

# Long-Term Outcomes after Infrainguinal Revascularization in Patients with Critical Limb Ischemia on End-Stage Renal Disease Patients (ESRD) and Comparison Results with Non-ESRD Population

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## ABSTRACT

Infrainguinal revascularization in end-stage renal disease patients is controversial, despite of patency and limb salvage rates observed in several studies. This study provides more favourable overall survival and amputation free-survival rates than the contemporary study of the same characteristics. The revascularization of patients with ESRD is frequently conditioned by poor survival. With the data we provide, approximately half of the patients were alived and their limb was salvaged at 3 years, and this is encouraging. Thus, we can be more aggressive in daily practice and offer revascularization in ESRD patients.

**Objective:** This study analyzed long-term outcomes and evaluate the benefits and limits of infrainguinal revascularization (IR) both surgical and endovascular revascularization with critical limb ischemia (CLI) in patients with and without ESRD.

**Material and Methods:** A total of 1188 patients were prospectively collected and analyzed retrospectively. We included 108 (9.1%) patients with ESRD and of them 70 (64.8%) receiving hemodialysis.

**Results:** The 30-day mortality rate was higher in ESRD group (5.6 vs. 1.8,  $p=0.009$ ). The second patency was similar in both groups at 1 and 3 years (87.6% and 85.3% vs. 82.9% and 81.6%). ESRD patients had a lower overall survival and amputation free-survival (AFS) (at 1 year 79.6% vs. 91.8% and at 3 years 57.9% vs. 79.1%,  $p<0.001$ ) and (at 1 year 68.2% vs. 78.8% and at 3 years 45.7% vs. 64.6%,  $p<0.001$ ) than non-ESRD patients. The limb salvage rates achieved excellent outcomes during follow-up at 1 and 3 years. (83.5% and 83.2% vs. 66.0% and 77.6% ( $p=0.194$ )). Cox regression analysis showed that hemodialysis was an independent predictor of all-cause mortality and AFS (HR=2.38, 95% CI 1.54- 3.68,  $p<0.001$ ). Octogenarian patients and coronary disease was independent predictor of all-cause mortality (HR=3.05, 95% CI 2.3-4.01,  $p<0.001$ ) and (HR=1.49, 95% CI 1.14-1.95,  $p=0.03$ ).

**Conclusions:** The long-term patency and limb salvage rates in patients who underwent IR with CLI and ESRD was comparable with non-ESRD patients. Despite, the overall survival and amputation free-survival rates was poorer in ESRD patients, we advocated for aggressive revascularization attitude in ESRD patients but we must individualize treatment decision and should be offered revascularization for patients with acceptable life expectancy.

**Keywords:** Vascular surgery; Critical limb ischemia; End stage renal disease

## INTRODUCTION

Critical Limb Ischemia (CLI) defines a sub-group of patients with peripheral arterial disease (PAD), who present ischemic pain at rest and/or ulcers and gangrene [1]. Patients with end-stage renal disease (ESRD) have a high incidence and prevalence of PAD. Some studies suggests a prevalence of 27.5-38% in the United

States with about 13% having a diagnosis of CLI [2,3] which is more prevalent in dialysis patients compared to non-dialysis kidney failure patients [4]. The most patients with ESRD have multiple systemic comorbidities (diabetes, hypertension, history of smoking, hyperlipidemia) and their arteries are affected by severe calcification and multiple distal occlusions [5,6].

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Infrainguinal revascularization (IR), open surgical and endovascular revascularization, in patients with ESRD, can be challenging and its management remains unclear [7,8]. In the 80-90s some authors defended primary amputation after observing high rates of amputations with an important associated morbimortality [9,10]. Some authors have advocated the aggressive management of critical limb ischemia in ESRD patients [11-15]. The aim of our study is to assess the feasibility and evaluate the benefits and limits of an IR (Open surgical and endovascular revascularization) for CLI in these very high risk patients.

