

EDITORIAL

Left Main Coronary Artery Disease in the new 2021 ACC/AHA/SCAI Guideline for Coronary Artery Revascularization: A word of criticism.

Ovidio A. García-Villarreal.

Mexican College of Cardiovascular and Thoracic Surgery. Monterrey, Nuevo Leon, MEXICO.

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Much attention has been lately focused on the importance of using ever-increasing less invasive approaches to treat heart diseases. In view of PCI being an off-pump procedure, it is imperative that we increase our understanding of it, by studying the correct meta-analyses designed for this purpose. In addition, it is almost inevitable that in an era of reliance on technology as an important adjunct as trouble shooter, coupled with any potential bias, that there is a need to examine a comprehensive view of the new 2021 ACC/AHA/SCAI Guideline for Coronary Artery Revascularization [1].

Every effort should be made to fully consider all the implications and effects of the several Classes of Recommendation (COR) contained in this new Guideline. The magnitude of change in the use of this kind of technology, such as PCI recommended by this Guideline, will set a pattern for the manner in which coronary artery disease (CAD) will be approached in the upcoming years.

By the same token, these cutting-edge technologies respect no boundaries and have evolved into a global dimension. Deployment of new technologies such as stents and other tools for PCI may be developments arising from a myriad of novel challenges in clinical practice, but their consequences must be painstakingly analyzed. Each of these concepts has their own unique attributes and distinctive considerations. Thus, it is totally understandable that designing and developing new technologies without examining all major potential implications, will ultimately limit the effectiveness of such procedures.

That said, the main concern is regarding the issue of left main (LM) CAD. The new 2021 ACC/AHA/SCAI Guideline for Coronary Artery Revascularization literally says “in selected patients with stable ischemic heart disease and significant LM stenosis for whom PCI can provide equivalent revascularization to that possible with CABG, PCI is reasonable to improve survival”. In this setting, the COR for the use of PCI is 2a. This observation is based on a single reference [2]. In this reference, the authors analyzed 12 studies comparing CABG with PCI, and of 7 studies comparing CABG with medical therapy by means of using a Bayesian method, in terms of only 1-year mortality. For PCI vs CABG, no difference among randomized clinical trials was found (OR,0.99; 95% Bayesian CI, 0.67-1.43). In the case of medical therapy compared to PCI, the former was associated with higher 1-year mortality (OR, 3.22; 95% Bayesian CI, 1.96-5.30). Hence, the authors conclude that PCI, “like CABG,” improves survival in patients with LM CAD [2]. It should be emphasized that the results investigated were exclusively 1-year mortality. Thus, the efficacy of this study to act as a reference for the COR 2a for PCI in LM CAD is questioned, as the conclusion is totally unfounded. Moreover, several authors have negatively criticized this Bayesian analysis.

Ye and Zang [3] have identified several irregularities in this network meta-analysis. Firstly, it is impossible to assess the statistical consistency of this analysis, given the fact that there was no direct comparison between PCI and medical therapy groups. Secondly, a significant heterogeneity between trials was identified regarding age, sex and medical therapy in the medical treatment group. Even when a meta-regression was applied to analyze the confounding effect, its statistical power is quite insufficient, due to the inclusion of only a few studies and some covariates which could not be adjusted. Thus, the validity of this network meta-analysis with a lack of true consistency, is insufficient. A word of

Corresponding author: Dr. Ovidio A. García-Villarreal
email: ovidiocardiotor@gmail.com

caution on the final results in this meta-analysis should be highlighted, especially with respect to their impact on the current guidelines [3].

According to Diamond [4], the equivalence of CABG and PCI, as suggested by Bittl et al. [2] is not supported by the analysis. There is a relative difference in the mortality ranges in favor of CABG over PCI, both in the hierarchical interval (39% vs 26%) and in the crossover design (45% vs 32%), respectively. The author also states that we would be compelled to assume that the treatments are equivalent, only if the mortality differences are less than those considered clinically important (ranging between $\pm 5\%$ and $\pm 10\%$). By this token, for the reported hierarchical interval, CABG and PCI are equivalent with only 27% probability ($\pm 5\%$) and 51% probability ($\pm 10\%$). In the case of reported cross-design interval, the treatments are equivalent with 22% probability ($\pm 5\%$) and 44% probability ($\pm 10\%$). For this reason, the equivalence between CABG and PCI cannot be supported any longer. The COR as 2a for PCI to treat LM CAD based upon this assumption, is both vague and misleading.

Brophy has also criticized the Bayesian analysis by Bittl [5]. When the EXCEL trial results, alone or in combination with those from SYNTAX, PRECOMBAT and NOBLE, are analyzed with the Bayesian methodology, the information obtained suggests that PCI is associated with lower long-term results than CABG in patients with LM CAD for all

events, including mortality [4]. In stark contrast with the analysis by Bittl [2], this study by Brophy included all RCTs from January 1996 to January 2020, comparing CABG to PCI for treatment of patients with LM CAD, considering 5-year follow-up data and not just those at 1-year mortality.

In conclusion, as more and more attention is being directed towards a higher COR for PCI over CABG, it is high time to consider the necessity to review this detail and its significance in the new Guideline for Coronary Artery Revascularization [1]. As we have shown throughout these comments, there is not enough evidence to support COR 2a for PCI in LM CAD, based only on the inference that "PCI, like CABG" improves survival compared with medical treatment. This may ultimately have clinical as well as legal implications in our daily practice routine and should be revised accordingly [6].

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REFERENCES

1. Lawton JS, Tamis-Holland JE, Bangalore S, Bates ER, Beckie TM, Bischoff JM, Bittl JA, Cohen MG, DiMaio JM, Don CW, Fremes SE, Gaudino MF, Goldberger ZD, Grant MC, Jaswal JB, Kurlansky PA, Mehran R, Metkus TS Jr, Nnacheta LC, Rao SV, Sellke FW, Sharma G, Yong CM, Zwischenberger BA. 2021 ACC/AHA/SCAI Guideline for Coronary Artery Revascularization: A Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. *Circulation*. (2021);CIR000000000001038. doi: 10.1161/CIR.0000000000001038.
2. Bittl JA, He Y, Jacobs AK, Yancy CW, Normand SL; American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines. Bayesian methods affirm the use of percutaneous coronary intervention to improve survival in patients with unprotected left main coronary artery disease. *Circulation*. 2013;127(22):2177-85. doi: 10.1161/CIRCULATIONAHA.112.000646.
3. Ye Y, Zhang S. Letter by Ye and Zhang regarding article, "Bayesian methods affirm the use of percutaneous coronary intervention to improve survival in patients with unprotected left main coronary artery disease". *Circulation*. 2014;129(4):e307. doi: 10.1161/CIRCULATIONAHA.113.004523.
4. Diamond GA. Letter by Diamond regarding article, "Bayesian methods affirm the use of percutaneous coronary intervention to improve survival in patients with unprotected left main coronary artery disease". *Circulation*. 2014;129(4):e308. doi: 10.1161/CIRCULATIONAHA.113.004321.
5. Brophy JM. Bayesian Interpretation of the EXCEL Trial and Other Randomized Clinical Trials of Left Main Coronary Artery Revascularization. *JAMA Intern Med*. 2020;180(7):986-992. doi: 10.1001/jamainternmed.2020.1647.
6. García-Villarreal OA. Professional Medical Liability, Lex Artis, Medical Malpractice, and Guidelines for the Clinical Practice. The importance of adhering to the current Clinical Guidelines in the daily practice. *Cir Card Mex* 2021; 6(3): 75-8.