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Opioid use following a total shoulder arthroplasty: who requires refills and for how long?



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Introduction: Pain control following a total shoulder arthroplasty (TSA) is multifactorial. The current standard of care includes the utilization of a multimodal analgesic approach including breakthrough prescription opioid medication in an effort to provide postoperative analgesia. While this original opioid prescription is sufficient for the majority of patients, some go on to require prolonged opioid use. Our study investigated patient risk factors associated with opioid refill postsurgery.

Methods: The Truven Marketscan® database was queried for all patients who underwent either a primary anatomic TSA or primary reverse TSA from 2010 to 2017. Opioid data were collected using National Drug Codes (NDC) from outpatient pharmacy claims. Only opioid-naïve patients were included. Patients were then grouped into 1 of 3 cohorts based on postoperative opioid use: 1) Patients with no additional refills, 2) patients with a minimum of one additional refill up through 6 months postoperatively, and 3) patients with additional refills and continued opioid use past 6 months.

Results: Of the total of 17,706 opioid-naïve patients that underwent a TSA, 10,882 (61.5%) did not have any additional refills, 4473 (25.3%) required an additional prescription within 6 months after surgery, and 2351 (13.3%) had prolonged opioid use beyond 6 months postoperatively. A dose-dependent relationship was identified between initial opioid prescription quantity and risk for refill and prolonged use. The prolonged use group was prescribed an equivalent of 20.0 more 5 mg oxycodone pills than the no refill group and 12.7 more than the refill group ($P < .001$). On multivariate analysis, younger age, female gender, and tobacco use, along with the comorbidities of coronary artery disease, clinical depression, diabetes, and rheumatic disease were all found to be predictive factors of prolonged opioid use.

Discussion: The dose-dependent relationship observed between original opioid prescription data and number of additional refills needed, suggests that initially overprescribing opioids may lead to prolonged dependency. This study also identified several independent risk factors for prolonged opioid use, including younger age, depression, and tobacco use. This study will hopefully help recognize high-risk patient populations and serve as the foundation for future studies into opioid prescription standardization and preoperative opioid education.

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In part as a byproduct of the campaign for better pain control and labeling pain as the fifth vital sign in the early 2000s¹, the opioid epidemic was born out of the increase in number of opioid pills prescribed. The opioid epidemic in the United States has been declared a national emergency that continues despite extensive

medical research and intense scrutiny.²⁹ Over the first decade of the 21st century, the opioid sales increased by 400%.¹⁶ More recently, there has been a near 3-fold increase in the number of people with an opioid use disorder,^{23,26} with the United States (US) making up 80% of the global opioid supply despite only representing 5% of the world's population.¹⁶ Most people's first exposure to opioids is via prescription medication,³² with many patients receiving prescriptions with the number of opioids well in excess of the number they will ultimately need to take for adequate pain control.²⁵ Orthopedic surgeons are among the leading prescribers of opiate medications,²³ and therefore, orthopedists have a substantial opportunity for improved opioid stewardship. For many opiate-naïve patients, the need to undergo an orthopedic surgery may represent

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the initial gateway to prolonged opiate use.^{5,10} Therefore, developing a procedure- and patient-specific understanding of risk factors for opiate misuse is essential to guide prescribing practices.

Despite the fact that the incidence of TSA in the United States is increasing exponentially,³³ there remains a limited amount of data investigating risk factors for opiate refill after TSA. Pain control following total shoulder arthroplasty (TSA) is warranted for patient satisfaction and improved outcomes. The current standard of care includes multimodal analgesia including nerve blockade, anti-inflammatories, and a breakthrough prescription of opiate pain medication.²¹ While the majority of patients achieve sufficient pain control with their original prescription, some go on to require additional refills or progress to prolonged opioid use.^{7,20} Identifying these patients and associated risk factors is critical as a single postsurgical refill has been shown to increase the potential of misuse by more than 40%.⁵

The purpose of this study was to define the association between the quantity of the initial opiate prescription and the need for a refill. Furthermore, we sought to identify patient-specific risk factors associated with opioid refill and prolonged postoperative use following TSA. We hypothesized that a higher number of oral morphine equivalents (OMEs) in the initial prescription would lead to a higher risk of refill and prolonged usage. We also hypothesized that certain modifiable risk factors would be independent predictors of prolonged or increased use.

