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The responsiveness and validity of the Rotator Cuff Quality of Life (RC-QOL) index in a 2-year follow-up study

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A R T I C L E I N F O

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Level of evidence: Basic Science Study; Validation of Outcome Instruments

Background: The Rotator Cuff Quality of Life (RC-QOL) index was developed to evaluate quality of life in patients with rotator cuff disease. This study provides additional psychometric testing in accordance with the Consensus-Based Standards for the Selection of Health Measurement Instruments guidelines.
Methods: This was a 2-year follow-up study on 66 patients (mean age, 59 ± 10 years) originally presenting with chronic full-thickness rotator cuff tears to a tertiary care center. The methodology involved testing internal consistency, content validity, and criterion validity. Responsiveness was evaluated using 3 strategies: 1) standardized response mean of the raw change scores; 2) Guyatt's Responsiveness Index; and 3) Global Rating Scales of improvement correlated to a quality of life measure.
Results: Content validity was confirmed with a Cronbach α of 0.92 (95% confidence interval, 0.92-0.95) and absence of floor and ceiling effects. Criterion validity was confirmed using the Western Ontario Rotator Cuff Index as a reference standard ($r = 0.87$, $P < .001$). The effect size of distribution-based methods of determining responsiveness was large (0.99-1.09) compared to that of mixed- and anchor-based methods (0.47-0.89). All responsiveness calculations met minimum requirements for acceptable thresholds.
Conclusion: The RC-QOL is a valid and responsive measure of health-related quality of life in patients with chronic rotator cuff pathology. The results of this study added to the methodologic quality assessment of the RC-QOL, completing 7 of 10 Consensus-Based Standards for the Selection of Health Measurement Instruments criteria.

The Rotator Cuff Quality of Life (RC-QOL) index is a disease-specific health-related patient-reported outcome measure (HR-PROM) used in evaluating health status and quality of life for patients with the full spectrum of rotator cuff disease.[14] Created in English, this tool has completed cross-cultural validation when translated into Italian, German, Turkish, Chinese, and Spanish.[4,15,22,32] Eleven studies have evaluated the psychometric properties of the RC-QOL in the context of the Consensus-Based Standards for the Selection of Health Measurement Instruments (COSMIN) guidelines.[3,4,8,14,15,22,23,26,29,30,32] The COSMIN guidelines consist of 10 criteria that can be used to assess whether a study has met the standards for good methodologic quality: internal consistency, reliability (ie, test-retest, interrater, intrarater),

This study was approved by the Conjoint Health Research Ethics Board at the University of Calgary (REB 14-1828).
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measurement error, content validity, construct validity (ie, hypothesis testing), structural validity, criterion validity, cross-cultural validity, responsiveness, and interpretability.[24] The RC-QOL has been evaluated on 7 of the COSMIN criteria.

Responsiveness of the RC-QOL has been assessed on 4 occasions but only by using a distribution-based approach.[3,8,23,29] HR-PROMs must demonstrate responsiveness where scores are sensitive to actual changes in health status. The estimation of the minimal clinically important difference (MCID), which is also used to determine the responsiveness of a tool, should be based on multiple strategies and triangulation of methods.[31] Distribution-based methods are derived from the statistical spread or variation of data using standard deviation (SD), standard error of the measurement, standardized response mean (SRM), and effect size (ES).[28] Anchor-based methods use relevant patient-rated, clinician-rated, and disease-specific variables that provide primary and meaningful estimates of an instrument's MCID.[31] Anchor-based methods compare changes in scores with an external marker as reference.[28] Traditional external anchors vary between Likert-type scales and visual analog scales (VAS). Research has shown that there is no significant difference in type of scales and little consensus on the best mode of questioning when implementing external anchors.[11,16]

The task of validating HR-PROMs is a continual process to confirm its value and use in research or clinical practice.[38] The RC-QOL should possess the full spectrum of recognized measurement properties, need to be clearly demonstrated, and need to be considered adequate. Therefore, the purpose of this study was is to provide additional psychometric assessment of the RC-QOL in the context of the COSMIN guidelines. This study will also evaluate responsiveness using 3 strategies: 1) SRM of the raw change scores; 2) Guyatt's Responsiveness Index (GRI); and 3) Global Rating Scales (GRS) of improvement correlated to quality of life measure.

Methods

Study design

This study was approved by the Conjoint Health Research Ethics Board at the University of Calgary. This study presents 2-year follow-up data on a cohort of 87 patients that originally presented to a tertiary care clinic: the University of Calgary Sport Medicine Centre.[8,9] These patients were initially referred to 1 of 3 orthopedic surgeons at the University of Calgary Sport Medicine Centre. Patients were identified from new and follow-up referrals from primary care physicians. Both nonsurgical and surgical patients were targeted. Following a surgical consultation, patients in the nonsurgical group were deemed to not require immediate surgical management and were treated with an evidence-based nonoperative program. Surgical patients had confirmed surgical dates or had already received surgical management for their shoulder problem. These 2 groups were chosen as a representative sample of patients with chronic rotator cuff tears currently presenting to point of care. Patients who a priori consented for future research were contacted and provided consent again for the 2-year study.

Inclusion criteria consisted of English-speaking and literate patients aged older than 18 years. Patients were included if they presented with a chronic full-thickness rotator cuff tear confirmed by ultrasonography or magnetic resonance imaging. Patients were excluded if they presented with concomitant symptomatic pathology of the affected shoulder (ie, instability, osteoarthritis); significant cervical spine pathology or radiculopathy or both; or gain issues (ie, workers' compensation or litigation). Individuals were also excluded if they were unable or unwilling to complete the study or provide informed consent. Patients completed Web-based versions of the RC-QOL,[14] the Western Ontario Rotator Cuff Questionnaire (WORC),[17] and 2 GRS[10,20] approximately 24 ± 6 months after their baseline questionnaire was completed.

Table I
Characteristics of study patients at baseline and the 2-year follow-up.

Category	Interval	Group	n	Mean (SD)
Age (yr)	Baseline	Overall	87	57 (10)
	2 yr	Overall	66	59 (10)
	Baseline	Nonsurgical	39	58 (12)
		Surgical	48	56 (8)
	2 yr	Nonsurgical	24	59 (11)
		Surgical	42	59 (10)
Sex (% of N)	Baseline	Overall	87	M: 60 (69%); F: 27 (31%)
	2 yr	Overall	66	M: 40 (62%); F: 26 (38%)
	Baseline	Nonsurgical	39	M: 28 (72%); F: 11 (28%)
		Surgical	48	M: 32 (67%); F: 16 (33%)
	2 yr	Nonsurgical	24	M: 13 (54%); F: 11 (46%)
		Surgical	42	M: 27 (64%); F: 15 (36%)

M, male; *F*, female; *SD*, standard deviation.

