Health-related quality of life influences surgical decisions in patients with rotator cuff disease

analysis of a randomized controlled trial

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Aims

Rotator cuff disease (RCD) can considerably decrease quality of life. Here, we investigated whether health-related quality of life (HRQoL) influences the need for surgery in patients with RCD.

Methods

We performed an analysis of 417 patients with symptomatic RCD who were recruited from two hospitals between June 2008 and December 2014 to be randomized to receive non-surgical or surgical treatment. After a three-month rehabilitation period, 36-Item Short-Form Health Survey questionnaire (SF-36), shoulder pain (visual analogue scale (VAS)), and shoulder function (Constant-Murley score) data were available from 191 still-symptomatic patients who were eligible for surgery. A control group was formed from 87 excluded patients who were no longer eligible for surgery due to relief of symptoms.

Results

Mean pain on the VAS was 51.3 (SD 20.1) in the patients eligible for surgery and 41.7 (SD 21.2) in the control group. The following domains of the SF-36 were associated with being eligible for surgery in univariate analyses: bodily pain, general health, vitality, social functioning, and emotional wellbeing. In multivariate analysis, only bodily pain was associated with pursuing surgical treatment. The RCD population's values for physical role, bodily pain, and physical functioning were poorer compared to the values of the general population.

Conclusion

Lower HRQoL, as indicated by the lower bodily pain score on the SF-36, was associated with the decision to undergo surgical treatment in patients with RCD. Therefore, HRQoL should be considered when determining treatment options for RCD.

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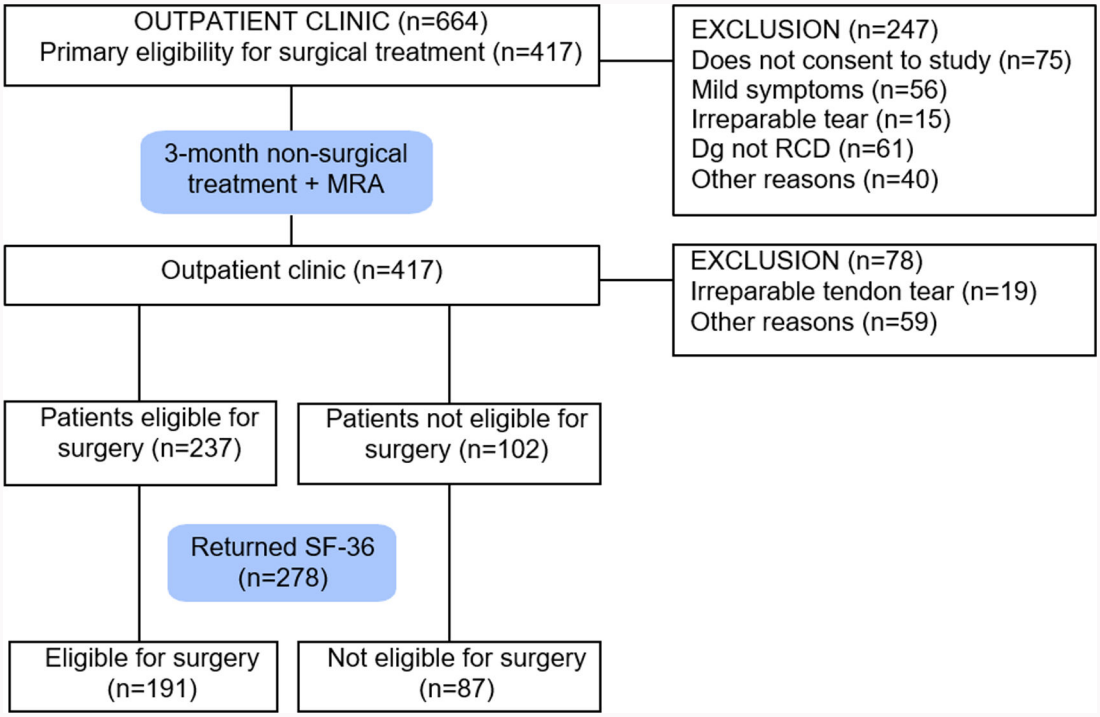

Fig. 1
Study flowchart on eligibility for rotator cuff surgery. Dg, diagnosis; MRA, magnetic resonance arthrography of the shoulder; RCD, rotator cuff disease; SF-36, 36-item Short Form Survey for health-related quality of life.

