CADTH ISSUES IN EMERGING HEALTH TECHNOLOGIES

INFORMING DECISIONS ABOUT NEW HEALTH TECHNOLOGIES

ISSUE 146

MARCH 2016

Portable Compression to Prevent Venous Thromboembolism After Hip and Knee Surgery: The ActiveCare System

CADTH

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Author: Leigh-Ann Topfer

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Funding: CADTH receives funding from Canada's federal, provincial, and territorial governments, with the exception of Quebec.

Views: The views expressed herein are those of CADTH and do not necessarily reflect the views of our funders.

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Cite as: Portable compression to prevent venous thromboembolism after hip and knee surgery: the ActiveCare system. Ottawa: CADTH; 2016 Mar. (CADTH issues in emerging health technologies; issue 146)

ISSN: 1488-6324 (online)

Summary

- Venous thromboembolism (VTE) (clots that form in a vein) is a common, but largely preventable, complication after orthopedic surgery.
- Preventive drug therapy (with anticoagulants or antiplatelets) is usually administered to lower the risk of VTE after orthopedic surgery.
- While the risk of major bleeding in orthopedic surgery is fairly low, this risk is increased by the use of preventive drug therapies.
- Portable compression systems may be used in addition to, or as an alternative to, drug therapy to prevent VTE.
- Although there is more evidence available for the ActiveCare portable compression systems than for other portable compression devices, there is uncertainty regarding the effectiveness of portable compression compared with newer drug therapies, and comparisons of different portable compression devices are needed.

Background

Venous thromboembolism (VTE) occurs when a blood clot forms in a vein. VTE includes both deep vein thrombosis (DVT) — a blood clot that commonly forms in a vein deep in the tissue of the legs — and pulmonary embolism (PE) — a blockage in the pulmonary artery (the artery that transports blood from the heart to the lungs). These clots are often asymptomatic and resolve spontaneously. However, large clots may detach and migrate to the lungs, causing a potentially fatal PE.[1] People who have had a VTE may experience additional clots, postthrombotic syndrome — chronic leg pain, swelling, and leg ulcers — or pulmonary hypertension (high blood pressure that affects the lungs and right side of the heart).[2,3]

VTE is a common complication following surgery, and a frequent reason why patients are re-admitted to the hospital.[4,5] Lower limb surgeries such as hip and knee replacements, and hip fracture repair are associated with a particularly high risk for VTE — mainly due to decreased blood flow during and after surgery, and reduced patient mobility during recovery.[3,5,6] However, VTE is largely avoidable with appropriate preventive measures.[3,7] The occurrence of DVT after surgery is also a possible indicator of decreased patient safety.[7,8] Estimates of the risk for VTE in orthopedic surgeries when preventive measures are not used are shown in Table 1.

Table 1: Estimated Incidence of Venous Thromboembolism in Major Orthopedic Surgery Without Preventive Measures

Type of Orthopedic Surgery	DVT	PE
Hip replacement	39%	6%
Knee replacement	53%	1%
Hip fracture surgery	47%	3%

DVT = deep vein thrombosis; PE = pulmonary embolism.
Source: Sobieraj et al.[9]

With preventive drug therapies — typically blood-thinning (antithrombotic) agents — the incidence of symptomatic VTE in patients prior to hospital discharge decreases to approximately 0.5% after hip replacement and 1.0% after knee replacement.[8] However, drug therapy is also associated with an increased risk for adverse events — in particular, bleeding. Major bleeding can cause stroke or blood loss requiring transfusion, and may require re-hospitalization and re-operation.[10] Drug therapies may also increase the risk of post-surgical complications, such as infection.[10] Non-drug interventions to prevent VTE offer an alternative or additional preventive strategy for some patients.

