List of International & National Presentations & Publications

Hetal Shah

L.M. College of Pharmacy, Ahmedabad, India
❖ PRESENTATIONS AT INTERNATIONAL & NATIONAL CONFERENCES


*J Am Coll Cardiol 2006; 47: pg 50B*


*J Am Coll Cardiol 2006; 47: pg 310A*


*J Am Coll Cardiol 2006; 47: pg 370A*
*J Am Coll Cardiol* 2006; 47: pg 17B

*Eur Heart J* 2006; 27 (Abstract Supplement): pg 485

*Eur Heart J* 2006; 27 (Abstract Supplement): pg 949

*Eur Heart J* 2006; 27 (Abstract Supplement): pg 949

*Eur Heart J* 2006; 27 (Abstract Supplement): pg 202

*Eur Heart J* 2006; 27 (Abstract Supplement): pg 202

*Eur Heart J* 2006; 27 (Abstract Supplement): pg 344


❖ RESEARCH PAPERS


❖ REVIEW ARTICLES & BOOK CHAPTERS


atherectomy well, without bradycardia, and thus pacing was not required. The second angioplasty wire was removed and the stent was treated with stent implantation with excellent acute results.

Conclusions: Cablewire pacing is safe and feasible during rotational atherectomy of the left coronary arteries, precluding the need for placement of a temporary transvenous catheter.

A-22

BENEFICIAL EFFECTS OF DISTAL PROTECTION DEVICE IN REDUCING THE USE OF INTRACORONARY VASODILATORS AND GLYCOPROTEIN IB/IIA RECEPTOR ANTAGONISTS DURING PERCUTANEOUS CORONARY INTERVENTIONS

KEYUR PARIKH, MILAN CHAG, URMIL SHAH, HEMANG BAXI, ANISH CHANDRAKAR, AJAY NAIK, HETAL SHAH, I.K. GOYAL, Sterling Hospital, India, Ahmadabad, India, Care Cardiology Consultants, Ahmedabad, India

Objectives: Distal embolization with no or slow reflow occurs in approximately 15% of the patients with acute coronary syndromes (ACS) undergoing percutaneous interventions (PCI) with poor outcome. Early results using distal balloon protection (DBP) system in ACS appear promising. This investigation was to evaluate the usefulness of DBP (Guard wire-plug, Medtronic) during primary, rescue or delayed angioplasty after acute myocardial infarction (AMI) or in ACS patients and usage of concomitant intracoronary vasodilator drugs or GPIb/IIa antagonists with or without DBP.

Methods: It was a prospective trial based on stratic randomization of 105 patients of AMI or ACS scheduled for an angiography at Sterling Hospital within 24 hours after the onset of symptoms, were recommended for PCI with or without the help of DBP. The patients were divided into two groups: 1) PCI done with the use of DBP (52 patients) 2) PCI done without the use of DBP (51 patients). At the end of the study we evaluated the need of GPIb/IIa antagonists and intracoronary (IC) vasodilators and TIMI/TMP II flow during the procedure.

Results: There was a significant improvement in TIMI (0.74 ± 0.19 to 2.91 ± 0.05, p < 0.0001) and TMP (0.64 ± 0.17 to 2.72 ± 0.09, p < 0.0001) in patients where DBP was used. Patients without DBP also showed a significant improvement in TIMI (1.65 ± 0.17 to 2.91 ± 0.05, p < 0.0001) and TMP (0.64 ± 0.17 to 2.72 ± 0.09, p < 0.0001) but to a lesser extent.

Conclusions: Use of DBP is beneficial in high-risk patients with or without the use of GPIb/IIa antagonists and IC vasodilators to optimize to TIMI III/TMP I flow. In patients where DBP was used only 7.7% of the patients required administration of IC vasodilators to further optimize TIMI III/TMP I flow. In patients with DBP only 29% required the additional use of GPIb/IIa receptor antagonists (eptifibatide in 11.5%, abciximab in 8% and tirofiban in 9.5%), as compared to 100% usage in patients where DBP was not used (51% eptifibatide, 33% abciximab and 16% tirofiban).

A-23

PERCUTANEOUS SUBCLAVIAN ARTERY CLOSURE - A UNIQUE USE OF PERCLOSE

MOHAMMED HABEEB AHMED, IMMED SADIQ, GEORGIOS I. PAPADOANNOU, FRANCIS J KIERNAN, RAYMOND G MCKAY, CHURCHILL PRAKASH, University of Connecticut, School of Medicine/Harford Hospital, Harford, Connecticut, Harford Hospital, Harford, Connecticut

Objective: Central venous access is an integral part of intensive care unit (ICU) management of patients. The subclavian artery being a non-compressible artery, if inadvertently punctured during central venous catheter placement has a potential for serious complications including pseudoaneurysm, arteriovenous fistula and hemorrhage. Surgical closure is complex and associated with morbidity involving osteotomy of the middle third of the clavicle. We report a case of percutaneous subclavian artery puncture closure performed with an arterial closure device.

Methods: A 75 year old female with past medical history of hypertension, dyslipidemia and obesity was admitted with chest pain associated with atrial arrhythmias. A day later the developed multiple 5 – 10 second pauses followed by electrocardiographic evidence of anterior wall injury and biomarker positive near ST elevation myocardial infarction (STEMI). Cardiac catheterization revealed diffuse triple vessel disease. Multiple periods of asystole accompanied by rapid atrial fibrillation and atrial tachycardia were noted. A temporary transvenous pacemaker inserted via the femoral route was inadvertently pulled out by the patient. Long pauses of asystole lasting 5-10 seconds were noted. Bedside central venous access for temporary pacemaker wire placement was attempted. During left subclavian vein access, the left subclavian artery was punctured and a sheath was placed in it. Surgical consultation was obtained for permanent pacemaker insertion and possible thoracotomy. Patient was taken to the operating room where the sheath was removed and the subclavian artery puncture closed percutaneously. Under fluoroscopy a guidewire was placed into the descending aorta. Contrast injections were used to confirm vessel size and position. A 6 Fr PERCLOSE device was advanced over the guidewire to the level of the proximal aorta. The guidewire was removed and the device was further advanced to obtain arterial marking. The foot was deployed and pulled back to resistance. The sutures were deployed and advanced to the arteriotomy site in the usual fashion. No external bleeding was noted. Brachial, radial and ulnar pulses were palpable. Chest fluoroscopy revealed no evidence of aortic/an pulmonary emauxma or pneumothorax. At 24 hours the site was stable with no evidence of any effusion. Hematoma and X-ray chest was normal.

Results: Discussion: Inadvertent arterial system access with central catheters can be associated with significant morbidity and mortality. Specifically in cases of subclavian artery puncture, being a non-compressible artery, the treatment options are limited. Surgery can be complicated and risky.

Conclusions: We present this case outlining the use of PERCLOSE as a simple, easy to use maneuver in closing the subclavian artery punctures. Review of literature has only two similar cases reported.

