Midterm results on a new self-expandable covered stent combined with branched stent grafts: Insights from a multicenter Italian registry

Luca Bertoglio, MD,[a] Alessandro Grandi, MD,[a] Gian Franco Veraldi, MD,[b] Raffaele Pulli, MD,[c] Michele Antonello, MD,[d] Stefano Bonvini, MD,[e] Giacomo Isernia, MD,[f] Raffaello Bellosta, MD,[g] Francesco Buia, MD,[h] *and* Roberto Silingardi, MD,[i] on behalf of the COBRA Registry Collaborators, *Milan, Verona, Bari, Padua, Perugia, Brescia, Bologna, and Modena, Italy*

ABSTRACT

Objective: To investigate the technical periprocedural and midterm outcomes of endovascular repairs with multibranched endovascular repair or iliac branch devices combined with a new self-expanding covered stent.

Methods: The COvera in BRAnch registry is a physician-initiated, multicenter, ambispective, observational registry (ClinicalTrials.gov Identifier: NCT04598802) enrolling patients receiving a multibranched endovascular repair or iliac branch devices procedure mated with Bard Covera Plus (Tempe, AZ) covered stent, designed to evaluate the outcomes of the covered stent mated with patient-specific and off-the-shelf branched stent graft. Primary end points were technical success, branch instability, and freedom from aortic and branch-related reintervention within 30 days and at follow-up. Preoperative characteristics, comorbidities, and outcomes definitions were graded according to the Society for Vascular Surgery reporting standards.

Results: Two hundred eighty-four patients (76 years; range, 70-80 years; 79% males) in 24 centers were enrolled for a total of 708 target vessels treated. The covered stents were mated with an off-the-shelf graft in 556 vessels (79%) and a custom-made graft in 152 (21%). Three hundred seven adjunctive relining stents in 277 vessels (39%) were deployed, of which 116 (38%) were proximal, 66 (21%) intrastent, and 125 (41%) distal. Adjunctive relining stent placement was more frequent when landing in a vessel branch instead of the main trunk (59% vs 39%; $P = .031$), performing a percutaneous access (49% vs 35%; $P < .001$), using a stent with a diameter of 8 mm or greater (44% vs 36%; $P = .032$) and a length of 80 mm or greater (65% vs 55%; $P = .005$), when a post-dilatation was not performed (45% vs 29%; $P < .001$) and when an inner branch configuration was used (55% vs 35%; $P < .001$). Perioperative technical bridging success was 98%. Eight patients (3%) died in the perioperative period. Two deaths (1%) were associated with renal branch occlusion followed by acute kidney injury and paraplegia. Follow-up data were available for 638 vessels (90%) at a median of 32 months (Q1, Q3, 21, 46). Branch instability was reported in 1% of branches. Forty-six patients (17%) died during follow-up, nine (3%) of them owing to aortic-related causes. Primary patency rates at 1, 2, and 3 years were 99% (581/587), 99% (404/411), and 97% (272/279), respectively. Branch instability was associated with patient-specific devices (9% vs 4%; $P = .014$) and intrastent adjunctive stent placement (12% vs 2%; $P = .003$), especially when a bare metal balloon-expandable stent was used (25% vs 3%; $P < .001$).

Conclusions: The use of this new self-expanding covered stent mated with branched endografts proved to be safe and feasible with high technical procedural success rates. Low rates of branch instability were observed at midterm follow-up. Comparative studies with other commercially available covered stents are warranted. (J Vasc Surg 2023;77:1598-606.)

Keywords: Branched; Endovascular procedures; Thoracoabdominal aortic aneurysm; Aorto-iliac aneurysm; Covered stent; Self-expandable; Instability

From the Division of vascular Surgery, Vita-Salute San Raffaele University, IRCCS San Raffaele Scientific Institute, Milan[a]; the Division Vascular Surgery, Integrated University Hospital of Verona, Verona[b]; the Division Vascular Surgery, Department of Cardiothoracic Surgery, University of Bari School of Medicine, Bari[c]; the Vascular and Endovascular Surgery Unit, Department of Cardiac, Thoracic, Vascular Sciences and Public Health, University of Padua, Padua[d]; the Department of Vascular Surgery, Santa Chiara Hospital, Trento[e]; the Unit of Vascular and Endovascular Surgery, Santa Maria della Misericordia Hospital, Perugia[f]; the Division of vascular Surgery, Cardiovascular Department, Poliambulanza Foundation, Brescia[g]; the Pediatric and Adult Cardio-Thoracovascular, Onchoematologic and Emergencies Radiology Unit, IRCCS Azienda Ospedaliero-Universitaria di Bologna, Bologna[h]; and the Division of vascular Surgery, Ospedale Civile di Baggiovara, Azienda Ospedaliero-Universitaria di Modena, University of Modena and Reggio Emilia, Modena.[i]

Bard (Tempe, AZ) paid to IRCCS San Raffaele Hospital a research grant for the study (NCT04598802).

Author conflict of interest: L.B. is a consultant and proctor for Cook Medical (Cook Medical Inc, Brisbane, Australia). G.I. is a consultant for Artivion (Artivion, Kennesaw, GA).

Presented at the Thirty-sixth Annual European Society for Vascular Surgery Annual meeting, Rome, Italy, September 20-23, 2022.

Additional material for this article may be found online at www.jvascsurg.org.

Correspondence: Luca Bertoglio, MD, Division of Vascular Surgery, Vita-Salute San Raffaele University, IRCCS San Raffaele Scientific Institute, Via Olgettina, 60, 20132 Milan, Italy (e-mail: luca.bertoglio@unibs.it).

The editors and reviewers of this article have no relevant financial relationships to disclose per the JVS policy that requires reviewers to decline review of any manuscript for which they may have a conflict of interest.

0741-5214

https://doi.org/10.1016/j.jvs.2023.02.007

Thoracoabdominal and aortoiliac aneurysm endovascular treatment using branched endografts combined with covered stents is routine worldwide. Recent studies reported encouraging perioperative and midterm results.[1-6] While being standard practices in many aortic centers, the stent graft designs, the procedural steps, and the materials employed are left to the physician's preference and personal experience.[7-11] The covered stents are used to connect the main aortic stent graft with the target vessels; therefore, their performance is critical both to maintain the perfusion of critical aortic side branches and to successfully exclude the aneurysmal pathology over time.

Balloon- and self-expandable covered stent have been successfully used during multibranched endovascular repair (BEVAR) and combined with IBD[8,12-14]; however, their use in this domain is always off-label, and outside of their instructions for use (IFU). For example, the two off-the-shelf currently commercially available BEVAR devices[15,16] recommend in their IFU to employ a self-expandable covered stent mated with their devices, but surprisingly, none of the commercially available covered stents is certified for this specific use or mentioned in their IFU. For this reason, different investigational studies have been proposed to evaluate the covered stent performance in this specific domain to subsequently update the IFU or fulfil the regulatory body's requirements.

This article aims to report the results of a physician-initiated, multicenter registry designed to investigate the short and midterm performance of a self-expanding covered stent (Covera Plus, Bard Tempe, AZ) combined with branched endografts during BEVAR and IBD procedures.

