred to as the "intend-to-stop" group) and the surgeons who indicated that they did not intended to do so (hereafter referred to as the "intend-to-continue" group). The background characteristics, current usage of radiography, and response to each barrier and facilitator were compared between the intend-to-stop and intend-to-continue groups. Differences between groups were tested with χ^2. The Fisher exact test was used when the number of observations in a cell was less than 6. These analyses were stratified for distal radius and ankle fractures.

Barriers and facilitators with a significant difference between groups ($p < 0.05$) were considered as potential predictors. Next, as individual barriers and facilitators may be related to others, we included all potential predictors in a multivariate logistic regression model ($p < 0.05$), with use of a backward stepwise, likelihood ratio method. The intention to stop performing routine radiographs was analyzed as the dependent variable, and the barriers and facilitators were analyzed as the independent variables. All analyses were performed with use of SPSS Statistics for Windows (version 23; IBM Corp, Armonk, NY).

RESULTS

Respondent Characteristics

Of the e-mail invitations sent to 236 Dutch orthopedic trauma surgeons, 7 failed to be delivered and 1 surgeon indicated that he or she did not work as an orthopedic trauma surgeon anymore, resulting in 228 invitations. The questionnaire was completed by 130 orthopedic trauma surgeons (response rate 57%). The reason for nonresponse was not verified.

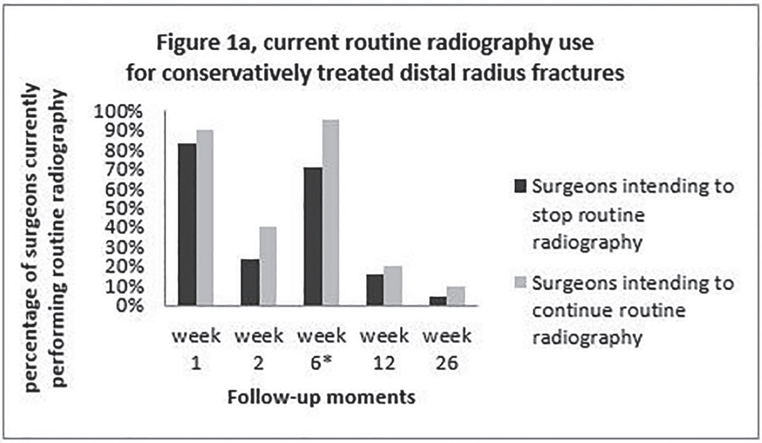
Table I shows the baseline characteristics of the respondents. The vast majority (95%) were male, and the mean age was 48 years. Of the respondents, 55% treat over 50 distal radius fractures and 34% treat over 50 ankle fractures annually. There were no differences in baseline characteristics between the intend-to-stop and intend-to-continue groups (data not shown).

Table I. Baseline characteristics of respondents

			Orthopedic trauma Surgeons (n=130)
Gender: Male		n (%)	124 (95)
Age		mean (±)	48.3 (8.4)
Work experience	0-5 years	n (%)	22 (17)
	6-10 years		44 (34)
	11-15 years		16 (12)
	16-25 years		32 (25)
	>25 years		16 (12)
Work environment *(multiple options possible)*	University hospital	n (%)	26 (20)
	Teaching hospital		56 (43)
	General hospital		58 (45)
Patients per year: *Distal radius*	0	n (%)	1 (1)
	1-10		1 (1)
	11-30		25 (19)
	31-50		31 (24)
	>50		72 (55)
Patients per year: *Ankle*	0	n (%)	1 (1)
	1-10		1 (1)
	11-30		41 (31)
	31-50		43 (33)
	>50		44 (34)

Table II. Number of orthopedic trauma surgeons with the intention to stop taking routine radiographs at weeks 6 and 12 if proven not to be effective in the WARRIOR trial

		Respondents (n=130)
Intention to stop taking routine radiographs	***n (%)***	
Yes, in distal radius and ankle fractures		92 (70.8)
Yes, in distal radius fractures only		18 (13.8)
Yes, in ankle fractures only		4 (3.1)
No		16 (12.3)



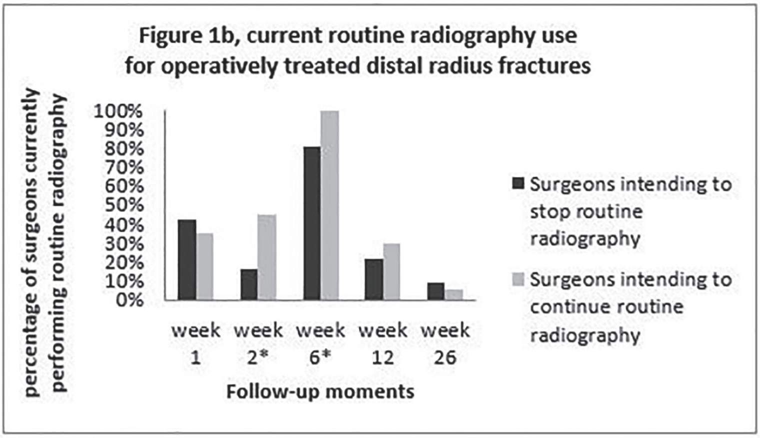


Figure 1. Percentage of surgeons who currently order routine radiographs on specific follow-up moments for (a) nonoperatively and (b) operatively treated distal radius fractures, separately for the surgeons who intend to stop or continue ordering routine radiographs if these are proven not to be effective. An asterisk (*) indicates a significant difference between the surgeon groups for specific follow-up moments.

In total, 71% of the orthopedic trauma surgeons had the intention to stop taking radiographs routinely for both distal radius fractures and ankle fractures if these radiographs were proven not to be effective in the Warrior-trial (Table II)

The current radiographic follow-up strategy used by the responding orthopedic trauma surgeons for nonoperatively and operatively treated distal radius fractures is depicted in Figure 1. Results are reported separately for both groups. The current follow-up strategy for ankle fractures is highlighted in the same manner in Figure 2. Overall, the

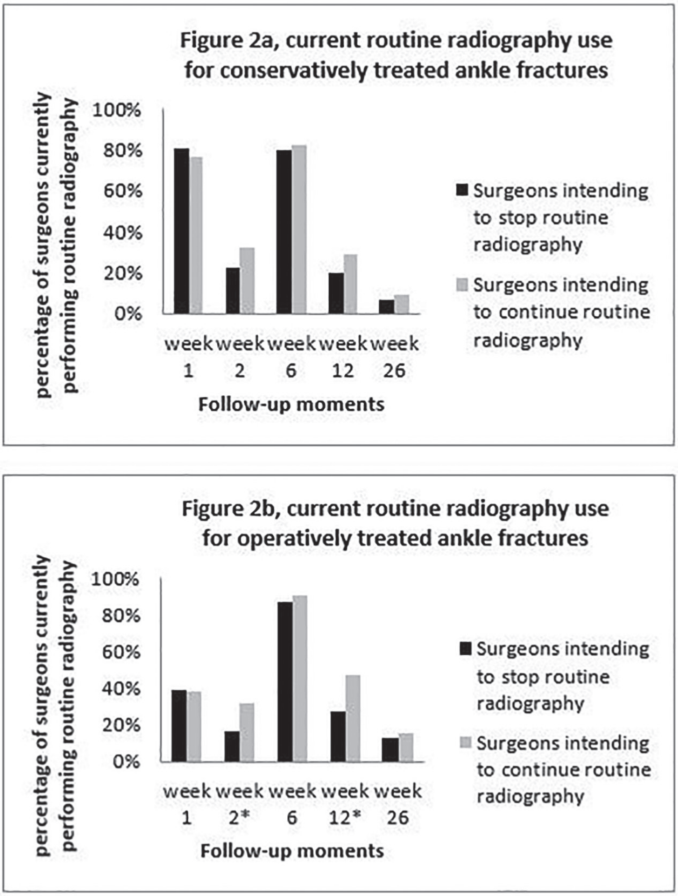


Figure 2. Percentage of surgeons who currently order routine radiographs on specific follow-up moments for (a) nonoperatively and (b) operatively treated ankle fractures, separately for the surgeons who intend to stop or continue ordering routine radiographs if these are proven not to be effective. An asterisk (*) indicates a significant difference between the surgeon groups for specific follow-up moments.

