Complications of Peripheral Endovascular Intervention

Hossam Zaghlol Msc., Amr Abdulbaky MD, Hassan Soliman MD, Ashraf Hedaiet MD
Department of General Surgery, Cairo University

ABSTRACT

Objectives: to study the complications that may occur during and after endovascular intervention, how to minimize it and its definitive management. It also aims to assess factors that affect occurrence of complications and types and rate of complications in comparison to other studies. Methods: A prospective study included 128 patients who had peripheral endovascular intervention during the period from November 2009 to July 2010, they were properly assessed and followed during and after the procedure to find out patients who developed complications. Results: Complications occurred in 25 patients, 6 patients were claudicants while 19 patients had critical limb ischemia. Femoral artery access, Ipsilateral antegrade access was used in 12 limbs, ipsilateral retrograde access was used in 7 limbs and contralateral retrograde access was used in 3 limbs. Brachial artery access was used in 4 limbs, all on the left upper limb. Retroperitoneal bleeding, Perforation and Spasm occurred in one case for each. Haematoma occurred in 3 cases while 8 cases had thrombosis. Dissection occurred in 4 cases and Failure of thrombolytic therapy occurred in 2 cases. Occlusion developed in 3 cases and Restenosis occurred in 4 cases. Consequences of angioplasty ended with surgical repair in 7 cases, limb loss were the results in 4 cases and there was a case of mortality. Conclusions: PTA of lower limb arteries is a safe procedure, minimally invasive and is clinically effective in the majority of very elderly patients with CLI. Although occurrence of complications, the proper management of these complications may save the limb. The availability and high quality equipments are essential to achieve optimal results in endovascular procedures.

Keywords: complications, peripheral, endovascular, intervention

INTRODUCTION

The atherosclerotic disease in chronic critical limb ischemia is characterized by diffuse and multilevel arterial involvement. Chronic critical limb ischemia causes significant morbidity and mortality in the population, with an estimated incidence of 500 to 1000 per million people per year. In the past two decades, endovascular therapy has revolutionized the treatment of patients with vascular disease. In this group of patients with multiple medical problems, advanced age and high surgical risk, endovascular therapy plays a leading role in providing effective revascularization and limb salvage, while limiting the operative risk as compared with vascular surgery.

As technology and knowledge progress, the frequency of complications resulting from endovascular therapy has declined. Unfortunately, these complications have not been eliminated. Vascular surgeons must be prepared for a range of situations, which may occur during the course of or following endovascular therapy.

Complications of endovascular interventions vary between fatal outcomes, mortalities, severe, moderate and even minor morbidities. However, proper orientation, anticipation and early Identification of these complications may prevent its occurrence or even improve the outcome and the results. Moreover, the study of these complications provide an audit of the work in order to provide better improvement of health services.

PATIENTS & METHODS

This study included 128 patients (130 limbs) presented to kasr Al Ainy teaching hospital complaining of chronic lower limb ischemia. They had peripheral endovascular intervention during the period from November 2009 to July 2010. Complications occurred in 25 patients. Complications were defined as any unanticipated event deleterious to the health of the patient related to the arteriographic procedure in the judgment of a trained clinical observer. Complications of endovascular therapy include groin hematoma, arteriovenous fistula, pseudoaneurysm, retroperitoneal hematoma,
axillary and brachial artery access-related injury, dissection, arterial perforation or rupture, embolization, device-related infection, restenosis, occlusion, renal failure, myocardial infarction (fatal), cerebrovascular accident (fatal), chronic device failure due to stent fracture, broken wires, malfunctioning stents and embolization of catheter shaft material has been reported in almost all vessel areas.

The study included all patients who had angioplasty for chronic lower limb ischemia during this period. They were assessed clinically for their: epidemiological features (age and gender), risk factors (smoking, diabetes, hypertension, cardiac disease, renal impairment and chronic obstructive pulmonary disease), clinical presentation (Incapacitating claudication, rest pain and tissue loss (ulcers, gangrene, non healing wound or infection), clinical examination: (pulses, presence of infection and scar for previous surgery).

All patients had routine duplex study and laboratory investigation.

The patients were admitted one day before or on the day of the procedure, a loading dose of clopidogrel 300 mg was given at the night of the procedure, both groins were prepared using an antiseptic solution (povedin).

Femoral access was either ipsilateral antegrade (in lesions involving the mid to distal femoro-popliteal or infra-popliteal arteries) or contralateral retrograde (in atherosclerotic lesions of the iliac, CFA, ostial lesion of the profunda femoris or proximal SFA and obesity) based on the lesion site in the femoropopliteal segment from the finding of the duplex or diagnostic angiographic study. Anatomic and fluoroscopic localization of the common femoral artery was done for all patients. Brachial access was for ostial lesion of the common iliac artery difficult to be accessed through femoral access.

