hemodynamic conditions. A saccular aneurysm without collateral branch will thrombose quickly. If a collateral branch is present the flow is directed towards this branch leading to shrinkage of the aneurysm. Animal experiments show excellent results. Moreover, as demonstrated in animal and human studies this MFM* preserves the collateral branches allowing the possibility to cover any artery without compromising the flow (renal, digestive arteries, supra aortic vessels…)
Results: 40 peripheral An. (iliac:23, femoral:1, popliteal:5, renal:8, mesenteric:1, carotid: 1, Subclavian : 1) were treated with the MFM* (male:31, mean age 62+/-8 y) (52 stents Ø 5 to 14 mm; length 40 to 120 mm) were implanted to treat these aneurysms, by femoral approach (39 cases), brachial approach (1 case), Technical success in all patients. No complications. All An. thrombosed with diameter reduction in some pts. The thrombosis could take several weeks depending on the importance of collateral branches. 6 month to 36 month follow up will be presented and we will discuss the time needed to achieve exclusion of the An. All the side branches remained patent.
Conclusions: A new concept of stent, the MFM* (without any covering) is developed to treat An. It opens a new approach to treat peripheral An. avoiding most of the complications encountered with current endovascular techniques. The results obtained seem promising. A larger study is ongoing.

TCT-134

Transvenous Phrenic Nerve Stimulation in the Treatment of Central Sleep Apnea in Patients with Reduced Ejection Fraction: A Report from the remedē® System Pilot Study

Piotr Ponikowski[1], Piotr Ponikowski[1], Dariusz Jagielski[1], Olaf Oldenburg[2], Ralph Augostini[3], Steven Krueger[4], Adam Kolodziej[1], Klaus-Jurgen Gutleben[5], Rami Khayat[3], Andrew Merliss[4], Shahrokh Javaheri[6], William Abraham[7]
[1]4th Military Hospital/Medical University, Wroclaw, Poland, [2]9Heart and Diabetes Centre NRW, Ruhr University Bochum, Bad Oeynhausen, Germany, [3]The Ohio State University, Columbus, OH, [4]Bryan LGH Hospital, Lincoln, NE, [5]Heart and Diabetes Centre NRW, Ruhr University Bochum, Bad Oeynhausen, Germany, [6]University of Cincinnati College of Medicine, Cincinnati, OH, [7]The Ohio State Univeristy, Columbus, OH

Background: Central sleep apnea (CSA), usually presenting as Hunter-Cheyne-Stokes Breathing, occurs in approximately 35% of patients with heart failure. Current treatment options for CSA have been limited and focus on mask based therapies and therefore are highly dependent on tolerability and adherence. A novel therapy utilizing phrenic nerve stimulation was developed using the remedē System, a transvenous, fully implantable system that is intended to restore a normal breathing pattern throughout the night. This is the first presentation of the study cohort with reduced ejection fraction (EF) to evaluate of the remedē® System through 3 and 6 months.
Methods: Subjects received a remedē® System consisting of a respistimTM transvenous stimulation lead (in either the left pericardiophrenic or right brachiocephalic vein) and a remedē® pulse generator which was placed in the pectoral area and secured in a normal fashion. Thirty-five subjects with predominantly central sleep apnea were enrolled. Subjects had an ejection fraction $< 40\%$ Subjects (age 65±9 years) and were able to be evaluated at 3 and 6 months of therapy. 62% percent of subjects had a concomitant cardiac device and 86% of subjects had chronic heart failure symptoms. Standard PSG criteria were used for classification of respiratory events and arousals.
Results: Both 3 and 6 month data demonstrate significant improvements in apnea-hypopnea index (AHI), central apnea index, oxygen desaturation index of 4%, arousal index, REM sleep and sleep efficiency. In addition, there were significant improvements in quality of life at 6 months seen both in MLWHF (p=0.0012) and NYHA Classification (p<0.0001).

Changes in Respiratory and Symptoms with 6 months of remede System Therapy

Parameter	Baseline Mean +/- Std Dev	3 Months Mean +/- Std Dev	6 Months Mean +/- Std Dev	Paired T-test (Baseline to 6 Months
Apnea Hypopnea Index (n/hr)	51±15	25±13	24±13	<0.0001
Central Apnea Index (n/hr)	30±15	5±9	4±7	<0.0001
Oxygen Desaturation Index 4% (n/hr)	47±19	24±13	24±13	<0.0001
Arousal Index (n/hour)	39±17	26±11	27±13	0.0002
Sleep Efficiency (%)	68±18	76±16	80±13	0.0002
REM sleep (%)	10±6	16±8	18±6	<0.0001
MLWHFQ	33±23	NA	24±21	0.0012
Epworth Sleepiness Scale	7.4±3.5	NA	4.7±2.9	<0.0001

Conclusions: Treatment of CSA with the remedē® System significantly improves both respiratory and sleep parameters as well as symptoms of heart failure, in patients with reduced EF. These favorable changes in pathophysiological consequences of sleep apnea may lead to improvements in outcomes in patients with heart failure.

