OSSERVATORIO SIFO DISPOSITIVI MEDICI

a cura del Laboratorio SIFO di Farmacoeconomia

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Assegnato a

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Neuroradiology. 2012 Jan;54(1):43-50.

Complication rates using balloon-expandable and self-expanding stents for the treatment of intracranial atherosclerotic stenoses : analysis of the INTRASTENT multicentric registry.

Kurre W, Brassel F, Brüning R, Buhk J, Eckert B, Horner S, Knauth M, Liebig T, Maskova J, Mucha D, Sychra V, Sitzer M, Sonnberger M, Tietke M, Trenkler J, Turowski B, Berkefeld J; INTRASTENT study group.

INTRODUCTION: Using balloon-expandable stents (BES) for treatment of intracranial stenoses, high inflation pressures and rigidity of the device are regarded as major drawbacks limiting feasibility and safety of the procedure. Self-expanding stents (SES) were developed to facilitate lesion access and to allow for less aggressive dilatation. We analyzed data of the INTRASTENT multicentric registry to assess whether self-expanding stents significantly reduced peri-interventional complication rates.
METHODS: Records of intracranial stent procedures were entered consecutively into the registry. Datasets were divided into two groups according to the type of stent used. For outcome measurement, we chose three categories: TIA/minor stroke [modified Rankin score (mRS) <2], disabling stroke, and patient death. Clinical outcome was compared between BES and SES. We analyzed types of adverse events occurring in each group in addition.
RESULTS: Of 409 atherosclerotic lesions, 254 were treated with BES and 155 with SES. Technical success rates were 97.6% and 98.7%, respectively. Adverse event rates were 4.9%, 3.7%, and 0.8% for TIA/nondisabling stroke, disabling stroke, and death in the BES group compared with 5.3%, 6.0%, and 4.0% in the SES group. The differences were not statistically significant. We observed more perforator strokes after use of BES, but thromboembolic events occurred more often in the SES treatment group.
CONCLUSION: Data of the INTRASTENT registry do not support the hypothesis that introduction of SES lowered the overall complication rate of intracranial stent procedures. There might be an advantage using self-expanding stents in vessel segments with important perforating arteries.

Gastrointest Endosc. 2012 Jan;75(1):174-8. **Technical feasibility and safety of a new, implantable reflux control system to prevent gastroesophageal reflux in patients with stents placed through the lower esophageal sphincter.** Hirdes MM, Vleggaar FP, Laasch HU, Siersema PD. BACKGROUND: When an esophageal stent is placed through the lower esophageal sphincter (LES), gastroesophageal reflux symptoms may persist despite high-dose proton pump inhibitor therapy. A recently developed, short segment, uncovered nitinol stent with a tricuspid-like valve can be placed inside a previously placed esophageal stent. OBJECTIVE: To evaluate the technical feasibility and safety of a reflux control system (RCS) in distally placed esophageal stents. DESIGN: A prospective case series. SETTING: Two tertiary-care referral centers. PATIENTS: This study involved 10 patients who had an "open" stent placed through the LES and 1 patient with severe bile reflux after esophagojejunostomy. INTERVENTION: Placement of an RCS with fluoroscopic and (in selected cases) endoscopic guidance, from April to October 2010. MAIN OUTCOME MEASUREMENTS: Technical success of RCS placement and complications. RESULTS: Placement of an RCS was successful on the first attempt in all patients; complete expansion to the wall of the host stent was confirmed by fluoroscopy in all cases. In 3 patients, the host stent migrated in <1 month with the RCS still inside. In 8 patients, the RCS was in place for a median of 134 days (range 33-225 days). Three patients died because of malignant disease progression. Eight RCSs were removed endoscopically, together with the host stent without complications. RCS migration did not occur. LIMITATIONS: Small number of patients, nonrandomized design, lack of pH measurements. CONCLUSION: Placement of an RCS in a host stent is technically feasible and safe. An RCS can be considered in symptomatic patients with open esophageal stents to prevent gastroesophageal reflux.	**Lab SIFO Farmacoeconomia**
J Surg Oncol. 2012 Jan;105(1):60-5. doi: 10.1002/jso.22059. **Outcomes following oesophageal stent insertion for palliation of malignant strictures: A large single centre series.**	**Lab SIFO Farmacoeconomia**

Battersby NJ, Bonney GK, Subar D, Talbot L, Decadt B, Lynch N. BACKGROUND: Self-expanding metal stents (SEMS) are an accepted intervention for malignant dysphagia. Stents vary in ease of insertion, removability, migration and occlusion rates. This series reports the complications, morbidity and mortality associated with several SEMS. METHOD: A prospective database of patients undergoing fluoroscopic guided oesophageal stent insertion for malignancy between June 2001 and June 2009 was analysed. Patient demographics, intervention outcomes and tumour variables were correlated with stent failure and patient survival. Multivariate analysis was performed to evaluate predictors for stent failure. RESULTS: Two hundred and seventy-three stents were deployed using nine different types of SEMS. The median Mellow-Pinkas dysphagia score significantly improved from 3 to 1 post-stent insertion ($P<0.001$), with a technical success rate of 98%. Stent complications occurred in 95 (36%) patients [recurrent dysphagia $n=49$ (19%), migration $n=24$ and occlusion $n=25$]. Multivariate analysis demonstrates that the covered Niti S stent fails significantly more than the double-layered Niti S stent ($OR=4$, $P<0.005$). CONCLUSION: Oesophageal stent insertion provides good palliation for malignant dysphagia, however recurrent dysphagia remains a problem. This major complication occurs more frequently with covered Niti S stents than double-layered Niti S stents. This finding may aid the stent choice used in advanced oesophageal malignancy.	
Eur J Cardiothorac Surg. 2012 Jan;41(1):113-8. **Importance of evaluating conduction block in radiofrequency ablation for atrial fibrillation.** Gersak B, Kiser AC, Bartus K, Sadowski J, Harringer W, Knaut M, Wimmer-Greinecker G, Pernat A. OBJECTIVE: Atrial fibrillation (AF) is the most frequently diagnosed cardiac arrhythmia. Anti-arrhythmic drugs may be used to suppress ectopic foci and interrupt reentry circuits, but are often insufficient to treat recurrent AF and have a number of adverse effects. Alternative therapies, such as catheter and surgical ablation, have been explored. This investigation examines the importance of assessing exit block when performing surgical ablation during beating-heart treatment of AF. METHODS: This was an evaluation of pooled data from multicenter prospective results obtained in AF patients who received ablation with a new, irrigated, vacuum-integrated device that creates linear lesions during beating-heart/open-chest or minimally invasive, port-access procedures. Electrocardiogram or Holter data were collected intra-operatively and at 1, 3, 6, and 12 months. Outcomes were also evaluated for patients who were or 'were not' tested for exit block following the ablation procedure.	**Lab SIFO Farmacoeconomia**

