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Is it necessary to wear compression stockings and how long should they be worn for preventing post thrombotic syndrome? A meta-analysis of randomized controlled trials

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ABSTRACT

Background: Post thrombotic syndrome (PTS) is a serious complication of deep venous thrombosis (DVT). There were always debates on the efficacy of elastic compression stockings (ECS) in prevention for post thrombotic syndrome.
Objective: To assess effects of elastic compression stockings and ECS's wearing time on post thrombotic syndrome after diagnosis of deep venous thrombosis.
Methods: PubMed, Cochrane Library, Embase, Web of Science were last searched on 23 November 2022 for studies assessing effects of elastic compression stockings or theirs wearing time on post thrombotic syndrome after diagnosis of deep venous thrombosis.
Results: 9 randomized controlled trials were included. Wearing elastic compression stockings was associated with a statistically reduction in the overall post thrombotic syndrome rate (RR 0.73, 95 % CI 0.53 to 1.00; $P = 0.05$; $I^2 = 82$ %). No significant difference in severe post thrombotic syndrome rate, recurrent deep venous thrombosis rate, and death rate was seen whether wearing elastic compression stockings or not. The pooled effect of studies comparing different wearing time of elastic compression stockings showed no significant difference in post thrombotic syndrome rate, severe and moderate post thrombotic syndrome rate, recurrent deep venous thrombosis syndrome rate and death rate.
Conclusions: Wearing ECS can reduce the risk of developing PTS after DVT and a wearing time of less than or equal to 1 year is comparable to 2 years wearing. The results support ECS's role as a foundation therapy for preventing PTS.

1. Introduction

Venous thromboembolism (VTE) is the third most common cardiovascular disorder, with two thirds of all cases presenting with deep venous thrombosis (DVT) [1]. Post thrombotic syndrome (PTS) is a form of chronic venous insufficiency secondary to prior DVT, and half of the patients are expected to suffer from PTS within the first 1–2 years [2,3]. Though not lethal, no effective treatment has yet been developed for established PTS, and this syndrome can significantly impact the function and quality of life of patients, with adverse effects comparable to chronic diabetes mellitus, osteoarthritis or chronic lung diseases [4–6]. Thus, there is an urgent need to find effective measures to prevent PTS for patients after DVT.

The current-available prevention methods for PTS mainly include anticoagulation, elastic compression stockings (ECS) therapy, physical exercise, and thrombolysis [7]. Owing to safety and convenience reasons, ECS plays an important role in preventing PTS. However, whether the routine use of ECS can effectively prevent PTS after DVT is still controversial [8–12], and the recent guidelines also held different opinions on this issue [13–15]. Moreover, considering that ECS may cause discomfort to the patients in their daily life, the optimal wearing duration of ECS is also a widespread concern [16–18].

Abbreviations: PTS, post thrombotic syndrome; DVT, deep venous thrombosis; ECS, elastic compression stockings.

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The primary objective of this meta-analysis was to compare the overall PTS rate, moderate and severe PTS rate between patients wearing ECS routinely and those not wearing or wearing placebo, as well as to compare the PTS rate between patients wearing ECS for different durations after DVT. The secondary objective was to compare the recurrent rate of DVT and death rate between patients wearing ECS and those not wearing or wearing placebo.

2. Methods

This meta-analysis was performed according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines [19]. The study protocol was registered on PROSPERO (CRD42022381162).

2.1. Search strategy and selection criteria

The electronic databases of PubMed, Cochrane Library, Embase, and Web of Science were searched from inception to 23 November 2022. According to the search strategy listed in the Appendix. The references from review articles and major texts were also reviewed to include additional studies. After removing duplicate articles, four reviewers (JHM, WJL, YFX, HT), who were paired into two teams, independently screened the titles and abstracts of preliminarily-retrieved studies. The inclusion criteria were: (1) studies comparing between patients wearing ECS and those not wearing or wearing placebo, and/or comparing between patients wearing ECS for different durations; (2) studies in which the PTS was diagnosed by Villata scale, Ginsberg measure, Brandjes scale, CEAP (clinical, etiological, anatomic, pathophysiological) classification, Venous Clinical Severity Score (VCSS) or Widmer Scale [20]; (3) studies reporting the incidence rate of PTS; and (4) studies that are RCTs. The exclusion criteria were: (1) studies focusing on non-DVT patients; (2) studies that used distal DVT ECS for the prevention of DVT; or (3) studies focusing on patients wearing ECS after the diagnosis of PTS. Disagreement on the eligibility of any full-text articles was resolved by discussing with a senior author (SGG).

