Venous Thromboembolic Disease Reduction With a Portable Pneumatic Compression Device

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Abstract: This study compares a miniaturized, portable, sequential, pneumatic compression device (ActiveCare continuous enhanced circulation therapy [CECT] system) (Medical Compression Systems Ltd, Or Aqiva, Israel), with a nonmobile, nonsequential device on the ability to prevent postoperative deep venous thrombosis (DVT) after joint arthroplasty. All patients were treated with low-molecular-weight heparin, application of 1 of the 2 devices perioperatively, and routine duplex screening. The CECT system had better compliance (83% of the time vs 49%), lower rates of DVT (1.3% compared with 3.6%), reduction in clinically important pulmonary embolism (0 compared to 0.66%), and shorter length of hospital stay (4.2 vs. 5.0 days). The portable CECT system proved significantly more effective than the standard intermittent pneumatic compression when used in conjunction with low-molecular-weight heparin for DVT prevention in high-risk orthopedic patients.
Key words: venous thromboembolic disease, THA, prevention.

Venous thromboembolic disease remains a major source of morbidity after joint arthroplasty. Despite extensive research there is a lack of consensus as to what constitutes the most appropriate strategy for prevention of this complication. The ultimate goal of any prophylactic regimen in joint arthroplasty surgery is to prevent pulmonary embolism (PE), deep venous thrombosis (DVT), and postphlebitic syndrome. The American College of Chest Physicians publishes guidelines that recommend the routine use of pharmacologic agents for thromboembolism prevention following total joint arthroplasty [1,2].

Although chemical prophylaxis with either warfarin or low-molecular-weight heparin effectively reduces the incidence of DVT after total joint arthroplasties, many orthopedic surgeons utilize intermittent pneumatic compression (IPC) devices in addition to drug treatment [3]. Intermittent pneumatic compression devices have been shown to increase the velocity of venous blood flow in the lower extremities. Increased flow velocity overcomes venous stasis, a primary DVT formation mechanism [4-11].

The major disadvantage of the currently available IPC devices is their size, weight, and requirement for continuous attachment to an external power source. These features contribute to a record of poor compliance, which limits the efficacy of such devices [12]. Moreover, it has been found that education of nursing and other staff did not significantly improve compliance [12-14], suggesting that inherent problems related to devices and sleeve design are probably the main impediment to acceptable rates of compliance. In addition, there is little data to support the clinical utility of the different hemodynamic profiles of IPCs in current use.

A recently developed device (ActiveCare continuous enhanced circulation therapy [CECT] system)

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(Medical Compression Systems Ltd, Or Aqiva, Israel) consisting of a miniature, battery-operated and, therefore, portable pneumatic compression system offers a more ergonomically appealing method of delivering intermittent venous compression. Its ease of use is postulated to allow for the continuous delivery of therapy to the patients' from the time of anesthetic induction to hospital discharge, simplifying treatment, reducing nursing involvement, and increasing patients' compliance [15,16]. Although small in size, this device provides effective, sequential venous compression, with a higher peak venous velocity measured at the common femoral vein compared with other systems [17].

The standard protocol at our institution employs a multimodal approach to thromboembolic prophylaxis that includes early mobilization, a pharmacologic agent, and a mechanical IPC device. The hypothesis of this performance study was that the efficacy of the mechanical prophylaxis could be enhanced through the use of the portable CECT system by allowing for improved compliance in the clinical setting.

Materials and Methods

Study Design

This was a retrospective review of a nonrandomized, comparative performance study that was conducted at a single medical center. The study was designed to report on the results of a product conversion that took place at our medical center. As such, it included the entire patient population under clinical care during the time frames, and reflected the daily decision-making algorithms of the medical center. It was designed initially as a product trial and at the completion of the product trial the data was retrospectively reviewed and the study approved by the institutional review board. The investigation had as its specific purpose to evaluate the relative contribution of the 2 devices to DVT prophylaxis and, so, was designed as a comparative study of these 2 devices, with no other change in clinical care pathways. The devices were evaluated in sequence. Each of the evaluated devices was used exclusively during its specific evaluation period.

