July 2015-Rapid Review Evidence Summary

McGill University Health Centre: Division of Nursing Research and MUHC Libraries

What evidence exists that describes the efficacy of mechanical prophylaxis for venous thromboembolism (VTE) in adult surgical patients?

This report aims to summarize the best available evidence around the efficacy of mechanical methods in the prevention of VTE, specifically deep vein thrombosis (DVT) and pulmonary embolism (PE) in adult surgical patients during postoperative hospitalization and following discharge. This information is to guide the development of MUHC VTE prophylaxis guidelines.

Key Messages:

- Venous thromboembolism (VTE) including deep vein thrombosis (DVT) and pulmonary embolism (PE) remains one of the most common and preventable hospital-acquired complications in the surgical population.
- Pharmacological and mechanical interventions, alone or in combination, are currently recommended by clinical practice guidelines as prophylaxis in the prevention of VTE during hospitalization and once the patient is discharged home.
    - Mechanical methods for VTE prophylaxis include intermittent pneumatic compression (IPC), graduated compression stockings (GCS) and venous foot pumps (VFP).
    - The recommended use of pharmacological, mechanical, both or none for prophylaxis is dependent on an assessment of the patient's risk level for developing VTE and for contraindications to treatments.
- Overall, the evidence on mechanical methods indicates that they are effective in VTE prophylaxis:
    - The evidence shows a reduction of asymptomatic and symptomatic DVT rates in using mechanical methods such as IPC and GCS in several surgical populations.
    - The reduction of PE and fatal PE rates using mechanical methods is less clear.
    - The combination of mechanical with pharmacological methods was demonstrated in some studies to have additive beneficial effects on preventing DVT in the surgical population.
    - The methods for application and duration of the mechanical prophylaxis and duration of evaluation for VTE varied from one study to another.
    - The overall quality of the reviewed evidence was moderate to high with multiple systematic reviews.
- The use of mechanical methods in the clinical setting is challenged by a number of issues, including lack of clarity around fit, timing/frequency of administration, duration of administration and compliance by patients and healthcare professionals.

Who is this summary for?

This summary was requested by Debbie Watson, ERAS Care Pathway Coordinator &
Denis Gaumond, Chairperson Clinical Practice Review Committee at the MUHC.

Information about this summary:

This report covers a broad collection of literature and evidence sources with a search emphasis on systematic reviews.

This summary includes:

Key findings from a broad collection of recently published literature (from 2012-2015) and evidence sources.

This summary does not include:

Recommendations, additional information, or detailed description of the interventions in the studies.

1. Background:

Venous thromboembolism (VTE), which includes deep vein thrombosis (DVT) and pulmonary embolism (PE), has been identified as one of the most preventable causes of hospital death. A massive PE has been identified as the cause of death in about 10% of hospitalized patients [1]. In addition to risk of mortality with VTE, the risk of long term consequences to patients has also been identified and can include bleeding, future thrombus formation and post-thrombolic syndrome.

Contents:

The risk of VTE and its complications can extend beyond hospitalization and up to at least 3 months for surgical patients. Risk factors for post-surgical VTE have been identified and depend on a number of procedure and patient related factors. Classification systems to aid health care professionals in assessing risk levels for VTE are available and can support decision making for appropriate evidence-based prophylaxis (for example, the Caprini score, see [1] for a modified version.) In addition, clinical practice guidelines have been developed and updated to support VTE prophylaxis and treatment in the health care setting for surgical patients [2].

Primary VTE prophylaxis includes early and frequent mobilization, pharmacological/chemical prophylaxis, mechanical methods or a combination of the above. Numerous pharmacological methods including anti-coagulants and anti-thrombotic agents are available and have been studied extensively but will not be discussed here (for further information, see [3]). Major concerns from practitioners regarding the use of pharmacological prophylaxis include the increased risk of bleeding, though these events are reported to be rare [1]. Mechanical prophylaxis has been recommended as an alternative when pharmacological methods are contraindicated, though they have been much less extensively studied. These methods include intermittent pneumatic compression (IPC) devices, graduated compression stockings (GCS) and venous foot pumps (VFP). They function by compressing the thigh, calf or foot muscles in an active or passive manner to increase blood flow. They are preferred by some because they do not increase bleeding postoperatively, and claim to exhibit few if any complications with use. According to the ACCP guidelines:

- Mechanical prophylaxis is recommended for patients who have a high risk of bleeding, or contraindication to anticoagulants for all surgical procedures.
- Mechanical prophylaxis is recommended as an alternative to pharmacological methods in patients undergoing laparoscopic surgery,
- Mechanical prophylaxis are recommended in combination with pharmacological methods in high risk general surgery, bariatric surgery and coronary artery bypass surgery.

