Observational analysis of Endovascular complications of superficial femoral artery diseases (Prospective Study)

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ABSTRACT

Purposes: *For observing the most common obstacles or complications that were in need for immediate intervention during endovascular treatment of superficial femoral artery diseases, and how to deal with.*
Background: *Endovascular intervention of superficial femoral artery (SFA) diseases has been introduced new types of complications. Rapid identification of complications allows rapid remediation and improving outcomes.* ***Patients and methods:*** *This is a retrospective observational cohort study that was conducted over a period of 4 years on complicated 120 patients of femoral artery disease that underwent immediate endovascular intervention. Patients were classified according to type of SFA lesions(stenosis , occlusion, aneurysm) and anatomical segment of SFA involved (either proximal, or distal),association with popliteal and tibial arteries diseases).* ***Results:*** *Distal SFA lesions are more than twice encountered than proximal SFA lesions. The proximal SFA failed endovascular management is more common than the distal SFA. The proximal SFA lesions are less likely to be dealt with endovascular in comparison to the distal SFA lesions P-value; 0.03. The common complications are the flow limiting dissections(26.8%), thrombosis(24.7%) ,and residual stenosis $\geq$ 30(19.4%).Complications that was in need for immediate intervention were reported as 1% to 27%. Emergency surgery was used for complicated proximal SFA and in failed endovascular intervention for the distal segment complications; P-value; 0.01. Technical success was reported in 96.6% after endovascular intervention & 61.5% after Surgical treatment; P-value; 0.04.*
Conclusion: *Complications of endovascular intervention of SFA may have devastating outcomes that can threaten limb and life. The proximal SFA failed endovascular management is more common than the distal SFA. The proximal SFA lesions are less likely to be dealt with endovascular in comparison to the distal SFA lesions Adequate awareness of these complications, how frequent it affects the proximal and distal SFA lesions, will allow achieving excellent technical ,and clinical outcomes. New endovascular technologies can improve the safety and efficacy of revascularization procedures.*
Key words: *Endovascular intervention, SFA Disease, Complications.*

INTRODUCTION

The most common complication of endovascular intervention of superficial femoral artery is the puncture .Detailed anatomy understanding would avoid these complications.[1,2]

Although endovascular procedures are overall less invasive in nature, these procedures can have different complications. Complications during the procedure include thrombosis, dissection, rupture and embolization. Device specific complications include device fracture and embolization. [3,4,5]

Distal embolization rate is 1% to 3.8% .It can occur and may result in "trashing" of runoff vessels. It is more with atherectomy devices, thrombus in the chronic total occlusion lesions. If embolization occurs, endovascular salvage can be tried, by thrombectomy devices, open thrombectomy, or surgical bypass. [6-8]

Post angioplasty dissection is considered common among complication(7%), demonstrated by contrast material stagnating within dissection plane without washout, treated by sustained inflation of a low-pressure balloon to "tack down" the flap. If this failed , there is still a significant (>30% or flow-limiting) dissection then a stent is used. Small dissection planes can be tolerated if there is no distal stenosis and no thrombus development, particularly if the dissection is retrograde to the flow of blood. [9-11]

Arterial perforation (during angioplasty) can result in life-threatening bleeding, especially in atherosclerotic vessels. Over distention of a calcified vessel that has lost its elastic compliance

can result in disruption of all layers of the arterial wall and frank perforation especially in infrainguinal vessels. [12]

Arterial spasm(more common in younger patients) rarely leads to a serious complication during angioplasty, causing severe symptoms of pain .Also device failure which includes angioplasty balloon rupture prior to stent expansion, stent embolization, guidewire fracture, and catheter fracture. [9,11]

PATIENTS AND METHODS

All patients underwent evaluation by complete history taking , full clinical examination ,investigations including ABI, duplex scanning, CT angiography before intervention to detect the site , extent of the disease. Evaluation of the patients' comorbidities by ECG or echocardiography.

The current study was conducted after approval from local ethical committee of Cairo and Benha universities and Benha Insurance Hospitals and obtaining written fully informed patients consent. This study was undertaken on all patients undergoing technically successful endovascular intervention and have complications at the vascular unit of General surgery Department, Cairo and Benha University Hospitals and Department of Vascular Surgery, Benha Insurance Hospitals were considered for inclusion in this study from November 2015 till **September** 2019.