TCT-135

Antegrade Transapical Branched Aortic Arch Endograft – a Feasibility Study in Pigs

Sabine Wipper[1], Christina Lohrenz[1], Oliver Ahlbrecht[1], Mohamad Akkra[1], Sebastian W. Carpenter[1], Nikolaos Tsilimparis[1], Eike S. Debus[1], Christian Detter[1], Axel Larena-Avellaneda[1], Tilo Kölbel[1]
[1]University Heart Center Hamburg, Hamburg, Germany

Background: To describe the technique and proof the concept of a complete transapical deployment of a single sidebranch arch endograft in a porcine model.
Methods: Eight domestic pigs were operated with antegrade transapical delivery of a single-sidebranch arch endograft including a mating stentgraft to the innominate artery. Technical feasibility, operating time, radiation parameters and hemodynamic changes were studied according to standardized protocol during baseline (T0), after establishing of the transapical access and through-and-through wire (T1) and after stent-graft deployment (T2). Myocardial and cerebral perfusion were assessed by fluorescent-microspheres (FM) and transit-time-flow measurement (TTFM).
Results: Transapical access, introduction and deployment of the endograft, sidebranch catheterization and deployment of the mating stent-graft were feasible in 6 of the 8 animals with unimpeded perfusion of the innominate artery. One animal was lost during transapical access, one during sire-branch catheterization. The mean operating and fluoroscopy times were 157±47min and 15.9±3.2min. During introduction and deployment of the stent-graft transient aortic valve insufficiency occurred in all animals. Hemodynamic stability recovered within ten minutes after retrieval of the delivery system in all animals. The innominate artery was patent with unchanged TTFM-flow measurements throughout the procedure. FM evaluation revealed stable myocardial and cerebral perfusion.
Conclusions: Antegrade transapical access to the aortic arch for implantation of a single sidebranch arch endograft is feasible in a porcine model with reversible impact on hemodynamic measures during deployment. Transapical access allows for deployment of a complex endograft through a single large bore access-site in a porcine model. It might be a future treatment option for selective patients.

TCT-136

Results of a Novel Interatrial Shunt Therapy for Heart Failure and Preserved or Mildly Reduced Ejection Fraction

Finn Gustafsson[1], Filip Malek[2], Petr Neuzil[3], Vivek Reddy[4], Lars Sondergaard[1], Tony Walton[5], David Kaye[6]
[1]Rigshospitalet, Copenhagen, Denmark, [2]Na Holmoce Hospital, Prague, CZ, [3]Nemocnice na Homolce, Prague, Czech Republic, [4]Mount Sinai School of Medicine, New York, USA, [5]Alfred Hospital, Melbourne, Victoria, [6]Baker IDI Heart and Diabetes Institute, Melbourne, Australia

Background: Diastolic dysfunction develops in most cardiac conditions, and leads to elevation of left ventricular filling pressures and heart failure. We report the initial experience with a novel device intended to lower left atrial pressure by creating a small permanent atrial septal shunt. The objective of the study was to evaluate safety and potential benefits of the Intra Atrial Shunt Device (IASD™) System in patients with symptomatic heart failure with preserved or mildly reduced ejection fraction, despite appropriate medical management.
Methods: The first 6 patients in a prospective multicenter feasibility study were enrolled under an approved protocol. Key inclusion criteria were: EF > 45%; PCWP at rest ≥ 15 or exercise ≥ 25mm Hg; or ≥ 1 hospitalization for heart failure within prior 12 months; or persistent NYHA Class III/IV for at least 3 months.
Results: Mean age, EF, and NYHA Class were 75 Y, 57 %, and III, respectively. Most patients had multiple comorbidities. The IASD Device was successfully implanted in each patient using standard interventional techniques and guidance. One SAE (complete heart block) occurred within 30 days, and resolved (pacemaker). The SAE was not related to the procedure or device. At 30 days, PCWP was reduced, and at 30 days clinical symptoms had improved in 5 of 6 patients. Additional follow-up data will be presented.

