Intravascular Lithotripsy in an Underexpanded Stent Due to a Severely Calcified Distal Left Main Lesion

Our case was performed at an outreach facility where there was no surgical backup.

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Abstract

Severe coronary artery calcification is one of the most challenging scenarios encountered during percutaneous coronary intervention. Coronary artery calcification is associated with higher rates of stent failure and is linked to poor outcomes in percutaneous coronary intervention. Many technologies like non-compliant balloons, high pressure balloons, cutting/scoring balloons, and laser and atherectomy procedures have been developed to manage such dense, calcific lesions, but these technologies are not devoid of complications. Intravascular lithotripsy is a relatively new technology that dispenses circumferential mechanical energy to fracture the calcium and assist in stent expansion. Here, we present a case of a distal left main stent underexpansion that was successfully treated with intravascular lithotripsy.

Introduction

Severe coronary artery calcification (CAC) poses a great challenge for percutaneous coronary intervention (PCI). CAC is an independent predictor for stent failure and major adverse cardiac events.[1,2] Heavy calcification leads to stent underexpansion and eventually, stent failure.[3] Multiple technologies including high-pressure noncompliant (NC) balloons, cutting/scoring balloons, and rotational/orbital/laser atherectomy have been used to treat calcific lesions, but are associated with a high procedural complication rate.[4] The effectiveness of these tools is further reduced in cases of deep, thick, and circumferential calcific lesions. Intravascular lithotripsy (IVL) modifies thick, deep, circumferential calcified plaque[5,6] by employing the circumferential distribution of the high-pressure sonic waves to fracture both superficial and deep calcium.[4] We present what we believe to be the first case using IVL in the distal left main (LM) for stent underexpansion due to heavy calcification.

Case Description

An 88-year-old gentleman with a past medical history of hypertension, chronic kidney disease with a creatinine of 2 mg/dL, peripheral vascular disease (complete left internal carotid artery occlusion and moderate left internal carotid artery stenosis), and hyperlipidemia presented to the clinic with progressive, lifestyle-limiting angina despite optimal medical therapy. Four years ago, he presented with symptomatic severe aortic stenosis and later was found to have severe ostial left main (LM) and ostial left circumflex (LCX) disease that was managed with a drug-eluting stent (DES) (a 3 mm x 32 mm Xience Alpine [Abbott Vascular]). His stent procedure was closely followed by transcatheter aortic valve replacement (TAVR) with a 26 mm Sapien 3 (Edwards Lifesciences) for severe aortic valve stenosis (Video 1, available online).

The patient's electrocardiogram showed sinus rhythm with left bundle branch block and echocardiography demonstrated a normal left ventricular ejection fraction with a transvalvular aortic mean gradient of 10 mmHg. On further evaluation, his nuclear stress test showed severe anterior ischemia. A review of his previous angiograms demonstrated an underexpanded stent in the distal LM that was potentially constrained by a circumferential calcific lesion (Figure 1). Intravascular ultrasound (IVUS) and atherectomy were not utilized during the index procedure. The patient underwent cardiac catheterization via the right femoral approach, which demonstrated severe in-stent restenosis (ISR) of the distal LM due to an underexpanded/undersized stent (Figure 2), confirmed on assessment of the non-contrast chest imaging and IVUS, with a minimum stent area (MSA) of 4 mm^2 (Figure 3). Given the patient was not a surgical candidate, further percutaneous management was elected as the best management strategy since the patient had refractory angina despite medical therapy. Mechanical support with large-bore access was not feasible, given the vascular disease in his lower extremities had worsened, and with severe carotid disease, the patient was not a candidate for axillary large-bore devices. He was pre-treated with aspirin and clopidogrel before the PCI.

