

TEVAR Alone Versus the STABLE Technique for Acute Complicated TBAD

A review of the history of the STABLE technique and data from two post hoc comparative analyses comparing these approaches.

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Thoracic endovascular aortic repair (TEVAR) is the first-line therapy for acute complicated type B aortic dissection (TBAD).¹ The first goal is to treat complications such as malperfusion and/or exclude aortic rupture to save the patient's life. The principal function of TEVAR is to exclude/cover the main proximal entry tear, thereby redirecting aortic flow exclusively toward the true lumen, and ultimately decreasing the pressure within the false lumen. In a subset of patients with specific anatomic features, early TEVAR might reduce the risk of aneurysmal degeneration during follow-up by promoting early aortic remodeling. Various treatment options have been proposed to reduce early mortality and reduce late aneurysmal degeneration. In this article, we focus on potential benefits of extending TEVAR with a bare-metal stent implanted within the true lumen beyond the thoracoabdominal aortic junction, which is known as the *PETTICOAT* or *STABLE* technique.

HISTORY OF THE STABLE TECHNIQUE

Before the advent of TEVAR via stent graft placement, endovascular options were restricted to visceral artery stenting and/or intimal flap fenestration for TBAD.² Since the first publications in 1999,^{3,4} TEVAR has evolved to be the best invasive treatment strategy. In our practice, TEVAR for acute TBAD is restricted to complicated cases, defined as aortic rupture (frank or periaortic effusion) and/or organ malperfusion syndrome. However, some authors have suggested consideration of other criteria as well, such as large aortic diameters at onset, refractory pain, and/or persistent hypertension, to define complicated dissections.⁵

In 2005, Mossop et al published their initial experience combining thoracic endografting with a self-expandable bare stent placed distally,⁶ which was called the *PETTICOAT* strategy. This technique has two main

goals: (1) to increase the expansion of the true lumen and thus reduce malperfusion, and (2) to promote aortic remodeling. Several authors have reported their experience with this strategy,^{7,8} and Cook Medical has developed an aortic bare-metal stent specifically for dissection treatment. Cook's Zenith Dissection endovascular system, comprising a stent graft component and the distal bare stent component specifically for dissection treatment, was evaluated in the STABLE I and II studies.^{9,10} The STABLE I study assessed an earlier iteration of the device combination (Zenith TX2 stent grafts and stainless steel bare stents) in patients who were treated at up to 90 days from dissection symptom onset and presented with a wide range of indications. The STABLE II pivotal study, conducted later, evaluated the current device system (barbless stent grafts and nitinol bare stents) in patients who presented with only acute, complicated TBAD. Both studies assessed outcomes up to 5 years, but neither compared the results of this combined strategy to endografting alone. We thus conducted two secondary analyses comparing the results from the STABLE cohorts to the results from high-volume European aortic centers, where endografting alone was performed to treat acute complicated TBAD.^{11,12}

AORTIC REMODELING

Aortic remodeling is a combination of true lumen expansion and false lumen thrombosis and shrinkage. It is well described in the literature that TEVAR promotes aortic remodeling at the level of the endograft but has little or no influence on the aorta beyond the diaphragm. There has been scarce literature on the impact of bare stent placement at the level of the thoracoabdominal aorta on aortic remodeling.^{8,13}

In this context, we conducted a post hoc comparative analysis of two groups of patients surviving 1 year after

