OSSERVATORIO SIFO DISPOSITIVI MEDICI

a cura del Laboratorio SIFO di Farmacoeconomia

coordinatori del progetto

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Assegnato a

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Am J Obstet Gynecol. 2011 Jan;204(1):74.e1-8. Epub 2010 Oct 20.

Trocar-guided mesh repair of vaginal prolapse using partially absorbable mesh: 1 year outcomes.

Milani AL, Hinoul P, Gauld JM, Sikirica V, van Drie D, Cosson M; Prolift+M Investigators.

Collaborators: Goepel C, Lucente V, Khandwala S, Reisenauer C, VanDrie D, de Cuyper E, Cosson M, Milani F, Lobodasch K, Noesselt T, Seeger D.

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OBJECTIVE: To evaluate anatomic and functional outcomes at 1-year following trocar-guided transvaginal prolapse repair using a partially absorbable mesh.
STUDY DESIGN: Prospective multicentre cohort study at 11 international sites. One hundred twenty-seven patients with pelvic organ prolapse stage ≥ III had surgery and were evaluated at 3 months and 1-year postsurgery compared with baseline.
Instruments of measurements: Pelvic Organ Prolapse Quantification, Pelvic Floor Distress Inventory-20, Pelvic Floor Impact Questionnaire-7, Pelvic Organ Prolapse/Urinary Incontinence Sexual Function Questionnaire-12, and Patients Global Impression of Change.
RESULTS: Anatomic success, defined as prolapse stage ≤ I in the treated vaginal compartments, was 77.4% (95% confidence interval, 69.0-84.4%). Significant improvements in bother, quality of life, and sexual function were detected at 3 months and 1 year compared with baseline. At 1-year after surgery, 86.2% of patients indicated their prolapse situation to be "much better." Mesh exposure rate was 10.2% and rate of de novo dyspareunia 2% at 1 year.
CONCLUSION: These results demonstrate improved anatomic support, associated with excellent functional mprovements, without apparent safety concerns.

Am J Surg. 2011 Jan;201(1):85-90. Epub 2010 Jun 9. **Open intraperitoneal versus retromuscular mesh repair for umbilical hernias less than 3 cm diameter.** Berrevoet F, D'Hont F, Rogiers X, Troisi R, de Hemptinne B. Department of General and Hepatobiliary Surgery and Liver Transplantation Service, University Hospital Medical School, Ghent, Belgium. frederik.berrevoet@ugent.be BACKGROUND: mesh techniques are the preferable methods for repair of small ventral hernias, as a primary suture repair shows high recurrence rates. The aim of this prospective study was to compare the retromuscular sublay technique with the intraperitoneal underlay technique for primary umbilical hernias. METHODS: from February 2004 to April 2007, all patients treated for umbilical hernias with maximum diameters of 3 cm were prospectively followed. During the first period of 15 months, all patients were treated with retromuscular repair using a large pore mesh (Vypro). After that period, for all patients, mesh repair using an intraperitoneal Ventralex patch was performed. All patients underwent general anesthesia. This analysis included 116 patients, of whom 56 had retromuscular repair (group I; mean age, 54.8 years; mean body mass index, 28.2 kg/m(2)) and 60 had open intraperitoneal repair (group II; mean age, 48.1 years; mean body mass index, 29.4 kg/m(2)). Operating time was evaluated as skin-to-skin time, and drain management was noted for both techniques. Follow-up was $\geq$ 2 years for all patients, and both early and late complications were registered,including seroma and hematoma formation, wound infection, fistula formation, and recurrence rates. Preoperative and postoperative pain was evaluated using a visual analogue scale (range, 0-10) on the day of the first outpatient visit; on postoperative days 1, 7, and 21; and after 1 year. Quality of life was estimated using the EQ-5D questionnaire 1 year after surgery. All data were analyzed using SPSS version 15 software. Wilcoxon's rank-sum test was used to analyze continuous variables, and repeated-measures analysis of variance was used for visual analogue scale scores. The $\chi(2)$ test and Fisher's exact test were used to assess the differences between categorical data. P values < .05 were considered statistically significant. RESULTS: the mean operative times were 79.9 minutes in group I and 33.9 minutes in group II (P < .001). The mean hospital stay was significantly longer in group I (3.8 vs 2.1 days, P < .001). Seromas and superficial wound infections in theearly postoperative period were not different between both groups, although seromas occurred more frequent in the retromuscular group. Postoperative visual analogue scale scores were significantly lower with the intraperitoneal technique at all time points (P < .003, repeated-measures analysis of variance). However, 3 patients with the Ventralex patch had to be readmitted for severe pain. The recurrence rate was higher with the intraperitoneal repair (n = 5 [8.3%] vs n = 2 [3.6%]) than for the retromuscular mesh repair, but not statistically significant. Quality of life was comparable in the two groups after 1 year. CONCLUSIONS: the open intraperitoneal technique using a Ventralex mesh for umbilical hernias seems a very	**Dario Maratea**