Instruments

Rotator Cuff Quality of Life index

The RC-QOL consists of 34 questions and 5 subscales: symptoms and physical complaints (SYMPTOMS), 16 items; work-related concerns (WORK), 4 items; recreational activities, sports participation, or competition concerns (SPORTS), 4 items; lifestyle concerns (LIFESTYLE), 5 items; and social and emotional concerns (SOCIAL/EMOTIONAL), 5 items. Each question is scored on a 100-mm VAS from 0 (most symptomatic) to 100 (asymptomatic). The quality of life score is calculated by taking an average of items answered by respondents. For example, if the patient answered all 34 items, 34 values are summed, divided by 3400, and multiplied by 100. Patients are given the option of answering "not applicable" to 14 questions. These responses are treated as if these items had never been offered to the patient. If the patient answered "Not applicable" to 14 questions, these responses are treated as missing by design, and the sum of the remaining questions is divided by the new denominator and then multiplied by 100 (ie, 2000/[3400 − 1400]*100). A score of 0 reflects the worst quality of life (most symptomatic), and a score of 100 reflects the best quality of life (asymptomatic).

Western Ontario Rotator Cuff Questionnaire

The only other Canadian English-based rotator cuff-specific PROM, the WORC, consists of 21 items representing 5 domains each with a 100-mm VAS response option. The 5 domains include physical symptoms (SYMPTOMS), 6 items; sports and recreation (SPORTS), 4 items; work (WORK), 4 items; lifestyle (LIFESTYLE), 4 items; and emotions (SOCIAL/EMTIONAL), 3 items. Each question is also scored on a 100-point VAS but with reversed interpretations where "0" indicates asymptomatic and "100" indicates most symptomatic. The maximum possible score is 2100, meaning worst possible symptoms, and the best or asymptomatic score is 0. The WORC does not have any "Not-applicable" options. For a more clinical friendly interpretation, this study reported the WORC score as a percentage by subtracting the total score from 2100, dividing by 2100, and multiplying by 100. This allows for ease of comparison to the RC-QOL and also for similar interpretations where 0% indicates the lowest functional status level and 100% indicates the highest functional status level.

Table II
Baseline and 2-year follow-up scores of the RC-QOL index and WORC.

Category	Interval	Group		n	Mean (SD)	*P* value
RC-QOL (yr)	Baseline	Overall		87	49 (22)	
		Loss to follow-up patients removed		66	47 (22)	.001
	2 yr	Overall		66	74 (24)	
	Baseline	Overall	Nonsurgical	39	47 (20)	.386
			Surgical	48	50 (23)	
		Loss to follow-up patients removed	Nonsurgical	24	56 (19)	.389
			Surgical	42	42 (22)	
	2 yr	Overall	Nonsurgical	24	77 (20)	.494
			Surgical	42	73 (25)	
WORC score	2 yr	Overall		66	73 (23)	<.001
	2 yr	Nonsurgical		24	75 (21)	
		Surgical		42	71 (25)	
RC-QOL change score (raw)	2 yr	Overall		66	27 (28)	
	2 yr	Nonsurgical		24	21 (24)	
		Surgical		42	31 (42)	

RC-QOL, Rotator Cuff Quality of Life; *SD*, standard deviation; *WORC*, Western Ontario Rotator Cuff.

Global Rating Scales

Two GRS were used as anchor-based methods to evaluate the responsiveness of symptoms and function: A 7-point GRS was adapted from the study by Greco et al,[10] and a VAS GRS was adapted from the study by Lafave et al[20] ranging from −100 (significantly worse) to +100 points (significantly improved).

Reliability

To assess the homogeneity of items, internal consistency was measured using Cronbach's alpha (α) calculations. Internal consistency was examined for both the overall RC-QOL and WORC and each subscale. The questions in each subscale were analyzed to determine the degree to which they fit into that subscale (SYMPTOM, WORK, SPORTS/RECREATION, LIFESTYLE, and SOCIAL/EMOTIONAL).[28]

Content validity

Floor and ceiling effects were calculated to assess content validity. Floor and ceiling effects were calculated at 15%, 20%, 25%, and 30% stratifications using the RC-QOL at baseline and RC-QOL and WORC at the 2-year follow-up interval.

Criterion validity

Criterion validity was measured by means of concurrent validity. The RC-QOL was correlated to the WORC at the 2-year time interval (24 ± 6 months). A nonparametric Spearman rank correlation test (r_S) and Lin's concordance correlation coefficient (rc) were used to compare the mean scores of the RC-QOL and the WORC.

Responsiveness

Responsiveness was determined using 3 strategies: 1) SRM of the raw change scores (SRMraw; distribution-based method); 2) GRI (distribution-based method requiring anchor-based MCID); and 3) GRS of improvement correlated to a quality of life measure (anchor-based method).[16]

Standardized response mean

The SRM is the ratio of individual change to the SD of that change.[6] A large SRM indicates that the change is large relative to the background variability in the measurements.[6] The SRMraw was restricted to patients who experienced change and was calculated as the ratio of the mean raw change score (s_{change}) to the SD of that raw change score ($\bar{x}_{post} - \bar{x}_{pre}$).[28] These calculations were completed using Equation 1:

Equation 1. SRM equation for calculating important difference.[2]

$$SRMraw = \frac{\bar{x}_{post} - \bar{x}_{pre}}{s_{change}} \quad (1)$$

Guyatt's Responsiveness Index

GRI is a distribution-based method requiring an anchor-based MCID using the smallest difference between baseline and post-test stage representing the meaningful change in a group using a 7-point VAS GRS.[18,21] This use of an external anchor in combination with the statistical spread of the data provides a mixed approach to responsiveness. Patients reported "Somewhat worse" or "Somewhat better" on the 7-point GRS. In the absence of an external anchor, or for comparative purposes, MCID was calculated using the distribution-based approach using the mean change scores.[18] The GRI was calculated using both mixed (GRI_{Mixed}) and distribution-based ($GRI_{Distribution}$) methods, whereby MS_E is the mean squared error of the response obtained from an analysis of variance model that examines repeated observations of the measure in clinically stable subjects.[12] These calculations were completed using Equation 2:

Equation 2. Guyatt's Responsiveness Index equation for calculating important difference.[12]

$$GRI = \frac{MCID}{\sqrt{2*MS_E}} \quad (2)$$

GRS correlation

GRS correlation is an anchor-based method of determining responsiveness and compares changes in scores with an external marker as reference.[18,27] This external marker compares a secondary response by patients to indicate their perceived level of change. A correlation coefficient was used to determine the relationship between the mean change score in the RC-QOL between the baseline and 24-month scores with a 7-point GRS and again with a VAS GRS.[20] Values of 0.2, 0.5, and 0.8 were used to represent small, moderate, and large effects, respectively.[39] The SRMraw[16,25] was restricted to patients who experienced change and was calculated as the ratio of the mean raw change score to the SD of that raw change score. The change group was defined as patients who were included in the extremes of the 7-point GRS. These

