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ORIGINAL ARTICLE

Shockwave intravascular lithotripsy as a novel strategy for balloon undilatable heavily calcified chronic total occlusion lesions

Piotr Rola[1, 2], Adrian Włodarczak[1], Mateusz Barycki[2], Maciej Pęcherzewski[1], Jan Jakub Kulczycki[1], Marek Szudrowicz[1], Artur Jastrzębski[1], Łukasz Furtan[1], Adrian Doroszko[3], Maciej Lesiak[4]

[1]Department of Cardiology, The Copper Health Center (MCZ), Lubin, Poland
[2]Department of Cardiology, Provincial Specialized Hospital, Legnica, Poland
[3]Department of Internal Medicine, Hypertension and Clinical Oncology, Wroclaw Medical University, Wroclaw, Poland
[4]1st Department of Cardiology, Poznan University of Medical Sciences, Poznan, Poland

Abstract

Background: *The successful percutaneous coronary intervention (PCI) in chronic total occlusion (CTO) improves the long-term outcome in patients with coronary artery disease (CAD). Heavy calcification remains one of the strongest predictors of an unfavorable outcome of PCI. In this case series study, shockwave intravascular lithotripsy (S-IVL)-a novel balloon-based coronary system facilitating modification of calcified coronary lesions was evaluated.*

Methods: *The study population consisted of five heavily calcified, undilatable-CTOs lesions treated with S-IVL selected out of all consecutive CTO-PCI patients performed at two high-volume cardiac centers.*

Results: *The registry included 5 patients successful CTO — S-IVL procedures with an average J-CTO of 2.6 points. In the short-term follow-up period, including the first 30 days, no cases of acute in-stent thrombosis, target lesion failure, or major adverse cardiac and cerebrovascular events were noted.*

Conclusions: *The present data suggest that this approach can be safe and useful in the treatment of complex calcified CTO lesions.* (Cardiol J 2023; 30, 5: 677–684)

Key words: chronic total occlusion, coronary artery disease, percutaneous coronary intervention, shockwave intravascular lithotripsy, calcified lesions, undilatable lesions, chronic stable angina

Introduction

A coronary chronic total occlusion (CTO) is defined as complete occlusion of a coronary artery for a duration of greater than 3 months based on angiographic evidence. Approximately one-quarter of patients undergoing diagnostic coronary angiography, CTO-lesions can be found [1, 2]. Advances in the percutaneous coronary intervention (PCI) techniques in the management of CTO have improved the success rate of this procedure in over 80% of high-volume expert centers, however, data from the "real-life" registry suggests that the success rate is far below the mentioned level, achieving approximately 60% [3]. As it was proven, the successful CTO PCI procedure improves the

Address for correspondence: Piotr Rola, MD, PhD, Department of Cardiology, Provincial Specialized Hospital, ul. Iwaszkiewicza 5, 55–220 Legnica, Poland, tel: +48 767211443/+48 888272007, fax: +0048 7672110, e-mail: piotr.rola@gmail.com

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long-term outcome of patients with coronary artery disease (CAD) [4]. Despite apparent clinical benefits, the risk of complications associated with these complex PCI procedures is significantly higher, compared to the non-CTOs [5].

To have better planning and to predict the short-term outcome, the J-CTO-score was proposed as an angiographic scale of the degree of difficulty of CTO-PCI [6]. One of five variables that increase the difficulty of the PCI-CTO procedure, in this well-validated scale, is the presence of calcifications in the body of the occlusion. A similar relationship between target lesion calcification and clinical outcome is observed in non-CTO PCI procedures [7]. The crucial mechanism leading to these unfavorable results is mainly connected with short- and long-term stent failure (fracture, poor expansion, malapposition followed by an increased rate of stent thrombosis and in-stent restenosis). Furthermore, calcifications increase the rate of peri-procedural complications particularly, life-threatening coronary artery perforation [8].

A proper lesion preparation before stent implantation has been established as a prerequisite to achieving adequate PCI results. Numerous strategies aimed at the crossing and appropriate preparation of calcified plaques have been implemented in the CTO-tool box [9]. Conventional procedures were divided into the balloon-dependent group (non-compliant [NC], ultrahigh-pressure balloon (OPN) or cutting/scoring catheter) exerting an internal pressure on the lesion, and atherectomy devices (rotational, laser, and orbital) focused on removing (pulverizing) the atherosclerotic plaque. Therefore, calcified lesions continue to be one of the most challenging CTO interventions, where optimal angiographic results and satisfying long-term outcomes are hard to achieve.

