TCT-354

Plaque Excision Is An Effective Treatment Option for Diabetic Patients: Results from the DEFINITIVE LE Study

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Background: Diabetes has been associated with an increased risk of peripheral arterial disease (PAD) and worse outcomes following treatment. The DEFINITIVE LE study was a global study that assessed the effectiveness of plaque excision using the SilverHawk® and TurboHawkTM systems (Covidien/ev3, Plymouth, MN) for endovascular treatment of PAD in femoropopliteal and tibial-peroneal arteries.
Methods: 800 patients with a total of 1023 infrainguinal lesions were enrolled in DEFINITIVE LE and underwent revascularization with plaque excision. Follow-up assessments occurred at pre-discharge, 30 days, 3 months (for patients with RCC 5 or 6), 6 months and 1 year post-procedure. Endpoints were assessed by independent angiographic and duplex core laboratories and adverse events were adjudicated by a Clinical Events Committee. The primary endpoint for claudicants was primary patency (defined using both PSVR $\leq$ 2.4 and PSVR $\leq$ 3.5and estimated by Kaplan-Meier methods). Secondary assessments included change in Rutherford Clinical Category, ankle-brachial index, the Walking Impact Questionnaire, EQ-5D quality of life and adverse events.
Results: Preliminary results are shown pending database closure and monitoring; final results will be presented at TCT 2012. The study enrolled 600 subjects (745 lesions) with claudication, 46.7% (280/600) of which had diabetes. Subjects with diabetes differed significantly from those without diabetes in multiple baseline characteristics, but acute and 1-year outcomes were largely similar. Demographics, lesion characteristics and outcomes are shown below.

Characteristic/ Outcome	Diabetics (n=280, 345 lesions)	Non-diabetics (n=320, 400 lesions)	P-value
Age (yrs)	67.6 ± 9.7	71.1 ± 10.8	<0.001
Female	41.4%	46.3%	0.24
Caucasian	63.2%	79.4%	<0.001
History and risk factors			
Hypertension	95.0%	88.8%	0.007
CHF	18.6%	8.4%	<0.001
Renal insufficiency	22.9%	11.3%	<0.001
Myocardial infarction	22.9%	14.7%	0.011
Current or former smoker	47.1%	59.4%	0.003
Mean lesion length (cm)	7.6 ± 5.3	7.5 ± 5.3	0.84
Baseline diameter stenosis	71.9% ± 17.1%	73.5% ± 19.0%	0.25
Post-plaque excision stenosis	23.8% ± 12.3%	23.9% ± 13.7%	0.89
Device success	78.4%	74.0%	0.17
1-year primary patency (PSVR 2.4)	77.2%	74.0%	0.46
1-year primary patency (PSVR 3.5)	80.9%	79.9%	0.64

Conclusions: Plaque excision is an effective treatment modality for patients with diabetes. It may be particularly appealing in diabetic patients because it removes the plaque, opens the lumen and preserves future treatment options in this progressive disease.

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Coronary Stents In Patients With Diabetes Mellitus: The Diabetes And Drug-Eluting Stent (DiabeDES IV) Randomized Angiography Trial

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Background: Diabetes mellitus is associated with accelerated progression of coronary artery disease and impaired outcome after percutaneous coronary interventions. The aim of this study was to evaluate angiographic and clinical outcomes after the implantation of everolimus-eluting Xience V/Promus (EES) and sirolimus-eluting Cypher Select+ (SES) stents in patients with diabetes.
Methods: The study was a Danish multicenter, open-label, randomized trial. We randomized 213 patients with diabetes and coronary artery disease to EES (n=108) or SES (n=105) implantation. Angiographic follow-up was performed after 10 months. All patients were followed clinically for 18 months. The primary end point was angiographic in-stent late luminal loss. Secondary end points included angiographic restenosis rate, the need for target lesion revascularization (TLR) and major adverse cardiac events (MACE).
Results: At 10-month angiographic follow-up, in-stent late lumen loss was 0.20 ± 0.53 mm and 0.11 ± 0.49 mm (p=0.28), and angiographic restenosis rate was 3.8 % and 5.2 % (p=0.72) in the EES and SES groups, respectively. At 18-month clinical follow-up, MACE events had occurred in 15 (14%) patients in the EES group and 18 (17%) patients in SES group (p=0.53), with TLR performed in 5 (5%) and 8 (8%) patients in the two groups (p=0.37).
Conclusions: Stent implantation with EES or SES is associated with similar angiographic and clinical outcome in patients with diabetes mellitus and coronary artery disease.

