A miniature and mobile intermittent pneumatic compression device for the prevention of deep-vein thrombosis after joint replacement

Peleg Ben-Galim, Ely L Steinberg, Yishai Rosenblatt, Nata Parnes, Aharon Menahem and Ron Arbel

Department of Orthopedic Surgery "B", Tel-Aviv Sourasky Medical Center, Sackler Faculty of Medicine, Tel-Aviv University, Tel-Aviv, Israel
Correspondence PB-G: pelegbg@walla.co.il
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ABSTRACT **The WizAir-DVT is a miniature, lightweight (690 g), battery-operated and mobile intermittent pneumatic compression device (ICD), which enables continuous intraoperative use and immediate patient mobilization postoperatively. We compared its efficacy with a commonly used ICD, the Kendall SCD. Peak femoral vein flow velocity was measured in 20 apparently healthy volunteers at rest and with each device: we found no significant differences between them. A second prospective, randomized, clinical trial was used to compare the efficiency of the device in preventing deep venous thrombosis (DVT) after joint replacement in 50 patients (n = 25/group). None developed DVT. Doppler ultrasonography revealed no significant differences. The WizAir-DVT antithrombotic compression device is as safe and effective as the Kendall SCD.**

Mechanical prophylaxis of deep venous thrombosis (DVT), after joint replacement, includes different types of elastic stockings and intermittent pneumatic calf compression devices that have almost no side effects. Intermittent pneumatic compression devices (ICDs) have been shown to be as effective in prevention of DVT and pulmonary embolism (PE) as coumadin, heparin and low molecular weight heparin (LMWH) and are free of the side effects of excessive bleeding (Santori et al. 1994, Westrich and Sculco 1996, Salvati et al. 2000, Ginzburg et al. 2003). In fact, ICDs have almost no side effects and are very well tolerated by patients. They substantially increase femoral venous blood flow and venous emptying and are safely employed either during or after surgery (Comerota and Chouhan 1997, Dai et al. 1999, Delis et al. 2000). Moreover, while assuring high venous blood flow and emptying of the lower limbs, ICDs also exert a systemic endogenic fibrinolytic effect (Comerotta and Chouhan 1997, Salvati et al. 2000).

The disadvantages associated with the use of currently available ICDs include noncompliance due to limited mobility of the patients who are confined to this static device, thus postponing hospital discharge and rehabilitation (Camerota and Chouhan 1997, Cornwell et al. 2002). In contrast, the WizAir DVT device (Medical Compression Systems DBN-Ltd, Or Aqiva, Israel) is easily portable. It is battery-operated and weighs only 690 g (including rechargeable battery). Its sleeves can be sterilized and, unlike the large and bulky ICDs, it can be used intraoperatively without compromising the field of surgery and then offer easier postoperative patient ambulation with no delay in rehabilitation. We compared the effect of the lightweight WizAir DVT ICD device to the more common Kendall SCD device (Kendall, Mansfield, MA, USA) which we have used routinely in our department.

Patients and methods

During the years 1999–2000, we conducted two trials in order to evaluate the efficiency of the WizAir DVT device in comparison to the Kendall SCD device.

In the preliminary trial, we evaluated the peak femoral vein blood flow velocity of 20 apparently healthy volunteers three times, once during rest and once with each device. The femoral vein was assessed using a duplex ultrasound (Toshiba, Corevision) and a 7.5 MHz linear vascular probe. Before any measurement was taken, the volunteers rested for 10 min in order to allow them to reach their basic pulse rate. Femoral vein flow was evaluated with the subjects lying immobile in the supine position. Resting peak flow velocity was recorded, after which either the WizAir DVT device or the Kendal SCD device was randomly chosen for testing peak femoral flow velocity first and then swapped for the other one using the same test protocol. Results were determined by comparing peak pre-compression curves with the peak curves using the compression devices. Since baseline velocities varied substantially, peak curve velocities were calculated individually for each volunteer. Results were calculated as per cent change in peak curve velocity (improvement in blood flow), during the use of each ICD as compared to the resting base values.

The clinical trial was prospective and randomized (closed envelopes were randomly drawn for each patient). 50 patients undergoing elective joint replacement surgery (total hip or total knee) were randomly divided into two subgroups, one treated with the WizAir DVT and the other with the Kendall SCD device.