However, issues with compliance for use during hospitalization and after discharge are significant and relate to the nature of the evidence as well as patient, healthcare professional and organizational barriers. The application of mechanical methods varies from one study to another and from one device to another, creating confusion. As well, in many studies evaluating mechanical methods, asymptomatic DVT was measured as an outcome, which has been questioned as being clinically relevant. These need to be considered when weighing the evidence around mechanical prophylaxis in adult surgical patients.

This rapid review will present summaries of the best available evidence for adults (over 18) who underwent a surgical procedure, and where a mechanical prophylaxis was evaluated with or without chemical prophylaxis. Detailed search strategies were developed by an experienced librarian (specific search terms are available upon request). Sources include: Medline via Ovid SP, Embase, CINAHL and The Cochrane Library. Search concepts included Subject Headings and text words. Search date: March 26, 2015. Duplicate titles, articles that were out of scope, and studies with poor or poorly described methodology were discarded by the Evidence informed Decision Making-Advisor (EIDM-A). Additionally, JBI Connect and UptoDate were also searched by the EIDM-A for background documents. The analysis of studies and the report were prepared by the EIDM-A and reviewed by the librarian.

Due to the high number of potential studies, this review will present only those that were published from 2012-2015, with the exception of some evidence-based resources. The studies that were reviewed are mainly systematic reviews and RCTs of moderate to high quality, including important Cochrane reviews. As well, other evidence-based practice reports were summarized. A list of all the articles found and reviewed is available upon request (sonia.castiglione@muhc.mcgill.ca).

Levels of Evidence (adapted from OHRI KTA Evidence Summary document)

Each piece of evidence presented in this summary is assigned a level.

This assignment is based on the evidence being presented and not on the claim made by the authors.

- **Platinum:** systematic reviews and meta-analysis
- **Gold:** Randomized controlled trials
- **Silver:** Observational studies (non-randomized trials, case-control, time-series, cohort studies, case series, literature reviews, qualitative studies.)
- **Bronze:** Expert committee guidelines, reports or opinions, commentary or editorials.
- **Level of evidence** cannot be determined.

2. Summary of Findings:

a. Evidence specific to GCS

A 2014 Cochrane systematic review combined the results of 19 moderate quality RCTs that evaluated the use of GCS for DVT prophylaxis with or without another method of prophylaxis in adult hospitalized patients (excluding stroke.) Adult patients undergoing general and orthopedic surgeries constituted 72% of the sample analyzed for DVTs using the radioactive I^{125} fibrinogen update (FUT) assay and phlebography to confirm diagnosis. The authors classified the patients as being in the moderate to high risk groups for DVT. No patients were found to be in the low risk groups. Mostly thigh-length GCS were applied either on the day of admission or on the day of surgery and were removed at discharge and for a small group of patients, 2 weeks after discharge. In the control group, some patients did not receive any prophylaxis or were given varying chemical prophylaxis or sequential compression.

Patients in the treatment group received GCS in addition to the comparison controls (with or without prophylaxis.) In all trials, the addition of GCS significantly reduced the occurrence of DVTs in the hospitalized patients, and lowered incidence of proximal DVTs and PEs (though the sample was small). The authors conclude that "there is robust evidence […] that the use of GCS should be used in all surgical patients at risk of developing DVT" despite the heterogeneity of the methods used in the reviewed studies. [4]

b. Evidence specific to lower joint surgical procedures with various mechanical methods

