Arthroplasty Today 6 (2020) 118–122

Contents lists available at ScienceDirect

Arthroplasty Today

journal homepage: http://www.arthroplastytoday.org/

Original research

Portable compression devices in total joint arthroplasty: poor outpatient compliance

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ARTICLE INFO

Article history:
Received 18 September 2019
Received in revised form
26 November 2019
Accepted 8 December 2019
Available online 6 March 2020

Keywords:
Portable compression devices
Joint arthroplasty
Deep vein thrombosis
Outpatient compliance

ABSTRACT

Background: Aspirin and mechanical compression devices are approved means of venous thromboembolism (VTE) prophylaxis after total joint arthroplasty. Prior studies of mechanical compression pumps after joint arthroplasty have been limited to the inpatient setting. The purpose of this study was to evaluate outpatient compliance and utilization factors in a rural population after elective hip or knee arthroplasty.
Methods: Utilization for portable pneumatic compression pumps after joint arthroplasty was prospectively recorded (hours). Compliance was defined as the recommended 20 hours per day. A questionnaire 2 weeks postoperatively assessed factors that may contribute to noncompliance. Patients were followed up for 90 days postoperatively to record VTE events.
Results: Data were collected for 115 joint arthroplasty patients (50 hips, 65 knees). Postdischarge day one had the highest average usage at 13.2 hours/day (66.0%, range 0%-100%), but this number fell to 4.8 hours/day (24.0, range 0%-100%) by day 14. Patient compliance (>20 hours use/day) was highest on postdischarge day one at 40 patients (34.7%). By postdischarge day 14, patient compliance fell to 17 patients (14.8%). Difficulty using the pumps ($P = .027$) and pump-associated heat ($P = .009$) were significantly associated with patient compliance. A deep vein thrombosis and nonfatal pulmonary embolism were recorded in 2 separate patients.
Conclusions: This study demonstrated poor outpatient compliance with portable pneumatic compression devices. Poor compliance was related to pump heat and difficulty with pump use. Even with poor compliance, a low incidence of VTE events was observed.

Introduction

Venous thromboembolism (VTE) is a concerning complication after total joint arthroplasty. Before the routine use of prophylaxis, the rate of symptomatic VTE events was between 15 and 30% [1]. With the routine use of thromboprophylaxis, current rates of symptomatic VTE are approximately 0.9% after hip arthroplasty and 1.9% after knee arthroplasty [2].

Chemoprophylaxis after total joint arthroplasty has become the standard of care and includes oral or injectable agents. The American College of Chest Physicians (ACCP) developed a revised set of guidelines in 2012 for chemoprophylaxis after total hip (THA) or total knee arthroplasty (TKA). For patients undergoing THA or TKA, the ACCP recommends "low molecular weight heparin (LMWH); fondaparinux; dabigatran; apixaban; rivaroxaban; low-dose unfractionated heparin; adjusted-dose vitamin K antagonist; aspirin (all grade 1B); or an intermittent pneumatic compression device (grade 1C) for a minimum of 10 to 14 days" [1]. Chemoprophylaxis with agents that affect the clotting cascade carries an increased risk of bleeding, hematoma, wound drainage, infection, and wound-healing problems. In patients at increased bleeding risk, the ACCP recommends an intermittent pneumatic compression

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 https://doi.org/10.1016/j.artd.2019.12.004.

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https://doi.org/10.1016/j.artd.2019.12.004

device (IPCD) or no prophylaxis after major orthopaedic surgery (grade 2C) [1]. The bleeding rates associated with IPCD usage are considerably smaller than with chemoprophylaxis [3].

Aspirin and intermittent pneumatic compression devices are considered approved means of VTE prophylaxis after total joint arthroplasty by the Surgical Care Improvement Project [1,4]. Mechanical compression devices are particularly appealing due to the lower risk of bleeding and wound complications after total joint arthroplasty. The proposed mechanism by which mechanical compression devices prevent deep vein thrombosis (DVT) is via compression of the leg vasculature to increase venous flow from the legs, which results in the release of endothelial-derived relaxing factors and urokinase [5-8]. Urokinase and the endothelial-derived relaxing factors help to prevent thrombosis formation and break down clots as they are forming. Within 30 minutes, mechanical compression devices increase concentrations of fibrinogen degradation and tissue plasminogen activator, while decreasing concentrations of plasminogen activator inhibitor. Within 10 minutes of stopping mechanical compression devices, these concentrations return to the baseline and fibrinolytic efficacy is lost [9]. There is minimal risk associated with intermittent pneumatic compressive device usage, with rare case reports of peroneal nerve palsy and compartment syndrome [10,11].

