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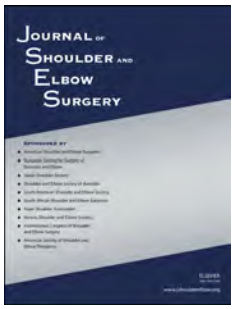

Low-Dose Aspirin and the Rate of Symptomatic Venous Thromboembolic Complications Following Primary Shoulder Arthroplasty

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Investigation performed at The Rothman Institute-Thomas Jefferson, Departments of Orthopaedic Surgery & Shoulder/Elbow Surgery

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Low-Dose Aspirin and the Rate of Symptomatic Venous Thromboembolic Complications Following Primary Shoulder Arthroplasty

Abstract

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

Methods: A retrospective review of prospectively collected complications occurring within 90 days of 2,394 primary shoulder arthroplasties performed over a three-year period at a single institution was conducted. Patients were preoperatively risk stratified into medically high, moderate or low risk as part of a standardized navigated care pathway. 81 mg ASA (low-dose) was routinely used once daily for 6 weeks for chemoprophylaxis unless alternative medications were deemed necessary by the medical team. Baseline demographic information, medical comorbidities, postoperative VTE prophylaxis as well as rates of clinically symptomatic VTE were assessed.

Results: Symptomatic VTE occurred following 0.63% (15/2,394) of primary shoulder arthroplasties. There were 9 patients with deep vein thrombosis (DVT) and 6 with pulmonary emboli (PE). 81 mg ASA was utilized in 2,141 (89.4%) of patients, which resulted 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 prior DVT, asthma and cardiac arrhythmias were significantly more likely to have a VTE ($P < .05$). Complications occurred in 4 patients (0.19%) associated with low-dose ASA and one patient (0.63%) associated with a novel oral anticoagulant medication.

Conclusion: Routine use of low-dose ASA results in very low risk of VTE and medication associated complications following primary shoulder arthroplasty. Preoperative medical risk stratification can potentially identify patients at high risk for 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, mortality 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 to upper extremity arthroplasty.[6, 14, 15] VTE following 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 Orthopedic Surgeons indicated that in "the absence of reliable evidence", physicians should use mechanical and/or chemoprophylaxis for perioperative VTE prophylaxis in patients undergoing shoulder arthroplasty.[8] Moreover, no specific pharmacologic recommendations were provided to guide surgeons.[8]

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 0.2-0.7%,[4, 5, 9, 10, 12, 22] whereas institutional studies range from 1-2.6%.[7, 13, 19-21] While 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, insufficient follow-up capture and are often unable to offer relevant prognostic

information regarding prophylactic treatment.[4, 5, 9, 12] Several database studies only report 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 for chemoprophylaxis following shoulder arthroplasty is unclear. Surgeons must balance the risk of postoperative VTE with bleeding related complications. Despite the significant morbidity associated with VTE, some authors suggest that VTE prophylaxis may be unnecessary even in high risk patients.[9, 11] Recent systematic reviews highlight 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 33% of VTE occurred in patients that had not been placed on postoperative prophylactic treatment and only 17% of patients received new prophylactic treatment following shoulder arthroplasty.[11] However, recent evidence also demonstrates increased wound complications, infections and revision shoulder arthroplasty in patients who are therapeutically anticoagulated following shoulder arthroplasty.[1]

The purpose of this study is to determine the rates of symptomatic VTE in patients who have been preoperatively risk stratified and 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

A retrospective review of prospectively collected complications occurring within 90 days of primary shoulder arthroplasty at a single institution was conducted between 2016-2019 following IRB approval (#20E.252). Inclusion criteria included age greater than 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 2,394 primary arthroplasties, including 1,198 total shoulder arthroplasties (TSA), 1,187 reverse shoulder arthroplasties (RSA) and 9 hemiarthroplasties (HA). All patients received intermittent pneumatic compression devices intraoperatively coupled with some form of postoperative chemoprophylaxis. Postoperative prophylaxis with 81 mg of aspirin (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 were preoperatively risk stratified into medically high, moderate or low risk as part of a standardized navigated care pathway at our institution (Appendix 1). All shoulder arthroplasties were entered into a database where 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 also conducted to ensure thorough event capture.

