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TRAUMA

Surgical treatment is not cost-effective compared to nonoperative treatment for displaced distal radius fractures in patients 65 years and over

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Aims
The purpose was to compare operative treatment with a volar plate and nonoperative treatment of displaced distal radius fractures in patients aged 65 years and over in a cost-effectiveness analysis.

Methods
A cost-utility analysis was performed alongside a randomized controlled trial. A total of 50 patients were randomized to each group. We prospectively collected data on resource use during the first year post-fracture, and estimated costs of initial treatment, further operations, physiotherapy, home nursing, and production loss. Health-related quality of life was based on the Euro-QoL five-dimension, five-level (EQ-5D-5L) utility index, and quality-adjusted life-years (QALYs) were calculated.

Results
The mean QALYs were 0.05 higher in the operative group during the first 12 months (p = 0.260). The healthcare provider costs were €1,533 higher per patient in the operative group: €3,589 in the operative group and 2,056 in the nonoperative group. With a suggested willingness to pay of €27,500 per QALY there was a 45% chance for operative treatment to be cost-effective. For both groups, the main costs were related to the primary treatment. The primary surgery was the main driver of the difference between the groups. The costs related to loss of production were high in both groups, despite high rates of retirement. Retirement rate was unevenly distributed between the groups and was not included in the analysis.

Conclusion
Surgical treatment was not cost-effective in patients aged 65 years and older compared to nonoperative treatment of displaced distal radius fractures in a healthcare perspective. Costs related to loss of production might change this in the future if the retirement age increases.

Level of evidence: II

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Introduction
Fractures of the distal radius among the elderly are one of the most prevalent fractures,[1] and a burden to the individual patient.[2] Even though most patients recover to a state at, or close to, pre-injury function, some suffer loss of function, e.g. persistent pain, loss of wrist motion, and reduced grip strength.[3] The burden to society is mainly in acute costs of treating the fracture and aiding the recovery, but for patients with marked sequelae the need for healthcare resources may continue. Non-displaced fractures are usually treated nonoperatively, whereas surgery may improve the functional results in displaced fractures, at a potentially higher cost.[4] Several different operative methods are commonly used.[5,6] They vary in invasiveness, implant costs, hospitalization and need for follow-up.

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Studies in elderly patients comparing operative and nonoperative treatment has not provided consistent results.[7,8] A randomized controlled trial (RCT) comparing cast immobilization and volar locking plates for displaced distal radius fractures was performed at Oslo University Hospital. The main conclusion was that nonoperative treatment was noninferior to operation, and that most elderly patients can be treated nonoperatively.[3] Despite this, operative treatment is increasing in number and invasiveness, also in elderly patients.[9] The total healthcare provider costs are high due to the incidence of these fractures, and the choice of treatment influence the costs.[10]

Increasing costs related to operations for distal radius fractures, in combination with the uncertainty of clinical benefit after operation, makes health economic evaluations important.

We conducted a cost utility analysis (CUA) alongside the RCT. The aim of the study was to present a cost-effectiveness analysis of operative versus nonoperative treatment based on the findings in the RCT. The costs are presented in the healthcare perspective, which includes resource use and costs that are of interest for the healthcare provider (both in hospital and after discharge) during treatment.

Methods

Design. Independent patients aged 65 years and older with a displaced low-energy fracture of the distal radius were assessed. The patients were seen in the emergency department and underwent initial closed reduction and casting. Patients with an unsatisfactory primary closed reduction or secondary displacement after specific radiological criteria were eligible and randomized to operative or continued nonoperative treatment.

The patients in the operative group were treated with open reduction and a volar locking plate (VLP) fixation (DVR anatomical plate, Zimmer Biomet, USA), while the patients in the nonoperative group continued cast immobilization for a total immobilization time of five to six weeks.[3]

The study was approved by the Regional Ethical Committee for North Norway (2014/672) and the local Data Protection Officer (2014 3830) and registered in ClinicalTrials.gov (NCT02336035) 9 January 2015. The study was performed in accordance with the Helsinki Declaration.[11] All patients received oral and written information. Participation was voluntary and based on written consent.

