

Is intermittent calf compression better than electrical calf stimulation in preventing deep vein thrombosis in high-risk surgical patients?

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## SUMMARY STATEMENT

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## REQUEST

Is intermittent calf compression better than electrical calf stimulation in preventing DVT in high-risk surgical patients?

## REQUESTED BY

**Associate Professor Bruce Waxman**, Director, Academic Surgical Unit, Dandenong Hospital Clayton.

# METHODOLOGY

## Search Strategy

The Centre for Clinical Effectiveness defines the 'best available evidence' as that research we can identify that is least susceptible to bias. We determine this according to pre-defined National Health and Medical Research Council (NHMRC, 2000) criteria (see Appendix 1).

First, we search for systematic reviews, evidence based clinical practice guidelines, health technology assessments and randomised controlled trials. If we identify sound, relevant material of this type, the search stops. Otherwise, our search strategy broadens to include studies that are more prone to bias, less generalisable or have other methodological difficulties. We include case-control and longitudinal cohort studies in our critical appraisal reports. While we cite observational and case series studies, and narrative reviews and consensus statements, in our reports we do not critically appraise them. Such studies can produce accurate results but they are generally too prone to bias to allow determination of their validity beyond their immediate setting.

## Details of Evidence Request

Patients (Subjects):	High-risk patients for deep vein thrombosis
Intervention:	Intermittent calf compression
Comparison:	Electrical calf stimulation
Outcome:	Prevention of deep vein thrombosis (DVT)

## Search terms

(see Appendix 2 for exact search strategy)

Intervention:	Intermittent calf compression, compression, compression therapy
Comparison:	Electrical calf stimulation, electric stimulation therapy
Other:	Calf

## Resources Searched

We searched the following databases and Internet websites:

The Cochrane Library (CD-ROM)- Issue 3, 2001

Medline (OVID)- 1966 to July week 3 2001

Clinical Evidence (OVID)- Issue 5, June 2001

EBM Reviews ACP Journal Club – 1991 to March/April 2001

CINAHL (OVID)- 1982 to July week 2 2001

PREMEDLINE (OVID)- July 30, 2001

National Guideline Clearinghouse- July 31, 2001

NHS R & D Health Technology Assessment Programme July 13, 2001

## Refinements, Searching & Reporting Constraints

We included items of evidence that were available to us on 31 July 2001. We only included articles published in English. Critical appraisal was performed on the subset of studies published in English.

## RESULTS

From our sources we identified 3 articles related to the request that were categorised as follows.

Table 1: Study design of articles retrieved by search

Study Design	Number included
Systematic reviews or meta-analyses	0
Evidence-based clinical practice guidelines	0
<b>Randomised controlled trials</b>	<b>1</b>
Pseudorandomised controlled trials	0
<b>Controlled trials, cohort or case-control analytic studies</b>	<b>1</b>
<b>Unknown</b>	<b>1</b>

An article was excluded from further appraisal as follows

Reason for exclusion	Number
Unable to determine study design/level of evidence (full article can not be retrieved due to time constraints)	1

This left us with two articles for appraisal. Based on our refinements, searching and reporting constraints we are reasonably confident these two articles represent the most relevant findings published to date.

## EVIDENCE SUMMARIES

### Format

Evidence summaries are presented as spreadsheets attached to this report. Each spreadsheet contains the article citation, details of the study design, patient description, scientific validity of the article, results, and pertinent remarks from the authors and Centre for Clinical Effectiveness reviewer.

## REFERENCES

### ARTICLES CRITICALLY APPRAISED FOR THIS REPORT

1. Faghri,P.D.; Van Meerdervort,H.F.; Glaser,R.M.; Figoni,S.F (1997). Electrical stimulation-induced contraction to reduce blood stasis during arthroplasty. IEEE Transactions on Rehabilitation Engineering 5 (1): 62-69
2. Nicolaidis A. N., C. Miles, et al. (1983). Intermittent sequential pneumatic compression of the legs and thromboembolism-deterrent stockings in the prevention of postoperative deep venous thrombosis. Surgery 94 (1): 21-5

### ARTICLES NOT CRITICALLY APPRAISED

#### Unable to determine study design/level of evidence due to time constraints

1. Storti, S.; Crucitti, P.; Cina, G. (1996). Risk factors and prevention of venous thromboembolism. Rays 21 (3): 439-60

## APPENDIX 1

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## Levels Of Evidence

Based on "How to use the evidence: assessment and application of scientific evidence" (National Health & Medical Research Council, Canberra, 2000):

Level I	Evidence obtained from a systematic review (or meta-analysis) of all relevant randomised controlled trials.
Level II	Evidence obtained from at least one randomised controlled trial.
Level III	-1 Evidence obtained from pseudorandomised controlled trials (alternate allocation or some other method).
	-2 Evidence obtained from comparative studies (including systematic reviews of such studies) with concurrent controls and allocation not randomised, cohort studies, case control studies or interrupted time series with a control group.
	-3 Evidence obtained from comparative studies with historical control, two or more single-arm studies or interrupted time series without a parallel control group.
Level IV	Evidence obtained from case series, either post-test or pretest/post-test.

