ORIGINAL ARTICLE

# INFRAPOPLITEAL BYPASS IN PATIENTS ON DIALYSIS: PATENCY AND SURVIVAL

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## Abstract

***Objectives:*** *Portugal has one of the highest prevalence of patients on a regular dialysis program.*

*This population has a higher incidence of peripheral arterial disease with higher rates of postoperative morbidity and mortality. Our goal was to compare outcomes between dialysis and non-dialysis patients with chronic limb threatening ischemia (CLTI) submitted to infrapopliteal bypass.*

***Materials and Methods:*** *A retrospective single-center study of infrapopliteal bypass for CLTI was performed between 2012 and 2019. Patients were divided in two groups based on dialysis status (group 1 incorporated patients on dialysis). Primary end point was 1-year freedom from CLTI. Secondary end points were limb-salvage, survival and primary (PP) and tertiary patency (TP) rates at 3 years of follow-up.*

***Results:*** *A total of 352 infrapopliteal bypasses were performed in 310 patients with CLTI. Fourteen percent of the revascularizations were performed on dialysis patients (48/352). Median age was 73 years (interquartile range - IQR 15) and 74% (259/352) were male. Median follow-up was 26 months (IQR 42). Overall, 92% (325/352) had tissue loss and 44% (154/352) had some degree of infection.*

*The majority of revascularization procedures were performed with vein grafts (61%, 214/352).*

*The 30-day mortality was 4% (11/310), with no difference between groups (p = 0.627). Kaplan-Meier analysis showed no difference between groups regarding freedom from CLTI (76% vs. 79%; HR 0.96, CI 0.65–1.44, p=0.857), limb-salvage (70% vs. 82%; HR 1.40, CI 0.71–2.78, p=0.327) and survival (62% vs. 64%; HR 1.08, CI 0.60–1.94, p=0.799). PP rates were 39% in group 1 and 64% in group 2 (HR 1.71, CI 1.05–2.79, p=0.030). TP rates were not different between groups (57% and 78%; HR 1.79, CI 0.92–3.47, p=0.082).*

***Conclusion:*** *Infrapopliteal bypass for CLTI, on dialysis patients, resulted in lower PP rates. No differences were observed in freedom from CLTI, TP, limb salvage and survival.*

***Keywords:*** *Chronic Limb Threatening Ischemia; End-Stage Renal Disease; Dialysis*

## INTRODUCTION

The incidence and prevalence of end-stage renal disease (ESRD) has been increasing in recent years. Portugal has one of the highest incidence and prevalence rates of dialysis patients in Europe (244 per million population (pmp) vs 132pmp and 1906 pmp vs 985 pmp, respectively).[1]

Patients with ESRD have a higher incidence of peripheral arterial disease (PAD) with increased rates of chronic limb threatening ischemia (CLTI) and, consequently, a greater risk of limb loss. [2,3]

ESRD is associated with higher postoperative morbidity and mortality rates, in a wide scope of surgical procedures, including vascular interventions.3,4 However, this high-risk population is frequently excluded from studies and, consequently, from guidelines. [2]

ESRD patients with CLTI often have distal anatomical pattern of PAD, with heavily calcified arteries.[5] Our institutional experience has previously been published for distal[6] and ultradistal[7] revascularization. The aim of the present study was to compare postoperative outcomes of infrapopliteal bypass for CLTI, in dialysis versus non-dialysis patients.

## MATERIAL AND METHODS

### Study population

All patients submitted to infrapopliteal bypass for CLTI between 2012 and 2019 were included. A retrospective analysis was performed in a single center with a limb preservation program. Baseline demographic and clinical characteristics, perioperative details and follow-up data were collected from medical records. All patients provided informed consent before surgery.

Patients were divided in two groups based on dialysis status. Group 1 included all patients on dialysis and group 2 incorporated non-dialysis patients.