A recent study [10] suggests that shockwave intravascular lithotripsy (S-IVL) (Shockwave Medical Inc., Fremont, United States) a novel balloon-based coronary system converting electrical energy into mechanical force (acoustic wave with high-pressure amplitude) can facilitate modification of heavily calcified coronary lesions. Presented herein is early real-world experience with the S-IVL device in the setup of the CTO procedure.

Methods

The study population consisted of 5 carefully selected cases out of all consecutive patients with clinical indications for CTO-PCI at the documented cardiac centers from May 2019 to April 2021. All patients were treated in two high-volume interventional cardiology centers (conducting over 1000 PCI procedures each annually). From all pre-screened cases (192), patients were selected with mild and severe calcification (102 patients). Calcific deposits were assessed by angiography as mild (spots), moderate (involving ≤ 50% of the reference lesion diameter), and severe (involving > 50% of the reference lesion diameter). From this group, patients with "undilatable" lesions were selected. For the purpose of this paper the balloon undilatable, CTOs lesions were defined as lesions after the successful crossing of a guidewire through the CTO-body and initial successful pre-treatment with a low diameter NC balloon (NCB) catheter or with rotational atherectomy (RA) (4 cases of RA in prescreened 192 CTO procedures — all performed due "uncrossable" lesion with a low-profile balloon catheter or microcatheter) with coexisting significant (over 20% of the diameter) under expansion with NCB size 1:1 to vessel diameter inflated with high-pressure inflation at least of 20 atm.

There were no angiographic exclusion criteria regarding lesion anatomy such as the length, tortuosity, severity, prior stent placement or, J-CTO score. Figure 1 provides the details on the "lesion-related" angiographic and periprocedural inclusion criteria to this registry. Safety parameters, including coronary perforation, no-reflow, ventricular arrhythmias, and the major adverse cardiac and cerebrovascular events (MACCE) that occurred in-hospital and 30-day after primary hospitalization, were recorded. MACCE was defined as a composite endpoint including acute coronary syndrome, cerebrovascular events, major bleeding, need for repeated revascularization, or death.

Ethical review and approval were waived for this study due to the fact that it is a retrospective analysis of clinical cases and the techniques used in this study were used as bail-out techniques in order to save lives, however, patient written informed consent for PCI procedure was given as well as the use of patient information and images.

Case 1

A 66-year-old female with hypertension, hyperlipidemia, diabetes type 2, history of non ST-segment elevation myocardial infarction (NSTEMI) 1 year prior, treated with PCI and 3 drug eluting stent (DES) implantations to the left anterior descending (LAD) and D1, was admitted to our center to perform the stage procedure of CTO-right coronary artery (RCA) (J-CTO score 3 points) (Fig. 2.1A) due to recurrent angina

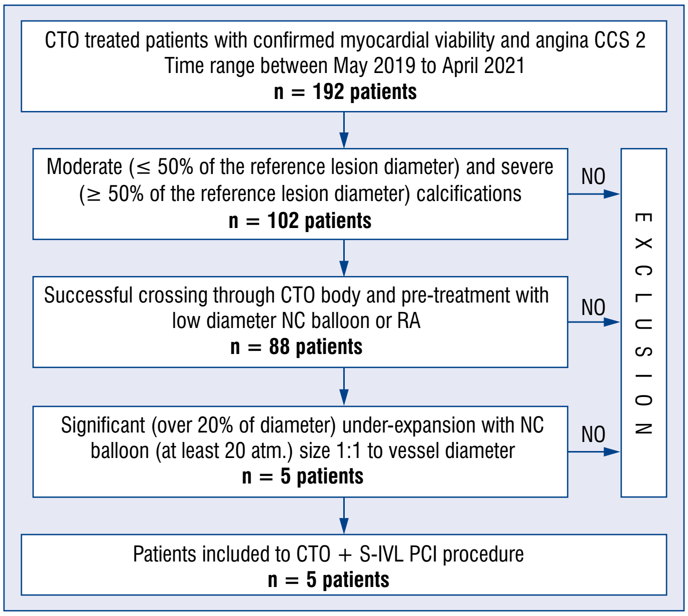

Figure 1. Lesion-related angiographic and procedural inclusion and exclusion criteria to the study; CTO — chronic total occlusion; CCS — Canadian Cardiovascular Society scale; NC — non-compliant; S-IVL — shockwave intravascular lithotripsy; PCI — percutaneous coronary intervention; RA — rotational atherectomy.

