Cost-Effectiveness of Cement Augmentation Versus No Augmentation for the Fixation of Unstable Trochanteric Fractures

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Background: A previous randomized controlled trial (RCT) demonstrated a trend toward a reduced risk of implant-related revision surgery following fixation with use of a Proximal Femoral Nail Antirotation (PFNA) with TRAUMACEM V+ Injectable Bone Cement augmentation versus no augmentation in patients with unstable trochanteric fractures. To determine whether this reduced risk may result in long-term cost savings, the present study assessed the cost-effectiveness of TRAUMACEM V+ cement augmentation versus no augmentation for the fixation of unstable trochanteric fractures from the German health-care payer's perspective.

Methods: The cost-effectiveness model comprised 2 stages: a decision tree simulating clinical events, costs, and utilities during the first year after the index procedure and a Markov model extrapolating clinical events, costs, and utilities over the patient's lifetime. Sources of model parameters included the previous RCT, current literature, and administrative claims data. Outcome measures were incremental costs (in 2020 Euros), incremental quality-adjusted life-years (QALYs), and incremental cost-effectiveness ratios (ICERs). Model uncertainty was assessed with deterministic and probabilistic sensitivity analyses.

Results: The base-case analysis showed that fixation with cement augmentation was the dominant strategy as it was associated with cost savings (€50.3/patient) and QALY gains (0.01 QALY/patient). Major influential parameters for the ICER were the utility of revision, rates of revision surgery within the first year after fixation surgery, and the costs of augmentation and revision surgery. Probabilistic sensitivity analyses demonstrated that estimates of cost savings were more robust than those of increased QALYs (66.4% versus 52.7% of the simulations). For a range of willingness-to-pay thresholds from €0 to €50,000, the probability of fixation with cement augmentation being cost-effective versus no augmentation remained above 50%.

Conclusions: Fixation with use of cement augmentation dominated fixation with no augmentation for unstable trochanteric fractures, resulting in cost savings and QALY gains. Given the input parameter uncertainties, future analyses are warranted when long-term costs and effectiveness data for cement augmentation are available.

Level of Evidence: Economic and Decision Analysis Level II. See Instructions for Authors for a complete description of levels of evidence.

Trochanteric hip fractures occur predominantly in older patients and are associated with high rates of mortality and morbidity, poor functional outcomes, and reduced quality of life[1,2]. Patients at risk for these fractures often present with advanced stages of osteoporosis and overall poor bone quality, which increase the risk of complications[3,4]. Intramedullary nails are widely used for the treatment of trochanteric fractures[5]. Mechanical complications following nailing

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procedures are not uncommon, with overall rates of as high as 20.5%[6]. Reported rates of catastrophic failures such as implant cut-out or cut-through requiring reoperation have ranged from 2.2% to 12%[7-10]. Besides osteoporotic bone, risk factors for mechanical failure include the quality of fracture reduction, implant position, and tip-apex distance[11-13].

Optimizing implant design is crucial to avoid these complications. The Proximal Femoral Nail Antirotation (PFNA) (DePuy Synthes)[14] and TFN-ADVANCED Proximal Femoral Nail System (TFNA) (DePuy Synthes)[15] were developed to improve the rotational and angular stability of these nails for fracture fixation. The helical blade (the head element of the PFNA and TFNA) compacts the surrounding cancellous bone during insertion, enhancing the biomechanical anchorage[15-17]. Cement augmentation has been associated with improved anchorage of the head element of the nail in the femoral head and greater cut-out resistance[18-21]. Several studies have shown that the increased implant stability with a PFNA with TRAUMACEM V+ Injectable Bone Cement (DePuy Synthes) may allow early mobilization[22] and promote functional recovery[22-25].

