Predictors of success of retrograde angioplasty of superficial femoral artery occlusive diseases

Original Article

Ibrahim S. Abd Elaziz, Bassam M. Mannaa, Alaa Abdel Halim, AbdElaty M. Sakr and Mohamed H. Abdelmawla

Department of General and Vascular Surgery, Faculty of Medicine, Beni-Suef University, Beni-Suef, Egypt.

ABSTRACT

Background: Endovascular procedures are considered effective and safe as management options in cases of superficial femoral artery (SFA) atherosclerotic occlusive diseases especially retrograde access procedure which gives a high technical success rate and a high percentage of lower limb salvage with a low risk of complications and morbidity.

Patients and Methods: This is a prospective study clinical trial one arm conducted on 50 patients suffering from critical lower limb ischemia with SFA occlusive diseases (Rutherford classification category 2–6) presented from May 2020 to June 2022 to the Vascular Department, Beni-Suef University Hospital, and Vascular Departments, Military Hospitals.

Results: The patency was kept in technical successful cases at 1, 3, 6, and 12 months in 100, 96, 92, and 80% of cases, respectively.

Conclusion: There are many factors that predict the success of retrograde angioplasty in management of SFA occlusive diseases, maximize the likelihood of successful CTO crossing and pose the patency and amputation rates.

Key Words: Occlusive diseases, patency rates and limb salvage, retrograde angioplasty, superficial femoral artery.

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Corresponding Author: Bassam M. Mannaa, MSc, Department of General and Vascular Surgery, Faculty of Medicine, Beni-Suef University, Beni-Suef, Egypt. **Tel.:** 01061012660, **E-mail:** bassamvascular@gmail.com

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INTRODUCTION

The retrograde popliteal approach was initially limited and served as a backup option. However, refinements to this technique have made this an attractive option, and it has been advocated as a first-line treatment in selected patients[1].

The nature of the lesion affects both the success rate and the long-term patency also more distal and longer lesions are more technically challenging and less likely to stay open, and the presence of calcification is associated with a lower success rate[2].

The major causes of technical failure in sub intimal angioplasty are failure of reentry and elastic recoil[2].

Patency is adversely affected by renal insufficiency, current smoking, diabetes, and the number of patent runoff vessels. Evidence supporting this comes from the finding that the value of the ABPI (ankle brachial pressure index) after sub intimal angioplasty is an independent predictor of avoiding CLI (critical limb ischemia) or IC (intermittent claudication) after successful revascularization[3].

PATIENTS AND METHODS:

This is a prospective study clinical trial one arm conducted on 50 patients suffering from critical lower limb ischemia with superficial femoral artery (SFA) occlusive diseases (Rutherford classification category 2 to 6) presented from May 2020 to June 2022 to the Vascular Department, Beni-Suef University Hospital and Vascular Departments, Military Hospitals.

Statistics were gathered via patient registration data.

Ethical approval was obtained from the Research Ethical Committee, faculty of medicine. Beni Suef University, approval NO: FMBSUREC/09052021/Mannaa.

Inclusion criteria

(a) Patients with age more than 40 years.

(b) Disabling claudicating pain.

(c) SFA stenosis or occlusion.

(d) De novo lesion

Exclusion criteria

(a) Acute limb ischemia.

(b) Hypersensitivity to contrast material.

(c) Renal function impairment.

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(d) Previous major amputation.

(e) Unsalvageable limb with extensive ischemic ulceration or gangrene.

(f) Terminal patient.

All patients were subjected to

Pre-procedural preparation

History taking, clinical examination, duplex scanning, and computed tomography angiography.

Steps of the procedure

The procedure will be done in an angiography suit under fluoroscopic guidance with vascular imaging capabilities and following a complete aseptic technique. At the end of each procedure, the details of the technique will be documented individually regarding.

Crossover sheaths were used to access the arterials via the contralateral CFA.

Cases with failure trials to cross the osteal SFA lesion from the previous accesses, ipsilateral retrograde trans-popliteal or trans-pedal access were tried at the same session with the use of either Sub-intimal arterial Flossing with antegrade retrograde access (SAFARI) technique or snaring from above. Retrograde trans-popliteal or trans-pedal access can be done from the beginning.

