

## ORIGINAL ARTICLE

# Prasugrel versus Clopidogrel for Acute Coronary Syndromes without Revascularization

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## ABSTRACT

## BACKGROUND

The effect of intensified platelet inhibition for patients with unstable angina or myocardial infarction without ST-segment elevation who do not undergo revascularization has not been delineated.

## METHODS

In this double-blind, randomized trial, in a primary analysis involving 7243 patients under the age of 75 years receiving aspirin, we evaluated up to 30 months of treatment with prasugrel (10 mg daily) versus clopidogrel (75 mg daily). In a secondary analysis involving 2083 patients 75 years of age or older, we evaluated 5 mg of prasugrel versus 75 mg of clopidogrel.

## RESULTS

At a median follow-up of 17 months, the primary end point of death from cardiovascular causes, myocardial infarction, or stroke among patients under the age of 75 years occurred in 13.9% of the prasugrel group and 16.0% of the clopidogrel group (hazard ratio in the prasugrel group, 0.91; 95% confidence interval [CI], 0.79 to 1.05;  $P=0.21$ ). Similar results were observed in the overall population. The pre-specified analysis of multiple recurrent ischemic events (all components of the primary end point) suggested a lower risk for prasugrel among patients under the age of 75 years (hazard ratio, 0.85; 95% CI, 0.72 to 1.00;  $P=0.04$ ). Rates of severe and intracranial bleeding were similar in the two groups in all age groups. There was no significant between-group difference in the frequency of nonhemorrhagic serious adverse events, except for a higher frequency of heart failure in the clopidogrel group.

## CONCLUSIONS

Among patients with unstable angina or myocardial infarction without ST-segment elevation, prasugrel did not significantly reduce the frequency of the primary end point, as compared with clopidogrel, and similar risks of bleeding were observed. (Funded by Eli Lilly and Daiichi Sankyo; TRILOGY ACS ClinicalTrials.gov number, NCT00699998.)

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\*The Targeted Platelet Inhibition to Clarify the Optimal Strategy to Medically Manage Acute Coronary Syndromes (TRILOGY ACS) investigators are listed in the Supplementary Appendix, available at NEJM.org.

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## Rivaroxaban in Patients with a Recent Acute Coronary Syndrome

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### ABSTRACT

#### BACKGROUND

Acute coronary syndromes arise from coronary atherosclerosis with superimposed thrombosis. Since factor Xa plays a central role in thrombosis, the inhibition of factor Xa with low-dose rivaroxaban might improve cardiovascular outcomes in patients with a recent acute coronary syndrome.

#### METHODS

In this double-blind, placebo-controlled trial, we randomly assigned 15,526 patients with a recent acute coronary syndrome to receive twice-daily doses of either 2.5 mg or 5 mg of rivaroxaban or placebo for a mean of 13 months and up to 31 months. The primary efficacy end point was a composite of death from cardiovascular causes, myocardial infarction, or stroke.

#### RESULTS

Rivaroxaban significantly reduced the primary efficacy end point, as compared with placebo, with respective rates of 8.9% and 10.7% (hazard ratio in the rivaroxaban group, 0.84; 95% confidence interval [CI], 0.74 to 0.96;  $P=0.008$ ), with significant improvement for both the twice-daily 2.5-mg dose (9.1% vs. 10.7%,  $P=0.02$ ) and the twice-daily 5-mg dose (8.8% vs. 10.7%,  $P=0.03$ ). The twice-daily 2.5-mg dose of rivaroxaban reduced the rates of death from cardiovascular causes (2.7% vs. 4.1%,  $P=0.002$ ) and from any cause (2.9% vs. 4.5%,  $P=0.002$ ), a survival benefit that was not seen with the twice-daily 5-mg dose. As compared with placebo, rivaroxaban increased the rates of major bleeding not related to coronary-artery bypass grafting (2.1% vs. 0.6%,  $P<0.001$ ) and intracranial hemorrhage (0.6% vs. 0.2%,  $P=0.009$ ), without a significant increase in fatal bleeding (0.3% vs. 0.2%,  $P=0.66$ ) or other adverse events. The twice-daily 2.5-mg dose resulted in fewer fatal bleeding events than the twice-daily 5-mg dose (0.1% vs. 0.4%,  $P=0.04$ ).

#### CONCLUSIONS

In patients with a recent acute coronary syndrome, rivaroxaban reduced the risk of the composite end point of death from cardiovascular causes, myocardial infarction, or stroke. Rivaroxaban increased the risk of major bleeding and intracranial hemorrhage but not the risk of fatal bleeding. (Funded by Johnson & Johnson and Bayer Healthcare; ATLAS ACS 2-TIMI 51 ClinicalTrials.gov number, NCT00809965.)

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\*Investigators in the Anti-Xa Therapy to Lower Cardiovascular Events in Addition to Standard Therapy in Subjects with Acute Coronary Syndrome—Thrombolysis in Myocardial Infarction 51 (ATLAS ACS 2-TIMI 51) are listed in the Supplementary Appendix, available at [NEJM.org](http://NEJM.org).

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## Chronic cerebrospinal venous insufficiency in amyotrophic lateral sclerosis

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**Aim.** CCSVI probably is not only a risk factor for development of MS, but it is the basic ethiopathogenetical factor. The dysfunction of the blood brain barrier (BBB) appeared as a result of CCSVI can also be one of the main reasons for triggering of neurodegenerative or autoimmune processes in MS. Following this hypothesis we can assume that CCSVI is the main ethiopathogenetic factor in other neurodegenerative diseases such as amyotrophic lateral sclerosis (ALS). Up to this moment the literature has no data for Doppler or Venography examination for CCSVI in patients with ALS. The aim of this research is screening of ALS patients for CCSVI using EchoDoppler and venography.

**Methods.** Seven patients with ALS were examined.

**Results.** The patients diagnose was confirmed based on clinical symptoms and electromyography. Both jugular vein (draining the blood from the brain) and the azygos vein (draining the blood from the spinal cord) were examined by EchoDoppler and venography. In all of the patients with ALS CCSVI was determined- severe stenosis in jugular veins. In five of the patients was determined severe stenosis in the azygos vein. In all of our patients endovascular therapy was performed- balloon dilatation of jugular and azygos vein with good angiographic result- normal blood flow and diameter of the veins.

**Conclusion.** The discovery of CCSVI in seven patients with ALS is probably not a coincidence and raises the necessity of conduction

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of a systematic research for CCSVI in of patients with ALS.

Key words: Venous insufficiency - Brain - Amyotrophic lateral sclerosis - Echocardiography, Doppler.

Amyotrophic lateral sclerosis (ALS) or motor neuron disease is a neurodegenerative disease presenting with progressive muscle paralysis as a result of cerebral and spinal motor neuron degeneration.<sup>1-4</sup> The disease is often called Lue Garry disease- the name of a famous American baseball player suffered and died from ALS in 1939. The disease has first been described by Augustus Waller in 1850 and later by a French physician named Jean-Martin Charcot in 1869.<sup>2-6</sup> The disease is rare- 5.2/100 000 people.<sup>2-17</sup> The average age is 60 years, men are more affected then women. Around 2/3 of the patients have spinal form presented with muscle fibrillations, cramps and weakness in upper and lower limbs muscles. Later the patients develop muscle atrophy and paralysis. Bulbar form of ALS is developed in 25% of the patients and it is resent-

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Case report - Cardiac general

Emergency surgical intervention after unsuccessful percutaneous transluminal angioplasty and stenting of aortic coarctation<sup>☆</sup>

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Abstract

Coarctation of thoracic aorta is an uncommon diagnosis in adults. Catheter-based intervention consisting of primary ballooning and stenting is becoming one of the methods of choice for the treatment of native coarctation. We describe the case of a young adult with coarctation of the aorta treated unsuccessfully with percutaneous transluminal angioplasty and stent implantation that resulted in stent migration into the aortic arch and led to an urgent operative intervention. In one step, we performed the evacuation of the foreign body from the aortic arch as well as the treatment of the aortic coarctation through an extra-anatomical vascular graft interposition between the ascending and descending thoracic aorta. In this article, we discuss the need for emergency surgical intervention in this case.

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Keywords: Coarctation; Stent migration; Percutaneous transluminal angioplasty; Extra-anatomical bypass

1. Introduction

Coarctation of the aorta (CoA) is a relatively common defect that accounts for 5–8% of all congenital heart defects. Often, the diagnosis of CoA is missed or delayed until the patient develops hypertension leading to congestive heart failure, a condition common in infants, which if uncorrected can also be associated with aortic rupture, myocardial infarction, infective endocarditis, or stroke [1]. Since 1944, various surgical techniques have been used. Catheter-based intervention consisting primary of ballooning and/or stenting became an accepted form for the treatment of native coarctation [2].

