# Single crural artery angioplasty in healing of ischemic diabetic foot ulcers: a cohort study

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**Aim**
The aim of this study is to show the efficacy of single crural artery angioplasty for diabetic wounds as regard to healing rate, patency rate, mean change in ankle brachial index (ABI), and limb salvage.

**Patients and methods**
A prospective observational cohort included diabetic patients with critical limb ischemia (Rutherford-5 and 6) who underwent percutaneous infrapopliteal angioplasty for single crural artery. Follow-up for complete wound healing, improving in ABI, patency rate, and limb salvage were done up to 1 year.

**Results**
In total, 42 patients with median age 56 years (interquartile range=0.06). In total, 27 patients had a diseased single crural artery and 15 patients had lesions in multiple crural arteries. The mean ABI for them was improved significantly after the procedure ($P$=0.0001). Complete wound healing occurred in 31 (73.8%) cases, patency rate at 12 months was 73.8%, and limb salvage rate was 88.1%, we found a significant difference in rate of change in ABI average between the healed group and nonhealed group ($P$=0.006), further analysis using receiver-operating characteristic curve found that the cutoff value of 0.2184 increase in ABI can predict complete wound healing (sensitivity=74.2% and specificity=72.7%).

**Conclusion**
Single crural artery angioplasty is a safe and effective procedure for management of diabetic patients with ischemic leg ulcers.

**Keywords:**
angioplasty, critical limb ischemia, crural artery, diabetic foot, foot ulcers, limb salvage

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## Introduction

Diabetes mellitus is one of the metabolic diseases that have a great impact on limb loss; the neuropathic affection leads to insensate foot liable for repeated trauma and foot ulceration, also, it induces new pressure points on the sole, making it liable for ulceration, on the other side, premature atherosclerosis leads to reduction in foot perfusion, and impairs the healing power of the tissues [1]. Untreated leg ulcers increase the liability for gangrene, limb loss, and high mortality rate [2].

Several noninvasive tools are used to diagnose critical limb ischemia (CLI), including ankle brachial index (ABI), ankle pressure, toe pressure, color Doppler ultrasound, and transcutaneous oxygen pressure [3]. However, computed tomography angiography is considered an accurate diagnostic method that helps to establish a definitive treatment plan [4].

Diabetic foot complicated with critical ischemia should be managed with an individualized approach, combining an optimal glycemic control, frequently foot care, treatment of the underlying risk factors, prophylactic use of antibiotics, and the intervention of an expert multidisciplinary team. In this condition, revascularization techniques may be used in order to improve tissue perfusion and wound healing.

Before intervention, cessation of smoking, control of blood pressure, blood glucose level, and lipid profile plus anti-ischemic measures must be implemented [5]. Intervention involves endovascular balloon dilatation, stenting, or bypass according to the degree of complexity of each lesion [6].

The aim of this study was to assess the efficacy of single crural artery revascularization in healing ischemic ulcers, patency rate, and limb salvage.

## Patients and methods

Between June 2020 and May 2021, patients complicated by CLI Rutherford classification (grade III, category 5 and 6) were enrolled in a prospective observational single-center cohort study at the cardiothoracic and vascular surgery center (Mansoura University). We included diabetic patients who were diagnosed with infrapopliteal lesions and underwent single crural angioplasty to increase the blood flow to their feet prior to ulcer debridement.

We excluded nondiabetics and patients with severe foot infection having high risk for amputation by WIFI score [7]. Also, patients with known history to dye allergy, severe renal impairment, and patients with proximal-vessel disease (aortoiliac or femoropopliteal) were excluded, patients with multiple infrapopliteal disease and underwent balloon dilatation angioplasty for more than one crural vessel were excluded from the study.

After obtaining IRB approval, patients' demographics, medical history, clinical presentation, and associated comorbidities were recorded. Physical examination, including palpation of femoral and popliteal pulse and exclusion of aneurysms, was done. ABI was measured in all cases. Routine laboratory investigations (blood picture, serum creatinine and blood glucose level, liver functions, and coagulation profile) were performed. All patients were instructed to do preoperative computed tomographic angiography.