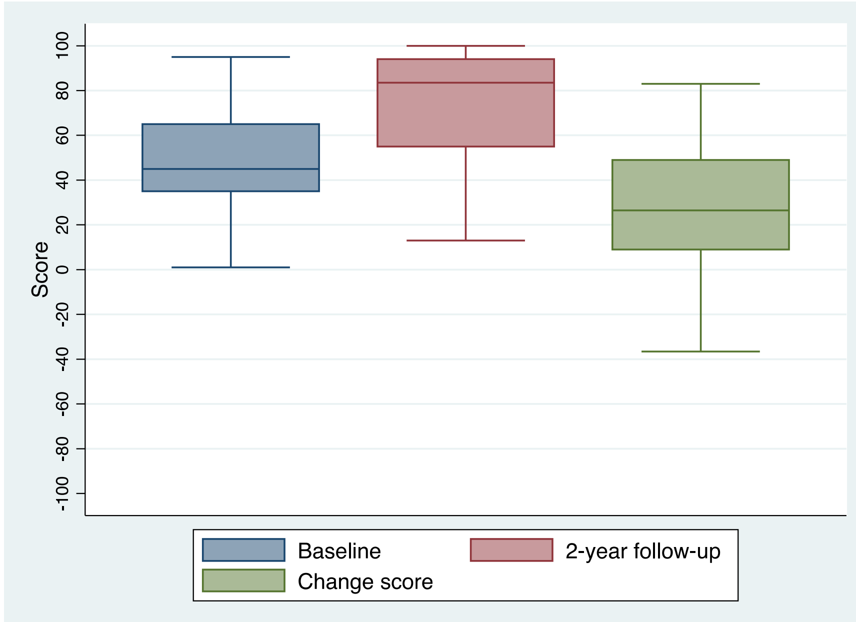

Figure 1 Median Rotator Cuff Quality of Life (RC-QOL) index scores at baseline (n = 87), 2-year follow-up interval (n = 66), as well as change score between time intervals (n = 66).

Table III
Cronbach's α of the RC-QOL index (baseline and 2-yr follow-up) (n = 87) and WORC (2-yr follow-up) (n = 63).

Domain	Cronbach's α (n)α	Cronbach α	
		Nonsurgical (n)	Surgical (n)
RC-QOL (baseline)	0.919 (87)	0.937 (39)	0.929 (48)
SYMPTOM	0.922 (87)	0.937 (39)	0.932 (48)
WORK	0.920 (87)	0.945 (39)	0.928 (48)
SPORTS	0.920 (87)	0.940 (39)	0.929 (48)
LIFESTYLE	0.918 (87)	0.937 (39)	0.927 (48)
SOCIAL/EMOTIONAL	0.922 (87)	0.933 (39)	0.932 (48)
RC-QOL (2 yr)	0.911 (63)	0.932 (27)	0.920 (36)
SYMPTOM	0.913 (63)	0.933 (27)	0.923 (36)
WORK	0.914 (39)	0.940 (16)	0.926 (23)
SPORTS	0.916 (63)	0.936 (27)	0.923 (36)
LIFESTYLE	0.910 (63)	0.932 (27)	0.919 (36)
SOCIAL/EMOTIONAL	0.915 (63)	0.936 (27)	0.924 (36)
WORC (2 yr)	0.910 (63)	0.932 (27)	0.920 (36)
SYMPTOM	0.932 (63)	0.934 (27)	0.923 (36)
WORK	0.930 (63)	0.932 (27)	0.922 (36)
SPORTS	0.938 (63)	0.934 (27)	0.922 (36)
LIFESTYLE	0.932 (63)	0.933 (27)	0.925 (36)
EMOTIONAL	0.943 (63)	0.935 (27)	0.925 (36)

RC-QOL, Rotator Cuff Quality of Life; *WORC*, Western Ontario Rotator Cuff.

patients reported either "Very much worse" or "Very much better" on the scale. Similar to the study by Beninato et al,[2] patients that reported "A little worse", "No change", and "A little bit better" were considered "Unchanged" or "Stable", in that there would be no reported change by the patient or the change would be perceived as little to none in these cases. In calculating the MCID, patients that reported "Somewhat worse" or "Somewhat better" were defined as those patients who reported the smallest detectable change. Those categories were the next available point above or below responses that were considered stable. The MCID was determined by the smallest absolute change scores in patients that perceived change.[37] Variation of data was calculated using a 1-way analysis of variance of change scores in patients reporting little to no change.[18,21]

Statistical analysis

Data analyses were computed using Stata Statistical Software: Release 14 (StataCorp., College Station, TX, USA),[34] and statistical significance was accepted at the $P < .05$ level. All primary analyses were subsequently stratified based on surgical status. Independent t-tests were used to compare homogeneity of variance in age, sex, and RC-QOL scores between nonsurgical and surgical patients at baseline and 2-year time intervals. A paired t-test was also used to detect significant changes in patients' RC-QOL scores between baseline and the 2-year time interval.

Results

Eighty-seven patients were entered in the study at baseline (60 males, 27 females) with a mean age of 57 years (range, 27-78 years). Sixty-six patients (40 males and 26 females) participated at the 2-year follow-up interval with a mean age of 59 years (range, 29-80 years). At the 2-year interval, no patients declined participation, and 21 patients (24%) were lost to follow-up. Researchers were unable to contact 12 patients, and 9 did not return questionnaires within the allotted timeframe (24 ± 6 months). The median timeframe for completing follow-up questionnaires was 27 months following baseline (SD, 2; range, 22-30 months).

Table I presents baseline and 2-year follow-up demographic data. Age and sex were not statistically different between baseline and 2-year follow-up samples ($P = .778$ and $P = .783$, respectively) or between the surgical and nonsurgical groups at baseline ($P = .147$ and $P = .137$, respectively) and at 2-year follow-up ($P = .160$ and $P = .204$, respectively). Table II presents baseline and 2-year follow-up RC-QOL scores, RC-QOL change, and WORC scores. Mean RC-QOL scores at baseline ($P = .389$) and at the 2-year follow-up ($P = .494$) were not statistically different between the nonsurgical and surgical groups. However, there was a significant change in RC-QOL scores from baseline to 2 years (mean + 27; SD, 28; $P < .001$). Median RC-QOL scores at baseline and at the 2-year follow-up and

Table IV
Floor and ceiling effects of the RC-QOL index and WORC in up to 94 patients at baseline and 2-yr intervals.

