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Mechanical revascularization using Solitaire AB device for acute limb ischemia secondary to popliteal and infrapopliteal embolic occlusion

Maofeng Gong, Yangyi Zhou, Xu He, Liang Chen, Boxiang Zhao, Jie Kong, Haobo Su and Jianping Gu

Abstract

Objective: Acute limb ischemia is one of the most common arterial emergencies. The data of mechanical revascularization using Solitaire AB device coupled with thromboaspiration for the treatment of popliteal and infrapopliteal acute limb ischemia are limited. The aim of this study was to review the preliminary safety and effectiveness.

Methods: We performed a single-center retrospective review of patients with popliteal and infrapopliteal acute limb ischemia treated with Solitaire AB device coupled with thromboaspiration from February 2019 to May 2020. Adjunctive balloon angioplasty was performed to correct coexisting atherosclerotic stenosis. Technical success was defined as successful deployment of the Solitaire AB device across the occlusive segment and successful retrieval without the use of adjunctive catheter-directed thrombolysis or balloon angioplasty. Clinical success was defined as the relief of symptoms related to acute limb ischemia. Follow-up outcomes were also reviewed.

Results: There were 15 consecutive patients who underwent 16 Solitaire AB devices. Technical success was achieved in 11 (73.3%) patients. Of the unsuccessful patients, double-stent retrievers were employed in 1 (6.7%) patient. Two patients who encountered residual clots in distal small arteries underwent adjunctive catheter-directed thrombolysis. An adjunctive balloon angioplasty was required in 1 (6.7%) patient. All patients had notable acute limb ischemia symptom relief after the procedures. Clinical success was achieved in 14 (93.3%) patients. Besides one patient encountered minor amputation, the major amputation was prevented in all patients. No device-related complications or distal embolization events were recorded during the procedures. At the follow-up of 12 months, all surviving patients remained symptom-free, the patency was achieved in 12 (80%) patients and the limb salvage was 100%.

Conclusions: Preliminary outcomes suggest that mechanical revascularization using Solitaire AB device coupled with manual thromboaspiration appears to be a rapid, safe, and effective modality that appears to reduce the requirement for catheter-directed thrombolysis.

Advances in knowledge: These findings may add a promising recanalization therapy for acute embolic occlusion of the acute limb ischemia secondary to popliteal and infrapopliteal arteries.

Keywords

Acute limb ischemia, below the knee, embolism, percutaneous mechanical thrombectomy

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Department of Vascular and Interventional Radiology, Nanjing First Hospital, Nanjing Medical University, Nanjing, Jiangsu PR China

Corresponding authors:
Haobo Su, Department of Vascular and Interventional Radiology, Nanjing First Hospital, Nanjing Medical University, Nanjing, Jiangsu 210006, PR China.
Email: doctorsuhaobo@163.com

Jianping Gu, Department of Vascular and Interventional Radiology, Nanjing First Hospital, Nanjing Medical University, Nanjing, Jiangsu 210006, PR China.
Email: cjr.gujianping@vip.163.com

Introduction

Acute limb ischemia (ALI), referred to as ischemia symptoms that emerge within 2 weeks, is one of the most common arterial emergencies.[1,2] Among the most common causes, majority of the cases are associated with acute embolism.[3] Limb viability is compromised as there is insufficient time for new vessels growth to compensate for the sudden interruption of perfusion.[3,4] Hence, ALI can be catastrophic without prompt treatments and is a potential lethal event that can result in not only amputation (12%–50% of cases) but also death (20%–40% of cases).[2,4] As the majority of adverse outcomes occur within the initial days after presentation, rapid and effective revascularization following an episode of ALI is pivotal, as it will most likely improve the prognosis. Therefore, for acute, viable or marginally threatened ALI, timely revascularization aiming at restoring perfusion is recommended.[1,2]

However, determination of the optimal options for revascularization of popliteal and infrapopliteal ALI remains particularly challenging.[5] The surgical and endovascular approaches have been a long-standing topic of debate.[6,7] Two recent guidelines, the European Society of Cardiology and European Society for Vascular Surgery guidelines,[2,8] have put a spotlight on an evolution toward less invasive procedure, which may be an opportunity to encourage endovascular in addition to surgical revascularization. A variety of endovascular modalities aimed at chemical or mechanical removal of the emboli,[9,10] including catheter-directed thrombolysis (CDT), pharmacomechanical thrombectomy, microfragmentation thrombectomy, have been small-scale reported. But no one has proven superiority over the others.

