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Experience of Diabetic Foot Management and Frequency of Limb Salvage at a Tertiary Care Hospital in Pakistan

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Abstract

In developing country such as Pakistan the number of diabetic patients is increasing due to sedentary life style, obesity, urbanization and complications of diabetes like Diabetic Foot Ulcer (DFU) are also on a rise. Pakistan is ranked seven in the world of having largest population of diabetes in Pakistan with prevalence of 7.6% to 11% in adults 34, 35. The prevalence of PAD in Pakistani diabetic patients is 31.6% with amputation risk of 16% which is a significant number of cases that should be diagnosed and treated early for limb salvage 36, 37. A vascular surgery service in Pakistan is deficient with only handful of qualified surgeons and trainers. Till date there is no study on the ischemic complications of diabetic foot in Pakistan and their treatment outcomes. We present our data of 388 patients treated in our hospital with ischemic diabetic foot ulcer.

Objective: To describe the outcome of patients treated for diabetic foot with multidisciplinary approach in a tertiary care unit and to determine limb salvage rate in those patients having ischemic complications of diabetic foot.

Methodology: A retrospective study conducted in a tertiary care hospital, from January 2015 to June 2020. Data was collected using electronic medical record in SIH. Inclusion criteria were diabetic patients >18 years old with foot ulcer while, those less than 18 years, and having autoimmune disease were excluded from the study. Three hundred and eighty-eight diabetics (type 1 & type 2) were included in the study. The data was collected and analyzed in SPSS 23. P value of <0.05 was considered significant.

Results: Out of total 1,127 patients analyzed only 388 patients were included in our study. 195 of these patients had mild PAD (Peripheral arterial disease) who were treated with daily dressing and debridement only. Remaining 193 patients had significant PAD. 97 of these patients underwent angioplasty and 96 underwent surgical bypass. 16 patients underwent angioplasty and stenting of iliac vessels. Superficial femoral artery angioplasty was performed in 13 patients and below-knee balloon angioplasty was performed in 55 cases without use of stents. Good 1-year patency rates were achieved in proximal lesions 82% as compared to distal lesions 66%. Femoral to popliteal bypass was performed in 71 patients and femoral to distal bypass in 25 patients. Limb salvage rate in the angioplasty group was 85% while in the surgical bypass group was 96% after 01 year follow up.

Conclusion: Good patency and limb salvage rates can be achieved with early detection and treatment of ischemic diabetic foot. We need large randomized control trials to search for the best available treatment options for diabetic patients in Pakistan.

Keywords: Diabetes mellitus; Foot ulceration; Amputation; Angioplasty; Revascularization; Diabetic ischemic foot; Ischemia

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Introduction

WHO defines diabetes as chronic, metabolic disease characterized by elevated levels of blood glucose (or blood sugar), which leads over time to serious damage to the heart, blood vessels, eyes, kidneys, and nerves. About 422 million people worldwide were living with diabetes in 2014 and it is a major cause of amputation due to non-healing foot ulcers with infection and neurovascular involvement. 0 Prevalence of diabetes in Pakistan is 8.6% [1].

Diabetic Foot Ulcer (DFU) is a major health problem. It defined as the presence of full-thickness lesion distal to the ankle [2]. Its prevalence worldwide is 6.3% with 5.5% in Asia and 5.1% in Europe. It is more common with type 2 diabetes [3]. Besides financial burden it is responsible for 70% of non-traumatic amputations in the western world [4]. Diabetic foot is also common in Pakistan with

prevalence of 4% and 10%, and the amputation rate following foot ulceration is 8% to 21% [5].

Risk factors for diabetic foot ulcer include peripheral vascular disease, peripheral neuropathy, duration of diabetes mellitus, high levels of HbA1C [6,7]. Risk factors for developing DFU due to Peripheral Arterial Disease (PAD) was 20% and regarding Diabetic Peripheral Neuropathy (DPN) was 82% [8].

PAD in diabetic patients is diffuse and most severe in distal foot arteries. Ischemic lower limb disease in diabetes either can be due to atherosclerosis or by medial arterial calcification occluding the arteries rather than stenosis [9]. Improving blood supply in ischemic diabetic foot is essential part of diabetic foot management in addition to wound care and control of infection. Bypass graft surgery and Percutaneous Transluminal Angioplasty (PTA) are two options used to improve tissue perfusion of ischemic diabetic feet.

