

EFFECT OF MECHANICAL COMPRESSION ON THE PREVALENCE OF PROXIMAL DEEP VENOUS THROMBOSIS AS ASSESSED BY MAGNETIC RESONANCE VENOGRAPHY

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Background: Patients have been shown to be at greater risk for deep venous thrombosis, particularly proximal thrombosis, after total hip arthroplasty. Proximal thrombi are more likely to develop into pulmonary emboli than are distal thrombi. The purpose of this randomized, prospective study was to compare the prevalence of pelvic and proximal lower-extremity deep venous thrombosis after primary total hip arthroplasty between patients treated with an impulse mechanical compression device for prophylaxis and those treated with prophylactic stockings.

Methods: One hundred patients were evaluated, with use of magnetic resonance venography, for proximal deep venous thrombosis after total hip arthroplasty. Fifty patients were treated with a mechanical compression device on both lower extremities, and the other fifty patients received only prophylactic stockings. Both groups of patients received hypotensive epidural anesthesia and 325 mg of aspirin twice a day.

Results: Overall, proximal deep venous thrombi were found in 15% of the 100 patients. Of the fifty patients treated with mechanical compression, 8% (four) had a positive venogram. Of the fifty control patients, 22% (eleven) had a positive venogram ($p < 0.05$). However, overall the rate of occlusive thrombi was 6% (six) compared with an overall rate of nonocclusive thrombi of 9% (nine). The rate of occlusive thrombi was 2% (one of fifty) in the study group and 10% (five of fifty) in the control group ($p = 0.04$).

Conclusions: On the basis of this study, we concluded that patients managed with total hip arthroplasty benefit from a reduction in the rates of femoral and pelvic deep vein thrombosis when they are treated with hypotensive epidural anesthesia, mechanical compression, and aspirin and are subsequently assessed with magnetic resonance venography.

The rates of proximal venous thrombi following total hip arthroplasty have been reported to range from 14% (seven of fifty patients) to 29% (thirty-nine of 134 patients)¹⁻⁶. The more proximal the thrombi, the greater the risk for development of a pulmonary embolus⁷⁻¹⁰. With the advent of magnetic resonance venography, these potentially dangerous proximal thrombi, including pelvic thrombi, can now be accurately defined and located^{11,12}. Magnetic resonance venography can also be used to determine the effectiveness of a prophylactic regimen for prevention of these proximal thrombi.

Pneumatic compression devices have been found to reduce the likelihood of clots developing in the lower extremities following orthopaedic, general, and prostatic surgery and neurosurgery at rates equivalent to, and without the hemorrhagic complications of, pharmacological prophylaxis^{3,13-18}. In the present study, we sought to examine the efficacy of inter-

mittent pneumatic compression in preventing proximal deep venous thrombosis in the lower extremities following primary total hip arthroplasty. The mechanical compression device chosen for the study, VenaFlow (Aircast, Summit, New Jersey), produced a greater increase in peak venous velocity (300%) than did other pneumatic compression devices¹⁹⁻²¹.

We used magnetic resonance venography to screen for thrombi in the proximal veins. There have been questions about the efficacy and accuracy of conventional detection techniques, such as Doppler ultrasound and venography, for assessing proximal and pelvic clots^{11,16,20,22-26}. Magnetic resonance venography has been shown to successfully confirm clinically suspected deep venous thrombosis of the abdomen, pelvis, and extremities^{24,27}. Thus, the rates of proximal thrombi in this study were obtained with use of the most sensitive technology currently available.