RESULTS: A total of 93 patients were treated (61 open-chest surgeries, 32 port-access procedures). There were no device-related complications and no operative mortality. At 341 days' average follow-up, 71/86 (83%) patients were free from AF, 66/86 (77%) were in sinus rhythm, and 60/86 (70%) were free from AF and off Class I and III anti-arrhythmic drugs (AADs). At 12 months, 23/23 (100%) patients with exit block confirmed were AF free compared with 13/21 (62%) patients with exit block not tested ($p \leq 0.01$, Fisher's exact test); 20/23 (87%) were in sinus rhythm compared with 12/21 (57%) patients with exit block not tested ($p \leq 0.05$, Fisher's exact test); and 20/23 (87%) were AF free without Class I and III AADs compared with 10/21 (48%) patients with exit block not tested ($p \leq 0.01$, Fisher's exact test). Both open-chest and port-access procedures yielded decreases in left-atrial size from baseline to 6 months' follow-up. Patients undergoing port-access procedures also observed an increase in left-ventricular ejection fraction, which was also significant at 6 months. CONCLUSION: Patients in whom exit block was confirmed following an ablation procedure were more likely to have successful clinical outcomes. Since testing for exit block must be performed on a beating heart, total epicardial beating-heart ablation may provide an important treatment for AF, providing intra-operative feedback indicative of long-term outcomes.	
Lancet Neurol. 2012 Feb;11(2):140-9. **Subthalamic deep brain stimulation with a constant-current device in Parkinson's disease: an open-label randomised controlled trial.** Okun MS, Gallo BV, Mandybur G, Jagid J, Foote KD, Revilla FJ, Alterman R, Jankovic J, Simpson R, Junn F, Verhagen L, Arle JE, Ford B, Goodman RR, Stewart RM, Horn S, Baltuch GH, Kopell BH, Marshall F, Peichel D, Pahwa R, Lyons KE, Tröster AI, Vitek JL, Tagliati M; SJM DBS Study Group. BACKGROUND: The effects of constant-current deep brain stimulation (DBS) have not been studied in controlled trials in patients with Parkinson's disease. We aimed to assess the safety and efficacy of bilateral constant-current DBS of the subthalamic nucleus. METHODS: This prospective, randomised, multicentre controlled trial was done between Sept 26, 2005, and Aug 13, 2010, at 15 clinical sites specialising in movement disorders in the USA. Patients were eligible if they were aged 18-80 years, had Parkinson's disease for 5 years or more, and had either 6 h or more daily off time reported in a patient diary of moderate to severe dyskinesia during waking hours. The patients received bilateral implantation in the subthalamic nucleus of a constant-current DBS device. After implantation, computer-generated randomisation was done with a block size of four, and patients were randomly assigned to the stimulation or control group (stimulation:control ratio 3:1). The control group received implantation without activation for 3 months. No blinding occurred during this study, and both patients and investigators were aware of the treatment group. The primary outcome variable was the change in on time without bothersome dyskinesia (ie, good quality on time) at 3 months as recorded in patients' diaries. Patients were followed up for 1 year. This trial is registered with	**Lab SIFO Farmacoeconomia**

