



TIVS versus Non-TIVS management of limb vascular injury in limb salvage: systematic review and meta-analysis

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Abstract

Background To compare the postoperative complications between temporary intravascular shunts (TIVS) and non-TIVS management in limb salvage surgery for severe limb trauma, and to provide reference for clinical decision making.

Methods The literature on postoperative complications of limb salvage with and without TIVS was searched in PubMed, Cochrane Library, Embase and MEDLINE from January 2000 to December 2023. References were screened and extracted according to inclusion and exclusion criteria, and meta-analysis was performed using RevMan5.4 software.

Results 8 studies were included, including 1375 cases, 329 of which used TIVS and 1046 of which did not. Compared with no TIVS group, TIVS group was associated with a lower rate of amputation (OR = 0.48, 95%CI: [0.29, 0.82], $P = 0.007$) and less limb ischemic time (SMD = -0.96, 95%CI: [-1.17, -0.74], $P < 0.00001$), the incidence of thrombosis (OR = 1.48, 95%CI: [0.46, 4.78], $P = 0.51$), fasciotomy (OR = 0.84, 95%CI: [0.30, 2.36], $P = 0.75$) and infection (OR = 0.88, 95%CI: [0.35, 2.19], $P = 0.78$) were not statistically significant.

Conclusion Compared with no TIVS group, TIVS group may reduce amputation rate and limb ischemia time, prospective multi-centre studies are needed for further evaluation.

Keywords Temporary intravascular shunt · Amputation · Infection · Fasciotomy · Thrombosis

Introduction

Extremity vascular injury tend to occur in explosion and gunshot injury, traffic injury, high fall injury and Industrial injury. Vascular injury will cause local bleeding and distal limb ischemia. If not timely intervention, it will cause limb necrosis and other risks [1, 2].

Since the advent of temporary vascular shunts (TIVS) in the early twentieth century, TIVS has been widely used in extremity vascular injury [3, 4]. Many studies have shown that TIVS can quickly restore limb blood supply, reduce limb ischemia time, and improve limb salvage [5–10]. However, some literatures have different reports, they advocated that TIVS were prone to thrombosis, bacterial adhesion infection, and secondary vascular injury, which could not enhance the limb salvage [11]. There remains debate regarding the utilization of TIVS, therefore, we performed a meta-analysis of

postoperative complications with or without TIVS in vascular injury of limbs, which was the first meta-analysis to combine complication data for use of TIVS in clinic.

Materials and methods

Literature search

The review was performed in accordance with the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-analyses). We systematically searched PubMed, Cochrane Library, Embase, Medline for literature comparing postoperative complications in limb salvage with and without temporary vascular shunt (TIVS) for vascular injury in extremities. We considered studies published between January 2000 to December 2023, for which there were no language restrictions. The search terms used in the title, abstract and keyword fields include temporary vascular shunt as follows: (“temporary vascular shunt” OR “temporary intravascular shunt” OR “temporary arterial shunt” OR “temporary shunt”).

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Study selection

The titles and abstracts of the retrieved literature were evaluated by two investigators (D.X and F.Z). If the abstract did not provide sufficient data, the full text was reviewed. The inclusion criteria were as follows: (1) A clinical study comparing postoperative complications with and without TIVS in patients with vascular injury in the extremities. (2) The sample size of each group should more than 5 cases. (3) The study types were cohort study, case-control study and randomized controlled study. The exclusion criteria were as follows: (1) Case reports, reviews, reviews, systematic reviews, and non-comparative studies. (2) Animal experimental research, anatomical research. (3) Research with incomplete data, data must be available for the same complication in both groups.

Data extraction and quality assessment

Literature data conforming to the criteria were extracted by two independent reviewers (D.X and F.Z) and coordinated by a third reviewer (X.W) when there were disagreements, disagreements were resolved by consensus. The extracted data included first author, publication year, study design, number of patients, indication, gender, age, injury severity score(ISS), hospital length of stay(HLOS), limb ischemic time, the incidence of amputation, thrombosis, fasciotomy and infection. The quality of each included studies was assessed using the Newcastle–Ottawa Scale (NOS) [14]. The Grading of Recommendations Assessment, Development, and Evaluation (GRADE) system was used to assess the quality of evidence [15].

