

Angioplasty versus Medical Treatment in Oligosymptomatic Patients: Is It Time to Stop it?

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The long-awaited BARI 2-D¹ study has just been published in the New England Journal of Medicine. In the part that would be of interest to cardiologists, 2,368 patients with type 2 diabetes and coronary artery disease were randomized into two groups: optimal treatment for diabetes, and revascularization therapy, either by surgery or angioplasty. The randomization was performed independently of the selecting of optimal therapy for each patient, which was left at the discretion of the physicians; the study was not a comparison between angioplasty and surgery.

Analyzing the publication of supplements, we observed that most patients were mildly symptomatic. Of the total, 17% were asymptomatic; and 21.4% did not have angina, but what the researchers considered to be an “angina equivalent”. Of the patients with angina, most were in functional class I or II; only 8.6 % were in angina class III or IV; and only 9.5% had unstable angina. Demonstrating the predominantly non-surgical conditions of the patients, only 17% had an ejection fraction of less than 50%; only 30% had three-vessel disease; and only 13% had a proximal left anterior descending artery obstruction. It was thus a sample of patients with generally minor angiographic changes, in many of whom myocardial revascularization, by any method, would be questionable: surgical revascularization would be questionable because they did not meet the traditional angiographic indication criteria (left main, three vessels with poor ventricular function, or three vessels with proximal left anterior descending obstruction); and coronary angioplasty would be questionable because they were diabetic, and especially because they were mildly symptomatic. The results were as the expected by anyone accompanying such studies over the past 27 years²⁻⁸. The 5-year mortality was 11.7% in the revascularization therapy group, and 12.2% in the clinical treatment group (NS). There was no difference in major events, deaths, heart attacks, or

strokes: 22.8% in the revascularization group, and 24.1% in the clinical treatment group (NS). Angioplasty did not reduce mortality (10.8% versus 10.2%) or events (21.1% versus 23%). Surgery has not significantly reduced mortality (13.4% versus 16.4%), although it has reduced events (22.4% versus 30.4%), possibly because it was indicated for a subgroup of patients with more extensive lesions.

On learning the results of the study, the American Society of Interventional Cardiology issued a statement reminding that drug-eluting stents are the best option for diabetics with coronary artery disease, and that they have been used in a minority (30%) of patients. Actually the limited use of drug-eluting stents may have contributed to the poor outcome of angioplasty in terms of reducing events, but not in terms of reducing mortality. Moreover, there is evidence of the existence of subgroups of stable patients in whom the benefits of PCI were higher than those found in the patients of the Bari-2D study⁹. But it is worth questioning something much simpler: Does this study add anything to what we already know? After the results of six randomized studies (seven with the COURAGE study, totaling more than 5,000 patients) which uniformly showed no benefit of angioplasty in patients with mild symptoms, why test it once more in patients with so few symptoms, often non-surgical patients, and with the aggravating circumstance of diabetes? Given all that is already known, hasn't the time come to stop randomized studies like this, especially when confronted with the certainty that the clinical judgement tend to better separate the treatment options as universally agreed and already proven by the MASS II study¹⁰.

Before a new, large and expensive study comparing coated stents with medical treatment in similar patients is conducted, these questions must be answered.

Key words

Angioplasty; therapeutics; drug-eluting stents; oligosymptomatic patients.

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References

1. The BARI 2D Study Group. Frye RL, August P, Brooks MM, Hardison RM, Kelsey SF, et al. A randomized trial of therapies for type 2 diabetes and coronary artery disease. *N Eng J Med.* 2009; 360 (24): 2503-15.
2. Hueb WA, Bellotti G, Oliveira SA, Ariè S, de Albuquerque CP, Pileggi F. The Medicine angioplasty or surgery study (MASS): a prospective, randomized study for single proximal left anterior stenosis descending artery stenosis *J Am Coll Cardiol.* 1995; 26 (7): 1600-5.
3. Parisi AF, Folland ED, Hartigan P. A comparison of angioplasty with medical therapy in the treatment of single-vessel disease. *N Eng J Med.* 1992; 326 (1): 10-6.
4. Folland ED, Hartigan PM, Parisi AF. Percutaneous transluminal coronary angioplasty versus medical therapy for stable angina pectoris. *J Am Coll Cardiol.* 1997; 29 (7): 1505-11.
5. Coronary angioplasty versus medical therapy for angina: the second randomized intervention treatment of angina (RITA-2) trial participants. *Lancet.* 1997; 350 (9076): 461-8.
6. Pitt B, Waters D, Brown WV, van Boven AJ, Schwartz L, Title LM, et al. Aggressive lipid-lowering therapy compared with angioplasty in stable coronary artery disease. *N Eng J Med.* 1999; 341 (2): 70-6.
7. Hueb W, Soares PR, Gersh BJ, Cesar LAM, Luz PL, Puig LB, et al. The medicine, angioplasty, or surgery study (MASS-II): a randomized, controlled clinical trial of three therapeutic strategies for multivessel coronary artery disease: one-year results. *J Am Coll Cardiol.* 2004; 43 (10): 1743-51.
8. Boden WE, O'Rourke RA, Teo KK, Hartigan PM, Maron DJ, Kostuk WJ, et al. Optimal therapy for stable coronary disease. *N Eng J Med.* 2007; 356 (15): 1503-16.
9. Schomig A, Mehilli J, Waha A, Waha A, Seyfarth M, Pache J, et al. A meta-analysis of 17 randomized trials of a percutaneous coronary intervention-based strategy in patients with stable coronary artery disease. *J Am Coll Cardiol.* 2008; 52 (11): 894-904.
10. Pereira AC, Lopes NH, Krieger JE, Oliveira SA, Cesar LA, Ramires JA, et al. Clinical judgment and treatment options in stable multivessel coronary artery disease: results from the one year follow up of the MASS II. *J Am Coll Cardiol.* 2006; 48 (5): 948-53.