

was used in 905 cases (45.2%), subintimal tracking and re-entry (STAR) in 333 cases (16.6%), and contrast-guided STAR in 29 cases (1.4%). The mean patient age was 64.2 ± 10 years, 86% were men, and 34.9% had prior coronary artery bypass graft surgery. Cases in which LAST was used were less complex with a lower J-CTO score (2.50 ± 1.32 vs. 2.95 ± 1.10 , $P < 0.001$). There was no difference in technical (75.0% vs 78.4%, $P = 0.337$) and procedural success (72.2% vs 75.5%, $P = 0.384$) and major cardiac adverse events (MACEs) (2.08% vs 3.55%, $P = 0.352$) between LAST and non-LAST cases. However, cases in which the LAST technique was used required less procedure and fluoroscopy time (Figure 1A). A primary LAST technique was associated with higher technical and procedural success rates and a similar MACE rate compared with a secondary LAST technique (Figure 1B).

CONCLUSION LAST is used in 7.2% of ADR CTO PCI cases and is associated with similar technical and procedural success rates and major complication rates but lower procedural and fluoroscopy time compared with ADR cases that did not use LAST.

CATEGORIES CORONARY: Complex and Higher Risk Procedures for Indicated Patients (CHIP)

TCT-320

Pharmacokinetic and Pharmacodynamic Profile of PL-ASA, a Novel Phospholipid-Aspirin Complex Liquid Formulation, Compared to Enteric-Coated Aspirin at an 81-mg Dose – Results From a Prospective, Randomized, Crossover Study



Francesco Franchi,¹ David Schneider,² Jayne Prats,³ Weihong Fan,⁴ Fabiana Rollini,¹ Lanonya Been,⁵ Heidi Taatjes-Sommer,⁶ Efthymios Deliaris,⁷ Dominick Angiolillo⁶
¹University of Florida, College of Medicine-Jacksonville, Jacksonville, Florida, USA; ²Department of Medicine, Cardiovascular Research Institute, University of Vermont, Burlington, Vermont, USA; ³Elysis, Carlisle, Massachusetts, USA; ⁴PLx Pharma, Inc, Sparta, New Jersey, USA; ⁵University of Florida, Jacksonville, Florida, USA; ⁶University of Vermont Medical Center, Burlington, Vermont, USA; ⁷Science and Strategy Consulting, Basking Ridge, New Jersey, USA

BACKGROUND Immediate-release (IR) aspirin (ASA) is associated with a risk of mucosal damage in the upper gastrointestinal (GI) tract. Enteric-coated (EC) ASA was designed to reduce GI discomfort and bleeding and is the established standard of care in secondary prevention. However, there is evidence that EC-ASA results in greater variability in absorption and antiplatelet effect than IR-ASA. PL-ASA, a novel Food and Drug Administration-approved, liquid-filled phospholipid ASA capsule, is an IR formulation designed to release aspirin in the duodenum, thus limiting GI toxicity, while still providing fast and complete drug absorption and potent and reliable cyclooxygenase-1 inhibition. Previous studies have compared the 325-mg dose of PL-ASA with IR-ASA and EC-ASA, and the current study is the first to investigate the 81-mg dose, which is most commonly used in clinical practice.

METHODS The current study is a randomized, open-label, crossover study assessing the comparative pharmacodynamic (PD) and pharmacokinetic (PK) profiles following treatment with a single 81-mg dose of PL-ASA versus EC-ASA under fasting conditions in subjects ($n = 36$) between 50 and 75 years of age. Subjects are randomly assigned at a 1:1 ratio to either PL-ASA followed by EC-ASA or EC-ASA followed by PL-ASA with a 14-day washout period between the 2 study drugs. Following each study drug administration, blood draws for PK and PD, including thromboxane B2 (TxB2), and platelet aggregation assessments are performed at multiple time points up to 24 hours. PK parameters of acetylsalicylic acid and salicylic acid will be compared. PD assessments will include the comparison between PL-ASA and EC aspirin of the time to 99% inhibition of serum TxB2, incidence of $\geq 99\%$ inhibition of TxB2, and platelet aggregation following arachidonic acid and collagen stimuli.

RESULTS The study is currently recruiting, and results will be presented at the meeting.

CONCLUSION The current study will provide data on the comparative PK and PD profiles of PL-ASA, a novel IR-ASA capsule formulation, versus commonly used EC-ASA at an 81-mg dose.

