

VILNIUS UNIVERSITY

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OPERATIVE TREATMENT OF ROTATOR CUFF TEARS:
EVALUATION OF THE CHANGES OF SHOULDER FUNCTION AND HEALTH-
RELATED QUALITY OF LIFE

Summary of doctoral dissertation
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VILNIAUS UNIVERSITETAS

Sigitas RYLIŠKIS

PETIES SĄNARIO BŪKLĖS IR PACIENTŲ GYVENIMO KOKYBĖS POKYČIŲ
ĮVERTINIMAS GYDANT ROTATORIŲ SAUSGYSLIŲ PLYŠIMUS OPERACINIU
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ABBREVIATIONS

ADL	activities of daily living
ASES	American Shoulder and Elbow Surgeons standardized assessment
cm ²	centimeters squared
CS	Constant scale
ICC	interclass correlation coefficient
mm	millimeters
MRI	Magnetic Resonance Imaging
QoL	health-related quality of life
RCT	chronic rotator cuff tears
SAL	Shoulder activity level
SAS	Shoulder activity scale
SRM	Standardized response means
SF-36v2	Version 2 of the SF-36 Health Survey (standard form)

SF-36v2 subscales for:

PF	physical functioning,
RP	role physical,
BP	bodily pain,
GH	general health,
VT	vitality,
SF	social function,
RE	role emotional,
MH	mental health

SPADI	Shoulder pain and disability index
SSI	Shoulder Severity Index
SST	original version of the Simple Shoulder Test
SST-LT	Lithuanian version of the Simple Shoulder Test
UCLA	University of California at Los Angeles scale
WORC	Western Ontario Rotator Cuff Index

1. INTRODUCTION

1.1. Background

Chronic rotator cuff tears (RCT) are one of the most common pathologies seen in a shoulder surgeon's practice. This pathology is mainly related to degenerative changes in rotator cuff tendons during the aging process and repetitive micro trauma. Some of the patients with RCT are asymptomatic, while others have pain and impairment of shoulder function that cause limitations of activities of daily living (ADL). These patients should be treated either conservatively or operatively depending on duration and severity of the symptoms, general health status and patients expectations. It was determined that operative treatment for RCT is effective. After the anatomical reconstruction of rotator cuff tendons we can expect pain relieve, improvement of the shoulder function and health-related QoL. Previous studies have determined that age, gender, rotator cuff tear size, and medical and social comorbidities are associated with worse preoperative shoulder function and/or health related quality of life (QoL). Worse clinical outcomes after operative treatment were associated with older patients with poor quality of the tendon, fatty degeneration of the muscles and failure to adequately mobilize the tendon. Worse clinical outcomes were also seen for patients with worker's compensation claims and lower preoperative expectations, but medical comorbidities did not affect the final shoulder function. These studies did not evaluate shoulder activity level, which may be important as a prognostic factor for surgical decision-making. Looking for new and better prognostic factors for patients with various shoulder disorders, Brophy et al. developed a shoulder activity scale (SAS) for measuring shoulder activity level (SAL). Developers of the scale hypothesized that SAL could be an important prognostic variable relating to outcome. This variable has not been routinely evaluated and we are not aware of any studies that focused on the SAL as a potential prognostic variable in patients with RCT. Operative treatment of RCT in Lithuania accounts more than 10 years, but after reviewing of the literature we did not found studies about the patients with RCT. We have no data about the changes of shoulder function and health-related QoL after operative treatment of RCT.

During the last three decades there was significant development in the field of outcome measurements in medicine. Since then orthopaedic surgeons started to develop and introduce shoulder joint specific measuring tools for scientific research and clinical practice. The main reason for developing new instruments was the opinion that existing scales have one or more limitations and their use in clinical practice may be problematic. These limitations can be related to instrument's quality (psychometric properties) or/and to the complexity of the instrument. The University of California at Los Angeles (UCLA) shoulder score has been criticized for the development of the instrument without direct patient input, selecting of improper ("double-barreled") items or for the item ("overall satisfaction") that allows the instrument to be used only after the intervention. These problems may lead to poor psychometric properties of the instrument. The Constant (CS) and the American Shoulder and Elbow Surgeons (ASES) shoulder scales require experienced examiner to administer the test, additional instruments to measure range of motion and muscle strength. These scoring systems are time-consuming and may preclude their use in clinical practice.

There are no valid patient-based assessment tools for the shoulder joint in Lithuania. Development of one more new instrument for a small country is unnecessary. This work is not easy and requires considerable investment of both mental and fiscal

resources; it hardly will be better than existing tools and may add more confusion in the literature.

The Simple Shoulder Test (SST) was developed and first published in 1992 as a quick, practical and inexpensive patient-based and joint specific measurement instrument. Test-retest reliability, construct validity, responsiveness of the SST have been studied in several studies and the SST proved to be simple and effective tool for measuring the results of treatment. For this reason we decided to make the SST available for Lithuanian speaking population. Using of simple, valid and widely accepted outcome assessment tool will help us to improve quality of scientific research in shoulder surgery.

1.2. The aim of the study

To evaluate changes of the shoulder function and health-related quality of life after operative treatment of rotator cuff tears.

1.3. Objectives of the study

1. To evaluate shoulder function and health-related QoL for the patients with RCT selected for operative treatment using Constant scale, the Simple Shoulder Test (SST) and SF-36v2.
2. Prospectively evaluate the changes of shoulder function and health-related QoL after repair of full-thickness RCT at the minimum of 12 months follow-up period.
3. To determine the relationship between the shoulder function and health-related QoL, demographic, clinical and structural variables in the preoperative and postoperative patient groups after rotator cuff repair.
4. To determine the relationship between the SAL, demographic, clinical and structural variables in the preoperative patient group and to evaluate prognostic value of the SAL after open rotator cuff repair.
5. To perform cross-cultural adaptation of the SST and to test psychometric properties of the Lithuanian version of the SST in hospitalized and ambulatory patient groups.

1.4. The scientific novelty of the study

This was the first study in Lithuania which included complex evaluation of the patients with RCT before and after operative treatment using well known evaluation instruments (SF-36v2, CS and SST). We prospectively evaluated the changes of shoulder function and health-related QoL after the open rotator cuff repair. This was the first attempt to analyze Shoulder activity level (SAL) in the preoperative assessment of patients with rotator cuff tears. We also evaluated prognostic value of the SAL in operative treatment of patients with RCT. Cross-cultural adaptation of the Simple Shoulder Test was performed and psychometric properties of the Lithuanian version of the SST were established in hospitalized and ambulatory patient groups.

2. MATERIALS AND METHODS

2.1. The study population

The original patient group consisted of 108 prospectively evaluated consecutive patients with chronic rotator cuff tears who were admitted to the hospital for operative treatment between April 2007 and January 2008. The control group consisted of 92 individuals with healthy dominant shoulders which were evaluated using the SST-LT. This group involved patients (n=82) from the same hospital who were treated in different departments (urology, gynecology, traumatology) due to different pathology and individuals from the hospital's staff. This investigation was approved by the research ethics board. Patients were informed about the study and signed an informed consent form. Patients who had a clinical diagnosis of RCT confirmed by MRI, shoulder symptoms that had been present for a minimum of 3 months, and ineffective conservative treatment, were selected for operative treatment. Open surgery was performed for all patients and rehabilitation program was started on the first day after the operation.

All the patients were divided into several separate groups to accomplish five objectives of our study. Preoperative and postoperative status of the patients, evaluation of the psychometric properties of the SST-LT was analyzed separately and data about the patients was referred in the separate tables (Tab. 1, 6 and 11). For evaluation of psychometric properties of the SST-LT we used data collected from 108 preoperative patients. But for analysis of the shoulder function and health-related QoL in the preoperative patient group we had to exclude 2 patients and use data collected from the 106 patients because for these two patients operation findings were not properly documented. Preoperative status was analyzed for the patients with RCT in different stages of the disease. There were patients with partial, full-thickness and massive RCT (n=106). Changes of the shoulder function and health-related QoL were analyzed in postoperative group, which included patients after repair of full-thickness RCT only (n=87). Outcomes for the patients after another kind of operations performed due to partial or massive RCT (subacromial decompression, muscle tendon transfer, n=19, 14.2%) were not analyzed in the present study.

2.2. Methods

Preoperative assessment

Preoperatively, all patients were examined by one operating shoulder surgeon. All items of the Constant scale (CS) (pain, ADL, active external and internal rotation) were evaluated and documented during an interview, and the active range of motion (forward flexion, abduction) was measured with a goniometer. Additionally, shoulder pain was estimated with a 0 – 10 point numerical scale (NS) by patient recall. The abduction strength was measured in the scapular plane with the arm abducted 90° and the elbow extended using the Kern digital dynamometer (Kern & Sohn GmbH, Balingen, Germany. Weighing range Max.15 kg, readout d=20g, reproducibility 20g, linearity 0.5%) following a reliable technique. For statistical analysis of the shoulder strength, we used the mean values of 3 repetitive measurements. For measuring pain, we used the NS scores; for both ADL (0-20 points) and active range of motion (ROM) (0-40 points) we used separate scores from the CS. For evaluation of intratester reliability of the strength measurements we measured shoulder muscle strength of the healthy shoulder for 60 of 106 preoperative patients again after average 13.3 weeks interval. During this period

healthy shoulder developed no changes and remained symptom free. Data from the initial and the second evaluation were compared and ICC was calculated.

For comparison of pathologic and healthy shoulders we composed two control groups. The results of the SST-LT and CS were compared between these groups. For comparison of CS scores we used contralateral (healthy) shoulder of the same patient. For comparison of the SST-LT scores we selected separate control group of individuals (n=92) from the same hospital with healthy dominant shoulders who were treated in different departments (urology, gynecology, traumatology) due to different pathology (n=82), and individuals from the hospital's staff (n=10).

After an observer-based evaluation, all patients completed patient-based questionnaires without assistance. Shoulder function was evaluated using a self-assessment shoulder evaluation tool, the SST, which contains 12 questions. The questions require only "yes" or "no" responses and each question equally weighted at 8.3 points in a 0 - 100 points scale. For assessment of general health status, the patients completed a questionnaire regarding possible medical comorbidities (back pain, hypertension, degenerative joint disease, heart disease, diabetes, peptic ulcer disease, depression, pulmonary disease, cancer, rheumatoid arthritis, kidney problems, liver problems, problems with the blood) and severity of these comorbidities. Patients receiving any financial support from national institutions due to one or more illness were defined as having severe comorbidities. Patients were instructed to mark only those diseases that were still present during the current hospitalization. We did not verify the patients' self-assessment of these comorbidities in any databases or medical records. We measured the SAL using the Shoulder Activity scale. The first part of the scale has numerically scored items, and measures SAL using specific questions about various activities (minimum 0 maximum 20 points in the scale). The other part has two alpha-scored items (sport questions). For statistical analysis, we used the two parts of the scoring system separately.

