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META-ANALYSIS

Li et al: Iliac vein stenting outcomes

Iliac vein stenting outcomes in non-thrombotic and thrombotic diseases: A systematic review and meta-analysis

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ABSTRACT

Iliac vein stenting (IVS) is an endovascular revascularization procedure for iliac venous outflow obstruction. We aimed to synthesize the efficacy and safety of IVS across iliac vein disease phenotypes and follow-up horizons. Following a pre-registered protocol (PROSPERO CRD42024606701), we systematically searched Embase, Scopus, PubMed, Web of Science, and Cochrane Library on October 5, 2024. Without restricting study design, we included English-language reports with at least 10 patients that reported at least one prespecified outcome (or convertible data) and excluded studies with additional core therapies or duplicated cohorts. Diseases were classified as non-thrombotic iliac vein compression syndrome (NIVCS), post iliac vein thrombotic syndrome (PIVTS), chronic iliac vein obstruction (CIVO, that is, NIVCS or PIVTS), and acute thrombotic iliac vein obstruction (ATIVO, that is, a CIVO patient with acute ipsilateral thrombosis). The primary outcome was cumulative primary patency (CPP); secondary outcomes comprised ulcer healing, edema and pain relief, quality-of-life improvement, revised Venous Clinical Severity Score change, and adverse events. CPPs at prespecified intervals were extracted for each disease category and pooled in separate meta-analyses. Twenty-seven studies (4,782 patients) were included; demographic, intraoperative, and outcome data were systematically abstracted. Pooled CPPs were consistently high, particularly for NIVCS, and were lower when thrombotic components were present (PIVTS and ATIVO), while other efficacy outcomes generally improved and serious complications were uncommon. In conclusion, across diverse iliac vein diseases and follow-up periods, IVS demonstrates good efficacy and safety; this unfunded study supports IVS as a prominent treatment option.

Keywords: Iliac vein, stents, venous thrombosis.

INTRODUCTION

In 1957, May and Thurner first reported the abnormal obstructive hyperplasia of the iliac vein wall after chronic compression [1]. Cockett named this iliac vein obstruction (IVO) "iliac vein compression syndrome" for the first time based on findings from venography and surgery [2]. This disease can cause chronic venous congestion in the lower limbs, leading to a series of clinical symptoms, and is a common cause of chronic venous disease [3]. Additionally, it has been reported that a significant proportion of patients with acute deep vein thrombosis (DVT) in lower limbs have ipsilateral chronic iliac vein occlusion [4, 5]. In order to distinguish from IVO without acute thrombosis, we call this kind of disease acute thrombotic IVO (ATIVO). The old thrombus of iliac vein after acute DVT may cause post-thrombotic syndrome (PTS), a kind of chronic venous disease, namely, post iliac vein thrombotic syndrome (PIVTS). We refer to non-thrombotic iliac vein compression syndrome (NIVCS) without acute / chronic thrombotic components and PIVTS as chronic IVO (CIVO).

Generally, for CIVO patients, revascularization will be considered only when the symptoms are significant [3]. And including ATIVOs, luminal stenosis of at least 50% is recognized as the anatomical indication for revascularization in all patients with IVO [6-8]. Endovascular procedures are the first-line opinion for IVOs [3]. The general consensus is that percutaneous transluminal angioplasty (PTA) alone is not sufficient to treat IVOs because of frequent immediate elastic recoil of the treated vein segment and therefore stenting is usually needed [3, 9, 10]. So, the stent patency after iliac vein stenting (IVS) and its closely related clinical efficacy have naturally become the focus of attention. In recent years, research results on the above outcomes have been increasingly reported. Due to the lack of strong classical controls, the vast majority of studies were single arm [11-13]. However, the post-IVS cumulative primary patencies (CPPs) were markedly different according to the patient category. For example, Kwak et al. reported a 2-year postoperative CPP of 95.5% for ATIVO patients [14], while Kim et al. reported only 70.5% [15]. Moreover, a variety of adverse events (back pain, stent thrombosis, contralateral DVT, etc.) after IVS have also been reported, with large differences among the results similarly. For example, Moini et al. reported a cumulative rate of stent thrombosis of 10.2% during a 6-month follow-up period for PIVTS patients [13], whereas such events never occurred during

Tang et al.'s 2-year follow-up period for CIVO patients[16]. After extensive search but no results, we hoped to have a comprehensive understanding of the efficacy and safety outcomes of IVS for different IVO patients in different follow-up periods. Therefore, we conducted this systematic review and performed meta-analyses with different CPPs as the outcomes of interest.

MATERIALS AND METHODS

Study protocol

According to the PRISMA framework, this study was registered on the PROSPERO platform (CRD42024606701). All data were from published literatures and did not include any individual identification information. Therefore, no ethical approvals and consent forms of the patients were required. The PRISMA 2020 checklist is shown in [Table S1](#).

Search strategy

A systematic search in Excerpta Medica Database (Embase), Scopus, PubMed, Web of Science (WOS), and Cochrane Library was performed on October 5, 2024. During the primary search, any literature with title containing "iliac vein / iliac venous" and "stent / stenting" could be included in the selection process. The literature search was independently performed by ML. The search strings used in each database are detailed in [Table S2](#).

Study selection

Without limiting the follow-up period, the post-IVS CPP was set as the primary outcome of interest. The secondary outcomes of interest included postoperative efficacy outcomes and safety outcomes. The former included ulcer healing, edema relief, pain relief, quality of life (QoL) improvement, and revised Venous Clinical Severity Score (rVCSS) improvement [17]. The latter included foreign body sensation, back pain, puncture hematoma, pulmonary embolism (PE), all-cause death, stent thrombosis, stent fracture, stent collapse, contralateral DVT, ipsilateral DVT / recurrence, PTS. All outcomes of interest were not redefined, i.e., the original definitions from literatures were adopted. And all of them were planned to be recorded in the form of cumulative rate over a period. As long as a literature reported at least one outcome of interest in the above form or data available for indirect

calculation, and met the following conditions simultaneously, it could be included in the review; otherwise it would be excluded: 1) the language of publication was English; 2) the literature was not published in abstract form only; 3) in addition to IVS, there were no other core treatment modalities in the study; 4) there were at least 10 patients in a population series; 5) the data in the literature was not duplicated with that in other published literature.

All the retrieved literature information was imported into the Endnote 21 software, followed by duplicate removal and abstract review. Then, the full texts of all available literatures that passed the preliminary screening were downloaded and read to identify those that could be finally included into the study. Two authors (ML and SW) independently performed the study selection. Any discrepancies were resolved by consensus.

Data extraction

After identifying the included literatures, data on literature, population, IVS procedure, follow-up period and each outcome of interest (measure) were extracted. All outcome measures were set as cumulative percentages with 95% confidence interval (CI), that is, the cumulative number of cases in some period divided by the total number of cases at the beginning of follow-up. In this division calculation, missing data would not be included in either the numerator or the denominator. Data extraction was performed by a pair of independent authors (ML and JZ). Any discrepancies were resolved by consensus.

Quality assessment

All the included literatures were assessed by the Joanna Briggs Institute (JBI) checklist [18] and the Agency for Healthcare Research and Quality's (AHRQ) cross-sectional study quality evaluation items [19] simultaneously. The JBI's quality assessment tool for prevalence research includes 9 items that evaluate the overall quality of prevalence research in terms of sampling methods, research objects, data collection, and analysis methods; the item is scored 1 point if the answer is "yes" and scored 0 points if the answer is "no", "not clear" or "not applicable". The AHRQ's cross-sectional study quality evaluation items contain 11 domains; "yes" is scored 1 point, and "no" or "not clear" is scored 0 points. All included literatures were classified as having "low" (0-3 points), "medium" (4-7 points) or "high" (8-11 points)

methodological quality. For each literature, the lower quality class between the two assessment systems was adopted. Quality assessment was performed by a pair of independent authors (ML and CL). When the two authors had different opinions on some assessment result, the worse one was taken.

Statistical analysis

Stata (Stata Corp., College Station, TX, USA) version 16.0 was used for all statistical analyses. Meta-analyses of all outcome measures were performed using the Metaprop command [20] of the Freeman-Tukey (F-T) double arcsine transformation of data [21] to derive the pooled effect sizes (ESs) with 95% CI. The fixed and random effects models were both used for the analyses [22]. In software, the basic meta-analysis command was: metaprop e n, random ftt cimethod (exact). In addition to textual description, the pooled analysis results of outcome measures of interest are presented as forest plots. For any hypothesis test, only the results with a p value less than 0.05 could be considered statistically significant. All pooled analyses were performed independently by ML.