METHODS

Registry design and participating centers. The COvera in BRAnch (COBRA) registry is a physician-initiated, multicenter, ambispective, observational registry (ClinicalTrials.gov Identifier: NCT04598802) enrolling patients treated with BEVAR or IBD procedures using the Bard Covera Plus self-expandable covered stent that was designed to evaluate the short-term and midterm outcomes of the covered stent mated with patient-specific and off-the-shelf branched stent grafts. The study protocol, an electronic case report form, and the patient's consent form were approved by the institutional Ethics Committee of the coordinating center in October 2020 (148/int/2020) and complied with the Declaration of Helsinki. Each participating center (Supplementary Table I, online only) had institutional review board approval and all patients consented to chart reviews. All centers consented to a written data sharing agreement and clinical data were recorded in a de-identified electronic database for subsequent analysis.

ARTICLE HIGHLIGHTS

- **Type of Research:** Multicenter national registry (COBRA Registry — N CT04598802)
- **Key Findings:** There were 708 branches mated with the Bard Covera Plus covered stent with a perioperative technical bridging success of 98% and 1-, 2-, and 3-year patency rates of 99% (581/587), 99% (404/411), and 97% (272/279), respectively.
- **Take Home Message:** This new self-expanding covered stent mated with branched endografts proved to be safe and feasible with high technical success and patency rates.

Registry inclusion and exclusion criteria. The registry included all consecutive patients treated electively or urgently with a BEVAR or IBD procedure during the study period (January 2018 to June 2022), in whom at least one Covera Plus covered stent was implanted. All aortic pathologies were considered for repair according to contemporary guidelines.[17] Both patient-specific and off-the-shelf branched endografts from different manufacturers were allowed. Exclusion criteria were patients younger than 18 years of age, pregnant or lactating, with active systemic or cutaneous infection or inflammation, with bleeding diathesis or coagulopathy, or not willing to participate in the data collection.

Definitions, reporting standards, and end points. Primary end points were technical success, branch instability, primary clinical success, and freedom from aortic- and branch-related reintervention within 30 days and at follow-up performed according to the site's custom clinical practice. Secondary end points were the role of preoperative patient risk factors and anatomical characteristics of treated aortic side branches on branch-related outcomes. Preoperative characteristics, comorbidities, and outcomes were graded according to the reporting standards for thoracic, abdominal, and fenestrated/branched endovascular repair issued by the Society for Vascular Surgery and the American Association for Vascular Surgery grading system.[18] Briefly, technical success was defined as the successful bridging stent graft deployment of all vessels, with aneurysm exclusion, without any signs of type I or type III endoleak, and with no evidence of stenosis or occlusion and mating stent dislocation or kinking at intraoperative completion angiography. Clinical success was defined as technical success in the absence of disabling permanent clinical sequelae and complications. Branch instability was defined as any branch-related complications and/or required reinterventions.[19] Branch-related complications were considered type I or III endoleaks, stenosis or occlusion, stent kinking or fracture, migration or

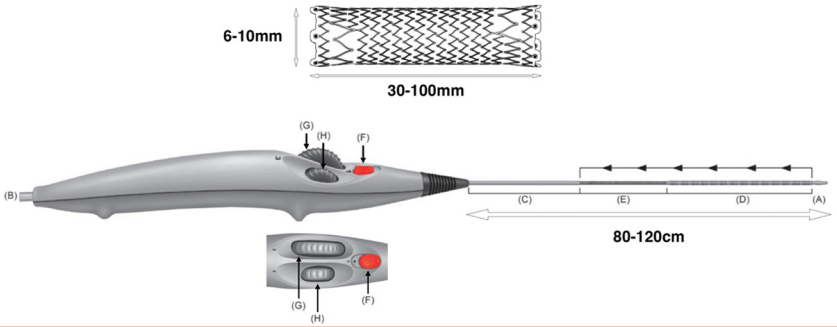

Fig 1. (Top) Covered stent. The Covera Plus Vascular is a highly flexible, self-expanding covered stent made of expanded polytetrafluoroethylene encapsulating a nitinol (nickel-titanium) stent framework, with a carbon impregnated inner lumen (blood contact surface). The Covera Plus Vascular Covered Stent is available in diameters ranging from 6 to 10 mm and lengths ranging from 30 to 100 mm. Highly radiopaque Tantalum markers at the covered stent ends contribute to placement control and accuracy. The proximal and distal ends of the stent are a bit flared to provide better apposition and accuracy during deployment. **(Bottom)** Delivery system. The guidewire lumen is situated inside the inner catheter, which carries an atraumatic tip **(A)** at the proximal end of the system and enters a female Luer connection **(B)** at the distal end of the handle. A proximal white stability sheath **(C)** is connected to the distal end of the handle and remains stationary throughout the deployment process. The distal catheter portion (30 cm in length) is made of two segments: the transparent covered stent delivery sheath **(D)**, in which the compressed covered stent resides; and a darker brown, smaller diameter extension catheter **(E)**. At the time of deployment, the entire distal catheter retracts toward the handle while the dark catheter segment is drawn inside the white stability sheath until the covered stent is fully deployed. The rotation of the large wheel **(G)** on the handle starts the retraction movement of the distal catheter and the deployment of the covered stent. The large deployment wheel allows initiation of the stent deployment and a slower deployment rate whereas the small deployment wheel **(H)** may be used for faster deployment. The Covera Plus Vascular Covered Stent device is an over-the-wire delivery system compatible with 0.035" (0.89 mm) guidewires and 8F to 9F introducer sheaths depending on the stent diameter. The delivery system working lengths are 80 cm and 120 cm.

dislocation, and rupture. Branch-related reinterventions were defined as unprogrammed secondary interventions required to treat branch-related complications. Primary patency was the maintenance of target artery patency after covered stent deployment and secondary patency was the maintenance of patency after reintervention for stenosis/occlusion and implied primary patency failure. Branch stenosis or occlusion was defined as a computed tomography angiography (CTA) lumen diameter reduction of more than 50% compared wit the index procedure and duplex finding for renal arteries (peak systolic velocity of >2.5 m/s).[20]

Device description and covered stent sizing. The Covera Plus Vascular is a self-expanding covered stent comprised of expanded polytetrafluoroethylene encapsulating a nitinol (nickel-titanium) stent framework (Fig 1). The inner lumen of the covered stent (blood contact surface) is carbon impregnated. The Covera Plus Vascular covered stent is available in a variety of diameters (from 6 to 10 mm) and lengths (from 30 to 100 mm). The preoperative CTA scans were analyzed to plan the procedural strategy and decide the graft components based on the patient's anatomy and according to each center's protocol. The anatomical CTA measurements of target vessels were entered in a dedicated section of the electronic case report form. The bridging stent was sized according to the diameter of the target vessel and the length from the branch to within the target vessel to obtain a minimum 15-mm distal landing zone.

