## STEMI and High Risk Patients Moscone West, 2nd Floor, Room 2003 Tuesday, October 29 2013, 1:00 PM-3:15 PM

Abstract nos: 40-48

## TCT-40

BASELINE BLEEDING RISK AND ARTERIAL ACCESS SITE PRACTICE IN RELATION TO PROCEDURAL OUTCOMES FOLLOWING PERCUTANEOUS CORONARY INTERVENTION

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Background: Transradial access (TRA) has been associated with reduced access site related bleeding complications and mortality following percutaneous coronary intervention (PCI), although it is unclear whether these observed benefits are influenced by baseline bleeding risk. We have therefore investigated this relationship by quantifying baseline bleeding risk, TRA utilisation and procedure related outcomes in a large number of patients undergoing PCI enrolled in the British Cardiovascular Intervention Society (BCIS)database of PCI procedures performed in the United Kingdom.

**Methods:** Baseline bleeding risk was calculated using a modification of the Mehran bleeding risk scores in 348,689 PCI procedures undertaken in patients in the United Kingdom between 2006 - 2011. Four categories for bleeding risk were defined for the modified Mehran risk score (MMRS): low (<10), moderate (10-14), high (15-19), and very high (>20). The impact of baseline bleeding risk on 30 day mortality and its relationship with access site was studied.

**Results:** TRA was independently associated with a 35% reduction in 30-day mortality (OR 0.65, 95% CI 0.59-0.72, p<0.0001), with the magnitude of mortality reduction related to baseline bleeding risk (MMRS < 10: OR 0.73; 95% CI 0.62-0.86); MMRS >20 (OR 0.53; 95% CI 0.47-0.61). In patients with a MMRS <10, TRA was used in 71,771/166083 PCI procedures (43.2%) compared to 8,655/21559 (40.1%) patients with MMRS >20, illustrating that TRA was used less in those at highest risk from bleeding complications (P<0.0001).

Conclusions: TRA is independently associated with a reduction in 30-day mortality and the magnitude of this mortality effect relates to baseline bleeding risk, with those at highest risk of bleeding complications gaining the greatest benefit from adoption of the TRA during PCI. Paradoxically, use of TRA was lower in those patients most at risk of bleeding complications. Our data suggests that adopting optimal access site practice guided by simple assessment of baseline bleeding risk, has the potential to significantly improve PCI related patient outcomes.

## TCT-41

One-year Results From the MASTER Trial, a Prospective, Randomized, Multicenter Evaluation of an Embolic Protection Stent (MGuard) in Patients with STEMI Undergoing Primary PCI

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**Background:** Suboptimal myocardial reperfusion in pts with STEMI undergoing primary PCI is common, and results in increased infarct size and mortality. The MGuard is a novel thin strut bare metal stent with a PET mesh covering designed to trap and exclude thrombus and friable atheromatous debris prior to distal embolization. We performed a prospective, randomized, multicenter trial to evaluate whether use of the MGuard stent improves myocardial reperfusion in pts with STEMI undergoing primary PCI.

Methods: Pts with symptoms of AMI undergoing PCI of a single de novo native coronary lesion were eligible for enrollment, and were randomized 1:1 to PCI with

either the MGuard stent or any commercially available DES or BMS. The primary endpoint was the rate of complete ( $\geq 70\%$ ) ST-segment resolution (STR) 60-90 mins post-procedure. Secondary endpoints included TIMI flow, clinical outcomes through 1 year, and lumen late loss and binary restenosis at 13 months in 50 MGuard patients. **Results:** The primary endpoint of post-procedure complete ST-segment resolution was significantly improved in patients randomized to the MGuard stent compared with control patients (57.8% vs. 44.7%; p=0.008). The MGuard stent also resulted in superior rates of TIMI-3 flow (91.7% vs. 82.9%, p=0.006). Mortality (0% vs. 1.9%, p=0.06) and major adverse cardiae events (1.8% vs. 2.3%, p=0.75) at 30 days were not significantly different between patients randomized to the MGuard stent and control stent, respectively. Twelve month follow-up is ongoing.

Conclusions: MASTER is the first large randomized trial evaluating the ability of a novel mesh covered stent to improve myocardial reperfusion in patients with STEMI undergoing primary PCI. The MGuard embolic protection stent compared with conventional metal stents resulted in superior rates of epicardial coronary flow and complete STR. Complete analysis of the final 12-month clinical results and the 13-month angiographic endpoints will be presented at the meeting.

## TCT-42

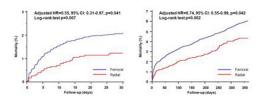
Superior Outcomes Associated With Radial Versus Femoral Access In Non-ST Elevation Myocardial Infarction: An Observational Cohort Study of 10,095 patients. Results Of The Radial Versus Femoral Access In Mortality Reduction In Non-ST Elevation Myocardial Infarction (REALITY-NSTEMI) Study

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Background: Compared with trans-femoral access (TFA), trans-radial access (TRA) reduces mortality in ST elevation MI (STEMI). Whether TRA confers a mortality benefit in non-ST elevation MI (NSTEMI) is unclear. This study sought to compare TRA versus TFA for percutaneous coronary intervention (PCI) in patients with NSTEMI

Methods: We examined an observational cohort of 10,095 patients with NSTEMI treated with PCI between 2005-2011 at 8 tertiary cardiac centers in London, UK. The following clinical outcomes were analyzed: all cause mortality; MACE (major adverse cardiovascular events); and NACE (net adverse cardiovascular events: MACE combined with bleeding events).

**Results:** Over a 6 year period, TRA was used in 23% of patients. TRA was associated with a significant reduction in bleeding (0.23% vs. 0.97%, p=0.001) and access site complications (0.35% vs. 1.00%, p=0.003). Multivariate analysis identified TRA as independent predictor for in-hospital MACE (OR=0.60, 95% CI:0.38-0.93, p=0.023); in-hospital NACE (OR=0.68, 95% CI:0.45-0.97, p=0.033); 30-day mortality (HR=0.55, 95% CI:0.31-0.97, p=0.041); 6-month mortality (HR=0.59, 95% CI:0.41-0.87, p=0.007); 1-year mortality (HR=0.74, 95% CI:0.55-0.99, p=0.042). When excluding patients with bleeding events, TRA still remained an independent predictor for survival.



Conclusions: In this large registry of patients with NSTEMI, TRA appears to be an independent predictor for survival. These data indicate that other factors besides a reduction in bleeding may be contributory and lend support for prospective randomized evaluation of TRA in NSTEMI.