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NEUROCRITICAL CARE SOCIETY

ORIGINAL WORK

# Sequential Pneumatic Compression in the Arm in Neurocritical Patients with a Peripherally Inserted Central Venous Catheter: A Randomized Trial

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## Abstract

**Background:** Peripherally inserted central venous catheters (PICCs) are increasingly used for parenteral access in critically ill hospitalized patients, but they increase the incidence of upper extremity deep venous thrombosis (UE DVT). Sequential compression devices (SCDs) applied to the legs effectively reduce lower extremity DVT, but have not been tested in the arms. Our objective was to determine whether SCDs applied to the arm may reduce the risk of PICC-associated UE DVT.

**Methods:** This was a retrospective study of randomized, single-center, controlled clinical trial on patients hospitalized in the intensive care unit with critical neurological illness who had a PICC and were not receiving anticoagulants. Between January 2014 and October 2016, patients were randomized 1:1 to an intervention group having a custom SCD applied to the arm harboring the PICC or to a control group. The primary endpoint was ultrasound-detected UE DVT.

**Results:** Following randomization of 77 subjects, the study was terminated due to excess DVT in the treatment arm. UE DVT was detected in 18 subjects (29.0%), and it was more frequent among those in the SCD group (13/31 [41.9%] vs. the control group 5/31 [16.1%]; $p = 0.049$). After accounting for crossovers, the difference was still significant (12/28 [43.0%] vs. 6/34 [17.6%]; $p = 0.048$). Yet, symptomatic UE DVT ($n = 3$) and pulmonary embolism without evidence of lower extremity DVT ($n = 2$) were only observed in patients who were not wearing the SCD on the arm.

**Conclusions:** Although UE DVT is commonly associated with PICC use, the results of this trial do not support the use of SCD on the arm for DVT prevention. Further research on this strategy may nonetheless be justified.

**Trial Registration:** This trial was registered in ClinicalTrials.gov under the identifier NCT01670188.

**Keywords:** Deep venous thrombosis, Upper extremity, Intermittent pneumatic compression, Sequential compression device

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## Introduction

Peripherally inserted central venous catheters (PICCs) were initially conceived for a long-term administration of total parenteral nutrition and intravenous medications in the outpatient setting [1]. More recently, PICCs have become increasingly used for the treatment of critically ill patients in the intensive care unit (ICU) [2, 3]. When compared with centrally inserted, non-tunneled central venous catheters, PICCs have the advantages of being easier to insert and having a lower risk of causing mechanical complications during their insertion [1]. Specialized insertion teams have been created in some centers [4]. Yet, PICCs increase the risk of upper extremity deep venous thrombosis (UE DVT) [5–11].

The reported incidences of UE DVT among patients with a PICC have been quite variable across studies depending on the characteristics of the patient cohort, whether surveillance diagnostic studies were used to detect asymptomatic events, and the type of catheter utilized [6, 12]. Nonetheless, a meta-analysis of 64 studies demonstrated that the risk of PICC-related UE DVT is greatest among critically ill patients, with a combined weighted frequency of 13.91% (95% CI 7.68–20.14) [5]. Thus, identifying safe ways of reducing this risk would be valuable in clinical practice, particularly for patients in whom therapeutic anticoagulation could be hazardous.

Sequential compression devices (SCDs) have been shown to reduce the incidence of lower extremity DVT among hospitalized patients, and they are consistently used for this indication in the ICU [13, 14]. The intermittent pneumatic compression exerted by these devices facilitates venous drainage and prevents blood stasis, consequently reducing the risk of clot formation [15]. In addition, SCDs might stimulate fibrinolysis [16], which would explain the observation that the risk of lower extremity DVT could be lowered when SCDs are applied to the arm [17]. Yet, SCDs are most effective locally and their use in the legs is probably insufficient to minimize the risk of PICC-related UE DVT.

Consequently, we designed the current pilot trial to evaluate whether the use of an SCD custom-made for the arm could lower the risk of UE DVT among patients with neurocritical illness and a PICC who were not receiving chemoprophylaxis with anticoagulants.