The end points evaluated included: rate of venous thromboembolic (VTE) events, both PE and DVT; hospital length of stay (LOS); compliance as measured by the amount the device was worn; and patient, nursing, and physician acceptance of the conversion.

Devices

Two devices were compared: the ActiveCare CECT system and the Flowtron IPC device, historically used in the hospital.

The Flowtron Excel pump (Huntleigh Healthcare Ltd, Luton, UK) is a traditional calf-length, single-bladder IPC device. It is attached to the bed of the patient and must remain plugged into the wall. When a patient leaves the bed for ambulation, bathroom use, or transport, the device is routinely disconnected.

The ActiveCare CECT system is a miniaturized, battery-powered, sequential device. It weighs 1.6 lb and can function on battery power for 6 hours. As such, it can be worn by the patient during ambulation or transportation so that therapy can

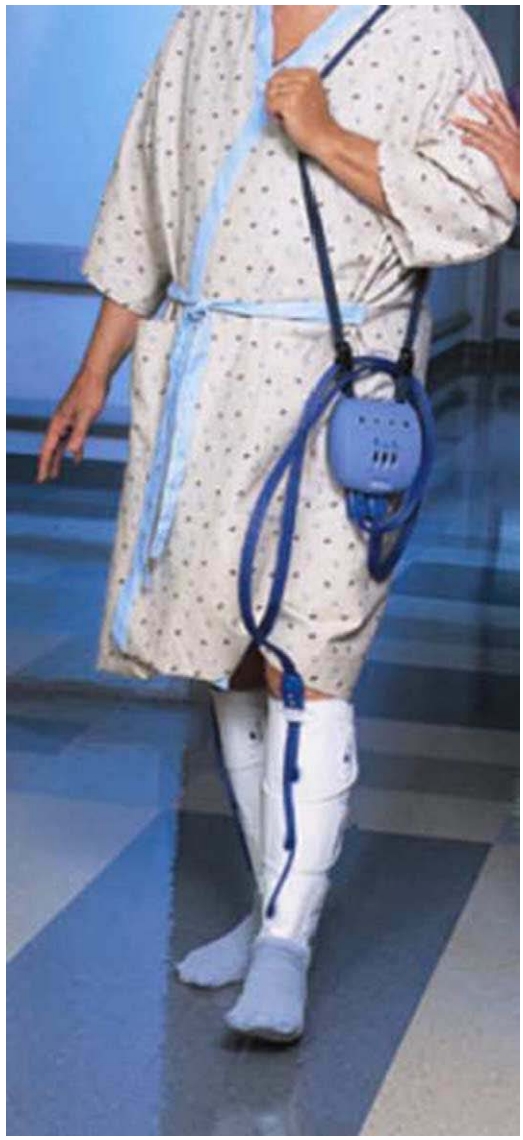

Fig. 1. Continuous enhanced circulation therapy device as worn by patient.

be delivered continuously without interruptions throughout the entire recovery period (Fig. 1). The device recharges when attached to an external power source with an AC adapter. Despite its miniaturization, it has a proven hemodynamic profile that produces clinically sufficient peak venous velocity in the common femoral vein. Calf sleeves were used during the study in both groups.

Protocol

All patients who were scheduled for elective primary or revision hip or knee replacement surgery received a pneumatic compression device in the preoperative area immediately before surgery. This device is used on the contralateral limb during surgery and then on both lower extremities after surgery. Each device remained with the patient for the duration of hospital stay or up to the diagnosis of VTE. Enoxaparin was added, starting 12 to 24 hours postoperatively at a dose of 30 mg subcutaneously twice daily for knees or 40 mg subcutaneously once daily for hips, as per the routine protocol and at the discretion of the clinical team. Nursing and physician staffs were in-serviced before the initiation of the new device trial. They were instructed to use the devices whenever possible according to protocols already in use. The CECT device was used on a group of 250 consecutive patients, and the outcome measures for this group were compared to those of a similar group of patients who had received the Flowtron device during the immediately preceding time interval. There were no other protocol changes in the well established clinical care pathways in use during the study period. Only adult subjects (18-90 years old) were included in the analysis.

