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Implantation Of Biofreedom® Drug-coated Stents With Very Short Dual Antiplatelet Therapy In Patients At High Bleeding Risk: First Real-world Data

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BACKGROUND Patients at high risk of bleeding requiring percutaneous coronary intervention (PCI) are a challenging group who need careful evaluation of both their thrombotic and bleeding risks. Deciding on duration and intensity of antithrombotic management is difficult and has to be well balanced. In these patients, a polymer-free metallic stent coated with biolimus-A9 (Biofreedom®) followed by a one-month dual antiplatelet therapy has shown to be safer and more effective when compared to a bare metal stent during a two year follow-up (LEADERS-free trial). Yet, data on safety and efficacy outside a trial are scare. Therefore, we analyzed this regimen in a real-world scenario.

METHODS Between November 2015 and August 2016, Patients at high bleeding risk and indication for PCI were treated with Biofreedom® stents followed by a DAPT consisting of aspirin (100 mg/day) and clopidogrel (75 mg/day) for one month. Clinical follow-up was performed to evaluate the safety and efficacy of this therapeutic regimen. Therefore, patients were followed by standardized telephone interview.

RESULTS Overall, 93 patients were enrolled in this study (mean age 73 ± 11 years; 28 female (30 %)). Mean HASBLED-score was 2.9 ± 0.86. High bleeding risk characteristics were: High HASBLED-score (≥ 3) in 66 pt., age ≥ 75 y (51 pt.), indication for oral anticoagulation (63 pt.), tumor (21 pt.), need for non-cardiac surgery (16 pt.), and history of severe bleeding (9 pt.). In sum 113 interventions were performed. Patients received a mean of 1.84 ± 1.13 stents. No stent thrombosis occurred during a mean follow-up of 6.1 ± 2.7 months. Nine patients died during follow-up, all deaths were not related to bleeding events or myocardial infarction. In six patients (6%), bleeding events occurred.

CONCLUSION In patients at high risk of bleeding, implantation of the polymer-free metallic stent coated with biolimus-A9 (Biofreedom®) followed by a one-month dual antiplatelet therapy was safe and effective in a real-world scenario, no stent thrombosis occurred.

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Three-year Clinical Outcomes Of Biomime Sirolimus-eluting Coronary Stent System With A Biodegradable Polymer In Coronary Artery Disease Patients: A Long-term Follow-up Of The meriT-2 Study

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BACKGROUND The development of biodegradable polymer-coated Sirolimus-Eluting Coronary Stent (SES) System for the treatment of coronary artery diseases has resulted inconsiderable improvements in clinical outcomes. The aim of the meriT-2 study was to determine the long-term safety and performance of the BioMime Sirolimus-Eluting Coronary Stent System (Meril Life Sciences Pvt. Ltd., Gujarat, India) for the treatment of coronary artery disease patients.

METHODS The meriT-2 was a prospective, multicenter study conducted in 250 patients at 11 Indian sites. The primary endpoint was major adverse cardiac events (MACE) defined as a composite of cardiac death, myocardial infarction (MI) and target lesion revascularization (TLR) at 30 days after the procedure. The primary efficacy endpoint was in-stent late lumen loss (LLL) at eight months. The secondary endpoints were MACE and stent thrombosis (ST)at one-year follow-up. The clinical follow-up was performed at the following time points: 30 days, six months, one year, and three-year after index procedure. Recently, follow-up was performed at three-year and the resultant cumulative MACE was analyzed.

RESULTS Follow-up at three-year was available for 242 patients (96.8%). Among those 123 (49.2%) patients had hypertension and 91 (36.4%) patients with diabetes mellitus. Out of 355 lesions, 63.4% lesions were type B2/C as defined by the ACC/AHA guidelines. The cumulative MACE was 18 (7.4%), including 2(0.8%) cardiac deaths, 4 (1.6%) MI, and 12 (4.8%) any-TLR. Stent thrombosis was observed in 3 (1.2%) patients.

CONCLUSION Long-term clinical outcomes of BioMime SES at 3 year follow-up demonstrated excellent safety and performance in a coronary artery disease patient population with a high prevalence of hypertension, diabetes and complex lesions.

