Optional management of failed endovascular intervention for infrainguinal arterial occlusive disease

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Received: 10 December 2023
Revised: 8 January 2024
Accepted: 20 January 2024
Published: 22 March 2024

The Egyptian Journal of Surgery 2024, 43:465–472

Introduction
Endovascular treatment is increasingly chosen as the first option for treating infrainguinal peripheral arterial disease. Although open surgical bypass provides the most durable option for limb salvage, it has substantial morbidity and mortality.
Aim
The aim of the study is to determine the causes of failure of endovascular intervention and treatment modalities of failed endovascular intervention and results of each modality.
Patients and methods
A prospective case series study that addresses the outcomes of managing 40 patients with chronic limb ischemia due to femoropopliteal disease treated by endovascular intervention, and the intervention was failed. Causes of failure within 30 days were analyzed.
Results
We had 13 (27.5%) females and 27 (72.5%) males; their age ranged from 45 to 77 years with a mean of 62.20±7.44. Presentation with rest pain: three (7.5%) patients, minor tissue loss: 18 (45%) patients, major tissue loss: 19 (47.5%) patients the length of lesion was between 5 and 10 cm in three (7.5%) patients and more than 10 cm in 37 (92.5%) patients. Runoff in anterior tibial artery: 23 (57.5%) patients, posterior tibial artery: 19 (47.5%) patients, and peroneal artery: 15 (37.5%) patients. We had no complications in 26 (65%) patients, failure to pass in 12 (30%) patients, and distal embolization in two (5%) patients as intraprocedural complications. During the 30-day follow-up: Acute stent thrombosis in 7 (17.5%) cases, flow-limiting dissection in 8 (20%) cases, residual stenosis in 3 (7.5%) cases, acute thrombosis in 2 (5%) cases, missed iliac lesions in 2 (5%) cases, post-procedural distal arterial tree embolization in 2 (5%) cases, and clinical failure was the cause in 2 (5%) cases. The management was: Redo endovascular in 18 (45%) patients, surgical bypass in 14 (35%) patients, primary amputation in six (15%) patients, and medical treatment in two (5%) patients. After 6 months follow-up limb salvage was in 57.5% of the cases with transmetatarsal amputation in 69.6% of them and major amputation was in 42.5% of the cases
Conclusion
Failed endovascular intervention procedures within 30 days were associated mainly with long lesions. So, surgical bypass appeared to be superior to endovascular intervention for long lesions. Improvements in endovascular equipment and angioplasty technique might ultimately improve the outcome results and decrease the failure rate of endovascular interventions

Keywords:
bypass, endovascular, failure

Egyptian J Surgery 43:465–472

1110-1121

Introduction

Peripheral arterial disease manifesting is responsible for more than 400 000 hospital admissions per year in the United States alone and is a marker for significant cardiovascular morbidity [1].

Although open surgical bypass provides the most durable option for limb salvage, but it has substantial morbidity and mortality. Thus, endovascular techniques, as a less invasive treatment, have become an accepted option for the treatment of lower extremity ischemia in many centers [2].

Because of the perceived higher failure rates in patients with more severe lesions, many surgeons have avoided attempting percutaneous repair in these patients for fear of, primarily, precluding or interfering with the success of a bypass procedure [3].

 DOI: 10.4103/ejs.ejs_307_23

Also, redo interventions are more difficult as the lesions tend to be more complex than in the first time, often requiring stenting with longer or overlapping stents or the use of drug-eluting stents, but it is still easier than surgical intervention [4].

Patients and methods

This is a prospective case series study that addresses the results of the management of 40 patients with chronic limb ischemia due to femoropopliteal disease treated by endovascular intervention, and the study analyzes the causes of intervention failure within 30 days.

Those patients were among patients who visited Kasr AL Ainy Hospital vascular clinic between February 2017 and February 2020 with symptoms of claudication, rest pain, or tissue loss.

The patients signed an institutional approved informed consent, which made patients fully aware of the investigations and the nature of the procedure.

On the basis of the identified causes of failure and according to the patient's general conditions, the affected arterial segment, availability of tools and limb condition, the treatment modalities to manage that failure were determined (medical, surgical, redo endovascular, amputation or combined treatment). And the clinical outcome was studied during the follow-up.

The follow-up was after 1 month, 3 months, and then after 6 months for each case.

The patients were not selected on demographic or comorbidity basis.

