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A systematic review of covered balloon-expandable stents for treating aortoiliac occlusive disease

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ABSTRACT

Objective: To evaluate and compare studies reporting the outcomes of the use of covered balloon-expandable (CBE) stents for the treatment of aortoiliac occlusive disease.

Methods: A systematic literature search was conducted to identify studies that investigated the use of CBE stents for the treatment of aortoiliac occlusive disease and were published between 2000 and 2019. Baseline demographic data, procedural variables, and long-term outcomes were extracted from publications for analysis.

Results: A total of 15 published articles about 14 studies were included in the review. Of these, eight studies were prospective clinical trials and six studies were retrospective real-world studies. The articles included data regarding five different CBE stents, namely, the iCast/Advanta V12, Viabahn VBX, BeGraft, LifeStream, and JOSTENT. Lesion severity was higher in real-world studies, with more TransAtlantic Inter-Society Consensus Classification class D lesions and a higher percentage of occlusions. All studies showed high rates of technical success and patency over the course of 12 months. Long-term data were only available for the iCast/Advanta V12 device, which had a primary patency rate of 74.7% at 5 years.

Conclusions: CBE stents are a viable treatment option for patients with complex aortoiliac lesions because of their high rates of technical success and favorable patency across all devices at 12 months. However, long-term data are only available for a single device, the iCast/Advanta V12. The results of using this device were favorable over the course of 5 years. (J Vasc Surg 2020;72:1473-86.)

Keywords: Aortoiliac occlusive disease; Covered balloon-expandable stent; iCast Advanta V12; Viabahn VBX; BeGraft

The past two decades have witnessed a paradigm shift to endovascular strategies as the preferred treatment for mild-to-moderate aortoiliac occlusive disease (AIOD).[1] Primary stenting is associated with excellent procedural success and acute outcomes for short lesions. However, diffuse, heavily calcified, and occlusive lesions continue to create the risk for technical failures. Furthermore, stenting of TransAtlantic Inter-Society Consensus Classification (TASC) class C/D lesions is associated with significantly lower long-term primary patency rates than surgical bypass.[2-4] Therefore, current TASC II guidelines recommend open surgery for TASC D (and select TASC C) lesions,[1,5] despite increased risks for early morbidity and mortality and greater use of hospital resources.[6,7] Because patients with TASC D lesions often have multiple comorbid conditions and are poor candidates for open surgery, practitioners are increasingly gravitating toward endovascular approaches, regardless of the lesion type. Although primary patency rates achieved after stenting anatomically complex lesions are unlikely to surpass those of the surgical approach, secondary patency rates after stenting TASC C/D lesions are approximately equivalent to those of surgical bypass.[8-10] Owing to decreasing disparity in outcomes observed across lesion types,[11] the American College of Radiology advocated an endovascular-first approach regardless of the

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TASC classification in its 2017 American College of Radiology Appropriate Use Criteria.[12]

Roles of differing stent designs (covered vs bare metal stents [BMS] and self-expanding vs balloon-expandable stents) have yet to be fully delineated for AIOD treatment. The choice between self-expanding and balloon-expandable stents is further complicated by the lack of comparative data.[13] Covered balloon-expandable (CBE) stents may be optimal for complex lesions, particularly those involving aortic bifurcation.[14] The Gore Viabahn VBX balloon-expandable endoprosthesis (W. L. Gore & Associates, Flagstaff, Ariz) and LifeStream covered iliac stent (Bard Peripheral Vascular, Inc, Tempe, Ariz) received approval from the U.S. Food and Drug Administration for the treatment of iliac arteries in 2017[15,16]; however, the iCast CBE stent (Atrium Medical, Merrimack, NH) is commonly used for AIOD. We conducted a systematic literature review of all published studies reporting outcomes specific to AIOD treatment with CBE stents.

METHODS

Search strategy and output. A literature search was conducted using MEDLINE and the Cochrane Library, encompassing publications between January 1, 2000, and May 7, 2019. The PRISMA guidelines were used. Individual searches revealed four CBE stents used for AIOD (iCast/Advanta V12, Viabahn VBX, Bentley BeGraft, and Bard LifeStream). Generic search strings were used to capture any publication regarding CBE stents used in the aortoiliac arteries. The full search strategy is summarized in Supplementary Table I (online only). A total of 403 unique references were identified, with one additional reference added manually. A PRISMA flow chart of the included studies is shown in the Fig. Abstract screening was conducted by two independent reviewers: a primary screening reviewer and a second reviewer who provided quality control. Citations were supervised and reviewed by the authors. Publications were excluded if they met one or more of the following criteria: (1) reports included no data regarding CBE stents; (2) reports were not related to AIOD treatment; (3) reports were limited to bench testing; (4) reports were limited to animal studies; (5) reports were of trial design/methodology without outcomes; (6) the work was a literature review, editorial, or commentary; (7) fewer than five patients were included in the study; or (8) the full publication was unavailable in English. Most references (333 [82.6%]) were excluded during abstract screening because they met exclusion criterion 1 or 2. Additionally, 6 bench testing publications, 5 animal studies, 6 methods articles, 14 literature reviews/editorials/commentaries, 5 case reports, and 2 abstracts with no full publications in English were identified. Thirty-three abstracts were flagged for review of the full article. Eighteen publications were excluded after the full article was reviewed; of these, nine

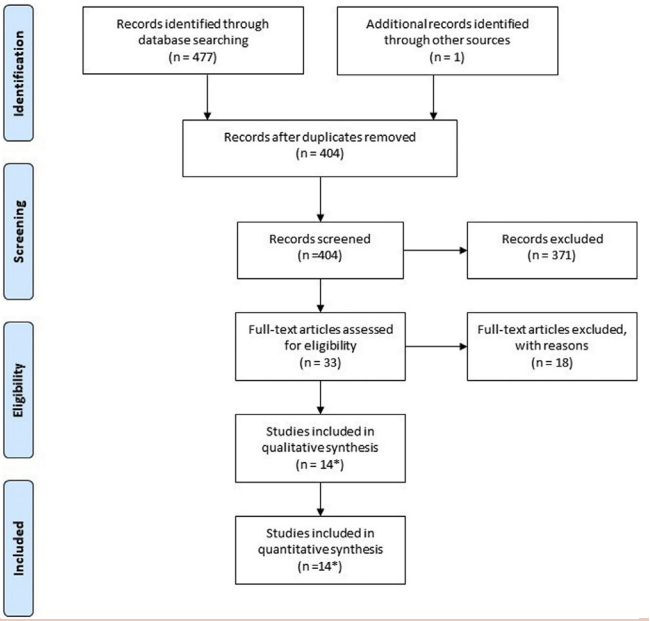

Fig. PRISMA flow chart of studies identified and included in the review analysis. *Fifteen works reporting 14 studies were included for analysis.