(Canadian Cardiovascular Society [CCS] II) and confirmed myocardial viability in transthoracic echocardiogram (transthoracic echocardiography with the left ventricular ejection fraction 60%). PCI was performed via right femoral access (AL 1.0 7F) and contralateral injection by left radial JL 4.0 (6F).

Using several guidewires Fielder XT (Asahi-INTECC); Progress 140 (Abbott Vascular, Santa-Clara, United States) the distal part of RCA with Gaia3 (Asahi-INTECC) was achieved. Despite the use of the 7F guiding extension Guidezilla (Boston Scientific, Marlborough, United States) all attempts of crossing the lesion with the microcatheter and a low-profile balloon 1.0 mm × 10 mm failed. Considering the severe calcifications, the successful crossing of a lesion was achieved with Turnpike Gold135 (Vascular Solutions LLC, Minneapolis, United States) — microcatheter with threaded tip. In the next step multiple successful high-pressure inflation was performed (Fig. 2.1B) with balloon catheters 1.0 mm × 10 mm; 1.5 mm × 15 mm, and NCB 2.5 mm × 15 mm.

Despite lesion preparation we observed a significant "dogbone effect" on the NCB 3.0 mm × × 15 mm (21 atm.) (Fig. 2.1C). Hence, the S-IVL using a 3.0 mm × 12 mm catheter was performed. Delivery of the device was facilitated by guide extension. After the application of 80 ultrasonic pulses, full expansion was obtained (Fig. 2.1D). Three overlapping DES 3.5 mm × 15 mm; 3.0 mm × 38 mm and 3.0 mm × 38 mm (16 atm.) implantation was followed by a 3.5 mm × 20 mm (22 atm.) and 3.75 mm × 8 mm (20 atm.) NCB post-dilation. Finally, a satisfying angiographic result was obtained (Fig. 2.1E).

Case 2

An 80-year-old female with hypertension, hyperlipidemia, diabetes type 2, paroxysmal atrial fibrillation, history of ischemic stroke was admitted to the cath-lab presenting NSTEMI. Coronary angiogram revealed heavily calcified significant long lesion of the dominant RCA with coexisting chronic occlusion of LAD (J-CTO score 3 points) (Fig. 2.2A) due to ongoing ischemia (resting chest pain) rescue PCI of RCA with 3 DES implantation was performed via right radial (AL 1.0 6F).

Five days later due to recurrent angina despite optimal medical therapy, CTO of LAD via left radial access was performed (EBU 7F). After wiring a distal part of the LAD with microcatheter and Gaia Second (Asahi-INTECC). Flow to artery was restored by inflation of 1.5 mm × 20 mm balloon catheter and 2.5 mm × 15 mm NCB (Fig. 2.2B). However, significant under-expansion of NCB 3.5 mm × 15 mm was observed in the proximal part of a lesion (Fig. 2.2C).

