EVIDENCE FOR EFFICACY OF OFF-PUMP CORONARY ARTERY BYPASS SURGERY: FACTS AND FADS

To the Editor:

We recently read the reply to the Editor by Benedetto and associates,¹ highlighting fundamental issues concerning meta-analyses. Interestingly, in an attempt to justify that meta-analyses of randomized controlled trials (RCTs) are the gold standard evidence to address controversial issues, they knowingly or unknowingly claim that “no RCT has ever confirmed the benefits of beating-heart coronary surgery implied by observational studies.”¹ Unfortunately, this claim from learned researchers like Benedetto and associates is contrary to the current best available evidence.²

Off-pump coronary artery bypass (OPCAB) surgery, since its resurgence in the early 1990s, has remained a highly scrutinized technique. The past decade was an era of trials and tribulations for OPCAB with more than 100 RCTs, over 300 observational studies, 60 propensity score analyses, and same number of meta-analyses of RCTs, as well as observational and propensity matched studies verifying every aspect and outcome of OPCAB. There is overwhelming evidence from both meta-analyses of RCTs as well as propensity score analyses to confirm safety and efficacy of OPCAB.^{2,3} The majority of these RCTs and meta-analyses have shown that outcomes of OPCAB are either comparable or superior to on-pump coronary artery bypass surgery.^{2,3} In fact, OPCAB is associated with reductions in the risks for stroke (50%), atrial fibrillation (30%), wound infection (48%), and acute kidney injury (70%). OPCAB also reduces transfusion and inotrope requirements, ventilation time, intensive care unit and hospital stays, and in-hospital and 1-year direct costs.^{2,3}

There is no denying the fact that, whereas there is abundant evidence in

favor of OPCAB, there is also evidence that fails to show convincing benefits of OPCAB.⁴ In view of the conflicting evidence, there is a need for the cardiac surgical community to call for a forum and make specific recommendations. If it is agreed that the evidence is against OPCAB, then those performing such procedures should stop because they are affecting the quality of care of thousands of patients worldwide.⁵ If, on the other hand, it is agreed that the evidence for benefit of OPCAB is conclusive, then the implications are of a different order. However, until a verdict is reached, as responsible researchers and physicians it is important that we adopt an unbiased approach to analyze the available information's content for consistency, coherence, and clarity, thereby differentiating facts from fads.

Shahzad G. Raja, MRCS,
FRCSEd(C-Th)

Mohamed Amrani, PhD, FETCS
Department of Cardiac Surgery
Harefield Hospital
London, United Kingdom

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IF WE ARE UNCRITICAL, WE SHALL ALWAYS FIND WHAT WE WANT

To the Editor:

We thank Raja and associates for their comments on our recent letter to

Editor.¹ In that letter, we observed that in observational studies comparing radial artery versus saphenous vein graft, the better patency rate observed for radial artery is surely biased by native vessel quality. Randomization avoids this important limitation. We stated that the dangerous effect of selection bias has also emerged in observational studies reporting beating-heart bypass advantages over on-pump surgery, which were not confirmed in randomized controlled trials.² Apparently, Raja and associates did not like the latter statement.

However, this is not a personal point of view but a fact that every physician may read in a widely quoted international cardiovascular journal.² It is obvious that in surgical series, beating-heart bypass has been preferentially adopted when good quality target vessels were present. This aspect has heavily biased results in retrospective analysis even when propensity analysis was adopted.

Results coming from randomized controlled trials that compare not similar but “exactly” the same patients reached the following conclusions as reported in widely quoted journals:

- No significant difference between off-pump and on-pump coronary artery bypass grafting in the rate of the 30-day composite outcome; the overall rate of graft patency was lower in the off-pump group than in the on-pump group.³
- No major differences in 30-day outcomes in high-risk patients randomized to off-pump versus on-pump coronary bypass surgery: the Best Bypass Surgery Trial.⁴
- Coronary artery bypass grafting performed off-pump had lower overall graft patency rate than on-pump. Thirty-day complications, neuropsychologic functioning, and 1-year clinical and functional outcomes were not statistically different between the 2 techniques.⁵

Every surgeon who routinely perform beating-heart bypass should be conscious about these results, make the patients aware, and discuss with them the opportunity to perform beating-heart bypass.

