# Revascularization in diabetic foot ulcer and outcome

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# ABSTRACT

**Background & objective:** Diabetes is a major public health problem regionally and globally. The prevalence of diabetes and pre-diabetes in general population of Bangladesh is high. Diabetic foot ulcer is a distressing complication for the patients and his family with lifetime risk for foot ulcers in people with diabetes is very high, which may lead to long time morbidity and loss of limb. The present study was intended to determine the outcome of ongoing treatment modalities in diabetic foot ulcers.

**Methods:** This prospective interventional study was done in Combined Military Hospital Dhaka between Jan 2017 to Jan 2020. During the period a total of 267 diabetic patients with foot ulcer reported to the Cardiovascular Surgery Department. Of them 192 patients were suspected to have ischaemic ulcer and included in the study. Revascularization was done by peripheral angiogram and angioplasty or by open surgery. The outcome variables were ulcer healing, minor and major amputations.

**Result:** Revascularization was done in 141(76.2%) patients – percutaneous angioplasty in 120(85.1%) and revascularization by open surgery in 21(14.9%) patients. A total 44(23.8%) patients were treated conservatively. Among them poor anatomy of vasculature for revascularization was present in 19(10.3%) patients, physical condition not suitable for any interventions in 17(9.2%) patients, extensive gangrene/ulcer of foot needing primary amputation in 8(4.3%) patients. In conservative group (n = 44) ulcer healed in 13(29.5%) patients, not healed for > 1 year in 12(27.5%) patients and in 15(34%) patients, major amputation was needed to control infections and save life. Four patients (9%) died of other comorbid conditions. In revascularization group (n=141), ulcer healed in 110(78%), not healed for > 1 year in 7(5%) and in 13(9.2%) patients, major amputation was needed to control infections and save life. Eleven patients died due to other comorbid conditions (7.8%). Overall limb salvage rate at our center was 76.8%.

**Conclusion:** Overall limb salvage rate and ulcer healing rate are much better after revascularization of diabetic foot ulcer. Timely and proper intervention of diabetic foot ulcer can help salvage the limbs and improve quality of life and reduce social burden.

Key words: Diabetic foot ulcer, peripheral arterial disease, limb salvage, angioplasty.

## **INTRODUCTION:**

Diabetes is a major public health problem regionally and globally. In 2019, the International Diabetes Federation estimated that 465 million (9.3%) people worldwide had diabetes, and by 2045, the number may rise to 700 million (10.9%).<sup>1</sup> The pooled prevalence of diabetes in the general population of Bangladesh is 7.8% and prevalence of pre-diabetes is 10.1%.<sup>2</sup> Diabetes is a notorious disease with many serious potential sequelae, including large vessel arterial disease & microvascular dysfunction. Diabetic foot ulcer is a distressing complication with

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lifetime risk for foot ulcers in people with diabetes being 15%.<sup>3</sup>

Development of diabetic foot ulcer is attributed to many interacting factors; the most common ones being peripheral neuropathy and peripheral arterial disease (PAD).<sup>4</sup> Peripheral arterial disease is an important precipitating factor in the development of diabetic foot ulcer.<sup>4</sup> Peripheral arterial disease is a common large vessel complication of diabetes, implicated in tissue loss in up to half of the patients with diabetic foot ulcer.<sup>5</sup> Diabetic patients with PAD commonly show involvement of the arteries below the knee, especially at the tibial and peroneal arteries, and involvement of the profunda femoris.<sup>6</sup>

Diabetic ulcers always require vascular evaluation, and when ischaemia is suspected the diagnostics should be organised rapidly to ensure revascularisation without delay. Foot ulcer in patients with diabetes is associated with an increased risk of lower limb amputation, and thus the primary aim of treatment for ischemic foot ulcer is limb preservation.<sup>4</sup> Invasive revascularization, including open reconstructive surgery and/or endovascular intervention, is the most effective treatment that may improve peripheral circulation and remedy symptoms.<sup>4</sup> The fundamental aim of any successful revascularization is to achieve pulsatile flow to the foot. Two methods are currently available for peripheral bypass surgery and peripheral angioplasty.<sup>7</sup> Current literature shows that percutaneous transluminal angioplasty (PTA) is the first choice of procedures in revascularization of the lower limb.<sup>7</sup> The present study was conducted to determine the efficacy of ongoing treatment modalities to heal diabetic foot ulcer and prevent limb loss.