Treatment effects and health utilities. To measure health utilities the EuroQoL five-dimension five-level (EQ-5D-5L) utility index was used.[12] The EQ-5D-5L is a generic and preference-based measure of health-related quality of life. It is based on five dimensions: mobility, self-care, activities of daily life, pain, and anxiety and/or depression. For each dimension, the patient scores five possible levels of function (no problem to severe problem). This results in a five-digit number that describes the patient's health state. The participants completed the EQ-5D-5L at inclusion (as a recall pre-injury score) and after three-, six- and 12 -month follow-up. Health gains were expressed as quality-adjusted life years (QALYs), which were derived from the EQ-5D-5L utility index scores, using the Danish crosswalk value set.[13,14] QALYs were calculated with the area under the curve (AUC) method combining time and the utility indices. Other outcome measures from the clinical trial included the Quick Disabilities of the Arm, Shoulder and Hand questionnaire (Quick-DASH),[15,16] Patient Rated Hand and Wrist Evaluation score (PRWHE),[17,18] and a single question on satisfaction with wrist function.

Resource use and costs. Costs used for initial and operative treatment, including hospital admissions, were measured for each study group. Resource use after the initial treatment were collected prospectively at follow-up after three, six, and 12 months. The patients reported admissions to hospital, number of visits to physiotherapist, need of home nursing, or stay at a nursing home. Information about duration of operations, stay at the postoperative ward, initial hospital stay, sick leave, and medication use was collected from the electronic medical records. Production loss was calculated based on days of sick leave and official wage statistics.[19]

Prices for resource use were collected and costs for each group were calculated with cost year 2020 (Table I). Costs were calculated in Norwegian kroner (NOK) and converted into Euro (€) using the exchange rate from September 2020 (10 NOK = €1 €).

Data analysis/cost utility analysis. In the cost utility analysis, the goal was to determine the costs per QALY. The intention-to-treat principle was used to retain the advantage of randomization. Independent-samples *t*-tests were performed for the individual costs and QALYs. Incremental cost-effectiveness ratio (ICER) was calculated by dividing the difference in costs in the two groups by the difference in QALYs. A positive ICER represents the additional cost per gained QALY and indicates the relationship between costs and gain in health-related quality of life. This is considered in light of the willingness to pay (WTP) set by Ministry of Health and Care Service.[25] WTP for a year in perfect health (for QALY gained) in Norway is based on the disease severity.[26] For patients with less severe conditions, the indicative limit for WTP is approximately NOK 275,000,[25] or € 27,500. Lower ICERs correspond to better value (i.e. lower cost per unit of additional effectiveness). However, the WTP varies between countries and over time: a previous Norwegian publication on distal radius fractures used a threshold of € 55,800.[27]

Statistical analysis. Missing data from EQ-5D-5L were assessed and considered to be missing at random, therefore

Table I. Cost categories, units, and valuation in Norwegian kroner and €.

