

# OSSERVATORIO SIFO DISPOSITIVI MEDICI

a cura del Laboratorio SIFO di Farmacoeconomia

coordinatori del progetto

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

**Assegnato a**

*J Am Coll Cardiol. 2011 Feb 1;57(5):538-45.*

**Randomized comparison of percutaneous coronary intervention with sirolimus-eluting stents versus coronary artery bypass grafting in unprotected left main stem stenosis.**

Boudriot E, Thiele H, Walther T, Liebetrau C, Boeckstegers P, Pohl T, Reichart B, Mudra H, Beier F, Gansera B, Neumann FJ, Gick M, Zietak T, Desch S, Schuler G, Mohr FW.

Department of Internal Medicine/Cardiology, University of Leipzig-Heart Center, Germany.

Comment in:

*J Am Coll Cardiol. 2011 Feb 1;57(5):546-8.*

**OBJECTIVES:** The purpose of this randomized study was to compare sirolimus-eluting stenting with coronary artery bypass grafting (CABG) for patients with unprotected left main (ULM) coronary artery disease.

**BACKGROUND:** CABG is considered the standard of care for treatment of ULM.

Improvements in percutaneous coronary intervention (PCI) with use of drug-eluting stents might lead to similar results. The effectiveness of drug-eluting stenting versus surgery has not been established in a randomized trial.

**METHODS:** In this prospective, multicenter, randomized trial, 201 patients with ULM disease were randomly assigned to undergo sirolimus-eluting stenting (n = 100) or CABG using predominantly arterial grafts (n = 101). The primary clinical end point was noninferiority in freedom from major adverse cardiac events, such as cardiac death, myocardial infarction, and the need for target vessel revascularization within 12 months.

**Maria Carmela Leo**

**RESULTS:** The combined primary end point was reached in 13.9% of patients after surgery, as opposed to 19.0% after PCI (p = 0.19 for noninferiority). The combined rates for death and myocardial infarction were comparable (surgery, 7.9% vs. stenting, 5.0%; noninferiority p < 0.001), but stenting was inferior to surgery for repeat revascularization (5.9% vs. 14.0%; noninferiority p = 0.35). Perioperative complications including 2 strokes were higher after surgery (4% vs. 30%; p < 0.001). Freedom from angina was similar between groups (p = 0.33).

**CONCLUSIONS:** In patients with ULM stenosis, PCI with sirolimus-eluting stents is inferior to CABG at 12-month follow-up with respect to freedom from major adverse cardiac events, which is mainly influenced by repeated revascularization, whereas for hard end points, PCI results are favorable. A longer follow-up is warranted. (Percutaneous Coronary Intervention [PCI] With Drug-Eluting Stents [DES] Versus Coronary Artery Bypass Graft [CABG] for Patients With Significant Left Main Stenosis; NCT00176397).

*Radiology. 2011 Feb;258(2):546-53. Epub 2010 Dec 3.*

**Remodeling technique for endovascular treatment of ruptured intracranial aneurysms had a higher rate of adequate postoperative occlusion than did conventional coil embolization with comparable safety.**

Pierot L, Cognard C, Anxionnat R, Ricolfi F; CLARITY Investigators.  
Department of Neuroradiology, Reims University, Hôpital Maison-Blanche, 45 rue  
Cognacq-Jay, 51092 Reims, France. lpierot@gmail.com

**PURPOSE:** To compare the safety and efficacy of the remodeling technique with that of conventional coil embolization in a large multicenter series involving the endovascular treatment of ruptured intracranial aneurysms, the CLARITY study (Clinical and Anatomic Results in the Treatment of Ruptured Intracranial Aneurysms).