2.2. Data extraction

The two teams of reviewers, independently extracted the desired data from the included studies using a standardized form, including: first author, year of publication, country, number of included patients, participant characteristics, initiation of wearing ECS after DVT, ECS characteristics, comparison groups, PTS definition, compliance, mean follow-up, and incidence of aimed outcome. If any data was missing, we would contact the corresponding authors to request for the original information as far as possible; if failed, the values would be extracted from figures using Plot Digitizer. Disagreements, if any, were resolved through discussion.

2.3. Quality assessment

The two teams of reviewers were then independently assessed the risk of bias of the included studies using the Cochrane Collaboration's risk of Bias Tool [21] based on seven domains (random sequence generation, allocation concealment, blinding of participants and personnel, blinding of outcome assessment, incomplete outcome data, selective reporting, and other bias). For each domain, the studies were rated as low, unclear, or high risk of bias, as appropriate. Discrepancies, if any, were resolved by consensus or by discussing with a senior author (SGG).

2.4. Statistical analysis

The outcome of this study was the PTS rate, recurrent DVT, and death rate, which was extracted in the form of a dichotomous variable as an absolute number and patient number. The outcome was pooled by the Mantel-Haenszel method, and was presented as a risk ratio with 95 % confidence interval. The I^2 statistic was used to assess the statistical heterogeneity between studies. When I^2 was below 50 %, the level of heterogeneity was judged acceptable and fixed effects models were chosen for analysis; otherwise, random effects models were used. All analyses were performed using Review Manager (RevMan, version 5.4).

3. Results

3.1. Literature search

Fig. 1 shows the flow chart of literature search and study selection. After screening the titles and abstracts of preliminary-retrieved articles, 2059 studies were excluded. Then, 29 studies were reviewed by full text and 20 of them were eliminated based on the inclusion and exclusion criteria. Eventually, a total of 9 RCTs [3,17,18,22–27] were included in our final analyses.

3.2. Baseline study characteristics

Of the 9 RCTs included, there were 7 studies [3,22–27] that compared between patients wearing ECS and those not wearing or wearing placebo, involving a total of 1694 subjects (852 wearing ECS and 842 not wearing or wearing placebo). There were two studies [17,18] that compared between patients wearing ECS for different durations, involving a total of 1383 subjects (699 wearing ECS for 2 years and 684 wearing for less than or equal to 1 year). The baseline characteristics of the included RCTs are presented in Table 1. The types of ECS used in all studies were at knee height. In the two studies [22,23], the patients initiated the use of ECS at 6 or 12 months after the diagnosis of DVT. All studies reported the overall PTS rate, while 6 of them also reported the severe PTS rate.

3.3. Quality assessment

There were 3 studies [18,22,24] rated as a high risk of bias. Only the SOX trial [25] had no identified bias. Unclear bias was mainly related to the blinding of patients, except for studies [23,25] in which the patients wore placebo stockings. The detailed distribution of bias is shown in Fig. 2.

3.4. Primary outcome

3.4.1. Overall PTS rate, moderate and severe PTS rate

In the studies [3,22–27] that compared between patients wearing ECS and those not wearing or wearing placebo, the overall pooled effect showed that the use of ECS was associated with a statistically significant reduction in the overall PTS rate (RR 0.73, 95 % CI 0.53 to 1.00; $P = 0.05$; $I^2 = 82$ %) (Fig. 3A). Then, a further analysis was performed on high-quality studies [3,25–27] only. Of the 7 studies, two [22,24] were excluded for high risk of bias and one [23] was excluded for unknown randomization and concealment. The pooled effect of the remaining 4 studies still indicated a statistically significant reduction in the overall PTS rate (RR 0.66, 95 % CI 0.44 to 0.99; $P = 0.05$; $I^2 = 88$ %) (Fig. 3B). There were 4 studies [3,25–27] that reported the severe PTS rate and the pooled effect indicated t no statistically significant difference (RR 0.61, 95 % CI 0.29 to 1.31; $P = 0.21$; $I^2 = 62$ %) (Fig. 3C). Then, a further analysis was performed on the moderate PTS rate in these 4 studies [3,25–27] and the pooled effect showed that there was no statistically significant difference either (RR 1.03, 95 % CI 0.98 to 1.09; $P = 0.21$; $I^2 = 71$ %) (Fig. 3D).