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majority of respondents indicated to order radiographs after approximately 6 weeks for both nonoperatively (75%) and operatively treated distal radius fractures (84%), as well as for both nonoperatively (81%) and operatively treated (88%) treated ankle fractures. Respondents from the intend-to-stop group were significantly less likely to obtain radiographs as a routine part of their current practice. For distal radius fractures, less radiographs were made at 6 weeks when treated nonoperatively (71% versus 95%, $p < 0.05$). For operatively treated distal radius fractures, less radiographs were made at week 2 (16% versus 45%, $p < 0.05$) and week 6 (81% versus 100%, $p < 0.05$). For operatively treated ankle fractures, less radiographs were ordered at week 2 (16% vs 32%, $p < 0.05$) and week 12 (27% vs 47%, $p < 0.05$). At other time points, there were no differences between groups.

The Influence of Barriers and Facilitators

Table III shows the barriers and facilitators in the questionnaire for each domain of the framework according to Grol and Wensing and the overall percentages of orthopedic trauma surgeons who did or did not agree with these barriers and facilitators. The three most frequently perceived barriers for omitting routine radiographs were in the domain of the patient and the domain of the external environment. The statements involved were as follows: follow-up radiographs of distal radius and ankle fractures at 6 and 12 weeks after trauma “give the patient certainty about the healing process” (65.4% agreement), “are necessary to evaluate the interim outcome of the treatment, besides other parameters such as function or pain” (58.5% agreement), and “are necessary for medicolegal protection” (56.2% agreement). The three facilitators that the respondents most frequently agreed with were on the domain of the organizational context and the domain of the patient. They included the statements that not standardly taking

Table III. Agreement with barriers and facilitators among respondents

	Percentage that Agrees with statement
The professional	
Follow-up radiographs of distal radius and ankle fractures around 6 and 12 weeks after trauma…	
… are necessary to evaluate the treatment outcome, because I often change my policy based on the radiographs taken at 6 and 12 weeks (B)	*20.0%*
... are essential for the surgeon to learn how to interpret radiographs (B)	*21.5%*
… provide me with essential feedback about the treatment outcome (B)	*50.0%*
… provide me with certainty about the treatment outcome(B)	*21.5%*
Not standardly taking radiographs of wrist and ankle fractures at week 6 and 12 weeks …	
… leads to a lower workload for the surgeon (F)	*32.3%*

Table III. Agreement with barriers and facilitators among respondents (continued)

	Percentage that Agrees with statement
The patient	
Follow-up radiographs of distal radius and ankle fractures around 6 and 12 weeks after trauma…	
… are necessary to evaluate the treatment outcome, because patients do not adequately report their complaints beyond the initial 2 weeks of follow-up (B)	*16.2%*
… are necessary to provide custom care (B)	*37.7%*
… are necessary to make a prognosis (B)	*44.6%*
… are necessary to correctly evaluate the final outcome of the treatment (B)	*51.5%*
… are necessary to evaluate the interim outcome of the treatment, besides other parameters such as function or pain (B)	*58.5%*
… give the patient certainty about the healing process (B)	*65.4%*
Not standardly taking radiographs of distal radius and ankle fractures around week 6 and 12 weeks after trauma…	
… leads to significantly less radiation exposure for the patient (F)	*42.3%*
… leads to a cost-reduction for the patient (F)	*46.9%*
… results in more patient-friendly care (F)	*57.7%*
… results in timesaving for the patient (F)	*79.2%*
The organizational context	
Not standardly taking radiographs of distal radius and ankle fractures around week 6 and 12 weeks after trauma…	
… is only possible with the support of the plastic surgery department (F)	*19.2%*
… is only possible with the support of the radiology department (F)	*21.5%*
… is only possible with the support of the orthopedic department (F)	*41.5%*
… leads to less workload in the surgical department (F)	*46.9%*
… leads to less workload in the radiology department (F)	*85.4%*
… results in lower healthcare costs for the Netherlands (F)	*82.3%*
External environment	
Follow-up radiographs of distal radius and ankle fractures around 6 and 12 weeks after trauma…	
… are necessary for medicolegal protection (B)	*56.2%*
Not standardly taking radiographs of distal radius and ankle fractures around week 6 and 12 weeks after trauma…	
… is only possible if it is incorporated in the national protocol (F)	*43.8%*
… is only possible if it is incorporated in the regional protocol (F)	46.9%
… is only possible if it is incorporated in the local protocol (F)	72.3%
No items were on the level of Innovation, Social context	

Legend:
B = barrier
F = facilitator

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radiographs of distal radius and ankle fractures around 6 and 12 weeks after trauma "leads to less pressure on the radiology department" (85.4% agreement), "results in lower healthcare costs for the Netherlands" (82.3 % agreement), and "results in time saving for the patient" (79.2% agreement).

Table IV shows the percentage of surgeons who agreed with the barriers and facilitators in the questionnaire when grouped to the intention to omit radiographs. For distal

Table IV. Agreement with barriers and facilitators separately for surgeons who intend to stop or continue with ordering routine radiographs, if these are proven not to be effective for distal radius fractures or ankle fractures

	Distal radius fractures		Ankle fractures	
	Stop (n=110)	Continue (n=20)	Stop (n=96)	Continue (n=34)
The professional				
Follow-up radiographs of distal radius and ankle fractures around 6 and 12 weeks after trauma…				
… are necessary to evaluate the treatment outcome, because I often change my policy based on the radiographs taken at 6 and 12 weeks (B)	21 (19%)	5 (25%)	16 (17%)	10 (29%)
... are essential for the surgeon to learn how to interpret radiographs (B)	23 (21%)	5 (25%)	22 (23%)	6 (18%)
… provide me with essential feedback about the treatment outcome (B)	**50 (46%)***	**15 (75%)**	45 (47%)	20 (29%)
… provide me with certainty about the treatment outcome(B)	62 (56%)	13 (65%)	56 (58%)	19 (56%)
Not standardly taking radiographs of wrist and ankle fractures at week 6 and 12 weeks…				
… leads to a lower workload for the surgeon (F)	39 (36%)	3 (15%)	**37 (39%)**	**5 (15%)**
The patient				
Follow-up radiographs of distal radius and ankle fractures around 6 and 12 weeks after trauma…				
… are necessary to evaluate the treatment outcome, because patients do not adequately report their complaints beyond the initial 2 weeks of follow-up (B)	17 (16%)	4 (20%)	16 (17%)	5 (15%)
… are necessary to provide custom care (B)	40 (36%)	9 (45%)	33 (34%)	16 (47%)
… are necessary to make a prognosis (B)	47 (43%)	11 (55%)	39 (41%)	19 (56%)
… are necessary to correctly evaluate the final outcome of the treatment (B)	54 (49%)	13 (65%)	46 (48%)	21 (62%)
… are necessary to evaluate the interim outcome of the treatment, besides other parameters such as function or pain (B)	61 (56%)	15 (75%)	52 (54%)	24 (71%)
… give the patient certainty about the healing process (B)	71 (65%)	14 (70%)	65 (68%)	20 (59%)

Table IV. Agreement with barriers and facilitators separately for surgeons who intend to stop or continue with ordering routine radiographs, if these are proven not to be effective for distal radius fractures or ankle fractures (continued)

