

Medical Policy



Title: Postsurgical Home Use of Limb Compression Devices for Venous Thromboembolism Prophylaxis

Related Policy: ▪ *Pneumatic Compression Pumps for Treatment of Lymphedema and Venous Ulcers (for Home Use)*

Professional

Original Effective Date: April 9, 2013
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Populations	Interventions	Comparators	Outcomes
Individuals: • With moderate-to-high postsurgical risk of venous thromboembolism and no contraindication to pharmacologic prophylaxis	Interventions of interest are: • Home use of a limb compression device as an adjunct to anticoagulation	Comparators of interest are: • Anticoagulation only	Relevant outcomes include: • Overall survival • Symptoms • Morbid events • Treatment-related morbidity
Individuals: • With moderate-to-high postsurgical risk of venous thromboembolism and a contraindication to pharmacologic prophylaxis	Interventions of interest are: • Home use of a limb compression device	Comparators of interest are: • No outpatient venous prophylaxis or other methods of mechanical prophylaxis	Relevant outcomes include: • Overall survival • Symptoms • Morbid events • Treatment-related morbidity

DESCRIPTION

Antithrombotic prophylaxis is recommended for surgical patients at moderate-to-high risk of postoperative venous thromboembolism (VTE), including deep vein thrombosis (DVT) and pulmonary embolism (PE), based on the surgical procedure and/or patient characteristics. For some types of surgery (e.g., major orthopedic surgery), there is a particularly high risk of VTE due to the nature of the procedure and the prolonged immobility during and after surgery. Common patient risk factors include increasing age, prior VTE, malignancy, pregnancy, and significant comorbidities. Increased risk of bleeding is a contraindication to anticoagulation as are adverse effects and allergic reactions. Limb compression devices have been used as an adjunct or alternative to anticoagulation in the home setting for patients in the postoperative period as a method to reduce VTEs.

Objective

The objective of this evidence review is to determine whether the use of limb compression devices in the home setting improves the net health outcome for patients at risk of venous thromboembolism in the postsurgical period.

Background

RISK OF VENOUS THROMBOEMBOLISM

Orthopedic Surgery

Antithrombotic prophylaxis is recommended for surgical patients at moderate-to-high risk of postoperative venous thromboembolism (VTE), including deep vein thrombosis (DVT) and pulmonary embolism (PE). Patients may be classified as moderate-to-high risk of VTE based on the surgical procedure and/or patient characteristics. For some types of surgery, such as major orthopedic surgery, there is a particularly high-risk of VTE due to the nature of the procedure and the prolonged immobility during and after surgery. The specific orthopedic procedures of concern are total knee arthroplasty, total hip arthroplasty, and hip fracture surgery. For these surgeries, all patients undergoing the procedure are considered at high-risk for VTE.

Other surgeries with an increased risk of VTE include abdominal surgery, pelvic surgery, cancer surgery, and surgery for major trauma. For these types of surgeries, the risk varies. There are numerous patient-related risk factors such as increasing age, prior VTE, malignancy, pregnancy, and significant comorbidities that can be used in conjunction with the type of surgery to determine risk. There are tools for assessing VTE risk in surgical patients, such as the modified Caprini Risk Assessment Model used in developing the 2012 American College of Chest Physicians (ACCP) guidelines on VTE prevention. However, in clinical practice, this and similar instruments are not regarded as definitive for the assessment of individual patient risk. Pharmacologic prophylaxis is indicated for patients at moderate-to-high risk for VTE. As described in the ACCP guidelines, there are preferred antithrombotic prophylaxis regimens according to procedure and patient risk characteristics.^{1,4,}

Pharmacologic Prophylaxis

Pharmacologic prophylaxis is effective at reducing postoperative VTE but also has risks. The main risk is bleeding, although other adverse events such as allergic reactions and development of heparin antibodies can occur. Contraindications to pharmacologic prophylaxis include previous intolerance to these agents and increased risk of bleeding. Most patients undergoing major surgery will not have an increased risk of bleeding precluding the use of anticoagulants, because these patients would also likely have had a contraindication to the surgery itself and, thus, are

likely to avoid the procedure. However, there are some cases in which patients with a high bleeding risk will undergo major surgery, such as patients with severe renal failure who require an essential procedure. Other patients may develop contraindications during the episode of care. For example, patients who have excessive bleeding during or after surgery, or patients who develop bleeding complications such as a gastrointestinal bleed, are considered to have a contraindication to anticoagulants. There are a few surgeries for which anticoagulants are contraindicated or avoided, most notably some neurosurgical procedures. Assessment and quantitation of bleeding risk can be performed using instruments such as HAS-BLED scoring system,⁶ although these tools were not developed specifically for the postoperative period.

Major orthopedic surgeries have a high-risk of DVT due to venous stasis of the lower limbs as a consequence of immobility during and after surgery. Also, direct venous wall damage associated with the surgical procedure itself may occur. DVTs are frequently asymptomatic and generally resolve when mobility is restored. However, some episodes of acute DVT can be associated with substantial morbidity and mortality. The most serious adverse consequence of acute DVT is PE, which can be fatal. Pulmonary embolism occurs when a DVT blood clot detaches and migrates to the lungs. Also, DVT may produce long-term vascular damage that leads to chronic venous insufficiency. Without thromboprophylaxis, the incidence of venographically detected DVT is approximately 42% to 57% after total hip replacement, and the risk of PE is approximately 1% to 28%.⁷ Other surgical patients may be at increased risk of VTE during and after hospitalization. For example, it is estimated that rates of VTE without prophylaxis after gynecologic surgery are 15% to 40%.⁵

Thus, antithrombotic prophylaxis is recommended for patients undergoing major orthopedic surgery and other surgical procedures who are at increased risk of VTE. For patients undergoing major orthopedic surgery, clinical practice guidelines published by the ACCP (2012) recommended that one of several pharmacologic agents or mechanical prophylaxis be provided rather than no thromboprophylaxis.¹ The guidelines further recommended the use of pharmacologic prophylaxis during hospitalization, whether or not patients are using a limb compression device. A minimum of 10 to 14 days of prophylaxis is recommended, a portion of which can be post discharge home use.

