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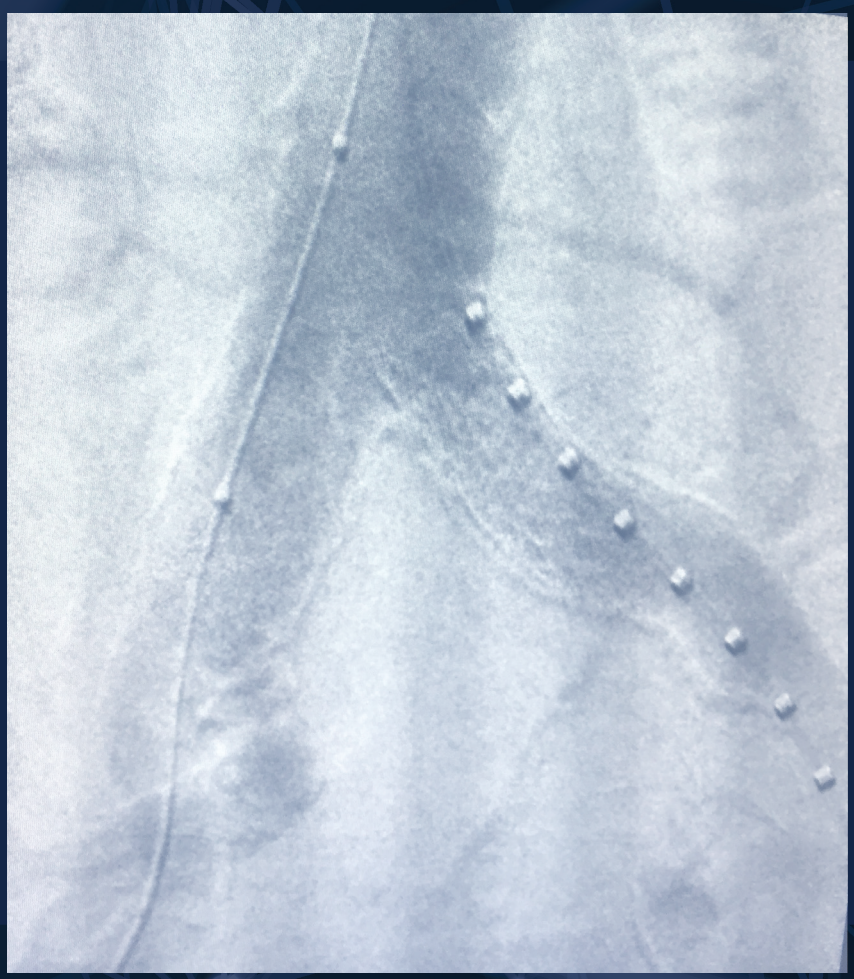
ADVANTA V12



TRUSTED. RELIABLE. PROVEN.

Examining the publications and real-world experience that established the Advanta V12 as the benchmark for balloon expandable covered stents.

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Advanta V12: A Balloon Expandable Covered Stent Worth My Trust

By Eric L.G. Verhoeven, MD, PhD

DEAR COLLEAGUES,

I would like to welcome you to this special publication on the most proven balloon expandable covered stent we have at our reach today.

I have been using Getinge's Advanta V12 balloon expandable covered stent from the very beginning, and I quickly became comfortable and satisfied with its performance.

For more than 15 years, Advanta V12 has paved the road for covered stents, setting the benchmark in terms of patency, predictability, and quality.

The clinical supplement that you have in your hands is a compilation of important publications that evidences the unmatched efforts of Getinge to consistently record Advanta V12 as the most trusted, reliable, and proven balloon expandable covered stent on the market today.

The facts don't lie. Advanta V12 has touched > 500,000 lives. It is the *only* balloon expandable covered stent with long-term real-world data,[1] has the greatest number of TransAtlantic Inter-Society Consensus D lesions treated in trials,[1] and is the only device with a primary patency rate of 74.7% at 5 years.[1]

Getinge's balloon expandable covered stent has certainly earned its place in history. Its landmark study, COBEST, has become *the* reference for all newcomers, and I personally look forward to continuing to use Advanta V12 and its portfolio additions in my practice.

I hope you enjoy this reading. ■

1. Mwipatayi BP, Ouriel K, Anwari T, et al. A systematic review of covered balloon-expandable stents for treating aortoiliac occlusive disease. J Vasc Surg. 2020;72:1473-1486.e2. doi: 10.1016/j.jvs.2020.01.084

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Synopsis of "A Systematic Review of Covered Balloon-Expandable Stents for Treating Aortoiliac Occlusive Disease"

Reviewing an extensive literature analysis on Advanta V12 compared with other covered balloon expandable stents for patients with complex aortoiliac lesions.

By Jean-Paul P.M. de Vries, MD, PhD

"A Systematic Review of Covered Balloon-Expandable Stents for Treating Aortoiliac Occlusive Disease" is the first extensive analysis that supports the use of covered balloon expandable (CBE) stents as a viable solution to treat aortoiliac occlusive disease (AIOD), even for complex cases when lesions have a higher percentage of occlusions.[1] Conducted by B. Patrice Mwipatayi, MD, et al, this peer-reviewed work was recently published in the *Journal of Vascular Surgery*. The review outlines key differences between Advanta V12 balloon expandable covered stent (Getinge) and its competitors in objective clinical terms.[1] With more than 15 years of clinical experience and the only stent included in the review used in real-world procedures, the Advanta V12 is a trusted, reliable, proven solution for the treatment of aortoiliac disease.[2-7] In this article, we distill the results of this seminal review and support the claims of safety, efficacy, and advantages of the Advanta V12.