	Distal radius fractures		Ankle fractures	
	Stop (n=110)	Continue (n=20)	Stop (n=96)	Continue (n=34)
Not standardly taking radiographs of wrist and ankle fractures at week 6 and 12 weeks…				
… leads to significantly less radiation exposure for the patient (F)	**52 (47%)**	**3 (15%)**	45 (47)	10 (29%)
… leads to a cost-reduction for the patient (F)	**57 (52%)**	**4 (20%)**	**52 (54%)**	**9 (27%)**
… results in more patient-friendly care (F)	**70 (64%)**	**5 (25%)**	**64 (67%)**	**11 (32%)**
… results in timesaving for the patient (F)	**92 (84%)**	**11 (55%)**	**85 (89%)**	**18 (53%)**
<u>The organizational context</u>				
Not standardly taking radiographs of wrist and ankle fractures at week 6 and 12 weeks…				
… is only possible with the support of the plastic surgery department (F)	22 (20%)	3 (15%)	20 (21%)	5 (15%)
… is only possible with the support of the radiology department (F)	23 (21%)	5 (25%)	22 (23%)	6 (18%)
… is only possible with the support of the orthopedic department (F)	48 (43%)	6 (30%)	41 (43%)	13 (38%)
… leads to less workload in the surgical department (F)	**57 (52%)**	**4 (20%)**	**53 (55%)**	**8 (24%)**
… leads to less workload in the radiology department (F)	97 (88%)	14 (70%)	**88 (92%)**	**23 (68%)**
… results in lower healthcare costs for the Netherlands (F)	**98 (89%)**	**9 (45%)**	**88 (92%)**	**19 (56%)**
<u>External environment</u>				
Follow-up radiographs of distal radius and ankle fractures around 6 and 12 weeks after trauma …				
… are necessary for medicolegal protection (B)	60 (55%)	13 (65%)	52 (54%)	21 (62%)
Not standardly taking radiographs of wrist and ankle fractures at week 6 and 12 weeks…				
… is only possible if it is incorporated in the national protocol (F)	49 (45%)	8 (40%)	45 (47%)	12 (35%)
… is only possible if it is incorporated in the regional protocol (F)	**56 (51%)**	**5 (25%)**	**50 (52%)**	**11 (32%)**
… is only possible if it is incorporated in the local protocol (F)	81 (74%)	13 (65%)	71 (74%)	23 (68%)

Legend for table IV:
B = barrier
F = facilitator
Bold = a significant difference between groups (p <0.05)

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radius fractures, responses concerning one of the barriers and seven of the facilitators showed a difference between the intend-to-stop group and the intend-to-continue group. For ankle fractures, responses concerning eight facilitators showed a difference as well. A large degree of overlap existed between the found facilitators in distal radius fractures and ankle fractures.Based on the univariate analyses (Table IV), one of the barriers and a total of nine facilitators for omitting routine radiography were included in the multivariate logistic regression analyses, predicting the intention to stop performing

Table V. Multivariate logistic regression analysis predicting the intention to stop ordering routine radiographs at 6 and 12 weeks after trauma if proven not effective for distal radius fractures and ankle fractures. All numbers presented as the Odds Ratio (95% Confidence interval)

	Distal radius fractures	Ankle fractures
The professional		
Follow-up radiographs of distal radius and ankle fractures around 6 and 12 weeks after trauma …		
… provide me with essential feedback about the treatment outcome (B)	OR 0.38 (0.11–1.29)	-
Not standardly taking radiographs of wrist and ankle fractures at week 6 and 12 weeks…		
… leads to a lower workload for the surgeon (F)	-	OR 1.09 (0.23–5.14)
The patient		
Not standardly taking radiographs of wrist and ankle fractures at week 6 and 12 weeks…		
… leads to significantly less radiation exposure for the patient (F)	OR 2.20 (0.51–9.11)	-
… leads to a cost-reduction for the patient (F)	OR 1.81 (0.47–6.95)	OR 1.66 (0.62–4.50)
… results in more patient-friendly care (F)	OR 3.33 (0.99–11.20)	OR 2.25 (0.83–6.11)
… results in timesaving for the patient (F)	OR 1.01 (0.21–4.76)	**OR 4.84 (1.63–14.37)**
The organizational context		
Not standardly taking radiographs of wrist and ankle fractures at week 6 and 12 weeks…		
… leads to less workload in the surgical department (F)	OR 0.679 (0.11–3.42)	OR 0.96 (0.28–3.23)
… leads to less workload in the radiology department (F)	-	OR 1.81 (0.49–6.65)
… results in lower healthcare costs for the Netherlands (F)	**OR 5.38 (1.61–17.99)**	**OR 4.38 (1.45–13.28)**
External environment		
Not standardly taking radiographs of wrist and ankle fractures at week 6 and 12 weeks…		
… is only possible if it is incorporated in the regional protocol (F)	**OR 3.66 (1.08– 12.40)**	**OR 2.66 (1.01–6.99)**

Legend for table V:
B = barrier
F = facilitator
Bold = a significant difference between groups (p <0.05)

radiographs at 6 and 12 weeks if proven not to be effective. Table V shows that for distal radius fractures, two facilitators remained in the final model and were found to be independently associated with the intention to stop ordering routine radiographs. Respondents from the intend-to-stop group were more convinced that not taking routine radiographs will result in lower healthcare costs for the Netherlands (Odds Ratio [OR], 5.38; 95% Confidence Interval [CI], 1.61 to 17.99).

These respondents were also more likely to value the regional protocols (OR, 3.66; 95% CI, 1.08 to 12.4). For ankle fractures, three facilitators were found to be independently associated with the intention to omit routine radiography if proved to be not clinically effective. Respondents from the intend-to-stop group were more convinced that omitting routine radiography for ankle fractures would lead to lower healthcare costs as well (OR, 4.38; 95% CI, 1.45 to 13.28).

Moreover, for ankle fractures, these respondents also value the regional protocol more (OR, 2.66; 95% CI, 1.01 to 6.99). Furthermore, for ankle fracture patients, the facilitator "not standard taking radiographs result in time saving for the patient" was another independent predictor for the intention of omitting routine radiography (OR, 4.84; 95% CI, 1.63 to 14.37).

DISCUSSION

The present study was conducted in order to identify which barriers and facilitators among orthopedic trauma surgeons influence the abandonment of potential low-value diagnostic imaging for patients with distal radius and ankle fractures. In the present study, multiple barriers and facilitators for reducing low-value diagnostic imaging were acknowledged by the consulted orthopedic trauma surgeons. We identified two facilitators that were independently associated with the intention to omit routine radiography in distal radius fracture patients. Three facilitators showed to be of influence on the intention to stop ordering routine radiographs in ankle fracture patients, if the WARRIOR-trial would prove these routine radiographs to be ineffective. The other reported barriers and facilitators could not be identified to be independently associated with the intended behavior of the respondents. Two of the aforementioned facilitators showed to be of influence on both distal radius and ankle fracture patients: The notion that reducing the number of radiographs during follow-up of distal radius and ankle fracture leads to cost-savings for the healthcare system and the need of incorporation of the trial's findings in the regional protocol. A future de-implementation strategy, assuming that the WARRIOR trial will provide evidence for the reduction of the number of routine radiographs without compromising the quality of care, should focus on changing the current protocols into protocols with fewer radiographs on a regional level. Besides that, a thorough cost-effectiveness analysis needs to be performed, in order to confirm the assumption that implementation of such a protocol will lead to a reduction in cost.

To our knowledge, no previous studies on barriers and facilitators for de-implementation of routine radiographs have been conducted. Voorn et al. assessed barriers among orthopedic surgeons and anesthesiologists for the intention to stop the use of erythropoietin (EPO) and blood salvage in total hip and total knee arthroplasty.[24] They found that the intention to stop EPO and blood salvage was related to current blood management protocols, as well as to their own technical skills, patient safety, and a lack of interest to save money. The availability of up-to-date protocols and clinical guidelines also plays an important role in implementation. For instance, the framework of Cabana et al. [28] shows that awareness of and familiarity with a protocol or guideline influences the knowledge of the physicians. This is the first requirement for behavior change. De-implementation of the routine radiographs during follow-up of distal radius and ankle fractures by revising the current protocol could be a first step towards the change in behavior of surgeons. At the domain of the patient, saving time when no radiograph of the ankle is needed is a facilitator more frequently acknowledged by respondents from the intend-to-stop group. In the organizational context, the potential decrease in cost when reducing the number of radiographs might also prove to be a good starting point for omitting this type of low-value care. From literature, it is known that dissemination of protocols alone is not enough to change behavior of surgeons. As shown by Prior et al., more educational outreach, such as oral presentation on local, regional, and national levels, is needed to inform the surgeons about the newly incorporated protocol. This kind of outreach is needed to effectively lead to the abandonment of routine radiography at 6 and 12 weeks for distal radius and ankle fractures.[29] Although four out of six barriers and facilitators perceived most frequently by the orthopedic trauma surgeons in the present study were not independently associated with the intention to stop performing routine radiographs, these barriers and facilitators can still be useful in the educational outreach to inform the surgeons about the revised protocol.

