Does diabetes mellitus predispose to both rotator cuff surgery and subsequent failure?

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\textbf{Background:} Diabetes mellitus (DM) may be associated with the etiology of rotator cuff disease; however, its effect on healing after surgical rotator cuff repair (RCR) is not well characterized. The purposes of this study are to analyze the association between DM and surgical RCR, the association between DM and revision RCR after RCR, and the association between DM and the cost of RCR.

\textbf{Methods:} A retrospective analysis of claims data of privately and publicly insured subjects from the Truven Health MarketScan database from 2008 to 2017 was conducted, collecting RCR cases and controls matched for age, sex, year of RCR, and first and last year in the database. Multivariable logistic regression models were used to compare DM incidence within the RCR and control groups after adjusting for all matching variables plus region, insurance plan type, tobacco use, and Charlson comorbidity index (CCI). Cox proportional hazard models were used to compare rates of revision RCR between DM and non-DM groups after adjusting for patient age, sex, year of RCR, plan type, and CCI. Generalized estimating equations were used to analyze RCR cost, and exponentiated regression coefficients were reported to represent cost ratios.

\textbf{Results:} The full analysis cohort consisted of 292,666 RCR cases and matched controls. The adjusted odds of having RCR surgery in diabetic patients was 48% higher (odds ratio \(= 1.48 [95\% \text{ confidence interval (CI) 1.46 to 1.51}], P < .001\)) than nondiabetics. DM was not significantly associated with revision RCR after RCR when adjusting for age, sex, region, plan type, tobacco use, year of RCR, and CCI (hazard ratio \(= 1.03, 95\% \text{ CI 0.99 to 1.07}, P = .17\)). Diabetes was associated with a higher cost of RCR by 3% (ratio \(= 1.03, 95\% \text{ CI 1.02 to 1.03}, P < .001\)).

\textbf{Conclusions:} Diabetic patients are at a higher risk of undergoing RCR surgery; however, there is no association between DM and subsequent rotator cuff revision surgery.

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Rotator cuff disease is the most common shoulder disorder treated by orthopedic surgeons, with a prevalence of approximately 20.7% within the general population.\textsuperscript{28,34} Diabetes mellitus (DM) is also a common endocrine disease with an estimated prevalence of 9.3% worldwide.\textsuperscript{33} Arthroscopic rotator cuff repair (RCR) is rapidly rising in incidence.\textsuperscript{20} Failure of healing after RCR, however, has been reported in up to 90% of cases in the worst case scenarios.\textsuperscript{5,6,11,21} While initial tear size is reported to be the most significant factor that affects tendon healing,\textsuperscript{2} various other factors have been identified that influence rotator cuff tendon healing—including age, muscle fatty infiltration and atrophy, muscle-tendon unit retraction, smoking, osteoporosis, repair construct, rehabilitation, biology, and genetic predispositions.\textsuperscript{4,8,10,13,15,17,21,29–32} Evidence also suggests that DM is associated with the etiology of rotator cuff tendinopathy and may also influence healing after RCR.\textsuperscript{3} Understanding the influence of DM on the pathogenesis of rotator cuff disease, as well as healing after RCR, may help surgeons in the development of prevention strategies as well as strategies to improve healing rates after RCR.

Several studies have identified DM as a risk factor for rotator cuff tendinopathy among both the working and general
Recent evidence showed that patients with diabetes had a 2.11-fold higher risk of rotator cuff disorders compared with those without diabetes, and a Finnish, population-based cross-sectional study showed that patients with insulin-dependent diabetes had an 8.8-fold increased risk for rotator cuff tendinitis. However, while these studies have addressed tendinopathy and tendinitis, it is unknown whether DM is a risk factor for rotator cuff tears and thus a risk factor for an increased incidence of surgical treatment in the form of RCR. Furthermore, while Cho et al demonstrated that sustained hyperglycemia increased the possibility of anatomic failure at the repaired rotator cuff, it remains unclear whether DM itself is a risk factor for revision RCR after RCR. A large retrospective database analysis of these relationships would be a favorable approach because it offers a very large, multiple-center, generalizable sample and the ability to correct for multiple comorbid factors.

