



## CROSS SECTIONAL STUDY

# Outcome and Prognosis of Lower Limb Angioplasty on Treatment of Patients with Diabetic Foot Syndrome (DFS): A Single Center Experience for 2 Years

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## Abstract

**Introduction:** The endpoint of this study is to evaluate the outcome and prognosis of lower limb angioplasty on treatment of patients with DFS. The aim of the study was to evaluate effectiveness and limb salvage potential of lower limb in patients with DFS.

**Methodology:** A retrospective cross-sectional study was conducted using electronic medical record reviews among patients diagnosed with Diabetic Foot Syndrome (DFS) who underwent angioplasty treatment. The study duration encompassed data collected from DFS-admitted patients receiving treatment between January 2020 and January 2022. Assessment of the outcomes of lower limb angioplasty involved a follow-up of patients, evaluating improvements in clinical symptoms and physical examination findings. To evaluate micro circulatory disorders, CTA of the lower limb from the level of the abdominal aorta to the dorsalis pedis was performed and evaluated by a qualified radiologist.

**Results:** The study included a total of 69 participants with mean age of the participants was 66.39 ( $\pm 10.35$ ) years. The majority of participants were male (73.9%), while the majority of participants did not experience complications after the procedure (94.2%). The reported complications included fever and paracetamol administration (40.0%), dissection at the origin of the peroneal artery (20.0%), severe hypotension (20.0%), and acute thrombosis of PTA and peroneal artery (20.0%). The majority of participants reported that it had improved after the procedure by more than 75% (69.6%), while 11.6% reported an improvement of more than 50%, and smaller proportions reported improvements of more than 25% (4.3%) or no difference (7.2%).

The change in Hemoglobin A1C (HA1C) levels after surgery showed a significant association with the incidence of amputation ( $p = 0.003$ ). Likewise, the presence of another wound on the same foot showed a significant association with amputation ( $p = 0.012$ ). The location of arterial involvement showed a significant association with amputation ( $p = 0.015$ ).

**Conclusion:** The findings of this research indicate that angioplasty of the lower extremities is a safe and efficacious treatment option for those afflicted with diabetic foot syndrome.

## Introduction

Diabetic foot syndrome (DFS) poses considerable obstacles in terms of patient management owing to its intricate pathophysiology and possible complications [1]. Diabetes-related foot complications (DFS) comprise a range of ailments affecting the foot, such as peripheral arterial disease (PAD), neuropathy, and foot ulcers [2]. Within the realm of treatment alternatives, lower extremity angioplasty has garnered acknowledgment as a beneficial intervention. The objective of this operation is to reinstate circulation to the impacted limbs by the use of balloon catheters or stents to dilate stenotic or occluded arteries [3]. Diabetes mellitus (DM) is the most common human endocrine disease, with an increasing proclivity for complications. Diabetic foot syndrome

(DFS), along with diabetic retinopathy, nephropathy, neuropathy, and cardiovascular system damage, is one of the most serious and dangerous complications of diabetes. Foot problems affect a significant number of diabetic patients, while peripheral arterial lesions affect 50% of DFS patients, and are the primary cause of poor outcomes in this group of patients [4,5]. The progressive deterioration of blood supply to the lower extremities, combined with concurrent infections associated with wounds and cracks caused by various microtraumas of the foot, and which are insignificant and invisible even to the patient, results in the development of purulent and necrotic complications in the feet, which, together with the progression of concomitant diseases, increases the risk of negative outcomes by increasing the frequency of limb amputations [6-8]. Naturally, after a high amputation of a limb, a patient's quality of life is significantly lower, which is an important criterion for determining treatment efficacy [6-8]

DFS is frighteningly prevalent among patients with diabetes, with an incidence ranging from 15% to 25% [9-11]. Affected persons are profoundly impaired in terms of quality of life and functional status due to this disorder, which also results in elevated rates of illness, hospitalization, and healthcare expenditures [12]. In addition to being linked to an increased likelihood of lower extremity amputations, DFS underscores the criticality of discovering efficacious treatment approaches. Angioplasties of the lower limbs has surfaced as a potentially effective treatment for DFS patients, with the objectives of enhancing limb perfusion, facilitating wound healing, and averting amputations [13]. Using stents or balloon catheters, percutaneous transluminal angioplasty (PTA) is performed on obstructed or stenosed arteries [14]. It has demonstrated promise as a minimally invasive substitute for surgical revascularization and has the capacity to increase limb salvage rates.