After the arterial access was punctured, angioplasty was done.

Postinterventional surveillance

Clinical data were collected and recorded at each clinic visit. Follow-up was conducted in our vascular surgery outpatient clinic at 1, 3, and 6 months regarding the following points:

Based on Rutherford's upward categorical shift greater than or equal to 2 Rutherford category improvement, with absence of rest pain and/or progressive tissue healing during the follow-up period of this study and wound healing in less than or equal to 4 months after the intervention was documented.

Secondary endpoints

Minor and major complications.

RESULTS:

Statistical analysis

MedCalc ver. 20 was used for data entry, processing, and statistical analysis (MedCalc, Ostend, Belgium). The following significant tests were applied: receiver operating characteristic (ROC) Curve analysis, Pearson's correlation, logistic regression analysis, Paired t, Student's t, and χ^2 testing. Data were shown, and appropriate analysis was carried out based on the kind of data (parametric and nonparametric) that were collected for every variable. *P values* were regarded as statistically significant if they were less than 0.05 (5%) or 5.

P value: level of significance

P>0.05: Nonsignificant (NS).

P<0.05: Significant (S).

P<0.01: Highly significant (HS).

Descriptive statistics

If the numerical data is parametric, the mean, range, and standard deviation (±SD) are used; for nonparametric data, the median and inter-quartile range (IQR) are used. The quantity and proportion of data are not numerical.

Analytical statistics

The statistical significance of the difference between the means of the two study groups was evaluated using the Student's t test.

Matched the statistical significance of the difference between the means of two (paired) research groups was evaluated using the Student's t test.

Two qualitative variables were examined for a link using the χ^2 test.

Analysis of correlation (using Pearson's method): The correlation coefficient, represented by the symbol 'r,' indicates the direction and intensity of a linear relationship between two variables and may be used to evaluate the degree of link between two quantitative variables.

When predicting whether an event will occur based on a collection of independent factors, logistic regression is helpful. Though it works best when the dependent variable is qualitative (categorical), it is comparable to a linear regression model.

In our study, the average age was 61.8±7.7 SD years. Nearly all of the data from the most recent epidemiological research indicated that older people had a higher incidence of PAD[4].

Table 1: Preoperative assessment among the patients

Variables	Frequency (%)/Mean±SD
ABPI	0.38±0.08
Length of lesion (mm)	133.4±69.5
Rutherford category	
Rutherford 1	3 (6)
Rutherford 2	10 (20)
Rutherford 3	9 (18)
Rutherford 4	8 (16)

Rutherford 5	12 (24)
Rutherford 6	8 (16)
C TOP class	
Class 1	0
Class 2	22 (44)
Class 3	0
Class 4	28 (56)
Type of lesion	
Occlusion	46 (92)
Stenosis	4 (8)
Runoff distal	
None	4 (8)
1 Runoff	18 (36)
2 Runoffs	14 (28)
3 Runoffs	14 (28)

In our study, patients are presented according to the Rutherford phases I, II, and III (tissue loss, claudication, and rest pain). 54, 16, and 30% of these talks were distributed, in that order. According to Eleissawy[5], the distribution of presentations was 44, 20, and 36%, respectively. In Singh *et al*.'s study from 2021, the percentages were 11, 56, and 33%, respectively. Additionally, according to Patel *et al*. (2018), the distribution of presentations was 6.6, 32.1, and 61.3%, respectively (Table 1).

The first research to classify peripheral CTOs and pinpoint contributing variables is CTOP. Without increasing the likelihood of problems, CTO mapping that makes use of the CTOP categorization really raises the rate of crossing. Using their C-TOP approach[6], divided the anatomy of the proximal and distal caps into four distinct categories. According to our analysis, type II (44%), then C-TOP IV (56%), was the most prevalent kind (Table 1).

Noh and his colleagues in their study had 42 (27.5%) cases with only SFA lesions, 94 (61.4%) cases with SFA, and infra-popliteal lesions and 17 (11.1%) cases with SFA, popliteal and infra-popliteal lesions[7]. In our study, Regarding Runoff distal; (36%) of patients had 1 Runoff, (28%) had 2 Runoffs, and (28%) had 3 Runoffs which mean good runoff and only SFA lesion (Table 1).