publications were not about CBE stents. Six publications did not present stratified outcomes (ie, the study did not distinguish outcomes using CBE stents vs other therapeutic modalities)[13,17-21] and three presented outcomes of fewer than five patients treated with CBE stents.[22-24] A total of 15 publications (14 studies) were ultimately included in this review and underwent data extraction (Table I).[14,25-38]

The complete dataset comprised patients treated in both the prospective trial and retrospective, real-world settings. Clinical trial setting conformed to strict inclusion and exclusion criteria of the protocol. Patients involved in retrospective studies were treated in actual practice and had relatively fewer restrictions than those involved in the prospective studies; however, the patient population for these studies was purposefully selected. The study by Tewksbury et al[38] excluded all but TASC D lesions, the study by Sabri et al[37] included only kissing stents, the 2012 study by Grimme et al[30] excluded kissing stents, and the 2015 study by Grimme et al[31] included only patients treated using covered endovascular reconstruction of the aortic bifurcation technique.

Datapoints and statistical analysis. Baseline anatomic variables, preprocedural ankle-brachial index (ABI), procedural variables, and outcome data were extracted. Variables of interest were determined according to the consensus of both reviewers and a physician (K.O.) and finalized after review of the full article and determination of which variables had adequate data across multiple studies to merit inclusion. Outcomes of interest included

technical success, ABI, primary patency, secondary patency, freedom from target lesion revascularization (TLR), amputation, mortality at 6 months, and mortality at 12 months. To perform a cumulative assessment of variables, the overall proportion was calculated by combining the values from each study; the logit approximation was used to calculate 95% confidence intervals.

Devices of interest. In addition to using generic search terms aimed at capturing relevant publications regarding CBE stents for AIOD, the strategy included performing individual searches designed to capture publications regarding the following CBE stents used to treat AIOD: Gore Viabahn VBX Balloon Expandable (7f-8F sheath devices; W. L. Gore & Associates), Bard LifeStream covered iliac stent (6F-8F sheath devices; Becton, Dickinson and Bard Company, Tempe, Ariz), Bentley BeGraft peripheral stent (6F-7F sheath; Bentley Innomed GmbH, Hechingen, Germany), and Atrium iCast covered stent (known as the Advanta V12 stent outside of the United States, 6F-7F sheath devices; Getinge, Merrimack, NH). The JOSTENT (6F-7F sheath; JoMed, Atlanta, Ga) CBE stent was not prespecified but was identified in the search and included in the review.

RESULTS

Study selection. Among the 14 selected studies, eight were prospective and six were retrospective. Of the prospective studies, three were pilot/feasibility studies performed in Europe and Oceania[26,28,32] and five were safety/efficacy trials performed in Europe, Oceania, and the United States.[14,25,27,34-36] Of the retrospective studies, all were about the Advanta V12/iCast, three were performed in the United States,[29,33,37] two were in Europe,[30,31] and one was in Oceania.[38] The search identified nine published studies of the Advanta V12/iCast, two of the Viabahn VBX, one of the BeGraft, one of the LifeStream, and one of the JOSTENT. Three studies (one prospective, two retrospective) had a two-arm design with a BMS as the comparator; all others were single-arm studies. In total, the complete dataset included 1012 patients and 1463 limbs treated with CBE stents for AIOD. Of these, 680 patients (926 limbs) were treated in a clinical trial setting and 332 patients (537 limbs) in a real-world setting.

Baseline characteristics and index procedure. Disease severity and lesion characteristics diverged notably across the clinical trial and real-world populations (Table II). Clinical trial populations were predominantly male (range, 59.0%-78.5%) compared with real-world populations (range, 26.6%-75.5%). Patients treated in clinical trials had lesser severe lesions than those treated in nontrial or real-world settings. Few TASC D lesions were treated in the clinical trial setting (range, 0%-14.9%); most clinical trial populations had TASC A/B lesions. TASC D lesions comprised 15.4% to 100% of treated lesions. Similarly, the number of occlusions treated ranged from 8.8% to 17.1% in clinical trial populations and from 42.6% to 63.3% in real-world populations.

Technical success was almost uniform: 100.0% in six of eight of the clinical trials and more than 98.0% in the other two clinical trials. Technical success ranged from 95.0% to 100.0% in the real-world retrospective studies (Table III). Low rates of procedural complications occurred in both clinical trial and real-world settings, with the most common being vessel dissection (16.7%), hematoma (0%-15.5%), distal embolism (0%-3.8%), and stent dislodgement (≤1.9%; Table III).

Patency. At 12 months, primary patency rates ranged from 89.1% to 96.9% in the clinical trial setting and from 83.6% to 92.0% in real-world studies (Table IV). Secondary patency rates, when recorded, were similar across the two settings. In four of five retrospective studies reporting secondary patency, rates ranged from 95.0% to 100.0%, with a single study reporting a 12-month patency rate of 87.8%. In the three clinical trials with 12-month secondary patency data available (two with Viabahn VBX and one with LifeStream presenting 9-month patency), rates ranged from 91.9% to 100.0%. Twelve-month secondary patency rates for studies reporting predominantly on TASC C/D lesions[31,38] were similar to those reporting on TASC A/B lesions.

Target lesion revascularization. Overall, 12-month freedom from TLR ranged from 89.6% to 100.0% (Table IV). Because Kaplan-Meier estimates of freedom from TLR were not provided beyond 12 months in most studies, a 24-month time point was not included for this data point. Three retrospective studies reporting freedom from TLR at 12 months indicated that rates ranged from 89.6% to 100.0%; however, in five prospective studies, the rates ranged from 96.1% to 97.4%. Grimme et al[31] reported the lowest freedom from TLR rate at 12 months (88.2%).

Mortality and amputation. No mortalities within 30 days of the index procedure were reported by the clinical trials contributing data to this end point. Mortality that occurred later were provided using a broad range of methodology and intervals across the different studies (Supplementary Table II, online only). Only one major amputation, in Laird et al.'s study (1/155 [0.6%]),[35] occurred during follow-up (Supplementary Table II, online only).