The Solitaire AB device (Medtronic, Minneapolis, Minnesota, USA) is a self-expanding stent that can facilitate clot retrieval.[11] Mechanical thrombectomy using Solitaire AB device has been proven to be an important adjunctive reperfusion therapy for acute ischemic stroke (AIS)[12] and acute mesenteric ischemia (AMI).[11] Yet, the reports in the setting of ALI remain limited. In this study, we preliminary applied a mechanical thrombectomy technique with Solitaire AB device coupled with thromboaspiration for the treatment of popliteal and infrapopliteal ALI.

Methods

Study design

This was a retrospective cohort study that confirmed popliteal and infrapopliteal ALI patients who underwent mechanical thrombectomy using Solitaire AB device as first-line treatment at a single academic center from February 2019 to May 2020. Off-label use of the Solitaire AB device was approved by the hospital ethical committee. Informed consent of patients who underwent the Solitaire AB device approach was obtained from the patient's relatives. Data such as clinical notes, laboratory values, procedure images, and procedure reports was retrospectively derived from the medical database system and paper records.

Study population

A total of 15 consecutive patients (mean age 72.3 years, 46.7% male (n = 7)) with ALI secondary to popliteal and infrapopliteal embolic occlusion underwent endovascular revascularization with Solitaire AB device coupled with thromboaspiration during the study period were available to be reviewed. ALI was diagnosed in the majority of patients with urgent duplex ultrasound and CT arteriography (CTA) following limb ischemia manifestations. The mean duration of ischemia symptoms before presentation was extremely variable between cases, was 2.4 ± 1.3 days. Eleven of 15 patients (73.3%) experienced a history of diagnosed atrial fibrillation. With regard to the ischemia classification (details are shown in Supplementary Table) of patients, two cases (13.3%) of grade I ischemia, 8 (53.3%) cases of grade IIa ischemia, 5 (33.3%) cases of grade IIb ischemia, and none of grade III ischemia. The demographics, comorbidities, presentation, and lesion characteristics are summarized in Table 1.

Management strategies details

The procedure-related information including the diameter of the target vessel; length of embolic occlusion; and presence and severity of coexisting stenosis in the popliteal and infrapopliteal arteries was obtained in CTA. Then, the therapeutic approach was left to the discretion of the treatment group, consisting of three interventional radiologists with at least 15 years of experience. The procedural details were performed as follows.

The introducer applied as a primary conduit to manipulate was a 6-F short sheath inserted via the nonischemic femoral artery route under the conscious sedation. Then, diagnosis arteriography was conducted before the procedure to assess the perfusion of ischemia calf. The Solitaire AB device was first designed for neurological disease, and the diameters and lengths available were 4 mm, and 6 mm, and 10 mm, 20 mm, and 30 mm. Under systemic heparinization, all Solitaire AB devices were employed based on the insertion of a 6-F support sheath (Super Arrow-Flex; Tele flex Inc., Wayne, Pennsylvania, USA) which was selectively placed close to target occlusive artery. All of the 15 patients with distal arterial bifurcation were involved, and underwent a single-stent retriever. Following 6-F guiding catheter (Mach1 Peripheral Guide Catheter; Boston Scientific, Marlborough, Massachusetts, USA) was advanced into the origin, a 2.7-F microcatheter (Progreat; Terumo Corporation, Tokyo, Japan) was navigated to traverse the trunk and then beyond the distal of

Table 1. Demographics, comorbidities, presentation, and lesion characteristics of ALI patients.

Characteristic	Value
Age, years, mean ± SD (range)	72.3 ± 15.6 (39–91)
Male sex, n (%)	7 (46.7)
Duration of symptoms at presentation, days, mean ± SD (range)	2.4 ± 1.3
Risk factors, n (%)	
Diabetes mellitus	11 (73.3)
Coronary artery disease	4 (26.7)
Rheumatic heart disease	3 (20.0)
Previous cerebrovascular accident	6 (40.0)
Renal insufficiency	1 (6.7)
Hypertension	12 (80.0)
Hyperlipidemia	7 (46.7)
Diagnosed atrial fibrillation	11 (73.3)
History of smoking	7 (46.7)
History of peripheral artery disease	2 (13.3)
Medication, n (%)	
Warfarin	2 (13.3)
Aspirin	4 (26.7)
Clopidogrel	2 (13.3)
Statin	3 (20.0)
Clinical presentation, n (%)	
Pain	14 (93.3)
Pallor	13 (86.7)
Pulselessness	15 (100)
Poikilothermia	13 (86.7)
Paresthesias	12 (80.0)
Paralysis	11 (73.3)
Ischemia level (clinical categories according to Rutherford[†]), n (%)	
I (viable limb)	2 (13.3)
IIa (marginally threatened limb)	8 (53.3)
IIb (immediately threatened limb)	5 (33.3)
III (irreversible limb)	0

