



Research Brief

One-year outcomes in patients who underwent coronary intravascular shockwave lithotripsy for highly-calcified coronary lesions



Sarah Gibbs ^{a,*}, Evan J. Wiens ^{a,b}, Kunal Minhas ^{a,b}

^a Department of Internal Medicine, University of Manitoba, Winnipeg, Manitoba, Canada

^b Section of Cardiology, University of Manitoba, Winnipeg, Manitoba, Canada

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ABSTRACT

Intravascular lithotripsy (IVL) is associated with excellent angiographic and short-term results in patients with calcified lesions requiring percutaneous coronary intervention. We conducted a 1-year follow up of a retrospective cohort of 47 patients (61 lesions) who underwent IVL. The primary outcome was target vessel revascularization (TVR) at 1-year from index procedure. Four percent of patients required TVR within 1 year; 96% who underwent IVL remained free from repeat intervention on the same vessel. One patient suffered a myocardial infarction; the culprit vessel had not been previously treated with IVL. IVL is an effective and durable modality for treatment of highly calcified coronary lesions in high-risk patients.

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1. Introduction

Coronary calcification increases the risk of complications in patients undergoing percutaneous coronary intervention (PCI) as coronary calcium may limit stent expansion, increase the chances of stent malposition, and induce polymer damage, thereby impairing drug delivery.^{1,2} These factors increase the risk of sub-optimal stent expansion, which is the strongest predictor of stent thrombosis and restenosis.^{1,3} Calcified coronary lesions are increasingly common due to the aging population and the increasing rates of diabetes and chronic renal disease.⁴ Several techniques, such as rotational and orbital atherectomy, exist to manipulate coronary calcium.¹ However, these techniques have been associated with increased risk of complication including coronary dissection, perforation, and distal embolization.^{1–3,5,6} Furthermore, rotational atherectomy is ill-advised in the setting of acute coronary syndrome (ACS) due to the risk of distal embolization of thrombotic material.⁷

Coronary intravascular lithotripsy (IVL) is a novel technique which delivers localised sonic pressure waves that circumferentially disrupt vascular calcium with minimal soft tissue

injury.^{2,3} IVL has been shown to have excellent angiographic and short-term clinical results in patients with heavily calcified lesions who require percutaneous coronary intervention in both randomized and observational studies.^{2,5,8–10} However, limited data exist regarding long-term outcomes. A recently published follow-up study of the Disrupt CAD III clinical trial cohort showed low rates of major adverse cardiac events (MACE), target vessel revascularization (TVR), and stent thrombosis at one year.¹¹ However, to our knowledge, there is minimal data examining the real-world long-term outcomes of patients undergoing IVL outside of a clinical trial setting.

It is important to confirm clinical trial results with real-world data. We previously published a study examining the immediate periprocedural and 30-day outcomes in a real-world IVL cohort; this study found nearly 100% angiographic success and low complications rates at 30 days.¹⁰ In order to help better define long-term outcomes, we conducted a follow-up of the same high-risk cohort over a 1-year period following IVL.

2. Methods

We conducted a retrospective review of patients who underwent IVL at a regional referral cardiac catheterization laboratory from September 1, 2019–January 31, 2021 and survived index hospitalization. Baseline demographic, procedural, and angiographic data was collected from the catheterization laboratory database. Clinical data was obtained from the electronic medical

* Corresponding author. Department of Internal Medicine, Max Rady College of Medicine, University of Manitoba, Room GC430, Health Science Centre, 820 Sherbrooke Street, Winnipeg, Manitoba, R3A 1R9, Canada.

E-mail address: gibbs1@myumanitoba.ca (S. Gibbs).

record. Procedural data including the use of optical coherence tomography (OCT) and intravascular ultrasound (IVUS), as well as other calcium modifying techniques, was gathered from the electronic medical record. Outcome ascertainment was made upon chart review by a single author except in the cases of uncertainty regarding an outcome, for which the chart was reviewed by multiple authors and consensus reached.

The primary outcome was need for TVR within the 1-year following the index procedure. Secondary outcomes included cardiovascular mortality and freedom from further coronary intervention on a vessel not previously treated with IVL.

The study was approved by the Health Research Ethics Board of the University of Manitoba.

3. Results

Of the 50 patients included in the initial cohort,¹⁰ 47 patients (61 lesions) survived index hospitalization and were included in the study. Baseline characteristics of the cohort can be found in Table 1, and the cohort was described in detail previously.¹⁰ The median age of the cohort was 71 years; 38% of patients were female. 72% of patients presented with non-ST-elevation ACS as the indication for initial IVL. 26% of patients underwent IVL for lesions of the left main coronary artery, and 28% underwent IVL for in-stent restenosis (ISR). Of a total of 47 patients (61 lesions), 5 (10%) received repeat PCI within 12 months, primarily for recurrent angina. Of these, the culprit vessel in 3 patients was a vessel which was not previously treated with IVL. The other 2 patients (4% of patients, 3% of lesions) required TVR within 1 year; 96% of patients who underwent IVL remained free from repeat intervention on the same vessel. One

Table 1
Baseline clinical data.

