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Intravascular Lithotripsy for Coronary calcium – A Case series and literature review

S-IVL for calcified coronaries

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Abstract

BACKGROUND

Coronary Calcium poses a challenge for the interventional cardiologist often leading to stent underexpansion of stent and subsequent ishcemic events. Aggressive ballon postdilatation though helpful is usually inadequte. Multiple plaque ablation techniques are in vogue but they are technically demading and are not without complicaions. S-IVL(Shockwave intravascular lithotripsy) has emerged as use freindly and effective mechanism to calcium managemnt with high safety margin. A series of trials (DISRUPT CAD I-IV) have demonstrated both short term and long term safety and efficacy of the technique. As experience with the technique grows more and more therapy areas like In stent restenosis are being covered by the S-IVL.

CASE SUMMARY

We report a series of two cases successfully managed with S-IVL therapy at our center.The first case is of a 57 year old smoker who presented with ACS. His left anterior descending coronary artery revealed calcified 90% stenosis on angiogram and a combination of superficial-deep calcium on intracoronary imaging.The calcium was treated with 20 pulses of S-IVL to create discontinuity and a sirolimus eluting DES was successfully implanted.The second case is that of elderly lady who presented with stable angina and demonstrated diffuse calcified lesions in LAD on angiogram.She also demonstrated a mixture of superficial and deep seated calcium zones on imaging.S-IVL therapy was applied to generate fracture in calcium and two overlapping DES were implanted successfully without any complications.

CONCLUSION

S-IVL is an emerging, efficient ,user friendly and safe therapy for managing intracoronary calcium in routine interventional practice.

Core Tip: The presence of severe Calcification in coronary arteries poses a challenge for the interventional cardiologist.If inadequately addressed, it leads to inadequate stent expansion, difficulty in delivery of stent/balloon, balloon rupture , stent dislodgement, stent thrombosis and even perforation.The management spectrum includes high pressure non compliant balloon, non slip element balloon, cutting balloon and atherectomy devices. However, their use is associated with various procedural complications representing an unmet need. Intravascular lithotripsy (IVL) is a novel technique utilizing ultrasonic wave to in disrupt the calcium in vessel wall while retaining them in situ.Shockwave-IVL is now USFDA approved for management in calcium in coronary arteries. After the success of S-IVL being demonstrated in de novo coronary arteries in DISRUPT-CAD trial series I-IV, a recent follow up data has affirmed its long term safety too.The applications of S-IVL are now wading into uncharted waters like - in stent restenosis and venous grafts.A combination with Rota-ablation referred to "Rotatripsy" is also being utilized for balloon uncrossable lesion previous considered it's Achille's heel. With more & more accumulation of data and growing expertise of operators with S-IVL it is turning out to be an indispensable tool in catheterization laboratory.

INTRODUCTION

Calcified coronary artery lesions continue to be one of the pivotal challenges faced by interventional cardiologists. Stent underexpansion due to calcified lesions is a strong predictor of procedural failure and may lead to various acute complications,such as stent thrombosis and long-term stent restenosis.[1] Although aggressive balloon

dilatation can sometimes achieve adequate room for stent deployment,the degree of final luminal gain is often limited. Furthermore, in eccentric lesions, high-pressure balloon dilatation can lead to overstretching of the noncalcified wall with minimal impact on the calcified lesion, which exacerbates the risk for coronary dissection and perforation.[2]

Shockwave intravascular lithotripsy (S-IVL) or Intravascular lithotripsy (IVL; Shockwave Medical Inc., Santa Clara, CA, USA) has recently been approved by the United States Food and Drug Administration (USFDA) for plaque modification in calcified coronary lesions. Contrary to rotational atherectomy, S-IVL uses ultrasonic waves to interrupt the calcium arc while retaining the residual chunks inside the vessel wall. Optical coherence tomography (OCT) substudy of the DISRUPT-CAD trial revealed that circumferential lithotripsy fractures the superficial as well as deep layers of calcium, thereby enhancing the plaque compliance.[3] S-IVL is quite safe and easy to perform. Moreover, the traditional complications associated with rotational atherectomy,viz. distal microembolization, slow or no-flow, coronary perforation, and bradycardia necessitating temporary pacing lead insertion, are not seen in lithotripsy. Herein, we share our experience with shockwave lithotripsy in two separate scenarios and a brief review of literature.

