TCT-24

Long-Term Clinical Outcomes For Primary Angioplasty with Resolute Zotarolimus Eluting Stent in ST-Segment Elevation Acute Myocardial Infarction

Carlo Di Mario[1], Stephan Windecker[2]
[1]Imperial College London, London, United Kingdom, [2]Bern University Hospital, Bern, Switzerland

Background: Historically bare metal stents were considered standard of care for ST-segment elevation acute myocardial infarction (STEMI). There is limited data on STEMI patients treated for primary angioplasty with ResoluteTM zotarolimus-eluting stent (R-ZES) and the everolimus-eluting stent (EES).
Methods: The global RESOLUTE program enrolled STEMI patients in 4 trials: RESOLUTE-All Comers (RAC), RESOLUTE International, RESOLUTE China, and RESOLUTE China Registry. The multicenter R-AC trial randomized patients to R-ZES vs. EES. STEMI was a prespecified subset analysis. Target Lesion Failure (TLF) was defined as a composite of death from cardiac causes (CD), target vessel myocardial infarction (TV-MI), and target lesion revascularization (TLR). Stent thrombosis (ST) was defined as ARC definite/probable ST.
Results: Among 7618 patients who received R-ZES in the pooled RESOLUTE clinical program, 854 had STEMI. Mean age was 59±12 years, 81% of patients were men, 23% had diabetes mellitus, and patients had on average 1.4±0.7 lesions treated. The 4-year Kaplan-Meier incidence of TLF was 11.5%, TLR 4.8%, CD/TV-MI 8.2%, CD 5.5%, TV-MI 2.7%, and ST 1.9%. Among the 2292 patients randomized in R-AC, 122 STEMI patients were treated with R-ZES and 158 with EES. There were no significant differences at 5 years in TLF, TLR, CD, TV-MI, or ST, but there was a significant reduction in all cause death / TV-MI with R-ZES (5.1% vs 9.0%, p=0.036) (Table).
Conclusions: A pooled analysis of complex STEMI patients treated with R-ZES found R-ZES to be associated with excellent and sustained clinical outcomes. Additionally, long-term outcomes with R-ZES in STEMI patients were numerically lower than or similar to EES; however, R-ZES had a significant reduction in all cause death/TV-MI as compared to EES at 5 years. Submitted on behalf of the RESOLUTE Global Clinical Program.

	R-ZES (N=118)	EES (N=155)	p-value
Target Lesion Failure, % (n)	7.6% (9)	10.3% (16)	0.528
Target Lesion Revascularization, % (n)	2.5% (3)	1.9% (3)	1.00
All cause death	5.1% (6)	12.3% (19)	0.055
Cardiac death	3.4% (4)	5.8% (9)	0.404
Non cardiac death	1.7% (2)	6.5% (10)	0.075
CD/TV-MI, % (n)	5.1% (6)	9.0% (14)	0.248
All cause death/TV-MI	6.8% (8)	15.5% (24)	0.036
ARC Definite/Probable Stent Thrombosis, % (n)	0.8% (1)	1.3% (2)	1.00

TCT-25

A Real-World Single Centre Experience Using The Self–Expanding Coronary Stent

Luca Mariani[1], Pierfrancesco Grossi[1], Simona Silenzi[1], Stefano Volpe[1], Procolo Marchese[1], Luciano Moretti[1]
[1]Mazzoni Hospital, Ascoli Piceno, Italy

Background: A coronary self-expanding stent (Stentys S.A., Paris, France) may overcome the drawback of difficult stent sizing and avoid stent malapposition with consequent risk of restenosis and thrombosis. This feature should be particularly useful in case of primary percutaneous coronary interventions (PCI) in patients with ST-elevation myocardial infarction (STEMI) or in the presence of complex coronary anatomy like coronary ectasia (a segment of artery > 1.5 times the diameter of adjacent segments) or bifurcations.
Methods: We tasted the efficacy and safety of this stent in consecutive patients undergoing PCI in our centre. The decision to use a self-expanding stent was at discretion of the operator. The primary endpoint was the composite of the following major adverse cardiac and cerebrovascular events (MACCE) at 12 months: death, recurrence of myocardial infarction, target vessel revascularization (TVR) and stroke.
Results: 82 patients (mean age: 64 +/-15; men: 83%; diabetes: 22%) treated with a self-expanding stent were enrolled. The indications for PCI were STEMI in 62%, non ST-elevation myocardial infarction (NSTEMI)/unstable angina in 21%, and stable angina in 17%. 40% of patients had ectatic coronary arteries (with a vessel diameter > 4.5 mm) and 18% coronary bifurcated lesions. DES/BMS ratio was 56/26. Two patients (2.4%) experienced MACCE at 12 months. In both of them a geographic miss during stent deployment with non complete coverage of the lesion leads to TVR after few months.
Conclusions: The self-expanding stent showed a low rate of clinical events in routine clinical practice. This stent is particularly useful in case of difficult stent sizing like STEMI, coronary ectasia or bifurcations. Self-expanding stent deployment is different compared to the traditional stents and a learning curve is needed in order to avoid geographic miss and achieve a good result of the procedure.

