Diagn Interv Radiol 2025; DOI: 10.4274/dir.2024.242868

INTERVENTIONAL RADIOLOGY

ORIGINAL ARTICLE

Short-term outcomes of the iCover balloon-expandable covered stent for iliac artery lesions

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PURPOSE

To describe the short-term follow-up results of the recently introduced iCover balloon-expandable covered stents for iliac artery lesions.

METHODS

All consecutive patients treated with iCover balloon-expandable covered stents between March 2022 and August 2023 were retrospectively reviewed. The primary endpoint was target lesion revascularization (TLR) at 6 months. Secondary endpoints included major adverse events, freedom from TLR throughout the follow-up period, primary and secondary patency, and clinical and technical success.

RESULTS

In the study population of 40 adult patients (87.5% men, mean age: 63.5 ± 11 years), the mean follow-up period was 6.2 ± 2.8 months. A total of 98 stents of various sizes were implanted. The technical success rate was 100%. Freedom from TLR was 95.8% [95%, confidence interval (CI): 95%–96.6%], the primary patency rate was 91.7% (95%, CI: 89.8%–93.6%), and the secondary patency rate was 95.8% (95%, CI: 95%–96.6%) at 6 months. The all-cause mortality rate was 5%.

CONCLUSION

These real-world data demonstrate a high technical and clinical success rate, a high 6-month primary patency rate, and a low requirement for TLR. These are promising indicators for the safety and efficacy of iCover stents.

CLINICAL SIGNIFICANCE

Balloon-expandable covered stents are frequently used in iliac artery atherosclerotic disease. This study shows that the short-term follow-up results of the new iCover stent are satisfactory, indicating its safety and efficacy.

KEYWORDS

Angiography, balloon-expandable covered stent, iliac artery disease, peripheral, stent

Endovascular treatment, particularly stent implantation procedures, is widely used, with high technical success and patency rates in peripheral artery stenoses and occlusions, such as those found in the aorto-iliac, subclavian, and mesenteric arteries.[1,2] Covered stents are theoretically known to reduce restenosis rates by limiting neointimal hyperplasia and thrombosis and providing early luminal endothelialization.[3] The use of covered stents is common in treating conditions such as arteriovenous fistula, iliac aneurysms, and peripheral arterial disease.[4,5]

Balloon-expandable and self-expandable stent grafts show similar performance in mid-term results.[6,7] In a study by Krankenberg et al.[8] examining uncovered stents for the treatment of iliac artery occlusive disease, self-expandable stents showed lower rates of restenosis and target lesion revascularization (TLR) compared with balloon-expandable stents at a 1-year

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Received 23 May 2024; revision requested 23 June 2024; accepted 22 July 2024.

Epub: 19.08.2024

Publication date: 30.12.2024

DOI: 10.4274/dir.2024.242868

You may cite this article as: Canyiğit M, Beşler MS. Short-term outcomes of the iCover balloon-expandable covered stent for iliac artery lesions. *Diagn Interv Radiol.* 2025;31(1):52-57.

follow-up. Balloon-expandable stents have advantages over self-expandable stents, including higher radial strength and more predictable deployment.[9] In the DISCOVER trial, no difference was found in the rates of freedom from restenosis and TLR between covered and bare-metal stents at a 2-year follow-up for common iliac artery atherosclerotic disease.[10] Some studies have shown that, compared with bare-metal stents, covered stents can increase freedom from TLR in aorto-iliac arterial disease and be advantageous and preferable in more complex and severely calcified lesions.[11,12] The 5-year results of the COBEST study demonstrate that covered stents provide higher patency in aorto-iliac occlusive disease compared with bare-metal stents in long-term follow-up.[13]

For these reasons, the use of covered stents in iliac artery diseases is becoming more widespread. Currently, there are no original studies or case reports in the literature regarding the recently introduced iCover stents for iliac artery lesions. This study aims to evaluate the safety and short-term effectiveness of the iCover stents using real-world data.

