TCTAP 2022

Periprocedural Myocardial Infarction or Injury in Novel (Low-Speed Following High-Speed) Versus Conventional (High-Speed) Rotational Atherectomy Technique for Heavily Calcified Coronary Artery Lesions

The Primo-Rota Pilot Study

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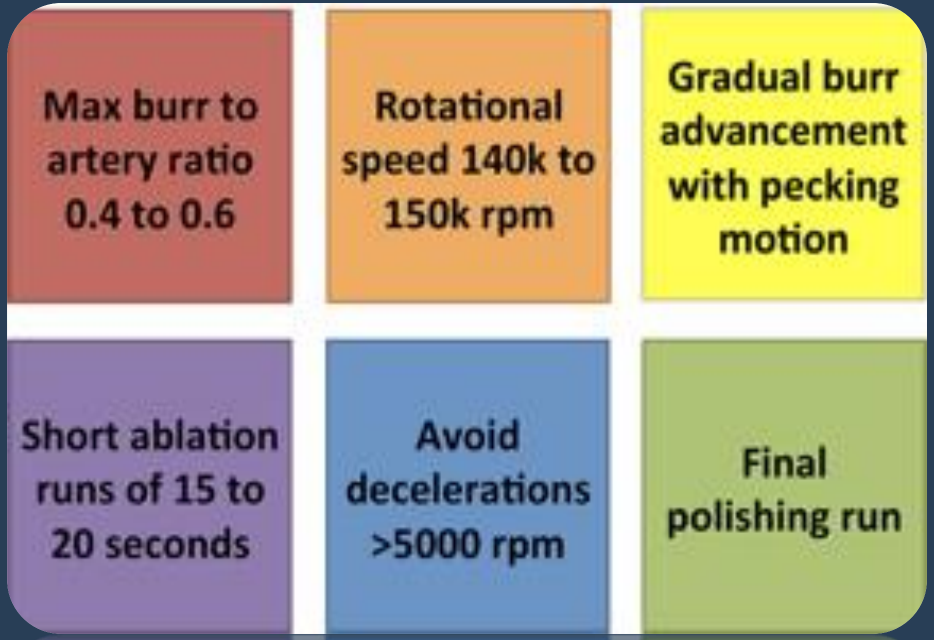
Disclosure

- I do not have potential conflict of interest

Background

- The current best practices recommendations for RA has led to substantial improvements in procedural safety and a reduced rate of associated complications



Kern, M. J. & Seto, Arnold, H. *Interventional Cardiology Review third edition*. (lippincott williams and wilkins, 2018).

Complications of Rotational Atherectomy in the Drug-Eluting Stent Era

Series	Year	N	Death, %	Myocardial Infarction, %	Dissection, %	Perforation, %	Slow-Flow / No-Reflow, %
Kawamoto et al[65]	2016	1176	0.6	7.4	7.0	1.0	1.1
ROTAXUS trial[20]	2013	120	1.7	1.7	3.3	1.7	0.0
Abdel-Wahab et al[66]	2013	205	1.5	2.4	4.4	0.5	2.0
Naito et al[67]	2012	233	0.0	1.3	1.7	0.4	…
Benezet et al[68]	2011	102	1.0	1.0	[illegible]	[illegible]	[illegible]
Dardas et al[69]	2011	184	0.0	…	…	…	…
Garcia de Lara et al[70]	2010	50	4.0	14.0	2.0	2.0	0.0
Rathore et al[71]	2010	391	1.0	6.9	5.9	2.0	2.6
Vaquerizo et al[72]	2010	63	0.0	3.2	…	…	…
Furuichi et al[73]	2009	95	0.0	3.2	2.1	1.1	1.1
Clavijo et al[74]	2006	81	0.0	19.8	1.9	…	…

ROTAXUS indicates Rotational Atherectomy Prior to TAXUS Stent Treatment for Complex Native Coronary Artery Disease.

PMI incident = 1 - 19.8%

Circ Cardiovasc Interv. 2019;12:e007448.

Evolution of Definitions of Periprocedural MI

2000
1st Universal Definition:
Trop T or CKMB

2007
2nd Universal Definition:
Trop T

2012
3rd Universal Definition:
Trop T

2013
SCAI :
CKMB or Trop T

2018
3rd Universal Definition:
Trop T

J Am Heart Assoc.
2014;3:e001086
doi: 10.1161/JAHA.114.001086

Circulation: Cardiovascular Interventi

ORIGINAL ARTICLE

Prognostic Impact of P Myocardial Infarction in Elective Percutaneous C

BACKGROUND: The magnitude of prognostically rel injury after percutaneous coronary interventions rema defined. The Society for Cardiovascular Angiography (SCAI) proposed marked biomarker elevations to defi myocardial infarction (PMI). These consensus-based t been validated in the era of high-sensitivity cardiac tr to assess the prognostic impact of SCAI-defined PMI prog electi

METH electi cente postp nonel in pat all-cau multivariable analyses, patients with SCAI-defined PM a higher risk of 1-year mortality (12.9% versus 2.5%, ratio 4.10, 95% CI 2.51–6.68; P<0.001) as well as ca (11.4% versus 2.1%, adjusted hazard ratio 4.21, 95 P<0.001). Based on receiver operating characteristics prognostic threshold of hs-cTnT was >10×URL, obser patients. This threshold showed lower specificity (85. but higher sensitivity (25.4% versus 8.2%) and bette for prediction of 1-year mortality compared with the value of troponin.

CONCLUSIONS: In patients undergoing elective perc interventions, SCAI-defined PMI emerged as an indep specific, but insensitive predictor of 1-year mortality. between sensitivity and specificity was observed at a hs-cTnT (10× URL) in this cohort.

ESC European Society of Cardiology
European Heart Journal (2018) 0, 1–10
doi:10.1093/eurheartj/ehx799

CLINICAL RESEARCH
Interventional cardiology

Periprocedural myocardial infarction and injury in elective coronary stenting

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Received 9 September 2017; revised 17 October 2017; editorial decision 20 December 2017; accepted 21 December 2017

Aims To assess the incidence, risk factors and prognosis of periprocedural myocardial infarction (MI) and myocardial injury in patients undergoing elective percutaneous coronary intervention (PCI).

... by ischaemic events (3.2% vs. 0.6%, HR 5.9, 95% CI 2.9–20; P < 0.0001). At 1-year, the risk of ischemic events remained higher in the periprocedural MI and myocardial injury group (adjHR = 1.7, 95% CI 1.1–2.6; P = 0.004).

Conclusions Periprocedural MI and injury are frequent complications of elective PCI associated with an increased rate of cardiovascular events at 30 days and 1 year.

Keywords Periprocedural myocardial infarction • Angioplasty • Revascularization • Percutaneous coronary intervention

Introduction

Percutaneous coronary intervention (PCI) technique has dramatically improved within the past 40 years to become the most widely used approach for myocardial revascularization. Constant innovations in catheters, wires, and stent technology have led to safer and more successful procedures, especially in elective setting.[1] Acute stent thrombosis [Type 4b myocardial infarction (MI)], new plaque rupture leading to acute coronary thrombotic occlusion (Type 1 MI), stroke or death remain serious, and rare PCI-related complications.[2] In contrast, periprocedural MI (Type 4a MI) and myocardial injury are much more frequent and usually considered as benign.[3–7]

In 2012, the third universal definition of MI[8] was the first to provide a clinically oriented definition of both Type 4a MI and myocardial injury. Biochemical myocardial injury defined as an isolated rise in cardiac biomarkers was differentiated from a periprocedural proven

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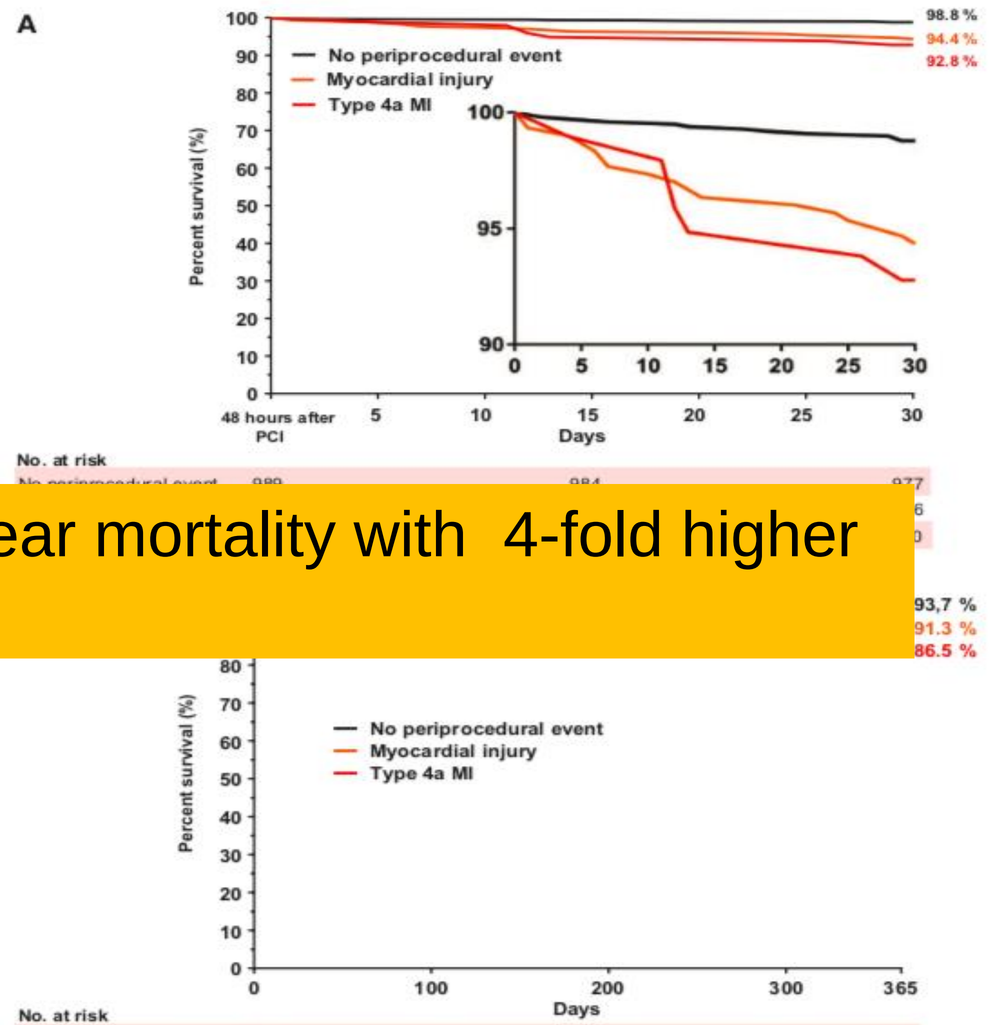


