Effect of branch length and tortuosity on the outcomes of branched endovascular repair of thoracoabdominal aneurysms using self-expandable bridging stent-graft

Michele Piazza, MD, Francesco Squizzato, MD, Andrea Xodo, MD, Alberto Gubert, MD, Franco Grego, MD, *and* Michele Antonello, PhD, *Padua, Italy*

ABSTRACT

Objective: We investigated the effect of the length and tortuosity of directional branches on the mid-term outcomes of branched endovascular aneurysm repair (BEVAR) for thoracoabdominal aortic aneurysms (TAAA).

Methods: We retrospectively reviewed single-center data of consecutive patients who had undergone BEVAR for TAAA from 2015 to 2019. Three-dimensional computed tomography angiogram reconstructions (Aquarius iNtuition software; TeraRecon, Durham, NC) of the first postoperative imaging studies were used to measure the branch total length (TL), branch vertical length (VL), and branch tortuosity index (TI). The branch TL was measured as the centerline distance between the branch proximal radiopaque marker and the distal edge of the bridging stent. The VL was measured as the centerline distance between the branch distal radiopaque marker and the origin of the target artery. The TI was measured in accordance with the Society for Vascular Surgery reporting standard. The primary endpoint was freedom from branch instability, defined as any branch-related death, occlusion, or rupture and any reintervention for stenosis, endoleak, or disconnection. Cox proportional hazards were used to identify predictors of branch instability. A penalized spline function was used to identify the relationship between branch instability and the branch TL and VL.

Results: Postimplantation analysis was conducted on 32 TAAAs (extent I-III, n = 18 [56%]; extent IV, n = 14 [44%]), with 123 arteries included through a directional branch. A covered self-expanding bridging stent was used in all cases. Intraoperative reinforcement with an additional bare metal stent was performed in 85 cases (69%). The overall freedom from branch instability at 3 years was 88% (95% confidence interval [CI], 81%-94%). Five cases of occlusion and eight cases of branch-related endoleak occurred. A concomitant endoleak and severe stenosis requiring intervention developed in three cases. The Cox model with splines showed that the minimal risk of branch instability was achieved with a branch TL of 60 to 100 mm ($P = .002$) and a branch VL of 25 to 50 mm ($P = .038$). A TI of >1.15 was a predictor of branch complications (hazard ratio [HR], 8.6; 95% CI, 2.4-31.4; $P < .001$). After multivariate analysis, aneurysm diameter (HR, 1.08; 95% CI, 0.03-1.15; $P = .003$), TI >1.15 (HR, 6.81; 95% CI, 2.17-27.33; $P < .001$), and TL <60 or >100 mm ($P = .002$) were significantly associated with branch instability.

Conclusion: The branch length and TI seemed to play an important role in BEVAR outcomes. The lowest branch instability rates were obtained with a branch TL of 60 to 100 mm, and this should be considered during planning and implantation. A branch TI >1.15 might require a more strict monitoring to prevent mid- and long-term complications. (J Vasc Surg 2021;■:1-9.)

Keywords: Bridging stent; Branched endovascular aneurysm repair; Self-expandable stent graft; Thoracoabdominal aneurysm

The presence of a thoracoabdominal aortic aneurysm (TAAA) represents one of the most challenging pathologic entities in vascular surgery. The endovascular approach to the management of aneurysmal disease has progressively achieved more acceptance over open surgical repair owing to its less invasive approach and lower morbidity and mortality rates.[1,2] In the past two decades, several reports have described the efficacy of dedicated fenestrated or branched devices for endovascular aortic repair.[3,4] The technological improvements in both the main aortic endograft and the bridging stents have made it possible to achieve excellent results, not only during short-term, but also during mid-term, follow-up.

In particular, branched endovascular aortic repair (BEVAR) has been used more often for TAAAs with a large aneurysmal sac. These devices are based on a directional branch (usually caudally directed) attached to the main aortic endograft and opening into the aneurysm sac lumen. A bridging covered stent is then required to

From the Division of Vascular and Endovascular Surgery, Department of Cardiac, Thoracic and Vascular Sciences, Padua University.

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Correspondence: Michele Piazza, MD, Division of Vascular and Endovascular Surgery, Department of Cardiac, Thoracic and Vascular Sciences, Padua University, Via Giustiniani, 2, Padua 35128, Italy (e-mail: mikpia79@hotmail.com).

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seal the connection between each directional cuff to the target visceral and renal arteries to obtain sac exclusion. Thus, the bridging stent often has a long course and can be associated with different grades of tortuosity.

To guarantee effective sealing and durability of the "branch system," the bridging stent must ideally manage a combination of different characteristics, because it requires the presence of sufficient radial force to maintain the seal at the branch origin, adequate flexibility during its course to reduce kinking, and a smooth transition at its distal edge to the target vessel to avoid intimal hyperplasia. Several studies have reported that some preoperative anatomic characteristics might influence the outcomes, especially for renal vessels; artery orientation,[5] implantation angles,[6] and tortuosity[7] seem to represent the most challenging situations. In addition, renal arteries often have a smaller caliber and greater mobility. Thus, all these aspects together might be the cause of the greater reintervention rate for renal vessels compared with visceral vessels.[7]

To the best of our knowledge, only a single previous study has evaluated the role of branch tortuosity on renal vessels.[7] However, no previous studies have conducted a specific postimplantation analysis on the effects of branch tortuosity or demonstrated any specific role of branch length for renal or visceral vessels on the early and mid-term outcomes after BEVAR. Furthermore, in the field of BEVAR, the use of self-expanding stent-grafts (SESGs) and balloon expandable stent-grafts (BESGs), or a combination, has been wide, depending on operator preference. Also, many reports have combined the outcomes of patients treated with fenestrated devices and the outcomes of those treated with branched devices. Thus, assessing the strengths and weakness of each specific endovascular approach for BEVAR has remained difficult. The purpose of the present study was to evaluate the early and mid-term outcomes of a uniform cohort of patients with TAAAs treated with BEVAR using SESGs as the bridging stent.

ARTICLE HIGHLIGHTS

- **Type of Research:** A single-center, retrospective study
- **Key Findings:** The total length of the branch, the vertical distance between the branch gate and target vessel, and branch tortuosity play a role in determining mid-term target vessel instability after branched endovascular aneurysm repair for thoracoabdominal aortic aneurysms. In particular, a total branch length of 60 to 100 mm ($P = .002$), a vertical length of 25 to 50 mm ($P = .038$), and a tortuosity index of <1.15 (hazard ratio, 8.6; $P < .001$) were associated with fewer target vessel complications.
- **Take Home Message:** During planning and implantation, branch stability can be maximized with a total branch length of 60 to 100 mm and a vertical length of 25 to 50 mm. A tortuosity index >1.15 might require more careful follow-up.

