The Predictors of Success and Effectiveness of Tibial Angioplasty in Patients with Critical Limb Ischemia

Hossam Elmahdy, M.D, Walied Eldaly, M.D, Baker Ghoneim, M.D
Vascular Surgery Unit, Kasr Alainy Faculty of Medicine, Cairo University

ABSTRACT

Patients and Methods: *This study includes 46 patients with CLI were admitted to the Department of Vascular Surgery, in our institute between June 2014 and March 2016and assessed for peripheral endovascular procedures.* ***Results:*** *A total of 46 limbs underwent tibial artery endovascular interventions. The mean age was 53-77years.A total of 14 patients with TASC C (stenoses 1-4 cm, occlusions 1-2 cm, and extensive stenoses at the tibial trifurcation) and 32 patients with TASC D (occlusions >2 cm and diffuse tibial vessel disease) . The primary patency rate was at 1 year45.65%. .The limb salvage rate 73.91% at 1 year follow up. The amputation rate at 1 year was 26%. predictors of limb loss at 1 year included chronic renal insufficiency (58.33%, P<0.02)and absence of plantar foot arch(66.6%,p<0.04),single peroneal intervention(3 cases).* ***Conclusion:*** *TAEI is safe, effective in treatment of BK disease in the vascular specialist armamentarium. It leads to limb salvage with low morbidity and mortality in patients with CLI and should be used as a first line treatment in the majority of patients, especially in those with significant multi co morbidities. However, differences in outcome between the available technologies are still not proven concerning the long term patency.*

INTRODUCTION

Tibial artery endovascular interventions (TAEIs) have become a first line of revascularization in most centers in patients with tibioperoneal occlusive disease.[(1)] Several studies have revealed the efficacy and safety of TAEI for the treatment of critical limb ischemia (CLI).1 However, low patency rates with high restenosis after endovascular interventions of such procedures are among the limitations of TAEIs, with a high rate of restenosis and consequent reinterventions. Meanwhile, Tibial restenosis and re-interventions have been traditionally deemed to be benign and successful regarding limb salvage.[(2)]

The primary goal in treating patients with CLI is limb salvage with maintenance of quality of life, not patency, making endovascular treatment the best approach.[(3)] This study focuses on a one year follow up for TAEI done on a group of patients presented to our institute between June 2014 and March 2016 regarding the outcome (patency and limb salvage) and predictors of success.

PATIENTS AND METHODS

This study includes 46 patients with CLI (rest pain and tissue loss plus Ankle systolic pressure below 50 mm Hg or toe pressure below 30 mmHg) were admitted to the Department of Vascular Surgery, in our institute between June 2014 and march 2016 and assessed for peripheral endovascular procedures. All patients were preoperatively assessed with duplex ultrasound (DUS) scanning and submitted to angiography. All vascular lesions were classified according to the modified TransAtlantic Inter-Society Consensus (TASC) classifications for tibioperoneal occlusive disease. [(4)]

Procedure details.

All patients were admitted to the vascular surgery department 1 day prior to the preprogrammed intervention, All endovascular interventions were performed in a dedicated angiographic room equipped with a C-Arm (OEC 9800; GE Medical System, Salt Lake City, Utah). All procedures were performed under local anesthesia. Ipsilateral antegrade percutaneous access was used in all cases.

Introducer sheaths (6F) were used and standardized bolus of 5000 IU of unfractionated heparin was administered via sheath. During the procedure, interventions were performed with an intention to establish in-line arterial flow to the foot. At least one tibial artery was revascularized.

Prior to endovascular treatment, diagnostic angiography was performed to quantify lesion extent. 0.014 and 0.018 inch wires were used in

most of the cases with 0.035 wire used selectively in some cases where along occlusion needed to be passed subintimally. Plain old balloon (POB) Angioplasty was done using 3mm balloons 80-120 cm (Amphirion deep,Medtronic)

In cases with renal insufficiency, after taking the appropriate consent of possible deterioration of kidney function, co management with nephrologists trying to optimize the renal function is practiced and the least amount of dye was used with the possibility of renal dialysis after the procedure.

Postoperative angiography confirmed technical success.

Postinterventional patient management.

Postinterventional anti-platelet therapy included a dual-antiplatelet- aggregation regimen comprising 75 mg of clopidogrel and 150 mg of asprin per day for 4 weeks, followed by at least one of these drugs indefinitely.

Outcome assessment and follow-up.

Technical success was determined as less than 30% of final residual stenosis measured at the narrowest point of the treated segment. Patency was defined as the absence of recurrent occlusion causing more than 50% reduction in diameter of the treated segment, as documented by DUS scanning or angiography.

