Calf-Thigh Sequential Pneumatic Compression Compared with Plantar Venous Pneumatic Compression to Prevent Deep-Vein Thrombosis after Non-Lower Extremity Trauma

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Abstract

Objective: To compare the effectiveness of calf-thigh sequential pneumatic compression devices with the effectiveness of plantar venous intermittent pneumatic compression devices in prevention of venous thrombosis after major trauma.

Subjects and Methods: We evaluated 181 consecutive patients after major trauma without lower extremity injuries that precluded the use of pneumatic compression devices. We randomly assigned 149 patients to either calf-thigh sequential pneumatic compression or plantar venous pneumatic compression. After blinding the observers to the method of prophylaxis against deep-vein thrombosis, we performed bilateral compression ultrasonography on or before day 8 after randomization.

Results: Among 149 randomized patients, 62 who received calf-thigh sequential pneumatic compression and 62 who received plantar venous intermittent pneumatic compression devices completed the trial. Thirteen patients randomized to plantar venous intermittent pneumatic compression (21.0%) and 4 patients randomized to calf-thigh sequential pneumatic compression (6.5%) had deep-vein thrombosis ($p = 0.009$). Seven of 13 patients with deep-vein thrombosis after prophylaxis with plantar venous intermittent pneumatic compression had bilateral deep-vein thromboses, whereas all 4 patients with deep-vein

thrombosis after prophylaxis with calf-thigh sequential pneumatic compression had unilateral deep-vein thrombosis.

Conclusion: Calf-thigh sequential pneumatic compression prevents deep-vein thrombosis more effectively than plantar venous intermittent pneumatic compression after major trauma without lower extremity injuries.

Key Words: Deep-vein thrombosis, Pulmonary embolism, Trauma, Pneumatic compression devices.

Venous thromboembolism commonly complicates major trauma. [1-4] In a prospective study, Geerts et al. identified deep-vein thrombi by contrast venography in 58% of 349 trauma patients. [1] Thrombi involved the proximal deep veins of 18% of these patients. Pulmonary embolism can complicate the course of major trauma, having been reported in 2 to 22% of patients after major trauma. [3-5] Furthermore, pulmonary embolism is a common cause of death in patients who survive initial traumatic injuries. [1-2,4]

Investigators have defined the effectiveness of methods to prevent venous thromboembolism for a number of high-risk situations. [6] However, there is limited information with respect to the effectiveness of methods to prevent venous thromboembolism after major trauma. [6,7] Geerts et al. found that low-molecular-weight heparin was more effective than low-dose unfractionated heparin for the prevention of venous thromboembolism after major trauma. [7] Anticoagulants were not given to patients who had intracranial blood on computed tomograms or patients with bleeding that remained uncontrolled 36 hours after the injury. Approximately one of seven major trauma victims cannot receive anticoagulant prophylaxis against venous thromboembolism because of the risk of additional bleeding. [6,8] Intermittent pneumatic compression devices are often used to prevent venous thromboembolism for such patients. [5-7,9,10] Recent studies in orthopedic patients suggest that pneumatic devices that forcibly eject blood from the plantar venous plexus of the foot can prevent deep-vein thrombosis. [11] However, the relative effectiveness of pneumatic compression devices for the prevention of venous thromboembolism after major trauma remains uncertain. Therefore, we compared the effectiveness of calf-thigh sequential pneumatic compression with the effectiveness of plantar venous intermittent pneumatic compression in patients with major trauma. The primary outcome measure was deep-vein thrombosis detected by bilateral compression ultrasonography on or before day 8 after randomization.

PATIENTS AND METHODS

The study protocol was approved by the LDS Hospital institutional review board, and patients or their surrogates were asked to provide written informed consent.

Patients

We assessed the eligibility of consecutive patients who had sustained major trauma and who were admitted to the Shock Trauma-Respiratory Intensive Care Unit of the LDS Hospital. Eligible patients included those

who were more than 13 years old and who had recent (within 24 hours) severe head injuries (Glasgow Coma Scale score < 9) and/or major trauma and were expected to be bedridden for more than 72 hours. Patients with external fixation devices or casts that precluded the use of calf-thigh sequential pneumatic compression devices on either or both legs, patients who were not expected to live more than 24 hours, and patients whose injuries occurred more than 24 hours before admission to the Shock Trauma-Respiratory Intensive Care Unit were not eligible.

Study Design and Interventions

We conducted a randomized clinical trial in which the patients were stratified before randomization by the presence or absence of femoral venous catheters. Assessment of eligibility and randomization were performed by research nurses (N.K. and S.Y.) in consultation with the principal investigators (T.M.D. and C.G.E.). The random assignment system was developed by the statistical data center at the LDS Hospital (D.H.). Eligible individual patients without exclusions were assigned randomly (on the basis of a computerized random numbers table) to receive either calf-thigh sequential pneumatic compression devices (Kendall, SCD Compression System, Mansfield, Mass) or plantar venous intermittent pneumatic compression devices (PlexipulseR, NuTech, San Antonio, Tex). Random assignments were blocked in groups of four to control for the presence of femoral venous catheters. Individual prophylaxis assignments were written on cards and placed in sealed opaque envelopes with only the order of assignment and stratification displayed. The statistical data center maintained a paper record of random assignments.