Heterogeneity assessment

The analysis was performed using a random effects model first. The heterogeneity was assessed and reported as a percentage using the I^2 index value [23] and as a p value using the Cochrane Q test [24]. If the I^2 statistic was $\geq 50\%$ or the p value was ≤ 0.10 , the heterogeneity across included literatures was high; otherwise, the heterogeneity was considered low. Once the heterogeneity within a random effects model was high, the literature with the lowest weight in the model was excluded and the calculation was performed again. If a highly heterogeneous model was still obtained, the above literature would be re included and the one with the second lowest weight in the original model would be excluded, and then the calculation would be redone. And so on, until the model with low heterogeneity was obtained. Only the random effects model that included at least 3 literatures with low heterogeneity across them would be initially adopted. Then, the outcomes of the literatures included in this model were re pooled and analyzed using a fixed effects model, to obtain the final adopted ES. The heterogeneity assessment was performed independently by YY.

Sensitivity analysis

After obtaining a final adopted model, the checking calculation was performed by omitting the included literatures one by one, to analyze the sensitivity of the model. The natural logarithm (ln) conversion was performed on all new ES values obtained by recalculating after omitting the included literature one by one respectively. Once a ln(new SE) value which was far away from the ES obtained by the previous final adopted model or even beyond its 95% CI range, was obtained after omitting some literature, the final model was considered to be unstable. The sensitivity analysis was performed independently by YY.

Publication bias assessment

The publication bias of each final adopted model was assessed using the Egger's test [25], respectively. A p value less than 0.05 means a high bias. And the funnel plots were also be drawn [26]. An apparently asymmetric plot with the ES value as axis reflects a high bias. The publication bias assessment was performed independently by CS.

Evidence quality grade assessment

After finishing the meta-analyses, we used the Grading of Recommendations Assessment, Development and Evaluation system (GRADE) to evaluate the qualities of evidence and make recommendations. Each result was graded as high, moderate, low, or very low. Since the included studies were all retrospective, the results were initially set as low, and the rating was raised as appropriate. The assessment was performed independently by CS.

RESULTS

Characteristics of literatures

We initially identified 1,136 articles by searching the 5 academic databases, of which 218 were evaluated after re-moving duplicates. And 75 articles were retained after the title abstract sieve. After reviewing the full text, twenty-seven were finally included in this study [11-16, 27-47]. The PRISMA flowchart of study selection is shown in Figure 1.

The publication years of the 27 included articles ranged from 2002 to 2024, with the majority (74.1%) presenting retrospective observational studies. After assessment,

it was believed that 55.6% of the articles were of high quality and there were no articles of low quality. The sample populations for these studies were from the United States (29.6%), China (18.5%), and other countries. Some articles reported data from different populations simultaneously, resulting in the extraction of 33 case series, which were then divided into NIVCS group (9 series), PIVTS group (5), CIVO group (9), and ATIVO group (10). The largest series had a sample size of 1104 patients (CIVOs) [32], while the smallest series had 11 (pregnant ATIVOs) [39]. The characteristics and assessment results of literatures are summarized in [Table 1](#).

Preoperative and intraoperative data of patients

Except for the literature that only reported ATIVOs with an average age of 28 [39], the average age of included patients ranged from 41.9 (ATIVOs) to 72.0 (NIVCSs) [40, 41], and the proportion of females ranged from 25.0 (NIVCSs) to 86.7 (ATIVOs) [13, 43]. Compared with the contralateral, the left lower limbs had higher proportions of the diseases. For the Clinical, Etiological, Anatomical, Pathophysiological (CEAP) classification [48], patients with C3 to C4 were the most. The extractable data showed that the diameter of stent used was mostly less than 20mm, and the total length of the unilateral stents after implantation was mostly less than 100mm. The preoperative and intraoperative data of patients are summarized in [Table S3](#).

Summary of CPP data in different follow-up periods

The reported follow-up periods ranged from 6 months to 13 years [13, 43, 45, 46]. According to the available data, the CPPs of 6 months, 1 year, 2 years, 3 years, 4 years and 5 years in different patient series were extracted respectively. Except for those in a literature on CIVOs, the CPPs of 6 months and 1 year all exceeded 80% [47]. The CPP data in different follow-up periods are summarized in [Table 2](#).

Meta-analyses of various CPPs and certainties of evidences

After IVS, 6mo and 2y CPPs of NIVCSs, 6mo CPPs of PIVTSs, 1y and 2y CPPs of CIVOs, and 6mo, 1y, and 2y CPPs of ATIVOs all could be pooled for meta-analysis due to sufficient literature data. Due to the universal high heterogeneities of the random effects models obtained by pooling the results of the remaining three literatures, regardless of which one was omitted, the meta-analysis results of CIVOs' 1y CPP were not adopted [16, 30, 44, 47]. Other pooled analyses yielded models with low heterogeneity, with only the model of ATIVOs' 2y CPP showing high publication

bias ($p = 0.012$ for Egger's test). The processes of meta-analyses and the certainties of the obtained evidences are presented in [Table 3](#). The forest plots, sensitivity analysis results, and funnel plots of each adopted model are shown in [Figure 2, 3, 4, 5, 6, 7, 8](#), respectively.

The efficacy outcomes of IVS other than CPP

Although there was limited data available on the efficacy outcomes other than CPP that can be extracted, the results are generally satisfactory ([Table S4](#)). Moini et al. reported that the cumulative complete ulcer healing rates of PIVTSs and NIVCSs at 6 months after IVS were 31.0% and 42.4%, respectively [[13](#)]. While the results of three other studies showed that the post-IVS cumulative rate of CIVOs at 17, 24, and 29 months were all 100% [[16, 42, 47](#)]. The cumulative edema relief rate of CIVOs at 6th month was 80.0-100% [[13, 46](#)]. And Ye et al. reported that the above cumulative rate of NIVCSs still reached 89.1% at the fourth year [[34](#)]. Only Moini et al. reported specific pain relief rates, namely cumulative rates of 98.7% and 100% of PIVTSs and NIVCSs at the 6th month, respectively [[13](#)]. The results of Raju et al.'s study showed that the 2-year cumulative QoL improvement rate of CIVOs was 46.6% [[28](#)]. It is reported that the rVCSS scores of NIVCSs and PIVTSs decreased by an average of 4.72 and 7.77 respectively at the 6th postoperative month [[13](#)]. Lim et al.'s study did not report a specific follow-up period and showed an average decrease of 5.75 in rVCSS scores for CIVOs [[30](#)]. In addition, although specific rates or values were not reported, some studies had shown statistically significant ($p < 0.05$) changes after IVS on the efficacy variables for various CIVOs [[16, 28, 30, 34, 42, 47](#)].

The safety outcomes of IVS

The included studies had reported a variety of adverse events after IVS that were difficult to classify and all postoperative rather than intraoperative ([Table S5](#)). Those representative events and their cumulative rate were extracted. There were significant differences in the incidence of back pain among the studies (1.6% for ATIVOs but 66.0% for CIVOs), but they all had the tendency of self-healing [[27, 38](#)]. Serious events were rare. The incidence of all cause death ranged from 0 to 4.5% (up to 21 months of follow-up) [[14, 42](#)]. And in reported studies, the incidence of PE was consistently 0 [[16, 29, 36, 44, 47](#)]. Among the stent related adverse events, stent collapse and stent thrombosis seemed to be slightly more common, with an incidence

of 3.3-11.3% and 0-10.2%, respectively [13, 33, 35, 43]. DVT events were occasionally reported, with incidence rates of 0-8.5% on the ipsilateral side and 0-11.4% on the contralateral side, respectively [15, 16, 31, 42]. In addition, the incidence of PTS in ATIVOs after IVS was 2.2-21.6% [12, 36].

DISCUSSION

This study systematically reviewed and analyzed the outcomes of each population in different follow-up periods after IVS. The results show that, IVS has satisfactory efficacy and safety. The following is a discussion centered around generalizability of findings across populations, healthcare systems, and stenting technique.

The true prevalence of IVO is high. Kibbe et al. reported that the frequency of significant compression of iliac vein was as high as 24% in an asymptomatic population [49]. It was reported that the diagnostic rate of IVO was 15% in patients with chronic venous disease (CVD) and 30% in those with DVT [4, 5, 34]. Chen et al. have pointed out that iliac vein stenosis exceeding 50% could increase the risk of DVT by about 10 times [50]. In clinical practice, as clinical physicians deepen their understanding of various IVOs, the accuracy of diagnosing this disease is increasing.

The etiology of most CIVO lesions can be classified into two categories: external compression and old thrombus in the lumen [1, 51, 52]. The core promising treatment method is IVS. Obviously, the post-IVS CPPs of the two diseases mentioned above were quite different [29, 41, 45]. In addition, Kim et al.'s study showed that once fresh thrombosis occurred at the CIVO lesion, the postoperative CPP seemed to tend to decrease [15]. Therefore, according to the pathological state of the lesions during IVS, we divided IVO into three different types: NIVCS, PIVTS and ATIVO, and analyzed their postoperative CPPs to try to avoid the bias caused by heterogeneity.