Statistical analyses

Meta-analysis was performed using Revman 5.4 software. Continuity variables were represented by mean difference (MD), and dichotomous variables were represented by odds ratio (OR). Heterogeneity was determined according to I^2 statistical. When $I^2 < 50\%$, the heterogeneity was low, and fixed effect model was used. On the contrary, it indicates that the heterogeneity is high, and the random effects model is used. $P < 0.05$ was considered statistically significant. Visual analysis of funnel plots and the Egger test were used to evaluate the literature for bias. We adopted sensitivity analysis to assess the robustness of outcome by omitting one study at a time. We also performed subgroup analyses according to identity of patients (soldiers and civilians), to seek for the source of heterogeneity.

Results

Search

Figure 1 presents the Flow diagram of search and selection of studies. A total of 8 articles were included 6 retrospective cohort studies and 2 prospective cohort studies.

Study characteristics

The 8 studies included 1375 patients, 329 used TIVS and 1,046 did not. Basic information of included studies and data of postoperative complications were described in Table 1.

Summary of the main overall results of included studies was showed in Table 2. The quality of evidence was analyzed by the GRADE system (Table 3). The outcome of amputation was moderate quality and limb ischemic time was low quality. The quality of evidence was very low for the outcome of thrombosis, fasciotomy and infection. Quality assessment of the included studies by Newcastle–Ottawa Scale revealed two nine-star studies, three eight-star studies, three seven-star studies (Table 4). The publication bias is reported visually using funnel plots (Fig. 2).

Amputation

Seven studies compared the rates of amputation with and without TIVS, involving 1084 cases, 22 amputations in 257 cases with TIVS and 97 amputations in 827 cases without TIVS (Fig. 3). There was low heterogeneity among studies ($P = 0.16$, $I^2 = 35\%$), so fixed-effect model was used. The results showed that the amputation rate after TIVS was significantly lower than that without TIVS (OR = 0.48, 95%CI: [0.29, 0.82], $P = 0.007$), and the difference was statistically significant. The funnel plot was asymmetrical which suggested a high risk of publication bias. The Egger test result was indicative of a publication bias ($P = 0.006$).

Limb ischemic time

Four studies compared limb ischemia time with and without TIVS, involving a total of 457 cases (Fig. 4). There was low heterogeneity among studies, so fixed-effect model was used ($P = 0.25$, $I^2 = 27\%$). The results showed that the limb ischemia time after TIVS was significantly lower than that without TIVS (SMD = -0.96 , 95%CI:

