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REVIEW

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Review of intravascular lithotripsy for treating coronary, peripheral artery, and valve calcifications

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Abstract

Management of intracoronary calcium (ICC) continues to be a challenge for interventional cardiologists. There have been significant advances in calcium treatment devices. However, there still exists a knowledge gap regarding which devices to choose for the treatment of ICC. The purpose of this manuscript is to review the principles of intravascular lithotripsy (IVL) and clinical data. The technique of IVL will then be compared to alternative calcium treatment devices. Clinical data will be reviewed concerning the treatment of coronary, peripheral artery and valvular calcifications. Controversies to be discussed include how to incorporate IVL into your practice, what is the best approach for treating calcium subtypes, how to approach under-expanded stents, what is the ideal technique for performing IVL, how safe is IVL, whether imaging adds value when performing IVL, and how IVL fits into a treatment program for peripheral arteries and calcified valves.

KEYWORDS

coronary artery disease, interventional devices/innovation, peripheral arterial disease

1 | PRINCIPLES OF OPERATION

Intravascular lithotripsy (IVL was originally developed to deliver pulsatile acoustic pressure waves to fracture arterial calcifications and improve vessel compliance while minimizing vessel injury. IVL is designed to modify both intimal and medial calcium across a wide range of vascular applications (Table 1). IVL catheter houses multiple emitters integrated within a noncompliant balloon to mitigate uncontrolled thermal injury. The catheter is connected via a cable to the electric generator, which is programmed to deliver a pre-defined number of pulses depending on the IVL catheter type, at a rate of 1 pulse/s.[1]

The mechanism of calcium fracture by an acoustic wave is based on the IVL emitter generating electric arcing that creates vapor bubbles in the surrounding electrolyte solution. The rapid collapse of these bubbles generates high-energy acoustic waves, or shockwaves, which impart compressive stress, distributed circumferentially to calcified plaques due to differing acoustic impedance than soft tissues (Figure 1). Residual microbubbles need to be removed following every 10 electric pulses, because residual

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Abbreviations: CAC, coronary artery calcification; CN, calcified nodule; ELCA, excimer laser coronary atherectomy; HPNCB, high-pressure noncompliant balloons; ISR, in-stent restenosis; IVL, intravascular lithotripsy; IVUS, intravascular ultrasound; MAC, mitral annular calcification; MACE, major adverse cardiovascular event; OA, orbital atherectomy; OCT, optical coherence tomography; PCI, percutaneous coronary intervention; RA, rotational atherectomy; TAVR, transcatheter aortic valve replacement; TMVR, transcatheter mitral valve replacement.

Aleksandra B. Gruslova and Ibrahim Halil Inanc are co-first authors and making equal contributions to this paper.

TABLE 1 Shockwave intravascular lithotripsy (IVL) catheter characteristics.

Catheter type	Application	Balloon diameter (mm)	Length (mm)	Max pulse count	Guidewire compatibility (in)	Sheath compatibility	Working length (cm)
S4	Peripheral (small vessel)	2.5–4.0	40	160	0.014	5F	135
M5	Peripheral (medium vessel)	3.5–6.0	60	300	0.014	6F	110
		6.5–7.0	60	300	0.014	7F	110
M5+	Peripheral (medium vessel)	3.5–6.0	60	180	0.014	6F	135
		6.5–7.0	60	180	0.014	7F	135
L6	Peripheral (large vessel)	8.0–9.0	30	300	0.018	7F	110
		10.0–12.0	30	300	0.018	8F	110
C2	Coronary	2.5–4.0	12	80	0.014	6F	138

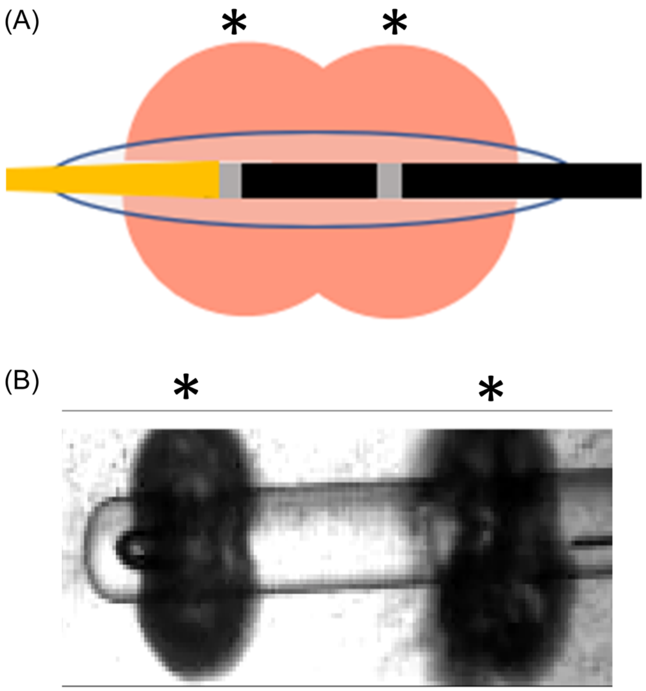

FIGURE 1 Intravascular lithotripsy (IVL) catheter designs. (A) Cartoon of coronary shockwave electric IVL catheter (C2) with two emitters (*) in balloon. Acoustic pressures are aligned with the emitter. (B) Cavitation bubbles generated by laser IVL catheter with two emitters (*). [Color figure can be viewed at wileyonlinelibrary.com]

bubbles interfere with the proper formation of the next series of bubbles.

To transmit acoustic waves into the arterial wall, the balloon should make contact with the arterial wall.[2] An IVL balloon, filled with a 50:50 saline/contrast mixture, is critical because ions are required for electric arc formation and propagation. The balloon is inflated to a subnominal pressure (4 atm) because higher pressures diminish the size of bubble formation and reduce the subsequent amplitude of pressure generation. Since IVL delivers unfocused circumferential lithotripsy, the pressure field effect decreases with distance from emitters.

