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[Intervention Review]

Different types of intermittent pneumatic compression devices for preventing venous thromboembolism in patients after total hip replacement

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ABSTRACT

Background

Total hip replacement (THR) is an effective treatment for reducing pain and improving function and quality of life in patients with hip disorders. While this operation is very successful, deep vein thrombosis (DVT) and pulmonary embolism (PE) are significant complications after THR. Different types of intermittent pneumatic compression (IPC) devices have been used for thrombosis prophylaxis in patients following THR. Available devices differ in compression garments, location of air bladders, patterns of pump pressure cycles, compression profiles, cycle length, duration of inflation time and deflation time, or cycling mode such as automatic or constant cycling devices. Despite the widely accepted use of IPC for the treatment of arterial and venous diseases, the relative effectiveness of different types of IPC systems as prophylaxis against thrombosis after THR is still unclear.

Objectives

To assess the comparative effectiveness and safety of different IPC devices with respect to the prevention of venous thromboembolism in patients after THR.

Search methods

For this update the Cochrane Peripheral Vascular Diseases Group Trials Search Coordinator searched the Specialised Register (November 2014), CENTRAL (2014, Issue 10). Clinical trial databases were searched for details of ongoing and unpublished studies. Reference lists of relevant articles were also screened. There were no limits imposed on language or publication status.

Selection criteria

Randomized and quasi-randomized controlled studies were eligible for inclusion.

Data collection and analysis

Two review authors independently selected trials, assessed trials for eligibility and methodological quality, and extracted data. Disagreement was resolved by discussion or, if necessary, referred to a third review author.

Main results

Only one quasi-randomized controlled study with 121 study participants comparing two types of IPC devices met the inclusion criteria. The authors found no cases of symptomatic DVT or PE in either the calf-thigh compression group or the plantar compression group during the first three weeks after the THR. The calf-thigh pneumatic compression was more effective than plantar compression for reducing thigh swelling during the early postoperative stage. The strength of the evidence in this review is weak as only one trial was included and it was classified as having a high risk of bias.

Authors' conclusions

There is a lack of evidence from randomized controlled trials to make an informed choice of IPC device for preventing venous thromboembolism (VTE) following total hip replacement. More research is urgently required, ideally a multicenter, properly designed RCT including a sufficient number of participants. Clinically relevant outcomes such as mortality, imaging-diagnosed asymptomatic VTE and major complications must be considered.

PLAIN LANGUAGE SUMMARY

Different types of intermittent pneumatic compression devices for preventing venous thromboembolism after total hip replacement

Total hip replacement (THR) is an orthopedic procedure which has been performed for decades now to reduce pain and improve function and quality of life in people with severe hip disorders. It shows excellent results in terms of both improved function and value for money. While this operation is very successful, patients are at high risk of developing venous thromboembolic disease such as deep vein thrombosis (DVT) and pulmonary embolism (PE) in the immediate postoperative period. Intermittent pneumatic compression (IPC) devices are used to decrease the risk of such events. There are several different types of IPC device with variations in their design, including the rate and means of compression. We looked for randomized controlled trials which compared different types of IPC devices for preventing venous thromboembolism in patients after THR. We found one study with 121 participants comparing a calf-thigh compression device with a foot (plantar) compression device. There were no cases of symptomatic DVT or PE either in the calf-thigh compression group or the plantar compression group in the first three weeks after the THR. The calf-thigh pneumatic compression was more effective than plantar compression for reducing thigh swelling one week following surgery. The postoperative swelling in the calf-thigh pump group was reduced earlier than in the plantar pump group. However, other outcomes such as imaging-diagnosed asymptomatic VTE were not determined and it is not possible to draw reliable conclusions from this single study with a high risk of bias. We therefore suggest that more primary research is required to allow an informed choice of IPC device for preventing venous thromboembolism following THR.

BACKGROUND

Description of the condition

Total hip replacement (THR) was first performed by Charnley in the 1960s (Charnley 1961). It is a surgical procedure whereby the diseased cartilage and bone of the hip joint is replaced with artificial materials. Total hip replacement is an option for nearly all patients with diseases of the hip that cause chronic discomfort and significant functional impairment. According to the annual National Hospitals Discharge Survey, approximately 193,000 THRs were performed in the United States in 2002, and by 2006 that number went up to 231,000. Current estimates reach as high as 300,000 surgeries per year (DeFrances 2008). It is estimated that in England more than 30,000 THRs were performed at a cost of GBP 140 million between 1998 and 1999 (Mobasheri 2006).

While these operations are very successful, deep vein thrombosis (DVT) and pulmonary embolism (PE) are significant complications after THR (Kim 2003; Sikorski 1981; Yoo 2009). Total hip replacement is associated with a well known risk of DVT because the operative maneuvers that are needed to implant prosthetic components obstruct femoral vein flow, the patient is relatively immobile for several days after the operation compared to their preoperative state and the physiology of the venous system appears to be altered for some weeks postoperatively (McNally 1993). The occurrence of asymptomatic venous thromboembolism (VTE) after THR among patients not receiving postoperative pharmacoprophylaxis ranges from 28% to 70% (Cordell-Smith 2004; Dunn 1994; Kim 2003).

Orthopedic surgeons generally believe that it is desirable to employ pharmacological or mechanical methods, or both, as prophylaxis against VTE after THR (Friedman 2010; MacLellan 2007; O'Reilly 2005; Silbersack 2004). The Cochrane review by Kakkos et al showed that combined intermittent pneumatic leg compression and pharmacological prophylaxis can significantly reduce the incidence of DVT compared with compression or pharmacological prophylaxis alone (Kakkos 2008). Pharmacological prophylactic measures all carry an associated risk of bleeding. Major bleeding has been reported to occur in 1.5% to 2% of patients treated postoperatively with pharmacological prophylactics. This may cause morbidity and, rarely, even mortality. Moreover, some patients are distressed by the drug injections and a small proportion of patients may refuse the injections or will not accept any prolongation of that form of prophylaxis postdischarge despite a continuing high VTE risk (MacLellan 2007). When pharmacological methods cannot be used, mechanical methods become crucial for VTE prophylaxis.