The calf-thigh sequential pneumatic compression devices consisted of four calf and two thigh plastic chambers that inflate sequentially to a pressure of 45 mm Hg. The calf chambers inflated sequentially from the ankle to the knee at 5-second intervals (as recommended by the manufacturer). The two thigh chambers then inflate sequentially in a proximal direction. All chambers remain inflated for 5 seconds, then deflate simultaneously. The PlexipulseR has a single chamber that inflates for 2 seconds and cycles every 20 seconds. The chamber pressure was set to 160 mm Hg (as recommended by the manufacturer).

Saline solutions maintained the patency of intravenous access devices. We prohibited the use of dextran, desmopressin acetate, heparin, oral anticoagulants, fibrinolytic agents, dipyridimole, or aspirin until the efficacy end point had been evaluated. Graduated compression stockings were not permitted. A member of the study team monitored compliance with the study protocol daily by checking proper application and fitting of the plastic sleeves and proper functioning of the pump. No patients were excluded for noncompliance.

Detection of Venous Thrombosis

On day 8 (or earlier if death or transfer were imminent), each patient underwent bilateral compression ultrasonography (duplex) according to previously described methods. [12] The examination included the common femoral, saphenous, superficial femoral, popliteal, and calf veins. Compression ultrasonography was performed with a high resolution gray-scale instrument (Ultra Mark 9 with High Definition Imaging, Advanced Technology Lab, Bothell, Wash). Immediately before these examinations, we removed the calf-

thigh sequential pneumatic compression devices or plantar venous intermittent pneumatic compression devices from the patient and the patient's room to maintain an assessment that was blinded to the method of venous thromboembolism prophylaxis. Compression ultrasonography was performed by registered vascular technologists who were blind to the method of prophylaxis. Compression ultrasonography was interpreted by a physician (S.M.), who was blind to the method of venous thromboembolism prophylaxis. Deep-vein thrombosis was diagnosed when a venous segment could not be compressed by gentle pressure from the ultrasound probe. Deaths during the first 2 weeks after trauma were reviewed independently by three physicians (J.F.O., T.P.C., L.W.) who did not know the method of venous thromboembolism prophylaxis. They reviewed all clinical and radiologic records. When autopsies or medical examiner investigations were performed, this information was provided to the physician reviewers. They identified the cause of death as well as whether or not venous thromboembolism was suspected or proven. They also characterized the death as insidious or abrupt. [13]

Outcome Measures

The principal end point was deep-vein thrombosis, which was detected by compression ultrasonography. Venous thrombosis was classified as proximal deep-vein thrombosis when the thrombus involved or extended into deep veins proximal to the trifurcation of calf veins.

Statistical Analysis

We compared proportional characteristics of the two prophylaxis groups with the Pearson chi squared test; and we compared continuous characteristics (e.g., age), with the Mann-Whitney test. We calculated the predicted risk for venous thromboembolism without prophylaxis for each patient according to a previously derived prediction equation. [7]

Two analyses that used logistic regression were planned in advance. The first analysis compared rates of venous thrombosis in patients who completed the study protocol after randomization to calf-thigh sequential pneumatic compression with rates of venous thrombosis in patients who completed the study protocol after randomization to plantar venous intermittent pneumatic compression (completer analysis). This analysis adjusted for the stratification variable as well as potential confounders with statistically significant imbalance at baseline (i.e., coma score and blood transfusions). The method of venous thromboembolism prophylaxis was withheld from the data analyst by identifying the two groups as "A" and "B" until the data analysis was completed.

The second analysis compared the rates of deep venous thrombosis in patients who were randomized to calf-thigh sequential pneumatic compression with rates of deep venous thrombosis in patients who were randomized to plantar venous intermittent pneumatic compression (intent to treat analysis). This analysis adjusted only for the stratification variable (i.e., presence of a femoral venous catheter), and it assumed treatment failure (i.e., deep-vein thrombosis) for all patients who did not undergo compression ultrasonography. Because treatment failure is unlikely for all patients who did not undergo compression ultrasonography, sensitivity analysis was performed. We examined the logistic regression results when the

percentage of prophylaxis failures varied from 0 to 100% for patients who did not undergo compression ultrasonography.

Before the study, we estimated that a study sample of 130 evaluable patients was needed to obtain 80% power at an alpha level of 0.05 (two tailed) to detect a 20% difference in the two prophylactic methods (Fleiss' estimate with continuity correction). We estimated a 15% "lost to end point" rate, and we planned to enroll 149 patients. The study had 90% power at the 5% significance level to distinguish a prophylaxis failure rate of 8.5% versus 31% in a two-sided intention-to-treat analysis, and 80% power to similarly distinguish failure rates of 11% and 31%.