TCT-26

Comparison of everolimus-eluting and paclitaxel-eluting coronary stents in patients undergoing primary percutaneous coronary intervention: 5 year follow-up from the COMPARE I trial

Georgios J. Vlachojannis[1], Kees-Jan Royaards[1], Marielle A. Koper[1], Adriaan O. Kraaijeveld[1], Bianca M Boxma-de Klerk[1], Jochem Wassing[1], Martin van der Ent[1], Pieter C. Smits[2]
[1]Maasstad Hospital, Rotterdam, Netherlands, [2]Maasstad Hospital Rotterdam, Rotterdam, Netherlands

Background: Long-term all-comers data of the current generation everolimus-eluting stent (Xience™ V, Abbott Vascular, Santa Clara, CA, USA) compared to the first generation paclitaxel-eluting stent (Taxus™ Liberté, Boston Scientific, Natick, MA, USA; PES) in patients undergoing primary percutaneous coronary intervention (PCI) for ST-elevating myocardial infarction (STEMI) are scarce.
Methods: The COMPARE I study was a prospective, randomized, single-center, all-comers trial randomly allocating patients to receive either EES or PES (1:1). It is to date the only randomized trial comparing EES to PES in a true all-comers population with an independent adjudicated 5-year follow-up. We performed a post-hoc sub-analysis in patients treated with primary PCI. The pre-specified endpoint was major adverse cardiovascular events (MACE) defined as the composite of the safety endpoints death or myocardial infarction (MI) and the efficacy endpoint target vessel revascularization (TVR).
Results: Of the 1800 study patients, 452 patients underwent primary PCI for STEMI (25.1%) of whom 240 were treated with EES and 212 with PES. At 5 years EES was superior to the PES with a significant lower incidence of the endpoints MACE and TVR. Moreover, EES showed a trend for reduction in MI and target lesion revascularization. No significant differences were found in rates of death and definite/probable stent thrombosis. The 5 year outcomes are tabulated.

Events at 5 years	EES (n=240)	PES (n=212)	Relative Risk [95% CI]	p-value
Death	6.7% (16)	8.5% (18)	0.79 [0.41-1.50]	0.46
Myocardial Infarction	6.7% (16)	10.8% (23)	0.61 [0.33-1.13]	0.11
Target Vessel Revascularization	5.8% (14)	11.3% (24)	0.51 [0.27-0.97]	0.04
Target Lesion Revascularization	5.4% (13)	9.4% (20)	0.57 [0.29-1.12]	0.10
Def./Prob. Stent Thrombosis	3.8% (9)	4.7% (10)	0.80 [0.33-1.92]	0.61
MACE (Primary Endpoint)	14.6% (35)	23.1% (49)	0.63 [0.42-0.93]	0.02

Conclusions: At 5-years EES reduced significantly MACE in patients treated with primary PCI for STEMI compared to PES which was mainly driven by lower rates of TVR.

