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Patients with fibromyalgia have increased risk of 90-day postoperative adverse events following arthroscopic rotator cuff repair



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Level of evidence: Level III; Retrospective Cohort Comparison Using Large Database; Prognosis Study **Background:** Arthroscopic rotator cuff repair (RCR) is a common surgical intervention for symptomatic rotator cuff tears when conservative management fails. Understanding the potential correlation of shortand long-term outcomes associated with defined comorbidities can help with patient selection, counseling, and related care pathways. The association of fibromyalgia, one potential comorbidity, with outcomes following RCR has not been reported in the literature.

Methods: Patients with and without fibromyalgia diagnosed prior to undergoing RCR were identified from the PearlDiver Mariner161 database between 2016 and April 30, 2022, using Current Procedural Terminology codes. The exclusion criteria were age less than 18 years, a diagnosis of neoplasm, trauma, or infection within 90 days prior to surgery, and postoperative records of fewer than 90 days. Patients with and without fibromyalgia were matched in a 1:4 ratio based on age, sex, and Elixhauser Comorbidity Index. Ninety-day adverse events were assessed. Severe adverse events were defined as the occurrence of sepsis, surgical site infection, cardiac events, deep vein thrombosis, or pulmonary embolism. Minor adverse events were defined as the occurrence of wound dehiscence, urinary tract infection, pneumonia, transfusion, hematoma, or acute kidney injury. Also identified was the occurrence of any adverse event, emergency department (ED) visits, and readmission. These outcomes were compared with multivariate analysis. 1-year revisions were assessed with Kaplan—Meier curves and compared with the log-rank test.

Results: In total, 295,169 RCR patients were identified, of which fibromyalgia was noted for 12,366 (4.2%). Following matching, the final cohort sizes for those with and without fibromyalgia were 11,387 and 45,354, respectively. Diagnosis of fibromyalgia was independently associated with increased risk of all individual adverse events as well as aggregated incidence of severe, minor, and any adverse events (P < .0001 for all). Additionally, patients with fibromyalgia had independently 90-day increased odds of ED utilization (P < .0001). There was no statistically significant difference in reoperation between the cohorts within 1 year of surgery.

Discussion and Conclusion: Fibromyalgia was associated with significantly increased 90-day post-operative adverse events and ED visits. These findings are relevant in surgical planning but are also balanced by a lack of difference in 1-year revisions.

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Rotator cuff tears are common, affecting 30-65% of people over 50 years old. 41,44,49 To address this, rotator cuff repair (RCR) is becoming increasingly common for symptomatic patients who have failed conservative therapy. An estimated 75,000 RCR surgeries are performed in the United States annually, with a rising trend year over year due to the aging population. 47 In fact, since the early 2000s, there has been an over 100% increase in the number of

RCRs.^{4,46} In light of this, there is the need for investigating and optimizing the outcomes following RCR surgeries, particularly pertaining to common comorbidities.

One such chronic condition that RCR patients may present with is fibromyalgia. This is a chronic condition that affects 2-8% of the world's population and is characterized by widespread musculo-skeletal pain, intestinal disorders, and fatigue. 42 The pathogenesis of fibromyalgia is not well understood, but it has been linked to inflammatory, endocrine, immune, psychosocial, and genetic factors. 42 Fibromyalgia has also been associated with other common chronic conditions, such as diabetes, neurological disorders, and infections. 30

Given its prevalence, prior studies have investigated the incidence of adverse events following varying orthopedic surgeries for

This study was deemed exempt by the Yale Institutional Review Board; IRB Protocol ID: 2000028988 (Exempt).