Prior studies have demonstrated a direct correlation between compression device compliance and thrombosis prevention [12]. The biggest concern for mechanical compression devices, especially in the outpatient setting, is patient compliance. Although primarily evaluated in an inpatient setting, only a few studies have evaluated compliance in an outpatient setting. In a study by Colwell Jr. et al., LMWH was compared with a mobile compression device and aspirin after total hip arthroplasty. Patient compliance with the mobile compression device was found to be 83% of the time for a mean of 11 days after surgery [13]. Another study evaluating sequential compression device usage in postoperative urologic patients found an overall compliance rate of 78.6% [14]. Reasons for noncompliance with mobile compression devices include skin irritation, sleep disturbance, general discomfort, and noise intolerance [13].

Few studies have evaluated outpatient compliance of mobile compression devices after joint arthroplasty, and the efficacy and outpatient compliance of compression devices in a rural population remains unknown. The purpose of this study was to evaluate outpatient compliance of portable compression devices in a rural patient population undergoing elective primary unilateral total hip or knee arthroplasty. Secondary purposes were to identify patient characteristics and factors associated with compression device compliance and satisfaction.

Materials and methods

After obtaining Institutional Review Board approval, patients undergoing elective primary unilateral total knee or hip arthroplasty between March 2014 and March 2015 were prospectively enrolled at our university-based center for joint replacement. Informed consent was obtained from all patients. Overall, 115 patients undergoing elective primary total joint arthroplasty (50 hips, 65 knees) were enrolled. Inclusion criteria included patients undergoing unilateral primary total hip or knee arthroplasty, age $\geq$18 years, considered low risk for VTE, and no contraindications to sequential compression device usage [15]. Exclusion criteria included history of DVT or pulmonary embolism (PE), history of peptic ulcer disease, allergy to aspirin, or patients currently on anticoagulation for pre-existing disease.

Patients received aspirin (325 milligrams) once daily along with mobile sequential compression devices to be worn for 2 weeks postoperatively. During the course of their preoperative arthroplasty education session, patients and their family members were instructed on the proper use and wear of the ActiveCare + SFT portable compression device (Medical Compression Systems, Inc., West Hills, CA) by nursing staff. Before discharge from the hospital, this information was reinforced to the patient. Patients were also counseled on the importance of compliance with the sequential compression devices, and it was recommended that patients wear the compression devices at least 20 hours per day for optimal effectiveness at preventing a DVT. An instructional booklet was given to patients and their families detailing proper usage, wear, recommendations, and troubleshooting tips. At the conclusion of the education sessions, all patients signed a form indicating that they received the pumps and understood the recommended instructions. The compression device uses an internal sensor to apply intermittent sequential pressure to the leg in sync with changes in respiratory-related venous phasic flow which helps to optimize peak venous velocity to reduce the risk of clot formation. The disposable limb sleeves are secured with Velcro and connected with a plastic hose to the pump which can be carried with battery power and recharged as needed. This device provides a peak pressure of 50 mm Hg; the typical cycle is 8 seconds of compression, which is followed by 36-56 seconds of decompression. The device is able to measure compliance via an internal timer in the pump unit that records the amount of time that the device is properly functioning.

The number of hours that patients utilized the portable pneumatic compression pumps after discharge was prospectively recorded over the first 2 weeks postoperatively. At the first follow-up appointment (approximately 2 weeks after surgery), patients answered a questionnaire indicating factors that may contribute to usage such as age, gender, education, comfort, and difficulties with use. Compliance was defined as wearing the compression device for the recommended 20 hours per day based on prior reports and recommendations in the literature [13]. Patient demographics including age, gender, body mass index, THA or TKA, and operative side were recorded. Complications including infection, reoperation, and major or minor bleeding were recorded. Major bleeding was defined as bleeding requiring rehospitalization, prolonged hospitalization, or repeat surgery for drainage. Minor bleeding was defined as wound drainage or a drop in hemoglobin not requiring transfusion.