TCT-27

Comparison of Novel Zotarolimus-Eluting Cobalt-Chromium Stents and Everolimus-Eluting Platinum-Chromium Stents in Patients of the Randomized DUTCH PEERS Trial Presenting with Acute Myocardial Infarction

Clemens von Birgelen[1], Marije M. Löwik[2], Ming Kai Lam[2], Hanim Sen[2], Peter W. Danse[3], Gillian A. Jessurun[4], Melvyn Tjon Joe Gin[5], Rutger Anthonio[6], Frits H. de Man[7], Raymond Hautvast[5], Gerard C. Linssen[8], Liefke van der Heijden[9], Kenneth Tandjung[2], Carine J. Doggen[10], Gert van Houwelingen[2]
[1]Thoraxcentrum Twente & University of Twente, Enschede, The Netherlands, [2]Thoraxcentrum Twente, The Netherlands, [3]Rijnstate Hospital, The Netherlands, [4]N/A, Emmen, Netherlands, [5]Department of Cardiology, Rijnstate, Arnhem, The Netherlands, Arnhem, Gelderland, [6]Scheper Hospital, The Netherlands, Medical Center Alkmaar, The Netherlands, [7]Thoraxcentrum, Medisch Spectrum Twente, Enschede, Overijsel, [8]Ziekenhuisgroep Twente, The Netherlands, University of Twente, The Netherlands, [9]Thoraxcentrum MST, Enschede, Overijssel, [10]MIRA – Institute for Biomedical Technology and Technical Me, Enschede, Netherlands

Background: Biocompatible durable polymer coatings for drug-eluting stents (DES) were developed to reduce the risk of stent thrombosis, which is generally increased in the setting of acute myocardial infarction (MI). These coatings are used on novel, flexible, and highly deliverable third-generation DES, investigated in the randomized, multicenter, all-comer DUTCH PEERS (TWENTE II) trial. Of the 1,811 eligible all-comer patients of DUTCH PEERS, 817 (45%) were treated in the setting of acute MI.
Methods: We assessed the one-year safety and efficacy of the Resolute Integrity zotarolimus-eluting stent (ZES) (Medtronic, Santa Rosa, CA, USA) and Promus Element everolimus-eluting stent (EES) (Boston Scientific, Natick, MA, USA) in 817 DUTCH PEERS patients who were treated for acute MI. One-year follow-up data of

all patients were obtained; adverse events were externally adjudicated by an independent committee. The primary endpoint was target vessel failure (TVF) at 1-year, a composite of cardiac death, target vessel related MI, and clinically indicated target vessel revascularization. Secondary endpoints included all the individual components of the primary endpoint, the incidence of stent thrombosis (ST), and the patient-oriented clinical endpoint (POCE).
Results: Patient and lesion characteristics did not differ between groups with the only exception being higher proportions of severely calcified lesions (87/548(16%) vs. 108/500(22%), p=0.02) and stent postdilatation in EES (402/548 (73%) vs. 400/500 (80%), p=0.01). At one year, TVF did not differ significantly between the two stent arms (20/421(5%) vs. 15/396 (4%, p=0.50). In addition, POCE was 8% (32/421) for ZES and 6% (23/396) for EES (p=0.31). Definite-or-probable ST rates were very low and similar in both groups (2/421 (0.5%) vs. 1/396 (0.3%), p=1.00).
Conclusions: One-year follow-up of DUTCH PEERS patients, who were treated for acute MI, demonstrated excellent clinical results with a similar and sustained safety and efficacy of the Resolute Integrity ZES and the Promus Element EES.

TCT-28

Comparison Of Outcomes For Primary Percutaneous Coronary Intervention During Out Of Working Hours Versus In Working Hours: An Observational Cohort Study Of 11,461 Patients

M Bilal Iqbal[1], Charles D. Ilsley[1], Ghada Mikhail[2], Ramzi Khamis[2], Andrew Archbold[3], Tom Crake[4], Sam Firoozi[5], Sundeep S. Kalra[6], Charles Knight[3], Pitt Lim[5], Anthony Mathur[3], Pascal Meier[4], Roby Rakhit[7], Simon Redwood[8], Mark Whitbread[9], Dan Bromage[3], Krishnaraj Rathod[3], Andrew Wragg[3], Philip A. MacCarthy[10], Miles C. Dalby[1], Iqbal S. Malik[2]
[1]Royal Brompton & Harefield NHS Foundation Trust, Middlesex, United Kingdom, [2]Imperial College Healthcare NHS Trust, London, United Kingdom, [3]Barts Health NHS Trust, London, United Kingdom, [4]University College London Hospital NHS Foundation Trust, London, United Kingdom, [5]St Georges Hospital NHS Trust, London, United Kingdom, [6]King's College Hospital NHS Foundation Trust, London, United Kingdom, [7]Royal Free London NHS Foundation Trust, London, United Kingdom, [8]King's College London/ St Thomas' Hospital, London, United Kingdom, [9]London Ambulance Service, London, United Kingdom, [10]King's College London, London, United Kingdom

