DOI: https://doi.org/10.53350/pjmhs211562063

ORIGINAL ARTICLE

Below Knee Angioplasty Results in Diabetic aAnd Non-Diabetic Patients

AFGHANI REZA[1], CHERAGHALI ROOZBEH[2]
[1]Thoracic Surgeon, Assistant professor Of surgery, Golestan university of medical sciences, Gorgan, Iran af_med75@yahoo.com
[2]Roozbeh Cheraghali MD (Corresponding author and post publication corresponding author)
Assistant Professor of Surgery, Vascular & Endovascular Surgery, Golestan University of Medical Sciences (GOUMS), Gorgan, Iran. Dr.r.Cheraghali@goums.ac.ir
Roozbehcheraghali81@gmail.com
Address: Sina Hospital,Hassan Abad Sq., Tehran 1136746911 ,Iran. Tel:+98-21-66348564 Fax:+98-21-66348564

ABSTRACT

Ten to 25 % of all diabetic patients will develop a lower limb ulcer in their lifetime. Ankle-brachial index is not accurate in diabetic patients .The resting systolic toe pressure (TP) may be a measure of small arterial function within the periphery.

Objective: The purpose of this article is to consider the effect of below-knee angioplasty on systolic toe pressure changes in diabetic patients with critical limb ischemia.

Methods/Materials: In this prospective study 114 patients, were included who satisfied the inclusion criteria: patients with critical limb ischemia in the form of tissue loss(ulcer or gangrene) or rest pain, presence of below-knee vessel lesion, and absence of proximal vessels lesion or stenosis. We evaluated the effect of angioplasty on toe pressure of diabetic patients and compared them to non-diabetics.

Results: Among 114 patients, 78(68/4%) were men and 36(31/6%) were women. Diabetic patients were 96(84/2%) and non-diabetics were 18 (15.8%). In Paired T-Test analysis we compared toe pressure values of each patient before and after angioplasty and it was a significant difference in both Diabetic and non-diabetic groups.(0.00 and 0.008 respectively). The mean of systolic toe pressure before angioplasty had no difference between the 2 groups (PValue: 0.13). The mean of toe pressure in non-diabetic patients was 42±31.9 and in diabetics was 25.6 and after angioplasty, the mean of toe pressure raised 44.3 in non-diabetics and 19.4 in diabetics.

Conclusions: Systolic toe pressure is a valuable tool to evaluate and predict angioplasty effect on below-knee ulcers especially in diabetic patients.

Keywords: Below knee Angioplasty, Systolic toe pressure, Diabetes

INTRODUCTION

The worldwide incidence and prevalence of diabetes mellitus (DM) are increasing (1). Ten to 25 % of all diabetic patients will develop a lower limb ulcer in their lifetime(2,3). An ulcer imposes significant limitations on the patient and requires a complex treatment plan to heal properly; these factors increase the economic and social burden of the disease. At least 50% of the patients with lower limb ulcers have an underlying peripheral arterial disease (PAD). In such cases, revascularization of the limb may be required to restore blood flow to the distal limb (4,5)The risk of major amputation in patients with a diabetic foot ulcer is 8%–29%, and the mortality rate is 39%–80% in patients who have undergone major amputation(6,7)

In comparison with nondiabetics, diabetics have been noted to have a lower incidence of aortoiliac disease, the same incidence of femoropopliteal disease, and a higher incidence of involvement of the arteries distal to the popliteal artery. (8,9)

Angioplasty is the first line of treatment of PAD, especially in diabetic patients. Surgery will be kept until the end of treatment lines, given the co-morbidities and surgery complications.(10)

Revascularisation is indicated whenever a diabetic patient with a lower leg ulcer has any of the following characteristics: ankle-brachial index (ABI) < 0.8, ankle systolic pressure < 80 mmHg or a systolic toe pressure(TP) < 40 mmHg, or a transcutaneous oxygen tension (TcO2) < 40 mmHg and with at least one imaging exam demonstrating flow atherosclerotic lesion below the inguinal ligament: duplex ultrasound or angiography (by computed tomography, magnetic resonance imaging (MRI) or digital subtraction) (3)

The resting systolic toe pressure (TP) is a measure of small arterial function in the periphery. TP is used in addition to the ankle-brachial index when screening for peripheral arterial disease (PAD) of the lower limb in those with diabetes, particularly in the presence of lower limb medial arterial calcification. It may be used as an adjunct assessment of lower limb vascular function and as a predictor of wound healing.(11) It is currently used as an adjunct to the ABI when screening for PAD of the lower limb in those with diabetes, particularly in the presence of ABI results exceeding 1.3 or 1.4. (11)

Low TP has also been demonstrated to be predictive of foot ulcer healing outcomes, with a TP of 1.1 mg/dl. A 1.0 ml/kg/hr saline infusion, 0.5 ml/kg/h in 1200 mg twice daily on the day before and the day of the procedure.