Therefore, the purposes of this study are: to analyze (1) the association between DM and surgical RCR, (2) the association between DM and revision surgery post-RCR, and (3) the association between DM and the cost of RCR. We hypothesize that DM will associate with RCR, the need for revision surgery after RCR, and increased cost of RCR.

Materials and methods

Data source and sample selection

This retrospective study was conducted using the Truven Health MarketScan Commercial Claims Database of privately and publicly insured patients from 2008 to 2017. Truven MarketScan combines 2 separate databases, a commercial database and a supplemental Medicare database, and contains claims from 260 contributing employers, 40 health plans, and government and public organizations representing ~161 million lives. This administrative claims database also includes a variety of fee-for-service, preferred provider organizations, and capitated health plans. It thus represents a large sample representative of the employed and insured United States population.

The enrollment data provided beneficiaries’ demographic data—including age, employment status, geographical region, and sex. These data also provided the beneficiaries’ insurance plan data, which included plan type and enrollment status. Medical service claims provide detailed inpatient and outpatient encounter information, including date and setting of service; provider type; plan- and patient-paid amounts; International Classification of Diseases, 9th and 10th revision, Clinical Modification (ICD-9-CM and ICD-10-CM) diagnosis and procedure codes; Current Procedural Terminology, 4th edition (CPT-4) codes; and Healthcare Common Procedure Coding System procedure codes.

Statistical analysis

Patients with a diagnosis of rotator cuff tear (RCT) (ICD-9-CM: 726.10, 726.13, 727.61, 840.4; ICD-10-CM: M75.100, M75.110, M75.120, S43.429A) and surgical RCR (ICD-9-CM: 83.63 or CPT 29827, 23410, 23412, 23420) in any inpatient or outpatient service claim between January 1, 2008, and December 31, 2017, who were between 18 and 64 years of age were considered for inclusion in this study. The patient’s first claim date for RCR served as the index date, and the patient was followed up until the end of her or his continuous insurance enrollment. For purpose (1) of this study, matched controls without a history of RCT and subsequent RCR (1:1, on age ± 0 years, sex, year of RCR ± 0 years, and first and last year in the database ± 0 years) were obtained for comparison to patients with a history of RCT and subsequent RCR. Patients were stratified into 2 groups based on exposure to a diagnosis of DM: (1) patients with DM (ICD-9-CM: 250.x; ICD-10: E10, E11) and (2) patients without DM (Fig. 1).

For purpose (1) of this study, the primary outcome was RCT (ICD-9-CM: 726.10, 726.13, 727.61, 840.4; ICD-10-CM: M75.100, M75.110, M75.120, S43.429A) with accompanying RCR (CPT 29827, 23410, 23412, 23420). For purpose (2), the primary outcome was requiring a revision RCR (CPT 29827, 23410, 23412, 23420) after prior RCR. For purpose (3), total costs (gross payments to a provider for a service) 3 months post index procedure were compared between the 2 groups. The specific purpose of the cost analysis was to analyze costs related to surgery and it was felt that this period of time best reflected the time period during which surgical complications occur. Comorbidity was assessed using the Charlson comorbidity index (CCI). Inpatient diagnoses throughout the patient’s lifetime pre-index were used to construct the CCI for each patient. Comorbid tobacco use disorder (ICD-9-CM 305.1, V15.82; ICD-10: F17.x, Q99.33, P04.2, P96.81, T65.2, Z57.31, Z71.6, Z72.2, Z78.7, Z72.0, Z87.891,F17.2) was examined as a potential risk factor. Demographic variables were extracted, including age, sex, insurance type, and region.

Univariable and multivariable logistic regressions were used to construct the RCR outcome to the exposure of DM, where the multivariable model adjusted for all matching variables (age, sex, first and last year in the database) plus region, insurance plan type, tobacco use, and a modified CCI (calculated excluding points from diabetes to avoid over adjustment). Odds ratios (ORs) were reported with 95% confidence intervals (CIs) and P values. Model fit was examined using Hosmer & Lemeshow goodness of fit test. C-statistics and R-squared were calculated for each model. Cumulative incidence of revision RCR over time were presented graphically using Kaplan-Meier plots stratified by exposure. Univariable and multivariable Cox proportional hazard models were used to compare revision RCR to the exposure of DM, where the multivariable model adjusted for patient age, sex, year of RCR, duration in the database, plan type, and CCI. Hazard ratios (HRs) were reported with 95% CIs and P values. Proportional hazard assumptions were examined visually by plotting Schoenfeld residuals against time.