## Methods

### Trial Design

Between January 2014 and October 2016, all patients admitted to the Neuroscience ICU at Mayo Clinic, Rochester, and receiving a PICC were screened for study participation. Patients were invited to participate in the study unless they were receiving anticoagulation (prophylactic or therapeutic), had history of recurrent unprovoked DVTs or a defined thrombophilia, had lymphedema, had trauma affecting the arm, or the PICC was expected to be removed within the following 5 days. Randomization using sealed opaque envelopes occurred within 12 h following PICC insertion after obtaining informed consent from the patient or legal surrogate. The study was approved by our Internal Review Board, and the trial was registered in ClinicalTrials.gov under the identifier NCT01670188. The investigators were responsible for monitoring the safety of the study (no independent data safety and monitoring board was mandated by the Internal Review Board).

Patients were randomized to an active group in which an SCD was applied as continuously as possible to the arm harboring the PICC or to a control group. Randomization was performed using sequentially numbered, sealed envelopes stratified by age and sex (four sets of envelopes corresponding to each of the four strata). Because of practical reasons, neither patients nor caregivers were blinded to the treatment arm. As per our standard practice, all patients had a 5-French, double-lumen PICC (unless specifically requested by the treating team because of greater need for access). The PICC was placed preferentially through the right basilic vein, under ultrasound guidance and advanced until the tip of the catheter reached the superior vena cava (tip placement confirmed using electrocardiographic technology). The SCD employed in this study was especially designed by DJO Global for its application in the arm (Fig. 1). The device was a modified version of the VenaFlow system approved for prevention of DVT in the legs. Subjects wore a netted sleeve underneath the SCD to keep it in place. All patients were treated with bilateral SCDs on the legs as per routine practice in our

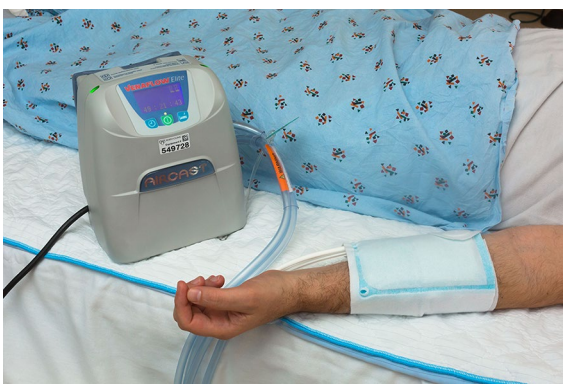

**Fig. 1** Photograph of SCD for application on the arm designed for this trial

ICU. Patients were only treated with anticoagulants in any dose if a thrombosis was diagnosed.

Subjects were examined with venous compression ultrasonography of the relevant arm 5–7 days after PICC insertion and, if the PICC was still in place, 12–14 days post-insertion. All ultrasounds were reviewed by two vascular radiologists, including one of the investigators (TAM or BDL). Sonographers and radiologists were blinded to the group assignment. Cases of disagreement were resolved by consensus. Sonographers were instructed to fill a data collection form that included the following elements: vein visualization, presence of thrombus, location of thrombus, deep venous system involvement, vein compressibility and venous wall thickening.

### Endpoints

The primary endpoint of the study was the rate of ultrasound-confirmed UE DVT (symptomatic and asymptomatic) in the arm harboring the PICC. Acute UE DVT was defined as non-compressible, distended, occlusive or non-occlusive filling defect in the brachiocephalic, subclavian, axillary or brachial veins (thrombus confined to the cephalic and basilic veins was considered superficial vein thrombosis). Secondary endpoints were symptomatic UE DVT, extensive UE DVT, combined rate of DVT and pulmonary embolism, asymptomatic UE DVT, lower extremity DVT and adverse effects attributable to the SCD. Extensive UE DVT was considered present when the thrombus involved the axillary, subclavian or brachiocephalic veins.

### Statistical Analysis

Based on the available literature at the time of the trial design, for our power calculation, we estimated an incidence of ultrasound-detected PICC-related DVT of 35% for the control group. For the use of SCD to be clearly justified, we decided that it should reduce the number of events by more than two-thirds; consequently, we estimated an incidence of ultrasound-detected PICC-related DVT of 10% for the SCD group. Using these numbers, we calculated that 51 patients per group would provide 80% power to detect a difference with a cutoff $p$ value of 0.05. However, enrollment was stopped before reaching target because of safety concerns.

Results were analyzed using modified intention to treat analysis where subjects with upper extremity ultrasound were only included in the analysis. Given the possibility of crossovers because of local discomfort, the conduction of a secondary analysis per protocol (i.e., as treated) was also pre-specified. Descriptive summaries are reported as median and range for continuous variables and frequencies and percentages for categorical variables. Comparisons between groups were assessed with the Fisher exact test for categorical variables and the Wilcoxon rank sum test for continuous variables, as applicable. All tests were two-sided, and $p$ values $< 0.05$ were considered statistically significant. Analysis was performed using SAS software version 9.4 (SAS Inc. Cary, NC).

