Hybrid procedure for the treatment of immediately threatened acute on chronic lower limb ischemia

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Background
Several methods have been postulated for the treatment of acute on chronic lower limb ischemia; among them, the hybrid procedure (combined open thrombectomy and angioplasty) is gaining popularity. It is aimed at clearing the vessel and treating the underlying vessel lesion in one step.
Patients and methods
A total of 23 patients admitted to the vascular department were eligible for inclusion in this study. They were subjected to thromboembolectomy, followed by endovascular balloon dilatation with or without stenting. Data regarding the risk factors, procedure success, and complications were recorded.
Results
Hybrid procedures showed 83% immediate technical success and 74% primary limb salvage rate up to 1 month with no early complications. Infrapopliteal lesions were the most difficult to treat and the leading cause of limb loss.
Conclusion
The hybrid procedure provides an accepted outcome in treating immediately limb-threatening acute on chronic lower limb ischemia.

Keywords:
angioplasty, hybrid procedure, threatened ischemia, thrombectomy

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Introduction

Patients with chronic limb ischemia are at an increased risk for limb loss [1], especially if complicated by an acute event, turning it to an acute on chronic status, which magnifies the amputation rates if left untreated [2]. Successful treatment of patients with acute on chronic lower limb ischemia has always been a challenge for the vascular surgeon.

Options to treat this difficult vascular emergency are limited and none of them gives optimal results. One of them is endarterectomy with arterial bypass [3], an option that is not suitable in most patients due to the loss of the distal run-off by the load of the thrombus, and the expected short patency rate due to the long bypass if successfully created.

Another option is the catheter-directed thrombolysis (CDT), which is a modern alternative to the systemic thrombolysis procedure. In this case, thrombolytic therapy is carried out through an intra-arterial catheter placed within the thrombus to achieve a regional thrombus dissolution with relatively less systemic effect compared with what would occur with systemically administered thrombolysis. However, time to achieve reperfusion with thrombolytics can be as long as 1.5 days. In addition, there is a need to take the patient back to the Operative theater to treat the underlying lesion. Moreover, thrombolytics are also associated with a 5–15% risk for systemic bleeding complications including major intracranial hemorrhage [3–5].

The combined use of endovascular and open techniques (hybrid) in the same surgical setting has been suggested to be effective in treating critical limb ischemia [6–8]. It has the advantage of rapidly clearing the vessel and efficiently treating the underlying stenosis/occlusion in one session.

While nearly most of the previously published studies described the hybrid procedure as a Common Femoral Artery (CFA) endarterectomy with proximal/distal (or both) angioplasty for critical limb ischemia, the present study aimed at applying the same hybrid principles for treating a more challenging condition. Therefore, this study aimed at assessing the ability of open thrombectomy with endovascular balloon dilatation with or without stenting (as a hybrid procedure) in treating immediately threatened acute on chronic lower limb ischemia and its complications.

Patients and methods

This prospective study was conducted between May 2013 and May 2015 at Suez Canal University Hospital, Ismailia, Egypt. After obtaining approval from the local ethics committee and informed consent from the patient before the operation. All patients admitted to the vascular department diagnosed with acute on chronic ischemia were included in the study. They were diagnosed according to the following criteria:

(1) Presence of pain, paralysis, paraesthesia, pallor, coldness and absence of pulse.
(2) Previous history of claudicating pain.
(3) Chronic ischemic symptoms and signs in the other limb.
(4) Reduced ankle brachial pressure index in the noncomplaining limb.
(5) Presence of risk factors (age, diabetes, hypertension, hyperlipidemia, ischemic heart disease, atrial fibrillation, and cardiac valvular disease).
(6) The presence of arterial wall atherosclerosis detected after undergoing the duplex examination.

The limb status of the patients was categorized according to the recommended standards for reports dealing with lower extremity ischemia [9]. In addition to the duplex examination, all participants underwent the following investigations: complete blood count, prothrombin time, partial thromboplastin time, serum creatinine, fasting blood sugar/random blood sugar, and ECG.