METHODS

Patient population. A retrospective review of prospectively collected data was performed of consecutive patients who had undergone BEVAR from 2016 to 2019. Only patients with an intact TAAA who had undergone BEVAR with the use of covered SESGs as the main bridging stents were included. Urgent and emergency procedures (n = 2) and patients who had received BESGs as main bridging stents (n = 3 patients; 1 for a celiac artery and 2 for a superior mesenteric artery [SMA]) were excluded from the present analysis. The institutional review board waived the requirements for the present retrospective study.

Data collection and definitions. The demographics, clinical characteristics, cardiovascular risk factors, and operative and postoperative variables were collected. Aneurysm classification was determined by the extent of aneurysmal disease evaluated using computed tomography (CT) angiography (CTA) in accordance with the Crawford classification. The early postoperative period was defined as the first 30 days or during the hospital stay if >30 days. Major adverse events were defined using a composite endpoint and included any-cause mortality, severe acute kidney injury (>50% decrease in estimated glomerular filtration rate), new-onset dialysis, myocardial infarction, respiratory failure requiring prolonged mechanical ventilation or reintubation, paraplegia, stroke, bowel ischemia requiring surgical resection or intensive medical care, and estimated blood loss >1 L. Spinal cord ischemia was classified in accordance with current reporting standards.[8]

The follow-up protocol included clinical examination, laboratory studies, and imaging studies before discharge, at 3, 6, and 12 months postoperatively, and annually thereafter for the first 5 years. The imaging evaluation included CTA or CT without contrast and duplex ultrasonography of the renal mesenteric arteries.

Device design. Both custom-made and off-the shelf devices were included. Patient-specific devices were based on the Cook Zenith (Cook Medical Inc, Brisbane, Australia) or the Jotec (Jotec GmbH, Hechingen, Germany) platform. The Cook t-Branch was used as the off-the-shelf endograft. Additional proximal aortic components or distal components were added if needed, as determined by the thoracic aorta and infrarenal aortoiliac anatomy, respectively. The options for vessel incorporation were large (8 mm) or small (6 mm) directional branches. In general, in our clinical practice, the choice of using branches, instead of fenestrations, varies depending on the aneurysm extent, vessel angulation, and

diameter of the aortic lumen. In general, directional branches were preferred for TAAAs (extent I-IV) if the paravisceral aorta had an inner aortic lumen-free diameter >3 cm in the paravisceral area. No upward-oriented branches were used in the present series. The Cook t-Branch endograft was considered as the first option for cases with aneurysm anatomic suitability, in accordance with the current instructions for use.[9]

Target vessel stenting. Catheterization and stenting of the target vessels were usually performed from a left brachial surgical access. The right brachial access was used as a second option in cases of left side unavailability. No preloaded catheters or guidewires were used. All directional branches were stented using a SESG as the main bridging stent (Viabahn [WL Gore and Associates, Flagstaff, Ariz]; Fluency or Covera [both, CR Bard, Inc, Tempe, Ariz]). The stent was usually deployed to achieve a standard seal length of 20 mm into the target artery. A shorter protrusion was occasionally required because of an early vessel bifurcation, and a longer protrusion was sometimes preferred in cases of vessel tortuosity. The cuff segment was reinforced with a short BESG only if deployment of the SESG did not complete overlap with the cuff proximally. If multiple bridging stents were required, the stents were overlapped for ≥20 mm. An adjunctive self-expandable bare metal stent (BMS) was used in cases of intraoperative evidence of branch or target artery tortuosity after stent-graft implantation. In particular, a short (30-40 mm in length) BMS was used to accommodate to the target vessel curvature in the case of intraoperative findings of a significant kink at the transition between the distal edge of the bridging stent and the native vessel or in case of stent kinking resulting from the target vessel's ostium unfavorable orientation. A single, longer BMS (60-100 mm in length) was used to prevent branch kinking during its entire course (both at the distal edge and for its entire course into the aortic sac aneurysm). The technical assessment of the stented target vessels included determination of the position, integrity, and patency and the presence of endoleak. The assessment was performed using completion digital subtraction angiography and the first postoperative CTA study.

The postoperative medical therapy was standardized for all patients and consisted of dual antiplatelet therapy for 30 days with aspirin and clopidogrel, followed by long-term single antiplatelet therapy with aspirin. If the patient required anticoagulation for other medical reasons, this was usually continued, after weighting the risks and benefits of the medical therapy.

Geometric assessment. All preoperative and postoperative measures were performed using the Aquarius iNtuition software, version 4.4.13 (TeraRecon, Durham, NC). The preoperative anatomic characteristics included aortic paravisceral angulation, target vessel orientation, and target vessel kinking. A previously validated standardized method was used for the measurements using a semiautomatically generated aortic centerline on volume-rendered three-dimensional reconstructions.[10] To measure the "paravisceral aortic angulation," the three-dimensional reconstruction was turned 360° perpendicular to the centerline at the level of the suprarenal aortic flexion point, and the sharpest angle of the centerline was considered the true aortic angle. "Target vessel orientation" was measured as the angle of origin in relation to the aortic centerline.[6] The target vessels were classified as upward oriented if the angle was <60°, downward oriented if the angle was >120°, and straight if the angle was between 60° and 120°.[5] "Target vessel kinking" was defined as any angulation >30° within 20 mm from the origin of the target vessel.

The geometric characteristics of the postimplantation branches were assessed at the first postoperative CTA (before discharge). These included the branch total length (TL), branch vertical length (VL), and branch tortuosity index (TI). The branch centerline was generated, and the branch TL was measured as the distance between the branch proximal radiopaque marker and the distal edge of the bridging stent along the branch centerline. The VL was measured as the distance between the branch cuff distal radiopaque marker and the origin of the target artery along the aortic lumen centerline. The branch TI was defined as the ratio of the centerline length of the bridging stent over the linear distance, measured from the end of the branch cuff to the distal end of the covered bridging stent (Fig 1) on three-dimensional CT reconstructions.[7,11] Also, the target vessel sealing length was measured as the centerline length of the covered stent protruding inside the target artery.