ClinicalTrials.gov, number NCT00552474. FINDINGS: Of 168 patients assessed for eligibility, 136 had implantation of the constant-current device and were randomly assigned to receive immediate (101 patients) or delayed (35 patients) stimulation. Both study groups reported a mean increase of good quality on time after 3 months, and the increase was greater in the stimulation group (4•27 h vs 1•77 h, difference 2•51 [95% CI 0•87-4•16]; p=0•003). Unified Parkinson's disease rating scale motor scores in the off-medication, on-stimulation condition improved by 39% from baseline (24•8 vs 40•8). Some serious adverse events occurred after DBS implantation, including infections in five (4%) of 136 patients and intracranial haemorrhage in four (3%) patients. Stimulation of the subthalamic nucleus was associated with dysarthria, fatigue, paraesthesias, and oedema, whereas gait problems, disequilibrium, dyskinesia, and falls were reported in both groups. INTERPRETATION: Constant-current DBS of the subthalamic nucleus produced significant improvements in good quality on time when compared with a control group without stimulation. Future trials should compare the effects of constant-current DBS with those of voltage-controlled stimulation. FUNDING: St Jude Medical Neuromodulation Division.	
Knee. 2012 Jan;19(1):36-40. **The Twin Peg Oxford partial knee replacement: the first 100 cases.** White SH, Roberts S, Jones PW. We present the clinical results of the first 100 patients who received the Twin Peg Oxford partial knee replacement which has a 15° extra femoral surface for contact in deep flexion, and has two pegs for more secure fixation. We measured the clinical outcome 2 years after the medial unicompartmental arthroplasty using patient and surgeon derived outcome measures. The results showed a mean Oxford Knee Score of 41, a mean American Knee Society Objective Score of 93 and a Functional Score of 84, a mean range of motion of 130° and a high satisfaction rate. Results were significantly better in male patients. There were no deaths, infections, dislocations, fractures or revisions. There were no pathological radiolucencies suggestive of early loosening. We conclude that the Twin Peg Oxford partial knee replacement shows excellent clinical and radiological results at 2 years. For surgeons who have concern over the risk of femoral loosening with the single peg Oxford knee, or seek an improved surface area of contact in full flexion, this implant offers an excellent alternative.	**Lab SIFO Farmacoeconomia**
Female Pelvic Med Reconstr Surg. 2012 Jan-Feb;18(1):41-5. **TVT-Secur (Hammock) versus TVT-Obturator: a randomized trial of suburethral sling operative procedures.**	**Lab SIFO Farmacoeconomia**

Hota LS, Hanaway K, Hacker MR, Disciullo A, Elkadry E, Dramitinos P, Shapiro A, Ferzandi T, Rosenblatt PL. OBJECTIVES: This study aimed to compare TVT-Secur (TVT-S) and TVT-Obturator (TVT-O) suburethral slings for treatment of stress urinary incontinence (SUI). METHODS: This was a single-center, nonblinded, randomized trial of women with SUI who were randomized to TVT-S or TVT-O from May 2007 to April 2009. The primary outcome, SUI on cough stress test (CST), and quality-of-life and symptom questionnaires (Pelvic Floor Distress Inventory [PFDI-20] and Pelvic Floor Impact Questionnaire [PFIQ-7]) were assessed at 12 weeks and 1 year. RESULTS: Forty-three women were randomized to TVT-S and 44 to TVT-O. There were no differences in median baseline PFDI-20 and PFIQ-7. Twenty-two (52.4%) of 42 participants randomized to TVT-S had a positive CST result at evaluation after 12 weeks or 1 year, whereas 4 (9.1%) of the 44 in the TVT-O group had a positive CST result. The intent-to-treat analysis showed that the risk of a positive CST result was 6 times higher after TVT-S than TVT-O (risk ratio, 6.0; 95% confidence interval [CI], 2.3-16.0). Among women not lost to follow-up, the risk ratio for a positive CST result after TVT-S compared with TVT-O was 17.9 (95% CI, 2.5-128.0) at 12 weeks and 3.5 (95% CI, 1.1-11.0) at 1 year. Both TVT-S and TVT-O resulted in improved quality of life and symptoms at 12 weeks. There was no difference between the groups for PFDI-20 (P = 0.40) or PFIQ-7 (P = 0.43). A similar pattern was seen at 1 year (P = 0.85 and P = 0.36). CONCLUSIONS: The TVT-S seems to have a higher risk of positive postoperative CST result; however, the procedures result in similar improvements in quality of life and symptoms.	
Int Orthop. 2012 Jan;36(1):35-41. **Revision hip arthroplasty using a cementless modular tapered stem.** Pattyn C, Mulliez A, Verdonk R, Audenaert E. PURPOSE: Here we report the short-term clinical and radiological results of the Profemur®-R cementless modular revision stem. METHODS: Between June 2002 and May 2006, 68 revision hip arthroplasties were consecutively performed using this stem. Survival at a mean follow-up of 5.2 years was 94%. According to the Paprosky classification, the femoral defect was classified as type 1 in 39 hips (57.3%), type 2 in 18 hips (26.5%), type 3A in ten hips (14.7%) and type 3B in one hip (1.5%). RESULTS: The Harris Hip Score was 49.57 before surgery and averaged 78.28 at the latest follow-up. The Merle d'Aubigne score improved from 9.15 preoperatively to 14.30 postoperatively. Stem stability rated according to the Agora Roentgenographic Assessment (ARA) scoring system averaged 5.22, suggesting a high likelihood of a durable implant. CONCLUSION: The revision prosthesis examined in this study can be considered a viable and useful option in revision hip arthroplasty, even in patients with bony femoral defects.	**Lab SIFO Farmacoeconomia**