Methods

Study design

This single-center, retrospective study was approved by the Ankara Bilkent City Hospital Review Board (decision number: E2-23-4066, date of approval: 10.05.2023). It received a waiver of informed consent and was conducted in accordance with the Declaration of Helsinki. All consecutive patients treated with iCover stents during the study period, between March 2022 and August 2023, were assessed. Patients with stents implanted in the subclavian artery (n = 7), renal artery (n = 3), celiac artery (n = 2), and brachiocephalic truncus (n = 1) were excluded. The study population consisted of 40 adult patients treated for common and external iliac arteries (Figure 1). Among these patients (87.5% men, mean age: 63.5 ± 11 years), the mean follow-up period was 6.2 ± 2.8 months (Table 1). Patients included in the study had symptomatic peripheral arterial disease in the iliac arteries, with severe stenosis or occlusions ranging from claudication limiting quality of life to tissue loss (Rutherford category 3 or higher). All procedures were performed by an interventional radiologist with 20 years of experience in peripheral artery interventions.

Demographic characteristics, comorbidities, stenosis or occlusion locations, procedural adverse events, pre-procedural symptoms, follow-up examinations, and post-procedural antiplatelet medication compliance were recorded.

The iCover balloon-expandable expanded polytetrafluoroethylene (e-PTFE)-covered stent (iVascular, Barcelona, Spain) was compatible with a 0.035-inch guidewire, catheter lengths of 80 or 140 cm, and 6F or 7F introducer sheaths. It was available in various diameters (5–10 mm) and lengths (17–57 mm). Stents with a diameter of 5–8 mm allowed post-dilation up to 10 mm, whereas those with a diameter of 9–10 mm permitted post-dilation up to 12 mm.

The femoral artery was preferred for vascular access in 35 patients, whereas the brachial artery was chosen in five patients. A 7F introducer sheath was inserted. At the beginning of the procedure, 70 U/kg heparin was administered as an intravascular bolus. After confirming significant stenosis or occlusion with digital subtraction angiography, the lesion was crossed with a 0.035-inch guidewire. The native vessel diameter and lesion length were measured on a case-by-case basis, and a stent was deployed. Pre-dilation or post-dilation was performed using a non-compliant balloon if necessary. An additional 2,500 U heparin dose was administered every hour if the procedure lasted a long time. The procedure was concluded if <30% residual stenosis was seen on post-procedural angiography.

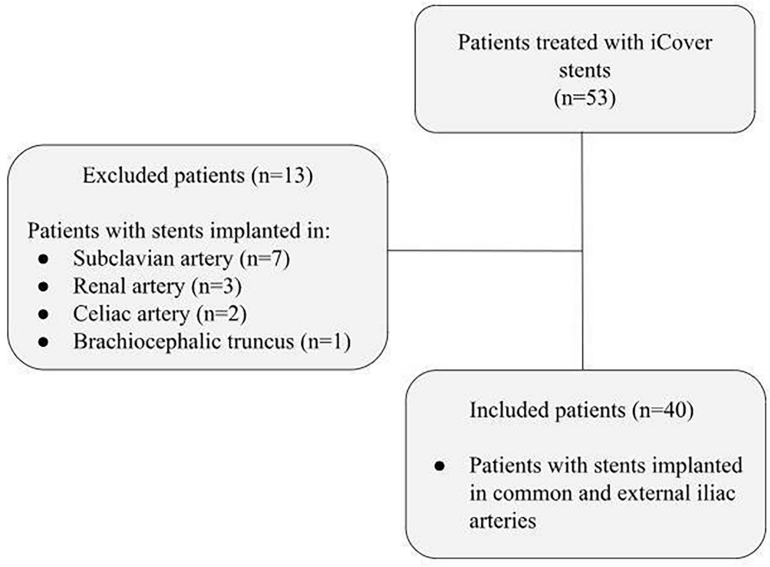

Figure 1. Flowchart of patient selection.

Main points

- Balloon-expandable covered stents can be used for iliac artery lesions.
- The novel iCover stents have demonstrated satisfactory freedom from target lesion revascularization and high primary and secondary patency rates in short-term follow-up.
- According to the study results, the newly introduced stents are safe and effective for the treatment of iliac artery atherosclerotic disease.

Table 1. Baseline characteristics of the study population

Characteristic	Total (n = 40)
Gender, men	35 (87.5)
Age, years	63.5 ± 11
Hypertension	28 (70)
Diabetes mellitus	22 (55)
Coronary artery disease	20 (50)
Smoking (pack/years)	22.5 [0–40]
Peripheral arterial bypass graft history	3 (7.5)
Previous endovascular treatment in the target lesion area	5 (12.5)
Limb amputation history	1 (2.5)

Data are presented as number (percentage), mean ± standard deviation, and median [interquartile range 25–75].