Patients with the following criteria were excluded from the study:

(1) Those with nonviable limb, as they were subjected to primary amputation.
(2) Those with viable limb (Rutherford category I), as they were subjected to preparation and nonurgent revascularization by using the endovascular or bypass procedure.
(3) Patients with Rutherford category IIa (marginally threatened limb), as they were subjected to thrombolysis.
(4) Patients with comorbid disease, which may affect or contraindicate the outcome; congestive heart failure, impaired kidney function, chronic liver disease Child B and C.
(5) Patients with known allergy to contrast.

The remaining eligible patients, Rutherford category IIb (immediately threatened), were included in the study. After obtaining an informed consent, they were subjected to the following.

Methods

Technique for hybrid procedure

Under local anesthesia, the CFA was dissected, clamped, and a small arteriotomy incision was made. After formal embolectomy with a Fogarty catheter, proximal and distal angiography were carried out using a 6-Fr sheath inserted through the arteriotomy. Lesions were crossed by a 0.035 inch Terumo wire (Terumo Corporation, Tokyo, Japan), dilated with appropriate size balloon; a stent was routinely deployed for iliac lesions and selectively for distal lesions if still stenosed despite repeated dilatation or in case of a flow-limiting dissection. Arteriotomy was closed directly with a 6–0 prolene suture and with venous patch if endarterectomy was performed.

All patients received low molecular weight heparin following the procedure for 3 days and received dual antiplatelets for 3 months.

In addition to the completion angiography, symptoms and signs of ischemia were assessed in all patients immediately after the end of the procedure, on discharge, after 1 week, and after 1 month. Complications including rethrombosis, bleeding, wound hematoma, infection, or tissue loss were recorded.

Study end points

(1) Failure to restore the circulation.
(2) Inability to achieve vessel clearance from clots.
(3) Inability to treat the initial lesion.
(4) Distal embolization that ends by loss of the limb.
(5) Rethrombosis within the first day after the end of each procedure.
(6) Rethrombosis after discharge from the hospital.
(7) The treated vessels patent for 1 month after discharge.

Success was defined as angiographic evidence of residual stenosis less than 30% with axial flow to at least one patent tibial artery by the end of the procedure. This should stay patent for at least 1 month with restenosis less than 50% of the vessel diameter detected by duplex.

Results

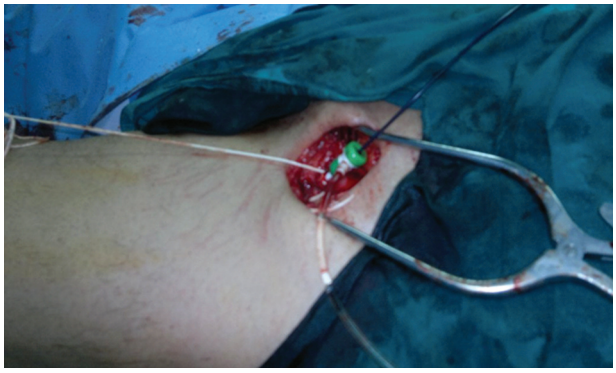
We were able to recruit 23 patients. Patients' age ranged between 53 and 78 years, with a mean of 63

Table 1 Demographic data and risk factors (*N*=23 patients)

Variables	Number of patients [*n* (%)]
Age	
Mean±SD	63±2.8
Sex	
Male	17 (74)
Female	6 (26)
Diabetes	21 (91)
Hypertension	22 (96)
IHD	19 (83)
Hyperlipidemia	18 (78)
AF	2 (9)
Smoking	18 (78)

AF, atrial fibrillation; IHD, ischemic heart disease.

Figure 1



6-Fr sheath after thrombectomy through the CFA arteriotomy.

±2.8 years. The demographic data and risk factors are summarized in Table 1.

All procedures were conducted under local anesthesia, through a groin incision (Fig. 1). After the initial vessel clearance, the remaining vessel stenosis/occlusion was carried out in the femoropopliteal region in 17 patients (74%), followed by the tibials in 10 patients (43%), and the least were in the iliac artery, which were found in only two patients (9%). The lesions were located in more than one region in few patients, as shown in Table 2.