There have been recent advances in understanding the mechanisms of action of IVL.[3] The current accepted mechanism of increased vessel compliance with IVL is calcium plate fracture. However, computational studies emphasize the role of calcification near fibrous tissues in plaque biomechanics. Calcium plates in plaque can cause stress concentrations that amplify stresses near the calcium plate—fibrous tissue insertion.[4] This residual stress depends on the orientation of the collagen fibrils as they insert into the calcium plate. The highest tissue stress occurs when collagen inserts into the calcium plate in a longitudinal direction (perpendicular insertion). Recent studies using X-ray diffraction have confirmed this hypothesis.[5,6] Thus, when IVL fractures the calcium plate, it can lead to stress release of the calcium plate - fibrous tissue junctions. This second mechanism is termed debonding and is demonstrated in Figure 2.

2 | SAFETY OF IVL

2.1 | Short-term complications

The safety of IVL for modifications of coronary artery calcification has been repeatedly demonstrated. In the DISRUPT CAD I, II, II, and IV studies,[7–9] patient-level pooled analysis of those studies showed 92.4% procedural success and 92.7% 30-day survival rate without MACE.[10] Although no complications were observed in the DISRUPT studies, perforations have been reported in some studies and case reports.[11,12] In the PROGRESS-CTO study, Kostantinis et al. investigated the clinical safety of IVL use in CTO lesions. They reported a mean number of pulses per lithotripsy run was 33 ± 32, with a success rate of 90.1%, and two (2.4%) IVL-related perforations.[12] Simsek et al.[11] reported a case of coronary perforation after 40 intracoronary IVL pulses were delivered in a freshly implanted underexpanded stent.

According to a meta-analysis including 980 patients from eight observational studies, clinical and angiographic successes were

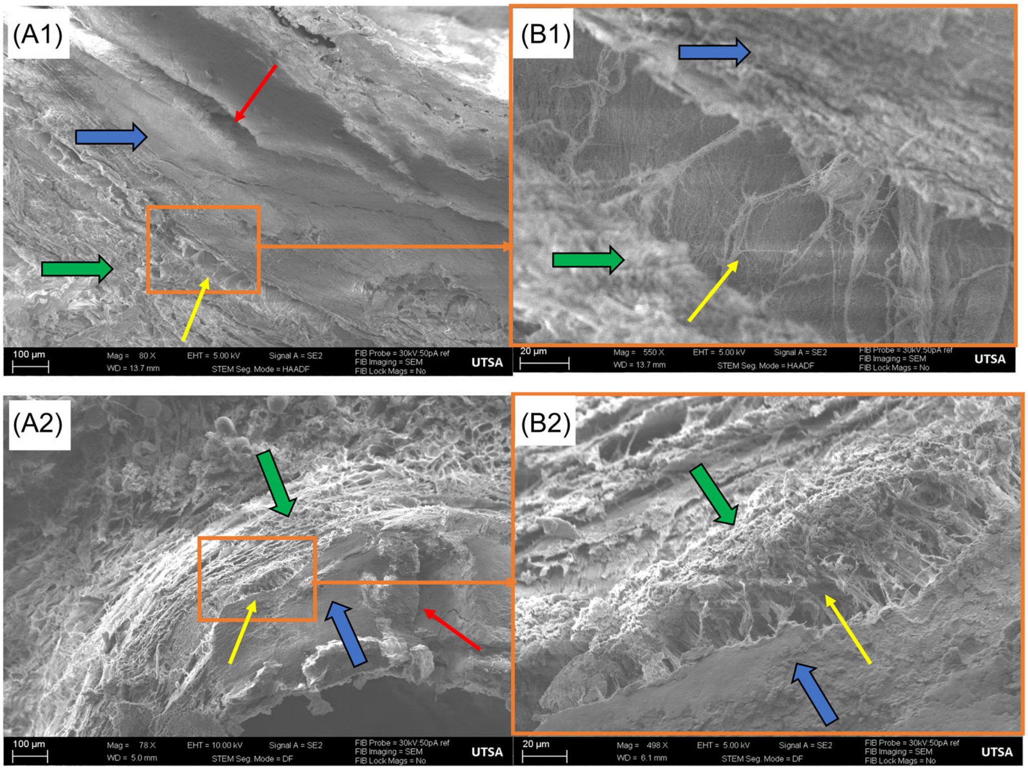

FIGURE 2 Scanning electron microscopy images of ex-vivo calcified human coronary arteries after laser intravascular lithotripsy (IVL) treatment. (A) Images at low magnification (×80) showing calcium fractures and debonding at the calcium—noncalcium plate junction. (B) Zoomed area at the debonding edge (orange box), ×500. Blue arrow—calcium plate, green arrow—fibrous tissue, red arrow—calcium fracture, and yellow arrow—debonding. [Color figure can be viewed at wileyonlinelibrary.com]

achieved in 95.4% and 97%, respectively.[13] Coronary dissections (more than type B) and perforations occurred in 0.5% and 0.4% of the cases, respectively. The 30-day survival without MACE was 95.1%. Another recent meta-analysis included 354 patients from 13 studies that reported pooled procedural success rate of 88.7% and a MACE rate of 1.7%.[14] The pooled procedural complication rate was 1.6% (two cases of dissection, one perforation, and one periprocedural MI due to IVL balloon rupture). CAD II and CAD III studies showed that IVL has a low complication rate with a high procedural success rate in the treatment of severely calcified CAD (calcium fractures occurred in 78.7% and 67.4% of lesions, respectively).[7,8] 99% procedural success with only a 3% complication rate was reported for a European multicenter study that undertook high-volume complex coronary interventions.[15]

Kiron et al.[16] reported for the first time postcardiac injury syndrome causing pericardial tamponade 1 week after an IVL procedure. They applied 60 pulses of IVL for an ostial circumflex lesion and 20 pulses using the same IVL balloon for LAD stenosis. The patient was readmitted due to pericardial tamponade and atrial fibrillation. The pericardial fluid had a neutrophil-dominant exudate.