Data analyses. Continuous variables are expressed as median, first quartile and third quartile (Q1-Q3) for non-normal distribution and as mean and standard deviation for a normal distribution, and differences between groups are tested with the Mann-Whitney test or the two-sided *t* test, respectively. Categorical variables are expressed as counts and percentages and the χ^2 or Fischer exact test is used for comparison analysis. Survival or patency was compared using the Kaplan-Meier analysis and the log-rank test. A *P* value of less than .05 was used to determine statistical significance. The primary analysis is not adjusted for covariates. A logistic regression model using stepwise selection will be used, if necessary, to identify predictors of the different end points. Data will be entered into the model if they present a univariate *P* value of less than .05. In the multivariable analyses, clinical factors or potential confounding variables will be expressed as odds ratios with a 95% confidence interval. Wizard Statistics (Version 1.9.38, EvanMiller.org) and R-Studio (R Version 4.0.0, RStudio, Inc, Boston, MA) software for MacOS were used.

Table I. Demographics and aortic pathology description of the entire cohort (n = 228)

Characteristics	Values
Males	172 (75)
Connective tissue disease	8 (4)
Suspected	2 (25)
Confirmed	6 (75)
Age, years	76 (70-80)
BMI, kg/m^2	25.4 (23.4-28.7)
≥25	113 (49)
≥30	39 (32)
Creatinine, mg/dL	1.0 (0.9-1.5)
Hypertension	211 (92)
Controlled with one drug	86 (41)
Controlled with 2 drugs	79 (37)
Requires >2 drugs	45 (21)
Smoking	
Active	79 (34)
Smoked in the last 10 years	97 (42)
Never smoked	50 (22)
Diabetes	29 (13)
Adult onset, controlled with diet or oral agent	21 (72)
Adult onset, insulin controlled	7 (23)
Juvenile onset	1 (3)
Hyperlipidemia	160 (70)
Mild elevation, readily controlled by diet	22 (14)
Requiring drugs to control	125 (78)
Severe elevation to require dietary and drug control	13 (8)
Neurological disease	45 (20)
Asymptomatic but with disease evidence	25 (57)
Transient or temporary stroke	14 (31)
Complete stroke with permanent deficit or acute stroke	6 (13)
Cardiac disease	103 (45)
Asymptomatic but with either remote myocardial infarction by history (6 mo), occult myocardial infarction by electrocardiogram, or fixed defect on dipyridamole thallium or similar scan	59 (57)
Stable angina, no angina but significant reversible perfusion defect on dipyridamole thallium scan, ejection fraction 25% to 45%, or history of congestive heart failure that is now well compensated	39 (38)
Unstable angina, symptomatic, poorly compensated, or recurrent congestive heart failure, ejection fraction (25%, myocardial infarction within 6 months)	5 (5)
Pulmonary disease	93 (40)
Asymptomatic or mild dyspnea on exertion, pulmonary function tests 65%-80% of predicted	54 (58)
Between 1 and 3	30 (32)
Vital capacity of <1.85 L, FEV_1 <1.2 L or <35% of predicted, maximal voluntary ventilation <50% of predicted, PCO_2 of >45 mm Hg, supplemental oxygen use medically necessary, or pulmonary hypertension	6 (7)
PTCA/CABG	61 (27)
CABG	10 (16)
PTCA	45 (74)
Both	6 (10)
ASA score	3 (3-3)
3	146 (63)
4	56 (24)
Anticoagulant therapy	37 (16)
Unfractionated or low molecular weight heparin	5 (14)
Vitamin K antagonist	19 (51)
Direct oral anticoagulant (dabigatran, apixaban, etc)	10 (27)
Direct parenteral anticoagulant (bivalirudin, argatroban etc)	0 (0)
Antiplatelet therapy	196 (85)
Single	168 (85)
Double	27 (14)

ASA, American Society of Anesthesiologists; *BMI*, body mass index; *CABG*, coronary artery bypass graft; *FEV*, forced expiratory volume; PCO_2, partial pressure of carbon dioxide; *PTCA*, percutaneous transluminal percutaneous angioplasty.
Values are number (%) or median (first quartile and third quartile).

RESULTS

Two hundred twenty-eight patients (median age, 76 years; range, 70-80 years; 75% male) in 24 centers underwent an endovascular aneurysm procedure with a Bard Covera Plus covered stent combined with a BEVAR. The demographics of the cohort are listed in Table I and the aortic pathology in Table II. A total of 653 target vessels were treated: 147 celiac trunks, 189 superior mesenteric arteries, 308 renal arteries, 3 common hepatic arteries, 2 inferior mesenteric arteries, and 1 splenic artery.

Table II. Aortic pathology description for the entire cohort (n = 228)

Aortic pathology	No. (%) or median (first quartile and third quartile)
Etiology	
Atherosclerotic	213 (93)
Post dissection	17 (7)
Extent	209 (91)
TAAA extent I	18 (9)
TAAA extent II	39 (19)
TAAA extent III	55 (26)
TAAA extent IV	42 (20)
Complex abdominal aneurysm (short neck, juxtarenal, pararenal)	24 (11)
Infrarenal	30 (14)
Iliac involvement	36 (16)
Bilateral	14 (39)
Monolateral	16 (44)
Maximum thoracic aortic diameter, mm	50 (32-63)
Maximum abdominal aortic diameter, mm	56 (45-65)
Maximum right iliac diameter, mm	13 (11-16)
Maximum left iliac diameter, mm	13 (11-16)
Right iliac stenosis occlusion	19 (8)
<25%	5 (26)
25%-50%	5 (26)
>50	2 (11)
Occluded	7 (37)
Left iliac stenosis occlusion	12 (4)
<25%	6 (50)
25%-50%	2 (17)
>50	2 (17)
Occluded	2 (17)

TAAA, thoracoabdominal aortic aneurysm.

The vessel's characteristics and procedural details are shown in Supplementary Table II (online only). The covered stents were mated with an off-the-shelf graft in 593 branches (78%) and a custom-made graft in 145 branches (22%). Five hundred nine branches were from Cook Medical (Bloomington, IN), and 139 from JOTEC (Jotec GmbH, Hechingen, Germany).

Sixty-seven branches (10%) were treated under local anesthesia, with an operative time of 270 minutes (range, 215-330 minutes), a dose area product of 287 Gycm^2 (range, 215-330 Gycm^2), a contrast medium of 200 mL (range, 150-260 mL), and a fluoroscopy time of 80 minutes (range, 56-104 minutes). A final cone beam CTA assessment was obtained in 165 vessels (25%). Six hundred fourteen vessels (94%) were branched from an upper extremity access (brachial or axillary) and 33 (6%) from a femoral access with a steerable sheath. The covered stents were deployed mainly via an 8F (51%), 9F (13%), or 12F (25%) sheath through a cutdown access in 466 vessels (72%). The covered stents were post-dilated in 229 cases (35%) and 287 adjunctive relining stents were deployed in 259 vessels (40%), of which 105 (37%) proximally, 66 (25%) intrastent, and 116 (44%) distally (Table III).

