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Clinical Outcome of Endovascular Therapy vs Open surgery for for acute iliac artery thrombosis: a retrospective cohort study

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Abstract

Objective

This single-center retrospective cohort study compared open surgery(Open) versus endovascular therapy (EVT) for acute lower limb ischemia.

Methods

A total of 92 patients were enrolled (37 in the Open group, 55 in the EVT group). The primary endpoints were major adverse limb events (MALE) and cardiovascular/cerebrovascular mortality(MACE) .

Results

The open surgery group had lower rates of clinically driven target lesion revascularization (5.02% vs. 22.01%) and MALE (10.38% vs. 33.76%) at one year (HR for MALE = 0.34, P = 0.047). No significant difference was observed in major adverse cardiovascular and cerebrovascular events (MACE) between the two groups (HR = 1.86, P = 0.239). Subgroup analyses revealed that in patients aged ≥ 80 years, female sex, hemoglobin < 160 g/L, platelet count ≥ 180, or urea ≥ 6.28, open surgery was associated with a significantly higher risk of MACE (HR = 7.69, 10.44, 5.99, 9.76, and 9.90, respectively; all P < 0.05). In patients aged < 80 years, open surgery had a lower risk of MALE (HR = 0.17, P = 0.028). In patients with neutrophil count < 7, the aspiration group had a significantly lower risk of MALE than open surgery (HR = 0.12, P = 0.048).

Conclusion

Open thrombectomy may be superior to aspiration thrombectomy in preventing limb-related events at one year, but it carries higher cardiovascular and cerebrovascular risks in elderly, female, anemic, or those with elevated platelet count or renal dysfunction. Treatment should be individualized.

Clinical trial registration

Not applicable. This study was a retrospective observational cohort study and was not a clinical trial.

Introduction

Acute limb ischemia (ALI), a vascular surgical emergency, has clinical outcomes that directly impact limb viability and patient survival, carrying high risks of amputation and mortality[1,2]. Although its overall incidence is relatively low, the number of ALI cases is increasing due to population aging and the

growing burden of atherosclerotic disease[3,4]. The urgency of treatment is extreme, as delayed management can lead to irreversible tissue necrosis, with a 30-day mortality rate of 5%–15% and a persistently high risk of amputation [2,5].Among the anatomical distributions of ALI, occlusions at the iliac artery level hold particular clinical significance. As the main inflow tract for lower limb perfusion, acute thrombosis of the iliac artery rapidly causes extensive limb ischemia, often resulting in more severe symptoms and presenting greater technical challenges and complexity for revascularization[6,7] .In the face of acute iliac artery thrombosis, rapid restoration of blood flow is the primary treatment goal. Traditionally, open surgical revascularization has been the cornerstone of therapy. This includes Fogarty catheter embolectomy for embolic occlusions; for in-situ thrombosis due to severe atherosclerotic stenosis or occlusion, arterial endarterectomy, patch angioplasty, or aorto-iliac/femoral bypass grafting may be required [1,3,5]. The advantage of open surgery lies in its ability to directly and rapidly remove thrombus and address underlying arterial pathology, making it particularly suitable for cases of severe ischemia requiring immediate reperfusion. However, it is more invasive, demands better overall patient fitness, and carries a non-negligible risk of perioperative complications such as myocardial infarction, stroke, hemorrhage, and compartment syndrome[8,9]. Endovascular techniques offer a minimally invasive alternative for ALI, with a diverse array of strategies. These include catheter-directed thrombolysis (CDT), which infuses thrombolytic agents to dissolve the clot; percutaneous mechanical thrombectomy (PMT), using aspiration or rheolytic devices for physical clot removal; and balloon angioplasty with or without stenting for underlying stenoses or occlusions[10–12]. These techniques can be used alone or in combination, forming "hybrid" procedures—for example, combining femoral artery cutdown for thrombectomy with endovascular angioplasty[13,14]. Due to their minimally invasive nature, endovascular therapies may theoretically reduce the risk of systemic perioperative complications and shorten hospital stays, though they might be associated with a higher rate of early re-intervention[8,9,15].

The evidence comparing endovascular therapy and open surgery presents a complex and sometimes contradictory picture. Several large observational studies and meta-analyses suggest that, in the general ALI population, an endovascular-first strategy is associated with lower in-hospital mortality, myocardial infarction, major bleeding, and fasciotomy rates, although amputation rates in most studies show no significant difference between the two approaches[8,16,17]. These benefits may vary based on the etiology and severity of ischemia. For instance, some studies have found that for embolic etiology, an endovascular-first approach may be associated with a higher long-term amputation risk compared to open surgery[15]. Conversely, CDT has been associated with lower long-term mortality[15]. These differences highlight the need for individualized treatment strategy selection, taking into account etiology, ischemia classification, anatomical characteristics of the lesion, patient comorbidities, and available medical resources[18,19]. Specifically for the iliac artery region, evidence directly comparing the two treatment modalities is scarcer. While studies have confirmed the safety and efficacy of endovascular treatment for chronic iliac artery occlusions, even in long-segment disease[6,20], it remains unclear whether these conclusions can be extrapolated to the urgent scenario of acute thrombosis. Currently, there is a lack of high-quality prospective randomized controlled trials (RCTs) that specifically

focus on the entity of acute iliac artery thrombosis and systematically compare modern endovascular techniques with open surgery in terms of limb salvage rates, long-term patency, survival, and cost-effectiveness [17,21]. This evidence gap often leads clinicians to base their decisions for such patients on personal experience, device availability, and institutional tradition rather than on high-level evidence.Therefore, a thorough investigation and clear elucidation of the comparative clinical outcomes of endovascular therapy versus open surgery specifically in the context of acute iliac artery thrombosis are of significant practical and clinical importance for optimizing treatment pathways and improving patient prognosis.

Materials and Methods

Study Design

This is a single-center, retrospective, observational cohort study designed to compare the safety and efficacy of surgical thrombectomy versus percutaneous mechanical aspiration thrombectomy as the initial revascularization strategy for acute limb ischemia (ALI). The study protocol was approved by the Medical Ethics Committee of the Affiliated Hospital of Chengdu University of Traditional Chinese Medicine. (2022KL-091). The requirement for written informed consent was waived by the Medical Ethics Committee of the Affiliated Hospital of Chengdu University of Traditional Chinese Medicine because of the retrospective design and use of de-identified clinical data.

Patient Population

We retrospectively and consecutively enrolled all patients admitted for ALI who underwent revascularization therapy between December 2022 and December 2024, identified from our hospital's electronic medical record system. The diagnosis of ALI was based on typical clinical presentation (such as the "6P": pain, pallor, pulselessness, paresthesia, paralysis, and poikilothermia) and confirmed by imaging studies (computed tomography angiography, duplex ultrasound, or conventional angiography).

