



Case Report

Intravascular ultrasound-guided shockwave treatment of stents overlapping underexpansion of calcified left anterior descending artery



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ARTICLE INFO

Article history:

Received 4 May 2019

Received in revised form 3 July 2019

Accepted 8 July 2019

Keywords:

Lithoplasty

Stent underexpansion

Calcified left anterior descending artery

ABSTRACT

Heavily calcified lesions may limit optimal stent deployment resulting in stent underexpansion, thus increasing the risk of restenosis and thrombosis. We describe the case of overlapping stents underexpansion treated with a shockwave intravascular lithoplasty system (Shockwave Medical Inc., Santa Clara, CA, USA). A 65-year-old man with angina, underwent coronary angiography and intravascular ultrasound showing restenosis, in a site of overlapping stents, due to calcified tissue. Shockwave lithoplasty balloon was able to break calcified tissue in a site of overlapping stents, allowing subsequent vessel dilation and repeat stent implantation with optimal final stent expansion.

<Learning objective> Heavily calcified lesions may limit optimal stent deployment resulting in stent underexpansion. Treating stent underexpansion or restenosis due to calcified tissue is a great challenge. Shockwave lithoplasty is effective in breaking calcified tissue also in a site of overlapping stents. The improved plaque compliance allows to repeat stent implantation with optimal final stent expansion.

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Introduction

Treatment of calcified coronary artery stenosis represents a great challenge for the interventional cardiologist, since it is associated with several technical difficulties. Indeed, heavily calcified lesions may limit optimal stent deployment resulting in stent underexpansion, thus increasing the risk of restenosis and thrombosis. Treatment of stent underexpansion or restenosis due to calcified tissue is more difficult than treating the mere calcified stenosis. In some case reports it has been proposed the use of rotational atherectomy or excimer laser to destroy calcific deposits and obtain the full stent expansion [1–3].

In recent years, the shockwave intravascular lithoplasty (IVL) system (Shockwave Medical Inc., Santa Clara, CA, USA), a technology combining a balloon angioplasty catheter with the use of sound waves, has been employed for the treatment of

calcified lesions with promising results. It seems to create micro fracture in calcified lesions without affecting soft tissue, allowing a better stent delivery and expansion. In previous papers, the use of this tool has been described to break calcium deposits, cause of stent underexpansion, allowing complete stent apposition [4–8].

In the present paper, we report a case of in-stent restenosis and underexpansion in the site of overlapping stents due to calcified plaque, treated with the IVL system.

Case report

A 65-year-old man with hypertension, dyslipidemia, and diabetes came to us for observation of exertional angina. His medical history reported previous coronary artery disease treated with two overlapping drug-eluting stents (DES) on left anterior descending artery (LAD) (Synergy; Boston Scientific, Marlborough, MA, USA; 2.75 × 12 mm and 3.0 × 24 mm), three stents on right coronary artery (Synergy; 3 × 18 mm) and two stents on the left circumflex artery (Synergy; 2.5 × 16 mm and 2.75 × 16 mm).

Coronary angiography (percutaneous coronary intervention) and intravascular ultrasound (IVUS) revealed stent restenosis and under-expansion at the site of the DES overlap due to heavily

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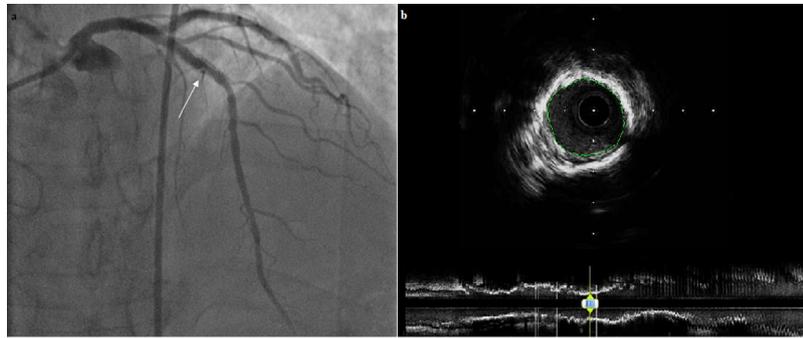


Fig. 1. Coronary angiography (a) and intravascular ultrasound (b) showing stent under-expansion.

calcified tissue with minimal lumen area of 4.8 mm^2 (Fig. 1a and b, Online Video 1). After several attempts with non-compliant balloons, coronary shockwave lithoplasty was chosen to treat this lesion (Online Video 2).

In detail, a $3.25 \times 12 \text{ mm}$ IVL balloon was conducted at the lesion level and inflated to 4 atm. Four cycles of ultrasound energy of 10 s were applied. The balloon is then inflated to 6 atm for 15–20 s after each pulse to enhance balloon contact area. Once finished lithoplasty treatment, two platinum chromium everolimus-eluting stents of $4.0 \text{ mm} \times 12 \text{ mm}$ and $3.5 \times 48 \text{ mm}$ were deployed at 22 atm. Angiographic and IVUS control showed good angiographic result with a minimal lumen area of 7.9 mm^2 (Fig. 2a and b, Online Video 3).

