Deep Vein Thrombosis Prevention in Joint Arthroplasties

Continuous Enhanced Circulation Therapy vs Low Molecular Weight Heparin

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Abstract: Deep vein thrombosis prevention efficacy using a new, miniature, mobile, battery-operated pneumatic system (continuous enhanced circulation therapy [CECT] system) combined with low-dose aspirin was compared to enoxaparin. One hundred twenty-one patients who underwent total hip or knee arthroplasty were prospectively randomized into 2 groups. The study group was treated by the CECT system starting immediately after the induction of anesthesia. Postoperatively, a daily 100-mg aspirin tablet was added. The control group received 40 mg of enoxaparin per day. Bilateral venography was performed at the fifth to eight postoperative day. In the CECT group, as compared to the enoxaparin group, there was a significantly lower overall rate of DVT and proximal DVT. Safety profiles were similar in both groups. The combination of the CECT device with low-dose aspirin is more effective than enoxaparin in preventing deep-vein thrombosis after lower limb arthroplasties. **Key words:** deep vein thrombosis, low molecular weight heparin, arthroplasty, total knee arthroplasty, total hip arthroplasty, aspirin, continuous enhanced circulation therapy, intermittent pneumatic compression, compliance.

The ultimate goal of any prophylactic regimen in joint arthroplasty surgery is to prevent the formation of DVT and postphlebitic syndrome, as well as the occurrence of pulmonary emboli. Most authors recommend routine prophylaxis for thromboembolism prevention after total joint arthroplasty [1,2]. The rationale is based on the high prevalence of venous thromboembolism among hospitalized patients, the clinically silent nature of the disease in most of the patients, and the potential morbidity and mortality associated with thrombi. Both DVT and pulmonary embolus (PE) produce few specific symptoms, and clinical diagnosis is unreliable [2]. Prophylaxis can be either mechanical or chemical. Although chemical prophylaxis, particularly with use of low molecular weight heparin, effectively reduces the frequency of DVT as diagnosed with venogram after total joint arthroplasty, many orthopedic surgeons are concerned about the potential for soft-tissue side effects and hemorrhagic complications, especially during the operation itself and immediately after, and therefore, are attracted to mechanical prophylactic methods [3]. Total hip arthroplasty (THA) and total knee arthroplasty (TKA) are associated with venous stasis, which is an important etiologic factor in the

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Submitted February 23, 2004; accepted April 19, 2005.
No benefits or funds were received in support of this study.
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0883-5403/06/1906-0004$32.00/0
doi:10.1016/j.arth.2005.04.031

development of DVT. The operative maneuvers that are needed to implant prosthetic components obstruct venous blood flow [4]; the patient is relatively immobile for several days after the operation, and the physiology of the venous system appears to be altered for some weeks postoperatively [5]. Intermittent pneumatic compression (IPC) devices cyclically inflate air-filled cuffs, leading to an increase venous blood flow velocity. Increased flow velocity overcomes venous stasis, the primary DVT formation mechanism. Increased fibrinolysis is the secondary mechanism by which IPC decreases DVT formation [6-12]. However, the major disadvantage of the currently available IPC devices is their size, weight, and requirement for continuous attachment to an external power source. Poor compliance with proper use of the current stationary devices by both patients and nursing staff significantly limits their efficacy [13].

A recently developed device (WizAir continuous enhanced circulation therapy [CECT] System, MCS Ltd, Or-Akiva, Israel) is a miniature, battery operated, and fully mobile pneumatic compression system, thus, simplifying treatment and increasing patient's compliance [14,15]. Even though small, this device was shown to provide state of the art hemodynamic profile [16]. The high compliance achieved with this device encouraged us to try a new treatment protocol for DVT prophylaxis after orthopedic surgery using a combination of mechanical prophylaxis and low-dose aspirin, that is, a combination of a theoretically very potent mechanical device, with low-cost, low-risk, moderately effective chemical prophylaxis. The rationale for the combination of treatment agents is the multifactorial nature of DVT. It has been more than a century since Virchow [17] described his triad. The proposed treatment affects both the stasis arm and the antiaggregation arm of the triad. The CECT system affects DVT rates by accelerating blood flow and venous peak flow velocity. Aspirin's main effect on clot formation is achieved through inhibition of platelet function. The combined regimen of CECT and aspirin allows minimal drug dosage, thus, decreasing the risk of gastrointestinal side effects.

The aim of the current study was to compare the frequency of thromboembolism after THA and TKA in patients who were randomized to be managed either with the CECT-based protocol (with aspirin) or low molecular weight heparin, on the basis of the Marder's classification of DVT [18]. To the best of our knowledge, a prospective randomized trial that compared the combination of a pneumatic device and low-dose aspirin with low molecular weight heparin, on the basis of venogram-detected DVT, was not previously published.

Materials and Methods

Study Design

This was a prospective randomized study conducted at a single medical center. Blinding was not considered feasible, because even if placebo injections were used, the pump action could not be masked. Instead, comparison of 2 clinically applicable DVT prevention protocols was performed. Both TKA and THA were included in the study. Though the incidence of DVT differs between these groups, it was estimated that because of the randomization process, similar numbers of each procedure would be treated according to either protocol.

Patient Selection

All patients who were scheduled for unilateral primary THA or TKA between April 2001 and September 2002 at Assaf Harofe Medical Center were considered for inclusion in the trial[1]. All women included were postmenopausal. Exclusion criteria were refusal of consent, long-term anticoagulant therapy, treatment with antiaggregant medication for the last 10 days, known hypersensitivity to contrast medium or aspirin or low molecular weight heparin, previously diagnosed venous thromboembolism (VTE), concurrent thrombosis process, and enrollment in another clinical trial. One hundred forty-two patients were screened. Six patients were dropped after screening. One hundred thirty-six patients were randomized to the study. Fifteen were dropped after randomization (7 in the CECT group and 8 in the enoxaparin group). All 15 dropouts were classified as missing completely at random. One hundred twenty-one patients completed the study—60 in the enoxaparin group and 61 in the CECT group.

Randomization

Randomization was performed before the operation with the use of sealed envelopes containing a slip indicating the allocation, which had been derived from a computer-generated sequence. Patients either received the enoxaparin or the CECT-based protocol.

[1] Patients were contributed by either Dr Halperin or Dr Robinson. No benefits were received or will be received by the authors in material or in kind in conjunction with this study.