How to Avoid and Manage Puncture Site Complications?

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Introduction: Recently percutaneous transluminal angioplasty (PTA) using catheter-based interventions has become the first-line option in the treatment of lower limb ischemia as it improves all patients' symptoms with a relatively lower complication rate.

Aim of work: Evaluation of puncture site complications, their incidence, management & how to avoid it.

Results: This study was conducted on 163 patients with PAD, 99 (60.7%) males. Patients age ranged between 44 to 87 years with a median of 63 years, 8 (4.9%) patients were complaining of severe claudication, 31 (19%) presented with ischemic rest pain, patients with minor & major tissue loss were 79 (48.4%) & 45 (27.6%) respectively. Sixteen patients had puncture site complications; hematoma 11 (6.14%), pseudoaneurysm (PSA) 3 (1.6%), dissection 1 (0.56%) & 1 (0.56%) case with arteriovenous fistula. Patients > 60 years & female gender had a higher number of complications. Regarding puncture site complications management: 11 (68.75%) patients were managed conservatively, 2 (12.5%) with U/S guided compression, 2 (12.5%) by open surgical repair and 1 (6.25%) patient with low-pressure balloon inflation for 5 minutes.

Conclusion: Puncture site complications could be avoided or reduced by risk assessment, meticulous puncture technique, usage of Doppler ultrasound and proper compression. It could be managed by minimally invasive procedures with good results, but surgery remains a role in difficult, resistant and complicated cases.

Key words: Puncture site complications, angioplasty, lower limb ischemia.

Introduction

The treatment of lower limb ischemia has changed dramatically because of the explosion of catheter-based interventions. Recently percutaneous transluminal angioplasty (PTA) has become the first-line option in the treatment of lower limb ischemia as it allows the healing of ulcers, diminution of rest pain and improvement of claudication distance with lower complications rate.[1]

Like any therapeutic procedure, endovascular procedures such as angioplasty and stenting carry a risk of complication to the patient. Though with proper training these complications can usually be successfully managed by endovascular procedure, improper management may be overwhelmed by the need for emergency surgery, limb loss, functional disability, and death. It is paramount that physician operators have the proper training and ability to anticipate, recognize, complications as they arise during endovascular procedures.[2]

Endovascular procedures expand the scope of patients who are eligible for treatment of infrainguinal occlusive disease. Several newer techniques are developing that substantially increase the spectrum of treatment options. Patients with critical limb ischemia have also shown a higher procedural complication rate than those who are complaining of claudication. When endovascular complications do occur, over 86% are usually evident in the angiographic suite and almost all are evident within 5 hours post procedure.[3]

Acute vascular complications at the endovascular procedure site include arterial perforation either at the site of balloon inflation or distally by the guide wire, dissection, thrombosis, spasm, side branch occlusion, and equipment failure. Perforation has been reported in 0–2.3% of patients.[4] These complications ranged from minor to severe limb or life-threatening which require urgent interventions.[5] Data from the vascular quality initiative looking at patients with critical limb ischemia show the rate of access site hematoma 3% overall and access site occlusion at 0.2%.[6]

Predicting which patients are at greatest risk for access site injury is crucial for the interventionist. By identifying higher-risk groups, risk reduction plans can be constructed and complications can be decreased. Endovascular specialist physicians will have a good clinical outcome by early detection of complications and treating it once it arises to achieve excellent clinical outcomes.[7]

Aim of work

The main objective of this study was to mention and discuss the incidence of puncture site complications that happened during or shortly after PTA for treating lower limb ischemia, how to avoid it and results of the management procedures for our Egyptian patients.

Patients and methods

One hundred sixty-three patients with manifestations of lower limb ischemia, underwent percutaneous transluminal angioplasty and were observed for developing puncture site complications during or shortly after the procedure and they were followed up for one month. All primary procedures were

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done under local anesthesia in the angio-suite at the vascular surgery department in Kafrelsheikh University Hospital and multiple vascular centers in Egypt from September 2023 to March 2024. This study was approved by the ethical committee in Kafrelsheikh University and all patients signed consents before going through this study.

Patients were assigned into four groups according to the access site; Group 1: common femoral artery (151), Group 2: popliteal artery (5), Group 3: brachial artery (4) and Group 4: tibial arteries (3). All were studied for immediate puncture site complications (Hematoma, retroperitoneal hematoma, arteriovenous fistula (AVF), dissection and thrombosis) that occurred the percutaneous transluminal angioplasty of lower limb arteries and late complications (Pseudoaneurysm and AVF).

Patients included in this study were suffering from lower limb ischemia with Rutherford class 3 to 6 clinically, with any morphological lesion according to TASC II classification and underwent complications during PTA.

However patients excluded from this study were those unsuitable for angioplasty as they were complaining of renal insufficiency, contrast allergy, and procedures with late complications (After one month).

All patients underwent evaluation by complete history taking about personal data, risk factors (smoking, DM, hypertension, dyslipidemia),co-morbidities (previous stroke, angina, MI and CKD), previous PAD interventions to one or both legs, previous amputation, history of presenting symptom (rest pain or tissue loss) and previous coronary intervention (CABG, PCI). All patients were assessed regarding the risk for puncture site complications.