**MATERIALS AND METHODS:** The institutional review board approved the CLARITY study, and written informed consent was obtained from all patients. A total of 768 patients (age range, 19-80 years; mean age ± standard deviation, 51.0 years ± 11.1) with 768 ruptured aneurysms were treated with either conventional coil embolization (608 patients, 79.2%) or the remodeling technique (160 patients, 20.8%). Patient and aneurysm characteristics, the rate of adverse events related to the treatment or initial intracranial hemorrhage, and patient outcome were compared between treatment groups by using the  $\chi^2$ , Fisher exact, or Student ttest. **RESULTS:** The overall rate of treatment-related complications, with or without clinical manifestations, was 17.4% (106 of 608 patients) with coil embolization and 16.9% (27 of 160 patients) with remodeling (P = .999). The difference in the rates of thromboembolic events, intraoperative rupture, and early repeat bleeding between the treatment groups was not statistically significant. The cumulative morbidity and mortality rate related to the treatment in the remodeling group (3.8%, six of 160 patients) was similar to that in the coil embolization group (5.1%, 31 of 608 patients) (P = .678). Likewise, the global cumulative morbidity and mortality rates related to both the treatment and the initial hemorrhage did not differ significantly between groups (16.2% [26 of 160 patients] with remodeling

**Eleonora Cesqui**

and 19.6% [119 of 608 patients] with coil embolization,  $P = .366$ ). The rate of adequate aneurysm occlusion, however, was significantly higher in the remodeling group (94.9%, 150 of 158 aneurysms) than in the coil embolization group (88.7%, 534 of 602 aneurysms) ( $P = .017$ ).

**CONCLUSION:** In our large series of patients treated for ruptured aneurysms, the remodeling technique-despite being performed in aneurysms with unfavourable characteristics-was as safe as conventional coil embolization and more efficacious in terms of the rate of adequate postoperative occlusion. These results indicate that the remodeling technique can be routinely used in the treatment of ruptured aneurysms.

*BJU Int. 2011 Feb;107(3):426-32. doi: 10.1111/j.1464-410X.2010.09501.*

**Treatment of neurogenic male urinary incontinence related to intrinsic sphincter insufficiency with an artificial urinary sphincter: a French retrospective multicentre study.**

Chartier Kastler E, Genevois S, Gamé X, Denys P, Richard F, Leriche A, Saramon JP, Ruffion A.

Service d'Urologie, Groupe hospitalier Pitié-Salpêtrière, Assistance Publique Hopitaux de Paris, Université Paris-VI, Paris, France.

**OBJECTIVE:** To assess results and morbidity of the periprostatic insertion of an artificial urinary sphincter (AUS) in adult male patients with a neurogenic bladder.

**PATIENTS AND METHODS:** A retrospective study was carried out on 51 adult male patients operated on in four urologic academic wards from April 1988 to January 2008. Among these patients, 31% (16/51) had spina bifida and 69% (35/51) had spinal cord injury. All patients suffered urinary incontinence secondary to sphincteric deficiency, and this was associated with detrusor overactivity in 39% of them (leading in these cases to an added bladder augmentation). Perfect continence was defined as a period of dryness of at least 4 h between two self-intermittent catheterizations (SIC) or spontaneous micturitions, moderate incontinence as nocturnal leakage or need to wear protection once during the day or for stress leakage, while severe incontinence was defined as uncontrollable leakage causing patient discomfort.

**RESULTS:** Mean age at the procedure was 35 years (18-58). Mean follow-up was 83months (CI 95%, 65-101). At the end of the study, 15 patients (29.4%) were lost to follow-up. One patient (2%) died shortly after the procedure from a pulmonary infection. Post-operative morbidity was observed in 19% (10/50) of the patients (8 urinary tract infection, 1 failure to perform SIC, 1 intracranial hypertension). Of the patients in our study 74% had perfect or moderate continence with a working AUS after a 10-year follow-up

**CONCLUSIONS:** We present a specific study on adult patients with a neurological lesion leading to bladder dysfunction treated by a periprostatic AUS. This procedure was effective in restoring urinary incontinence in the

**Donata Iozzi**

vast majority of our patients with an acceptable morbidity.