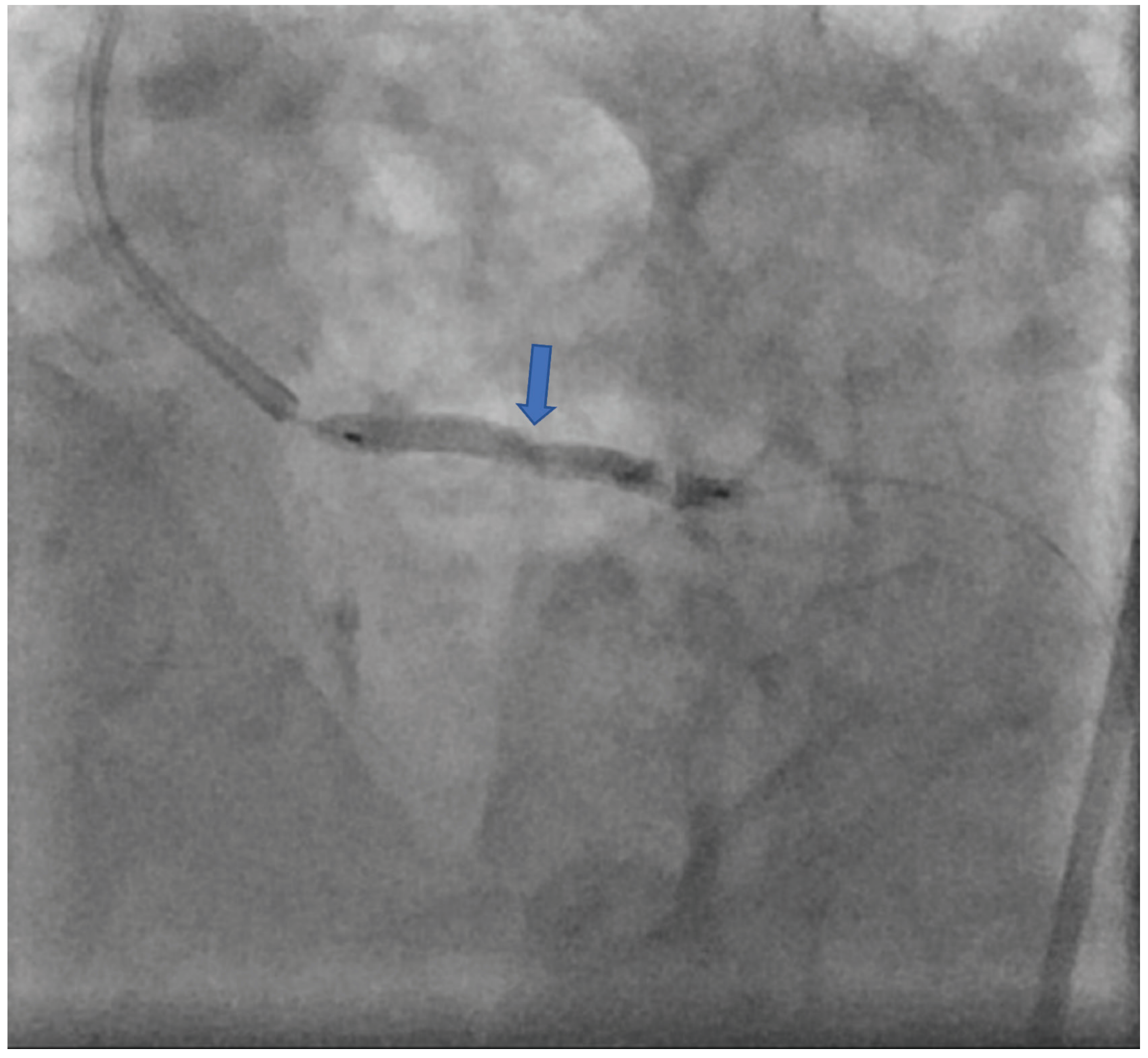

Figure 1. Left anterior oblique (LAO)/cranial projection demonstrated the underexpansion of the 3 mm x 32 mm Xience Alpine drug-eluting stent (Abbott Vascular) in the distal left main artery.

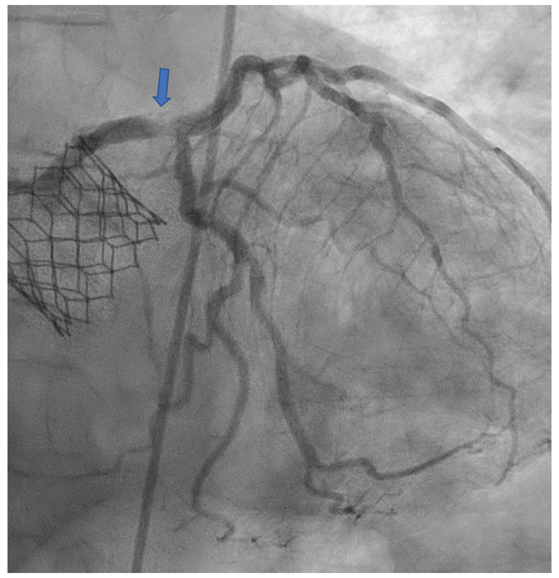

Figure 2. A straight caudal projection showing distal left main coronary artery severe in-stent restenosis (blue arrow).