Strengths and Limitations

By conducting semi-structured interviews, a complete set of barriers and facilitators based on an established framework was provided for the survey, which can be seen as one of the strengths of the present study. While orthopedic trauma surgeons with an interest in development or revision of protocols would have been more likely to participate, it is questionable whether their responses would be any different than those of surgeons who do not have an interest in this area. With a response rate of 57%, which is much higher than the responses found in other surveys among surgeons,[24, 30, 31] the chance of response bias is moderate. Additionally, the number of respondents was large (n=130), further reducing the risk of response bias. The facilitators that were independently associated with the intention to stop performing the routine radiographic imaging are likely to be relevant to convince surgeons to stop performing routine radiographs.

CONCLUSIONS

Identifying barriers and facilitators among orthopedic trauma surgeons regarding the use of a protocol with fewer radiographs is crucial for successful deimplementation of routine radiography for distal radius and ankle fractures. The majority of orthopedic trauma surgeons intend to follow newly published evidence on the reduced use of routine radiographs. When comparing the intend-to-stop and intend-to-continue groups, several independently associated facilitators can be identified. The identified facilitators can be of value for the development of a tailored deimplementation strategy. In this particular case, the strategy should focus on adjusting the current regional protocols into protocols with less routine radiographs and local, regional, and national education. This education should target the potential benefits of the implementation of these protocols in the terms of cost-savings and time efficiency. The education on these protocols will also create familiarity with the study outcomes, and a higher awareness among orthopedic trauma surgeons.

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General discussion and future perspectives

Worldwide, healthcare expenditures are rising rapidly. To combat this growing problem, physicians are challenged to reduce costs while delivering high-quality healthcare. One of the ways to achieve this is to reduce the so-called 'low-value care'. In 2012, the 'Choosing Wisely' campaign was introduced to combat this problem.[1] Choosing Wisely aims towards choice of care that is 'necessary, relatively safe, and supported by evidence'. Routine radiography for distal radius fractures and ankle fractures without a clear indication or without impact on fracture treatment or patient reported outcomes is a good example of potentially low-value care. In that vein, the generally accepted principle of routine radiographic follow-up for those with distal radius fractures and ankle fractures would appear to warrant further examination, particularly given their common occurrence.

While distal radius fractures and ankle fractures have been studied extensively, most of those efforts focused on recovery following surgery, to the detriment of other areas where knowledge is lacking, such as the use and added value of routine radiography in the follow-up of extremity fractures. Prior to conducting the Warrior Trial, we employed a broad search strategy in order to identify what was known on the use of routine follow-up radiography in those with upper or lower extremity fractures. To our dismay, we found that not much was known. At that time (October 2018), we identified only eleven studies, all of them retrospective.[2-12] We were, therefore, not able to answer our research questions validly, which is summarized in Chapter 2.

In short, eight studies reported modifying their treatment strategy based upon the radiographs (percentages of modifications ranging from 0% to 2.6%). Just two of these studies used a comparative design. All the studies concluded that routine follow-up radiographs do not have important clinical consequences. This is in accordance with routine radiography for other conditions, such as knee osteoarthritis or low-back pain.[13, 14] The level of evidence was low, therefore, the results should be interpreted with caution.

CURRENT PRACTICE

In the current treatment and follow-up protocols, patients with a fractured ankle or distal radius are treated with either operative fixation or plaster immobilization. Patients receive follow-up with frequent monitoring in the outpatient clinic. Routine radiographs are performed in order to monitor fracture healing. A detailed report which describes how four level-1 trauma centers in the Netherlands organized follow-up for these patients, and how often routine radiographs are utilized during this follow-up is outlined in Chapter 3. For the purpose of that study, we focused on follow-up after the initial three weeks of treatment because these protocols are more standardized. In short, the vast majority (98.8%) of routine radiographs after three weeks of follow-up did not lead to a change in treatment strategy, but led to an increase in cost, effort and radiation exposure.

A standardized follow-up regimen, with routine radiographs obtained at fixed moments certainly can have benefits. Having a uniform follow-up protocol can aid less experienced physicians in delivering a constant level of care. Also, radiographs might protect physicians against litigation claims. This is not a common problem in the Netherlands but may be an important driver in other parts of the world, where physicians are at greater risk for malpractice litigation. However, given the large differences in both patient-specific and fracture-specific criteria, a standardized, one-size-fits-all approach seems outdated.

The most important limitation to the study outlined in Chapter 3 was its retrospective design. This limited the validity of our results. In order to provide a higher level of evidence, a prospective trial was needed. The Warrior trial was designed to evaluate whether a reduction in routine radiography for patients with a distal radius fracture or ankle fracture is effective, safe and cost-effective compared with usual care.

THE WARRIOR TRIAL

The Warrior trial was designed as a prospective, randomized controlled trial (RCT) with a four-armed design comparing reduced imaging with usual care for both ankle fractures and distal radius fractures. The inclusion criteria of the study were broad, and we had few exclusion criteria. Therefore, the external validity of the results can be considered appropriate for Western societies. The primary outcome measure was functional outcome,[15] and we opted for a non-inferiority design because we hypothesized that reducing the number of routine radiographs would be beneficial, but need not be more effective. By choosing a non-inferiority design, it was possible to prove that reducing the number of radiographs was not worse than standard care. If reduced imaging is non-inferior for function outcome, other benefits (such as lower cost, fewer side-effects or less burden for patients or the healthcare system) might then favor the implementation of reduced imaging.

Methods

Functional outcome was measured by the Olerud-Molander Ankle Score (OMAS) for those with ankle fractures,[16] while the Disabilities of the Arm, Shoulder and Hand (DASH) questionnaire[17] was used to measure functional outcome in patients with distal radius fractures. Secondary outcomes included functional outcome measured with the American Academy of Orthopaedic Surgeons (AAOS) foot and ankle questionnaire for ankle fracture patients,[18] functional outcome measured with the Patient-Rated Wrist/Hand Evaluation for distal radius fracture patients,[19, 20] Health Related Quality of Life (HRQoL), pain, self-perceived recovery, complications and costs. Participating hospitals[†] were representative of usual care.

Results

The results suggest that reduced imaging does not lead to worse outcomes in those with ankle and distal radius fractures as compared to usual care. Other outcome parameters such as AAOS scores, HRQoL, pain, and self-perceived recovery did not differ between groups either and complication rates were similar. For both ankle fractures and distal radius fractures, participants which were randomized to reduced imaging received a median of 1 radiograph less compared to those who received usual care. Clinical and functional outcomes for ankle fracture patients are reported in more detail in Chapter 4 and outcomes for patients with a distal radius fracture are reported in detail in Chapter 6.

Limitations

There are several limitations, but perhaps the most important one is the choice of the primary outcome measure. In retrospect, it could have been more appropriate to focus on the number and type of complications. It could be argued that reducing the number of routine radiographs might result in a delayed detection of a complication or fail to detect it altogether. This could be an important reason to continue routine radiographic monitoring in those with extremity fractures. This is especially so, if a missed complication could result in irreversible harm, or result in high medical malpractice compensations. A small cost saving per patient for an enormous group could be nullified by a single malpractice claim, particularly in countries where medical litigation is more common than in the Netherlands. However, it is important to realize that the current timing of follow-up radiographs is empirical with no scientific basis for detecting complications.

