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Current applications, procedural and 1-year outcomes of Rotatripsy for the treatment of calcified coronary lesions

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Abstract

Background: Intravascular lithotripsy (IVL) combined with rotational atherectomy (RA), known as Rotatripsy, is used to treat severe coronary artery calcification (CAC), though data on efficacy, midterm safety and use sequence is limited. We aimed to identify indicators for Rotatripsy use and to assess its safety and success rates, both acutely and at 1-year follow-up.

Methods: Patients undergoing Rotatripsy for severe CAC across six centers from May 2019 to December 2023 were included. Demographic, clinical, procedural and follow-up data were collected. Efficacy endpoints included device success (delivery of the RA-burr and IVL-balloon across the target lesion and administration of therapy without related complications), technical success (TIMI 3 flow and residual stenosis <30% by quantitative coronary analysis) and procedural success [composite of technical success with absence of in-hospital major adverse cardiovascular events (MACE: cardiac death, myocardial infarction or target vessel revascularization). Safety endpoints comprised Rotatripsy-related complications and MACE at 1-year follow-up.

Results: A total of 114 patients (75 ± 9 years, 78% male) underwent Rotatripsy for 120 lesions. In the majority of procedures RA was followed by IVL, mostly electively (n = 68, 57%) but also for balloon underexpansion (n = 37, 31%) and stent crossing failure (n = 1, 1%). Diverse and complex target lesions were addressed with an average SYNTAX score of 24.6 ± 13.0. Device, technical and procedural success were 97%, 94% and 93%, respectively. Therapy-related complications included two (2%) coronary perforations, one (1%) coronary dissection and one (1%) burr

Abbreviations: ACS, acute coronary syndrome; ICI, intracoronary imaging; IVL, intravascular lithotripsy; IVUS, intravascular ultrasound; LAD, left anterior descending coronary artery; MACE, major adverse cardiovascular events; MI, myocardial infarction; OCT, optical coherence tomography; PCI, percutaneous coronary intervention; QCA, quantitative coronary analysis; RA, rotational atherectomy; RCA, right coronary artery; TVR, target vessel revascularization.

entrapment. At 1-year follow-up(present in 77(67%) patients), MACE occurred in 7(9%) cases.

Conclusions: Over a 1-year follow-up period, Rotatripsy was safe and effective, predominantly using RA electively before IVL.

KEYWORDS

coronary artery calcification, intravascular lithotripsy, rotational atherectomy, rotatripsy

1 | INTRODUCTION

Severe coronary artery calcification (CAC) is increasingly encountered during percutaneous coronary intervention (PCI). Currently, approximately up to one-fourth of patients undergoing PCI exhibit CAC,[1,2] which is associated with stent underexpansion, leading to worse periprocedural and clinical outcomes.[3–6] Addressing this issue requires effective lesion preparation to improve stent expansion and outcomes. In the modern landscape of interventional cardiology, a variety of techniques is available, including noncompliant-/ultrahigh-pressure-/cutting-/scoring- and intravascular lithotripsy (IVL)-balloons and atheroablative methods such as excimer laser coronary angioplasty, orbital atherectomy and rotational atherectomy (RA).[7–9] Among these, RA is the most frequently used atheroablative technique in balloon-uncrossable lesions, using a high-speed rotating abrasive burr to specifically modify superficial calcium deposits before stenting.[10,11] Conversely, IVL represents an innovative balloon-based plaque modification approach, utilizing sonic pressure waves to selectively fracture calcium deposits in the whole arterial vessel wall, both superficially and deeply.[12–16] IVL and RA might also be used complementary (known as Rotatripsy) to treat severe CAC during PCI. While the combined therapeutic potential of IVL and RA has been primarily documented through case series, -reports and several retrospective studies, the focus was largely on the short-term efficacy and safety of the procedure, particularly examining the approach of applying IVL for balloon underexpansion or stent crossing failure after RA.[17–23] However, data on the longer-term safety and effectiveness of Rotatripsy, as well as detailed intracoronary imaging (ICI) and quantitative coronary analysis (QCA) data are lacking. In addition, information about alternative sequences of Rotatripsy-therapy and their clinical indications is scarce. This study aimed to explore the various sequences employed in Rotatripsy, identify the clinical indications, and evaluate its procedural success and 1-year outcomes to provide a comprehensive assessment of its safety and effectiveness.

2 | METHODS

2.1 | Population and data collection

In this all-comers international multicenter registry, patients (> 18 years) who underwent PCI for severe CAC lesions with IVL and RA were retrospectively enrolled across six centers in two European countries between 2018 and 2024. IVL was performed in all cases by using the Shockwave Intravascular Lithotripsy Coronary System (Shockwave Medical, Santa Clara, California), while RA was performed with the Rotablator™ or ROTAPRO (Boston Scientific, Marlborough, Masschusetts). Decisions regarding technical aspects of IVL and RA (timing, burr/IVL-balloon size, burr/vessel ratio, number of pulses delivered, maximal inflation pressure), utilization of high-pressure pre- and post-dilatation, supplementary stent placement, and use of ICI for procedural optimization were left at the operator's discretion, with subsequent documentation of these decisions. Demographic, clinical, procedural and follow-up data were collected from the hospital electronic records. Angiographic and ICI data were analyzed in a centralized core-laboratory at the Leiden University Medical Center. Patients who were unable to provide informed consent were excluded from the study. The local ethical committee at each institution approved the retrospective analysis of clinically collected data.

2.2 | Definitions and imaging analysis

Upfront Rotatripsy was defined as performing RA and IVL before stenting. This consisted of an elective combined approach of RA and IVL, IVL used after RA-failure and IVL used before RA. An elective combined approach was defined as RA used upfront to facilitate IVL-balloon passage. RA-failure was defined as balloon underexpansion or stent crossing failure post-RA. Bail-out Rotatripsy was defined as the use of IVL after RA and stenting to treat acute stent underexpansion.