Endpoints. The primary endpoint was freedom from branch instability, defined as any branch-related death, rupture, or occlusion or any reintervention for stenosis, endoleak, or disconnection.[3] The secondary endpoints were primary patency of the target vessels and freedom from related endoleaks. Primary patency was defined as uninterrupted patency from the index procedure until occlusion or any stent reintervention for stenosis.

Statistical analysis. The results are reported as numbers and percentages for categorical variables and as the mean ± standard deviation for continuous variables. Time-dependent outcomes are reported using Kaplan-Meier estimates. Because the event of death could have precluded the occurrence of branch-related complications, a cumulative incidence function was implemented to estimate the incidence of branch instability from the competing risks data.[12] Cause-specific univariate and multivariate Cox proportional hazards models

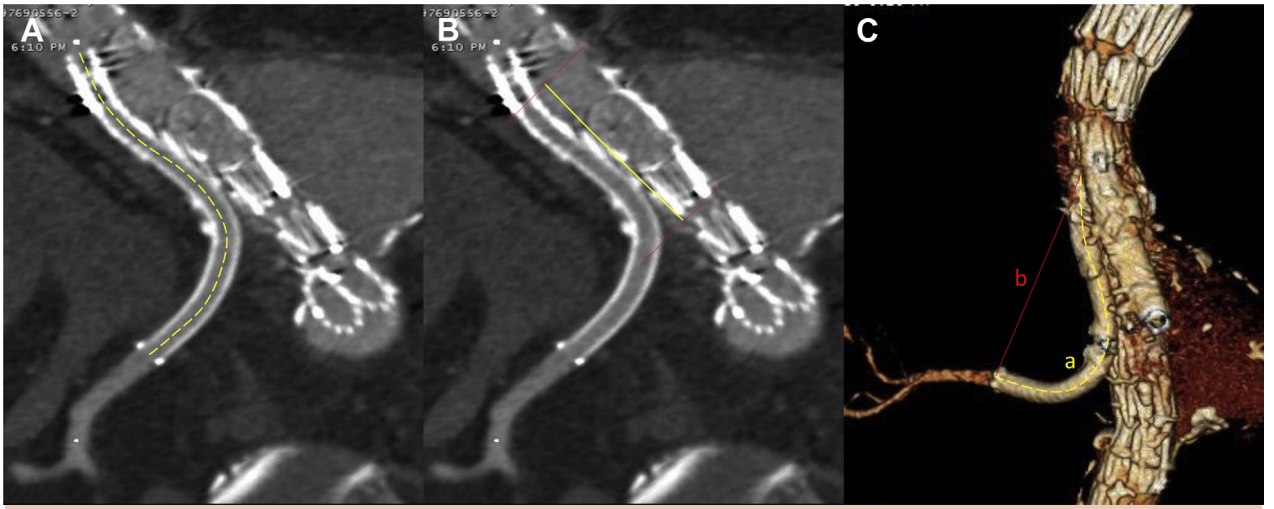

Fig 1. Measurements of the branch total length (TL), vertical length (VL), and tortuosity index (TI). **A,** The TL was measured as the centerline distance (*yellow dashed line*) between the branch proximal radiopaque marker and the distal edge of the bridging. **B,** The VL was measured as the distance between the branch cuff distal radiopaque marker and the origin of the target artery along the aortic lumen centerline (*yellow line*). **C,** The branch TI was measured as the ratio of the centerline length of the bridging stent (*a*) over the linear distance (*b*), measured between the end of the branch cuff and the distal end of the covered bridging stent.

were used to identify the clinical, procedural, and anatomic predictors of target vessel instability. The regression coefficients provided by the cause-specific regression analysis can be interpreted as the relative effect of the corresponding covariate on the relative increase in the rate of occurrence of branch instability in those currently event free.[12] A subgroup analysis was conducted selectively in the subset of renal arteries and celiac and mesenteric arteries. A stepwise selection of covariates was performed, and the most parsimonious multivariable model with inclusion of significant factors and confounders was selected as the final multivariable model. Only a univariate analysis was performed for the subgroup analysis because of the low number of events and the risk of overfitting. Firth's penalized maximum likelihood bias reduction method was applied for cases of complete or quasicomplete data separation. To assess the linearity of the relationship between branch TL, VL, and TI and the presence of branch instability, a penalized spline smooth function was used without prespecified knots. This eventually allowed for the identification of the cutoffs to split the continuous variables into two or more categories, using clinically significant cutoffs to be tested on univariate and multivariate analysis. The unit included in the analysis for branch instability was the single target vessel. Because patient-specific factors can also affect branch-related outcomes, a frailty model was used to incorporate heterogeneity between individuals using a random effects model. In brief, a frailty is an unobserved random proportionality factor that modifies the hazard function of related observations (ie, the target vessels in our case). A P value of $<.05$ was used to determine statistical significance. The R, version 3.5.2, software (R Foundation for Statistical Computing, Vienna, Austria) was used for statistical analysis.

RESULTS

Of the 32 patients, 18 had had extent I to III TAAAs (56%) and 14 had had extent IV TAAAs (44%), with 123 target arteries incorporated through a directional branch. Most patients (81%) were men, and the mean age was 67.6 ± 11.1 years. The patients' demographics and risk factors are presented in Table I. Most patients had an atherosclerotic aneurysm (n = 30; 97%), with two also having chronic dissection (6%). One patient had Marfan disease but had been deemed unfit for open repair. The mean maximum aneurysm diameter was 65.3 ± 11.2 mm. Other anatomic characteristics regarding the diameter and orientation of the target vessels are shown in Table II. Only a single renal artery was incorporated in five cases owing to chronically unilateral occlusion in three or previous nephrectomy in two.

An off-the-shelf stent-graft was used in 15 patients (46%). The main bridging stent was a Viabahn (WL Gore and Associates) in 21 side branches (17%), a Fluency (CR Bard Inc) in 61 (50%), and a Covera (CR Bard Inc) in 41 (33%). The Viabahn and Covera stents were preferred for the renal arteries because of the longer available lengths (P = .117; Table III). A short balloon-expandable stent was used to improve the proximal attachment to the cuff in 30 branches (24%). An adjunctive BMS was used in 85 branches (69%): in 52 (61%) to reinforce the

Table I. Patient demographics and risk factors

Variable	Mean ± SD or No. (%)
Demographics	
Age, years	67.6 ± 11.1
Male sex	26 (81.3)
Risk factors	
Hypertension	29 (90.6)
DM	4 (12.5)
Dyslipidemia	21 (65.6)
CAD	19 (59.4)
COPD	5 (15.6)
CKD	15 (46.8)
PAD	3 (9.4)
Previous laparotomy	10 (31.3)
SVS score	0.97 ± 0.46

CAD, Coronary artery disease; *CKD,* chronic kidney disease; *COPD,* chronic obstructive pulmonary disease; *DM,* diabetes mellitus; *PAD,* peripheral artery disease; *SD,* standard deviation; *SVS,* Society for Vascular Surgery.

bridging stent at its distal edge because of unfavorable orientation of the target vessel and in 18 (21%) to avoid kinking in the bridging stent at the target artery ostium. Finally, in 15 cases (18%), a single 60- to 100-mm-long BMS was used to both reinforce the bridging stent into its course in the aneurysm sac and avoid distal kinking. The overall mean number of stents per target vessel was 2 ± 0.7.