Clinical Characteristics	N = 47
Female sex (%)	18 (38%)
Median Age (IQR)	71 (10.5)
Median body mass index (IQR)	28.17 (6.68)
Hypertension (%)	38 (81%)
Dyslipidemia (%)	38 (81%)
Diabetes (%)	26 (55%)
eGFR ml/min/1.73 m ²	>60 30 (64%) 45–59 7 (15%) 30–44 6 (13%) 15–29 3 (6%) <15 1 (2%)
Current Smoker (%)	5 (11%)
Former Smoker (%)	16 (34%)
Previous Stroke or TIA (%)	6 (13%)
Peripheral Artery Disease (%)	6 (13%)
Left ventricular ejection fraction <40% (%)	7 (15%)
Initial Presentation	Stable Angina 11 (24%) NSTEMI-ACS 34 (72%) STEMI 2 (4%)
Target Vessel	LMCA 11 (23%) LAD 20 (43%) LCx 9 (19%) RCA 15 (32%) Other 3 (6%)
IVL for ISR (%)	28
IVUS (%)	17 (36%)
OCT (%)	20 (43%)
Other calcium modification techniques	Rotational Atherectomy 7 (15%) Cutting Balloon 12 (26%)

eGRF = estimated glomerular filtration rate (CKD-EPI); ISR = in-stent restenosis; IVL = intravascular lithotripsy; IVUS = intravascular ultrasound; LAD = left anterior descending artery; LCx = left circumflex artery; LMCA = left main coronary artery; NSTEMI-ACS = non-ST-elevation acute coronary syndrome; OCT = optical coherence tomography; RCA = right coronary artery; STEMI = ST elevation myocardial infarction; TIA = transient ischemic attack.

patient suffered an MI within 1 year; the culprit vessel in this case had not previously been treated with IVL. Two patients died of non-cardiovascular causes. There was no incidence of cardiovascular mortality in the cohort.

Of the 2 patients who required TVR, IVUS imaging was used prior to the index IVL-assisted PCI in both cases. In one of the patients, IVUS showed ISR likely due to stent fracture in a previously treated mid-RCA, and a new stent was deployed following IVL. Upon this patient's re-presentation with angina, OCT showed thrombus and neo-intimal hyperplasia within the previously stented area, with some suspicion of stent under-expansion distally. There were no notable findings on initial IVUS imaging in the other patient.

4. Discussion

In this follow up study, we demonstrated the durability of IVL-optimized stent implantation up to 1 year in a cohort of patients with highly calcified coronary lesions. In contrast to previous studies, including the Disrupt CAD III clinical trial, our study cohort consisted of higher risk patients including those with ACS, stent failure, LMCA intervention and complex combination therapy with rotational atherectomy and IVL (Table 1).

Building upon previous studies showing excellent angiographic outcomes with IVL, our study suggests that these results are sustained over time (Table 2).^{2,8,10,11} IVL was associated with very low rates of TVR at one year, and repeat coronary intervention was predominantly on vessels not previously treated with IVL. Our findings support the Disrupt CAD III¹¹ study in showing efficacy of IVL at 1 year. However, rates of endpoints in our study were less common than in Disrupt CAD III (4% vs 11.9% for TVR). The reasons for this are unclear and could be due to incomplete outcome ascertainment in our study. However, this is felt to be unlikely because our center is the only regional catheterization laboratory, and we would therefore have record of any patient who required TVR or invasive assessment. Other possibilities include random variation from the relatively small sample size, or greater success due to improved real-world experience with the modality outside of the clinical trial setting.

Our cohort was high risk clinically and procedurally. The low rates of MACE and TVR in our study support the use of IVL as a sustainable method of treating calcified coronary lesions, even in patients with ACS.

Limitations of this study relate to the nature of the retrospective design and absence of a contemporaneous control cohort of patients receiving treatment with other calcium-modification techniques. Information regarding the severity of the lesions, such as detailed intracoronary imaging findings and extent of calcification, was also limited by nature of the study design. However, all patients would have had calcium deposition severe enough to warrant IVL in the opinion of the interventionalist; this is therefore a

Table 2
Outcomes for patients treated with IVL at 12 months following the index intervention (N = 47 patients, 61 lesions).

Primary Outcome (TVR)	2 (4%)
Secondary Outcomes:	
Freedom from Re-intervention	42 (89%)
Repeat PCI	Total 5 (11%) De novo lesions 3
Cardiovascular deaths	0 (0%)
Non-CV related deaths	2 (4%)
MI	1 (2%)

CV = cardiovascular; MI = myocardial infarction; PCI = percutaneous coronary intervention; TVR = target vessel revascularization.

good representation of a “real-world” patient population and practice pattern. Definitive conclusions and subgroup analyses are also limited by our relatively small sample size, although to our knowledge this is the largest real-world study describing 1-year outcomes in patients undergoing IVL to date. Further study regarding longer-term outcomes with IVL and larger patient groups is required to definitively determine the characteristics and outcomes of IVL, and its optimal applications.

IVL is an effective and durable modality for treatment of highly calcified coronary lesions.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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