Abstract

Post-thrombotic syndrome (PTS) is a chronic condition that develops in 20-50% of acute deep vein thrombosis (DVT) patients. Its burden includes increased costs, decreased quality of life, and decreased personal productivity. This initiative’s purpose is to prevent PTS progression.
Key words: Deep-vein thrombosis, Post-thrombotic syndrome, American College of Chest Physician guidelines

Post-thrombotic syndrome (PTS) is a chronic condition that develops in 20-50% of patients with previously diagnosed acute DVT; the risk may increase as much as five to ten-fold with a recurrent, ipsilateral DVT (Kahn, Ginsberg, & Houston, 2008a). PTS is classified based on clinical signs/symptoms, such as pain, swelling, erythema, and ulcers (Stain et al., 2005). The overall prevalence of PTS is influenced by the incidence of DVT, but it is estimated that 330,000 people currently suffer from PTS in the United States. Forty percent of patients with a DVT will develop some degree of PTS, with 5-10% developing severe symptoms, such as ulceration (Kahn, Partsch, Vedantham, Prandonis, & Kearon, 2009). The risk of developing PTS extends beyond 1 year (7%) with 14% at five years, 20% at 10 years, and 27% at 20 years post-DVT (Mohr et al., 2000)

Quality of life, disability, and cost define the burden of PTS. The quality of life for patients with PTS can be compared with other chronic diseases, including arthritis, angina, congestive heart failure, chronic lung disease, diabetes, or cancer (Kahn et al., 2008b). This debilitating syndrome impacts quality of life with the presentation of pain, swelling, cramps, and itching that intensify with standing and walking, leading to a decrease in daily activities. PTS has been found to be a predictor of quality of life based on the VEINES-quality of life (VEINES-QOL) tool (Ashrani & Heit, 2009). In populations with chronic venous diseases, PTS has been a key predictor of quality of life immediately following DVT occurrence and within two years (Kahn et al., 2005; Kahn et al., 2008b). Disability from PTS causes an estimated loss of two million workdays annually, leading to a decrease in personal and professional productivity
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(Ashrani & Heit, 2009; Kahn et al., 2008a). PTS patients with detrimental venous ulcers have reported higher rates of absenteeism, more job losses, and more financial challenges due to an abundance of medical expenses (Ashrani & Heit, 2009; Kahn et al., 2008a). The debilitating effects from severe PTS can have a devastating effect on quality of life and activities of daily living.

The prevalence and chronicity of PTS contribute to overall health care costs (Kahn & Gingsberg, 2004). The most expensive complication of PTS is venous ulcers. In the United States, the mean annual cost per person with PTS is estimated at $7,000, with the average cost of treating venous ulcers at $10,000 per patient per year (Ashrani & Heit, 2009). An estimated annual direct cost of venous ulcers in the United States is at least $200 million (Ashrani & Heit, 2009). Western European countries estimate the overall total cost of chronic venous disease to be from $720 million to $1 billion (USD) annually (Kreidy, 2011). Therefore, focusing on the prevention of PTS by implementing evidence based practices can be a cost-effective strategy for health care organizations (Ashrani & Heit, 2009).

Literature Review

Standardization for PTS

In the United States, the American College of Chest Physician (ACCP) guidelines are widely accepted and recommended evidence-based guidelines for prevention and treatment of venous thromboembolism disease, including antithrombotic therapy. These guidelines emphasize the use of compression stockings, early ambulation, anticoagulation, and adherence for successful PTS prevention outcomes (see Figure 1.).

Standardization for PTS is important; inconsistent provider diagnosis and treatment can lead to variances in outcomes, which impacts hospital stays, costs, and continuity of care (Kahn
However, diagnosing PTS is difficult because no gold standards exist to measure or test for PTS. In patients with a confirmed DVT who present with typical clinical symptoms, PTS is often suggested as the diagnosis. Some objective tests for venous valvular incompetence include Doppler ultrasound or plethysmography, but true diagnosis of PTS cannot be made in the absence of clinical symptoms (Kahn & Ginsberg, 2004). Thus, the consistent use of ACCP guidelines for PTS prevention and treatment would facilitate standardization among providers.

