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Efficacy of intermittent compression devices for thromboembolic prophylaxis in major abdominal surgery: a systematic review and meta-analysis

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Key words
deep vein thrombosis, intermittent pnuematic compression devices, pulmonary embolism, surgery, venous thromboembolism.

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Abstract

Background: The benefits of mechanical prophylaxis for the prevention of venous thromboembolism (VTE) in abdominal and pelvic surgery are uncertain, with different guidelines stating that graduated compression stockings (GCS) and intermittent pneumatic compression devices (IPCDs) can be used either alone or in combination. To review the efficacy of IPCDs in preventing VTE following abdominal and pelvic surgery.

Methods: A systematic review was conducted, identifying relevant literature reporting clinical trials conducted in abdominopelvic surgery, comparing the effect of IPCDs alone or in combination with no prophylaxis, GCS and chemical prophylaxis. The review identified studies reported from 1966 to 2022 in Medline, Embase, PubMed and Cochrane databases for randomized controlled trials.

Results: Thirteen RCTs involving 1914 participants were identified. IPCDs were superior to placebo (OR VTE 0.39; 95% CI 0.20–0.76) but not superior to other forms of prophylaxis (OR 0.83; 95% CI 0.30–2.27) or to GCS alone (OR 0.9; 95% CI 0.24–3.36). The addition of IPCDs to GCS compared with GCS alone was beneficial (OR 0.45; 95% CI 0.23–0.91) as was the addition of IPCDs to standard perioperative chemoprophylaxis (OR 0.25; 95% CI 0.09–0.74). The overall quality and reliability of trials were low, with high risk of bias.

Conclusions: IPCDs are more effective than placebo in reducing VTE rates but are not more effective than other forms of thrombo-prophylaxis (chemical or mechanical) following abdominal and pelvic surgery. There is poor quality evidence to suggest that they might have a role as additional prophylaxis when combined with GCS and chemical prophylaxis.

Introduction

Globally, over 4.2 million people die in the 30 days following surgery, making it the third most frequent cause of death after ischaemic heart disease and stroke.[1] One of the most significant reasons for this post-operative mortality is venous thromboembolism (VTE), a disease that includes deep vein thrombosis (DVT) and pulmonary embolism (PE). It is estimated that 25% of patients suffer from VTE after major abdominal surgery in the absence of prophylaxis.[2] In Australia, symptomatic VTE is a major health problem with an annual incidence of 160 per 100 000 for DVT, 20 per 100 000 for symptomatic non-fatal pulmonary embolism and 50 per 100 000 for fatal autopsy-detected PE.[3]

The key to minimizing post-operative VTE is early mobility and the judicious use of prophylaxis.[2] Recommendations for VTE prophylaxis in surgical patients are risk-based and include a combination of chemical prophylaxis, graduated compression stockings (GCS) and/or intermittent pneumatic compression devices (IPCDs).[3,4] In Australia, clinicians were guided by the 2009 National Health and Medical Research Council (NHMRC) VTE

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guidelines[5] until they were rescinded in 2018 and not replaced, due to limitations in the evidence for VTE prophylaxis. In the absence of clear guidelines, institutions, organizations and Australian states developed their own guidelines based on expert judgement, leading to wide variation in clinical practice.

The Royal Australasian College of Surgeons[3] recommends the routine use of low molecular weight heparin (LMWH) daily for 5–10 days in conjunction with graduated compression devices and/or IPCDs following surgery for all patients:

(1) having intra-abdominal or pelvic surgery
(2) considered as moderate to high risk for VTE
(3) over the age of 40 and
(4) having surgery longer than 45 min

Both the National Institute of Clinical Excellence (NICE)[6,7] and the American College of Chest Physicians[8] allow for more physician and institution freedom with respect to the choice of mechanical prophylaxis. They recommend that those patients undergoing major abdominal surgery, in whom there are no contraindications, should receive chemical prophylaxis, however, mechanical prophylaxis can be either GCS or IPCDs. These recommendations were grade 2C and based on a consensus amongst experts or weak evidence.[8]

Over the past 30 years, IPCDs have been widely marketed. They are large, single use, plastic tubular devices that are placed over the lower limbs. They work by squeezing the calf muscles, thereby improving blood flow from the periphery and preventing venous stasis.[9,10] Several studies, mostly manufacturer-sponsored, have shown these devices to be effective at improving venous flow rates and reducing imaging-detected DVTs. However, there is no evidence that the peak venous velocity produced by a system is a valid measure of medical performance.[11] For patients having surgery and who are at risk of bleeding, IPCDs are known to reduce VTE rates post-operatively,[12,13] but there is uncertainty regarding the clinical benefit when used in conjunction with chemical prophylaxis and/or GCS.