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patients with fibromyalgia. ^{6,10,36,37,43} This has been studied for patients undergoing total hip arthroplasty³² and total knee arthroplasty (TKA). ^{36,43} These studies found that patients with fibromyalgia were more likely to develop at least one medical ^{36,37} or one surgical ⁴³ complication compared to a nonfibromyalgia control cohort as well as experiencing higher readmission rates. ³⁷ This has also been assessed for lumbar fusions. ¹⁰

Specifically, within the shoulder population, two studies have evaluated patient-reported outcomes of fibromyalgia patients in cohort studies. Cheng et al evaluated fibromyalgia characteristics of 100 patients undergoing shoulder arthroscopy and found that the fibromyalgia score was associated with poor quality of recovery but not postoperative pain or opioid use. Gurel et al evaluated 18 patients undergoing arthroscopic RCR with fibromyalgia and found them to have similar patient-reported outcome measures to a matched group of control patients. However, both of these studies evaluated relatively small cohorts, and neither evaluated general medical perioperative adverse events or rates of revision. The current study aimed to leverage a large, national, administrative database to address the above-noted limitations of the existing literature by assessing arthroscopic RCR in those with vs. without fibromyalgia.

Materials and methods

Study population

Data was obtained from the PearlDiver Mariner161 national administrative claims database (PearlDiver Technologies, Colorado Springs, CO, USA). This dataset contains medical information for approximately 161 million individuals and has been well-established in orthopedic or shoulder research. 7,9,16,18,21,25,32,34,35,39 As data is outputted in deidentified and aggregated form, studies utilizing this database were deemed exempt from review by our institutional review board.

Patients undergoing primary arthroscopic RCR between 2016 and April 30, 2022 were identified with the Current Procedural Terminology (CPT) code 29827. The cohort was limited to those with a rotator cuff tear indication on the same day as their procedure. Rotator cuff tear diagnosis was isolated by using the International Classification of Diseases (ICD), 10th revision diagnostic codes M75.101, M75.102, M75.111, M75.112, M75.121, and M75.122. Patients were excluded if they were under the age of 18 at the time of operation, had a diagnosis of neoplasm, trauma, infection within 90 days prior to surgery, had an open RCR and complete rotator cuff reconstruction with acromioplasty, or had less than 90 days of postoperative follow-up on record.

Patients with a diagnosis of fibromyalgia prior to surgery were identified using ICD-10 code M79.7. Age, sex, and Elixhauser Comorbidity Index (ECI, a measure of overall comorbidity burden ^{17,23,24,26,40}) were abstracted. ECI is a composite index that includes many common comorbidities, such as diabetes, hypertension, and failure of various organ systems as well as others. ¹¹ Therefore, specific comorbidities that are included in ECI were not individually controlled for in this study. Individuals with fibromyalgia were matched on a 1:4 basis to those without based on age, sex, and ECI.

Postoperative adverse events

Postoperative events within 90 days from the procedure were identified using previously described methods. ^{8,14} The 90-day postoperative window was chosen due to its widespread use in the literature for analyzing complications following shoulder surgery. ^{7,19,28,29,45} Adverse events were further aggregated into

severe and minor adverse events (MAEs). Severe adverse events (SAE) were defined as the occurrence of sepsis, surgical site infection, cardiac events, deep vein thrombosis, or pulmonary embolism. MAEs were defined as the occurrence of wound dehiscence, urinary tract infection, pneumonia, transfusion, hematoma, or acute kidney injury. Any adverse events (AAEs) were defined as the occurrence of an SAE or MAE.

Additionally, healthcare resource utilization was measured during the 90-day postoperative period. Emergency department (ED) visits were identified with the CPT codes 99281, 99282, 99283, 99284, and 99285, as previously reported.²⁷ Readmissions were assessed based on built-in PearlDiver database functionality, as previously described.^{8,14}

1-year revision surgeries were then assessed. Laterality was determined from ICD-10 codes previously used as an inclusion criterion and was present for all patients in this cohort. Ipsilateral shoulder surgery was defined as arthroscopic débridement of damaged tissue, additional arthroscopic RCR, open RCR for acute, and chronic rotator cuff tear indications, acromioplasty, or total shoulder arthroplasty. These procedures were identified with the following CPT codes: 29823, 29827, 23410, 23412, 23420, and 23472.