A 2014 Cochrane review found one study comparing the effectiveness and safety of different IPC devices: calf-thigh pumps vs plantar pumps worn for 4 hours per day for 21 days, in the prevention of VTE following total hip replacement. No cases of symptomatic DVT or PE were found in the 121 participants in either intervention group. None of the patients received any pharmacological prophylaxis agents. The risk of bias was found to be high in this one study. Therefore, the authors concluded that "until adequate evidence regarding the efficacy and acceptability of interventions is available, definitive recommendations cannot be made." [5]

A 2014 Cochrane review performed a meta-analysis of 11 RCTs to determine the effectiveness of continuous passive motion (CPM) therapy for preventing VTE in adult patients after total knee arthroplasty (TKA). A total of 808 patients were randomized to receive CPM or usual care following surgery. There was no mention of other prophylaxis methods used and DVT was not the primary outcome in most of the studies. The results showed that there was no difference in the incidence of DVT (diagnosis method varied) after TKA in either group. The authors report that "the quality of the evidence was low" and therefore not enough evidence is available to conclude CPM's effectiveness.[6]

✳ A 2014 prospective randomized study compared two different IPC devices, alternate sequential compression device (ASCD) & simultaneous sequential compression device (SSCD), on the incidence of DVT as a primary outcome. 34 adult patients with a moderate to high risk of VTE underwent spine and knee surgeries (including total knee arthroplasties) and were randomized to either IPC devices postoperatively without any background prophylaxis. The IPC devices were applied for 6 cycles per day consisting of 2-hours of compression and 2-hours of interruption (where patients were able to ambulate). Asymptomatic DVTs between postoperative day 4 and day 7 developed in 7 patients in both groups (%20), without any significant difference in the type of IPC device used. The authors concluded that "both devices contributed to preventing DVTs" compared to reported rates in other trials, however, the effect of early and regular mobilization and a small sample size needs to be considered.[7]

A 2013 systematic review commissioned by the Agency for Healthcare Research and Quality, compared the efficacy and safety of combined chemical and mechanical VTE prophylaxis versus either method alone in adult patients undergoing total knee or total hip replacement (TKR or THR). 6 RCT were reviewed that the authors noted were of good to fair quality. The prophylaxis methods varied greatly each of the studies with respect to the chemical or mechanical method used, as well as the duration of use. The authors concluded that the "combination of pharmacologic and mechanical prophylaxis decreases the risk of DVT in comparison to pharmacologic prophylaxis alone in patients undergoing either THR or TKR." However, there was insufficient data to comment on the effect on PE or fatal PE. In addition a lack of evidence was available to determine the effect of combined prophylaxis versus mechanical prophylaxis alone in adult patients undergoing major orthopedic surgery. [8]

A 2013 meta-analysis evaluated the efficacy of venous foot pumps in the prevention of DVT and PE compared to chemical prophylaxis agents following unilateral THR & TKR in patients. For THR surgeries, 851 patients randomized to the venous foot pump showed a significant decrease in diagnosed DVT rate vs Heparin or Lovenox

alone. Patients who had a TKR surgery and were randomized to the foot pump also showed a reduction in DVT rate, but this was not significant. When the studies for both surgeries were combined, the effect of foot pumps on DVT was not significant. The authors recommend the use of venous foot pump devices "alone or in combination with less potent chemoprophylaxis [as] an effective strategy in lowering the rate of postop thromboembolic event. The quality of this meta-analysis is deemed to be fair. [9]

A 2012 systematic review and meta-analysis compared the efficacy of combined intermittent compression and chemical prophylaxis versus either modality alone in adult patients undergoing either hip or knee replacement surgeries. Although some studies reviewed used graduated compression stockings in both the treatment and control groups, there nonetheless demonstrated a reduction in the incidence of DVT detected by ultrasound and/or venography at discharge and 12 days post-op in patients recovering from total knee or total hip replacement therapy. 3 of the reviewed studies measured DVT incidence at 3 months post op but due to the small number of events, no further analysis was done. The authors conclude that "the use of intermittent mechanical compression augments the efficacy of anticoagulation in preventing DVT in both hip and knee arthroplasty." [10]