There are examples of using peripheral IVL catheters during coronary interventions due to resistant calcium and the need for higher delivery of atmospheres. However, due to balloon oversizing, complications have been reported. The FDA MAUDE Database reported three complications, including one IVL balloon-related perforation and one aortocoronary dissection.[17] Yarusi et al.[18] used the peripheral IVL catheter in a total of nine patients, of which three were LMCA, three were RCA, and three were LAD lesions. They reported one transient Mobitz type-II AV block (RCA ostial lesion), one aortocoronary cusp dissection, and transient hypotension due to the insertion of a peripheral IVL-balloon into RCA.[18]

2.2 | Long-term complications

Data on long-term side effects are limited to observational studies. Based on the 1-year results of the DISRUPT CAD III study, Kereiakes et al.[19] reported that MACE, target lesion failure (TLF), and stent thrombosis occurred in 13.8%, 11.9%, and 1.1% of patients, respectively. The 20-month clinical follow-up results from a prospective, multicenter, single-arm study including 109 patients showed that MACE and TVR rates of 5.6% and 1.85%, respectively. According to the 20-month clinical follow-up results of a multicenter observational study including 273 patients, MACE and TLR occurred in 6% and 11% of patients, respectively.[20]

2.3 | Risk of arrhythmia

Despite the demonstrated safety of IVL in multiple trials, it is necessary to mention asynchronous ventricular pacing. Two reports of ventricular fibrillation were entered into the FDA MAUDE database, and a third case was published,[21] as well as three reports of atrial fibrillation/flutter.[22–24] Still, given the many patients treated with IVL, this safety has not been a concern. The mechanism of pacing is unclear. Electric pacing is surely one mechanism, but there are also reports of ultrasonic waves resulting in ion channel current modulation. The tetrodotoxin-resistant Nav1.5 channel is the most common Na+ channel isoform in cardiomyocytes. Previous studies have demonstrated the mechanical sensitivity of this channel.[25,26] Which of these two competing mechanisms is the actual cause of cardiac pacing is still unclear.

3 | IVL VERSUS OTHER CONTEMPORARY CALCIUM-MODIFYING TECHNIQUES

There are no randomized controlled trials comparing IVL with other calcium-modifying techniques. The studies in the literature are retrospective, observational, and mainly comparing IVL with rotational atherectomy (RA) or high-pressure noncompliant (HPNCB) balloons. A retrospective study comparing IVL and HPNCB dilatation showed that the IVL group had higher procedural success (82.5% vs. 61.4%; $p = 0.0035$) with similar MACE at 12-months (10.5% vs. 11.1%; $p = 0.22$).[27] In another study with 101 patients, the effects of IVL compared with RA in calcified coronary lesions, procedural success, complication rates, and 6-month MACE were similar. However, the median fluoroscopy time was shorter in the IVL group. There were also two coronary perforations in the RA group and one coronary perforation in the IVL group.[28] In a recent study, functional outcomes of IVL and RA were compared in 210 patients. The IVL group had greater reductions in in-stent pressure gradients demonstrated with fractional flow reserve.[29] In summary, IVL appears to have greater procedural success and reduction in fluoroscopy time, although more studies are still needed.

While atherectomy devices provide calcific segment modification by direct contact with the vessel wall, they may cause procedural complications such as vessel perforation and dissection, by cutting too deep in the vessel layers. This may lead to impaired vascular healing due to tunica media or adventitial layer damage, which may cause in-stent restenosis. Ueno et al.[30] defined a perivascular "halo" confirmed by both optical coherence tomography (OCT) and intravascular ultrasound (IVUS) imaging suggesting that edema due to tunica media and adventitia damage was present after RA. Since circumferential sonic pressure waves also can affect noncalcium plaque, post-IVL procedural inflammation may occur. Recent studies have demonstrated inflammation of the media and adventitia layers in response to IVL,[31] which may lead to negative remodeling. Future studies investigating the long-term impact of IVL, and other calcium modification techniques, are also needed.

Excimer laser coronary angioplasty (ELCA) is also described in the literature as a solution where the atherectomy catheter but not the IVL balloon can cross a stenosis due to excessive calcification.[32,33] However, ELCA at 308 nm wavelength is not able to ablate calcium in atherosclerotic lesions.[34] They were developed to ablate protein and thus clots or plaque-containing lesions. Any success they have in ablating calcified atherosclerotic lesions may be due to the presence of strongly absorbing residual contrast, blood, or both in the lasing field. ELCA-induced micro-cavitations can be created even when lasing during saline flushes because the contrast and blood cannot be totally cleared from the artery. A comparison of contemporary calcium-modifying techniques is provided in Table 2.

4 | CORONARY SUBTYPES

4.1 | Eccentric verses concentric lesions

Although IVL can be used in severely calcified concentric lesions, there is less data on eccentric lesions. The pooled patient data from DISRUPT coronary artery disease (CAD) I and DISRUPT CAD II studies included 47 eccentric and 133 concentric lesions and demonstrated that intraprocedural complications such as vessel perforation, abrupt closure, and slow or no-reflow were similar in both eccentric and concentric lesions.[35] The MACE rates were similar in both groups during 30-day follow-up (eccentric 8.7% vs. concentric 6.0%, $p = 0.80$). Another study compared the effect of IVL on eccentric ($\leq 180°$) and concentric ($> 180°$) calcific lesions by analyzing OCT images from pooled data of DISRUPT CAD I, II, III, and IV OCT substudies.[36] They concluded that IVL contributed an increased luminal gain and stent expansion at similar rates in both groups (Figure 3). However, the depth, width, and number of fractures were 13-fold higher in concentric lesions. Similarly, Mattesini et al.[37] evaluated the effect of IVL on concentric (21 lesions, mean calcium arc 289 ± 53°) and eccentric (10 lesions, mean calcium arc 140 ± 24°) calcific lesions using OCT. They found that there was no statistical difference in terms of in-stent minimal luminal area (MLA), acute gain, periprocedural complications, and 30-day mortality. Again, the number of calcium fractures were significantly higher in the concentric lesion group (92% vs. 38%, $p = 0.03$). This finding may be due to OCTs inability to image calcium fractures deep in eccentric lesions. It has also been previously demonstrated that OCT cannot image all calcium fractures compared to the standards of histology and microCT.[3] It can be concluded that IVL offers a low risk of intraprocedural complications while providing adequate stent expansion in both concentric and eccentric calcific coronary lesions.