A-24

TRANSRADIAL CATHETERIZATION WITH ENDOCARDIAL BIOPSY: EARLY EXPERIENCE WITH A PROMISING TECHNIQUE

CAREY D MOYER, MARK KOZAK, STEVEN E ETTINGER, CHARLES E CHAMBERS, PATRICK H MCNULTY, IAN C GILCHRIST, Pennsylvania State University, Hershey, Pennsylvania

Objective: Transradial cardiac catheterization is perceived to be limited to arterial procedures. During the veins of the forearms, we have converted many of our arterial/venous cardiac procedures to a transradial approach.

Methods: After consent, patients underwent bilateral heart catheterizations including cardiac biopsy. A 7F long introducer sheath was placed via a large median forearm veins. Right heart catheterization was performed via a 120 cm balloon tipped catheter thru this introducer. Echocardiographic biopsy was performed thru the same forearm vein with a 7F Argon biotome, 2.4 mm X 105 cm biopsy forcep was advanced to the intraventricular septum for multiple biopsies. Coronary angiography/left heart catheterization was performed using standard transradial approach.

Results: Systemic heparin was not used. The long sheath was then removed and occlusive dressing placed at the venous entry site while arterial heparinization was obtained with a standard femoral}

Conclusions: Transradial cardiac catheterization is perceived to be limited to arterial procedures. During the veins of the forearms, we have converted many of our arterial/venous cardiac procedures to a transradial approach. We now describe this practice as it is extended to endocardial biopsies.

Methods: After consent, patients underwent bilateral heart catheterizations including cardiac biopsy. A 7F long introducer sheath was placed via a large median forearm veins. Right heart catheterization was performed via a 120 cm balloon tipped catheter thru this introducer. Echocardiographic biopsy was performed via the same forearm vein with a 7F Argon biotome, 2.4 mm X 105 cm biopsy forcep was advanced to the intraventricular septum for multiple biopsies. Coronary angiography/left heart catheterization was performed using standard transradial approach. Systemic heparin was not used. The long sheath was then removed and occlusive dressing placed at the venous entry site while arterial heparinization was obtained with a standard femoral}

Results: All patients (N=8) were male with a mean age 55 years undergoing post-cardiac transplantation management. Duration of all of the procedures, including left and right heart catheterization and biopsy, was 73.6 [range 40-95] minutes. All tolerated the procedure well with no procedural complications including no episodes of venous or arterial bleeding, bruising, vascular compromise or phlebitis. One patient had the procedure repeated a year later from the same site without incident.
OCCLUSIONS (CTOS): THE RESULTS OF A MULTICENTER REGISTRY

RICHARD W. HELSER, ROMAS J. KIRVATIUS, JOHN F. ROBB, KENNETH W. BARAN, ROBERT M. KIPPERMAN, EMERSON C. PERIN, TONY S. DAS, PAUL S. GILMORE, RONALD WAKSMAN, DONALD W. LEE, MAGEH G. GHALLA, DONALD S. HAIM, Saint Joseph's Hospital and Medical Center, Phoenix, Arizona; Arizona Heart Institute, Phoenix, Arizona; Tattoo Northside Hospital Medical Center, Lebanon, New Hampshire; United's John F. Kennedy Medical Center, St. Paul, Minnesota; Oklahoma Heart Hospital, Oklahoma City, Oklahoma; Teen Heart Institute, Houston, Texas; Presbyterian Hospital of Dallas, Dallas, Texas; University of Florida for Jacksonville, Florida; Georgia University Hospital, Washington University of Columbia, Glendale Memorial Hospital, Glendale, California; Mercy Medical Center, Des Moines, Iowa; Beth Israel Deaconess Medical Center, Boston, Massachusetts.

Objective: We report our multi-center experience in the comparison of the safety and efficacy of OCR with either guide wire systems (GWS) or guided radiofrequency energy (GRE) to traverse CTOS in native coronary arteries after failed attempts with a conventional guide wire. (Safe-Steer™ and Safe-Steer™ device respectively, IntraVascular Therapeutics, Inc., Carlsbad, California)

Methods: When the CTO was crossed using OCR, routine angiography with or without stents were performed. A total of 116 patients in 21 sites in native arteries were treated with OCR + GRE and followed for 30 days. 145 patients received OCR + GWS. Efficiency was determined by achievement of distal lumen gain wire position. Safety was assessed by major adverse coronary events (MACE) defined as death, myocardial infarction, target vessel revascularization, and clinical performance. The mean age and male sex distribution was 59 years and 77% for OCR + GWS and 62 years and 80% for OCR + GRE. Lesion length was 29 ± 12 mm for OCR + GWS and 27 ± 10 mm for OCR + GRE.

Results: See Table 1 for results.

Conclusions: OCR combined with GRE or GWS is both efficacious and safe in the treatment of CTOS that fail conventional guide wire therapy. OCR improves successful crossing of such lesions. Success rates were somewhat higher when OCR is combined with GRE than with GWS, however MACE is higher in OCR + GRE than with OCR + GWS.

<table>
<thead>
<tr>
<th>Parameters</th>
<th>(mins ± SEM)</th>
<th>(mins ± SEM)</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Time for lesion crossing</td>
<td>with OCR</td>
<td>without OCR</td>
<td></td>
</tr>
<tr>
<td>Guardwire (n=20)</td>
<td>2.74 ± 0.93</td>
<td>2.83 ± 0.55</td>
<td>0.934</td>
</tr>
<tr>
<td>Guardwire+DPD(n=20)</td>
<td>2.64 ± 0.69</td>
<td>2.83 ± 0.55</td>
<td>0.934</td>
</tr>
</tbody>
</table>

C-17

PREVENTORS OF RED BLOOD CELL TRANSFUSION FOLLOWING PERCUTANEOUS CORONARY INTERVENTION


Objective: A significant percentage of patients require transfusion of red blood cells (RBC) for anemia and bleeding following percutaneous coronary intervention (PCI), but the predictors of this adverse event have not been previously described.

Methods: RBC transfusion was performed in 5.2% of 1398 patients undergoing 1527 coronary interventions performed between 12/1/02 and 11/30/05. The study group consisted of 70.6% males and 29.4% females with a mean age of 64.1±12.8 years. Cardiovascular risk factors included diabetes in 29.2%, hypercholesterolemia in 55.2%, smoking in 79.0%, and family history in 43.3%. Co-morbidities included history of renal insufficiency in 10.9%, peri-procedural vascular disease in 10.9%, and malignancy in 14.0%. Active infection in 8.2% and anticoagulation with coumadin in 3.5%.

Indications for transfusion included stable angina in 18.3%, unstable angina in 25.6%, non-ST-elevation MI in 22.3% and ST-elevation MI in 15.6%. Pre-intervention anemia (defined as HCT < 39 in males and < 36 in females) was present in 45.4% (25.7%). Coronary stenting was performed in 92.0% with adjunctive use of unfractionated heparin in 70.9%, low molecular weight heparin in 8.3%, direct thrombin inhibitors in 16.6%, Glycoprotein Ilb/IIIa inhibitors in 63.9%, and pre-hospitalization thrombolytics in 6.4%. Cross closure was achieved with the use of Angioseal or Perclose devices in 91.3%. Hematoma post-intervention were noted in 3.6%, reobturation hematomas in 0.4%, and surgical repair of vascular complications was required in 0.3%.

