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The Journal of Arthroplasty

journal homepage: www.arthroplastyjournal.org

Primary Arthroplasty

Risk-Stratified Venous Thromboembolism Prophylaxis After Total Joint Arthroplasty: Aspirin and Sequential Pneumatic Compression Devices vs Aggressive Chemoprophylaxis



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ARTICLE INFO

Article history:

Received 3 December 2015

Received in revised form

30 December 2015

Accepted 18 January 2016

Available online 16 March 2016

Keywords:

venous thromboembolism

pulmonary embolism

deep venous thrombosis

risk stratification

cost

ABSTRACT

Background: Venous thromboembolism (VTE) is a major concern after total joint arthroplasty (TJA). We evaluated a risk-stratified prophylaxis protocol for patients undergoing TJA.

Methods: A total of 2611 TJA patients were retrospectively studied. Patients treated with an aggressive VTE chemoprophylaxis protocol were compared with patients treated with a risk-stratified protocol utilizing aspirin and sequential pneumatic compression devices (SPCDs) for standard-risk patients and targeted anticoagulation for high-risk patients.

Results: We found equivalence in terms of VTE prevention between the 2 cohorts. There was a decrease in adverse events and readmissions among the risk-stratified cohort, although this did not reach statistical significance. A statistically significant reduction in costs ($P < .001$) was experienced with the use of aspirin/SPCDs compared with aggressive anticoagulation agents within the risk-stratified cohort.

Conclusion: The use of aspirin/SPCDs in a risk-stratified TJA population is a safe and cost-effective method of VTE prophylaxis.

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As our understanding of the risk of venous thromboembolic (VTE) disease after total joint arthroplasty (TJA) improves and the number of available prophylactic options increases, practitioners continue to debate what constitutes the optimal VTE prevention protocol. Historically, the incidence of VTE among TJA patients without prophylaxis is reported to be nearly 50% [1]. Despite advances in VTE prevention with current prophylaxis measures, an estimated 0.3%–4.3% of patients will have a clinically symptomatic deep vein thrombosis (DVT) [2,3], whereas 0.14%–1.1% [4,5] experience a symptomatic pulmonary embolism after TJA. The incidence of VTE increases the morbidity and mortality associated with TJA [6]. Furthermore, patients who sustain a VTE have longer hospital stays, increased rates of readmission, and overall higher

health care costs [5,7]. The demand for total knee arthroplasty (TKA) and total hip arthroplasty (THA) is predicted to grow significantly in the coming years necessitating the optimization of prophylaxis measures to decrease the utilization of health care resources and improve the morbidity and mortality associated with TJA operations.

The choice of VTE prophylaxis is a balance between safety and efficacy. Traditionally, aggressive anticoagulation agents such as low molecular weight heparin, vitamin K antagonists, and factor Xa inhibitors have been the standard of care in the prevention of VTE disease. Despite their proven efficacy in VTE prevention, these agents are potentially associated with increased complications, including: bleeding, infection, wound problems, and need for readmission and/or reoperation [8,9]. In an effort to reduce these complications, clinicians explored the use of less aggressive means of prophylaxis. These methods include aspirin and sequential pneumatic compression devices (SPCDs). SPCDs are effective in preventing VTE regardless of the chosen pharmaceutical prophylaxis agent [10,11]. These devices are believed to decrease clot formation in the lower extremity by increasing the velocity of venous blood flow along with stimulating the release of endothelial-derived relaxing factors that may decrease clot formation [12].

One or more of the authors of this paper have disclosed potential or pertinent conflicts of interest, which may include receipt of payment, either direct or indirect, institutional support, or association with an entity in the biomedical field which may be perceived to have potential conflict of interest with this work. For full disclosure statements refer to <http://dx.doi.org/10.1016/j.arth.2016.01.065>.

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<http://dx.doi.org/10.1016/j.arth.2016.01.065>

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The latest American Academy of Orthopaedic Surgery (AAOS) and the American College of Chest Physicians (ACCP) VTE prevention guidelines include aspirin and SPCDs as an acceptable form of VTE prophylaxis after TJA if the patients do not have other risk factors for VTE [13,14].