Take home message

- Lower health-related quality of life (HRQoL), as indicated by the lower bodily pain score on the Short-Form 36-item questionnaire, is associated with the decision to undergo surgical treatment in patients with rotator cuff disease (RCD).
- Therefore, HRQoL should be taken into consideration when choosing treatment modalities for RCD.

Introduction

Among adults, rotator cuff disease (RCD) is the most common cause of prolonged shoulder pain and disability. The disease has a multifactorial aetiology, including intrinsic (e.g. genetics, vasculature) and extrinsic (e.g. trauma, biomechanics) factors.[1] In RCD, tendon damage occurs in a continuum of acute-to-chronic changes, which range from tendinopathy without frayed tendons to a full-thickness tendon tear.[2-5]

Many studies, historical and recent, have shown that subacromial decompression and non-surgical treatments provide equivalent results in RCD without a full-thickness tendon lesion.[5-18] Despite the increasing evidence against surgery for RCD without a full-thickness tendon lesion, surgery is still considered appropriate by many surgeons.[19] The efficacy of rotator cuff tendon repair in full-thickness ruptures remains controversial.[13-1517,,18] According to current data, patients with RCD should undergo adequate non-surgical treatment before surgical treatment is considered.[5]

To the best of our knowledge, no previous studies have evaluated health-related quality of life (HRQoL) as a predictor for surgery in patients with RCD. The aim of this study was to investigate whether any of the scales of the 36-Item Short-Form Health Survey questionnaire (SF-36)[20] for HRQoL are associated with surgery after the three-month rehabilitation period in patients with RCD.

Methods

This prospective study was conducted in two hospitals (Central Finland Hospital and Oulu University Hospital) between June 2008 and December 2014. The Ethics Committee of the Central Finland Health Care District approved the trial on 23 May 2007.

The detailed study protocol of our randomized controlled trial (RCT) (trial registration: ClinicalTrials.gov, NCT00695981 and NCT00637013) was reported previously.[5] Briefly, 664 patients who presented with long-term (> three months) symptoms attributable to RCD were screened (Figure 1). These patients were selected according to predetermined inclusion and exclusion criteria from among referrals to secondary care from primary and occupational healthcare centres and private clinics. The research group physicians interviewed the patients and performed structured examinations and, together with the patient, completed the assessment for eligibility. Of these, 417 patients met the initial eligibility criteria for surgical treatment and provided written informed consent. After inclusion, patients received a referral to outpatient physiotherapy. In addition, the study physiotherapists instructed the patients to start a pragmatic, three-month, outpatient-based rehabilitation period, including therapeutic exercises and other non-surgical methods. Subsequently, they underwent magnetic resonance arthrography (MRA) and were evaluated by a specialist orthopaedic surgeon (KP) for final study eligibility (i.e. eligibility for surgery). MRA images were evaluated by the clinical radiologist on duty (MS). A full-thickness tendon tear was diagnosed if contrast medium, attributable to a

Table I. Demographic data and clinical characteristics of patients who were either eligible or not eligible for rotator cuff disease surgery. Adjusted for sex, age, dominant upper limb, duration of pain, and full-thickness rupture.

Varialbe	Not eligible for surgery (n = 87)	Eligible for surgery (n = 191)	p-value
Female, n (%)	31 (36)	85 (45)	0.164*
Age, mean (SD)	56 (9)	55 (8)	0.341†
Duration of pain, months, median (IQR)	9 (5 to 18)	12 (7 to 24)	0.020†
Dominant upper limb, n (%)	46 (53)	122 (64)	0.082*
Traumatic onset, n (%)	14 (16)	31 (16)	0.977*
Pain, VAS, mean (SD)	41 (21)	51 (20)	< 0.001†
Rest	26 (23)	38 (25)	< 0.001†
Arm activity	55 (25)	63 (23)	0.011†
Night	46 (29)	55 (28)	0.012†
CMS (SD)	57 (16)	58 (15)	0.951†
Pain in other locations, n (%)			
Lower limb	29 (34)	63 (33)	0.950*
Neck	13 (15)	22 (12)	0.423*
Thoracic spine	24 (28)	52 (28)	0.944*
Lumbar spine	17 (20)	54 (29)	0.122*
Full-thickness rupture, n (%)	31 (36)	90 (47)	0.073*

*Chi-squared test.
†Independent-samples t-test.
CMS, Constant-Murley score; VAS, visual analogue scale.

Table II. Univariate and multivariate logistic regression analysis on the relation of 36-Item Short-Form Health Survey questionnaire domains with eligibility for rotator cuff disease surgery.