### Classification systems

Wound and infection grade from the Society for Vascular Surgery WIfI staging system was determined to classify all wounds.8 Segmental femoropopliteal (FP) and infrapopliteal (IP) grades were determined from preoperative angiograms and reviewed by one of the authors. GLASS stage was determined combining FP and IP grades according to the literature. [9]

### Clinical end points and variable definitions

The primary end point was 1-year freedom from CLTI. Secondary end points were limb salvage, survival, primary (PP) and tertiary patency (TP) rates at 3 years of follow-up. Freedom from CLTI was defined as a combination of freedom from major index limb amputation, complete wound healing and absence of ischemic rest pain within a period of 12 months. Tertiary patency, as described by Soderstrom et al, was defined as patency of an infrapopliteal revascularization graft, including redo bypasses replacing more than half of the original graft and both infow and outfow anastomosis.[10] Chronic Kidney Disease (CKD) was defined as an estimated glomerular filtration rate of less than 60 mL/min/1.73m$^2$ determined with the Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI).[11]

### Statistical analysis

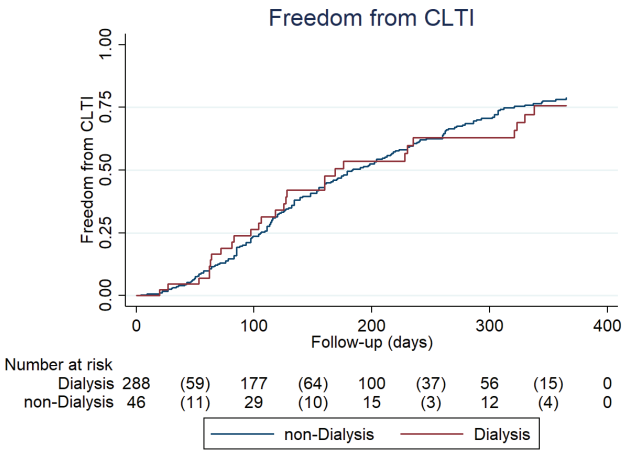


**Figure 1** *Cumulative Kaplan-Meier estimate of primary end point, freedom from Chronic Limb Threatening Ischemia, in the dialysis and non-dialysis group.*