One perioperative death (3%) occurred due to meningitis, likely resulting from the use of a spinal drain. The major adverse event rate was 28%. The specific early complications are listed in Table III.

The postimplantation geometric analysis showed that the mean branch TL was 83.5 ± 21.7 mm, with a mean VL of 45.3 ± 17.8 mm and a TI of 1.13 ± 0.23 (Supplementary Table I, online only). The bridging stent TL was significantly longer for the renal arteries (89.9 ± 20.7 mm) compared with the length for the celiac and mesenteric arteries (77.5 ± 20.9 mm; $P = .001$). Similarly, the VL (50.1 ± 18.4 mm vs 40.8 ± 50.1 mm; $P = .003$) and TI (1.25 ± 0.25 vs 1.08 ± 0.17; $P < .001$) were higher for the renal arteries. A significant linear relationship was found between the branch TL and TI ($\beta = 0.004$; $R^2 = 0.18$; $P < .001$), which was mainly driven by the renal arteries ($\beta = 0.006$; $R^2 = 0.21$; $P < .001$) and not the celiac and mesenteric arteries ($\beta = 0.001$; $R^2 = 0.03$; $P = .145$; Supplementary Fig 1, online only). Comparing the off-the-shelf devices with the patient-specific grafts, the TL (85 ± 20.4 mm vs 81.9 ± 22.9 mm; $P = .430$), VL (47.6 ± 15.1 mm vs 42.7 ± 20.0 mm; $P = .134$), and TI (1.19 ± 0.27 vs 1.14 ± 0.15; $P = .194$) were similar. The similarity was maintained after stratification by artery type—celiac and mesenteric: TL, 79.6 ± 21.2 mm vs 75.5 ± 20.7 mm ($P = .438$); VL, 43.4 ± 14.7 mm vs 38.2 ± 16.9 mm ($P = .197$); and TI, 1.07 ± 0.05 vs 1.11 ± 0.20 ($P = .324$); renal: TL, 90.2 ± 18.4 mm vs 89.7 ± 23.5 mm ($P = .923$); VL, 51.6 ± 14.7 mm vs 48.3 ± 22.2 mm ($P = .498$); and TI, 1.25 ± 0.3 vs 1.22 ± 0.18 ($P = .185$). The mean target vessel sealing length was 22.9 ± 12 mm (renal arteries, 21.8 ± 10.3 mm; celiac and mesenteric arteries, 23.9 ± 15.1 mm; $P = .373$).

The median follow-up was 21 months. After 36 months of follow-up, five occlusions and eight branch-related endoleaks had occurred. Seven of these were type III endoleaks due to incomplete attachment of the branch components. One type IC endoleak had developed owing to insufficient sealing at the level of the target renal artery. A concomitant type III endoleak and severe kink or stenosis requiring intervention was noted in three renal arteries during follow-up. No branch-related deaths or ruptures had occurred. Of the five patients with occlusion, four had had a VL >25 mm, three a TL >100 mm, and four a TI >1.15. Of the eight patients with an endoleak, five had had a VL <25 mm or TL <50 mm. Comparing the geometric characteristics from the last available CTA vs those from the first postoperative CTA for the patients with branch instability during follow-up showed no significant changes in the measured mean VL (33.7 ± 12.9 mm vs 33.5 ± 11.8 mm; $P = .967$), TL (73.6 ± 16.1 mm vs 74.2 ± 17.5 mm; $P = .876$), and TI (1.15 ± 0.10 vs 1.16 ± 0.08; $P = .780$).

The overall freedom from branch instability at 3 years was 87.5% (95% confidence interval [CI], 81%-94%). The overall freedom from branch instability at 3 years was 89.0% (95% CI, 80%-97%) for the celiac and mesenteric arteries and 86.2% (95% CI, 77%-96%) for the renal arteries ($P = .700$; Supplementary Fig 2, online only). The overall primary patency was 97% (95% CI, 94%-100%), and the freedom from branch-related endoleak was 89.6% (95% CI, 84%-96%). The estimated cumulative incidence using the competing risk analysis was 11.5% ± 0.1% for branch instability and 17.1% ± 0.1% for overall mortality.

Cox proportional hazards with a penalized splines function was used to test the relationship between the postoperative geometric measures and branch instability during follow-up. The TL and VL were not significantly associated when considered as a linear function (TL: hazard ratio [HR], 0.99; 95% CI, 0.96-1.02; $P = .456$; VL: HR, 0.99; 95% CI, 0.95-1.02; $P = .383$). However, the association was significant when considered as a nonlinear relationship (TL, $P = .002$ with three degrees of freedom; VL, $P = .038$ with three degrees of freedom). For branch TI, the association was not significant as a nonlinear relationship ($P = .440$ with three degrees of freedom). However, an overall increase in the risk for branch complications (HR >1) was observed for a TI >1.15 (HR, 8.65; 95% CI, 2.37-31.43; $P = .001$; Fig 2). In particular, a TL <60 mm (HR, 6.59; 95% CI, 2.15-20.29; $P < .001$) or >100 mm (HR, 3.19; 95% CI, 1.07-9.51; $P = .037$), a VL <25 mm (HR, 5.32; 95%

Table II. Anatomic data (n = 32 patients; n = 123 target arteries)

