iCARUS Study Review

Balloon expandable covered stent for iliac artery lesions: 3-year results.

By John R. Laird, MD

The iCast balloon expandable covered stent (Getinge), as it is named in the iCARUS study, received FDA clearance in the United States in 2007 for the treatment of tracheobronchial strictures. It is marketed outside the United States for the treatment of renal and iliac artery disease under the brand name Advanta V12.

Primary or selective stent implantation is a common revascularization option for patients with iliac artery occlusive disease.[1] Both balloon expandable and self-expanding stents have demonstrated high procedural success rates and satisfactory mid- and long-term patency.[2] However, self-expanding stents may have less predictable deployment compared with balloon expandable stents that have greater radial strength, which is an advantage for ostial or calcified lesions.[2]

The Advanta V12 balloon expandable covered stent (Getinge)*† has been shown to consistently improve patient outcomes for renal and iliac artery disease by restoring iliac and renal artery patency, reducing restenosis and reintervention rates, improving ankle-brachial index (ABI), and sustaining symptom relief.[3,4] As the only covered stent with randomized controlled data up to 8 years[3] and > 500 publications,[5] Advanta V12 has shown significantly higher patency compared with bare-metal stents (BMSs) year after year, even in the most challenging TransAtlantic Inter-Society Consensus (TASC) C and D lesions.[3]

The COBEST trial was the first multicenter trial to directly compare balloon expandable covered stents with BMSs for the treatment of iliac artery occlusive disease and established a definite, enduring patency benefit with Advanta V12 compared with the balloon-expandable BMS.[1] For more information on the COBEST trial, see page 8 in this supplement.

To support a premarket application in the United States, the iCARUS trial was conducted in 24 sites in the United States and one site in Germany to evaluate the safety and effectiveness of iCast covered stent for the treatment of iliac artery atherosclerotic lesions.

iCARUS STUDY OVERVIEW

The iCARUS trial was a single-arm, prospective, multicenter study that enrolled 152 patients at 25 sites. Patient selection mirrored the real-world patient population, with no restrictions placed on the number of target lesions treated or number of stents used. In addition, kissing stents and overlapping stents were permitted, as well as total occlusions. From October 2007 to October 2010, 264 iCast stents were implanted in 94 men and 58 women (mean age, 65.2 years), with 53.9% having two or more stents implanted. Patients were aged ≥ 18 years and had lifestyle-limiting claudication or ischemic rest pain. Follow-up clinical assessments, including ABI, Rutherford-Becker score, and/or physical examination to identify limb ischemia and document adverse events, occurred at 1, 6, and 9 months and 1, 2, and 3 years.[2]

The primary endpoint of the iCARUS trial was the composite rate of death within 30 days, target lesion revascularization (TLR) within 9 months, or restenosis of the iliac artery detected on angiography at 9 months. Secondary endpoints included major adverse vascular events at 30 days, primary patency, freedom from TLR through 3 years, and clinical success, assessed both early (30 days) and late (6, 9, and 12 months).[2]

TAKEAWAY POINTS

iCARUS is a single-arm investigational device exemption study with 3-year follow-up:

- Real-world patient population with multiple lesions and bilateral disease.
- The study showed sustained clinical benefit with freedom from TLR up to 3 years.[2]

iCARUS STUDY RESULTS

Procedural Characteristics

Although there was a low percentage of TASC C and D lesions in this study (5.8%), patients had anatomic complexities encountered in current practice, such as bifurcation lesions, total occlusions, severe calcification, eccentric lesions, and concomitant common iliac artery and external iliac artery lesions. The number of lesions per patient and/or the use of multiple stents was generally on

the high end relative to other iliac studies. More than half of the per-protocol population (81 of 152 patients; 53.3%) had lesions treated at the aortic bifurcation, many of which required a kissing stent procedure. Total occlusions were present in 17.1% of patients (12.3% of lesions), which is commensurate with other iliac stent–approved studies.[2]

Early Results

Primary endpoint results of the iCARUS trial included no deaths at 30 days and sustained clinical benefit with freedom from TLR of 97.2% within 9 months. Of the four (2.9%) patients who experienced a TLR within 9 months, two were nonclinically driven TLRs. The 9-month primary composite endpoint rate was 8.1% (10/123; upper limit of 95% CI, 13.4%; $P = .005$), which was below the performance goal of 16.57%.[2]

Encouraging results were also reported in the secondary endpoints, with 9-month primary patency (defined as continuous flow without revascularization, bypass, or target limb amputation) achieved in 96.4%. Device and acute procedural success were achieved in 98.7% and 92.7%, respectively. Early clinical success was seen in 88.7% of patients at 30 days.[2]

Long-Term Results

Three-year data from the iCARUS trial further demonstrated the device's long-term benefit. The trial reported sustained clinical improvement, with late clinical success in 72.4% of patients at 3 years, as well as freedom from TLR of 86.6%. Additionally, six (4.9%) patients with evaluable imaging at follow-up experienced restenosis detected on duplex ultrasound or angiography at 9 months; however, three of these patients had no clinical symptoms to support the duplex ultrasound finding and did not require reintervention throughout the 36-month study duration.[2]

CONCLUSION

Aligned with previously conducted studies, the iCARUS study demonstrated that iCast is safe and effective for treatment of atherosclerotic iliac artery lesions, with sustained clinical benefit and a low rate of TLR out to 3 years. Designed with a unique polytetrafluoroethylene covering technology, the iCast inspires confidence with high patency and low reintervention rates for aortoiliac occlusive disease.[3] ■

1. Bekken JA, Jongsma H, de Vries JP, Fioole B. Self-expanding stents and aortoiliac occlusive disease: a review of the literature. Med Devices (Auckl). 2014;7:99-105. doi: 10.2147/MDER.S60594
2. Laird JR, Loja M, Zeller T, et al. iCast balloon-expandable covered stent for iliac artery lesions: 3-year results from the iCARUS multicenter study. J Vasc Interv Radiol. 2019;30:822-829.e4. doi: 10.1016/j.jvir.2018.12.707
3. Mwipatayi BP, Sharma S, Daneshmand A, et al. Durability of the balloon-expandable covered versus bare-metal stents in the covered versus balloon expandable stent trial (COBEST) for the treatment of aortoiliac occlusive disease. J Vasc Surg. 2016;64:83-94.e1. doi: 10.1016/j.jvs.2016.02.064
4. Laird JR. iCast™ balloon expandable covered stent for iliac artery lesions: 3-year results from the ICARUS multicenter study. Presented at: VEITHsymposium; November 15-19, 2016; New York, New York.
5. Data on file at Getinge (complete Getinge bibliography).

*Advanta V12 is the name of the product outside the United States. iCast is the name of the product in the United States. Advanta V12 is identical to the iCast branded product in the United States.
†The Advanta V12 covered stent system is indicated for restoring and improving the patency of iliac and renal arteries. Renal approval includes 5–7-mm diameter Advanta V12 sizes. In Canada, the Advanta V12 covered stent indication excludes renal arteries. The Advanta V12 stent is not available in the United States. iCast is FDA approved for the treatment of tracheobronchial strictures produced by malignant neoplasms.

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