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# EFFECTIVENESS OF INTERMITTENT PULSATILE ELASTIC STOCKINGS FOR THE PREVENTION OF CALF AND THIGH VEIN THROMBOSIS IN PATIENTS UNDERGOING ELECTIVE KNEE SURGERY

R. Hull, T.J. Delmore, J. Hirsh, M. Gent, P. Armstrong, R. Lofthouse, A. MacMillan, I. Blackstone, R. Reed-Davis and R.C. Detwiler
Departments of Pathology, Medicine and Clinical Epidemiology & Biostatistics, McMaster University Medical Centre and Departments of Medicine and Surgery, Chedoke Hospital, Hamilton, Ontario, Canada

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ABSTRACT

Intermittent calf compression (ICC) prevents postoperative venous thrombosis (VT) but has not been previously tested in patients who remain immobilized for prolonged periods. We have evaluated a pulsatile elastic stocking in a randomized trial of 61 patients who underwent elective knee surgery. The stockings were worn for up to 17 days or until patient discharge and did not produce patient discomfort. The patients were well matched for age, sex, type of operation and aspirin use. Bilateral venography was performed on all patients 14-17 days postoperatively or earlier if the $^{125}$I-fibrinogen scan became positive. Nineteen of the 29 patients (65.5%) in the control group and 2 of 32 patients (6.3%) in the stocking group developed deep VT ($p<0.001$). Popliteal or femoral VT was found in 7 patients in the control group and in no patients in the stocking group ($p<0.01$). The effectiveness of ICC was not influenced by age, sex, previous venous disease or aspirin administration, although it is possible that aspirin may have provided some protection in the control group.

## INTRODUCTION

Intermittent calf compression using inflatable boots has been shown to significantly reduce the frequency of postoperative $^{125}$I-fibrinogen detected venous thrombi in randomized clinical trials of patients who have had general surgical, neurosurgical and prostatic surgical procedures (1-6). In many studies, intermittent pneumatic compression was reported to be effective even when its period of application was limited to the operative and early postoperative period. However, if used only in the peroperative period, intermittent calf compression may not be effective in patients who are immobilized

for prolonged periods. Thus, in a recent study of patients with intracranial disease, pneumatic calf compression for 5 days significantly reduced the frequency of thrombosis while the pneumatic devices were worn but this protection was lost in patients who remained immobile after the devices were removed, negating their early benefit (5).

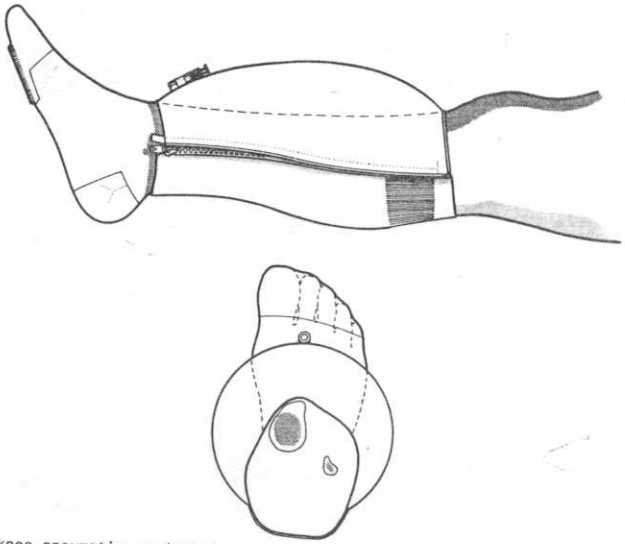
We have evaluated an inflatable pneumatic elastic stocking which compresses the calf intermittently by inflation of a pneumatic bladder contained in an anterior pouch of the stocking. The stocking is permeable to air and therefore is relatively cool and can be worn for prolonged periods without producing patient discomfort. The objective of the study was to test the effectiveness of intermittent pneumatic calf compression in a randomized clinical trial of patients undergoing elective knee surgery. This patient group was selected for study because it was reported to be associated with a very high risk of postoperative venous thrombosis (7). The stockings were worn for up to 17 days postoperatively and the presence or absence of venous thrombosis was determined in all patients by bilateral ascending venography.