Limb Compression Prophylaxis

The ACCP guidelines have also noted that compliance is a major issue with the home use of limb compression devices for thromboprophylaxis and recommended that, if this prophylactic option is selected, use should be limited to portable, battery-operated devices. Moreover, ACCP recommended that devices be used for 18 hours a day. A 2009 nonrandomized study found that there was better compliance with a portable battery-operated limb compression device than with a nonmobile device when used by patients in the hospital following hip or knee replacement surgery.⁸

Nonorthopedic Surgery

Pharmacologic and Limb Compression Prophylaxis

The ACCP (2012) also issued guidelines on VTE prophylaxis in nonorthopedic surgery patients.⁴ For patients undergoing general or abdominal-pelvic surgery who have a risk of VTE of 3% or higher, the ACCP has recommended prophylaxis with pharmacologic agents or intermittent pneumatic compression rather than no prophylaxis. For patients at low-risk for VTE (~1.5%), the

guidelines have suggested mechanical prophylaxis. Unlike the guidelines on major orthopedic surgery, which recommend a minimum of 10 to 14 days of VTE prophylaxis, the guidelines on nonorthopedic surgery patients do not include a general timeframe for prophylaxis. They have, however, defined “extended duration” pharmacologic prophylaxis as lasting 4 weeks; the latter is recommended only for patients at high-risk for VTE, undergoing abdominal or pelvic surgery for cancer, and who are not otherwise at high-risk for major bleeding complications.

National clinical guidelines have not specifically recommended the use of limb compression devices in the post-discharge home setting. However, given the availability of portable, battery-operated devices, there is interest in the home use of limb compression devices for VTE prevention following discharge from the hospital for major orthopedic and nonorthopedic surgery.

REGULATORY STATUS

A large number of pneumatic and peristaltic limb compression devices have been cleared for marketing by the FDA through the 510(k) process for indications including prevention of DVT. A sample of portable devices cleared by the FDA include (FDA product code: JOW):

- AIROS 6 Sequential Compression Device (AIROS Medical, Inc.): This device is safe for both home and hospital use.
- Plexus RP100 Disposable Portable Deep Vein Thrombosis Prevention Device (Alleva Medical [D.G.] Ltd: This device is for home or clinical settings and is powered by an internal rechargeable battery.
- AeroDVx™ System (Sun Scientific Inc): This device is for hospital or outpatient use.
- VenaPro™ Vascular Therapy System (InnovaMed Health): This device is battery-powered.
- Venowave™ VW5 (Venowave): This device is battery-powered and strapped to the leg below the knee.
- ActiveCare®+S.F.T. System (Medical Compression Systems): The device applies sequential pneumatic compression to the lower limb; it has the option of being battery-operated. Foot compression is achieved with the use of a single-celled foot sleeve. Calf and thigh compression requires the use of a 3-celled cuff sleeve.
- Restep® DVT System (Stortford Medical): This lightweight device uses single-chamber pressure cuffs attached to the patient’s lower legs.
- Kendall SCD™ 700 Sequential Compression System (Covidien): This pneumatic compression device can be used in the clinic or at home; it has a battery-powered option.
- PlasmaFlow™ (ManaMed): This system is portable, to be used at home or in a clinical setting.

A full listing of products cleared by the FDA can be found at the following link:

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?start_search=1&Center=&Panel=&ProductCode=JOW&KNumber=&Applicant=&DeviceName=&Type=&ThirdPartyReviewed=&ClinicalTrials=&Decision=&DecisionDateFrom=&DecisionDateTo=01%2F23%2F2021&IVDProducts=&Redact510K=&CombinationProducts=&ZNumber=&PAGENUM=500

POLICY

- A. Postsurgical home use of limb compression devices for venous thromboembolism (VTE) prophylaxis may be considered **medically necessary** in patients with a contraindication to pharmacologic agents (see Policy Guidelines), in the following situations:
1. After major orthopedic surgery (total hip arthroplasty, total knee arthroplasty, hip fracture surgery);
OR
 2. After major nonorthopedic surgery or other orthopedic procedures in patients who are at moderate or high risk of VTE (see Policy Guidelines)
- B. Postsurgical home use of limb compression devices for venous thromboembolism (VTE) prophylaxis is considered **experimental / investigational** in all other situations, including, but not limited to:
1. After major orthopedic surgery (total hip arthroplasty, total knee arthroplasty, hip fracture surgery) in patients without a contraindication for anticoagulation; **OR**
 2. After major nonorthopedic surgery or other orthopedic procedures in patients without a contraindication for anticoagulation who are at moderate or high risk of VTE (see Policy Guidelines)
- C. Postsurgical home use of limb compression devices for VTE prophylaxis for periods longer than 30 days postsurgery is **not medically necessary**.
- D. Home use of limb compression devices for venous thromboembolism (VTE) prophylaxis after all other surgeries is considered **experimental / investigational**.

Policy Guidelines

This section reviews guidance on contraindications to using anticoagulants, determining risk for bleeding, determining risk for venous thromboembolism (VTE), and duration of treatment postoperatively.

