Original Article

Cost-Utility Analysis of Arthroscopic Rotator Cuff Repair: A Prospective Health Economic Study Using Real-World Data

Cécile Grobet, M.Sc., Laurent Audigé, Ph.D., Klaus Eichler, M.D., Flurina Meier, M.Sc., Beatrice Brunner, Ph.D., Simon Wieser, Ph.D., and Matthias Flury, M.D.

Purpose: To assess the change in quality of life (QOL) and costs for patients with rotator cuff tears after arthroscopic rotator cuff repair (aRCR) compared with continued nonoperative management, using real-world evidence. **Methods:** Patients indicated for aRCR were included in a prospective study and followed up to 2 years after surgery (postop) for all measurements. QOL (EQ-5D-5L) and shoulder function (Constant Score, Oxford Shoulder Score, subjective shoulder value) were assessed. Sixteen major insurance companies provided all-diagnoses direct medical costs in Swiss francs (CHF; 1 CHF = 1.03 USD). Baseline data at recruitment and costs sustained over 1 year before surgery (preop) served as a proxy for nonoperative management. Total direct medical costs to gain 1 extra quality-adjusted life year (QALY) were calculated as the incremental cost-effectiveness ratio (ICER; mean of 2 years postop compared with 1 year preop) from a societal perspective. Subgroup analyses were separately performed for traumatic (trauma-OP) and degenerative (degen-OP) rotator cuff tear patients. Sensitivity analyses for aRCR patients included more intensive nonoperative treatment with corresponding QOL gain. The relationship between QOL and shoulder function was explored using regression analysis. **Results:** For 153 aRCR patients (mean age 57 years; 63% male), the mean EQ-5D index improved from 0.71 (preop) to 0.94 (1 year postop) and 0.96 (2 years postop). Mean total costs increased from 5,499 CHF (preop) to 17,116 CHF (1 year postop), then decreased to 4,226 CHF (2 years postop). The ICER for all aRCR patients was 24,924 CHF/QALY (95% confidence interval [CI] 16,742 to 33,106) and 17,357 CHF/QALY (95% CI 10,951 to 23,763) and 36,474 CHF/QALY (95% CI 16,301 to 56,648) for the trauma-OP and degen-OP groups, respectively. QOL and shoulder function were significantly associated ($P < .001$). **Conclusions:** For RC patients treated at a specialized Swiss orthopaedic clinic, aRCR is a cost-effective intervention associated with clinically relevant improvement in QOL up to 2 years after repair compared with prior nonoperative management. **Level of Evidence:** Economic Analyses − Developing an Economic Model, Level II

Rotator cuff (RC) tears are frequently painful and associated with limitations in shoulder motion and strength that can result in impairment affecting everyday activities and working ability. They are caused either by direct trauma or age-related degenerative changes. RC tears increasingly affect the working population, with a current average insurance payment of 26,412 Swiss Francs (CHF) per trauma case in

Switzerland, which includes direct medical costs as well as worker compensation claims; the latter is paid in 64% of cases, with a mean duration of 97 sick leave days.[1] Both nonoperative and operative treatments of RC tears can lead to significant improvements over time.[2,3] Nontraumatic degenerative RC tears may be primarily managed in a nonoperative manner.[2-5] The outcome of nonoperative treatment within the first 3 months has a prognostic value extending up to 5 years.[6] However, up to 25% of these patients undergo surgery within 1 and 5 years because of unsatisfactory outcome.[4] Traumatic and massive tears may benefit from early surgery, with arthroscopic rotator cuff repair (aRCR) providing substantial pain relief and increasing shoulder function in affected patients.[7]

Triggered by rising health care costs, health economic evaluations have become part of the assessment of surgical interventions in orthopaedics.[8] Yet cost-utility analyses of upper-extremity interventions are rare and mostly based on hypothetical scenarios and modeled data derived purely from the literature.[9] There is a lack of using real-world data—collected from individual electronic health records of patients, claims and billing activities, disease registries, etc.—to illustrate the relationship between patient benefit reported in the form of patient-reported outcome measures (PROMS) and costs in a real-world setting. These data are essential to assess the value of health care for society.[10] In Switzerland, there is no explicit threshold prescribed for society and its willingness to pay for a certain amount of value: for example, costs involved for 1 additional quality-adjusted life year (QALY). Nevertheless, the threshold of 100,000 CHF/QALY has been recommended for high-income countries.[11]

The purpose of this study was to assess the change in quality of life (QOL) and costs for patients with RC tears after aRCR compared with continued nonoperative management using real-world evidence. The hypothesis was that QOL would substantially improve after surgery, resulting in an acceptable cost-utility ratio for aRCR patients treated at a specialized Swiss orthopaedic hospital.

Methods

Design

A health economic investigation was performed to assess patient benefits and costs associated with aRCR compared with nonoperative management of RC tears using a before-and-after-surgery comparison (pre-post design). The study protocol was approved by the Cantonal Ethics Committee of Zurich, Switzerland, and was registered at ClinicalTrials.gov (NCT01954433).

Patients

Patients aged ≥18 years who were diagnosed with a partial or complete RC tear indicated for aRCR and

provided written informed consent were eligible for study inclusion. All consecutive patients with RC tears of traumatic origin as well as patients with degenerative tears were included. For the latter, an unsuccessful nonoperative approach (i.e., after ≥3 months of physiotherapy in combination with anti-inflammatory medication) was seen as an indication for surgical repair. Patients with irreparable tears were excluded. Additional exclusion criteria included general medical contraindications to surgery, any revision operation, tumor/malignancy, any disease process that would preclude accurate evaluation (e.g., neuromuscular, psychiatric, or metabolic disorder), recent history of substance abuse, legal incompetence, pregnancy, or participation in any other study that could influence the results of the present study. Eligible patients were consecutively enrolled until a total of 150 patients were operated and did not fulfill any exclusion criteria or drop out within 2 weeks after surgery. Baseline parameters included patient sociodemographic data, general health status, anamnesis, and shoulder condition. RC tears (partial or full-thickness tear and involved tendons) were initially assessed using magnetic resonance imaging (MRI) and confirmed intraoperatively according to a modified Patte classification.[12] Preoperative MRI was also used to grade the extent of RC fatty infiltration.[13]