The presence of severe CAC was determined by the operator during the procedure both angiographically (fluoroscopic visualization of radiopacities at both sides of the vessel wall and/or incomplete noncompliant balloon expansion) and by ICI when available. On intravascular ultrasound (IVUS) CAC was defined as a hyperechoic signal with acoustic shadowing, while on optical coherence tomography (OCT) CAC appeared as a signal-poor area with sharply delineated borders.[5,6,8,24] All diagnostic angiograms were graded according to the SYNTAX score algorithm.[25]

Quantitative coronary analysis (QCA) and ICI were retrospectively analyzed offline to evaluate luminal gain following Rotatripsy. QCA was performed pre- and post-Rotatripsy and stenting, using Medis Suite QCA (2D/3D) software (Medis Suite 4.0.24.4; Medis Medical Imaging System BV, Leiden, The Netherlands). Measurements included minimum lumen diameter (minimum LD) and percentage diameter stenosis (percentage DS). Analysis of IVUS and OCT was performed using QCU-CMS 4.69 (Leiden University Medical Center, Leiden, The Netherlands). When available, ICI measurements were performed, including reference vessel diameter (RVD), reference vessel area (RVA) and minimum lumen area (MLA). Percentage DS and percentage area stenosis (percentage AS) were calculated using the formulas ([RVD-MLD]/RVD)*100 and ([RVA-MLA]/RVA)*100, respectively. As in the majority of cases the ICI catheter is unable to pass the target lesion initially, we compared the specified variables of the first available recording pre-PCI (after lesion passage) and post-PCI and Rotatripsy.

2.3 | Study endpoints

The primary endpoint of the study was defined as the achievement of procedural success, a composite of residual stenosis <30% (assessed by QCA), final Thrombolysis In Myocardial Infarction (TIMI) 3 coronary flow and absence of in-hospital major adverse cardiovascular events (MACE: cardiac death, nonfatal target vessel myocardial infarction (MI) or clinically driven target lesion revascularization). Secondary endpoints included device success (defined as successful employment of the IVL-catheter and RA-burr to the target lesion, and delivery of IVL pulses and RA-therapy without direct angiographic complications), technical success (defined as the presence of TIMI 3 flow and a residual stenosis <30%) and the occurrence of MACE and all-cause mortality before discharge and at 1 year follow-up after Rotatripsy.

2.4 | Statistical analysis

Continuous variables are presented as either the mean ± standard deviation or median with interquartile range (25th–75th percentile), as appropriate. Differences between paired continuous variables were assessed with the paired t-test if normally distributed, otherwise the Wilcoxon signed-rank test was used. Categorical variables were reported as frequencies and percentages and were analyzed using the $\chi2$ or Fischer exact test. Kaplan-Meier analysis was performed to estimate cumulative survival free of MACE at 1-year follow-up. Statistical analysis was performed with SPSS for Windows version 25.0 (IBM, Armonk, New York). All tests were two-sided, and a $p < 0.05$ was considered statistically significant.

3 | RESULTS

A total of 114 patients underwent Rotatripsy for 120 lesions. The mean age was 74.7 ± 8.8 years, and 79% was male. The baseline patient characteristics are summarized in Table 1 and the characteristics of the lesions treated with Rotatripsy in Table 2. Fifty-eight patients (51%) presented with ACS compared to 56 patients (49%) with chronic coronary syndrome (CCS). The left anterior descending artery (LAD) ($n = 66$, 55%) was the most frequently treated target vessel with diverse target lesion subtypes being addressed including bifurcation- ($n = 36$, 30%), ostial- ($n = 21$, 18%), CTO- ($n = 8$, 7%) and in-stent ($n = 14$, 12%) lesions. The average SYNTAX score was 24.6 ± 13.0.

TABLE 1 Baseline demographics and medical history.

	Overall (*n* = 114)
Age, years	74.7 ± 8.8
Male, n(%)	90(79)
Diabetes, n(%)	52(46)
Hypertension, n(%)	86(75)
Hypercholesterolemia, n(%)	77(68)
Peripheral artery disease, n(%)	20(18)
Family history of CAD, n(%)	13(11)
Chronic kidney disease (GFR < 60 ml/min/1.73m^2), n(%)	42(37)
Syntax score	24.6 ± 13.0
Left ventricular ejection fraction	
Good (> 50%)	59(52)
Reasonable (30-50%)	44(39)
Poor (20-30%)	9(8)
Very poor (< 20%)	1(1)
Unknown	2(1)
Smoking history, n(%)	55(48)
Previous stroke, n(%)	10(9)
Previous MI, n(%)	38(33)
Previous PCI, n(%)	39(34)
Previous CABG, n(%)	17(15)
Clinical presentation	
Chronic coronary syndrome	56(49)
Unstable angina, n(%)	21(18)
NSTEMI, n(%)	33(29)
STEMI, n(%)	4(4)

Abbreviations: CABG, coronary artery bypass graft surgery; MI, myocardial infarction; NSTEMI, non-ST-segment elevation myocardial infarction; PCI, percutaneous coronary intervention; STEMI, ST-segment elevation myocardial infarction.

The procedural parameters are listed in Table 3. The mean burr size was 1.5±0.2 mm with a mean maximum rotational speed of 171±15k rpm and mean burr/vessel ratio of 0.4±0.1. The average number of IVL-pulses per procedure was 68±25, with an IVL-balloon size of 3.5±0.5 mm. In the majority of cases ($n = 106$, 88%) RA was performed before IVL. Among these cases, IVL was electively combined with RA in 68 (57%) lesions (Figure 1) and utilized for balloon underexpansion or stent crossing failure after RA in 37 (31%)

TABLE 2 Lesion characteristics.

