

## LATE-BREAKING CLINICAL TRIALS

### ACUTE CORONARY SYNDROMES (STEMI, NSTEMI, ACS) (TCTAP A-001)

#### TCTAP A-001

##### The Temporal Trends of Incidence, Treatment, and In-Hospital Mortality of Acute Myocardial Infarction over 15 Years in a Taiwanese Population

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**BACKGROUND** The study was conducted to examine the nationwide temporal trends of incidence, treatment, and short-term outcomes for acute myocardial infarction (AMI) over a 15-year period in Taiwan.

**METHODS** We identified patients who were hospitalized for incident AMI between 1997 and 2011 from the inpatient medical claim data set of the National Health Insurance Research Database. Age- and sex-adjusted incidence and in-hospital mortality rates were calculated for AMI, and separately for ST-segment elevation and non-ST-segment elevation myocardial infarction (STEMI and NSTEMI).

**RESULTS** A total of 144,634 patients were identified. The incidence rates (per 100,000 populations) of AMI increased from 30 in 1997 to 42 in 2011, which was mainly driven by the increase of NSTEMI. The in-hospital mortality rate after AMI decreased from 9.1% in 1997 to 6.5% in 2011, which was also driven by the case mortality rate for NSTEMI. Although the in-hospital mortality rates significantly decreased from 7.3% to 5.1% between 1997 and 2003 for STEMI, it did not change significantly from 2004 to 2011. Moreover, AMI patients undergoing revascularization treatment, particularly PCI, was the most important independent predictor for improved in-hospital survival.

**CONCLUSION** The results of this study demonstrated a recent dramatic increase in the incidence rates and a decrease in short-term mortality in patients with NSTEMI; whilst the incidence and in-hospital mortality of STEMI only modestly changed over time in Taiwan. Further quality improvement approaches for AMI prevention and treatment to favorably affect the incidence and outcomes from both.

### CHRONIC TOTAL OCCLUSION (TCTAP A-002)

#### TCTAP A-002

##### Clinical Outcomes of Re-Attempt Percutaneous Coronary Intervention for Chronic Total Occlusion: Insights from Japanese Retrograde Summit Registry

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**BACKGROUND** According to previous reports, patients with previously failed or not attempted chronic total occlusion (CTO) percutaneous coronary intervention (PCI) had a poor clinical outcome including significantly higher rate of cardiac mortality, therefore, CTO recanalization should be considered. On the other hand, CTO lesions which had previously attempted PCIs but failed were independent predictors as successful interventional revascularization in itself. Moreover, clinical outcomes of re-attempt PCI for CTO have not been well elucidated.

The aim of this study is to evaluate clinical outcomes of re-attempt PCI for CTO lesions which had previously attempted but failed, compared to initial attempted PCI for CTO lesions via the Japanese Retrograde Summit Registry.

**METHODS** The data of 3,185 cases between January 2009 and December 2013 from 56 centers in Japan were used for the analysis to clarify efficacy and safety of re-attempt CTO-PCI. The patients were classified into two groups whether the CTO-PCI was attempted followed previous unsuccessful procedure or initial attempt.

**RESULTS** 325 patients received re-attempted CTO-PCI (10.2%), of those 102 (31.4%) cases were treated by same operator as previous procedure. Re-attempted group had more lesion complexities, especially which had significantly higher mean J-CTO score ( $2.78 \pm 0.99$  vs.  $1.41 \pm 0.98$ ,  $p < 0.0001$ ). CTO-PCIs in the right coronary artery were more often undertaken in both groups. Procedure success rate was significant low in the re-attempted group (82.5% vs. 89.1%,  $P = 0.004$ ). On the other hand, re-attempted CTO-PCI lesions were treated more frequently with the retrograde approach (63.8% vs. 28.0%,  $p < 0.0001$ ) and had longer procedural times, fluoroscopic times, higher radiation dose and more contrast administration compared to initial attempted CTO-PCI lesions. Moreover, success rate of re-attempt PCI that performed same operator is also significant low compared to different operator (67.7% vs. 89.2%,  $P = 0.004$ ). No significant differences were observed in occurrence of MACCE and other complications. Calcified lesion was an independent predictor of procedure failure.

**CONCLUSION** Re-attempted CTO-PCI lesions were more complicated, therefore it might be required to pursue successful interventional revascularization with complex procedure including higher use of the retrograde approach. However, the results indicate that the safety and efficacy of re-attempt CTO-PCI, in that case the preoperative evaluation of lesion calcification and selection of the operator should be considered carefully.

### BIORESORBABLE VASCULAR SCAFFOLDS (TCTAP A-003 AND TCTAP A-004)

#### TCTAP A-003

##### Two Years Results Following Bioresorbable Vascular Scaffold Implantation in ST-Segment Elevation Myocardial Infarction Patients

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**BACKGROUND** The first experiences with bioresorbable vascular scaffold (BVS) in STEMI patients showed that the implantation of this device during primary PCI (PPCI) is feasible and associated with encouraging early and mid-term efficacy outcomes. However concerns raised about BVS safety because a not negligible thrombosis rate was reported within the first 30 days after implantation. Since no data are currently available on very late (>12 months) BVS performance after PPCI, we evaluated the 2-years clinical outcomes following BVS implantation in the STEMI setting.

**METHODS** A multicenter prospective cohort analysis was performed on consecutive STEMI patients who underwent PPCI with BVS implantation (within the Registro Absorb Italiano: RAI Registry. Clinical Trials.gov Identifier: NCT02298413). End-point of this analysis was the occurrence of a device oriented composite end-point (DOCE: cardiac death, target vessel myocardial infarction [TV-MI], ischemia-driven target lesion revascularization [ID-TLR]) at 24 months follow-up.

**RESULTS** Between December 2012 and February 2014, 1,232 STEMI patients underwent primary PCI at the participating centers. Of these, 74 (6.0%) received a BVS, 18 (24.3%) of them were multiple and overlapping. Mean patient age was  $54.4 \pm 10.5$  years. Final TIMI 3 flow was obtained in 73 (98.6%) cases. Within 30 days follow-up 2 (2.7%) patients experienced a non fatal TV-MI due to sub-acute BVS thrombosis while on dual anti-platelet therapy (DAT). Between 30 days and 24-months we reported: 1 (1.3%) non fatal TV-MI due to very late BVS thrombosis (16 months after the index procedure, 2 days after DAT discontinuation) and 2 (2.7%) ID-TLR (both within 12 months). All the events were successfully managed with re-PCI. The DOCE at 24 months follow-up occurred in 6.7% of patients (5/74).

**CONCLUSION** Our long-term follow-up in a consecutive cohort of STEMI patients treated with BVS implantation shows that DOCE rate is relatively low. Larger studies are needed to better assess the potential influence of BVS implantation techniques and DAT duration on early and late/very late BVS failure in STEMI patients.