Operative Management and Rehabilitation

All aRCR patients were inpatients at a specialized Swiss orthopaedic hospital. The surgical procedure was performed according to standard internal and international guidelines in a beach-chair position under general anesthesia.[14] Any repair procedure was carried out or directly supervised by 1 of 7 experienced specialist shoulder surgeons performing >50 aRCRs annually. After diagnostic arthroscopy, the biceps tendon was tenotomized when required, and for most patients, standard acromioplasty was performed. The ruptured tendons were mobilized until they could be repositioned on the original footprint with the least possible tension. All surgeons used knotless suture bridge fixation, typically with 2 medial and 2 lateral anchors for the supraspinatus. Additional medial anchors for the subscapularis and infraspinatus were used as needed. Rotator cuff tear patterns and associated pathologies, operative details including repair techniques for each involved tendon, and additional procedures (i.e., acromioclavicular resection, acromioplasty, capsulotomy, biceps treatment, and superior labrum anterior to posterior treatment) as well as intraoperative complications were recorded immediately after surgery.

All patients began a standard 3-phase postoperative physiotherapy scheme for their operated shoulder, which included 6 weeks of immobilization with an abduction pillow and passive mobilization, followed by

Recruitment

Patients with diagnosed rotator cuff tear
enrolled between November 2013
and March 2015 (177 patients)

Exclusion (n = 11)
- declined surgery (n = 7)
- disease that precluded accurate
  evaluation (n = 1)
- withdrawn consent (n = 2)
- required number of 150 operations
  and 2-week follow-up complete (n = 1)

Preoperative

166 patients enrolled

Exclusion (n = 13)
- no rotator cuff rupture (n = 5)
- other surgery than aRCR (n = 7)*
- externally performed aRCR (n = 1)

Total included operated patients
n = 153 (= 100%)

2 weeks

153 patients expected
Followed-up: n = 150 (98%)

3 months

153 patients expected
Followed-up: n = 153 (100%)

Drop-out (n = 1)

6 months

152 patients expected
Followed-up: n = 152 (99%)

Drop-out (n = 2)

12 months

150 patients expected
Followed-up: n = 148 (97%)

Drop-out (n = 3)

24 months

147 patients expected
Followed-up: n = 147 (96%)

* Other surgery than aRCR (n = 7):
- debridement of irreparable tear, acromioplasty,
  tenodesis of long biceps tendon (LBT)
- acromioplasty, tenodesis LBT, AC joint resection,
  margin convergence of irreparable tear, bursectomy
- tenodesis LBT, bursectomy
- debridement, acromioplasty, bursectomy
- open RCR
- debridement of irreparable tear, tenodesis LBT
- debridement of irreparable tear, acromioplasty,
  tenotomy LBT, AC joint resection,

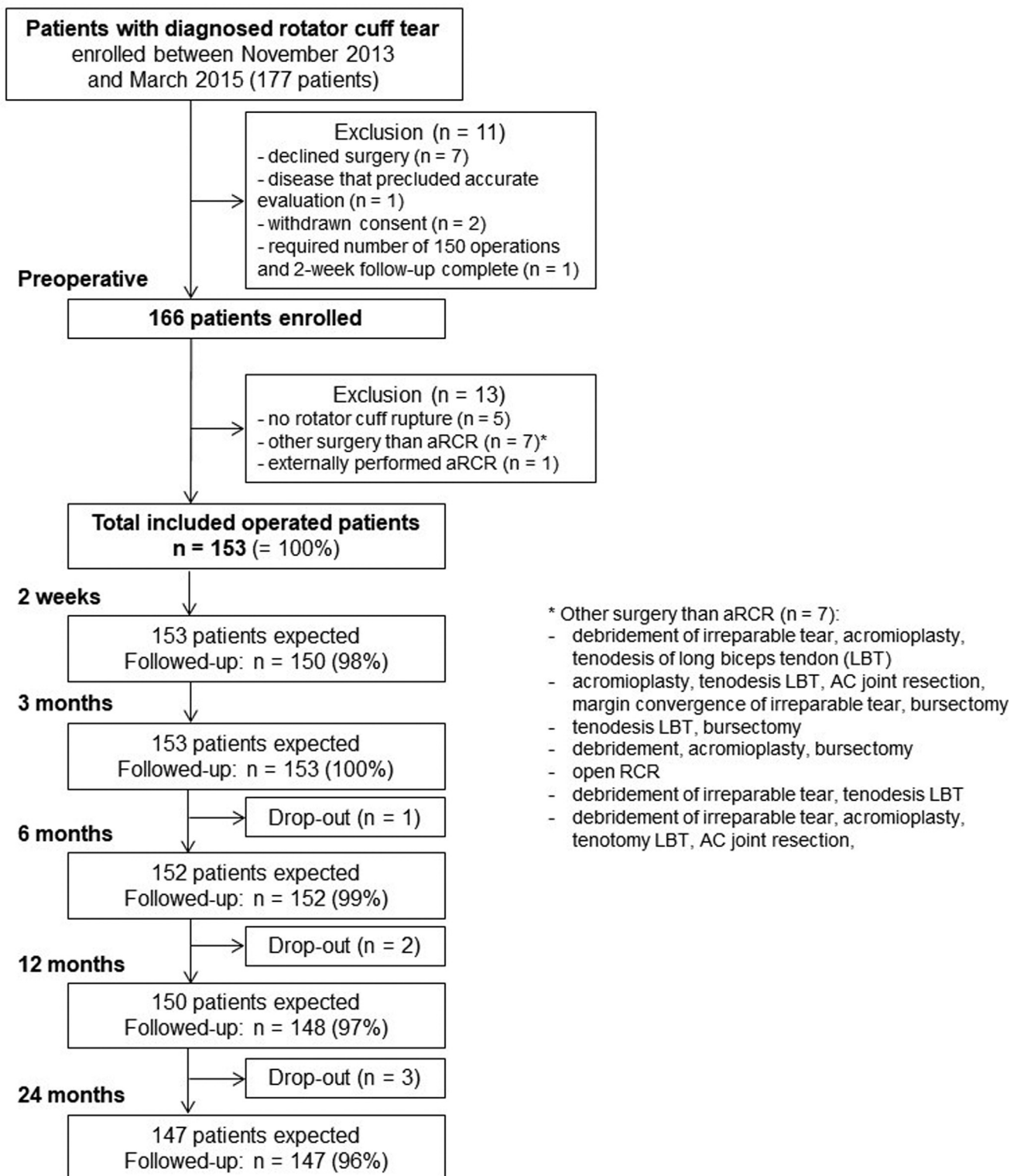**Figure 1.** Study flow. Patient recruitment and follow-up flowchart.

