Journal of Integrative Cardiology

Review Article

ISSN: 2058-3702

Shockwave coronary lithoplasty for the treatment of under-expanded stent

Eliezer Joseph Tassone*, Cesare Tripolino, Gaetano Morabito, Placido Grillo, Bindo Missiroli

Department of Cardiac Surgery, Cardiology Unit, Sant 'Anna Hospital, Catanzaro, Italy

Abstract

The presence of coronary calcification is a hard challenge for the interventional cardiologist, as it is associated with incomplete stent expansion and frequently stent failure. In recent years, innovative techniques has been developed to treat coronary calcific lesions such as rotational atherectomy. However, many of them are burdened with an increased procedural risk. Recently, a new technique called "Shockwave Coronary Lithoplasty System" has been introduced in order to treat calcific coronary lesions with greater safety. Shockwave procedure allows treating the most calcific coronary lesions with simplicity and safety. This system employs the sound waves, similar to that used for treating kidney stone, in order to crush the calcific lesions. In this minireview we explain the characteristics of the method and we provide a description of the technique in detail on the basis of the preliminary experience of the first cases. In particular, we will demonstrate that this technique is more effective and safer than traditional techniques employing atherectomy, also providing for the first time a therapeutic chance for the treatment of under-expanded stents in many clinical contexts.

Introduction

Coronary artery calcifications (CAC) represent a challenge to the interventional cardiologist, as they are often hard to treat with conventional balloon angioplasty [1]. The prevalence of CAC is increasing as well as their impact on PCI procedures and outcomes. In fact, several risk factors as well as chronic inflammatory conditions, lead to calcium deposition in the coronary arteries. All these conditions cause endothelial damage and subsequent inflammatory response which are the promoters of calcium deposition in the arterial wall. On the other hand, because intravascular imaging techniques, such as intravascular ultrasound (IVUS) and optical coherence tomography are used not routinely, CAC are often underestimated [2]. It is known that the presence of CAC is associated with incomplete and/or asymmetrical stent expansion as well as lower rates of procedural success, greater risk of angiographic complications, and a greater prevalence of subsequent adverse events [3]. Moreover, CAC represent a risk factor for stent deformation because they associate with reduction in drug concentration and uptake into the vessel wall from stent in addition to its underexpansion [4,5].

Current techniques to debride calcific stenosis include standard or high-pressure non-compliant balloons, cutting/scoring balloons, or atherectomy. Recent evidence indicates that coronary atherectomy is utilized in less than 5% of PCI patients compared to a CAC prevalence of 30%. Therefore, most of patients with CAC are still treated with Plain Old Balloon Angioplasty (POBA) and Drug Eluting Stent (DES). In fact, this technique may lead to vascular wall injury and coronary dissection or perforation [5,6]. Recently, therapeutic armamentarium has been enriched by the so-called "Shockwave Coronary Lithoplasty System" [6,7]. It consists in a novel technology combining a balloon angioplasty catheter with the use of sound waves, similar to that used for treating kidney stones. Lithoplasty catheter emits sound waves aimed to disrupt arterial calcifications before stent implantation. Preliminary evidences suggest that it is a sure and reliable tool to overcome calcified stenosis in the coronary tree.

Description

We previously describe the first cases of patients with stent under-expansion due to a pre-existing calcium depot successfully treated with the shockwave coronary lithoplasty system [8,9]. Briefly, we reported the case of a 60-year-old Caucasian man with clinical history of primary coronary angioplasty (PCI) and stenting of ramus intermedius coronary artery (RI) performed about one month ago in another Center. An angiographic control study was performed after 1 month that revealed a critical calcific re-stenosis of RI with the evidence at IVUS study of the under-expansion of previously implanted DES due to calcium depots. After group discussion, in consideration of the difficulty to perform a stenting procedure in the previous calcific stent as well as the risk of rotational atherectomy, lithotripsy-enhanced disruption of calcium beyond the stents was performed with the Shockwave Coronary Lithoplasty System. We previously reported another case of a 77-year-old Caucasian woman successfully treated with Shockwave Lithoplasty in which angiographic study revealed stent under-expansion at its proximal edge and critical stenosis in medium and distal traits of left anterior descending artery (LAD). Also, in this case IVUS study helped us to better characterize the lesion at the stent level, confirming the stent under-expansion due to heavily calcified plaque [9]. After these descriptions, other cases were reported that showed the use of lithoplasty fort the treatment of under-expanded stent. Tovar Forero et al. reported the case of a 74-year old man undergoing coronary angiography for class III angina [10]. Angiographic study showed the

