



Article

Outcomes of Directional Branches of the T-Branch Off-the-Shelf Multi-Branched Stent-Graft

Konstantinos Spanos^{1,2,*} , Tomasz Jakimowicz³ , Petroula Nana² , Christian-Alexander Behrendt¹ , Giuseppe Panuccio¹, George Kouvelos² , Katarzyna Jama³, Ahmed Eleshra¹, Fiona Rohlfss¹ and Tilo Kölbel¹

¹ German Aortic Center Hamburg, Department of Vascular Medicine, University Heart & Vascular Center, 20251 Hamburg, Germany

² Department of Vascular Surgery, University Hospital of Larissa, Faculty of Medicine, School of Health Sciences, University of Thessaly, 41110 Larissa, Greece

³ Department of General, Vascular and Transplant Surgery, Medical University of Warsaw, 02-091 Warsaw, Poland

* Correspondence: spanos.kon@gmail.com; Tel.: +30-241350-1739

Abstract: Background: A controversy on bridging covered stent (BCS) choice, between self-expanding (SECS) and balloon-expandable (BECS) stents, still exists in branched endovascular repair. This study aimed to determine the primary target vessel (TV) patency in patients treated with the t-Branch device and identify factors impairing the outcomes. Methods: A retrospective study was undertaken, including patients treated with the t-Branch (Cook Medical, Bloomington, IN, USA) between 2014 and 2019 (early 2014–2016; late 2017–2019). The endpoint was the primary patency (CT: celiac trunk, SMA, superior mesenteric artery, RRA: right renal artery, LRA: left renal artery) during the follow-up. Any branch instability event was assessed. The factors affecting the patency were determined using multivariable regression models and Kaplan–Meier analyses. Results: In total, 2018 TVs were analyzed; 1542 SECSs and 476 BECSs. The CT patency was 99.8% (SE 0.2%) at the 1st month, with no other event. The SMA patency was 97.8% (SE 1) at the 12th month. The RRA patency was 96.7% (SE 2) at the 24th month. The LRA patency was 99% (SE 0.4) at the 6th month. Relining was the only factor independently associated with the SMA patency (OR 8.27; 95% CI 1.4–4.9; $p = 0.02$). The freedom from instability was 62% (SE 4.3%) and 45% (SE 5.4%) at the 24th month and 36th month. No significant difference was identified between the BECSs and SECSs in the early or late experience. Conclusion: BCS for the t-Branch branches performed with a good primary patency during the short-term follow-up. The type of BCS did not influence the patency. Relining might be protective for SMA patency.

Keywords: thoraco-abdominal aortic aneurysm; t-Branch; endovascular repair; off-the-shelf stent graft; bridging covered stent; balloon-expandable covered stent; self-expanding covered stent; relining



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1. Introduction

The endovascular treatment of complex aortic aneurysms (thoracoabdominal, pararenal, and juxtarenal) has been widely accepted as a safe and effective technique [1–5]. Fenestrated and branched endovascular aneurysm repair (F/B-EVAR) has demonstrated high rates of technical and clinical success and low early post-operative mortality [6–9]. F/B-EVAR seems to offer a benefit regarding early mortality and perioperative complications compared to open repair [6,10]. F/B-EVAR techniques have evolved during the last two decades, thus the high-level evidence on the long-term durability of these devices is still limited, although experienced centers have reported low target vessel occlusion and reintervention rates [6,10,11].

The durability of the bridging covered stents (BCS) is of great importance in patients treated with B-EVAR using directional branches to connect to thoracoabdominal target vessels (TVs). Complications that can occur with BCSs include: endoleak, kinking, fracture,

migration, occlusion, and stenosis. Over time, the combination of progression of vascular disease, endothelial proliferation, continuous arterial movement, and material fatigue may also affect TVs patency [12]. There is a controversy for the choice of BCSs for B-EVAR: a self-expanding (SECS) or balloon-expandable covered stent (BECS). The evidence is based on retrospective studies and case series, thus, currently, a high-level guideline recommendation does not exist. In general, the benefits of SECSs are their flexibility and conformability, while BECSs have a smaller profile and may offer a more precise deployment.

The aim of this study was to assess the primary patency of TVs in directional branches of patients treated with the t-Branch at two academic aortic centers, analyzing each target vessel and the factors that are associated with its patency; the secondary aim was to analyze the impact of BCSs type on its patency.

2. Materials and Methods

2.1. Study Design

The study design and early outcomes have been previously described [3]. A retrospective observational study was undertaken including two aortic centers: the German Aortic Center Hamburg, Department of Vascular Medicine, University Heart and Vascular Center, Hamburg, Germany and the Department of General, Vascular and Transplant Surgery, Medical University of Warsaw, Poland. All patients were treated using the t-Branch (Cook Medical, Bloomington, IN, USA) in an elective or urgent setting for a complex abdominal aortic aneurysm AAA [juxta-renal, supra-renal, or after previous endovascular abdominal aortic aneurysm repair (EVAR)] and thoracoabdominal aortic aneurysm (TAAA) between 2014 and 2019. The cohort was divided into two treatment periods, 2014–2016 (early) and 2017–2019 (late). No common standardized pre- or postoperative protocol existed for the two centers. The decision for B-EVAR was based on an individual patient assessment through interdisciplinary aortic boards. The data were collected at each center and then, retrospectively and anonymously inserted into a single electronic database. The demographic data, past medical history, cardiovascular risk factors, pre-operative comorbidities, intra-operative and peri-operative details, and early post-operative morbidity and mortality were also recorded according to the Strengthening the Reporting of Observational studies in Epidemiology (STROBE) statement, as it has been previously reported in detail [13]. The branch instability definition included branch stenosis or occlusion with the need of re-intervention, branch related endoleak, or dislocation [12].

