OSSERVATORIO SIFO DISPOSITIVI MEDICI

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Sabrina Trippoli – Valeria Fadda – Dario Maratea – Andrea Messori

Assegnato a

Dario Maratea

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Hydrogel-coated coils versus bare platinum coils for the endovascular treatment of intracranial aneurysms (HELPS): a randomised controlled trial.

White PM, Lewis SC, Gholkar A, Sellar RJ, Nahser H, Cognard C, Forrester L, Wardlaw JM; HELPS trial collaborators.

BACKGROUND: Coated coils for endovascular treatment of cerebral aneurysm were developed to reduce recurrence and retreatment rates, and have been in clinical use for 8-9 years without robust evidence to determine their efficacy. We assessed the efficacy and safety of hydrogel-coated coils.

METHODS: This randomised trial was undertaken in 24 centres in seven countries. Patients aged 18-75 years with a previously untreated ruptured or unruptured cerebral aneurysm of 2-25 mm in maximum diameter were randomly allocated (1:1) to aneurysm coiling with either hydrogel-coated coils or standard bare platinum coils (control). Randomisation was done with a computer-generated sequence, stratified by aneurysm size, shape, and dome-to-neck ratio; intention to use assist device; and by region. Participants and those assessing outcomes were masked to allocation. Analysis was by modified intention to treat (excluding missing data). Primary outcome was a composite of angiographic and clinical outcomes at 18-month follow-up. We also did prespecified subgroup analyses of characteristics likely to be relevant to angiographic outcome. This study is registered as an International Standard Randomised Controlled Trial, number ISRCTN30531382.

FINDINGS: 249 patients were allocated to the hydrogel coil group and 250 to the control group. In 44 of 467 patients for whom an 18-month composite primary outcome was unavailable, 6-month angiographic results were used. 70 (28%) patients in the hdrogel group and 90 (36%) control patients had an adverse composite primary outcome, giving an absolute reduction in the proportion of adverse composite primary outcomes with hydrogel of 7·0% (95% CI -1·6 to 15·5),odds ratio (OR) 0·73 (0·49-1·1, p=0·13). In a prespecified subgroup analysis in recently ruptured aneurysms, there were more adverse composite primary outcomes in the control group than in the

hydrogel group-OR 2·08 (1·24-3·46, p=0·014). There were 8·6% fewer major angiographic recurrences in patients allocated to hydrogel coils-OR 0·7 (0·4-1·0, p=0·049). There were five cases of unexplained hydrocephalus in not-recently-ruptured aneurysms in the hydrogel coil group and one case in the control group. INTERPRETATION: Whether use of hydrogel coils reduces late aneurysm rupture or improves long-term clinical outcome is not clear, but our results indicate that their use lowers major recurrence. FUNDING: MicroVention Inc.	
N Engl J Med. 2011 May 12;364(19):1826-36. **Anterior colporrhaphy versus transvaginal mesh for pelvic-organ prolapse.** Altman D, Väyrynen T, Engh ME, Axelsen S, Falconer C; Nordic Transvaginal Mesh Group. BACKGROUND: The use of standardized mesh kits for repair of pelvic-organ prolapse has spread rapidly in recent years, but it is unclear whether this approach results in better outcomes than traditional colporrhaphy. METHODS: In this multicenter, parallel-group, randomized, controlled trial, we compared the use of a trocar-guided, transvaginal polypropylene-mesh repair kit with traditional colporrhaphy in women with prolapse of the anterior vaginal wall (cystocele). The primary outcome was a composite of the objective anatomical designation of stage 0 (no prolapse) or 1 (position of the anterior vaginal wall more than 1 cm above the hymen), according to the Pelvic Organ Prolapse Quantification system, and the subjective absence of symptoms of vaginal bulging 12 months after the surgery. RESULTS: Of 389 women who were randomly assigned to a study treatment, 200 underwent prolapse repair with the transvaginal mesh kit and 189 underwent traditional colporrhaphy. At 1 year, the primary outcome was significantly more common in the women treated with transvaginal mesh repair (60.8%) than in those who underwent colporrhaphy (34.5%) (absolute difference, 26.3 percentage points; 95% confidence interval, 15.6 to 37.0). The surgery lasted longer and the rates of intraoperative hemorrhage were higher in the mesh-repair group than in the colporrhaphy group (P<0.001 for both comparisons). Rates of bladder perforation were 3.5% in the mesh-repair group and 0.5% in the colporrhaphy group (P=0.07), and the respective rates of new stress urinary incontinence after surgery were 12.3% and 6.3% (P=0.05). Surgical reintervention to correct mesh exposure during follow-up occurred in 3.2% of 186 patients in the mesh-repair group. CONCLUSIONS: As compared with anterior colporrhaphy, use of a standardized, trocar-guided mesh kit for cystocele repair resulted in higher short-term rates of successful treatment but also in higher rates of surgical complications and postoperative adverse events. (Funded by the Karolinska Institutet and Ethicon; ClinicalTrials.gov number, NCT00566917.).	**Non Assegnato**