All patients gave written consent for revascularization by percutaneous transluminal angioplasty (PTA). Access was gained via ipsilateral puncture of common femoral artery. A 6-Fr sheath was placed and bolus of 5000-IU heparin was injected intra-arterially. Infrapopliteal lesions were crossed using 0.018' or 0.035' guide wires. A 4–5-Fr Bern catheter was used to support and advance the wire. Balloon dilatation was performed using 2.5–3-mm balloons at 10 atmospheres. Debridement was done after revascularization and follow-up was done.

Primary outcomes were wound-healing rate, patency rate, and duration of wound healing. Secondary outcomes were limb salvage and 30-day mortality. Follow-up was done to observe wound healing and time to complete healing, duplex assessment to ensure arterial patency, ABI was recorded postoperatively, and rate of change in ABI was recorded for each patient (ΔABI).

Statistical data analysis was performed using SPSS 14.0 software (SPSS Inc., Chicago, Illinois, USA). Qualitative data were described using number and percent, while quantitative data were described using mean and SD for parametric data, and median with interquartile range (IQR) for nonparametric data. Patency rate and limb salvage were calculated by Kaplan–Meier analysis. Comparing between means using Students *t* test in case of parametric variables or Mann–Whitney test in case of nonparametric variables, the results were considered significant if *P* value less than 0.05.

## Results

In total, 42 diabetic patients (18 ladies and 25 gentlemen) with CLI Rutherford classification (category 5 and category 6) were referred for infrapopliteal angioplasty. The median age was 56 (IQR=0.06), and mean ABI was 0.3867±0.0311. The median wound size was of 12.97 (IQR=6.21 $cm^2$) (Table 1).

Based on computed tomography angiography images, 21 (50%) patients had stenotic infrapopliteal lesions and 21 (50%) had totally occluded segments. The planter arch was intact and complete in 26 (61.9%) patients, and 16 (38.1%) patients showed incomplete planter arch. In total, 27 (64.3%) patients had diseased single crural vessel, whereas 15 (35.7%) patients had two or more crural vessels diseased. According to angiosome theory, in 22 (52.4%) of the patients, the ulcer was along the distribution of the diseased vessel (Table 2). There was no calcification encountered inside the atheromatous plaques in all examined arteries.

All patients underwent single crural angioplasty either on selective basis when one diseased crural (tibial) vessel was encountered or obligatory due to the

**Table 1 Demographic and clinical data of the studied patients (*N*=42)**

| | |
|---|---|
| Median age (years) (IQR) | 56 years (0.06) |
| Sex [*n* (%)] | |
| Male | 24 (57) |
| Female | 18 (43) |
| BMI ($kg/m^2$) (mean±SD) | 30.01±3.84 |
| Median wound area ($cm^2$) (IQR) | 12.97 $cm^2$ (6.21) |
| Hypertension [*n* (%)] | 30 (71.4) |
| DM [*n* (%)] | 42 (100) |
| Smoking [*n* (%)] | 27 (64.3) |
| Dyslipidemia [*n* (%)] | 20 (47.6) |
| Ischemic heart diseases [*n* (%)] | 6 (14.3) |

DM, diabetes mellitus; IQR, interquartile range.

inability to revascularize more than one vessel, when there is a multivessel affection, the median time for the procedure was 120 min (IQR=60). The mean ABI postoperatively was 0.6257±0.0084, we observed a significant improvement compared with preoperative ABI ($P$=0.0001) (Table 3).

**Table 2 Radiologic data (*N*=42)**

| | | |
|---|---|---|
| Lesion type [*n* (%)] | Total occlusion | 21 (50%) |
| | Stenosis | 21 (50) |
| Lesion length [*n* (%)] | Short segment <5 cm | 23 (54.8) |
| | Long segment >5 cm | 19 (45.2) |
| Planter arch [*n* (%)] | Complete arch | 26 (61.9) |
| | Incomplete arch | 16 (38.1) |
| Vessels affected [*n* (%)] | Single crural vessel | 27 (64.3) |
| | Two or more crural vessels | 15 (35.7) |
| Angiosome concept [*n* (%)] | Angiosome-related | 22 (52.4) |
| | Non-angiosome-related | 20 (47.6) |