As a result, the primary goal of treatment in DFS patients is to reduce the percentage of high amputations while preserving weight bearing function of the foot. To reduce the frequency of amputations, treatment methods aimed at improving blood supply to the lower extremities are pathogenetically justified. To date, in addition to conservative therapy for lower extremity ischemia, indirect revascularization procedures, vascular bypass procedures, and endovascular interventions are used, which are of particular interest because they are non-traumatic for the patient. Studies demonstrate that endovascular procedures significantly improve the treatment outcomes for DFS patients [15]. Simultaneously, there are studies presenting treatment outcomes in patients for whom revascularization procedures were either technically impossible or not indicated due to coexisting diseases; however, the developed ulcers resolved within a year without revascularization [15].

Positive findings have been documented in studies examining the efficacy of lower limb angioplasty in patients diagnosed with DFS [6,16-18]. Achieved angioplasty outcomes include enhanced perfusion to the affected limbs, better wound healing, and a decreased likelihood of major amputations [19]. It has been proven that high technical success rates result in an immediate increase in arterial blood flow and alleviation of ischemia symptoms [18]. Diverse factors impact the prognosis of lower limb angioplasty in patients with DFS. Critical factors of treatment results include the degree of vascular disease, the occurrence of concurrent neuropathy, and the sufficiency of wound care [17,18]. Favorable prognoses are the result of timely diagnosis, suitable patient selection, and multidisciplinary management that includes interventional radiologists, diabetologists, and vascular surgeons.

The endpoint of this study is to evaluate the outcome and prognosis of lowerlimb angioplasty on treatment of patients with DFS. The aim of the study was to evaluate effectiveness and limb salvage potential of lower limb in patients with DFS.

## Methodology

A retrospective cross-sectional study was conducted using electronic medical record reviews among patients diagnosed with Diabetic Foot Syndrome (DFS) who underwent angioplasty treatment. The study duration encompassed data collected from DFS admitted patients receiving treatment between January 2020 and January 2022.

Non-random sampling, specifically convenience sampling, was employed for participant selection. The study cohort consisted of diabetic patients with DFS who underwent angioplasty treatment. The target population was diabetic patients with DFS who underwent angioplasty treatment, and the study location was a single center in Riyadh, Saudi Arabia.

The inclusion criteria for this study were as follows: 1) being a diabetic patient, 2) having a diagnosis of DFS, 3) both genders, and 4) being above 14 years of age. Patients under 14 years of age and those deemed unstable for the angioplasty procedure were excluded from the study. Data collection was performed through a retrospective cross-sectional review of electronic medical records of the identified patients with DFS. The data collection period spanned from January 2019 to January 2022. All patients meeting the inclusion criteria were included in the study after applying the selection criteria. Diagnosis of DFS was based on clinical symptoms, physical examination findings, and computed tomography angiography (CTA).

Assessment of the outcomes of lower limb angioplasty involved a follow-up of patients, evaluating improvements in clinical symptoms and physical

examination findings. To evaluate microcirculatory disorders, CTA of the lower limb from the level of the abdominal aorta to the dorsalis pedis was performed and evaluated by a qualified radiologist. Subsequently, lowerlimb angioplasty was performed, documented in the patient files, and patients were discharged with follow-up extended from 6 months up to 1 year. The follow-up involved assessing clinical symptoms, physical examination findings, and monitoring cases of amputation reduction.

Descriptive statistics, such as frequencies, means, and standard deviations, were used to summarize the demographic and clinical characteristics of the study population. Inferential statistical analysis was conducted to assess the association between angioplasty treatment and clinical outcomes. The specific statistical tests used depended on the nature of the variable and research questions, including chi-square tests, t-tests, or regression analysis as appropriate. A p-value of less than 0.05 was considered statistically significant.