A clinical evaluation and imaging using computed tomography angiography (CTA) were used for patients' surveillance during the follow-up. This study complied with the Declaration of Helsinki. As this was a retrospective analysis of the anonymized data, no approval from the local ethics committee was required, and no patient informed consent was obtained for the study.

2.2. Procedure

The detailed technique of t-Branch implantation has been described previously [13]. The TVs which were attempted to be catheterized and stented were celiac trunk (CT), superior mesenteric artery (SMA), RRA (right renal artery), and LRA (left renal artery). The left axillary artery was the most used access to the directional branches. The SECSs used were Viabahn (W. L. Gore & Associates, Flagstaff, AZ, USA); Fluency (Bard Peripheral Vascular, Tempe, AZ, USA); or Covera (Bard Peripheral Vascular, Tempe, AZ, USA), while the BECSs were Advanta V12 (Atrium Maquet Getinge Group, Mijdrecht, The Netherlands), BeGraft (Bentley, Innomed GmbH, Hechingen, Germany), or VBX (W. L. Gore & Associates, Flagstaff, AZ, USA). Relining with a bare metal stent was at the discretion of the operator and patient's anatomic characteristics. A relining of the bridging stents was performed using balloon-expandable or self-expanding stents (Genesis-Palmaz (Cordis Corporation, Cardinal Health company, Milpitas, CA, USA); a Zilver (Cook Medical, Bloomington, IN, USA); Protégé-EverFlex (Medtronic/Covidien, Minneapolis, MN, USA); or Wallstent (Boston Scientific Corporation, Marlborough, MA, USA)] in the case of severely angulated

or tortuous visceral arteries or long distances between the visceral branch and the target vessel ostium. If a branch was not stented during the procedure, it was occluded using an Amplatzer Vascular Plug (St. Jude Medical, St. Paul, MN, USA), with or without a prior extension with a BECS, [14] and combined with a coil embolization when deemed necessary.

2.3. Endpoints

The endpoints were the primary patency of the bridging stents for each target vessel during the follow-up and the identification of factors that may be associated with the patency. The secondary outcomes were the impact of the BCS type, SECS vs. BECS, on the patency for each target vessel.

2.4. Statistical Analysis

The categorical data were expressed as the absolute numbers and/or percent prevalence (%) in the study cohort and continuous variables as the means standard deviation. In the statistical analysis for the continuous variables, the independent *t*-test for normally distributed data and the Mann–Whitney U test for nonparametric data were used. The Pearson χ^2 test or the Fisher exact test was used for the categorical variables, as appropriate. The primary patency of TVs and the comparison of the primary patency rates between the SECS vs. BECS with the log-rank test and Kaplan–Meier curves were generated. The univariate analysis of the factors associated with the branch patency such as one's age, the clinical presentation, the diameter of the aneurysm, the gender, whether there was any previous aortic repair, the type of bridging covered stent (BECS vs. SECS), the number of covered stents, and the relining was undertaken for the SMA, RRA, and LRA branches. An analysis was not undertaken for CT as only one event was reported. Multivariable regression models were used to determine the independent association of the risk factors with the patency for each branch and the mortality, while controlling for possible confounders. The model selection was based on an enter procedure. The missing data was handled by KS, AE, and TJ. No correction for multiple hypothesis testing was applied. A *p* value was considered significant when it was <0.05. The statistical analysis was performed by SPSS 22.0 for Windows software (IBM Corp, Armonk, NY, USA).

3. Results

3.1. Patients' Characteristics

Between January 2014 and December 2019, 542 patients (mean age, 70.5 ± 8.5 years; 388 males [72%]) underwent an endovascular repair using the t-Branch endograft. Based on the Crawford classification, among the patients with TAAA (90%; 487/542), 31 (5.7%) were categorized as type I, 73 (13.4%) as type II, 118 (21.7%) as type III, 233 (43%) as type IV, and 32 (5.9%) as type V. Twenty-two (4%) patients were treated due to a juxta-renal AAA (4 were symptomatic with abdominal pain, 3 presented with a contained rupture, and 15 had an AAA diameter >90 mm and it was decided by the patient not to wait for a custom-made device, that could take up to 8 weeks), 19 (3.5%) due to supra-renal AAA and, 14 due to an AAA (contained ruptures or previously AAA intervention). Only 5 patients had a history of previous aortic dissection. The technical success rate was 97% (526/542) for the main procedure. Early outcomes have been presented recently [3]. Demographics, co-morbidities, and past medical history are shown in Table 1, distributed in two groups: patients with TV patency vs. those with a loss of patency of at least one TV during FU.

