# OSSERVATORIO SIFO DISPOSITIVI MEDICI

a cura del Laboratorio SIFO di Farmacoeconomia

coordinatori del progetto

***Sabrina Trippoli – Valeria Fadda – Dario Maratea – Andrea Messori***

**Assegnato a**

**Dario Maratea**

*N Engl J Med. 2011 Apr 14;364(15):1395-406. Epub 2011 Apr 4.*

**Percutaneous repair or surgery for mitral regurgitation.**

Feldman T, Foster E, Glower DG, Kar S, Rinaldi MJ, Fail PS, Smalling RW, Siegel R, Rose GA, Engeron E, Loghin C, Trento A, Skipper ER, Fudge T, Letsou GV, Massaro JM, Mauri L; EVEREST II Investigators.

Evanston Hospital, NorthShore University Health System, Evanston, IL 60201, USA. tfeldman@northshore.org

Comment in
N Engl J Med. 2011 Apr 14;364(15):1462-3.

BACKGROUND: Mitral-valve repair can be accomplished with an investigational procedure that involves the percutaneous implantation of a clip that grasps and approximates the edges of the mitral leaflets at the origin of the regurgitant jet.
METHODS: We randomly assigned 279 patients with moderately severe or severe (grade 3+ or 4+) mitral regurgitation in a 2:1 ratio to undergo either percutaneous repair or conventional surgery for repair or replacement of the mitral valve. The primary composite end point for efficacy was freedom from death, from surgery for mitral-valve dysfunction, and from grade 3+ or 4+ mitral regurgitation at 12 months. The primary safety end point was a composite of major adverse events within 30 days.
RESULTS: At 12 months, the rates of the primary end point for efficacy were 55% in the percutaneous-repair group and 73% in the surgery group (P=0.007). The respective rates of the components of the primary end point were as follows: death, 6% in each group; surgery for mitral-valve dysfunction, 20% versus 2%; and grade 3+ or 4+ mitral regurgitation, 21% versus 20%. Major adverse events occurred in 15% of patients in the percutaneous-repair group and 48% of patients in the surgery group at 30 days (P<0.001). At 12 months, both groups had improved left ventricular size, New York Heart Association functional class, and quality-of-life measures, as compared with

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| baseline.<br>CONCLUSIONS: Although percutaneous repair was less effective at reducing mitral regurgitation than conventional surgery, the procedure was associated with superior safety and similar improvements in clinical outcomes. | |
| *N Engl J Med. 2011 May 5;364(18):1718-27. Epub 2011 Apr 4.*<br>**Randomized trial of stents versus bypass surgery for left main coronary artery disease.**<br><br>Park SJ, Kim YH, Park DW, Yun SC, Ahn JM, Song HG, Lee JY, Kim WJ, Kang SJ, Lee SW, Lee CW, Park SW, Chung CH, Lee JW, Lim DS, Rha SW, Lee SG, Gwon HC, Kim HS, Chae IH, Jang Y, Jeong MH, Tahk SJ, Seung KB.<br><br>Heart Institute, Center for Medical Research and Information, University of Ulsan College of Medicine, Asan Medical Center, Seoul, South Korea. sjpark@amc.seoul.kr<br><br>BACKGROUND: Percutaneous coronary intervention (PCI) is increasingly used to treat unprotected left main coronary artery stenosis, although coronary-artery bypass grafting (CABG) has been considered to be the treatment of choice.<br>METHODS: We randomly assigned patients with unprotected left main coronary artery stenosis to undergo CABG (300 patients) or PCI with sirolimus-eluting stents (300 patients). Using a wide margin for noninferiority, we compared the groups with respect to the primary composite end point of major adverse cardiac or cerebrovascular events (death from any cause, myocardial infarction, stroke, or ischemia-driven target-vessel revascularization) at 1 year. Event rates at 2 years were also compared between the two groups.<br>RESULTS: The primary end point occurred in 26 patients assigned to PCI as compared with 20 patients assigned to CABG (cumulative event rate, 8.7% vs. 6.7%; absolute risk difference, 2.0 percentage points; 95% confidence interval [CI], -1.6 to 5.6; P=0.01 for noninferiority). By 2 years, the primary end point had occurred in 36 patients in the PCI group as compared with 24 in the CABG group (cumulative event rate, 12.2% vs. 8.1%; hazard ratio with PCI, 1.50; 95% CI, 0.90 to 2.52; P=0.12). The composite rate of death, myocardial infarction, or stroke at 2 years occurred in 13 and 14 patients in the two groups, respectively (cumulative event rate, 4.4% and 4.7%, respectively; hazard ratio, 0.92; 95% CI, 0.43 to 1.96; P=0.83). Ischemia-driven target-vessel revascularization occurred<br>in 26 patients in the PCI group as compared with 12 patients in the CABG group (cumulative event rate, 9.0% vs. 4.2%; hazard ratio, 2.18; 95% CI, 1.10 to 4.32; P=0.02).<br>CONCLUSIONS: In this randomized trial involving patients with unprotected left main coronary artery stenosis, PCI with sirolimus-eluting stents was shown to be noninferior to CABG with respect to major adverse cardiac or cerebrovascular events. However, the noninferiority margin was wide, and the results cannot be considered clinically directive. | **Nessuna scheda dispositivo non più commercializzato in Italia** |
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*Lancet. 2011 Apr 9;377(9773):1241-7. Epub 2011 Apr 1.*