4.2 | Calcified nodule—Cracking the rock

IVL can be used effectively in calcified nodules (CN). CN may require more IVL cycles than the usual 80 to modify the eccentric dense calcium and additional HPNCB inflations to ensure that the CN is

TABLE 2 Contemporary calcium-modifying techniques.

	Principle	Advantages	Disadvantages
IVL	Lesion modifying via pulsatile sonic pressure waves	– More effective and safe – Minimal risk of dissection/perforation/distal embolism – May contribute to better stent expension and lower post-PCI instent FFR gradients – No wire-bias since the energy is distributed circumferentially – Effective in modifying both superficial & deep calcification – Effective calcium modification behind stent struts – Safe in calcific lesion containing dissection/thrombus – Can be easily applied in bifurcation and eccentric lesions	– Limited use in case of balloon uncrossable calcific lesions – Not ideal for long calcific lesions due to its high cost
RA/OA	Mechanically debulking of superficial calcific plaque	– Works well to modify balloon-uncrossable lesions – Useful in superficial calcifications – Can be used to modify calcific nodules – Cost-effective for long lesions	– Increased risk of distal embolism/flow-limiting vessel dissection/no-reflow/occlusion/perforation/need of bailout stenting[a] – Perforation risk higher in angulated lesions – Increased cost/procedure duration/radiation exposure in case of periprocedural complication – Wire-bias – Operator-expertise needed – Higher risk of complication in dissected/thrombus-containig lesions – Trapping risk in in-stent lesions[a] – Higher risk of complication in ostial lesions – Higher risk of side branch loss in calcific bifurcation lesions – Inhomogeneous lesion modification in eccentric lesions – Contraindicated in SVG lesions
ELCA	– Generating pulses of short wavelength and high-energy ultraviolet light. – Photochemical, phototermal, and photomechanical properties	– Effective for both eccentric, concentric, and instent lesions – Higher dilation pressures especially when applied to aline infusion technique – Effective in instent calcific restenosis – Can be applied in SVG, bifurcation, ostial, and CTO lesions	– Increased risk of perforation – Not recommended if there is a long length of subintimal guidewire positioning

Abbreviations: CTO, chronic total occlusion; ELCA, excimer laser coronary atherectomy; FFR, fractional flow reserve; IVL, intravascular lithotripsy; OA, orbital atherectomy; PCI, percutaneous coronary intervention; RA, rotational atherectomy; SVG, saphenous vein graft.

[a] Less risk for OA.

fully fractured. However, data on clinical efficacy and outcomes of IVL in patients with CN are limited.[38,39] Ali et al.[40] analyzed pooled OCT data from DISRUPT I, II, III, and IV studies, including 54 CN and 194 non-CN. They demonstrated that both groups had similar procedural outcomes in terms of acute luminal gain and minimal stent area. Further, despite a higher calcium burden in CNs, they demonstrated a greater number of IVL-induced fractures in CNs. There is also a case report written by Warisawa et al. that they observed that despite multiple RA attempts to treat a nodular circumflex ostial stenosis, they could not achieve enough calcium modification for stent placement. OCT imaging showed significant deep fractures after 40 cycles of IVL with an acceptable luminal gain.[41]

4.3 | Treatment of long calcified lesions and cost-effectiveness

Long calcified coronary lesions are not an ideal application of IVL due to its cost. Each IVL catheter costs about $4700, and the current electric IVL technology is only compatible with 12 mm balloons. Adding additional wires and electrodes would increase the diameter

