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Percutaneous Coronary Intervention or Coronary Artery Bypass Graft for Unprotected Left Main Coronary Artery Disease: The Endless Debate

The "state-of-the-art" paper written by Taggart et al. (1) calls into question the current evidence in support of percutaneous coronary intervention (PCI) for the treatment of unprotected left main stem disease. In view of the fact that current guidelines still indicate coronary artery bypass grafting (CABG) as the "standard of care," the authors conclude that the use of drug-eluting stents (DES) in "off-label" cases should be discouraged and that good surgical

with revascularization up to 24 months, and in the TOSCA-2 (Total Occlusion Study of Canada) trial (24), a substudy of the OAT study, there was a trend toward more favorable remodeling.

The results of the OAT study do not prove or disprove the benefits of late revascularization in patients similar to the patients in the OAT study and certainly do not apply to the entirety of post-AMI patients. Unfortunately, despite the efforts of investigators like the OAT Investigators, only 3,560 patients have been randomized to date, and they may not be enough to draw meaningful conclusions and/or identify subgroups of patients with greatest benefit or risk from late revascularization.

We thank Dr. Džavik and colleagues for this opportunity to clarify that our analysis was not designed to prove or disprove the findings of the OAT study, which likely applies to a minority of patients after AMI. Instead, we set out to analyze all available evidence and demonstrated the benefit of late revascularization of the IRA late after AMI.

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candidates with unprotected left main coronary artery (ULMCA) disease should undergo surgical revascularization. These conclusions, although absolutely reasonable, raise 2 questions: 1) Is CABG really proven to perform better than PCI in this subset of patients? 2) Is CABG to be recommended in all good surgical candidates?

In an attempt to justify their conclusion, the authors presented 6 studies conducted in patients with ULMCA disease who had undergone CABG. Of note, none of these studies had clinical follow-up periods of longer than 2 years, and only 2 out of 6 had a clinical follow-up longer than 1 year (Lu et al. [2] and Yeatman et al. [3]). The mortality rate of 5% to 6% reported by these studies is truly encouraging. However, the authors did not mention the impressive occurrence of post-procedural morbidity in these patients. In the study conducted by Lu et al. (2) on 1,197 patients who underwent CABG for ULMCA, the rates of in-hospital adverse events were the following: mortality 2.8%, renal failure 3.9%, gastrointestinal complications 3.6%, stroke 2.2%, post-procedural myocardial infarction 7.1%, reopening for bleeding 2.8%, sternal wound infection 4.2%, chest infection 5.3%, ventilation >48 h 6%, stay after operation >14 days 9.3%. The incidence of death in patients undergoing CABG for ULMCA disease was reported to be 11.3% at 1 year in the Cleveland Clinic Foundation Data (4), 12.8% at 3 years in the New York Bypass Surgery Registry (5), 13.2% at 5 years in the study conducted by d’Allonnes et al. (6), and 22.6% at 5 years in the Duke Cardiology Database (7). These results are far worse than those reported by the authors and do not appear to be superior to those reported in several PCI studies.

In discussing the experience with bare-metal stents (BMS), the authors presented the results from earlier PCI studies that enrolled almost exclusively high-risk patients. The “poor” late outcomes after ULMCA stenting with BMS are compared with the excellent results obtained in the SoS (Stent or Surgery) trial. This comparison of “apples versus pears,” i.e., left main disease in high-risk patients versus 2- to 3-vessel disease in stable patients, is not a proper scientific argument. In that specific study, the comparison between CABG and PCI resulted in no statistically significant differences in terms of death, myocardial infarction, or stroke at 1-year follow-up (8). With regard to DES implantation, the authors describe a selection of studies that presents an important nonhomogeneity in terms of trial design: consecutive (e.g., Valgimigli et al. [9], Lee et al. [10]) vs. selective (de Lezo et al. [11]) patient enrollment and, in some studies, the use of DES was not exclusive (e.g., approximately 40% of patients from the Bologna Registry received BMS). Moreover, the authors did not take into account the importance and influential outcomes of the various stenting techniques used for distal left main disease.

It therefore seems difficult to draw any conclusions from the pooling of these results and, furthermore, compare them with the outcomes obtained in the surgical literature. In the DELFT (Drug Eluting stent for LeFT main) registry (12), the 3-year incidence of cardiac death, target vessel revascularization, and major adverse cardiovascular events (MACE) in the elective subgroup was 6.2%, 16%, and 30.5%, respectively. Recent studies conducted on patients with ULMCA who underwent surgical revascularization reported a similar incidence of death, a lower incidence of TVR, but an apparently greater incidence of MACE (9,13).

Additionally, it was noted by the authors that distal left main disease is a major and independent predictor of MACE at mid-term follow-up (9) and argued that: “the precise anatomical location and complexity of left main stenosis . . . have negligible influence on the success of CABG.” Two issues deserve further clarification with respect to this statement: 1) In patients undergoing PCI, distal left main disease is associated with a higher risk for reintervention but not necessarily death or myocardial infarction, which are predominantly affected by surgical risk status. 2) To the best of our knowledge, there are no data supporting the notion that outcomes after surgery are not affected by the location of the lesion within the left main stem. Distal left main disease may simply be a marker of severe, diffuse coronary disease and, as such, carry with it a worse prognosis irrespective of the final revascularization strategy.