CASE PRESENTATION

Chief complaints

Case 1-

Our patient was a 57-year-old man who smoked and was admitted with a diagnosis of acute coronary syndrome(ACS).

Case 2 -

AA 58-year-old woman with chronic stable angina (CCS Class III) presented to a peripheral hospital where her coronary angiogram revealed triple vessel disease.

History of present illness

Case 1- He presented with intermittent retrosternal chest pain at rest with radiation to arm for past 7 days.

Case 2- She had effort angina despite medical therapy for past 4 mo.

History of past illness

Case 1-There was no past history of any specific illness.

Case 2-There was no past history of any specific illness.

Personal and family history

Case 1- He was chronic smoker and there was no family history of CAD.

Case 2-She was nonsmoker, non diabetic and had no family history of CAD.

Physical examination

Case 1 - He was hemodynamically stable at admission was with blood pressure of 134/70 mm of Hg and pulse rate of 80/minute.

Case 2 - She was hemodynamically stable at admission was with blood pressure of 124/78 mm of Hg and pulse rate of 68/minute.

Laboratory examinations

Case 1-

A 12 Lead electrocardiogram was normal except for a q wave and t wave inversion in lead III.His routine biochemistry and hemogram were within normal limits.His cardiac troponin value was 0.016 (N <0.014 ng/mL).

Case 2-

A 12 Lead electrocardiogram was unremarkable as was her routine biochemical and hematological profile.

Imaging examinations

Case 1-

He exhibited normal left ventricular functions without any regional wall motion abnormality on Echocardiography. Coronary angiography was performed with an intention to revascularize, which revealed calcific 90% stenosis in the proximal left anterior descending coronary artery (LAD), 70%–80% stenosis in the major obtuse marginal artery (OM),and 80% stenosis in the distal left circumflex coronary artery (LCX) artery (Figure 1a & 1b).

Case 2

The LAD showed severe calcified 90% stenosis in the proximal-mid part, whereas LCX exhibited 30%–50% disease in the distal part. There was mild disease in the left main coronary artery (LMCA), whereas the non-dominant right coronary artery (RCA) had severe stenosis. The patient was referred to our center for revascularization (Figure 4 a–c). Her left ventricular ejection fraction (LVEF) was 62%.

MULTIDISCIPLINARY EXPERT CONSULTATION

Case 2

After the meeting of the cardiac team, she was given the options of coronary artery bypass graft surgery (CABG) and percutaneous coronary intervention (PCI) to the LAD, and she opted for the latter.

FINAL DIAGNOSIS

Based on clinical , biochemical and angiographic features a diagnosis of ACS-Unstable Angina with calcified double vessel disease was made in first case. In the second case , chronic stable angina with calcified triple vessel disease was made.

TREATMENT

Case 1-

The lesion in the proximal LAD was predilated using a 2.5mm × 10 mm semicompliant balloon. Subsequently, OCT was performed to evaluate the degree of calcium, which revealed both superficial and deep circumferential calcium (Figure 1c to 1e.). An IVL

balloon catheter (C2IVL from Shockwave Medical Inc., Santa Clara, CA) measuring 3mm × 12mm was then placed across the lesion and dilated at 4 atmospheric pressure (atm). Ten pulses of shock wave were then delivered, followed by IVL balloon dilatation at 6 atm. The cycle was repeated twice, which resulted in calcium fractures as seen in OCT performed after IVL (Figure 2). Next, a 3.0 × 40mm sirolimus eluting stent was deployed at 10 atm. The lesion was then post dilated with 3.5 × 12mm noncompliant balloon. The final angiographic run revealed TIMI 3 flow and well expanded without any residual dissection (Figure 3). A corresponding OCT run revealed a well-expanded and opposed stent, with a minimum stent area of 6.2 cm^2.

