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Low-dose aspirin and the rate of symptomatic venous thromboembolic complications following primary shoulder arthroplasty

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Background: Venous thromboembolism (VTE) events are infrequent but potentially catastrophic complications following orthopedic surgery. There is currently a paucity of evidence regarding the role of chemoprophylaxis with low-dose aspirin (acetylsalicylic acid [ASA]) after shoulder arthroplasty.

Methods: We conducted a retrospective review of prospectively collected complications occurring within 90 days of 2394 primary shoulder arthroplasties performed over a 3-year period at a single institution. Patients preoperatively underwent risk stratification into medically high risk, moderate risk, or low risk as part of a standardized navigated-care pathway. For chemoprophylaxis, 81 mg of ASA (low dose) was routinely used once daily for 6 weeks unless alternative medications were deemed necessary by the medical team. Baseline demographic information, medical comorbidities, and postoperative VTE prophylaxis, as well as rates of clinically symptomatic VTE, were assessed.

Results: Symptomatic VTE occurred after 0.63% of primary shoulder arthroplasties (15 of 2394). There were 9 patients with deep vein thromboses and 6 with pulmonary embolisms. Eighty-one milligrams of ASA was used in 2141 patients (89.4%), resulting in an overall VTE rate of 0.56%. Medically high-risk patients were significantly more likely to have a VTE ($P = .018$). Patients with a history of deep vein thrombosis, asthma, and cardiac arrhythmia were significantly more likely to have a VTE ($P < .05$). Complications occurred in 4 patients (0.19%) associated with low-dose ASA and 1 patient (0.63%) associated with a novel oral anticoagulant medication.

Conclusion: Routine use of low-dose ASA results in a very low risk of VTE and medication-associated complications following primary shoulder arthroplasty. Preoperative medical risk stratification can potentially identify patients at high risk of postoperative VTE.

Level of evidence: Level III; Retrospective Case-Control Comparison; Prognosis Study

Keywords: Shoulder arthroplasty; prophylaxis; VTE; DVT; pulmonary embolism; aspirin

Venous thromboembolism (VTE) after orthopedic surgery can result in significant morbidity, death, and financial burden.[11,16,17] The overall incidence, risk factors, and postoperative VTE prophylaxis strategies have been more rigorously studied following lower-extremity arthroplasty compared with upper-extremity arthroplasty.[6,14,15] VTE following

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shoulder arthroplasty is infrequent; however, the highly variable incidence is likely influenced by the paucity of high-quality literature coupled with the infrequency of VTE events.[4,5,9,12] Clinical practice guidelines from the American Academy of Orthopaedic Surgeons indicated that in "the absence of reliable evidence," physicians should use mechanical prophylaxis and/or chemoprophylaxis for perioperative VTE prophylaxis in patients undergoing shoulder arthroplasty.[8] Moreover, no specific pharmacologic recommendations were provided to guide surgeons.[8]

The current literature demonstrates a discrepancy in the rates of VTE following shoulder arthroplasty when comparing large state or national databases and institutional registries. Large databases often report rates of VTE ranging from 0.2% to 0.7%,[4,5,9,10,12,22] whereas rates in institutional studies range from 1% to 2.6%.[7,13,19-21] Although large state or national databases may be useful for estimating the incidence and prevalence of VTE, these studies are subject to coding and clerical errors, as well as insufficient follow-up capture, and are often unable to offer relevant prognostic information regarding prophylactic treatment.[4,5,9,12] Several database studies have only reported immediate in-hospital postoperative complications or complications that required inpatient treatment, therefore underestimating disease burden.[5,9,12] Large institutional studies may be more accurate in capturing patient-specific data; however, no current evidence includes preoperative risk stratification and adequate information on postoperative chemoprophylaxis.