POSTERS

Gender, Age, and Other Demographic Considerations

Hall D

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

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TCT-356

Circumferential Therapeutic Ultrasound for the Treatment of Resistant Hypertension: Preliminary Results of Human Feasibility Study (SOUND-ITV)

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Background: Renal artery sympathetic denervation using radiofrequency (RF) energy has been shown to reduce blood pressure in patients with resistant hypertension. However, energy forms like RF which rely on conductive heating cause transmural arterial damage before achieving denervation of the periarterial sympathetic nerve plexus. In vitro and pre-clinical testing has demonstrated that therapeutic ultrasound energy can induce differential injury to the nerve fibers while sparing the arterial wall. We now report on the preliminary results of a first-in-human feasibility trial with this novel therapeutic ultrasound system in patients with refractory hypertension.
Methods: Ten patients with a history of drug-resistant hypertension were enrolled in the SOUND-ITV study. The ultrasound catheter (Sound Interventions, Inc, Stony Brook, NY), incorporating a cylindrical transducer encased within a novel non-cylindrical, non-occlusive balloon was advanced into the renal arteries through a sheath. Ultrasound energy was delivered in a circumferential manner to both renal arteries; an average of 1.8 applications were delivered to each renal artery. Energy delivery time was less than 2 minutes per patient. Renal artery diameters ranged from 5.0-8.6 mm.
Results: Patients with a baseline systolic office BP > 160 mmHg demonstrated a significant reduction in the office BP at 1 month follow-up: the average BP drop of -31/-10 mmHg. All patients tolerated the procedures well with deep sedation. There was no device or energy-related spasm. Acutely and through follow-up, there were no device or procedure related complications. Arteries were assessed post procedure by angiography (n=10) and IVUS (n=7). No changes in arterial size were observed.

Conclusions: This first-in-man experience demonstrates the ability of circumferential intravascular therapeutic ultrasound to significantly improve blood pressure in patients with resistant hypertension. Longer term follow-up is necessary to confirm these results.

TCT-357

Trends and Outcomes Of Primary Percutaneous Coronary Intervention (PPCI) In Octogenarians Including A Comparison Between Radial and Femoral PPCI Strategies: A Single Centre Experience

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Background: An ageing UK population in combination with a preference for treating acute myocardial infarction (AMI) with PPCI has lead to an increase in the number of octogenarians treated with PPCI. The aim of the study was to provide an insight into clinical and procedural characteristics of octogenarian PPCI including in-hospital outcomes, mortality and a comparison between radial and femoral PPCI strategies.
Methods: From April 2007 to August 2011, consecutive octogenarians treated with PPCI at our institute were retrospectively included in the study cohort. Baseline characteristics, procedural results and in-hospital outcomes were analysed. A matched pair analysis was performed comparing 37 octogenarians with 37 patients < 80 years treated with PPCI in 2010. Finally, an intra-age analysis was performed comparing outcomes between radial and femoral PPCI procedures. All cause mortality was taken at end points of in-hospital, 30 days and 1 year.
Results: 177 octogenarians were treated with PPCI during the study period. The annual proportion of octogenarians increased significantly to as many as 1 in 5 cases (7.0% to 20.0%, p<0.05). Overall in hospital mortality was 14.7% (n=26) with the highest mortality in patients > 95 years (33.3%). Compared to patients < 80 years, octogenarians had significantly longer median procedural times (58 mins vs 43 mins, p < 0.05), median discharge times (5 days vs 3 days, p < 0.05) and more post procedural complications. In comparison to femoral PPCI, radial PPCI by high volume operators was associated with fewer vascular complications and shorter discharge times. Radial PPCI was associated with significantly lower mortality at 1 year than femoral PPCI, 11.1% (n=4) vs 28.5% (n=39) respectively (p<0.05).
Conclusions: The proportion of octogenarian PPCI patients has increased. This is a high risk population with longer procedures, more post procedural complications and longer discharge times compared to younger patients. The study demonstrated that radial PPCI by high volume operators resulted in fewer vascular complications, shorter discharge times and lower mortality at 1 year compared to femoral PPCI, consistent with recently published randomised trials.

TCT-358

Food And Drug Administration Approved Cardiovascular Medical Devices: A Ten Year Review Of The Participation Of Women And Ethnic Subgroups

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Background: For some diseases, different demographic subgroups may have different prevalence, diagnosis, disease progression and treatment outcomes. Although cardiovascular disease (CVD) is the number one killer for women and men, women have historically been underrepresented in cardiovascular clinical trials (CVCTs). To accurately assess sex differences in the safety and efficacy of medical devices, it is necessary to have representation of both sexes in clinical trials to allow for sex specific analysis. The purpose of this study was to assess the participation of women and ethnic subgroups in CVCTs submitted in support of medical device premarket applications (PMAs) approved by the US FDA from 2002 to 2011.
Methods: All CVCTs in approved PMAs between 2002-2011 were included in the study. Descriptive analyses of the study participants' ethnicity and sex were done. Demographic data from PMAs were analyzed in 12 month intervals to detect any trends in the participation of women and ethic subgroups.
Results: One hundred cardiovascular PMAs were approved between 2002 and 2011. One PMA was excluded from review as it addressed a pediatric population. Women's participation in PMA CVCTs was: 2002 (31.1%), 2003 (35.8%), 2004 (27.9%), 2005 (36.3%), 2006 (27.1%), 2007 (38.5%), 2008 (34%), 2009 (32.8%), 2010 (26.9%) and 2011 (39.6 %). The average women's percentage of participation in PMAs for this 10-year period was 32.9%. Twenty-one PMAs included ethnicity data with the following average participation rates: White (85.9 %), African American (8.3%), Hispanic (2.9%), Asian (1.3 %), Native Hawaiian (‹1%), Native American (‹1%), Other (1.3%).
Conclusions: This ten year review indicates that there is no recognizable trend and that women's participation in CVCTs in approved PMAs ranged from 26.9 to 39.6% over the ten year period. There is a need to increase reporting of data by ethnicity. An increase in the numbers of ethnic subgroups participating in CVCTs would allow for outcomes analysis in these populations.