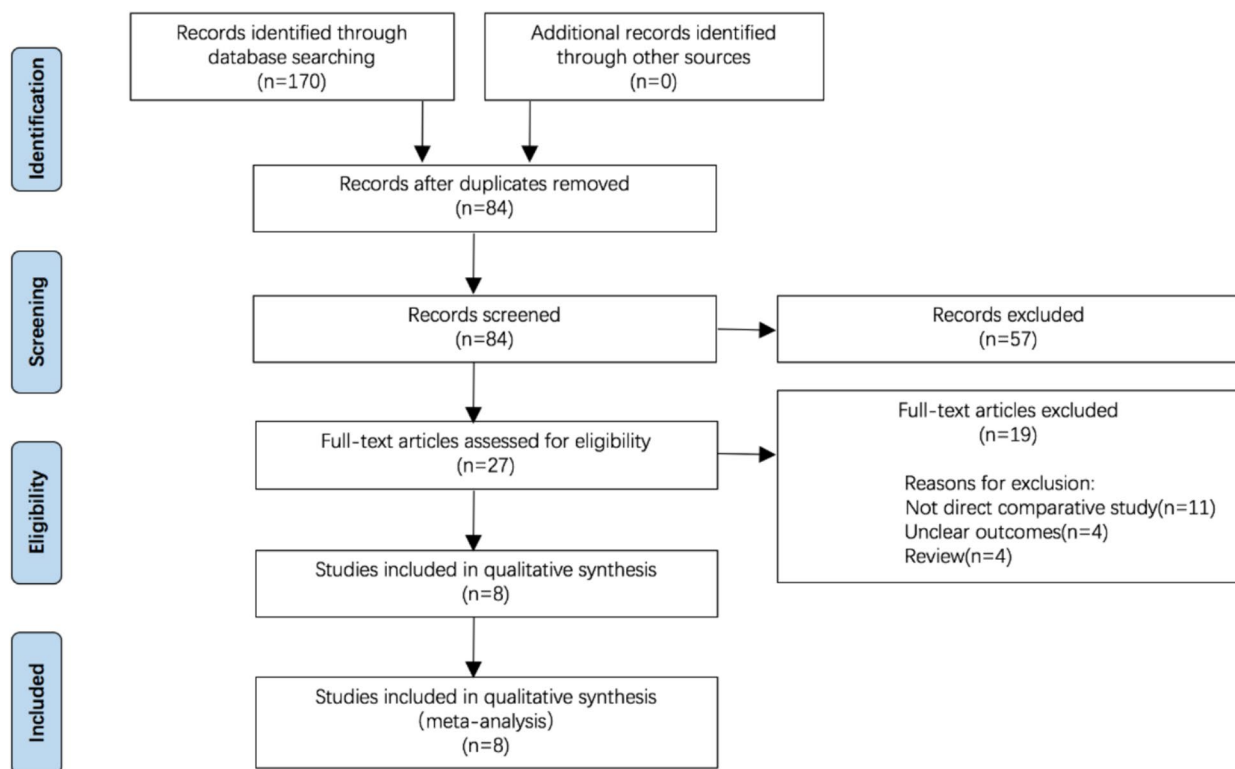


Fig. 1 Flowchart diagram of included literatures

$[-1.17, -0.74]$, $P < 0.00001$), and the difference was statistically significant. The funnel plot was symmetrical which suggested a low risk of publication bias. The Egger test result was negative of a publication bias ($P = 0.547$).

Fasciotomy

The rate of postoperative fasciectomy with and without TIVS was compared in 5 literatures, involving a total of 987 cases, of which 114 of 204 cases were performed with TIVS and 325 of 783 cases were performed without TIVS (Fig. 5). Because of high heterogeneity among studies, a random effects model was used ($P < 0.0001$, $I^2 = 84\%$). The results showed that there was no significant difference in fascial incision rate between TIVS and TIVS ($OR = 0.57$, 95%CI: $[0.19, 1.70]$, $P = 0.31$). We performed leave-one-out sensitivity analyses and found that there were not any changes in the overall effect measures. No significant differences in soldiers or civilians were found between the TIVS group and the no-TIVS group among the subgroups. The funnel plot was asymmetrical which suggested a high risk of publication bias. The Egger test result was indicative of a publication bias ($P = 0.005$).

Infection

Two studies compared the incidence of infection after TIVS use with no TIVS use, involving a total of 787 cases, of which 7 out of 102 cases using TIVS and 30 out of 685 cases without TIVs were infected (Fig. 6). There was low heterogeneity among studies, so fixed-effect model was used ($P = 0.38$, $I^2 = 0\%$). The results showed that the incidence of infection after TIVS was not significantly different from that without TIVS ($OR = 0.88$, 95%CI: $[0.35, 2.19]$, $P = 0.78$). The funnel plot was asymmetrical which suggested a high risk of publication bias. The Egger test was not used for infection because only two literatures mentioned it.

Thrombosis

The incidence of thrombus after TIVS was compared with that without TIVS in three studies, involving a total of 1035 cases, of which 20 out of 181 cases with TIVS and 54 out of 854 cases without TIVs developed thrombus (Fig. 7). Because of high heterogeneity among studies, a random effects model was used ($P = 0.04$, $I^2 = 69\%$). The results showed that the incidence of thrombus after TIVS was not significantly different from that without TIVS ($OR = 1.48$, 95%CI: $[0.46, 4.78]$, $P = 0.51$). Due to limited numbers of

Table 1 Basic information of included studies

Study	Year	Study type	Number of patients		Age (years)		Gender		ISS ^a	HLOS (days) ^a	
			TIVS	No TIVS	TIVS	No TIVS	males	female		TIVS	No TIVS
Hasde et al. [5]	2018	RCS	24	72	28.04	28.41	91	5	NR	NR	NR
Ball et al. [6]	2010	RCS	7	15	35	32	NR	NR	NR	21	18
Borut et al. [7]	2010	RCS	46	34	23.5	24.24	NR	NR	15 ± 5.05	12.9 ± 10.18	NR
Hossny et al. [8]	2004	PCS	7	10	30.1	28.3	NR	NR	9.3 ± 3.49	9.9 ± 3.57	NR
Polez et al. [9]	2020	PCS	78	613	35.85	34.83	578	113	18.83 ± 11.76	14.93 ± 10.46	NR
Gifford et al. [10]	2009	RCS	64	61	25.5	27	NR	NR	17.6 ± 9.9	15.1 ± 8.5	NR
Wlodarczyk et al. [12]	2018	RCS	72	219	35.3	36.7	192	99	15.92 ± 10.6	14.56 ± 8.9	> 15d(58.3%) > 15d(56.4%)
Martinelli et al. [13]	2023	RCS	31	22	NR	NR	30	23	17	18	NR
Study											
			Amputation		Fasciotomy		Infection		Thrombosis		ischemic time(minutes)
			TIVS	No TIVS	TIVS	No TIVS	TIVS	No TIVS	TIVS	No TIVS	TIVS
Hasde et al. [5]			1	17	7	33	5	20	NR	NR	290.4 ± 110.4
Ball et al. [6]			0	7	3	14	NR	NR	NR	NR	357 ± 115.2
Borut et al. [7]			6	7	NR	NR	NR	NR	NR	NR	NR
Hossny et al. [8]			0	4	NR	NR	NR	NR	NR	NR	NR
Polez et al. [9]			4	51	45	221	2	10	11	29	268.8 ± 74.14
Gifford et al. [10]			10	7	42	37	NR	NR	NR	NR	329.5 ± 42.84
Wlodarczyk et al. [12]			NR	NR	NR	NR	NR	NR	9	23	119 ± 120
Martinelli et al. [13]			1	4	17	20	NR	NR	0	2	250.2 ± 142.2
											348.6 ± 75.6

