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## Bailout Intravascular Lithotripsy for the Treatment of Acutely Underexpanded Stents in Heavily Calcified Coronary Lesions: A Case Series

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### ABSTRACT

Stent underexpansion is a common problem in heavily calcified coronary lesions treated with percutaneous coronary intervention, and has been associated with in-stent restenosis, stent thrombosis and, subsequently, poor clinical outcomes. Adequate preparation of heavily calcified coronary lesions (e.g. using non-compliant balloons, cutting/scoring balloons, rotational/orbital atherectomy or intravascular lithotripsy) prior to stent implantation is essential in preventing stent underexpansion. However, in certain cases the deployed stent may remain underexpanded despite extensive lesion preparation. To date, no consensus exists on how to treat stent underexpansion in this scenario.

We present a cases series in which post-stenting intravascular lithotripsy was performed to treat acute stent underexpansion in heavily calcified lesions, describing the technical aspects, angiographic results as well as clinical outcomes at mid-term follow-up.

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### Contents

1. Introduction . . . . .	189
2. Case series . . . . .	190
2.1. Case 1 . . . . .	190
2.2. Case 2 . . . . .	190
2.3. Case 3 . . . . .	191
2.4. Case 4 . . . . .	192
2.5. Case 5 . . . . .	192
3. Discussion . . . . .	193
4. Conclusions . . . . .	194
Funding . . . . .	194
References . . . . .	194

**Abbreviations:** D1, First diagonal branch; DAPT, Dual antiplatelet therapy; DES, Drug-eluting stent; ELCA, Excimer laser coronary angioplasty; IVL, Intravascular lithotripsy; LAD, Left anterior descending coronary artery; LCx, Left circumflex coronary artery; LIMA, Left internal mammary artery; MACE, Major adverse cardiovascular events; NCB, Non-compliant balloon; NSTEMI, Non-ST segment elevation myocardial infarction; PCI, Percutaneous coronary intervention; RCA, Right coronary Artery; RA, Rotational atherectomy.

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### 1. Introduction

Heavily calcified coronary lesions are present in about 20% of patients undergoing percutaneous coronary intervention (PCI) [1]. Lesion preparation before stent implantation in this anatomical scenario is essential to facilitate stent delivery and achieve an optimal stent expansion. Despite the plethora of tools available to adequately prepare these lesions (e.g. non-compliant balloon (NCB), cutting/scoring balloons, rotational atherectomy (RA), excimer laser coronary angioplasty

(ELCA) and intravascular lithotripsy (IVL)) [2], the deployed stent may remain underexpanded in certain cases. Stent underexpansion is an important risk factor for stent thrombosis and in-stent restenosis, leading to poor clinical outcomes [3,4].

The management of stent underexpansion in heavily calcified coronary lesions is considered very challenging. Moreover, no consensus exists with regard to the optimal approach to the treatment of stent underexpansion in such lesions.

Coronary IVL has recently been introduced as a novel modality for de novo preparation of severely calcified coronary lesions with good outcomes [5]. The CE marking was granted in 2017, based on initial results of the DISRUPT CAD I [6], and US Food and Drug Administration approved recently the use of IVL for this indication.

Hypothetically, cracking the calcium preventing stent expansion by using IVL may also be an attractive approach to the management of stent underexpansion after PCI. Using IVL for this indication carries the risk of damaging the drug polymer, increasing the risk of eventual stent thrombosis and restenosis. Hence, the manufacturer does not yet recommend using IVL in patients with previous stenting within 5 mm of the target lesion [7]. Whether or not the theoretical effect of IVL on the drug polymer has any clinical impact on patient's outcome has not been yet fully elucidated.

In this case series, we evaluated the immediate angiographic success by means of quantitative coronary angiography using validated software (Medis Suite 4.0.24.4; Medis Medical Imaging System BV, Leiden, The Netherlands) as well as the mid-term clinical outcomes after using IVL as a bail-out strategy for acutely severely underexpanded stents in heavily calcified coronary lesions.