The entire cohort of patients was retrospectively reviewed. Baseline demographic information (age, sex, body mass index (BMI)), medical comorbidities, history of prior VTE, type of arthroplasty performed, preoperative medication history as well as 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 emboli (PE). DVTs were diagnosed by ultrasound whereas PEs were diagnosed by computed tomography. Additionally, any bleeding related complications either from 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 (those with VTE and those without VTE) to evaluate risk factors (i.e. postoperative medications, gender, type of surgery, smoking/alcohol use, medical/social scores, and past medical history). Categorical variables were evaluated by chi-square analysis when possible, otherwise the Fisher's Exact test was performed. Odds ratios (OR) were calculated for risk factors that were found to be significant. Additional stratification analysis was performed on patients that were found to be scored as "high risk" patients based on the medical score and on those that had a prior history of a VTE event. Continuous variables (i.e. age, BMI) were assessed utilizing Mann-Whitney *U* test. A post hoc power analysis was performed to ensure accurate reporting of findings. All statistical analysis was carried out on Statistical Package for the Social Science (SPSS) version 26 (IBM Corp., Armonk, NY, USA). The alpha risk was set to 0.05 for all tests to estimate statistical significance.

Results

Symptomatic VTE and Risk Factors

Symptomatic VTE occurred in 0.63% (15/2,394) of patients 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, gender, BMI, type of arthroplasty, smoking and alcohol history were not significantly associated with VTE (Table I). Patients who were preoperatively identified as medically high-risk had a significantly higher rate of VTE compared to medically low-risk patients (1.6% vs 0.5%; $P = .018$). Univariate analysis demonstrated that patients with a history of prior DVT, asthma and cardiac arrhythmias were significantly more likely to have a VTE ($P < .05$) (Table II). Multivariate analysis was not performed secondary to the low number of overall events.

VTE prophylaxis

All patients received some form of postoperative VTE prophylaxis following shoulder arthroplasty (Table III). Low-dose ASA (81 mg) was utilized as VTE prophylaxis in 2,141 (89.4%) patients, resulting in an overall VTE rate of 0.56% (12/2,141). The VTE rate in patients who received other medications for postoperative prophylaxis was 1.2% (3/253), however this difference was not statistically significant ($P = .325$). Medically low-risk patients received ASA for VTE prophylaxis significantly more often compared to high-risk patients (96.6% vs. 80.5%; $P = < .001$). In medically high-risk patients, VTE occurred in 7/454 (1.5%) of patients treated with postoperative ASA compared to 2/110 (1.8%) who received other medications for prophylaxis ($P = .690$). Post hoc analysis demonstrated that we were underpowered to evaluate the effect of ASA compared to other chemoprophylaxis medications in this population and would need a total of 1,691 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 prior DVT. Of these patients, 95 received prophylaxis with ASA (2/95, 2.1% VTE) and 38 received other chemoprophylaxis

(1/38, 2.6% VTE) (P = 1.000). Post hoc analysis demonstrated that we were underpowered and would need a total of 742 patients with a history of DVT to assess the effect of specific medications on postoperative prophylaxis.

Complications of VTE prophylaxis/treatment

A total of 5 bleeding related complications in the entire cohort. Among patients treated with low-dose ASA for VTE prophylaxis, 4/2,141 (0.19%) had a postoperative hematoma that underwent aspiration in the office. Two of these patients required more than one aspiration and two patients ultimately returned to the operating room for an additional intervention. One patient initially treated with RSA had a hematoma evacuation and polyethylene exchange. The other patient developed a superficial infection from repeated hematoma aspiration and required surgical irrigation and débridement. One patient with a history of atrial fibrillation who received a novel oral anticoagulant medication (dabigatran) postoperatively developed a bleeding esophageal ulcer that required surgical intervention to control. Of the patients who were diagnosed with a VTE, bleeding complications secondary to VTE treatment occurred in 1/15 (6.7%).

Discussion

Routine use of low-dose ASA as chemoprophylaxis results in very low risk of VTE events and medication associated complications following primary shoulder arthroplasty. This study also demonstrates that preoperative medical risk stratification can potentially identify patients at higher risk for postoperative VTE events. Patients with certain risk factors such as prior DVT, asthma and cardiac arrhythmia were identified to be at increased risk for 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 which may warrant alternative treatment.

In this study, symptomatic VTE occurred following 0.63% (15/2,394) of primary shoulder arthroplasties, 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%. Similar to our study, Singh et al[19] and Kolz et al[11] reported a retrospective analysis of prospectively collected data in the Mayo Clinic Total Joint registry. Singh et al[19] reported symptomatic VTE (PE: 0.72% and DVT 0.45%) in 42/3480 (1.2%) of patients undergoing primary shoulder arthroplasty from 1976-2008. Kolz et al[11] recently published an updated series, capturing patients from 2001-2017 and noted symptomatic VTE in 24/5,906 (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 prior VTE event.[4, 12, 19, 20] However, Kolz et al[11] recently published the largest single institution series with approximately 5,900 shoulder arthroplasties and did not find prior VTE to be a significant risk factor. Navarro et al[13] reported on approximately 2,500 patients undergoing shoulder arthroplasty, however excluded those with a prior history of VTE from their analysis. In this current study, prior DVT, cardiac arrhythmia and asthma were significantly associated with higher risk of VTE. These findings are similar to what is reported by Day et al,[4] where 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 also consistent with other recent

literature.[11, 13] Moreover, we were able to utilize prospectively performed medical risk stratification to identify that high-risk patients had significantly increased VTE risk compared to low-risk patients. This has not previously been demonstrated following shoulder arthroplasty.