For evaluation of health-related QoL we used the SF-36v2, which was obtained from the Quality Metric Incorporated Company. The SF-36v2 was developed to measure eight health attributes using eight multi-item subscales. The instrument has two scoring options: 0-100 scoring (transformed scores) and norm-based scoring. For comparison of the SF-36v2 results with these of healthy population we did not compose separate control patient group. We used general population norms of the SF-36v2 to which our results were compared.

A detailed protocol for registering intraoperative findings was developed, and the precise configuration and size of the tear were documented. Open surgery was performed for all patients. The area of the tear (tear size) in centimeters squared was calculated using the base of the tear along the former insertion site times the depth of muscle retraction according to Ellman. Shoulder contracture was documented if the patient under anesthesia had restriction of passive ROM and manipulations before the surgery were performed. Changes of the shoulder function and health-related QoL were analyzed in postoperative patient group, which included patients after repair of full-thickness RCT only (n=91). From this postoperative group we excluded 15 (14.2%) patients who had another kind of operations due to partial or massive RCT (subacromial decompression, muscle tendon transfer). Shoulder function and health-related QoL was evaluated using the same methods as in preoperative assessment. Preoperative and postoperative data were compared and changes of shoulder function and health-related

QoL were established. Postoperative data were also compared with that of control groups. Prognostic value of the SAL, relationship of structural, demographic and clinical variables with outcomes of the treatment was analyzed in postoperative patient group.

All questionnaires were inspected for unanswered items. We detected that 10 patients returned incomplete questionnaires. In each case, the items left unanswered were different. We gave these questionnaires back to the patients, and asked them to review and complete the blank items. After that, we received all questionnaires with no missing data.

Cross-cultural adaptation of the Simple Shoulder Test was performed according to the recommendations of the American Academy of Orthopaedic Surgeons for the cross-cultural adaptation of health status measures. The SST was initially translated from English into the Lithuanian language by two independent translators whose mother tongue was Lithuanian. During this process the translators had task to transform all measures into metric system (i.e. pounds to kilograms, yards to meters, gallons and pints to litres). The first translator was aware of the process, the intent of each item and of the questionnaire as a whole. The other translator was neither aware nor informed of the concepts being quantified and she had no medical background. Two translators and a recording observer prepared one common translation (synthesized version). The back-translations into the original language were produced by two independent translators whose native tongue was English. They used synthesized version of questionnaire and were blind to the original version. They were neither aware of nor informed about the concepts explored in the questionnaire and had no medical background. Our expert committee consisted of a methodologist, orthopaedic surgeons, a language professional and translators. After reviewing the original questionnaire and all translated versions together with written reports, we detected problematic words and phrases that should be revised. In the first and second questions the word "comfortable" may cause confusion, to translate directly for an average Lithuanian person. In order to avoid this polysemantic word the expert committee decided to use simple word "ramus" which is comparable to the English word "calm". After revision of the questions 9 and 10, we had to change "soft ball" to another object. The game Soft ball is not played in Lithuania and nobody knows what a "soft ball" looks like. We decided to replace "soft ball" to "medium sized apple" ("vidutinio dydžio obuolys") because every ordinary Lithuanian person knows what it is. In the questions 8, 9, 10 and 11 the term "extremity" ("galūnė"), which is usually used in scientific language, may not be understood correctly by our patients. We decided to use simple word "ranka" which is analogous word to "upper extremity" and very similar to English word "arm" in order to avoid possible jargon terms in the SST-LT. During transformation of all measures into metric system we made the received numbers round to the nearest whole numbers or to the nearest most suitable numbers for the practical use. We think that this final calculation is acceptable and will not affect the intent of given items because the meanings of received numbers are very close to those cited in the original version of the SST. The expert committee stated that equivalence between the English and the Lithuanian pre-final version of the SST was reached in four areas: semantic, idiomatic, experiential and conceptual equivalence. The Lithuanian pre-final version was tested by 20 Lithuanian speaking persons with rotator cuff injury (n=7), subacromial impingement (n=5), calcifying tendonitis (n=2), arthrosis (n=2), shoulder instability (n=3) and posttraumatic shoulder stiffness (n=1) at the upper extremity clinics. Each person completed the questionnaire and had a short interview.

Each respondent explained how he or she understood the meaning of every item, in what way they were going to perform every activity and if they were familiar with all the objects included in the questionnaire. After testing of the pre-final version we did not make any revisions and concluded that the SST-LT was completed.

Test of the Final version

Testing of psychometric properties of the SST-LT was performed in hospitalized and ambulatory patient Groups A and B (Table 11). Group A consisted of 108 prospectively evaluated consecutive patients diagnosed with chronic rotator cuff tears who were admitted to the hospital for the operative treatment. Eighty patients from the original patient group were evaluated at the follow-up examination from 12 to 18 weeks (mean 13.53) after surgery. These patients were included in the ambulatory patient Group B. Internal consistency and validity of the SST-LT were evaluated for hospitalized patient Group A and ambulatory patient Group B. The content validity was evaluated by calculating floor (the lowest possible score) and ceiling effects (the highest possible score) for the overall SST-LT. The construct validity was tested by comparing the overall SST-LT scores to the overall CS scores, the domain “physical functioning” of the Lithuanian SF-36v2, shoulder related pain, shoulder muscle strength, forward flexion and abduction. We tested six developed hypotheses:

1. Patients with lower CS scores will have lower SST-LT scores.
2. Patients with lower “physical functioning” scores of the Lithuanian SF-36v2 will have lower SST-LT scores.
3. Patients with greater shoulder related pain will have lower SST-LT scores.
4. Patients with less strength of the injured arm will have lower SST-LT scores.
5. Patients with less forward flexion in the injured shoulder will have lower SST-LT scores.
6. Patients with less abduction in the injured shoulder will have lower SST-LT scores.

For hypotheses number 3 to 6 testing we used separated scores from the CS for the pain, shoulder strength, forward flexion and abduction. In Group A we tested validity of the separate strength questions (No. 5-7) of the SST-LT. Every positive response to each question was nominated for one (1) point and negative response to question for zero (0) point. The final strength score was calculated by summing received strength points (minimum 0 points and maximum 3 strength points). We developed additional construction: patients who responded positively to more strength questions and received more strength points will have higher shoulder muscle strength measurements with digital dynamometer. Test-retest reliability was calculated for Group C (Table 11) which included 63 patients from the original patient group who completed the SST-LT again at the next day (one day interval).

2.3. Statistical analysis

For statistical analysis, we used the raw CS scores (0–100 point scoring) without adaptation to the patient's age and gender, 0-100 point scoring for the SST and 0–100 point scoring (transformed scores) for the SF-36v2. Descriptive data are presented as a mean and standard deviation. Two independent samples were compared using common Student's t test. If variables did not follow a normal distribution, a non parametric Mann-Whitney test was used. The categorical data were analyzed using Chi-square or Fisher's exact tests. A stepwise linear regression analysis was used to determine relationship between dependent and independent variables in both preoperative and postoperative patient groups. We developed several separate models where we evaluated relationship between dependant (SAL, CS, SST-LT, SF-36v2) and independent variables (the age, gender, duration of symptoms, shoulder contracture, tear size, the number and the presence of severe medical comorbidities, participation in sports). Independent predictor entered the model if its significance was less than 0.05. Correlations of age with parameters of interest were examined using the Spearman correlation test. The same test was used to determine correlation significance for all constructs in establishing construct validity of the SST-LT. Cronbach's alpha, item-total correlations and item-removal analysis were used to assess internal consistency of the SST-LT. The intraclass correlation coefficient (ICC) with 95% confidence interval was determined for test-retest reliability of the overall SST-LT and intratester reliability of the shoulder muscle strength measurements. The level of significance was set at $p=0.05$. Responsiveness of the SST-LT, CS and SF-36v2 was established by calculating Standardized response means (SRM) using formula: SRM = Mean postoperative scale – Mean preoperative scale)/Standard deviation of the change in the scale. All data analyses were performed with SPSS software (version 16.0 for Windows; SPSS, Chicago, IL).

3. RESULTS

3.1. Characteristics of the study population

We evaluated 106 patients selected for operative treatment (preoperative group) and 92 individuals with healthy dominant shoulders (control SST-LT group). Control SST-LT group consisted of 82 patients treated in different departments due to different pathology in the same hospital (traumatology department n = 41, toxicology n = 10, urology n = 9, abdominal surgery n = 7, LOR n = 5, vascular surgery n = 5, plastic surgery n = 4, gynecology n = 1) and 10 individuals from the hospitals staff. These patients were evaluated using the SST-LT. For evaluation of intratester reliability we examined 60 patients of the preoperative group (Table 1).

Table 1. Patient groups for evaluation of preoperative shoulder function and intratester reliability of strength measurements

Parameter	Preoperative group	Intratester reliability of strength measurements (healthy shoulder)	Control SST-LT group (healthy shoulder)
n	106	60	92
Gender [n (%)]: Males Females	65 (61,3) 41 (38,7)	38 (63,3) 22 (36,7)	50 (54,3) 42 (45,7)
Age (years): Mean Minimum Maximum SD	56,4 33 78 9,7	55,6 33 68 8,64	57,5 33 80 12,8
Rotator cuff tears [n (%)]: Full-thickness Partial Massive	91 (85,8) 11 (10,4) 4 (3,8)		

SST-LT – Lithuanian version of the Simple Shoulder Test, SN – standard deviation

3.2. Shoulder function and health-related QoL in the preoperative patient group

Constant scale

There was significant difference in the overall scores of the CS and scores of the separate subscales between pathological and control (healthy) shoulders ($p < 0.001$)(Table 2).

