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Systematic Review on the Effectiveness of Anti-Embolism Stockings; A Need to Re-Evaluate the Evidence

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Abstract

Objectives: To systematically review randomized controlled trials that have evaluated elasticated thrombo-embolic graduated compression stockings as prophylaxis of deep venous thrombosis in various health situations.

Design: Searches were carried out in the Cochrane Central Register of Controlled Trials, Medline, EMBASE and CINAHL and the results hand searched for trials registered up to March 2021.

Participants: A total of 26 relevant randomized controlled trials involving 8,279 participants were systematically reviewed.

Main Outcome Measures: Trials were independently assessed and data extracted for the occurrence of deep vein thrombosis, pulmonary embolism and skin ulceration.

Public and Patient Involvement: There was no patient or public involvement for this study.

Results: The occurrence of deep vein thrombosis was 306/4159(7.4%) with the stocking compared to 492/4120(11.9%) without the stockings (RR 0.49, 95% CI 0.39-0.62). The occurrence of pulmonary embolism was also reduced from 43/3419(1.3%) to 23/3416(0.7%) (RR 0.56, 95% CI 0.35-0.91). These findings may be biased due to the potential underreporting of negative studies and the subsequent changes to clinical practice. For the three large contemporary studies involving 5,171 participants, these failed to show any statistically significant reduction in thrombosis, with deep vein thrombosis confirmed in 158/2572(6.1%) participants in those allocated to stocking, as opposed to 171/2599(6.6%) in the control group (RR 0.92, 95% CI 0.74-1.16).

Conclusion: The current recommendations regarding the use of thrombo-embolic stockings need to be re-evaluated, as their effectiveness at reducing the occurrence of post-operative deep vein thrombosis is minimal based on the current evidence and clinical practices.

Introduction

Graduated compression stockings have been advocated as a method of reducing the risk of deep vein thrombosis for both medical and surgical patients [1]. It is thought that the external pressure of the stockings increases the blood flow in the deep veins of the leg and thereby reduces the risk of thrombosis. The stockings may be knee length or thigh length [1]. Despite being in routine clinical use for over 50 years now, until recently there has been little critical evaluation of their effectiveness.

Over the years there has been a change of practice from the stockings being used as the only method of thrombo-embolic prophylaxis to being used in conjunction with pharmacological thrombo-embolic prophylaxis such as heparin. Currently the National Institute of Clinical Excellence for the United Kingdom states that anti-embolism stockings can be considered after orthopaedic surgery and used as an alternative to intermittent pneumatic compression for abdominal surgery and other major surgical procedures [2]. The cost of a single pair of elastic stockings is £10-£25 per pair (12-30 euro, 14-34 US dollars). The annual cost of using compression stockings for the United Kingdom may exceed £62 million ($79 million, 72 million euro) [3].

With the continuing development of evidence-based medicine there has been a questioning of the effectiveness of compression stockings. This has led to a number of larger randomized controlled

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trials on this topic. This review builds on earlier systematic reviews on this topic [4, 5] by including the more recently published studies.

Patients and Methods

Searches were carried out to identify all contemporary randomised controlled trials (from 2017 onwards) that compared the use of graduated compression stockings with a control group with no stockings. The searches were performed in Medline, EMBASE, CINAHL, Cochrane and ClinicalTrials.gov using the following search strategy.

(VenoTrain* or Ulcertec or SurePress* or ComfortPro or Comfort-Pro or "Ulcer Kit" or Sigvaris).ti,ab. OR ((stocking* or hosiery or tights or sock or socks or bandage*) and compres*).ti,ab. OR exp Compression Bandages/ OR exp Stockings, Compression/ AND ("randomised control* trial*" or "randomized control* trial*" or RCT or random*).ti,ab. Searches for previous systematic reviews on this topic were also performed. From these reviews, which included the Cochrane review on this topic, all listed included, excluded and ongoing studies were reviewed. This was used to identify all studies prior to 2017. Articles in all languages and published and unpublished studies were considered for inclusion, as were trials of both above and below knee stockings. We included both randomised and quasi-randomised trials in which the method of randomisation was insecure. Exclusion were non-randomized and retrospective studies.

