Balloon angioplasty versus stenting of sequential tandem lesions in superficial femoral and popliteal arteries

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Objective: To compare Efficacy and durability immediately, after one, 6 months results of balloon angioplasty alone versus balloon angioplasty and stenting of multiple tandem lesions in superficial femoral artery (SFA).
Methods: percutaneous transluminal angioplasty (PTA) with dilatation was done for 20 cases (group I) and PTA and stenting was done for 20 cases (group II) with (stenosis or occlusion).
Results: On stratifying our cases according to TASC II classification, cases showed that in group I: 11(55%), 9 (45%) TASC B and C respectively, group II: 9 (45%), 11(55%) TASC B and were C lesions of the SFA. At one month, six month follow up, group I: 3occluded cases, no more occluded cases while in group II: all cases were successful, 9 cases occluded respectively.
Conclusion: Although primary stenting of SFA provide excellent results in patients with TASC B& C lesions (short term). It doesn't provide Superior (Mid-term) to results to angioplasty alone. (Leave no Metal behind Policy).

Keywords:
angioplasty, stenting, tandem, Trans-Atlantic Inter-Society Consensus

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Introduction

Egypt will have at least 8.6 million adults with diabetes and will have the 10th largest population of diabetic patients in the world by 2030 [1]. Many studies have shown an association between diabetes mellitus and the development of peripheral artery disease (PAD). Overall, intermittent claudications (IC) is about twice as common among diabetic patients than among nondiabetic patients. In patients with diabetes, for every 1% increase in hemoglobin A1c, there is a corresponding 26% increased risk for PAD [2].

Occlusion of the superficial femoral artery (SFA) can lead to claudication and can contribute to chronic critical ischemia. For patients with claudication, aggressive risk factor modification and exercise programs are recommended, and interventions are reserved for failures of this therapy. For critical ischemia, revascularization, if possible, is the standard of care. During the last few years, the treatment of SFA occlusive disease has undergone a shift in management within these paradigms to include more aggressive endoluminal therapy [3].

The SFA extending to the proximal popliteal artery (PA) segment is the most commonly diseased vasculature. More than 50% of all PAD cases involve the SFA and PA. Femoropopliteal disease is often characterized by long, diffuse lesions, long occlusions (as opposed to mild focal stenoses). The unique slow-flow and high resistance environment in the femoropopliteal region creates a milieu that seems to increase the prevalence of de-novo disease [4].

The technical and clinical success rates of the endovascular therapy for the stenotic and occlusive lesions in the femoropopliteal artery have reached over 95% due to the improvements in new generation devices, but long-term patency, however, remains an unsolved issue [5].

The Trans-Atlantic Inter-Society Consensus (TASC) II B lesions of SFA were defined as multiple lesions (stenoses or occlusions) measuring 5 cm or less, single stenosis or occlusion of 15 cm or less not involving the infrageniculate PA, single or multiple lesions in the absence of continuous tibial vessels to improve inflow for a distal bypass, heavily calcified occlusions of 5 cm in length, or a single popliteal stenosis [5].

The TASC II C lesions were defined as multiple stenoses or occlusions totaling more than 15 cm with or without heavy calcification, or recurrent stenoses or occlusions that need treatment after two endovascular interventions [5].

Nitinol stents have been used for long time, which have demonstrated superior primary patency to balloon angioplasty alone. Catheter-based interventions serve as a first-line intervention for many patients with

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infrainguinal occlusive disease. Angioplasty with or without stenting offers the advantage of low morbidity, decreased convalescence, and high patient acceptance. However, longevity and cost-effectiveness remain a concern [6].

Technological advances continue to occur at an ever increasing pace with the intent of increasing the durability of infrainguinal endovascular procedures. Some have suggested that primary nitinol stenting of the SFAs and PAs can provide results that are superior to angioplasty and selective stenting alone and extend the anatomic indications for endovascular intervention. However, stents add considerable cost to any percutaneous intervention and should demonstrate clear benefit before their routine use can be advocated or current treatment recommendations changed [6].