Table 1. Baseline Characteristics

Characteristic	All aRCR Patients n (%)	All aRCR Patients Mean (SD)	Trauma-OP n (%)	Trauma-OP Mean (SD)	Degen-OP n (%)	Degen-OP Mean (SD)
Patients	153		92		61	
Age at surgery (y)		56.9 (8.2)		55.4 (8.1)		59.2 (8.0)
Male sex	97 (63)		66 (72)		31 (51)	
Comorbidities	54 (35)		23 (25)		31 (51)	
Duration of shoulder problems						
<1 mo	22 (15)		21 (21)		1 (2)	
1 to 3 mo	39 (25)		32 (35)		7 (11)	
3 to 6 mo	29 (19)		14 (15)		15 (25)	
6 mo to 1 y	33 (22)		17 (18)		16 (26)	
>1 y	30 (20)		8 (9)		22 (36)	
Working	110 (72)		75 (82)		35 (57)	
Workload reduced before aRCR	31 (28)		28 (37)		3 (9)	
Nonoperativeerative treatment						
Steroid infiltration	49 (32)		20 (22)		29 (48)	
Oral medication	122 (80)		77 (84)		45 (74)	
Physical therapy	70 (46)		38 (41)		32 (52)	
No treatment	14 (9)		7 (8)		7 (11)	
Rotator cuff tear pattern						
SSC	7 (5)		7 (8)			
SSP	85 (56)		41 (45)		44 (72)	
SSP and ISP	24 (16)		19 (21)		5 (8)	
SSP and SSC	26 (17)		17 (18)		9 (15)	
SSP and SSC and ISP	11 (7)		8 (9)		3 (5)	
Tear severity*						
Partial tear	29 (18)		10 (11)		19 (28)	
Single full tear	71 (44)		39 (42)		32 (48)	
Two or 3 tendons (only 1 full)	29 (18)		20 (22)		9 (13)	
Massive tear	31 (19)		24 (26)		7 (10)	
Fatty infiltration of involved RC muscles†						
Stage 0	95 (62)		58 (65)		37 (57)	
Stage 1	50 (32)		23 (26)		27 (42)	
Stage 2	9 (6)		8 (9)		1 (2)	
Patient-reported shoulder pain at night						
Never or occasionally	68 (44)		39 (42)		29 (48)	
Every night	85 (56)		53 (58)		32 (52)	
Constant score (0 = worst, 100 = best)	146	48 (17)	88	44 (17)	58	53 (14)
Oxford Shoulder Score (0 = worst, 48 = best)	153	27 (8)	92	26 (8)	61	28 (8)
Subjective shoulder value (%)	152	48 (21)	92	47 (20)	60	49 (21)
EQ-5D-5L utility index (Germany)	152	0.71 (0.23)	92	0.72 (0.21)	60	0.69 (0.26)
EQ-VAS (0 = worst, 100 = best)	153	70 (18)	92	72 (16)	61	68 (19)

aRCR, arthroscopic rotator cuff repair; degen-OP, aRCR patients with degenerative rotator cuff tears; EQ-VAS, EQ-5D General Health Visual Analogue Scale; ISP, infraspinatus; RC, rotator cuff; SD, standard deviation; SSC, subscapularis; SSP, supraspinatus; trauma-OP, aRCR patients with traumatic rotator cuff tears.

*Gerber et al.[27]

†Fuchs et al.[13]; using magnetic resonance imaging: stage 0, normal muscle; stage 1, some fatty streaks; stage 2, <50% fatty muscle atrophy.

active mobilization and coordination training for 4 weeks, and finally specific progressive resistance exercises.

Patient-Reported and Clinical Outcomes

The primary outcome for this study was the change in QOL and costs of aRCR. Patients were followed up at 7 time points throughout the study period: at enrollment and at the time of hospital admission shortly before surgery (both occurring within the 1-year preop period), and at 2 weeks, 3 months, 6 months, and 1 and 2 years after surgery (e-Supplement 1). Work status and PROMS were documented at all 7 time points, whereby patients completed questionnaires covering QOL, shoulder function, employment conditions, return to work, and activities of daily living. Questionnaires were completed in electronic form either on a tablet computer at the clinic or at home after receiving an email invitation; patients preferring to complete the questionnaires at home on a paper form returned their responses by mail. QOL was assessed using the European Quality of Life 5 Dimensions 5 Level (EQ-5D-5L)

Figure 2. Utility index (EQ-5D-5L) over time. Quality of life (utility index) for arthroscopic rotator cuff repair patients as measured by the European Quality of Life 5 Dimensions 5 Level (EQ-5D-5L) questionnaire at each follow-up time point (range −0.66 to 1.0; minimal clinically important difference [MCID] = 0.074 points).[23] The horizontal dashed line indicates the utility index for the health state we assumed patients would maintain throughout the entire follow-up period if they had not undergone surgery.
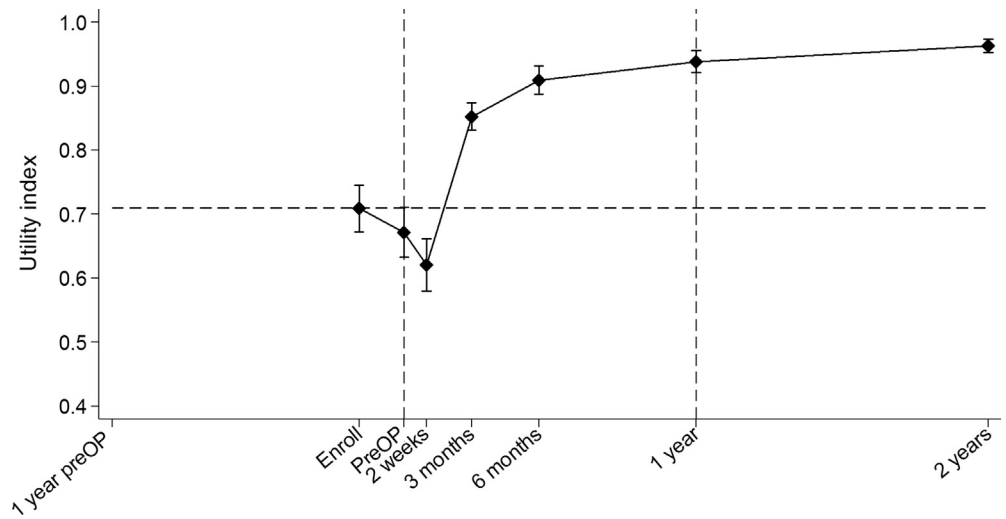
questionnaire.[15] The EQ-5D-5L responses were converted into utilities (ranging from −0.66 [lowest QOL] to 1 [highest QOL])[15] using the EQ-5D-5L value set for Germany.[16] The EQ-5D is valid and reliable and the most frequently used instrument to evaluate health states using utilities and to calculate quality-adjusted life years (QALYs).[17] Patient-reported shoulder function was assessed using the Oxford Shoulder Score (OSS)[18] and subjective shoulder value (SSV).[19]