**Compression Stockings**

The ACCP has continued to evaluate randomized clinical trials for the efficacy of compression stockings for the prevention of PTS following acute DVT. For the majority of trials, early and long-term results favor knee-high elastic compression stockings with a 30-40 mm Hg ankle gradient pressure, post-proximal DVT (Grade IA). Compression therapy may include use of bandages or elastic compression and should be started soon after starting anticoagulant therapy. Compression is recommended for a minimum of two years and beyond if the patient has continuous symptoms of PTS and stockings are helpful (Guyatt, Akl, Crowther, Gutterman, & Schunemann, 2012). The feasibility of stocking application refers to both the short- and long-term ability of patients and their caregivers to apply and remove stockings (Kearon et al., 2008).

Overall, early use of compression stockings may prevent or substantially reduce the incident of PTS in patients with acute DVT (Brandjes & Buller, 1997; Prandoni et al., 2004). Prevention of PTS was found following direct application of compression stockings post-DVT, with mild to moderate PTS occurring in 20% of patients in the stocking group compared to 47% in the non-stocking group (Brandjes & Buller, 1997). Reduced incidence of PTS was found in patients diagnosed with first episode proximal DVT who wore compression stockings after 6
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months (40% to 21%), after 1 year (47% to 22%), and after two years (49% to 25%) (Prandoni et al. 2004).

This preventive effect or reduced risk may stem from the size of the residual thrombus and venous patency (Arpaia, Cimminiello, Mastrogiacoma, & Gaudenzi, 2007). Arpaia et al. (2007) found compression stockings are safe and effective if applied immediately post-DVT diagnosis, with an increase in recanalized venous segments and popliteal patency.

However, thigh-length compression stockings do not offer better protection against PTS when compared to below-knee compression, and they are less well-tolerated (Prandoni et al., 2012). Thigh-length versus below-knee compression elastic stockings were compared in the prevention of PTS. Assessments and follow-up were completed throughout a 36-month period. PTS developed in 32.6% of the 135 patients randomized to thigh-length and in 35.6% of the 132 patients assigned to below-knee compression stockings. More compression stocking side effects developed in the thigh-length group, which led to noncompliance and early discontinuation of stocking use (Prandoni et al., 2012). Overall, compression stockings have been found to be effective in the prevention and treatment of PTS following diagnosis of DVT.

**Early Ambulation**

Historically, early treatment of acute DVT was strict bed rest and anticoagulation, suggesting that ambulation would mobilize the clot and possibly lead to pulmonary embolism. Based on the ACCP 2012 guidelines, early ambulation, exercise, and leg compression are not detrimental in patients with PTS or DVT, and can decrease pain and swelling. Partsch and Blattler (2000) found that, by the second day in DVT adult patients, compression and early ambulation reduced pain and leg circumference, compared to nine days in the bed rest group (p<0.05), while the risk of pulmonary emboli was not significantly increased. Exercise has also
been found to be an important factor in preventing or stabilizing venous symptoms, reducing calf circumference and improving flexibility (Isma et al., 2007; Kahn, Azoulay, Hirsch et al., 2003; Padberg, Johnston, & Sisto, 2004). If edema and pain are too severe, ambulation can be deferred at that time and the use of compression therapy is recommended (Guyatt et al., 2012).

**Anticoagulation**

The ACCP 2012 guidelines by Guyatt et al. (2012) provide evidence-based recommendations for antithrombotic therapy after DVT. Antithrombotic therapy is significant in the prevention of recurrence of DVT and the progression of PTS. Patients with acute DVT of the leg should have vitamin K antagonist (VKA) therapy as initial treatment (e.g., Warfarin). Bridging, in conjunction with VKA therapy, should include same-day initiation of parenteral anticoagulation, such as a low molecular weight heparin (LMWH), fondaparinux, or intravenous (IV) unfractionated heparin (UFH) (Grade 1B). The initiation of VKA in patients with acute DVT should be started immediately (Grade 1B), and the decision between fondaparinux and LMWH should be based on local and individual considerations of cost, availability, and familiarity (Guyatt et al., 2012). Overall, anticoagulation is a crucial factor in DVT treatment and resolution and must be started immediately upon DVT diagnosis.

