

Clinical and paraclinical characteristics and early outcomes of endovascular treatment using drug-eluting stents for chronic lower extremity peripheral arterial disease at Thong Nhat Hospital

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Summary

Background: Chronic lower extremity Peripheral Arterial Disease (PAD) has shown a rising trend in both patient prevalence and lesion complexity. This situation underscores an urgent need for effective, minimally invasive, and widely applicable therapeutic strategies. Among the available treatment modalities, the interventional drug-eluting stent placement is increasingly recognized by many studies for its effectiveness and safety in this group of patients. **Objective:** To describe the clinical characteristics, paraclinical characteristics and early results of the group of patients with chronic lower extremity peripheral arterial disease treated with endovascular therapy using drug-eluting stent placement at Thong Nhat Hospital. **Subjects and methods:** A case series study on 35 patients diagnosed with chronic lower extremity peripheral arterial disease who underwent endovascular therapy with drug-eluting stent placement at the Department of Thoracic Cardiology, Thong Nhat Hospital from January 2022 to June 2024. **Results:** The average age in the study was 73.9 ± 10.1 years old. Most patients were male (71.4%). Cardiovascular risk factors were all high, of which hypertension and lipid metabolism disorders were the most common (97.1% and 100%). Intermittent claudication symptoms according to Rutherford III classification using the highest rate (37.1%). On Doppler ultrasound sonography of the lower extremity arteries, the complete occlusion of a blood vessel accounted for a large proportion (74.3%). The technical success rate was 100%, all lesions were passed. The most used method of vascular closure is by automatic suturing device (74.3%). The mean intervention time was 118 ± 44 minutes, with a gradual increase in time according to the complexity of the lesion. There were 4 cases of post-interventional complications (11.4%), with no systemic complications related to the intervention recorded. The most used site for drug-eluting stent placement is the superficial femoral artery (40%). **Conclusion:** The application of drug-eluting stents in the treatment of chronic lower extremity peripheral arterial disease brings good initial results, even in complex cases with many risk factors.

Keywords: Chronic lower extremity peripheral arterial disease, drug-eluting stent, clinical, paraclinical, early result.

Received: 7/11/2025, *Accepted:* 8/12/2025

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I. BACKGROUND

In recent years, the prevalence and complexity of chronic lower extremity Peripheral Arterial Disease (PAD) have been increasing globally and in Vietnam. A systematic review estimated that over 230 million people worldwide were living with PAD in 2015 ¹.

Patients often present at advanced stages with Critical Limb-Threatening Ischemia (CLTI), where multilevel arterial lesions contribute to a poor prognosis. Without treatment, the one-year risk of amputation is 43% and mortality is 25% ². This situation underscores an urgent need for effective, minimally invasive, and widely applicable therapeutic strategies.

Current treatment for chronic lower extremity PAD includes surgical revascularization and endovascular intervention. While surgical methods, such as bypass, carry inherent risks for elderly patients with complex lesions and multiple comorbidities, endovascular therapy has progressively shown advantages as a minimally invasive approach, reducing hospital stay and complication rates ³.

However, early endovascular strategies using Plain Old Balloon Angioplasty (POBA) or Bare Metal Stents (BMS) are limited by high rates of restenosis or in-stent occlusion. These failures are often difficult to manage, requiring complex techniques and carrying a high risk of complications. Consequently, Drug-Eluting Stents (DES) were developed and studied to overcome these limitations ⁴.

Although extensive international data supports the efficacy of DES in PAD, this remains an advanced technique in Vietnam with limited published clinical data. Therefore, a study to describe the clinical, paraclinical characteristics, and early outcomes of DES implantation in this patient population is essential.

II. SUBJECT AND METHOD

Study design: retrospective case series.

Time and setting: The study was conducted from January 2022 to June 2024 at the Department of Thoracic Cardiology, Thong Nhat Hospital

Study population: All patients diagnosed with chronic lower extremity PAD who were indicated for revascularization via endovascular methods were eligible.

Inclusion criteria:

Patients with chronic lower extremity PAD diagnosed via clinical assessment (Rutherford classification) and paraclinical testing (Ankle-Brachial Index (ABI), Doppler ultrasound, or CTA)

Patients who underwent primary endovascular intervention with DES implantation

Patients must have comprehensive medical records containing complete clinical and paraclinical information documented before, during, and after the treatment process to ensure the accuracy of the collected data.