Clinical trials evaluating the use of IPCDs are limited due to small sample size and different populations being analysed together resulting in diverse and inconsistent conclusions. In this meta-analysis we sought to assess the effect of IPCDs on VTE rates following abdominal and pelvic surgery with comparison to (i) no prophylaxis; (ii) chemical prophylaxis alone; or (iii) chemical prophylaxis with GCS.

Methods

Types of studies

In this review, only randomized controlled trials comparing the effect of IPCDs (IPCDs) with no prophylaxis or compared with a combination of either GCS and LMWH or single modalities. Publications were excluded if they were not randomized, included IPCDs in each group, compared different compression devices, were not published in a peer review journal or did not have the primary outcome of VTE. The diagnostic measures included were ascending venography, 125 I-fibrinogen uptake test, Ultrasound Doppler, CT pulmonary angiography or autopsy. Studies using D-dimer solely, thermographic methods or other isotopic methods, or clinical methods alone were excluded.

Types of participants

Patients 18 years or over undergoing major abdominal surgery, including general surgical, gynaecological and urological patients. Major surgery was defined as any invasive operative procedure in which a more extensive resection is performed, for example, a body cavity is entered, organs are removed or normal anatomy is altered.[14]

Types of outcome measures

The review outcomes were DVT and/or pulmonary embolism (PE) evaluated within an appropriate post-operative time (30 days for DVT and 90 days for PE), including fatal PE identified at autopsy. Ideally, the outcomes measures should have been performed by blinded technicians (assessor-blinding).

Study selection and quality

Two reviewers (NL and FR) searched the following electronic databases; Medline, Cochrane controlled register, PubMed and Embase. Details of the search strategy are reported in the Data S1. The search results were saved in Endnote reference manager software (Clarivate, version 9) and then uploaded to Covidence systematic review software (Veritas Health Innovation, Melbourne, Australia) after duplicates were removed.

All titles and abstracts from the database search (COVIDENCE) were independently screened against the inclusion criteria. Disparity was discussed and referred to a third party (PR) for resolution. After identifying suitable trials, both reviewers (NL and FR) independently extracted trial characteristics and outcomes from each article using a pre-designed data extraction spreadsheet. The reviewers also independently performed quality assessment of each article, including; sequence generation, allocation concealment, blinding of participants, personnel and blinding of outcome assessors for all outcomes, incomplete outcome data, selective outcome reporting, and other sources of bias. The grading for each of the trials followed the Cochrane approach: High risk, Low risk or Unclear. The authors of articles deemed unclear were contacted but none responded.

Statistical analysis

The primary outcomes for this review and meta-analysis were VTE; either DVT or PE. A random effects model using the DerSimonian-Laird estimator was used to estimate the pooled effect of IPCDs on VTE occurrence compared with active and placebo controls. A fixed effects model was used to estimate the pooled effect of IPCDs on DVT occurrence. A continuity correction was applied, i.e. where 0 events were seen, a value of 0.5 was used to avoid extreme confidence intervals or lack of model fitting. The odds ratios along with the 95% CIs were reported. Publication bias was examined using funnel plots and the trim and fill method.[15–18] The significance of the duration of wearing

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the IPCDs amongst the randomized controlled trials (RCTs) was unable to be performed by meta-regression due to insufficient information.

Results

Characteristics of the included trials

The initial electronic search identified 2507 potential studies (Fig. 1 (PRISMA diagram)). Of these, 93 were duplicates and removed. The remaining 2414 articles were then screened by title and abstract. A total of 2362 were excluded leaving 52 studies for full-text review. A further 31 articles were excluded for the following reasons: incorrect outcomes, wrong study design including systematic review or meta-analysis; not in English; ineligible intervention; ineligible comparators; full text not available; incomplete study or abstract only. Of the 21 trials identified from the literature and evaluated in detail, a further eight studies were excluded due to IPCDs being in both the intervention and the control group.

Description of studies

The final set of studies meeting the inclusion criteria were 13 trials[19–31] (Fig. S2) from eight countries involving a total of 2157 patients that underwent general, gynaecological or urological surgery (Table 1).