Table 2 The results of pathological and control (healthy) shoulders evaluated using Constant scale*

Parameter	Preoperative patient group (n = 106)		p value
	Pathologic shoulder	Control (healthy) shoulder	
Pain: (0 – 10 point scale)	5.6 ± 1.9 (range 1.3-10.0)	0.0	< 0.001
Activities of daily living (0 – 20 point scale)	7.41 ± 4.3 (range 0.0 – 18.0)	19.6 ± 1.3 (range 14.0 – 20.0)	< 0.001
Active range of motion (0-40 point scale)	23.2 ± 11.2 (range 0.0 – 40.0)	38.4 ± 3.4 (range 20.0 – 40.0)	< 0.001
Strength (kg)	3.1 ± 2.62 (range 0.0 – 10.3)	7.0 ± 2.8 (range 2.1 -13.7)	< 0.001
Total Constant score (0 -100 point scale)	43.0 ± 19.0 (range 0.0 – 80.0)	87.1 ± 9.1 (range 52.0 – 100.0)	< 0.001

*The results are reported as mean and standard deviation

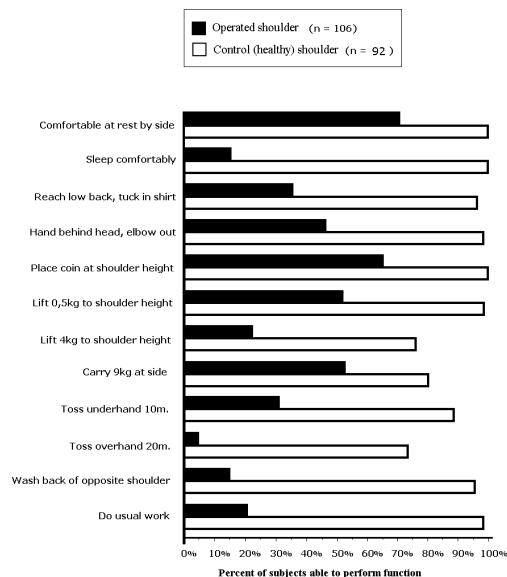
Intratester reliability of the shoulder muscle strength

The initial measurements of the contralateral (healthy) shoulder muscle strength were (the mean and standard deviation) 7.10 ± 2.90 kg (range 0.00 – 13.04 kg), and the repeated measurements were 7.38 ± 2.89 kg (range 0.00 – 13.54 kg). The ICC between the two measurements was 0,951 [95% CI; 0,918–0,971].

Simple Shoulder Test - LT

The mean score and standard deviation for the SST was 36 ± 21.4 points (range 0 - 92) and in the control group 92 ± 11.23 (range 33.3 - 100.0 points). Differences of the total SST-LT scores and scores for the separate twelve items between two groups were significant ($p < 0,001$) (Fig. 1). There were no significant differences in gender ($p = 0.351$) and age ($p = 0.556$) between preoperative and control patient groups.

Fig. 1 Bar graph represents differences in responses between preoperative ($n = 106$) and control (healthy) shoulders ($n = 92$) evaluated using the Simple Shoulder Test - LT. Differences between the results of separate 12 items in both groups were significant ($p < 0,001$).



Health-related QoL

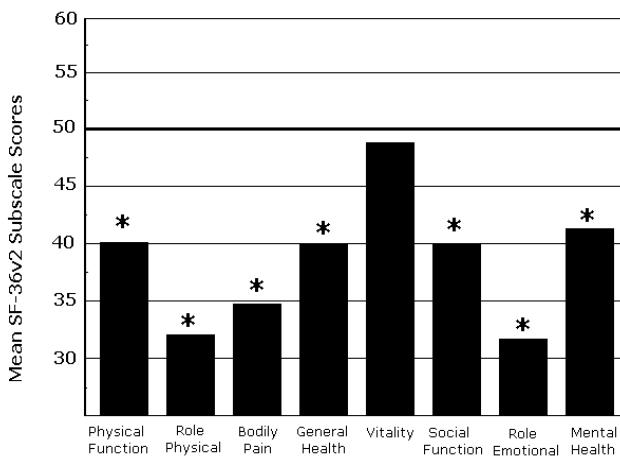
The transformed and norm-based scores for separate eight subscales of the SF-36v2 for preoperative patient group are reported in Table 3. Norm-based scores of our patient group and those of age and gender matched general population controls were significantly different ($p < 0,001$), except subscale VT where the difference was not significant (Fig 2).

Table 3. The transformed and norm-based scores for separate eight subscales of the SF-36v2 for preoperative patient group ($n=106$) with rotator cuff tears*

Parameter	0-100 point scoring (transformed score)	Norm-based scoring
Physical function	$60,05 \pm 20,41$	$40,22 \pm 8,59$
Role physical	$36,62 \pm 21,26$	$32,02 \pm 8,33$
Bodily pain	$35,40 \pm 17,89$	$34,82 \pm 7,56$
General health	$50,17 \pm 19,02$	$40,14 \pm 9,07$
Vitality	$56,13 \pm 22,29$	$48,91 \pm 11,14$
Social function	$61,79 \pm 25,87$	$40,18 \pm 11,29$
Role emotional	$48,03 \pm 25,13$	$31,64 \pm 11,72$
Mental health	$59,81 \pm 22,38$	$41,45 \pm 12,60$

*The results are reported as mean and standard deviation

Fig 2. Bar graph showing the mean Short Form-36v2 subscale scores calculated using norm-based scoring for the preoperative patients with rotator cuff tears (n=106). The horizontal line at 50 points represents the general population mean score in each subscale, and the asterisks indicate significant differences between the groups ($p < 0,001$)



General health status in the preoperative patient group

Seventy - seven (72.6%) patients [46 males (60%)] had one or more medical comorbidities and 20 (18.9%) patients (10 males) had severe comorbidities and received financial support from the state institutions. The frequency of self-reported medical comorbidities for our preoperative patient group is reported in Table 4.

Table 4. Frequency of self-reported medical comorbidities for 106 patients with rotator cuff tears

Comorbidity	No. (%) of patients
Back pain	51 (48.1)
Hypertension	45 (42.5)
Degenerative joint disease	20 (18.9)
Coronary heart disease	15 (14.2)
Diabetes	9 (8.5)
Peptic ulcer disease	3 (2.8)
Depression	12 (11.3)
Pulmonary disease	8 (7.5)
Cancer	0
Rheumatoid arthritis	1 (0.9)
Kidney problems	5 (4.7)
Liver problems	2 (1.9)
Blood problems	1 (0.9)

Pathology

The mean duration of symptoms was 19.6 ± 57.8 months (range 3 – 444, median 6 months). The mean size of the tear was $5.6 \pm 5.8 \text{ cm}^2$ (range 0–24 cm^2). There were 91 (85.8%) patients whose shoulders had full-thickness tendon tears, 11 (10.4%) with partial and 4 (3.8%) with massive tears. Eighteen (17%) patients had shoulder contracture.

3.3. Shoulder activity level in the preoperative assessment of patients with rotator cuff tears

The mean score and standard deviation for the SAL in the overall patient group was 10.7 ± 5.39 . Seventeen (16%) patients were involved in sports (16 males and 1 female). One patient was a professional athlete, four others participated in sports with organized officiating, and the remaining twelve patients participated in sports only occasionally.

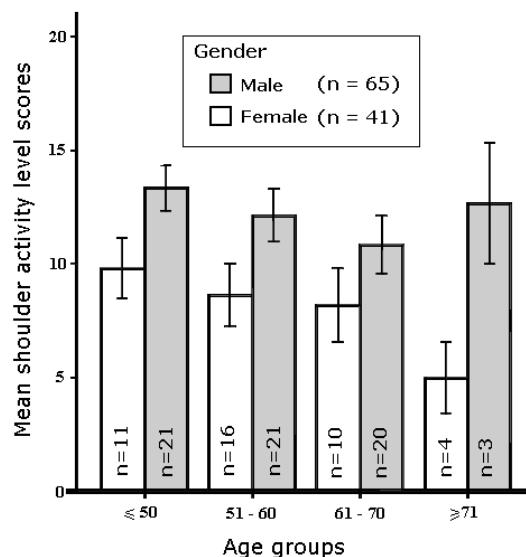
Multivariate regression analysis revealed positive association of the SAL with male gender and negative associations with the presence of severe comorbidities and age. Data (the final step) from the multivariate regression analysis is reported in Table 5. Distribution of the SAL scores by gender and age is demonstrated in Fig. 3.

Table 5. Data from the multivariate regression analysis

Dependent variable	Independent variable	Regression coefficient	β	p value
Shoulder activity level [$R^2 = 0.207$, adjusted $R^2 = 0.183$, $p_{\text{ANOVA}} < 0.001$]	Male gender	3.264	0.297	0.001
	Severe comorbidities	-3.150	-0.230	0.012
	Age (years)	-0.102	-0.183	0.043

R – coefficient of determination, β – standardized linear regression coefficient

Fig. 3 Bar graph showing distribution of the mean shoulder activity level scores by gender and age. The error bars represent one standard deviation.



After stratifying the patient group according to gender we determined that the SAL scores were lower for female patients ($p < 0.001$) than for males. The mean score and standard deviation for the SAL in female patient group was 8.5 ± 4.9 and in male patient group was 12.1 ± 5.2 . Additional analysis of the male patient group revealed that the SAL scores were not significantly higher for those patients who were active in sports than those for sedentary patients ($p = 0.261$) which is the rationale for the additional alpha sports score. Male patients had higher the SF-36v2 scores for health-related QoL (Fig. 4), higher total SST scores for shoulder function ($p < 0.001$) (Fig. 5) and shorter duration of symptoms ($p = 0.002$) than females. We found that females had lower shoulder strength than males ($p < 0.001$) and this was the only subscale in the CS which differed between males and females. There were no differences in the total CS scores between males and females ($p = 0.142$).

Fig. 4 Bar graph showing the mean Short Form-36v2 subscale scores for males (n = 65) and females (n = 41) with rotator cuff tears.