### Role of the Sponsor

Financial support for research coordination, ultrasound evaluations, statistical analysis and custom SCDs were provided by DJO Global (Vista, CA). The sponsor did not have any participation in the analysis of the results or the writing of this report.

## Results

We enrolled 77 into the trial, 37 randomized into the SCD group and 40 to the control group, before the study was terminated because of safety concerns. Of those 77 subjects, 15 were excluded. The reasons for exclusion were PICC removal before first ultrasound ($n=7$), discharge before first ultrasound ($n=3$), patient's request to be withdrawn from the study because of discomfort wearing the SCD on the arm ($n=3$) and death before first ultrasound ($n=2$). Thus, 62 subjects, 31 randomized to each group, were evaluated with at least one ultrasound. Three subjects subsequently refused to wear the SCD within the first 24 hours after enrollment due to local discomfort; these subjects were considered cross-overs. As a consequence, 28 subjects were actually treated with the SCD and 34 were not (Fig. 2).

Median age in the entire cohort was 56 years (interquartile range [IQR] 48–66), and 40 (64.5%) were women. The most common primary diagnosis was subarachnoid hemorrhage in 32 subjects ($n=51.6\%$). Thirteen (21.0%) patients were active smokers, and four (6.5%) had active

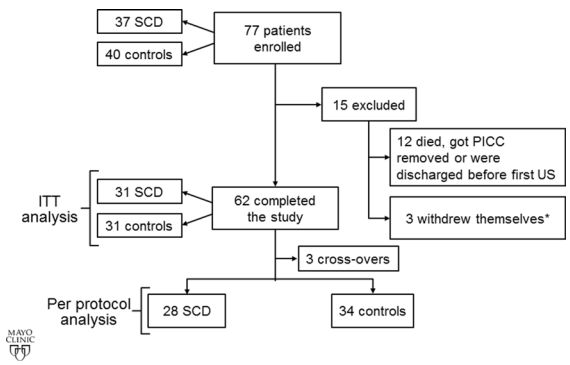


**Fig. 2** Trial flow diagram. US, ultrasound. *Two subjects refused to use the SCD upon first attempt at placement. **These three subjects refused to continue wearing the SCD before the first ultrasound

**Table 1 Baseline characteristics of the trial cohort**

| Variable | SCD group ($n=31$) | Control group ($n=31$) |
|---|---|---|
| Age* | 62 (27–83) | 52 (18–83) |
| Female sex | 20 (64.5) | 20 (64.5) |
| Primary diagnosis | | |
| TBI | 1 (3.2) | 4 (12.9) |
| SAH | 16 (51.6) | 17 (54.8) |
| ICH | 3 (9.7) | 4 (12.9) |
| Other | 11 (35.5) | 6 (19.4) |
| Hypertension | 13 (41.9) | 17 (54.8) |
| Diabetes mellitus | 5 (16.1) | 5 (16.1) |
| CHF | 1 (3.2) | 2 (6.5) |
| Previous VTE | 1 (3.2) | 1 (3.2) |
| Surgery within previous month | 2 (6.5) | 2 (6.5) |
| Smoking | | |
| None | 15 (48.4) | 11 (35.5) |
| Past | 11 (35.5) | 12 (38.7) |
| Active | 5 (16.1) | 8 (25.8) |
| Cancer | | |
| None | 26 (83.9) | 27 (87.1) |
| Past | 2 (6.5) | 3 (9.7) |
| Active | 3 (9.7) | 1 (3.2) |
| Coma | 7 (22.6) | 13 (41.9) |
| Intubation | 19 (61.3) | 20 (64.5) |
| Neurosurgical intervention | 27 (87.1) | 26 (83.9) |
| Hemiparesis on PICC arm | 3 (9.7) | 6 (19.4) |
| Site of PICC access | | |
| Basilic vein | 23 (74.2) | 23 (74.2) |
| Cephalic vein | 2 (6.5) | 0 (0) |
| Brachial vein | 6 (19.4) | 8 (25.8) |
| PICC duration | 8 (4–31) | 8 (4–19) |

All shown as median (range) or *n* (%)

*CHF* congestive heart failure, *ICH* intracranial hemorrhage, *PICC* peripherally inserted central venous cather, *SAH* subarachnoid hemorrhage, *SCD* sequential compression device, *TBI* traumatic brain injury, *VTE* venous thromboembolism

**p* value from Wilcoxon rank sum test is statistically significant ($p=0.03$)

cancer. Nine (14.5%) patients had hemiparesis affecting the arm harboring the PICC. Three patients had triple-lumen catheters because of greater need for access, and the PICC was inserted into the basilic vein in 46 patients (74.2%), the brachial vein in 14 (22.6%) and the cephalic vein 2 (3.2%). Median duration of PICC use was 8 days (IQR 5–12). There were no major baseline differences between the two groups (Table 1).