In our patient, the CoA was treated initially with primary ballooning and stenting, followed by migration of the stent into the aortic arch, which led to urgent surgical intervention, performed in one step for evacuation of the stent from the aortic arch and repair of the coarctation with a vascular graft interposition between the ascending and descending aorta.

2. Case report

A 19-year-old male with postductal CoA was urgently admitted to our unit from the cardiology department with stent migration into the aortic arch after interventional

treatment with percutaneous transluminal angioplasty and stenting of the coarctation with a Smart stent (Cordis S.M.A.R.T. Control Nitinol Stent System, Cordis®-Corporation, Miami Lakes, FL, USA) of 14×60 mm followed by two postdilations with balloons of 10×30 mm and 12×20 mm. In this patient, the persistent ductus arteriosus had been ligated at the age of nine months.

The physical examination was within normal limits. A contrast-enhanced computed tomography (CT)-scan of the chest revealed a long narrowing of the descending aorta distal to the origin of the left subclavian artery. The origins of the arch vessels did not show any sign of narrowing. Transesophageal echocardiography demonstrated a CoA with a diameter of 6 mm, a systolic pressure gradient of 60 mmHg across the coarctation, and a mean gradient (MnGr) of 36 mmHg. Angiography confirmed these findings (Fig. 1), demonstrating a systolic pressure gradient of 60 mmHg across the coarctation and showing the migrated stent in the aortic arch.

The patient underwent one-step surgery for evacuation of the migrated stent from the aortic arch, and extra-anatomical bypass grafting from the ascending aorta to the descending thoracic aorta for repair of the CoA through a median sternotomy. The femoral artery and the brachiocephalic trunk were cannulated. Venous drainage was established with a single 'two-stage' venous cannula placed into the right atrium, and cardiopulmonary bypass was routinely instituted. A ventricular vent was placed via the right superior pulmonary vein. Cooling was commenced. The ascending aorta was cross-clamped. Myocardial protection

<sup>☆</sup> Presented at World Society of Cardio-Thoracic Surgeons 2010, Chennai, India, October 23, 2010.

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Case report - Cardiac general

Emergency surgical intervention after unsuccessful percutaneous transluminal angioplasty and stenting of aortic coarctation<sup>☆</sup>

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1. Introduction

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## ◆ CLINICAL INVESTIGATION ◆

## Safety Profile of Endovascular Treatment for Chronic Cerebrospinal Venous Insufficiency in Patients With Multiple Sclerosis

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**Purpose:** To evaluate the safety of endovascular treatment of chronic cerebrovascular insufficiency (CCSVI) in patients with multiple sclerosis (MS).

**Methods:** In a 1-year period, 461 MS patients (261 women; mean age 45.4 years, range 21–79) with CCSVI underwent endovascular treatment of 1012 venous lesions during 495 procedures [34 (6.9%) reinterventions]. While balloon angioplasty was preferred, 98 stents were implanted in 76 patients for lesion recoil, restenosis, or suboptimal dilation. The procedures were analyzed for incidences of major adverse events (death, major bleeding, or clinical deterioration of MS), access site complications, procedure-related complications, and procedural safety-related variables (fluoroscopy and contrast times). The complication rates were compared to published data for similar endovascular methods.

**Results:** There were no deaths, major bleeding events, or clinical deterioration of MS. Access site complications included limited groin hematoma (5, 1.0%); there were no arteriovenous fistulas or puncture site infections. Systemic complications included only rare cardiac arrhythmias (6, 1.2%). Procedure-related complications included vein rupture (2, 0.4%), vein dissection (15, 3.0%), acute in-stent/in-segment thrombosis (8, 1.6%), and acute recoil (1, 0.2%); there was no stent migration or fracture or distal embolization. Mean fluoroscopy time was 22.7 minutes, and mean contrast volume was 136.3 mL.

**Conclusion:** Endovascular therapy appears to be a safe and reliable method for treating CCSVI. Innovations such as purpose-specific materials and devices are needed, as are case-controlled and randomized data to establish efficacy in ameliorating MS symptoms.

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**Key words:** venous insufficiency, multiple sclerosis, balloon angioplasty, stent, endovascular treatment, safety

Chronic cerebrospinal venous insufficiency (CCSVI) is described as a state of impaired venous brain drainage due to obstructions in the internal jugular veins (IJVs), the vertebral veins, and/or the azygos vein, leading to changes in the

See commentary pages 324 and 326

normal intra- and extracranial hemodynamics and development of bypassing collaterals.<sup>1</sup> Accumulating data that the obstructions in

these veins is associated with developmental abnormalities led to inclusion of CCSVI in the classification of venous malformations by the International Union of Phlebology.<sup>2</sup>

This hemodynamic state has been found to be prevalent in patients multiple sclerosis (MS).<sup>1,3,4</sup> A pathogenetic mechanism of neuron injury was proposed based on increased secondary intracranial venous pressure, which disrupts the tight junctions in the microvasculature.

The authors have no commercial, proprietary, or financial interest in any products or companies described in this article.

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## Safety Profile of Endovascular Treatment of CCSVI in Patients With MS

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### Objective:

Recently the chronic cerebrospinal venous insufficiency was recognized to be highly associated with multiple sclerosis. Although CCSVI causative relation with MS is still uncertain, it looks like it plays an important role in the pathogenesis of the disease. Thus, it is common sense to expect that treatment of CCSVI would result in clinical benefit – either stop of the progression of the disease or reverse its course. Initial research in endovascular treatment for this condition was performed over a small group of patients showing promising results. Later, in the scientific literature were published conclusions that considering such a treatment approach could compromise patient safety and even be life threatening. Herewith we present safety data from endovascular treatment of patients with MS and modified Doppler-sonographic criteria for CCSVI conducted for the period from January 2010 to November 2010.

### Methods Used:

During that period 472 patients with MS were screened, 461 met the sonographic criteria for CCSVI and that was confirmed in 100% of the cases by consequent phlebography. Overall 495 interventional procedures were performed, of which 34 (6.9%) were re-interventions due to variety of reasons. Patient profile baseline characteristics: Gender - 200 Males and 261 Females; Age: mean of 45.44 (21 - 79) years; MS clinical types: PP - 25.4%, RR - 36.7%, SP - 37.9%; Mean MS duration from diagnosis in months: 124.3 (0-600); Baseline EDSS score - 5.22 (0 - 9.5); Therapeutic background: patients on any medical treatment for MS: 60.6%, patients receiving no medicinal treatment for MS: 39.4%. A total of 1012 venous lesions (0-3 lesions or mean of 2.2 lesions per initial intervention) were treated by endovascular methods of which: 1. Angiographic lesions of right internal jugular vein > 50%: n = 379; 2. Angiographic lesions of left internal jugular vein > 50%: n = 394; and 3. Angiographic lesions of the azygos vein > 50%: n = 239. As a primary strategy percutaneous transluminal balloon angioplasty was used, but 87 nitinol self-expandable stents were implanted in 67 patients for non dilatable lesions and another 11 stents during re-interventions mainly for restenosis. The interventions were analyzed for incidence of complications as follows: 1. Major adverse events: death, major bleeding, clinical deterioration of MS; 2. Access site complications: limited groin haematoma, AV fistula and puncture site infection; 3. Non-interventional procedure related complications: rhythm disorders, vascular injury during diagnostic maneuvers; 4. Interventional complications: vein wall rupture, vein wall dissection, acute (up to the 24 h after the procedure) in-stent or in-segment thrombosis or recoil, stent migration or fracture and distal embolization; 5. General procedural safety measurements: mean fluoroscopic time and mean volume of contrast used. Then we compared the established complication rates in the cohort of the patients treated for CCSVI with complication incidence encountered in similar endovascular methods for other vascular territories.

### Results:

Our registry showed the following incidence of complications: Major adverse events: Death 0%; Major bleeding events - 0%; Clinical deterioration of MS: 0%; Access site complications: limited groin haematoma - 1.01% (n=5) of which one case required minor vascular surgery repair; AV fistula formation - 0%; Puncture site infection - 0%; Non-interventional procedure related complications: Rhythm and conductance disorders - 1.2% (AF n=4, VT n=1 and VF n=1); Vascular injury during diagnostic maneuvers - 0%; Interventional complications: Vein rupture - 0.4% (n=2); Vein dissection - 3.03% (n=15); Acute target lesion failure (in-stent thrombosis, in-segment thrombosis and recoil within the first 24 hours) - 1.8% (n=9); Stent migration or fracture - 0%; Distal embolization - 0%; General procedural safety measurements: Mean fluoroscopic time - 22.7 minutes; Mean volume of contrast used - 136.3 milliliters.