Statistical analysis

Patient characteristics were compared prior to matching to assess for differences between the cohorts. Pearson's Chi-squared test was used to compare sex, and Welch's t-test was used to compare differences in age and ECI. Patients with fibromyalgia were then matched based on age, sex, and ECI in a 1:4 ratio to the control group, and the matched cohorts were recompared to verify that previous differences were resolved.

Ninety-day postoperative events between matched cohorts were then compared. Univariate analysis was completed using Pearson's chi-squared test or Fisher's exact test, as indicated. Multivariate analysis was performed using a logistic regression controlling for age, sex, and ECI. Independent odds ratios (OR) and 95% confidence intervals (CI) were obtained for fibromyalgia relative to the control cohort.

One-year survival to second shoulder surgery was assessed using a Kaplan—Meier survival curve. Statistical significance for differences between survival curves was assessed with a log-rank test.

All statistical analysis was performed within the PearlDiver Bellwether software (PearlDiver, Colorado Springs, Colorado) and GraphPad Prism 10.1.2 (GraphPad Software, San Diego, CA, USA). The statistical significance was defined as P < .05.

Results

Study population

A total of 295,169 patients were identified who had undergone arthroscopic RCR and met the inclusion criteria for the study, of which fibromyalgia was identified for 12,366 (4.2%) (Table I). Patients with a fibromyalgia were of significantly younger mean age than those without (56.7 ± 9.0 vs. 60.0 ± 10.0 , P < .0001). Compared to the control cohort, patients with fibromyalgia also had a greater mean ECI score (6.7 ± 3.7 vs. 4.0 ± 3.1 , P < .0001) and were more likely to be female (90.0% vs. 46.3%, P < .0001).

Patients with and without fibromyalgia were matched using a 1:4 ratio based on these patient characteristics. Following the match, differences in age, ECI, and sex were statistically insignificant (Table I).

Table IDescriptive characteristics of adult patients with and without fibromyalgia who underwent arthroscopic RCR.

	Non-matched RCR groups		P value	Matched RCR groups (4:1)		P value
	Non-fibromyagia	Fibromyalgia		Non-fibromyalgia	Fibromyalgia	
Total	282,803 (95.8%)	12,366 (4.2%)		45,354 (79.9%)	11,387 (20.1%)	
Age (mean \pm SD)	60.0 ± 10.0	56.7 ± 9.0	<.0001	57.4 ± 8.8	57.3 ± 8.8	.6853
Sex			<.0001			1
Female	130,861 (46.3%)	11,131 (90.0%)		40,525 (89.4%)	10,175 (89.4%)	
Male	151,941 (53.7%)	1235 (10.0%)		4829 (10.6%)	1212 (10.6%)	
ECI (mean \pm SD)	4.0 ± 3.1	6.7 ± 3.7	<.0001	6.3 ± 3.4	6.3 ± 3.4	.4417

ECI, Elixhauser Comorbidity Index; SD, Standard Deviation; RCR, Rotator Cuff Repair.

A 4:1 match controlling for age, sex, and ECI, is shown.

Statistically significant results are bolded and correspond to P < .05.

Table IIUnivariable analyses of 90-day complications and 90-day readmissions of matched cohorts.