Angiography and PTA: -Both groins were prepared using an antiseptic solution, povodin iodine. All equipment was checked including monitors, connections, and stents. The patient lies in a supine position and the procedures were performed under local anesthesia, Xylocaine 2%.

- An ipsilateral antegrade femoral access following anatomical localization of the CFA and sonar-guided. We used 6Fr sheath.

- 10.000 IU of heparin was routinely administered intra-arterially at the beginning, and additional heparin was given if the procedure took more than an hour..
- A balloon was introduced after injecting the dye intra-arterial. Wires 0.014 fr, balloons 3 or 2.5 were used.

The balloon was inflated at a pressure around 8 mmHg for 2 minutes then proceed to the next lesion distally, and finally, inject dye to be sure that the vessel is patent. If the wire passed till the end of the vessel, we inflated the balloon retrograde and inject dye again.

We injected routinely nitroglycerin intra_arterial at the end of the procedure.

Finally, we did completion an angiogram intra-operative. At the end of the procedure, hemostasis was obtained by local compression, and patients were observed for postoperative complications.

Toe Systolic pressure(TP) was measured one day before angioplasty, and also the day after the procedure. TP data were pooled into three categories:

0–29 mmHg, 30–49 mmHg, and ≥ 50 mmHg.(O)we divided patients in 3 groups based on before and after BTK angioplasty TP.

Statistical Analyses: All statistical analyses were performed using SPSS version 18. Group-specific baseline characteristics are presented as percentages and continuous variables as mean SD. Group variables were compared using Pearson's chi-square test and For observed tables less than 5 we reported Fisher's Exact test. For continuous variables, a Shapiro-Wilk test was run to test the normality of the variables. Variables were then compared by analysis of variance, as the continuous variables in each group were normally distributed. Paired T-test was used to compare the continuous value of TP before and after in each case. A p-value < .05 was considered statistically significant.

RESULTS

Among 57 patients, 39(68/4%) were men and 18(31/6%) were women. Diabetic patients were 48(84/2%) and non-diabetics were 9 (15.8%). Six of them had ESRD (10.5%) and 51(89.5%) had no ESRD. The ESRD patients were those who had renal failure because of other causes, not diabetes. The mean age of diabetic patients was 68.81±9.01 and the mean age of non-diabetics was also 68.77±12.51.

There was no difference between the frequency of male and female in diabetic and non-diabetics with Fisher's Exact Test(Pvalue:1.00)

Table1 – Frequency of sex in 2 groups.

		Diabetes		Total
		no	yes	
sex	male	6(66.7%)	33(68.8%	39
	female	3(33.3%)	15(31.2%	18

The frequency of co-morbidities, smoking, and opium usage are listed in table 2.

	Yes/No	Frequency (percentage)	diabetic	nondiabetic	Pvalue
Cerebro vascular Accident	yes	6(10.5%)	6(12.5%)	0	0.57
	no	51(89.5%)	42(87.5%)	9(100%)	
Coronary Artery Disease	yes	25(43.9%)	25(52.1%)	0	0.003
	no	32(56.1%)	23(47.9%)	9(100%)	
Hypertension	yes	23(40.4%)	20(41.7%)	3(33.3%)	0.72
	no	34(59.6%)	28(58.3%)	6(66.7%)	
Opium	yes	6(10.5%)	4(8.3%)	2(22.2%)	0.23
	no	51(89.5%)	44(91.7%)	7(77.8%)	
Hyperlipidemia	yes	5(8.8%)	3(6.2%)	2(22.2%)	0.17
	no	52(91.2%)	45(93.8%)	7(77.8%)	
smoking	yes	12(21.1%)	10(20.8%)	2(22.2%)	1.00
	no	45(78.9%)	38(79.2%)	7(77.8%)	

As shown in Table 2, Diabetes was a risk factor for Coronary artery disease with OR=2.08 (95% CI:1.55-2.80).

