J Shoulder Elbow Surg (2020) 29, S67–S72

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Journal of Shoulder and Elbow Surgery

www.elsevier.com/locate/ymse

Therapeutic postoperative anticoagulation is a risk factor for wound complications, infection, and revision after shoulder arthroplasty

Jourdan M. Cancienne, MD[a,*], John T. Awowale, MD[b], Christopher L. Camp, MD[c], Ryan M. Degen, MD[d], Brian Shiu, MD[e], Dean Wang, MD[f], Brian C. Werner, MD[b]

[a]*Southern Orthopaedic Specialists, New Orleans, LA, USA*
[b]*Department of Orthopaedic Surgery, University of Virginia, Charlottesville, VA, USA*
[c]*Department of Orthopedic Surgery, Mayo Clinic, Rochester, MN, USA*
[d]*Fowler Kennedy Sports Medicine Clinic, Western University, London, ON, Canada*
[e]*Ruxton Professional Center, University of Maryland School of Medicine, Towson, MD, USA*
[f]*Division of Sports Medicine, Department of Orthopaedic Surgery, UC Irvine Health, Orange, CA, USA*

Background: The purpose of the present study was to examine the relationship between postoperative therapeutic anticoagulation, wound complications, infection, and revision.

Methods: Using a national insurance database from 2007 to 2016, patients who underwent shoulder arthroplasty with an indication for postoperative therapeutic anticoagulation in the case of atrial fibrillation or acute postoperative venous thromboembolism were identified. Those with a prescription for a therapeutic anticoagulant within 2 weeks of surgery were identified and compared with controls without postoperative therapeutic anticoagulant prescriptions. Wound complications and postoperative infection at 3 and 6 months, and revision shoulder arthroplasty at 6 months and all time points were then compared in the database using a multivariable logistic regression analysis.

Results: A total of 17,272 patients were included, including 684 patients who received therapeutic anticoagulation and 16,588 controls. Patients receiving therapeutic anticoagulation experienced increased wound complications at 3 months (odds ratio [OR] 3.0, 95% confidence interval [CI] 2.0-4.6, $P < .0001$) and 6 months (OR 2.5, 95% CI 1.7-3.8, $P < .0001$). Patients receiving therapeutic anticoagulation also experienced increased rates of wound infection at 3 months (OR 1.5, 95% CI 1.1-2.0, $P = .007$) and 6 months (OR 1.8, 95% CI 1.4-2.3, $P < .0001$). Finally, patients receiving therapeutic anticoagulation experienced increased rates of revision surgery at 6 months (OR 1.8, 95% CI 1.3-2.5, $P = .0003$) and within 9 years (OR 1.5, 95% CI 1.1-2.0, $P = .007$).

Conclusions: Wound complications and revision rates in patients undergoing shoulder arthroplasty who require postoperative therapeutic anticoagulation are significantly elevated compared with controls.

Level of evidence: Level III; Retrospective Cohort Comparison; Large Database Analysis; Treatment Study

Keywords: Total shoulder arthroplasty; bleeding complications; anticoagulation; wound complications; periprosthetic infection; revision surgery

This study meets exempt criteria for our Health Sciences Research Institutional Review Board (UVA IRB-HSR) for the following reasons, as described on the UVA IRB-HSR website: "4. Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects."

*Reprint requests: Jourdan M. Cancienne, MD, Southern Orthopaedic Specialists, 2731 Napoleon Avenue, New Orleans, LA 70115, USA.
E-mail address: canciennejourdan@gmail.com (J.M. Cancienne).

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https://doi.org/10.1016/j.jse.2019.11.029

Wound complications following joint replacement can be a devastating complication leading to prolonged postoperative morbidity, lower patient-reported outcome scores, revision surgery, and higher overall health care costs.[1] The connection between wound complications and the use of therapeutic anticoagulation has been well studied after knee and hip arthroplasty. McDougall et al retrospectively reviewed 268 patients and found that those requiring therapeutic anticoagulation in the perioperative period following hip arthroplasty had increased risk of deep joint infection, wound drainage, and superficial infection.[15] Similarly, Patel et al[17] reported an increased incidence of wound drainage associated with low-molecular-weight heparin use following total hip and total knee arthroplasty and that each additional day of prolonged wound drainage following surgery increased the risk of wound infection 42% following total hip arthroplasty and 29% following total knee arthroplasty. Managing patients undergoing lower extremity arthroplasty with therapeutic anticoagulation is a balance between the risk of thromboembolic disease and bleeding-related complications.