Contraindications to Anticoagulants

The main contraindication to anticoagulants is a high risk of bleeding. However, there is no absolute threshold at which anticoagulants cannot be used. Rather, there is a risk-benefit continuum that takes into account benefits of treatment and risks of bleeding. There may also be intolerance to specific agents, although uncommon. Intolerance may result from allergic reactions or adverse events. Finally, when heparin preparations are used, serum antibodies and heparin-induced thrombocytosis can develop, precluding further use of heparin products.

Guidance on Determining High Risk for Bleeding

American College of Chest Physicians (ACCP) guidelines on prevention of VTE in orthopedic surgery patients listed the following general risk factors for bleeding (Falck-Ytter et al, 2012):

- "Previous major bleeding (and previous bleeding risk similar to current risk)
- Severe renal failure
- Concomitant antiplatelet agent
- Surgical factors: history of or difficult-to-control surgical bleeding during the current operative procedure, extensive surgical dissection, and revision surgery"

The guidelines indicated, however, that "...specific thresholds for using mechanical compression devices or no prophylaxis instead of anticoagulant thromboprophylaxis have not been established."

The 2016 ACCP guidelines addressing antithrombotic therapy for VTE disease outlined risk factors for bleeding with anticoagulant therapy and estimated the risks of major bleeding for patients in various risk categories (see Table PG1) (Kearon et al, 2016).

Risk factors include (1 point per risk factor):

- "Age >65 y
- Age >75 y
- Previous bleeding
- Cancer
- Metastatic cancer
- Renal failure
- Liver failure
- Thrombocytopenia
- Previous stroke
- Diabetes
- Anemia
- Antiplatelet therapy
- Poor anticoagulant control
- Comorbidity and reduced functional capacity
- Recent surgery
- Alcohol abuse
- Nonsteroidal anti-inflammatory drug."

Table PG1. Guidelines for Risk of Bleeding

Risk Factors	Estimated Absolute Risk of Major Bleeding		
	Low Risk (0 Risk Factors)	Moderate Risk (1 Risk Factor)	High Risk (≥2 Risk Factors)
Anticoagulation 0-3 mo, %			
Baseline risk	0.6	1.2	4.8
Increased risk	1.0	2.0	8.0
Total risk	1.6	3.2	12.8
Anticoagulation after first 3 mo, %/y			
Baseline risk	0.3	0.6	≥2.5
Increased risk	0.5	1.0	≥4.0
Total risk	0.8	1.6	≥6.5

Adapted from Kearon et al (2016).

Clinical guidelines from the American Academy of Orthopaedic Surgeons (Mont et al, 2011) have indicated that:

"Patients undergoing elective hip or knee arthroplasty are at risk for bleeding and bleeding-associated complications. In the absence of reliable evidence, it is the opinion of this work group that patients be assessed for known bleeding disorders like hemophilia and for the presence of active liver disease which further increase the risk for bleeding and bleeding-associated complications. (Grade of Recommendation: Consensus) Current evidence is not clear about whether factors other than the presence of a known bleeding disorder or active liver disease increase the chance of bleeding in these patients and, therefore, the work group is unable to recommend for or against using them to assess a patient's risk of bleeding. (Grade of Recommendation: Inconclusive)"

Guidance on Duration of Use

In patients with contraindications to pharmacologic prophylaxis who are undergoing major orthopedic surgery (total hip arthroplasty, total knee arthroplasty, hip fracture surgery), ACCP guidelines are consistent with use of intermittent limb compression devices for 10 to 14 days after surgery. (Falck-Ytter et al, 2012) The ACCP suggestion on extended prophylaxis (up to 35 days) was a weak recommendation that did not mention limb compression devices as an option.

In the ACCP guidelines on VTE prophylaxis in patients undergoing nonorthopedic surgery, the standard duration or “limited duration” of prophylaxis was not defined. However, “extended duration” pharmacologic prophylaxis was defined as 4 weeks; which was recommended only for patients at high risk for VTE undergoing abdominal or pelvic surgery for cancer and not otherwise at high risk for major bleeding complications.

Guidance on Determining Risk Level for Nonorthopedic Surgery

The ACCP guidelines on prevention of VTE in nonorthopedic surgery patients included the following discussion of risk levels (Gould et al, 2012):

“In patients undergoing general and abdominal-pelvic surgery, the risk of VTE varies depending on both patient-specific and procedure-specific factors. Examples of relatively low-risk procedures include laparoscopic cholecystectomy, appendectomy, transurethral prostatectomy, inguinal herniorrhaphy, and unilateral or bilateral mastectomy. Open-abdominal and open-pelvic procedures are associated with a higher risk of VTE. VTE risk appears to be highest for patients undergoing abdominal or pelvic surgery for cancer...

Patient-specific factors also determine the risk of VTE, as demonstrated in several relatively large studies of VTE in mixed surgical populations. Independent risk factors in these studies include age >60 years, prior VTE, and cancer; age ≥60 years, prior VTE, anesthesia ≥2 h, and bed rest ≥4 days; older age, male sex, longer length of hospital stay, and higher Charlson comorbidity score; and sepsis, pregnancy or postpartum state, central venous access, malignancy, prior VTE, and inpatient hospital stay >2 days. In another study, most of the moderate to strong independent risk factors for VTE were surgical complications, including urinary tract infection, acute renal insufficiency, postoperative transfusion, perioperative myocardial infarction, and pneumonia.”

In 2007 (reaffirmed in 2012), the American College of Obstetricians and Gynecologists (ACOG) revised its risk classification for VTE in patients undergoing major gynecological surgery (American College of Obstetricians and Gynecologists, 2007):

“Low: Surgery lasting less than 30 minutes in patients younger than 40 years with no additional risk factors.