RESULTS

Between February 14, 1994, and August 10, 1996, 181 eligible patients were admitted to the Shock Trauma-Respiratory Intensive Care Unit who had sustained major trauma resulting in a coma score less than 9 and/or injuries anticipated to cause immobility for more than 72 hours (Figure 1). During the same time period, 102 patients were admitted with multiple trauma and leg fractures that precluded the use of calf-thigh sequential pneumatic compression devices, and 36 patients were admitted after multiple trauma who were not expected to live 24 hours. One hundred forty-nine patients were assigned randomly to either calf-thigh sequential pneumatic compression devices (n = 74) or plantar venous intermittent pneumatic compression devices (n = 75). Two patients who were assigned calf-thigh sequential pneumatic compression and two patients who were assigned plantar venous intermittent pneumatic compression erroneously received the opposite device. Four patients assigned to plantar venous intermittent pneumatic compression devices and two patients assigned to calf-thigh sequential pneumatic compression devices had the protocol violated when they were given subcutaneous heparin. Seven patients assigned to plantar venous intermittent pneumatic compression could not undergo compression ultrasonography (five patients died and one patient was transferred before compression ultrasonography could be performed, and one patient refused compression ultrasonography). Eight patients assigned to calf-thigh sequential pneumatic compression were withdrawn (six patients died, one patient was transferred before compression ultrasonography could be performed, and one patient refused compression ultrasonography).

The general aspects of the study protocol were followed. No patient wore graduated compression stockings, and no patient received aspirin, Coumadin, or dextran.

A total of 149 patients compose the intent to treat group (Table 1). Both prophylaxis groups were young, predominately male, and most patients had sustained closed head injuries as the result of motor vehicle crashes. The two treatment groups had similar risks for venous thromboembolism, as estimated by the Equation derivedby Geerts et al. [7] Patients prophylaxed by plantar venous intermittent pneumatic compression had a higher coma score and were less likely to have received blood transfusions than patients prophylaxed by calf-thigh sequential pneumatic compression. These same differences were noted in the 124 patients who completed the study protocol and underwent bilateral lower extremity compression ultrasonography (Table 2).

Review of the hospital course of those patients who died did not reveal evidence of venous thromboembolism (Table 3). No patient had a vena cava filter placed before compression ultrasonography, and no patient underwent venography, ventilation, and perfusion lung scanning or pulmonary angiography for clinically suspected acute pulmonary embolism. However, five patients (three patients prophylaxed with calf-thigh sequential pneumatic compression and two patients prophylaxed with plantar venous intermittent pneumatic compression) underwent compression ultrasonography before day 8 because of clinically suspected deep-vein thrombosis. None of these studies revealed deep-vein thrombosis.

Deep-Vein thrombosis

Thirteen of 62 patients (21.0%) who completed prophylaxis with plantar venous pneumatic compression devices and 4 of 62 patients (6.5%) who completed prophylaxis with calf-thigh sequential pneumatic compression devices had deep-vein thrombi detected by compression duplex ultrasonography ($p = 0.009$). Seven of 13 patients with deep-vein thrombosis after prophylaxis with plantar venous intermittent pneumatic compression had bilateral deep-vein thromboses, whereas all 4 patients with deep-vein thrombosis after prophylaxis with calf-thigh sequential pneumatic compression had unilateral deep-vein thrombosis. Proximal deep-vein thrombi were detected in 1 of 62 patients (1.6%) prophylaxed with calf-thigh sequential pneumatic compression devices, and 3 of 62 patients (4.8%) prophylaxed with plantar venous intermittent pneumatic compression devices (Table 4). A subgroup analysis of the two prophylaxis groups showed that 2 of 12 patients (16.7%) who had femoral venous catheters and were prophylaxed with plantar venous intermittent pneumatic compression devices developed proximal deep-vein thrombi, whereas no proximal deep-vein thrombi were detected in 9 patients who had femoral venous catheters and were prophylaxed with calf-thigh sequential pneumatic compression devices.

Thirteen patients prophylaxed with plantar venous intermittent pneumatic compression had a varied distribution of deep-vein thromboses. Bilateral thromboses were observed in soleal sinuses ($n = 3$), left popliteal and right peroneal veins ($n = 1$), soleal and peroneal veins ($n = 1$), right posterior tibial and left peroneal veins ($n = 1$), and right peroneal and left peroneal and posterior tibial veins ($n = 1$). Unilateral thromboses were observed in the left common femoral vein ($n = 2$), right greater saphenous vein ($n = 1$), right soleal and peroneal veins ($n = 1$), left peroneal vein ($n = 1$), and right soleal sinuses ($n = 1$). Four patients prophylaxed with calf-thigh sequential intermittent pneumatic compression had unilateral deep-vein thromboses. Thrombi were identified in the left soleal sinus ($n = 1$); left posterior tibial vein ($n = 1$); right peroneal and posterior tibial veins ($n = 1$); and the left popliteal, peroneal, and superficial femoral veins ($n = 1$).

Intent to treat analysis assigned treatment failure (i.e., deep-vein thrombosis) to patients for whom compression ultrasonography was not obtained. With this method, 18 of 75 patients (24.0%) assigned to plantar venous intermittent pneumatic compression and 12 of 74 patients (16.2%) assigned to calf-thigh sequential pneumatic compression devices either had deep-vein thrombosis detected by compression ultrasonography or had this end point assigned because outcome data were not available ($p = 0.0593$).

