



ORIGINAL ARTICLE

Heal or no heel: Outcomes of ischaemic heel ulcers following lower limb revascularization from a multi-ethnic Asian Cohort in Singapore

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Abstract

Ischaemic diabetic heel ulcers are difficult to treat and prognosis is often guarded. The aim was to document our outcome of treating heel ulcers following revascularization in a predominantly diabetic Asian cohort presenting with chronic limb threatening ischaemia from Singapore. Retrospective cohort study (n = 66, 66 limbs) over a 5-year period. Data were collected from hospital electronic health records. Outcomes included time to healing, amputation free survival (AFS), and mortality. Minimum follow-up period was 6 months. Multivariate regression analysis was performed to look for factors associated with poor outcome. Mean age was 67.4 ± 8.8 years. 62/66 (93.9%) were diabetics. Mean wound size at presentation was 3.6 ± 2.3 cm. Mean Wound, Ischaemia, Foot Infection (WIFI) score was 5 ± 1.6 . 12/66 (18%) patients had a patent posterior tibial artery pre-operatively. Straight line flow was restored in only 31/66 (46.9) patients but 47/66 (71.2%) had successful limb salvage. Median time to wound healing was 90.0 (IQR 60-180) days. A median of 1 (IQR 0-2) wound debridement was required. Patients who underwent negative pressure dressing (23/66; 34.8%) required a median of 26 (IQR 13-33) cycles to achieve healing. Amputation free survival (AFS) was 72% and 68% at 6- and 12-months, respectively. Mortality rate was 16.7% and 19.7% at 6- and 12-months, respectively. Low albumin level and initial Rutherford class were independent predictors of worse 6-month AFS. Outcomes of heel ulcers post revascularisation may not be as poor as previously described. Persistent attention to wound care with multidisciplinary effort is needed for optimal healing.

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KEYWORDS

diabetic, endovascular, heel ulcer, outcome, posterior tibial artery, revascularization

1 | INTRODUCTION

Ischemic ulcers that occur in the heel region are widely considered to be severe, notoriously difficult to treat, and often associated with a poor prognosis, especially in patients with diabetes and peripheral vascular disease (PVD).¹ It typically develops due to trauma to a foot diseased with diabetic neuropathy, and fails to heal due to underlying disease in the peripheral arteries, which results in poor blood supply.² Tissue loss may result, with superimposed infection, which easily progresses to osteomyelitis due to relatively little soft tissue coverage over the calcaneum.³ Approximately 20% ulcers in patients with chronic limb threatening ischaemia (CLTI) occur in the heel.⁴ It is typically considered to be more problematic than forefoot ulcers for several reasons. Firstly, the heel has a unique single angiosomal blood supply from the posterior tibial artery (PTA),⁵ the occlusion of which results in failure of healing and a below knee amputation is likely to ensue. This is in contrast to the forefoot which has multi-angiosomes overlap from the anterior tibial artery (ATA) and peroneal artery, allowing for collateral blood supply. Second, the location of the heel is such that any major lower limb amputation (LEA) may preclude a patient from future ambulation, whereas a forefoot amputation is relatively less morbid and is likely to preserve ambulatory function.⁶

Outcomes of heel ulcers are hence poor, often with resultant major LEA and death.⁵ Previous studies of amputation rates in patient with diabetic heel ulcers found major LEA rates ranging from 7.1% to 25%⁷ and 5-year survival rates of 22% to 50%.⁷ Patients with heel ulcers are a significant burden to the healthcare system often requiring repeat wound debridement surgeries, application of numerous cycles of expensive wound care products, and undergo adjunctive treatments such as oxygen therapy.⁷

The guarded prognosis associated with ischaemic heel ulcers has been linked to patient, disease and treatment factors. Smoking, diabetes, and renal failure patients have been reported to have worse outcomes.^{2,5,8} Larger ulcers at presentation (>4 cm), the presence of underlying osteomyelitis and poor vascularity have also been linked to poorer outcomes.² PTA occlusion impedes wound healing of heel ulcer.⁹ Treatment of heel wounds require a multi-modal approach, involving revascularisation, wound care, and antimicrobial therapy.⁷

Key Messages

- Amputation free survival of heel ulcers post revascularisation is better than previously described in the literature.
- Achieving indirect revascularisation did not have worse outcomes than direct revascularisation.
- With dedicated multidisciplinary care and persistence in wound management, wound healing may still be achieved in this difficult area of the body.