Improvement in the ABI. Eight studies provided prestenting and poststenting ABI values (Table V). ABI measurements across studies ranged from 0.59 to 0.77 before stenting and from 0.84 to 0.99 at 12 months. The most significant ABI improvement was reported by Bosiers et al,[26] with a mean ABI measurement of 0.59 at

Table I. Study design of reviewed publications

Author	Year of publication	Study design	Study location
Bismuth et al[25]	2017	Prospective, nonrandomized, single-arm IDE trial	US and NZ
Bosiers et al[26]	2007	Prospective, nonrandomized, single-arm feasibility study	Belgium
Deloose et al[27]	2017	Prospective, nonrandomized, single-arm study	Belgium
Gaxotte et al[28]	2003	Prospective, nonrandomized, single-arm feasibility study	France
Giles et al[29]	2008	Retrospective, single-arm study	US
Grimme et al[30]	2012	Retrospective, single-arm study	The Netherlands
Grimme et al[31]	2015	Retrospective, single-arm study of consecutively treated patients	The Netherlands and Belgium
Holden et al[32]	2017	Prospective, nonrandomized, single-arm pilot study	NZ
Humphries et al[33]	2014	Retrospective, two-arm study	US
Laird et al[34]	2019	Prospective, nonrandomized, single-arm IDE trial	US and Germany
Laird et al[35]	2019	Prospective, nonrandomized, single-arm IDE trial	US, Europe, and NZ
Mwipatayi et al[14,36]	2011 2016[g]	Prospective, two-arm RCT (COBEST)	Australia
Sabri et al[37]	2010	Retrospective, two-arm study of consecutively treated patients	US
Tewksbury et al[38]	2015	Retrospective, single-arm study	Australia

AOB, Aortic bifurcation; *CERAB,* covered endovascular reconstruction of the aortic bifurcation; *COBEST,* Covered Versus Balloon-Expandable Stent Trial; *IDE,* investigational device exemption; *NZ,* New Zealand; *US,* United States.
Patient/limb denominators listed are specific to patients treated with CBEs for aortoiliac occlusive disease. Patients treated with covered balloon-expandable stents for other indications (Gaxotte et al,[28] renal arteries; Giles et al,[29] multiple vessels) or with a two-arm study design (two-arm study design with BMS comparator arm in studies reported by Mwipatayi et al,[14,36] Sabri et al,[37] and Humphries et al[33]) are not reflected in patient/limb denominators.
[a]All but one patient completed the 9-month follow-up in this study (no mean follow-up provided).
[b]All but one patient completed the 12-month follow-up in study reported by Holden et al[32] (no mean follow-up provided); similarly, Deloose et al[27] reported outcomes through 12 months (no further follow-up statistics provided).
[c]All patients completed the 6-month follow-up in this study (no mean follow-up provided).
[d]Median, not mean, follow-up statistics provided.
[e]There were 49 patients with 66 treated limbs in total for all anatomical locations. However, only 40 of those treated limbs were relevant to iliac.
[f]All patients were treated with the CERAB technique involving deployment of three Advanta V12 stents (one 12-mm stent deployed in the distal aorta and two 8-mm stents creating a new AOB and extending into the common iliac arteries). Therefore, all patients were bilaterally treated.
[g]This study is a retrospective analysis of the COBEST study.
[h]In the COBEST trial, 61.6% of patients had the 5-year follow-up available (35 patients died, 3 moved away, and 10 were lost to follow-up across the total two-arm patient population). Two publications (Mwipatayi et al 2011[14] and Mwipatayi et al 2016[36]) were used to provide trial data.

baseline, 0.98 immediately after stenting, and 0.99 at 12 months. The smallest ABI improvement was reported by Holden et al,[32] with mean ABI measurements of 0.79 at baseline and 0.95 at 12 months.

Comparison of devices. A comparison of the results of each CBE stent included in the review is shown in Table VI. The iCast/Advanta was the most common device studied in the literature (10/15 [66.7%]) comprising 611 treated patients. The VBX device was the focus of two articles (13.3%) that included 164 patients. The LifeStream, BeGraft, and JOSTENT devices were included in one article each, with 155, 70, and 12 patients, respectively. The iCast/Advanta V12 population included more TASC D lesions than the populations treated with other devices (27.5% vs 1.3%, 2.9%, and 6.7% for the LifeStream Stent, BeGraft, and VBX devices, respectively). Most lesion treated with the LifeStream and BeGraft devices were TASC A lesions (61.9% and 77.1%, respectively). Increased complexity of the iCast/Advanta V12 group may have been attributable to the inclusion of retrospective real-world studies; the iCast/Advanta V12 system was the only device with published real-world data. This system also had the longest published follow-up, ranging up to 60 months; follow-up of treatment with other devices ranged from 6 to 12 months.

Technical success was high for all devices. Although primary patency was reported for all devices, varying time points and definitions were used. The randomized prospective study of Advanta V12 (Covered Versus Balloon-Expandable Stent Trial [COBEST]) and four retrospective studies (all performed using the iCast/Advanta V12) reported a 24-month primary patency rate range of 72.0% to 92.0% and secondary patency rate range of at 24 months of 92.0% to 100.0% (Table IV). The COBEST study also reported primary patency rates at 48 (79.9%) and 60 (74.7%) months. As per the Viabahn VBX trials, the VBX device had a 6-month primary patency of 100%, a 9-month primary patency of 96.7%, and a 12-month primary patency of 96.6%. The single arm IDE trial evaluating the LifeStream device reported a 9-month primary patency rate of 89.1%. The BeGraft 1-year primary patency rate was 94.4% and the only recorded primary patency rate for Jostent was 92.0% at 6 months.

Table I. Continued.

Recruitment	Device used	Patients	Treated limbs	Mean follow-up, months
2013-2015	Viabahn VBX	134	201	9[a]
2004-2006	Advanta V12	65	91	8.3
2014-2015	BeGraft	70	93	12[b]
1 year (unspecified)	JOSTENT	12	12	6[c]
2005-2007	iCAST	49	40[e]	13
2003-2010	Advanta V12	87	115	31[d]
2009-2014	Advanta V12	103	206[f]	12[d]
NR-2015	Viabahn VBX	30	43	12[b]
2006-2012	iCAST	37	64	22
2007-2010	iCAST	152	206	36
2014-2015	Lifestream	155	197	9
2006-2008	Advanta V12	62	83	60[h]
2002-2007	iCAST	26	52	20[d]
2010-2012	Advanta V12	30	60	14.3[d]

All CBEs apart from the JOSTENT reported freedom from TLR at various timepoints. The iCast/Advanta V12 stent had 88.2 - 94.3% freedom from TLR at 12 months, 86.6% at 36 months, and 67.4% at 60 months. The VBX and BeGraft stents both had freedom from TLR of 96.6% and 96.7%, respectively, at 12 months. The LifeStream stent had a 96.1% freedom from TLR at 9 months.

