Clinical and Procedural Characteristics

Case #	Age	Sex	Coronary Dominance	Hemodynamic support	Access	Guide	Wire	Anticoagulation	Antiplatelet	Ejection Fraction	Total Fluoroscopy Time	Total Contrast Volume
1	43	M	Right-dominant with patent stents	No	Femoral	7F-EBU 3.75	BMW	Bivalirudin	Aspirin + Prasugrel	58%	45.9 min	450 mL
2	71	M	Right-dominant with patent vessel	No	Femoral	6F-EBU 4.5	BMW	Bivalirudin	Aspirin + Clopidogrel	50%	23.6 min	225 mL
3	80	M	Right-dominant with patent vessel	No	Radial	7F-EBU 3.5 (sheath less)	BMW	Heparin	Aspirin + Ticagrelor	68%	18.9 min	165 mL
4	68	W	Right-dominant; 100% occlusion	Impella 2.5 LVAD	Femoral	7F-EBU 3.75	BMW/Wiggle	Heparin	Aspirin + Ticagrelor	62%	32.6 min	220 mL
5	70	M	Right-dominant; patent RCA stents	IABP	Femoral	7F-EBU 3.5	BMW	Bivalirudin	ASA + Clopidogrel	63%	13.1 min	135 mL
6	83	W	Right-dominant; 90% prox RCA	Impella CP	Femoral	7F-EBU 3.5	BMW	Bivalirudin	ASA + Ticagrelor	27%	26.7 min	250 mL

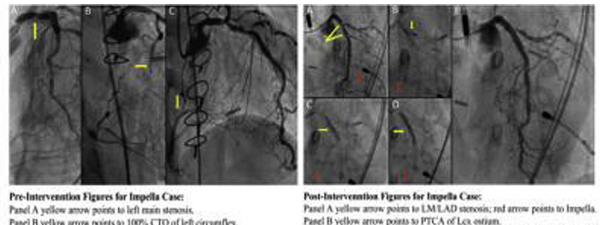
Angiographic Details of Left Main Lesion and Outcomes

Case #	LM Pre-Intervention Stenosis	LM Lesion Length	LM Stent Implanted	LM Post-Intervention Stenosis	Non-LM PCI (Total Vessels Treated)	Total # of Stents implanted	Clinical Procedural Success	Technical Success	Periprocedural Complications
1	90%	25 mm	Promus 3.5x20	0%	Prox & mid LAD, diagonal branch (3)	4	Yes	Yes	None
2	70%	8 mm	Promus 4.0x12	0%	None (1)	1	Yes	Yes	None
3	70%	15 mm	Promus 4.0x16	0%	Prox LAD (2)	2	Yes	Yes	Right forearm hematoma
4	80%	28 mm	Promus 4.0x32	0%	Mid LAD, LCX (2)	1	Yes	Yes	CK-MB 22.2
5	70%	34 mm	Promus 2.75x38 mm	0%	Prox LAD, LCX (2)	1	Yes	Yes	None
6	LM equivalent (90% ostial LCX& 70% ostial LAD)	20 mm LAD, 12 mm LCX	Xience 3.0x23 mm in LAD & Xience 3.0x15 mm in LCX	0%	LAD, LCX, and RCA (3)	3	Yes	Yes	None

for simple coronary lesions has been demonstrated. The objective of this study was to demonstrate the feasibility of robotic PCI for unprotected left main stenosis.

METHODS The robotic CorPath 200 robotic system (Corindus Vascular Robotics, Waltham, MA) consists of a robotic arm mounted on the cardiac catheterization table that consists of a drive housing a single-use sterile cassette, which is connected to the guiding catheter. While sitting in the non-sterile, radiation-shielded cockpit, the operator remotely controls delivery and removal of intracoronary devices including the guidewire, angioplasty balloons, and stents. The database for the ongoing PRECISION registry was queried at a single center to identify all unprotected left main robotic PCI procedures performed and outcomes are reported.

RESULTS During the study period 102 robotic PCI procedures were performed our center of which 6 were identified as unprotected left main stenosis (age 69±14 years; 67% male). All 6 subjects underwent successful PCI (fluoroscopy time 26.8±11.4 min, with an average of 1.8 stents and 2.2 vessels treated/patient). Clinical and procedural success was 100%. Three of the 6 subjects underwent robotic left main PCI without hemodynamic support while 2 were supported with percutaneous left ventricular hemodynamic assistance using the Impella 2.5 device (Abiomed, Danvers, MA) and 1 with intra-aortic balloon pump.



Pre-Intervention Figures for Impella Case:
Panel A yellow arrow points to left main stenosis.
Panel B yellow arrow points to 100% CTO of left circumflex.
Panel C shows the left to right collaterals to the distal RCA

Post-Intervention Figures for Impella Case:
Panel A yellow arrow points to LM/LAD stenosis; red arrow points to Impella.
Panel B yellow arrow points to PTCA of Lcx ostium.
Panel C &D shows the PTCA and stenting of LAD respectively (yellow arrows)
Panel E shows final result.