Each patient was prescribed clopidogrel (75 mg) daily for 6 months and lifelong acetylsalicylic acid (100 mg).

Outcome measures

Primary patency was defined as <50% restenosis on Doppler ultrasound or computed tomography angiography, along with no revascularization, bypass surgery, or target limb amputation. A peak systolic velocity ratio of <2 corresponded to a diameter stenosis of <50%. Secondary patency was defined as the patency of the target lesion after treatment of a reocclusion through either a surgical bypass or endovascular intervention. Procedural success was defined as <%30 residual stenosis on final angiography. Clinical success was defined as at least a one-point improvement in the Rutherford category for iliac artery lesions.

The primary endpoint was TLR at 6 months. Secondary endpoints included major adverse events (death, myocardial infarction at 30 days, stent thrombosis, acute limb ischemia, target limb amputation, or procedure-related major bleeding), freedom from TLR, primary and secondary patency, and clinical and technical success rates. Reintervention was performed for >50% stent restenosis accompanied by clinical symptoms.

Clinical examinations and symptom assessments were conducted at 1, 3, 6, and 12 months of follow-up, noting any adverse events. Stent patency was assessed using computed tomography angiography or Doppler ultrasound (if the glomerular filtration rate was <60 mL/min) routinely at 3- and 6-month follow-ups, or during clinical follow-up examinations if improvement was not achieved according to clinical success criteria.

Statistical analysis

Statistical analysis was conducted using SPSS 26.0 (IBM, Armonk, NY, USA). In descriptive statistics, the normality of data distribution was determined by the Shapiro–Wilk test. Continuous variables were expressed as mean ± standard deviation, median (range: minimum–maximum), or median (interquartile range: 25–75), whereas categorical variables were expressed as numbers and percentages. Patency rates and freedom from TLR during follow-up were calculated using Kaplan–Meier estimates.

Results

A total of 98 stents were implanted in 40 patients for iliac artery diseases. The intervention was performed on the common iliac artery in 55% of the patients, on the external iliac artery in 30%, and on both the common and external iliac arteries in 15%. Stents were implanted in the stenosis area in 21 patients (52.5%) and in the occlusion area in 19 patients (47.5%). The stents had a median diameter of 8 mm (range: 6–10 mm) and a median length of 37 mm (range: 27–57 mm) (Table 2). One patient with extensive aorto-iliac disease was treated using the covered endovascular reconstruction of the aortic bifurcation technique. The technical success rate was 100%, and the overall clinical success rate was 90%.

During follow-up, stent occlusion was detected in the common iliac arteries of two patients. One of these patients underwent aortofemoral bypass surgery. The other patient had a reintervention with the deployment of an iCover stent, and the newly deployed stent was patent at the 6-month follow-up. It was found that these patients, who experienced stent occlusion, had discontinued clopidogrel after the 1st month post-procedure, continuing only with acetylsalicylic acid. Freedom from TLR was 95.8% [95%, confidence interval (CI): 95%–96.6%], the primary patency rate was 91.7% (95%, CI: 89.8%–93.6%), and the secondary patency rate was 95.8% (95%, CI: 95%–96.6%) at 6 months (Figures 2-4).

In one patient, during iliac artery stent deployment, plaques migrated to the terminal aorta, necessitating the placement of kissing stents. In another patient who underwent stent placement in the external iliac artery, plaque migrated to the internal iliac artery, which was managed by deploying an uncovered stent in the internal iliac artery. Similarly,

Table 2. The sizes and numbers of deployed stents

Diameter (mm)–length (mm)	Number of stents (n = 98)
6–27	1
6–37	10
6–57	4
7–27	10
7–37	4
7–57	15
8–27	8
8–37	8
8–57	10
9–27	7
9–37	8
9–57	8
10–27	1
10–37	4

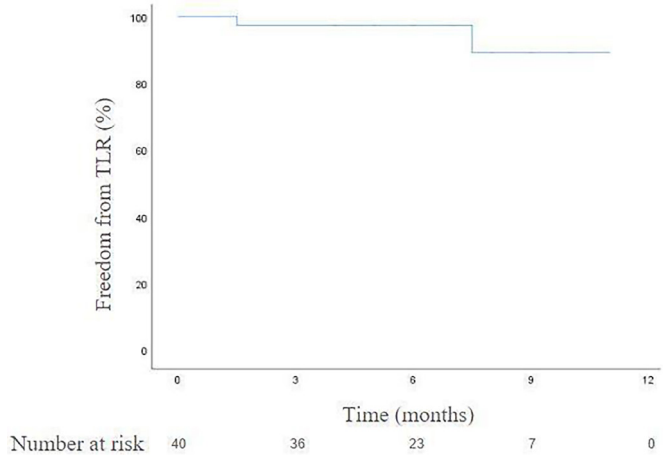

Figure 2. Kaplan–Meier estimate of freedom from target lesion revascularization throughout the follow-up period. TLR, target lesion revascularization.