Kammerlander et al. previously conducted a large multicenter randomized controlled trial (RCT) to compare clinical and patient outcomes of PFNA use with and without TRAUMACEM V+ cement augmentation in patients with closed unstable trochanteric fractures[25]. The results showed that although both treatments led to comparable outcomes in terms of improving patient mobility, there was a trend toward a lower risk of reoperation related to the implant when cement augmentation was used (0 reoperations [0%] versus 6 reoperations [4.4%], including 3 each due to mechanical failure and symptomatic implant migration). A lower reoperation rate could lead to cost savings in the long term, although the costs and quality-of-life benefits of fixation with cement augmentation have not been quantified. Given the increasingly limited budgets of many health-care systems, robust economic evaluations would assist clinical decision-making and would provide valuable information to patients and payers. The purpose of the present study was to determine whether cement augmentation was cost-effective compared with no augmentation for the fixation of closed trochanteric fractures using a PFNA in the German health-care setting.

Materials and Methods

Overview and Model Structure

The base-case analysis assumed a cohort of 1,000 patients with demographic and clinical characteristics similar to those in the RCT by Kammerlander et al.[25]. The analysis included adults (age, ≥75 years; 83% female) with a closed unstable trochanteric fracture due to low-energy trauma, an indication for fixation with a PFNA. The cohort underwent 2 treatment scenarios differentiated by the index procedure, specified as the initial fracture fixation with or without cement augmentation.

The model consisted of 2 components: a short-term decision tree model and a long-term Markov state-transition model[26]. The decision tree model simulated clinical events, based on those experienced by the patients in the RCT[25], and their associated costs and utilities during the first year after the index procedure (Fig. 1-A). Three clinical events were simulated: (1) successful surgery (no revision procedures needed), (2) revision surgery related to the implant, and (3) death. The time-heterogeneous Markov model assumed that surviving patients transitioned to 2 initial health states, either "recovered with no revision" or "recovered with 1 revision" (Fig. 1-B). Patients then either remained in these states or transitioned to additional revision surgery or death. The revision surgery state captured all-cause ipsilateral revisions. The model allowed patients to undergo a maximum of 2 revisions, featured a cycle length of 1 year, and reflected a lifetime horizon. Tunnel states were implemented to consider the increased mortality rates at 1 year and 2 years after a successful index procedure if revision procedures had been performed. Half-cycle correction was included because patients could transition from one state to another at any time during the cycle duration.

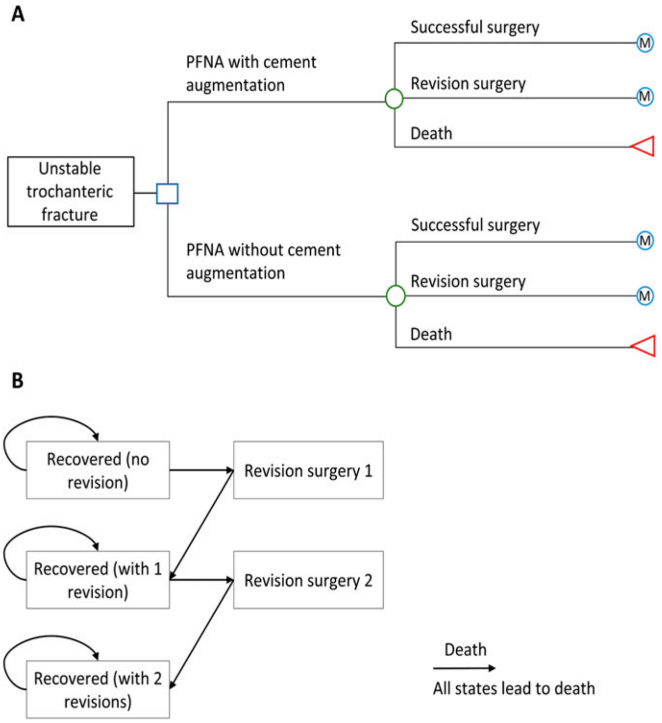

Fig. 1

Figs. 1-A and 1-B Model structure. The 2-stage model consisted of a short-term decision tree model (1 year after the index procedure) (**Fig. 1-A**) and a long-term Markov state-transition model (from the second year after the index surgery to lifetime) (**Fig. 1-B**).