Case 2-

Because of severe calcification of the LAD, imaging-assisted PCI was planned. The lesion in the proximal LAD was predilated using a 2.5 mm × 12 mm noncompliant balloon to allow the passage of the OCT catheter, which revealed both superficial and deep circumferential calcium (Figure 4 d–f). In view of the deep calcium, we selected S-IVL as the plaque modification strategy. An IVL balloon (C2IVL from Shockwave Medical Inc., Santa Clara, CA) measuring 2.5mm × 12mm was then placed across the distal lesion and dilated at 4 atm. Subsequently, 10 pulses of shock waves were delivered, followed by dilatation at 6 atm. The cycle was repeated twice in the proximal lesions too. Subsequently, two overlapping sirolimus-drug-eluting stents (DES), 2.5mm × 30mm (distal) followed by 3mm × 21mm (proximal), were deployed at 10–12 atm. The lesions were then post dilated with a noncompliant balloon (sequentially 2.5mm and 2.75mm and subsequently 3.0 mm). Unfortunately, the OCT catheter could not be maneuvered into the LAD for final imaging as the patient became transiently unstable after post dilatation because ofthe slow-flow/no-reflow phenomenon. However, following intracoronary pharmacotherapy, the final angiography revealed thrombolysis in myocardial infarction (TIMI) 3 flow without residual dissection or stenosis (Figure 5).

OUTCOME AND FOLLOW-UP

Both patients were doing good on 30 days and 3 mo follow up without any symptoms.

DISCUSSION

Coronary calcification is a part of the ageing process and is exacerbated by concomitant cardiovascular risk factors and comorbidities.[4,5] Approximately 20% of the coronary interventions are complicated by severe calcific lesions, which are independent predictors of procedural failure and adverse cardiac events in the future.[6,7] Moreover, calcific lesions heighten the risk for procedural complications and increase the procedural time. Characteristics of calcific lesions, viz. location inside the coronary arteries (superficial vs. deep) and calcium burden (thickness of the calcified plaque, arc angle subtended, and longitudinal extension), are the factors that[Editor1] determine plaque compliance, stent delivery, adequate stent expansion, and finally, procedural success and long-term outcomes.[8]

Several techniques are available for modifying severely calcified coronary lesions, including high pressure noncompliant balloons, scoring balloons, cutting balloons, rotational/orbital atherectomy, and excimer laser. These devices cause plaque compression or plaque debulking and are not without complications, such as distal embolization, slow flow, coronary dissection, and perforation. Moreover, they are less successful if the calcification is deep, thick, or eccentric and the tissue injury occurring in the process may induce uncontrolled neointimal proliferation and restenosis.[9]

IVL is a novel technique for bed preparation in severely calcified lesions in coronary as well as peripheral arteries. Calcium fractures are achieved with pulsatile mechanical energy delivered *via* lithotripsy emitters mounted inside a low-pressure balloon catheter (max 4–6 atm). The electrohydraulic-generated high-speed sonic pressure waves pass through the soft vessel wall tissue and selectively modify the subendothelial calcium, which disrupts the calcified plaque. IVL has been approved by the USFDA for the treatment of calcified peripheral lesions and has obtained the CE mark for coronary lesions.

Mechanism of IVL

The mechanism of IVL is similar to the commonly utilized electrohydraulic lithotripsy (EHL) or commonly referred to as extracorporeal shockwave lithotripsy (ESWL) for fragmentation of urogenital tract stones.[10] IVL therapy uses same technology with some modifications to address vascular calcium. The adaptations done include the incorporation of lithotripsy emitters on the shaft of a balloon angioplasty catheter which delivers localized pulsatile acoustic pressure waves circumferentially to modify vascular calcium

In EHL, a spark gap discharge between two electrodes causes the formation of an acoustic pressure wave within the transmitting fluid medium. This pressure wave that expands spherically outwards from the emitter. The Energy discharged from the spark gap results in the formation of a plasma vapor bubble and this immediately follows the initial acoustic shockwave. The rapid expansion and collapse of the vapor bubble which is known as a cavitation bubble and secondary shockwaves causing stone fracture on encountering differing acoustic impedances, such as the transition from soft tissue to calcified tissue.

 EHL spark gap technology was leveraged for use in IVL, but several modifications were done to ensure effective and safe intravascular treatment. Three key modifications were done for IVL:

 1) IVL pressure waves deliver tissue-safe positive and minimal peak negative pressure pulses allowing sufficient compressive force to modify vascular calcium. This helps in mitigating soft tissue injury due to excessive cavitation or tensile stress

2) pressure wave emitters are enclosed within an inflated, fluid-filled balloon to prevent thermal injury

3) multiple emitters are present in series along the shaft of the catheter for longitudinal treatment of the calcified vessel.