Correspondence to: Eliezer Joseph Tassone, Department of Cardiac Surgery, Cardiology Unit, Sant 'Anna Hospital, Catanzaro, Italy, E-mail: eliezerjoseph.tassone@gmail.com

Key words: *Coronary calcification, atherectomy, under-expanded stent, coronary angioplasty, coronary lithoplasty*

Received: June 01, 2020; **Accepted:** June 10, 2020; **Published:** June 15, 2020

presence of a great calcified stenotic lesion that compromised the DES implantation despite the utilization of post-dilatation non-compliant balloon at high-pressure. Thus, the decision to use a shockwave balloon was successfully made, confirming the useful and safety of lithoplasty also for the under-expanded stent. Alfonso et al. recently described the case of a 63-year old man with acute coronary syndrome due to severe, heavily calcified, new lesion in a large obtuse marginal branch and in-stent restenosis in the left anterior descending coronary artery previously treated about 15 years ago [11]. Several conventional and noncompliant balloons at very high pressure such as the use of different scoring balloons failed to dilate the lesions. Therefore, coronary lithoplasty was successfully used to dilate both the lesions before DES implantation as demonstrated by the excellent angiographic and OCT result. Recently we reported another case that confirm the usefulness and safety of shockwave lithoplasty also in the context of ST elevation myocardial infarction [12]. An 80-year-old Caucasian man with ST elevation myocardial infarction underwent emergent coronary angiography showing complete intrastent thrombosis at the proximal trait of LAD. After thrombus removal, it was evident that stent under-expansion at its proximal edge was caused by vascular calcification. Coronary shockwave lithoplasty allowed to treat this lesion. After calcium deposits disruption we were able to obtain complete stent expansion.

Our initial experience encourages us to use coronary lithoplasty in all conditions in which the presence of coronary calcification does not allow a correct stent implantation. Furthermore, the lithoplasty Shockwave has proved to be safe and effective for the treatment of under-expanded stents. Below we present our experience in the use of Shockwave Coronary Lithoplasty to treat the under-expanded stents providing furthermore an explanation of the employed method. In (Table 1) are reported the clinical characteristics of 10 patients examined. In particular, 8/10 patients were diabetics, all patients had dyslipidemia and arterial hypertension; 8/10 patients had history of myocardial infarction, all patients had stable angina at recovery; echocardiographic examination revealed a preserved function for most of them. (Table 2) shows the characteristics of the coronary lesions found during the first angiographic study performed few years ago and the subsequent procedures (included type, length and diameter of stents utilized, as well as the ballon characteristics). Finally, in (Table 3) the procedures performed during Shockwave Lithoplasty are reported. In particular, angiographic study revealed a critical re-stenosis in site of previous stent implantation. IVUS study confirmed the presence of under-expansion of previously implanted DES due to calcium depots with a significant reduction of the Minimal Lumen Area (MLA). In detail, a 3.0-4.0 x 12 mm Lithoplasty balloon (Shockwave Medical, Fremont, California) was used to pre-dilate and treat the entire length of disease. It was inflated to 4-12 atm, with 2-8 cycles of ultrasound energy of 10 seconds. Once the lithoplasty treatment was completed, a non-compliant balloon (ApolloTM 3.0-4.0 x 15-21 mm, Skyler Scientific, Malaysia) inflated at 12-20 atm was used to post-dilate the stent struts. IVUS after cycles of "Shockwave" showed significant area gain > 75%. In 3/10 patients the procedure was completed with DES implantation after lithoplasty, 1 patient underwent to drug-eluting balloon treatment. Excellent post procedure angiographic result was obtained (TIMI 3), as well as the MLA on IVUS final control. Patients were discharged in good condition and without symptoms.