There were five papers in abdominal surgery[19–23] and six studies in gynaecological oncology.[24–29] The remaining two involved patients undergoing urological procedures.[30,31]

Results

Intermittent pneumatic compression devices versus placebo

In total, five studies compared IPCDs to placebo; 264 versus 280, respectively.[19,20,22,24,27] IPCDs were more effective than no prophylaxis in reducing VTE: OR 0.39 (0.20, 0.76) (Fig. 2). There was low heterogeneity amongst these studies, with an I-squared of 33.5% ($P = 0.1978$).

Intermittent pneumatic compression devices versus other interventions

Nine studies compared IPCDs to another intervention (GCS or chemical prophylaxis); 697 versus 722, respectively.[21–23,25,26,28–31] IPCDs were no more effective than other interventions in reducing VTE: OR 0.83 (0.30, 2.27) (Fig. 3).

Three studies compared IPCDs against LMWH; 273 versus 278, respectively.[26,28,29] IPCDs were no more effective than LMWH in reducing VTE: OR 1.40 (0.56, 3.49) (Fig. 4).

Four studies compared IPCDs against heparin; 204 versus 224 respectively.[21,22,25,31] IPCDs were no more effective than heparin in reducing VTE: OR 1.49 (0.64, 3.50) (Fig. 5).

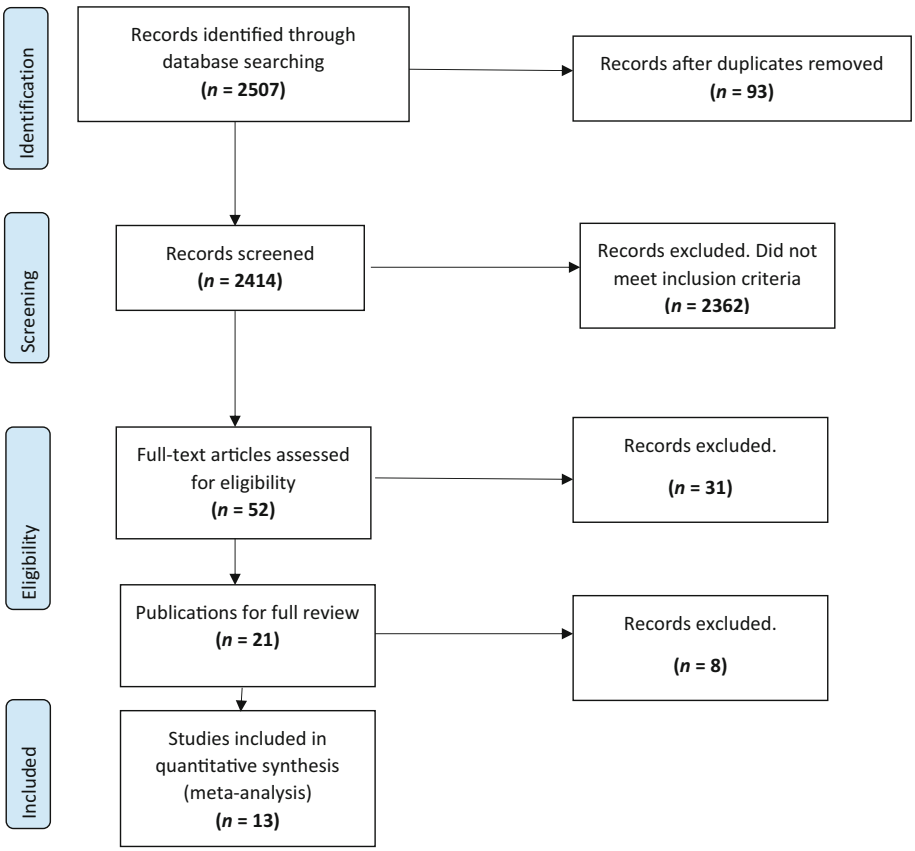

Fig. 1. PRISMA flow diagram.

