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Impact of Renal Impairment on Immediate and Midterm Results of Endovascular Management of Peripheral Arterial Disease

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ABSTRACT

Background: Peripheral artery disease (PAD) is highly common and more severe among patients who have chronic kidney disease (CKD), due to vascular calcification. This calcification complicates diagnosis and treatment, requiring tools like the PACSS scoring system for accurate assessment. This research aimed to assess the impact of renal impairment on different modalities and outcomes of endovascular management of femoro-popliteal atherosclerotic arterial disease.

Methods: This single-center prospective cohort study included 47 patients with chronic kidney disease (CKD) who presented with disabling claudication or critical limb ischemia due to femoro-popliteal atherosclerotic disease and were treated using an endovascular approach. All patients were subjected to radiological investigation [arterial duplex was done before and after endovascular procedure].

Results: Analysis of the endovascular procedure revealed that patients with high Ca score had high incidence of stenting by a rate of 64.7 % (P=0.033). Analysis of the endovascular procedure revealed that patients with high Ca score had high incidence of stenting by a rate of 64.7 % (P=0.033). During follow up, the clinical presentation of the patients had also impact on the clinical outcome. The patients presented with major tissue loss had poor clinical outcome in comparison with other patients (P=0.028).

Conclusions: Chronic kidney disease (CKD) is linked to unfavorable 12-month clinical outcomes in patients undergoing endovascular revascularization for peripheral arterial disease (PAD).

KEYWORDS: Renal Impairment, Endovascular Management, Peripheral Arterial Disease, Chronic Kidney Disease.

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INTRODUCTION

Peripheral artery disease (PAD) is a major global health concern, currently estimated to affect around 200 million adults worldwide. Its incidence continues to rise, with reported increases of 13.1% in high-income nations and nearly 28.7% in low- and middle-income countries. The disease carries a considerable burden, being strongly associated with long-term cardiovascular complications, increased mortality, and a heightened risk of limb loss [1]. Among the various predisposing factors for peripheral arterial disease (PAD), chronic kidney disease (CKD)—characterized by a glomerular filtration rate (GFR) less than 60 mL/min/1.73 m²—has been identified as a significant independent contributor. The occurrence of PAD in patients with CKD is notably high, affecting approximately 24% to 37% of this population. Moreover, individuals with more advanced stages of CKD often present with greater degrees of tissue ischemia, delayed wound healing, and more severe limb-threatening manifestations [2].

Clinically, the ankle–brachial index (ABI) remains a simple and widely used diagnostic tool for PAD, with values between 0.9 and 1.4 considered normal. An ABI below 0.9 typically supports the diagnosis of PAD. However, in CKD patients, ABI results require careful interpretation, as CKD and comorbid conditions such as diabetes are often associated with extensive vascular calcification (VC). This calcification leads to arterial stiffness and may cause falsely elevated ABI readings due to non-compressible vessels [3].

Vascular calcification represents a pathological response to metabolic and inflammatory insults. The underlying mechanisms involve multiple interrelated processes, including increased serum calcium and phosphate concentrations, abnormal stimulation of osteogenic pathways within vascular tissues, impaired regulation of mineral deposition, and phenotypic transformation of vascular smooth muscle cells (VSMCs) and macrophages into cells resembling osteoblasts or osteoclasts [4].

The presence of VC, particularly in infra-inguinal arteries, poses major technical and prognostic challenges during endovascular interventions for PAD. It can predispose to vessel dissection, perforation, distal embolization, and ultimately unfavorable clinical

outcomes [4]. To objectively assess the extent and distribution of arterial calcium, several angiographic classification systems have been introduced, with the Fluoroscopy/Digital Subtraction Angiography (DSA)-based Peripheral Arterial Calcium Scoring System (PACSS) being the most widely utilized [5].

The present study aimed to evaluate the impact of renal impairment on the procedural characteristics and clinical outcomes of endovascular treatment in patients with femoro-popliteal atherosclerotic arterial disease.