Fig. 1-A

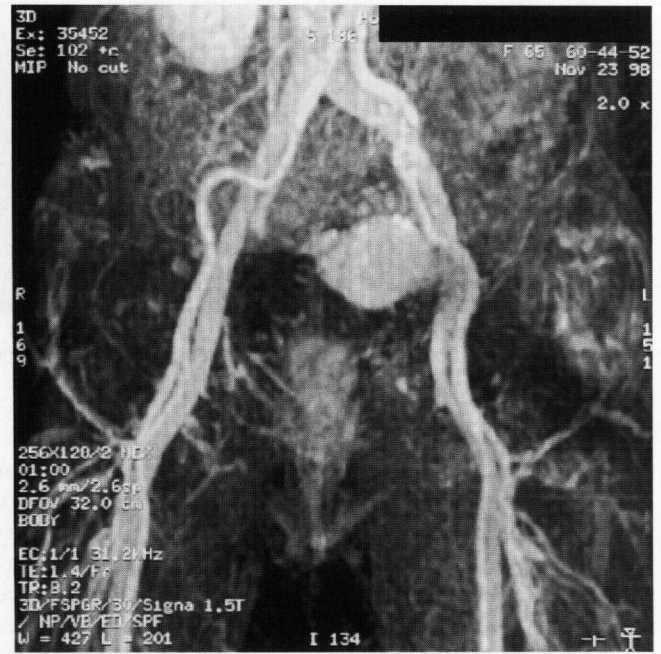


Fig. 1-B

Figs. 1-A, 1-B, and 1-C Subtraction reformation angiogram from a volumetric acquisition following administration of gadolinium contrast medium.

Fig. 1-A Arteriographic phase discloses a normal appearance of the external iliac and common femoral vessels after a left total hip arthroplasty.

Fig. 1-B Combined arterial and venous phases demonstrate regional vascular anatomy. Note the enhancement in the uterus, which is a normal finding.

Materials and Methods

Patients in whom primary total hip arthroplasty had been performed by one of two senior surgeons (E.A.S. or T.P.S.) provided informed consent, as per the terms of our Institutional Review Board approval. The patients were prospectively randomized into either the experimental group or the control group. Any patient with a history of venous thrombi, pulmonary emboli, or peripheral vascular disease was defined as a high-risk patient and was excluded from the study, as were patients for whom aspirin or magnetic resonance imaging was contraindicated. Contraindications to magnetic resonance venography included a documented allergy to gadolinium, a pacemaker, certain otologic and penile implants, and most cerebral aneurysm clips. In addition, patients in whom an indwelling vascular stent and/or inferior vena cava filter had been placed less than six weeks before the magnetic resonance venography were not scanned and thus were excluded from the study. The presence of an orthopaedic implant, including a total hip prosthesis, did not preclude effective magnetic resonance imaging. All patients received hypotensive epidural anesthesia during surgery, which is customary at our institution.

One hundred patients who were to undergo total hip arthroplasty were prospectively randomized. Immediately following surgery, in the Post Anesthetic Care Unit, the Vena-Flow pneumatic compression device was applied to both lower extremities of the patients in the experimental group, whereas only elastic stockings were applied in the control group. Both groups received 325 mg of aspirin twice a day and all underwent an identical rehabilitation program.

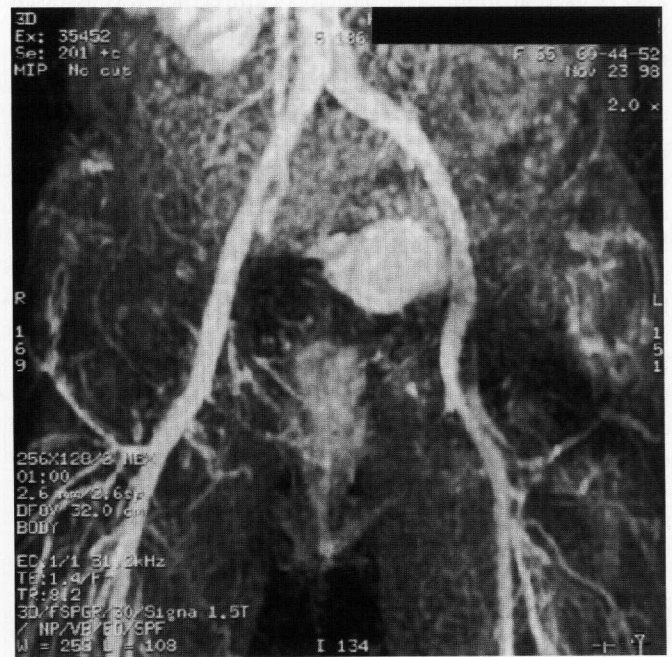


Fig. 1-C

Subtraction venographic image (obtained by subtracting Fig. 1-A from Fig. 1-B) creates a magnetic resonance venogram. Note the superior visualization of the profunda femoris vessels as well as the small branch vessels in the pelvis. Scrutiny of individual source images is essential in order to disclose areas of thrombus formation. The presence of the total hip prosthesis does not preclude effective vascular imaging.



Fig. 2
Axial source image from a volumetric assessment following administration of gadolinium after a recent right total hip arthroplasty. There is a non-occlusive thrombus in the right external iliac vein (arrow).