### Conclusion:

We compared our data to data published in the scientific literature regarding complications accompanying right heart catheterization procedures, a number of trials with endovascular angioplasty and stenting of veins and arteries. Our conclusion is that the endovascular therapy is safe and reliable method for treatment for CCSVI, but calling for innovations such as development of purpose specific materials and devices preventing restenosis/rethrombosis.

may benefited from step down care unit. Our study, however, was limited by small number of subjects especially in K2 group.

#### OP-017

### COMPARISON OF CORONARY ARTERY BYPASS GRAFTING WITH PERCUTANEOUS CORONARY INTERVENTION FOR UNPROTECTED LEFT MAIN CORONARY ARTERY DISEASE

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**Objective:** Coronary artery bypass grafting (CABG) is the optimal treatment option for left main coronary artery disease (LMCAD). However, as a consequence of the advances in interventional cardiology, there is a constant debate between cardiac surgeons and interventional cardiologists on the optimization of the medical approach to LMCAD.

The aim of the study was to assess the efficacy of LMCAD treatments by comparing the mid-term outcomes of CABG and percutaneous coronary intervention (PCI) with bare metal stents (BMSs) or drug-eluting stents (DESs).

**Methods:** Our study population was comprised of 199 consecutive patients admitted with unprotected LMCAD. All of the patients were not randomly assigned to PCI (88 patients) or CABG (111 patients). Patients in the PCI group were subdivided into BMS group (48 patients) and DES group (34 patients).

The primary clinical end point consisted of death of the cardiac origin alone, stroke and acute coronary syndrome (ACS). ACS was a composite of target vessel revascularization (TVR) and acute myocardial infarction (AMI) or unstable angina (UA). Follow-up was approximately 12 months.

**Results:** Patients assigned to PCI were of higher operative risk than patients scheduled for CABG (EuroSCORE  $6.49 \pm 4.09$  vs.  $4.81 \pm 2.67$ ,  $p=0.0032$ ). In the PCI procedures  $1.21 \pm 0.46$  BMSs and  $1.15 \pm 0.36$  DESs were implanted with a total stent length of  $16.88 \pm 9.35$  mm for BMSs and  $15.79 \pm 6.73$  mm for DESs. All of the 111 patients scheduled for bypass surgery received the LIMA-to-LAD graft (100%).

Comparison of the group that received DESs with the CABG group did not reveal any differences in MACCE occurrence (21% vs. 16%,  $p=ns$ ). Patients in the CABG and PCI groups died with equal frequency (11% vs. 16%,  $p=ns$ ). The mortality rate in CABG group was higher compared to DES (11% vs. 3%,  $p=0.049$ ). The rate of ACS was higher in the PCI group than in the CABG group (13% vs. 4%,  $p=0.016$ ). The rate of TVR was 7% in PCI patients and 4% in CABG patients.

**Conclusions:** Despite the fact that patients treated with PCI were of higher operative risk, PCI with DES was shown to be comparable to CABG in terms of mortality, stroke and ACS. However the frequency of repeat revascularizations remains a constant concern with PCI. The risk of TVR in PCI should be balanced against the invasiveness of surgical procedures.

#### OP-018

### MANUAL THROMBASPIRATION IN PPCI IN STEMI – RETROSPECTIVE ANALYSIS OF SINGLE CENTER EXPERIENCE

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**Objective:** Primary percutaneous coronary intervention is effective in opening the infarct-related artery in patients with STEMI. In up to 40% of patients undergoing primary PCI, a persistent ST-elevation can be observed despite the presence of a TIMI 3 flow. Adjunctive manual thrombectomy is associated with improved postprocedural TIMI flow, higher MBG, lower peak enzyme levels and faster resolution of ECG changes. Despite the available data the detailed aspects of the indications, benefits and risks with utilization of thrombaspiration devices remain to be established.

The aim of our study is to evaluate the utility of manual thrombaspiration in the setting of PPCI of STEMI in terms of immediate clinical outcomes, angiographic results and ECG markers of myocardial damage.

**Methods:** The study is a retrospective analysis of the data on all consecutive patients presenting to the Interventional Cardiology Unit at Tokuda Hospital Sofia within 12 hours of symptom onset of STEMI. Patients with TIMI 0–1 flow in the IRA or visible thrombus on coronary angiography are included in analysis. Data on in-hospital mortality, occurrence of angiographic no reflow, duration of hospital stay and ST-elevation resolution is compared relative to utilization of manual thrombaspiration. Thrombaspiration, pre-dilatation and stent implantation were performed as per standard clinical practice and at operator discretion.

**Results:** 278 patients met the criteria for inclusion in the analysis. Thrombaspiration was performed in 67% of the patients. Mean ischemic time is 316 min and is equal in both groups. Baseline clinical characteristics (age, gender, risk factor distribution preceding MI, IRA) are balanced between the groups. Analysis data shows higher rates of immediate (44% vs. 30%,  $p<0.05$ ) and cumulative day 1 (63% vs. 51%,  $p<0.05$ ) complete ST-elevation resolution. There is a non-significant trend towards reduced mortality in the thrombaspiration group (2.9% vs. 4.9%,  $p<0.5$ ) and lower rates of angiographic no-reflow (5% vs. 3.4%). No device-related complications were observed in the studied group. Length of hospital stay was not influenced by utilization of thrombaspiration (3.31 vs 3.53 days).

**Conclusions:** Our retrospective analysis confirms previous published data that use of adjunctive manual thrombaspiration in STEMI is safe procedure with significant improvement of ECG markers of myocardial damage. The observed trend for improved survival additionally reinforces the concept of clinical utility of manual thrombaspiration in the setting of PPCI in the present patient population.

#### OP-019

### XIENCE NILE, EGYPTIAN REAL WORLD PROSPECTIVE MULTICENTRE XIENCE V REGISTRY

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**Objective:** To study the safety and efficacy of the Xience V among Egyptian patients in a prospective multicenter all-egypt registry.

**Methods:** 426 consecutive patients were included in 20 centers. The exclusion criteria were very limited (Primary PCI for S in-stent restenosis, using additional stents other than the Xience V).

**Primary endpoint:** MACE at 180 days: Composite rate of all-cause mortality, Myocardial Infarction (MI) and Target Vessel Revascularization (TVR) at 180 days.

**Secondary endpoints:**

- MACE at 12 months.
- Composite rate of Cardiac Death and MI at 6 & 12 months.
- Stent thrombosis as per ARC definition at 6 & 12 months.

**Results:** Mean age was 57.9 years, 84% were males, 56% were diabetics and 37.1% had a prior MI. 69% had type I lesions, 54% had moderate to severe tortuosity. 426 patients received 568 stents, maximum number of stents per patient was 4, patient/stent ratio 1.3, 52% had multivessel disease and 71.8% received only one stent.

## OP-062

**HYBRID TECHNIQUES FOR TREATMENT OF VARICOSE VEINS: COMBINED NEW AND CONVENTIONAL TECHNOLOGIES**

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**Objective:** We assessed the safety and efficacy of combined endovenous laser treatment (ELT) and traditional techniques for treatment of the saphenous veins insufficiency, based on experience, increasing endolaser procedure in patient often treated with stripping.

**Methods:** Since September 2007 to June 2010, 704 ELT procedures have been performed (great and small Saphenous vein) using a diode laser 980 nm wavelength (LASEmaR1000-Eufoton, Italy) by a kit that includes optical fibers of 600 micron (KIT INVE, Eufoton, Italy). Local Echo-guided anesthesia have performed in all cases. Laser power is variable regarding veins diameter from 6 to 12 watts settled in semi-continuous mode and the energy supplied is personalized to morphologic vein characteristics. Power is always personalized to echographic vein patterns (diameter, wall thickness, anatomic deep). In the 94% of all patients other techniques have been associated: microflebotomy (86%), varicectomy (12%), perforator vein closure (4%), stripping of lower extremity of great saphenous vein (GSV) (7%). This last procedure (stripping) combined to ELT is performed when tortuosity of GSV prevent laser endovenous treatment.

**Results:** In all cases (100%) has been detected the subjective symptomatology's fading, with an objective improvement of symptomatology after 1 month of the operation and of aesthetic profile. At 3 months after operation, in the 99.9% of all cases has been detected a complete occlusion of vein treated, and in the 0.01% of cases has been detected an early recanalization of Saphenous vein (initial learning curve only).

