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## Comments about REVIVED-BCIS2 Trial

### Comentários sobre o REVIVED-BCIS2 Trial

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REVIVED-BCIS2 Trial (ClinicalTrials.gov number NCT01920048) is a multicenter clinical trial that enrolled 700 patients with ventricular dysfunction and ischemic cardiomyopathy,<sup>1</sup> and compared percutaneous coronary intervention (PCI) with optimal medical therapy (OMT). The primary endpoint was all-cause death or hospitalization due to heart failure (HF), in a mean follow-up of 3.4 years.

The results showed no difference between the groups as to the primary endpoint.

The secondary endpoints were as follows: ejection fraction after 6 months and 1 year, quality of life, death, hospitalization due to HF (isolated components of the primary endpoint), acute myocardial infarction (MI), unplanned revascularization, levels of N-terminal B-type natriuretic peptide (NT-proBNP) fragments, angina class according to the Canadian Cardiovascular Society (CCS), major bleeding and costs. The only parameter that was different and favorable to PCI was the need for unplanned revascularization, which was four-fold higher in the OMT group (2.9% versus 10.5%; hazard ratio – HR – 0.27; CI95% 0.13-0.53).

The study is very interesting and has unarguable merits. However, studies involving PCI and OMT often have limitations, and some have been discussed by the authors, others mentioned in an excellent editorial,<sup>2</sup> and a few more we identified after a critical reading of the article. The result of these considerations is summarized below:

1. The study did not determine the agreement between the revascularized coronary arteries and the viable myocardial segments. It is known this is almost impossible to assess without invasive physiology, but this method was not employed in the study. Therefore, the authors concluded they could not affirm that the viability tests predicted changes in segment contractile function after OMT or PCI, or even if these changes were related to clinical outcomes; this issue has already been discussed in COURAGE.<sup>3</sup>
2. There were 37 less outcomes than expected in the clinical trial. This caused an impact in the statistical power of the sample, that is, instead of an 85% power of the test to detect an HR of 0.70, at 5% significance, the test power dropped to 82%. Even though, given the HR for the primary endpoint (0.99) and 95%CI, the probability of type II error is low.
3. Follow-up time is crucial in this type of study, since the positive effects sometimes will only be observed after 5 to 10-year follow-up, as demonstrated by the STICH trial,<sup>4</sup> which compared surgery with OMT in ischemic cardiomyopathy.
4. The researchers should have described the anatomical location/extension of the coronary disease and its correlation with physiological tests in more detail. Was the degree of cardiomyopathy appropriately explained by the present atherosclerotic disease? Half of the patients in this study presented only two-vessel disease, and only two lesions and two vessels were treated, in average, per patient. This is not the ideal scenario, when revascularization is expected to improve ventricular function.
5. Considering the benefit in mortality obtained in STICH, it is very probable that the patients with more extensive and significant coronary disease in REVIVED have been referred to coronary artery bypass graft and excluded from the study. Such limitation may have hindered the beneficial effect of treatment.

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6. A more appropriate study design would address the lesions of all recruited patients by invasive physiology assessment, which would enable a more precise correlation between lesion and ischemia, and consequently, lesion and viability.
7. It draws attention that in the OMT group, 37 patients (10.5%) were revascularized during follow-up (29 by PCI and 8 by coronary artery bypass graft), whereas in the PCI group, only 10 patients (2.9%) required another revascularization. This accounts for almost four times more revascularized patients in the OMT group. In the article, the authors did not discuss to what extent the difference in the amount of unplanned revascularizations could have influenced in the primary endpoint.

### FINAL CONSIDERATIONS

This clinical trial supports the increasingly growing importance of using drug therapy oriented by the most updated guidelines to treat ischemic ventricular dysfunction, regardless of patients being revascularized or not.<sup>2</sup> This had already been demonstrated in the ISCHEMIA trial<sup>5</sup> and, mainly in analysis of subgroups of this study, which enrolled 398 patients with ejection fraction between 35% and 45%, there was a clear benefit of revascularization over OMT after a 4-year follow-up.<sup>6</sup>

Other considerations can only be inferred after a long-term follow-up of these patients, which will allow better evaluation of the impact of revascularization in clinical

outcomes. Further studies are warranted, mainly with a more precise approach of the anatomical and functional assessment of coronary lesions and their correlation with ischemia and ventricular dysfunction.

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