There was no statistical difference between signs of patients in 2 groups(Fisher's Exact Test:0.75)

Table 3 – signs of critical limb ischemia in 2 groups

		Non-diabetic	Diabetic	
signs	ulcer	3(33.3%)	32(66.7%)	35
	gangrene	6(66.7%)	16(33.3%)	22
Total		9	48	57

We had 3 complications in these patients: one disecssion (2.1%) and one extravasation(2.1%) in diabetics and just one Extravasation in a nondiabetic group(11.1%).

The frequency of patients in each group of TP is listed in the below table divided by diabetic and non-diabetic patients.

Table 4- frequency of patients in each group of Toe pressure before and after angioplasty.

	TP Before Diabetic Group			TP After Diabetic Group		TP Before Non-Diabetic		TP After Non-Diabetic	
Toe Pressure (mmHg)		Frequency	%	Frequency	%	Frequency	%	Frequency	%
	0-29	30	62.5	23	47.9	3	33.3	0	0
	30-49	6	12.5	6	12.5	0		1	11.1
	>=50	11	22.9	18	37.5	6	66.7	8	88.9
	Total	47	97.9	47	97.9	9	100	9	100
Missing		1	2.1	1	2.1	-	-	-	-
Total		48	100.0		48	9	100	9	100

In Paired T-Test analysis we compared TP values of each patient before and after angioplasty and it was significant in both Diabetic and non-diabetic groups.(0.00 and 0.008 respectively). The mean of systolic toe pressure before angioplasty had no difference between the 2 groups (P-value: 0.139).

The mean of TP in non-diabetic patients was 42±31.94 and in diabetics was 25.61 and after angioplasty, the mean of toe pressure raised 44.3 in non-diabetics and 19.4 in diabetics, statistically different. (0.022)

Table 5 –Mean of systolic Toe pressure in diabetic and non-diabetic patients.

	No Diabetic group		diabetics		P value
	Mean	Std. Deviation	Mean	Std. deviation	
age	68.7778	12.51777	68.8125	9.01690	0.99
Toe pressure before angioplasty	42.0000	31.94918	25.6170	29.59917	0.13
Toe pressure after angioplasty	86.333	21.93	45.0213	45.04562	0.01
Toe pressure changes	44.33	38.22	19.40	27.26	0.022

The mean of toe pressure changes reduces as the patients' age rise, but there was no statistical difference between age groups.(Pvalue:0.22)

Table 6- mean of Toe pressure changes after angioplasty in age groups.

Age groups	Number	Mean	Std. deviation
50-59	11	29.40	42.57
60-69	19	24.78	22.96
70-79	17	28.82	34.87
80-89	10	5.60	11.80
total	57	23.41	30.32

DISCUSSION

Several clinical series have demonstrated that angioplasty alone can promote limb salvage in CLI patients with infrapopliteal disease with 12-month limb salvage rates as high as 75%. Although higher complexity tibial disease has been traditionally treated surgically, Schmidt et al. reported 95.6% limb salvage at 12 months for complicated (average length 184 mm with 64.9% occlusions) infrapopliteal disease. A recent meta-analysis showed that even with severe tibial disease and poor distal run-off, reasonable rates of limb salvage can be achieved with angioplasty alone. (14)

In Korea, Bae et al.analyzed 205 cases of endovascular recanalization for chronic severe critical limb ischemia and reported a technical success rate of 85%, major amputation rate of 2%, one-year limb salvage rate of 94.8%, and three-year limb salvage rate of 92.0%. Their limb salvage rate was >90% after appropriate IP-PTA, which emphasizes the importance of recanalization of at least one infrapopliteal artery that supplies blood directly to the lesion. (6)

Lopentalo et al. concluded that diabetes is an obvious risk factor in infragenicular atherosclerotic lesions.(15) Ferraresi et al. concluded that of the 634 patients with CLI (Rutherford 5and 6),431 (68%) had diabetes mellitus. (16) We had 84.2% diabetes in our patients.

Early reports on the effectiveness of revascularization in patients with diabetes and PAD were not encouraging and led some to suggest that diabetes was associated with a characteristic occlusive small-vessel arteriopathy, consequently leading to a nihilistic attitude towards revascularization.

In two studies that reported the outcomes of patients with diabetes and critical limb ischemia who were not revascularized, the limb salvage rate was 54% at 1 year (17-18).

Subsequent studies indicated that revascularization can have good results in patients with diabetes and an ischemic foot ulcer (19).