Ankle brachial index was evaluated before and after revascularization procedures; in patients in whom the ABI could not be accurately measured, toe pressure was recorded. Clinical improvement was achieved if wound healing has produced improvement of at least two Rutherford categories.

Primary endpoint:

- Primary patency and secondary patency
- Limb salvage means freedom from any form of major amputation, i.e, above ankle level

Follow-up consists of a clinical examination and DUS scanning at 3, 6 and 12 month.

Statistical analysis

Data were statistically shown in range, mean, standard deviation (SD), median, frequencies and percentages when appropriate. Mann Whitney U test was used to contrast quantitative variables between the study groups. Chi square ($\chi 2$) test was performed to compare categorical data. Exact test was used as an alternative when the predictable frequency is less than 5. A probability value (p value) less than 0.05 was considered statistically significant. All statistical calculations were done by computer programs Microsoft Excel 2003 and SPSS ("Statistical Package for the Social Science; SPSS Inc., Chicago,IL, USA") version 15 for Microsoft Windows.

RESULTS

A total of 46 limbs underwent tibial artery endovascular interventions. The mean age was 53-77years, with male/female ratio, 22/24 patients demographics are listed in Table 1.

All interventions included a tibial artery angioplasty without proximal intervention. All patients were treated for critical limb ischemia; Runoff status is shown in figure 1.

A total of 14 patients with TASC C (stenoses 1-4 cm, occlusions 1-2 cm, and extensive stenoses at the tibial trifurcation)and 32 patients with TASC D (occlusions >2 cm and diffuse tibial vessel disease) tibial lesions, were treated with BTK angioplasty. 7 cases (15.21%) of tibial interventions were done for stenoses and 39cases (84.78%) for occlusions. Postprocedure intervention, The mean ABI increased from 0.42 ±0.15 preintervention to 0.83±0.2 postintervention (P <0.001).

Postprocedural complications are described in table 2.

At 3 months, the primary patency rate was 91.3%, while at 6 months it was 63.04% and at 1 year,it was 45.65% (figure 2). The limb salvage rate at 3 months was 93.47%, while it was 80.43% at 6 months and 73.91% at 1 year follow up. The amputation rate at1 year was 26.08%, 3 cases had early amputation in the first 3 months, (2 cases were without runoff and 1 case had a single peroneal intervention), other 6 cases had amputation at 6 months follow up (1case was without runoff, 1 case was a single peroneal intervention,4 cases with dual or single tibial intervention).

Factors associated with limb loss at 1 year included chronic renal insufficiency (7 cases, 58.33%, P<0.02) and absence of plantar foot arch (8 cases 66.6%, p<0.04),single peroneal intervention (3 cases), the lesion's crossing mode (5 cases out of 6 cases crossed in subintimal mode, 83.33%) and early thrombosis (2 cases,16.6%). (figure 3)

Table 1: Patients clinical and lesion characteristics

Patient clinical and lesion characteristics	
Number of patients	46
Male/Female ratio	22/24
Age (rang)	53-77 years
Risk Factors,(number,%)	
DM	42 (91.3%)
HTN	35 (76.08%)
Current Smoker	21 (45.65%)
Dislipidemia (Cholesterol level>120mg/dl)	7 (15.21%)
CRF	2 (4.34%)
Pre-existing renal insufficiency(creatinine level>2 mg/dl)	11 (23.91%)
Ischemic heart disease	19 (41.30%)
Presentation	
Category4 (Rutherford)	12 (26.08%)
Category5 (Rutherford)	18 (39.13%)
Category6 (Rutherford)	16 (34.78%)
TASC classification	
TASC C	14 (30.43%)
TASC D	32 (69.56%)
Lesion Morphology	
Stenosis	7 (15.21%)
Occlusion	39 (84.78%)
ABI, mean±SD	0.42±0.15
TBI, mean±SD	0.42±0.03
Crossing Mode	
Intraluminal	40 (86.95%)
Subintimal	6 (13.05%)

Table 2 : Postprocedural complications

Postprocedural complications	***%(n)***
Groin hematoma	(6.5%) 3
Pseudoaneurysm	(4.3%)2
Thrombosis	(4.3%)2
Acute Renal Failure	(2.17 %)1
MI	(2.17%) 1