At 6 months after operation has been detected a recanalization of Saphenous vein in the 1.5% of 145 operated patients. At 12 months after operation has been detected a long regurgitation without usual relapses in the 0.46% of 32 operated patients. No major complications occurred. One DVT (0.0012%) occurred. Local transient paraesthesia at the ankle and midcalf level occurred in 5 patients (0.006%). In the 74% of patients we observed that vein treated disappear after 6 months. In all (100%) of patient treated with combined technique ELT-stripping we assessed a total improvement of aesthetical and functional aspects.

**Conclusions:** The endovenous laser treatment (ELT) of Saphenous veins is a minimally invasive surgical intervention, that often can be combined to other techniques performable by a Day-Surgery ever under ultra-sound guide and by a topical anesthesia. It can ensure good clinical and aesthetic results avoiding invasive procedures like stripping. Combined techniques personalized to the patient's vein situation permit to obtain better results and better satisfaction of patients.

## OP-063

**ENDOVASCULAR TREATMENT OF CHRONIC CEREBROSPINAL VENOUS INSUFFICIENCY IN PATIENTS WITH MS – SAFETY REPORT AND MID TERM CLINICAL RESULTS**

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**Objective:** Recently the chronic cerebrovascular venous insufficiency was recognized as highly associated with multiple sclerosis. Although CCSVI causative relation with MS is still uncertain, it looks like it plays an important role in the pathogenesis of the disease. Initial research in endovascular treatment is promising results. Herewith we present safety data and midterm clinical results from endovascular treatment of CCSVI in patients with MS performed in the period from January 2010 to November 2010.

**Methods:** 495 interventions (total of 1012 lesions) were performed of which 34 (6.9%) were re-interventions due to variety of reasons. Patient baseline characteristics: 200 Males; mean age 45.44 (21–77) years; MS clinical course: PP – 25.4%, RR – 36.7%, SP – 37.9%; Mean MS duration: 124.3 months, mean EDSS score at admission 5.22 (0–9.5); 2.19 lesions per patient were treated; right jugular vein = 379; left jugular = 394; and AZYGOS = 239. Percutaneous transluminal balloon angioplasty was the preferred method. 87 nitinol self-expandable stents were implanted in non dilated lesions. These interventions were analyzed for incidence: death, major bleeding, stent migration, vascular complication, rhythm disturbances, pneumothorax during the hospital stay, worsening or improving of MS during 6 month follow-up.

**Results:** Death: 0; Major Bleeding: 0; Stent Migration: 0; Vascular complications: 29 (6.3%) Rupture of truncular vein – Acute (within 24 hrs) in-stent thrombosis – 5. Acute post-stent thrombosis – 3; Acute restenosis – 1; Dissection of truncular vein – 15; Vascular complications requiring surgical repair: 1 for Punctate haematoma: 4. Rhythm and conduction disturbances: 6. AF – 4 (all reversed to sinus rhythm), 1 case of VF – turned to h significant LM disease (treated with stenting during the second hospital stay). Pneumothorax: 0. Mean reduction of EDSS score in the f-up 1.25 points.

**Conclusions:** We compared our data to data regarding complications accompanying right heart catheterization procedure and a limited number of trials with endovascular angioplasty and stenting of veins. Since all endovascular procedures were performed with materials that were not dedicated for the specific purposes also compared safety data from early stages of coronary angioplasty and stenting. We concluded that the endovascular therapy is a safe and reliable method for treatment of CCSVI. The initial clinical results are promising but a randomized study is necessary to prove the real value of this new method of treatment =

## OP-064

**ONE YEAR CLINICAL OUTCOMES OF MISAGO-SX NITINOL STENT IN THE TREATMENT OF OCCLUDED LESIONS IN SUPERFICIAL FEMORAL OR POPLITEAL ARTERIES**

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**Objective:** Percutaneous interventions in totally occluded superficial femoral (SFA) and popliteal arteries are associated with worse short and long term outcomes. Our aim was to evaluate performance of Misago<sup>®</sup> SX nitinol stent in these challenging lesions.

**Methods:** We studied 280 patients having at least one occluded lesion in SFA or popliteal arteries. The primary endpoint was absence of clinically driven target lesion revascularization at 12 months. Data were entered electronically and monitored online and on-site. All serious adverse events were adjudicated by an independent clinical event committee.

**Results:** The patients were 69±10 years old, 64.6% male, 65.4% smokers and 31.8% had diabetes mellitus. Average lesion length 77.9±41.0 mm with the mean RVD of 5.2±0.57 mm and 62% moderately or massively calcified. 74% of the lesions were i

meses com EPV grave submetidos a VPB sob anestesia geral por via venosa anterógrada. A relação balão-anel foi de 1,2 a 1,4.

**Resultados.** De 9/99 a 10/09, 75 pacientes (mediana de idade e peso: 30 dias e 3,8 kgs, respectivamente) foram submetidos à VPB. O anel valvar mediu  $7,9 \pm 1,3$  mm e a relação balão/anel foi  $1,37 \pm 0,22$ . Após a VPB, houve queda significativa ( $p < 0,001$ ) da pressão sistólica do VD de  $91,5 \pm 25,8$  para  $49,3 \pm 20$  mmHg, da relação das pressões VD/sistêmica de  $1,36 \pm 0,4$  para  $0,7 \pm 0,3$  e do gradiente transvalvar de  $72,3 \pm 26,2$  para  $3,8 \pm 3,9$  mmHg e aumento significativo da PA de  $69,3 \pm 19,7$  para  $73,5 \pm 19,3$  mmHg e da artéria pulmonar de  $20,9 \pm 5,4$  para  $29,1 \pm 10,4$  mmHg. Houve parada cardíaca em 3 pacientes (4%), com 2 óbitos (2,6%). Complicações vasculares ocorreram em 1 paciente (1,3%). No seguimento, não houve necessidade de redilação por restenose nem de troca valvar por insuficiência pulmonar grave.

**Conclusão.** A VPB em pacientes menores que 6 meses mostrou-se factível e efetiva, com baixa taxa de complicações relacionadas ao procedimento, resultando em melhora imediata dos parâmetros hemodinâmicos e baixa probabilidade de reintervenções durante o seguimento.

## 145

## ANALYSIS OF DOOR-TO-BALLOON AND SYMPTON-TO-BALLOON TIMES OF THE PATIENTS WITH ACUTE MYOCARDIAL INFARCTION TREATED IN TOKUDA HOSPITAL-SOFIA: THREE-YEARS EXPERIENCE

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**Introduction.** Door-to-balloon (DTBT) and symptom-to-balloon times (STBT) are two important predictors for the STEMI-patients' outcomes. They also serve as indicators for the organization of a PCI-capable hospital on one hand and for a national health-providing system on the other.

**Objective.** Analysis of DTBT and STBT for the PCI-treated patients with STEMI in a single center for a three-year period.

**Methods.** For the three-year period 294 STEMI patients treated with primary PCI were included in the analysis. The source information gathered was statistically processed with the use of descriptive, nonparametric and graphic analyses.

**Results.** The average DTBT for year 2007, 2008 and 2009 were 46,08, 44,48 and 51,70 minutes respectively ( $p > 0,05$ ). The mean STBT for year 2007, 2008 and 2009 were 402, 351 and 484 minutes respectively with high variability ( $p > 0,05$ ).

**Conclusion.** For the three-years period over 94,4% of the patients were treated in the 90 minute limit of door-to-balloon time as recommended by the guidelines. Despite of the fast reaction in the PCI centre the STEMI patients have long STBT - over 6 hours, which does not change positively through the three-year period. To analyze the reasons for such time delay a unified national registry of acute coronary syndromes is needed.

## 146

## IMPACTO DOS STENTS FARMACOLÓGICOS EM PACIENTES COM DOENÇA ARTERIAL CORONARIANA ESTÁVEL SUBMETIDOS A INTERVENÇÃO CORONÁRIA PERCUTÂNEA NA PRÁTICA CLÍNICA DO MUNDO REAL

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**Introdução.** Estudos recentes sugerem ausência de benefício da intervenção coronária percutânea (PCI) com stents convencionais (BMS) em relação à terapia clínica otimizada em pacientes selecionados com doença arterial coronariana (CAD) estável. Nós avaliamos o impacto dos stents farmacológicos (DES) nos pacientes com CAD estável na prática clínica do mundo real.