	Non- fibromyalgia (n = 45,354)	Fibromyalgia (n = 11,387)	P value
AAE	2045 (4.5%)	1977 (17.4%)	<.0001
SAEs	647 (1.4%)	558 (4.9%)	<.0001
Sepsis	135 (0.3%)	171 (1.5%)	<.0001
Surgical site infection	81 (0.2%)	103 (0.9%)	<.0001
Cardiac events	101 (0.2%)	95 (0.8%)	<.0001
Deep vein thrombosis	254 (0.6%)	185 (1.6%)	<.0001
Pulmonary embolism	210 (0.5%)	127 (1.1%)	<.0001
MAEs	1662 (3.7%)	1567 (13.4%)	<.0001
Wound dehiscence	34 (0.1%)	65 (0.6%)	<.0001
Urinary tract infection	968 (2.13%)	1124 (9.9%)	<.0001
Pneumonia	369 (0.8%)	445 (3.9%)	<.0001
Transfusion	24 (0.1%)	30 (0.3%)	<.0001
Hematoma	34 (0.1%)	33 (0.3%)	<.0001
Acute kidney injury	252 (0.6%)	221 (1.94%)	<.0001
ED visit	3760 (8.3%)	3146 (27.6%)	<.0001
Readmissions	495 (1.1%)	137 (1.2%)	.3343

AAE, any adverse event; SAE, sever adverse event; MAE, minor adverse event; ED, emergency department.

Statistically significant results are bolded and correspond to P < .05.

Postoperative adverse events

The univariate analysis of 90-day adverse events is shown in Table II. Patients with a prior diagnosis of fibromyalgia were more likely to experience each of the assessed individual adverse events, and aggregated AAEs, SAEs, and MAEs than those without (P < .0001 for all). Those with fibromyalgia were more likely to have an ED visit during the 90-day postoperative period (27.6% vs. 8.3%, P < .0001), but not statistically more likely to be readmitted.

Multivariable logistic regression was conducted controlling for age, ECI, and sex (Table III, Fig. 1). Patients with fibromyalgia had statistically greater ORs for AAEs (OR: 4.69, 95% CI: [4.38, 5.01], P < .0001), SAEs (OR: 3.60, 95% CI: [3.20, 4.04], P < .0001), and MAEs (OR: 5.01, 95% CI: [4.65, 5.39], P < .0001). Compared to the control cohort, the fibromyalgia cohort was also found to have significantly greater independent ORs for each individual SAE and MAE (P < .0001 for all). Additionally, patients with fibromyalgia had a significantly greater OR for having an ED visit during this period compared to patients without the condition (OR: 4.51, 95% CI: [4.27, 4.77], P < .0001).

Fig. 2 displays a 1-year Kaplan—Meier curve for subsequent surgeries. There was not a statistically significant difference in survival to second shoulder surgery by log-rank test between the two matched study cohorts.

Discussion

Patients undergoing arthroscopic RCR may have preexisting conditions, such as fibromyalgia, that may correlate with

Table IIIMultivariable analyses (controlling for age, sex, and ECI) of 90-day adverse events of those with reactive to without fibromyalgia.

	Fibromyalgia OR (95% CI)	P value
AAEs	4.69 (4.38, 5.01)	<.0001
SAEs	3.60 (3.20, 4.04)	<.0001
Sepsis	5.10 (4.07, 6.41)	<.0001
Surgical site infection	5.06 (3.78, 6.79)	<.0001
Cardiac events	3.75 (2.82, 4.98)	<.0001
Deep vein thrombosis	2.92 (2.41, 3.53)	<.0001
Pulmonary embolism	2.41 (1.92, 3.00)	<.0001
MAEs	5.01 (4.65, 5.39)	<.0001
Wound dehiscence	7.58 (5.04, 11.61)	<.0001
Urinary tract infection	5.16 (4.72, 5.64)	<.0001
Pneumonia	5.01 (4.35, 5.76)	<.0001
Transfusion	4.94 (2.89, 8.53)	<.0001
Hematoma	3.85 (2.37, 6.22)	<.0001
Acute kidney injury	3.59 (2.98, 4.31)	<.0001
ED visit	4.51 (4.27, 4.77)	<.0001
Readmissions	1.09 (0.90, 1.32)	.3544

AAE, any adverse event; SAE, sever adverse event; MAE, minor adverse event; ED, emergency department; CI, confidence interval; OR, odds ratio; ECI, Elixhauser Comorbidity Index.