ALI: Acute limb ischemia.
Continuous data are presented as the means ± SD; categorical data are given as the counts (percentage).
[†]This is an identical replica of the table in the 1997 publication by Rutherford et al. with the exception of the asterisks.

the occlusive clot segment over the micro guidewire. After the vasculature distal to the clot was visualized on microcatheter arteriography, a Solitaire AB device was introduced via the microcatheter, and the device was deployed across the occlusive clot. For a patient experienced unsuccessful thrombectomy, the Y-stent technique (incorporating two stent retrievers are inserted parallelly through two microcatheter access points to each distal branch) was employed. Before clot retrieval deployment, the 6-F guiding catheter was advanced as close to the proximal aspect of the thrombus as possible. After 5 min waiting period, both stents and microcatheter are retrieved together out of the guiding catheter completely while continuous suction performed by manual thromboaspiration using a 60-mL negative pressure syringe (VacLok; Merit Medical Systems, Inc., South Jordan, Utah) was maintained.

If residual in distal thrombus was found after thrombectomy, further widely used alternative conjunction with CDT was considered, subsequently received a continuous infusion of reduced dose recombinant tissue plasminogen activator (rt-PA) at an infusion rate of 0.01 mg/kg/h for further treatment. Patients who underwent adjunctive CDT met the exclusion criteria for thrombolytic contraindications. Mechanical revascularization with Solitaire AB device was no more than three passes in this study. In patients who had > 50% coexisting atherosclerotic stenosis remained after emboli removal, adjunctive balloon angioplasty was performed. At the end of mechanical revascularization procedure, low molecular weight heparin (Hebei Changshan Shan Biochemical Pharmaceutical; Shijiazhuang, China) therapy at a dose of 100 IU/kg per 12 h was started immediately. And then, oral anticoagulation with rivaroxaban 20 mg once daily and statin therapy (atorvastatin, 20 mg/d) was prescribed after discharge.

Definitions of outcome and safety measures

Our primary outcome was technical success of the procedure, which was defined as the successful deployment of Solitaire AB device as initial treatment across the occlusive segment and the successful retrieval without the need to adjunctive CDT or additional balloon angioplasty. Clinical success (improvement in clinical status) was defined as the relief of symptoms related to ALI in accordance to the accepted guidelines,[2,8] or an improvement in the ischemia grade of at least one category with objective evidence of hemodynamic change (at least 0.1 increase in ABI). The requirement of necessary adjunctive CDT to treat residual clots in distal small arteries and balloon angioplasty to treat coexisting atherosclerotic stenosis to obtain sufficient distal perfusion within the same hospital stay was recorded, but not considered a clinical failure. Limb salvage was defined as freedom from major amputation (performed above the ankle), and maintained functional autonomy (walking or standing). Patency was determined in concordance to accepted ESVS guidelines.[2] Safety was classified as major or minor complications in accordance with the criteria of the classification scale of Society of Interventional Radiology (SIR).[13]

Follow-up

Outpatient standardized follow-ups were performed by our institution at 1 months, 3 months, 6 months, and 12 months post-procedure via ankle–brachial index (ABI), duplex ultrasound and/or CTA; additional procedures and complications were recorded during the follow-up period.

Statistical analysis

The *SPSS* statistical software package (version 23.0; *SPSS* statistical software, Chicago, Illinois, USA) was used to perform all statistical analyses in this study. Continuous variables are expressed as the mean ± SD. Qualitative variables are presented as numbers and percentages. When assessing the correlation between pre- and postprocedural ABI variables, a paired *t*-test was used. Findings with a *p*-value less than 0.05 were deemed statistically significant.