Methods

Data source and cohort selection

This is a review of the Truven Health MarketScan Commercial Claims and Encounters and Medicare Supplemental and Coordination of Benefit databases (Truven Health, Ann Arbor, MI, USA). The database was queried from January 1, 2010 through December 31, 2017. The Truven database is a commercially available, nationwide insurance database that includes information on over 240 million patients and offers the ability to track patients who have continual enrollment longitudinally. Additionally, the Truven database is advantageous in that it includes information on outpatient pharmaceutical claims.

We queried the database for patients undergoing Total Shoulder Arthroplasty (TSA) using the Current Procedural Terminology (CPT) code 23472 (Arthroplasty, glenohumeral joint; total shoulder, glenoid and proximal humeral replacement). Patients <18 year old, those with a history of prosthetic joint infection, and those undergoing a revision shoulder arthroplasty or TSA for the treatment of a fracture were excluded from the study. To allow sufficient time to collect preoperative data, comorbidities, and postoperative prescription data, only patients who were continuously enrolled for at least 6 months preoperatively and 12 months postoperatively were included. This 18-month study period was broken down into 4 separate periods: 1) preoperative period, 2) surgical period, 3) refill period, and 4) prolonged use period. These study periods are shown to scale and defined in Figure 1.

Given the aim of the study, we only included patients who were “opioid naïve”, which we defined as any patient with no opioid prescriptions filled during the preoperative period (6 months to 6 weeks prior to surgery). Similar to previously published methodology,^{13,15} opioid prescriptions filled during the surgical period (6 weeks before surgery through the 2 weeks after) were designated as original prescriptions and it was assumed that the intended use of these prescriptions was for perioperative and postoperative pain control. To control for the possibility of patients not filling their prescription through their insurance plan (ie, using a discount pharmacy or rebate program [eg, GoodRx]), those patients without

an original opioid prescription were excluded from the study population. A complete selection algorithm is outlined in Figure 2.

Baseline patient data

Baseline patient demographic information, comorbidities, and medication data were collected for the preoperative period: demographics (age and sex), obesity (defined as body mass index ≥ 30), chronic kidney disease, alcohol use disorders, tobacco use, hypertension, hyperlipidemia, coronary artery disease, congestive heart failure, diabetes, rheumatic disease, depression, and anxiety.

Each patient’s opioid pain medication data for the entire 18-month study period was collected using the National Drug Codes (NDCs) included in the Truven database. The use of NDCs in large database studies has been widely utilized.^{2,36} After isolating the opioid therapeutic class (ie, hydrocodone, oxycodone, morphine, hydromorphone, codeine, and so forth), we recorded the prescription dose and quantity. We then used this information to calculate OMEs according to publicly available opioid conversion tables, similar to that shown in Figure 3.²⁸ In order to provide a standardized, clinically applicable outcome measure, OMEs were then converted to total pill quantity and presented as the number of 5 mg oxycodone tablets.

Postoperative outcomes

Patients were divided into 1 of 3 separate cohorts based on their opioid use during the postoperative periods defined in Figure 1. The first cohort, designated as “No Refill”, included those patients who did not fill an opioid prescription outside of the perioperative surgical period. The second, “Refill” cohort included patients who filled at least one additional opioid prescription during the refill period, lasting up to 6 months after surgery. The third, “Prolonged Use” cohort included those patients who filled at least one opioid prescription during both the refill period and prolonged use period, thus indicating continued opioid use for longer than 6 months after TSA.

Statistical analysis

After allotting patients to their respective cohorts (based on postoperative opioid use, as mentioned previously), we used chi-square analysis to compare baseline characteristics and comorbidities between groups. We then performed multiple 2-sample t-tests to compare original opioid prescription data including quantity of pills and OMEs between the cohorts. Binomial logistic regression was then used to assess independent risk factors associated with additional opioid refills, while controlling for the baseline demographic and comorbid data included in Table I. For this analysis, we compared the refill and prolonged use groups to the no refill cohort as reference. We are reporting results as odds ratios (ORs) with 95% confidence intervals. A *P* value of <0.05 was selected as representing significance for this study. All statistical analysis was done using SAS, version 9.4 (SAS, Cary, NC, USA) statistical software.