Moderate: Surgery lasting less than 30 minutes in patients with additional risk factors; surgery lasting less than 30 minutes in patients aged 40 to 60 years with no additional risk factors; major surgery in patients younger than 40 years with no additional risk factors.

High: Surgery lasting less than 30 minutes in patients older than 60 years or with additional risk factors; major surgery in patients older than 40 years or with additional risk factors.

Highest: Major surgery in patients older than 60 years plus prior venous thromboembolism, cancer, or hypercoagulable state.”

RATIONALE

The most recent literature update was performed through January 25, 2021.

Evidence reviews assess the clinical evidence to determine whether the use of a technology improves the net health outcome. Broadly defined, health outcomes are length of life, quality of life, and ability to function, including benefits and harms. Every clinical condition has specific outcomes that are important to patients and managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and

whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of technology, 2 domains are examined: the relevance and the quality and credibility. To be relevant, studies must represent 1 or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial (RCT) is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. RCTs are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

MODERATE-TO-HIGH POSTSURGICAL RISK OF VENOUS THROMBOEMBOLISM AND NO CONTRAINDICATION TO PHARMACOLOGIC PROPHYLAXIS

Clinical Context and Therapy Purpose

The purpose of home use of a limb compression device as an adjunct to anticoagulation is to provide a treatment option that is an alternative to or an improvement on existing therapies, such as anticoagulation only, in patients with moderate-to-high postsurgical risk of venous thromboembolism (VTE) and no contraindication to pharmacologic prophylaxis.

The question addressed in this evidence review is: Does the use of limb compression devices in the home setting reduce the risk of VTE in the postsurgical period?

The following PICO was used to select literature to inform this review.

Populations

The relevant population of interest are individuals with moderate-to-high postsurgical risk of VTE and no contraindication to pharmacologic prophylaxis.

Interventions

The therapy being considered is home use of a limb compression device as an adjunct to anticoagulation.

Comparators

Comparators of interest include anticoagulation only. Treatments include an anticoagulation regimen and conventional therapy.

Outcomes

The general outcomes of interest are overall survival, symptoms, morbid events, and treatment-related morbidity.

The existing literature evaluating home use of a limb compression device as an adjunct to anticoagulation as a treatment for moderate-to-high postsurgical risk of VTE and no contraindication to pharmacologic prophylaxis has varying lengths of follow-up. While studies

described below all reported at least 1 outcome of interest, longer follow-up was necessary to fully observe outcomes.

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

1. To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
2. In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
3. To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
4. Studies with duplicative or overlapping populations were excluded.

Review of Evidence

This section focuses on evidence that post-discharge use of limb compression devices (commonly referred to in the literature as intermittent pneumatic compression [IPC] devices) in addition to pharmacologic agents provide an incremental benefit to the net health outcome compared with pharmacologic agents alone. The ideal study design to address patients with moderate-to-high postsurgical risk of VTE and no contraindication to pharmacologic prophylaxis is a superiority RCT comparing VTE prophylaxis consisting of pharmaceutical agents plus limb compression devices with pharmacologic agents alone. No RCTs with this study design were identified for patients discharged after major orthopedic surgery or other types of major surgery. There are, however, RCTs and meta-analyses of RCTs comparing medication plus compression devices with medication alone in surgical patients in the hospital setting. These studies may not permit inferences to the post discharge home setting, however, they are briefly summarized for informational purposes below.

Systematic Reviews

Multiple meta-analyses of RCTs have compared pharmacological VTE prophylaxis plus an IPC device with medication alone in surgical patients in the hospital setting.^{9,10,11,12,13} Surgical populations represented in these analyses include patients undergoing abdominal, cardiac, neurologic, and orthopedic surgery. Commonly reported outcomes include the occurrence of deep vein thrombosis (DVT), symptomatic DVT, and PE. In addition to an IPC device, cointerventions with other mechanical prophylaxis strategies (graduated compression stockings, etc.) have also been reported in some analyses. Overall, findings from meta-analyses suggest that the in-hospital addition of an IPC device to pharmacologic management improves VTE prophylaxis, especially for the prevention of DVT. Findings related to the risk of PE are more limited because analyses might have been underpowered due to the small number of PE events. The post-discharge setting has important characteristics that preclude making inferences from the inpatient setting. Patient characteristics vary because discharged patients tend to be healthier than those in the hospital. Characteristics of home use also vary (e.g., treatment consistency, duration, application errors in use).

Section Summary: Moderate-to-High Postsurgical Risk of Venous Thromboembolism and No Contraindication to Pharmacologic Prophylaxis

For individuals who have a moderate-to-high postsurgical risk of VTE and no contraindication to pharmacologic prophylaxis who receive home use of an IPC device as an adjunct to anticoagulation, there are no RCTs assessing the incremental benefit of home use of an IPC

device. Meta-analyses of RCTs have compared medication plus an IPC device with medication alone in surgical patients in the hospital setting. Relevant outcomes are overall survival, symptoms, morbid events, and treatment-related morbidity. Results of these meta-analyses suggest that in-hospital addition of an IPC device to pharmacologic management improves VTE prophylaxis. Limitations of these meta-analyses include: not distinguishing between asymptomatic and symptomatic DVT, sparse data on PE, and results generally not stratified by patient risk or specific intervention(s). Moreover, these trials do not permit inferences to the post-discharge home setting, since the post-discharge setting differs in important respects from the hospital setting. Discharged patients tend to be healthier than those in the hospital. Factors such as treatment consistency, duration, and application errors in use differ in the home.