While there are studies in the literature that investigate the effect of specific treatments for heel ulcers, such as dressing type¹⁰⁻¹² or extent of partial calcaneotomy,¹³ few studies exist which report the outcome of heel ulcer healing after revascularisation.^{4,9,14,15} Meloni et al⁴ compared outcomes of heel versus nonheel ulcers post endovascular surgery and found slower healing, more major amputations, and deaths in the heel ulcer group. Mohapatra et al,⁹ in comparing outcomes of heel versus forefoot ulcers post revascularisation, found lower 1-year amputation free survival (AFS) in those with heel ulcers. This was attributed to the demographic of patients who develop heel ulcers having poorer medical premorbid status. A better understanding of the success rates of revascularisation and subsequent wound healing would assist in deciding the necessity and type of revascularisation to offer patients. The aim of this study was to review the outcomes of patients who underwent revascularisation for ischaemic heel ulcers and investigate factors contributing to poorer prognosis and wound healing.

2 | METHOD

A retrospective review was performed of all patients presenting with heel ulcers who underwent lower limb revascularisation surgery at a 1700-bed tertiary institution in Singapore (Singapore General Hospital) over a 5-year period (January 2015 to December 2019). All

clinical data were retrieved from a computerised clinical database (Sunrise Clinical Manager, Eclipsys Corporation, Atlanta, GA, USA). The local Institutional Review Board approved this study (CIRB number: 2018/2995).

Revascularisation procedures were performed either by vascular surgeons or vascular interventional radiologists. We have adopted an endovascular first revascularisation policy as the majority of our patients are diabetic and do not have suitable venous conduits for femoral distal bypass. In addition, atherosclerotic occlusive disease is multilevel and vessels have a high degree of medial wall calcification, making sewing on a bypass difficult. All formal wound debridements and amputations were performed by vascular surgeons in the operating theatre environment under regional or general anaesthetic. Wounds were cared for by multidisciplinary teams involving the vascular surgeons, wound nurses, and podiatrists. The decision for the use of negative pressure dressing was primarily made by the vascular surgeon with input from the podiatrists and wound nurses, taking into consideration having largely clean wounds that would benefit from negative pressure to aid granulation, the ability to apply the dressing to the shape of the wound, the patient's financial ability to afford prolonged dressing.

Basic data on demographics, comorbidities, medication, preoperative investigations were collected. Patient pre-operative fitness was quantified via the American Society of Anaesthetist (ASA) score¹⁶ and the modified frailty score.¹⁷ Wound factors investigated included duration and size of wound, Rutherford score,¹⁸ Trans-Atlantic Inter-Society Consensus Document II (TASC II) grade,¹⁹ Wound, ischaemia, foot infection (WIFI) score,²⁰ previous revascularisation surgery, preoperative patency of posterior tibial artery and radiological evidence of calcaneal osteomyelitis. Treatment factors included nature of revascularization, vessels revascularized, use of drug eluting balloon (DEB) to maintain luminal patency from restenosis and achievement of straight-line flow to the heel, proportion of open and endovascular procedures and success of revascularisation. Treatment data on surgeries required and use of adjunctive wound products were also collected. Outcomes investigated included time to full wound healing, length of stay, need for major LEA, complications as classified by the Clavien-Dindo scoring,²¹ 30-day readmission rate, functional status at 6 months, AFS, mortality, and improvement in Rutherford score.

2.1 | Definitions

Time to wound healing was defined as the time from initial presentation to at least 70% re-epithelialisation of the heel wound.^{22,23} Major LEA was defined as amputation

above the ankle. Wound debridement was defined as the removal of unhealthy tissue in the operating theatre environment, short of a formal partial calcaneotomy. A patient was assessed for osteomyelitis based on preoperative radiographical changes. Heel ulcers were classified as Rutherford 5 if they were localised heel ulcers of three centimetres or less in diameter and Rutherford 6 if they were more than three centimetres and had underlying tendon exposed, had frank gangrene or were unsalvageable with major tissue loss.

