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	
Radiology: Volume 261: Number 2—November 2011 **Percutaneous transluminal angioplasty versus turbostatic carbon-coated stents in infrapopliteal arteries: InPeria II trial.** Rand T, Lammer J, Rabbia C, Maynar M, Zander T, Jahnke T, Müller-Hülsbeck S, Scheinert D, Manninen HI. PURPOSE: To determine the clinical outcome and the success of stent application for high-grade lesions of the infrapopliteal arteries compared with treatment with percutaneous transluminal angioplasty (PTA) in critical limb ischemia (CLI). MATERIALS AND METHODS: In this ethics board-approved randomized prospective study, PTA or stent application was performed on 131 lesions in 88 patients with CLI. The primary end points were clinical improvement after endovascular treatment and limb salvage rate. Secondary end points were defined by the minimal lumen diameter (MLD) before and after the revascularization procedure, percentage of residual diameter stenosis (DS), binary restenosis rate (>50% DS and >70% DS), and incidence of target lesion revascularization at 9-month follow-up. RESULTS: At 3 months, the clinical status in the PTA group was less improved than that in the stent group (P = .008). At 9 months, there had been five minor and two major amputations in the PTA group and five major and five minor amputations in the stent group. MLD was significantly larger and the percentage of DS was significantly less in the stent group at completion angiography. At 9 months, the angiographic control showed better trends for the stent group in comparison to the PTA group despite that no significant differences were detected (MLD, 1.19 mm ± 0.92 vs 1.02 mm ± 1.02; DS, 38.68% ± 25.47 vs 43.31% ± 28.37). CONCLUSION: Infrapopliteal stent application is an effective treatment modality in CLI. The PTA and stent groups were essentially equal at 3 and 9 months except for the difference in clinical improvement in the stent group at 3 months	**Lab SIFO Farmacoeconomia**
Br J Surg. 2011 Nov;98(11):1537-45. doi: 10.1002/bjs.7646. Epub 2011 Aug 24. **Randomized clinical trial of fibrin sealant versus titanium tacks for mesh fixation in laparoscopic umbilical hernia repair.** Eriksen JR, Bisgaard T, Assaadzadeh S, Jorgensen LN, Rosenberg J. BACKGROUND: The use of tacks for mesh fixation may induce pain after surgery for ventral hernia. The aim of this study was to compare postoperative pain after laparoscopic ventral hernia repair (LVHR) with conventional mesh fixation using titanium tacks versus fibrin sealant (FS). METHODS: This randomized clinical trial included patients with an umbilical hernia defect ranging from 1•5 to 5 cm at	**Lab SIFO Farmacoeconomia**

three Danish hernia centres. Participants were assigned randomly to FS or titanium tack fixation. The primary outcome was acute pain, defined as the mean pain score on days 0-2 after surgery, measured on a 0-100-mm visual analogue scale (VAS). RESULTS: Forty patients were included, of whom 38 were available for intention-to-treat analysis after 1 month. Patients in the FS group reported less pain than those in the tack group on days 0-2, both at rest (median 19 versus 47 mm; P = 0•025) and during activity (38 versus 60 mm; P = 0•014). The absolute difference in pain score between groups was 19 (95 per cent confidence interval 3 to 34) and 20 (4 to 35) mm at rest and during activity respectively. Patients in the FS group resumed normal daily activity earlier (after median 7 versus 18 days; P = 0•027) and reported significantly less discomfort. No recurrences were observed. CONCLUSION: Mesh fixation with FS in LVHR was associated with less acute postoperative pain, discomfort and a shorter convalescence than tack fixation. Long-term follow-up is needed to show whether the effect of FS fixation persists in terms of chronic pain and recurrence. Registration number: NCT00842842 (http://www.clinicaltrials.gov).	
J Thorac Cardiovasc Surg. 2011 Nov;142(5):1122-9. **Expanded polytetrafluoroethylene conduits and patches with bulging sinuses and fan-shaped valves in right ventricular outflow tract reconstruction: multicenter study in Japan.** Miyazaki T, Yamagishi M, Maeda Y, Yamamoto Y, Taniguchi S, Sasaki Y, Yaku H. OBJECTIVE: There is no optimal substitute for right ventricular outflow tract (RVOT) reconstruction in congenital heart defects. Expanded polytetrafluoroethylene (ePTFE) valved conduits and patches may be a good alternative to homografts and bovine jugular veins. We have developed a fan-shaped ePTFE valve and an ePTFE valved conduit and patch with bulging sinuses with the aim of enhancing the long-term valve function. METHOD: Bulging sinuses were constructed on ePTFE conduits and patches as described previously (J Thorac Cardiovasc Surg. 2007;134:327-32). Between February 2001 and January 2011, 794 patients (aged 14 days to 56.8 years old; median, 2.0 years old) had ePTFE valves implanted for RVOT reconstruction at 52 Japanese institutes. Conduits with a fan-shaped ePTFE valve were implanted in 325 patients and a patch with a fan-shaped ePTFE valve was implanted in 469 patients. Valve function was assessed by a series of echocardiograms postoperatively. RESULTS: The mean follow-up was 3.6 years (1.1 months to 10.0 years). Freedom from reoperation at 10 years was 95.4% in patients with conduits and 92.3% in those with patches. Pulmonary insufficiency was mild or nonexistent in 95.0% of patients with conduits and 79.6% of patients with patches. The pressure gradient between the right ventricle and the pulmonary artery was 14.0 ± 13.2 mm Hg in patients with conduits and 11.6 ± 11.6 mm Hg in patients with patches. CONCLUSIONS: Fan-shaped ePTFE valved conduits and patches with bulging sinuses have a high freedom from reoperation and prevent pulmonary insufficiency. They represent a promising material for RVOT reconstruction.	**Lab SIFO Farmacoeconomia**
J Thorac Cardiovasc Surg. 2011 Nov;142(5):1002-9, 1009.e1. **Exclusion of the left atrial appendage with a novel device: early results of a multicenter trial.**	**Lab SIFO Farmacoeconomia**

