

About the Use of DES (Drug-Eluting Stents) in Real Life: the Importance of Registries

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We read with great interest the excellent review article written by Expedito Ribeiro and Henrique B. Ribeiro¹, in the July 2010 Archives. The review is a conclusive answer to the main questions that gave rise to such review: a) is the benefit of drug eluting stents (DES) in reducing the rate of target vessel revascularization as robust in the real world as in randomized trials? b) Is DES safe when used for off-label indications in comparison with bare-metal stents (BMS)?

I know that this was not the intention of the authors, but the uninformed reader might conclude, in light of the title and table of registries, that DES reduce mortality when compared to non-DES. Even though the registries are useful, they are obviously an inferior methodology when we compare procedures, since they are likely to have selection biases and confounding factors that even the best adjusting techniques cannot eliminate. The data of a registries led to the hypothesis, now disproved, that DES would increase mortality

in comparison with BMS in the so-called “real world”. It is also in view of registries that many people consider that cardiac surgery is superior to percutaneous coronary intervention for endpoint with mortality, but this is something that has also been progressively disproved.

The data mentioned of the DESIRE study also demonstrated that it is impossible to use registries as a means of comparison between DES and BMS: patients using DES were older, had more diabetes and had undergone revascularization procedures more frequently, while those using BMS had acute myocardial infarction. We can speculate that other factors, such as the presence of unstable angina, severe comorbidities, socioeconomic status, difficulty in using antiplatelet drugs and greater size of vessels affected, could be more present in the BMS group. Due to all of the foregoing, the comparison between DES and BMS in such registry is a virtually impossible task.

Meta-analyses of randomized trials are the gold standard for comparison between procedures and the main article mentioned itself shows² that there was no difference in mortality between DES and BMS, whether in on-label indications or in off-label indications.

Keywords

Drug-eluting stents/utilization.

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References

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Reply

In response to the letter to the editor about the article published in: *Arq. Bras. Cardiol.* 2010; 95 (1) [Brazilian Archives of Cardiology]: 131-134, “*Uso de stents farmacológicos na ‘vida real’: a importância dos registros*” [“use of drug-eluting stents in ‘real life’: the importance of records”], we provide the following justification:

“We appreciate the comments about our article. They were very pertinent and emphasize the importance of the topic. Since the initial experience with conventional stents (bare-metal stents) compared with balloon angioplasty alone, it has been evident that stents did not cause a reduction in mortality, but rather a reduction in acute complications and restenosis. Drug-eluting stents (DES) have come to further

improve the outcome of percutaneous coronary intervention, especially by reducing restenosis. However, after the beginning of widespread use of DES, the Swedish publication, knowledgeably mentioned in the comment, raised the possibility that there could be an increase in mortality mainly due to the increase in late and very late thrombosis with DES. However, this was not confirmed by subsequent studies. Even the recent meta-analyses cited by us show significant reduction in re-interventions in randomized trials and registries, with a decrease in mortality also being shown in such records.

We agree with the fact that we cannot draw definitive conclusions from nonrandomized trials, such as registries, due to the inherent limitations cited. However, it was demonstrated that, in general, the stents drastically reduced the rates of acute complications and restenosis. Moreover, drug-eluting stents are safe and their results are even better in the case of restenosis, making it possible to reduce re-intervention.”

Henrique B. Ribeiro