Two review authors (MA, MJP) independently screened titles and abstracts, assessed full texts of potentially eligible studies for inclusion, and independently assessed risk of bias for each study. The main aspects of trial methodology were secure randomisation versus quasi-randomisation, blinding of the assessors of thrombosis and use of screening for all patients. In addition, the risk of bias tool in the Cochrane handbook for systematic reviews and interventions was used [6]. All identified trials were independently assessed and data for the outcomes of deep vein thrombosis, pulmonary embolism and skin ulceration were extracted by two reviewers. Disagreement was resolved following discussion between all authors. Differences were resolved by discussion.

For each study, relative risks and 95% confidence intervals were calculated. Results from individually randomized trials were pooled using the fixed effects model of Mantel-Haenszel. Heterogeneity between comparable studies was tested with the use of a standard Chi-square test. For a chi- squared result of less than 0.1 or an I squared of greater than 50% then the random effects model of DerSimonian and Laird. Subgroup analysis was undertaken for studies that used no additional prophylaxis versus those that used additional prophylaxis. Analysis between these groups included Fisher exact test, relative risk (RR), and 95% Confidence intervals (CI). Funnel plots for the outcomes of deep vein thrombosis and pulmonary embolism were constructed and analysis for funnel plot asymmetry was with the Harboard's modified test for small study effects.

Results

A total of 26 studies involving 8,279 patients were identified and included. (Figure 1, Table 1). Ten studies related to general surgery [3, 7-31]. These studies involved 741 patients, the majority of whom had undergone major abdominal surgery. A more recent study involving 1,905 patients the majority of which were having elective general surgery, but also included were 86 having urological surgery, 44 ear nose and throat surgery, 36 neurosurgery, 18 plastic

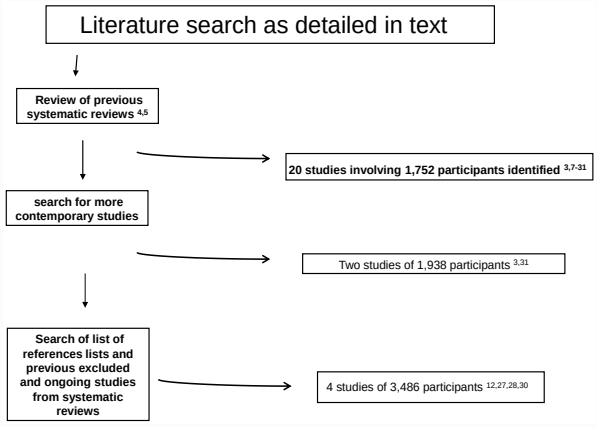

Figure 1: Flow diagram for identification of studies.

surgery, 11 orthopaedic surgery and 2 vascular surgery [2]. All eight studies related to orthopaedic surgery were solely for elective hip and knee arthroplasty apart from one study in which 39/795(4.9%) of participants had emergency hip fracture surgery [28]. In total, these eight studies involved 1,471 participants. Also identified were single studies for vascular surgery with 252 participants [17], neurosurgical patients with 161 participants [22] and two studies for gynecological surgery with 278 participants [16, 31]. Also identified were three studies conducted to assess the effectiveness of compression stockings in non-surgical patients, with two of them on post stroke patients with 2,615 participants [27, 30] and one study on post myocardial infarction patients with 160 participants [24].

All studies used screening for all randomized patients for deep vein thrombosis and assessed for their quality of methodology (Table 2). 13 of these studies stated this assessment was by a blinded assessor. Most of the early studies used radioactive labeled fibrinogen but there was a change over the years to using ultrasound venography. Other methods used were contrast venography and strain gauge plethysmography. For 14 of the studies the stockings were the sole method of thrombo-embolic prophylaxis whilst the remainder used an additional method, normally a heparin, for all randomized participants.