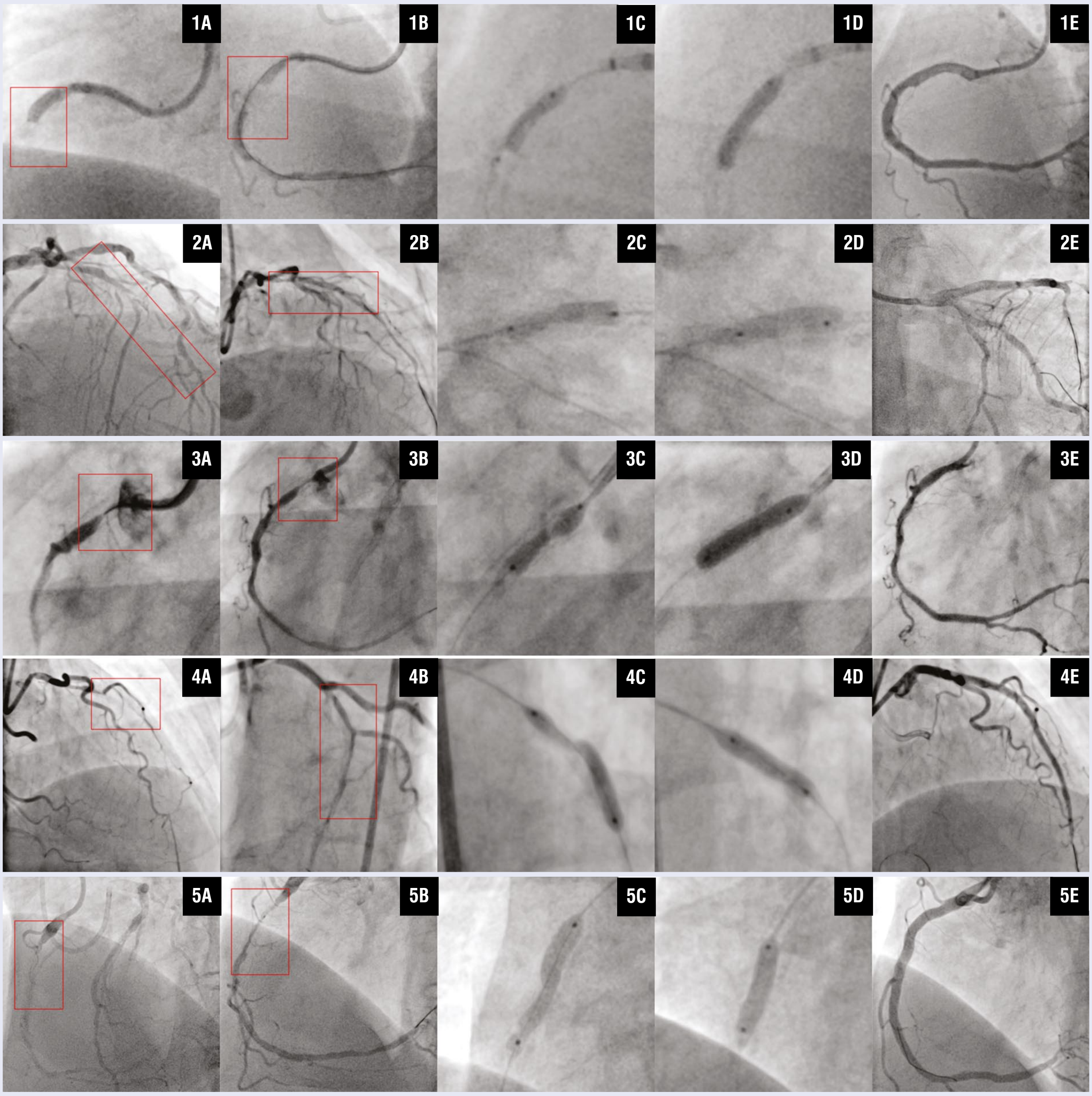

Figure 2. Series of cases: intervention images Case I: **1A.** Primary chronic total occlusion (CTO) lesion; **1B.** Undilatable lesion; **1C.** Underexpansion of 3.0 mm × 15 mm non-compliant balloon (NCB); **1D.** Shockwave intravascular lithotripsy (S-IVL) balloon 3.0 mm × 12 mm; **1E.** Final angiogram; Case II: **2A.** Primary CTO lesion; **2B.** Undilatable lesion; **2C.** Underexpansion of 3.5 mm × 15 mm NCB; **2D.** S-IVL balloon 3.5 mm × 12 mm; **2E.** Final angiogram; Case III: **3A.** Primary CTO lesion; **3B.** Undilatable lesion; **3C.** Underexpansion of 3.5 mm × 15 mm NCB; **3D.** S-IVL balloon 3.5 mm × 12 mm; **3E.** Final angiogram; Case IV: **4A.** Primary CTO lesion; **4B.** Undilatable lesion; **4C.** Underexpansion of 3.5 mm × 20 mm NCB; **4D.** S-IVL balloon 3.5 mm × 12 mm; **4E.** Final angiogram; Case V: **5A.** Primary CTO lesion; **5B.** Undilatable lesion; **5C.** Underexpansion of 3.5 mm × 20 mm NCB; **5D.** S-IVL balloon 3.5 mm × 12 mm; **5E.** Final angiogram.

Hence, S-IVL (3.5 × 12 mm) with full expansion after 40 pulses of therapy was performed (Fig. 2.2D) and subsequent rapture of S-IVL balloon catheter without any sequelae. Three overlapping DESs: 2.5 mm × 32 mm; 3.0 mm × 24 mm, and 3.5 mm × 16 mm were implanted with final post-dilated with 3.5 mm NCB (22 atm) and Thrombolysis in Myocardial Infarction 3 flow at the end of the procedure (Fig. 2.2E).