Inclusion and Exclusion Criteria

Patients were included if they: (1) were aged ≥ 18 years; (2) were diagnosed with non-traumatic ALI (symptom duration ≤ 7 days) classified as Rutherford class I (viable), IIa (marginally threatened), or IIb (immediately threatened) upon initial presentation; and (3) underwent initial revascularization via either surgical thrombectomy or percutaneous mechanical aspiration thrombectomy (using a dedicated aspiration system). Patients were excluded if they: (1) presented with upper limb ischemia or Rutherford class III (irreversible ischemia) ALI; (2) had ischemia directly caused by trauma, dissection, or vasculitis; (3) received initial conservative management or primary amputation; (4) had contraindications to antiplatelet, anticoagulant, or thrombolytic agents; or (5) had insufficient clinical data for analysis. Based on the initial revascularization strategy, patients were divided into two groups: the Open Thrombectomy group and the Aspiration Thrombectomy group.

Treatment Protocol and Procedural Details

All patients underwent preoperative non-invasive imaging to characterize the lesion. In the Open Thrombectomy group, the standard procedure involved femoral artery cutdown and Fogarty catheter thrombectomy. Adjunctive procedures such as patch angioplasty, bypass grafting, or hybrid procedures were performed at the surgeon's discretion. In the Endovascular Therapy group, the primary technique was thrombus aspiration using dedicated catheters (e.g., Acostream, Roterax, Angiojet). Following thrombus removal, adjunctive balloon angioplasty (PTA) or stenting could be performed to address underlying atherosclerotic lesions. In both groups, if residual thrombus was identified intraoperatively, additional adjunctive therapies, including catheter-directed thrombolysis (CDT), could be administered per operator judgment.

Outcome Measures and Definitions

The primary endpoint was major adverse limb events (MALE) and cardiovascular/cerebrovascular mortality. Secondary endpoints included clinically driven target lesion revascularization (CD-TLR) and major amputation (amputation above the ankle). CD-TLR was defined as any repeat intervention on the target lesion driven by recurrent clinical symptoms. MALE was defined as a composite of CD-TLR and major amputation.

Medical Therapy

Upon diagnosis of ALI, all patients received immediate anticoagulation with heparin (unfractionated or low-molecular-weight). During the procedure, a weight-adjusted bolus of heparin (70 IU/kg) was administered, with additional doses given as needed to maintain an activated clotting time between 225–250 seconds. Postoperatively, all patients received dual antiplatelet therapy (aspirin 75–100 mg/day plus clopidogrel 75 mg/day) for at least 30 days, followed by indefinite single antiplatelet therapy. Patients with concomitant atrial fibrillation were discharged on combined anticoagulation and single antiplatelet therapy, with the latter typically discontinued after one month.

Data Collection and Statistical Analysis

Two independent investigators reviewed the electronic medical records and extracted data, with cross-verification to ensure accuracy. Collected data included demographic characteristics, comorbidities, preoperative ischemic severity (Rutherford class), procedural details (devices used, procedural time, stent/balloon use), laboratory parameters, and all outcome measures. Continuous variables are presented as mean (standard deviation) or median (interquartile range) and were compared using the Student's t-test or Mann-Whitney U test, as appropriate. Categorical variables are presented as frequencies (percentages) and were compared using the chi-square test or Fisher's exact test. For time-to-event analysis, we used the cumulative incidence function (CIF) to estimate event probabilities, accounting for competing risks. Cox regression models were used to investigate the association between treatment modalities and the endpoints of MALE and major adverse

cardiovascular/cerebrovascular events (MACE). Subgroup analyses were performed based on factors such as age and laboratory parameters to explore potential effect modifiers and assess the robustness of the primary findings across different patient populations. All statistical analyses were performed using R software version 4.3.3, with a two-sided P-value < 0.05 considered statistically significant.

Results

During the study period (December 2022 to December 2024), a total of 92 patients were enrolled, with 37 patients (40.2%) in the endovascular therapy (EVT) group and 55 patients (59.8%) in the open surgery group(Fig. 1). A comparison of baseline characteristics between the two groups is presented in Table 1. The mean age in the EVT group (74.70 ± 12.10 years) was significantly higher than that in the open surgery group (65.42 ± 12.84 years; P < 0.001). There were no statistically significant differences between the groups in terms of BMI, hypertension, hyperlipidemia, smoking history, coronary artery disease, atrial fibrillation, diabetes, renal insufficiency, cerebral infarction, COPD, or history of peripheral arterial disease (all P > 0.05). No significant difference was observed in Rutherford classification (P = 0.248). Regarding acute ischemia classification, the distribution between the EVT and open surgery groups approached statistical significance (P = 0.051). Notably, no patients in the EVT group had grade III ischemia, whereas 14.55% of the open surgery group did.

Table 1
Baseline data and clinical characteristics

Variables	Total (n = 92)	EVT (n = 37)	Open (n = 55)	Statistic	*P*
Age, years	69.15 ± 13.29	74.70 ± 12.10	65.42 ± 12.84	3.48	**< .001**
BMI, kg/m^2	23.89 ± 4.18	23.59 ± 4.22	24.09 ± 4.17	-0.56	0.576
Hypertension, n(%)	44 (47.83)	22 (59.46)	22 (40.00)	3.36	0.067
Hyperlipidemia, n(%)	3 (3.26)	3 (8.11)	0 (0.00)	2.40	0.122
Current smoking, n(%)	33 (35.87)	11 (29.73)	22 (40.00)	1.01	0.314
Coronary Artery Disease, n(%)	8 (8.70)	3 (8.11)	5 (9.09)	0.00	1.000
Atrial Fibrillation, n(%)	10 (10.87)	5 (13.51)	5 (9.09)	0.11	0.744
Diabetes Mellitus, n(%)	16 (17.39)	9 (24.32)	7 (12.73)	2.07	0.150
Renal Dysfunction, n(%)	3 (3.26)	3 (8.11)	0 (0.00)	2.40	0.122
Cerebral infarction, n(%)	5 (5.43)	2 (5.41)	3 (5.45)	0.00	1.000
COPD, n(%)	1 (1.09)	1 (2.70)	0 (0.00)	-	0.402
History of PAD, n(%)	16 (17.39)	8 (21.62)	8 (14.55)	0.77	0.380
Rutherford Classification, n(%)				1.34	0.248
R4	88 (95.65)	37 (100.00)	51 (92.73)		
R5	4 (4.35)	0 (0.00)	4 (7.27)		
Acute Ischemia Grading, n(%)				-	0.051
I	10 (10.87)	4 (10.81)	6 (10.91)		
IIa	23 (25.00)	8 (21.62)	15 (27.27)		
IIb	51 (55.43)	25 (67.57)	26 (47.27)		
III	8 (8.70)	0 (0.00)	8 (14.55)		

