TITLE: Knee-High Versus Thigh-High Compression Devices: A Review of the Clinical and Cost-Effectiveness

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CONTEXT AND POLICY ISSUES:

Deep vein thrombosis (DVT) is a blood clot (thrombus) that forms in a deep vein when blood flow is abnormally slow or the vein is damaged.\textsuperscript{1,2} Approximately 90\% of DVTs occur in leg veins, although clinically significant thrombi can also form in the arm and pelvis veins.\textsuperscript{1,2} DVTs are often asymptomatic. Patients with an untreated DVT may develop post-thrombotic syndrome, which is associated with leg pain, chronic swelling, venous insufficiency, and skin ulceration.\textsuperscript{3} In some cases, thrombi break free and travel to the lungs, where they may become lodged in a pulmonary artery (pulmonary embolism). Small clots may go unnoticed, but extensive blockages can cause shortness of breath, dizziness, fainting, and sometimes death.\textsuperscript{2,3}

In the US, the annual incidence of DVT is 80 per 100,000 individuals,\textsuperscript{4} and DVT is responsible for 600,000 hospitalizations each year.\textsuperscript{3,5,6} The risk of venous thrombosis in hospitalized patients is considerably higher than in the general population, varying from 10\% to 80\%.\textsuperscript{7} DVT-associated pulmonary embolism causes 200,000 deaths each year, making it the leading cause of preventable in-hospital death among Americans.\textsuperscript{3,5,6} The incidence of DVT after surgery is between 0\% and 1.3\%; patients undergoing orthopaedic, neurological, and major pelvic procedures are especially vulnerable.\textsuperscript{2,5,8} In Canada, the rate of post-admission pulmonary embolism and DVT is 0.4\%.\textsuperscript{9}

Because of the occult nature of DVT, pharmacological and mechanical prophylactic measures (thromboprophylaxis) are usually employed to reduce its occurrence in high-risk patients.\textsuperscript{3} Pharmacological interventions include anticoagulants such as low-dose unfractionated heparin, low molecular weight heparin, and fondaparinux.\textsuperscript{4,10} However, these drugs are associated with an increased risk of bleeding and are not appropriate for all patients.\textsuperscript{3}
Mechanical methods, which include pneumatic compression therapy and graduated compression stockings (GCS), apply external pressure to the extremities to increase venous blood flow. Pneumatic compression therapy involves applying one or more inflatable cuffs to the arm, calf, calf and thigh, or foot. A pump inflates and deflates the cuffs either simultaneously at regular intervals (intermittent compression devices) or in a sequence starting from the distal end of the arm or leg and moving upwards (sequential compression devices). Intermittent compression devices (ICDs) and sequential compression devices (SCDs) are contraindicated in patients who are mobile or have injuries in the lower extremities. These devices can also increase intraoperative blood loss and cause skin ulceration, blistering, and common peroneal nerve palsy. GCS, which can be knee-high or thigh-high, act by maintaining a pressure gradient that is highest at the ankle and lowest at the top of the leg. Mechanical methods are usually used in patients who are at high risk of bleeding or as an adjunct to anticoagulant-based prophylaxis.

As most clinically important DVTs occur above the knee, it is generally thought that thigh-high devices provide greater benefit than knee-high devices. This report will summarize the evidence for the clinical and cost-effectiveness of knee-high and thigh-high compression devices for thromboprophylaxis.

RESEARCH QUESTIONS:

1. What is the clinical effectiveness of knee-high compression devices compared with thigh-high compression devices in patients who would be prescribed mechanical compression devices for thromboprophylaxis?

2. What is the cost-effectiveness of knee-high compression devices compared with thigh-high compression devices for patients who would be prescribed mechanical compression devices for thromboprophylaxis?

METHODS:

A limited literature search was conducted on key health technology assessment resources, including PubMed, The Cochrane Library (Issue 4, 2008), the University of York Centre for Reviews and Dissemination (CRD) databases, ECRI, EuroScan, and international HTA agency websites. A focused Internet search was also conducted. The results include articles published between January 2003 and November 2008, and are limited to English language publications only. Filters were applied to limit the retrieval to systematic reviews, health technology assessments, meta-analyses, guidelines, economic studies, randomized controlled trials, and controlled clinical trials.

HTIS reports are organized so that the higher quality evidence is presented first. Therefore, health technology assessment reports, systematic reviews, and meta-analyses are presented first. These are followed by economic evaluations, randomized controlled trials, controlled clinical trials, and evidence-based guidelines.

SUMMARY OF FINDINGS:

The literature search identified one systematic review. Other systematic reviews were found that contained duplicate studies, but only the most recent and comprehensive review was included. No health technology assessments or economic evaluations were identified. Two recent
comparative studies (one quasi-randomized and one non-randomized trial) were identified that were not included in the systematic review. Eight clinical practice guidelines were found that had specific recommendations regarding the length of compression devices to be used for patient thromboprophylaxis.

