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Comparison of Clinical outcomes of Infragenicular Angioplasty between diabetic and non-diabetic patients with Peripheral Arterial Occlusive Disease

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Abstract

Background: Infragenicular angioplasty could salvage most of limbs under amputation impendence. We aim in our study to detect the results of infragenicular angioplasty in diabetic and non-diabetic patients with critical lower limb ischemia (CLI).

Patients and methods: Between April 2014 and May 2017,infragenicular angioplasty was carried out on 139 patients out of 154 patients (as 15 patients missed the follow up program or their data were lost) with CLI (Rutherford category 4,5 or 6) whom attended to The Vascular surgery Department of Qena University and Assiut University Hospitals. After obtaining informed written consent from all subjects, they were divided into diabetic group (n=62) and non-diabetic group (n=77).For all subjects pre-procedure, ankle brachial indexes (ABI) and computed tomography angiography (CTA) had been done. The percutaneous transluminal angioplasty (PTA) procedure was done alone or combined with stenting. The investigated outcomes comprised rest ABI, primary, secondary patency rates and finally limb-salvage rates 6, 12, 24 and 36 months after treatment.

Results: There were no significant differences between both groups in technical success rate (98.4 *vs.* 100%, P=0.133).Primary , secondary patency rates and limb salvage rates 6,12,24 and 36 months in both diabetic and non-diabetic groups were not significantly different (p value>0.001) The mean value of ankle brachial indexes was significantly increased after intervention (0.397 ± 0.125 versus 0.779 ± 0.137, t=-25.780, P<0.001) in diabetic group and (0.406 ± 0.101 versus 0.786 ± 0.121, t=-37.221, P<0.001) in non-diabetic group. Perioperative 30 day mortality was 0%. Major complications were groin hematoma in 7.3%, and formation of pseudo- aneurysms in 2.1% of subjects.

Conclusion: Infragenicular percutaneous angioplasty is a valuable option in CLI management with low risk of both morbidity and mortality. The efficiency and outcomes of interventional procedures in diabetic patients is similar to that in non-diabetics.

Keywords: Angioplasty; Critical limb ischemia; Diabetes; Infragenicular arteries

Introduction

Despite surgical bypass is considered the gold standard due to better anatomical and clinical durability compared to other revascularization methods for critical lower limb ischemia (CLI), [1-3] percutaneous transluminal angioplasty (PTA) in peripheral arterial occlusive disease (PAOD) is a valuable way of treating CLI, and has similar outcomes to those of bypass surgery [4,5].

Diabetes is a common event in PAOD patients and is increasing in its incidence [6] CLI patients with diabetes have a more bad prognosis than non-diabetic ones [7]. One adverse complication of PAOD is gangrene, which is responsible for nearly 50% of amputations in diabetic subjects in the Western world [8].

Although many literatures concerning diabetic CLI patients determined that infragenicular intervention in these patients may salvage many limbs under threat of amputation, these trials studied heterogeneous ischemia stages such as claudication, resting pain or tissue lesions and, in addition the most frequently managed arteries were the distal popliteal artery and the tibioperoneal trunk, with diameters more similar to those of above-knee than those of the smaller below-knee arteries [9-16].

In our study we aim to compare the outcomes of infragenicular angioplasty in a population of consecutive diabetic and non-diabetic patients hospitalized for CLI management.

Patients and Methods

Between April 2014 and May 2017 a retrospective study was carried out on 139 patients out of 154 patients (as 15 patients missed the follow up program or their data were lost) with CLI (Rutherford-Becker grades 17, 4, 5, or 6) whom have attended to the Vascular Surgery Department of Qena University Hospital and Assiut University Hospital and had been managed with infragenicular angioplasty. The patients were classified into 2 groups, the diabetic group (n=62) and the non-diabetic group (n=77). A written informed consent was taken from all subjects included in the study. The study was approved by the

Medical Ethical Committee of Qena University Hospital. Before procedure, rest ankle brachial indexes (ABI) measurement and computed tomography angiography (CTA) were done in all studied patients. Indications of procedure were disabling claudication or limb-threatening ischemia and lower extremity arterial lesions detected in CTA [17].