VenaFlow is an impulse calf-compression device that produces more than a 300% increase in peak venous velocity measured at the common femoral vein²⁰. All study patients were treated with the compression device for the entire duration of the postoperative hospital stay, generally four or five days. For the first twenty-four hours postoperatively, the device was used continuously, until the patient stood for the first time with the help of the physical therapist. For the next three to four-day period, the device was removed only for trips to the bathroom, walking (two, three, or four times a day), physical therapy, and sitting in a chair. The device was always used at night. The patient's compliance was assessed several times a day by the attending physician, research assistant, and nursing staff.

Magnetic resonance venography was performed with a 1.5-tesla magnetic system (Horizon LX; General Electric Medical Systems, Milwaukee, Wisconsin) on the third, fourth, or fifth postoperative day (see Appendix). Three or four sets of contrast-enhanced images were obtained without interval delay, in order to ensure that both arterial and venous phase images were made (Figs. 1-A, 1-B, 1-C, and 2). The criterion for the diagnosis of acute deep venous thrombosis was a complete absence of flow within the vessel or an intravascular area of low signal intensity surrounded by high signal intensity, the latter of which reflects flowing blood. Signal dephasing at areas of bifurcation, caused by flow turbulence, was not considered indicative of thrombosis. Areas of questionable flow artifacts noted with time-of-flight techniques were further studied with contrast-enhanced techniques, in order to ensure the definitive presence or absence of thrombosis.

All magnetic resonance venography studies were interpreted by one of two senior radiologists blinded as to whether the patients had been treated with the mechanical compression device or the elastic stockings. As per our institution's protocol, any patient with a positive venographic result was initially treated with a therapeutic dose of enoxaparin followed by warfarin. Enoxaparin treatment was continued only until a therapeutic warfarin level (an international normalized ratio of >1.8) was achieved.

A power analysis was performed with the assumption of a 30% prevalence of proximal deep venous thrombosis, as as-

sessed with magnetic resonance venography, and an attempt to detect a 5.0% difference between the experimental and control groups with a 95.0% confidence level (power = 0.8). Statistical analysis of the outcome (proximal deep venous thrombosis) was performed with a chi-square test. Patient factors such as age, gender, height, weight, and hemoglobin levels were compared between treatment groups with use of the t test, to ensure that no factor besides the prophylactic regimen was influencing the results. Additionally, other patient demographics, such as hematocrit, platelet count, prothrombin time, and activated partial thromboplastin time were analyzed with the Mann-Whitney U test.

One hundred patients treated with primary total hip arthroplasty completed the study. Fifty patients were treated with the mechanical compression device after surgery, and fifty were treated with elastic stockings. Of the fifty patients treated with the VenaFlow device, 62% (thirty-one) were female and 38% (nineteen) were male. The average age of these patients was 70.1 years. Of the fifty patients treated with elastic stockings, 62% (thirty-one) were female and 38% (nineteen) were male. The average age of these patients was 67.5 years. No significant difference with regard to height; weight; gender; preoperative or postoperative hemoglobin level, hematocrit, or platelet count; or preoperative prothrombin time or activated partial thromboplastin time (all p values > 0.05) (see Appendix) was noted between the study arms. In addition, with the numbers available, no significant difference with regard to those factors was noted between patients who tested positive for a deep venous thrombosis and those who tested negative (all p values > 0.05) (see Appendix).

Results

Overall, proximal deep venous thrombosis developed in 15% of the 100 patients (Fig. 3). All thrombi were located on the side of the operation. A proximal clot developed in 8% (four) of the fifty patients treated with the mechanical compression device and in 22% (eleven) of the fifty patients who were not treated with the mechanical compression device (p < 0.05). No clinically symptomatic deep venous thrombosis or pulmonary embolism developed in any patient.