This review found that most of the IVO lesions in the included studies were located on the left side, and even those in some studies were all left-hand [15, 31]. This is consistent with the results of other studies [1, 4, 5]. We believe that the reason is due to congenital anatomical reasons, the left iliac vein is more vulnerable to external compression comparing with the contralateral. The clinical characteristics of patients with different types of IVO are different. As a common cause of CVD, CIVO can lead to mild varicose veins and severe skin ulcers that are difficult to heal. Some evaluation methods based on clinical manifestations are widely adopted, such as the

CEAP classification, the Villalta scale and the rVCSS [17, 48, 53]. Venous claudication, usually described as heaviness and pain during exercise subsiding during rest, is a non-objective and poorly validated symptom [54]. It is not included in formal scoring systems, but may affect clinicians' treatment decisions [3]. On the other hand, the clinical manifestations of ATIVO patients are mostly acute. The evaluation of its severity is more focused on the burden and location of thrombus, in order to further predict the risk of PE [55].

For ATIVO patients, the indication for IVS was generally considered to be imaging diagnosis of iliac vein diameter or area stenosis of at least 50% and the removal of most of the fresh thrombus at the stenosis site, even if there was no clinical manifestation of CIVO before the onset of DVT [12, 15, 27, 36]. IVO is widely considered a risk factor for DVT recurrence [56-58], therefore we support the use of IVS in combination with thrombectomy. On the other hand, researchers generally believed that for CIVO patients, even if they have the above anatomical characteristics ($\geq 50\%$ stenosis), as long as their chronic clinical manifestations are mild or even non-existent, they do not need to undergo stenting [13, 30, 33, 45]. Additionally, some researchers have not considered iliac vein stenosis reaching 50% as an anatomical indication for IVS. Rizvi et al. pointed out in the study that stenting would be considered only when the residual stenosis of iliac vein after PTA still reached 50% [41]. But, Taha et al. believe that a diameter stenosis of up to 50%, or extensive intraluminal fibrosis, or a residual stenosis of up to 30% after DVT with venous collaterals, all should be considered as the indication for stenting [47].

Undoubtedly, the continuous patency of the iliac vein stent is the key to maintaining good postoperative efficacy. This review aimed to reveal the satisfactory post-IVS CPPs. After reasonable statistical analyses, several models containing specific ES values were obtained. After analyzing these results, the following three points had been summarized. First, the study by Hgel et al., which was included in this review, showed that the postoperative 2y CPP of CIVO was 84.3%, while the 5y CPP remained as high as 82.4% [44]. The other two included studies also showed that the postoperative 5-y CPP of ATIVOs could still be maintained at over 90% [39, 43]. In addition, after meta-analysis, it was found that the postoperative 2y CPP of NIVCSs was still as high as 98.4%. These results reveal that the high CPPs can be maintained for a long time. Second, after meta-analysis, the post-IVS 6mo CPP of

PIVTSs and ATIVOs were 87.5% and 94.8%, respectively, which seemed to be much lower than that of NIVCSs without thrombosis (99.6%). And the estimated 2y CPP of CIVO was also significantly lower than that of NIVCSs (71.0% vs. 98.4%). These results showing higher postoperative CPPs of NIVCSs are consistent with the findings reported in multiple previous studies on different IVO populations [13, 29, 40, 45]. The above indicates that the presence of thrombus tissue is likely to have a significant negative impact on the patency of iliac vein stents. In depth, we believe that this may be related to the obstruction of the stent inflow and outflow caused by thrombosis [59, 60]. Unfortunately, in order to fully cover the thrombus in the inflow and/or outflow, the stent may need to be extended below the inguinal ligament and/or into the inferior vena cava, which will also affect the patency of the stent and increase the risk of contralateral DVT [11, 59]. Third, the estimated 6mo post-IVS CPP of ATIVOs seemed to be better than that of PIVTS (94.8% vs. 87.5%). And Robertson et al.'s study, which analyzed the two groups of population separately, also reported a similar result (86.2% vs. 84.2%) [45]. Most researchers believed that for ATIVOs, one of the prerequisites for implementing IVS is to use various thrombolysis modalities to almost completely remove the thrombus on the affected side [12, 15, 27, 31, 36]. This further confirms the importance of unobstructed inflow and outflow in maintaining stent patency.

In addition to the CPP, this review also summarizes other efficacy outcomes of IVS. It can be observed that, most of all the included studies indicated significant improvements on the chronic symptoms (including ulcer, edema, pain, and decreased QoL) of the vast majority of CIVO. Moini et al. reported a complete ulcer healing rate of 31-42% at 6 months after IVS for CIVO [13]. However, other studies with longer follow-up periods (at least 17 months) have reported significantly better or even up to 100% healing rates [34, 42, 47]. This seems to reflect that IVS is indeed effective for ulcers, but ulcer healing takes time. And, the effect of IVS on reducing edema or pain and improving the quality of life has also been proved by many studies [13, 16, 28, 30, 34, 42, 46, 47]. Therefore, we believe that with the help of the proven long-term stent patency, IVS can improve the symptoms of IVOs for a long time and prevent the progression of CVD.

Not only the efficacy, but also the safety of IVS should be paid attention to. It was noted that the most common adverse event after IVS seemed to be back pain (the

highest incidence was 66%) [38]. Although it had a high incidence rate, studies indicated that its degree was mild and it had a tendency towards self-healing, so no special treatment is necessary [27, 29, 37, 38]. Some researchers attributed it to the larger stent diameter and the PTA before stent implantation [61, 62]. But Snow et al. believed that the diameter and length of the stent are not predictors for it [38]. After a stent was implantation, the risk of complications arising from this foreign body itself has always been concerned. The most common types of stent events reported were thrombosis, migration, fracture, and collapse. Even during long follow-up periods, their incidences were very low (even generally 0), regardless of the type of IVO patients [16, 33, 42, 47]. We believe that this is the guarantee for maintaining the high patency of stent. Unlike the other two studies that reported a 0% incidence of ipsilateral DVT after IVS for CIVO, Kim et al.'s study reported an 8.5% incidence of that for ATIVO within an average of postoperative 14 months [16, 31, 42]. Kim et al. believed that ipsilateral DVT (i.e. recurrence) was associated with retained inferior vena cava filter and stent thrombosis [31]. This seems to suggest that for ATIVO, IVS may indirectly cause DVT recurrence in the ipsilateral lower limb through stent thrombosis. However, the prevalence of recurrent DVT is higher than that of the first DVT, and many risk factors are related to the recurrence of DVT. Therefore, more studies are needed to reveal whether IVS is an independent risk factor for the recurrence of ipsilateral lower limb DVT of ATIVO. The incidence of contralateral DVT was reported to be 9% or even 11% within 2 to 3 years after IVS [11, 15]. The excessive extension of the stent into the inferior vena cava leading to obstruction of blood flow in the contralateral lower limb was widely believed to be highly correlated with contralateral DVT [11, 15, 31]. And Kim et al. believe that contralateral DVT was also associated with the stent thrombosis [31]. As a condition of DVT, one of the main long-term complications of ATIVO is PTS. The controlled study by Ming et al. directly indicated that for ATIVO, IVS was an independent preventive factor of PTS (Cox regression, odds ratio = 0.541, $p = 0.012$) [12]. And the other two included studies also reported very low incidences (2.2% and 11.5%, respectively) of PTS after IVS [27, 36]. The above data were both cumulative rates for more than 2 years follow-up, which are significantly lower than the reported incidences of PTS within 1 year of proximal DVTs receiving anticoagulant alone and receiving anticoagulant combining thrombus removal procedure, which were both over 40% [63]. The

principle by which IVS reduces the risk of PTS was believed to restore the patency of iliac vein, thereby increasing the velocity and flow of venous blood in the lower limb [12, 27, 36]. Overall, after review, IVS has a high level of safety for various IVOs.

It should be pointed out that this presented study has some limitations. First, the units used to calculate the incidence of outcomes were not uniform among the included studies. For example, in some studies, the primary patency rate was equal to the number of patients with primary patency divided by the total number of patients, while in some other studies, the "patient" in the formula was replaced by "limb". So, the error in pooled analyses increased. Second, among the included studies, the selection criteria for patients undergoing IVS were not very consistent. For example, some studies regarded IVS as the initial preferred therapy for patients with confirmed IVO lesions, while others regarded it as an alternative after PTA failed. This selection bias might increase the heterogeneity among studies. Third, the sample sizes in pooled analyses were limited. There have not been many studies on the outcomes of IVS. In order to minimize heterogeneity, different IVO patients and different follow-up periods were distinguished during the pooled analyses, further reducing the sample sizes. Then the statistical power had been reduced as a result. Fourth, due to the small sample sizes, the tests for publication bias might lead to a small sample effect, thereby reducing statistical power.