Parameter	Baseline	Follow-up (d)
m PCWP (mmHg)	18.8	14.3 (30)
(n=5)		
m RAP (mmHg)	11.5	12 (30)
n=4		
RVSP (mmHg)	49.5	52.5 (30)
n=4		
6 MWD (m)	318.5	343.3 (90)
n=4		
NT-Pro-BNP (pmol/L)	294.4	237 (90)
n=4		
MLWHF score	41.8	32.3 (90)
n=4		

Conclusions: This initial data demonstrates that the shunt device can be safely implanted and early clinical improvement can be obtained in patients with heart failure and preserved or mildly reduced ejection fraction. Longer term follow-up is warranted.

Antiplatelets and Antithrombins

Moscone West, 1st Floor

Tuesday, October 29, 2013, 3:30 PM–5:30 PM

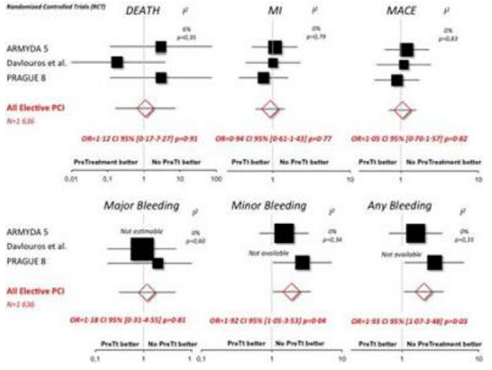
Abstract nos: 137-166

TCT-137

No benefit of Clopidogrel Pretreatment in stable patients undergoing elective PCI

Anne Bellemain-Appaix[1], Stephen A. O'Connor[2], Johanne Silvain[3], Michel Cucherat[4], Jean-philippe collet[5], Francois Bernasconi[6], Gilles Montalescot[7]
[1]CH La Fontonne Antibes, Antibes, France, [2]Pitié Salpétrière Hospital, Paris, France, [3]Pitie Salpetriere, Paris, France, [4]Chu Lyon, Lyon, MS, [5]Pitié Sapetriere, Paris, France, [6]CH La Fontonne Antibes, Antibes, MS, [7]N/A, Paris, France

Background: Although Clopidogrel pretreatment is recommended (class I-C) for stable CAD patients scheduled for elective PCI, the benefit of this strategy compared to an administration at the time of PCI has not been shown on hard clinical outcome. We performed a systematic review and meta-analysis of all RCTs to evaluate the impact of clopidogrel pretreatment on mortality and major bleeding after elective PCI for stable CAD, as compared with no pretreatment. An additional metaanalysis was done on registries.
Methods: We included studies on elective PCI from MEDLINE, EMBASE, CCTR databases that reported clinical data on mortality and major bleeding. A random-effect model was applied. Pretreatment was defined as the administration of clopidogrel before PCI. The primary efficacy and safety endpoints were all-cause mortality and major bleeding, respectively. Secondary endpoints included MACE, MI, Stroke, UVR, Stent Thrombosis (ST), minor and any bleeding.
Results: Of the 392 titles identified, 6 (3 RCTs and 3 observational) met the inclusion criteria, published between Aug-2004 and Dec-2012. Of 13628 patients, 1636 were from RCTs. 55% underwent PCI. Results from the analysis of RCTs are shown in Figure I. ST, stroke and UVR were not different between groups. In the analysis of observational data, there was no difference between groups for all cause death, MI and ST, nor in bleeding. Only MACE and UVR were decreased.



Conclusions: Clopidogrel pretreatment is not associated with a reduction of mortality, MACE or ischemic endpoints in stable CAD scheduled for elective PCI, but with an excess of minor and any bleeding.

TCT-138

Clopidogrel Pretreatment in Non ST Elevation Acute Coronary Syndroms: no effect on mortality, decrease in ischemic endpoints at a price of more major bleeding.