All patients who presented to us were subjected to detailed clinical evaluation and examination for avoidance of contrast allergy, complete laboratory assessment for avoidance of renal insufficiency and arterial duplex ultrasound imaging study and CT angiography of both lower limbs for diagnosis and assuring the preparation.

Management procedures

All interventions were done in an angio suite under local anesthesia. Target vessels were accessed through either antegrade ipsilateral common femoral artery puncture or retrograde contralateral femoral artery puncture as in cases of iliac lesions then performing a cross over technique. In some cases the target vessels were accessed through the popliteal puncture, tibial arteries or trans brachial approach.

After the access was obtained the sheath was placed. In most cases 6f sheaths were used. Then arteriography was done and an average 5000IU of heparin was injected through the sheath according to the patient's body weight, then the angioplasty was done.

When the procedure was completed, the arterial access sheath was removed immediately and hemostasis achieved by manual compression. Digital compression was held proximal to the skin puncture site for 15-20 minutes followed by applying gauze and compression bandage and mobilization was delayed for 6-12 hours.

The access site was assessed for immediate complications

Hematoma: groin hematoma was managed by compression, follow-up CT for detection of the extent of the hematoma, serial hemoglobin assessment every 6 hrs until stabilization of the patient, blood transfusion when needed, interval duplex US to rule out pseudoaneurysm.

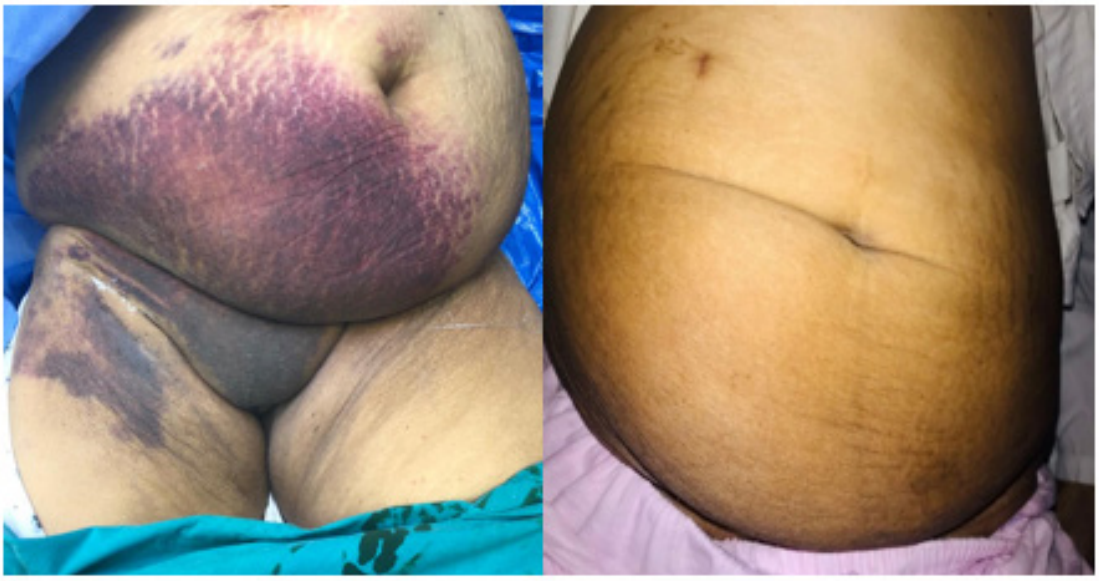
The brachial hematoma was managed conservatively by compression, serial hemoglobin and hot fomentations **(Figs. 1, 2).**

Pseudoaneurysms are focal arterial dilatations not contained by the three layers of the normal arterial wall. It develops when an injured blood vessel hemorrhages. A hematoma is formed and then cavitates, making communication with the original vessel wall. Thus PSA wall consists only of organized clot. They were managed by follow-up duplex for small aneurysms, US-guided compression over the neck of the pseudoaneurysm which leads to sac thrombosis, groin exploration and surgical repair if failed US guided compression.

For acute access closure or thrombosis urgent arterial exploration was done and confirming the absence of pulsation distal to the puncture site that was managed by thrombectomy or thromboendarterectomy of the artery followed by closure of the arteriotomy by venous patch.

All patients were followed up post-procedure to detect if there is any mortality or limb loss related to puncture site complications **(Fig. 3).**

The arteriovenous fistula was managed by retrieval of the access and the balloon was advanced ante grade through other access and then inflated at a low pressure for 5 mints, if failed open surgical exploration was done later **(Fig. 4).**



A B

Fig 1: A: Major groin hematoma extending to anterior abdominal wall. B: Complete resolution with follow up.

Fig 2: Major groin hematoma and resolution sequele along 1 month.