There is less data available examining the effect of therapeutic anticoagulation in the perioperative period after shoulder arthroplasty to guide upper extremity arthroplasty surgeons. Hematoma formation following shoulder arthroplasty has been linked to decreased postoperative range of motion, increased pain, and decreased patient-reported outcome scores. Moreover, hematoma formation has been implicated as an independent risk factor for infection following shoulder arthroplasty. A retrospective study by Cheung et al reported that 7 of 9 patients who underwent surgical evacuation for hematoma formation following reverse total shoulder arthroplasty had positive intraoperative cultures following their reoperation.[7]

The risks and benefits of therapeutic postoperative anticoagulation must be fully appreciated and understood by modern orthopedic surgeons, as upward of 2 million people in North America are pharmacologically anticoagulated.[4] There are numerous disease processes that require chronic therapeutic anticoagulation, the most common indication being atrial fibrillation.[10] Although atrial fibrillation is by far the most common reason for the use of therapeutic anticoagulation during the perioperative period, postoperative venous thromboembolism (VTE) must also be considered. A study by Tashjian et al[23] examined 533 shoulder arthroplasties within the first 90 days following surgery and found a symptomatic VTE rate of 2.6% and pulmonary embolism rate of 2.3%. Another study reviewing Medicare data from a total of 2,639,788 combined hip, knee, and shoulder arthroplasty patients found that VTE complications occurred in 30,227 (1.2%) lower extremity arthroplasties and 695 (0.53%) upper extremity arthroplasties.[8] Accordingly, the goal of the present study was to determine if there were any differences in rates of wound complications, postoperative infection, or revision shoulder arthroplasty in patients treated in the perioperative period with therapeutic anticoagulation following shoulder arthroplasty. We hypothesized that the use of therapeutic anticoagulation in the perioperative period after shoulder arthroplasty would be associated with increased rates of wound complications, wound infection, and revision shoulder arthroplasty given similar findings in the lower extremity arthroplasty literature.

Methods

Database

A national insurance patient records database, the PearlDiver Patient Records Database (www.pearldiverinc.com; Colorado Springs, CO, USA), was used for this study. This database contains data from Medicare as well as several private insurers such as UnitedHealthcare and Humana. The data for the present study were taken from the Humana data set within PearlDiver, as this data set is the only one that contains prescription drug information, which was necessary to identify patients on therapeutic anticoagulation. The PearlDiver Humana data set contains procedural volumes, basic patient demographics, laboratory data, and numerous other patient data with International Classification of Diseases, 9th Revision (ICD-9) and 10th Revision (ICD-10), diagnoses and procedures or Current Procedural Terminology (CPT) codes. This data set covers patients insured from 2007 to 2016 and, overall, contains data for approximately 20 million patients with orthopedic diagnoses. All data are deidentified and anonymous; therefore, this study was exempt from our local institutional review board approval.

Study cohort

The database was first queried for patients undergoing total shoulder arthroplasty, including anatomic and reverse shoulder arthroplasty, using CPT code 23472. The target study group were patients receiving therapeutic anticoagulation postoperatively. As doses of some of the therapeutic agents are not reliably available in the database, we instead elected to choose patients who received anticoagulation for one of 2 diagnoses that require therapeutic dosing: a diagnosis of atrial fibrillation or an acute postoperative VTE. These were both identified by either ICD-9 or ICD-10 coding. Within this subgroup of patients, only those with a confirmed prescription for an anticoagulant that can be given at a therapeutic dose within 2 weeks of surgery were identified. The following anticoagulant medications were identified: warfarin (Coumadin), enoxaparin (Lovenox), rivaroxaban (Xarelto), fondaparinux (Arixtra), apixaban (Eliquis), and dabigatran (Pradaxa). Patients with a VTE within 1 year prior to the surgery and those without a minimum of 6 months of database follow-up were excluded. Control patients were identified using the same CPT codes, with no prescriptions for postoperative anticoagulation. Initially 23,158 patients were identified who underwent shoulder arthroplasty or reverse total shoulder arthroplasty between 2007 and 2016 after performing the query through the database. Of these, 17,748 were found to have a minimum of 6 months' follow-up, with 476 patient patients being excluded for documentation of VTE before undergoing their shoulder arthroplasty. Thus, the final study group consisted of 17,272 patients meeting the inclusion criteria.