**Adherence**

Post-DVT patients must adhere to PTS prevention strategies and the ACCP 2012 guideline recommendations to have successful outcomes after their initial injury. It is important for health care team members to educate and stress the importance of compression stockings, early activity, anticoagulation, and adherence to alleviate signs and symptoms of PTS and enhance personal quality of life and productivity. Continuous patient support and education on available resources will be essential to successful patient outcomes and adherence. Figure 2 on
strategies to improve PTS patient adherence is based on a successful adherence model for multiple sclerosis patients (Worley, 2012). This model is applicable to the prevention of PTS and may help guide professionals in developing successful adherence outcomes in venous disease treatment therapies.

**PTS Diagnosis**

There are three clinical scales used for the diagnosis and severity of PTS, including the Villalta or Prandoni, CEAP classification, and the Ginsberg scale. The Villalta scale (see Figure 3.), first known as the Prandoni scale, recently has been recommended by the Scientific and Standardization Committee of the International Society on Thrombosis and Haemostasis as the standard to define and clinically determine PTS (Prandoni & Kahn, 2009). In 2009, the Thrombosis Interest Group of Canada (TIGC) developed clinical guidelines for PTS and recommended the use of the Villalta scale to diagnose and grade the severity of PTS. Developed in the 1990s, the Villalta scale has been studied and used in various trials. Kahn (2009) best describes the scale, which consists of five patient-rated symptoms, including pain, cramps, heaviness, paresthesia, and pruritis, and six clinician-rated physical signs, including pretibial edema, skin induration, hyperpigmentation, pain during calf compression, venous ectasia, and redness. The signs and symptoms are rated on a four-point scale, 0=none, 1=mild, 2=moderate, 3=severe. A total score ranges from 0-33. Patients are classified as having PTS if their summed score is 5 or greater, or if a venous ulcer is present in the leg with a previous DVT. The most recent classification of severity includes scores 0-4 (no PTS), 5-9 (mild), 10-14 (moderate), and scores 15 and greater as severe (Kahn, 2009). Adequate inter-observer reliability ensures clinicians can generalize if patients have or do not have PTS, using the Villalta scale as a diagnostic tool. Rodger et al. (2008) identified that the physical examination findings included in
the Villalta scale, to assess post-thrombotic syndrome, have good to excellent inter-observer reliability (kappa scores ranging from 0.4 to 0.8). In addition to reliability, the Villalta scale has been correlated with relevant health outcomes, such as patient-perceived health burden, quality of life, and associations with anatomic and physiologic abnormalities associated with chronic venous disease (Kahn, 2009).

**Clinical Problem**

Post-DVT evidence-based practices to prevent PTS are needed within health systems. A previous DVT quality improvement project conducted within the emergency department of a Nebraska Methodist hospital had identified that standard practices for DVT treatment and prevention of PTS prior to discharge were not consistently followed. Therefore, an organizational assessment was conducted to assess current acute care DVT treatment within the inpatient population during 2011. The assessment involved a retrospective chart review on acute DVT patients, comparing the care they received to the ACCP 2012 guidelines and current evidence-based practices on PTS prevention.

**Quality Indicators**

The purpose of this project was to develop and implement a quality improvement initiative at Nebraska Methodist hospital for hospitalized patients with acute DVT to prevent the progression of PTS through education and DVT discharge instruction revisions. The aims of the project included: 1) Conducting an organizational assessment of DVT treatment within the inpatient population during 2011; 2) Comparing organizational results of 2011 DVT inpatient treatments with the recommended ACCP 2012 evidence-based practice guidelines through retrospective chart review to identify PTS preventive strategies; 3) Developing and implementing a quality improvement initiative to prevent the progression of PTS; 4) Conducting
nursing and provider education based on the ACCP 2012 guidelines for post-DVT patients to prevent PTS; and 5) Revising current patient post-DVT discharge instructions to include PTS prevention strategies, compression stockings (30-40 mm Hg) for up to two years, and early ambulation.