Results: Univariate predictors of transfusion (p < 0.01) included older age, female sex, renal insufficiency, peripheral vascular disease, hemorrhagic disease, malignancy, active infection, anticoagulation with coumadin, steroid use, unfractionated heparin use, congestive heart failure, diabetes, cardiogenic shock, emergency procedures, and large hematomas > 6 cm. Multivariate predictors of transfusion (OR, CI) included older age (1.04, 1.001-1.058), female sex (3.65, 1.53-8.7), hemorrhagic disease and angiographic parameters, the total time involved in various steps of the procedure were recorded TIMI flow and TMP grade were also recorded.

Results: The total procedural time in PCI using the Guardwire Plus was less as compared to PCI without the device (p=0.004). The time required after DPD wire crossing to reach optimal TIMI flow, as well as the time after PTCA balloon inflation to reach optimal TIMI flow was significantly less with use of Guardwire Plus (p<0.01). Use of Guardwire also showed a significant reduction in the incidence of no-reflow (p<0.01) as well as lesser use of intracoronary vasodilators and GP IIb/IIIa receptor inhibitors. Final TIMI III flow and TMP III grade was significantly greater with use of Guardwire Plus as compared to PCI without its use (p<0.01).

Conclusions: The study shows that the use of PercuSurge Guardwire Plus with experienced operators in fact reduces the total procedural time in addition with benefit of better and faster optimal TIMI flow and TMP grade in primary/rescue PCI.

C-16

REVASCULARIZATION IN ACUTE MYOCARDIAL INFARCTION USING PERCUTANEOUS DISTAL PROTECTION (RAPID)

KEYUR H. PARikh, HETAL SHAH, MILAN CHag, URMIL SHAH, HEMANG BAXI, ANISH CHANDRANA, AJAY NAIR, R.K. OYOJUL: Sterling Hospital, Ahmedabad, India; Sterling Hospital, India, Ahmedabad, India

Objective: In spite of evidence of efficacy of the Perceome Guardwire Plus Temporary Occlusion and Aspiration System-Medtronic/Guardwire Plus/Distal Protection Device-DPD) in primary/ rescue PCI (Percutaneous Coronary Intervention) in AMI (acute myocardial infarction) to overcome distal embolization leading to distal microocclusion, the system is underscored due to the misconceptions that it is complicated and time consuming. Since our center has experience of over 90 cases of Guardwire Plus in PCI in AMI, we undertook a prospective study to evaluate the total procedural time involved in PCI and the efficacy of the device to improve TIMI flow and FMP, with or without the use Guardwire Plus.

Methods: 40 prospective AMI patients having angiographically thrombus-lesions and undergoing PCI with or without the use of Guardwire Plus at the operator's discretion were enrolled in the study on random basis. Along with the conventional demographic characteristics and angiographic parameters, the total time involved in various steps of the procedures were recorded TIMI flow and TMP grade were also recorded.

Results: The total procedural time in PCI using the Guardwire Plus was less as compared to PCI without the device (p=0.004). The time required after DPD wire crossing to reach optimal TIMI flow, as well as the time after PTCA balloon inflation to reach optimal TIMI flow was significantly less with use of Guardwire Plus (p<0.01). Use of Guardwire also showed a significant reduction in the incidence of no-reflow (p<0.01) as well as lesser use of intracoronary vasodilators and GP IIb/IIIa receptor inhibitors. Final TIMI III flow and TMP III grade was significantly greater with use of Guardwire Plus as compared to PCI without its use (p<0.01).

Conclusions: The study shows that the use of PercuSurge Guardwire Plus with experienced operators in fact reduces the total procedural time in addition with benefit of better and faster optimal TIMI flow and TMP grade in primary/rescue PCI.
The RR adjusted for age and conventional risk factors, resulted 4.85 (95% CI 3.55-6.33) When added to age and other risk factors, the presence of PMI contributed significantly to model predicting cardiovascular events (Likelihood Ratio 9.10, p<0.003).

Conclusions In postmenopausal women, knowledge of PMI provides incremental information regarding the risk of developing cardiovascular events in addition to that defined by conventional cardiovascular risk assessment.

2827-71 First in Human Implanted Device in Pulmonary Artery Using Acoustic Telemetry Based on Noninvasive Ultrasound Activation and Communication

Keyur H Parikh, Hadi G Shah, Mian C Cheg, Uma G Shah, Hemang A Baxi, Ansh H Chardavai, Ajay M Niek, Joyal H Shih, Joseph Rozmanian, The Heart Care Clinic Ahmedabad, India, Remon Medical Technologies Ltd, Israel

Background The left ventricular end diastolic pressure (LVEDP) is a critical hemodynamic parameter, which is the basis for decomposition of events in Congestive Heart Failure (CHF). The LVEDP correlates with the Pulmonary Artery diastolic pressure (PAPD) RemonCHIP Implant (Remon technologies,Israel) measures the pressure waveform in the pulmonary artery (PA) based on non-invasive acoustic activation and communication, as frequently as necessary and non-invasively. The objective of the study was to determine safety and functionality of the RemonCHIP(R) and its ability to accurately measure PAPD in CHF patients.

Methods 10 NYHA class III/IV patients were included in the first in Man study Usual PA Homodyne measurement was performed using a Miller Catheter The RemonCHIP implant (3mm x3mm x16mm), made of Titanium case, encapsulating an energy exchanger, control chip, pressure sensor and energy reservoir with ultrasound capabilities was percutaneously implanted, using a delivery system (internal jugular approach) in the Right Main PA. A self-expandable nitinol anchor for positioning of the implant is attached to the implant. When interrogated by the desktop system, through a heart line transducer, in contact with the chest. RI is activated. The energy exchanger (pulsed electromagnetic transducer) converts applied external ultrasound pressure to electrical energy. Once energized, the control chip interrogates the pressure sensor and ultrasonically transmits the digital reading to an external receiver.

Results The RemonCHIP implant was deployed in 10 patients. By placing the transducer on the patient's chest, high quality accurate (compared to Miller catheter placed simultaneously in the PA) pressure waveforms were obtained using the Remonchip(R) at 3 months of follow-up, there has been no adverse events.

Conclusions Continuous noninvasive monitoring of PA pressure by an implantable device may improve management and prognosis of CHF. As opposed to the Chronic Implantable Hemodynamic Monitor, which measures the right ventricular pressure and derives an estimated PAPD by an algorithm, the RemonCHIP Implant measures the PAPD directly and non-invasively from its location in the Right PA.

2927 Acute Myocardial Infarction: Achieving the Best Results

POSTER SESSION

Tuesday, March 14, 2006, 12:30 p.m.-4:00 p.m.
Georgia World Congress Center, Hall B1
Presentation Hour: 1:30 p.m.-2:30 p.m.

2927-29 Early and Late Survival in Patients with Shock Due to Right Ventricular Versus Left Ventricular Infarction Following Primary Percutaneous Coronary Intervention for ST Elevation Myocardial Infarction

Bruce Brodsky, Thomas Stockley, Charles Hansen, Barbara Brachial, Mark Pulsipher, William Downey, Lauderdale Cardiovascular Research Foundation and Masoni Cone Heart and Vascular Center, Greensboro, NC

Background Postmortem studies have shown similarly high in-hospital mortality in patients with cardiogenic shock due to RV and LV infarction, but there is little data comparing survival using primary PCI.