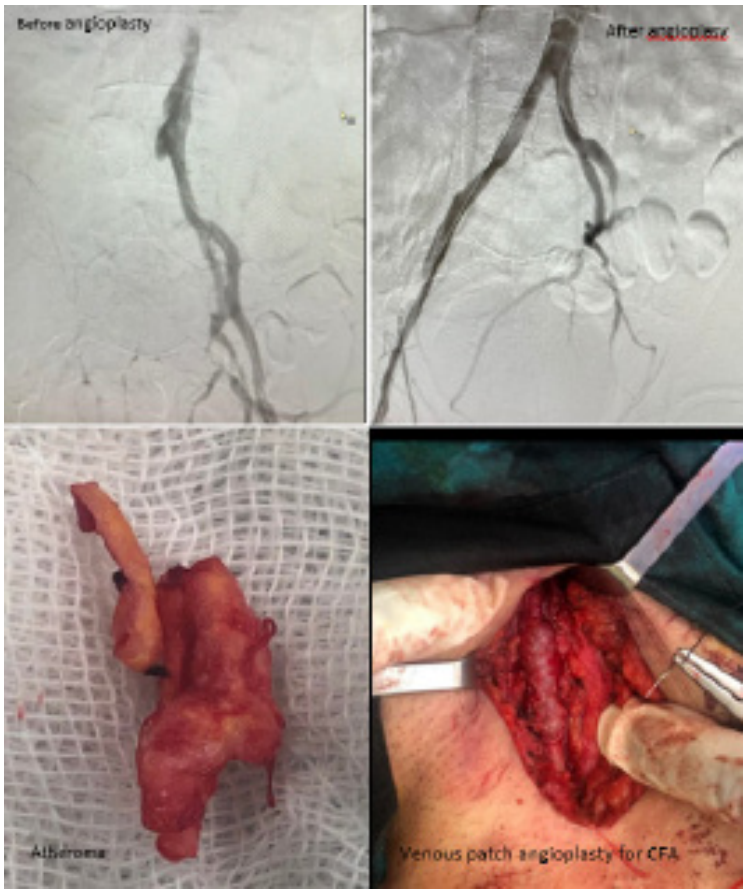


Fig 3: Left lower limb acute ischemia after successful angioplasty for Rt common iliac artery, managed by left CFA endarterectomy and closure of arteriotomy by venous patch.

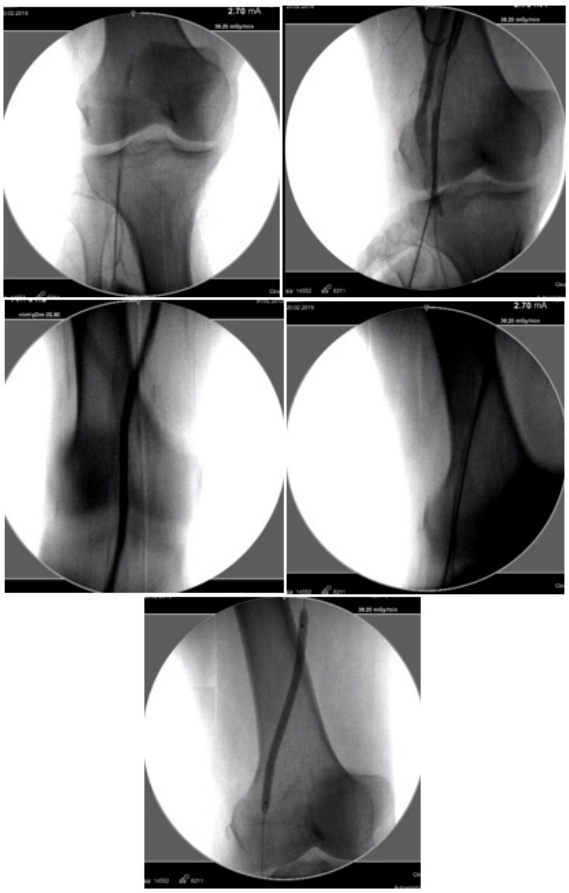


Fig 4: Pop. Artery AVF managed by retrieval of the pop access and antegrade balloon inflation.

Results

The current study was a descriptive study that was conducted on 163 patients complaining of lower limb ischemia; 99 (60.7%) males and 64 (39.2%) females. Patients with age less than 50 years old were 14 (8.58%), from 50 to 60 years old were 43 (26.38%) but patients older than 60 years were 106 (65.03%), the median age for all patients was 63 years. All patients in the current study underwent angioplasty to treat lower limb ischemia. According to risk factors and co-morbidities of the patients; 123 (75.4%) were diabetic, 86 (52.7%) were smokers, 119 (73%) were hypertensive, 62 (38%) with ischemic heart disease, 16 (9.8%) had a previous stroke and 74 patients (45.3 %) had more than 2 risk factors and co-morbidities.

As regards symptoms presented by the patients in the study; 8 (4.9%) patients were complaining of severe claudication that harmed their lifestyle (Rutherford category 3), 31 (19%) presented with ischemic rest pain (Rutherford category 4), 79 (48.4%) presented with minor tissue loss (Rutherford category 5), 45 (27.6%) presented with major tissue loss (Rutherford category 6)

Puncture sites for the endovascular interventions in the current study were distributed as was 179 access for 163 patients; common femoral artery 167 (93.3%), popliteal access was 5 (2.8%), brachial artery 4 (2.2%) and tibial arteries access were 3 (1.7%). 148 patients had single access (145 femoral access and 3 brachial access), 14 patients had double access (6 bilateral femoral, 5 popliteal and femoral, 3 tibials and femoral) 1 patient had triple access (Brachial and bilateral femoral).