**Métodos.** De maio/2002 a abril/2009, 3.744 pacientes com CAD estável (an-

gina estável ou isquemia silenciosa com teste funcional positivo para a isquemia) que se submeteram à PCI foram alocados em 2 braços, onde DES (n=1.519) e BMS (n=2.225) estavam disponíveis como estratégias de PCI.

**Resultados.** A idade média era de 62 anos ( $p=ns$ ), e 30% tinha diabetes ( $p=ns$ ). O DES tinha maior proporção do sexo masculino (78 vs 65%,  $p < 0,001$ ), e menos infarto miocárdico (IM) prévio (20 vs 34%,  $p < 0,001$ ). A artéria descendente anterior foi tratada em 37 vs 36% ( $p=ns$ ), mas o DES teve lesões mais complexas (tipo B2/C em 66% vs 43%,  $p < 0,001$ ). O sucesso angiográfico e do procedimento foi similar (99,6 vs 99%, e 98,5 vs 99%; respectivamente). Desfechos clínicos tardios em seguimento médio de 3,2 anos (tabela).

**Conclusões.** O DES demonstrou superioridade sobre o BMS como uma estratégia terapêutica primária nos pacientes com CAD estável, incluindo taxas significativamente mais baixas de revascularização do vaso-alvo. Houve taxas similares de morte, IM e trombose de stent.

| Desfechos clínicos (incidência cumulativa) | DES   | BMS   | p     |
|--|-------|-------|-------|
| Morte por qualquer causa                   | 3,20% | 4,00% | ns    |
| IM não-fatal                               | 3,10% | 2,00% | ns    |
| Revascularização de lesão-alvo             | 3,90% | 8,80% | 0,003 |
| Trombose de stent                          | 1,20% | 0,90% | ns    |

## 147

## EVOLUÇÃO CLÍNICA TARDIA DE MULHERES SUBMETIDAS A INTERVENÇÃO CORONÁRIA PERCUTÂNEA (ICP). AS DIFERENÇAS EM RELAÇÃO AOS HOMENS PERSISTEM?

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**Introdução.** O sexo feminino tem sido descrito como um preditor de pior evolução clínica em pts submetidos à intervenção coronária percutânea (ICP). Consequentemente, inúmeros esforços tem sido incorporados na prática clínica com objetivo de otimizar os resultados neste subgrupo de alto risco. No entanto, o impacto da ICP moderna em mulheres permanece controverso.

**Métodos.** Total de 1.825 pts (552 mulheres vs. 1.273 homens) encaminhados para ICP eletiva ou de urgência em hospital terciário entre Jan/08 e Jan/09.

**Resultados.** Comparadas aos homens, as mulheres apresentavam maior média de idade (63 vs. 61 anos,  $p=0,001$ ), mais diabetes (35 vs. 26%,  $p < 0,001$ ), hipertensão (89 vs. 80%,  $p < 0,001$ ), dislipidemia (75 vs. 62%,  $p < 0,001$ ), insuficiência renal (40 vs. 24%,  $p < 0,001$ ); mas menos tabagismo atual (17 vs. 23%,  $p=0,001$ ) e IAM prévio (41 vs. 48%,  $p=0,005$ ). Com relação à apresentação clínica, 52% das mulheres tinham angina estável vs. 42% dos homens ( $p < 0,001$ ). O vaso-alvo mais acometido foi a DA (34 vs. 33%,  $p=NS$ ), e stents farmacológicos foram utilizados em torno de 30% em ambos os grupos. O sucesso angiográfico (96,2 vs. 97,5%) e do procedimento (96,9 vs. 96,5) foram similares. No entanto, as mulheres apresentaram mais complicações vasculares (3,6 vs. 1,9%,  $p=0,03$ ). A Tabela apresenta os resultados preliminares do seguimento tardio até 6 meses (n=1.151).

**Conclusões.** Neste estudo incluindo pts provenientes da prática diária tratados com ICP, o sexo feminino demonstrou maior perfil de risco e pior evolução intrahospitalar devido, principalmente, à maior taxa de complicações vasculares. Resultados preliminares do seguimento de 6 meses mostraram baixa incidência de eventos, sem diferença significativa entre os sexos. O seguimento completo de 6 meses será apresentado no Congresso.

| Eventos           | Mulheres | Homens | p  |
|-------------------|----------|--------|----|
| Morte cardíaca    | 1,40%    | 1%     | NS |
| IAM               | 0,60%    | 0,80%  | NS |
| RLA               | 0%       | 0,10%  | NS |
| Trombose de stent | 0%       | 0,50%  | NS |

## Closing of a Right Ventricle Perforation With a Vascular Closure Device

Ivo Petrov,\* MD and Christo Dimitrov, MD

Vascular closure devices are a proven alternative to pure mechanical femoral compression after endovascular procedures. Their off-label use is uncommon and is usually restricted for atypical vascular sites—subclavian arteries and even descending aorta. We report for the first time a case of a successful percutaneous closure of a perforated right ventricle, using the Angio Seal femoral closure device. This was done after an attempt for pericardiocentesis in a high risk patient with carcinoma and cardiac tamponade, which was complicated with perforation of the right ventricle. The closure device successfully stopped the bleeding in the pericardium and spared the patient the need of open surgery and general anesthesia. A successful pericardial drainage was performed after this, and the patient was discharged with clinical improvement. Our literature review did not find descriptions of similar application of a vascular closure device. Our opinion is that such approach is effective and safe and may be used in some extreme and critical situations and in patients at high surgical risk. © 2009 Wiley-Liss, Inc.

**Key words:** pericardiocentesis puncture site; cardiac tamponade; closure-vascular access; right ventricle; perforation

### INTRODUCTION

Vascular closure devices have been created to increase patients' comfort after an endovascular procedure. Although they are widely used, their off-label use is uncommon and is usually restricted to atypical vascular sites, such as subclavian arteries and even descending aorta, [1–3]. Their therapeutic use is even more unusual. Right ventricle perforation is a frequent and life-threatening complication of pericardiocentesis, especially in postoperative patients with pericardial adhesions. It usually requires open surgery, which, in high risk patients and patients in poor general condition is often a risky step. Therefore, all alternative measures have to be considered.

Here, we report a case of an iatrogenic right ventricle perforation during pericardiocentesis, which was successfully closed percutaneously, using a collagen plug arterial puncture closure device—Angio-Seal (St. Jude Medical).

### CASE REPORT

A 61-year-old female presented to the out-patient department with symptoms of severe dyspnea, cough, extreme fatigue, and thoracic pain. The patient had a history of carcinoma of the large intestine, which was operated 2 years ago. Four months ago, she had a pericardiocentesis and drainage because of pericardial tamponade, followed by VATS, pericardial fenestration,

and right pleurodesis. At presentation, the ECG was with low-voltage ventricular waves and supraventricular extrasystoles (Fig. 1). The chest X-ray revealed an extremely enlarged pericardial shadow, as well as a probable effusion in the right hemithorax (Fig. 2). The cardiac ultrasound revealed a massive pericardial effusion, estimated at about 800 ml, causing diastolic compression of the left ventricle (Fig. 3A–C). The patient was admitted in the thoracic surgery department for pericardiocentesis and drainage. A central venous catheter was placed in the pericardium via a subxiphoid puncture. Immediately after this an excessive bleeding through the catheter was observed, followed by tachycardia, hypotension, and hemodynamic instability. A perforation of the right ventricle was suspected and the patient was emergently transferred to the cardiac cathlab. A direct pressure wave was recorded from the

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Conflict of interest: Nothing to report.

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## Endovascular recanalisation for chronic cervical internal carotid artery occlusion

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**Aims:** Selective group of patients with cervical internal carotid artery occlusion (ICAO) may benefit from revascularisation. The feasibility of endovascular ICAO recanalisation has been reported recently. We update our results of 73 ICAO patients undergoing endovascular recanalisation, focusing on clinical events, vascular complications and predictors for technical success.

**Methods and results:** Endovascular recanalisation for ICAO was attempted in 73 consecutive patients (66 men;  $67.8 \pm 10.3$  years old) with either recurrent neurological deficit or objective ipsilateral hemisphere ischemia. In-hospital and 3-month adverse events were recorded. Successful recanalisation was achieved in 47 patients (64%, 47/73). 3-months cumulative stroke/death rate was 3.7% (3/73), including 1 in-hospital fatal non-ipsilateral stroke, 1 in-hospital minor ipsilateral stroke secondary to systemic hypotension and 1 sudden cardiac death 2 months after procedure without definite cause. Vascular complications developed in 4 patients (5.5%, 4/73) without clinical sequel. The predictors of procedural success are patients with recurrent symptom after occlusion documentation, absence of neck radiotherapy history, and shorter duration of occlusion.

