The added value of routine radiographs in wrist and ankle fractures

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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.

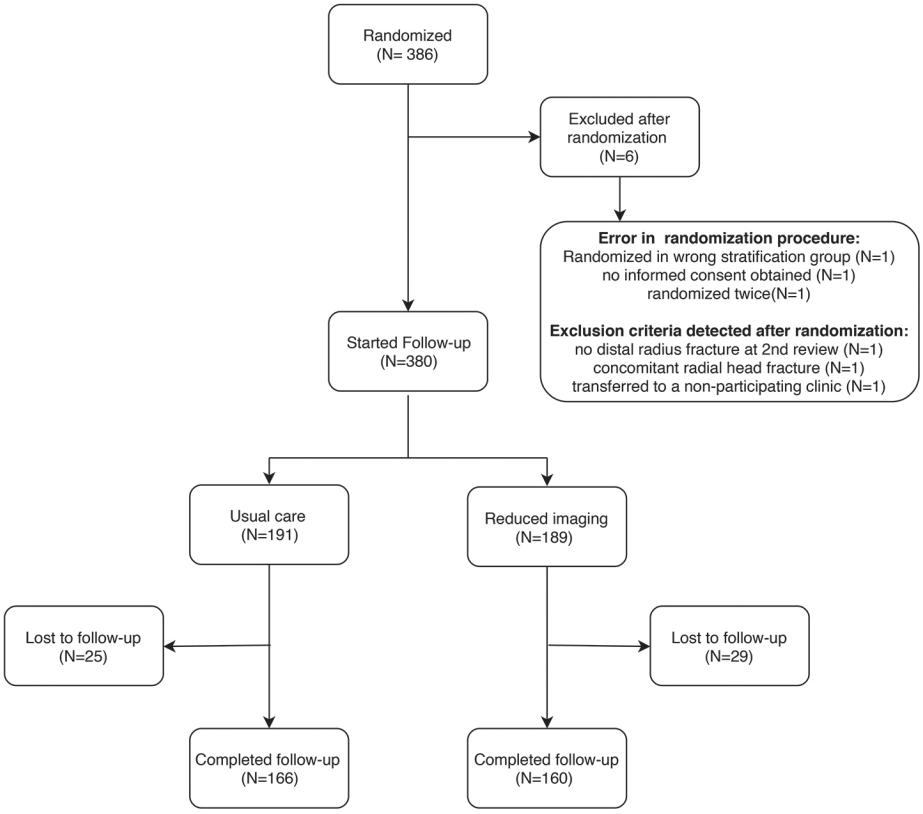


Figure 1. Flowchart of patients.

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

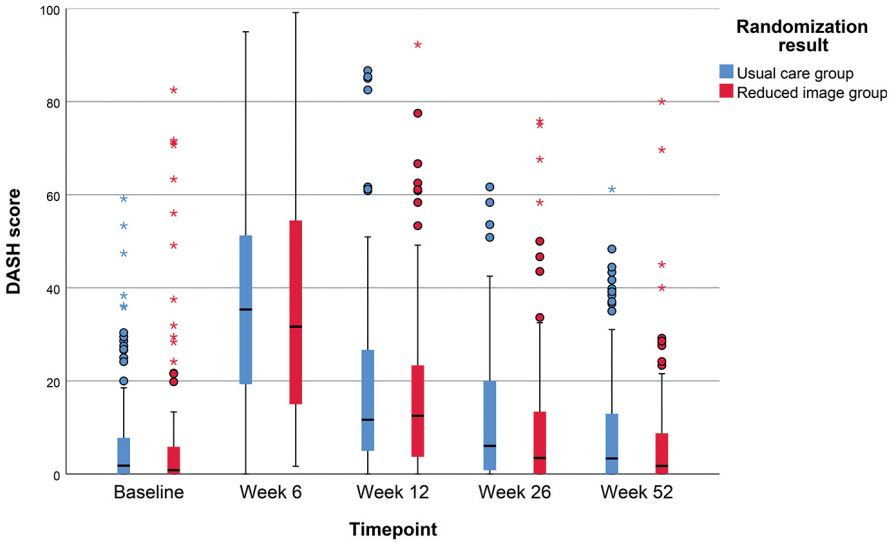


Figure 2: Box plot of DASH scores over time. Horizontal line in box = median, top and bottom of box = interquartile range, whiskers = 1.5 times the interquartile range, circles = outliers, and asterisks = extreme outliers

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).