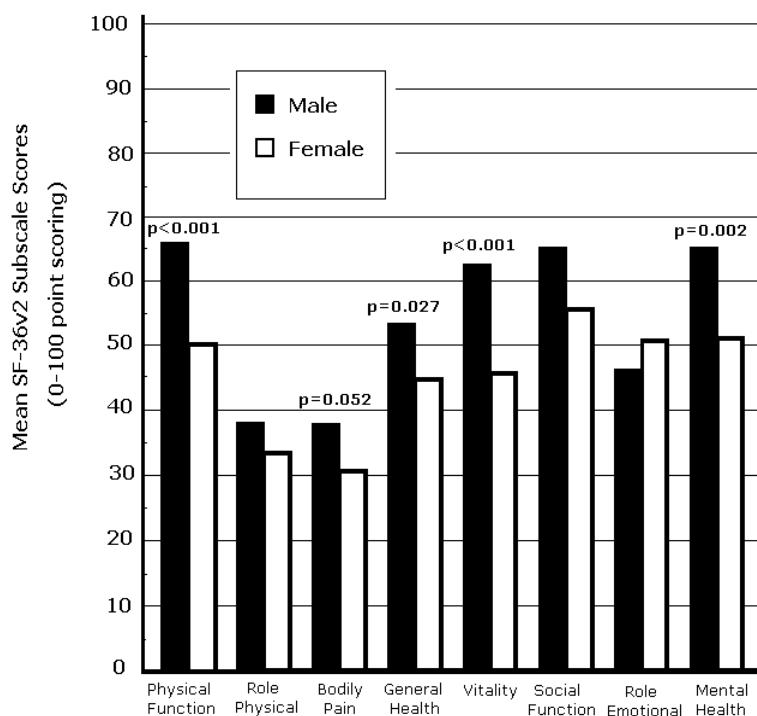
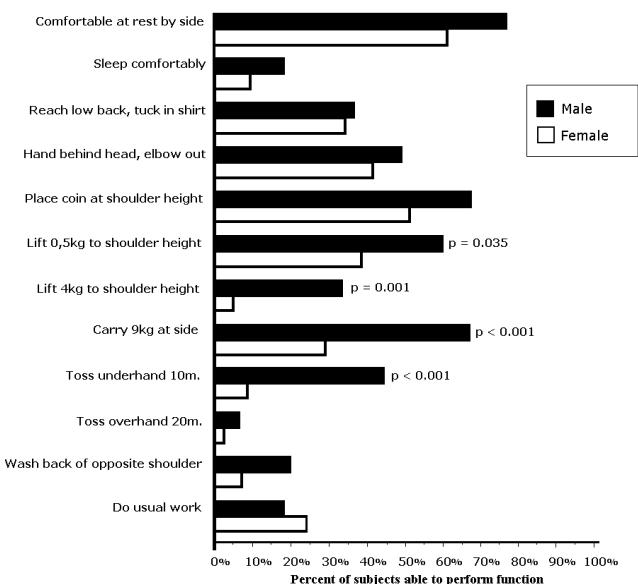


Fig. 5 Bar graph represents differences in responses between males (n = 65) and females (n = 41) to the 12 items of the Simple Shoulder Test.



The twenty patients with severe comorbidities had lower SAL scores ($p = 0.005$) than those who had no such comorbidities (the mean and standard deviation for the SAL was 7.5 ± 6.16 versus 11.4 ± 4.94). They also had longer duration of symptoms ($p = 0.027$) and worse scores on all eight subscales of the SF-36v2 [PF, GH and VT ($p < 0.001$); SF ($p = 0.001$); RP ($p = 0.007$); MH ($p = 0.005$); RE ($p = 0.025$) and BP ($p = 0.040$)], but did not have significant differences between the SST ($p = 0.175$) and the CS ($p = 0.583$) scores. Patient age ($p = 0.098$) and gender ($p = 0.248$) were not significantly different between patients who did or who did not have severe comorbidities.

Patient age correlated with the SAL ($\rho = -0.208$; $p = 0.033$) but not with the duration of symptoms ($\rho = 0.076$, $p = 0.437$), the total CS scores ($\rho = -0.021$; $p = 0.831$) or the total SST scores ($\rho = -0.093$; $p = 0.344$) for shoulder function. There was a correlation with subscale GH of the SF-36v2 ($\rho = -0.246$; $p = 0.011$) for health-related QoL.

Relationship of demographic, structural and clinical parameters with preoperative shoulder function and health-related QoL

We developed ten separate regression models where we evaluated relationship between dependant (CS, SST-LT, separate subscales of the SF-36v2) and independent variables (the age, gender, duration of symptoms, shoulder contracture, tear size, the number and the presence of severe medical comorbidities, participation in sports). We determined that male gender, shoulder contracture and severe medical comorbidities were essential variables related with shoulder function and health-related QoL.

3.4. Shoulder function and quality of life after operative treatment

We had 91 patients operated due to full-thickness rotator cuff tears. Two patients refused to arrive for follow-up examination because of tight business schedule and other two patients because of worsening of their general health status. Postoperative status was evaluated for 87 (95.6%) patients after the average follow-up time for 13.6 months (from

12 to 23 months). Demographic structural and clinical data about postoperative patient group is reported in Table 6, and the frequency of self-reported medical comorbidities is reported in Table 7.

Table 6. Demographic, structural and clinical data for 87 patients operated for full-thickness rotator cuff tears

Parameter	Patients with full-thickness rotator cuff tears (n=87)
Gender [n (%)]	M:F = 51 (58.6): 36 (41.4)
Age (years)	56.2 ± 9.4 (range 33 - 78)
Dominant shoulder [n (%)]:	Dominant : nondominant 54(62.1): 33(37.9)
Duration of the symptoms (months)	22.04 ± 63.56 (range 3 - 444) mediana 6
Tear size (cm ²):	5.23 ± 5.33 (range 0.25 – 24.0) mediana 3
Shoulder contracture [n (%)]:	13 (14.9)
Shoulder activity level (points)	11 ± 5.19
Sports involvement [n (%)]:	15 (17.2)
Patients with medical comorbidities [n(%)]:	62 (71.3)
Patients with severe comorbidities (receiving financial support) [n(%)]:	14 (16.1)

Table 7. Frequency of self-reported medical comorbidities for 87 patients with full-thickness rotator cuff tears

Comorbidity	No. (%) of patients
Back pain	42 (48.3)
Hypertension	35 (40.2)
Degenerative joint disease	14 (16.1)
Coronary heart disease	12 (13.8)
Diabetes	8 (9.2)
Peptic ulcer disease	3 (3.4)
Depression	11 (12.6)
Pulmonary disease	7 (8.0)
Cancer	0
Rheumatoid arthritis	1 (1.1)
Kidney problems	5 (5.7)
Liver problems	2 (2.3)
Blood problems	1 (1.1)

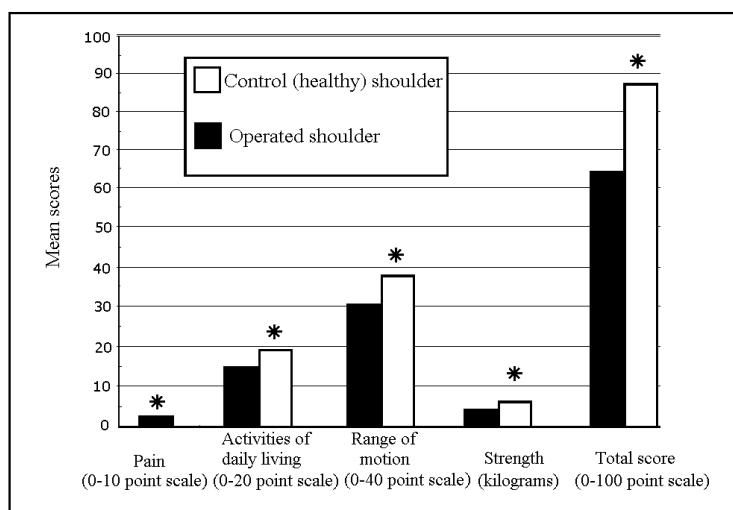
Changes of the shoulder function Constant scale

We compared preoperative and postoperative results of the CS and found significant difference between the total CS scores and scores for all separate CS subscales (Table 8). The similar results were revealed after comparison of postoperative results of the CS with the results of control group (Fig 6). After evaluation of the preoperative and postoperative CS results we determined significant clinical change of the CS. Standardized response means (SRM) was high (0.88).

Table 8. Comparison of the preoperative and postoperative results of the CS for 87 patients with full-thickness rotator cuff tears. All results are reported as mean and standard deviation

Parameter	Constant score		p value
	Preoperative	Postoperative	
Pain (0 – 10 point scale)	5.7 ± 1.9	2.5 ± 2.2	< 0.001
Activities of daily living (0 – 20 point scale)	7.3 ± 4.4	15.3 ± 5.59	< 0.001
Active range of motion (0-40 point scale)	23.3 ± 11.2	30.4 ± 10.0	< 0.001
Strength (kg)	3.1 ± 2.6	4.3 ± 2.5	0.003
Total Constant score (0 -100 point scale)	42.8 ± 19.2	64.8 ± 20.1	< 0.001

Fig 6. The Constant scores for postoperative and control groups.



*All p values < 0,001

Simple Shoulder Test

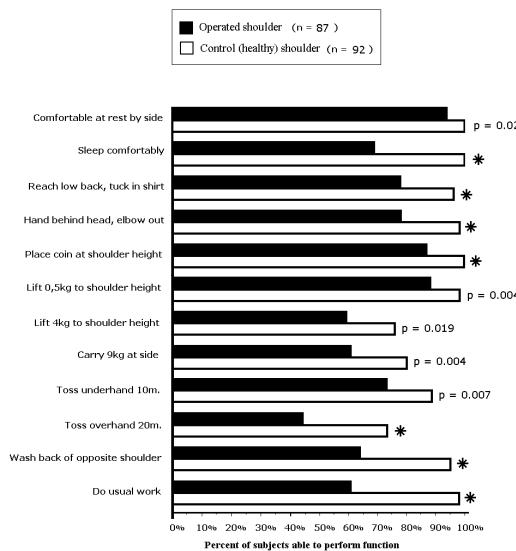
We compared preoperative and postoperative results of the SST-LT and found significant difference between the total SST-LT scores and scores for all separate twelve items ($p < 0.001$)(Table 9). Before operation and after the operation the results of the SST-LT were (mean and standard deviation) 35.9 ± 21.04 and 71.6 ± 28.85 . The similar results were revealed after comparison of postoperative results of the SST-LT with the results of control group (Fig. 7). After evaluation of the preoperative and postoperative SST-LT results we determined significant clinical change of the SST-LT. Standardized response means (SRM) was high (1.11).

Table 9. Evaluation of preoperative and postoperative shoulder function using the Simple Shoulder Test – LT (n = 87)

Number of the SST-LT question	Positive responses (%)		p value
	Preoperative	Postoperative	
1.	60 (69.0)	82 (94.3)	< 0.001
2.	11 (12.6)	60 (69.0)	< 0.001
3.	34 (33.1)	68 (78.2)	< 0.001
4.	41 (47.1)	68 (78.2)	< 0.001
5.	56 (64.4)	76 (87.4)	< 0.001
6.	45 (51.7)	77 (88.5)	< 0.001
7.	18 (20.7)	52 (59.8)	< 0.001
8.	46 (52.9)	53 (60.9)	< 0.001
9.	28 (32.2)	64 (73.6)	< 0.001
10.	4 (4.6)	39 (44.9)	< 0.001
11.	14 (16.1)	56 (64.4)	< 0.001
12.	18 (20.7)	53 (60.9)	< 0.001

SST-LT – Lithuanian version of the Simple Shoulder Test

Fig. 7 Bar graph represents differences in responses between postoperative ($n = 87$) patient group and control group ($n = 92$) to the 12 items of the Simple Shoulder Test-LT, and the asterisks indicate significant differences between the groups ($p < 0.001$)



Changes of the health-related quality of life

We compared preoperative and postoperative results of the SF-36v2 and found significant difference between the scores for all separate 8 subscales. After evaluation of the preoperative and postoperative results we determined different clinical changes for separate 8 subscales of the SF-36v2. Calculated Standardized response means ranged from small (0.36) to high (0.98) (Table 10).

