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Anthony J. Comerota, MD, Mira L. Katz, MLA, RVT, John V. White, MD, Philadelphia, Pennsylvania



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# Why Does Prophylaxis With External Pneumatic Compression for Deep Vein Thrombosis Fail?

Anthony J. Comerota, MD, Mira L. Katz, MLA, RVT, John V. White, MD, Philadelphia, Pennsylvania

External pneumatic compression (EPC) devices are increasing in popularity for deep vein thrombosis (DVT) prophylaxis. Patients who have these devices applied postoperatively are assumed to have effective prophylaxis, although a number of extensive postoperative DVT complications have been observed. This study evaluates the proper application of EPC devices in patients in intensive care units and regular nursing floor units and assesses whether dedicated in-service instruction can improve proper use.

In a prospective study of 138 patients with 2 or more risk factors for postoperative DVT, it was found that patients on routine nursing units had properly functioning EPC devices during 48% (306 of 636) of the visits compared with 78% (312 of 398) of the visits in the intensive care unit (ICU) ( $p < 0.0001$ ). Follow-up of patients transferred from an ICU to a regular nursing unit showed that functional application decreased from 82% (129 of 157) to 33% (40 of 122) ( $p < 0.005$ ). The compression sleeves were not applied in 84% of the nonfunctional devices and were properly in place but the pump nonfunctional in 16%. Unfortunately, dedicated in-service instruction did not improve the proper use of EPC.

Although proper application of EPC is better in the ICU compared with regular nursing units, improper use is frequent and failure of DVT prophylaxis with EPC devices may be due to improper use, rather than failure of the method itself.

Postoperative deep venous thrombosis (DVT) remains a major problem in the United States [1]. The early consequences of venous thromboembolic disease are serious, and significant long-term morbidity can also occur. Effective and safe prophylaxis in high-risk patients is desirable. Pharmacologic means of DVT prophylaxis have proven efficacy [2-4], but acceptance has been slow in many medical communities. This is likely due to the clinical silence of postoperative DVT and the low incidence of clinically significant pulmonary embolism (PE), coupled with the fear of bleeding complications from these drugs [5].

External pneumatic compression (EPC) devices have proven to be effective in general surgical, urologic, obstetric, gynecologic, neurosurgical, and orthopedic patients (Table I) [4,6-15]. In 1986, the National Institutes of Health (NIH) Consensus Development Conference on the Prevention of Venous Thrombosis and Pulmonary Embolism endorsed EPC as an effective prophylactic measure [1]. EPC is an attractive alternative to pharmacologic prophylaxis because these mechanical devices have no inherent risk.

After release of the NIH Consensus Report, EPC devices were purchased, and a program for their use was developed for the surgical services at Temple University Hospital. Within a short period of time, however, an unexpectedly high number of patients experienced postoperative venous thromboembolic complications, despite EPC devices being used for prophylaxis. These cases raised physician concern and created doubt about the efficacy of EPC. Observing several patients who had EPC ordered led us to question whether these devices were being properly used, in which case it might not be a failure of the prophylactic method but rather a failure of the proper application of the technique. This prospective study was designed to answer the following questions: (1) How often are EPC devices properly applied and functioning? (2) Is there a difference in compliance between patients in intensive care units and routine nursing services? and (3) Does nursing education increase the proper application and use of EPC devices?

## PATIENTS AND METHODS

One hundred thirty-eight patients having 2 or more risk factors for DVT and who had EPC devices ordered for prophylaxis of postoperative DVT were prospectively studied. Risk factors included male sex, age over 40 years, an operation lasting more than 2 hours, a major orthopedic procedure or neurosurgical procedure, obesity, neoplasm, congestive heart failure, or a previous history of venous thrombosis or pulmonary embolism. The Kendall Sequential External Pneumatic Compression Device (model 5320) was used, which has an 11-second sequen-

From the Department of Surgery, Temple University Hospital, Philadelphia, Pennsylvania.

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Requests for reprints should be addressed to Anthony J. Comerota, MD, Department of Surgery, Temple University Hospital, Broad and Ontario Streets, Philadelphia, Pennsylvania 19140.