This is a prospective observational cohort study that was conducted on complicated 120 patients of femoral artery disease, where the complications occur during the procedure that underwent immediate endovascular intervention over a period of 4 years. Exclusion criteria included arterial access complication, patients with bilateral limbs lesions, or recurrent lesions.

Patients were classified according to: anatomical segment involved (proximal, and distal SFA),associated popliteal and tibial arteries, and type of SFA lesions (stenosis, chronic total occlusion). All patients were observed for immediate complications that occur after gaining arterial access, while doing the endovascular intervention of SFA lesions that needed further interventions to end the procedure successfully, to save the limb, or the patient.

Interventions:

Patients were admitted one day before or on the day of the procedure. All interventions were done in angio suite (Philips; Allura X per FD 20/722028164) , C-arm image intensifier with road mapping was used. Patients were placed in supine position, prepped (both groins), locally anaesthetized sometimes combined with sedation in irritable patients.

The arterial access was done(either ultrasound guided or not) through: Antegrade ipsilateral common femoral artery puncture for distal SFA lesions or Contralateral retrograde femoral puncture, performing crossover technique for proximal SFA lesions **.** In cases of failure of previous 2 accesses; Retrograde ipsilateral puncture of the popliteal artery where the patient lies on prone or lateral decubitus position **,** or transtibial access were used. **.**

After gaining access a standard 6F sheath was inserted and free arterial flow is allowed to confirm the right position of the sheath. Diagnostic angiography was done to confirm data obtained by preoperative investigations .

All patients were treated according to the standards, Completion angiography was done to assess the result of the endovascular therapy. There should be rapid forward flow through the treated segment with no residual stenosis $\underline{\geq}$ 30%. Dissections in the wall of the artery were expected and did not imply a poor result unless they were flow limiting.

Acute complications that needed further interventions included arterial perforation, flow limiting dissection, thrombosis, residual stenosis ≥30%, spasm of distal arteries, device embolization, and equipment failure.

For thrombosis; if the patient was critically affected; thrombectomy was done during the angioplasty by fogarty over the wire ,or open surgical thrombectomy. But if the patient wasn't critically affected; thrombolytic therapy was applied via Uni Fuse catheter (Angiodynamics); 15, 40 or 50cm or Fontaine catheter (Boston Scientific); 30 or 50cm according the length affected) i.e. Tissue Plasminogen Activator (Actylase; 50mg) (2 bottles, one powder and another solution 50ml: 0.5-1 mg/hour; 25-50 ml/hr of 10 mg /500 ml normal saline.

Arterial perforation, or rupture could occur both at the site of balloon angioplasty, and distally from the guidewire. The perforation is either in

proximal (ostial lesions) or distal. Intervention for proximal perforation or rupture included; balloon tamponade, covered stent **,** or open surgical repair by interposition graft, bypass surgery, vein patch or direct closure. Intervention for distal lesions perforation ,or rupture included balloon dilatation by larger diameter balloon, stenting or surgery (bypass or interposition graft) for residual stenosis ≥30% or flow-limiting dissection.

In arterial spasm vasodilator agent (nitroglycerine; 50-100 µg) was administered inside the sheath, occasionally, a guidewire may have to be removed to distinguish refractory spasm from dissection. But if there was device embolization; it was removed by vascular snare and grasping forceps.

In equipment failure; failed balloon deflation (air lock) was managed with continuous negative pressure with endoflator or a large (20 ml or larger) syringe but if failed to pass into sheath; over inflation was done to rupture this balloon and withdrawn into the sheath with rotation to fold its wings. Balloon herniation was treated by traction to the catheter during inflation but if failed; this problem was solved by using a longer balloon. Balloon rupture was managed by switching to another balloon using its shoulder for dilatation but if this balloon ruptured switching to a thicker and more puncture resistant polymer balloon also if ruptured; a stent was applied , the lesion is dilated through the stent ; if this balloon ruptured on the end of the stent; the balloon was replaced by another one and the end of the stent was dilated last. Balloon catheter that didn't track along the standard guidewire; this wire was exchanged for a stiffer guidewire and the balloon tracked if failed tracking; long sheath was applied.