elegant and quick technique. However, possibly because of the less controllable mesh deployment, recurrence rates seem higher. In case open mesh repair is the preferred treatment, a retromuscular repair should be the first choice.	
J Urol. 2011 Jan;185(1):175-8. Epub 2010 Nov 13. **New ureteral stent design does not improve patient quality of life: a randomized controlled trial.** Davenport K, Kumar V, Collins J, Melotti R, Timoney AG, Keeley FX Jr. Bristol Urological Institute, Bristol, UK. DrKimDav@aol.com PURPOSE: Ureteral stents result in significant morbidity in many patients. Manufacturers have altered stent design and composition to minimize symptoms. The Polaris™ stent is made of a Percuflex® combination, providing a firm proximal aspect with a softer distal aspect to minimize symptoms. In this prospective, randomized study we compared symptoms and quality of life after stent insertion to determine whether this stent is better tolerated than the InLay® stent. MATERIALS AND METHODS: Between September 2002 and September 2006 we randomized 159 patients requiring stent insertion for stone disease to receive the InLay or the Polaris ureteral stent. Patients were asked to complete the validated Ureteral Stent Symptom Questionnaire 2 weeks after stent insertion and 1 week after removal. RESULTS: A total of 98 patients completed and returned each questionnaire, including 45 with the InLay and 53 with the Polaris. There were no significant differences between the groups on any health domain assessed. In the InLay and Polaris groups 91% and 94% of patients experienced pain with the stent in situ, which decreased to 40% and 43%, respectively, after stent removal. The urinary symptom score with the stent in situ was equal in the 2 groups (32, maximum 55). Of the InLay and Polaris groups 60% and 66% of patients, respectively, would be against receiving a further stent due to symptoms ($p = 0.79$). CONCLUSIONS: The Polaris stent, designed with the specific aim of improving urinary symptoms and pain ssociated with ureteral stents, continues to have a significant detrimental effect on patient quality of life.	**Valeria Fadda**
Eur J Vasc Endovasc Surg. 2011 Jan;41(1):61-7. Epub 2010 Nov 20. **In situ revascularisation with silver-coated polyester prostheses and arterial homografts in patients with aortic graft infection--a prospective, comparative, single-centre study.** Pupka A, Skora J, Janczak D, Plonek T, Marczak J, Szydełko T. Department of Vascular, General and Transplantation Surgery Medical University Wroclaw, Borowska 213, 50-556 Wroclaw, Poland.	**Valeria Fadda**

