EDITORIAL

Fractional Flow Reserve Guided PCI as Compared with Coronary Bypass Surgery. *"BUT will they respect it?"*

The great enemy of the truth is very often not the lie – deliberate, contrived, and dishonest – but the myth – persistent, persuasive, and unrealistic.

- John Kennedy –

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Palabras clave: Revascularización coronaria; Enfermedad arterial coronaria; Intervención coronaria percutánea.

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I have read the article that was recently published on New England Journal of Medicine by Fearon et al. [1]. It is a multicenter, international, noninferiority trial, in which patients with three-vessel coronary artery disease were randomly assigned to undergo Coronary Artery Bypass Graft (CABG) or Fractional Flow Reserve Guided (FFR-guided) Percutaneous Coronary Intervention (PCI) with current-generation zotarolimus-eluting stents. The primary end point was the occurrence within 1-year of a major adverse cardiac or cerebrovascular event, defined as death from any cause, myocardial infarction, stroke, or repeat revascularization. Noninferiority of FFR-guided PCI to CABG was prespecified as an upper limit of less than 1.65 for the 95% confidence interval of the hazard ratio. Secondary end points included a composite of death, myocardial infarction, or stroke; safety was also assessed.

A total of 1500 patients underwent randomization at 48 centers. Patients assigned to undergo PCI received a mean (±SD) of 3.7 ± 1.9 stents, and those assigned to undergo CABG received 3.4 ± 1.0 distal anastomoses. The 1-year incidence of the composite primary end point was 10.6% among patients randomly assigned to undergo FFR-guided PCI and 6.9% among those assigned to undergo CABG (HR, 1.5; 95% CI, 1.1 to 2.2), findings that were not consistent with noninferiority of FFR-guided PCI (P=0.35 for noninferiority).

The incidence of death, myocardial infarction, or stroke was 7.3% in the FFR-guided PCI group and 5.2% in the CABG group (HR, 1.4; 95% CI, 0.9 to 2.1). The incidence of major bleeding, arrhythmia, and acute kidney injury was higher in the CABG group than in the FFR-guided PCI group.

They concluded that patients with three-vessel coronary artery disease, FFR-guided PCI was not found to be noninferior to CABG with respect to the incidence of a composite of death, myocardial infarction, stroke, or repeat revascularization at 1-year of follow-up.

It is important to mention what the current guidelines tell us about such of these cases. The European guidelines for myocardial revascularization, PCI is a class 1A recommendation for the treatment of patients with three-vessel disease and a low SYNTAX score (≤ 22). For those with an intermediate-to-high SYNTAX score, however, PCI is not recommended (class III). In contrast, CABG surgery is a class 1A recommendation in patients regardless of SYNTAX score [2].

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On the other hand, the American guidelines for the treatment of stable ischemic heart disease, CABG is a class 1 recommendation (level of evidence B) for the treatment of patients with three-vessel disease, with the guidelines stating "it is reasonable" to choose CABG over PCI in patients with complex three-vessel CAD (SYNTAX score > 22) who are good candidates for surgery. PCI, in this setting, is a IIb recommendation, meaning it is "of uncertain benefit" [3].

In others studies the event curves start separating at 2 to 3 years. In SYNTAX, there was no difference at 1 year. In EXCEL, there was no difference, same with NOBLE. In FREEDOM, it took 2 or 3 years for the curves to separate. So, the curves will spread over time, particularly for those higher-complexity patients [4-7].

When reviewing the graph of this study, it is easy to realize how in one year the curves are already separated. So, if we take the evidence from this trial, as well as from previous trials, it is a very convincing result that confirms the superiority of CABG versus PCI in three-vessel coronary artery disease. Now, the patients undergoing CABG had a mean of 4.2 lesions and received a mean of 3.4 distal anastomoses; 97% received a left internal thoracic artery graft, and 25% received multiple arterial grafts. The question is: what improvement will there be if we use more arterial grafts? We need to do it!

The results obtained would require prospective randomized trials to validate. However, it is important that is only about 1-year data, the curves will spread over time, particularly for those higher-complexity patients. If at 1-year there is already this benefit from surgery, I think that is supportive of a surgical approach in these patients.

This study provides both physicians and patients more contemporary data and information about options and expected outcomes in patients with multivessel disease. The current trial involved routine measurement of FFR to guide PCI, with the expectation that the use of FFR would lead to more judicious stenting — that is, an FFR-guided strategy would result in PCI being used to treat only functionally significant lesions, which have been shown to be associated with higher rates of adverse events when treated with medications alone, and would avoid unnecessary stenting of non–flow-limiting lesions, which respond as well to medical therapy alone as they do to PCI (and may even respond better to medical therapy alone).

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