2.2 | Statistical analysis

Descriptive statistics of demographic and clinical variables were performed based on patients or procedures as the unit of analysis, as appropriate. Survival probability was computed based on individual, from date of the first operation. Univariate analysis was conducted on categorical outcomes using logistic regression. Variables with $P < .01$ were selected for multivariate analysis. Among these variables, correlated variables were identified using a correlation coefficient $> |0.4|$, and the variable with lowest univariate p value is chosen out of each group of correlated variables. Remaining variables were entered into a stepwise selection model based on Akaike's Information Criterion (AIC). The AIC estimates the relative quality of a set of models based on fit and parsimony. Apart from 30-day unplanned readmission, which was analysed on a procedure level, other outcomes (mortality, amputation rate, and ambulation status) were analysed on a patient level with reference from the first procedure.

We also analysed the association between the demographic and clinical variables with survival on the patient level using the Cox proportional hazards model. Similarly, univariable analysis was done, and variables with $P < .01$ were entered into a stepwise multivariable Cox regression. All analyses were conducted in R version 3.4.2.²⁴

3 | RESULTS

3.1 | Baseline characteristics

Over the study period, 66 cases of heel ulcer underwent revascularisation. Demographic data and medical comorbidities are summarised in Table 1. 30/66 (45.5%) were male with mean age of 67.4 ± 8.8 years old. 59/66 (89.4%) had ASA scores of 3 or 4 and the mean modified frailty score was $4.0 (\pm 1.5)$. 62/66 (93.9%) had hypertension, 51/66 (77.3%) hyperlipidaemia, 62/66 (93.9%) diabetes, 37/66 (56.1%) end stage renal disease, and 40/66 (60.6%)

TABLE 1 Baseline characteristics (n = 66)

Demographics	n (%)
Mean age (\pm SD) (years)	67.4 (\pm 8.8)
Sex (male)	30 (45.5%)
Race	
Chinese	37 (56.1)
Indian	11 (16.7)
Malay	10 (15.2)
Eurasian/Caucasian	8 (12.1)
Smoking	10 (15.2)
Body mass index (BMI) kg/m ² (\pm SD)	23.1 (\pm 4.5)
Comorbidities	
Hypertension	62 (93.9)
Hyperlipidemia	51 (77.3)
Diabetes mellitus	62 (93.9)
Chronic renal disease	37 (56.1)
End stage renal disease on PD/HD	31 (47.0)
Ischaemic heart disease	40 (60.6)
ASA 3 or 4	59 (89.4)
Modified frailty score	4.0 (\pm 1.5)
Medications	
Antiplatelet agent	54 (81.8)
Statin use	53 (80.3)
Investigations	
Raised white cell count ($>10 \times 10^9/L$)	37 (56.1)
Low haemoglobin ($<10 \times 10^{12}/L$)	27 (40.9)
HbA1c	7.7 (\pm 1.6)
Low serum albumin (<35 g/L)	39 (59.1)

ischaemic heart disease. 54/66 (81.8%) patients were on some form of antiplatelet therapy. 37/66 (56.1%) had elevated white cell count on admission, 27/66 (40.9%) anaemia, and 39/66 (59.1%) were hypoalbuminemic.

3.2 | Wound characteristics and peripheral arterial disease status

Wound and blood supply information are summarised in Table 2. The median duration of heel ulcers prior to presentation was 30.6 (IQR 18.5-90.0) days. Mean wound size was 3.62 (\pm 2.3) cm. 33/66 (50%) were Rutherford 6. The mean WIFI score was 5.0 (\pm 1.7). 28/66 (42.4%) had infrainguinal TASC II grade C or D atherosclerotic lesions and 48/66 (72.8%) had infrapopliteal TASC II grade of C or D lesions. 12/66 (18.2%) had a patent PTA preoperatively, and 60/66 (90.9%) of patients had

TABLE 2 Wound characteristics and peripheral arterial disease status (n = 66)

Characteristic	N (%)
Median duration of wound/symptoms (IQR) (days)	30.6 (18.5-90.0)
Mean size of wound (\pm SD) (cm)	3.62 (\pm 2.3)
Rutherford score	
5	33 (50)
6	33 (50)
WIFI score (\pm SD)	5.0 (\pm 1.7)
TASC II grade (Infrainguinal)	
A	23 (34.8)
B	15 (22.7)
C	19 (28.8)
D	9 (13.6)
TASC II grade (Infrapopliteal)	
A	5 (7.6)
B	13 (19.7)
C	30 (45.5)
D	18 (27.3)
Previous ipsilateral revascularisation	11 (16.7)
Preoperative patency of posterior tibial artery	12 (18.2)
Inframalleolar disease	60 (90.9)
Radiological evidence of heel osteomyelitis	14 (21.1)

inframalleolar disease. 14/66 (21.1%) patients had radiological evidence of calcaneal osteomyelitis.