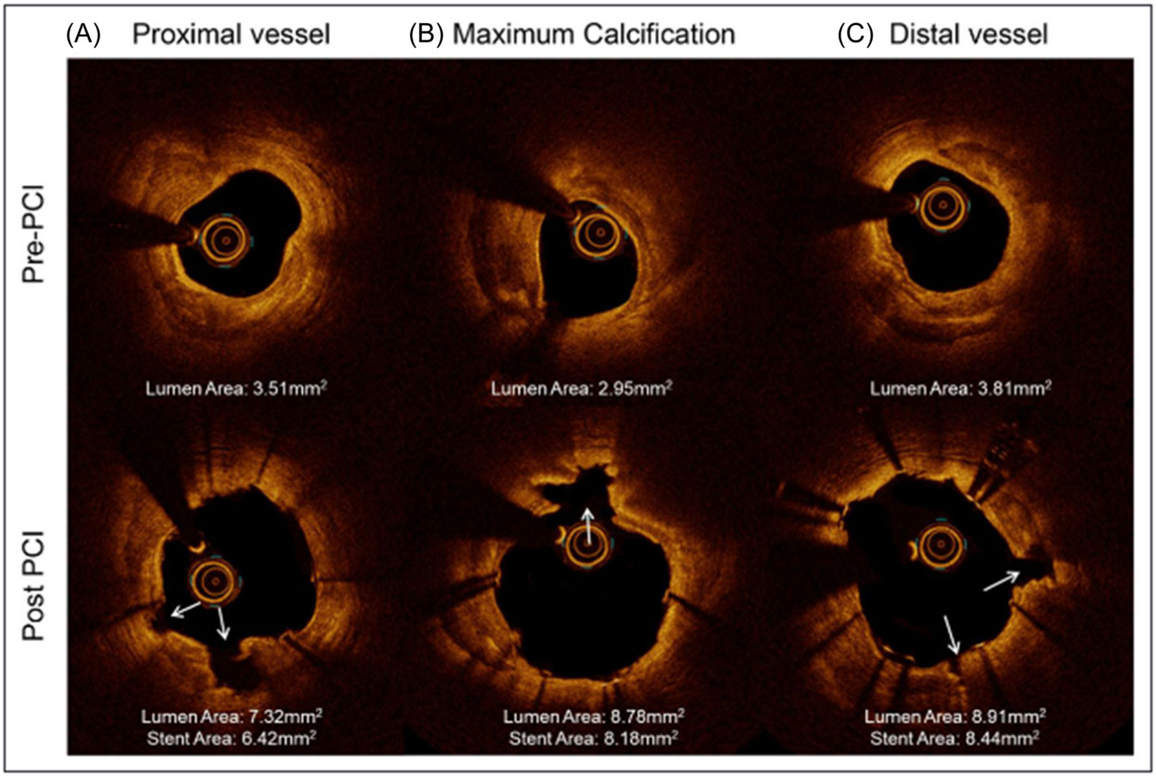

FIGURE 3 Example of optical coherence tomography (OCT) images of Shockwave Intravascular Lithotripsy for lesion modification for: (A) Concentric plaque; and (B) and (C) eccentric plaque, both treated successfully. Top, prepercutaneous coronary intervention (PCI): (A) Severe calcification is present on the OCT image in the proximal vessel. (B) At the site of maximal calcification, there is greater than 270° calcification with minimal thickness >1 mm and minimal luminal area of 2.95 mm^2. (C) Severe calcification is present on the OCT image in the distal vessel. Bottom, Post-PCI: (A) Calcium fracture is identified in two locations (white arrows) on OCT coregistered with the pre-PCI image. (B) At the site of maximal calcification, there is a calcium fracture (white arrow) liberating stent expansion and an acute gain of 5.83 mm^2. (C) At the distal vessel, calcium fracture is identified in two locations (white arrows) on OCT co-registered with the pre-PCI image.[7] [Color figure can be viewed at wileyonlinelibrary.com]

of the electric IVL device. A lesion that occupies a third to a half of a coronary artery is too expensive to utilize IVL. Three to four IVL catheter systems would be required at a cost ranging between $14,100–$18,800. A more cost-effective approach would be to use a single rotablator burr to decalcify the entire long lesion. The cost of Boston Scientific's rotablator for a single burr is approximately $1925 resulting in cost savings. The problem of using RA on long lesions is the higher risk of no reflow. However, this risk is currently estimated to be low ranging between 1.1% and 2.6%.[42]

It is also worth noting that CMS has recently increased reimbursement for the performance of coronary IVL. Three new DRGs (323, 324, and 325) have been created to describe PCIs that utilize coronary IVL, with and without major complications and comorbidities, including full expansion of previously deployed stents.

4.4 | Calcified bifurcation stenoses

Plaque debulking at a coronary bifurcation with an atherectomy device may lead to loss of side branches due to the use of a single wire. An alternative approach is IVL because it does not shift calcified plaque into side branches. Further, both bifurcation vessels can be protected with wires during the performance of IVL. This approach can extend to the ostia of calcified side branches, and it can be used in conjunction with a second non-IVL kissing balloon.[43] Although true bifurcation lesions were excluded in the DISRUPT CAD III study, 34.4% of the lesions in the DISRUPT CAD IV study consisted of bifurcation lesions. A high procedural success was achieved without no-reflow.[9] Thus, IVL is a compelling option for bifurcation stenoses.

4.5 | Under-expanded stents

Stent under-expansion, or "stent regret," is a major risk factor for in-stent restenosis (ISR) and stent thrombosis. Stent under-expansion has been demonstrated in 42% of ISR.[44] Imaging with OCT and IVUS are not always required in identifying and treating stent under-expansion. In some cases, under-deployed stents can be recognized with fluoroscopy including stent boost, as well as their successful re-expansion.

Promising results have been reported with ELCA using saline during the procedure with little damage to surrounding tissues in the treatment of stent under-expansion.[45] ELCA procedures are reported to provide better calcium modification when contrast is used instead of saline where there is extensive calcification behind the stent.[45] In a recent study including 81 ISR lesions, there were significant calcium fractures detected with OCT in the ELCA-treated group compared to the high-pressure balloon group (ELCA: 61%, high-pressure balloon: 12%, $p < 0.01$).[46] In addition, ELCA using contrast resulted in more calcium fractures than lesions treated using saline.[46] A candidate mechanism for calcium fracture when using ELCA is shockwave generation due to strong absorption by contrast of nanosecond pulse duration excimer laser light (308 nm). A concern of using laser outside of a balloon is that the vapor bubble collapse can cause arterial wall damage as the vapor bubbles[47] are less controlled, and risk of unintended vessel damage may be greater.[48,49]

The use of IVL has been proposed as an alternative approach to stent under-expansion, because the energy is contained within the balloon, mitigating risk of vessel disruption. Some encouraging results have been reported, both for previously implanted stents and as a rescue strategy immediately after stent implantation in cases of resistance to full stent expansion. IVL may be safer than ELCA by transmitting 50 atm pressure waves to the calcific tissue behind the stent struts with only 4 atm in the IVL balloon.[48]

The SMILE registry, designed as a multicenter and retrospective study, included a total of 34 patients with 39 under-expanded stents.[50] There was a significant increase in minimal stent area (MSA) on OCT/IVUS imaging with 87.1% procedural success (an increase of at least 1 mm^2 in MSA), and there was no periprocedural complications or death at 30-day clinical follow-up. Notably, two of the lesions with procedural success had multiple stent layers, and one had an acute under-expanded stent. Similarly, the multicenter IVL-DRAGON study analyzed 62 patients and the procedural success rate (a relative stent expansion >80%) was reported as 72.6% without any target lesion revascularization (TLR)/target vessel myocardial infarction (TV-MI) during 30-day follow-up.[44] Recently, in the multicenter CRUNCH registry, 70 patients with resistant under-expanded stents in coronary arteries were analyzed for procedural outcomes and observed for 49 days after the procedure.[51] The procedural success was 92.3% with no IVL-related complications or MACE during follow-up. IVL was applied as a bail-out strategy in 41.4% of patients, and 21.4% had a double stent layer.

Thus, rather than being an alternative to other technologies, IVL is becoming the preferred technology for treating stent under-expansion. For instance, IVL has been reported to be effective in situations where there is insufficient calcium modification. Alawami et al.[52] reported a case of an under-expanded stent in the circumflex despite several attempts using high-pressure balloons (both for pre- and postdilatation) and RA (Figure 4A,B). The lesion was fully expanded after 70 pulses of IVL, and OCT imaging after 4-month follow-up revealed no evidence of stent recoil or in-stent restenosis (Figure 4C).

4.6 | RotaTripsy—A hybrid approach

Obstructive calcifications can make electric IVL difficult to deliver. For instance, the published typical diameter of a calcified vessel lumen is 0.8 mm, while electric IVL has a diameter of 1.2 mm.[53] Although guide extension catheters can be used to deliver IVL, they may not be successful. As a result, interventional cardiologists may use alternative calcium-modifying devices to facilitate the delivery of IVL.