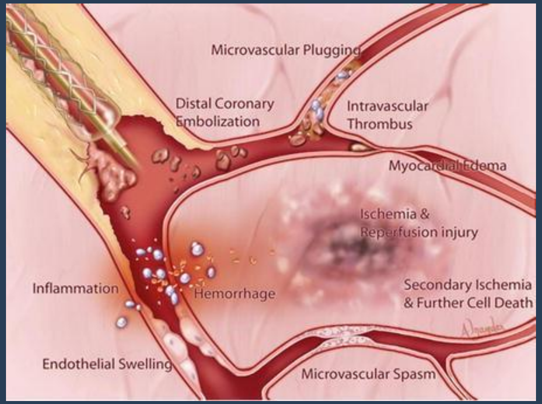
No. at risk	0	100	200	300	365
No periprocedural event	989	974	961	944	923
Myocardial Injury	301	286	283	279	275
Type 4a MI	97	88	86	85	81

PMI as an independent predictor of 1-year mortality with 4-fold higher risk in post PCI MACE

1. *Circ. Cardiovasc. Interv.* **11**, 1–11 (2018).
2. *Eur. Heart J.* **39**, 1100–1109 (2018)

Rotational atherectomy and periprocedural MI:
Potential Mechanism

1. Distal embolism of atheromatous debris and thrombotic debris
2. Platelet activation and thrombosis leading to microvascular plugging of platelets and neutrophils
3. Neuro-hormonal activation and modulation of vascular and myocardial functions
4. Oxidative stress and inflammation



European Heart Journal (2011) 32, 23–32

Evidence of RA speed and platelet aggregation

- Platelet activation was decreased by lowering the rotational speed

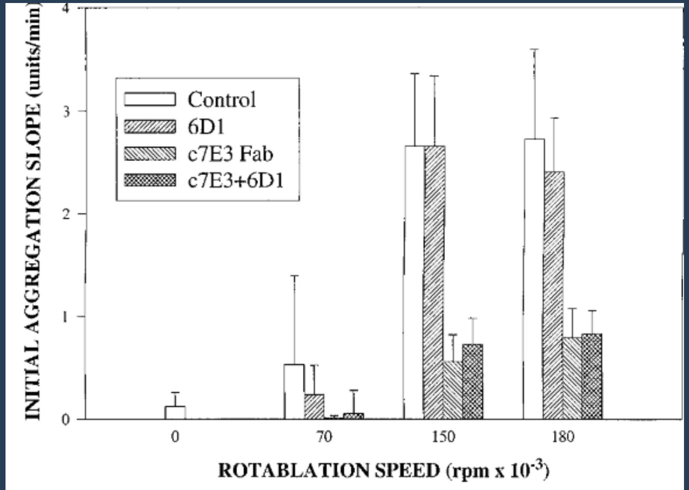
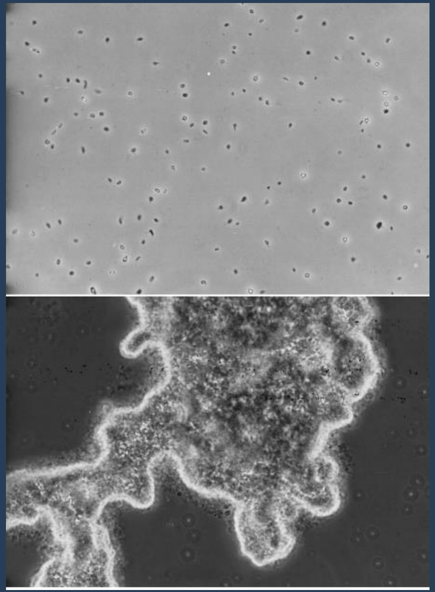


Figure 3. Effect of rotablation on platelet aggregation and effects of antibodies 6D1 and c7E3 Fab. Platelet aggregation results expressed as slope (mean+SD) in transmission light units/min plotted against Rotablator speed. $P<0.001$ for the c7E3 Fab and c7E3+6D1 groups compared with control (no treatment) groups. N=10.

Circulation, vol. 98, no. 8, pp. 742–748, 1998.



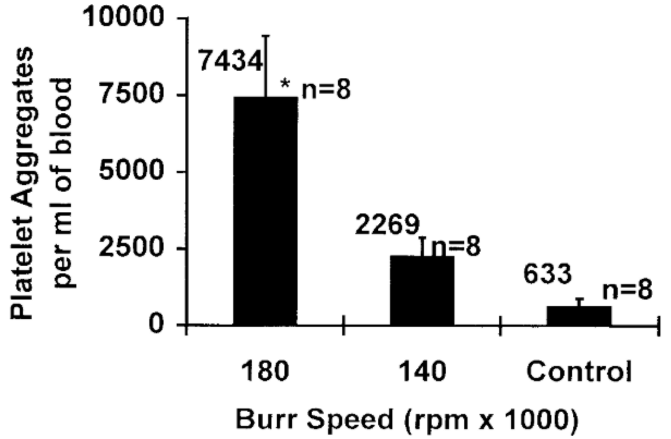


Fig. 5. Effect of different rotational speeds on platelet aggregation. Results are shown as platelet aggregates per ml of blood. Aggregates shown within the range of 20–130 μm in diameter. The number of aggregates is decreased at 140,000 and the control (0 rpm). (n = 8, $P < 0.0001$ for 180,000 vs. 140,000, 180,000 vs. control, and for 140,000 vs. control.)

Catheterization and Cardiovascular Diagnosis, vol. 45, no. 2, pp. 208–214, 1998

European expert consensus on rotational atherectomy - Contemporary rotational atherectomy

180,000 - 200,000 rpm → 135,000 - 180,000 rpm

	Traditional	Contemporary
Arterial access	Femoral 8 Fr	Radial (6-7.5 Fr) or femoral (6-8 Fr), depending upon burr size requirement and operator experience
Guiding catheter	Judkins catheters	Single curve with strong support. Operator preference but stable catheter position required
Guidewire	Floppy rotawire or extra support rotawire for aorto-ostial lesions	Rotawire placement not always straightforward. Use of regular wire placement, with exchange using microcatheter placement often required
[illegible]	[illegible]	[illegible] is [illegible] complications
Ablation speed	180,000 to 200,000 rpm	Plaque modification usually achieved at low speeds (135,000 to 180,000 rpm) to reduce risk of complications
Temporary pacemaker	Always for dominant RCA and left main PCI	Smaller burrs at lower speeds have led to lower incidence of transient heart block. Many operators use atropine to treat, avoiding any complications of temporary pacemaker placement
Rotablation flush	Rotablation cocktail with verapamil, nitrates and heparin in saline recommended	Rotablation cocktail with verapamil, nitrates and heparin in saline recommended

EuroIntervention 2015;11:30-36. DOI: 10.4244/EIJV11I1A6

Rotational Atherectomy Speed

Beneficial effect of rotational atherectomy with low platform speed on late outcomes

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Received 2 October 2002; received in revised form 1 March 2003; accepted 11 March 2003

Abstract

Background: Modification of rotational atherectomy (RA) procedures might be expected to alter restenosis rates. *Methods and results*: From June 1998 (period 2), platform speed was decreased to 150,000–160,000 rpm from the 170,000–190,000 rpm performed from August 1997 to May 1998 (period 1). Patients for the two periods (period 1: 62 patients, 70 lesions; period 2: 85 patients, 91 lesions) demonstrated comparable clinical and angiographic baseline data, allowing immediate and late outcomes to be evaluated for comparison. Restenosis rates in periods 1 and 2 were 57.9% and 33.8%, respectively ($P = 0.01$). Platform speed and lesion length were independent predictors of restenosis by multivariate logistic regression analysis. *Conclusions*: RA with a low platform speed (150,000–160,000 rpm) can be performed with a high success rate and with a lower incidence of restenosis than with a high platform speed (170,000–190,000 rpm).

