



Hybrid Treatment for Ischemic Limb Salvage in Patients with Subacute Complex Infringuinal Arterial Occlusions

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Abstract:

To evaluate safety and efficacy of a hybrid technique using a Fogarty catheter and an angioplasty balloon to retrieve organized thrombosis then endovascular therapy for underlying chronic lesions in subacute ischemic limbs with complex long infringuinal arterial occlusions. Retrospective study. Patients presented with Rutherford (4:6) critical limb threatening ischemia (CLTI) and reported acute pain onset or worsening of existing symptoms and presented between 15 days and 3 months duration. Included cases underwent hybrid management for limb salvage performing short time inflation with angioplasty balloon to disrupt fibrosis then passing a Fogarty catheter to retrieve thrombosis and finally treating the underlying arterial lesions. Patient characteristics and comorbidities were reported; degree of disease in the crural vessels was described using the Society of Vascular Surgery modified runoff score. Pedal runoff was assessed according to pedal arch state. Study outcomes included technical success, 1-year patency, limb salvage, and amputation free survival (AFS) rates. Fifty-four patients (mean age 57.2), with a mean symptom duration of 7.3 ± 2.6 weeks, underwent the described hybrid management protocol. Mean runoff score was 7.5 ± 1.3 . Distal embolization was reported in 11 (20.4%) cases. Technical success was 90.7%. Primary, assisted primary, and secondary patency rates were 64.8%, 75.9%, and 79.6%, respectively. The 1-year AFS was 77.8%. Limb salvage rate was 88.9%. This study suggests that reported hybrid revascularization modality is considered a safe and effective alternative for treating subacute ischemic limb patients.

Keywords Subacute · Limb ischemia · Hybrid

Introduction

Current recommendations still overlook the subacute (> 14 days and < 3 months) ischemic phase and consider patients presenting with > 14 days lower extremity ischemia as chronic. This timely presentation from onset of symptoms often entails an organizing thrombus amidst arterial occlusion. Because of the rapid organization and adherence of the clot to the arterial wall in this ischemic phase, this marks its difficult retrievability and failure of simple endoluminal aspiration or delayed surgical thrombectomy using a Fogarty catheter.[1]

The advent of percutaneous thrombectomy devices and debulking procedures aimed to downgrade of TASC stage of occluded arterial segments and unveil the culprit lesion to be

treated, with the main purpose to decrease incidence of distal embolization and reduce the bleeding risk or technical failures with increasing dose of thrombolytics at this specific presentation.[2, 3] However, different studies reported varying rates of possible complications with the mostly widely used rheolytic thrombectomy devices such as distal embolization, vessel perforation, beside the possible technical failure.[4–7]

We justify the need to report this experience in the era of effective endoluminal thrombectomy devices for the following reasons: possible non-availability, no adjuvant thrombolytic use with the described technique, suggests a less invasive solution to avoid long bypass surgery or sometimes, non-option CLTI in similar situations of bad distal runoff or absent vein conduit and finally to combat the idea of distal embolization with effective surgical retrieval and managing distal chronic lesions last.

The aim of the current study was to evaluate safety and efficacy of hybrid management using a Fogarty catheter and an angioplasty balloon to retrieve organized thrombosis then endovascular therapy for underlying chronic lesions as an

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alternative solution to treat subacute ischemic limbs with complex long infringuinal arterial occlusions.

Methods

This is a case series analysis of patients treated rather homogeneously between January 2016 and August 2017 in vascular surgery unit of a tertiary referral hospital using hybrid technique for limb salvage in subacute arterial occlusion in lower extremity as described in the procedure section. Our Institutional Review Board approved the current study protocol developed in accordance with the Helsinki Declaration. All patients gave written informed consent prior to revascularization.

Patients were identified when presenting with Rutherford (4:6) critical limb threatening ischemia (CLTI) and reported acute pain onset or worsening of existing symptoms between 15 days and 3 months duration. Subacute ischemic limb categorization was based on clinical criteria and duplex identification of thrombus component within occluded arterial segments as described in other studies. All included patients presented in the non-acute stage and so we evaluated our patients using the Rutherford classification for peripheral arterial occlusive disease that includes a description for clinical presentation and hemodynamic parameters. [1, 8–10] Selected patients for further analysis were (1) those with long complete occlusion of all femoropopliteal segment plus infragenicular 3 leg vessel disease, (2) without significant inflow arterial disease, and (3) who underwent a *planned* hybrid technique for limb salvage performing short time inflation with angioplasty balloon then passing a Fogarty catheter to retrieve thrombus and finally treating the underlying chronic arterial lesions.