Results

Cohort distribution and patient-specific risk factors for prolonged opioid use

From 2010 to 2017, we identified 17,706 patients meeting our specified inclusion and exclusion criteria from the Truven database (Fig. 2). Those patients were then separated into the 3 cohorts as

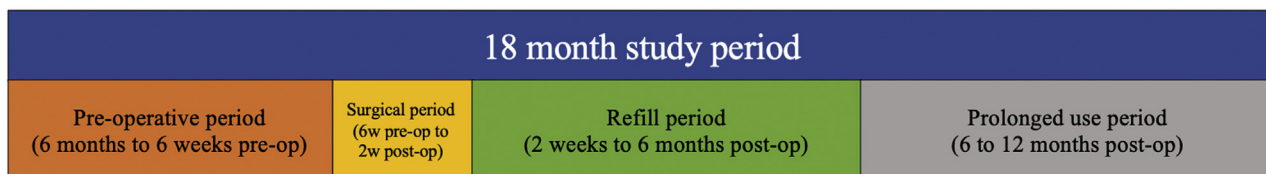


Figure 1 Timeline of defined study periods represented to scale.

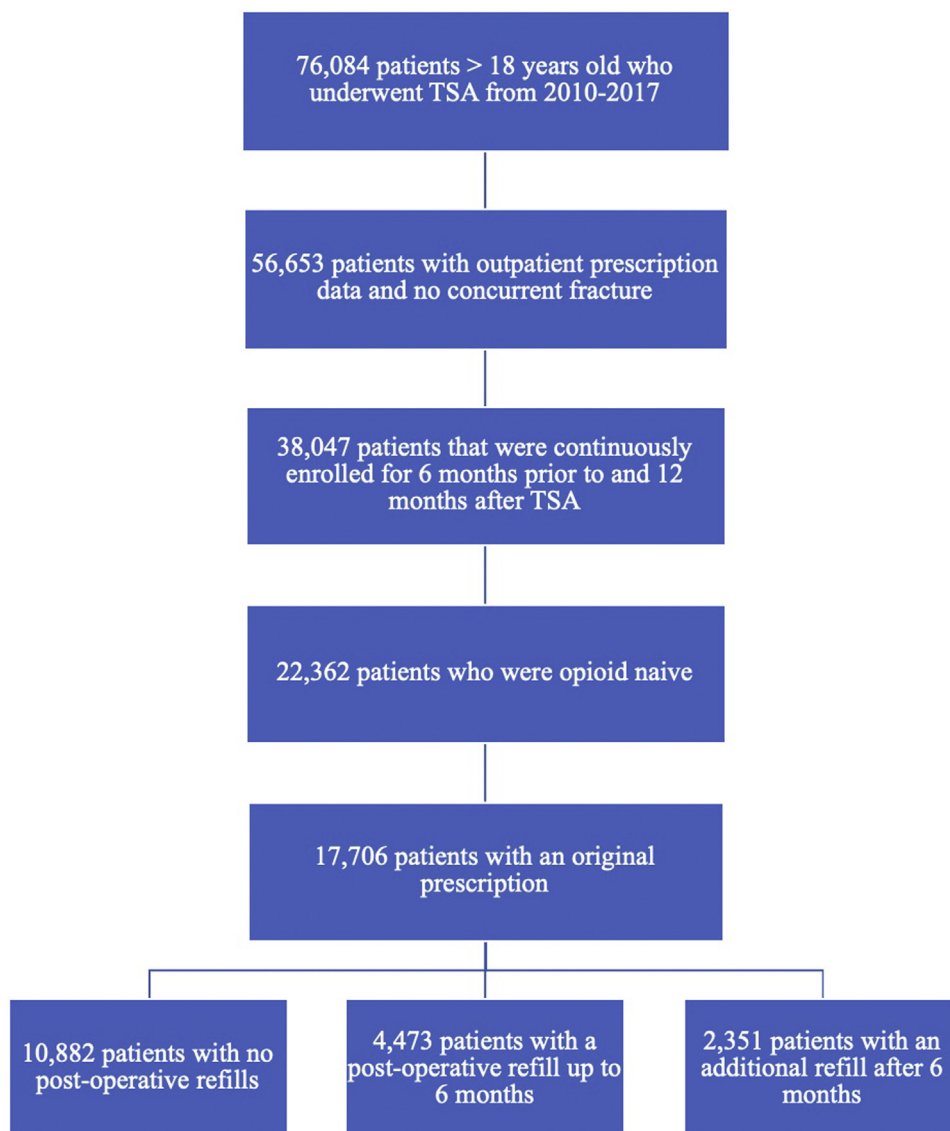


Figure 2 Study cohort selection of patients undergoing total shoulder arthroplasty (TSA) using Truven MarketScan database, 2010-2017.

described previously and the distribution of patients is shown in Figure 1. The majority (61.5%) of patients who underwent TSA did not require any additional opioid refill after their original prescription, while 25.3% required at least one refill and 13.3% went on to have prolonged postoperative use (Table I).

Chi-squared analysis revealed multiple differences in baseline demographic and comorbidities between groups. Patients requiring a refill or prolonged opioid use were more often young and female when compared to those who did not require a refill ($P < .001$). There were also significant differences between groups

in several examined comorbidities including obesity, tobacco use, coronary artery disease, diabetes, rheumatic disease, depression, and anxiety ($P \leq .003$). While some of these differences were small, the occurrence of each condition was universally higher in the prolonged use group. Table I.

Subsequently, multivariate analysis was performed controlling for the variables listed in Table I, in order to determine independent risk factors associated with additional opioid refills (Table II). Younger age was associated with a higher risk, as patients 18-54 year old had significantly higher odds of needing an opioid refill or