In all major institutions, current standard approach to patients presenting with significant ULMCA disease is to have them evaluated by both interventional cardiologists and cardiac surgeons and to reach the decision to opt for PCI or surgery by consensus, on the basis of: 1) hemodynamic conditions; 2) lesion characteristics; 3) vessel size; 4) the presence of comorbidities; 5) quality of arterial and/or venous conduits for grafting; and 6) patient and/or referring physician preferences. Patients are always fully informed about the potential risks and outcomes of both the surgical and the percutaneous approaches. Stating that “patients are influenced into making a pre-ordained choice” and that cardiologists “instigate” patients in making these choices is speculative.

Should all good candidates for surgery go to surgery and poor candidates to PCI? So far, there is no strong evidence that one approach is better than the other in terms both of clinical outcomes and quality of life (QoL). A recent meta-analysis by Bravata et al. (14) of 23 randomized controlled trials showed no difference between PCI and CABG in terms of mortality at 10 years’ follow-up. Health-related QoL is of particular value in coronary artery disease, because the objective of intervention is not only to avoid clinical adverse outcomes but also to relieve symptoms and improve function and ability to participate in daily activities. Long-term studies comparing QoL related to these 2 therapeutic strategies are not available but the results coming from the available literature reported so far no major differences (15–18).

Current guidelines still recommend surgical revascularization as the primary procedure in ULMCA patients, but considering them as “the body of criminal law” is not always appropriate. Guidelines are dynamic and in constant flux and have to be updated according to new evidences coming from clinical experience, and not vice-versa. It is important to realize that new-generation DES approved for clinical use, new technical strategies, and prolonged dual-antiplatelet treatment have significantly decreased the risk of adverse events (including late in-stent thrombosis) after PCI.

Randomized clinical trials are necessary to shine a light on this endless debate. The LEMANS trial (19) is the only reported randomized trial comparing PCI versus CABG for ULMCA disease. The increased short-term complication rate in the CABG group appeared to be minimized by stressing similar 1-year MACE results in the 2 groups. Moreover, no late in-stent thrombosis occurred both in the BMS and in the DES groups, demonstrating that percutaneous treatment of ULMCA is safe.

Results of the complete SYNTAX (TAXUS Drug-Eluting Stent Versus Coronary Artery Bypass Surgery for the Treatment of Narrowed Arteries) study, which enrolled 700 randomized patients with ULMCA disease, will be presented at the 2008 European Society of Cardiology congress. Until then, judicious individual assessment of each patient should prevail, that is to say, we should keep trying to...
treat patients—that do not fit in the current recommendations—according our current clinical experience and judgment.

“On the mountains of truth you can never climb in vain: either you will reach a point higher up today, or you will be training your powers so that you will be able to climb higher tomorrow.”

Friedrich Nietzsche (20)

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We are grateful to Dr. Meliga and colleagues for their interest in our article (1). They raise several important issues that we will address in a similar order.

The first issue deals with mortality and morbidity after coronary artery bypass grafting (CABG). As referenced in our article (1), the mortality for all 5,003 patients with left main stem stenosis undergoing CABG in the United Kingdom in 2003 was 3% (and <2% in 17,000 without left main stem [LMS] stenosis and 1% in 3,102 patients in the ART [Arterial Revascularisation] trial). Because enough is known about post-CABG complications, risk models have been developed to reliably predict their occurrence, whereas similar data are quite lacking in the percutaneous coronary intervention (PCI) domain.

In addition, although all postoperative morbidity is unsatisfactory, the reality is that, with the exception of stroke (1% to 2%), most of it is self-limiting and of little consequence to the patient over the long term. To equate early postoperative morbidity to the reduced survival and marked increase in the need for reintervention with PCI over the long term is arguably a false economy. Furthermore, long-term mortality from CABG (as well as PCI) may also reflect other co-existing morbidities, rather than being attributable to ischemic heart disease.

With regard to bare-metal stents, we stated explicitly that superior results were obtained in lower-risk patients and that, as for CABG, the results of PCI would also be disadvantaged by greater-risk patients. Although Dr. Meliga and colleagues state that there was no significant difference in mortality between CABG and PCI in the soS (Stent or Surgery) trial at 1 year, it should be noted that, at 5-year follow-up in this study (2), there was a significant reduction in the risk of mortality with CABG (6.6%) versus PCI (10.9%), reinforcing the well-known observation that the benefit of CABG often accrues with time. We agree with Dr. Meliga and colleagues that substantial heterogeneity among drug-eluting stent trials precludes pooling them together. Accordingly, we did not perform a meta-analysis. Our aim was simply to present all the published studies in the literature.

The complexity and precise anatomical location of distal left main stem disease, along with its frequently associated multivessel coronary disease, is not relevant during CABG because bypass and coronary artery bypass graft surgery. Ann Intern Med 2007;147:703-16.


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