

OSSERVATORIO SIFO DISPOSITIVI MEDICI

a cura del Laboratorio SIFO di Farmacoeconomia

coordinatori del progetto

Sabrina Trippoli – Valeria Fadda – Dario Maratea – Andrea Messori

Assegnato a

Stroke. 2011 Mar;42(3):675-80. Epub 2011 Feb 9.

Safety of stenting and endarterectomy by symptomatic status in the Carotid Revascularization Endarterectomy Versus Stenting Trial (CREST).

Silver FL, Mackey A, Clark WM, Brooks W, Timaran CH, Chiu D, Goldstein LB, Meschia JF, Ferguson RD, Moore WS, Howard G, Brott TG; CREST Investigators.

University Health Network, University of Toronto, Toronto, Ontario, Canada.

BACKGROUND AND PURPOSE: The safety of carotid artery stenting (CAS) and carotid endarterectomy (CEA) has varied by symptomatic status in previous trials. The Carotid Revascularization Endarterectomy Versus Stenting Trial (CREST) data were analyzed to determine safety in symptomatic and asymptomatic patients. **METHODS:** CREST is a randomized trial comparing safety and efficacy of CAS versus CEA in patients with high-grade carotid stenoses. Patients were defined as symptomatic if they had relevant symptoms within 180 days of randomization. The primary end point was stroke, myocardial infarction, or death within the periprocedural period or ipsilateral stroke up to 4 years.

RESULTS: For 1321 symptomatic and 1181 asymptomatic patients, the periprocedural aggregate of stroke, myocardial infarction, and death did not differ between CAS and CEA (5.2% versus 4.5%; hazard ratio, 1.18; 95% CI, 0.82 to 1.68; P=0.38). The stroke and death rate was higher for CAS versus CEA (4.4% versus 2.3%; hazard ratio, 1.90; 95% CI, 1.21 to 2.98; P=0.005). For symptomatic patients, the periprocedural stroke and death rates were 6.0%±0.9% for CAS and 3.2%±0.7% for CEA (hazard ratio, 1.89; 95% CI, 1.11 to 3.21; P=0.02). For asymptomatic patients, the stroke and death rates were 2.5%±0.6% for CAS and 1.4%±0.5% for CEA (hazard ratio, 1.88; 95% CI, 0.79 to 4.42; P=0.15). Rates were lower for those aged <80 years.

CONCLUSIONS: There were no significant differences between CAS versus CEA by symptomatic status for the primary CREST end point. Periprocedural stroke and death rates were significantly lower for CEA in symptomatic patients. However, for both CAS and CEA, stroke and death rates were below or comparable to those of previous

Valeria Fadda

<p>randomized trials and were within the complication thresholds suggested in current guidelines for both symptomatic and asymptomatic patients.</p>	
<p><i>J Vasc Surg. 2011 Mar;53(3):574-82. Epub 2011 Jan 6.</i> Initial clinical experience with a sac-anchoring endoprosthesis for aortic aneurysm repair. Donayre CE, Zarins CK, Krievins DK, Holden A, Hill A, Calderas C, Velez J, White RA.</p> <p>Harbor/UCLA Medical Center, Torrance, Calif 90502, USA. cdonayre@cox.net</p> <p>OBJECTIVE: All current aortic endografts depend on proximal and distal fixation to prevent migration. However, migration and rupture can occur, particularly in patients with aortic necks that are short or angulated, or both. We present our initial clinical experience with a new sac-anchoring endoprosthesis designed To anchor and seal the device within the aneurysm sac.</p> <p>METHODS: The initial worldwide experience using a new endoprosthesis for the treatment of aortic aneurysms (Nellix Endovascular, Palo Alto, Calif) was reviewed. The endoprosthesis consists of dual balloon-expandable endoframes surrounded by polymer-filled endobags designed to obliterate the aneurysm sac and maintain endograft position. Clinical results and follow-up contrast computed tomography (CT) scans at 30 days and 6 and 12 months were reviewed.</p> <p>RESULTS: The endograft was successfully deployed in 21 patients with infrarenal aortic aneurysms measuring 5.7 ± 0.7 cm (range, 4.3-7.4 cm). Two patients with common iliac aneurysms were treated with sac-anchoring extenders that maintained patency of the internal iliac artery. Infusion of 71 ± 37 mL of polymer (range, 19-158 mL) into the aortic endobags resulted in complete aneurysm exclusion in all patients. Mean implant time was 76 ± 35 minutes, with 33 ± 17 minutes of fluoroscopy time and 180 ± 81 mL of contrast; estimated blood loss was 174 ± 116 mL. One patient died during the postoperative period (30-day mortality, 4.8%), and one died at 10 months from non-device-related causes. During a mean follow-up of 8.7 ± 3.1 months and a median of 6.3 months, there were no late aneurysm- or device-related adverse events and no secondary procedures. CT imaging studies at 6 months and 1 year revealed no increase in aneurysm size, no device migration, and no new endoleaks. One patient had a limited proximal type I endoleak at 30 days that resolved at 60 days and remained sealed. One patient has an ongoing distal type I endoleak near the iliac bifurcation, with no change in aneurysm size at 12 months.</p> <p>CONCLUSION: Initial clinical experience with this novel intrasac anchoring prosthesis is promising, with successful aneurysm exclusion and good short-term results. This new device platform has the potential to address the anatomic restrictions and limitations of current endografts. Further studies with a longer follow-up time are needed.</p>	<p>Non assegnato</p>
<p><i>Eur J Vasc Endovasc Surg. 2011 Mar;41(3):337-43. Epub 2010 Dec 8.</i> Outcome and safety of Aorfix™ stent graft in highly angulated necks – a prospective observational study (arbiter 2). Weale AR, Balasubramaniam K, Macierewicz J, Hardman J, Horrocks M.</p>	<p>Non assegnato</p>