In 542 patients, 2018 TVs were connected to the directional branches of the t-Branch; 1542 TVs were connected using SECSs; and 476 using BECSs (Table 2). In 91%, 8%, and 1% of the TV, one, two, or three SECSs were used, respectively, while in 87%, 12%, and 1% of the TV, one, two, or three BECSs were used, respectively. Thus, it was more common to use >1 BCS in BECSs than in SECSs (12.6% vs. 8.7%; *p* = 0.01). A relining was performed in 86% of SECSs and 32% of BECSs (Table 2). Table 3 shows the diameters of bridging covered stents that were used.

Table 1. Demographics, co-morbidities, past-surgical history, and clinical presentation. CAD: coronary artery disease; HT: hypertension; HL: hyperlipidemia; COPD: chronic obstructive pulmonary disease; DM: diabetes mellitus; EVAR: endovascular aneurysm repair; AAA: abdominal aortic aneurysm; TAA: thoracic aortic aneurysm; TAAA: thoraco-abdominal aortic aneurysm.

Demographics	Total (n = 542)	Patency (n = 530)	Loss of Patency (n = 12)	p Value
Age	70.5 ± 8	71.3 ± 7	69.8 ± 11	0.77
BMI	26 ± 4	25 ± 6	23.8 ± 3	0.08
Aneurysm diameter	7.5 ± 2.5	7.6 ± 2.2	7.1 ± 1.6	0.76
Male	388 (72%)	379 (72%)	9 (75%)	0.84
Female	154 (28%)	151 (28%)	3 (25%)	
CAD	287 (53%)	284 (54%)	3 (25%)	0.028
HT	497 (92%)	485 (92%)	11 (92%)	0.35
HL	332 (61%)	329 (62%)	3 (25%)	0.004
Smoking	292 (54%)	286 (54%)	6 (50%)	0.57
COPD	102 (19%)	99 (18.6%)	3 (25%)	0.57
DM	88 (16%)	88 (16.7%)	0 (0%)	0.1
Renal insufficiency				
0	335	326 (61%)	9 (75%)	0.91
1	197	194 (37%)	3 (25%)	
2	9	9 (1.8%)	0	
3	1	1 (0.2%)	0	
Previous ascending or arch repair	25 (4.6%)	25 (5%)	0	0.42
Previous EVAR	78 (14.4%)	77 (15%)	1 (8%)	0.48
Previous AAA	90 (16.6%)	85 (16%)	5 (42%)	0.033
Previous TAA	72 (13.3%)	68 (13%)	4 (33%)	0.06
Status of aneurysm				
Non-ruptured	339	330 (62%)	9 (75%)	0.46
Contained	46	45 (8.5%)	1 (8%)	
Symptomatic	157	155 (29%)	2 (16%)	
Type of aneurysm				
Juxta-renal	22	22	0	
Supra-renal	19	19	0	
TAAA Type I	31	31	0	
TAAA Type II	73	70	3	
TAAA Type III	118	117	1	
TAAA Type IV	233	228	5	
TAAA Type V	32	30	2	
Infra-renal	14	13	1	

Table 2. This table shows type and number of bridging covered stents that were used for each target vessel. CT: coeliac trunk; SMA: superior mesenteric artery; RRA: right renal artery; LRA: left renal artery; BX: balloon expandable; SX: self-expanding.

	Total	BX	1	2	3	Relining	1	2	SX	1	2	3	Relining	1	2	3
CT	485	110	97	13	0	30 (27%)	30	0	375	356	17	2	295 (79%)	290	5	0
SMA	520	101	86	14	1	27 (27%)	27	0	419	394	21	4	342 (82%)	337	5	0
RRA	506	116	107	8	1	42 (36%)	40	2	390	344	45	1	305 (78%)	291	13	1
LRA	507	149	126	23	0	54 (36%)	52	2	358	314	41	3	276 (77%)	254	11	1
Total	2018	476	416	58	2	153 (32%)	149	4	1542	1408	124	10	1218 (86%)	1172	34	2

Table 3. This table shows the diameters of bridging covered stents that were used. BX: balloon expandable; SX: self-expanding; CT: coeliac trunk; SMA: superior mesenteric artery; RRA: right renal artery; LRA: left renal artery.

mm	Total	CT		SMA		RRA		LRA					
	N	BX	SX	N	BX	SX	N	BX	SX	N	BX	SX	
5	2	0	0	0	0	0	0	0	0	2	2	0	
6	500	5	3	2	3	2	1	254	55	199	238	67	171
7	239	6	3	3	10	2	8	108	17	91	115	24	91
8	537	230	48	182	210	37	173	51	6	45	46	14	32
9	201	80	20	60	106	23	83	2	0	2	13	4	9
10	157	65	10	55	87	14	73	2	1	1	3	1	2
11	2	2	0	2	0	0	0	0	0	0	0	0	0
12	26	11	0	11	15	0	15	0	0	0	0	0	0

3.2. Patency Rates

The CT patency rate was 99.8% (SE 0.2%) at 1 month, while no other event was identified for up to 3 years of the follow-up (Figure 1a). The SMA patency rate was 99.4% (SE 0.3%), 99.1% (SE 0.5), and 97.8% (SE 1) at the 1-, 3-, and 12-month follow-up, respectively, with no other event during the follow-up (Figure 1b). The RRA patency rate was 99.8% (SE 0.2%), 98.8% (SE 0.6), and 96.7% (SE 2) at the 1st, 3rd, and 24th month, respectively (Figure 1c). The LRA patency rate was 99.4% (SE 0.3%) and 99% (SE 0.4) at the 1st and 6th month, respectively, with no other event during the follow-up (Figure 1d). The TV patency is depicted in the Kaplan–Meier curves in Figure 1a–d.