PATIENTS AND METHODS

This prospective cohort study was conducted at a single center and enrolled 47 patients of both genders diagnosed with chronic kidney disease (CKD) who suffered from chronic lower limb ischemia caused by atherosclerotic femoro-popliteal arterial disease classified as Trans-Atlantic Inter-Society Consensus (TASC) II types C and D. All participants were symptomatic, corresponding to Rutherford categories 3 to 6, and had a glomerular filtration rate (GFR) exceeding 90 mL/min/1.73 m². The study was carried out between March 2022 and May 2023 following approval from the Ethical Committee of the Faculty of Medicine, Cairo University, Egypt. Each patient provided written informed consent prior to inclusion in the study.

Patients were excluded if their ischemia was of non-atherosclerotic origin, if they presented with acute limb ischemia, had previously undergone vascular intervention (surgical or endovascular) in the affected limb, or if the limb was deemed non-salvageable.

All patients underwent a comprehensive evaluation that included detailed history taking and thorough clinical examination. The clinical assessment involved measurement of blood pressure, pulse rate, temperature, and respiratory rate, in addition to examination of the affected lower limb for laterality, skin temperature, peripheral pulses, trophic skin changes, ischemic ulcers, gangrene, or previous amputations. The severity of peripheral arterial disease (PAD) was classified according to the Rutherford staging system. Laboratory investigations included complete blood count (CBC), coagulation profile, renal and hepatic function tests, lipid profile, and fasting blood glucose. Radiological assessment consisted of arterial duplex ultrasonography performed both before and after the endovascular procedure. Arterial lesions were categorized based on the Trans-Atlantic Inter-Society Consensus (TASC) II classification, while the degree of vascular calcification was graded during fluoroscopy using the Peripheral Arterial Calcium Scoring System (PACSS).

Chronic kidney disease (CKD) is characterized by a persistent reduction in renal function lasting at least three months and is classified into five stages according to the glomerular filtration rate (GFR). In this study, GFR was calculated using pre-procedural serum creatinine levels in conjunction with patient demographic data, following the Modification of Diet in Renal Disease (MDRD) formula: estimated GFR = 186 × (serum creatinine)^–1.54 × (age)^–0.203 × 0.742 (for females) × 1.210 (for African Americans). Based on the Kidney Disease Outcomes Quality Initiative (KDOQI) classification, renal function was categorized as follows: stage 1 (GFR ≥ 90 mL/min/1.73 m²), stage 2 (60–89 mL/min/1.73 m²), stage 3A (45–59 mL/min/1.73 m²), stage 3B (30–44 mL/min/1.73 m²), stage 4 (15–29 mL/min/1.73 m²), and stage 5 (<15 mL/min/1.73 m²).

Procedure: loading dose of Clopidogrel (300mg) was taken one day before procedures in the absence of contraindication. Endovascular interventions were performed under local anesthesia. Ipsilateral ante-grade common femoral artery (CFA) access was selected provided that the proximal superficial femoral artery (SFA) was patent by duplex using six French sheaths. Otherwise, the contralateral approach was selected using six French cross over sheath.

The patients were given systemic heparin (100 IU/Kg of unfractionated heparin). Angiography was done using co2 ± dye (nonionic iodinated contrast) in some patients. The diseased femoro-popliteal segment was crossed using 4 French catheter and soft angled hydrophilic guide wire (0.035 or 0.018 inch) intraluminal or sub-intimal if intraluminal failed. The diseased femoro-popliteal segment was treated by either angioplasty (plain ballon or drug-coated balloon (DCB)) or by angioplasty and stenting (self-expanding stent for SFA or supera stent for popliteal artery). Finally conventional angiography was done.

Post procedure: the patients were admitted in inpatient department for adequate hydration, monitoring of vital signs, removal of CFA puncture compression after one day, assessment of tissue loss if it needs debridement. They were discharged within 24 to 48 hours on duel antiplatelet, cilostazol and antibiotics for tissue loss.

Follow up:

Follow-up visits in outpatient clinics were scheduled for the 3rd, 6th, 12th month post procedure. It included health education, correction of risk factors, clinical examination (assessment of clinical improvement and popliteal pulse) and arterial duplex to assess the patency of treated segments. Primary, assisted-primary, and secondary patency rates were evaluated according to the Society for Vascular Surgery (SVS) reporting standards for lower extremity ischemia. Primary patency was defined as the proportion of patients who maintained an open arterial segment without restenosis or occlusion throughout the follow-up period. Assisted-primary patency referred to patients who remained free from occlusion, including those who required additional endovascular procedures to restore or maintain patency in segments that developed restenosis. Secondary patency represented patients who regained or maintained vessel patency following further endovascular intervention in previously occluded arterial segments. Restenosis was identified as a reduction in luminal diameter exceeding 50%, as detected by duplex ultrasonography.
The primary outcome was technical success of endovascular revascularization (angiographic: patent femoro-popliteal arterial segment with residual stenosis < 30% and no flow limiting dissection and clinically: palpable popliteal pulse) and incidence of cervical intraepithelial neoplasia (CIN). The secondary outcomes were patency of treated arterial segment: assessed by arterial duplex at 3rd, 6th, 12th month, clinical success: wound healing, reliving of rest pain and improving of claudication distance