All patients underwent balloon angioplasty for the underlying lesion/lesions. Stents were used in only three patients (13%), two of them for iliac stenosis and one for superficial femoral artery flow-limiting dissection.

By the end of the procedure, radiological success was achieved in 19 patients (83%) (Figs. 2 and 3), and the mean resting ABPI rose from 0.28±0.051 preoperatively to 0.82±0.06 after the procedure. In

Table 2 Location of the underlying vessel lesion (*N*=23)

Sites	*n* (%)
Iliac	2 (9)
Femoropopliteal	17 (84)
Tibials	10 (43)

the remaining four patients (17%), revascularization was not possible as the vessel was not completely cleared and we ended by a distal obstruction with no distal run-off or collaterals. In addition, in two more patients (9%), rethrombosis occurred within the first day and rethrombectomy was not successful. Therefore, the affected limb was salvaged in 17 out of the 23 patients (74%) and remained thus for the first follow up at 1 month.

Direct closure of the arteriotomy was performed in 14 patients (61%), while the remaining nine patients (39%) had endarterectomy and therefore closed with patch angioplasty.

Regarding the characteristics of the patients who had unsuccessful procedure or thrombosis after the initial success, in addition to the fixed presence of diabetes, hypertension and ischemic heart disease in all of them, the most prominent feature was the presence of tibial lesion that was not amenable for revascularization. These characters in comparison with the characters of the limb salvage group of patients are summarized in Table 3.

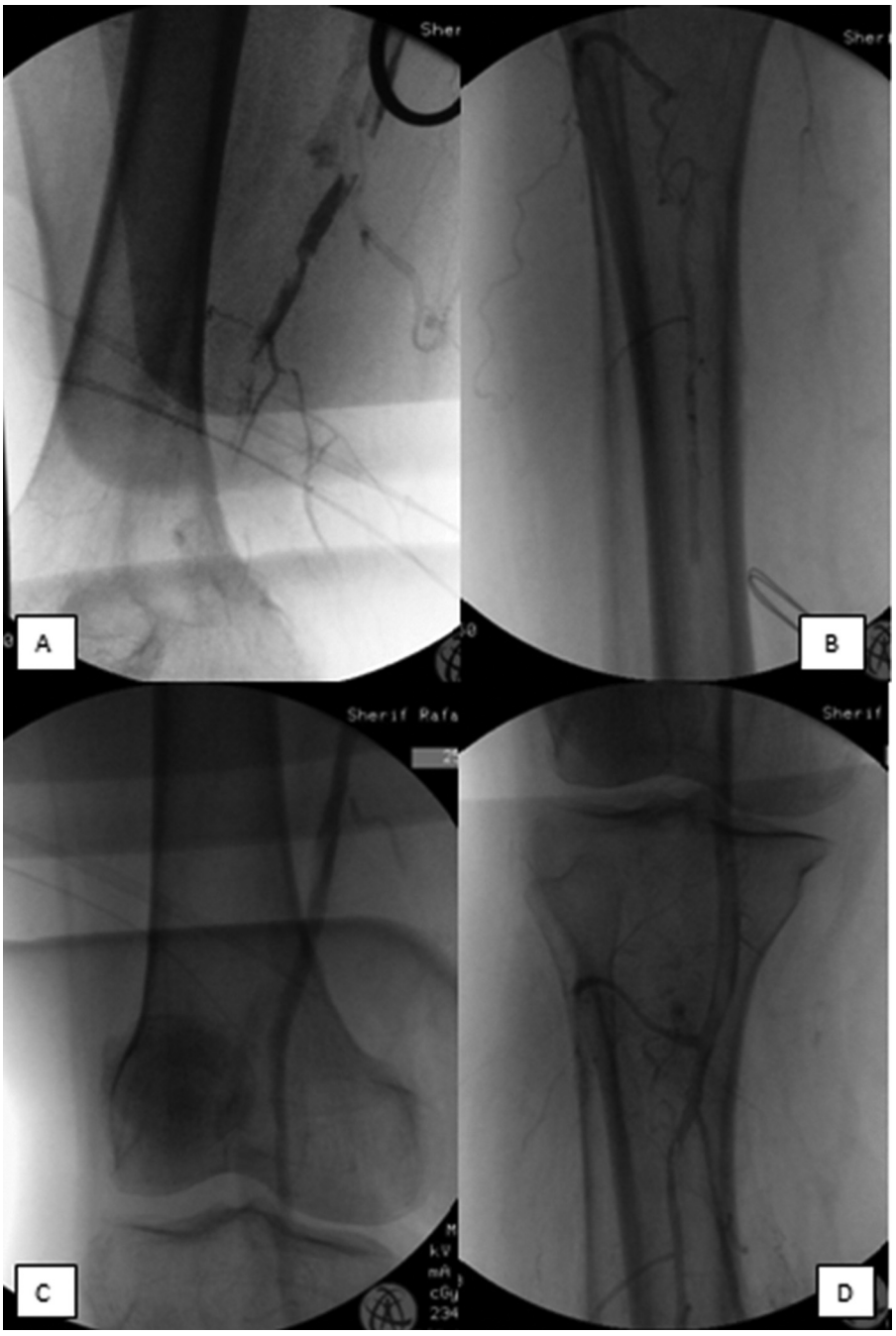
Regarding the complications, a part form bruises and minimal wound hematoma, none of the 17 limb-salvaged patients suffered bleeding or infection or rethrombosis within the first-month follow-up. In two of them, toe amputation was performed, which healed with no progression.