Although there have been systematic reviews summarizing the outcomes of IVS, the presented study further demonstrates the efficacy and safety of IVS by distinguishing among different types of IVO patients and various follow-up periods. However, there are still few relevant prospective controlled studies, and we look forward to the publication of more such studies.

CONCLUSION

For various IVOs, IVS helps maintain long-term primary patency, improve clinical manifestations and quality of life, and is safe. Therefore, this modality should hold an important position in the treatment for IVOs.

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TABLES AND FIGURES WITH LEGENDS

Table 1. Characteristics and assessment results of literatures

Reference	JB score	AHRQ score	Quality level	Publication year	Study type	Country	Enrolled year	Enrolled population	Population amount
Xue [27]	7	8	M	2014	RO	China	2006-2011	ATIVO	61
Raju [28]	8	8	H	2002	RO	USA	1997-2000	CIVO	292
Jiang [29]	7	9	M	2024	RO	China	2020-2022	NIVCS	55
Jiang [29]	7	9	M	2024	RO	China	2020-2022	PIVTS	28
Le [11]	9	8	H	2018	RO	Korea	2004-2017	NIVCS	111
Ming [12]	9	8	H	2017	RO	China	2011-2015	ATIVO	116
Lim [30]	7	7	M	2020	RO	Singapore	2014-2019	CIVO	87
Kim [31]	9	9	H	2020	RO	Korea	2004-2018	ATIVO	130
Satwah [32]	9	7	M	2021	RO	USA	2015-2019	CIVO	1104
Alsheekh [33]	8	8	H	2017	RO	USA	2012-2014	NIVCS	623
Ye [34]	8	8	H	2012	RO	China	2000-2012	NIVCS	205
Jeon [35]	7	8	M	2010	RO	Korea	1999-2007	ATIVO	30
Jiang [36]	8	8	H	2019	RO	China	2014-2016	ATIVO	46
Raju [37]	6	6	M	2014	RO	USA	NE	CIVO	NE
Snow [38]	9	7	M	2023	RO	USA	2014-2021	CIVO	627
Dasari [39]	7	8	M	2017	RO	USA	2007-2014	ATIVO	11

								(pregnancy)	
Kim [15]	8	8	H	2022	RO	Korea	2001-2018	ATIVO	44
Abdul-Haqq [40]	8	8	H	2017	RC	UK	2003-2015	NIVCS	NE
Abdul-Haqq [40]	8	8	H	2017	RC	UK	2003-2015	PIVTS	NE
Rizvi [41]	8	8	H	2018	RO	USA	2013-2014	NIVCS	210
Kwak [14]	7	7	M	2005	RO	Korea	2000-2004	ATIVO	22
Moini [13]	9	8	H	2019	RC	Iran	2015-2017	NIVCS	88
Moini [13]	9	8	H	2019	RC	Iran	2015-2017	PIVTS	76
Lichtenberg [42]	8	8	H	2021	PC	Germany	2016-2017	NIVCS	29
Lichtenberg [42]	8	8	H	2021	PC	Germany	2016-2017	PIVTS	50
Foegh [43]	7	6	M	2022	RO	Denmark	NE	ATIVO	45
Tang [16]	7	7	M	2022	PC	Singapore	2018-2019	CIVO	60
Hügel [44]	9	8	H	2022	PC	Switzerland	2008-2020	CIVO	108
Robertson [45]	8	8	H	2022	RO	USA	2016-2021	NIVCS	41
Robertson [45]	8	8	H	2022	RO	USA	2016-2021	PIVTS	38
Robertson [45]	8	8	H	2022	RO	USA	2016-2021	ATIVO	29
Cooke [46]	9	8	H	2022	PO	USA	2011-2021	CIVO	376
Taha [47]	7	7	M	2020	PO	Egypt	2016-2019	CIVO	40

Abbreviations: JBI: Joanna Briggs Institute; AHRQ: Agency for Health Care Research and Quality; M: Medium; H: High; RO:

Retrospective observation; RC: Retrospective control; PC: Prospective control; PO: Prospective observation; NE: Not extracted;

ATIVO: Acute thrombotic iliac vein occlusion; CIVO: Chronic iliac vein occlusion; NIVCS: Non-thrombotic iliac vein compression syndrome; PIVTS: Post iliac vein thrombotic syndrome.

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Table 2. Data on cumulative primary patency

Reference	Enrolled population	Mean follow-up period	CPP-6mo, %	CPP-1y, %	CPP-2y, %	CPP-3y, %	CPP-4y, %	CPP-5y, %
Xue [27]	ATIVO	31mo	95.1	91.8	90.2	88.5	NE	85.2
Raju [28]	CIVO	2y	NE	NE	71.0	NE	NE	NE
Jiang [29]	NIVCS	3y	94.5	94.5	94.5	94.5	NE	NE
Jiang [29]	PIVTS	3y	88.5	85.4	85.4	85.4	NE	NE
Le [11]	NIVCS	3y	NE	NE	NE	NE	NE	NE
Ming [12]	ATIVO	NE	NE	NE	NE	NE	NE	NE
Lim [30]	CIVO	NE	95.7	92.8	NE	NE	NE	NE
Kim [31]	ATIVO	14mo	NE	NE	NE	NE	NE	NE
Satwah [32]	CIVO	NE	NE	NE	NE	NE	NE	NE
Alsheekh [33]	NIVCS	1y	NE	NE	NE	NE	NE	NE
Ye [34]	NIVCS	4y	NE	NE	NE	NE	98.7	NE
Jeon [35]	ATIVO	1y	NE	83.3	NE	NE	NE	NE
Jiang [36]	ATIVO	2y	97.8	95.7	91.1	NE	NE	NE
Raju [37]	CIVO	2y	NE	NE	69.1	NE	NE	NE
Snow [38]	CIVO	NE	NE	NE	NE	NE	NE	NE
Dasari [39]	ATIVO (pregnancy)	63mo	NE	NE	NE	NE	NE	90.9
Kim [15]	ATIVO	25mo	NE	70.5	70.5	NE	NE	NE

Abdul-Haqq [40]	NIVCS	20mo	NE	NE	NE	97.2	NE	NE
Abdul-Haqq [40]	PIVTS	20mo	NE	NE	NE	73.7	NE	NE
Rizvi [41]	NIVCS	499d	98.7	98.3	97.9	NE	NE	NE
Kwak [14]	ATIVO	21mo	NE	95.5	95.5	NE	NE	NE
Moini [13]	NIVCS	6mo	98.8	NE	NE	NE	NE	NE
Moini [13]	PIVTS	6mo	88.2	NE	NE	NE	NE	NE
Lichtenberg [42]	NIVCS	24mo	NE	NE	95.5	NE	NE	NE
Lichtenberg [42]	PIVTS	24mo	NE	NE	96.0	NE	NE	NE
Foegh [43]	ATIVO	13y	NE	NE	NE	NE	NE	> 94.0*
Tang [16]	CIVO	29mo	NE	92.4	87.1	NE	NE	NE
Hügel [44]	CIVO	41mo	NE	90.7	84.3	83.3	82.4	82.4
Robertson [45]	NIVCS	6mo	97.6	NE	NE	NE	NE	NE
Robertson [45]	PIVTS	6mo	84.2	NE	NE	NE	NE	NE
Robertson [45]	ATIVO	6mo	86.2	NE	NE	NE	NE	NE
Cooke [46]	CIVO	6mo	NE	NE	NE	NE	NE	NE
Taha [47]	CIVO	17mo	80.0	76.0	NE	NE	NE	NE

*: Data reported in the literature is a value that extend beyond post-operative 5 years. Abbreviations: ATIVO: Acute thrombotic iliac vein occlusion; CIVO: Chronic iliac vein occlusion; NIVCS: Non-thrombotic iliac vein compression syndrome; PIVTS: Post iliac vein thrombotic syndrome; mo: Months; y: Year(s); d: Days; NE: Not extracted; CPP: Cumulative primary patency.