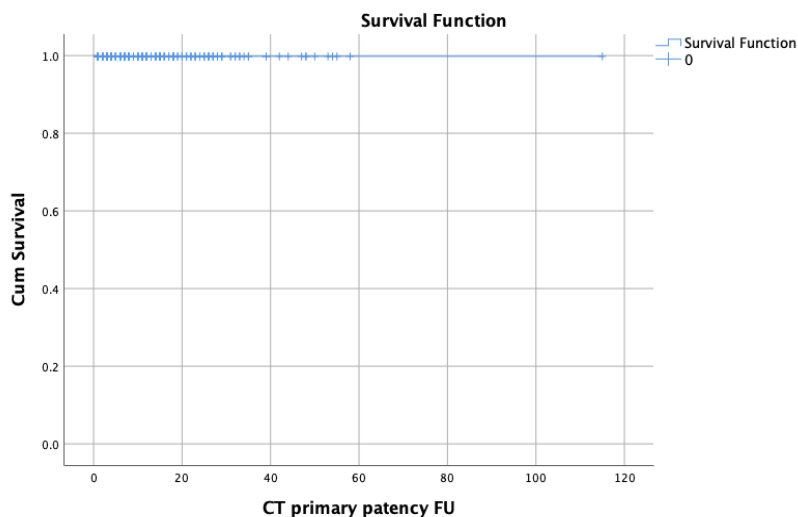
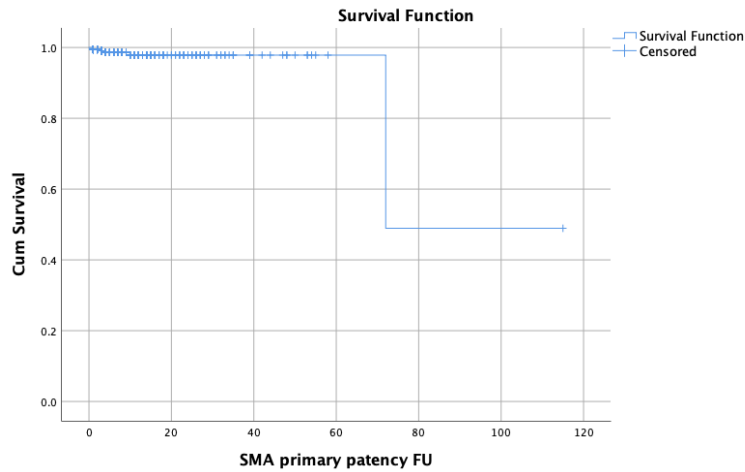


Figure 1. Cont.

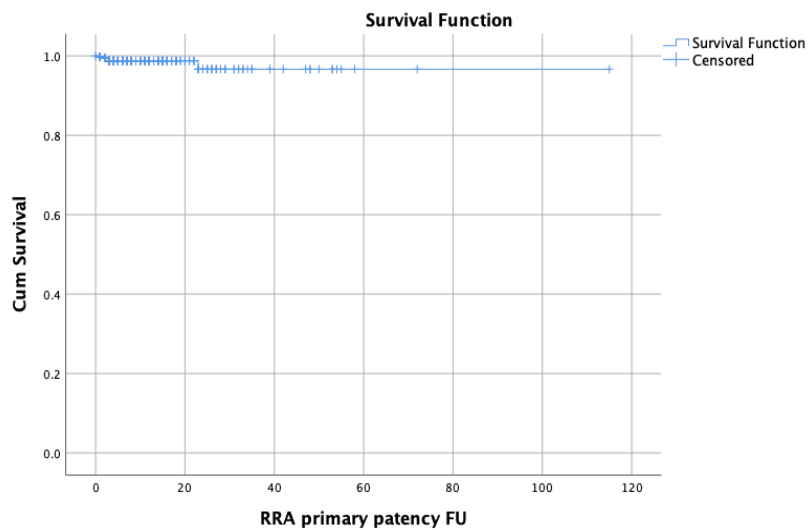
Months	1	3	6	12	24	36
Patients at risk	467	251	155	100	40	13
Events	1	1	1	1	1	1
Percentages	99.8%					
SE	0.2					

(a)



Months	1	3	6	12	24	36	72
Patients at risk	514	279	171	111	44	18	1
Events	3	4	4	5	5	5	6
Percentages	99.4%	99.1%		97.8%			49%
SE	0.3	0.5		1			34

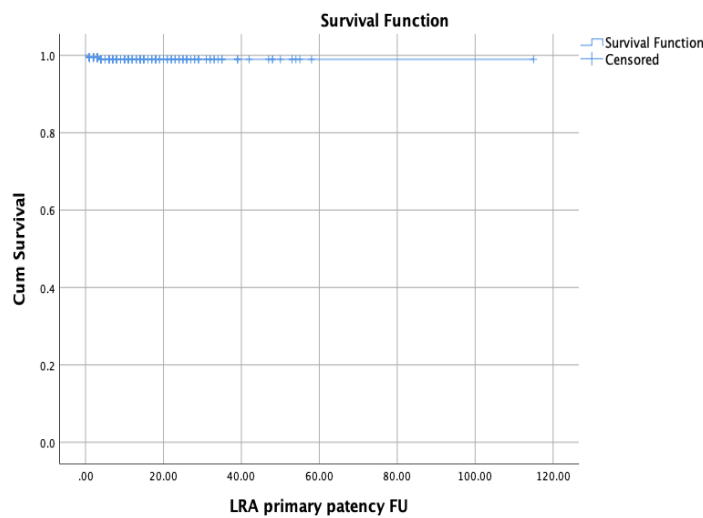
(b)



