Definition and Characterization of Coronary Calcification

Subjects: Pharmacology & Pharmacy
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Coronary artery calcification is increasingly prevalent in our patient population. It significantly limits the procedural success of percutaneous coronary intervention and is associated with a higher risk of adverse cardiovascular events both in the short-term and long-term.

coronary artery calcification | intravascular imaging | percutaneous coronary intervention

1. Introduction

The prevalence of moderate to severe calcification in coronary lesions being treated with percutaneous coronary intervention (PCI) is between 18 to 24%, according to recent meta-analyses and multiethnic registries [1][2][3]. Advanced age, diabetes mellitus, hypertension, hyperlipidemia, smoking, and chronic kidney disease are associated with coronary calcification [4]. Due to increasing age and comorbidities of patients undergoing PCI, the prevalence of severely calcified coronary lesions is increasing [5]. Severe coronary calcification is independently associated with increased major adverse cardiac events following PCI [2][5]. In addition to long-term adverse outcomes, treatment of calcified coronary lesions also poses significant technical challenges. It is associated with an increased likelihood of procedural failure (such as balloon uncrossability or stent under-expansion), complications (such as coronary dissection, coronary perforation, or balloon rupture), and periprocedural mortality and morbidity [5][6]. The periprocedural assessment of the extent and thickness of coronary calcium is critical for calcium modification planning [7][8]. There are many technologies available to modify severely calcified plaques, such as non-compliant (NC) balloons, rotational, orbital and laser atherectomy, and intravascular lithotripsy (IVL) [9]. Each of these modalities of calcium modification has advantages and disadvantages. The contemporary algorithm for treating severely calcified lesions with a preference for one device over the other is changing, especially with the advent of IVL. The selected relevant clinical trials that support their clinical use, as depicted in **Table 1**.

Table 1. Relevant clinical trials for the treatment of coronary calcification.

Study	Study Arms	Relevant Endpoint(s)	Outcomes/Results *	Conclusions
		Cutting Balloon Angioplasty		

Study	Study Arms	Relevant Endpoint(s)	Outcomes/Results *	Conclusions
GRT [10]	CBA vs. PTCA	Binary restenosis after 6 months	CBA: 31.4% PTCA: 30.4% *p* = NS	No reduction in restenosis with CBA after 6 months.
REDUCE (unpublished)	CBA vs. PTCA	Binary restenosis after 6 months	CBA: 32.7% PTCA: 25.5% *p* = NS	No reduction in restenosis with CBA after 6 months.
RESCUT [11]	CBA vs. PTCA for ISR	Binary restenosis after 7 months	CBA: 29.8% PTCA: 31.4% *p* = NS	No reduction in recurrent ISR with CBA after 7 months.
CBA before DES [12]	CBA before DES vs. BA	Minimum stent CSA (mm^2), Acute lumen gain (mm^2)	CBA:6.26 ± 0.4, 3.74 ± 0.38 BA:5.03 ± 0.33, 2.44 ± 0.29 *p* = 0.031, 0.015	CBA achieved larger lumen CSA and larger lumen gain compared to BA.
Mechanisms of Acute Lumen Gain Following Cutting Balloon Angioplasty in Calcified and Noncalcified Lesions [13]	CBA vs. BA in calcified and non-calcified group	ΔEEM CSA (mm^2), ΔP + M CSA (mm^2), Δlumen CSA (mm^2)	Calcified lesions: CBA: 1.4 ± 1.7, −2.3 ± 1.9, 3.7 ± 1.5 BA: 1.2 ± 1.2, −1.8 ± 1.9, 3.0 ± 1.5 *p* = NS, NS, 0.05 Non-calcified lesions: CBA: 1.0 ± 1.8, −2.9 ± 2.1, 3.9 ± 1.9 BA: 1.6 ± 1.8, −2.0 ± 1.9, 3.6 ± 1.6 *p* = NS(0.11), 0.03, NS	In calcified lesions, CBA achieves a larger lumen gain vs. BA. In noncalcified lesions, there is larger plaque reduction with CBA but no difference in lumen gain vs. BA.
Scoring Balloon Angioplasty				
Intimal disruption and cobalt-chromium DES [14]	SBA vs. BA	Stent expansion, lumen eccentricity, intimal disruption frequency, extent	SBA: 68%, 0.94, 68%, 122° BA: 62.1%, 0.80, 0.8, 65° *p* = 0.017, 0.18, 0.035, 0.035	SBA achieved increased stent expansion with similar lumen eccentricity when compared with BA. SBA had more frequent and extensive intimal disruption when compared with BA.
Predilatation with SBA vs. NC [15]	SBA vs. NC	Stent expansion (mm), in-stent late loss after 1 year (mm)	SBA: 70.7 ± 11.2, 0.71 ± 0.63 NC: 69.1 ± 11.1,	SBA achieved decreased in-stent late loss when