**Davide Paoletti**

# Unrestricted randomised use of two new generation drug-eluting coronary stents: 2-year patient-related versus stent-related outcomes from the RESOLUTE All Comers trial.

Silber S, Windecker S, Vranckx P, Serruys PW; RESOLUTE All Comers investigators.

Collaborators: Windecker S, Serruys PW, Richardt G, Kelbaek H, van Boven AJ, Linke A, Buszman PE, Klauss V, Sohn HY, Silber S, Wijns W, Macaya C, DiMario C, Manoharan G, Kornowski R, Garot P, Ischinger T, Leber AW, Garot P, Bartorelli AL.

Heart Centre at the Isar, Munich, Germany. sigmund@silber.com

Comment in
Lancet. 2011 Apr 9;377(9773):1213-4.

BACKGROUND: In the RESOLUTE All Comers trial, the Resolute zotarolimus-eluting stent was non-inferior to the Xience V everolimus-eluting stent for the primary stent-related endpoint of target lesion failure (cardiac death, target vessel myocardial infarction, and ischaemia-driven target lesion revascularisation) at 1 year. However, data for long-term safety and efficacy from randomised studies of new generation drug-eluting coronary stents in patients treated in routine clinical practice are scarce. We report the prespecified 2-year clinical outcomes from the RESOLUTE All Comers trial.

METHODS: In 2008, patients with at least one coronary lesion 2.25-4.0 mm in diameter, with greater than 50% stenosis, were randomly assigned to a Resolute zotarolimus-eluting stent or a Xience V everolimus-eluting stent at 17 centres in Europe and Israel. Randomisation was by an interactive voice response system stratified by centre. Study investigators were not masked to treatment allocation; but those who did data management and analysis, and patients were masked. There were no restrictions as to the number of vessels or lesions treated, or the number of stents implanted. We assessed prespecified safety and efficacy outcomes at 2 years with specific focus on patient-related composite (all death, all myocardial infarction, all revascularisation) and stent-related composite outcomes. Analyses were by intention to treat. This study is registered with ClinicalTrials.gov, number NCT00617084. FINDINGS: 1140 patients were assigned to the zotarolimus-eluting stent and 1152 to the everolimus-eluting stent; 1121 and 1128 patients, respectively, completed 2-year follow-up. The patient-related outcome (231 [20.6%] zotarolimus vs 231 [20.5%] everolimus; difference 0.1%, 95% CI-3.2 to 3.5; p=0.958) and stent-related outcome (126 [11.2%] vs 121 [10.7%]; difference 0.5%, -2.1 to 3.1; p=0.736) did not differ between groups, although rates of the stent-related outcome were substantially lower than were those for the patient-related outcome. Three patients in each group (0.3%) had very late (after 1 year) stent thrombosis.