Adjunctive stent placement was more frequent when the covered stent was not landed into the main vessel trunk (42 vs 29%; $P = .016$) of target vessel (because of its shortness, <20 mm), performing a percutaneous access instead of surgical exposure in any access vessel (51% vs 36%; $P < .001$), using a stent with a diameter of 8 mm or greater (44% vs 36%; $P = .032$) and a length of 80 mm or greater (44% vs 35%; $P = .025$), when a post-dilatation was not performed (47% vs 28%; $P < .001$) and when an inner branch configuration was used (58% vs 35%; $P < .001$). No relationship to the approach has been found.

Perioperative technical success was 98%. The reported causes of technical failure were two type I/III endoleaks owing to distal migration of the stent during deployment requiring relining, three vessel occlusions, one stent rupture requiring relining, and four deployment mechanism failure, which required the implantation of either a new Covera Plus or a different bridging stent. In-hospital mortality rate was 3% (8 patients). Follow-up was available for 585 vessels (90%) in 160 patients (70%) at a median of 32 months (range, 21-46 months). Follow-up was performed by CTA for 395 vessels (68%) and by duplex ultrasound for 190 vessels (32%). Branch instability was reported in 1% of branches: two covered stent relinings (celiac trunk and superior mesenteric artery) for a type IC endoleak, and seven stent occlusions (one celiac trunk, one right renal artery, and five left renal arteries). The celiac trunk and two renal artery patients refused treatment. Four of the occluded renal arteries were treated by thromboaspiration, three of which were successfully.

Forty-two patients (20%) died during follow-up, nine (6%) of whom owing to aortic-related causes. Two deaths (1%) were associated with renal branch occlusion followed by acute kidney injury and paraplegia. Primary patency rates at 1, 2, and 3 years were 99% (581/587), 99% (404/411), and 97% (272/279), respectively (Figs 2 and 3). All intraoperative variables associated to the branches (device type, access, and need for adjunctive stent placement) were evaluated to analyze the branch instability which resulted in being more frequent when using a custom-made device (9% in all custom made devices vs 4% in all off-the-shelf devices; $P = .014$) and when an adjunctive stent was placed intrastent (12% vs 2%; $P = .003$), especially when a bare balloon-expandable stent was used (25% vs 3%; $P < .001$). Analyzing the

Table III. Intraprocedural details and outcomes of the entire cohort

	Celiac trunk (n = 147)	SMA (n = 189)	RRA (n = 165)	LRA (n = 143)	OTH (n = 6)	Tot (n = 653)
Deployment problems	3 (2)	3 (2)	2 (1)	5 (4)	0 (0)	13 (2)
Bridging technical success	144 (99)	186 (98)	163 (99)	140 (99)	6 (100)	639 (98)
Endoleak I/III	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Vessel perforation	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Vessel occlusion	0 (0)	0 (0)	1 (100)	0 (0)	0 (0)	1 (1)
Unintended overstenting or collateral	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Other	1 (1)	2 (1)	0 (0)	1 (1)	2 (18)	6 (1)
Adjunct maneuvers	1 (1)	0 (0)	0 (0)	1 (1)	0 (0)	2 (1)
Adjunctive stent placement	54 (37)	70 (37)	69 (42)	62 (44)	4 (44)	259 (40)
Prophylactic	31 (58)	42 (65)	38 (55)	32 (51)	1 (9)	144 (55)
Narrow aortic/iliac lumen	1 (2)	1 (1)	2 (3)	0 (0)	0 (0)	4 (2)
In-stent stenosis	7 (13)	2 (3)	5 (8)	9 (15)	0 (0)	23 (9)
Distal end dissection	1 (2)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Endoleak	0 (0)	1 (1)	1 (2)	0 (0)	0 (0)	2 (1)
Bleeding	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Mismatch stent end – vessel	1 (2)	3 (4)	3 (5)	4 (7)	1 (9)	12 (5)
Acute transition stent – vessel	7 (13)	5 (7)	11 (16)	6 (10)	0 (0)	29 (11)
Other	6 (10)	13 (18)	8 (12)	11 (18)	2 (18)	40 (17)
Proximal	19 (37)	34 (18)	24 (15)	25 (18)	3 (27)	105 (37)
Bare balloon expandable	2 (10)	3 (9)	2 (8)	2 (8)	0 (0)	9 (9)
Bare self-expandable	0 (0)	3 (9)	0 (0)	0 (0)	0 (0)	3 (3)
Covered balloon expandable	17 (90)	23 (68)	18 (75)	20 (80)	2 (67)	79 (75)
Covered self-expandable	0 (0)	5 (15)	4 (17)	3 (12)	1 (33)	13 (12)
Intrastent	17 (31)	16 (9)	18 (11)	114 (9)	1 (9)	66 (25)
Bare balloon expandable	10 (59)	1 (7)	9 (50)	7 (50)	0 (0)	26 (42)
Bare self-expandable	7 (41)	14 (86)	9 (50)	7 (50)	1 (100)	37 (55)
Covered balloon expandable	0 (0)	1 (7)	0 (0)	0 (0)	0 (0)	1 (2)
Covered self-expandable	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Distal	22 (40)	29 (15)	33 (20)	30 (22)	4 (36)	116 (44)
Bare balloon expandable	2 (9)	2 (7)	3 (9)	5 (17)	0 (0)	11 (9)
Bare self-expandable	16 (72)	16 (55)	23 (79)	18 (60)	2 (50)	74 (63)
Covered balloon expandable	4 (19)	7 (25)	4 (12)	3 (10)	0 (0)	18 (15)
Covered self-expandable	0 (0)	4 (14)	3 (9)	4 (13)	2 (50)	13 (11)

HYP, Hypogastric arteries; *LRA*, left renal artery; *OTH*, other; *RRA*, right renal artery; *SMA*, superior mesenteric artery.

outcomes of the Covera covered stents that were not relined, technical success was achieved in 388 branches (98%) and only one required a reintervention (celiac trunk relining for a type IC endoleak). No significant different in patency rates at follow-up were observed (Fig 4).

DISCUSSION

Study results. The quest for an ideal bridging stent supporting different characteristics along its length and guaranteeing a stable anchorage to the main body, while also ensuring excellent flexibility in the intermediate area and avoiding kinks in the most distal portion, has not yielded satisfactory results yet.[12] Balloon-expandable stents have a higher radial stiffness, lower flexibility, and they can crush and deform due to extrinsic compression. In contrast, self-expandable devices are more flexible, allow radial compliance, and are conceived to better accommodate tortuous anatomies.[21] These two types of stents have also been adopted in combination to achieve as close to the ideal characteristics as possible.[22] The Covera plus covered stent combines the positive features of self-expandable stents with lengths range as well as balloon-expandable covered stents regarding visibility and precise deployment. This finding is further confirmed by the present study results as a 98% technical success rate was achieved. As far as stent graft patency is concerned, a recent meta-analysis