Except for distal embolization, procedural complications, such as rupture and hematoma, were not reported for the LifeStream, BeGraft, and Jostent devices. The rate of procedural rupture ranged from 0.0% to 1.9% for the iCast/Advanta V12 device and 0.0% for the Viabahn VBX device. The rates of procedural hematoma were increased for both devices with one retrospective single arm iCast/Advanta V12 study noting 16 cases (15.5%) of groin hematomas that were classified as minor complications and left untreated. Excluding this trial, the rates of procedural hematomas ranged from 0.0% to 3.3% for the iCast/Advanta V12 stent and 0.7% for the Viabahn VBX stent. Distal embolization rates of 0.0% were recorded for most studies, with the exception of 1 LifeStream and 3 iCAST/Advanta V12 studies that recorded rates of 0.65%, 3.8%, 0.7%, and 3.3%, respectively.

Comparisons with BMS. Three studies (one randomized controlled trial [RCT] and two retrospective studies) evaluated midterm outcomes with CBE stents vs BMS.[14,33,36,37] The COBEST compared 83 patients treated with the Advanta V12 with 85 patients treated with various BMS (both balloon expandable and self expanding).[14,36] Baseline characteristics were similar for the two groups, but a greater percentage of patients treated with the V12 had TASC C/D lesions (49.2% vs 27.3%). Uniform technical success and similar rates of procedural complications were observed in both cohorts. At 5 years, primary patency was significantly higher in the covered stent group (74.7% vs 62.9%; $P = .01$) despite a higher degree of lesion severity in this group. Secondary patency, although higher in patients treated with CBE stents, did not achieve statistical significance ($P = .05$). However, secondary patency was higher in patients with TASC C/D lesions treated with covered stents ($P = .015$). Differences between CBE stents and BMS achieved statistical significance only in patients with TASC C/D lesions.

Table II. Baseline characteristics of reviewed publications

Author	No.[a]	Male	TASC A	TASC B	TASC C	TASC D
Bismuth et al 2017[25,b]	134	79 (59.0)	50 (37.3)	41 (30.6)	32 (23.9)	11 (8.2)
Bosiers et al 2007[26]	65	51 (78.5)	NR	NR	NR	NR
Deloose et al 2017[27]	70	4 (64.3)	54 (77.1)	10 (14.3)	4 (5.7)	2 (2.9)
Gaxotte et al 2003[28]	12	17 (73.9)	NR	NR	NR	NR
Giles et al 2008[29]	49	37 (75.5)	NR	NR	NR	NR
Grimme et al 2012[30]	87	73 (63.5)	40 (34.8) n = 115	41 (35.7) n = 115	7 (6.1) n = 115	27 (23.5) n = 115
Grimme et al 2015[31]	103	51 (49.5)	0 (0.0)	6 (5.8)	9 (8.7)	88 (85.4)
Holden et al 2017[32]	30	18 (60.0)	7 (23.3)	9 (30.0)	14 (46.6)	0 (0.0)
Humphries et al 2014[33,d]	37	19 (51.4)	18 (28.1) n = 64	21 (32.8) n = 64	11 (17.2) n = 64	14 (21.9) n = 64
Laird et al 2019[34]	152	94 (61.8)	131 (58.7) n = 223	79 (35.4) n = 223	13 (5.8) n = 223	0 (0.0) n = 223
Laird et al 2019[35]	155	107 (69.0)	96 (61.9)	42 (27.1)	15 (9.7)	2 (1.3)
Mwipatayi et al 2011/2016[14,36]	62	56 (67.7)	0 (0.0) n = 67	34 (50.7) n = 67	23 (34.3) n = 67	10 (14.9) n = 67
Sabri et al 2010[37]	26	17 (65.4)	7 (26.9)	9 (34.6)	6 (23.1)	4 (15.4)
Tewksbury et al 2015[38]	30	8 (26.6)	0 (0.0)	0 (0.0)	0 (0.0)	30 (100.0)

NR, Not reported; *RF*, Rutherford Classification.
Denominators presented in the left column represent the total patient number (in two-arm studies, total patient number in the covered stent arm). Studies varied in the method of reporting baseline anatomic data, with some authors choosing to report TransAtlantic Inter-Society Consensus Classification data per patient and others reporting per limb. In publications with lesion categorization and other anatomic data reported per limb (the preferred method), limb denominators are listed below data entry. Continuous data are presented as mean (standard deviation provided where available) and categorical data are presented as number (%).
[a]All patients treated with the kissing stent technique were considered to have aortic bifurcation (AOB) involvement.
[b]The authors stated that of 201 treated vessels, 154 (77%) were common iliac artery (CIA) only, 31 (15%) were external iliac artery (EIA) only, and 16 (8%) were CIA-EIA. However, the authors also confirm that 42.5% of lesions were treated with the kissing stent technique, which we would consider to also comprise AOB involvement. Owing to their method of treatment description, we cannot ascertain the percentage with AOB-CIA-EIA vs that with the AOB-CIA treatment; therefore, we have erred based on the author description of vessel involvement in this table. However, 42.5% of treated lesions had AOB involvement.
[c]One additional patient was categorized as Rutherford class 6.
[d]Stated vessel involvement per authors. However, 27 of 37 treated lesions required the kissing stent technique. Treatment of the distal aorta is also described in the work. Owing to the method of the treated vessel description, we have erred based on the author description; however, 73% of treated lesions had AOB involvement.
[e]Two additional patients were categorized as Rutherford class 0.

Sabri et al[37] reported similar conclusions in their retrospective study of 54 consecutive patients treated with kissing CBE stents or BMS at the aortoiliac bifurcation. Similar to COBEST, a greater percentage of patients treated with CBE stents had TASC C/D lesions (38.0% vs 7.0%); additionally, 46.0% of patients with CBE stents had common iliac artery occlusions compared with 10.0% of those with BMS. Technical success and procedural complication rates were similar across groups. Clinical improvements ($P = .02$) and primary patency at 1 year (83.6%-96.6%) and 2 years (68.0%-92.0%) were significantly higher ($P = .02$) in the CBE stent group, despite more complex lesion characteristics in this group.

A retrospective comparison of 37 patients treated with CBE stents and 125 treated with balloon-expandable BMS by Humphries et al[33] indicated significantly improved patency rates at 3 years in the BMS group. A multivariate analysis found that TASC classification and other baseline and procedural variables were not predictors of late primary patency. The only predictive factors were 12-month adherence to antiplatelet therapy and indication for the index procedure.

DISCUSSION

The available evidence regarding CBE stents for AIOD showed that the treatment of TASC A/B lesions is associated with high technical success rates, low procedural complication rates, and excellent 12-month primary and secondary patency rates. CBE stent treatment of more anatomically complex lesions, for example, TASC C/D lesions and chronic total occlusions that predominate in real-world settings, is associated with a slightly higher rate of procedural complications and later stent

Table II. Continued.