Laboratory Findings

Compared to the open surgery group(Table 2), the EVT group had significantly lower red blood cell (RBC) count (4.20 ± 0.67 vs. 5.40 ± 1.27, P < 0.001) and hemoglobin (HGB) levels (132.38 ± 18.97 vs. 158.15 ± 33.23, P < 0.001). No significant differences were found between the groups for other parameters,

including white blood cell count, lymphocyte count, monocyte count, platelet count, C-reactive protein, coagulation function (PT, INR, APTT, FIB), D-dimer, urea, creatinine, NT-proBNP, and myoglobin (all $P > 0.05$). The difference in myoglobin levels approached the threshold for significance ($P = 0.061$).

Table 2
Hematilogic index

Variables	Total (n = 92)	EVT (n = 37)	Open (n = 55)	Statistic	*P*
WBC, 10^9/L	8.93 ± 3.73	8.81 ± 4.00	9.01 ± 3.58	-0.20	0.840
LYMPH, 10^9/L	1.24 ± 0.45	1.27 ± 0.57	1.22 ± 0.35	0.41	0.680
MONO, 10^9/L	0.71 ± 1.13	0.56 ± 0.26	0.81 ± 1.47	-0.81	0.419
RBC, 10^9/L	4.89 ± 1.21	4.20 ± 0.67	5.40 ± 1.27	-4.24	**< .001**
HGB, g/L	147.30 ± 30.72	132.38 ± 18.97	158.15 ± 33.23	-3.70	**< .001**
PLT, 10^9/L	182.86 ± 99.08	199.42 ± 130.15	170.82 ± 68.19	1.08	0.286
CRP, mg/L	33.33 ± 39.46	21.80 ± 40.83	41.01 ± 37.40	-1.53	0.133
PT, sec	14.23 ± 3.57	14.00 ± 3.72	14.40 ± 3.50	-0.41	0.682
INR	1.12 ± 0.37	1.10 ± 0.40	1.14 ± 0.35	-0.43	0.672
APTT, sec	39.04 ± 13.04	36.02 ± 8.34	41.23 ± 15.36	-1.51	0.138
FIB, g/L	4.14 ± 1.40	4.20 ± 1.38	4.09 ± 1.44	0.27	0.784
D-dimer, ug/ml	3.33 ± 3.37	3.42 ± 3.79	3.26 ± 3.09	0.17	0.862
UREA, mmol/L	6.14 ± 2.43	6.59 ± 2.12	5.82 ± 2.62	1.20	0.236
Crea, umol/L	82.77 ± 29.38	79.70 ± 25.38	85.01 ± 32.19	-0.67	0.506
NT-proB, pg/ml	3491.56 ± 7221.82	2851.70 ± 7049.18	3986.94 ± 7429.74	-0.57	0.568
MYO, ng/ml	555.19 ± 1014.07	262.35 ± 341.26	774.81 ± 1273.53	-1.92	0.061

Table 3. Operation procedure

Variables	Total (n = 92)	EVT (n = 37)	Open (n = 55)	Statistic	*P*
Operation time, min	144.22 ± 56.87	105.95 ± 37.95	169.96 ± 53.02	-6.75	**< .001**
Rate of thrombus clearance, n(%)				3.23	0.072
Grade 0: Complete clearance of	86 (93.48)	32 (86.49)	54 (98.18)		

Variables	Total (n = 92)	EVT (n = 37)	Open (n = 55)	Statistic	*P*
thrombus from the vessel lumen					
Grade 1: Segmental thrombus, lumen is partially patent	6 (6.52)	5 (13.51)	1 (1.82)		
Abdominal, n(%)	7 (7.61)	0 (0.00)	7 (12.73)	3.45	0.063
Thrombus involving the site, n(%)					
Femoral-popliteal artery	69 (75.00)	28 (75.68)	41 (74.55)	0.02	0.902
Infra-popliteal artery	46 (50.00)	16 (43.24)	30 (54.55)	1.13	0.288
Ballon, n(%)	64 (69.57)	30 (81.08)	34 (61.82)	3.88	**0.049**
Stent, n(%)	31 (33.70)	18 (48.65)	13 (23.64)	6.19	**0.013**
t: t-test, χ^2: Chi-square test					
SD: standard deviation					

Procedure-Related Metrics

As shown in Table 3, operative time was significantly longer in the open surgery group than in the EVT group (169.96 ± 53.02 minutes vs. 105.95 ± 37.95 minutes, P < 0.001). The difference in thrombus clearance rate (complete vs. segmental) did not reach statistical significance (P = 0.072), although the rate of complete clearance was higher in the open surgery group (98.18%) than in the EVT group (86.49%). No significant differences were found between the groups regarding thrombus involvement of the femoropopliteal (P = 0.902) or infrapopliteal arteries (P = 0.288). Concurrent abdominal thrombus locations were observed only in the open surgery group (12.73% vs. 0%), with the difference approaching statistical significance (P = 0.063). The proportion of patients receiving balloon angioplasty was significantly higher in the EVT group (81.08% vs. 61.82%, P = 0.049), as was the proportion receiving stents (48.65% vs. 23.64%, P = 0.013).

Follow-up Outcomes

During the 12-month follow-up period, 8 of the 92 patients were lost to follow-up (Fig. 1). The median follow-up time was 12 months (interquartile range: 1–16). Primary and secondary outcomes are shown in Fig. 2. Within the first postoperative month, the incidence of major adverse cardiovascular events (MACE) was higher in the open surgery group (23.64%) than in the EVT group (13.51%, P = 0.233). Within the first postoperative year, there were 2 major amputations in the open surgery group and 4 in the EVT

group. Compared to the EVT group (clinically driven target lesion revascularization [CD-TLR]: 22.01%; major adverse limb events [MALEs]: 33.76%), the open surgery group had lower rates of CD-TLR (5.02%) and MALEs (10.38%) at one year.