Patients were followed up for 90 days postoperatively to record any VTE events. VTE was defined as a diagnosis of a DVT or PE within 90 days of undergoing joint arthroplasty. DVT was defined as a symptomatic blood clot also confirmed by venous duplex imaging. PE was defined as a symptomatic blood clot confirmed by chest computed tomography (CT) scan. At our institution, patients are not routinely screened for DVT or PE unless they are symptomatic or clinical suspicion exists.

Continuous variables were reported using mean and standard deviation. Categorical variables were reported using ratios and percentages. Correlation analysis was used to evaluate the significance of associations between response variables, percentage use, and percentage compliance. Analysis of variance was used to analyze continuous variables. Statistical analysis was performed using JMP 11.0.0 (SAS Institute Inc., Cary, NC). A P-value of <0.05 was considered statistically significant.

Results

Over the study period, 115 patients (50 hips, 65 knees) met the inclusion criteria. Usage data were not collected on 4 patients because of failure to return the pumps. The average age of patients was 59.7 years (range 34-80 years); 47 patients (40.9%) were male. The average length of stay in the hospital after joint arthroplasty was 1.99 days (range 0-7 days). Overall, 102 patients (88.7%) completed the postoperative questionnaire at an average of

19.3 ± 12.3 days after surgery. Patients self-reported wearing the compression device an average of 15.9 ± 4.9 hours per day.

Postdischarge day one had the highest average usage at 13.2 hours per day (66.0%, range 0%-100%), but this number fell to 4.8 hours per day (24.0%, range 0%-100%) by postdischarge day 14. The average hours per day worn declined over the first 2 weeks after discharge ($R^2 = 0.9869$; Fig. 1). Patient compliance (>20 hours use/day) was highest on postdischarge day one at 40 patients (34.7%). By postdischarge day 7, only 21 patients (18.2%) wore the device for the recommended >20 hours per day. Patient compliance declined over the first 2 weeks after discharge, and only 17 patients (14.8%) wore the compression devices >20 hours per day by postdischarge day 14 ($R^2 = 0.8761$; Fig. 2).

There was no difference in compliance between hip and knee arthroplasty ($P = .316$). No significant association between usage and compliance was noted based on age ($P = .77$), education ($P = .84$), or overall satisfaction (0.21) with the pumps (Table 1). The heat created by the pump sleeves was negatively correlated ($r = -0.27$) and significantly associated with patient compliance ($P = .009$). Difficulty with pump use was also negatively correlated ($r = -0.23$) and significantly associated with patient compliance ($P = .027$). There was no significant association between compliance and pump noise ($P = .68$), pain ($P = .90$), or tightness ($P = .74$). Pump compliance was not significantly associated with sweating ($P = .09$), numbness ($P = .38$), skin irritation ($P = .28$), falls ($P = .39$), or insomnia ($P = .71$) related to pump usage.

In the 90-day follow-up period, one patient experienced a recorded DVT confirmed by venous duplex imaging. One patient also suffered a nonfatal PE confirmed by chest CT scan. One patient stopped wearing the pumps because of blister formation. Zero patients (0%) experienced infection or reoperation during the study period. No patients (0%) experienced any major or minor bleeding events during the study period.

Discussion

The results of this study demonstrated poor outpatient compliance in a rural population with the use of portable pneumatic compression devices after total joint arthroplasty. Compliance, defined as wearing the compression devices at least 20 hours per day, was highest on postdischarge day one at 35% but fell below 20% by postdischarge day 7. In our study, both compliance and the average number of hours per day the compression devices were worn steadily declined over the first 2 weeks postoperatively. These compliance numbers are lower than previously published studies reporting compliance with mobile compression devices after total joint arthroplasty ranging from 73% to 90% [13,16-18]. However, most of these studies only monitored compliance during hospitalization after total joint arthroplasty and did not continue to monitor compliance after discharge.