OPIOID (doses in mg/day except where noted)	CONVERSION FACTOR
Codeine	0.15
Fentanyl transdermal (in mcg/hr)	2.4
Hydrocodone	1
Hydromorphone	4
Methadone	
1-20 mg/day	4
21-40 mg/day	8
41-60 mg/day	10
≥ 61-80 mg/day	12
Morphine	1
Oxycodone	1.5
Oxymorphone	3

Figure 3 OME conversion table of commonly prescribed opioids. From “Calculating Total Daily Dose of Opioids For Safer Dosage”. Available at: https://www.cdc.gov/drugoverdose/pdf/calculating_total_daily_dose-a.pdf. Accessed October 3, 2020.

Table 1
Demographics and comorbidities of postoperative opioid use groups.

	Postoperative opioid use groups			P value
	No refill	Refill	Prolonged use	
Total, n (%)	10,882 (61.5)	4473 (25.3)	2351 (13.3)	
Average age, (SD)	67.98 (9.79)	66.38 (9.83)	65.92 (9.95)	<.001
Age group ^a				
18-54	925 (8.5)	418 (9.3)	268 (11.4)	<.001
55-64	3245 (29.8)	1602 (35.8)	863 (36.7)	
65-74	3573 (32.8)	1442 (32.2)	712 (3.3)	
75+	3139 (28.8)	1011 (22.6)	508 (21.6)	
Sex ^a				
Male	6125 (56.3)	2375 (53.1)	1182 (5.3)	<.001
Female	4757 (43.7)	2098 (46.9)	1169 (49.7)	
Comorbidities ^a				
Obesity	1322 (12.1)	583 (13.0)	347 (14.8)	.002
Renal disease	554 (5.1)	250 (5.6)	128 (5.4)	.416
Alcohol abuse	103 (.9)	33 (.7)	28 (1.2)	.167
Tobacco use	395 (3.6)	192 (4.3)	135 (5.7)	<.001
Hypertension	7117 (65.4)	2924 (65.4)	1591 (67.7)	.095
Hyperlipidemia	5975 (54.9)	2473 (55.3)	1321 (56.2)	.518
Coronary artery disease	2112 (19.4)	874 (19.5)	527 (22.4)	.003
Congestive heart failure	434 (4.0)	191 (4.3)	114 (4.8)	.156
Diabetes	2127 (19.5)	919 (2.5)	585 (24.9)	<.001
Rheumatic disease	508 (4.7)	200 (4.5)	154 (6.6)	<.001
Depression	850 (7.8)	470 (1.5)	317 (13.5)	<.001
Anxiety	326 (3.0)	170 (3.8)	104 (4.4)	.001

SD, standard deviation.

