the TRUE Dilatation™ Balloon Valvuloplasty Catheter in patients undergoing transcatheter aortic valve implantation (TAVI).
Methods: Between January and May 2012, a total of 18 patients (pts) with high grade aortic stenosis underwent valvuloplasty of the aortic valve using the TRUE Dilatation™ Balloon Valvuloplasty Catheter prior to TAVI. Several performance measures were evaluated and graded from 1 to 10, which 10 indicating best performance.
Results: Subjects were 83 ± 6 years old, logistic EuroSCORE 16 ± 7%, STS 9.6 ± 4.5. The mean aortic gradient was 48±19mmHg, the valve orifice area was 0.66± 0.19 cm^2. BAV was successful in all cases. Neither balloon nor annular rupture occurred in any case,. Balloon inflation and deflation times were less than 2 seconds, The grade for the performance measure "ease of catheter insertion through introducer sheath" was 9.3±0.5 points, 9.1±0.5 for "ease of passing catheter over aortic arch, ease of catheter crossing over aortic valve" 9.2±0.7 points, for "speed of balloon inflation" 9.6±0.6 points, for "ability to dilate aortic valve without balloon slippage" 8.9±1.7 points, and for "speed of balloon deflation" 8.9±1.1 points. Five pts (28%) received and Edwards SAPIEN XT and 12 pts (72%) a Medtronic CoreValve Prosthesis after BAV. The 30 day stroke and mortality rates were zero and 5.6%.
Conclusions: This study shows that the TRUE Dilatation™ Balloon Valvuloplasty Catheter has an excellent performance with fast inflation and deflation times in patients with severe aortic stenosis in the absence of harmful side effects.

TCT-109

A New Generation Transcatheter Heart Valve with a Novel Nanocomposite Material and Fully Retrievable Design

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Background: Transcatheter aortic valve implantation (TAVI) procedures offer remarkable benefits for high risk patients with severe aortic stenosis. However, the current TAVI devices are associated with complications such as lack of repositionability, paravalvular leakage and atrio-ventricular block. Moreover, there is no long-term clinical data about the durability of current tissue-derived TAVI prostheses and leaflet degradation during the loading into the catheter remains a serious concern.
Methods: A new generation transcatheter aortic valve (TAV) has been developed by our group at University College London. The UCL-TAV benefits from leaflets made of a novel nanocomposite polymer encompassed by a self-expandable Nitinol stent. The polymer is composed of a polycarbonate urea urethane soft segment (PCU) and hard segment derived from polyhedral oligomeric silsesquioxane (POSS) nanoparticles through covalent bonding forming pendant chain functional groups. POSS-PCU nanocomposite possesses enhanced physiochemical properties, resistance to calcification and thrombosis with superior in-vivo biostability. It has been successfully implanted in human in the form of a small calibre bypass graft, lacrimal duct conduit, and more recently as the world's first synthetic trachea. The UCL-TAV design allows for multi-stage expansion of the prosthesis providing controlled deployment, and is fully retrievable in the case of misplacement.
Results: POSS-PCU demonstrated superior mechanical properties compared to porcine and bovine pericardial tissues. Initial prototypes of UCL-TAV were successfully produced using a consistent manufacturing technique, and tested for collapse and re-expansion over several cycles with no observable structural damage. Owing to its thin polymeric leaflets membrane, the valve can be crimped in to a catheter equal to or less than 18 Fr to provide easier vascular access, and the design has improved anchoring and sealing with no need for excessive radial force.
Conclusions: Having a fully retrievable design as well as an advanced material, the UCL-TAV can overcome the main limitations of current TAVI devices. The UCL-TAV is currently under pre-clinical evaluation.