CATEGORIES CORONARY: Pharmacology/Pharmacotherapy

TCT-321

Abstract Withdrawn



TCT-322

Prevention of Radial Artery Occlusion After Transradial Access Using Nitroglycerin (Patens Trial)



Roberto Léo da Silva,¹ Rodrigo Joaquim,¹ Pedro Beraldo,² Alexandre Abizaid,³ Ramiro Vieira,¹ Vanderlei Pereira, Jr.,² Renata Viana,³ Amanda Sousa,³ Fausto Feres,³ Jose Costa, Jr.³
¹Instituto de Cardiologia de Santa Catarina, São José, Santa Catarina, Brazil; ²Santa Casa de Misericórdia, Marília, São Paulo, Brazil; ³Instituto Dante Pazzanese de Cardiologia, São Paulo, São Paulo, Brazil

BACKGROUND The use of transradial access (TRA) for coronary catheterization has increased over the years because of the reduced rates of vascular complications and easier postprocedural management. Radial artery occlusion (RAO) remains the Achilles heel of TRA. Intra-arterial nitroglycerin could result in a significant reduction of RAO. The vasodilation may enhance antegrade flow in the artery that reduces stasis-induced thrombosis, but it could also minimize endothelial trauma when used early in the procedure. The main objective of this study is to evaluate whether nitroglycerin at the beginning or end of TRA may preserve the patency of the artery.

METHODS We conducted a prospective, multicenter, randomized, 2×2 factorial, placebo-controlled, 2-blinded study and enrolled patients submitted to catheterization by TRA. Patients received either 500 μ g nitroglycerin or placebo given intra-arterially through the sheath at 2 moments: early, after sheath insertion, and late, at the end of the radial procedure. All patients received at least 5,000 UI heparin, sheaths were removed immediately after the catheterization, and a radial pneumatic wristband was applied intending patent or minimum pressure hemostasis. The primary outcome was the incidence of RAO, verified by Doppler evaluation within the first 24 hours, and every patient with confirmed RAO was further evaluated 30 days later.

RESULTS A total of 1,894 patients were enrolled, with a mean age of 61.7 ± 10.3 years. The majority (61.6%) were male, and 36.5% had diabetes. The clinical indication was ACS in 47.9%. RAO occurred in 49 patients (2.6%) by Doppler evaluation. Fifteen patients (30.6%) showed re-establishment of flow at 30-day Doppler assessment. Nitroglycerin, as compared with placebo, did not reduce the risk of RAO in either of the 2 moments used (early: 2.4% vs 2.8%, $P = 0.65$ or late: 2.8% vs 2.4%, $P = 0.65$, respectively). In the multivariate analysis, the size of the radial artery, obtaining access with a single puncture, operator inexperience, and the presence of spasm were associated with RAO.

CONCLUSION In the present study, the use of nitroglycerin is not associated with a reduced incidence of RAO regardless of the administration time.

CATEGORIES OTHER: Vascular Access: Coronary

TCT-323

Is There a Difference in the Types of Complex High-Risk but Indicated Percutaneous Coronary Interventions (CHIP) Undertaken and Their Outcomes Among Different Racial Groups? Insights From a National Cohort

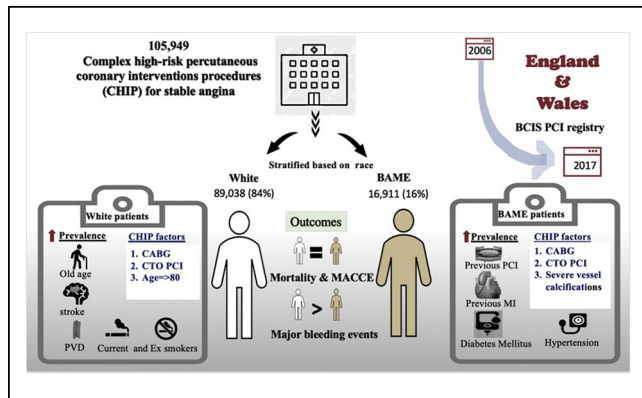


Warkaa Shamkhani,¹ Tim Kinnaird,² Harindra Wijeyesundera,³ Peter Ludman,⁴ Muhammad Rashid,⁵ Mamas Mamas¹
¹Royal Stoke Hospital, Keele University, Stoke-On-Trent, United Kingdom; ²University Hospital of Wales, Cardiff, United Kingdom; ³Sunnybrook Health Sciences Centre/University of Toronto, Toronto, Ontario, Canada; ⁴Queen Elizabeth Hospital, Birmingham, United Kingdom; ⁵Keele University, Stoke-on-Trent, United Kingdom

BACKGROUND In contemporary practice, complex high-risk but indicated percutaneous coronary intervention (CHIP) is increasingly common. Data on race-based differences in the nature of CHIP and their clinical outcomes in patients with stable coronary artery disease (CAD) are limited.