The IVL shockwaves are unfocussed which produces much lower energy flux density (the amount of acoustic energy per unit area) as compared to ESWL. Much less energy is required here as the IVL shockwaves are initiated in close proximity to the target vascular calcium. In addition IVL Integration of a semi-compliant balloon with emitters

on the shaft has several advantages. Firstly, the mixture of contrast and saline in balloon dissipate heat generated during the formation of vapor bubbles and shields the emitters from direct contact with the vessel wall. Since the balloon is deflated in between two cycles, it helps in dissipating heat and residual gas bubbles allowing tissue perfusion and preventing ischemia. Secondly, it provides mechanical support which minimizes any tissue deformation during IVL therapy. Lastly as the integrated balloon is thin and acoustically transparent, it provides efficient fluid-to tissue transmission and effective coupling of IVL pressure pulse propagation from emitter to vascular wall. The appropriately sized IVL balloon catheter inflated at subnominal pressure (4 atm) produces efficient ring calcium fracture avoiding barotraumas.

Components of the IVL System

The IVL system comprises the following components:

(1) <u>The IVL generator</u>: The IVL generator is a portable and rechargeable orthogonal "box" weighing 6.8 kg and measuring 28 cm × 15.2 cm x 29.2cm, which delivers small electrical pulses of up to 3000 V of electrical energy. The discharge frequency is one pulse per second (1 Hz), and the maximum number of continuous pulses per cycle is fixed and depends on the type of the IVL catheter used. The machine is user friendly and comprises [Editor2] two buttons, one for power and the other one for delivering energy. There are no external connections, except from the IVL connector cable. There is a color-coding that depicts the number of pulses remaining after each cycle and the size of the IVL catheter being used.[9,11-13]

(2) <u>The IVL connector cable</u>: The IVL connector cable is 1.53m in length and containstwo magnetic poles. One pole is connected to the IVL generator, and the other one is specially designed with a push button that triggers energy emission and is connected directly to the proximal end of the IVL catheter. forms the route and the gate for electrical energy transfer from the IVL generator to the IVL catheter.[9, 11-13]

(3) <u>The IVL catheters</u>: The IVL catheters are balloon angioplasty catheters that possess a series of unfocused electrohydraulic lithotripsy emitters, which convert electrical energy into sonic pressure pulses. The sonic pressure waves travel circumferentially

and create a spherical field at an effective pressure of approximately 50 atm. The waves selectively disrupt and fracture the calcium in situ and alter the vessel compliance while minimizing the injury and maintaining the integrity of the fibroelastic components of the vessel wall. The catheters are available in different sizes, internal design, and maximum cycles and total pulses based on their use in coronary or peripheral vessels.[9, 11-13]

Technical aspects of IVL

In general, the coronary IVL balloon is sized 1:1 to the reference artery ratio and is inflated to low pressure (4 atm). One cycle of ultrasound energy, i.e., 10 pulses over 10 s, is delivered. This process is followed by IVL balloon dilatation to the size of the reference vessel according to the balloon compliance chart. The procedure should be repeated to provide a minimum of 20 pulses in the target lesion, with a period of deflation in between the pulses to allow for distal perfusion. The required number of cycles depends upon the lesion resistance; however, a maximum of 80 pulses (8 cycles) can be emitted by a single catheter. If the lesion length exceeds the balloon length (12mm), the balloon can be repositioned and the lithotripsy repeated. Although the currently available IVL balloon is relatively bulky, contemporary rapid exchange guide extension catheters can accommodate it easily and aid in its smooth delivery.