OBJECTIVE: The aim of our study was to evaluate the effectiveness of in situ revascularisation with the use of arterial homografts and silver-coated prostheses in the treatment of aortic graft infection. MATERIALS: A total of 77 consecutive patients (74 males, three females, mean age: 58 years), hospitalised between 2001 and 2008, were enrolled into the study. Patients were assigned to three groups: group 1 (n = 24)--fresh arterial homograft with subsequent immunosuppression, group 2 (n = 26)--fresh arterial homograft without immunosuppression and group 3 (n = 27)--silver-coated prosthesis. METHODS: The course of infection was assessed by scintigraphy with (99m)Technetium-labelled leucocytes, Duplex-Doppler ultrasound, angio-computed tomography (CT) and microbiological examination. RESULTS: The mean follow-up was 22.8 (±10.1) months. There was a significant decrease in leucocyte accumulation around the graft among all groups (group 1: p = 0.012, group 2: p = 0.006 and group 3: p = 0.021). The postoperative mortality rate in groups 1,2 and 3 was 8%, 23% and 11%, respectively. The postoperative morbidity was 35% in group 2, 16% in group 1 and 7% in group 3. CONCLUSION: Our study suggests that silver-coated prostheses can be as effective as arterial allografts in the treatment of infections of vascular prostheses.	
J Thorac Cardiovasc Surg. 2011 Jan;141(1):91-7. **Outcomes of coronary artery bypass grafting and reduction annuloplasty for functional ischemic mitral regurgitation: a prospective multicenter study (Randomized Evaluation of a Surgical Treatment for Off-Pump Repair of the Mitral Valve).** Grossi EA, Woo YJ, Patel N, Goldberg JD, Schwartz CF, Subramanian VA, Genco C, Goldman SM, Zenati MA, Wolfe JA, Mishra YK, Trehan N. New York University School of Medicine, New York, NY 10016, USA. OBJECTIVE: Functional ischemic mitral regurgitation is a complication of ventricular remodeling; standard therapy is reduction annuloplasty and coronary artery bypass grafting. Unfortunately, outcomes are retrospective and contradictory. We report a multicenter study that documents the outcomes of reduction annuloplasty for functional ischemic mitral regurgitation. METHODS: Twenty-one centers randomized 75 patients to the coronary artery bypass grafting + reduction annuloplasty subgroup that was the control arm of the Randomized Evaluation of a Surgical Treatment for Off-pump Repair of the Mitral Valve trial. Entry criteria included patients requiring revascularization, patients with severe or symptomatic moderate functional ischemic mitral regurgitation, an ejection fraction 25% or greater, a left ventricular end-diastolic dimension 7.0 cm or less, and more than 30 days since acute myocardial infarction. All echocardiograms were independently scored by a core laboratory. Reduction annuloplasty was achieved by device annuloplasty. Two patients underwent immediate intraoperative conversion to a valve replacement because reduction annuloplasty was unable to correct mitral regurgitation; as-treated results are presented. RESULTS: Thirty-day mortality was 4.1% (3/73). Patients received an average of 2.8 bypass grafts. Mean follow-up	**Sabrina Trippoli**

was 24.6 months. Mitral regurgitation was reduced from 2.6 ± 0.8 preoperatively to 0.3 ± 0.6 at 2 years. Freedom from death or valve reoperation was 78% ± 5% at 2 years. There was significant improvement in ejection fraction and New York Heart Association class with reduction of left ventricular end-diastolic dimension. Cox regression analyses suggested that increasing age (P = .001; hazard ratio, 1.16 per year; 95% confidence interval, 1.06-1.26) and renal disease (P = .018; hazard ratio, 3.48; 95% confidence interval, 1.25-9.72) were associated with decreased survival. CONCLUSIONS: Coronary artery bypass grafting + reduction annuloplasty for functional ischemic mitral regurgitation predictably reduces mitral regurgitation and relieves symptoms. This treatment of moderate to severe mitral regurgitation is associated with improved indices of ventricular function, improved New York Heart Association class, and excellent freedom from recurrent mitral insufficiency. Although long-term prognosis remains guarded, this multicenter study delineates the intermediate-term benefits of such an approach	
Eur J Vasc Endovasc Surg. 2011 Jan;41(1):13-25. Epub 2010 Sep 25. **Comparison of surveillance versus aortic endografting for small aneurysm repair (CAESAR): results from a randomised trial.** Cao P, De Rango P, Verzini F, Parlani G, Romano L, Cieri E; CAESAR Trial Group. Collaborators: Cao P, Verzini F, De Rango P, Setacci C, Riambau V, Brunkwall J, Bell P, von Bockel H, Fiorani P, Ivancev K, Chinea B, Parlani G, Torsello G. Vascular Surgery Unit, Department of Cardioscience, Hospital S. Camillo-Forlanini, Piazza C. Forlanini, Rome, Italy. piergiorgio.cao@gmail.com Comment in: Eur J Vasc Endovasc Surg. 2011 Jan;41(1):26-7. BACKGROUND: Randomised trials have failed to demonstrate benefit from earlysurgical repair of small abdominal aortic aneurysm (AAA) compared with surveillance. This study aimed to compare results after endovascular aortic	**Nessuna scheda dispositivo non più commercializzato in Italia**