The puncture site complications which happened the during endovascular intervention were 16 and were classified according to type into; hematoma 11 (6.14%), Retroperitoneal hematoma (RPH) 0, pseudoaneurysm 3 (1.6%), Dissection 1 (0.56%), 1 (0.56%) case with Arteriovenous fistula.

From all puncture site complications that happened during endovascular intervention each type incidence rate was; hematoma in 11 patients (68.75%), Retroperitoneal hematoma 0, pseudoaneurysm in 3 patients (18.75%), Dissection 1 patient (6.25%) and 1(6.25%) case with Arteriovenous fistula **(Fig. 5).**

According to the site of puncture-related complications they were distributed as; common femoral artery 13 (7.8%) from all femoral access, popliteal access was 1 (20%) from all pop access, brachial artery 2 (50%) and tibial arteries access complications were 0.

The femoral access site complications were distributed according to type into hematoma 9 (69.2%), Retroperitoneal hematoma 0, pseudoaneurysm 3 (23%), Dissection 1 (7.7%) and no cases with arteriovenous fistula.

The popliteal access site complications were one case with arteriovenous fistula, and the brachial access site complications were two cases of hematoma.

According to sheath size 172 (96%) access were done by sheath 6F and 7(4%) accesses were done by sheath 8F. hematoma rate was 9(5.2%) in cases with sheath 6F but was 2(28.5%) in cases with sheath 8F. 2 cases (1.1%) developed PSA with sheath 6F access but one (14.2%) case had PSA post sheath 8F access. One case of acute artery occlusion with sheath 6F and one case of AVF with sheath 6F **(Table 1, Fig. 6).**

According to gender in this study there were 99 males developed 6(6%) hematomas, 2 (20%) PSAs, a case of dissection (1%) and a case of AVF (1%) but 64 females they developed 5 (7.8%) hematomas and one (1.5%) PSA **(Table 2).**

Patients with age less than 50 years old one patient had PSA (7.1%), from 50 to 60 years old access site complications were 3 (7%) hematomas but patients older than 60 complications were: 8 (7.5%) hematomas, 2 (1.9%) PSAs, one (0.9%) AVF and one (0.9%) case with dissection **(Fig. 7).**

In this study there were 15 patients with multiple access as follows 14 patients had double access (6 bilateral femoral, 5 popliteal and femoral, 3 tibials and femoral) 1 patient had triple access (brachial and bilateral femoral) with overall 31 accesses. They developed 3 (9.7%) hematomas, one (3.2%) PSA, one (3.2%) AVF and one case (3.2%) of dissection. In patients with single access the puncture site complications were: 8 (5.4%) hematomas and two cases of PSA (1.3%) **(Table 3, Fig. 8).**

In this study there were 35 patients with US guided access as follows 28 femoral accesses, 4 POP and 3 tibial accesses. They developed 1 (2.9%) hematomas, no PSA, no AVF and no dissection. In patients without US-guided access the puncture site complications were: 10 (6.9%) hematomas, 3 cases of PSA (2%), one (0.7%) case of dissection and one (0.7%) case developed pop AVF. **(Table 4, Fig. 9).**

In 16 cases puncture site complications had happened and trials for management were done through; 11 (68.75%) conservative follow-up measures, 2 (12.5%) US guided compression, 2 (12.5%) open surgical repair and 1 (6.25%) low-pressure balloon inflation for 5 minutes.

All hematomas were successfully managed by conservative follow-up measures, 2(66.7%) cases of PSA were managed by US-guided compression, one (33.3%) PSA was managed by surgical exposure and direct repair, the dissection case was managed by surgical endarterectomy, stabilization of distal

flab by tacking sutures and closure with a venous patch. The case with POP. AVF was managed by Retrieval of the POP. Access and balloon inflation at low pressure at the site of AVF for 5 minutes.

In the current study there were no cases of limb loss or mortality due to puncture site complications.

Statistical analysis and data interpretation:

Data analysis was performed by SPSS software, version 18 (SPSS Inc., PASW statistics for Windows version 18. Chicago: SPSS Inc.). Qualitative data were described using numbers and percentage. Quantitative data were described using median (Minimum and maximum) (Interquartile range) for non-normally distributed data and mean± Standard deviation for normally distributed data after testing normality using the Kolmogrov-Smirnov test / Shapiro Wilk test . The significance of the obtained results was judged at the (0.05) level.Chi-Square, Fischer exact tests were used to compare qualitative data between groups as appropriate.