The procedure starts with diagnostic angiography to confirm the site, the type (either stenotic or occlusive) and length of the lesion and the presence of distal runoff. Completion angiography was done at the end of the procedure to confirm success or occurrence of complications: intimal flap dissection, extravasation, contained haematoma.

The arterial sheath was routinely removed immediately after the procedure and mobilization was delayed for 12-24 hours. Digital compression was held proximal to the skin puncture site for 15-20 minutes. Most patients were discharged on the second day following the procedure after receiving instructions on risk factors control and treatment including Aspirin 150 mg/day for life, clopidogrel 75 mg/day for at least 3 months and atorvastatin according to the presence or absence of dyslipidemia.

Postprocedural evaluation included: Pulse and blood pressure that were followed up to assess haemodynamics of the patient and presence of signs of allergic reactions and radiotoxicity. Local examination was done while both lower limbs and upper limbs of the patient were exposed to elicit manifestation of ischemia (absent pulse, colour changes, anesthelia, paralysis, coldness), manifestations of haematoma or pseudoaneurysm (color changes, local swelling over puncture site, pulsating swelling and ooz of blood from puncture site), manifestations of arteriovenous fistula (dilated veins with palpable thrill, distal ischemic manifestations and pulsating swelling and manifestations of retroperitoneal haematoma (lower abdominal swelling and bruises).

Post procedural duplex scan was ordered in cases of thrombosis of the arterial tree with impaired arterial blood flow. It was also useful to differentiate between a pseudoaneurysm with expansile pulsations and a localized haematoma. It also had a therapeutic role in treatment of pseudoaneurysms. Some cases required arterial angiography as in cases with restenosis following PTA whatever the modality of treatment, to go for another PTA or surgical procedure.

All patients will be followed up daily for three days, weekly for a month and monthly for three months regarding occurrence of complications which include mortality, major medical morbidity (stroke, renal failure, myocardial infarction), severe reaction to contrast medium, arterial dissection, atheroemboli, access site complications as pseudo aneurysm, arteriovenous fistula and hematomas, need for emergency surgical intervention especially cases with acute limb ischaemia and haemorrhagic complications, and amputation rate following angioplasty.

For every patient who had any of the complications, the following data were recorded: Indications of the primary procedure, risk factors i.e. diabetic, cardiac, hypertensive and renal
failure, access method, type of the guide wire, size of the balloon (diameter and length), indication for stenting, size of the stent.

Lesions were categorized as involving the aortoiliac segment, femoropopliteal segment and infrapopliteal segment. Occurrence of complications either minor or major and acute or delayed.

RESULTS

This study included 128 patients (130 limbs) and 162 lesions (62 iliac, 72 femoropopliteal, 26 infrapopliteal and 2 grafts) presented to Kasr Al Ainy teaching hospital complaining of chronic lower limb ischemia. They had peripheral endovascular intervention done during the period from November 2009 to July 2010.

Table 1: Complications of angioplasty

<table>
<thead>
<tr>
<th>Complications</th>
<th>NO</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>All cases</td>
<td>25</td>
<td>19.23%</td>
</tr>
<tr>
<td>Retroperitoneal bleeding</td>
<td>1</td>
<td>0.77%</td>
</tr>
<tr>
<td>Haematoma</td>
<td>3</td>
<td>2.31%</td>
</tr>
<tr>
<td>Thrombosis</td>
<td>8</td>
<td>6.15%</td>
</tr>
<tr>
<td>Perforation</td>
<td>1</td>
<td>0.77%</td>
</tr>
<tr>
<td>Spasm</td>
<td>1</td>
<td>0.77%</td>
</tr>
<tr>
<td>Dissection</td>
<td>4</td>
<td>3.07%</td>
</tr>
<tr>
<td>Failure of thrombolytic therapy</td>
<td>2</td>
<td>1.54%</td>
</tr>
<tr>
<td>Restenosis</td>
<td>4</td>
<td>3.07%</td>
</tr>
<tr>
<td>Occlusion</td>
<td>3</td>
<td>2.31%</td>
</tr>
<tr>
<td>Surgical repair</td>
<td>7</td>
<td>5.38%</td>
</tr>
<tr>
<td>Limb loss</td>
<td>4</td>
<td>3.07%</td>
</tr>
<tr>
<td>Mortality</td>
<td>1</td>
<td>0.77%</td>
</tr>
</tbody>
</table>

Complications occurred in 25 patients (table 1). The age of the patients ranged from 48 to 95 years with a mean age of 56.74 year. Most of the complications occurred between 56 & 65 years. The study included 20 (80%) males and 5 (20%) females. In our study, 13 patients (52%) were smokers, 16 patients (64%) were diabetics, 12 patients (48%) were hypertensives, 5 patients (20%) had coronary artery disease and no patients had impaired renal functions.