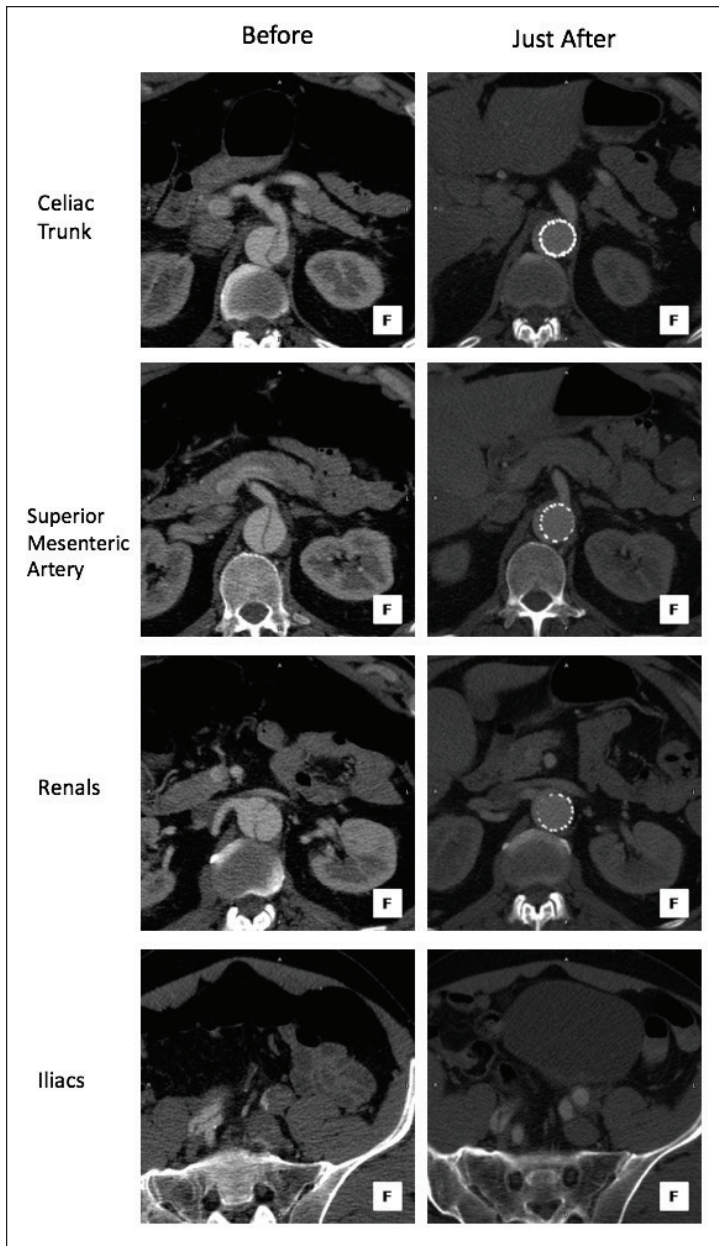


Figure 1. Images of a patient treated for acute complicated TBAD with the STABLE technique. In the left column, slices of the preoperative CTA show collapse of the true lumen along the aorta beyond the thoracoabdominal junction. In the right column, slices of the immediate postoperative CTA exhibit a satisfying opening of the true lumen scaffolding by the bare-metal stent toward the abdominal aorta.

endovascular treatment of an acute complicated type B dissection, with available CT at baseline and at 12 months: one group was treated with TEVAR alone ($n = 45$) at three high-volume institutions in Lille, France; Caen, France; and Malmö, Sweden; the other group was treated with

the PETTICOAT strategy ($n = 39$) in the STABLE I study.¹¹ A thorough morphological analysis of the aorta, including changes in aortic volumes, was conducted through 1 year, and details of the initial and secondary procedures were collected.

During the initial procedure, the length of aorta covered by the endograft within the descending thoracic aorta was comparable in both groups (184.0 ± 48.7 mm in TEVAR alone vs 166.6 ± 47.2 mm in STABLE; $P = .11$). In terms of clinical outcomes at 1 year, the reintervention rates were similar between the two groups (11.1% in TEVAR alone vs 12.8% in STABLE). In terms of aortic remodeling results, while both groups showed significant remodeling in the thoracic aorta (true lumen increase and false lumen decrease in aortic volume), we observed some differences in the abdominal aorta. Only the STABLE group exhibited a statistically significant increase in true lumen volume at the level of the abdominal aorta, most prominently seen on the postoperative as compared to the preprocedure CT scans ($P < .001$), as well as from postprocedure to 1 year ($P = .035$), while the changes within the TEVAR alone group were not statistically significant. When compared between the two groups, the overall change in the true lumen volume from preprocedure to 1 year was greater in the STABLE group (16 cm^3) than in the TEVAR group (10 cm^3) but was not statistically significant ($P = .10$).

From these results, we hypothesized that this early benefit of true lumen expansion in the abdominal aorta, in relation to the implantation of a bare self-expandable stent in the true lumen, could have an impact on the outcomes of patients presenting with malperfusion at onset (Figure 1). We thus conducted the study described thereafter.

MALPERFUSION

We performed a second post hoc comparative analysis focusing on short-term outcomes of two patient groups treated for acute TBAD with malperfusion (imaging findings and/or clinical signs) diagnosed at onset.¹² The first group ($n = 41$; from Lille, France and Malmö, Sweden) was treated with TEVAR alone, whereas the second group ($n = 84$; from both the STABLE I and STABLE II studies) was treated with the composite device design.

At presentation, comparable organ system involvement in malperfusion was depicted, and both groups showed

similar lengths of dissection and similar locations of the proximal and distal aspects of the dissection. The STABLE patients presented with a higher American Society of Anesthesiologists class, greater prevalence of renal insufficiency, and worse preoperative hypertension and renal function status (according to Society for Vascular Surgery scores) compared with the TEVAR patients. Both groups received a median of one stent graft component (range, 1–2 for TEVAR alone vs 1–3 for STABLE; $P = .66$). Additional selective stenting of visceral and renal branches was required in 46% of TEVAR patients and 30% of STABLE patients after endograft deployment ($P = .08$).

The 30-day mortality rate in the STABLE group was half of that in the TEVAR group, but this difference was not statistically significant (8.3% [7/84] vs 17.1% [7/41]; $P = .22$). Malperfusion-related mortality, defined as deaths caused by bowel/mesenteric ischemia or multiple organ failure, was statistically lower in the STABLE group (2.3% [2/84] vs 12.2% [5/41]; $P = .038$). The 30-day rates of morbidity such as renal failure requiring dialysis, bowel ischemia, and neurologic events were similar between the groups, as were the 30-day rates of secondary interventions (7.3% for TEVAR alone and 7.1% for STABLE group). Similar to findings from our earlier aortic volume study, the amount of true lumen diameter increase was statistically significantly greater in the STABLE group than in the TEVAR group in the abdominal aorta ($P < .001$) but not in the thoracic aorta ($P = .835$).

CONCLUSION

Our volume analysis comparing TEVAR and STABLE showed no statistically significant difference in terms of overall aortic remodeling at 1 year, but the STABLE cohort showed a significant increase of true lumen volume in the abdominal aorta postoperatively. This more prominent true lumen expansion in the distal aorta was also observed at postprocedure in the composite device group in our second study focusing on acute type B dissections in the setting of malperfusion and may have contributed to alleviation of branch vessel malperfusion. In this study, TEVAR + bare-metal stenting showed a twofold reduction in all-cause early mortality, albeit statistically insignificant, and statistically significantly lower 30-day malperfusion-related mortality in patients with acute TBAD with malperfusion compared to TEVAR alone.

Our results suggest that aortic bare-metal stenting in addition to endografting of the proximal descending thoracic aorta should be proposed for patients with malperfusion at onset to improve early survival. Larger cohorts and prospective randomization of patients to both treatment options would be required to confirm these results. ■

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