## 2. Case series

### 2.1. Case 1

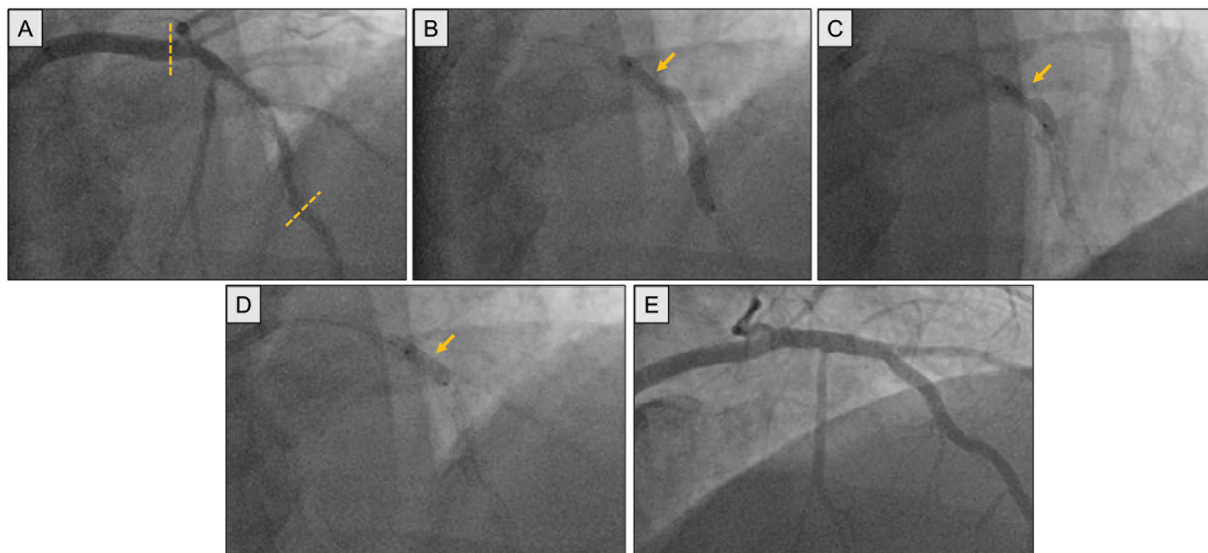
A 70-year-old male patient, with hypertension, type II diabetes mellitus, peripheral arterial disease and previous myocardial infarction was referred to our hospital from another center with the diagnosis of non-ST segment elevation myocardial infarction (NSTEMI).

Coronary angiography showed a heavily calcified lesion in the proximal to mid left anterior descending coronary artery (LAD) (Fig. 1A, dotted) as a culprit lesion. Initial predilatation of the lesion with a 2.5 mm