At the end of the study out of 46 claudicants, 6 patients (12.5 %) developed complications, while out of 82 patients with critical limb ischaemia, 19 patients (23.1%) developed complications.

Table 2: Demonstrates the number of complications in relation to affected segments.

<table>
<thead>
<tr>
<th>Affect ed segment</th>
<th>Number</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aortoiliac</td>
<td>3</td>
<td>12%</td>
</tr>
<tr>
<td>Femoropopliteal</td>
<td>9</td>
<td>36%</td>
</tr>
<tr>
<td>Infrafemoral</td>
<td>3</td>
<td>12%</td>
</tr>
<tr>
<td>Combined aortoiliac, femoropopliteal, and infrapopliteal angioplasty</td>
<td>2</td>
<td>8%</td>
</tr>
<tr>
<td>Aortoiliac and femoropoplite</td>
<td>2</td>
<td>8%</td>
</tr>
<tr>
<td>femoropopliteal and distal angioplasty</td>
<td>4</td>
<td>16%</td>
</tr>
<tr>
<td>Graft occlusion</td>
<td>1</td>
<td>4%</td>
</tr>
</tbody>
</table>

Femoral artery access: Ipsilateral antegrade access was used in 12 (48%) limbs, ipsilateral retrograde access was used in 7 (28%) limbs and Contralateral retrograde access was used in 3 (12%) limbs. Brachial artery access: was used in 4 (16%) limbs, all on the left upper limb.

All patients had PTA. Stenting was carried out in 15 (60%) limbs. Primary stenting was performed in 9 (36%) limbs, stenting to cover flow limiting dissection following PTA was done in 2 (8%) limbs, stenting due to residual stenosis was done in 4 (16%) limbs.
Retroperitoneal haemorrhage occurred in one limb (0.77%), the puncture was high antegrade in an obese female and the sheath was removed immediately after the procedure. The patient needed surgical intervention in the form of closure of the puncture point by direct suture.

Localised Haematoma at the puncture site occurred in 3 limbs (2.31%). The access site in all cases was ipsilateral antegrade femoral access. It was managed conservatively in the form of bed rest, follow up of the vital signs, hot fomentation and local application of local paints.

Thrombosis occurred in 8 cases (6.15%): 7 cases were for femoropopliteal lesions and one for infrapopliteal disease and was managed as follows: Thrombolytic therapy was used in one case but failed. Surgical interventions were used in 3 cases: Femoropopliteal bypass in 2 cases. The third case had popliteal thrombectomy, endarterectomy and patch angioplasty. The posterior tibial pulse was restored and the patient had forefoot amputation.

Conservative management was used in 2 cases: These two cases improved clinically (no more rest pain). Primary amputation was done in 2 cases.

Perforation of the posterior tibial artery occurred during PTA of the SFA & posterior tibial artery. It was managed by withdrawal of the wire, reintroduction in the proper plane then sealing of the perforation by an inflated balloon for 20 minutes and the patient had posterior tibial pulse.

Spasm occurred in one case (0.77%). She had PTA of both SFA & posterior tibial artery then completion angiography showed spasm which was managed by nitroglycerin 200 micro/20 ml that was repeated once with no response. Then PTA of the SFA was used and the pedal pulse was restored.

Dissection occurred in 4 (3.07%) cases; common iliac artery occlusion in 3 cases and SFA stenosis in one case. Stenting was done in 3 cases and PTA in one case.
Figure (3): Dissection of the LT CIA extending to the aorta: A) Dissection extending to the aorta. B) After PTA.

Figure (4): Flow limiting dissection of upper popliteal artery: A) Dissection of the upper popliteal a. B) Stent C) Flow after stent deployment

Failure of thrombolytic therapy occurred in 2 (1.54%) cases one case after thrombosed femoropopliteal graft 12 hours after the operation. We used streptokinase 250,000 IU bolus then 100,000 IU /hour which have failed and the patient had amputation and the 2nd case was mentioned above with thrombosis.

Complications during follow-up

Restenosis occurred in 4 (3.07%) cases following PTA of the common iliac artery. They showed restenosis 6 months after the procedure. 3 cases were treated using PTA and one case treated with stenting.