Colwell Jr. et al. conducted a prospective, randomized VTE prevention trial to compare the safety and efficacy of mobile compression devices to LMWH after total hip arthroplasty and noted 83% compliance with a similar pneumatic compression device used in our study [13]. Compliance was defined as wearing the compression device for at least 20 hours per day, similar to our study. In that study, patients wore the compression device for a mean of 20.1 hours per day for 11 days after hip arthroplasty, which was much different from our results in a rural population. Westrich et al. examined compliance of a pneumatic foot compression device after unilateral total knee arthroplasty in 100 patients and noted an overall compliance rate of 90.1%, but compliance was only monitored during hospitalization [18]. Froimson et al. compared a portable sequential compression device with a nonmobile device after joint arthroplasty in 1354 patients and found significantly higher compliance with the portable compression device (83% vs 49%), but, once again, compliance was only monitored during an inpatient setting [17]. Robertson et al. investigated compliance and satisfaction of 2 mechanical devices for DVT prophylaxis after total joint arthroplasty in 224 patients and noted compliance rates of 73% for thigh-high compression devices compared with 77% for foot pump prophylaxis [16]. Although

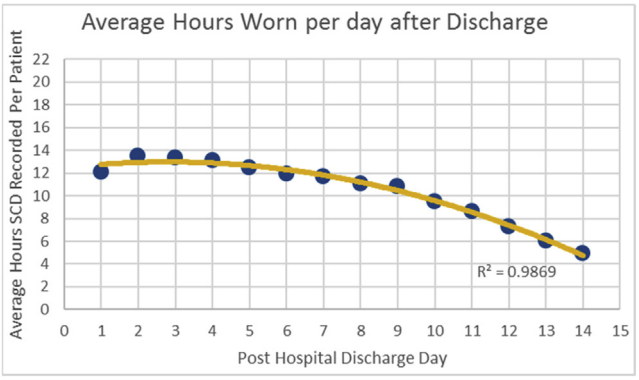

Figure 1. Shows the average hours per day that patients wore the portable serial compression devices up to postdischarge day 14. As demonstrated in the chart, the hours per day worn decreased linearly from the early postoperative period to postdischarge day 14 ($R^2 = 0.9869$).

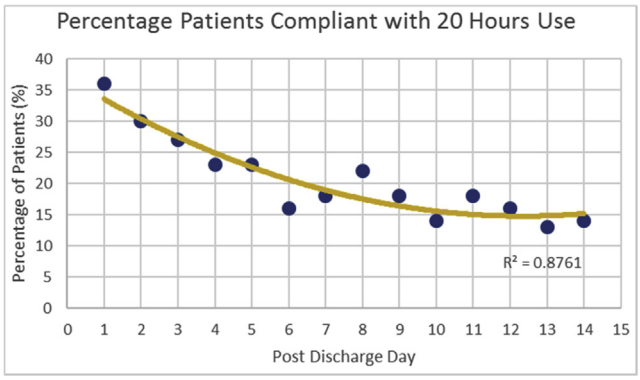

Figure 2. Percentage of patients compliant with the portable serial compression devices steadily decreased over the first 2 weeks after discharge ($R^2 = 0.8761$).

Table 1
Correlation between usage variables and compliance with portable compression devices.

Variable	Correlation with and compliance	*P*-value
Education	0.022	.84
Age	0.0297	.77
Overall experience (rate 1-5)	0.13	.21
Were the pumps:		
Noisy	0.0426	.68
Painful	0.013	.9
Hot	−0.27	.009[a]
Difficult to put on/off	−0.23	.027[a]
Tight	0.03	.74
Did the pumps cause:		
Sweating	0.17	.09
Numbness	−0.09	.38
Skin irritation	−0.112	.28
Trips or falls	0.09	.39
Insomnia	−0.04	.71

[a] Significant difference $P < .05$.

compliance for mobile compression devices after total joint arthroplasty ranged from 73% to 90% in these studies, only one of the studies monitored compliance entirely in an outpatient setting.

Although not powered for such analysis, even with poor compliance, we observed a low incidence of VTE events. In our study, one patient (0.8%) experienced a symptomatic DVT confirmed with venous duplex imaging. One patient (0.8%) also experienced a nonfatal PE confirmed by CT scan. The incidence of DVT and PE in our study is similar to that reported in the literature. A study by Colwell Jr. et al. that compared a similar mobile compression device to LMWH after total hip arthroplasty in 414 patients reported distal DVT rates of 3% and proximal DVT rates of 2% in the mobile compression group, which was similar to the DVT rates in the LMWH group (3% distal DVT rates, 1% proximal DVT rates). The rates of nonfatal PE were 1% in both the compression and LMWH groups [13]. A large multicenter registry of 3060 patients by Colwell Jr. et al. evaluated the efficacy of a similar mobile compression device with or without aspirin compared with standard pharmacological protocols in patients after total hip or knee arthroplasty. Symptomatic VTE rates in patients using the mobile compression device (0.92%) were noninferior (at a margin of 1%) to rates reported for various pharmacological prophylaxis previously reported in the literature, including warfarin, enoxaparin, dabigatran, and rivaroxaban [19]. Multiple other studies have demonstrated the efficacy and success of mobile compression devices in preventing VTE in patients after total joint arthroplasty [17,20-25]. Despite the success of pneumatic compression devices in the prevention of VTE events, patient compliance and proper use of the devices remains a significant concern.