aneurysm repair (EVAR) or surveillance in AAA <5.5 cm. METHODS: Patients (50-79 years) with AAA of 4.1-5.4 cm were randomly assigned, in a 1:1 ratio, to receive immediate EVAR or surveillance by ultrasound and computed tomography (CT) and repair only after a defined threshold (diameter ≥5.5 cm, enlargement >1 cm /year, symptoms) was achieved. The main end point was all-cause mortality. Recruitment is closed; results at a median follow-up of 32.4 months are here reported. RESULTS: Between 2004 and 2008, 360 patients (early EVAR = 182; surveillance = 178) were enrolled. One perioperative death after EVAR and two late ruptures (both in the surveillance group) occurred. At 54 months, there was no significant difference in the main end-point rate [hazard ratio (HR) 0.76; 95% confidence interval (CI) 0.30-1.93; p = 0.6] with Kaplan-Meier estimates of all-cause mortality of 14.5% in the EVAR and 10.1% in the surveillance group. Aneurysm-related mortality, aneurysm rupture and major morbidity rates were similar. Kaplan-Meier estimates of aneurysms growth ≥5 mm at 36 months were 8.4% in the EVAR group and 67.5% in the surveillance group (HR 10.49; 95% CI 6.88-15.96; p < 0.01). For aneurysms under surveillance, the probability of delayed repair was 59.7% at 36 months (84.5% at 54 months). The probability of receiving open repair at 36 months for EVAR feasibility loss was 16.4%. CONCLUSION: Mortality and rupture rates in AAA <5.5 cm are low and no clear advantage was shown between early or delayed EVAR strategy. However, within 36 months, three out of every five small aneurysms under surveillance might grow to require repair and one out of every six might lose feasibility for EVAR. Surveillance is safe for small AAA if close supervision is applied. Long-term data are needed to confirm these results.	
Urology. 2011 Jan;77(1):30-5. Epub 2010 Oct 20. **A randomized prospective controlled study for assessment of different ureteral occlusion devices in prevention of stone migration during pneumatic lithotripsy.** Farahat YA, Elbahnasy AE, Elashry OM. Tanta University, Faculty of Medicine, Urology Department, Tanta, Egypt. Comment in: Urology. 2011 Jan;77(1):35. OBJECTIVE: To compare the safety and efficacy of two different ureteral occlusion devices (stone cone and entrapment net) in preventing retrograde stone migration during ureteroscopic pneumatic lithotripsy. Proximal migration of stone fragments during ureteroscopic lithotripsy is a common problem, especially when the pneumatic lithotripter is used for stone fragmentation. PATIENTS AND METHODS: A total of 195 patients with proximal ureteric stones were prospectively randomized into one of three groups in this study, with 65 patients in each group. In group I, the Stone Cone was used as a	**Fabiola Del Santo**