C-statistics and R-squared were calculated for each model. Univariable and multivariable models for RCR cost were constructed using Gamma regression obtained from generalized estimating equations. Statistical analyses were conducted using R v3.6.2 Statistical significance was evaluated at α = 0.05. All tests were 2 sided.

Results

The association of primary RCR in patients with DM

The full analysis cohort consisted of 229,986 RCR cases and their matched controls (Table 1). Owing to matching on age, sex and duration in the database, the average age was 54 years (SD = 7.7), there were 42.3% females, and the duration in the database was 4.4 years (SD = 2.7) for subjects in both the groups. Among the RCR cases, 17.9% (41,157/229,986) were diagnosed with DM, as compared to 13% (29,927/229,986) in the control group. Tobacco abuse made up 18.8% (43,223/229,986) of the RCR cases, 17.9% (41,157/229,986) were diagnosed with DM (ICD-9-CM: 250.x; ICD-10: E10, E11) and (2) patients without DM (Fig. 1).

Table II (N = 433,001) shows the odds ratio of undergoing RCR in the univariate and multivariate models. The odds of undergoing RCR is 48% higher in patients with DM (OR = 1.48 [95% CI 1.46 – 1.51], P < .001) than nondiabetic patients after adjusting for age, sex, region, insurance plan type, occupation, tobacco use, the number of years in the database, year, and CCI (calculated excluding diabetes). The association between diabetes and RCR was less than the association between tobacco abuse and RCR, which had an odds
The association of revision RCR in patients with DM

Table III shows the characteristics of RCR patients by DM status. Patients with DM had a mean age of 56.3 ± 6.2 as compared to 53.5 ± 7.9 of the nondiabetic RCR cases. 42.9% (17,665/41,157) of patients with DM were female, while 42.2% (79,703/188,829) of the nondiabetic RCR cases were female. Mean duration (years) in the database was 4.7 ± 2.7 for the diabetic RCR patients, as compared to 4.3 ± 2.7 for the nondiabetic RCR patients. 30.3% (12,461/41,157) of the diabetic RCR patients were active full-time employees, compared to 33.6% (63,492/188,829) of the nondiabetic RCR patients. 67% (25,717/41,157) of the diabetic RCR patients had a preferred provider organization insurance plan, compared to 68.5% (120,569/188,829) of the nondiabetic RCR cases. Postoperative infections in the DM group occurred at a rate of 0.7% (289/41,157) as compared to 0.4% (848/18,829). Mean CCI was 1.5 ± 1.2 in the diabetic RCR patients, while CCI was 0.3 ± 0.7 in the nondiabetic RCR patients. Tobacco abuse in the DM group was 19.6% (8069/41,157) as compared to 18.6% (35,154/188,829) of nondiabetic RCR patients.

The cost of RCR in patients with DM

Table V (N = 214,365) demonstrates ratios in RCR cost for DM and other patient characteristics. In the univariable model, DM ratio of 3.91 ([95% CI 3.86 – 4.02], P < .001) in the multivariate model.
status was associated with a higher cost of RCR by 7% (95% CI 1.06 – 1.08, P < .001). In the multivariate model, however, DM status was associated with a higher cost of RCR by 3% (95% CI 1.02 – 1.03, P < .001). Cost of RCR also varied significantly by region (Table V). When compared to a comprehensive insurance plan, the insurance plan type of point of service, preferred provider organization, consumer-directed health plan, and high-deductible health plan were associated with a higher cost of RCR by 12% (95% CI 1.04 – 1.10, P < .001), 9% (95% CI 1.07 – 1.11, P < .001), 9% (95% CI 1.07 – 1.12, P < .001), and 7% (95% CI 1.04 – 1.10, P < .001) respectively. Tobacco abuse and CCI were also associated with a higher cost of RCR of 2% (95% CI 1.01 – 1.03, P < .001) and 9% (95% CI 1.08 – 1.09, P < .001) respectively.