Domain	RC-QOL (baseline)		RC-QOL (2-yr)		WORC (2-yr)	
	Floor effect (%)	Ceiling effect (%)	Floor effect (%)	Ceiling effect (%)	Floor effect (%)	Ceiling effect (%)
Overall	0.0	0.0	0.0	3.2	0.0	6.3
SYMPTOM	1.1	1.1	0.0	4.8	0.0	6.3
WORK	6.4	0.0	0.0	0.0	0.0	9.5
SPORTS	5.3	1.1	0.0	9.5	0.0	4.8
LIFESTYLE	0.0	1.1	0.0	6.3	1.6	11.1
SOCIAL/EMOTIONAL	0.0	3.2	0.0	14.3	1.6	19.0

RC-QOL, Rotator Cuff Quality of Life; *WORC*, Western Ontario Rotator Cuff.

Table V
Floor and ceiling effects of the RC-QOL index at baseline and the RC-QOL and WORC index at the 2-yr follow-up interval in up to 36 surgical and up to 27 nonsurgical patients with rotator cuff disease.

Domain	RC-QOL (baseline)				RC-QOL (2-yr)				WORC (2-yr)			
	Nonsurgical (% of n = 27)		Surgical (% of n = 36)		Nonsurgical (% of n = 27)		Surgical (% of n = 36)		Nonsurgical (% of n = 27)		Surgical (% of n = 36)	
	Floor	Ceiling	Floor	Ceiling	Floor	Ceiling	Floor	Ceiling	Floor	Ceiling	Floor	Ceiling
Overall	0.0	0.0	0.0	0.0	0.0	3.7	0.0	2.8	0.0	0.7	0.0	5.6
SYMPTOM	0.0	3.7	0.0	2.8	0.0	3.7	0.0	5.6	0.0	0.0	0.0	2.8
WORK	11.1	0.0	8.3	0.0	0.0	0.0	0.0	0.0	0.0	11.1	0.0	8.3
SPORTS	7.4	3.7	8.3	0.0	0.0	7.4	0.0	11.1	0.0	11.1	0.0	5.6
LIFESTYLE	0.0	3.7	0.0	0.0	0.0	7.4	0.0	5.6	0.0	11.1	2.8	11.1
SOCIAL/EMOTIONAL	0.0	11.1	0.0	0.0	0.0	14.8	0.0	13.9	0.0	18.5	2.8	19.4

RC-QOL, Rotator Cuff Quality of Life; *WORC*, Western Ontario Rotator Cuff.

change score between the 2 intervals are visually represented in Figure 1.

Reliability

Table III presents the Cronbach's α of the RC-QOL at baseline and the RC-QOL and WORC at the 2-year interval, stratified by surgical status. At the 2-year interval, 24 patients reported work-related questions as not applicable, thus decreasing the sample size for calculating α to 39 patients for this specific domain. The Cronbach's α for the RC-QOL ranged from 0.918 to 0.922 at baseline and 0.910 to 0.916 at the 2-year interval. After stratifying by surgical status at the 2-year mark, the sample sizes dropped to 16 nonsurgical and 23 surgical patients. The Cronbach's α for the baseline nonsurgical cohort ranged from 0.933 to 0.945, and that for the surgical cohort ranged from 0.927 to 0.932 with similar values at the 2-year mark. These ranges are similar to the WORC at the 2-year interval (0.910-0.943). The similarities in comparing baseline and follow-up scores suggests unidimensionality of scales in the RC-QOL and WORC (ie, all items measure the same construct to the same extent).

Three outliers were identified in the 66-patient 2-year follow-up cohort. One outlier was a patient that completed questionnaires at 1 month postoperatively. It has been shown that change reported from 0-3 months postoperatively in patients that have undergone rotator cuff repairs is not statistically significant in groups similar to those in this study when using the RC-QOL.[14] This patient report is unlikely to represent true change in quality of life status. The second outlier was a patient that reported a change score of +60 points on the RC-QOL while reporting no change on both the 7-point GRS and VAS GRS. A change score as substantial as 60 points out of a possible 100 points should be expected to have a similar response in both GRS. The third patient reported "Somewhat better" on the 7-point GRS and +90 on the VAS GRS; however, this only improved by +1 point on the RC-QOL between time points. This change score of 1 point is unlikely to be clinically relevant if the patient is reporting notable differences on 2 separate GRS. All outliers were excluded from the reliability analysis.

Content validity

Floor and ceiling effects were calculated to further determine content validity of the RC-QOL and WORC (Table IV) and to further determine content validity of the RC-QOL and WORC for nonsurgical and surgical groups (Table V). There were no floor or ceiling effects in the RC-QOL at baseline or at the 2-year follow-up interval and when stratified by surgical status. There is evidence of ceiling effects (>15%) in both nonsurgical and surgical patients using the WORC within the SOCIAL/EMOTIONAL domain.

Criterion/concurrent validity

The relationship between the RC-QOL and WORC scores at the 2-year time interval is visually represented in Figure 2. The Shapiro-Wilk W test denied the normality of the study data as the RC-QOL and WORC tested at 0.88 ($P < .001$) and 0.92 ($P < .001$), respectively. Therefore, the nonparametric Spearman rank correlation test (r_S) and Lin's concordance correlation coefficient (r_c) were used to compare the RC-QOL and WORC scores. All tests showed a similar strong correlation between scores at the 2-year interval (0.88, $P < .001$) (Table VI).

Responsiveness

A summary of change scores for the domains of RC-QOL is provided in Table VII. Mean change scores were consistently higher in all domains for surgical patients when comparing to nonsurgical patients.