Diabetic patients enrolled in the study treated either by oral hypoglycemic or insulin therapy and had a casual plasma glucose concentration ≥ 200 mg/dl or fasting plasma glucose ≥ 126 mg/dl or 2-h plasma glucose ≥ 200 mg/dl during an oral glucose tolerance test [18]. End-stage renal disease patients were not recruited in the study since this particular condition is accompanied with worst results as extensive arterial calcification was detected in those particular patients.

Procedure

Before intervention, all patients received aspirin (150 mg, daily) and plavix (75 mg) twice daily then maintained indefinitely after angioplasty and for diabetic patients the best blood sugar control was achieved. Vascular access for infragenicular angioplasty was obtained by ipsilateral or contralateral femoral artery puncture. An antegrade approach was considerably used when there no combined lesions requiring proximal iliac or femoral angioplasty and in non-obese patients, due to better catheters & wires control and handling in cases of total occlusion. Procedures were done through a 5 F or 6 F introducer sheath (length 11-45 cm). Selective angiography was carried out to detect the lesions and for measurement of the extent of lesions via 4 F or 5 F angio catheter. Intravenous unfractionated heparin (5,000 units) was given to all patients before crossing the lesions. The lesions were crossed either transluminally or via subintimal access by variable set of hydrophilic guide wires (0.035, 0.018 or 0.014 inch).Guide wires were supported by 4 F or 5 F angled catheter. Infragenicular PTA was done with suitably sized noncompliant balloons (2.5-8.0 mm diameter) for the treated artery, with inflation duration ranging from 60 to 180 seconds at 6 to 15 atmosphere of pressure. Stent was deployed selectively for flow-limiting dissections and for > 30% residual stenosis.

Post procedure completion angiography was performed for assessment of distal run off condition and the presence or absence of residual stenosis. Technical success is dilatation of all treated lesions resulting in <30% residual stenosis with sufficient antegrade flow; suboptimal outcome is sluggish flow and/or residual stenosis 30-50% after repeated trials of dilatation. Primary clinical success is an improvement of at least one clinical category of Rutherford-Becker grading [17]. Primary patency is defined as permanent patency with no re-intervention whether angioplasty, surgery carried out on or at the edges of the treated lesions, or amputations. Limb salvage means prohibition of major amputation. Major amputation is either below or above the knee amputation but minor amputation is defined as transmetatarsal or toes amputations

Follow up

Patients were evaluated postintervention and then at 6-month intervals by clinical examination (distal pulses and existence or absence of claudication or rest pain) and by vascular laboratory tools (ABI and arterial duplex ultrasound).Patency was detected at first by duplex ultrasound of the treated arteries and secondarily by ABI and clinical picture. Loss of patency by duplex is determined as the existence of an occlusion or a restenosis accompanied with a velocity ratio of greater than 4:1 (relative to the segment proximal to the treated lesion) while PTA failure was defined as absence of patency by anatomic or hemodynamic measures with no efficient revascularization. Patency of arteries believed to be lost once occlusion or restenosis was detected in any of managed lesions.

Statistical analysis

All data were analyzed using SPSS version 15.0 .Continuous variables were described as means and standard deviations. Categorical variables were presented with percentages and frequencies. Student's t test and chi square test were used to estimate differences between groups in basic characters and ABI changes pre and post primary procedure. Patency both primary and secondary plus limb salvage rates were compared by log-rank basis. The difference was considered statistically significant at $p<0.001$.

Results

In the 139 studied patients, the two groups did not differ significantly in demographic characters and basic ABI (Table 1). Mean subject age was 64.7 ± 11.0 in diabetic group while it was 65.2 ± 9.8 in the non-diabetic group with 86 male patients (61.8%) and the rest 53 patients were females (38.2%).

