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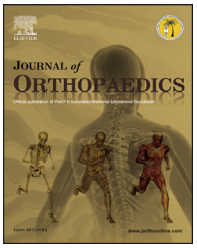

Original Article

Flowtron foot-pumps for prevention of venous thromboembolism in total hip and knee replacement

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ABSTRACT

Introduction: Mechanical prophylaxis with foot-pumps provides an interesting alternative to chemical agents in the prevention of venous thromboembolism following major orthopaedic surgery procedures. The aim of this prospective study was to assess efficacy and safety of the Flowtron® foot-pumps system following total hip and knee replacement. The foot pumps were used as main tool for prevention of thromboembolic events, in most cases in association with a variety of chemicals.

Methods: The primary endpoint of the study was to assess the incidence of deep vein thrombosis and pulmonary embolism after total hip and knee replacement. The secondary endpoints included postoperative bleeding, swelling, bruising and wound ooze.

Results: 424 consecutive patients were included in the study. Symptomatic deep vein thrombosis was detected in 7 patients (1.6%). All symptomatic deep vein thromboses were detected after discharge before the six week follow-up clinic. Five non-fatal pulmonary embolisms occurred (1.2%). Only one patient presented a major wound bleeding (0.2%). The mean difference of swelling of thigh pre-versus postoperatively was only 22.8 mm.

Discussion: In conclusion, thromboembolism prophylaxis after total hip and knee replacement using Flowtron® foot-pumps as main prevention tool of an individualised protocol appears effective and safe. This is the first clinical report related to this popular brand of foot pumps.

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1. Introduction

Deep vein thrombosis (DVT) and pulmonary embolism (PE) are significant complications following total hip (THR) and knee replacement (TKR). The American College of Chest Physician advocates the use of chemical prophylaxis.[1] However, a large number of orthopaedic surgeons resisted a standard regimen of chemical prophylaxis as suggested by cardio-pulmonology guidelines in favour of individualised judgements for the single patient.[3]

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At our Institution, pneumatic foot compression devices (AV-Impulse system Orthofix Vascular Novamedix, Andover, UK) have been used for more than a decade as main tool of venous thromboembolism prevention in the postoperative in-hospital recovery period of patients undergoing elective THR and TKR. The AV-impulse foot compression system has shown a proven benefit in preventing thromboembolic events.[6,10,11,13,15] Following a tendering process by the local District Health board, a new device, the Flowtron Universal compression system was introduced (Flowtron®, ArjoHuntleigh, Luton, UK). This system, even if quite similar to the original AV-Impulse, lacks of published data for clinical validation.

The aim of this prospective study was to monitor safety and efficacy of the Flowtron foot pumps in the prevention of thromboembolic disorder in patients following THR and TKR.

2. Material and methods

All patients admitted at our institution from July 1011 to December 2012 with degenerative osteoarthritis of the hip or knee for THR or TKR management were considered for inclusion in the study. The criteria for exclusion were: diagnosed active malignancy; known bleeding diatheses; gastrointestinal ulceration or bleeding. The study was approved by the local Ethics Committee. All surgical procedures were carried out or directly supervised by experienced orthopaedic surgeons. Spinal anaesthesia was used in the large majority of patients. All patients used foot-pumps during hospital stay. The foot-pump slippers were fitted to both feet in the recovery room or in the ward as soon as possible after surgery, and the pneumatic machine was activated. The nurses were advised to fit and start the foot-pump system whenever the patient was not bearing weight. In some patients, the surgeon advised use of foot-pumps without simultaneous application of antithrombotic stockings.[11,16]

Various chemicals were prescribed in combination with the foot-pumps. However, in some young and healthy patients the surgeon elected to use only foot pumps for prevention of venous thromboembolism. Low-molecular-weight heparin (LMWH, Clexane, 20–40 mg), Rivaroxaban (Xarelto), or Dabigatran (Pradaxa) were used in patients rated high-risk for DVT and PE (previous history of DVT/PE, positive family history of DVT/PE, high body-mass index and any other condition with expected difficulties to mobilise postoperatively). Aspirin was used in all other patients. Physical therapy, range of motion exercises, and mobilisation with partial or full weight-bearing were usually initiated on the first postoperative day.

The pneumatic compression cycle (30 seconds) of the Flowtron® foot pumps differs from the AV-impulse system in that it inflates over a 3 s period compared to the 0.4 second inflation time followed by 3 second hold time of the AV-impulse system. Both devices inflate to a pressure of 130 mmHg. The foot pads are remarkably different, with a thinner, lighter design of the Flowtron system. Patients were free to terminate treatment with the foot-pump at any time. If foot-pump use was discontinued for more than 6 consecutive hours, the patient was excluded from the study, maintaining chemicals prophylaxis. At discharge, all patients were managed with graduated compression stockings and aspirin or other chemicals until full weight-bearing was permitted or at discretion of the surgeon.

Patients with clinical signs of DVT were investigated with ultrasound scans of lower extremity veins and those with clinical signs of PE underwent computed tomography pulmonary angiogram (CTPA). The patient commenced therapeutic LMWH with bridging warfarin therapy in case of DVT or PE imaging confirmation. Swelling and bruising of the thigh and oozing of the wound were assessed and scored using published criteria.[10,15]

2.1. Statistical analysis

The continuous demographic data of the patients were analysed with use of a two-tailed, unpaired *t* test. For rank-scaled data, median values were given with the interquartile range. Relative frequencies of unpaired samples were compared with use of Fisher's exact test. Unpaired groups of continuous data without assumption of normal distribution were compared with use of the Mann–Whitney *U* test. Two-sided *p* values of $p \leq 0.05$ were considered significant. Correction for multiple comparisons was done with the method of Hommel to control type-I error. All calculations were carried out with use of SPSS for Windows (version 9; SPSS, Chicago, Illinois).

3. Results

A total of 464 consecutive patients were considered for allocation into the study. Eight patients were excluded and 32 patients discontinued the use of foot pumps during their hospital stay. The reason for termination was sleep disturbances and/or discomfort around the ankle. 424 patients were included in the study. Table 1 show the demographic detail of the 424 patients. Thirty patients were managed with Flowtron foot pumps only (7%). The remaining 394 patients were given additional chemical prophylaxis: 330 patients on Aspirin (78%), 34 patients on Clexane (8%), 4 patients on Dabigatran (1%), 26 patients on Rivaroxaban (6%). 137 patients did not use compression stocking while using the foot pumps.

The primary outcome measure of this study was the incidence of DVT and PE. Symptomatic DVT was detected in 7 patients (1.6%) (Table 2). All symptomatic DVTs occurred and were detected after discharge. One patient was diagnosed with DVT at day 6 postoperatively and the remaining six patients were diagnosed after day 10 postoperatively. Six of the 7 patients underwent TKR and received Aspirin as chemical prophylaxis. The patient who underwent THR, received

Table 1 – Patient demographics (mean and standard deviation).

Patients = 424	
Gender (M/F)	1/1.5
Age (years)	66.9 ± 10.7
Body mass index (kg/m^2)	32.6 ± 7.1
Duration of hospital stay (days)	5.1 ± 3.5
TKR/THR	267/157

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