Routine clinical examinations were performed by physicians at enrollment as well as the 3- and 6-month postoperative time points, and by a study assistant at the time of hospital admission shortly before surgery. Examinations included shoulder range of motion and muscle strength in 90° abduction, overall shoulder function as measured by the Constant Score (CS),[20] and occurrence of postoperative complications.[21]

Cost and Productivity Data

Direct medical costs (all medical expenses including aRCR-related costs) and productivity data of aRCR patients were collected for 3 time periods: (1) the year before surgery (preop period), (2) surgery and the consecutive first postoperative year, and (3) the second postoperative year (e-Supplement 1). In a similar manner, the costs and productivity data for patients during nonoperative management were considered in the year before enrollment as well as the first and second years after enrollment. Sixteen major Swiss health and accident insurance companies provided direct medical inpatient and outpatient cost data extracted from their claims database. Costs included all-diagnosis direct medical costs of all treatments, complications, drugs, and consultations covered by the mandatory health and accident insurance companies, pertaining to the inpatient and outpatient sector for each patient across all hospitals and other providers. All inpatient costs represent 45% of the total inpatient costs in the Swiss health system, and therefore, these costs were adjusted by dividing the provided inpatient costs by 0.45.

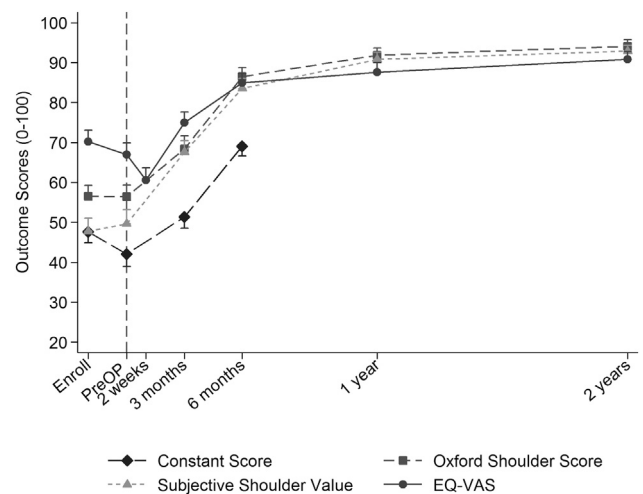Productivity losses due to shoulder complaints resulting from a RC tear only were assessed at

Figure 3. Shoulder function and quality of life over time. Outcome scores for arthroscopic rotator cuff repair patients are shown at each follow-up time point. Clinical examinations for the Constant Score (range 0 to 100; minimal clinically important difference [MCID] = 8.3 points)[28] were performed up to the 6-month follow-up and patient-reported outcomes up to 2 years after surgery. The original scale of the Oxford Shoulder Score ranging from 0 to 48 was adapted to 0 to 100 for presentation purposes (MCID adapted for range 0 to 100 = 11.0 points).[28] Subjective shoulder value: Subjective evaluation of shoulder function by the patient in relation to normal shoulder function (range 0% to 100%). EQ-VAS = EQ-5D General Health Visual Analogue Scale (range 0 to 100 points; MCID = 7.18 points).[28]

Table 2. Direct medical costs and productivity losses in Swiss Francs (CHF)

	n	Preoperative Year (CHF)	First Postoperative Year (CHF)	Second Postoperative Year (CHF)	n*	Incremental Costs (CHF)
Operated (aRCR) patients						
Direct medical costs	130	5,499 (6,167)	17,116 (10,058)	4,226 (7,998)	116	5,009 (7,139)
Inpatient cost data	130	963 (3,480)	12,129 (8,580)	1,872 (6,152)		
Outpatient cost data	130	4,535 (4,106)	4,987 (3,286)	2,354 (3,290)		
Productivity loss	88	42,001 (44,067)	25,565 (23,188)	5,415 (14,523)		
Trauma-OP patients						
Direct medical costs	77	4,313 (5,569)	14,843 (4,581)	1,531 (3,406)	66	3,704 (4,388)
Inpatient cost data	77	657 (2,627)	10,659 (2,977)	352 (1,597)		
Outpatient cost data	77	3,656 (3,840)	4,183 (2,639)	1,179 (2,355)		
Productivity loss	59	49,547 (45,554)	28,325 (24,595)	4,438 (11,471)		
Degen-OP patients						
Direct medical costs	53	7,221 (6,626)	20,418 (14,197)	8,140 (10,742)	50	6,732 (9,420)
Inpatient cost data	53	1,408 (4,428)	14,264 (12,722)	4,080 (9,043)		
Outpatient cost data	53	5,813 (4,180)	6,154 (3,778)	4,060 (3,707)		
Productivity loss	29	26,649 (37,030)	20,425 (19,686)	7,296 (19,211)		

NOTE. Data are presented as mean (standard deviation).

aRCR, arthroscopic rotator cuff repair; degen-OP, aRCR patients with degenerative rotator cuff tear; trauma-OP, aRCR patients with traumatic rotator cuff tear.