## PATIENTS AND METHODS

All patients aged 30 and over who had elective knee surgery performed by one of the five participating orthopedic surgeons were entered into a randomized trial comparing inflatable, below knee pneumatic stockings (Fig. 1) with a control group. Patients in both groups received routine physiotherapy. They had the objectives of the study explained to them and signed a consent form. Patients were excluded from the study if there was a history of allergy to radio-opaque dye used in venography, if they had severe peripheral arterial disease, or if there was skin ulceration. All patients excluded from the study were documented. The use of aspirin was not discouraged but the frequency of administration and the dose used in the 24 hours immediately preceeding surgery and in the postoperative period was documented in all patients.

Prior to randomization, patients were stratified on the basis of whether or not they had a history of previous venous thrombosis and within each of the four surgical categories which were 1) arthroplasty, 2) high tibial osteotomy, 3) menisectomy, and 4) a miscellaneous group. Patients were randomized at the time of surgery using a system of sealed envelopes. The inflatable stockings were fitted peroperatively to both legs immediately following wound closure. The stockings extended to just below the knee and were provided in four sizes which were fitted according to the diameter of the patient's calf. They were worn either until the patient was discharged from hospital or for 17 days, at which time all patients were fully ambulant. Intermittent calf compression was achieved by inflation of a pneumatic bladder which was contained in a pouch inserted in the anterior and anteromedial and lateral aspects of the stocking. Inflation of the bladder resulted in compression of the calf by increasing circumferential tension on the stocking (Fig. 1). The bladder in the anterior pouch was inflated by an electrical compression pump to achieve a skin pressure beneath the stocking of 50 mm Hg over a period of 5 seconds. This pressure was maintained for an additional 15 seconds for a total inflation time of 20 seconds. The bladder was then deflated for a period of 60 seconds. The cycle times described above were selected on the basis of hemodynamic studies using impedance plethysmography which was performed in 100 patients prior to commencement of the randomized clinical trial. At the pressure selected, calf emptying reached a plateau by 10 seconds and returned to baseline volumes by 50 seconds.

FIG. 1



Below-knee pneumatic graduated pressure stocking: Intermittent calf compression is achieved by inflation of the pneumatic bladder contained in a pouch inserted in the anterior and antero-medial and lateral aspects of the stocking. Inflation of the bladder results in compression of the calf by increasing circumferential tension on the stocking.

In patients who required a plaster cast, the cast was applied over the stocking with the bladder fully inflated. The bladder was then able to inflate and deflate under the anterior aspect of the cast to produce calf compression without interfering with the function of the cast.

The preparation of $^{125}$I-fibrinogen and the scanning technique and its interpretation have been previously described (8). The patients were injected with $^{125}$I-fibrinogen 48 hours postoperatively to minimize the extravascular accumulation of radioisotope due to extravasation of $^{125}$I-fibrinogen into the area of the wound. The scanning points adjacent to the site of surgery (points 5 and 6 on the lower thigh and point 1 in the calf) were disregarded as being uninterpretable.

Bilateral ascending venography was performed by the method of Rabinov and Paulin (9) on day 14-17 in all patients except those having tibial osteotomies or in those who developed a positive leg scan. Patients who underwent tibial osteotomy had venography performed on day 7-10, just prior to the reapplication of a walking plaster. Patients who developed positive leg scans had venography performed within 24-48 hours of this development. In patients who were discharged from hospital before day 14, venography was performed on an outpatient basis on day 14-17.

The endpoint used to detect venous thrombosis was venographically demonstrable thrombosis involving the deep veins of the calf, popliteal, femoral or iliac veins. The radiographic criterion used for venous thrombosis was the presence of an intraluminal filling defect that was constant in all films. If non-filling of a venous segment was seen, the patient was re-injected with contrast medium to obtain better definition. If the defect was not constant in all films, or if a part of the deep venous system was poorly visualized despite repeated examination, the venogram was coded as inadequate. Venograms were interpreted independently by two experienced observers with disputes resolved through adjudication by a third. The venograms were interpreted without knowledge of the leg scan result and without knowledge of the group to which the patient was randomized. Venograms were reported as negative, positive for venous thrombosis, or inadequate for interpretation.

All patients were followed up in an outpatient clinic after discharge from hospital.

## RESULTS

Sixty-three patients were eligible for entry into the study but two were excluded because of a history of allergy to the radio-opaque dye used in venography. Of the 61 patients entered into the study, 32 were randomized into the stocking group and 29 into the untreated control group. Venography was technically adequate in 60 of the 61 patients but was inadequate, despite a repeated examination, in one patient in the control group.