The LM was engaged with a 7 French (F) XB 3.5 guide catheter (Cordis Corporation). A workhorse coronary wire was advanced to the distal left anterior descending (LAD) coronary artery and another workhorse wire was advanced to the distal obtuse marginal. Serial inflations with 3.5 mm x 20 mm NC balloon were performed at 20 atmospheres (atm) in the distal LM. A kissing balloon inflation (KBI) was done using two 3.5 mm x 12 mm NC balloons at 12 atm. The ostium of the left circumflex (LCX) and distal LM was further prepared using a 4 mm x 10 mm Wolverine cutting balloon (Boston Scientific) at 12 atm. The distal LM lesion did not yield, despite multiple balloon inflations. Hence, a 4 mm x 12 mm IVL balloon (Shockwave Medical) was used at 4 atm for 40 pulses. These inflations had to be supported with intravenous norepinephrine boluses. Later, a 4 mm x 12 mm NC balloon was used and the result showed adequate expansion across the LCX ostium. A double-kissing culotte was completed and the proximal LAD was stented with a 3.5 mm x 24 mm Synergy Megatron (Boston Scientific) at 12 atm. Proximal optimization technique (POT) was performed using a 5 mm x 12 mm NC balloon at 20 atm. The LCX was re-crossed using another workhorse wire and the jailed LCX wire was removed. The side struts were opened using a 2 mm x 12 mm semi-compliant balloon, followed by KBI with two 4 mm x 12 mm NC balloons at 12 atm. Re-POT was done using 5.5 mm x 12 mm NC balloon at 22 atm with an excellent result (Figure 4). The final IVUS demonstrated a MSA of 11 mm^2 in the distal LM, and 9 mm^2 MSA was attained in the ostium of the LAD and LCX (Figure 5). Total contrast used in the procedure was 30 mL, as IVUS was used significantly during the PCI in view of the complex lesion, as well as the patient's pre-existing renal impairment. He was discharged the next day after post PCI hydration with dual antiplatelet therapy for six months and he had no change in creatinine at the end of one week. At four weeks, the patient is well without any angina and is asymptomatic from a cardiac perspective.