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Table 1 General characteristics of included trials

Study	Location of study	Population	No of patients	Intervention	Control group	Patient setting IPCDs†	Control
Butson *et al.*, 1981	Canada	General abdominal surgery	119	62	57	IPCDs	No prophylaxis
Clark-Pearson *et al.*, 1984	USA	Gynaecological malignancy Surgery	107	55	52	IPCDs	No prophylaxis
Clark-Pearson *et al.*, 1993	USA	Gynaecological malignancy surgery	208	101	107	IPCDs	Heparin
Gao *et al.*, 2012	China	Gynaecological surgery	108	52	56	IPCDS + GCS	GCS‡
Hills *et al.*, 1972	UK	General abdominal surgery	140	70	70	IPCDs	No prophylaxis
Kosir *et al.*, 1996	USA	General abdominal surgery	108	25 38	45	IPCDs	No Prophylaxis Heparin
Maxwell *et al.*, 2001	USA	Gynaecological malignancy surgery	111	106	105	IPCDs	LMWH§
Mellbring *et al.*, 1986	Sweden	Major abdominal surgery	108	54	54	IPCDs	Heparin
Hansberry *et al.*, 1991	USA	urologic surgery	49	24 24	25 25	IPCDs + GCS IPCDs	Heparin GCS
Nagata *et al.*, 2015	Japan	Gynaecological Surgery	30			IPCDs	LMWH
Sang *et al.*, 201	China	Gynaecology surgery malignant or benign	625	153 156	153 157	IPCDs + GCS IPCDs + LMWH + GCS	GCS LMWH + GCS
Van Arsdalen *et al.*, 1983	USA	urologic surgery	37	16	21	IPCDs	GCS
Lobastov *et al.*, 2021	Russia	High risk abdominal	407	39	61	IPCDs + LMWH + GCS	LMWH + GCS

†IPCDs, intermittent pneumatic compression devices.

‡GCS, graduation compression stockings.

§LMWH, low molecular weight heparin.

Two studies compared IPCDs against GCS; 40 versus 46, respectively.[30,31] IPCDs were no more effective than GCS in reducing VTE: OR 0.90 (0.24, 3.36) (Fig. 6).

Incremental benefit of IPCDs

Two studies compared IPCDs and GCS against GCS; 205 versus 215, respectively References 27 and 29. The combination of IPCDs and GCS was more effective than GCS alone in reducing VTE: OR 0.45 (0.23, 0.91) (Fig. 7).

Two studies compared IPCDs, LMWH and GCS against LMWH and GCS; 360 versus 360 respectively.[23 and 29] Combinations of IPCDs, LMWH and GCS were more effective than LMWH and GCS in reducing VTE: OR 0.25 (0.09, 0.74) (Fig. 8).

Assessment of risk of bias in included studies

Risk of bias was assessed using version 2 of the Cochrane risk of bias tool for randomized trials (RoB 2).[32] Every study had at least one domain with high risk of bias, i.e. not a single study rated as having low risk of bias overall (Table 2). The high risk of bias is mainly due to the nature of the study; unable to blind participants and practitioners (Table S3). Many biases were present across the studies (Table S4), but most importantly, there are 6 of 13 that have

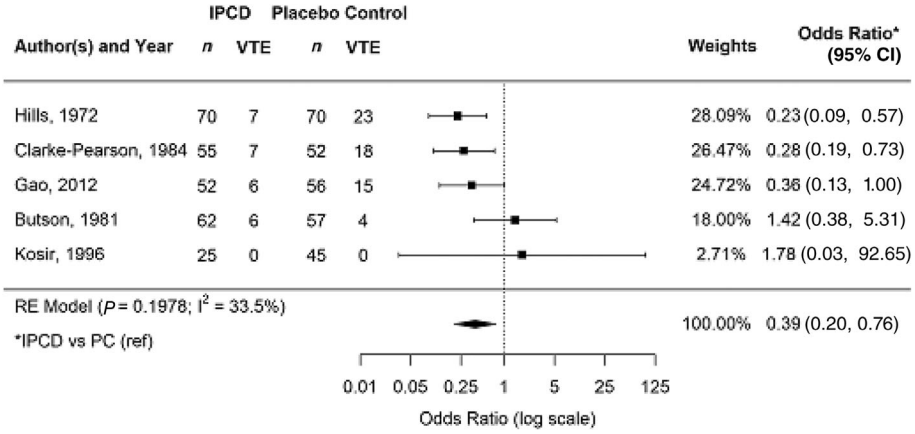

Fig. 2. Intermittent pneumatic compression devices *vs*. placebo (no active comparator).