Months	1	3	6	12	24	36
Patients at risk	517	275	169	110	46	15
Events	1	4	4	4	5	5
Percentages	99.8%	98.8%			96.7%	
SE	0.2	0.6			2.2	

(c)

Figure 1. Cont.



Months	1	3	6	12	24	36
Patients at risk	514	277	169	107	41	16
Events	3	3	4	4	4	4
Percentages	99.4%		99%			
SE	0.3		0.4			

(d)

Figure 1. (a) Patency of coeliac trunk (CT) bridging covered stent. SE: standard error; (b) Patency of superior mesenteric artery (SMA) bridging covered stent. SE: standard error; (c) Patency of right renal artery (RRA) bridging covered stent. SE: standard error; (d) Patency of left renal artery (LRA) bridging covered stent. SE: standard error.

Freedom from any TV instability was 96.8% (SE 0.8%), 93% (SE 1.3%), 88.4% (SE 1.9), 79% (SE 2.8), 62% (SE 4.3%), and 45% (SE 5.4%) at the 1st, 3rd, 6th, 12th, 24th, and 36th month (Supplementary Figure S1).

In total, twelve patients had a loss of patency in one or more TVs; in those patients, 16 TVs were occluded (Table 4). Nine patients were treated electively (9/12) and 13 of the TVs (13/16) were lost within the initial four months of the follow-up. A univariate analysis of the factors associated with the branch patency was undertaken for the SMA, RRA, and LRA branches. An analysis was not undertaken for the CT branches, as only one event was reported during the follow-up. The univariate analysis did not identify any significant factors associated with the left or right RA branch patency.

The univariate analysis for the factors affecting the SMA branch patency identified relining (with a bare metal stent) as the only associated factor. After a multivariate regression analysis (Table 5), relining with the bare metal stent was associated with a better SMA branch patency (OR 8.27; 95% CI 1.4–4.9; $p = 0.02$).

Table 4. Description of patients with loss of patency in one or more target vessels. AAA: abdominal aortic aneurysm; TAAA: thoraco-abdominal aortic aneurysm; BCS: bridging covered stents; BECS: balloon-expandable covered stent; SECS: self-expanding covered stent.

N	Age	AAA Diameter	Clinical Presentation	Type of Aneurysm	TV Occlusion	Time of Event in Months	Type of BCS	Number of BCS	Relining	Number of BMS
1	74	7.4	Asymptomatic	Type IV TAAA	RRA	2	SECS	1	1	1
2	85	6.2	Asymptomatic	Type III TAAA	LRA	1	SECS	1	1	1
					SMA	1	SECS	1	1	1
					CT	1	SECS	1	0	0
3	79	7	Asymptomatic	Type IV TAAA	SMA	1	SECS	1	1	1
4	66	6.8	Asymptomatic	Type IV TAAA	RRA	3	BECS	1	1	1
5	82	6.7	Contained ruptured	Type V TAAA	SMA	1	BECS	1	0	0
6	44	12	Asymptomatic	Type IV TAAA	LRA	1	SECS	1	1	1
7	68	6.5	Asymptomatic	Type IV TAAA	RRA	3	SECS	1	1	1
8	66	5.7	Asymptomatic	Type II TAAA	LRA	4	SECS	1	0	0
					SMA	72	SECS	1	0	0
9	72	6.3	Symptomatic	Type II TAAA	SMA	10	SECS	2	0	0
10	61	5.8	Asymptomatic	Infrarenal	RRA	23	SECS	1	0	0
11	57	7.1	Asymptomatic	Type V TAAA	SMA	3	SECS	1	0	0
12	78	6.5	Symptomatic	Type II TAAA	RRA	1	SECS	1	0	0
					LRA	1	SECS	1	0	0