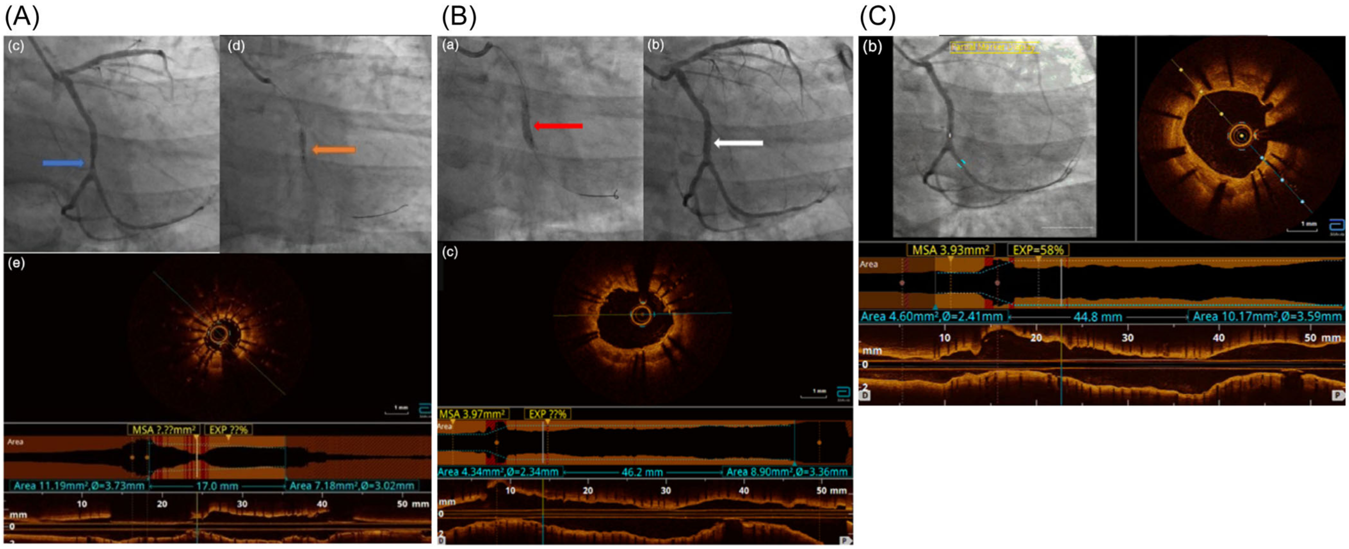

FIGURE 4 Intravascular lithotripsy to treat an underexpanded coronary stent. (A) Under-expansion of LCX stent after rotablation and NC balloon. (B) Fully expanded stent after intravascular lithotripsy (IVL). (C) 4-month follow-up showing well-endothelialized stent.[52] [Color figure can be viewed at wileyonlinelibrary.com]

Hybrid RotaTripsy, where RA is followed by IVL, may be an effective approach for otherwise balloon-uncrossable calcified lesions. RA and IVL have different mechanisms. RA removes superficial calcium, while IVL creates calcium fractures in superficial and deep calcium plates.[2,54] Jurado-Roman et al.[55] in 2019 reported the first successful case of RotaTripsy for the middle LAD with multiple 360° calcium rings. Other clinicians began to successfully apply this approach for severe calcified lesions with a poor crossing profile.[56–60] Recently, two small studies (with 21 and 34 patients, respectively) demonstrated feasibility of RotaTripsy for un-dilatable heavily calcified coronary artery lesions.[61,62] One limitation of this approach is the expense of using these two devices in a single patient.

It is currently unknown how often IVL is not the primary device to cross a calcified lesion. The only publication available is a multicenter European study which noted that prior RA was needed in 17% of cases (190 patients).[15] We conducted an international survey to examine this question. Interventional cardiologists participated in an anonymous online survey and were asked the four following questions: (A) what percentage of time can you not initially cross a calcified coronary stenosis with IVL, (B) if you cannot cross with IVL, what device is your second go to device? (C) Is OCT or IVUS your preferred calcium imaging device, and (D) in what region of the world do you practice?

A total of 58 physicians participated in the survey, 76% of whom were from North America, 19% from Europe, and the remaining from South America, Asia and the Middle East. About half of the operators fail to cross calcified lesions with a Shockwave IVL catheter up to 30% of the time. 32.7% of operators had problems crossing in 31%–60% of cases, while the remaining 12% of clinicians had problems crossing in most of their cases (Figure 5A). If IVL cannot cross, the preferred device is RA (59%) and noncompliant balloon (36%), and rarely OA (3%) or laser atherectomy (1%) (Figure 5B). 83% of surveyed clinicians prefer to use IVUS imaging to assess calcified lesions (Figure 5C).

5 | USE OF IVL TO TREAT PERIPHERAL STENOSES

There are two types of peripheral IVL catheters referred as M5 and S4. The mechanism of action is similar to coronary IVL catheters, but they have five emitters instead of two. The M5 catheter has balloon diameters ranging from 3.5 to 7 mm and balloon length of 60 mm (working length 110 cm) compatible with either 6F or 7F sheath. The S4 catheter is preferred for below-knee peripheral interventions. It has a hydrophilic coating, lower crossing profile, better flexibility, a length of 40 mm (working length 135 cm) and is compatible with a 5F sheath. The maximum numbers of pulses with the M5 and S4 catheters are 300 (10 cycles with 30 pulses each) and 160 (8 cycles with 20 pulses each), respectively.

