ORIGINAL ARTICLE

INFRAPOPLITEAL BALLOON ANGIOPLASTY FOR CRITICAL LIMB ISCHEMIA

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Abstract

Background: Lower extremity peripheral arterial disease (PAD) is a major cause of morbidity and mortality. Percutaneous endovascular therapy is an alternative to surgery for the treatment of PAD. While infrapopoliteal PTA was restricted to patients with short stenotic lesions or poor candidates for bypass, recently it has been used preferentially over bypass surgery by some groups due to the advent of new devices and techniques. The growing experience with endovascular therapy justifies an assessment of crural PTA. The aim of this study is reviewing our results **in** infrapopliteal angioplasty stratifying patients by anatomic characteristics according to the TASC classification.

Patients and Methods: This study was conducted at Arab Contractors Medical Center and Mansoura University Hospital on 80 patients during the period from Jan 2009 till April 2013. Inclusion criteria were rest pain, ulceration and tissue necrosis. Exclusion criteria were life threatening infection, Burger's disease and multilevel lesions. All patients were investigated by colour duplex scan, C.T.Aor M.R.A. The TASC "I" classification for tibioperoneal occlusive disease was done. All procedures were done with local anesthesia, sometimes sedation was needed for irritable patients.

Cases were performed preferentially through antigrade ipsilateral femoral access and rarely through retrograde contralateral access. All patients were anticoagulated with 10,000 IU heparin after initial angiography.

We used 6F sheaths for ipsilateral antigrade access and 8F sheath for retrograde contralateral access, 4F vertebral catheters were used with 0.035 floppy angled giudewire (Terumo, Somerest, ND), 0.018, 0.014 hydrophilic wire (Boston Scientific, Natick, Mass) or glide wire. Five cases had direct tibial vessel puncture using fluoroscopic guidance had been done. Angioplasty was performed with low profile balloon (Amphirion Deep, Invatec, Italy) 2.5 to 3F. Balloon was inflated for 1 to 3 minutes.

If vasospasm occurred; administration of 50-400 mcg of nitroglycerin was helpful.

After the procedure, patients were given 600 mg loading dose of clopidogrel, if the patient didn't receive it preoperatively, maintained on 75 mg daily dose for 3 months to one year, along with aspirin and statins.

Results: During the study period, 80 patients underwent PTA [14 (17.5%) for rest pain and 66 (82.5%) for tissue loss] after exclusion of five cases from the study due to failure of guide-wire passage. Antigrade access was used in 73 cases (91.25%) and seven cases (8.75%) retrograde access was performed due to difficult puncture. Primary patency was 58.75% at first year and 48.75% at second year.

First year primary patency for TASC A through D was 83.3%, 87.5%, 45%, 34.6% respectively. And for Second year was TASC A through D was 72.2%, 68.75%, 40%, 26.9% respectively. Limb salvage at 1 year: 81%, and at 2 year: 75%.

Conclusion: PTA is recommended as first line of treatment for TASC A, B, C lesions and TASC D patients who are not candidate for bypass. But more studies are needed to compare long term follow up between PTA and bypass in TASC D lesions.

Keywords: Peripheral arterial disease, percutaneous endovascular therapy, TASC, Angioplasty.

INTRODUCTION

Lower extremity peripheral arterial disease (PAD) is a major cause of morbidity and mortality. Symptoms range from claudication to critical limb ischemia (CLI), which is presented by rest pain, ulceration, and gangrene. Surgery is reserved for CLI.(1)

Surgical approaches are associated with an increased risk for systemic and local complications due to comorbidities that characterize patients with PAD. So, percutaneous endovascular therapy is an alternative to surgery for the treatment of PAD.(2)

Early studies of percutaneous angioplasty (PTA) of the tibioperoneal vessels reported 1-year patency rates of <15%, leading the authors to conclude this was suboptimal therapy that should be reserved for patients with no other options of treatment.(3) Indeed, for patients with CLI, surgical bypass grafting with autogenous conduit remains the gold standard, with 5-year limb salvage rates > 80%.(4) However, many patients who require arterial revascularization for CLI do not have an adequate saphenous vein, so alternate conduits with inferior patency and limb salvage rates must be used.(5,6)