One major advantage of mobile compression devices compared with chemoprophylaxis is decreased rates of bleeding, drainage, and wound-healing problems after total joint arthroplasty. In our study, no patients (0%) experienced any major or minor bleeding events in the 3 months after hip or knee arthroplasty. The previously mentioned study by Colwell Jr. et al. noted similar results. In over 400 patients, they found a significant decrease in major bleeding events in the mobile compression group (0%) compared with the LMWH group (6%) after total hip arthroplasty ($P = .0004$). In that study, 11 patients in the LMWH group experienced major bleeding, which consisted of anemia requiring prolonged hospitalization (5 patients), anemia with hypotension (2 patients), hematoma requiring prolonged hospitalization or rehospitalization (2 patients), urinary bleeding (1 patient), and increased wound drainage requiring rehospitalization (1 patient) [13]. The risk of major bleeding events with chemoprophylaxis like LMWH is a major concern. For patients at increased bleeding risk, the ACCP recommends an intermittent IPCD or no prophylaxis after major orthopaedic surgery (grade 2C) [1]. The American Academy of Orthopaedic Surgeons offers a consensus recommendation that patients with a history of a known bleeding risk should receive mechanical prophylaxis only [4]. Therefore, it is important to identify patients at increased bleeding risk and continue to evaluate for effective alternative means of DVT prophylaxis like mobile compression devices.

In our study, poor compliance was significantly associated with the heat of the pumps ($P = .009$) and difficulty with pump use ($P = .027$). Compliance with the mobile compression devices was not related to overall satisfaction with the pumps ($P = .21$), insomnia ($P = .71$), pump noise ($P = .68$), or skin irritation ($P = .27$). Other studies have found similar reasons for noncompliance with mobile compression devices after total joint arthroplasty. Colwell Jr. et al. identified noise intolerance, skin rash, and warmth of the device as reasons for noncompliance with mobile compression devices after hip arthroplasty [13]. In a study by Robertson et al., the most common reasons for noncompliance with sequential compression devices were related to heat/sweating and overall discomfort [16]. Another commonly reported complaint with compression devices is sleep disturbance, although this was not an issue with patients in our study [26]. The general consensus among these studies is that poor compliance with mobile compression devices is most closely related to pump heat, difficulty with use, and overall discomfort.

Our study must be interpreted with knowledge of the limitations. The lack of blinding and randomization in this study is a limitation, although the prospective nature of data collection is notable. The rates of DVT and PE are also likely underrepresented in our study because only patients who were symptomatic received a duplex ultrasound or CT scan; thus patients with an asymptomatic DVT or PE were not captured. The study is also likely underpowered to detect all factors leading to poor compliance.

Conclusions

In conclusion, despite the efficacy and success of portable pneumatic compression devices in preventing VTE after total joint arthroplasty, patient compliance and proper utilization remain significant concerns especially in a rural outpatient setting. It is important to continue to evaluate the need and indication for these devices in the prevention of VTE, particularly in patients with a contraindication to chemoprophylaxis. The adjustment of recommended hours of usage in the outpatient setting should be evaluated to improve defined compliance without affecting rates of VTE. Future randomized controlled trials should monitor outpatient cost, compliance, and efficacy of portable compression devices compared with standard chemoprophylaxis after total joint arthroplasty.

Acknowledgments

This project was aided by a grant from the Orthopaedic Research and Education Foundation (OREF), with funding provided by The Aircast Foundation. Research reported in this publication was supported by the National Institute of General Medical Sciences of the National Institutes of Health under Award Number 5U54GM104942-04. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health.

Conflict of interests: M. Dietz is a Heraeus Medical consultant/speaker; B. Frye is a Biomet consultant/speaker; B. Lindsey is a Biomet consultant/speaker and receives research support from Global Life Technologies and Stryker; the other authors declare no potential conflicts of interest.

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