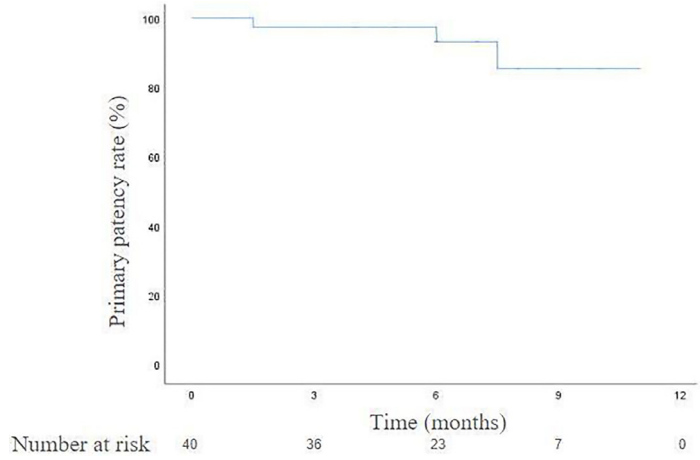

Figure 3. Kaplan–Meier estimate of primary patency throughout the follow-up period.

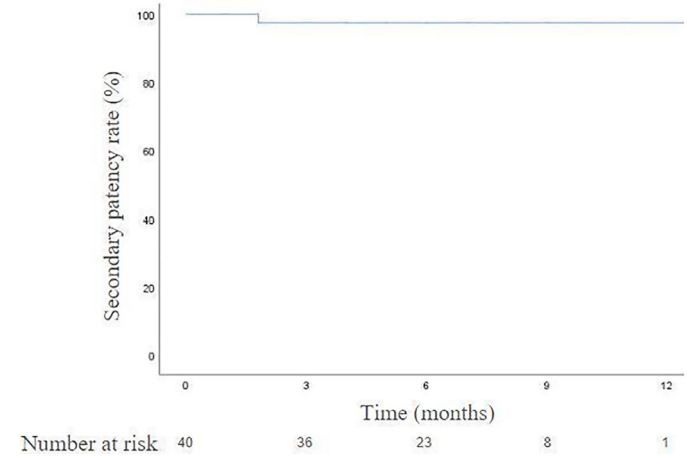

Figure 4. Kaplan–Meier estimate of secondary patency throughout the follow-up period.

in a patient where stent placement was performed in the external iliac artery through brachial artery access, plaque migrated from the terminal aorta to the contralateral external iliac artery, requiring the placement of a stent in that region as well. Vascular access adverse events included a femoral artery pseudoaneurysm in one patient, which was corrected with manual compression. No structural concerns, such as stent fracture or kinking, were encountered. No major amputations of the target limb occurred during follow-up.

The all-cause mortality rate was 5% (n = 2). No in-hospital mortality was observed within the first 30 days. After 30 days, mortality unrelated to endovascular procedures occurred. One patient experienced gastrointestinal bleeding due to anticoagulant and antiplatelet therapy for graft thrombosis after bypass surgery in the target vessel, and another patient with colon cancer and acute pulmonary edema died.

Discussion

In this study observing early outcomes of a newly introduced balloon-expandable stent in 40 patients, real-world data was evaluated. The use of stents in iliac arteries and short-term follow-up results were examined. Despite a median follow-up of 6 months, the absence of technical failures, high clinical improvement rates, and elevated primary and secondary patency rates, along with a high rate of freedom from TLR, suggest the safety and effectiveness of the stent in treating iliac artery disease.