No other events or complications (including reoperations for reasons unrelated to the implant) were considered in the model because they were assumed to be balanced between groups on the basis of the results of the RCT[25]. Cement-related complications, such as leakage, toxicity, and pulmonary embolism, were not simulated because they were assumed to be immaterial to the differences in costs or utilities[25] for the following reasons: (1) they are very rare following the fixation of trochanteric fractures[18,22-25,27] and are much rarer following that procedure than they are following other procedures, such as arthroplasty[28] and vertebroplasty[29,30]; (2) a leakage test was routinely done before the augmentation, thereby lowering the risk of leakage; and (3) we were not aware of any reports of disutility associated with cement-related complications in fracture care.

Model Parameters

Clinical Inputs

For the decision tree model, probabilities of events were estimated from the RCT data (Table I)[25]. For the Markov model, patients were assigned a background mortality rate based on the national life tables for Germany[31]. Given the lack of published data on the long-term effect of cement augmentation on revision and mortality outcomes, rates of revision surgery after the first year were assumed to be the same between treatment groups. Revision and mortality rates were estimated from survival analyses (Cox semiparametric model) of patient cohorts with hip fracture and nail implantation procedures between 2000 and 2020 from the U.S. Medicare Standard Analytical File (SAF) database, matched to the RCT population by age, sex, and Charlson Comorbidity Index[32]. The mortality rate was assumed to be elevated for the first 2 years after a successful index procedure or after a revision procedure in both treatment groups.

Costs

Costs (in Euros) were considered from the health-care payer's perspective in Germany and were inflated to the 2020 consumer price index with use of data obtained from the Federal Statistical Office of Germany[33]. The costs of revision surgery, outpatient visits, and rehabilitation following revision were included in the model. Cost data were obtained from German Diagnosis-Related Groups[34], published literature[35-37], and expert opinion (Table I). For the augmentation group, the material costs of augmentation and leakage-test costs were obtained from the German DePuy Synthes price list, and costs related to additional operating room (OR) time (an estimated 5-minute increase in average surgical time based on the RCT[25]) were calculated with use of an OR rate of €15/minute[38]. Costs related to the index procedure or other complications were not considered because these were assumed to be identical for both treatment groups. Costs were discounted at 3% per year[39].

Effectiveness

Effectiveness was measured in quality-adjusted life-years (QALYs) by aggregating utilities over time. Utility is a quality-of-life measure anchored at 0 (death) and 1 (perfect health). One year of perfect health equals 1 QALY, whereas 1 year of less-than-perfect health equals <1 QALY; the magnitude of the reduction depends on the severity of the health state. Utilities for the decision tree model were estimated with use of the RCT utility results[25], which were assessed with the EQ-5D (EuroQol-5 Dimensions-3 Levels) instrument and were calculated with use of the German time trade-off value set provided by the EuroQol group[40]. Utilities for the Markov model were obtained from published literature[27,41]. We assumed that disutility due to revision surgery only impacted patient utility in the cycle in which it occurred. QALYs were discounted at 3% per year[39].

Base-Case Analysis

Model outcomes were mean incremental costs per patient, incremental QALYs per patient, and the incremental cost-effectiveness ratio (ICER). The ICER was calculated as the incremental cost to gain an extra QALY (€/QALY) for PFNA use with augmentation compared with no augmentation.

Sensitivity Analyses

Sensitivity analyses were performed to systematically evaluate the impact of assumed or uncertain model parameters on the overall results (see Appendix). Model parameters included probabilities and utilities of the events (successful surgery, revision surgery, and death), cost data, and the discount rate. A series of 1-way deterministic sensitivity analyses were conducted to determine which parameters did or did not significantly influence the costs, QALYs, and ICER of the base-case scenario by varying model parameters independently in their 95% confidence intervals (CIs), when available, or using baseline values ± 15%. A probabilistic sensitivity analysis, consisting of a parametric Monte Carlo simulation with 10,000 iterations, was conducted to determine the overall confidence of the model results by varying any number of model parameters at once with use of their respective probability distributions. Results were presented as cost-effectiveness scatterplots illustrating the proportion of iterations that favored one strategy over the other in terms of costs or QALYs. Cost-effectiveness acceptability curves (CEACs) were constructed to show the probability that fixation with cement augmentation was cost-effective compared with no augmentation across a range of willingness-to-pay (WTP) thresholds from €0 to €50,000.