In the two studies [17,18] that compared between patients wearing ECS for different durations, the overall pooled effect showed that there was no statistically significant reduction in both the overall PTS rate (RR 1.18, 95 % CI 0.75 to 1.85; P = 0.48; $I^2 = 76$ %) (Fig. 4A) and the severe PTS rate (RR 1.66, 95 % CI 0.64 to 4.31; P = 0.30; $I^2 = 6$ %) (Fig. 4B),

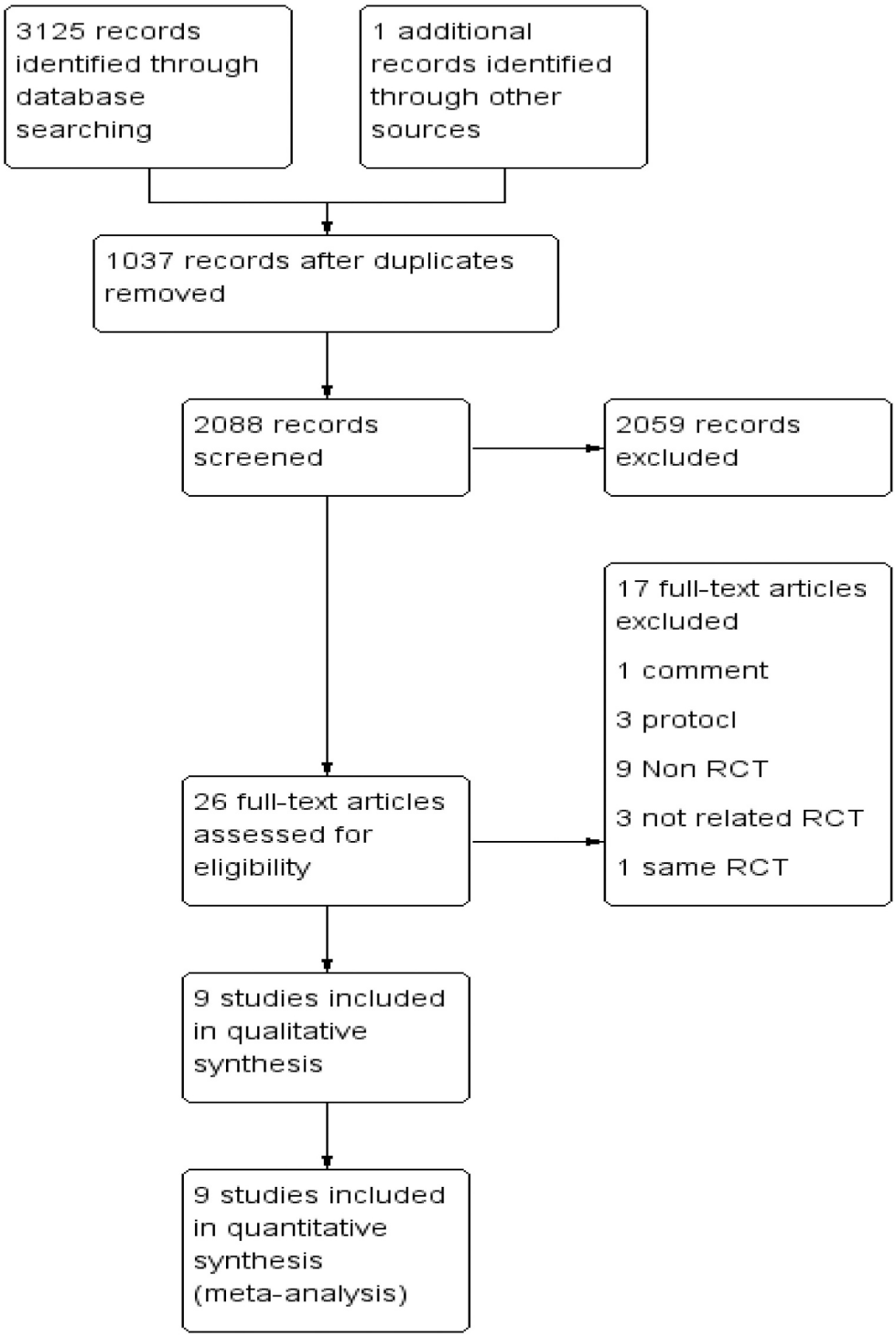

Fig. 1. Flow chart of literature retrieval.

and the moderate PTS rate (RR 1.16, 95 % CI 0.66 to 2.03; P = 0.61; I^2 = 83 %) (Fig. 4C).

3.5. Secondary outcome

3.5.1. Recurrent DVT rate and death rate

There were 4 studies [3,25–27] that reported the recurrent DVT rate and the pooled effect indicated no statistically significant difference (RR 0.95, 95 % CI 0.65 to 1.41; *P* = 0.81; I^2 = 0 %) (Fig. 5A). There were 6 studies [3,22,23,25–27] that reported the death rate during follow-up and no statistically significant difference was identified either (RR 0.99, 95 % CI 0.72 to 1.35; *P* = 0.93; I^2 = 0 %) (Fig. 5B).