Previous studies have shown that angioplasty alone or with selective stenting have yielded acceptable rates of primary patency in the treatment of short-segment TASC A and B lesions [6].

Patients and methods

This prospective study was conducted on 40 patients presenting mainly to the Vascular and Endovascular Department in Kasr Al Ainy Hospital, Cairo University, between October 2011 and February 2013. All patients presenting with femoropopliteal occlusive disease with multiple tandem SFA and PA lesions (stenosis and/or occlusion) were included in the study. Percutaneous transluminal angioplasty with dilatation only was performed for 20 cases and percutaneous transluminal angioplasty with dilatation and stenting was performed for 20 cases. All patients admitted had to sign a written informed consent form before undergoing treatment.

Patient sex, demographics, presence of comorbidities, history of smoking, indication for intervention, and the use of anticoagulation therapy were recorded. The procedure, possible complications, benefits, risks, and other alternative interventions were all explained to the patients and informed consent was obtained.

Methodology

Clinical assessment

History taking and clinical examination was carried out for all patients, which included the following:

(1) Age and sex.
(2) Major risk factors for atherosclerosis, such as diabetes mellitus, smoking, hypertension, hyperlipidemia, and ischemic heart disease.
(3) Clinical assessment of the patient, degree of ischemia, claudication distance, tissue loss, gangrene, motor power, capillary circulation, color changes, and pulsations (most palpable distal pulse).

Preprocedural investigations

(1) Routine laboratory tests, including complete blood picture, kidney and liver function tests, coagulation profile and blood glucose level, and lipid profile, were carried out.
(2) Patients were scheduled for duplex scanning before intervention with ankle brachial index (ABI) and peak systolic velocities; duplex scanning was performed for all cases.
(3) Computerized topographic angiography (CTA) was resorted to only if duplex was not conclusive.
(4) Echocardiography was performed.

Selection criteria for the study

Inclusion criteria:

(1) Having critical limb ischemia (rest pain, gangrene) with multiple sequential short stenoses or occlusions of the SFA and PA.
    (a) TASC II B: Multiple lesions (stenoses or occlusions), each measuring 5 cm or less, or single stenosis or occlusion of 15 cm or less not involving the infrageniculate PA.
    (b) TASC II C: Multiple stenoses or occlusions totaling more than 15 cm.

Exclusion criteria:

(1) Having iliac artery lesions (stenoses or occlusions).
(2) Having orificial occlusion of the SFA.
(3) Having long lesions of the SFA and/or PA.

All endovascular procedures were performed in the angiosuite under local anesthesia.

For every patient, the following data were recorded:

(1) The location and length of the arterial lesion.
(2) Size of the balloon (diameter and length).
(3) Size of the stent (diameter and length) and type.
(4) Quality of distal runoff.
(5) Complications and their management.

Procedural data

(1) Access site:

The ipsilateral femoral approach was used in 16/20 (80%) limbs in group I and in 14/20 (70%) limbs in group II. The contralateral (crossover) approach was

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used in 4/20 (20%) limbs in group I and in 6/20 (30%) limbs in group II.

(2) Sheath size:
In 35 cases, the 6-Fr sheath was used, whereas in five cases the 8-Fr sheath was used.

(3) Wires:
In this study, Terumo 0.035 inch was the principle wire of angioplasty; 0.014 inch was used in one case.

(4) Passage of wire:
Intraluminal passage of the wire was the main technique used in 25 cases (62.5%), whereas subintimal route was used in 15 cases (37.5%).

(5) Balloon angioplasty (group I):
Balloon angioplasty was performed in all cases (20 limbs). The balloon diameter ranged from 5 to 6 mm and balloon length ranged between 40 and 80 mm. Inflation pressure ranged between 8 and 12 ATM. Inflation time ranged between 60 and 120 s.

(6) Stent deployment (group II):
Stenting (self-expandable nitinol) with one stent was carried out with predilatation in 17 of 20 (85%) cases, stenting with two stents was carried out in two of 20 (10%) cases, and stenting with three stents was carried out in one of 20 (5%) cases. In all patients, the diameter was 6 mm and stent length ranged between 60 and 150 mm.