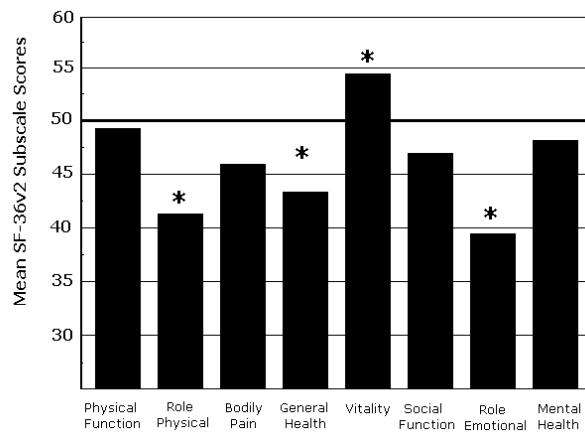
Table 10. The results of eight separate subscales of the SF-36v2 before and after the operation. Comparison of the SF-36v2 results and clinical change for all subscales

Parameter	Patients with full-thickness rotator cuff tears* (n=87)			Clinical change
	Preoperative	Postoperative	p value	SRM
Physical function	60.97 ± 19.48	79.42 ± 20.38	< 0.001	0.78
Role physical	37.78 ± 21.13	60.70 ± 27.57	< 0.001	0.73
Bodily pain	33.81 ± 15.37	61.88 ± 25.43	< 0.001	0.98
General health	51.21 ± 18.78	57.88 ± 20.04	0.025	0.36
Vitality	56.96 ± 21.97	67.02 ± 18.59	0.002	0.44
Social function	63.50 ± 25.66	77.44 ± 21.21	< 0.001	0.51
Role emotional	49.61 ± 25.47	64.75 ± 26.61	< 0.001	0.45
Mental health	61.09 ± 21.15	71.58 ± 19.45	0.001	0.51

*Values are given as the mean and standard deviation in the 0-100 point scoring (without adaptation to patients' gender and age). SRM – Standardized response means

After comparison of postoperative results of the SF-36v2 with the results of age and gender matched general population controls we revealed significant difference for four subscales ($p < 0.001$)(Fig. 8).

Fig. 8 Bar graph showing the mean Short Form-36v2 subscale scores calculated using norm-based scoring for the postoperative patients with rotator cuff tears (n=87). The horizontal line at 50 points represents the general population mean score in each subscale, and the asterisks indicate significant differences between the groups ($p < 0.001$)



Prognostic value of the Shoulder activity level

We developed regression model where we evaluated relationship between preoperative SAL scores (dependant) and the age, gender, duration of symptoms, shoulder contracture, tear size, the number and the presence of severe medical comorbidities, participation in sports, postoperative results of the CS, SST-LT and SF-36v2 (independent variables). Multivariate regression analysis ($R^2 = 0,132$, *adjusted R*² = 0,122, $p_{ANOVA} < 0,001$), revealed positive relationship of the SAL with subscale PF of the SF-36v2 (regression coefficient 0,092, standardized regression coefficient $\beta = 0,363$; $p = 0,001$).

Relationship of demographic, structural and clinical parameters with postoperative shoulder function and health-related QoL

We developed ten separate regression models where we evaluated relationship between dependant (CS, SST-LT, separate subscales of the SF-36v2) and independent variables (the age, gender, duration of symptoms, shoulder contracture, tear size, the number and the presence of severe medical comorbidities, participation in sports). We determined that severe medical comorbidities and sports participation was associated with the outcomes (shoulder function and health-related QoL).

Having determined that sports and severe medical comorbidities were associated with outcomes we stratified patient group in to three subgroups (patients with severe comorbidities (n=14), patients involved in sports (n=15) and general group (n=58), where we calculated SRM for all these subgroups separately. We determined that in sports and general groups the SRM for the CS and SST-LT was large but for patients with severe comorbidities SRM was small (Fig. 9). SRM for SF-36v2 was also different in these three patient subgroups (Fig. 10).

Fig. 9 Differences in Standardized response means for the Constant and the Simple Shoulder Test scores between three patient groups after operative treatment for full-thickness rotator cuff tears

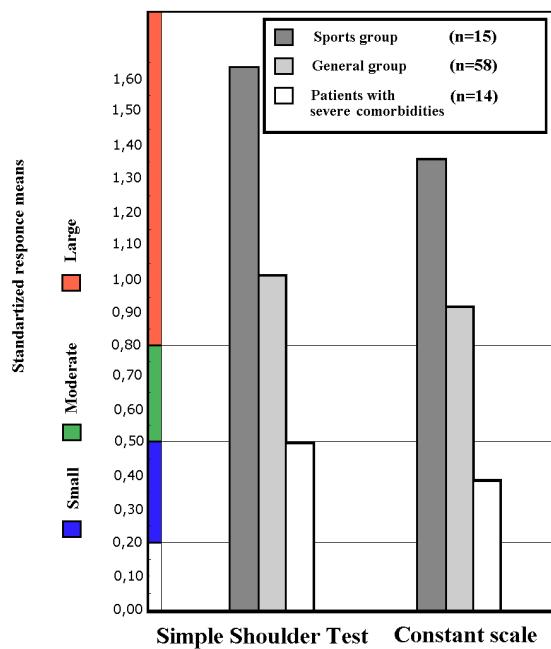
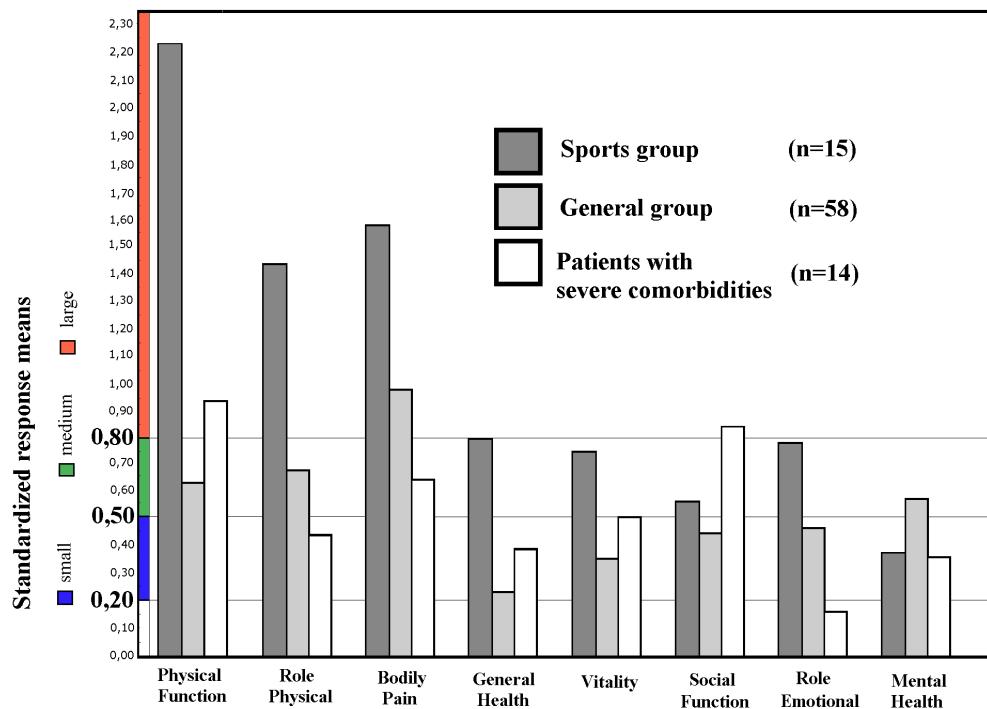


Fig. 10 Differences in Standardized response means for the separate eight subscale scores of the SF-36v2 between three patient groups after operative treatment for full-thickness rotator cuff tears



3.5. Psychometric properties of the Lithuanian version of the Simple Shoulder Test

Psychometric properties of the SST-LT were analyzed in hospitalized patient group selected for operative treatment for RCT (Group A and C) and ambulatory patients (Group B) evaluated at the follow-up examination from 12 to 18 weeks (mean 13.53) after surgery (Table 11). Table 12 summarizes data of the SST-LT, CS and PF scores of the SF-36v2.

Table 11. Group demographics and type of rotator cuff injury

Parameters	Group A (hospitalized)	Group B (ambulatory)	Group C (test-retest)
n	108	80	63
Gender [n (%)]:			
Male	67 (62.0)	53 (66.3)	39 (61.9)
Female	41 (38.0)	27 (33.8)	24 (38.1)
Age (years):			
Mean	56.5	56.3	57.6
Minimum	33	33	39
Maximum	78	78	78
Std. deviation	9.6	9.0	8.9
Rotator cuff tear [n (%)]:			
Full-thickness	90 (83.3)	71 (88.8)	53 (84.1)
Partial	14 (13.0)	6 (7.5)	6 (9.5)
Massive	4 (3.7)	3 (3.8)	4 (6.4)

Table 12. Scores for the two groups of patients evaluated using the shoulder joint-specific and generic health instruments

Assessment tool	Scores	Group A (n=108)	Group B (n=80)
Simple Shoulder Test-LT	Mean Minimum Maximum Std. deviation	34.88 0.0 83.33 21.68	56.67 0.0 100.0 27.54
Constant scoring Scale	Mean Minimum Maximum Std. deviation	42.89 0.00 80.00 18.9	51.50 9.00 90.00 19.7
Subscales for: Pain	Mean Std. deviation	5.80 2.70	9.33 3.16
Forward flexion	Mean Std. deviation	6.70 2.9	7.38 2.37
Abduction	Mean Std. deviation	6.14 3.00	6.75 2.47
Strength	Mean Std. deviation	6.42 5.45	6.76 4.3
Physical functioning (Lithuanian SF-36v2)	Mean Std. deviation	60.04 20.21	73.19 20.67

There were no significant differences in age (0.019, p=0.890), gender (0.350, p=0.555) and pathology (0.411, p=0.522) between Group A and B. The Cronbach's alpha in Group A was 0.722. Analysis of the item – total correlation revealed that the question number 1 and 2 had very low correlation (0.210 and 0.128) with the total SST-LT score. After item-removal analysis and deleting items number 1 and 2 from the SST-LT Cronbach's alpha increased to 0.724 and 0.729. The Cronbach's alpha in Group B was 0.844. Question number 1 had the lowest correlation (0.326) with the total SST-LT score. After deleting this item from the scale Cronbach's alpha remained unchanged (Table 13). The ICC between the two tests in Group C was 0.96 with the 95% confidence interval (0.94-0.98).