Patient risk factors including diabetes mellitus, hypertension, dyslipidemia, renal impairment, smoking and history of ischemic heart disease, clinical presentation (Rutherford classification), and duration of symptoms were reported. Preoperative pulse examination and ankle brachial index (ABI) measurement were performed for all cases.

Duplex examination took 30 to 45 min for each limb examined, and findings were recorded on duplex map. That was our initial important step to differentiate the subacute from chronic arterial lesions as follows: the diseased segment was detected and investigated for its length, diameter, wall structure affection, and clot component. Removable thrombus was defined when duplex reported conclusive images with the presence of intraluminal echoes, absence of color flow and detected definite intimal lining in occluded segment. Chronicity in occluded arterial segments was noticed with interrupted intima or calcified walls whether linear or circumferential and reduced diameters. We considered non-visualized arterial segments as chronic. Multidetector CT

angiography was routinely performed to describe length and extension of arterial occlusion, runoff score, and pedal runoff.

The degree of disease in the crural vessels was described using the Society of Vascular Surgery modified runoff score.⁸ A score of 0 is assigned to a vessel with < 20% stenosis, a score of 1 for a 21% to 49% stenosis, 2 for 50% to 99% stenosis, 2.5 for a vessel occluded over an area less than half its length, and 3 for an occlusion greater than half the vessel length. Each tibial vessel was assigned a number from 0 to 3, then 1 was added to the product of the sum of all three leg vessels, resulting in a decimal scoring system from 1 that describes a widely patent runoff to 10 for no major vessel runoff.

Pedal runoff was assessed according to pedal arch state as follows: (type 1) patent arch with retrograde flow, (type 2) patent arch with no retrograde flow, (type 3) diseased or partially occluded arch, and (type 4) non-visualized arch.

Procedure description

All procedures were performed by senior vascular surgeons in a hybrid operative room using a Philips BV Pulsera mobile C-arm. A contralateral retrograde femoral approach was performed with a 5 French introducer Sheath. Unfractionated heparin (5000 units) was routinely injected after inserting the sheath. Complete preinterventional arteriography evaluating the inflow and outflow of the ischemic limb was performed.

Passage of a guiding wire (Glidewire advantage, Terumo Medical Corporation, Somerset, NJ, USA) followed by a 5 Fr straight guiding catheter (CXI catheter, Cook Medical Inc., Bloomington, IN, USA) was tried in all cases trying to understand areas of thrombosis through easy wire passage and areas of underlying chronic lesions as perceived by difficulty in wire traversal. Distal intraluminal location was verified with dye injection.

In order to disrupt the fibrous cap in old thrombosis and facilitate retrieval, short inflation times of an angioplasty balloon of (5–6 mm diameter, 80:150 mm length) was done in all occluded segments. At that point, selective angiography in work area reveals opacified thrombotic material. Then, a 5-cm longitudinal groin incision under local anesthesia was performed to expose the common femoral artery and origin of the superficial femoral and *profunda femoris* arteries. Thrombus retrieval was achieved through transverse arteriotomy and passage of over the wire Fogarty thrombectomy catheter (Edwards Fogarty catheters, Edwards Lifesciences, CA, USA) that was intentionally used in order to ensure crossing in the same restored lumen and for selective leg vessel passage if deemed necessary. Completion angiography, from crossover sheath after arteriotomy closure, was performed by the end of the procedure to confirm > 95% thrombus removal and unveil the underlying lesion that was treated as indicated. Steps were repeated in case of residual thrombosis till

reaching the technical success point. Underlying chronic lesions were treated with plain balloon angioplasty and bailout bare metal stenting (BMS) in case of residual stenosis > 30% or flow limiting dissections. Long angioplasty balloon was inflated at nominal pressure for at least 3 min.

The final angiogram included visualization of the infrapopliteal and pedal arteries to rule out distal embolization. All patients were kept after the procedure on aspirin (100 mg/day) and warfarin with adjusted INR (2:3). A case presentation is demonstrated in Fig. 1.

Technical success was defined as restoration of antegrade flow and complete or near complete (95% by volume) removal of the thrombus followed by treatment of underlying chronic lesion to achieve inline flow without residual stenosis of > 30% or flow limiting dissections.