R.J.Hinchliffe, et.al declared in their systematic review in 2016, in most studies of the anatomical distribution pattern of the PAD, ankle-brachial pressure index, toe pressure, or transcutaneous oxygen tension measurements, wound characteristics were reported poorly, although prospective studies have shown the effect of these factors on healing or amputation rate. (20)

Ankle Brachial index is not accurate in diabetic patients so we decided to investigate systolic toe pressure changes after below-knee angioplasty in diabetic patients. Studies on the association between TP and patient outcomes are scarce. A few studies have demonstrated the predictive effect of TBI on cardiovascular mortality and morbidity, irrespective of the diabetic status of the patient.(21) In a Study, Wickström et al. designed, which included > 700 patients with TP measurements, a linear correlation between TP and TBI with cardiovascular and overall mortality were shown(22). The role of TBI in diagnosing PAD is indefinable, and criteria for stratifying normal versus pathological TBI remain ambiguous. Guidelines recommend < 0.70 as a cutoff, but this is not entirely evidence-based.(22) No data are confirming the utility of TBI in the early detection of PAD among diabetics. In a recent Dutch study, which included patients with an ABI <= 1.4, diabetes appeared to falsify ABI and TBI similarly. In their study, 7% of patients with a TBI>= 0.25 had a TP < 30 mmHg. There are some articles, used TP, TBI or ABI for detection of PAD but as we mentioned earlier, evidence about Toe pressure outcomes after BTK angioplasty are rare, especially in diabetic patients whom we can't rely on their ABIs.

One of our limitations was that we didn't follow patients after hospital discharge and a larger population and follow-up time are needed to know more about the usage of before and after TP to predict the success rate of angioplasty and limb salvage in diabetic patients. There was no statistical Effect of age on TP changes after angioplasty and it might be because of a small number of patients in some age groups and larger studies are needed.

Complications of Angioplasty: The complications of angioplasty are normally minor and rarely require surgical intervention. Gardiner et.al reviewed complications of angioplasties. The commonest complication occur at puncture site ,hematoma(4%) puncture site thrombosis (1%) and false aneurysm formation(1%). Complications at the angioplasty site are rare (8). we observed our patients for 24 hours after angioplasty and had 2 extravasations(3.5%) and one disecssion(1.8%).

Complications of tibial angioplasties have been documented in recent reports. In the Saab series, there were two groin hematomas out of17 angioplasties. Schwarten reported thrombosis 32 at the angioplasty site in four out of125cases. (8)

Bakal et al. reported three major complications out of 57 procedures, one death due to cardiac arrest and two puncture site hematomas (8).

CONCLUSION

In this observational study, we evaluated the effect of angioplasty on toe pressure of diabetic patients and compared them to non-diabetics, Although the mean age of both groups was the same we didn't match all risk factors. A larger study may need to compare TP changes in diabetic and normal patients.

REFERENCES

1. Carolina Dutra Queiroz Flumignan, Fábio Cabral Freitas Amaral, Ronald Luiz Gomes Flumignan,et al. Angioplasty and stenting for below the knee ulcers in diabetic patients: protocol for a systematic review. Syst Rev. 2018; 7: 228.
2. Hingorani A, LaMuraglia GM, Henke P, Meissner MH, Loretz L, Zinszer KM, et al. The management of diabetic foot: a