Inclusion criteria and patient selection:

Patients were enrolled in study irrespective of their age, sex, or comorbidity, provided that they do not prevent the endovascular procedure.

The failure was defined according to the type of the failure:

(1) Technical failure: Failure to revascularize femoropopliteal target lesion following attempted endovascular intervention
(2) Clinical failure:
    (a) Failure to increase an ABI of less than 0.10–0.15 or decrease in ABI following attempt of endovascular intervention with technical success within 1 month.
    (b) Failure to increase of at least one point on the' Rutherford scale for chronic limb ischemia' following attempted endovascular intervention with technical success within 1 month

Failure criteria

Failure was decided if one of these were found:

(1) Intra procedure
    (a) Inability to cross the lesion
    (b) Residual stenosis greater than 30%
    (c) Flow limiting dissection
    (d) Acute thrombosis or recoil
    (e) Acute stent thrombosis
    (f) Distal embolization
(2) Post procedure (during the 30-day follow-up):
    (a) Clinical
        (1) Failure to improve claudication distance
        (2) Failure to improve rest pain
        (3) Failure to attempt ulcer healing or gangrene demarcation
        (4) Complication such as acute on top of chronic ischemia
        (5) Recurrence of symptoms after improving (eg. incapacitating claudication, rest pain)
        (6) Absence of previously retrieved distal pulse obtained after endovascular procedure
        (7) Decrease in ABI, no change or increase less than 0.10–0.15.
    (b) Radiological

Duplex ultrasound (DUS)

The main radiological investigation we relied on was the duplex ultrasound as it being safer, more accurate regarding hemodynamics, and availability in our clinic.

DUS was done after the procedure to assess the APSV and then after 1 month, 3 months, and 6 months if there no any clinical problems that indicate urgent investigations.

The duplex was a useful tool in detecting the nature of recurring ischemia and the causes of procedural failures.

Radiological findings by DUS

(1) Occlusion or restenosis of the revascularized segment by more than 30% of the PSV
(2) Distal embolization and target vessel thrombosis
(3) Acute stent thrombosis
(4) Arterial dissection
(5) Missed proximal lesions

CT. angiography (CTA)
It was indicated for redo cases or those who need distal tibial bypass surgery.

Exclusion criteria
Patients with chronic limb ischemic due to femoropopliteal diseases who underwent endovascular intervention with successful revascularization of the lesion and demonstrated clinical improvement in during the 30-days follow-up period

Decision making
The 40 patients can be categorized according to the type of early failure into:

(1) Technical failure was the main cause of failure in 38 cases:
   (a) Intra-procedure (14 cases)
      (1) Inability to cross the lesion in 12 cases
      (2) Distal arterial tree embolization in two cases
   (b) Postprocedure (26 cases)

During the 30-day follow-up:

(1) Acute stent thrombosis in 7 cases
(2) Flow-limiting dissection in 8 cases
(3) Residual stenosis in 3 cases
(4) Acute thrombosis in 2 cases
(5) Missed iliac lesions in 2 cases
(6) Distal arterial tree embolization in 2 cases
(7) Clinical failure was the cause in 2 cases

The procedure
Most of these cases were done in the angio suite or operating room under anesthesia and after the procedure the patients were home discharged except patients who needed urgent debridement or transmetatarsal amputation.

The Management Was

(1) Redo endovascular in 18 patients
(2) Bypass in 14 patients
(3) Primary amputation in six patients
(4) Medical treatment in two patients

Procedure evaluation
Primary endpoints

(1) Limb salvage.
(2) Healing of ulcers

Secondary endpoint

(1) Improvement in claudication distance.
(2) Improvement in ankle brachial index

Statistical analysis
Recorded data were analyzed using the Statistical Package for the SocialSsciences, version 20.0 (SPSS Inc., Chicago, Illinois, USA). Quantitative data were expressed as mean± standard deviation (SD).

Qualitative data were expressed as frequency and percentage.

The following tests were done:

(1) Chi-square (χ^2) test of significance was used to compare proportions between qualitative parameters.
(2) Independent samples t-test of significance was used when comparing between two means.
(3) The confidence interval was set to 95%, and the margin of error accepted was set to 5%. So, the P-value was considered significant as the following:
(4) Probability (P-value)
   (a) *P*-value less than or equal to 0.05 was considered significant.
   (b) *P*-value less than or equal to 0.001 was considered highly significant.
   (c) *P*-value greater than 0.05 was considered insignificant.