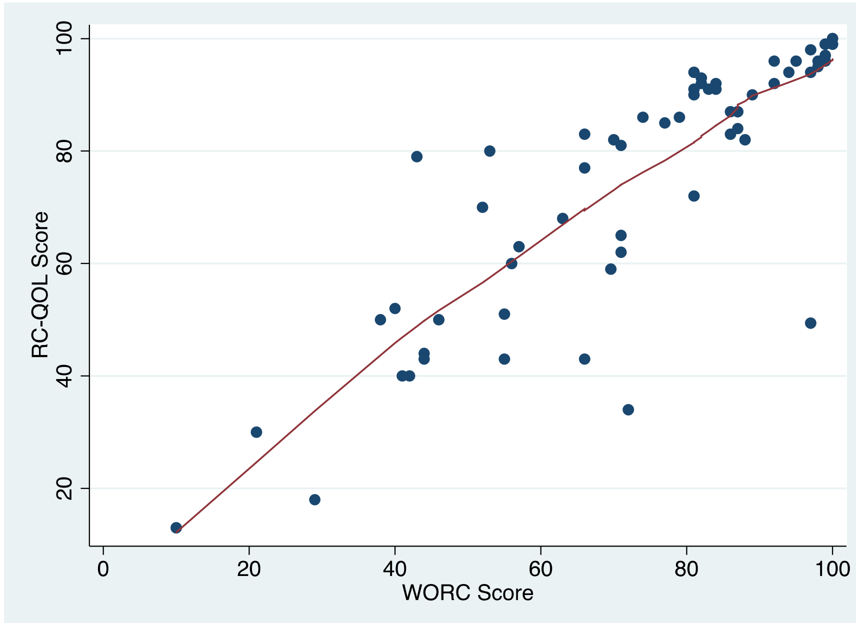

Figure 2 Rotator Cuff Quality of Life (RC-QOL) index scores correlated to Western Ontario Rotator Cuff (WORC) index scores in 63 patients with confirmed rotator cuff disease at 2-year follow-up interval.

Table VI
Correlation of the RC-QOL index and WORC scores at the 2-yr interval using Pearson and Spearman correlation coefficients and Lin's CCC.

Group	Correlation	RC-QOL vs. WORC
Overall (n = 63)	Pearson r	0.87 ($P < .001$)
	Lin's CCC r_c	0.87 ($P < .001$)
Nonsurgical (n = 27)	Spearman r_s	0.88 ($P < .001$)
	Pearson r	0.92 ($P < .001$)
	Lin's CCC r_c	0.92 ($P < .001$)
Surgical (n = 36)	Spearman r_s	0.80 ($P < .001$)
	Pearson r	0.85 ($P < .001$)
	Lin's CCC r_c	0.80 ($P < .001$)

CCC, Concordance Correlation Coefficient; *RC-QOL*, Rotator Cuff Quality of Life; *WORC*, Western Ontario Rotator Cuff.

Standardized response mean

SRM was calculated to represent distribution-based methods using SD of the sample (s). Calculations using 63 observations provided an SRM of 0.99. This represents a large ES or large difference between baseline and 2-year follow-up scores.[5] SRM was calculated for both surgical ($n = 36$) and nonsurgical groups (n = 27). Nonsurgical and surgical groups provided an SRM of 0.91 and 1.09, respectively, which represents a large ES.[5]

Guyatt's Responsiveness Index

GRI_{Mixed} was calculated using an MCID of 13 points. This provided a GRI of 0.48, a small effect.[5] $GRI_{Distribution}$ was calculated using an MCID representing mean change scores (27.97 points). $GRI_{Distribution}$ was calculated as 1.03, a large effect.[5,39] The denominator representing the variation of scores for stable patients was not statistically significant ($P < .49$). The nature of the GRI requires information on the spread of data in patients that are considered "unchanged" or "stable." Of the surgical patients at the 2-year interval, only 1 patient was reported as stable; therefore, variation in data was not calculated, and the GRI for surgical patients could not be determined. The GRI was recalculated for nonsurgical patients. Using both mixed- and distribution-based methods, results for nonsurgical patients are outlined in Table VIII. Using the same cutoff points as in the primary analysis, GRI_{Mixed} was calculated using an MCID of 13 points. This provided a GRI of 0.43, a small effect.[5] $GRI_{Distribution}$ was calculated using an MCID representing mean change scores (26.85 points). $GRI_{Distribution}$ was calculated as 0.89, a large effect.[5,39] The denominator representing the variation of scores for stable patients was not statistically significant ($P < .41$).

GRS correlation

The Shapiro-Wilk W test confirmed normal distribution of the data (0.98, $P < .49$). Therefore, a correlation using Pearson r coefficient calculation (Table IX) was completed between the 7-point GRS and raw RC-QOL change scores (Fig. 3), as well as the VAS GRS and the raw RC-QOL change scores (Fig. 4). The correlation between the 7-point GRS and raw RC-QOL change scores is 0.44 ($P < .001$). This represents a positive modest relationship.[28] The correlation between the VAS GRS and raw RC-QOL change scores was 0.42 ($P < .0001$). This also represents a positive modest relationship.[28]

A correlation using Pearson r coefficient calculation (Table IX) was completed between the 7-point GRS and raw RC-QOL change scores, as well as the VAS GRS and the raw RC-QOL change scores for both surgical (Figs. 5 and 6, respectively) and nonsurgical patients (Figs. 7 and 8, respectively). The correlation between the 7-point GRS and raw RC-QOL change scores was 0.45 ($P < .01$) for surgical patients. This represents a positive modest relationship.[28] The correlation between the VAS GRS and raw RC-QOL change scores for surgical patients is 0.42 ($P < .01$). This represents a positive modest relationship.[28] The correlation between the 7-point GRS and raw RC-QOL change scores was 0.45 ($P < .02$) for nonsurgical patients. This represents a positive modest relationship.[28] The correlation between the VAS GRS and raw RC-QOL change scores was 0.44 ($P < .02$). This also represents a positive modest relationship.[28]

Discussion

The purpose of this study was to provide additional methodological assessment of the RC-QOL. The RC-QOL was previously

Table VII
Summary of absolute RC-QOL index change scores from baseline to 2-yr follow-up for patients with confirmed rotator cuff tears.

Domain change score	Overall Absolute mean change score ± SD (n)	Nonsurgical absolute mean change score ± SD (n)	Surgical Absolute mean change score ± SD (n)
SYMPTOM	34 ± 23 (63)	25 ± 23 (28)	40 ± 26 (36)
WORK	30 ± 21 (40)	27 ± 17 (17)	33 ± 24 (23)
SPORT	20 ± 26 (63)	32 ± 22 (28)	47 ± 29 (36)
LIFESTYLE	40 ± 25 (63)	35 ± 22 (28)	44 ± 27 (36)
SOCIAL/EMOTIONAL	25 ± 20 (63)	20 ± 17 (28)	30 ± 21 (36)
RC-QOL	33 ± 21 (63)	26 ± 18 (28)	38 ± 23 (36)

RC-QOL, Rotator Cuff Quality of Life; *SD*, standard deviation.

Table VIII
GRI calculations of the RC-QOL index using mixed- and distribution-based methods in up to 63 patients with confirmed rotator cuff disease.

Group (*n*)	GRI method	MCID	MS_E of stable patients	GRI
Overall (63)	GRI_{Mixed}	13	371.07 ($P < .49$)	0.48
	$GRI_{Distribution}$	27.97		1.03
Nonsurgical (27)	GRI_{Mixed}	13	451.33 ($P < .41$)	0.43
	$GRI_{Distribution}$	26.85		0.89

GRI, Guyatt's Responsiveness Index; *MCID*, minimal clinically important difference; *MSE*, mean squared error; *RC-QOL*, Rotator Cuff Quality of Life.