J Craniomaxillofac Surg. 2012 Jan;40(1):71-7. **The use of absorbable polyglactin/polydioxanon implant (Ethisorb(®)) in non-surgical closure of oro-antral communication.** Burić N, Jovanović G, Krasić D, Tijanić M, Burić M, Tarana S, Spasić M. Oro-antral communications (OAC) greater than 4-5 mm in diameter can seldom be counted on to heal spontaneously without the necessity for surgical closure. The initial experience in applying an absorbable polyglactin/polydioxanon implant (Ethisorb(®)), in non-surgical closure of OAC ranging from 5 to 7 mm in diameter, is presented. Twelve patients of varying ages with OAC up to 72 h in duration, have been treated with Ethisorb(®). Failures were not demonstrated in the form of the creation of an oro-antral fistula (OAF), and in all patients, OAC-s were closed with the epithelization of post-extraction wounds up to 21 days after implantation of Ethisorb(®). Based on these initial encouraging results, we propose that an Ethisorb(®) biopolymeric absorbable implant can be used in selected clinical cases for non-surgical closure of OAC.	**Lab SIFO Farmacoeconomia**
Catheter Cardiovasc Interv. 2012 Jan 1;79(1):84-9. **Direct stenting compared to balloon predilation in drug-eluting stents: one-year outcomes from the DEScover Registry.** Abbott JD, Earl T, Vlachos HE, Selzer F, Vaidya KA, Romero A, Kip KE, Williams DO. OBJECTIVES: We sought to examine the determinants and outcomes of direct stenting (DS) compared to predilation with drug-eluting stents (DES). BACKGROUND: Limited data suggest that DS with DES is feasible and may reduce restenosis compared to predilation. Whether DS improves clinical outcomes in unselected patients treated with DES is unknown. METHODS: DEScover is a prospective, multicenter, observational study of percutaneous coronary intervention that enrolled patients in 2005. The analysis cohort included 4,210 patients who received a DES and had a single lesion treated with DS (n = 1,651) or predilation (n = 2,559) at the discretion of the operator. Multivariable analysis was performed for 1-year outcomes. RESULTS: DS was performed in 39.2% of patients. The direct stent patients were younger, less often male, and had a lesser extent of CAD. DS was performed less often in patients presenting with an acute myocardial infarction (MI) and more often in stable angina and elective procedures. Lesion characteristics differed with DS performed less often for calcified lesions, high-grade stenoses (>90%), and bifurcation lesions. Lesion postdilation was less	**Lab SIFO Farmacoeconomia**

common in direct stent patients (42.1% vs. 50.7%, P = 0.0001). Complete procedural success was similar (99.8% vs. predilation 99.7%, P = 0.46). At 1 year, there was no difference in the adjusted hazard ratios of death (0.67, 0.44-1.04, P = 0.08), MI (1.05, 0.66-1.67, P = 0.83), stent thrombosis (0.38, 0.13-1.14, P = 0.08), TLR (0.75, 0.48-1.17, P = 0.21), TVR (0.89, 0.64-1.23, P = 0.47), and major adverse coronary event (0.88, 0.71-1.09, P = 0.24). CONCLUSIONS: DS with DES is commonly performed in clinical practice and results in similar long-term outcomes as predilation	
Eur J Cardiothorac Surg. 2012 Jan;41(1):121-5. **Safety and feasibility of intra-operative device closure of atrial septal defect with transthoracic minimal invasion.** Chen Q, Cao H, Zhang GC, Chen LW, Chen DZ. OBJECTIVE: The study aims to evaluate the safety and feasibility of intra-operative device closure of atrial septal defect with transthoracic minimal invasion. METHODS: From May 2006 to June 2009, 252 patients with secundum-type atrial septal defect closure were enrolled in our institution. The patients were divided into two groups, with 182 patients in group I with intra-operative device closure and 72 in group II with surgical closure. In group I, the patients' age ranged from 3 months to 62 years (mean±standard deviation, 19.0±16.7 years). This approach involved a transthoracic minimal invasion that was performed after full evaluation of the atrial septal defect by transthoracic echocardiography, deploying the device through the delivery sheath to occlude the atrial septal defect. RESULTS: In group I, 180 patients were occluded successfully under this approach. The size of the occluder device implanted ranged from 6 to 48 mm. Minor complications occurred, which included transient arrhythmias (n=23) and pleural effusion (n=15). Two patients with postoperative cardiac arrest were successfully cardiopulmonary resuscitated. Another two patients with occluder dislodged back into the right atrium were turned to surgical repair with cardiopulmonary bypass on the postoperative day. In group II, all patients were occluded successfully, and almost all patients needed blood transfusion and suffered from various minor complications. All discharged patients were followed up for 1-5 years. During this period, we found no recurrence, no thrombosis, even no device failure. In our comparative studies, group II had significantly longer intensive care unit (ICU) stay and hospital stay than group I ($p<0.05$). The cost for group I was less than group II ($p<0.05$). CONCLUSIONS: Intra-operative device closure of atrial septal defect with transthoracic minimal invasion is a safe and feasible technique. It had the advantages of cost savings, yielding better cosmetic results, and leaving less trauma than surgical closure.	**Lab SIFO Farmacoeconomia**

J Surg Oncol. 2012 Jan;105(1):60-5. doi: 10.1002/jso.22059. **Outcomes following oesophageal stent insertion for palliation of malignant strictures: A large single centre series.** Battersby NJ, Bonney GK, Subar D, Talbot L, Decadt B, Lynch N. Department of Upper GI Surgery, Stockport NHS Foundation Trust, Stepping Hill Hospital, Stockport, Cheshire, UK. nicholasjohnbattersby@gmail.com BACKGROUND: Self-expanding metal stents (SEMS) are an accepted intervention for malignant dysphagia. Stents vary in ease of insertion, removability, migration and occlusion rates. This series reports the complications, morbidity and mortality associated with several SEMS. METHOD: A prospective database of patients undergoing fluoroscopic guided oesophageal stent insertion for malignancy between June 2001 and June 2009 was analysed. Patient demographics, intervention outcomes and tumour variables were correlated with stent failure and patient survival. Multivariate analysis was performed to evaluate predictors for stent failure. RESULTS: Two hundred and seventy-three stents were deployed using nine different types of SEMS. The median Mellow-Pinkas dysphagia score significantly improved from 3 to 1 post-stent insertion ($P < 0.001$), with a technical success rate of 98%. Stent complications occurred in 95 (36%) patients [recurrent dysphagia n = 49 (19%), migration n = 24 and occlusion n = 25]. Multivariate analysis demonstrates that the covered Niti S stent fails significantly more than the double-layered Niti S stent (OR = 4, $P < 0.005$). CONCLUSION: Oesophageal stent insertion provides good palliation for malignant dysphagia, however recurrent dysphagia remains a problem. This major complication occurs more frequently with covered **Niti S stents** than double-layered Niti S stents. This finding may aid the stent choice used in advanced oesophageal malignancy.	**Lab SIFO Farmacoeconomia**
J Hand Surg Am. 2012 Jan;37(1):47-54. **Objective functional outcomes and patient satisfaction after silicone metacarpophalangeal arthroplasty for rheumatoid arthritis.** Waljee JF, Chung KC.	**Lab SIFO Farmacoeconomia**