Study	Study Arms	Relevant Endpoint(s)	Outcomes/Results *	Conclusions
			0.23 ± 0.52 p = NS, 0.03	compared to NC after 1 year. There was no difference in stent expansion between SBA and NC groups.
		Rotational Atherectomy		
ERBAC [16]	RA vs. ELCA vs. PTCA	Procedural success $^{\Sigma}$, TVR after 6 months	RA: 89%, 42.4% ELCA: 77%, 46% PTCA: 80%, 31.9% p = 0.0019, 0.013	RA achieved superior procedural success when compared with ELCA and PTCA, but both RA and ELCA had unfavorable late outcomes when compared with PTCA.
COBRA [17]	RA vs. PTCA	Binary restenosis after 6 months	RA: 49% PTCA: 51% p = 0.35	RA did not reduce restenosis after 6 months when compared with PTCA.
DART [18]	RA vs. PTCA in small vessels (2–3 mm)	TVF after 12 months	RA: 30.5% PTCA: 31.2% p = 0.98	RA did not reduce TVF after 12 months when compared with PTCA.
STRATAS [19]	Aggressive RA (B/A 0.7–0.9) with PTCA (<1 bar) vs. routine RA (B/A < 0.7) with PTCA (4 bar)	Binary restenosis after 6 months	Aggressive: 58% Routine: 52% p = NS	Aggressive RA debulking did not reduce restenosis after 6 months when compared with routine RA debulking.
CARAT [20]	Aggressive RA (B/A > 0.7) vs. Routine RA (B/A = 0.7)	MACE after 6 months	Aggressive: 36.3% Routine: 32.7% p = NS	Aggressive RA debulking did not reduce MACE after 6 months compared with routine RA debulking.

Study	Study Arms	Relevant Endpoint(s)	Outcomes/Results *	Conclusions
ROOSTER [21]	RA (B/A = 0.7) vs. PTCA for diffuse ISR with IVUS guidance	TLR after 9 months	RA: 32% PTCA: 45% *p* = 0.04	RA achieved less TLR after 9 months compared with PTCA in diffuse ISR.
ARTIST [22]	RA (B/A = 0.7) vs. PTCA for diffuse ISR with IVUS guidance in a subset	MACE after 6 months	RA: 80% PTCA: 91% *p* = 0.0052	PTCA achieved a lower MACE when compared to RA in diffuse ISR.
ROTAXUS [23]	RA with DES vs. DES	Late lumen loss (mm) after 9 months	RA with DES: 0.31 ± 0.52 DES: 0.44 ± 0.58 *p* = 0.04	RA before DES achieved increased late lumen loss when compared to DES alone.
Prepare-CALC [24]	RA vs. modified CSA	Successful stent delivery and expansion, late lumen loss (mm) after 9 months	RA: 98%, 0.22 ± 0.41 CSA: 81%, 0.16 ± 0.40 *p* = 0.001, 0.21	RA achieved greater success at stent delivery and expansion than CSA and had similar late lumen loss rates after 9 months.
Orbital Atherectomy				
ORBIT I [25]	OA single arm	Device success $^{\int}$ Procedural success $^{\iint}$ TLR, MACE after 6 months	Device success: 98% Procedural success: 94% TLR, MACE (6 months): 2%, 8%	OA successfully facilitated stent delivery with a low cumulative TLR and MACE after 6 months.
ORBIT II [26]	OA single arm	Safety endpoint $^{\Omega}$ (95% CI) Efficacy endpoint $^{\Psi}$ (95% CI)	Safety endpoint: 89.6% (86.7–92.5%) Efficacy endpoint: 88.9% (85.5–91.6%)	OA significantly exceeded the primary safety and efficacy endpoints of 83% and 82% respectively. OA also improved in-hospital and 30-day outcomes compared