Table 1. Clinical characteristics of patients

Patients	1	2	3	4	5	6	7	8	9	10
Age (years)	60	77	65	66	80	62	59	57	69	63
Gender	Male	Female	Male	Male	Male	Male	Male	Male	Male	Male
Hypertension	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Diabetes	None	Yes	Yes	Yes	Yes	Yes	None	Yes	Yes	None
Dyslipidaemia	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Smoker	Yes	None	None	Yes	Yes	None	None	None	Yes	None
History of MI	Yes	Yes	Yes	None	Yes	None	Yes	Yes	Yes	Yes
History of CABG	None	None	None	None	None	None	None	None	None	None
History of AF	None	Yes	None	None	None	Yes	None	None	None	None
History of PAD	None	None	Yes	None	None	Yes	None	None	None	None
LVEF	60%	45%	55%	50%	45%	50%	45%	55%	50%	60%
SA at admission	Yes	Yes	Yes	Yes	Yes	Yes	None	Yes	Yes	Yes

MI: Myocardial Infarction; CABG: Coronary Artery Bypass Graft; AF: Atrial Fibrillation; PAD: Peripheral Artery Disease; LVEF: Left Ventricular Ejection Fraction; SA: Stable Angina.

Table 2. Lesions and procedural characteristics at first angiographic study

Patients	1	2	3	4	5	6	7	8	9	10
Date of first PCI	15/05/18	19/12/13	12/8/14	18/6/15	13/02/17	22/05/18	13/03/18	21/07/15	05/07/2018	15/04/2018
Target lesion	RI	LAD	LAD	LAD	LAD	LAD	CX	LAD	RCA	LAD
Stent type	Onyx	Resolute	Synergy	Onyx	Onyx	DES	Onyx	DES	DES	Resolute
Stent diameter (mm)	3	2,5	2,75	3,5	3	3	2,75	3	3	3
Stent length (mm)	18	26	24	15	22	22	20	20	20	20
Atm	18	16	16	20	18	22	18	20	20	20
Postdilatation NCb	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
NC balloon diameter (mm)	3,5	2,75	3,25	3,75	3,5	3,25	3	3,25	3,5	3,5
NC balloon length (mm)	15	15	15	15	15	15	15	15	15	15
Atm	20	16	20	24	20	20	22	20	20	20

NC: Non-Compliant; Atm: Atmosphere; RI: Ramus Intermedius; LAD: Left Anterior Descending Artery; CX: Circumflex coronary artery; RCA: Right Coronary Artery; DES: Drug Eluting Stent (unspecified)