Table 13. Item-total analysis of the Simple Shoulder Test-LT

The SST-LT questions	Group A (n=108)		Group B (n=80)	
	Item-total correlations	Cronbach's alpha if item deleted	Item-total correlations	Cronbach's alpha if item deleted
1.	0.210	0.724	0.326	0.844
2.	0.128	0.729	0.515	0.832
3.	0.321	0.709	0.600	0.825
4.	0.472	0.686	0.561	0.829
5.	0.540	0.675	0.467	0.836
6.	0.470	0.686	0.515	0.833
7.	0.520	0.682	0.552	0.829
8.	0.258	0.719	0.464	0.836
9.	0.444	0.691	0.580	0.827
10.	0.259	0.718	0.528	0.832
11.	0.390	0.701	0.563	0.828
12.	0.256	0.716	0.462	0.837

SST-LT - Lithuanian version of the Simple Shoulder Test

In Group A seven patients had the lowest (floor effect 6.5%) and no one patient had the highest possible score in the SST (ceiling effect 0.0%). In Group B one patient had the lowest (floor effect 1.3%) and 7 patients had the highest possible score in the SST (ceiling effect 8.8%). In both patient groups correlations by construct were moderate (from 0.506 to 0.786 ($p<0.001$) except two cases: 1) correlation was high ($\rho=0.881$, $p<0.001$) with the shoulder joint specific instrument CS in the patient Group B and 2) correlation was weak ($\rho=0.492$, $p<0.001$) with domain "physical functioning" of the Lithuanian SF-36v2 in Group A. All correlations in Group B were higher (from 0.607 to 0.881, $p<0.001$) than those in Group A (from 0.492 to 0.735, $p<0.001$) (Table 14).

Table 14. Correlations by construct with the overall scores of the Simple Shoulder Test-LT

Constructs	Group A (n=108)	Group B (n=80)
1. Constant score	0.730	0.881
2. Physical Functioning (Lithuanian SF-36v2)	0.492	0.715
3. Pain	0.506	0.607
4. Strength	0.610	0.611
5. Forward flexion	0.580	0.786
6. Abduction	0.535	0.765

Spearman correlation, all p values <0.001

During the testing of additional construction related to the SST-LT strength questions No. 5-7, we determined, that observer-based strength measurements with digital dynamometer showed a moderate correlations with the results of separate three questions ($\rho = 0.527$, $\rho = 0.632$, $\rho = 0.527$, all p values < 0.001) and with the total shoulder strength score ($\rho = 0.702$; $p < 0.001$). All three questions had better ability to measure shoulder strength than every separate question alone.

4. CONCLUSIONS

1. Patients with rotator cuff tears had worse scores for the shoulder function and health-related quality of life.
2. We determined significant improvement in shoulder function and health-related quality of life after rotator cuff repair at the minimum of 12 months follow-up, but shoulder function did not reach the level of healthy (control) shoulders.
3. In the preoperative patient group, shoulder function and health-related quality of life was associated with male gender, shoulder contracture and severe comorbidities, but in the postoperative patient group association was determined with severe comorbidities, sports involvement and duration of the symptoms.
4. In the preoperative patient group, Shoulder activity level had relationship with patient gender, general health status and age, and in the postoperative patient group such relationship was determined with subscale Role physical of the SF-36v2. Shoulder activity level was not prognostic variable associated with shoulder function.
5. The Lithuanian version of the Simple Shoulder Test can be used as joint specific self-assessment tool in a population of individuals with rotator cuff tears.

LIST OF PUBLICATIONS ON THE TOPIC OF THE DISSERTATION

1. Ryliskis S, Brophy RH, Kocius M, Marx RG. Shoulder activity level in the preoperative assessment of patients with rotator cuff tears. *Knee Surg Sports Traumatol Arthrosc* 2009 September 3. Doi: 10.1007/s00167-009-0904-z.
2. Ryliskis S, Piesina E, Kocius M, Marx RG. Cross-cultural adaptation and psychometric properties of the Lithuanian version of the Simple Shoulder Test. *Acta Medica Lituanica*. 2008; 15: 163–168.
3. Ryliskis S, Kocius M, Marx RG. Paciento įvertintos ir tyrejo išmatuotos peties raumenų jėgos palyginimas. *Lietuvos chirurgija*. 2008; 6: 216–222.
4. Broga R, Ryliškis S. Peties sukamujų raumenų plyšimų operacinis gydymas. *Medicinos teorija ir praktika* 2002; 31: 206–209.

CONCISE INFORMATION ABOUT THE AUTHOR

Education

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PhD studies at Vilnius University Faculty of Medicine, Clinic of Rheumatology, Orthopaedics and traumatology and Reconstructive surgery

1998 – 2002

Orthopaedic and traumatology residency in Vilnius University Emergency Hospital

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Primary residency in Vilnius University “Red Cross” Hospital

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Medicine studies at Vilnius University Faculty of Medicine

Work experience

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Orthopaedic and trauma surgeon in Vilnius University Emergency Hospital

1998 – 1999

Doctor’s assistant in Vilnius University Emergency Hospital

RESUME IN LITHUANIAN

Peties sānario būklēs ir pacientų gyvenimo kokybēs pokyčių īvertinimas gydant rotatorių sausgyslių plyšimus operaciniu būdu

ĮVADAS

Viena dažniausiai peties sānario ligų, su kuria susiduria chirurgai ortopedai, yra rotatorių sausgyslių plyšimai (RSP). Tyrimai rodo, kad RSP dažniausiai susiję su peties sānario amžiniai degeneraciniai pakitimai. Autopsijų duomenimis, 39% žmonių, vyresnių negu 60 metų, ir 73% žmonių, vyresnių negu 70 metų, turi RSP. Klinikinėse studijose, tyrusiose asimptominius pacientus, nustatyta 23% sausgyslių plyšimų atvejų nuo 50 iki 59 metų amžiaus grupėje ir 51% vyresnių nei 80 metų amžiaus grupėje. Jaunesniems negu 40 metų amžiaus žmonėms RSP diagnozuojama rečiau. Ši patologija daugiau siejama su sausgyslių pasikartojančiu fiziniu perkrovimu ir mikrotraumavimu (sportas, sunkus fizinis darbas pakeltomis rankomis) negu vien tik su amžiniai degeneraciniai pakitimai. Neseniai nustatyta, kad RSP rizika rūkančių žmonių yra didesnė negu nerūkančių.

Ne visi žmonės kreipiasi į gydytoją pagalbos, nes tik nedidelė dalis plyšimų yra simptominiai. Pacientai skundžiasi skausmu peties sānario srityje ir/arba rankos funkcijos sutrikimais. Patologiniai pokyčiai sukelia ne tik vietinius pažeisto sānario negalavimus. Sergant RSP pablogėja žmogaus gyvenimo kokybė. RSP gydymo taktika priklauso nuo simptomų trukmės, funkcijos sutrikimo laipsnio, paciento amžiaus, fizinio aktyvumo, bendros paciento fizinės ir psichinės būklės, jo lūkesčių. Įvertinus pirmiau minėtus kriterijus, pacientas gydomas konservatyviai arba operaciniu būdu. Pasaulinėje literatūroje nurodoma, kad operacinis gydymas veiksmingas. Atlikus nuplyšusios sausgyslės prisiuvimo operaciją išnyksta arba sumažėja skausmas, pagerėja peties sānario funkcija, sumažėja sānario artrozės ir raumenų riebalinės degeneracijos rizika, pagerėja paciento gyvenimo kokybė.

Nors operacinis RSP gydymas Lietuvoje taikomas jau apie 10 metų, tačiau, apžvelgus Lietuvos ortopedų traumatologų išspausdintus straipsnius, nepavyko rasti išsamių tyrimų tų pacientų, kuriems yra peties rotatorių sausgyslių plyšimų. Nėra duomenų apie pacientų gyvenimo kokybę, peties sānario būklę ir sveikatos pokyčius gydant RSP operaciniu būdu. Lietuvoje neturime nė vieno peties sānariui specifinio klausymo su ištirtomis psichometrinėmis savybėmis.

Kiekvieno gydymo metodo tikslas yra pagerinti paciento būklę. Sveikatos pokyčių matavimas yra vertingas mokslinių tyrimų objektas ir vienintelis būdas sužinoti gydymo rezultatus. Tai vienas iš pagrindinių uždavinių, kuris yra svarbus pacientui, gydytojui, ligoninių administracijai ir kitoms su sveikatos apsauga susijusioms įstaigoms.

Darbo tikslas

Ištirti peties sąnario būklės ir pacientų gyvenimo kokybės pokyčius gydant rotatorių sausgyslių plyšimus operaciniu būdu.

Darbo uždaviniai

1. Ištirti pacientų, atrinktų operaciniam gydymui dėl rotatorių sausgyslių plyšimo, gyvenimo kokybę naudojant *SF-36v2* ir įvertinti patologiškai pakitusio peties sąnario būklę naudojant sąnariui specifinę *Konstanto skalę* ir *Paprastąjį peties klausimyną*.
2. Perspektyviai įvertinti peties sąnario būklės ir gyvenimo kokybės pokyčius rekonstravus viso storio rotatorių sausgyslių plyšimus praėjus mažiausiai 12 mėnesių po operacijos.
3. Ištirti demografinių, struktūrinių ir klinikinių duomenų ryšį su peties sąnario funkcija ir gyvenimo kokybe prieš operaciją ir su operacinio gydymo rezultatais.
4. Ištirti priešoperacinės grupės pacientų peties aktyvumo lygio ryšį su demografiniais, struktūriniais ir klinikiniais parametrais ir įvertinti šio parametro prognozinę vertę gydant RSP operaciniu būdu.
5. Pritaikyti Lietuvai sąnariui specifinį klausimyną *Simple Shoulder Test* (liet.: Paprastasis peties klausimynas) ir ištirti jo psichometrines savybes.

Darbo naujumas

Šiame darbe pirmą kartą Lietuvoje išsamiai nagrinėjama pacientų, kuriems yra RSP, gyvenimo kokybė ir peties sąnario būklė naudojant pasaulyje gerai žinomas skales ir klausimynus (*SF-36v2*, *CS* ir *SST-LT*). Pirmą kartą Lietuvoje perspektyviai įvertinamas operacinio gydymo veiksmingumas ir paciento sveikatos pokyčiai po šio gydymo. Pirmą kartą išanalizuotas *peties aktyvumo lygio*, demografinių, struktūrinių ir klinikinių parametrų ryšys su paciento peties sąnario funkcija ir gyvenimo kokybe prieš operaciją ir su operacinio gydymo rezultatais. Lietuvai pritaikytas pasaulinėje praktikoje plačiai naudojamas ir pripažintas *SST* klausimynas. Tai pirmasis ir vienintelis Lietuvoje peties sąnariui specifinis klausimynas su ištirtomis psichometrinėmis savybėmis.