METHODOLOGY

Utilizing Medline and the Cochrane Library, researchers employed an exhaustive search of the literature to identify relevant studies published between 2000 and 2019, which resulted in 404 references. Baseline anatomic variables, procedural variables, and outcome data were identified and compared. Outcomes of interest included technical success, ankle-brachial index (ABI), primary and secondary patency, freedom from target lesion revascularization (TLR), amputation, 6-month mortality, and 12-month mortality. Eight exclusion criteria were developed, including "no data on CBE stents" and "not related to AIOD treatment," among others. These criteria helped screen the initial 404 references down to 14 studies (eight prospective, six retrospective) tied to five CBE stents, including Advanta V12 (nine studies), Viabahn VBX (Gore & Associates; two studies), BeGraft (Bentley; one study), LifeStream (BD Interventional; one study), and Jostent (Abbott; one study).

BACKGROUND

During the past 20 years, endovascular strategies have become the preferred treatment for mild to moderate AIOD.[6] Long, diffuse, heavily calcified lesions continued to create risk of technical failure, with stenting of TransAtlantic Inter-Society Consensus (TASC) C/D lesions associated with long-term primary patency rates that were lower than with surgical bypass. This was confirmed in TASC II guidelines that recommended open surgery for TASC D (and some TASC C) lesions.[6]

Despite this guidance to the contrary, practitioners are gravitating toward endovascular approaches, even with TASC C/D lesions. Physicians are increasingly concerned that patients with complex lesions often have comorbidities, present greater risk for open surgery, and require significant hospital resources to treat. Although primary patency rates achieved after stenting complex lesions are not likely to surpass those of the surgical approach, secondary patency rates after stenting TASC C/D lesions are approximately equivalent. This narrowing of outcomes across lesion types emboldened the American College of Radiology to advocate an endovascular-first approach in its 2017 appropriate use criteria, regardless of TASC classification.[8]

STUDY OVERVIEW

The complete review of the 14 selected studies included 1,012 patients and 1,463 limbs treated with CBE stents for AIOD. Of these, 680 patients and 926 limbs were treated in a clinical trial, and 332 patients and 537 limbs were treated in real-world settings. The Advanta V12 was included in all six retrospective studies. Three of the 14 studies had a two-arm design, with bare-metal stent (BMS) as the comparator. All others were single-arm studies.

There was a significant disparity between the clinical trial and real-world populations concerning disease severity and lesion characteristics. Patients treated in clinical trials had far

less severe lesions than those treated in real-world settings. For example, < 15% of TASC D lesions were treated in the clinical setting. Likewise, occlusions were treated at a rate of 8.8% to 17.1% in the clinical setting compared with 42.6% to 63.3% in the retrospective real-world population. Technical success was similar for both groups, with 98% to 100% in the trials and 95% to 100% in the real-world studies. Low rates of procedural complications (< 16.8%) were observed in both settings, with vessel dissections and hematomas as the most common.[1]

RESULTS

The clinical trial setting achieved slightly higher primary patency rates compared to real-world studies, ranging from 89.1% to 96.9% in the clinical trial setting and 83.6% to 92% in real-world studies at 1 year. Secondary patency rates were similar across both settings. Four of five retrospective studies indicated secondary patency rates from 95% to 100%. There were three clinical trials with available 12-month secondary patency data (two with Viabahn VBX, one with LifeStream on 9-month patency), ranging from 91.9% to 100%. Interestingly, secondary patency rates were similar for TASC C/D and TASC A/B lesions among studies reporting 12-month data.[1]

A smaller chasm was observed in TLR data between real-world settings and clinical studies. In the three retrospective studies reporting freedom from TLR at 12 months, rates ranged from 89.6% to 100%; however, the rates ranged from 96.1% to 97.4% in five prospective studies.[1]

ABI values were reported in eight studies. The greatest ABI improvement was exhibited by the Advanta V12 in Bosiers et al, with a mean ABI measurement of 0.59 at baseline, 0.98 immediately poststenting, and 0.99 at 12 months.[4] The smallest ABI improvement was reported by Holden et al with the Gore CBE stent, which reported mean ABI measurements of 0.79 at baseline and 0.95 at 12 months.[9] Combining the eight studies with pre- and poststenting ABI values, measurements ranged from 0.59 to 0.77 prestenting and from 0.84 to 0.99 at 12 months.[1]

DEVICE COMPARISON

The Advanta V12 was the most prolific device studied in the literature (67%) and was used in the treatment of 60% of the 1,012 patients. The Viabahn VBX was the focus of two articles (13%; 164 patients). The LifeStream (155 patients), BeGraft (70 patients), and Jostent (12 patients) were each included in one article. The Advanta V12 population also included more TASC D lesions than the other devices (approximately 28% for Advanta V12 vs 1%, 3%, and 7% for LifeStream, BeGraft, and Viabahn VBX, respectively). Most lesions treated with the LifeStream (62%) and BeGraft (77%) were TASC A. The increased complexity of the Advanta V12 population is due to a preponderance of real-world procedures. Equally significant, the Advanta V12 also had the longest published follow-up, up to 60 months compared with 6 to 12 months for the other devices.[1]

