

P2642

Long-term outcomes of unprotected left main coronary artery bifurcation lesions treated by second-generation drug-eluting stent implantation: 1-stent vs. 2-stent strategy

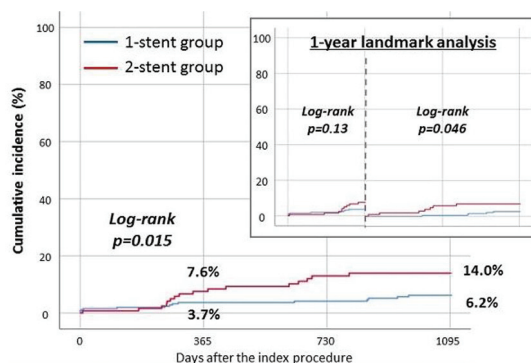
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Background: Whether long-term outcomes of unprotected left main coronary artery (ULMCA) bifurcation lesions treated by second-generation drug-eluting stent (G2-DES) implantation depend on the stenting strategies remain unclear.

Purpose: We aimed to clarify the effects of the stenting strategies on long-term outcomes of ULMCA bifurcation lesions treated by G2-DES implantation by comparing the 1-stent strategy with the 2-stent strategy.

Methods: We examined 389 ULMCA bifurcation lesions in which G2-DES was implanted from the left main stem to the main branch between 2005 and 2014 and classified them into 2 groups by stenting strategy: 259 lesions treated by the 1-stent strategy (1-stent group) and 130 lesions by the 2-stent strategy (2-stent group). Serial angiographic follow-up was scheduled 8 months (midterm) and 20 months (late-term) after the procedure. Clinical outcome measures were defined as the 3-year cumulative incidences of all-cause death, cardiac death, any target lesion revascularization (TLR), and definite or probable stent thrombosis. Angiographic outcome measures were defined as in-stent restenosis (ISR) and late catch-up phenomenon. ISR was defined as restenosis >50%, and late catch-up phenomenon as ISR, except for ISR occurring within 1 year after the procedure. ISR detected at midterm follow-up was excluded from late-term analysis.

Results: The median clinical follow-up period was 3.5 years (the first and third quartiles, 2.7 and 4.2 years). The angiographic follow-up rates were 81.5% at midterm follow-up and 62.8% at late-term follow-up. In the 2-stent group, culotte stenting was performed on 91.5% (119/130 lesions). Between the 1-stent and 2-stent groups, no significant differences existed in the 3-year cumulative incidences of all-cause death (16.2% vs. 19.3%, $p=0.50$), cardiac death (7.1% vs. 9.3%, $p=0.38$), and definite or probable stent thrombosis (1.2% vs. 1.6%, $p=0.77$). Stent thrombosis occurred in 5 patients, in all of whom it occurred within 7 days after the procedure. The 3-year cumulative incidence of any TLR was significantly higher in the 2-stent group than in the 1-stent group (6.2% vs. 14.0%, $p=0.015$). In a 1-year landmark analysis, no significant difference existed in the 1-year cumulative incidence of any TLR (3.7% vs. 7.6%, $p=0.13$), whereas the cumulative incidence of any TLR beyond 1 year was significantly higher in the 2-stent group than in the 1-stent group (2.6% vs. 6.9%, $p=0.046$). No significant difference existed in the midterm ISR rate (16.8% vs. 19.4%, $p=0.57$), whereas the late catch-up phenomenon rate was significantly higher in the 2-stent group than in the 1-stent group (1.5% vs. 12.7%, $p=0.001$).



	No. at risk	259	223	204	140
1-stent group	No. of events		9	10	14
	No. at risk	130	107	94	62
2-stent group	No. of events		9	15	16

Any target lesion revascularization

Conclusion: In ULMCA bifurcation lesions treated by G2-DES implantation, lesions treated by the 2-stent strategy had significantly higher rates of any TLR than those treated by the 1-stent strategy, which may be associated with late catch-up phenomenon.

P2643

Risk-adjusting key outcome measures in a clinical quality registry of PCI: development of a highly predictive model without the need to exclude very high risk conditions

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Background: Robust risk-adjustment is a critical component of mature clinical quality registries, allowing key outcomes to be reported in a fair and meaningful way. The Victorian Cardiac Outcomes Registry (VCOR) is the largest state-funded clinical quality registry for cardiac procedures in Australia. Established in

2012, VCOR encompasses all 30 percutaneous coronary intervention (PCI) hospitals in the state of Victoria.

Purpose: In order to report risk-adjusted outcomes, the registry aimed to develop a highly predictive risk-adjustment model for 30-day all-cause mortality. We also explored in a sub-group model whether extreme high-risk conditions of cardiogenic shock (CS) and out-of-hospital cardiac arrest (OHCA) should be excluded to optimise predictive accuracy.