Ethical considerations were taken into account throughout the study. The study protocol was reviewed and approved by the appropriate Institutional Review Board (IRB) or Ethics Committee. Patient confidentiality and privacy were ensured by de-identifying the collected data and strictly limiting access to authorized researchers. Informed consent was not required for this retrospective study as it involved the analysis of anonymized data from electronic medical records. The study was conducted in compliance with relevant ethical guidelines and regulations, ensuring the rights and welfare of the study participants.

## Results

Table 1 presents the demographic factors of the participants in the study. The study included a total of 69 participants with Diabetic Foot Syndrome (DFS) who underwent angioplasty treatment. The mean age of the participants was 66.39 years with a standard deviation (SD) of 10.35. The majority of participants were male (73.9%), while 26.1% were female. Regarding medical history, 84.1% of participants had a history of hypertension, 50.7% had a history of cardiac disease, 24.6% were smokers, and 11.6% had quit smoking.

Table 2 provides an overview of the characteristics of the stenosis or occlusion observed in the participants. The most common location of stenosis or occlusion was the femoral artery (54.4%), followed by the anterior tibial artery (39.7%) and the posterior tibial artery (42.6%). The majority of cases had multiple stenosis or occlusion (73.9%), and the majority of these cases were both calcified and non-calcified (56.5%). The severity of stenosis or occlusion varied, with 72.5% of cases having stenosis or occlusion greater than 75%.

Table 3 provides information about the characteristics of the surgery performed. Local anesthesia was used

for the majority of cases (98.6%), while only one case (1.4%) required general anesthesia. The antegrade puncture of the ipsilateral common femoral artery was the most common method of puncture (68.1%). Balloon recanalization was the most frequently used method (66.7%), followed by balloon and stent (15.9%). The mean size of the vascular sheath used was 6.37 (SD 2.12) and the mean size of the balloon was 2.96 (SD 1.85). The amount of heparin used had a mean value of 7101 (SD 9697). The majority of cases did not require the use of a stent (69.6%).

Table 4 presents the outcomes of lower limb angioplasty in the treatment of patients with diabetic foot syndrome. The majority of participants did not experience complications after the procedure (94.2%), while 5.8% did experience complications. The reported complications included fever and paracetamol administration (40.0%), dissection at the origin of the peroneal artery (20.0%), severe hypotension (20.0%), and acute thrombosis of PTA and peroneal artery (20.0%). Regarding wound healing, 82.6% of participants

**Table 1:** Demographic factors of the participants (N = 69).

		Count	Column N%
<b>Age (Years)</b>	<b>Mean (SD)</b>	<b>66.39 (10.35)</b>	
Gender	Male	51	73.9%
	Female	18	26.1%
History of hypertension	No	11	15.9%
	Yes	58	84.1%
History of cardiac disease	No	34	49.3%
	Yes	35	50.7%
History of smoking	No	52	75.4%
	Yes	17	24.6%
History of quit smoking	No	61	88.4%
	Yes	8	11.6%

**Table 2:** Characteristics of the stenosis or occlusion.

		Count	Column N%
Location of stenosis or occlusion	Femoral artery	37	54.4%
	Iliac artery	10	14.7%
	Pedal artery	9	13.2%
	Popliteal artery	11	16.2%
	Anterior tibial artery	27	39.7%
The stenosis/occlusion	Posterior tibial artery	29	42.6%
	Peroneal artery	19	27.9%
	Single	18	26.1%
	Multiple	51	73.9%
	Non calcified	17	24.6%
The stenosis/occlusion	Calcified	13	18.8%
	Both	39	56.5%
Severity of stenosis/occlusion	< 25 %	2	2.9%
	25-50%	7	10.1%
	51-75%	10	14.5%
	> 75 %	50	72.5%