## APPENDIX 2

### Search strategy

	<b>Search terms for:</b> Cochrane library, medline, National Guideline ClearingHouse, EBM Reviews –ACP Journal Club, etc.
1	exp electric stimulation/ or electrical stimulation.mp
2	Electric stimulation therapy/ or electrical stimulation therapy. mp
3	Electric stimulation.tw
4	Electrotherapy.tw
5	Therapeutic electric stimulation.tw
6	Electrical calf stimulation.tw
7	Or/1-7
8	Intermittent calf compression.mp or exp *compression therapy/ or exp *compression garments/
9	Intermittent compression therapy.mp
10	Intermittent compression of calf.tw
11	Intermittent compression device\$.mp
12	or/8-12
13	7 and 12
14	Cal\$.mp
15	13 and 14
16	Limit 15 to English language

\$ wildcard indicating truncation

<p style="text-align: center;"><b>Evidence Summary Therapy/Intervention</b></p> <div style="border: 1px solid black; padding: 5px; margin-top: 10px;"> <p>Is intermittent calf compression better than electrical calf stimulation in preventing DVT in high-risk surgical patients?</p> </div>	<p><b>Study 1</b></p>	<p><b>Study 2</b></p>
<p><b>STUDY DESIGN &amp; NHMRC LEVELS OF EVIDENCE</b></p>	<p>Randomised controlled trial (Level II Evidence)</p>	<p>Comparative Study (Level III Evidence)</p>
<p><b>DESCRIPTION:</b> Patients (subjects), Intervention, Comparisons, Outcomes, Inclusion &amp; Exclusion Criteria</p>	<p><b>Setting:</b> USA  <b>Patients:</b> Those (n=30) undergoing total hip &amp; knee arthroplasty.  <b>Intervention:</b> Sequential compression device (SCD) and compression stocking (TED) [n=15, 40% males, 66.4±7.3 years).  <b>Comparison:</b> Electrical Stimulation (ES) and TED [n=15, 53.3% males, 60.7±9.7 year].  <b>Outcomes:</b> Stroke volume, cardiac output, heart rate, total peripheral resistance, and mean arterial pressure were assessed pre surgery, at 15 min, 30 min, 45 min, 60 min, 75 min, 90 min, and post surgery.  <b>Exclusion criteria:</b> Patients with a positive ultrasound or prior deep vein thrombosis (DVT).</p>	<p><b>Setting:</b> England  <b>Patients:</b> Those (n=150, &gt;30 years) with major abdominal operations  <b>Intervention:</b> Intermittent sequential compression and TED stockings (n=50, mean± SD age was 57.3±13.4 years).  <b>Comparisons:</b> two groups  <ul style="list-style-type: none"> <li>• Electrical calf stimulation (n=50, mean ± SD age was 59.2±16.6 years).</li> <li>• Low-dose subcutaneous heparin 5000 IU in 0.2 ml of saline administered 2 hours before operation and then every 12 hours until discharge (n=50, mean±SD age was 58.6±13.3 years).</li> </ul> <b>Outcome:</b> Incidence of deep venous thrombi (DVT)  <b>Exclusion criteria:</b> Not stated</p>
<p><b>VALIDITY:</b> Methodology, rigour, selection</p>	<p><b>Randomisation:</b> Method not stated  <b>Blinding:</b> Not stated  <b>All patients accounted for:</b> Yes  <b>Patients treated equally:</b> Yes.  <b>Similar groups:</b> Yes</p>	<p><b>Randomisation:</b> Yes, by drawing and opening a sealed envelope.  <b>Blinding:</b> Not clear  <b>All patients accounted for:</b> Yes  <b>Patients treated equally:</b> Yes  <b>Similar groups:</b> Yes.</p>
<p><b>RESULTS:</b> Generally favourable or unfavourable, specific outcomes of interest, estimate of experimental effect and precision if appropriate</p>	<p>Stroke volume and cardiac output were higher throughout surgery in the ES group compared to the SCD group. The heart rate was consistently lower during electrical stimulation for both groups. Total peripheral resistance did not change in the ES group but increased in the SCD group. There was significant stage effect for the mean arterial pressure in the SCD group but not for the ES group.</p>	<p>All the patients were scanned with the 125I-fibrinogen test for the whole stay in hospital. The incidence of 125I-fibrinogen detected deep venous thrombi was 18% in electrical calf stimulation group, 9% in low-dose subcutaneous heparin group, and 4% in intermittent sequential compression group.</p>
<p><b>AUTHOR(S) CONCLUSIONS:</b> Limitations, implications for practice and research</p>	<p>"Although results show skeletal muscle activation to promote venous return, further study is required to evaluate long-term effects of ES on preventing DVT and PE."</p>	<p>"The regimen of intermittent sequential compression and TED stockings is as effective as low-dose subcutaneous heparin. Electrical calf stimulation is less effective"</p>
<p><b>OUR COMMENTS:</b> Opportunity for bias, weakness and strength</p>	<p><b>Potential for bias:</b> Lack of information on randomisation method and blinding.  <b>Weakness/es:</b></p> <ul style="list-style-type: none"> <li>• Randomisation method not described</li> <li>• Not clear if assessors were blinded</li> <li>• Not clear how and why 30 patients were recruited onto the study.</li> </ul>	<p><b>Potential for bias:</b> The three groups were similar. Patients were first stratified into four groups according to the risk of DVT prior to randomisation. Lack of information on blinding.  <b>Weakness/es:</b></p> <ul style="list-style-type: none"> <li>• The authors did not acknowledge the limitations of their study and its implication to clinical practice.</li> </ul>