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**TABLE I**  
Comparative Studies Using Intermittent External Pneumatic Compression (EPC) for Postoperative Deep Vein Thrombosis (DVT) Prophylaxis

Reference	Patients	Patient Group	% Incidence of DVT	
			Control	EPC
[6]	310	Orthopedic	49	24
[7]	128	Neurosurgery	19	2
[8]	107	Gynecology	35	13
[9]	104	Orthopedic	19	2
[10]	100	General surgery	30	12
[11]	96	General surgery	—	4
[12]	95	Neurosurgery	25	9
[4]	168	Mixed	36	11
[13]	61	Orthopedic	66	6
[14]	53	Urology	25	7
[5]	146	Neurosurgery	18	6

**TABLE II**  
Overall Results in 138 Patients Receiving External Pneumatic Compression Devices

	No. of Patients	No. of Visits	Functioning	% Compliance	
Hospital room	84	636	306	48	
Intensive care unit†	54	398	312	78	p < 0.0001*
Total	138	1,034	618	60	

\* $\chi^2$  analysis with one degree of freedom.

†Patients followed from intensive care unit to hospital room (n = 21) had compliance fall from 82% (129 of 157) to 33% (40 of 122) (p < 0.005).

**TABLE III**  
Results in 85 Patients Who Received an External Pneumatic Compression Device and Who Were Attended by Minimally Trained Nursing Staff

	No. of Patients	No. of Visits	Functioning	% Compliance	
Hospital room	51	466	230	49	
Intensive care unit†	34	307	237	77	p < 0.0001*

\* $\chi^2$  analysis with one degree of freedom.

†Patients followed from intensive care unit to hospital room (n = 11) had compliance fall from 82% (94 of 115) to 30% (21 of 71).

tial compression phase followed by a 60-second vent phase. Kendall Anti-Em stockings (Kendall Co, Boston, MA) were applied to the patients' legs under the inflatable sleeves. The stockings and EPC devices were applied in the operating room after induction of anesthesia. The compression pump was set at 35 to 55 mm Hg pressure at the ankle.

Daily rounds were made on each patient at random

times. Patients were visited no more than twice in 1 day. Patients were followed until they became fully ambulatory, at which time EPC was discontinued. During each patient visit, the EPC device was checked for proper application of the inflatable sleeves and proper functioning of the EPC pump.

Patients were divided into two groups depending on their hospital location. Patients in the intensive care unit (ICU) were compared with patients sent directly to routine nursing units.

The results were also analyzed according to nursing education. Group I consisted of patients whose nurses received routine but minimal instructions on the proper application and the importance of EPC. After an evaluation of the results of the initial cohort of patients, an educational program was developed and presented to the nursing units involved. Group II consisted of patients whose nurses received dedicated in-service training sessions, which emphasized the importance of DVT prophylaxis and in which printed instructions on the proper application and use of EPC devices were distributed.

Statistical analysis of the data was performed with the  $\chi^2$  test with one degree of freedom.

**RESULTS**

Table II summarizes the results of this study. Patients (groups I and II) on routine nursing units had the EPC device properly applied and functioning 48% (306 of 636) of the time compared with 78% (312 of 398) of the time for ICU patients. The difference between the two locations was statistically significant (p < 0.0001). In a cohort of 21 patients followed from the ICU to a routine nursing unit, compliance dropped from 82% (129 of 157) to 33% (40 of 122) (p < 0.005).

The data in Table III summarize the group I patients who were treated by nurses receiving only brief instruction for the rationale and proper application of EPC. Table IV summarizes group II patients who were treated on nursing units receiving formalized instruction including in-service sessions and printed materials. Although there was consistently better performance in the ICU setting compared with the routine nursing units, there was no difference in compliance in group I patients compared with group II patients, indicating that nursing education programs did not lead to improved application of EPC.

The status of the EPC devices in all patients is summarized in Table V. Interestingly, of the patients with nonfunctioning EPC devices, 21% (18 of 86) in the ICU and 15% (50 of 330) on routine nursing units had sleeves properly applied but the compression pump was not functioning (either the pump was not plugged into the electrical outlet, the power switch was not turned on, or the air hose connecting the pump to the sleeve was compressed).

**COMMENTS**

EPC is becoming increasingly popular for DVT prophylaxis. It has been shown to be effective for a broad spectrum of patients at risk for venous thromboembolic complications, and there are only two reported cases of

**TABLE IV**  
Results in 53 Patients Who Received an External Pneumatic Compression Device and Who Were Attended by Comprehensively Trained Nursing Staff

	No. of Patients	No. of Visits	Functioning	% Compliance
Hospital room	33	170	76	45
Intensive care unit <sup>†</sup>	20	91	75	82

\* $\chi^2$  analysis with one degree of freedom.

<sup>†</sup>Patients followed from intensive care unit to hospital room (n = 10) had compliance fall from 83% (35 of 42) to 37% (19 of 51).