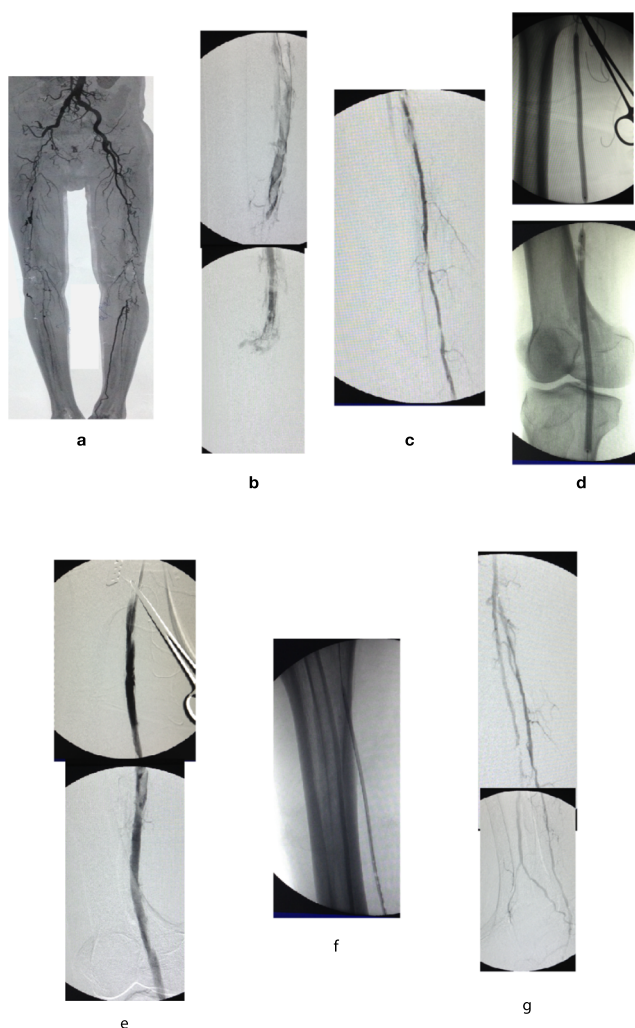


Fig. 1 Case presentation for the described technique. **a** MDCT showing long femoropopliteal occlusion on the right side. **b** Selective angiography within occluded SFA confirming thrombosis. **c** Catheter reached a distal chronic diseased posterior tibial artery as the run off for this case. **d** Short time inflations using angioplasty balloon to disrupt fibrosis in subacute thrombosis. **e** Selective SFA angiography showing successful thrombus removal. **f** Angioplasty of leg arteries (peroneal and posterior tibial). **g** Final infragenicular angiography

Follow-up

ABI, toe pressure measurements, and duplex scanning were performed for all patients at days 1 and 7 postoperative, then at 3-, 6-, and 12-month follow-up visits. Angiography was performed when duplex imaging suggested greater than 50% restenosis or when clinically indicated. The aim of days 1 and 7 evaluation was to detect early thrombosis, possible complications as dissection, pseudoaneurysm, hematoma.

Study end points were patency, limb salvage, and 1-year amputation free survival rates as defined by the society of interventional radiology (SIR). [11] Primary patency rate defined as time from the revascularization procedure to either revision or the first occurrence of thrombosis of the treated segment. Primary assisted patency is defined as the time from the revascularization procedure to thrombosis, irrespective of any interval therapy to restore or maintain flow within the treated segment. Secondary patency is defined as the time from the procedure to the permanent loss of flow in the treated segment, irrespective of any interval therapies. One-year amputation free survival (AFS) was defined as first major amputation or death from any cause whichever occurred first. Major amputation is an amputation proximal to the ankle level. Limbs that required major amputation (above- or below-knee) were considered as *failed* salvage. Limbs that required minor amputation (toe, ray, or trans-metatarsal amputation) but ultimately healed were considered successful limb salvage.

Statistical analysis was performed using SPSS 20 software (SPSS Inc, Chicago, Ill). Descriptive statistics were used, with continuous variables expressed as mean \pm standard deviation and categorical data expressed as percentages. Univariate analysis was performed with the χ^2 for categorical variables. Kaplan-Meier analysis was used to estimate patency rates, limb salvage and 1-year AFS. A value of $P < .05$ was considered significant for all analyses.

Results

During study period, 54 patients (mean age 57.2 ± 13.4 years) underwent a hybrid revascularization procedure to achieve limb salvage for this particular subacute ischemic limb presentation. All patients reported a mean symptom duration (acute pain or worsening of existing situation) of 7.3 ± 2.6 weeks. Long total occlusion of all femoropopliteal segment was a dominant feature in the current study. The mean runoff score was 7.5 ± 1.3 . Patient characteristics and comorbidities are shown in Table 1.

