OSSERVATORIO SIFO DISPOSITIVI MEDICI

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Intra-aortic balloon counterpulsation and infarct size in patients with acute anterior myocardial infarction without shock: the CRISP AMI randomized trial.

Patel MR, Smalling RW, Thiele H, Barnhart HX, Zhou Y, Chandra P, Chew D, Cohen M, French J, Perera D, Ohman EM.

CONTEXT: Intra-aortic balloon counterpulsation (IABC) is an adjunct to revascularization in patients with cardiogenic shock and reduces infarct size when placed prior to reperfusion in animal models.
OBJECTIVE: To determine if routine IABC placement prior to reperfusion in patients with anterior ST-segment elevation myocardial infarction (STEMI) without shock reduces myocardial infarct size.
DESIGN, SETTING, AND PATIENTS: An open, multicenter, randomized controlled trial, the Counterpulsation to Reduce Infarct Size Pre-PCI Acute Myocardial Infarction (CRISP AMI) included 337 patients with acute anterior STEMI but without cardiogenic shock at 30 sites in 9 countries from June 2009 through February 2011.
INTERVENTION: Initiation of IABC before primary percutaneous coronary intervention (PCI) and continuation for at least 12 hours (IABC plus PCI) vs primary PCI alone.
MAIN OUTCOME MEASURES: Infarct size expressed as a percentage of left ventricular (LV) mass and measured by cardiac magnetic resonance imaging performed 3 to 5 days after PCI. Secondary end points included all-cause death at 6 months and vascular complications and major bleeding at 30 days. Multiple imputations were performed for missing infarct size data.
RESULTS: The median time from first contact to first coronary device was 77 minutes (interquartile range, 53 to 114 minutes) for the IABC plus PCI group vs 68 minutes (interquartile range, 40 to 100 minutes) for the PCI alone group (P = .04). The mean infarct size was not significantly different between the patients in the IABC plus PCI group and in the PCI alone group (42.1% [95% CI, 38.7% to 45.6%] vs 37.5% [95% CI, 34.3% to 40.8%], respectively; difference of 4.6% [95%

CI, -0.2% to 9.4%], P = .06; imputed difference of 4.5% [95% CI, -0.3% to 9.3%], P = .07) and in patients with proximal left anterior descending Thrombolysis in Myocardial Infarction flow scores of 0 or 1 (46.7% [95% CI, 42.8% to 50.6%] vs 42.3% [95% CI, 38.6% to 45.9%], respectively; difference of 4.4% [95% CI, -1.0% to 9.7%], P = .11; imputed difference of 4.8% [95% CI, -0.6% to 10.1%], P = .08). At 30 days, there were no significant differences between the IABC plus PCI group and the PCI alone group for major complications (n = 7 [4.3%; 95% CI, 1.8% to 8.8%] vs n = 2 [1.1%; 95% CI, 0.1% to 4.0%], respectively; P = .09) and major bleeding or transfusions (n = 5 [3.1%; 95% CI, 1.0% to 7.1%] vs n = 3 [1.7%; 95% CI, 0.4% to 4.9%]; P = .49). By 6 months, 3 patients (1.9%; 95% CI,0.6% to 5.7%) in the IABC plus PCI group and 9 patients (5.2%; 95% CI, 2.7% to 9.7%) in the PC I alone group had died (P = 12). CONCLUSION: Among patients with acute anterior STEMI without shock, IABC plus primary PCI compared with PCI alone did not result in reduced infarct size	
Lancet. 2011 Sep 10;378(9795):997-1005 **Bronchoscopic lung-volume reduction with Exhale airway stents for emphysema (EASE trial): randomised, sham-controlled, multicentre trial.** Shah PL, Slebos DJ, Cardoso PF, Cetti E, Voelker K, Levine B, Russell ME, Goldin J, Brown M, Cooper JD, Sybrecht GW; EASE trial study group. BACKGROUND: Airway bypass is a bronchoscopic lung-volume reduction procedure for emphysema whereby transbronchial passages into the lung are created to release trapped air, supported with paclitaxel-coated stents to ease the mechanics of breathing. The aim of the EASE (Exhale airway stents for emphysema) trial was to evaluate safety and efficacy of airway bypass in people with severe homogeneous emphysema. METHODS: We undertook a randomised, double-blind, sham-controlled study in 38 specialist respiratory centres worldwide. We recruited 315 patients who had severe hyperinflation (ratio of residual volume [RV] to total lung capacity of ≥0•65). By computer using a random number generator, we randomly allocated participants (in a 2:1 ratio) to either airway bypass (n=208) or sham control (107). We divided investigators into team A (masked), who completed pre-procedure and post-procedure assessments, and team B (unmasked), who only did bronchoscopies without further interaction with patients. Participants were followed up for 12 months. The 6-month co-primary efficacy endpoint required 12% for greater improvement in forced vital capacity (FVC) and 1 point or greater decrease in the modified Medical Research Council dyspnoea score from baseline. The composite primary safety endpoint incorporated five severe adverse events. We did Bayesian analysis to show the posterior probability that airway bypass was superior to sham control (success threshold, 0•965). Analysis was by intention to treat. This study is registered with ClinicalTrials.gov, number NCT00391612. FINDINGS: All recruited patients were included in the analysis. At 6 months, no difference between treatment arms was noted with respect to the co-primary efficacy endpoint (30 of 208 for airway bypass vs 12 of 107 for	**Lab SIFO Farmacoeconomia**