Scenario Analysis

Compared with previous published studies[42-44], the rates of implant-related revision surgery were lower in the RCT[25]; this could be because the RCT was conducted in tertiary trauma centers staffed by skilled and experienced orthopaedic surgeons. Therefore, the base-case analysis may represent a conservative cost-effectiveness estimate. In order to model potential outcomes from centers with diverse levels of surgeon skill and experience, a scenario analysis was conducted by assuming higher probabilities of revision surgery in the decision tree model on the basis of the recent meta-analysis by Rompen et al.[45]. The probabilities of revision surgery for fixation with augmentation and without augmentation were assumed to be 1.6% and 7.4% ($p = 0.009$), respectively.

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The study was supported by the AO Foundation via AO Trauma. The AO Foundation had no role in the design of this study, its execution, analyses, interpretation of the data, or the decision to submit the results.

Results

Base-Case Analysis

In the base-case analysis, fixation with augmentation reduced the mean total cost per patient by €50.3 compared with fixation without augmentation (€785.2 versus €835.4) (Table II).

TABLE I Model Parameters**

Variables	Value	Reference/Source
Population characteristics		
Cohort size	1,000	—
Mean age at first surgery *(yr)*	85	25
Male sex *(%)*	17.0%	25
Decision tree model (1st year after index surgery)		
Probabilities		
Without augmentation		
Revision surgery	4.4%	25
Successful surgery*	85.2%	25
Death†	10.4%	25
With augmentation		
Revision surgery	0%	25
Successful surgery*	89.6%	25
Death†	10.4%	25
Utilities		
Successful surgery* after fixation	0.73	25
Disutility (multiplier) of revision surgery	0.85	25
Markov model (2nd year after index surgery to lifetime)		
Probabilities of revision surgery		
1st revision surgery given a successful index surgery	Time-dependent	Survival analyses‡
1 year after successful index surgery	0.43%	
2 years after successful index surgery	0.30%	
≥3 years after successful index surgery	0.40%	
2nd revision surgery	2.4%	Survival analyses‡
Probability of death		
Mortality given a successful index procedure, year 2† (relative risk)	1.57	Survival analyses‡
Mortality given a successful index procedure, ≥3 years†	Background mortality	31
Mortality after revision, year 1 (relative risk)	2.13	Survival analyses‡
Mortality after revision, year 2 (relative risk)	1.57	Survival analyses‡
Background mortality	—	31
Utilities		
Successful surgery*, SE	0.735, 0.028	41
Disutility (multiplier) of revision surgery	0.85	25
Costs and use of health-care resources		
Total cement augmentation costs	€550.8	
Cement augmentation material costs	€475.8	List price
Increased OR time (5 minutes, €15/minute)	€75	25, 38
Leakage test costs	€12.0	List price
Revision surgery cost§	€10,033.0	34
No. of outpatient visits following revision	2.0	35, expert opinion
Costs per outpatient visit following revision	€65.1	37
No. of days of rehabilitation	21.0	35, expert opinion
Costs per day of rehabilitation#	€128.4	36

**See Appendix A (Technical Appendix) for the probability distributions of model parameters used in the sensitivity analyses. SE = standard error, OR = operating room. *Successful surgery refers to successful index surgery with no revision surgery needed. †Increased mortality was included for 2 years after successful index surgery. The mortality parameter from trial data (for year 1 after index surgery) was used in the decision tree. Relative risk calculated on the basis of survival analyses was used in the Markov model (for year 2 after index surgery). We assumed baseline background mortality in year 3 onward. ‡Survival analyses were performed with use of the U.S. Medicare Standard Analytical File database. §German Diagnosis-Related Groups (DRGs) reimbursement (€8,474.2) plus nursing cost (€1,558.8). The nursing cost was calculated as the nursing intensity weights (0.8169) multiplied by the nursing compensation factor (€163.09) and an average length of stay of 11.7 days for DRG I47A. #DRG reimbursement.