<p>Department of Vascular Surgery, Royal United Hospital, UK.</p> <p>Comment in Eur J Vasc Endovasc Surg. 2011 Mar;41(3):344-5.</p> <p>Comment on Eur J Vasc Endovasc Surg. 2011 Mar;41(3):334-6.</p> <p>OBJECTIVES: Severe neck angulation is associated with poor outcome following endovascular aneurysm repair. The aim was to study the safety and early outcome of patients with infrarenal aortic aneurysms with severe neck angulation (60-90°) treated with the Aorfix™ endovascular stent graft.</p> <p>DESIGN/METHODS: This was a non-randomized prospective observational study of 30 patients with infra-renal abdominal aortic aneurysms with highly angulated necks. Outcomes were primary technical success, 30 day and short term (30 days-6 months) clinical success and other patient morbidity at 30 days.</p> <p>RESULTS: Median neck angulation was 81.2°. Initial technical success was 93.3% (n = 28) with 2 stents deployed too low. Intra-operatively 3 patients initially had type I endoleaks, but all were resolved by ballooning. 30 day clinical success was 96.7%: there were no type I or type III endoleaks observed, and no reports of graft thrombosis or migration. Early clinical failure was accounted for by one perioperative death (3% mortality). No aneurysm-related interventions were required during follow-up. At 6 months two patients were reported as having type I endoleaks, although both sacs have reduced in size. Neither has required intervention. No patient has died due to aneurysm rupture or required removal of the endograft.</p> <p>CONCLUSION: The results of this study support the continued application of the Aorfix™ graft to the highly angulated neck.</p>	
<p><i>J Vasc Surg. 2011 Mar;53(3):565-73. Epub 2010 Nov 26.</i></p> <p>Final operative and midterm results of the European experience in the RELAY Endovascular Registry for Thoracic Disease (RESTORE) study.</p> <p>Riambau V, Zipfel B, Coppi G, Czerny M, Tealdi DG, Ferro C, Chiesa R, Sassi C, Rousseau H, Berti S;</p> <p>RELAY Endovascular Registry for Thoracic Disease RESTORE Investigators.</p> <p>Hospital Clinic Provincial, Barcelona, Spain. vriambau@clinic.ub.es</p> <p>PURPOSE: Thoracic endovascular aortic repair is increasingly becoming the standard treatment of many thoracic aortic pathologies. New reliable and accurate stent grafts are emerging to widen the endovascular treatment options. We report the results of RELAY (Bolton Medical, Barcelona, Spain) in the large RELAY Endovascular Registry for Thoracic Disease (RESTORE) European registry.</p>	<p>Non assegnato</p>

METHODS: RESTORE is a multicenter, prospective European registry involving 22 centers in seven European countries. The RELAY device is composed of a stent graft (self-expanding nitinol stents and a polyester vascular graft) and a delivery device specifically designed for the thoracic aorta. Included were acute and elective patients presenting with a variety of pathologies (aneurysms, dissections, ulcerations, intramural hematomas, pseudoaneurysms) and lesions in different aortic and anatomic locations (ascending, arch, descending and thoracoabdominal).

RESULTS: The registry enrolled 304 patients from April 2005 to January 2009. All-cause mortality at 30 days was 7.2%. Freedom from all cause mortality and freedom from device- and procedure-related mortality at 2 years were 78.5% and 95.9%, respectively. An average of 1.26 graft components were used per patient, with a technical success of 97.7% irrespective of the etiology. Early endoleak rate was 4.6%. Perioperatively, stroke and paraplegia were registered in 1.6% and 2.0%, respectively.

CONCLUSIONS: The results of RESTORE support the safety of thoracic endovascular aortic repair with the RELAY stent graft, even in acute and complicated situations. The device was highly efficient in angulated aortic anatomies, with acceptable mortality and a low rate of neurologic complications.

