

Modelling the Functional Comorbidity Index as a predictor of health-related quality of life in patients with glenoid labrum disorders

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ABSTRACT

Background/aim: Health-related quality of life (HRQoL) is increasingly assessed within orthopaedic research. For those patients presenting with glenoid labral pathologies, there is little information on how baseline comorbidities affect long-term outcomes and HRQoL. This study aimed to investigate a model, including baseline comorbidities and demographics, to predict change in 2-year HRQoL scores in adult patients with glenoid labral tears or degenerations.

Methods: Participants provided Functional Comorbidity Index (FCI) scores and self-completed the Western Ontario Rotator Cuff (WORC) index at 6, 12 and 24 months. Univariable and multivariable linear regressions were performed to assess predictive quality of baseline comorbidities and demographics on the primary outcome measure of interest (change in WORC score).

Results: Multivariate regression with a continuous scaled FCI ($\beta=617.8$, $p=0.042$), age (by decade) ($\beta=297$, $p<0.01$), surgical group ($\beta=-476.69$, $p<0.01$) and an interaction term between FCI and age ($\beta=-103.65$, $p=0.03$) were significant predictors of change in WORC scores at 2-year follow-up ($r^2=0.293858$). Multivariate regression with FCI scaled categorically reported only patients with three comorbidities ($\beta=-454.06$, $p=0.057$) and age (by decade) ($\beta=156.87$, $p=0.04$) as the only significant predictors of change in WORC scores at 2-year follow-up ($r^2=0.1279$).

Conclusion: The continuous FCI model is better suited to predict future WORC and HRQoL scores among this patient population. Patients reporting with higher numbers of baseline comorbidities improved significantly more than patients with fewer comorbidities. This information on expected change in HRQoL scores among patients with a wide range of FCI scores at baseline may help guide treatment decisions based on these criteria.

INTRODUCTION

In the USA, a high prevalence of shoulder dysfunction is associated with high societal cost and patient burden. In 2013, a reported 86 690 work-related shoulder injuries and illnesses involving days away from

Key messages

What are the new findings?

- The Functional Comorbidity Index model predicts future Western Ontario Rotator Cuff (WORC) and health-related quality-of-life scores among adults with glenoid labral tears or degenerations.
- Patients with higher numbers of baseline comorbidities improved significantly more than patients reporting fewer comorbidities.
- Improvement in WORC score diminished with increasing patient age.

How might it impact clinical practice in the near future?

- Our findings provide details as to the changes expected in quality of life in patients with rotator cuff disease with concomitant labral pathologies following treatment.
- Our results also help determine how baseline comorbidities may predict difference in changes in the quality of life of these patients.

work occurred in the USA.¹ In 2005, the treatment measures of shoulder pain accumulated to an estimated annual cost of \$39 billion.²

Glenoid labral lesions can often lead to significant discomfort and restriction during daily living activities, as well as various sporting activities.³ Labral pathology can be classified morphologically as torn, degenerated or blunted. The most common mechanisms of injury include chronic, repetitive microtrauma secondary to overhead throwing-type movement or an acute fall onto the outstretched hand.⁴ Diagnosis of these pathologies can be optimally performed using MR arthrography. The prevalence of these tears can vary from 6% in the general population to 35% in the sporting population.^{5 6}



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Treatment options for patients presenting with glenoid labral pathology include both surgical and non-surgical interventions. Multiple reports document successful outcomes with operative repair of glenoid labrum tears (specifically superior labrum anterior posterior tears).^{5–7–15} Arthroscopic repair of these injuries can be performed with good postoperative outcomes and a low rate of recurrent labral injury.¹⁶ Non-operative repair of these same lesions has also been associated with successful outcomes.¹⁷

Quality of life is a main outcome measure in orthopaedics due to the simple fact that most orthopaedic interventions do not increase a patient's life span, so survival is not a realistic outcome measure.¹⁸ The health-related quality of life (HRQoL) measures are increasingly used within orthopaedic research, as clinicians look beyond strictly functional outcomes to physical, psychological and social factors.¹⁹ These patient-reported outcome measures often include assessments of pain and the ability to perform daily activities, but many other qualities may be assessed as well, such as satisfaction and the ability to perform sporting activities.^{20–22}

The incentive for this shift from a biomedical model to a psychosocial model has been influenced by research addressing the relationship to HRQoL and successful outcomes within a variety of orthopaedic disciplines, including labral and rotator cuff disease.^{23–25} A growing body of literature over the past 30 years has investigated HRQoL with regard to orthopaedic patients presenting with shoulder pathologies, both at baseline and after surgical interventions. It is the intent of this investigation to determine a baseline model that is better able to predict improvement in HRQoL scores after 2-year follow-up in a cohort of patients with labral pathologies.