One alternative to drug therapy is compression therapy. For many years, compression devices have been used to prevent VTE.[11] Renewed attention has focused on using these devices to avoid adverse events associated with drug therapies.[12,13]

Compression devices include graduated compression stockings, as well as many different types of pumps that deliver compression.[12] Mechanical compression uses various methods to apply compression to the foot, calf, and/or thigh to enhance blood circulation and prevent blood clots.[12] These devices deliver compression in various ways.[11] In general, they improve blood circulation by preventing pooling of blood in the veins (venous stasis) and enhancing the natural breakdown of blood clots (fibrinolysis).[14-16] The more hours that compression therapy is used each day, the more effectively it helps prevent VTE.[17,18] However, poor patient and caregiver compliance with compression therapy can result in less-than-optimal use of this therapy.[6,19] Compression therapy may also help reduce pain and swelling, and improve wound healing.[20]

The Technology

ActiveCare (Medical Compression Systems, Or Akiva, Israel) products are mechanical compression devices first developed in Israel in the 1990s, under the brand name WizAir.[21] The devices — ActiveCare+S.F.T., ActiveCare DVT, and ActiveCare+DTx — are small, portable units that allow the patient to wear the device while walking. The disposable, inflatable compression sleeves wrap around the lower legs and fasten with Velcro.[15,22] The sleeves connect to a lightweight (0.74 kg) pump that can be battery powered for five to six hours before recharging.

The ActiveCare+S.F.T. system delivers sequential compression and decompression synchronized with the patient's respiration and venous flow.[23] The ActiveCare+DTx system can also detect changes in blood flow that may indicate obstruction (although it is not intended for diagnostic use).[20] ActiveCare compression increases peak venous blood flow by 66%, with a maximum pressure of 50 mm Hg during inflation of the sleeves.[22] Pressure is applied for eight seconds, followed by 36 to 56 seconds of decompression.[22]

ActiveCare devices can be used during surgery and during recovery in hospital, as well as at home. The devices can provide any combination of foot, calf, and thigh compression on one or both legs,[6] and include a monitor that records patient use and compliance with the therapy.[22]

Regulatory Status

ActiveCare devices are not yet licensed by Health Canada. In the US, they have FDA 510(k) approval (substantially equivalent to similar devices) as a Class II device for prescription use only.[20,24] They are also commercially available in Europe and elsewhere.[23]

Other portable compression devices with Class II licences (marketing allowed) from Health Canada include Venowave (Saringer Life Science Technologies, Stouffville, Ontario); Restep DVT (Stryker Sustainability Solutions, Tempe, Arizona); VenaPro (InnovaMed Health, San Antonio, Texas); and Kendall SCD 700 Sequential Compression System (Covidien, Mansfield, Massachusetts).[25]

Patient Group

Patients who undergo hip or knee replacement or hip fracture surgery usually receive therapies to prevent VTE.[19] From 2013 to 2014, nearly 50,000 Canadians had a hip replacement, and about 60,000 had knee replacement surgery.[26] Approximately 30,000 Canadians suffer a hip fracture each year and make up another group of potential users of portable compression.[27] The number of patients undergoing these surgical procedures is expected to increase as the population ages.[28]

In addition to orthopedic surgery patients, patients undergoing other surgical interventions or who have other medical conditions may also be at increased risk for VTE.[29]

Patients who may benefit from using portable compression devices to prevent VTE include both those for whom preventive drug therapy is:

- Indicated (i.e., those not at an increased risk of bleeding, who would use portable compression in addition to drug therapy), and
- Contraindicated (i.e., those at an increased risk of bleeding, who would use portable compression alone).

Current Practice

Preventive interventions for VTE may be either chemical (e.g., drugs) or mechanical (e.g., compression devices), or a combination of both.[19]

Patients prescribed chemical prophylaxis typically receive doses of drugs that prevent blood clots by inhibiting factors needed for blood clots to form (anticoagulants) or by preventing platelet cells from clumping together (antiplatelets). Common anticoagulants include warfarin, enoxaparin (low-molecular-weight heparin), rivaroxaban, or dabigatran, while ASA (acetylsalicylic acid; i.e., Aspirin) is a commonly prescribed antiplatelet.[28,30] Choosing which preventive therapies to use involves balancing the individual patient's risk for VTE with that for bleeding — a possible adverse event with preventive drug therapies. Achieving this balance can be challenging, particularly for those without known risk factors for VTE.[28]

In addition to increasing the risk of bleeding, some drug therapies require frequent blood tests (e.g., warfarin) or daily injections (e.g., low-molecular-weight heparin) — both of which may be uncomfortable or inconvenient for patients.[22]

The 2012 American College of Chest Physicians (ACCP) guidelines on prevention of VTE in orthopedic surgery patients recommend prophylactic drug therapies for patients undergoing total hip or knee replacement or intermittent pneumatic compression.[31] Compression should be used for 10 to 14 days for at least 18 hours per day.[31] Only portable compression devices that record usage are recommended. In patients receiving preventive drug therapy, adding compression therapy while in hospital is suggested. In addition, a longer period of prophylaxis (up to 35 days) should be considered. Low-molecular-weight heparin is preferred to other prophylactic drug therapies and other alternatives, including compression, unless otherwise contraindicated.[32] Compression alone or no prophylaxis at all may be used in patients at risk for bleeding.

