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Balancing Thromboprophylaxis and Bleeding in Total Joint Arthroplasty: Impact of Eliminating Enoxaparin and Predonation and Implementing Pneumatic Compression and Tranexamic Acid

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ABSTRACT

Background: Venous thromboembolic disease (VTED) after total hip arthroplasty (THA) and total knee arthroplasty (TKA) poses substantial risk. Pharmacologic prophylaxis against VTED can cause bleeding, transfusion, and associated complications. The ActiveCare+SFT is a portable, intermittent pneumatic compression device (IPCD), providing equivalent VTED prophylaxis to pharmacologic agents without associated bleeding. Tranexamic acid (TXA) is an antifibrinolytic that reduces blood loss after THA and TKA. Our objective was to measure blood transfusion and VTED after eliminating enoxaparin, introducing an IPCD, eliminating autologous blood transfusion, and administering TXA during primary TKA and THA.
Methods: Four consecutive cohorts of THA and TKA patients were studied. Group A, the historical control, received enoxaparin VTED prophylaxis. Group B received IPCD VTED prophylaxis. Group C received IPCD VTED prophylaxis along with TXA (1 g intravenous at incision and closure). Groups A, B, and C predonated 1 unit of autologous blood. Group D received IPCD VTED prophylaxis, TXA as above, but did not donate blood preoperatively.
Results: Seventeen of 50 patients (34%) in Group A, 7 of 47 (14.9%) patients in Group B, 4 of 43 (9.3%) patients in Group C, and 0 of 46 patients in Group D received transfusions. There were no major symptomatic VTED events.
Conclusion: Using an IPCD and TXA and discontinuing enoxaparin and preoperative autologous blood donation eliminated blood transfusion in primary THA and TKA without any increase in VTED. Using an IPCD instead of enoxaparin, adding TXA, and eliminating preoperative autologous donation each had an incremental dose response effect. This protocol provides effective VTED prophylaxis equivalent to pharmacologic methods and eliminates transfusion risk in the primary THA and TKA population.

Total hip arthroplasty (THA) and total knee arthroplasty (TKA) are associated with a documented risk of venous thromboembolic disease (VTED) and significant blood loss leading to anemia, transfusion, and associated complications [1,2]. Traditionally, recommendations for prophylaxis against VTED have involved some form of anticoagulation, which has exacerbated the potential for blood loss [1]. In turn, attempts at minimizing blood loss by less aggressive anticoagulation or topical or systemic medications to enhance coagulation have resulted in a real or perceived risk of an increased incidence of VTED [3]. Optimizing VTED prophylaxis along with minimizing blood loss and its associated complications until recently have been nearly mutually exclusive.

In 2012, the American College of Chest Physicians revised its guidelines to include the use of a unique intermittent pneumatic compression device (IPCD) as an acceptable prophylaxis against VTED after THA and TKA when used for a minimum of 10 to 14 days rather than no antithrombotic prophylaxis (class 1C recommendation) [1]. In particular, the ActiveCare+SFT (synchronized flow technology), a portable, battery-operated, IPCD device, meant to be worn continuously, and sequenced to the respiratory system to enhance peak venous velocity, was specifically referenced in these guidelines [4,5]. The device enhances the peak venous velocity by monitoring the respiratory-related venous phasic flow and

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Table 1
Demographic Background Data and Length of Stay by Cohort.

Treatment Group	Age at Time of Surgery (SD)	Height (SD)	Weight (SD)	BMI (SD)	Female (%)	Right-Sided Procedure (%)	TKA (%)	LOS (SD)
Enoxaparin/autodonation	67.9 (10.20)	65.61 (4.62)	182.66 (40.84)	30.13 (7.95)	33 (66.0)	33 (66.0)	31 (62.0)	2.38 (0.6)
ActiveCare/autodonation	66.63 (9.69)	67.09 (3.91)	190.23 (45.98)	29.35 (4.68)	30 (63.8)	25 (53.2)	28 (59.6)	2.49 (0.83)
ActiveCare/TXA/autodonation	67.51 (8.17)	66.42 (4.79)	189.51 (43.37)	30.63 (6.76)	23 (53.5)	26 (60.5)	25 (58.1)	2.56 (1.12)
ActiveCare/TXA/no autodonation	67.79 (9.56)	66.63 (5.03)	186.85 (44.55)	29.32 (5.12)	23 (50.0)	24 (52.2)	30 (65.2)	2.41 (0.69)
P value	.91	.45	.83	.71	.32	.47	.91	.93

All data are presented as mean (standard deviation [SD]) or mean (percentage).
BMI, body mass index; TKA, total knee arthroplasty; TXA, tranexamic acid; LOS, length of stay.

triggering compression when resistance is lowest and flow can be maximized. The increased flow resulting from the synchronized compression and respiratory cycle significantly reduces stasis and resultant VTED. The data supporting its use in both THA and TKA demonstrate equivalent VTED prophylaxis efficacy to formal anticoagulation with significantly less bleeding and transfusion risk [5].