Results

Outcomes of technical and clinical success

Procedure characteristics and outcomes are outlined in Table 2. All patients underwent Solitaire AB devices coupled with manual thromboaspiration as a first-line treatment, the mean of target vessel diameter was 5.3 ± 0.6 mm (range: 4.5–7.0 mm) and the mean of embolic length was 24.1 ± 8.0 mm (range: 10–40 mm); therefore, the available size of solitaire AB device applied was consisted of one 6 mm × 30 mm and one 4 mm × 20 mm sizes. The mean operation procedure time was 1.2 ± 0.3 h. After mean of 2.2 ± 0.7 passes thrombectomy attempts, technical success was

Table 2. Procedure characteristics by this treatment and outcomes.

Characteristics	Value
Technical success of colt removal, n (%)	
With primary intervention only	11 (73.3)
Double-stent retrievers employed	1 (6.7)
Including adjuvant CDT	2 (13.3)
Adjunctive angioplasty after embolus removal	1 (6.7)
Duration of operation procedure, h, mean ± SD	1.2 ± 0.3
Passes thrombectomy attempts, n (%)	2.2 ± 0.7
Total duration of thrombolysis, d, mean ± SD	1.3 ± 0.4
Rt-PA dose, mg	7.5 ± 3.5
ABI scores	
Pretreatment	0.32 ± 0.06
Treatment completion	0.79 ± 0.18
Clinical success, n (%)	14 (93.3)
Patency at 12months, n (%)	12 (80)
Limb salvage at 12 months, n (%)	15(100)
Solitaire-related 30-day complications, n (%)	0
All 30-day complications, n (%)	
Minor (SIR A, B: nominal or no therapy, no consequence)	1 (6.7)
Major (SIR C, D, E: requires therapy or permanent sequelae)	0 (0)
Major death (SIR F: death)	0 (0)
Procedure-related distal embolization	0 (0)
In-hospital length of stay, d, n (%)	4.3 ± 1.0

ABI: ankle–brachial index; CDT: catheter-directed thrombolysis; Rt-PA: recombinant tissue plasminogen activator; SIR: Society of Interventional Radiology.
Continuous data are presented as the means ± SD; categorical data are given as the counts (percentages).