Cost categories	Unit	Unit price, NOK	Unit price, €	Reference (source)
Outpatient clinic primary contact incl. reduction and cast	Per visit	3,770	377	CCP + DRG[20]
Outpatient clinic control	Per visit	1,679	168	CCP + DRG[20]
Hospitalization due to fracture	Per event	23,133	2,313	CCP + DRG[20]
Physiotherapist	per visit	590	59	CCP and tariff[21]
Home nursing	per hour	463	46	Bærum municipality[22]
Removal of stitches, GP office	Per visit	136	14	CCP and GP-tariff[23]
Surgical equipment and medication during surgery				
Volar locking plate	Per operation	3,850	385	OD, OUH (cost of plate and screws, disposable material)
Removal of plate	Per operation	412	41	OD, OUH (disposable material)
CTR	Per operation	412	41	OD, OUH (disposable material)
Corrective osteotomy	Per operation	3,850	385	OD, OUH (cost of plate and screws, disposable material)
Cephazolin IV under op	Per dose (2 g)	56	6	NMA[24]
General anaesthesia costs	Per operation	400	40	Emergency division, Dep. for anaesthesiology, OUH
Brachial plexus anaesthesia cost	Per operation	250	25	Emergency division, Dep. for anaesthesiology, OUH
Lidocaine /epinephrine 1 mg/ml	Per dose (20 ml)	36	4	NMA[24]
Costs for sterilization and assets amortization (volar plate and corrective osteotomy)	Per surgery	300	30	Assumed 300 NOK per surgery (Image intensifier during surgery, surgical equipment amortization, sterilization)
Personnel costs				
Orthopaedic surgeon	Per hour	910	91	SSB[19]
Anaesthesiologist	Per hour	910	91	SSB[19]
Nurse – surgical and anaesthesia	Per hour	1,575	158	SSB[19]
Postoperative care before discharge	Per hour	525	53	SSB[19]
Total costs per operation (sum of costs above)				
Primary volar locking plate	Per operation	10,257	1,026	OD, OUH (personnel, surgical equipment, antibiotics)
Removal of plate	Per operation	5,992	599	OD, OUH (personnel, surgical equipment, antibiotics)
CTR	Per operation	3,977	398	OD, OUH (personnel, surgical equipment, antibiotics)
Corrective osteotomy	Per operation	12,419	1,242	OD, OUH (personnel, surgical equipment, antibiotics)
Medication after discharge				
Oxycodone slow release	10 mg ×3	10	1	NMA[24]
Oxycodone fast release	5 mg ×6	18	2	NMA[24]
Paracetamol	1 g ×100	64	6	NMA[24]
Paracetamol	500 mg ×50	41	4	NMA[24]
Paracetamol, codeine	500 mg/30 mg ×20	85	9	NMA[24]
Tramadolhydrochlorid	50 mg ×20	67	7	NMA[24]
Tramadolhydrochlorid	50 mg ×100	113	11	NMA[24]
Tramadolhydrochlorid	75 mg ×20	84	8	NMA[24]
Ibuprofen	600 mg ×30	56	6	NMA[24]
Diclofenac	50 mg ×20	59	6	NMA[24]
Radiology				
Radiographs	Per scan	1,200	120	OUH, Radiology department
CT scans	Per scan	2,500	250	OUH, Radiology department

The Unit price for somatic specialist health care was set to 45,808 NOK in 2019.[20] 40% were added to wages for societal costs.
CCP, cost per patient; CTR, carpal tunnel release; DRG, diagnosis-related group; NMA, The Norwegian Medicines Agency; NOK, Norwegian kroner; OD, orthopaedic division; OUS, xx University Hospital; SSB, Statistics Norway.

utility scores were imputed with a multiple imputation method based on age, affected side, arm dominance, and scores from Quick-DASH, PRWHE, and satisfaction with wrist function throughout follow-up. The statistical

Table II. Baseline characteristics for the analyzed patients.

Characteristic	Nonoperative group	Operative group
Age at baseline, yrs (n)		
65 to 75	20	16
75+	30	34
Women, n (%)	42/50 (84)	47/50 (94)
Right hand affected, n (%)	19/50 (38)	23/50 (46)
Working*, n	2	5

*All patients working were on sick leave for a period ranging from two to nine weeks.

analyses were performed using SPSS 26 (IBM Corp, USA), Excel 16 for Mac (Microsoft Corporation, USA and Tree Age Pro Healthcare ((TreeAge Software, USA). To illustrate the uncertainty of the ICER, the costs and effect pairs were bootstrapped with 1,000 replications and plotted on a cost-effectiveness plane (CE-plane).[28]

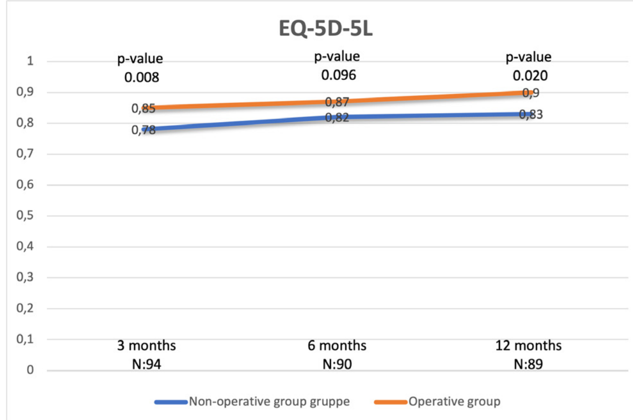

Fig. 1

Mean EuroQoL five-dimension, five-level index score at follow-up for the two groups, p-values from t-tests.

