

Use of stent angioplasty in patients with acute myocardial infarction

Uso de stent en la angioplastia del paciente con infarto agudo de miocardio

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To the Editor:

We read with interest the article by Drs Gómez Recio and Lázaro García¹ published in CorSalud, and do not agree with their approach because of the controversy on this issue, which is why the following comments are issued.

In the section related to acute myocardial infarction (AMI) it is stated that recent studies suggest there is no benefit of drug-eluting stent (DES) on bare metal stents (BMS) in the context of patients with ST-segment elevation myocardial infarction (STEMI) undergoing percutaneous coronary intervention (PCI).

In this sense, an analysis of the evidence found on the subject has been carried out, where researchers converge and diverge on several points. There is much debate about the safety of DES use regarding BMS in STEMI patients; this is due to the risk of stent thrombosis (StT) the treatment of prolonged dual antiplatelet therapy and patient adherence to treatment.

In 2010, the MISSION² trial and SESAMI³ at 3 years and PASEO⁴ at 4, showed similar death and reinfarction rates when the use of DES vs. BMS was compared in STEMI patients, with less need for repeat revascularization with DES. This evidence was considered by the American College of Cardiology (ACC) and American Heart Association (AHA) as they moved the indication of primary PCI with DES from class IIb to IIa⁵.

The results at 5 years of PASON⁶ trial showed that the main variables: major adverse cardiac and cere-

brovascular events (MACCE), recurrent infarction and target lesion revascularization (TLR), were comparable in DES (18, 6%) and BMS (21.8%) [hazard ratio (HR): 0.82, confidence interval (CI) 95 %: 0.8 to 1.18, p = 0.28] , the incidence of probable or definite StT was 4.2 % with DES and 3.4% with BMS, and concluded that there were no differences in MACCE, or StT, while the very late StT was observed only with DES.

A systematic review of MEDLINE, EMBASE and Cochrane Central databases on the efficacy and long-term safety (> 3 years) between DES and BMS, in STEMI patients, showed that DES significantly reduced need for target vessel revascularization (TVR), with no increase in mortality, reinfarction, and total StT, but with increased very late StT.

The article cited by Gómez Recio and Lázaro García¹ comparing the safety and efficacy of first-generation DES to BMS in the context of STEMI is a meta-analysis of 15 randomized controlled trials with more than 7,850 patients, the results were similar in probable and definite StT, while the overall analysis showed a less frequent TVR with DES, and a greater benefit in the first year after implantation. The benefit of this first generation of DES in primary PCI is reduced TVR and a lower tendency towards less definite StT, with increased risk of StT as time goes by⁸.

Wallace *et al.*⁹ in a meta-analysis of eight randomized clinical trials evaluated the long-term results (≥ 3 years) of first-generation DES (sirolimus or paclitaxel)

compared to BMS in STEMI and found that the use of the former was associated with less TLR [odds ratio (OR): 0.48, CI: 0.37 to 0.61], TVR (OR 0.53, CI 0.42 to 0.66) and MACCE (OR 0.69, CI 0.56 to 0.84), and StT incidence was not different between the two groups (OR 1.02, CI 0.76 to 1.37). These authors concluded that treatment with first-generation DES decreased the need for revascularization without increasing StT, mortality or recurrent AMI. De Lucas *et al.*¹⁰ reported similar results in another meta-analysis of 15 trials with 6,200 patients, where DES and BMS were compared in the same context set out above, and found that DES implantation significantly reduced the occurrence of TVR [12.7 vs. 20.1 %, HR (95 % CI): 0.57 (0.50 to 0.66), $p < 0.001$], with no significant differences in terms of mortality, reinfarction and StT, but with increased very late thrombosis.

DEBATER¹¹ registry, that compared the use of DES (sirolimus) and BMS in STEMI, both with abciximab and without it, was a prospective, randomized trial where the main variables were: MACCE, repeat revascularization and bleeding. The results at one year showed that MACCE were lower in the sirolimus DES group (16.5 vs. 25.8 %; $p = 0.001$), mainly due to less need for revascularization (9.8 vs. 16.8 %; $p = 0.003$), while abciximab reduced early StT at the expense of major bleeding complications (5.7 vs. 2.8 %; $p = 0.03$).