Description of the intervention

As early as the 1800s, physicians experimented with the concept of improving blood circulation by exerting external pressure on the legs. The physiological pumping mechanism of the foot and the venous foot pump have been described ever since then (Delis 2000; Gardner 1983). Intermittent pneumatic compression (IPC) devices consist of an inflatable cuff wrapped around the leg or foot and an electrical pneumatic pump that inflates the cuff with air, compressing the deep veins and displacing blood proximally. This assumes the presence of competent venous valves. The veins refill by forward flow from the arteries when the cuffs deflate and thereby the IPC devices stimulate and maintain pulsatile blood flow in the deep veins. There are a number of ways of applying IPC, using

single or multiple chambers or bladders or by using different types of pumps and compression cycles, for example, and with variations in inflation and deflation times. Differences between devices relate in part to the frequency and rate of inflation, the anatomic location (such as plantar, calf, and calf-thigh) and type of compression. Available devices differ in the length and location of the sleeve and the bladder, the frequency and duration of activation, the rate at which the pressure increases, the maximum pressure that is achieved, and whether the compression is simultaneous or sequential. IPC has been used to prevent the development of blood clots during long periods of rest, for example during surgery. It has also been used to treat limb swelling, for example in patients with lymphedema or venous leg ulcers (Chen 2001).

How the intervention might work

IPC consists of a garment which is fitted to the calf or foot and is inflated by a pump. As the garment inflates with air it compresses the veins and pushes the blood back to the heart. The garment deflates again after a few seconds. This action mimics the squeezing action on the veins by the calf or foot muscles when walking. IPC devices not only provide a pressure gradient that facilitates venous blood flow towards the heart, they also provide a cyclical flow that acts to prevent blood stasis in the femoral vein (Whitelaw 2001). Moreover, while assuring high venous blood flow and emptying of the lower limbs, IPC devices exert a systemic endogenous fibrinolytic effect (Comerota 1997; Jacobs 1996; Kohro 2005).

IPC devices can be used intraoperatively (Neudecker 2002) in so far as pharmacological prophylaxis is very often not used before the first postoperative day to avoid bleeding. Patients who are managed with spinal or epidural anaesthesia do not recover active motion of the lower extremities for a few hours after the operation, which further compromises the venous return. The prompt application of IPC devices increases venous flow, preventing or minimizing the formation and propagation of clots. Other advantages of IPC devices over pharmacological prophylaxis include their postoperative reduction of pain and skin edema, and the fact that laboratory monitoring is not required.

Why it is important to do this review

Despite the widely accepted use of IPC for the treatment of arterial and venous diseases, the effectiveness of different types of IPC systems as prophylaxis against thrombosis after THR is still unclear. The goal of the current review is to provide evidence on the effect of different types of IPC systems in the prevention of VTE for patients after THR.

OBJECTIVES

The aim of this review was to assess the comparative effectiveness and safety of different intermittent pneumatic compression (IPC) devices with respect to the prevention of venous thromboembolism (VTE) in patients after total hip replacement (THR).

METHODS

Criteria for considering studies for this review

Types of studies

We considered randomized controlled trials (RCTs) and quasi-randomized controlled trials (quasi-RCTs) for inclusion in this review. Quasi-RCTs are those studies in which the allocation procedure is unlikely to be adequately concealed, such as using odd-even numbers or according to patients' social security numbers, date of birth or hospital identification (ID) numbers.

Types of participants

Patients aged 18 years and older who had undergone THR and with or without concomitant use of other types of thromboprophylactic measures together with IPC devices. If available, we planned to exclude studies with patients who presented with DVT at baseline.

Types of interventions

Different programs of IPC used in patients after THR.

1. IPC systems with different compression garments, such as circumferential bladders (encompass the whole limb) or non-circumferential bladders (only compress along part of the circumference of the limb).
2. IPC systems with a different location of air bladders, such as thigh, calf or foot compression, a combination of these sites, or the whole limb.
3. IPC systems with different patterns of pump pressure cycles, such as uniform compression (a single pressure applied to all parts of the limb under compression simultaneously); sequential compression (a single pressure applied to parts of the limb in sequence, with multiple bladders) or graded sequential compression (a gradient of pressure produced by inflating each bladder to different pressures).
4. IPC systems with different compression profiles.
5. IPC systems with different cycle length, duration of inflation time and deflation time, or different cycling model such as automatic cycling devices (sequential compression device response compression system), or constant cycling devices.

Studies using different types of IPC devices in combination with another method of prophylaxis (for example compression stockings, heparins, warfarin, early ambulation, etc) were eligible for inclusion providing comparisons could be made between the IPC device interventions.

Types of outcome measures

Primary outcomes

1. Symptomatic VTE
2. Symptomatic proximal and distal DVT (fatal and non-fatal) venographically or sonographically diagnosed
3. Symptomatic non-fatal PE diagnosed by ventilation-perfusion (V/Q) lung scan, spiral computed tomography (CT), or pulmonary angiography
4. Death related to embolic event (fatal PE)
5. Imaging-diagnosed asymptomatic VTE

Secondary outcomes

1. Bleeding (fatal bleeding or non-fatal bleeding which involved a critical organ or required re-operation, clinically overt bleeding

outside the surgical site, hemoglobin decrease > 2 g/dL or requiring transfusion of more than two units of blood)

2. Edema
3. Complications arising from the use of IPC devices, such as leg compartment syndrome, common peroneal nerve injury, etc
4. Death
5. Patient satisfaction and adherence to treatment

Search methods for identification of studies

There were no limits imposed on languages or publication status.