^a Presented as n (% of opioid use group) (95% confidence interval).

prolonged opioid use when compared to those 75+ years old (OR 0.46, $P < .001$; OR 0.65, $P < .001$, respectively). Female gender was associated with increased odds for additional refills (OR 1.20, $P < .001$) and prolonged use (OR 1.37 $P < .001$). Comorbidities associated with increased odds of requiring an additional refill up through 6 months postoperatively were coronary artery disease

(OR 1.10, $P = .042$) and clinical depression (OR 1.29, $P < .001$). These comorbidities were also risk factors for prolonged opioid use, along with tobacco use, diabetes, and rheumatic disease. Depressed patients were at the highest risk for prolonged opioid use (OR 1.59, $P < .001$) followed by current tobacco users (OR 1.51, $P < .001$).

Table II
Adjusted odds of risk factors for postoperative opioid use.*

Risk factor	Postoperative opioid use groups			
	Refill		Prolonged use	
	Odds ratio	P value	Odds ratio	P value
Age group				
18-54	[Reference]	-	[Reference]	-
55-64	1.06 (0.93-1.21)	.381	0.84 (0.72-0.99)	.036
65-74	0.84 (0.73-0.96)	.009	0.58 (0.49-0.68)	<.001
75+	0.65 (0.56-0.75)	<.001	0.46 (0.39-0.55)	<.001
Sex				
Male	[Reference]	-	[Reference]	-
Female	1.20 (1.12-1.29)	<.001	1.37 (1.25-1.51)	<.001
Comorbidities				
Obesity	0.98 (0.88-1.10)	.777	1.05 (0.92-1.19)	.517
Renal disease	1.16 (0.99-1.36)	.063	1.03 (0.84-1.26)	.802
Alcohol abuse	0.68 (0.46-1.02)	.061	1.02 (0.66-1.57)	.933
Tobacco use	1.16 (0.97-1.38)	.105	1.51 (1.23-1.85)	<.001
Hypertension	1.03 (0.95-1.11)	.531	1.10 (0.99-1.22)	.080
Hyperlipidemia	0.99 (0.92-1.07)	.849	0.97 (0.88-1.07)	.514
Coronary artery disease	1.10 (1.00-1.21)	.042	1.36 (1.21-1.53)	<.001
Congestive heart failure	1.08 (0.90-1.30)	.391	1.09 (0.88-1.37)	.434
Diabetes	1.07 (0.98-1.17)	.132	1.35 (1.21-1.51)	<.001
Rheumatic disease	0.91 (0.76-1.07)	.248	1.34 (1.11-1.62)	.003
Depression	1.29 (1.14-1.45)	<.001	1.59 (1.38-1.84)	<.001
Anxiety	1.10 (0.91-1.33)	.343	1.09 (0.87-1.38)	.454

*Compared to patients with no postoperative refill; Significant values are highlighted in bold.

Original opioid prescription and implications for prolonged use

To complete our primary objective, we then compared original opioid prescription data filled during the surgical period between the groups. The average amount of OMEs originally prescribed was higher in the Refill and Prolonged Use groups when compared to those in the No Refill group (Table III). For example, when compared to those with no refill, patients who had prolonged postoperative opioid use received an average of 150 more total OMEs ($P < .001$). In a more clinically applicable metric converting OMEs to 5 mg oxycodone tablets, the Refill and Prolonged Use groups were initially prescribed an average of 7.3 more pills and 20 more pills, respectively, than the No Refill group.