All devices reported primary patency; however, different time durations and definitions were used, complicating comparisons. The randomized prospective study of Advanta V12 (COBEST) and four retrospective studies (each also employing Advanta V12) reported a 24-month primary patency range of 72% to 92% and a 24-month secondary patency range of 92% to 100%. The Viabahn VBX trials reported 6-, 9-, and 12-month primary patency rates of 100%, 96.7%, and 96.6%, respectively. The single-arm investigational device exemption trial evaluating LifeStream reported a 9-month primary patency of 89.1%. At 1 year, the BeGraft primary patency rate was 94.4%. Jostent had only one recorded primary patency rate: 92% at 6 months. The COBEST trial with the Advanta V12 was the only study to report longer-term primary patency data, with durations at 48 (79.9%) and 60 (74.7%) months (Table 1).[1]

COMPARISONS WITH BMS

Three studies evaluated outcomes with CBE stents versus BMSs (one randomized controlled trial, two retrospective studies). In COBEST, 83 patients treated with the Advanta V12 were compared with 85 patients treated with balloon expandable and self-expanding BMSs. Although the baseline characteristics were similar, a greater percentage of patients treated with the Advanta V12 had TASC C/D lesions (49.2% vs 27.3%). At 5 years, primary patency was significantly higher in the Advanta V12 group (74.7% vs 62.9%), despite its higher degree of lesion severity. Secondary patency was not statistically different, but rates were significantly higher in patients with TASC C/D lesions treated with the Advanta V12 CBE.[1]

DISCUSSION

Direct comparisons among stents should be made cautiously due to differences in lesion severity, patient populations, and follow-up lengths. The reviewed clinical trial studies were composed of patients with mild to moderate AIOD and simple lesions, based on study designs to meet regulatory approval. For example, the two Viabahn VBX studies excluded patients with lesions requiring atherectomy or laser ablation and enrolled patients with the shortest lesion lengths of the reviewed studies, ultimately reporting the best primary patency rates at 12 months.[1]

The retrospective studies that used the Advanta V12 were largely all-comer studies that provided realistic anatomic profiles to physicians who choose CBE stents in actual practice. These patients had a high percentage of TASC C/D lesions, chronic total occlusions, and critical limb ischemia. Logically, advanced lesion severity would be associated with more procedural complications and diminished 12-month

TABLE 1. TECHNICAL SUCCESS AND PRIMARY PATENCY					
	Advanta V12	Viabahn VBX	LifeStream	BeGraft	Jostent
No. of studies	9	2	1	1	1
No. of patients	611	164	155	70	12
Technical success range	95%–100%	100%	98.3%	100%	100%
Primary patency range					
6 mo	87.2%–97%	100%	NR	NR	92%
9 mo	96.4%	96.7%	89.1%	NR	N/A
12 mo	86.3%–96.4%	96.6%	N/A	94.4%	N/A
18 mo	77%–87.3%	N/A	N/A	N/A	N/A
24 mo	68%–92%	N/A	N/A	N/A	N/A
36 mo	72%	N/A	N/A	N/A	N/A
48 mo	63.4%–79.9%	N/A	N/A	N/A	N/A
60 mo	74.7%	N/A	N/A	N/A	N/A
Abbreviations: N/A, not available; NR, not reported.					

primary patency rates. However, there was little difference between real-world and clinical trial outcomes with respect to 12-month patency. The same was true at 24 months; however, outcomes beyond 12 months were limited to only the Advanta V12, preventing head-to-head comparisons with other CBE stents. The technical success and freedom from TLR were also similar among all devices at 12 months. Again, beyond 12 months, data were only available for the Advanta V12.[1]

Comparisons of BMS versus CBE are also important, with the decision often based on cost (BMSs are less expensive). However, the higher cost of CBE stents might be offset by improved outcomes through reduced reintervention rates. Covered stents also avoid appositional defects and their attendant hemodynamic consequences, as well as the potential for hyperplastic ingrowth through BMS interstices, creating a smoother lumen. Additionally, the covering of a CBE device likely protects against iliac artery rupture or disruption, as illustrated by the low procedural complication rates.[1]

TAKEAWAY POINTS

- Long-term data were only available for the Advanta V12, which had a primary patency rate of 74.7% at 5 years.
- The Advanta V12 is the only CBE stent with evidence from real-world studies, with a greater severity of cases compared to other CBE stents.

CONCLUSIONS

The reviewed data clearly provide evidence of CBE stents as effective treatment for AIOD, demonstrating high technical success and 12-month patency rates. In addition, the data support CBE stents compared with BMSs for complex aortoiliac lesions because of their benefits—which, at least for Advanta V12, appear to last up to 5 years. However, with favorable long-term data only available for one device (Advanta V12) used in real-world settings, new randomized trials are needed to compare different stent designs (ie, self-expanding and balloon expandable) and their impacts on outcomes.[1] ■

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Jean-Paul P.M. de Vries, MD, PhD
Disclosures: Consultant for Getinge.

PN011604 REVAA

I trust **Advanta V12** for its outstanding performance with **reliable** and **proven** outcomes.

– Tilo Kölbel (Germany)

Advanta V12 is my first choice of balloon expandable covered stents for the treatment of complex lesions. It has gained my **trust** thanks to its **reliable** performance and real world, long term data.