**Table 3:** Characteristics of the surgery.

		Count	Column N%
Type of anesthesia	Local	68	98.6%
	General anesthesia	1	1.4%
Type of puncture	Antegrade puncture of the ipsilateral common femoral artery	47	68.1%
	Retrograde of the contralateral common Femoral artery	22	31.9%
Method of recanalization	No use	2	2.9%
	stent	10	14.5%
	balloon	46	66.7%
	Ballon + stent	11	15.9%
Size of vascular sheath	Mean (SD)	6.37 (2.12)	
Size of balloon	Mean (SD)	2.96 (1.85)	
Amount of heparin use	Mean (SD)	7101 (9697)	
Type of stent	Non	48	69.6%
	4-5 mm self-expandable	14	20.3%
	8 mm 2 expandable stent in iliac	1	1.4%
	both Balloon expandable, and 4-5mm self-expandable	6	8.7%

**Table 4:** The outcomes of lower limb angioplasty on treatment of patients with diabetic foot syndrome.

		Count	Column N%
Complication after procedure	No	65	94.2%
	Yes	4	5.8%
Complication	Fever and given paracetamol	2	40.0%
	Dissection at origin of peroneal artery	1	20.0%
	Severe hypotension and Green code then preturn normal.	1	20.0%
	Acute thrombosis of PTA and peroneal artery which was managed immediately by thrombectomy and thrombolysis post angiogram	1	20.0%
Did the wound heal	No	12	17.4%
	Yes	57	82.6%
Did the wound come back in the same place	No	62	89.9%
	Yes	7	10.1%
Did you have another wound on same foot	No	58	84.1%
	Yes	11	15.9%
Did you have a foot amputation, if yes, at any level?	No	51	73.9%
	1.00	1	1.4%
	Yes, above ankle	2	2.9%
	Yes, Below knee	2	2.9%
	Yes, Toe	12	17.4%
	Yes, above the knee	1	1.4%
Do you think that the procedure improved the level of foot health and approximately how much?	No, it gets more worse	5	7.2%
	There is no difference	5	7.2%
	yes, it has improved more 25%	3	4.3%
	yes, it has improved more 50%	8	11.6%
	yes, it has improved more 75%	48	69.6%
Change in HA1C	Decreased	35	50.7%
	No change	19	27.5%
	Increased	15	21.7%
Change in HA1C	Decreased	16	23.2%



reported that the wound had healed, while 17.4% reported that it had not. The majority of participants did not experience a recurrence of the wound in the same place (89.9%) or develop another wound on the same foot (84.1%). In terms of amputation, 73.9% of participants did not undergo foot amputation, while 26.1% did, with various levels of amputation reported. When asked about the improvement in foot health after the procedure, the majority of participants reported that it had improved by more than 75% (69.6%), while 11.6% reported an improvement of more than 50%, and smaller proportions reported improvements of more than 25% (4.3%) or no difference (7.2%). Regarding changes in HA1C levels, 50.7% of participants experienced a decrease, 27.5% reported no change, and 21.7% reported an increase.

Regarding gender, there was no statistically significant difference in the incidence of amputation between males and females ( $p = 0.719$ ). Among males, 23.5% underwent amputation, while among females; the amputation rate was slightly higher at 27.8%. The change in Hemoglobin A1C (HA1C) levels after surgery showed a significant association with the incidence of amputation ( $p = 0.003$ ). Patients who experienced a decrease in HA1C levels had a lower amputation rate of 11.4%, whereas those with no change in HA1C had a relatively higher amputation rate of 52.6%. The history of hypertension did not show a significant association with amputation ( $p = 0.325$ ) nor history of cardiac

disease ( $p = 0.442$ ). The history of smoking ( $p = 0.903$ ) and quitting smoking ( $p = 0.369$ ) did not show significant associations with the incidence of amputation. The presence of a recurrent wound in the same place did not significantly impact the amputation rate ( $p = 0.799$ ). Likewise, the presence of another wound on the same foot showed a significant association with amputation ( $p = 0.012^*$ ) where patients with another wound on the same foot had a higher amputation rate of 54.5%, compared to 19.0% among those without another wound. The location of arterial involvement showed a significant association with amputation ( $p = 0.015$ ). The highest amputation rate was observed for patients with involvement of the anterior tibial artery (37.0%), followed by the peroneal artery (36.8%). The lowest amputation rates were seen in patients with involvement of the femoral artery (18.9%), iliac artery (20.0%), and pedal artery (11.1%) (Table 5).