Procedural outcome

Initial procedural technical success was considered to have occurred when, angiographically, less than 30% residual stenosis measured at the narrowest point of arterial lumen was obtained.

Clinical success was considered to have occurred in the form of regaining of pulse, revascularization warmth, disappearance of rest pain, good capillary circulation, or good healing of ulcer or minor amputation.

Most patients were discharged on the second day following the procedure after receiving instructions on risk factors, control measures, and treatment, which included aspirin 150 mg/day for life, clopidogrel 75 mg/day for at least 1 month, and atorvastatin according to the presence or absence of dyslipidemia.

Follow-up

Patients were followed up immediately after the procedure for the following:

(1) Palpable pulses (popliteal and pedal).
(2) Femoral hematoma and retroperitoneal hemorrhage.
(3) Acute thrombosis (acute ischemia).
(4) Blood transfusions.
(5) Acute renal failure.
(6) Prolonged hospitalization.
(7) The need for minor or major amputation [major amputation was defined as loss of a sufficiently functional foot remnant (to allow standing and walking) and necessitating the fitting of prosthesis – that is, above and below knee amputations for the purposes of this study. Minor amputation constituted Ray and forefoot amputations [7]].
Subsequently, 1 and 6 months later the patients were followed up for the following:
(8) Tissue loss (healing of ulcers and dry gangrene).
(9) Restenosis and reocclusion.
(10) Operative intervention (open surgery).

Results

Table 1.

Detection of the patency and survival of the angioplasty/angioplasty and stent after 1 month and after 6 months

At 1-month follow-up, three occlusions were seen in group I (dilatation) (success rate was 85%), whereas in group II all cases were patent (success rate was 100%). The successful cases fulfilled the criteria of angiographic and clinical success mentioned above.

At 6-month follow-up, no occlusions were detected in group I (dilatation), whereas in group II occlusions were detected in nine cases (primary patency was 55%).

Follow-up

Group I: Follow-up in group I was smooth, except for two cases with forefoot amputations.

Group II: Three cases needed forefoot amputations and two cases needed above-knee amputation. In addition, two cases had puncture site hematoma (Figs 1 and 2).

Discussion

The present study was conducted on 40 patients; 20 cases were managed with PTA without stenting and 20 cases were managed with PTA with stenting for femoropopliteal occlusive disease that fulfilled the selection criteria. According to the TASC classification, we had all cases (40) with TASC II type B and C lesions.

Table 1 Demographic features, clinical presentation, and clinical examination of patients

Item	Patients treated with dilatation only (group I) [*n* (%)]	Patients treated with dilatation and stent (group II) [*n* (%)]	
Demographic features			
Age groups (years)			
40–50	4 (20)	4 (20)	
51–60	3 (15)	3 (15)	
61–70	11 (55)	2 (20)	
71–80	2 (10)	11 (55)	
Sex (%)			
Male	55		
Female	45		
Risk factors			
Diabetes	20 (100)	20 (100)	
Hypertension	18 (90)	16 (80)	
Hyperlipidemia	10 (50)	10 (50)	
Cardiac abnormality	9 (45)	7 (35)	
COPD	0 (0)	1 (5)	
Smoking	12 (60)	11 (55)	
Renal failure	0 (0)	0 (0)	
Stroke	3 (15)	4 (20)	
History			
Previous amputation	0 (0)	1 (5)	
Previous angioplasty	2 (10)	0 (0)	
Previous arterial bypass	0 (0)	0 (0)	
Previous coronary bypass	0 (0)	2 (10)	
Clinical presentation			
Rest pain	5 (25)	7 (35)	
Tissue loss	15 (75)	13 (65)	
Lesion description			
TASC classification			
TASC-B	11 (55)	9 (45)	$P = 0.378$
TASC-C	9 (45)	9 (45)	
Sites of occlusions and stenoses			
Stenosis only			
SFA	8 (40)	11 (55)	$P > 0.004$
SFA and pop	9 (45)	3 (15)	
Pop and PTA	1 (5)	0 (0)	
Pop and ATA	0 (0)	0 (0)	
Occlusions only			
SFA	0 (0)	3 (15)	$P > 0.008$
SFA and pop	0 (0)	1 (5)	
Stenosis and occlusion sites			
SFA	2 (10)	0 (0)	$P > 0.005$
SFA and pop	0 (0)	4 (20)	