There is no study conducted in Pakistan involving the management of diabetic foot with ischemic complications involving the use of PTA and bypass surgery as treatment options. Our study includes above mention modalities with wound care and infection control to determine the incidence, risk factors and success of management of diabetic foot with ischemic complications.

Methodology

A retrospective analysis of diabetic patients presenting to vascular clinic from January 01st, 2015 till June 30th, 2020 was performed using SPSS 21 software. All patients between ages of 18 to 90 years having ulcer on foot and absent pulses in the foot were included in the study. All non-diabetic patients presenting with foot ulcer, having other causes of neuropathy were excluded from the study. All diabetic patients having only neuropathic foot ulcer were also excluded from the study.

A total of 1,127 patient records were reviewed and after applying our inclusion criteria 388 patients were included in our study. All patients had detailed history and physical examination taken and foot ulcers were classified according to Wagner's and University of Texas classifications (Table 1 and 2). Written consent was taken from all patients. All the patients had their Ankle Brachial Index (ABPI) checked. Patients with vascular compromise either having ABPI of <0.7 or >1.4, signs of ischemia or rest pain had vascular imaging followed by MDT discussion. Vascular investigations consisted of CT Angiography (CTA), MR Angiography (MRA) in renal patients having high creatinine, and 05 patients had CO2 angiography done due to renal failure. Conventional angiography was performed in those patients undergoing endovascular treatment. Our MDT consisting of a vascular surgeons and interventional radiologists planned vascular interventions in the form of angioplasty, surgical bypass or combination of both with or without wound debridement. Those having signs of infections had an empirical antibiotic therapy with correction of blood supply if needed and eventually debridement. All the patients had their follow-ups at 1 week, 6 weeks and 3 months, 6 months and 1 year. All the data was collected and analyzed in spss 21.

Results

Out of total 1127 patients analyzed 664 (58.9%) patients had neuropathic diabetic foot ulcers with palpable pulses on examination. These patients were excluded from our study.463 patients who were ischemic or neuro-ischemicon examination were further analyzed

Table 1: Frequency table.

Wagners Grade			
		Frequency	Percent
Valid	0	49	4.3
	1	36	3.2
	2	468	41.5
	3	370	32.8
	4	188	16.7
	5	16	1.4
	Total	1127	100

Table 2: University of Texas grade.

University Of Texas Grade			
		Frequency	Percent
Valid	0C	251	22.2
	1A	4	0.3
	1C	271	24
	1D	18	1.6
	2B	38	3.37
	2C	99	8.8
	2D	282	25
	3C	93	8.2
	3D	71	6.3
	Total	1127	100

Table 3: Distribution of diabetic foot patients.

Parameters	
Total number of cases	463
Age (mean ± SD)	55.52±10.6 years
Gender	
Male n (%)	55.70%
Female n (%)	44.20%
Duration of diabetes (mean ± SD)	8.57 ±6.36 years
BMI (mean ± SD)	29.43±5.81
HbA1c % (mean ± SD)	8.5%±1.8%
Peripheral Arterial Disease(PAD)	21
Peripheral Arterial Disease + Peripheral Neuropathy (PN)	78.9
Foot ulcers	95.5% (n=1077)
Charcot foot	0.35% (n=4)

(Table 3). 75 (6.6%) patients had infected gangrenous lower limb on presentation that were unsalvageable and had to undergo major amputation (above or below knee amputation). 81 (20.8%) of the remaining patients had pure Peripheral Arterial Disease (PAD) while 307 (78.9%) had mixed peripheral neuropathy and PAD. Treatment of these patients with PAD was divided between angioplasty with or without debridement and surgical treatment including bypass with or with debridement. Debridement included removal of dead tissue with or without minor amputation of toes or phalanges. 55.7% of the patients were males while 44.2% were females with mean duration of diabetes of 8.57 years (Table 3). 47.1% were smokers, 43.5% were hypertensive and 55.5% had ischemic heart disease (Table 4). 195 (50.2%) patients had mild PAD (no significant disease found on CTA

Table 4: Risk factor distribution.