Table IX
Pearson Correlation of raw RC-QOL index change scores over a 2-yr period and the 7-point and VAS GRS.

Group (n)	GRS	Correlation
Overall (63)	7-Point	0.44 ($P < .001$)
	VAS	0.42 ($P < .0001$)
Nonsurgical (27)	7-Point	0.45 ($P < .02$)
	VAS	0.44 ($P < .02$)
Surgical (36)	7-Point	0.45 ($P < .0056$)
	VAS	0.42 ($P < .0111$)

RC-QOL, Rotator Cuff Quality of Life; *VAS GRS*, visual analog global rating scales.

evaluated in 2015 using the criteria of the COSMIN guidelines.[8] This study evaluated the RC-QOL at the 2-year follow-up and provides additional methodological support for reliability, validity, and responsiveness.

Reliability was assessed using Cronbach's α. In the baseline study, Cronbach's α was 0.96, with an internal consistency for each subscale ranging from 0.72 to 0.94.[8] In the 2-year follow-up study, Cronbach's α was 0.91, ranging from 0.91 to 0.94 in the subscales and ranging from 0.87 to 0.94 and 0.91 and 0.94 for surgical and nonsurgical groups, respectively. With respect to the exploratory analysis, the RC-QOL subscales had excellent internal consistency at both time intervals. These results are within normal limits when used for clinical purposes as this questionnaire is intended. In this 2-year follow-up study, the WORC was used as a reference standard and relatively stable Cronbach's α between domains (0.91-0.94).

Floor and ceiling effects were used to evaluate content validity. In the baseline study, no floor or ceiling effects were found as no patients scored at the lowest end and no more than 2.9% at the highest end.[8] In the 2-year study, there was also an absence of floor or ceiling effects in the RC-QOL overall and within each domain. Thus, the RC-QOL was not only able to measure the entire spectrum of a patient's condition but also discriminate between patients doing poorly and those doing well. A ceiling effect was found in 3 questions of the SOCIAL/EMOTIONAL domain of the WORC. This may affect the WORC's discrimination properties in rotator cuff patients.

Criterion validity was assessed in the 2-year study by means of concurrent validity using the Spearman rank correlation (r_s) and Lin's concordance correlation coefficient (r_c). Strong positive correlations were found between the RC-QOL and the WORC using the Spearman rank correlation and Lin's concordance correlation coefficient, suggesting a similar relationship—0.87, $P < .001$, and .87, $P < .001$, respectively. In addition, when correlations were assessed based on surgical status, correlations were stronger for nonsurgical patients (0.88-0.92) than for surgical patients (0.80). Both trends indicate that as WORC scores increase, RC-QOL scores also increase. This provides additional methodological support for criterion validity of the RC-QOL using the WORC as a reference standard.

In the baseline study, responsiveness was only measured using distribution-based approaches.[8] In the 2-year follow-up study, responsiveness was evaluated using both distribution and anchor-based methods. In comparing results, it is important to understand the term ES. In quantitative research, the context of this study, ES is often described as the magnitude of the difference between groups.[36] This contrasts with the absolute ES that was described above as the mean change score. Absolute ES does not consider the variability in scores, in that not every subject achieved the average outcome.[35] Cohen's term *d* is an example of this type of ES index. Cohen classified ES as small (0.2), medium (0.5), and large (0.8).[5] These categories, however, do not take into account other variables such as the accuracy of the HR-PROM nor the varying characteristics of the study population. The purpose of ES cutoffs simply provides a general guideline for comparative purposes.

The SRM, as well as $GRI_{Distribution}$, demonstrated a large ES of the RC-QOL in all groups. SRM ranged from 0.91 to 1.09 among the 3 groups. The $GRI_{Distribution}$ was calculated as 0.89 in the overall group, a large effect.[5] Although the $GRI_{Distribution}$ score appears to be more conservative, both calculations indicate that the RC-QOL was able to detect a statistically large difference between baseline and 2-year follow-up scores using 2 different distribution-based methods.

The RC-QOL using 2 external anchors, a 7-point Likert-style GRS and a 100-mm VAS as the second GRS, showed positive modest correlations for all groups.[5] All correlations were statistically significant. The low correlation of these tests in comparison to those of the distribution-based methods does not indicate that the RC-QOL demonstrates poor sensitivity to change, but rather that the external anchor may not be able to capture the same snapshot of quality of life in these patients.[13,31] Revicki et al recommend 0.30-0.35 of Cohen's cutoff points of 0.30-0.35 as the minimum correlation threshold and acceptable association between an external anchor and a HR-PROM change score.[31] Using these guidelines, the correlation to both external anchors exceeds the minimum threshold for responsiveness.

The literature has indicated the usefulness of the mixed-method calculations to confirm MCID.[1] These methods allow for external, anchor-based information regarding change in conjunction with sample variance, or statistical characteristics, to provide a responsiveness score. In the context of this study, GRI_{Mixed} provided scores using anchor-based MCID of the RC-QOL and the variance of the

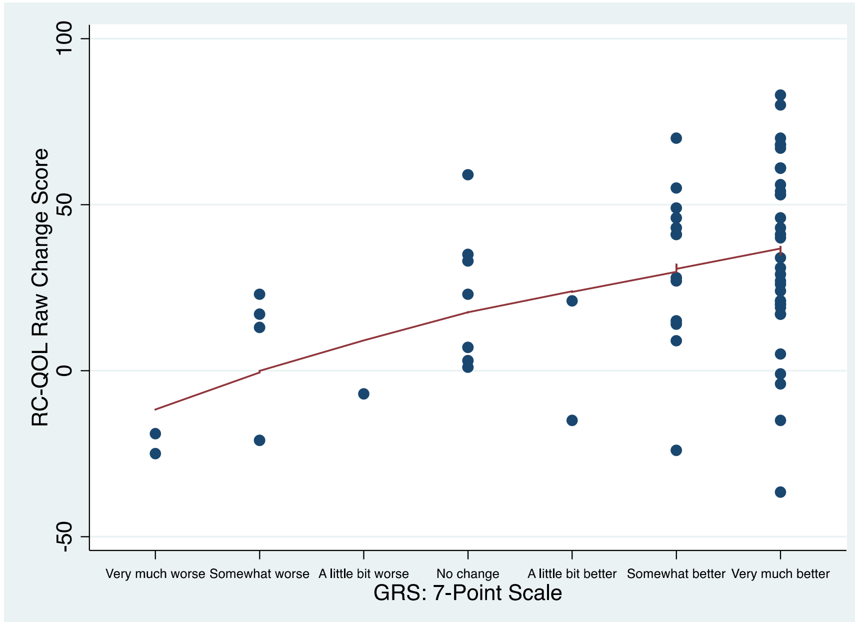

Figure 3 Raw Rotator Cuff Quality of Life (RC-QOL) index change score between 2-year time intervals vs. the 7-point global rating scale (7-point GRS) in patients with rotator cuff disease.