Discussion

Treatment of calcified in-stent restenosis represents a challenge for the interventional cardiologist since it is hard to overcome with the common devices. Current techniques to debride calcific stenoses include standard or high-pressure non-compliant balloons, cutting/scoring balloons, or rotational atherectomy. However, these techniques may lead to vascular wall injury and coronary dissection or perforation. The use of rotational atherectomy to ablate the metallic struts of severely underexpanded stents has been reported in some cases, but it remains a risky procedure due to potential burr entrapment [1,2]. Alternatively, the IVL through the use of ultrasonic waves, may weaken calcium linkage and improve plaque compliance [4–8].

The IVL system is a novel technology that integrates angioplasty balloon catheter device with the calcium-disrupting power of sonic pressure waves. Each lithoplasty catheter incorporates

multiple lithotripsy emitters activated with the touch of a button after the balloon is inflated. In detail, the balloon is inflated to 4 atm using a mixture of saline and contrast solution to achieve balloon–vessel wall apposition. Subsequently, a small electrical discharge at the emitters vaporizes the fluid and creates a rapidly expanding bubble within the balloon. The technology minimizes trauma within the artery by delivering pulsatile sonic pressure waves locally to effectively fracture both intimal and medial calcium in the artery wall but pass through surrounding soft vascular tissue in a safe manner. Once the calcium has been modified, the vessel can be dilated using low pressures. The IVL system received US Food and Drug Administration approval in 2016, and has been available in Europe since 2015. Safety and performance are supported by clinical data from results of DISRUPT CAD I, a prospective multi-center single-arm study, enrolling 60 patients, conducted in seven centers in Europe and Australia. The study evaluated the use of the IVL system as a treatment for moderate to severe calcification at coronary arteries level prior to stent implantation [8].

The DISRUPT CAD II trial is an ongoing post market study examining the safety and performance of the IVL system for the treatment of narrowed coronary arteries, in a sample of 120 patients recruited at 15 sites in Europe. The primary endpoint of the study will evaluate major adverse cardiac events post procedure including: cardiac-related death, heart attack, and intervention to treat the coronary artery that was previously treated at the procedure visit. The results of this trial are not yet available.

Studies using optical coherence tomography, demonstrated that ultrasonic waves generated through the lithoplasty balloon create micro-fracture in the calcium deposits, so allowing a better

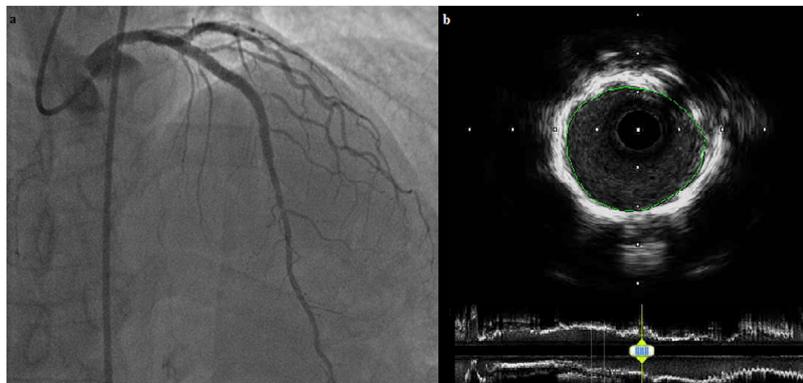


Fig. 2. Coronary angiography (a) and intravascular ultrasound (b) showing final result.

stent delivery and implantation [7]. In addition, while other devices (i.e. rotational atherectomy) generate microparticles that embolize distally, large calcium fragments generated by lithoplasty seem to remain in situ, not impairing microcirculation. Given its mechanism of action, the complications linked to lithoplasty are minimal. In a recent study, the Disrupt PAD II, the authors evaluated the safety and performance of IVL, to modify intimal and medial calcium in stenotic peripheral arteries. The one month major adverse events rate was only 1.7% with one grade D dissection that resolved following stent placement [9]. Similarly, Soriano et al. reported a case of coronary dissection due to the rupture of the inflated lithoplasty balloon in a 47-year old man [10]. The results of ongoing larger trials might help to better understand the rate of vascular complications.

In the present case IVL was able to obtain the result even in calcified intrastent tissue in a site of DES overlap, allowing subsequent vessel dilation and repeat stent implantation with adequate final stent expansion.

Conflict of interest

The authors declare that there is no conflict of interest.

Appendix A. Supplementary data

Supplementary data associated with this article can be found, in the online version, at <https://doi.org/10.1016/j.jccase.2019.07.004>.

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