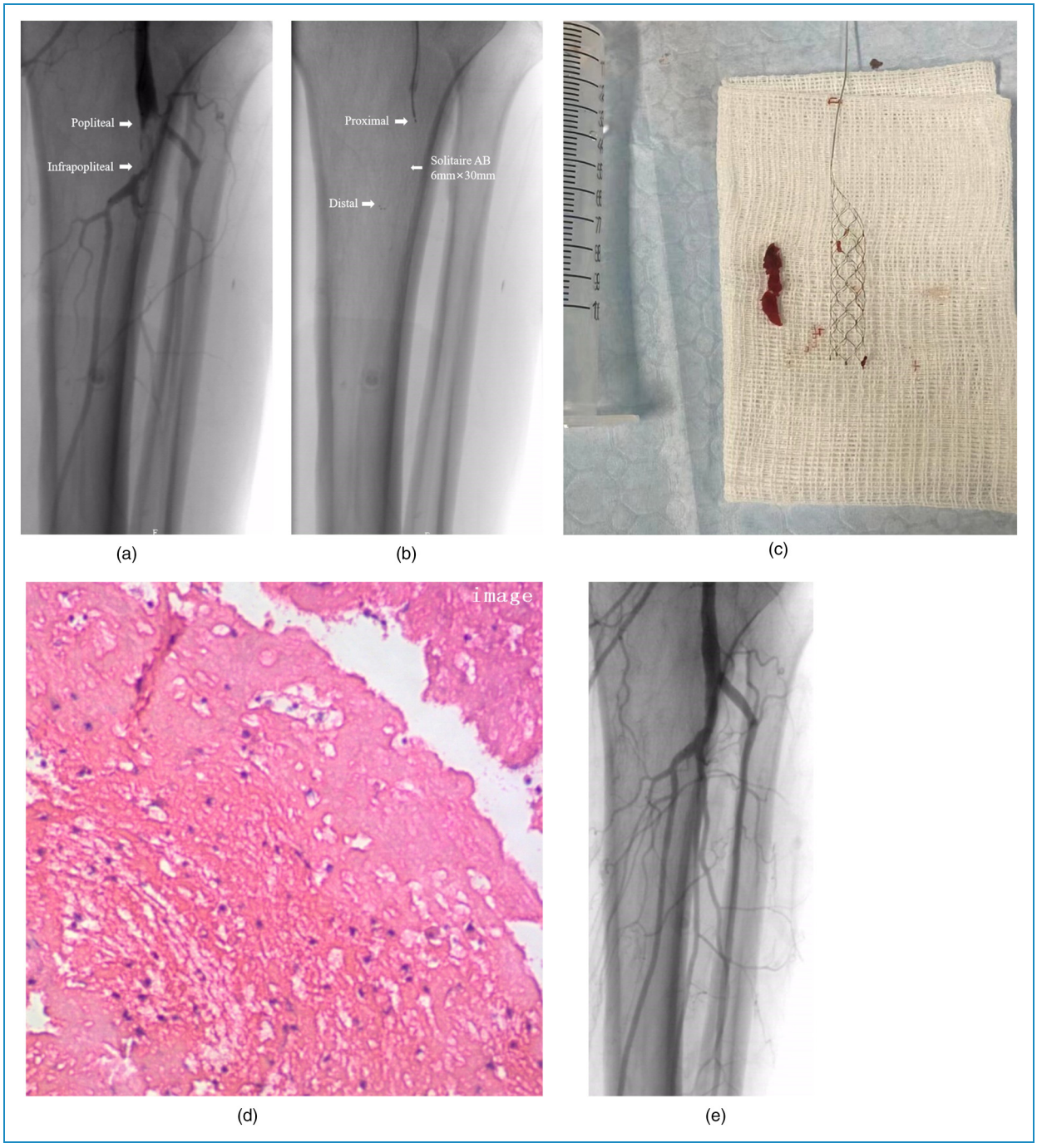

Figure 1. Angiographic images from a 67-year-old male who presented with acute limb ischemia (ALI) secondary to popliteal and infrapopliteal embolic occlusion were successfully treated using a Solitaire AB device in combination with thromboaspiration. (a) Diagnostic angiography showed the occlusion of left popliteal artery as well as of infrapopliteal artery involved. (b) A Solitaire AB device (6 mm × 30 mm) was deployed across the occlusive segment (white arrowhead shows the mark at the proximal and distal end of the Solitaire AB device). (c) Clot retrieved by Solitaire AB device is presented. (d) Pathology showed the main constituent element of clot retrieved was cellulose and hemoglobin. (e) After two passes of Solitaire AB device, recanalization of the occlusion was achieved without distal embolization.

achieved in 11 (73.3%) patients. Figure 1. (a-e) shows a successful thrombectomy procedure. A patient who experienced unsuccessful thrombectomy, subsequently underwent a successful thrombectomy double-stent retrievers, the size of solitaire AB stent used was double consisted of one 6 mm × 30 mm and one 4 mm × 20 mm sizes. Two

(13.3%) patients encountered residual clots in distal small arteries underwent adjunctive CDTs, the mean of duration and the dosage used was 1.3 ± 0.4 days and 7.5 ± 3.5 mg, respectively. At completion, an additional balloon angioplasty for coexisting chronic stenosis to obtain sufficient distal reperfusion was performed in one (6.7%) patient, and the recanalization of the stem of the popliteal artery was achieved. The group indicated a short mean of 4.3 ± 1.0 days in-hospital length of stay. All patients had notable symptom relief after the procedures, the ABI was significantly improved from pre-procedure measurements to those after treatment completion ($t = -10.06$, $p < 0.001$). Besides a patient of grade IIb who encountered minor amputation of single toe, the surgical amputation was prevented in remain patients. Clinical success estimates were achieved in 93.3% of patients (14/15). Of these, the clinical success rates of patients in ischemia grades I, IIa, and IIb were 100% (2/2), 100% (8/8), and 80.0% (4/5), respectively.

Complications and treatment therapy

No device-related complications or distal embolization events were recorded during the procedures. One (6.7%) patient who underwent adjunctive CDT encountered a minor complication in which the hematoma of the puncture site and local pressure dressing for observation and treatment of minor hemorrhage was applied. Fortunately, this event was resolved without permanent sequelae. No major amputation or death was recorded.