Table 3. Meta-analyses of various CPPs and certainties of evidences

Outcome	Included literatures initially	Heterogeneity of initial REM (I^2 and p for Q test)	Omitted literature	Heterogeneity of new REM (I^2 and p for Q test)	Population size	ES obtained from new REM	ES obtained from final FEM	Sensitivity analysis result	Publication bias and p for Egger's test	Certainty of evidence ^a	Alteration to initial rating
6mo CPP of NIVCS	[13] [29] [41] [45]	56.742%, 0.074	[29]	12.651%, 0.318	339	0.995 (95% CI, 0.981-1.000)	0.996 (95% CI, 0.984-1.000)	Stable	Low, 0.084	Low	0
2y CPP of NIVCS	[29] [41] [42]	39.798%, 0.190	NA	NA	294	0.977 (95% CI, 0.940-0.998)	0.984 (95% CI, 0.965-0.996)	Unstable	Low, 0.392	Low	0
6mo CPP of PIVTS	[13] [29] [45]	< 0.001%, 0.800	NA	NA	142	0.875 (95% CI, 0.813-0.927)	0.875 (95% CI, 0.813-0.927)	Stable	Low, 0.813	Low	0
2y CPP of CIVO	[16] [28] [37] [44]	71.088%, 0.016	[44]	< 0.001%, 0.549	569	0.710 (95% CI, 0.672-	0.710 (95% CI, 0.672-	Stable	Low, 0.418	Low	0

						0.746)	0.746)				
6mo CPP of ATIVO	[27] [36] [45]	43.981%, 0.168	NA	NA	136	0.944 (95% CI, 0.876-0.989)	0.948 (95% CI, 0.901-0.982)	Stable	Low, 0.435	Low	0
1y CPP of ATIVO	[14] [15] [27] [35] [36]	71.722%, 0.007	[15]	7.976%, 0.353	159	0.924 (95% CI, 0.871-0.965)	0.924 (95% CI, 0.875-0.963)	Stable	Low, 0.828	Low	0
2y CPP of ATIVO	[14] [15] [27] [36]	69.809%, 0.019	[15]	< 0.001%, 0.831	129	0.917 (95% CI, 0.860-0.962)	0.917 (95% CI, 0.860-0.962)	Stable	High, 0.012	Very low	-1 ^b

^a: High certainty: We are very confident that the true effect lies close to that of the estimate of the effect; moderate certainty: We are moderately confident in the effect estimate; low certainty: Our confidence in the effect estimate is limited; very low certainty: We have very little confidence in the effect estimate. ^b: The reason for lowering the rating was a a suspect of publication bias. Abbreviations: CPP: Cumulative primary patency; NIVCS: Non-thrombotic iliac vein compression syndrome; PIVTS: Post iliac vein thrombotic syndrome; CIVO: Chronic iliac vein occlusion; ATIVO: Acute thrombotic iliac vein occlusion; REM: Random effects model; NA: Not applicable; ES: Effect size; CI: Confidence interval; FEM: Fixed effects model.

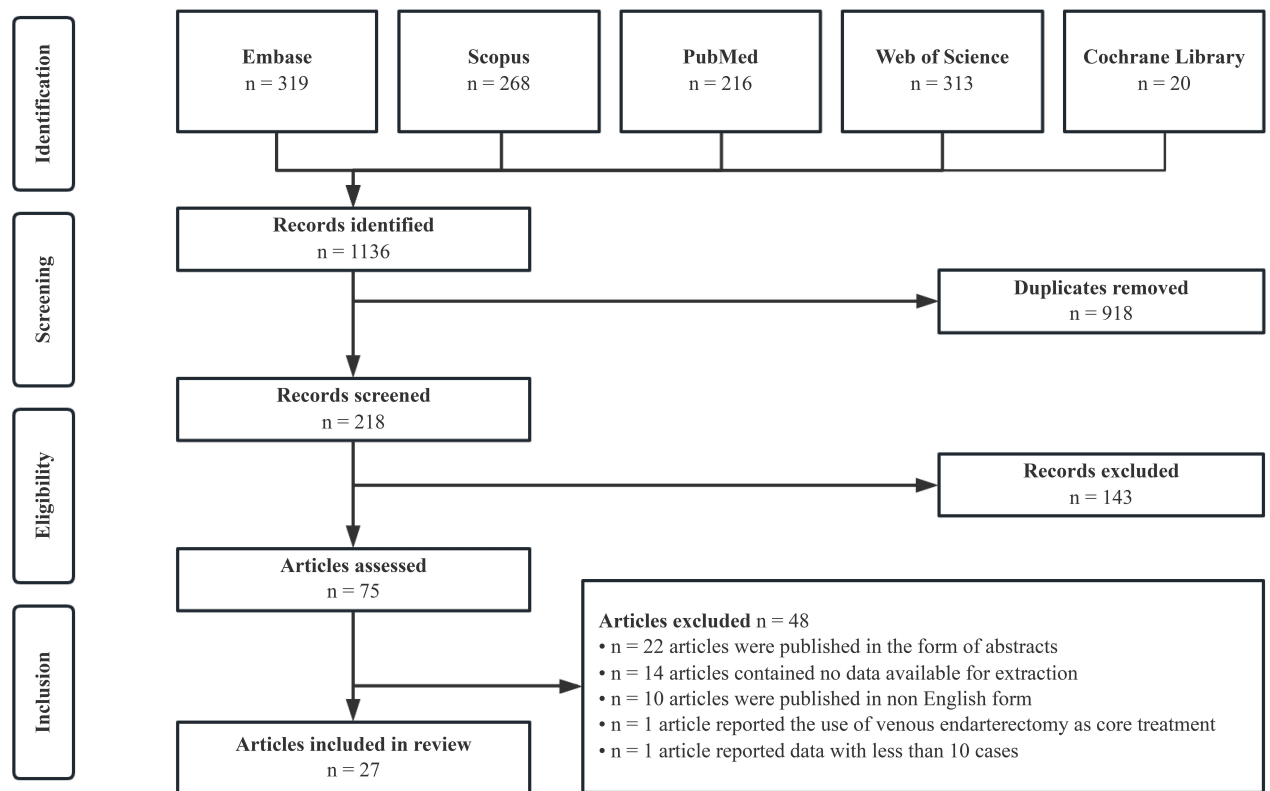


Figure 1. PRISMA flowchart

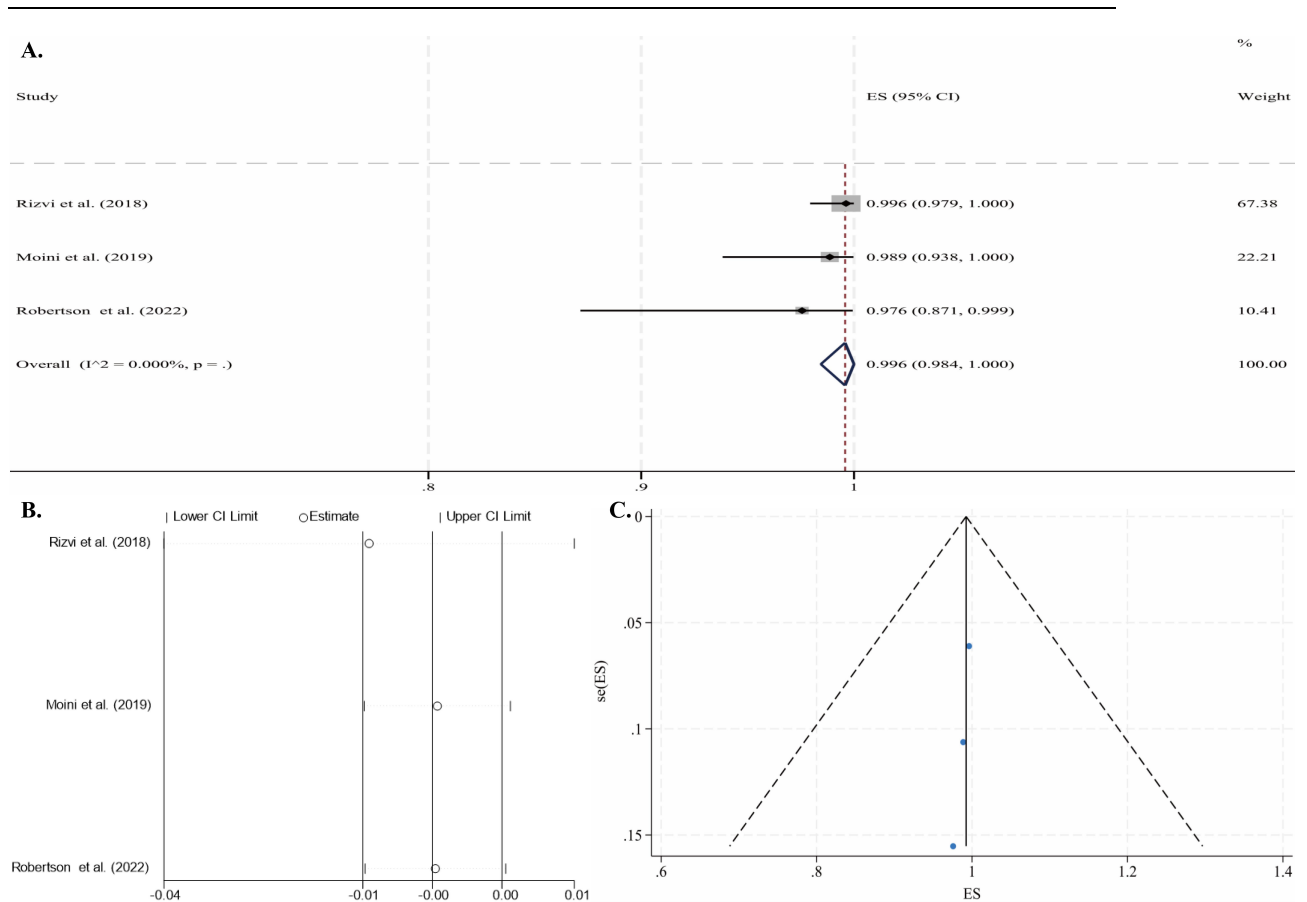


Figure 2. Pooled analysis for the 6-month CPP of NIVCSs (fixed-effect model).