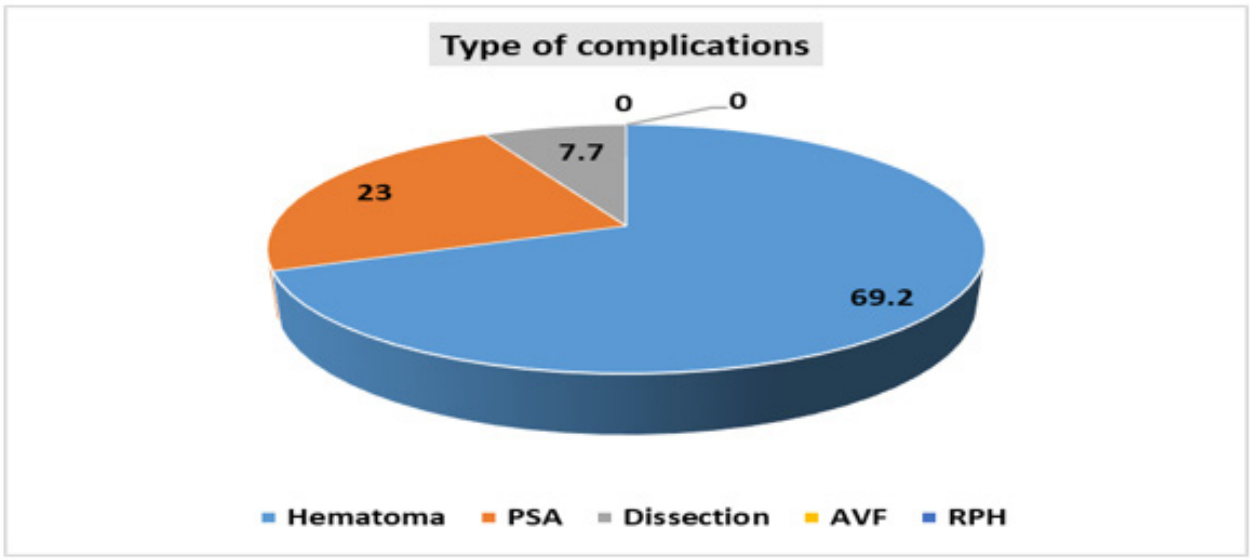


Fig 5: Types of CFA access complications.

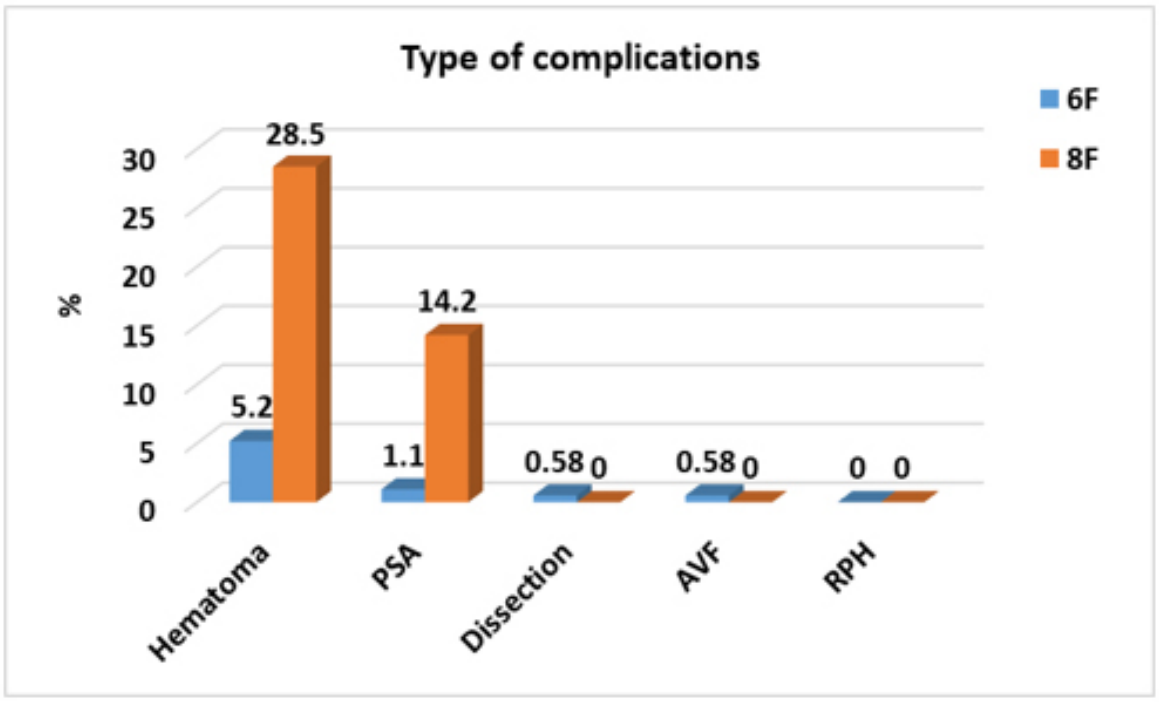


Fig 6: Relation between sheath size and complications.