Background: Primary percutaneous coronary intervention (PPCI) is the treatment of choice for ST-elevation myocardial infarction (STEMI). The optimum delivery of this service requires an integrated, multi-disciplinary, consultant-led, protocol-driven approach. It is widely recognised that resources including availability of medical personnel are limited during out of working hours, particularly at night. Currently, it is unclear whether PPCI during working hours is associated with improved outcomes.
Methods: We conducted an observational analysis for 11,461 patients with STEMI who underwent PPCI between 2004-2011 at all 8 tertiary cardiac centres in London, UK. The primary outcome was all-cause mortality at 1 year. We defined working hours as 9am-5pm (Mon-Fri). We compared outcomes in patients treated out of working hours (OWH) versus in working hours (IWH). Cox-proportional hazard models built using a stepwise variable selection process were used to determine independent predictors for mortality. We used propensity-based matching methods to adjust for measured confounders; and instrumental variable analyses to adjust for non-measured confounders.
Results: Of the 11,461 patients in the analysis, 7494 patients (65.3%) were treated with PPCI during OWH. There was no difference in 1-year mortality rates when comparing OWH vs. IWH (8.6% vs. 7.8%, p=0.151). Multivariate analysis demonstrated that PPCI during OWH was not a predictor for 1-year mortality (HR=1.11, 95%CI: 0.94-1.32, p=0.201). When stratifying OWH into 2-hourly intervals, multivariate analyses demonstrated that there was no particular time interval that was associated with increased mortality. When analysing 5228 patients in propensity-matched cohorts, again, PPCI during OWH was not a predictor for 1-year mortality (HR=1.10, 95%CI: 0.90-1.34, p=0.356). Using enrollment year as an instrumental variable, PPCI during OWH did not affect mortality (absolute difference=2.1%, 95% CI:-12.6%,16.8%, p=0.888).
Conclusions: In this observational analysis of unselected STEMI patients, PPCI outside routine working hours compared to within routine working hours is safe with no difference in 1-year mortality.

TCT-29

CLINICAL AND ANGIOGRAPHIC PROFILE OF PATIENTS UNDERGOING PRIMARY: DATA FROM FIRST NATIONWIDE REGISTRY

ABDURRAZZAK GEHANI[1], SALAH ARAFA[1], A/RAHMAN ARABI[1], MAGDIH YACOUB[2]
[1]HEART HOSPITAL, DOHA, Qatat, [2]QCRC, QATAR, DOHA, Qatat

Background: This briefly describes the set up and the preliminary results of the "first Nationwide" 24/7 Primary PCI for ST-Elevation Myocardial Infarction Program in the gulf region.
Methods: In our center over 3500 diagnostic and 1500 Interventional PCI, including Primary PCI procedures were performed in 2013. With this experience, we proceeded to setup a nationwide Primary PCI program such that all patients with St-Elevation Myocardial Infarction (STEMI) were referred seamlessly for immediate Primary PCI through coordination of all Cardiology, Emergency and Ambulance services in the whole country, and under one control and command center. Since its establishment, we hereby report 422 patients underwent Primary PCI in 6 months. The clinical and angiographic data were collected and analyzed.
Results: Primary PCI was performed in 422 patients with STEMI (10 months data will be presented at the conference). The mean age was 50+/-9.5 years. The program allowed faster and direct transfer of patients to the Primary PCI facility leading very short Door-to-Balloon Time (DBT) of 52.8±25 min (>94% of patients were < 90 min). For those referred from non-Primary PCI facility, 77% had DBT of < 120 min (as stated in the guidelines)(mean of 80±20.7 min). The overall in-hospital mortality for Primary PCI patients was 2.8%. Radial approach was used in nearly half the patients (43.5%) and femoral in the other 56.5% with similar DBT for both. More precisely, the time from arrival to Cath lab to Balloon Dilatation (procedure time) was similar for both approaches 18.6±8.3 min for femoral) and (17±7.2 min for Radial). Overall, less than TIMI III flow (i.e. TIMI 0, I or II) was found in 85% of patients before Primary PCI, of these, full TIMI III flow was achieved in 93% of those cases. Achievement of this TIMI III flow was also similar between Femoral and Radial approaches.
Conclusions: This is the first coordinated "Nationwide" Primary PCI program in the gulf region. The data emphasize how good communication allows Primary PCI for all STEMI patients, at a very short DBT and with low in-hospital mortality. Radial and Femoral approaches were used almost equally with similar achievement of TIMI III flow and procedure time.