METHODS

Study design

This was a retrospective cohort study. A sample of 123 consecutive patients presenting with glenoid labral pathologies (tears or degenerations) from July 2010 to December 2013 was identified retrospectively by reviewing data in a shoulder registry.

Inclusion/exclusion criteria

Inclusion criteria: (1) greater than 18 years of age, (2) labral tear of any size or reported labral degeneration and (3) the first tear/degeneration of the affected shoulder. Exclusion criteria: (1) a labral tear in which complete footprint coverage is not possible (for the surgical group); (2) history of prior surgery, fracture, dislocation or infection of the affected shoulder and (3) less than 2 years of follow-up data.

Data collection

Study approval was obtained from the University of Michigan Institutional Review Board (#HUM00056320).

Participants provided baseline demographic information and completed a previously validated paper-based outcome measure. Outcome measure data included the Functional Comorbidity Index (FCI) and Western Ontario Rotator Cuff (WORC) index. Participants completed follow-up WORC indexes at 6 months, 12 months and 2 years via mailed paper-based forms that included standardised instructions.

Measures

The primary outcome measure used was the WORC index. The WORC index is a valid, reliable and responsive HRQoL self-assessment measurement tool for shoulder disease.^{26–27} A recently published study determined the WORC to have the best psychometric evidence for its measurement properties among all shoulder instruments.²⁸ Items included in the instrument were determined based on a literature review, along with discussions among patients, orthopaedic surgeons, sports and family physicians and physiotherapists. The WORC includes 21 questions encompassing 5 domains. The domains include pain and physical symptoms (six questions), sports and recreation (four questions), work function (four questions), social function (four questions) and emotional function (three questions). In addition to these questions, a 100 mm visual analogue scale is included. Scores range from 0 to 2100, with a defining feature of a higher score indicating worse shoulder function.

The FCI was the primary predictor measure used. The FCI was developed specifically for use in the general population with physical function, not mortality, as the outcome of interest. The FCI can be used to adjust for the effect of comorbidity on physical function in the same manner that other indices are used to adjust for the effect of comorbidity on mortality.²⁹ The FCI contains 18 diagnoses scored by adding the number of 'yes' answers, with a score of 0 indicating no comorbid illness and a score of 18 indicating the highest number of comorbid illnesses. Comorbidities assessed by the index include: arthritis, hypertension, asthma, hearing impairment, visual impairment, gastrointestinal disease, chronic obstructive pulmonary disease/emphysema, osteoporosis, angina, anaemia, congestive heart failure or heart disease, heart attack, neurological disease, stroke/transient ischemic attack, peripheral vascular disease, diabetes mellitus (type I or II), depression, degenerative disc disease and obesity.

Statistical analysis

A sample-size calculation was performed with $\alpha=0.05$, $\beta=0.10$ using an $r^2=0.1892$ between WORC and FCI (G*Power V.3.1.9.2), which resulted in a total sample of 58 being required. Descriptive and inferential analyses were conducted using SAS V.9.4 (SAS Institute, Cary, North Carolina, USA). Univariable and multivariable linear regressions were performed to assess

predictive quality of variables on the primary outcome measure of interest. These predictors included age, sex, surgical group, FCI scaled continuously and FCI scaled categorically. Additional analyses were performed on each individual comorbidity contained within the FCI.