Electronic searches

For this update the Cochrane Peripheral Vascular Diseases Group Trials Search Coordinator (TSC) searched the Specialised Register (last searched November 2014) and the Cochrane Central Register of Controlled Trials (CENTRAL) 2014, Issue 10, part of *The Cochrane Library*, www.thecochranelibrary.com. See [Appendix 1](#) for details of the search strategy used to search CENTRAL. The Specialised Register is maintained by the TSC and is constructed from weekly electronic searches of MEDLINE, EMBASE, CINAHL, AMED, and through handsearching relevant journals. The full list of the databases, journals and conference proceedings which have been searched, as well as the search strategies used are described in the [Specialised Register](#) section of the Cochrane Peripheral Vascular Diseases Group module in *The Cochrane Library* (www.thecochranelibrary.com).

The following trial databases were searched by the TSC for details of ongoing and unpublished studies using the terms pneumatic and compression and hip:

World Health Organization International Clinical Trials Registry <http://apps.who.int/trialsearch/>;
ClinicalTrials.gov <http://clinicaltrials.gov/>;
ISRCTN registry <http://www.isrctn.com>

Searching other resources

We searched the reference lists of retrieved studies and those of narrative and systematic reviews to find additional potentially relevant studies.

Data collection and analysis

Selection of studies

We selected studies if the study design, population and interventions were clearly described, if data were provided separately by intervention group, and if VTE was diagnosed using objective, accepted criteria. Two review authors (Zhao JM and He ML) independently reviewed complete copies of each study and indicated on a study eligibility form if the study should be included, excluded, or if they were undecided. We resolved disagreements regarding study inclusion by discussion between the two review authors and, if necessary, by the involvement of a third independent review author (Xiao ZM). We contacted the corresponding author for clarification if it was unclear whether a trial was eligible for inclusion. All studies marked as 'undecided' by a review author were discussed further between the two review authors and then included or excluded.

Data extraction and management

Two review authors (Zhao JM and He ML) independently extracted the data using standard forms. We resolved any differences through discussion with the third author (Xiao ZM). We attempted to obtain any missing data from the corresponding authors. We extracted the following information from included and excluded studies:

- descriptive data for the people in the trial (including age, sex and all reported risk factors);
- type of IPC device used;
- duration of application of IPC device;
- incidence of adverse events (PE, superficial vein thrombosis, thrombophlebitis, edema, leg compartment syndrome, common peroneal nerve injury, etc);
- investigations used to diagnose thrombosis and adverse events;
- details of the outcome measures, as stated above.

Assessment of risk of bias in included studies

Two review authors (Zhao JM and He ML) independently assessed the risk of bias of each trial according to Higgins 2011 as described below, recorded the information in a table and provided a narrative description in the text. We resolved disagreements by discussion or by involving a third review author (Xiao ZM). We contacted the corresponding study authors for clarification if information was unclear.

(1) Sequence generation (checking for possible selection bias). Was the allocation sequence adequately generated?

We categorized the method used to generate the allocation sequence as:

- low risk of bias (any truly random process e.g. random number table; computer random number generator);
- high risk of bias (any non-random process e.g. odd or even dates of birth; hospital or clinic record numbers);
- unclear risk of bias.

(2) Allocation concealment (checking for possible selection bias). Was allocation adequately concealed?

We categorized the method used to conceal the allocation sequence as:

- low risk of bias (e.g. telephone or central randomization; consecutively numbered sealed opaque envelopes);
- high risk of bias (open random allocation; unsealed or non-opaque envelopes; alternation; date of birth);
- unclear risk of bias.

(3) Blinding. Because complete blinding of treatment is impossible in trials relevant to this review, we did not assess blinding in the review.

(4) Incomplete outcome data (checking for possible attrition bias through withdrawals, dropouts, protocol deviations). Were incomplete outcome data adequately addressed?

For each study and for each outcome, we described the completeness of data including attrition and exclusions from the analysis. We noted whether attrition and exclusions were reported, the numbers included in the analysis at each stage (compared with the total number of randomized participants), reasons for

attrition or exclusion where reported, and whether missing data were balanced across groups or were related to outcomes. Where sufficient information was reported or supplied by the trial authors, we re-included missing data in the analyses.

We categorized the methods as:

- low risk of bias;
- high risk of bias;
- unclear risk of bias.

(5) Selective reporting bias. Were reports of the study free of suggestion of selective outcome reporting?

We described how we investigated the possibility of selective outcome reporting bias and what we found. We assessed the methods as:

- low risk of bias (where it is clear that all of the study's prespecified outcomes and all expected outcomes of interest to the review have been reported);
- high risk of bias (where not all the study's prespecified outcomes have been reported; one or more reported primary outcomes were not prespecified; outcomes of interest were reported incompletely and so cannot be used; study failed to include results of a key outcome that would have been expected to have been reported);
- unclear risk of bias.

(6) Other sources of bias. Was the study apparently free of other problems that could put it at a high risk of bias?

We described any important concerns we had about other possible sources of bias (for example, whether there was a potential source of bias related to the specific study design or whether the trial was stopped early due to some data-dependent process). We assessed other sources of bias as:

- low risk of bias;
- no risk of bias;
- unclear risk of bias.

Measures of treatment effect

We planned to group and analyze studies by type of intervention, study design and type of outcome. Depending on the structure of the retrieved data, we planned to use risk ratios or risk differences as measures of treatment effect. Based on our assessment of the degree and nature of heterogeneity across studies, we planned to decide which measure to use and whether to combine different types of measures or report them separately.

Unit of analysis issues

We intended to not analyze studies with non-standard designs, except multiple treatment groups.

Dealing with missing data

Whenever possible, we contacted the original investigators to request missing data. We did not intend to use any statistical methods to impute or model missing data.

Assessment of heterogeneity

We planned to consider clinical and methodological sources of heterogeneity across studies that could make it inappropriate

to present summary risk estimates, such as important variations in study design, participant characteristics, types of intervention, definitions of study outcomes, differing durations and completeness of study follow up, and analysis (degree of adjustment for confounders, measure of effect used).