ISS injury severity score, *HLOS* hospital length of stay, *RCS* retrospective cohort study, *PCS* prospective cohort study, *NR* not report

^aData are reported as mean ± SD, mean (range) or mean alone

Table 2 Summary of the main overall results in this meta-analysis

Outcome	No. of studies	Patients	Events		OR (95% CI)	I ² (%)	P value
			TIVS	No TIVS			
Amputation	7	1084	22(8.6)	97(11.7)	0.48(0.29, 0.82)	35	0.007
Limb ischemic time	4	457	230.8 ± 47.9 ^a	318.1 ± 33.8 ^a	−0.96(−1.17, −0.74) ^b	27	<0.00001
Fasciotomy	5	987	114(55.9)	325(41.5)	0.57(0.19, 1.70)	84	0.31
Infection	2	787	7(6.9)	30(4.4)	0.88(0.35, 2.19)	0	0.78
Thrombosis	3	1035	20(11.0)	54(6.3)	1.48(0.46, 4.78)	69	0.51

TIVS temporary vascular shunts group, no TIVS no temporary vascular shunt group

Data presented as number, number (%), or mean ± standard deviation

Boldface P values represent statistical significance

^aStandard Error

^bStd Mean difference

Table 3 The Grading of Recommendations Assessment, Development, and Evaluation (GRADE) system assessment for the quality of evidence

Outcome	No. of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Quality
Amputation	7	Observational	No	No	No	No	None	Moderate
Limb ischemic time	4	Observational	No	No	No	No	None	Low
Fasciotomy	5	Observational	Serious	No	No	Serious	Reporting bias	Very low
Infection	2	Observational	No	No	No	No	Reporting bias	Very low
Thrombosis	3	Observational	No	No	No	No	Reporting bias	Very low

High quality: Further research is very unlikely to change our confidence in the estimate of effect

Moderate quality: Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate

Low quality: Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate

Very low quality: We are very uncertain about the estimate

studies, we did not perform any subgroup analyses and sensitive analyses. The funnel plot was symmetrical which suggested a low risk of publication bias. The Egger test was not used for infection because only three literatures mentioned it.

Discussion

In 1915, Tuffier designed a paraffin-coated silver tube as a temporary vascular pipe for the establishment of early limb blood perfusion [16], which was the earliest practice of TIVS technology. The idea of TIVS is to quickly restore blood supply to limbs, reduce ischemia time, and improve limb preservation rate by bridging a temporary pipe for damaged blood vessels [17]. Some scholars have reported that TIVS is prone to cause secondary vascular injury, infection and other problems [11], so there is still some controversy over whether to use TIVS or not. In this study, there was no statistical significance in the incidence of fasciotomy, infection and thrombosis between TIVS and non-TIVS group,

while in the amputation rate and limb ischemia time, TIVS group was significantly better than non-TIVS group.