Sensitivity analysis that varied the proportion of assigned outcomes from 100% prophylaxis failures (i.e., deep-vein thrombi assigned to all patients who did not undergo compression ultrasonography) to 0% prophylaxis failures (i.e., no deep-vein thrombi assigned to patients who did not undergo compression ultrasonography) showed that the p value ranged from 0.029 to 0.059 as the proportion of assigned outcomes varied from 0 to 100%.

Bleeding

Overall, 1 of 149 randomized patients (0.7%) and none of the 124 patients who completed the trial had major bleeding. No episode of major bleeding occurred among 75 patients assigned to plantar venous intermittent pneumatic compression devices; and 1 episode of major bleeding occurred among 74 patients assigned to calf-thigh sequential pneumatic compression devices. This episode of major bleeding resulted from a ruptured aorta 4 days after randomization.

Other

Although case reports have described complications with the use of pneumatic compression devices, [14-16] we did not identify complications attributable to either device during this study.

DISCUSSION

The results of this study suggest that calf-thigh sequential pneumatic compression is more effective than plantar venous intermittent pneumatic compression for the prevention of deep-vein thrombosis after major trauma that does not involve the lower extremities. We observed lower overall rates of deep-vein thrombosis when calf-thigh sequential pneumatic compression devices were used, and we found bilateral deep-vein thrombi more often when plantar venous intermittent pneumatic compression devices were used. To the best of our knowledge, this is the only randomized controlled trial that has compared pneumatic compression devices used to prevent deep-vein thrombosis after major trauma. A clinical trial, which randomized trauma victims with lower risks for bleeding and more lower extremity orthopedic injuries, showed that a low-molecular-weight heparin more effectively prevented deep-vein thrombosis than low doses of unfractionated heparin. [7] The present study complements the comparison of low-molecular-weight heparin and unfractionated heparin by providing comparative data for methods used to prevent venous thromboembolism in patients with injuries that preclude anticoagulant prophylaxis, e.g., patients who have closed head injuries. Because plantar venous intermittent pneumatic compression devices often can be applied (and calf-thigh sequential pneumatic compression devices cannot) in the setting of trauma that involves the lower extremities, plantar venous compression devices may be useful with or without anticoagulants when lower extremity injuries preclude the use of calf-thigh sequential pneumatic compression.

Study procedures minimized bias. We identified consecutive eligible patients and randomly assigned the majority to either calf-thigh sequential pneumatic compression or plantar venous intermittent pneumatic compression within 24 hours of major trauma. To ensure that femoral venous catheters were used with

equivalent frequencies in both groups, we stratified the random assignments for the presence of these catheters. The two patient groups were not significantly different with respect to most baseline characteristics that were not controlled by stratification. The majority of patients in both groups were young males who had sustained major head trauma in a motor vehicle crash, although the plantar venous pneumatic compression group had higher coma scores and were less likely to have received a blood transfusion during the first 24 hours of hospitalization. Our analysis of the patients who completed the study protocol adjusted for these baseline differences. We avoided diagnostic suspicion bias by performing compression ultrasonography in high proportions (83% and 84%) of both groups without knowledge of the prophylactic method. We avoided interpretation bias by interpreting compression ultrasonography without knowledge of clinical findings or the method of prophylaxis against venous thrombosis.

The comparison of prophylaxis methods by intention-to-treat analysis was marginally statistically significant (odds ratio = 0.47, p = 0.0593), whereas the analysis of completers showed a significant difference in favor of calf-thigh sequential pneumatic compression (odds ratio = 0.15, p = 0.009). Sensitivity analysis indicated that the rate of deep-vein thrombosis assigned to noncompleters influenced the p value for the intention-to-treat analysis, e.g., an assigned deep-vein thrombosis rate of 50% results in p = 0.0381. Post hoc power calculations indicate that the study had 47% power to detect the observed reduction in the rate of deep-vein thrombosis. Thus, the data suggest a type II error in the intention-to-treat analysis. This suggestion may lead some to conclude that calf-thigh sequential pneumatic compression prevents deep-vein thrombosis at least as effectively as plantar venous pneumatic compression. We concluded that the data were more compatible with the interpretation that calf-thigh sequential pneumatic compression prevents deep-vein thrombosis more effectively than plantar venous pneumatic compression after major trauma without lower extremity injuries.

Both calf-thigh sequential pneumatic compression and plantar venous intermittent pneumatic compression prevent deep-vein thrombosis after high risk surgical procedures. In small clinical trials of patients who underwent hip or knee replacement procedures [11,17-19] or who sustained hip fractures, [20] plantar venous intermittent pneumatic compression prevented deep-vein thrombosis more effectively than no prophylaxis, aspirin, graduated compression stockings, or combinations of these methods. Calf-thigh sequential pneumatic compression prevents deep-vein thrombosis more effectively than no prophylaxis after hip replacement [21] or orthopedic trauma, [22] but these devices may not prevent proximal deep-vein thrombosis as effectively as warfarin after total hip replacement. [23] Our observations suggest that the risks of trauma patients without lower extremity injuries are similar to patients with intracranial disease, in whom calf vein thrombi occur more often than proximal deep-vein thrombi and in whom intermittent pneumatic compression is effective. [24] The effectiveness of calf-thigh sequential pneumatic compression in the trauma population that we studied may not be generalizable to trauma populations with orthopedic trauma (e.g., pelvic fractures) for which proximal deep-vein thrombosis is more likely. Subcutaneous enoxaparin effectively reduces the rate of proximal deep-vein thrombosis for such patients, but permits a relatively high rate of calf-vein thrombosis. [7]