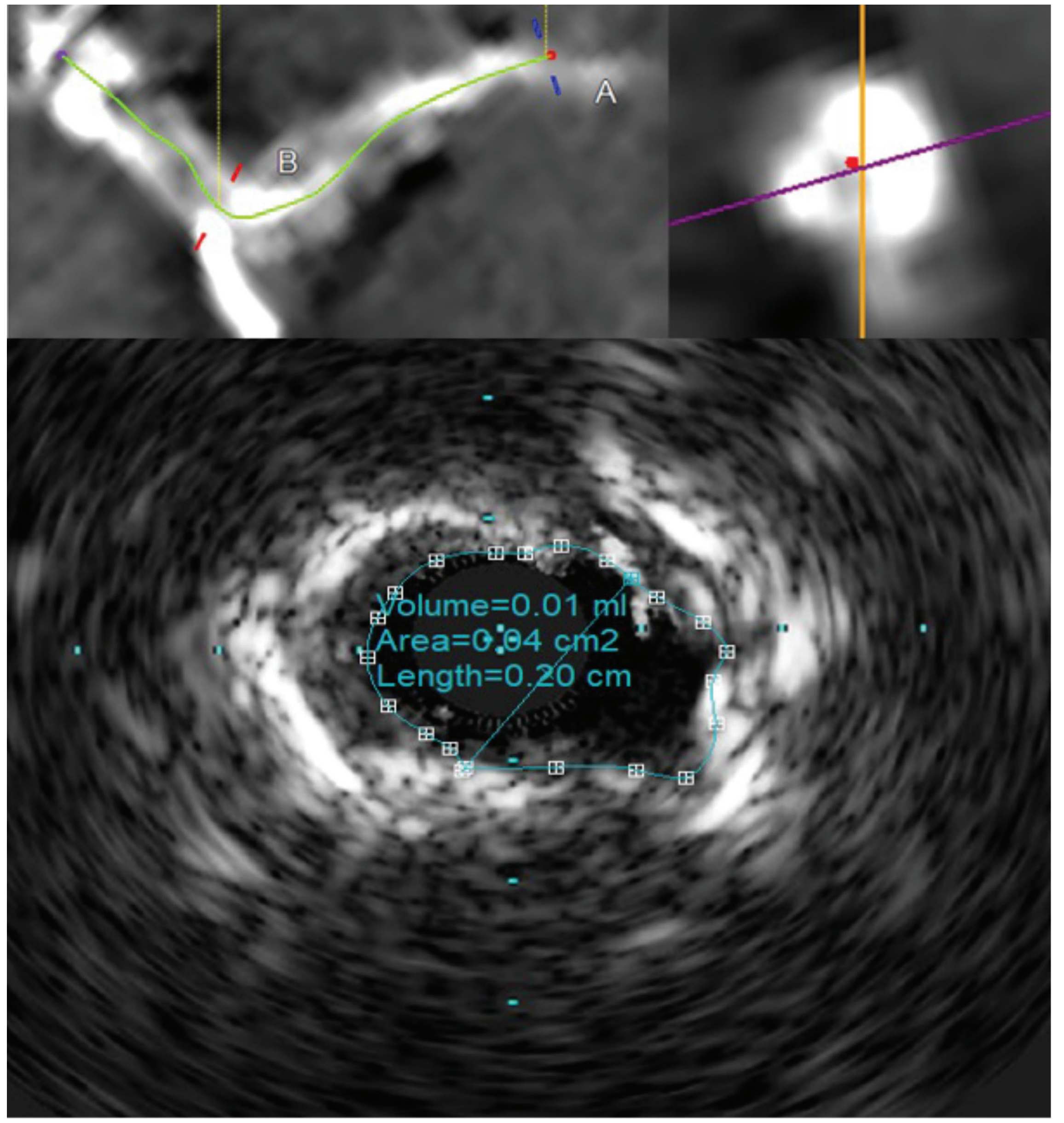

Figure 3. (Top panel) Center line processing of the chest computed tomography demonstrating a circumferential calcific nodule in the distal left main (point B in cross-section) and (below panel) intravascular ultrasound demonstrating the etiology of stent failure. A minimum stent area of 4 mm^2 results predominantly from an underexpanded/undersized stent.

Discussion

In this case, we have described the successful use of IVL to manage an underexpanded stent due to severe CAC in the distal LM. To the best of our knowledge, this is the first case that has reported the use of IVL for stent underexpansion in the distal LM. IVL is currently off-label for in-stent restenosis, but is an invaluable tool in the arsenal. The index procedure was challenging, given the patient had a severe aortic stenosis and a complex calcific left main lesion. It is likely the operators were not able to utilize a full arsenal of atherectomy devices. Previous reports have been described wherein a balloon aortic valvuloplasty was followed by Protected PCI.[7] However, this strategy can potentially result in major vascular complications.[8] Our case was performed at an outreach facility where there was no surgical backup. IVL, being a safe and effective procedure with minimal complication rates, can be considered in hospitals without surgical reserves and possibly in ambulatory surgical centers. It is an excellent alternative to staged atherectomy procedures.

The role of NC balloon dilations, cutting and scoring balloons, intracoronary laser, rotational atherectomy, and orbital atherectomy in ISR has been previously described, but each tool comes