In the case of limb vascular injury, limb ischemia time is an important factor for limb survival and functional recovery. Muscle degeneration occurs after 6 h of ischemia, and irreversible limb injury occurs after 12 h [18, 19]. This study showed that the ischemia time of TIVS group was significantly less than that of the non-TIVS group, and TIVS enabled the limb to receive blood perfusion as soon as possible through temporary bridging of blood vessels. In 2019, Hasde et al. [5] conducted a retrospective study on patients with lower limb artery injury in the Syrian civil war and found that the limb ischemia time of patients in the TIVS group was significantly lower than that in the non-TIVS group. Włodarczyk et al. [12] made statistics on limb trauma patients with vascular injury in 6 level I trauma centers in the United States, and found that the ischemia time of the non-TIVS group was almost twice that of the TIVS group. David et al. [20] performed a novel type of temporary intravascular shunting for an amputated hand by connecting ulnar arteries and superficial femoral arteries. This reduced

Table 4 Quality assessment of the included studies by Newcastle–Ottawa quality assessment scale

Author	year	Representativeness of the exposed cohort	Selection of the nonexposed cohort	Ascertainment of exposure	Outcome of interest was not present at start of study	Comparability of cohorts on the basis of the design or analysis	Assessment of outcome	Was follow-up long enough for outcomes to occur	Adequacy of follow up of cohorts	Total
Hasde et al. [5]	2018	0	1	1	1	0	1	1	1	6
Ball et al. [6]	2010	1	1	1	1	1	1	1	1	8
Borut et al. [7]	2010	0	1	1	1	0	1	1	1	6
Hossny et al. [8]	2004	1	1	1	1	2	1	1	1	9
Polcz et al. [9]	2020	1	1	1	1	2	1	1	1	9
Gifford et al. [10]	2009	0	1	1	1	0	1	1	1	6
Włodarczyk et al. [12]	2018	1	1	1	1	1	1	1	1	8
Martinelli et al. [13]	2023	1	1	1	1	1	1	1	1	8

ischemia time of the hand and resulted in a good long-term functional outcome.

Osteofascial compartment syndrome is a devastating limb complication, and timely fascial incision and relaxation is necessary [21–23]. It has been reported that TIVS can quickly restore blood supply, reduce ischemia–reperfusion injury, the incidence of compartment syndrome and the rate of late fasciectomy [24], but there was no significant statistical significance in the rate of fasciectomy between two groups, which may be related to that some studies had made preventive partial fasciectomy before using TIVS, which would affect the data of TIVS' function for fasciectomy [25].

There were few literatures on the incidence of thrombosis and infection included in this study, showing no statistical significance in the incidence of thrombosis and infection. In terms of the incidence of thrombosis, although TIVS has been proved to reduce ischemic time, the incidence of thrombosis in TIVS group in this study was higher than that without TIVS (11.0% vs 6.3%). This may be related to the longer retention time of TIVS. It has been reported that complications such as thrombosis and infection are related to TIVS retention time. Sarah et al. [26] conducted a retrospective study on patients who used TIVS in their trauma center from 2005 to 2013, and found that no complications occurred in patients whose TIVS retention time was less than 6 h. Over 6 h, 31.2% of patients had thrombosis and other complications. Oliver et al. [27] retrospectively reported that one-fifth of the patients with TIVS retained for more than 24 h had thrombosis. Ding et al. [28] applied TIVS to the superior mesenteric artery injury control surgery in pigs, and found that the use of TIVS for more than 9 h would damage vascular endothelial cells, resulting in thrombosis and other complications.

The results of this meta-analysis showed that the amputation rate of the TIVS group was significantly lower than that of the non-TIVS group, although the ISS score of limb injury was generally higher than that of the TIVS group, which was also reported in many non-controlled studies. Suvit et al. [29] reported that after early use of TIVS in 33 patients with severe limb vascular injury from 1996 to 2000, none of which resulted in amputation, he suggested that early use of TIVS is important, in addition to reducing ischemic time, but also allowing surgeons to manage other limb injuries promptly and safely. Taller et al. [30] reported a retrospective study on American military wounded with severe limb injuries during the Iraq War and found that early use of TIVS could make the wounded safely and stably transferred to regional trauma centers, and the eventual limb preservation rate reached 100%.

The current study has some limitations. First, only 8 studies were included for analysis, most of which were retrospective studies, and there was a lack of randomized controlled studies with high evidence value, which could not eliminate the