Anne Bellemain-Appaix[1], Stephen A. O'Connor[2], Johanne Silvain[3], Michel Cucherat[4], Jean-Philippe Collet[5], Francois Bernasconi[6], Gilles Montalescot[7]
[1]CH La Fontonne Antibes, Antibes, France, [2]Pitié Salpétrière Hospital, Paris, France, [3]Pitie Salpetriere, Paris, France, [4]Chu Lyon, Lyon, MS, [5]Pitié Sapetriere, Paris, France, [6]CH La Fontonne Antibes, Antibes, MS, [7]Pitié-Salpêtrière University Hospital, Paris, France

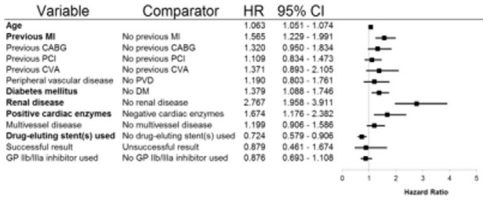
Background: Clopidogrel pretreatment is recommended for the treatment of NSTEACS patients (class I-B), at a time when the final revascularization strategy is not known. A previous meta-analysis focused on randomized trials suggested a tiny benefit in patients undergoing PCI. We performed a new meta-analysis of not only RCTs but also registries to assess the impact of clopidogrel pretreatment in NSTEACS patients. We evaluated the global effect independently of revascularization ("All" analysis) and in patients undergoing PCI ("PCI" analysis).
Methods: We included studies on NSTEACS from MEDLINE, EMBASE, CCT and Biomedcentral. A random-effect model was applied. Pretreatment was defined as the administration of clopidogrel before PCI or catheterization. Primary efficacy and safety endpoints were all-cause mortality and major bleeding respectively, at longest follow up available. Secondary endpoints included Major Adverse Cardiac Events (MACE), Stroke, Stent Thrombosis, UVR.
Results: Of the 393 titles identified, 6 articles (3 RCTs and 3 observational studies) met the inclusion criteria, published between August 2004 and January 2013, including 28 350 patients, in those 14 678 from RCTs. 52% underwent PCI. Among NSTEACS patients, clopidogrel pretreatment was not associated with a lower risk of mortality ("all": OR=0,85, 95%CI(0,66-1,08), p=0,18 or "PCI": OR=0,81, 95% CI(0,58-1,13), p=0,22). When considering all of studies (RCTs and registries) together, the reduction in Ischemic endpoints (OR=0,81, 95%CI(0,7-0,94), p=0,006) is counterbalanced by an increase in major bleeding (OR=1,28, 95%CI(1,12-1,46), p=0,0002). The reduction in ischemic endpoints is no more significant in the "PCI" analysis (OR=0,82, 95%CI(0,65-1,03), p=0,10) while there is still an excess of major bleeding in these patients (OR=1,2, 95%CI(1-1,44), p=0,048). ST, stroke and UVR were not different between groups (pretreatment vs. no) in both analyses.
Conclusions: Clopidogrel pretreatment is not associated with a reduction of mortality in NSTEACS patients; the reduction of MACE is counterbalanced by major bleeding for "all" and "PCI" patients. The concept of systematic pretreatment in NSTE-ACS patients needs reappraisal in the contemporary era.

TCT-139

The effect of glycoprotein IIb/IIIa inhibitors on mortality and MACE following PCI for NSTEMI/UA

James P. Howard[1], Daniel A. Jones[1], Krishnaraj Rathod[1], Ajay Jain[1], Charles Knight[1], Anthony Mathur[1], Andrew Wragg[1]
[1]Barts Health NHS Trust, London, United Kingdom

Background: Meta-analyses of PCI in NSTEMI/UA have shown GPIIbIIIa inhibitors to be associated with a reduction in major adverse cardiac events at 30 days. However, many of the trials were carried out before the routine use P2Y12 inhibitors which act up-stream of GPIIbIIIa mediated platelet aggregation. Studies performed in the clopidogrel yield conflicting results and registry data indicates that these agents are less safe than trials would indicate.
Methods: We undertook an observational study at an interventional cardiology center involving 5,227 patients undergoing PCI for NSTEMI/UA and receiving clopidogrel and aspirin. GPIIbIIIa use was at the discretion of the operator. Primary outcome was all cause mortality assessed at a median follow up of 4.6 years (IQR 3.0 - 6.2 years).
Results: 43.6% of patients were treated with GP IIb/IIIa inhibitors. The patients were younger, more likely to be male, and have fewer comorbidities including previous MI, CKD and PVD. They were less likely to suffer multivessel disease and more likely to have a successful angiographic result. Kaplan-Meier analysis showed GP IIbIIIa inhibitor use was associated with improved survival (p<0.001) and reduced MACE (p=0.011), but increased bleeding (p=0.001). On multivariate analysis the benefits were lost for both survival (HR 0.876; 95% CI 0.693 – 1.108; p=0.501) and MACE (HR 1.036; 95% CI 0.883 – 1.216).



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