**Health technology assessments**

No health technology assessments were indentified.

**Systematic reviews and meta-analyses**

A quantitative systematic review by Sajid et al. (2006)\(^{13}\) examined the effectiveness of knee-high and thigh-high GCS for thromboprophylaxis in hospitalized patients and high-risk airline passengers on long haul flights. Only the results for hospitalized patients are reported here. The literature search, which spanned from January 1976 to June 2005, included four electronic databases (MEDLINE, EMBASE, CINAHL, and the *The Cochrane Library*). The reference lists of retrieved articles were also pearled for additional trials. Randomized controlled trials were included if they reported DVT as an outcome, used objective diagnostic tests to identify DVT, reported independent, blinded assessment of diagnostic test results, and specified predefined criteria for abnormal test results. The quality of the systematic review was poor (as determined by the AMSTAR instrument\(^{14}\) for systematic reviews) because the quality of the included studies was not assessed and the method of data extraction was not described. In addition, publication bias within the study sample was not evaluated.

The review included 14 randomized controlled trials, five of which provided results in hospitalized patients (n=592). The odds ratio for developing DVT in surgical patients wearing knee-high GCS was 1.01 (95% confidence interval 0.35 to 2.90) compared with thigh-high GCS. The authors concluded that there was no detectable difference in DVT rates between the two stocking lengths. Overall, hospitalized patients wearing knee-high GCS had a 6% risk of developing DVT compared with 4% for those wearing thigh-high GCS, although there was significant heterogeneity among the included studies.\(^{13}\)

**Randomized controlled trials**

A prospective, quasi-randomized controlled trial\(^{15}\) assessed the effectiveness of thigh-high and knee-high GCS in 50 patients undergoing total knee joint replacement between October 2002 and May 2003. Patients were assigned to treatment groups according to their year of birth. The participation rate was 100%, but it was unclear whether the patients were recruited consecutively. The GCS were applied before and after surgery. Calf pumps were also fitted after surgery, but were removed once the patients were mobile. Limb measurements and other patient data were recorded by nurses who were not involved in the study. Patient exclusion criteria were not applied. High-risk patients or those with a history of DVT received low molecular weight heparin prophylaxis. Of the 47 patients completing the study, 24 (14 men, 10 women) received knee-high GCS and 23 (11 men, 12 women) wore thigh-high GCS. The average age of the two groups ranged from 70 to 72 years. Patients were followed up until discharge (5 to 10 days). There was no apparent difference between the patient groups with respect to sex ratio, age, or operated side, but a statistical comparison was not reported. There were no DVTs or wound infections reported, and the amount of swelling in the operated knee was the same for both treatment groups. Most of the patients assigned thigh-high GCS found them uncomfortable.
Controlled clinical trials

Proctor et al. (2001) conducted a prospective comparison of five different pneumatic compression devices among 1350 inpatients from April to September 1999. Each device was used exclusively for a 30-day period in the hospital wards of a large academic medical centre. Incidences of DVT and pulmonary embolism were identified by conducting venous duplex ultrasound scans in patients before discharge and examining diagnostic vascular laboratory and radiology records. The comparison between knee-high and thigh-high devices was a secondary aim of the study, so demographic details for patients in these two groups were not reported. Thus, it is unclear if there were important baseline differences between the intervention groups. The mean age of patients in the five device groups ranged from 53.2 to 55.7 years.

None of the patients died as a result of thromboembolism. DVT occurred in 3.6% (31/853) of patients with knee-high devices and 3.4% (17/497) of those with thigh-high devices. Patients with DVT were older (58 versus 54 years), used the pumps longer (11 versus 7 days), and had better compliance (16 hours versus 12 hours per day) than those without DVT. A second method of prophylaxis was used in 275 patients, but the distribution of these patients between the two intervention groups was not reported. Proximal DVTs were more common in patients wearing thigh-high devices (71%) than those with knee-high devices (52%), but the difference was not statistically significant (P=0.21).

Economic evaluations

No economic evaluations comparing knee-high compression devices to thigh-high compression devices were indentified.

Guidelines

Although many clinical practice guidelines mention the use of compression devices for thromboprophylaxis, few specify an optimal length. The most common reason cited for this omission is lack of evidence. Some guidelines have made more specific recommendations (Table 1), but the conflicting guidance reflects the uncertainty surrounding this question.