TCT-30

Clinical Predictors and Long-term Impact of Enzymatic Infarct Size After Primary PCI in STEMI: The HORIZONS-AMI Trial

Tomotaka Dohi[1], Akiko Maehara[2], Bernhard Witzenbichler[3], Ke Xu[4], Melissa Nichols[4], Sorin Brener[5], Roxana Mehran[6], Gary S. Mintz[7], Gregg W. Stone[8]
[1]Columbia University Medical Center and Cardiovascular Research Foundation, New York, NY, [2]Cardiovascular Reserach Foundation and Columbia University Medical Center, New York, United States, [3]Charité Campus Benjamin Franklin, Berlin, Germany, [4]Cardiovascular Research Foundation, New York, NY, [5]New York Methodist Hospital, Brooklyn, United States, [6]Icahn School of Medicine at Mount Sinai, New York, NY, [7]Cardiovascular Research Foundation, Washington, United States, [8]Columbia University Medical Center and the Cardiovascular Research Foundation, New York, United States

Background: We sought to elucidate: 1) the predictors of enzymatic infarct size assessed by peak CK-MB in pts with ST-segment elevation myocardial infarction (STEMI) undergoing primary percutaneous coronary intervention (PCI); and 2) the impact of peak CK-MB on cardiac mortality at 3 years.
Methods: HORIZONS-AMI was a prospective, open-label, multicenter, dual-arm, 2×2 factorial randomized trial in pts with STEMI presenting < 12 hours after symptom onset. The 2 randomization arms consisted of 1) bivalirudin alone vs heparin plus a glycoprotein IIb/IIIa inhibitor; and 2) TAXUS paclitaxel-eluting stents (PES) vs bare metal stents (BMS). We evaluated infarct size according to peak CK-MB ratio (peak-CK-MB/upper limit of normal [ULN]).
Results: Peak CK-MB ratio was available in 3068 of 3345 patients (91.7%). Median peak CK-MB ratio was 13.9 (IQR 5.8 to 32.4). By linear regression, the independent predictors of peak CK-MB ratio were US location (p< 0.0001), LAD culprit location (p< 0.0001), baseline TIMI grade 0/1 flow (p< 0.0001), and post-stent balloon dilatation (p=0.04). Beta-blocker use before PCI predicted lower peak CK-MB (p=0.03). In a covariate-adjusted Cox regression model, peak CK-MB ratio was an independent predictor of 3-year cardiac mortality (Table).

Table. Independent Predictors of 3-year Cardiac Mortality

	Hazard ratio	95% Confidence Interval	P Value
Peak CK-MB ratio (per 100 ULN)	1.13	1.04 to 1.22	0.002
Age (per 5 years)	1.20	1.09 to 1.31	0.0001
Diabetes mellitus	2.18	1.42 to 3.33	<0.001
Culprit lesion of proximal LAD	1.62	0.95 to 2.76	0.08
PCI of left main artery	4.19	1.67 to 10.53	0.002
Killip class 2-4	2.45	1.51 to 3.97	<0.001
Baseline creatinine (per 0.1 mg/dL)	1.05	1.03 to 1.07	<0.001
Bivalirudin use (vs. UFH+GPI)	0.47	0.31 to 0.72	<0.001
Acquired thrombocytopenia	1.84	1.19 to 2.87	0.007
Major bleeding	2.53	1.56 to 4.11	<0.001

PCI=percutaneous coronary intervention; UFH=unfractionated heparin; GPI=glycoprotein IIb/IIIa inhibitor.

Conclusions: In this large-scale prospective trial of patients with STEMI undergoing primary PCI, enzymatic infarct size estimated by peak CK-MB ratio was an independent predictor of 3-year cardiac mortality. Further studies are warranted to identify interventions to reduce infarct size after primary PCI.