4. Discussion

Our findings suggested that the use of ECS could significantly reduce the risk of PTS for patients after DVT but had no advantage in reducing the recurrent DVT rate and death rate. We also found that the outcome of wearing ECS for 2 years was comparable to that of wearing for less than or equal to 1 year in terms of the risk of PTS.

Table 1
Study characteristic.

Study	Country	Patient number		Mean (SD or range) age, years		Sex (female/male)		Initiation of ECS after DVT	Characteristic of ECS	Comparison group	PTS definition	Compliance	Mean (SD or range) follow-up	Incidence rate		
		Intervention	Control	Intervention	Control	Intervention	Control							Total	Intervention	Control
Randomized controlled trials about ECS versus none ECS																
Aschwanden 2008	Switzerland	84	85	64·1 (52·9–72·5)	63·8 (45·3–70·8)	30/54	40/45	6 months	Knee high, 26–36 mm Hg	No stockings	Skin changes/ CEAP	91·60 %	3·2 (2 months–6·8 years) years in ESC group 2·9 (1·5 months–7·0 years) years in None ESC group	16.57 %	13.10 %	20.00 %
Brandjes 1997	Netherlands	96	98	60 (17)	59 (17)	42/54	44/55	2–3 weeks	Knee high, 30 mm Hg	No stockings	Villalta	76 %	76 (60–96) months in both groups	51.03 %	31.25 %	70.41 %
Ginsberg2001	Canada	24	23	62·0 (33–78)	60·5 (24–87)	10/14	11/12	1 year	Knee high, 20–30 mm Hg	Placebo stockings	Ginsberg	NA	55·0 (2·0–97·3) months in ESC group 59·1 (18·3–97·2) months in None ESC group	2.13 %	0.00 %	4.35 %
Jayaraj 2015	USA	36	33	48 (14)	47 (16)	18/18	16/17	2 days	Below knee, 30–40 mm Hg	No stockings	Villata	60 %	24 months in both groups	75.36 %	80.56 %	69.70 %
Kahn 2014	Canada	409	394	54·3 (15·3)	54·8 (15·8)	154/255	166/ 228	2 weeks	Knee high, 20–40 mm Hg	Placebo stockings	Villata/ Ginsberg	62 %	24 months in both groups	42.84 %	43.03 %	42.64 %
Prandoni2004	Italy	90	90	60·1 (18·5)	63·0 (18·9)	48/42	55/35	7 days	Below knee, 30–40 mm Hg	No stockings	Villalta	87 %	24 months in both groups	37.22 %	25.56 %	48.89 %
Yang 2021	China	113	119	60·6 (12·0)	57·8 (14·1)	65/48	67/52	Within 28 days	Knee high, 30–40 mm Hg	No stockings	Villalta	94 %	24 months in both groups	43.53 %	37.17 %	49.58 %
Randomized controlled trials about different wearing time of ECS																
Mol 2016	Netherlands	262	256	57 (14)	56 (14)	104/152	107/ 155	NA	Knee high, 34–46 mm Hg, 1 year wearing	Same type, 2 years wearing	Villata	NA	24 months in both groups	16.41 %	19.92 %	12.98 %
Cate-Hoek 2018	Netherlands	437	428	56·3 (15·7)	58·1 (14·6)	177/251	184/ 253	Within 24 h	Knee high, 30–40 mm Hg, 6 months wearing	Same type, 2 years wearing	Villata	NA	24 months in both groups	28.09 %	27.57 %	28.60 %

In randomized controlled trials about ECS versus none ECS, intervention group wear ECS and control group wear placebo or no stockings. In randomized controlled trials about different wearing time of ECS, intervention group wear less than or equal to 1 year compression stockings and control group wear 2 years compression stockings. ECS, elastic compression stockings; NA, not addressed.