Subgroup Analysis of MACE Risk (Open Surgery vs. EVT)

In the overall cohort, the hazard ratio (HR) for MACE with open surgery compared to EVT was 1.86 (95% CI 0.66–5.22, P = 0.239, Fig. 3). Subgroup analysis based on baseline data revealed significant interaction effects for age (P for interaction = 0.029) and sex (P for interaction = 0.03). Among patients aged ≥ 80 years, the risk of MACE was significantly higher with open surgery compared to EVT (HR 7.69, 95% CI 1.63–36.28, P = 0.01), whereas no significant difference was observed in patients aged < 80 years (HR 0.74, 95% CI 0.17–3.31, P = 0.695). Similarly, female patients had a significantly higher MACE risk with open surgery (HR 10.44, 95% CI 1.28–85.12, P = 0.028), while no significant difference was found in male patients (HR 0.78, 95% CI 0.22–2.76, P = 0.697). Current smoking (P for interaction = 0.051), diabetes (P for interaction = 0.061), and stent use (P for interaction = 0.082) showed trends toward interaction. Subgroup analysis of hematological parameters (Fig. 4) revealed significant interaction effects for RBC (P for interaction = 0.006), HGB (P for interaction = 0.012), platelet count (PLT) (P for interaction = 0.02), and urea (UREA) (P for interaction = 0.044). Specifically, among patients with RBC ≥ 5.50, open surgery was associated with a significantly lower MACE risk compared to EVT (HR 0.13, 95% CI 0.02–0.93, P = 0.043), whereas among patients with RBC < 5.50, open surgery showed a trend toward higher risk (HR 3.43, 95% CI 0.96–12.43, P = 0.058). For patients with HGB < 160, open surgery carried a significantly higher MACE risk than EVT (HR 5.99, 95% CI 1.29–27.76, P = 0.022), with no significant difference observed for HGB ≥ 160 (HR 0.40, 95% CI 0.09–1.81, P = 0.235). Similarly, among patients with PLT ≥ 180, open surgery was associated with a significantly higher MACE risk (HR 9.76, 95% CI 1.23–77.27, P = 0.031), while no significant difference was seen for PLT < 180 (HR 0.55, 95% CI 0.14–2.20, P = 0.02). For patients with UREA ≥ 6.28, open surgery was associated with a significantly higher MACE risk (HR 9.90, 95% CI 1.21–80.86, P = 0.032), whereas no significant difference was observed for UREA < 6.28 (HR 0.81, 95% CI 0.23–2.86, P = 0.739).

Subgroup Analysis of MALEs Risk (Open Surgery vs. EVT)

In the overall cohort, the hazard ratio for major adverse limb events (MALEs) at one year with open surgery compared to EVT was 0.34 (95% CI 0.12–0.99, P = 0.047, Fig. 5). Subgroup analysis showed a significant interaction effect for age (P for interaction = 0.004). Among patients aged < 80 years, open surgery was associated with a significantly lower risk of MALEs at one year compared to EVT (HR 0.17, 95% CI 0.32–0.82, P = 0.028), whereas no significant difference was observed in patients aged ≥ 80 years (HR 0.74, 95% CI 0.17–3.31, P = 0.695). Sex (P for interaction = 0.192), hypertension (P for interaction = 0.101), current smoking (P for interaction = 0.61), diabetes (P for interaction = 0.445), cerebral infarction (P for interaction = 1), history of peripheral vascular disease (P for interaction = 0.997), and stent implantation (P for interaction = 0.499) showed trends toward interaction. Subgroup analysis of hematological parameters (Fig. 6) revealed a significant interaction for neutrophil count (NEUT). Among

patients with NEUT < 7, EVT was associated with a significantly lower risk of MALEs at one year compared to open surgery (HR 0.12, 95% CI 0.02–0.06, P = 0.048). No significant interaction effects were observed for RBC (P for interaction = 0.148), PLT (P for interaction = 0.514), albumin (ALB) (P for interaction = 0.119), or UREA (P for interaction = 0.964).

Discussion

This single-center retrospective cohort study compared initial revascularization strategies for acute lower limb ischemia (ALI), systematically evaluating the safety and efficacy of traditional surgical open thrombectomy (OT) versus contemporary percutaneous mechanical thrombectomy (PMT). The key finding is that while the overall risk of major adverse cardiovascular and cerebrovascular events (MACE) at one year was comparable between the two strategies, OT was associated with a significantly lower risk of one-year major adverse limb events (MALEs). Further analysis revealed that the treatment effect was not uniform but was significantly modified by baseline patient characteristics. In subgroups of patients who were older (≥ 80 years), female, or had pre-operative anemia or specific hematological abnormalities, open surgery was associated with a significantly elevated risk of MACE. These results, for the first time in the context of a direct comparison of these specific techniques, systematically delineate a multidimensional risk profile influencing therapeutic decision-making, strongly suggesting that the revascularization strategy for ALI should shift from a "one-size-fits-all" approach to individualized selection based on refined risk stratification.

The observed lack of a significant difference in overall MACE risk aligns with existing evidence on the comparable efficacy of open surgical and endovascular therapies. A meta-analysis incorporating six studies showed no statistically significant differences in mortality or amputation rates at one, six, and twelve months between the two methods[22]. Another large-scale analysis based on the US National Inpatient Sample also reported comparable risks for the composite endpoint of in-hospital death or major amputation between PMT and OT[9]. However, our finding of a significantly lower one-year MALEs risk in the OT group warrants in-depth analysis. This may partly reflect baseline and treatment pattern differences between the two groups in our study. Patients in the endovascular therapy (EVT) group were older and had lower pre-operative hemoglobin levels, suggesting potentially more fragile baseline health. Concurrently, the EVT group had a significantly higher proportion of adjunctive balloon angioplasty and stent implantation during the procedure. While this reflects the philosophy of actively addressing underlying atherosclerotic lesions with endovascular techniques, it may also imply more prominent residual stenosis after initial thrombus removal or a greater reliance on correcting the underlying pathology, potentially increasing the need for future re-interventions. A 2024 large-scale comparative study based on a nationwide Japanese database suggested that in patients without peripheral artery disease (PAD), open surgery was associated with lower risks of in-hospital death and amputation than endovascular therapy[23]. Our findings partially echo this but emphasize that in a mixed cohort including PAD patients, open surgery may still hold an advantage in preventing limb-related events.