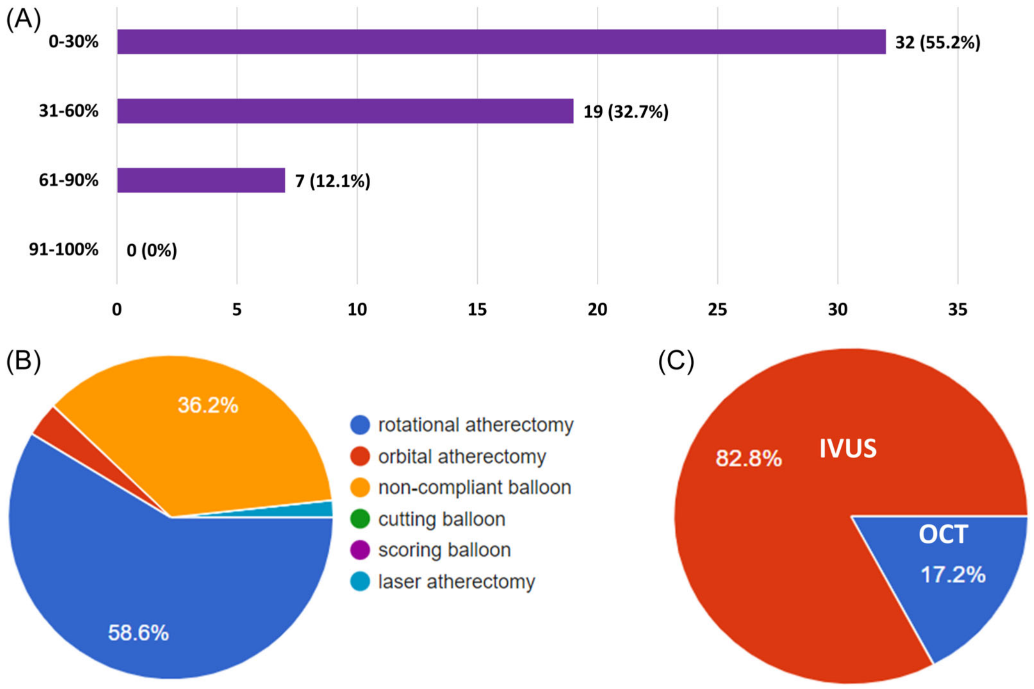

FIGURE 5 Interventional cardiologists' responses to an international survey on IVL practice. (A) Question #1 “What is the estimated percentage (%) of calcified lesions in your practice that you cannot cross with Shockwave IVL catheter?” (B) Question #2 “Which device do you choose to cross a calcified lesion if Shockwave IVL catheter will not cross?” (C) Question #3 “Which imaging technology do you use to assess calcified lesions?” IVL, intravascular lithotripsy; IVUS, intravascular ultrasound; OCT, optical coherence tomography. [Color figure can be viewed at wileyonlinelibrary.com]

DISRUPT PAD III has provided important data on the successful use of IVL in moderate or severe femoropopliteal lesions. In this study, IVL or percutaneous transluminal angioplasty (PTA) was performed to prepare the lesions before drug-coated balloon (DCB) or stenting. Compared to the PTA group, the IVL group had higher procedural success and balloon/stent expansion with significantly lower residual stenosis and flow-limiting dissection rates.[63] The midterm (2 year follow-up) results of the same study revealed that primary patency was significantly higher in IVL group (70.3% vs. 51.3%).[64]

The subanalysis of the DISRUPT III study, which included 114 calcific infrapopliteal lesions, presented promising results regarding the use of the S4 IVL catheter in below-knee calcific lesions. In addition to successful IVL catheter delivery to all of the lesions, flow-limiting dissection, perforation, distal embolization, slow flow, no-reflow, and abrupt closure were not observed in any of the patients suggesting safety and effectivity of IVL.[65]

The effect of IVL on calcific plaque under the stent strut has also been reported in the carotid and lower extremities. Kang et al. reported the first successful clinical use of IVL due to repeated stent recoil in two layers of under-expanded carotid self-expanding stents.[66] Tabaza et al. also reported the first successful clinical use of IVL in peripheral stent under-expansion.[67] Based on this evidence, IVL can modify the calcific plaque under a peripheral stent, improving stent expansion. However, the long-term impact of this approach will need to be examined in larger clinical studies.

6 | IMAGING AND IVL

Pre-PCI IVUS and OCT imaging may facilitate the selection of which device to use based on the morphology and location of the calcium. For instance, coronary calcium localization can be superficial, which can be addressed with RA, or deep, which is ideal for IVL. Its distribution can be focal, which can be treated with a noncompliant balloon, circumferential, best treated with IVL, or longitudinal which is best treated with RA to reduce cost. Mintz et al.[68] in his IVUS versus angiography study (*n* = 1155 arteries) showed that target lesion calcium was superficial in 48%, deep in 28%, and both superficial and deep in 24%. Mintz et al.[68] also showed that IVUS was twice as sensitive for detection of calcified lesions as standard fluoroscopy. Thus, the pattern of coronary calcification can dictate which device to use.

There are important articles using point-based systems for both OCT and IVUS parameters that predict when full stent expansion will occur. Since OCT is more advantageous than IVUS in terms of the evaluation of calcium thickness and post-IVL calcium fractures due to its higher resolution, the calcium scoring system currently used to identify lesions where calcium modification would be beneficial before stent implantation is OCT-based.[37,69] Recently, a new IVUS-based model to predict full stent expansion has also been developed.[70]

7 | BEST PRACTICES TO INCORPORATE IVL INTO CALCIUM MANAGEMENT

The algorithm in Figure 6 was created from review of previously published calcium management schemes,[37,71–75] as well as the literature in the current article. Figure 6 emphasizes the importance of first attempting balloon dilation of the calcified stenosis with high-pressure balloons to determine if plaque modification is required as assessed by intravascular imaging scoring systems.[69,70] If there is significant calcification by the scoring systems (3–5 points), then advanced calcium-modifying devices become more relevant to complete the procedure.

8 | FUTURE APPLICATIONS AND OFF LABEL USE

IVL has applications beyond the treatment of calcified arteries. Although these are off-label uses, lithotripsy may be an effective solution for patients with valve stenoses with severe calcification. Lithotripsy may improve the ellipticity index of the aortic annulus and thereby limit the paravalvular leak of transcatheter aortic valve replacement (TAVR). Lithotripsy before valve placement may also limit the need for permanent pacemaker placement by modifying calcium and reducing the risk of iatrogenic bundle branch blocks or complete heart block. Lithotripsy may also be of value during the rare occasions when stenotic aortic valves cannot be crossed with the TAVR device. There are two reported cases where one undersized 7 mm balloon[76] and another with simultaneous use of three 7 mm balloons were needed to allow passage of larger balloons.[77] Another approach for treating aortic stenosis is the use of transcatheter debridement device (TDD).[78] It uses low-intensity ultrasound shockwaves for calcium fracture in the native aortic or bioprosthetic valves with the aim of restoring the leaflet pliability to regain an adequate flow as an alternative to TAVR. Using a combination of different frequencies, 100 kHz and 3 MHz. However, to date it has only been tested on ex-vivo human aortic valves.

