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Long-term Clinical Outcomes After the Treatment of Coronary Stenosis With Sirolimus-coated Balloon Angioplasty: Results From NANOLUTE Real-World Registry

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BACKGROUND Over past the decade, drug-coated balloons have emerged as an effective treatment for coronary stenosis with and advantage of delivering the anti-proliferative agent to the clogged vessel without any metallic implant. We sought to assess the world's first sirolimus-coated balloon (SCB) -Magictouch (Concept Medical) in the treatment coronary atherosclerotic disease.

METHODS NANOLUTE is a multi-centre, prospective, and real-world study. The measured endpoint was MACE (major adverse cardiac events) at 1 year. MACE component encompassed target lesion revascularization (TLR), target vessel myocardial infarction (TV-MI), and cardiac death. To derive the device performance in long run, we calculated MACE at extended follow-up at 2 years and 3 years.

RESULTS Four hundred thirty-eight patients were included in the study, with a total of 516 PCI procedures on 465 lesions, all treated with SCB. Of the 465 lesions, 45.81% were in-stent restenotic lesions, and de-novo accounted for 54.19%. Among those de-novo lesions, 43.87% were located in small coronary vessels (RVD $\leq$ 2.75 mm). The event characteristics were depicted in Table 1. MACE rates were 4.33%, 5.1%, and 7.72% at 1 year, 2 years and 3 years, respectively. The follow-up for the rest of the patients is yet to come, as NANOLUTE is an ongoing registry. There was no increment in events at 2- and 3-year follow-up.

Table 1

N (%)	1 Year N=393*	2 Years N=330*	3 Years N=220*
MACE	17(4.33)	17(5.1)	17(7.72)
TLR	15(3.82)	15(4.5)	15(6.81)
TV-MI	1(0.25)	1(0.3)	1(0.45)
Cardiac Death	1(0.25)	1(0.3)	1(0.45)

*Number of patients completed follow-up through October 2017

CONCLUSION The present study demonstrated that SCB is a valid revascularization strategy in an all-comers population of patients with coronary atherosclerotic disease with an acceptable rate of cardiac events up to 3 years of follow-up.

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Epidemiology and Predictors of In-hospital Mortality of Takotsubo Cardiomyopathy

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BACKGROUND Takotsubo cardiomyopathy (TCM) is an increasingly reported transient non-ischemic regional systolic dysfunction of the left ventricle. We sought to examine temporal trends in incidence of TCM and identify clinical characteristics and predictors of in-hospital mortality.

METHODS The study population was derived from the HCUP-National Inpatient Sample for the years 2007-2013. ICD-9 CM codes were used to identify patients with TCM undergoing coronary angiography during the same admission. Baseline patient characteristics and in-hospital all-cause mortality were assessed. Multivariate analysis was used to adjust for baseline confounders.

RESULTS Seventy-two thousand five hundred fifty-nine admissions with a diagnosis of TCM were identified during the study period. A significant increase in the incidence of TCM was observed from 11.1 cases per 100,000 hospitalizations in 2007 to 43.8 cases per 100,000 hospitalizations in 2013 ($p<0.001$). One thousand eight hundred twenty-five (2.5%) patients died prior to hospital discharge. Expired patients were more likely to be older (69.2 vs. 66.4, $p<0.0001$), diabetic, with a higher baseline clinical risk. After multivariate adjustment, independent predictors of mortality included age, female gender, alcohol disorders, hypertension, acute kidney injury, multiple myeloma, chronic obstructive pulmonary disease, peripheral vascular disease, pulmonary hypertension, arrhythmias, peri-endo-myocarditis and hepatitis. (Table 1)

CONCLUSION Hospital admissions for TCM have significantly increased in the U.S. during the last six years. In-hospital mortality is infrequent in patients hospitalized with TCM. Nevertheless, multiple modifiable and non-modifiable factors are associated with a significant increase in mortality.