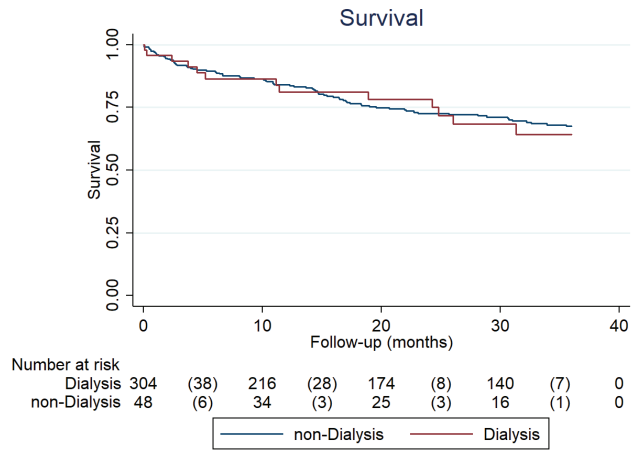


**Figure 3** *Cumulative Kaplan-Meier estimate of survival in the dialysis and non-dialysis group.*

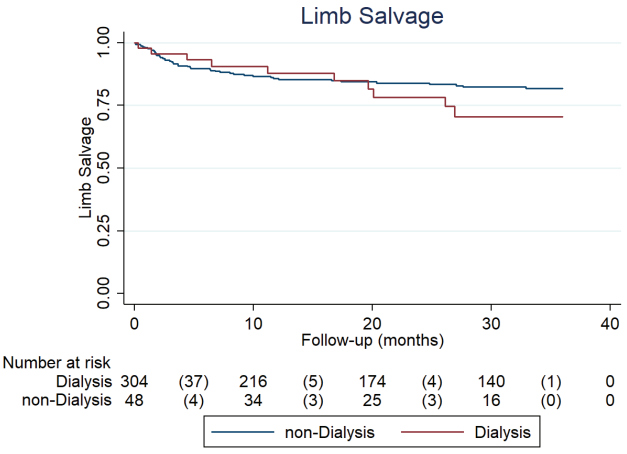


**Figure 2** *Cumulative Kaplan-Meier estimate of limb salvage in the dialysis and non-dialysis group.*

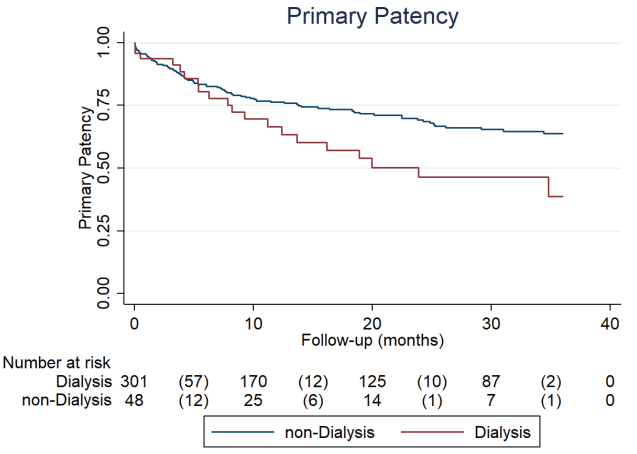


**Figure 4** *Cumulative Kaplan-Meier estimate of primary patency in the dialysis and non-dialysis group.*

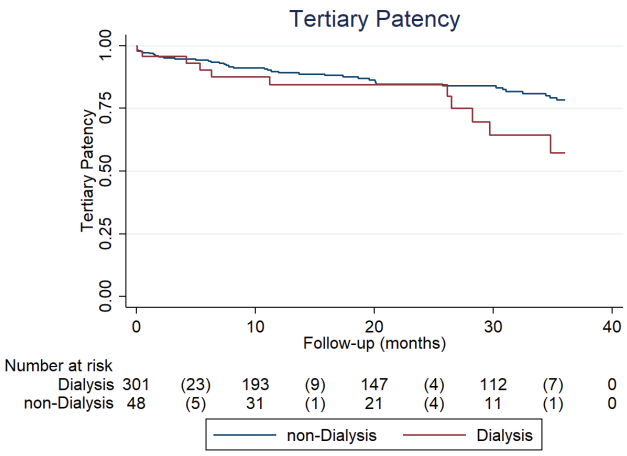


**Figure 5** *Cumulative Kaplan-Meier estimate of tertiary patency in the dialysis and non-dialysis group.*

Statistical analysis was carried out using Stata 12.1 (StataCorp®, Lakeway Drive, College Station, Texas, USA). Continuous variables were presented as median with interquartile range from 25th to 75th percentile (IQR), and categorical variables were presented as absolute numbers with percentage values. Time-to-event end points were presented with Kaplan–Meier estimates with patients censored at major amputation, death, or last follow-up. All analyses were considered statistically significant if a two-tailed p value $< .05$ was observed.

## RESULTS

A total of 352 infrapopliteal bypasses were performed in 310 patients with CLTI. Fourteen percent of the revascularizations (48/352) were performed on dialysis patients (group 1). Overall, 74% were male (259/352) and dialysis patients were younger, with a median age of 68 years (interquartile range - IQR 15). Patients' characteristics and clinical data are summarized in Table I. Most of the patients had hypertension (93%, 328/352) and diabetes (76%, 268/352), with an increased prevalence of coronary artery disease in group 1 (48% vs. 33%, p=0.049). Contralateral lower limb revascularization was also more common in group 1 (35% vs. 21%, p=0.042). Overall, 92% (325/352) had tissue loss and 44% (154/352) had some degree of infection. GLASS III stage was more frequent in group 2 (69% vs. 84%). There was no difference in WIfI classification between groups.

The majority of revascularization procedures were performed with inverted vein grafts (61%, 214/352) and the remaining 39% (138/352) with HePTFE grafts. The usage of HePTFE grafts was not significantly different between groups (44% in group 1 and 39% in group 2, p=0.526). Surgical details are summarized in table II. Peroneal artery was the most common outflow vessel in both groups (27% and 32%).