sham control; posterior probability 0•749, below the Bayesian success threshold of 0•965). The 6-month composite primary safety endpoint was 14•4% (30 of 208) for airway bypass versus 11•2% (12 of 107) for sham control (judged non-inferior, with a posterior probability of 1•00 [Bayesian success threshold >0•95]). INTERPRETATION: Although our findings showed safety and transient improvements, no sustainable benefit was recorded with airway bypass in patients with severe homogeneous emphysema.	
N Engl J Med. 2011 Sep 15;365(11):993-1003. Epub 2011 Sep 7. **Stenting versus aggressive medical therapy for intracranial arterial stenosis** BACKGROUND: Atherosclerotic intracranial arterial stenosis is an important cause of stroke that is increasingly being treated with percutaneous transluminal angioplasty and stenting (PTAS) to prevent recurrent stroke. However, PTAS has not been compared with medical management in a randomized trial. METHODS: We randomly assigned patients who had a recent transient ischemic attack or stroke attributed to stenosis of 70 to 99% of the diameter of a major intracranial artery to aggressive medical management alone or aggressive medical management plus PTAS with the use of the Wingspan stent system. The primary end point was stroke or death within 30 days after enrollment or after a revascularization procedure for the qualifying lesion during the follow-up period or stroke in the territory of the qualifying artery beyond 30 days. RESULTS: Enrollment was stopped after 451 patients underwent randomization, because the 30-day rate of stroke or death was 14.7% in the PTAS group (nonfatal stroke, 12.5%; fatal stroke, 2.2%) and 5.8% in the medical-management group (nonfatal stroke, 5.3%; non-stroke-related death, 0.4%) (P=0.002). Beyond 30 days, stroke in the same territory occurred in 13 patients in each group. Currently, the mean duration of follow-up, which is ongoing, is 11.9 months. The probability of the occurrence of a primary end-point event over time differed significantly between the two treatment groups (P=0.009), with 1-year rates of the primary end point of 20.0% in the PTAS group and 12.2% in the medical-management group. CONCLUSIONS: In patients with intracranial arterial stenosis, aggressive medical management was superior to PTAS with the use of the Wingspan stent system, both because the risk of early stroke after PTAS was high and because the risk of stroke with aggressive medical therapy alone was lower than expected. (Funded by the National Institute of Neurological Disorders and Stroke and others; SAMMPRIS ClinicalTrials.gov number, NCT00576693.).	**Lab SIFO Farmacoeconomia**