Figure 2 details the results for the occurrence of deep vein thrombosis for the 26 included studies with results presented chronologically and for the different surgical operations or medical condition. Deep vein thrombosis occurred for 306/4159(7.4%) allocated to stockings versus 492/4120(11.9%) without the stockings (RR 0.49, 95% CI 0.39-0.62). A funnel plot was constructed for the main outcome of deep vein thrombosis (Figure 3). This showed clear asymmetry. Harbord's modified test for small study effects confirmed this (p=<0.0001) indicating a high probability of missing studies. For the three large contemporary studies involving 5,171 participants, these failed to show any statistically significant reduction in thrombosis, with deep vein thrombosis confirmed in 158(6.1%) participants in those allocated to stocking, as opposed to 171(6.6%) in the control group (RR 0.92, 95% CI 0.74-1.16) [3, 28, 30].

Comparison of studies that used no supplementary prophylaxis versus those that used additional prophylaxis was undertaken. For those studies that used no additional prophylaxis the occurrence of deep vein thrombosis was 107/925(11.6%) with stockings versus 203/849(23.9%) for no stockings (RR 0.46, P value <0.0001, 95%

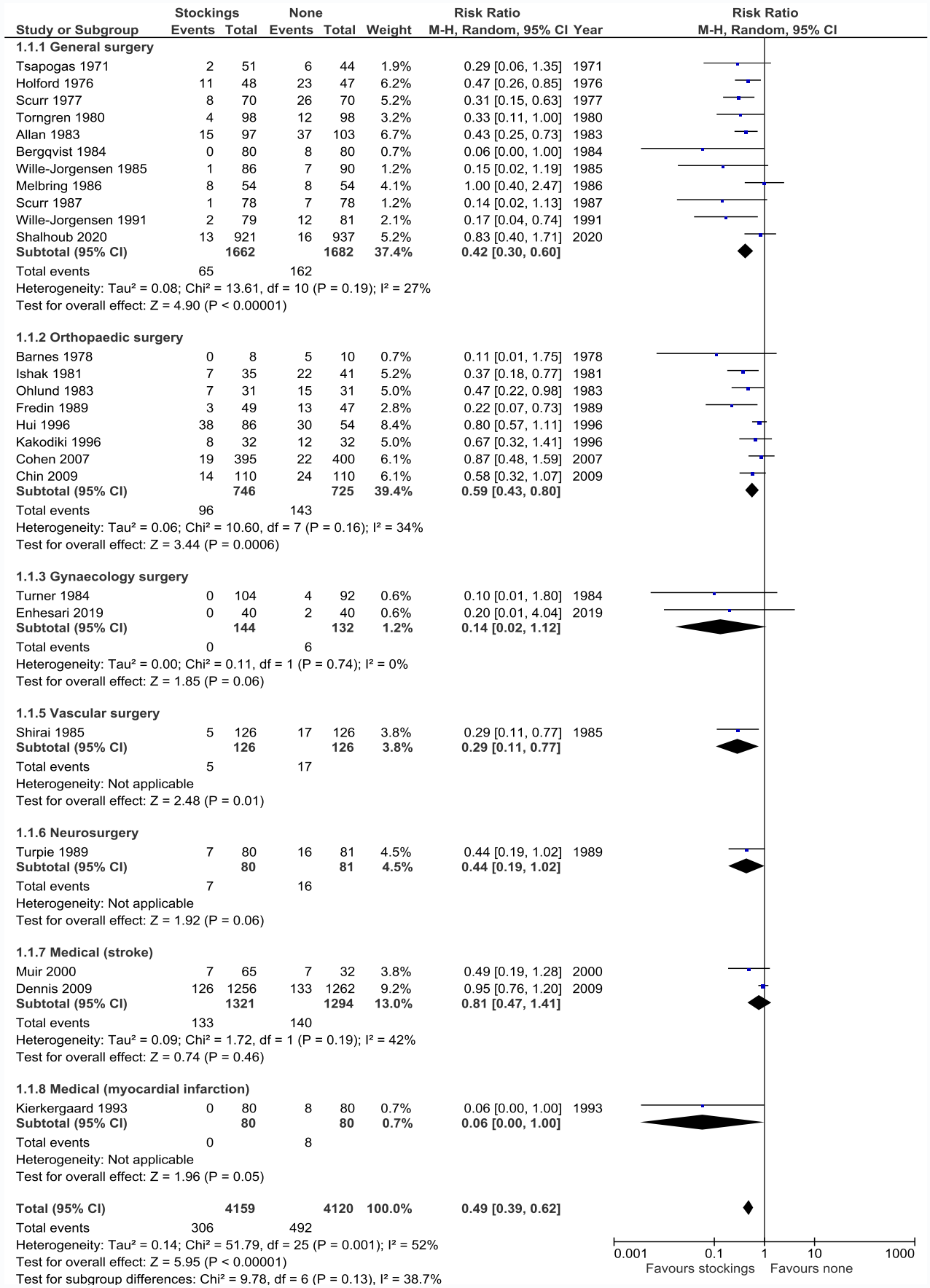

Figure 2: Forrest plot for the occurrence of deep vein thrombosis.

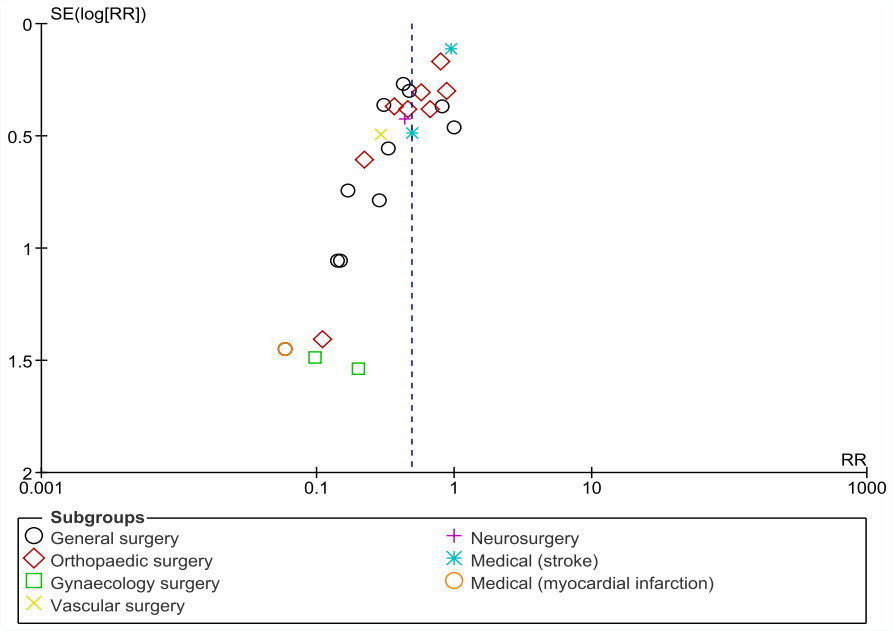

Figure 3: Funnel plot for the occurrence of deep vein thrombosis.