Thirty-day mortality was 5% (2/37) and 3% (9/273) in group 1 and group 2, respectively (p = 0.627). Median follow-up was 26 months (IQR 42). One-year freedom from CLTI was 78% with no difference between groups (76% vs. 79%; HR 0.96, CI 0.65–1.44, p=0.857). Additionally, there were no significant differences in 3-year limb-salvage (70% vs. 82%; HR 1.40, CI 0.71 – 2.78, p=0.327) and survival rates (62% vs. 64%; HR 1.08, CI 0.60 – 1.94, p=0.799). Three-years PP rates were significantly different, with 39% in group 1 and 64% in group 2 (HR 1.71, CI 1.05 – 2.79, p=0.030). However, TP rates were not different between groups (57% and 78%; HR 1.79, CI 0.92 – 3.47, p=0.082). Bypass-related and clinical outcomes are reported in detail in table III and the Kaplan-Meyer curve in figures 1-5.

## DISCUSSION

In a single-center retrospective study of patients submitted to infrapopliteal bypass for CLTI, based on dialysis status, no significant difference was found in the primary end point of freedom from CLTI at 1 year. Patients on dialysis had lower primary patency rates at 3 years, but no significant differences were found for tertiary patency, limb salvage and survival rates.

Several studies report higher perioperative and long-term mortality rates in dialysis patients.[3,4,12] Nevertheless, in this group of patients, the literature is very inconsistent regarding limb salvage and graft patency rates, and completely omits a very important clinical outcome - freedom from CLTI.[3,4] Moreover, there is a scarcity of contemporary studies on the results of open revascularization for distal and ultradistal disease, let alone on dialysis patients.

The baseline characteristics of our sample are comparable to previously published series, with younger but very comorbid patients on the ESRD group, as demonstrated by CAD and previous contralateral limb revascularization rates.[3,13] However, contrary to the literature, we did not find a significant difference in DM rates, with a high prevalence in both groups (group 1 – 81% and group 2 – 75%).[3]

The 30-day mortality was 5% in group 1, with no significant difference from non-dialysis patients. This finding is in line with the lowest perioperative mortality rates published in literature, which range from 3% to 18%.[4,14,15]

ESRD patients have generally been associated with poorer outcomes, especially survival and limb salvage rates, following lower extremity revascularization.[2–4,12] Kumada et al and Cox et al reported lower 5-year survival rates for ESRD vs. non-ESRD (57% and 55% vs. 83% and 72%, respectively).[16,17] Similarly, Cheng et al registered a significant difference in survival between patients with ESRD, CKD and normal renal function at 3-years of follow-up (72% vs. 96% vs. 94% at 3-years, respectively).3 We reported similar results for dialysis patients (64% survival at 3-years) but, in our series, no statistically significant difference for non-dialysis patients was found (67% survival at 3-years). This particularly low 3-year survival rate in

**Table 1** **Baseline characteristics of 352 limbs with chronic limb-threatening ischemia (CLTI) submitted to distal bypasses.**