Results
Forty patients with chronic limb ischemia due to femoropopliteal disease underwent endovascular intervention, and this intervention failed within 30 days. Most of these cases were performed in the angio suite in Kasr Al Ainy Teaching Hospital under local anesthesia, and after the procedure the patients were home discharged except patients who needed urgent debridement.

In all, 13 (27.5%) females and 27 (72.5%) males were enrolled in the study. Their age ranged from 45 to 77 years (mean 6262.20±7.44).

Twenty-eight (70.%) patients were diabetics, 28 (70.0%) were hypertensive, 26 (65.0%) were smokers, and 12 with cardiac diseases (30.0%).

Clinical presentation: rest pain in three (7.5%) patients, minor tissue loss in 18 (45%); major tissue loss in 19 (47.5%) patients, while the length of the lesion was between 5 and 10 cm in three (7.5%) patients and more than 10 cm in 37 (92.5%) patients.

Thirty-six patients presented with occlusion (90%). Among them, 36/40 had occlusion in the superficial femoral artery (94.4%), 10 (27.8%) in the popliteal

artery and 18 (50%) in the infrapopliteal artery, while stenosis was seen in 16/40 patients (40%) who had it in the superficial femoral artery 7 (43.8%), 10 (62.5%) in the popliteal and 7 (43.8%) in the infrapopliteal artery

Runoff in the anterior tibial artery was observed in 23 (57.5%) patients, posterior tibial artery in 19 (47.5%), and in the peroneal artery in 15 (37.5%) patients.

Causes of early failure: intraprocedural and post-procedural (Fig. 1)

Distribution of patients according to their Redo management:(Table 1)

Distribution of patients according to their type of bypass:(Table 2)

Distribution of patients according to their Redo endovascular:(Table 3)

(1) Ballooning in four cases
(2) Stenting in 13 cases:
    (a) Iliac stenting in two cases
    (b) SFA stenting after crossing the lesion by CTO wire and ballooning in three cases
    (c) Ballooning and stenting in eight cases
(3) Failure to cross the lesion in one case.
(4) No use of drug-eluting balloon or stents.

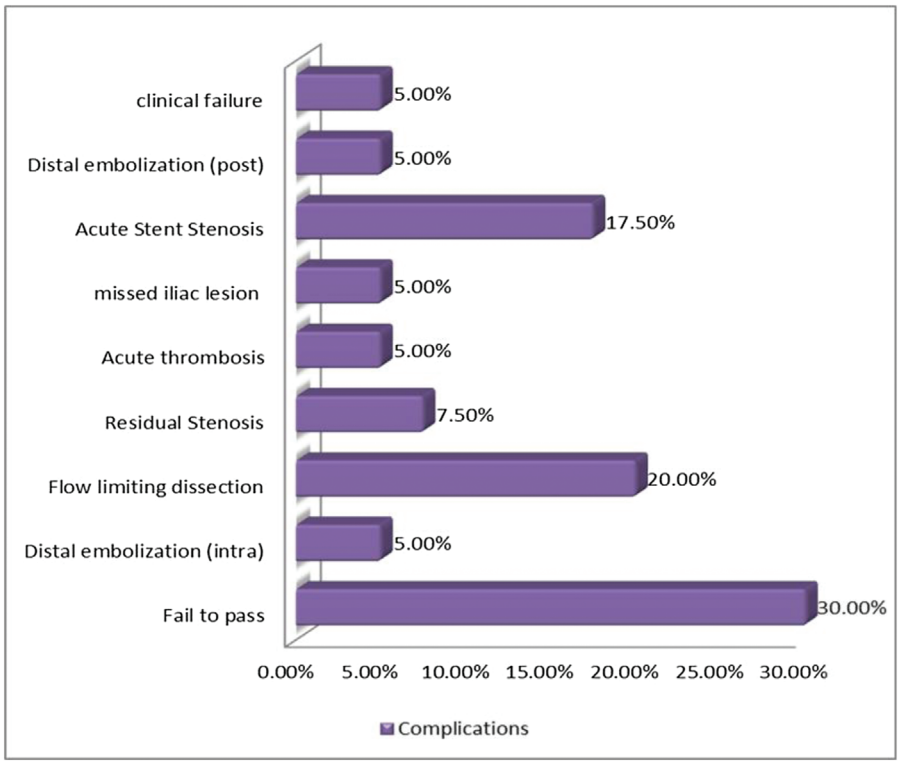
During the 6 month follow-up: Eight cases from the redo endovascular group ended up with major amputation : Three cases with below-knee amputation (BKA) and five cases with above-knee amputation (AKA).