But stent insertion was done in the patients where there were elastic recoil (residual stenosis ≥30%); (If the balloon inflates fully, but the stenosis persists), a flow-limiting dissection; (prolonged balloon inflation can be performed to (tack down) the flap If this fails, other presentations such as recurrent lesions after a recent PTA or long segment occlusions. A self-expanding stent was used . The stent should not be oversized relative to the diameter of the SFA. The stent should be long enough to cover the lesion with 5-10mm coverage of the normal artery on either side of the lesion.

Then; auxiliary procedures like tibial angioplasty were performed when needed to enhance and augment the outflow vessels. Long tibial balloons low-profile with diameters from 2 or 3 mm (less than 4F) designed for tibial angioplasty purposes . They are made to work on a 0.035" , 0.014" or 0.018 ". The wire is left across the lesion for access and an intra-arterial nitroglycerin (50-100 µg) is given, a check angiogram is performed and redilatation is done whenever required.

The endpoint of the procedure which means the procedure was salvaged, was unrestricted forward flow of contrast with no evidence of significant (≥30%) residual stenosis. The run-off was assessed at the end of the procedure for the occurrence of distal embolization caused by the PTA or stent insertion. Lastly; PTA of any relevant tibial lesions is performed during the same procedure. When the procedure was completed, the arterial access sheath was removed immediately, when more than 5000 IU of heparin was given, the sheath removal was delayed until aPTT normalizes. Hemostasis achieved by manual compression. Digital compression was held proximal to the skin puncture site for 15-20 minutes and mobilization was delayed for 6-12 hours.

Follow up:

Clinical follow-up consisted of pulse examination and evaluation of the ulcer or amputation site healing or resolution of infection.

Clinical outcomes, and complications following the procedure were reported. All patients were re-examined after one week to check for access site complications and to confirm patency.

Statistical analysis:

Analysis of data was done by using Statistical Package for Social Sciences (SPSS) version 16 (Bristol university; in United Kingdom). Quantitative data were presented as mean and standard deviation and were analyzed by ANOVA test. Qualitative data was presented as numbers and percentages and were analyzed by using Chi-square. (P-value <0.05) was considered significant while (P-value <0.01) was considered highly significant. But (P-value >0.05) was considered insignificant. Sample size was calculated with power of 90% with marginal error 5%.

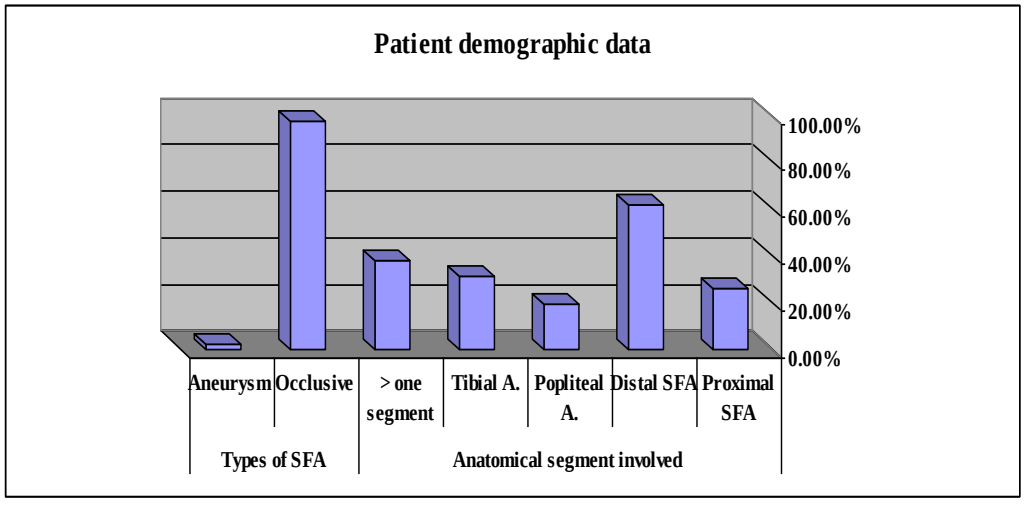
RESULTS

This prospective observational cohort study was conducted on 120 patients; 74 (61.7%) males and 46 (38.3%) females with age over 41 years; risk factors and co-morbidities; 56 (46.7%) of patients were smokers, 31 (25.8%) patients were diabetics, 19 (15.8%) patients were hypertensive, 2 (6.7%) while 23 (19.2%) patients had more than one co-morbid disease; There were 46 patients (38.3%) who had more than one segment angioplastied, **Tab. (1), Graph. (1)**