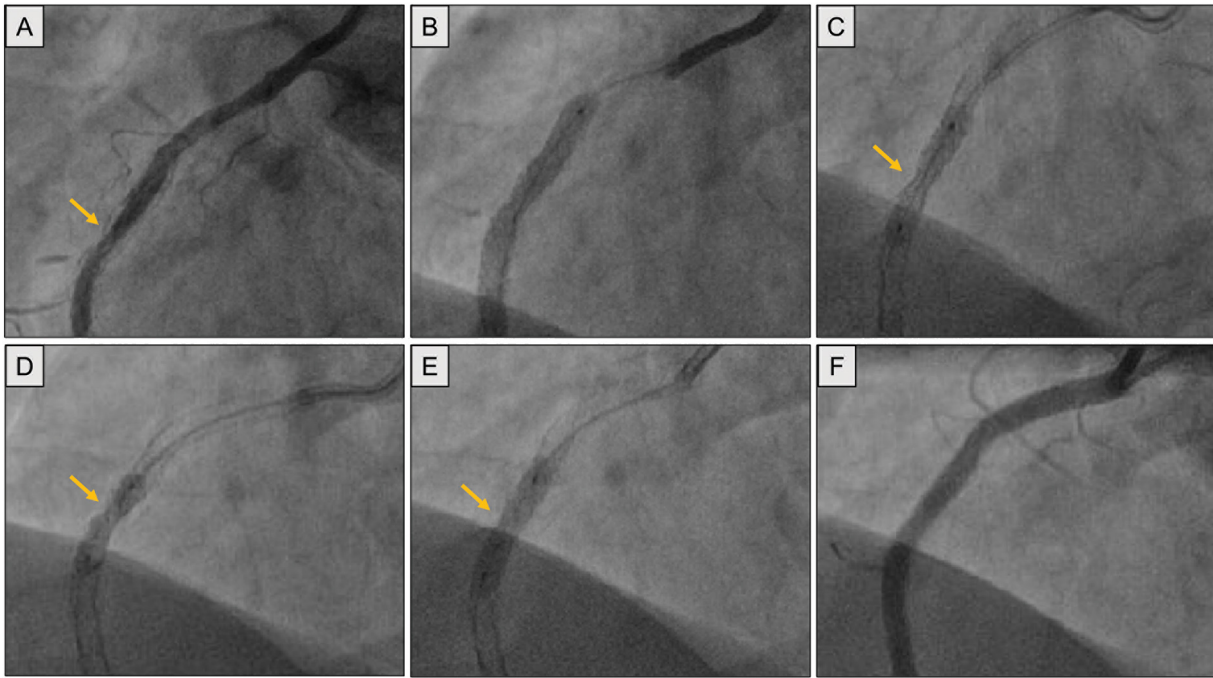
semi-compliant balloon at high pressure (20 atm) showed an inadequate balloon expansion. RA was then successfully performed with a 1.5 mm burr. Subsequently, a 3.0–38 mm Promus Elite (Boston Scientific, Natick, MA, USA) drug-eluting stents (DES) was implanted at high pressure (18 atm) (Fig. 1B, arrow). The proximal stent portion remained markedly underexpanded despite of prolonged postdilatation with a 3.0 mm NCB up to 24 atm (Fig. 1C, arrow). Therefore, we decided to use a 3.5–12 mm IVL balloon (Shockwave medical Inc., Santa Clara, California) inflated at 4 atm and 80 pulses were delivered in-stent (Fig. 1D, arrow). Followed by postdilatation with 3.5 mm NCB at 20 atm. A second 3.5–20 mm DES was implanted proximally and inflated up to 14 atm. The final angiographic result showed clear improvement of stent expansion after IVL (Fig. 1E). Dual antiplatelet therapy (DAPT) with aspirin and clopidogrel was prescribed for a year, after which he continued with aspirin and statins. At 24-months follow-up, he remained free of anginal complaints or major adverse cardiovascular events (MACE).

### 2.2. Case 2

A 52-year-old male patient, with a history of dyslipidemia and previous PCI of the right coronary artery (RCA) with two CYPHER DES (Cordis, Santa Clara, CA, USA) and first diagonal branch (D1) with an Express-II DES (Boston Scientific, Natick, MA, USA) in 2003, presented in our hospital with an anterior ST-segment elevation myocardial infarction. Primary PCI of the LAD was performed with a 3.0–30 mm Resolute Onyx (Medtronic, Santa Rosa, California) DES implanted with good angiographic result. The RCA showed diffuse severe in-stent restenosis (Fig. 2A, arrow). Staged PCI of the RCA was performed during hospitalization. Initially, the RCA lesion was predilated with a 3.0 mm NCB at high pressure (22 atm), showing adequate balloon expansion. Three overlapped 3.0–38 mm, 3.5–38 mm and 4.0–22 mm Resolute Onyx DES (Medtronic, Santa Rosa, California) were subsequently implanted from distal to proximal and inflated up to 14 atm. Inadequate expansion of the stent implanted at the mid-segment was observed (Fig. 2B). Postdilatation was performed with a 3.5–15 mm NCB up to 28 atm, after which the stent remained markedly underexpanded (Fig. 2C, arrow). Bail-out IVL was then performed with a 4.0–12 mm IVL balloon inflated at 4 atm, delivering 80 pulses in-stent (Fig. 2D, arrow). The stent was then postdiluted with a 3.5–15 mm NCB up to 30 atm



**Fig. 1.** Significant coronary lesion involving the proximal and mid segment of the LAD (Panel A, dotted lines). After predilatation, a 3.0–38 mm DES was implanted, showing suboptimal stent expansion at the proximal portion of the stent (Panel B, arrow), which remained despite of aggressive postdilatation with 3.0 mm non-compliant balloon (Panel C, arrow). IVL was then applied, improving significantly stent expansion (Panel D, arrow; Panel E).