The number of diabetic patients was 62 (44.6%) while non-diabetic patients were 77 (55.4%) with no significant difference between the 2 groups regarding age, sex nor diabetes as p value>0.001. Majority of patients had significant risk factors as smoking; hypertension and coronary artery disease with no difference either (Table 1).

Patient characters	Diabetic group (n=62)	Non diabetic group (n=77)	Test result	P value
Age	64.7 ± 11.0	65.2 ± 9.8	-0.308	>0.001(0.759)
Male	37(59.7%)	49(63.6%)	0.228	>0.001(0.633)
History of smoking	33(53.2%)	45(58.4%)	0.379	>0.001(0.538)
Hypertension	36(58.1%)	53(68.8%)	1.729	>0.001(0.189)
Coronary artery disease	19(30.6%)	21(27.3%)	0.191	>0.001(0.662)
Insulin treatment	45(72.6%)	0(0%)	Fisher's exact Test	<0.001(0.000) (significant)
Pre-intervention ABI	0.396 ± 0.125	0.406 ± 0.101	0.113	>0.001(0.910)

Site of lesion				
Iliac artery	26(23.2%)	32(23.7%)	0.002	>0.001
Femoral	51(45.5%)	61(45.2%)	0.202	
Popliteal	19(17%)	23(17%)	0.01	
Tibial	16(14.3%)	19(14.1%)	0.023	
Clinical symptoms				
Claudication			1.106	>0.001
Rest pain			0.091	
Gangrene or tissue loss			0.286	

Table 1: ABI: Ankle Brachial Index, P value<0.001 is considered significant.

The mean values of ABI were significantly increased after primary intervention (0.397 ± 0.125 versus 0.779 ± 0.137, t=-25.780, P<0.001) in diabetic group and (0.406 ± 0.101 versus 0.786 ± 0.121, t=-37.221, P< 0.001) in non-diabetic group.

Primary and secondary patency rates for all procedures and limb-salvage rates for all subjects (Table 2). The differences between two groups regarding these variables were not significant (P>0.001).

Eighty three percutaneous procedures (32 PTA alone, 51 PTA plus Stenting) comprised 62 primary interventions and 21 re-interventions were carried out in 62 diabetic patients while in 77 non-diabetic patients 103 PTA (39 PTA alone, 64 PTA plus stenting) comprised 77 primary procedures and 26 re-interventions were carried out.

All lesions were categorized by site: 58 were iliac lesions (23.5%), 112 were femoral lesions (45.3%) (Figure 1), 42 were popliteal lesions (17.0%) while tibial lesions were 35 (14.2%) (Figure 2). 6, 12, 24 & 36 months 1ry &2ry patency rates for different lesions in either groups are listed in Tables 3 and 4.

		6 months	12 months	24 months	36 months	P Value
1ry patency rate	Diabetic (n=62)	88.7% ± 4.0%	62.3% ± 6.6%	55.3% ± 7.0%	46.5% ± 7.5%	> 0.001
	Non(n=77)	90.9% ± 3.3%	71.8% ± 5.4%	71.8% ± 5.4%	60.9% ± 6.2%	
2ry patency rate	Diabetic	93.5% ± 3.1%	82.3% ± 5.1%	70.8% ± 6.5%	65.7% ± 7.0%	
	Non diabetic	96.1% ± 2.2%	91.6% ± 3.3%	82.7% ± 4.8%	71.8% ± 6.2%	
Limb salvage Rate	Diabetic	95.2% ± 2.7%	87.7% ± 4.4%	85.5% ± 4.8%	81.9% ± 5.8%	
	Non diabetic	97.4% ± 1.8%	94.4% ± 2.7%	90.6% ± 3.7%	83.1% ± 5.4%	

Table 2: The results of 1ry, 2ry patency rates and limb-salvage rates for all patients 1ry, primary, 2ry, secondary.