Domain	Univariate	Multivariate
	OR (95 % CI)	**OR (95 % CI)**
Physical Functioning per SD	0.91 (0.68 to 1.19)	
Role Physical per SD	0.82 (0.63 to 1.07)	
Bodily Pain per SD	0.64 (0.48 to 0.84)	0.64 (0.48 to 0.84)
General Health per SD	0.71 (0.54 to 0.95)	
Vitality per SD	0.73 (0.55 to 0.98)	
Social Functioning per SD	0.69 (0.51 to 0.92)	
Role Emotional per SD	0.83 (0.63 to 1.10)	
Emotional wellbeing per SD	0.72 (0.54 to 0.97)	

Multivariate: forward selection. Only the variables which entered into the model are shown. Adjusted for sex, age, dominant upper limb, duration of pain, and full-thickness rupture.
OR, odds ratio.

full-thickness tendon tear, was detected in the subacromial space on MRA.

After three months of rehabilitation, 187 patients were randomized to our primary RCT. The median duration of pain was 12 months (IQR 7 to 24) in patients eligible for surgery and nine months (IQR 5 to 18) in patients who were not eligible for surgery. As surgery is an option in randomization, these patients were eligible for rotator cuff surgery in the present study. An additional 50 patients were eligible for surgery because they did not consent to randomization due to severe symptoms, and a decision was made on surgical treatment by consensus between the patient and the orthopaedic surgeon. The symptoms of 102 patients had been relieved during the three-month rehabilitation period. The rehabilitation protocol was described in the supplementary material of our RCT.[5] These patients were no longer considered eligible for surgery by consensus between the orthopaedic surgeon and patient. All patients were invited to complete the self-administrated SF-36 for HRQoL. The study physiotherapists also examined the patients for the Constant-Murley score (CMS)[21] for shoulder function, and the patients completed the visual analogue scale (VAS) for pain.

The demographic data and clinical characteristics of the patients who were either eligible or not eligible for rotator cuff surgery are shown in Table I. The mean pain at rest, during arm activity, and during the night was significantly higher in patients eligible for surgery than in patients who were not eligible for surgery. The median duration of pain prior to recruitment was longer in patients who were eligible for surgery than in patients who were not eligible for surgery. Neither frequency of full-thickness ruptures nor CMS differed between the groups (Table I).

The primary outcome measure was the decision on surgical treatment (yes/no) three months from the preliminary recruitment.

We evaluated the influence of the SF-36 life score domains on eligibility for surgery. SF-36 is a comprehensive short-form generic profile HRQoL patient-reported outcome measure (PROM) yielding eight health concepts, from which four physically and four emotionally and psychosocially orientated health summary scores are derived.[22,23] The physical domains consist of physical functioning related to limitations in physical activity; physical role function, reflecting limitations in daily activities due to physical problems; bodily pain; and general health perception. The emotional and psychosocial domains consist of vitality, dealing with energy and fatigue; social functioning, reflecting limitations in social activity; and emotional role function, reflecting limitations in daily activities due to emotional problems and mental wellbeing. Each category is scored on a scale of 0 to 100, where 0 represents the worst overall health status and 100 the best health status.[24]

We assessed shoulder function (CMS) and pain (VAS) three months following the preliminary recruitment. A VAS (0 to 100, 100 = worst possible pain) score was calculated as the mean value for pain at rest, during arm activity, and at night during the previous week. The study physiotherapists measured shoulder function with the CMS (0 to 100, 100 = best).[21] The pain-free (VAS < 30) shoulder range of motion was measured by a goniometer.[25] With the arm abducted 90°, the maximal isometric shoulder abduction strength was measured. We used a modified method of measuring the strength by calculating the mean of three efforts instead of the best out of three, as described by Constant et al.[21] Abduction

