Conclusions: This first-in-man experience demonstrates the ability of cineru-.

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

Parisha Khan1, Pitt Lim2
1St George’s Hospital, London, London, 2St Georges’ Hospital, London, London, London

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 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 time (58 mins vs 43 mins, p < 0.05), median discharge time (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

Beverly Gallareze1, Dipali Dave1
1FDA, Silver Spring, MD

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 ethnic 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 distribution: 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

Refaj Showkathali1, Ed Boston-Griffiths1, Hetalkumar Patel1, Anil Ramoutar1, John Davies1, Alamgir Kabir1, Reto Gammul1, Jeremy Sayer1, Gerald Clesham1, Paul Kelly1, Rajesh Aggarwal1
1The Essex Cardiothoracic Centre, Basildon, United Kingdom

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 octoge-

narians are compared with younger patients (Table 1). The total 30-day mortality for patients ≥ 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 PCI patients, 1.7%, 0% and 5% of patients undergoing PCI for NSTE-ACS, 0% and 0.85% and 0.85% of patients undergoing PCI for stable angina respectively.

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

Marc Bedossa1, Guillaume Leurent1, Isabelle Couderc1, Philippe Druelles1, Jean Philippe Hacoc1, Benoit Miquel1, Dominique Boulmier1, Herve le Breton1
1Department of Cardiology, Rennes, France, 2Emergency Care Unit, Rennes, France, 3Clinique St Laurent, Rennes, France, 4CH Lorient, Lorient, France, 5CH St Breuc, St Brieuc, France

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 (ORB1)”, a prospective registry of STEMI patients admitted within 24 h of symptom onset to an interventional cardiology centre in

B102 JACC Vol 60/17/Suppl B | October 22–26, 2012 | TCT Abstracts/POSTER/Gender, Age, and Other Demographic Considerations
Brittany (France). Main data about clinical presentation and management were compared according to the gender.

**Results:** Among 5000 patients included in the ORBI registry, 1174 patients (23.5%) were women (mean age: 68.8±14 vs 60.8±12 for men, p<0.0001), with significant differences in their cardiovascular risk factors, especially hypertension (54 vs 36%, p<0.0001), dyslipidemia (44 vs 52%, p<0.0001) and current smoking (25 vs 41%, p<0.0001). As presented in table 1, there are some significant differences in the management of women: delays of reperfusion are longer, partially due to longer delays between symptom onset and call for medical assistance. Thrombolytic agents are less used in women, and coronary angiography is less performed. Moreover, morbi-mortality is higher in women: intra hospital women mortality is 9.0%, vs 4.4% for men (p<0.0001). Last, there is a significant underused in all of the recommend treatments at discharged.

### Table 1: Gender-based analysis of Everolimus-eluting stent safety in the Bern-Rotterdam cohort

<table>
<thead>
<tr>
<th>Prescription at discharge</th>
<th>Aspilone</th>
<th>Clopidogrel/Prasugrel</th>
<th>Beta blockers</th>
<th>Angiotensin-converting enzyme inhibitor</th>
<th>Statine</th>
<th>Cardiovascular rehabilitation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Men n = 3826</td>
<td>3584 (98%)</td>
<td>3506 (95%)</td>
<td>3349 (91%)</td>
<td>2481 (67%)</td>
<td>3475 (95%)</td>
<td>3577 (47%)</td>
</tr>
<tr>
<td>Women n = 1174</td>
<td>1022 (95%)</td>
<td>993 (93%)</td>
<td>940 (88%)</td>
<td>652 (62%)</td>
<td>955 (89%)</td>
<td>267 (27%)</td>
</tr>
</tbody>
</table>

*p-values* presented as median ± standard deviation.

**Conclusions:** Despite numerous awareness campaigns about management of STEMI in women, it still includes significant differences, resulting a higher morbidity and mortality.

---

**TCT-361**

Gender-based Analysis of Everolimus-Eluting Stent Safety in the Bern-Rotterdam Cohort

Giulio Stefanini1, Lorence Bühler1, Michael Magro2, Bindu Kalesan1, Masanori Tanaka1, Cihan Simsek3, Peter Wenaweser4, Ron Van Domburg4, Bernhard Meier1, Peter Juni3, Patrick Serruys4, Stephan Windecker4

1Bern University Hospital, Bern, Switzerland, 2Thoraxcenter, Erasmus MC, Rotterdam, Rotterdam, 3CTU Bern & Institute of Social and Preventive Medicine, Bern, Switzerland, 4Thoraxcenter, Erasmus MC, Rotterdam, Rotterdam

**Background:** Everolimus-eluting stents (EES) improve safety compared with early-generation sirolimus-eluting (SES) and paclitaxel-eluting stents (PES). However, it is unknown whether the benefits in terms of safety are consistent among female and male patients.