Our study aimed to evaluate the feasibility of retrograde tibiopopliteal endovascular procedures for limb salvage in patients with high SFA occlusive lesions and CLI. To achieve this, we demonstrated various procedures and assessed their effectiveness in terms of success and failure rates, patency, and limb salvage rates.

In this study (Table 2), 25 (50%) pedal puncture were performed, whereas popliteal accesses were accessed in 17 (34%) patients. ATA and PTA were used in eight (16%) patients for retrograde access. The choice between popliteal and pedal accesses depends on which one is the most suitable and accessible.

Table 2: Technical success among the patients

Variables	Frequency (%)
Access	
ATA	1 (2)
Pedal	25 (50)
Popliteal	17 (34)
PTA	7 (14)
Crossing the lesion	
Intimal	37 (74)
Subintimal	13 (26)

Ismail said that the study's access sites were trans-popliteal (11.67%), trans-pedal (13.33%), and contralateral CFA (75%)[8].

The passage of the wire during the procedures in our study was intra-luminal in 37 (74%) cases and sub-intimal in 13 (26%) cases. The procedures techniques were 56% intra-luminal and 44% sub-intimal[9] (Ismail) reported that wire passed intra-luminal in 50% of cases, sub-intimal in 33.3% of cases, and failure of passage in 16.7% of cases[8].

Technical success is characterized by continuous arterial patency to the SFA without significant extravasation or visible flow-limiting lesions, such as residual stenosis more than 30% or flow-limiting dissection. In our study, 50 (100%) instances had effective technical intervention; 90% of patients experienced symptom alleviation, and 90% of patients were able to restore distal pulses. According to Bildirici and Fujihara the technical success rates were 83.3, 96.3, and 100%, respectively[10,11].

With respect to the data on postoperative outcomes, as in (Table 3) the average ABPI was 1.05±0.13. In technical successful instances, the patency was maintained at one, three, six, and twelve months in 100, 96, 92, and 80% of cases, respectively, during the follow-up of the examined cases. These findings concur with those of related research, as El Yamany found that at 1, t3, and 6 months, respectively, the patency rate was 100, 91, and 86%. Additionally, Abd El Fatah noted that at one1, 3, and 6 months, respectively, the patency rate in their trial was 100, 82, and 78%[12,13].

Table 3: Clinical success among the patients

Variables		Frequency (%) / Mean±SD
ABPI		1.05±0.13
Distal pulses	Patent	45 (90)
Relief of symptoms	Relieved or healed	45 (90)

In reference to limb salvage following endovascular therapy of CLI, our study pointed to encouraging outcomes in this respect. At 1, 3, 6x, and 12 months, our limb salvage rate is 100, 96, 92, and 84%, respectively. The results of Barillà were also encouraging, with limb salvage rates of 95, 91, and 86% after 1, 3, and 6 months, respectively[14].

In 10 (20%) of the technical successfully group's cases, we found loss of patency during the follow-up programme as a result of re-stenosis at the 12-month follow-up. The majority of patients underwent successful endovascular revascularization treatments again; three instances occurred after three months, and the remaining five occurred after 6 months. During the follow-up visits, Eleissawy and his colleagues found 16% of individuals with acute thrombosis and 12% of instances with re-stenosis[5].

Table 4: Amputation rate among the patients

Variables		Frequency (%)
Amputation rate (1 month)	–ve	0
Amputation rate (3 months)	+ve	2 (4)
Amputation rate (6 months)	+ve	2 (4)
Amputation rate (12 months)	+ve	8 (16)
Overall amputation rate	+ve	**12 (24)**

Regarding the Amputation rate; 12 (24%) of patients had Amputation; most of them are minor amputations. The remaining two cases underwent major amputation (Table 4).

In our study, patients were classified according to outcomes into two independent groups Occluded group have 10 patients, and Patent group have 40 patients (Table 5).

Table 5: Patency rate among the patients

Variables		Frequency (%)
Patency rate (1 month)	Patent	50 (100)
Patency rate (3 months)	Patent	48 (96)
Patency rate (6 months)	Patent	46 (92)
Patency rate (12 months)	Patent	40 (80)
Overall patency rate	Occluded	10 (20)
	Patent	**40 (80)**

A comparative study between the two groups revealed a nonsignificant difference as regards the age and sex of the patients (*P>0.05*). Also, the study between the two groups' revealed nonsignificant difference as regards HTN and IHD (*P>0.05*) (Table 6).

