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Felix Neba
St. Catherine University

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Graduated Compression Stockings to Prevent Venous-Thromboembolism

A critical appraisal of the literature

Felix C Neba

St Catherine University

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Articulation of the problem/disease and its relationship to clinical practice

Deep vein thrombosis (DVT) and pulmonary embolism (PE), collectively referred to as venous thromboembolism (VTE), is a major cause of morbidity and mortality. VTE accounts for 10% of unexpected fatalities in US hospitals annually, killing more people than AIDS, breast cancer and highway fatalities combined (Agency for Healthcare Research and Quality (AHRQ), 2012). There are approximately two million cases of VTE each year in the United States, with more than half of those cases occurring in the hospital. Fatal VTE results in the highest cause of unexpected hospital deaths in the United States, killing upwards of 200,000 people annually: Half of these deaths are potentially preventable (AHRQ, 2012). Despite known and proven anticoagulant prevention options, not everybody can benefit from anticoagulant medications because of clinically significant risk for major bleeding. Graduated compression stockings are commonly used in the hospital and nursing home settings to prevent VTE in patients with significant risk factors for major bleeding. The effectiveness of graduated compression stockings in preventing VTE in this category of patients is, however, not sufficiently established. The aim of this paper is to critically appraise the research supporting the use of graduated compression stockings to prevent VTE.

PICO:

Can graduated compression stockings prevent VTE in medical-surgical patients with a high risk for major and clinically significant bleeding compared to those with a routine or standard care?

P: Medical-surgical patients with risk for bleeding (improve bleeding score of ≥ 7)

I: Graduated compression stockings

C: Routine/standard care (No graduated compression stockings)

O: Incidence of VTE

Because of advanced age and multiple co-morbidities, VTE disproportionately impacts elderly patients. There are approximately 100/100,000 cases of VTE in the general population per year in the United States compared to approximately 500/100,000 cases over the age 80 (White, 2003). The geriatric nurse practitioner, irrespective of his/her practice setting, should have a good understanding of VTE and when to use graduated compression stockings for prevention of VTE. Evidence based medicine implores providers to seek treatment options that are proven to be effective. The fundamental question therefore is one of effectiveness. Can graduated compression stockings actually prevent VTE in medical-surgical patients who cannot receive anticoagulant medications?

Understanding of the disease and its implications for quality of life

VTE accounts for an estimated 10% of all in-hospital sudden deaths (AHRQ, 2012) and is associated with long term morbidities which negatively impact a patient's quality of life. Chronic complications of VTE include post-thrombotic syndrome, pulmonary hypertension, and recurrent VTE. These may decrease a patient's quality of life and create a significant financial burden in long term treatment costs for the patient and society at large (AHRQ, 2012). For each potentially preventable VTE, in addition to being life threatening and debilitating, it costs the patient an additional 10,000 dollars per DVT and 20,000 dollars per PE in in-hospital costs

(AHRQ, 2012). In the era of budget deficits and cost cutting, the Center for Medicare and Medicaid is in the process of classifying hospital acquired VTE in its list of non-reimbursable hospital conditions (AHRQ, 2012).

Though lumped together as VTE, almost all of the fatalities associated with VTE are directly related to pulmonary embolisms with or without DVT. While DVT may occur in any of the venous circulation, the veins of the lower extremities are more often involved and about 90% of all pulmonary embolisms caused by deep vein thrombosis results from thrombi formed in the proximal veins at or above the knee (Fiebach, Kern, Thomas & Zielgelstein, 2007).

VTE results from three primary abnormalities commonly referred to as the Virchow's triad and include "stasis or turbulent blood flow, disruptions in the integrity of vascular wall and the hypercoagulability of the blood" (Fiebach et al. 2007). Any condition that predisposes an individual to one or more of the Virchow's triad significantly increases his or her risk for VTE. Some of these predisposing risk factors include; advanced age, with a sharp increase in VTE after age 60, ethnicity (more common in African Americans and Caucasian Americans), pregnancy/oral contraceptives, hospitalization, prolonged immobilization, obesity (BMI >= 30), patients in intensive care units, hormonal replacement therapy, congestive heart failure, respiratory failure, COPD, surgery, cancer patients, active chemotherapy patients, stroke/paralysis, trauma/fracture, varicose vein, central venous catheters placement and nephrotic syndrome, (Fiebach et al. 2007).

Population:

For the purpose of this paper, the population will be defined as medical-surgical patients with a Padua risk assessment model (PRAM) score of ≥ 4 and an improved bleeding risk score of ≥ 7 .

Interventions and intended outcome

The interventions are use of graduated compression stockings versus routine/standard care and the primary outcome is the incidence of VTE.

Methods

This paper is a review of five high quality randomized controlled trials (RCTs) and meta-analysis of RCTs. To be considered for a review, the study must meet the following inclusion criteria; must be a RCT or meta-analysis of RCTs, must include persons above 50-years-old, study must not be older than 20 years, participants must have no active VTE symptoms/diagnosis before the start of the study and the article must be published in the English language.