TIRIAMIEJI IR TYRIMO METODAI

Klinikinis tyrimas vyko nuo 2007 metų balandžio iki 2009 metų gegužės Vilniaus universitetinės greitosios pagalbos ligoninės Ortopedijos traumatologijos centre (VGPUL). Jam atlikti gautas Lietuvos bioetikos komiteto leidimas. Iš viso šiame klinikiniame tyrime dalyvavo 200 pacientų. Tiriamųjų grupę sudarė nuo 2007 balandžio iki 2008 vasario perspektyviai ištirti ir iš eilės į ligoninę paguldyti operaciniam gydymui 108 pacientai. Kontrolinę grupę sudarė 92 žmonės, kurių dominuojančios rankos peties sąnariai sveiki ir kuriems palyginimui buvo ištirta peties sąnario būklė naudojant SST-LT. Šiame darbe operaciniu būdu gydyti pacientai buvo suskirstyti į keletą grupių išskeltiems uždaviniams įgyvendinti: priešoperacinės ir pooperacinės pacientų būklės įvertinimas, SST-LT psichometrinį savybių ištyrimas buvo nagrinėti atskirai, todėl pacientų duomenys pateikti atskirose lentelėse. SST-LT psichometrinėms savybėms tirti buvo panaudoti priešoperacinės grupės 108 tiriamųjų duomenys, o peties sąnario būklės ir gyvenimo kokybės analizei prieš operaciją – 106-ių tos pačios grupės tiriamųjų duomenys, nes dviejų pacientų operacijų duomenys buvo nedokumentuoti.

Prieš operaciją visi pacientai buvo ištirti vieno operuojančio peties chirurgo vadovaujantis CS vertinimo skale. Peties raumenų jėga buvo išmatuota pagal Johanssono ir kt. metodiką skaitmeniniu dinamometru. Po to visi tiriamieji pacientai įvertino ligos pažeisto peties sąnario būklę pagal sąnariui specifinių SST-LT, sudarytą iš 12 klausimų. Patologiškai pakitusio peties sąnario būklei palyginti su sveiko sąnario būkle suformavome dvi kontrolines grupes. Šiose grupėse buvo palyginami ligos pažeistų ir sveikų peties sąnarių CS ir SST-LT vertinimo rezultatai. Su sveikata susijusios gyvenimo kokybės vertinimas atliktas pasitelkiant klausimyną SF-36v2, dažniausiai naudojamą gydymo rezultatams vertinti ortopedijoje. Rezultatams palyginti naudojome mūsų pacientų SF-36v2 normomis pagrįsto skaičiavimo rezultatus su amžių ir lyti atitinkančiomis bendrosios žmonių populiacijos normomis. Bendra paciento sveikatos būklė buvo nustatoma pagal gretutinių ligų skaičių ir jų sunkumą. Pacientai, kurie gaudavo invalidumo pašalpą, buvo įvardyti kaip turintys sunkią ligą. Peties aktyvumo lygis (PAL) įvertintas naudojant peties aktyvumo skalę (PAS). Peties sąnario patologijai įvertinti buvo sudarytas specialus protokolas, kuriamo buvo dokumentuojamas rotatorių sausgyslių plyšimo dydis, peties sąnario kontraktūra ir svarbiausi operacijos etapai. Pacientų būklės pokyčiams įvertinti sudaryta pooperacinė pacientų grupė, kuriems operacijos metu buvo rekonstruotas viso storio sausgyslės plyšimas. Peties sąnario būklė ir gyvenimo kokybė ištirta tokiais pačiais metodais kaip ir prieš operaciją. Peties sąnario būklės ir gyvenimo kokybės pokyčiai buvo įvertinti lyginant galutinius rezultatus su pacientų būkle prieš operaciją. Pooperacinė peties sąnario būklė taip pat buvo palyginta su kontrolinėmis grupėmis (sveikų pečių būkle), o gyvenimo kokybė – su amžių ir lyti atitinkančiu sveikų bendrosios populiacijos žmonių normomis. Originalaus *Simple Shoulder Test* (SST) kalbinis ir kultūrinis pritaikymas Lietuvai buvo atliktas remiantis Amerikos ortopedų akademijos rekomendacijomis.

REZULTATAI

Iš viso buvo ištirta 106 pacientų, atrinktų operaciniams gydymui, ir 92 kontrolinės grupės pacientai. SST-LT kontrolinę grupę sudarė aštuoniasdešimt du dėl kitos patologijos besigydantys įvairiuose VGPUL skyriuose pacientai ir 10 žmonių iš ligoninės personalo. Šiemis pacientams sveiko peties sąnario būklė buvo įvertinta naudojant SST-LT. Palyginus priešoperacinius atskirų subskalių ir visos CS skalės rezultatus su kontroliniais (sveiko) peties rezultatais gautas statistiškai reikšmingas skirtumas ($p < 0,001$). Pirmą kartą dinamometru išmatuota sveiko peties raumenų jėga buvo $7,10 \pm 2,90$ kg (nuo 0,00 kg iki 13,04 kg), o pakartotinai išmatuota – $7,38 \pm 2,89$ kg (nuo 0,00 kg iki 13,54 kg). Apskaičiuotas VKK $0,951$ [95% PI; 0,918–0,971]. SST-LT balų vidurkis ir standartinis nuokrypis prieš operaciją buvo $36 \pm 21,44$ (nuo 0 iki 91,6 balų), o kontrolinėje grupėje – $92 \pm 11,23$ (nuo 33,3 iki 100,0 balų). Bendri SST-LT balų rezultatai ir atskirų dylikos SST-LT atsakymų į klausimus rezultatai abiejose grupėse skyrėsi reikšmingai ($p < 0,001$). Operacijai atrinktų pacientų ir bendros žmonių populiacijos, atitinkančios amžių ir lyti, SF-36v2 rezultatai (išskyrus EG subskalę) tarpusavyje reikšmingai skyrėsi. Septyniasdešimt septyni pacientai (72,6%), iš kurių 46 (59,74%) vyrai, turėjo vieną arba daugiau gretutinių ligų, o 20 (18,9%) pacientų (10 vyru) turėjo sunkią ligą, dėl kurios gaudavo invalidumo pašalpą. Peties simptomų trukmės vidurkis iki operacijos buvo $19 \pm 57,8$ mėnesio (nuo 3 iki 444 mėnesių, mediana 6 mėnesiai). Rotatorių sausgyslių plyšimo dydis (vidurkis ir standartinis nuokrypis) buvo $5,56 \pm 5,83$ cm² (nuo 0,0 iki 24,0 cm²). 91 (85,8%) pacientui buvo diagnozuotas viso storio sausgyslės plyšimas, 11 (10,4%) dalinis ir 4 (3,8%) platus sausgyslių plyšimas. Aštuoniolikai pacientų (17%) nustatyta peties sąnario kontraktūra. PAL balų vidurkis ir standartinis nuokrypis bendroje pacientų grupėje buvo $10,7 \pm 5,39$. Septyniolika (16 %) pacientų (16 vyru ir 1 moteris) sportavo. Vienas pacientas buvo profesionalus sportininkas, kiti keturi buvo sportininkai mėgėjai ir nuolatos lankė treniruotes, o kiti 12 sportuodavo tiktais retkarčiais. Pasitelkiant sudarytą tiesinės regresijos modelį buvo atlikta analizė ir nustatytas teigiamas PAL ryšys su lytimi ir neigiamas ryšys su sunkiomis gretutinėmis ligomis ir amžiumi. Nustačius PAL ryšį su paciento lytimi, amžiumi ir gretutinėmis ligomis, tarpusavyje atskirai buvo palyginti vyru ir moterų, pacientų su ir be sunkių ligų PAL, SST-LT, SF-36v2 rezultatai ir simptomų trukmė. Taip pat buvo ištirta paciento amžiaus koreliacija su pirmiau minėtais parametrais. Sugrupavę pacientus pagal lyti nustatėme, kad moterų PAL balai buvo žemesni negu vyru ($p < 0,001$). PAL balų vidurkis ir standartinis nuokrypis moterų grupėje buvo $8,4 \pm 4,95$, o vyru – $12,1 \pm 5,2$. Papildoma PAL analizė vyru grupėje parodė, kad sportuojančių pacientų PAL balai nebuvo reikšmingai aukštesni už nesportuojančių ($p = 0,261$). Moterims simptomų iki operacijos trukmė buvo ilgenė negu vyrams ($p < 0,002$). Vyru SF-36v2 ir SST-LT vertinimo balai buvo geresni negu moterų. Nustatėme, kad moterų peties raumenų jėga buvo mažesnė negu vyru ($p < 0,001$) ir tai buvo vienintelė CS subskalė, kurios rezultatai vyru ir moterų skyrėsi. Reikšmingo skirtumo tarp vyru ir moterų bendrų CS rezultatų nenustatėme ($p = 0,142$). Dvidešimties pacientų, sergančių sunkiomis gretutinėmis ligomis, PAL rezultatai buvo blogesni už pacientų, kurie tokį ligų neturėjo (PAL vidurkis ir standartinis nuokrypis $7,5 \pm 6,16$ versus $11,4 \pm 4,94$ ($p = 0,005$)). Šių pacientų simptomų trukmė buvo ilgesnė ($p = 0,027$) ir blogesni SF-36v2 visų subskalių rezultatai [FA, BS and EG ($p < 0,001$); SR ($p = 0,001$); KA ($p = 0,007$); EB ($p = 0,005$); EA ($p = 0,025$) ir KS ($p = 0,040$)], tačiau PPK ($p = 0,175$) ir CS ($p = 0,583$)

rezultatai reikšmingai nesiskyrė. Pacientams, sergantiems sunkiomis gretutinėmis ligomis, ir tiems, kurie tokią ligą neturėjo, reikšmingo skirtumo tarp amžiaus ($p = 0,098$) ir lyties ($p = 0,248$) nenustatėme. Pacientų amžius koreliavo su PAL ($\rho = -0,208$; $p = 0,033$), tačiau reikšmingos koreliacijos su simptomų trukme ($\rho = 0,076$, $p = 0,437$), bendrais CS rezultatais ($\rho = -0,021$; $p = 0,831$) ar SST-LT rezultatais ($\rho = -0,093$; $p = 0,344$) nenustatėme. Pacientų amžius koreliavo su SF-36v2 subskalės BS rezultatais ($\rho = -0,246$; $p = 0,011$). Nustatėme, kad vyriškoji lytis, peties sąnario kontraktūra ir sunkios gretutinės ligos buvo pagrindiniai kintamieji, susiję su priešoperacine peties sąnario funkcija ir gyvenimo kokybe.