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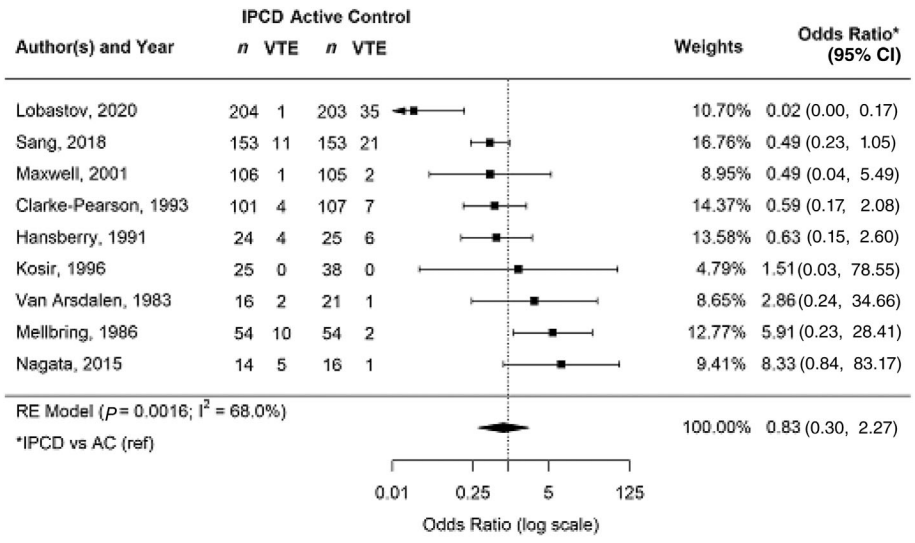

Fig. 3. Intermittent pneumatic compression devices versus active control.

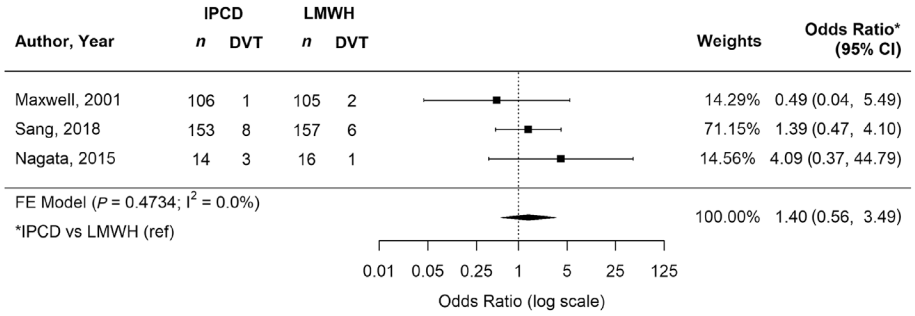

Fig. 4. Intermittent pneumatic compression devices versus low molecular weight heparin (LMWH).

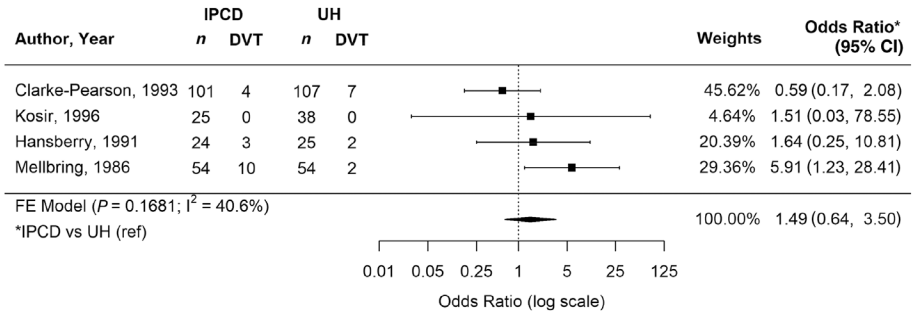

Fig. 5. Intermittent pneumatic compression devices versus unfractionated heparin.

high risk due to incomplete data and all but one has high-risk for other biases due to very small sample sizes.

Discussion

The aim of this systematic review was to determine the efficacy of IPCDs in the prevention VTE following abdominal and pelvic surgery. The findings suggest that IPCDs are more effective than placebo at preventing VTE, but no more effective than other forms of prophylaxis. This review also found that the efficacy of IPCDs improves when used in combination with other modalities.