Despite several studies evaluating the efficacy and safety profile of anticoagulation, there is no clear consensus on the ideal strategy for each individual patient. At our institution, we implemented a risk-stratified VTE prophylaxis protocol consistent with the guidelines from AAOS and ACCP. Our aim was to use the least aggressive, clinically effective form of VTE prophylaxis appropriate for the individual patient risk factors. Through a risk-stratification protocol, we aim to lower or maintain our incidence rates of VTEs, while minimizing the side effects of the chemoprophylaxis. Our hypothesis is that patients who undergo risk stratification to individualize their anticoagulation regimen would show no difference in the rate of VTEs while decreasing the risks associated with aggressive chemoprophylaxis.

Material and Methods

Patients

This is an institutional review board–approved study conducted at a single academic institution. Using our electronic medical record system, we identified patients who underwent TJA between the dates of October 2013 and October 2014. Our inclusion criteria for this study were any patients who had a primary, revision, or bilateral total knee or hip arthroplasty. We excluded the month of April 2014, as this period was a transition month when the postoperative venous thromboembolism prophylaxis protocol was updated to implement the risk-stratification strategy based on the presence of risk factors. A total of 2611 patients who underwent a total knee or hip arthroplasty were included in this study.

Patients were divided into 2 cohorts; those who received TJA from October 2013 to March 2014 (cohort 1) and those who received TJA from May 2014 to October 2014 (cohort 2). All patients

in cohort 1 received aggressive anticoagulation regardless of the presence of risk factors. A department-wide risk-stratification protocol was adopted during the period for cohort 2. TJA patients were classified as either high or standard risk for venous thromboembolism (Fig. 1).

Risk Stratification

Medical charts of patients in cohort 2 were reviewed, and those with one or more of the following risk factors were placed in the high-risk group: history of prior DVT or pulmonary embolism, active cancer treatment, body mass index >40, or current smoker. These patients received aggressive prophylaxis with either enoxaparin (40 mg subcutaneous daily for 2–4 weeks), rivaroxaban (10 mg oral daily for 14 days), or warfarin (target international normalized ratio 2–3). Patients with no risk factors were deemed to be standard risk and placed on the aspirin and/or SPCDs protocol. Standard-risk patients were instructed to take a 325 mg enteric-coated aspirin twice daily for 28 days and discharged with an SPCD (ActiveCare + S.F.T device, Medical Compression Systems or Akiva, Israel) for their bilateral lower extremities to be worn 20 hours daily for a period of 28 days. SPCDs devices used were lightweight (1.65 lb), mobile units that could be powered with the use of a rechargeable battery or AC/DC adapter. Standard-risk patients were instructed on the use of SPCDs including an educational video on the device use before discharge from the hospital.

Postoperative Care and VTE Surveillance

Each patient, regardless of cohort, received the same perioperative care. This included taking a 325 mg enteric-coated aspirin the evening before surgery and using SPCDs on the nonoperative limb during the operation. There was no difference in the physical therapy and rehabilitation received by patients in the 2 cohorts. Standard VTE monitoring was used with no additional surveillance measures. Patients with clinical symptoms of DVT received a duplex ultrasonography, whereas those with clinical symptoms suggesting