N Engl J Med. 2011 May 5;364(18):1718-27. Epub 2011 Apr 4. **Randomized trial of stents versus bypass surgery for left main coronary artery disease.** Park SJ, Kim YH, Park DW, Yun SC, Ahn JM, Song HG, Lee JY, Kim WJ, Kang SJ, Lee SW, Lee CW, Park SW, Chung CH, Lee JW, Lim DS, Rha SW, Lee SG, Gwon HC, Kim HS, Chae IH, Jang Y, Jeong MH, Tahk SJ, Seung KB. BACKGROUND: Percutaneous coronary intervention (PCI) is increasingly used to treat unprotected left main coronary artery stenosis, although coronary-artery bypass grafting (CABG) has been considered to be the treatment of choice. METHODS: We randomly assigned patients with unprotected left main coronary artery stenosis to undergo CABG (300 patients) or PCI with sirolimus-eluting stents (300 patients). Using a wide margin for noninferiority, we compared the groups with respect to the primary composite end point of major adverse cardiac or cerebrovascular events (death from any cause, myocardial infarction, stroke, or ischemia-driven target-vessel revascularization) at 1 year. Event rates at 2 years were also compared between the two groups. RESULTS: The primary end point occurred in 26 patients assigned to PCI as compared with 20 patients assigned to CABG (cumulative event rate, 8.7% vs. 6.7%; absolute risk difference, 2.0 percentage points; 95% confidence interval [CI], -1.6 to 5.6; P=0.01 for noninferiority). By 2 years, the primary end point had occurred in 36 patients in the PCI group as compared with 24 in the CABG group (cumulative event rate, 12.2% vs. 8.1%; hazard ratio with PCI, 1.50; 95% CI, 0.90 to 2.52; P=0.12). The composite rate of death, myocardial infarction, or stroke at 2 years occurred in 13 and 14 patients in the two groups, respectively (cumulative event rate, 4.4% and 4.7%, respectively; hazard ratio, 0.92; 95% CI, 0.43 to 1.96; P=0.83). Ischemia-driven target-vessel revascularization occurred in 26 patients in the PCI group as compared with 12 patients in the CABG group (cumulative event rate, 9.0% vs. 4.2%; hazard ratio, 2.18; 95% CI, 1.10 to 4.32; P=0.02). CONCLUSIONS: In this randomized trial involving patients with unprotected left main coronary artery stenosis, PCI with sirolimus-eluting stents was shown to be noninferior to CABG with respect to major adverse cardiac or cerebrovascular events. However, the noninferiority margin was wide, and the results cannot be considered clinically directive. (Funded by the Cardiovascular Research Foundation, Seoul, Korea, and others; PRECOMBAT clinicalTrials.gov number, NCT00422968.).	**Sabrina Trippoli**