Inclusion criteria were age >60 years and surgery consisting of primary elective total hip replacement (THR), or total knee replacement (TKR). Patients who had previous surgery in the same lower limb or were currently being treated with anticoagulant medications (e.g. Coumadin) were excluded, as were patients with any condition that might affect coagulation (e.g. varicose veins, coagulopathy, thrombocyte disorders, cancer or previous DVT). Anti-aggregant medications (e.g. aspirin) were discontinued at least 14 days before surgery. The study was approved by our institutional ethics committee. All patients received a thorough explanation of the nature of this study and signed an informed consent statement before they were randomly assigned to one of the two study groups.

Patients in the Kendall SCD group received the routine treatment in our department, which included heparin (5000 units BID for 6 days following surgery) and a pneumatic compression device applied to both legs using the Kendall SCD immediately following surgery. The device was operated continuously with a pressure of 35–55 mmHg for 5 consecutive days. An ICD sleeve removal that was required for any reason (e.g. hygiene-showering) was accomplished in as short a time as possible and never lasted more than 20 min.

Patients in The WizAir DVT group underwent an identical treatment to that of the Kendall SCD group. Both devices employed knee-length calf cuffs with three pneumatic cells. The WizAir DVT features low-volume compartments calf-sleeve design, employing sequential compression pressures of 50 mmHg (± 10) with a duration of 6 sec every minute.

On the sixth postoperative day, each patient underwent Doppler ultrasonography to examine the deep and superficial veins of the lower limbs (i.e. the iliac, femoral and popliteal veins). A senior radiology specialist in ultrasound radiology performed all the examinations.

Statistics

Statistical analysis for the preliminary (volunteer) trial was performed using the paired t-test (parametric) and the Wilcoxon test (nonparametric). The results comparing the two clinical groups were analyzed statistically using the binomial test confidence interval. The hypothesis testing significance was calculated for the whole group of 50 patients, with the power of the test being greater than 0.70.

Results

The preliminary trial showed a mean increase in femoral vein peak flow of 66% during the application of the WizAir DVT, and this increase was 65% with the Kendall SCD device ($p = 0.9$). Thus, both compression devices increased femoral vein

peak flow velocity substantially and to the same extent.

Patients in the WizAir DVT and Kendall groups were of similar age and sex distribution. There were no differences between the groups with respect to blood loss or blood replacement. Anesthesia and surgery were similar for all patients, and were performed by the same team of surgeons in the same operating room using the same techniques and surgical protocols.

All patients completed the clinical trial and no adverse events or non-compliance was reported. Clinically, there were no reports of DVT or PE. DVT was not detected in any of the 50 patients and there were no significant differences in the results of the Doppler examinations.

Subcutaneous heparin treatment (5000 i.u. BID) maximally lowers the incidence of DVT to 25% (Salvati 2000). Thus, the absence of any case of DVT among the 50 study patients is significantly lower than that expected for treatment with heparin alone ($p < 0.001$). Moreover, the 95% confidence interval for the proportion of DVT, based on the binomial distribution, is 0–0.1. Thus, the significant additional DVT prophylaxis observed in both of our study groups is attributable to ICD treatment.

The WizAir DVT device is portable, hanging from the shoulder strap like a lady's purse, thus permitting immediate postoperative patient ambulation.

Discussion

Numerous studies have shown that ICDs are as effective as pharmacological treatment in the prevention of DVT and PE after joint replacement surgery (Santori et al. 1994, Westrich and Sculco 1996, Salvati et al. 2000, Ginzburg et al. 2003). Thus, the side effects associated with a specific treatment modality become pivotal issues in determining the more preferable among the various options. Bleeding has been reported to occur in 2–10% of patients treated with pharmacological prophylactics postoperatively. This may cause morbidity and, rarely, even mortality (Planes et al. 1996, Salvati et al. 2000). It has been well established that initiation of DVT formation usually occurs during the operation itself (Santori et al. 1994, Meissner and Huszcza 1996, Salvati et al. 2000). It is in this crucial period that ICDs could offer their most prominent prophylactic protection, insofar as pharmacological prophylaxis is seldom used before the first postoperative day for fear of profuse bleeding. Other advantages of ICDs over pharmacological prophylaxis include their postoperative reduction of pain and skin edema and the fact that laboratory monitoring is not required (Dai et al. 1999). ICDs exert a systemic endogenic fibrinolytic effect while they mechanically enhance femoral vein blood flow (Comerota and Chouhan 1997, Inada et al. 1998, Dai et al. 1999).