### Discussion

In patients with DM, the odds of undergoing RCR surgery was 48% higher when compared with their nondiabetic counterparts, after adjusting for various factors. While the odds of undergoing subsequent surgical revision RCR was significantly associated with DM in the univariate model, after correcting for age, sex, region, plan type, tobacco use, year of RCR, and CCI there was no association. In the cost analysis, DM significantly associated with a 3% increase in all billable costs 3 months after RCR; however, this effect likely is not consequential and only significantly different due to the size of the cohort.

This study demonstrated that DM is associated with a higher risk of RCR. This finding is consistent with other large population-based studies. Lin et al reported a 47% higher risk of rotator cuff disease among individuals with DM, which is consistent with our finding of 48% increased odds.14 Our findings showed that DM significantly associated with rotator cuff disease in both men and women, while another reported that this effect was only present in men.23 A Finnish study demonstrated that patients with DM had an 8.8-fold increased risk of developing rotator cuff tendinitis.16 The study only included patients between the ages of 30-64, however, while our study included patients between the ages of 18-64, which may bias our results towards the null hypothesis. Overall, our results are consistent with the current literature and provide generalizable results for adult patients within the United States. These results further support the hypothesis that rotator cuff tears are a metabolic disease, in which tendon degeneration occurs partially secondary to systemic factors. This hypothesis further supported by recent studies demonstrating an increased incidence of rotator cuff disease in patients with hyperlipidemia.14,35

This study also demonstrated that DM does not significantly associate with rotator cuff revision surgery when adjusting for age, sex, region, plan type, tobacco use, year of RCR, and CCI. To our knowledge, this is the first database study in a general population analyzing the effect of DM on RCR failure and reoperation. Cho et al performed a retrospective analysis of 64 diabetic patients with medium- to large-sized tears with supraspinatus fatty infiltration and showed that patients with DM had a 21.5% increased rate of RCR failure. The study also reported a higher rate of revision RCR among patients with poorly-controlled hyperglycemia when compared to patients with controlled HbA1c levels.12 Our study does not control for tear size or for glycemic control, and our analysis does not measure RCR failure, only subsequent revision RCR, which is an imperfect correlate with failure. However, it does control for various comorbid factors and offers a much larger sample size. Having a diagnosis of DM alone, may not predispose patients to subsequent reoperation. Based upon these findings, the
medical comorbidity of DM alone should not be used as a contra-
indication to RCR. Finally, this study reported that DM significantly associates with a higher cost in health-care expenses 3 months post-RCR. Other studies have analyzed RCR cost and the patient-, as well as, physician-specific variables that affect cost1,12,18; however, to the best of our knowledge, this study is the first to analyze the effect of DM on RCR cost. While an effect was demonstrated when controlling for region, insurance type, CCI, age, sex, and date of RCR, the effect (3%) is not large enough to be clinically significant, and thus likely does not reflect an important or explainable difference. Our analysis is limited in that it reports all health-care costs within 3 months from the index date. It may be that a more comprehensive cost-analysis would arrive at a different finding.

This study has limitations that are inherent to a claims-based database analysis. Information is limited to diagnosis and procedure codes entered by individual physicians’ offices without consideration for standard diagnostic criteria. The presenting symptoms, chronicity, or the size of the rotator cuff tear cannot be ascertained from the database. Therefore, we are unable to comment on the appropriateness of the procedure performed. Our study only evaluated individuals between the ages of 18 and 64, which excludes older subjects who may have different rates of healing post-RCR. Also, our study does not differentiate between type 1 vs type 2 DM, well-controlled from poorly controlled DM, DM without complications and DM with complications. The database limits us in how the patients are adhering to their medications; thus, interpretations on the isolated effect of hyperglycemia on rotator cuff tendinopathy cannot be distinguished. Future studies analyzing the effects of healing post-RCR in insulin-dependent versus insulin-independent DM are warranted. Our study characterized tobacco use disorder using a broad range of ICD-9-CM and ICD-10-CM billings codes, which may overreport smoking habits in the population. Additionally, laterality could not be ascertained from the data; thus, the odds of revision surgery may not be representative of the ipsilateral shoulder. Furthermore, many inherent factors can increase the risk of RCR failure, such as rotator cuff tear size and fatty atrophy. Additionally, both the ICD-10-CM codes for atraumatic and traumatic RCT were utilized, limiting our analysis in that not all tears included were degenerative. We did not subdivide between rotator cuff tear types and between diabetes types as we were concerned that the coding data may not be accurate at this level of granularity. While specific demog-
ographics and other comorbid conditions were controlled for in the multivariate analyses, many other factors were not as this infor-
mation is not reported to the database. Finally, MarketScan does not include patients who have noncommercial insurances such as Medicaid or a significant portion of Medicare, which includes those who are unemployed. Therefore, there may be inherent socioeconomic biases in the data. However, a large administrative database such as MarketScan can provide insight into nationwide practice patterns and raise questions for further study.