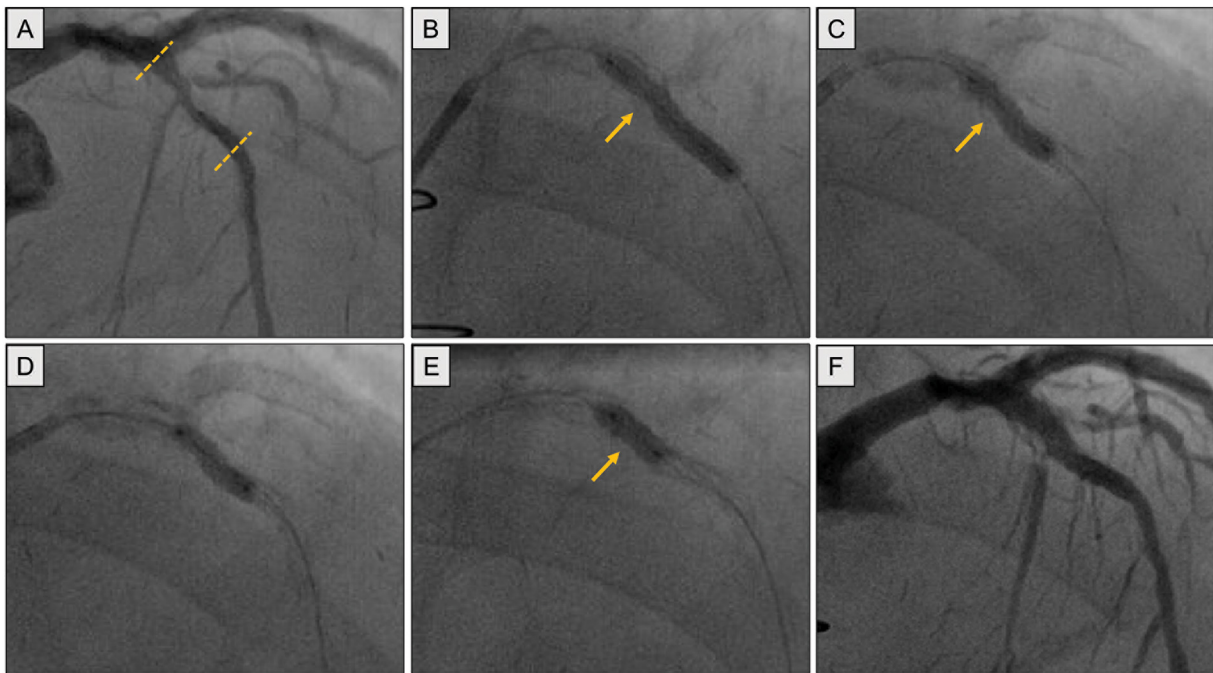


**Fig. 2.** Significant in-stent restenosis in a previously implanted stent in the proximal and mid RCA (Panel A, arrow). After lesion preparation, a 3.5–38 mm DES was implanted at the target lesion and inflated up to 20 atm (panel B) showing poor stent expansion despite of postdilatation at high pressures (panel C, arrow). IVL was then performed (Panel D) followed by postdilatation with 3.5 mm non-compliant balloon at high pressure, with significant improvement of stent expansion (Panel E, arrow; Panel F).

(Fig. 2E, arrow). The final angiographic image shows a satisfactory stent expansion (Fig. 2F). DAPT with aspirin and prasugrel was prescribed for a year, after which he continued with aspirin and statins. At 15-months follow up, the patient remained asymptomatic and no MACE were reported.

### 2.3. Case 3

A 68-year-old male patient was referred to our hospital because of NSTEMI. He was known with hypertension, type II diabetes mellitus, dyslipidemia and previous coronary artery bypass graft with a left



**Fig. 3.** Significant coronary lesion involving the proximal and mid segment of the LAD (Panel A, dotted lines). During placement of a 3.0–22 mm DES proximally, suboptimal stent expansion was observed (Panel B), which remained after postdilatation with a 3.5 mm non-compliant balloon at high pressure (Panel C). Subsequently, IVL was performed (Panel D) followed by postdilatation at high pressures (Panel E), allowing an adequate stent expansion (Panel F).