Section of Plastic Surgery, Department of Surgery, University of Michigan Health System, Ann Arbor, MI 48109-5340, USA. PURPOSE: Patient satisfaction is an essential measure of quality of care for rheumatoid arthritis. Prior research demonstrates that patient satisfaction improves after silicone metacarpophalangeal arthroplasty (SMPA) despite minimal change in hand function. The purpose of this study was to identify the level of objective functional recovery that yields satisfaction after SMPA. We hypothesized that measurable gains in objective hand function after SMPA will discriminate between satisfied and dissatisfied patients. METHODS: In this prospective, multicenter, cohort study, we observed 46 patients with rheumatoid arthritis and metacarpophalangeal (MCP) joint subluxation for 2 years after reconstructive surgery. We derived satisfaction scores from the Michigan Hand Outcomes Questionnaire, ranging from 0 (least satisfied) to 100 (most satisfied), and dichotomized them using the Cohen large effect size. We measured hand function at baseline and follow-up including strength (grip strength and pinch strength), finger position (extensor lag and ulnar drift), and MCP arc of motion. We constructed receiver operating characteristic curves to identify optimal cutoffs in hand function that correspond with satisfaction. RESULTS: At 2 years of follow-up, patients who achieved an extension lag of 30° or less were considered satisfied, which represented a 52% improvement (preoperative lag = 63°). Similarly, patients who gained improvement in ulnar drift from an average of preoperatively 62° to 9° postoperatively were satisfied. Finally, patients who achieved an improvement in MCP arc of motion from an average of 21° to 31° postoperatively were satisfied. No improvements in grip or pinch strength corresponded with postoperative patient satisfaction. CONCLUSIONS: Patients were satisfied with only modest gains in grip and pinch strength after silicone metacarpophalangeal arthroplasty. However, maintaining finger position, without recurrence of ulnar drift or extensor lag, and MCP arc of motion corresponded with patient satisfaction in the postoperative period. TYPE OF STUDY/LEVEL OF EVIDENCE: Therapeutic II.	
J Heart Lung Transplant. 2012 Jan;31(1):27-36. **Neurocognitive function in destination therapy patients receiving continuous-flow vs pulsatile-flow left ventricular assist device support.** Petrucci RJ, Rogers JG, Blue L, Gallagher C, Russell SD, Dordunoo D, Jaski BE, Chillcott S, Sun B, Yanssens TL, Tatooles A, Koundakjian L, Farrar DJ, Slaughter MS. BACKGROUND: The HeartMate II (Thoratec Corp, Pleasanton, CA) continuous-flow left ventricular assist device (LVAD) improved survival in destination therapy (DT) patients during a randomized trial compared with pulsatile-flow LVADs. This study documented changes in cognitive performance in DT patients from that trial to determine if there were differences between continuous-flow and pulsatile-flow support.	**Lab SIFO Farmacoeconomia**

METHODS: Data were collected in a sub-study from 96 HeartMate II continuous-flow and 30 HeartMate XVE pulsatile-flow LVAD patients from 12 of the 35 trial sites that followed the same serial neurocognitive (NC) testing protocol at 1, 3, 6, 12, and 24 months after LVAD implantation. Spatial perception, memory, language, executive functions, and processing speed were the domains assessed with 10 standard cognitive measures. Differences over time and between LVAD type were evaluated with linear mixed-effects modeling. RESULTS: From 1 to 24 months after LVAD implantation, changes in NC functions were stable or showed improvement in all domains, and there were no differences between the continuous-flow and pulsatile-flow groups. Data at 24 months were only available from patients with the continuous-flow LVAD due to the limited durability of the HeartMate XVE device. There was no decline in any NC domain over the time of LVAD support. Missing data not collected from patients who died could have resulted in a bias toward inflated study results. CONCLUSIONS: The NC performance of advanced heart failure patients supported with continuous-flow and pulsatile-flow LVADs shows stabilization or improvement during support for up to 24 months.	
J Am Coll Cardiol. 2012 Jan 3;59(1):16-23. **Classification and clinical impact of restenosis after femoropopliteal stenting.** Tosaka A, Soga Y, Iida O, Ishihara T, Hirano K, Suzuki K, Yokoi H, Nanto S, Nobuyoshi M. OBJECTIVES: The purpose of this study was to investigate the relationship between angiographic patterns of in-stent restenosis (ISR) after femoropopliteal (FP) stenting and the frequency of refractory ISR. BACKGROUND: In-stent restenosis after FP stenting is an unsolved problem. The incidence and predictors of refractory restenosis remain unclear. METHODS: This study was a multicenter, retrospective observational study. From September 2000 to December 2009, 133 restenotic lesions after FP artery stenting were classified by angiographic pattern: class I included focal lesions (≤50 mm in length), class II included diffuse lesions (>50 mm in length), and class III included totally occluded ISR. All patients were treated by balloon angioplasty for at least 60 s. Recurrent ISR or occlusion was defined as ISR or occlusion after target lesion revascularization. Restenosis was defined as >2.4 of the peak systolic velocity ratio by duplex scan or >50% stenosis by angiography. RESULTS: Sixty-four percent of patients were male, 67% had diabetes mellitus, and 24% underwent hemodialysis. Class I pattern was found in 29% of the limbs, class II in 38%, and class III in 33%. Mean follow-up period was 24 ± 17 months. All-cause death occurred in 14 patients; bypass surgery was performed in 11 limbs, and major amputation was performed in 1 limb during the follow-up. Kaplan-Meier survival curves showed that the rate of recurrent ISR at 2 years was 84.8% in class III patients compared with 49.9% in class I patients ($p < 0.0001$) and 53.3% in class II patients ($p = 0.0003$), and the rate of recurrent occlusion at 2 years was 64.6% in class III patients compared with 15.9% in class I patients ($p < 0.0001$) and 18.9% in class II patients ($p < 0.0001$).	**Lab SIFO Farmacoeconomia**