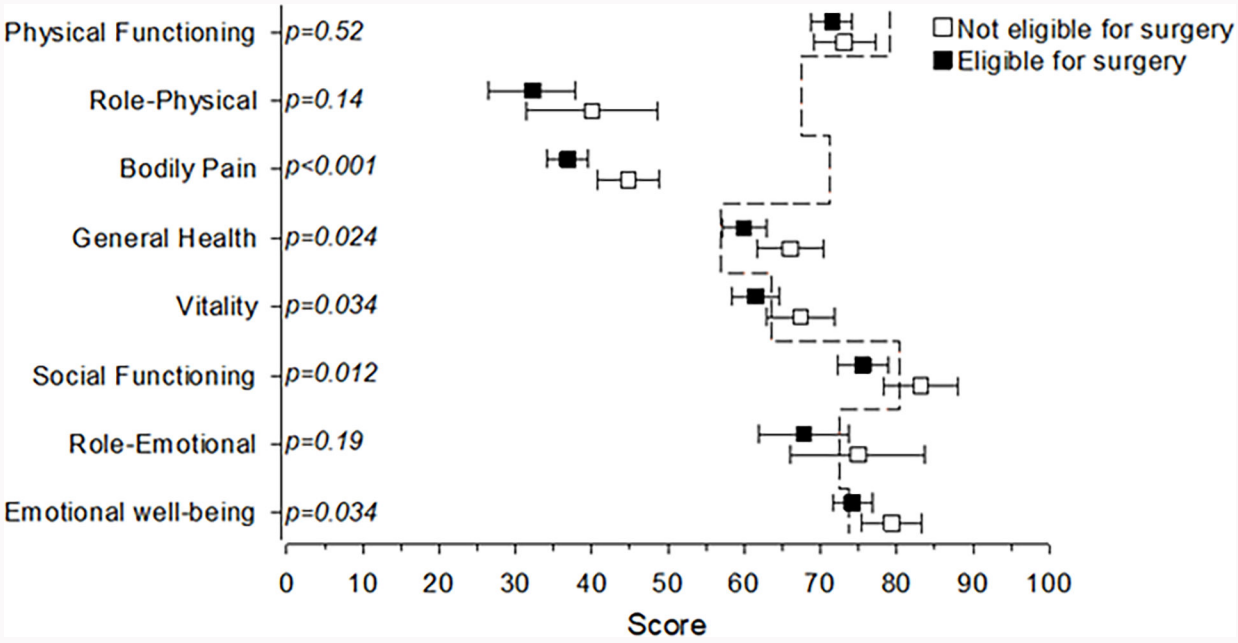

Fig. 2
Domains of the 36-Item Short-Form Health Survey questionnaire (SF-36) quality of life score. p-values (adjusted for sex, age, dominant upper limb, duration of pain, and presence of full-thickness rupture) indicate the difference between the study groups. Whiskers represent 95% CIs. Age- and sex-matched healthy controls from the study by Aalto et al[26] are shown by the dashed line.

strength was rated zero when the patient could not achieve the measuring position at 90° abduction.

Statistical analysis

This study is a data analysis from a previously reported RCT.[5] A separate sample size calculation for this analysis was not feasible. The data are presented as means with SDs, medians with IQRs, or frequencies with percentages. Statistical comparisons between groups were achieved using independent-samples *t*-test or chi-squared test as appropriate. Univariate and multivariate (stepwise, forward selection) logistic regression analyses were performed to identify SF-36 domains associated with eligibility for surgery. The Finnish general population's values on the eight SF-36 domains were weighted to match the sex and age distribution of the study population.[26] Comparison between the study groups and the general population was performed using 95% CIs. Adjusted comparison between the study groups on the eight SF-36 domains was performed using analysis of covariance (ANCOVA). The normality of variables was evaluated graphically and by using the Shapiro-Wilk W-test. The effect size was measured using Cohen's *d*, and simulations were used to calculate post-hoc power. The Stata v. 17.0 (StataCorp, USA) statistical package was used for statistical analyses.

Results

Out of 417 patients, 278 returned the HRQoL questionnaire. Of these, 191 patients were eligible and 87 were no longer eligible for surgery (Figure 1).

The mean Physical Health summary score was 37 (SD 8) for patients who were eligible and 39 (SD 9) for patients not eligible for surgery (p = 0.037, independent-samples *t*-test). The mean Mental Health summary score was 52 (SD 12) for patients eligible for surgery and 55 (SD 10) for patients not eligible for surgery (p = 0.049, independent-samples *t*-test).

The following domains of the SF-36 predicted surgery in univariate analysis: bodily pain, general health, vitality, social functioning, and emotional wellbeing. In multivariate analysis, only bodily pain entered into the model as an associating factor for surgery (Cohen's *d*: 0.45 (95% CI 0.10 to 0.89)) (Table II).