J Neurol Neurosurg Psychiatry. 2011 Mar;82(3):278-82. Epub 2010 Sep 22.

Progressive occlusion of aneurysms in Neuroform Stent-assisted treatment of intracranial aneurysms.

Yahia AM, Latorre JG, Gordon V, Whapham J, Swarnkar A, Fessler RD.

Department of Neurology, Upstate Medical University, Syracuse, New York, USA.
yahia25@hotmail.com

INTRODUCTION: The long term effect of Neuroform stent in progressive occlusion of intracranial aneurysms is not yet completely understood. Here the effect of the Neuroform stent in progressive occlusion of intracranial aneurysms and clinical outcome is reported.

METHODS: Consecutive patients treated with the Neuroform stent from January 2003 to July 2007 were prospectively enrolled. Patients' demographics, immediate and delayed rate of occlusion, and clinical outcomes using the National Institution of Health Stroke Scale (NIHSS) and the Glasgow Outcome Scale (GOS) were recorded.

RESULTS: Neuroform stent placement was attempted in 72 patients, including 10 ruptured cases. However, stent placement could not be accomplished in two patients who were not included for analysis. Mean age was 50 ± 14 years and mean aneurysm diameter was 10.28 ± 5.9 mm. Immediate complete occlusion was observed in 31 (44%), neck remnants in 29 (41%) and subtotal occlusion in 10 (14%). Angiographic follow-up was available in 59 cases; complete occlusion was observed in 48/59 (81%), neck remnant in 7/59 (13%) and recanalisation in 4/49 (7%). Of 39 patients with immediate incomplete obliteration, progressive complete occlusions were achieved in 25/31 (81%), no changes in two and recanalisation in four cases. The majority of patients had good outcomes (GOS 1 or NIHSS 0 in 66/70 (94%), GOS 2 or NIHSS 2 in one patient and GOS 3 or NIHSS 4 in three at the 90 day follow-up visit.

CONCLUSIONS: The Neuroform stent assisted neck remodelling technique improves progressive obliteration of

**Trapanese
Maria**

<p>intracranial aneurysms with a low recanalisation rate and good clinical outcome.</p>	
<p><i>N Engl J Med.</i> 2011 Mar 17;364(11):1016-26. Quality of life after PCI with drug-eluting stents or coronary-artery bypass surgery. Cohen DJ, Van Hout B, Serruys PW, Mohr FW, Macaya C, den Heijer P, Vrakking MM, Wang K, Mahoney EM, Audi S, Leadley K, Dawkins KD, Kappetein AP;</p> <p>Synergy between PCI with Taxus and Cardiac Surgery Investigators.</p> <p>Saint Luke's Mid America Heart Institute, University of Missouri-Kansas City, Kansas City, MO 64111, USA. dcohen@saint-lukes.org</p> <p>BACKGROUND: Previous studies have shown that among patients undergoing multivessel revascularization, coronary-artery bypass grafting (CABG), as compared with percutaneous coronary intervention (PCI) either by means of balloon angioplasty or with the use of bare-metal stents, results in greater relief from angina and improved quality of life. The effect of PCI with the use of drug-eluting stents on these outcomes is unknown.</p> <p>METHODS: In a large, randomized trial, we assigned 1800 patients with three-vessel or left main coronary artery disease to undergo either CABG (897 patients) or PCI with paclitaxel-eluting stents (903 patients). Health-related quality of life was assessed at baseline and at 1, 6, and 12 months with the use of the Seattle Angina Questionnaire (SAQ) and the Medical Outcomes Study 36-Item Short-Form Health Survey (SF-36). The primary end point was the score on the angina-frequency subscale of the SAQ (on which scores range from 0 to 100, with higher scores indicating better health status).</p> <p>RESULTS: The scores on each of the SAQ and SF-36 subscales were significantly higher at 6 and 12 months than at baseline in both groups. The score on the angina-frequency subscale of the SAQ increased to a greater extent with CABG than with PCI at both 6 and 12 months (P=0.04 and P=0.03, respectively), but the between-group differences were small (mean treatment effect of 1.7 points at both time points). The proportion of patients who were free from angina was similar in the two groups at 1 month and 6 months and was higher in the CABG group than in the PCI group at 12 months (76.3% vs. 71.6%, P=0.05). Scores on all the other SAQ and SF-36 subscales were either higher in the PCI group (mainly at 1 month) or were similar in the two groups throughout the follow-up period.</p> <p>CONCLUSIONS: Among patients with three-vessel or left main coronary artery disease, there was greater relief from angina after CABG than after PCI at 6 and 12 months, although the extent of the benefit was small. (Funded by Boston Scientific; ClinicalTrials.gov number, NCT00114972.).</p>	<p>Carolina Laudisio</p>