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The Application of Intermittent Pneumatic Compression Devices for Thromboprophylaxis

An observational study found frequent errors in the application of these mechanical devices in ICUs.

Venous thromboembolism (VTE), including deep vein thrombosis (DVT) and pulmonary embolism, is common, though preventable, in critical care. DVT can occur in critical illness despite thromboprophylaxis. The reported incidence of DVT in critically ill patients receiving thromboprophylaxis varies from 3% to 15%, depending on the population studied and the methods of DVT detection.[1-4] A report of VTE in patients receiving thromboprophylaxis in a medical ICU showed DVT present in 2% of patients on admission and 10% diagnosed during the ICU stay; risk factors included prior history of VTE, renal failure, the use of vasopressors, and the transfusion of platelets.[2] In a 2012 study, pulmonary embolism was found in 33% of patients with known DVT, and 46% had received thromboprophylaxis.[5]

Thromboprophylaxis, using either chemical or mechanical strategies or both, can reduce the incidence of VTE in the critically ill, and VTE prophylaxis is recommended for all critically ill patients.[6] Anticoagulation has been better studied than mechanical strategies. Current guidelines recommend either unfractionated or low-molecular-weight heparin for critical care patients.[6] The efficacy of and the role for mechanical devices such as graduated compression stockings and intermittent pneumatic compression (IPC) devices is less clear: there are fewer studies and they've produced conflicting results. Evidence suggests that IPC devices are less effective than chemical strategies in DVT prevention but superior to no prophylaxis.[7-10] IPC devices do not appear to have an impact on pulmonary embolism. The sole use of mechanical prophylaxis is recommended in patients who are bleeding or at high risk for bleeding; pharmacologic agents can be substituted for or added to mechanical prophylaxis when bleeding risk decreases.[11]

Unfortunately, VTE prophylaxis is often not provided as indicated and is recognized as a focus for performance improvement by public agencies and private organizations concerned with patient safety, including the Centers for Medicare and Medicaid Services, the National Quality Forum, the Joint Commission, and the Agency for Healthcare Research and Quality.[12] A recent analysis of national quality initiatives in this area concluded that, despite the availability of evidence-based guidelines for VTE prevention, strategies are underused and inappropriately prescribed.[12] Hospitals were charged with identifying areas for improving VTE prophylaxis, including risk assessment, appropriate prescribing, monitoring, and follow-up. To date, most quality improvement efforts have centered on educating health care providers and developing risk assessment models, evidence-based guidelines, and computerized alerts.

Mechanical prophylactic devices such as IPC devices, used widely in practice, are applied, maintained, and monitored exclusively by nursing personnel—RNs, LPNs, and certified nursing assistants. IPC devices operate by applying pressure to the extremity in either a uniform or graduated fashion (they're often collectively referred to as "sequential compression devices," or SCDs, even when the compressions are not applied sequentially). An electrically operated pump intermittently inflates sleeves wrapped around the lower legs or the lower legs and thighs, compressing the veins and increasing venous blood flow toward the heart. The IPC device system used exclusively in our facility had a single posterior bladder in each wraparound calf sleeve designed to inflate uniformly

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ABSTRACT

Objective: Because venous thromboembolism (VTE) can be a devastating consequence of critical illness, patients should receive thromboprophylaxis using chemical or mechanical strategies or both. Mechanical strategies such as intermittent pneumatic compression (IPC) devices are in widespread use; this study sought to assess clinicians' adherence to ordered IPC devices in critically ill patients.

Methods: A month-long prospective, observational study was conducted in a convenience sample of 108 mechanically ventilated patients in four adult ICUs in an urban academic medical center. Observations of prescribed IPC device applications were made twice daily by nurses using a standardized checklist.

Results: Nine hundred sixty-six observations were made of 108 patients, 47 (44%) of whom were ordered to receive thromboprophylaxis with IPC devices alone and 61 (56%) to receive IPC devices in combination with an anticoagulant. Errors in IPC device application were found in 477 (49%) of the observations. Patients received no IPC prophylaxis in 142 (15%) of total observations. In 45 of 342 (13%) of the observations, IPC devices were the only type of thromboprophylaxis ordered. Half of the misapplications related to improper placement of sleeves to legs. Misapplications did not differ in type or frequency between shifts.