MODERATE-TO-HIGH POSTSURGICAL RISK OF VENOUS THROMBOEMBOLISM AND A CONTRAINDICATION TO PHARMACOLOGIC PROPHYLAXIS

Clinical Context and Therapy Purpose

The purpose of home use of a limb compression device is to provide a treatment option that is an alternative to or an improvement on existing therapies, such as no outpatient venous prophylaxis or other methods of mechanical prophylaxis, in patients with a moderate-to-high postsurgical risk of VTE and a contraindication to pharmacologic prophylaxis.

The question addressed in this evidence review is: Does the use of limb compression devices in the home setting reduce the risk of VTE in the postsurgical period?

The following PICO was used to select literature to inform this review.

Populations

The relevant population of interest are individuals with a moderate-to-high postsurgical risk of VTE and a contraindication to pharmacologic prophylaxis.

Interventions

The therapy being considered is the home use of a limb compression device.

Comparators

Comparators of interest include no outpatient venous prophylaxis or other methods of mechanical prophylaxis. Treatment includes conventional therapy.

Outcomes

The general outcomes of interest are overall survival, symptoms, and morbid events.

The existing literature evaluating home use of a limb compression device as a treatment for moderate-to-high postsurgical risk of VTE and a contraindication to pharmacologic prophylaxis has varying lengths of follow-up. While studies described below all reported at least 1 outcome of interest, longer follow-up was necessary to fully observe outcomes.

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

1. To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;

2. In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
3. To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
4. Studies with duplicative or overlapping populations were excluded.

Review of Evidence

This section addresses whether a post discharge limb compression device (commonly referred to in the literature as an IPC device) use in moderate-to-high risk patients with a contraindication to pharmacologic prophylaxis improves the net health outcome compared with no post-discharge VTE prophylaxis. The ideal study design is an RCT comparing limb compression devices with no prophylaxis after hospital discharge. However, there may be ethical and practical barriers to conducting such a study, especially in higher-risk patients. Alternatively, a network meta-analysis could indirectly compare outcomes of limb compression device use with no VTE prophylaxis. No RCTs or network meta-analyses of post-discharge use in patients with contraindication to pharmacologic prophylaxis were identified. Briefly summarized below are data from inpatients comparing limb compression device use to no prophylaxis.

Systematic Reviews

A few meta-analyses of RCTs have compared IPC devices to no prophylaxis in the hospital setting.^{14,15,16} Populations include surgical and nonsurgical patients, including critically ill patients in a medical or surgical intensive care unit (ICU). Commonly reported outcomes include the occurrence of DVT and PE. As with the meta-analyses reviewed above, there was heterogeneity of participants and interventions. Studies using a no prophylaxis control group might have included lower risk patients and some studies involving higher risk patients also included pharmacologic prophylaxis across groups. Overall, findings from meta-analyses suggest that the in-hospital addition of an IPC device improves VTE prophylaxis over no prophylaxis, especially for the prevention of DVT; 2 of the 3 meta-analyses also saw statistically significant reductions in the incidence of PE.

Randomized Controlled Trials

To draw inferences about the benefit of limb compression devices post-discharge in these patients, the feasibility of home use should be considered. An unblinded RCT by Sobieraj-Teague et al (2012) compared the use of a portable battery-operated IPC device with usual care alone in patients undergoing cranial or spinal neurosurgery.¹⁷ All patients were also prescribed graduated compression stockings and 20% to 25% used anticoagulants. Patients were evaluated at 9 days postsurgery, and those discharged earlier were permitted to use an IPC device at home (median duration of hospitalization, 4 days). Patients who used the IPC device post-discharge received home visits at least daily to optimize compliance. Three (4%) of 75 patients in the IPC group and 14 (19%) of 75 patients in the usual care group developed VTE; the difference between groups was statistically significant ($p=0.008$). Among evaluable patients in the IPC group, 23.3% were continuous users, 53.4% were intermittent users, and 23.3% discontinued use (this includes both inpatient and outpatient use). The mean duration of IPC device use was 6.6 days. Findings would suggest that in-home use of IPC devices is feasible with adequate post-discharge planning and support.

Section Summary: Moderate-to-High Postsurgical Risk of Venous Thromboembolism and a Contraindication to Pharmacologic Prophylaxis

For individuals who have a moderate-to-high postsurgical risk of VTE and a contraindication to pharmacologic prophylaxis who receive home use of an IPC device, there are no RCTs assessing the incremental benefit of home use of an IPC device. A few meta-analyses of RCTs have compared VTE prophylaxis with an IPC device to no prophylaxis in surgical patients in the hospital setting, and 1 RCT evaluated the feasibility of post-discharge home use of an IPC. Relevant outcomes are overall survival, symptoms, morbid events, and treatment-related morbidity. Results from meta-analyses suggest that in-hospital use of an IPC device improves VTE prophylaxis over no prophylaxis. Limitations include heterogeneity of participants and interventions; studies using a no prophylaxis control group might have included lower risk patients and some studies involving higher risk patients also included pharmacologic prophylaxis across groups. Nonetheless, the inference is supported that in patients with a contraindication to pharmacologic prophylaxis, post-discharge use of an IPC device is superior for VTE prophylaxis compared with no prophylaxis. A study of the post discharge use of an IPC device combined with home visits showed that home use is feasible. With post discharge planning and support, home use of an IPC device in moderate-to-high risk patients who have a contraindication to pharmacologic prophylaxis is likely to improve VTE prevention.