Methods Consecutive pts with STEMI treated with primary PCI (n=2498) were prospectively enrolled in a registry from 1984-2005 and followed for 6.5 years Cardiogenic shock was defined by conventional cardiovascular risk assessment and its ability to accurately measure PADP in CHF patients.

Results Of 192 patients with RV shock, 50% were men, AMI location was anterior in 45% of cases. One-year follow-up data will be available in November 2005, and final results, including the angiographic sub-study, will be presented at the meeting.

2927-74 Final Results of the Typhoon Study A Multicenter Randomized Trial Comparing the Use of Sirolimus-Eluting Stents to Bare Metal Stents in Primary Angioplasty for Acute Myocardial Infarction

Charles Blouin, Roland Moreau, Emmanuel Tzavari, Kevin Beatt, Eric Baroody, Didier Cabez, Michel Stabile, Iliya Markov, Andras Engeli, Massimo Marigliano, Ana Ceberan, Christopher Bode, AP-HF, Paris, France, Universite de Lille, Freiburg, Germany

Background Sirolimus-Eluting Stents (SES) have been proven to reduce restenosis and re-intervention compared to bare metal stents (BMS). However, their safety and efficacy in acute myocardial infarction (AMI) have not yet been demonstrated in a large randomized trial with clinical end-points.

Methods TYPHOON (trial to Assess the Use of the Cypher® stent in Acute Myocardial Infarction Treated with Balloon Angioplasty) is a multi-center randomized single-blind trial comparing SES to BMS in primary PTCA for AMI. Patients were included if they presented with AMI (defined as prolonged chest pain with ST segment elevation) of less than 12 hours duration and a culprit lesion in a native coronary artery suitable for stenting Exclusion criteria were Prior myocardial infarction, Killip class > 2, bifurcation disease with > 50% stenosis proximal or distal to the artery requiring revascularization, severe multi-vessel disease of the non-culprit artery requiring CABG. Patients were randomized after the culprit lesion was visualized to receive either SES (Cyphur™ or Cypher Select™) or BMS. The primary end-point was target vessel failure at one year post-procedure defined as target vessel revascularization, myocardial infarction or cardiac death that could not be clearly attributed to a vessel other than the target vessel. Secondary end-points included in-hospital, 1, 6, and 12 month major adverse cardiac events. Based on sample size estimation, enrollment of 700 patients was planned. An interim follow-up angiographic sub-study was programmed in 200 patients from selected centers.

Results Between October 2003 and September 2004, 718 patients from 48 centers were enrolled. Mean age was 59 ± 12 years, 78% were men. AMI location was anterior in 45% of cases. One-year follow-up data will be available in November 2005, and final results, including the angiographic sub-study, will be presented at the meeting.

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Effect of Metoprolol CR/XL on Pulmonary Artery Pressure in Patients With Heart Failure Treated Using First in Human Implantable Device Responding to Ultrasonic Signal


Background: Beta blockers (BB) do improve morbidity and mortality in patients with Congestive Heart Failure (CHF). There is limited information on Left Ventricular End Diastolic Pressure (LVEDP), Pulmonary Artery pressure (PAP) including PA Diastolic Pressure (PADP) after the use of BB in ambulatory patients with CHF. Frequent, noninvasive, monitoring of PAP, provides necessary direction of therapy in CHF. Remosn® (Remosn Technologies, Israel) is a test of this kind, implantable device responding to ultrasonic signals for the noninvasive monitoring of PAP. The study investigates the effect of Metoprolol CR/XL (MIXL) on the PAP as monitored by the implantable device in ambulatory patients with heart failure (HF) during the first 2 weeks of treatment.

Methods: A first in man, prospecive single arm study (N=10) in NYHA class III HF patients with LVEF = 35 to 45%, and a mean age of 69±7 years, were enrolled for the study. After 2 weeks of treatment with the device, PAP was recorded. Additionally, PAP was recorded after 25 mg/day MIXL, and up to 50 mg/day MIXL for 2 weeks using the MERit-T HF regimen. PAP/PADP were regularly monitored.

Results: The mean baseline PAP of the patients was 33 (22 to 51) mmHg systolic and 17 (14 to 24) mmHg diastolic before giving MXL. The mean baseline systemic blood pressure (SBP) and heart rate (HR) were 113±18 mmHg systolic, 77±17 mmHg diastolic and 60±13 beats/min, respectively. After 2 weeks of 25 mg/d MIXL, the mean PAP rose to 38±15 (32 to 53) mmHg systolic and 19±7 (11 to 31) mmHg diastolic (p<0.05). After up titration to 50 mg MIXL, the mean PAP rose to 36±9 (30 to 40) mmHg systolic (p<0.05) and 17±5 (9 to 27) mmHg diastolic (p=0.12) after 12 weeks of treatment.

Conclusions: Loading Metoprolol CR/XL in CHF patients shows early increase in the PAP, that appears to be as well tolerated as they are in patients not taking daily AAD. Further dose escalation may be considered and could aid in determining the optimal dose of Metoprolol CR/XL in patients with heart failure.
LONG-TERM SILDENAFIL ADMINISTRATION IMPROVES AORTIC STIFFNESS AND WAVE REFLECTIONS IN PATIENTS WITH ERECTILE DYSFUNCTION OF VASCULAR ORIGIN
Charalampos Vlachopoulos, Nikolaos Ioakimidis, Konstantinos Rokkas, Konstantinos Azmouridis, Nikolaos Alexopoulos, Konstantinos Tzanos, Athanasios Askitis, Christodoulos Stefanadis, Athens Medical School, Hippokration Hospital, Athens, Greece

Background: Aortic stiffness and wave reflections are prognosticators of cardiovascular risk. We have previously shown that sildenafil has an acute beneficial effect on aortic stiffness. Whether sildenafil has a long-term beneficial effect on aortic stiffness and wave reflections with chronic daily administration has not been determined.

Methods: The effects of a 2-week long treatment with sildenafil on aortic stiffness were studied in 11 men (age 58±15 years) with vasculogenic erectile dysfunction (ED). The study was carried out on two separate arms, one with sildenafil (100 mg) daily and one with placebo according to a randomized, placebo-controlled, double-blind, cross-over design. All measurements were performed 24 hours after the last sildenafil intake. Carotid-femoral pulse wave velocity (PWV) was measured as an index of aortic stiffness using an automated, non-invasive device (Complior®) and augmentation index (Alx) as a measure of wave reflections using a validated system (Sphygmocor®).

Results: Daily sildenafil intake led to a significant sustained decrease in PWV and Alx, indicating a decrease in aortic stiffness and wave reflections (p<0.05, figures). There were no significant changes in systolic and diastolic pressure.

Conclusions: This study shows for the first time that chronic treatment with sildenafil has a favourable effect on aortic stiffness and wave reflections in patients with ED. This finding may have important implications for patients receiving sildenafil therapy for ED.
Telomeres Shortening in Patients With Coronary Artery Disease Is Due to the Reduced Telomerase Activity Depending on the Severity of the Disease

Marco L. Rossi, Nicola Manziello, Elena Corda, Danilo Zavattaro, Parents, Lucio Belli, Gabriela Gasparini, Paolo Pagnetti, Patrizio Pizziello, Istituto Clinico Humanitas, Rozzano-Milano, Italy. ICOSI Posilvio Care Manifett, Parma, Italy.