The weight and bulkiness of currently available ICDs makes their intraoperative use cumbersome, and their postoperative use confines the patient to the static device and postpones mobilization and rehabilitation for the duration of treatment. Furthermore, this confinement has been reported to be associated with patient non-compliance (Cornwell et al. 2002). The WizAir DVT was developed in order to overcome these problems. Patients in the study group walked about with the device hanging by a strap from the shoulder (like a lady's handbag)

as early as the second postoperative day (Figure). This portability permits early ambulation without interruption of compression therapy.

Among apparently healthy volunteers, measurement of peak flow velocity in the femoral vein showed a similar, significant enhancement using either the WizAir DVT or the Kendall SCD.

In the clinical trial which involved two similar groups of patients undergoing either THR or TKR, there was no significant difference between the two devices in preventing DVT. Without prophylaxis, these patients would be expected to have a 50-70% incidence of DVT (Planes et al. 1996, Salvati et al. 2000). The absence of any case of DVT among the 50 study patients demonstrates the effectiveness of ICDs in TEE prophylaxis. Furthermore, this allows us to conclude that the WizAir DVT device is as effective in the prevention of DVT as other commercially available devices, such as the Kendall SCD. Finally, the continuous use of this ICD device at home can contribute to earlier hospital discharge, a feature that should lead to significant gains in cost-effectiveness.

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Comerota A J, Chouhan V. The fibrinolytic effects of intermittent pneumatic compression. Ann Surg 1997; 226: 306-14.

Cornwell E E 3rd, Chang D, Velmahos G, Jindal A, Baker D, Philips J, Bonar J, Campbell K. Compliance with sequential compression device prophylaxis in at-risk trauma patients: a prospective analysis . Am Surg 2002; 68 (5): 470-3.

Dai G, Gertler J P, Kamm R D. The effects of external compression on venous blood flow and tissue deformation in the lower leg. J Biomech Eng 1999; 121: 557-65.

Delis K T, Azizi Z A, Nicolaidis A N. Optimum intermittent pneumatic compression stimulus for lower-limb venous emptying. Eur J Vasc Endovasc Surg 2000; 19: 261-9.

Ginzburg E, Cohn S M, Lopez J, Jackowski J, Brown M, Hameed S M. Randomized clinical trial of intermittent pneumatic compression and low molecular weight heparin in trauma. Br J Surg. 2003; 90 (11): 1338-44.

Inada K, Koike S, Shirai N, Matsumoto K, Hirose M. Effects of intermittent pneumatic leg compression for prevention of postoperative deep venous thrombosis with special reference to fibrinolytic activity. Am J Surg 1988; 155: 602-5.

Meissner A J, Huszcza S. Surgical strategy for management of deep venous thrombosis of the lower extremities. World J Surg 1996; 20: 1149-55.

Planes A, Vochelle N, Darmon J-Y. Risk of DVT after hospital discharge in patients having undergone T.H.R: double blind randomized comparison of enoxaparin vs. placebo. Lancet 1996; 348: 224-8.

Salvati E A, Pellegrini V D, Sharrock H N E, Lotke P A, Murray D W, Potter H, Westrich G H. Recent advances in venous thromboembolic prophylaxis during and after total hip replacement. J Bone Joint Surg (Am) 2000; 82: 252-67.

Santori F S, Vitullo A, Stopponi M, Santori N, Ghera S. Prophylaxis against deep-vein thrombosis in total hip replacement – comparison of heparin and foot impulse pump. J Bone Joint Surg (Br) 1994; 76: 579-83.

Westrich G H, Sculco T P. Prophylaxis against deep venous thrombosis after total knee arthroplasty. Pneumatic plantar compression and aspirin compared with aspirin alone. J Bone Joint Surg (Am) 1996; 78 (6): 826-34.