coronary surgeons has already failed once, and would fail again.

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See Article page 591.

Commentary: Coronary surgery ART and two tablets for a headache

Chaim Locker, MD

The ART (Arterial Revascularization Trial)¹ investigators submit another post-hoc study with important insights from the trial. They investigated one of the more controversial subjects in coronary surgery: outcomes of off-pump versus on-pump coronary artery bypass grafting (CABG). They compared 1252 patients who underwent off-pump CABG with 1699 on-pump CABG patients enrolled in the ART.² Ninety-five percent of patients completed 10 years of follow-up. The authors used propensity matching (1078 pairs of patients) and mixed-effect Cox model to compare long-term outcomes between the 2 groups. They concluded that in the ART, off-pump CABG patients had similar risk of death over 10 years and similar risk of the composite of death, myocardial infarction, stroke, and repeat revascularization compared with on-pump CABG patients. Moreover, they claim that the equipoise between off-pump versus on-pump surgery was not influenced by the use of bilateral internal thoracic artery (BITA) and multiple arterial grafting versus single internal thoracic artery (SITA).

The authors should be commended for this investigation for several reasons. The quality and quantity of the data are undoubtedly excellent. The authors are world-renowned

From the Department of Cardiovascular Surgery, Mayo Clinic, Rochester, Minn. Disclosures: Author has nothing to disclose with regard to commercial support. Received for publication March 1, 2020; accepted for publication March 3, 2020; available ahead of print March 19, 2020.

Address for reprints: Chaim Locker, MD, Department of Cardiovascular Surgery, Mayo Clinic, 200 First St SW, Rochester, MN 55905 (E-mail: lekerlocker.chaim@mayo.edu).

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Chaim Locker, MD

CENTRAL MESSAGE

In the ART off-pump and on-pump CABG are associated with similar long-term outcomes. The insights from the ART are very important and reflect the need to define coronary surgery as a subspecialty.

experts in coronary surgery, and the quality of analysis and the construction of the manuscript are outstanding. Moreover, their courageous investigation and thoughtful analysis may indicate on some additional flaws in the construction and pre-set of the ART, but alternatively, could be considered as important contributing insights to “real-life practice.”

However, there are some questions and comments to be raised:

1. The authors present superb results of the off-pump group with: (1) comparable number of grafts >3 in the off-pump versus on-pump group. (2) Only 2.5% conversion rate from off-pump to on-pump surgery. (3) Rates of 3-vessel-disease and “worse quality of native vessels” were more prevalent in the off-pump group. (4) BITA grafts were more likely to be used in the off-pump group, which is unexpected for itself, and as previously shown

in the ART, was an overall technical challenge, with a high and surprising 14% crossover rate from BITA to SITA group, and maybe confounding the ART's results. Hence, it seems that the surgeons performing off-pump surgeries in ART were very experienced in coronary surgery and experts in off-pump surgery. If so, can we draw practical conclusions based on this study and generalize this message to everyday practice? External validity is a major issue for all randomized clinical trials in general, and ART is of no exception, but those outcomes should still be cautiously inspected.

2. The major criticism on the ROOBY (Randomized On/Off Bypass) trial³ was presumably the lack of experience of surgeons performing the off-pump operations. The CORONARY⁴ and the GOPCAB⁵ trials showed that by experienced off-pump surgeons, all differences in outcomes were mitigated between the 2 techniques. Indeed, follow-up was only up to 5 years, and the current study extends follow-up to 10 years, which is important. However, it seems that previous studies reflected extremes of inexperience versus expertise in off-pump surgery. Importantly, of 159 surgeons in the ART, 98 surgeons performed only on-pump cases, 40 surgeons performed both, and 21 surgeons performed only off-pump surgery. Moreover, from the stratification into 5 subgroups for "individual surgeon off-pump volume," there were 118 patients operated off-pump by low off-pump volume surgeons, and 232 patients operated on-pump by high-volume off-pump surgeons. In addition, the lack of information on the reasons for preferring off-pump over on-pump technique and vice versa among surgeons in ART raises the question why a surgeon who is routinely performing only on-pump CABG switches to off-pump surgery and vice versa? A change in surgeon's regular practice reflects unusual circumstances that would turn the procedure into greater risk with all resulting consequences, no matter the reason, unless he would be 1 of the 40 surgeons routinely performing both operations. Hence, to mitigate bias, wouldn't it be prudent to investigate only the 40 surgeons performing comfortably both techniques? Unfortunately, those performed an average of 21 cases with greater prevalence of on-pump surgery, and there were very few surgeons with the same proportion of off-pump and on-pump surgeries, whereas most of the off-pump surgeries were performed by surgeons who did a very limited number of on-pump surgeries, and therefore the sample of such "ideal" analysis would probably be underpowered for interpretation. Of note, the majority of off-pump surgeries in ART were actually performed by a very restricted number of surgeons.
3. As the ART was not designed to compare off- versus on-pump surgery, an individual surgeon's off-pump experi-

ence before being recruited in trial was not recorded. Therefore, the authors decided to use the total number of off-pump cases performed in ART as a proxy of off-pump experience and used the 75th percentile of off-pump volume distribution as index of experience (>10 off-pump procedures within ART). One could argue with this questionable definition but not with the superb results of those surgeons, which speak for themselves and probably validate this definition.