internal mammary artery graft (LIMA) to the LAD and D1 sixteen years prior to presentation. Coronary angiography showed three-vessel disease, with a heavily calcified mid-LAD with subtotal stenosis, subtotal stenosis in the distal RCA and another subtotal stenosis in a large obtuse marginal; the LIMA bypass was occluded after the anastomosis with D1. Percutaneous treatment of the LAD and obtuse marginal branches was decided upon. The LAD lesion was predilated with a 3.0 mm NCB at high pressure (24 atm) with adequate balloon expansion on fluoroscopy. Subsequently, a 3.0–22 mm Resolute Onyx DES (Medtronic, Santa Rosa, California) was implanted and inflated up to 18 atm, showing however suboptimal stent expansion (Fig. 3A,B arrow). Prolonged postdilatation with a 3.5 mm NCB up to 20 atm was performed, with minimal improvement (Fig. 3C). Henceforth, we decided to perform in-stent IVL as bail-out strategy to facilitate stent expansion. A 4.0–12 mm IVL was inflated at 4 atm and a total of 70 pulses were delivered in-stent (Fig. 3D). Then, postdilatation was done with 4.0–8 mm NCB up to 20 atm (Fig. 3E). Final angiography showed a significant improvement of stent expansion after IVL (Fig. 3F). DAPT with aspirin and ticagrelor was prescribed for a year. Statins and other previous medications were continued. At 12-months follow-up, he remained free of complaints and without any reported adverse cardiovascular events.

#### 2.4. Case 4

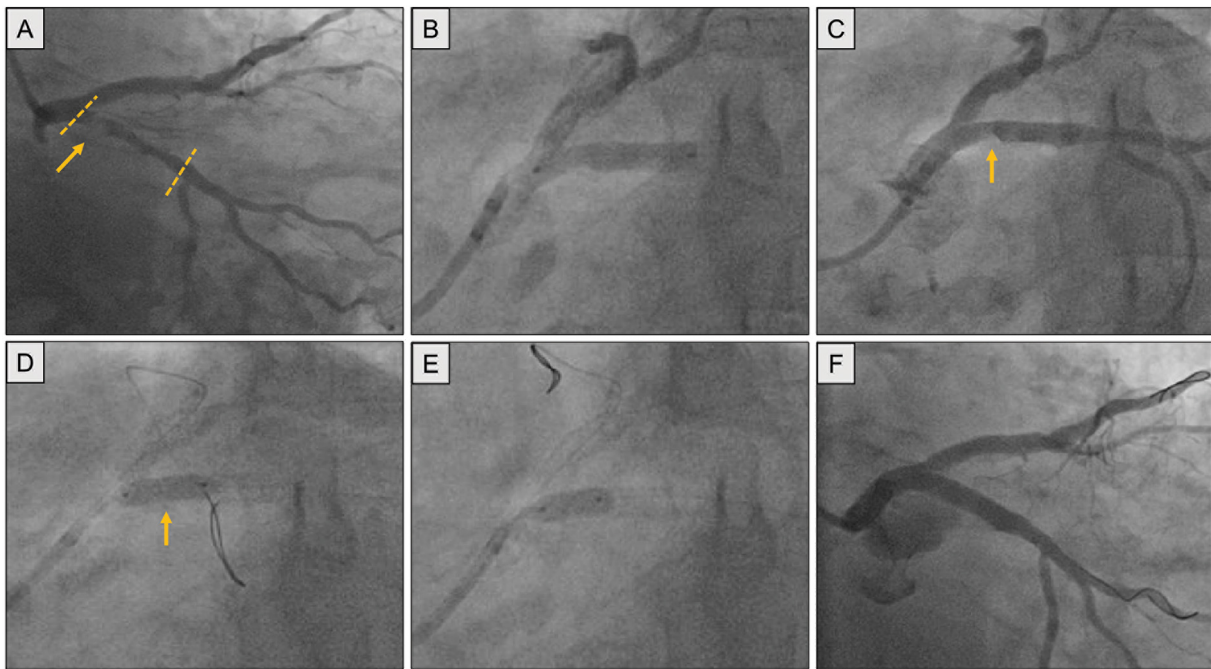
A 76-year-old female patient with a history of hypertension, type II diabetes mellitus and previous PCI of the LAD and D1 bifurcation (T and small protrusion technique) with implantation of two DES was admitted in our hospital because of NSTEMI.