Results

Overall, 100 patients were included from January 2015 to September 2017, 50 in each group (Table II). A total of 14 patients were included due to unsuccessful primary reduction, and 86 patients after secondary displacement. EQ-5D-5L mean utility score was higher in the operative group at all follow-ups (Figure 1). There was a statistically significant difference in mean QALYs in favour of the operative group of 0.05 (95% confidence interval (CI) 0.01 to 0.09) during the first year.

The first EQ-5D-5L value was meant to represent a pre-injury value, however six patients reported their post-injury scores for Quick-DASH, PRWHE and EQ-5D-5L instead; therefore these scores were treated as missing. Two patients did not attend any scheduled follow-ups. Furthermore, there were one or two values of EQ-5D-5L missing in 13 more patients. Hence, QALYs were imputated in a total of 21 patients. Information on resource use was lacking in the e ight patients who withdrew from further follow-up during the first year. Hospital admissions during the first year for reasons clearly not related to the distal radius fracture were not included. These included two patients diagnosed with cancer in need of chemotherapy, one patient who needed follow-up due to cognitive impairment, two patients who suffered a cerebral insult several months after the fracture, and one patient who had a secondary trauma after four months, resulting in a periprosthetic femoral fracture. In addition, one patient was admitted to another hospital because of an infection with Herpes Zoster, and one underwent elective total hip arthroplasty at another hospital.

Cost utility analysis. Mean costs per patient were €1,533 higher in the operative group (Table III). The main reason was the costs related to the primary operation. Further, the operative group had a higher rate of hospitalization, more external physiotherapy, and more outpatient visits.

Costs related to loss of productivity were relatively low due to the high rate of retirement, but still higher than the total costs for primary surgery in the operative group (total cost production loss: €68,855). Loss of production was not included in the CUA due to a low number of patients working and an uneven distribution between the groups (Table II).

The ICER was €30,660. The uncertainty of the ICER is presented in Figure 2. The cost-effectiveness acceptability curve shows the likelihood of each treatment option to be cost-effective at a given WTP (Figure 3). Nonoperative treatment had a likelihood of 55% to be cost-effective for a WTP of €27,500. The Tornado diagram (Figure 4) shows the different cost categories and their impact on ICER.

Discussion

As expected, the costs were higher in the operative group, mainly due to the cost of the initial surgery. Later, the costs were similar between the groups. There was, however, a tendency towards higher costs for radiographs and aftercare in the operative group. There were two corrective osteotomies in the nonoperative group, which only led to a modest increase in cost per patient. Even though the QALYs were higher in the operative group, operative treatment was not cost-effective due to an ICER above (€30,660) the set willingness to pay of €27,500 (Figure 2 and Table III). However, the ICER was close to the WTP threshold.

The randomized trial by Hassellund et al[3] concluded that nonoperative treatment was non inferior to operation with a volar plate. This conclusion was based on the clinically non-relevant differences observed after 12 months, especially for the prespecified main outcome measure, Quick-DASH, with a five-point difference in median between the groups ($p = 0.206$, Mann Whitney U test). Further, the difference in PRWHE favoured the operative group, but the difference was not statistically significant

Table III. Resource use and costs (€).

Variable	Nonoperative group			Operative group		
	Resource use	Total costs	Average cost per patient	Resource use	Total costs	Average cost per patient
Initial hospital costs						
Outpatient clinic, index emergency contact	45	16,965	377	47	17,719	377
Outpatient clinic control (before inclusion)	86	14,439	321	95	15,951	339
Hospitalization due to fracture, days	1	640	14	2	10,880	232
Total costs per operation						
Primary volar locking plate	0	0	0	46	46,952	999
Removal of plate	0	0	0	2	1,218	26
CTR	1	398	9	2	795	17
Corrective osteotomy	2	2,554	57	0	0	0
Medication use after discharge						
Sum of medication (listed in Table I)	54	384	9	208	986	21
Radiology						
Radiographs	197	23,640	525	229	27,480	585
CT scans	8	2,000	44	13	3,250	69
Additional follow-up costs						
Physiotherapist	262	15,458	344	368	21,712	462
Outpatient clinic	83	15,279	340	117	19,644	418
Home nursing	15	695	15	44	2,037	43
Sum		92,452	2,056		168,622	3,589