3.3 | Interventions

65/66 (98.5%) underwent endovascular revascularization and 1/66 (2.5%) underwent open surgical bypass (Table 3). Straight line flow was established in 31/66 (47%) patients. No patients required repeat endovascular revascularization after their first procedure during the course of wound healing. The mean number of vessels revascularised was 2.5 (SD 1.0). 36/66 (54.5%) patients required formal wound debridement, with median number of debridements being 1 (IQR 0-2). 4/66 (6.1%) of patients required partial calcaneotomy. 23/66 (34.8%) underwent negative pressure dressing, with a median of 26 (IQR 13-33) cycles of dressing changes required to achieve wound healing. 6/66 (9.1%) received additional oxygen delivery treatment and 3/66 (4.5%) underwent either split skin graft or free flap surgery.

TABLE 3 Interventions (n = 66)

Revascularisation	
Type of procedure	
Endovascular	65 (98.5)
Open bypass	1 (1.5)
Vessels revascularized	
Femoral/popliteal	45 (68.2)
Tibioperoneal trunk	18 (27.3)
ATA	34 (51.5)
PTA	28 (42.4)
Peroneal	18 (27.3)
Use of drug eluting balloon	39 (59.1)
Straight line blood flow achieved	31 (46.9)
Wound debridement	
Need for wound debridement	36 (54.5%)
Number of wound debridement during admission, median (IQR)	1 (0-2)
Partial calcanectomy	4 (6.1%)
Adjunctive wound care	
Simple dressing	66 (100%)
Negative pressure dressing	23 (34.8%)
Oxygen delivery device	6 (9.1%)
Split skin graft/free flap	3 (4.5%)

3.4 | Outcomes

51/66 (77.3%) had successful limb salvage. AFS was 72.7% and 68.2% at 6 and 12 months, respectively. Overall Survival (OS) was 83.3% at 6 months and 80.3% at 12 months. Mortality was 3%, 10.6%, 16.7%, 19.7% at 30 days, 3, 6, and 12 months, respectively. Cumulative incidence was demonstrated on a competing analysis graph (Figure 1). 47/66 (71.2%) patients eventually achieved wound healing, with median time to healing being 90 (IQR 60-180) days (Table 4). 12/66 (18.2%) patients required major LEA with median time to amputation being 24.5 (IQR 10.5-53.75) days. 25% of all amputations were primary LEA. 18/66 (27.3%) patients required readmission within 30 days. Reasons for readmission include wound related complications (12/18), care related issues (3/18), and unrelated medical conditions (3/18). The proportion of patients who achieved pre-morbid ambulation was 36/62 (54.5%) at 3 months, 33/59 (50%) at 6 months, and 32/59 (48.5%) at 1 year. 32/66 (48.4%) of patients saw improvements to their Rutherford score post revascularisation (Figure 2).

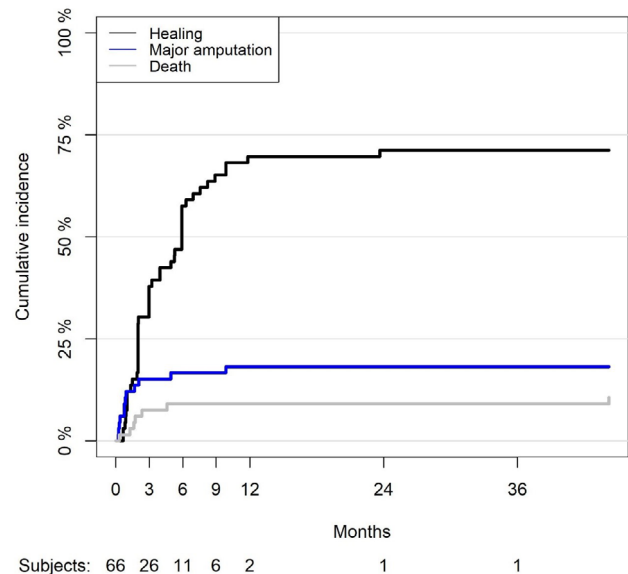


FIGURE 1 Competing analysis graph (wound healing/ amputation/death)

