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Original Research

Ambulatory Portable Pneumatic Compression Device as Part of a Multimodal Aspirin-Based Approach in Prevention of Venous Thromboembolism in Outpatient Total Knee Arthroplasty

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ABSTRACT

Background: The purpose of this study is to review the incidence of symptomatic venous thromboembolism (VTE) in patients undergoing outpatient primary total knee arthroplasty (TKA) who used a portable pneumatic compression device as part of their VTE prophylaxis protocol.
Methods: A retrospective review of all outpatient primary TKA procedures in which patients used ambulatory pneumatic compression pumps as part of their multimodal VTE prophylaxis was performed from 2016 through 2018. This yielded a cohort of 1131 patients (1453 TKAs). An aspirin (ASA)-based protocol was used in patients with standard VTE risk receiving either 81 mg or 325 mg of ASA twice daily for 6 weeks postoperatively. High-risk patients received a stronger chemoprophylaxis for 2 weeks followed by ASA for 4 weeks. Pneumatic compression pumps were worn for 23 hours/day for 14 days.
Results: VTE prophylaxis medication was 81-mg ASA in 56% of patients, 325-mg ASA in 10% of patients, and stronger chemoprophylaxis in 34% of patients. Patients were considered morbidly obese (body mass index >40 kg/m^2) in 267 (18.4%) procedures. Ninety-seven (6.7%) patients had a preoperative history of VTE event. Forty-nine duplex ultrasounds were performed (3.3% of TKAs). Confirmed VTE events were documented in only 5 (0.3%) patients. All VTEs occurred in high-risk patients who were discharged on stronger chemoprophylaxis. The time (days) to VTE was 3, 3, 7, 45, and 88 days.
Conclusion: The use of portable pneumatic compression pumps as part of a multimodal VTE prophylaxis protocol aided in a very low rate of symptomatic VTE events in patients undergoing outpatient primary TKA.

Introduction

Although total knee arthroplasty (TKA) is overall a safe procedure, the risk of complications such as venous thromboembolism (VTE) still remains. VTE includes deep venous thrombosis (DVT) and/or pulmonary embolism (PE) and occurs as a result of Virchow's triad: venous stasis, endothelial injury, and hypercoagulability [1]. The goal of multimodal VTE prevention is to reduce each of these associated variables; chemoprophylaxis targets the hypercoagulable state, while patient mobilization and mechanical pneumatic compression devices decrease venous stasis. The historically reported rates of VTE after lower extremity arthroplasty range from 1% to 15% [2-5]. Modern-day rates of symptomatic VTE have decreased substantially in part due to improvements in perioperative protocols and early mobilization [6-11].

With these improvements in VTE prevention, chemoprophylaxis has shifted away from higher risk medications such as warfarin to drugs with a lower incidence of bleeding such as aspirin (ASA) [12]. In many patients, ASA is as effective as Coumadin, low-molecular-weight heparin, and Factor Xa inhibitors in prevention of VTE [13]. Furthermore, low-dose 81-mg ASA given twice daily has shown to be as effective as higher dose of 325-mg ASA [6]. Those patients with a higher risk profile including obesity and/or history of VTE are still commonly recommended to have a stronger prophylaxis rather than ASA [14,15].

Along with anticoagulant medication, mechanical pneumatic compression has been shown to decrease rates of symptomatic VTE

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after TKA [16]. The symptomatic VTE rates using mechanical compression alone have been reported at 0.92%, which is comparable with more aggressive anticoagulation protocols [17]. In addition, prolonged outpatient use of pneumatic compression further decreases the incidence of VTE over isolated inpatient use [18].

The study authors have been performing outpatient TKA at a free-standing ambulatory surgery center since 2013 using an ASA -based, multimodal, and risk-stratified approach for venous thromboembolic disease prevention [19]. The authors have published on the safety of outpatient arthroplasty [20,21]; however, a detailed analysis of VTE in this population has not been performed. The purpose of this study is to evaluate the incidence of symptomatic VTE in patients undergoing outpatient TKA using an ASA -based risk-stratified protocol along with ambulatory portable pneumatic compression device as VTE prophylaxis.

Material and Methods

A retrospective review of all outpatient primary TKA procedures in which patients used ambulatory pneumatic compression pumps (Compression Solutions LLC, Tulsa, OK) as part of their multimodal VTE prophylaxis was performed from 2016 through 2018. During this study period, the institution's protocol was to prescribe ambulatory compression pumps to all patients undergoing arthroplasty. Patients were excluded if they declined research (119 patients), had missing records of discharge anticoagulant medication (61 patients), or refused ambulatory calf pumps (11 patients). This yielded a cohort of 1131 patients (1453 TKAs).