| Characteristics | Group 1 (Dialysis) (n=48) | Group 2 (Non-dialysis) (n=304) | Total (n=352) | *p value* |
|---|---|---|---|---|
| Basic demographics | | | | |
| Male gender | 36 (75%) | 223 (73%) | 259 (74%) | .862 |
| Age, years † | 68 (15) | 74 (15) | 73 (15) | .034 |
| BMI, kg/m² † | 26 (8) | 26 (5) | 26 (6) | .499 |
| | | | | |
| Smoking status | | | | |
| Current smoker | 6 (13%) | 55 (18%) | 61 (17%) | .416 |
| Former smoker | 10 (21%) | 58 (19%) | 68 (19%) | .844 |
| History of smoking | 17 (35%) | 114 (38%) | 131 (37%) | .873 |
| | | | | |
| Comorbidity | | | | |
| Hypertension | 46 (96%) | 282 (93%) | 328 (93%) | .756 |
| Diabetes | 39 (81%) | 229 (75%) | 268 (76%) | .467 |
| CAD | 23 (48%) | 99 (33%) | 122 (35%) | .049 |
| CKD (eGFR<60 mL/min/1.73m²)* | 48 (100%) | 86 (28%) | 134 (38%) | < 0.005 |
| Previous lower limb revascularization | | | | |
| Contralateral | 17 (35%) | 65 (21%) | 82 (23%) | .042 |
| Ipsilateral | 9 (19%) | 65 (21%) | 74 (21%) | .849 |
| ASA 4 | 14 (29%) | 37 (12%) | 51 (14%) | .004 |
| WIfI | | | | |
| Wound class | | | | .092 |
| 0 | 3 (6%) | 24 (8%) | 27 (8%) | |
| 1 | 10 (21%) | 96 (32%) | 106 (30%) | |
| 2 | 33 (69%) | 150 (49%) | 183 (52%) | |
| 3 | 2 (4%) | 34 (11%) | 36 (10%) | |
| Foot infection class | | | | .203 |
| 0 | 34 (71%) | 164 (54%) | 198 (56%) | |
| 1 | 6 (13%) | 65 (21%) | 71 (20%) | |
| 2 | 8 (17%) | 71 (23%) | 79 (22%) | |
| 3 | 0 (0%) | 4 (1%) | 4 (1%) | |
| | | | | |
| GLASS Stages | N=45 | N=237 | N=282 | .019 |
| I | 3 (7%) | 16 (7%) | 19 (7%) | |
| II | 11 (24%) | 22 (9%) | 33 (12%) | |
| III | 31 (69%) | 199 (84%) | 230 (82%) | |
| | | | | |
| Preprocedural medication | | | | |
| Statin | 33 (69%) | 181 (59%) | 214 (61%) | .267 |
| Antiplatelet | 34 (71%) | 171 (56%) | 205 (58%) | .060 |

* Chronic kidney disease was defined as an estimated glomerular filtration rate of less than 60 mL/min/1.73m2 determined with the Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI). † Continuous variables were presented as median with interquartile range from 25th to 75th percentile.

Abbreviations: ASA, American Society of Anesthesiologists physical status classification system; BMI, body mass index; CAD, coronary artery disease; CKD, chronic kidney disease; GLASS, Global Anatomic Staging System.

**Table 2** **Surgical details of 352 limbs with chronic limb-threatening ischemia (CLTI) submitted to distal bypasses.**

| Surgical bypasses | Group 1 (Dialysis) (n=48) | Group 2 (Non-dialysis) (n=304) | Total (n=352) |
|---|---|---|---|
| Inflow | | | |
| Iliac sector | 4 (8%) | 4 (8%) | 8 (2%) |
| Femoral sector | 25 (52%) | 193 (63%) | 218 (62%) |
| Popliteal below knee | 17 (35%) | 97 (32%) | 114 (32%) |
| Tibioperoneal sector | 2 (4%) | 10 (3%) | 12 (3%) |
| | | | |
| Outflow | | | |
| Tibioperoneal trunk | 2 (4%) | 6 (2%) | 8 (2%) |
| Peroneal artery | 13 (27%) | 96 (32%) | 109 (31%) |
| Anterior tibial artery | 10 (21%) | 60 (20%) | 70 (20%) |
| Dorsalis pedis artery | 13 (27%) | 65 (21%) | 78 (22%) |
| Posterior tibial artery | 6 (13%) | 45 (15%) | 51 (14%) |
| Plantar artery | | 18 (6%) | 18 (5%) |
| Anterior tibial/dorsalis pedis* | 1 (2%) | | 1 (0%) |
| Anterior tibial/peroneal* | | 1 (0%) | 1 (0%) |
| Dorsalis pedis/plantar* | 1 (2%) | | 1 (0%) |
| Peroneal/perforating branch* | | 1 (0%) | 1 (0%) |
| Peroneal/plantar* | | 1 (0%) | 1 (0%) |
| Peroneal/anterior tibial* | | 1 (0%) | 1 (0%) |
| Peroneal/ dorsalis pedis* | 2 (4%) | 4 (1%) | 6 (2%) |
| Plantar/dorsalis pedis* | | 1 (0%) | 1 (0%) |
| Popliteal/peroneal* | | 1 (0%) | 1 (0%) |
| Posterior tibial/plantar* | | 1 (0%) | 1 (0%) |
| Posterior tibial/anterior tibial* | | 3 (1%) | 3 (1%) |
| | | | |
| Conduit | | | |
| Vein | 27 (56%) | 187 (62%) | 214 (61%) |
| HePTFE | 21 (44%) | 117 (38%) | 138 (39%) |

*Refers to both outflow vessels of inverted T bypass.

