Efficacy and Effectiveness of Multivessel Coronary Revascularization in Diabetic Patients

To the Editor,

Cardiovascular disease is the leading cause of death in diabetic patients. Results from recent large clinical trials with drug-eluting stents or the combination of antiplatelet aggregators have shown an improved prognosis in these patients. Coupled with technological development, this has led to an increase in the number of revascularized patients, both percutaneously and surgically. Nevertheless, doubt exists as to whether these therapeutic improvements apply to patients seen in daily practice, given the limitations associated with clinical trials, eg, selected populations and little external validity. In fact, we still do not know whether efficacy translates into effectiveness, which highlights the need for well-designed registries and studies with "non-selected patients" in order to complete the scientific information that is already available.

We studied 344 diabetic patients with multivessel disease who were revascularized consecutively between 2000 and 2004, analyzed in studies by our group[1,2]: 132 with surgery, 104 with drug-eluting stents, and 108 with conventional stents. We attempted to determine the percentage of patients who fulfilled the inclusion criteria for large clinical trials on revascularization in diabetic patients,[3-6] defined by: age <80 years, ejection fraction >35%, no prior history of angioplasty or coronary surgery, no disease of the left common trunk, or the impossibility to treat percutaneously or surgically. We studied the clinical, angiographic and prognostic differences compared with our potentially eligible diabetic patients.

Just 153 (44.5%) patients would have been eligible to participate in a clinical trial: 61% of the surgical patients, 50% of those treated with drug-eluting stents and 42% of those treated with conventional stents. The causes of exclusion were: age >80 years (2.3%), depressed ejection fraction (15%), prior coronary surgery (5.5%), prior angioplasty (7%), left coronary artery disease (16%) and being unable to receive either of the two treatments (41.3%). The eligible patients were younger (65.4 vs 67.3 years; P=.02), less often had renal insufficiency or heart failure, and had a lower additive EuroSCORE (3.9 vs 5.8; P<.01), less angiographic severity (SYNTAX score) and a greater ejection fraction (58% vs 47.5%; P<.01); these patients also had greater rates of complete revascularization than the patients who would not have been eligible. After a follow-up of 24 months, the mortality was higher in the non-eligible patients (15.6% vs 6.9%; P=.017), with no significant differences concerning non-fatal AMI (6.7% vs 6.9%) or the need for revascularization (11.3% vs 13.9%).

In the SYNTAX study,[7] 70% of the patients included in the angioplasty registry (excluded from the general clinical trial) were there because of accompanying disorders compared with 70% of the patients in the surgery registry, who had complex anatomies. The patients in the angioplasty registry had a worse clinical and angiographic profile than those included in the trial: older age, more insulin-dependent diabetic patients and patients with chronic obstructive pulmonary disease, and greater EuroSCORE and SYNTAX scores. The results are similar to those found in our series, with a greater rate of combined events at one year in the registry (20.4% vs 17.8%), at the expense of mortality (7.3% vs 4.4%).

In conclusion, over half the diabetic patients with multivessel disease in our series failed to fulfill the criteria to participate in a clinical trial. The group of patients that were not eligible had a more complex clinical and angiographic profile and prognosis was worse in terms of medium-term mortality.

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