Background: Short telomeres have been documented in coronary artery disease (CAD) but the mechanisms of telomeres' length and telomeres shortening are accelerated in cells with low TERT activity Patients with CAD have shorter telomeres than controls. We wanted to clarify whether telomere shortening in leukocytes of patients with CAD as due to an increased cell turnover or a consequence of low TERT activity or a primary genetic abnormality by investigating the telomere length and the TERT activity.

Methods: We evaluated consecutively 20 patients with single, with 20 with 2 and 20 with three coronary vessels disease over 24 coronary angiography for CAD and 20 patients without CAD underwent coronary angiography for screening before valve surgery. The two groups did not differ for demographic, clinical, and angiographic characteristics.

Telomeres length was assessed by quantitative PCR (Q-PCR) and TERT activity by TRAP-EZ chemistry.

Results: Telomeres mean length and TERT activity were significantly lower in patients with three coronary vessels disease VS patients with single or two vessels disease and without CAD (see table).

Conclusion: Telomeres shortening may be due to a reduction in TERT activity rather than the increased cell turnover due to inflammatory processes, a reduction in the activity of P53 enzyme might render more susceptible to atherosclerotic risk factors.

In 2005, the pilot trial was performed for 5 days prior to the procedure, 26 pts were assigned to receive placebo (100 mg bid) and 26 pts had Clopidogrel (75 mg bid) for 48 hours post procedure.

Results: Comparison between the two groups did not show any difference in age, sex, smoking and extension of coronary artery disease. Also, there was no difference in any technical aspect of PCI. Detection of markers of myocardial infarction above the usual normal limit was significantly lower in the placebo vs. group (25% vs. 35% for creatine kinase-MB (p < 0.001), 20% vs. 45% for troponin-I (p = 0.004) and 52% vs. 75% for troponin-T (p = 0.009). Myocardial infarction by creatine kinase-MB determination was less commonly seen after PCI in the clopidogrel than in the placebo group (5% vs. 16%, p = 0.025). Postprocedural peak levels of creatine kinase-MB (2.6 ± 1.5 times normal, p < 0.001) were also significantly lower in the placebo vs. control group. No significant side effect was reported by the two groups of patients.

Conclusions: Posttreatment with clopidogrel 200 mg b.i.d. for 5 days significantly reduced procedural myocardial injury in elective PCI. These findings indicate that the antithrombotic action of Clopidogrel inhibition may provide a highly protective action to cardiovascular disease. A multicenter randomized study is now ongoing and complete results will be available by 2006.

Delayed Thrombolysis-induced Platelet fibrin Clot Generation by Clopidogrel A New Dose-related Effect Demonstrated by Thrombelastography in Patients Undergoing Coronary Artery Stenting

Paul A. Gurbel, Kevin Hellen, Kiril Geyer, Nikhil Aggarwal, Uddaya Thiryu, Sina Center for Thrombosis Research, Backlund, MD, Indiana University at South Bend, South Bend, IN. Background: Thrombin generation is dependent on platelet activation and clodipogrel reduces platelet activation in patients undergoing stenting. However, the effect of the clodipogrel loading dose on the rate of thrombus-induced platelet-fibrin clot formation is unknown in this patient population.

Methods: Using thrombelastography we measured the time to platelet-fibrin clot formation (R), a marker of the speed of thrombogenesis, in 120 patients undergoing elective coronary artery stenting treated with standard and high loading doses of clopidogrel. Platelet reactivity to ADP was measured using light transmittance aggregometry (LTA) was determined simultaneously. Measurements were made immediately before and at 24 hours after clot injury.

Results: Clodipogrel produced a prolongation in R (44 ± 1.4 mm vs. 54 ± 1.7 mm, p < 0.001) that directly correlated with the change in platelet aggregation (r = 0.85, p < 0.001). Prolongation in R was greatest in patients treated with a high loading dose (p = 0.004).

Conclusions: Delayed thrombolysis-induced platelet-fibrin clot formation as measured by TEG is a newly reported dose-related effect of clopidogrel that contributes to the overall antithrombotic profile of the drug in patients undergoing stenting. The effect was more marked in patients loaded with 600 mg, lending further mechanistic support for the dose of clodipogrel as a more effective antithrombotic regimen than the standard 300 mg dose.

Platelet Aggregation and Time to Platelet-Fibrin Clot Formation

<table>
<thead>
<tr>
<th>Group</th>
<th>Total Mean</th>
<th>300 mg</th>
<th>600 mg</th>
<th>p-value (300 mg vs. 600 mg)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clodipogrel</td>
<td>25 ± 1.6</td>
<td>14 ± 1.1</td>
<td>26 ± 1.1</td>
<td>0.002</td>
</tr>
<tr>
<td>Clodipogrel</td>
<td>17 ± 1.7</td>
<td>13 ± 1.5</td>
<td>22 ± 1.8</td>
<td>0.03</td>
</tr>
<tr>
<td>Placebo</td>
<td>30 ± 1.2</td>
<td>17 ± 1.2</td>
<td>32 ± 1.8</td>
<td>0.004</td>
</tr>
</tbody>
</table>

Platelet reactivity among the three groups

<table>
<thead>
<tr>
<th>Group</th>
<th>Mean AA</th>
<th>Mean 5 μM ADP Assaying (%)</th>
<th>Mean 20 μM ADP Assaying (%)</th>
<th>Mean 50 μM ADP Assaying (%)</th>
<th>Platelet aggregation (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>SAT</td>
<td>13 ± 2.8</td>
<td>64 ± 11.4</td>
<td>67 ± 11.9</td>
<td>71 ± 11.9</td>
<td>7.4 ± 0.9</td>
</tr>
<tr>
<td>AMI</td>
<td>64 ± 11.4</td>
<td>64 ± 11.4</td>
<td>67 ± 11.9</td>
<td>71 ± 11.9</td>
<td>7.4 ± 0.9</td>
</tr>
<tr>
<td>Control</td>
<td>37 ± 9.1</td>
<td>64 ± 11.4</td>
<td>67 ± 11.9</td>
<td>71 ± 11.9</td>
<td>7.4 ± 0.9</td>
</tr>
</tbody>
</table>

Platelet reactivity vs. Control

<table>
<thead>
<tr>
<th>Group</th>
<th>p-value for SAT vs. Control</th>
<th>p-value for AMI vs. Control</th>
</tr>
</thead>
<tbody>
<tr>
<td>SAT</td>
<td>0.02</td>
<td>0.05</td>
</tr>
<tr>
<td>AMI</td>
<td>0.02</td>
<td>0.05</td>
</tr>
</tbody>
</table>

First-in-Man Coronary Sinus Narrowing With a Reducer Stent: A Possible Alternative Percutaneous Treatment for Patients With Refractory Angina

Shweta Bhat, Gad Karen, Hoon Severt, Achik Seth, Shweta Bhat-Murahar, Anup B. Naik, Ahanon Mecina, Praeun Chandra, Hithal Sihal, Keyur H. Patankar, Sorayya Tek Hospital, Tel Aviv, Israel.