Follow-up and limb freedom from amputation

All patients were alive when discharged from the hospital and were followed up thereafter. During the follow-up time of 12 months (range: 12–26 months), the patency rate of popliteal artery at 1 month, 6 months, and 12 months were 100% (15/15), 93.3% (14/15), and 80% (12/15) respectively. Freedom from recurrent ALI symptoms was achieved in 93.3% patients, and one patient encountered a secondary embolic event at 12 months, the reintervention was successful accomplished. The limb salvage was 100% (15/15) during follow-up period.

Discussion

The therapeutic approaches applied in popliteal and infrapopliteal ALI can theoretically be classified as surgical revascularization or endovascular revascularization. However, the present studies of ALI are limited to an impure subset of patients with popliteal and infrapopliteal lesions or do not report the efficacy and safety for infrapopliteal lesions.[2,5,14] Thereby, the exact status for popliteal and infrapopliteal embolic occlusion has not been achieved. As limited literatures reported, the surgical revascularization (using a Fogarty catheter) for popliteal and infrapopliteal ALI is associated with high risk of emboli loss and perioperative complications.[6,15] Therefore, the importance of less-invasive endovascular recanalization stands out for thromboembolism involving small vessels.[9] However, these techniques have different adverse event profiles. CDT is one of the most commonly favored and well-established techniques of endovascular recanalization.[5] It has been reported with satisfactory results and few complications,[5,15] whereas this treatment modality used solely is limited by a higher-level nursing care unit, prolonged reperfusion time, and increased risk of bleeding, especially in advanced age patients. Meanwhile, several mechanical techniques, such as pharmaco-mechanical, microfragmentation thrombectomy devices, including AngioJet catheters and Rotarex catheters, have created a new era for mechanical thrombectomy therapies.[16] Mechanical thrombectomy therapies had been proven with similar limb salvage, overall survival, and secondary patency rates when compared to CDT alone.[17] Although the working mechanism of mechanical thrombectomy fundamentally differs, limited evidence showed that these devices needed to be in combination with CDT in majority of patients to achieve a higher technical success rate and longer patency rate, moreover, these is associated with concomitant risks of spasm, dissection, vessel rupture, plaque disruption, and distal embolization.[17]

Previous studies showed that more extensive ALI occurred in patients with embolic occlusion than those with thrombotic occlusion.[2,3] Atrial fibrillation may still be considered as the main etiology of embolic occlusion. 73.3% of patients in this study experienced abrupt severe symptoms with a history of diagnosed atrial fibrillation, without collateral formation on arteriography, which seems to be in accordance.[2] Although CDT used solely has been reported with a satisfactory outcome in thrombotic occlusion, it may be unsuitable due to an inherent hard texture characteristic of emboli.[13,14] In addition, most of the selected patients in our study are in ischemia categories IIa (53.3%) and IIb (33.3%), the disadvantage of CDT is that it opens the lumen slowly, ischemia may aggravate during CDT treatment if the emboli are not removed in a timely manner.[13] Despite the AngioJet and Rotarex devices are both available at our institution, were considered unsuitable due to the marginally effect and higher require of ongoing CDT for smaller vessels, which were also reported in previous study.[14] All mentioned above were the primary concerns in our patients, thus, an emergency revascularization technique option of Solitaire AB devices, for popliteal and infrapopliteal ALI were selected as an alternative to attempt under the discretion of the treatment group. In this study, this was successful attempted as a stand-alone technique in majority patients, adjunctive CDT was performed in 13.3% (2/15) patients to obtain sufficient distal reperfusion, for the reason of residual clot in distal

small arteries where the Solitaire AB device could not safely reach. Based on limited evidence, this combined technique appears to reduce the requirement for adjunctive CDT when compared to that almost 50% in AngioJet reported.[14]

Wick et al.[18] first reported a successful recanalization using Solitaire device was achieved in an acute embolic occlusive patient with ALI. Subsequently, a modification that in combination Solitaire device and thromboaspiration were made in a vitro study, revealed the advantages of reducing the risk of distal embolism, as well leading to better recanalization rate than the Solitaire device alone.[19] As an expansion, the off-label applied study has reconfirmed it in patients who underwent popliteal and infrapopliteal ALI by achieving better technical and longer patency rate with no serious complications. Clot retrieval is performed by the deployment of Solitaire AB directly into an occluded artery with a diameter of 5.3 ± 0.6 mm, in order to improve the thrombectomy efficacy and reduce the risk of further distal embolization, additional thromboaspiration using a 6-F guiding catheter is combined in this study. This coupled technique appears to have the functions including both stent deployment, which enables immediate flow restoration, and an aspiration device,[11] which allows definitive clot removal from an occluded artery.