CONCLUSIONS: Restenotic patterns after FP stenting are important predictors of recurrent ISR and occlusion.	
Yonsei Med J. 2012 Jan;53(1):83-90. doi: 10.3349/ymj.2012.53.1.83. **Early experience using a left atrial appendage occlusion device in patients with atrial fibrillation.** Kim YL, Joung B, On YK, Shim CY, Lee MH, Kim YH, Pak HN. PURPOSE: Atrial fibrillation (AF) is one of the major risk factors for ischemic stroke, and 90% of thromboembolisms in these patients arise from the left atrial appendage (LAA). Recently, it has been documented that an LAA occlusion device (OD) is not inferior to warfarin therapy, and that it reduces mortality and risk of stroke in patients with AF. MATERIALS AND METHODS: We implanted LAA-ODs in 5 Korean patients (all male, 59.8 ± 7.3 years old) with long-standing persistent AF or permanent AF via a percutaneous trans-septal approach. RESULTS: 1) The major reasons for LAA-OD implantation were high risk of recurrent stroke (80%), labile international neutralizing ratio with hemorrhage (60%), and 3/5 (60%) patients had a past history of failed cardioversion for rhythm control. 2) The mean LA size was 51.3 ± 5.0 mm and LAA size was 25.1 × 30.1 mm. We implanted the LAA-OD (28.8 ± 3.4 mm device) successfully in all 5 patients with no complications. 3) After eight weeks of anticoagulation, all patients switched from warfarin to anti-platelet agent after confirmation of successful LAA occlusion by trans-esophageal echocardiography. CONCLUSION: We report on our early experience with LAA-OD deployment in patients with 1) persistent or permanent AF who cannot tolerate anticoagulation despite significant risk of ischemic stroke, or 2) recurrent stroke in patients who are unable to maintain sinus rhythm.	**Lab SIFO Farmacoeconomia**
J Neurosurg. 2012 Jan;116(1):135-44. Epub 2011 Nov 4. **The Barrow Ruptured Aneurysm Trial.** McDougall CG, Spetzler RF, Zabramski JM, Partovi S, Hills NK, Nakaji P, Albuquerque FC. OBJECT: The purpose of this ongoing study is to compare the safety and efficacy of microsurgical clipping and endovascular coil embolization for the treatment of acutely ruptured cerebral aneurysms and to determine if one treatment is superior to the other by examining clinical and angiographic outcomes. The authors examined the null hypothesis that no difference exists between the 2 treatment modalities in the setting of subarachnoid hemorrhage (SAH). The current report is limited to the clinical results at 1 year after treatment. METHODS: The authors screened 725 patients with SAH, resulting in 500 eligible patients who were enrolled	**Lab SIFO Farmacoeconomia**

prospectively in the study after giving their informed consent. Patients were assigned in an alternating fashion to surgical aneurysm clipping or endovascular coil therapy. Intake evaluations and outcome measurements were collected by nurse practitioners independent of the treating surgeons. Ultimately, 238 patients were assigned to aneurysm clipping and 233 to coil embolization. The 2 treatment groups were well matched. There were no anatomical exclusions. Crossing over was allowed, but primary outcome analysis was based on the initial treatment modality assignment. Posttreatment care was standardized for both groups. Patient outcomes at 1 year were independently assessed using the modified Rankin Scale (mRS). A poor outcome was defined as an mRS score > 2 at 1 year. The primary outcome was based on the assigned group; that is, by intent to treat. RESULTS: One year after treatment, 403 patients were available for evaluation. Of these, 358 patients had actually undergone treatment. The remainder either died before treatment or had no identifiable source of SAH. A poor outcome (mRS score > 2) was observed in 33.7% of the patients assigned to aneurysm clipping and in 23.2% of the patients assigned to coil embolization (OR 1.68, 95% CI 1.08-2.61; p = 0.02). Of treated patients assigned to the coil group, 124 (62.3%) of the 199 who were eligible for any treatment actually received endovascular coil embolization. Patients who crossed over from coil to clip treatment fared worse than patients assigned to coil embolization, but no worse than patients assigned to clip occlusion. No patient treated by coil embolization suffered a recurrent hemorrhage. CONCLUSIONS: One year after treatment, a policy of intent to treat favoring coil embolization resulted in fewer poor outcomes than clip occlusion. Although most aneurysms assigned to the coil treatment group were treated by coil embolization, a substantial number crossed over to surgical clipping. Although a policy of intent to treat favoring coil embolization resulted in fewer poor outcomes at 1 year, it remains important that high-quality surgical clipping be available as an alternative treatment modality	
Catheter Cardiovasc Interv. 2012 Jan 1;79(1):167-73. doi: 10.1002/ccd.23257. **Carotid artery revascularization with distal protection in high-surgical-risk patients in routine clinical practice: rationale and design of the CABANA safety surveillance program.** White CJ, Avula SB, Mintz RT, Iskander A, Chervu A, Feldman RL, Schermerhorn ML, Woo HH, Hopkins LN. BACKGROUND: Continuous improvement in carotid artery stenting (CAS) outcomes, especially for periprocedural death and stroke in high-surgical-risk patients, have been seen in recent randomized trials of CAS versus carotid endarterectomy and CAS registries. However, these studies use stringent inclusion/exclusion criteria for patient, institution, and physician selection. The Carotid Stenting Boston Scientific Surveillance Program (CABANA) study was initiated to evaluate periprocedural outcomes with modern versions of the Carotid Wallstent and FilterWire EZ System for operators with a wide range of clinical specialties, CAS experience and training levels, in patients with a broad range of high-surgical-risk conditions and lesion types. METHODS: This prospective, single-arm study enrolled 1,097 subjects with 1,098 carotid artery lesions at 99 study	**Lab SIFO Farmacoeconomia**