Case 3

A 66-year-old female, with hypertension, hyperlipidemia, diabetes type 2, with lower extremity peripheral artery disease (PAD), history of myocardial infarction with ST-segment elevation myocardial infarction myocardial infarction (STEMI) treated percutaneously with implantation of 3 DES to RCA, with subsequent scheduled implantation of 3 DES to LAD 11 years ago, was admitted to hospital with the symptoms of dyspnea and chest pain (II class in the CCS scale) despite optimal medical therapy. Magnetic resonance imaging revealed persistent viability of myocardium in the area of the inferior wall.

Coronary angiogram revealed: CTO of RCA in previously implanted stents (Fig. 2.3A) with no significant lesion in the left coronary system. By right radial access CTO-PCI was performed with successful crossing lesion with Gaia Second (Asahi-INTECC), after an exchange of guidewires the flow in RCA was restored with 1.0 mm × 15 mm (18 atm) baloon catheter (Fig. 2.3B). However, significant underexpansion of NCB 3.5 mm × 15 mm balloon catheter at 22 atm in proximal stent was observed (Fig. 2.3C). Therefore the S-IVL catheter 3.5 mm × 12 mm was used. After the application of 80 ultrasonic pulses, full expansion was obtained (Fig. 2.3D). In the next step in the previously implanted DES, NCB 4.0 mm × 15 mm was performed (22 atm) with subsequent implantation DES 4.0 mm × 15 mm (16 atm).

After restoring a flow to RCA a significant lesion in the distal part of RCA was revealed. It was predilatated with NCB 2.5 mm × 15 mm (16 atm) and was followed by DES 2.75 mm × 15 mm (14 atm) implantation. Finally, a satisfying angiographic result was obtained (Fig. 2.3E).

Case 4

62-year-old female with hypertension, hyperlipidemia, rheumatoid arthritis and hypothyroidism was admitted to hospital due to recurrent angina class II CCS. Pre-PCI echocardiography revealed mild contractility disorders in the area of the intraventricular septum with preserved global ejection fraction of the left ventricular. Coronary angiogram revealed CTO of the middle part of LAD (J-CTO score 3) (Fig. 2.4A).

Percutaneous coronary intervention via right femoral access Ebu 3.5 7F and contralateral injection by right radial AL1.0 was performed (7F). Using the anterograde wire escalation technique the distal part of LAD was achieved with Progress 140 (Abbott Vascular) and microcatheter. The flow was restored by inflation of balloon catheter 2.0 mm × 15 mm (16 atm) (Fig. 2.4B). Despite previous lesion preparation, a significant "dogbone effect" on the NCB 3.5 mm × 20 mm (22 atm) (Fig. 2.4C) was observed. Thus, the S-IVL catheter 3.5 mm × 12 mm was used and after the application of 30 ultrasonic pulses, full expansion was obtained (Fig. 2.4D). Three overlapping DESs 3.5 mm × × 18 mm; 3.0 mm × 48 mm and 2.5 mm × 18 mm (16 atm) implantation was followed by a 4.0 mm × × 8 mm (22 atm) NCB postdilation. Finally, a satisfying angiographic result was obtained (Fig. 2.4E).

Case 5

68-year-old male with hypertension, hyperlipidemia, diabetes type 2, history of NSTEMI 6 months prior treated with PCI and DES implantation to the LAD and circumflex artery was admitted to hospital to perform stage CTO-RCA (J-CTO score 2) (Fig. 2.5A). Control echocardiography revealed slight contractility disorders in the area of the inferior wall with preserved left ventricular systolic function (ejection fraction 50%).