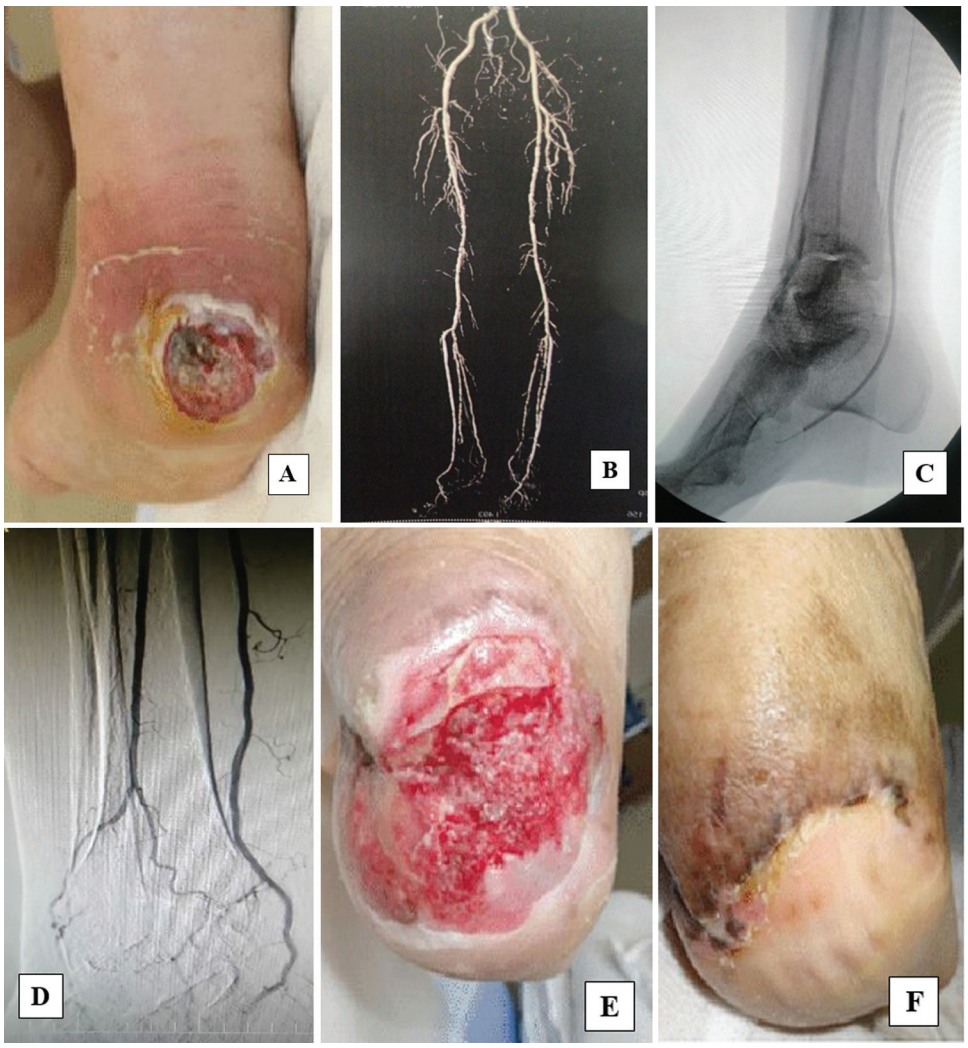
On follow-up, we observed complete wound healing in 31 (73.8%) cases (Fig. 1), the mean time for healing was 43.7±16.4 days. The risk factors for incomplete healing are summarized in Table 4, we found the most risk factors for failure of wound healing are nontargeted revascularization (absent angiosome), presence of ischemic heart disease, hypertension, multivessel affection, and the rate of change in ABI (ΔABI) (Table 5).