Table (1): Patients demographic data:

Data			Findings	
			Number (%)	***Mean ± SD (range)***
Age (years)	Strata	41-55	44 (36.7%)	46.3±5.2
		≥55	76 (63.3%)	61.7±6.9
	Total		***120 (100%)***	
Gender	Females ♀		46 (38.3%)	
	Males ♂		74 (61.7%)	
Risk factors & co-morbidities	Smoking		56 (46.7%)	
	Diabetics		31 (25.8%)	
	Hypertensive		19 (15.8%)	
	Previous cardiac stroke		5 (4.2%)	
	Previous stroke		3 (2.5%)	
	More than one co-morbid		23 (19.2%)	
Anatomical segment involved	Proximal SFA		31 (25.8%)	
	Distal SFA		74 (61.7%)	
	Popliteal A.		23 (19.2%)	
	Tibial A.		38 (31.7%)	
	> one segment		46 (38.3%)	
Types of SFA lesions	Occlusive		117 (97.5%)	
	Aneurysm		3 (2.5%)	

Data are presented as numbers, mean ± SD & percentages.



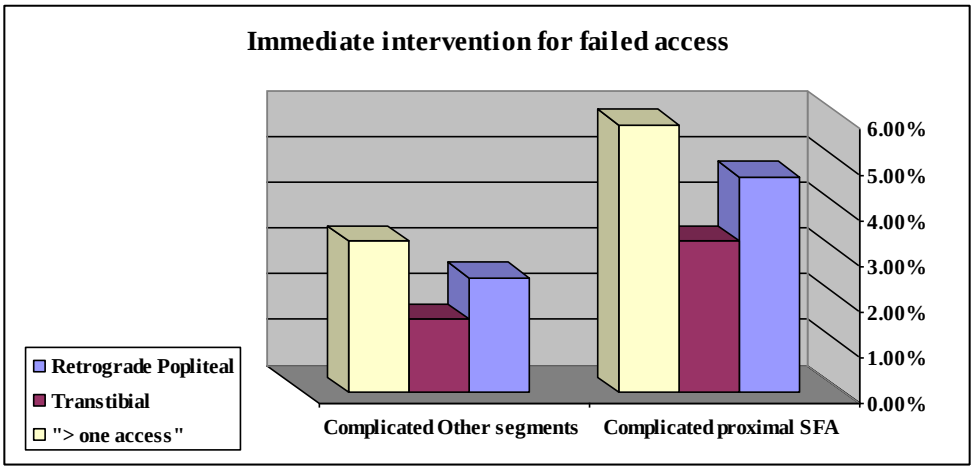
Graph. (1): **Patients demographic data**

The planed procedure was balloon angioplasty applied in all patients(except the 3 aneurysms patients); but immediate intervention used for failed access was more in proximal SFA as compare with other SFA segments , including fluoroscopic guided retrograde popliteal access in 5 (4.7%) patients, transtibial in 4 (3.3%) patients; three cases by duplex guided posterior tibial artery, and one case by open cut down of anterior tibial artery. **Tab. (2), Graph. (2)**

Table (2): Immediate intervention for failed access:

Immediate intervention	Complicated proximal SFA (n =104)	Complicated Other segments (n =180)	Statistical analysis
Retrograde Popliteal	5 (4.7%)	3 (2.5%)	**X^2=3.61, P=0.4**
Transtibial	4 (3.3%)	2 (1.6%)	
"> one access"	7 (5.83%)	4 (3.3%)	

Data are presented as numbers; percentages & using Chi square test (X^2).



Graph. (2): Immediate intervention for failed access.

