The Use of a Mobile Compression Device Following a Lower Extremity Total Joint Arthroplasty Can Provide Venous Thromboembolic Prophylaxis Comparable to Current Pharmacological Anticoagulation Protocols

McKel A. Roskelley

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The Use of a Mobile Compression Device Following a Lower Extremity Total Joint Arthroplasty Can Provide Venous Thromboembolic Prophylaxis Comparable to Current Pharmacological Anticoagulation Protocols

Abstract

Background: Venous thromboembolisms (VTE) are an important complication following arthroplasty of the knees and hips, and proper prophylaxis protocol continues to be a source of debate in the medical community. In the past patients have been managed with pharmaceutical anticoagulants (eg, LMWH), mechanical compression, or a combination of the two. The inability to use mechanical compression on an outpatient basis has limited its use in the past, but the introduction of an outpatient mobile compression devices (MCDs) that monitors compliance has brought mobile compression devices to the forefront of VTE prophylaxis research. The aim of this review is to evaluate the use of MCDs as compared to pharmaceutical anticoagulants.

Methods: Exhaustive search was conducted using Medline-OVID, CINAHL, and Web of Science using the keywords: mobile compression. All results were reviewed and selected according to the predefined eligibility criteria. Relevant articles were assessed for quality using GRADE.

Results: Two studies met inclusion criteria and were included in this systematic review. A randomized control trial with 414 participants was unable to determine equivalency between the MCD and LMWH at VTE prophylaxis due to small sample size. They were however able to demonstrate a significant decrease in major bleeding events with use of the MCD. A prospective observational study with 23,260 participants demonstrated statistically noninferior VTE prophylaxis between the MCD group and the pharmaceutical anticoagulant group.

Conclusion: Use of a MCD following a total joint arthroplasty (TJA) in the lower extremity may provide statistically noninferior VTE prevention rates when compared to the current pharmacological treatment options. Unlike pharmacologic anticoagulants, the use of a MCD does not increase the risk of a major bleeding event. This elimination of major bleeding complications makes implementation of MCD use following a TJA instead of anticoagulants a promising option for cost effective VTE prophylaxis.

Keywords: Mobile compression, Arthroplasty, Venous thromboembolism, pharmaceutical anticoagulants

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Degree Name
Master of Science in Physician Assistant Studies

First Advisor
Anjanette Sommers, PA-C, MS

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Keywords
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Subject Categories
Medicine and Health Sciences

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The Use of a Mobile Compression Device Following a Lower Extremity Total Joint Arthroplasty Can Provide Venous Thromboembolic Prophylaxis Comparable to Current Pharmacological Anticoagulation Protocols

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A Clinical Graduate Project Submitted to the Faculty of the School of Physician Assistant Studies Pacific University Hillsboro, OR

For the Masters of Science Degree, 08.08.15

Faculty Advisor: Annjanette Sommers, PA-C, MS

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Abstract

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[Acknowledgements redacted for privacy]
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List of Abbreviations

AAOS  American Academy of Orthopaedic Surgeons
DVT   Deep Vein Thrombosis
IPCD  Intermittent Pneumatic Compression Device
LMWH Low Molecular Weight Heparin
MCD   Mobile Compression Device
PE    Pulmonary Embolism
THA   Total Hip Arthroplasty
TJA   Total Joint Arthroplasty
TKA   Total Knee Arthroplasty
VTE   Venous Thromboembolism

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Appendix A: Preventing venous thromboembolic disease in patients undergoing elective hip and knee arthroplasty: Clinical practice guideline of AAOS 2011 recommendations
BACKGROUND

There were approximately 200,000 total hip arthroplasty (THA) and 400,000 total knee arthroplasty (TKA) procedures performed in the US in 2003, and this number has only increased since then with an estimated 250,000 THA and 600,000 TKA procedures performed in 2010.\textsuperscript{1} Although these are both extremely successful surgeries that can greatly improve a patient’s quality of life, they are associated with development of venous thromboembolic disease. During the thirty days following the initial surgery it is reported that 2.2 percent (95% CI: 1.4-3.0) of patients experienced symptomatic non-fatal venous thromboembolism (VTE) and 0.05% (95% CI: 0.0-0.12) experienced a fatal pulmonary embolism (PE).\textsuperscript{2} These patients all received an unspecified form of VTE prophylaxis, without which the VTE and PE rates would be much higher. It is therefore widely agreed within the medical community that some form of VTE prophylaxis should be implemented in total joint arthroplasty (TJA) postop patients, but an ideal prophylactic protocol has yet to be identified.