Keywords: Coronary intervention; Restenosis; Rotational atherectomy

The Incidence of Slow Flow After Rotational Atherectomy of Calcified Coronary Arteries:
A Randomized Study of Low Speed Versus High Speed

Kenichi Sakakura,* MD, Hiroshi Funayama, MD, Yousuke Taniguchi, MD, Yoshimasa Tsurumaki, MD, Kei Yamamoto, MD, Mitsunari Matsumoto, MD, Hiroshi Wada, MD, Shin-ichi Momomura, MD, and Hideo Fujita, MD

Objectives: The purpose of this randomized trial was to compare the incidence of slow flow between low-speed and high-speed rotational atherectomy (RA) of calcified coronary lesions. Background: Preclinical studies suggest that slow flow is less frequently observed with low-speed than high-speed RA because of less platelet aggregation with low-speed RA. Methods: This was a prospective, randomized, single center study. A total of 100 patients with calcified coronary lesions were enrolled and randomly assigned in a 1:1 ratio to low-speed (140,000 rpm) or high-speed (190,000 rpm) RA. The primary endpoint was the occurrence of slow flow following RA. Slow flow was defined as slow or absent distal runoff (Thrombolysis in Myocardial Infarction [TIMI] flow grade ≤ 2). Results: The incidence of slow flow in the low-speed group (24%) was the same as that in the high-speed group (24%) ($P = 1.00$; odds ratio, 1.00; 95% confidence interval, 0.40–2.50). The frequencies of TIMI 3, TIMI 2, TIMI 1, and TIMI 0 flow grades were similar between the low-speed (TIMI 3, 76%; TIMI 2, 14%; TIMI 1, 8%; TIMI 0, 2%) and high-speed (TIMI 3, 76%; TIMI 2, 14%; TIMI 1, 10%; TIMI 0, 0%) groups ($P = 0.77$ for trend). The incidence of periprocedural myocardial infarction was the same between the low-speed (6%) and high-speed (6%) groups ($P = 1.00$). Conclusions: This randomized trial did not show a reduction in the incidence of slow flow following low-speed RA as compared with high-speed RA (UMIN ID: UMIN000015702).

Key words: rotational atherectomy; low-speed; high-speed; slow flow; randomized trial

ACC.18

1078
JACC March 20, 2018
Volume 71, Issue 11

Interventional Cardiology

CLINICAL EFFECTS OF LOW SPEED ROTATIONAL ATHERECTOMY ON THE POST-INTERVENTIONAL MICROCIRCULATION

Poster Contributions
Poster Hall, Hall A/B
Saturday, March 10, 2018, 10:00 a.m.-10:45 a.m.

Session Title: Plaque Morphology and Intravascular Imaging
Abstract Category: 23. Interventional Cardiology: IVUS and Intravascular Physiology
Presentation Number: 1115-272

Hindawi
Journal of Interventional Cardiology
Volume 2019, Article ID 9282876, 7 pages
https://doi.org/10.1155/2019/9282876

WILEY | Hindawi

Research Article

A Novel Rotablator Technique (Low-Speed following High-Speed Rotational Atherectomy) Can Achieve Larger Lumen Gain: Evaluation Using Optimal Frequency Domain Imaging

Takanobu Yamamoto, Sawako Yada, Yuji Matsuda, Hirofumi Otani, Shunji Yoshikawa, Taro Sasaoka, Yu Hatano, Tomoyuki Umemoto, Daisuke Ueshima, Yasuhiro Maejima, Kenzo Hirao, and Takashi Ashikaga

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Academic Editor: Magnus Settergren

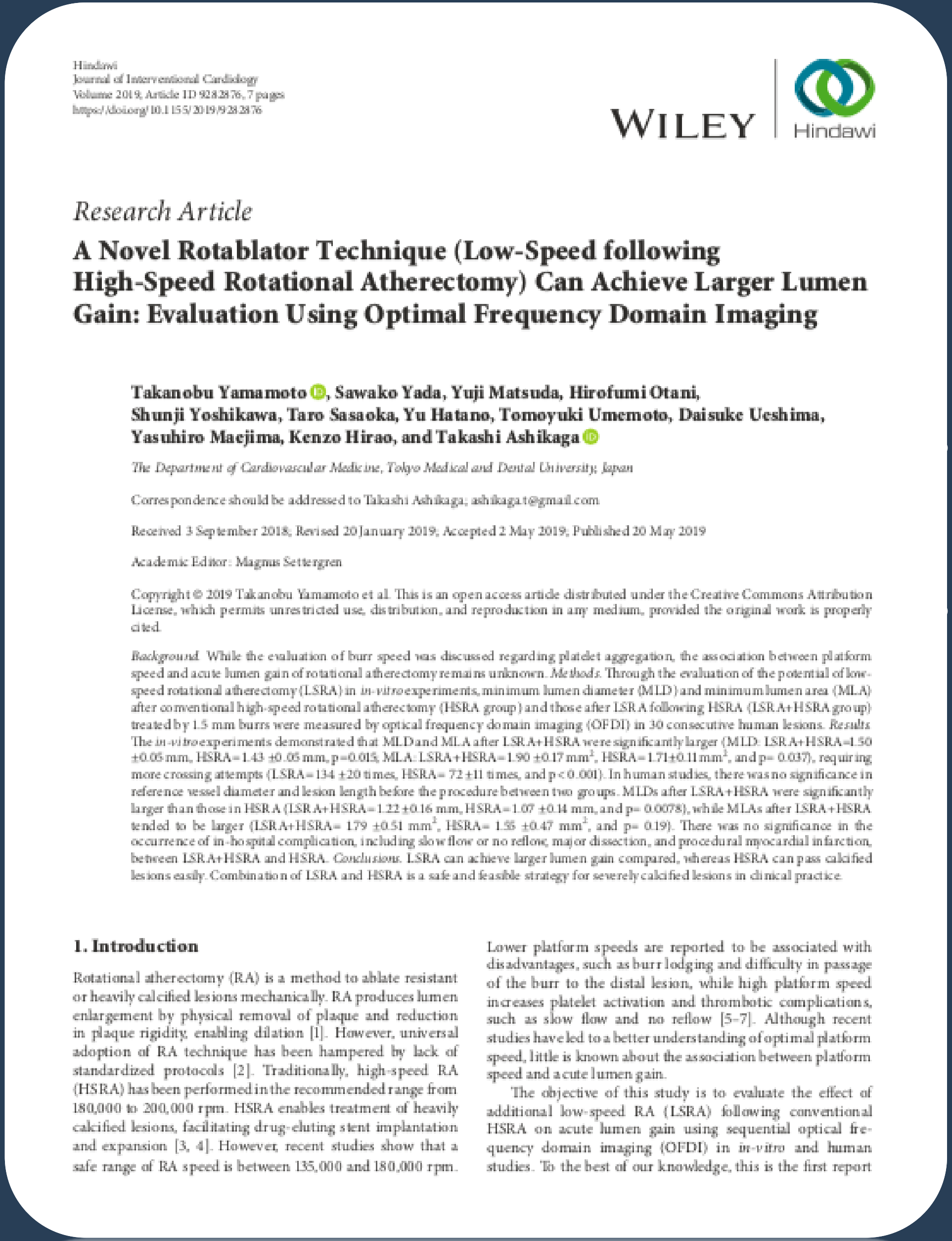
Background. While the evaluation of burr speed was discussed regarding platelet aggregation, the association between platform speed and acute lumen gain of rotational atherectomy remains unknown. *Methods.* Through the evaluation of the potential of low-speed rotational atherectomy (LSRA) in *in-vitro* experiments, minimum lumen diameter (MLD) and minimum lumen area (MLA) after conventional high-speed rotational atherectomy (HSRA group) and those after LSRA following HSRA (LSRA+HSRA group) treated by 1.5 mm burrs were measured by optical frequency domain imaging (OFDI) in 30 consecutive human lesions. *Results.* The *in-vitro* experiments demonstrated that MLD and MLA after LSRA+HSRA were significantly larger (MLD: LSRA+HSRA=1.50 ±0.05 mm, HSRA=1.43 ±0.05 mm, p=0.015; MLA: LSRA+HSRA=1.90 ±0.17 mm^2, HSRA=1.71±0.11 mm^2, and p= 0.037), requiring more crossing attempts (LSRA=134 ±20 times, HSRA= 72 ±11 times, and p < 0.001). In human studies, there was no significance in reference vessel diameter and lesion length before the procedure between two groups. MLDs after LSRA+HSRA were significantly larger than those in HSRA (LSRA+HSRA=1.22 ±0.16 mm, HSRA=1.07 ±0.14 mm, and p= 0.0078), while MLAs after LSRA+HSRA tended to be larger (LSRA+HSRA= 1.79 ±0.51 mm^2, HSRA= 1.55 ±0.47 mm^2, and p= 0.19). There was no significance in the occurrence of in-hospital complication, including slow flow or no reflow, major dissection, and procedural myocardial infarction, between LSRA+HSRA and HSRA. *Conclusions.* LSRA can achieve larger lumen gain compared, whereas HSRA can pass calcified lesions easily. Combination of LSRA and HSRA is a safe and feasible strategy for severely calcified lesions in clinical practice.

1. Introduction

Rotational atherectomy (RA) is a method to ablate resistant or heavily calcified lesions mechanically. RA produces lumen enlargement by physical removal of plaque and reduction in plaque rigidity, enabling dilation [1]. However, universal adoption of RA technique has been hampered by lack of standardized protocols [2]. Traditionally, high-speed RA (HSRA) has been performed in the recommended range from

Lower platform speeds are reported to be associated with disadvantages, such as burr lodging and difficulty in passage of the burr to the distal lesion, while high platform speed increases platelet activation and thrombotic complications, such as slow flow and no reflow [5–7]. Although recent studies have led to a better understanding of optimal platform speed, little is known about the association between platform speed and acute lumen gain.