A 2014 non-randomized prospective non-inferiority trial collected data from a registry on the incidence of symptomatic venous thrombosis and/or pulmonary embolism during or after hip/knee arthroplasty in 3060 patients in the United States. All adult patients had a mobile compression device applied to the non-surgical leg during the procedure and then following the procedure, applied to the operated leg for a minimum of 10 days with or without aspirin and were followed for three months postop for VTE complications. Overall, 23 patients (0.75%) experienced DVT and 5 patients experienced PE following lower joint arthroplasty with a mobile compression device. The results demonstrated that this treatment was not worse (at a margin of 1.0%) compared to previously published rates of symptomatic VTE for the standard pharmacological prophylaxis which included warafarin, enoxaparin, rivaroxaban, and dabigatran. They recommend that "surgeons consider the use of this mobile compression device with or without asprin for prophylaxis as an alternative to pharmacological prophylaxis" in these patients. [11]

c. Evidence from other surgical populations with various mechanical methods

A 2013 systematic review determined the optimal perioperative VTE prophylaxis for adult patients undergoing craniotomy for brain tumor. In a subset of the analysis, 4 RCTs evaluated the effect of IPC and GCS on asymptomatic DVT. It was found that the use of mechanical methods, in particular, IPC, showed a clear reduction in DVT from 28% in the control group (no treatment) to 5% in the ICP group. This effect was significantly enhanced with the addition of low molecular weight heparin (LMWH) to the mechanical method with what the authors refer to as a "modest increase in the frequency of major bleeding" compared to mechanical prophylaxis alone. The authors recommend the use of mechanical methods for the reduction of VTE preoperatively to discharge in neurooncological patients with the addition of LMWH the day after surgery. [12]

A 2013 Cochrane systematic review was conducted to determine the most effective thromboprophylaxis of VTE in people undergoing major amputation of a lower extremity. No RCTs or quasi-RCTs were found examining mechanical prophylaxis including antiembolic stocking, IPC devices and foot impulse devices (foot pumps) in this population. [13]

A 2012 open trial investigated the efficacy and safety of a new portable battery powered calf compression device in neurosurgical patients on asymptomatic DVT and symptomatic VTE. 150 patients were randomized to receive the venowave system or control while receiving the prescribed VTE prophylaxis at the discretion of the neurosurgeon which usually included knee-length GCS and in some cases pharmacological prophylaxis (25% and

20% in the intervention and control groups respectively). The Venowave device was applied within 4 hours of surgery at removed at around 7 days post-op. The results demonstrated a statistically significant reduction in DVT in the venowave group compared to the control group, where there reduced risk was 79% in hospitalized neurosurgery patients. [14]

3. Additional Sources

- A 2015 UpToDate evidence decision making summary on the prevention of VTE in surgical patients recommends the use of mechanical devices specific to the surgical risk group classification based contraindications for pharmacological prophylaxis, surgical procedure and on the modified Caprini Risk Assessment. Mechanical thromboprophylaxis, (usually IPC) is recommended for low risk general and abdominal-pelvic surgery (Caprini score 1 and 2) and for patients with contraindications to anticoagulants. They also report that IPC may have additive benefits to patients already on low molecular weight heparin for prevention of DVT, but with no effect on PE. They add that GCS may also be effective at improving rates of DVT prevention in combination with a chemical prophylaxis but that there are few high quality studies available. [3]

- In a 2013 evidence summary of systematic reviews and evidence-based guidelines, the Joanna Briggs Institute provided best practice recommendations on the prevention and prophylaxis of VTE. For patients undergoing hip or knee arthroplasty and for patients at high risk of VTE, they strongly recommended (grade A) a combined mechanical and anti-coagulation approach to prophylaxis. [15]

- In 2012, *Safer Healthcare Now!* updated their VTE Prevention Getting Started Kit to support organizations in taking an evidence-based approach to thromboprophylaxis in at-risk patients. The kit supports the recommendations issued by the ACCP's 2008 and 2012 guidelines for medical and surgical patients, which includes the use of mechanical prophylaxis. Specifically, if anti-coagulation is contraindicated or in patients with high risk of bleeding, GCS and/or IPC is to be used, and reassessed daily to consider starting an anti-coagulant. Mechanical prophylaxis is also indicated as an alternative to chemical prophylaxis in patients undergoing coronary artery or bypass surgery, and patients deemed at high risk during laparoscopic surgery. Mechanical prophylaxis is recommended as an alternative to chemical prophylaxis in patients with high risk of VTE for major general surgery, and those undergoing bariatric surgery (IPC as major recommendation.) This kit also highlights the barriers for an organizational approach to VTE prophylaxis including individual patients, physician, hospital and system level challenges. [1]