## **METHODS:**

This prospective interventional study was carried out in Combined Military Hospital, Dhaka between January 2017 to January 2020. A total of 267 diabetic patients with foot ulcer reported to the Cardiovascular Surgery Department during the study period. Of them 192 were suspected to have ischaemic ulcer and were included in the study. Patients with foot ulcer, absent pedal pulse and diabetes mellitus were included. Neuropathic ulcer and venous ulcer with present pedal pulses were excluded from the study. Based on clinical characteristics, patients were divided into revascularization (n = 141) and conservative (n =44) groups. Ankle-Brachial pressure and toe pressure were measured, and duplex scan and/or CT angiogram was performed subsequently. Revascularization was done either by peripheral angiogram and angioplasty/stenting or by open surgery. Adjunctive therapy with local wound care and antibiotics were given. All patients were followed up for at least 1 (one) year. Outcome variable was time to wound healing, need for minor / major amputations and overall limb salvage rate.

## **RESULTS:**

Of the 192 study subjects, 7(3.6%) were lost after the first observation. The rest 185 were followed up with a mean follow-up period of  $18 \pm 8$  months (range: 1- 42 months). Majority of the patients was > 60 years old. A male preponderance (82.1%) was observed in the series with male-female ratio being roughly 4:1. Most (86%) of the patients had type 2 diabetes with a disease duration of >15 years. A substantial proportion (84%) of them was hypertensive as well. Only a small proportion (10.8%) of patients had end-stage renal disease and were undergoing haemodialysis. The history of coronary artery disease or cerebral ischemic attack was present in 65(35%) and 26(14%) of patients respectively. A sizable (42%) proportion of them was smoker. The mean HbA1c was  $7.5 \pm 0.6\%$  and LDL cholesterol was  $101 \pm 5$  mg/dl. Nearly 40% of the ulcers were > 5 cm<sup>2</sup>. Infection was present in 115(62%) cases. In the revascularization group (n=141), percutaneous angioplasty was performed in 120(85.1%) and open surgery in 21(14.9%) cases. Of the rest 44(23.8%) patients who were treated conservatively. Of them 19(10.3%) were done so, for poor anatomy of vasculature for revascularization, 17(9.2%) were with physical condition unsuitable for any interventions, 8(4.3%) had extensive gangrene/ulcer of foot needing primary amputation. In the conservative group, ulcer was healed in 13(29.5%) cases and not healed in 12(27.5%) cases despite being treated for > 1year,

15(34%) patients needed major amputation to control infections and save life and 4(9%) patients died due to other comorbid conditions.

In the revascularization group, ulcer was healed in 110(78%) cases, not healed for > 1year in 7(5%) cases, 13(9.2%) patients needed major amputation to control infections and save life and 11(7.8%) patients died of other comorbid conditions. Overall limb salvage rate was 76.8%.

Table I: Table 1: Baseline characteristics of the patients:					
Characteristics	All (n=185)	Revascularization (n=141)	Conservative (n=44)		
Age (years)	62.89	62.51	64.12		
Male(%)	152(82.1) *	116(82.2)	36(81.1)		
Co morbidities					
Hypertension	155(83.7)	118(83.6)	37(84)		
DM	160(86.4)	121(85.8)	39(88.6)		
Coronary artery diseases	65(35)	49(34.7)	16(36.3)		
Chronic kidney diseases	20(10.8)	12(8.5)	08(18)		
Cerebral ischaemic stroke	26(14.0)	11(7.8)	15(34)		
Smoker	80(43.0)	54(38.0)	26(59.0)		
Mean HbA1C (%)	$7.5\pm0.6$	$7.5\pm0.6$	$7.5\pm0.6$		
Mean LDL (mg/100ml)	101 ± 5	101 ± 5	101 ± 5		

\*Figures in the parentheses denote corresponding percentage

#### Table II. Outcome of treatment after Revascularization (n=141)

Outcome	Frequency	Percentage
Ulcer healed with or without reconstructive surgery/ Minor amputation of toes	110	78.0
Ulcer not healed in 1 year	7	5.0
Major amputation	13	9.2
Patients died due to other comorbid conditions	11	7.8