Ann Surg. 2011 May;253(5):961-7. **Endoscopic transpapillary stenting or conservative treatment for pancreatic fistulas in necrotizing pancreatitis: multicenter series and literature review**. Bakker OJ, van Baal MC, van Santvoort HC, Besselink MG, Poley JW, Heisterkamp J, Bollen TL, Gooszen HG, van Eijck CH; Dutch Pancreatitis Study Group. OBJECTIVE: Endoscopic transpapillary stenting (ETS) of the pancreatic duct facilitates ductal outflow and may reduce time to pancreatic fistula closure. However, data on the feasibility of ETS in patients with necrotizing pancreatitis are scarce. BACKGROUND: Pancreatic fistulas often occur after intervention in necrotizing pancreatitis and frequently close only after months of conservative treatment METHODS: From a prospective cohort of patients with acute pancreatitis admitted in 15 hospitals (2004-2007), all patients who underwent ETS or conservative treatment for a pancreatic fistula were identified. Safety, feasibility, and outcome of ETS were evaluated. Furthermore, a literature review was performed for similar studies in necrotizing pancreatitis. RESULTS: Of 731 patients with acute pancreatitis, 19 patients were treated with ETS and 16 patients were treated conservatively for a pancreatic fistula. Fistula closure was achieved in 16 of 19 patients (84%) in the ETS group and in 8 of 12 patients (75%) in the conservative group (P = 0.175). The median time to fistula closure after ETS was 71 days (interquartile range [IQR] 34-142) compared with 120 days (IQR 51-175 days) in the conservative group (P = 0.130). Complications were observed in 6 patients. A total of 10 studies reporting the results of 281 patients with stent placement for pancreatic fistulas were included in the literature review. Fistula closure was achieved in 200 patients (71%). Stent-related complications were reported in 9% of patients. CONCLUSIONS: ETS seems a feasible and safe alternative to conservative treatment in patients with pancreatic fistulas after intervention for necrotizing pancreatitis.	**Nessuna scheda** **Non è possibile ricavare il nome del dispositivo dal testo dello studio**
Eur J Vasc Endovasc Surg. 2011 May;41(5):668-73. Epub 2011 Mar 3. **The Scandinavian Propaten(®) trial - 1-year patency of PTFE vascular prostheses with heparin-bonded luminal surfaces compared to ordinary pure PTFE vascular prostheses - a**	**Non Assegnato**

randomised clinical controlled multi-centre trial. Lindholt JS, Gottschalksen B, Johannesen N, Dueholm D, Ravn H, Christensen ED, Viddal B, Flørenes T, Pedersen G, Rasmussen M, Carstensen M, Grøndal N, Fasting H. OBJECTIVE: To compare 1-year potencies' of heparin-bonded PTFE [(Hb-PTFE) (Propaten(®))] grafts with those of ordinary polytetraflouroethylene (PTFE) grafts in a blinded, randomised, clinically controlled, multi-centre study. MATERIALS AND METHODS: Eleven S candinavian centres enrolled 569 patients with chronic functional or critical lower limb ischaemia who were scheduled to undergo femoro-femoral bypass or femoro-poplitaeal bypass. The patients were randomised 1:1 stratified by centre. Patency was assessed by duplex ultrasound scanning. A total of 546 patients (96%) completed the study with adequate follow-up. RESULTS: Perioperative bleeding was, on average, 370 ml with PTFE grafts and 399 ml with Heparin-bonded PTFE grafts (p = 0.32). Overall, primary patency after 1 year was 86.4% for Hb-PTFE grafts and 79.9% for PTFE grafts (OR = 0.627, 95% CI: 0.398; 0.989, p = 0.043). Secondary patency was 88% in Hb-PTFE grafts and 81% in PTFE grafts (OR = 0.569 (0.353; 0.917, p = 0.020)). Subgroup analyses revealed that significant reduction in risk (50%) was observed when Hb-PTFE was used for femoro-poplitaeal bypass (OR = 0.515 (0.281; 0.944, p = 0.030)), and a significant reduction in risk (50%) was observed with Hb-PTFE in cases with critical ischaemia (OR = 0.490 (0.249; 0.962, p = 0.036)). CONCLUSION: The Hb-PTFE graft significantly reduced the overall risk of primary graft failure by 37%. Risk reduction was 50% in femoro-poplitaeal bypass cases and in cases with critical ischaemia	
Ann Surg. 2011 May;253(5):879-85. **External pancreatic duct stent decreases pancreatic fistula rate after ancreaticoduodenectomy: prospective multicenter randomized trial.** Pessaux P, Sauvanet A, Mariette C, Paye F, Muscari F, Cunha AS, Sastre B, Arnaud JP; Fédération de Recherche en Chirurgie (French). Pôle des Pathologies Digestives, Hépatiques et de la Transplantation, Hôpital de Hautepierre, Université de Strasbourg, France. patrick.pessaux@chru-strasbourg.fr OBJECTIVE: Pancreatic fistula (PF) is a leading cause of morbidity and mortality after pancreaticoduodenectomy (PD). The aim of this multicenter prospective randomized trial was to compare the results of PD with an external drainage stent versus no stent. METHODS: Between 2006 and 2009, 158 patients who underwent PD were randomized intraoperatively to either receive an external stent inserted across the anastomosis to drain the pancreatic duct (n = 77) or no stent (n = 81). The criteria of inclusion were soft pancreas and a diameter of wirsung <3 mm. The primary study end point was PF rate	**Nessuna scheda** **Non è possibile ricavare il nome del dispositivo dal testo dello studio.**