3.3. Balloon-Expandable vs. Self-Expanding Covered Stents

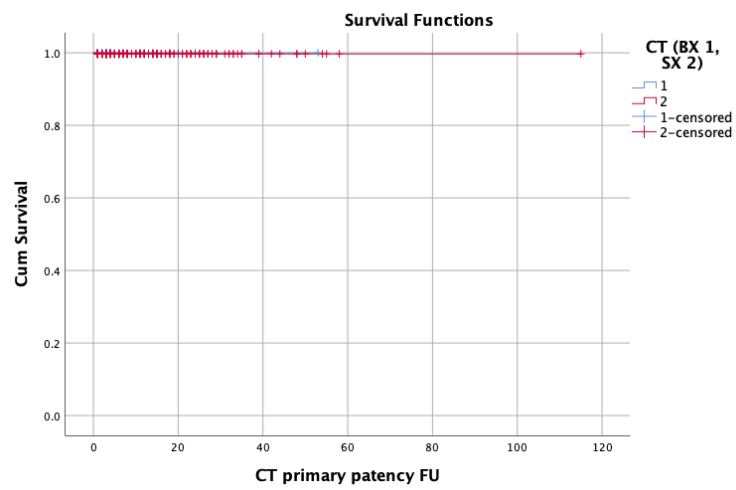
In the sub-analysis of the primary patency between the BECSs and SECSs, there was no statistically significant patency difference for the CT; in the BECS group, the CT patency was 100% up to 2 years, while in the SECS group, the CT patency was 99.7% (SE 0.3) at the 1st month while no other event was reported during the follow-up ($p = 0.5$, Figure 2a). There was also no difference in terms of patency for the SMA bridging stent, thus in the BECS group, the SMA patency was 99% (SE 1) at the 1st month, while no other event was reported, while in the SECS group, the SMA patency was 99.5% (SE 0.4), 99.1% (SE 0.6), and 98.6% (SE 1) at 1st, 3rd, and 12th months, respectively, with no other event during the follow-up ($p = 0.86$, Figure 2b). There was no difference in terms of the patency for the RRA bridging stent. In the BECS group, the RRA patency was 97.3% (SE 2.3) at the 3rd month, while no other event was reported, while in the SECS group, the RRA patency was 99.7% (SE 0.3), 98.8% (SE 0.7), and 96.5% (SE 2.4) at the 1st, 12th, and 24th month, respectively ($p = 0.78$, Figure 2c). Finally, no difference was noted in the patency for the LRA, thus in the BECS group, the LRA patency was 100% with no event during follow up, while in the SECS group, the LRA patency was 99.1% (SE 0.5) and 98.5% (SE 0.8) at the 1st and 6th month, respectively, with no other event during the follow-up ($p = 0.22$, Figure 2d).

Table 5. Univariate and multivariate analysis of factors associated with target vessel patency. SMA: superior mesenteric artery; RRA: right renal artery; LRA: left renal artery; CT: coeliac trunk; BX: balloon expandable; SX: self-expanding.

Univariate Analysis of SMA Patency		Multivariate			CI	
Age	0.28	Relining	0.02	8.27	1.4	49
Clinical presentation	0.36	BX vs. SX	0.26			
Diameter of aneurysm	0.72					
Gender	0.23					
Previous aortic repair	0.65					
BX vs. SX	0.11					
Relining	0.01					
Numbers of stents	0.83					
Univariate analysis of RRA patency						
Age	0.89					
Clinical presentation	0.44					
Diameter of aneurysm	0.71					
Gender	0.76					
Previous aortic repair	0.17					
BX vs. SX	0.48					
Relining	0.42					
Numbers of stents	0.21					
Univariate analysis of LRA patency						
Age	0.62					
Clinical presentation	0.36					
Diameter of aneurysm	0.81					
Gender	0.35					
Previous aortic repair	0.67					
BX vs. SX	0.07					
Relining	0.14					
Numbers of stents	0.3					
Univariate analysis of LRA patency	Not feasible with only one event					

3.4. Early vs. Late Experience

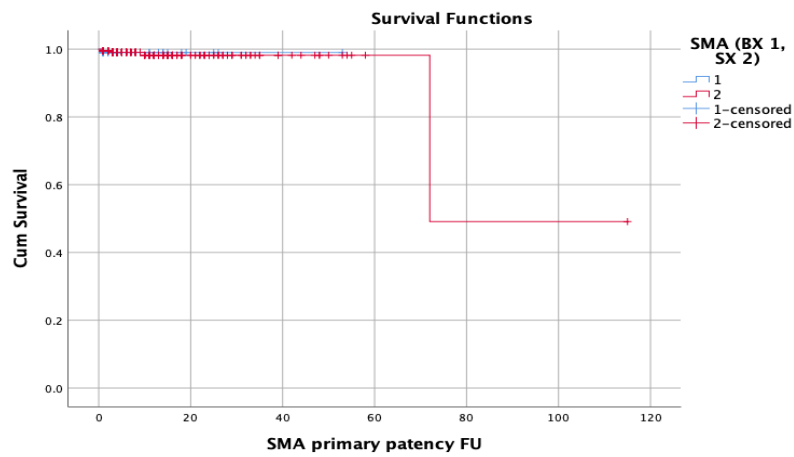
One hundred and fifty-four patients (28%) were treated from 2014 to 2016, whereas 388 patients (72%) were treated from 2017 to 2019. In the sub-analysis in terms of the level of experience, there was no significant patency difference for the CT; in the early group, the CT patency was 99.2% (SE 0.8) in first month, with the occurrence of no other event, while in the late group, the CT patency was 100%, and no event was reported during the follow-up ($p = 0.09$, Supplementary Figure S2a). There was also no difference in terms of the patency for the SMA bridging stent, thus in the early group, the SMA patency was 98.6% (SE 0.9) and 96.8% (SE 2) at the 1st and 12th month, while in late group, the SMA patency was 99.7% (SE 0.3), 99.2% (SE 0.6), and 98.5% (SE 0.9) at the 1st, 3rd, and 6th month, respectively ($p = 0.21$), with no other event occurring (Supplementary Figure S2b). There was no difference in terms of the patency for the RRA bridging stent. In the early group, the RRA patency was 99% (SE 1) at the 3rd month, while no other event was reported, while in late group, the RRA patency was 99.7% (SE 0.3), 98.7% (SE 0.8), and 93.2% (SE 5.4) at the 1st, 12th, and 24th month, respectively ($p = 0.39$, Supplementary Figure S2c). Finally, no difference was noted in the patency for the LRA, thus in the early group, the LRA patency was 99.3% (SE 0.7) and 98% (SE 1.4) at the 1st and 6th month, with no other event occurring, while in the late group, the LRA patency was 99.5% (SE 0.4) at the 1st month, with no other event ($p = 0.38$, Supplementary Figure S2d).