TABLE 4 Outcomes

Complete wound healing	47 (71.2%)
Time to complete healing (days), median (IQR)	90 (60-180)
Length of stay in hospital (days), median (IQR)	7 (1-22)
Need for major lower limb amputation (AKA/BKA)	12/66 (18.2%)
Time to major lower limb amputation (days), median (IQR)	25 (11-54)
Need for repeat revascularisation in 1 year	8 (12.1%)
Complications (Clavien Dindo 3 and above)	3 (4.5%)
30-day readmission	18 (27.3%)
Independent ambulatory status post-revascularisation among surviving patients	
3 months (n = 59)	33(55.9%)
6 months (n = 55)	30 (54.5%)
12 months (n = 53)	28 (52.8%)

3.5 | Analysis of 6-month AFS

Factors which predicted a lower 6-month AFS included low albumin ($P < .01$), WIFI score ($P = .02$), and Rutherford class ($P < .01$) (Figure 3). Multivariate analysis showed that low albumin (OR 5.4, SD 1.0, $P < .01$) and presenting Rutherford class (OR 1.31, SD 0.7, $P < .01$) were significant independent predictors.

3.6 | Analysis of 12-month AFS

Univariate analysis of 12-month AFS showed that factors which predicted a lower 12-month AFS included low albumin ($P < .01$), WIFI score ($P = .03$), and Rutherford

class ($P = .02$). Multivariate analysis showed that low albumin (OR 9.5, SD 0.8, $P < .01$) and Rutherford class (OR 3.2, SD 0.6, $P = .07$) were independent predictors, of which only low albumin was significant.

3.7 | Analysis of 6-month OS

Univariate analysis of 6-month OS showed that factors which predicted a lower OS included Rutherford class ($P = .01$) and preoperative PTA patency ($P = .01$). Multivariate analysis showed Rutherford class (OR 6.4, SD 1.1, $P = .01$) and preoperative PTA patency (OR 1.51, SD 0.84, $P = .02$) were both significant independent predictors.

3.8 | Analysis of 12-month OS

Univariate analysis of 12-month OS showed that factors which predicted a lower 12-month OS included low albumin ($P = .02$), Rutherford class ($P < .03$), and preoperative PTA patency ($P = .04$). Multivariate analysis showed low albumin (OR 9.5, SD 1.1, $P = .03$),