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Safety, Feasibility And Success of Radial- Versus Femoral-Access Robotic Percutaneous Coronary Intervention: Results From the Multicenter PRECISION Registry

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BACKGROUND Limited data exist for robotic PCI outcomes via transradial access (TRA). The goal of this study was to compare clinical and technical success for radial- vs femoral access robotic PCI.

METHODS The multicenter PRECISION registry (n=11 sites) collected clinical and procedural data of robotic PCI procedures utilizing the CorPath 200 System (Corindus Vascular, Waltham, MA). Technical success was defined as procedural success (residual stenosis <30%; TIMI 3 flow) with robotic PCI while clinical success required absence of major adverse cardiovascular events (MACE: cardiac death, myocardial infarction, or clinically driven target vessel revascularization).

RESULTS 501 patients with 607 lesions were treated with robotic PCI with TRA in 310 (62%) and TFA in 191 (38%) patients. Technical success rates were 92.4% and 86.7% (TRA vs TFA), respectively (P=0.03) and clinical success rates were 99.4% and 94.7% respectively (P=0.002) (Table). Nine serious adverse events (SAE) (1.9% radial vs 1.6% femoral, p=1.0) unrelated to the CorPath 200 System occurred during the study period. Of these 9 SAEs, three (3) were determined MACE as defined by the protocol.

Patient and Lesion Characteristics and Procedure Outcomes

Patient Characteristics	TFA N=191	TRA N=310	P Value
Age (Mean ± SD)	68.5±12.3	64.7±12.1	0.001
Male Gender (%)	74.9%	75.2%	1.00
BMI (Mean ± SD)	29.1±5.3	31.1±6.1	0.002
Diabetes Mellitus (%)	48.2%	31.9%	0.0003
Prior PCI (%)	55.0%	45.2%	0.035
Prior CABG (%)	19.4%	14.2%	0.14
Hypertension (%)	88.0%	81.6%	0.06
Hyperlipidemia (%)	91.1%	81.3%	0.003
Current Cigarette Smoker – last year (%)	19.4%	31.4%	0.004
Cerebral Vascular Disease	8.4%	5.2%	0.19
Congestive Heart Failure	11.5%	11.9%	1.00
Peripheral Vascular Disease	12.6%	11.3%	0.67
Lesion Characteristics	**N=236**	**N=371**	
Lesion Location – n/N (%)			0.21
Left Main	5/236 (2.1%)	1/368 (0.3%)	
Left Circumflex	56/236 (36.4%)	98/368 (26.6)%	
Left Anterior Descending	102/236 (43.2%)	152/368 (41.3%)	
Right Coronary	70/236 (29.7%)	109/368 (29.6%)	
Ramus	3/236 (1.3%)	8/368 (2.2%)	
ACC/AHA Lesion Classification – n/N (%)			<0.0001
A	18/231 (7.8%)	41/364 (11.3%)	
B1	72/231 (31.2%)	89/364 (24.5%)	
B2	37/231 (16.0%)	124/364 (34.1%)	
C	104/231 (45.0%)	110/364 (30.2%)	
Procedure Characteristics			
Number of Stents/CorPath Lesion - mean ± SD (N=cases completed robotically)	1.1±0.4 (207)	1.1±0.4 (342)	0.17
Contrast Volume (ml) - mean ± SD	176.4±78.7	200.3±107.7	0.06
Fluoroscopy Time (min) - mean ± SD (N)	15.2±9.1	14.1±7.5	0.50
Procedure Time - mean ± SD (N)	66.3 ± 31.0 (131)	57.0 ± 23.0 (276)	0.004
PCI Procedure Time - mean ± SD (N)	43.9 ± 23.3 (189)	39.0 ± 20.0 (310)	0.02
DAP (mGy*cm2) - mean ± SD (N) median [IQR]	110128 ± 139283 (172) 69775 [42333, 124676]	112396 ± 167242 (264) 94128 [46946, 148271]	0.046
Cumulative Dose (mGy)	1541 ± 3960 (137) 1066 [636, 1648]	1939 ± 4731 (301) 1385 [827, 2168]	0.0004