---

4. References:

1. Geerts, W.H., et al. *Venous Thromboembolism Prevention. Getting Started Kit.* Safer Healthcare Now! 2012.
2. Guyatt, G.H., et al., *Executive Summary: Antithrombotic Therapy and Prevention of Thrombosis, 9th ed: American College of Chest Physicians Evidence-Based Clinical Practice Guidelines.* Chest, 2012. **141**(2 Suppl): p. 7S-47S.
3. Pai, M. and J.D. Douketis, *Prevention of venous thromboembolic disease in surgical patients*, in *UpToDate*, L.L.K. Leung and J. Mandel, Editors. 2015: Waltham, MA.
4. Sachdeva, A., et al., *Graduated compression stockings for prevention of deep vein thrombosis.* Cochrane Database of Systematic Reviews, 2014. **12**: p. CD001484.

5. Zhao, J.M., et al., *Different types of intermittent pneumatic compression devices for preventing venous thromboembolism in patients after total hip replacement.* Cochrane Database of Systematic Reviews, 2014. **12**: p. CD009543.
6. He Mao, L., et al. *Continuous passive motion for preventing venous thromboembolism after total knee arthroplasty*. Cochrane Database of Systematic Reviews, 2014. DOI: 10.1002/14651858.CD008207.pub3.
7. Koo, K.H., et al., *Comparison of clinical and physiological efficacies of different intermittent sequential pneumatic compression devices in preventing deep vein thrombosis: A prospective randomized study.* CiOS Clinics in Orthopedic Surgery, 2014. **6**(4): p. 468-475.
8. Sobieraj, D.M., et al., *Comparative effectiveness of combined pharmacologic and mechanical thromboprophylaxis versus either method alone in major orthopedic surgery: a systematic review and meta-analysis.* Pharmacotherapy:The Journal of Human Pharmacology & Drug Therapy, 2013. **33**(3): p. 275-83.
9. Pour, A.E., et al., *Is venous foot pump effective in prevention of thromboembolic disease after joint arthroplasty: a meta-analysis.* Journal of Arthroplasty, 2013. **28**(3): p. 410-7.
10. Kakkos, S.K., et al., *Combined (mechanical and pharmacological) modalities for the prevention of venous thromboembolism in joint replacement surgery.* Journal of Bone & Joint Surgery - British Volume, 2012. **94**(6): p. 729-34.
11. Colwell Jr, C.W., et al., *A mobile compression device for thrombosis prevention in hip and knee arthroplasty.* Journal of Bone & Joint Surgery, American Volume, 2014. **96**(3): p. 177-183.
12. Salmaggi, A., et al., *Perioperative thromboprophylaxis in patients with craniotomy for brain tumours: a systematic review.* Journal of Neuro-Oncology, 2013. **113**(2): p. 293-303.
13. Robertson, L. and A. Roche, *Primary prophylaxis for venous thromboembolism in people undergoing major amputation of the lower extremity.* Cochrane Database of Systematic Reviews, 2013. **12**: p. CD010525.
14. Sobieraj-Teague, M., et al., *Randomized controlled trial of a new portable calf compression device (Venowave) for prevention of venous thrombosis in high-risk neurosurgical patients.* Journal of Thrombosis & Haemostasis, 2012. **10**(2): p. 229-35.
15. Sharma, L., *Venous Thromboembolism: Prevention and Prophylaxis.* Joanna Briggs Institute Evidence Summary, 2015.

For additional questions, comments or updates on this topic, please contact:

Tara Landry, MUHC Librarian tara.landry@muhc.mcgill.ca or Sonia Castiglione, EIDM-Advisor sonia.castiglione@muhc.mcgill.ca

This summary should be cited as:

Castiglione SA & Landry T. What evidence exists that describes the efficacy of mechanical prophylaxis for venous thromboembolism (VTE) in adult surgical patients? Rapid Review Evidence Summary. McGill University Health Centre; July 2015.