Exclusion criteria:

Patients with chronic non-atherosclerotic lower extremity vascular disease: Takayasu's arteritis, Buerger's disease, and causes of occlusion due to compressive etiologies

Patients who were lost to 3-month follow-up.

Patients with incomplete medical records.

Patients with aortic lesions (excluded).

Data collection: Data were retrospectively collected from paper-based and electronic medical records, as well as the imaging archive. Information gathered included patient demographics, clinical and paraclinical characteristics - including the pre-interventional, intra-interventional, post-interventional periods and complications.

Statistical analysis: Data were processed and analyzed using Stata 16.0 software.

Research ethics: The study was approved by the Ethics Committee in Biomedical Research of Thong Nhat Hospital.

III. RESULTS

Table 1. Baseline characteristics of the study population (n = 35)

Characteristic	Frequency	Percentage (%)
Age (years), Mean $\pm$ SD	73,9 $\pm$ 10,1	46 – 87*
Age group		
< 65	7	20,0
65 - 80	16	45,7
> 80	12	34,3
Gender		
Male	25	71,4
Female	10	28,6
Risk factors		
Smoking	20	57,1
Diabetes mellitus	16	45,7
Hypertension	34	97,1
Dyslipidemia	35	100
Coronary artery disease	9	25,7
Carotid/vertebral artery disease	8	22,9
Cardiovascular disease	10	28,6
COPD	4	11,4
Chronic Kidney Disease (CKD)	21	60,0

* Min-Max range

The mean age of the study was 73.9 ± 10.1 years, ranging from 46 to 87 years. The 65–80 age group was the most prevalent (45.7%), whereas 20.0% of participants were under 65 years and 34.3% were over 80 years. Regarding gender, there was a notable disparity, with a predominance of males (71.4%) compared to females (28.6%).

Hypertension and dyslipidemia were the most common risk factors (97.1% and 100.0%, respectively), indicating that the majority of patients had underlying cardiovascular disease. Diabetes mellitus was also a significant risk factor, with a prevalence of nearly 50%. The prevalence of smoking was high (57.1%), which is a primary cause of vascular disease. Other cardiovascular comorbidities were present in approximately 25% of patients; furthermore, chronic kidney disease (CKD) was also highly prevalent (60.0%).

Table 1. Clinical and paraclinical characteristics (n = 35)

Characteristic	Frequency	Percentage (%)
Pre-interventional Rutherford clinical classification		
3	13	37,1
4	9	25,7
5	10	28,6
6	3	8,6
Pre-intervention ABl, Mean $\pm$ SD	0,53 $\pm$ 0,20	

Characteristic	Frequency	Percentage (%)
Pre-intervention ABI group		
>0.7-0.9	4	12,5
0.4-0.7	24	75
<0.4	4	12,5
Vascular lesions on Doppler ultrasound		
Lesion type		
Stenosis	9	25,7
Chronic total occlusion	26	74,3
Lesion characteristic		
Atherosclerosis only	24	68,6
Atherosclerosis with chronic thrombus	11	31,4

The Rutherford classification reflects the severity of chronic lower extremity Peripheral Arterial Disease. Rutherford class 3 was the most predominant (37.1%), indicating that a large portion of patients presented with severe claudication without limb threat. However, a significant proportion of patients (62.9%) presented with chronic limb-threatening ischemia (CLTI), corresponding to Rutherford classes 4-6; among these, 37.1% exhibited ulceration or infection.

The mean pre-intervention Ankle-Brachial Index (ABI) was 0.53 ± 0.20 . Among the 35 patients, three had an ABI > 1.3. A majority of patients (87.5%) had moderate to severe ABI values.

On Doppler ultrasound, chronic total occlusions (CTOs) accounted for a large proportion of lesions (74.3%). Furthermore, atherosclerotic lesions were present in all patients, with simple atherosclerosis being the predominant finding (68.6%).