Implications: The researchers observed frequent misapplications of ordered IPC devices. Future study is necessary to illuminate the consequences of such errors.

Keywords: critical care, deep vein thrombosis, intermittent pneumatic compression devices, mechanical ventilation, pulmonary embolism, thromboprophylaxis, venous thromboembolism

to 40 mmHg (or to a pressure selected by the operator) on a 60-second, automatically timed cycle (12 seconds of inflation and 48 seconds of deflation). Sequential compression devices employ a pattern of compression in which chambers in the sleeve inflate sequentially: the ankle bladder inflates initially to a maximum pressure (45 to 50 mmHg), followed by inflation of more proximal bladders to lower pressures at the calf (35 mmHg) or thigh (30 mmHg). Inflation cycles of 11 seconds of compression followed by 60 seconds of relaxation are common.

A practice alert on VTE prevention issued by the American Association of Critical-Care Nurses directed critical care nurses to ensure that such devices be fitted properly and remain in use at all times, unless removed for cleaning or skin assessment.[1] Likewise, guidelines from the American College of Chest Physicians on mechanical methods of thromboprophylaxis explicitly recommend careful attention to proper use of these devices.[11] Despite this emphasis, little evidence is available on the implementation of mechanical prophylaxis in the critically ill.

Given the importance of VTE prophylaxis, indications that effective measures may be underused or incorrectly applied, and the crucial role of nurses in these endeavors, we investigated the use of IPC devices for thromboprophylaxis in four adult critical care units in our facility. Our primary aim was to observe and describe the adherence to ordered mechanical thromboprophylaxis. Our secondary aim was to evaluate whether the time of day or the unit location affected the accuracy in application of the IPC devices.

METHODS

Study design. Since our goal was to examine real-time IPC device applications and perhaps to improve mechanical thromboprophylaxis, we chose to conduct a direct-observation study. We believed this method would be the most appropriate way to understand existing clinical practices. We anticipated that our results could provide a first step in informing changes in practice and provide focus for future research.

Despite the availability of evidence-based guidelines for VTE prevention, strategies are underused and inappropriately prescribed.

Sampling. We selected a convenience sample of patients undergoing mechanical ventilation at an urban academic medical center during a one-month period in four adult ICUs: a cardiac critical care unit, a medical ICU, a neuroscience ICU, and a surgical ICU. The study was approved by the institutional review board, and because it was observational in nature, informed consent was waived.

Data collection. During the 31-day study period (January 1 to 31, 2011), patients were observed twice

Table 1. Observations of Intermittent Pneumatic Compression Device Applications, by Unit and Shift

Units	No. of Patients	7 AM to 7 PM		7 PM to 7 AM	
		No. of Observations	No. of Observations with Misapplications (% of total shift observations)	No. of Observations	No. of Observations with Misapplications (% of total shift observations)
Unit A: cardiac critical care unit	5	16	5 (31)	22	13 (59)
Unit B: medical ICU	20	47	20 (43)	48	11 (23)
Unit C: neuroscience ICU	43	190	44 (23)	197	94 (48)
Unit D: surgical ICU	40	207	147 (71)	239	143 (60)
Total	108	460	216 (47)	506	261 (52)

each day for the duration of their mechanical ventilation or until the data collection period ended or they died. Patients' age and sex, the unit location, and orders for VTE prophylaxis were recorded. Adherence to ordered IPC devices (Flowtron Excel, manufactured by ArjoHuntleigh Inc.) in use in all ICUs at the time of data collection was ascertained by nurses observing the devices twice daily, once during the day shift (7 AM to 7 PM) and once during the night shift (7 PM to 7 AM).

The observers were six RN data collectors employed by the medical center, including three of us (EE, KK, PAS), using a checklist we devised according to the manufacturer's operating instructions. Data collection assignments were completed by date and shift; that is, each day one observer completed all observations during the day shift and another during the night shift. Patients, visitors, and staff nurses were not aware of the study or the observers' purpose. If observers were asked about the purpose of their visits to the bedside, they were instructed to say that they were "checking on therapies ordered for patients receiving mechanical ventilation." The observers made no attempts to influence the use of IPC devices.

Observations were not recorded if a patient was off the unit or preparing to leave the unit; personal hygiene procedures were being performed; in-bed assessments, tests, or therapies were in progress; the patient refused ordered IPC devices; or care was being withdrawn at the end of life.