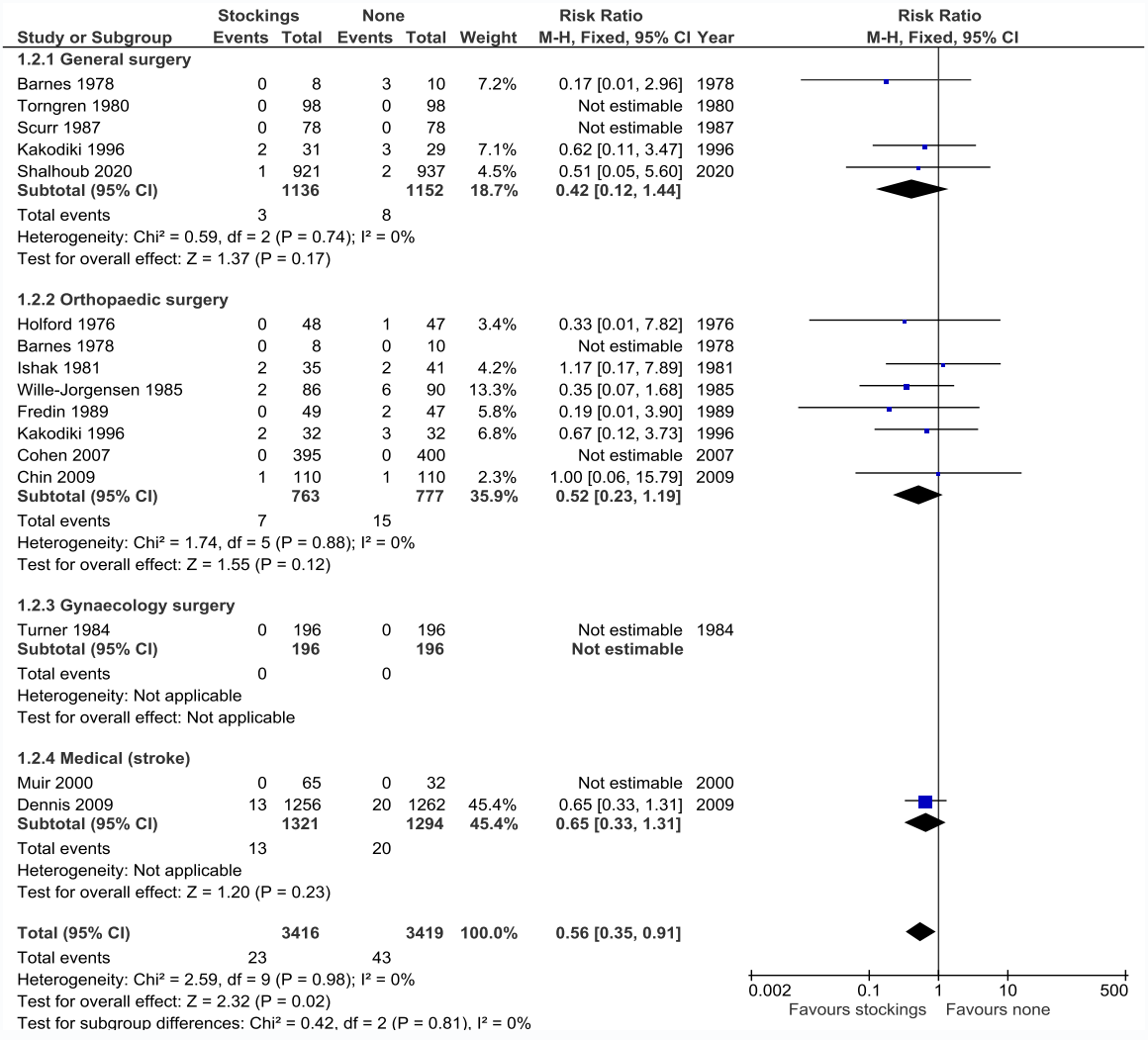

Figure 4: Forrest plot for the occurrence of pulmonary embolism.

Table 1: Characteristics of included studies presented chronologically.