The general population's values on the eight SF-36 domains were compared and weighted to match the sex and age distribution of the study population.[26] The bodily pain score was lower in subjects eligible for surgery than in those who were not eligible (p < 0.001) (estimated post-hoc power 0.89). In addition, the values for general health (p = 0.024), vitality (p = 0.034), social functioning (p = 0.012), and emotional wellbeing (p = 0.034, all ANCOVA) were lower in subjects eligible for surgery than in those who were not eligible. A difference between the study population and general population in domain values was found for physical role, bodily pain, and physical functioning (Figure 2).

Discussion

Our aim was to study whether the HRQoL is associated with eligibility for surgical treatment in patients with RCD. We demonstrated that lower bodily pain on the SF-36 is associated with the decision to undergo surgical treatment for RCD.

The decision to operate is the result of a common understanding between the patient and surgeon. A goal of rotator cuff surgery is to improve the quality of life, which is an important factor when discussing treatment options with patients. Quality of life is an individual's subjective perception of their life situation based on the prevailing cultural context and norms in relation to their own goals, expectations, values,

and interests. It can vary over time and is prone to change in accordance with the patient's life situation.[27]

To the best of our knowledge, the importance of the SF-36 HRQoL questionnaire in choosing treatment options for RCD, including both non-full-thickness and full-thickness tendon lesions, has not been studied previously. SF-36 has been used in a few previous studies to assess HRQoL in patients with full-thickness rotator cuff tear, suggesting that patients' daily activities and sleep are extensively affected by the deficit. Yoo et al[28] found improvement in all domains of the SF-36 in patients with healed and re-torn rotator cuffs after arthroscopic rotator cuff repair, even though the scores in healed patients were significantly higher. Chung et al[29] demonstrated that arthroscopic rotator cuff repair significantly improved patients' HRQoL both physically and mentally. Physical scores were lower in patients with older age, female sex, diabetes, and a low level of sports activity. Mental scores were lower in female patients.[28–32]

Moosmayer et al[13] found the largest within-group improvement in both surgically and non-surgically treated patients at 12 months for the physical component summary score of the SF-36. Neither the physical nor mental health-related scores differed between the groups.

The primary analyses of our previous RCT demonstrated that the quality of life of RCD patients improved after both surgical and non-surgical treatment.[5] We did not observe a significant difference between these groups in intention-to-treat analysis. Subgroup analysis of the RCT suggested that improvement in quality of life 24 months after surgical treatment exceeded non-surgical care regarding the bodily pain domain, but not the other domains.[5] However, structural factors play a limited role in predicting pain and function in patients with rotator cuff tears.[33]

Samsa et al[34] suggested in their literature review that the minimal clinically important difference (MCID) for the SF-36 is typically three to five points. Hays and Morales[22] recommended appropriate caution in interpreting that range, because improvement that does not exceed the MCID may still be worthwhile if it is cheap enough or free to obtain.

The strengths of our study are a relatively large study population of 278 patients who returned the SF-36 HRQoL questionnaire. Our study population consisted of the recruited patients for our previously reported RCT, but the data were collected before randomization. Thus, the population is different and larger than that of the RCT.[5]

The pragmatic approach increases the generalizability of the findings. An additional advantage of our study is that we used outcome measure tools commonly used to evaluate RCD patients. The SF-36 quality of life score is a widely used HRQoL survey instrument and is fast to self-administer. This makes it easy to compare our data with others'. The involvement of multiple orthopaedic surgeons and other doctors and personnel in this multicentre study increases the reliability of the results.

Our study patients did not go through intensively regulated physiotherapy between the preliminary and final recruitment.[5] Instead, non-surgical treatment was pragmatic, meeting each patient's needs and facilities. Many RCTs and treatment guidelines regarding RCD favour long-term active exercise therapy and up to 15 physiotherapy sessions.[6,8] However, this concept was questioned by the GRASP trial, which showed no difference between progressive physiotherapy consisting of six or more sessions and one session with a physiotherapist.[35]

Our research setting can only be applied to determine the eligibility for surgery. Here, we did not study whether the patients were really operated on later or not. We used the CMS, which is prone to measurement errors due to different measuring techniques.[21,36,37] A limitation of the study is that approximately one-third of the 417 recruited candidates failed to return the questionnaire, either completely or partly, especially those who were excluded from randomization to our RCT.

Lower HRQoL, as indicated by the lower bodily pain score on the SF-36, is associated with the decision to undergo surgical treatment in patients with RCD. Therefore, HRQoL should be taken into consideration when choosing treatment methods for RCD.

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Data sharing
The datasets generated and analyzed in the current study are not publicly available due to data protection regulations. Access to data is limited to the researchers who have obtained permission for data processing.

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