#### Table III. Outcome of treatment after conservative treatment (n = 44)

Outcome	Frequency	Percentage
Ulcer healed with or without reconstructive surgery/ Minor amputation of toes	13	29.5
Ulcer not healed in 1 year	12	27.5
Major amputation	15	34
Patients died due to other comorbid conditions	4	9

Table IV. The reasons for no revascularisation for 44 limbs, and their outcome

Reason	Frequency	Percentage
Poor anatomy of vasculature for revascularization	19	10.3
Physical condition not suitable for any interventions	17	9.2
Extensive gangrene/ulcer of foot need primary amputation	8	4.3

Procedure	Frequency	Percentage	
Percutaneous angioplasty +/- Stenting	120	85.1	
Open surgery	1	14.9	

Table V. Revascularisation Procedure.



Fig. 1a: Gangrene of 2<sup>nd</sup> toe of left foot



Fig. 1b: Critical stenosis of popliteal, anterior tibial and posterior tibial artery



Fig. 1b: Critical stenosis of popliteal, anterior tibial and posterior tibial artery



Fig.1d: Ulcer healed following amputation of 2<sup>nd</sup> toe

#### **DISCUSSION:**

In the present study overall limb salvage rate was 76.8%. After revascularization ulcer healed in 78% cases and after conservative treatment in 29.5% cases. Dayananda et al reported a high limb salvage rate of 75.8% at the end of one year by using infrapopliteal angioplasties in diabetic patients.<sup>11</sup> Saab et al also reported a clinical success rate of 58.7% in a general population comprising of diabetic and non-diabetic patients.<sup>12</sup> In another study, Faglia et al achieved a 5-year primary patency of 88% in diabetic patients undergoing peripheral angioplasty.<sup>13</sup> Zhu and colleagues<sup>14</sup> showed that subintimal angioplasty for arterial lesions below the ankle in diabetic patients could achieve a limb salvage rate of 94.6%. Ulcer healing rate and overall limb salvage

rate are better after revascularization of ischaemic diabetic foot ulcers.

Atheromatous disease in diabetic patients is diffuse and tends to affect more distal vessels with multiple straightforward less lesions that are for revascularization procedures.9 Therefore, management of DFU (an ischaemic ulcer) depends on site and size of the wound, blood supply to the foot, infection and deformity of the foot. The basic aim of any successful revascularization is to achieve pulsatile flow to the foot. The two methods currently available are peripheral angioplasty and bypass surgery. We, usually favor an "angioplasty first" revascularization strategy, as this offers several advantages including better tolerability by the patient and repeatability in case of re-occlusion. The angioplasty is intended to achieve free flow from the aorta down to foot arteries either a patent dorsalis pedis or plantar arch with ultimate aim of treatment being salvaging the limb and achieving ulcer healing. Limb salvaging is feasible, safe and cost-effective in a substantial proportion of diabetic patients with DFU. Multivessel disease can be treated with angioplasty and procedure can be repeated if needed.

Arterial bypass surgery has traditionally been the main treatment with a well-documented long-term patency and limb salvage rate. However, technical and anatomical limitations such as the availability of the long vein graft, the presence of infection near the site of planned distal anastomosis and comorbidity of the patient often make surgery technically challenging and difficult. Outcome of surgical revascularization is hampered due to multivessel occlusion, narrow caliber artery/inflow and poor distal runoff. Hinchliffe and associates reported that over 60% of ulcers were healed within 1-year follow-up following revascularization with either open bypass surgery or endovascular techniques. Another study demonstrated improved rates of limb salvage associated with revascularization compared with the results of conservatively treated patients.<sup>10</sup>

#### **CONCLUSION:**

Overall limb salvage rate and ulcer healing rate is much better after revascularization of diabetic foot ulcer. Timely and proper intervention of diabetic foot ulcer can help salvage the limbs and improve quality of life and reduce social burden. Percutaneous transluminal angioplasty (PTA) is the first choice of procedures in revascularization of the lower limb which is effective and easily tolerable by the patients with multiple comorbidities.

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