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Research Article

Endovascular Limb Salvage for Haemodialysis Patients: A Retrospective 10-Year Review

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ABSTRACT

Objectives: Endovascular revascularization is a commonly used method for limb salvage in haemodialysis patients with Chronic Limb Threatening Ischemia (CLTI). This study was to determine the long-term limb and survival outcomes in this highly co-morbid population.

Methods: A single center, retrospective review of all endovascular procedures performed for limb salvage from 1/2010-1/2020 was undertaken. Inclusion criteria were patients on haemodialysis, presenting with infra-inguinal peripheral vascular disease resulting in CLTI. CLTI was defined as ischaemic pain at rest or the presence of tissue loss. The primary outcome measure was limb salvage at 30 days, 1, 2 and 3 years. The secondary outcome measures were amputation free survival and all-cause mortality along the same time periods.

Results: 39 patients (mean age 69.8 years) underwent 47 endovascular procedures. Mean length of follow-up of 24.8 ± 26.9 months. EVT indication for tissue loss was 80.7%. Limb salvage rate at 30-days, 1 year and 3 years limb salvage was 87.2%, 76.9% and 74.4%. Mortality at 30-days, 1 year and 3 years was 17.9%, 51.3% and 69.2%. One year amputation-free survival was poor at 48.7%. Patients undergoing minor amputations <30 days after EVT were more likely to have a major amputation (OR 2.4, 95% CI 0.17-32.8). Partial or unsuccessful angioplasty did not increase the risk of major amputation (OR 1.03, 95% CI 0.22-4.68).

Conclusion: EVT is safe and has adequate limb salvage outcomes however mortality in this group is high, reflecting the co-morbid nature of this patient cohort when presenting with CLTI. Patients undergoing debridement or minor amputation <30 days from EVT have a higher risk of major amputation. Further research is required to determine factors affecting survival within this population to allow appropriate patient selection for EVT.

Keywords: Angioplasty; Haemodialysis; Chronic limb; Threatening ischaemia

INTRODUCTION

Chronic Limb Threatening Ischemia (CLTI) in patients on haemodialysis is a challenging clinical entity with a estimated prevalence of 15-25% in this patient cohort [1,2]. Heavy vascular calcification typically seen in in End-Stage Renal Failure (ESRF), combined with complex distal lesions result in patients often presenting with established tissue loss or gangrene [1].

Despite the complexities of intervention in this highly comorbid population, revascularization has been shown to have favorable limb salvage rates [3]. Open surgery has encouraging short-term results but the long-term outcomes are not as favourable; A meta-analysis of infra-inguinal bypass in ESRF patients demonstrates limb salvage of 67% but a 5-year survival of only 23% [3-5].

Although open surgery is often deemed to have longer patency, the poor survival and multiple co-morbidities in this patient cohort leads to Endovascular Treatment (EVT) being an appealing treatment modality [1]. Despite ESRF itself having been demonstrated to be a risk-factor for EVT failure and poorer long term patency comparative to surgery, EVT does appear to have acceptable long term limb salvage outcomes and is therefore frequently the modality of choice in this patient population [1,6,7].

This review was performed to determine the long-term limb and survival outcomes of infra-inguinal endovascular revascularization in our local haemodialysis population over a 10-year time period.

LITERATURE REVIEW

A retrospective review was performed of all haemodialysis patients

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within the institution undergoing EVT from 1/2010 to 1/2020. Events were identified from the electronic radiology database: Angiogram events for patients with an eGFR<30 and the terms "haemodialysis", "dialysis", "renal replacement therapy" were identified. Angiograms were included if clinical indications included symptoms and signs of CLTI as defined by the Global Vascular Society guidelines for CLTI [8].Full inclusion and exclusion criteria are defined in Table 1.

Patient demographics including age, co-morbidities and follow-up was obtained from electronic health records as well as procedural data. Success was defined as treatment achieving in-line arterial flow to the foot. Partial success was defined as successful angioplasty some of the targeted disease resulting in improved qualitative flow but where in-line arterial flow was not achieved. Re-intervention was defined as a previously treated segment requiring further treatment. Limb salvage outcomes were recorded from electronic records including amputation date and type of amputation. Major amputation was defined as any amputation above the ankle joint.

Neither ethical approval nor patient consent was sought due to the retrospective nature of the study. Statistical analysis was performed using IBM SPSS Statistics for Macintosh, Version 27.0.0

DISCUSSION

2938 angiogram events were identified over the 10-year time study period. Of these, 47 angioplasties in 39 patients fulfilled the inclusion criteria and inclusion into the review is shown in Figure 1.

Of the included patients, the mean length of follow-up was 24.8 ± 26.9 months and demographics are shown in Table 2. In this elderly diabetic population, the pattern of disease demonstrated was typically distal in nature. Angioplasty was successful in the majority of patients without complication and outcomes are demonstrated in Table 3. A single case resulted in distal embolization to the TP stem, which was managed conservatively as the patient was asymptomatic and the run-off vessels were already heavily diseased. This complication did not result in limb loss. Groin haematoma occurred in 3 cases; none required intervention. Repeat angioplasty was performed in 4 patients with time between interventions ranging from 2.23-17.4 months. A staged surgical bypass after EVT was performed in a single case on the same admission.