First author of study	Year	Number of participants	Type of surgery / medical condition	Type of stocking	Secure randomization	Blinding of assessors	Screening for deep vein thrombosis	Other prophylaxis used for both groups
Tsapogas [7]	1971	95	Major Abdominal surgery	Thigh	Yes	Not mentioned	I-fibrinogen, venography	None
Holford [8]	1976	95	Major thoracic or abdominal surgery	Thigh	Yes	Not mentioned	I-fibrinogen	None
Scurr [9]	1977	70	Major Abdominal surgery	Thigh	Yes	Not mentioned	I-fibrinogen	None
Barnes [10]	1978	18	Total hip arthroplasty	Thigh	Yes	Not mentioned	Ultrasound	None
Torngren [11]	1980	98	Major Abdominal surgery	Thigh	No	Not mentioned	I-fibrinogen	LMWH
Ishak [12]	1981	76	Total hip arthroplasty	Thigh	No	Not mentioned	Venography	Dextran for 59/76
Allan [13]	1983	200	Abdominal surgery	Not stated	Yes	Yes	I-fibrinogen	None
Ohlund [14]	1983	62	Elective hip surgeries	Not stated	Unknown	Not mentioned	I-fibrinogen	Dextran
Bergqvist [15]	1984	160	Abdominal surgery	Thigh	Yes	Not mentioned	I-fibrinogen	Dextran
Turner [16]	1984	196	Major gynaecological surgery	Not stated	Yes	Yes	I-fibrinogen	None
Shirai [17]	1985	252	Vascular surgery	Thigh	Unknown	Not mentioned	I-fibrinogen	None
Wille-Jorgensen [18]	1985	176	Major Abdominal surgery	Thigh	Yes	Yes	I-fibrinogen, venography	LMWH
Mellbring [19]	1986	114	Major Abdominal surgery	Thigh	Yes	Not mentioned	I-fibrinogen	LMWH and dihydroergoramine
Scurr [20]	1987	78	Major surgical operations	Thigh	Yes	Not mentioned	I-fibrinogen, Doppler US, maximum venous outflow by strain-gauge plethysmography	Sequential compression device
Fredin [21]	1989	96	Total hip arthroplasty	Thigh	Unknown	Yes	I-fibrinogen	Dextran
Turpie [22]	1989	239	Neurosurgical patients	Thigh	Yes	Yes	I-fibrinogen, plethysmography, venography if any +ve	None
Wille-Jorgensen [23]	1991	160	Abdominal surgery lasting more than one hour	Not stated	Yes	Not mentioned	I-fibrinogen + /-venography as needed	Heparin or Dextran
Kierkergaard [24]	1993	160	Acute myocardial infarction	Thigh	Unknown	Yes	I-fibrinogen, maximum venous outflow by strain-gauge plethysmography	None
Hui [25]	1996	140	Total hip and knee arthroplasty	Thigh and calf	Unknown	Not mentioned	Venography	None
Kakodiki [26]	1996	64	Total hip arthroplasty	Thigh	Yes	Yes	Venography and lung scans	LMWH
Muir [27]	2000	97	Stroke	Not stated	Yes	Yes	Ultrasound	None
Cohen [28]	2007	795	Hip surgery	Thigh	Yes	Yes	Ultrasound	Fondaparinux
Chin [29]	2009	220	Total knee arthroplasty	Not stated	Unknown	Yes	Ultrasound	None
Dennis [30]	2009	2518	Stroke	Thigh	Yes	Yes	Ultrasound	Various
Enhesari [31]	2019	80	Hysterectomy	Calf	Unknown	Not mentioned	Ultrasound	Heparin
Shalhoub [3]	2020	1858	Elective surgery	Thigh and calf	Yes	Yes	Duplex ultrasound	LMWH

LMWH=low molecular weight heparin

CI 0.34 to 0.61). For those studies in which the patients received additional thrombo-embolic prophylaxis (Table 1) then the occurrence of deep vein thrombosis was 199/3234(6.2%) with stockings versus 289/3271(8.8%) with no stockings (RR 0.52, P value <0.0001, 95% CI 0.36 to 0.74).

