ASSESSMENT OF FLEXIBLE NITINOL STENT PATENCY FOR MANAGEMENT OF FEMOROPOPLITEAL DISEASE

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INTRODUCTION

Peripheral artery disease (PAD) is a condition causing arterial narrowing, primarily affecting blood flow to the legs and feet. It is influenced by risk factors like diabetes and smoking, leading to pain, tissue loss, and gangrene. PAD affects 3% to 12% of the global population, with severe cases more common in women and individuals over 40.

The femoro-popliteal artery is a key site for PAD, facing mechanical stresses like compression and torsion. Balloon angioplasty is the first-line treatment, but its limited durability often necessitates stenting for better vessel patency. Traditional stents, including laser-cut types, have drawbacks like fractures and inflammation. Advances in biomimetic materials have led to flexible nitinol stents (e.g., Supera stent), designed to withstand stress and improve outcomes. Lesions are classified using TASC II criteria based on type, length, and location. This study evaluates the effectiveness of flexible nitinol stents in femoropopliteal disease management.

AIM OF THE WORK

The aim of this study was to evaluate the flexible nitinol stent in the management of femoropopliteal disease.

PATIENTS AND METHODS

The study was conducted on 20 patients in Alexandria university hospital and other vascular centers in Alexandria in the period between May 2022 till January 2025.

Written informed consent was obtained from all patients before enrollment and all patients were assigned to the same treatment protocol.

Inclusion criteria:

- Patients with intermittent and lifestyle-limiting claudication, pain at rest in the affected limb or with ipsilateral tissue loss, and with lesions in popliteal artery or superficial femoral artery or both with presence of at least one leg artery for distal runoff.
- Patients with femoropopliteal disease, who will require percutaneous transluminal angioplasty (PTA) and stent.
- Planned follow-up available for at least 24 months.

Written informed consent to participate in the study and agreement to comply with the study protocol must be obtained from the patient prior to initiation of any study-mandated procedure and randomization.

Exclusion Criteria:

- Patients who cannot receive dual antiplatelet therapy (aspirin 100mg and clopidogrel 75mg) or anticoagulation therapy.
- Participation in another study with investigational drug/device within the 30 days preceding and during the present study
- Previous enrolment into the current study.
- Prior stenting at the location of intended stenting.
- Patients who are judged to have a lesion that prevents complete inflation of an angioplasty balloon or proper placement of the stent or stent delivery system.
- Enrolment of study investigator, his/her family members, employees and other dependent persons.
- If female and of childbearing potential: known pregnancy or a positive urine pregnancy test (confirmed by a positive serum pregnancy test), or lactating.
- Patients with creatinine clearance < 30 mL/kg/ min, history of severe allergy to nitinol (nickel titanium), iodinated contrasts, and with significant atherosclerotic disease in aortoiliac and/or femoral territories.

Methods:

Baseline assessments: CBC, Coagulation profile, Renal function, Inflammatory markers, Duplex finding and CTA.

Outcome measure: stent patency.

Treatment: Endovascular balloon dilatation and stenting using flexible nitinol stent.

RESULTS

Table 1: Relation between Number of run off tibial vessels with Follow up stent patency (n=20)

	N	Number of run off tibial vessels		U	p
		Mean ± SD.	Median (Min. – Max.)		
3 months					
Occluded	3	1.33 ± 0.58	1.0 (1.0 – 2.0)	10.000	0.118
Patent	17	2.06 ± 0.56	2.0 (1.0 – 3.0)		
Died	0	–	–		
6 months					
Occluded	5	1.40 ± 0.55	1.0 (1.0 – 2.0)	14.500*	0.042*
Patent	15	2.13 ± 0.52	2.0 (1.0 – 3.0)		
Died	0	–	–		
12 months					
Occluded	8	1.63 ± 0.74	1.50 (1.0 – 3.0)	26.000	0.098
Patent	12	2.17 ± 0.39	2.0 (2.0 – 3.0)		
Died	0	–	–		

SD: **Standard deviation**
U: Mann Whitney test
p: p value for Relation between Number of run off tibial vessels with Follow up
*: Statistically significant at $p \leq 0.05$

Table 2: Relation between risk factor control with follow up stent patency (n=20)

	Risk factor control				χ^2	p
	No (n = 4)		Yes (n = 16)			
	No.	%	No.	%		
3 months						
Occluded	3	75.0	0	0.0	14.118*	FEp=0.004*
Patent	1	25.0	16	1.00		
Died	0	0.0	0	0.0		
6 months						
Occluded	4	100.0	1	6.3	15.000*	FEp=0.001*
Patent	0	0.0	15	93.8		
Died	0	0.0	0	0.0		
12 months						
Occluded	4	100.0	4	25.0	7.500*	FEp=0.014*
Patent	0	0.0	12	75.0		
Died	0	0.0	0	0.0		
24 months						
Occluded	4	100.0	6	37.5	5.000	MCp=0.111
Patent	0	0.0	8	50.0		
Died	0	0.0	2	12.5		

χ^2: **Chi square test** **FE: Fisher Exact test** **MC: Monte Carlo test**
p: p value for comparison between the studied categories
*: Statistically significant at $p \leq 0.05$

CONCLUSION

Flexible nitinol stent was effective in the management of femoropopliteal disease with mean of overall flexible nitinol stent patency of 17.25 months. However, at the end of the study 40% of stents stay patent and major amputation occurred in 2 patients (10%) and 2 patients (10%) died.

Also, the study highlights the significant relation between stent patency and compliant to post operative medication, risk factor control, run off tibial vessels and stent deployment site.