The role of chemoprophylaxis following shoulder arthroplasty is unclear. Surgeons must balance the risk of postoperative VTE against the risk of bleeding-related complications. Despite the significant morbidity associated with VTE, some authors have suggested that VTE prophylaxis may be unnecessary even in high-risk patients.[9,11] Recent systematic reviews have highlighted the dramatic lack of VTE prophylaxis in patients undergoing shoulder arthroplasty.[3,18] Dattani et al[3] noted that either mechanical or pharmacologic prophylaxis was not mentioned in nearly 90% of the studies in their recent systematic review. The largest single-institution series to date reported that 33% of VTE events occurred in patients who had not received postoperative prophylactic treatment and only 17% of patients received new prophylactic treatment following shoulder arthroplasty.[11] However, recent evidence has also demonstrated increased wound complications, infections, and revision shoulder arthroplasty in patients who receive therapeutic anticoagulation following shoulder arthroplasty.[1]

The purpose of this study was to determine the rates of symptomatic VTE in patients who have undergone preoperative risk stratification and have been treated with a standardized chemoprophylactic regimen following primary shoulder arthroplasty. Furthermore, we sought to determine the risk factors for VTE and report the complications of VTE chemoprophylaxis.

Materials and methods

We conducted a retrospective review of prospectively collected complications occurring within 90 days of primary shoulder arthroplasty at a single institution between 2016 and 2019. The inclusion criteria included age $>$ 18 years at the time of primary shoulder arthroplasty for any indication. Patients were excluded if they underwent a procedure other than primary shoulder arthroplasty or if there was insufficient information in the electronic medical record to determine outcome measures. We included a total of 2394 primary arthroplasties, comprising 1198 total shoulder arthroplasties, 1187 reverse shoulder arthroplasties, and 9 hemiarthroplasties. All patients received intermittent pneumatic compression devices intraoperatively coupled with some form of postoperative chemoprophylaxis. Postoperative prophylaxis with 81 mg of aspirin (acetylsalicylic acid [ASA]) was routinely used once daily for 6 weeks unless alternative medications were deemed necessary by the treating surgeon in conjunction with the patient's medical providers. All patients underwent preoperative risk stratification into medically high risk, moderate risk, or low risk as part of a standardized navigated-care pathway at our institution (Supplementary Appendix S1). All shoulder arthroplasties were entered into a database in which adverse event data, through hospital reports and the clinical electronic medical record, were prospectively entered by a dedicated member of the clinical staff. All patients were contacted by phone approximately 90 days following surgery to ascertain whether they had any emergency department visits, readmissions, or complications. Additionally, a retrospective review of the electronic medical record was conducted to ensure thorough event capture.

The entire cohort of patients was retrospectively reviewed. Baseline demographic information (age, sex, and body mass index [BMI]), medical comorbidities, history of VTE, type of arthroplasty performed, preoperative medication history, and postoperative VTE prophylaxis were identified. Reported complications within 90 days of shoulder arthroplasty were retrospectively reviewed for clinically symptomatic VTE, including deep vein thrombosis (DVT) and pulmonary embolism (PE). DVTs were diagnosed by ultrasound, whereas PEs were diagnosed by computed tomography. Additionally, any bleeding-related complications from either VTE prophylaxis or VTE treatment within 90 days were reviewed.

Statistical analysis

Descriptive statistics were determined and expressed as means, standard deviations, and percentages. Two cohorts were created (patients with VTE and patients without VTE) to evaluate risk factors (ie, postoperative medications, sex, type of surgery, smoking history, alcohol use, medical and social scores, and medical history). Categorical variables were evaluated by χ^2 analysis when possible; otherwise, the Fisher exact test was performed. Odds ratios were calculated for risk factors that were found to be significant. We performed additional stratification analysis of patients who were deemed "high-risk" patients based on the medical score and patients who had a history of a VTE event. Continuous variables (ie, age and BMI) were assessed with the Mann-Whitney U test. A post hoc power analysis was performed to ensure accurate reporting of findings. All statistical analyses were carried out using SPSS software (version 26; IBM,

Armonk, NY, USA). The α risk was set to .05 for all tests to estimate statistical significance.