Percutaneous coronary intervention was performed via right radial access AL 1.0 7F with contralateral injection by left radial Ebu 3.5 7F. The CTO lesion was crossed with Gaia Third (Asahi-INTECC) and microcatheter, after wire exchange on extra support successful predilatation of a lesion with inflation 1.5 mm × 20 mm balloon catheter and 2.5 mm × 15 mm NCB was performed (Fig. 2.5B). However significant underexpansion of NCB 3.5 mm × 20 mm (22 atm) was observed (Fig. 2.5C). As result, the S-IVL 3.5 mm × 12 mm balloon was then passed and 4 cycles of lithotripsy were delivered (Fig. 2.5D). Two overlapping DES were implanted to RCA — 3.5 mm × 26 mm (16 atm); 3.5 mm × 40 mm (14 atm). Additional postdilatation with NCB 4.0 mm × 15 mm (20 atm) was performed. Due to what was revealed in control angiogram, a significant lesion in the distal part of RCA after predilatation with 3.0 mm × 15 mm NCB, thus DES 3.0 mm × 24 mm was implanted with reasonable angiographic resolution (Fig. 2.5E).

Results

The present case-series registry includes 5 patients with successful CTO procedures with heavy calcifications within the CTO — body which primary was undilatable with NCB treated with S-IVL (Table 1). Details on the clinical, procedural, and postprocedural characteristics are provided. All the patients were at "difficult" or "very difficult" stage in the degree of difficulty according to the J-CTO with an average of 2.6 points. On average, patients undergoing the CTO procedure received

Table 1. Clinical, procedural, and postprocedural characteristics of patients.

Clinical data	Case 1	Case 2	Case 3	Case 4	Case 5
Age [years]	66	80	66	62	68
Hypertension	Yes	Yes	Yes	Yes	Yes
Type 2 diabetes mellitus	Yes	Yes	No	No	Yes
Hyperlipidemia	Yes	Yes	Yes	Yes	Yes
Atrial fibrillation	No	Yes	No	No	No
Post PCI status	Yes	Yes	Yes	No	Yes
Primary diagnosis	CAD-CCS II*	CAD-UA CCS III*	CAD-CCS II*	CAD-CCS II*	CAD-CCS II*
Treated vessel	RCA	LAD	RCA	LAD	RCA
Access	7F FEM	7F RAD	7F RAD	7F FEM	7F RAD
J-CTO score	3	3	1	3	2
Syntax score	10	29,5	10	15,5	14
IVL diameter [mm]	3.0	3.5	3.5	3.5	3.5
Number of pulses	80	40	80	30	40
DES size [mm]	3.0 × 38	3.5 × 16	4.0 × 15	3.5 × 18	3.5 × 40
DES pressure [atm]	16	16	15	16	14
Amount of contrast [mL]	140	300	150	320	300
Radiation dose [mGy]	1657	1416	1382	1649	1611
Fluoroscopy time [min]	26.2	24.1	17.5	22.4	37.5

CAD-CSS II — stable coronary artery disease in second class according to Canadian Cardiovascular Society; DES — drug eluting stent; FEM — femoral; IVL — intravascular lithotripsy; J-CTO — Japanese Multicenter CTO Registry; LAD — left anterior descending; PCI — percutaneous coronary intervention; RAD — radial; RCA — right coronary artery; UA — unstable angina

242 mL (140 mL – 320 mL) of contrast — no post-procedural renal failure was noticed and absorbed 1543 mGy (1382 mGy – 1657 mGy) of radiation. In 1 case peri-procedural complication occurred. After the application of 40 sonic pulses, an S-IVL balloon catheter rapture we observed without any consequences for the patient. In the short-term follow-up period including the first 30 days, no cases of acute in-stent thrombosis or target lesion failure were noted. There was no case of the in-hospital MACCE nor MACCE observed within the 30 days after the intervention. The majority of procedures were performed by the radial approach (7F)

Discussion

This is, according to available research, is among the first-in-man case series studies to demonstrate the efficacy and safety of use S-IVL during the PCI-CTO procedures in CAD. So far, in the literature, mainly single case reports can be found [11, 12] and one recently published higher number study [13] using the intravascular lithotripsy as a part of the armamentarium in CTO procedures. Data suggest that undergoing successful CTO revascularization, compared to unsuccessful CTO recanalization, is associated with clinical benefit as well as improvement in long-term outcome [14]. As it was revealed, heavy calcifications are associated with lower success rate, and higher complication rates of CTO procedures [15]. Unsuccessful crossing through the occlusion with a guidewire is the most common mechanism of CTO-PCI failure [16]. However, another frequently observed mechanism of the CTO-PCI failure is device-uncrossable CTO lesions, defined as an inability of passage of a balloon after successful guidewire crossing (balloon uncrossable lesions) or an inability to expand fully the catheter despite the use of multiple balloon inflations (balloon undilatable lesions). For lesions that are not balloon-crossable, RA or orbital atherectomy are justifiable options. Balloon undilatable lesions are technically demanding and associated with worse outcomes. Prevalence of this phenomena is rater common (6–12% of all CTO procedures) [17, 18].