RF 1	RF 2	RF 3	RF 4	RF 5	Occlusions	Lesion length
0 (0.0)	26 (19.4)	101 (75.4)	7 (5.2)	0 (0.0)	28 (13.3) n = 210	26.6 ± 16.3 n = 209
0 (0.0) n = 91	49 (53.8) n = 91	30 (33.0) n = 91	12 (13.2) n = 91	0 (0.0) n = 91	8 (8.8) n = 91	41.2 n = 91
0 (0.0)	22 (31.4)	43 (61.4)	2 (2.9)	3 (4.3)	13 (14.0) n = 93	34.3 n = 93
NR	NR	NR	NR	NR	NR	NR
NR	NR	NR	NR	NR	NR	NR
0 (0.0)	17 (14.8)	72 (62.6)	9 (7.8)	11 (9.6)	49 (42.6) n = 115	NR
0 (0.0)	0 (0.0)	64 (82.1)	20 (19.4)	17 (16.5)[c]	NR	NR
0 (0.0)	5 (17.0)	24 (80.0)	1 (3.0)	0 (0.0)	4 (9.3) n = 43	31.6 n = 43
NR	NR	NR	NR	NR	NR	42 ± 18 n = 64
4 (2.0) n = 205	76 (37.1)[e] n = 205	116 (56.6) n = 205	7 (3.4) n = 205	0 (0.0) n = 205	26 (17.1)	25.4 ± 16.8 n = 223
0 (0.0)	24 (15.5)	118 (76.1)	13 (8.4)	0 (0.0)	21 (10.7) n = 197	29.2 ± 17.1 n = 197
2 (3.2)	17 (27.4)	25 (40.3)	15 (24.2)	3 (4.8)	8 (12.9)	NR
NR	NR	NR	NR	NR	12 (46.2)	NR
NR	NR	NR	NR	NR	19 (63.3)	NR

graft occlusion than TASC A/B lesions. Secondary patency rates and clinical improvements of TASC A/B and TASC C/D lesions, however, were similar.

The decision to use BMS or CBE stents for AIOD is often based on cost.[33,36] For lesions with evidence indicating significantly improved outcomes with CBE stents, the cost may be offset by a reduced rate of reinterventions. Appositional defects and their attendant hemodynamic consequences, as well as the potential for hyperplastic ingrowth through BMS interstices, are avoided by covered stents, which create a smooth hemodynamically favorable lumen and resist hyperplastic ingrowth.[33,36] Additionally, the covering of a CBE device protects against iliac artery rupture and disruption as illustrated by the low rates of procedural complications in Table III. CBE therapy exposes the patient to hypercoagulable tendencies of all prosthetic conduits. However, this concern may be minor in the aortoiliac position, where the surface area-to-volume ratio heavily favors patency, as it does with open prosthetic reconstructions in this anatomy.[39] Considering both design attributes, CBE stents are well-suited for complex and/or severe lesions. Our review exclusively focused on CBE stents to understand clinical trial and real-world outcomes specific to the CBE stent design and AIOD disease subset of peripheral arterial disease. Although other well-designed systematic reviews of this topic have been conducted, they pooled balloon-expandable and self-expanding covered stents or all endovascular therapies for AIOD[10,40] and used different methods of analysis.

The only RCT that compared CBE stents and BMS for AIOD indicated that the primary patency rate at 5 years was significantly higher in the CBE stents cohort. Although there is no breakdown of patency rates based on individual TASC category, we believe the available information indicates that high patency can be still be

Table III. Procedural characteristics of reviewed publications

Author	Procedural rupture	Procedural hematoma	Distal embolization	Miscellaneous procedural complications	Adjunct procedures	Kissing stent technique	Technical success
Bismuth et al 2017[25] (n = 134)	0 (0.0)	1 (0.7)	0 (0.0)	4 patients (3.0%) had 5 procedure-related SAEs (CFA pseudoaneurysm, hematoma, loss of limb pulse, hypovolemic shock, and altered mental status [underlying dementia])	NR	57 (42.5)	134 (100.0)
Bosiers et al 2007[26] (n = 65)	0 (0.0)	0 (0.0)	0 (0.0)	No procedural or acute complications	18 limbs (19.8%) received 27 SE stents to treat coexisting femoropopliteal disease and establish adequate runoff	56 (61.5)[a] n = 91	65 (100.0)
Deloose et al 2017[27] (n = 70)	NR	NR	0 (0.0)	NR	Outflow-limiting lesions were treated per hospital standard	NR	70 (100.0)
Gaxotte et al 2003[28] (n = 12)	NR	NR	0 (0.0)	3 patients (25.0%) had procedural complications (2 dissections and 1 ISR)	NR	NR	12 (100.0)
Giles et al 2008[29] (n = 40)	NR	NR	NR	4 patients (6.1%) had access site complications across all treated vessels[c]	NR	NR	38 (95.0)
Grimme et al 2012[30] (n = 87)	1 (1.1)	NR	0 (0.0)	2 patients (2.3%) had procedural complications (1 EIA rupture, 1 stent dislodgement)	In 26 procedures (29.9%), additional stents were used (17 SE MBS, 5 BE BMS, 4 SE covered stents).	0 (0.0)	86 (98.9)
Grimme et al 2015[31] (n = 103)	2 (1.9)	16 (15.5)[d]	NR	15 patients (14.6%) had procedural complications (10 dissections, 2 ruptures, 1 thrombus formation, 2 stent dislodgements)	21 patients (20.4%) underwent concomitant CFA and/or distal EIA endarterectomy[e]	0 (0.0)	98 (95.1)
Holden et al 2017[32] (n = 30)	NR	NR	NR	No MAEs occurred before hospital discharge (minor complications not reported)	NR	10 (33.3)	30 (100.0)

Table III. Continued.

Author	Procedural rupture	Procedural hematoma	Distal embolization	Miscellaneous procedural complications	Adjunct procedures	Kissing stent technique	Technical success
Humphries et al 2014[33] (n = 37)	NR	1 (2.7)	NR	1 patient (2.7%) exhibited an access site complication (hematoma, managed conservatively) following the use of a closure device (sole patient requiring closure device)	1 patient (2.7%) was treated for concomitant infrainguinal disease	27 (73.0)	37 (100.0)
Laird et al 2019[34] (n = 152)	1 (0.7)	2 (1.4)	1 (0.7)	7 patients (4.6%) had procedural adverse events: procedure-related bleeding requiring transfusion (n = 4), acute limb ischemia (n = 2), myocardial infarction within 30 days (n = 2), arterial rupture (n = 1), and distal embolization (n = 1)	NR	NR	150 (98.7)
Laird et al 2019[35] (n = 155)	NR	NR	NR	1 patient had a tibial artery embolization	NR	24 (10.5)	226 (98.3)
Mwipatayi et al 2011/2016[14,36] (n = 62)	NR	NR	NR	[b]	5 limbs with femoropopliteal bypass grafts, 4 with CFA endarterectomy, 4 limbs required SFA stenting	43	83 (100.0)
Sabri et al 2010[37] (n = 26)	NR	NR	1 (3.8)	3 patients (11.5%) had major complications (vascular dissection, distal embolism)	Additional EIA interventions performed concomitantly in 14 patients (54%; 12 received stents, 2 PTA); concomitant femoropopliteal revascularization was performed in 5 patients (19%)	26 (100.0)	26 (100.0)

(Continued on next page)

Table III. Continued.