Clinical studies on IVL (Table 1)

<u>Randomized trial data</u>

DISRUPT CAD I Trial: This trial was a prospective multicenter study designed to evaluate the safety of IVL in 60 patients with heavily calcified coronary lesions. The incidence of major adverse cardiac events (MACE), defined by cardiac death, MI, and target vessel revascularization (TVR), was low (5% at 30 days and 8.6% at 6 mo). Clinical success rate (defined by a residual stenosis of <50% and no in-hospital MACE) and device success rate (defined by successful device delivery and IVL treatment at target lesion) were high (95% and 98.3%, respectively). The major mechanism for calcium modification was fracture, as evidenced on OCT, and it was independent of the depth.[14]

DISRUPT CAD II Trial: This trial was also a prospective multicenter study involving 120 patients with severe coronary artery calcium and an indication for revascularization. The primary endpoint was in-hospital MACE (cardiac death, MI, and TVR). Furthermore, an OCT substudy was performed to elucidate the mechanism of calcium modification. The incidence of primary endpoint was 5.8%, and there was no evidence of abrupt closure, slow flow-no reflow, or perforation. Post PCI OCT showed calcium fracture in 78.7% of the lesions.[15]

DISRUPT CAD III Trial: This trialwas a larger multicenter international study that enrolled 431 patients with severely calcified de novo lesions undergoing PCI. The primary safety endpoint was freedom from MACE at 30 days,[Editor3] and the primary efficacy endpoint was procedural success. The overall primary safety endpoint achieved was 92.2%, whereas the procedural success rate was 92.4%. The study also noted that the procedure was well tolerated, with a low rate of periprocedural complications. An OCT substudy showed calcium fracture in 67.4% of the lesions.[16]

DISRUPT CAD IV Trial: This trial was a prospective multicenter study designed for Japanese regulatory approval for coronary interventions. Again, the primary safety endpoint was freedom from MACE at 30 days, and the primary efficacy endpoint was procedural success (residual stenosis <50%). A propensity-matched historical control group was used for the comparison. The primary endpoints were noninferiority for freedom from MACE at 30 days (CAD IV93.8% vs.control 91.2%, $P = 0.008$) and procedural success (CAD IV93.8% vs.control 91.6%, $P = 0.007$). There were no complications in the form of perforations, abrupt closure, or slow-flow/no-reflow during the procedure.[17]

Pooled Analysis of the DISRUPT Trials- A pooled analysis of thefour abovementioned studies comprising 628 patients enrolled at 72 sites spread across 12 countries was performed.[18] Severe calcium was seen in almost all patients, with an average calcium segment size of 41.5 mm. The efficacy and safety outcomes were achieved in approximately 92% of the patients, whereas the 30-day cardiac death and stent

thrombosis rates were <1% each. Perforation, abrupt closure, and slow flow were characteristically absent.

Long-term follow-up: Long-term (1 year) follow-up data were published recently.[19] The MACE rate at 1 year was low at 13.8% (vs.7.8% at day 30 *vide supra*). The cardiac death and stent thrombosis rates were low at 1.1% each. Repeat revascularization (ischemia-driven) rates were also low at 4.3% for the target lesion and 6% for the target vessel.

<u>Registry experience</u>

A total of 71 patients from three centers who were eligible for IVL were taken into a prospective registry. Three patient groups participated, namely primary IVL therapy (Group A) with calcified de-novo lesions (*n* = 39 Lesions), secondary IVL therapy (Group B) for patients with failed dilatation of lesion with noncompliant balloon (*n* = 22 Lesions), and tertiary IVL therapy (Group C) for patients with stent underexpansion after previous stenting (*n* = 17 Lesions). The primary endpoints were procedural success (<20% residual stenosis) and safety outcomes. The mean diameter of the pre-IVL stenosis was 71.8% ±13.1%, which reduced to 45.1% ±17.4% after IVL and 17.5% ±15.2% after the stenting. Similarly, the mean minimal lumen diameter increased from 1.01±0.49 mm at baseline to 1.90±0.61mm after IVL and 2.88±0.56 mm after the stenting. The procedural success rates were 84.6% (Group A), 77.3% (Group B), and 64.7% (Group C). There was no in-hospital MACE.[20]

In another registry, patients treated with IVL were studied retrospectively to assess the clinical and angiographic outcomes of coronary IVL use in all-comers with moderate to severe calcified coronary lesions. The primary endpoint was in-hospital MACE (cardiac death, MI, and TVR), and the secondary endpoints were clinical success (stent expansion with <30% in-stent restenosis (ISR) and no in-hospital MACE) and angiographic success. A total of 50 calcified lesions were treated with IVL in 45 patients divided into three subgroups,similar tothe above registry:primary IVL therapy (*n* = 23 Lesions), secondary IVL (*n* = 15 Lesions), and tertiary IVL (*n* = 12 Lesions). The mean diameter of the stenosis decreased from 63.2% ±10.2% at baseline to 33.5% ±10.9% post IVL (p<0.001) and 15% ±7.1% post stenting (p<0.001). The mean minimal lumen

diameter increased from 1.1±0.3 mm at baseline to 1.90±0.5 mm post IVL and 2.80±0.50 mm post stenting. The overall clinical success and angiographic success rates were 90% and 94%, respectively.[21]