Table I ICD-9 codes and procedure codes used to identify complications

Complication	Code	Diagnosis/procedure
Wound complications		
	ICD 998.13	Seroma complicating a procedure
	ICD 998.14	Hematoma complicating procedure
	ICD 998.15	Infected postoperative seroma
Wound infections		
	ICD 996.66	Infection due to internal prosthesis
	ICD 998.59	Postoperative infection
	ICD 682.3	Cellulitis of the arm
	ICD 996.67	Infection and inflammatory reaction due to other internal orthopedic device, implant, and graft
	ICD 711.91	Infectious arthritis shoulder area
	ICD 711.81	Arthropathy associated with other infectious and parasitic diseases, shoulder region
	ICD 996.69	Infection and inflammatory reaction due to other internal prosthetic device, implant, and graft
Revision arthroplasty		
	ICD 81.97	Revision joint replacement upper extremity
	CPT 23473	Revision of total shoulder arthroplasty, including allograft when performed; humeral or glenoid component
	CPT 23474	Revision of total shoulder arthroplasty, including allograft when performed; humeral and glenoid component

ICD-9, International Classification of Diseases, 9th Revision; *CPT*, Current Procedural Terminology.

From the 17,272 patients who met the inclusion and exclusion criteria, 196 (1.13%) were diagnosed with an acute VTE within 2 weeks postoperatively and anticoagulants were prescribed. There were an additional 2064 patients (11.94%) who had a diagnosis of atrial fibrillation, of which 684 were found to have documented use of anticoagulants within 2 weeks of their arthroplasty. This resulted in 684 patients in the anticoagulation group and 16,588 in the nonanticoagulation control group.

Outcomes

Three primary outcome measures of interest were evaluated at 2 time points each: wound complications within 3 and 6 months postoperatively, wound infection within 3 and 6 months postoperatively, and revision arthroplasty within 6 months and up to 9 years (database limit) postoperatively. All complications were identified using ICD-9 codes for diagnoses and CPT codes for procedures. All of the included codes are summarized in Table I.

Statistical analysis

Complications were compared between the study and control groups using a multivariable binomial logistic regression analysis controlling for the following patient demographics and comorbidities: age, sex, body mass index, tobacco use, alcohol use, and medical comorbidities that included hypertension, hyperlipidemia, coronary artery disease, congestive heart failure, peripheral vascular disease, chronic kidney disease, chronic lung disease, chronic liver disease, inflammatory arthritis, depression, hypercoagulable disorders, and thyroid disease, many of which are included in the Charlson Comorbidity Index score.[6] Adjusted odds ratios with 95% confidence intervals were calculated, with $P < .05$ considered significant. All statistical analyses were completed in the embedded software within PearlDiver (R Project for Statistical Computing).

Results

Although the overall rate of wound complications was low (0.76%), there was a significant increase in the rate of wound complications in the anticoagulation group compared with controls (ORs 2.5-3.0, $P < .0001$) (Table II). Similarly, the overall rate of wound infection in the study was 2.76%; however, the rate of wound infection at 3 and 6 months in the anticoagulated group (3.4%-4.0%) was significantly higher than in the control group (2.1%-2.7%) (ORs 1.5-1.8, $P = .007$ and $P < .0001$, respectively) (Table II). Revision arthroplasty in anticoagulated patients also demonstrated a significantly increased rate at 6 months (2.49%) compared with controls (1.80%) (OR 1.8, $P = .0003$) (Table II). The increased risk of revision in the anticoagulated study group was also significant up to 9 years after the index procedure at 4.53% (OR 1.5, $P = .007$) (Table II).

Discussion

This study illustrates an increased rate of postoperative complications following total shoulder arthroplasty in therapeutically anticoagulated patients. In many instances, as with the patients in our study, therapeutic anticoagulation postoperatively is necessary, but the findings of this study at least should encourage surgeons to warn patients of possible complications associated with anticoagulation and use any

Table II Comparison of complications

Complication	Time period	Study (n = 684)	Controls (n = 16,588)	Adjusted OR (95% CI)	*P* value
		n (%)	n (%)		
Wound complication	3 mo	10 (1.46)	95 (0.57)	3.0 (2.0, 4.6)	<.0001
	6 mo	11 (1.61)	121 (0.73)	2.5 (1.7, 3.8)	<.0001
Wound infection	3 mo	23 (3.36)	351 (2.12)	1.5 (1.1, 2.0)	.007
	6 mo	27 (3.95)	449 (2.71)	1.8 (1.4, 2.3)	<.0001
Revision arthroplasty	6 mo	17 (2.49)	298 (1.80)	1.8 (1.3, 2.5)	.0003
	Up to 9 y	31 (4.53)	570 (3.44)	1.5 (1.1, 2.0)	.007

OR, odds ratio; *CI*, confidence interval.

methods possible to reduce the risk of hematoma in patients who may require postoperative anticoagulation.