METHODS We obtained data on percutaneous coronary intervention (PCI) for stable CAD performed in England and Wales from January 1, 2006, to December 31, 2017, from the British Cardiovascular Intervention Society (BCIS) registry. The collected data were retrospectively analyzed and stratified by race. Multivariate regression analysis was performed to assess the relationship between CHIP, race, and outcomes.

RESULTS Of a total of 424,290 procedure records in the BCIS registry, 105,949 (24.97%) were CHIP; 89,038 (84%) were performed in White and 16,911 (16%) in Black, Asian, and minority ethnic (BAME) patients (Figure 1). BAME patients were younger (median: 68.1 years vs 70.6 years). A previous coronary artery bypass graft was the commonest CHIP factor in both White and BAME patients (33.4% vs 38.3%, respectively; $P < 0.001$) followed by chronic total occlusion (CTO) PCI (31.9% vs 32%, respectively; $P = 0.769$). The third common CHIP factor was age above 80 (23.6% in the Whites and severe vessel calcification in BAME patients (18.8%). BAME patients had significantly higher rates of diabetes (41.1% vs 23.6%, respectively; $P < 0.001$), hypertension (68% vs 66.5%, $P < 0.001$), previous PCI (43.7% vs 37.6%, $P < 0.001$), and previous myocardial infarction (44.9% vs 42.5%, $P < 0.001$) compared with White patients. Mortality (adjusted odds ratio [aOR]: 1.07; 95% confidence interval [CI]: 0.8-1.5; $P = 0.659$) and major adverse cardiovascular and cerebral event (MACCE) (aOR: 0.9; 95% CI: 0.8-1.1; $P = 0.564$) risks were similar among races, although the bleeding risk (aOR: 0.69; 95% CI: 0.6-0.9; $P = 0.002$) was lower.



CONCLUSION In this large national analysis of CHIP procedures, BAME patients were younger and had worse cardiometabolic risk profiles. There were race-based differences in the type of CHIP procedures. BAME patients had 30% fewer odds for bleeding and similar odds of death and MACCEs to those of their White counterparts.

CATEGORIES CORONARY: Complex and Higher Risk Procedures for Indicated Patients (CHIP)

TCT-324
Features and Outcomes of Transcatheter Aortic Valve Replacements for Small Aortic Valve Annuli

In-Ho Chae,¹ In Tae Moon,² Si-Hyuck Kang,¹ Chang-Hwan Yoon,¹ Tae-Jin Youn¹
¹Seoul National University Bundang Hospital, Seongnam-si, Korea (Republic of); ²Uijeongbu Eulji Medical Center, Uijeongbu-si, Korea (Republic of)

BACKGROUND Transcatheter aortic valve replacement (TAVR) in a small annulus may cause patient prosthesis mismatch (PPM), and data on the outcomes of small annulus TAVR are limited. This study aimed to 1) report the prevalence, features, and outcomes of small annulus TAVR and 2) compare the efficacy and safety of the 2 widely used TAVR valves in this patient population.

METHODS All patients treated with TAVR between June 2015 and June 2018 at 21 TAVR centers in Korea were analyzed from the Korean TAVR registry. The primary outcome was procedure-related complications and the major adverse cardiac outcome. The secondary outcome was aortic regurgitation (AR), paravalvular AR, effective orifice area (EOA) index, and PPM. We compared outcomes of 1) small annulus (annular diameter < 20 mm) and nonsmall annulus valves and 2) balloon-expandable valves (BEVs) and self-expandable valves (SEVs) among patients with small annulus valves.