– Alvaro Razuk (Brazil)

The use of **Advanta V12** ensures a **reliable** and **proven** solution in treating severe iliac occlusive disease.

– Jean-Paul de Vries (Netherlands)

Advanta V12

Trusted. Reliable. Proven.

Advanta V12 has been my preferred stent for many years, with **reliable** performance and **proven** long term results.

– Eric Verhoeven (Germany)

Advanta V12 is a superior choice of balloon expandable stent thanks to **proven** and **reliable** long term performance.

– Bijan Modarai (UK)

Not all balloon expandable covered stents are the same. In case of severe iliac occlusive disease, the **Advanta V12** is the only stent that is **proven** and **reliable**, with good results, according to the COBEST trial.

– Patrice Mwipatayi (Australia)

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COBEST Landmark Study Review

Study demonstrates long-term patency of covered stents versus bare-metal stents for aortoiliac occlusive disease.

By B. Patrice Mwipatayi, MD, MMed, MClinEd, FCS, FRACS

Approximately 8.5 million people aged 40 years or older in the United States have peripheral artery disease (PAD),[1] a consequence of an aging, less active population. Aortoiliac occlusive disease (AIOD) is one expression of PAD that results in partial or total vascular occlusion due to atherosclerosis. AIOD typically begins in the distal aortic segment near the origin of the common iliac arteries and progresses deceptively with concurrent, effective collateral development.[2] Indications for intervention include disabling or progressive claudication, ischemic rest pain, and tissue loss. Based on the severity and ultimate diagnosis, current guidelines recommend either endovascular or surgical intervention for patients who have significant functional disability that is vocation- or lifestyle-limiting and otherwise unresponsive to medical or exercise therapy.

Reproducible classification systems are crucial to objective evaluation and treatment of patients and to validate clinical trials when comparing medical, surgical, and endovascular treatment paradigms. The TransAtlantic Inter-Society Consensus (TASC) II (updated in 2007 with increased emphasis on PAD) classifies AIOD by location and severity and recommends treatment options. Based on the group's recommendations, TASC A lesions should garner excellent results from endovascular management alone; TASC B lesions should have good results from endovascular management, with endoluminal interventions as a first approach; TASC C lesions should receive superior long-term results from surgical management, with endovascular techniques reserved for surgical high-risk patients; and TASC D lesions should be treated by open surgery.[3]

Since the publication of the TASC II document in 2007, a number of scientific publications and observational reports have documented the rapid adoption of endovascular therapy as a primary strategy for the treatment of symptomatic PAD. Although TASC II provides a disciplined framework to compare therapeutic techniques, it has been the advancement of endovascular techniques that has resulted in an increase in the adoption of the endovascular-first strategy for even the most complex TASC II D lesions, thus decreasing the number of anatomies that are primarily referred for open surgical revascularization.[4] COBEST is one such trial that supports an alternative treatment for the most complex of revascularization scenarios.[5]

STUDY OVERVIEW

In 2006, COBEST was the first multicenter trial to investigate the patency of covered stents over bare-metal stents (BMSs) for the treatment of AIOD. Conducted between January 2006 and December 2008 with 13 physicians across eight major Australian centers, COBEST started with 125 patients and 168 iliac arteries. Assignments were random and binary, with patients receiving either a balloon expandable covered stent (Advanta V12 balloon expandable covered stent, Getinge*) or a commercially available BMS.[6]

The Advanta V12 is a low-profile, premounted, balloon expandable covered stent made of radial expandable 316-L stainless steel that provides a smooth-flow lumen. Encapsulated within a patented one-piece polytetrafluorethylene covering, the technology enables uniform expansion without ridges or folds, prevents tissue from prolapsing through the expanded stent, and offers an effective barrier against neointimal hyperplasia.[7]

The primary endpoints of the initial study included freedom from binary restenosis and stent occlusion of

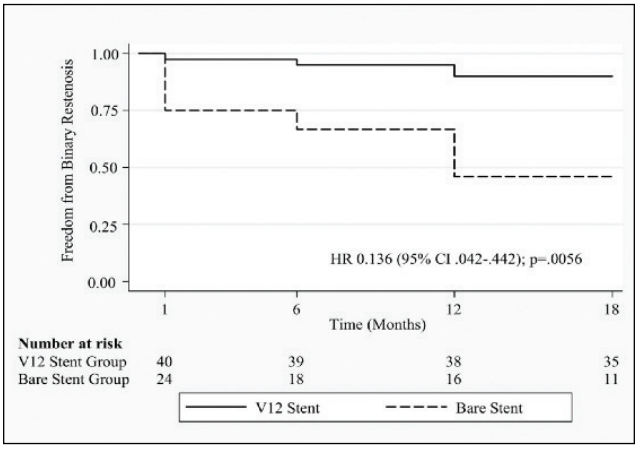

Figure 1. Kaplan-Meier curves demonstrating freedom from binary restenosis for the intention-to-treat population. HR, hazard ratio.

the treated area, as determined by ultrasound imaging, quantitative visual angiography, or both. Secondary endpoints included stent patency (as assessed by the TASC classification), stent integrity, and target vessel revascularization. Postprocedural follow-up was conducted at 1, 6, 12, and 18 months.[6]