Data analysis. We analyzed data using Microsoft Excel spreadsheets and SPSS software version 15. Data analysis was performed using mean and range functions.

RESULTS

One hundred twenty-three patients in the adult ICUs were identified as receiving mechanical ventilation during the data collection period. Thirteen patients who received chemical thromboprophylaxis alone were excluded from our analysis, as were two patients without any order for thromboprophylaxis. A total of 966 observations of the remaining 108 patients were made during the study period; 42 (39%) of the patients were female, and the average age was 60 years (range, 16 to 90 years).

The ordered thromboprophylaxis was IPC devices for 47 (44%) of the 108 patients and chemical agents plus IPC devices for 54 (50%) of them. Seven patients (6%) received both mechanical prophylaxis and therapeutic doses of an anticoagulant for atrial fibrillation. One patient in the IPC device-only group received graduated compression stockings in addition to IPC devices.

As shown in Table 1, patient observations of IPC device prophylaxis were made twice daily in the four adult critical care units. Of note, all units used a daily-rounds checklist that included prompts for thromboprophylaxis. The number of observations completed per patient ranged from one to 60, with a mean of nine. Errors in the application of IPC devices were found in 477 of the 966 (49%) observations. Overall, unit B (which consisted primarily of medical patients) had the lowest percentage of observed misapplications (33%), and unit D (primarily surgical patients) had the highest percentage (65%). Two hundred sixteen (47%) IPC device misapplications were observed on the day shift and 261 (52%) on the night shift.

The types of IPC device misapplications that occurred are summarized in Table 2. Evaluations were

made according to the following types of possible error:

1. The IPC device equipment was not at the patient's bedside within 12 hours of order placement in the patient's record.
2. The leg sleeves were at the bedside but were not applied.
3. The sleeve was deliberately limited to one leg, and the "single leg" mode on the device was not selected.
4. One or both sleeves were applied to the leg or legs without adequately securing the Velcro wraps, the sleeves were placed too high or too low relative to the calf or calves, or the inflatable bladder was rotated off the calf or calves.
5. One or both of the hoses on the sleeves were not connected to the IPC device pump.
6. The pump was at the bedside but was not turned on or was not inflating properly. If the pump was off, other parameters were not evaluated.
7. The pump pressure was not within 5 mmHg of the recommended pressure (40 mmHg) and no specific pressure was ordered, or an alarm indicating higher or lower than expected pressure or pump failure occurred at the time of observation.

Misapplications occurred in 49% of observations and did not differ in type or frequency between shifts. Notably, ordered mechanical prophylaxis was entirely absent in 142 of 966 (15%) observations because the machine was not at the bedside, the pump was not working, or the sleeves were not applied. Failure to deliver therapy at the time of observation was encountered in 45 of 342 (13%) observations of patients in whom IPC devices were the only ordered method of thromboprophylaxis.

of incorrect pump pressure settings involved unordered pressure settings of 50 mmHg found repeatedly in two patients.

DISCUSSION

We did not set out to evaluate the screening of VTE risk or the appropriateness of ordered thromboprophylaxis in critical care patients. Rather, we chose to examine whether thromboprophylaxis using IPC devices was implemented as ordered. To our knowledge, this is the first report of systematic observations of mechanical thromboprophylaxis practices in critically ill patients. We elected to study ICU patients receiving mechanical ventilation to ensure that all patients studied would be considered at moderate or severe risk for VTE and because in those patients IPC device use would less likely be affected by patient preferences and ambulation.

Although the evidence of their effectiveness is mixed, IPC devices are commonly used in clinical practice. Indeed, we found that IPC devices were ordered in 88% of mechanically ventilated patients eligible for inclusion in our study, a finding similar to those reported by previous investigators in various populations. In the last 15 years, the use of IPC devices was observed in 68% of medical ICU patients,[13] 93% of surgical patients,[14] and 97.5% of severe trauma patients[15] receiving VTE prophylaxis. And investigators have raised concerns about how well mechanical prophylaxis is applied in clinical practice.[10] Our observations found frequent misapplication, with no association to time of day, and ordered IPC devices missing altogether at times.