Summary of Evidence

For individuals who have a moderate-to-high postsurgical risk of VTE and no contraindication to pharmacologic prophylaxis who receive home use of an intermittent pneumatic compression (IPC) device as an adjunct to anticoagulation, there are no RCTs assessing the incremental benefit of home use of an IPC device. Multiple meta-analyses of RCTs have compared medication plus an IPC device with medication alone in surgical patients in the hospital setting. Relevant outcomes are overall survival, symptoms, morbid events, and treatment-related morbidity. Results of these meta-analyses suggest that in-hospital addition of an IPC device to pharmacologic management improves VTE prophylaxis. Limitations of these meta-analyses include: not distinguishing between asymptomatic and symptomatic deep vein thrombosis; sparse data on pulmonary embolism; and results generally not stratified by patient risk or specific intervention(s). Moreover, these trials do not permit inferences to the post-discharge home setting, since the post-discharge setting differs in important respects from the hospital setting. Discharged patients tend to be healthier than those in the hospital. Factors such as treatment consistency, duration, and application errors in use differ in the home. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have a moderate-to-high postsurgical risk of VTE and a contraindication to pharmacologic prophylaxis who receive home use of an IPC device, there are no RCTs assessing the incremental benefit of home use of an IPC device. Meta-analyses of RCTs have compared VTE prophylaxis with an IPC device to no prophylaxis in surgical patients in the hospital setting, and 1 RCT evaluated the feasibility of post discharge home use of an IPC device. Relevant outcomes are overall survival, symptoms, morbid events, and treatment-related morbidity. Results from meta-analyses suggest that in-hospital use of an IPC device improves VTE prophylaxis over no prophylaxis. Limitations include heterogeneity of participants and interventions; studies using a no prophylaxis control group might have included lower risk patients and some studies involving higher risk patients also included pharmacologic prophylaxis across groups. Nonetheless, the inference is supported that in patients with a contraindication to

pharmacologic prophylaxis, post-discharge use of an IPC device is superior for VTE prophylaxis compared with no prophylaxis. A study of the post discharge use of an IPC device combined with home visits showed that home use is feasible. With post discharge planning and support, home use of an IPC device in moderate-to-high risk patients who have a contraindication to pharmacologic prophylaxis is likely to improve VTE prevention. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

SUPPLEMENTAL INFORMATION

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the evidence review conclusions.

Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in 'Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

American College of Chest Physicians

In 2016, the American College of Chest Physicians (ACCP) (updated its 2012 evidence-based guideline¹⁸, on antithrombotic therapy and prevention of thrombosis.² The 2016 update, which addressed antithrombotic therapy for venous thromboembolism (VTE), outlined risk factors for bleeding with anticoagulant therapy and estimated the risks of major bleeding for patients in various risk categories (see Table 1).

Risk factors include (1 point per factor):

- "Age >65 y
- Age >75 y
- Previous bleeding
- Cancer
- Metastatic cancer
- Renal failure
- Liver failure
- Thrombocytopenia
- Previous stroke
- Diabetes
- Anemia
- Antiplatelet therapy
- Poor anticoagulant control
- Comorbidity and reduced functional capacity
- Recent surgery
- Alcohol abuse
- Nonsteroidal anti-inflammatory drug."

Table 1. Guidelines for Risk of Bleeding

Risk Factors	Estimated Absolute Risk of Major Bleeding		
	<i>Low Risk (0 Risk Factors)</i>	<i>Moderate Risk (1 Risk Factor)</i>	<i>High Risk (≥2 Risk Factors)</i>
Anticoagulation 0-3 mo, %			
Baseline risk	0.6	1.2	4.8
Increased risk	1.0	2.0	8.0
Total risk	1.6	3.2	12.8
Anticoagulation after first 3 mo, %/y			
Baseline risk	0.3	0.6	≥2.5
Increased risk	0.5	1.0	≥4.0
Total risk	0.8	1.6	≥6.5

Adapted from Kearon et al (2016).²

In a 2017 review of ACCP 2012 and American Academy of Orthopaedic Surgeons 2011 guidelines on antithrombotic therapy and prevention of VTE in patients undergoing orthopedic and nonorthopedic surgery, the ACCP recommended the use of limb compression devices in orthopedic surgical patients^{19,1}:

2.1.1 “In patients undergoing total hip arthroplasty (THA) or total knee arthroplasty (TKA), we recommend use of one of the following for a minimum of 10 to 14 days rather than no antithrombotic prophylaxis: low-molecular-weight heparin (LMWH), fondaparinux, apixaban, dabigatran, rivaroxaban, low-dose unfractionated heparin (LDUH), adjusted-dose vitamin K antagonist (VKA), aspirin (all Grade 1B), or an intermittent pneumatic compression device (IPCD) (Grade 1C).”

2.5 “In patients undergoing major orthopedic surgery, we suggest using dual prophylaxis with an antithrombotic agent and an IPCD during the hospital stay (Grade 2C).”

2.6 “In patients undergoing major orthopedic surgery and increased risk of bleeding, we suggest using an IPCD or no prophylaxis rather than pharmacologic treatment (Grade 2C).”

“The efficacy of mobile mechanical compression devices alone has not been compared with any chemoprophylaxis agent in an appropriately powered randomized trial. In addition, concerns have arisen with regard to patient compliance after hospital discharge and the high cost of these devices.”