Coronary angiography showed patent stents in LAD-D1 and a proximal heavily calcified subtotal occlusion in the left circumflex coronary artery (LCx) (Fig. 4A, arrow). Initial predilatation of the LCx lesion with a 3.0 mm NCB at 18 atm was performed (Fig. 4B), with reasonable balloon expansion, followed by the implantation of a 4.0–22 mm Resolute Onyx DES (Medtronic, Santa Rosa, California) inflated up to 14 atm. Angiographic control revealed an inadequate expansion of the stent (Fig. 4C, arrow), which could not be solved by performing prolonged,

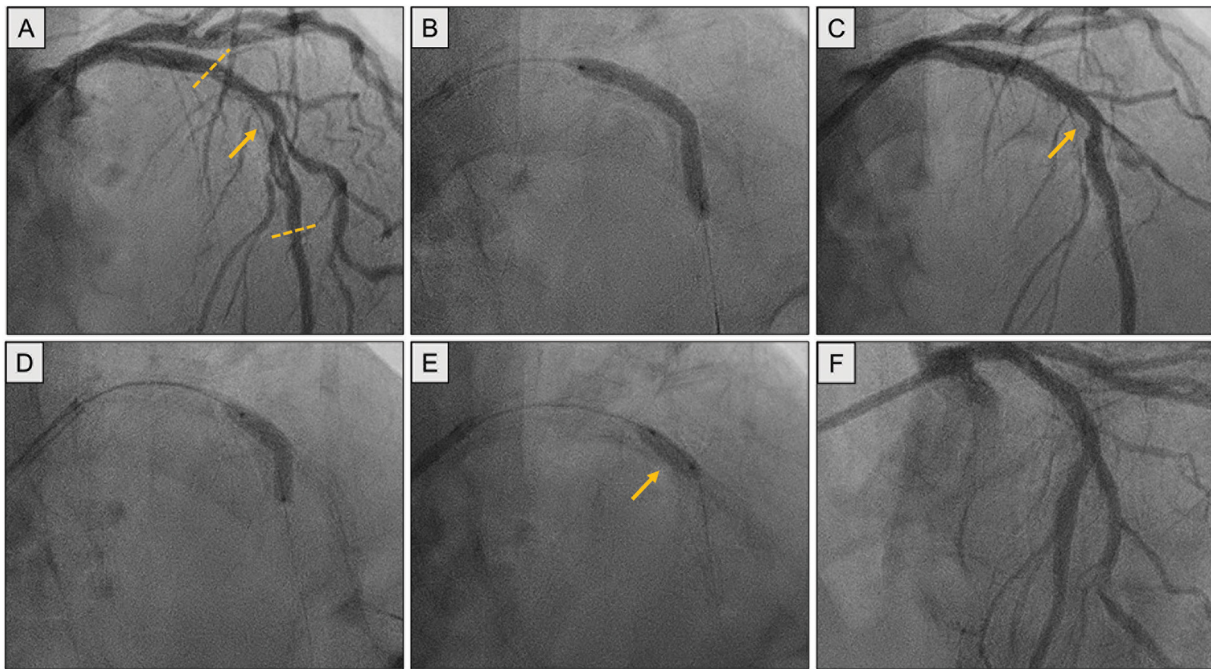
high pressure (20 atm) postdilatation with a 4.0–8 mm NCB. Bail-out in-stent IVL was performed as an attempt to optimize stent expansion. A 4.0–12 mm IVL balloon was inflated up to 4 atm and, subsequently, 80 pulses were delivered in-stent (Fig. 4D). Then, postdilatation was performed with 4.0–8 mm NCB up to 24 atm (Fig. 4E). Final angiography showed an evident improvement of stent expansion (Fig. 4F). DAPT with aspirin and prasugrel was prescribed for a year, being statins further continued. At 7-months follow-up, he confirmed being asymptomatic and no adverse cardiovascular events were documented.