Anatomic data	No. (%) or Mean ± SD
Crawford classification	
I	2 (6.3)
II	11 (34.4)
III	5 (15.6)
IV	14 (43.7)
Type of aneurysm	
Atherosclerotic	30 (93.7)
Chronic dissection	2 (6.3)
Previous aortic repair	
Ascending aorta	6 (18.7)
Thoracic aorta	1 (3.1)
Abdominal aorta	8 (25.0)
Aneurysm maximum diameter, mm	65.3 ± 11.2
Aneurysm diameter, mm (SMA level)	4.5 ± 4.1
Paravisceral aortic angulation, °	21 ± 15
Paravisceral aortic angulation >45°	6 (18.7)
Celiac artery	n = 32
Diameter, mm	9.1 ± 1.2
Angulation, °	128.5 ± 31.7
Upward orientation (<60°)	0 (0)
Straight (60°-120°)	12 (37.5)
Downward orientation (>120°)	20 (62.5)
Kinking	6 (18.7)
SMA	n = 32
Diameter, mm	9.0 ± 0.9
Angulation, °	121.4 ± 21.9
Upward orientation (<60°)	0 (0)
Straight (60°-120°)	17 (53.1)
Downward orientation (>120°)	15 (46.8)
Kinking	2 (6.3)
Renal arteries	n = 59
Diameter, mm	6.7 ± 0.9
Angulation, °	91.7 ± 31.8
Upward orientation (<60°)	11 (18.6)
Straight (60°-120°)	33 (55.9)
Downward orientation (>120°)	15 (25.4)
Kinking	14 (23.7)

SD, Standard deviation; *SMA*, superior mesenteric artery.

CI, 1.18-24.05; $P = .030$) or >50 mm (HR, 3.56; 95% CI, 1.04-12.17; $P = .008$; Supplementary Table II, online only), and TI >1.15 (HR, 8.65; 95% CI, 2.37-31.43; $P = .001$) were significantly associated with an increased risk of branch instability at 3 years. The knots of the splines functions, identifying the cutoffs for the TL, VL, and TI, were the same when the renal arteries and celiac trunk–SMA were considered individually. The univariate analysis also identified aneurysm extension (extent IV: HR, 0.12; 95% CI, 0.03-0.57; $P = .007$) and aneurysm maximum diameter (HR, 1.11; 95% CI, 1.05-1.18; $P < .001$) as a predictor of branch instability. Smaller diameter branch vessels (HR, 1.59; 95% CI, 1.14-2.22; $P = .007$) and bridging stents (HR, 1.59; 95% CI, 1.14-2.22; $P = .007$) resulted in a greater risk of branch complications. However, an upward orientation for the target artery (HR, 1.34; 95% CI, 0.41-4.36; $P = .814$), kinking of >30° (HR, 2.13; 95% CI, 0.64-7.01; $P = .213$), and target vessel sealing length (HR, 0.79; 95% CI, 0.22-2.53; $P = .660$) were not significantly associated with the risk of branch complications. The use of an adjunctive BMS (HR, 1.62; 95% CI, 0.36-7.29; $P = .533$) did not significantly affect the development of branch complications. Also, when considering only the subset of target arteries with high tortuosity (TI >1.15), the use of a BMS was not significantly associated with improved outcomes (HR, 0.80; 95% CI, 0.17-3.78; $P = .780$).

The multivariate analysis showed that a branch TL <60 mm or >100 mm ($P = .002$) was a significant predictor of branch instability, after adjustment for the aneurysm maximum diameter (HR, 1.08; 95% CI, 1.03-1.15; $P = .003$), a TI >1.15 (HR, 6.81; 95% CI, 2.17-27.33; $P < .001$; Table IV), and target artery orientation (HR, 1.68; 95% CI, 0.15-2.64; $P = .444$).

DISCUSSION

BEVAR interventions are planned using a main aortic endograft that can be based on an off-the-shelf directional branch device from one company (t-Branch from Cook) or a custom device from two companies (Cook and Jotec). In relation to the branch length and tortuosity, a custom-made aortic device can have the advantage of construction with each single cuff at a different level according to the specific distance required from the single target vessel, thus allowing an adequate branch length for each artery. The off-the-shelf t-Branch could have some limitations related to the fixed standard position of the cuffs, which, during implantation, is primarily driven by the position of the SMA (with the SMA cuff deployed 2.5 cm above the orifice).[4] Thus, the distance from the renal cuffs to the renal ostia could be longer. In our experience, the length of the renal branches did not show significant differences between the use of custom and off-the-shelf devices. Also, no differences were found between the two types of main aortic stent-graft design in the geometric analysis. This might have been related to our strict respect for the instructions for use for off-the-shelf devices. Similar to our results, a maximum vertical distance of 50 mm between the branch cuff and the vessel orifice is recommended for the Cook t-Branch. We believe that less favorable geometric conformations and worse outcomes would be obtained with more liberal indications. Therefore, at present, we consider the use of off-the-shelf devices when it is possible to achieve the optimal vertical length (25-50 mm) and branch length (60-100 mm) found

Table III. Procedural data and early outcomes (n = 32 patients; n = 123 target arteries)

Procedural data	No. (%) or Mean ± SD
Patients	32 (100)
Main aortic stent-graft design	
Patient specific	17 (53.1)
Off the shelf	15 (46.8)
Stent-graft type	
Cook, patient specific	12 (37.5)
Cook, t-Branch	15 (46.8)
Jotec, COLT	5 (15.6)
Target vessel	
Celiac artery	32 (100)
SMA	32 (100)
RRA	29 (90.6)
LRA	30 (93.7)
Early (30-day) outcomes	
Any MAE	9 (28.2)
Death	1 (3.1)
EBL >1000 mL	4 (12.5)
Spinal cord injury	2 (6.2)
Stroke/TIA	1 (3.1)
MI	0 (0)
AKI	2 (6.2)
Respiratory failure	2 (6.2)
GI complications	1 (3.1)
Target vessels	123 (100)
Target vessels per patient, No.	3.8 ± 0.3
Stents used per target vessel, No.	
Mean ± SD	2.0 ± 0.7
1	24 (19.5)
2	70 (56.9)
3	29 (23.6)
Type of main bridging stent	
Viabahn (WL Gore)	21 (17.1)
CT	3 (14.3)
SMA	3 (14.3)
RRA or LRA	15 (71.4)
Fluency (CR Bard)	61 (49.6)
CT	19 (31.1)
SMA	19 (31.1)
RRA or LRA	23 (37.7)
Covera (CR Bard)	41 (33.3)
CT	10 (24.4)
SMA	10 (24.4)
RRA or LRA	21 (51.2)
Adjunctive BMS	85 (69.1)
Adjunctive balloon-expandable stent	30 (24.4)

AKI, Acute kidney injury; *BMS*, bare metal stent; *CT*, celiac trunk; *EBL*, estimated blood loss; *GI*, gastrointestinal; *LRA*, left renal artery; *MAE*, major adverse event; *MI*, myocardial infarction; *RRA*, right renal artery; *SD*, standard deviation; *SMA*, superior mesenteric artery; *TIA*, transient ischemic attack.

in our results. Otherwise, we prefer patient-specific devices.