defined as amylase-rich fluid (amylase concentration >3 times the upper limit of normal serum amylase level) collected from the peripancreatic drains after postoperative day 3. CT scan was routinely done on day 7. RESULTS: The 2 groups were comparable concerning demographic data, underlying pathologies, presenting symptoms, presence of comorbid illness, and proportion of patients with preoperative biliary drainage. Mortality, morbidity, and PF rates were 3.8%, 51.8%, and 34.2%, respectively. Stented group had a significantly lower overall PF (26% vs. 42%; P = 0.034), morbidity (41.5% vs. 61.7%; P = 0.01), and delayed gastric emptying (7.8% vs. 27.2%; P = 0.001) rates compared with nonstented group. Radiologic or surgical intervention for PF was required in 9 patients in the stented group and 12 patients in the nonstented group. There were no significant differences in mortality rate (3.7% vs. 3.9%; P = 0.37) and in hospital stay (22 days vs. 26 days; P = 0.11). CONCLUSION: External drainage of pancreatic duct with a stent reduced. PF and overall morbidity rates after PD in high risk patients (soft pancreatic texture and a nondilated pancreatic duct).	
Eur J Vasc Endovasc Surg. 2011 May;41(5):625-34. Epub 2011 Feb 15. **Open or endovascular repair of aortoenteric fistulas? A multicentre comparative study.** Kakkos SK, Antoniadis PN, Klonaris CN, Papazoglou KO, Giannoukas AD, Matsagkas MI, Kotsis T, Dervisis K, Gerasimidis T, Tsolakis IA, Liapis CD. OBJECTIVES: To compare aortoenteric fistula (AEF) outcome after endovascular (EV-AEFR) or open repair (O-AEFR). DESIGN: Multicentre retrospective comparative study. MATERIALS/METHODS: 25 patients with AEF (24 secondary, 23 males, median age 75 years) after aortic surgery (median four years). Preoperative sepsis was evident in 19 cases. Eight patients were managed with EV-AEFR and 17 with O-AEFR. RESULTS: The two groups were comparable in preoperative characteristics. In-hospital mortality after EV-AEFR was lower compared to O-AEFR (0% and 35%, respectively, p = 0.13). Similarly, morbidity after EV-AEFR was lower compared to O-AEFR (25% and 77%, respectively, p = 0.028). There was a trend for worse recurrence-free, sepsis-free, re-operation-free and AEF-related death-free rates after EV-AEFR, while the early survival advantage of EV-AEFR was lost after two years and the overall long-term survival rates (perioperative mortality included) of the two groups were similar. Preoperative sepsis had no effect on recurrence and sepsis-free rates (p = 0.94 and p = 0.92, respectively), but it was associated with worse two year overall survival (24% vs 50%, p = 0.32). On multivariate analysis, the number of symptoms (two vs one) at presentation was the single predictor of worse re-operation rates, AEF-related and overall survival. CONCLUSIONS: EV-AEFR was associated with no postoperative mortality in this study and can achieve satisfactory	**Nessuna scheda** **Non è possibile ricavare il nome del dispositivo dal testo dello studio**