	Months	1	3	6	12	24	36
BECS	Patients at risk	100	39	12	7	1	
	Events	0	0	0	0	0	
	Percentages						
	SE						
SECS	Patients at risk	323	187	129	82	34	12
	Events	1	1	1	1	1	1
	Percentages	99.7%					
	SE	0.3%					

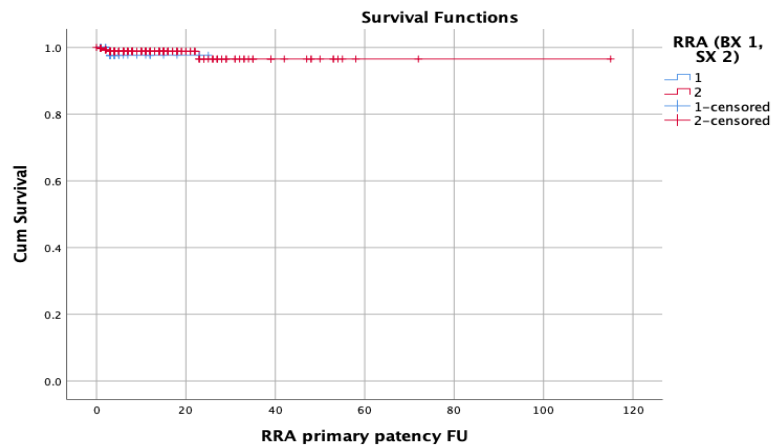
(a)

Figure 2. Cont.



	Months	1	3	6	12	24	36	72
BECS	Patients at risk	99	43	15	11	3		
	Events	1	1	1	1	1		
	Percentages	99%						
	SE	1						
SECS	Patients at risk	401	227	152	99	41	17	1
	Events	2	3	3	4	4	4	5
	Percentages	99.5%	99.1%		98.6%			49%
	SE	0.4	0.6		1			35

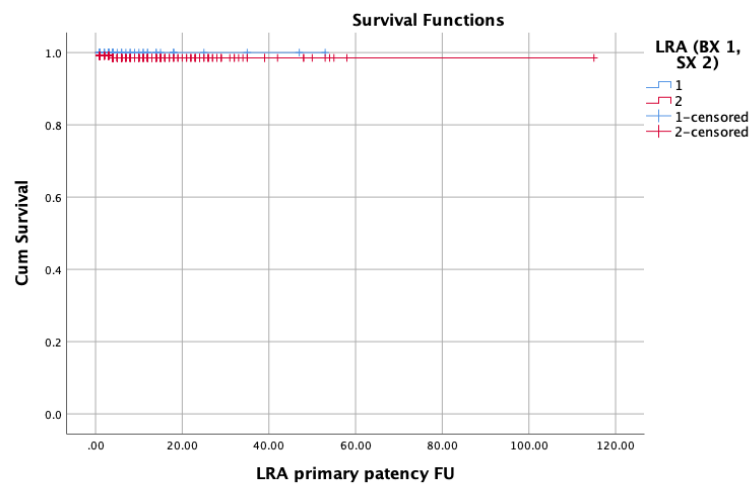
(b)



	Months	1	3	6	12	24	36
BECS	Patients at risk	110	42	10	6	1	
	Events	0	1	1	1	1	
	Percentages		97.3%				
	SE		2.3				
SECS	Patients at risk	373	213	146	95	38	15
	Events	1	3	3	3	4	4
	Percentages	99.7%	98.8%			96.5%	
	SE	0.3	0.7			2.4	

(c)

Figure 2. Cont.



	Months	1	3	6	12	24	36
BECS	Patients at risk	142	60	21	11	3	2
	Events	0	0	0	0	0	0
	Percentages						
	SE						
SECS	Patients at risk	338	199	136	89	35	13
	Events	3	3	4	4	4	4
	Percentages	99.1%		98.5%			
	SE	0.5		0.8			

(d)

Figure 2. (a) Sub-analysis between balloon-expandable covered stents (BECSs) and self-expanding covered stents (SECSs) for primary patency of coeliac trunk (CT) bridging covered stent. SE: standard error; (b) Sub-analysis between balloon-expandable covered stents (BECSs) and self-expanding covered stents (SECSs) for primary patency of superior mesenteric artery (SMA) bridging covered stent. SE: standard error; (c) Sub-analysis between balloon-expandable covered stents (BECSs) and self-expanding covered stents (SECSs) for primary patency of right renal artery (RRA) bridging covered stent. SE: standard error; (d) Sub-analysis between balloon-expandable covered stents (BECSs) and self-expanding covered stents (SECSs) for primary patency of left renal artery (LRA) bridging covered stent. SE: standard error.