Differences in the basic mechanisms of action of pneumatic compression devices may explain the relative ineffectiveness of plantar venous intermittent pneumatic compression. In general, intermittent pneumatic

compression devices relieve venous stasis by accelerating venous blood flow. [25,26] They may also induce fibrinolytic activity in the veins. [27-30] However, intermittent pneumatic compression devices differ significantly. For example, investigators have reported that a knee-high single-pulse pneumatic compression device produces greater venous blood flow augmentation than calf-thigh sequential pneumatic compression. [31] However, calf-thigh sequential pneumatic compression more effectively enhances fibrinolytic activity than uniform compression, [28] and devices that compress more tissue produce greater local fibrinolysis. [28] Thus, increased local fibrinolysis or differences in venous flow acceleration may explain the lower rates of deep-vein thrombosis that we observed when calf-thigh sequential pneumatic compression was used to prevent deep-vein thrombosis.

The rates of deep-vein thrombosis and major bleeding that we observed after major trauma are not directly comparable to those reported previously. [7,9,32] Differences in patient characteristics and in methods used to detect deep-vein thrombosis invalidate such comparisons. The present study excluded patients with lower extremity injuries that precluded the use of calf-thigh sequential pneumatic compression devices. This characteristic is a strong risk factor for the development of deep-vein thrombosis after major trauma, and its absence from the study population likely explains the observation that our patients' predicted risk for deep-vein thrombosis was lower than that in the population studied by Geerts et al. [7] Furthermore, we used compression ultrasonography to detect deep-vein thrombosis. Compression ultrasonography is less sensitive than contrast venography for the detection of asymptomatic deep-vein thrombosis after elective hip or knee arthroplasty. [33] Thus, it is likely that additional deep-vein thrombi would have been detected if the present study had used bilateral contrast venography rather than compression ultrasonography, although the sensitivity of compression ultrasonography for the detection of asymptomatic deep-vein thrombi after major trauma is not known. However, the rates of deep-vein thrombi that we report are comparable to those reported for similar populations studied with compression ultrasonography, [5,34-36] and the bias of nondetection should apply evenly to the two treatment arms of our clinical trial. Clinical (symptomatic) deep-vein thrombosis did not occur during the study protocol, nor subsequently, although formal follow-up for symptomatic venous thromboembolism was not performed. The absence of symptomatic venous thromboembolism is not surprising, given the low rates reported when prophylaxis is administered to similar high risk populations. [37,38] Major bleeding complications occurred infrequently, despite potentially serious risks for bleeding complications

.In summary, the results of this randomized controlled clinical trial suggest that calf-thigh sequential pneumatic compression prevents deep-vein thrombosis more effectively than plantar venous intermittent pneumatic compression after major trauma without lower extremity injuries. These findings are clinically relevant for patients who have contraindications for anticoagulant prophylaxis, and they may also contribute to the design of studies that evaluate combinations of mechanical and anticoagulant prophylaxis for patients at high risk for venous thromboembolism after major trauma.