*Patients with complete cost data and corresponding quality-adjusted life years.

enrollment, at the time of hospital admission shortly before surgery, and at 3 months, 6 months, and 1 and 2 years after surgery using the Work Productivity and Activity Impairment Questionnaire − Specific Health Problem Version 2.0 (WPAI-SHP)[22] consisting of 6 questions on absenteeism (absence from work) and presenteeism (reduced productivity when at work) during the last 7 days. Additional work-related data included (1) the number of hours usually worked per week, (2) whether the level of employment had been reduced due to the RC tear, (3) the duration of absence from work after surgery, and (4) the current monthly personal income in brackets of 2,000 CHF to ≥16,000 CHF.

Statistical Analysis

The power analysis considered a predetermined sample size of 150 operated patients to detect a clinically important change in QOL of 0.074[23] in this group. This calculation was based on a standard deviation of
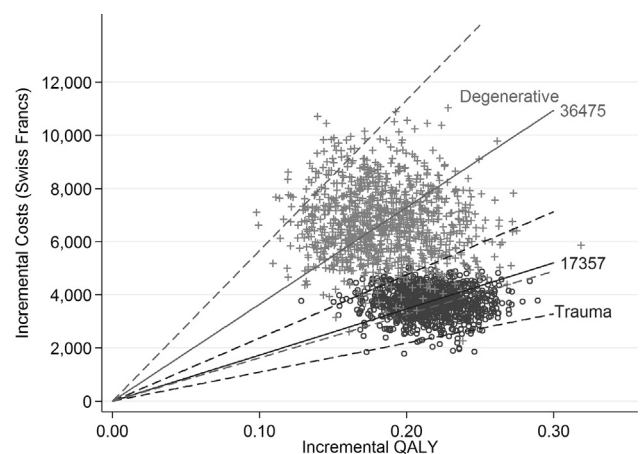

Figure 4. Cost-effectiveness plot using direct medical costs. Incremental cost-effectiveness ratio (ICER) for patients with traumatic and degenerative rotator cuff tears (black and grey bold lines, respectively) and the 95% confidence interval (dashed lines). Incremental costs, direct medical costs; QALY, quality-adjusted life years

Table 3A. Sensitivity analysis of incremental cost-effectiveness ratios (ICERs) for arthroscopic rotator cuff repair (aRCR) compared with nonoperative treatment including all patients (n = 116)

| Lower utility Index (Compared with Utilities of aRCR at 2 years after Enrollment) | Hypothetical Nonoperative Treatment | | | |
| | Increased Costs (in the First year after Enrollment Compared with the year before Enrollment owing to More Intensive Nonoperative Treatment; CHF) | | | |
	No Increased Costs (**Base Case**)	110% Increased Costs	120% Increased Costs	140% Increased Costs
5% lower	50,712 (33,409 to 68,015)	47,820 (30,648 to 64,991)	44,927 (27,851 to 62,003)	39,142 (22,142 to 56,142)
7.7% lower (= MCID)	44,859 (30,235 to 59,484)	42,301 (27,728 to 56,874)	39,742 (25,190 to 54,294)	34,624 (20,023 to 49,225)
10% lower	40,762 (27,883 to 53,642)	38,437 (25,569 to 51,306)	36,112 (23,228 to 48,996)	31,462 (18,467 to 44,457)
15% lower	34,076 (23,803 to 44,350)	32,133 (21,821 to 42,444)	30,189 (19,819 to 40,559)	26,301 (15,755 to 36,848)
No improved utility index for nonoperative treatment (**base case**)	**24,924 (16,703 to 33,146)**	23,503 (15,314 to 31,692)	22,081 (13,908 to 30,254)	19,237 (11,045 to 27,429)

NOTE. ICERs presented with 95% confidence interval. Several ICERs for aRCR are shown for different combinations of (1) cost increase due to more intensive nonoperative treatment and (2) lower utility index levels for a hypothetical nonoperative treatment. Bold figures indicate the base case.

CHF, Swiss Francs; MCID, minimal clinically important difference.

0.30, a significance level of 0.05, and a power of 80% while considering a maximum loss to follow-up of 10%.

All data were entered into a web-based electronic database using REDCap Software 6.16.5 (Vanderbilt University, Nashville, TN)[24] and exported for analysis into Intercooled Stata 14.2 (StataCorp, College Station, TX).

Baseline patient sociodemographic data and RC tear diagnostic, functional, and operative parameters were tabulated using standard descriptive statistics for all operated patients and separately for traumatic aRCR (trauma-OP) (classified by the accident date documented in the local clinic patient information system) and degenerative aRCR (degen-OP) patients. The change of QOL was analyzed using a paired *t* test and reported as the mean with its 95% confidence interval (95% CI). QALYs were calculated by multiplying utilities with the length of time over which health state was experienced. The assumption was that the health state between 2 assessment points was equal to the mean of the utilities recorded at these points. For the base case, it was assumed that if patients had not undergone surgery, they would have maintained their preoperative health state throughout the follow-up period under evaluation.

Annual direct medical costs (all-diagnosis costs including aRCR-related costs) were calculated for each 1-year period. The incremental cost-effectiveness ratio (ICER) was calculated by dividing the difference in annual costs (postoperative period minus preop period) by the difference in QALYs. Results were calculated for the entire sample as well as for trauma-OP and degen-OP patient subgroups. The 95% CIs of costs and ICER were calculated using nonparametric bootstrapping methods.[25]

Productivity losses for the patient population, which had a labor type pattern representative of RC tear patients in Switzerland, were calculated by multiplying the accumulated productivity losses due to health-related (i.e., shoulder-specific) absenteeism and presenteeism[26] with annual earnings. These losses were extrapolated over the time between 2 questionnaires. For example, patients reporting to be still out of work 3 months after surgery who then reported working at 50% of their full-time level of employment 6 months after surgery were considered as working at 25% of their full-time level of employment between 3 and 6 months after surgery. Costs were reported in 2017 CHF (conversion rate to USD, 1.03; to Euro, 0.85; to British pound, 0.76). Current standards for performing health economic evaluations were applied.[8]

The changes of all outcome parameters from baseline to each follow-up assessment were analyzed using generalized linear mixed models to account for repeated measurements. The relationship between shoulder

Table 3B. Sensitivity analysis of incremental cost-effectiveness ratios (ICERs) for Degen-OP compared with Degen-nonoperative treatment including patients with degenerative tears (n = 50)