We planned to investigate heterogeneity amongst trials by using a standard χ^2 test with significance set at $P < 0.10$; and using the I^2 statistic ($> 50\%$ would be considered as substantial heterogeneity). Further, we planned to visually examine the forest plots for degree of overlap in the confidence intervals of effect estimates of the included studies, as poor overlap can indicate the presence of heterogeneity.

If statistical heterogeneity was detected, we intended to attempt to identify potential sources of heterogeneity and, where possible, conduct analyses stratified on these factors. We will also reserve the option to not combine data into single summary estimates of risk.

Assessment of reporting biases

We planned to analyze publication bias using the funnel plot method. We intended to statistically assess funnel plot asymmetry. It is, however, important to realize that publication bias is only one of a number of possible causes of funnel plot asymmetry.

Data synthesis

We planned to analyze the data using Review Manager 5. We intended to combine results unless clinical and methodological heterogeneity or statistical heterogeneity (non-overlapping confidence intervals) was unreasonable. We planned to pool dichotomous data using the risk ratio and calculate the number needed to treat, when appropriate. We planned to apply the intention-to-treat principle. However, if there was a discrepancy in the number randomized and the number analyzed in each group, we intended to calculate the percentage loss to follow up in each

group and consider using a different type of analysis. We planned to use a fixed-effect meta-analytic model unless there was statistically significant heterogeneity between trials, in which case we intended to use a random-effects model. If heterogeneity proved to be substantial, it may be unwise to perform a meta-analysis.

Subgroup analysis and investigation of heterogeneity

We planned to use subgroup analysis to explore possible sources of heterogeneity. Possible sources of heterogeneity are:

- (1) age range of the participants, e.g. young patients (18 to 59 years) or old patients (older than 60 years);
- (2) duration of intervention;
- (3) with or without concomitant use of other types of thromboprophylactic measures.

Sensitivity analysis

We planned to include only RCTs and quasi-RCTs and carry out sensitivity analysis according to the mode of randomization. We considered randomization using computer-generated numbers or random number tables as adequate modes of randomization. If, in future updates of this review, more trials are included and it is not clear how participants were allocated to groups, we will seek clarification from the authors of the studies.

RESULTS

Description of studies

See: [Characteristics of included studies](#); [Characteristics of excluded studies](#).

Results of the search

See: [Figure 1](#).

Figure 1. Study flow diagram.

Included studies

Only one study reporting results from a total of 121 participants met our inclusion criteria and was included in the review ([Fujisawa 2003](#)). Summary details of the only included study are given in the [Characteristics of included studies](#) table.

[Fujisawa 2003](#) was a single-center study. The study aimed to assess: (1) thrombogenesis by using the D-dimer level before and after THR, and (2) the patients' postoperative swelling by measuring the thigh and lower leg circumferences. A total of 121 patients who had undergone THR were allocated to the calf-thigh pump group (n = 58) or to the plantar pump group (n = 63). The study included 18 men and 103 women. The mean

age of the calf-thigh pump group was 61.36 years and for the plantar pump group it was 62.21 years. Immediately after the operation, all patients were fitted with either a calf-thigh pump or a plantar pump. The fitting time for both groups was four hours per day over a period of 21 days. The circumferences of the thigh and the lower leg were measured at 6 a.m. on the day of the operation and again at the same time on days three, seven, 14, and 21 postoperatively. The postoperative measurement values were compared with the preoperative measurements (taken as 100%) to evaluate the patients' postoperative swelling. In the study there was no information on the incidence of death related to embolic event or imaging-diagnosed asymptomatic VTE. We failed to retrieve the unpublished data from the primary authors.

Excluded studies

Three studies (Ben-Galim 2004; Froimson 2009; Westrich 2000) were excluded for a variety of reasons, as listed in the table

Characteristics of excluded studies. The reasons for exclusion were: participants undergoing elective joint replacement (either total hip or total knee) surgery and report did not specify the number of patients with THR (Ben-Galim 2004), study did not have an eligible study design (Froimson 2009), cross-over study with no relevant clinical outcomes (Westrich 2000).

Risk of bias in included studies

We assessed the risk of bias for Fujisawa 2003 by utilising the 'Risk of bias' assessment tool. This considers sequence generation, allocation concealment, blinding of physicians and participants, incomplete outcome data, selective outcome reporting and other potential threats to validity. See Figure 2 and Figure 3.

Figure 2. Risk of bias graph: review authors' judgements about each risk of bias item presented as percentages across all included studies.

Figure 3. Risk of bias summary: review authors' judgements about each risk of bias item for each included study.

Allocation

The allocation procedure was described as in the order in which the participants had been hospitalized, thus introducing a high level of bias into the study.

Blinding

Complete blinding of treatment was impossible for patients and investigators. There was no evidence that outcome assessors were blinded during the conduct and analysis of the study.

Incomplete outcome data

The increased ratio of the circumference of the thigh and the lower leg were shown in figures and the standard deviations were not provided.

Selective reporting

A prepublished protocol was not available to check the predefined outcomes.

Other potential sources of bias

No other sources of bias were identified.

Effects of interventions

Due to there being a single included study (Fujisawa 2003) a meta-analysis could not be performed. Therefore, the results are presented in a descriptive manner.

Primary outcomes

1. Symptomatic VTE

Fujisawa 2003 reported that there were no reports of symptomatic DVT or PE among either group of participants during the study period (first three weeks after operation).

2. Symptomatic proximal and distal DVT (fatal and non-fatal)

Fujisawa 2003 reported that there were no symptomatic DVTs among either group of participants during the study period (first three weeks after operation).

3. Symptomatic non-fatal PE

Fujisawa 2003 reported that there were no reports of symptomatic PE among either group of participants during the study period (first three weeks after operation).

4. Death related to embolic event (fatal PE)

Fujisawa 2003 reported that all patients completed the study, meaning there were no deaths during the study period.