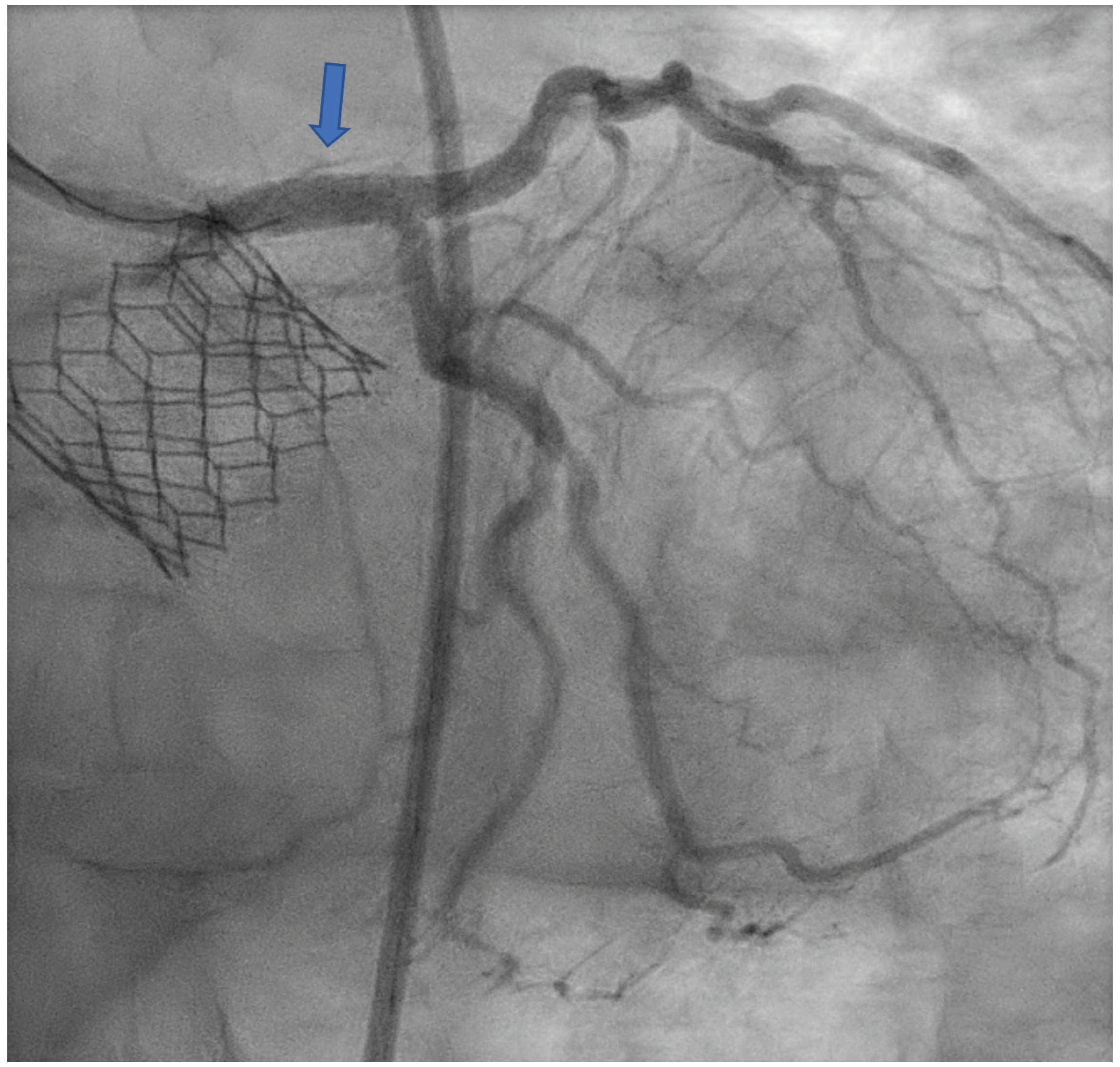

Figure 4. A straight caudal projection showing resolution of the in-stent restenosis in the distal left main coronary artery (blue arrow).

with its own, respective limitations.[9,10] NC balloon dilations create inadequate force to fracture the extrinsic calcium and provide inadequate stent expansion despite the high pressure.[5] Atherectomy devices are associated with drastic complications such as slow-flow/no-flow phenomena, dissection, and perforation.[5] To help overcome these shortcomings, a novel, percutaneous technique used to treat deep calcium, IVL (Shockwave Medical), has been developed.[11] The IVL system is comprised of a single-use catheter with multiple lithotripsy emitters that are encompassed in a balloon. IVL works by releasing high-speed, sonic pressure waves in a circumferential field that crosses the vessel wall soft tissue, selectively affecting the subendothelial calcium, fracturing the calcium deposits, and altering the vessel compliance.[12]

IVL provides multiple advantages over specialty balloons or atherectomy techniques.[5] It does not