Ailawadi G, Gerdisch MW, Harvey RL, Hooker RL, Damiano RJ Jr, Salamon T, Mack MJ. OBJECTIVE: Up to 90% of embolic strokes that occur in patients with atrial fibrillation originate from the left atrial appendage. Exclusion of the left atrial appendage during cardiac surgery may decrease the future risk of stroke, especially in patients with atrial fibrillation or at high risk for developing atrial fibrillation. We report the initial results of a multicenter Food and Drug Administration trial to assess the safety and efficacy of a novel left atrial appendage exclusion clip. METHODS: Patients undergoing elective cardiac surgery via median sternotomy with atrial fibrillation or a Congestive Heart Failure, Hypertension, Age > 75 Years, Diabetes Mellitus, Stroke score greater than 2 were eligible for concomitant AtriClip (Atricure Inc, Westchester, Ohio) device insertion. Device insertion (35, 40, 45, and 50 mm) was performed at any point after sternotomy on or off cardiopulmonary bypass. Safety was assessed at 30 days, and efficacy of left atrial appendage exclusion was assessed at operation (by transesophageal echocardiography) and 3-month follow-up (by computed tomography angiography or transesophageal echocardiography). RESULTS: A total of 71 patients (mean age, 73 years) undergoing open cardiac surgery at 7 US centers were enrolled in the study. The left atrial appendage in 1 patient was too small and did not meet eligibility criteria; the remaining 70 patients had successful placement of an AtriClip device. Intraprocedural successful left atrial appendage exclusion was confirmed in 67 of 70 patients (95.7%). Although significant adverse events occurred in 34 of 70 patients (48.6%), there were no adverse events related to the device and no perioperative mortality. At 3-month follow-up, 1 patient died and 65 of 70 patients (92.9%) were available for assessment. Of the patients who underwent imaging, 60 of 61 patients (98.4%) had successful left atrial appendage exclusion by computed tomography angiography or transesophageal echocardiography imaging. CONCLUSIONS: In this small study, safe and atraumatic exclusion of the left atrial appendage can be performed during open cardiac surgery with the AtriClip device with greater than 95% success and appears to be durable in the short term by imaging. Long-term studies are needed to evaluate the efficacy in the prevention of stroke.	
BJOG. 2011 Nov;118(12):1518-27 **Primary surgical repair of anterior vaginal prolapse: a randomised trial comparing anatomical and functional outcome between anterior colporrhaphy and trocar-guided transobturator anterior mesh.** Vollebregt A, Fischer K, Gietelink D, van der Vaart CH. OBJECTIVE: To compare anterior colporrhaphy with a trocar-guided transobturator mesh procedure (Avaulta(®) anterior). DESIGN: Randomised, controlled trial. SETTING: Three teaching hospitals. POPULATION: Women with a symptomatic cystocele at least stage II requiring primary surgical correction. METHODS: A total of 125 women were assessed at baseline and 1-year follow up. A sacrospinous hysteropexy or posterior colporrhaphy was performed when indicated. MAIN OUTCOME MEASURES: The primary outcome was the	**Lab SIFO Farmacoeconomia**

difference in anatomical cure (defined as Pelvic Organ Prolapse-Quantification <stage II cystocele). Secondary outcomes were complications, self-reported urogenital symptom severity, and quality of life, as measured with validated questionnaires. RESULTS: In all, 64 women were allocated to the anterior colporrhaphy group and 61 to the mesh group; 58/64 women versus 56/61 completed 12 months of follow-up analysis. Compared with the anterior colporrhaphy group, the mesh reduced the risk of anatomical failure at 12 months follow up from 59 to 9% (risk reduction 50.3%, 95% CI 35.5-65.1). Only three (5%) re-operations for anatomical failure in the anterior colporrhaphy group were performed versus 0% in the mesh group. Functional outcome improved significantly at 12 months on almost all domains, with similar results between groups. Mesh exposure occurred in two (4%) women. Baseline dyspareunia disappeared significantly more often after an anterior colporrhaphy (80%) than in the mesh group (20%). There was a trend towards more de novo dyspareunia in the mesh group (15% versus 9%). CONCLUSIONS: Primary cystocele repair with trocar-guided transobturator mesh resulted in a statistically significant better anatomical outcome compared with the anterior colporrhaphy. However, functional outcome was similar between groups.	