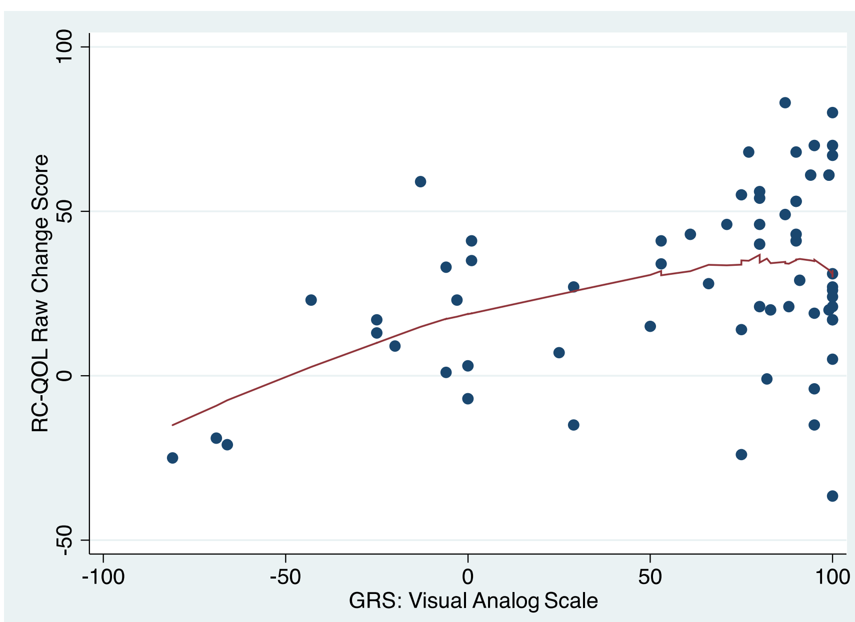

Figure 4 Raw Rotator Cuff Quality of Life (RC-QOL) index change score between 2-year time intervals vs. the visual analog global rating scale (VAS GRS) in patients with rotator cuff disease.

change scores. Ultimately, this method exhibited small ES, or a small difference between baseline and 2-year follow-up scores, in the overall group as well as in nonsurgical patients (0.48 and 0.43).

The RC-QOL provides clinicians with an insight into the symptomatic, functional, and psychological aspects that pertain specifically to patients with rotator cuff disease. This becomes most important when developing appropriate treatment and management strategies. The RC-QOL also provides a combined score in addition to individual subscale scores, allowing it to serve as an evaluative, discriminative, and predictive instrument.[3,14]

While the WORC has been shown in this study to correlate well with the RC-QOL, they differ in several aspects. First, the RC-QOL evaluates activities that are more physically demanding (ie, mopping the floor, carrying 4.54-6.8 kg). These activities substantially affect symptoms in patients with rotator cuff disease.[14] Second, the RC-QOL demonstrates its ability to discriminate patients in the SOCIAL/EMOTIONAL domain when assessing patients overall and when comparing surgical and nonsurgical groups. The WORC has not demonstrated this in the sample group. Lastly, the RC-QOL provides patients with the option of answering “Not applicable” on

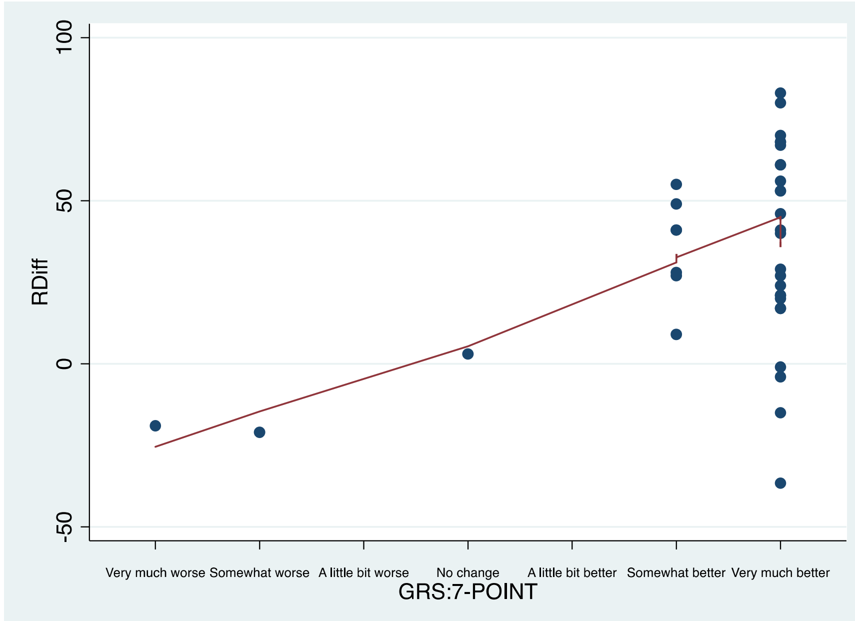

Figure 5 Raw Rotator Cuff Quality of Life (RC-QOL) index change score between 2-year intervals vs. the 7-point global rating scale (7-point GRS) in surgical patients with rotator cuff disease.

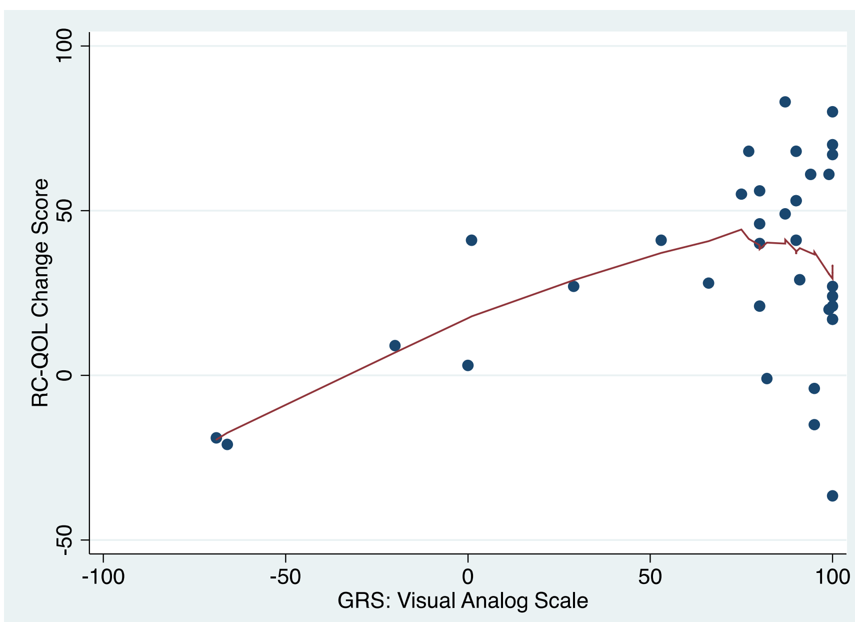

Figure 6 Rotator Cuff Quality of Life (RC-QOL) index change score between 2-year intervals vs. the visual analog global rating scale (VAS GRS) in surgical patients with rotator cuff disease.