TCT-359

Percutaneous Coronary Intervention In Octogenarians: Single High Volume United Kingdom Center Experience

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Background: Octogenarians constitute an increasing proportion of patients referred for percutaneous coronary intervention (PCI) for stable angina and acute coronary syndromes (ACS). However, there are limited outcome data for PCI in this group. We evaluated the outcome of PCI in patients aged ≥ 80 yrs and compared them with younger patients treated in our centre.
Methods: We analysed all patients aged ≥ 80 yrs who underwent PCI in our unit between Sept 2009 and Dec 2010. We defined major bleeding as the need for at-least one unit of red cell transfusion.
Results: Of the 2931 patients who underwent PCI in our unit during the study period, 401 (13.7%) patients were ≥80 yrs of age. Of these, 163 (40.6%) had primary PCI (PPCI) for STEMI, 120 (29.9%) had PCI for non ST elevation ACS (NSTEACS) and 118 (29.4%) had PCI for stable angina. The demographic, procedural data and mortality of octogenarians are compared with younger patients (Table 1). The total 30-day mortality for patients aged ≥ 80 yrs was 8.7% compared with 1.3% for those aged <80 yrs (P<0.0001). This highly significant mortality difference was almost entirely to a fivefold higher mortality in patients aged ≥ 80 yrs (20.2%) undergoing primary PCI (PPCI) for STEMI compared with younger patients (3.9%). (Table 1) In Octogenarians, non fatal MI, non fatal CVA and major bleeding occurred in 1.5%, 0.5% and 3.2% of all PCI patients, 2.5%, 0.6% and 3.1% of PPCI patients, 1.7%, 0% and 5% of patients undergoing PCI for NSTE-ACS, 0%, 0.85% and 0.85% of patients undergoing PCI for stable angina respectively.

n (%)	≥ 80 yrs n=401	<80 yrs n= 2530	p value
Age (mean±SD)	84 ± 4	63 ± 10.2	<0.0001
Male	225 (56.1)	1917 (75.8)	<0.0001
PPCI for STEMI	163 (40.6)	765 (30.2)	<0.0001
PCI for NSTE-ACS	120 (29.9)	739 (29.2)	0.77
PCI for stable angina	118 (29.4)	1026 (40.6)	<0.0001
Diabetes	70 (17.5)	402 (15.9)	0.38
Cardiogenic shock	15 (3.7)	54 (2.1)	0.07
Previous MI	135 (33.7)	599 (23.7)	<0.0001
Previous CABG	33 (8.2)	158 (6.2)	0.13
Previous PCI	55 (13.7)	488 (19.3)	0.007
No of stents (mean±SD)	1.55 ± 1.1	1.45 ± 0.9	0.05
LMS involvement (≥75% stenosis)	14 (3.5)	44 (1.7)	0.03
Single vessel PCI	303 (75.6)	2073 (81.9)	0.003
DES usage (at least 1 DES)	196 (48.9)	1667 (65.9)	<0.0001
In-hospital mortality	25 (6.2)	24 (0.9)	<0.0001
Total 30-day mortality	35 (8.7)	34 (1.3)	<0.0001
30-day mortality in PPCI	33 (20.2)	30 (3.9)	<0.0001
30-day mortality in NSTE-ACS	2 (1.7)	3 (0.4)	0.15
30-day mortality in Stable angina	0	1 (0.1)	1

Conclusions: In this consecutive series from a high volume tertiary centre, patients aged ≥ 80 yrs undergoing PCI have 30-day mortality rates similar to younger patients treated for stable angina or NSTEACS. Further studies are required to refine treatment strategies in unselected patients aged ≥ 80 yrs undergoing PPCI for STEMI.

TCT-360

Is there a Different of Management for ST-Elevation Myocardial Infarction regarding Gender? Myth or Reality? Data from a Prospective Registry of 5000 Patients

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Background: A few studies suggest a difference in management of ST elevation Myocardial Infarction (STEMI) by gender. We will evaluated this point and the implications from a prospective registry of 5000 patients.
Methods: We analyzed data collected in a 6 years period in the "Observatoire Régional Breton sur l'Infarctus (ORBI)", a prospective registry of STEMI patients admitted within 24 h of symptom onset to an interventional cardiology centre in

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