Occlusion occurred in 3 (2.31%) cases following PTA & stenting of the common iliac artery. In two cases, the cause of occlusion was stent maldeployment. These were treated by aortobifemoral bypass and the other was managed by a stent, deployed in the contralateral artery after 6 months.

Figure (5): Stent maldeployment inside the aorta following angioplasty of stenotic lesion in the CIA.
Surgical intervention were performed in 7 (5.38%) cases, three cases had femoropopliteal by pass, 2 cases had aortobifemoral by pass due to stent maldeployment, one had popliteal thrombectomy and closure over a patch and one case had retroperitoneal bleeding needed exploration and closure of the puncture point by direct suture.

Limb loss occurred in 4 (3.07%) cases. three cases had primary amputation and thrombolytic therapy preceded one case.

Mortality occurred only in one case (0.77%) which had acute thrombosis, femoropopliteal by pass, above knee amputation, disarticulation and death after 20 days.

DISCUSSION

In this study, the patient’s age varied between 48 and 95 years with a mean age of 56.74 year, they included 20 males (80%) and 5 females (20%), 13 patients (52%) were smokers, 16 (64%) were diabetics, 12 (48%) were hypertensives, 5 (20%) had coronary artery disease and no patients had impaired renal functions. None of the registered demographic or clinical parameters were predictors of complications in other studies and this coincides with our results.

Most of the published studies reported that the primary indication for intervention is intermittent claudication. In our study, 76% of patients had presented with CLI. This higher percentages of critical ischemia than other studies may be attributed to shift of indication of vascular intervention in the European community to include the claudicants and not just critical limb ischemia (CLI).

The difference of occurrence of complications between claudicants and critical limb ischemia is highly significant, this is because limbs with critical ischemia tend to have multilevel and distal disease. Also, the interventionists tend to be more aggressive when dealing with a patient with a critical limb ischaemia because treatment failure may result in limb loss.

In our study, the rate of complications was 19.23%. Studies recorded lower rates of complications (14%)10, (15%) 11, (10.5%)12 (4.3%)14. Although a higher rate of complications as 33% and 26% have been reported in other literature15,16. These results may reflect not only differing populations and operator experiences, but also the use of different reporting criteria. Hasson et al., (1990) classified technical PTA failure as complications while Axisa et al., (2002), reported a lower rate of complications as they considered only the patients suffering a major medical complication (2.4%) and patients requiring emergency surgical intervention (2.3%)10,11,12

In the current study puncture site complications occurred in 4 cases (3.07%), retroperitoneal haemorrhage in one case (0.77%) which needed surgical intervention & localized haematoma occurred in 3 cases (2.33%) which were managed conservatively. We found that puncture site complications mainly occur in obese females especially when using antegrade femoral puncture as shown in our results, Jeans and his colleagues reported that retroperitoneal bleeding is a rare complication, but it should be kept in mind especially when heparin infusion or thrombolytic therapy are used.13,16

Thromboembolic complications represent one of the most distressing complication that face the interventionist. In our study we had 8 cases (6.15%) that showed acute thrombotic occlusion. The study by Axisa et al, mentioned that acute limb ischemia represented the commonest cause of emergency surgical intervention as it occurred in 21 (1.5%) procedures. Pekka and his colleagues stated that a total of 12 (4.06%) thromboembolic complications were registered. while Belli and his colleagues reported that there were 20 (1.7%) cases of occlusion due to either thrombosis or embolism.10,11,12

Various methods were reported to manage thromboembolic complications which include: Conservative management was used for 2 cases in this study while used for one case in Pekka and his colleagues.12

Thrombolysis was used in one case in this study and was followed by surgical intervention, in the study by Pekka and his colleagues, four of the six distal embolizations were successfully treated with local thrombolysis using urokinase. While Belli and his colleagues reported that 10 cases were successfully treated during the course of the procedure by thrombolysis.11,12

Local thrombolysis and redilatation was used in a dilated iliac artery that occluded the day after the PTA in the study by Pekka and his
colleagues. Catheter suction was used by Papavassillou and his colleagues to aspirate thirty-eight emboli and five cases were managed by the "push and park" technique. While Belli and his colleagues used this technique to aspirate 6 emboli.

Surgical embolectomy was required in one case in this study and was performed successfully. Papavassillou and his colleagues used it in two cases while Axisa and his colleagues used it in 6 cases.

Bypass operations were required in 3 cases in our study, one of which preceded by thrombolysis that failed and followed by thrombectomy, surgical endarterectomy and patch angioplasty at the popliteal bifurcation and he had pedal pulse, the other two cases had femoropopliteal bypass which were successful. Axisa and his colleagues used bypasses for 7 cases. While Pekka and his colleagues had one patient with immediate thrombosis of the recanalized superficial femoral artery occlusion, popliteal artery embolus led to critical ischemia. Local thrombolysis was ineffective, but the patient was successfully treated with an in situ venous femoropopliteal bypass.