Author	Procedural rupture	Procedural hematoma	Distal embolization	Miscellaneous procedural complications	Adjunct procedures	Kissing stent technique	Technical success
Tewksbury et al 2015[38] (n = 30)	0 (0.0)	1 (3.3)	1 (3.3)	2 patients (6.7%) had procedural complications (1 hematoma managed conservatively, 1 ISR requiring thrombectomy with distal emboli to the IIA)	4 patients (13.3%) required open distal revascularization at the index procedure; 2 patients (6.6%) underwent concomitant CFA endarterectomy; 2 patients (6.6%) had femorofemoral or femoropopliteal bypass grafting	20 (66.6)	30 (100.0)

BE, Balloon expandable; *BMS*, bare-metal stent; *CFA*, common femoral artery; *EIA*, external iliac artery; *ISR*, in-stent restenosis; *MAE*, material adverse event; *MBS*, main branch stent; *NR*, not reported; *PTA*, percutaneous transluminal angioplasty; *SAE*, serious adverse event; *SE*, self-expanding; *SFA*, superficial femoral artery.
Denominators presented in the left column represent total patient number (in two-arm studies, total patient number in the covered stent group). Language regarding complications (ie, referring to complications as "major" or procedure-related) is per publication.
[a]Number with the kissing stent technique used is inferred per the authors' statement that lesions located at the aortic bifurcation (AOB) were treated with the kissing stent technique (56 lesions located at the AOB in this study).
[b]In the COBEST trial report, authors state only that procedural complications including hemorrhage, flow-limiting dissection, lymph leak, and seroma formation, occurred at statistically similar rates in the two arms — however, no rates were provided. This rate is based on 66 total patients in the complete study.
[c]Access site complications reported in this series were not specified by vessel (several treated vessels included in this series): access complications did include one dissection that resulted in CFA/SFA thrombosis and one brachial artery bleeding event.
[d]Minor complications included 16 groin hematomas that were left untreated and 2 pseudoaneurysms, 1 rebleeding, and 1 case of atrial fibrillation.
[e]Additionally, five patients underwent further PTA in the EIAs (one received stenting).

expected in TASC C and TASC D lesions. This assessment can be made from the observance that CBE stents used in studies with higher percentages of TASC C and TASC D lesions do not have a significantly different patency than studies with higher percentages of TASC A lesions. Furthermore, although the secondary patency rate was higher for limbs treated with CBE stents; the difference was not significant. In subset analyses, however, secondary patency rate and freedom from binary restenosis rate were significantly higher for patients treated with CBE stents for TASC C/D lesions.[14,36] A retrospective two-arm study of 54 consecutively treated patients found a high patency and clinical improvement at 2 years for CBE stents, despite a significantly greater percentage of TASC C/D lesions and unilateral occlusions in the CBE stents group.[37] These results must be viewed in the context of the study design; patients were originally treated with BMS until CBE stents became available; after that point, CBE stents were almost exclusively used.[37]

The other two-arm study identified during our review reported opposite conclusions.[33] First, compared with CBE stents, BMS use was associated with improved patency rates at 3 years. Second, the TASC classification and other anatomic characteristics were not predictive of primary patency.[33] However, the authors of the aforementioned publication acknowledged that imbalanced cohort sizes and diminishing sample sizes during the midterm follow-up may have affected statistical analyses of patency and other outcomes. Additionally, this was a retrospective single-center trial, whereas the COBEST and Dutch Iliac Stent Trial: COVERed balloon-expandable vs uncovered balloon-expandable stents in the common iliac artery (DISCOVER)[40] trials are both prospective and multicenter.

A meta-analysis of study outcomes was considered during the early stages of the review design. However, this strategy was ruled out during screening owing to limited publications identified during our search. Similarly, it was decided that data would not be pooled across studies because of the diversity of study designs and quality of data reporting. This review comprised data from eight clinical trials (including one RCT) and six retrospective studies. Available literature predominantly includes studies of the iCast/Advanta V12 (three prospective and all six retrospective real-world studies). This finding was not surprising, because the iCast/Advanta V12 has been

Table IV. Patency and freedom from target lesion revascularization (*TLR*) at 12 and 24 months

	12 Months			24 Months	
Author	Primary patency	Secondary patency	Freedom from TLR	Primary patency	Secondary patency
Bismuth et al 2017[25]	96.9[a]	99.5[a]	97.4[a]	NR	NR
Bosiers et al 2007[26]	91.1	NR	NR	NR	NR
Deloose et al 2017[27]	94.4	NR	96.7	NR	NR
Gaxotte et al 2003[28]	NR	NR	NR	NR	NR
Giles et al 2008[29]	84.0	100.0	100.0[b]	77.0[c]	100.0
Grimme et al 2012[30]	83.6	87.8	89.6	NR	NR
Grimme et al 2015[31]	87.3	95.0	88.2	82.3	95.0
Holden et al 2017[32]	96.6	100.0	96.6	NR	NR
Humphries et al 2014[33]	85.0	96.0	NR	72.0	92.0
Laird et al 2019[34]	96.4[a]	NR	97.2[a]	NR	NR
Laird et al 2019[35]	89.1[a]	91.9[a]	96.1[a]	NR	NR
Mwipatayi et al 2011/2016[14,36]	96.4[d]	96.4[d]	[d]	82.2	96.3
Sabri et al 2010[37]	92.0	NR	NR	92.0	NR
Tewksbury et al 2015[38]	90.0	97.0	NR	79.0	97.0

NR, Not reported.
Kaplan-Meier estimate of freedom from TLR was not provided beyond 12 months in most of the included studies; therefore, this end point is only included at 12 months. Patency estimates were listed to the tenth place after the decimal when provided. Values are percent.
[a]Patency and TLR at 9 months.
[b]No Kaplan Meier estimate of freedom from TLR was provided; however, only 1 revascularization was performed in this series (in a renal artery).
[c]Patency at 18 months.
[d]The 12-month patency information was provided by the primary investigator of the Covered Versus Balloon-Expandable Stent Trial (COBEST) trial. The COBEST trial publications reported primary patency rates at 18, 24, 48, and 60 months, with primary patency rates of 88.5%, 82.2%, 79.9%, and 74.7%, respectively. The secondary patency rate at 18 months was 96.3% and remained the same through 60 months. Target vessel revascularization was visualized with the Kaplan-Meier curve; however, no rate was provided at any time point.