The literature was searched using the following databases: Medline, CINAHL, EBSCOhost and the Cochrane review. The keyword combinations used for the search were VTE and graduated compression stockings, mechanical prophylaxis, TED Stockings and gradient compression stockings. Several articles were reviewed: five articles that met the all-inclusive criteria were selected for the paper.

Thorough review, synthesis and analysis of evidence-based literature

Graduated compression stockings are a widely used alternative to anticoagulant medications to prevent VTE in patients with a high risk for major bleeding, but its efficacy is still debatable and in some instances, their use is associated with adverse skin and circulatory events.

In a Cochrane review of nine randomized trials of 2637 airline passengers assigned to wearing compression stockings or no compression stockings, three passengers in the compression stocking group had symptomless deep vein thrombosis compared to forty-seven in the non-stocking group. The authors concluded that the use of compression stockings to prevent DVT was statistically significant ($P < 0.0001$) (Clark, Hopewell, Juszczak, Eisinga & Kjeldstrom, 2006). In another study in which 1317 post-operative knee patients were randomized to wear full length graduated compression stockings for seven days or to receive daily subcutaneous injections of low molecular weight heparin (Nadroparin) for 7 days, Camporese et al. (2008) found out that the incidence of symptomatic, asymptomatic and all cause fatality was 3.2% (21/660) in the graduated compression stockings group compared to 0.9% (6/657) in the low molecular weight heparin group. With an absolute difference of 2.3% and a p-value of 0.005, Camporese et al. (2008) concluded that low molecular weight heparin reduced VTE and all-cause mortality over graduated compression stockings. Similarly, a meta-analysis of 2 un-confounded randomized controlled studies with 2615 stroke patients in two separate graduated compression stockings trials compared mechanical prophylactics for VTE. Naccarato, Grandi, Dennis & Sandercock, (2010), in this study, concluded that graduated

compression stocking use was not statistically significant in reducing deep vein thrombosis (odds ratio 0.88, 95% CI 0.72 to 1.08) or death (OR 1.13, 95% CI 0.87 to 1.47) in stroke patients. In a similar study, 2518 immobile acute stroke patients from 64 centers in the UK, Italy, and Australia, were assigned via a central randomization system into a routine care and thigh length graduated compression stockings group or to routine care only (Dennis et al. 2009). This study found that the incidence of VTE was 10% (126/1256) in the graduated compression stocking group and 10.5% in the routine care only group (133/1262). The absolute risk reduction between the two groups was statistically not significant at 0.5% (95% CI -1.9% to 2.9%). The authors concluded that thigh high graduated compression stockings did not reduce the incidence of VTE in hospital patients with acute stroke (Dennis et al., 2010). In another randomized controlled trial in which 98 patients with acute immobilization from stroke were randomly assigned to graded compression stockings or to standard care group, the difference in the incidence of VTE between the two groups was not significant (Muir, Watt, Baxter, Grosset & Lee, 2000). At 7 days after treatment, deep vein thrombosis was detected in 7/65 patients with graded stockings compared to 7/32 in patients in the control. With an odds ratio of 0.43% (95% CI 0.14 to 1.36), the authors concluded that graduated compression stockings reduced the incidence of VTE compared to the control but the reduction was not statistically significant and may have been due to the effect of a small sample size (Muir et al., 2000). Similarly, another study evaluated 150 patients with intracerebral hemorrhages who were randomly assigned to elastic stockings or elastic stockings combined with intermittent pneumatic compression boots (IPC) (Lacut et al., 2005). After 10 days of treatment the incidence of asymptomatic deep vein thrombosis detected by ultrasound was 4.7% in the elastic stockings and IPC group compared

to 15.9% in the elastic stocking group alone. There were more DVTs in the elastic stockings group alone than the combined elastic and IPC group and the authors concluded IPC was more effective in reducing VTE than elastic stockings, (Lacut et al., 2005).

Graduated compression stockings were associated with adverse skin events including ulcers, blister, skin breaks and skin necrosis (Dennis et al., 2009; Naccarato et al., 2010)

Comparison and contrast study findings on the prevention on VTE using GCS

Author and year	GCS findings	Adverse skin event	Sample size & study subjects
Clark et al (2006)	Effective	None reported	N=2637 airline
Camporese et al (2008)	Not effective	Not reported	N= 1317 post-operative knee patients
Naccarato et al (2010)	Statistically not significant	reported	N= 2615 stroke patients
Denis et al (2009)	Not effective	reported	N=2518 stroke
Lacut et al (2005)	Not effective	Not reported	N= 150 stroke patient

Muir et al (2000)	Not significant	Not reported	N=98 stroke patients
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Limitation of the studies

The small sample size in the research done by Muir et al. (2008) and Lacut et al. (2005) of n=98 and n=150 respectively decreases the power of the studies and may not adequately represent the broader population. Secondly, only stroke and post-operative knee patients are represented in the studies. The medical characteristics and the comorbidities of these patients may not be a true representation of the broader population and extrapolating the findings from these studies to the general population may not be appropriate. Thirdly, some of the studies were meta-analyses. A meta-analysis is only as good as the original study: If the original study was poorly done, it may adversely affect the outcome of a meta-analysis, because the authors are unable to control extraneous and other confounding variables during a meta-analysis.