Primary Outcome

The primary outcome measure was the prevalence of VTE complications. Patients were clinically evaluated twice daily, and routine screening duplex ultrasonography was performed on all patients on the second or third postoperative days, depending on scheduling availability. The criteria for a positive venous study included lack of vein compressibility or visualization of thrombus. Patients with clinically suspected PE were evaluated by radiographic studies including ventilation/perfusion lung scan or spiral computed tomography. Only objectively confirmed pathologies were recorded. All thrombi detected were treated with full dose heparin or enoxaparin and warfarin sodium until an international normalized ratio value of between 2 and 3 was reached. Then, warfarin alone was administered for a period of 6 months.

Secondary Outcomes

The incidence of other clinically relevant adverse events and hospital LOS were recorded in both groups.

In order to further evaluate the effect of the unique properties of the new CECT system on patients' compliance, built-in counters were used for monitoring the amount of time the ActiveCare device was actually in use. As no counter exists for the Flowtron unit, no direct comparison was possible. However, nurses were asked to report compliance rates after each shift. These were recorded to help in assessing compliance with this device. Total compliance was quantified as the ratio of the total number of minutes each device was used divided by the total number of minutes the subject was enrolled (expressed as percentile).

At the completion of hospitalization the treating physician, nursing staff, and the patient were asked to complete a short 1-page form addressing their satisfaction with the new device.

Data Analysis

All data were expressed as mean ± SD. Efficacy analyses were performed on all patients completing the study and who had a technically interpretable duplex scan. Univariate analysis was used to compare the basic characteristics and outcomes between the two groups. The χ^2 test and the independent t test were conducted for categorical and numerical variables respectively. Comparison in small subgroups was performed by Fisher exact test and by Mann-Whitney U test for categorical and numerical variables, respectively. The study primary outcome, incidence of DVT, was assessed using 95% confidence interval with normal approximation to binomial distribution. A 2-tailed P value of less than .05 was taken to be significant.

Results

Study Subjects

During a 15-month interval, 1810 consecutive joint arthroplasty patients were available for review. This period included the 12 months before the conversion from Flowtron to the CECT device and the 3 months of CECT use. All patients in this group survived surgery, and there were no deaths during 30 days of follow-up. One thousand five hundred sixty patients, who were operated upon during the first 12 months of the study, received the Flowtron device for DVT prophylaxis;1354 remained in the study at time of analysis. All patients followed our

DVT prophylaxis standard protocol, which is based upon a combination of enoxaparin and IPCs. During the last 3 months of the study, the standard stationary IPC system was replaced by the CECT system. Two hundred fifty patients were enrolled in the CECT arm of the study. At time of analysis, 223 remained in the study. The approximate 10% exclusion rate in both groups was secondary to patients being included in the sequence but whose surgery was a procedure other than either a primary or revision arthroplasty. Patients treated for tumor, fracture, or resection arthroplasty were excluded from analysis.

Baseline characteristics including age, gender, type of arthroplasty, and their comormidities were comparable in the two groups (Table 1). There were no statistically significant differences between the 2 treatment groups with regard to their DVT risk scores and their safety profiles.

Thromboembolism

Deep venous thrombosis was identified by routine duplex scans in 49 of 1354 patients in the standard IPC group (3.6%) compared to 3 of 223 in the CECT group (1.3%). Clinically important PE was objectively confirmed in 9 patients, all of them in the IPC group (0.66%). The cumulative VTE rate reached 4.3% when the standard IPC device was used and was reduced to 1.3% in the CECT system: a relative risk reduction of 70%. The differences between the groups are statistically significant for cumulative VTE rates ($P < .05$). The statistical power behind these study results is 95%.

Hospitalization

The average hospital LOS in the 61 patients who did develop VTE was found to be 10 ± 6 days compared to 5 ± 3 days in the patients who did not ($P < .0001$). Patients treated with the CECT system had an average hospital stay of 4.2 ± 3.2 days, compared to 5 ± 3.7 days in the patients treated with the IPC. The shorter hospital stay in patients treated with CECT was likely most directly related to the lower rate of DVT in this patient group, as there was no difference in hospital stay when the patients with VTE were excluded.