The 2011 American Academy of Orthopaedic Surgeons (AAOS) guidelines recommend that, given the absence of good-quality evidence, patients with a known risk for VTE receive combined prophylaxis with both drug therapy and mechanical compression, while patients with a known risk for bleeding should receive mechanical compression alone.[32,33] Patients who are not at risk for VTE or bleeding should receive preventive drug therapy and/or compression therapy.[33] However, the most effective drug or compression therapy is unknown.[33] In addition, although evidence suggests that extending drug therapy for approximately one month, rather than the usual seven to 10 days, appears to be beneficial,[9] the optimal duration of therapy is still unknown.[33] The AAOS also recommends early mobilization, which it notes is "of low cost, minimal risk to the patient, and consistent with current practice."[32]

Recent systematic reviews have confirmed that using both drug and mechanical compression reduces the risk of DVT over that achieved with drug therapy alone.[9,34,35]

Figure 1: Patient Wearing Portable Mobile Compression Device

Reproduced with permission: Froimson MI, et al. *J Arthroplasty* 2009;24(2):310-316.

Methods

Literature Search Strategy

The literature search for this bulletin included the following bibliographic databases: PubMed, the Cochrane Library (2015, Issue 11), and the Centre for Reviews and Dissemination databases (DARE, NHS EED, and HTA). Grey literature was identified by searching relevant sections of the CADTH Grey Matters checklist (https://www.cadth.ca/resources/finding-evidence/grey-matters-practical-search-tool-evidence-based-medicine). No methodological filters were applied. The search was limited to English-language documents published within the last five years (2009 to November 2015). Regular PubMed alerts were established to update the search until March 1, 2016.

The Evidence

Clinical Effectiveness

The 2010 manufacturer-funded Deep Vein Thrombosis (DVT) Prevention in Total Hip Arthroplasty: Continuous Enhanced Circulation Therapy (CECT) Versus Low Molecular Weight Heparin (LMWH) trial (the SAFE trial) was a randomized, unblinded, prospective study of 410 patients who underwent total hip replacement at nine US centres.[22] The study compared the safety and effectiveness of compression therapy using ActiveCare+S.F.T. with or without ASA to anticoagulation therapy with enoxaparin.[22] Several patients in each group withdrew from the study or were not available for follow-up assessment. Three hundred and eighty-six patients completed the efficacy component of the study — 196 in the compression group and 190 in the anticoagulation group. Both groups received treatment for 10 days. Patients with previous VTE or a known bleeding disorder were excluded from the study.[22]

The compression group in the SAFE trial began using ActiveCare+S.F.T. during surgery and continued its use while in hospital and at home.[22] One hundred and twenty-five patients in the compression group (63%) received 81 mg ASA daily at the discretion of their physician. Patients in the anticoagulation group received 30 mg enoxaparin every 12 hours until hospital discharge, followed by 40 mg once daily at home.[22] Ten to 12 days after surgery, all patients received duplex ultrasonography of both legs to detect DVT.[22] Patients with a negative ultrasound scan were followed for an additional 10 to 12 weeks for late signs of VTE, bleeding, or other complications.[22]

In the SAFE trial, 10 VTEs (5%) — including eight DVTs and two PEs — were detected in the compression group.[22] Ten patients (5%) in the anticoagulation group also had VTEs (eight DVTs and two PEs). All VTEs in both patient groups were successfully treated. No deaths were reported. The trial included enough patients to demonstrate the safety of compression therapy compared with anticoagulation therapy, but was not large enough to conclusively determine its comparative efficacy.[22]

Patients in the SAFE trial who received ASA in addition to compression had rates of VTE similar to those who did not take ASA.[22] Because ASA use was discretionary and not an explicit criterion in the study design, the efficacy of treatment in the compression group may have appeared better than if compression therapy had been used alone. In addition, discretionary use of ASA may have increased bleeding in the compression group. The results of the study should be considered with these potential biases in mind.