CTR, carpal tunnel release.

throughout. The difference between the groups in favour of operation was higher in the early follow-up for both scores. We did not find clinically relevant differences in range of motion, grip strength, and complications between the groups.[3] We have documented higher costs in the operative group with the primary operation as the most important factor (Table III). Following this line of thought, one could conclude that the CUA supports nonoperative treatment in accordance with the main conclusion from the original randomized trial paper.[3]

The reported minimal clinically important difference (MCID) for EQ-5D-5L varies from 0.03 to 0.54 with an average of 0.18.[29] This indicates that our difference of 0.05 to 0.07 is in the lower range of the estimated MCIDs. Most estimates of the MCID, however, are based on patients with chronic medical conditions. The clinical pathway with primary reduction of the fractures, and unacceptable primary reduction or secondary displacement, as inclusion criteria, led to the need for extra outpatient visits. This led to higher costs in the operative group compared to a pathway where the decision to operate had been taken immediately. If the patients were included based on initial radiographs, however, we would have included some patients that did not redisplace and may have been less likely to benefit from surgery. With less displacement, one could think that nonoperative treatment would be preferable and that this might increase, to the economic benefit of nonoperative treatment. However, the clinical trial indicated the elderly patients tolerated displacement well, and the benefit of surgery might be early motion rather than avoiding malunion.

Despite the high rate of retirement, costs related to loss of production were relatively high. Rate of retirement was not evenly distributed between the groups in this trial, and therefore not included in the cost analysis. It may be speculated that the faster recovery observed in the operative group would reduce the period of sick leave in a working elderly population, analogous to the findings of Mulders and Hammer in a younger age group,[27,30] and thus make operative treatment cost-effective. Numerous countries are increasing the age of retirement to make pension financing sustainable.[31] In light of this, we expect to see more elderly patients with distal radius fractures working in the future.

Costs related to hospitalization was higher in the operated patients, even though 80% of the operated patients were treated as outpatients. We observed a more frequent use of home nursing and physiotherapy in the operative group. An explanation for this may be more pain and reduced function early after surgery, but it may also be due to an expectation in patients and care providers that the more invasive primary treatment requires more use of other resources, rather than an actual difference in needs. We have not found other publications with data from