Lesion	Patency rate	6 months	12 months	24 months	36 months
Iliac (n=26)	1ry	100%	87.5% ± 6.8%	82.6% ± 7.9%	75.1% ± 10.2%
	2ry	100%	95.8% ± 4.1%	90.8% ± 6.2%	82.5% ± 9.7%
Femoral (n=51)	1ry	88.2% ± 4.5%	73.2% ± 6.4%	67.7% ± 7%	58.6% ± 8.6%
	2ry	94.1% ± 3.3%	89.8% ± 4.3%	84.5% ± 5.5%	73.2% ± 7.8%
Popliteal (n=19)	1ry	78.9% ± 9.4%	42.1% ± 11.3%	42.1% ± 11.3%	42.1% ± 11.3%
	2ry	84.2% ± 8.4%	73.7% ± 10.1%	62.7% ± 11.2%	55.8% ± 11.9%
Tibials (n=16)	1ry	75.0% ± 10.8%	53.8% ± 12.9%	30.8% ± 12.5%	30.8% ± 12.5%

	2ry	87.5% ± 8.3%	67.3% ± 12%	43.6% ± 13.6%	43.6% ± 13.6%

Table 3: The results of primary and secondary patency rates for variable lesions in diabetic group.

Lesion	Patency rate	6 months	12 months	24 months	36 months
Iliac (n=32)	1ry	96.9% ± 3.1%	86.5% ± 6.3%	77.5% ± 8.3%	71.1% ± 9.8%
	2ry	100% ± 0%	100% ± 0%	90.3% ± 6.5%	83% ± 5.7%
Femoral (n=61)	1ry	93.4% ± 3.2%	80.9% ± 5.2%	73.9% ± 6.1%	52.8% ± 8.6%
	2ry	95.1% ± 2.8%	93.3% ± 3.2%	88.7% ± 4.4%	83% ± 5.7%
Popliteal (n=23)	1ry	82.6% ± 7.9%	63.2% ± 10.4%	47.7% ± 11.1%	39.8% ± 11.7%
	2ry	100% ± 0%	90.5% ± 6.4%	75.9% ± 9.4%	56.9% ± 11.8%
Tibials (n=19)	1ry	73.7% ± 10.1%	55.3% ± 11.9%	34.5% ± 12%	34.5% ± 12%
	2ry	89.5% ± 7%	71.6 ± 10.8%	57.8% ± 12.4%	38.6% ± 13.9%

Table 4: The results of 1ry & 2ry patency rates for different lesions in non-diabetic group.

Figure 1a-c: Angiography shows totally occluded superficial femoral artery. **d-f:** End result after balloon angioplasty.

Interventional success rate in diabetic group is 98.4% (61/62). Wire failure to cross a total occlusion had happened in only one patient (1.6%) and clinically the patient was not deteriorating by the trial. Later on that subject had undergone a distal bypass with successful outcome while the procedural success rate in non-diabetic group is 100% (77/77). Periprocedure 30 day mortality was 0%. Some access complications had happened and comprised groin hematoma (7.3% of subjects) and pseudo aneurysms (2.1% of subjects), both of them were managed conservatively.

The mean time of follow up in all subjects was 26.2 ± 15.3 months (6-48 months). After determination of restenosis 47 subjects has approved re-intervention with 80.9% success outcome (38/47). During the follow up duration the total rate of PTA re-intervention was 33.8% (47/139). After failure of percutaneous therapy or restenosis, 21 patients with limb-threatening underwent surgical bypass for limb-salvage with success rate 76.2% (16/21) while in 19 subjects lower limb major amputations had been performed.

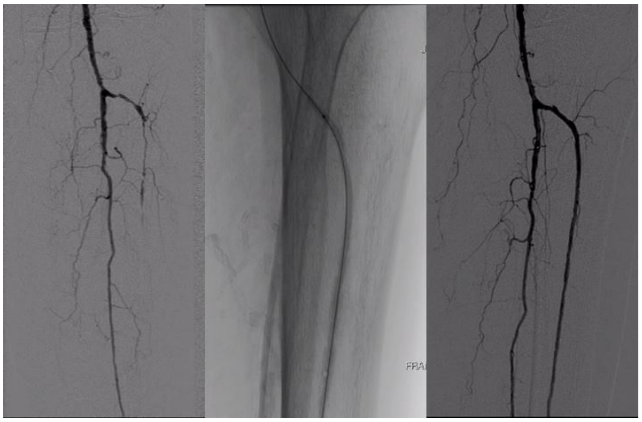

Figure 2: Transluminal infragenicular angioplasty of the anterior tibial artery.