The two groups of patients were comparable (Table 1) in terms of age, sex, history of previous DVT, type of operation and preoperative aspirin use at entry to the study. In addition, the use of aspirin postoperatively was comparable in the two groups; 75% in the stocking group and 72% in the control group. All patients had a tourniquet applied throughout the operative procedure. Plaster of Paris back slabs or casts were applied to 23 patients in the stocking group and 21 control patients postoperatively.

The pulsatile stockings were worn for a mean of 12.2 days ($\pm$ 5 SD). In one patient, the stockings were removed prematurely at 5 days because of leg discomfort. The other 31 patients completed the protocol and did not find the stockings uncomfortable.

TABLE 1

Comparison at Entry of Patients in Stocking Group and Control

| | | Stocking | Control |
|---|---|---|---|
| Age | 30 - 39 | 2 | 3 |
| | 40 - 59 | 13 | 9 |
| | 60 + | 17 | 17 |
| Sex | M:F | 13:19 | 9:20 |
| History of Previous DVT | Yes | 6 | 4 |
| | No | 26 | 25 |
| Type of Operation | Menisectomy | 7 | 4 |
| | Total knee replacement | 13 | 14 |
| | Tibial osteotomy | 7 | 4 |
| | Other operations | 5 | 7 |
| Peroperative Tourniquet | Yes | 32 | 29 |
| Plaster of Paris Dressing or Cast | Yes | 23 | 21 |
| | No | 9 | 8 |
| Current ASA Use | Yes | 9 | 8 |
| | No | 23 | 21 |

The incidence of venographically detected acute thrombosis is shown in Table 2. Two of the 32 patients in the stocking group (6.3%) had a DVT during their stay in hospital compared with 19 of the 29 patients in the control group (65.5%). This observed difference is statistically highly significant ($X^2_1 = 21.12, p<0.001$). The thrombi that occurred in the two patients in the stocking group were confined to the calf, whereas 7 of the 19 thrombi in the

control group showed proximal extension into the popliteal or femoral vein. This observed difference in the incidence of proximal vein thrombosis is also statistically significant ($p<0.01$). No patient showed clinical evidence of pulmonary embolism.

TABLE 2

Incidence of Venographically Confirmed DVT

| | DVT | No DVT | Totals |
|---|---|---|---|
| Stocking Group | 2 | 30 | 32 |
| Control Group | 19 | 10 | 29 |

The observed benefit of stockings was not influenced by the patient's age, sex, the presence of previous venous thrombosis, or the nature of the operation performed (Table 3). The most important potentially confounding variable was the concomittant use of aspirin. The proportions of patients using aspirin, either the day before surgery or in the postoperative period, were comparable in the two groups. Of those who took aspirin, the mean daily dose was higher in the control group both preoperatively (2.8 grams/day in the control group as compared with 1.5 grams/day in the stocking group) and postoperatively (1.7 grams/day in the control group as compared with 1.3 grams/day in the stocking group). Table 4 shows the incidence of deep vein thrombosis in the two groups when cross-classified according to aspirin use preoperatively and postoperatively. All patients who took aspirin preoperatively continued aspirin use postoperatively.

The frequency of DVT in the control group was higher in non-aspirin takers (76%) than in the aspirin takers (38%) preoperatively and there was a 100% frequency of DVT in the non-aspirin takers postoperatively compared with a frequency of 53% in the aspirin takers postoperatively. Thus, in the control group there was a two-fold difference between the frequency of DVT between aspirin users and non-aspirin users and, in those who took aspirin postoperatively, this observed difference was statistically significant ($p<0.05$). However, these data need to be interpreted with some caution since these patients were not randomized to aspirin or no aspirin and the reported observed differences may be due to some other associated factor.

The important issue to resolve here is whether our ability to draw inferences about the benefit of pulsatile elastic stockings has been compromised by the uncontrolled use of aspirin. A more detailed analysis within aspirin takers and non-aspirin takers reveals that the use of aspirin did not confound the analysis or interpretation of results. Of those patients who took aspirin after surgery, 2 out of 24 (8.3%) had DVT in the stocking group compared with 11 out of 21 (52.4%) in the control group ($p<0.01$). Of those patients who did not take aspirin after surgery, 0 out of 8 (0%) had DVT in the stocking group compared to 8 out of 8 (100%) in the untreated control group ($p<0.001$). Hence, there is a statistically highly significant benefit of the pulsatile elastic stockings irrespective of whether or not the patients also took aspirin postoperatively.