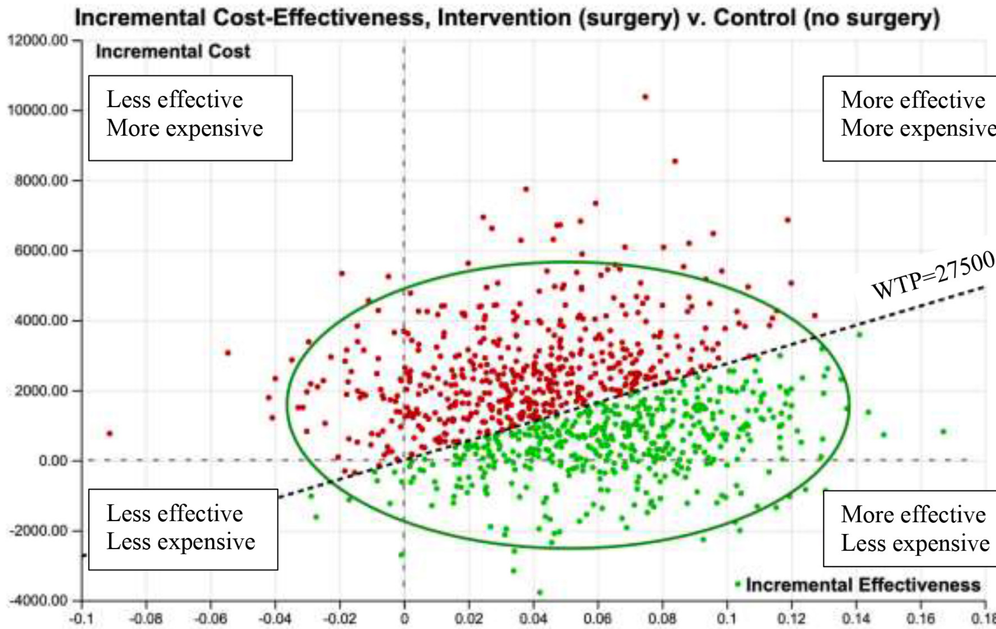

Fig. 2

The cost-effectiveness scatterplot showing the uncertainty of the incremental cost-effectiveness ratio (ICER) in the base-case analysis. Incremental cost is on the y-axis and incremental effectiveness on the x-axis. Each quadrant represents whether surgery is either more or less effective and more or less costly. The upper right quadrant shows more effective but also more costly treatment, and it is interpreted in relation to willingness to pay (WTP) (€27,500) line: above the line are ICERs that are not cost-effective, while below the line are the ones that are cost-effective. 45% of ICER iterations are above the WTP line, and are hence considered not cost-effective. The rest are inferior or under the WTP threshold.

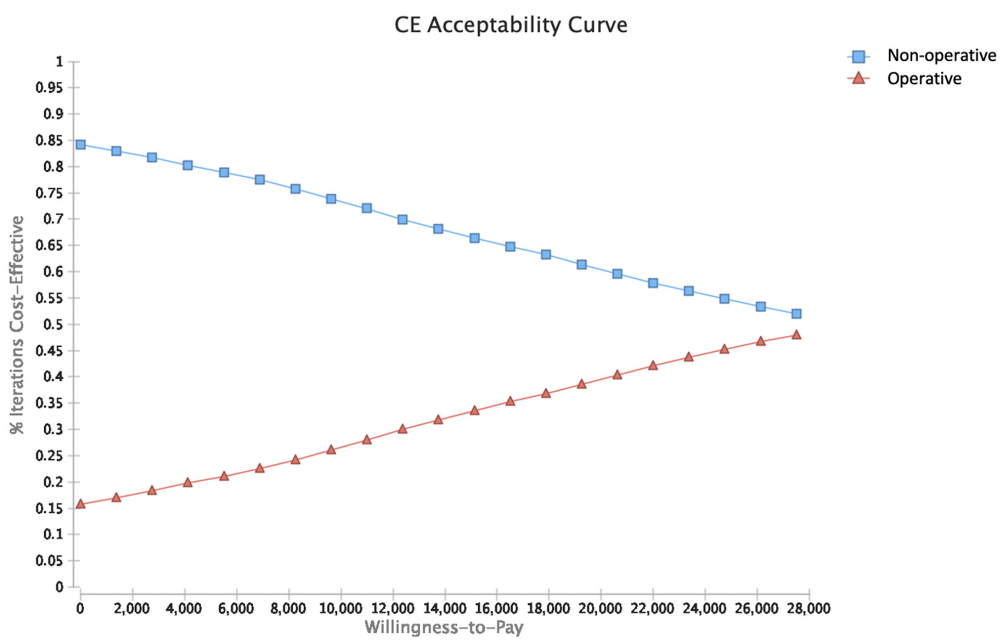

Fig. 3

Acceptability curve presenting the relative cost-effectiveness as a function willingness to pay (WTP). For each WTP value, the graph determines the percentage that favours each strategy. Operative group is presented in blue and non-surgery in red.

RCTs comparing cost and QALYs among elderly patients after operative and nonoperative treatment. Yoon et al[32] recently published a cost-effectiveness analysis based on a RCT with three operative treatment options, and also a parallel nonoperative treatment group (same inclusion criteria, but the patients self-selected to nonoperative treatment) in patients aged over 60 years. They did not find any relevant differences in QALYs throughout