RESULTS

One hundred twenty-three patients met the inclusion criteria for which we had complete baseline data. Of these, 82 were males and 41 were females (table 1). The mean baseline WORC score was 1117.8 (95% CI 1033.8 to 1201.8) and the mean FCI score reported was 2.14 (95% CI 1.81 to 2.46). Out of a possible 18 comorbidities assessed by the FCI, scores within this

population ranged from 0 to 9. Patients were divided into groups based on the number of comorbidities they presented with at baseline: zero (n=23), one (n=31), two (n=28), three (n=12), four (n=16) and five or more (n=13). The most common comorbidities within the population included congestive heart failure or heart disease (n=56) and obesity (n=45). The least common comorbidities observed were myocardial infarction and neurological disease (n=0).

Multivariate regression found that FCI scaled continuously ($\beta=617.8$, $p=0.042$), age (by decade) ($\beta=297$, $p<0.01$), surgical group ($\beta=-476.69$, $p<0.01$) and an interaction term between FCI and age ($\beta=-103.65$, $p=0.03$) were significant predictors of change in WORC scores at 2-year follow-up ($r^2=0.293858$) (table

Table 1 Demographics, clinical features and baseline outcome scores

Variable	Mean/n*	SD/%*	95% CI
Age	61.04	9.88	(59.28 to 62.8)
Gender			
Male	82	66.67	
Female	41	33.33	
Body-mass index	28.58	5.56	(27.59 to 29.57)
Labral pathology			
Tear	52	42.28	
Degeneration	71	57.72	
Smoking			
Yes	8	6.5	
No	115	93.5	
WORC index	1117.8	456.6	(1033.8 to 1201.8)
Functional Comorbidity Index	2.14	1.82	(1.81 to 2.46)
Zero	23	18.70	
One	31	25.20	
Two	28	22.76	
Three	12	9.76	
Four	16	13.01	
Five or more	13	10.57	
Individual comorbidities	n	%	
Arthritis	29	23.58	
Osteoporosis	6	4.88	
Asthma	11	8.94	
Chronic Obstructive Pulmonary Disease/emphysema	2	1.63	
Angina	3	2.44	
Congestive Heart Failure or heart disease	56	45.53	
Myocardial Infarction	0	0.00	
Neurological disease	0	0.00	
Stroke or Transient Ischemic Attack	2	1.63	
Peripheral Arterial Disease	9	7.32	
Upper Gastrointestinal disease	24	19.51	
Depression	17	13.82	
Anxiety	8	6.50	
Visual impairment	14	11.38	
Hearing impairment	2	1.63	
Degenerative disc disease	13	10.57	
Diabetes	22	17.89	
Obesity	45	36.59	

*Continuous data presented as mean, SD. Categorical data presented as n, %.
MI, myocardial infarction; WORC, Western Ontario Rotator Cuff index.

Table 2 Multivariate regression with continuous Functional Comorbidity Index (FCI) as predictor of change in Western Ontario Rotator Cuff score ($r^2=0.293858$)

Parameter	β estimate	SE	95% Confidence limits	p Value
Intercept	-2184.71	671.45	-3521.75, -847.68	0.002
FCI	617.80	298.52	23.36, 1212.23	0.042
Age (decade)	297.00	105.75	86.43, 507.57	0.006
FCI \times age	-10.36	4.77	-19.86, -0.87	0.033
Gender	168.78	119.60	-69.37, 406.94	0.162
Surgical intervention	-476.69	117.22	-710.11, -243.28	<0.01

FCI, Functional Comorbidity Index.

2). Multivariate regression with FCI scaled categorically reported only patients with three comorbidities ($\beta=-454.06$, $p=0.057$) and age (by decade) ($\beta=156.87$, $p=0.04$) as the only significant predictors of change in WORC scores at 2-year follow-up ($r^2=0.1279$) (table 3). As baseline FCI scores increased, change or improvements in WORC scores increased (figure 1).

Univariate regression was performed to determine the influence each individual comorbidity had on the change in WORC scores after 2-year follow-up (table 4). Angina ($p=0.05$) was the only significant comorbidity associated with a change in WORC score. Visual impairment ($p=0.08$) and diabetes ($p=0.10$) were marginally significant predictors. Any comorbidity reporting a β with a magnitude greater than the WORC's minimally important difference of 267 was included in a final multivariable model (table 5). None of these comorbidities were significantly predictive of change in WORC score.