4. It is intriguing if the expertise in off-pump surgery in ART reflects a marker to overall expertise in coronary surgery and if the crossover rate from BITA to SITA in this subgroup of off-pump surgeons was as low as the low conversion rate from off to on-pump surgery. This might also explain the increased rate of cardiovascular death in patients receiving SITA versus BITA? The authors found that high off-pump volume surgeons were more likely to perform BITA grafting using off-pump technique. This is surprising, since BITA grafting, particularly if sequential ITA grafts are needed, is more difficult to perform without cardiopulmonary bypass, especially if extensive atherosclerotic disease is present. For low-volume off-pump surgeons, the use of pump technique did not influence the use of BITA or SITA grafting, while interestingly, surgeons performing on-pump CABG only presented the lowest rate of BITA grafting.
5. Although no significant interaction terms were uncovered in both studies, it is puzzling that in the ART, in the "as-treated" analysis of patients, the 10-year survival rate in the multiple arterial group was significantly better compared with the SITA group (adjusted hazard ratio [HR], 0.81; 95% confidence interval, 0.68-0.95), but when stratified by on-pump versus off-pump surgical technique in the current study, multiple arterial grafting did not show any 10-years survival advantage between groups.
6. When performed by low-volume off-pump surgeons, off-pump surgery resulted in a significantly lower number of grafts and high conversion rates and was associated with a significantly increased risk adjusted incidence of cardiovascular death (HR, 2.4) and stroke (HR, 4.0) at 10 years. This makes sense, is probably the major message of this investigation that confirms results obtained from previous studies, and emphasizes the importance of expertise in coronary surgery. It seems that the previous and current published invaluable insights from the ART (although non-randomized), may be more important than its indecisive final outcome. Those are further emphasizing the fact that coronary surgery is a specialized operation that in experienced hands produces superior outcomes.

Coronary surgery is a subspecialty. It requires expertise and a combination of technical skills that if you don't own them, you may disservice your patients. Skeletonized

meticulous harvest of the BITA conduits to the appropriate length and quality,⁶ the use of arterial conduits in various configurations without limiting yourself only to the in situ grafting configuration, capability of performing both off-pump and on-pump CABG at the same proficiency level when required, all those including others, are not just “recommendations” any more but incumbent prerequisites upon a coronary surgeon.

Finally, the openly well-discussed flaws in the ART as well as the recent striking discoveries with the controversial EXCEL (Evaluation of the Xience Everolimus-Eluting Stent vs Coronary Artery Bypass Surgery for Effectiveness of Left Main Revascularization)⁷ trial opened a narrow loophole reflecting somewhat on the quality and fragility of scientific randomized clinical trials. Physicians should have the integrity to explore flaws in their clinical conduct as well as in their clinical research, so patients could rely upon their actual surgical capabilities, unbiased clinical judgment, and on authoritative medical guidelines based on accurate and well-designed research, as perfectly recently stated: “We’re not talking about 2 tablets for a headache. We’re talking about people dying.”⁸

See Article page 591.

Check for updates

Commentary: Off-pump coronary arterial bypass grafting, a demanding instrument only for a master?

Sung Jun Park, MD, and Joon Bum Kim, MD, PhD

On-pump conventional coronary arterial bypass grafting (CABG) surgery has been a gold standard for surgical

From the Department of Thoracic and Cardiovascular Surgery, Asan Medical Center, University of Ulsan College of Medicine, Seoul, South Korea.

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Address for reprints: Joon Bum Kim, MD, PhD, Department of Thoracic and Cardiovascular Surgery, Asan Medical Center, University of Ulsan College of Medicine, 88, Olympic-Ro-43-Gil, Songpa-Gu, Seoul, Korea 05505 (E-mail: jbkim1975@amc.seoul.kr).

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Joon Bum Kim, MD, PhD (left), and Sung Jun Park, MD (right)

CENTRAL MESSAGE

As off-pump CABG seems to obtain comparable long-term outcomes with on-pump surgery only when performed by experts, structured training platforms need to be developed and organized.