Discussion

The opioid epidemic in the United States is well documented and has caused significant patient harm as well as utilization of valuable resources.²⁹ Given the adverse effects of opioid medication, investigations into limiting patient exposure to opioids and reducing the potential for prolonged use are of significant clinical importance. Orthopedic surgery is known to be a potential gateway to prolonged opioid use in the setting of inappropriate prescribing habits, especially in opioid-naïve patients.¹⁰ This iatrogenic opioid dependence is particularly concerning and provides a clinical opportunity for intervention and future prevention. Furthermore, it likely will improve outcomes after shoulder arthroplasty, as not only is prolonged opioid usage associated with poor outcomes after TSA,^{6,22,24,31} higher utilization of opioids postoperatively is correlated with worse satisfaction with the surgery.^{4,25,35} In this study, we identified the rate of and risk factors for prolonged opioid use following TSA in the opioid-naïve patient, as well as correlated the initial prescription number to the risk for prolonged postoperative opioid usage.

The results of this investigation demonstrated a dose-dependent relationship between original opioid prescription quantity and the need for both an opioid refill and for prolonged

opioid use over 6 months after surgery. On average, patients that obtained a refill and went on to prolonged use were initially prescribed 7.3 and 20.0 more 5 mg oxycodone pills, respectively (55 and 150 more OMEs, respectively) than those not requiring a refill. We also identified several patient-specific risk factors that were associated with increased odds of requiring additional opioid refills following TSA. Specifically, younger patient age, female gender, coronary artery disease, and depression each independently increased the odds of refill and prolonged use. Additionally, potentially modifiable risk factors, such as tobacco use and depression, significantly increase the odds of prolonged opiate use.

The dose-dependent relationship identified in this study between original prescription and subsequent opioid refills among opiate-naïve patients undergoing primary TSA represents an important discovery and consideration. Historically, surgeons have based opiate prescriptions on anecdotal experience, prescriber convenience, or even to the discretion of trainees.⁸ The common assumption has been that larger initial prescriptions will decrease the burden of patient phone calls and refill requests.¹⁴ However, similar to other nonorthopedic¹⁸ and orthopedic^{26,37} studies, our results contradict this assumption, suggesting that patients who are given more opiates will request and utilize more opiates. Our findings are similar to prior literature across a range of surgical procedures. Scully et al investigated opiate refill rates across 13 common orthopedic and general surgery procedures and analyzed the impact of initial prescription duration on probability of a refill.²⁶ They found that following musculoskeletal procedures, as prescription duration increased past 15 days refill rates increased incrementally. In another study of 1372 opiate-naïve patients undergoing total knee arthroplasty, patients who required a refill initially received a 46.7% larger initial opioid prescription.³⁷ The mounting evidence that patients who are given more opiates initially will ultimately require more opiates postoperatively highlights the importance of preoperative opioid education, managing patient expectations, and standardizing prescribing practices to minimize the risk of iatrogenic dependence. Furthermore, as this study demonstrates that the quantity of opioids initially prescribed

Table III
Comparison of original opioid prescription data.

	Postoperative opioid use groups		
	No refill	Refill	Prolonged use
Total OME ^a	741.25 (722.9–759.5)	796.08 (769.9–822.2)	891.18 (855.3–927.0)
Average difference	0	54.8 (21.8–87.9)	149.9 (107.2–192.7)
P value ^b	–	.001	<.001
Quantity prescribed ^a	98.83 (96.4–101.3)	106.14 (102.7–109.6)	118.82 (114.0–123.6)
Average difference	0	7.3	20.0
P value ^b	–	.005	<.001

OME, oral morphine equivalents.

Bold represents statistical significance.

^aPresented as average (95% confidence interval).

^bP value when compared to no refill group; quantity standardized to 5mg oxycodone tablets.

will not reduce the number of required refills, we propose that surgeons should consider prescribing conservatively without undue concern for the burden of refill requests.²⁷

Although this study demonstrates the clear association between higher quantity of opioids prescribed and the need for a refill postoperatively, it is not able to establish a clear algorithm for standardization of opioid prescribing practices. Multimodal pain control has been shown to effectively reduce opiate demand after lower¹⁷ and upper extremity²¹ arthroplasty. Martusiewicz et al prospectively analyzed the opiate consumption of 50 patients after TSA and found that with the use of an interscalene block catheter for 3 days, the majority of the patient's consumed <25 5mg oxycodone tablets.²⁰ The same patients additionally reported satisfaction with their postoperative pain control. Interestingly, the average initial prescription for the 17,706 patients in our study was greater than 90 5 mg oxycodone tablets. This snapshot of national prescribing practices suggests that current practice is likely excessive, placing patients at risk for prolonged use and contributing a large number of pills at risk for diversion to society. Additionally, a multimodal regimen (eg, an interscalene catheter, non-narcotic anti-inflammatories) is shown to be beneficial and a multidisciplinary approach for high-risk patients should be considered. Future studies into the role of multimodal pain regimens are critical to help standardize and ultimately reduce the number of opioids prescribed for procedures such as TSA.