The standard of care pertaining to VTE prophylaxis following shoulder arthroplasty is not clearly established. Current clinical practice guidelines from the American Academy of Orthopedic Surgeons recommend by consensus opinion due to the lack of evidence that mechanical 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 in the American Shoulder and Elbow Surgeons (ASES) did not use anything for prophylaxis and less 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 utilized a large national insurance database to evaluate the effects of therapeutic anticoagulation following shoulder arthroplasty. Compared to patients who did not receive any postoperative anticoagulation, there was a significantly higher rate of wound complications, wound infection and the need for revision surgery. In this 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[4] reported that postoperative bleeding complications occurred in 0.19% of patients following TSA. Our current study demonstrates that only 0.19% of patients treated with low-dose ASA had bleeding related complications, which is consistent with the aforementioned literature and does not appear to indicate increased risk.

Current literature pertaining to VTE following shoulder arthroplasty is insufficient to evaluate the role for chemoprophylaxis. The main shortcoming of current evidence is the inability to report the incidence 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 0.41% symptomatic VTE in approximately 5,900 primary shoulder arthroplasties, which interestingly was three times lower than 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 nothing for 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.

This study has several limitations. Although all 90-day complication data was prospectively collected, the data was retrospectively analyzed, which subjects it to potential bias. Additionally, the complication data was 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 due 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 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 for 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 than more aggressive chemoprophylaxis in patients at high risk for VTE.

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Figure and Legends

Table I. Baseline demographics including body mass index (BMI) of patients undergoing total shoulder arthroplasty (TSA), reverse shoulder arthroplasty (RSA) and hemiarthroplasty (HA) comparing those with VTE to those without. * Indicates a comparison of high-risk and low-risk patients.

Table II. Univariate analysis of comorbidities as potential risk factors. DVT = deep vein thrombosis; VTE = venous thromboembolism.

Table III. Medications used as postoperative chemoprophylaxis following shoulder arthroplasty. Note: some patients were on more than one medication. NOAC = Novel oral anticoagulant; VTE = venous thromboembolism

Appendix I. Medical and Social Scoring Assessment

Table I

	No VTE	VTE	P-value
Female/Male (%)	51.8/48.2	66.7/33.3	0.252
Age	68.4±9.3	68.1±9.3	0.638
BMI	29.9±6.1	32.9±7.8	0.145
Surgery			0.809
TSA	50.0%	53.3%	
RSA	49.6%	46.7%	
Hemiarthroplasty	0.4%	0.0%	
Medical			0.018*
High	23.8%	60.0%	
Moderate	24.4%	0.0%	
Low	51.8%	40.0%	
Social			1.000
High	8.5%	6.7%	
Moderate	17.9%	6.7%	
Low	73.6%	86.7%	
Smoking History	46.3%	40.0%	0.760
Alcohol	59.7%	46.2%	0.321

BMI = body mass index, TSA = Total Shoulder Arthroplasty, RSA= Reverse Shoulder Arthroplasty, VTE = Venous Thromboembolism

TABLE II

Comorbidities	Number with risk factor (% of cohort)	Number with VTE (% of those with risk factor)	P-value	Odds Ratio
Prior DVT	133 (5.7%)	3 (2.3%)	0.049	4.2 (1.2-15.2)
Asthma	286 (13.3%)	6 (2.1%)	<0.001	5.8 (1.9-17.4)
Cardiac Arrhythmia	267 (11.8%)	6 (2.2%)	0.003	4.5 (1.5 -13.4)
High Cholesterol	1046 (46.4%)	5 (0.5%)	0.423	n/a
Heart Disease	374 (16.6%)	5 (1.3%)	0.053	n/a
Obstructive Sleep Apnea	465 (20.6%)	5 (1.1%)	0.160	n/a

VTE = Venous Thromboembolism, DVT= Deep Vein thrombosis

Table III

	Number (% of cohort)	VTE (%)	P-value
ASA 81 mg	2141 (89.4)	12 (0.56)	0.206
ASA 325 mg	40 (1.7)	0 (0.0)	1.000
Clopridogrel	74 (3.1)	1 (1.4)	0.381
Lovenox	23 (1.0)	0 (0.0)	1.000
Warfarin	61 (2.5)	0 (0.0)	1.000
NOAC	160 (6.7)	2 (1.3)	0.265

ASA= aspirin, NOAC= Novel Oral Anticoagulant, VTE = Venous Thromboembolism