TABLE 3

Incidence of DVT Within Prognostic Factors

| | | Stocking | | Control | |
|---|---|---|---|---|---|
| | | No DVT | DVT | No DVT | DVT |
| Age | 30-39 | 2 | 0 | 2 | 1 |
| | 40-59 | 13 | 0 | 5 | 4 |
| | 60 + | 15 | 2 | 3 | 14 |
| Sex | M | 13 | 0 | 3 | 6 |
| | F | 17 | 2 | 7 | 13 |
| Previous DVT | Yes | 6 | 0 | 0 | 4 |
| | No | 24 | 2 | 10 | 15 |
| Operation | Menisectomy | 6 | 1 | 2 | 2 |
| | Total Knee | 12 | 1 | 4 | 10 |
| | Tibial Osteo | 7 | 0 | 0 | 4 |
| | Other | 5 | 0 | 4 | 3 |

TABLE 4

Incidence of DVT for Aspirin and Non-Aspirin Users

| | | Stocking | | Control | |
|---|---|---|---|---|---|
| | | No DVT | DVT | No DVT | DVT |
| Aspirin use Day prior to surgery | Yes | 8 | 1 | 5 | 3 |
| | No | 22 | 1 | 5 | 16 |
| Aspirin use after surgery | Yes | 22 | 2 | 10 | 11 |
| | No | 8 | 0 | 0 | 8 |

Sixteen of the 21 patients with thrombosis were identified by leg scanning which was performed through a plaster cast or bandages of variable thickness. One of 40 patients without venous thrombosis had a positive leg scan which was associated with extensive ecchymosis.

Patients were followed up after discharge from hospital at a mean time of 2.8 months. Two patients were lost to follow-up and one patient who was in

the control group died of a stroke during the follow-up period. The remaining 58 patients were alive and had no clinical evidence of venous thrombosis or pulmonary embolism.

## DISCUSSION

This study has demonstrated that intermittent calf compression using an inflatable pneumatic stocking is highly effective in preventing venous thrombosis in patients who have elective knee surgery. Because of the nature of the intervention, it was not possible to use a double blind design but care was taken to exclude assessment bias by performing venograms on all patients and by ensuring that this endpoint was evaluated without knowledge of the patient group or the leg scan results. Thus, these findings both support and extend previous studies (1-6) which demonstrated that intermittent calf compression was effective in reducing the frequency of leg scan detected thrombosis in patients undergoing general surgery, neurosurgery and prostatic surgery (1-6). The patients were well matched for age, sex, type of operation, use of peroperative tourniquet and postoperative plaster cast and for the use of aspirin pre and postoperatively.

An important potentially confounding variable was the concomittant use of aspirin in both groups. There was an impressive difference in the frequency of DVT observed between patients in the control group who did and did not use aspirin during the study. A similar association between aspirin usage and venous thrombosis was reported by McKenna in a non-randomized study of patients undergoing total knee replacement (7). Since in our study and McKenna's study patients were not randomized for aspirin usage, it cannot be concluded that this association is causal although the results are highly suggestive. However, in our study the benefit of stockings was striking irrespective of whether or not aspirin was used; thus, in those taking aspirin postoperatively there was a reduction from 52% to 8% and in those not taking aspirin a reduction from 100% to 0%. In each case, the observed benefits were statistically highly significant ($p<0.01$). The frequency of venous thrombosis of 65.5% in the control group is high compared to most other elective surgical procedures but is in the same range as that reported by McKenna and associates in patients undergoing total knee replacement (7). The inflatable stockings also prevented the occurrence of proximal vein thrombosis which was demonstrated in 24% of patients in the control group but in no patient in the stocking group.

Patients who developed venous thrombosis were treated with heparin and clinically detected pulmonary embolism was not observed and there were no in-hospital fatalities.

Patient compliance was good and the stockings only had to be removed prematurely in one patient who complained of discomfort. The stockings were worn during ambulation and could be readily disconnected and reconnected to the compression pump by either the patient or the nursing staff and did not interfere with the process of ambulation nor did it limit patient mobility. The stockings were comfortable to wear and were not associated with excessive heat or sweating.

These results show that intermittent calf compression is effective even in patients who are immobilized for long periods.

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