May, 2019
Low speed 110,000



Hindawi
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WILEY Hindawi

Research Article

A Novel Rotablator Technique (Low-Speed following High-Speed Rotational Atherectomy) Can Achieve Larger Lumen Gain: Evaluation Using Optimal Frequency Domain Imaging

Takanobu Yamamoto, Sawako Yada, Yuji Matsuda, Hirofumi Otani, Shunji Yoshikawa, Taro Sasaoka, Yu Hatano, Tomoyuki Umemoto, Daisuke Ueshima, Yasuhiro Maejima, Kenzo Hirao, and Takashi Ashikaga

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Background. While the evaluation of burr speed was discussed regarding platelet aggregation, the association between platform speed and acute lumen gain of rotational atherectomy remains unknown. *Methods.* Through the evaluation of the potential of low-speed rotational atherectomy (LSRA) in *in-vitro* experiments, minimum lumen diameter (MLD) and minimum lumen area (MLA) after conventional high-speed rotational atherectomy (HSRA group) and those after LSRA following HSRA (LSRA+HSRA group) treated by 1.5 mm burrs were measured by optical frequency domain imaging (OFDI) in 30 consecutive human lesions. *Results.* The *in-vitro* experiments demonstrated that MLD and MLA after LSRA+HSRA were significantly larger (MLD: LSRA+HSRA=1.50 ±0.06 mm, HSRA=1.43 ±0.05 mm, p=0.015; MLA: LSRA+HSRA=1.90 ±0.17 mm^2, HSRA=1.71±0.11 mm^2, and p= 0.037), requiring more crossing attempts (LSRA=134 ±20 times, HSRA= 72 ±11 times, and p < 0.001). In human studies, there was no significance in reference vessel diameter and lesion length before the procedure between two groups. MLDs after LSRA+HSRA were significantly larger than those in HSRA (LSRA+HSRA=1.22 ±0.16 mm, HSRA=1.07 ±0.14 mm, and p= 0.0078), while MLAs after LSRA+HSRA tended to be larger (LSRA+HSRA= 1.79 ±0.51 mm^2, HSRA= 1.55 ±0.47 mm^2, and p= 0.19). There was no significance in the occurrence of in-hospital complication, including slow flow or no reflow, major dissection, and procedural myocardial infarction, between LSRA+HSRA and HSRA. *Conclusions.* LSRA can achieve larger lumen gain compared, whereas HSRA can pass calcified lesions easily. Combination of LSRA and HSRA is a safe and feasible strategy for severely calcified lesions in clinical practice.

1. Introduction

Rotational atherectomy (RA) is a method to ablate resistant or heavily calcified lesions mechanically. RA produces lumen enlargement by physical removal of plaque and reduction in plaque rigidity, enabling dilation [1]. However, universal adoption of RA technique has been hampered by lack of standardized protocols [2]. Traditionally, high-speed RA (HSRA) has been performed in the recommended range from 180,000 to 200,000 rpm. HSRA enables treatment of heavily calcified lesions, facilitating drug-eluting stent implantation and expansion [3, 4]. However, recent studies show that a safe range of RA speed is between 135,000 and 180,000 rpm. Lower platform speeds are reported to be associated with disadvantages, such as burr lodging and difficulty in passage of the burr to the distal lesion, while high platform speed increases platelet activation and thrombotic complications, such as slow flow and no reflow [5–7]. Although recent studies have led to a better understanding of optimal platform speed, little is known about the association between platform speed and acute lumen gain.

The objective of this study is to evaluate the effect of additional low-speed RA (LSRA) following conventional HSRA on acute lumen gain using sequential optical frequency domain imaging (OFDI) in *in-vitro* and human studies. To the best of our knowledge, this is the first report

- A Novel rotational atherectomy technique has shown to achieve larger lumen gain
- Large lumens could be obtained using LSRA.
  - 110,000 rpm would produce more vibration amplitude than 190,000 rpm, which would lead to higher acute lumen gain without burr sizing up

J Interv Cardiol. 2019;2019:9282876.

HSRA/LSRA Vs HSRA

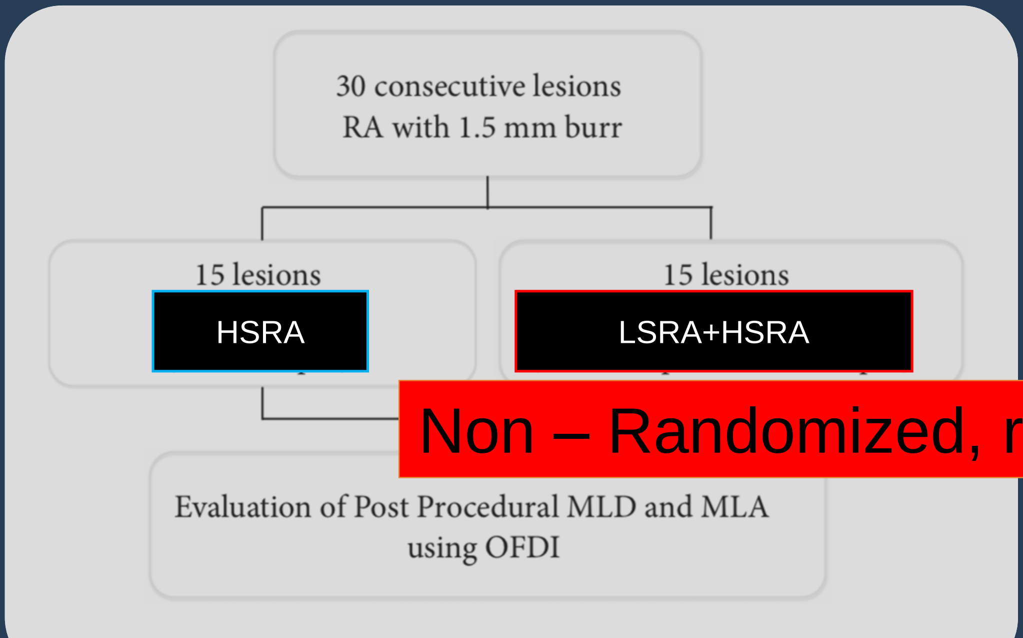


Figure 3: *Study Flowchart of Human Studies.* 30 lesions in patients

Non – Randomized, retrospective study

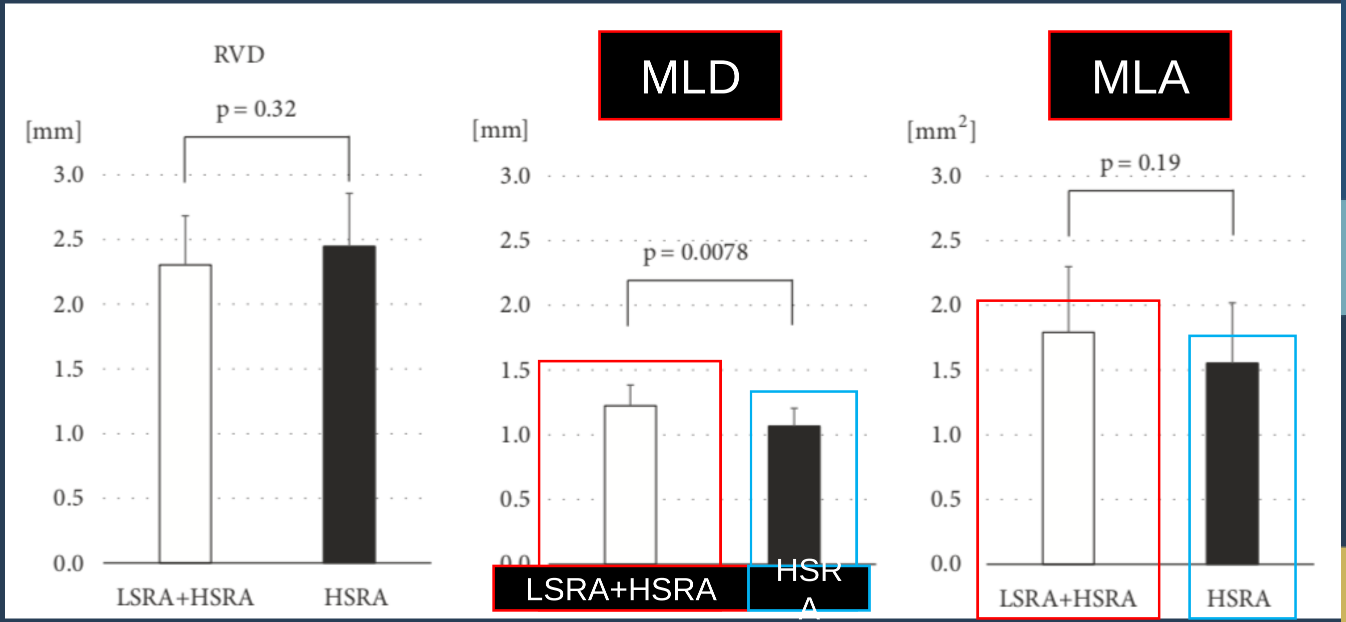


Table 4: In-hospital outcomes.

	HSRA (n= 15)	LSRA+HSRA (n= 15)	P value
Slow flow or no reflow	4 (27)	2 (13)	0.36
Major dissection	1 (7)	0 (0)	0.31
Perforation	0 (0)	0 (0)	1.00
Side branch occlusion	0 (0)	0 (0)	1.00
Procedural MI	2 (13)	2 (13)	1.00

Values are n (%) or mean ±SD.

Journal of Interventional Cardiology, vol. 2019, Article ID 9282876, 7 pages, 2019.