There are some caveats with these conclusions, however. Only 4 of the 13 RCTs in this paper were published in the last 20 years. Many of the papers are of low quality while 10 of the 13 RCTs contained less than 200 participants. Despite this, there are some robust conclusions that can be drawn from the data. IPCDs are effective at preventing VTE in patients having abdominal and pelvic surgery, despite the small number of trials (and participants) comparing IPCDs to placebo. However, the outcomes are in keeping with other trials performed in different disciplines of surgery particularly orthopaedics and neurosurgery, with published guidelines for VTE prophylaxis.[6,12,13,33–37] With this in mind, IPCDs should be used for the surgical patient in which chemical prophylaxis may be contraindicated (usually due to the risk of haemorrhage) (Table 3).

Determining which of the two main forms of mechanical prophylaxis (IPCDs or GCS) is superior in preventing VTE, for the average patient undergoing abdominal or pelvic surgery, is more

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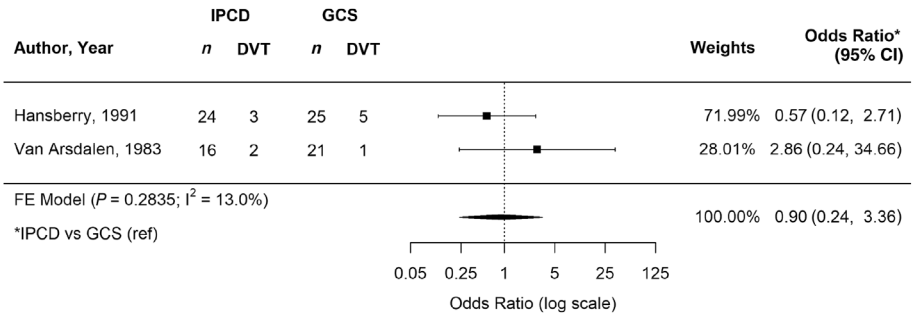

Fig. 6. Intermittent pneumatic compression devices versus graduated compression stockings.

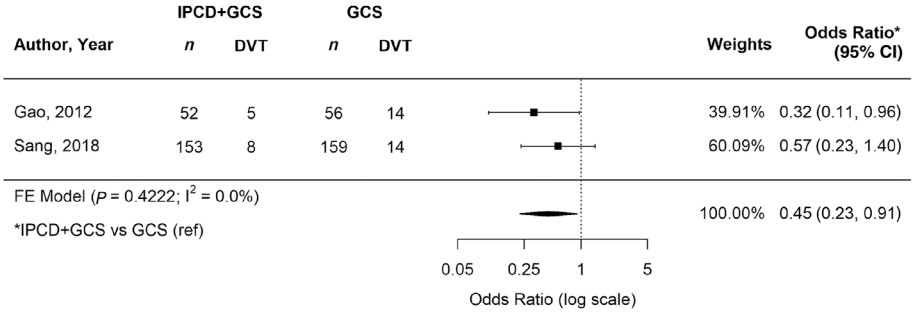

Fig. 7. Intermittent pneumatic compression devices + graduated compression stockings + versus graduated compression stockings.

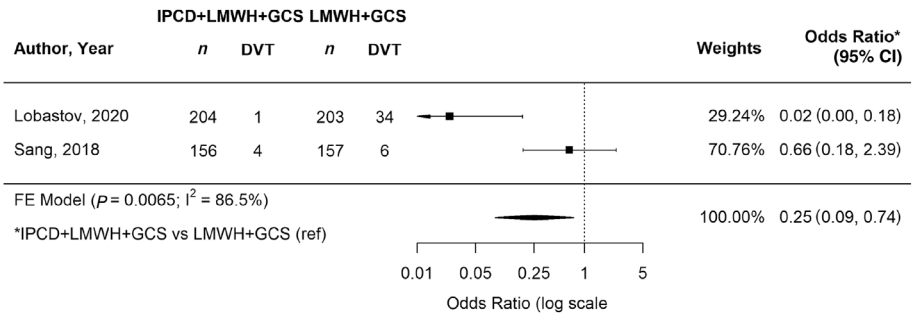

Fig. 8. Intermittent pneumatic compression devices + graduated compression stockings + LMWH versus LMWH + graduated compression stockings.

difficult. The data from this review suggests that there is no difference between the two, but the evidence is weak and of low quality. The wide confidence intervals seen in the direct comparison of IPCDs and GCS are consistent with the limited evidence available, (only two RCTs involving 86 participants to guide our practice). Clearly more work is required in this area, and this has led to the slightly inconsistent recommendations for these patients. The NICE guidelines (UK) state that anticoagulant medication plus *either* GCS *or* IPCDs should be used during and following abdominal and pelvic surgery.[6,7] The Royal Australasian College of Surgeons guidelines differ slightly, recommending that GCS and/or IPCDs be used for this group of patients.[3] Given the additional cost and potential waste associated with IPCDs in comparison to GCS, coupled with evidence suggesting low compliance with IPCDs[38] and their hindrance to patient mobility, there would seem to be a cogent argument, in line with enhanced recovery after surgery (ERAS) principles, in favour of GCS if only one form of mechanical prophylaxis could be employed.