TABLE II Results of the Base-Case and Scenario Analyses**

	Costs *(€)*	QALYs	Incremental Costs* *(€)*	Incremental QALY*	ICER *(€/QALY)*
Base-case analysis					
Augmentation	785.2	3.558	−50.3	0.01	−8,821.3 (dominant)
No augmentation	835.4	3.552	—	—	—
Scenario analysis†					
Augmentation	1,008.1	3.556	−245.3	0.01	−32,670.5 (dominant)
No augmentation	1,253.4	3.548	—	—	—

**Results are shown as costs or QALYs per patient. QALY = quality-adjusted life-year, ICER = incremental cost-effectiveness ratio. *Incremental costs and incremental QALYs were calculated as costs and QALYs of augmentation minus costs and QALYs of no augmentation. †In the scenario analysis, higher rates of revision surgery (1.6% for augmentation and 7.4% for no augmentation) were assumed in the decision tree model. These rates were based on the meta-analysis by Rompen et al.[45].

Over a lifetime, fixation with augmentation yielded an incremental benefit of 0.01 QALY/patient. Fixation with augmentation was the dominant strategy, with lower costs and higher QALYs from the German health-care payer's perspective.

Sensitivity Analyses

Results of the 1-way deterministic sensitivity analyses are shown in tornado diagrams. The ICER was most sensitive to the variation in the utility of revision, rates of revision surgery in the decision

