The SAVE RITA trial at 5 years: More evidence is needed to transform a vein to an artery

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Mario Gaudino, MD (left), and Stephen E. Fremes, MD (right).

In this issue of *The Journal of Thoracic and Cardiovascular Surgery*, Kim and colleagues¹ report the angiographic results of the Saphenous Vein Versus Right Internal Thoracic Artery as a Y-Composite Graft (SAVE RITA) trial at 5 years. Kim and colleagues¹ are to be commended for carrying out an angiographic randomized trial with excellent midterm follow-up.

The study was conceived with the aim of evaluating the hypothesis that saphenous vein (SV) grafts are noninferior to right internal thoracic artery grafts when used as a Y composite proximally anastomosed to the left internal thoracic artery (LITA) graft. The SV grafts were not manually distended but were allowed to dilate when exposed to arterial pressure. The SAVE RITA trial proposes that as the SV is anastomosed to the proximal part of the LITA, vascular mediators produced by the artery can protect the vein from development of atherosclerosis. In addition, the SV is exposed to a different pattern of circulatory stress than when attached directly to the aorta. It is of note, however, that the site of proximal anastomosis (aorta vs LITA) has been shown not to affect the patency rate of other conduits, such as the radial artery and the right internal thoracic artery itself.^{2,3} Another key aspect of the trial is that all patients underwent an off-pump, no-touch, anaortic operation. Revascularization performed without aortic manipulation has been reported to be associated with fewer cerebral events.⁴

The SAVE RITA trial was planned as a noninferiority trial, with what we consider to be a large noninferiority margin of 8%. A smaller, more clinically acceptable difference would have required a larger sample size. In fact, similar trials aimed at assessing the difference in patency between an arterial and a venous conduit had much larger sample sizes.^{5,6} In addition, Kim and colleagues¹ analyzed the patency data such that the unit of analysis was the distal anastomosis, with the assumption that the anastomoses are independent of one another. This is clearly false, because

grafts within each patient have 2 levels of dependence—one at the patient level and another at the graft level (because all grafts were composite and sequential). A more conservative statistical approach would have required a larger sample size as well. Finally, with 186 subjects, this analysis is clearly largely underpowered to detect even large differences in clinical events, and the study therefore must be viewed as purely descriptive in this regard.

In conclusion, the 5-year analysis of the SAVE RITA is a nice description of the midterm patency rate of SV grafts proximally anastomosed to the LITA. The use of a systematic anaortic technique is commendable. Arteriovenous composite grafting remains a bail-out option for most surgeons. This study suggests that very good results can be achieved when a minimally manipulated SV graft is used, although the use of SV extensions should be avoided. Replication of these results in larger studies and longer clinical and angiographic follow-up of the SAVE RITA patients are obviously needed before wider adoption is recommended for patients with other grafting options.

Central Message

SAVE RITA trial reports good results of vein grafts proximally anastomosed to internal thoracic artery; however, methodologic limitations preclude conclusions on the comparison with other conduits.

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