Sometimes, journals with a low impact factor tend to publish works with less reliable conclusions.⁶

Karl Popper, one of the most influential philosophers of science of the 20th century, said: "If we are uncritical we shall always find what we want: we shall look for, and find, confirmations, and we shall look away from, and not see, whatever might be dangerous to our pet theories."⁷

Umberto Benedetto, MD
Giovanni Melina, MD
Emiliano Angeloni, MD
Riccardo Sinatra, MD
University of Rome Sapienza
II Faculty of Medicine
Department of Cardiac Surgery
Rome, Italy

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ENDOSCOPIC VERSUS OPEN SAPHENOUS VEIN HARVEST TECHNIQUE IN THE RANDOMIZED ON/OFF BYPASS (ROOBY) TRIAL

To the Editor:

We read with interest the article by Zenati and colleagues¹ describing the results of endoscopic versus open saphenous vein harvest technique on coronary artery bypass grafting (CABG) outcomes.¹ The authors performed a subgroup analysis of the Randomized On/Off Bypass (ROOBY) trial, designed to evaluate differences in clinical outcomes between patients undergoing on- and off-pump CABG.² Of the 2203 patients recruited into the original trial, 1471 (66.8%) had conduit data recorded and 894 (40.6%) had angiographic follow-up at 1 year. These latter 2 groups formed the basis of the subgroup analysis, in which the authors found inferior rates of saphenous vein graft patency and increased repeat revascularization rates in the endoscopic vein harvest (EVH) group.

This interesting article has some limitations that should be considered.

1. Learning curve. The study began in 2002, when EVH uptake in the United States was low (<10%). The variability in experience levels, the effect of the learning curve, and the potentially low number of cases per institution or practitioner should be considered when interpreting these findings.
2. Technical details. Data regarding technical details during conduit harvest and intraoperative flow characteristics were unfortunately not recorded during this study and may have an effect on graft patency.
3. Selection bias. The primary purpose of the study was not to compare vein harvest techniques. Surgeons were encouraged to use whichever harvesting technique they preferred, and a selection bias may exist with unmeasured

confounders affecting surgeons' decision to use an EVH approach.

4. Repeat revascularization rates. The authors provide minimal insight into the potential reasons for the observed increased revascularization rates in the EVH group. It is interesting to note that in the whole population studied (n = 1414), there was no difference in revascularization rates between the EVH and open vein harvest groups (5.2% vs 3.5%, *P* = .13). Were the revascularizations symptom-driven or simply the result of an "occulo-stenotic reflex"? If the latter is true, then indeed the clinical relevance of the finding of increased saphenous vein graft occlusion in the EVH group is unclear. Furthermore, recent evidence from a large observational trial using both multivariable- and propensity-adjusted analyses actually shows a survival advantage and no increase in revascularization rates with the EVH technique.⁵
5. Literature review. Finally, at least 2 important articles examining the long-term clinical impact of EVH were omitted in the discussion. Our group recently published a large observational study showing no association between EVH and midterm freedom from death or readmission to hospital for cardiac catheterization, repeat revascularization, acute coronary syndromes, or heart failure.³ Allen and colleagues⁴ found no difference in 5-year outcomes in a small but randomized study.

We do strongly agree with the authors' conclusions that the time has come for a large prospective, randomized study examining both angiographic and clinical outcomes in patients undergoing CABG with open or endoscopic saphenous vein harvesting. It will be important for such a trial to have strict protocols regarding EVH technique and the experience of the vein harvester, and some