TCT-110

First Experience With A Novel Anatomically Adapted Percutaneous Heart Valve For The Tricuspid Position

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Background: Percutaneous tricuspid valve implantation has received little attention, mainly due to the unstructured annulus and the associated difficult stentframe anchoring. Tricuspid regurgitation is commonly a result of right ventricle-dilation secondary to left heart diseases. A novel anatomically adapted tricuspid heart valve prosthesis, consisting of a vena cava superior-stent (CSA) and a tricuspid annulus-stent (ASA) connected by flexible struts, was developed. Anatomical CT-data of a porcine heart (65 kg, female) was post-processed using Mimics and 3-matic (Materialise, Leuven, Belgium) and relevant dimensions were considered in the stent design process. The anchoring of the prosthesis relies primarily on the CSA-stent and is supported by the valved ASA-stent. First experience with this anchoring concept, using a design with an additional vena cava inferior-stent, was gained in animal trials which demonstrated the feasibility of the concept.
Methods: Finite element simulations were performed with Abaqus (Simulia, Providence, USA) to analyze the crimping process of the arched stent-construct and the loading on a straight catheter. A custom trileaflet heart valve was sewn into the 40 mm diameter ASA-stent, using bovine and porcine pericardium for the leaflets and a sealing skirt, respectively. The smallest diameter was determined by crimping tests and a catheter was adapted. The physiological function of the new prosthesis sample was tested in-vitro inside a mock-loop, specifically designed for the simulation of the right heart. The valved stent-construct was introduced into an anatomical silicone-model of the right heart to analyze the adaptation to the heart structure and the prosthesis' function in-vitro.
Results: The arched stent-construct of a vena cava superior-stent, five struts and a large valved tricuspid annulus-stent could be crimped to fit the custom delivery catheter system. The in-vitro tests showed good adaptation, enough flexibility of the struts, good seal and a physiological pressure of 5/40 mmHg was applied.
Conclusions: The percutaneous tricuspid valve approach was proven to work with two different designs, one already assessed in animal trials and one successful in in-vitro tests.

TCT-111

First In Man Experience with a Two-part, Exchangeable Leaflet Bioprosthetic Valve

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Background: Revalving failed bioprostheses with transcatheter valves cannot be done routinely because of diminished EOA and concerns for their long-term durability. A two-part rapidly exchangeable tissue valve has been developed as an alternative. The design of the valve was inspired by the off-patent features of the Edwards Perimount/Magna series. It is a two-component valve where the permanent base can be implanted without the leaflets, improving visibility and hence speed of implant. The removable leaflet set can later be exchanged via transapical access, off-pump.
Methods: Animal studies have shown calcification resistance superior to the Perimount, and bench studies show greater EOA than the Magna, and durability greater than 200 million cycles at a closing pressure of 200 mmHg. In its first clinical use, 23-mm size valves were implanted into three men, two with bicuspid valves and one with senile aortic valve stenosis. Two were placed with infra-annular pledgets and one with supra-annular pledgets. The base was inserted first and then the leaflet set was attached with the aid of clear plastic shields that protected the 2-mm high post.
Results: Placement of the base first allowed easier valve insertion, as tall commissural posts, found in current pericardial valves were not present to obstruct suture tying. Furthermore, the absence of leaflets allowed additional infra-valvular sutures to be placed without difficulty.
Conclusions: This new valve shows promise for easier insertion and good durability. In addition it may facilitate leaflet-set exchange, should it deteriorate later. Further study appears to be justified for early and late results.

TCT-112

Two-Way, Real-Time Interaction by Means of a Novel Telecommunications Software; Improves Management Of Patients With ST-Segment Elevation Myocardial Infarction

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Background: A pre-hospital electrocardiogram (ECG) improves the management of patients with ST-segment elevation myocardial infarction (STEMI). Current telecommunication systems do not permit real-time interaction with first responders in the field or with care providers at referring hospitals. Our institution has developed a novel telecommunications system based on a software application that is downloadable to multiple platforms to permit real-time, two-way video and voice interaction over a secured, HIPPA compliant network.
Methods: We hypothesized that the use of the CodeHeart application (CHap) for patients with possible acute coronary syndrome will reduce door-to-balloon (DTB) times of STEMI patients. Therefore, all STEMI system activations after implementation of the CHap system, were prospectively entered into a database. Consecutive CHap activations were compared to routine activations as controls, during the same time period (03/14/2011 to 12/31/2011). System quality measures were calculated and compared using Student's t test or the Mann-Whitney U test as appropriate.
Results: A total of 360 STEMI system activations occurred. 62 (17%) employed CHap and 298 (83%) routine channels. DTB times were reduced by the use of CHap when compared to controls (95.3±35' vs. 154.6±102.4', p=0.0009) as were first call-to-balloon times (68.9±29.3' vs. 91.7±40', p=0.004), which highlights our network's response efficiency for transferred patients. The percentage of catheterization laboratory activations for a true STEMI was higher with the use of CHap, although this trend did not reach statistical significance. [CHap 38/62 (61.3%) vs. routine 148/298 (49.7%), p=0.12].
Conclusions: The implementation of a two-way telecommunications system that allows for real-time interactions between interventional cardiologists and referring practitioners