The more recent studies published on IPCDs have tended to concentrate on whether the additional use of this form of mechanical prophylaxis is beneficial when other forms of prophylaxis are employed. It could be said that standard practice for this group of patients is to employ chemical prophylaxis.[3–8] However, combined chemical and mechanical prophylaxis could also be considered standard.[3–8] The latest Cochrane review on the combined use of IPCDs and chemical prophylaxis suggests superiority of the combination over IPCDs alone for DVT prevention and superiority of combination versus chemical alone for PE prevention. The majority of studies in the Cochrane review were performed on different patient cohorts to this systematic review, namely orthopaedic and neurosurgical patients. Two RCTs in this review ($n = 720$) did look at the benefit of IPCDs additional to combined chemical and GCS prophylaxis.[23,29] Although the two studies had conflicting results, the overall data seems to suggest a benefit from combining all three forms of therapy, driven by the result of the larger study ($n = 407$) that concentrated on very high-risk patients (Caprini score > 11) and had a high rate of VTE (16.7%) and mortality (4.9%) in the control group. This would suggest that the addition of IPCDs might provide more benefit with a higher background risk of VTE but may not necessarily be generalizable to the whole cohort of abdominopelvic surgery. The Cochrane review on extended thromboprophylaxis with LMWH for abdominal and pelvic surgery

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Table 2 Assessment of bias

RCT	Sequence generation	Allocation concealment	Blinding of participants and personnel	Blinding of outcome assessment	Incomplete outcome data	Selective outcome reporting	Other bias
Hills 1972	Low risk of bias	Low risk of bias	High risk of bias	Unclear risk of bias	Low risk of bias	Low risk of bias	High risk of bias
Butson 1981	Low risk of bias	Low risk of bias	High risk of bias	Unclear risk of bias	High risk of bias	Low risk of bias	High risk of bias
Van Arsdalen 1983	Low risk of bias	Unclear risk of bias	High risk of bias	High risk of bias	High risk of bias	Low risk of bias	High risk of bias
Clark-Pearson 1984	Low risk of bias	Low risk of bias	High risk of bias	High risk of bias	High risk of bias	Low risk of bias	High risk of bias
Mellbring 1986	Low risk of bias	Low risk of bias	High risk of bias	Unclear risk of bias	High risk of bias	Low risk of bias	High risk of bias
Hansberry 1991	Unclear risk of bias	Unclear risk of bias	High risk of bias	Unclear risk of bias	High risk of bias	Low risk of bias	High risk of bias
Clark-Pearson 1993	Low risk of bias	Unclear risk of bias	High risk of bias	Unclear risk of bias	High risk of bias	Low risk of bias	High risk of bias
Kosir 1996	Unclear risk of bias	Unclear risk of bias	High risk of bias	Low risk of bias	Low risk of bias	Unclear risk of bias	High risk of bias
Maxwell 2001	Low risk of bias	Low risk of bias	Unclear risk of bias	High risk of bias	Low risk of bias	Low risk of bias	High risk of bias
Gao 2012	Low risk of bias	Unclear risk of bias	High risk of bias	Unclear risk of bias	Low risk of bias	Low risk of bias	High risk of bias
Nagata 2015	Low risk of bias	Low risk of bias	High risk of bias	Low risk of bias	Low risk of bias	Low risk of bias	High risk of bias
Sang 2018	Low risk of bias	Unclear risk of bias	High risk of bias	Unclear risk of bias	Low risk of bias	Low risk of bias	Low risk of bias
Lobastov 2021	Low risk of bias	Low risk of bias	Unclear risk of bias	Low risk of bias	Low risk of bias	Low risk of bias	High risk of bias

suggested a reduction in symptomatic VTE from 1% to 0.1% with extended LMWH therapy.[39] Adherence to extended LMWH prophylaxis in higher-risk patients may therefore render the use of IPCDs clinically irrelevant despite potential efficacy.