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| INTERPRETATION: Similar safety and efficacy outcomes were sustained between two new generation drug-eluting stents at 2-year follow-up. The greater number of patient-related than stent-related events in patients with complex clinical and lesion characteristics emphasises that during long-term follow-up, the optimisation of secondary prevention is at least as important as the selection of which new generation drug-eluting stent to implant in a specific lesion. FUNDING: Medtronic (USA). | |
| *J Urol. 2011 Apr;185(4):1350-5. Epub 2011 Feb 22.*<br>**Randomized trial of tension-free vaginal tape and tension-free vaginal tape-obturator for urodynamic stress incontinence in women.**<br><br>Teo R, Moran P, Mayne C, Tincello D.<br><br>Leicester Royal Infirmary, Worcester, United Kingdom. Rod.c.teo@uhl-tr.nhs.uk<br><br>PURPOSE: We compared the efficacy and complications of tension-free vaginal tape and tension-free vaginal tape-obturator.<br>MATERIALS AND METHODS: Women with pure urodynamic stress incontinence undergoing only primary continence surgery were randomized to tension-free vaginal tape or tension-free vaginal tape-obturator at 2 centers between March 2005 and March 2007. Primary outcome was objective cure rate at 6 months, defined by a 24-hour pad test of less than 5 gm. Secondary outcomes were the subjective cure rate on the Patient Global Impression of Improvement, quality of life on the King's Healthcare Questionnaire and symptom severity scores on the International Consultation on Incontinence Questionnaire.<br>RESULTS: A total of 127 women were recruited. The study was stopped early due to excess leg pain in the tension-free vaginal tape-obturator group. Of the women 66 were randomized to tension-free vaginal tape and 61 were randomized to tension-free vaginal tape-obturator. Analysis was done by intent to treat. The objective and subjective cure rate at 6 months for tension-free vaginal tape vs tension-free vaginal tape-obturator was 69.7% vs 72.1% and 72.7% vs 67.2% (p = 0.76 and 0.49, respectively). Cure rates at 1 year were similar but loss to followup was high. Objective and subjective cure rates at 1 year for tension-free vaginal tape vs tension-free vaginal tape-obturator were 50% vs 41% and 53% vs 42.6% (p = 0.31 and 0.24, respectively). More women complained of leg pain after receiving a tension-free vaginal tape-obturator (26.4% vs 1.7%, p = 0.0001). The incidence of perioperative complications was low and similar between the groups. Time to discharge home and time to normal activity were not significantly different.<br>CONCLUSIONS: Short-term cure rates at 6 months were similar. Tension-free vaginal tape-obturator caused more transient leg pain. Each procedure achieved a high cure rate and a low complication rate. | **Nessuna scheda**<br>**Non è possibile ricavare il nome del dispositivo dal testo dello studio.** |