Dėl viso storio sausgyslės plyšimo buvo operuotas 91 pacientas. Du pacientai atsisakė atvykti pakartotinės apžiūros ir dalyvauti tyrime dėl laiko stokos, kiti du – dėl pablogėjusios bendros sveikatos būklės. Pooperacinė būklė įvertinta 87 (95,6%) pacientams po operacijos praėjus vidutiniškai 13,6 mėn. (nuo 12 iki 23 mėnesių). Ankstyvųjų gydymo komplikacijų diagnozuota nebuvo. Palyginus priešoperacinius CS vertinimo rezultatus su pooperacionais, statistiškai reikšmingas skirtumas apskaičiuotas visoms atskiroms subskalėms ir bendriems skalės rezultatams. Mažiausias rezultatų pagerėjimas nustatytas jėgos subskalei. Remiantis priešoperacionais ir pooperacionais CS rezultatais, nustatytais kliniškai svarbus peties sąnario būklės pokytis. Standartizuoto atsako į gydymą (SAG) koeficientas buvo didelis (0,88). Palyginus galutinius CS rezultatus su kontrolinės grupės rezultatais statistiškai reikšmingas skirtumas apskaičiuotas visoms atskiroms subskalėms ir bendriems skalės rezultatams. Palyginus priešoperacinius su galutiniai SST-LT vertinimo rezultatais po operacijos, statistiškai reikšmingas skirtumas ($p < 0,001$) apskaičiuotas visiems 12 klausimų ir bendriems skalės rezultatams. Prieš operaciją ir po operacijos bendras SST-LT rezultatas (vidurkis ir standartinis nuokrypis) buvo $35,9 \pm 21,04$ ir $71,6 \pm 28,85$. Remiantis priešoperacionais ir pooperacionais SST-LT rezultatais nustatytais kliniškai svarbus peties sąnario būklės pokytis. SAG koeficientas buvo didelis (1,11). Palyginus galutinius SST-LT rezultatus su kontrolinės grupės rezultatais statistiškai reikšmingas skirtumas apskaičiuotas visiems 12 klausimų ir bendriems skalės rezultatams. Mažiausias skirtumas buvo nustatytas tarp atsakymų į pirmą klausimą (Ar jūsų petys ramus, laikant ranką nuleistą prie šono?) ($p = 0,02$) ir septintą (Ar galite nelenkdamas alkūnės pakelti 4 kg iki pečių lygio?) ($p = 0,019$). Po operacijos ir kontrolinės grupės bendras SST-LT rezultatas (vidurkis ir standartinis nuokrypis) buvo $71,64 \pm 28,85$ ir $92,39 \pm 11,23$ ($p < 0,001$). Palyginus priešoperacinius SF-36v2 vertinimo rezultatus su galutiniais rezultatais po operacijos, statistiškai reikšmingas skirtumas apskaičiuotas visoms aštuonioms subskalėms. Didžiausias klinikinis pokytis įvyko KS subskalėje. Remiantis priešoperacionais ir pooperacionais SF-36v2 rezultatais, atskiroms subskalėms nustatyti klinikinio pokyčio koeficientai (SAG) buvo nevienodi – nuo mažo (0,36) iki didelio (0,98). Palyginus galutinius SF-36v2 rezultatus su lyti ir amžių atitinkančių bendros populiacijos žmonių rezultatais statistiškai reikšmingas skirtumas apskaičiuotas keturioms subskalėms. EG subskalės reikšmės viršija nustatytais bendros populiacijos normas ($p < 0,001$), o KA, BS ir EA subskalių reikšmės nuo bendros populiacijos normų atsilieka ($p < 0,001$). Sudarytame tiesinės regresijos modelyje (priklasomas kintamasis buvo prieš operaciją nustatytais PAL, o nepriklasomi kintamieji – amžius, lytis, peties sąnario kontraktūra, simptomų trukmė, plyšimo dydis, gretutinių ligų skaičius ir jų sunkumas, sportas; pooperacioniai SST-LT, CS ir SF-36v2 rezultatai) buvo atlikta analizė ($R^2 = 0,132$, adjusted $R^2 = 0,122$, $p_{ANOVA} < 0,001$), kurios metu nustatytais teigiamas PAL ryšys su SF-

36v2 subskale FA (regresijos koeficientas 0,092, standartizuotas regresijos koeficientas $\beta = 0,363$, $p = 0,001$). Nustatėme, kad sunki gretutinė liga (neigiamas ryšys) ir sportas (teigiamas ryšys) buvo susiję su pooperacine peties sąnario funkcija. Šešių SF-36v2 subsaklių rezultatai (išskyru EA ir EB) turėjo neigiamą ryšį su sunkiomis gretutinėmis ligomis. Sportas turėjo teigiamą ryšį su SF-36v2 fizinių aktyvumą (FA) ir kasdienės veiklos apribojimą (KA ir EA) vertinančių subskalių rezultatais, o simptomų trukmę – neigiamą ryšį su BS, EG, SR, EA ir EB subskalių rezultatais. Paaiškėjus, kad sportas ir sunkios gretutinės ligos turi ryšį su pooperacine pacientų būkle, visa grupė buvo padalyta į tris pogrupius, kuriuose atskirai apskaičiuotos ir tarpusavyje palygintos SAG reikšmės. Nustatėme, kad sportuojančių pacientų ir bendrosios grupės pacientų klinikinis CS ir SST-LT pokytis buvo didelis, o sunkią gretutinę ligą turinčių pacientų skalių pokytis mažas. Pacientų gyvenimo kokybės pokyčiai po operacijos taip pat skyrėsi. Sportuojančių pacientų subskalių FA, KA, KS ir BS klinikinis pokytis buvo didelis, kitų trijų subskalių (EG, SR, EA) vidutinis ir tiktais vienos subskalės (EB) mažas. Sunkia liga sergantiems pacientams EA subskalės kliniškai svarbaus pokyčio nebuvo. Kitų keturių subskalių (KA, BS, EG, EB) klinikinis pokytis buvo mažas, KS vidutinis ir tiktais vienai FA subskalei buvo apskaičiuotas didelis klinikinio pokyčio koeficientas.

SST-LT psichometrinės savybės buvo tiriamos išnagrinėjus operacijai atrinktų hospitalizuotų pacientų (grupės A ir C) ir po operacijos atvykusiu į konsultaciją ambulatorinių (grupė B) pacientų duomenis. Pacientai buvo suskirstyti į atskiras grupes nustatytiems tikslams ištirti. Hospitalizuotų pacientų grupėje A Cronbacho α koeficientas buvo 0,722. Atlikę vieneto ir visumos analizę, nustatėme, kad pirmas ir antras klausimai labai silpnai koreliavo (0,210 ir 0,128) su viso SST-LT rezultatu. Išnagrinėjė klausimyną klausimo pašalinimo metodu nustatėme, kad pašalinus vieną po kito pirmą ir antrą klausimus iš PPK, Cronbacho α koeficientas pakilo iki 0,724 ir 0,729. Ambulatorinių pacientų grupėje B Cronbacho α koeficientas buvo 0,844. Pirmas klausimas turėjo mažiausią koreliaciją (0,326) su visu SST-LT klausimyno rezultatu. Pašalinus šį klausimą iš klausimyno, Cronbacho α koeficientas išliko nepakitęs. Grupėje C (SST-LT stabilumas laiko atžvilgiu) apskaičiuotas VKK buvo lygus 0,96 [95% PI; 0,94–0,98]. Hospitalizuotų pacientų grupėje A septyni pacientai surinko mažiausią galimų balų skaičių („grindų“ efektas 6,5%) tačiau nė vienas pacientas nesurinko aukščiausio SST-LT galimų balų skaičiaus („lubų“ efektas 0,0%). Ambulatorinių pacientų grupėje B vienas pacientas surinko mažiausią galimų SST-LT balų skaičių („grindų“ efektas 1,3%), o septyni pacientai – didžiausią („lubų“ efektas 8,8%). Abiejose pacientų grupėse atskiroms konstrukcijoms apskaičiavome vidutinius koreliacijos koeficientus nuo 0,506 iki 0,786 ($p < 0,001$), išskyrus du atvejus: 1) grupėje B koreliacija su peties sąnariui specifinio instrumento CS rezultatais buvo stipri ($\rho = 0,881$; $p < 0,001$), 2) grupėje A koreliacija su SF-36v2 subskalės FA (fizinis aktyvumas PF) rezultatais buvo silpna ($\rho = 0,492$; $p < 0,001$). Nagrinėjant konstrukcijų pagrįstumą, visų koreliacijų koeficientai buvo aukštesni grupėje B (nuo 0,607 iki 0,881; $p < 0,001$) negu grupėje A (nuo 0,492 iki 0,735; $p < 0,001$).

IŠVADOS

1. Peties sąnario būklės ir pacientų gyvenimo kokybės vertinimo rezultatai prieš operaciją buvo blogesni už kontrolinių (sveikų) grupių rezultatus.
2. Praėjus mažiausiai 12 mėnesių po rotatorių rekonstrukcinės operacijos, peties sąnario būklė ir pacientų gyvenimo kokybė reikšmingai pagerėjo, tačiau peties sąnario būklė nepasiekė kontrolinių grupių rezultatų ir nuo jų reikšmingai skyrėsi.
3. Priešoperacinės grupės pacientų peties sąnario būklė ir gyvenimo kokybė turėjo ryšį su vyriškaja lytimi, peties sąnario kontraktūra ir sunkiomis gretutinėmis ligomis, o pooperacinės grupės pacientų tokis ryšys buvo nustatytas su sunkiomis gretutinėmis ligomis, sportavimu ir simptomu trukme.
4. Priešoperacinės grupės pacientų peties aktyvumo lygis turėjo ryšį su vyriškaja lytimi, sunkiomis gretutinėmis ligomis ir pacientų amžiumi, o pooperacinės grupės – su SF-36v2 subskalės Fizinis aktyvumas (FA) rezultatais. Peties aktyvumo lygis nebuvo prognozinis kintamasis, susijęs su peties sąnario būkle gydant rotatorių sausgyslių plyšimus operacijos būdu.
5. Paprasto peties klausymo lietuviškojo varianto psichometrinės savybės leidžia ji naudoti lietuviškai kalbantiems ligoniams, turintiems rotatorių sausgyslių plyšimą.

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