The clear role of the length of the bridging stent for BEVAR is controversial. In their analysis of 306 caudally directed cuffs, Reilly et al[13] did not find the length to be a predictor of worse outcomes. For BEVAR, a mean good distance between the cuff and the arterial orifice of the target vessel of ≤50 mm has been generally accepted.[4] Also, the length of renal branches has generally been considered to be longer than that of the visceral vessels. This was clearly confirmed by our results, with the length significantly longer and tortuosity significantly greater ($P = .001$ and $P < .001$, respectively).

Our analysis of the branch TL showed that it was not significantly associated with a greater risk of adverse events if modeled as a linear function (HR, 0.99; 95% CI, 0.96-1.02; $P = .456$). However, it was possible to identify an overall optimal length of 60 to 100 mm. After stratification by type of target artery, a greater risk of branch instability was maintained for both renal and visceral vessels with a TL <60 mm. However, the greater rate of complications with a TL >100 mm was mainly driven by the renal arteries. Thus, a branch that is too short could also have an effect. In our series, of the eight endoleaks, five (62 %) had occurred in branches with a TL <50. A possible explanation is that a short branch could have a greater risk of stent-graft misalignment or loss of sealing owing to the continuous stress of downward forces of the pulsatile flow exerted on the main aortic endograft in relation to the fixed point of the cuffs. A longer bridging stent with a smoother transition and gentler angle might prevent the occurrence of these stress forces over time. In contrast, the need for a bridging stent that is too long (TL >100 cm) might result from the presence of large aneurysm sacs or preexisting severe anatomic angulations. Geometric branch modifications intended to increase the degree of angulation have been recently demonstrated by de Niet et al[14] during a 5-year period. This finding might be in line with our results (of the five cases of occlusion, the TL was >100 mm in three), with the assumption that the longer the bridging stent, the greater the risk of kinking exacerbation, thus predisposing to occlusion.

The type of stent used as a bridging stent might play a major role, especially in relation to length and tortuosity. Previous direct comparisons of SESGs and BESGs failed to demonstrate any significant differences in terms of occlusion or reintervention after BEVAR.[15] New-generation BESGs, such as the Viabahn balloon-expandable stent (VBX; W.L. Gore and Associates) might provide advantageous results because they are designed as a bridging stent for the off-the-shelf branched device TAMBE. Also, the wide range of available lengths could be helpful. However, they could be still be too short (maximum length, 79 mm) for some renal arteries and could require an additional BMS in the case of kinking.[16,17] Recent

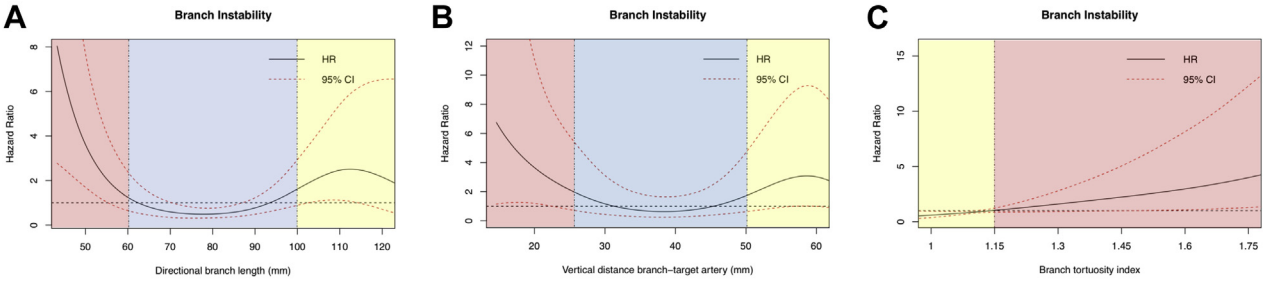

Fig 2. Penalized splines functions describing the hazard ratio (HR) of branch instability vs the branch total length (TL) **(A)**, vertical length (VL) **(B)**, and tortuosity index (TI) **(C)**.

Table IV. Final multivariate Cox proportional hazards model for target vessel instability

Variable	HR (95% CI)	*P* value
Maximum aneurysm diameter	1.08 (1.03-1.15)	**.003**
Tortuosity index >1.15	6.81 (2.17-27.33)	**<.001**
Bridging stent total length, mm		**.002**
<60	4.29 (1.37-15.43)	
60-100	Reference	
>100	1.22 (1.00-12.40)	
Target artery		.444
CT-SMA	Reference	
Renal vessels	1.68 (0.15-2.64)	

CI, Confidence interval; *CT-SMA*, celiac trunk–superior mesenteric artery; *HR*, hazard ratio.
Boldface *P* values represent statistical significance.

evidence has suggested that SESGs might be advantageous compared with BESGs in BEVAR, especially for the renal arteries.[16] In our practice, the routine use of SESGs has resulted in lower efficacy at the cuff level, with 24% of branches reinforced preventively with a BESG to improve the proximal seal.

Regarding tortuosity, usually three critical flexion points will be present in the bridging stent's route. The first is inside the aneurysm sac, where it turns from a downward to a more horizontal direction. The second is at the level of the target artery ostium, and the third, at the distal landing transition of the bridging stent with the artery. The first and second flexion points might be more influenced by the aneurysm size and target artery orientation in relation to the aorta. In particular, the larger the aneurysm sac, the longer and more tortuous can be the course of the bridging stent. This consideration was corroborated by our results, with the multivariate analysis showing that the aneurysm diameter was a predictor of branch instability ($P < .001$). The third flexion point is strictly related to the anatomy of the target artery, with eventual tortuosity or kinking. These last two aspects might be more evident with renal arteries, for which poor outcomes with BEVAR have been reported in cases of unfavorable artery implantation angles,[6] orientation,[5] and tortuosity.[7]

After bridging stent implantation, a self-expanding BMS will often be used to smooth the transition between the SESGs and the native artery, an approach that has also been adopted at several high-volume centers.[16] Similarly, a BMS will sometimes be used to reinforce the tract into the sac or at the target artery orifice if excessive tortuosity is present to reduce future fatigue, kinking, or compression that could cause occlusion or endoleaks over time. In our experience, we have used a BMS in all cases of suspected branch tortuosity (at points 1, 2, and/or 3), which was ≤69% of cases.[5]