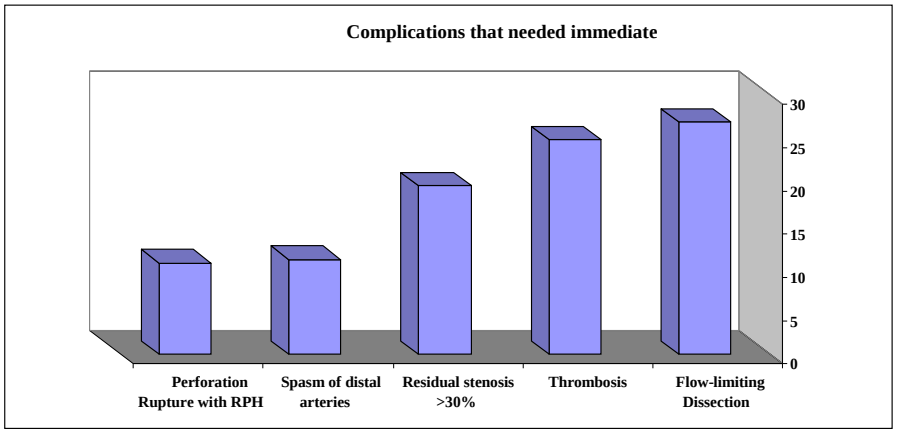
Complications that was in need for immediate intervention were reported as 1% to 27%. **Tab. (3), Graph. (3)**.

Tab. (3): complications that needed immediate intervention:

Complications	Findings	
	No	**%**
Flow-limiting Dissection	76	26.8
Thrombosis	70	24.7
Residual stenosis ≥30%	55	19.4
Spasm of distal arteries	31	10.9
Perforation or Rupture with RPH	30	10.5
Arteriovenous fistula (AVF)	12	4.23
Equipment failure	7	2.46
Device embolization	3	1.06
Total complications	284	100%

Data are presented as numbers; percentages & ranges.

(Note that; there more than one complication in the same patient; total complications number; 284 in 120 patients).



Graph. (3): complications that needed immediate intervention.

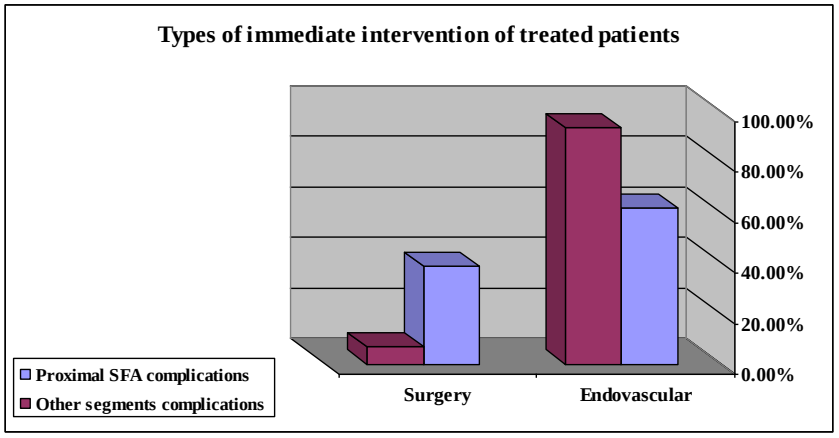
As regard to type of immediate intervention used; endovascular intervention was with limited use in complicated proximal SFA but was successful in treatment of most other segment complications. Emergency surgery was used for complicated proximal SFA and in failed endovascular intervention for other segment complications**. Table (4), Graph. (4).**

Tab. (4): Types of immediate intervention of treated patients:

Immediate intervention	Proximal SFA complications (n =104)	Other segments(distal) complications (n =180)	P-Value
Endovascular	64 (61.5%)	168 (93.3%)	0.03
Surgery	40 (38.5%)	12 (6.7%)	0.01

Data are presented as numbers; percentages.

The absolute risk reduction of immediate endovascular intervention in proximal SFA is =38.5%.The absolute risk reduction of immediate endovascular intervention in distal SFA is 6.7%.



Graph. (4): Types of immediate intervention of treated patients.