Following the described hybrid technique, distal embolization was reported in 11 (20.4%) cases. Technical success was 90.7%. Pedal runoff (non-visualized arch) was the only variable significantly affected the immediate outcome ($P <$

Table 1 Patient characteristics and comorbidities

Variable	
Sex <i>N</i>	
Male	37 (68.5%)
Female	17 (31.5%)
Age, years	
Mean ± SD	57.2 ± 13.4
Comorbidities, <i>N</i> (%):	
DM	34 (63%)
HTN	24 (44.4%)
Smoking	35 (64.8%)
IHD	32 (59.3%)
Renal impairment	15 (27.8%)
Rutherford staging, <i>N</i> (%):	
Stage 4	16 (29.5%)
Stage 5	34 (63%)
Stage 6	4 (7.5%)
Runoff score:	
Mean ± SD	7.5 ± 1.3
Pedal runoff, <i>N</i> (%):	
Type 1	14 (25.9%)
Type 2	24 (44.4%)
Type 3	12 (22.2%)
Type 4	4 (7.5%)

DM diabetes mellitus, HTN hypertension, IHD ischemic heart disease

0.0001), while distal embolization did not ($P = 0.7$) in the current study analysis.

Plain balloon angioplasty was used to treat all underlying chronic lesions successfully except for three cases where bare metal stenting (single 6 mm * 200 mm BMS deployed in SFA) was deemed necessary for flow limiting dissections.

Short autogenous bypass procedure was performed to treat a proximal superficial femoral artery pseudoaneurysm in single case. No adjuvant thrombolysis was reported in the current series.

Excluding the technically failed cases ($n = 5$), primary, assisted primary, and secondary patency rates were 64.8%, 75.9%, and 79.6%, respectively. The 1-year AFS was 77.8%. Limb salvage rate was 88.9%. Figures 2 and 3 demonstrate Kaplan-Meier curves and analysis of current study outcomes.

Discussion

The development of the balloon catheter by Fogarty in 1963 revolutionized surgical treatment of acute limb ischemia and consequently decreased the risk to life and limb. [12] However, thrombotic ischemia in native vessels with underlying chronic lesions increased failure rates of simple passage of

a Fogarty catheter to distal vasculature and surgical solutions composed of endarterectomy or long bypasses. Patients with subacute occlusions (14 days and 3 months) possibly form 10% to 15% of those presenting with “chronic” limb ischemia. The timing of presentation may affect the composition of the occluded vessel, with more likelihood of harboring thrombosis of varying degree of organization. [1, 2] The aim of reducing the clot burden in this patient subgroup is to downgrade the TASC class of the treated lesions, potentially making endovascular intervention more effective or provide another alternative beside long bypass option recommended for TASC D occlusions. [13]

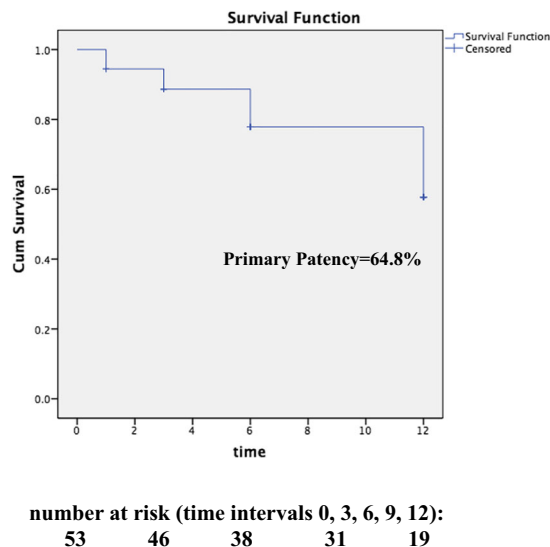
There is a general consensus that venous grafts should be used in infra-inguinal bypass grafting whenever possible. The conduit of choice is the autogenous great saphenous vein, which has proven to be superior to alternative grafts in terms of patency and complication rates.[14, 15] However, limitations for such modality remain the availability of suitable conduit, vein diameter which is a controversial issue and the state of the distal runoff. Selim et al.[16] reported the outcomes of 157 infrainguinal bypasses in CLTI using a reversed saphenous conduit in 2 groups: > 3 mm conduit and < 3 mm conduit. Most of procedures were femorodistal bypass (77.8%). The primary, assisted primary, and secondary patency rates at 1 year for vein conduits < 3 mm were 51.2%, 82.6%, and 82.6%, respectively, compared to 68.4%, 93.3%, and 95.2%, respectively, in the > 3-mm group.