(A) Forest plot of individual studies and the overall estimate; (B) Leave-one-out sensitivity analysis (each study omitted in turn); (C) Funnel plot with pseudo 95% confidence limits. Abbreviations: NIVCS: Non-thrombotic iliac vein compression syndrome; CPP: Cumulative primary patency; ES: Effect size; CI: Confidence interval.

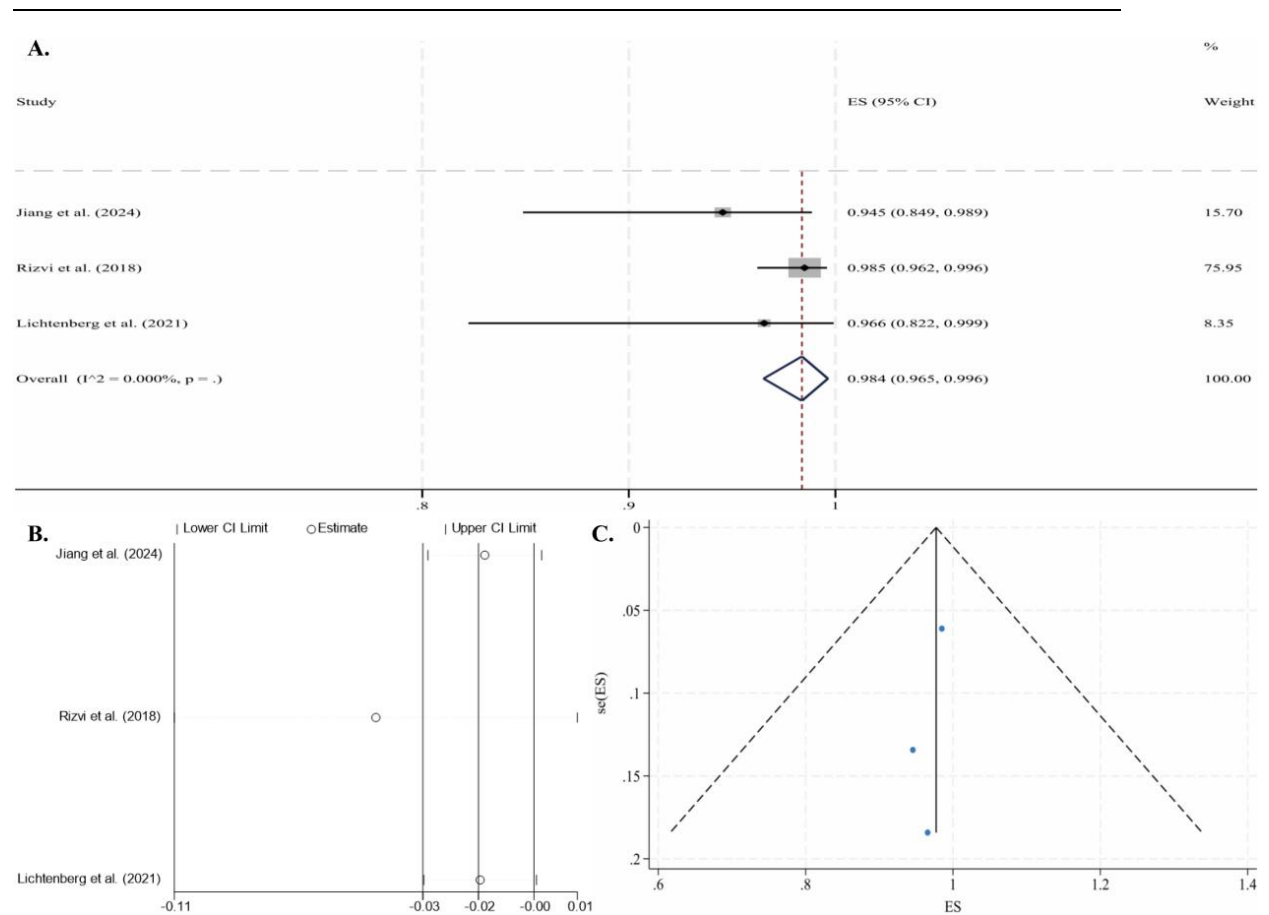


Figure 3. Pooled analysis for the 2-year CPP of NIVCSs (fixed-effect model). (A)

Forest plot of individual studies and the overall estimate. (B) Leave-one-out sensitivity analysis (each study omitted in turn). (C) Funnel plot with pseudo 95% confidence limits. Abbreviations: NIVCS: Non-thrombotic iliac vein compression syndrome; CPP: Cumulative primary patency; ES: Effect size; CI: Confidence interval.

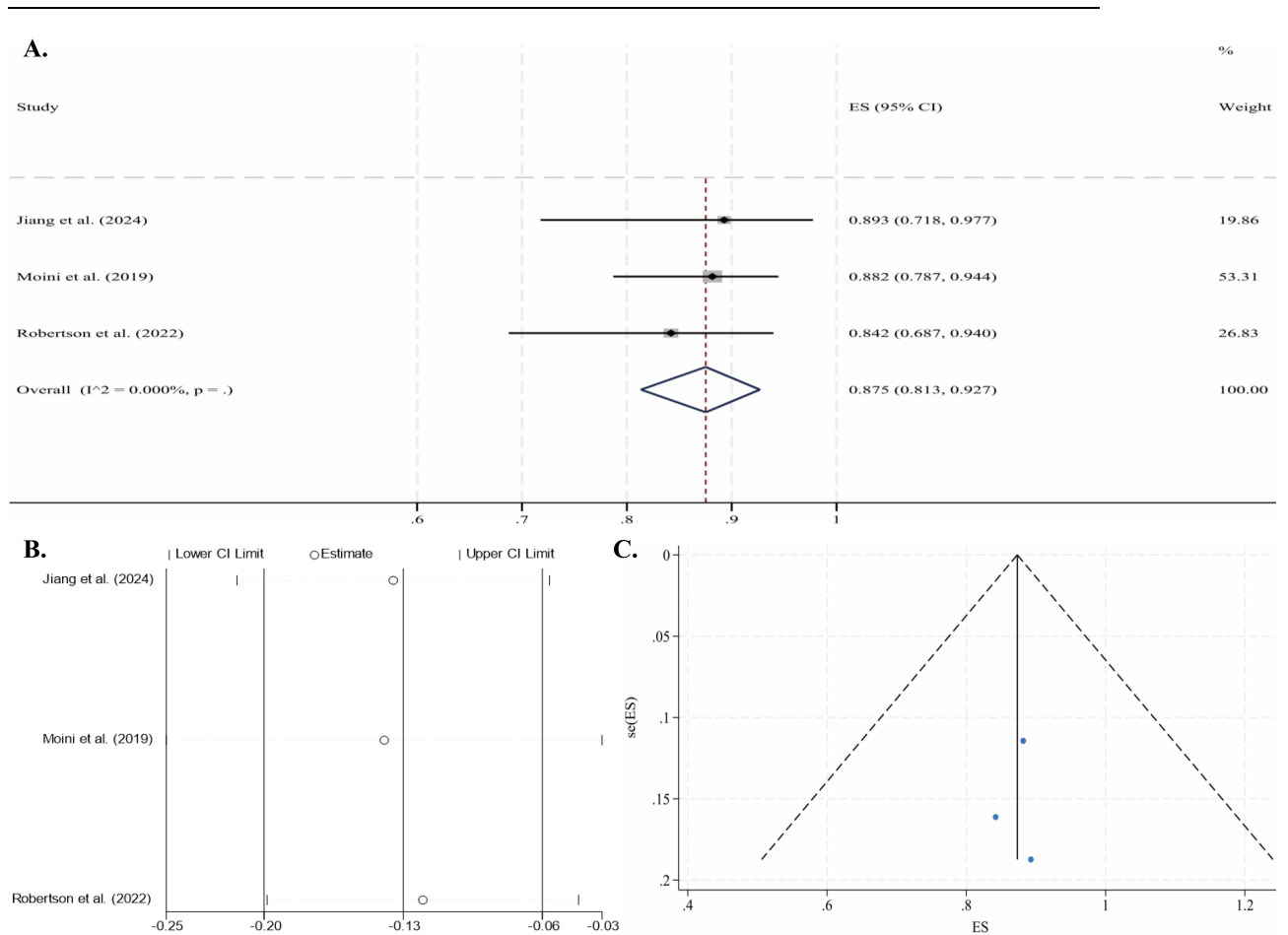


Figure 4. Pooled analysis for the 6-month CPP of PIVTSs (fixed-effect model). (A)

Forest plot of individual studies and the overall estimate. (B) Leave-one-out sensitivity analysis (each study omitted in turn). (C) Funnel plot with pseudo 95% confidence limits. Abbreviations: PIVTS: Post iliac vein thrombotic syndrome; CPP: Cumulative primary patency; ES: Effect size; CI: Confidence interval.