The effect modification revealed by the subgroup analysis is the most clinically informative finding of this study. First, the sharply increased MACE risk after open surgery in very elderly patients (≥ 80 years) aligns with previous observations in this population. Studies have shown that mortality for nonagenarians (≥ 90 years) undergoing surgery for ALI can be as high as 22.9%[24]. The risk trend in our elderly subgroup reinforces the notion that minimally invasive endovascular therapy may offer better safety for frail older populations[25]. Second, the significantly higher MACE risk for female patients undergoing open surgery compared to males resonates with recent research focusing on sex-based differences. A multicenter study noted that women had a significantly higher risk of death within 30 days after ALI treatment compared to men[26]. While another propensity score-adjusted analysis did not identify sex as an independent risk factor[27], our study suggests that women may face higher cardiovascular risks specifically in the context of open surgery. The underlying mechanisms may relate to differences in vascular anatomy, comorbidity burden, or response to surgical stress[28]. Third, pre-operative anemia (low hemoglobin) was clearly identified as a strong predictor of poor outcomes with open surgery. This is supported by extensive literature: anemia is an independent risk factor for mortality and amputation in patients with PAD[29], and in patients with chronic limb-threatening ischemia, pre-operative hemoglobin below 10 g/dL is associated with significantly higher immediate and long-term mortality[30]. Anemia may affect prognosis by limiting tissue oxygen supply, exacerbating ischemic injury, and serving as a marker of systemic disease severity. Furthermore, inflammatory markers such as the neutrophil-lymphocyte ratio and platelet-lymphocyte ratio have been shown to predict amputation and mortality risk in ALI patients[31–33], collectively indicating that a patient's systemic inflammatory status, nutrition, metabolism, and renal function are indispensable dimensions of pre-operative risk assessment.

These findings have clear implications for clinical practice. The 2024 ACC/AHA guidelines for the management of lower extremity PAD emphasize the importance of comprehensive treatment[34], and the subgroup analyses in our study provide specific decision points. Treatment strategy selection should be a dynamic evaluation process, integrating ischemic severity, etiology, lesion anatomy, and individual patient risk. For relatively young, male patients without severe anemia, if their vascular anatomy is suitable and life expectancy is long, open surgery, aiming for a lower long-term re-intervention rate, might be a reasonable choice. Conversely, for patients who are elderly, female, or have pre-operative anemia or elevated inflammatory markers, the initial strategy should prioritize less invasive endovascular techniques to avoid potentially significantly increased perioperative cardiovascular and cerebrovascular risks. It is crucial to emphasize that regardless of the revascularization method, intensive post-procedural medical therapy remains the cornerstone for improving outcomes. The VOYAGER PAD trial demonstrated that for patients with symptomatic PAD after revascularization, adding low-dose rivaroxaban to aspirin significantly reduced the risk of major adverse limb events, including ALI, with consistent benefit across both surgical and endovascular revascularization subgroups[35,36].

Of course, interpreting the conclusions of this study requires consideration of its inherent limitations. The retrospective single-center design inevitably introduces selection bias; for example, the EVT group

was older and had more pronounced anemia. Although multivariable adjustment was employed, residual confounding may persist. The sample size was relatively limited, and particularly in subgroup analyses, the confidence intervals for some risk estimates were wide, affecting the precision of the conclusions. The median follow-up of 12 months is insufficient for assessing the long-term durability of revascularization, especially the patency after stent placement. Different thrombectomy devices were used within the EVT group, and their efficacy may vary, but this study did not compare devices. Furthermore, the lack of patient-reported outcome measures (e.g., quality of life, functional status) limits the comprehensive assessment of treatment benefits.

Future research should aim to address these shortcomings. A priority is to conduct multicenter prospective registry studies or randomized controlled trials to validate the high-risk subgroup characteristics identified here within a prospective framework, and to attempt to build predictive models integrating clinical, imaging, and hematological indicators to guide treatment decisions. Longer-term follow-up of patients undergoing endovascular therapy, especially mechanical thrombectomy, is needed to clarify re-stenosis patterns and predictive factors to optimize post-operative monitoring and intervention timing. Exploring whether perioperative management strategies targeting modifiable risk factors (e.g., pre-operative anemia, inflammation) can improve outcomes is another valuable direction. Differences in efficacy and safety among various thrombus removal devices (e.g., simple aspiration, mechanical fragmentation) for specific thrombus burdens and etiologies also need to be clarified in larger samples. Ultimately, incorporating functional recovery and quality of life into core outcome measures is essential for a more complete evaluation of the comprehensive value of different revascularization strategies for patients with ALI.

Conclusion

In summary, this study preliminarily indicates that for revascularization in acute lower limb ischemia, surgical open thrombectomy and percutaneous mechanical thrombectomy demonstrate comparable efficacy in terms of limb salvage and survival rates at one year. Open thrombectomy may offer advantages in achieving immediate and complete revascularization, while mechanical thrombectomy, as a minimally invasive method, may demonstrate a more favorable risk-benefit profile in elderly patients, albeit often requiring more frequent adjunctive endovascular procedures to address underlying lesions. Clinical decision-making should be based on multifactorial considerations, including patient age, comorbidities, outflow status, thrombus characteristics, as well as operator experience and institutional resources, leading to an individualized treatment strategy. Future multicenter, prospective, randomized controlled studies are needed to further define the optimal positioning of these two techniques for different patient subgroups.

Human Ethics and Consent to Participate declarations

The study protocol was approved by the Medical Ethics Committee of the Affiliated Hospital of Chengdu University of Traditional Chinese Medicine. (approval No. 2022KL-091). The requirement for written

informed consent was waived by the Medical Ethics Committee of the Affiliated Hospital of Chengdu University of Traditional Chinese Medicine because this was a retrospective observational study using de-identified clinical data. The study was conducted in accordance with the Declaration of Helsinki.

Declarations

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Clinical trial registration

Not applicable. This study was a retrospective observational cohort study and was not a clinical trial.

Availability of Data and Materials

The datasets used and/or analyzed during the current study are available from the corresponding author upon reasonable request.

Declaration of conflicts of interest

The authors declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

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CRediT authorship contribution statement

Qiqi Wang: Conceptualization, Data curation, Formal analysis, Investigation, Methodology, Supervision, Validation, Writing-original draft. Wei Huang: Investigation, Resources, Conceptualization, Data curation, Formal analysis, Methodology. Yang Liu: Data curation, Investigation, Resources. Chunshui He: Data curation, Investigation. J. Benichou: Data curation, Formal analysis, Funding acquisition, Methodology, Validation, Writing-original draft, Writing- review & editing. Haijun Wei: Data curation, Investigation. Y. Benhamou: Conceptualization, Data curation, Formal analysis, Investigation, Methodology, Supervision, Validation, Writing-original draft, Writing-review & editing.