Despite significant advances in the prevention and treatment of VTE, PE remains the most common preventable cause of hospital death. It is estimated that approximately 150,000 to 200,000 deaths per year occur in the United States due to PE.\textsuperscript{3} The risk of post-operative VTE depends upon a number of factors including the type of surgery, the degree of invasiveness, the type of anesthesia, and the duration of postoperative immobilization. There are also numerous patient-related risk factors such as increasing age, prior history of VTE, presence of malignancy, obesity, hypercoagulable states or concurrent medical comorbidities.\textsuperscript{4} All of these factors are taken into consideration when stratifying patients as very low risk, low risk, moderate risk, or
high risk for postoperative VTE. Patients undergoing THA and TKA are automatically considered high risk independent of other factors due to the relatively high occurrence of postoperative VTE in the absence of prophylaxis. It has been estimated that approximately 6 percent of TJA patients will experience a VTE if prophylactic measures are not implemented. This increased risk is due to multiple factors including the invasive nature of the surgery, the position of the extremity during surgery, and the use of a thigh tourniquet.\textsuperscript{5}

The American Association of Orthopaedic Surgeons (AAOS) released a new set of clinical practice guidelines in 2011 that included an algorithm-like approach for VTE prophylaxis following a lower extremity TJA (Appendix A). At the time of the AAOS guideline publication they listed “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”\textsuperscript{6} as a moderate recommendation. According to AAOS a moderate recommendation implies a practitioner should follow a guideline but remain alert to patient preferences as well as any new information that may arise. The AAOS guidelines\textsuperscript{6} also remain unclear as to which prophylactic strategy is most beneficial, reporting this decision should be based on clinical judgment and patient preference until emerging evidence suggests otherwise. It is important they take into consideration the harms of each therapy when making this decision (eg bleeding risk related to anticoagulant therapy).

Since the release of the 2011 AAOS guidelines for VTE prophylaxis following a lower extremity TJA there have been multiple studies released comparing the efficiency of mobile compression devices to pharmacologic anticoagulants. In the past, use of intermittent pneumatic compression devices (IPCD) has been limited due to size, weight, and necessity for a continuous
external power source, which led to poor patient compliance. The development of a MCD consisting of a small, battery-operated system that delivers portable, intermittent venous compression allowing for increased compliance and therefore increased efficacy has renewed interest in pneumatic compression for VTE prophylaxis.

The new MCD is designed to apply intermittent, sequential pressure to the leg in correlation to the patient’s respiratory related venous phasic flow. This application of intermittent compression increases the peak velocity of venous blood flow which leads to a reduction in clot formation. It is thought that increasing the blood flow velocity combined with pulsatility leads to a release of endothelial derived factors and urokinase which are responsible for the reduction in clot formation. The effectiveness of the MCD is largely based on patient compliance so the unit allows for monitoring through use of an internal timer that detects the amount of time the device is properly functioning and being worn by the patient. This information is then displayed on a small screen located on the device. Can the use of a mobile compression device following a lower extremity total joint arthroplasty provide venous thromboembolic prophylaxis comparable to current pharmacological anticoagulation protocols?

**METHODS**

An exhaustive search of available medical literature was conducted using Medline-OVID, CINAHL, and Web of Science using the keyword: mobile compression. The search was then further narrowed using the decided upon eligibility criteria. Inclusion criteria required all relevant studies contain human participants who underwent a lower extremity TJA procedure along with a systematic approach to monitoring for VTE events. Included studies also had to compare the occurrence of VTE events in TJA postop patients when using a MCD or a pharmaceutical anticoagulant. Studies involving only combinations of the two VTE prophylaxis
methods or that did not include a pharmacological anticoagulant comparison group were excluded. Commentaries on preexisting studies and any results assessing MCD use for VTE prophylaxis in situations other than TJA were also excluded. The remaining relevant articles were assessed for quality using Grading of Recommendations, Assessment, Development, and Evaluation (GRADE).11

RESULTS
The initial search using the keyword mobile compression yielded nine articles for review. After assessing the articles according to the determined eligibility criteria a total of four articles remained. Two of the remaining articles assessed the same randomized control trial10,12 while the other two articles assessed the same prospective observational study.13,14 See Table I.