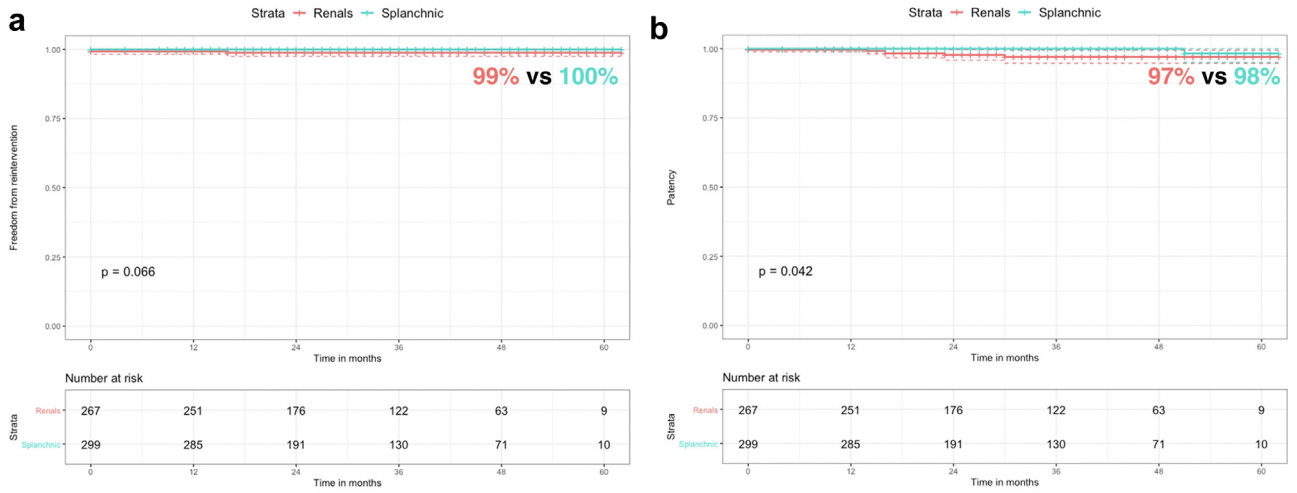

Fig 2. Kaplan-Meier curves comparing **(a)** freedom from reintervention (100 vs 99%; $P = .066$) and **(b)** primary patency for splanchnic and renal arteries (98 vs 97%; $P = .042$) at a mean follow-up of 32 months (range, 21-46 months).

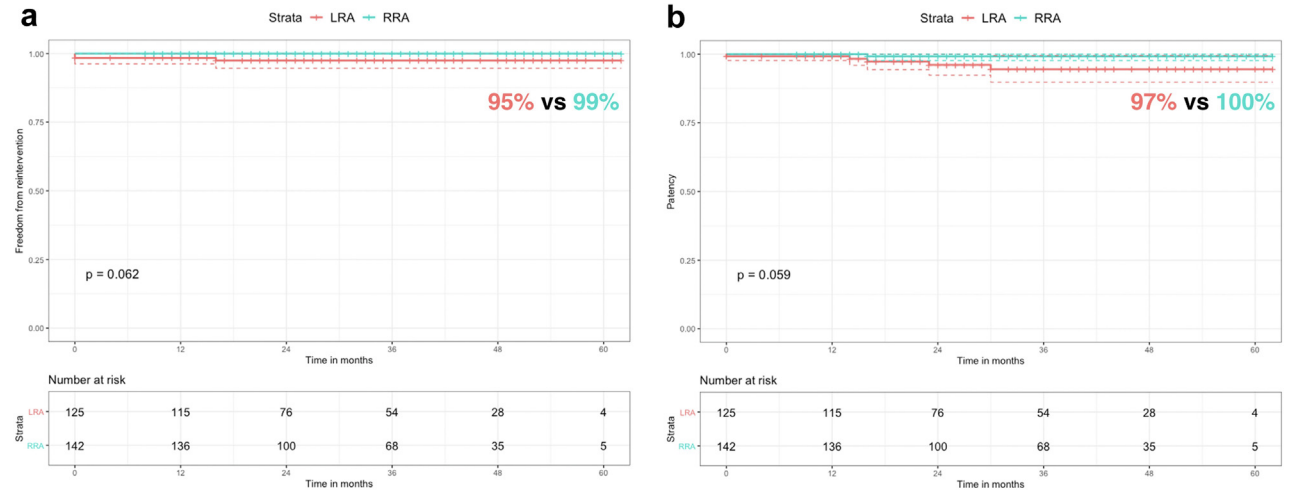

Fig 3. Kaplan-Meier curves comparing **(a)** freedom from reintervention (99 vs 95%; $P = .062$) and **(b)** primary patency (100 vs 97%; $P = .059$) for right renal arteries (*RRA*) and left renal arteries (*LRA*)at a mean follow-up of 32 months (range, 21-46 months).

found comparable primary and secondary rates between self- and balloon-expandable covered stent grafts.[23] In the present study, the patency rates at 1 and 2 years of 98% and 97%, respectively, are in line with previous publications on the same stent graft.[10,11] A lower patency rate at follow-up was recorded when comparing renal vs visceral vessels ($P = .042$) (Figs 2 and 3).

Relining stents. The need for adjunctive stent placement in the present cohort reached 40%, in line with the current literature[8,23]; 50% were placed prophylactically according to the operator's judgement in absence of actual acute angles, dissection, or any other discernable deployment problem. Although conflicting data exists regarding the role of relining,[8,24] in the present series the use of a bare metal balloon-expandable for intrastent relining had a lower patency rate at follow-up. Currently available literature has shown that both self- and balloon-expandable covered stents can be applied safely and effectively during BEVAR, and a recent meta-analysis confirms the primary patency and endoleak rates of the literature for both stent types.[23] However, further investigations are needed on the role of relining and its impact on patency. Self-expandable stent grafts, in previous reports, have all been relined using bare metal stents and provided a high patency rate.[25] The continuous inner forces of a self-expanding bare metal stent in any bridging stent may increase the total force to the vessel wall and, therefore, increase patency. However, intrastent relining may decrease the luminal diameter.