#### 2.5. Case 5

An 80-year-old male patient, known with hypertension and symptomatic severe aortic stenosis, underwent an elective coronary angiography prior to transcatheter aortic valve implantation. On coronary angiography, three-vessel coronary artery disease with extensive calcification was observed, for which ad-hoc PCI was performed. The mid-segment of the RCA was successfully treated with RA and implantation of two overlapping DES. The proximal LCx lesion was treated with predilatation with NCB and implantation of one DES. The mid-LAD lesion showed heavy calcification as well (Fig. 5A, arrow), being predilated initially with a 3.0 mm NCB inflated up to 16 atm, with suboptimal balloon expansion. IVL was then performed with a 3.0 mm IVL balloon inflated up to 4 atm, delivering 70 pulses. Subsequently, two overlapping 3.0–30 mm and 2.75–9 mm Orsiro DES (Biotronik AG, Bülach, Switzerland) were implanted and inflated up to 12 atm (Fig. 5B). Significant stent recoil with subsequent stent underexpansion was observed on angiography (Fig. 5C, arrow). It was decided to perform bail-out in-stent IVL in order to improve stent expansion. The 3.0 mm IVL balloon was inflated in-stent up to 4 atm and 10 pulses were delivered in-stent (Fig. 5D). Then, postdilatation was again performed with a 3.0–8 mm NCB up to 20 atm (Fig. 5E). Final angiography showed a clear improvement of the stent expansion (Fig. 5F, arrow). DAPT with aspirin and clopidogrel was prescribed for 6 months, and statins and other previous medication were continued. At 6-months follow-up, he remained free of symptoms. However, his clinical course



**Fig. 4.** Target coronary stenosis at the proximal LCx (Panel A, dotted arrows). After lesion preparation with predilatation, a 4.0–22 mm DES was implanted (Panel B) with marked stent underexpansion at the proximal portion (Panel C, arrow). IVL was applied with a 4.0–12 mm balloon (Panel D, arrow) and postdilatation at high pressure was performed (Panel E), with a satisfactory result (Panel F).



**Fig. 5.** Significant stenosis in a long coronary segment involving the proximal and mid LAD (Panel A, dotted lines). Focal suboptimal stent expansion was noted during stent implantation (Panel B and C, arrow), which persisted after postdilatation at high pressures (Panel D). IVL was performed, followed by postdilatation with non-compliant balloon (Panel E, arrow), improving significantly stent expansion (Panel F).

was complicated by a lacunar cerebral infarction following transcatheter aortic valve implantation performed two weeks after coronary revascularization.

A summary of procedural, postprocedural and follow-up characteristics of the patients described is presented in Table 1.

### 3. Discussion

The coronary IVL system consists of a balloon catheter with two integrated emitters, a lithotripsy generator and a connector cable. These emitters create sonic pressure waves that selectively fracture coronary calcium (both superficial and deep) with an effective pressure of 50 atm and alter vessel compliance [6]. This distinctive nature of IVL makes it, at least in theory, very suitable for treating acute stent underexpansion resulting from heavy coronary calcification. The theoretical downside of IVL in this context may be the potential disruption of drug polymer integrity which may lead to inadequate stent epithelization and its potentially associated deleterious effects. Hence, Shockwave Medical does not yet recommend using IVL in patients with previous stenting within 5 mm of the target coronary lesion. However, whether the potentially associated risk of IVL-induced drug polymer damage are higher than the well-defined risks of stent underexpansion remains unknown. In our case series, in which angiographic success was achieved in all 5 cases with a final residual stenosis <30%, no in-

hospital or mid-term MACE was reported. This preliminary results provide a glimpse about the potentially favorable clinical effect of this strategy.

Alternative strategies to resolve stent underexpansion, such as NCB, RA or ELCA have been studied in the past. NCB inflations at high pressures are the most widely available and used method for resolving stent underexpansion. In all 5 cases described in this series, NCB alone could not resolve stent underexpansion, necessitating additional techniques to improve stent expansion and consequent long-term stent patency. Previously, Ferri et al. showed that RA can be safely performed to resolve in stent restenosis caused by stent underexpansion resistant to NCB inflation. Still, periprocedural complications (coronary artery dissection) occurred in 6.3%, while the procedure was unsuccessful in 12.5% and repeat revascularization was necessary in 13.3% of patients in their series [8]. This may be explained by the notion that RA cannot discriminate between superficial calcium and stent struts, damaging the struts and the drug polymer may limit short- or long-term vessel patency. Moreover, RA seems unsuitable to treat acute stent underexpansion as this inevitably damages the stent struts in the underexpanded segment. Nonetheless, in their case report Herzum et al. showed the latter can be performed, but the case self-evidently required implantation of a second stent [9]. Likewise, Latib et al. showed ELCA can be used to manage stent underexpansion with little periprocedural complication rate (7.1% periprocedural myocardial infarction and 3.6%

**Table 1**

Summary of procedural, postprocedural and follow up characteristics of patients treated with IVL for acute stent underexpansion.