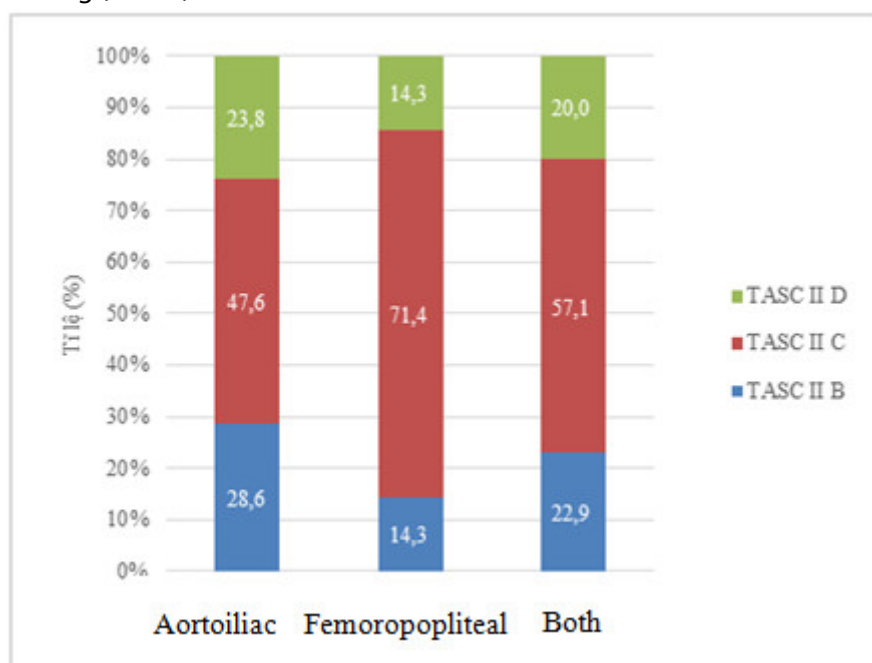


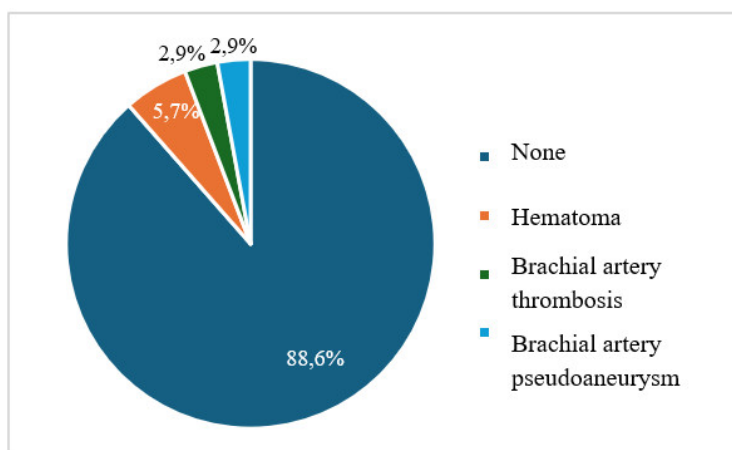
Figure 1. TASC II Vascular lesion classification

TASC II C lesions accounted for the majority in both the aortoiliac (47.6%) and femoropopliteal (71.43%) levels. Severe TASC II D lesions accounted for 20% of all cases, and TASC II B lesions accounted for 22.9%

Table 3. Procedural characteristics

Characteristic	Frequency	Percentage (%)
<i>DES placement location</i>		
Common iliac artery	11	31,4
External iliac artery	10	28,6
Superficial femoral artery	14	40,0
<i>Procedural time for lesions (minutes), Mean $\pm$ SD</i>		
TASC B	8	96,3 $\pm$ 27,2
TASC C	20	117 $\pm$ 46,6
TASC D	7	145,7 $\pm$ 43,1
Overall	35	118 $\pm$ 44,3
<i>Lesion crossing technique</i>		
Failed to cross lesion	0	0
Intraluminal	30	85,7
Subintimal	5	14,3

The Superficial femoral artery was the most frequent intervention site (40.0%) The mean procedural time was 118 ± 44.3 minutes, and the data indicated that higher lesion complexity was associated with longer procedural times. Technical success, as defined by successful lesion crossing, was achieved in 100% of cases. An intraluminal crossing technique was utilized in 85.7% of procedures, with subintimal crossing used in 14.3%.

**Figure 2.** Rate of intra-interventional complications

Four patients (11.4%) experienced complications after intervention. All complications were local and related to the vascular access site, including one brachial artery thrombosis (2.9%), one brachial artery pseudoaneurysm (2.9%), and two access-site hematomas (5.7%). No systemic complications related to the intervention were recorded in this study.