Thirteen of the fifteen thrombi were detected in the ex-

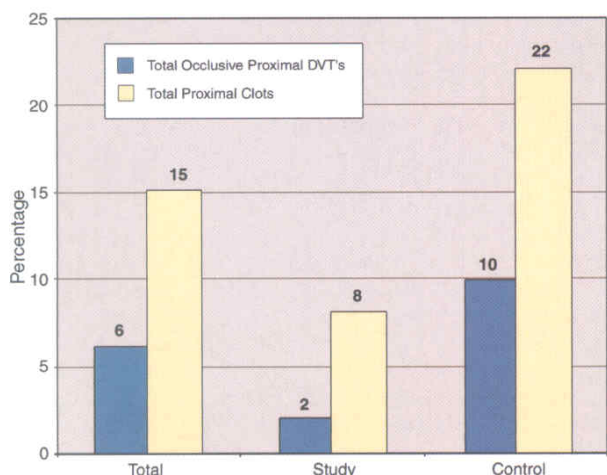


Fig. 3
Total percentage of proximal thrombi and percentage of occlusive clots in the total series, the study group, and the control group. The difference between the percentages of identified clots that were occlusive in the study and control groups was large but not significant ($p = 0.2$).

ternal iliac vein (Fig. 2), one was detected in the profunda femoris vein, and one was detected in the superficial femoral vein. The average size (and standard deviation) of the fifteen thrombi was 2.37 ± 1.164 cm (Table I). The average size of the

eleven thrombi reported in the control group was 2.0 ± 0.91 cm, and six of the eleven thrombi were nonocclusive. The average size of the four thrombi reported in the study group was 3.3 ± 1.38 cm, and three of the four thrombi were nonocclusive. The rate of occlusive thrombi was 6% (six of 100) overall, 2% (one of fifty) in the study group, and 10% (five of fifty) in the control group ($p = 0.04$).

Discussion

Numerous studies have shown that, by enhancing blood flow in the deep veins of the lower limb, mechanical compression devices are effective in reducing the rate of deep venous thrombosis following total hip arthroplasty^{19,20,27-36}. Hull et al.¹⁵ and others^{27,28,30,31,33,35,36} used venography and duplex ultrasonography to show a reduction in proximal deep venous thrombosis with mechanical compression. However, two early studies of pneumatic compression demonstrated a decrease in distal deep venous thrombosis but a worrisome increase in proximal deep vein thrombosis^{3,28}. This increased rate may have been due to use of older forms of pneumatic compression with inherent low stroke volumes. Low stroke volume and subsequent low velocity may not be adequate to increase blood flow through the femoral veins and, particularly, through the pelvic veins. The VenaFlow mechanical compression device used in the present study provides a rapid impulse inflation compressing the calf veins through two overlapping air cells every sixty seconds. The asymmetrical compression maximizes

TABLE I Deep Venous Thrombi

| Case | Treatment Group | Findings of Magnetic Resonance Venography | | |
|------|-----------------|---|----------------------------|-----------------|
| | | Size of Clot (cm) | Location of Clot* | Occlusive Clot† |
| 1 | Control | 2.5 | R external iliac vein | Yes |
| 2 | Control | 3.3 | R external iliac vein | Yes |
| 3 | Control | 1.1 | R external iliac vein | Yes |
| 4 | Control | 1.2 | R external iliac vein | Yes |
| 5 | Control | 1.2 | L external iliac vein | Yes |
| 6 | Control | 2.0 | L external iliac vein | No |
| 7 | Control | 3.5 | R external iliac vein | No |
| 8 | Control | 3.0 | R external iliac vein | No |
| 9 | Control | 1.9 | L external iliac vein | No |
| 10 | Control | 1.2 | R profunda femoris vein | No |
| 11 | Control | 1.4 | L superficial femoral vein | No |
| 12 | Study | 3.2 | L external iliac vein | Yes |
| 13 | Study | 1.5 | R external iliac vein | No |
| 14 | Study | 3.8 | L external iliac vein | No |
| 15 | Study | 4.8 | R external iliac vein | No |

*All clots were ipsilateral ($p = 0.2$). †More of the clots were occlusive in the control group (five of eleven) than in the study group (one of four).

blood velocity and total blood flow, which results in greater venous ejection compared with that provided by circumferential compression^{19,20}. Additionally, the inflation rate has a profound effect on venous velocity. In a previous comparative study of venous hemodynamics after total joint arthroplasty, the VenaFlow was noted to increase peak venous velocity at the level of the common femoral vein by almost 300% above the baseline^{20,23}, which was the greatest increase offered by the devices that were studied.