## Discussion

In the present study, the efficacy of lower limb angioplasty as a treatment for diabetic foot syndrome patients was evaluated (DFS). A variety of demographic variables, stenosis or occlusion features, surgical procedures, and procedure outcomes were investigated in the study. Through an extensive examination of the outcomes and their connections to the extant body of literature, we shall furnish a full synopsis of the discoveries.

**Table 5:** The relation between incidence of amputation and demographic and surgical characteristics.

		Amputation				P- value
		No		Yes		
		Count	Row N%	Count	Row N%	
Gender	Male	39	76.5%	12	23.5%	0.719
	Female	13	72.2%	5	27.8%	
C Change in HA1C after surgery	Decreased	31	88.6%	4	11.4%	0.003*
	No change	9	47.4%	10	52.6%	
	Increased	12	80.0%	3	20.0%	
History of hypertension	No	7	63.6%	4	36.4%	0.325
	Yes	45	77.6%	13	22.4%	
History of cardiac disease	No	27	79.4%	7	20.6%	0.442
	Yes	25	71.4%	10	28.6%	
History of smoking	No	39	75.0%	13	25.0%	0.903
	Yes	13	76.5%	4	23.5%	
History of quit smoking	No	47	77.0%	14	23.0%	0.369
	Yes	5	62.5%	3	37.5%	
Did the wound come back in the same place	No	47	75.8%	15	24.2%	0.799
	Yes	5	71.4%	2	28.6%	
Did you have Another wound on same foot	No	47	81.0%	11	19.0%	0.012*
	Yes	5	45.5%	6	54.5%	
Location	Femoral artery	30	81.1 %	7	18.9 %	0.015*
	Iliac artery	8	80.0%	2	20.0 %	
	Pedal artery	8	88.9%	1	11.1%	
	Popliteal artery	10	90.9%	1	9.1%	
	Anterior tibial artery	17	63.0%	10	37.0%	
	Posterior tibial artery	20	69.0%	9	31.0%	
	Peroneal artery	12	63.2%	7	36.8%	

The demographic profile of the individuals indicated that a significant proportion were male, which is consistent with other research that has established a greater incidence of DFS among males [20]. Based on the participants' mean age of 66.39 years, it can be concluded that DFS primarily impacts the elderly population. This discovery supports other investigations that established older age as a substantial risk factor for DFS [21,22]. The subjects' elevated incidence of hypertension, heart illness, and smoking history aligns with the widely recognized correlation between these variables and the onset of DFS [2,23].

In relation to the attributes of stenosis or occlusion, the femoral artery had the highest frequency of occurrence, with the anterior and posterior tibial arteries following suit. This distribution is consistent with the established patterns of vascular involvement in DFS, which have been documented in prior research [24]. A significant proportion of patients demonstrated multiple stenosis or occlusion, with a considerable number containing both calcified and non-calcified lesions. The results of this study align with the intricate characteristics of DFS, which can encompass numerous artery segments and differing levels of calcification [25].

Local anesthetic was utilized more frequently during the surgical operations included in the study, which is consistent with the current standard of care for endovascular treatments for DFS. Local anesthetic provides numerous benefits, such as decreased occurrence of systemic problems and enhanced comfort for the patient [26]. In lower limb angioplasty treatments, antegrade puncture of the ipsilateral common femoral artery was the most often used technique, indicative of its broad application [27]. Recanalization of balloons, either independently or in conjunction with stenting, constituted the prevailing approach utilized. This aligns with the conventional strategy employed in the management of arterial stenosis or occlusion in DFS, which seeks to enhance limb perfusion and reinstate blood circulation [28].

In general, the results of the lower limb angioplasty operation were favourable. A significant proportion of the participants remained asymptomatic, providing further evidence of the procedure's efficacy and safety within this particular group of patients. The problems that were documented, including fever, dissection, hypotension, and acute thrombosis, were in line with recognized concerns that are commonly associated with angioplasty procedures [29,30]. The minimal frequency of problems, however, indicates that the surgery may be executed with satisfactory safety.