Further analysis for change of ABI using the receiver-operating characteristic curve denoted that area under

**Table 3 The difference between mean ankle brachial index preprocedure and postprocedure**

| Variables | Preprocedure | Postprocedure | *t* test | *P* |
|---|---|---|---|---|
| Ankle brachial index | | | | |
| Mean±SD | 0.3867±0.0311 | 0.6257±0.0084 | −5.645 | 0.0001 |

**Figure 1**




A 66-year-old male patient DM, HTN, presented with right heal ulcer (Rutherford grade 6) (a), CT angiography revealed multiple stenotic segments in the posterior tibial artery (b), intraoperative images confirmed the diagnosis (c), and balloon dilatation of the posterior tibial artery was done ensuring complete plantar arch (d), the patient underwent debridement of the ulcer after revascularization and follow-up at 1 month (e), and complete healing at 3 months (f). CT, computed tomography; DM, diabetes mellitus; HTN, hypertension.

**Table 4 Predictors of incomplete healing**

| | Odds ratio | Relative risk |
|---|---|---|
| Nontargeted revascularization | 4.22 (CI=0.932–19.131) | 2.933 (CI=0.901–9.553) |
| Ischemic heart disease | 3.5 (CI=0.589–20.813) | 2.25 (CI=0.822–6.158) |
| Hypertension | 5.5 (CI=0.62–48.817) | 4 (CI=0.573–27.934) |
| Two or more crural vessels affected | 1.75 (CI=0.429–7.136) | 1.5 (CI=0.549–4.098) |
| Total occlusion | 0.781 (CI=0.197–3.106) | 0.833 (CI=0.3–2.314) |
| Smoking | 0.571 (CI=0.14–2.33) | 0.667 (CI=0.244–1.821) |
| Dyslipidemia | 0.536 (CI=0.13–2.208) | 0.629 (CI=0.216–1.83) |
| Incomplete planter arch | 0.107 (CI=0.012–0.937) | 0.163 (CI=0.023–1.153) |

CI, confidence interval.

**Table 5 The rate of change in mean ankle brachial index in healed group and nonhealed group**

| Variables | Healed group | Nonhealed group | *Z* | *P* |
|---|---|---|---|---|
| Change in ankle brachial index (ΔABI) | | | | |
| Mean±SD | 0.2435±0.0354 | 0.2089±0.0286 | −2.76 | 0.006 |

the curve equaled 0.783, with a cutoff value of 0.2184 increase in ABI, it can give probability of wound healing with sensitivity=74.2% and specificity=72.7%, while 0.2462 increase can give probability of wound healing with sensitivity=51.6% and specificity=90.9% (Fig. 2).

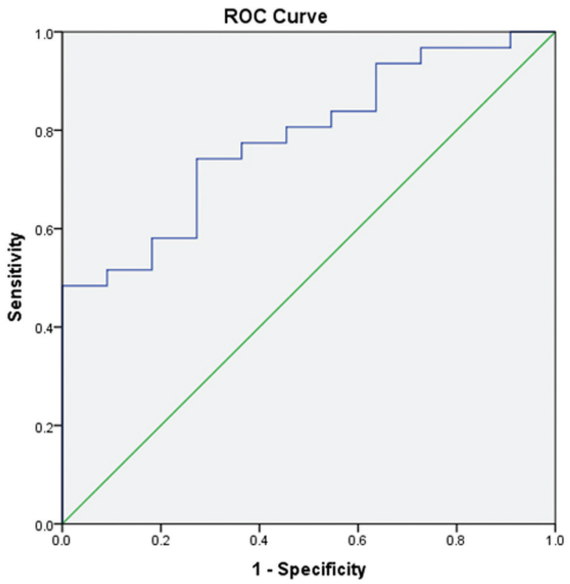
Primary patency reached 73.8% after 12 months of follow-up. Reocclusion occurred in 11 (26.2%) cases (Fig. 3). Neither of the cases died during the 30 days postprocedure nor for 1-year follow-up (Table 6).

Major amputation was done in five (11.9%) cases. Limb salvage rate after 12 months was 88.1% (Fig. 4). The major risk factors for major amputation are analyzed and summarized in Table 7, the most important risk factors for major amputation were ischemic heart disease, incomplete planter arch, smoking, presence of total occlusion, and multivessel affection.