DISCUSSION

An important factor influencing the perception of HRQoL scores is the presence of concomitant diseases or conditions. Evaluating a patient's premorbid status is important as it assists understanding of potential return to functional levels, independence and societal participation and quality of life. Little is known about

how concurrent diseases influence the HRQoL of patients with glenoid labrum pathologies. In this study, we aimed to predict future HRQoL outcomes with baseline FCI scores, both continuously and categorically.

It is important to note that the WORC is scored on an inverse scale, meaning a negative change in WORC score displays improvement in quality of life. We initially modelled the continuous FCI parameter (with an interaction term) to predict the change in WORC scores. Our model reported greater changes in HRQoL scores as patients reported more comorbidities at baseline (table 2). All of the predictors in this model were also statistically significant, except for gender. But, given the potential non-linear relationship between the FCI and WORC change scores, this linear model could be misleading.

Similar findings were obtained when FCI was modelled categorically. Due to the potential violation of linearity between FCI scores and WORC change scores, this model may more accurately represent the data for this sample. We found that patients reporting three or more comorbidities at baseline improved more than patients reporting zero comorbidities, and that the change was large (i.e., greater than MID for the WORC). The categorical FCI model had a higher r^2 value than the continuous FCI model, but the only significant predictor was whether patients opted for

Table 3 Multivariate regression with categorical Functional Comorbidity Index (FCI) as predictor of change in Western Ontario Rotator Cuff score ($r^2=0.317282$)

Parameter	β estimate	SE	95% Confidence limits	p Value
Intercept	-855.03	487.58	-1826.56, 116.50	0.08
FCI category				
One	23.43	167.73	-310.77, 357.64	0.89
Two	154.70	179.39	-202.74, 512.14	0.39
Three	-404.04	217.08	-836.58, 28.51	0.07
Four	-174.39	204.86	-582.58, 233.80	0.40
Five or more	-27.26	231.83	-489.20, 434.68	0.91
Age (decade)	82.90	71.86	-60.28, 226.09	0.25
Gender	132.78	123.80	-113.90, 379.47	0.29
Surgical intervention	-533.21	119.92	-772.16, -294.26	<0.01

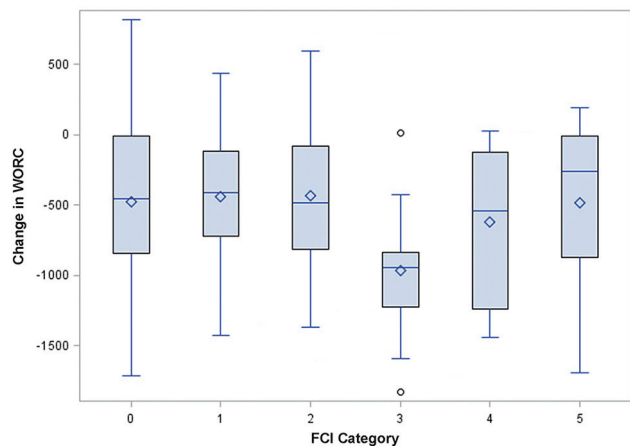


Figure 1 Change in Western Ontario Rotator Cuff (WORC) index scores from baseline to 2-year follow-up by Functional Comorbidity Index (FCI) scores.

surgical or non-surgical treatment of their labral pathology.

The finding that increased baseline FCI scores were associated with greater improvements in WORC scores was unexpected, as several previous studies have demonstrated higher levels of comorbidities associated with lower HRQoL scores.^{30–33} However, our outcome was coded as a change in WORC score from baseline to 2-year follow-up. It may be reasonable to expect patients in this population presenting with higher numbers of comorbidities at baseline to have worse baseline HRQoL scores as well. These multimorbidity patients have more ‘room to improve’ than patients with zero, one or even two comorbidities. This may help explain our findings that patients with higher

levels of comorbidities improved on average more than patients with less than two comorbidities.

The type of intervention was statistically significant in every regression analysis performed. Patients in our population receiving operative treatment significantly improved more than patients who opted for non-surgical treatment. In addition, age was found to be a significant predictor of change in WORC scores. As patient age increased, improvements in WORC scores diminished. This finding is supported widely throughout surgical literature, as older patients do not have the same healing ability as younger patients.