Postoperative wound complications following total shoulder arthroplasty can significantly compromise the normally excellent outcomes.[11] The finding of increased rate of wound complications at all time points in patients requiring therapeutic anticoagulation should not be overlooked as seromas and wound drainage have been associated with increased risk of infection. Saleh et al[18] preformed a retrospective review of patients undergoing lower extremity arthroplasty noting both hematoma formation and persistent postoperative drainage more than 2.5 days as significant predictors of surgical site infection.

The finding of increased rate of wound infection in anticoagulated patients was predictable, as it correlates with the increased rate of wound complications. This finding is significant as the morbidity of an infection in a postoperative total shoulder arthroplasty can be quite severe, leading to potential revision surgery and increased health care costs. Padegemis et al[16] performed a database review of 82,498 total shoulder arthroplasties and found that the median hospitalization cost following a prosthetic joint infection was $17,163 compared with $16,132 for the index total shoulder arthroplasty.

Perhaps the most clinically important finding of our study was the increased rate of revision surgery, as revision total shoulder arthroplasty has a profound impact on patient outcomes. Although we cannot determine the exact reason for revision arthroplasty, it is natural to assume that at least some of this increased risk of revision is associated with the wound and infectious complications encountered early in the recovery period. In the setting of revision for infection, this may require a staged treatment protocol usually necessitating interim antibiotic spacer treatment and intravenous antibiotics for at least 6 weeks before reimplantation of components.[21]

Given the increased risk of postoperative wound complications and potential revision surgery for patients undergoing therapeutic anticoagulation, the clinician's first response may be to hold anticoagulation regardless of the reason; however, it is important to remember the need for therapeutic anticoagulation. As discussed earlier, the vast majority of patients receiving therapeutic levels of therapeutic anticoagulation have atrial fibrillation.[10] Atrial fibrillation untreated can present an annual risk of ischemic stroke of 1.3%; however, there is a risk reduction of 61% when treated with oral anticoagulants.[2] The risk of postoperative VTE, though less than in lower extremity total joint arthroplasty, is not negligible.[8] Willis et al[26] prospectively followed 100 patients who underwent total shoulder arthroplasty and screened them with Doppler ultrasonography and found 13% had evidence of VTEs, with a 3% rate of pulmonary embolism. Our study found a rate of 1.13% for VTE following shoulder arthroplasty, which is comparable to other studies regarding VTE following upper extremity surgery. Though this rate seems low, the sequela of potential pulmonary embolism should not be overlooked by the surgeon, obviating the need for therapeutic anticoagulation in this scenario.

As there are no studies to our knowledge looking at wound complications in therapeutically anticoagulated shoulder arthroplasty patients, we compared much of our results to lower extremity data. Our findings of a wound complication rate of 1.61% and a wound infection rate of 3.95% were slightly below previously reported studies concerning lower extremity arthroplasty. Haighton et al[12] looked at outcomes following total hip and total knee arthroplasty in patients with perioperative therapeutic anticoagulation vs. prophylactic dosing and found rates of wound drainage of 44% and deep wound infection of 11% in hip arthroplasty. They also reported that among their total hip arthroplasty patients, the therapeutic anticoagulation group had significantly higher rates of hematoma formation, neuropraxia due to hematoma, and subsequent procedures to evacuate the hematoma. Simpson et al[19] studied 149 consecutive total knee arthroplasties undergoing therapeutic anticoagulation and reported a prolonged wound drainage rate of 26.8%, deep infection rate of 6.0%, and revision rate of 4.7%. McDougall et al[15] found a revision rate of 5.61% in therapeutically anticoagulated total hips and knees compared with 2.23% in controls, which is comparable to our study's revision rate of 4.53%. Although not specifically addressed in our study, another potential adverse event from increased bleeding is the need for transfusion. Della Valle et al[24] looked at 44 patients undergoing unilateral lower extremity arthroplasty

who required therapeutic anticoagulation perioperatively and found a significant increase in the mean transfusion requirement in the anticoagulated group of 1.8 units of packed red blood cells to 0.8 units in the control group.