## PATIENTS AND METHODS

A total of 1188 procedures were done to CLI at the Department of Vascular Surgery, Getafe University Hospital (Madrid-Spain) between 1991 and 2013. This research was approved by our Ethical Committee. Epidemiological data, demographics characteristics, operative data and postoperative outcomes were prospectively collected and analyzed retrospectively. The study included patients who underwent surgical revascularization with infrainguinal bypass with autologous graft and endovascular procedures. All patients presented objective clinical and/or hemodynamic criteria for CLI [1]. All cases were reviewed and discussed for decision making and daily vascular meetings in our Department. All patients signed informed consent.

After procedures patients received low molecular weight heparin during their postoperative hospital stay and were treated with 100 mg aspirin once a day indefinitely. The patients who placed stent were treated with 75 mg clopidogrel orally for at least one month. Routine follow-up included clinical examination, ankle-brachial index and Doppler ultrasound at 1, 3, 6 and 12 months, and then every year.

Glomerular Filtration (GF) is the best rate to assess renal function. Serum creatinine and GF levels of patients were determined 24 hours before the procedure. Different equations can be used to calculate the GF. We used the MDRD equation:  $[186 \times \text{serum creatinine} \times \text{patient's age in years} \times 1.210 \text{ (if black race)} \times 0.742 \text{ (if female)}]$ . Patients were classified according to their GF, into the stages of chronic kidney disease (CKD) defined by the KDOQI guidelines [16].

- GF:  $>90 \text{ ml/min/m}^2 \rightarrow$ CKD class 1.
- GF:  $60\text{-}89 \text{ ml/min/m}^2 \rightarrow$ CKD class 2.
- GF:  $30\text{-}59 \text{ ml/min/m}^2 \rightarrow$ CKD class 3.
- GF:  $15\text{-}29 \text{ ml/min/m}^2 \rightarrow$ CKD class 4
- GF:  $< 15 \text{ ml/min/m}^2 \rightarrow$ CKD class 5.

ESRD was defined as those patients with GF  $<30 \text{ ml/min/m}^2$ , CKD class 4 and 5.

Short-term outcomes (30-day): were analyzed amputation and mortality rates, major adverse limb event (MALE), major adverse cardiovascular event (MACE). MALE included any ipsilateral amputation or vascular re-intervention on the initial side of revascularization.

Long-term outcomes were analyzed primary and second patency, limb salvage, overall survival, amputation free-survival (AFS) and freedom from MALE at 1 and 3 years. AFS required the absence of either amputation or death.

MALE, MACE and freedom from MALE were defined according to the Objective Performance Goals (OPGs) [17].

The patients that underwent procedures with non-autologous graft (only below the knee arteries), as well as emergency procedures for acute embolic limb ischemia and patients with acute renal failure were excluded.

In the present study, the CLI treatment outcomes of patients with and without ESRD were compared.

## Statistical Analysis

Statistical analysis was performed using a SPSS statistical software (SPSS v. 16.0.Inc., Chicago, Ill., USA). For comparison of the demographics and epidemiological data between two groups, a Chi-squared test for categorical variables and the T-student test for continuous variables were used. Differences were considered significant when the P-value was  $<0.05$ . Patency, limb salvage, overall survival and amputation free-survival rates were estimated by Kaplan-Meier Methods. The differences in survival rates between both groups were evaluated by Log-Rank Test and the Cox regression methods. Only variables with a  $p < 0.10$  in univariate analysis were included in the Cox regression model.