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Figures

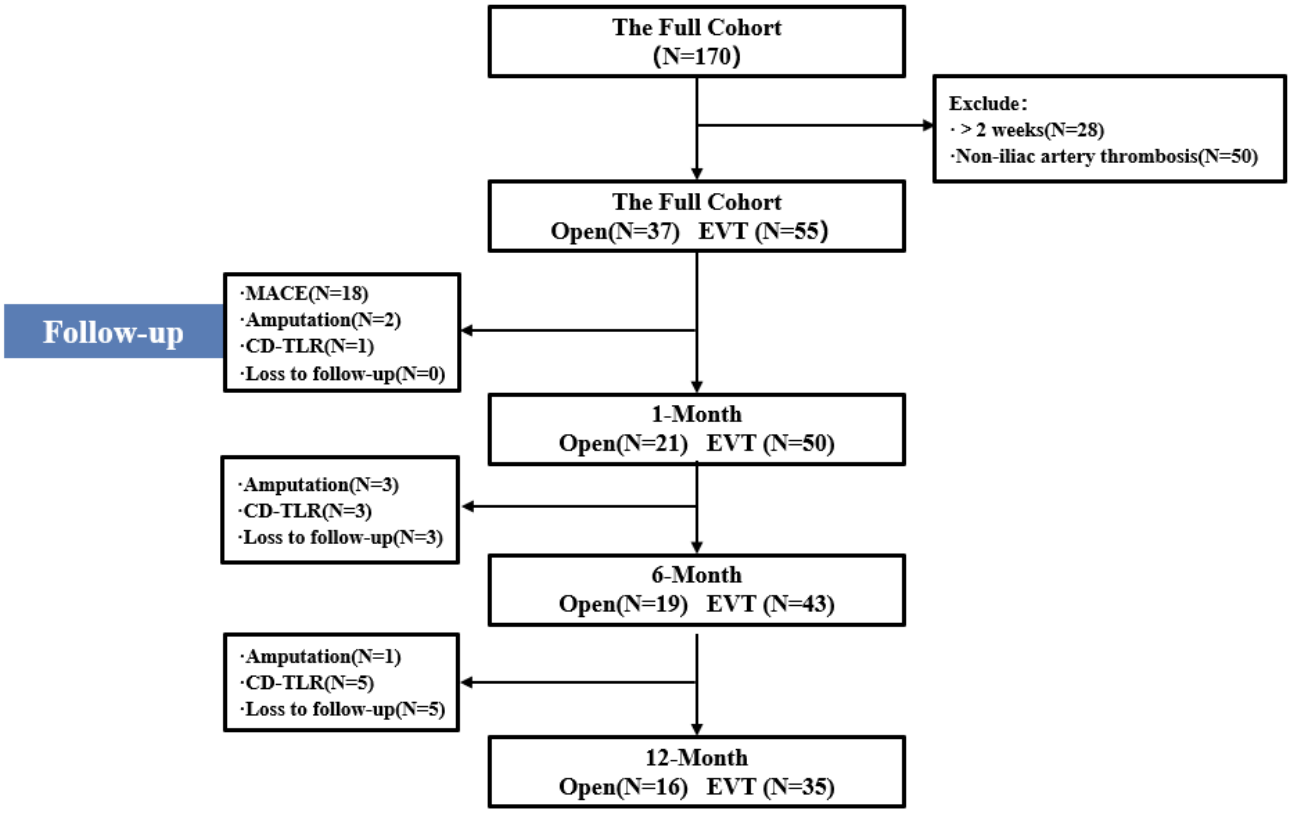


Figure 1

Patient selection process. EVT, endovascular therapy；Open，open surgery

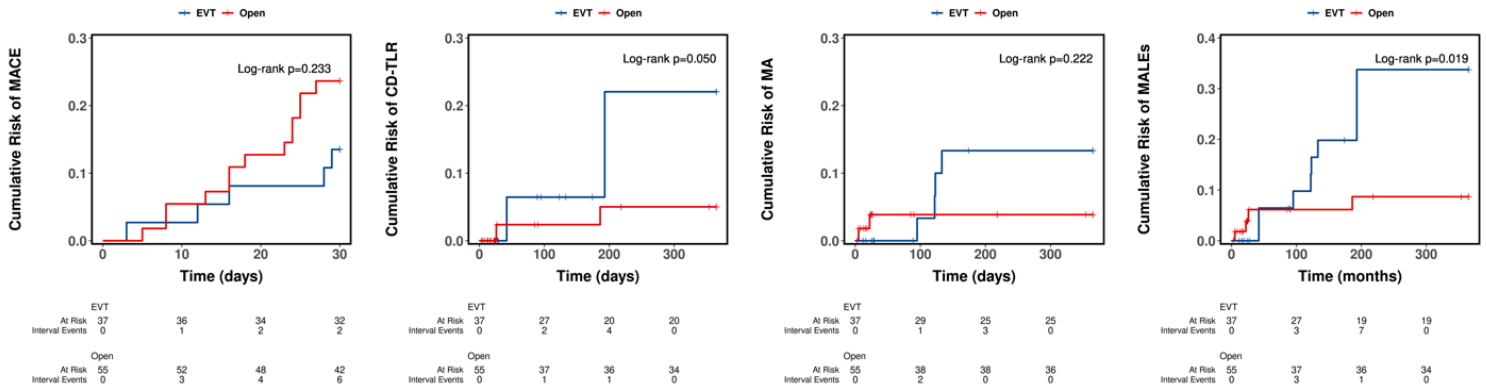
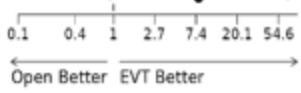


Figure 2

Incidence of major adverse cardiovascular events (MACE)、clinically-driven target limb revascularization (CD-TLR), major amputation(MA), and major adverse limb events (MALEs).