Abbreviation: HePTFE, heparin-bonded expanded polytetrafluoroethylene.

non-dialysis patients, can be explained by the higher prevalence of diabetes (75%) and tissue loss (92%) in group 2. Additionally, only 58% of the revascularizations reported by Cheng et al were infrapopliteal.[3]

One of the most striking findings in our study was the absence of significant difference in limb salvage rates at 3 years, contrary to most of the literature.[12,13] However this is not a first in literature, as Cox et al reported similar results, with 3-year limb-salvage rates of 62% in ESRD vs. 68% for non-ESRD.[17]

Freedom from CLTI is a time-integrated measure of clinical disease severity recommended by Global Vascular Guidelines on the Management of CLTI to describe the total impact of surgical interventions.[5] Because this is a relatively recent concept, we haven't found reports of this outcome in revascularized ESRD patients. Nevertheless, Söderström et al. reported a wound healing rate of 75% at 1-year after infrainguinal bypass for CLTI with tissue loss.[18] This outcome compares favorably to our reported 78% rate of freedom from CLTI at 1-year.

The conduit of choice for bypass surgery is autologous vein graft, but, when unavailable prosthetic grafts can be an alternative.[5] Our study incorporated around 40% of prosthetic revascularizations in both groups, which, to our knowledge, in unprecedented in literature for infrapopliteal bypass. Kumada et al reported that 1% of the revascularizations in patients on dialysis were performed with prosthetic graft.[16]

**Table 3** **Bypass-related and clinical outcomes of a total of 352 distal bypasses to treat chronic limb-threatening ischemia (CLTI).**

| Outcome and time point | Group 1 (Dialysis) (n=48) | Group 2 (Non-dialysis) (n=304) | Total (n=352) | *p value** |
|---|---|---|---|---|
| Limb-specific end points | | | | |
| Freedom from CLTI at 12 months | 76% | 79% | 78% | .857 |
| Limb Salvage | | | | |
| 1 year | 88% | 86% | 86% | .684 |
| 2 years | 78% | 84% | 83% | .634 |
| 3 years | 70% | 82% | 80% | .327 |
| | | | | |
| Survival-related end points | | | | |
| 30 day - mortality | 2 (5%) | 9 (3%) | 11 (4%) | 0.627 |
| Survival (n=307) | | | | |
| 1 year | 81% | 84% | 84% | .692 |
| 2 years | 78% | 73% | 73% | .573 |
| 3 years | 64% | 67% | 67% | .818 |
| | | | | |
| Bypass-related end points | | | | |
| Primary patency | | | | |
| 1 year | 67% | 76% | 75% | 0.282 |
| 2 years | 46% | 69% | 66% | 0.030 |
| 3 years | 39% | 64% | 60% | 0.030 |
| Tertiary patency | | | | |
| 1 year | 84% | 89% | 89% | 0.426 |
| 2 years | 84% | 85% | 85% | 0.082 |
| 3 years | 57% | 78% | 76% | 0.082 |

*p value determined with log rank test comparing both groups.
Abbreviations: CLTI, chronic limb-threatening ischemia.

This study has the inherent limitations of a retrospective, single-center study with a limited number of patients. Nevertheless, it is one of the largest reports of infrapopliteal bypass in ESRD patients. There may be a selection bias, as some patients were suitable for more than one revascularization technique. We also highlight the heterogeneity of our series, given the considerable rate of prosthetic graft bypasses (about 40%). However, the influence of this conduit heterogeneity on limb related outcomes is curtailed by an equivalent prevalence of prosthetic bypass on both groups (44% vs. 38%). Finally, we did not evaluate functional or quality of life outcomes, which could provide a better insight into the value of revascularization in this frail population.

## CONCLUSION

Dialysis patients with CLTI exhibited lower 3-year PP rates following infrapopliteal bypass. However, no differences were observed in 3-year TP, limb salvage and survival, nor in freedom from CLTI at 1-year. These results support open revascularization as a safe and effective treatment for CLTI patients on dialysis.

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