CONCLUSIONS This is the first report demonstrating the feasibility of robotic PCI for unprotected left main stenosis. Left main disease was treated robotically in the absence and presence of adjunctive hemodynamic support. Though this report demonstrates the feasibility of performing robotic PCI in a high-risk cohort of patients, further studies are needed to examine the safety and effectiveness of this approach in a larger sample of patients.

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

KEYWORDS Impella, Left main coronary artery disease, Robotics

TCT-403

Procedural, In-Hospital And One-Year Outcome Of Provisional Versus Planned Rotational Atherectomy In Complex Calcified Coronary Lesions

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BACKGROUND Rotational atherectomy (RA) is recommended by current guidelines as a provisional (bailout) procedure for heavily calcified or severely fibrotic coronary lesions that cannot be crossed by a balloon or adequately dilated before stenting. There is little information available on procedural, in-hospital, and long term outcome of provisional RA as compared to a planned rotablation strategy for complex calcified coronary lesions.

METHODS We performed a retrospective cohort study of all consecutive patients treated with RA for complex calcified coronary lesions at our institution between November 2002 and February 2014. Clinical follow-up was obtained at 1 year by either clinic visit or telephone interview.

RESULTS During this time interval we identified a total of 512 patients treated for 559 coronary lesions. 204 patients (39.8%) with 221 lesions and 308 patients (60.2%) with 338 lesions were treated with provisional and planned RA respectively. Overall, 380 patients (74.2%) were males, 34.5% had diabetes mellitus and 7.2% had severe chronic renal failure. A history of myocardial infarction was documented in 18.1% of the provisional RA population and 27.9% of the elective RA group (p=0.03). Other baseline clinical characteristics were similar. Provisional RA group had significantly less lesions located in LAD (41.2% vs 57.1%. p=0.002) or involving a bifurcation (28.5% vs 41.1%, p=0.002), but had more chronic total occlusions (12.7% vs 2.4%, p<0.001) and more type B2/C lesions (89.6% vs 80.8%, p=0.005). DES were implanted in 84.2% and 87.6% of lesions in the provisional and planned RA groups, respectively. Coronary dissections occurred more frequently in the provisional RA group (8.6% vs 4.4%, p=0.04), and the mean procedural duration and median fluoroscopy time were also longer in that group (111 ± 50 min vs 76 ± 35 min, p<0.001 and 32 min IQR 21-51 vs 18 min IQR 14-28, p<0.001). Angiographic success (defined as residual stenosis < 30%) was lower in the provisional RA group (93.7% vs 97.6%, p=0.02). In-hospital death occurred in 6 patients (2.9%) in the provisional RA group and in 4 patients (1.3%) in the elective RA group (p=0.21). In-hospital major adverse cardiac events (MACE) defined as death, MI and target vessel revascularization (TVR) were significantly higher in the provisional RA group (10.3% vs 5.5%, p=0.04). At one year follow-up (available for 94.8% of patients), there was no statistically significant difference in the rates of MACE (18.3% for provisional RA vs. 18.6% p=0.52), death (6.5% vs 5.9% p=0.51), spontaneous MI (1.3% vs 2.7%, p=0.29) and TVR (11.3% vs 11.4%, p=0.52) between the two groups.

CONCLUSIONS In a comparison of provisional and planned RA in a large cohort of patients treated for complex calcified coronary lesions,

improved angiographic success, shortened procedural time and a reduction of in-hospital events can be obtained with a strategy of planned RA for selected lesions. However, this strategy does not affect clinical outcomes at one year.

CATEGORIES CORONARY: Artherectomy (excluding thrombectomy)

KEYWORDS Bailout, Percutaneous coronary intervention, Rotational atherectomy

TCT-404

Risk of Stroke of Percutaneous Coronary Intervention in Patients with Stable Coronary Artery Disease: a Systematic Review and Meta-analysis of Contemporary Randomized Clinical Trials

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BACKGROUND Stroke is a rare but serious adverse event associated to PCI. However, the relative risk of stroke between stable patients undergoing a direct PCI strategy and those undergoing OMT has not been established yet.

METHODS We performed a meta-analysis of 6 contemporary randomized control trials in which 5673 patients with SCAD were randomized to initial PCI or OMT. Only trials with stent utilization more than 50% were included. Study endpoint was the rate of stroke during follow up.

RESULTS Mean age of patients ranged from 60 to 65 years and stent utilization ranged from 72% to 100%. Rate of stroke was 2.0% at a weighted mean follow up of 55.3 months. On pooled analysis, the risk of stroke was similar between patients undergoing a PCI plus OMT and those receiving only OMT (2.2% vs. 1.8%, OR on fixed effect = 1.24 95% CI: 0.85-1.79). There was no heterogeneity among the studies (I2 = 0.0%, P = 0.15). On sensitivity analysis after removing each individual study the pooled effect estimate remains unchanged.