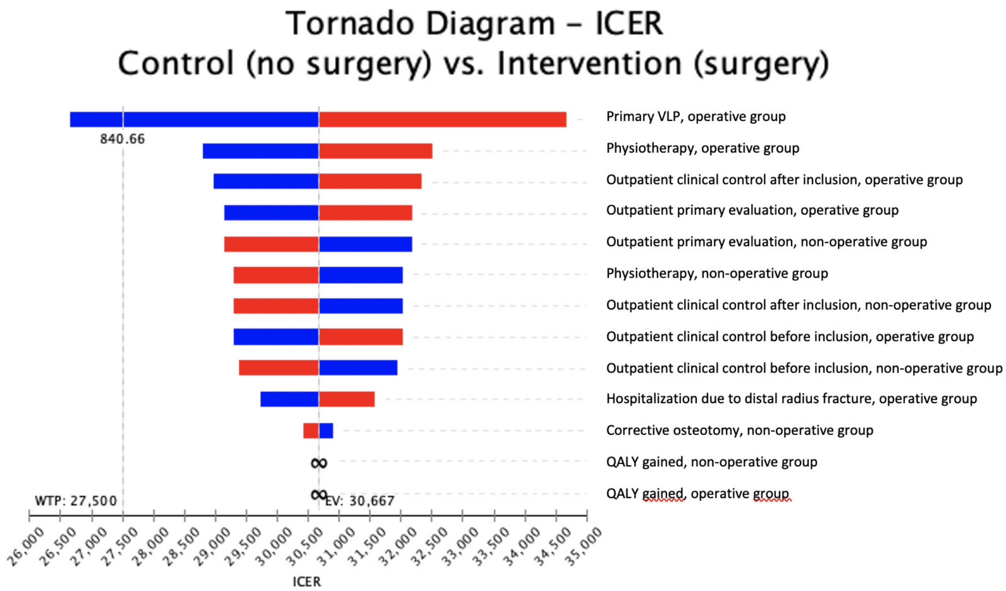

Fig. 4

A Tornado diagram is a set of one-way sensitivity analyses comparing the effect of the different variables on the incremental cost-effectiveness ratio (ICER). Tornado reports the range of ICERs generated for each parameter's uncertainty range (lower and upper range showing their impact on change in ICER). Costs of primary surgery and productivity loss were variables that had the largest impact on the ICER. EV, expected value (of ICER); QALY, quality-adjusted life year; WTP, willingness to pay. VLP, volar locking plate.

follow-up, and the costs were lowest in the nonoperative group. Mulders et al[30] published the cost related to nonoperative treatment and cost-effectiveness comparing nonoperative and operative treatment in an adult population with extra-articular fractures. They found that operative treatment was cost-effective, due to both better clinical results and lower costs due to reduced sick leave in the operative group. In our present work, in an elderly population, the healthcare costs were similar to the non-working patients in the by Mulders et al.[30]

Hammer et al[27] compared volar locking plate with external fixation, and Tubeuf et al[33] and Karantana et al[34] compared volar locking plate fixation with percutaneous pinning. These studies, performed in younger patients, found similar QALYs in the groups, and showed higher initial costs in the volar locking plate group. Hammer et al[27] found differences in production loss and therefore concluded that operation was cost-effective, while Tubeuf et al[33] and Karantana[34] concluded that operation was not cost-effective.

The present study has some inherent limitations. There are potential problems with generalizability, such as being from a single institution with specific routines, only one fracture pattern, i.e. dorsally displaced low-energy fractures, and a relatively low number of patients. The lack of blinding of both patients and health personnel might lead to a placebo effect of surgical treatment, and this might explain the differences in outcome scores. Patients were recruited either after unsuccessful primary reduction or after secondary displacement in cast. This may have led to a bias towards accepting conservative treatment, but this procedure was in line with the pre-trial clinical pathway in our department. The need of informal support from caregivers was not recorded, hence we do not know if the groups were differing in these needs. Even so, we believe that our results are valid. The present study demonstrates comparable study groups, a high compliance with study protocol, and a high rate of follow-up, with relatively few missing data.

It is likely that there are subgroups of patients who would benefit functionally from surgery, and patients with especially high functional demand might benefit more from a fast recovery. Our trial was not powered for subgroup analyses and this needs further research.

This CUA compared operative and nonoperative treatment of secondary displaced distal radius fractures and could not demonstrate that operative treatment was cost-effective. Our current findings are, however, close to the WTP threshold, and primary operative treatment might be cost-effective in other circumstances. However, the difference in QALYs is close to the MCID and must be interpreted in light of a modest difference between the patient groups with similar clinical results after one-year follow-up.

Take home message

- The difference in health-related quality of life between operative and nonoperative treatment groups for distal radius fractures was small and in favour of operation.
- The cost in the operative group was higher and outweighed the increase in quality of life.

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