## Discussion

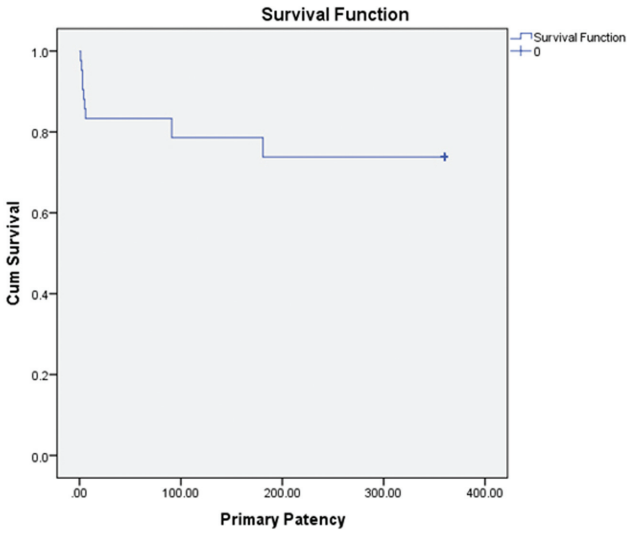
Diabetic foot ulcers complicated with CLI are a serious medical condition that can lead to major amputation if left untreated [8], the main goal for treating ischemic diabetic foot ulcer is to establish adequate blood flow toward the ulcer bed either by direct revascularization of the target vessel or by indirect revascularization through an intact planter arch [9,10]. However, the complexity of the lesions and multivessel affection that renders the establishment of adequate blood flow is quite challenging and a lengthy procedure in those patients.

**Figure 2**




Receiver-operating characteristic (ROC) curve showing the change of ABI (ΔABI) and the complete healing of ischemic ulcer's area under the curve (AUC) was 0.783. ABI, ankle brachial index.

**Figure 3**

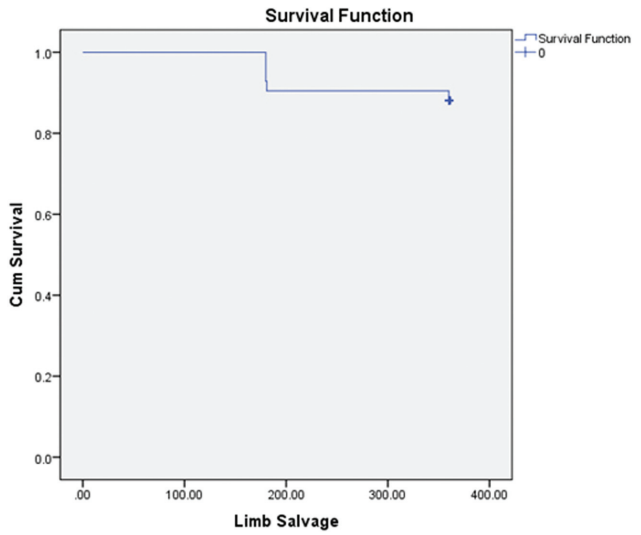



Primary patency after angioplasty on 12-month follow-up.

**Table 6 Summary of the outcomes at 12 months (*N*=42)**

| | |
|---|---|
| Compete healing [*n* (%)] | 31 (73.8) |
| Reocclusion [*n* (%)] | 11 (23.9) |
| Mortality [*n* (%)] | 0 |
| Major amputation [*n* (%)] | 5 (11.9) |

**Figure 4**




Limb salvage at 12-month follow-up.

**Table 7 Predictors for major amputation**

| | Odds Ratio | Relative risk |
|---|---|---|
| Ischemic heart disease | 5.5 (CI=0.695–43.514) | 4 (CI=0.835–19.162) |
| Incomplete planter arch | 2.769 (CI=0.409–18.743) | 2.438 (CI=0.456–13.043) |
| Total occlusion | 1.583 (CI=0.236–10.605) | 1.5 (CI=0.278–8.079) |
| Smoking | 2.435 (CI=0.247–24.039) | 2.222 (CI=0.273–18.119) |
| Two or more crural vessels affected | 1.231 (CI=0.182–8.33) | 1.2 (CI=0.225–6.401) |
| Absent angiosome | 0.704 (CI=0.105–4.713) | 0.733 (CI=0.136–3.949) |
| Hypertension | 0.556 (CI=0.081–3.83) | 0.6 (CI=0.114–3.153) |
| Dyslipidemia | 0.237 (CI=0.024–2.325) | 0.275 (CI=0.033–2.259) |

CI, confidence interval.