In contrast to femoropopliteal PTA, infrapopoliteal PTA has been less frequently used and still controversial due to heterogeneous results so offered predominantly to patients with CLI.(7) Although infrapopoliteal "crural" PTA was restricted to patients with short stenotic lesions or poor candidates for bypass;(8) crural PTA recently has been used preferentially over bypass surgery by some groups due to the advent of new devices and techniques. The growing experience with endovascular therapy justify an assessment of crural PTA.(9,10)

Recently, the bypass versus angioplasty in severe ischemia of the leg (BASIL) study suggested that if the anatomy is conductive for angioplasty, primary PTA might be an appropriate first therapy even if the patient is a good candidate for bypass. However, ideal anatomy was not well defined in BASIL.(11)

The Transatlantic Intersociety Consensus (TASC) "I" criteria represents a standardized definition for lesion characteristics.(12,13) Outcomes of tibial PTA are difficult to predict from the existing literature owing to a lack of details regarding indications for intervention and lesion characteristics.(14-18)

The primary goal in treating CLI is limb salvage and maintenance of quality of life, not patency.(19,20)

The purpose of this study is reviewing our results in infrapopliteal angioplasty stratifying patients by anatomic characteristics according to the TASC classification.

MATERIAL AND METHODS

This study was conducted at Arab Contractors Medical Center and Mansoura University Hospitals on 85 patients during the period from Jan 2009 till April 2013.

Inclusion criteria were rest pain, ulceration and tissue necrosis. Exclusion criteria were life threatening infection, Burger's disease and multilevel lesions. {66 patients (82.5%) presented by ulceration and tissue necrosis, and 14 patients (17.5%) presented by rest pain}.

All patients were subjected to thorough history taking for any comorbidity, general examination and routine laboratory investigations including complete blood picture, kidney function tests, liver function tests, fasting blood sugar, coagulation profile and lipid profile.

All patients were investigated by colour duplex scan, C.TA., and MRA in cases of severe renal impairment.

The TASC "I" classification for tibioperoneal occlusive disease is detailed as follows:

TASC A: a single stenosis < 1 cm long.

TASC B: multiple focal (<1 cm) stenosis of tibial or peroneal arteries, including up to two focal stenosis at the tibial trifurcation or short tibial or peroneal stenosis in conjunction with femoropopliteal disease.

TASC C: longer stenosis of 1 to 4 cm, occlusion 1 to 2 cm or extensive stenosis involves the trifurcation.

TASC D: occlusion > 2 cm long or diffuse disease.

All procedures were done with local anesthesia, sometimes sedation was needed for irritable patients.

Cases were performed preferentially through antigrade ipsilateral femoral access and rarely through retrograde contralateral access. All patients were anticoagulated with 10,000 IU heparin after initial angiography.

We used 6F sheaths for ipsilateral antigrade access and 8F sheath for retrograde contralateral access, 4F vertebral catheters were used with 0.035 floppy angled giduewire (Terumo, Somerest, ND), 0.018, 0.014 hydrophilic wire (Boston Scientific, Natick, Mass) or glide wire. Five cases had direct tibial vessel puncture using fluoroscopic guidance Angioplasty was performed with low profile balloon (Amphirion Deep, Invatec, Italy) 2.5 to 3F. Balloon was inflated for 1 to 3 minutes.

If vasospasm occurred; administration of 50-400 mcg of nitroglycerin was helpful.

After the procedure, patients were given 600 mg loading dose of clopidogrel, if the patient didn't received it preoperatively, maintained on 75 mg daily dose for 3 months to one year, along with aspirin and statins.

Angiographic success was considered when all technically accessible lesions were treated with < 30% residual stenosis. Hemodynamic success was defined:ABI increase of at least 0.1[21] Clinical success was defined as at least one upward clinical categorical shift, improvement of rest pain, improvement of wound or ulcer healing.