Pros and Cons of High Speed and low speed RA

	Pros	Cons
High Speed	Minimizes friction and enables the burr to easily navigate through tortuous stenotic vessels	Greater platelet aggregation , microcavitation, hemolysis → Higher thrombotic complications – slow flow – no reflow
		Prolonged burr contact with the vascular wall generates a considerable amount of heat, which can adversely affect complication and restenosis
Low speed	Lesser platelet aggregation	Difficulty in passage of the burr to distal lesion
	Lesser thrombotic complications	Longer procedural time

Comparison of
Periprocedural Myocardial infarction/injury
Novel (Low-Speed following High-Speed)
versus
Conventional (High speed)
Rotational Atherectomy Technique for
Heavily Calcified Coronary Artery Disease

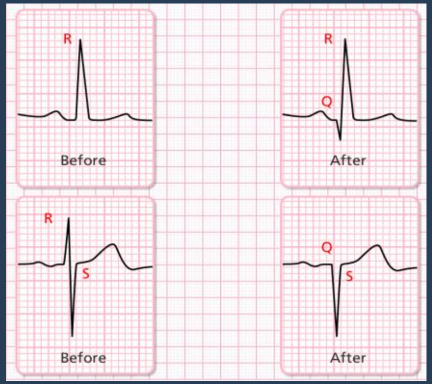
Objectives

- **Primary Objective**
    - To compare the incidence of periprocedural MI (infarction/injury) in 2 groups (HSRA Vs LSRA+HSRA).
- **Secondary Objectives**
    - To compare the incidence of hospital outcomes in 2 groups
    - To compare immediate post RA luminal gain between 2 groups
    - To compare the optimal stent result between 2 groups

Fourth Universal Definition of Type 4a MI (2018)

x

Myocardial Injury



OR

European Heart Journal (2018) 39, 3281–3300

Study Design

- Prospective, Observational, single-center study
- Study period
  - January 2019 – May 2021
- Indications for RA:
  1. Angiographically moderate or severe calcified lesions
  2. Diffuse lesions expected to be difficult to stent
  3. Ostial lesions
  4. Failure to cross the lesion with an OCT/IVUS catheter tip

Method - Inclusion criteria:

Clinical inclusion criteria

1. Age above 18 years with Informed written consent
2. Anginal symptoms and/or reproducible ischemia in the target area by ECG, functional stress testing or fractional flow reserve
3. Angiographically proven coronary artery disease

Angiographic inclusion criteria

1. Target reference vessel diameter between 2.25 and 4.0 mm by visual estimation
2. Luminal diameter reduction of 50-100% by visual estimation
3. Failure to cross the lesion with an OCT catheter
4. Severe calcification of the target lesion
   - Optical coherence tomography : Calcific plaque maximum angle >180°; maximum thickness >0.5 mm; length >5 mm *

*EuroIntervention. 2018;13:e2182–e2189.
#Am Heart J. 1999 Jan;137(1):93-9.

Exclusion criteria:

Clinical exclusion criteria	Angiographic exclusion criteria
1. Myocardial infarction within 1 week 2. Decompensated heart failure 3. Limited long-term prognosis due to other conditions	1. Target lesion is in a coronary artery bypass graft 2. Target lesion is an in-stent restenosis 3. Target vessel thrombus

STUDY DESIGN

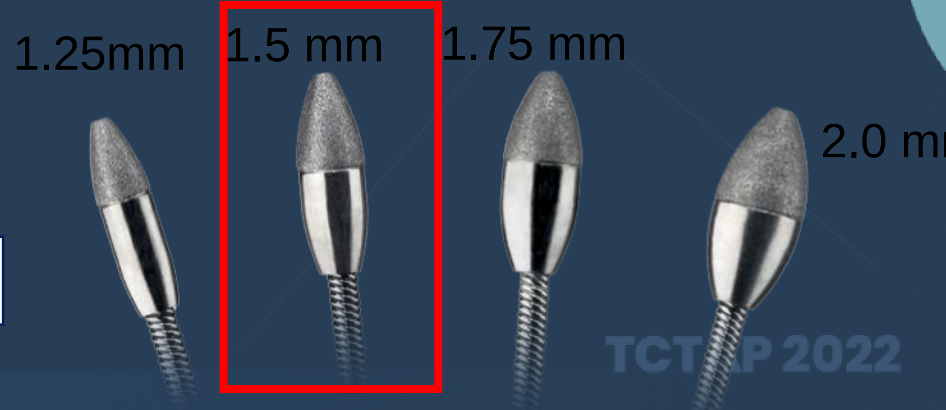
All patients with heavily calcified coronary artery who underwent RA