**Methods:** A total of 12,339 consecutive patients were treated at 2 academic institutions between 2002 and 2009, 11,954 patients – 3,112 women (26%) and 8,842 men (74%) – completed last follow-up and were included in this analysis. EES were implanted among 1,100 women (35%) and 3,001 men (34%), whereas early-generation SES or PES were used among 2,012 women (65%) and 5,941 men (66%). We performed a stratified analysis of clinical outcomes between EES and early-generation SES or PES according to gender. Adjustment was performed with inverse probability of treatment weighting. Primary endpoint was ARF definite stent thrombosis (ST).**

**Results:** During follow to 4 years (median 2.9 years), the use of EES reduced the risk of definite ST to a similar extent in women (RR 0.41, 95%CI 0.28-0.59) and men (RR 0.40, 95%CI 0.20-0.78; p-interaction=0.95) compared with early-generation SES and PES. This was paralleled by a similar reduction in the risk of myocardial infarction with EES over early-generation SES and PES among women (RR 0.59, 95%CI 0.46-0.77) and men (RR 0.47, 95%CI 0.29-0.75; p-interaction=0.52), as well as the composite of cardiac death and myocardial infarction among women (RR 0.72, 95%CI 0.56-0.84) and men (RR 0.82, 95%CI 0.65-1.04; p-interaction=0.32). In addition, EES provided a comparable efficacy benefit in terms of target-vein revascularization among women (RR 0.69, 95%CI 0.59-0.80) and men (RR 0.52, 95%CI 0.39-0.70; p-interaction=0.32) compared with early-generation SES and PES.

**Conclusions:** Newer generation EES provide a similar safety benefit among women and men, with a consistent reduction in the risk of definite ST and myocardial infarction compared with early-generation SES and PES during long term follow-up.

---

**TCT-362**

Incidence, background, treatment strategies and the prognosis in very elderly patients with acute myocardial infarction – from Japanese multicenter database

Takafumi Yamane1, Junichi Kotani1, Hiroki Sakamoto2, Masaharu Ishihara1, Yoshinori Araya3, Wataru Shinzu1, Satoshi Yasuda1, Hideo Kasuoka1, Hiroyuki Yokoyama1

1National Cerebral and Cardiovascular Center, Osaka, Japan, 2National cerebral and cardiovascular center, Osaka, Japan, 3Osaka National Hospital, Osaka, Japan

**Background:** Aging society has changed the component of the population in world wide, especially Japan is the most progressive. Therefore, classifying elderly patients, particularly those 75 years and older, as a single cluster may overlook differences in elderly patients. The aim of this study was to investigate how difference of clinical characteristics and outcomes of elderly hospitalized with acute myocardial infarction (AMI) vary based on age.

**Methods:** We analyzed 3723 consecutive patients who enrolled as AMI from 27 hospitals during 2005 to 2009 in Japan. We categorized patients into four groups based on their age: younger than 65 years (n=1418), 65 to 74 years (n=1027), 75 to 84 years (n=935) and 85 years and older (n=343).

**Results:** Older patients were more likely to be women and to have hypertension, renal insufficiency, less likely to have dyslipidemia, diabetes, smoking. Primary percutaneous coronary intervention (PCI) was performed at a high frequency in all groups (88.9% vs 86.3% vs 81.3% vs 73.8%; P<0.0001, respectively). In-hospital mortality rate rose gradually with age. (28 vs 6.4% vs 12.5% vs 19.8%; P<0.0001, respectively), and the same tendency can be seen whether they received primary PCI (2.6% vs 4.9% vs 9.6% vs 16.2%; P<0.0001, respectively) or not (3.8% vs 16.3% vs 25.1% vs 30.0%; P=0.0001, respectively). In multivariable analysis, age was one of the important predictor of in-hospital mortality.

**Conclusions:** Despite high prevalence of primary-PCI in elderly in Japan, aging is strongly associated with in-hospital mortality.