through one year follow up and major adverse limb effect: repeated endovascular therapy, surgical revision, or major amputation during follow up within 12 months.

Sample Size Calculation:

Drawing on findings from prior comparable research and using five-year amputation-free survival as the main outcome measure, the sample size for this prospective study was estimated with the aid of Epi-Calc 2000 software. With an assumed statistical power of 80%, a significance level (α) of 0.05, a null hypothesis proportion of 62%, and an anticipated effect proportion of 40%, the minimum required sample size was calculated to be 38 subjects. Allowing for an estimated dropout rate of 10%, the total sample size was adjusted to include 42 participants.

Statistical analysis

All collected data were entered into Microsoft Excel 2013 and subsequently analyzed using the Statistical Package for Social Sciences (SPSS), version 24. Quantitative variables following a normal distribution were described as mean values with their corresponding standard deviations, whereas skewed data were summarized using the median and interquartile range. Categorical variables were represented as frequencies and percentages. Relationships between categorical parameters were examined through cross-tabulations, with comparisons carried out using the chi-square test or Fisher's exact test when required. The independent samples t-test was applied for normally distributed quantitative data, while the Mann–Whitney U test served as the nonparametric alternative for non-normally distributed variables. A p-value below 0.05 was taken as the threshold for statistical significance.

RESULTS

Sex, age distribution, medical risk factors and comorbidities and methods of revascularization were enumerated in this figure. Figure 1