Strengths of this study include a large sample size, a well-validated patient-reported outcome measure and comprehensive and complete data extraction and follow-up. Study limitations include single-centre patient information, as well as deriving the patient population from a shoulder registry intended for rotator cuff pathology. Despite controlling for rotator cuff pathology, it may prove useful to investigate the effects of baseline comorbidities on the HRQoL of patients presenting only with glenoid labrum pathology.

Coding our outcome as a change in WORC from baseline to 2-year follow-up influenced our results and interpretations of the relationship between baseline FCI and HRQoL scores. Future studies may be better equipped to investigate this relationship if the outcome were coded in a different manner. It may be more clinically informative if the outcome were a binary variable defined by whether a patient improved their WORC score by a validated minimally important difference of 267.00 points.³⁴ Another potential possibility of scoring the outcome could be whether a patient

Table 4 Univariate regression modelling the individual comorbidity within the Functional Comorbidity Index and change in Western Ontario Rotator Cuff (WORC) scores

Comorbidity	β estimate	SE	95% CI	p Value
Arthritis	-111.63	155.04	-420.17 to 196.92	0.47
Osteoporosis	11.18	274.26	-534.62 to 556.98	0.97
Asthma	-142.39	220.60	-581.40 to 296.62	0.52
COPD/emphysema*	528.95	595.01	-655.15 to 1713.05	0.38
Angina*	-1172.80	583.38	-2333.77 to -11.83	0.05
CHF or heart disease	-165.35	130.58	-425.22 to 94.51	0.21
Stroke or TIA*	-581.69	420.44	-1418.39 to 255.02	0.17
PAD	-167.42	251.31	-667.55 to 332.71	0.51
Upper GI disease	-122.84	169.20	-459.55 to 213.87	0.47
Depression	-86.43	220.96	-526.17 to 353.30	0.70
Anxiety	-79.63	304.53	-685.68 to 526.41	0.79
Visual impairment*	351.46	196.67	-39.92 to 742.84	0.08
Hearing impairment*	-309.27	596.94	-1497.22 to 878.67	0.61
Degenerative disc disease	-60.84	234.77	-528.04 to 406.37	0.80
Diabetes*	299.24	181.32	-61.53 to 660.01	0.10
Obesity	-126.48	131.08	-387.29 to 134.32	0.34

Myocardial infarction and neurological disorder removed from model due to zero patients presenting with these comorbidities.

*Indicates comorbidity with β estimate greater than minimally important difference of 267.00 for WORC index.

COPD, chronic obstructive pulmonary disease; WORC, Western Ontario Rotator Cuff index.

Table 5 Adjusted multivariate regression modelling the comorbidities with β estimates greater than the minimally important difference of 267 for the Western Ontario Rotator Cuff index

	β estimate	SE	95% CI	p Value
Intercept	-545.61	79.11	-703.23 to -387.98	<0.01
Arthritis	-194.95	158.75	-511.26 to 121.37	0.22
COPD/emphysema	202.44	621.16	-1035.26 to 1440.13	0.75
Angina	-790.68	862.86	-2509.98 to 928.61	0.36
Stroke or TIA	-354.71	628.64	-1607.31 to 897.89	0.57
Visual impairment	333.17	226.20	-117.55 to 783.89	0.15
Hearing impairment	-292.39	582.15	-1452.34 to 867.56	0.62
Diabetes	253.09	192.68	-130.83 to 637.01	0.19

COPD, chronic obstructive pulmonary disease.

reached a certain WORC score threshold (eg, reducing the patient's WORC below 700).

Despite a slightly better fit according to the r^2 value, the continuous FCI model is better suited to predict future WORC and HRQoL scores among this patient population. This study provides important information on expected outcomes in patients presenting with labral pathologies along with certain comorbidities. Patients reporting higher numbers of baseline comorbidities improved HRQoL scores significantly more than patients with lower numbers of comorbidities. In addition, age and surgical intervention were strongly predictive of improvements in HRQoL among this patient population. These findings provide useful information in regards to expected outcomes in patients presenting with multimorbidities at baseline.

Competing interests None declared.

Ethics approval Study approval was obtained from the University of Michigan Institutional Review Board (HUM00056320).

Provenance and peer review Not commissioned; externally peer reviewed.

Data sharing statement On request, the senior author JJJ can provide access to the raw data associated with this study.

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