Risk factors	Frequency
Age > 60y	52%
Smoker	47.10%
Hypertension	43.50%
Ischemic heart disease	55.50%
Diabetes mellitus type II	79.30%
Diabetes mellitus type I	20.70%
Antiplatelets	55.10%
Statins	68.10%

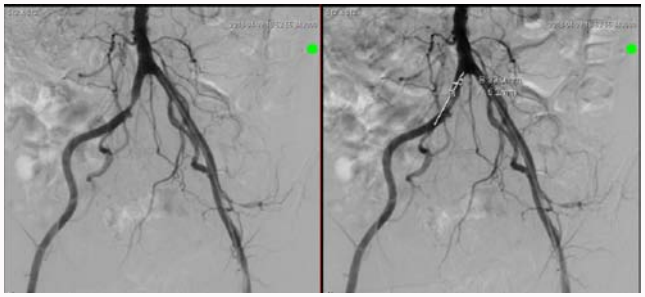

Figure 1: Left common iliac stenosis.

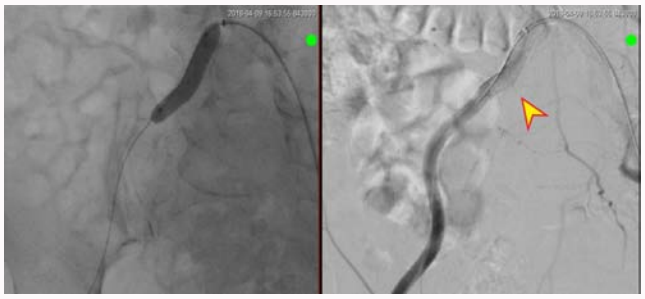

Figure 2: Ballooning and stenting (arrow) in the same patient. Stent used was 8 mm × 40 mm Balloon mounted Stent (Cook).

or duplex ultrasound) and were treated with debridement/minor amputation with regular dressing of the wound.

193 (49.7%) patients had moderate to severe PAD who underwent surgical or radiological interventions (Table 4). 97 (50.25%) of these patients underwent endovascular treatment with or without debridement of the wound (Figures 1-4). 16 (16.4%) patients underwent angioplasty and stenting of iliac vessels. Superficial femoral artery angioplasty was performed in 13 (13.4%) patients and below knee balloon angioplasty was performed in 55 (56.7%) cases without use of stents. Combined above knee and below knee angioplasties was performed in 8 (8.2%) cases. Good 1-year patency rates were achieved in proximal lesions 82% as compared to distal lesions 66%. None of the patients had any complication at the time of intervention. Two patients had uncontrolled bleeding from access site in recovery room in whom surgical repair of the femoral artery pseudo aneurysm was performed. One patient who had iliac angioplasty and stenting underwent successful repeat angioplasty after one year due to stenosis at bifurcation of iliac vessel. Four patients who previously underwent angioplasties of femoral or popliteal vessels underwent supra genicular fem pop bypass in 3 and fem distal bypass in one patient. Nineteen patients who previously had below knee angioplasties

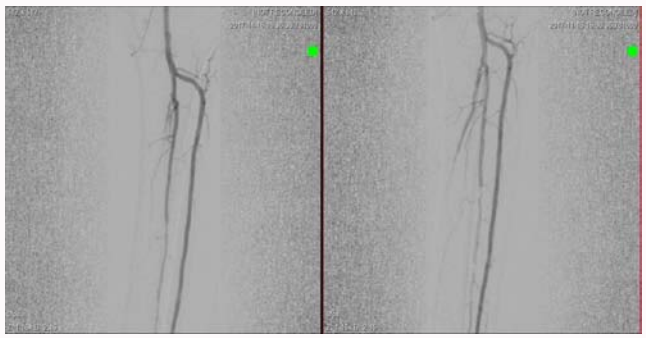

Figure 3: Successful angioplasty of the peroneal artery with a 0.018 inch wire & 2.5 to 2.0 mm × 210 mm (eV3 Nanocross) balloon.