Tonessen et al.[17] were first to suggest the concept of decreasing clot load in chronic occlusions with the hope of decreasing early rethrombosis and increasing patency rates, based on the observations of up to 40% failure 24 h after femoropopliteal angioplasty. Because of the high cost and risks involved with the lengthy thrombolytic therapy, various methods have been used to debulk the clot component of subacute and chronic occlusions in various arterial beds, mainly with the intention of reducing the incidence of distal embolization after an intervention.[2, 3, 18]

Although there are various thrombectomy devices, their effectiveness decreases as the age of the clot increases, with more organization and adherence to the arterial wall. Duc et al.[2] reported their results with Rotarex thrombectomy device (Straub Medical, Wangs, Switzerland) designed for thrombus removal in acute ($n = 17$) and subacute ($n = 24$) femoropopliteal occlusions. Distal embolization was observed in 24%, and vessel perforation in 12% of the cases, early reocclusion in 10%.

Kasirajan et al.[19] reported their experience in acute and subacute occlusions in a variety of arterial beds by using the Angiojet thrombectomy device with adjunctive thrombolysis. They reported technical failure of 15.6%, partial success was 22.9% and successful recanalization of 61.4%. Adjunctive thrombolysis was used in 58% of cases. Patency at 6 months

Fig. 2 Primary patency rate



was 79%. Local complications were noted in 18.6% and amputation rate of 9.3%,

Saxon et al.[20] reported their results with thrombus aspiration in a series of 79 patients using Penumbra/Indigo system. Complete thrombus removal and restoration of normal flow was achieved in 77.2% of patients (61 of 79) after all endovascular treatment was completed. No patients required surgical revascularization. No device-related adverse events occurred.

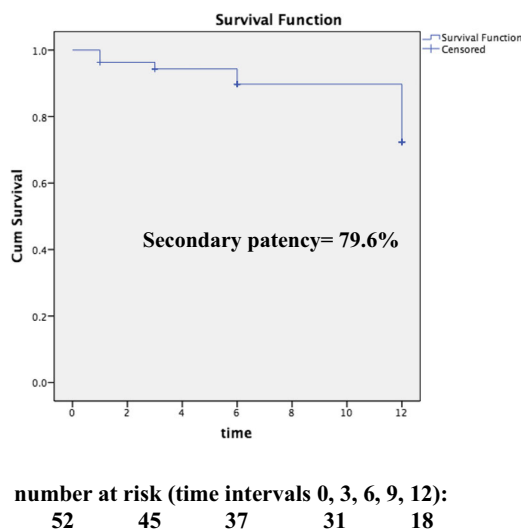
In the light of current data, percutaneous thrombectomy devices are considered an important tool in the armamentarium of interventionists aiming limb salvage; however, potential unavoidable limitations are a fact. That could be limited resources, lacking patient reimbursement, needed technical expertise, reported failure rates in certain situations and possible complications.

We report our experience in treating 54 patients with subacute limb ischemia using hybrid revascularization

alternative. This technique could offer a suitable treatment option in long occlusions with unsuitable distal runoff for a conventional bypass surgery as demonstrated in Fig. 1, in absence of suitable vein conduit or unavailability of percutaneous thrombectomy devices. The main technical targets were to achieve passage of the Fogarty catheter to distal vasculature, disrupt fibrous cap and fibrosis within old thrombosis to achieve retrievability and finally to treat underlying chronic lesions. Technical success was achieved in 90.7%, reported distal embolization in 20.4%, 12-month primary, assisted primary, and secondary patency rates were 64.8%, 75.9%, and 79.6% respectively. Limb salvage rate was 88.9%.

Despite higher rate of distal embolization, that did not affect the outcome as successfully retrieved after passage of Fogarty catheter. In a series of 22 patients (38 crural arteries), micro tibial embolectomy was effective to retrieve emboli from crural and pedal vasculature in 21 (95.4%) cases. [21]

Fig. 3 Secondary patency rate



Reported failures in the current cohort were linked to pedal runoff condition. That was reported in four cases having a type 4 arch (non-visualized arch) and single case with type 3 (diseased/partially occluded arch) confirming that pedal run state in such patient presentation is the key for success.

Non randomization, small sample size, and lack of long-term follow-up are considered main study limitations. We have not performed any cost analysis for the current treatment protocol. In addition, lack of a comparison group treated with either conventional bypass or exclusive endovascular modality was encountered due to the beforementioned circumstances.

Conclusion

According to data analysis, this study suggests that proposed technique formed of repeated short inflation with angioplasty balloon to disrupt fibrosis and pave the way then a Fogarty catheter to retrieve thrombosis followed by treatment of underlying chronic lesions is a safe and effective and could offer another revascularization modality for treating subacute ischemic limb patients.

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Compliance with ethical standards

Conflict of interests The authors declare that they have no conflict of interest.

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