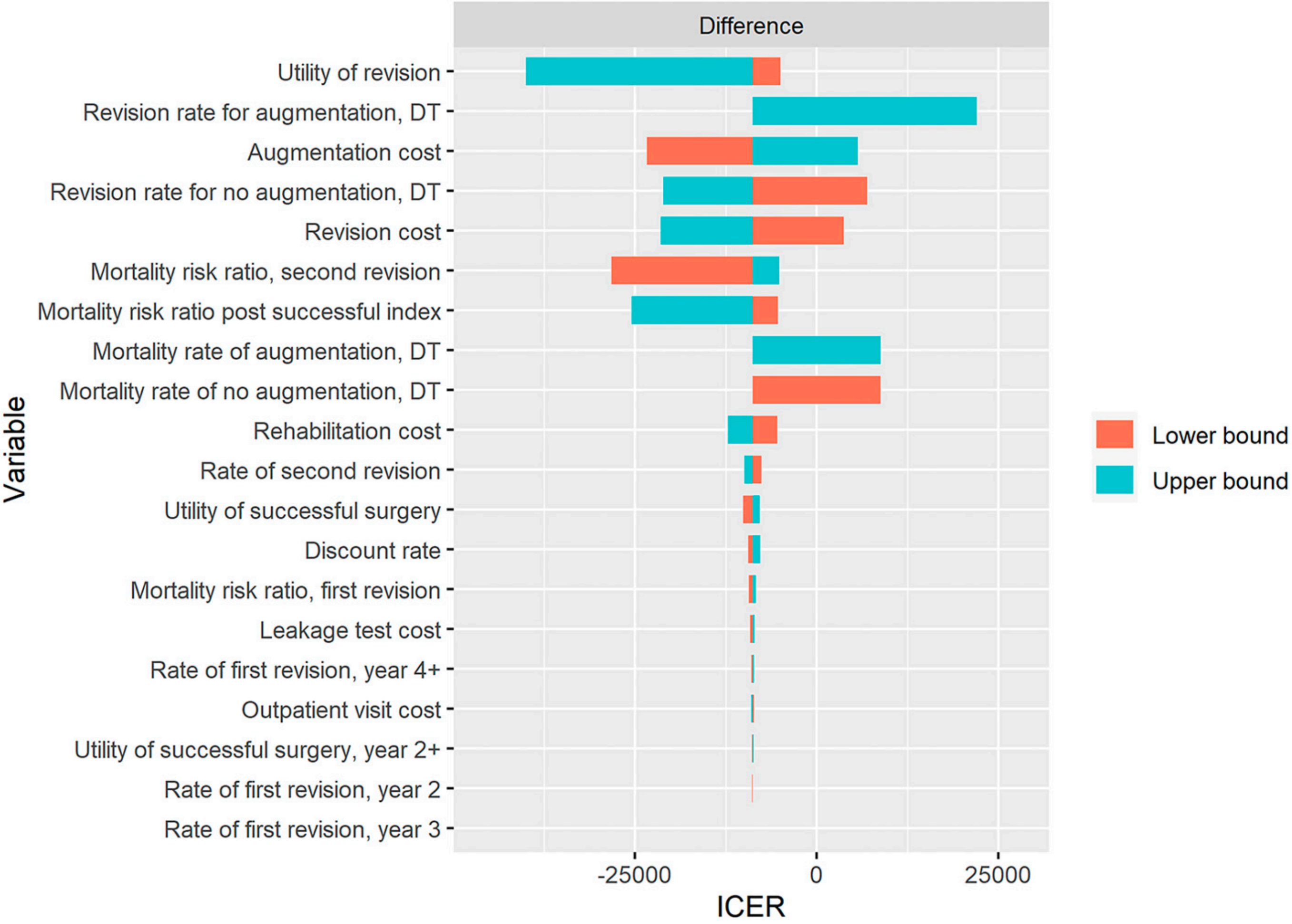

Fig. 2

Tornado diagram showing the influence of model parameters on the incremental cost-effectiveness ratio (ICER). DT = decision tree.

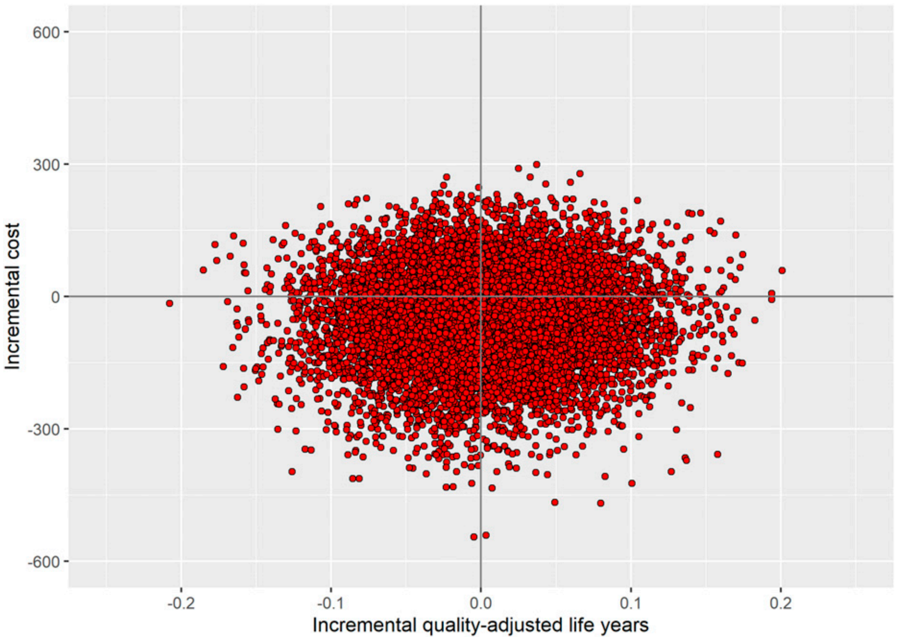

Fig. 3

Incremental cost-effectiveness scatterplot illustrating the distribution of incremental costs and incremental quality-adjusted life-years (QALYs) of individual iterations of the probabilistic sensitivity analysis comparing fixation with cement augmentation versus fixation without augmentation. Each point in the scatterplot represents 1 iteration (i.e., an incremental cost-effect pair). Each quadrant corresponds to increased or decreased costs and improved or reduced QALYs compared with fixation without augmentation. Points falling in the lower right quadrant, with negative incremental costs and positive QALY gains, indicate iterations in which augmentation is less costly and more effective (i.e., QALY gains), whereas points falling in the upper left quadrant, with positive incremental costs and reduced QALYs, indicate the opposite. The upper right quadrant indicates augmentation being more costly and more effective (i.e., QALY gains), whereas the lower left quadrant indicates augmentation being less costly and less effective (i.e., reduced QALYs). The scatterplot is slightly weighted in the 2 lower quadrants. Fixation with cement augmentation was associated with lower costs and increased QALYs in 66.3% and 59.4% of the 10,000 iterations, respectively.

tree model, the costs of augmentation and revision surgery, and the mortality risk ratio in the Markov model (Fig. 2). Revision rates in the decision tree model and the costs of augmentation and revision surgery were the major drivers of incremental between-group cost differences (see Appendix B, Figure S1). Incremental QALYs were predominantly influenced by mortality rates in the decision tree model (see Appendix C, Figure S2).