*J Vasc Surg. 2011 Feb;53(2):293-8. Epub 2010 Nov 4.*

**Long-term results of Talent endografts for endovascular abdominal aortic aneurysm repair.**

Verhoeven BA, Waasdorp EJ, Gorrepati ML, van Herwaarden JA, Vos JA, Wille J, Moll FL, Zarins CK, de Vries JP.

Department of Vascular Surgery, St Antonius Hospital, Nieuwegein, The Netherlands.  
b.verhoeven@antoniuziekenhuis.nl

**BACKGROUND:** Since the introduction of endovascular aneurysm repair (EVAR), long-term follow-up studies reporting single-device results are scarce. In this study, we focus on EVAR repair with the Talent stent graft (Medtronic, Santa Rosa, Calif).

**METHODS:** Between July 2000 and December 2007, 365 patients underwent elective EVAR with a Talent device. Patient data were gathered prospectively and evaluated retrospectively. By American Society of Anesthesiologists category, 74% were categories III and IV. Postoperative computed tomography (CT) scanning was performed before discharge, at 3, 12 months, and yearly thereafter. Data are presented according to reporting standards for EVAR.

**RESULTS:** The mean proximal aortic neck diameter was 27 mm (range, 16-36 mm), with a neck length <15 mm in 31% (data available for 193 patients). Deployment of endografts was successful in 361 of 365 patients (99%). Initially, conversion to laparotomy was necessary in four patients. Primary technical success determined by results from computed tomography (CT) scans before discharge was achieved in 333 patients (91%). Proximal type I endoleaks were present in 28 patients (8%) during follow-up, and 14 of these patients needed additional treatment for type I endoleak. The 30-day mortality for the whole Talent group was 1.1% (4 of 365). Follow-up to 84 months is reported for 24 patients. During follow-up, 122 (33%) patients died; in nine, death was abdominal aortic aneurysm (AAA)-related

(including 30-day mortality). Kaplan-Meier estimates revealed primary clinical success rates of 98% at 1 year, 93% at 2 years, 88% at 3 years, 79% at 4 years, 64% at 5 years, 51% at 6 years, and 48% at 7 years. Secondary interventions were performed in 73 of 365 patients (20%). Ten conversions for failed endografts were performed. Life-table yearly risk for AAA-related reintervention was 6%, yearly risk for conversion to open repair was 1.1%, yearly risk for total mortality was 8.9%, and yearly risk for AAA-related mortality was 0.8%.

**CONCLUSION:** Initially, technical success of endovascular aneurysm repair (EVAR) using the Talent endograft is high, with acceptable yearly risk for AAA-related mortality and conversion. However, a substantial amount of mainly endovascular reinterventions is necessary during long-term follow-up to achieve these results.

**Valeria Fadda**

*Lancet. 2011 Feb 19;377(9766):658-66.*

**Wireless pulmonary artery haemodynamic monitoring in chronic heart failure: a randomised controlled trial.**

Abraham WT, Adamson PB, Bourge RC, Aaron MF, Costanzo MR, Stevenson LW, Strickland W, Neelagaru S, Raval N, Krueger S, Weiner S, Shavelle D, Jeffries B, Yadav JS; CHAMPION Trial Study Group.

Ohio State University Heart and Vascular Center, Columbus, OH, USA.

Comment in:

*Lancet. 2011 Feb 19;377(9766):616-8.*

**BACKGROUND:** Results of previous studies support the hypothesis that plantable haemodynamic monitoring systems might reduce rates of hospitalisation in patients with heart failure. We undertook a single-blind trial to assess this approach.