Results

Symptomatic VTE and risk factors

Symptomatic VTE occurred in 0.63% of patients (15 of 2394) within 90 days of primary shoulder arthroplasty. There were 9 patients with DVT (0.37%) and 6 with PE (0.25%). The mean time from surgery to DVT diagnosis was 19.3 days (range, 6-41 days), whereas the mean time from surgery to PE diagnosis was 4.6 days (range, 2-6 days). Age, sex, BMI, type of arthroplasty, smoking history, and alcohol use were not significantly associated with VTE (Table I). Patients who were preoperatively identified as medically high-risk patients had a significantly higher rate of VTE than medically low-risk patients (1.6% vs. 0.5%, $P = .018$). Univariate analysis showed that patients with a history of DVT, asthma, and cardiac arrhythmia were significantly more likely to have a VTE ($P < .05$) (Table II). Multivariate analysis was not performed because of the low number of overall events.

Table I Baseline demographic characteristics including BMI of patients undergoing TSA, RSA, and HA comparing those with VTE and those without VTE

	No VTE	VTE	*P* value
Female/male, %	51.8/48.2	66.7/33.3	.252
Age, yr	68.4 ± 9.3	68.1 ± 9.3	.638
BMI	29.9 ± 6.1	32.9 ± 7.8	.145
Surgery, %			.809
TSA	50.0	53.3	
RSA	49.6	46.7	
HA	0.4	0.0	
Medical, %			.018*
High	23.8	60.0	
Moderate	24.4	0.0	
Low	51.8	40.0	
Social, %			>.999
High	8.5	6.7	
Moderate	17.9	6.7	
Low	73.6	86.7	
Smoking history, %	46.3	40.0	.760
Alcohol use, %	59.7	46.2	.321

BMI, body mass index; *TSA*, total shoulder arthroplasty; *RSA*, reverse shoulder arthroplasty; *HA*, hemiarthroplasty; *VTE*, venous thromboembolism.

* Comparison of high- and low-risk patients.

VTE prophylaxis

All patients received some form of postoperative VTE prophylaxis following shoulder arthroplasty (Table III). Low-dose ASA (81 mg) was used as VTE prophylaxis in 2141 patients (89.4%), resulting in an overall VTE rate of 0.56% (12 of 2141). The VTE rate in patients who received other medications for postoperative prophylaxis was 1.2% (3 of 253); however, this difference was not statistically significant ($P = .325$). Medically low-risk patients received ASA for VTE prophylaxis significantly more often than did high-risk patients (96.6% vs. 80.5%, $P < .001$). Among medically high-risk patients, VTE occurred in 7 of 454 patients (1.5%) treated with postoperative ASA compared with 2 of 110 patients (1.8%) who received other medications for prophylaxis ($P = .690$). Post hoc analysis showed that our study was underpowered to evaluate the effect of ASA compared with other chemoprophylaxis medications in this population and would have required a total of 1691 high-risk patients to have a sufficient sample size for analysis. A total of 133 patients (5.7%) in our cohort had a history of DVT. Of these patients, 95 received prophylaxis with ASA (with a VTE rate of 2.1% [2 of 95]) and 38 received other chemoprophylaxis (with a VTE rate of 2.6% [1 of 38]) ($P > .999$). Post hoc analysis demonstrated that our study was underpowered and would have required a total of 742 patients with a history of DVT to assess the effect of specific medications on postoperative prophylaxis.

Complications of VTE prophylaxis and treatment

A total of 5 bleeding-related complications occurred in the entire cohort. Among patients treated with low-dose ASA for VTE prophylaxis, 4 of 2141 (0.19%) had postoperative hematomas that underwent aspiration in the office. Two of these patients required >1 aspiration, and 2 patients ultimately returned to the operating room for an additional intervention. One patient initially treated with reverse shoulder arthroplasty underwent hematoma evacuation and polyethylene exchange. In the other patient, a superficial infection developed from repeated hematoma aspiration; surgical irrigation and débridement were required. In 1 patient with a history of atrial fibrillation who received a novel oral anticoagulant medication (dabigatran), a bleeding esophageal ulcer developed postoperatively and required surgical intervention to control. Among the patients in whom a VTE was diagnosed, bleeding complications secondary to VTE treatment occurred in 1 of 15 (6.7%).