## RESULTS

The mean length of the follow-up was  $31.5 \pm 30.6$  months. We included 108 (9.1%) ESRD patients (64.8% on hemodialysis) and 1080 non-ESRD patients. The demographic and procedure data in the study (overall series) are shown in Table 1. The average patients age was  $70.6 \pm 8.1$  vs.  $70.1 \pm 11.2$  ( $p=0.701$ ). ESRD group had most patients a history of smoking, DM, hypertension and coronary disease. Ulcer or gangrene was the indication of revascularization in 74.5% ( $n=886$ ) of the overall cohort (ESRD: 88.0% vs. non-ESRD: 73.2%). The level of revascularization was similar in both groups. Type of revascularization were surgical revascularization (50.9% vs. 73.4%) and endovascular procedures (49.1% vs. 26.6%) respectively. These results are shown in Table 2.

Compared ESRD patients, the non-ESRD group had lower

**Table 1:** Baseline characteristics and operative data who underwent infrainguinal revascularization for critical limb ischemia.

Patient's characteristics	Number of patients (%)
Age (years)	70.2 $\pm$ 11,2
Octogenarian	246 (20.7)
Male (gender)	885 (74.5)
Diabetes Mellitus	769 (64.7)
Hypertension	782 (65.8)
Coronary artery disease	293 (24.6)
Pulmonary disease	203 (17.1)
Hyperlipidaemia	334 (28.1)
Cerebrovascular disease	164 (13.8)
Smoking	692 (58.2)
<b>Indication of revascularization</b>	
Rest pain	302 (25.4)
Ulcer/gangrene	886 (74.5)
<b>Level of revascularization</b>	
Femoropopliteal	578 (48.6)
Below the knee vessels (BTK)	610 (51.3)
<b>Type of revascularization</b>	
Open surgery	848 (71.4)
Endovascular revascularization	340 (28.6)
ESRD on hemodialysis	70 (5.9)

mortality rate at 30-day (5.6% vs. 1.8% (6 vs. 19 patients) ( $p=0.009$ )). The amputation and MALE rates were 2.8% vs. 5.4% (3 vs. 58 patients) ( $p=0.24$ ) and 5.6% vs. 12.8% (6 vs. 138 patients) ( $p=0.028$ ). At 30-day peri-operative MACE rates was 8.3% vs. 4.0% (9 vs. 43 patients) ( $p=0.035$ ). This data can be explained the higher mortality rate on ESRD patients (Table 2).

Primary and second patency rates are illustrated in Table 3. Primary and second patency rates at 1 and 3 years were 73.8% and 62.5% vs. 68.9% and 59.8%, 87.6% and 85.3% vs. 82.9% and 81.6%, respectively.

The limb salvage, overall survival and AFS rates can be observed in Table 4. The limb salvage rates at 1 and 3 years was similar (83.5% and 83.2% vs. 66.0% and 77.6% ( $p=0.194$ )). ESRD patients had significantly lower overall survival (at 1 year 79.6% vs. 91.8% and at 3 years 57.9% vs. 79.1%,  $p<0.001$ ), and AFS (at 1 year 68.2% vs. 78.8% and at 3 years 45.7% vs. 64.6%,  $p<0.001$ ) than non-ESRD patients. Freedom MALE was 50.2% vs. 42.4% and 37.9% vs. 28.5% ( $p=0.18$ ) at 1 and 3 years, respectively (Figure 1).

Independent predictor of limb salvage, overall survival and AFS rates are shown in Table 4. Cox regression analysis identified

**Table 2:** Baseline characteristics and operative data on patients with and without end-stage renal disease who underwent infrainguinal revascularization for critical limb ischemia in the overall population.