Figure 1

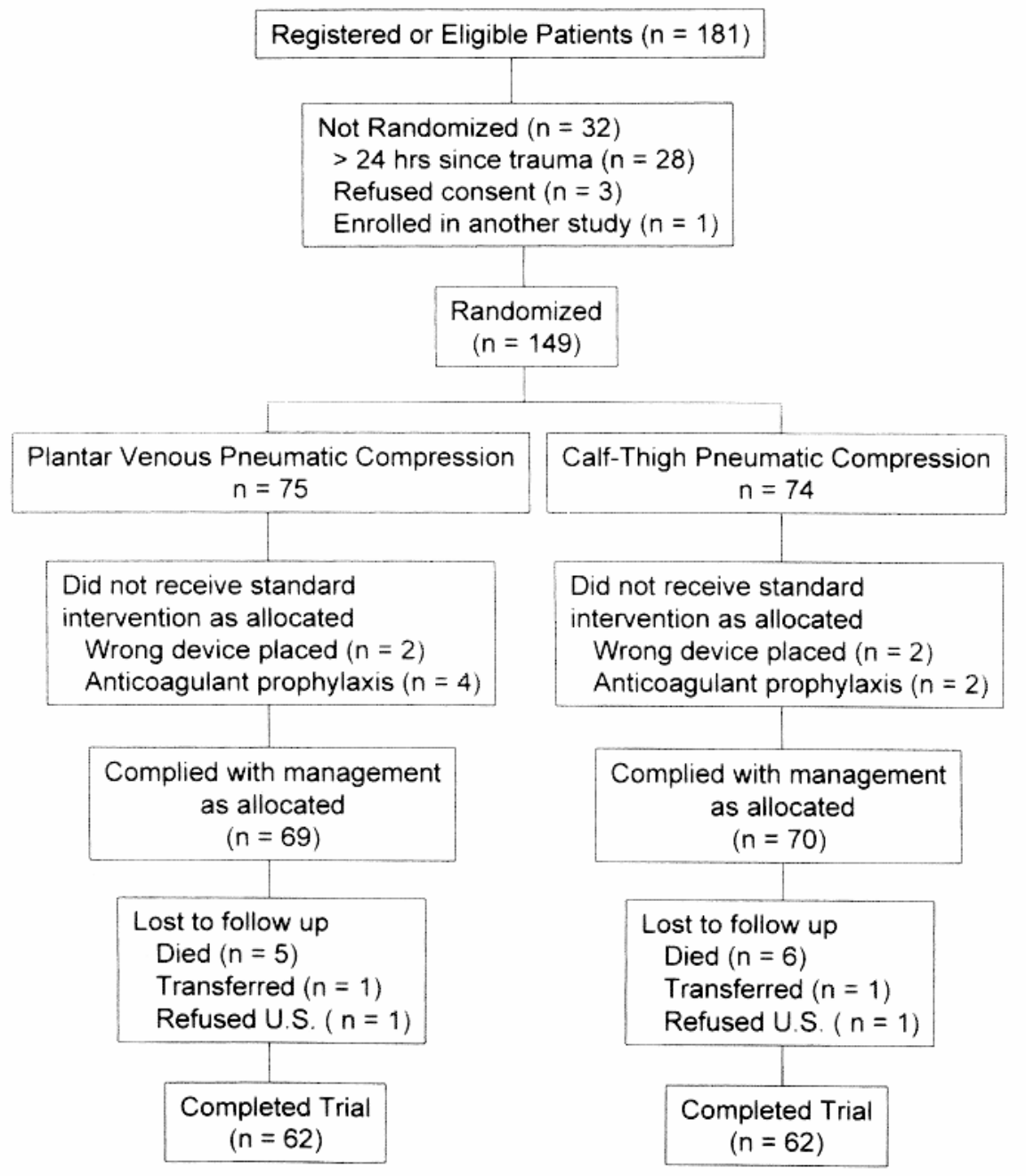

Figure 1. Study profile. Of 181 eligible patients, 32 did not qualify for randomization. Twenty-five patients (13 patients assigned to plantar venous pneumatic compression and 12 patients assigned to calf-thigh pneumatic compression) did not complete the trial. One patient in each intervention group refused compression ultrasonography.

Table 1

Characteristic	Calf-Thigh (n = 74)	Plantar Venous (n = 75)
Age, yr, mean (SD)	33.9 (19.7)	30.2 (16.0)
Male, n (%)	49 (66.2)	51 (68.0)
Cause of trauma, n (%)		
Motor vehicle crash	57 (77.0)	45 (60.0)
Pedestrian	6 (8.1)	7 (9.3)
Fall	4 (5.4)	13 (17.3)
Gunshot	6 (8.1)	6 (8.0)
Other	1 (2.7)	4 (5.3)
Sites of major injury, n (%)		
Head	62 (83.8)	61 (81.3)
Face	23 (31.1)	14 (18.7)
Chest	39 (52.7)	44 (58.7)
Abdomen	17 (23.0)	22 (29.3)
Upper limb	10 (13.5)	10 (13.3)
Other	26 (35.1)	26 (34.7)
Injury Severity Score, mean (SD)	31.0 (11.6)	30.2 (13.1)
Glasgow Coma Scale score, mean (SD)	8.4 (4.0)	9.7 (3.9)[b]
Apache II, mean (SD)	11.9 (5.1)	10.6 (5.0)
Femoral vein catheter, n (%)	13 (17.6)	14 (18.7)
Surgery performed, n (%)	12 (16.2)	10 (13.3)
Blood transfusions,[a] n (%)	43 (58.1)	27 (36.0)[b]
Days to compression ultrasound, mean (SD)	7.1 (2.5)	6.9 (2.2)
Risk of venous thrombosis,[c] % (SD)	34 (26)	27 (21)

[a] Number of patients who required blood transfusion during the first 24 hours.
[b] $p < 0.05$ Pearson χ^2 test for count data or Mann-Whitney test for continuous data.
[c] Predicted risk of deep-vein thrombosis from the equation of Geerts et al.[7]

Table 1. Characteristics of 149 patients who were assigned deep-vein thrombosis prevention randomly

