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

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Abstract

In branched endovascular repair, there is still debate regarding the best Bridging Covered Stent (BCS) to use, namely between Self-Expanding Covered Stent (SECS) and Balloon-Expandable Covered Stent (BECS). The purpose of this study was to assess the primary Target Vascular (TV) patency in patients receiving t-Branch treatment and to pinpoint elements affecting results. Patients treated with the t-Branch between 2014 and 2019 were included in a retrospective research. The primary patency (right renal artery, left renal artery, superior mesenteric artery, celiac trunk) during the follow-up was the endpoint. Every instance of branch instability was evaluated. Using Kaplan-Meier analyses and multivariable regression models, the factors influencing the patency were identified. A total of 2018 TVs, including 1542 SECSs and 476 BECSs, were examined. The first month had no further events, and the CT patency was 99.8% (SE 0.2%). At the 12th month, the SMA patency was 97.8% (SE 1). At the 24th month, the RRA's patency was 96.7% (SE 2). At the sixth month, the LRA's patency was 99% (SE 0.4). The SMA patency was only positively correlated with relining. At the 2^{4th} and 36^{th} months, the freedom from instability was 62% and 45%, respectively. In either the early or late experience, no discernible difference between the BECSs and SECSs was found. During the short-term follow-up, BCS for the t-Branch branches functioned well in terms of primary patency. The patency was unaffected by the BCS type. Relining could safeguard SMA patency.

Keywords: Thoraco-abdominal aortic aneurysm • Endovascular repair • Off-the-shelf stent graft • Bridging covered stent • Self-expanding covered stent

Introduction

It is well acknowledged as a secure and efficient method to treat complicated aortic aneurysms (thoracoabdominal, pararenal, and juxtarenal). Low early post-operative mortality and high rates of technical and clinical success have been shown for Fenestrated and Branching Endovascular Aneurysm Repair (F/B-EVAR). In comparison to surgical repair, F/B-EVAR appears to have advantages in terms of early mortality and postoperative problems. Although seasoned facilities have reported minimal target vessel occlusion and reintervention rates, high-level evidence on the long-term durability of these devices is still scarce due to the evolution of F/B-EVAR procedures over the past two decades.

When B-EVAR is used to treat patients, the Bridging Covered Stents (BCS) that link to the thoracoabdominal target arteries utilizing directional branches must be extremely durable. BCSs are susceptible to endoleak, kinking, breakage, migration, occlusion, and stenosis complications. The patency of TVs may eventually be impacted by the combination of developing vascular illness, endothelial proliferation, ongoing artery movement, and material fatigue. It is debatable whether Self-Expanding Covered Stents (SECS) or Balloon-Expandable Covered Stents (BECS) should be used as BCSs for B-EVAR. An overall suggestion for a high-level guideline does not yet exist because the evidence is based on retrospective research and case series. The flexibility and conformability of SECSs are generally their advantages, but BECSs have a smaller profile and may provide a more precise deployment.

The primary goal of this study was to evaluate the primary patency of TVs in directional branches of patients treated with the t-Branch at two academic aortic centers. The secondary goal was to evaluate the effect of BCS type on the patency of each target vessel. Early results and the study's design have been previously discussed. 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, participated in a retrospective observational study. Between 2014 and 2019, all patients were treated for complex Abdominal Aortic Aneurysm (AAA) (juxta-renal, supra-renal, or after prior Endovascular Abdominal Aortic Aneurysm Repair (EVAR)) and Thoracoabdominal Aortic Aneurysm (TAAA) using the t-Branch (Cook Medical, Bloomington, IN, USA). Early 2014-2016 and late 2017-2019 therapy periods were used for the cohort. For the two centers, there was no consistent preoperative or postoperative regimen. An individual patient evaluation conducted by interdisciplinary aortic boards served as the basis for the decision to do B-EVAR. The information was gathered at each center and then anonymously and retroactively added to a single electronic database. According to the Strengthening the Reporting of Observational studies in Epidemiology (STROBE) statement, which has been previously described in detail, the demographic information, past medical history, cardiovascular risk factors, pre-operative comorbidities, intra-operative and perioperative details, and early postoperative morbidity and mortality were also recorded. The definition of branch instability included dislocation, branch related endoleak, or branch stenosis or occlusion requiring re-intervention. Patients were monitored during the follow-up utilizing imaging techniques such Computed Tomography Angiography (CTA) and clinical evaluation. This research conformed with the Helsinki Declaration. A local ethical committee's clearance was not necessary for this retrospective analysis of the anonymized data, nor was patient informed consent acquired for the study.