Patient 's characteristics	Overall Series		
	ESRSD	No ESRD	p-value
Age (years)	70.61 ± 8.1	70.19 ± 11.2	0.701
Octogenarian	14 (13)	232 (21.5)	0.032
Male (gender)	73 (67.6)	812 (75.2)	0.084
Diabetes Mellitus (DM)	89 (82.4)	680 (63.0)	<0.001
Hypertension	90 (83.3)	692 (64.1)	<0.001
Coronary artery disease	49 (45.4)	224 (22.6)	<0.001
Pulmonary disease	13 (12.0)	190 (17.6)	0.001
Hyperlipidaemia	40 (30.0)	295 (27.3)	<0.032
Cerebrovascular disease	16 (14.8)	148 (13.7)	<0.001
Smoking	51 (47.2)	642 (59.4)	0.014
<b>Indication of revascularization</b>			
Rest pain	13 (12.0)	289 (26.8)	
Ulcer/gangrene	95 (88.0)	791 (73.2)	
<b>Level of revascularization</b>			
Femoropopliteal	52 (41.8)	526 (48.7)	
Below the knee vessels (BTK)	56 (51.9)	554 (51.3)	
<b>Type or revascularization</b>			
Open surgery	55 (50.9)	793 (73.4)	
Endovascular revascularization	53 (49.1)	287 (26.6)	
ESRD on hemodialysis	70 (64.8)		

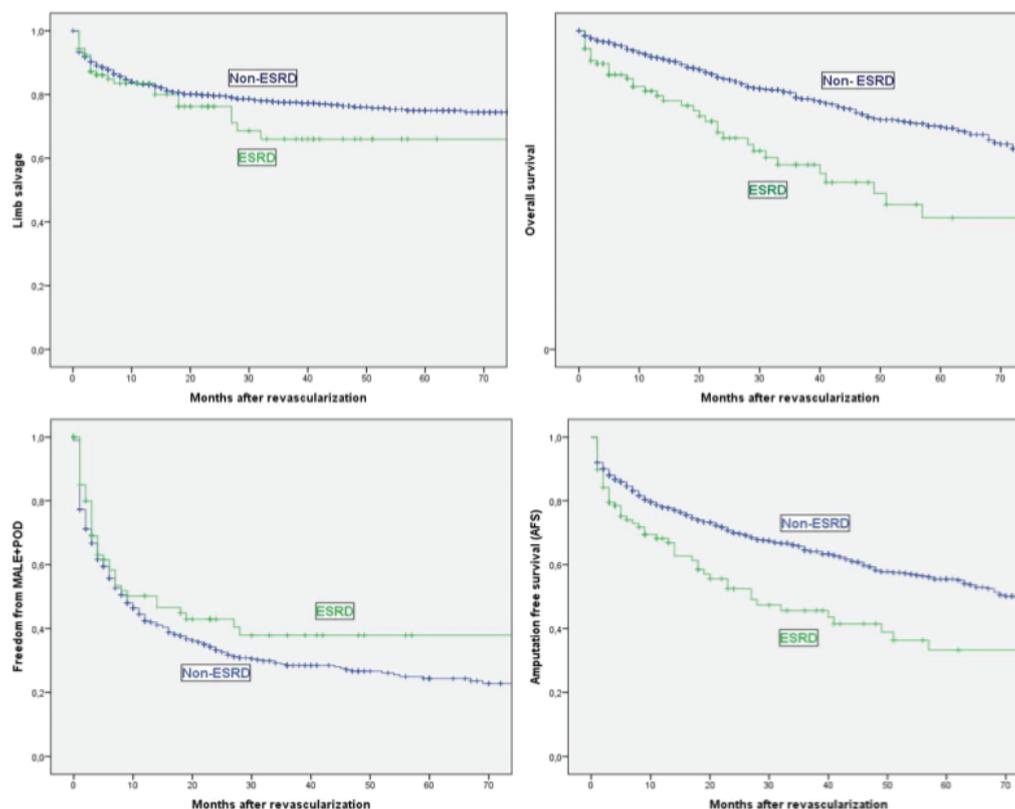
**Table 3:** Primary and second patency at 1 and 3 years.