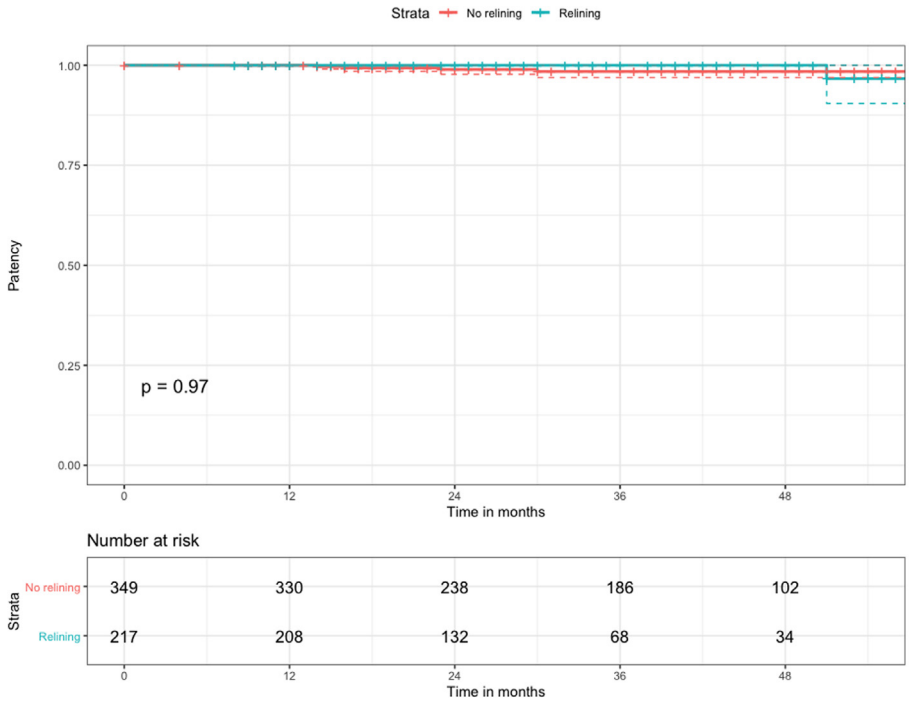

Fig 4. Kaplan-Meier curves comparing the patency rates for relined vs nonrelined covered stent ($P = .097$).

Further investigations into a diameter and angulation threshold for relining to achieve the optimal benefit could clarify the questions arising regarding its beneficial role.

Transfemoral with steerable sheath. Although the use of a complete transfemoral approach using steerable sheaths is gaining more and more attention in the endovascular field owing to its lower stroke and embolization rates, it makes device selection even more significant.[26-29] In the present cohort, all four device failures, as well as two distal stent migrations, happened in branches bridged through transfemoral access with steerable sheaths. It is possible that the acute curvature of the steerable sheath through which the stent graft was advanced interfered with the delivery mechanism, making it undeployable with the wheels owing to the excessive friction. A lower profile (6F) delivery system is expected to be released on the market and new tests would be necessary to judge the covered stent deliverability through transfemoral access; in the meantime, delivery via a transfemoral approach is not recommended according to the authors' experience with this covered stent. As the transfemoral approach gains more traction, further studies on the transfemoral delivery of covered stents through a steerable sheath may shed some light on which ones should be used owing to low complication rates.

Study limitations. The ambispective, nonrandomized design is a limitation of the present study. Heterogeneous technical experiences and approaches were possible confounders. The procedures were performed by trained endovascular operators on complex endovascular procedures, but a learning curve should be considered when testing a new device. Furthermore, the absence of long-term follow-up may have an impact on the present analysis, and while the images and data were analyzed by experienced vascular surgeons, the absence of core laboratory validation may present a limitation.

CONCLUSIONS

The new self-expanding covered Bard Covera Plus stent mated with branched endografts proved to be safe and feasible with high technical procedural success rates. Short-term and midterm follow-up observed low rates of branch instability. Larger follow-up data are needed and comparison with other commercially available covered stents is warranted. Covera Plus stent graft should be used cautiously during a TFA, avoiding acute angles during its placement to avoid deployment issues.

AUTHOR CONTRIBUTIONS

Conception and design: LB, AG, RS
Analysis and interpretation: LB, AG
Data collection: AG, GV, RP, AM, SB, GI, RB, FB, RS
Writing the article: LB, AG
Critical revision of the article: LB, AG, GV, RP, AM, SB, GI, RB, FB, RS
Final approval of the article: LB, AG, GV, RP, AM, SB, GI, RB, FB, RS

Statistical analysis: LB, AG
Obtained funding: Not applicable
Overall responsibility: LB