ureteral occlusive device; in group II, the N-Trap was used; and in group III (control group), the patients underwent pneumatic lithotripsy without any ureteral occlusive device. RESULTS: The ureteroscopic procedure was completed successfully in 180 patients; 63 patients in group I, 59 patients in group II, and 58 patients in group III. Patients in group I showed significantly lower incidence of stone migration compared with the other 2 groups (P <.05). Both ureteral occlusive devices significantly lowered the incidence of residual fragments (>3 mm), ureteral trauma, operative time, and the need for ureteral stenting compared with control group. The stone-free rate at 3 weeks was 95.24%, 83.05%, and 72.41% in groups I, II, and III, respectively. The patients in group I had a statistically significant stone-free rate compared with the other two groups (P <.05). Auxiliary procedures were required in 3 (4.76%), 10 (16.94%), and 16 cases (27.58%) in groups I, II, and III, respectively. CONCLUSION: The use of Stone Cone or N-Trap is valuable during ureteroscopic pneumatic lithotripsy for treatment of proximal ureteral stones. Both devices significantly diminish residual fragments, the incidence of ureteral wall trauma, and the need for the auxiliary procedure. However, the stone cone was more effective in preventing proximal stone migration and the subsequent stone-free rate.	
Acta Neurochir Suppl. 2011;108:183-6. **Percutaneous surgical treatment in lumbar spinal stenosis with Aperius-PercLID: indications, surgical technique and results.** Menchetti PP, Postacchini F, Bini W, Canero G. Florence University, Via Jacopo Nardi, 15, 50132, Firenze, Italy. menchetti@islass.org Interspinous spacers have recently been used in the treatment of lumbar spinal stenosis. In vitro studies have demonstrated a reduction in facet joint forces by 68% and annulus pressures by 63%. MRI studies have demonstrated increased canal and neural foraminal area after implantation of these devices. Previous studies by Zucherman et al. (Spine 30:1351-1358, 2005) demonstrated patient satisfaction rates of 71-73%.We carried out a multicentric retrospective study to assess the clinical outcomes following percutaneous posterior decompression using an interspinous spacer device (Aperius™-PercLID™ System; Kyphon-Medtronic). A total of 70 patients were included in the study. All of them had evidence of radiologically and clinically proven lumbar stenosis. The average age was 63.5 years. Patients completed the Zurich Claudication Questionnaire (ZCQ) and recorded pain levels on a Visual Analogue Scale (VAS). Average stay in hospital was 2 days. The average improvement in ZCQ included both symptomatic pain disappearance and functional ambulatory recovery. The average VAS pain score improved from 8.2 to 3.6 (scale of 1 to 10). The overall patient satisfaction rate was 76%. No complications were detected at 6 months' follow-up.	**Sara Simbula**

Circulation. 2011 Jan 25;123(3):274-81. Epub 2011 Jan 10. **Strut coverage and late malapposition with paclitaxel-eluting stents compared with bare metal stents in acute myocardial infarction: optical coherence tomography substudy of the Harmonizing Outcomes with Revascularization and Stents in Acute Myocardial Infarction (HORIZONS-AMI) Trial.** Guagliumi G, Costa MA, Sirbu V, Musumeci G, Bezerra HG, Suzuki N, Matiashvili A, Lortkipanidze N, Mihalcsik L, Trivisonno A, Valsecchi O, Mintz GS, Dressler O, Parise H, Maehara A, Cristea E, Lansky AJ, Mehran R, Stone GW. Division of Cardiology, Cardiovascular Department, Ospedali Riuniti di Bergamo, Bergamo, Italy. guagliumig@gmail.com BACKGROUND: The safety of drug-eluting stents in ST-segment elevation myocardial infarction (STEMI) continues to be debated. Pathological studies have demonstrated an association between uncovered struts and subsequent stent thrombosis. Optical coherence tomography can detect stent strut coverage in vivo on a micron-scale level. We therefore used optical coherence tomography to examine strut coverage in patients with STEMI treated with paclitaxel-eluting stents (PES) and bare metal stents (BMS). METHODS AND RESULTS: In the Harmonizing Outcomes With Revascularization and Stents in Acute Myocardial Infarction (HORIZONS-AMI) trial, patients with STEMI were randomized 3:1 to PES or BMS implantation. In a formal substudy, optical coherence tomography at 13 months was performed in 118 consecutive randomized patients (89 PES, 29 BMS) in whom 188 stents were assessed (146 PES and 42 BMS). A total of 44 139 stent struts were analyzed by an independent core laboratory blinded to stent assignment. The primary prespecified end point, the percentage of uncovered stent struts per lesion at follow-up, was 1.1 ± 2.5% in BMS lesions versus 5.7 ± 7.0% in PES lesions ($P < 0.0001$). Malapposed struts were observed in 0.1 ± 0.2% of BMS lesions versus 0.9 ± 2.1% of PES lesions ($P = 0.0003$). Percentage net volume obstruction was 36.0 ± 15.4% with BMS and 19.2 ± 11.3% with PES ($P < 0.0001$). CONCLUSIONS: In patients with STEMI undergoing primary percutaneous coronary intervention, implantation of PES as compared with BMS significantly reduces neointimal hyperplasia but results in higher rates of uncovered and malapposed stent struts as assessed by optical coherence tomography at 13-month follow-up. Further studies are required to determine the clinical significance of these findings.	**Non assegnato**
Circulation. 2011 Jan 4;123(1):79-86. Epub 2010 Dec 20. **Randomized comparison of final kissing balloon dilatation versus no final kissing balloon dilatation in patients with coronary bifurcation lesions treated with main vessel stenting: the Nordic-Baltic Bifurcation Study III.** Niemelä M, Kervinen K, Erglis A, Holm NR, Maeng M, Christiansen EH, Kumsars I, Jegere S, Dombrovskis A, Gunnes P, Stavnes S, Steigen TK, Trovik T, Eskola M, Vikman S, Romppanen H, Mäkikallio T, Hansen KN,	**Non assegnato**