All surgeries were performed with the use of tourniquet and all patients received oral or intravenous tranexamic acid. Peripheral nerve blocks were performed to include an adductor canal and posterior capsular block. A periarticular injection was performed with local anesthetic and epinephrine. General endotracheal anesthesia was used in all patients. Patients typically ambulated within 2 hours of surgery and were discharged once all criteria were met.

An ASA-based VTE prophylaxis protocol was used with patients of standard VTE risk receiving either 81 mg or 325 mg of ASA twice daily for 6 weeks postoperatively. Our standard protocol switched to 81 mg of ASA in 2017. Higher risk patients received a stronger chemoprophylaxis (fondaparinux, enoxaparin, rivaroxaban, etc.) for 2 weeks followed by ASA for 4 weeks unless the patient had an ASA contraindication.

There is currently no validated tool to stratify patients as "high risk" for VTE [22]. In collaboration with our internal medicine colleagues, patients were determined to be at high risk if they were obese with a body mass index (BMI) >40 kg/m^2, had a history of VTE event, were in a hypercoagulable state, and/or had active cancer. All patients, regardless of risk or chemoprophylaxis, were discharged with ambulatory pneumatic compression pumps and instructed to wear them for 23 hours/day for 14 days after surgery.

Office notes and outside medical treatment documents were reviewed for duplex ultrasounds performed and confirmed VTE events of DVT and/or PE. Surgery center and durable medical equipment records were reviewed to confirm patients received the ambulatory pneumatic compression pumps. Postoperative discharge VTE medication was recorded.

All patients signed a general research consent, approved and monitored by an independent institutional review board (Western IRB, Puyallup, WA), which allows inclusion in retrospective reviews.

Results

The mean patient age was 59.1 years (range, 25 to 81 years), and the mean BMI was 35.2 kg/m^2 (range, 18 to 66 kg/m^2). The gender was female in 58% of patients. Patients were considered morbidly obese (BMI >40 kg/m^2) in 267 (18.4%) procedures. Ninety-seven (6.7%) patients had a preoperative history of VTE event. VTE prophylaxis medication was 81 mg of ASA in 56% of patients, 325 mg of ASA in 10% of patients, and stronger chemoprophylaxis in 34% of patients.

A total of 49 duplex ultrasounds were performed (3.3% of TKAs). Confirmed VTE events were documented in only 5 (0.3%) patients. This included 3 DVTs and 2 PEs. Four of the five patients with VTE were morbidly obese. All VTEs occurred in high-risk patients who were discharged on stronger chemoprophylaxis: fondaparinux in 4 patients and rivaroxaban in 1 patient. Two of the five patients with VTE had a previous history of VTE event. The time (days) to VTE was 3, 3, 7, 45, and 88 days.

Discussion

The principal finding of this study was the use of portable pneumatic compression pumps as part of a multimodal ASA -based VTE prophylaxis protocol aided in a very low rate of symptomatic VTE events in patients undergoing outpatient primary TKA. The only VTE events that occurred were in "high-risk patients," denoting a 0% symptomatic VTE incidence in standard-risk patients treated with ASA and ambulatory pneumatic compression pumps.

The efficacy of a risk-stratified VTE prophylaxis protocol as used in this study is supported by other surgeons. Nam et al. used a protocol in which standard-risk patients were treated with ASA and portable compressive devices for 10 days, whereas those patients determined to be at "high risk" were given warfarin therapy and only compression devices while an inpatient. They reported a VTE incidence of 0.5% using this protocol. After their initial promising results, their study institution removed obesity, age >70 years, and multiple medical comorbidities from being "high risk" and treated these patients with the same ASA-based portable pneumatic protocol. With this change, 83% of patients were categorized as standard risk, and there was no significant difference in VTE events in this standard-risk group [15]. Our institution has continued to view obese patients as "high risk," but neither medical comorbidities (outside of hypercoagulable states) nor advanced age is routinely treated with higher risk prophylaxis.

The last clinical practice guidelines produced by the American Academy of Orthopaedic Surgeons on VTE prophylaxis in arthroplasty were published in 2011. The recommendation from those clinical practice guidelines was for either pharmacologic or mechanical VTE prophylaxis [23]. The subsequent guidelines from the American College of Chest Physicians echoed similar recommendations. Chemoprophylaxis and pneumatic compression devices were both given "grade 1" recommendations, which denotes there was certainty that the benefits of these treatments outweighed the potential risks [24]. No subsequent guidelines have been published, but there is a fair amount of research that can aid in supporting the use of ambulatory compression pumps [25-27].