Table 2

Characteristic	Calf-Thigh (n = 62)	Plantar Venous (n = 62)
Age, yr, mean (SD)	32.8 (18.6)	30.2 (15.9)
Male, n (%)	40 (64.5)	44 (71.0)
Cause of trauma, n (%)		
Motor vehicle crash	47 (75.8)	37 (59.7)
Pedestrian	5 (8.1)	5 (8.1)
Fall	4 (6.5)	11 (17.7)
Gunshot	6 (9.7)	5 (8.1)
Other	0 (0.0)	4 (6.5)
Sites of major injury, n (%)		
Head	53 (85.5)	50 (80.6)
Face	20 (32.3)	12 (19.4)
Chest	32 (51.6)	39 (62.9)
Abdomen	12 (19.4)	18 (29.0)
Upper limb	10 (16.1)	8 (12.9)
Other	20 (32.3)	23 (37.1)
Injury Severity Score, mean (SD)	31.2 (12.2)	30.7 (12.7)
Glasgow Coma Scale score, mean (SD)	8.4 (3.8)	10.1 (3.7)[b]
Apache II, mean (SD)	11.6 (4.7)	10.6 (5.0)
Femoral vein catheter, n (%)	9 (14.5)	12 (19.4)
Surgery performed, n (%)	10 (16.1)	10 (16.1)
Blood transfusions,[a] n (%)	33 (53.2)	22 (35.5)[b]
Days to compression ultrasound – mean (SD)	7.1 (2.5)	6.8 (2.3)
Risk of venous thrombosis,[c] % (SD)	29 (23)	24 (18)

[a] Number of patients who required blood transfusion during the first 24 hours.
[b] $p < 0.05$ Mann-Whitney test for continuous variables; Pearson χ^2 test for count data.
[c] Predicted risk of deep-vein thrombosis from the equation of Geerts et al.[7]

Table 2. Clinical characteristics of 124 patients who completed the study

Table 3

Plantar Venous (n = 5)	Calf-Thigh (n = 6)
CHI[1] (A)	CHI[1] (A)
CHI[2], SCI (I)	Hemorrhage, ruptured aorta (A)
CHI[1] (A)	CHI, multiorgan failure (I)
CHI[2] (I)	CHI[1] (A)
CHI[1] (A)	CHI[2] (I)
	Cardiac arrhythmia

[a] CHI[1], closed head injury with herniation; CHI[2], severe CHI with withdrawal of ventilator support after criteria for brain death were satisfied; SCI, spinal cord injury; (I), insidious; (A), abrupt. See reference 13.

Table 3. Causes of deaths as adjudicated independently by three physician reviewers ([a])

Table 4

Type	Calf-Thigh n (%)	Plantar Venous n (%)
All deep-vein thrombi	4/62 (6.5)	13/62 (21.0)[a]
Proximal deep-vein thrombi	1/62 (1.6)	3/62 (4.8)

[a] $p = 0.009$; χ^2 test corrected by logistic regression for presence of femoral venous catheters and for potential confounders with statistically significant imbalance at baseline, i.e., coma score and need for blood transfusion during the first 24 hours.

Table 4. Rates of deep-vein thrombosis for 124 patients who completed the study

REFERENCES

1. Geerts WH, Code KI, Jay RM, Chen E, Szalai JP. A prospective study of venous thromboembolism after major trauma. N Engl J Med. 1994;331:1601-1606.

2. Sevitt S, Gallagher N. Venous thrombosis and pulmonary embolism; a clinico-pathological study in injured and burned patients. Br J Surg. 1961;48:475-489.

3. Shackford SR, Moser KM. Deep venous thrombosis and pulmonary embolism in trauma patients. J Intensive Care Med. 1988;3:87-98.

4. O'Malley KF, Ross SE. Pulmonary embolism in major trauma patients. J Trauma. 1990;30:748-750.

5. Gersin K, Grindlinger GA, Lee V, Dennis RC, Wedel SK, Cachecho R. The efficacy of sequential compression devices in multiple trauma patients with severe head injury. J Trauma. 1994;37:205-208.

6. Clagett GP, Anderson FA, Heit J, Levine MN, Wheeler HB. Prevention of venous thromboembolism. Chest 1995;108(suppl):313S-334S.

7. Geerts WH, Jay RM, Code KI, et al. A comparison of low-dose heparin with low-molecular weight heparin as prophylaxis against venous thromboembolism after major trauma. N Engl J Med. 1996;335:701-707.

8. Shackford SR, Davis JW, Hollingsworth-Fridlund P, Brewer NS, Hoyt DB, Mackersie RC. Venous thromboembolism in patients with major trauma. Am J Surg. 1990;159:365-369.

9. Knudson MM, Lewis FR, Clinton A, Atkinson K, Megerman J. Prevention of venous thromboembolism in trauma patients. J Trauma. 1994;37:480-487.

10. Comerota AJ, Katz ML, White JV. Why does prophylaxis with external pneumatic compression for deep-vein thrombosis fail? Am J Surg. 1992;164:265-268.

11. Westrich GH, Sculco TP. Prophylaxis against deep venous thrombosis after total knee arthroplasty: pneumatic plantar compression and aspirin compared with aspirin alone. J Bone Joint Surg Am. 1996;78:826-834.

12. Talbot SR. B-mode evaluation of peripheral veins. Semin Ultrasound CT MR. 1988;9:295-319.

13. Hull RD, Raskob GE, Pineo GF, et al. Subcutaneous low-molecular-weight heparin compared with continuous intravenous heparin in the treatment of proximal-vein thrombosis. N Engl J Med. 1992;326:975-982.

14. Pittman GR. Peroneal nerve palsy following sequential pneumatic compression. JAMA. 1989;261:2201-2202.

15. Parra RO, Farber R, Feigl A. Pressure necrosis from intermittent pneumatic compression stockings. N Engl J Med. 1989;321:1615.