5. Imaging-diagnosed asymptomatic VTE

This outcome was not assessed in the included study.

Secondary outcomes

1. Bleeding

This outcome was not assessed in the included study.

2. Edema

The circumferences of the thigh and lower leg were measured to evaluate postoperative swelling of the legs. The measurements were taken at 6 a.m. on the day of the operation and again at the same time on days three, seven, 14, and 21 postoperatively. Each measurement value was the median of three measurements; and was compared with the preoperative measurement (taken as 100%). On postoperative days three, 14 and 21, no significant differences were seen between the two groups. However, by postoperative day seven, the increased ratio of the circumference of the thigh in the calf-thigh pump group was significantly smaller (by 1.98%, $P < 0.01$) than in the plantar pump group. With regard to time-dependent changes of the postoperative swelling reduction, the calf-thigh pump group showed a significant reduction from day three to day seven (1.76%, $P < 0.01$) and from day seven to day 14 (2.11%, $P < 0.001$). The plantar pump group showed deterioration on day seven compared to on day three followed by a significant reduction (3.68%, $P < 0.001$) from day seven to day 14. Therefore, the postoperative swelling in the calf-thigh pump group was reduced earlier than in the plantar pump group. However, the results were shown by figures and the standard deviations were not provided.

3. Complications arising from the use of intermittent pneumatic compression (IPC) devices

This outcome was not assessed in the included study.

4. Death

Fujisawa 2003 reported that all patients completed the study, meaning there were no deaths during the study period.

5. Patient satisfaction and adherence to treatment

This outcome was not assessed in the included study.

DISCUSSION

Summary of main results

The aim of this review was to examine the efficacy and safety of different intermittent pneumatic compression (IPC) devices with respect to the prevention of venous thromboembolism (VTE) in patients after total hip replacement (THR). Literature about this issue is scarce. The results of this systematic review remain inconclusive due to a lack of suitable RCTs. Only one study was found which fulfilled the eligibility criteria for inclusion in this systematic review. The included study aimed to assess (1) thrombogenesis by using the D-dimer level before and after THR, and (2) the patients' postoperative swelling by measuring

the thigh and lower leg circumferences. The authors reported that no cases of symptomatic DVT or PE occurred either in the calf-thigh compression group or the plantar compression group during the first three weeks after the THR. The calf-thigh pneumatic compression was found to be more effective than plantar compression for reducing thigh swelling during the early postoperative stage. This study was however judged to be at risk of several important biases. Until more trials become available we cannot make robust conclusions regarding the effectiveness of different types of IPC systems as prophylaxis against thrombosis after THR.

Overall completeness and applicability of evidence

The included study followed patients for only three weeks after THR. It is unknown if three weeks is an optimal timeframe to assess prophylaxis against intravascular coagulation and leg swelling following THR. To assess the longevity of the intervention effect, a longer time frame of follow up would have been required. The IPC devices were applied only four hours a day, which might have prevented the true difference of the two devices to be evident. In addition, short usage time does not reflect the patients' compliance, which is crucial in reducing VTE rates. The D-dimer level was measured to evaluate intravascular coagulation preoperatively and postoperatively, but the D-dimers are not useful in operated patients because they may be elevated after surgery (Dindo 2009). Finally, the design of the only included study overlooks some important outcomes, for example mortality and imaging-diagnosed asymptomatic VTE. These outcomes should be explored in future studies in order to assess the efficacy and safety of different IPC devices more thoroughly.

Quality of the evidence

This review has identified a single quasi-RCT which has been found to be at risk of several biases. The weaknesses of the trial include that (1) the patients were allocated in the order in which they had been hospitalized, so selection bias was determined to be high; (2) it is impossible to blind patients or clinicians when using physical interventions; (3) there is no evidence that outcome assessors were blinded during the conduct and analysis of the study, and the increased ratios of the circumference of the thigh and the lower leg were shown in figures and the standard deviations were not provided.

Potential biases in the review process

None of the review authors were involved in any of the included or excluded studies. Furthermore, no review author has any commercial or other conflict of interest.

Extensive electronic and manual searches were conducted to search for relevant articles, and all studies were independently assessed for inclusion by two review authors. In order to reduce the publication bias in the review process, clinical trial databases (<http://apps.who.int/trialsearch/>; <http://clinicaltrials.gov/>; <http://www.controlled-trials.com/>) were searched by the Trials Search Coordinator (TSC) for details of ongoing and unpublished studies and no relevant studies were found. Therefore, we believe that we have included all relevant studies. We attempted to deal with missing information and data by contacting the authors of Fujisawa 2003, however our attempt has so far not been successful.

Agreements and disagreements with other studies or reviews

To date, no review has evaluated the efficacy and safety of different IPC devices for preventing VTE in patients after THR. Apart from [Fujisawa 2003](#), two studies were found that report on this issue. Ben-Galim et al ([Ben-Galim 2004](#)) reported a prospective, randomized clinical trial. Fifty patients undergoing elective joint replacement surgery (either total hip or total knee) were randomly divided into two subgroups, one treated with the WizAir DVT device and the other with the Kendall sequential compression device (SCD). Both devices employed knee-length calf cuffs with three pneumatic cells. The WizAir DVT device is a miniature, light-weight, battery-operated and mobile IPC device, which enables continuous intraoperative use and immediate patient mobilization postoperatively. All the patients received routine treatment after operation, which included heparin (5000 units twice daily for six days following surgery) and an IPC device applied to both legs immediately following surgery. Clinically, there were no reports of DVT or PE. On the sixth postoperative day, each patient underwent Doppler ultrasonography and DVT was not detected in any of the 50 patients. The authors concluded that the WizAir DVT device is as safe and effective as the Kendall SCD.