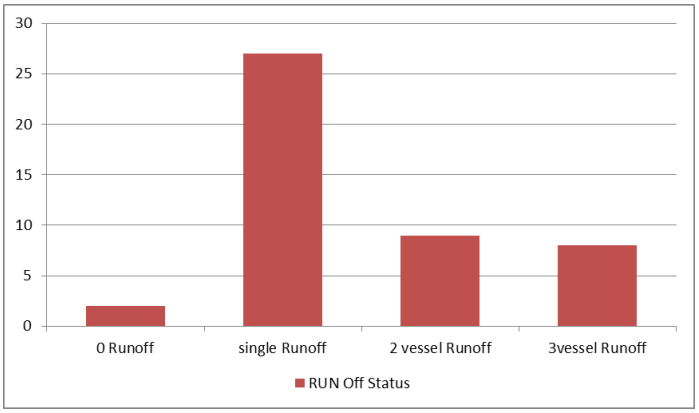

Fig. 1: Runoff Status

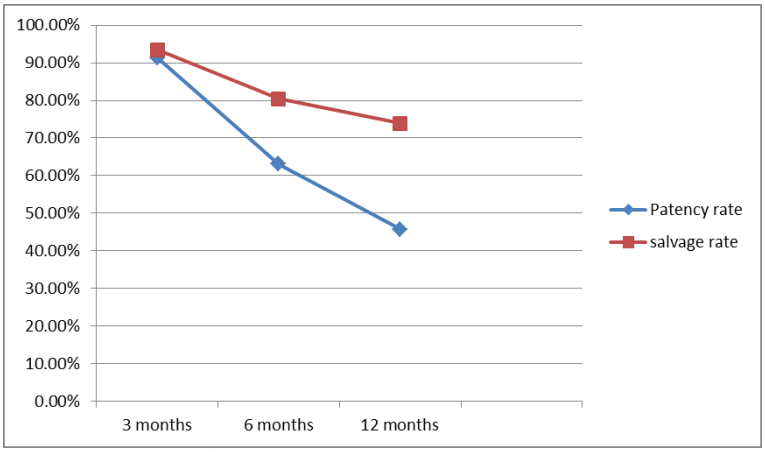

Fig. 2: 1[ry] patency and limb salvage rate of TAEIs

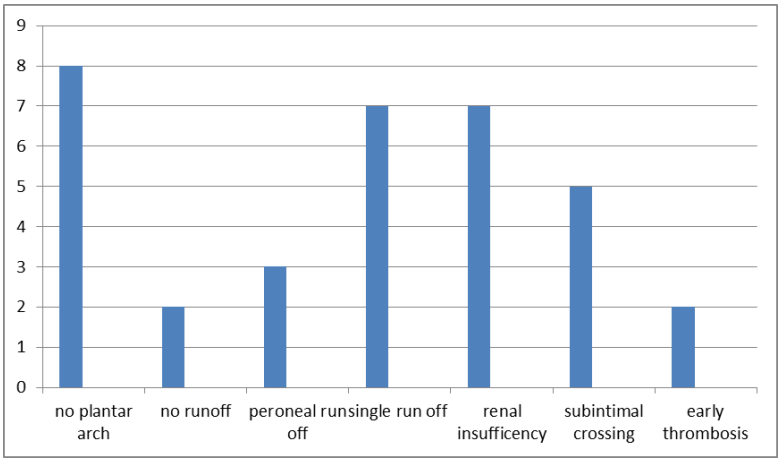

Fig. 3: Predictors of failure in the Amputated

DISCUSSION

Endovascular interventions for the treatment of critical limb ischemia have become the first-line approach in many centers.[6] Romiti et al,[7] stated a 1-year primary and secondary patency rates of 58% and 68%, respectively, with a limb salvage rate of 86% and patient survival of 98% in the setting of infrapopliteal angioplasty for the treatment of CLI.

In the report by Sadek et al, a limb salvage rate of 81% at 12 months was reported.[6]

Giles et al,[8] noted a limb salvage rate of 84% at 12 months. In the current study, we report a primary patency at 1 year of 45.65% and a limb salvage rate of 73.91%. Most of limbs treated in this study showed CLI with poor run off status in 63.04%, not amenable to bypass surgery. TAEI was offered as a bailout for most of our cases included in the study especially those who had poor pedal run off which had an impact over the survival rates shown in other studies. Most of the tibial interventions in our study were done for occlusions,(84.78%) predicting a worse outcome for the comparative salvage rate in other studies.

We believe that an isolated tibial intervention may have a greater local disease burden, which would increase the chance of recurrence and limit the effectiveness of single-level intervention as stated by Sadek et al.[6]

26.08% of our patients required major amputation all-through the study despite of the attempts at limb salvage were done and this was attributed to the great local disease burden, most of the cases presented with Rutherford categories V,VI, poor run off status, and unavailability of a good saphenous or arm conduit for bypass surgery.