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				to historic controls with severe CAC.
Laser Atherectomy				
LAVA [27]	ELCA vs. PTCA in native vessels or SVG	MACE after 6 months	ELCA: 28.9% PTCA: 23.5% *p* = 0.55	ELCA did not reduce MACE after 6 months compared with PTCA in native vessels or SVG.
AMRO [28]	ELCA vs. PTCA in native vessels	MACE after 6 months	ELCA: 33.3% PTCA: 29.9% *p* = 0.55	ELCA did not reduce MACE after 6 months compared with PTCA in native vessels.
Intravascular Lithotripsy				
DISRUPT CAD I [29]	Coronary IVL single arm	Safety endpoint Ω Effectiveness endpoint Ψ	Safety endpoint: 95% Effectiveness endpoint: 98.5%	Coronary IVL safely and effectively aided stent placement with minimal perioperative complications.
DISRUPT CAD II [30]	Coronary IVL single arm	Safety endpoint Ω Effectiveness endpoint Ψ Calcium fractures measured by OCT Mean stent expansion	Safety endpoint: 100% Effectiveness endpoint: 94.2% Calcium fractures: 67.4% Mean stent expansion: 101.7% [33]	Coronary IVL safely and effectively aided stent placement with minimal perioperative complications. OCT demonstrated that calcium fractures were an underlying mechanism for IVL. Coronary IVL allowed for excellent stent expansion.
DISRUPT CAD III [31]	Coronary IVL single arm [5]	Safety endpoint Ω (lower-bound of 95% CI) Effectiveness endpoint Ψ (lower-bound of 95% CI)	Safety endpoint: 92.2% (89.9%, *p* = 0.0001) Effectiveness endpoint: 92.4% (90.2%, *p* = 0.0001)	Coronary IVL safely and successfully assisted with stent delivery. The lower bounds of the 95% CI for the safety and effectiveness endpoints exceeded the performance

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Study	Study Arms	Relevant Endpoint(s)	Outcomes/Results *	Conclusions
				goal of 84.4% and 83.4%[8] respectively.
DISRUPT CAD IV [32]	[35] Coronary IVL single arm	Safety endpoint Ω [34]: CAD IV cohort vs. propensity matched historical IVL control group Effectiveness endpoint $^{\Psi}$: CAD IV cohort vs. propensity matched historical IVL control group	Safety endpoint: 93.8% vs. 91.2%, p = 0.008 Effectiveness endpoint: 93.8% vs. 91.6%, p = 0.007 [36]	Coronary IVL safely and effectively aided stent placement with minimal perioperative complications. The results from coronary IVL in the Japanese CAD IV cohort were non-inferior to those from a study of patients treated with IVL in the USA and Europe.

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Table 2. Classification of calcified coronary lesion severity based on intravascular imaging.

Severity	OCT-Based Calcium Score • Calcium Arc of >180° (2 Points), 90–180° (1 Point) • Calcium Length of >5 mm (1 Point) • Calcium Thickness of >0.5 mm (1 Point)	IVUS-Based Calcium Score • Length of Calcium (>270°) of >5 mm (1 Point) • Presence of 360° Circumferential Calcium (1 Point) • Vessel Diameter of ≤3.5 mm (1 Point) • Presence of a Calcified Nodule (1 Point)
Mild to moderate	0–3	0–1
Severe	≥4	≥2

Abbreviations: IVUS, intravascular ultrasound; OCT, optical coherence tomography.

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2. Definition and Characterization of Coronary Calcification

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