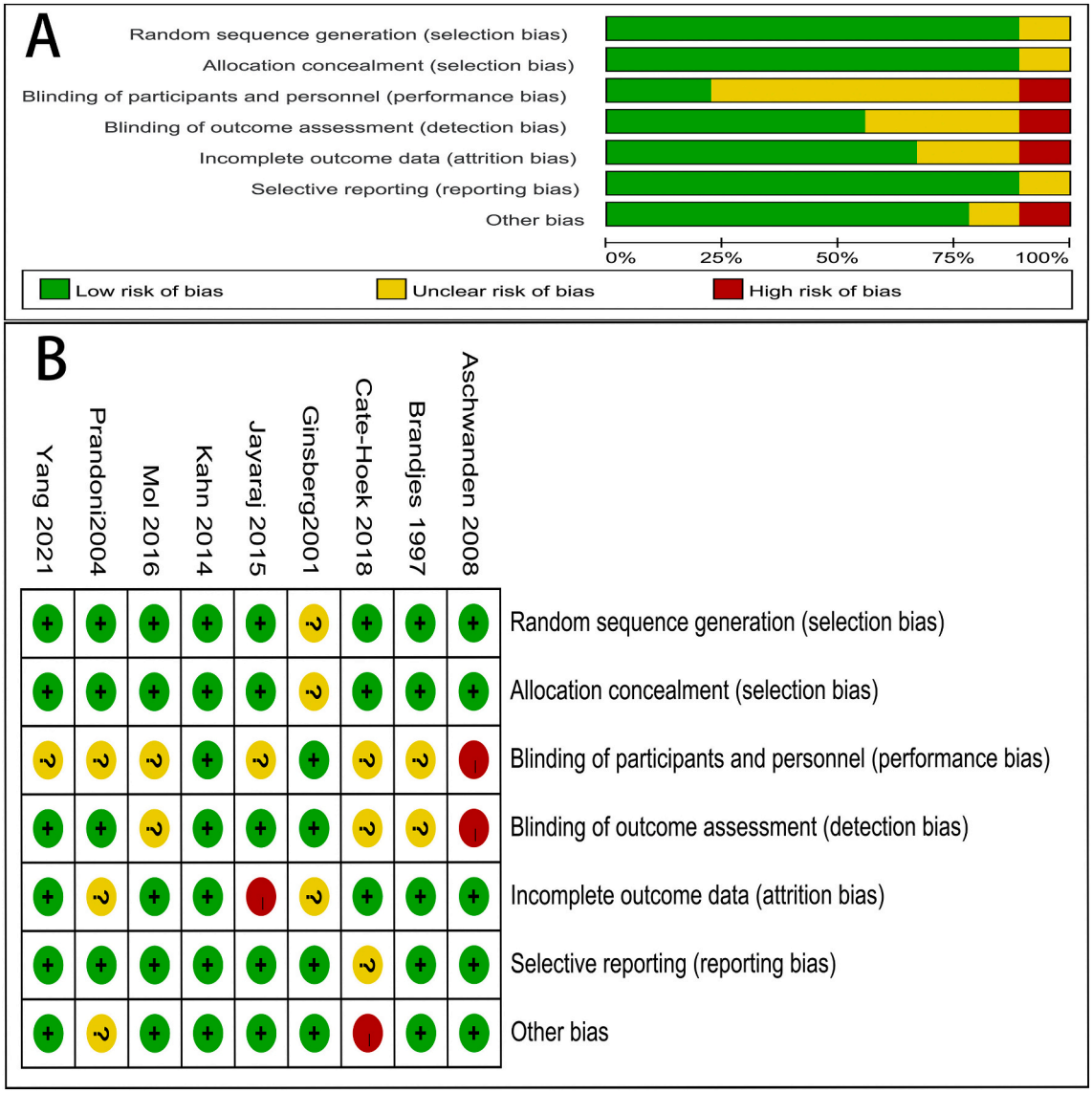

Fig. 2. Graph of the risk of bias for the included RCTs (A); Graph of the risk of bias summary for the included RCTs (B).

In 2016, Subbiah et al. [28] conducted a similar meta-analysis, which suggested that the use of ECS could not significantly reduce the risk of developing PTS in patients with DVT. Though their analysis was rigorous, recent studies have continued to investigate the effectiveness of ECS in preventing PTS. By including the latest published articles, our pooled results seemed to support that ECS could effectively reduce the incidence of PTS.

The SOX trial [25] played an important role in establishing the current guidelines issued by the American College of Chest Physicians (ACCP) [15], the American Society of Hematology (ASH) [14], and the European Society for Vascular Surgery (ESVS) [13], which are all against the routine use of ECS. The SOX is a rigorous trial, especially for its use of placebo stockings, which can effectively reduce the subjective bias derived from the patients to some degree. This method, however, is difficult to achieve in most of other studies. Nonetheless, in view of a comparatively low level of compliance and high level of loss to follow-up, there were also concerns over the SOX trial [29]. Combining our present analysis results, we tend to support that ECS can indeed provide benefits to patients after DVT.

As for the duration of wearing ECS, the OCTAVIA trial [17] reported that stopping wearing ECS after 1 year seemed to be no inferior to wearing ECS for 2 years. Further analysis of the OCTAVIA trial suggested that thrombus score $\geq$ 3, BMI $\geq$ 26, duration of symptoms before diagnosis $\geq$ 8 days, and Villalta score ranged 2–4 were independent predictors of PTS in patients with proximal DVT who completed the compliant use of ECS for 1 year [16]. The IDEAL DVT trial [18] reported that the individualized ECS therapy for 6 months was comparable to the standard duration of 2 years. The pooled effects of these two trials suggested that the ECS therapy with a duration less than or equal to 1 year seemed to be no inferior to 2-year therapy. The routine use of ECS may bring about troubles to the patients' daily life, so according to our results, patients after 6 or 12 months of ECS therapy should be evaluated comprehensively based on the above predictors of PTS to determine the necessity to continue.