Table 1: Inclusion and exclusion criteria.

Inclusion criteria	Exclusion criteria
Haemodialysis EVT indication CLTI: Presence of rest pain >2 weeksor tissue loss/ulceration Infra-inguinal disease	Dialysis method other than haemodialysis EVT indication: Aneurysmal disease Diagnostic angiogram, no procedure performed Aorto-iliac disease

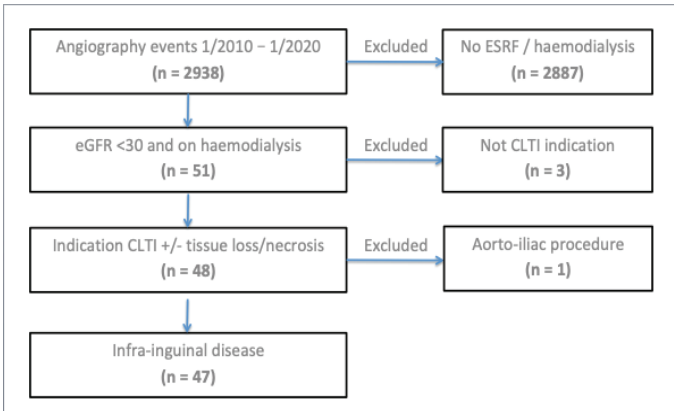


Figure 1: Flow diagram demonstrating inclusion into the study.

Table 2: Demographics and distribution of disease.

Patient demographics and distribution of disease	
Age	69.8 years
Male	74.4 %
Diabetic	74.4 %
Smoker	30.8 %
Ischaemic heart disease	66.7%
EVT indication tissue loss	80.7 %
Femoro-popliteal disease	19.2 %
Femoro-popliteal and crural disease	34.0 %
Crural disease	46.8 %

Table 3: Angioplasty outcomes.

Angioplasty immediate outcomes (%)		
Success	Full	74.5
	Partial	21.3
	Failure	4.3
Complications	Groin haematoma	7.6
	Distal embolisation	2.5
	Reintervention	10.2
	Surgical revascularization	2.5

Crural angioplasty target distribution is shown in Table 4. For crural revascularization, the Anterior Tibial Artery (ATA) was the most common target, followed by peroneal and Posterior Tibial Artery (PTA). Very few patients had 2-vessel intervention and only a single patient had all 3 crural vessels treated. Successful crural revascularization did not have lower risk of amputation (OR 0.31, 95% CI 0.04-2.17). Isolated peroneal revascularization also did not result in higher amputation risk than revascularization of the ATA/PTA vessels (OR 0.42, 95% CI 0.04-4.12).

Overall limb salvage was 74.4%. Healing without surgical management was successful in 51.3%. Minor amputation or debridement was required in 25.6%; of these 8 required a single intervention, 4 a second and 2 patients requiring a third procedure. Major amputation occurred in 23.0%, all below knee amputations. 35.7% of those undergoing debridement or minor amputations ended up with a below knee amputation. Short-term mortality was low at 17.9% but late mortality high as demonstrated in Table 5. Amputation free survival was 76.9%, 48.7% and 35.8% over 30 days, 1 and 2 years respectively.

Figure 2 shows cumulative survival in the cohort over the follow-up time period. This demonstrates the significant mortality occurring within the first year after intervention.

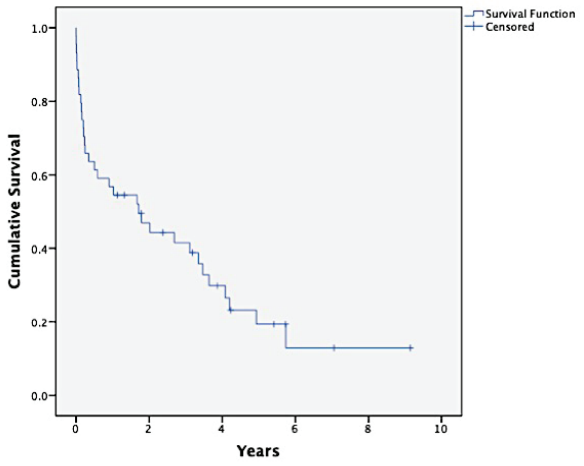
Time from EVT to minor amputation ranged from 0.03-3.23 months (Median 0.40, IQR 1.81). Time from EVT to major amputation ranged from 0.13-24.3 months (Median 1.16, IQR 1.66). Patients undergoing minor amputations <30 days after EVT were more likely to have a major amputation (OR 2.4, 95% CI

Table 4: Crural angioplasty targets.