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improves overall DTB time and transfer time. In addition, it has the potential to decrease the frequency of false activations, therefore improving cost-efficiency of a network's STEMI system.

TCT-113

Focal Treatment of Lower Extremity Post-PTA Dissection Using The Tack-It Endovascular Staple Device: First-in-man Trial With One Year Follow-up

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Background: The purpose of this study was to evaluate the safety, feasibility, and results of using the Tack-It Endovascular Stapler™ to manage post-PTA dissection. Stents are used to manage of post-PTA dissection of the lower extremity arteries. This generally provides an acceptable post-intervention angiographic result but has long-term disadvantages such as in-stent restenosis and fracture. Focal treatment of post-PTA dissection and avoidance of stent placement in this setting is the function of the Tack-It device.
Methods: A total of 15 limbs (11 patients) with 25 lesion treatment sites were treated with the study device between December, 2009 and March, 2010. In the study group, 7 subjects had lesion treatments in one leg and 4 subjects had lesion treatments treated in bilateral extremities for lesions of the SFA, popliteal, or tibial arteries or a combination of these. Indications were CLI in 9 of the 15 limbs and claudication in 6.
Results: Acute technical success for luminal patency at the end of the study procedure was achieved with Tack placement and tissue apposition in 100% of all treated dissections. 50 Tacks were placed and placement was accurate in 96% (48/50). Tack placement successfully provided a smooth, post-angioplasty blood vessel surface and permanently secured post-PTA dissections. Mean procedure time was 51 minutes (range 10 – 128 minutes). Mean fluoroscopy time was 13 minutes (range 5 – 30 minutes). Two patients died and 2 were lost to follow-up during the year after the procedure. There were no device related complications. There were no major limb amputations. 18 of the 25 lesions were available for follow-up at one year. There was recurrent stenosis (>50%) in 3 of 18. One patient with gangrene and a popliteal occlusion returned with a recurrent stenosis at 3 months and required repeat angioplasty and Tack placement for a TLR rate of 4%. Overall angiographic patency at one year was 83.3%.
Conclusions: Use of the Tack-It Endovascular Stapler™ to manage post-PTA dissections is safe and feasible, and resulted in permanent securement of dissection flaps without stent placement and with reasonable angiographic patency at one-year.

TCT-114

Feasibility of Noninvasive Atherectomy: Plaque Ablation with Cavitation-Based Focused Ultrasound (Histotripsy)

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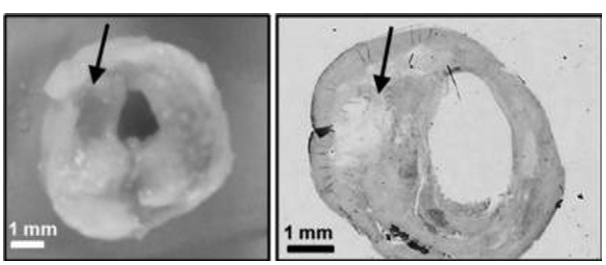
Background: Histotripsy is a novel technique that uses high-amplitude focused ultrasound pulses to create cavitation in a targeted tissue, with resultant mechanical breakdown of the tissue structure. Ultrasound imaging provides feedback for the therapy, including targeting and monitoring treatment progression. We assessed the feasibility of histotripsy for ablating large vessel plaque.
Methods: Human plaque specimens obtained from carotid or femoral endarterectomy were fixed to a gelatin substrate and placed in a water tank. In 4 samples, the focus was scanned within the plaque to try to create a channel through it. In 3 samples, multiple fixed focal ablations were performed to evaluate erosion rate. Histological analysis was performed post treatment to examine ablation efficacy for different plaque types.
Results: Tissue breakdown was evident in most samples. Cavitation was observed by B-Mode imaging on the surface or within the plaque volume during treatment, indicating the region of disruption. Channels up to 1 cm were created within the bulk of the plaque. Ablation rate was strongly dependent on plaque type: fatty material could be ablated within a few seconds in the focus, while very fibrous material required ~5-15 minutes per focal volume. No damage was observed to calcific material. The figure shows gross morphology (left) and histology (right) of a channel created adjacent to the lumen in a fibrous-fatty plaque.
Conclusions: Histotripsy provides a noninvasive method of ablation of atherosclerotic plaque. We are currently exploring the feasibility of this technique for treatment of femoral-popliteal disease.