Tranexamic acid (TXA), an antifibrinolytic, has become a well-accepted modality to reduce blood loss at the time of THA and TKA [6,7]. The growing body of literature has effectively dispelled the theoretical concern for increased VTED risk [7-11].

We hypothesized that combining a synchronized IPCD with the use of intravenous TXA during THA and TKA would substantially reduce blood loss and the risk of transfusion without increasing the occurrence of VTED.

Methods

Design and Study Population

The institutional review board approved this study. This study represents a retrospective analysis of prospectively gathered data. Between September 19, 2013 and November 4, 2014, data regarding preoperative care, surgical procedure, postoperative care, hemoglobin (Hb) levels, transfusions, and complications for all TKA and THA patients of a senior orthopedic surgeon were recorded. Patients were chronologically divided into 4 study groups as follows: group A: enoxaparin/autodonation, group B: IPCD/autodonation, group C: IPCD/TXA/autodonation, and group D: IPCD/TXA/no autodonation.

Enoxaparin was administered as a 30-mg subcutaneous injection twice daily starting 18-24 hours after wound closure while the patient was hospitalized, and as a 40-mg daily subcutaneous injection after discharge, for a total of 14 days.

The IPCD was applied in the preoperative holding area to the nonoperative limb and to the operative limb in the operating room on completion of the surgery. The patients were instructed to wear the device at least 20 hours per day for 14 days postoperatively. TXA was administered intravenously at a dose of 1000 mg at the time of incision and again on commencement of closure. Postoperative Hb was measured in the postanesthesia care unit, and then again daily for the first 2 hospital days, and as necessary thereafter. Patients with an Hb level of <8 gm/dL or with symptomatic anemia were transfused 1 unit at a time until stable. Exclusion criteria for this study were patients undergoing a revision TKA or THA, patients who had undergone previous surgery during the study period, patients with diagnosed anemia or blood disorders, patients with a history of VTED, and patients with recent bleeding events.

Statistical Analysis

Statistical analysis was performed using analysis of variance and the Kruskal-Wallis test for numerical variables and the chi-square, Fisher exact, and Cochran-Armitage trend tests for categorical variables. A 2-sided .05 significance level was used throughout. Post hoc power analysis was carried out according to the study's hypothesis and yielded power of ≥95%. Statistical calculations were made using SAS version 9.2 (SAS Institute, Cary, NC) and nQuery Advisor, version 6.0 (Janet D. Elashoff, 2005).

Results

Two hundred forty-four surgeries were recorded during the study period, and 186 surgeries remained after excluding patients not meeting the inclusion criteria. There were 50 patients in group A, 47 in group B, 43 in group C, and 46 in group D. The age, height, weight, body mass index, sex, operation side, specific procedure performed, and length of stay did not significantly differ between any of the groups (Table 1).

The percent of patients transfused decreased significantly with the addition of each intervention. Thirty-four percent of patients in the enoxaparin/autodonation group were transfused, which decreased to 14.9% of patients in the IPCD/autodonation group, 9.3% of patients in the IPCD/TXA/autodonation group, and 0% of patients in the IPCD/TXA/no autodonation group ($P < .0001$; Table 2, Fig. 1). In addition, the number of units transfused per patient was reduced sequentially with each additional intervention from 0.4 (20 of 50) to 0.15 (7 of 47) to 0.14 (6 of 43) to 0 (0 of 46). This was accomplished without any significant increase in complications ($P = .24$), including no increase in symptomatic deep vein thrombosis (DVT) and pulmonary embolism (PE). There were no deaths in this series (Table 3).

Hb levels measured preoperatively and postoperatively, as well as the lowest recorded postoperative Hb level, differed significantly when compared by group ($P = .039$, .043, <.0001, respectively; Table 4). The change in Hb level demonstrated reduced Hb loss with the addition of each intervention. Each intervention sequentially reduced the drop in Hb from postoperative to lowest Hb and from preoperative to lowest Hb. Preoperative to lowest postoperative Hb decreased significantly in a stepwise fashion from 3.98 to 3.84 to 3.41 to 3.39 in each group, respectively ($P = .02$). Changes in postoperative to lowest postoperative Hb levels also decreased significantly in a stepwise fashion from 1.82 to 1.77 to 1.36 to 1.20 for each group, respectively ($P = .003$). Finally, preoperative to

Table 2
Transfusion Data by Cohort.

Treatment Group	Units Transfused/ Patient (SD)	Number Transfused/ Group	Percent Transfused/ Group
Enoxaparin/autodonation	0.4 (0.61)	17/50	34
ActiveCare/autodonation	0.15 (0.36)	7/47	14.9
ActiveCare/TXA/autodonation	0.14 (0.47)	4/43	9.3
ActiveCare/TXA/no autodonation	0	0/46	0
P value	<.0001	<.0001	<.0001

SD, standard deviation; TXA, tranexamic acid.