Discussion

Despite that bypass surgery using the below ankle outflow vessels should be deemed as the basic management in CLI patients with

infragenicular arterial disease [19] this demands a good vein conduit and one patent foot artery at least and is accompanied with significant perioperative death, postsurgical complications, myocardial ischemia, and even redo surgery for graft thrombosis [20].

CLI and its serious complications as gangrene are more likely to occur in diabetics with higher morbidity and mortality than non-diabetics [21,22]. Moreover, diabetes is the potential ascertained factor of failure of graft failure in CLI patients [23].

For these previous causes, infragenicular angioplasty is nowadays suggested to be the primary management of CLI in diabetic subjects [5,9,13-15].

As a result of small size and length of the treated arteries, infragenicular angioplasty had been accused by a high restenosis rate; moreover, it is still vague whether the clinical success of infragenicular angioplasty is a result of technical success alone [24-27]. The technical success rate in our study was 98.4% in diabetic group and 100% in non-diabetic group. Hyeon et al [28], showed that no significant differences between both groups in the technical success rate (78% of diabetic vs. 84% in non-diabetic P>0.001) as well.

A former study investigated the efficacy of PTA as the first-choice revascularization maneuver in CLI patients with diabetes [5]. It declared that in 1.7% of subjects major amputations have been performed; the 5-year primary patency was 88% while 5-year survival was 74%. That study, anyhow, investigated a heterogeneous treated arteries including iliac and superficial femoral arteries inspite of being a prospective study. A contemporary retrospective study analyzed the long-term results post infragenicular angioplasty in CLI diabetic patients [29] and it declared that the limb salvage rate was 93%, subjects that have undergone minor amputation were 64% while mortality rate was 9% after a mean follow up duration of 1,048 days. While in our study PTA for limb-threatening ischemia with or without diabetes showed that primary patency rates at 36 months of 46.5% and 60.9% respectively. But, secondary patency rates were more feasible at 65.7% and 71.8%, and more remarkably, limb salvages rates were 81.9% and 83.1% at 36 months. The mortality and major morbidity in our subjects managed for limb-threatening ischemia with PTA was only 0 and 8.1%, respectively, in comparison with routine mortalities and morbidities of 5% and 30% for operative bypass [30].

Regarding multi-segment arterial lesions in CLI subjects, It is recognized that PTA was an effective and functional therapeutic alternative for short iliac arterial stenosis however the long term outcomes in complicated iliac lesions like long occlusions were relatively low. The 3- year primary patency rates in PTA group alone were less than 60% [31,32] ; while primary patency rates in PTA plus stenting group reached up to 90% [33-35]. Bosch and colleagues [36] found that the technical success rate of iliac angioplasty plus stenting was higher than that in PTA group alone but without statistically significant difference. In our subjects, 1and 3-year primary patency rate of iliac lesions in diabetic group and non-diabetic group were 87.5%, 75.1% and 86.5%, 71.1%, in order. Bakken and colleagues [37] declared that the clinical results of femoral angioplasty in diabetics were preferable than those of non-diabetics. In our work, 1, 3 years primary patency rate for femoral angioplasty in diabetic and non-diabetic groups were nearly comparable (73.2%, 58.6% and 80.9%, 52.8%).

With respect to femoral stenting and its role in PAOD management, a controversy still present is concerning that issue. In one study [38] which comprised 453 patients who have been undergone femoropopliteal PTA alone and 481 patients who have been undergone femoropopliteal angioplasty plus stenting, the 1-year 1ry patency rates post PTA alone ranged from 45% to 84.2% and at 2 years it fluctuated from 25% to 77.2%, the 1-year 1ry patency rates PTA plus stenting group fluctuating from 63% to 90%, and 2-year 1ry patency extending from 46% to 87%.