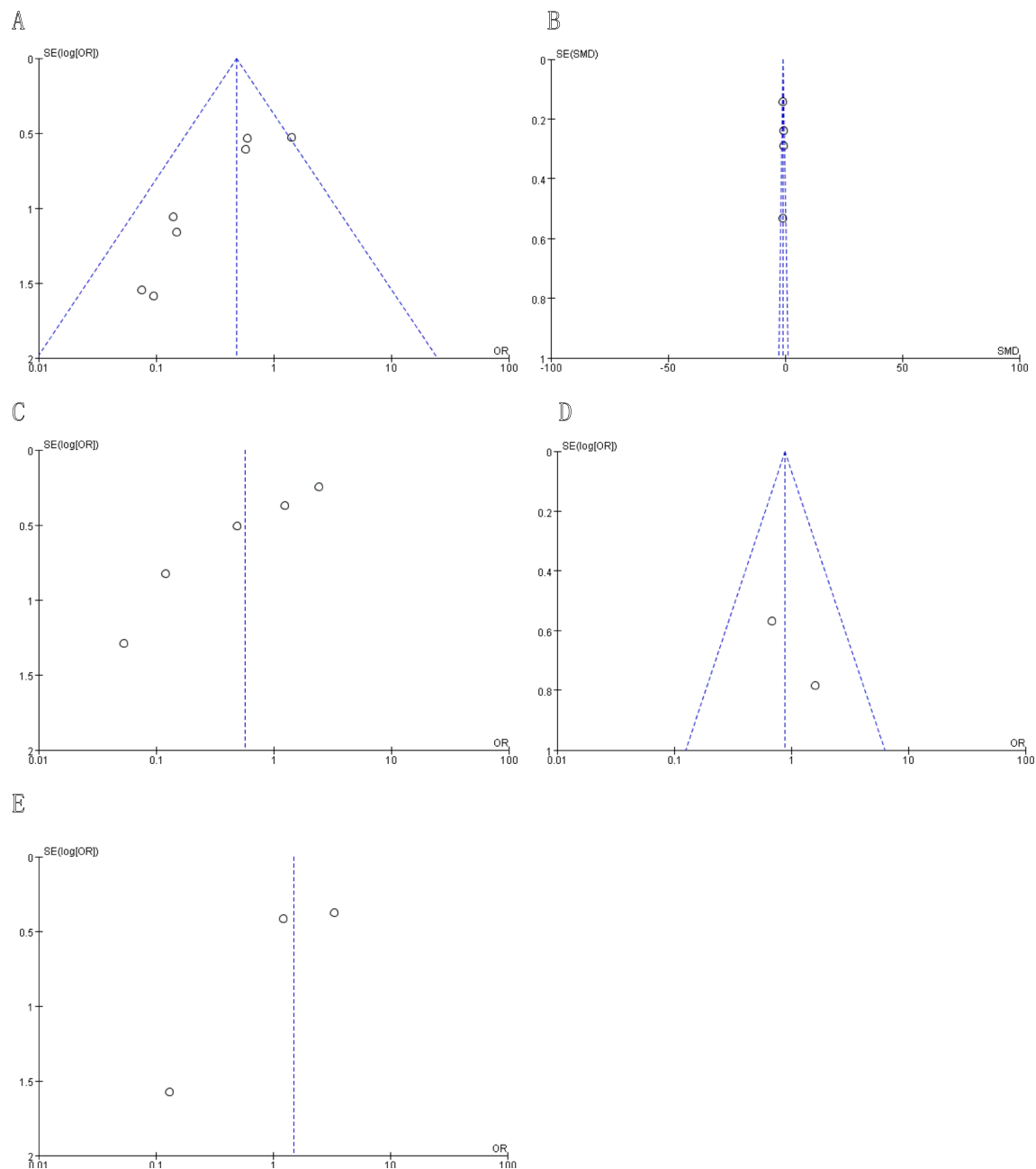


Fig. 2 A, Funnel plot for Amputation. B, Funnel plot for Limb ischemic time. C, Funnel plot for Fasciotomy (random effects model used because of high heterogeneity [$I^2=84\%$]). D, Funnel plot for

Infection. E, Funnel plot for Thrombosis (random effects model used because of high heterogeneity [$I^2=69\%$]). OR, Odds ratio; SE, standard error; SMD, Std Mean difference

bias caused by the type of study. Second, according to the ISS score obtained by statistics, the degree of limb injury in the non-TIVs group is more serious than that in the TIVs group, which will lead to a certain bias of results. Third, the retention time of TIVs, anticoagulant drugs and TIVs materials, also affected the occurrence of limb complications. The influence of the above factors on limb complications should be further explored in the future to reduce the risk of infection and vascular damage caused by TIVs. Fourth, the possibility

of publication bias was high, as demonstrated by the results from Funnel Plot. Finally, the HLOS, cost, patient satisfaction and other evaluation indicators are suggested to be added in analysis.