Table 3. Lesions and procedural characteristics of ShockWave Lithoplasty

Patients	1	2	3	4	5	6	7	8	9	10
Date of lithoplasty	19/06/18	11/07/18	30/11/18	10/12/18	22/03/2019	24/05/2019	31/05/2019	03/09/2019	05/11/2019	05/11/2019
Angio-stenosis (%)	85	80	80	75	100	70	70	70	80	75
Pre-IVUS MLA (mmq)	3,2	2,86	4,2	/	2,05	/	3,45	4,76	4,39	3,89
Predilatation	None	None	None	Yes	None	None	None	Yes	Yes	None
Lithoplasty balloon diameter (mm)	3	3	3,5	3,5	4	3,5	3,5	3,5	3,5	3
Lithoplasty balloon lenght (mm)	12	12	12	12	12	12	12	12	12	12
Litoplasty pulses	30	20	40	80	70	80	80	80	70	80
Lithoplasty balloon inflation (atm)	6	6	4	6	10	6	10	10	10	12
Postdilatation	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
NC balloon diameter (mm)	3,25	3	3,5	3,5	4	3	3,5	3,5	3,5	3,5
NC balloon lenght (mm)	15	15	21	15	21	15	15	15	15	21
Atm	12	18	20	14	14	16	12	20	20	20
DES/DEB implantation after Lithoplasty	None	None	DES	DES	DES	None	DEB	None	None	None
DES type	/	/	Synergy	Synergy	Synergy	/	DEB Agent	/	/	/
DES diameter (mm)	/	/	3,5	4	3,5	/	3,0	/	/	/
DES lenght (mm)	/	/	48	20	48	/	30	/	/	/
Atm	/	/	22	22	22	/	22	/	/	/
Post- IVUS MLA (mm)	7,47	6,37	7,83	14,93	7,45	8,25	7,87	9,30	7,67	6,95
IVUS- MLA gain (mm)	4,27	3,51	3,63	/	5,40	/	4,42	4,54	3,28	3,06
IVUS- MLA gain (%)	133	122	86	/	263	/	128	95	75	79

Atm: Atmosphere; IVUS: Intravascular Ultrasound; MLA: Minimal Lumen Area; NC: Non-Compliant; DES: Drug Eluting Stent; DEB: Drug-Eluting Ballon; IVUS: IntraVascular UltraSound; MLA: Minimum Lumen Area.

Conclusion

We reported some of the few cases in which the "Shockwave" method is used [7-12]. In particular, we describe the first cases in which this method is used to treat a calcified re-stenosis in a site of previous stenting. Present data confirm that Shockwave procedure allows the most calcific coronary lesions to be treated with simplicity and safety also in case of stent under-expansion. These lesions are very hard to treat because calcium deposits wrapping the stents does not allow a correct expansion. The Lithoplasty Shockwave System is a novel technology that uses the principle of lithotripsy, already widely used in urology for the treatment of kidney stones. The system consists of a balloon catheter, equipped with lithotripsy emitters positioned on the useful length of the balloon, and a generator (connected to the catheter with a connecting cable) that is used to activate, by means of a button, the lithotripsy cycles and therefore the emission of shock waves that, in practice, weaken calcium linkage and enhances plaque compliance. Once the calcium has been modified, the vessel can be dilated using low pressure. The Lythoplasty system received FDA approval in 2016. Its main use is finalized to treat calcified lesions in several vascular districts, such as coronary, iliac, femoral, popliteal, and renal arteries [13,14]. The novelty of these data consists in the in the use of Shockwave to treat the calcified re-stenosis of the previously treated lesions in a site of under-expanded stent. In these cases the Lithoplasty Shockwave system seems to be the only possible method to safely treat the lesions because they represent the calcific re-stenosis in the context of previous stents, which therefore contraindicate other preparatory procedures such as rotational atherectomy (Rotablator), a system that pulverizes the calcific plaque, increasing however the procedural risk. The less invasiveness and the greater safety of this method, compared to others that use traditional atherectomy, could encourage its use in the limit situations in which the contraindication to surgery represents an obstacle to the treatment of coronary stenosis, with the risk that many of these patients remain untreated and without any potential benefit of revascularization therapy.

A wider diffusion of the Shockwave Lithoplasty System would allow studying its effects in the short and long term on samples of a larger population in order to be able to validate its use in the common interventional practice. In conclusion, our experience demonstrates for the first time that Lithoplasty system might represent a new useful tool for the treatment of stent under-expansion secondary to calcified plaque.

Conflicts of interest

The authors have no conflicts of interest to declare.

Author Contributions

E.J. Tassone and G. Morabito for the conception of the work; G. Morabito, P. Grillo and B. Missiroli for the acquisition data; E. J. Tassone and C. Tripolino for the analysis data; E-J. Tassone, C. Tripolino and G. Morabito for the interpretation of data; E. J. Tassone for drafting the work; E. J. Tassone, G. Morabito and B. Missiroli for revising the work and final approval of the version to be published.

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