Increased Coronary Sinus (CS) pressure redistributes collateral blood flow into intrinsic territories of the myocardium, reduces ischemic damage and infarct size. CS narrowing might offer an alternative treatment for patients with refractory angina who are not candidates for revascularization. The CS Reducer is a percutaneous implantable stent-like device, designed to establish CS narrowing and to elevate CS pressure. The Reducer is a stainless-steel mesh balloon expandable stent. Implantation of the device generally leads to a 3-mm shape with a diameter of 3.0 mm at its center and 8-12 mm at both ends. In the acute presentation or from pre-existing tendencies toward higher CS pressure.

Results: Our current cohort consisted of 17 patients with refractory angina who were not candidates for revascularization. The CS Reducer was successfully deployed in 16 patients with refractory angina. The Reducer was associated with reduced mortality and improved ischemic and cardiac functional parameters. To evaluate the CS Reducer as a potential alternative therapy for patients with refractory angina who are not candidates for revascularization.

Conclusions: The CS Reducer is feasible and safe, and may present a novel effective tool to treat patients with refractory angina who are not candidates for revascularization.
**Abstract 83719**

**denotes a mandatory field**

**Abstract Information**

**Abstract Submitter:** Doctor Parikh Keyur - keyurparikh@gmail.com

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**Number:** 83719

**Title:** First in man measurement of diurnal variation in pulmonary artery systolic and diastolic pressure in heart failure patients using an innovative implantable device responding to ultrasonic signals

**Evaluation Topic:** 16.01 - Autonomic nervous system and humoral regulations

**Acronym Abbreviation:** 16.01

**On Behalf of:** The Heart Care Clinic

**Category:** Bedside

**Options:** None

**Abstract Authors**

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**Abstract Content**

**Purpose:** Diurnal variation in left ventricular end diastolic pressure and pulmonary artery (PA) pressures (PAP) has important consequences in patients with Congestive Heart Failure (CHF). Very few studies have been done in ambulatory CHF patients to look at diurnal variations in PAP. The Remon CHF implant (Impressure®) measures the systolic and diastolic pressure waveform in the PA based on non-invasive acoustic activation and communication.

**Methods:** It was a first-in-man, prospective, single arm study. 10 NYHA class III/IV CHF patients with LVEF 26.8 ± 4.3% were enrolled for the Impressure® implantation, a first of its kind device (3mm x 3mm x 16mm) placed percutaneously via internal jugular vein, permanently in the right PA. Using ultrasonic signals it generates the PAP waveforms on a desktop system. Following the implantation, all the patients were monitored ambulatory for the changes in PAP and other related hemodynamic parameters over a 24 hour cycle every fortnight. PA systolic and diastolic pressure was monitored noninvasively using this device every 2 hours during day time and every 3 hours during night. All patients received 1mg/2mg Lorazepam (Ativan®) at bedtime along with the conventional CHF therapies.

**Results:** The mean(±SD) age of the patients was 45±10 years (25-58 years range). For the whole group, the mean(±SD) daytime systolic PA pressure was 28.8±1.3mm Hg and diastolic PA pressure was 15.47±0.47mm Hg. During the night, systolic PAP rose to 31.56±0.56mm Hg (p<0.001) and the diastolic to 15.99±0.57mm Hg (p<0.001). The mean increase in systolic pressure from day to night was 2.76±3.35mm Hg and in diastolic pressure from day to night was 1.89±1.52mm Hg. In eight out of ten patients, there was a rise in the PAP at night.

**Conclusions:** In CHF patients, nocturnal rise in pulmonary artery pressure (both systolic and diastolic) may be responsible for the worsening of these patients symptoms at night or early morning. Noninvasive measurements by this novel implant may assist the daily monitoring of these patients including their nocturnal changes and adjustment of therapy.
Purpose: Increase in Left Ventricular End Diastolic Pressure (LVEDP), Pulmonary artery (PA) pressure and limitation of exercise capacity are common findings in Congestive Heart Failure (CHF). An implantable device responding to ultrasonic signals named the Remon CHF implant (Impressure®) is a first of its kind for the noninvasive monitoring of PA pressure. The study investigates pulmonary hemodynamic changes during exercise and its relationship with exercise capacity in CHF.

Methods: It was a First-In-Man, prospective, single center, single arm study. 10 NYHA class III/IV CHF patients with LVEF 26.5±4.3 % were enrolled for the Impressure® (3mm x 3mm x 16mm) implantation, a device placed percutaneously via internal jugular vein, permanently in the Right Main PA. It responds to ultrasonic signals to a desktop system and generates the PA pressure waveform. Treadmill Exercise test (TMT) following standard Bruce Protocol was done at the end of one month of the implantation. PA pressure was measured immediately before and after the exercise and on recovery using the noninvasive Impressure®.

Results: All the patients finished the symptom limited TMT with a peak heart rate of >90% of targeted heart rate. The mean±SD exercise time was 6.37±2.2 minutes, corresponding to 8±2 metabolic equivalents. Resting PA pressures were 32.7±11.1/17.1±7.8 mm Hg. The PA pressure immediately after the TMT was 49.0±17.9/24.1±11.2 mm Hg. The systemic blood pressure preTMT was 111±18/71±7 mmHg which post TMT rose to 144±28/82±10 mmHg (p<0.01). The mean heart rate preTMT 81±3 beats/min after exercise increased to 105±19 beats/min (p=0.001). The mean increase in the PA pressure due to exercise was 16.3(±10.2) mm Hg systolic (p<0.001) and +6.9(±5.8) mm Hg diastolic (p=0.004).

Conclusions: The study shows a significant rise in PA pressure and more importantly, PA Diastolic pressure following exercise in CHF patients limiting their exercise capacity. This increase in PA pressure may be secondary to either ischemia or Left ventricular dysfunction or both. Management of these CHF patients should be tailored to avoid this exertional rise in PA Diastolic pressure either by avoiding ischemia or by improving Left ventricular dysfunction. Noninvasive measurement by this novel device, Impressure® may assist in daily precise management of these patients.
Purpose: Limitation of exercise capacity is seen in congestive Heart Failure (CHF) with increased Left Ventricular End Diastolic Pressure; Pulmonary Artery Pressure (PAP) and PA Diastolic Pressure (PADP). Metoprolol CR/XL (MXL) has however shown to improve morbidity and mortality in CHF. This study evaluates the effect of MXL on exercise capacity and PAP in patients with CHF, using Remon CHF implant (Impressure®), a first of its kind device for the non-invasive monitoring of PAP.

Methods: It was a first-in-man, prospective, single arm study. 10 NYHA class III/IV CHF patients (LVEF 26.5±4.3 %) had Impressure placed via internal jugular vein permanently in the Right PA. Using ultrasonic signals it generates the PAP waveforms on the desktop system. All the patients underwent Treadmill test (TMT) and PAP was measured before and after the exercise. MXL 25mg/day was then loaded in all the patients and uptitrated two weekly using the MERIT-HF criteria to reach 200mg/d dose, with regular follow up TMT and PAP monitoring.