Sample and Setting

A sample of 75 charts was retrospectively reviewed. Inclusion criteria included patients a) age 19 and older, classified as an inpatient status, who had been b) diagnosed with a lower extremity DVT by positive duplex ultrasonography (ICD-9 codes 451.1, 453.4-453.52) from January 1, 2011, through December 31, 2011. All adult women who were diagnosed as pregnant were excluded. Of the sample of charts, 52% were men and 48% were women, with a mean of 63 years of age. The average length of stay was 5.5 days. Only 11 of 75 patients received thrombolytic therapy, 16% currently smoked or used tobacco, 27% currently had or had a history of cancer, and 43% had a history of a previous DVT or pulmonary embolism.

Ethical Considerations

Permission for the completion of this project was obtained through the Institutional Review Boards (IRB) of the participating hospital and academic institution, Creighton University. After both IRBs approved the evidence-based project, the investigator began the retrospective chart review within the medical records department.

Action Plan

Following the chart review, the investigator completed the data analysis process to determine gaps within the treatment of post-DVT patients in comparison to the ACCP 2012 antithrombotic treatment guidelines and current literature. Thereafter, a formal, multidisciplinary team meeting, lead by the investigator, took place at the hospital facility to share and discuss the
results of the retrospective chart review with service leaders, clinical educators, providers, and
the performance improvement coordinator. Based on the results, decisions by the
multidisciplinary team included developing an education presentation program, given to the
facility’s Nursing Practice Council and Provider Journal Club, and revising patient DVT
discharge instructions. A pre-and post-test with a sample case study was given to the presenting
audience to evaluate and apply the concepts of the presentation. In addition, patient post-DVT
discharge instructions were altered in KRAMES, the hospital’s discharge instruction program, to
be congruent with the current practice guidelines on PTS prevention recommendations and DVT
care.

Results

Data was obtained on provider orders and completion of the orders by staff. The results
of the written orders by providers for post-DVT patients are described in Table 1. Of the 15% of
patients who received the order for compression stockings day one or day two, only 55% of staff
put them on day one or day two, 9% of staff put them on after day two, and 36% of staff did not
put them on at all. Of the 40% of patients who received the order for ambulation/activity as
tolerated day one or day two, only 13% of the patients ambulated in the hallway or by physical
therapy. At discharge, 25 patients went to a facility and 50 patients went home; 7% had written
or printed specific post-DVT care discharge instructions and 2% had written or printed specific
post-DVT education upon discharge home, respectively. All patients who went home on
anticoagulation had appropriate discharge education on precautions for bleeding risk.

Evaluation
Based on the results of the retrospective chart review and recommendations by the multidisciplinary team, a PTS prevention education program was developed. The 30-minute program target population was providers and nursing staff; hence, the Nursing Practice Council and the Provider Journal Club completed the program in fall 2012. See Table 2 for mean test scores.

Common misconceptions from the Nursing Practice Council included ordering sequential compression devices over compression stockings, the belief that early ambulation in DVT patients causes pulmonary emboli, and the belief that compression stockings show no benefit in post-DVT patients in prevention of PTS. Common misconceptions from the Provider Journal Club included the belief that compression stockings show no benefit in post-DVT patients in prevention of PTS, that, upon discharge, patients should not receive education on their risk for PTS, and consequently, compression stockings should be encouraged for up to two years. The majority of participants in both groups agreed or strongly agreed the program was helpful and would be beneficial in their practice on post-DVT patient care.