Follow up: Patients were followed up weekly for one month, and then every 3 months for 1 year, and every 6 months thereafter, or more frequently if stenosis were detected or to monitor wound healing. Patency was assessed with duplex ultrasound. Ankle brachial pressure index is measured.

Salvage was defined as freedom from major amputation (below or above knee). Toe, ray or transmetatarsal amputations were considered minor amputations, not any higher amputations.

Statistical analysis: The statistical analysis of data done by using excel program and SPSS program statistical package for social science version 10.

The description of the data done in form of mean (+/-) SD for quantitative data .And Frequency & proportion for Qualitative data.

The analysis of the data was done to test statistical significant difference between groups.

For quantitative data student t-test was used to compare between two groups. Chi square test was used for qualitative data.

N.B: P is significant if < or = 0.05 at confidence interval 95%.

Patency and limb salvage was done using Kaplan –Meier curve.

RESULTS

During the study period, 80 patients underwent PTA {14 (17.5%) for rest pain and 66 (82.5%) for tissue loss} after exclusion of five cases from the study due to failure of guide wire passage (one of failed cases needed urgent femorotibial bypass, another one improved clinically, post procedure, due to opening of new collaterals spontaneously during the procedures, the other three cases needed below knee amputation). Demographic data, comorbidities, clinical presentation and hospital stay are summarized in (Table 1). The median hospital stay was 5.1 days (range 3 – 16 days). Most of cases stay for one day before intervention and 2 days after except if there is periprocedure morbidity, complications or the need for amputation (either minor or major).

Antigrade access was used in 73 cases (91.25%) and seven cases (8.75%) retrograde access was performed due to hostile anatomy from previous surgery or due to high femoral bifurcation.

Intraprocedural complications: Flow limiting spasm occurred in 5 patients (6.25%) had been treated by nitroglycerin injections. Thrombosis occurred in 6 patients (7.5%), two of them had been treated by aspiration and four patients had been treated by thrombolytic therapy.

Post procedural complications: (Table 2): One patient (1.25%) died 3 weeks after discharge of unknown cause. Two patients (2.5%) developed transient contrast nephropathy. Three patient (3.75%) developed groin hematomas treated conservatively. Two patients developed pseudoaneurysm, one treated by ultrasound guided compression and the other expanding pseudoaneurysim treated by surgical repair. One patient developed symptomatic microembolism to the big toe and inner aspect of the second toe improved with

antiplatelet and analgesics.

Mean follow up was 14 months with a range of (6–28 months). Primary patency was 58.75% at first year and 48.75% at second year (Table 3).

First year primary patency for TASC A through D was 83.3%, 87.5%, 45%, 34.6% respectively. And for Second year was TASC A through D was 72.2%, 68.75%, 40%, 26.9% respectively. Limb salvage at one year was 81% and at 2 years was 75%.

Two patients (2.5%) needed major amputation inspite of successful primary patency one because of severe life threatening infection of the foot (below knee amputation) and the other developed skin necrotic patches14 months after intervention, that was rapidly progressive diagnosed as vasculitis (above knee), this patient was diabetic and dialysis dependent, he died 3 weeks after amputation.

Failure of primary patency occurred in 41 patients (51.25%) of these 4 patients underwent major amputation and 25 patients (31.25%) were managed by repeated balloon angioplasty, resulting in 16 arteries remain patent for more than one year and 9 patients failed, and the remaining 12 patients treated conservatively by cilostazol, naftidrofuryl and oral anticoagulant. {5 patients underwent surgical bypass grafting using saphenous graft leading to limb salvage in 3 patients and eventual amputation in 2 patients, and the other 4 patients (two of them underwent below knee amputation and 2 patients died without more intervention)}. Wound completely closed or improved in 42 patients (63.6%) (Out of 66 patients presented by tissue loss), stable in 14 patients (21.2%), and worse in 10 patients (15.2%). The remaining 14 patients were presented by rest pain (9 patients (64%) improved, 3 patients (21.5%) were stable, 2 patients (14.5%) worse.

Table 1. Demographic Data and patients characters.