Discussion

A hybrid procedure is suggested to be effective in treating the acute event (thus salvaging the limb) and minimizing the recurrence through improving the underlying pathology [10]. It has been used with promising results in a less aggressive presentation of peripheral vascular disease. The current study aimed at using this procedure in a more challenging group of patients, in whom other modalities of treatment may not be suitable.

Patients in this study shared the same risk factors expected for the selected group of patients. Ankle Brachial Pressure Index The percentage of those risk factors was high among the studied population, which explains the aggressiveness of the disease and the

Figure 2

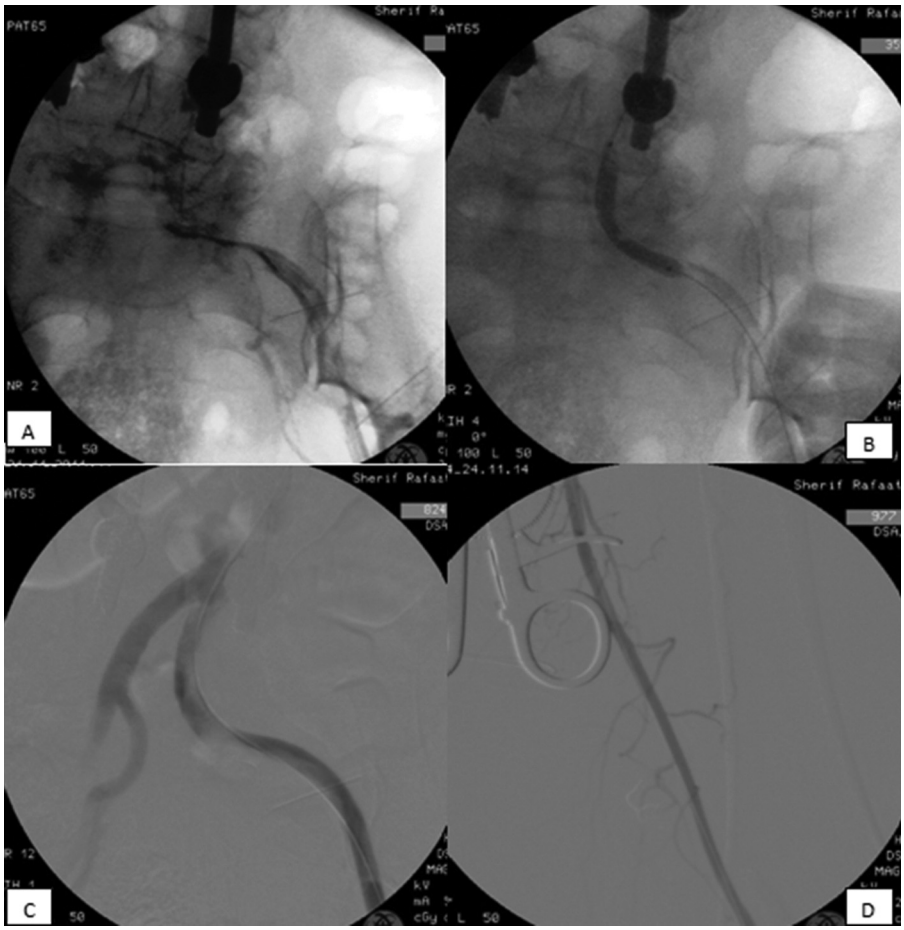


Superficial femoral artery (SFA), popliteal, and tibial procedure; (a, b) after initial thrombectomy, (c, d) after balloon angioplasty. SFA, superficial femoral artery; CIA, common iliac artery.

presentation, as expected for the recruited patients to run this study.

Limb salvage rate in the present study was 74%. However, the technical success rate was 82.6%. Matsagkas his colleagues reported a higher technical success rate of 96.6%; this was because the presentation of the selected group of patients in their study was significantly less severe than that for our group of patients: more than half of the patients in their study belonged to Rutherford category IV [10], whereas all of our patients belonged to immediately threatened category IIb. A similarly high success rate was reported in other studies [11,12], even when compared with open surgery [13,14], and satisfactory results were obtained when used for more proximal lesions [15,16]. This means that shifting to a less severe form of presentation may result in better outcomes. The study included a relatively small number of patients due to the selected type of presentation. However, this was the same in the several comparable studies, where the number of studied patients ranged between 37 and 44 [10,11].

Figure 3



Iliac procedure; (a) after initial iliac thrombectomy; (b) left CIA balloon angioplasty; (c, d) postprocedure angiography.