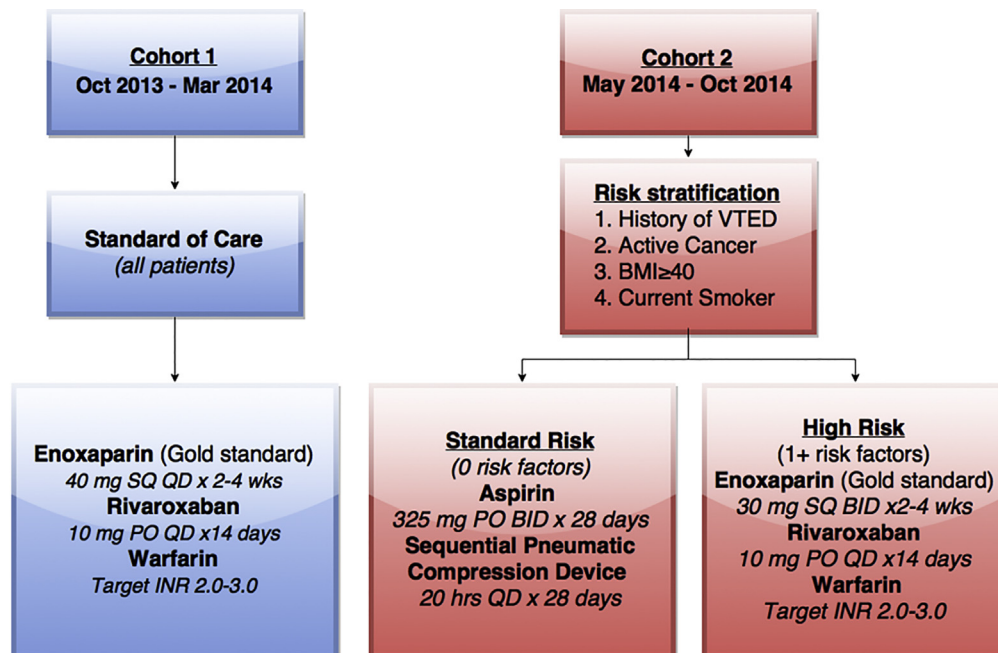


Fig. 1. Flowchart illustrating the VTE prophylaxis protocol before (cohort 1) and after (cohort 2) the implementation of a risk-stratification approach based on the presence of patient risk factors for VTE. BMI, body mass index.

a pulmonary embolism (PE) received a spiral computer tomography PE protocol scan. Postoperative clinical follow-up care differed based on surgeon preference, but typical practice was for patients to have an initial visit 2–4 weeks after surgery and the next visit at 6–10 weeks after surgery.

Postoperative Complications and Quality Metrics

A chart review of all the patient medical records was performed to record demographics, comorbidities, DVT, pulmonary embolus, superficial infection, deep infection, bleeding complications, and 30-day readmissions. If a patient was readmitted, the reason for readmission was recorded as either infection, wound/bleeding related, trauma, VTE, or other. The “other” category included medical complications or issues unrelated to DVT prophylaxis. Billing and quality performance data were used to obtain quality metrics associated with the hospital admission, including total hospital costs, infection rates, and readmission rates.

Statistical Analysis

All demographics were summarized using descriptive statistics. Statistical analysis between the cohorts was performed utilizing the chi-square test for categorical variables and independent *t* test for continuous variables. Results were deemed to be significant at a *P* value less than .05. All statistical analysis was performed using IBM SPSS software version 22 (IBM, Armonk, NY).

Results

We identified a total of 2611 consecutive TJA patients between the dates of October 1, 2013 and October 31, 2014 excluding April 2014. Cohort 1 (aggressive-only prophylaxis patients) consisted of 1203 patients who received aggressive modes of VTE prophylaxis. Cohort 2 (risk-stratified patients) consisted of 1408 patients who were risk-stratified and then given the appropriate type of VTE prophylaxis. In the risk-stratified group there were 565 high-risk patients who all received aggressive prophylaxis and 843 standard-risk patients who received prophylaxis with aspirin (ASA) and SPCDs. Descriptive statistics between the 2 cohorts including age (*P* = .489), gender (*P* = .769), and body mass index (*P* = .552) were statistically similar (Table 1).

A total of 19 VTE events occurred in the 1203 patients in the aggressive-only prophylaxis cohort for a VTE rate of 1.58%. A total of 21 VTE events occurred in the 1408 patients in the risk-stratified cohort yielding a VTE rate of 1.49%. There was no statistically significant difference in the incidence of VTE between the aggressive-only and risk-stratified cohorts (*P* = .855). Patients within the risk-stratified cohort demonstrated no statistical difference in the VTE rate (*P* = .249) between high-risk patients treated with aggressive prophylaxis (1.95%; 11 of 565) and standard-risk patients treated with ASA/SPCDs (1.19%; 10 of 843) (Table 2).

Thirty-day all-cause readmission rates were found to be decreased among risk-stratified patients; however, this did not

Table 1
Descriptive Statistics of the Preoperative Demographics of the Aggressive-Only VTE Prophylaxis Patients (Cohort 1) and the Risk-Stratified Patients (Cohort 2).