Understanding patient-specific risk factors that predispose to opioid misuse after surgery is critical to inform safe and responsible prescribing, as well as target preoperative interventions and education. Prior studies have investigated risk factors for prolonged opioid use in patients undergoing soft tissue procedures of the hand, upper extremity, and shoulder,^{11,12,19} but few have focused on TSA. Chatha et al reported that TSA patients on preoperative narcotics were 3.5 times more likely to develop postoperative dependence.⁷ Similarly, in a cohort of 12,038 TSA patients, Khazi et al identified chronic preoperative opioid use as the strongest risk factor for ongoing use at 12 months postoperatively, followed by chronic lung disease, age <65, chronic pain disorders, psychiatric diagnoses, and EtOH abuse also reaching statistical significance.¹³ However, given that these prior studies included patients on preoperative opioids, it is difficult to determine risk factors for those who are opioid naïve preoperatively. This is important given iatrogenic opioid dependence is of significant concern. Our data suggest that in opioid-naïve patients, factors such as younger age, female gender, active tobacco use, depression, coronary artery disease, diabetes, and rheumatic disease are at higher risk prolonged opioid use after TSA. Of particular importance are the potentially modifiable risk factors, such as tobacco use and depression, that may benefit from preoperative optimization and additional education. Possibly these higher risk patients should also

receive a tailored multimodal and even multidisciplinary pain management strategy to minimize risk of patient harm. Given our results, this should include a reduction in the number of pills initially prescribed.

While the results of this investigation are informative, there are multiple limitations to this investigation and the results of this study should be interpreted with these in mind. First, as with the analysis of any large database, we are reliant on accurate ICD and CPT coding within patient records. Second, we used NDC codes to identify preoperative opioid prescriptions. While there is significant precedence in the literature for this,^{9,30,34} we are again reliant on accurate coding. Additionally, utilizing the CPT code 23472 in our methodology limits the ability to differentiate between anatomic shoulder arthroplasty and reverse shoulder arthroplasty. Finally, the Truven Marketscan database contains information only on patients with private, employee sponsored medical insurance or those with Medicare supplemental insurance. Uninsured patients, those with other private insurance plans not included by the Marketscan database, those with Medicare advantage, and those with Medicaid would not be included in this analysis, potentially limiting the generalizability to these specific patient cohorts.

Despite these limitations, the Truven Marketscan database represents a strength of the current investigation. The database allows for analysis of a large number of patients and unlike many administrative national databases (like the National Inpatient Sample) includes information from both inpatient and outpatient encounters. Additionally, the database allows for longitudinal follow-up as long as the patient remains enrolled in their health-care plan. Last, the database tracks administered prescriptions. Therefore, we were able to track preoperative opioid prescriptions for the 6-month preoperative period and through a year postoperatively. This is much more than the 30–90 days allowed by most other regional and national databases.³

Conclusions

Among opiate-naïve patients undergoing primary TSA, the study findings identified a dose-dependent relationship between initial opiate prescription and risk of subsequent refill and prolonged use. Additionally, risk factors for additional refills or prolonged usage included patient demographics (eg, young age, female gender), comorbidities (eg, depression, diabetes mellitus, rheumatic disease), and behavioral characteristics (eg, tobacco usage). Surgeons can utilize these findings to counsel patients on their preoperative risk, optimize potentially modifiable risk factors preoperatively, and implement a patient-specific and possibly multidisciplinary pain management strategy for high-risk patients. Furthermore, this information highlights the importance of initial

opioid prescription size and identifies an area where physicians can strive to reduce their contribution to opioid dependence.

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