Thayssen P, Aberge L, Jensen LO, Hervold A, Airaksinen J, Pietilä M, Frobert O, Kellerth T, Ravkilde J, Aarøe J, Jensen JS, Helqvist S, Sjögren I, James S, Miettinen H, Lassen JF, Thuesen L; Nordic-Baltic PCI Study Group.

Collaborators: Thuesen L, Lassen JF, Thayssen P, Steigen T, Gunnes P, Åberge L, Vikman S, Niemela M, Kervinen K, Airaksinen J, Erglis A, Kumsars I, Maeng M, Holm NR, Højdahl H, Jegere S, Bargsteen H, Højdahl H, Maeng M, Thygesen K, Nikus K.

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BACKGROUND: It is unknown whether the preferred 1-stent bifurcation stenting approach with stenting of the main vessel (MV) and optional side branch stenting using drug-eluting stents should be finalized by a kissing balloon dilatation (FKBD). Therefore, we compared strategies of MV stenting with and without FKBD.
METHODS AND RESULTS: We randomized 477 patients with a bifurcation lesion to FKBD (n=238) or no FKBD (n=239) after MV stenting. The primary end point was major adverse cardiac events: cardiac death, non-procedure-related index lesion myocardial infarction, target lesion revascularization, or stent thrombosis within 6 months. The 6-month major adverse cardiac event rates were 2.1% and 2.5% (P=1.00) in the FKBD and no-FKBD groups, respectively. Procedure and fluoroscopy times were longer and more contrast media was needed in the FKBD group than in the no-FKBD group. Three hundred twenty-six patients had a quantitative coronary assessment. At 8 months, the rate of binary (re)stenosis in the entire bifurcation lesion (MV and side branch) was 11.0% versus 17.3% P=0.11), in the MV was 3.1% versus 2.5% (P=0.68), and in the side branch was 7.9% versus 15.4% (P=0.039) in the FKBD versus no-FKBD groups, respectively. In patients with true bifurcation lesions, the side branch restenosis rate was 7.6% versus 20.0% (P=0.024) in the FKBD and no-FKBD groups, respectively.
CONCLUSIONS: MV stenting strategies with and without FKBD were associated with similar clinical outcomes. FKBD reduced angiographic side branch (re)stenosis, especially in patients with true bifurcation lesions. The simple no-FKBD procedures resulted in reduced use of contrast media and shorter procedure and fluoroscopy times. Long-term data on stent thrombosis are needed