In 2012, the ACCP recommendations on the use of limb compression devices in nonorthopedic general and abdominal-pelvic surgical patients, stratified by patient risk of VTE and risk of bleeding are listed in Table 2.⁴

Table 2. Recommendations on Limb Compression Device Use in Nonorthopedic General and Abdominal-Pelvic Surgical Patients

Patient Risk Group	Recommendation	GOR
Very low risk (<0.5%)	"[W]e recommend that no specific pharmacologic or mechanical prophylaxis be used other than early ambulation."	1B 2C
Low risk for VTE (~1.5%)	"[W]e suggest mechanical prophylaxis, preferably with intermittent pneumatic compression (IPC), over no prophylaxis."	2C
Moderate risk for VTE (~3%) and not at high risk of bleeding	"[W]e suggest low-molecular-weight heparin (LMWH), low-dose unfractionated heparin, or mechanical prophylaxis with IPC over no prophylaxis."	2B 2B 2C
Moderate risk for VTE (~3%) and high risk for major bleeding complications or in whom bleeding consequences would be particularly severe	"We suggest mechanical prophylaxis, preferably with IPC, over no prophylaxis."	2C
High risk for VTE (~6.0%) and not at high risk of bleeding	"[W]e recommend pharmacologic prophylaxis with LMWH or low-dose unfractionated heparin over no prophylaxis. In these patients, we suggest adding mechanical prophylaxis with elastic stockings or IPC to pharmacologic prophylaxis."	1B 1B 2C
High risk for VTE (~6.0%) and high risk for major bleeding complications or in whom bleeding consequences would be particularly severe	"[W]e suggest use of mechanical prophylaxis, preferably with IPC, over no prophylaxis until the risk of bleeding diminishes and pharmacologic prophylaxis may be initiated."	2C
High risk for VTE, both LMWH and unfractionated heparin contraindicated or unavailable and not at high risk for major bleeding complications:	"[W]e suggest low-dose aspirin, fondaparinux, or mechanical prophylaxis, preferably with IPC, over no prophylaxis."	2C
High risk for VTE, undergoing abdominal or pelvic surgery for cancer and not otherwise at high risk for major bleeding complications	"[W]e recommend extended-duration, postoperative, pharmacologic prophylaxis (4 weeks) with LMWH over limited-duration prophylaxis."	1B

Adapted from Gould et al (2012)⁴.

GOR: grade of recommendation; IPC: intermittent pneumatic compression; LMWH: low molecular weight heparin; VTE: venous thromboembolism.

Note that a standard duration of prophylaxis was not defined. An "extended-duration" prophylaxis was defined as lasting 4 weeks.

American Academy of Orthopaedic Surgeons

In 2011, the American Academy of Orthopaedic Surgeons (2011) updated its guidelines on the prevention of VTE in patients undergoing elective hip and knee arthroplasty.³ The guidelines included the following recommendations relevant to this evidence review:

5. "The work group suggests the use of pharmacologic agents and/or mechanical compressive devices for the prevention of venous thromboembolism in patients undergoing elective hip or knee arthroplasty, and who are not at elevated risk beyond that of the surgery itself for venous thromboembolism or bleeding. (Grade of Recommendation: Moderate) Current evidence is unclear about which prophylactic strategy (or strategies) is/are optimal or suboptimal. Therefore, the work group is unable to recommend for or against specific prophylactics in these patients. (Grade of Recommendation: Inconclusive) In the absence of reliable evidence about how long to employ these prophylactic strategies, it is the opinion of this work group that patients and physicians discuss the duration of prophylaxis. (Grade of Recommendation: Consensus)

6. In the absence of reliable evidence, it is the opinion of this work group that patients undergoing elective hip or knee arthroplasty, and who have also had a previous venous thromboembolism, receive pharmacologic prophylaxis and mechanical compressive devices. (Grade of Recommendation: Consensus)

7. In the absence of reliable evidence, it is the opinion of this work group that patients undergoing elective hip or knee arthroplasty, and who also have a known bleeding disorder (e.g., hemophilia) and/or active liver disease, use mechanical compressive devices for preventing venous thromboembolism. (Grade of Recommendation: Consensus)"

American College of Obstetricians and Gynecologists

The 2007 (reaffirmed 2018) American College of Obstetricians and Gynecologists updated its practice bulletin on prevention of deep vein thrombosis (DVT) and pulmonary embolism after gynecologic surgery.⁵ As with ACCP recommendations discussed above, prophylaxis recommendations varied by patient risk level. For patients at moderate and high-risk of DVT, intermittent pneumatic compression (IPC) was one of the recommended options for DVT prophylaxis. For patients at highest risk (i.e., >60 years plus prior VTE, cancer, or molecular hypercoagulable state), IPC or graduated compression stockings plus low-dose unfractionated heparin or low-molecular-weight heparin were recommended as prophylactic options. For all but the highest risk patients, the practice bulletin stated that, when IPC devices were used, "the devices should be used continuously until ambulation and discontinued only at the time of hospital discharge." For the highest risk patients, the bulletin stated that continuing prophylaxis for 2 to 4 weeks after discharge should be considered.

American Orthopaedic Foot and Ankle Society

In 2020, the American Orthopaedic Foot and Ankle Society re-approved a position statement on VTE prophylaxis after foot and ankle surgery. It stated that: "There is currently insufficient data for the American Orthopaedic Foot & Ankle Society (AOFAS) to recommend for or against routine VTE prophylaxis for patients undergoing foot and ankle surgery. Further research in this field is necessary and is encouraged."²⁰ The position statement further notes the following with regards to the use of mechanical prophylaxis: "Mechanical prophylaxis such as elastic compression stockings and sequential compression calf pumps or foot pumps on the contralateral extremity can be utilized intraoperatively and continued postoperatively through the duration of the hospital stay. While the true efficacy of this modality in foot and ankle surgery is unknown, complications are negligible and compression pumps may be considered in both the outpatient and inpatient setting. Whether there is a threshold duration of the surgical procedure for which these are beneficial is unknown, as is the optimal duration of their use post-operatively."

American Society of Hematology

In 2019, the American Society of Hematology issued guidelines for the prevention and management and of venous thromboembolism in surgical hospitalized patients.²¹ Following are 2 suggestions for patients undergoing major surgery:

Recommendation 3: For those "who receive mechanical prophylaxis,...[use] intermittent compression devices over graduated compression stockings (conditional recommendation based on very low certainty in the evidence of effects)."

