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Research Brief

Real-world outcomes in treatment of highly calcified coronary lesions with intravascular shockwave lithotripsy

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ABSTRACT

Real-world data regarding the efficacy and safety of coronary intravascular lithotripsy (IVL) are lacking. We conducted a study of 50 consecutive patients (64 lesions) who underwent IVL. 3 patients suffered in-hospital mortality unrelated to the IVL; there was no other occurrence of MACE up to 30 days. Angiographic success was nearly universal (98% of patients with residual stenosis <50%, 96% of patients with TIMI 3 flow) and complication was rare, including among patients undergoing IVL for in-stent restenosis or left main coronary artery lesions. In a high-risk real-world cohort, IVL was a safe and effective treatment for highly-calcified coronary lesions.

1. Introduction

Intravascular lithotripsy (IVL) has been developed for the management of heavily calcified lesions, and has been shown to produce excellent angiographic and long-term outcomes in small single-arm and registry studies[1,2,3] and most recently in a multicenter non-randomized trial of 431 patients.[4] However, it has been well documented that characteristics of patients comprising cardiac clinical trials are distinctly different from the population of cardiac patients in the real world.[5] We therefore conducted a retrospective review of patients undergoing IVL at a tertiary care center, with the goal of further defining real-world outcomes of IVL in a high-risk population.

2. Methods

We conducted a retrospective review of consecutive patients undergoing IVL at a regional referral cardiac catheterization laboratory between September 1, 2019–January 31, 2021. Baseline demographic and clinical data was collected for all patients (Table 1). Procedural, angiographic, laboratory, and outcome data was obtained from a centralized database and the comprehensive electronic medical record.

The primary outcome was major adverse cardiac event (MACE) at 30-days, which was defined as death, MI, or target-vessel revascularization. Secondary outcomes included angiographic success (defined as post-procedural target-vessel stenosis <50%) and freedom from angina. Data regarding adverse events was collected including IVL-induced ventricular capture or ventricular arrhythmia, coronary no-reflow, coronary perforation or dissection, pericardial effusion or tamponade, periprocedural MI, periprocedural cardiac biomarker rise, and Bleeding Academic Research Consortium (BARC) class 3 or 5 bleeding.[6] Additional exploratory analyses were undertaken in patients in whom IVL was used for treatment of in-stent restenosis (ISR) and in whom rotational atherectomy was used in conjunction with IVL (so-called RotaTripsy).[3]

3. Results

A total of 50 patients underwent IVL during the study period. There was a high prevalence of comorbidity. Acute coronary syndrome (ACS) was the most common indication for PCI (Table 1).

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Table 1
Baseline clinical, demographic, and angiographic characteristics of patients undergoing coronary intravascular lithotripsy.

Clinical characteristics	N = 50
Female sex (%)	18 (36)
Median age (IQR)	71.5 (66.3–77.5)
Median body mass index (IQR)	28.0 (23.9–31.1)
Hypertension (%)	41 (82)
Dyslipidemia (%)	41 (82)
Diabetes (%)	28 (56)
eGFR ml/min/1.73m^2 (%)	**>60** 30 (60)
	45–59 9 (18)
	30–44 7 (14)
	15–29 3 (6)
	<15 1 (2)
Current smoker (%)	5 (10)
Former smoker (%)	18 (36)
Previous stroke or TIA (%)	6 (12)
Peripheral artery disease (%)	7 (14)
Left ventricular ejection fraction <40% (%)	7 (14)
Previous myocardial infarction (%)	30 (60)
Prior CABG (%)	7 (14)
Prior PCI (%)	27 (23)
Presentation (%)	**Stable angina** 11 (22)
	NSTE-ACS 36 (72)
	STEMI 3 (6)
Baseline pharmacotherapy (%)	*N = 50*
ASA	30 (60)
P2Y12i	22 (44)
Oral anticoagulant	9 (18)
Statin	38 (76)
ACEi or ARB	35 (70)
Beta blocker	36 (72)
Procedural characteristics (%)	*N = 50 patients, 64 lesions*
In-stent restenosis	13 (26)
Chronic total occlusion	9 (18)
Bifurcation lesion	11 (22)
Multivessel PCI	14 (28)
LMCA PCI	12 (24)
Target vessel	**LMCA** 12 (24)
	LAD 22 (44)
	LCx 12 (24)
	RCA 15 (30)
	Other 3 (6)

ACEi = angiotensin converting enzyme inhibitor; ARB = angiotensin receptor blocker; CABG = coronary artery bypass grafting; P2Y12i = P2Y12 receptor inhibitor; eGFR = estimated glomerular filtration rate (CKD-EPI); ESRD = end-stage renal disease; LAD = left anterior descending artery; LCx = left circumflex artery; LMCA = left main coronary artery; NSTE-ACS = non-ST-elevation acute coronary syndrome; PCI = percutaneous coronary intervention; PPI = proton pump inhibito; RCA = right coronary artery STEMI = ST-elevation myocardial infarction; TIA = transient ischemic attack.