Endovascular Aortic Repair and Thoracic Endovascular Aortic Repair

Hall D

Tuesday, October 23, 2012, 8:00 AM–10:00 AM

Abstract nos: 115-132

TCT-115

Hybrid endovascular repair for aortic arch pathology: intermediate outcomes and complications

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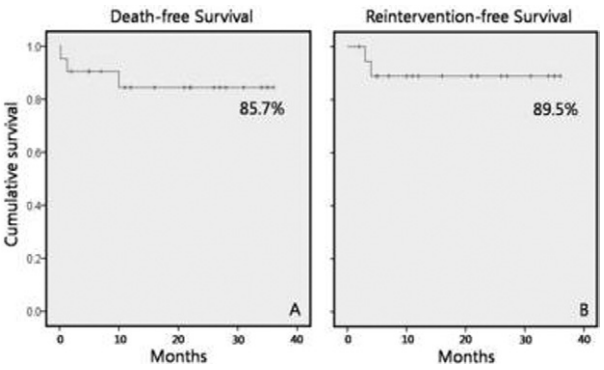
Background: To evaluate the outcomes of hybrid endovascular repair for aortic arch pathology.
Methods: This study was a retrospective analysis involving patients who underwent hybrid endovascular repair for aortic arch pathologies.
Results: Twenty-one patients (16 men; mean age, 64.7±16.2 years) with aortic arch pathologies were treated by hybrid endovascular repair. The indications for treatment included increased aneurysm size in 16 cases (71.4%), rupture or impending aneurysmal rupture in 5 cases (23.8%), and rapid growth of aortic dissection (≥ 10mm/y) in 1 case (4.8%). Supra-aortic vessel transposition and stent-graft implantation were achieved in all cases. Two types of stent-graft was used, as follows: the Seal thoracic stent-graft in 14 patients (66.7%); and the Valiant stent grafts in 7 patients (33.3%). Peri-operative complications affected 5 patients (23.8%), as follows: bleeding (n=4, 19.0%); stroke (n=3, 14.3%); renal failure (n=2, 9.5%); vascular injury (n=1, 4.8%), and respiratory failure (n=1, 4.8%). Two patients died within 30 days (9.5%). Technical success was achieved in 15 patients (71.5%). Early endoleaks were noted in 4 patients (19.0%). One patient died during follow-up (mean, 21.3±11.6 months) due to a de novo aortic dissection. Persistent early endoleaks were noted in 4 patients (19.0%); 2 of the 4 patients were successfully managed with implantation of additional stent-grafts. No late onset endoleaks were noted.



Conclusions: Hybrid treatment with supra-aortic vessel transposition and endovascular repair may be an option in frail patients in who open procedures is too risky.

TCT-116

A New Concept Of Stent: The Multilayer Flow Modulator. First Human Study In Thoraco Abdominal And Abdominal Aortic Aneurysms.

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Background: Thoraco Abdominal Aortic Aneurysms (TAAA) and Abdominal Aortic Aneurysms (AAA) are traditionally treated surgically, but more and more by interventional procedures (endografts, fenestrated grafts) with a high technical success rate but high complications rate (mortality 9-12%, endoleacks 10-20%, branch occlusion 3-11%, neurological complications 5-11%). We developed a new concept of stent, the Multilayer

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