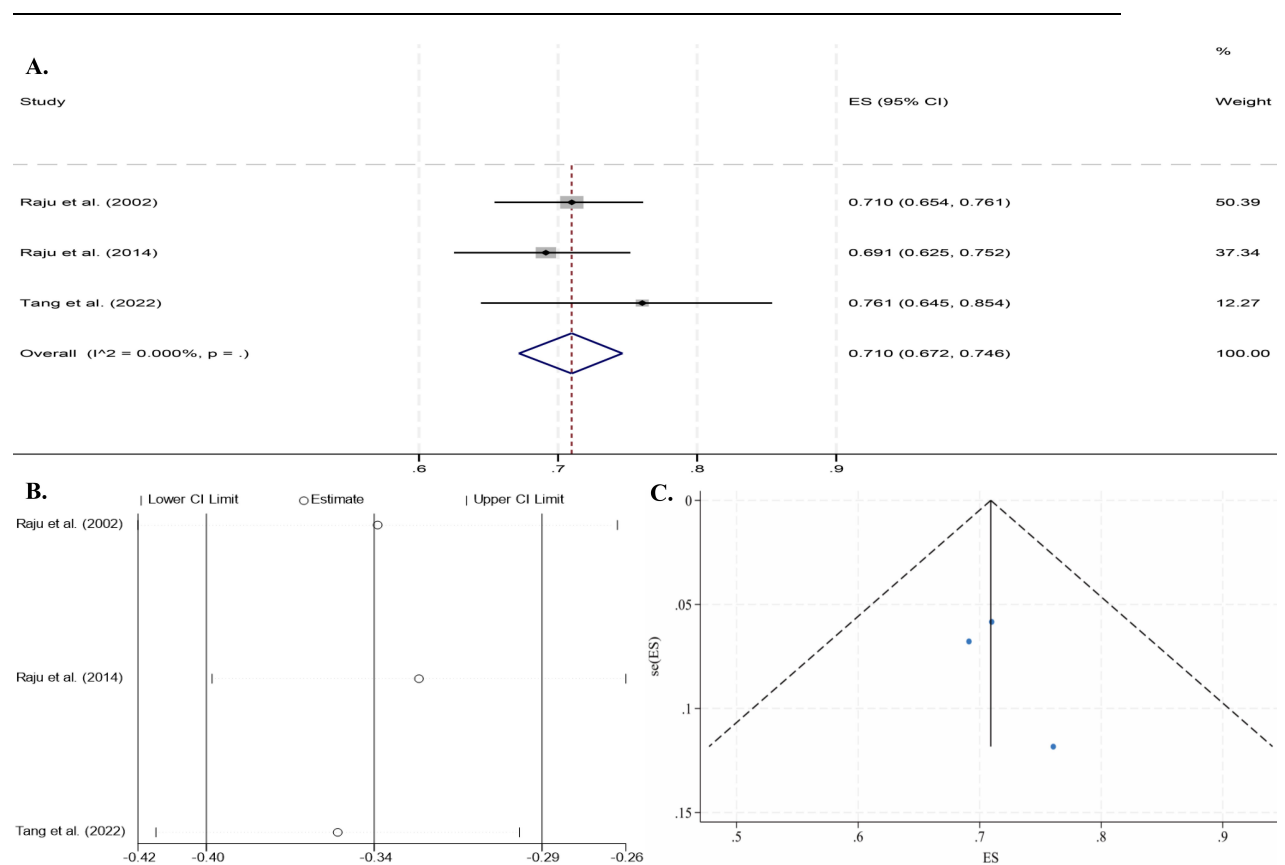


Figure 5. Pooled analysis for the 2-year CPP of CIVO (fixed-effect model). (A) Forest plot of individual studies and the overall estimate. (B) Leave-one-out sensitivity analysis (each study omitted in turn). (C) Funnel plot with pseudo 95% confidence limits. Abbreviations: ES: Effect size; CI: Confidence interval; CPP: Cumulative primary patency; CIVO: Chronic iliac vein obstruction.

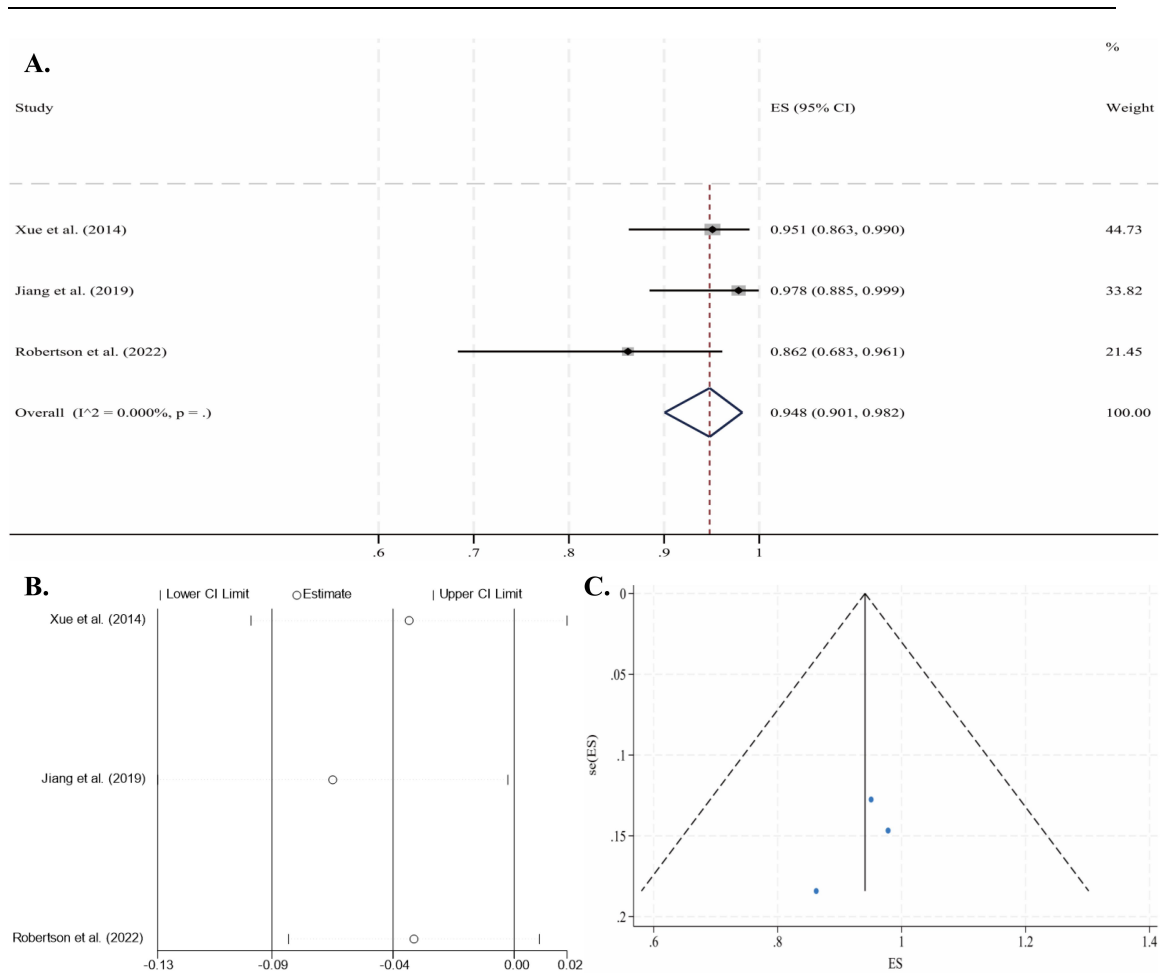


Figure 6. Pooled analysis for the 6-month CPP of ATIVOs (fixed-effect model).