(Note that; there more than one complication in the same patient; total complications number; 284 in 120 patients).

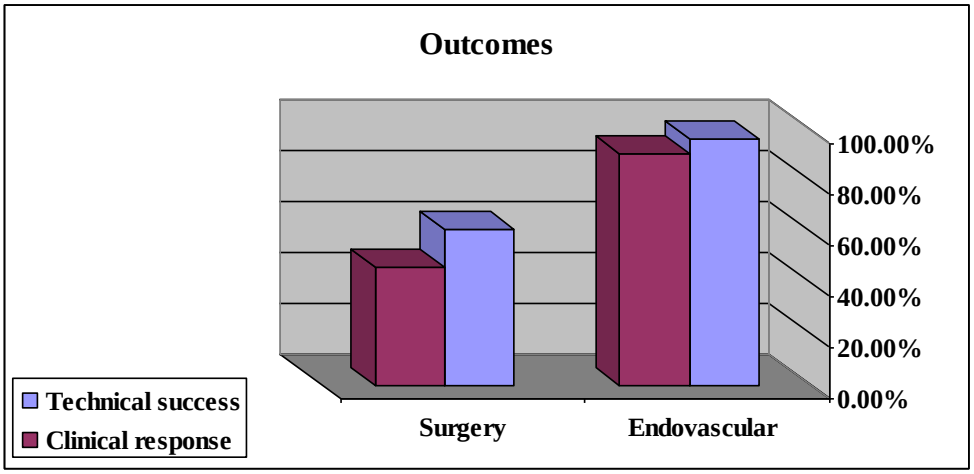
Upon review of outcomes; there were Primary outcome parameter; Technical success was reported in 96.6% after endovascular intervention & 61.5% after surgical treatment. Secondary outcome parameters; Clinical response was reported in 91.4% after endovascular intervention & 46.2% after Surgical treatment. **Tab. (5), Graph. (5)**

Tab. (5): Outcomes of the treated patients:

Outcomes	*Endovascular treated group* (n =232)	*Surgically treated group* (n =52)	P-Value
Technical success	224 (96.6%)	32 (61.5%)	0.04
Clinical response	212 (91.4%)	24 (46.2%)	0.001

Data are presented as numbers; percentages & ranges.

The absolute risk reduction , and relative risk reduction of the technical success of the endovascular treated group is 8%,.4% respectively.The absolute risk reduction , and relative risk reduction of the technical success of the surgically treated group is 20%,.3.8% respectively.



Graph. (5): Outcomes of the treated patients.

DISCUSSION

Limb-salvage patients have also shown a higher procedural complication rate than have claudicants. When endovascular complications do occur, over 86% are usually evident in the angiographic suite and almost all are evident within 5 hours postprocedure. As in all procedures, it is proper training and anticipation of the potential for a complication that will be most likely to prevent it. [(13)]

Endovascular surgery provides valuable therapeutic options for patients with either lesser forms of disease or strong indications for intervention with high operative risk. [(1)]

The current study was conducted on 120 patients; 74 (61.7%) males and 46 (38.3%) females with Age over 41 years; confirming data from epidemiological studies suggesting increased incidence of PAD in aging population. "Selvin et al." reported that the incidence of PAD is 14.5% in patients >69 years. [(14)]

Immediate intervention used for failed access was more in proximal SFA and included fluoroscopic guided retrograde popliteal access in 5 (4.7%) patients. "Shi et al." evaluated the efficacy of a dual femoral-popliteal access in CTO of SFA in 21 cases and stated that flush occlusion of SFA presents a unique challenge, in which advance techniques such as retrograde recanalization from popliteal artery are increasingly being used. [(15)]

Transtibial access was used in 4 (3.3%) patients; three cases by duplex guided posterior tibial artery and one case by open cut down of anterior tibial artery. This access was used successfully when other accesses were failed as mentioned by "Fusaro et al" [(16)]

Acute vascular complications of the current study needed immediate intervention were reported as 1% to 27%. [(11)] ; Most of these complications were flow-limiting dissection, thrombosis, residual stenosis ≥30%. Perforation or rupture was observed in 30 (10.5%) cases and equipment failure was only in 7 (2.46%). These

were comparable to study done by "Schillinger et al" who reported that Acute vascular complications at the endovascular procedure site include arterial perforation, dissection, thrombosis, spasm, side branch occlusion, and equipment failure. [17]