Figure 4 details the results for pulmonary embolism for the 16 studies that reported this outcome. Overall, the occurrence of pulmonary embolism was reduced from 43/3419(1.3%) to 23/3416(0.7%) (RR 0.56, 95% CI 0.35-0.91). The funnel plot for this outcome did not show any significant asymmetry.

Table 2: Detailed assessment of study methodology based on Cochrane methodology.

First author of study	Year	Random sequence generation (selection bias)	Allocation concealment (selection bias)	Blinding of outcome assessment	Incomplete outcome data	Selective reporting	Other bias
Tsapogas [7]	1971	Low	Unclear	Unclear	Low	Low	Unclear
Holford [8]	1976	Unclear	Low	Unclear	Low	Low	Low
Scurr [9]	1977	Low	Unclear	Unclear	Low	Low	Low
Barnes [10]	1978	Unclear	Low	Unclear	Low	Low	High
Torngren [11]	1980	High	High	Unclear	Low	Low	Low
Ishak [12]	1981	High	High	Unclear	Low	Low	Low
Allan [13]	1983	Low	Unclear	Low	Low	Low	Low
Ohlund [14]	1983	Unclear	Unclear	Unclear	Low	Low	Low
Bergqvist [15]	1984	Low	Unclear	Unclear	Low	Low	Unclear
Turner [16]	1984	Low	Unclear	Low	Low	Low	Low
Shirai [17]	1985	Unclear	Unclear	Unclear	Unclear	Unclear	Unclear
Wille-Jorgensen [18]	1985	Low	Unclear	Low	Low	Low	Low
Mellbring [19]	1986	Unclear	Low	Unclear	Low	Low	Low
Scurr [20]	1987	Unclear	Unclear	Unclear	Low	Low	Unclear
Fredin [21]	1989	Unclear	Unclear	Low	Low	Low	Low
Turpie [22]	1989	Unclear	Low	Low	Low	Low	Low
Wille-Jorgensen [23]	1991	Low	Low	Unclear	Low	Low	Unclear
Kierkergaard [24]	1993	Unclear	Unclear	Low	Low	Low	Low
Hui [25]	1996	Unclear	Unclear	Unclear	Low	Low	Unclear
Kakodiki [26]	1996	Low	Low	Low	Low	Low	Unclear
Muir [27]	2000	Low	Low	Low	Low	Low	Low
Cohen [28]	2007	Unclear	Low	Low	Low	Low	Low
Chin [29]	2009	Unclear	Unclear	Low	Low	Low	Low
Dennis [30]	2009	Low	Low	Low	Low	Low	Low
Enhesari	2019	Unclear	Unclear	Unclear	Low	Low	Low
Shalhoub [3]	2020	Low	Unclear	Low	Low	Low	Low

The occurrence of adverse effects of stockings and compliance with wearing the stockings was poorly documented in most studies. Only three studies documented the occurrence of leg ulcers or skin breakage with combined figures of 65/2287(2.8%) for the stockings versus 16/2309(0.7%) without the stockings (RR 3.99, 95% CI 2.34-6.81) [3, 29, 30]. Thromboembolic stockings were reported to be uncomfortable to wear and difficult to fit and stay in place [22, 25]. For the study of Hui, 23% of those with thigh length stockings and 16% of those with below knee stockings requested their removal [25].

Discussion

Anti-embolism stockings have been used routinely for hospital inpatients on both medical and surgical wards since the 1950's. It is only recently that a more critical appraisal of their benefits and potential disadvantages has been made. Their use was initially as a treatment for varicose veins and venous insufficiency of the leg and then later used as a method for reducing the risk of venous thrombosis. The early evidence for their benefit in this situation was from theoretical studies and case reports. It was not until the 1970's that any randomized trials were undertaken. The early randomized studies were all on a small number of patients comparing stockings versus no stockings as the sole method of thrombo-prophylaxis. As listed in Table 1 these earlier studies involved small numbers of patients and were primarily related to abdominal surgery. All these studies consistently reported the benefit of the stocking.