Froimson et al ([Froimson 2009](#)) reported a retrospective review of a non-randomized, comparative study. This study compared a miniaturized, portable, sequential IPC device (the ActiveCare continuous enhanced circulation therapy (CECT) system) with a non-mobile, non-sequential device (the Flowtron IPC device) on the ability to prevent postoperative DVT after joint arthroplasty. Of a total of 1577 consecutive joint arthroplasty patients included in the review, 1354 received the Flowtron IPC device and 223 received the ActiveCare CECT system. All patients received the IPC device in the preoperative area immediately before surgery. This device was used on the contralateral limb during surgery and then on both lower extremities after surgery. Each device remained with the patient for the duration of his or her hospital stay or up to the diagnosis of VTE. Enoxaparin was administered starting 12 to 24 hours postoperatively at a dose of 30 mg subcutaneously twice daily for knees or 40 mg subcutaneously once daily for hips. The patients were clinically evaluated twice daily and those with clinically suspected PE were evaluated by a V/P lung scan or spiral CT. Duplex ultrasonography was performed on the second or third postoperative days for DVT diagnosis. The ActiveCare CECT system

had better compliance (83% of the time versus 49%), lower rates of DVT (1.3% compared with 3.6%), a reduction in clinically important PE (0% compared to 0.66%) and shorter length of hospital stay (4.2 versus 5.0 days). The authors concluded that the ActiveCare CECT system was more effective than the Flowtron IPC device when used in conjunction with low molecular weight heparin for DVT prevention in patients after joint arthroplasty.

AUTHORS' CONCLUSIONS

Implications for practice

In the one study which met our inclusion criteria for this review, no cases of symptomatic DVT or PE were found in the calf-thigh compression group or the plantar compression group during the first three weeks after the THR. We also found evidence that the calf-thigh pneumatic compression was more effective than plantar compression for reducing thigh swelling during the early postoperative stage. However, this evidence is based on a very small underpowered study with a high risk of bias. Furthermore, other outcomes associated with interventions, such as mortality and imaging-diagnosed asymptomatic VTE, are unknown. Therefore, until adequate evidence regarding the efficacy and acceptability of interventions is available, definitive recommendations cannot be made.

Implications for research

More research is urgently required, ideally a multicenter, properly designed RCT including a sufficient number of participants to increase statistical power and allow assessments of outcomes in the long term. These prospective trials should have adequate follow up and the IPC devices should have sufficient usage time per day. In addition, clinically relevant outcomes such as mortality, imaging-diagnosed asymptomatic VTE and major complications must be considered. What's more, this systematic review only compared the efficacy of calf-thigh compression and plantar compression in the prevention of VTE; other types of IPC devices have not been tested in RCTs. Therefore, future trials should attempt to compare the efficacy of different types of IPC devices for preventing VTE after THR.

ACKNOWLEDGEMENTS

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REFERENCES

References to studies included in this review

Fujisawa 2003 {published data only}

Fujisawa M, Naito M, Asayama I, Kambe T, Koga K. Effect of calf-high intermittent pneumatic compression device after total hip arthroplasty: Comparative analysis with plantar compression on the effectiveness of reducing thrombogenesis and leg swelling. *Journal of Orthopaedic Science* 2003;**8**(6):807-11.

References to studies excluded from this review

Ben-Galim 2004 {published data only}

Ben-Galim P, Steinberg E, Rosenblatt Y, Parnes N, Menahem A, Arbel R. A miniature and mobile intermittent pneumatic compression device for the prevention of deep-vein thrombosis after joint replacement. *Acta Orthopaedica* 2004;**75**(5):584-7.

Froimson 2009 {published data only}

Froimson MI, Murray TG, Fazekas AF. Venous thromboembolic disease reduction with a portable pneumatic compression device. *Journal of Arthroplasty* 2009;**24**(2):310-6.

Westrich 2000 {published data only}

Westrich GH, Specht LM, Sharrock NE, Sculco TP, Salvati EA. Pneumatic compression hemodynamics in total hip arthroplasty. *Clinical Orthopaedics and Related Research* 2000;**372**:180-91.

Westrich GH, Specht LM, Sharrock NE, Windsor RE, Sculco TP, Haas SB, et al. Pneumatic compression enhancement of venous flow in total hip and knee arthroplasty: a comparison of devices. *Orthopaedic Transactions* 1997;**21**(2):521.

Additional references

Charnley 1961

Charnley J. Arthroplasty of the hip. A new operation. *Lancet* 1961;**1**(7187):1129-32.

Chen 2001

Chen AH, Frangos SG, Kilaru S, Sumpio BE. Intermittent pneumatic compression devices-physiological mechanisms of action. *European Journal of Vascular and Endovascular Surgery* 2001;**21**(5):383-92.

Comerota 1997

Comerota AJ, Chouhan V, Harada RN, Sun L, Hosking J, Veermansunemi R, et al. The fibrinolytic effects of intermittent pneumatic compression: mechanism of enhanced fibrinolysis. *Annals of Surgery* 1997;**226**(3):306-13; discussion 313-4.

Cordell-Smith 2004

Cordell-Smith JA, Williams SC, Harper WM, Gregg PJ. Lower limb arthroplasty complicated by deep venous thrombosis. Prevalence and subjective outcome. *The Journal of Bone and Joint Surgery. British volume* 2004;**86**(1):99-101.

DeFrances 2008

DeFrances CJ, Lucas CA, Buie VC, Golosinskiy A. 2006 National Hospital Discharge Survey. National Health Statistics Reports 2008, issue 5:1-20.

Delis 2000

Delis KT, Slimani G, Hafez HM, Nicolaides AN. Enhancing venous outflow in the lower limb with intermittent pneumatic compression. A comparative haemodynamic analysis on the effect of foot vs. calf vs. foot and calf compression. *European Journal of Vascular and Endovascular Surgery* 2000;**19**(3):250-60.

Dindo 2009

Dindo D, Breitenstein S, Hahnloser D, Seifert B, Yakarisik S, Asmis LM, et al. Kinetics of D-dimer after general surgery. *Blood Coagulation and Fibrinolysis* 2009;**20**(5):347-52.