Patient Group	PPx	n	Age	% Female	BMI
Cohort 1	Aggressive	1203	63.72 ± 11.1	61.01	30.5 ± 6.7
Cohort 2	Aggressive	565	64.9 ± 11.2	64.60	31.7 ± 7.9
	ASA	843	63.4 ± 11.0	59.55	29.4 ± 5.5
Significance			<i>P</i> = .489	<i>P</i> = .769	<i>P</i> = .552

ASA, aspirin; VTE, venous thromboembolism; BMI, body mass index.

reach statistical significance (*P* = .622). Patients in the aggressive-only cohort experienced a 2.49% (30 of 1203) readmission rate, whereas patients in the risk-stratified cohort experienced a readmission rate of 2.20% (31 of 1408). Among patients within the risk-stratified cohort, the readmission rates between high- and standard-risk patients again favored the ASA/SPCDs group but was not statistically significant (*P* = .563), with high-risk patients treated with aggressive prophylaxis having a readmission rate of 2.48% (15 of 565) and standard-risk patients treated with ASA/SPCDs having a readmission rate of 2.02% (17 of 843).

The reasons for readmissions in the aggressive-only prophylaxis cohort were; infection in 1.3% (15 of 1203), wound or bleeding complications in 0.5% (6 of 1203), trauma in 0.4% (5 of 1203), VTE in 0.1% (1 of 1203), and “other” in 0.2% (3 of 1203) patients. The reason for readmission in the risk-stratified cohort was because of infection in 1.3% (19 of 1408), wound or bleeding complications in 0.2% (3 of 1408), trauma in 0.3% (4 of 1408), VTE in 0.0% (0 of 1408), and “other” in 0.4% (5 of 1408). None of the differing rates between cohorts reached statistical significance. A comprehensive list of the VTE events and readmissions experienced in each cohort and subgroup are summarized on Table 3.

Total hospital costs between the 2 cohorts were statistically similar (*P* = .674). However, within the risk-stratified cohort, the standard-risk patients treated with ASA/SPCDs had an 18.15% lower cost than the high-risk patients who received more aggressive VTE prophylaxis. This cost difference was clinically significant (*P* < .001).

Discussion

The purpose of this study was to review our institution's adopted risk-stratification algorithm to provide effective VTE prophylaxis while lowering the potential for complications related to anticoagulation. Our study demonstrated that there was no difference in VTE rate with a risk-stratified combination of aspirin and SPCDs for standard-risk patients and aggressive anticoagulation in high-risk patients as compared with the nonrisk-adjusted aggressive anticoagulation agents for all TJA patients. There was a statistically similar readmission rate and overall adverse event rate between both cohorts. Readmissions and adverse events were less in the risk-stratified cohort; however, the size of the study was underpowered to achieve statistical significance. Most importantly, in our current value-driven health care environment, episode of care costs of standard-risk patients treated with aspirin and SPCDs within the risk-stratified cohort were significantly less (18%) than high-risk patients treated with aggressive anticoagulation patients.

There is an increasing amount of data supporting the use of SPCDs in combination with aspirin as an effective form of VTE prophylaxis with a lower complication rate after TJA. Our study was underpowered and was not able to show a significant reduction in wound complications with the use of less aggressive VTE prophylaxis. However, other studies have demonstrated this reduction. Nam et al [15] conducted a prospective study of 1859 patients undergoing THA utilizing similar risk-stratification measures, with the “routine” risk cohort prescribed aspirin/SPCDs whereas the “high” risk cohort was prescribed warfarin. They found a significantly lower rate of major bleeding and wound complication in the “routine” risk cohort as compared with a “high” risk cohort. Similar to our findings, there was no difference in the VTE event rate among the 2 cohorts. Colwell et al [16] conducted a multicenter study comparing the use of a SPCD in 3060 patients after TJA and found that it was noninferior to the use of warfarin, enoxaparin, rivaroxaban, and dabigatran. The only exception was in the TKA group, where rivaroxaban demonstrated a 1% improvement in venous thromboembolic disease incidence. It is important to note, however, that bleeding complications with rivaroxaban after TJA have

Table 2

The Rate of VTE, Readmissions, Hospital Costs and Adverse Events Among the Aggressive-Only VTE Prophylaxis Patients (Cohort 1) and the Risk-Stratified Patients (Cohort 2).