COBEST: 18-MONTH DATA

Aortoiliac lesions treated with the Advanta V12 were significantly more likely to remain free from binary restenosis than those treated with a BMS (Figure 1). Freedom from occlusion was higher in lesions treated with a covered stent than in those treated with a BMS. Subgroup analyses demonstrated a significant difference in freedom from binary restenosis for covered stents in TASC C and D lesions compared with BMSs.[6]

Results at 18 months also revealed that covered stents were superior to BMSs in maintaining patency for TASC C and D lesions and equivalent to BMSs for TASC A and B lesions. In addition, the covered stent group experienced fewer reinterventions compared with the BMS group at 6, 12, and 18 months.[6]

Unlike BMSs, covered stents can exclude plaque and endothelium, potentially mitigating late luminal loss by halting migration and proliferation of cells through open stent struts. This may result in a reduction of restenosis caused by intimal hyperplasia. Covered stents may also offer the benefit of being less thrombogenic than BMSs.[6] The short-term results of the COBEST study warranted a follow-up review to determine if the initial patency advantage of covered stents compared with BMSs in aortoiliac lesions would be sustained in the longer term.

COBEST: 5-YEAR DATA

A retrospective post hoc analysis of COBEST was performed, extending the original 18-month data to 5 years to evaluate the durability of the initial results. With the 5-year data, 77 of the 125 patients (61.6%; 119 limbs, 62 in the covered stent group and 57 in the BMS group) were assessed at 60 months for the primary and secondary endpoints, with particular attention paid to outcomes stratified according to TASC lesion severity.[5]

The primary endpoint was the rate of primary patency, defined as uninterrupted patency (lack of stenosis of > 50% or occlusion of the treated segment) determined by ultrasound imaging or quantitative visual angiography after the procedure. The secondary endpoints included assisted primary patency, secondary patency, and freedom from all-cause death (probability of survival).[5]

The COBEST 5-year results showed that the Advanta V12 had a significantly higher patency rate than the BMS at 5 years (74.7% vs 62.9%). On subgroup analysis, the covered stent showed significantly higher patency (Figure 2) and survival benefit in TASC C and D lesions compared with the BMS. Moreover, fewer patients received target limb revascularization in the covered stent group than in the BMS group, with a twofold lower incidence of reintervention; however, there was no statistically significant difference in the rate of amputations between the groups.[5]

TAKEAWAY POINTS

- COBEST provides a basis for the use of Advanta V12 in AIOD, with a definite and enduring patency benefit in the long-term follow-up compared with the balloon expandable BMS.
- The benefit of covered stents was seen in more complex TASC C and D lesions, as demonstrated in the initial COBEST randomized controlled trial.
- Patients who receive Advanta V12 are less likely to need a reintervention.

ADVANTA V12: DESIGNED FOR SUPERIOR RESULTS

The Advanta V12 forms a mechanical barrier, excluding the plaque and endothelium, thereby limiting intimal hyperplasia by preventing migration of macrophages into the endothelium. If allowed to migrate into the endothelium, these macrophages release further proinflammatory agents (eg, cytokines) that contribute to initiating the process of neointimal hyperplasia and subsequent

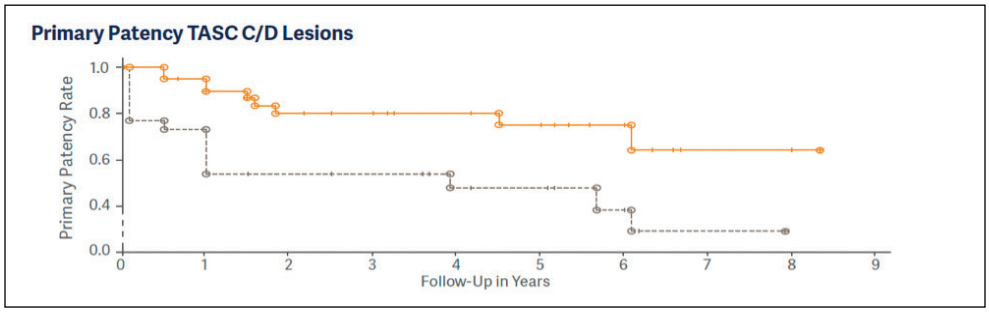

Figure 2. Patency evaluated at 18, 24, 48, and 60 months (Advanta V12: 95.1%, 82.1%, 79.9%, 74.7% vs BMS: 73.9%, 70.9%, 63%, 62.9%). Orange line = Advanta V12; dashed line = BMS.

restenosis. BMSs do not form this protective barrier and hence may be associated with a higher risk of restenosis. In addition, the decreased risk of iliac rupture in patients who have covered stents may lead to improved dilation with the use of higher inflation pressures, which may also explain the poorer patency seen in patients with BMSs in this study.[5] Produced by Getinge, the proven and trusted Advanta V12 is conformable, deliverable, and flexible to track through tortuous arteries and flex to accommodate the iliac arteries. Furthermore, its ability to postdilate up to 16 mm provides additional customization to the patient's anatomy.

CONCLUSION

COBEST has become a landmark study, supporting Advanta V12 as a choice of treatment in AIOD. The 5-year results of the COBEST trial demonstrate that the Advanta V12 has an enduring patency advantage over the BMS in both the short and long term. The Advanta V12 stent has been shown to consistently improve patient outcomes by restoring iliac patency, reducing restenosis and reintervention rates, improving ankle-brachial indices, and sustaining symptom relief.[5] As the only covered stent with randomized controlled data up to 8 years, the Advanta V12 stent demonstrates superior patency versus BMSs year after year, even in the most challenging TASC C and D lesions.[5] ■

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7. Data on file at Getinge.