Subgroup	EVT*	Open*	HR (95% CI)	P value	P for interaction
Overall	5/37 (13.5)	13/55 (23.6)	1.86 (0.66, 5.22)	0.239	
Age					0.029
<80	3/24 (12.5)	4/44 (9.1)	0.74 (0.17, 3.31)	0.695	
≥80	2/13 (15.4)	9/11 (81.8)	7.69 (1.63, 36.28)	0.01	
Gender					0.03
Male	4/22 (18.2)	6/42 (14.3)	0.78 (0.22, 2.76)	0.697	
Female	1/15 (6.7)	7/13 (53.8)	10.44 (1.28, 85.12)	0.028	
Hypertension					0.397
No	1/15 (6.7)	8/33 (24.2)	3.84 (0.48, 30.69)	0.205	
Yes	4/22 (18.2)	5/22 (22.7)	1.33 (0.36, 4.94)	0.674	
Current smoking					0.051
No	2/26 (7.7)	10/33 (30.3)	4.25 (0.93, 19.43)	0.062	
Yes	3/11 (27.3)	3/22 (13.6)	0.49 (0.10, 2.42)	0.38	
Atrial Fibrillation					0.998
No	5/32 (15.6)	10/50 (20.0)	1.32 (0.45, 3.87)	0.608	
Yes	0/5 (0.0)	3/5 (60.0)		0.999	
Diabetes Mellitus					0.061
No	1/28 (3.6)	11/48 (22.9)	6.99 (0.90, 54.18)	0.063	
Yes	4/9 (44.4)	2/7 (28.6)	0.60 (0.11, 3.26)	0.55	
Renal Dysfunction					
No	2/34 (5.9)	13/55 (23.6)	4.27 (0.96, 18.91)	0.056	
Yes	3/3 (100.0)	0/0 (0)			
Cerebral infarction					0.998
No	5/35 (14.3)	10/52 (19.2)	1.40 (0.48, 4.09)	0.541	
Yes	0/2 (0.0)	3/3 (100.0)		0.999	
COPD					
No	5/36 (13.9)	13/55 (23.6)	1.81 (0.64, 5.07)	0.262	
Yes	0/1 (0.0)	0/0 (0)			
History of PAD					0.998
No	2/29 (6.9)	13/47 (27.7)	4.31 (0.97, 19.10)	0.055	
Yes	3/8 (37.5)	0/8 (0.0)		0.999	
Rutherford classification					
R4	5/37 (13.5)	13/51 (25.5)	2.03 (0.72, 5.69)	0.18	
R5	0/0 (0)	0/4 (0.0)			
Infrapopliteal artery thrombus					0.317
No	3/21 (14.3)	9/25 (36.0)	3.07 (0.83, 11.35)	0.093	
Yes	2/16 (12.5)	4/30 (13.3)	1.02 (0.19, 5.55)	0.985	
stent					0.082
No	4/19 (21.1)	8/42 (19.0)	0.92 (0.28, 3.04)	0.887	
Yes	1/18 (5.6)	5/13 (38.5)	7.85 (0.92, 67.29)	0.06	



* no. of events / total no. (%)

Figure 3

Subgroup analysis of MACE risk (Open vs. EVT) –Demographic and comorbidity subgroups.

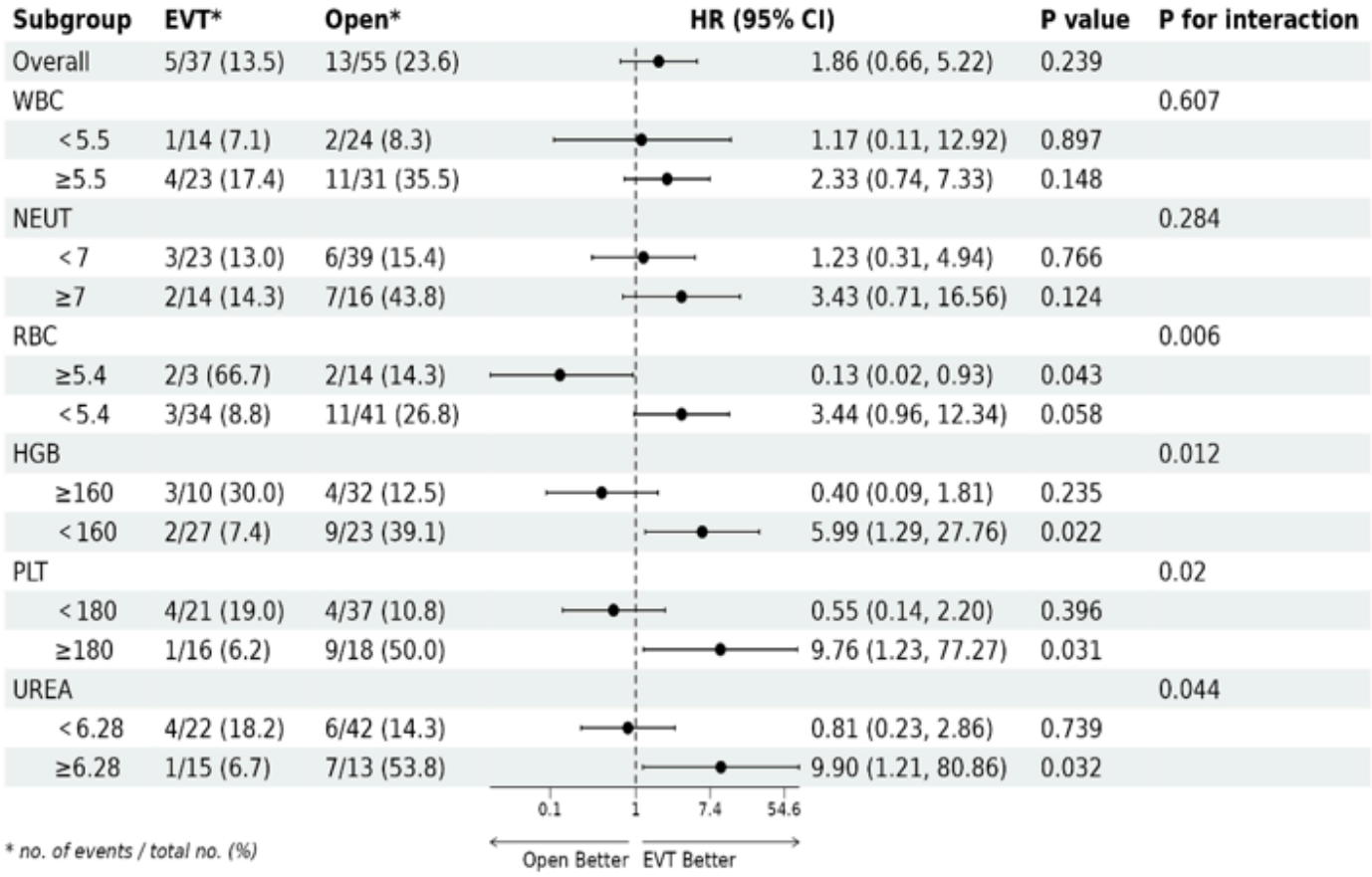


Figure 4

Forest plot of subgroup analyses for MACE (Open vs. EVT) - baseline blood markers