	Overall (*n* = 120)
Target vessel	
LM, n(%)	27(23)
LAD, n(%)	66(55)
LCx, n(%)	15(13)
RCA, n(%)	32(27)
Lesion characteristics	
Bifurcation, n(%)	36(30)
Ostial, n(%)	21(18)
Tortuous, n(%)	3(3)
CTO, n(%)	8(7)
Long-segment, n(%)	92(77)
In-stent, n (%)	14(12)

Abbreviations: CTO, chronic total occlusion; LAD, left anterior descending artery; LCx, left circumflex artery; LM, left main; RCA, right coronary artery.

and 1 (1%) patients respectively. Additionally, IVL served as a bailout strategy after RA and stenting in 10 (8%) (Figure 2) and preceded RA in 4 (3%) lesions, particularly when balloon/stent delivery failed after IVL. Alternative plaque modification techniques besides RA, IVL and noncompliant balloon inflation were used in 16(13%) target lesions either between RA and IVL ($n = 7$, 6%) or after Rotatripsy ($n = 6$, 5%). Cutting balloon inflation ($n = 15$, 13%) was the most used concomitant strategy. After Rotatripsy, a stent was implanted in 116 (97%) lesions whereas DEB was delivered in 3 (3%) lesions.

QCA analysis (Table 4) showed significantly improved minimum LD (0.9 ± 0.6 mm vs. 2.9 ± 0.7, $p < 0.001$) and percentage diameter stenosis (72.1 ± 17.2 vs. 16.4 ± 9.5, $p < 0.001$) when comparing pre- and post-Rotatripsy values. The mean luminal gain after Rotatripsy was 2.1 ± 0.8 mm. ICI was conducted for procedural optimization in 69 (58%) of the target lesions of which IVUS was used in 60 (87%) and OCT in 9 (13%) cases. Of these cases, ICI was performed in the minority of target lesions ($n = 27$, 23%) before application of Rotatripsy. Additionally, 59 (49%) target lesions underwent ICI after Rotatripsy and stenting. Furthermore, ICI was utilized between IVL and RA in 34 (28%) instances, and in 16 (13%) cases it was applied after Rotatripsy but before stenting. Matching pre- and post-PCI values were available for analysis in 27 patients. The minimum LD (1.9 ± 0.5 mm vs. 3.2 ± 0.5 mm, $p < 0.001$), MLA (3.7 ± 1.7 mm vs. 9.2 ± 2.6 mm, $p < 0.001$), percentage diameter stenosis (51.1 ± 12.4% vs. 17.4 ± 7.9%, $p < 0.001$) and percentage area stenosis (68.6 ± 12.9% vs. 21.9 ± 12.8%, $p < 0.001$) improved significantly following Rotatripsy (Table 4).

Device success was reached in 110 (97%) patients. In the remaining patients, complications occurred that were directly related to the IVL or RA procedure, including coronary perforation ($n = 2$, 2%), coronary dissection (n = 1, 1%) and Burr

TABLE 3 Procedural characteristics.

	Overall (n = 120)
Rotatripsy approach	
Upfront (RA-IVL-stent), n(%)	106(88)
Upfront (IVL-RA-stent), n(%)	4(3)
Bail-out (RA-stent-IVL), n(%)	10(8)
Rotablation	
Number of burrs used	
1, n(%)	107(89)
2, n(%)	12(10)
3, n(%)	1(1)
Burr size	1.5±0.2
1.25, n(%)	30(25)
1.5, n(%)	67(56)
1.75, n(%)	17(14)
2.0, n(%)	6(5)
Burr size/reference vessel diameter ratio	0.4±0.1
Maximum rotational speed, rpm	171.000±15.000
High pressure pre-dilatation, n(%)	34(28)
High pressure post-dilatation, n(%)	83(69)
Lithotripsy reason	
Before RA	4(3)
Elective combined approach, n(%)	68(57)
Balloon underexpansion post RA, n(%)	37(31)
Stent crossing failure post RA, n(%)	1(1)
Post-RA stent underexpansion (bail-out), n(%)	10(8)
IVL	
Balloon diameter, mm	3.5±0.5
Number of pulses	68±25
High pressure pre-dilatation, n(%)	85(71)
High pressure post-dilatation, n(%)	84(70)
Other plaque modification techniques, n(%)	16(13)
Pre rotatripsy, n(%)	4(3)
Cutting balloon, n(%)	3(3)
ELCA, n(%)	1(1)
In between rotatripsy, n(%)	7(6)
Cutting balloon, n(%)	7(6)
OPN balloon, n(%)	1(1)
Post rotatripsy	6(5)
Cutting balloon, n(%)	5(4)
OPN balloon, n(%)	2(2)
Treatment after rotataripsy	
Stenting, n(%)	116(97)

TABLE 3 (Continued)

	Overall (n = 120)
Stent diameter, mm	3.6±0.5
Stent length, mm	45±25
Drug-coated balloon, n(%)	3(3)
Overall parameters (*n* = 114)	
Vascular access site	
Radial, n(%)	74(65)
Femoral, n(%)	42(37)
Brachial, n(%)	2(2)
Humeral, n(%)	1(1)
Guiding cathether size (Fr)	
6, n(%)	39(34)
7, n(%)	59(52)
8, n(%)	10(9)
Unknown, n(%)	6(5)
Procedural time, min	123.0±44.7
Fluoroscopy time, min	42.9±24.2
Contrast volume, ml	209.2±87.3

Abbreviations: ELCA, excimer laser coronary angioplasty; IVL, intravascular lithotripsy; OPN, ultrahigh pressure balloon; RA, rotational atherectomy.

entrapment (*n* = 1, 1%) (Table 5). Technical success and procedural success were achieved in 107 (94%) and 106 (93%) patients, respectively (Tables 5 and 6). Among the complications (*n* = 9, 8%), two perforations occurred after IVL post RA-failure. The first occurred in the left circumflex artery after using a 1.5 mm Burr and 2.5 mm IVL-balloon, treated with long balloon inflation. The second occurred in the LAD after 1.5 mm Burr and 4.0 IVL balloon inflation, and was treated with 3 covered stents. A third perforation, unrelated to Rotatripsy, occurred in the mid RCA due to high-pressure NC post-dilatation and was treated with two covered stents. Additionally, a coronary dissection was caused by inflating a 4.0 mm IVL-balloon in the proximal RCA and treated with two covered stents. A 1.25 mm Burr entrapment in the left main-LAD, likely due to the small burr-vessel ratio in a heavily calcified long-segment target lesion was successfully resolved (Table 5).