centers. Investigators were grouped into one of three tiers according to whether they had a high, medium, or low level of previous CAS experience and were also categorized by their CAS-credential-based training requirements for the CABANA study. Follow-up at 30 days includes clinical evaluation and independent neurological and NIH stroke scale assessments. The primary endpoint rate of 30-day composite stroke, death, and MI, as well as the rates of these individual events, will be evaluated across the overall study, by physician experience tier, and by physician training tier. DISCUSSION: The evaluation of periprocedural CAS safety in a real-world environment with modern devices in high-surgical-risk patients treated by physicians with a broad range of training and experience will better inform treatment decisions in the future.	
Int Urogynecol J. 2012 Jan;23(1):93-8. **TVT SECUR System: Final results of a prospective, observational, multicentric study.** Bernasconi F, Napolitano V, Natale F, Leone V, Lijoi D, Cervigni M. INTRODUCTION AND HYPOTHESIS: This is an observational multicentre prospective study into the complications and effectiveness of TVT SECUR™. METHODS: One hundred forty-seven patients with urodynamic or occult Stress Urinary Incontinence (SUI) were enrolled. Outcome measures at 6, 12 and 24 months were: objective cough test; subjective responses to PGI-S questionnaire and Visual Analogue Score. Statistical analysis: Wilcoxon Test; Monte Carlo Exact Test. RESULTS: Ninety-five urodynamic SUI and 41 occult SUI patients were treated using transobturator (H-position) or retropubic (U-position) approach (110 vs. 26 patients). Cure rates at 6, 12, and 24 months were 87.5%, 88.6% and 89.5%. Failure rates at all follow-ups were similar for urodynamic and occult SUI. The U-position failure rate was comparable to H-position at short-term but significantly higher at mid-term. Familiarity with the technique brought significantly higher success rates. CONCLUSIONS: TVT SECUR is safe, effective and versatile, but has an appreciable learning curve.	**Lab SIFO Farmacoeconomia**
Int Urogynecol J. 2012 Jan;23(1):99-104. **TVT-O vs. TVT for the treatment of SUI: a non-inferiority study.** Yang X, Jiang M, Chen X, Tong X, Li H, Qiu J, Shao L. INTRODUCTION AND HYPOTHESIS: This study aimed to prospectively compare, in terms of efficacy and safety, the tension-free vaginal tape (TVT) and the transobturator vaginal tape inside-out (TVT-O) procedure for stress urinary incontinence.	**Lab SIFO Farmacoeconomia**

METHODS: A cough stress test was applied to the objective outcomes, while urinary incontinence-specific quality of life questionnaire was applied to the subjective outcomes. A test for non-inferiority was carried out for detecting the success rate between the two groups. RESULTS: The objective success rates were found to be 95.4% (62/65) in the TVT group and 96.4% (108/112) in the TVT-O group. No significant difference was found between these two groups in the success rate by non-inferiority test ($P < 0.0005$), with significant improvement in quality of life and no significant difference in patient satisfaction rates in the two groups ($P > 0.05$). CONCLUSIONS: In the study, the TVT-O procedure could be defined to be identical to the TVT approach in success rate by non-inferiority test.	
Arthroscopy. 2012 Jan;28(1):8-15. A prospective, randomized evaluation of acellular human dermal matrix augmentation for arthroscopic rotator cuff repair. Barber FA, Burns JP, Deutsch A, Labbé MR, Litchfield RB. Plano Orthopedic Sports Medicine and Spine Center, Plano, Texas 75093, USA. PURPOSE: To prospectively evaluate the safety and effectiveness of arthroscopic acellular human dermal matrix augmentation of large rotator cuff tear repairs. METHODS: A prospective, institutional review board-approved, multicenter series of patients undergoing arthroscopic repair of 2-tendon rotator cuff tears measuring greater than 3 cm were randomized by sealed envelopes opened at the time of surgery to arthroscopic single-row rotator cuff repair with GraftJacket acellular human dermal matrix (Wright Medical Technology, Arlington, TN) augmentation (group 1) or without augmentation (group 2). Preoperative and postoperative functional outcome assessments were obtained by use of the American Shoulder and Elbow Surgeons (ASES), Constant, and University of California, Los Angeles scales. Gadolinium-enhanced magnetic resonance imaging (MRI) evaluation of these repairs was obtained at a mean of 14.5 months (range, 12 to 24 months). Adverse events were recorded. RESULTS: There were 22 patients in group 1 and 20 in group 2 with a mean age of 56 years. The mean follow-up was 24 months (range, 12 to 38 months). The ASES score improved from 48.5 to 98.9 in group 1 and from 46.0 to 94.8 in group 2. The scores in group 1 were statistically better than those in group 2 ($P = .035$). The Constant score improved from 41.0 to 91.9 in group 1 and from 45.8 to 85.3 in group 2. The scores in group 1 were statistically better than those in group 2 ($P = .008$). The University of California, Los Angeles score improved from 13.3 to 28.2 in group 1 and from 15.9 to 28.3 in group 2 ($P = .43$). Gadolinium-enhanced MRI scans showed intact cuffs in 85% of repairs in group 1 and 40% in group 2 ($P < .01$). No adverse events were attributed to the presence of the matrix grafts.	**Lab SIFO Farmacoeconomia**