Patient Group	PPx	n	Total VTE	% VTE	Readmit	RR %	Adverse Events	%AE	% Cost Δ
Cohort 1	Aggressive PPx	1203	19	1.58	30	2.49	48	3.99	+7.86
Cohort 2	Aggressive PPx	565	11	1.95	14	2.48	24	4.25	+18.15
	ASA/SPCDs	843	10	1.19	17	2.02	27	3.20	—
	Total	1408	21	1.49	31	2.20	51	3.62	+7.29
Total		2611	40	1.53	61	2.34	99	3.79	+7.55
Significance			P = .855		P = .622		P = .624		P = .674

ASA, aspirin; RR, Readmission Rate; AE, Adverse Events; PPx, Prophylaxis; VTE, venous thromboembolism; SPCDs, sequential pneumatic compression devices.

been reported to be higher than other anticoagulants [17]. A recent review article on the use of mobile compression devices after TJA showed strong support for the use of below-the-knee compression devices and placed emphasis on the growing advantages of mobile devices in becoming the standard of care for VTE prevention [3].

The VTE rate was 1.59% in our aggressive-only cohort and 1.49% in our risk-stratified cohort with no significant difference between the groups. Within the risk-stratified cohort, the VTE rate was lower among the standard-risk patients (1.19%) as compared with the high-risk patients (1.95%) as would be predicted but was not statistically significant likely due to the underpowered nature of the study. Brown et al [18] conducted a pooled analysis of 14 randomized control trials of VTE prophylaxis among patients undergoing TJA and found no difference in symptomatic DVTs, PEs, and fatal PEs among patients who were assigned aspirin as compared with warfarin, enoxaparin, and fondaparinux. In terms of retrospective studies, Bozic et al [19] studied 93,840 primary TKA patients, and those prescribed aspirin for VTE prophylaxis had identical or lower rates of VTE compared to those on aggressive agents. Similar large-scale studies have shown the same result among THA patients [20]. This present study adds to the literature that the use of aspirin/SPCDs provides equivalent prophylaxis for VTE among standard-risk patients.

Our VTE prophylaxis risk-stratification protocol demonstrated cost savings without effecting quality, thus, increasing value. Alternative payment strategies for TJRs based on value and quality are becoming increasingly prevalent. Beginning on April 1, 2016, the Centers for Medicare and Medicaid Services will require nearly one third of hospitals performing TJAs to participate in its Comprehensive Care for Joint Replacement program [21]. This program requires cost savings for total joint episodes of care. Thus, any intervention which adds value by decreasing costs and either maintains or improves quality is becoming increasingly important.

There is little data regarding the cost effectiveness of the use of a mobile compression device in combination with aspirin. We found a significant cost decrease in the aspirin/SPCD subgroup of the risk-stratified cohort. It is important to note that our cost savings identified in our study cannot solely be attributed to the use of aspirin/SPCDs and was likely multifactorial given that those patients with less medical comorbidities generally have lower costs of care. Other studies have compared costs associated with the use of aggressive chemoprophylaxis compared to aspirin/SPCDs. Colwell et al [22] performed a decision tree cost analysis comparing the

10-day use of enoxaparin or 10 days of SPCD use. Parameters analyzed included cost of medications and/or devices, laboratory procedures, hospital length of stay, and physician visits. Final analysis showed that the use of an SPCD would save an estimated \$369.50 per patient. Kapoor et al [23] similarly found a cost saving of \$1300 for the 4-week use of aspirin compared with enoxaparin after THA and TKA. This study did not include use of SPCDs, but the margin was large enough that even with the cost of the device factored in there is still a potential for significant savings.