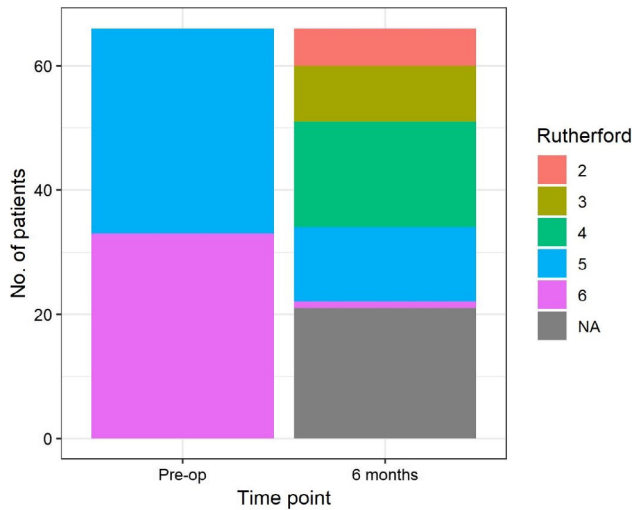


FIGURE 2 Change in proportion of Rutherford 5 and 6 post revascularisation

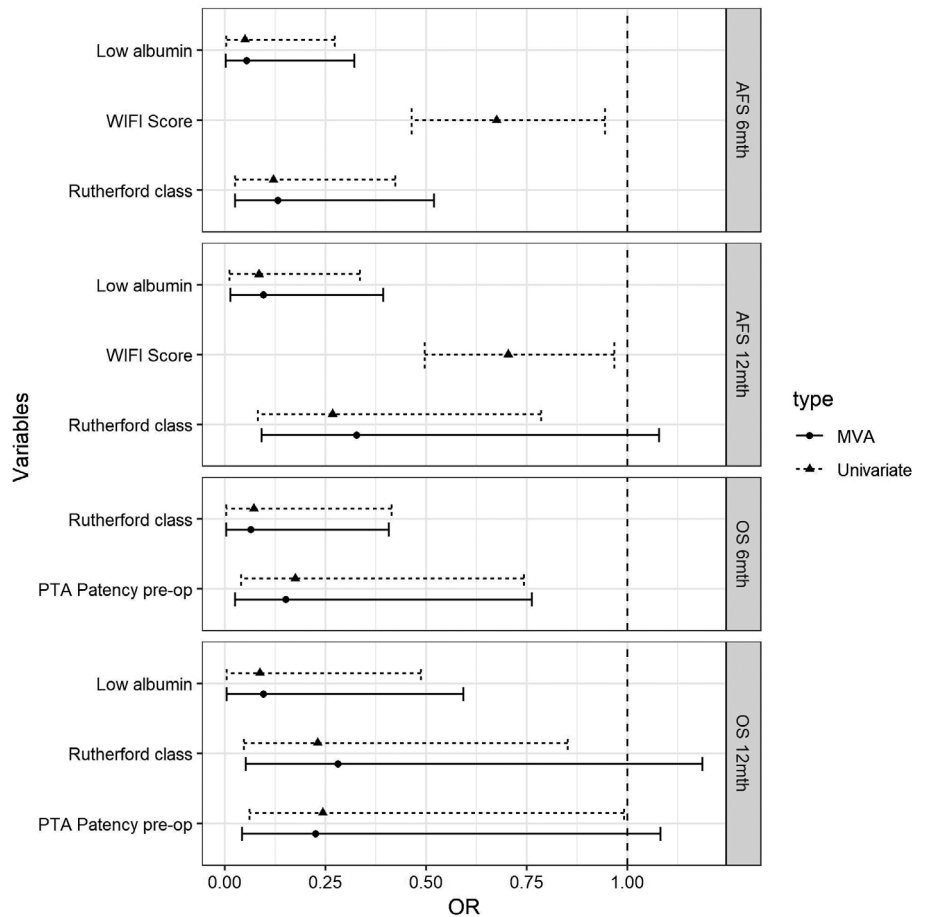


FIGURE 3 Multivariate regression showing variables associated with outcome

Rutherford Class (OR 2.8, SD 0.77, $P = .10$) and preoperative PTA patency (OR 2.25, SD 0.80, $P = .06$) to be independent predictors, with only low albumin reaching significance.

One's ethnicity, including Chinese, Malay, Indian, Eurasian, or Caucasian was not a significant predictor of 6- and 12-month AFS and overall survival. Patients with initial Rutherford score of 6 was associated with significantly poorer 6- and 12-year AFS and overall survival compared with patients with an initial Rutherford score of 5 ($P < .03$).

4 | DISCUSSION

The results of our study suggest that outcomes of heel ulcers post revascularisation were not as poor as previously suggested. Our study population fitted the description of typical vasculopathies, with multiple medical comorbidities, elevated ASA and high modified frailty scores, and requiring antiplatelet and statin therapy. They had severe foot wounds with mean WIFI score of 5, most of which had inframalleolar arterial disease and preoperative occlusion of the PTA. Revascularisation was mostly endovascular. Only one patient underwent open bypass, and this was because the patient had long segment occlusion of the common femoral artery involving the origin of the profunda femoris. Multiple wound debridements were needed, with the use of adjunctive wound treatment such as negative pressure dressing, oxygen delivery device, and grafting. Complete healing occurred in over 70% patients, requiring a median of 90 days to occur. 18.2% of patients eventually required major LEA but those that required one declared themselves relative early (median time 24 days). 19.7% patients eventually died within 1 year of revascularisation, which is in keeping with the literature of a 20% mortality rate for CLTI patients.²⁵