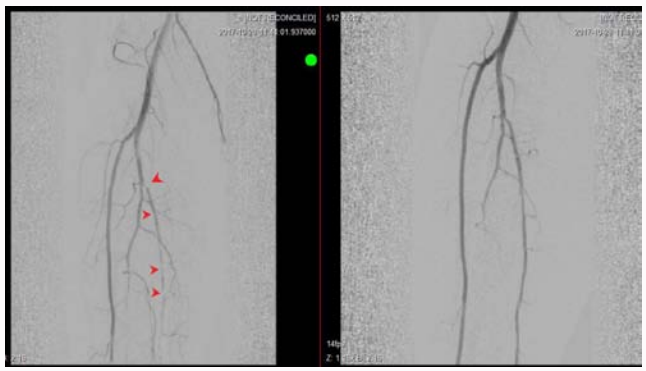

Figure 4: Successful angioplasty of posterior tibialartery. (Arrows show multiple stenosis).

Table 5: Presenting complains of different patients.

Presentation	Frequency
Claudication	99.1
Rest Pain	64.1
Gangrene	53.9

Table 6: Treatment summary.

Treatment Options	Frequency
Angioplasty ± debridement	97
Iliac angioplasty and stenting	16
Femoral angioplasty	13
Popliteal angioplasty	5
Below knee angioplasty	55
Anterior Tibial Artery (ATA)	28
Posterior Tibial Artery (PTA)	10
Peroneal artery	17
Surgical bypass ± debridement	96
Fem-pop bypass	71
Fem-distal bypass	25
Combined above/below knee angioplasties	8
Combined angioplasty and bypass procedure	5
Minor amputations	195
Major amputations	75
Below knee amputations	45
Above knee amputations	30
Debridement	664

Table 7: Patency rates of surgical options.

	FEM POP e Reversed GSV	FEM POP e graft	FEM DISTAL e GSV
Primary patency	93.90%	60%	80%

Table 8: Patency rates of endovascular option.

	Iliac angioplasty + stenting	Fem pop Angioplasty + stenting	Below knee Angioplasty alone
Primary patency	93.70%	77.70%	65.40%

underwent repeat angioplasties which was successful in 4 patients only. Fifteen patients had diffuse atherosclerotic disease which was not amendable to further endovascular intervention.

96 (49.7%) patients underwent surgical bypass with femoral to popliteal bypass in 71 patients and femoral to distal bypass in 25 patients. Reversed great saphenous vein was used as the conduit in 86 (89.5%) cases undergoing fem-pop or fem-distal bypass while ePTFE graft were used in 5 (7%) of patients with unsuitable or unavailable vein for fem-pop bypass. Patency rates were better with great saphenous vein grafts versus ePTFE grafts in both above knee and below knee bypasses. Patency rates were also better in more proximal lesions 91% in above knee bypasses versus 85 % in below knee bypasses. Four patients needed revision of fem-pop bypass after 1 year. Two patients who underwent fem-pop bypass using ePTFE graft developed graft thrombosis and their bypass was revised. Five patients with fem-distal bypass were revised in one-year time. One patient from fem-pop vein graft, 2 patients from fem-pop ePTFE graft and 1 patient from fem-distal bypass underwent major amputations in follow up after 01 and 02 years' time. Limb salvage rate in the angioplasty group was 85.4% while in the surgical bypass group was 95.8%.

Discussion

Diabetic foot ulcer is a full thickness wound through epidermis and dermis involving foot below the ankle characterized by delayed healing [14]. 15% of diabetic patients will develop foot ulcer in their life time and 14% to 24% of these will require an amputation but 85% of these amputations can be prevented by early detection and surgical or radiological intervention [15,16].

In diabetic patients the most common cause of hospitalization is diabetic foot ulcer [16]. According to a systemic review by Thorud et al. [7] the 5-year mortality rate was 53% to 100% among diabetic foot patients with any amputation, and in patients with major amputations, ranging from 52% to 80%. Mortality after below-the-knee amputation was from 40% to 82% and after above-the-knee amputation from 40% to 90%. Amputation further adds to the socioeconomic burden with high mortality rate and psychological issues [7].

The pathophysiology of diabetic foot ulcer is multifactorial. One factor is peripheral neuropathy which cause loss of protective sensation and muscle coordination leading to unnoticed repeated foot trauma and increased mechanical stress [17]. Another factor is macrovascular and microvascular angiopathies contributing to delay wound healing. According to Magdy et al. [9] 86.7% of patients had neuropathic DFUs, 11.1% of them had ischemic DFUs and 2.2% had neuro-ischemic DFUs [9-18].