The SAFE trial defined major bleeding as bleeding that required a longer hospital stay or re-hospitalization, surgery, or other interventions to resolve, or was life-threatening or determined to be the cause of death. No patients in the compression group experienced major bleeding compared with 11 patients (6%) who experienced major bleeding in the anticoagulation group. [22]

Patients in the compression group of the SAFE trial used the device for an average of 20 hours per day (or 83% of the prescribed treatment time), for an average of 11 days.[22] Improved compliance with portable compression was also noted in earlier studies that compared portable compression to standard compression devices.[36,37] The authors hypothesize that the longer daily duration of compression therapy may be at least partly responsible for improved outcomes in the compression group.[22]

A manufacturer-funded prospective study at one US centre, published in 2016, assessed a risk-stratification protocol for VTE prevention in patients undergoing unilateral hip or knee replacement or revision surgery.[38] The study included 3,143 patients divided into low-risk (2,222) and high-risk (921) prophylaxis regimen groups. Patients were excluded from the study if they had a history of DVT, PE, or wound healing complications; were undergoing multiple surgeries; were taking immunosuppressant drugs or long-term warfarin; or were receiving kidney dialysis. High-risk patients included those

with heart disease, chronic obstructive pulmonary disease, other restrictive lung diseases, type 1 or type 2 diabetes, multiple medical comorbidities, a family history of VTE, or those with limited weight-bearing capability one day after surgery. All patients received portable compression with the ActiveCare+S.F.T. device. The low-risk group used portable compression for 10 days for a target of 23 hours per day and received 325 mg of ASA two times a day. The high-risk group used portable compression only during their hospital stay. They also received warfarin anticoagulation therapy for four weeks and were asked to wear compression stockings for six weeks. All patients received the same rehabilitation interventions, including early mobilization.[38]

Six weeks after surgery, 13 (0.7%) VTEs had occurred in the low-risk group and four (0.5%) had occurred in the high-risk group. [38] Major bleeding events were significantly lower in the low-risk group: seven (0.4%) compared with 16 (2.0%) in the high-risk group. The authors concluded that, in appropriately risk-stratified patients, portable compression and ASA was not inferior to warfarin use in preventing VTE. Moreover, the authors noted that approximately 70% of all patients could potentially avoid more "aggressive" anticoagulation drug therapy and instead receive VTE prophylaxis with portable compression and ASA. Regarding compliance with compression therapy, more than 84% of patients in the low-risk group used the portable compression device for at least 18 hours per day.[38]

A 2014 patient registry study, funded by the manufacturer of ActiveCare, assessed portable compression using the ActiveCare+S.F.T. device in 3,060 patients at 10 US centres.[30] The study was designed to determine whether ActiveCare+S.F.T., with or without ASA, was as effective as anticoagulation therapy for reducing the risk for VTE. Patients were excluded from the study if they had a history of VTE, cancer, or a bleeding disorder.[30] Patients received ActiveCare+S.F.T. therapy for at least 10 days after surgery and some patients received ASA at the discretion of their physician. The registry recorded symptomatic DVTs or PEs that occurred within three months of surgery. Data from published clinical trials were used for the comparative group of patients who received anticoagulation therapy. The investigators attempted to address selection bias in the comparison group by using similar inclusion and exclusion criteria for the ActiveCare+S.F.T. group and by enrolling patients with similar demographics.[19]

In total, 28 patients in the ActiveCare+S.F.T. group (0.92%) experienced symptomatic VTE (23 DVTs and five non-fatal PEs).[30] The study was too small to determine the effect of adding ASA to ActiveCare. Rates of VTE with anticoagulation therapies alone ranged from 0.64% with rivaroxaban to 2.2% with warfarin. Bleeding rates and patient compliance with ActiveCare+S.F.T. therapy were not recorded in the registry. The study concluded that ActiveCare+S.F.T. was as effective as most anticoagulation therapies, with the exception of rivaroxaban in knee replacement surgery.[30]