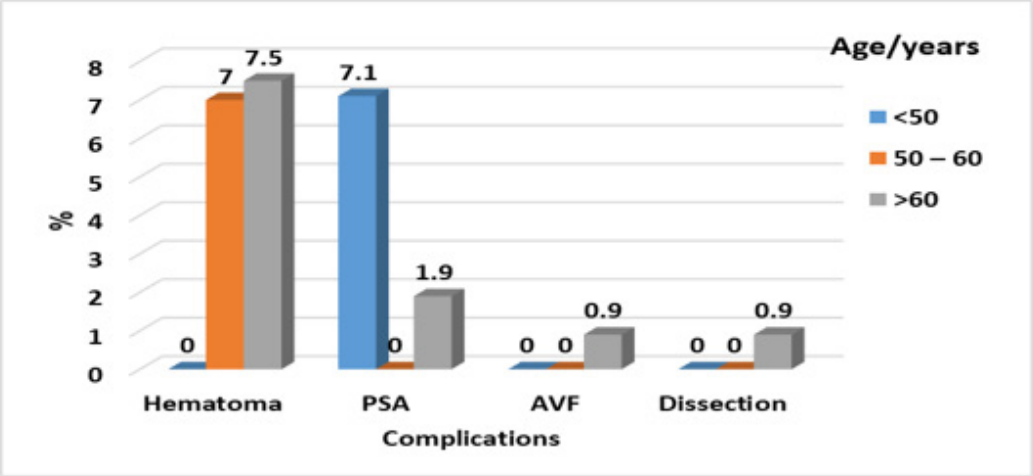


Fig 7: Relation between age and complications.

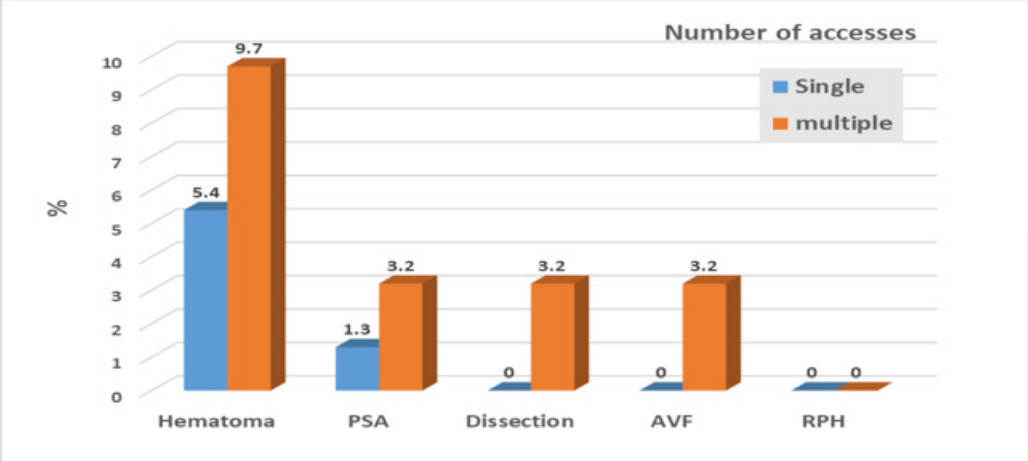


Fig 8: Relation between number of accesses and complications.

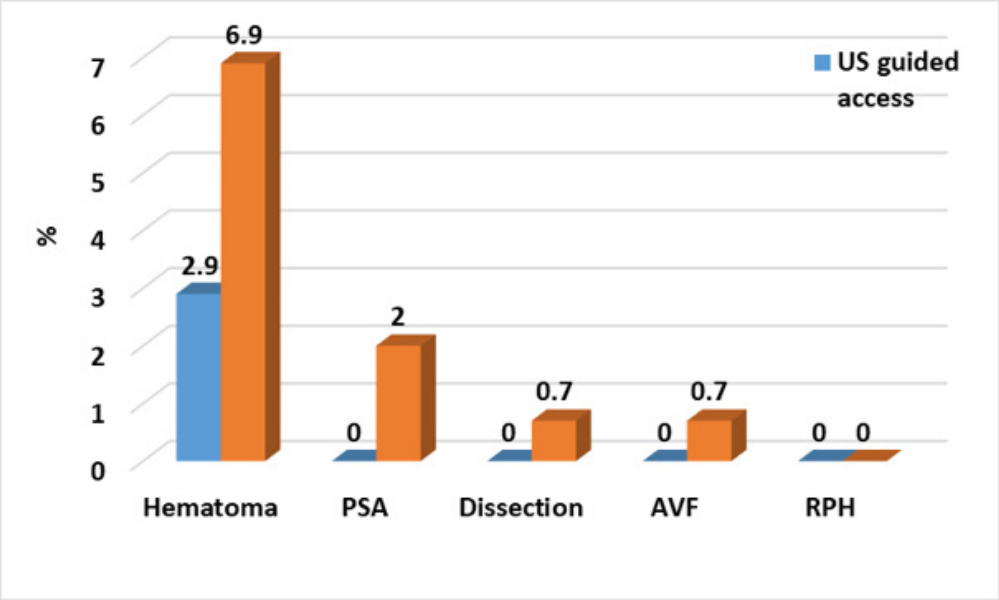


Fig 9: Difference between US guided access and palpatory method.

Table 1: Distribution of the puncture site complications according to sheath size (n = 16), showing statistically significant difference in complications rate (hematoma & PSA) when using 8F sheath in comparison with 6F

	6F n=172 (%)	8F n=7(%)	$\chi^{2/FET}$	P Value
Type of complications				
Hematoma	9/172 (5.2%)	2/7 (28.5%)	6.35	0.01*
PSA	2/172 (1.1%)	1/7 (14.2%)	7.03	0.008*
Dissection	1/172 (.58%)	0	0.041	0.839
AVF	1/172 (.58%)	0	0.246	0.619
RPH	0	0	..	…

Table 2: Distribution of the puncture site complications according to gender

	Male (N=99)	Female (N=64)	χ^{2FET}	P Value
Type of complications				
Hematoma	6/99 (6 %)	5/64 (7.8%)	0.189	0.663
PSA	2/99 (2 %)	1/64 (1.5%)	0.045	0.832
Dissection	1/99 (1%)	0	0.650	0.419
AVF	1/99 (1%)	0	0.650	0.419
RPH	0	0	….	….