Randomized Control Trial
This prospective, randomized, multicenter control trial10,12 was discussed in two of the eligible articles. This trial was designed to assess the efficacy of an MCD at VTE prophylaxis when compared to that low molecular weight heparin (LMWH). Between June 2006 and June 2008, 414 patients provided consent to participate in the study at the nine different participating sites,. Of these patients only 395 were included in the overall analysis of safety and 389 were included in the assessment of efficacy. Patients were excluded from both groups due to failure to meet the inclusion criteria, withdrawal of consent prior to surgery, missing the postop venous ultrasound to screen for DVT, or failure to attend the 10-week postop follow-up. The inclusion criteria for this RCT included an age of eighteen years or older with a scheduled unilateral total hip arthroplasty (THA). Any patients with a history of VTE, a coagulation disorder, a solid malignant tumor, peptic ulcer disease, or major surgery in the past three months were excluded from the study.10,12
A computer-generated randomization schedule was used to place the patients into either the MCD or the LMWH group. The group allocation was not concealed from the study coordinators, surgeons, or study participants. For those in the LMWH group the LMWH was started the morning after surgery at a 30mg dose every 12 hours. Once the patient was discharged from the hospital the dose was decreased to 40mg once a day for 10 days. For those in the MCD group, devices were placed on bilateral calves immediately after the initiation of anesthesia and patients were advised to continue using the device for 10 days. It is important to note that the patients in the MCD group were allowed to have 81mg of aspirin a day at the discretion of their surgeon. A subgroup analysis was conducted and showed no significant difference between patients in the MCD group who were taking aspirin compared to those who were not, and, therefore, the results were not reported separately. The patients in both groups were advised to return 10 to 12 days after surgery for a bilateral duplex ultrasound of both lower extremities. All positive scans were then reviewed by an independent neurologist who was blinded to previous interpretation results, study site, and treatment group. All patients with a positive scan were treated according to individual site protocols. Those with a negative scan were followed for an average of 10 weeks and monitored for signs of DVT, PE, or rehospitalization. Patients were also closely monitored for major bleeding complications which this study defined as bleeding that required rehospitalization or prolonged hospitalization, required any intervention, endangered critical organs, was life threatening, or caused death.

Of the 386 patients that were evaluated for efficacy of VTE prevention, 16 patients experienced a DVT and four patients experienced a PE. The MCD group reported 8 (4.1%) DVT and 2 (1%) PE occurring in the 196 participants. The LMWH group reported 8 (4.2%) DVT and 2 (1%) PE occurring in the 190 participants (see Table I). Although major bleeding
complications are not being assessed in the systematic review it is noteworthy that when evaluated for safety, major bleeding occurred in 11 (6%) of the 194 patients in the LMWH group and 0 (0%) of the 198 patients in the MCD group (see Table I).10,12

The authors of both articles10,12 assessing this prospective, randomized, multicenter control trial reported that although the data presented in this study suggests equivalent VTE prevention efficacy between the MCD and LMWH, it would require a larger number of participants to evaluate for efficacy. They were also unable to blind due to the nature of the treatments being administered. The authors concluded that although they were able to demonstrate superior safety using the MCD, a larger study is required to determine equivalency or superiority of treatment options.10,12

It is important to note that Medical Compression Systems, the company responsible for manufacturing the MCD, provided funding for this study. They had no input on study design, data collection, data analysis, or article preparation.10,12

**The Prospective Observational Study**

This prospective observational study13,14 was discussed in two articles. This noninferiority study was designed to demonstrate approximately the same efficacy of an MCD at VTE prophylaxis when compared to that of different pharmaceutical anticoagulant. Data was collected from April 1, 2011 to September 30, 2011 from 10 different sites and analyzed at one designated site. The eligibility criteria were the same as those implemented in the RCT discussed above.10,12 After implementing the eligibility criteria there were 23,260 eligible participants. Of these, 3,060 were treated using a MCD and 20,200 were treated with varied pharmaceutical anticoagulants. These anticoagulants included warfarin, enoxaparin, rivaroxaban, and
In this study each anticoagulant was assessed individually, but for the purpose of this systematic review all the anticoagulants will be assessed together.\textsuperscript{13,14}

Unlike the previously discussed RCT, only patients that presented with VTE symptoms within 3 months of surgery were evaluated and included in the results. At the 3 month postop appointment all patients completed a questionnaire with routine questions regarding DVT and PE events. All patients were also examined by a trained clinician for swelling, redness, tenderness, or excessive warmth of the extremities at this 3 month visit. Patients presenting with DVT symptoms were evaluated with duplex ultrasonography, and those with PE symptoms were evaluated with spiral CT-angiography.\textsuperscript{14}

