The added value of routine radiographs in wrist and ankle fractures

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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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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).

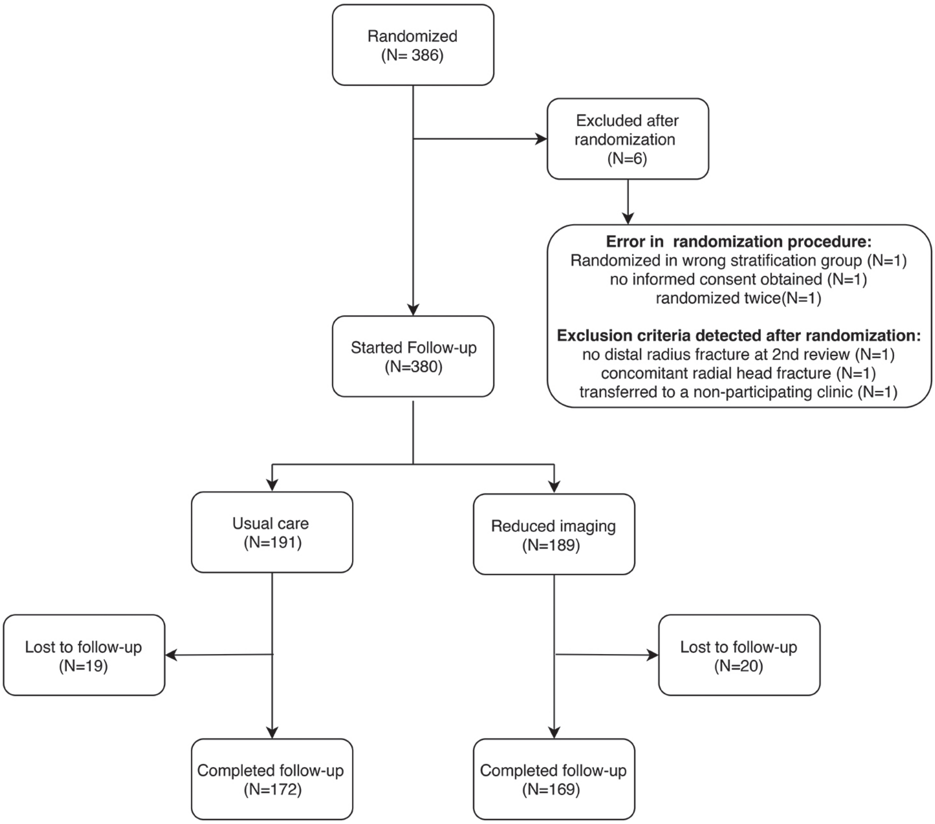

Figure 1. Flowchart of patients.

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.

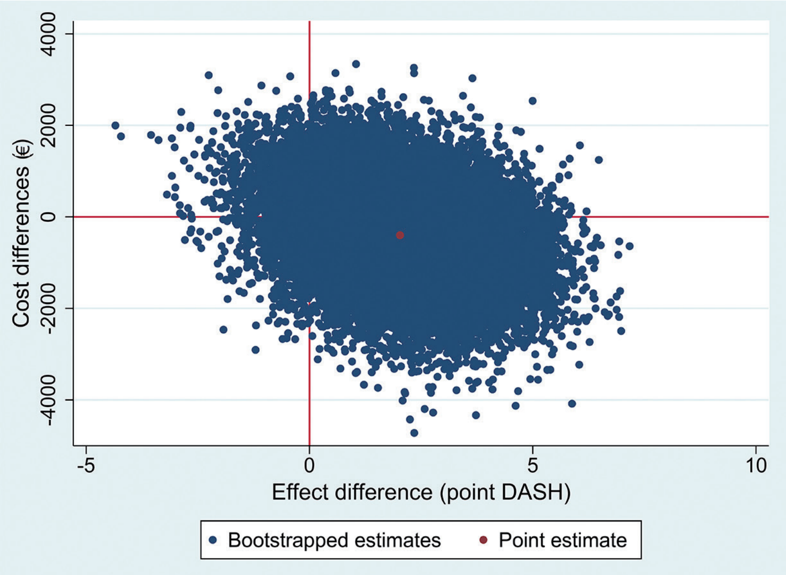

Figure 2. Cost-effectiveness plane for DASH, representing the results from the 5000 bootstrapped replications, and the point estimate. Higher on the Y-axis corresponds to costlier than control, more right on the X axis corresponds to more effective than control.