Recommendation 4: For those "who receive pharmacologic prophylaxis,...[use] combined prophylaxis with mechanical and pharmacological methods over prophylaxis with pharmacological agents alone (conditional recommendation based on very low certainty in the evidence of effects). Remark: For patients considered at high risk of VTE, combined prophylaxis is particularly favored over mechanical or pharmacological prophylaxis alone."²¹.

U.S. Preventive Services Task Force Recommendations

Not applicable.

Ongoing and Unpublished Clinical Trials

There are currently no ongoing and unpublished trials that might influence this review as of January 2021.

CODING

The following codes for treatment and procedures applicable to this policy are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

CPT/HCPCS

E0650	Pneumatic compressor, nonsegmental home model
E0651	Pneumatic compressor, segmental home model without calibrated gradient pressure
E0652	Pneumatic compressor, segmental home model with calibrated gradient pressure
E0660	Nonsegmental pneumatic appliance for use with pneumatic compressor, full leg
E0666	Nonsegmental pneumatic appliance for use with pneumatic compressor, half leg
E0667	Segmental pneumatic appliance for use with pneumatic compressor, full leg
E0669	Segmental pneumatic appliance for use with pneumatic compressor, half leg
E0670	Segmental pneumatic appliance for use with pneumatic compressor, integrated, 2 full legs and trunk
E0671	Segmental gradient pressure pneumatic appliance, full leg
E0673	Segmental gradient pressure pneumatic appliance, half leg
E0676	Intermittent limb compression device (includes all accessories), not otherwise specified

ICD-10 Diagnoses

The appropriate ICD-10 diagnoses consistent with the medical criteria and intent of the policy should be used.

REVISIONS	
04-09-2013	Policy added to the bcbsks.com web site.
	Effective for Institutional providers 30 days after the Revision Date.
12-07-2015	Policy published 11-6-2015. Effective 12-7-2015.
	Revised title to "Postsurgical Outpatient Use of Limb Compression Devices for Venous Thromboembolism Prophylaxis" from "Outpatient Use of Limb Pneumatic Compression Devices for Venous Thromboembolism Prophylaxis"
	Description section updated
	In Policy section: <ul style="list-style-type: none"> ▪ In Items C and D added "or non-major orthopedic surgery" to read, "after major non-orthopedic surgery or non-major orthopedic surgery" ▪ In Items A, B, C, D, E, F removed the word "pneumatic" to read, "...limb compression devices..." ▪ Policy Guidelines updated.
	Rationale section updated
	In Coding section: <ul style="list-style-type: none"> ▪ Removed HCPCS code: E0675 ▪ ICD-10 codes not added due to the high volume of ICD-10 codes (over 850) ▪ Removed specific ICD-9 codes. ▪ Added the phrase "The appropriate ICD-9 or ICD-10 diagnoses consistent with the medical criteria and intent of the policy should be used."
References updated	
12-01-2016	Revised Title to "Postsurgical Home Use of Limb Compression Devices for Venous Thromboembolism Prophylaxis" from "Postsurgical Outpatient Use of Limb Compression Devices for Venous Thromboembolism Prophylaxis"
	Description section updated
	In Policy section: <ul style="list-style-type: none"> ▪ Revised to current language from the language below. This update represented primarily a format change combining medically necessary items together and E/I items together. No change of intent is noted. "A. Outpatient use of limb compression devices for venous thromboembolism (VTE) prophylaxis after major orthopedic surgery may be considered medically necessary in patients with a contraindication to pharmacological agents i.e., at high risk for bleeding. B. Outpatient use of limb compression devices for venous thromboembolism (VTE) prophylaxis after major orthopedic surgery is considered experimental / investigational in patients without a contraindication to pharmacological prophylaxis. C. Outpatient use of limb compression devices for venous thromboembolism (VTE) prophylaxis after major non-orthopedic surgery or non-major orthopedic surgery may be considered medically necessary in patients who are at moderate or high risk of venous thromboembolism (VTE) (see Policy Guidelines) with a contraindication to pharmacological agents i.e., at high-risk for bleeding. D. Outpatient use of limb compression devices for venous thromboembolism prophylaxis (VTE) after major non-orthopedic surgery or non-major orthopedic surgery is considered experimental / investigational in patients who are at moderate or high risk of venous thromboembolism (VTE) without a contraindication to pharmacological prophylaxis and in patients who are at low risk of venous thromboembolism (VTE). E. Outpatient use of limb compression devices for venous thromboembolism (VTE) prophylaxis after all other surgeries is considered experimental / investigational. F. Outpatient use of limb compression devices for venous thromboembolism (VTE) prophylaxis for periods longer than 30 days post-surgery is not medically necessary. ▪ In Item D revised "Outpatient" to "Home" to read "Home use of limb compression devices..." ▪ Updated Policy Guidelines updated

REVISIONS	
	Rationale section updated
	References updated
04-28-2017	In Title section: ▪ Added " See Also: Pneumatic Compression Pumps for Treatment of Lymphedema and Venous Ulcers"
	Description section updated
	In Policy section: ▪ Policy Guidelines updated
	Rationale section updated
	References updated
04-11-2018	Updated Description section.
	Updated Rationale section.
	In Coding section: ▪ Removed reference to ICD-9 coding.
	Updated References section.
04-24-2019	Updated Description section.
	Updated Rationale section.
	Updated References section.
09-18-2020	Updated Description section.
	Updated Rationale section.
	Updated References section.
05-05-2021	Updated Description section.
	Updated Rationale section.
	Updated References section.

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