Table V. Ankle-brachial index (*ABI*) before and after stenting

Author	Baseline ABI	1-Month ABI	6-Month ABI	12-Month ABI	18-Month ABI
Bismuth et al 2017[25] (n = 201)	0.77 ± 0.22	NR	NR	0.97 ± 0.18[a]	NR
Bosiers et al 2007[26] (n = 91)	0.59 ± 0.12	0.98 ± 0.07	0.98 ± 0.06	0.99 ± 0.04	NR
Deloose et al 2017[27] (n = 93)	NR	[b]	[b]	[b]	NR
Gaxotte et al 2003[28] (n = 12)	NR	NR	NR	NR	NR
Giles et al 2008[29] (n = 40)	0.62 ± 0.18	0.83 ± 0.26	0.84 ± 0.22	0.84 ± 0.21	0.86 ± 0.16
Grimme et al 2012[30] (n = 115)	0.66 ± 0.24	0.89 ± 0.21[e]	NR	NR	NR
Grimme et al 2015[31] (n = 206)	0.64 ± 0.21	0.91 ± 0.14[e]	NR	NR	NR
Holden et al 2017[32] (n = 43)	0.79	NR	NR	0.95	NR
Humphries et al 2014[33] (n = 64)	NR	NR	NR	NR	NR
Laird et al 2019[34] (n = 201)	0.73 ± 0.23	NR	NR	NR	NR
Laird et al 2019[35] (n = 197)	NR	NR	NR	NR	NR
Mwipatayi et al 2011/2016[14,36] (n = 83)	0.65 ± 0.03	0.91 ± 0.03	0.89 ± 0.02	0.94 ± 0.02	0.94 ± 0.02[a,c]
Sabri et al 2010[37] (n = 52)	R: 0.74 ± 0.21 L: 0.61 ± 0.18	R: 0.83 ± 0.23 L: 0.87 ± 0.22[d]	NR	NR	R: 0.80 ± 0.21 L: 0.88 ± 0.17[d]
Tewksbury et al 2015[38] (n = 60)	NR	NR	NR	NR	NR

L, Left; *NR*, not reported; *R*, right.
Denominators presented in the left column represent total number of limbs treated (in two-arm studies, total number limbs treated with covered stents). Values are mean ± standard deviation.
[a]Latest ABI recorded at 9 months.
[b]Authors did not report the mean ABI values at each follow-up visit; rather, Deloose et al[27] reported the mean change in the ABI at each interval. At 1 month, the ABI improved by a mean 0.27 points (n = 63); at 6 months, it improved by 0.28 points (n = 51); at 12 months, it improved by 0.29 points (n = 50).
[c]ABI also captured at 24 months (0.96 ± 0.04) and at 60 months (0.90 ± 0.05)
[d]Poststenting ABI values were provided from the time of hospital discharge and at the latest follow-up, with a median follow-up of 20 months. No overall mean ABI values were recorded; they were only recorded per limb.
[e]ABI captured after the procedure.

Table VI. Comparison of evidence on covered balloon-expandable (CBE) stents

	iCast/Advanta V12	Viabahn VBX	Lifestream	BeGraft	Jostent
No. of studies	9	2	1	1	1
Clinical trials	3	2	1	1	1
Real-world studies[a]	6	0	0	0	0
No. of patients	611	164	155	70	12
Follow-up range, months	8.3-60.0	9-12	9	12	6
TASC classification, % [95% CI][b,c]					
TASC A	31.2% [27.7%-34.9%] n = 628	34.8% [27.9%-42.4%] n = 164	61.9% [54.1%-69.2%] n = 155	77.1% [65.9%-85.5%] n = 70	NR
TASC B	30.0% [26.8%-34.0%] n = 628	30.5% [23.9%-37.9%] n = 164	27.1% [20.7%-34.6%] n = 155	14.3% [7.9%-24.6%] n = 70	NR
TASC C	11.0% [8.8%-13.7%] n = 628	28.0% [21.7%-35.4%] n = 164	9.7% [5.9%-15.4%] n = 155	5.7% [2.2%-14.3%] n = 70	NR
TASC D	27.5% [24.2%-31.2%] n = 628	6.7% [3.8%-11.7%] n = 164	1.3% [0.3%-5.0%] n = 155	2.9% [0.7%-10.7%] n = 70	NR
Technical success, range	95.0%-100%	100%	98.3%	100%	100%
Primary patency, months, range					
6	87.2%-97.0%	100%	NR	NR	92%
9	96.4%	96.7%	89.1%	NR	NA
12	83.6%-96.4%	96.6%	NA	94.4%	NA
18	77.0%-87.3%	NA	NA	NA	NA
24	68.0%-92.0%	NA	NA	NA	NA
36	72.0%	NA	NA	NA	NA
48	63.4%-79.9%	NA	NA	NA	NA
60	74.7%	NA	NA	NA	NA
Freedom from TLR, months, range					
6	92.4%-99.3%	100.0%	98.1%	NA	NA
9	97.2%	97.4%	96.1%	NA	NA
12	88.2%-94.3%	96.6%	NA	96.7%	NA
24	85.6%-88.3%	NA	NA	NA	NA
36	86.6%	NA	NA	NA	NA
48	67.4%	NA	NA	NA	NA

CI, Confidence interval; *NA*, not available; *NR*, not reported; *TASC*, TransAtlantic Inter-Society Consensus Classification.
[a]Retrospective studies.
[b]Percentage of lesions in the total population (sum of lesions in each category/total lesion reported); 95% CI was calculated using the Logit approximation.
[c]N values recorded for TASC classification represent the number of lesions.

clinically used for this indication for nearly 20 years, whereas the newer CBE stents (BeGraft, Viabahn VBX; LifeStream) are currently limited to use in regulatory trials. Furthermore, the JOSTENT is no longer available in the market; therefore, its data are limited to publications of its feasibility in trials performed during the early 2000s. Off-label use of endovascular aortic stent grafts for abdominal aortic aneurysms to treat severe AIOD was not included in this review; however, they are of interest because of their promising results.[41,42]

Clinical trial populations mainly comprised patients with mild to moderate AIOD and relatively straightforward lesions, mostly owing to study design for regulatory approval. The two recent Viabahn VBX studies excluded any patients with lesions requiring atherectomy or laser ablation. These studies, which also enrolled subjects with the shortest lesion lengths of any of the reviewed studies, found the highest primary patency rates at 12 months. The retrospective studies identified during our review were largely "all-comer" reports and, as such, provided a better understanding of the anatomic profile presenting to clinicians who choose CBE stents in actual practice. Many of these patients had TASC D lesions, chronic total occlusions, and critical limb ischemia. Advanced lesion severity was associated with more procedural complications and diminished 12-month primary patency rates. However, there were no differences between real-world and clinical trial outcomes with respect to 12-month patency and midterm follow-up.