Table 6: Comparison between the two groups as regards Socio-demographic data using Student's t and χ^2 Chi square tests

	Occluded group (10) [*n* (%)]	Patent group (40) [*n* (%)]	Student's *t* test
Variable	Mean±SD	Mean±SD	*P* value
Age (years)	58.2±9.7	62.8±6.9	=0.090
			Chi square test
Variable	Occluded group (10)	Patent group (40)	*P* value
Sex			
Female	6 (60)	16 (40)	=0.2593
Male	4 (40)	24 (60)	

Table 7: Comparison between the two groups as regards Risk factors using Chi square test

Variable		Occluded group (10)	Patent group (40)	Chi square test *P* value
Smoking	+ve	8 (80)	14 (35)	=0.011*
DM	+ve	8 (80)	18 (45)	=0.049*
HTN	+ve	6 (60)	30 (75)	=0.3496
IHD	+ve	4 (40)	22 (55)	=0.4005

Comparative study between the two groups revealed; a significant increase in pre-operative smoking and DM, in the occluded group; compared with patent group (*P<0.05*, respectively) (Table 7).

Table 8: Comparison between the two groups as regards preoperative assessment using Student's t and χ^2 tests

	Occluded group (10)	Patent group (40)	Student's *t* test
Variable	Mean±SD	Mean±SD	*P* value
ABPI	0.31±0.03	0.4±0.08	=0.003**
Length of lesion (mm)	177±47.1	122.5±70.3	=0.025*
			Chi square test
Variable	Occluded group (10)	Patent group (40)	*P* value
Rutherford category			
Rutherford 1	0	3 (7.5)	=0.032*
Rutherford 2	0	10 (25)	
Rutherford 3	2 (20)	7 (17.5)	
Rutherford 4	0	8 (20)	
Rutherford 5	6 (60)	6 (15)	
Rutherford 6	2 (20)	6 (15)	
C TOP class			
Class 1	0	0	=0.011*
Class 2	8 (80)	14 (35)	

Class 3	0	0	
Class 4	2 (20)	26 (65)	
Type of lesion			
Occlusion	10 (10)	36 (90)	=0.3020
Stenosis	0	4 (10)	
Runoff distal			
None	0	4 (10)	=0.009**
1 Runoff	8 (80)	10 (25)	
2 Runoffs	2 (20%)	12 (30)	
3 Runoffs	0	14 (35)	

Regarding preoperative assessment using Student's t and χ^2 tests

We found a highly significant decrease in pre-operative ABPI and significant increase in pre-operative Length of lesion in occluded group; compared with patent group (*P<0.01*) (*P<0.05*), respectively.

Moreover, it showed a highly significant increase in preoperative In the patent group, the Rutherford category, C TOP class, and runoff distal were all lower than in the occluded group (*P <0.05*). Nonetheless, indicated a nonsignificant difference in lesion kind (*P>0.05*) (Table 8).

Table 9: Comparison between the two groups as regards technical data using χ^2 test

			Chi square test
Variable	Occluded group (10)	Patent group (40)	*P* value
Access			
ATA	1 (10)	0	=0.01**
Pedal	1 (10)	24 (60)	
Popliteal	5 (50)	12 (30)	
PTA	3 (30)	4 (10)	
Crossing the lesion			
Intimal	4 (40)	33 (82.5)	=0.006**
Subintimal	6 (60)	7 (17.5)	

In reference to the access during the surgery, a comparison between the two groups showed that the patent group had a significantly higher intimal lesion and pedal access than the occluded group (*P<0.05*, respectively) (Table 9).