Dunn 1994

Dunn ID, Hui AC, Triffitt PD, Crozier AE, Gregg PJ, Sinclair ME, et al. Plasma D-dimer as a marker for postoperative deep venous thrombosis. A study after total hip or knee arthroplasty. *Thrombosis and Haemostasis* 1994;**72**(5):663-5.

Friedman 2010

Friedman RJ, Gallus A, Gil-Garay E, FitzGerald G, Cushner F. Practice patterns in the use of venous thromboembolism prophylaxis after total joint arthroplasty--insights from the Multinational Global Orthopaedic Registry (GLORY). *American Journal of Orthopedics* 2010;**39**(9 Suppl):14-21.

Gardner 1983

Gardner AM, Fox RH. The venous pump of the human foot-preliminary report. *Bristol Medico-Chirurgical Journal* 1983;**98**(367):109-12.

Higgins 2011

Higgins JPT, Green S, editors. Cochrane Handbook for Systematic Reviews of Interventions Version 5.1.0 [updated March 2011]. The Cochrane Collaboration, 2011. Available from www.cochrane-handbook.org.

Jacobs 1996

Jacobs DG, Piotrowski JJ, Hoppensteadt DA, Salvator AE, Fareed J. Hemodynamic and fibrinolytic consequences of intermittent pneumatic compression: preliminary results. *Journal of Trauma: Injury, Infection and Critical Care* 1996;**40**(5):710-6; discussion 716-7.

Kakkos 2008

Kakkos SK, Caprini JA, Geroulakos G, Nicolaides AN, Stansby GP, Reddy DJ. Combined intermittent pneumatic leg compression and pharmacological prophylaxis for prevention of venous thromboembolism in high-risk patients. *Cochrane Database of Systematic Reviews* 2008, Issue 4. [DOI: [10.1002/14651858.CD005258.pub2](https://doi.org/10.1002/14651858.CD005258.pub2)]

Kim 2003

Kim YH, Oh SH, Kim JS. Incidence and natural history of deep-vein thrombosis after total hip arthroplasty. A prospective

and randomised clinical study. *The Journal of Bone and Joint Surgery. British volume* 2003;**85**(5):661-5.

Kohro 2005

Kohro S, Yamakage M, Sato K, Sato JI, Namiki A. Intermittent pneumatic foot compression can activate blood fibrinolysis without changes in blood coagulability and platelet activation. *Acta Anaesthesiologica Scandinavica* 2005;**49**(5):660-4.

MacLellan 2007

MacLellan DG, Fletcher JP. Mechanical compression in the prophylaxis of venous thromboembolism. *Australian and New Zealand Journal of Surgery*. 2007;**77**(6):418-23.

McNally 1993

McNally MA, Mollan RA. Total hip replacement, lower limb blood flow and venous thrombogenesis. *The Journal of Bone and Joint Surgery. British volume* 1993;**75**(4):640-4.

Mobasheri 2006

Mobasheri R, Gidwani S, Rosson JW. The effect of total hip replacement on the employment status of patients under the age of 60 years. *Annals of the Royal College of Surgeons of England* 2006;**88**(2):131-3.

Neudecker 2002

Neudecker J, Sauerland S, Neugebauer E, Bergamaschi R, Bonjer HJ, Cuschieri A, et al. The European Association for Endoscopic Surgery clinical practice guideline on the pneumoperitoneum for laparoscopic surgery. *Surgical Endoscopy* 2002;**16**(7):1121-43.

O'Reilly 2005

O'Reilly RF, Burgess IA, Zicat B. The prevalence of venous thromboembolism after hip and knee replacement surgery. *Medical Journal of Australia* 2005;**182**(4):154-9.

CHARACTERISTICS OF STUDIES

Characteristics of included studies [ordered by study ID]

Fujisawa 2003

Methods	Design: Randomized trial. Method of randomization: 121 patients were randomly allocated in the order in which they had been hospitalized. Method of allocation: 121 patients were randomly allocated in the order in which they had been hospitalized. Blinding of outcomes assessors: Not described.
Participants	Source population: Not described. Sample size: The calf-thigh pump group: 58, The plantar pump group: 63. Subject selection: Inclusion: Patients who had undergone THA. Exclusion: Patients with a history of DVT, pulmonary embolism, congestive heart failure, venous insufficiency, or the presence of a malignant tumor. Mean age: The calf-thigh pump group: 61.36, The plantar pump group: 62.21.

Sikorski 1981

Sikorski JM, Hampson WG, Staddon GE. The natural history and aetiology of deep vein thrombosis after total hip replacement. *The Journal of Bone and Joint Surgery. British volume* 1981;**63-B**(2):171-7.

Silbersack 2004

Silbersack Y, Taute BM, Hein W, Podhaisky H. Prevention of deep-vein thrombosis after total hip and knee replacement. Low-molecular-weight heparin in combination with intermittent pneumatic compression. *The Journal of Bone and Joint Surgery. British volume* 2004;**86**(6):809-12.

Whitelaw 2001

Whitelaw GP, Oladipo OJ, Shah BP, DeMuth KA, Coffman J, Segal D. Evaluation of intermittent pneumatic compression devices. *Orthopedics* 2001;**24**(3):257-61.

Yoo 2009

Yoo MC, Cho YJ, Ghanem E, Ramteke A, Kim KI. Deep vein thrombosis after total hip arthroplasty in Korean patients and D-dimer as a screening tool. *Archives of Orthopaedic and Trauma Surgery* 2009;**129**(7):887-94.

References to other published versions of this review

Zhao 2012

Zhao JM, He ML, Xiao ZM, Li TS, Wu H, Jiang H. Different types of intermittent pneumatic compression devices for preventing venous thromboembolism in patients after total hip replacement. *Cochrane Database of Systematic Reviews* 2012, Issue 11. [DOI: [10.1002/14651858.CD009543.pub2](https://doi.org/10.1002/14651858.CD009543.pub2)]

Fujisawa 2003 (Continued)

Gender (%):
Males: 18, females: 103.
The calf-thigh pump group: 86.2% female,
The plantar pump group: 84.1% female.