Since our study focused on the functional outcome of an entire group, a single or a small number of outliers with a missed complication are not likely to result in worse outcomes. A study which focused on complications as its primary outcome measure would provide the best evidence, however, such a design is not feasible because it would require a very large sample size. Typical complications that could be diagnosed on radiographic

[†] Leiden University Medical Center (LUMC), University medical Center Groningen (UMCG), Amsterdam University Medical Centers (A-UMC), Haaglanden Medical Center (HMC), ZiekenhuisGroep Twente (ZGT), Zaans Medical Center (ZMC), Flevoziekenhuis Almere.

imaging in our study were non-union, malunion, failing of the osteosynthesis and secondary dislocation. We recorded 13 of these complications in 246 patients with an ankle fracture (5.3%) and 14 in 326 patients with a distal radius fracture (4.3%) with an equal distribution between usual care (15/294 = 5.1%) and reduced imaging groups (12/278 = 4.3%). Powering a study on an outcome that is this rare and consequently will not lead to a large difference between groups, would have resulted in thousands of participants per group. Obviously, that is not a realistic option within the frame of a RCT.

When analyzing our results, the equal distribution of radiographic complications suggests that no complications were missed in the reduced-imaging group. But since the study was not powered to detect such a difference, these results should be interpreted with caution. A possible explanation why reducing the number of routine radiographs did not lead to missed complications might be that patients with a non-union, malunion or a secondary dislocation, typically exhibit other symptoms, such as pain or diminished range-of-motion. Since these symptoms were indications to obtain radiographs in the reduced-imaging group, we may have missed patients with asymptomatic complications. One might argue whether this has clinical consequences. If a patient, for instance, has a slight malunion, but is not exhibiting any symptoms, it is questionable whether it is necessary or desirable to correct this malunion.

A second limitation regards the subgroup analyses, which we performed for operatively treated and non-operatively treated patients. The percentage of patients that received operative treatment of a distal radius fracture was lower (12.6%) than we had estimated based upon our retrospective study (20%). Our results suggest no worse outcomes for the reduced imaging strategy, although this should be interpreted with caution because this analysis was underpowered. However, the chance that a routine radiograph of an asymptomatic patient leads to detection of a complication which is likely to influence treatment strategy is thought to be negligible. Therefore, routine radiography would appear not necessary for those with an operative fixation of their distal radius fracture. Another subgroup analyses that might have been interesting to explore include comparing outcomes for patients with an unstable fracture managed non-operatively. This was not conducted because there were insufficient numbers as we did not power for this subgroup.

A third limitation is the number of protocol violations. For patients in the usual care group, it was obligatory to obtain a radiograph both at 6 and 12 weeks of follow-up. We witnessed that, mainly in patients with a distal radius fracture, not all patients randomized to usual care received both follow-up radiographs. Out of 166 patients with a distal radius fracture randomized to usual care, just 97 (58%) had a radiograph both at week 6 and 12. This might indicate that the current follow-up protocol for distal radius fractures is overly cautious and that in regular clinical practice clinicians may already carefully consider whether an additional radiograph is needed or not. On the other hand, this might also be a result of the information we provided to participating clinicians about the research question and study design. This may have created more awareness about the usefulness of routine radiographs during follow-up.

In contrast, in those with an ankle fracture, protocol violations were predominantly observed in the reduced imaging group. The protocol violations in this group usually occurred if a radiograph was made at week 6 or 12 when the clinical indication was not present or registered. Out of 118 ankle fracture patients randomized to reduced imaging, 59 had a protocol violation (50%). This high number might be, however, an indication that the reason for radiographs was not accurately reported. It might also indicate that physicians regarded the number of radiographs in the reduced imaging protocol for ankle fractures as insufficient. Despite this, we do not believe that these protocol violations introduced bias. We performed a per-protocol analysis for ankle fracture patients. Those results were similar to the main analysis, therefore, the effect of the protocol violations on our results seems limited.

In both the ankle fracture group as well as in the distal radial fracture group there was a reduction of one radiograph in the reduced imaging group in comparison with the usual care group. This difference was lower than hypothesized (i.e., one, instead of two) in both the ankle fracture and the distal radius fracture group. This might be due to the number of protocol violations. The median number of radiographs in both reduced imaging and usual care was higher in patients with an ankle fracture (usual care median 5, reduced imaging median 4) than in patients with a distal radius fracture (usual care median 4, reduced imaging median 3). This was apparent in our retrospective study as well. Ankle fracture patients received a higher number of radiographs during follow-up (median 3 [Chapter 3]) when compared to distal radius fracture patients (mean 1.8).[12] In the interviews conducted for our implementation study (Chapter 8), more respondents were willing to stop obtaining follow-up radiographs for patients with a distal radius fracture (110/130, 85%) than for patients with an ankle fracture (96/130, 74% [$p < 0.05$]).

Upon further examination of these findings, it would appear that the proposed omission of both the week 6 and 12 radiograph for distal radius fracture patients is deemed safe and could be implemented readily. Whereas for ankle fracture patients, a radiograph at either week 6 or week 12 is highly valued by physicians. Implementation of a follow-up protocol that either omits the week 6 or the week 12 radiograph, therefore, seems feasible. This reduction of one radiograph can be justified with the results of the Warrior trial.

COST-EFFECTIVENESS

Since functional outcomes are not negatively influenced in those with ankle and wrist fractures who were assigned to the reduced imaging group, the question remained whether there was an effect on healthcare costs.

A cost-effectiveness analysis was performed for both patients with an ankle fracture and for patients with a distal radius fracture. In a cost-effectiveness analysis, the cost and effects of an intervention are compared with the cost and effects of a comparator. The effects are typically expressed as Quality-Adjusted Life Year (QALY); the most optimal comparator is usual care. The cost-effectiveness analysis results in the incremental cost of an intervention compared to the comparator per QALY gained.

In the Netherlands, an amount of €20,000 to €80,000 is deemed an acceptable cost per QALY.[21] For both groups, we found a significant reduction in the costs for radiographic imaging in the reduced imaging group (Chapter 5 and 7). For either fracture location, the median reduction in radiographs was 1. This leads to an average cost saving of €48 for both ankle fractures and distal radius fractures. For a single patient this reduction seems rather small. However, since the incidence of these fractures is high, total cost savings for the Dutch population (approximately 17 million inhabitants) are estimated to be €4.1 million annually.[‡] Other costs, including the overall costs, showed no significant differences between the groups. The probability of reduced imaging being cost-effective for QALYs compared to usual care for ankle fractures was 0.45 (45%) at a willingness to pay of €20,000 per QALY. This is considered low. The probability that the reduced imaging follow-up strategy was cost-effective for distal radius fractures was much higher: 0.8 at a willingness to pay of €20,000 per QALY, which increased to 0.9 at a willingness to pay of €80,000 per QALY.

The approach commonly used for a cost-effectiveness analysis (i.e., how much additional costs are needed per QALY gained) is most suitable for trials with either a superiority design, or a trial where there is a distinct difference in QALYs between groups. In our trial, the difference in QALYs between groups was negligible. For patients with an ankle fracture it was -0.008 QALY (95% CI -0.06 to 0.04) and for patients with a distal radius

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[‡] Based upon an incidence of 30,000 ankle fractures and 55,000 distal radius fractures

fracture it was 0.025 QALY (95% CI -0.01 to 0.06). Small cost savings and little effect on QALYs may lead to a less accurate cost-effectiveness analysis. This explains why a similar cost saving led to a completely different probability of cost-effectiveness. Another thing we observed was the nullification in costs for radiography by much higher costs for other items, such as absenteeism, presenteeism, hospital admission or surgical fixation of the fracture. As a result, overall costs had large confidence intervals, and did not differ between groups. The fact that these major cost items were comparable does, however, indicate that there were no large financial drawbacks associated with reduced imaging.