	<p><b>Strength/s:</b></p> <ul style="list-style-type: none"> <li>• Patient gave a signed consent</li> <li>• Patient characteristics provided (mean age &amp; sex).</li> <li>• Study approved by hospital authorities.</li> </ul> <p>This article only compared venous return in patients undergoing total hip and knee arthroplasty using ES and SCD techniques. Further study is warranted to compare and evaluate the effectiveness of SCD and ES on preventing DVT and PE.</p>	<p><b>Strength/s:</b></p> <ul style="list-style-type: none"> <li>• Patients were stratified into four groups according to the risk of DVT (low risk, moderate risk, high risk, extremely high risk) before randomisation</li> <li>• Randomisation method stated.</li> <li>• All patients were studied with I-fibrinogen test starting the day before operation and continued until they were discharged.</li> </ul>
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## EXPLANATION OF TERMINOLOGY USED IN SPREADSHEET

**Level of evidence:** A hierarchy of study evidence that indicates the degree to which bias has been eliminated in the study design.

**Intervention:** A therapeutic procedure such as treatment with a pharmaceutical agent, surgery, a dietary supplement, a dietary change or psychotherapy.

**Randomisation:** A process of allocating participants to treatment or control group within a controlled trial by using a random mechanism, such as coin toss, random number table or computer-generated random numbers. Study subjects have an equal chance of being allocated to an intervention or control group; thus, the two groups are comparable. Randomisation ensures that the results are not biased by the selection of particular types of patients to receive a specific therapy.

**Blinding:** Blinding or masking is a process used in epidemiological studies and clinical trials in which the observers and the subjects have no knowledge as to which treatment groups subjects are assigned. It is undertaken in order to minimise bias occurring in patient response and outcome measurement.

**All patients accounted for:** Once patients are randomly allocated to a specific group and withdraw before study conclusion, they have to be accounted for in order to ensure that patients withdrawing from the study are not significantly different from those continuing in the study. The final analysis should be conducted on an intention-to-treat basis, which includes the results of withdrawn patients in the analysis.

**Patients treated equally:** To be able to attribute any difference in the observed outcome to the intervention, study patients need to be treated equally in every way except for the intervention being evaluated.

**Similar groups:** Baseline characteristics of patients that are also likely to affect results should be evenly distributed between the intervention and control groups. Following proper randomisation, patients' attributes would be expected to be equally distributed between groups.

### **Validity:**

Of measurement: an expression of the degree to which a measurement measures what it purports to measure; it includes construct and content validity.

Of study: the degree to which the inferences drawn from the study are warranted when account is taken of the study methods, the representativeness of the study sample, and the nature of the population from which it is drawn (internal and external validity, applicability, generalisability).

**Potential for bias:** Bias is a systematic deviation of a measurement from the 'true' value leading to either an over (or under) estimation of the treatment effect. Bias can originate from many different sources (including allocation of patients, measurement, interpretation, publication and review of data).