Lower utility Index (Compared with Utilities of Degen-OP 2 years after Enrollment)	Hypothetical Degen-Nonoperativeeerative Treatment			
	Increased Costs (in the First year after Enrollment Compared with the year before Enrollment owing to More Intensive Nonoperative Treatment)			
	No Increased Costs (**Base Case**)	110% Increased Costs	120% Increased Costs	140% Increased Costs
5% lower	76,640 (31,680 to 121,599)	72,433 (28,477 to 116,389)	68,227 (25,188 to 111,266)	59,814 (18,329 to 101,299)
7.7% lower (= MCID)	66,954 (30,988 to 102,919)	63,279 (27,907 to 98,651)	59,604 (24,757 to 94,451)	52,254 (18,238 to 86,271)
10% lower	60,037 (29,533 to 90,541)	56,742 (26,625 to 86,858)	53,446 (23,659 to 83,234)	46,856 (17,544 to 76,169)
15% lower	49,347 (26,152 to 72,541)	46,638 (23,590 to 69,686)	43,930 (20,986 to 66,873)	38,513 (15,650 to 61,375)
No improved utility index for nonoperative treatment (**base case**)	**36,475** (17,188 to 55,762)	34,473 (15,463 to 53,483)	32,471 (13,703 to 51,238)	28,467 (10,073 to 46,861)

NOTE. ICERs presented with 95% confidence interval. Several ICERs for degen-OP are shown for different combinations of (1) cost increase due to more intensive nonoperative treatment and (2) lower utility index levels for a hypothetical degen-nonoperative treatment. Bold figures indicate the base case.

CHF, Swiss Francs; Degen-OP, operated patients with degenerative rotator cuff tear; Degen-nonoperative, nonoperatively treated patients with degenerative rotator cuff tear; MCID, minimal clinically important difference.

function (CS, SSV, OSS) and QOL utility index over time was explored with scatter plots as well as regression analysis, while adjusting for the baseline index.

Sensitivity Analysis

One major assumption in the primary analysis (base case) of this study was that the QOL index of patients continuing a hypothetical nonoperative management would remain constant over time. However, 2 recent meta-analyses highlighted that patients with degenerative tears who undergo intensified physiotherapy instead of surgery would improve their QOL.[2,3] Even though these patients would not achieve the same QOL levels as operated patients after 2 years of follow-up, the difference would not exceed the minimal clinically important difference (MCID). Therefore, a sensitivity analysis was conducted to simulate an improvement in QOL within the nonoperative treatment setting for the whole patient group (hypothetical nonoperative group) and for patients with degenerative tears (hypothetical degen-nonoperative group).

In addition to the base case (i.e. no improvement in QOL after nonoperative management), a linear increase in QOL was simulated from the time point of a hypothetical more intensive nonoperative treatment until the 2-year follow-up using 4 values of mean utility of the aRCR group (i.e., all operated patients): −5%; −7.7% (corresponding to the MCID of −0.07 utilities); −10%; and −15% (e-Supplement 2). In addition to the base case (i.e., no increased costs), hypothetically increased direct medical costs in the nonoperative and degen-nonoperative group due to more intensive nonoperative management in the year after enrollment were also considered, assuming 110%, 120%, or 140% of the documented costs of the preop year for the first year after enrollment. The costs in the second year after enrollment, in turn, were considered similar to the year before enrollment.

Results

Patient Enrollment and Baseline Characteristics

Between November 2013 and March 2015, 177 patients were enrolled (Figure 1). Twenty-four patients (14%) were excluded because of ineligibility (including 7 who declined aRCR surgery), and 6 patients (4%) dropped out during the study. The final sample included 92 traumatic (60%) and 61 degenerative tears, and the majority (94%) were hospitalized for 3 to 4 days. Table 1 summarizes the baseline characteristics, PROMS, and clinical outcomes for all aRCR patients as well as the subgroups, trauma-OP and degen-OP.

Patient-Reported and Clinical Outcomes

From a baseline value of 0.71, the EQ-5D utility index dropped after surgery, but improved substantially by a

Figure 5. Return-to-work rates over time. Kaplan-Meier curve showing the percentage of patients returning to work after arthroscopic rotator cuff repair; m, months; y, years.
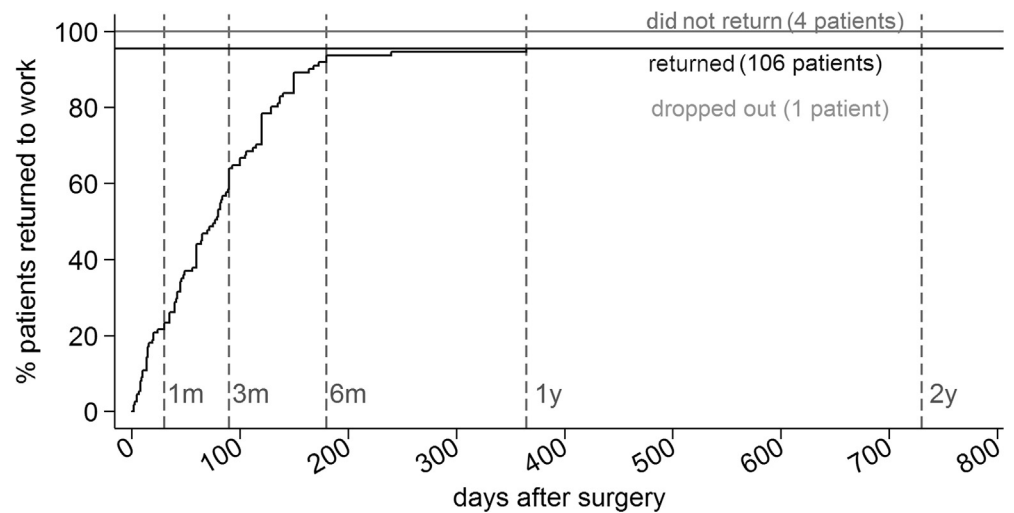
mean of 0.26 for aRCR patients at the end of the first and second postoperative years (*P* < .001; Figure 2); similar observations were made for the trauma-OP and degen-OP subgroups (e-Supplement 3). All other baseline PROMS also improved substantially for the aRCR as well as trauma-OP and degen-OP groups until 1 year after surgery and remained at that level in the second postoperative year (*P* < .001; Figure 3 and e-Supplement 3).