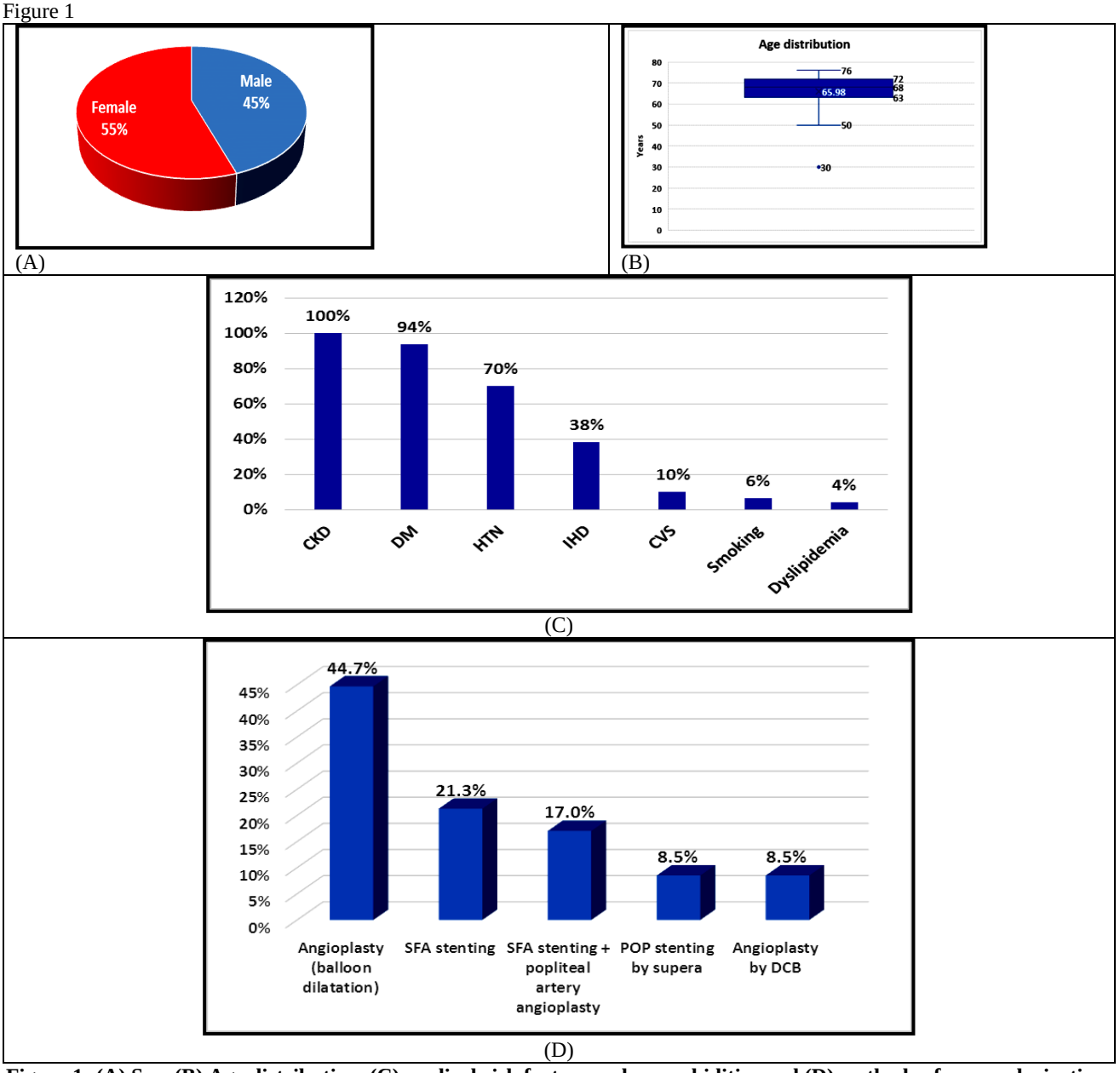


Figure 1: (A) Sex, (B) Age distribution, (C) medical risk factors and comorbidities and (D) methods of revascularization among study population

Renal condition, clinical presentation, arterial lesion and calcium score were enumerated in this table. Table 1

Table 1: Renal condition, clinical presentation, arterial lesion and calcium score among study population

		N= 47
Renal condition		
CKD stage	3a	2(4.3%)
	3b	20(42.6%)
	4	22(46.8%)
	5	3(6.4%)
Creatinine		2.26±0.85
Post creatinine		2.24±1.17
Clinical presentation and arterial lesion		
Rutherford stage	3	6(12.8%)
	4	6(12.8%)
	5	14(29.8%)
	6	21(44.7%)
	3	37(78.7%)
TASC II classification	C	10(21.3%)
	D	6(12.8%)
Calcium score	0	5(10.6%)
	1	5(10.6%)
	2	9(19.1%)
	3	11(23.4%)
	4	17(36.2%)

Data are presented as mean ± SD or frequency (%). CKD: Chronic Kidney Disease, TASC: Trans-Atlantic Inter-Society Consensus.

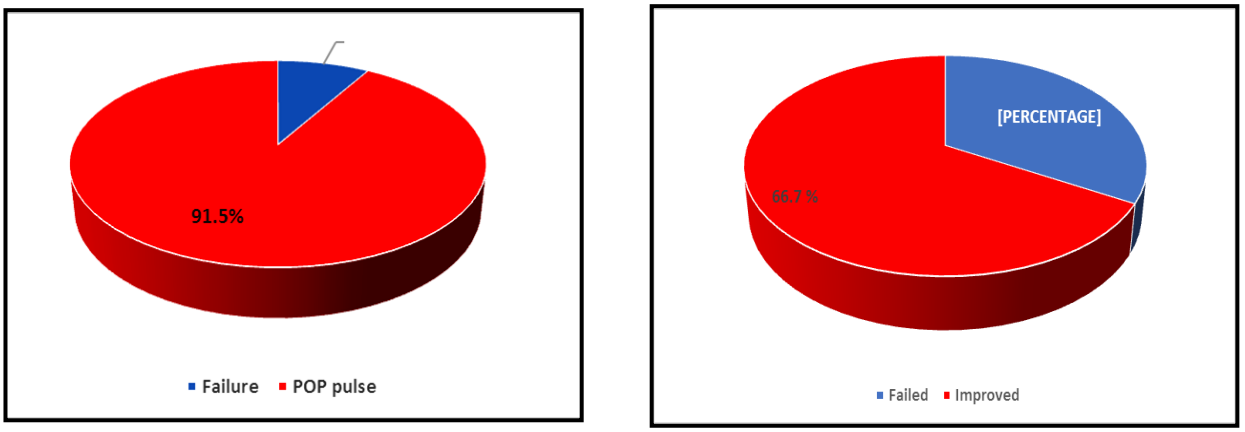
Analysis of the endovascular procedure revealed that patients with high Ca score had high incidence of stenting by a rate of 64.7 % (P=0.033). Table 2