(1) One case from CTO wire and stenting was failed and fem-distal bypass was done and the case ended with AKA after 1 month.
(2) The case from the ballooning group developed distal arterial tree embolization and ended with AKA.

Table 1 Distribution of patients according to their management (*n*=40)

Management	Total (n=40)
Bypass	
No	26 (65%)
Yes	14 (35%)
Redo endovascular	
No	22 (55%)
Yes	18 (45%)
Amputation	
No	34 (85%)
Yes	6 (15%)
Medical	
No	38 (95%)
Yes	2 (5%)

Figure 1



Pie chart distribution of patients according to the cause of technical failure.

Table 2 Distribution of patients according to their type of bypass (*n*=14/40)

Bypass	Total (*n*=40)
No	26 (65.0%)
Yes	14 (35.0)
Procedure (*n*=14)	
Bypass	8 (57.1%)
Endarterectomy and bypass	6 (42.9%)
Bypass (*n*=14)	
Fem Distal	9 (64.3%)
Fem POP	5 (35.7%)
Conduit (*n*=14)	
GSV	11 (78.6%)
Synthetic	3 (21.4%)
Postoperative (*n*=14)	
ATA	3 (21.4%)
Failed	3 (21.4%)
PTA	8 (57.1%)
Management of failed	
AKA	3 (21.4%)

Table 3 Distribution of patients according to their redo endovascular (*n*=18/40)

Redo endovascular	Total (*n*=40)
No	22 (55%)
Yes	18 (45%)
Intervention (*n*=18)	
Stenting	8 (44.4%)
Ballooning	4 (22.2%)
CTO (chronic total occlusion) wire and stenting	3 (16.7%)
Iliac stenting	2 (11.1%)
CTO (chronic total occlusion)	1 (5.6%)
Access No. (*n*=18)	
1	14 (77.8%)
2	4 (22.2%)
Access side (*n*=18)	
Ipsilateral	10 (55.6%)
Contralateral	4 (22.2%)
Ipsilateral and contralateral	4 (22.2%)
Access passage (*n*=18)	
Intraluminal	14 (77.8%)
Subintimal and intraluminal	4 (22.2%)
Wire (*n*=18)	
CTO wire (chronic total occlusion)	4 (22.2%)
Terumo wire 0.35	14 (77.8%)
Stenting (*n*=18)	
No	5 (27.8%)
Yes	13 (72.2%)
Site of intervention (*n*=18)	
Fail to pass	1 (5.6%)
Iliac	2 (11.1%)
SFA	15 (83.3%)
Complication	
Distal embolization	1 (5.6%)
Failed	1 (5.6%)
Management	
AKA	1 (5.6%)
Femoro-posterior bypass	1 (5.6%)

Table 4 Distribution of patients according to their primary amputation (*n*=40)

Amputation	Total (*n*=40)
No	34 (85%)
Yes	6 (15%)
AKA	6/6 (100%)

(3) The three cases that ended with BKA were from the stenting group, where failure occurred due to residual stenosis which was diagnosed post-procedure in the follow-up period.
(4) The remaining three cases that ended with AKA were from the stenting group, where failure occurred due to flow-limiting dissection which was diagnosed post –procedure in the follow-up period.

Distribution of patients according to primary amputation: (Table 4)

The all cases underwent primary AKA with spinal anesthesia and fish mouth stamp with no drains were left in the wound.

Distribution of patients according to medical Treatment:(not critical limb ischemia and compensated after early failure of original procedure)

The two cases who did not do any intervention and continued on medical treatment (aspirin 75 mg daily, clopidogrel 75 mg daily, statins, cilostazol 100 mg twice daily and naftidrofuryl 200 once daily).

Limb salvage: After 6-month follow-up (Fig. 2)

(1) Twenty-three patients had limb salvage, which accounted for 57.5% of the cases with 16 patients (69.6%) undergoing minor amputation in the form of transmetatarsal amputation (TMA).
(2) Seventeen (42.5%) underwent major amputation: 14/17 (82.4%) with AKA, 3/17 (17.6) with BKA.