Table 10: Comparison between the two groups as regards Clinical success using Student's t and χ^2 tests

	Occluded group (10)	Patent group (40)	Student's *t* test
Variable	Mean±SD	Mean±SD	*P* value
ABPI	0.96±0.1	1.08±0.12	=0.008**
			Chi square test
Variable	Occluded group (10)	Patent group (40)	*P* value
Distal pulses good			
Patent	7 (70)	38 (95)	=0.019*
Relief of symptoms			
Relieved or healed	7 (70)	38 (95)	=0.019*

In the postoperative outcome data: our study showed a highly significant increase in post-operative ABPI, Distal pulses, and Relief of symptoms, in the patent group; compared with occluded group (*P<0.05*, respectively) (Table 10).

Table 11: Comparison between patients as regards serial ABPI measurements

	Pre-operative measurement	Postoperative measurement	Paired *t* test
Variable	Mean±SD	Mean±SD	*P* value
ABPI	0.38±0.08	1.05±0.13	<0.0001**

During follow-up: We further analyzed and compared 50 (paired) groups of patients according to the serial laboratory measurements and found a marked increase in ABPI in both groups; during the serial pre and postoperative measurements with a highly significant increase in ABPI measurements (*P<0.0001*) in patent group (Table 11 and Fig. 1).

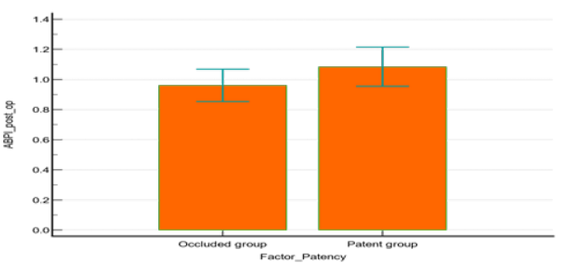

Fig. 1: Comparison between the two groups as regards postoperative ABPI.

Correlation studies between postoperative outcomes; and its relative independent predictors (baseline clinical, pre-operative, technical variables) conducted with multiple, logistic regression analysis, Pearson's correlation coefficient and ROC curve analysis (as suitable).

Table 12: Pearson's correlation analysis for baseline clinical/ preoperative/technical factors associated with postoperative ABPI

	Postoperative ABPI	
Associated factor	R	*P* value
Age (years)	0.1973	=0.1696
Smoking	0.09188	=0.5257
DM	–0.07887	=0.5861
HTN	0.02002	=0.8902
IHD	0.2178	=0.1286
Preoperative ABPI	0.2000	=0.1638
Length of lesion (mm)	0.005193	=0.9714
Rutherford category	–0.3863	=0.0056**
C TOP class	0.2172	=0.1297
Runoff distal	0.005193	=0.9714
ATA access	–0.06382	=0.6597
Pedal access	0.3595	=0.01*
Popliteal access	–0.1333	=0.3561
PTA access	–0.3103	=0.028*
Ballooning with stenting	0.1188	=0.4112

First, Pearson's correlation analysis shows that; preoperative pedal access, had a highly significant positive correlation with postoperative ABPI (*P=0.01*) and preoperative Rutherford category, and PTA access had a highly significant negative correlation with postoperative ABPI (*P<0.01*) but, according the Logistic regression analysis shows that; after applying (Forward method) and entering some predictor variables; the increase in Rutherford category; had an independent effect on increasing the probability of Amputation occurrence; with a significant statistical difference (*P=0.011*) (Table 12).

Table 13: Logistic regression model for the factors affecting patency occurrence using forward method

Predictor factor	Coefficient	OR	*P* value
(Constant)	–6.23517		
Preoperative ABPI	21.76273	2.83	0.008**

As in (Table 13) Logistic regression analysis shows that; after applying (Forward method) and entering some predictor variables; the increase in pre-operative ABPI; had an independent effect on increasing the probability of Patency occurrence; with significant statistical difference (*P=0.008*).

Table 14: Receiver operating characteristic-curve of each access artery to predict patients with successful patency

Variable	AUC	Sensitivity (%)	Specificity (%)	*P* value
ATA access	0.679	50	85.71	0.1199
Pedal access	0.660	96	36	0.04*
Popliteal access	0.571	29.41	84.85	0.4194
PTA access	0.633	42.86	83.72	0.2825

By using ROC-curve analysis, Pedal access predicted patients with successful patency, with poor (66%) accuracy, sensitivity= 96% and specificity= 36% (*P=0.04*). Although ATA, Popliteal and PTA accesses, showed nonsignificant predictive values regarding successful patency (*P>0.05*) (Table 14).