The median follow-up time after the Rotatripsy procedure was 365 (182–365) days. One year follow-up was available in 77 (67%) patients, in which MACE was observed in 7 (9%) (Table 6 and Figure 3). Of these events, one (1%) occurred before hospital discharge and was not related to failure of Rotatripsy therapy (in-hospital death caused by pneumonia leading to a combination of cardiogenic and septic shock). The events occurring during follow-up comprised 5 (4%) TVR's and 1 (1%) conservatively treated non-ST elevation MI. Figure 4

4 | DISCUSSION

The present study analyzed the safety and efficacy of the combined approach of RA and IVL, known as Rotatripsy, for the treatment of severe CAC, both acutely as at 1-year follow-up. Apart from providing a longer follow-up period, the present study expands existing knowledge by providing a thorough angiographic and ICI evaluation beyond what earlier studies on the subject have offered. The main findings are: (1) Rotatripsy demonstrated high procedural success rates across diverse clinical and anatomical settings; (2) the high efficacy of Rotatripsy was accompanied by low complication rates and adverse event rates at 1-year follow-up and (3) in the majority of Rotatripsy-procedures, RA was electively employed before IVL.

In this study, RA was electively employed before IVL in the majority of the cases. In this approach, RA is electively performed in balloon-uncrossable lesions to target superficial and concentric calcium, enabling the IVL-balloon to pass and fracture deeper calcium, facilitating stent delivery and expansion. Therefore, this elective Rotatripsy approach might particularly be useful for long-segment heavily calcified lesions, which may have different types of calcification present that can be targeted by the two debulking techniques (concentric and superficial calcification by RA and more focal and deep calcium by IVL). Notably, 77% of the target lesions were long-segment (Table 2) with a new stent length of 45 ± 25 mm (Table 3). This study sets itself apart for the previously published Rota-Shock study, where most IVL-procedures were performed because of RA-failure, such as balloon underexpansion and stent crossing failure after RA.[22] The variation in treatment approach is illustrated by slightly higher utilization of burrs smaller than 1.5 mm (25% in the present study vs. 16% in the Rota Shock study) and a mean burr-size of 0.4 (compared to 0.5 in the Rota-Shock study). As reported earlier, smaller burrs might be strategically chosen (in the elective combined approach) to provide lesion passage for the IVL-balloon in a very severe and deeply calcified plaque which the operator deems uncrossable without RA. This approach may therefore be considered as ‘true Rotatripsy’, utilizing the synergistic effects of both therapies to target both superficial and deep calcium in severely calcified plaques. An explanation of the variation in therapy approach between both studies might be the marginally higher rate of ICI performed before RA and IVL to assess lesion morphology and guiding the treatment strategy (23% in this study and 15% in the Rota-Shock study). However, a higher prevalence of ICI in these complex lesions should always be pursued to guide the Rotatripsy procedure. Additionally, it may be attributed to the longer inclusion period of the present study (5 years), compared to the inclusion period of 2 years in the Rota-Shock study. Moreover, operators tend to become more accustomed to the Rotatripsy-technique, leading them to choose the electively combined approach more frequently over time.

In this real-world all-comers registry, the treated patient population was complex. First of all, 51% of patients presented with ACS. The use of IVL and RA in acute cases was initially contra-