**TABLE V**  
Overall Results of Application of External Pneumatic Compression (EPC): Intensive Care Unit (ICU) Versus Hospital Room

EPC Status	% of Visits (ICU) (n = 398)	% of Visits (Hospital Room) (n = 636)
EPC functioning	78 (312)*	48 (306)*
EPC not functioning	22 (86)	52 (330)
Sleeves off	17 (68)	44 (280)
Sleeves on/pump off	5 (18)	8 (50)

\*Numbers in parentheses represent actual number of visits.

associated complications [16,17]. Low-dose subcutaneous heparin has been shown to reduce postoperative DVT and fatal pulmonary embolism [2]; however, EPC has been shown to be more effective in some studies, and physicians need not worry about potential bleeding complications [4,14]. Therefore, it is not surprising that EPC has been rapidly accepted for DVT prophylaxis.

The efficacy of intermittent EPC is achieved through three mechanisms: (1) by increasing the velocity of venous return, thereby reducing stasis; (2) by stimulating regional fibrinolytic activity, thereby reducing hypercoagulability; and (3) by reducing or preventing operative venodilation, thereby reducing endothelial damage. Nicolaidis and colleagues [18] demonstrated that EPC devices minimize stasis by significantly increasing the velocity of femoral venous flow and that sequential compression increased velocity more than single-chamber compression. EPC has also been shown to increase endogenous fibrinolytic activity in the treated limb, and the lytic effect has been detected systemically [19,20]. The magnitude of the fibrinolytic response correlated with the volume of tissue compressed. The application of elastic compression also has been shown to reduce the diameter of the medial gastrocnemius vein during general surgical operations [21]. In separate studies, operative venodilation directly and significantly correlated with venographically proven postoperative DVT [22], and, in the canine model, operative venodilation led to venous endothelial damage [23]. Therefore, EPC can potentially affect all three limbs of Virchow's triad, by avoiding stasis, by modifying hypercoagulability, and by reducing endothelial damage.

Salzman and colleagues [24] demonstrated in urologic patients that equivalent protection from postoperative DVT can be obtained from short-term EPC application (operating and recovery room) compared with long-term application, when convalescence was short and patients resumed full ambulation in the early postoperative period. The prospect of short-term application providing protection to some patients is appealing, because the principal obstacle to the broader use of EPC prophylaxis is rejection by patients who find the inflatable sleeves uncomfortable. Unfortunately, many patients are not fully ambulatory in the early postoperative period, and their

venous thromboembolic risk extends well beyond the recovery room. In some patients, effective prophylaxis may be required for weeks, since the risk of developing venous thromboembolic complications is related to the duration of bed rest and their underlying illness.

This study addresses the issue of the compliance rate of mechanical devices for DVT prophylaxis. We were surprised at the high percentage of improperly applied and/or nonfunctional EPC devices on routine nursing units. These observations differ from those of a previous report that documented only a 6% noncompliance rate [6]. In other studies, the lack of EPC compliance was due mainly to patient discomfort. We found that in 16% of the nonfunctional units, the sleeves were properly applied. However, there were other technical reasons for nonfunction. Either the devices were not turned on or were not plugged into electrical outlets, or the hose connecting the sleeves to the pump was compressed by the wheels of the hospital bed. These errors should be easily corrected; however, removal of the sleeves by patients when a nurse is not in attendance remains a problem.

By the very nature of this study, we did not expect 100% compliance; however, we thought an 80% to 90% compliance rate was reasonable. It was not surprising to find significantly better utilization in the ICU setting, since the nurse is in constant attendance with the patient, and patients are more critically ill, sedated, and less likely to object to the inflatable sleeves.

The observation that nursing education failed to improve proper use of the EPC devices was initially discouraging, although not entirely unexpected. This can be partly explained by patients removing the devices because of discomfort or inconvenience after the nurse has left the room. Additionally, since the devices are relatively simple to apply, it is unlikely that confusion about their application or use leads to poor compliance.

In summary, although EPC devices have demonstrated efficacy, venous thromboembolic complications occurring during their use may be due to a high frequency of noncompliance, especially in patients on routine nursing care units. When mechanical prophylaxis is ordered for patients at high risk for postoperative DVT, and especially for those patients who have no safe alternative form of prophylaxis, physicians and nursing personnel should

recognize the likelihood of noncompliance and extend their efforts to insure proper functional application of these devices. We believe that patient education is important, and, with additional effort in this area, the compliance rate of EPC should improve.