The higher risk of bleeding events with stronger chemoprophylaxis has led many surgeons and researchers toward the use of ASA -based VTE prophylaxis regimens [6,12,13,25]. Parvizi et al reported a 0.1% to 0.3% incidence of VTE in a low-risk VTE population undergoing lower extremity arthroplasty with ASA chemoprophylaxis [6]. In that study, high-risk patients, such as those with a history of VTE or morbid obesity, were excluded, and patients only wore compression devices in the hospital [6]. The standard-risk patients in the present study had a very similar rate of symptomatic VTE.

The use of mobile compression devices alone or with ASA after lower extremity arthroplasty has shown similar VTE rates to more potent chemoprophylaxis in standard-risk patients [25-27]. In a multicenter analysis, Colwell et al. reported a VTE incidence of

0.92% in 3060 low-risk patients who used ambulatory compression pumps alone after hip and knee arthroplasty. This incidence was noninferior to patients receiving chemoprophylaxis alone [26]. Colwell et al previously performed a randomized study of ambulatory pumps compared with heparin and found that pumps had equivalent incidence of DVT and VTE as well as significantly less bleeding events [27]. Similarly, Arsoy et al. reported no difference in the VTE rates between mobile compression devices with ASA compared with low-molecular-weight heparin with significantly less bleeding events and related complications with the compression device group [25].

Some concerns have arisen about patient compliance with the use of portable compression devices. However, given the lightweight and small size of these devices, a relatively high level of compliance has been reported [15,28]. Froimson et al. compared a mobile, sequential, and pneumatic compression device with a nonmobile, nonsequential device. Compliance was 83% in the mobile group compared with 49% in the nonmobile group. Furthermore, the mobile group had a nearly 3 times lower DVT rate at 1.3% [28]. Nam et al noted 84.5% compliance of wearing the mobile compression pumps for greater than 18 hours/day [15].

This study has several limitations. First are the inherent shortcomings of a retrospective review such as inaccuracies of documentation. For example, more patients may have had a VTE event that was potentially not documented. The retrospective review also provides lower quality of evidence than a prospective randomized study or case-control study. Unfortunately, a historical control group was not available for analysis. The purpose of this research, however, was not to show superiority of one treatment over another but rather demonstrate the overall safety and effectiveness of a risk-based VTE prophylaxis model. The lack of a control group limits the conclusions that can be drawn about the ambulatory calf pump's effectiveness alone as all patients had other forms of VTE prophylaxis including chemoprophylaxis and early mobilization. Another limitation is the heterogenicity in chemoprophylactic medication. Even within the ASA treatment group, some patients received 325 mg and some 81 mg. However, this diversity in medication use reflects real-world practices as part of a risk-based VTE prophylaxis protocol. We were also not able to quantify how compliant the patients were with the use of the pneumatic compression devices. Devices, although capable, were not interrogated for compliance.

Conclusion

The use of portable pneumatic compression pumps as part of an ASA-based multimodal VTE prophylaxis protocol aided in a very low rate of symptomatic VTE events in patients undergoing outpatient primary TKA.

Conflict of interest

Direct funding for the study was provided by Compression Solutions LLC, Tulsa, OK.