Besides the wearing duration, the pressure of ECS is also a crucial factor that affects the patients' comfort. To improve the patients' level of compliance, the pressure of ECS should also be cautiously taken into consideration while formulating the ECS therapy. According to Galanaud JP et al. [30], the 25 mm Hg ECS was almost as effective as 35 mm Hg ECS in preventing PTS.

Furthermore, in patients with DVT, the presence of residual vein thrombosis is a known risk factor for the development of PTS. [31] A prospective cohort study by Prandoni P et al. [32] discovered that for patients with proximal DVT, the adequate use of ECS can reduce the risk

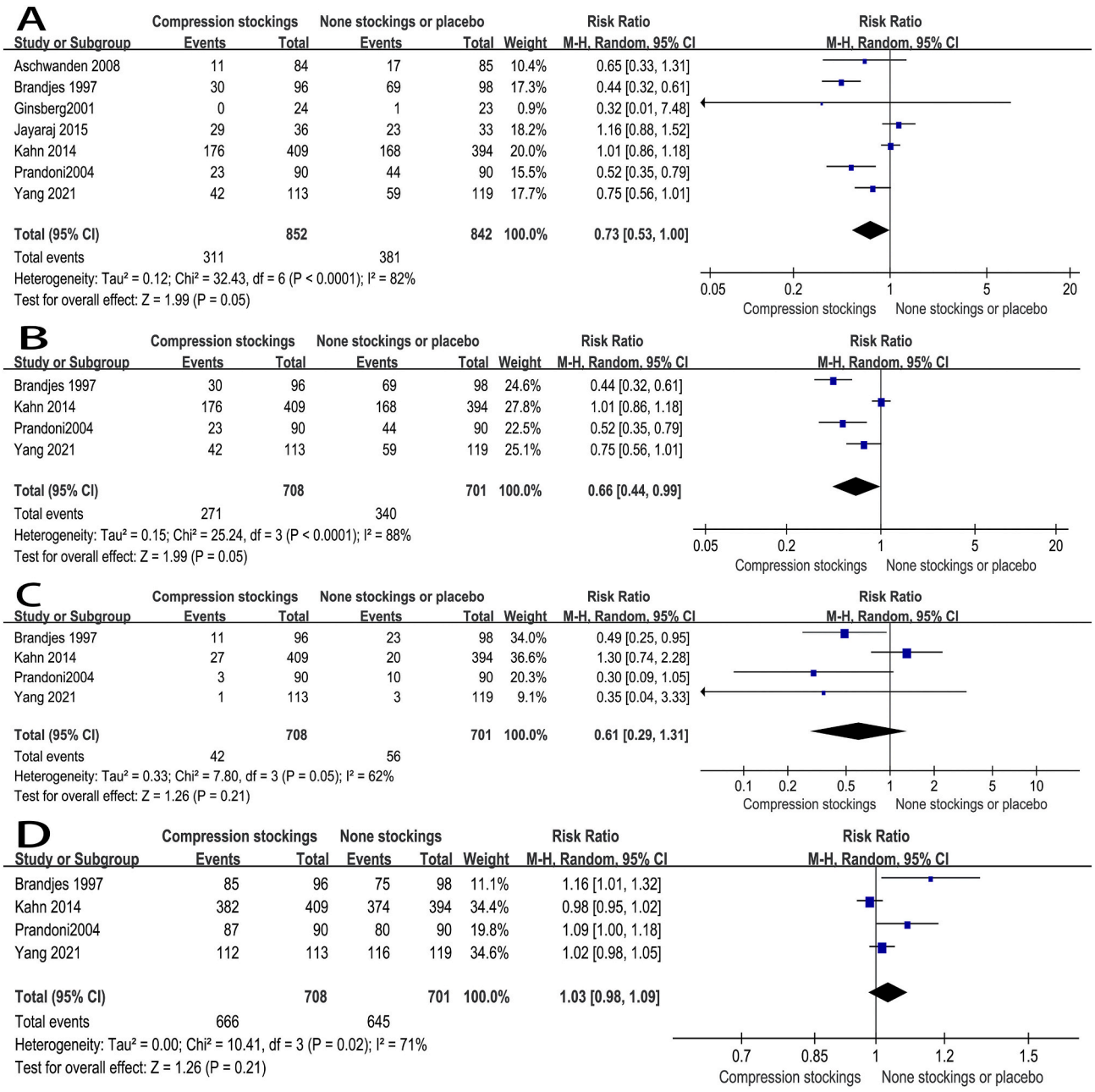

Fig. 3. Effect of elastic compression stockings in preventing post thrombotic syndrome after deep venous thrombosis (A), sensitivity analysis of highest quality studies (B; defined as without high risk of bias; Aschwanden and colleagues [22] and Jayaraj and colleagues [24]; Ginsberg and colleagues [23] was excluded for unclear risk of randomization and allocation concealment), severe (C) and moderate post thrombotic syndrome (D).

of developing PTS in those who still had residual vein thrombosis 3 months after treatment. These findings point out a promising new research direction for improving patient outcomes.