## REFERENCES

1. National Institutes of Health Consensus Development Conference. Prevention of venous thrombosis and pulmonary embolism. *JAMA* 1986; 256: 744-9.
2. Collins R, Scrimgeour A, Yusuf S, Peto R. Reduction in fatal pulmonary embolism and venous thrombosis by perioperative administration of subcutaneous heparin: overview of results of randomized trials in general, orthopedic and urologic surgery. *N Engl J Med* 1988; 318: 1162-73.
3. Comerota AJ, White JV. The use of dihydroergotamine and heparin in the prophylaxis of deep vein thrombosis. *Chest* 1986; 89: 389-95.
4. Borow M, Goldson H. Postoperative venous thrombosis: evaluation of five methods of treatment. *Am J Surg* 1981; 141: 245-51.
5. Pachter HL, Riles TS. Low-dose heparin: bleeding and wound complications in the surgical patient: a prospective randomized study. *Ann Surg* 1977; 186: 669-72.
6. 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: 2313-7.
7. Turpie AGG, Gallus AS, Beattie WS, Hirsh J. Prevention of venous thrombosis in patients with intracranial disease by intermittent pneumatic compression of the calf. *Neurology* 1977; 27: 435-8.
8. Clarke-Pearson DL, Synan IS, Hinshaw WM, Coleman RE, Creasman WT. Prevention of postoperative venous thromboembolism by external pneumatic calf compression in patients with gynecologic malignancy. *Obstet Gynecol* 1984; 63: 92-8.
9. Hartman JT, Pugh JL, Smith RD, Robertson WW, Yost RP, Janssen HF. Cyclic sequential compression of the lower limb in prevention of deep venous thrombosis. *J Bone Joint Surg [Am]* 1982; 64: 1059-62.
10. Hills NH, Pflug JJ, Jeyasingh K, Boardman L, Calnan JS. Prevention of deep vein thrombosis by intermittent pneumatic compression of calf. *BMJ* 1972; 1: 131-5.
11. Nicolaidis AN, Miles C, Hoare M, Jury P, Helmis E, Venniker R. Intermittent sequential pneumatic compression of the legs and thromboembolism deterrent stockings in the prevention of postoperative deep venous thrombosis. *Surgery* 1983; 94: 21-5.
12. Skillman JJ, Collins REC, Coe NP, *et al.* Prevention of deep vein thrombosis in neurosurgical patients: a controlled, randomized trial of external pneumatic compression boots. *Surgery* 1978; 83: 354-7.
13. Hull R, Delmore TJ, Hirsh J, *et al.* Effectiveness of intermittent pulsatile elastic stockings for the prevention of calf and thigh vein thrombosis in patients undergoing elective knee surgery. *Thromb Res* 1979; 16: 37-45.
14. Coe NP, Collins REC, Klein LA, *et al.* Prevention of deep vein thrombosis in urologic patients: a controlled, randomized trial of low-dose heparin and external pneumatic compression boots. *Surgery* 1978; 83: 230-4.
15. Black PM, Crowell RM, Abbott WM. External pneumatic calf compression reduces deep venous thrombosis in patients with ruptured intracranial aneurysms. *Neurosurgery* 1986; 18: 25-8.
16. Parra RO, Farber R, Feigel A. Pressure necrosis from intermittent pneumatic compression stockings [letter]. *N Engl J Med* 1989; 321: 1615.
17. Pittman GR. Peroneal nerve palsy following sequential pneumatic compression [letter]. *JAMA* 1989; 261: 2201-2.
18. Nicolaidis AN, Fernandes JF, Pollock AV. Intermittent sequential pneumatic compression of the legs in the prevention of venous stasis and postoperative deep venous thrombosis. *Surgery* 1980; 87: 69-76.
19. Tarney 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: 489-96.
20. Inada K, Koike S, Shirai N, Matsumoto K, Hirose M. Effects of intermittent pneumatic leg compression for prevention of postoperative deep venous thrombosis with special reference to fibrinolytic activity. *Am J Surg* 1988; 156: 602-5.
21. Coleridge-Smith P, Hasty JH, Scurr JH. Prophylaxis for deep vein thrombosis—the effect of graduated compression stockings on venous distention. Proceedings of the American Venous Forum, Ft. Lauderdale, Florida, February 20-22, 1991.
22. Comerota AJ, Stewart GJ, Alburger PD, White JV. Operative venodilation: a previously unsuspected factor in the etiology of postoperative deep vein thrombosis. *Surgery* 1989; 106: 301-9.
23. Stewart GJ, Alburger PD, Stone EA, Soszka TW. Total hip replacement induces injury to remote veins in a canine model. *J Bone Joint Surg [Am]* 1983; 65: 97-102.
24. Salzman EW, Ploetz J, Bettman M, Skillman J, Klein L. Intraoperative external pneumatic compression to afford long-term prophylaxis against deep vein thrombosis in urologic patients. *Surgery* 1980; 87: 239-42.