Results: 8 out of 10 patients were taken into analysis. All the 8 patients had symptom limited TMT. The baseline mean±SD exercise time (EXtime) was 6.8±2.2 mins and 8.4±2.2 METS (metabolic equivalent(s)). The baseline rest PAP was 30.6±9.1/16.1±8.0 mm Hg, which after TMT rose to 46.4±14.7/22.6±10.5 mm Hg (p<0.05). After 2 weeks of loading 25mg/d MXL, the EXtime was 6.96±2.2 mins and METS 8.6±2.3. The post TMT PAP was 51.6±15.9/23.7±4.9 mmHg (p=0.05 for systolic PAP rise). After 50mg/d MXL dose EXtime was 7.86±2.7 mins (p=0.09) and METS 9.4±2.6. PAP post TMT did not show significant change as compared to previous follow up. On reaching 100mg/d MXL, there was no significant change in the EXtime, METS or post TMT PAP (52.5±18.1/23.4±9.6 mmHg). On reaching the target dose of 200mg/d MXL, the EXtime increased significantly to 8.0±2.6 mins and 9.7±2.6 respectively (p=0.03 for both), however no significant change was observed in post TMT PAP (52.1±17.7/23.6±8.6 mmHg). Post TMT Heart Rate decreased significantly from 106±9 per min at baseline to 89±13 per min at 200mg/d MXL (p=0.01).

Conclusions: MXL treatment in CHF patients produce a slight insignificant increase in systolic PAP at baseline and after exercise (with decrease in peak exercise systemic BP and HR) but improves the exercise capacity in selected patients. This supports the recommendation for slow and careful uptitration of MXL in CHF patients.
First in man non-invasive monitoring of pulmonary artery pressure from an implantable device using acoustic telemetry: a one year follow-up data

Purpose: The left ventricular end diastolic pressure (LVEDP), a critical hemodynamic parameter serves as the basis for most decompensation events in Congestive Heart Failure (CHF). Frequent monitoring of pulmonary artery (PA) pressure (PAP) supplies the feedback loop for direction of therapy, which presently is available invasively by Swans-Ganz catheterization. Remon CHF Implant (Impressure®) measures the PAP waveform based on non-invasive acoustic activation and communication, as frequently as necessary. Following successful animal studies, this first-in-man pilot study is set up to demonstrate the delivery system, safety and functionality of Impressure® in ambulatory patients.

Methods: 10 NYHA class III/IV patients were included in the study. Baseline hemodynamic assessment was obtained prior to implantation by Right Heart Catheterization (RHC). A control pressure measurement was also performed using a Millar Catheter. The Impressure® (3mm x 3mm x 16mm), made of titanium case, encapsulating an energy exchanger, control chip, pressure sensor and energy reservoir with ultrasonic capabilities was percutaneously implanted, using a delivery system (internal jugular approach) in the Right PA. It was positioned using a self expandable nitinol anchor attached to it. When interrogated by the desktop system, through a handheld transducer, in contact with the chest, Impressure is activated. The energy exchanger (piezoelectric transducer) converts applied external ultrasonic pressure to electrical energy. Once energized, the control chip interrogates the pressure sensor and ultrasonically transmits the digital reading to an external receiver. PAP was measured using the Impressure® till 6 months. RHC was repeated at 6 months for authenticating the Impressure®'s functionality and accuracy. One year follow up will also be studied.

Results: The Impressure® was deployed in the right PA in 10 patients. High quality accurate (compared to Millar catheter) pressure waveforms were obtained using the implant and the external desktop system. PA pressures were accurately available till 6 months. Impressure®'s functionality and accuracy were comparable to the control pressure measurements from Millar Catheter at baseline and 6 months. Patients are being followed for 1 year.

Conclusions: Impressure®'s unique telemetric technology enables easy repeated non-invasive measurement of the PAP waveform and PA Diastolic pressure in ambulatory patients. Such continuous non-invasive monitoring of PAP by an implantable device may improve the prognosis and management of CHF patients.
### Abstract 86167

**Purpose**

Patients with heart failure will develop increases in pulmonary venous and arterial pressures. Reduction in pulmonary artery pressure (PAP) with improved cardiac output is a good clinical indicator of response to therapy. PAP measurement helps to assess efficacy of treatment. Assessment of PAP by contrast echocardiography is one such available non-invasive method. Remon CHF implant (Impressure®) is a first of its kind device for the non-invasive monitoring of PAP. This study compares the functionality and precision of this device in measuring systolic PAP as compared to conventional contrast echocardiography.

**Methods**

It was a first-in-man, prospective single arm study in 10 NYHA Class III/IV CHF patients with LVEF 26.5±4.3% enrolled for the Impressure® implantation. The Impressure® (3mm x 3mm x 16mm), made of titanium case, encapsulating an energy exchanger, control chip, pressure sensor and energy reservoir with ultrasonic capabilities was percutaneously implanted, using a delivery system (internal jugular approach) in the right PA. A self-expandable nitinol anchor is attached to it for its positioning. On interrogation by a handheld transducer, in contact with the chest, Impressure® is activated and based on non-invasive acoustic activation and communication PAP waveforms are generated on the desktop system. Following the implantation, PAP was measured using this novel device non-invasively and by contrast echocardiography (Vivid 4, GE) by two blinded independent echocardiographers. Intravenous saline was used for the echocardiography to obtain adequate tricuspid regurgitation Doppler signal for right ventricular and PA systolic pressure assessment.

**Results**

The mean (±SD) systolic PAP measured by contrast echocardiography was 38.2±10.2 mm Hg whereas by Impressure® was 38.3±17.7 mm Hg. The Impressure® also measured non-invasively Diastolic PAP which was 19.0±11.5 mm Hg. Systolic PAP measurement from contrast echocardiography correlated only fairly with Impressure® (r=0.68, p=0.03). Additionally, Systolic or mean PAP or repeated measures as available with Impressure® are not possible with contrast echocardiography Doppler.

**Conclusions**

Impressure®s unique telemetric technology enables easy repeated non-invasive measurement of the PA pressure waveform and PA Diastolic pressure in ambulatory patients. Such frequent non-invasive monitoring of PAP by an implantable device may improve the management of patients with CHF and PAH and should reduce need for repeated hospitalization and better optimization of drug therapy.
First in Man study: effect of Metoprolol CR/XL on diurnal variation in pulmonary artery pressure assessed non-invasively using an innovative implantable device responding to ultrasonic signals

Purpose:
Beta blockers (BB) have been shown to improve morbidity and mortality in Congestive Heart Failure (CHF). Diurnal variation and more importantly nocturnal rise in pulmonary artery pressure (PAP) may have increased risk of developing paroxysmal nocturnal dyspnoea. Remon CHF implant (Impressure®) is an innovative device for the noninvasive monitoring of PAP. This study investigates the effect of Metoprolol CR/XL (MXL) on diurnal variation in PAP in CHF patients.

Methods:
It was a First-In-Man, prospective, single arm study in 10 NYHA class III/IV CHF patients with LVEF 26.5 ± 4.3 % enrolled for the Impressure® implantation percutaneously via internal jugular vein, permanently in the Right PA. It generates PAP waveform on a desktop system using ultrasonic signals. All patients received conventional therapies except BB. After a month, MXL 25 mg/d was loaded in the patients and uptitrated two weekly by the MERTT-HF criteria. These ambulatory patients were noninvasively monitored for PAP every 2 hours in day time and every 3 hours during night for a 24 hrs cycle at baseline (no MXL) and after reaching 100mg/d and 200mg/d MXL dose.