**Conclusions:** Procedural death and stroke rate of endovascular ICAO recanalisation is lower than the 6% threshold for symptomatic carotid stenosis. Certain vascular complications may develop during or after the procedure, but patient's safety is not compromised.

## BULgarian Carotid Artery Stenting versus Surgery Study (BULCASSS): Randomized single center trial. Late results.

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*Iokuda Hospital, Department Cardiology, Sofia, Bulgaria*

**Aims:** To compare CAS to CEA in patients with asymptomatic and symptomatic carotid stenosis in a prospective, randomised single center trial (BULCASSS)

**Methods and results:** Between 2001 and 2004 in a single center 219 patients were randomly assigned to either CAS or CEA: 101 vs 118. Primary endpoint: Comparative periprocedural and for a 4-year follow-up incidence of nonfatal stroke, acute myocardial infarction (AMI), transitory ischemic attack (TIA), death, combined MAE. Secondary endpoint: Analysis of the restenosis in the CAS group. No significant differences were found in the incidence of periprocedural endpoints between CAS and CEA groups. For the 4-year follow up the incidence of AMI, stroke, death and combined MAE were 4.00% vs 4.20% ( $p > 0.05$ ); 4.00% vs 4.20% ( $p > 0.05$ ); 6.00% vs 9.20% ( $p > 0.05$ ); 9.00% vs 13.60% ( $p > 0.05$ ) for the CAS and CEA group respectively. The restenosis rate at 4 years in the CAS group was significantly higher in the balloon-expandable vs self-expandable stents - 21.4% vs 1.2% ( $p = 0.009$ ).

**Conclusions:** BULCASSS suggests that carotid stenting is equivalent to carotid endarterectomy. The preventive role of both methods regarding stroke rate are equivalent. The balloon expandable stents are not suitable for CAS, as confirmed by other studies.

## THROMBASPIRATION IN PATIENTS WITH STEMI VS STANDART PCI TREATED IN TOKUDA HOSPITAL SOFIA

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**Objective:** To analyze the rate of adjunctive use of IIb/IIIa inhibitors in patients with STEMI treated with primary PCI+thrombaspisation vs standard PCI in one interventional center.

**Methods:** For the period 01.2007 – 09.2009 a number of 328 patients with STEMI were treated with primary PCI in "Tokuda Hospital Sofia". Amongst them, 201 (61%) patients had angiographic evidence of thrombus and TIMI 0 distal flow. These were candidates for PCI either with or without thrombaspisation. In 127 there was either no thrombus, or TIMI distal flow > 0 and were not included in the analysis. In 179 patients (89%) a single manual aspiration device – Thrombuster II (Kaneka) was used. The 6 Fr. catheter was used in 116 pts (65%) and the 7 Fr. catheter was used in 63 pts (35%) The remaining 22 patients had a standard PCI procedure.

**Results:** The use of GPIIb/IIIa inhibitors was needed in 33% of all 201 cases, or 68 pts. GPIIb/IIIa inhibitors were used in 52 pts (29%) in the group with thrombaspisation vs 11 pts (49%) in the group without thrombaspisation.

**Conclusion:** The routine use of manual thrombaspisation devices in patients with acute coronary artery thrombosis and TIMI 0 distal flow may reduce the use of GPIIb/IIIa inhibitors during primary PCI.

## THROMBASPIRATION IN PATIENTS WITH STEMI VS STANDART PCI TREATED IN TOKUDA HOSPITAL SOFIA

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**Objective:** To analyze the rate of adjunctive use of IIb/IIIa inhibitors in patients with STEMI treated with primary PCI+thrombaspiration vs standard PCI in one interventional center.

**Methods:** For the period 01.2007 – 09.2009 a number of 328 patients with STEMI were treated with primary PCI in "Tokuda Hospital Sofia". Amongst them, 201 (61%) patients had angiographic evidence of thrombus and TIMI 0 distal flow. These were candidates for PCI either with or without thrombaspiration. In 127 there was either no thrombus, or TIMI distal flow > 0 and were not included in the analysis. In 179 patients (89%) a single manual aspiration device – Thrombuster II (Kaneka) was used. The 6 Fr. catheter was used in 116 pts (65%) and the 7 Fr. catheter was used in 63 pts (35%) The remaining 22 patients had a standard PCI procedure.

**Results:** The use of GPIIb/IIIa inhibitors was needed in 33% of all 201 cases, or 68 pts. GPIIb/IIIa inhibitors were used in 52 pts (29%) in the group with thrombaspiration vs 11 pts (49%) in the group without thrombaspiration.

**Conclusion:** The routine use of manual thrombaspiration devices in patients with acute coronary artery thrombosis and TIMI 0 distal flow may reduce the use of GPIIb/IIIa inhibitors during primary PCI.

168

◆ CASE REPORT ◆

## Endovascular Repair of Dissecting Thoracic Aortic Aneurysm in a Patient With Turner Syndrome

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**Purpose:** To report a rare case of dissecting thoracic aortic aneurysm in a young patient with Turner syndrome owing to complete or partial monosomy of the X chromosome.

**Case Report:** A 22-year-old patient with Turner syndrome presented with a 2-month history of voice loss and dysphagia. Multislice computed tomography (MSCT) disclosed a large (53×75-mm) aneurysm with focal dissection affecting the distal part of the aortic arch and the proximal descending aorta, partially involving the left subclavian artery. A TAG endoprosthesis was implanted without complications. MSCT scans at 3 and 6 months after the procedure showed good position and patency of the stent-graft, with total exclusion and shrinkage of the aneurysm. After 1 year of follow-up, she is doing well, without voice disturbances or dysphagia.

**Conclusion:** Although cardiovascular malformations are common in patients with Turner syndrome, dissecting thoracic aortic aneurysm is unusual. Stent-graft repair would appear to be feasible in this situation, but long-term implantation in young patients has not been explored.

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**Key words:** Turner syndrome, thoracic aorta, thoracic aortic dissection, endovascular repair, stent-graft

Turner syndrome, originally described in 1938 by Henry Turner, is a result of complete or partial monosomy of the X chromosome. It is relatively common, affecting about 1 in 2500 live female births. The most common features of the syndrome are short stature and gonadal dysgenesis, but the most serious abnormalities are congenital cardiovascular anomalies, especially coarctation of the aorta, bicuspid aortic valve, and aortic dissection.<sup>1-4</sup> Turner syndrome has also been associated with other vascular anomalies, such as anomalous pul-

monary venous return and persistent left superior vena cava.<sup>5</sup> Retrospective analyses suggest that hypertension, coarctation, and bicuspid aortic valve are the main risk factors for aortic dissection.<sup>1</sup>

In cases of Turner syndrome, it is important to clearly detect anatomical details before making a decision as to the best type of treatment. Thoracic vascular anomalies can be reliably assessed by multislice computed tomography (MSCT), which enables precise depiction of arterial and venous anatomy and

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RESULTS OF LEFT MAIN CORONARY ARTERY STENTING

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**OBJECTIVES:** We examined the immediate and mid-term outcomes of unprotected left main coronary artery (LMCA) stenoses in patients with normal or near-normal left ventricular (LV) function. **DESIGN:** From January 2001 to July 2003 21 consecutive patients with LMCA stenoses and LVEF above 30% were treated with stents. 12 (57%) were protected with patent LIMA graft and 9 (43%) were not. Twelve (57%) were in high-risk (H/R) CCS class stable angina, 7 (33%) were with unstable angina and 3 (14%) were in the course of anterior MI. For 16 (72%) the procedure was elective and for six (29%) urgent. Five patients (23%) received Aspirin and one (4.7%) received clopidogrel. The post-stent antithrombotic regimen was aspirin and clopidogrel. Patients were followed very closely with ECG stress-test every three months, monthly telephone interviews and follow-up angiography at 6 months.

**RESULTS:** The procedural success rate was 100% with no episodes of acute thrombosis, achieving a decrease in mean diameter stenosis from 73% to 13% (p < 0.01). Accordingly, the minimal lumen diameter (MLD) increased from 0.9 mm to 3.3 mm (p < 0.001). Six-month follow-up angiography performed in 12 of 21 patients. Clinical evaluation in all 21 patients had no serious events (death, myocardial infarction, repeat revascularization procedure) during a mean follow-up period of 20 months (range 5-30 months).