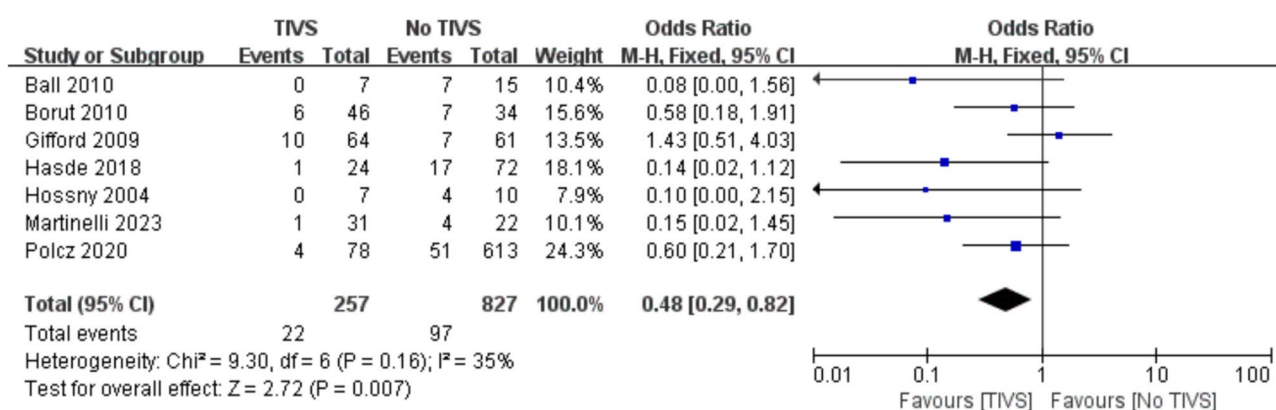


Fig. 3 Forest plots of comparison of amputation between two groups

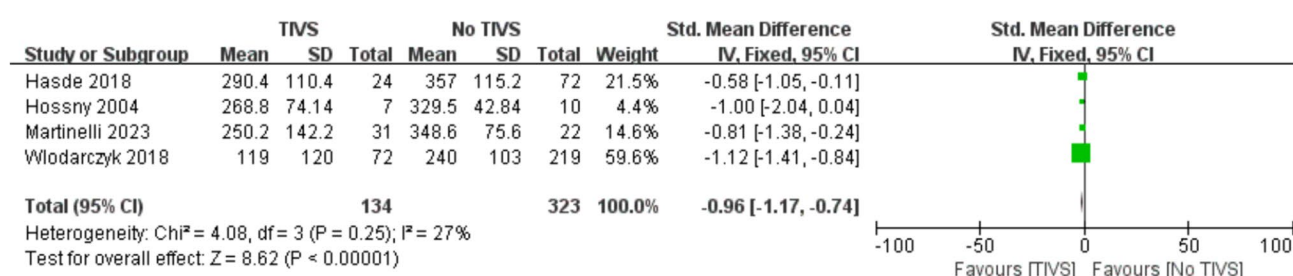


Fig. 4 Forest plots of comparison of limb ischemia time between two groups

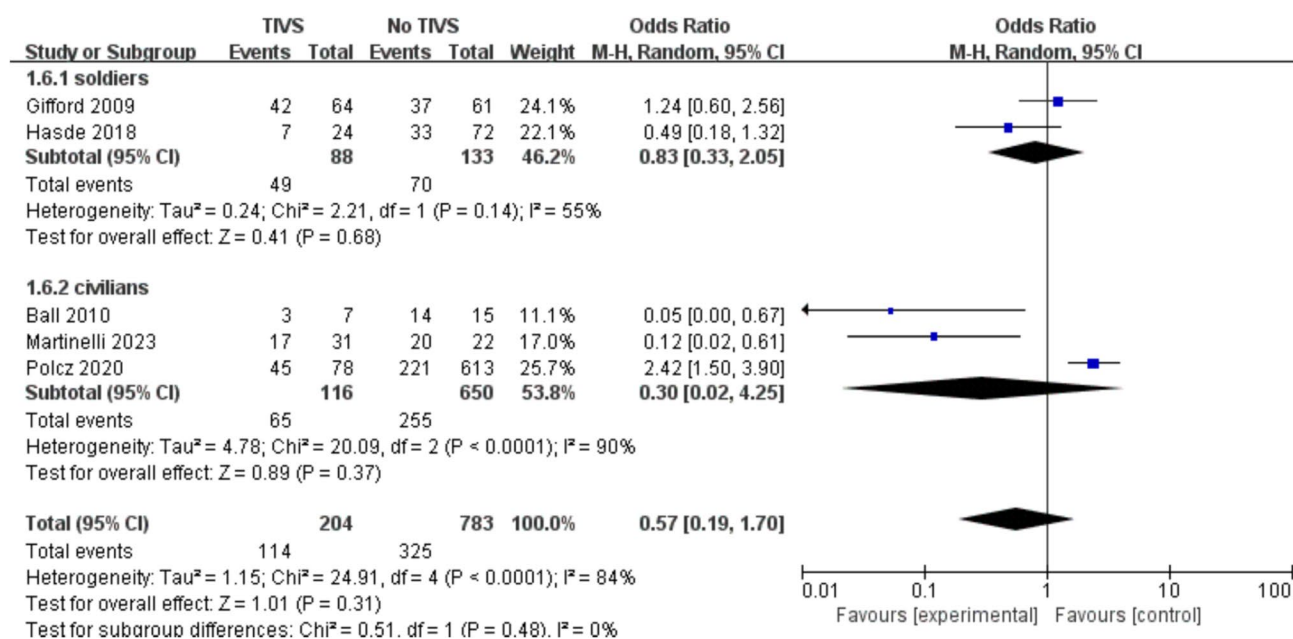


Fig. 5 Forest plots of comparison of fasciotomy between two groups (subgroup analyses)

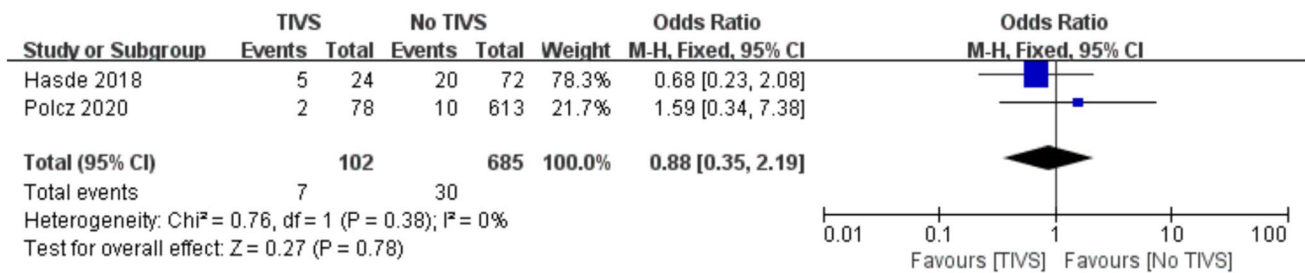


Fig. 6 Forest plots of comparison of Infection between two groups

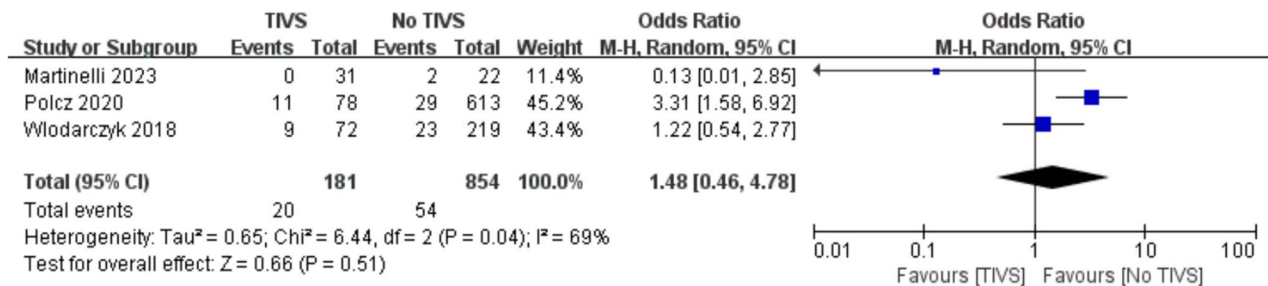


Fig. 7 Forest plots of comparison of thrombosis between two groups

Conclusions

The application of TIVS in limb salvage for vascular injury in extremities may have more advantages in terms of limb ischemia time and amputation rate. Large data, multi-center, high quality randomized controlled studies are still needed for further evaluation.

Author contribution Conception and design: DX, XW Analysis and interpretation: DX, FZ, SL Data collection: JL, ML, CL, JP Writing the article: DX, FZ Critical revision of the article: SL, JL, ML, CL, JP, XW Final approval of the article: DX, FZ, SL, JL, ML, CL, JP, XW Statistical analysis: DX, FZ, SL Overall responsibility: XW.

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Data availability No datasets were generated or analysed during the current study.

Declarations

Ethical approval Not applicable.

Competing interests The authors declare no competing interests.

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