The strengths of this study include a large sample size of consecutive patients from a single institution. This was a pragmatic analysis, closely mirroring the practice of a typical joint replacement surgeon. There are several limitations to this study that must be considered. This was a retrospective study used to assess the effectiveness of our institution's risk-stratification VTE protocol. Thus, our data collection relied on the accuracy of our electronic medical record which may have contained errors in coding or documentation. In addition, the 2 cohorts were not concurrent. We are not aware of any other treatment variables that changed between the periods of the 2 cohorts, and we believe that the consecutive nature of the cohorts minimized any unrecognized treatment differences. In addition, this is not a single surgeon study; therefore, there was variation in both surgical approaches and type of implanted components used for the procedures. We conducted no additional DVT/PE surveillance measures in addition to the typical standard of care. Although this limited the identification of the true number of possible VTE events, it focused our screening for clinical events that impacted patient care and was uniformly applied for all patients in both cohorts. This is also consistent with AAOS and ACCP guidelines that recommend against routine postoperative duplex ultrasonography for patients undergoing TKA and THA [13,14]. This study did not include an assessment of patient compliance in their use of SPCDs after discharge. All patients were educated before leaving the hospital on the proper use of a SPCD and received follow-up calls from a clinical care coordinator to reinforce SPCD compliance. Froimson et al [24] reported that mobile SPCDs do have a higher rate of compliance when compared with standard nonmobile devices (83% vs 49%), which was similar to prior findings by Murakami et al [25].

In terms of patient satisfaction, the use of SPCDs along with aspirin is associated with a high degree of patient satisfaction. The design of mobile devices has continued to improve in recent years with the latest devices being lighter and smaller, thus, increasing the

Table 3

Rates of DVT and PE Among the Aggressive-Only VTE Prophylaxis Patients (Cohort 1) and the Risk-Stratified Patients (Cohort 2) Along With the Reasons for Readmission.

	PPx	n	VTE			Reason for Readmission					
			DVT	PE	Total	Infection	Wound/Bleeding	Trauma	VTE	Other	Total
Cohort 1	Aggressive	1203	6 (0.5%)	13 (1.1%)	19 (1.6%)	15 (1.3%)	6 (0.5%)	5 (0.4%)	1 (0.1%)	3 (0.2%)	30 (2.5%)
Cohort 2	Aggressive	565	1 (0.2%)	10 (1.7%)	11 (1.9%)	8 (1.4%)	1 (0.2%)	2 (0.4%)	0 (0.0%)	3 (0.5%)	14 (2.5%)
	ASA/SPCD	843	1 (0.1%)	9 (1.1%)	10 (1.2%)	11 (1.3%)	2 (0.2%)	2 (0.2%)	0 (0.0%)	2 (0.2%)	17 (2.0%)
Cohort 2 total		1408	2 (0.1%)	19 (1.4%)	21 (1.5%)	19 (1.3%)	3 (0.2%)	4 (0.3%)	0 (0.0%)	5 (0.4%)	31 (2.2%)

DVT, deep vein thrombosis; VTE, venous thromboembolism; SPCD, sequential pneumatic compression device; PE, pulmonary embolism; ASA, aspirin. Bolded values represent the total values from cohort 1 and cohort 2.

ease of use for patients. This is increasingly important as patient experience is considered an indicator of quality, and patient satisfaction is a part of most performance-based reimbursement strategies, including Centers for Medicare and Medicaid Services's Comprehensive Care for Joint Replacement program [26]. Aspirin is a medication that is easy to acquire due to the minimal cost and over the counter availability with minimal adverse effects compared with relatively expensive subcutaneously injectable enoxaparin. Although oral warfarin itself is available in inexpensive generic forms, its use includes the added costs of routine testing for patients.

Summary

Our study demonstrated that the use of a VTE risk-stratification protocol designed to provide the appropriate intensity of VTE prophylaxis for individual patients following TJA is safe and cost effective. Patients are at no greater risk of VTE with a risk-stratified protocol that considers individual patient characteristics in determining the ideal intensity of prophylaxis. The combination of aspirin and a mobile compression device provides a reasonable alternative to the traditional aggressive chemoprophylaxis agents while avoiding bleeding-associated complications in selected standard-risk patients. In the current environment of value-based care, this type of protocol is becoming increasingly important. Larger, perhaps multicentered, studies are required to demonstrate any decrease in complications associated with our risk-stratification protocol.

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