4. Discussion

During the past decade, the endovascular treatment of complex aortic aneurysms with fenestrated and branched stent grafts became a popular option due to its low perioperative mortality and morbidity [1–9,15,16]. Custom-made devices (CMD), designed upon each patient’s specific anatomy, offer a dedicated treatment solution and allow an individual position of fenestrations and directional branches depending on the patient’s anatomy. However, a long production time can delay treatment and make CMDs inappropriate for the most urgent and emergency cases. The t-Branch was launched in 2012 in Europe as the first off-the-shelf standardized multibranch endograft with four directional branches for the endovascular treatment of complex aortic aneurysms, offering an alternative for patients needing either an elective or urgent management.

In a recent systematic review on the BEVAR outcomes, including seven retrospective studies and 197 patients, the primary branch patency was 98.2% during the follow-up period [17]. In the current study, which includes >500 patients who have been treated with the t-Branch, the branch patency rate was >97% at 12 months, with a low number of branch occlusion events in a follow-up of up to 3 years, confirming the good outcomes of previous studies. The level of experience did not have any impact on the outcomes. In this analysis, most of the events occurred during the initial 3 months of the follow-

up. This finding highlights the need for a close surveillance in the early post-operative phase. The duplex ultrasound, along with the assessment of fenestrations and branches, may be an alternative imaging which decreases the risks associated with CTA use during the follow-up [18–20]. Recent studies have indicated the promising outcomes of a late revascularization of occluded renal arteries as TVs in complex endovascular aortic repair, highlighting the importance of a follow-up in those patients [21,22].

Currently, no dedicated BCS is available for use in directional branches. The available BCSs that are used are either self- or balloon-expandable and have not been designed for this purpose and their use is off-label [23]. In general, the benefits of SECSs are considered their flexibility, conformability, and longer length as the rationale for their superiority over BECSs, while BECSs have a smaller profile and may offer a more precise deployment, but >1 BCS may be needed, as it was also shown in our study [24–26]. In this study, we compared the use of BECS vs. SECS in terms of the patency rate in >2000 TV, by analyzing each TV separately. Both types of BCSs showed excellent outcomes in terms of patency, irrespectively the TV during follow up. To date, no RCT comparing the different covered stent types is available in the literature. Recent studies on newer balloon-expandable devices have provided conflicting outcomes; Tenorio et al. reported a significantly higher TV-instability rate for BECSs while Motta et al. reported comparable outcomes [26–29].

The relining of BCSs is used in order to reinforce compressed BCSs or smoothen a kinked distal landing zone. In this analysis, relining was more common in SECSs. The SMA branch patency was significantly better when relining was done. However, we should be cautious with this outcome, since 86% of the SECSs were relined vs. 32% of the BECSs. Additionally, it cannot be excluded that the relining of a TV could be the common practice of the physician rather than the need for a relining due to other potential reasons. No specific recommendation regarding relining has been made so far in publications and guidelines and its utilization is usually at the discretion of the operator, taking into account TVs anatomy, angulation, stenosis, or kinking [26–29]. Potentially, a combination of self-expanding and balloon-expandable stents incorporates the mechanical properties of both devices, which may have an impact on patency outcomes [25].

Limitations

The main limitation of this study is its retrospective observational nature which introduces an unsolved challenge of residual confounding. Two experienced centers were involved, which may be adherent to different protocols for preoperative, perioperative, and postoperative practice. Another limitation is the use of bridging stents of different generations. Additionally, an analysis on different companies was not amendable since most of the times the choice of a stent-graft depended on the availability in each center. Some important information was also missing in the database, such as if there was a specific indication intra-operatively for relining. A bare metal stent for the relining was not amendable, although this would be difficult since some physicians are more aggressive with the relining while others are only so in specific cases. The availability of each bare metal stent might be also different; thus, this would be another bias. Another limitation was the absence of any analysis on the potential compression and possible kinking of the bridging stents, and the size of the aorta at the level of the renal arteries and the degree of aortic kinking at the branching site. With the use of off-the-shelf devices with a standard branch orientation, there might be in some degree a compromise with some of the branches as the positioning is not necessarily perfect for all the vessels; such an analysis was not mendable in this study. Additionally, an antiplatelet treatment could not be assessed to determine its impact on the bridging stent graft patency as there were no details on whether the patients were adherent to them during the follow-up. However, this remains the largest study presenting the primary patency outcomes of >2000 TVs.

5. Conclusions

The bridging covered stents for the directional branches of the t-Branch perform with good primary patency outcomes during a short-term period. The type of covered stent, either a BECS or SECS, its clinical presentation, and its previous aortic repair did not influence the patency. A relining might be protective in terms of the patency for the SMA bridging stent.

Supplementary Materials: The following supporting information can be downloaded at: <https://www.mdpi.com/article/10.3390/jcm11216513/s1>, Figure S1: freedom from target vessel instability. SE: standard error; Figure S2: (a) sub-analysis between early and late experience for primary patency of coeliac trunk (CT) bridging covered stent. SE: standard error; (b) sub-analysis between early and late experience for primary patency of superior mesenteric artery (SMA) bridging covered stent. SE: standard error; (c) sub-analysis between early and late experience for primary patency of right renal artery (RRA) bridging covered stent. SE: standard error; (d) sub-analysis between early and late experience for primary patency of left renal artery (LRA) bridging covered stent. SE: standard error.

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