Table 1. Characteristics of Included Trials

Trial name or first Author	Years of enrollment	Year of publication	Design of the trial	Inclusion criteria	Exclusion criteria	Primary endpoint	Number of patients	Definition of OMT	Stent use (%)	Follow up (months)
MASS II	1997 - 2001	2004	Single-center RCT	Angiographically documented proximal multivessel disease (>70% stenosis) **and** documented ischemia (positive stress testing or stable angina CCS II-III)	Unstable angina, acute MI, LVEF < 40%, previous PCI or CABG, single vessel disease, LMA stenosis ≥ 50%	composite of: - cardiac death - MI - refractory angina	408	Nitrates Aspirin Beta-blockers CCB ACE-I Statin	NA	60
Hambrecht et al.	1997 - 2001	2004	Single-center RCT	Male < 70 yr Stable-angina (CCS I-III) **and** documented myocardial ischemia by stress-test **and** at least 1vessel disease (≥ 75% by visual assessment)	ACS < 2 months, LMA > 25%, high-grade LAD proximal disease, LVFE < 40%, Insulin dependent diabetes mellitus, CABG or PCI within previous 12 months	ischemic events: - cardiac death - stroke - resuscitation after cardiac arrest - CABG - angioplasty - worsening angina requiring hospitalization	101	exercise training AND guidelines recommended medical therapy	100	12
COURAGE	1999 - 2004	2007	Multicenter RCT	Stable CAD **or** medically stabilized CCS IV angina plus stenosis ≥70% in at least 1 of proximal epicardial coronary artery **and** objective of myocardial ischemia **or** stenosis >80% **and** typical angina without provocative tests.	CCS IV angina, markedly positive stress test, refractory heart failure, LVEF < 30%, revascularization within the previous 6 months	composite of: - death - non fatal MI	2287	aspirin (or clopidogrel) long acting metoprolol, amplodipine, isosorbide mononitrate, lisiniopril (or losartan) simvastatin (alone or in combination with ezetimibe)	94	60
JSAP	1991 - 1997	2003	Single-center RCT	30-75 yr Stable low-risk CAD and 1 or 2 vessel disease (≥ 75% according to AHA classification or ≥ 60% on quantitative CA)	high-risk CAD (3 vessel, left main or ostial LAD); chronic total obstruction; ACS; LVEF < 50%; PCI not indicated; tendency to bleed or severe pneumonia; previous CABG with graft stenosis as responsible lesion; PCI or OMT already prescribed	Composite of: - death - ACS - cerebrovascular accidents - emergency hospitalization	384	NA	75	60
BARI 2D	2001 - 2005	2009	Multicenter RCT (2 x 2 factorial design)	Type 2 diabetes mellitus plus CAD (≥50% stenosis of major epicardial coronary artery and a positive stress test **or** ≥70% stenosis associated with typical angina)	Required immediate revascularization, LMA disease, creatinine > 2.0 mg/dl, Glycated Hb > 13%, NYHA Class III or IV, PCI or CABG within the previous 12 months, liver dysfunction	Overall mortality	1605	as guideline recommendation	91	60
FAME 2	2010 - 2012	2012	Multicenter RCT	Stable CAD **or** angina pectoris CCS class 4 subsequently stabilized medically (minimum 7 days); **or** atypical or no chest pain but documented ischemia on non-invasive testing; plus At least one stenosis ≥50% in at least one major native coronary artery (≥ 2.5mm) and supplying viable myocardium **and** eligible for PCI **and** FFR value <80%	Age < 21 yo; CABG best treatment; LMA disease requiring revascularization; Less than 1 week STEMI or Non-STEMI; Prior CABG; Contra-indication to dual antiplatelet therapy; LVEF < 30%; Severe LV hypertrophy (defined as a septal wall thickness at echocardiography of more than 13 mm); concomitant need for valvular or aortic surgery; Extremely tortuous or calcified coronary arteries precluding FFR measurements; Life expectancy < 2 years;	composite of: - death - non fatal MI - urgent revascularization	888	aspirin, beta-blocker, ACE-I (or ARB), Atorvastatin (alone or in combination with ezetimibe)	100 (II-generation DES)	24

Abbreviations: ACE-I = angiotensin converting enzyme inhibitors; ACS = acute coronary syndrome; AHA = American Heart Association; ARB = angiotensin receptor blockers; CA = coronary angiography; CABG = coronary artery bypass grafting; CAD = coronary artery disease; CCB = calcium channel blockers; CCS = Canadian cardiac society; DES = drug eluting stent, FFR = fractional flow reserve; LAD = left anterior descendent artery; LMA = left main artery; LVEF = left ventricular ejection fraction; NYHA = New York Heart Association; OMT = optical medical therapy; RCT = randomized controlled trial; MI = myocardial infarction; PCI = percutaneous coronary intervention; STEMI = ST elevation myocardial infarction.