Several limitations in this study should be highlighted. First of all, an obvious level of clinical and statistical heterogeneity was detected across the included studies. The heterogeneity may be rooted in the differences in the ECS types, the onset of using ECS after diagnosis of DVT, the definition of PTS, and the bias from study design, especially in terms of compliance and blinding. We performed sensitivity analyses for the onset of use, definition of PTS, and study design, in which the heterogeneity was not statistically-significantly reduced. Secondly, some of the included studies were at high risk of bias, which might affect the reliability of the results. Thus, we performed a specific analysis on high-quality studies only in order to improve the reliability. We excluded trials with a high risk of bias, as well as Ginsberg's trial, from our analysis. This was because Ginsberg's trial had an unknown risk of bias in terms of randomization and concealment, which could potentially introduce significant bias. However, our final conclusion was not impacted by this decision. When we included Ginsberg's trial, the resulting RR was 0.65, with a 95 % CI ranging from 0.44 to 0.97, which still provided support for the efficacy of ECS. Lastly, there were only two studies that compared the wearing duration of ECS, and one of them was judged as of high risk. Therefore, more high-quality studies are needed in order to confirm the optimal wearing duration.

5. Conclusion

Our results support that the routine use of ECS after diagnosis of DVT can reduce the risk of developing PTS, and the wearing duration of less than or equal to 1 year is no inferior to that of 2 years. This suggests that