This report builds on previous systematic reviews on this topic [4, 5]. Both these reviews reported on only the earlier studies and including 1,681 and 1,752 participants respectively. The studies reported tended not to use any other method of thrombo-prophylaxis and tended to report a higher occurrence of deep vein thrombosis. All studies also used universal screening for all patients therefore the figures quoted in Figure 2 are for the occurrence of both symptomatic and asymptomatic thrombosis, with the majority being asymptomatic [32]. A meta-regression using Stata 15.1 using year as the dependent variable was undertaken. It showed that the effect estimates were dependent upon the year of publication of the study. The contemporary studies have generally involved a larger number of patients. The three largest studies to date on this topic [3, 28, 30] accounted for 62% of the patients included in this review. These three studies all failed to show any significant reduction in the occurrence of thrombosis, but did report increased complications with leg ulcers.

Additional concerns related to the evidence base from randomized trials is illustrated in Figure 3. Visual inspection of the funnel plot for the occurrence of deep vein thrombosis demonstrates that potentially smaller studies which showed no benefit for the stockings are absent,

as shown by the missing right-hand side of the funnel. It has been well documented that such small studies with negative findings may not be published. Statistical analysis of this funnel plot gives a high probability that there has been a lack of reporting of such studies. Were such potentially missing and unreported studies identified and included, the results would show no statistical significance for stockings. In summary, this indicates that the analysis of data from Figure 2 is unreliable.

Figure 2 also suggests the effectiveness of anti-embolic stockings may vary for different conditions, potentially being effective after general surgical operations but of no efficacy after stroke. It is possible that the paralysis of the limb after a stroke will reduce the effectiveness of a compression stocking and furthermore the reduced limb sensation may increase the risk of adverse complications.

A further confounding factor within these studies is the length of the stocking used. Both below knee and thigh length anti-embolism stockings can be used, with the majority of studies included in this review using thigh length stockings (Table 1). There is limited evidence to suggest the thigh length stockings may be slightly more effective in comparison to the below the knee stockings. A review of five studies comparing the two types reported a trend to favor of the thigh length stockings although the result was not statistically significant (Odds radio 1.48, 95% confidence interval 0.80-2.71) [33].

There are a number of other significant issues related to anti-embolism stockings. They should not be used or only with caution in those with peripheral vascular disease, peripheral neuropathy, local skin damage or skin irritation, known allergy, major limb deformity or severe leg oedema [2]. The stockings need to be measured to ensure the correct fit and may need to be re-measured with oedema of the leg with post-operative swelling as occurs after arthroplasty surgery [2]. They should be worn both day and night till the patient no longer has significantly reduced mobility. In addition, the stockings may also need to be replaced if they become contaminated.

Over the last 40 years, there have been a number of changes to clinical practice with a recognition of the risks of bed rest and an encouragement of earlier mobilization of patients after surgery or an acute medical event. In addition, there has been greater adoption of routine use of pharmacological chemical thrombo-prophylaxis. These factors in conjunction with the findings of potential flaws from the historical studies, makes the additional use of thrombo-embolic stockings questionable. Other changing practices related to thrombo-embolic complications is the simplified diagnoses of thrombosis with venous ultrasound and treatment of thrombosis with oral direct oral anticoagulants (DOAC's). This means hospital admission and anti-coagulation monitoring is no longer required for the majority of cases [33].

In conclusion the evidence base related to thrombo-embolic stockings is changing and their use in current clinical practice is now questionable. At best, the effectiveness of stockings for reducing the occurrence of venous thrombosis is marginal. Further randomized trials using clinical outcomes for surgical patients with adequate patient numbers are required. Current guidelines on thrombo-prophylaxis may need to re-evaluate their recommendations based on the emerging evidence and changing practices.

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