	Alive (N=70,734)	Expired (N=1,825)	P	Multivariate OR (95% CI)	P
Baseline Characteristics					
Age	66.4 ± 12.8	69.2 ± 13.6	<0.0001	1.01 (1.01 – 1.02)	<0.0001
Female	63,108 (89.2%)	1,437 (78.7%)	<0.0001	1.70 (1.50 – 1.92)	<0.0001
Current Tobacco use	12,224 (17.3%)	299 (16.4%)	0.331	-	-
History of Tobacco use	22,804 (32.2%)	485 (26.6%)	<0.0001	0.80 (0.72 – 0.90)	<0.0001
Alcohol Related Disorders	2,695 (3.8%)	102 (5.6%)	<0.0001	1.30 (1.05 – 1.61)	0.018
Hypertension	45,671 (64.6%)	1,038 (56.9%)	<0.0001	1.24 (1.12 – 1.37)	<0.0001
Diabetes Mellitus	16,830 (23.8%)	444 (24.3%)	0.598	-	-
Dyslipidemia	33,934 (48.0%)	504 (27.6%)	<0.0001	0.45 (0.41 – 0.51)	<0.0001
Acute Kidney Injury	6,260 (8.9%)	640 (35.0%)	<0.0001	4.18 (3.74 -4.68)	<0.0001
Chronic renal Failure	4,783 (6.8%)	243 (13.3%)	<0.0001	1.04 (0.89 – 1.22)	0.588
History of Stroke	862 (1.2%)	14 (0.8%)	0.089	0.55 (0.32 – 0.94)	0.029
CHF	22,905 (32.4%)	801 (43.9%)	<0.0001	0.95 (0.86 – 1.05)	0.331
COPD	13,589 (19.2%)	500 (27.4%)	<0.0001	1.48 (1.32 – 1.66)	<0.0001
Anxiety Disorders	10,202 (14.4%)	133 (7.3%)	<0.0001	0.531 (0.44 – 0.64)	<0.0001
Peripheral Vascular Disease	3,814 (5.4%)	196 (10.7%)	<0.0001	1.87 (1.59 – 2.19)	<0.0001
Pulmonary Hypertension	4,500 (6.4%)	210 (11.5%)	<0.0001	1.47 (1.26 – 1.72)	<0.0001
Heart Valve Disorders	9,800 (13.9%)	225 (12.3%)	0.065	0.77 (0.66 – 0.89)	0.001
Arrhythmias	22,157 (31.3%)	931 (51.0%)	<0.0001	1.88 (1.70 – 2.08)	<0.0001
Peri-Endo-Myocarditis	10,312 (14.3%)	361 (19.8%)	<0.0001	1.25 (1.11 – 1.41)	<0.0001
Cardiac and Circulatory Congenital anomalies	965 (1.4%)	26 (1.4%)	0.772	-	-
Inflammatory Bowel Disease	648 (0.9%)	24 (1.3%)	0.077	1.09 (0.71 – 1.67)	0.690
Hepatitis	928 (1.3%)	59 (3.2%)	<0.0001	1.58 (1.18 – 2.11)	0.002
SLE/Connective tissue disease	832 (1.2%)	29 (1.6%)	0.119	-	-
Rheumatoid Arthritis	2,055 (2.9%)	44 (2.4%)	0.231	-	-
HIV	122 (0.2%)	5 (0.3%)	0.256	-	-
Multiple Myeloma	73 (0.1%)	10 (0.5%)	<0.0001	2.91 (1.41 – 6.02)	0.004

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Long-term Safety of Bioresorbable Scaffolds: Insights From a Network Meta-analysis Including 91 Trials

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BACKGROUND This study was aimed at investigating the long-term safety and efficacy of the Absorb Bioresorbable Vascular ScaffoldTM (BVS), drug-eluting stents (DES), and bare metal stents (BMS).

METHODS Randomized controlled trials that compared 2 or more coronary stents or scaffolds and reported long-term clinical outcomes were included. Electronic search was done in PubMed, Embase, Cochrane Central Register of Controlled Trials, and relevant websites.

RESULTS A total of 91 randomized controlled trials that compared 2 or more coronary stents or scaffolds and reported long-term clinical outcomes ($\geq$2 years) comprising 105,842 patients were analyzed (mean follow-up, 3.7 years). Network meta-analysis showed that BVS had a significantly higher risk of definite or probable stent thrombosis (ST) than contemporary DES. The risk of very late ST was highest with the Absorb BVS among comparators. Pairwise conventional meta-analysis showed the elevated risk of ST with BVS compared to cobalt chromium everolimus-eluting stent was consistent across onset time such as early ($\leq$ 30 days), late (31 days - 1 year), and very late ST (>1 year) period. Furthermore, significantly higher risk of target lesion failure was observed with BVS, which was driven by both increased risk of target-vessel-myocardial infarction and ischemia-driven target-lesion revascularization.

CONCLUSIONS Implantation of Absorb BVS was associated with increased risk of long-term and very late ST compared to current-generation metallic DES, and the risk of scaffold thrombosis appeared to have a rising trend beyond 1 year.