*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.

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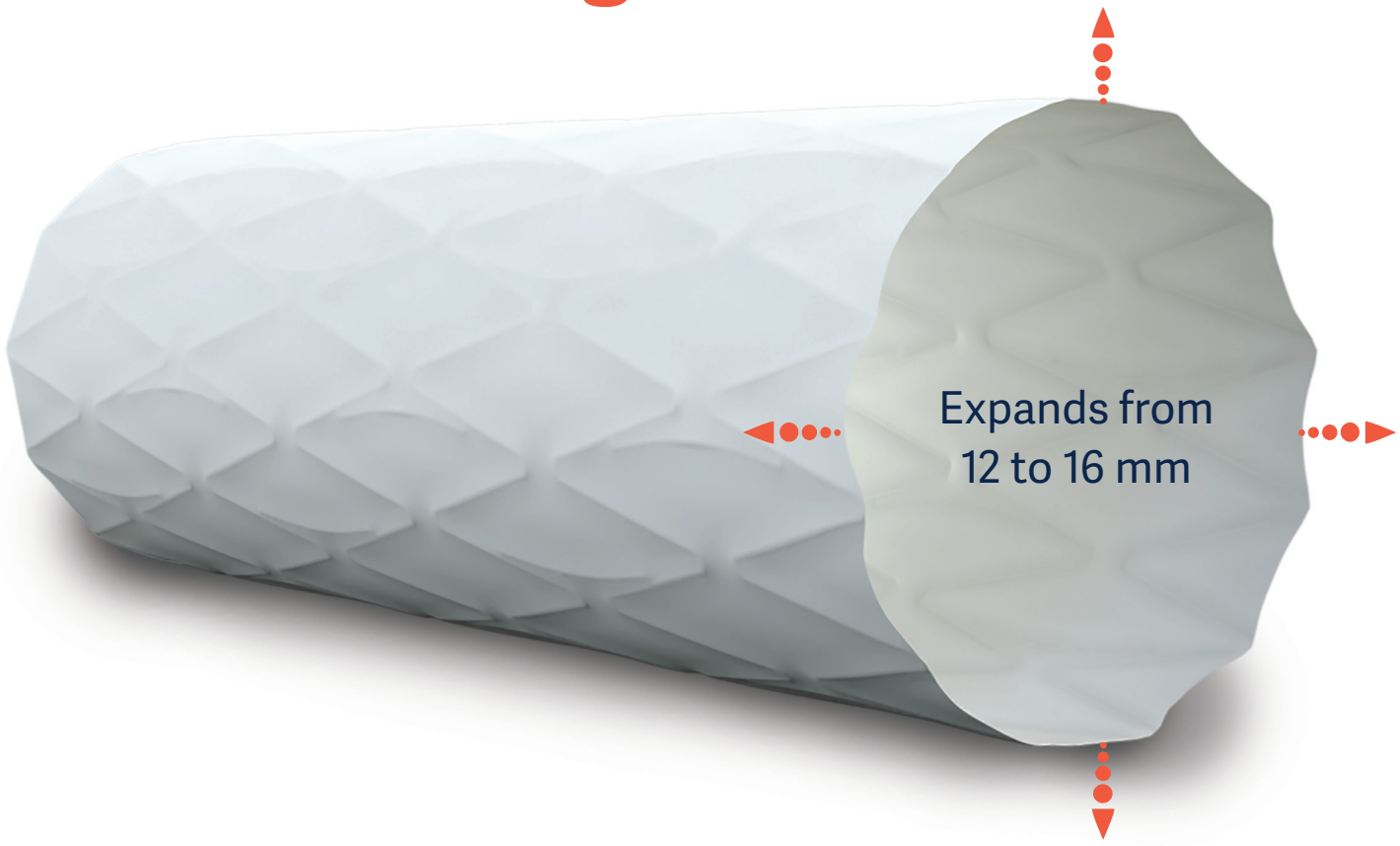
Disclosures: Consultant for Getinge, Biotronik, and Medtronic.

PN011605 REVAA

Advanta V12 Large Diameter



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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] ■

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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.

John R. Laird, MD
Disclosures: Consultant for Getinge.

PN011607 REVAA

CASE STUDY

Advanta V12 large diameter stent

Drs. Pond and Saeed share a case of high-grade stenosis in an ectatic common iliac artery treated with the Advanta V12 large diameter stent.

By Franklin Pond, MBBS, GDEB, FRACS, and Hani Saeed, MD, BPharm

A 77-year-old man was admitted under the nephrology team with severe critical limb ischemia in the left leg. His medical history included diagnosed ischemic heart disease and a pacemaker inserted in 2019, and balloon aortic valvuloplasty in January 2020 followed by transcatheter aortic valve implantation in February 2020 for severe aortic stenosis. He also had long-standing type 2 diabetes mellitus, end-stage renal failure on hemodialysis via an arteriovenous fistula in the left upper arm, chronic obstructive pulmonary disease secondary to smoking, obstructive sleep apnea, and dyslipidemia.

He was referred to our vascular unit with a 2-month history of severe rest pain in his left foot that woke him from sleep multiple times throughout the night and required him to hang his foot in a dependent position to relieve the pain. Prior to this, he experienced claudication symptoms in his left leg at short distances.