In contrast, previous literature on the outcome of heel ulcers post revascularisation were less optimistic. In comparing outcomes of heel and forefoot wounds, Mohapatra et al⁹ analysed 46 heel ulcers post open and endovascular revascularisation and reported one-year AFS of 48%, markedly below the 68% that we found. Meloni et al,⁴ in comparing heel versus nonheel ulcers post revascularisation reported heel ulcer healing rate of 50 heel ulcers to be 60% with mean time for healing to be 41 weeks. This disparity in outcome is likely multifactorial and highlights the plethora of factors involved in wound healing. Possible explanations include more comprehensive wound care locally involving a spectrum of wound products, more aggressive antimicrobial therapy, an emphasis of early mobility, and return to function with multidisciplinary care involved. Our data suggests

that with persistence in wound management, including undergoing multiple sessions of specialised negative pressure dressings and debridements, as well as dedicated multidisciplinary team involving wound nurses and podiatrists, heel wounds may have a better chance of healing post revascularisation. This coordinated effort is well established in our institution, which sees over 900 limb salvage procedures a year.²⁶

The results of the univariate and multivariate analyses were consistent with the existing literature. A higher WIFI score and Rutherford class predicted poorer AFS at 6 and 12 months, and Rutherford class and preoperative PTA occlusion predicted poorer overall survival at six and 12 months. This was to be expected, as ischaemia, especially with occlusion of the angiosomal supply of the heel, would lead to greater tissue loss and suggests a heavier burden of atherosclerosis systemically. However, traditional culprits, such as smoking status, frailty, presence of OM, were not identified as predictive factors of worse AFS or OS at six and 12 months. This could be due to a lack of power in the study to demonstrate the effect of these variables. Low serum albumin level predicted poorer 6 and 12-month AFS as well as 12-month survival. Serum albumin is often used as a marker for nutritional status, and low serum albumin is suggestive of a protein-energy deficit in the body, resulting in poor wound healing.²⁷ Low serum albumin has been linked to increased perioperative morbidity and mortality after lower limb bypass, length of stay, return to operating room,²⁸ and lower AFS in ulcer healing in patients with CLTI.²⁹ It is also seen in scoring systems predicting outcome of wound healing in patients with arterial ulcers.³⁰ This serves to highlight role of nutrition in wound healing, and the need for multidisciplinary care for patients to include dietitians and speech therapists.

Our findings also shed light to the role of angiosomal supply and restoring straight-line blood flow to the heel for wound healing. Heel wounds, which lacked direct angiosomal supply from the PTA was associated with poor OS. However, neither achievement of straight-line flow nor the revascularisation of PTA was found to be associated with improved OS or AFS. While only 47% of patients had straight line flow achieved, 71% of patients had wounds that healed completely. This suggests that while the lack of a straight-line blood flow may result in development of heel ulcers, indirect flow may be sufficient for healing to take place. Azuma et al,¹⁰ in studying the role of direct angiosomal revascularisation in foot wounds, found no difference in healing rates of the direct and indirect revascularisation groups. This suggests that in patients with arterial ulcers due to chronic limb ischaemia, a substantial network of collaterals may develop from neighbouring angiosomes that, with the aid

of revascularisation of the inflow vessels, may be sufficient to allow for wound healing perhaps slower if direct angiosomal revascularisation occurred.

A major shortcoming of the existing literature is that present studies have largely expressed outcomes of heel and other lower limb ulcers using the Kaplan Meier analysis.^{3,9} While useful in analysing outcomes with just two possibilities, such as death or survival, it does not adequately represent data with multiple possibilities. In the case of heel ulcers, complete healing, major amputation and death are possible outcomes, and this information is better studied using a competing analysis curve. Our study is the first that present this information, and brings to the literature valuable insight into the prognosis of heel ulcers that is useful for clinical decision making and patient counselling.

There are several limitations to this study, including its retrospective design, relevance in only centres that perform endovascular first revascularisation as well as its lack of comparative population, such as patients with heel ulcers that did not undergo revascularisation. Future recommendations include studying the other aspect of a heel ulcer, including the infection and wound care aspects, and how they interact with revascularisation to achieve successful wound healing.

5 | CONCLUSION

In summary, we found amputation free survival of heel ulcers post revascularisation to be better than previously described in the literature. Achieving indirect revascularisation did not have worse outcomes than direct revascularisation. With dedicated multidisciplinary care and persistence in wound management, wound healing may still be achieved in this difficult area of the body.

CONFLICT OF INTEREST

The authors declare no conflict of interest.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author upon reasonable request.

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