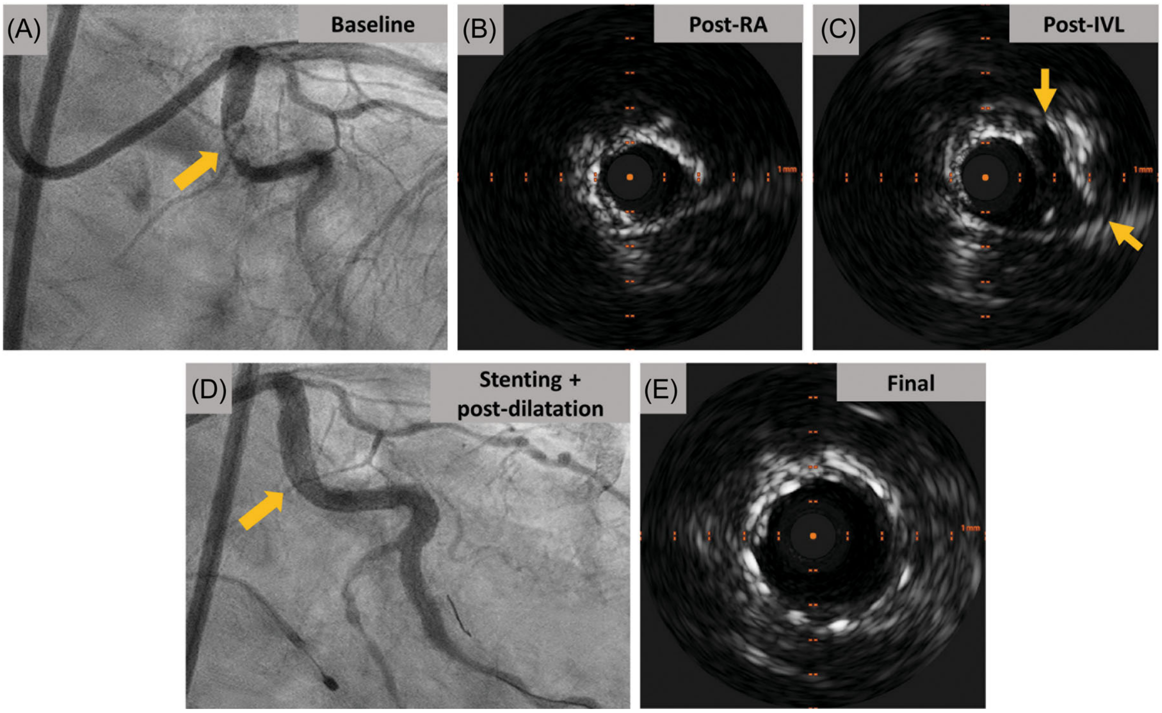

FIGURE 1 Upfront Rotatripsy. Elective sequential use of rotational atherectomy and intravascular lithotripsy for a severely calcified stenosis. (A) Baseline coronary angiogram with a severely calcified target lesion at the proximal left circumflex artery (LCx, arrow). (B) Intravascular ultrasound (IVUS), showing 360 degrees calcification after rotational atherectomy (RA). (C) Post- intravascular lithotripsy (IVL) (70 pulses) IVUS, showing calcium fractures (arrows). (D) Angiogram after stenting and post-dilatation, showing excellent stent expansion (arrow) and confirmed by IVUS (E). [Color figure can be viewed at wileyonlinelibrary.com]

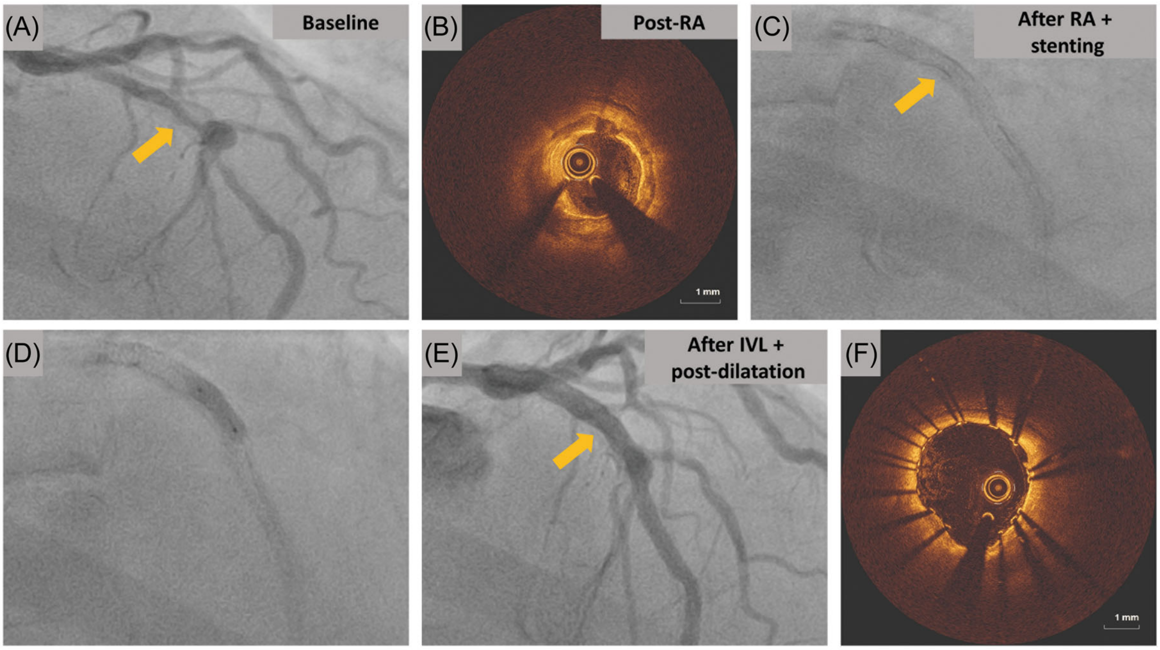

FIGURE 2 "Bail-out" Rotatripsy: intravascular lithotripsy for the treatment of stent underexpansion post-RA and stenting. (A) Baseline coronary angiogram showing a severely calcified stenosis of the proximal left anterior descending artery (LAD, arrow). (B) Optimal computed tomography (OCT) showing 360 degrees severe calcification after rotational atherectomy (RA). (C) Post-stenting fluoroscopic examination, pointing out the presence of focal stent infraexpansion (arrow), treated with intravascular lithotripsy (IVL) (80 pulses) (D). (E) Angiogram after stenting and post-dilatation, showing excellent stent expansion (arrow) and confirmed by OCT (E). [Color figure can be viewed at wileyonlinelibrary.com]

TABLE 4 Quantitative coronary and intracoronary imaging analysis.

	Pre-Rotatripsy	Post-Rotatripsy	*p*-value
Quantitative coronary analysis			
Minimum LD, mm	0.9 ± 0.6	2.9 ± 0.7	**<0.001**
Percentage DS	72.1 ± 17.2	16.4 ± 9.5	**<0.001**
Diameter gain, mm		2.1 ± 0.8	
Intracoronary imaging			
Minimum LD, mm	1.9 ± 0.5	3.2 ± 0.5	**<0.001**
MLA, mm^2	3.7 ± 1.7	9.2 ± 2.6	**<0.001**
Percentage DS	51.2 ± 12.4	17.4 ± 7.9	**<0.001**
Percentage AS	68.6 ± 12.9	21.9 ± 12.8	**<0.001**

Abbreviations: MLA, minimum lumen area; minimum LD, minimum lumen diameter; percentage DS, percentage diameter stenosis; percentage AS, percentage area stenosis;

TABLE 5 Complications.