Case number	Vessel treated	Lesion preparation	VL balloon size (mm)	Post dilation after IVL	Follow-up time	MACE during follow-up
Case 1	Mid LAD	2.5 mm SCB (20 atm) RA with 1.5 mm burr	3.5	NCB 3.5 mm (20 atm)	24 months	No
Case 2	Mid RCA	NCB 3.0 mm (22 atm)	4.0	NCB 3.5 mm (30 atm)	15 months	No
Case 3	Mid LAD	NCB 3.0 mm (24 atm)	4.0	NCB 4.0 mm (20 atm)	12 months	No
Case 4	Prox LCx	NCB 3.0 mm (18 atm)	4.0	NCB 4.0 mm (24 atm)	7 months	No
Case 5	Mid LAD	NCB 3.0 mm (16 atm) IVL 3.0 mm balloon, 70 pulses	3.0	NCB 3.0 mm (20 atm)	6 months	No

IVL = intravascular lithotripsy, LAD = left anterior descending coronary artery, LCx = left circumflex coronary artery, MACE = Major adverse cardiovascular events, NCB = Non-compliant balloon, RA = Rotational atherectomy, RCA = Right coronary artery, SCB = Semi-compliant balloon.

transient slow-flow) [10]. However, in their study only 10% ( $n = 3$ ) of the ELCA procedures were performed in de novo lesions. Hence, the question whether or not ELCA performs equally well in acute stent underexpansion remains unknown. Like RA, ELCA may damage both drug polymer and stent struts when used in acute stent underexpansion, possibly limiting long-term efficacy. Based on previous reports, IVL carries less periprocedural complications compared to RA and ELCA and may therefore be an interesting alternative to RA and ELCA in the context of stent underexpansion.

Several case reports and series have described the applicability of IVL in resolving delayed stent failure as a consequence of stent underexpansion [11–15]. Both angiographic and short-term clinical outcomes of acutely underexpanded stents treated with IVL have been reported in a single case from the SMILE registry [16] and in three separated case reports [17–19], all of them showing satisfactory final angiographic results and good clinical outcomes after 1 to 4 months of follow-up. Likewise, Yeoh et al. described the safety and efficacy of using IVL for stent underexpansion in a case series of thirteen patients, in which no MACE was reported both in-hospital and at 30-days follow-up [20]. However, in this case series only 2 out of 13 patients were treated with IVL in the initial procedure. Moreover, 8 out of 13 patients were treated with IVL at least 9 months after stent implantation. Since after 9 months around 90% of second generation DES are fully re-endothelialized [21], the deleterious effects derived from the use IVL (drug polymer damage) may be not relevant beyond this timepoint. Moreover, the aforementioned studies do not report mid- or long term results, preventing therefore to evaluate the clinical effects of this strategy. Hence, to our knowledge, this is the first case series to describe the mid-term clinical outcomes of patients with acutely underexpanded stents treated with IVL. The observed favorable outcomes suggest that the use IVL in acute stent underexpansion is an effective and, probably, safe strategy.

Several limitations should be acknowledged. Intracoronary imaging was not systematically used in all cases. Therefore, the predominant mechanism of stent underexpansion is not fully elucidated in these cases. Intracoronary imaging may have also improved pre- and post-stent implantation strategies. Still, mid-term clinical outcomes remained favorable even in the absence of intracoronary imaging. Finally, due to the nature of the presented data, no definitive conclusions can be derived from our analysis. Further research in larger cohorts and longer follow-up is necessary to confirm the safety and efficacy of IVL in the setting of acute stent underexpansion.

#### 4. Conclusions

Acute stent underexpansion in heavily calcified coronary lesion may occur despite of thoughtful lesion preparation. Post-stenting IVL may be considered as a safe and effective bail-out strategy to treat acute stent underexpansion, with promising mid-term clinical outcomes in this case series. These preliminary results should encourage further evaluation of the technique at a larger scale in order to confirm our findings.

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