**METHODS:** Patients with New York Heart Association (NYHA) class III heart failure, irrespective of the left ventricular ejection fraction, and a previous hospital admission for heart failure were enrolled in 64 centres in the USA. They were randomly assigned by use of a centralised electronic system to management with a wireless implantable haemodynamic monitoring (W-IHM) system (treatment group) or to a control group for at least 6 months. Only patients were masked to their assignment group. In the treatment group, clinicians used daily measurement of pulmonary artery pressures in addition to standard of care versus standard of care alone in the control group. The primary efficacy endpoint was the rate of heart-failure-related hospitalisations at 6 months. The safety endpoints assessed at 6 months were freedom from device-related or system-related complications (DSRC) and freedom from pressure-sensor failures. All analyses were by intention to treat. This trial is registered with ClinicalTrials.gov, number NCT00531661.

**FINDINGS:** In 6 months, 83 heart-failure-related hospitalisations were reported in the treatment group (n=270) compared with 120 in the control group (n=280; rate 0.31 vs 0.44, hazard ratio [HR] 0.70, 95% CI 0.60-0.84, p<0.0001). During the entire follow-up (mean 15 months [SD 7]), the treatment group had a 39% reduction in heart-failure-related hospitalisation compared with the control group (153 vs 253, HR 0.64, 95% CI 0.55-0.75; p<0.0001). Eight patients had DSRC and overall freedom from DSRC was 98.6% (97.3-99.4) compared with a prespecified performance criterion of 80% (p<0.0001); and overall freedom from pressure-sensor failures was 100% (99.3-100.0).

**INTERPRETATION:** Our results are consistent with, and extend, previous findings by definitively showing a significant and large reduction in hospitalisation for patients with NYHA class III heart failure who were managed with a wireless implantable haemodynamic monitoring system. The addition of information about pulmonary

**Dario Maratea**

<p>artery pressure to clinical signs and symptoms allows for improved heart failure management.  <b>FUNDING:</b> CardioMEMS.</p>	
<p><i>J Thorac Cardiovasc Surg.</i> 2011 Feb;141(2):487-91, 491.e1.</p> <p><b>Transcatheter aortic valve implantation using the axillary/subclavian access: feasibility and early clinical outcomes.</b></p> <p>Modine T, Obadia JF, Choukroun E, Rioufoul G, Sudre A, Laborde JC, Leprince P.</p> <p>CHRU de Lille, Paris, France. tmodine@yahoo.fr</p> <p><b>OBJECTIVE:</b> Retrograde transfemoral artery catheterization is the most common way of implanting a percutaneous aortic valve. But in some cases, this access cannot be used and the subclavian artery access may represent an alternative to the femoral route, even offering certain advantages. This article describes prosthetic aortic valve implantation using the subclavian arterial approach and reports the findings.</p> <p><b>METHODS:</b> The valve prosthesis is a self-expandable, nitinol-based device (CoreValve; Medtronic Inc. Minneapolis, Minn). The axillary or subclavian artery was exposed with a small incision. Rapid ventricular pacing was used to reduce cardiac output while a routine aortic balloon valvuloplasty was performed. Then, an 18F sheath was inserted into the axillary artery down into the ascending aorta. By using this method, a prosthesis was implanted in 17 patients (aged 71±11 years) whose surgical risk was deemed excessive because of severe comorbidity and in whom transfemoral catheterization was considered unfeasible or at risk of severe complications.</p> <p><b>RESULTS:</b> Subclavian arterial injury did not occur in any patient. The postprocedural aortic valve area increased from 0.6±0.3 cm<sup>2</sup> to 1.44±0.35 cm<sup>2</sup>. A transient ischemic attack occurred in 1 patient. Two patients experienced transitory brachial plexus deficit. There were no intraprocedural deaths. Two deaths occurred in the 30-day follow-up period.</p> <p><b>CONCLUSIONS:</b> This initial experience suggests that subclavian transarterial aortic valve implantation, in selected high-risk patients, is feasible and safe with satisfactory short-term outcomes.</p>	<p><b>Francesco D'Amici</b></p>