When comparing costs of patients with an ankle fracture and a distal radius fracture, we found that having an ankle fracture is more costly than a distal radius fracture for all cost categories. For the cost of secondary care, this might partly be due to a difference in what type of costs were included in this group. For ankle fractures, hospital admission and surgery were included in cost of secondary care. For distal radius fractures, these costs were not included due to an error in our analysis. This makes costs of secondary care in the ankle fracture group and distal radius fracture group less comparable. However, since the number of participants with a distal radius fracture that received surgery was similar (i.e., 21 participants with usual care and 20 participants with reduced imaging) it is unlikely that this has otherwise influenced our results. Other cost groups included the same items and are therefore comparable between those with ankle fractures and those with distal radius fractures. The fact that overall costs of an ankle fracture were more than double the costs of a distal radius fracture might explain why similar cost savings led to a higher probability of cost-effectiveness in those with distal radius fractures. The achieved cost saving of €48 is a relatively larger reduction when overall costs are less.

FUTURE PERSPECTIVES

It would appear that eliminating routine follow-up radiography can be introduced without sacrificing quality of care. However, it will require much effort on the part of healthcare professionals and organizations in order to implement these findings. In order to determine which factors might influence physicians and policymakers to implement our findings, and potential future findings for different fracture locations, more insight in physician behavior was necessary.

In Chapter 8, we evaluated which barriers and facilitators might play a role for physicians to implement the results of the Warrior trial. In short, we found that physicians were more willing to stop obtaining routine radiography if it would lead to financial savings, reduction in time wasted by their patients, and if our study findings were to be adopted in treatment protocols. Familiarity with study findings and adaptation of protocols is known from the literature to be of influence on behavioral change.[22] [23] Educational outreach, such as oral presentations, could inform stakeholders of these results and protocol adaptations.

For medicolegal reasons, alteration of treatment protocols may be the most important facilitator for individual caregivers. Being more cautious than the treatment protocol advises when deemed necessary is far easier to justify, than having to substantiate that omitting elements of a treatment protocol was safe. Medicolegal threats might not be a prime motivator in the Netherlands, but they might play a larger role in other healthcare systems.

CONCLUSION

Routine radiography in the follow-up of patients with an ankle fracture or a distal radius fracture is common practice in Western societies. The analyses contained in this thesis suggest that complications detected during routine radiography for those with ankle or distal radius fractures are rare, and that the number of routine radiographs can be reduced without compromising care. Follow-up radiography after three weeks should be stopped in those with distal radius fractures and can be reduced by at least one in those with ankle fractures. In other words, routine radiography for these patients is low-value care as defined by 'Choosing Wisely'. Healthcare professionals and organizations should focus their attention on how to implement these findings on a national level. Broadening the selection of patients to include other types of fractures or fractures at different locations would also help to implement our findings on a larger scale. Additionally, future studies are necessary in order to determine which patients might benefit from close fracture monitoring.

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Appendices

Summary
Nederlandse samenvatting
Curriculum Vitae
Dankwoord

SUMMARY

Ankle and distal radius fractures are two of the most common musculoskeletal injuries. Over the last decades their incidences have risen due to increasing participation in athletic activities and ageing of the population. Current national and international protocols recommend frequent outpatient clinic visits in which radiographs of the fractured extremity are obtained.

The general aim of this thesis was to evaluate the added value of routine radiography in the follow-up of ankle and distal radius fractures. Specifically, we were interested in investigating whether a follow-up protocol which focuses on reducing the number of routine follow-up radiographs was able to deliver care that was comparable to the current standard of care, but without sacrificing quality nor safety, whilst increasing cost-effectiveness.

Chapter 1 provides background information on the epidemiology of ankle and distal radius fractures. It also outlines the current standard of care during treatment and follow-up of the affected patients.

In **chapter 2** an overview of the current literature on routine radiography in extremity fractures is given. Despite the common occurrence of extremity fractures, limited data were available on the added value of routine radiography at the time that our systematic review was performed in 2018. We identified eleven studies; however, due to their retrospective design and thus incumbent biases, the resultant quality or certainty of the evidence was considered low. Despite this, the treatment plan was modified in a very small percentage of the cases (ranging from 0 to 2.6%); therefore, the added value of routine radiography seems limited.

Following our review in 2018, we conducted a retrospective analysis in four level 1 trauma centres in the Netherlands in order to determine the impact of routine radiographs on treatment strategy for patients with ankle fractures. **Chapter 3** illustrates that, in accordance with studies outlined in chapter 2, the use of routine radiographs in the follow-up of ankle fracture patients in the Netherlands was common. In total, 80% of radiographs obtained after more than three weeks of follow-up were considered routine, and only 1.2% of these radiographs resulted in a change of treatment strategy. However, due to its retrospective design, the strength of the evidence was also considered low given its limitations.

Chapters 4 and 5 report on the results of a multi-centre randomized controlled trial (RCT) in which participants with an ankle fracture were randomized between the current standard of care consisting of routine follow-up radiography (routine care) and a reduced imaging follow-up regimen. The clinical and functional outcomes outlined in **chapter 4** suggest that routine radiographs at week 6 and 12 can be omitted without compromising treatment outcomes. Specifically, functional outcome measured with the Olerud and Molander Ankle Score was non-inferior in the reduced imaging group, while secondary outcomes, such as American Association of Orthopedic Surgeons (AAOS) foot and ankle scores, Health-Related Quality of Life (HRQoL), pain, health perception and self-perceived recovery did not differ between groups. The median number of radiographs obtained was 4 in the reduced imaging group and 5 in the routine care group (a reduction of 20%). Similar numbers and types of complications were observed in both groups; therefore, modifying the current standard of care can be implemented without sacrificing quality nor safety. In **chapter 5** the results of the economic evaluation of the reduced-imaging follow-up strategy for ankle fracture patients are presented. Patients randomized to reduced imaging had a similar HRQoL in comparison with patients randomized to routine care. Costs for radiographic imaging were significantly lower in the reduced imaging group (a difference of €48 (95% CI: €-72 to €-28)). Other costs, including overall costs did not statistically differ between the groups. The probability of cost-effectiveness was 0.45 at a willingness-to-pay of €20,000 per QALY.

Chapters 6 and 7 report on the outcomes from the same RCT, but which focused on patients with a fracture of the distal radius. Similar to the results of the RCT on ankle fractures, functional outcome (measured with the Disabilities of Arm, Shoulder and Hand questionnaire [DASH]) was no worse than the reduced imaging group (**chapter 6**). Secondary outcomes such as HRQoL, pain and complications demonstrated similar outcomes between the groups. The number of radiographs obtained per patient decreased 25% to median 3 in the reduced imaging group from median 4 in the routine care group. The results of the economic evaluation described in **chapter 7** demonstrated similarities to the results of the study on ankle fractures. HRQoL was similar, and costs for radiographic imaging were significantly lower in the reduced imaging group (this reduction was €48 per patient (95% CI: -68 to -27)). The probability of cost-effectiveness was 0.8 to 0.9 at willingness-to-pay of €20,000 to €80,000 per QALY.

Following these analyses, we investigated which factors could encourage or discourage physicians to modify their practice behaviours, namely reduce their reliance on routine follow-up radiographs of extremities. These so-called "barriers and facilitators" were queried among orthopaedic trauma surgeons in the Netherlands (**chapter 8**). In total, 130 respondents (57%) completed the questionnaire, 71% indicated that they would stop ordering routine radiographs if they demonstrated no added value. In short, we identified three facilitators which were found to be independent predictors for the intention to de-implement routine radiographs: 1) 'the reduced imaging follow-up protocol will lead to lower healthcare costs'; 2) 'incorporation of the reduced imaging follow-up in regional protocols'; and 3) 'reduced imaging will result in time-savings for the patient'. There was no barrier that was found to be an independent predictor for the intention to reduce the reliance on routine radiographs. With the three facilitators in mind, a proper de-implementation strategy can be drafted for the Netherlands, and other populations similar as ours.