Four of the guidelines in Table 1 were well-reported, used systematic strategies to identify and grade the evidence, employed multidisciplinary panels to develop or review the guidelines, and explicitly linked recommendations with the supporting evidence. Three guidelines did not report their methods adequately, and it was unclear how the evidence was collected and synthesized into recommendations. The guideline by Jackson and Morgan was formulated for the anaesthetic department of a hospital by two authors without external input, and the supporting evidence for the recommendations was not appraised or cited.
Table 1: Summary of clinical practice guidelines providing recommendations on the length of compression devices for thromboprophylaxis

<table>
<thead>
<tr>
<th>Guideline</th>
<th>Topic/Target population</th>
<th>Synopsis of Recommendations</th>
</tr>
</thead>
<tbody>
<tr>
<td>American College of Obstetricians and Gynecologists(^{21})</td>
<td>Gynaecology patients</td>
<td>GCS, if used, should be limited to the knee-high length.</td>
</tr>
<tr>
<td>Blondin(^{22})</td>
<td>Elderly surgical patients</td>
<td>Consider knee-high GCS and ICDs for patients unable to wear thigh-high devices due to size, injury, or physician preference.</td>
</tr>
<tr>
<td>Gaber(^{17})</td>
<td>Immobile patients secondary to neurological impairment</td>
<td>Thigh-high GCS should be used.</td>
</tr>
<tr>
<td>Jackson and Morgan(^{24})</td>
<td>Paediatric surgical patients</td>
<td>Knee-high GCS are as effective as thigh-high GCS.</td>
</tr>
<tr>
<td>National Institute for Health and Clinical Excellence(^{18})</td>
<td>Patients undergoing surgery</td>
<td>Thigh-high GCS are recommended unless contraindicated.</td>
</tr>
<tr>
<td>Royal College of Obstetricians and Gynaecologists(^{19})</td>
<td>Pregnant women</td>
<td>Women with previous venous thromboembolism or thrombophilia should be encouraged to wear knee-high GCS throughout their pregnancy and for 6 to 12 weeks after delivery.</td>
</tr>
<tr>
<td>Scottish Intercollegiate Guidelines Network(^{20})</td>
<td>Prophylaxis of venous thromboembolism</td>
<td>Thigh-high GCS are preferred to knee-high GCS for prophylaxis of deep vein thrombosis.</td>
</tr>
<tr>
<td>Society of American Gastrointestinal and Endoscopic Surgeons(^{23})</td>
<td>Patients undergoing laparoscopic surgery</td>
<td>There are no data to support the use of pneumatic compression devices on the upper extremities during laparoscopic surgery.</td>
</tr>
</tbody>
</table>

GCS – graduated compression stockings; ICD – intermittent compression devices.

Limitations

The evidence base was small and of generally low quality. The most current systematic review rated poorly on the AMSTAR instrument, while the two comparative studies published since the review were limited by their non-randomized design.

As the rates of DVT and pulmonary embolism in patients receiving thromboprophylaxis are typically low, most of the published studies have insufficient power to detect significant differences in effectiveness between knee-high and thigh-high compression devices, even when a meta-analysis is possible.\(^{25}\) It is also difficult to ascribe any improvements in patient outcomes to a single thromboprophylactic modality because many of the studies used other forms of thromboprophylaxis in conjunction with the devices being investigated.\(^{13}\)

In the comparative studies, a comparison of preoperative patient characteristics for each of the study groups was not conducted, which made it impossible to identify biases that may have
been introduced by the lack of random allocation of study participants. In addition, factors that may influence the advent of DVT, such as body mass index and American Society of Anesthesiologists Physical Status Classification, were not investigated. Follow-up was typically short, with most studies only reporting patient outcomes up to discharge. This may result in an underestimation of DVT rates because patients remain at an increased risk of thromboembolism for up to four weeks after major surgery.\(^5\)

**CONCLUSIONS AND IMPLICATIONS FOR DECISION OR POLICY MAKING:**

The limited evidence from the few studies that have specifically compared the safety and effectiveness of knee-high and thigh-high mechanical compression devices in patients requiring thromboprophylaxis suggests that there is no difference between the two device lengths. However, the low rates of DVT and pulmonary embolism in patients receiving thromboprophylaxis mean that much larger studies are required before a definitive conclusion can be made. The uncertainty surrounding this question is reflected in the conflicting recommendations on device length found in clinical practice guidelines on patient thromboprophylaxis.

The efficacy of compression therapy is dependent on duration of use and correctness of fit.\(^{26}\) Compression devices that are improperly fitted are not only ineffective, but can also increase the risk of DVT.\(^{11,13}\) Most of the guidelines emphasized the importance of patient compliance and having the devices correctly fitted by qualified staff. There is some suggestion that patients find knee-high devices more comfortable than thigh-high devices, but further research is needed to confirm this.

The initial cost of knee-high mechanical compression devices is lower than for thigh-high devices,\(^8\) but there were no economic evaluations available to ascertain whether the lower capital investment is offset by costs associated with differences between the device lengths in terms of duration of hospital stay, medication use, and other patient outcomes. The limited evidence, costs of the devices, and patient preference should be considered when deciding between knee-high and thigh-high compression devices.

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