Statistically significant results are bolded and correspond to P < .05.

perioperative outcomes following their surgery. The current study found those with fibromyalgia to have greater odds of individual and aggregated adverse outcomes, as well as increased odds of ED visits following their surgery.

Fibromyalgia was identified for 4.2% of those undergoing arthroscopic RCR in the current study. This is consistent with the prevalence of fibromyalgia in the general population (approximately 2-8%).⁴² The fibromyalgia patient population was slightly younger and female predominant (90.0% females, 10.0% males), while also having a significantly greater comorbidity burden (measured by ECI) than the patient population without fibromyalgia. The greater comorbidity burden observed in the current study is consistent with prior literature that has demonstrated an association between fibromyalgia and comorbid intestinal disorders, diabetes, inflammation, infections, and neurological disorders.^{3,42} Additionally, the female gender predominance observed in the current study is consistent with prior studies, with some estimates suggesting a female-to-male gender ratio ranging from 2:1 to 9:1.^{36,50}

In comparing matched populations, the current study found that fibromyalgia patients were at increased odds of developing pneumonia after RCR. This finding is consistent with prior research regarding the correlation of fibromyalgia on postoperative pulmonary adverse events. Moore et al found that fibromyalgia patients were more likely to develop pneumonia, shortness of breath, and other respiratory abnormalities following TKA surgery in a large database study. Forti et al demonstrated that fibromyalgia diminishes patients' pulmonary function by decreasing respiratory

Risk of Complications Following RCR in Patients With Fibromyalgia vs. Without Fibromyalgia

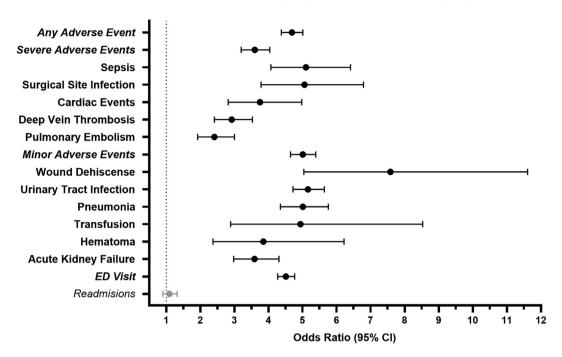


Figure 1 Forest plot of odds ratios with 95% CIs in the matched fibromyalgia cohort relative to the control cohort. Black bars are statistically significant, whereas gray bars are not. RCR, Rotator Cuff Repair; CI, Confidence Interval; ED, emergency department.

1-Year Revision-Free Survival in Patients With vs. Without Fibromyalgia

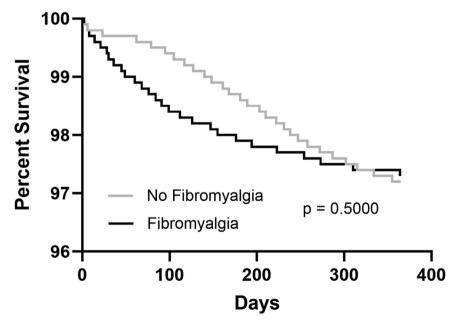


Figure 2 Kaplan—Meier curve comparing 1-year revision-free survival in adult patients who underwent arthroscopic RCR with fibromyalgia compared to patients without fibromyalgia. P value resulting from a log-rank test is shown. RCR, rotator cuff repair.

muscle endurance and inspiratory muscle strength.¹² Decreased pulmonary function may help explain why fibromyalgia patients had an increased odds of developing pneumonia after RCR.