(A) Forest plot of individual studies and the overall estimate. (B) Leave-one-out sensitivity analysis (each study omitted in turn). (C) Funnel plot with pseudo 95% confidence limits. Abbreviations: ATIVO: Acute thrombotic iliac vein obstruction; CPP: Cumulative primary patency; ES: Effect size; CI: Confidence interval.

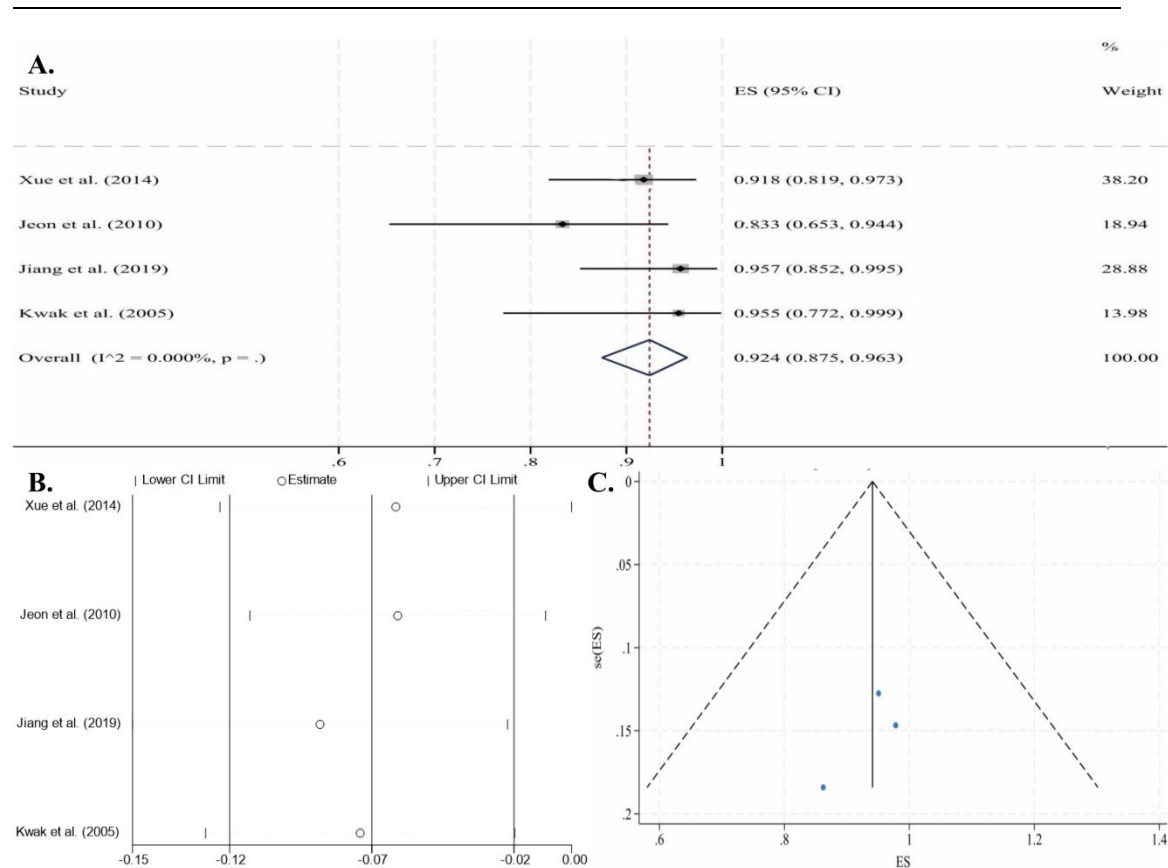


Figure 7. Pooled analysis for the 1-year CPP of ATIVOs (fixed-effect model). (A) Forest plot of individual studies and the overall estimate. **(B)** Leave-one-out sensitivity analysis (each study omitted in turn). **(C)** Funnel plot with pseudo 95% confidence limits. Abbreviations: ATIVO: Acute thrombotic iliac vein obstruction; CPP: Cumulative primary patency; ES: Effect size; CI: Confidence interval.

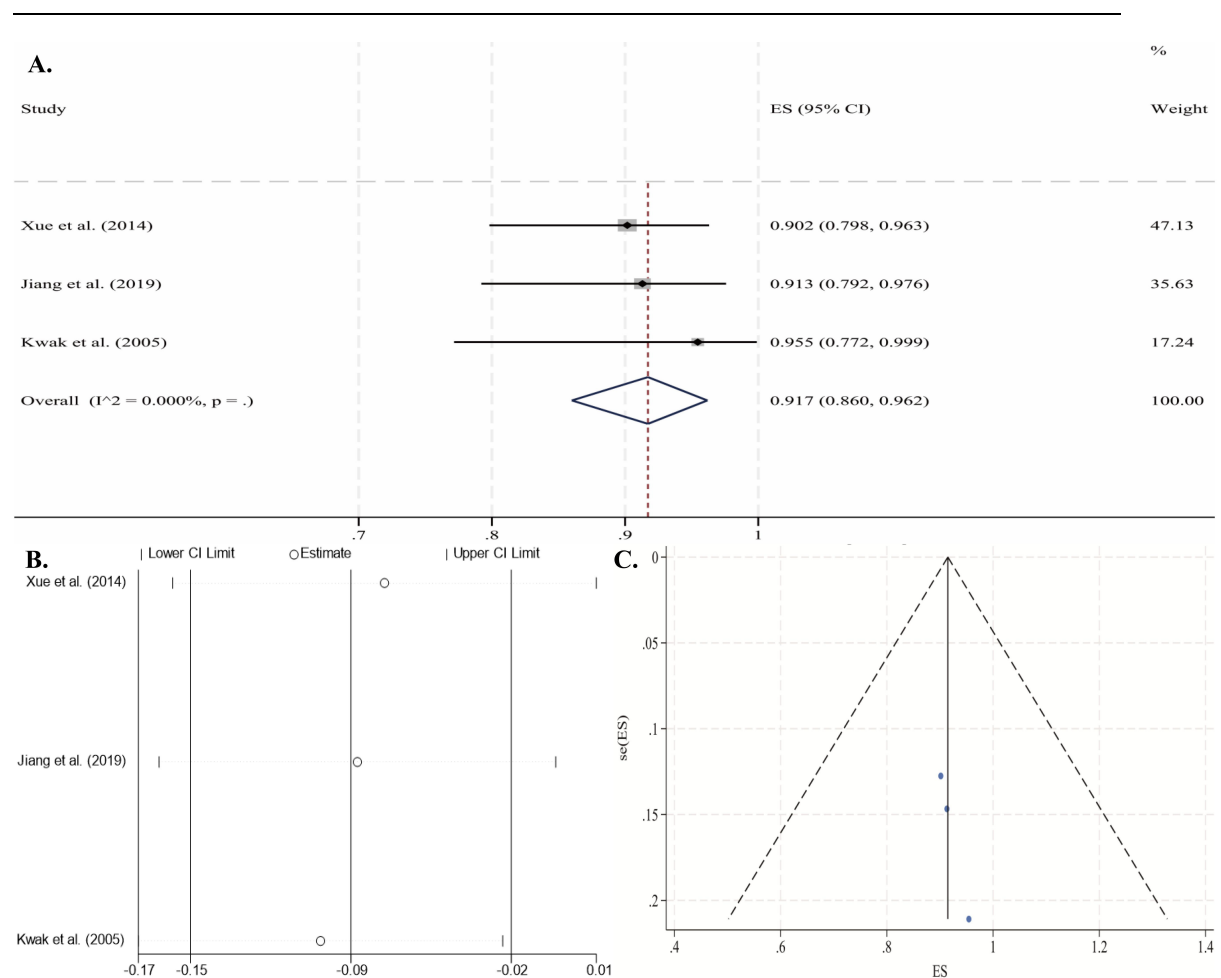


Figure 8. Pooled analysis for the 2-year CPP of ATIVOs (fixed-effect model). (A)

Forest plot of individual studies and the overall estimate. (B) Leave-one-out sensitivity analysis (each study omitted in turn). (C) Funnel plot with pseudo 95% confidence limits. Abbreviations: ATIVO: Acute thrombotic iliac vein obstruction; CPP: Cumulative primary patency; ES: Effect size; CI: Confidence interval.

SUPPLEMENTAL DATA

Supplemental data are available at the following link:

<https://www.bjbms.org/ojs/index.php/bjbms/article/view/12777/4022>

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