Table 1. Type of procedure is representative of all participants in the study; comorbidities represent only those with a VTE during the study period

	Controls	Study
Age	64.3 + 13.7	66 + 11.5
TKA	548 (40%)	87 (39%)
THA	533 (39%)	85 (38%)
TKR	90 (6.6%)	17 (7.6%)
THR	183 (13.5%)	34 (15%)
Diabetes	4	2
Prior VTE	10	2
CAD	7	0
Malignancy	4	0

TKA indicates total knee arthroplasty; THA, total hip arthroplasty; TKR, total knee revision; THR, total hip revision; CAD, coronary artery disease.

Compliance

The average compliance was found to be 83% ± 15% (20 h/d; 95% CI, 19.2-20.6 hours) for the CECT system, compared to 49% only for the standard IPC device, as reported by the nursing staff. Two of the patients in the CECT group who developed DVT were found to have significantly lower compliance (<50%) than the average for the group.

Device Acceptance

Both patients and nursing staff nicely accepted the new CECT device, and it was considered by all of the involved physicians to provide improved patient care.

Discussion

This report describes the impact of a simple change in clinical practice, with substitution of one IPC device for another, on the incidence of postoperative VTE disease. We have demonstrated a significant improvement in the clinical outcomes of our patient population, with a marked reduction in the incidence of clinically or radiographically documented venous thromboembolic events. These findings would suggest that not all IPC devices function equivalently and that there is a demonstrable difference between the 2 devices under study. It is also apparent that, despite the controversy regarding the efficacy of IPCs in general, when they are properly utilized, their efficacy can be shown.

There are differences in both the hemodynamic profile and the expected compliance between the 2 devices, and it is likely that these differences account for the improved outcomes demonstrated in the study group. Although both devices were used with knee high sleeves, the type of compression each offers differs significantly. The Flowtron device is a single-bladder device and does not offer sequential compression or a high peak velocity. It does provide singular compression to the calf veins and a measurable increase in venous flow. In contrast, the CECT system provides a sequential compression from distal to proximal and a high peak venous velocity.

In fact, the peak venous velocity of this new device has been previously reported as superior to another marketed IPC, the sequential compression device response system, with improved flow in the common femoral vein [15,17]. Although there is likely a measurable clinical impact from the particular type of compression used, the optimal characteristics for pneumatic devices is not yet clear [18]. Lachievich et al [19] prospectively compared 2 methods of calf compression and found that the device which provided a larger increase in peak venous velocity produced a lower rate of thromboembolism. The incidence of thrombi, as detected by duplex, was 8.4% for the rapid inflation, asymmetrical compression device, compared with 16.8% for the sequential compression device, suggesting that the higher peak venous velocity is a main factor contributing to the efficacy of a mechanical system. In the current study, the specific differences in type and intensity of compression may account for a portion of the clinical differences detected.

The portable design of the CECT system, as compared with the Flowtron device, allows for greater ease of use and promotes compliance. In fact, in previous studies the system was found to increase compliance by nearly 50% when compared to other IPCs [15,16]. In our study, we were able to demonstrate a 75% increase in compliance with the CECT device. In addition, 2 of the patients in the CECT group who developed VTE events were found to have compliance of less than 50% with the device. Although we included these patients in the analysis, excluding patients with documented poor compliance, would have made the results even more striking. Moreover, when compliance with the CECT device was greater than 85%, no patient developed evidence of thromboembolic complications, a point now emphasized at our institution.