However, we failed to demonstrate significant superiority using preventive reinforcement with BMSs in tortuous branches ($P = .533$). This aspect might nevertheless be considered a positive outcome, because branch instability in tortuous conditions was low compared with branches with a regular course that did require reinforcement. It is clear that tortuosity represents a strong factor influencing branch instability, with an eightfold risk when the TI is >1.15 and a greater effect on stent occlusion (four of the five occlusions were in branches with a TI >1.15). This result, obtained using SESGs, is in line with other outcomes reported with BESGs.[7,17]

The present study had some notable limitations. The study was a single-center, retrospective study with a limited number of patients. Also, the low number of events limited the power of the statistical analysis. However, our study was strengthened by the detailed geometric analysis and the inclusion of a homogeneous group of patients and procedures. Some aspects, such as the overlap of components or minor kinks at the junction with the target artery, were not specifically investigated. However, a standardized technique was used to manage such cases, with the use of a minimum 20-mm overlap and deployment of a BMS for cases of residual kinking, limiting the related bias. Our results, derived from a postimplantation geometric analysis, can be used to optimize the planned VL and TL during endovascular planning.

CONCLUSION

The total branch length, vertical branch-to-target artery distance, and TI seem to play important roles in determining the mid-term BEVAR outcomes. In our data, the lowest rates of branch instability occurred with a branch lengths of 60 to 100 mm and should be considered during planning and implantation. Additionally, a TI >1.15 was associated with an eightfold risk of branch complications and should prompt a more intense follow-up regimen to help prevent mid- and long-term complications.

AUTHOR CONTRIBUTIONS

Conception and design: MP, FS
Analysis and interpretation: MP, FS, FG, MA
Data collection: AX, AG
Writing the article: MP, FS
Critical revision of the article: MP, FS, AX, AG, FG, MA
Final approval of the article: MP, FS, AX, AG, FG, MA
Statistical analysis: MP, FS
Obtained funding: Not applicable
Overall responsibility: MP

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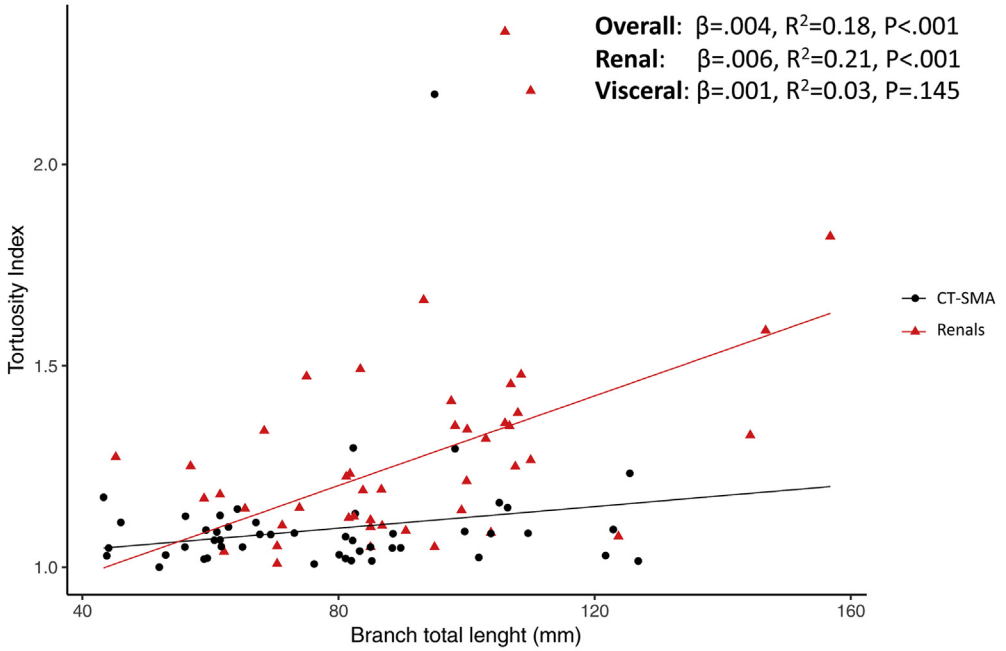
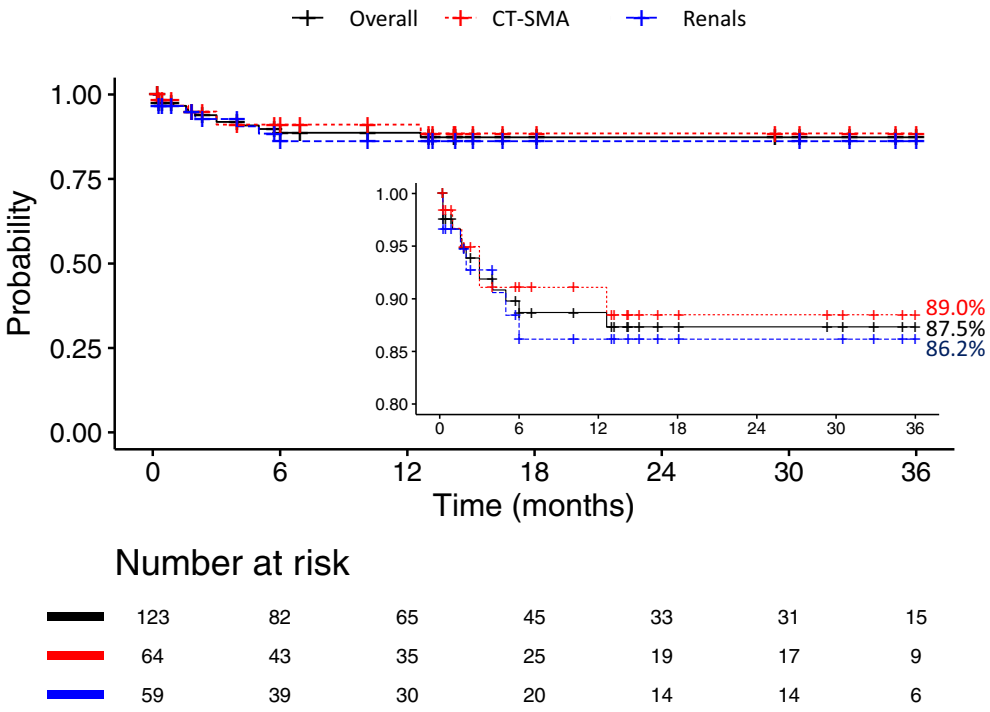


Supplementary Fig 1 (online only). Regression lines and scatter plots of tortuosity index vs total branch length, stratified by renal (*red line*) and celiac and mesenteric arteries (*black line*). The overall increase of tortuosity index along with the branch length is mainly driven by the renal arteries rather than the celiac and mesenteric arteries. *CT-SMA*, Celiac trunk—superior mesenteric artery.