LSRA+HSRA
100,000-120,000 + 190,000-200,000 rpm

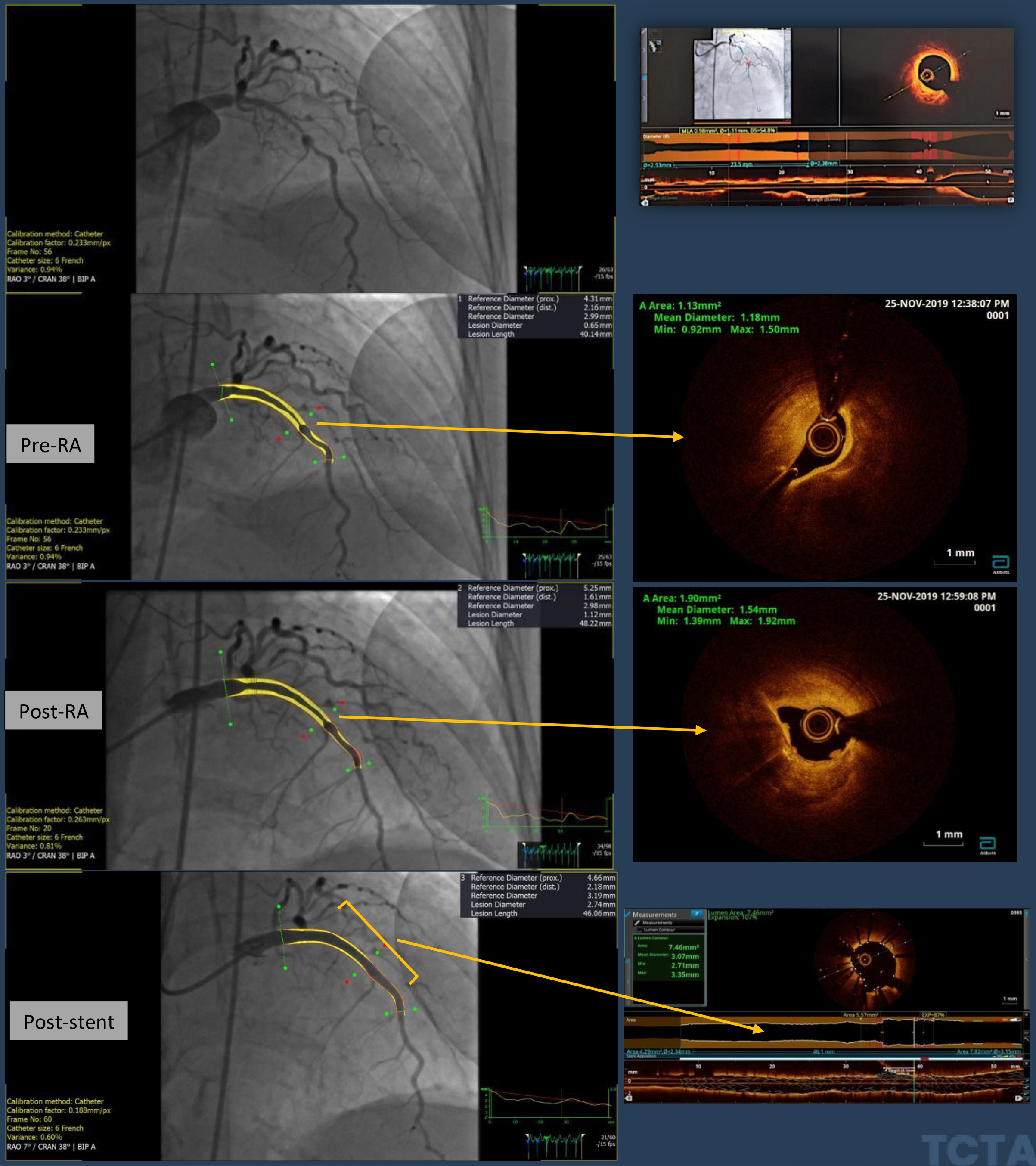
HSRA
190,000-200,000 rpm

Primary Out come

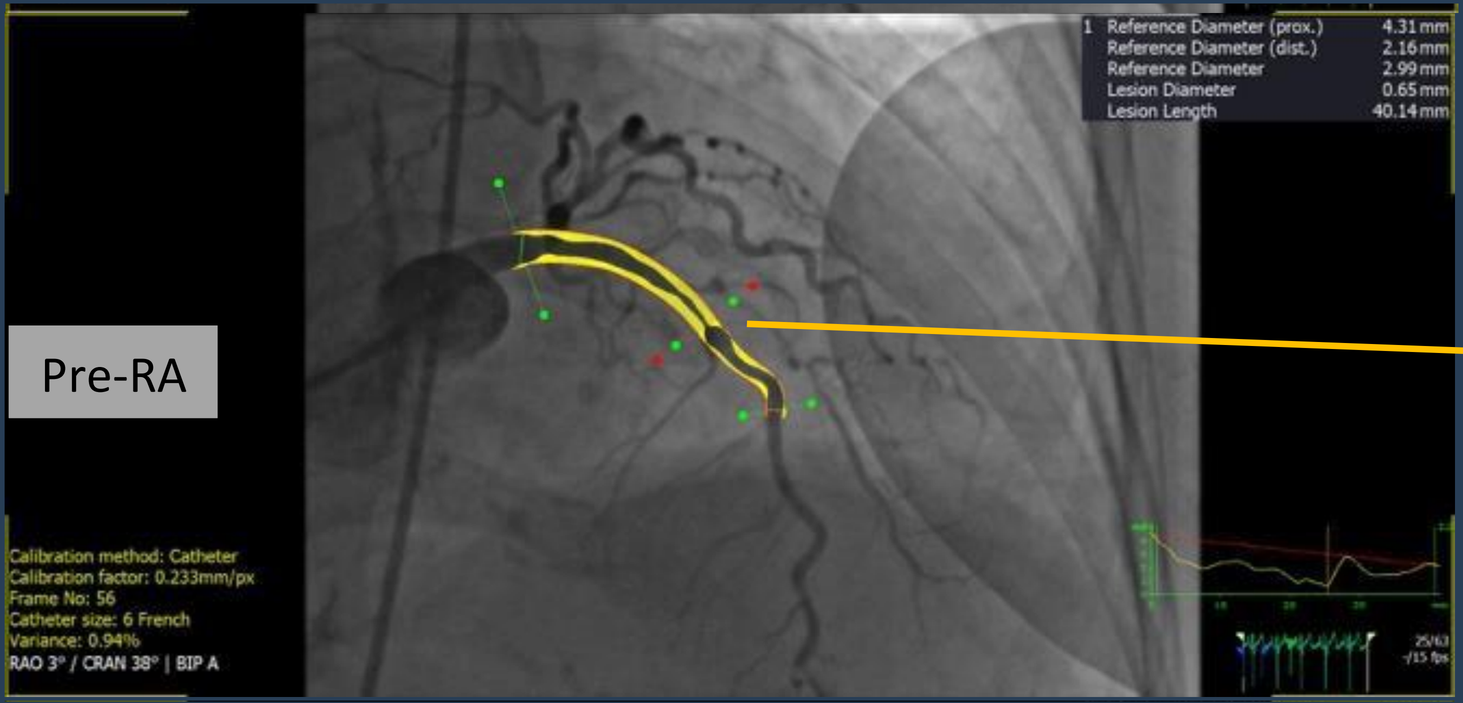
Secondary Out come



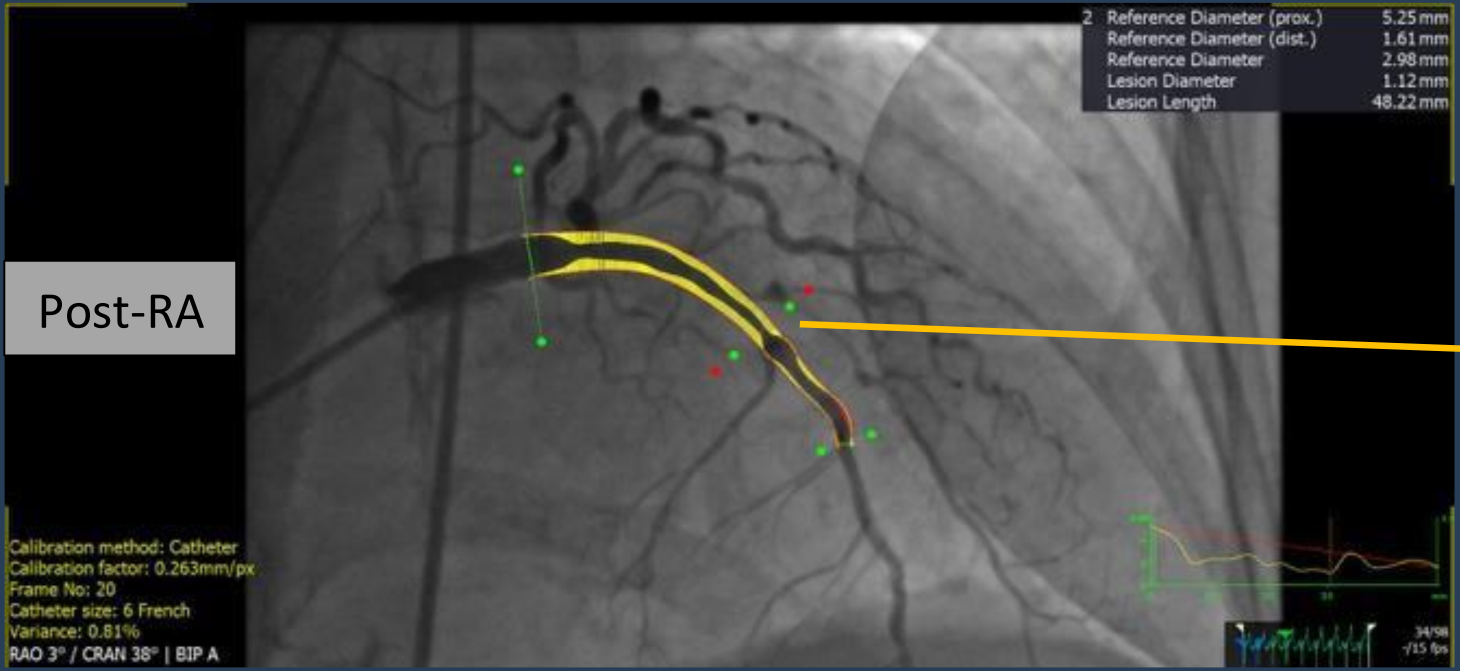
Representative case of RA using optical coherence tomography (OCT) and assessment of minimal luminal diameter (MLD) by Quantitative coronary angiography (QCA).

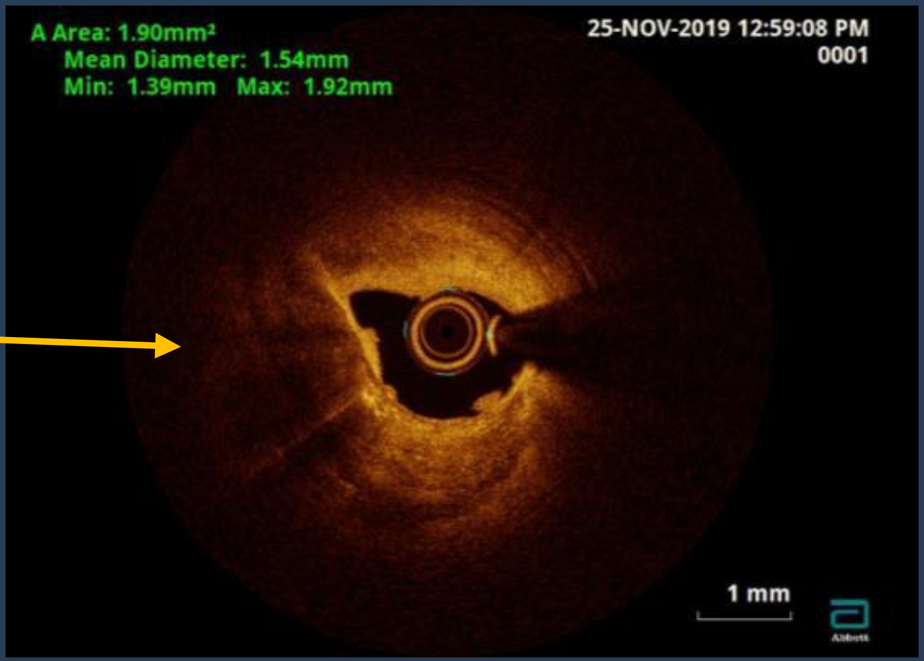


Pre- Rotational atherectomy

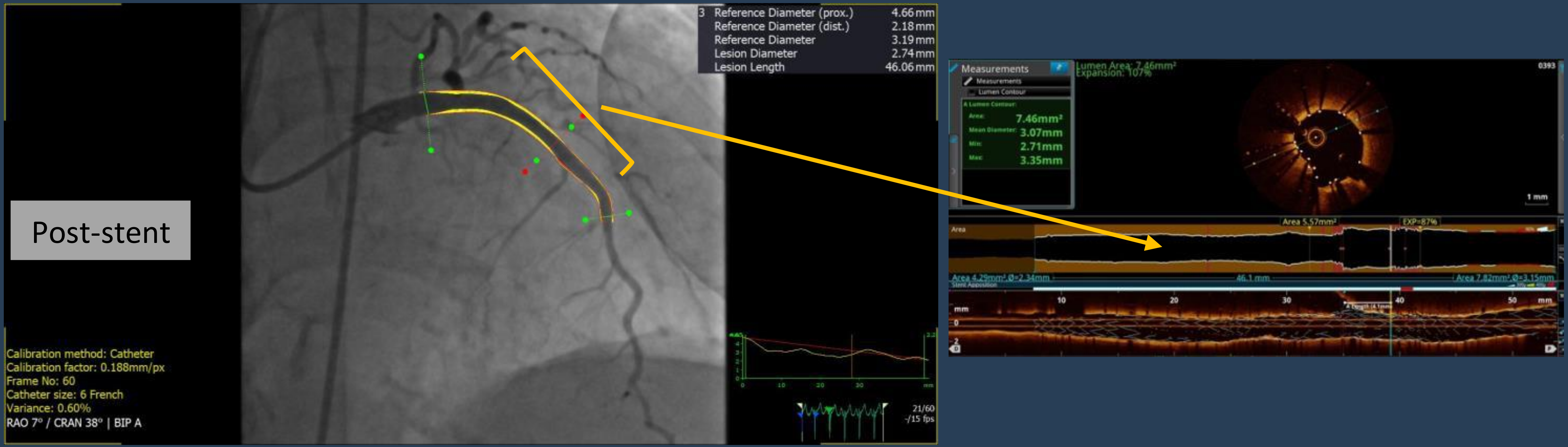


Post- Rotational atherectomy





Assessment of post-stenting optimization results.