Results:
8 out of 10 patients were taken into analysis. The baselines mean±SD daytime systolic PAP (SPAP) was 25.2±1.4 mm Hg and diastolic PAP (DPAP) was 14.1±0.6 mm Hg. During night, SPAP and DPAP were significantly (p<0.001) increased to 27.5±0.6 mm Hg and 16.0±0.5 mmHg respectively suggesting a nocturnal rise in PAP. Uptitration of MXL to 100mg/d caused an initial increase (p<0.05) in daytime SPAP and DPAP to 32.5±1.4 mmHg and 15.3±1.4 mmHg respectively with a further increase in nocturnal PAP: SPAP 35.7±1.7 mmHg and DPAP 17.7±1.0 mmHg at night (p<0.01 for both, compared to respective daytime and baseline night pressures). Further uptitration to 200mg/d showed a significant rise in daytime SPAP and DPAP to 34.0±1.0 mmHg and 15.5±1.5 mmHg respectively (p<0.05) as compared to baseline. However, at night, SPAP significantly dropped to 27.8±2.5 mmHg (p<0.01 as compared to daytime) and DPAP to 14.0±0.7 mmHg (p<0.05 compared to respective daytime and baseline). Uptitration of MXL in one patient resulted in deterioration of heart failure with a rise in PAP.

Conclusions: CHF patients do show a nocturnal rise in PAP. Slow and careful uptitration of MXL upto 200 mg/d may prevent this nocturnal rise as evident from the non invasive frequent monitoring by Impressure® device. Use of Impressure® device may help identifying beta blocker intolerance in certain patients.
First In Man: Direct Comparison Of Conventional Coronary Sinus Angiography And CT Angiography For Visualization And Sizing Of Coronary Sinus

Author Block: Keyur H Parikh1, Ajay M Naik1, Hetal A Shah1, Anush H Chandarana1, Milan C Chag1, Urmil G Shah1, Hemang A Baxi1, Joyal N Shah1, Aharon Medina2, Shmuel Banai2
1 The Heart Care Clinic, Ahmedabad, India 2 Tel Aviv Medical Center, Tel Aviv, Israel

Abstract

Background: During Cardiac Resynchronisation Therapy (CRT), Left Ventricular (LV) pacing is established by a pacemaker lead in a tributary of the Coronary Sinus (CS). Knowledge of the CS anatomy and variations may facilitate the implantation of LV leads. Multislice computed tomography (MSCT) has become an important tool for noninvasive evaluation of cardiovascular structures. No major data is currently available on the use of MSCT to visualize the CS anatomy and determine its size. The CS Neovasc Reducer® (Neovasc Medical Ltd, Israel) is a percutaneous implantable stent-like device, designed to establish a permanent narrowing of the CS and elevate CS pressure. As a part of screening and follow-up of the device in the first-in-man study, we evaluated the feasibility of MSCT (Phillips 40 Brilliance CT scanner) to visualize CS anatomy and tributaries in comparison with conventional Invasive Angiography (ANG).

Methods: 10 refractory angina patients were screened for this device implantation. Prior or immediately after implantation, all patients underwent MSCT to determine CS anatomy, size and location of the stent. The data so obtained was verified with the ANG at the time of implantation. CS ANG was performed via 11F introducer sheath from Right Internal Jugular vein into the mid portion of CS. CS size was determined by quantitative coronary angiography utilizing DDS-GEMNET version 3.0.4.10 (Camrime Medical System Inc.) software of GE Innova 2000 Cathlab. CS diameter was measured 2–4 cm distal to the CS ostium.

Results: The CS was well visualized in the MSCT comparable to the ANG. The mean (±SD) CS diameter was 8.3(±1.2) mm from MSCT and 7.12(±1.39) mm from ANG (p<0.05). There was moderate correlation between the CS size determination by the two modalities (r=0.66). The CS anatomy was very precisely seen in 3-dimensions with the MSCT, and correlated well with the ANG images of the CS.

Conclusions: MSCT appears to be a very promising modality for the non-invasive evaluation of the CS anatomy. Pre-implantation knowledge of the CS and venous anatomy may help to decide regarding CS lead placement for CRT and may save the fluoroscopy time, operator time and decrease the use of contrast during the CRT implantation.

Author Disclosure Block: K.H. Parikh, None
First In Man: MultiSlice CT Angiography Visualization Of An Innovative First-in-man Coronary Sinus Reducer Stent In Patients With Refractory Angina

Author Block: Keyur H Parikh1, Hetal A Shah1, Anish H Chandarana1, Ajay M Naik1, Milan C Chag1, Urmil G Shah1, Hemang A Baxi1, Joyal N Shah1, Aharon Medina11, Shmuel Banai2
1The Heart Care Clinic, Ahmedabad, India2Tel Aviv Medical Center, Tel Aviv, Israel

Abstract

Background: The Coronary Sinus (CS) Neovasc Reducer® (Neovasc Medical Ltd, Israel) is a percutaneous implantable device, to establish a permanent narrowing of the CS and elevate CS pressure. The Reducer® is a stainless steel, balloon expandable stent, which on implantation gets an hourglass shape with a diameter of 3.0 mm at its center and 8 - 12 mm at both ends. In patients with ischemic coronary artery disease, increased CS pressure results in redistribution of collateral blood into ischemic myocardium. In ischemic pig hearts, Reducer® implantation reduced mortality and improved ischemic and functional parameters. A first-in-man pilot study was undertaken to evaluate CS Reducer® implantation as an alternative therapy for patients with myocardial ischemia and refractory angina. Instead of a conventional Invasive Angiography, follow-up was done with Multislice computed tomography angiography (MSCT). Here we show, for the first time, the non-invasive evaluation of the CS and the Reducers using the MSCT (Phillips 40 Brilliance MSCT).

Methods: Ten patients underwent non-invasive evaluation by MSCT at 1 week, 3 months and 6 months following first in man implantation of the CS Reducers®.

Results: CS as well as the Reducers® were very well visualized. All were at the exact site of implantation in the CS without migration. All Reducers® were patent with no evidence of thrombosis throughout the follow up period. The mean Reducer® diameters as measured in the post-implantation MSCT were: proximal 11 ± 2 mm; distal 7.2 ± 1 mm and mid 3.0 ± 0.2 mm. The CS wall was constricted along with the hourglass shape of the Reducer®, thus leading to a reduction in the CS diameter. No blood flow around the narrowed mid-portion of the Reducers® was seen at 3 and 6 months follow-up. The transverse sections of the CS showed open lumen in all stents.

Conclusions: MSCT is an effective non-invasive tool to evaluate baseline CS anatomy, appropriate placement, patency and lumen diameter reduction following implantation of the CS Reducer® stents. New cardiac devices can be assessed non-invasively by MSCT with precise quantitative measurement, 3-D viewing and vessel wall effects may of which cannot be assessed by Invasive Angiography.

Author Disclosure Block: K.H. Parikh, None

Category (Complete): 15 Cardiac Imaging (Non-Coronary)
Presentation Format (Complete): Oral
Keyword (Complete): Imaging - Non-Invasive (and functional testing); New Devices; Stents - Other
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