RESULTS Among the total 660 patients, 70 patients had a small annulus with a mean annular diameter of 18.7 mm, whereas the mean diameter of the nonsmall annulus was 23.4 mm (Table 1). Both groups had similar complication rates (8.6% vs 6.6%, $P = 0.71$) and similar clinical outcomes at 1 year with 10.0% and 14.4% MACEs, respectively ($P = 0.41$). The small annulus group showed lower EOA index at 1

month than the nonsmall annulus group (0.99 cm²/m² vs 1.11 cm²/m², $P < 0.01$) and a higher PPM rate (moderate 25.0%, severe 8.2% vs moderate 17.3%, severe 1.9%, $P < 0.01$), whereas the gap narrowed at 1 year. BEVs and SEVs had similar complication rates (7.4% vs 9.8%, $P = 1.00$) and similar 1-year MACEs (18.5% vs 4.9%, $P = 0.16$). The EOA index was significantly greater with SEVs at 1 month, but the difference was not significant at 1 year. The risk of PPM also did not differ significantly. AR or paravalvular AR showed no difference.

	Small Annulus (n = 70)	Nonsmall Annulus (n = 590)	P Value
Mean annular diameter	18.7 mm	23.4 mm	0.00
Age, years	78.3 ± 5.3	78.6 ± 6.8	0.63
Sex, female	56 (80.0%)	276 (46.8%)	0.00
Procedure-related complications	6 (8.6%)	39 (6.6%)	0.71
1-month EOA index (cm ² /m ²)	0.99 ± 0.25	1.11 ± 0.32	0.01
1-month moderate to severe PPM rate	33.3%	19.2%	0.01
1-year EOA index (cm ² /m ²)	1.04 ± 0.24	1.09 ± 0.03	0.27
1 year moderate to severe PPM rate	22.9%	19.9%	0.72
1 year MACCE	7 (10.0%)	85 (14.4%)	0.41

CONCLUSION Small annulus TAVR with an annulus diameter less than 20 mm had favorable short-term clinical outcomes. BEVs and SEVs showed similar complication rates and clinical outcomes during at least the 1-year follow-up period.

CATEGORIES STRUCTURAL: Valvular Disease: Aortic

TCT-325
Ultra-Short-Term Evaluation of Coronary Vessel Wall Changes in Reference Segments Adjacent to Culprit Lesions in ST-Segment Elevation Myocardial Infarction

Kazuhiro Dan,¹ Hector Manel Garcia-Garcia,² Omar Yacob,² Kayode Kuku,² Miguel Adrian Diaz,³ Marco Valgimigli⁴
¹Ichinomiya Nishi Hospital, Ichinomiya, Japan; ²MedStar Washington Hospital Center, Washington, DC, USA; ³Public, Guadalajara, Michoacán, Mexico; ⁴Cardiocentro Ticino, Lugano, Switzerland

BACKGROUND Culprit lesions of ST-segment elevation myocardial infarction (STEMI) patients are friable, soft, and prone to disruption during primary percutaneous coronary intervention (pPCI). The presence of dissections in the reference vessel segment (RVS), adjacent to stented culprit lesions, and dynamic luminal changes in proximal or distal RVS have not yet been investigated. Therefore, we sought to assess the healing patterns of edge dissections and the changes of the lumen area at the RVS within 1 week after stent implantation in patients with STEMI.

METHODS In the MATRIX trial (ClinicalTrials.gov, NCT01433627), optical coherence tomography (OCT) was performed at the end of pPCI and within 1 week during staged PCI. The dissection in RVS was defined as follows: type 1, flap; type 2, cavity; type 3, double barrel; and type 4, fissure. We compared separately the fate of residual dissection and luminal area/dimension by OCT in the target vessel between primary and staged PCI, including 1-year clinical outcomes.

RESULTS Of 151 patients, 46 patients had dissections in 50 RVSs and did not experience a worse clinical outcome. Forty-four percent of dissections were type 1, 28% type 2, 16% type 4, and 12% type 3. Overall, 18% of the dissections healed. The mean lumen area of the RVS enlarged in 82 patients (59%) from pPCI to staged PCI. Compared with the proximal RVS, there was a significant increase in the lumen diameter at the distal RVS (0.06 ± 0.25 mm vs -0.01 ± 0.21 mm, $P = 0.01$).

CONCLUSION Dissections occur frequently after pPCI in STEMI, one fifth of them heal within 1 week and do not seem to negatively impact on clinical outcomes. The distal RVS lumen area increased compared with the proximal RVS, likely reflecting a different vasoconstriction pattern over time.

CATEGORIES CORONARY: Acute Myocardial Infarction