Enhanced recovery after surgery (ERAS) programs have changed many aspects of perioperative care following major abdominopelvic surgery and one of the key ingredients of ERAS is early mobilization. Early mobilization and ambulation as a strategy to prevent DVT is founded on the fact that immobilized patients are at high risk for DVT and PE.[40] This exposes two inherent shortcomings with the interpretation of this meta-analysis of IPCDs. The first and most obvious is that using IPCDs in the post-operative setting, prevents mobility. There are no intermittent compression devices currently that allow for mobilization without being disconnected, posing a challenge for the post-operative patient. The second issue is that only three RCTs in this meta-analysis References 23,26,29 employed ERAS in practice. This means the historical control groups in this meta-analysis are different to the ERAS era cohort that currently undergoes abdominal or pelvic surgery, potentially with a lower risk of VTE.

Although it was beyond the scope of this current review, none of the included studies looked at the aspect of cost and waste. In the

Table 3 Summary of VTE events

	No. of patients	No. studies	Control	Treatment	OR (95%)
Abdo/URO/GYN	407	1	5	0	0.09 (0, 1.61)
Abdominal	119	1	1	0	0.3 (0.01, 7.55)
Gynaecology	1446	6	11	10	1.08 (0.44, 2.64)
Urology	111	2	2	1	1.11 (0.14, 8.93)
DVT					
Abdo/URO/GYN	407	1	34	1	0.02 (0, 0.18)
Abdominal	421	3	27	23	0.57 (0.24, 1.35)
Gynaecology	1446	6	67	30	0.5 (0.32, 0.8)
Urology	111	2	8	5	1.18 (0.34, 4.14)
VTE					
Abdo/URO/GYN	407	1	35	1	0.02 (0, 0.17)
Abdominal	281	2	5	16	1.23 (0.37, 4.03)
Gynaecology	1446	6	78	39	0.55 (0.36, 0.84)
Urology	111	2	10	6	1.16 (0.37, 3.66)

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current clinical environment, the issue of general, and particularly plastic, waste needs to be considered.[41] IPCDs, being single-use plastic items, comes with considerable waste and cost to the health care system and society in general. While future studies need to address the clinical implications of VTE reduction they also need to address the relative benefits of any reduction with respect to cost and waste.

Future research should also focus on clinically appropriate endpoints, not surrogate ones. It appears easy, based on the studies in this review, to demonstrate with relatively small patient numbers, apparent differences in imaging or blood test results. Larger patient numbers would clearly be needed in future studies using relevant clinical outcomes.

Conclusion

IPCDs appear to be efficacious in preventing VTE formation. Their comparative efficacy with respect to other forms of thromboprophylaxis appears limited and is poorly studied. Their additional efficacy when used in combination with chemical prophylaxis is also limited although there may be a role for their use as additional therapy in the high-risk patient according to one RCT.

Clearly, more research is required to determine their role, when chemical prophylaxis is employed adequately, given their single-use patient application with respect to cost and plastic waste. A large multi-centre trial is required in order to evaluate their efficacy in the modern surgical era.

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Conflict of interest

None declared.

Author contributions

Natalie Lott: Conceptualization; data curation; formal analysis; investigation; methodology; visualization; writing – original draft; writing – review and editing. **Felicity Robb:** Data curation; methodology; visualization; writing – review and editing. **Erin Nolan:** Formal analysis; visualization; writing – review and editing. **John Attia:** Formal analysis; methodology; writing – review and editing. **Penny Reeves:** Supervision; writing – review and editing. **Jon Gani:** Supervision; writing – review and editing. **Stephen Smith:** Conceptualization; methodology; supervision; validation; writing – review and editing.

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Supporting information

Additional Supporting Information may be found in the online version of this article at the publisher's web-site:

Table S1 MESH terms in Medline (Main search)
Table S2. Characteristics of the studies of the effects of intermittent pneumatic compression devices and the risk of VTE
Table S3. Assessment of risk of bias
Table S4. Risk of bias summary: review author's judgements about each risk of bias item for each included study.
Figure S1. Funnel plot intermittent pneumatic compression devices *vs*. active control
Figure S2. Funnel plot intermittent pneumatic compression devices *vs*. Placebo

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