items, which can increase the risk of satisficing behavior.[19] This behavior, first described by Herbert Simon, indicates that people often satisfice, or settled for a good enough option, when making decisions.[33] Typically this occurs in respondents who lack the cognitive capacity to comprehend what is being asked or lack the motivation to answer it thoughtfully.[33] However, in this case, patients are less likely to satisfice because they are motivated by the perception that their answers will likely influence their medical care.

Another important clinical finding is that rotator cuff patients treated surgically may score higher than their nonsurgical counterparts at approximately 2 years after baseline. Mean change scores were consistently higher in all domains for surgical patients, improving by a mean score of +38 points compared to +26 in nonsurgical patients. This may suggest that the RC-QOL may be more responsive in a surgical population.

Limitation

The appropriate use of anchor-based methods of determining responsiveness ultimately depends on the quality of the external anchors. A limitation arises in that we cannot distinguish between

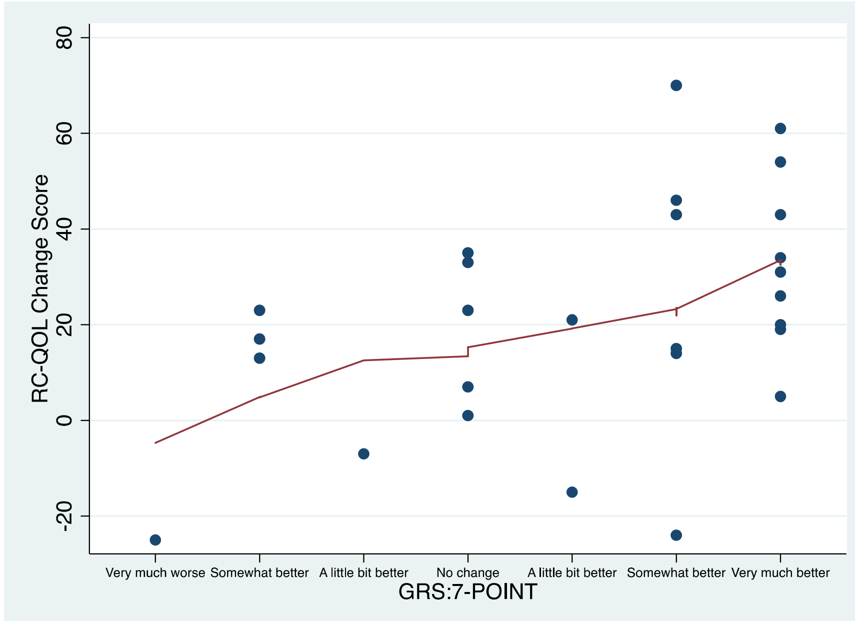

Figure 7 Raw Rotator Cuff Quality of Life (RC-QOL) index change score between 2-year intervals vs. the 7-point global rating scale (7-point GRS) in nonsurgical patients with rotator cuff disease.

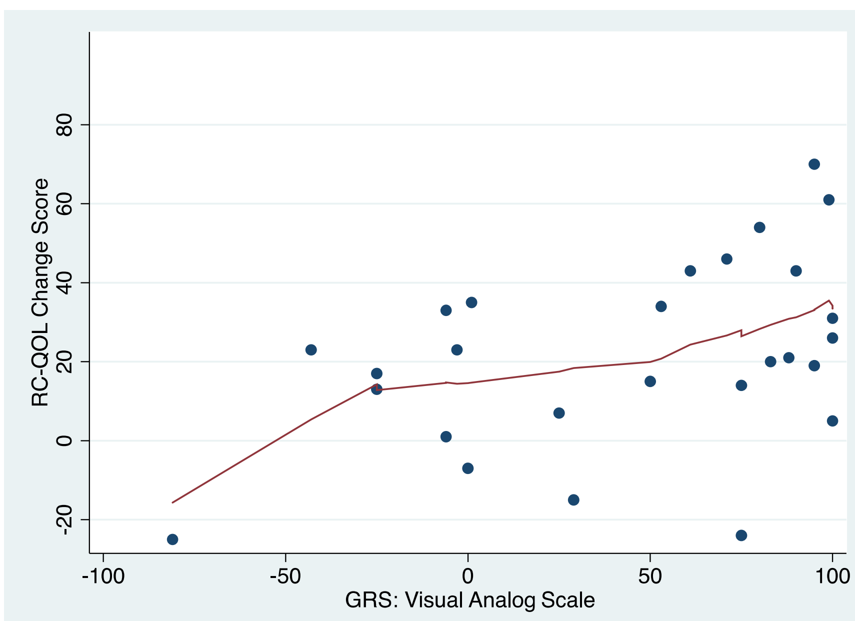

Figure 8 Rotator Cuff Quality of Life (RC-QOL) index change score between 2-year intervals vs. the visual analog global rating scale (VAS GRS) in surgical patients with rotator cuff disease.

the possibility of a poor index and the possibility of poor external anchors when evaluating these techniques. Additionally, an issue for any cohort study is loss to follow-up usually due to 2 concerns; the dropout rate is different between groups that are being evaluated, or the patients that decided to drop out are not the same as the patients that decided to participate.[7] A reasonable loss to follow-up differs within the literature but is typically as little as 5% with minor concerns for validity to >20% causing extreme concerns in affecting the validity of the study.[7] A loss of 25% to follow-up occurred at the 2-year follow-up interval of this study. While this appears to violate certain guidelines, it is important to note that patient groups that participated at the 2-year time interval were not statistically different in age and sex characteristics as those that participated at baseline.

Conclusion

The RC-QOL is an easy-to-administer, economical tool that accurately evaluates quality of life, discriminates between patients based on function, and has predictive properties that can provide insight into which patients will likely be successful with nonoperative treatment programs.[3,14] Due to a lack of consensus on appropriate measures of responsiveness, more testing using alternate distribution- and anchor-based analyses is important to further bolster the quality of the RC-QOL. Testing structural validity via exploratory factor analysis should be considered as the next step in evaluating the RC-QOL.

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