A noninferiority margin of 1.0\% was established based on absolute event rate differences. The authors determined that the MCD device would be considered noninferior if the upper bound of the one-sided 97.5\% confidence interval did not cross the noninferiority margin of 1.0\%. Symptomatic VTE occurred in 28 (0.92\%) of the 3060 patients treated with a MCD, and 221 (1.1\%) of the 20200 patients treated with pharmacologic anticoagulants (see Table I). Observed VTE rates using the MCD were noninferior that those for the pharmaceutical treatments. The one group that did not meet to noninferiority margin of 1.0\% were those in the TKA group that received rivaroxaban who had a 0.64\% incidence (implying that MCD failed to be demonstrated as noninferior).\textsuperscript{13,14}

The authors of both articles\textsuperscript{13,14} concluded that use of the MCD for lower extremity TJA postop patients provides a noninferior risk for development of a VTE when compared to current pharmaceutical protocols. Their recommendation is that surgeons consider using a MCD with or without aspirin for VTE prevention as an alternative to pharmacologic anticoagulants in patients following a lower extremity TJA.\textsuperscript{13,14}
It is important to note that once again this study was funded by Medical Compression Systems. As with the previous RCT, they did not participate in any of the data collection, analysis, or article preparation.\textsuperscript{13,14}

**DISCUSSION**

As the average age of the general patient population continues to increase it is likely the frequency of lower extremity arthroscopies will also increase.\textsuperscript{1} With this in mind, it is crucial that a standard VTE prophylaxis protocol is developed that accounts for VTE reduction rates, treatment complications, and cost analysis. The AAOS guidelines\textsuperscript{6} for VTE prophylaxis (see Appendix A) that were released in 2011 were inconclusive on the superiority or inferiority of pneumatic compression when compared to current pharmacologic anticoagulants.\textsuperscript{6} Since that time two new studies\textsuperscript{10,12-14} have emerged demonstrating both increased safety due to decreased major bleeding events as well as comparable efficiency at preventing VTE events using a MCD (see Table I).

Although patient safety and treatment efficacy are of the utmost importance it is also prudent for a clinician to consider the cost-effectiveness of the treatments in question. A model was constructed to assess for differences in cost-effectiveness between using the MCD and use of enoxaparin. It was estimated the MCD would cost $50 per day for a period of 10 days for a total of $500, while enoxaparin was estimated to cost a total of $544.96 for the 10 day period (see Figure I). The model showed a cost-effectiveness advantage of the compression device resulting in a savings of more than $3.69 million in a 10 000 patient cohort. This savings was primarily due to a decrease in the amount of major bleeding complications, which frequently require significant health care resources to treat.\textsuperscript{15}
The studies discussed above demonstrated not only comparable efficacy between the MCD and pharmaceutical anticoagulants, but also a significant decrease in major bleeding complications. These results coupled with the cost-effectiveness make use of a MCD a seemingly superior option to pharmaceutical anticoagulants. As always, it is necessary for a clinician to assess their options on a case-to-case basis and use their clinical judgment when determining the best course of action on an individual basis. It is also important that the risks and benefits be discussed with patients. Patient preference may play a large role in treatment selection since the MCD device relies so heavily on patient compliance.

Although the studies discussed above did demonstrate equal efficacy at preventing VTE as well as reducing major bleeding events it is important to consider the limitations of these studies. The initial study,\textsuperscript{10,12} although a RCT, was privately funded and non-blinded due to the nature of the treatments being administered which increased the risk of bias. The second, prospective observational study\textsuperscript{13,14} was done on a much larger scale, but was also privately funded. These limitations affected the overall GRADE of the studies (see Table I).\textsuperscript{11} A large scale, independently funded RCT is needed in the future to provide non-biased results.

**CONCLUSION**

Use of a MCD following a TJA in the lower extremity has statistically comparable VTE prevention rates when compared to the current pharmacological treatment options. Unlike pharmacologic anticoagulants, the use of a MCD does not increase the rise of a major bleeding event. This elimination of major bleeding complications makes implementation of MCD use following a TJA instead of pharmaceutical anticoagulants an attractive option for cost effective VTE prophylaxis. All cases must be assessed on an individual basis, and patient preference must
be taken into account, but clinicians should strongly consider using a MCD for TJA patients postoperatively.