Statistical Analysis

- **Categorical variables** - number and percentages and were compared using Fisher's exact test
- **Continuous variables** - the mean ± standard deviation (SD) and were compared using the two-sample t-test
- **Non-parametric continuous variables** - interquartile ranges (IQR)
- **Multivariable binomial regression analysis** - risk difference (RD) and its 95% confidence interval (CI) of PMI/PMJ between HSRA+LSRA and HSRA group
  - Potential confounders of periprocedural myocardial infarction or injury based on previous studies
  - - age [1,2], MVD [2], lesion length [3], stent length[2,4], stent diameter, imaging catheter uncrossable lesions[5],
  - burr to artery ratio , operator experience[6] and those significant difference characteristics between
  - HSRA+LSRA and HSRA were included in the final model.

1. Circ Cardiovasc Interv. 2016;9(11):1–6.
2. Eur Heart J. 2018;39(13):1100–9.
3. Circulation. 1994;89(2):882–92.
4. EuroIntervention. 2016;12(12):1448–56.
5. Sci Rep. 2020;10(1):1–9.
6. Cardiovasc Interv Ther. 2020;36(1):1–18.

RESULTS

Case enrollment

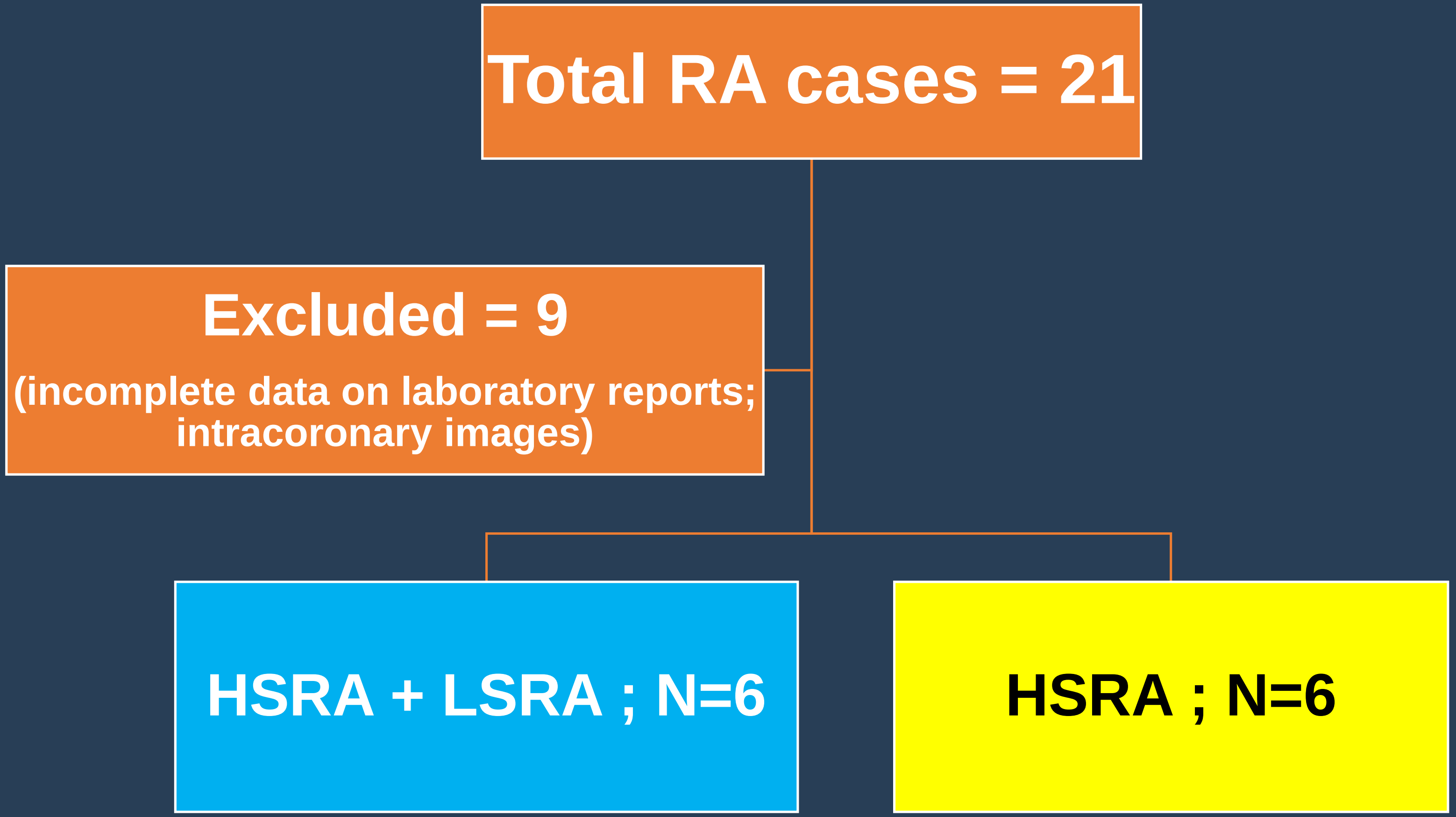


Table 1: Baseline characteristics

Parameters	LSRA+HSRA, n (%)	HSRA, n (%)	P value
Total	6 (50)	6 (50)	
Patient characteristic			
Age, years, mean (SD)	68.8 (10.1)	71.8 (7.1)	0.560
Male	5 (83)	2 (33)	0.240
Body mass index, kg/m^2, mean (SD)	25.6 (3.2)	23.3 (2.5)	0.200
Hypertension	4 (67)	6 (100)	0.450
Diabetes mellitus	4 (67)	2 (33)	0.570
Dyslipidemia	3 (50)	4 (67)	1.000
Chronic renal failure (creatinine>2 gm/dl)	2 (33)	2 (33)	1.000
Chronic renal failure on hemodialysis	1 (17)	1 (17)	1.000
Prior myocardial infarction	3 (50)	2 (33)	1.000
Current smoker	0 (0)	1 (17)	1.000
LV ejection fraction, %, (SD)	56.5 (14.9)	63.4 (14.3)	0.430
Multivessel disease	6 (100)	5 (83)	1.000
Medication			
Aspirin	5 (83)	5 (100)	1.000
Clopidogrel	3 (50)	3 (80)	1.000
Ticagrelor	1 (17)	1 (17)	1.000
Anticoagulant	1 (17)	1 (17)	1.000
Statin treatment	4 (67)	5 (83)	0.450

Table 2. Angiographic and procedural characteristics (n=12)

Parameters	HSRA/LSRA	HSRA	P value
Target lesion characteristics			
Left anterior descending artery	**4 (67)**	**5 (83)**	1.000
Left circumflex artery	2 (33)	0(0)	0.450
Right coronary artery	0 (0)	1 (17)	1.000
ACC/AHA B2/C lesion	3 (50)	4 (67)	1.000
Imaging catheter uncrossable	4 (67)	3 (50)	1.000
Procedural characteristics			
Approach site			
Radial	1 (17)	2 (33)	1.000
Femoral approach	**5 (83)**	**4 (67)**	
Guide catheter			
6F	2 (33)	6 (100)	0.064
7 Fr	**4 (67)**	0 (0)	
Guidewire used during rotational atherectomy			
RotaWire floppy	6 (100)	6(100)	-
Total run time	**96 (29.1)**	**83.7 (35.2)**	0.520
180,000 – 200,000 rpm, mean (SD)	51.0 (15.4)	83.7 (35.2)	
100,000 – 120,000 rpm, mean (SD)	45.0 (17.0)	0.0 (0.0)	
Burr-artery ratio, mean (SD)	0.5 (0.2)	0.6 (0.2)	0.570

Table 2. Angiographic and procedural characteristics (n=12)

	HSRA/LSRA	HSRA	
Cutting or scoring balloon before stenting			
Number, median (IQR)	1.0 (1.0, 2.0)	1.0 (1.0, 1.0)	0.530
Maximum diameter, mm, mean (SD)	2.8 (0.5)	2.8 (0.4)	1.000
Maximum pressure, atm, mean (SD)	17.7 (5.0)	17.2 (2.3)	0.850
Non-compliance balloon before stenting			
Number, median (IQR)	1.0 (0.0, 1.0)	0.5 (0.0, 1.0)	0.730
Maximum diameter, mm, mean (SD)	2.5 (0.6)	2.4 (0.1)	0.820
Maximum pressure, atm, mean (SD)	19.0 (6.2)	19.3 (1.2)	0.930
Stent			
Number, median (IQR)	2.0 (2.0, 2.0)	2.0 (1.0, 3.0)	0.720
Diameter, mm, mean (SD)	**(0.3) 3.1**	**2.6 (0.3)**	**0.009**
Total length, mm, mean (SD)	**47.7 (19.3)**	**55.3 (31.3)**	**0.620**
Adjunct post dilatation balloon after stenting			
Number, median (IQR)	2.0 (2.0, 2.0)	1.0 (1.0, 2.0)	0.019
Maximum balloon diameter, mm, mean (SD)	**4.0 (0.4)**	**3.0 (0.3)**	**0.003**
Maximum balloon pressure, atm, mean	[illegible]	[illegible]	[illegible]

Primary outcome :
Periprocedural myocardial infarction/injury

In Hospital Outcome	Total n (%)	LSRA+HSRA, n (%)	HSRA, n (%)	P value
Peri-procedural myocardial infarction	**2 (16.7)**	**0 (0)**	**2 (33)**	**0.450**
Peri-procedural myocardial injury	**7 (58.3)**	**4 (67)**	**3 (50)**	**0.450**
Peri-procedural myocardial infarction / injury	**9 (75)**	**4 (67)**	**5 (83)**	**1.000**
Final TIMI flow grade < 3	0 (0)	0 (0)	0 (0)	1.000