Multiple-vessel angioplasty is generally considered to be more effective in enhancing tissue perfusion than single-vessel reconstruction. However, this often comes at the cost of increasing the time of procedure, contrast administration, and radiation exposure without added benefit for wound healing [11–14]. Therefore, the aim of the study was to observe the outcome of single crural angioplasty on the healing rates and limb salvage.

This prospective observational study was carried out on 42 diabetic patients suffering from critical lower limb ischemia (Rutherford class III, category 5 and category 6) and underwent single crural angioplasty. Our study included 55% females and 45% males with mean age 56.53 years, and mean BMI 30.11 kg/m$^2$.

As well, the current study was supported by a multicenter study done by Faglia and colleagues, on 212 patients with CLI, in 191, the PTA was successful and in 28 patients, the PTA was not due to severe calcifications, the mean ABI was improved significantly when applied to 128 patients from 0.53 ±0.15 to 0.90±0.18 ($P$<0.0001), limb salvage achieved in 91.9% was aided by surgical reconstruction to nine cases [15], and in our study, limb salvage was achieved in 88.1% of the patients.

As well, the current study was supported by Sadaghianloo and colleagues, who aimed to assess the results of percutaneous angioplasty in patients with CLI and long tibial occlusions. The study enrolled 34 patients presenting with 37 CLI with long tibial occlusion (Rutherford-4 patients were 11%, Rutherford-5 patients were 81%, and Rutherford-6 were 8%). The median age was 75 years (range, 53–89 years), and 23 (68%) of the patients were men. The clinical success rate at 1 year, defined as wound healing without major amputation, was 65% [16], while in our study, the rate of wound healing occurred in 78.3% of the patients.

In addition, the study by Baumann and colleagues aimed to assess the extent of early recoil in patients with CLI undergoing conventional tibial balloon angioplasty. The study enrolled 30 consecutive CLI patients (Rutherford-4 patients were 40%, Rutherford-5 patients were 36.7%, and Rutherford-6 was 23.3%) (18 men, mean age 76.2±12.1 years) with 18 (60.0%) males. The study reported that primary patency was 58.1% after tibial angioplasty at 12 months, and limb salvage rate was 86.0% [17], while in our study, our results showed that the main patency rate was 84.8% in 12 months, limb salvage 88.1%.

In the current study, we found that the mean ABI was significantly improved from 0.384±0.047 preoperatively to 0.625±0.014 postprocedure. In agreement with our results, Tolva *et al.* [18] reported that the median ABI was significantly improved from 0.35 preoperatively to 0.74 postprocedure. We studied the relation between complete wound healing and the rate of change in ABI, we found a significant difference between both groups, thus, we placed our results on the receiver-operating characteristic curve to predict the point at which the healing of the ulcer can be predicted, and we found an increase in ABI by 0.218 that can predict wound healing.

Regarding outcome of the studied patients, our study showed that11 (23.9%) of the patients presented with reocclusion and no mortality was detected. Reocclusion was found among Rutherford-6 patients with major tissue loss and multiple comorbidities.

The study lacked the control arm (multiple crural arteries' angioplasty) and this was due to small weight of the recruited patients that went for multiple angioplasty and the short follow-up period, further studies should be done with large scale of the patients and multicenter sharing to give a stronger evidence.

## Conclusion

Single crural artery angioplasty can be done safely in diabetic patients presented with ischemic ulcers. Wound healing can be predicted in patients with higher ABI improvement. Further case–controlled studies with larger sample size and longer follow-up are needed to assess the independent risk factors and to emphasize our conclusion.

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Nil.

### Conflicts of interest

There are no conflicts of interest.

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