IV. DISCUSSION

The mean age of our study was 73.9 ± 10.1 years, with over 80% of patients aged 65 or older and a predominance of male patients (71.4%). This demographic is consistent with the study by Bosiers et al (2020), which reported a mean age of 69.9 years and 75% male patients⁵. This reflects the

established epidemiology of PAD being more common in elderly males.

Regarding risk factors, the near-universal prevalence of dyslipidemia (100%) and hypertension (97.1%), combined with high rates of smoking (57.1%), diabetes (45.7%), and coronary artery disease (25.7), is notable. This comorbidity burden appears relatively high compared to some international studies. For example, Bosiers et al (2020) reported rates for hypertension (91.1%), diabetes (42%), smoking (29.5%), and coronary artery disease (36.6%)⁵. While rates may vary, a high comorbidity burden is a hallmark of the chronic lower extremity PAD population.

A notable finding of our study was the high clinical severity of the study: 62.9% of patients presented with CLTI (Rutherford 4-6). This rate is significantly higher than that reported in the study by Bosiers et al. (2020), where only 8.7% of patients had CLTI⁵. However, our results are similar to a recent study by Lam Van Nut et al. (2023) at Cho Ray Hospital⁶. This discrepancy likely reflects patient selection and referral patterns, as major vascular centers often treat more complex cases where limb salvage, rather than just symptom improvement, is the primary goal.

Our study recorded a mean pre-intervention ABI of 0.53 ± 0.20 . Furthermore, 77% of patients had complex lesions classified as TASC II C or D. This result is similar to other domestic and international studies^{5,6}. According to TASC II guidelines, these complex lesions are traditionally prioritized for surgical bypass rather than endovascular intervention. However, the successful application of an endovascular-first strategy in this study highlights the significant advancements in endovascular techniques, materials, and operator experience. It also reflects a global trend of expanding endovascular indications to increasingly complex lesions.

In our study, 40% of patients received a drug-eluting stent in the superficial femoral artery (SFA) while this proportion was approximately 30% for each of the common iliac artery and external iliac

artery groups. Current international literature reports that the SFA is the primary location for DES placement^{5,7}. Our study initiated the use of DES in the iliac arteries, where the lesions were typically chronic total occlusions with severe atherosclerosis and a high risk of restenosis following conventional endovascular treatment alone.

The mean intervention time in our study was 118 minutes, systematically increasing with lesion complexity from 96 minutes for TASC B to 146 minutes for TASC D lesions. This procedure time is relatively high compared to some recent studies. The study by Kluckner et al. (2022) reported a mean intervention time of 72 ± 30 minutes⁸. This variation may be attributed to differences in lesion classification, specific techniques used, and the overall clinical status of the patients.

The technical success rate was 100%, based on the definition of successful lesion crossing. An intraluminal approach was used in 85.7% of cases, with a subintimal approach required in 14.3%. These findings are consistent with international reports on complex lesion interventions. For example, a study by Kluckner et al. (2022) reported that 22% of cases required retrograde popliteal access to successfully recanalize TASC C and D lesions in the femoropopliteal segment⁸. The study by Lam Van Nut et al. (2023) also reported a high success rate of 93.3%⁶.

The overall complication rate in our study was 11.4%. Critically, no mortality, infections, or severe systemic complications related to the intervention were recorded. This rate is within acceptable safety limits compared to other reports in the literature [6]. This suggests that endovascular intervention is a safe and effective method for treating lower extremity occlusive disease, even in high-risk, elderly patients.

Although this study focused primarily on early outcomes, long-term management remains a crucial component of PAD care. Strategies such as prolonged dual antiplatelet therapy, scheduled ABI monitoring, and structured follow-up imaging could play an important role in maintaining stent patency

and preventing restenosis. Incorporating these elements into future research may enrich the clinical relevance of the findings and help guide standardized long-term treatment protocols for patients undergoing drug-eluting stent placement. Future studies with larger cohorts may benefit from subgroup analyses stratified by TASC II classification or ABI severity to better delineate differences in procedural outcomes, including time, complication rates, and technical success. Such subgroup comparisons may help identify distinct patterns in patients with more advanced or multilevel disease.

V. CONCLUSION

Our study represented elderly, high-risk population with a high mean age, a male predominance, and a significant burden of cardiovascular comorbidities. Severe claudication (Rutherford 3) was the most common presentation, and both ABI and Doppler ultrasound findings indicated moderate-to-severe disease.

Following endovascular intervention with drug-eluting stents (DES), the observed complication rate was within acceptable safety limits.

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