The overall rate of proximal deep venous thrombosis in our study (15%) is at the high end of the range of rates (0% to 17%) reported in previous studies in which intermittent pneumatic compression was used^{27,37}. However, these rates include both occlusive and nonocclusive thrombi as assessed by magnetic resonance venography. The overall rate of occlusive thrombi was relatively lower (6%). In reports of other methods of prophylaxis, including low-molecular-weight heparin and Coumadin (warfarin), the rates of proximal thrombosis have ranged from 4% (three of seventy-four patients) to 9% (six of sixty-nine patients)^{22,37-40}. At our institution, the previously reported rate of proximal thrombi detected with venography screening was 4.3% (eighty-seven of 2037 patients) when hypotensive epidural anesthesia was used in conjunction with aspirin without pneumatic compression³⁷. The higher rate of proximal thrombi reported in the current study is likely due to the sensitivity of magnetic resonance venography, which also detects intrapelvic clots. In most previously published reports, ultrasonography or venography, which identify more distal thrombi, was used. The sensitivity of these traditional screening techniques for detecting proximal thrombi has been questioned^{11,16,20,22-26}. It is known that visualization of pelvic veins is limited with both contrast venography and Doppler ultrasonography^{16,26}. With contrast venography, opacification of the deep pelvic vessels is limited because of dilution from unspecified pelvic veins. Even with direct femoral vein puncture, visualization of the internal iliac branches is hampered (despite retrograde cannulation) by the normal direction of venous flow, which is against the direction of the contrast injection⁴¹. Doppler ultrasound of the pelvis is hampered by an inability to compress the deep pelvic vessels and by the potential for a postoperative ileus to reflect the ultrasound beam³⁷.

In a previous study, in-hospital pulmonary embolism was diagnosed with the use of ventilation-perfusion scans in 0.54% (eleven) of 2037 patients; however, only three of these eleven patients had a positive venogram³⁷. Furthermore, after discharge from the hospital, late pulmonary embolism occurred in 0.49% (ten) of the patients, all of whom had had a negative venogram prior to discharge. This finding lends credence to the concept that the occult source of these emboli may be within the deep veins of the pelvis, which are poorly visualized and often missed by traditional screening techniques.

With recent advances in magnetic resonance imaging, such as contrast-enhanced magnetic resonance angiography and fast-spin-echo techniques, it is possible to visualize the pelvic veins adjacent to metallic prosthetic components^{42,43}. In a study by Montgomery et al.²⁴, magnetic resonance venography

was found to be a sensitive screening examination for proximal deep venous thrombosis, with superior visualization of pelvic thrombi in patients with pelvic trauma. Thus, the rates of proximal thrombi in our study were obtained with the most sensitive techniques currently available for screening patients with total hip arthroplasty. Magnetic resonance venography can be performed on any patient for whom magnetic resonance imaging is not contraindicated^{16,24}.

The potential for morbidity increases as clots in the external and internal iliac venous system become more proximal⁷⁻¹⁰. In addition to the location of the clots, the size and occlusive nature of proximal thrombi may be important indicators of the risk of pulmonary embolus. Lotke et al.⁷ demonstrated a positive association between the size of a clot and the likelihood of a ventilation-perfusion scan showing an intermediate or high probability of pulmonary embolism. In the current study, all proximal thrombi were asymptomatic and incidentally detected by magnetic resonance venography. The patients with a proximal thrombus were treated with subcutaneous enoxaparin until a therapeutic dose of warfarin was achieved. No patient had clinical pulmonary embolus.

In this study, we found both occlusive and nonocclusive proximal thrombi. Other studies have suggested that the frequency of pulmonary emboli increases as the primary thrombus involves larger and more centrally located veins⁷⁻¹⁰. Thrombi that float freely at their central part are much more likely to embolize than are those that are adherent or retracted⁴⁴. Thus, the configuration of this portion of the thrombus is important in terms of the risk of an embolic phenomenon. Because of the limited number of patients in our study, we could not determine the relative risks of occlusive and nonocclusive proximal thrombi; however, there was a significant difference ($p = 0.04$) in the rates of occlusive clots between the study and control groups, which suggests an association between the use of mechanical compression and a lower rate of occlusive proximal thrombi.

Appendix

eA A description of the procedure for magnetic resonance venography and tables showing patient demographics according to treatment group and according to whether deep venous thrombosis developed are available with the electronic versions of this article, on our web site at www.jbjs.org (go to the article citation and click on "Supplementary Material") and on our quarterly CD-ROM (call our subscription department, at 781-449-9780, to order the CD-ROM). ■

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