FET: Fischer exact test , χ2:Chi-Square test ,*statistically significant

Table 3: Distribution of the puncture site complications according to number of accesses

	Single (n=148)	Multiple (n=31)	$\chi^{2/FET}$	P Value
Type of complications				
Hematoma	8/148 (5.4%)	3/31 (9.7%)	0.811	0.367
PSA	2/148 (1.3%)	1/31 (3.2%)	0.547	0.459
Dissection	0/148 (0%)	1/31 (3.2%)	4.80	0.173
AVF	0/148 (0%)	1/31 (3.2%)	4.8	0.173
RPH	0	0	…	….

FET: Fischer exact test , χ2:Chi-Square test ,*statistically significant.

Table 4: Distribution of the puncture site complications according to usage of US, (statistically significance difference in complications rate (Haematoma & PSA)

	US guided access (n=35)	Without US (n=15)	$\chi^{2/FET}$	P Value
Type of complications				
Hematoma	1/35 (2.9%)	10/144 (6.9%)	24.91	<0.001*
PSA	0/35 (0%)	3/144 (2%)	7.45	0.006*
Dissection	0/35 (0%)	1/144 (0.7%)	2.38	0.123
AVF	0/35 (0%)	1/144 (0.7%)	2.38	0.123
RPH	0	0	…	…..

FET: Fischer exact test , χ2:Chi-Square test ,*statistically significant.

Discussion

In every therapeutic procedure, endovascular procedures such as angioplasty and stenting carry an inherent risk of complication to the patient. Though with the proper training these complications can usually be successfully managed by endovascular procedures, improper management may lead to emergency surgery, limb loss, functional disability, and death. It is paramount that physician operators have the proper training and ability to anticipate and recognize, complications as they arise during endovascular procedures.[1]

Balloon angioplasty and stents expand the scope of patients who are eligible for treatment of infrainguinal occlusive disease. Several newer techniques are developing that substantially increase the spectrum of treatment options. Endovascular infrainguinal techniques are most useful in patients who are poor candidates for open surgery and in those with focal short-segment disease.

Limb-salvage patients have also shown a higher procedural complication rate than patients with claudications. When endovascular complications do occur, over 86% are usually evident in the angiographic suite and almost all are evident within 5 hours post procedure. As in all procedures, proper training and anticipation of the potential for a complication is the gold standard to prevent it.

Puncture site complications include acute complications such as hematoma, retroperitoneal hematoma, AVF, acute arterial occlusion and retrograde dissection. Later complications like pseudoaneurysms.

The current study was conducted on 163 patients complaining lower-limb ischemia; 99 (60.7%) males and 64 (39.2%) females. Patients with age less than 50 years old were 14 (8.5%), from 50 to 60 years old were 43 (26.3%) but patients older than 60 were 106 (65%) of all patients with mean age 64.24±12.42 which confirms the data from Gray A. et al 2019; mean age was 68.2± 9.1 and 70.9% of patients were men. This confirms that old age and men are more liable to PAD and complications during endovascular interventions. In Roberto M. 2020 mean age was 66.6± 12.8 and 64%of them were males.[8,9]

According to the risk factors and co-morbidities of the patients in the study; 123 (75.4%) were diabetic, 86 (52.7%) were smokers, 119 (73%) were hypertensive, 62 (38%) with ischemic heart disease, 16 (9.8%) had a previous stroke and 74 patients (45.3 %) had more than 2 risk factors and co-morbidities. Gray A. 2019 90% of patients were hypertensive, 43.5% were diabetic, 60% with CAD and 31% were smokers. But In Fujihara 2017 study: 789 patients with symptomatic SFA lesions 58.4% of patients were diabetic, 88.2% were hypertensive, 63.2% with CAD and 52.6% of patients had dyslipidemia. This study has more percentage of diabetic and hypertensive patients and less percentage of CAD patients.[8,10]

In this study regarding symptoms presented by the patients; 8 (4.9%) patients were complaining of severe claudications that harm their lifestyle (Rutherford category 3), 31 (19%) presented with ischemic rest pain (Rutherford category 4), 79 (48.4%) presented with minor tissue loss (Rutherford category 5), 45 (27.6%) presented with major tissue loss (Rutherford category 6) unlike fujihara 2017 and Gray A. 2019 studies. Fujihara 2017 only 35% of patients had CLI. Gray A. 2019 4.6% of patients had CLI. So the current study was conducted on a larger percentage of critical limb ischemia cases.[8,10]

Puncture sites for the endovascular interventions in the current study were distributed as 179 access for 163 patients; common femoral artery 167 (93.3%), popliteal access was 5 (2.8%), brachial artery 4 (2.2%) and tibial arteries access were 3 (1.7%). 148 patients had single access (145 femoral access and 3 brachial access), 14 patients had double access (6 bilateral femoral, 5 popliteal and femoral, 3 tibials and femoral) 1 patient had triple access (brachial and bilateral femoral) but in Murat G. 2013, Hamid R. 2015, and Manuel A 2003 studies they described complications from femoral artery accesses but Roberto M. 2020 included all accesses sites.[11-13]