	Tasc A (n = 18)	**Tasc B (n = 16)**	**Tasc C (n = 20)**	**Tasc D (n = 26)**
Age	65.57 ± 5.49	64.50 ± 10.35	64.10 ± 1.74	67.69 ± 8.63
Sex:				
Male	10 (55.6%)	12 (75%)	12 (60%)	14 (53.8%)
Female	8 (44.4%)	4 (25%)	8 (40%)	12 (46.2%)
Smoking	12 (66.7%)	10 (62.5%)	8 (40%)	16 (61.5%)
DM*	14 (77.8%)	10 (62.5%)	14 (70%)	16 (61.5%)
HTN*	16 (88.9%)	16 (100%)	16 (80%)	22 (84.6%)
Hyperlipidaemia	16 (88.9%)	10 (62.5%)	12 (60%)	12 (46.2%)
Renal insufficiency	4 (22.2%)	8 (50%)	6 (30%)	12 (46.2%)
Dialysis	0 (0%)	2 (12.5%)	6 (30%)	4 (15.4%)
Congestive Heart failure	0 (0%)	2 (12.5%)	8 (40%)	10 (38.5%)
Prior MI*	0 (0%)	2 (12.5%)	8 (40%)	8 (30.8%)
Cerebrovascular	4 (22.2%)	2 (12.5%)	6 (30%)	4 (15.4%)
Rest pain	6 (43%)	2 (14.3%)	2 (14.3%)	4 (28.4%)
Tissue loss	12 (66.7%)	14 (87.5%)	14 (70%)	26 (100%)
Hospital stay	3.67 ± 1.28	4.63 ± 2.0	5.50 ± 3.32	6.08 3.65

DM: Diabetes mellitus, **HTN:** Hypertension, **MI:** Myocardial infarction.

Table 2. Complication.

Post procedure	Tasc A (n = 18)	Tasc B (n = 16)	Tasc C (n = 20)	Tasc D (n = 26)	P value
Died	0 (0%)	0 (0%)	1 (33.3%)	0 (0%)	
Microembolism	0 (0%)	0 (0%)	1 (33.3%)	0 (0%)	
Hematoma	0 (0%)	1 (33.3%)	0 (0%)	2 (100%)	0.369
Pseudoaneurysm	0 (0%)	1 (33.3%)	1 (33.3%)	0 (0%)	
Nephropathy	1 (100%)	1 (33.3%)	0 (0%)	0 (0%)	

Table 3. Primary patency rate.

Primary patency	Tasc A (n = 18)	Tasc B (n = 16)	Tasc C (n = 20)	Tasc D (n = 26)	P value
1st y	15 (83.3%)	14 (87.5%)	9 (45%)	9 (34.6%)	< 0.001
2nd y	13 (72.2%)	11 (68.8%)	8 (40%)	7 (26.9%)	0.007

DISCUSSION

There is marked shift in primary management of infrainguinal occlusive disease from surgical bypass to percutaneous revascularization. Recently newly developed devices and techniques improved outcome and increased interest in infrapopoliteal PTA with lower complication rates.[23]

This study demonstrates that outcome of PTA depends on TASC classification. Outcome of TASC D lesions were significantly worse than other lesions. Also many patients may be not candidate for bypass; they should be treated by PTA.

Tibial artery interventional therapy has been proven to lead to limb salvage with low morbidity and mortality in patients with critical limb ischemia and should be used as a first line treatment modality in the majority of patients, especially in those with significant medical comorbidities.[24] However, differences in outcome between available devices are unknown and ways to increase long term patency remain poorly defined.[1] there are great difficulties in comparing results of infra-popliteal angioplasty as different studies have different outcome variables, lacks uniformity regarding procedural indication .also there are discrepancy regarding lesions characteristics segmental and multi-level disease pattern. Nevertheless reports by Kudo et al (2005) and by Haider et al (2006) found Tasc D lesions to have worse prognosis, and this is also reported by our study.

Intra-procedural complication rate (13,75%) in our study was equal as reported by Lyden (2009). All intra-procedural complications were managed in an endovascular fashion. No patient required emergency surgery to correct a procedural complication.