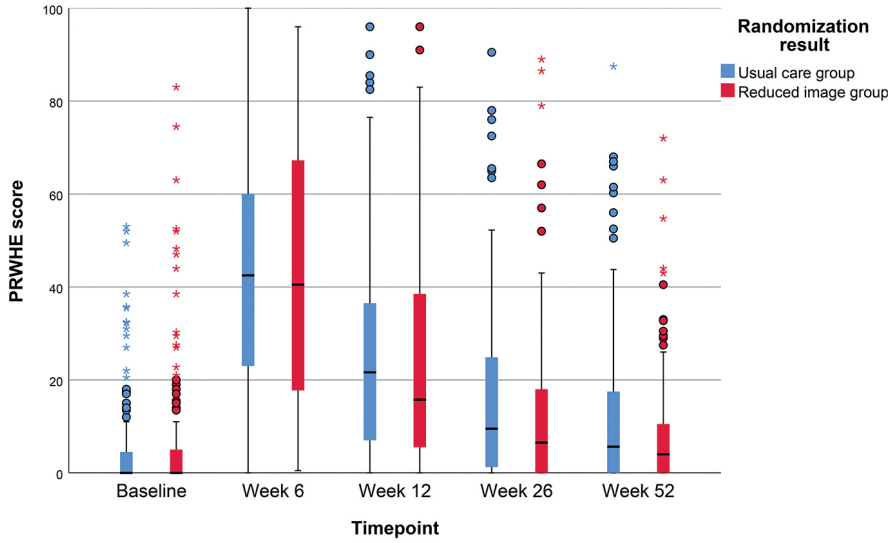


Figure 3: Box plot of PRWHE scores over time. Horizontal line in box = median, top and bottom of box = interquartile range, whiskers = 1.5 times the interquartile range, circles = outliers, and asterisks = extreme outliers

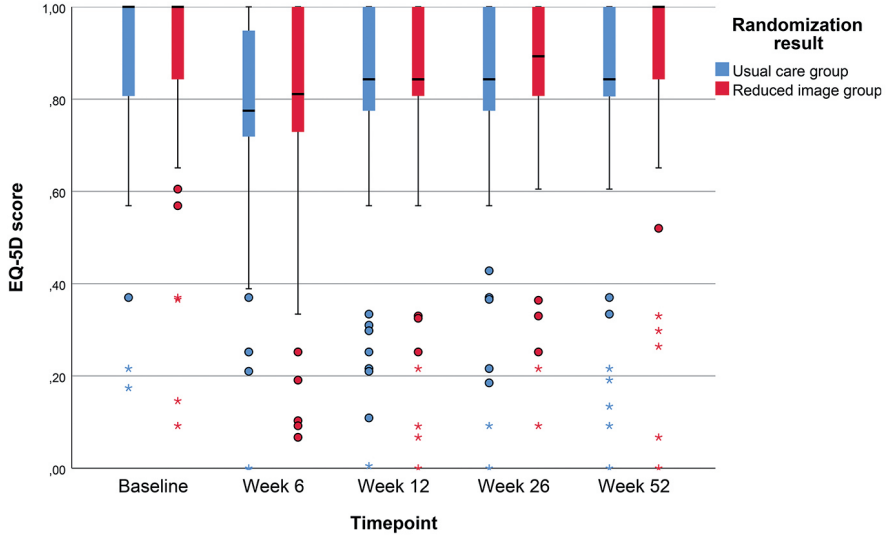
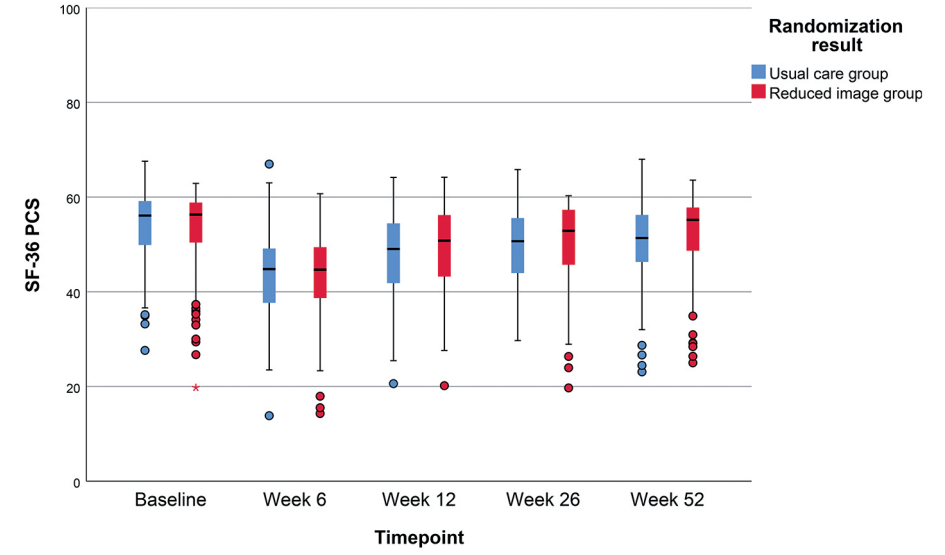


Figure 4: Box plot of EQ-5D-3L scores over time. Horizontal line in box = median, top and bottom of box = interquartile range, whiskers = 1.5 times the interquartile range, circles = outliers, and asterisks = extreme outliers