Table 15: Receiver operating characteristic-curve of each access artery to predict patients with amputation

Variable	AUC	Sensitivity (%)	Specificity (%)	*P* value
ATA access	0.506	25	76.19	0.9580
Pedal access	0.567	85.71	27.78	0.4423
Popliteal access	0.541	29.41	78.79	0.6407
PTA access	0.556	85.71	25.58	0.6147

Table 15 shows, by using ROC-curve analysis we concluded that all accesses showed non-significant predictive values regarding Amputation (all accesses are safe) (*P>0.05*).

DISCUSSION

The most frequent cause of PAD symptoms is SFA illness. Revascularization failure is mostly caused by an inability to cross a CTO (compltete total occlusion), which has a higher risk of complications. The development of an algorithm aimed at optimizing the probability of a successful CTO crossing might potentially enhance the overall procedural success rates of intricate endovascular operations, leading to better patient outcomes. Therefore, our goal was to assess the safety and effectiveness of the retrograde approach for overcoming SFA's chronic occlusion.

It is known that the occlusion cap at its proximal end of occlusion is more fibrous, calcified, and resistant to wire negotiation in comparison with the distal end. Thus, the wire can be advanced retrogradely with less difficulty. In addition, the occlusion cap is convex and smooth from above, so guide wire coming antegrade may slide over the cap entering the subintimal space or failed crossing. This CTOP (chronic total occlusion classification of plaque) categorization clinical application is critical because it may enable operators to prepare an endovascular strategy that includes treatment, crossover, and access from the outset of the case.

Without increasing the likelihood of problems, CTO mapping that makes use of the CTOP categorization

really raises the rate of crossing. Thus, we discovered that type II (44%), then C-TOP IV (56%), was the most prevalent kind.

Our study's goal was to ascertain whether retrograde tibiopopliteal endovascular procedures are a practical option for artery revascularization in patients with CLI and high SFA occlusive lesions. Of the patients in this study, 25 (or 50%) underwent pedal punctures, while 17 (or 34%) underwent popliteal accesses. In 8 (16%) cases ATA (anterior tibial artery) and PTA (posterior tibial artery) were employed.

This helps the passage of the wire during the procedures in our study was intra-luminal in 37 (74%) cases and sub-intimal in 13 (26%) cases, with minimal cases having mild complications (10%).

Also, this leads to the high percentage of technical success as 50 (100%) cases have a successful technical intervention with (90%) of patients regaining distal pulses and also (90%) had relief of symptoms.

In technical successful instances, the patency was maintained at one, three, six, and twelve months in 100, 96, 92, and 80% of cases, respectively, during the follow-up of the examined cases. Thus, we found that 10 (20%) of the instances had lost patency. In our investigation, patients were divided into two separate groups based on their results. There are ten patients in the occluded group and 40 in the patent group. Numerous research comparing the two groups showed that several variables, including smoking and diabetes mellitus, significantly ($P<0.05$) alter primary patency.

When comparing the occluded group to the patent group, we observed a highly significant drop in preoperative ABPI and a considerable rise in preoperative lesion length.

Moreover it showed highly significant increase in preoperative C TOP class, and Runoff distal, in patent group; compared with the occluded group.

Studies examining the relationship between postoperative results and their respective independent predictors reveal a significant positive connection between pre-operative pedal access and postoperative ABPI.

Pedal access predicted patients with successful patency by utilizing ROC-curve analysis. Using the Forward technique and the entry of certain predictor variables into the logistic regression analysis reveals that the rise in preoperative ABPI had an independent influence on raising the chance of Patency incidence, with a statistically significant difference ($P=0.008$).

CONCLUSION AND RECOMMENDATIONS

In instances with CLI, the retrograde access method yields a high proportion of lower limb salvage and a good technical success rate.

The pedal access treatment is preferred when both popliteal and pedal routes are available since it is more accessible and has less complications at the puncture site. Surveying the long-term results of endovascular care in terms of viability, patency, technical success, clinical success, limb salvage rates, and complications requires regular, stringent, thorough, and extended follow-up programmes.

CONFLICT OF INTEREST

There are no conflicts of interest.

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