Adequate preparation in such lesions is critical to avoid the short- and long-term complications. When inadequate, it can result in suboptimal stent expansion or fracture as well as a higher rate of stent thrombosis and in-stent restenosis. Currently, there are several therapeutic options to manage this clinical problem. Armamentarium for calcified lesion preparation is varied and consists of specialized balloon technology or atherectomy devices. Recently McQuillan et al. [19] proposed a clinical algorithm of different techniques that can be used in resistant lesions. The first line in the step-wise approach, using a different kind of balloon catheter was proposed. Besides classical NCBs, their algorithm recommends the use of ultrahigh-pressure balloons — OPN balloon or cutting/scoring balloons. As a second line, they suggest using an atherectomy device (rotational, orbital, or laser). In case of failure, the use of the S-IVL device is proposed, although as it was mentioned before there are only a few reports [20, 21] of such complex procedures. Such a stepwise approach allows for increasing the number of successful procedures, however, it increases the periprocedural complication rate. Especially when a more invasive strategy is used [22].

Unlike in the case of balloon uncrossable lesions where calcification occurs mainly superficially, causing occlusion of the inner lumen of the vessel, balloon undilatable lesions are more likely associated with the presence of profound calcium deposits. Therefore, classical methods of lesion preparation-balloon or atherectomy devices focused on the superficial plaque modification often remains insufficient. To date, the main method of management with these issues has been based on an escalation of device sizes. It was inextricably linked with the increased rate of acute peri-procedural complications: slow/no flow phenomena, dissection, or perforation of the vessel. Furthermore, this aggressive approach often requires the use of femoral access. It may partially result from better guide support and the necessity of larger burr size use. On the one hand, recent data suggests [23] that trans radial access is increasingly being used for CTO PCI and is associated with a similar outcome and a lower rate of major bleeding. On the other hand, a higher level of J-CTO score accompanied by an increased level of calcium deposits is responsible for the growth of the femoral access rate. By using S-IVL devices, it is possible to pass-by the use of an atherectomy device (with potentially large burr size) and potentially de-escalate the level of necessary "support need" from the guiding catheter which results in an increased rate of radial access procedures. The data from our case series seems to be consistent with this thesis — despite quite a high average J-CTO score (2.4) a majority of cases were performed by radial access (7F). This benefit of the S-IVL device is related to the mechanism of action which is a combination of several physical phenomena: amplitude of the pressure, stretching wave, cavitation, and lead to the defragmentation of deep calcium nodules [24]. In conclusion, S-IVL should rather be chosen instead of rotational devices in non-critical focal lesions with deep calcium deposits, particularly not susceptible to the predilatation NCB parallel to the vessels size. Initial data from real-life registries seems to support this thesis [25]. Despite all of this, the bulky nature of S-IVL must be taken into consideration, before proper guiding selection. Operators should also be aware of the size limitations of the S-IVL system (short 12 mm balloon catheters in diameter range 2.5–4.0 mm) and a restrained number of delivered ultrasonic pulses (80).

Since intravascular lithotripsy is a relatively novel method, safety concerns are not unfounded. In our registry, only one acute complication related to this device was observed — the burst of the S-IVL balloon. This device failure was described previously, it is rather common and hardly ever causes any sequelae [25, 26]. Nevertheless, some data suggest that S-IVL can induce ventricular arrhythmias [27] and future studies focused on the safety issue of this therapy are necessary. However, in the present "real-life" study, there is a lack of data from intravascular imaging (the decision to use intravascular ultrasound/optical coherence tomography was left to the discretion of the operators), it was presumed that it would provide valuable and precise information to increase the safety and efficacy of CTO-S-IVL procedures.

Although experience with S-IVL and calcified CTO lesion is unproven and limited mainly to lower limb arteries [28], the present early experience is favorable and provides encouraging preliminary data for future studies. Despite the current lack of strong data, the present case study suggests that S-IVL can be effective and safe to handle the balloon-undilatable lesions in the CTO.

Conclusions

In this case series describing the application of S-IVL in the PCI-CTO procedures, it was shown that the device was a useful tool to assist interventional cardiologists in complex calcified CTO lesions.

Conflict of interest: None declared

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