A 2015 conference presentation described preliminary results of a retrospective review of data on patients who underwent hip or knee replacement surgery.[39] Investigators assessed rates of DVT, PE, and bleeding complications in patients, following their hospital's new protocol of stratifying patients by risk. These patients were divided into two risk-stratified subgroups: 843 patients with no known risk factors for VTE who received portable compression (ActiveCare DVT for 18 hours per day) plus ASA (325 mg twice per day) for 28 days; and 565 patients with at least one risk factor for VTE who received anticoagulant therapy (low-molecular-weight heparin, warfarin, or rivaroxaban). The four risk factors considered were previous VTE, tobacco use, morbid obesity, and concurrent cancer treatment. These risk-stratified patients were compared with a historical cohort of 1,203 patients who had all received anticoagulant therapy. There was no statistically significant difference in the number of VTEs in the risk-stratified group (n = 21 or 1.49%) compared with those in the historical cohort (n = 19 or 1.58%), or in the number of adverse events (including VTE, infection, and bleeding) in the risk-stratified patients (n = 51 or 3.62%) compared with those in the historical cohort (n = 48 or 3.99%). Hospital costs were reported to be lower in the subgroup that received compression therapy and ASA, but actual costs were not shown. The investigators concluded that, in patients with no known risk factors for VTE, portable compression and ASA therapy provides equivalent VTE prevention to anticoagulant drug therapy, and at a lower cost.[39]

Without prophylaxis, the rate of VTE in patients having a knee replacement is high, and it is higher among patients who have both knees replaced in the same surgery (simultaneous bilateral knee replacement) than with patients who have only one knee replaced (unilateral knee replacement).[40] A small, non-randomized study published in 2015, of patients who had simultaneous bilateral knee replacement, compared

VTE prevention using portable compression therapy to anticoagulation therapy.[41] The portable compression group (n = 47) received ActiveCare+S.F.T (for 10 days both in and out of hospital) plus ASA (325 mg twice daily for six weeks). The anticoagulation therapy group (n = 49) received portable compression therapy while in hospital plus warfarin for four weeks. No symptomatic VTEs occurred in the portable compression group. One patient in the anticoagulation therapy group experienced a symptomatic DVT several weeks after surgery. Patients in the anticoagulation therapy group were assigned to that group because they were intolerant to ASA or were at higher risk for VTE. The study was too small to determine conclusively if there was a difference between groups, but the authors concluded that their results indicate this area is worthy of further research. However, a 2013 study by Levy et al. found that, in simultaneous bilateral knee replacement surgery, the use of ActiveCare+S.F.T. portable compression therapy alone did not provide adequate VTE prophylaxis and the benefits of adding drug therapy should be investigated further.[40,41]

A 2009 hospital-sponsored, retrospective review of 1,810 hip and knee replacement patients at one US centre compared VTE rates, treatment compliance, and length of hospital stay when using a portable compression device (ActiveCare CECT, an older ActiveCare device) to a stationary compression device (Flowtron Excel, a calf-length compression device).[36] Compression was provided throughout the patient's hospital stay. In addition to compression therapy, all patients received anticoagulation therapy with enoxaparin and early mobilization.[36] Two hundred and fifty patients received ActiveCare therapy and 1,560 received Flowtron Excel therapy during the 15-month study period. The final analysis included 223 ActiveCare patients and 1,354 Flowtron Excel patients. DVT was confirmed using duplex ultrasound in three patients (1.3%) in the ActiveCare group and in 49 patients (3.6%) in the Flowtron Excel group. No PEs occurred in the ActiveCare group, but nine (0.66%) were confirmed in the Flowtron Excel group. Patient compliance with treatment — defined as use of the compression therapy for at least 20 hours per day — was higher in the ActiveCare group (83%) than in the Flowtron Excel group (49%). However, compliance was recorded differently in the two groups — using the built-in monitor for the ActiveCare group and through nursing staff records for the Flowtron Excel group. Average hospital length of stay was slightly shorter in the ActiveCare group (4.2 days ± 3.2 days) than in the Flowtron group (5.0 days ± 3.7 days) — possibly due to the lower rate of DVTs in the ActiveCare group.[36]

A small, manufacturer-funded study, published in 2008, compared the use of anticoagulation therapy with low-molecular-weight heparin plus compression with ActiveCare DVT to the use of anticoagulation therapy alone. The study included 277 patients undergoing hip replacement surgery (n = 124) or knee replacement surgery (n = 153) at a single centre.[42] The study found a reduction in risk of DVT when ActiveCare DVT was added to anticoagulation therapy in patients undergoing knee replacement: five DVTs (6.6%), including one PE (occurred post-discharge), in the 76 patients in the ActiveCare DVT group, compared with 14 DVTs (19.5%) and one PE in the 77 patients in the drug-therapy-only group. However, there was no significant difference in rates of DVTs in the patients who underwent hip replacement surgery: one patient in the 65 patients in the ActiveCare DVT group (1.5%) and two patients (3.4%) in the 59 patients in the anticoagulation group.[42]

