DETRIMENTAL IMPACT OF ENDOSCOPIC VEIN HARVESTING: A WORD OF CAUTION

To the Editor:

We read with interest the article from Zenati and the coinvestigators¹ of the Randomized On/Off Bypass (ROOBY) trial about a secondary analysis on the population enrolled in such trial and reporting that endoscopic vein harvesting (EVH) is independently associated with vein graft failure and higher revascularization rates at 1 year. Nevertheless, such analysis yields consistent drawbacks and its conclusions should be carefully interpreted.

First, the mentioned study is not a prospective randomized trial aiming at the analysis of the endoscopic technique versus the open approach. In fact, it was a randomized, controlled, single-blind study comparing patients undergoing nonemergency coronary artery bypass grafting, either on-pump or off-pump. Therefore, any insight about the endoscopic technique was only obtained as a secondary analysis. As such, as is widely known, it may yield consistent limitations, despite the corrections obtained by complex statistical analysis.

Another major drawback of the study is related to the complete lack of information about the device used for EVH, that is a carbon dioxide-sealed (like the VasoView system [Maquet Inc, Rastatt, Germany]) or open system (like the Storz [Karl Storz GmbH & Co KG, Tuttlingen, Germany] or Sorin [Sorin S.p.A., Milan, Italy] system). In fact, as in any surgical technique, it is mandatory to describe the system used (either open or closed) to address any proper conclusion. One could argue that since the ROOBY trial was conducted in the United States, where the VasoView system is more popular, such device could have been used in the majority of cases, albeit no proper data are available. Nevertheless, the authors cited a manuscript by Rousou

and associates² reporting that EVH has a detrimental effect on the saphenous vein endothelium, which may lead to decreased graft patency and worse patient outcomes. It is mandatory to stress that such article refers exclusively to a sealed system (ie, the VasoView system) and its related damage.

Another critical limitation of the study is related to the fact that residual clot strands in EVH have been demonstrated to occur exclusively with sealed systems (thereby jeopardizing graft patency) and that preheparinization significantly reduces such risk³; however, no patients received such treatment according to the data provided in the ROOBY trial. It can also be inferred from the article that there was a high degree of variability in terms of operators' expertise, as the authors themselves outlined. Finally, no information has been provided about the site of EVH (either the thigh or the calf, the former being an easier site for the endoscopic technique); such information could have provided considerable insights about potential discrepancies occurring between the size of the graft used and the target vessel.

Therefore, given the aforementioned flaws, a conclusive statement about the detrimental impact of EVH on graft patency should not be drawn based on the results from the ROOBY trial.

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Reply to the Editor:

Bisleri, Cheema, and Muneretto take objection to the conclusion of our study¹ and propose that a "conclusive statement about the detrimental impact of EVH [endoscopic vein harvesting] on graft patency should not be drawn based on the results from the ROOBY trial." The issue of compromised late vein graft patency associated with EVH was first raised by the PREVENT-IV Investigators in their 2009 report (1-year vein graft patency: EVH = 76% vs open = 81%).² Subsequently, Puskas and associates³ confirmed this finding in their subanalysis of the EPIC trial (9 months of vein graft patency: EVH = 79% vs open = 91%). Our study was approved by the Veterans Affairs Cooperative Studies Program (CSP) #517 Executive Committee in 2002 as a preapproved subanalysis of the ROOBY trial⁴ because of a potential safety concern with EVH. The findings we reported (1-year vein graft patency: EVH = 74% vs open = 86%) fit within the existing literature and are meant to provide a word of caution related to using the EVH approach. We have already acknowledged all of the limitations of our analyses raised by Bisleri, Cheema, and Muneretto in the "Methods" and "Discussion" sections of our report. We believe that this timely letter provides additional support to the need for future rigorous randomized controlled trials: we are currently in the advanced planning phase for a large, multicenter randomized controlled

trial titled “Randomized Endovein Graft Prospective (REGROUP) Trial” sponsored by the Veterans Affairs CSP #588, to definitively address the issue of safety associated with EVH.

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