In 2013 the Journal of the American College of Cardiology published a meta-analysis of Palmerini *et al.*¹² which included 22 trials with 12,453 patients, and aimed to compare clinical outcomes in relation to safety and efficacy of first and second generation DES in STEMI patients. The results at one year showed that cobalt-chromium everolimus-eluting stent (CoCr-EES) was significantly associated with fewer cases of cardiac death, reinfarction, and StT than the BMS, and likewise CoCr-EES were associated with fewer cases of StT than paclitaxel DES, and sirolimus DES were associated with fewer cases of cardiac death and reinfarction than BMS. With these types of DES there was less need for repeat revascularization than with BMS, although the existence of very late StT persisted.

Distal embolization of thrombus fragments causing STEMI reduces myocardial reperfusion during PCI, which affects the capillaries and is associated with a worse long-term prognosis. In this line of research the MGuard stent was born, covered with a polyethylene mesh on the outer surface that hits the thrombus against the vessel wall and reduces distal emboli-

zation.

The MICAMI-MGUARD¹³ trial assesses the efficacy of this stent in the prevention of distal embolization compared with BMS; microvascular reperfusion criteria were: TIMI flow grade [acronym derived from the TIMI Study Group (Thrombolysis In Myocardial Infarction), created by Eugene Braunwald in 1984, used to designate the level of coronary flow during angiography], myocardial blush and corrected final TIMI. TIMI flow grade was similar in both groups and improved myocardial blush was observed in the MGuard group compared with BMS (mean 3.0 vs. 2.5; $p = 0.006$). Meanwhile, Costa *et al.*¹⁴ in the MASTER trial compared the complete ST-segment resolution ($\geq 70\%$) at 60-90 minutes after primary angioplasty by using BMS or DES in the control arm and MGuard stent in the other. Major secondary endpoints were resulting TIMI flow and myocardial blush. They concluded that the MGuard stents reduced distal embolization and increased myocardial perfusion compared with stents routinely used in primary angioplasty.

The COCHISE¹⁵ pilot trial included 223 consecutive STEMI patients randomized to primary PCI with open or closed cells stents. The major primary endpoint was the final corrected TIMI flow after the procedure, and it was found that the use of closed-cell stent was associated with improved coronary flow after PCI.

It has been traditionally considered that BMS restenosis is a stable lesion presented as a neointimal proliferation in the first 4-6 months, but the recent theory of neoatherosclerosis as the active mechanism responsible for much of restenosis and late stents thrombosis has emerged¹⁶. Histological studies have shown that while the neoatherosclerosis is a process common to BMS and DES, its incidence is higher and early in DES. Nevertheless, detection of risk lesions (thin capsule fibroatheromas and broken plaques) is more prevalent in BMS restenosis and appears in the majority of patients after 5 years of implantation¹⁷.

Moreover, in an analysis of PASSION¹⁸ trial the long-term clinical results after thrombus aspiration or conventional treatment with DES or BMS in primary PCI were assessed, and it was concluded that thrombus aspiration showed no differences at 2 years from the usual stenting technique for cardiac death, recurrent infarction and TLR (13.0 vs. 13.5%, HR: 0.96, CI: 95% 0.62 to 1.47, $p = 0.84$). Escaned *et al.*¹⁹ analyzed a series of STEMI patients treated with primary PCI, where only thrombus aspiration was

performed resulting in a significant reduction in the degree of thrombosis [$5 - 1$; (0 to 1.75) , $p < 0.001$], in the percentage of coronary stenosis (87.2 ± 21.3 to 11.3 ± 0.9 , $p < 0.001$) and in an increase of final TIMI flow [0 (0-2) 3 (3-3) $p < 0.001$] and of minimum luminal diameter (0.89 ± 1.01 to 2.42 ± 0.7 mm, $p < 0.001$). The no-reflow phenomenon was observed in only 2 patients. This series suggests that treatment with thrombus aspiration alone can be effective in selected cases, although these results should be validated in larger trials with better designs. In the INFUSE-AMI trial Stone *et al.*²⁰ randomized patients with occluded anterior descending artery into 4 groups (TIMI flow of 0, 1 or 2): intracoronary abciximab and then thrombus aspiration, abciximab without aspiration, aspiration without abciximab and the remaining without abciximab or aspiration, and found that infarct size in these patients at 30 days was significantly reduced with the use of intracoronary abciximab, but not with thrombus aspiration.

We consider the setting in which care and patient individualization are performed is a parameter to be used for the proper selection of the type of stent or the right technique in STEMI patients. The proper interpretation of the existing flood of scientific evidence and the proper monitoring of well-designed trials are more useful tools.

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