REFERENCES

1. Mirza AK, Tenorio ER, Kärkkäinen JM, Hofer J, Macedo T, Cha S, et al. Learning curve of fenestrated and branched endovascular aortic repair for pararenal and thoracoabdominal aneurysms. J Vasc Surg 2020;72:423-34.e1.
2. Tenorio ER, Oderich GS, Farber MA, Schneider DB, Timaran CH, Schanzer A, et al. Outcomes of endovascular repair of chronic post-dissection compared with degenerative thoracoabdominal aortic aneurysms using fenestrated-branched stent grafts. J Vasc Surg [Internet] 2020;72:822-36.e9.
3. Oikonomou K, Kopp R, Katsargyris A, Pfister K, Verhoeven EL, Kasprzak P. Outcomes of fenestrated/branched endografting in post-dissection thoracoabdominal aortic aneurysms. Eur J Vasc Endovasc Surg 2014;48:641-8.
4. Verzini F, Parlani G, Varetto G, Gibello L, Boero M, Torsello GF, et al. Late outcomes of different hypogastric stent grafts in aortoiliac endografting with iliac branch device: results from the pELVIS Registry. J Vasc Surg 2020;72:549-55.e1.
5. Zhang J, Brier C, Parodi FE, Kuramochi Y, Lyden SP, Eagleton MJ. Incidence and management of iliac artery aneurysms associated with endovascular treatment of juxtarenal and thoracoabdominal aortic aneurysms. J Vasc Surg 2020;72:1360-6.
6. Giosdekos A, Antonopoulos CN, Sfyroeras GS, Moulakakis KG, Tsilimparis N, Kakisis JD, et al. The use of iliac branch devices for preservation of flow in internal iliac artery during endovascular aortic aneurysm repair. J Vasc Surg 2020;71:2133-44.
7. Motta F, Parodi FE, Knowles M, Crowner JR, Pascarella L, McGinigle KL, et al. Performance of Viabahn balloon-expandable stent compared with self-expandable covered stents for branched endovascular aortic repair. J Vasc Surg 2020;73:410-6.e2.
8. Tenorio ER, Kärkkäinen JM, Mendes BC, DeMartino RR, Macedo TA, Diderrich A, et al. Outcomes of directional branches using self-expandable or balloon-expandable stent grafts during endovascular repair of thoracoabdominal aortic aneurysms. J Vasc Surg 2020;71:1489-502.e6.
9. Bertoglio L, Loschi D, Cambiaghi T, Mascia D, Kahlberg A, Melissano G, et al. Preliminary outcomes of the LifeStream balloon-expandable covered stent in fenestrated and branched thoracoabdominal endovascular repairs. J Endovasc Ther 2018;25:230-6.
10. Gennai S, Antonello M, Leone N, Migliari M, Andreoli F, Dall'Antonia A, et al. Early experience with the Covera stent graft as a bridging stent in branched thoraco-abdominal endovascular aneurysm repairs. J Vasc Interv Radiol 2019;30:1949-55.
11. Caradu C, Dubourg AP, Colacchio EC, Midy D, Bérard X, Ducasse E. Endovascular treatment of complex aneurysms with the use of covera stent grafts. J Vasc Interv Radiol 2019;30:1942-8.e1.
12. Mendes BC, Oderich GS. Selection of optimal bridging stents for fenestrations and branches. In: Endovascular aortic repair. Cham: Springer International Publishing; 2017. p. 359-74.
13. Kärkkäinen JM, Tenorio ER, Jain A, Mendes BC, Macedo TA, Pather K, et al. Outcomes of target vessel endoleaks after fenestrated-branched endovascular aortic repair. J Vasc Surg 2020;72:445-55.
14. Lima GB, Tenorio ER, Marcondes GB, Khasawneh MA, Mendes BC, DeMartino RR, et al. Outcomes of balloon-expandable versus self-expandable stent graft for endovascular repair of iliac aneurysms using iliac branch endoprosthesis. J Vasc Surg 2022;75:1616-23.e2.
15. Grandi A, Carta N, Cambiaghi T, Bilman V, Melissano G, Chiesa R, et al. Sex-related anatomical feasibility differences in endovascular repair of thoracoabdominal aortic aneurysms with a multibranched stent-graft. J Endovasc Ther 2021;28:283-94.
16. Bilman V, Cambiaghi T, Grandi A, Carta N, Melissano G, Chiesa R, et al. Anatomical feasibility of a new off-the-shelf inner branch stent graft (E-nside) for endovascular treatment of thoraco-abdominal aneurysms. Eur J Cardio-thoracic Surg 2020;58:1296-303.
17. Writing Committee, Riambau V, Böckler D, Brunkwall J, Cao P, Chiesa R, et al. Editor's choice — management of descending thoracic aorta diseases: clinical practice guidelines of the European Society for Vascular Surgery (ESVS). Eur J Vasc Endovasc Surg 2017;53:4-52.
18. Oderich GS, Forbes TL, Chaer R, Davies MG, Lindsay TF, Mastracci T, et al. Reporting standards for endovascular aortic repair of aneurysms involving the renal-mesenteric arteries. J Vasc Surg 2021;73:4S-52S.
19. Mastracci TM, Greenberg RK, Eagleton MJ, Hernandez AV. Durability of branches in branched and fenestrated endografts. J Vasc Surg 2013;57:926-33.
20. Sugimoto M, Panuccio G, Bisdas T, Berekoven B, Torsello G, Austermann M. Tortuosity is the significant predictive factor for renal branch occlusion after branched endovascular aortic aneurysm repair. Eur J Vasc Endovasc Surg 2016;51:350-7.
21. Duerig TW, Wholey M. A comparison of balloon- and self-expanding stents. Minim Invasive Ther Allied Technol 2002;11:173-8.
22. Gallitto E, Faggioli G, Fenelli C, Mascoli C, Pini R, Ancetti S, et al. The combined Use of a distal self-expandable and proximal balloon-expandable stent graft in bridging Hostile renal arteries in thoracoabdominal branched endografting. Ann Vasc Surg 2020;68:326-37.
23. Nana P, Spanos K, Brodis A, Panuccio G, Kouvelos G, Behrendt CA, et al. Meta-analysis of comparative studies between self- and balloon-expandable bridging stent grafts in branched endovascular aneurysm repair. J Endovasc Ther 2022:15266028221083458.
24. Abisi S, Gkoutzios P, Carmichael M, Patel S, Sallam M, Donati T, et al. The Early outcomes of BeGraft Peripheral plus in branched endovascular repair of thoracoabdominal aneurysms. J Endovasc Ther 2021;28:707-15.
25. Fernandez CC, Sobel JD, Gasper WJ, Vartanian SM, Reilly LM, Chuter TAM, et al. Standard off-the-shelf versus custom-made multibranched thoracoabdominal aortic stent grafts. J Vasc Surg 2016;63:1208-15.
26. Gallitto E, Faggioli G, Bertoglio L, Pratesi G, Isernia G, Goretti M, et al. Steerable sheath for cannulation and bridging stenting of challenging target visceral vessels in fenestrated and branched endografting. Ann Vasc Surg 2020;67:26-34.
27. Makaloski V, Tsilimparis N, Rohlffs F, Spanos K, Debus ES, Kölbel T. Use of a steerable sheath for retrograde access to antegrade branches in branched stent-graft repair of complex aortic aneurysms. J Endovasc Ther 2018;25:566-70.
28. Kapahnke S, Bürger M, Torsello GF, Omran S, Hinterseher I, Greiner A, et al. Cannulation of visceral vessels using a steerable sheath in fenestrated and branched aortic endografts. Ann Vasc Surg 2022;85:305-13.
29. Grandi A, D'Oria M, Melloni A, Calvagna C, Taglialavoro J, Chiesa R, et al. A scoping review on the approaches for cannulation of reno-visceral target vessels during complex endovascular aortic repair. Eur J Cardiothoracic Surg 2022;62:ezac478.

Submitted Dec 13, 2022; accepted Feb 14, 2023.

Additional material for this article may be found online at www.jvascsurg.org.

COBRA Registry Collaborators

Domenico Angiletta (Division Vascular Surgery, Department of Cardiothoracic Surgery, University of Bari School of Medicine, Bari, Italy); Roberto Chiesa (Division of vascular Surgery, Vita-Salute San Raffaele University, IRCCS San Raffaele Scientific Institute, Milan, Italy); Luca Di Marzo (Vascular and Endovascular Surgery Division, Department of Surgery "Paride Stefanini", Policlinico Umberto I, "Sapienza", University of Rome, Italy); Loris Flora (Division of vascular Surgery, AORN San Giuseppe Moscati, Avellino, Italy); Stefano Gennai (Division of vascular Surgery, Ospedale Civile di Baggiovara, Azienda Ospedaliero-Universitaria di Modena, University of Modena and Reggio Emilia, Modena, Italy); Rocco Giudice (Vascular and Endovascular Surgery Unit, San Giovanni - Addolorata Hospital, Rome, Italy); Massimo Lenti (Unit of Vascular and Endovascular Surgery, Santa Maria della Misericordia Hospital, Perugia, Italy); Nicola Leone (Division of vascular Surgery, Ospedale Civile di Baggiovara, Azienda Ospedaliero-Universitaria di Modena, University of Modena and Reggio Emilia, Modena, Italy); Mario D'Oria and Sandro Lepidi (Division of Vascular and Endovascular Surgery, Cardiovascular Department, University Hospital of Trieste ASUGI, Trieste, Italy); Andrea Melloni (Division of vascular Surgery, Vita-Salute San Raffaele University, IRCCS San Raffaele Scientific Institute, Milan, Italy); Luca Mezzetto (Division Vascular Surgery, Integrated University Hospital of Verona, Verona, Italy); Stefano Michelagnoli (Vascular and Endovascular Surgery, Department of Surgery, USL Toscana Centro, San Giovanni di Dio Hospital, Florence, Italy); Bruno Migliara (Vascular and Endovascular Unit, Department of Surgery, Pederzoli Hospital, Peschiera del Garda, Italy); Domenico Milite (Vascular and Endovascular Surgery Unit, "San Bortolo" Hospital, AULSS8 Berica, Vicenza, Italy); Davide Pacini (Department of Cardiovascular Surgery S. Orsola-Malpighi Hospital Alma Mater Studiorum - University of Bologna, Bologna, Italy); Enzo Palazzo (Division of vascular surgery, Casa del Sollievo della Sofferenza di San Giovanni Rotondo, Foggia, Italy); Alberto Pecchio (Division of Vascular Unit, Cardinal Massaia Hospital, Asti, Italy); Alberto Pegorer Matteo (Division of vascular Surgery, Cardiovascular Department, Poliambulanza Foundation, Brescia, Italy); Paolo Perini (Vascular Surgery, Cardio-Thoracic and Vascular Department, University Hospital of Parma, Parma, Italy); Michele Piazza (Vascular and Endovascular Surgery Unit, Department of Cardiac, Thoracic, Vascular Sciences and Public Health, University of Padua, Padua, Italy); Giovanni Pratesi (Vascular and Endovascular Surgery Unit, Ospedale Policlinico San Martino - IRCCS, Genoa, Department of Surgical Sciences and Integrated Diagnostic (DISC); University of Genoa, Genoa, Italy); Sonia Ronchey (Department of Vascular Surgery, San Filippo Neri Hospital, Rome, Italy); Nicola Spadoni (Department of Vascular Surgery, Santa Chiara Hospital, Trento, Italy); Nicola Tusini (Division of vascular Surgery, AO Reggio Emilia, Arcispedale S. Maria Nuova, Reggio Emilia, Italy); Fabio Verzini (Unit of Vascular Surgery, Department of Surgical Sciences, University of Turin, Turin, Italy).