Respiratory muscle training may be indicated as preparation for fibromyalgia patients undergoing RCR to reduce the risk of postoperative pulmonary complications, as studies have shown that respiratory muscle training may reduce the risk of respiratory-related complications.³¹ These findings are important for surgeons to consider preoperatively and postoperatively and may warrant the use of additional pneumonia prevention measures.⁴⁸

Additionally, the current study found that fibromyalgia patients were at an increased risk of thrombotic and cardiovascular events (including pulmonary embolism, deep vein thrombosis, and cardiac events) after RCR. This finding stands in contrast to other studies, which suggest that fibromyalgia is not a significant risk factor for thrombotic adverse events after TKA, total hip arthroplasty, and lumbar spine fusion. 33,36,37 However, the three aforementioned studies only evaluated the Medicare population from the Standard Analytical Filer database, which may be less representative than the patient population that was evaluated in the current study (161 million patients derived from several insurance plans). The increased statistical power and more representative patient population provides greater confidence in the effect of fibromyalgia as a risk factor for thrombotic adverse events following an RCR found in this study. This result is consistent with Molina et al's findings that patients with fibromyalgia were at increased risk of being in a prothrombotic state, increasing their risk of developing a thrombotic or vascular adverse event.³³ This may be due to endothelial dysfunction and arterial flow-mediated dilation arising from the chronic pain and inflammation seen in patients with fibromyalgia.² Thus, fibromyalgia may be a risk factor for developing thrombotic and cardiovascular adverse events following RCR due to the diminished vascular response and endothelial dysfunction seen in patients with fibromyalgia. Orthopedic surgeons may consider patients with fibromyalgia as candidates for increased thromboprophylaxis measures, such as oral administration of antithrombotic agents and mechanical interventions. 13

Furthermore, the current study elucidated that patients with fibromyalgia were more likely to develop adverse events related to infection and inflammation after RCR, including urinary tract infection, acute kidney injury, hemorrhage, transfusion, surgical site infection, wound dehiscence, and sepsis. This finding is concordant with prior studies demonstrating that fibromyalgia increases the risk of inflammation and infection following total joint arthroplasty. 6,37,43 This finding may be explained by the involvement of inflammatory pathways in the pathogenesis of fibromyalgia. More specifically, immunological factors, such as chemokines, lipid mediators, and oxidate stress may modulate the inflammatory state of fibromyalgia, although the details of this mechanism are still being investigated.⁵ Additionally, fibromyalgia has been associated with increased opioid usage following orthopedic surgery due to the overall elevated levels of pain experienced by these individuals.²² Studies have demonstrated an association between increased opioid usage and immunosuppression, ¹⁵ which may explain why the current study found that patients with fibromyalgia were at increased risk of developing an infectionrelated adverse event following surgery. These findings suggest that previous diagnosis of fibromyalgia may deserve inclusion in preoperative risk assessment prior to surgery, and that these patients may benefit from additional infection prevention measures, such as perioperative prophylactic antibiotics.³

Although this is the largest study to date assessing outcomes following RCR among patients with fibromyalgia, there are several limitations. The data utilized was reliant on ICD and CPT coding that could be prone to coding errors. Although matching was done to isolate fibromyalgia as a factor of interest, other factors could have had confounding effects. Specifically, ECI was used to quantify comorbidity burden as a composite score rather than controlling for individual patient factors. Future studies may wish to investigate the influence of specific comorbidities on outcomes following RCR for patients with fibromyalgia. Further, fibromyalgia has varying

degrees of symptom severity and type, and patients may have varying degrees of symptom control using conventional therapies used in fibromyalgia; however, this variation was not accounted for in our cohort. Finally, important outcomes, such as functional recovery and quality of life, are inaccessible within the PearlDiver database and stand as inherent limitations to the present study. Investigating these postoperative outcomes is an important direction of future research.

Conclusion

As the first study to analyze the effects of fibromyalgia on perioperative outcomes and revision rates following arthroscopic RCR, we found that fibromyalgia is a significant risk factor. It may thus be advisable to conduct more extensive risk management consultations and preoperative preparations, such as alleviation of pain and inflammation, for fibromyalgia patients to mitigate the effects of fibromyalgia prior to RCR.

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