A 2006 hospital- and university-funded study, using WizAir — the previous generation of ActiveCare — compared rates of DVT in 136 patients undergoing hip or knee replacement surgery at a single centre in Israel. Patients were randomized to receive either compression therapy plus ASA (100 mg per day), or anticoagulation therapy (40 mg of enoxaparin once daily by injection).[6] The duration of therapy was not specified. A total of 121 patients (61 in the compression group and 60 in the anticoagulation group) completed the study and were included in analysis. Five to eight days after surgery, each patient received venograms or duplex ultrasounds of both legs to detect DVT. Follow-up continued for three months. Four patients in the compression group had a DVT (6.6%) compared with 17 (28.3%) in the anticoagulation group. Patients who received compression had a shorter average hospital stay (8.8 ± 1.9 days) compared with the anticoagulation group (9.9 ± 2.7 days). Because all other rates of adverse events were similar between the groups, investigators concluded the difference in length of stay was due to the lower rate of DVT in the compression group.[6]

Patient Satisfaction and Compliance

A 2014 US study of ActiveCare+S.F.T. after hip replacement surgery found that 234 of the 247 patients (94.7%) who used the device said they would use it again.[43] Despite their overall satisfaction, 80.1% of patients felt the device was uncomfortable, 63.6% thought it was cumbersome, 31.6% found it noisy, 8.5% reported a rash from the inflatable sleeves, and 3.6% said it was painful to use. Some patients (10.1%) reported having a fall, which they attributed to the device, but no injuries were noted.[43]

Other than the ActiveCare studies, there is little evidence about other portable compression systems in hip and knee replacement surgery. Compliance with therapy may be improved with a fully portable compression unit that does not have to be disconnected and reconnected when the patient moves;[6,19] however, the available evidence showing improved compliance with portable compression is based on studies of patients in hospital, rather than at home.[1]

Other Considerations

A final consideration is a lack of research comparing portable compression to newer direct oral anticoagulants — such as apixaban, a direct factor Xa inhibitor. One small, industry-funded study in Canada found apixaban to be generally more cost-effective than current anticoagulant therapies — mainly due to fewer adverse events.[44]

Health Technology Assessments and Systematic Reviews

A 2012 assessment of the ActiveCare+S.F.T. by the University HealthSystem Consortium noted that ActiveCare+S.F.T was the first portable system to demonstrate safety and efficacy in a randomized controlled trial (the SAFE trial[22]).[21] The authors concluded that the portability of the device, and its ability to record compliance, may increase usage and improve efficacy.[21] However, criteria for selecting patients who would most benefit from using the device and the optimal duration of treatment were not known, and studies comparing ActiveCare+S.F.T. to newer drug therapies, including assessment of patient preferences for therapy, were still needed.[21]

A 2009 report by the University of Pennsylvania Health System Center for Evidence-based Practice assessed intermittent pneumatic compression devices for VTE prevention. It concluded that, while these devices reduced the risk of VTE, there is a lack of evidence comparing the effectiveness of the different devices.[45]

A 2007 assessment of the ActiveCare DVT system by the Australia and New Zealand Horizon Scanning Network, for the Health Policy Advisory Committee on Technology (HealthPACT), concluded that the portability of the device was an advantage over stationary compression devices; however, the clinical benefits appeared to be similar to those of other types of DVT prevention.[18]

In 2015, the US Department of Veterans Affairs funded a systematic review of compression therapy — alone and in combination with drug therapy — to prevent VTE in hospitalized patients undergoing various high-risk surgeries.[14,46] The review concluded that although the use of these devices is appropriate and should follow current clinical guidelines, there was little comparative effectiveness evidence to guide their selection.[46] Limited evidence suggested the use of compression devices alone may lower the risk of bleeding, and that the use of both compression and drug therapy reduced the risk for VTE.[14]