In **chapter 9,** I present general conclusions and discuss the clinical implications and future perspectives regarding the effectiveness and cost-effectiveness of routine radiography in ankle and distal radius fractures. This large multi-center study demonstrates that the number of routine radiographs in those with ankle and distal radius fractures can be reduced without sacrificing quality nor safety, while resulting in more cost-effective care

NEDERLANDSE SAMENVATTING

Enkelfracturen en distale radiusfracturen zijn twee van de meest voorkomende letsels van het steun- en bewegingsapparaat. De incidentie van deze letsels is de afgelopen decennia toegenomen door een toename van sportparticipatie en de vergrijzing. In de follow-up van deze letsels adviseren de huidige protocollen frequente en routinematige poliklinische controleafspraken, waarbij veelal röntgenfoto's worden gemaakt van de aangedane extremiteit.

Het doel van deze thesis was om de toegevoegde waarde van deze routinematige röntgenfoto's in de follow-up van patiënten met een pols of enkelfractuur te bepalen. Meer specifiek wilden wij onderzoeken of een follow-up protocol waarbij er minder gebruik wordt gemaakt van routinematige foto's zou leiden tot vergelijkbare kwaliteit van zorg tegen lagere kosten, waarbij zowel de kwaliteit, als de veiligheid van de patiëntenzorg niet in het gedrang zouden komen.

In **hoofdstuk 1** wordt meer achtergrondinformatie gegeven over de epidemiologie van enkelfracturen en distale radiusfracturen. Ook wordt de huidige standaardzorg voor behandeling en follow-up besproken.

Hoofdstuk 2 geeft de resultaten weer van het literatuuronderzoek en de systematische review die wij hebben uitgevoerd naar dit onderwerp. Ondanks dat enkelfracturen en distale radiusfracturen veelvoorkomende letsels zijn, waren er in 2018 maar weinig wetenschappelijke artikelen beschikbaar die een uitspraak deden over de toegevoegde waarde van routinematige röntgenfoto's. We hebben elf studies kunnen identificeren. Deze hadden echter allemaal een retrospectief studiedesign en daardoor een hoog risico op bias. Hierdoor was de methodologische kwaliteit laag, en konden geen harde conclusies worden verbonden aan de uitkomsten van deze studies. Desondanks viel wel op dat slechts in zeer kleine percentages (tussen de 0% en 2,6%) het behandelplan werd aangepast op basis van een routinematige röntgenfoto. De toegevoegde waarde van deze foto's lijkt daarmee beperkt.

Een retrospectieve analyse die door onze studiegroep is uitgevoerd over de invloed van routinematige röntgenfoto's in 4 level-1 traumacentra in Nederland kon in verband met de publicatiedatum nog niet in de systematische review worden meegenomen. De uiteenzetting van dit onderzoek in **hoofdstuk 3** laat zien dat het gebruik van routinematige röntgenfoto's in deze centra vaak voorkomt. Van alle foto's die zijn gemaakt na meer dan 3 weken follow-up was 80% routinematig. Slechts 1,2% van deze routinematige foto's leidde tot een aanpassing van het behandelplan. Echter doordat ook dit onderzoek retrospectief was, was ook onze studie gevoelig voor bias, en had het mede daardoor een lage bewijskracht.

Om meer zekerheid te kunnen geven over de toegevoegde waarde van routinematige röntgenfoto's was prospectief en gerandomiseerd onderzoek nodig. **Hoofdstuk 4 en hoofdstuk 5** beschrijven de resultaten van een multicenter gerandomiseerd onderzoek waarbij deelnemers met een enkelfractuur zijn gerandomiseerd tussen de toen gebruikelijke standaardzorg, waarbij na 6 weken en na 12 weken standaard een röntgenfoto werd gemaakt en een follow-up protocol met een verminderd aantal foto's. De functionele uitkomsten die worden beschreven in **hoofdstuk 4** laten zien dat zorgverleners routinematige foto's na 6 weken of na 12 weken achterwege kunnen laten, zonder dat dit leidt tot een slechtere uitkomst voor patiënten. Meer specifiek was de functionele uitkomst, gemeten met de Olerud and Molander ankle score, non-inferieur in de groep die had geloot voor minder foto's. Ook secundaire uitkomstmaten als de American Association of Orthopedic Surgeons (AAOS) foot and ankle scores, Health-Related Quality of Life (HRQoL), pijn en de zelfverklaarde gezondheidsperceptie en herstel verschilden niet tussen de beide groepen. Het mediane aantal röntgenfoto's dat gemaakt is in de totale behandeling van de patiënten liet een reductie zien van 20%. Het aantal röntgenfoto's was mediaan 5 in de groep die was gerandomiseerd naar routinematige röntgenfoto's en mediaan 4 in de groep die was gerandomiseerd naar het protocol met het verminderde aantal röntgenfoto's. Het aantal en type complicaties die geregistreerd zijn voor beide groepen verschilden niet van elkaar. Om die reden kan geconcludeerd worden dat zorgverleners routinematige foto's veilig achterwege kunnen laten, zonder dat dit leidt tot slechtere uitkomsten. De resultaten van de kosteneffectiviteitsanalyse van een nazorgprotocol met een verminderd aantal röntgenfoto's voor patiënten met een enkelfractuur worden beschreven in **hoofdstuk 5**. Patiënten die gerandomiseerd waren in de groep met het verminderde aantal foto's hadden een vergelijkbare HRQoL als patiënten gerandomiseerd naar de groep die de standaard zorg ontving. De kosten voor beeldvormend onderzoek waren significant lager in de groep met het verminderde aantal röntgenfoto's (€-48 [95%CI €-72 tot €-28]). Alle andere kosten, inclusief de totale kosten per patiënt, waren niet significant verschillend in beide groepen. De kans dat het follow-up protocol kosteneffectief is, was 0,45 bij een bereidheid om €20.000 te betalen per gewonnen QALY.

Met een gelijke studieopzet is er ook een RCT verricht naar de toegevoegde waarde van routinematige röntgenfoto's in de follow-up van patiënten met een distale radiusfractuur. De resultaten van het onderzoek naar de functionele uitkomst hiervan worden beschreven in **hoofdstuk 6**. Net zoals in de RCT die is verricht bij patiënten met een enkelfractuur was de functionele uitkomst, bij deze patiënten gemeten met de Disablities of Arm Shoulder and Hand vragenlijst (DASH), niet slechter in de groep waarbij minder routinematige foto's in de follow-up zijn gemaakt dan in de groep waarbij het standaard follow-up protocol is gevolgd. Ook de secundaire uitkomsten zoals HRQoL, Pijn, en complicaties waren vergelijkbaar in beide groepen. Het mediane aantal foto's dat in het gehele behandeltraject werd gemaakt verminderde met 25% in de groep die was gerandomiseerd naar het follow-up protocol waar foto's na 6 weken en na 12 weken alleen op klinische indicatie werden gemaakt. In deze groep zijn in de studieperiode mediaan 3 röntgenfoto's gemaakt, tegenover mediaan 4 rontgenfoto's in de groep met routinematige foto's na 6 weken en na 12 weken. **Hoofdstuk 7** beschrijft de resultaten van de kosteneffectiviteitsanalyse van het verminderen van het aantal routinematige röntgenfoto's in de follow-up van patiënten met een distale radiusfractuur. Ook bij dit letsel vonden we dat de kosten voor radiologische onderzoeken significant lager waren in de groep met het verminderde aantal foto's. De kostenbesparing in deze groep was €48 per patiënt (95% CI: €-68 tot €-27). De kans dat dit follow-up protocol kosteneffectief is, was aanzienlijk hoger. Deze kans was 0,8 bij een bereidheid om €20.000 te betalen per gewonnen QALY.

Deze kans steeg zelfs naar 0,9 bij een bereidheid om €80.000 te betalen per gewonnen QALY.