Crural angioplasty targets (%)	
ATA	38.9
Peroneal	16.7
PTA	13.9
Tibio-peroneal trunk	8.3
ATA+PTA	8.3
PTA+Peroneal	5.6
ATA+Peroneal	2.8
Tibio-peroneal trunk+Peroneal	2.8
ATA+PTA+Peroneal	2.8

Table 5: Mortality and amputation free survival.

	Limb salvage (%)	Mortality (%)	Amputation free survival (%)
30 day	87.2	17.9	76.9
1 year	76.9	51.3	48.7
2 year	76.9	61.5	38.5
3 year	74.4	69.2	23.1



Means and Medians for Survival Time

Mean[a]				Median			
		95% Confidence Interval				95% Confidence Interval	
Estimate	Std. Error	Lower Bound	Upper Bound	Estimate	Std. Error	Lower Bound	Upper Bound
2.784	.502	1.801	3.768	1.715	.679	.384	3.046

a. Estimation is limited to the largest survival time if it is censored.

Figure 2: Cumulative survival.

0.17-32.8). There was no significant difference between partial success and successful angioplasty in 30-day limb salvage (χ^2 1.95, p=.16). Partial or unsuccessful angioplasty did not increase the risk of major amputation (OR 1.03, 95% CI 0.22-4.68). Limb salvage was achieved in all 4 patients undergoing reintervention.

This series demonstrates adequate limb salvage rates with endovascular revascularization in haemodialysis patients presenting with CLTI. Early mortality and amputation-free survival in the 30 days after intervention is poor however, with a drastic increase in mortality over the first year. Similar results have been shown in other studies for patients undergoing any form of revascularization from this cohort, reflecting the highrisk nature of these patients [1,3]. With less than 40% survival at 2 years, it would appear that the current recommendations from the BASIL trial would suggest EVT to be appropriate in the majority of this population. Furthermore, there is evidence that an EVT approach in this cohort is favored by clinicians with over 60% of patients with ESRF undergoing EVT as opposed to surgery in a review of German registry data [1,9].

The disease pattern demonstrated in this series was typical of the haemodialysis population [1]. Although the sample size was small, there was no difference in outcome between angioplasty of crural disease comparative to femoro-popliteal lesions. Isolated peroneal revascularization appears sufficient for tissue loss; its efficacy supported by evidence in non-haemodialysis populations [10]. Unfortunately for this sample, data was unavailable for the site of the tissue loss so it is unknown whether direct revascularization of the relevant angiosome was achieved, a crucial limitation of this study. Evidence would suggest that limb salvage is better achieved with a direct approach; especially in diabetic patients and that this is of higher importance when EVT is the revascularization method of choice [11-13].

Identifying haemodialysis patients with a high likelihood of poor survival can be challenging and is key in informing the decision for revascularization. Patients undergoing revascularization with chronic kidney disease stage 5 have much poorer outcomes to those patients with stages 1-4 [3]. Biancari et al. demonstrated that for revascularizations in this population, an age >75 years was associated with poor survival for either surgical and endovascular methods [3]. The majority of the hemodialysis population generally possess these risk factors identified for poor outcomes, highlighting the fragile nature of these patients [3,14]. This is seen not only with peripheral vascular disease; dialysis patients with cardiac disease have also been shown to have a high late mortality and thus patients with symptomatic severe atherosclerosis should be scrutinized prior to undertaking revascularization [3,15]. A multi-disciplinary approach, in conjunction with nephrology input is essential to establish the life expectancy prior to revascularization attempts.

In this series where revascularization was successful but tissue loss required surgical debridement, the risk of major amputation was high. Mortality for those undergoing amputation was high. Poor healing potential therefore is likely to be a sign of generalized systemic decline in this cohort; inability of heal ischemic wounds being an independent risk factor for mortality as demonstrated in the literature [16]. A significant disadvantage of interpreting the minor surgical intervention in this study is that data was unavailable for whether minor amputations or debridement were planned prior to EVT and thus is not possible to determine whether minor amputations were as a result of failure to heal after EVT or performed as a planned procedure.

The limitations of this study are that the sample size is small, a feature common to many of the series reported in the literature. Pressure parameters such as toe pressures or trans-cutaneous oxygen saturations, both useful surrogate marker of the ability of tissue to heal, were unfortunately not available for the vast majority of the patients in the series [17,18]. Patency was also not studied in the long-term follow-up and thus it is unclear whether poor late outcomes were due to angioplasty failure or other factors. Finally, patients presenting with CLTI who did not undergo intervention or underwent surgical treatment primarily were not included due to the selection method; possibly allowing selection bias affecting both ends of the outcome scale.

CONCLUSION

Endovascular treatment yields acceptable results with minimal peri-procedural complications in haemodialysis patients presenting with CLTI. In this small sample, it appears that patients undergoing surgical intervention for tissue loss shortly after EVT are more likely to require major amputation; this may be reflective of either the extent of tissue loss or poor healing potential. This should be taken into account in surgical decision making and informing patient expectations. Further research is required to provide better prediction of survival to better inform patient selection for revascularization.

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