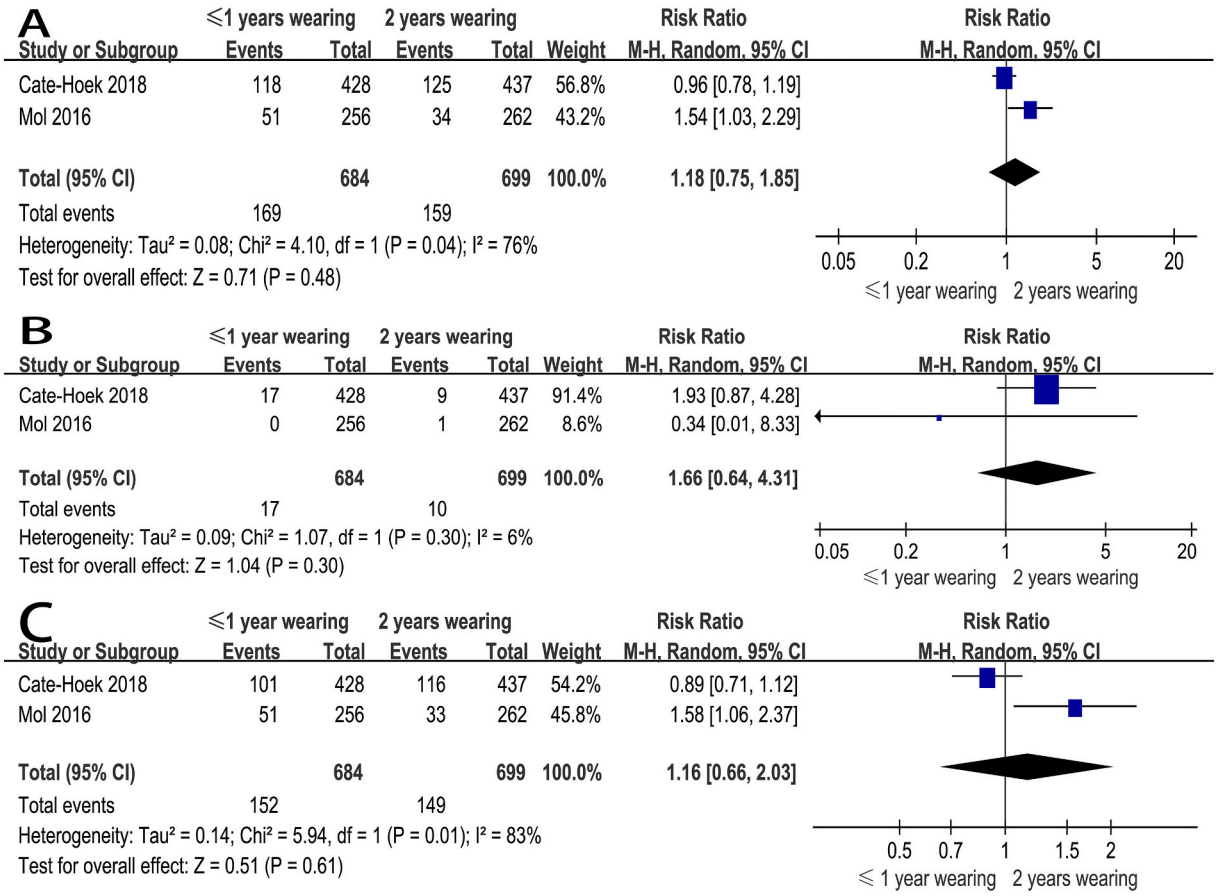

Fig. 4. Effect of different wearing time in preventing post thrombotic syndrome (A), severe (B) and moderate post thrombotic syndrome (C).

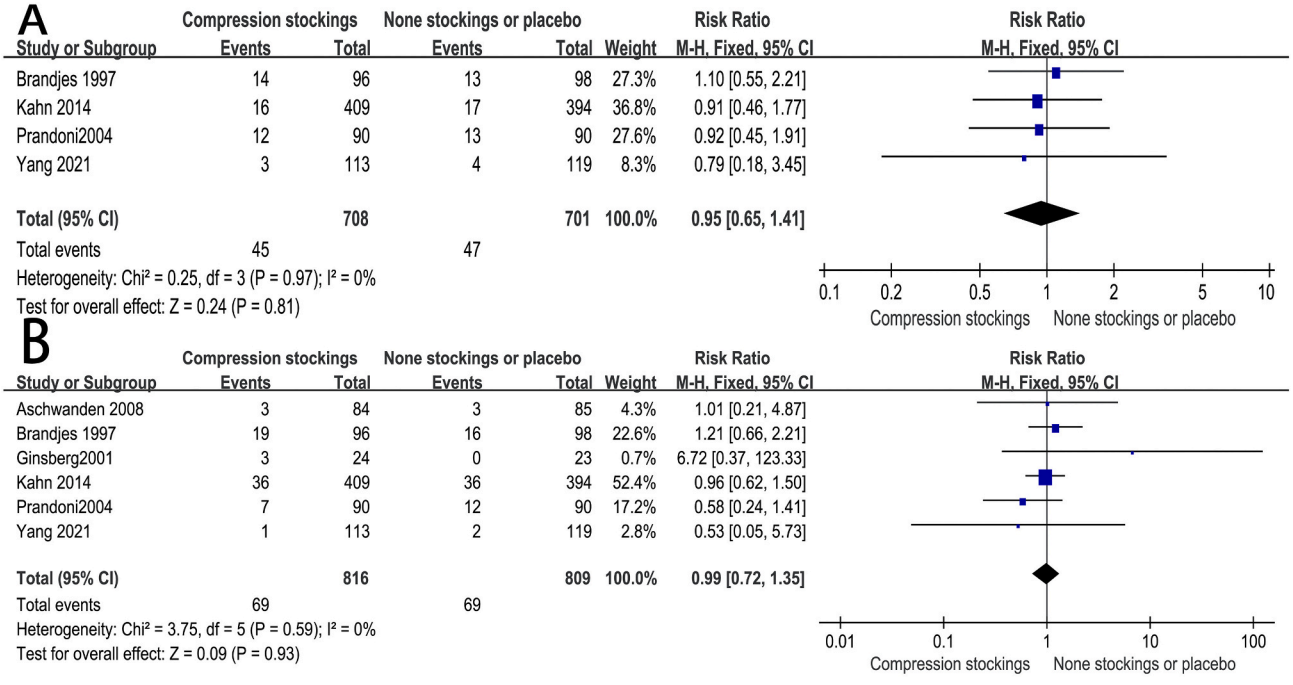

Fig. 5. Effect of elastic compression stockings in patients with deep venous thrombosis on recurrent deep venous thrombosis (A) and mortality (B; all-cause).

the conventional therapy of wearing ECS for 2 years is not necessary for all patients. However, more high-quality studies are needed to further confirm the necessity of wearing ECS and the optimal wearing duration for the purpose of preventing PTS.

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CRediT authorship contribution statement

JHM and SGG proposed the design, searched the literature, collected, analysed and interpret the data, and wrote the report. WJL, YFX, HT searched the literature, and collected, analysed and interpreted the data. YMW searched the literature, designed the figures and tables, and wrote the report.

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Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.thromres.2023.03.016.

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