Discussion

Routine use of low-dose ASA as chemoprophylaxis results in a very low risk of VTE events and medication-associated complications following primary shoulder arthroplasty. This study also demonstrates that preoperative medical risk

Table II Univariate analysis of comorbidities as potential risk factors

Comorbidity	No. with risk factor (% of cohort)	No. with VTE (% of those with risk factor)	*P* value	Odds ratio (95% confidence interval)
Prior DVT	133 (5.7)	3 (2.3)	.049	4.2 (1.2-15.2)
Asthma	286 (13.3)	6 (2.1)	<.001	5.8 (1.9-17.4)
Cardiac arrhythmia	267 (11.8)	6 (2.2)	.003	4.5 (1.5-13.4)
High cholesterol level	1046 (46.4)	5 (0.5)	.423	NA
Heart disease	374 (16.6)	5 (1.3)	.053	NA
Obstructive sleep apnea	465 (20.6)	5 (1.1)	.160	NA

VTE, venous thromboembolism; *DVT*, deep vein thrombosis; *NA*, not applicable.

Table III Medications used as postoperative chemoprophylaxis after shoulder arthroplasty

	n (% of cohort)*	VTE, n (%)	*P* value
ASA			
81 mg	2141 (89.4)	12 (0.56)	.206
325 mg	40 (1.7)	0 (0.0)	>.999
Clopidogrel	74 (3.1)	1 (1.4)	.381
Enoxaparin sodium	23 (1.0)	0 (0.0)	>.999
Warfarin	61 (2.5)	0 (0.0)	>.999
NOAC	160 (6.7)	2 (1.3)	.265

VTE, venous thromboembolism; *ASA*, acetylsalicylic acid (aspirin); *NOAC*, novel oral anticoagulant.

* Some patients received >1 medication.

stratification can potentially identify patients at higher risk of postoperative VTE events. Patients with certain risk factors such as prior DVT, asthma, and cardiac arrhythmia were identified to be at increased risk of VTE. Given the significant potential morbidity associated with postoperative VTE occurrence and treatment, strong consideration should be given to routine prophylaxis with low-dose ASA unless the patient has risk factors that may warrant alternative treatment.

In this study, symptomatic VTE occurred after 0.63% of primary shoulder arthroplasties (15 of 2394), including 9 patients with DVT (0.37%) and 6 with PE (0.25%). Patients treated with low-dose ASA for VTE prophylaxis had an overall VTE rate of 0.56%. Similarly to our study, Singh et al[19] and Kolz et al[11] reported retrospective analyses of prospectively collected data in the Mayo Clinic Total Joint Registry. Singh et al reported symptomatic VTE events (PE in 0.72% and DVT in 0.45%) in 42 of 3480 patients (1.2%) undergoing primary shoulder arthroplasty from 1976 to 2008. Kolz et al recently published an updated series, capturing patients from 2001 to 2017 and noted symptomatic VTE in 24 of 5906 (0.41%).

Various risk factors for VTE following shoulder arthroplasty have been reported; however, there is substantial heterogeneity.[4,9-12,19,20,22] The most commonly reported risk factor is a history of a VTE event.[4,12,19,20] However, Kolz et al[11] recently published the largest single-institution series, with approximately 5900 shoulder arthroplasties, and did not find prior VTE to be a significant risk factor. Navarro et al[13] reported on approximately 2500 patients undergoing shoulder arthroplasty; however, patients with a history of VTE were excluded from their analysis. In our study, prior DVT, cardiac arrhythmia, and asthma were significantly associated with a higher risk of VTE. These findings are similar to those reported in a study by Day et al,[4] in which prior VTE and cardiac arrhythmia were among the strongest risk factors for VTE. Additionally, age and trauma were not associated with an increased risk of VTE in our study, which differs from the findings of some authors.[11,19] The type of shoulder arthroplasty performed in our study did not influence VTE rates, which is consistent with other recent literature.[11,13] Moreover, we were able to use prospectively performed medical risk stratification to identify that high-risk patients had a significantly increased VTE risk compared with low-risk patients. This has not previously been demonstrated following shoulder arthroplasty.