On examination, he had no femoral, popliteal, or pedal pulses on the left leg. His feet were bilaterally cool with pitting edema to the midcalf. There was ischemic rubor evident in his left leg, and the Buerger test was positive. His motor movement and sensation were intact and equal bilaterally. The decision was made to obtain an aortobifemoral and bilateral lower limb CTA rather than an arterial duplex ultrasound because no femoral pulse was palpable on the left side.

The CTA showed a 14-mm left common iliac artery (CIA) with > 75% ostial stenosis and a short external iliac artery (EIA) stenosis (Figure 1). The common femoral artery (CFA), superficial femoral artery (SFA), and profunda femoris artery were found to be heavily calcified. Furthermore, the SFA was diseased in its entirety, with a short-segment occlusion in the mid-SFA and reconstitution at a diseased above-the-knee popliteal artery. The right CIA was patent, measuring 16 mm in diameter with no stenosis. Treatment options were discussed, but given the CFA disease and a TransAtlantic Inter-Society Consensus A lesion of the left CIA, a hybrid procedure was believed to be best to relieve the patient's rest pain.

After appropriate review and clearance by our anesthetics team as an inpatient, he underwent a left iliofemoral endarterectomy with profundaplasty and iliac stenting.

PROCEDURAL OVERVIEW

Under a general anesthetic, an iliofemoral endarterectomy and profundaplasty were performed, and the arteriotomy was repaired using vein patch.

Retrograde access was then achieved via the left CFA puncture under direct vision, and a 6-F Radifocus Introducer II sheath (Terumo Interventional Systems) was introduced. An angled Glidewire (Terumo Interventional Systems) was used to traverse the left CIA into the infrarenal aorta, and a pigtail catheter was then advanced and situated in the infrarenal aorta. Diagnostic runs were performed, confirming the > 75% left CIA ostial stenosis and further EIA stenosis.

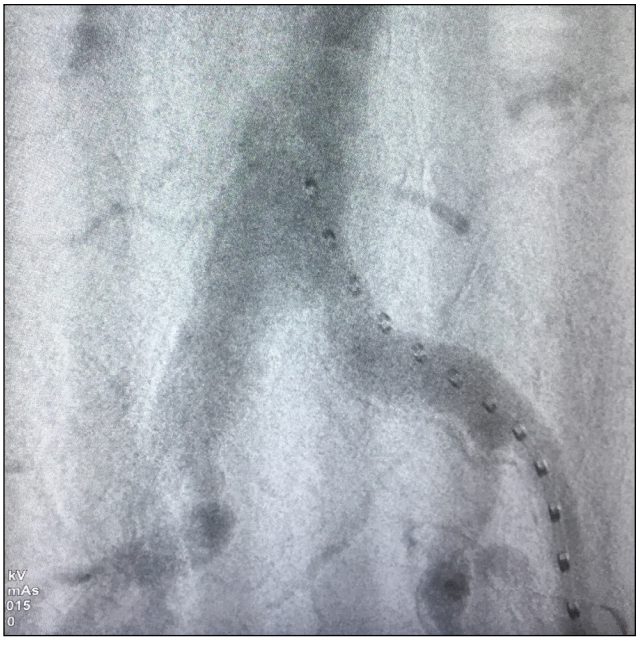

Figure 1. The initial angiogram. On the left side, the stenosis was located at the junction of the bifurcation.

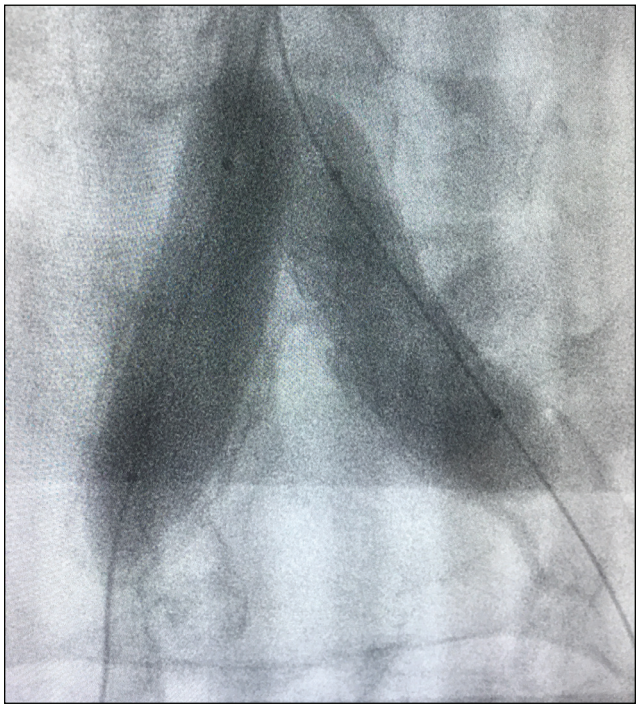

Figure 2. Postdilation with the kissing balloon technique of the Advanta V12.

