

The effect of lithoplasty on the coronary arteries

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Summary

We describe the case of a 79-year-old gentleman presenting with non-ST-elevation myocardial infarction and a heavily calcified bifurcation stenosis of the left anterior descending artery (LAD) and the diagonal branch. On optical coherence tomography (OCT), we encountered circular calcium in the LAD. Based on these findings, we decided to use intravascular lithoplasty (Shockwave Medical, Fremont, California) to prepare the extremely calcified lesion. The subsequent OCT investigation demonstrated calcium containing cracks in the intima and the media of the LAD. We were then able to treat the bifurcation lesion with two everolimus-eluting stents. The final OCT demonstrated good stent expansion and apposition. Extensive and deep calcified coronary artery disease represents a common cause for failure of percutaneous coronary interventions, including the inability to deliver a stent system or stent underexpansion, which represents an important determinant for in-stent restenosis or stent thrombosis. Our case illustrates how a heavily calcified LAD lesion can be relatively easily treated using the novel Shockwave Medical Coronary Lithoplasty balloon system[®].

Keywords: lithoplasty, percutaneous coronary intervention, stent, OCT, calcified lesion, angioplasty

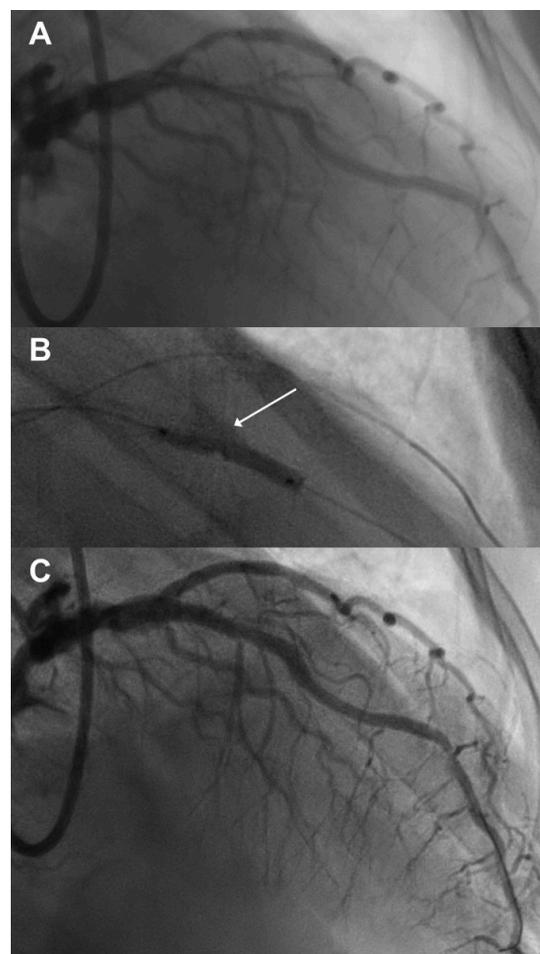
Case description

A 79-year-old gentleman with a known history of diabetes and arterial hypertension was diagnosed with non-ST-elevation myocardial infarction (NSTEMI) on the basis of typical chest pain at rest, anterior ST depression on the ECG and mildly elevated troponin T (450 ng/ml). He underwent urgent coronary angiography, where a heavily calcified bifurcation stenosis of the left anterior descending artery (LAD) and the diagonal branch was seen (fig. 1A). After discussion, the heart team settled on a percutaneous strategy. The patient was pretreated with aspirin, ticagrelor, atorvastatin and unfractionated heparin, and underwent a percutaneous coronary intervention (PCI) two days after coronary angiography.