Two settings exist where operative therapy should be used first with tibial bypass over interventional modalities. The first is when a total occlusion continuously includes the superficial femoral artery, popliteal artery, and tibial arteries. Interventional therapies are generally not durable enough to achieve wound healing in this setting. The second setting is for patients when the extent of tissue loss necessitates extended forefoot amputation or debridement, where interventional therapy may not restore enough flow to achieve limb salvage.[3,24]

Conrad et al (2009) said that, the use of PTA of the infrapopliteal vessels as a primary treatment when anatomically feasible bypass have voiced the concern that failure could result in the need for a more distal bypass or endovascular injury of target vessels could

result in the inability to identify a distal target artery for bypass. This was not identified in this study, where surgical crossover was undertaken in primary and secondary failure. However, Sanford et al. (2007) detailed 66 patients who underwent surgical bypass for failed PTA including 16 tibial vessels (24%), and reported a 12 month primary patency of 61%. They noted that 21% of patients in the PTA failure group required a bypass more distal than the original artery treated, emphasizing that the percutaneous procedure should always be undertaken with consideration of backup surgical options should the initial PTA fail.[21]

Hyeon et al (2012) found that the minimally invasive nature of infrapopliteal PTA has obvious appeal, it also has potential disadvantages: conversion of an elective to emergency procedure, loss of bypass targets or making them more distal, a less durable solution, lengthy procedures with hazards of radiation exposure, and the rising costs of care if multiple interventions are needed.

In our study the primary patency rate was 58.75% in first year, and 48.75% in second year which is similar to the results of Haidar et al. (2006).

Limb salvage rate reported by Sadek et al. (2009) was 84 % after two years which is higher than our results (75%).

In conclusions PTA of infrapopliteal vessels can be performed safely, with low morbidity and mortality. PTA is recommended as first line of treatment for TASC A, B, C lesions and TASC D patients who are not candidate to bypass. But more studies are needed to compare long term follow up between PTA and bypass in TASC D lesions whose are candidate to bypass.

REFERENCES

1. Sadek M, Ellozy SH, Turnbull IC, Lookstein RA, Marin ML, Faries PL. Improved outcomes are associated with multilevel endovascular intervention involving the tibial vessels compared with isolated tibial intervention. J Vasc Surg. 2009;49:638-44.

2. Kristina A.Giles, MD, Frank B. Pomposelli, MD, Allen D.Hamdan,MD,SethB.Blattman,MD,Haig Panossian BS, AND mARCl. Schermerhorn,MD Infrapopliteal angioplasty for critical limb ischaemia; relation of TransAtlantic InterSociety Consensus class to outcome in 176 limbs. J vasc surg. 2008;48;128-36.

3. Parson RE, Suggs WD, Lee JJ, Sanchez LA, Lyon RT, Veith FJ. Percutaneous transluminal angioplasty for the treatment of limb threatening ischemia: do the results justify an attempt before bypass grafting. J Vasc Surg. 1998;28:1066-71.

4. Nasr MK, McCarthy RJ, Budd JS, Horrocks M. Infrainguinal bypass graft patency and limb salvage rates in critical limb ischemia: influence of the mode of presentation. Ann Vasc Surg. 2003;17:192-7.

5. Faries PL, Logerfo FW, Arora S, Hook S, Pulling MC, Akbari CM, et al. A comparative study of alternative conduits for lower extremity revascularization: all autogenous conduit versus prosthetic grafts. J Vasc Surg. 2000;32:1080-90.

6. Conrad MF, Kang J, Cambria RP, Brewster DC, Watkins MT, Kwolek CJ, LaMuraglia GM. Infrapopliteal balloon angioplasty for the treatment of chronic occlusive disease. J Vasc Surg. 2009;50:779-805.

7. Kudo T, Chandra FA, Ahn SS. The effectiveness of percutaneous transluminal angioplasty for the treatment of critical limb ischemia: a 10-year experience. J Vasc Surg. 2005;41:423-35.

8. Spinosa DJ, Leung DA, Matsumoto AH, Bissonette EA, Cage D, Harthun NL, et al. Percutaneous intentional extraluminal recanalization in patients with chronic critical limb ischemia. Radiology. 2004;232:499-507.