Cost-Utility Analysis

Direct cost data were obtained for 130 patients (85%) who were insured by major Swiss insurance companies. Mean direct costs increased from 5,499 CHF (5,664 USD) in the year before surgery (comprising mainly outpatient costs) to 17,116 CHF (17,629 USD) in the first year after surgery (comprising the costs of surgery), with a shift toward increasing inpatient costs (Table 2);

this was followed by a decrease to 4,226 CHF (4,353 USD) in the second postoperative year, which was below the mean cost incurred before surgery. The same trend was seen for the trauma-OP and degen-OP subgroups, although second postoperative year costs were higher than preoperative costs for the latter.

The ICER for all aRCR patients was 24,924 CHF/QALY (95% CI, 16,742 to 33,106; 25,672 USD/QALY). The corresponding ICER for the trauma-OP group was 17,357 CHF/QALY (95% CI 10,951 to 23,763; 17,878 USD/QALY) and 36,475 CHF/QALY (95% CI 16,301 to 56,648; 37,569 USD/QALY) for the degen-OP group (Figure 4).

The sensitivity analyses resulted in ICERs ranging from 50,712 to 19,237 CHF/QALY (52,233 to 19,814 USD/QALY) for the whole patient group (Table 3A) and 76,640 to 28,467 CHF/QALY (78,939 to 29,321 USD/QALY) for patients with degenerative tears (Table 3B).
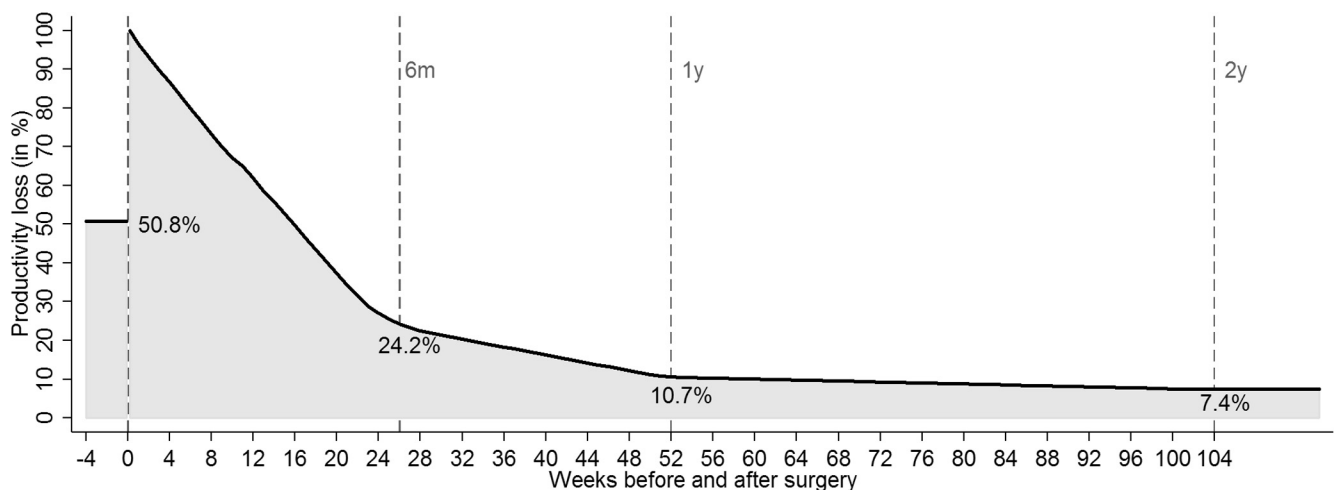

Figure 6. Productivity losses over time. Productivity losses of all arthroscopic rotator cuff repair patients (N = 97) until 2 years after surgery. The horizontal line between −4 and 0 weeks indicates the preoperative period.
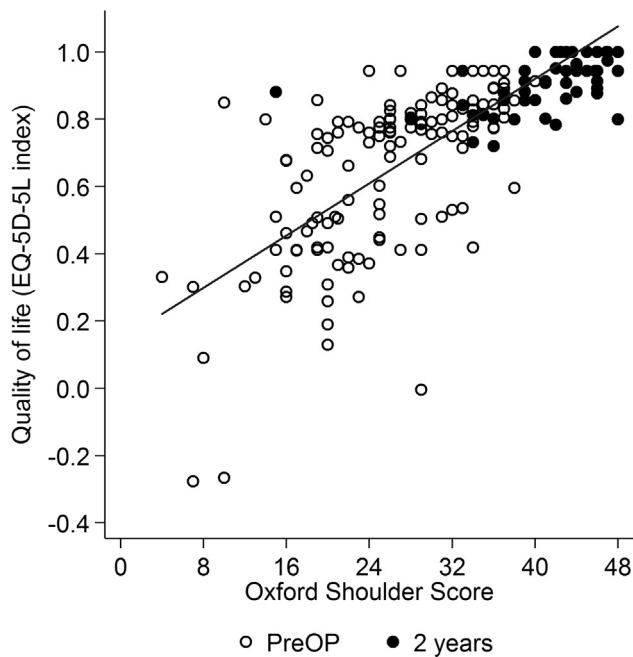
Figure 7. Association between quality of life and shoulder function over time. Each data point represents 1 patient preoperatively or 2 years after surgery. Scatter plot showing the association between quality of life (indicated by the European Quality of Life 5 Dimensions 5 Level [EQ-5D-5L] utility index; range 0.0 to 1.0; minimal clinically important difference [MCID] = 0.074[23] and the Oxford Shoulder Score (OSS; range 0 to 48; MCID = 4.7 and 6.0 for shoulder pain and function, respectively)[29] before and 2 years after surgery. The regression line indicates the association between quality of life and OSS at the preoperative time point.

Among a total of 110 working patients in the aRCR group, 31 patients (28%; 37% of 75 trauma-OP patients and 9% of 35 degen-OP patients) reduced their work activity either preop or before study enrollment. Preop productivity losses for 97 working patients with complete data were 56% and 40% of the work activity level for trauma-OP and degen-OP patients, respectively; these losses peaked after surgery. Operated patients returned to work on average after 77 days (Figure 5). Sixteen weeks after surgery, productivity losses decreased below preop levels (Figure 6). Mean productivity losses for the aRCR group were 42,001 CHF (43,261 USD) per patient in the year before surgery and decreased to 5,415 CHF (5,577 USD) ≤2 years after surgery (Table 2).