Systemic reviews and meta-analyses

In a meta-analysis performed by Sattar *et al* involving 282 patients from 4 studies, IVL significantly improved the sizeof the vessel lumen to facilitate coronary stent delivery and deployment in severely calcified plaques. The mean pre-IVL diameter was 1.01 mm, whereas the post-IVL mean diameter was 2.70 mm. The post-IVLlumen diameter was significantly higher than the pre-IVL mean diameter, with a mean difference of −4.16(95% confidence interval: from −5.08 to −3.24, *P* = 0.000001).[22]

In another meta-analysis performed by Sattar etal. involving 24 patients from case reports and series, a success rate of 100% was achievedfor stent implantation, with minimal complications. No significant differenceswere observed in the mortality rates of patients undergoing IVL forLAD,LCX, andLMCA. The mortality rate was higher in patients who had prior comorbidities or required more than three cycles of IVL.[23]

Kaul *et al* compared IVL with traditional rotational atherectomy in severely calcified coronary stenosis. Trials on rotablation and IVL revealed that the latter was safer than the former primarily because it reduced the risk for atheromatous embolization. The studies also revealed that IVL yielded better results for parameters such as acute lumen gain and residual stenosis; however, in-hospital MACE was better with rotablation.[24]

Limitations

One of the limitations of IVL is that it is contraindicated in angulated and tortuous coronary lesions because of its bulky design. The presence of uncrossable lesions may preclude its application; however, the use of hybrid techniques, such as "RotaTripsy," can overcome this shortcoming.

RotaTripsy: *When the balloon cannot cross!*

RotaTripsy refers to the hybrid and tandem utilization of rotablation followed by IVL for lesions with extremely severe calcification in which a balloon cannot cross the lesion or fails to expand. The initial use of rotablation allows the passage of the IVL balloon

while debulking the superficial calcium. The subsequent use of IVL fracturesthe deep calcium, thus leading to extraluminal gain. The technique aims to achieve the best of both contemporary avenues for managing calcium, i.e.,combining the advantages of the balloon-based ones and the ablation-based ones. In an observational study of 34 patients in a real-world setting, the technique attained 100% procedural success without any in-hospital MACE.[25] Another case series also demonstrated the safety and feasibility of the "RotaTripsy" technique underscoring the frequent coexistence of superficial and deep calcium on intracoronary imaging.[26]

IVL in in-stent restenosis

Although not approved for use in ISR, there are many emerging reports on the successful use of IVL in calcific ISR with DES where the use of noncompliant balloons and rotablation failed to produce satisfactory luminal gain.[27,28] Recently, a report has been published on the use of IVL for treating neointimal hyperplasia after bare metal stentimplantation where cutting balloon and nonslip element balloon had failed.[29] A single-center retrospective study found that angiographic success was achieved in all but one patient with an IVL-guided management strategy for moderate to severe ISR (65%–88% stenosis).[30] In the multicenter SMILE registry for ISR, IVL was utilized after the failure of noncompliant balloons. The use of IVL led to significant improvements in minimal stent area and minimal stent diameter in 87% of the patients[31]. There were no cases of death or stent thrombosis at 30 days.The recently published IVL-DRAGON registry (n = 62) has also explored the role of S-IVL in stent under-expansion[32]. The primary end point (stent expansion >80% as seen by qualitative coronary angiography) was seen in 72.5% cases. Significant increase in stent expansion following application of IVL was confirmed by contemporary imaging techniques - OCT (37.5 % to 86%) & IVUS (57% to 89%) also. Device oriented composite end point was seen in only 1.6%. Furthermore, there is a report [Editor4] on the combined use of IVL and brachytherapy in such cases[33]. Hence, the use of IVL in cases of ISR appears promising.