**CONCLUSIONS:** Stenting of LMCA stenoses should be considered a safe and effective alternative to CABG in patients with LVEF >30% and without complicated mid-term follow-up. REF1024

O119 - THE EFFECTS OF PRIOR BETA-BLOCKER THERAPY ON SERUM C-REACTIVE PROTEIN LEVELS BEFORE AND AFTER PERCUTANEOUS-CORONARY INTERVENTIONS

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**OBJECTIVES:** There are no studies in literature on the effect of beta-blockers (BB) on the changes in c-reactive protein (CRP) levels after percutaneous coronary interventions (PCI). On the basis of this we formulated a prospective randomized study to investigate the impact of BB usage on CRP in patients who underwent elective PCI. **METHODS:** This prospective study 300 patients with coronary artery disease were included. The patients were randomized to either metoprolol or to control group at least one week before the planned PCI. Blood samples for CRP were obtained before and after 6th, 24th and 36th hours after the procedure.

**RESULTS:** Of the 300 patients included, 150 received metoprolol 100 mg/day (Mean age 59.0±10.2 years, 106 male) and 150 did not receive any BB (Mean age 59.8±9.8 years, 114 male) and served as the control group. The baseline clinical characteristics of both groups were similar. The basal CRP levels between the two groups were similar in 40.8% of the BB group and 39.6% in the control group had elevated basal CRP levels. In the follow up CRP levels increased above normal in 85% of the BB group and 89.3% in the control group (p>0.05). CRP levels in the BB group at the 6th, 24th and 36th were lower than those in the control group, however this difference did not reach a statistical significance.

**CONCLUSIONS:** Prior BB therapy seems to have no effect on CRP levels before PCI, however it limits the CRP rise after PCI although not at a significant level. REF1745

COMPARISON OF THE PROCEDURAL CHARACTERISTICS OF PATIENTS UNDERGOING DIRECT AND PROVISIONAL STENTING

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**OBJECTIVES:** This study investigates some procedural aspects of 2 stenting strategies: direct and routine stenting and provisional stenting.

**DESIGN & RESULTS:** 32 consecutive patients with occlusive coronary disease were randomized to direct stenting (Group I, n=17) or provisional stenting (Group II, n=15). Provisional stenting was applied in 16 (66%) after PTCA due to suboptimal results (6 patients), dissection (9 patients), and threatened occlusion (3 patients). In 10 patients with provisional stenting, one stent was adequate for revascularization. In the other two patients, more than one stents were used (2 stents in one patient and 3 stents in the other patient). Direct stenting was applied in 2 patients (11%) in Group I. Balloon predilatation was necessary due to failure of stent crossing from the lesion in one patient. In second patient, a stent loss was encountered during stent tracking in a vessel with high tortuosity and balloon predilatation was needed. Total procedural time, fluoro time and utilized radiopaque contrast was lower in patients with direct stenting but the difference was not statistically significant. 20.1±13.1 vs 28.6±12.6 minutes (p=0.08), 10.3±5.5 minutes (p=0.39), 226±123cc vs 277±138cc (p=0.33) respectively.

**CONCLUSIONS:** Although direct stenting is a one-step shorter strategy in comparison with provisional stenting, this does not translate into shorter procedural and fluoro time and does not translate into lesser contrast amounts. In addition, unplanned predilatations may be necessary. Only 13% of patients undergoing direct stenting strategy. REF1204

O120 - THE EFFECTS OF PRIOR BETA-BLOCKER THERAPY ON TROPONIN-I LEVELS AFTER ELECTIVE PERCUTANEOUS CORONARY INTERVENTIONS

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**OBJECTIVES:** Beta-blockers (BB) have been shown to improve survival and reduce the risk of reinfarction in patients after myocardial infarction. Although in some recent studies some beneficial effect has been reported, the cardioprotective effects of BB in patients undergoing percutaneous coronary interventions (PCI) are not well described. The aim of the study was to investigate the impact of BB usage on troponin-I in patients who underwent elective PCI.

**METHODS:** In this prospective study, 287 patients with coronary artery disease were included. The patients were randomized to either BB or to control groups at least one week before the planned PCI. Blood samples for cardiac enzymes were obtained before the procedure and after 6th, 24th and 36th hours after the procedure.

**RESULTS:** Of the 287 patients included, 143 received metoprolol succinate 100 mg/day (age 59.0±10.1 years, 101 male) and 144 did not receive any BB (age 59.6±9.5 years, 109 male) and served as the control group. The baseline clinical characteristics of both groups were similar. The CK-MB and troponin-I levels of both groups were also similar before intervention (p>0.05). We did not observe a significant difference in elevation of troponin-I levels between the two groups after PCI. BB group 17 patients (11.9%), control group 10 patients (6.9%) (p>0.05).

**CONCLUSIONS:** Our study is the first randomized, prospective study conducted to evaluate the effect of BB usage on troponin-I levels after PCI. Prior BB therapy seems to have no cardioprotective effect on troponin-I rise after PCI. REF1763

**O192 - REPLACEMENT OF THORACIC AORTA IN TYPE-B AORTIC DISSECTION: MID-TERM RESULTS**

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**OBJECTIVES:** Surgical treatment in type-B aortic dissection is still controversial. Although medical approach is recommended in unsophisticated patient, surgical intervention is necessary in complicated dissection with uncontrolled pain, visceral malperfusion and high risk of rupture. Endovascular stent-grafts are an alternative approach currently.

**METHODS:** 29 aortic dissection type-B patients were operated between 1996 and 2003. Fourteen patients were in acute period, and 15 of them were chronic. Preoperative evaluations were done with computed tomography and magnetic resonance imaging.

**RESULTS:** Two of 14 acute dissection patients died in postoperative period. One of them was in hemodynamical shock. Monoparesis occurred in one patient, paralysis of the nervus recurrence was in one and diaphragm paralysis in another one. Two patients of 15 chronic dissections were lost after operation.

**CONCLUSIONS:** Risk of reoperation and persistence of the false lumen are commonly seen in chronic type-B dissection, in Marfan syndrome and in patients whom distal anastomosis was done to the both of true and false lumen.

REF1103

**O193 - THE SURGICAL APPROACHES OF TYPE-A AORTIC DISSECTION SECONDARY TO CARDIAC OPERATIONS**

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**OBJECTIVES:** The aim of this study is to investigate factors leading to Type A aortic dissection developed secondary to cardiac surgery and results of surgical treatment.

**METHODS:** Between 1993 and 2003, 14 patients underwent operation due to secondary aortic dissection in Kosuyolu Heart and Research Hospital and their operative data were reviewed retrospectively. There were 12 male and 2 female patients and mean age was 51.4±11.2 years (35-71). Six of the patients were admitted to the hospital with acute dissection and eight with chronic dissection. The mean interval between first operation and the development of dissection was 41,3±26,3 months (2-80).

**RESULTS:** We performed graft interposition to the ascending aorta in 10 case with secondary type A dissection, aortic root replacement with Bentall de Bono procedure in 3 cases and elephant trunk procedure in 1 case. Mortality was 35,71% with 5 patients. 3 of 6 patients with acute dissection and 2 of 7 patients with chronic dissection died during early postoperative period.

**CONCLUSIONS:** Although encountered infrequently, Type A aortic dissection developed secondary to cardiac operations is a clinical situation different from primary aortic dissection with high mortality and morbidity. Surgical indications for reoperations should be defined with great care.

REF220

**O194 - TRANSLUMINAL ENDOAORTIC PROSTHESIS IMPLANTATION FOR ACUTE ONSET AND CHRONIC AORTIC DISSECTIONS**

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**OBJECTIVES:** Transluminal endoaortic prosthesis implantation (TEPI) for aortic dissection is a relatively new procedure. The early and mid term outcomes of TEPI were analyzed and presented.

**METHODS:** From July 2002 to December 2003 fifteen patients (1 woman, 14 men, mean age 56.6 years) with an acute or subacute descending aorta dissections (DAD) underwent TEPI. TEPI was performed in acute DAD with dissection-related complications instead of emergency surgery. Seven chronic dissections were treated to prevent aneurysm enlargement and rupture. Excluder stent grafts (Gore) were used in 10 patients and Endofit (Endomed) in 10 pts.

**RESULTS:** TEPI was technically successful in all cases. One patient with retrograde acute dissection and rupture died (mortality 6.6%). One persistent proximal endoleak required additional open surgery. One patient required additional extension graft placement for second tear in the distal thoracic aorta. In two patients additional PCI was performed on a second session procedure because of severe CAD. No one tear or paraparesis occurred. Non-infectious febrile syndrome was registered in 9 pts. The average ICU stay was 1.3 days, the mean hospital stay 5.7 days. After hospital discharge, no patient died or suffered a rupture during an average follow-up of 11.5 months. CT follow-up showed effective tear sealing and normal true lumen flow in all cases. One open procedure or additional TEPI were performed.