In e-PTFE-covered stents, the surrounding membrane reduces cytokine and growth factor secretion, thereby inhibiting smooth muscle cell migration and neointimal tissue growth. This thin membrane decreases stent radial pressure, cutting off the connection between the vessel wall and blood flow, which helps reduce re-embolization.[14] Balloon-expandable and self-expandable covered stents, as well as bare-metal stents, offer various solutions in the primary treatment of peripheral arterial occlusive disease.[8,15,16] A study highlighting the use of balloon-expandable covered stents, especially in the iliac arteries, noted that these stents were clinically useful for addressing recurrent in-stent restenosis.[17] In this study, a balloon-expandable covered stent was used for the treatment of iliac artery reocclusion, and the newly deployed stent was patent at the 6-month follow-up.

In the guideline by the Society for Cardiovascular Angiography and Interventions regarding aorto-iliac arterial interventions, drug-eluting stents are not recommended for aorto-iliac arterial disease. However, self-expandable covered stents are suggested with a weak to moderate recommendation, whereas bare-metal stents are recommended at various levels. Balloon-expandable covered stents are endorsed with a moderate to strong recommendation. Specifically, balloon-expandable covered stents are strongly recommended for aorto-iliac bifurcation and common iliac artery locations, particularly in cases of moderate to severely calcified lesions.[18] In the ICE trial, the use of uncovered stents for treating iliac artery occlusive disease was compared. The results showed that self-expandable stents had better primary patency at a 1-year follow-up than balloon-expandable stents.[8] In the DISCOVER trial, at a 2-year follow-up for the treatment of common iliac artery atherosclerotic disease, the results for balloon-expandable covered stents and balloon-expandable bare-metal stents were similar.[10] In a study involving a 2-year follow-up on iliac axis occlusions, both self-expandable and balloon-expandable covered stents, used alone or in combination, achieved excellent patency rates.[19] For aorto-iliac occlusive disease, the long-term results of balloon-expandable covered stents provide acceptable patency rates.[13,20] The BOLSTER clinical trial demonstrated that balloon-expandable covered stents for iliac artery occlusive disease had 89.1% primary patency, 96% freedom from TLR, and 90.5% clinical improvement at the 9-month follow-up.[21] In the VISIBILITY study, a 9-month follow-up on atherosclerotic diseases of the common and external iliac arteries showed that balloon-expandable stents achieved a primary patency and freedom from target vessel revascularization rate of 95.8%.[22] Our study population's results, with 91.7% primary patency, 95.8% freedom from TLR, and 90% clinical success rates, are comparable with these short-term studies.

In cases of iliac artery occlusion where primary patency was not maintained and there was a need for TLR, after the 1st month, patients continued with acetylsalicylic acid medication alone due to non-compliance with dual antiplatelet therapy. While there is no consensus on the duration of use in peripheral arterial disease, dual antiplatelet therapy is considered more beneficial than mono antiplatelet therapy for preventing thrombotic adverse events following interventions.[23] Dual antiplatelet therapy prevents major adverse limb events such as loss of patency, TLR, and major amputation. However, as the duration of use increases, the rising risk of major bleeding should also be considered.[24] Strict adherence to the prescribed antiplatelet treatment is crucial for maintaining stent patency.

In the study conducted by Tomoi et al.[25], which treated aorto-iliac arterial disease in 149 patients using balloon-expandable covered stents, residual stenosis, artery rupture resolved with additional stenting, and acute stent thrombosis due to manual compression were encountered. In our study population, technical success was achieved in all patients, and plaque migration occurring during the procedure was treated without complications through stent implantation in three patients. In studies on balloon-expandable stent-grafts for iliac artery occlusions, the mortality rate was 4% in the VISIBILITY study and 4.5% in the BOLSTER study, with these rates being unrelated to the procedure.[21,22] The AVOCADO II study showed a 1-year overall survival rate of 93%.[25] Similarly, in this study, the mortality rate unrelated to the procedure was 5%.

This study has some limitations. First, it is a single-center, retrospective study that lacks a comparative analysis with another stent design. Additionally, mid- and long-term follow-up results were not available due to the recent release of the stent. Multicenter, prospective, randomized, and long-term follow-up studies should be conducted to improve our understanding of the safety and efficacy of this stent.

In conclusion, the early results of iCover balloon-expandable covered stents in the treatment of iliac artery disease are satisfactory. Therefore, this newly introduced stent can be used safely, similar to other balloon-expandable or self-expandable covered stents and bare-metal stents.

Conflict of interest disclosure

The authors declared no conflicts of interest.

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