Table 2: The relation between Ca score and method of intervention

N= 47						P
	0	1	2	3	4	
Angioplasty (balloon dilatation)	5(100.0%)	4(80.0%)	4(44.4%)	4(36.4%)	4(23.5%)	0.033*
Stenting	0(0.0%)	1(20.0%)	3 (33.3%)	7(63.6%)	11(64.7%)	
Angioplasty by DCB	0(0.0%)	0(0.0%)	2 (22.2%)	0(0.0%)	2(11.8%)	

Data is presented as frequency (%). *: Statistically significant at P ≤ 0.05. Ca: Calcium, DCB: Drug-Coated Balloon.

Technical success was achieved at 91.5%. Ante-grade and retrograde crossing of femoro-politeal lesions were impossible in 4 cases. All patients with successful crossing had popliteal pulse. For one year, the clinical success rate was 66.7%. Unhealed wounds were noticed in four patients, above knee amputation was done for eight patients and a below knee amputation was done for 2 patients due to infection and one patient experienced recurring of rest pain. Figure 2



(A) (B)

Figure 2: (A) Technical success and (B) clinical success among study population

During follow up, two patients died during the 1st two months one due to pulmonary edema and the other due to MI. These patients were excluded from follow up. All survived patients were followed up for one year at 3rd, 6th, 12th clinically by assessment of symptoms improvement and the presence of popliteal pulse and radiologically by arterial duplex. Table 3

Table 3: Patency during follow up among study population

		N=45
At three months	Primary patency	37(82.22 %)
	Assisted primary patency	38(84.44 %)
	Secondary patency	38(84.44%)
At six months	Primary patency	32(71.11 %)
	Assisted primary patency	35(77.78 %)
	Secondary patency	35(77.78%)
At 12 months	Primary patency	31(68.89 %)
	Assisted primary patency	35(77.78 %)
	Secondary patency	35(77.78%)

Data is presented as frequency (%).

Three was a significant difference between the relation between CKD stage and primary patency at one-year, clinical outcome and incidence of major adverse limb events (MALE) (P<0.05). Table 4

Table 4: The relation between CKD stage and 1ry patency at one-year, clinical outcome and incidence of MALE

	CKD stage (N=45)		P
	Impaired renal functions	End stage kidney disease	
At 12 months			
Patent	31 (73.8%)	0 (0%)	0.026*
Non-patent	11 (26.2%)	3 (100%)	
Clinical Outcome			
Failed	12 (28.6%)	3 (100.0%)	0.032*
Improved	30 (71.4%)	0(0.0%)	
Incidence of MALE			
No major adverse limb event	32 (72.7%)	0 (0%)	0.028*
Major adverse limb event	12 (27.3%)	3 (100%)	

Data is presented as frequency (%). *: Statistically significant at P ≤ 0.05. CKD: Chronic Kidney Disease, MALE: Major Adverse Limb Events.

During follow up, the clinical presentation of the patients had also impact on the clinical outcome. The patients presented with major tissue loss had poor clinical outcome in comparison with other patients (P=0.028). Table 5

Table 5: The relation between clinical presentation and clinical outcome

	Rutherford stage (N= 45)				P
	3	4	5	6	
Failed	0 (0%)	1 (16.7%)	5 (35.7%)	9 (47.4%)	0.028*
Improved	6 (100%)	5 (83.3%)	9 (64.3%)	10 (52.6%)	

Data is presented as frequency (%). *: Statistically significant at P ≤ 0.05.