Methods: Data were prospectively collected on 27,544 consecutive PCI procedures between 2014 and 2016. Twenty-eight patient risk factors and procedural variables associated with 30-day all-cause mortality were considered in the modelling process. For the multivariate, logistic regression analysis, collinear variables were excluded, with development and validation datasets utilised (70:30 ratio). Unknown or missing data were included in the reference category for estimated glomerular filtration rate (eGFR) and left ventricular ejection fraction (EF). Sensitivity analysis was conducted to compare the modelling process with a complete case and multiple imputation method analysis, with 1,000 bootstrap samples simulated for each model to determine significance of each variable. All analyses were conducted using STATA version 14.2.

Results: The final model had risk-adjustment for: CS, OHCA, eGFR, EF, angina type, mechanical ventricular support, octogenarians, complex lesions, percutaneous entry location and peripheral vascular disease. The C-statistic for the development dataset was 0.922 (95% CI: 0.908 to 0.937), with a C-statistic of 0.908 obtained for the validation dataset. The sub-group model provided statistically similar risk-adjusted outcomes ($p=0.162$). There was no difference in the variables selected in the model when applying a complete case assessment or by conducting multiple imputation for missing data.

Conclusions: Mature clinical quality registries can and should develop their own robust risk-adjustment models for key outcome measures. Our modelling technique resulted in high predictive accuracy that was comparable with the best performing risk-adjustment models worldwide. However, in contrast to other risk-adjustment models for cardiac registries, our model was robust enough not to require exclusion of extreme high-risk cases to maintain its high predictive accuracy.

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The Surgery after Stent (SAS) Registry: a gender-based analysis on clinical outcomes in women undergoing cardiac and non-cardiac surgery

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Background: There are poor data about antiplatelet therapy management during perioperative period in women with previous coronary stenting.

Purpose: The aim of the study is to analyze, within the SAS Registry, clinical differences, outcomes and complications between gender among pts already treated with PCI and stenting requiring any type of surgery.

Methods: All consecutive pts aged >18 years with prior coronary stent implantation (at any time) under evaluation for any type of surgery or operative endoscopic/endovascular procedure were screened. The thrombotic risk and the surgical hemorrhagic risk were classified according to a consensus document of Italian Society of Interventional Cardiology (GISE) approved by several national surgical societies. The pts were followed-up for 30 days after the surgical procedure. The primary endpoint was in-hospital net adverse clinical events (NACE), defined as the composite of all cause death, myocardial infarction, probable/definite stent thrombosis, and grade 3 bleeding complications according BARC definition, between gender. Secondary endpoints included major adverse cardiac events (MACE) and BARC>3 bleeding at 30 days following surgery.

Results: A total of 1105 pts were analyzed. Mean age was 70.5 years in the general population, while women were older (72 vs 70 yrs, $p<0.01$) than men. Recommendations of the Consensus Document were followed in 85% of pts, while in the remaining 15%, the recommendations were considered not applicable by the treating physician. Women had a higher incidence of orthopedic surgery (17.1% vs 7.9%, $p<0.01$), while vascular surgery and urologic interventions occurred mainly in men (17.6% vs 9%, $p 0.03$ and 18.9% vs 5.5%, $p<0.01$, respectively). The incidence of NACE during hospitalization in the overall population was 12.5% (13.6% in women and 12% in men, $P 0.6$). A trend towards a higher incidence of MACE was observed among women (4.5% vs 3.3% in men, $P 0.4$), despite not statistically significant, and no differences were observed in pts undergoing cardiac and non-cardiac surgery. In women the only predictor of 30-days MACE was diabetes mellitus (OR 19.99, CI 0.096 - 416.53, $P 0.05$), while no clinical predictors of 30-days MACE were registered in men. The rate of BARC ≥ 3 at 30 days was 10.7% in the general population and slightly higher (11.6%) among women vs. 10.9% of men ($P 0.79$). The only predictor of BARC ≥ 3 bleed-

ing in women was the total stented segment length (OR 0.9, CI 0.8–1, P 0.05). An additional predictor of bleeding in men, together with the ones already described as for the 30-days NACE was a prior cerebrovascular event (OR 3.25, CI 1.16 – 9.13, P 0.025).

Conclusions: Analysis of the two groups divided by gender showed that women have a statistically unfavorable trend towards in-hospital NACE, 30-day MACE and cumulative bleeding events, as previously described as complications of surgical and percutaneous procedures.

P2645

Purpose: We sought to analyze the 1-year clinical outcomes in COMBO PCI patients categorized using the PARIS bleeding risk score at baseline.