One of the predictors of failure in TAEI includes preoperative chronic renal insufficiency ($p<0.02$) however nothing in the literature supports this till the time being. As well, the isolated peroneal intervention as it is associated with poor wound healing is likely due to suboptimal pedal runoff, and possibly a greater local atherosclerotic burden.[9]

The absence of pedal foot arch was one of the most important predictive factor for failure in our series ($p<0.04$) and this was consistent with Fernandez et al,[10] who stated that interventions at the below the ankle level were associated with an more risk of limb loss, and did not have a good effect on the wound healing.

The association of pedal intervention with poor outcomes is likely explained by poor patency and diffuse below the ankle small vessel disease, and may be a reflection of a combination of overall greater burden of disease and a poor pedal runoff.[10]

Technologies like cryoplasty, directional atherectomy, orbital atherectomy, and laser atherectomy for treating tibial artery disease have not yet proved a good outcome with any of these technologies to be notably different than balloon angioplasty. Individual operator skill and experience can lead to acceptable outcome with these technologies; however, data regarding such technologies are restricted to short follow up with reflecting the outcomes between small series.[11]

Schmidt et al, in his first report of the use of DEBs BTK predict that they are safe and efficient in this arterial region and it has more than 60% reduction in the restenosis rate at 3 months when compared with studies used uncoated balloons,. Additionally, if restenosis occurred, it was more benign form with a favorable and focal pattern. The 1-year clinical results seems promising with more durable benefit. However, there are still further studies needed to verify the advantage of DEBs versus plain old balloon angioplasty in patients with CLI from BTK disease.[12]

CONCLUSION

TAEI is safe, effective in treatment of BK disease in the vascular specialist armamentarium. It leads to limb salvage with low morbidity and mortality in patients with CLI and should be used as a first line treatment in the majority of patients, especially in those with significant multi comorbidities. However, differences in outcome between the available technologies are still not proven concerning the long term patency. Factors which associated with poor outcome include renal insufficiency, absence of plantar arch, subintimal passage and early thrombosis.

Conflict of interest: none

Author Contributions:

Study conception: Baker Ghoneim and Walied eldaly
Data collection:all authors
Analysis: Hossam elmahdy
Investigation: all auhors
Writing: Baker Ghoneim and Hossam Elmahdy
Critical review and revision: all authors
Final approval of the article: all authors
Accountability for all aspects of the work: all authors

REFERENCES

1. Romiti M, AlbersM, Brochado-Neto FC, ,et al. Meta-analysis of infrapopliteal angioplasty for chronic critical limb ischemia. J Vasc Surg 2008;47:975-81.
2. Ryer EJ, Trocciola SM, Derubertis B,et al. Analysis of outcomes following failed endovascular treatment of critical limb ischemia. Ann Vasc Surg 2006;20:440-6.
3. Lyden S. Techniques and outcomes for endovascular treatment in the tibial arteries. JOURNAL OF VASCULAR SURGERY November 2009:volume 50:1219-23
4. Norgren L, Hiatt WR, Dormandy JA, et al. Inter-Society Consensus for the Management of Peripheral Arterial Disease (TASC II). Eur J Vasc Endovasc Surg 2007;33 (Suppl 1):S1-75.
5. Rutherford RB, Baker JD, Ernst C, et al. Recommended standards for reports dealing with lower extremity ischemia: revised version. J Vasc Surg 1997;26:517-38.
6. Sadek M, Ellozy SH, Turnbull IC, et al . Improved outcomes are associated with multilevel endovascular interventions involving the tibial vessels compared with isolated tibial intervention. J Vasc Surg 2009;49:638-43; discussion 643-4.
7. Romiti M, Albers M, Brochado-Neto FC, et al. Meta-analysis of infrapopliteal angioplasty for chronic critical limb ischemia. J Vasc Surg 2008;975-81.

8. Giles KA, Pomposelli FB, Spence TL, et al. Infrapopliteal angioplasty for critical limb ischemia: relation of TransAtlantic Intersociety Consensus class to outcome in 176 limbs. J Vasc Surg 2008;48:128-36.
9. Norgren L, Hiatt WR, Dormandy JA, et al . TASC II Working Group. Inter-Society Consensus for the Management of Peripheral Arterial Disease (TASC II). J Vasc Surg 2007; 45(Suppl S):S5-67.
10. Fernandez N, McEnaney R, Marone LK, et al. Predictors of failure and success of tibial interventions for critical limb ischemia. J Vasc Surg 2010;52:834-42.
11. Lyden S P,Techniques and outcomes for endovascular treatment in the tibial arteries. J Vasc Surg 2009;50:1219-23.
12. Schmidt A, Piorkowski M, Werner M, et al . First Experience With Drug-Eluting Balloons in Infrapopliteal Arteries; Restenosis Rate and Clinical Outcome
13. Journal of the American College of Cardiology; Vol. 58, No. 11, 2011