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| *J Urol. 2011 Apr;185(4):1356-62. Epub 2011 Feb 22*<br>**A randomized, controlled trial comparing an innovative single incision sling with an established transobturator sling to treat female stress urinary incontinence.**<br><br>Hinoul P, Vervest HA, den Boon J, Venema PL, Lakeman MM, Milani AL, Roovers JP.<br><br>Department of Obstetrics and Gynecology, Ziekenhuis Oost-Limburg, Genk, Belgium.<br><br>PURPOSE: Mid urethral sling procedures have become the surgical treatment of choice for female stress urinary incontinence. Innovative modifications of mid urethral sling procedures were recently introduced with the claim of offering similar efficacy and decreased morbidity. We compared the efficacy and morbidity of an innovative single incision mid urethral tape and an established transobturator procedure.<br>MATERIALS AND METHODS: We performed a prospective, randomized, controlled trial in 6 teaching hospitals in Belgium and The Netherlands between 2007 and 2009. A total of 96 patients received a TVT Secur™ single incision sling and 98 received a TVT™ Obturator System. We collected data on patient characteristics, surgery related parameters, adverse events, clinical followup, Urogenital Distress Inventory and SF-36® scores, validated questionnaires on daily life activities and visual analog scores objectifying pain. Followup was 1 year.<br>RESULTS: One-year followup was available for 75 single incision sling and 85 obturator system cases. Stress urinary incontinence could be objectified in 16.4% of the patients with a single incision sling and in 2.4% with an obturator system ($p < 0.05$). Stress urinary incontinence was subjectively reported by 24% of single incision sling and 8% of obturator system patients ($p < 0.05$). One year after surgery the mean ± SD UDI incontinence domain score in the single incision sling and obturator system groups was $21 \pm 24$ and $13 \pm 21$, respectively ($p < 0.01$).<br>Patients with a single incision sling experienced significantly less pain during the first 2 weeks after surgery ($p < 0.05$) and returned significantly earlier to normal daily activity. The OR of re-intervention for stress urinary incontinence 1 year after receiving a single incision sling vs an obturator system was 2.3 (95% CI 1.9-2.7).<br>CONCLUSIONS: The single incision sling procedure is associated with less postoperative pain and a lower objective cure rate than the obturator system procedure. | **Valeria Fadda** |
| *Am J Cardiol. 2011 Apr 1;107(7):990-4. Epub 2011 Feb 4.*<br>**Comparison of dual drug-eluting Cilotax stent and paclitaxel-eluting Taxus Liberte stent in native coronary artery lesions.**<br><br>Lee CW, Park DW, Seung KB, Kim PJ, Park HJ, Kim WJ, Lee JY, Kang SJ, Lee SH, Kim YH, Park SW, Park SJ. | **Non Assegnato** |

Division of Cardiology, Heart Institute, Asan Medical Center, University of Ulsan, Seoul, Korea.

Cilotax stent is a new type of drug-eluting stent (DES) designed to increase the antirestenotic performance of the paclitaxel-eluting stent and decrease the risk of stent thrombosis by the incorporation of cilostazol. Therefore, we investigated the safety and efficacy of Cilotax dual DESs and compared their performance to that of paclitaxel-eluting Taxus Liberte. Patients undergoing percutaneous coronary intervention for de novo coronary artery lesions at 2 centers in Korea were randomized to receive Cilotax (n = 55) or Taxus Liberte (n = 56) stents. The primary end point was in-segment late loss at 8 months. The 2 groups had similar baseline characteristics. Cilotax stent was not inferior to Taxus Liberte stent as determined by in-segment late loss (0.28 ± 0.30 vs 0.42 ± 0.45 mm, difference -0.14, 95% confidence interval -0.27 to -0.01, 1-sided p = 0.028 for noninferiority). In-stent late loss was significantly lower in the Cilotax than in the Taxus Liberte group (0.22 ± 0.31 vs 0.50 ± 0.55 mm, p = 0.002). Although in-segment restenosis rate did not differ significantly between the 2 groups (3.8% vs 10.9%, respectively, p = 0.271), in-stent restenosis rate was significantly lower in the Cilotax stent group (0% vs 10.9%, p = 0.027).
There was no stent thrombosis at 8 months in either group. Rates of death, myocardial infarction, and any target lesion revascularization at 8 months were 0%, 0%, and 1.9%, respectively, in the Cilotax group and 1.8%, 0% and 3.6%, respectively, in the Taxus Liberte group. In conclusion, the Cilotax stent was safe and effective in decreasing late loss, indicating that this stent represents a promising new type of DES system.