Conclusions

Patients with DM are at a higher risk of undergoing RCR surgery; however, there is no association between diabetes and subsequent rotator cuff revision surgery.

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Conflicts of interest: Peter Chalmers is a paid consultant for Arthrex and Mitek, is paid speaker for Depuy, serves on the editorial board for the Journal of Shoulder and Elbow Surgery, receives intellectual property royalties from Depuy, and has received other support from Tornier. Karch Smith, JJ Horns, Chong Zhang, and Angela Presson certify that they have no commercial associations (eg, consultan-
ties, stock ownership, equity interest, patent/licensing ar-
grangements, and so forth) that might pose a conflict of interest in connection with the submitted article. Jim Hotaling is a paid consultant for Tornier. Jim Hotaling is a paid consultant for Arthrex. This article was funded by a grant from the National Institutes of Health.

Table V

Univariable and multivariable gamma regression results comparing RCR cost to diabetes and other characteristics among RCR patients.

| Variable                  | Ratio in cost (95% CI) | P value | Ratio in cost (95% CI) | P value |
|---------------------------|------------------------|---------|------------------------|---------|
| Diabetes                  | 1.07 (1.06, 1.08)      | <.001   | 1.03 (1.02, 1.04)      | <.001   |
| Age (in 10 yrs)           | 1.03 (1.03, 1.03)      | <.001   | 1.01 (1.01, 1.02)      | <.001   |
| Sex: male                 | 1.02 (1.02, 1.03)      | <.001   | 1.03 (1.03, 1.03)      | <.001   |
| Region: Northeast vs. North Central | 0.95 (0.95, 0.96) | <.001   | 1.00 (0.99, 1.01)      | <.001   |
| South vs. North Central   | 0.95 (0.94, 0.95)      | <.001   | 0.94 (0.93, 0.95)      | <.001   |
| West vs. north Central    | 1.06 (1.05, 1.07)      | <.001   | 1.06 (1.05, 1.07)      | <.001   |
| Unknown vs. North Central | 0.82 (0.81, 0.84)      | <.001   | 0.83 (0.82, 0.85)      | <.001   |
| Insurance plan: EPO vs. comprehensive | 0.97 (0.94, 1.00) | .022    | 0.98 (0.95, 1.00)      | .10     |
| HMO vs. comprehensive     | 0.94 (0.92, 0.96)      | <.001   | 0.97 (0.95, 0.99)      | <.002   |
| POS vs. comprehensive     | 1.08 (1.06, 1.11)      | <.001   | 1.12 (1.10, 1.15)      | <.001   |
| PPO vs. comprehensive     | 1.06 (1.04, 1.08)      | <.001   | 1.09 (1.07, 1.11)      | <.001   |
| POS with capitation vs. comprehensive | 0.89 (0.85, 0.94) | <.001   | 0.93 (0.89, 0.98)      | <.002   |
| CDHP vs. comprehensive    | 1.08 (1.06, 1.11)      | <.001   | 1.09 (1.07, 1.12)      | <.001   |
| HDHP vs. comprehensive    | 1.08 (1.06, 1.11)      | <.001   | 1.07 (1.04, 1.10)      | <.001   |
| Tobacco abuse             | 1.04 (1.03, 1.05)      | <.001   | 1.02 (1.01, 1.03)      | <.001   |
| Year of RCR               | 1.04 (1.04, 1.04)      | <.001   | 1.04 (1.04, 1.04)      | <.001   |
| CCI                        | 1.09 (1.09, 1.10)      | <.001   | 1.09 (1.08, 1.09)      | <.001   |

CI, confidence interval; CCI, Charlson comorbidity index; RCR, rotator cuff repair; POS, point of service; PPO, preferred provider organization; CDHP, consumer-directed health plan; HDHP, high-deductible health plan.

N = 214,365.

1 From univariable models.

2 From multivariable model.
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