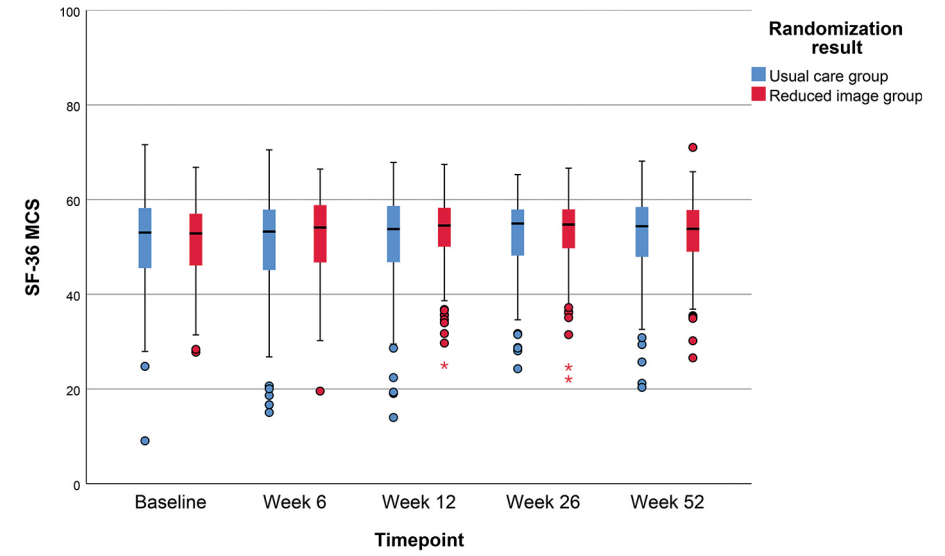


Figure 5: Box plots of PCS and MCS scores of the SF-36 questionnaire over time. Horizontal line in box = median, top and bottom of box = interquartile range, whiskers = 1.5 times the interquartile range, circles = outliers, and asterisks = extreme outliers

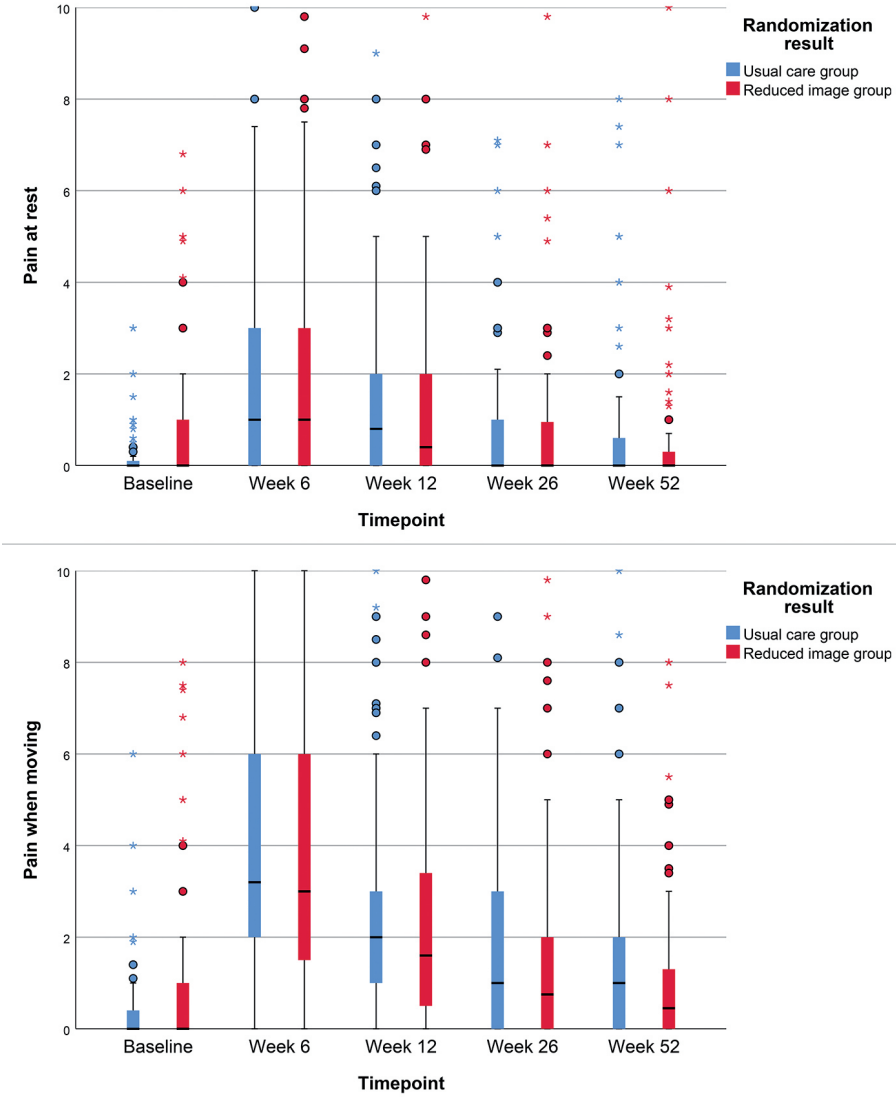


Figure 6: Box plots of pain scores over time. Horizontal line in box = median, top and bottom of box = interquartile range, whiskers = 1.5 times the interquartile range, circles = outliers, and asterisks = extreme outliers

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%)**

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)