	Overall *n* = 114
Complications, n(%)	9(8)
Dissection, n(%)	1(1)
Perforation, n(%)	3(3)
Slow flow, n(%)	0
No reflow, n(%)	1(1)
Abrupt vessel closure, n(%)	0
Hemodynamic instability, requiring intervention, n(%)	3(3)
Reanimation status, n(%)	(3)
Other, n(%)	(3)
Directly related to Rotatripsy, n(%)	4(4)
Perforation	2(2)
Dissection, n(%)	1(1)
Burr entrapment, n(%)	1(1)

indicated. However, recent studies have suggested efficacy of both techniques in this scenario.[26,27] Besides the high percentage of patients presenting with ACS, high rates of comorbidities (e.g., diabetes, hypertension, hypercholesterolemia and chronic kidney disease) and cardiac history (previous MI, PCI, and CABG), diverse high-risk target lesions were addressed, including bifurcation, ostial, long-segment and in-stent lesions.[28] The complexity of these cases is reflected by the high average SYNTAX score (24.6 ± 13.0). Even in this complex patient population, good procedural results (device, technical and procedural success) were achieved and were accompanied by low therapy-induced complication (4%) and in-hospital MACE rates (1%). These results suggest that Rotatripsy can be used even in complex patients presenting with ACS, and in diverse lesion

TABLE 6 Procedural outcomes and major adverse cardiovascular events.

	Overall
***n* = 114**	
Procedural outcomes	
Device success, n(%)	110(97)
Technical success <30%, n(%)	107(94)
Procedural success <30%, n(%)	106(93)
MACE	
In-hospital, n(%) (n = 114)	1(1)
30-days, n(%) (n = 106)	1(1)
6-months, n(%) (n = 93)	4(4)
1-year, n(%) (n = 77)	7(9)

Abbreviation: MACE, major adverse cardiovascular events.

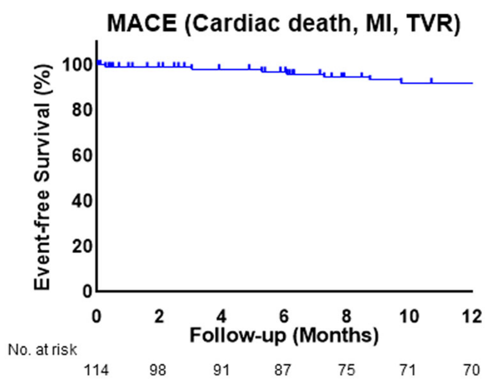

FIGURE 3 One-year major adverse cardiovascular events-free survival of patients treated with Rotatripsy. MI, myocardial infarction; TVR, target vessel revascularization. [Color figure can be viewed at wileyonlinelibrary.com]

characteristics. However, individual patient conditions and procedural considerations should always be taken into account to ensure the best outcomes. The high success rates are in line with previously published studies examining Rotatripsy as well as studies separately evaluating RA and IVL-therapy.[15,22,23,26,29] The therapy-induced complication rates (including angiographic complications as perforation and dissection and burr entrapment) and in-hospital MACE-rates were also comparable to those reported in the Rota-Shock study, and notably lower than those associated with RA-therapy alone.[22,30,31] The lower incidence of complications and in-hospital MACE after Rotatripsy compared to RA alone, might be explained by the strategic use of smaller burr-vessel ratios paired with the use of ICI to guide the procedure.[30] The results of the present study are therefore consistent with the short-term outcomes of previous studies examining Rotatripsy indicated for mainly RA-failure. Additionally, it reveals a markedly low 1-year MACE incidence of just 9%. This finding is substantially lower compared to the 1-year MACE-rate associated with RA-therapy alone (17.7% at 15-months follow-up),