The standard of care pertaining to VTE prophylaxis after shoulder arthroplasty is not clearly established. Current clinical practice guidelines from the American Academy of Orthopaedic Surgeons recommend by consensus opinion owing to the lack of evidence that mechanical prophylaxis and/or chemoprophylaxis be used for perioperative VTE prophylaxis after shoulder arthroplasty.[8] However, there is no recommendation pertaining to the type of chemoprophylaxis. Day et al[4] reported that the majority of surgeons surveyed who are members of the American Shoulder and Elbow Surgeons did not use any type of prophylaxis and fewer than 20% used ASA following shoulder arthroplasty. The low overall incidence of VTE coupled with the concern for postoperative bleeding and wound issues likely underlies these findings. Postoperative hematoma can be associated with wound infection, reoperation, and poor outcomes.[1,2] Cancienne et al[1] recently used a large national insurance database to evaluate the effects of therapeutic anticoagulation after shoulder arthroplasty. Compared with

patients who did not receive any postoperative anticoagulation, patients who received anticoagulation had significantly higher rates of wound complications, wound infection, and the need for revision surgery. In that study, wound complications were identified by the diagnosis codes for seroma or hematoma, which occurred in 0.57% of patients at 3 months in the control group (no anticoagulation).[1] Day et al reported that postoperative bleeding complications occurred in 0.19% of patients after total shoulder arthroplasty. Our study demonstrates that only 0.19% of patients treated with low-dose ASA had bleeding-related complications; this finding is consistent with the aforementioned literature and does not appear to indicate increased risk.

The current literature pertaining to VTE following shoulder arthroplasty is insufficient to evaluate the role of chemoprophylaxis. The main shortcoming of current evidence is the inability to report the incidence of and risk factors for VTE in a large group of patients who received prophylactic treatment. Rather, current studies are often only capable of reporting on the patients who experienced an adverse event, which effectively precludes analysis on prophylactic treatment. Kolz et al[11] reported a 0.41% symptomatic VTE rate in approximately 5900 primary shoulder arthroplasties; it is interesting to note that this rate was 3 times lower than that in the previous series from the same institution.[19] VTE prophylaxis was not standardized and was at the discretion of the treating surgeon. Thirty-three percent of the patients who sustained a VTE event, including almost 40% of the patients who had PE, received no prophylactic treatment, and only 17% of patients were prescribed new medication for VTE prophylaxis.[11] Tashjian et al[20] attempted to evaluate the role of ASA for chemoprophylaxis following shoulder arthroplasty; however, only 24% of the 533 patients in the study received ASA, therefore leaving the study underpowered.

Our study has several limitations. Although all 90-day complication data were prospectively collected, the data were retrospectively analyzed, which subjects these data to potential bias. Additionally, the complication data were collected through a database, which was dependent on individual upkeep and data input. We were also limited by the data available in the electronic medical record if we were unable to contact patients for additional information. After consultation with a statistician, we were only able to perform univariate analysis on the risk factors we identified owing to the low overall event rate. Furthermore, this study reflects the findings at a single institution, which may not represent the population in other geographic locations.

Conclusion

The results of this study demonstrate that routine use of low-dose ASA results in a very low risk of VTE events and bleeding-related complications following primary shoulder arthroplasty. Preoperative medical risk stratification can potentially identify patients at high risk of postoperative VTE. Given the significant potential morbidity associated with postoperative VTE coupled with the favorable results observed in this study, strong consideration should be given to routine prophylaxis with low-dose ASA unless certain patient comorbidities warrant alternative treatment. Further study is needed to determine whether ASA is equally effective and less susceptible to bleeding complications compared with more aggressive chemoprophylaxis in patients at high risk of VTE.

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Supplementary Data

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