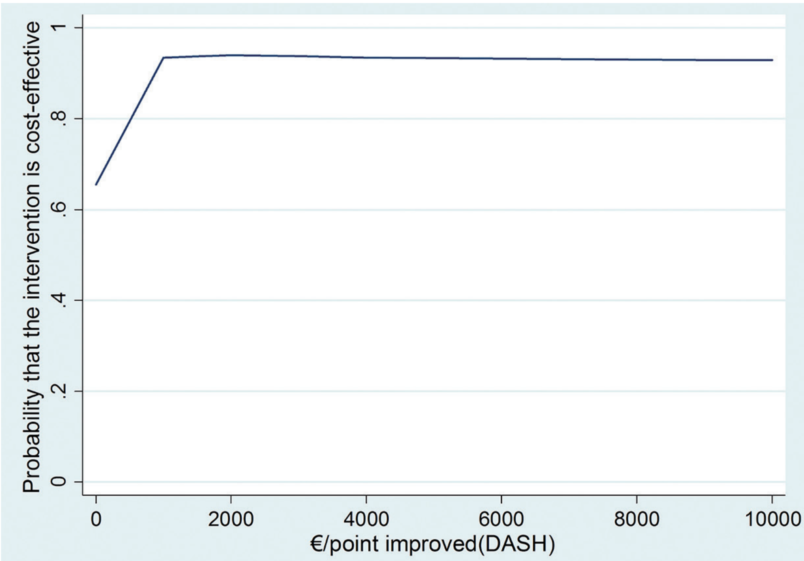

Figure 3. Cost-effectiveness acceptability curve for DASH, showing the probability of the intervention being cost-effective at a certain willingness to pay value per point DASH.

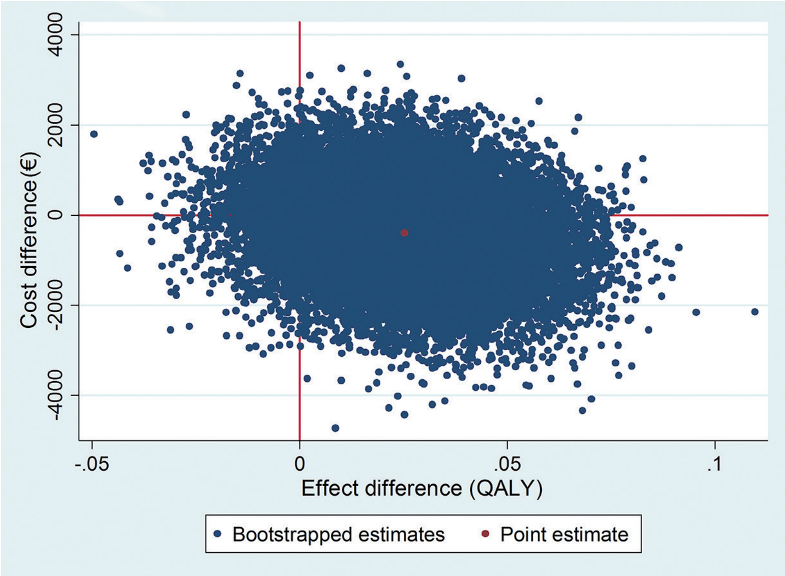

Figure 4. Cost-effectiveness plane for QALYs, representing the results from the 5000 bootstrapped replications, and the point estimate. Higher on the Y-axis corresponds to costlier than control, more right on the X axis corresponds to more effective than control.

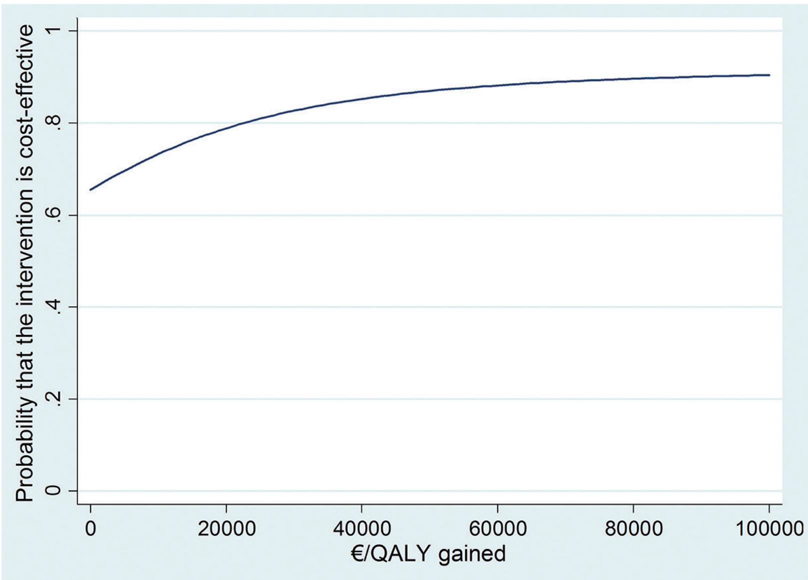

Figure 5. Cost-effectiveness acceptability curve for QALYs, showing the probability of the intervention being cost-effective at a certain willingness to pay value per QALY.

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)

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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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