9. Haider SN, Kavanagh EG, Forlee M, Colgan MP, Madhavan P, Moore DJ, et al. Two-year outcome with preferential use of infrainguinal angioplasty for critical ischemia. J Vasc Surg. 2006;43:504-12.

10. Romiti M, Albers M, Brochado-Neto FC, Durazzo AES, Pereira CAB, De Luccia N. Meta-analysis of infrapopliteal angioplasty for chronic critical limb ischemia. J Vasc Surg. 2008;47:975-81.

11. Adam DJ, Beard JD, Cleveland T, Bell J, Bradbury AW, Forbes JF, et al. BASIL trial participants. Bypass versus angioplasty in severe ischemia of the leg (BASIL): multicentre, randomized controlled trial. Lancet. 2005;366:1925-34.

12. Dormandy JA, Rutherford RB. TASC Working Group TransAtlantic Inter-Society Concensus (TASC). Management of peripheral arterial disease (PAD). J Vasc Surg. 2000;31:S1-296.

13. Norgren L, Hiatt WR, Dormandy JA, Nehler MR, Harris KA, Fowkes FGR. Inter-Society Consensus for the Management of Peripheral Arterial Disease (TASC II). Eur J Vasc Endovasc Surg. 2007;33:S1-75.

14. Hynes N, Mahendran B, Manning B, Andrews E, Courtney D, Sultan S. The influence of subintimal angioplasty on level of amputation and limb salvage rates in lower limb critical ischaemia: a 15-year experience. Eur J Vasc Endovasc Surg. 2005;30:291-9.

15. Danielsson G, Albrechtsson U,Norgen l, rIBBEe, Thome J,Zdanowski Z,. Percutaneous transluminal angioplasty of crural arteries;diabetees and other factors influencing outcome.Eur J Vasc Endovasc Surg. 2001;21:432-6.

16. ClairDG,DayalR,Faries PL,Bernham J, Nowygrod N, Lantis JC, et al Tibial angioplasty as an alternative strategy in patients with critical limb ischaemia; a 10- year experience.Ann vasc Surg. 2005;19;63-8.

17. Dorros G, Jaff MR, Dorros AM, Mathiak LM, He T. Tibioperoneal (outflow lesion) angioplasty can be used as primary treatment in 235 patients with critical limb ischemia: five-year follow-up. Circulation. 2001;104:2057-62.

18. Faglia F, Mantero M, Caminiti M, Caravaggi C, DeGiglio R, Pritelli C. Extensive use of peripheral angioplasty, particularly infrapopliteal, in the treatment of ischaemic diabetic foot ulcers: clinical results of a multicentric study of 221 consecutive diabetic subjects. J Intern Med. 2002;252:225-32.

19. DeRubertis BG, Faries PL, McKinsey JF, Chaer RA, Pierce M, Karwowski J, et al. Shitting paradigms in the treatment of lower extremity vascular disease: a report of 1000 percutaneous interventions. Ann Surg. 2007;246:415-22, discussion 22-4.

20. Lyden SP. Techniques and outcomes for endovascular treatment in the tibial arteries. J Vasc Surg. 2009;50:1219-23.

21. Sanford RM, Bown MJ, Sayers RD, London JN, Naylor AR, McCarthy MJ. Infrainguinal bypass grafting successful following failed angioplasty? Eur J Vasc Endovasc Surg. 2007;34:29-34.

22. Tsetis D, Belli AM. The role of infrapopliteal angioplasty. Br J Radiol. 2004;12:685-695.

23. Hyeon M R, Jung S k,Young GK,,Myeong K H,Yangsoo J and Donghoon C ;Clinical outcomes of infrapopliteal angioplasty in patients with critical limb ischemia; Korean Circ J. 2012;42:259-65.

24. Sadaghianloo N,Jean E.B, Declemy S, Mousnier A, Brizzi S,Hassan.R:Percutanous Angioplasty of long tibial occlusions in critical limb ischemia .Ann Vasc Surg; 2013;27:894-903.