SFA, superficial femoral artery; TASC, Trans-Atlantic Inter-Society Consensus; ATA, anterior tibial artery; COPD, chronic obstructive pulmonary disease.

This study was undertaken to determine whether the addition of primary stenting to angioplasty of the SFA and PA would improve the durability of these interventions in tandem lesions. The risk factors were examined as predictors of success, including age, sex, diabetes, hypertension, smoking history, and coronary artery disease (Table 2). The ages of the patients ranged from 41 to 75 years, with a mean age of 61.85 ± 9.79 years. The proportion of male patients was 55%, whereas the proportion of female patients was 45%. All patients (100%) had diabetes, 34 patients (85%) had hypertension (mean blood pressure: 152.60 ± 21.57 mmHg), 16 patients (40%) had cardiac abnormality, and 20 patients (50%) had hyperlipidemia. These factors did not affect patency rate within a relative 6 months of follow-up.

Conrad *et al.* [8] cited that hypertension, diabetes mellitus, renal failure, congestive heart failure, and long lesion length were associated with lower patency rates following angioplasty and stenting of femoropopliteal occlusive lesions in 12-month follow-up [8].

The higher incidence in male population was mentioned by Faglia *et al.* [7], Cull *et al.* [9], and Iida *et al.* [10], who reported that it ranged from 54 to 76%. However, in a study by Chisci *et al.* [11], the incidence in male sex was equal to that in female sex.

The higher incidence in male population may be attributed to the prevalence of predisposing factors (smoking, hyperlipidemia, stress of life, and hypertension).

Although hypercholesterolemia has not previously been directly correlated with worse outcomes for lower extremity vascular interventions, there is some evidence that lipid-lowering agents may help in controlling atherosclerotic disease in the lower extremities [12].

Endovascular treatment in diabetic patients with end-stage renal disease remains a challenge, mainly due to the presence of heavy calcification and the involvement of more than one vascular segment. Diabetic patients with critical ischemia and end-stage renal disease should be treated at an early stage, ideally before tissue loss appears [13].

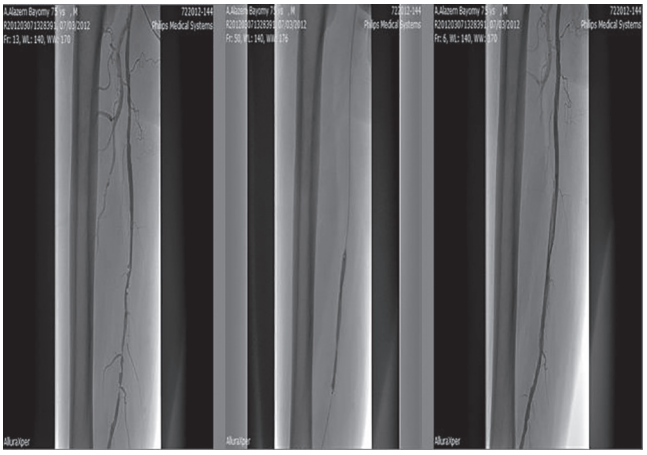
In our study, of patients treated with dilatation, five patients (25%) presented with rest pain and 15 patients (75%) presented with tissue loss (forefoot gangrene and toe and heel ulcers). However, among patients treated with dilation and stent, seven patients (35%) presented with rest pain and 13 patients (65%) presented with tissue loss.