**CONCLUSIONS:** TEPI is a reasonable treatment option for acute or chronic aortic dissection. Close follow-up examination is indicated. Long-term results have to be awaited to evaluate the real effectiveness of this method.

REF1104

**O195 - RESULTS OF SURGERY FOR AORTIC ROOT DILATATION WITH AORTIC VALVE-SPARING OPERATION**

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**OBJECTIVES:** Dilatation of the proximal aorta is known to be associated with valve anomaly as bicuspid valve regurgitation and may be responsible of aortic valve insufficiency even with normal aortic valve. Aortic valve sparing operation may be useful surgical techniques in these cases. We present our results using these procedures.

**METHODS:** From September 2001 to March 2004, 86 patients have been operated using sparing aortic valve procedures. In 61 patients (70%), reimplantation technique was performed. Of them, in 55 cases a new conduit, which mimic the natural Valsalva sinuses, has been used. Remodelling has been performed in 5 cases. In the other patients, reduction of sinotubular junction (STJ) has been done. Extended aorta replacement have been carried out. Bicuspid valve repair has been performed in 14 cases.

**RESULTS:** 30-days morbidity was low and 30-days mortality was 3.7% (3 cases). Freedom from reoperation at a mean follow-up of 29 months, is about 95.8%. At this time, the 93.1% of patients, present trivial or mild aortic regurgitation.

**CONCLUSIONS:** The valve sparing technique is feasible when aortic valve cusps are intact or moderately diseased and also in bicuspid valve. Our early results with the reimplantation technique, using Vascutek Valsalva conduit, are really satisfactory. Long term follow-up is mandatory to know if the new conduit Vascutek Valsalva prevents cusp deterioration. When aortic regurgitation is due to dilatation of the aortic root with normal Valsalva sinuses, Sinotubular Junction Reduction is really useful.

REF1105

**XVI. ANNUAL MEETING**  
**MEDITERRANEAN ASSOCIATION OF CARDIOLOGY AND CARDIAC SURGERY**  
September 26 - 29, 2004

**P412 - IVERMARK SYNDROME WITH COR TRIARIATUM, PRIMUM ASD, CLEFT MITRALE AND PULMONARY STENOSIS**

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**OBJECTIVES:** Ivemark syndrome is a very rare anomaly that includes complex cardiac malformations, splenic agenesis, and abnormalities of other abdominal organs, and accounts for 1-3% of all congenital heart defects. The syndrome carries high mortality rate, and the prognosis depends mainly the degree of the malformation of the heart.

**METHODS:** A 20 years-old female girl with facial dysmorphic features including narrow forehead, helix anomaly, hypotelorism, prominent nasal bridge, and mild mental retardation was admitted to our clinic. The cardiac malformation included cor triatriatum, primum ASD, cleft mitrale and pulmonary stenosis. She also had polysplenia, accessory gall bladder, dilatation of the intrahepatic ducts and the mesenteric artery. During the operation the membrane of the cor triatriatum was resected, primum ASD was closed with a pericardial patch, the cleft was sutured and commissurotomy was performed for the pulmonary stenosis.

**CONCLUSIONS:** Ivemark syndrome is a very rare anomaly, and cor triatriatum with this anomaly hasn't been reported previously. REF1116

**P414 - SURGICAL TREATMENT OF ATRIAL SEPTAL DEFECT IN PATIENTS WERE OVER 40 YEARS OLD**

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**OBJECTIVES:** In this retrospective study we sought the early and moderate term results of surgical treatment of atrial septal defect in patients over 40 years old.

**METHODS:** Between February 2001 and May 2004, 22 patients over 40 years old, underwent atrial septal defect repairment. Average age was 42,9 (42-72), 16 of them were male, 6 was female. All patients had dyspnea and palpitation. Average pulmonary artery systolic pressure was 28 ± 2 mmHg. 2 patients had additional coronary artery disease, 2 of them mixed mitral disease and 2 had residual atrial septal defect.

**RESULTS:** There was no hospital mortality. 19 of them were repaired primarily and 3 with pericardial patch. Coronary artery bypass grafting was performed in 2 patients. 1 patient performed mitral valve replacement and 1 mitral valve repairment. Severe supraventricular tachycardia occurred in 2 patients that revealed by medical treatment. During postoperative period echocardiography was performed to all patients.

**CONCLUSIONS:** Postoperative results are in elderly patients undergoing surgical treatment of atrial septal defect. Since nonsurgical approaches are not safe and effective, atrial septal defect are to be closed surgically in elderly patients. REF1134

**P413 - WOULD IT BE A SOLUTION TO SEVERE LOWER EXTREMITY ISCHEMIA NOT USING THE INTERNAL MAMMARY ARTERY UNDERGOING CORONARY HEART SURGERY PATIENT WITH PERIPHERAL ARTERIAL DISEASE?**

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**OBJECTIVES:** Lower extremity ischemia is a rare condition in patients with peripheral arterial disease undergoing open heart surgery (OHS) without IMA usage. We present a case with IDDM for 13 years that resulted in a lower extremity loss due to compartment syndrome secondary to ischemia who was undergone ACBG with saphenous graft. Causes of the ischemia are evaluated in patients undergone OHS with peripheral arterial disease.

**METHODS:** 57 years-old man was undergone ACBG because of acute coronary syndrome. Angiograph revealed peripheral arterial and three vessels disease. In postoperative period femoro-femoral bypass was planned due to cyanosis and compartment syndrome in the left lower leg. But it wasn't performed because of peroperative fibrotic femoral artery and angiographically not visualization of the superficial and deep femoral artery.

**RESULTS:** Lower extremity ischemia is seen 0.86% after OHS and often associated with IABP usage. Embolic events, vasospasm, perioperative or postoperative hypotension, inotropic or vasopressor usage are important causes. Acute ischemic cases had been reported due to disrapture of IMA - epigastric pathway secondary to conduit usage of IMA. Development of extremity ischemia is unusual, unless IMA is used. In diabetic vasculopathy, hypothermia, inflammatory response of CPB and coagulation abnormalities leading to collateral occlusion may result in ischemia. Also in diabetics, atheroembolic and hypercoagulability theories that results in spontaneous muscle necrosis, or the theory that combines the both theories may be acceptable.

**CONCLUSIONS:** Surgical revascularization should be done urgently in postoperative lower extremity ischemia. Vascular pathologies should be evaluated, fasciotomy should be performed in compartment syndrome. REF1123

**P415 - CAROTID ARTERY STENTING FOR POOR SURGICAL CANDIDATES WITH CONCOMITANT CAROTID, CORONARY AND PERIPHERAL PATHOLOGY**

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**OBJECTIVES:** The optimal treatment of poor surgical candidates with severe carotid stenosis and concomitant coronary and peripheral artery disease is uncertain. This study evaluated the efficacy of carotid artery stenting (CAS) in such patients in preventing stroke, myocardial infarction and death for the 30-day periprocedural period and stroke ipsilateral to the treated carotid artery during 1-year follow-up period.

**METHODS:** From June 2001 to June 2003 we treated 58 severe carotid stenoses and simultaneously 42 coronary and 18 peripheral artery lesions in 52 consecutive patients with mean age 64.3 ± 7.5 years, 28 (53.8%) symptomatic, 49 (94.2%) men. CAS was performed: 12 internal, 1 external, 3 common carotid and one vertebral artery. In 38 cases we performed bilateral CAS and intracoronary stenting (ICS), 38 unilateral CAS and ICS (in 13 of them peripheral stenting accompanied by 2-CAS and CABG, in one- vertebral stenting and CABG, in 3-CAS and peripheral procedure).

**RESULTS:** Carotid stenting was successful in all lesions. The average CA stenosis was 77.2% preprocedure and 9.4% postprocedure. There was no fatal cardiogenic shock (1.9%) and one minor stroke occurred during the procedure; two (3.8%) non-Q MI within 30 days. No ipsilateral strokes or death occurred during the mean follow-up period of 10.9 ± 1.9 to 19) months. At follow-up one patient (1.9%) showed asymptomatic restenosis, treated with re-PTA.

**CONCLUSIONS:** The results suggest a beneficial effect of CAS in elderly patients with high-grade carotid and concomitant coronary and peripheral artery stenoses who are not good surgical candidates. CAS should be considered treatment of choice for the management of these patients. REF1135