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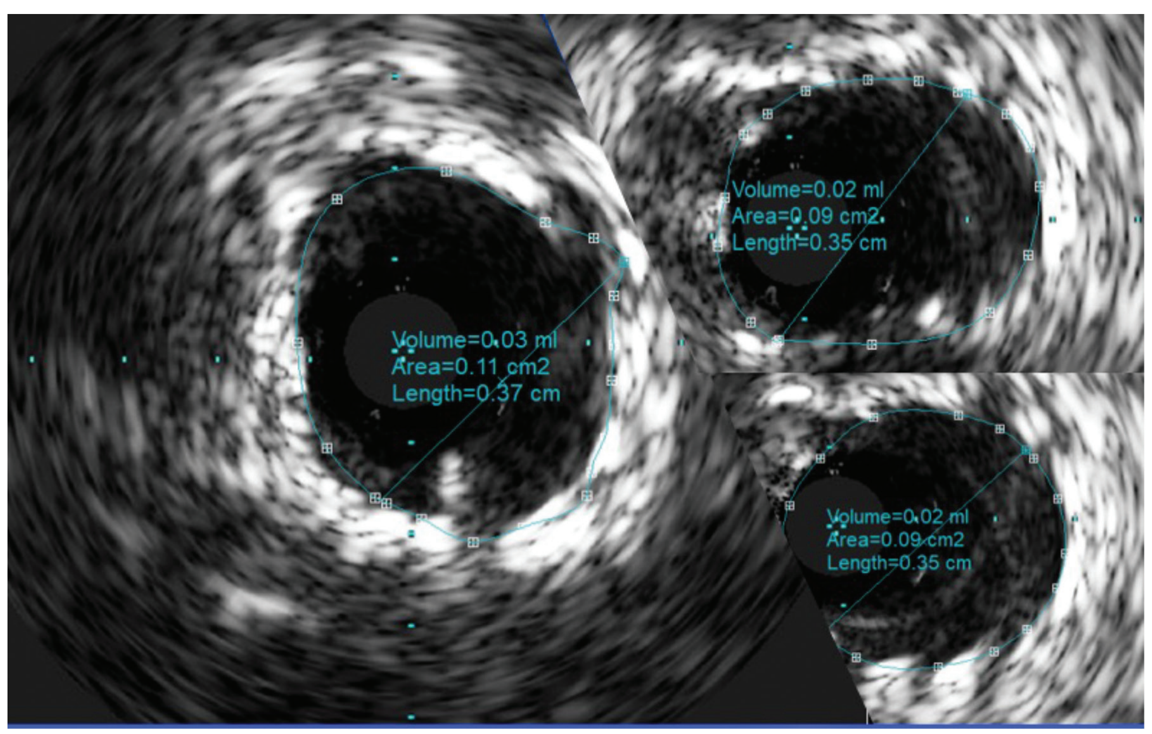

Figure 5. The final intravascular ultrasound demonstrated a minimum stent area (MSA) of 11 mm^2 in the distal left main and a 9 mm^2 MSA was attained in the ostium of the left anterior descending (LAD) and left circumflex arteries.

require any learning curve for operators comfortable with performing plain angioplasty, as it is similar to conventional, catheter-based PCI. As a balloon-based technique, the risk of distal embolization is lower compared to the atherectomy devices. In addition, calcified plaque modification is not based on guidewire bias, as energy is uniformly delivered over the lithotripsy emitter to fracture calcium.[5] Further, where conventional balloon techniques work on static barometric pressure, IVL dispenses ultrashort pulses of high-intensity acoustic energy circumferentially, which, in turn, results in modification of the calcified plaque.[5] Protection of side branches can easily be achieved in IVL by using a guidewire, in contrast to atherectomy procedures where wire entrapment or amputation can occur.[5]

Tizón-Marcos et al reported balloon rupture from a fractured calcium segment as a complication of IVL, and continuous fluoroscopy during the procedure is advised for early detection of the balloon leakage.[13] The safety and efficacy of IVL has also been demonstrated in the Disrupt CAD I study in 60 patients with severe CAC prior to

DES implantation.[6] The trial demonstrated successful stent delivery in all 60 patients, and device and clinical success in 59 and 57 patients, respectively. There were no major complications such as perforation, embolization, slow flow or no-reflow reported.[6] Disrupt CAD II further confirmed the safety of IVL, showing high procedural success without any dissection, perforation, acute vessel closure or slow/no re-flow phenomena.[5]

CAC is attributed with a higher risk of stent underexpansion, stent thrombosis, and ischemic target lesion revascularization.[14] Numerous cases have been reported in the literature that describe the use of IVL for stent underexpansion due to CAC.[12,13,15-27] We are aware of one case reporting a procedural complication of balloon rupture[13], but the remainder witnessed success without any drawbacks. The target vessel in these cases included either the left anterior descending artery, right coronary artery, left circumflex, or ramus intermedius, but our case was unique, as the intervention involved the left main coronary artery. Our case also demonstrated a successful IVL procedure without any periprocedural complications and excellent follow-up results.

Conclusion

IVL is a promising technology to treat stent underexpansion secondary to extrinsic calcification. It serves as a good alternative to existing atherectomy devices or balloon techniques with minimal complications, especially in cases of circumferential calcification. Further larger, randomized studies are required to evaluate the effectiveness and any complications related to this procedure. ■

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