Risk difference by multivariable binomial regression analysis

```
Generalized linear models                         No. of obs      =         12
Optimization     : MQL Fisher scoring             Residual df     =          2
                   (IRLS EIM)                     Scale parameter =          1
Deviance         =  1.271162682                   (1/df) Deviance =   .6355813
Pearson          =  .7498623999                   (1/df) Pearson  =   .3749312

Variance function: V(u) = u*(1-u)                 [Bernoulli]
Link function    : g(u) = u                       [Identity]

                                                  BIC             =  -3.698651
```

peri_injury	Risk Diff.	EIM Std. Err.	z	P>|z|	[95% Conf.	Interval]
HL	-.5467929	.0653859	-8.36	0.000	-.674947	-.4186388
age	.0580364	.0027552	21.06	0.000	.0526364	.0634364
mvd	0	(omitted)				
lesion_length	-.0170855	.0014599	-11.70	0.000	-.0199468	-.0142241
st_mean_dia	.7505765	.0699958	10.72	0.000	.6133872	.8877658
st_n	1.193516	.2381403	5.01	0.000	.7267691	1.660262
st_l_total	-.0271267	.0057291	-4.73	0.000	-.0383556	-.0158979
burr_art_ratio	.5643292	.1461099	3.86	0.000	.2779591	.8506993
operator	.152704	.1901053	0.80	0.422	-.2198955	.5253035
uncrossable	-1.237489	.275651	-4.49	0.000	-1.777755	-.6972225
_cons	-4.964374	.3434746	-14.45	0.000	-5.637571	-4.291176

LSRA/HSRA

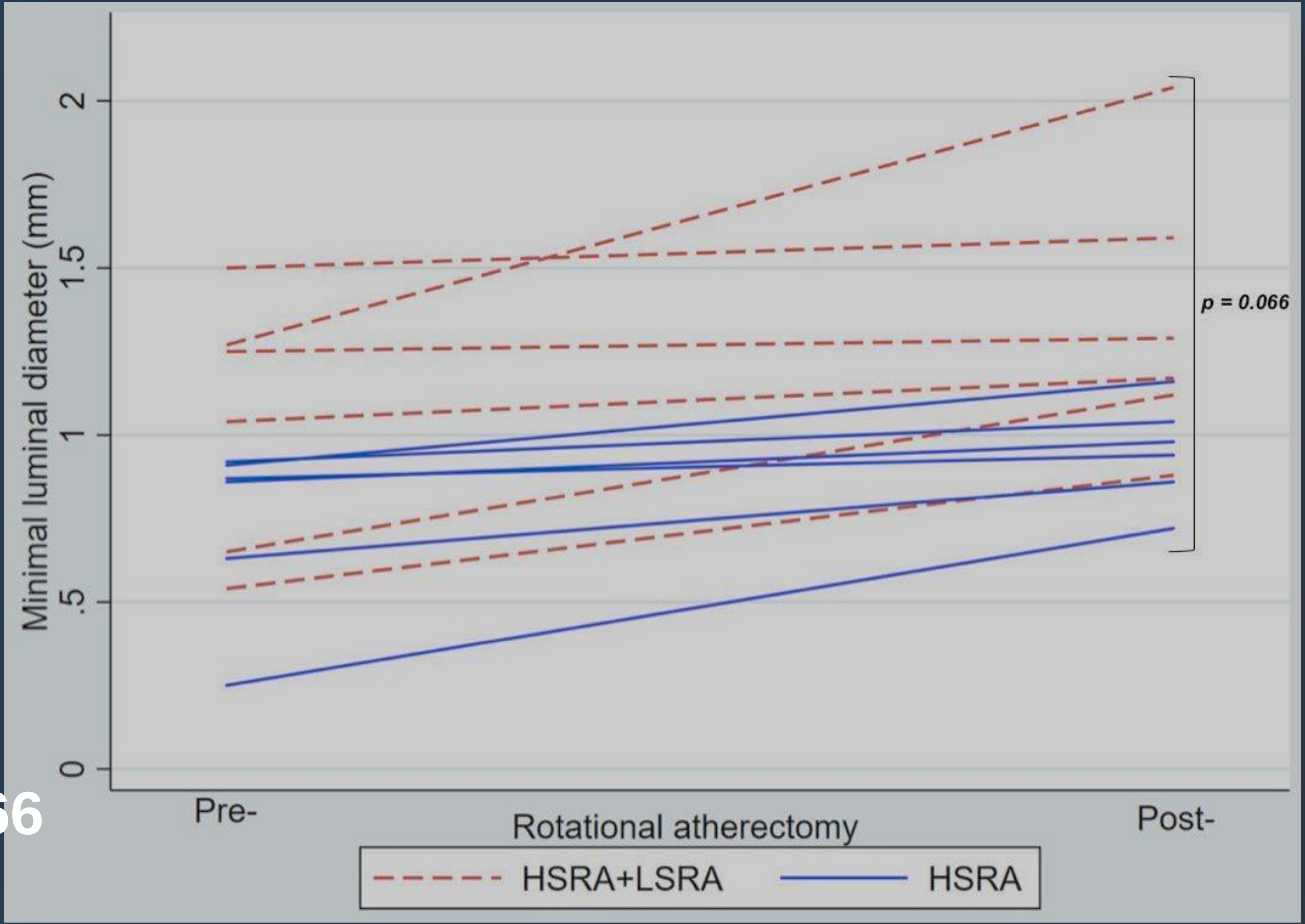
Primary outcome : Periprocedural myocardial infarction/injury

Risk difference by multivariable binomial regression analysis

Variable	Myocardial infarction or injury	
	Risk difference (95% CI)	P value
HSRA+LSRA	-0.55 (-0.67, -0.42)	<0.001

Secondary outcome : Luminal Gain

Comparison of <u>MLD</u> between pre-RA and post-RA in HSRA+LSRA and HSRA group by *QCA*

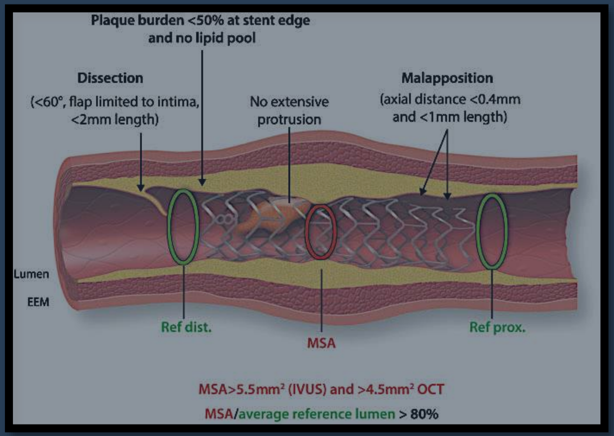


Adjusted mean difference 0.35 mm, 95% CI 0.027 mm - 0.727 mm, p=0.066

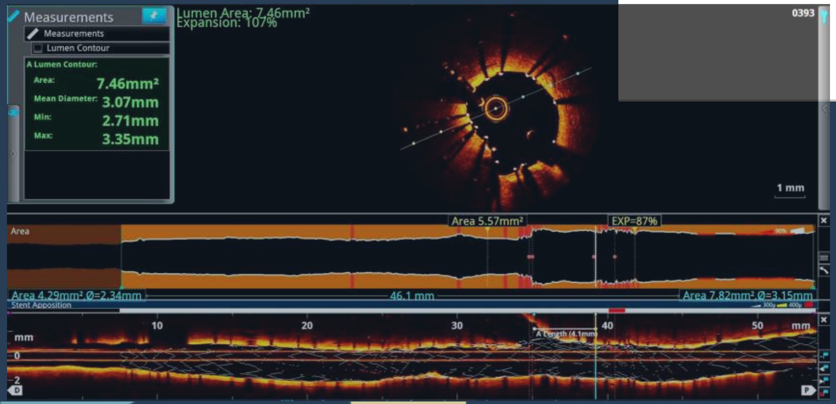
Secondary Outcome: Complications

Complication during procedure	LSRA+HSRA, n (%)	HSRA, n (%)	P value
Slow flow (< TIMI flow 3) immediate post RA	1 (17)	1 (17)	1.000
Major dissection	0 (0)	0 (0)	1.000
Perforation	0 (0)	0 (0)	1.000
Major vessel perforation (Type III) due to burr	0 (0)	0 (0)	1.000
Minor vessel perforation (Type II) due to guidewire	0 (0)	0 (0)	1.000
Major side branch occlusion	0 (0)	0 (0)	1.000
Burr entrapment	0 (0)	0 (0)	1.000
Transection of guidewire	0 (0)	0 (0)	1.000

Secondary Outcome: Optimal stent result



Criteria	HSRA+LSRA, n(%)	HSRA, n(%)	P value
Relative stent expansion > 80%	3 (50)	5 (83)	0.550
MSA > 4.5 mm^2 by OCT	4 (67)	2 (33)	0.570
Acute malapposition*	3 (50)	2 (33)	1.000
Dissection†	2 (33)	3 (50)	1.000



Comparison of *optimal stent result* between HSRA+LSRA & HSRA

Strength

- First study to compare incident periprocedural myocardial infarction between 2 techniques (LSRA/HSRA Vs HSRA)

Limitations

- A single – center study
- Small sample size
- Bias influenced by operator preference and experience cannot be controlled
- 2D QCA assessment of lumen diameter has limitations in accurately accessing the true lumen size and diameter stenosis

Conclusion

- Periprocedural myocardial infarction or injury during rotational atherectomy is common.
- For long heavily calcified coronary lesion, the novel technique of low-speed rotational atherectomy following high-speed rotational atherectomy significantly reduced the risk of periprocedural myocardial infarction or injury.
- There was trend towards larger post rotational atherectomy minimal luminal diameter in the new technique of low-speed rotational atherectomy following high-speed rotational atherectomy group .
- Further studies are needed to confirm these findings and its clinical impact on follow up major adverse cardiovascular events (MACE).

Thank you