Supplementary Fig 2 (online only). Kaplan-Meier estimates of freedom from branch instability for all target vessels, renal arteries, and celiac and mesenteric arteries. Standard error <10%. *CT-SMA,* Celiac trunk–superior mesenteric artery.

Supplementary Table I (online only). Results of postimplantation geometric analysis (n = 123 target arteries)

Variable	All vessels (n = 123)	Renal vessels (n = 59)	CT-SMA (n = 64)	*P* value
Bridging stent length, mm				
Mean ± SD	83.5 ± 21.7	89.9 ± 20.7	77.5 ± 20.9	**.001**
<60	17 (13.8)	4 (6.7)	13 (20.3)	**.012**
60-100	81 (65.8)	39 (66.1)	42 (65.6)	.956
>100	25 (20.3)	15 (25.4)	9 (14.1)	.072
Vertical distance, mm				
Mean ± SD	45.3 ± 17.8	50.1 ± 18.4	40.8 ± 50.1	**.003**
<25	15 (12.2)	5 (8.4)	10 (15.6)	.716
25-50	68 (55.3)	34 (57.6)	34 (53.1)	.956
>50	40 (32.5)	20 (33.8)	20 (31.3)	.142
Branch tortuosity index				
Mean ± SD	1.13 ± 0.23	1.22 ± 0.25	1.05 ± 0.17	**<.001**
>1.15	37 (30.1)	30 (50.8)	7 (10.9)	**<.001**
Target vessel seal length, mm	22.9 ± 12.0	21.8 ± 10.3	23.9 ± 15.1	.373

CT-SMA, Celiac trunk–superior mesenteric artery; *SD,* standard deviation.
Data presented as number (%), unless noted otherwise. Boldface *P* values represent statistical significance.

Supplementary Table II (online only). Univariate Cox proportional hazards for branch instability at 36 months

	All vessels		Renal vessels		Celiac and mesenteric vessels	
Variable	HR (95% CI)	*P* value	HR (95% CI)	*P* value	HR (95% CI)	*P* value
Aneurysm extent						
I-III	Reference	NA	Reference		Reference	
IV	0.12 (0.03-0.57)	**.007**	0.05 (0.01-0.43)	**.003**	0.32 (0.06-1.74)	.186
Aneurysm diameter, mm	1.11 (1.05-1.18)	**<.001**	1.24 (1.08-1.43)	**.003**	1.05 (0.98-1.13)	.157
Aortic angulation >45°	1.35 (0.43-8.56)	.143	2.01 (0.55-9.14)	.232	1.21 (0.27-10.75)	.334
Previous aortic intervention	0.31 (0.09-1.12)	.073	0.69 (0.15-3.11)	.632	NA	NA
Patient-specific stent-graft	0.21 (0.05-1.01)	.071	0.17 (0.02-1.37)	.096	0.28 (0.03-2.41)	.247
Bridging stent						
Length, mm						
Total	0.99 (0.96-1.02)	.456	1.01 (0.97-1.04)	.800	0.96 (0.91-1.01)	.123
<60	6.59 (2.15-20.29)	**<.001**	15.00 (12.62-64.3)	**.005**	7.50 (1.24-45.33)	**.028**
60-100	Reference	NA	Reference		Reference	
>100	3.19 (1.07-9.51)	**.037**	5.80 (1.40-32.33)	**.015**	2.31 (0.21-25.44)	.495
Diameter, mm	0.46 (0.25-0.80)	**.007**	NA	NA	0.31 (0.16-0.61)	**.001**
Vertical distance, mm						
Total	0.99 (0.95-1.02)	.383	0.99 (0.95-1.04)	.642	0.97 (0.91-1.02)	.316
<25	5.32 (1.18-24.05)	**.030**	23.62 (1.91-292.2)	**.018**	5.04 (0.58-43.37)	.140
25-50	Reference	NA	Reference	NA	Reference	NA
>50	3.56 (1.04-12.17)	**.008**	6.05 (1.21-59.10)	**.027**	1.32 (0.24-7.25)	.743
TI	1.51 (1.23-1.86)	**<.001**	1.47 (1.13-1.91)	**.004**	1.79 (1.19-2.68)	**.005**
TI >1.15	8.65 (2.37-31.43)	**.001**	17.97 (2.18-233.9)	**.003**	7.75 (1.55-38.53)	**.012**
BMS with TI >1.15	0.80 (0.17-3.78)	.780	0.74 (0.15-3.50)	.709	1.87 (0.41-8.48)	.414
Target vessel sealing length, mm	0.79 (0.22-2.53)	.660	0.72 (0.11-2.41)	.532	0.85 (0.30-5.13)	.774
Adjunctive BMS	1.62 (0.36-7.29)	.533	NA	NA	0.94 (0.17-5.14)	.943
Stents used, No.	0.67 (0.29-1.52)	.335	0.45 (0.12-1.75)	.252	0.71 (0.21-2.31)	.565
Target vessel						
CT-SMA	Reference	NA	NA	NA	NA	NA
Renal vessels	1.27 (0.43-3.78)	.667	NA	NA	NA	NA
Target vessel orientation						
Straight	Reference	NA	Reference	NA	Reference	NA
Upward >30°	1.34 (0.41-4.36)	.628	0.27 (0.02-2.20)	.272	NA	NA
Downward >30°	1.14 (0.38-3.39)	.814	1.09 (0.21-5.66)	.926	1.47 (0.27-8.09)	.652
Target vessel diameter, mm	0.45 (0.25-0.80)	**.007**	NA	NA	0.31 (0.15-0.61)	**<.001**
Target vessel kinking >30°	2.13 (0.64-7.01)	.213	2.44 (0.54-11.06)	.247	1.43 (0.16-12.56)	.748

BMS, Bare metal stent; *CI*, confidence interval; *CT-SMA*, Celiac trunk–superior mesenteric artery; *HR*, hazard ratio; *NA*, not applicable; *TI*, tortuosity index.
Boldface *P* values represent statistical significance.