Major amputation was done in three cases in this study. Axisa and his colleagues had eight patients who required a major amputation although six had undergone attempts to salvage the limb. Pekka and his colleagues had two patients who required major amputation, one patient with critical ischemia and with no patent crural vessels had distal embolization occluding crural collaterals. Local thrombolysis was ineffective, and subsequent below the knee amputation was required. In the other patient, PTA-site thrombosis was encountered during superficial femoral artery recanalization and amputation above the knee was necessary.

We found that the incidence of thrombosis for those undergoing isolated segment interventions increased as the procedure became more distal it occurred mostly in the femoropopliteal and infrapopliteal lesions, also late presentation and longer segment angioplasties were associated with greater risk of thrombosis which coincide with the surgical literature. Axisa and his colleagues mentioned that despite being relatively rare, acute ischemia following angioplasty carried a 38% risk of major limb amputation and a 14% risk of death.

Perforation occurred in one case, that of the posterior tibial artery, and managed by withdrawal of the wire reintroduction in the proper plane then sealing of the perforation by an inflated balloon for 20 minutes and the posterior tibial pulse was restored. Papavassillou and his colleagues had forty-five (4%) arterial segments were perforated, of which 26 were self-limiting and 19 required treatment by coil embolization. There was a single vessel rupture that was dealt with initially in the angiogram suite with a covered stent and then required surgery.

Belli and his colleagues considered perforation a complication only if surgical intervention was required. Only two perforations, both of which were in the iliac segment, required surgical repair.

We concluded that perforation through occluded arterial segments, although to be avoided, rarely leads to surgical intervention. The indications for coil embolisation are large defects that make it impossible to initiate a new dissection and/or a large defect that lead to rapid extravasation of contrast into the tissues.

Dissection occurred in 4 cases. Stenting was done in 2 cases, PTA in one case and conservative management for one case which was not flow limiting.

Spasm occurred in one case which managed by nitroglycerin 200 micro/20 ml repeated once then PTA of the SFA and the patient had pedal pulse.

PTA shouldn't be considered as a minor procedure in high risk patient population, although it is difficult to assess the direct relationship of PTA to the systemic complications but patients with critical ischemia tend to be more elderly and to have more advanced coronary and cerebrovascular disease. And this may render the decision of intervention or PTA.

Surgical intervention, limb loss and mortalities are three major serious complications that following angioplasty should be taken in consideration. Most studies reported that about (2-3%) of all patients undergoing lower limb angioplasty require surgical intervention.

The commonest single indication for emergency surgical intervention following angioplasty was acute limb ischemia. Some found no evidence that the risks were increased in patients undergoing more extensive
angioplasties as opposed to single segment procedures, although others have observed that longer segment angioplasties were associated with greater risk.\(^{14,17,18}\)

Primary and secondary limb loss occurred in 4 (3.01%) cases in this study. In the study by Axisa and his colleagues, the amputation rate was 1.1% while it was 0.2% in the study by Becker and his colleagues.\(^11\)

The overall 30-day mortality rate was 0.77% in our study due to acute thrombosis and amputation. In the study by Becker and his colleagues overall mortality was 0.2%. In Axisa and his colleagues eighteen patients (1.3%) died within 30 days of angioplasty. The principal cause of death was bronchopneumonia. Pekka and his colleagues showed that the overall 30-day mortality rate was 4%. The causes of the death were myocardial infarction, stroke, pneumonia, pulmonary embolism, and retroperitoneal bleeding. Belli and his colleagues reported that there were two deaths (0.2%) One patient developed cholesterol embolization and the second patient was a diabetic who became septicaemic following reperfusion of an ischemic foot.\(^{10,11,12}\)

**CONCLUSION**

Our study indicates that PTA of lower limb arteries is a safe procedure requires a short hospital stay, minimally invasive and is clinically effective in the majority of very elderly patients with CLI.

The timing of complications suggests it would be reasonable to perform percutaneous transluminal angioplasties and stenting on an outpatient basis in suitable patients.

The annual number of angioplasty procedures has increased dramatically throughout the world over the last 10 years. Although there remains considerable debate as to whether patients should be offered angioplasty or surgical reconstruction, evidence suggests that the increase in the angioplasty workload has not precipitated a parallel increase in either morbidity/mortality or the requirement for emergency surgical intervention.

**REFERENCES**