Methods: MASCOT was a prospective, multicenter, all-comer observational study (n=2614, 60 sites) with 1-year follow up. Patients were eligible if COMBO stent implantation was attempted. DAPT was prescribed per local guidelines. The validated PARIS bleeding risk score assesses risk based on 6 baseline variables: age, BMI, anemia, current smoking, chronic kidney disease and need for triple therapy. We stratified patients as low risk for PARIS score ≤ 3 and intermediate-high risk for score >3 . The primary endpoint was 1-year target lesion failure (TLF), defined as a composite of cardiac death, myocardial infarction (MI) not clearly attributed to a non-target vessel or clinically driven target lesion revascularization (TLR). DAPT cessation was systematically adjudicated using the PARIS registry definitions as discontinuation, interruption or disruption.

Results: Of the study cohort, 56% patients (n=1270) were at PARIS low bleeding risk and 44% (n=1009) were at PARIS intermediate to high bleeding risk. The intermed-high risk group included older patients and more women with higher prevalence of insulin treated diabetes, chronic kidney disease, anemia, heart failure and NSTEMI presentations. There were no differences in the rates of radial PCI (69.6% vs 73.0%), total stent length or stent diameter between the age groups. Intermed-high risk patients were more likely to be discharged on clopidogrel (73% vs. 65.4%) and oral anticoagulation (15.0% vs. 3.0%). See Figure 1. The incidence of 1-year TLF was significantly greater in intermed-high bleeding risk patients driven by higher cardiac death with similar rates of MI, TLR and ST. The rates of bleeding were significantly higher in PARIS intermed-high risk patients, as was the incidence of DAPT cessation during follow-up, driven by discontinuation.

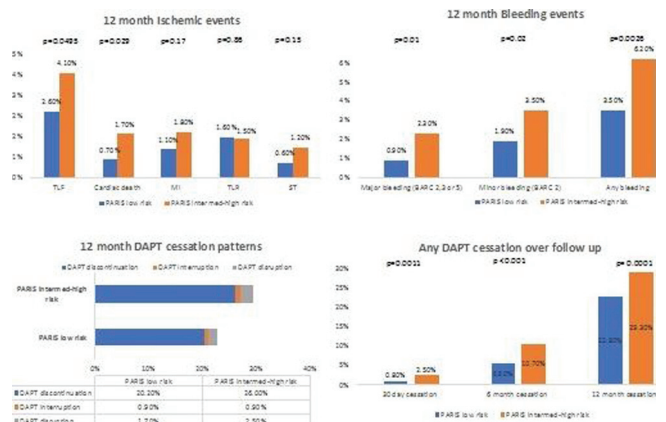


Figure 1

Conclusion(s): Patients with intermediate or high PARIS bleeding risk score had higher 1-year TLF after COMBO PCI driven by greater incidence of cardiac death, without differences in rates of MI, TLR or ST. Major, minor and any bleeding incidences were significantly greater in PARIS intermed-high risk patients. Routine use of the PARIS score at the bedside may easily assist clinicians in determining best pharmacotherapy strategies following PCI.

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NON-CORONARY CARDIAC INTERVENTION

P2647

Supra annular versus annular trans-catheter aortic valve implantation in patients with small aortic valve anatomy: does it really matter?

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Background: Trans-catheter aortic valve implantation (TAVI) is an established and valuable treatment option for patients with severe symptomatic aortic stenosis. The use of TAVI is rapidly expanding worldwide and the indications for TAVI are widening into lower risk populations in view of favorable outcomes among high and intermediate risk patients. TAVI for patients with smaller aortic valve (AV) anatomy is a challenging procedure due to specific anatomical difficulty and complications including annulus rupture, remaining high AV gradients and vascular complications.

Objective: To compare 30-day and 1-year outcomes between supra annular and annular design TAVI valves implantation in patients with small AV anatomy.

Methods: We have conducted a retrospective study between 2014–2017 including all TAVI patients with small AV anatomy defined by CT AV annulus area <430 mm². Annular design valve was the SAPIEN® (Edwards) where the supra-annular valves included the EVOLUT R (Medtronic) and ACURATE Neo (Symetis/Boston).

Results: 146 patients were included in the study. The mean age of the patients was 82.2±6.29 years, 71.9% were women. 87% had normal LV function. In 74 (50.7%) patients the SAPIEN® valve was implanted whereas in 72 (49.3%) patients the supra-annular design valves were used. Mean baseline aortic valve

ABSTRACT WITHDRAWN

P2646

COMBO PCI outcomes in patients categorized by baseline PARIS bleeding risk score: from the global MASCOT registry

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Background and introduction: The PARIS bleeding risk score has been validated for prediction of major bleeding events in all comer PCI patients. The MASCOT registry reported low 1-year target lesion failure rates in all-comer patients undergoing PCI with the COMBO dual therapy stent, a platform which may be advantageous in high bleeding risk patients allowing short dual antiplatelet therapy (DAPT) by virtue of faster endothelialization. Further, the REDUCE trial demonstrated the feasibility of 3months DAPT after COMBO PCI.