The LAD and the diagonal branch were dilated with a 2.5-mm regular noncompliant balloon at 14 atm to enable optical coherence tomography (OCT) and assessment of the extent and distribution of the angiographically visible calcium. Of note, the noncompliant balloon expanded incompletely, which emphasised the lesion's anticipated degree of calcification, as depicted in figure 1B (arrow). The

subsequent OCT run confirmed the prevalence of extensive circular calcium (fig. 2A). After predilatation, OCT indicated a minimum lumen area of 2.82 mm² within the treated segment. Based on those findings, we decided to use intravascular lithoplasty to optimally prepare the calcified lesion for stent implantation. A 3.0-mm balloon (Shockwave Medical, Fremont, California) was used at 4 atm to deliver six pulses. The OCT investigation after lithoplasty demonstrated calcium cracks in the intima and the media of the LAD (minimum lumen area 3.09 mm²)

Figure 1: (A) Initial angiogram indicating a heavily calcified proximal to mid left anterior descending artery stenosis; (B) incomplete expansion (arrow) of the 2.5-mm noncompliant balloon; (C) final angiogram after stenting.



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(fig. 2B). A 2.25×23 mm everolimus-eluting stent was placed in the diagonal branch and a 3.0×33 mm everolimus-eluting stent was implanted in the LAD with use of the mini-crush technique. The LAD was then post-dilated using a 3.5-mm noncompliant balloon at 16 atm followed by a final kissing balloon inflation (3.5-mm non-compliant balloon in the LAD and 2.5-mm noncompliant balloon in the diagonal branch). A good final angiographic result was achieved (fig. 1C). The next OCT demonstrated good expansion and apposition of the stent (minimum luminal area 5.38 mm^2 , stent expansion index 0.81) (fig. 2C–E). Since there was some malapposition within very proximal/ostial stent segment (21 struts with $>300\mu\text{m}$) (arrow, fig. 2E), a proximal optimisation procedure using a 4.0-mm noncompliant balloon was additionally performed. The patient was discharged home 2 days later. He is in good condition and free of any cardiac symptom 4 months after the procedure.

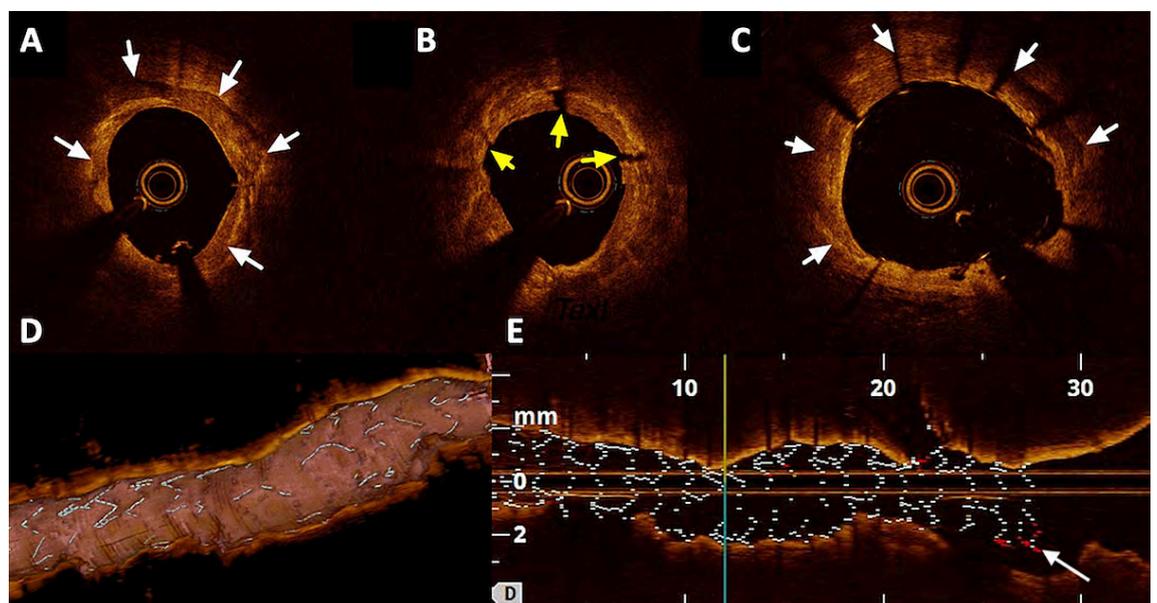
Discussion

Despite advances in procedural techniques and technology facilitating the treatment of complex lesions, extensive and deeply calcified coronary artery disease still represents a common cause for PCI failure, including the inability to deliver a stent system or stent underexpansion, which represents an important determinant for in-stent restenosis or stent thrombosis [1–3]. Interestingly, it is predicted that the burden of calcified coronary artery disease (CAD) will increase over the next decades as a result of demographic shifts, including aging societies, and a growing burden of cardiovascular risk factors, namely diabetes. Therefore, effective strategies to treat calcified lesions are crucial. Our case illustrates how a heavily calcified LAD lesion can be relatively easily treated using the novel Shockwave Medical Coronary Lithoplasty balloon system[®].