The OSS, SSV, and CS were significantly associated with the EQ-5D index at both preop and 2-year-postop time points ($P < .001$; Figure 7; EQ-5D index vs SSV and CS scatter plots not shown). The coefficients of determination (R^2) were 0.52, 0.46, and 0.42 for the OSS, SSV 2 years postop, and CS 6 months postop.

Discussion

For patients who underwent aRCR for traumatic and degenerative tears, there was a clinically relevant improvement in quality of life from 3 months to 2 years after surgery compared with the preop state, which was associated with improved shoulder function. The cost-utility ratio of aRCR was estimated at 24,924 CHF/QALY, which clearly falls below the suggested threshold of 100,000 CHF/QALY for high-income countries.[11]

This study presents real-world data for a consecutive series of aRCR patients treated at a large orthopaedic tertiary hospital. In contrast, the most recently published health economic studies are based on modeling techniques using estimated cost data.[30-34] For the vast majority of patients, standard nonoperative management failed, and based on the judgment of the experienced shoulder specialists, a different response to the reported shoulder problems was to be expected with surgery. Therefore, randomization of these patients between aRCR and intensive physical therapy was considered unethical and infeasible. The pre-post study design of the current study is a suitable approach given the circumstances of the clinical setting.

QOL as documented by the EQ-5D-5L utility index improved significantly, by 0.26 points. This is well above the estimated MCID of 0.074,[23] which was calculated from 11 patient groups not specifically including aRCR patients. The existing data on change in QOL in upper-extremity orthopaedic disorders using the EQ-5D-5L instrument are very limited.[17] The few studies reporting EQ-5D-5L utility indices for aRCR patients show consistent improvement in QOL of 0.20 and 0.19 at 1 and 2 years after surgery.[33,35] Furthermore, there is a QALY gain of 1.34 at 2 years after aRCR,[36] as well as a lifetime QALY gain of either 3.43[35] or 11.73.[31]

The ICER of aRCR patients was 24,924 CHF/QALY 2 years after surgery from a health care system perspective (base case). In the sensitivity analysis, the resultant ICER of 47,820 CHF/QALY for aRCR still falls below the cost-effectiveness threshold, even when considering a conservative assumption (QOL values: for the hypothetical nonoperative group, 5% less compared with aRCR patients; costs: slightly increased costs of 110% for more intensive nonoperative treatment compared with the year before enrollment). Two independent studies that compared aRCR versus nonoperative management found similar ICERs of 15,500 USD (15,106 CHF) and 30,001 GBP (39,501 CHF) per QALY, respectively.[31,36] Yet most of the work already published applied modeling techniques using estimated utility and cost data extracted from the literature.[30-32,34] Studies reporting on primary health economic data are rare. A prospective cost-utility study analyzed patients who underwent open or mini-open RC tear repair,[35] and 3 prospective health economic investigations

compared aRCR with physiotherapy or open RC repair[5,33,36] in patients aged >50 years with degenerative full-thickness tears. Two studies were conducted from a health care system perspective using direct medical costs for ICER calculation.[33,35] The remaining studies considered the societal perspective by analyzing productivity losses due to sick leave,[5,36] but either compared aRCR with open repair[36] or did not report an ICER.[5] A comparison of results across studies requires consideration of the case mix. Traumatic RC tear patients included in the current study were younger, less affected by comorbidities, and more often employed than patients affected by degenerative tears. These patient groups generate varying amounts of direct medical costs and productivity losses, which are likely related to their different demographic and health profiles.

Shoulder problems generated substantial preoperative productivity losses, with 80% of working patients having impairments, particularly those in the trauma-OP group, possibly owing to the presence of more severe RC lesions. Although return to work and increasing workloads were attained after an average of 77 postoperative days, it is unlikely that aRCR patients would have achieved a better working status if they had not undergone surgery. Nevertheless, it is not possible to speculate on what their status would have been, and therefore the associated costs were not included in the ICER calculation. Furthermore, the ICER considers only 2 years of follow-up, although the treatment effect of aRCR is expected to last far longer. Previous cost-utility studies considered the patient's remaining lifetime and noted good to excellent results for >90% of RCR patients, as well as low long-term revision rates at postoperative follow-ups ranging from 2 to 10 years.[30,35] Those studies assumed that expenses in the first postoperative year capture the majority of costs associated with RCR, and that fewer downstream costs would follow. Further investigation is required to assess whether a more favorable ICER would be achieved for aRCR with the studied patient collective over a long-term follow-up extending beyond 2 years.

Limitations

One main study limitation is the lack of a randomized study design.[8] However, a pre-post design, which has already been applied elsewhere,[37] was considered most feasible in this clinical setting; patients with traumatic tears or persisting pain after nonoperative management mainly consult specialty tertiary referral hospitals such as our clinic. With only 7 patients who declined surgery and had baseline characteristics poorly comparable to the aRCR patients, it proved inadequate to build an appropriate control group. Such an obstacle was encountered in another large cost-utility study owing to a high rate of crossovers to surgery (77%) within 2

years after enrollment,[36] as well as another more recent study with a 10-year follow-up period (27%) from the group of Moosmayer.[38] The high proportion of patients with previously unsuccessful nonoperative treatment contributed to the difficulties that were encountered in achieving a sizable comparison group who would have undergone continued and more intensive nonoperative care. By using preop data for comparative purposes, the strong assumption was that aRCR patients would remain in their same condition without surgery. With the sensitivity analyses, alternative scenarios were applied based on previous reports,[2,3] which considered successful nonoperative management for the whole patient group as well as for patients with degenerative tears. However, it is still unclear how likely these scenarios truly apply to the study patients. Furthermore, it must be considered that only all-diagnoses direct medical costs were available, which included costs of other health-related comorbidities or complications due to aRCR. Because of the pre-post study design, the use of this comprehensive cost data should nonetheless have limited impact on incremental costs, and any cost due to potential side effects of surgery can also be examined. Lastly, the results of this study need to be considered in terms of the local surgical routine undertaken at our clinic, and may differ in other institutions located particularly outside Switzerland.

Conclusions

For RC patients treated at a specialized Swiss orthopaedic clinic, aRCR is a cost-effective intervention associated with clinically relevant improvement in QOL up to 2 years after repair compared with prior nonoperative management.

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