The continuous variables were expressed as means standard deviation, while the categorical data were expressed as absolute numbers and/or percent prevalence (%) in the study group. The independent t-test for normally distributed data and the Mann-Whitney U test for nonparametric data were both utilized in the statistical analysis of the continuous variables. For the categorical variables, the appropriate test was either the Fisher exact test. The log-rank test and Kaplan-Meier curves were used to determine the primary patency of TVs and to compare the primary patency rates between the SECS and BECS. For the SMA, RRA, and LRA branches, the univariate analysis of the factors associated with the branch patency was conducted. These factors included age, clinical presentation, aneurysm diameter, gender, whether or not there had been any prior aortic repair, type of bridging covered stent (BECS vs. SECS), number of covered stents, and relining. Since there was only one event reported for CT, no analysis was done. While accounting for potential confounders, multivariable regression models were utilized to assess the independent relationships between the risk factors and the survival for each branch and the patency. An entry procedure was used to choose the model. KS, AE, and TJ took care of the missing data.

Discussion

Due to its low perioperative mortality and morbidity, endovascular treatment of complicated aortic aneurysms with fenestrated and branching stent grafts has grown in popularity over the past ten years. A specialized treatment option is provided by Custom-Made Devices (CMD), which are created based on the unique anatomy of each patient. These devices permit a personalized placement of fenestrations and directional branches in accordance with the patient's anatomy. CMDs are ineffective for the most urgent and emergency cases, however, because of a lengthy manufacture time, which can postpone treatment. The t-Branch, the first commercially available, standardized multibranched endograft with four directional branches for the endovascular treatment of complicated aortic aneurysms, was introduced in Europe in 2012. It provides patients needing either elective or urgent care with an alternative. The primary branch patency was 98.2% during the follow-up period in a recent systematic analysis on the BEVAR outcomes, which included seven retrospective studies and 197 patients. The branch patency rate was >97% at 12 months in the current study, which comprises more than 500 patients who have received t-Branch therapy, and there were few branch occlusion events over a follow-up of up to three years, reiterating the positive results of earlier investigations. The results were unaffected by the level of experience. The majority of the occurrences in this study happened in the first three months of the follow-up. This discovery emphasizes the necessity of close monitoring in the initial post-operative period. Duplex ultrasonography may be an alternate imaging technique that lowers the hazards connected to the use of CTA during the follow-up along with the evaluation of fenestrations and branches. The need of a follow-up in these patients has been highlighted by recent studies that show the positive results of a late revascularization of blocked renal arteries as TVs in complex endovascular aortic repair.

There isn't yet a specific BCS designed for usage in directional branches. The BCSs that are currently being utilized are either self-expanding or balloon-expandable, and their use is off-label. The advantages of SECSs over BECSs are often attributed to their flexibility, conformability, and greater length. BECSs have a smaller profile and may provide a more precise deployment, but as was also demonstrated in the study,>1 BCS may be required. In this study, we examined each TV independently to compare the employment of BECS vs. SECS in terms of the patency rate in 2000 TV. In terms of patency, both types of BCSs demonstrated great results, regardless of the TV during follow-up. There is currently no RCT that compares the various covered stent types in the literature. Relining BCSs is used to straighten a kinked distal landing zone or reinforce constrained BCSs. In this investigation, SECSs had a higher prevalence of relining. After relining, the SMA branch patency greatly improved. However, given that 86% of the SECSs and just 32% of the BECSs had new linings, we should proceed with caution. Furthermore, it cannot be ruled out that the doctor may reline TVs as part of routine procedure rather than out of necessity for other possible reasons. Relining has not yet been specifically advised in publications or guidelines; therefore, the decision to use it will typically depend on the operator's assessment of the TV's anatomy, including anyangulation, stenosis, or kinking. Potentially, a combination of self-expanding and balloon-expandable stents incorporates the mechanical characteristics of both devices, which could affect the patency results.

The primary drawback of this study is that it is retrospective observational, which poses the problem of residual confounding. Two seasoned facilities were involved, and it's possible that they follow various preoperative, perioperative, and postoperative practice procedures. The use of bridging stents from various generations is another restriction. The choice of a stent-graft frequently depended on what was available in each center, therefore it was not possible to amend an analysis of different firms. The database also lacked certain crucial information, such as whether there was a particular intra-operative indication for relining. Although this would be challenging because some doctors are more forceful with the relining while others are only so in certain circumstances, a bare metal stent for the relining was not amendable. Another bias would be if each bare metal stent had a different level of availability. Another drawback was the lack of any examination of the bridging stents' capacity for compression and kinking, as well as the size of the aorta at the level of the renal arteries and the degree of aortic kinking at the branching point. Since the positioning is not always ideal for all vessels when using off-the-shelf devices with a standard branch orientation, there may be a compromise with some of the branches; however, such an analysis was not possible in this study. Furthermore, because there was no information on whether the patients adhered to the antiplatelet treatment during the follow-up, its effect on the bridging stent graft patency could not be evaluated. This study, which examined the primary patency results of more than 2000 TVs, is still the largest one to date.

Conclusion

In the short term, the bridging covered stents for the directional branches of the t-Branch deliver good primary patency outcomes. The covered stent's BECS or SECS type, clinical characteristics, or history of aortic repair had no bearing on the patency. Regarding the SMA bridging stent's patency, relining might be beneficial.

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