In order to achieve an optimal PCI result, adequate lesion preparation is key. Traditionally, the use of noncompliant balloons at high-pressure, cutting/scoring balloons or atherectomy (rotational and orbital) have been suggested. Nevertheless, those devices generally have limited efficacy when it comes to treating eccentric, circular (more than 180°), thick or deep calcifications [4]. Whereas rotational atherectomy is effective in erasing superficial calcium and thus facilitating delivery of angioplasty devices, it has very little impact on deep and thick calcium, which ultimately limits balloon and stent expansion. On the other hand, available scoring/cutting and high-pressure balloons might inappropriately expand in deeply calcified vessels. Furthermore, complications, including deep dissections and perforations, are common concerns when using those devices.

In this context, shockwave intravascular lithoplasty (IVL) might represent a promising technology, which could overcome some of the aforementioned hurdles in calcified lesions. The appropriate device has recently received CE approval and is now available for treatment of CAD and peripheral vascular disease. The shockwave IVL devices apply localised pulsatile sonic pressure waves, which pass through soft tissue and modify and fracture the underlying calcium. This concept has similarities to urological extracorporeal lithoplasty. The Shockwave IVL system includes a catheter that integrates the emitters and is enclosed in an integrated angioplasty balloon mounted on a rapid exchange system, shockwave generator and connector cable. The balloon system is inflated at 4 atm to contact with the vessel wall, facilitating optimal energy delivery. By pushing a button on the cable connected the catheter, the lithoplasty cycle is activated and pulses once per second for ten seconds. After every cycle, the balloon is inflated up to 6 atm, which compresses the fractured calcium. A maximum of eight cycles of lithoplasty can be performed

Figure 2: (A) Initial optical coherence tomography (OCT) investigation depicting a left anterior descending lesion with circular calcifications; (B) OCT imaging after shockwave lithoplasty indicating cracks within the calcium; (C) final OCT run, which shows good expansion of the implanted stent; (D, E) 3D-reconstruction of the final OCT images and the rendered stent indicating good expansion and apposition (arrow indicating minimal proximal malapposition). (Final OCT measurements: minimum/ maximum diameter 3.08/4.28 mm; minimum lumen area 5.38 mm^2 .)



with the same catheter. As illustrated in our OCT images (fig. 2), the applied shock waves crack the deep and circular calcium, which ultimately facilitate stent implantation and expansion. The cracks were limited and deep, without affecting the noncalcified parts or outer layers of the vessel (e.g., therefore avoiding deep dissection or tears).

Recently presented preliminary data from the Disrupt Coronary Artery Disease (DISRUPT-CAD) study, enrolling 60 patients with severely calcified lesions treated with shockwave coronary IVL, indicated that the use of a lithoplasty balloon-based therapy resulted in 98% device success and facilitated 100% stent delivery [5]. Moreover, the authors indicated a low rate of major adverse cardiovascular events (MACE) of 5.0% with minimal vascular complications [5].

Here, we present here our initial experience with the Shockwave IVL system. Overall, we think this represents an innovative technology, which expands our armamentarium to tackle heavily calcified lesions. In order to select the appropriate lesions, we suggest performing intravascular imaging upfront. Additionally, predilatation using a noncompliant balloon might be helpful to determine the lesion's degree of calcification. In the case of incomplete balloon expansion, lithoplasty could become beneficial and efficacious. It is also important to note that IVL might not disrupt fibrotic and fibrocalcific lesions. However, there is a need to gain more insights from long-term follow-up studies assessing the safety and efficacy of IVL in complex CAD treatment.

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Disclosure statement

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