References

[1] Virchow RLK. Die Verstopfung den Lungenarterie und ihre Flogen. Beitr Exper Path Physiol 1846;2:1.
[2] Salvati EA, Pellegrini Jr VD, Sharrock NE, et al. Recent advances in venous thromboembolic prophylaxis during and after total hip replacement. J Bone Joint Surg Am 2000;82(2):252.
[3] Colwell Jr CW, Collis DK, Paulson R, et al. Comparison of enoxaparin and warfarin for the prevention of venous thromboembolic disease after total hip arthroplasty evaluation during hospitalization and three months after discharge. J Bone Joint Surg Am 1999;81(7):932.
[4] Leclerc JR, Gent M, Hirsh J, Geerts WH, Ginsberg JS. The incidence of symptomatic venous thromboembolism after enoxaparin prophylaxis in lower extremity arthroplasty: a cohort study of 1,984 patients. Canadian Collaborative Group. Chest 1998;114(2 Suppl Evidence):115S.
[5] White RH, Henderson MC. Risk factors for venous thromboembolism after total hip and knee replacement surgery. Curr Opin Pulm Med 2002;8(5):365.
[6] Parvizi J, Huang R, Restrepo C, et al. Low-dose aspirin is effective chemoprophylaxis Against clinically important venous thromboembolism following total joint arthroplasty: a preliminary analysis. J Bone Joint Surg Am 2017;99(2):91.
[7] Maradit Kremers H, Larson DR, Crowson CS, et al. Prevalence of total hip and knee replacement in the United States. J Bone Joint Surg Am 2015;97(17):1386.
[8] Gesell MW, González Della Valle A, Bartolomé Garcáia S, et al. Safety and efficacy of multimodal thromboprophylaxis following total knee arthroplasty: a comparative study of preferential aspirin vs. routine coumadin chemoprophylaxis. J Arthroplasty 2013;28(4):575.
[9] González Della Valle A, Serota A, Go G, et al. Venous thromboembolism is rare with a multimodal prophylaxis protocol after total hip arthroplasty. Clin Orthop Relat Res 2006;444:146.
[10] Leali A, Fetto J, Moroz A. Prevention of thromboembolic disease after noncemented hip arthroplasty. A multimodal approach. Acta Orthop Belg 2002;68(2):128.
[11] Ragucci MV, Leali A, Moroz A, Fetto J. Comprehensive deep venous thrombosis prevention strategy after total-knee arthroplasty. Am J Phys Med Rehabil 2003;82(3):164.
[12] Bala A, Huddleston 3rd JI, Goodman SB, Maloney WJ, Amanatullah DF. Venous thromboembolism prophylaxis after TKA: aspirin, warfarin, enoxaparin, or factor Xa inhibitors? Clin Orthop Relat Res 2017;475(9):2205.
[13] Wilson DG, Poole WE, Chauhan SK, Rogers BA. Systematic review of aspirin for thromboprophylaxis in modern elective total hip and knee arthroplasty. Bone Joint J 2016;98-B(8):1056.
[14] Mihara M, Tamaki Y, Nakura N, et al. Clinical efficacy of risk-stratified prophylaxis with low-dose aspirin for the management of symptomatic venous thromboembolism after total hip arthroplasty. J Orthop Sci 2020;25:156.
[15] Nam D, Nunley RM, Johnson SR, Keeney JA, Clohisy JC, Barrack RL. The effectiveness of a risk stratification protocol for thromboembolism prophylaxis after hip and knee arthroplasty. J Arthroplasty 2016;31(6):1299.
[16] Pavon JM, Adam SS, Razouki ZA, et al. Effectiveness of intermittent pneumatic compression devices for venous thromboembolism prophylaxis in high-risk surgical patients: a systematic review. J Arthroplasty 2016;31(2):524.
[17] Haynes J, Barrack RL, Nam D. Mobile pump deep vein thrombosis prophylaxis: just say not to drugs. Bone Joint J 2017;99-B(1 Supple A):8.
[18] Snyder MA, Sympson AN, Scheuerman CM, Gregg JL, Hussain LR. Efficacy in deep vein thrombosis prevention with extended mechanical compression device therapy and prophylactic aspirin following total knee arthroplasty: a randomized control trial. J Arthroplasty 2017;32(5):1478.
[19] Berend KR, Lombardi Jr AV. Multimodal venous thromboembolic disease prevention for patients undergoing primary or revision total joint arthroplasty: the role of aspirin. Am J Orthop (Belle Mead NJ) 2006;35(1):24.
[20] Crawford DA, Adams JB, Berend KR, Lombardi Jr AV. Low complication rates in outpatient total knee arthroplasty. Knee Surg Sports Traumatol Arthrosc 2020;28:1458.
[21] Berend KR, Lombardi Jr AV, Berend ME, Adams JB, Morris MJ. The outpatient total hip arthroplasty: a paradigm change. Bone Joint J 2018;100-B(1 Supple A):31.
[22] Eikelboom JW, Karthikeyan G, Fagel N, Hirsh J. American Association of Orthopedic Surgeons and American College of Chest Physicians guidelines for venous thromboembolism prevention in hip and knee arthroplasty thromboembolism prevention in hip and knee arthroplasty differ: what are the implications for clinicians and patients? Chest 2009;2:513.
[23] Mont MA, Jacobs JJ. AAOS clinical practice guideline: preventing venous thromboembolic disease in patients undergoing elective hip and knee arthroplasty. J Am Acad Orthop Surg 2011;19:777.
[24] Lieberman JR. American College of Chest Physicians evidence-based guidelines for venous thromboembolic prophylaxis: the guideline wars are over. J Am Acad Orthop Surg 2012;20(6):333.
[25] Arsoy D, Giori NJ, Woolson ST. Mobile compression reduces bleeding-related readmissions and wound complications after THA and TKA. Clin Orthop Relat Res 2018;476(2):381.
[26] Colwell Jr CW, Froimson MI, Anseth SD, et al. A mobile compression device for thrombosis prevention in hip and knee arthroplasty. J Bone Joint Surg Am 2014;96(3):177.
[27] Colwell Jr CW, Froimson MI, Mont MA, et al. Thrombosis prevention after total hip arthroplasty: a prospective, randomized trial comparing a mobile compression device with low-molecular-weight heparin. J Bone Joint Surg Am 2010;92(3):527.
[28] Froimson MI, Murray TG, Fazekas AF. Venous thromboembolic disease reduction with a portable pneumatic compression device. J Arthroplasty 2009;24:310.