Case: Popliteal occlusion was illustrated at Figure 3

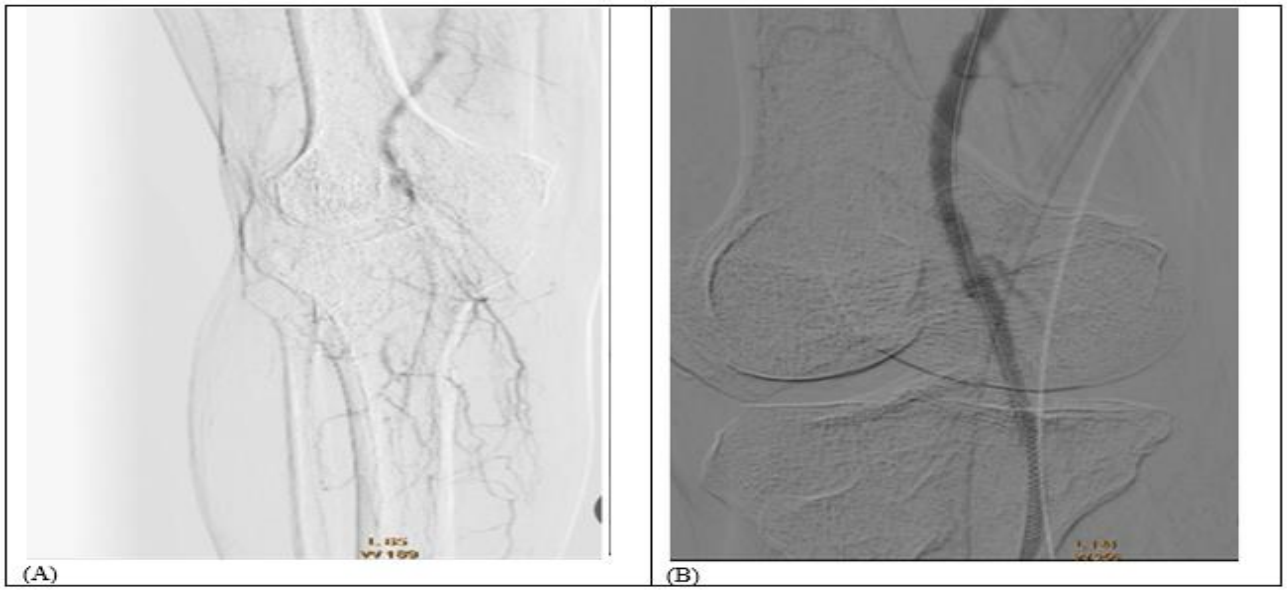


Figure 3 :(A) Popliteal occlusion and (B) Post angioplasty and supera stent deployment

DISCUSSION

Although numerous risk factors are implicated in the development of PAD, CKD has been recognized as an important independent contributor. The prevalence of PAD among individuals with CKD has been reported to range between 24% and 37%.[2].

In this study, diabetes was the commonest comorbidity by a rate of 93.6% which was similar to the incidence of diabetes among CKD patients in Kabir et al. [6] who showed that the CKD group had a higher incidence of diabetes and hypertension than the non-CKD group (74.96%, 95.53% respectively vs. 50.54%, 87.90 in non-CKD group, P< 0.05). In Moini et al. [7], the incidence of diabetes was 67.7% among non-CKD patients who underwent endovascular intervention for femoro-popliteal disease. These studies showed lower incidence of diabetes among non-CKD patients.

In our study, we analyzed TASCII C and D femoro-popliteal arterial lesion, the most common clinical presentation among CKD patient was major tissue loss at the rate of 44.7% which was similar to Kim et al. [8] who reported the high incidence of CLI among CKD patients (38.15% vs. 27.39% in non-CKD group, P <0.001) despite the high prevalence of TASCII D arterial lesions among non-CKD patients (32.70% vs. 27.46% in CKD group, P<0.003). In Fukase et al. [9], the patients with critical limb ischemia had a significantly higher prevalence of end-stage kidney disease than those without critical limb. These studies showed that the clinical presentation of CKD patients was worse than that of non-CKD patients despite the similarity of arterial lesions.
In our study, 36.2% of CKD patients had a high calcium score (score 4). These patients had a significantly higher incidence of stenting in comparison with the patients who had less degrees of arterial calcification (64.7%, P=0.033). Similarly, Fanelli et al. [10] who reported the higher incidence of stenting after balloon angioplasty among the patients with high degree of femoro-popliteal calcification (P<0.05).