By comparison, in a study of postoperative patients with two or more risk factors for VTE, IPC

Observers noted about half (51%) of all application errors involved the improper placement of IPC device sleeves on patients' legs.

Observers noted about half (51%) of all application errors involved the improper placement of IPC device sleeves on patients' legs. With rare exceptions, in which the Velcro straps on the sleeves were loose or broken, misapplications entailed one or both sleeves rotating off of the calf so that the inflatable bladder was over the lateral or anterior aspects of the lower leg. When prophylaxis was intended for a single leg, we observed the unapplied sleeve to be wrapped around a towel roll, whether or not the single leg mode was selected. Pressure alarms occurred relatively infrequently. A majority

devices were applied and functioning in 48% of daily observations made of patients on general nursing units and 78% of observations of ICU patients.[16] In a large-scale observational study of medical–surgical inpatients, ordered mechanical prophylaxis was present 60% of the time.[17] Twice-daily observations of surgical patients on general nursing units judged IPC prophylaxis to be effective in 61.5% of observations on surgical units and 48% of observations on medical units.[18] In a study of hospitalized trauma patients, counters were used to monitor the time IPC devices were applied and pumping, which equaled 59% of

Table 2. Observations of Intermittent Pneumatic Compression Device Misapplications

Checklist	No. of Observations with Misapplications		
	7 AM to 7 PM	7 PM to 7 AM	Both Shifts
1. Machine is at bedside	10	11	21
2. Sleeves are applied to patient	2	3	5
3. "Single leg" mode is selected if single leg is used	21	17	38
4. Sleeves are correctly applied to extremity(ies)	109	135	244
5. Sleeves are connected to the pump	0	0	0
6. Pump is turned on and is functioning	49	67	116
7. Pressure level is within recommended or ordered range	25	28	53
Total observations with misapplications (Total observations)	216 (460)	261 (506)	477 (966)

the total time subjects were studied.[19] In 227 postoperative trauma patients ordered to receive IPC devices, six observations of IPC device applications were made in a 24-hour period on each patient after transfer from the ICU.[20] IPC devices were properly applied and functioning in 53% of observations and in all six observations of 19% of patients; early afternoon followed by midmorning were the most common times for misapplications. Reasons proposed for substandard performance in the clinical application of IPC devices included shortcomings of current devices (size, weight, lack of battery option),[19] nursing workload and acuity,[19] lack of definitive evidence of efficacy,[8] failure of clinicians to appreciate the importance of mechanical prophylaxis,[18] inadequate patient and staff education,[17] no requirement to document IPC device use,[18] nurses' unfamiliarity with devices,[18] and patients' discomfort.[16] Notably, proper use of IPC devices did not improve after educational initiatives directed at nurses[16, 18] and patients.[18]

Our primary findings were that IPC devices are commonly prescribed and frequently misapplied. Of the 123 mechanically ventilated patients screened for inclusion in this study, 88% were ordered to receive mechanical prophylaxis with IPC devices either as sole or combination therapy. This high rate was likely influenced by the inclusion of patients with significant bleeding or bleeding risk (as occurs with recent neurosurgical procedures, intracranial hemorrhage, hematologic malignancies, and liver failure, with and without transplantation). We found misapplications of IPC devices in approximately half of all observations, with a range by unit of 33% to 65%. Overall, misapplications occurred almost equally between shifts.

Although we were able to describe the misapplications, we cannot discern their significance, because much is unknown about how these devices work, their influence on VTE risk, their efficacy in VTE prevention, and their optimal application and duration of use.

Virchow's classic description of factors basic to VTE included stasis or reduction in blood flow, vessel injury, and hypercoagulability. IPC devices are thought to reduce DVT risk by increasing the velocity of venous blood flow and by stimulating regional fibrinolytic activity.[7] Investigators recorded compression-related hemodynamic effects including increases in blood flow velocity in femoral veins,[21-23] and in a case study of one patient increased pulse pressure consistent with augmented venous return to the right heart.[24] Endogenous hematologic effects of systemic fibrinolysis have been confirmed with short-term application of IPC devices in healthy male volunteers[21, 23] but not in patients undergoing abdominal surgery.[25] When present, hemodynamic and hematologic outcomes can be affected by the type of device used[23] and may revert to baseline shortly after compressions are discontinued.[21]

A recent and excellent review of the evidence underpinning venous compression devices summarized issues that require further study[26]:

- What amount of leg coverage is optimal? Since the major vessels in the thigh are supplied by vessels in the calf, are thigh sleeves or compressions important to VTE prophylaxis?