Table 3 Comparison between the characters of the successful limb salvaged and the nonsalvaged groups

Variables	Limb salvaged group ($n=17$)	Nonsalvaged group ($n=6$)
Risk factors [*n* (%)]		
Diabetes	15 (88)	6 (100)
Hypertension	14 (82)	6 (100)
IHD	13 (76)	6 (100)
Hyperlipidemia	14 (82)	4 (67)
AF	2 (12)	0 (0)
Site of the underlying lesion [*n* (%)]		
Iliac	2 (12)	0 (0)
Femoropopliteal	17 (100)	0 (0)
Tibial	4 (24)	6 (100)

The argument of thrombolysis versus hybrid was excluded by selecting patients belonging to Rutherford category IIb, in whom wasting at least few hours to achieve vessel clearance by CDT was not possible. In addition, it would have required another endovascular session to treat the underlying lesion/lesions to maintain the vessel patency. However, in the current study, the hybrid procedure failed to save 60% of the patients presented with infrapopliteal lesions. It might be better if thrombolytic was used to clear these relatively small diameter vessels and diffuse through their branches and collaterals. This is a strong point in using CDT for patients with distal occlusion when presented in earlier stages category IIa (marginally threatened).

Regarding the cost of the procedure, although not measured, it is clear that the hybrid procedure costs less when compared with the CDT. The CDT costs include the expenses of the thrombolytic agent and the need for readmission to the operative room for the angioplasty step after vessel clearance. This cost is greater when compared with the much less price of the Fogarty catheter used during the hybrid procedure.

Conclusion

The indications for the use of the hybrid procedure for the treatment of peripheral ischemia may remain unclear. However, the current study showed it to be a good choice for acute on chronic lower limb ischemia, category IIb immediately threatened limb, with an accepted success rates in terms of limb salvage and postintervention complications.

Patients with tibial lesions are expected to have the worst results when treated with the hybrid procedure, and therefore should try another modality of treatment.

Conflicts of interest

There are no conflict of interest.

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