Among the 62 subjects that were evaluated with at least one ultrasound (24 had 2 ultrasounds), UE DVT was detected in 18 subjects (29.0%; 14 on the first ultrasound and 4 on the second ultrasound) and it was more frequent among those in the SCD group (13/31 [41.9%] vs. 5/31 [16.1%]; $p=0.049$) (Table 2). After accounting for crossovers, the difference was still significant (12/28 [43.0%] vs. 6/34 [17.6%]; $p=0.048$). There were no associations between baseline variables, including vein accessed for PICC placement, and occurrence of UE DVT (Supplemental Table).

Extensive UE DVT was noted in four subjects (6.5%) evaluated with at least one ultrasound. Two of them had been randomized to the SCD group and two to the control group. However, one of the two subjects with extensive UE DVT assigned to the SCD group had refused to wear the device (i.e., crossover) since the day after randomization. Thus, three of the four patients with extensive UE DVT had not been treated with SCD on the arm. Symptomatic UE DVT was diagnosed in three subjects (4.8%), two in the control group and the one crossover mentioned above. Pulmonary embolism (symptomatic but non-fatal) was diagnosed in two subjects (3.2%), one in the control group and the other in the same crossover subject; in both cases, there was concomitant extensive UE DVT and no evidence of DVT on ultrasound imaging of the legs. Consequently, symptomatic UE DVT and pulmonary embolism were only observed in patients who were not wearing the SCD on the arm. There were two episodes of lower extremity DVT; both were

**Table 2 Primary and main secondary endpoints**

| Endpoint | SCD group ($n=31$) | Control group ($n=31$) | Odds ratio 95% CI | *p* value** |
|---|---|---|---|---|
| UE DVT | 13 (41.9%) | 5 (16.1%) | 3.76 (1.14, 12.39) | 0.049 |
| Extensive UE DVT | 2 (6.5%)* | 2 (6.5%) | 1.00 (0.13, 7.59) | 1.0 |
| Symptomatic UE DVT | 1 (3.2%)* | 2 (6.5%) | 0.48 (0.04, 5.62) | 1.0 |
| Pulmonary embolism | 1 (3.2%)* | 1 (3.2%) | 1.00 (0.13, 7.59) | 1.0 |
| Lower extremity DVT | 2 (6.5%) | 0 (0%) | > 999 (0, > 999) | 0.492 |

*UE DVT* upper extremity deep venous thrombosis, *SCD* sequential compression device

*Including or representing the same subject who refused to wear the SCD from the day after randomization

***p* value from Fisher's exact test

asymptomatic and diagnosed on surveillance ultrasound ordered by the treating team. Both subjects had been assigned to the SCD group, and one of the two had a concomitant UE DVT.

The device was generally well tolerated, but local discomfort was reported by some subjects and limited participation or adherence. Three subjects were excluded from the study because they refused wearing the device immediately and three subjects were crossovers because they accepted to use the device initially but shortly after (within 48 h) decided to stop using it, and two other subjects reported discomfort and requested the device to be removed intermittently, but remained on the SCD group. Thus, there were five patients (13.5%) included in the study who reported discomfort with the device. There were no episodes of bruising or skin breakdown were noted. Median time on SCD was 153 h (IQR 124–256), and median time off was 6 h (IQR 3–10). Time off SCD was not associated with the occurrence of UE DVT.

## Discussion

Nearly one in three neurocritically ill patients had a PICC-related UE DVT on this pilot trial evaluating the potential utility of an SCD applied to the arm. The rate of UE DVT was actually higher among patients assigned to the SCD group and also among those who were actually adherent to the protocol. However, the clots observed in the SCD users were confined to the brachial vein. A much smaller number of patients had more serious venous thromboembolism (extending to more proximal veins, locally symptomatic or associated with pulmonary embolism), and those patients were mostly not using SCD on the arm.