- Does sequential compression offer any advantage over uniform compression in terms of augmented venous flow?
- What are the implications of circumferential leg inflation versus noncircumferential (calf bladder) inflation?
- Should graduated compression stockings be used in combination with intermittent compressions? What, if any, is the added benefit?

The findings of our observations suggest additional questions that future research should evaluate.

- Is there an optimal pressure range and duration of pressure application to augment venous flow and fibrinolysis?
- What if inflation does not occur over the calf veins? Is any or all therapeutic benefit lost?
- What, if any, are the consequences of intermittently stopping and starting pneumatic compressions? Does risk of VTE increase?

Without answers to these questions, we cannot comment on the potential consequences of what we observed to be IPC device misapplications. Our finding that in 15% of observations no compressions were given as ordered raises the question of whether these patients were at increased risk for thrombosis; we suggest that further study into this question be conducted.

Limitations. These observational data from a single medical center may not be indicative of practices elsewhere. Data were collected as single-point observations of mechanical prophylaxis practices. We did not intend to determine the duration of any misapplications found during observations or any other misapplications that occurred between observations. Observations were recorded for a one-month period only and specific patient characteristics such as diagnoses and length of stay were not ascertained. Thus, it's not possible to test for associations among IPC device misapplications, total duration of IPC device use, and patient attributes. It's possible that the frequent presence of data collectors on the units may have influenced nursing practice regarding IPC devices. If so, however, we anticipate that this awareness would likely have resulted in more diligence in the correct application of IPC devices. Also, numerous models of IPC devices are available; we studied one model only and cannot comment on other models. Finally, this observational study was designed to evaluate current thromboprophylaxis practices. We did not screen patients for the presence of VTE and do not know how many patients may have suffered from a failure of thromboprophylaxis.

IMPLICATIONS

Mechanical thromboprophylaxis using IPC devices is routine in critical care. We observed that this method of prophylaxis is not often applied as ordered and intended. We believe this provides an opportunity to focus attention and resources on understanding and remediating shortcomings in the use of IPC devices in critical care. Unfortunately, the evidence on which to formulate recommendations is sparse; what evidence there is on the effectiveness of IPC devices in thromboprophylaxis remains mixed. Additionally, we believe that most clinicians do not appreciate key features of IPC device applications; rather, IPC devices are considered straightforward interventions that do not require particular training or scrutiny.

Our suggestions for quality improvement in the area of IPC device use in clinical practice include

- advancing the evidence base for mechanical thromboprophylaxis.
- heightening awareness of critical elements of IPC device applications.
- developing standards and instructional procedures, based on the best evidence available, for the application of IPC devices.
- monitoring of clinicians' performance and the clarification of factors that promote or impede optimal IPC device use.
- implementing improvement strategies most likely to improve performance deficiencies.

At minimum, hospitals need written policies and procedures consistent with national evidence-based standards for thromboprophylaxis and ongoing quality monitoring to assess adherence. Our results suggest that daily checklists are not likely to prevent misapplications of a continuous therapy such as thromboprophylaxis with IPC devices. This is an opportunity for nurses to provide leadership in extending our knowledge of the factors that determine optimal application of IPC devices to reduce VTE risk. Further study will inform quality improvement endeavors by focusing on areas most in need of attention from both clinicians and device manufacturers.

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For example, we observed a problem in maintaining the inflatable bladder in the leg sleeves over the calf—a problem that could be addressed by more frequent checks by nursing personnel and better methods of securement by designers. Finally, studies on the effectiveness of thromboprophylaxis with IPC devices must consider the actual application of these devices and how observed shortfalls influence results. Otherwise, failure to apply them correctly may be misinterpreted as a failure of the therapy itself.

We suggest the following practical considerations of our findings:

- The effectiveness of IPC devices in reducing risk of thromboses may be compromised by misapplication of these devices.
- Increased vigilance by clinicians in the use of IPC devices is warranted.
- Unless evidence directs otherwise, experts' opinions and manufacturers' recommendations should be followed in applying IPC devices. ▼

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