The puncture site complications that happened during the endovascular intervention were 16 and were classified according to type into; hematoma 11 (6.14%), Retroperitoneal hematoma 0, pseudoaneurysm 3 (1.6%), Dissection 1 (0.56%), 1 (0.56%) case with Arteriovenous fistula, which was comparable with Hamid R. 2015 that reported minor bleeding and hematomas 6-10%, pseudoaneurysms 1-6%, occlusions >1% and AVF 0.01%. In Roberto M. 2020 from data on access site complications 92% of complications were PSAs, dissections were 11%, AVF 9% and RPH 9% but Roberto M. didn't include hematomas as complications.[9,12]

The site of puncture-related complications were distributed as; common femoral artery 13 (7.8%) from all femoral access, popliteal access was 1 (20%) from all pop access, brachial artery 2 (50%) and tibial artery access complications were zero but in Chandrasekar B. 2001 puncture site complications post cardiac catheterization were 4% which is less than the current study as the current study was conducted on PAD patients whom carries higher risk of complications as all of them had diseased arteries.[14]

In this study regarding femoral access site complications were distributed according to type

into hematoma 9 patients (69.2%), retroperitoneal hematoma zero, pseudoaneurysm 3 patients (23%), Dissection 1 patient (7.7%) and no cases with arteriovenous fistula. However the popliteal access site complications were one case with arteriovenous fistula, and the brachial accesses site complications were two cases of hematoma. Brachial accesses had more risk of hematomas than femoral access due to its smaller size and difficult compression. This confirm the data from Manuel A. 2003 CFA complications were 0.6% and other than femoral artery were 4.6%.[13]

According to sheath size 172 (96%) access were done by sheath 6F and 7(4%) accesses were done by sheath 8F. hematoma rate was 9(5.2%) in cases with sheath 6F but was 2(28.5%) in cases with sheath 8F. 2 cases (1.1%) developed PSA with sheath 6F access but one (14.2%) case had PSA post sheath 8F access. One case of acute arterial occlusion with sheath 6F and one case of AVF with sheath 6F. So larger sheaths carry a higher risk of puncture site complications. As in Kalish J. 2015 rate of hematoma was greater with a sheath size of more than 6F.[15]

According to gender in this study there were 99 males who developed 6(6%) hematomas, 2 (20%) PSAs, a case of dissection (1%) and a case of AVF (1%) but in 64 females they developed 5 (7.8%) hematomas and one (1.5%) PSA. So female gender carries a higher risk of hematomas which is like Roberto M.2020 and Manuel A. 2003.[9,13]

According to the age-related complications, In patients with age less than 50 years old one patient had PSA (7.1%), from 50 to 60 years old access site complications were 3 (7%) hematomas but for patients older than 60 complications were 8 (7.5%) hematomas, 2 (1.9%) PSAs, one patient (0.9%) AVF and one (0.9%) case with dissection. So patients with older age carry a higher risk of developing access site complications, which confirm the data from Roberto M.2020 mean age of complications was 66.6 years.[9]

In this study there were 15 patient with multiple access as follows 14 patients had double access (6 bilateral femoral, 5 popliteal and femoral, 3 tibials and femoral) 1 patient had triple access (brachial and bilateral femoral) with overall 31 accesses. They developed 3 (9.7%) hematomas, one (3.2%) PSA, one (3.2%) AVF and one case (3.2%) of dissection. In patients with single access the puncture site complications were: 8 (5.4%) hematomas and two cases of PSA (1.3%) so multiple accesses carry a higher risk of complications than patients with single access as multiple accesses reflect the difficulty of the lesions and severity of PAD.

In the current study usage of ultrasound (US) guided puncture significantly decreased access site complications which confirms the data from Murat G. 2013 and Kalish J. 2015 that in routine and selective Us-guided puncture, the groin hematoma decreased by 4.5% and major hematoma less than 0.8% so routine US-guided puncture was used as a protective measure to guard against hematoma occurance.[11,15]

In 16 cases with puncture site complications, trials for management were done through; 11 (68.75%) conservative follow-up measures, 2 (12.5%) US-guided compression, 2 (12.5%) open surgical repair and 1 (6.25%) low pressure balloon inflation for 5 minutes. Unlike Roberto M. 2020 all cases of PSAs managed Us-guided compression, thrombin injection and endovascular procedures. AVFs by stenting and coils, and dissections were managed by stenting and long-time balloon inflation.[9]

In the current study there were no cases of limb loss or mortality due to puncture site complications.

Conclusion

Puncture site complications could be avoided or reduced by risk assessment, meticulous puncture technique, usage of doppler ultrasound and proper compression. It could be managed conservatively or by minimally invasive procedures with good results, but surgery remains a role in difficult, resistant and complicated cases.

Recommendations

Encouragement of further training and performing larger studies using the most recent tools for avoiding and managing puncture site complications.

No conflict of interest in this study

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