Although the results of the above studies were clinically relevant, they did have limitations that may necessitate further research. A large scale, independently funded RCT is needed to produce high GRADE quality evidence. With this being said, the results are strong enough to conclude that use of a MCD device following a lower extremity TJA in place of pharmaceutical anticoagulants provides comparable VTE prophylaxis. When combined with the demonstrated decreased risk of major bleeding complications as well as increased cost-effectiveness, MCD should be considered as a first line option for postoperative VTE prophylaxis.
References


Tables

TABLE I. Characteristics of Reviewed Studies, GRADE profile: MCD vs. pharmaceutical anticoagulants for VTE prevention in TJA postop patients

<table>
<thead>
<tr>
<th>Quality Assessment</th>
<th>Summary of Findings</th>
<th>Importance</th>
</tr>
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<tbody>
<tr>
<td></td>
<td>Downgrade Criteria</td>
<td>Number of Patients</td>
</tr>
<tr>
<td>No. of Studies</td>
<td>Design</td>
<td>Limitation</td>
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<tr>
<td>Incidence of VTE</td>
<td>2</td>
<td>1 RCT 1 Observational</td>
</tr>
<tr>
<td></td>
<td>2</td>
<td>1 RCT 1 Observational</td>
</tr>
<tr>
<td>Incidence of DVT</td>
<td>2</td>
<td>1 RCT 1 Observational</td>
</tr>
<tr>
<td></td>
<td>2</td>
<td>1 RCT 1 Observational</td>
</tr>
<tr>
<td>Incidence of PE</td>
<td>2</td>
<td>1 RCT 1 Observational</td>
</tr>
<tr>
<td></td>
<td>2</td>
<td>1 RCT 1 Observational</td>
</tr>
<tr>
<td>Incidence of Major Bleeding Events</td>
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<td>1 RCT</td>
</tr>
</tbody>
</table>

*No blinding in the Colwell CW Jr 10 & Hardwick et al 12 (the RCT)
* Colwell CW Jr 10, Hardwick et al 12, Colwell CW Jr et al 13, & Colwell CW Jr et al 14 all contain the disclosure that funding was provided by Medical Compression Systems, the company responsible for manufacturing the MCD.

Figures
Appendices

**Appendix A**: Preventing venous thromboembolic disease in patients undergoing elective hip and knee arthroplasty: Clinical practice guideline of AAOS 2011 recommendations

<table>
<thead>
<tr>
<th>Recommendations</th>
<th>Grade of Recommendation</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. We recommend against routing postoperative duplex ultrasonography screening of patients who undergo elective hip or knee arthroplasty.</td>
<td>Strong</td>
</tr>
<tr>
<td></td>
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</tr>
<tr>
<td>2.</td>
<td>Patients undergoing elective hip or knee arthroplasty are already at high risk for venous thromboembolism (VTE). The practitioner might further assess the risk of VTE by determining whether these patients had a previous VTE. Current evidence is not clear about whether factors other than a history of previous VTE increase the risk of VTE in patients undergoing elective hip or knee arthroplasty and, therefore, we cannot recommend for or against routinely assessing these patients for these factors.</td>
</tr>
<tr>
<td>3.</td>
<td>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. 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, we are unable to recommend for or against using them to assess a patient’s risk of bleeding.</td>
</tr>
<tr>
<td>4.</td>
<td>We suggest that patients discontinue antiplatelet agents (eg, aspirin, clopidogrel) before undergoing elective hip or knee arthroplasty.</td>
</tr>
<tr>
<td>5.</td>
<td><strong>We suggest the use of pharmacologic agents and/or mechanical compressive devices for the prevention of VTE in patients undergoing elective hip or knee arthroplasty and who are not at elevated risk beyond that of the surgery itself for VTE or bleeding.</strong> Current evidence is unclear about which prophylactic strategy (or strategies) is/are optimal or suboptimal. Therefore, we are unable to recommend for or against specific prophylactic in these patients. 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 physician discuss the duration of prophylaxis.</td>
</tr>
<tr>
<td>6.</td>
<td>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 VTE, receive pharmacologic prophylaxis and mechanical compression device.</td>
</tr>
<tr>
<td>7.</td>
<td>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 (eg, hemophilia) and/or active liver disease, use mechanical compressive devices for preventing VTE.</td>
</tr>
<tr>
<td>8.</td>
<td>In the absence of reliable evidence, it is the opinion of this work group that patients undergo early mobilization following elective hip and knee arthroplasty. Early mobilization is of low cost, minimal risk to the patient, and consistent with current practice.</td>
</tr>
<tr>
<td>9.</td>
<td><strong>We suggest the use of neuraxial (such as intrathecal, epidural, and spinal) anesthesia for patients undergoing elective hip or knee arthroplasty to help limit blood loss, even though evidence suggests that neuraxial anesthesia does not affect the occurrence of venous thromboembolic disease.</strong></td>
</tr>
<tr>
<td>10.</td>
<td>Current evidence does not provide clear guidance about whether inferior vena cava filters prevent pulmonary embolism in patients undergoing elective hip and knee arthroplasty who also have a contraindication to chemoprophylaxis and/or known residual venous thromboembolic disease. Therefore, we are unable to recommend for or against the use of such filters.</td>
</tr>
</tbody>
</table>