The technical success in our study was 91.5% which was near to what was achieved by Kabir et al. [6] (92.8% in CKD group vs. 94.3% in the non-CKD group, P=0.160) and higher than that in Kim et al. [8] (85.7% vs. 89.6% in non-CKD group, P=0.050).
In our study, 1ry patency, assisted 1ry patency and secondary patency rates at 1-year follow-up were 68.89%, 77.78% and 77.78% respectively which was less than the patency rate was achieved by Gill et al. [11] at one-year follow up (1ry patency was 77% and secondary (2ry) patency was 93.9%). The 1ry patency was significantly better among non- hemodialysis dependent CKD patients (73.8% vs 0% among hemodialysis dependent patients, P=0.026). In comparison to non-CKD patients, Saydam et al. [12] reported high primary patency of fomoro-popliteal TASCII C lesions angioplasty of 89% and 93.5% secondary patency at 1-year. The low patency rate of CKD patients could be attributed to the rapid progression of arterial disease among these patients caused by the inflammatory and oxidative processes which were induced by CKD.

In the current study, the clinical success rate was 66.7% in one year. In comparison to non-CKD patients, the rate of clinical success was 98.2% in Guo et al. [13] and 91.3% in Saydam et al. [12].

In this study, we found two factors that predict the poor clinical outcomes among CKD patients: the clinical presentation of the patients as major tissue loss presentation was associated with a poor clinical outcomes (47.4% among stage 6 Rutherford patients vs. 35.7%, 16.7% and 0% among stage five, four and three Rutherford patients, P=0,028) and the stage of CKD as the hemodialysis dependent patients had a poor outcomes in comparison to the patient in the pre-dialysis stage (100% among hemodialysis patient vs. 28.6% among pre-dialysis patients, P=0.032).

In comparison with other studies including the outcome of endovascular intervention of femoro-popliteal segment in non-CKD patients, reported high rate of MALE (33.3%). The rate of re-intervention was 11.1 % and the rate of major amputation was 22.2%. In non-CKD patients, Guo et al. [13] MALE was only in the form of re-intervention at the rate of 17.2 % without incidence of major amputation.

In this study, the rate of MALE was significantly higher in the hemodialysis-dependent patients (100% vs. 27.3% in pre-dialysis patients, P=0.028). Similarly, Fukase et al. [9] showed that multivariable Cox hazard analysis revealed that hemodialysis was a strong independent predictor for MALE (heart rate (HR) 3.17; 95% CI 1.95–5.17, P<0.001) and all causes of death (HR 3.13; 95% CI 1.76–5.61, P<0.001).

In this study, among 12.8% of the patients in whom contrast material was used with CO2 for angiography, half of them experienced CIN one of them suffered from pulmonary edema and died on 5th day in ICU and the other two patients admitted to ICU and discharged after normalization of the kidney function. In comparison According to Guo et al. [13], a total of six minor complications (11.1%) were observed, including two cases of puncture site hematoma (3.7%), one case of acute renal insufficiency (1.9%), one case of contrast-induced encephalopathy (1.9%), and two cases of angina (3.7%). All these minor complications occurred in non-CKD patients and were successfully managed.

Our study showed that there was high risk of CIN with the use of contrast material among CKD patients without any high risk for any other complications such as puncture site complications.

In our study, we reported two cases of mortality, one patient died from pulmonary edema on 5th day post- operative as consequence of CIN and the other one died as consequence of acute MI two months post- operatively. Kim et al. [8] the rate of complication among the CKD group was 10.7% but showed no significant difference in comparison to non-CKD patients while the incidence of in-hospital death was higher among CKD patients than that in non-CKD patients' death (4.4% in CKD group vs. 1.2% in non-CKD group, P<0.001) in comparison with Kabir et al. [6] the periprocedural complication rate (7.69% vs. 6.65% in non-CKD group, P=0.047) and all-cause death (7.69% vs. 2.99% in non-CKD group, P<0.001) were significantly higher in the

CKD group

Conclusions

The presence of chronic kidney disease (CKD) at baseline should be recognized as an important clinical risk factor in patients scheduled for endovascular revascularization. CKD has been shown to negatively influence 12-month clinical outcomes following endovascular treatment for peripheral arterial disease (PAD). Furthermore, patients with end-stage renal disease (ESRD) tend to experience poorer overall outcomes, including higher rates of major amputation and re-intervention after endovascular management of femoro-popliteal arterial disease.

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Conflict of Interest: Nil

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