	Primary patency(%)		Second patency(%)	
	1 year	3 years	1 year	3 years
ESRD	73.8	62.5	87.6	85.3
No ESRD	68.9	59.8	82.9	81.6
<i>P value</i>	>0.05	>0.05	>0.05	>0.05

**Table 4:** Limb salvage, Amputation free survival and overall survival according to Cox regression analysis.

	Limb salvage(%)		Amputation free survival		Overall survival	
	HR (95%CI)	<i>P value</i>	HR (95%CI)	<i>P value</i>	HR (95%CI)	<i>P value</i>
Octogenarian	-	-	1.65(1.36-2.01)	0.001	3.05(2.3-4.01)	85.3
History of smoking	-	59.8	1.28(0.89-1.48)	0.036	-	-
Hypertension	-	>0.05	-	>0.05	-	>0.05
Hemodialysis	-	-	-	-	2.14(1.42-3.24)	-
Ulcer/gangrene	-	-	-	-	-	-
BTK TVR	-	-	-	-	-	-
Coronary disease	-	-	-	-	-	-
Hyperlipedaemia	2.19 (1.54-3.12)	0.001	1.54(0.97-1.35)	0.075	-	-
	1.48 (0.95- 1.96)	0.001	-	-	1.51(0.97-2.34)	0.064
	-	-	-	-	1.49(1.14-1.95)	0.03
	-	-	-	-	-	-

BTK (Below the knee vessel). TVR (Target vessel revascularized).



**Figure 1:** Limb salvage, overall survival, Freedom from MALE and Amputation free-survival to Kaplan-Meier Methods in ESRD and non-ESRD patients.

octogenarian patients and coronary disease were associated with significantly higher risk of all-cause mortality (HR=3.05, 95% CI 2.3-4.01,  $p<0.001$ ) and (HR=1.49, 95% CI 1.14-1.95,  $p=0.03$ ). The patients on hemodialysis was an independent predictor and was associated a higher risk of all-cause mortality survival and AFS (HR=2.38, 95% CI 1.54-3.68,  $p<0.001$ ). The patients underwent infrainguinal revascularization due ulcer or gangrene were a higher risk of amputation (HR=2.19, 95% CI 1.54-3.12,  $p<0.001$ ).

## DISCUSSION

ESRD is a huge problem that is growing. According to the U.S. Department of Health and Human Services, ESRD has increased by 600% over the past three decades [18], approximately 20% of the ESRD patients may need a vascular consultation. For this reason, CLI management of this population can be a challenging and we have to make the effort to find tools that allow us to offer each patient individually the best treatments.

The appropriate treatment of CLI in ESRD patients is unclear. Some studies advocated an aggressive approach that achieves good limb salvage rates, although all these studies agree on the poor overall survival rates of long-term [13,19]. A Metanalysis, Albers et al recommend that bypass grafting should not be offered patients with amount of tissue loss or extensive infection [5].

Compared with non-ESRD patients, multiple studies examining lower limb revascularization have previously shown ESRD population experience decreased patency, decreased limb salvage, and lower survival rates [4,11]. In despite, several studies and conventional wisdom have historically supported early vascular surgery referral and potential revascularization among ESRD patients.

This analysis of ESRD patients undergoing infrainguinal revascularization demonstrates promising results of long-term

overall survival rates in this population against previously reviewed studies.

The 30-day peri-operative mortality rates found after IR on ESRD patients (5.6%) was on par with those reported in another studies [2,11,18,20,21]. We suggested that probably, the higher mortality rates on ESRD patients can be explained due the higher MACE rate (8,3%, 9/108 patients). A meta-analysis evaluated the impact of kidney function on the outcome after surgery indicated that relative risk of 30-day mortality according to the decrease of the glomerular filtration. The relative risk was 3.57 (CI 95%) in CKD class 5, particularly after lower limb revascularization [22]. While there was a similar risk of 30-day amputation rate between both groups, the MALE was significantly higher on non-ESRD patients, due higher minor amputation rate in this group.