clinical practice guideline by the Society for Vascular Surgery in collaboration with the American Podiatric Medical Association and the Society for Vascular Medicine. J Vasc Surg. 2016;63(2 Suppl):3S–21S. doi: 10.1016/j.jvs.2015.10.003
3. HinchliffeRJ,BrownriggJRW,ApelqvistJ,BoykoEJ,FitridgeR,Mil lsJL,etal. IWGDF guidance on the diagnosis, prognosis and management of peripheral artery disease in patients with foot ulcers in diabetes. Diabetes MetabResRev.2016;32(Suppl1):37–44.
4. ReekersJA.The role of interventional radiology in the treatment of arterial diabetic foot disease.Cardio vasc Intervent Radiol.2016;39:1369–71.
5. RutherfordRB,BakerJD,ErnstC,JohnstonKW,PorterJM,AhnS,e tal. Recommended standards for reports dealing with lower extremity ischemia:
6. revisedversion.JVascSurg.1997;26:517–38.
7. Eui-Yong Jeon, Young Kwon Cho, Dae Young Yoon, Dae Jung Kim, and Jeong Joo Woo
8. Clinical outcome of angiosome-oriented infrapopliteal percutaneous transluminal angioplasty for isolated infrapopliteal lesions in patients with critical limb ischemia. Diagn Interv Radiol. 2016 Jan; 22(1): 52–58.
9. Todd R.VogelMD, MPHaRobin L.KrusePhDb. Risk factors for readmission after lower extremity procedures for peripheral artery disease. journal of Vascular Surgery
10. Volume 58, Issue 1, July 2013, Pages 90-97.e4
11. ME Edmonds, H. Walters . Angioplastyand the diabetic foot.VascularMedicineReview1995;6: 205-214
12. Caitlin W Hicks , Alireza Najafian , Alik Farber , Mahmoud B Malas , James H Black Matthew T Menard Christopher J Abularrage. Below-knee endovascular interventions have better outcomes compared to open bypass for patients with critical limb ischemia. Vascular Medicine
13. 2017, Vol. 22(1) 28 –34
14. *Marco Shaker & Marian Shehata. Role of balloon angioplasty in below the knee vessels treatment in diabetics. Open Journal of Clinical & Medical Case Reports. Volume 5 (2019)
15. Issue 12.
16. Peta Ellen Tehan, Alex Louise Barwick, Mathew Sebastian, and Vivienne Helaine Chuter. Diagnostic accuracy of resting systolic toe pressure for diagnosis of peripheral arterial disease in people with and without diabetes: a cross-sectional retrospective case-control study. J Foot Ankle Res. 2017; 10: 58.
17. Sonter J, Ho A, Chuter VH. The predictive capacity of toe blood pressure and the toe-brachial index for foot wound healing and amputation: a systematic review and meta-analysis. Wound Practice & Research. 2014;22(4):208–217. [Google Scholar]
18. Hinchliffe RJ, et al. IWGDF guidance on the diagnosis, prognosis and management of peripheral artery disease in patients with foot ulcers in diabetes. Diabetes Metab Res Rev. 2016;32(Suppl 1):37-44. [PubMed]
19. Arun K. Thukkani and Scott Kinlay. Endovascular Intervention for Peripheral Artery Disease. Circ Res. 2015 Apr 24; 116(9): 1599–1613.
20. Keeling A., Oife N., Khalid K.,Wang T., et al. Below Knee angioplasty in elderly patients: Predictors of major adverse clinical outcomes,European journal of Radiology.2009;49:213-218
21. Lepantalo,M. Apelqvist,J.,Setacci, C., Ricco ,J. B., De Donato ,et al. Chapter 5: diabetic foot.European Journal of Vascular and Endovascular Surgery. 2011;42: 60-74
22. LepäntaloM,MätzkeS.Outcome of unreconstructed chronic critical leg ischemia.
23. Eur J Vasc Endovasc Surg 1996; 11(2):153–7.
24. ElgzyriT,LarssonJ,ThörneJ,Eriksson KF,ApelqvistJ. Outcome of ischemic foot ulcer in diabetic patients who had no invasive vascular intervention. Eur J Vasc Endovasc Surg 2013; 46:110–7.
25. LoGerfoFW,CoffmanJD. Current concepts. Vascular and microvascular disease of the foot in diabetes. Implications for foot care. N Eng J Med 1984;311(25):1615–9.
26. R.J.Hinchliffe. J.R. W.Brownrigg G. Andros , J.Apelqvist, E. J. Boyko ,R.Fitridge ,J.L.Mills ,J.Reekers ,C.P.Shearman ,R.E.Zierler ,et al. Effectiveness of revascularization of the ulcerated foot in patients with diabetes and peripheral artery disease : a systematic review
27. Martín-Fuentes M, Herranz L, Saez-de-Ibarra L, Pallardo LF. Low toe-brachial pressure index predicts increased risk of recurrent cardiovascular disease in type 2 diabetes. Diabetes Care 2015;38(4):e53e4
28. E.WickströmaM.LaivuoribE.AroaR.T.SundcO.HauteroaM.Ven ermobJ.JalkanenaH.Hakovirtaa .Toe Pressure and Toe Brachial Index are Predictive of Cardiovascular Mortality, Overall Mortality, and Amputation Free Survival in Patients with Peripheral Artery Disease. European Journal of Vascular and Endovascular Surgery
29. Volume 53, Issue 5, May 2017, Pages 696-703