Discussion

Compression stockings are the single most effective treatment for delaying the deterioration of skin and subcutaneous lesions that occur in PTS (Cataldo et al., 2012). However, a significant finding in this quality improvement project was the lack of patient orders for compression stockings; when ordered, about half of the patients had no documentation of compression stockings being applied. In all patients, few had orders for compression stockings at discharge; this is slightly lower than what has been found in other studies. The MASTER registry, completed in 2009 by Arpaia, Carpenedo, Pistelli, Mastrogiacomo, Cimminiello, & Agnelli, found that 72.1% of patients enrolled from 2002 through 2004 who had lower extremity
DVT were prescribed compression elastic stockings at hospital discharge. Findings from Cataldo, Pereira de Godoy, & de Barros Jr. (2012) support the clinical indication of compression stocking recommendations within this project. Post-DVT patients should wear compression stockings (30-40 mm Hg) for the prevention of venous disease and PTS; likewise, Cataldo et al. (2012) concluded the prescription for compression stockings may specifically improve symptoms in up to 90% of those with pain, discomfort, and swelling in the legs.

Health care professionals understand that a patient’s lack of activity during their hospital stay can contribute to functional decline (Callen, Mahoney, Grieves, Wells, & Enloe, 2004). In this project, providers were more likely to write for “bedrest” versus “activity as tolerated/ambulation” in post-DVT patients within the first two days of hospital admission. Furthermore, the documentation of frequency of walking post-DVT patients early was minimal. Thus, providers should feel confident in prescribing ambulation among patients with a new DVT. Anderson, Overend, Godwin, Sealy, & Sunderji (2009) analyzed and reviewed the effects of early ambulation, the development of pulmonary embolism, and the progression of a new thrombus in patients with acute DVT. Mobility offers clinical benefits in acute DVT patients, with no significant difference between ambulation versus bedrest and the risk of developing a pulmonary embolism or the progression of the current thrombus (Anderson et al., 2009).

Although some studies have focused on the benefits of early ambulation in standard hospitalized patients, additional evidence is needed on the frequency of ambulation in post-DVT, hospitalized patients. The findings by Callen et al. (2004) on the frequency of hallway walking by hospitalized older adults are consistent with the findings from this project. Callen et al. (2004) found that, of the patients who were considered able to walk in the hallways, only 18.6% walked once, 5.1% walked twice, and a shocking 72.9% did not walk at all over a three-hour-period. The
median minutes walked was 5.5 and, of the patients who did walk in the hallways, most of them walked alone (Callen et al., 2004). In this setting and the setting of this project, hallway walking was limited for hospitalized patients, suggesting the need for future nursing and physical therapy activity interventions to keep hospitalized patients ambulant.

In this project, appropriate prescription of anticoagulation in acute DVT patients was evident. All patients were prescribed appropriate anticoagulation at 100% unless clearly contraindicated. Anticoagulation for post-DVT patients continues to be the standard of care. Randomized trials verifying the efficacy and safety of anticoagulant therapy for DVT and pulmonary embolism (PE) date back to the 1960s. The combination of vitamin K antagonist (VKA) and parental anticoagulation (e.g., unfractionated heparin) have shown a marked reduction in recurrent PE and mortality in DVT patients (Kearon et al., 2012). Providers should continue to review the ACCP 2012 guidelines for updates on suggested anticoagulation pharmacotherapy for DVT patients to improve outcomes.

The transition from the hospital to the community environment is a vital period contributing to successful patient outcomes and adherence to therapies. Discharge instructions tailor this transition and should include appropriate written or printed communication. In this project, few DVT patients received PTS prevention education at discharge that emphasized the use of compression stockings and frequent ambulation. In all patients going home on anticoagulants, there was adequate education on bleeding precautions; however, the documentation on knee-high medical compression stockings (30-40 mm Hg), frequent ambulation, and the importance of patient treatment adherence to recommended therapy was absent. Currently, there is limited research on post-DVT discharge instructions and adherence to therapies. Nonetheless, Callen, Alderton, and McIntosh (2008) have found that documentation
within electronic discharge summaries contains a higher number of errors and even omissions than handwritten instructions (p<0.05). Appropriate review of discharge instructions for accuracy and verifying patient understanding of instructions may ultimately reduce readmission rates and improve patient transitions to the community setting.