Teneinde onze onderzoeksresultaten in de praktijk te implementeren, hebben we onderzocht welke factoren voor zowel zorgverleners als patiënten van invloed zijn op de beslissing om de resultaten van het onderzoek over te nemen. Deze barrières en facilitatoren zijn vervolgens voorgelegd aan alle Nederlandse traumachirurgen. De resultaten van dit onderzoek staan beschreven in **hoofdstuk 8**. Het percentage traumachirurgen dat de vragenlijst heeft ingevuld bedroeg 57%. Van deze 130 respondenten gaf 71% aan te zullen stoppen met het routinematig aanvragen van röntgenfoto's, indien hiervan was aangetoond dat deze geen meerwaarde hebben. Drie facilitatoren konden worden geïdentificeerd die onafhankelijk van elkaar voorspellend waren voor de intentie om deze routinematige röntgenfoto's te de-implementeren. Ten eerste: 'Implementatie van een follow-up protocol met een verminderd aantal routinematige röntgenfoto's leidt tot lagere zorgkosten'; ten tweede: 'het follow-up protocol met een verminderd aantal routinematige röntgenfoto's moet worden aanbevolen in de regionale richtlijn'; en ten derde: 'Implementatie van een follow-up protocol met een verminderd aantal routinematige röntgenfoto's leidt tot een tijdsbesparing voor patiënten'. Geen van de onderzochte barrières bleek een onafhankelijke voorspeller voor de intentie om routinematige röntgenfoto's achterwege te laten. Gebruikmakende van de gevonden facilitatoren kan een de-implementatiestrategie worden opgesteld voor het Nederlandse zorgstelsel, en voor populaties die vergelijkbaar zijn aan de onze.

In **hoofdstuk 9** wordt de algehele conclusie van het onderzoek uiteengezet, en worden de implicaties en toekomstige perspectieven van het routinematig maken van röntgenfoto's in de follow-up van patiënten met een polsfractuur of een enkelfractuur bediscussieerd. Dit grote gerandomiseerde onderzoek toont aan dat het aantal routinematige röntgenfoto's kan worden verminderd zonder dat de kwaliteit van zorg, of de veiligheid van patiënten hieronder lijdt. Ook kan het verminderen van het aantal routinematige röntgenfoto's leiden tot meer kosteneffectieve zorg.

CURRICULUM VITAE

Pieter van Gerven was born on December 31, 1988 in Haarlem. After graduating from his secondary school "Het Stedelijk Gymnasium Haarlem" in 2007 he started his medical studies in Leiden. During his studies he developed an increasing interest in the field of surgery. After obtaining his bachelors degree in 2011, and his masters degree in 2015 he started working as a surgical resident not in training (ANIOS) at "Het Medisch Centrum Haaglanden" in the Hague. Here he developed both his clinical skills, as well as an interest in medical research. In 2017 he started as a full-time PhD-student at the department of Traumasurgery of the Leiden University Medical Centre (LUMC) with prof. I.B. Schipper and prof. M.W. van Tulder of "de Vrije Universiteit" in Amsterdam as his primary thesis advisors. During this period he was allowed to be a speaker at several national and international research conferences and his research articles were published in several leading journals in the field of orthopedic trauma surgery. From 2019 onwards he was combining his work as a PhD-student with a position as a resident not in training at the surgery department of the LUMC. After moving to Amsterdam in the spring of 2021, and a short period combatting the COVID-19 pandemic in the department of public health of the Netherlands (GGD), he continued his career as resident not in training at the surgery department of "het Zaans Medisch Centrum" in Zaandam. In June 2022, he transferred to "het Flevoziekenhuis" in Almere where he is currently working as resident not in training at the surgery department.

DANKWOORD

Allereerst gaat mijn dank uit naar alle deelnemers aan de Warrior trial. Daarnaast dank ik alle lokale hoofdonderzoekers en eenieder die voor inclusies een inspanning heeft geleverd. De data die door jullie inzet is gegenereerd, heeft in belangrijke mate bijgedragen aan de totstandkoming van dit proefschrift.

Een aantal mensen wil ik in het bijzonder bedanken.

Prof. dr. I.B. Schipper, beste Inger. Ik ben erg dankbaar voor het vertrouwen dat je in mij gesteld hebt toen je het Warrior project aan mij hebt toevertrouwd. De grote betrokkenheid bij mijn onderzoek en alle andere wetenschappelijke projecten van het TCW zijn een inspiratie voor mij geweest en ik hoop ook in de toekomst nog veel van je te mogen leren.

Prof. dr. M.W. van Tulder, beste Maurits. Het is voor mij een enorme verruiming van mijn blikveld geweest om als medisch promovendus door een promotor van buiten het ziekenhuis te zijn begeleid. Vanaf onze eerste ontmoeting heb ik jouw vertrouwen en ondersteuning gevoeld die zo cruciaal is bij een project als dit.

Dr. M.F. Termaat, beste Frank. Wat was het heerlijk om zo laagdrempelig bij je binnen te kunnen lopen tijdens mijn tijd in het LUMC waarbij jouw nuchtere houding en steun hielpen mij om mijn eigen keuzes te maken. Als grondlegger van het project ben ik daarnaast jou in het bijzonder dankbaar dat je deze promotieplek mogelijk hebt gemaakt en ik hoop van harte dat je trots bent op het eindresultaat.

Dr. S.M. Rubinstein, beste Sidney. Ik heb aan niemand anders binnen het team zoveel geleerd op methodologisch vlak waarbij het aangenaam was om met jou samen te werken aan onderdelen van de wetenschap die op dat moment nog onbekend voor mij waren. Jouw laatste check van mijn scientific English was daarnaast een welkome bijdrage.

Dr. P. Krijnen, beste Pieta. Wat was het fijn dat ik altijd met jou kon sparren als ik op organisatorisch vlak vast liep over hoe dit weer vlot te trekken. Ik ben heel bij dat jij op deze dag als lid van de promotiecommissie aanwezig bent.

Ingeborg Henkes, beste Ingeborg, als researchverpleegkundige heb jij als geen ander meters gemaakt (letterlijk) met alle vragenlijsten en het verwerken van alle data. Dank voor alle uren die hierin zijn gaan zitten.

Daarnaast wil ik graag dr. L. van Bodegom-Vos bedanken voor haar lessen rondom (de) implementatie en dr. J.M. van Dongen, voor het delen van jouw kennis aangaande kosteneffectiviteit.

Aan alle "Actieve Menschen" en in het bijzonder aan mijn kamergenoot Suzan, dank voor de verdieping in dat ándere deel wat een promotietraject zo de moeite waard maakt.

Marc, oudste maatje, klankbord, paranimf. Wat voel ik me gesteund dat jij hier vandaag naast me staat. Er is denk ik niemand die me zo de waarheid durft te zeggen als jij. Ik hoop dat je deze rol nog lang voor me kan en wil vervullen.

Lot, zussie, paranimf, en prachtige moeder van mijn neefje en nichtje. Wat leuk om dit moment met je samen te kunnen beleven. Dank voor alle momenten dat je er voor me bent geweest. Ook veel dank aan Lennart, waardoor dit proefschrift er zo fraai uitziet als dat het doet!

Pap en Miek, mijn trouwste supporters. Ooit leverde jij, pa, als eerste uit het gezin een academische prestatie. Nu mag ik hetzelfde doen en ik weet hoe trots dit je maakt. Miek, als "stieffie" al zoveel jaren in mijn leven. Je geeft dit kleur en bent altijd goudeerlijk naar me. Weet hoeveel ik van je hou en hoe belangrijk je voor me bent.

Mam, wat had ik je er toch graag bij gehad vandaag! Ik zette pas mijn eerste stapjes op het medische pad toen ik je verloor, maar toch weet ik dat jij bij de belangrijke momenten in mijn leven altijd over mijn schouder meekijkt en geniet van wat je ziet. Ik mis je, nog altijd.

Michelle, lieve Mies. Wat ben ik blij dat wij elkaar zijn tegengekomen! Inmiddels mag ik je mijn verloofde noemen. Naast dit proefschrift een van mijn grotere prestaties. Dank je wel voor je support, voor het bijschaven en dat je mij een (nóg) beter persoon maakt. Ik bewonder je werklust, je doorzettingsvermogen en je intrinsieke goedheid voor anderen. Ik zie ernaar uit nog vele jaren en vele mooie momenten samen te kunnen delen.