Probabilistic sensitivity analyses demonstrated that fixation with cement augmentation was associated with lower costs and increased QALYs in 66.4% and 52.7% of the 10,000 simulations, respectively (Fig. 3). The CEACs showed that fixation with cement augmentation was the dominant strategy regardless of the WTP threshold (Fig. 4). Given WTP thresholds of €25,000/QALY and €50,000/QALY, the probability that fixation with cement augmentation was cost-effective compared with no augmentation was 54.3% and 53.6%, respectively.

Scenario Analysis

Compared with the base-case analysis, the higher rates of revision surgery in the decision tree model in the scenario analysis, which might reflect more generalizable outcomes, generated more cost savings (−€245.3/patient) and similar QALY gains (0.01 QALY/patient) for fixation with cement augmentation (Table II).

Discussion

To our knowledge, the present study represents the first cost-effectiveness analysis of cement augmentation versus no augmentation during intramedullary nail fixation of closed unstable trochanteric fractures. Our base-case analysis showed that fixation with augmentation dominated fixation without augmentation as it was less costly and yielded better health outcomes as measured with QALYs. The savings associated with avoided revision surgery outweighed the initial costs associated with cement augmentation. As the difference in QALYs was small, results were driven predominantly by decreased costs, mostly as a result of avoided revision procedures. The small QALY gains were expected as augmentation did not meaningfully alter patients' long-term quality of life or life span. These results could provide policy-makers with useful information about the cost-effectiveness of cement augmentation from the health-care payer's perspective when deciding on hospital reimbursement schemes.

More cost-savings and QALY gains occurred within the first year after fixation surgery than over the remainder of the patient's lifetime because the model assumed differences in the rate of revision surgery only within the first year. This

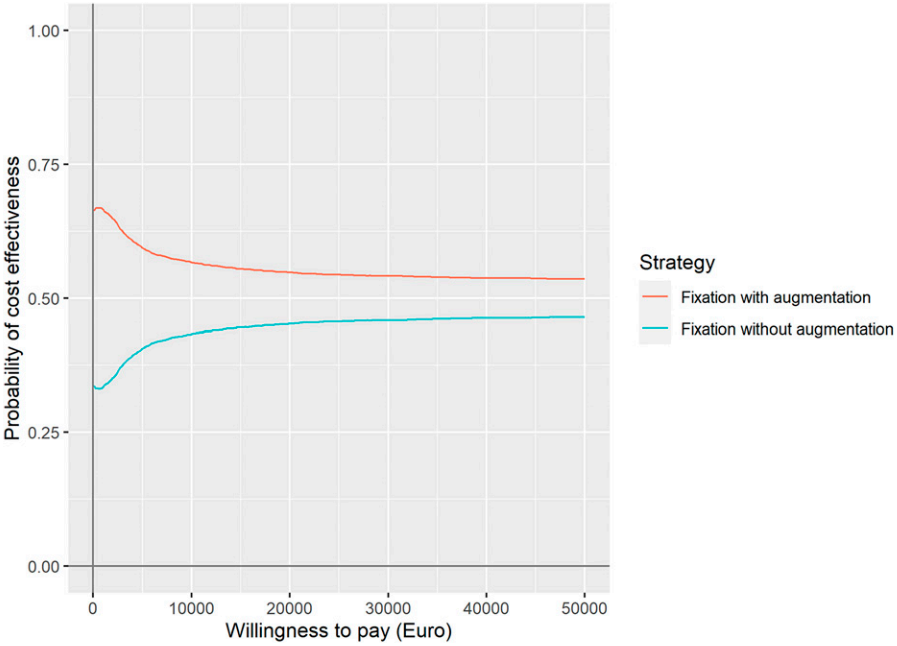

Fig. 4

Cost-effectiveness acceptability curves showing the probability of fixation with cement augmentation being cost-effective compared with fixation without augmentation over a range of willingness-to-pay (WTP) (λ) thresholds. The probability was identified from the incremental cost-effectiveness scatterplots as the proportion of the scatterplot points that fall below and to the right of a ray with a slope of λ drawn through the origin, i.e., the proportion of incremental cost-effect pairs with a value below λ. Given a WTP threshold of €25,000/QALY and €50,000/QALY, the probability that fixation with cement augmentation was cost-effective compared with no augmentation was 54.3% and 53.6%, respectively.