The same was true at 24 months, although outcomes beyond 12 months were limited to reports of the iCast/Advanta V12.

Side-by-side comparisons of the different CBE stents were limited owing to the lack of long-term follow-up for CBE stents that were not the iCast/Advanta V12. The technical success, patency, and freedom from TLR were similar among all devices at 12 months. Beyond 12 months, data were only available for the iCast/Advanta V12 device. Moreover, because this device was the only stent with evidence from real-world studies, direct comparisons should be made cautiously owing to differences in lesion severity and patient populations.

The Dutch DISCOVER trial, a multicenter RCT comparing balloon-expandable BMS and CBE stents, is nearing the end of enrollment.[40] The use of only balloon-expandable stents in both arms will make our study outcomes particularly interesting to practitioners. Further research should also include a cost-effectiveness analysis comparing costs and outcomes of BMS and CBE stents to inform health care resourcing and reimbursement decisions. Another area of interest for future research is of patients treated with a hybrid approach (endovascular stenting with planned distal revascularization such as common femoral artery endarterectomy)[5] vs an endovascular-only approach.[43] A limitation of the current review was the lack of level 1 evidence comparing CBE stents to other treatment options for AIOD; there was only one RCT about this topic.[14,36]

CONCLUSIONS

A review of the published evidence of CBE stents as the primary treatment for AIOD showed high technical success and patency rates at 12 months. However, favorable long-term data are only available for one device (iCast/Advanta) used in real-world settings. Long-term follow-up and real-world patient data are lacking for other devices. Moreover, new randomized trials are needed to compare different stent designs and their impacts on outcomes. CBE stents are preferred over BMS for complex aortoiliac lesions because of their benefits that appear to last up to 5 years, at least for the iCAST stent. Further robust comparative studies with long-term data will provide more information.

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AUTHOR CONTRIBUTIONS

Conception and design: BM, KO, TA, JW, ED, JP, JdV, RD
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Data collection: BM
Writing the article: BM, TA, JW
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Supplementary Table I (online only). MEDLINE search strategy

MEDLINE search No.	Search terms/operators Filters: publication date from 01 January 2000 to 07 May 2019	No. of search results
1	(["balloon expandable"] AND stent) AND iliac	139
2	(["balloon expanding"] AND stent) AND iliac	5
3	("covered stent") AND iliac	211
4	(viabahn) AND iliac	44
5	(VBX) AND iliac	1
6	(Bentley) AND iliac	2
7	(BeGraft) AND iliac	3
8	(Bard) AND iliac	30
9	(LifeStream) AND iliac	1
10	(iCAST) AND iliac	8
11	(Advanta) AND iliac	8
12	(V12) AND iliac	9
References identified		461
	Unique references	392
	Duplicates	69
	Unique references identified from Cochrane database literature search	11
	Total no. unique references identified via database	403
	Total no. manually added	1
	Total no. references identified for abstract review	404

Supplementary Table II (online only). Acute and midterm mortalities

Author	Mortality, 30 days	>30-day mortality	Amputation
Bismuth et al 2017[25]	0 (0.0)	1 death (0.7%) during 9 months follow-up after the procedure (cardiac arrest)	0 (0.0)
Bosiers et al 2007[26]	0 (0.0)[a]	2 deaths (3.0%) during 12 months follow-up after the procedure (mean follow-up, 8.3 months); both MI: 1 in 89 year-old woman at 2.5 months, 1 at 7 months	NR
Deloose et al 2017[27]	NR	95.6% 12-month Kaplan-Meier survival (unknown no. of deaths)	0 (0.0)
Gaxotte et al 2003[28]	0 (0.0)[b]	NR	NR
Giles et al 2008[29]	NR	NR	NR
Grimme et al 2012[30]	1 (1.1)[c]	16 deaths (18.4%) during 48 months follow-up after the procedure (mean follow-up, 31 months)	NR
Grimme et al 2015[31]	0 (0.0)	8 deaths (7.8%) during 24 months follow-up after the procedure (median follow-up, 12 months): 6 deaths owing to non-procedure-related causes, 2 deaths owing to unknown causes	0 (0.0)
Holden et al 2017[32]	0 (0.0)	1 death (3.3%) during 12 months follow-up after the procedure (not procedure related or device related)	0 (0.0)
Humphries et al 2014[33]	NR	97% 12-month KM survival (unknown number of deaths); 97% 24-month KM survival; 81% 36-month KM survival	2 amputations (3.1%) through 36 months (1 amputation in patient presenting with acute limb ischemia)
Laird et al 2019[34]	0 (0.0)	13 (8.6%) deaths during 3 years postprocedure follow-up (not procedure related or device related)	NR
Laird et al 2019[35]	0 (0.0)[d]	5 deaths during 9 months postprocedure follow-up (not procedure-related or device-related)	1 (0.6)
Mwipatayi et al 2011/2016[14,36]	0 (0.0)[e]	19.5% at 5 years for patients treated with CBE (all-cause)	0 (0.0)
Sabri et al 2010[37]	0 (0.0)[f]	NR	NR
Tewksbury et al 2015[38]	0 (0.0)	1 death (3.3%) during 24 months follow-up after the procedure (mean follow-up, 14 months): CHF with RF and ischemic heart disease	0 (0.0)

CBE, Covered balloon-expandable; *CHF,* congestive heart failure; *KM,* Kaplan-Meier; *NR,* not reported; *RF,* renal failure.
[a]Authors stated that no complications occurred during 30 days after the procedure; therefore, we inferred that no deaths occurred within this window.
[b]Authors stated there was no procedure-related death. As per standard, all deaths within 30 days of the index procedure are considered device or procedure related; therefore, we can infer that no deaths occurred in this window.
[c]Patient died 9 days after the procedure from multiple organ failure after laparotomy for duodenal bleeding.
[d]Authors stated that there were 22 events for the primary end point, which included 30-day procedural mortality. None of the 22 listed events were procedural mortalities; therefore, we can infer that no deaths occurred in this window.
[e]Information provided by the Covered Versus Balloon-Expandable Stent Trial Covered Versus Balloon-Expandable Stent Trial primary investigator.
[f]Patient died 9 days after the procedure from multiple organ failure after laparotomy for duodenal bleeding.