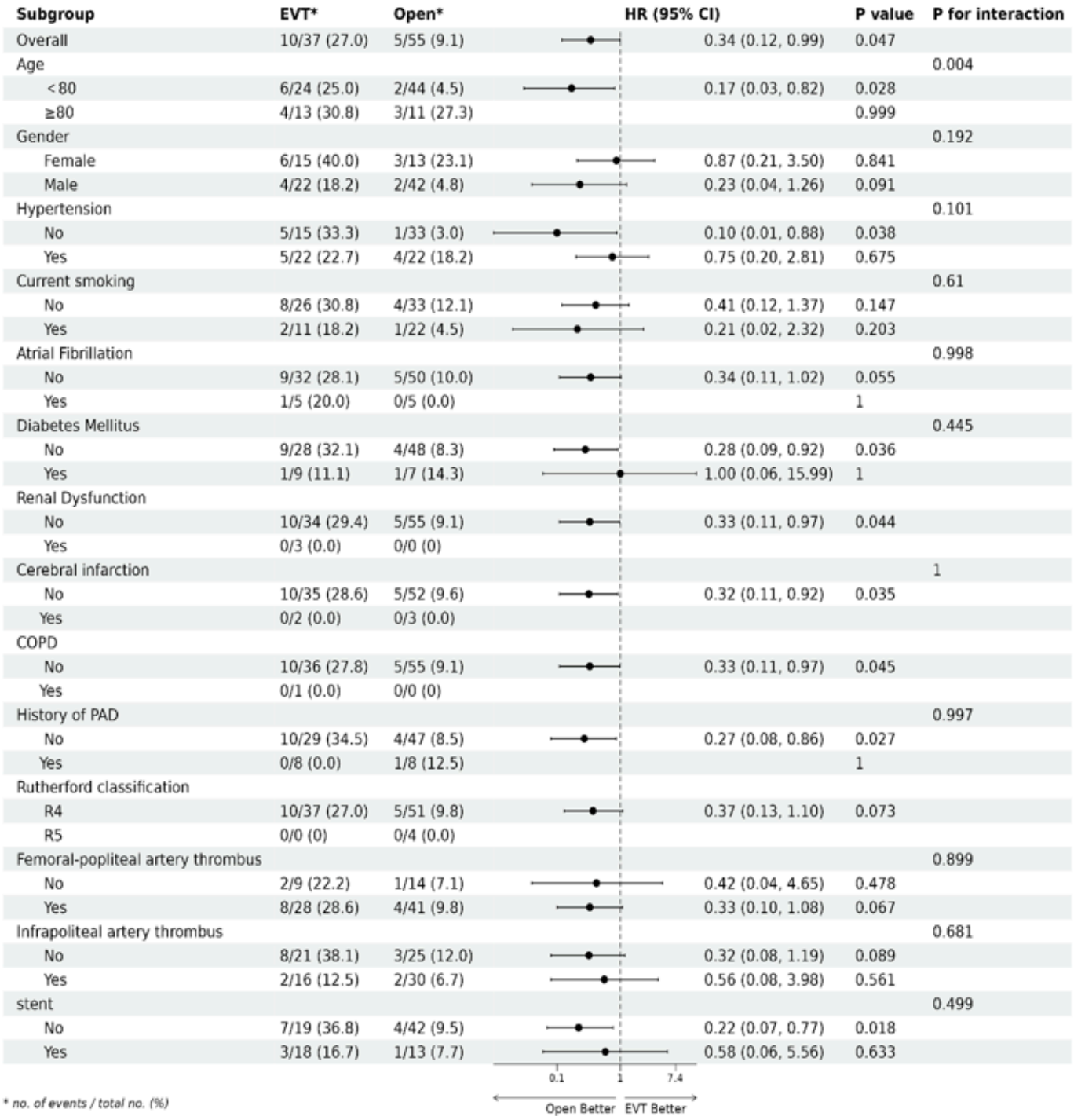


Figure 5

Subgroup analysis of MALEs risk (Open vs. EVT) –Demographic and comorbidity subgroups.

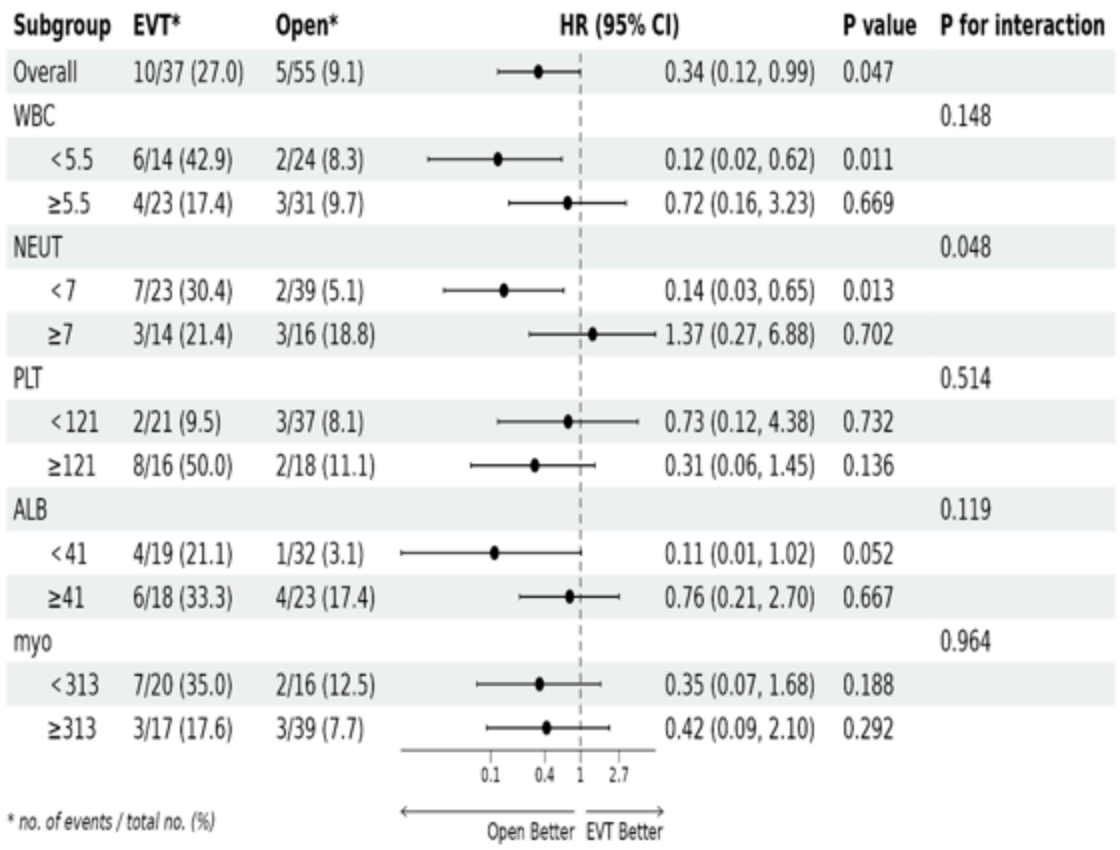


Figure 6

Forest plot of subgroup analyses for MALE (Open vs. EVT) - baseline blood markers