Interventions	<p>Type of IPC devices used:</p> <p>The calf-thigh pump group: Medomer Automatic Air Massager (Nitto Kohki, Tokyo, Japan), The plantar pump group: A-V impulse system (Orthofix Vascular Novamedix, Andover, UK). Interventions: Immediately after the operation, all patients were fitted with either a plantar pump or a calf-thigh pump. The fitting time for both groups was 4 hours per day over a period of 21 days in all patients. No anticoagulant drugs or antiembolism stockings were used.</p>
Outcomes	<p>Outcomes included in this review:</p> <ol style="list-style-type: none"> 1. Symptomatic DVT or PE; 2. Edema. <p>Other outcomes: D-dimer level.</p>
Notes	<p>The edema was evaluated by the changes in the circumference of the thigh and lower leg. The circumferences of the thigh and the lower leg were measured at 6 a.m. on the day of the operation and again at the same time on days three, seven, 14 and 21 postoperatively. The postoperative measurements were compared to the preoperative measurements, taken as 100%.</p>

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	High risk	121 patients who had undergone THA were randomly allocated in the order in which they had been hospitalized.
Allocation concealment (selection bias)	High risk	121 patients who had undergone THA were randomly allocated in the order in which they had been hospitalized.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Complete blinding of treatment is impossible for patients and investigators.
Blinding of outcome assessment (detection bias) All outcomes	High risk	There is no evidence that outcome assessors were blinded during the conduct and analysis of the study.
Incomplete outcome data (attrition bias) All outcomes	High risk	The increased ratio of the circumference of the thigh and the lower leg were shown by figures and the standard deviations were not provided.
Selective reporting (reporting bias)	Unclear risk	No description of the protocol was registered.
Other bias	Low risk	The two study groups were matched with regard to gender, age, leg operated on, duration of the operation, and body mass index.

Characteristics of excluded studies [ordered by study ID]

Study	Reason for exclusion
Ben-Galim 2004	Participants had undergone either total hip or total knee replacement. The article did not specify the number of patients with total hip replacement. We tried to contact the corresponding author for more information, but unfortunately we did not get a reply.
Froimson 2009	A retrospective review of a non-randomized study.
Westrich 2000	Randomized cross-over trial to evaluate the hemodynamic effects of several pneumatic compression devices. No relevant clinical outcomes.

APPENDICES

Appendix 1. CENTRAL search strategy

#1	MESH DESCRIPTOR Arthroplasty, Replacement, Hip EXPLODE ALL TREES	1170
#2	MESH DESCRIPTOR Hip Prosthesis EXPLODE ALL TREES	924
#3	MESH DESCRIPTOR Hip EXPLODE ALL TREES WITH QUALIFIERS SU	56
#4	(hip* and (replace* or arthroplast* or prosthe* or endoprosthe* or implant)):TI,AB,KY	3636
#5	tha:TI,AB,KY	447
#6	#1 OR #2 OR #3 OR #4 OR #5	3789
#7	MESH DESCRIPTOR Intermittent Pneumatic Compression Devices EXPLODE ALL TREES	72
#8	((pneumati* or sequential) near5 compres*):TI,AB,KY	397
#9	MESH DESCRIPTOR Lower Extremity EXPLODE ALL TREES WITH QUALIFIERS BS	1397
#10	((calf near4 (inflat* or pump* or compres* or squeeze*)):TI,AB,KY	88
#11	((foot near4 (inflat* or pump* or compres* or squeeze*)):TI,AB,KY	62
#12	((leg near4 (inflat* or pump* or compres* or squeeze*)):TI,AB,KY	116
#13	MESH DESCRIPTOR Blood Flow Velocity EXPLODE ALL TREES	2112
#14	((circulat* near3 assist*)):TI,AB,KY	20
#15	(flowtron or revitaleg or presssion or plexipulse):TI,AB,KY	4
#16	(a-v impulse):TI,AB,KY	27
#17	#7 OR #8 OR #9 OR #10 OR #11 OR #12 OR #13 OR #14 OR #15 OR #16	3866
#18	#6 AND #17	78

WHAT'S NEW

Date	Event	Description
11 December 2014	New search has been performed	Search rerun. No relevant studies identified.
11 December 2014	New citation required but conclusions have not changed	Search rerun. No relevant studies identified. No change to conclusions.

CONTRIBUTIONS OF AUTHORS

Zhao JM selected relevant trials, assessed trial quality, extracted data and wrote the review.

He ML conceived the idea for this systematic review and coordinated its development. He screened search results, selected articles for inclusion, assessed trial eligibility, extracted data and assessed trial quality.

Xiao ZM supervised all stages of the review and resolved disagreements in trial selection, assessment of trial quality and data extraction.

Li TS, Wu H and Jiang H contacted the original authors for missing data, performed data analysis, interpreted the data and wrote the review.

DECLARATIONS OF INTEREST

JMZ: None known

MLH: None known

ZMX: None known

TSL: None known

HW: None known

HJ: None known

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Internal sources

- No sources of support supplied

External sources

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DIFFERENCES BETWEEN PROTOCOL AND REVIEW

In the review, three clinical trial databases (<http://apps.who.int/trialsearch/>; <http://clinicaltrials.gov/>; <http://www.controlled-trials.com/>) were searched by the TSC for details of ongoing and unpublished studies, which was not mentioned in the protocol.

INDEX TERMS

Medical Subject Headings (MeSH)

*Intermittent Pneumatic Compression Devices; Arthroplasty, Replacement, Hip [*adverse effects]; Postoperative Complications [*prevention & control]; Randomized Controlled Trials as Topic; Venous Thromboembolism [*prevention & control]

MeSH check words

Humans