Supplementary Table I (online only). Participating centers and number of cases/branches collected

Center	No. of patients	No. of branches
Università degli studi di Modena - Struttura Complessa di Chirurgia Vascolare	42	131
IRCCS Ospedale San Raffaele - Divisione di Chirurgia Vascolare	44	102
Azienda Ospedaliera Universitaria Integrata di Verona - Polo Chirurgico "Pietro Confortini"	16	72
Università di Bari - Divisione di Chirurgia Vascolare ed Endovascolare	23	72
Università di Padova - Divisione di Chirurgia Vascolare	23	62
Fondazione Poliambulanza - Divisione di Chirurgia Vascolare, Dipartimento di Chirurgia Cardiovascolare	11	27
AULSS8 Berica - U.O.C. di Chirurgia Vascolare	7	26
Università di Bologna - Ospedale Sant'Orsola - Radiologia Interventistica e Cardiochirurgia	7	24
Ospedale Giuseppe Moscati - U.O. Chirurgia Vascolare	9	23
Ospedali di Trento e Rovereto - Chirurgia Vascolare ed Endovascolare Multizonale	8	21
Azienda Ospedaliera di Perugia - Chirurgia Vascolare	9	15
AOU Città della Salute e della Scienza, Ospedale Molinette - Struttura Complessa di Chirurgia Vascolare	4	11
Università La Sapienza - UOC di Fisiopatologia Chirurgica e delle Vasculopatie	4	11
Arcispedale Santa Maria Nuova - Chirurgia Vascolare	4	9
Azienda Sanitaria Universitaria Giuliano Isontina - Unità Clinica Operativa di Chirurgia Vascolare	3	8
Ospedale Policlinico San Martino - Chirurgia Vascolare	4	8
Ospedale San Filippo Neri - Chirurgia Vascolare	3	8
Ospedale P. Pederzoli - Chirurgia Vascolare ed Endovascolare	2	7
Ospedale San Giovanni di Dio - Chirurgia Vascolare	1	4
Policlinico Universitario "G. Martino" - Chirurgia Vascolare	1	3
Azienda Ospedaliera "S. Giovanni - Addolorata" - Chirurgia Vascolare	2	3
Università di Parma - Unità operativa Complessa di Chirurgia Vascolare	2	2
Casa del Sollievo e della Sofferenza — Unità operativa complessa di Chirurgia Vascolare	1	1
Ospedale Cardinal Massaia di Asti - Chirurgia Vascolare	0	0
Total	228	650

Supplementary Table II (online only). Vessel characteristics for the entire cohort

	Celiac trunk (n = 147)	SMA (n = 189)	RRA (n = 165)	LRA (n = 143)	OTH (n = 6)	Tot (n = 650)
Vessel stenosis	30 (20)	3 (2)	14 (9)	16 (12)	1 (11)	46 (5)
<25%	4 (13)	2 (67)	5 (36)	3 (19)	0 (0)	14 (30)
25%-50%	15 (50)	1 (1)	5 (36)	8 (50)	1 (100)	30 (64)
50%-75%	9 (30)	0 (0)	2 (14)	2 (13)	0 (0)	13 (28)
>75%	2 (7)	0 (0)	2 (14)	3 (19)	0 (0)	7 (10)
Median arcuate ligament syndrome	32 (22)	0 (0)	0 (0)	0 (0)	0 (0)	32 (5)
Aortic lumen at vessel origin, mm	38 (31-50)	40 (30-50)	38 (30-48)	39 (30-47)	31 (27-50)	38 (30-48)
Vessel landing zone						
Main trunk	144 (98)	189 (100)	163 (99)	137 (96)	6 (100)	639 (98)
Vessel bifurcation	3 (2)	0 (0)	2 (1)	6 (4)	0 (0)	11 (4)
Vessel diameter, mm	8 (7-9)	8 (7-9)	6 (5-6)	6 (5-7)	5 (5-6)	7 (6-8)
Vessel length, mm	30 (25-36)	37 (30-47)	37 (30-48)	32 (25-40)	49 (40-50)	35 (28-45)
Vessel course						
Downward	108 (74)	165 (88)	83 (51)	67 (47)	4 (66)	427 (65)
<15°	55 (51)	77 (47)	48 (59)	44 (67)	4 (100)	228 (53)
15°-30°	6 (6)	14 (9)	13 (16)	5 (7)	0 (0)	37 (9)
>30°	47 (43)	74 (44)	22 (25)	18 (26)	0 (0)	160 (25)
Horizontal	36 (25)	22 (11)	73 (44)	70 (49)	2 (33)	203 (32)
Upward	3 (1)	2 (1)	9 (5)	6 (4)	0 (0)	20 (3)
<15°	3 (100)	2 (100)	8 (88)	3 (50)	0 (0)	16 (80)
15°-30°	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
>30°	0 (0)	0 (0)	1 (12)	3 (50)	0 (0)	4 (20)
Ostium orientation, degrees	30 (15-345)	38 (0-360)	285 (270-300)	90 (75-98)	45 (30-323)	108 (30-300)
Stent						
Diameter, mm	9 (8-10)	9 (8-9)	7 (6-7)	7 (6-7)	8 (7-10)	8 (7-9)
Length, mm	80 (60-80)	80 (60-80)	80 (60-80)	80 (60-80)	60 (60-60)	80 (60-80)
Post dilatation	48 (33)	74 (40)	57 (35)	46 (33)	6 (55)	257 (37)
Branch						
Diameter, mm	8 (8-8)	8 (8-8)	6 (6-6)	6 (6-6)	8 (8-8)	8 (6-8)
Length, mm	21 (18-21)	18 (18-18)	18 (18-18)	18 (18-18)	18 (17-21)	18 (18-18)

HYP, hypogastric arteries; *LRA*, left renal artery; *OTH*, other; *RRA*, right renal artery; *SMA*, superior mesenteric artery.
Values are number (%) or median (first quartile and third quartile).