assumption was based on studies showing that the reduction in the risk of revision surgery associated with cement augmentation was predominantly seen within the first year after fixation surgery[45,46]. Probabilistic sensitivity analyses demonstrated that cost savings were robust to parameter uncertainty, whereas QALY gains were less robust to parameter uncertainty. For a range of WTP thresholds from €0 to €50,000, the probability of fixation with cement augmentation being cost-effective versus fixation without augmentation remained >50%. These results indicate a certain amount of decision uncertainties that need to be addressed in future analyses when long-term costs and effectiveness data for cement augmentation are available.

The scenario analysis attempted to generate a more generalizable estimate by assuming higher rates of revision surgery. These rates were obtained from a meta-analysis comparing cement augmentation with no augmentation during fixation of low-energy trochanteric fractures in patients >65 years old[45]. Although these rates were observed in cases implanted with a PFNA as well as other intramedullary nails, they potentially captured the more general effect of cement augmentation versus no augmentation. In this scenario, fixation with cement augmentation remained the dominant strategy, with more than double the cost-savings compared with those obtained in the base-case analysis. These results were not surprising because the rates of revision surgery were among the major drivers of ICER and cost differences.

Rather than using a WTP threshold, Germany adopted a proportional rule to evaluate cost-effectiveness and set the ceiling price of a new treatment, whereby the ICER of a new intervention compared with the next most effective intervention should not be higher than the ICER of the effective intervention compared with its next most effective alternative[47,48]. Therefore, 2 comparators are needed to apply this rule. Although our results, according to this rule and from the German health-care decision-makers' perspective, are not conclusive regarding the cost-effectiveness of fixation with augmentation, they may contribute to establishing consensus on the indications for augmentation in the fixation of trochanteric fractures.

The present study had several limitations. First, the base-case analysis relied heavily on the prior RCT, in which a small number of implant-related revision procedures were reported and the difference in the risk of revision surgery between augmentation and no augmentation was not significant. Second, the rates of revision surgery and mortality after revision surgery in the Markov model were obtained from analyses of the U.S. Medicare SAF database, which did not specify whether or not cement augmentation was used. On the basis of clinical expert opinion, it was assumed that these rates were comparable between the U.S. and German populations. This assumption is not expected to have had a major impact on the results as the Markov model assumed equal rates of revision surgery and mortality after revision surgery. Third, the costs of medications or diagnostic investigations associated with revision surgery were not considered in the model. Although these costs may constitute a small fraction compared with the costs of revision procedures, these omissions may underestimate the cost savings. Finally, as the cost-effectiveness analysis was performed in the German health-care setting, results may not be applicable to other health-care systems with different hospital reimbursement schemes and criteria for judging cost-effectiveness.

In conclusion, based on an RCT with low revision rates, the fixation of unstable trochanteric fractures using a PFNA with TRAUMACEM V+ cement augmentation dominated fixation with no augmentation, mainly because of cost savings. The major drivers of the ICER were the utility of revision, rates of revision surgery within the first year after fixation surgery, and the costs of augmentation and revision surgery. The scenario analysis using higher rates of revision surgery showed more cost savings and QALY gains for fixation with cement augmentation. Whether these findings can be generalized to other cement augmentation techniques warrants further research. Future research also should evaluate whether fixation with cement augmentation is more cost-effective among patients with a greater risk of revision surgery versus the population evaluated herein, which is already at relative high risk for revision, being >75 years of age.

Appendix

eA Supporting material provided by the authors is posted with the online version of this article as a data supplement at jbjs.org (http://links.lww.com/JBJS/H226). ■

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