Complications

Serious angiographic complications were witnessed in up to 2.1% of the patients in the pooled analysis of DISRUPT trials [18].These complications were dominated by dissections and slow flow. Perforations, no reflow, and abrupt closure were not reported. The data in the registries mirrored similar findings, with minimal complications and a predominance of dissections[20-21].Premature ventricular ectopic beats or "shocktopics" and asynchronous ventricular pacing were observed in some subjects on electrocardiogram(ECG) but were not associated with clinical consequences [34].Bradycardia at baseline (heartrate<65 bpm) was the most powerful predictor of ventricular capture although it also tended to occur in younger patients, those with higher creatinine levels, and those with previous infarction. Few case reports on transient atrial arrhythmias have also emerged, but the course was benign [35,36].The use of S-IVL in proximal coronary arteries has been associated with supraventricular tachyarrhythmias because of the anatomical proximity. Synchronization of the shock waves with R waves on the ECG has been suggested as a precautionary measure to ameliorate these arrhythmic effects.

Indications for S-IVL

Currently, Shockwave IVL is approved for severely calcified coronary lesions with clinical indications for revascularization. Intravascular imaging (especially OCT) can help identify severe lesions which will benefit from this novel technology thereby allowing judicious usage of this costly therapy. Calcium arc more than 180 degrees, calcium length more than 5mm and thickness more than 0.5mm indicate increased calcium burden which will necessitate specialized lesion modifying therapies[37]. Being a balloon based technology, this eliminated any specialized training and hence almost no learning curve. However, this makes balloon uncrossable lesions a contraindication for S-IVL.However, as previously described a combined approach with rotablation first followed by IVL – "Rotatripsy". Can be applied for such cases. In addition, Rotational or orbital atherectomy can be followed by S-IVL to address deeper and stubborn calcific lesions. A simplified algorithm by De Maria *et al* for heavily calcified coronary lesions places S-IVL into context[1].

S-IVL vis-a vis Contemporary Calcium therapies

Current techniques for calcium modification can be broadly divided into "Atherectomy" type and "Balloon" based. S-IVL offers many advantages over many of these techniques[1,9,38]. It obviates the need for any proprietary wire like Rota wire (Rotablation),Viper Wire (Orbital atherectomy) and the procedure is carried on a routine workhorse wire. This make it cost and time effective. Again being a balloon based technology, it doesn't require any additional equipment like advancer, foot pedal and saline infusion as needed for atherectomy devices. The technique also similar to the "run of the mill" monorail balloons used in daily interventional practice making it easy to master even for the beginners recusing the need for special training. It also offers uniform and circumferential calcium as the balloon emits acoustic waves all round compared to other local atherectomy techniques which might be subject to wire bias. There is also amelioration of any distal embolization as with atherectomy techniques like Rotablation and Orbital Atherectomy making it a safe procedure. The balloon inflation is done at low pressures compared to other balloon based methods (with some utilizing ultra high pressures) which has the potential to minimize vascular trauma and increase safety. There is no data of any reported case of perforation with S-IVL so far. There also no need to remove additional wires in vessel lumen like side branch wire or buddy wire as with other atherectomy techniques. Temporary pacemaker insertion again is not needed as with rotablation. Both superficial and deep calcium are taken care of by S-IVL whereas all the contemporary calcium modification techniques target only superficial calcium due to their localized at luminal surface of vessel. Very severe lesions where balloon cannot cross remain the Achille's heel for S-IVL.

CONCLUSION

Calcific coronary stenosis is one of the biggest challenges for interventional cardiologists. If not dealt properly, the condition can lead to inadequate stent expansion and result in stent thrombosis and restenosis. Techniques such as rotablation, orbital atherectomy, and excimer laser are commonly used to modify the coronary calcium;

however, they are associated with high procedural complications and are less successful in case of deep and eccentric calcium. S-IVL is a novel technique that selectively modifies the subendothelial calcium and is easy to perform. Based on the short-term and long-term success demonstrated in the DISRUPT-CAD trial series, S-IVL is being employed in hitherto unexplored areas, such as ISR, vein graft, and balloon uncrossable lesion (coupled with rotablation). S-IVL is gradually becoming an indispensable tool for managing calcified lesions in the cardiac catheterization laboratory.

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