Table 5 shows statistically significant difference between limb salvage (no and yes) according to minor and major tissue loss.

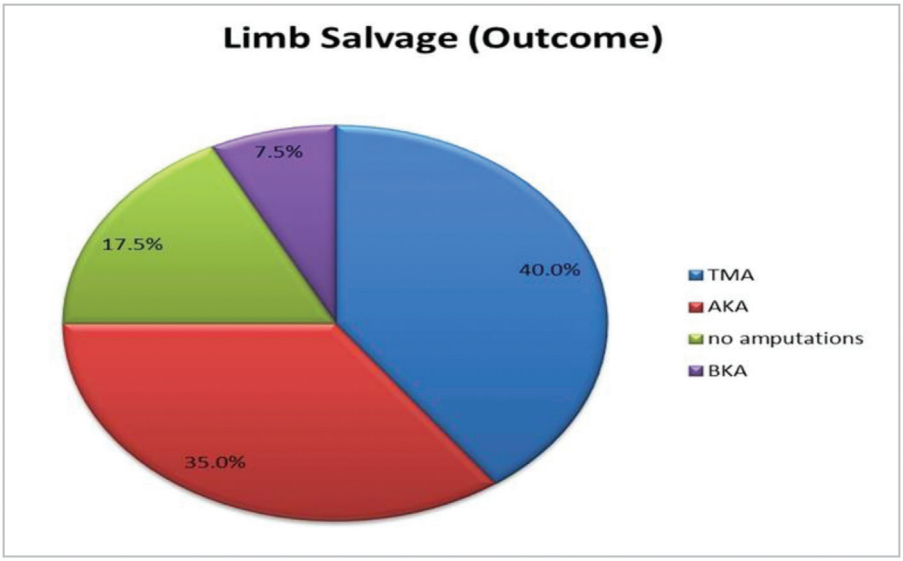
Table 6 shows a statistically significant difference between limb salvage (no and yes) according to distal runoff.

Table 7 Statistically significant association between limb salvage according to bypass and amputation

Discussion

Patients with and without bypass options often undergo initial attempts at endovascular

Figure 2



Pie chart distribution of patients according to their limb salvage.

Table 5 Comparison between limb salvage (no and yes) according to clinical presentation

	Limb Salvage			
Clinical Presentation	Yes (*n*=23)	No (*n*=17)	χ^2	*P*-value
Rest pain	3 (13%)	0	2.397	0.122
Minor tissue loss	15 (65.2%)	3 (17.6%)	8.937	0.003*
Major tissue loss	5 (21.7%)	14 (82.4%)	14.401	<0.001**
Length of lesion				
Between 5 and10 cm	2 (8.7%)	1 (5.9%)	0.112	0.738
More than 10 cm	21 (91.3%)	16 (94.1%)		

x2: Chi-square test, *P*-value greater than 0.05 NS, **P*-value less than 0.05 S, ***P*-value less than 0.001 HS.

Table 6 Comparison between limb salvage (no and yes) according to runoff

	Limb Salvage			
Runoff	No (*n*=17)	Yes (*n*=23)	χ^2	*P*-value
ATA	15 (65.2%)	8 (47.1%)	1.319	0.251
PTA	13 (56.5%)	6 (35.3%)	1.283	0.257
PER	7 (30.4%)	8 (47.1%)	1.153	0283
No.				
1	15 (65.2%)	13 (76.5%)	1.213	0.545
2	4 (17.4%)	3 (17.6%)		
3	4 (17.4%)	1 (5.9%)		

x2: Chi-square test, *P*-value greater than 0.05 NS, **P*-value less than 0.05 S.

revascularization before surgical therapy. Results for intervention vary by site. Distal lesions have fewer durable results but are being performed with increasing frequency, thus making the need for future reintervention more likely [5].

The most important drawback of endovascular intervention is the limited patency rate, which has been shown to be a 25% restenosis rate in the endovascular intervention [4].

Our study that addresses the results of the management of patients with chronic limb ischemia due to

Table 7 Comparison between limb salvage (no and yes) according to management

	Limb Salvage			
Management	Yes (23/40)	No (17/40	χ^2	*P*-value
Bypass (*n*=14)	11/14 (78.6%)	3/14 (21.4%)	7.016	0.008*
Redo endovascular (n=18)	10/18 (55.6%)	8/18 (44.4%)	0.115	0.735
Amputation (*n*=6)	0/6 (0.0%)	6/6 (100.0%)	8.333	0.004*
Medical (*n*=2)	2/2 (100.0%)	0/2 (0.0%)	1.000	0.317

x2: Chi-square test, *P*-value greater than 0.05 NS, **P*-value less than 0.05 S.

femoropopliteal disease treated by endovascular intervention. The intervention considered failed if it occurred within 30 days.