As it directly impacts patient morbidity and quality of life, wound healing is an essential outcome metric in DFS treatment. This finding is consistent with the efficiency of lower limb revascularization in facilitating

wound closure, as the majority of subjects experienced successful wound healing [31,32]. Nevertheless, a certain percentage of the participants encountered recurrence of wounds or the formation of fresh wounds. This emphasizes the necessity for comprehensive therapeutic options that target underlying vascular abnormalities, glucose control, and foot care education in order to prevent future wounds and the complex nature of DFS. Amputation of the foot is a notable worry among patients diagnosed with severe limb ischemia due to DFS [33]. A significant proportion of the individuals in this study had amputation, with different degrees of amputation recorded. Nevertheless, it is worth noting that a significant proportion of the subjects maintained their foot function, suggesting that lower limb angioplasty can indeed avert amputations in practice. This discovery is consistent with the current body of literature that underscores the significance of revascularization in mitigating the necessity for amputations among patients with DFS [34].

The self-reported improvement in foot health by the subjects subsequent to the angioplasty operation is an essential measure of subjective outcome. Significant gains were noted by the majority of individuals, with over 75 percent of them attesting to improved foot health. This discovery is promising and provides further evidence for the beneficial effects of revascularization on limb perfusion and wound healing among individuals with DFS [35,36]. The enhancements in foot health that have been documented align with prior research that has established the efficacy of angioplasty in mitigating symptoms associated with ischemia and enhancing functional outcomes [37,38].

Variations in hemoglobin A1C (HA1C) levels were also evaluated in the trial to gauge glycemic management. A considerable percentage of the subjects observed a reduction in HA1C levels subsequent to the angioplasty operation, suggesting that it had a beneficial effect on the management of diabetes. This discovery aligns with prior investigations that have revealed the advantageous impacts of revascularization on glycemic control among individuals with DFS [39]. Despite this, it is important to acknowledge that a subset of the subjects demonstrated either no change in HA1C levels or an increase, indicating the necessity for all-encompassing approaches to diabetes management that extend beyond revascularization only.

By augmenting the current corpus of knowledge on lower limb angioplasty in DFS, the findings of this research underscore the criticality of revascularization as an integral component of the comprehensive approach to managing this intricate condition. The results validate the existing guidelines and recommendations that advocate for the prompt revascularization of DFS patients in order to enhance circulation to the

limbs, facilitate the healing of wounds, and lower the risk of amputations [35]. In order to enhance patient outcomes, the study also emphasizes the necessity for a multidisciplinary strategy that tackles vascular problems, glycemic control, and foot care education, so highlighting the multifaceted character of DFS [40].

In line with prior research, our study demonstrated that a reduction in glycemic control (HA1C) levels subsequent to surgery was substantially correlated with a decreased likelihood of amputations [41-43]; this underscores the criticality of glycemic control in averting unfavorable consequences. Additionally, the existence of a concurrent wound on the identical foot was recognized as a substantial determinant of amputation risk, underscoring the imperative for all-encompassing approaches to wound management. In addition, amputation was significantly correlated with the site of arterial involvement, which is consistent with the notion that particular arterial segments, like the anterior tibial and peroneal arteries, are more prone to unfavorable results [44,45]. In order to reduce the risk of amputation in patients with DFS, these results add to the current body of knowledge and emphasize the significance of tailored patient care, including glycemic control, wound management, and targeted examination of arterial involvement.

In conclusion, the findings of this research indicate that angioplasty of the lower extremities is a safe and efficacious treatment option for those afflicted with diabetic foot syndrome. The intervention yielded positive results with regard to the restoration of foot health, prevention of amputations, and wound healing. Consistent with existing guidelines and research, these results support revascularization as a treatment option for DFS. However, additional research is required to investigate long-term consequences and validate these findings. To achieve optimal patient results and prevent future complications, the study emphasizes the need for a holistic strategy to DFS management that tackles vascular concerns, glycemic control, and foot care education.

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