According to Chisci *et al.* (2012) [11], of the 480 patients, 19.3% presented with rest pain, 37.4% presented with major tissue loss, and 43.3% presented with minor tissue loss. It is commonly recognized that a more severe state of the limb, especially Rutherford 6 ulcer/gangrene, more likely results in a higher major

Table 2 Risk factors in group I (dilatation only) and group II (dilatation and stent)

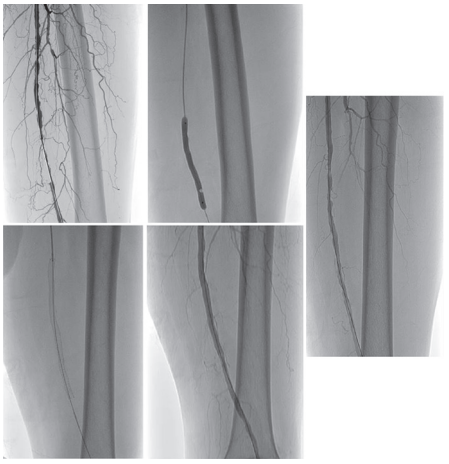
Risk factors	Group I (dilatation only)		Group II (dilatation and stent)	
	Patent at 6 months (*N* = 17) [*N* (%)]	Occluded at 6 months (*N* = 3) [*N* (%)]	Occluded at 6 months (*N* = 11) [*N* (%)]	Patent at 6 months (*N* = 9) [*N* (%)]
Diabetes mellitus	17 (100)	3 (100)	11 (100)	9 (100)
Hypertension	15 (88)	3 (100)	11 (100)	5 (55.5)
Hyperlipidemia	8 (47)	2 (67)	5 (45.5)	5 (55.5)
Cardiac abnormality	7 (41)	2 (67)	3 (27.3)	4 (44.4)
Renal	0 (0)	0 (0)	0 (0)	0 (0)
Smoking	9 (53)	3 (100)	6 (54.5)	5 (55.5)

Figure 1



Selected case from group I (dilatation only). Angiographic picture showing multiple stenoses of right superficial femoral artery (SFA), balloon dilatation of right SFA, and good filling of right SFA after balloon dilatation (no flow limiting dissection).

Figure 2



Selected case from group II (dilatation and stenting). Angiographic pictures showing multiple lesions and stent deployment in superficial femoral artery (SFA).

amputation rate. The need for major amputation is two-fold higher in patients with ulcers or gangrene than in patients with only rest pain [10].

In this study, total lesion length less than 5 cm was found in four patients (20%) in group I and in six patients (30%) in group II. Lesions measuring between 5 and 10 cm were found in four patients (20%) in group I and in three patients (15%) in group II. However, lesions measuring more than 10 cm were found in 12 patients (60%) in group I and in 11 patients (55%) in group II.

Schillinger *et al.* [14] reported an average lesion length of the treated segments in the stenting and PTA groups between 132 ± 71 and 127 ± 55 mm, respectively. Krankenberg *et al.* [15] reported a mean SFA lesion length between 4 and 5 cm in both groups.

It is logical that the results of angioplasty should be influenced by the type and severity of the occlusive lesion. This has been confirmed by several studies of femoropopliteal stenting [16]; the patency at 2 years was significantly better for single stenosis (71.7%) than for multiple stenoses (26.7%). It was mentioned by Setaccia *et al.* [17] that short SFA lesions (<5 cm) are preferably treated with angioplasty. Stenting of short lesions should only be performed when suboptimal results are obtained with PTA alone (level 1a; grade B). The preferred treatment of intermediate SFA lesions (5–15 cm) is PTA with primary bare nitinol stenting (level 1b; grade B).

The endovascular treatment of multilevel disease is thought to result in worse outcomes compared with the treatment of single-level disease of the femoropopliteal or aortoiliac vasculature, because each lesion has its own failure rate that results in an additive effect. In addition, patients with multilevel disease are frequently older, have more comorbidities, and have lower baseline ankle-brachial indexes than patients with single-level disease [18].

Schnieder [19] found that patients with stenosis had a more favorable outcome compared with those with occlusion, with a better patency and lower probability for technical failure at 1 year (7 vs. 18%) and lower complication rate (7 vs. 22%).