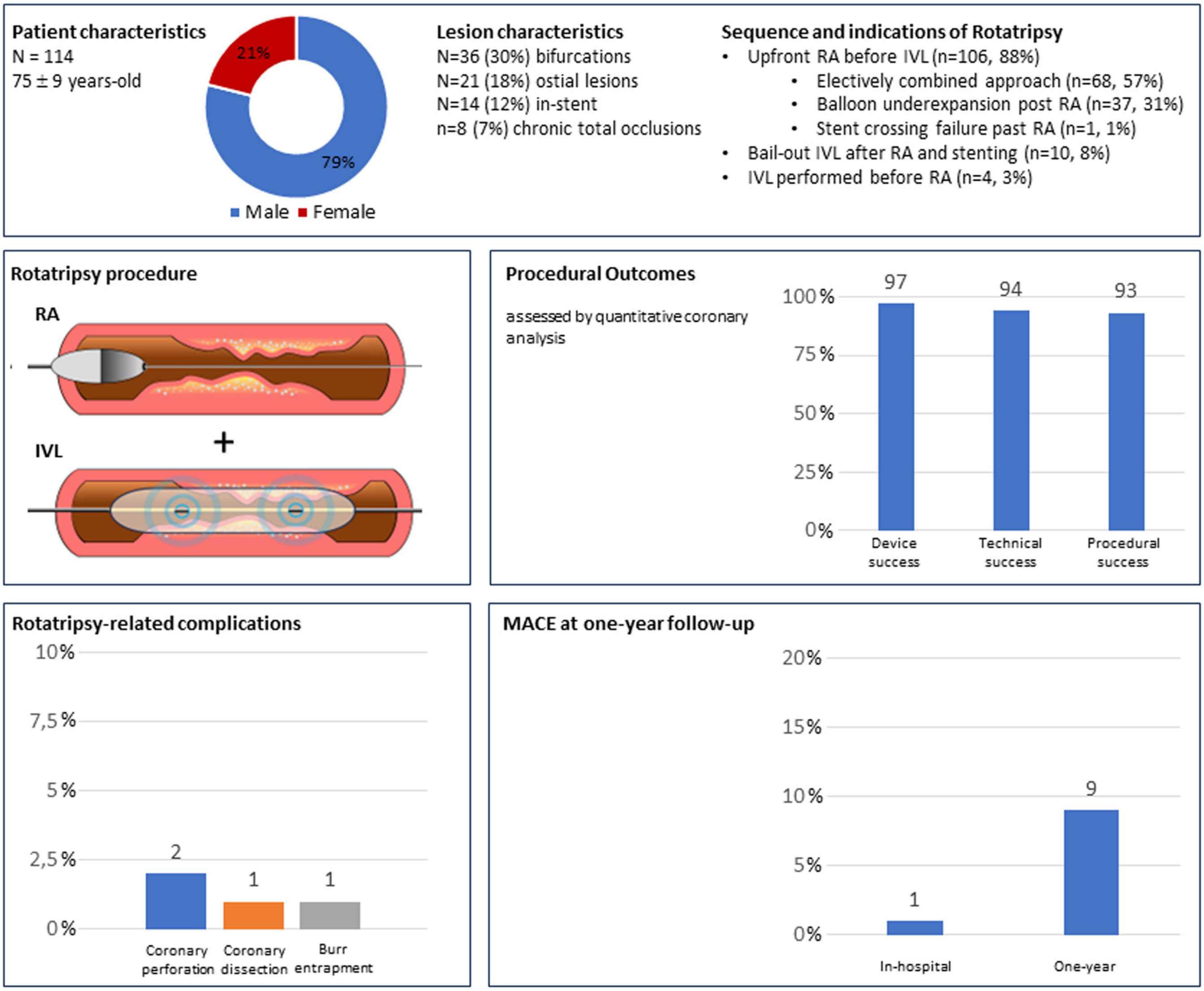

FIGURE 4 Central illustration. Patient and lesion characteristics, procedural outcomes, Rotatripsy-related complications and cardiovascular events at 1-year follow-up. Device success= delivery of RA-burr and IVL-balloon across the target lesion and administration of therapy without related complications; IVL, intravascular lithotripsy; MACE, major adverse cardiovascular events; procedural success, technical success with absence of in-hospital MACE; RA, rotational atherectomy; technical success, TIMI 3 flow and residual stenosis <30%. [Color figure can be viewed at wileyonlinelibrary.com]

underscoring the promising longer-term safety and efficacy of Rotatripsy.[31] Thus, the current study offers insight into the potential midterm advantages of Rotatripsy therapy, highlighting its low associated event-rates over a longer follow-up period even in a complex patient population. However, these findings have to be examined in larger prospective studies that might focus on the efficacy of different sequences of Rotatripsy for different target lesion subsets and clinical scenarios.

These promising outcomes at longer-term follow-up mitigate a primary concern regarding Rotatripsy—the costs associated with employing bot RA and IVL—by restricting the risk of future revascularization procedures. Moreover, using more cost-effective methods for lesion preparation that do not adequately address the issue might lead to suboptimal procedural outcomes, elevating risk of restenosis and thrombosis, potentially leading to future expenses.[32,33] In addition, using lesion preparation that does not adequately address the lesion, might lead to higher risk of peri-procedural complications, which enlarges the procedural time and its associated costs.

5 | LIMITATIONS

This study has several limitations that should be acknowledged, most of them arising from its observational design and its limited sample size. This is particularly relevant when interpretating the clinical outcomes observed. Additionally, the decisions regarding the timing of both RA and IVL, the utilization of high-pressure pre- and post-dilatation, the placement of supplementary stents, and the use of ICI for procedural optimization were left to the operator's discretion. Also, routine use of ICI before RA and IVL is not possible, because the catheter is unable to pass the initial target lesion in a significant number of cases. Additionally, ICI was not routinely performed after Rotatripsy. This hindered the assessment of the standalone treatment effect within Rotatripsy therapy. Finally, it is important to note that both RA and IVL involve considerable costs and may not be readily available in all centers.

6 | CONCLUSION

Rotatripsy demonstrated efficacy across diverse clinical and anatomical settings, with the majority of procedures electively employing RA before IVL. High success rates and low complication rates were observed, with few patients experiencing MACE before discharge and at 1-year follow-up.

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CONFLICTS OF INTEREST STATEMENT

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DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available on request from the corresponding author. The data are not publicly available due to privacy or ethical restrictions.