According to International Working Group on the Diabetic Foot guidelines when the ankle pressure is below 50 mmHg or the Ankle Brachial Index (ABI) is less than 0.5 urgent vascular intervention should be considered [19]. Any vascular intervention should be preceded by detail vascular mapping and discussion in MDT to find the best possible solution of individual cases. Peripheral Arterial Disease (PAD) is four times more common in diabetic patients with tibial and peroneal arteries most commonly involved [20,21]. Detailed history and examination is an important step in diagnosing the case. Signs and symptoms in these patients mainly consist of pain on walking and relief after rest, painful arch of the foot at rest especially at night, absent distal pulses, shiny skin of the legs with loss of hair and pallor on elevating the foot. Transcutaneous oxygen measurement, the Ankle-Brachial Index (ABI) and the absolute toe systolic pressure are some of the noninvasive test that can be performed during examination [22-24].

Duplex Ultrasonography (US) is safe, inexpensive, and accurate but operator dependent. It is mainly used for screening and surveillance purpose. It uses gray scale B mode and pulses wave Doppler for structural and functional properties of the vessel. The most common criteria used for the diagnosing a significant stenosis in the vessel is the Peak Systolic Velocity (PSV) ratio more than 2 across the stenosis with peak systolic velocity of more than 200 cm/s. This modality can be used for aortoiliac and femoropopliteal vessels using color duplex but studying vessels below knee is difficult, time consuming and needs expertise [25-27].

Computed Tomography Angiography (CTA) is the best diagnostic modality in our setup. CTA has faster scan time than MRA (Magnetic resonance angiography) with high spatial resolution and better for in-stent restenosis however it uses iodinated contrast agents that has limited it used in renal patients. There is also concern for exposure to ionizing radiation especially in young patients. In contrast MRA avoids radiation exposure, gadolinium enhanced and non-contrast approaches available but there is low risk of nephrogenic systemic fibrosis in advanced renal disease patients. Diabetic patients have heavily calcified vessels that can limit use of US and CTA. In these patients MRA is the investigation of choice [28].

DFUs are most commonly of neuroischemic variety on a background of vascular disease. The average time of healing of this kind of ulcer is 3 months (2 to 7) and 50% of these ulcers will heal without any vascular intervention [29,30]. But for the other 50% vascular intervention is necessary with the primary goal of limb salvage. According to a systemic review by Hinchliffe et al. [31] limb salvage rate was 80% to 85% and ulcer healing rate was 60% [31].

Vascular interventions are indicated in patients with reconstructible arterial pathology having unresolving pain at rest, non-healing chronic foot ulcers or ischemic toes with signs of critical limb ischemia. Surgical bypass has better long term patency rates than angioplasty but surgical intervention is tailored to individual patient needs. A study reports patency rate of 73% after popliteal-tibial bypass with limb salvage of 87% [32]. Another study reports primary patency of 46% and limb salvage 0f 84% after tibial angioplasty [33]. Sik et al. [11] study concluded the improved perfusion rates after PTA during first 4 weeks in ischemic diabetic foot [11]. Chang et al. [12] showed improved early and long term results with combining free tissue transfer (free flap) with angioplasty in these patients [12].

In developing country such as Pakistan the numbers of diabetic foot ulcers are increasing due to sedentary life style, obesity and as a result of urbanization. Pakistan is ranked seven in the world of having largest population of diabetes in Pakistan with prevalence of 7.6% to 11% in adults [34,35]. The prevalence of PAD in Pakistani diabetic patients is 31.6% which is a significant number of cases that should be diagnosed and treated early for limb salvage [36,37]. Vascular

surgery services in Pakistan is deficient with only handful of qualified surgeons and trainers. There is still no separate complete vascular unit in Pakistan who is delivering specialist endovascular services and training to meet the increasing demand in the country. We as a tertiary care hospital in Islamabad in collaboration with a hospital in Karachi are emerging as vascular training centers but there are still lack of resources and poor volume of cases due to low socioeconomic conditions of the patients and decrease referral from rural centers. Vascular surgery is an emerging specialty in Pakistan with the hope that a separate vascular center will exist in the country in every province providing its specialist services.

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