A 2014 Cochrane systematic review comparing different types of intermittent pneumatic compression devices to prevent VTE after hip replacement concluded that there was little evidence to support the use of one device over another.[11]

A 2012 systematic review of VTE prevention in hip and knee replacement patients found that the use of combined therapy — intermittent mechanical compression and drug therapy — reduced the occurrence of DVT in both hip and knee surgeries.[47] The studies were not large enough to determine a difference in effect on rates of PE.[47]

The US Agency for Healthcare Research and Quality (AHRQ) is currently updating its 2012 systematic review of VTE prophylaxis in orthopedic surgery.[9,10] Key questions to be addressed include the comparative efficacy of different interventions, including mechanical compression, the efficacy of combined preventive therapies, and the optimal regimens and duration of treatment.[10]

Adverse Events

Rare reports of compartment syndrome and peroneal nerve palsy have been reported with the use of compression devices in orthopedic surgery.[22,48] In the 2010 trial of ActiveCare+S.F.T., patients' reasons for removing the compression device included noise from the pump motor, mild skin rash, and warmth of the device on the legs.[15,22] A study of ActiveCare+S.F.T. in knee replacement patients reported no serious complications, but one patient found the compression uncomfortable and chose to receive drug therapy instead.[40]

The US FDA Manufacturer and User Facility Device Experience (MAUDE) database lists several reports of ActiveCare device

malfunction or adverse events, but most were deemed due to patient or caregiver error (e.g., use of the wrong electrical adaptor for the device or not performing routine skin checks to ensure the sleeves were not causing skin irritation), or not device-related (e.g., cardiopulmonary arrest after a patient had used the device without incident for 14 days in a rehabilitation facility).[49]

Administration and Cost

No Canadian pricing information is available.

A 2014 study estimated the cost of using the ActiveCare+S.F.T. at US$30 per day, or US$300 for a 10-day course of therapy.[43]

The 2012 University HealthSystem Consortium review estimated the US cost of the ActiveCare system to be approximately US$1,500, with an additional $30 to $50 for the disposable leg cuffs.[21] Estimated costs for using the device were approximately $200 for in-hospital use, and an additional $200 for at-home use (based on cost of renting the unit; the number of days of in-hospital and at-home use were not specified).

A US cost-effectiveness model — funded by the manufacturer — projected that the use of compression therapy instead of low-molecular-weight heparin would result in a cost savings of US $369.50 per patient — mainly due to the costs avoided in treating major bleeding events.[5]

Concurrent Developments

The geko device (FirstKind Ltd., High Wycombe, United Kingdom [UK]) is a disposable, portable electrostimulation unit that is strapped below the knee and used to stimulate the peroneal nerve (a nerve that affects sensation in, and movement of, the lower leg), causing muscle contractions in the lower leg and foot to increase blood flow back to the heart.[50] Recent guidance from the National Institute for Health Care Excellence (NICE) in the UK concluded that there is limited evidence on the geko device, but it is "supported for use in people at high risk of [VTE] and for whom other mechanical compression and prophylactic drug therapies are impractical or contraindicated."[50] The geko device is available in Canada, the US, and Europe and costs CDN$100 for each pair of disposable, daily use devices (Geoff Fournie, Perfuse Medtec, London, ON; personal communication, 2015 Dec 7).

Increasingly, early mobilization of patients is being used to prevent VTE. A systematic review of early mobilization for preventing VTE after hip or knee replacement surgery is underway.[51]

Rate of Technology Diffusion

The ActiveCare devices are not yet available in Canada and no information on their potential diffusion here was found.

Implementation Issues

Patient preferences may affect the choice of preventive therapy — some may want the convenience of drug therapy, while others may prefer to avoid the possible adverse effects of drug therapy, regardless of any minor inconveniences with compression therapy. Patient preferences with respect to newer drug therapies with more convenient dosing and potentially improved outcomes may differ from those for older drug therapies.[21]

Patient instruction in the use of mobile compression at home will require nursing staff time.[15] Patients should be warned about the risk of falling or becoming entangled or caught on objects if they use these devices when walking.[43]

As hospital stays become shorter, the need for portable compression devices that patients can use at home may increase.[12] Extending the period of preventive therapy may be beneficial, as many VTEs occur weeks or months after hospital discharge.[3,19,22] However, the optimal period of use of compression therapy once patients are ambulatory after surgery is still unknown.[21]

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