Limitations

The project includes a variety of limitations. First, the sample size for the retrospective chart review was fairly small. A larger sample size would give the results more power and significance. Second, many patients reviewed had multiple comorbidities or may have had a disability and would not be able to ambulate as readily. Third, the chart review was completed before the hospital implemented a KRAMES system for discharge instructions. Fourth, it was not reviewed whether the patient refused ambulation or compression stockings, which would justify noncompliance with therapies. Fifth, the electronic medical record was the only thing reviewed, and many activities could have occurred without proper charting (earlier or later). Finally, the overall education groups were small, impeding hospital-wide education on PTS prevention strategies. It was assumed that educated staff would educate their peers on the ACCP 2012 guidelines and PTS.

Conclusion

In conclusion, treatment of post-DVT patients is clearly defined in the ACCP 2012 guidelines to prevent the progression of PTS. Medical compression stockings (30-40 mm Hg) and early activity are encouraged for post-DVT patients to improve outcomes. Post-thrombotic prevention and treatment should start in the hospital and extend to the outpatient setting. More importantly, primary care providers must continue to assess patients for signs and symptoms of
PTS in post-DVT patients at follow-up appointments. The Villalta scale may be a useful tool for providers to communicate the severity of PTS across health care systems. The use of the Villalta scale would not only create a useful tool in practice, but suggests a standardized way to define and measure the severity of PTS for investigators in research (Kahn et al., 2009).

Increased cost, decreased quality of life, and increased disability define the serious burden of PTS; therefore, PTS preventative strategies should be emphasized within health systems. Substantial research has been conducted on PTS, but more studies are needed on new, innovative treatments.
References


_Blood, 119_(6), 1561-1565. doi: 10.1182/blood-2011-113919


Figure 1. PTS Prevention
Figure 2. Strategies for Improving PTS Patient Management and Adherence

Figure 3. Villalta Scale Assessment Symptoms and Clinical Signs Components

<table>
<thead>
<tr>
<th>Symptoms PICK ONE CHOICE ONLY FOR EACH SYMPTOM</th>
<th>None</th>
<th>Mild</th>
<th>Moderate</th>
<th>Severe</th>
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<tbody>
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<td>1. Pain</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
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<tr>
<td>2. Cramps</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
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<tr>
<td>3. Heaviness</td>
<td>☐</td>
<td>☐</td>
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<td>☐</td>
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<tr>
<td>4. Paresthesiae</td>
<td>☐</td>
<td>☐</td>
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<td>☐</td>
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<tr>
<td>5. Pruritis</td>
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<td>1. Pretibial edema</td>
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<td>2. Skin induration</td>
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<tr>
<td>3. Hyperpigmentation</td>
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<tr>
<td>4. Redness</td>
<td>☐</td>
<td>☐</td>
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<tr>
<td>5. Venous ectasia</td>
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<tr>
<td>6. Pain on calf compression</td>
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<th>Venous ulcer PICK ONE CHOICE</th>
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</table>

Source: Kahn, Partsch, Vedantham, Prandoni, & Kearon (2009). On behalf of the Subcommittee on Control of Anticoagulation of the Scientific and Standardization Committee of the International Society on Thrombosis and Haemostasis
Table 1

Post-DVT Written Provider Orders

<table>
<thead>
<tr>
<th>Order</th>
<th>Day 1 or Day 2 (N=75)</th>
<th>&gt; Day 2 (N=75)</th>
<th>At Discharge (N=75)</th>
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<tbody>
<tr>
<td>Compression stockings</td>
<td>15%</td>
<td>16%</td>
<td>16%</td>
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<tr>
<td>Ambulation/Activity as tolerated</td>
<td>40%</td>
<td>3%</td>
<td>-</td>
</tr>
<tr>
<td>Bed rest</td>
<td>53%</td>
<td>1%</td>
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Table 2

PTS Prevention Education Program Scores

<table>
<thead>
<tr>
<th>Group</th>
<th>Mean Pre-Test Score</th>
<th>Mean Post-Test Score</th>
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<tr>
<td>Nursing Practice Council</td>
<td>69% (N=30)</td>
<td>99% (N=30)</td>
</tr>
<tr>
<td>Provider Journal Club</td>
<td>93% (N=9)</td>
<td>100% (N=7)</td>
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