short and long-term results, comparable to O-AEFR. Further trials should focus on the role of EV-AEFR in patients at high risk for O-AEFR, due to shock or co-morbidities, or as a bridging procedure.	
Br J Surg. 2011 May;98(5):633-9. doi: 10.1002/bjs.7398. Epub 2011 Jan 19. **Randomized clinical trial comparing polypropylene or polydioxanone for midline abdominal wall closure.** Bloemen A, van Dooren P, Huizinga BF, Hoofwijk AG. BACKGROUND: Incisional hernia is a frequent complication of abdominal surgery, often requiring surgical intervention. This prospective randomized trial compared suture materials for closure of the fascia after abdominal surgery. METHODS: In 456 patients the abdominal fascia was closed with either non-absorbable (polypropylene; Prolene(®)) or absorbable (polydioxanone; PDS(®)) suture material. Follow-up was by clinical examination and ultrasonography at 6-month intervals. Outcome measures were incisional hernia, surgical-site infection and suture sinus. RESULTS: Some 223 patients were analysed after closure with Prolene(®) and 233 after PDS(®) . Median follow-up was 32 and 31 months respectively. There was no significant difference in the incidence of incisional hernia between the groups: 20·2 per cent (45 of 223) for Prolene(®) and 24·9 per cent (58 of 233) with PDS(®) (P = 0·229). Kaplan-Meier analysis showed a cumulative rate after 4 years of 23·7 and 30·2 per cent for Prolene(®) and PDS(®) respectively (P = 0·222). Secondary outcome measures showed no significant differences. CONCLUSION: The incidence of incisional hernia in both groups was higher than expected from previous literature. There were no significant differences between the two suture methods. Registration number: ISRCTN65599814 (http://www.clinical-trials.com).	**Non Assegnato**
Clin Orthop Relat Res. 2011 May;469(5):1291-6. **Is the vertebral expandable prosthetic titanium rib a surgical alternative in patients with spina bifida?** Flynn JM, Ramirez N, Emans JB, Smith JT, Mulcahey MJ, Betz RR. BACKGROUND: Nonambulatory children with myelodysplasia are most likely to develop spinal deformity. As the deformity progresses, the overall health of the patient deteriorates. Traditional management of the deformity with fusion results in a short trunk, crankshaft deformity, and spine and lung growth inhibition. One alternative that otentially minimizes these problems is the vertebral expandableprosthetic titanium rib (VEPTR). QUESTIONS/PURPOSES: We therefore asked whether the use of the VEPTR in immature nonambulating children	**Valeria Fadda**

with myelodysplasia with spinal deformity would (1) correct deformity; (2) allow growth; and (3) allow adequate respiratory function. PATIENTS AND METHODS: We identified 20 nonambulatory patients with myelodysplasia who were part of a multicenter Investigational Device Exemption study of 214 patients treated with the VEPTR system. Demographics, standard radiographic measurements, pulmonary function parameters, and complications in 16 patients were analyzed. Average age at first surgery was 48.6 months. The minimum followup was 25 months (mean, 59 months; range, 25-164 months). RESULTS: The Cobb angle decreased postoperatively in nine patients, increased less than 10° in five patients, and increased less than 20° in two patients. The mean increase in thoracic spinal length (growth) by year after the initial procedure with lengthening was 0.48 cm. Ventilatory function improved in 11 patients and deteriorated in five patients. Intraoperative complications occurred in two patients. Complications directly related to the implant were seven infections and five implant migrations. CONCLUSIONS: Our observations suggest VEPTR is a reasonable treatment option for spinal deformity in the immature, nonambulatory myelodysplasia population correcting the spinal deformity, allowing spinal growth, and maintaining adequaterespiratory function. The rate of complications is withn the range reported for spinal fusion using st andard approaches.	