OSSERVATORIO SIFO DISPOSITIVI MEDICI

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Long-term clinical outcomes of biodegradable polymer biolimus-eluting stents versus durable polymer sirolimus-eluting stents in patients with coronary artery disease (LEADERS): 4 year follow-up of a randomised non-inferiority trial.

Stefanini GG, Kalesan B, Serruys PW, Heg D, Buszman P, Linke A, Ischinger T, Klauss V, Eberli F, Wijns W, Morice MC, Di Mario C, Corti R, Antoni D, Sohn HY, Eerdmans P, van Es GA, Meier B, Windecker S, Jüni P.

BACKGROUND: The effectiveness of durable polymer drug-eluting stents comes at the expense of delayed arterial healing and subsequent late adverse events such as stent thrombosis (ST). We report the 4 year follow-up of an assessment of biodegradable polymer-based drug-eluting stents, which aim to improve safety by avoiding the persistent inflammatory stimulus of durable polymers.

METHODS: We did a multicentre, assessor-masked, non-inferiority trial. Between Nov 27, 2006, and May 18, 2007, patients aged 18 years or older with coronary artery disease were randomly allocated with a computer-generated sequence to receive either biodegradable polymer biolimus-eluting stents (BES) or durable polymer sirolimus-eluting stents (SES; 1:1 ratio). The primary endpoint was a composite of cardiac death, myocardial infarction, or clinically-indicated target vessel revascularisation (TVR); patients were followed-up for 4 years. Analysis was by intention to treat. This trial is registered with ClinicalTrials.gov, number NCT00389220.

FINDINGS: 1707 patients with 2472 lesions were randomly allocated to receive either biodegradable polymer BES (857 patients, 1257 lesions) or durable polymer SES (850 patients, 1215 lesions). At 4 years, biodegradable polymer BES were non-inferior to durable polymer SES for the primary endpoint: 160 (18•7%) patients versus 192 (22•6%) patients (rate ratios [RR] 0•81, 95% CI 0•66-1•00, p for non-inferiority <0•0001, p for superiority=0•050). The RR of definite ST was 0•62 (0•35-1•08, p=0•09), which was largely attributable to a lower risk of very late definite ST between years 1 and 4 in the BES group than in the SES group (RR 0•20, 95% CI 0•06-0•67, p=0•004). Conversely, the RR of definite ST during the first year was 0•99 (0•51-1•95; p=0•98) and the test for interaction between RR of definite ST and time was positive (p(interaction)=0•017). We recorded an interaction with time for events associated with ST but not for other events. For

primary endpoint events associated with ST, the RR was 0•86 (0•41-1•80) during the first year and 0•17 (0•04-0•78) during subsequent years (p(interaction)=0•049). INTERPRETATION: Biodegradable polymer BES are non-inferior to durable polymer SES and, by reducing the risk of cardiac events associated with very late ST, might improve long-term clinical outcomes for up to 4 years compared with durable polymer SES.	
Acta Obstet Gynecol Scand. 2011 Dec;90(12):1393-401. **Long-term outcome of porcine skin graft in surgical treatment of recurrent pelvic organ prolapse. An open randomized controlled multicenter study.** Dahlgren E, Kjølhede P; RPOP-PELVICOL Study Group. Collaborators: Gunnarsson J, Uustal Fornell E, Leman J, Magnussson C, Crafoord K, Konstantinova T, Andersson PO, Åkeson M, Paulsson G, Magnusson Å. OBJECTIVE: To determine the long-term objective and subjective outcomes of use of a porcine skin graft (Pelvicol) compared with conventional colporrhaphy in recurrent pelvic organ prolapse surgery and to analyze risk factors and safety. DESIGN: Open randomized controlled multicenter study. SETTING: Eight Swedish hospitals. POPULATION: 135 consecutive women with recurrent cystocele and/or rectocele admitted for vaginal prolapse surgery; 132 completed the study, 64 were randomly allocated to receive conventional colporrhaphy and 68 to Pelvicol. METHODS: Conventional anterior and posterior colporrhaphy and colporrhaphy with use of Pelvicol mesh reinforcement. Clinical evaluation by means of pelvic organ prolapse quantification (POP-Q) and symptom questionnaire preoperatively, three months and three years postoperatively. MAIN OUTCOME MEASURES: Anatomical and subjective outcome. Recurrence was defined as POP-Q ≥ stage 2. RESULTS: At three-month follow-up, early recurrence/surgical failures occurred significantly more often in the Pelvicol group, but at the three-year follow-up the recurrence rates were similar. The recurrence rates in the anterior compartment were 57-62% and 44-23% in the posterior compartment for the colporrhaphy and Pelvicol groups, respectively. Symptoms were substantially and equally reduced in the two groups after surgery. Sexual activity and function did not seem to be affected adversely in any group. The complication rate was low. Risk factors for anatomical recurrence were age, body mass index and preoperative stage of the prolapse. CONCLUSIONS: With the surgical technique used in this study, Pelvicol did not provide advantages over conventional colporrhaphy in recurrent pelvic organ prolapse concerning anatomical and subjective outcomes.	**Lab SIFO Farmacoeconomia**

Am J Cardiol. 2011 Dec 1;108(11):1600-5. Epub 2011 Aug 30. **Predictors and course of high-degree atrioventricular block after transcatheter aortic valve implantation using the CoreValve Revalving System.** Guetta V, Goldenberg G, Segev A, Dvir D, Kornowski R, Finckelstein A, Hay I, Goldenberg I, Glikson M. Transcatheter aortic valve implantation (TAVI) is a novel treatment for high risk or inoperable patients with symptomatic severe aortic stenosis. However, significant atrioventricular (AV) conduction system abnormalities requiring permanent pacemaker (PPM) implantation might complicate this procedure. We used best subsets logistic regression analysis to identify the independent predictors for the development of high-degree AV block (HDAVB) among 70 patients who underwent TAVI at 3 referral centers in Israel from 2008 to 2010. The mean age of the study patients was 83 ± 4.6 years. Of the 70 patients, 28 (40%) developed AV conduction abnormalities requiring PPM implantation within 14 days (median 2) of the procedure. The indications for PPM implantation were HDAVB (n = 25), new-onset left bundle branch block with PR prolongation (n = 2), and slow atrial fibrillation (n = 1). Best subsets logistic regression analysis showed that, among the 15 prespecified clinical, electrocardiographic, and echocardiographic candidate risk factors, only right bundle branch block at baseline (odds ratio 43; p = 0.002) and deep valve implantation (<6 mm from the lower edge of the noncoronary cusp to the ventricular end of the prosthesis, odds ratio 22; p <0.001) were independently associated with the development of periprocedural HDAVB. At 3 months of follow-up, HDAVB was still present in 40% of the patients who received PPM implantation for this indication. In conclusion, 40% of the patients who undergo CoreValve TAVI require PPM implantation after the procedure, with most cases (36%) associated with the development of postprocedural HDAVB. Baseline conduction abnormalities (right bundle branch block) and deep valve implantation (>6 mm) independently predicted the development of HDAVB and the need for PPM implantation after CoreValve TAVI.	**Lab SIFO Farmacoeconomia**