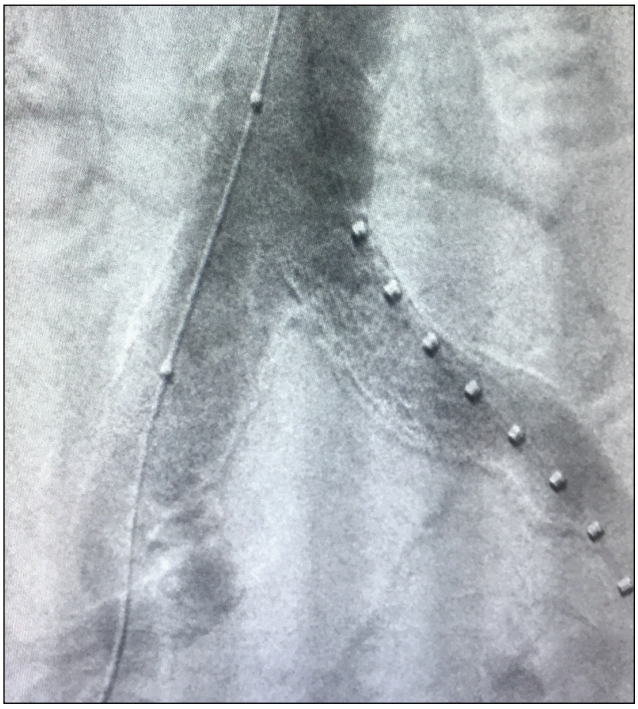

Figure 3. Completion angiography.

The 6-F sheath in the left CFA was upgraded to a 10-F sheath that was advanced into the distal aorta. Under ultrasound guidance, the right CFA was punctured, and a 6-F sheath was introduced. A 12- X 41-mm Advanta V12 balloon expandable covered stent (Getinge)* was deployed in the left CIA just above the bifurcation and postdilated using a 14- X 40-mm Armada 35 angioplasty balloon (Abbott). A 14- X 60-mm Armada 35 angioplasty balloon was then introduced via the contralateral right side, and the Advanta V12 was postdilated and shaped using a kissing technique (Figure 2). Further angioplasty of a short EIA stenosis was performed using an 8- X 40-mm Armada 35 angioplasty balloon with good result.

Completion angiography demonstrated a widely patent Advanta V12 with no residual stenosis in the left CIA or encroachment onto the right side (Figure 3). The left CFA puncture site was then repaired using a 6/0 Prolene suture (Ethicon, a Johnson & Johnson company), and the wound was closed. The right groin sheath was removed, and manual pressure was applied.

Postoperatively, the patient had a bounding left femoral pulse and improvement of his symptoms. He was no longer experiencing rest pain, and the ischemic rubor had resolved. He continued on dual antiplatelet and statin therapy in the perioperative period and required no additional medications or therapies. After a period of in-hospital recovery, the patient was transferred to a rehabilitation facility prior to discharge home. He was followed-up with an ultrasound 6-weeks postprocedure, which showed a patent stent.

CONCLUSION

Based on the angiographic outcome of this case, it can be established that the new Advanta V12 large diameter stent demonstrated all the expected characteristics and experience as the regular V12, including smooth trackability, predictable stent foreshortening, and solid evidence-based patency. ■

*The Advanta V12 covered stent is CE marked for restoring the patency of iliac and renal arteries. The Advanta V12 covered stent is not available in the United States.

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PN011608 REVAA

Advanta V12

Balloon expandable covered stent

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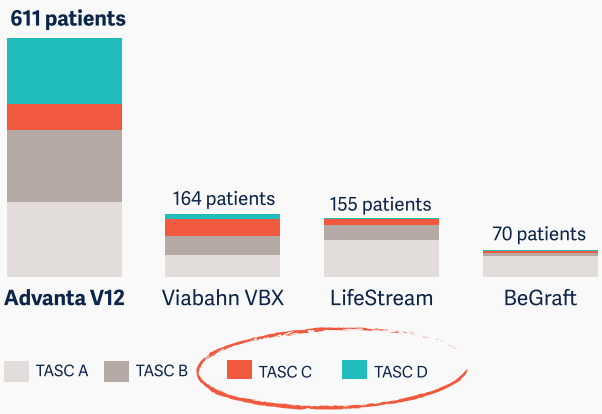
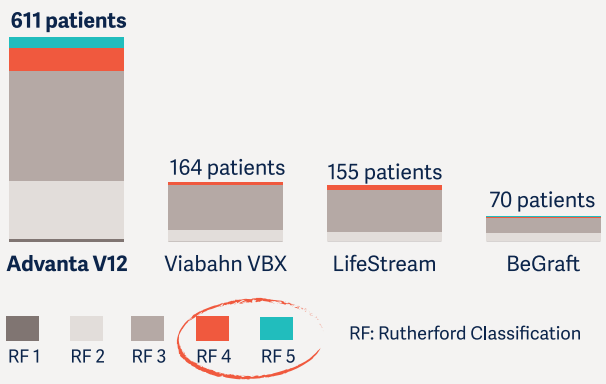
The only device with a primary patency rate of **74,7 %** at **5 years.***

Greater number of **TASC C/D lesions** treated in Advanta V12 trials.*



More severe disease treated in Advanta V12 trials.*



*Mwipatayi B, et al., A systematic review of covered balloon-expandable stents for treating aortoiliac occlusive disease. Journal of Vascular Surgery, 2020 August

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The Advanta V12 balloon expandable covered stent is CE marked and TGA approved for restoring and improving the patency of iliac and renal arteries. Renal approval is for 5-7 mm diameter arteries. Advanta V12 has Canadian Health Ministry license for restoring the patency of iliac lesions. The Advanta V12 stent is not available in the U.S. PN 011579 Rev AA