In the present study, stenting (self-expandable nitinol) with one stent was carried out with predilatation in 17/20 (85%) cases, stenting with two stents was carried out in 2/20 (10%) cases, and stenting with three stents was carried out in 1/20 (5%) cases. In all patients, the diameter was 6 mm and stent length ranged between 60 and 150 mm. Jerry *et al*. [20] reported that the correct diameter and length of the stent is critical in treating SFA disease. For self-expanding uncovered stents, slight oversizing of the stent (typically by ~10%) is appropriate.

Although stents have been increasingly used in the femoropopliteal segment, no convincing data exist to show that primary stenting dramatically improves outcome. SFA is subjected to many external forces (torsion, compression, flexion, extension, and contraction) that make stenting unpopular. However, after suboptimal balloon dilatation (dissection, residual stenosis, or recoil occurs), stenting can improve the outcome [17]. Data from multiple prospective trials and meta-analyses have been inconclusive with regard to patency and the routine use of stent implantation following angioplasty of femoropopliteal occlusive lesions [21].

In this study, at 1-month follow-up, three cases were occluded in group I (dilatation only) (eight 5% patency), whereas in group II (dilatation and stenting) all cases were successful (100% patency). At 6-month follow-up, it was found that group I had no more occluded cases (primary patency was 85%), whereas in group II nine cases were occluded (primary patency was 55%).

In a study by Baril *et al* [22], freedom from restenosis/occlusion was 58.9% at 12 months in cases that underwent PTA, whereas Cvetanovski *et al.* [16] reported a patency of 75% after stenting in 6 months, and Krankenberg *et al*. [15] reported patency rates in the stenting and PTA groups of 68 and 61%, respectively, after 12 months.

It is now recognized that the patency of revascularization is not as important as limb salvage, and actually there is a population of asymptomatic patients with subclinical lower extremity ischemia and very low perfusion pressures. These patients become symptomatic only when they develop incidental foot ulceration and do not have the circulatory reserve to heal. A boost in arterial perfusion, even transiently, usually allows healing of the ulcer. Once the ulcer is healed, maintenance of enhanced perfusion is not critical, and recurrent ischemia is usually well tolerated as the patient resumes the subclinical ischemic state [23].

Baril *et al.* [22] reported a major complication rate of 2% and no intervention-associated mortalities. Furthermore, the majority of patients treated were discharged home the same day or after one-night hospital stay, whereas in our study major complications of 5% were present in the form of above-knee amputation and minor complications of 5% in the form of groin hematoma.

Krankenberg *et al*. [15] concluded that balloon angioplasty in short femoropopliteal lesions (less than 5 cm in length) can result in similar clinical efficacy compared with primary stenting with respect to restenosis prevention, whereas Schillinger and colleagues concluded that primary stenting improved morphological and clinical outcomes in these patients, with a median SFA lesion length of 10 cm compared with PTA treatment.

We agree with the study by Setaccia *et al.* [17]. and disagree with the study by Krankenberg *et al*. [15] that despite the short period of follow-up, the results of balloon angioplasty in multiple short femoropopliteal lesions (each less than 5 cm in length) are far better compared with primary stenting.

Conclusion

Endovascular treatment of TASC II B and C lesions may be performed safely with minimal morbidity. Low preoperative ABIs, hypercholesterolemia, and longer lesions appear to be associated with higher rates of restenosis. Short SFA lesions (<5 cm) are preferably treated with angioplasty. Stenting of short lesions should only be performed when suboptimal results are obtained with PTA alone (e.g. flow limiting dissection, residual stenosis >25%, post-PTA stenosis). Primary stenting cannot be recommended in patients with multiple stenoses, located at the level of the femoropopliteal junction and upper PA, or for patients with TASC B lesions. Primary stenting of the SFAs and PAs can provide short durable results in patients with TASC B and TASC C lesions and may be an effective treatment strategy, but long-term results are far behind with balloon angioplasty alone.

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Conflicts of interest

There are no conflicts of interest.

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