Diagnostic tools/Instruments

Padua Risk Assessment Model (PRAM)

The Padua risk assessment model (PRAM) is a VTE assessment tool that assigns relative values to individual risk factors to obtain a total score for an individual. A total risk assessment model score (RAM) of ≥ 4 puts an individual at a significantly higher risk for VTE (Barbar et al., 2010).

Conditions	Points
Cancer, previous VTE, reduced mobility,	3

thrombophylic conditions	
Recent trauma or surgery in the past month	2
Age \geq 70, CHF, respiratory failure, acute myocardial infarction, Ischemic stroke, acute infection, rheumatologic disorder, hormones therapy, obesity or BMI \geq 30kg/m ²	1

The Padua risk assessment model is an important tool that can assist providers in discriminating between patients with high risk for VTE and patients with low risk. The model however does not appreciate or predict a patient's risk for bleeding. Taken alone, the model provides a very important tool in VTE risk stratification, but it is limited by its inability to predict the risk for bleeding.

IMPROVE (International Medical Prevention Registry on Venous thromboembolism) bleeding risk score

IMPROVE bleeding risk score is a tool designed by the Center for Outcome Research (2012), University of Massachusetts Medical School. Just like the Padua's risk assessment models, it assigns relative values to individual bleeding risk factors to obtain a total score for an individual patient.

IMPROVE bleeding risk score (Center for outcome research, 2012).

Conditions	Scores
Active gastro duodenal ulcer	4.5

Bleeding \leq 3 months prior to admission, platelet count <50 ,	4
Age >85 ,	3.5
Liver failure ,GFR <30 ,ICU/CCU admission	2.5
Central line, rheumatic disease, active cancer	2
Age 40-84 years,	1.5
Male, GFR 30-59	1

IMPROVE bleeding risk score of ≥ 7 puts a patient at a risk of experiencing major and clinically significant bleeding especially with anticoagulant medication use (Center for Outcome Research, 2012).

Practical application, clinical decision making and conclusion

Graduated compression stockings are a frequently used mechanical prophylaxis to prevent VTE in patients who cannot receive anticoagulant medication due to the risk for major and clinically significant bleeding. While studies in patients undergoing elective surgeries has shown some positive correlation between the use of graduated compression stockings and a reduction in the incidence of VTE post-operatively, extrapolation of this limited data to all surgical-medical patients who cannot benefit from prophylactic anticoagulant medications is debatable.

A raw appraisal of the findings of the studies reviewed for this project do not provide sufficient evidence to support the routine use of graduated compression stockings to reduce VTE. However, extrapolating the findings from these six studies to the entire population under investigation may not be

appropriate. Four of the six studies (Naccarato et al., 2010; Muir et al., 2000; Denis et al., 2009 & Lacut et al., 2005) were limited to patients with acute hemorrhagic stroke with gross immobilization. In addition to not being a true representation of the population under investigation for this paper, this group of patients tends to have more hemodynamic instability, with all cause morbidity and mortality excessively higher than that of population of the study. Secondly, in one study, Comporese et al. (2008) graduated compression stockings were compared to low molecular weight heparin. With the superior efficacy of low molecular weight heparin in preventing VTE already established in practice guidelines, the findings of the study that low molecular weight heparin prevented more VTE over graduated compression stockings cannot be appropriately interpreted to mean that graded compression stockings do not prevent VTE. It may just be that it is not as effective as low molecular weight heparin.

Two of the six studies reported adverse skin events, Dennis et al. (2009) & Naccarato et al. (2010). However, it appears that the events were related more to the inappropriate application of the stockings than intrinsically linked to the stockings.

Based on the literature reviewed for this paper, the routine use of graduated compression stockings to prevent VTE is statistically not significant. There is insufficient evidence from the studies reviewed to support the routine use of graduated compression stockings to prevent VTE in this population. It is, however, important to note that an intervention may not be statistically significant but yet is clinically significant. Furthermore, when graduated compression stockings are combined with other anti VTE interventions, the incidence of VTE is significantly lower than each of the interventions alone. In summary there is an apparent trend towards VTE reduction with graduated compression stockings though the reduction may not be statistically significant.

In a patient with significant VTE risk stratification that cannot benefit from anticoagulant medications because of severe risk for bleeding, it would be inappropriate for a provider not to consider the use of graduated compression stockings. However, due to the uncertainty in the effectiveness of graduated compression stockings as a mono-therapy in VTE prevention, providers can improve outcomes by combining it with other mechanical prophylaxis including intermittent pneumatic compression boots. Other options in settings such a nursing home where IPC may not be available include; early ambulation, assisted ambulation, physical therapy, and, appropriate turning/repositioning, getting up for meals, and, participation in recreational activities for bedridden immobile patients.

Considering the fact that the findings of the studies reviewed for this project do not provide sufficient evidence, coupled with the limitations of the studies and the potential for stockings to cause adverse skin events, it is recommended that future large scale randomized control studies be done to reliably appraise the safety, efficacy and health economics of graduated compression stockings as a mono-therapy in preventing VTE in this population.

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