The rate of ultrasound-detected UE DVT in our cohort is comparable with the previous literature using surveillance compression ultrasound in asymptomatic critically ill patients [3, 5]. The previous literature indicates that critical illness, cancer and larger catheters with more lumens are associated with greater risk of PICC-related DVT [5, 18–20]. Almost all of our patients had small-caliber (5-French), double-lumen catheters to minimize this risk [21, 22]. As noticed in our study, most PICC-related DVTs are asymptomatic [5, 6]. Yet, the occurrence of pulmonary embolism in association with proximal UE DVT in the absence of DVT in the legs has been well documented [6, 12].

The higher incidence of brachial vein thrombosis in the SCD group led to the termination of this pilot trial and indicates that using an SCD on the arm, as implemented in our study, is not safe for clinical practice. The reason for the increased rate ultrasound-detected brachial vein thrombosis in our SCD cohort is unclear. Yet, it is noteworthy that all cases of symptomatic venous thromboembolism in our cohort occurred in patients who were not using the SCD. Given that the number of these cases was very small, it is possible that this finding could have been coincidental. However, a protective effect of the SCD against the formation of larger thrombus and embolism cannot be entirely excluded.

Our trial has several limitations. The decision to stop the trial because of safety concerns could be questioned. A priori, we thought that the SCD device would confer minimal risks to the subjects. Our Institutional Review Board (IRB) agreed and consequently did not mandate the formation of an independent Data Safety Monitoring Board. The termination of the study followed an interim analysis prompted by slow pace of recruitment and the need to decide whether it would be worthwhile to extend the funding. To our surprise, we then found out about the excess rate of brachial vein thrombosis in the SCD arm of the study. At that point, we thought most prudent to terminate the study while accepting that this premature termination would render our results inconclusive.

Other limitations should also be noted. Lack of adherence to the use of SCD on the arm (withdrawals immediately after randomization, refusal to continue using the device shortly after randomization) made interpretation of the results less straightforward. Sepsis can induce a state of hypercoagulability; while sepsis was uncommon in our cohort, we did not formally collected information on its occurrence. The external validity of the findings is reduced by the exclusion of patients receiving prophylactic anticoagulation. This exclusion criterion obeyed to our intention to enrich our cohort with subjects at higher risk of UE DVT, especially considering that our practice is to use small PICCs (5-French, double lumen). Current guidelines support the use of anticoagulation in most neurocritical patients, including those with ventriculostomy catheters and intracranial hemorrhage [23], but it is not uncommon to find patients in any neurocritical care unit who are not treated with prophylactic anticoagulation. Furthermore, the value of chemoprophylaxis for PICC-related DVT is not well established [12], though it might be useful [24, 25].

UE DVT is a common problem among neurocritically ill patients who have a PICC, and it can be associated with major complications. Therefore, finding effective ways of preventing PICC-related UE DVT is a medical necessity. When possible, using smaller catheters and considering chemoprophylaxis with anticoagulation may help reduce the risk of PICC-related UE DVT. However, these strategies may be insufficient. While the results of this trial do not support the use of SCD on the arm, we believe that it does not negate the potential value of the concept. Additional testing with a refined implementation (e.g., combined with chemoprophylaxis, evaluating a

different SCD device, using a clinical primary endpoint) may be justified.

**Electronic supplementary material**
The online version of this article (https://doi.org/10.1007/s12028-019-00765-w) contains supplementary material, which is available to authorized users.

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**Author's Contribution**
AAR contributed study design, enrollment of subjects and manuscript preparation. JDH contributed enrollment of subjects and review of the manuscript. JM contributed statistical analysis and review of the manuscript. TAM contributed data collection (ultrasound read) and review of the manuscript. BDL contributed data collection (ultrasound read) and review of the mansucript. RDM contributed review of the manuscript.

**Source of Support**
Funding was provided by DJO Global.

**Compliance with Ethical Standards**

**Conflicts of Interest**
Alejandro A. Rabinstein received support from DJO Global for the conduction of the study (without personal remuneration). Jodi D. Hellickson, Thanila A. Macedo, Bradley D. Lewis, Jay Mandrekar, and Robert D. McBane II declare that they have no conflict of interest.

**Ethical Approval/Informed Consent**
The study was approved by the Mayo Clinic Institutional Review Board. All participants were enrolled into the study after they or they surrogate provided written informed consent.

## Publisher's Note



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