The present study demonstrated that mechanical revascularization using Solitaire AB device coupled with manual thromboaspiration is successful as a first-line endovascular technique in 73.3% of patients with ALI secondary to popliteal and infrapopliteal embolic occlusion. The robust technical success was achieved in a moderate time of 1.2 ± 0.3 h; moreover, the patency rate and limb salvage during follow-up at 12 months were, respectively, 80.0% and 100%. Limited data showed that this combined technique seems to have the advantages of pronounced removal of clot in a moderate time, speedy recanalization of reperfusion, and approving limb salvage and patency. Furthermore, this study suggests the combined technique can be performed relatively safely from the perspective of complications. A patient experienced an unsatisfactory thrombectomy, the complete stent expansion could not be achieved because of preexisting atherosclerotic plaques, which compromised the efficacy of the stent retriever. This phenomenon was also found during the treatment of AIS and AMI[11] at our institution. According to our limited experience, the unsatisfactory stent expansion also suggests that coexisting stenosis may exist, this combined technique seemed to have satisfactory efficacy for patients without coexisting atherosclerotic stenosis. Under this condition, adjunctive balloon angioplasty may help achieve rapid recanalization and correct coexisting stenosis. Given its potential usefulness in prompt recanalization, this combined technique could be an alternative modality for selected patients without chronic peripheral arterial stenosis diseases.

In the present study, a patient with a vessel diameter of 7.0 mm, over the size of Solitaire AB device applied, was difficult to promote sufficient revascularization in using a single Solitaire AB device. Therefore, before the mechanical recanalization procedure, target vessel diameter assessment using CTA was necessary. As such, modification was made in this individual, the use of double stent retrievers achieved robust success. Popliteal artery occlusion involving bifurcation has a recalcitrant and relatively large clot load exceeding the diameter of single stent, leading to a reduction in the possibility of successful recanalization. Typically in this condition, the application of a single-stent retriever or other rescue therapies such as CDT, thromboaspiration, balloon angioplasty, or stent placement may not achieve recanalization of all branches.[19,20] In the above case, single-stent retrievers could not trap the clot after three retrieval attempts. As a novel thrombectomy technique, double stent thrombectomy achieved a recanalization in above selected case, and the passe was one attempt, which may be attributed to that double stent had increased stent expansion degree and device surface, this can enhance the device purchase distal to the clot, increase the chances of dragging clot out. According to this limited experience, patients with refractory acute embolic occlusions at the bifurcation of popliteal artery may be potential candidates for this combined technique.

Some limitations of the present study should be mentioned. First, this was a preliminary retrospective study without a control group performed at a single institution over a period of one year. Second, the conclusions were inevitably hampered by a lack of robust data attributed to a small group of cases and experience, which should be interpreted with caution and be confirmed in further study in this field. Third, this study combined stent retrieval coupled with thromboaspiration as a whole technique, partly underwent adjunctive CDT, thereby was unable to evaluate the importance of each element. Moreover, data of this technique compared with other thrombectomy devices as well as the cost-effectiveness was lacking, which may help prompt the design of RCTs to definite which approach is better hoping to help clinicians choose for individual patients.

In conclusion, this study demonstrates that mechanical revascularization with the use of Solitaire AB device coupled with manual thromboaspiration appears to be a rapid, safe and effective modality. These findings may add a promising recanalization therapy for the selected patients with acute embolic occlusion of the ALI secondary to popliteal and infrapopliteal arteries, that appears to reduce the requirement for CDT. Future prospective large-scale trials regarding this combined technique need to be designed to further evaluate the exact role.

Availability of data and materials: The datasets generated and analyzed during the current study are not publicly available, as the experimental data are related to other experiments that are progressing but are available from the corresponding author upon reasonable request

Contributorship: Conception and design: MG, HS.
Analysis and interpretation: MG, JK.
Data collection: MG, YZ, BZ, JK.
Writing the article: MG, YZ.
Critical revision of the article: MG, XH, LC, JG.
Final approval of the article: MG, YZ, XH, LC, BZ, JK, HS, JG.
Statistical analysis: JK.
Overall responsibility: HS, JG.

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ORCID iD: Maofeng Gong https://orcid.org/0000-0002-4580-3232

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