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REFERENCES

1. Kawashima H, Serruys PW, Hara H, et al. 10-year all-cause mortality following percutaneous or surgical revascularization in patients with heavy calcification. *JACC: Cardiovasc Interv*. 2022;15(2):193-204.
2. Rheude T, Koch T, Joner M, et al. Ten-year clinical outcomes of drug-eluting stents with different polymer coating strategies by degree of coronary calcification: a pooled analysis of the ISAR-TEST 4 and 5 randomised trials. *EuroIntervention*. 2023;18(14):1188-1196.
3. Kobayashi Y, Okura H, Kume T, et al. Impact of target lesion coronary calcification on stent expansion. *Circ J*. 2014;78(9):2209-2214.
4. Lee MS, Shah N. The impact and pathophysiologic consequences of coronary artery calcium deposition in percutaneous coronary interventions. *J Invasive Cardiol*. 2016;28(4):160-167.
5. Madhavan MV, Tarigopula M, Mintz GS, Maehara A, Stone GW, Généreux P. Coronary artery calcification. *J Am Coll Cardiol*. 2014;63(17):1703-1714.
6. Mintz GS. Intravascular imaging of coronary calcification and its clinical implications. *JACC: Cardiovasc Imag*. 2015;8(4):461-471.
7. Kassimis G, Raina T, Kontogiannis N, et al. How should we treat heavily calcified coronary artery disease in contemporary practice? From atherectomy to intravascular lithotripsy. *Cardiovasc Revasc Med*. 2019;20(12):1172-1183.
8. Barbato E, Gallinoro E, Abdel-Wahab M, et al. Management strategies for heavily calcified coronary stenoses: an EAPCI clinical consensus statement in collaboration with the EURO4C-PCR group. *Eur Heart J*. 2023;44(41):4340-4356.
9. Jurado-Román A, Gómez-Menchero A, Gonzalo N, et al. Plaque modification techniques to treat calcified coronary lesions. Position paper from the ACI-SEC. *Rec-Interv Cardiol*. 2023;5(1):46-61.
10. Barbato E, Carrié D, Dardas P, et al. European expert consensus on rotational atherectomy. *EuroIntervention*. 2015;11(1):30-36.
11. Sharma SK, Tomey MI, Teirstein PS, et al. North American expert review of rotational atherectomy. *Circ Cardiovasc Interv*. 2019;12(5):e007448.
12. Hill JM, Kereiakes DJ, Shlofmitz RA, et al. Intravascular lithotripsy for treatment of severely calcified coronary artery disease. *J Am Coll Cardiol*. 2020;76(22):2635-2646.
13. Natalia M, Forero T, Daemen J. The coronary intravascular lithotripsy system. *Interv Cardiol Rev*. 2019;14(3):174-181.
14. Brinton TJ, Ali ZA, Hill JM, et al. Feasibility of shockwave coronary intravascular lithotripsy for the treatment of calcified coronary stenoses. *Circulation*. 2019;139(6):834-836.
15. Kereiakes DJ, Di Mario C, Riley RF, et al. Intravascular lithotripsy for treatment of calcified coronary lesions. *JACC: Cardiovasc Interv*. 2021;14(12):1337-1348.
16. Ali ZA, Brinton TJ, Hill JM, et al. Optical coherence tomography characterization of coronary lithoplasty for treatment of calcified lesions. *JACC: Cardiovasc Imag*. 2017;10(8):897-906.
17. Ielasi A, Loffi M, De Blasio G, Tespili M. "Rota-Tripsy": a successful combined approach for the treatment of a long and heavily calcified coronary lesion. *Cardiovasc Revasc Med*. 2020;21(11S):152-154.
18. Gonzálvez-García A, Jiménez-Valero S, Galeote G, Moreno R, López de Sá E, Jurado-Román A. "RotaTripsy": combination of rotational atherectomy and intravascular lithotripsy in heavily calcified coronary lesions: a case series. *Cardiovasc Revasc Med*. 2022;35:179-184.
19. Jurado-Roman A, Gonzalvez A, Galeote G, Jimenez-Valero S, Moreno R. RotaTripsy: combination of rotational atherectomy and intravascular lithotripsy for the treatment of severely calcified lesions. *JACC Cardiovasc Interv*. 2019;12(15):e127-e129.

20. Kaur N, Pruthvi CR, Sharma Y, Gupta H. Rotatripsy: synergistic effects of complementary technologies: a case report. *Eur Heart J Case Rep*. 2021;5(4):ytab083.
21. Dwivedi P, Dhulipala V, Kumar K, et al. Efficacy and safety of an upfront RotaTripsy strategy in the treatment of De Novo and In-Stent restenosis cases. *J Invasive Cardiol*. 2023;35(2):E70-E74.
22. Sardella G, Stefanini G, Leone PP, et al. Coronary lithotripsy as elective or bail-out strategy after rotational atherectomy in the Rota-Shock registry. *Am J Cardiol*. 2023;198:1-8.
23. Buono A, Basavarajaiah S, Choudhury A, et al. "RotaTripsy" for severe calcified coronary artery lesions: insights from a real-world multicenter cohort. *Cardiovasc Revasc Med*. 2022;37:78-81.
24. Tearney GJ, Regar E, Akasaka T, et al. Consensus standards for acquisition, measurement, and reporting of intravascular optical coherence tomography studies. *J Am Coll Cardiol*. 2012;59(12):1058-1072.
25. Sianos G, Morel MA, Kappetein AP, et al. The SYNTAX score: an angiographic tool grading the complexity of coronary artery disease. *EuroIntervention*. 2005;1(2):219-227.
26. Rodriguez-Leor O, Cid-Alvarez AB, Lopez-Benito M, et al. A prospective, multicenter, real-world registry of coronary lithotripsy in calcified coronary arteries: the REPLICA-EPIC18 study. *JACC Cardiovasc Interv*. 2024;17(6):756-767.
27. Chen YW, Lai CH, Su CS, et al. The procedural and clinical outcomes of rotational atherectomy in patients presenting with acute myocardial infarction. *Front Cardiovasc Med*. 2022;9:846564.
28. Bass TA. High-risk percutaneous coronary interventions in modern day clinical practice: current concepts and challenges. *Circ Cardiovasc Interve*. 2015;8(12):e003405.
29. Abdel-Wahab M, Richardt G, Joachim Büttner H, et al. High-speed rotational atherectomy before paclitaxel-eluting stent implantation in complex calcified coronary lesions. *JACC: Cardiovasc Interv*. 2013;6(1):10-19.
30. Tomey MI, Kini AS, Sharma SK. Current status of rotational atherectomy. *JACC: Cardiovasc Interv*. 2014;7(4):345-353.
31. Abdel-Wahab M, Baev R, Dieker P, et al. Long-term clinical outcome of rotational atherectomy followed by drug-eluting stent implantation in complex calcified coronary lesions. *Catheter Cardiovasc Interv*. 2013;81(2):285-291.
32. Kang SJ, Mintz GS, Park DW, et al. Mechanisms of in-stent restenosis after drug-eluting stent implantation: intravascular ultrasound analysis. *Circ Cardiovasc Interv*. 2011;4(1):9-14.
33. Fitzgerald PJ, Oshima A, Hayase M, et al. Final results of the Can Routine Ultrasound Influence Stent Expansion (CRUISE) study. *Circulation*. 2000;102(5):523-530.

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