In 73 subjects with mean 8 cm length femoral lesion, restenosis rates in the PTA plus stenting and PTA alone groups were 2.9% vs. 18.9%, 18.2% vs. 50.0%, and 34.4% vs. 61.1% at 3, 6, and 12 months as detected by duplex scan [39]. Perrio & colleagues [40] declared that 1 year femoral artery 1ry patency rates were 57% in PTA plus stenting group versus 53% in PTA alone group.

Kougias & colleagues [41] found that femoral artery 1ry patency for subintimal angioplasty alone and subintimal angioplasty plus covered stent deployment groups at 1 year was 28% vs. 75%, while 2ry patency was 37% vs. 84%. However in other study by Schmieder & colleagues [42] in the patients underwent subintimal angioplasty of the femoral and popliteal arteries, one-year 1ry and 2ry patency for angioplasty plus stenting group versus angioplasty alone group was 50% vs. 45% and 70% vs. 78%.

The management of infragenicular PAOD remains a clinical dilemma for vascular surgeons and interventionists. PAOD in diabetics is presented by long, distal & multiple calcified lesions with a higher proportion of occlusions with respect to stenosis [7,43]. The major hindrance to recanalization is the total calcified arterial occlusion, which does not allow balloon catheter crossing of the lesion [5].

Romiti et al. [44] declared that the immediate technical success rate of infragenicular PTA was 89%. After 12 & 36 months 1ry patency,2 ry patency and limb salvage rates were 77.4% ,48.6%, 83.3% and 62.9%, 93.4% and 82.4%, respectively.

Lejay et al. [45] found that the infragenicular angioplasty 1ry patency & limb salvage rates at 12 months were 60% and 85%, respectively. In our subjects, 6 & 12 months 1ry patency rate for tibial lesions in diabetic or non-diabetic groups were 75%, 53.8% and 73.7%, 55.3%. The result was lower than the results in other studies and this could be explained by the fact that 26 subjects out of 35 tibial lesions patients (26/35) in the study were suffered from proximal arterial occlusive lesions as well.

Moreover, the consequence of diabetics with PAOD could be ameliorated by taking cilostazol to reduce high sensitivity C-reactive protein levels and the soluble form of the CD40 ligand and to elevate the level of adiponectin, hence hindering the atherogenesis and chronic inflammation progression [46]. Furthermore, a current study declared that prostaglandin E1 in lipid microspheres enhanced walking ability and

Life quality as self-estimated by PAOD patients [47]. Besides, supervised training exercise enhanced cardiovascular mortality and morbidity in PAOD patients, which recommends that training exercise, could be deemed as a secondary prevention policy for those subjects [48].

However, we did not investigate the differences of technical and/or clinical outcomes vs. presence of medication and/or rehabilitation program and it is not the aim of our work.

Limitations of the Study

First, this was a retrospective study from two centers only so multicenter studies should be recommended. Also, applying of the current results to most CLI subjects has limited veracity as a result of small sample size of the study.

Second, we did not carry out follow-up angiography or utilize other imaging options for investigating the long-term patency in asymptomatic subjects.

Third, the efficiency of proximal PTA in cases requiring both proximal and distal angioplasty could not be recognized from that in distal angioplasty solely.

Finally, the follow-up period was quite not long enough so it could not sufficiently clarify the long term patency of PTA for PAOD, so further long term prospective studies should be recommended.

Conclusion

Percutaneous angioplasty nowadays is considered as a valuable substitute to open surgical bypass for CLI patients with a low risk of both morbidity and mortality. It does not prohibit necessary surgical revascularization and therefore should beholden as the favorable treatment for chronic lower extremity ischemia. The efficiency and outcomes of interventional procedures in diabetic patients is similar to that in non-diabetics.

Conflict of Interest

None of the authors have any conflicts of interest related to this study.

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