The importance of such increased compliance has been demonstrated in numerous previous studies, and the problem of consistent usage has been considered a major impediment to the routine use of IPC devices for prevention of DVT. Intermittent pneumatic compression devices have reported compliance of only 33% to 48% in real clinical setting [12-14]. Westrich and Sculco [20] were able to demonstrate a direct relationship between compliance and clinical efficacy of IPCs. In their study, total knee arthroplasty patients were given DVT prophylaxis consisting of either aspirin alone in the control group or aspirin with the addition of a foot pump in the treatment group. They found that, in the treatment group, patients who developed DVT used the foot pump for an average of only 13.4 h/d (56% of the time), whereas those who did not develop DVT used the foot pump for an average of 19.2 h/d (80% of the time), underscoring the key role of compliance in any prophylactic regimen. Clark-Pearson et al [21] reported a DVT rate of 9.1% in a group of gynecologic patients who were treated with IPC devices during surgery and the following 5 postoperative days. When treatment was reduced to include only the first 24 hours postoperatively, the DVT rate increased to 38.1%.

Early ambulation has been felt to be a useful adjunct in the prevention of VTE. Patients tethered to the bed by a fixed device IPC are prevented from ambulating until released from the device. This then places these 2 modalities at odds with each other. The patients in our series who received the CECT device were free to ambulate without awaiting such detachment and were thus more likely to have been more active. We were not able to quantify this factor and cannot comment on the impact that early ambulation may have played on the results in this study. It seems reasonable to assume that, by not placing IPC, therapy, and early ambulation into an either/or decision that the occurrence of each component of therapy will be more likely, thus favorably impacting outcomes.

The patients in our cohorts all received pharmacologic prophylaxis with enoxaparin, an anticoagulant proven to be effective in preventing VTE. Although the study effect may have been more apparent without this additional therapy, it was not felt to be safe or prudent to eliminate this element of care for this group of patients. In fact, our trial and review were designed to specifically evaluate the marginal impact of the change in IPC device in the normal clinical setting. It was felt that other institutions considering various devices would go about it in a similar way and that the information presented here would inform their clinical decision as they contemplated such a change. Nonetheless, the very low rate in the highly compliant patient using CECT has led us to pursue an evaluation into the relative contributions of the device and the pharmacologic agents. This has resulted in the design of a prospective randomized trial comparing the efficacy of the device alone vs the efficacy of enoxaparin as a single prophylactic agent.

The most important factors in selecting a mechanical prophylactic system are patient compliance, appropriateness of the site of compression, and effectiveness of the hemodynamic profile. The real challenge is achieving the optimal balance between these sometimes contradicting factors.

The current study shows that the CECT system combined with enoxaparin is significantly more

effective than IPC plus enoxaparin as a prophylactic protocol for DVT prevention in high-risk orthopedic patients. Furthermore, the new protocol has the potential to be significantly more cost-effective than the standard protocol.

The DVT rate in the CECT group was 3.4-fold lower than that of the IPC group, and no PE was observed in the patients treated with this protocol. This reduction in VTE events has high statistical significance. The average hospital LOS in the CECT group of patients was 24 hours shorter than in the IPC group, probably reflecting the major reduction in VTE events. Patients who experience a thromboembolic event after surgery have a significant increase in hospital LOS when compared to patients who do not experience this complication. Based on the data presented here, we estimate that the use of the CECT system has the potential to save 35 DVT events and 6 PE events for every 1000 operated patients. On top of important reduction in short- and long-term patients' morbidity, this reduction can be translated into a major cost savings [22].

We recognize that one shortcoming of this study is its retrospective design. A prospective randomized trial planned as a follow-up carries the shortcoming of industry sponsorship, whereas the present study, as part of our quality assurance and product evaluation efforts, was fully funded through hospital operations. Although the two treatment groups differed in the number of patients studied, this fact did not impact the statistical value of the data. Including more patients in the analysis may have increased the power of this study, and this analysis will continue with further use of the device. In addition, because the Flowtron device does not have a built-in monitor of compliance, we recognize that comparisons of compliance are inexact.

Summary and Conclusions

This study allowed us to objectively evaluate the clinical importance of a new miniature battery operated pneumatic compression device and compare it to the standard IPC currently in use. We found the evidence from this study convincing and the technological features of this novel device sufficient to support the selection of the CECT device for exclusive use at our institution. The CECT device used over our routine chemical agents significantly reduced the VTE events compared to the previous regimen of a fixed IPC device used with the same chemical agents.

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