Residual stenosis ≥30% was observed in 55 (19.4%). This was more than reported by Siracuse and Mckinsey [3]; who mentioned that during SFA angioplasty; residual stenoses of 30% or greater may occur with an estimated frequency of 5-10%. [11,18]

The development of intravascular stents had made it possible to successfully treat post angioplasty dissection when it was recognized on the angiographic table. Nevertheless, it added cost. In the current study; Flow-limiting dissections were reported in 76 (26.8%). Dissections may be occurred at branch points, in juxtaposition to very bulky or circumferential plaques, and in arteries with diffuse longitudinal plaque formation without natural cleavage planes, especially if plaque is heavily calcified. The superficial femoral artery, especially at its origin and in the adductor canal, tend to dissect. [1,3]

Perforations or rupture were observed in 30 (10.5%). Perforation has been reported in 0-2.3% of patients in a study done by "Schillinger et al". [25] In a study by "Hayes" 1409 patients undergoing peripheral angioplasty were evaluated and 52 (3.7%) had suffered a perforation. [18, 19]

AVFs were reported in this study in 12 (4.23%) which was more than the incidence mentioned by "Kelm et al"; 0.5% to 0.86%. Endovascular management of femoral AVFs has been reported with the advent of covered stents that results in immediate closure of the AVF without surgery. [21,22]

Clinically significant post angioplasty thrombosis & embolization may result in organ or limb loss. Thrombosis and distal embolization was reported in the current study in 70 (24.7%) patients which was more than mentioned by Gandini et al. [23]; 1% to 3.8%; the patient starts off with one problem (the lesion) and ends up with two problems (a partially treated and an ischemic or occluded outflow bed) this could be explained by sheath thrombosis with distal trash or as a result of instrumentation of a friable atherosclerotic complex lesions. [3]

Upon review of spasm of distal arteries; it was observed in 31 (10.9%). Most of these patients were relatively young as mentioned by "Zeller et al." who stated that "The occurrence of arterial vessel spasm appears to be more common in younger patients and severe pain may occur". [20]

In the present study; another source of procedural complications was related to device failure; 10 (3.5%), as mentioned by "Zeller et al." and "Schillinger et al." This included broken wire and embolization that was reported only in 3 patients; who were treated using vascular snare and grasping forceps. Failed balloon deflation was observed in three patients that were managed by balloon overinflation then lastly balloon rupture. Embolization was observed during dilation of a sharp or heavily calcified lesion in four patients that was treated with a stent then the lesion was dilated through the stent. [17, 20]

As regard to type of immediate intervention used; endovascular intervention was with limited use in complicated proximal SFA but was successful in treatment of most Other segment complications.[3]

Not every patient should undergo a procedure and not every lesion should be treated with endovascular techniques. When the risk of an endovascular procedure is too high or the potential for success is low, other alternatives should be considered. [1]

Surgery was applied in 40 (38.5%) of proximal SFA segment complications to treat residual stenosis ≥30% in 2 patients & flow-limiting dissection in patients by bypass surgery in 3 patients or interposition grafts in 2 patients and perforation or rupture in 2 patients by direct closure in perforation in one patient and vein patch closure in rupture in the other patient after proximal and distal control. But Surgery was applied in 12 (6.7%) of other segments complications (distal) to treat thrombosis in 3 patients by successful open thrombectomy in one patient and by pass surgery in 2 patients. This result was comparable to study done by "Hayes" [19] who reported that 6 (24%) underwent bypass surgery.

CONCLUSIONS

Complications of endovascular intervention of SFA may have devastating outcomes that can threaten limb and life. The proximal SFA failed endovascular management is more common than the distal SFA. The proximal SFA lesions are less

likely to be dealt with endovascular in comparison to the distal SFA lesions Adequate awareness of these complications, how frequent it affects the proximal and distal SFA lesions, will allow achieving excellent technical ,and clinical outcomes. New endovascular technologies can improve the safety and efficacy of revascularization procedures.

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