Some reports have reported different patency rates. In Table 5 are shown patency rates. We observed an excellent secondary patency in both groups at 1 and 3 years (85.3% vs. 81.6%). This outcomes demonstrate similar patency between ESRD cohort to controls with mild or no renal impairment ( $p<0,05$ ), according previous studies [23-25]. These data would be suggest the patients might in fact be dying with a patent graft or target vessel revascularized. Patency rates were markedly superior than data have been previously published in other studies [8,9,11,23].

Despite the excellent results of patency and limb salvage, clinically, independent ambulation and the quality of life are more relevant than these parameters. Some studies reported independent ambulation rates of 10-61% at one year [26-28]. Measures of quality of life in Non-ESRD patients underwent IR is higher to primary amputation, but this is certain in ESRD population [29].

The poor long-term survival, which is a consistent finding in all studies reviewed. In our study, limb salvage rate outcomes were no better than survival rates. Limb salvage, AFS and overall survival

Table 5: Early outcomes rates (at-30 days).

	ESRD(%)	Non-ESRD (%)	P value
Mortality	5.6	1.8	0.009
Amputation	2.8	5.4	0.24
MALE	5.6	12.8	0.28
MACE	8.3	4.0	0.035

at 1 and 3 years were 83.5% and 83.2% vs. 66.0% and 77.6% ( $p=0.0194$ ), 68.2% vs. 78.8% and 45.7% vs. 64.6%, ( $p<0.001$ ), 79.6% vs. 91.8% and at 3 years 57.9% vs. 79.1% ( $p<0.001$ ). These results were indicated excellent limb salvage, improving the overall survival in the ESRD population, although the overall survival rate is still poorer than non-ESRD group. Shroff [30] reported a mortality rate at 3 years ESRD patients who underwent coronary revascularization was 42%. This findings support that the severe arteries calcification is determinant of a worse survival in ESRD patients. As expected, the patients with ulcer or gangrene have a higher risk of amputation (HR=2.19, 95% CI 1.54-3.12,  $p<0.001$ ). Patients on hemodialysis was an independent predictor and was associated a higher risk of all-cause mortality and AFS (Table 4). Octogenarian patients were independent predictor of all-cause mortality. For the results obtained in the present study, we believe that revascularization in ESRD patients (including on hemodialysis) with CLI is necessary whenever feasible for the maintenance of quality of life. Risk stratification should be performed to improve both the safety and the efficacy of IR. Analyzing freedom from MALE half of the patients were amputated at 1 year (50.2% vs. 42.4%) and around a quarter of the patients at 3 years (37.9% vs. 28.5%) ( $p=0.18$ ). If we analyzed the events of AFS, we observed that the most of them were caused by deaths (70.8%). These data highlight the important mortality associated with ESRD population and importance of identifying patients who can benefit from a more conservative attitude.

There are a few studies that analyzed the cost/effectiveness of lower limb revascularization in ESRD patients. To support the decision to precede revascularization, Barshes [31], showed that the endovascular revascularization appears to be a cost-effective compared with a local wound care and primary amputation. In a previous study [32], they found surgical by pass to be a most cost-effective alternative to local wound care based a CLI population similar to PREVENT III trial [33], where the incidence of ESRD was 12%. More studies are needed to confirm the cost-effective of limb revascularization in ESRD patients and compared them with healthy population or initial class of CKD.

## CONCLUSIONS

Despite the poorer mortality and overall survival rates in patients with ESRD in previous cohorts, in this study we observed encouraging long-term results. In addition, the excellent patency and limb salvage rates were comparable with the non-ESRD group. We believe that should be aggressively performed lower limb revascularization in ESRD patients because we can greatly improve the independent ambulation and quality of life. The complete preoperative evaluation emphasizing of age and myocardial ischemia may be beneficial to select the patients who benefit of revascularization. Thus, despite we advocated for revascularization in ESRD patients, we must individualize treatment decision and should not be offered revascularization for patients with deep tissue loss or extensive infection.

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## CONFLICT OF INTEREST STATEMENT

The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

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