In our study, we found that technical failure occurred in 38 (95%) patients, while clinical failure was observed in two (5%) patients. In contrast, Hemant *et al.* found that technical failure in 72% and clinical failure in 28% [6] .

Of the 39 procedures that failed early with Galaria *et al.*, 29 (74%) cases failed immediately and 10 (26%) cases failed within the first 30 days following intervention [7]. Compared with our study, which reported intraprocedural failure in 14 patients (35%) and in the post-procedural follow-up period in 26 (65%) patients among the technically failed cases.

About 12 (30%) patients experienced early failed due to the inability to cross the lesion and four (10%) patients experienced failure due to distal arterial tree embolization, while Armstrong *et al.* found that 38% of cases failed due to inability to position the guidewires and 12% of cases were complicated due to distal arterial tree embolization [8].

Acute thrombosis occurred in two (5%) patients in our cases, which is same as the findings of Armstrong *et al.*, who reported that 5% of the early failed cases were due to thrombotic occlusions [8].

Flow-limiting dissection was found in eight (20%) patients in our study, while Armstrong *et al.* reported only one (1.2%) case with dissection [8].

Residual stenosis was found in three (7.5%) patients and two (5%) patients with missed proximal (iliac) lesions.

Scott M. Surowiec *et al.* reported that 7% of 329 patients who underwent angioplasty for SFA lesions failed immediately due to inability to cross the lesion [9].

Evan J. Ryer *et al.*, reported that only 3% of 246 patients with CLI due to infrainguinal lesions failed due to inability to cross the lesion or to re-enter intraluminal and only two patients failed post-procedure within 30 days [10].

In our study, surgical bypass was performed in 14 (35%) patients and redo intervention was done in 18 (45%) patients, while Charles *et al.* in their study reported that 23% and 66% of the early failed cases had undergone surgical bypass and redo endovascular intervention, respectively [11].

Bradbury AW *et al.* reported that 42% of early reintervened cases after peripheral endovascular intervention (PEI) underwent redo endovascular and 57% of the cases underwent surgical bypass [12]. Bradbury AW *et al.* reported that about 49% of patients with technical and early clinical failures of PEI underwent open bypasses [13].

Galaria *et al.* reported that out of 39 early failed PEI cases, 19 required subsequent bypass with 17% rate of amputation. 18, compared with our study, bypass was performed in 14 cases from 40 early failed PEI with 21% rate of amputation [14].

In our study of 25 bypasses after early failed endovascular interventions, Böckler *et al.* demonstrated a bypass failure rate of 50%, while in our study 14 bypasses were done with a failure rate of 21.5% [15]

In our study, no intervention was done in two (5%) cases and the patients continued on medical treatment, which is similar to the results of Charles S. Joels, *et al.* [11].

In our study, primary amputation was performed in six (15%) patients and were AKA, whereas Charles S. Joels, *et al.* reported that only 5% of cases had undergone major amputation [11].

The BASIL-2 trial showed that endovascular treatment is associated with improved outcomes (reduction in death or major amputation) compared with vein bypass .This trial contrasts with earlier trials (BASIL-1 and BEST-CLI), which found that vein bypass was associated with improved outcomes compared with endovascular treatment and our results that management with bypass had a statistical difference than endovascular and medical treatment [16].

The patients were followed up for 6 months at the outpatient clinic where clinical assessment was done.

Conclusion

(1) Early failure after the endovascular intervention of the superficial femoral artery alters future bypass options to more distal segments.
(2) Endovascular revascularization first strategy for critical limb ischemia results in high reintervention rates in elderly patients.

(3) Surgical bypass can be considered before using endovascular techniques for the early failure patients, resulting in acceptable limb salvage.
(4) Early failure of endovascular intervention in patients with major tissue loss mostly ends with major amputation
(5) More new studies on large number of patients are required to improve our clinical decision making and management as the BASIL-3 trial

Financial support and sponsorship
Nil.

Conflicts of interest
There are no conflicts of interest.

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