A total of 64 lesions were intervened upon, most commonly of the left anterior descending artery (LAD). About one quarter of patients underwent IVL involving the left main coronary artery (LMCA) (Table 1). In 80% of patients another device was used in conjunction with IVL, most commonly noncompliant (NC) balloon in 60%. 40% of patients underwent multiple advanced interventions prior to IVL.

Angiographic success occurred in 98% of patients. There was no incidence of arrhythmia or IVL-induced ventricular capture, coronary dissection, or no-reflow. Coronary perforation (Ellis type 1) occurred in 1 patient, was managed with balloon tamponade and Papyrus stent, and was of no clinical consequence. The device used immediately prior to detection of the perforation was an NC balloon.

In-hospital and 30-day outcomes were excellent, with a majority of patients being free from angina (Table 2). Asymptomatic biomarker rise and acute kidney injury (AKI) was rare, and there was no incidence of MACE, stroke, or major bleeding. 3 patients died for causes unrelated to IVL. The majority of the 12 patients with follow-up to 1 year were free from angina; 1 patient died of non-cardiac cause within 1 year after admission.

Among 13 patients who underwent IVL for ISR, angiographic success occurred in 100%, and none experienced death, MACE, or major bleeding at 30 days. A total 10 patients underwent Rotatripsy and all had angiographic success and were free from angina, MACE, major bleeding, or death at 30 days.

4. Discussion

In this real-world study, we demonstrate that IVL is an effective and safe option for PCI of highly calcified complex coronary lesion. Our study included patient cohorts not previously investigated including those with ACS, stent failure, LMCA intervention, and complex combination therapy such as RotaTripsy.

Consistent with the results of the Disrupt CAD III clinical trial,[4] angiographic success with IVL was nearly universal. More importantly, >90% of patients remained free of angina at 30 days. Notably, there were no instances of no-reflow, in contrast to rotational atherectomy in which it can occur in up to 3% of cases.[7]

In-hospital mortality occurred in 3 patients, but occurred despite successful IVL and not as a complication of the procedure; two patients died of progressive cardiogenic shock (related to ischemic cardiomyopathy in one patient and severe aortic stenosis in another) despite revascularization, and the other died of hypotension leading to asystolic cardiac arrest in the setting of ST-elevation myocardial infarction (STEMI). Otherwise, in-hospital and 30-day MACE did not occur, consistent with previous reports.[3,4]

In contrast to typical clinical trial populations, our cohort was a high-risk one both clinically and procedurally (Table 1). 80% of

Table 2
In-hospital, 30-day and 1-year clinical outcomes for patients undergoing intravascular coronary lithotripsy.

Clinical outcomes (%)	In-hospital N = 50	30-day N = 44	1-year N = 12
Death	3 (6)	0 (0)	1 (8)
MI	0 (0)	0 (0)	0 (0)
Creatine kinase >5x ULN	1 (2)	N/A	N/A
hsTnT >5x ULN	5 (10)	N/A	N/A
Target-vessel revascularization	0 (0)	0 (0)	0 (0)
Stent thrombosis	0 (0)	0 (0)	0 (0)
Stroke	0 (0)	0 (0)	1 (8)
Freedom from angina	45 (90)	41 (93)	10 (83)
Acute kidney injury	4 (8)	1 (2)	0 (0)
Need for renal replacement therapy	0 (0)	0 (0)	0 (0)
BARC 3 or 5 bleeding	0 (0)	1 (2)	1 (8)
Pericardial effusion	1 (2)	0 (0)	0 (0)

BARC = Bleeding Academic Research Consortium.

patients required the use of another intervention prior to deployment of IVL, and 40% of patients required multiple ancillary interventions, including rotational atherectomy.

Our cohort also included a large proportion of patients with ACS. IVL has not been tested in patients with ACS, and there have been concerns about using IVL in these patients due to the theoretical risk of thrombus degradation and subsequent distal embolization. There were no cases of distal embolization in our cohort. This is an important finding, as moderately or severely calcified lesions are commonly encountered in ACS.[8] Atherectomy devices are contraindicated and there are no data using specialty balloons in thrombotic lesions; our data is therefore helps establish the safety and efficacy of IVL in ACS patients.

Limitations of this study include those inherent in the retrospective nature of its design, including the fact that there was no control cohort of patients undergoing treatment of calcified lesions with other modalities, such as rotational atherectomy. Because of the relative novelty of IVL, long-term data is not yet available for most patients, and will be beneficial. Although the data were obtained from a comprehensive electronic medical record and catheterization laboratory database, it is impossible to guarantee complete ascertainment of baseline variables or outcomes.

5. Conclusion

In this real-world cohort study, IVL resulted in very high rates of angiographic and clinical success and very low rates of periprocedural complications, including in patients with ACS, stent failure, and left main coronary artery lesions.

Author statements

Authors roles: EJW- conceptualization, methodology, formal analysis investigation, writing- original draft, review & editing; JCS- investigation, writing-review & editing; YHW- investigation, writing-review & editing; QA-conceptualization, methodology, investigation; KM-conceptualization, writing-review & editing; supervision.

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Declaration of competing interest

The authors declare there are no competing interests.

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