16. Lachmann EA, Rook JL, Tunkel R, et al. Complications associated with intermittent pneumatic compression. Arch Phys Med Rehab. 1992;73:482-485.

17. Wilson NV, Das SK, Kakkar VV, et al. Thrombo-embolic prophylaxis in total knee replacement: evaluation of the A-V Impulse System. J Bone Joint Surg Br. 1992;74:50-52.

18. Fordyce MJF, Ling RSM. A venous foot pump reduces thrombosis after total hip replacement. J Bone Joint Surg Br. 1992;74:45-49.

19. Stannard JP, Harris RM, Bucknell AL, Cossi A, Ward J, Arrington ED. Prophylaxis of deep venous thrombosis after total hip arthroplasty by using intermittent compression of the plantar venous plexus. Am J Orthop. 1996;25:127-134.

20. Stranks GJ, MacKenzie NA, Grover ML, Fail T. The A-V Impulse System reduces deep-vein thrombosis and swelling after hemiarthroplasty for hip fracture. J Bone Joint Surg Br. 1992;74:775-778.

21. Hull RD, Raskob GE, Gent M, et al. Effectiveness of intermittent pneumatic leg compression for preventing deep-vein thrombosis after total hip replacement. JAMA. 1990;263:2313-2317.

22. Fisher CG, Blachut PA, Salvian AJ, Meek RN, O'Brien PJ. Effectiveness of pneumatic leg compression devices for the prevention of thromboembolism disease in orthopaedic trauma patients: a prospective, randomized study of compression alone versus no prophylaxis. J Orthop Trauma. 1995;9:1-7.

23. Francis CW, Pellegrini VD, Marder VJ, et al. Comparison of warfarin and external pneumatic compression in prevention of venous thrombosis after total hip replacement. JAMA. 1992;267:2911-2915.

24. Turpie AGG, Delmore T, Hirsh J. Prevention of venous thrombosis by intermittent sequential calf compression in patients with intracranial disease. Thromb Res. 1979;5:611-616.

25. Nicolaides AN, Fernandes JF, Pollock AV. Intermittent sequential pneumatic compression of the legs in the prevention of venous stasis and postoperative deep-vein thrombosis. Surgery. 1980;87:69-76.

26. Sigel B, Edelstein AL, Savitch L, Hasty JH, Felix WR. Type of compression for reducing venous stasis. A study of lower extremities during inactive recumbency. Arch Surg. 1975;110:171-175.

27. Salzman EW, McManama GP, Shapiro AH, et al. Effect of optimization of hemodynamics on fibrinolytic activity and antithrombotic efficacy of external pneumatic calf compression. Ann Surg. 1987;206:636-641.

28. Tarnay TJ, Rohr PR, Davidson AG, Stevenson MM, Byars EF, Hopkins GR. Pneumatic calf compression, fibrinolysis, and the prevention of deep venous thrombosis. Surgery. 1980;88:489-496.

29. O'Brien TE, Woodford M, Irving MH. The effect of intermittent compression of the calf on the fibrinolytic responses in the blood during a surgical operation. Surg Gynecol Obstet. 1979;149:380-384.

30. Ljungner H, Berqvist D, Nilsson IM. Effect of intermittent pneumatic and graduated static compression on factor VIII and the fibrinolytic system. Acta Chir Scand. 1981;147:657-661.

31. Flam E, Berry S, Coyle A, Dardik H, Raab L. Blood-flow augmentation of intermittent pneumatic compression systems used for the prevention of deep-vein thrombosis prior to surgery. Am J Surg. 1996;171:312-315.

32. Knudson MM, Collins JA, Goodman SB, et al. Thromboembolism following multiple trauma. J Trauma. 1992;32:2-11.

33. Wells PS, Lensing AWA, Davidson BL, et al. Accuracy of ultrasound for the diagnosis of deep venous thrombosis in asymptomatic patients after orthopedic surgery. A meta-analysis. Ann Intern Med. 1995;122:47-53.

34. Dennis JW, Menawat S, von Thron J, et al. Efficacy of deep-vein thrombosis prophylaxis in trauma patients and identification of high risk groups. J Trauma. 1993;35:132-138.

35. Knudson MM, Morabito D, Paiement GD, Shackleford S. Use of low molecular weight heparin in preventing thromboembolism in trauma patients. J Trauma. 1996;41:446-459.

36. Upchurch GR Jr, Demling RH, Davies J, Gates JD, Knox JB. Efficacy of subcutaneous heparin in prevention of venous thromboembolic events in trauma patients. Am Surg. 1995;61:749-755.

37. Leclerc JR, Gent M, Hirsh J, Geerts WH, Ginsberg JS, and Members of the Canadian Collaborative Group. The incidence of symptomatic venous thromboembolism during and after prophylaxis with enoxaparin: a multi-institutional cohort study in patients who underwent hip or knee arthroplasty. Arch Intern Med. 1998;158:873-878.

38. Robinson KS, Anderson DR, Gross M, et al. Ultrasonographic screening before hospital discharge for deep-vein thrombosis after arthroplasty: the postarthroplasty screening study. Ann Intern Med. 1997;127:439-445.