CONCLUSIONS: Acellular human dermal matrix augmentation of large (>3 cm) cuff tears involving 2 tendons showed better ASES and Constant scores and more frequent intact cuffs as determined by gadolinium-enhanced MRI. Intact repairs were found in 85% of the augmented group and 40% of the nonaugmented group (P <.01). No adverse events related to the acellular human dermal matrix were observed.	
Am J Obstet Gynecol. 2012 Jan;206(1):86.e1-9. **One-year objective and functional outcomes of a randomized clinical trial of vaginal mesh for prolapse.** Sokol AI, Iglesia CB, Kudish BI, Gutman RE, Shveiky D, Bercik R, Sokol ER. OBJECTIVE: The purpose of this study was to show 12-month outcomes of a randomized trial that compared vaginal prolapse repair with and without mesh. STUDY DESIGN: Women with stage ≥2 prolapse were assigned randomly to vaginal repair with or without mesh. The primary outcome was prolapse stage ≤1 at 12 months. Secondary outcomes included quality of life and complications. RESULTS: All 65 evaluable participants were followed for 12 months after trial stoppage for mesh exposures. Thirty-two women had mesh repair; 33 women had traditional repair. At 12 months, both groups had improvement of pelvic organ prolapse-quantification test points to similar recurrence rates. The quality of life improved and did not differ between groups: 96.2% mesh vs 90.9% no-mesh subjects reported a cure of bulge symptoms; 15.6% had mesh exposures, and reoperation rates were higher with mesh. CONCLUSION: Objective and subjective improvement is seen after vaginal prolapse repair with or without mesh. However, mesh resulted in a higher reoperation rate and did not improve 1-year cure.	**Lab SIFO Farmacoeconomia**
Surg Endosc. 2012 Jan;26(1):222-9. **Partially covered self-expanding metal stent for unresectable malignant extrahepatic biliary obstruction: results of a large prospective series.** Gómez-Oliva C, Guarner-Argente C, Concepción M, Jiménez FJ, Rodríguez S, Gonzalez-Huix F, Mugica F, Cabriada JL, Rodríguez C, Aguilar CG; Collaborating Group of the COBIWA Register. BACKGROUND: Endoscopic biliary stenting is a well-established palliative treatment in patients with unresectable malignant biliary strictures. Obstruction of uncovered self-expanding metal stent (SEMS) due to tumor ingrowth is	**Lab SIFO Farmacoeconomia**

the most frequent complication. Partially covered SEMS might increase stent patency but could favor complications related to stent covering, such as pancreatitis, cholecystitis, and migration. The aim of this study was to evaluate the efficacy and safety of partially covered SEMS in patients with an unresectable malignant biliary stricture. METHODS: Patients with malignant extrahepatic biliary obstruction treated endoscopically with partially covered SEMS were included in this multicenter, prospective, nonrandomized study. RESULTS: One hundred ninety-nine patients were endoscopically treated with partially covered SEMS in 32 Spanish hospitals. Clinical success after deep cannulation was 96%. Early complications occurred in 4% (3 pancreatitis, 2 cholangitis, 1 hemorrhage, 1 perforation, and 1 cholecystitis). Late complications occurred in 19.5% (18 obstructions, 10 migrations, 6 cholangitis without obstruction, 3 acute cholecystitis, and 2 pancreatitis), with no tumor ingrowth in any case. Median stent patency was 138.9 ± 112.6 days. One-year actuarial probability of stent patency was 70% and that of nonmigration was 86%. Multivariate analysis showed adjuvant radio- or chemotherapy as the only independent predictive factor of stent patency and previous insertion of a biliary stent was the only predictive factor of migration. CONCLUSIONS: The partially covered SEMS was easily inserted, had a high clinical success rate, and prevented tumor ingrowth. The incidence of possible complications related to stent coverage, namely, migration, pancreatitis, and cholecystitis, was lower than in previously published series.	
J Arthroplasty. 2012 Jan;27(1):88-94. **A prospective short-term outcome study of a short metaphyseal fitting total hip arthroplasty.** Kim YH, Kim JS, Joo JH, Park JW. The purpose of this study was to determine whether the short, metaphyseal fitting femoral stem would achieve stable fixation without diaphyseal fixation. A total of 126 patients (144 hips) were included in the study, and their mean age was 53.9 years (26-65 years). The mean duration of follow-up was 4.5 years (4-5 years). The predominant diagnosis was osteonecrosis of femoral head (88 of 144 hips, or 61%). The mean preoperative Harris hip score was 45 points, which improved to 96 points by the final follow-up. Western Ontario and McMaster Universities Osteoarthritis score and patient's activity score were improved substantially at the final follow-up. This short, metaphyseal fitting cementless femoral component achieved stable fixation without diaphyseal fixation, and there was minimal stress-shielding bone resorption in the calcar region.	**Lab SIFO Farmacoeconomia**