When managing patients undergoing shoulder arthroplasty, wound complications can lead to disastrous sequela as therapeutic anticoagulation has been well linked in the literature to hematoma formation and wound drainage.[12,15,17] Physicians must be more vigilant with patients undergoing total shoulder arthroplasty while being therapeutically anticoagulated considering the risk of increased wound complications such as drainage as several studies have documented the connection between drainage and increased risk of wound infection. Saleh et al[18] looked at lower extremity arthroplasty and found that hematoma formation and postoperative drainage were independent risk factors for surgical site infections with increased ORs of 11.8 and 1.32, respectively. Wound infection following any type of arthroplasty is a dreaded complication, many times resulting in an additional operation, protracted course of antibiotics, and often staged revision surgery. This complication should be fully appreciated, as our study did show a high risk of wound infection in anticoagulated patients. Boddapati et al[5] reviewed 10,371 patients undergoing primary total shoulder arthroplasty and found the rate of wound infection to be 0.33%, whereas our study reported a rate of 3.95% at 6 months in anticoagulated patients. Revision total shoulder arthroplasty is known to negatively impact patient outcomes; for example, Kim et al[13] examined patient-reported outcomes over 2 years following revision shoulder arthroplasty and found revision following an infection showed the least improvement. The cost to the hospital is also greatly increased in the setting of revision. Wagner et al[25] determined that the cost to the hospital nearly doubles for a 2-stage shoulder arthroplasty revision needed for infection compared with the index procedure. A wide range of revision rates following surgery have been reported, from 3%-27% at 10 years following total shoulder arthroplasty.[9,20,22] Our study found revision rates at the lower end of 3.44% in our control group and 4.53% in our anticoagulated group, which highlights the heterogeneity of study results across institutions and emphasizes the need for further research between patient populations. Given our study results and the large impact therapeutic anticoagulation can have on total shoulder arthroplasty outcomes, ways to mitigate these risks must be appreciated. In the setting of patients with atrial fibrillation, the need for therapeutic anticoagulation should be assessed and possibly omitted by the clinician as there are numerous risk stratification scoring systems, the most popular being the CHADS2 scoring system.[3] Tranexamic acid is another modality that must be considered as an adjunct to help combat the risk of hematoma and drainage. Kuo et al[14] conducted a meta-analysis reviewing tranexamic acid use in shoulder arthroplasty and found that patients who received perioperative tranexamic acid had a significantly lower transfusion rate, less estimated blood loss (249 mL difference), less change in hemoglobin, and less postoperative drainage (95.41 mL difference). Although drain placement has shown varying results in lower extremity arthroplasty, with studies showing an increased risk of the need for blood transfusion, there has been little data regarding drain use in upper extremity arthroplasty—which adjunct may be considered in total shoulder arthroplasty patients with increased risk factors for hematoma formation.[27] The surgeon should be hypervigilant in every aspect of care when performing a shoulder arthroplasty on a patient undergoing therapeutic anticoagulation, be it meticulous layered closure or aggressive antibiotic therapy in those with tenuous wound healing in the postoperative period.

There were several limitations to the study, which are common to large-database analysis as the resultant data are limited to specific codes, of which a presumed small percentage is miscoded or not documented at all. One limitation to our study included the potential crossover rates between the wound complications, wound infections, and revision arthroplasty groups. One needs to recognize that many of these patients likely had multiple ICD-9 codes, which would have captured them in all 3 groups or conversely just in a single group depending on how they were coded. Although the operative outcomes in this study were revision shoulder arthroplasty, rates were likely higher for other operations such as superficial débridements and washouts; however, these were not captured. We were also unable to determine the precise need for revision given that the ICD-9 codes for revision does not capture this parameter; specifying the reason for revision is important and is an area that needs further research. Wound complication ICD-9 codes were used as a surrogate for wound drainage, which was not specifically listed as an independent code. Although we attempted to capture all wound drainage events with multiple wound complication codes, we presumably missed some wound drainage events. Another limitation of the study was its inability to determine the exact dosing of the various anticoagulants used or the time when patients with atrial fibrillation discontinued their anticoagulant use prior to surgery and the exact time it was restarted. We attempted to standardize anticoagulant use using the ICD-9 codes of atrial fibrillation and acute postoperative VTE as these theoretically captured patients requiring therapeutic dosing of anticoagulants; however, variations in individual drug pharmacology should be taken into consideration as multiple drugs were included.

Conclusions

Patients with acute VTE or atrial fibrillation requiring therapeutic postoperative anticoagulation after total

shoulder arthroplasty are at an increased risk for wound complications, infection, and revision shoulder arthroplasty. Although it is often necessary to use therapeutic anticoagulation for these reasons, surgeons should warn patients of the potential risks and should be diligent about hemostasis intraoperatively to reduce the risk of hematoma formation.

Disclaimer

The authors, their immediate families, and any research foundations with which they are affiliated have not received any financial payments or other benefits from any commercial entity related to the subject of this article.

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