Access is an important aspect when planning and performing TAVR. The transfemoral (TF) approach is considered the standard for TAVR, but calcific lesions of femoral or iliac arteries might be uncrossable, especially if circular calcifications are present. Vascular complications during TAVR are still a common complication of the procedure with an incidence of 1%–10%.[79] Recently, IVL has emerged as a treatment option for heavily calcified stenotic lesions, enabling the transfemoral approach. There are publications regarding how to incorporate IVL into TAVR procedures including preprocedural planning based on the TAVR-CT.[80] Sawaya et al.[81] also discussed IVL-assisted TF-TAVI (*n* = 50 patients). He concluded that peripheral IVL appears to be a safe and effective solution for TAVR candidates with co-existing iliofemoral calcifications. Using peripheral IVL to facilitate TF access should be part of the TAVR algorithm, aiming to maintain the safety profile and superior outcomes of traditional TF-TAVR.

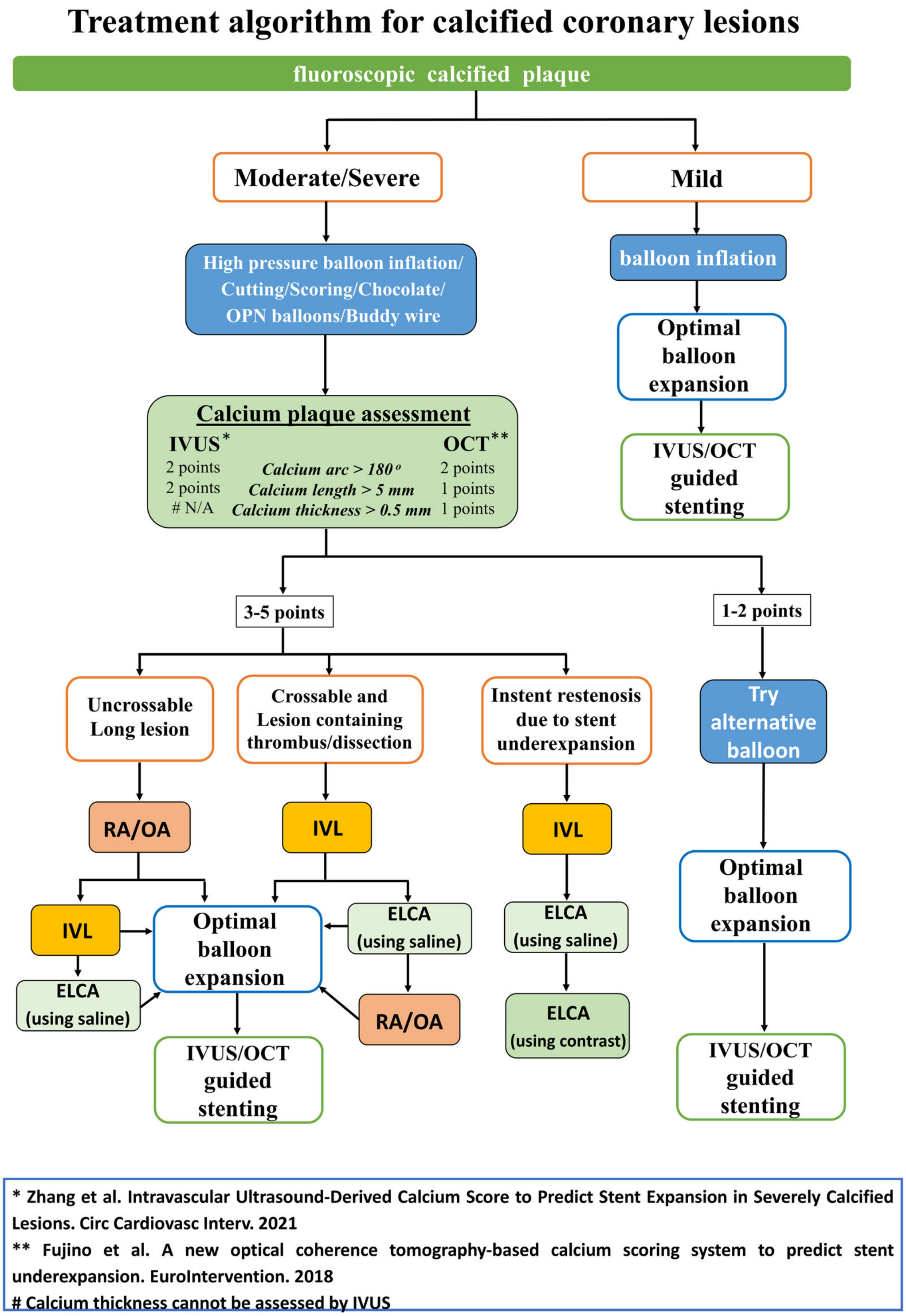

FIGURE 6 Treatment algorithm for calcified coronary lesions. ELCA, excimer laser coronary atherectomy; IVL, intravascular lithotripsy; IVUS, intravascular ultrasound; OA, orbital atherectomy; OCT, optical coherence tomography; RA, rotational atherectomy. [Color figure can be viewed at wileyonlinelibrary.com]

Another application is for mitral annular calcification (MAC) and rheumatic mitral stenosis to allow transcatheter mitral valve replacement (TMVR). Four case reports demonstrated that lithotripsy can be used in calcific rheumatic mitral stenosis, before valve implantation to improve expansion and apposition.[82–84] They used multiple IVL balloons simultaneously across the mitral valve. There are additional cases of the treatment with simultaneous 7 mm IVL balloons across the mitral valve.[83–85] The complexity of transcatheter mitral valve lithotripsy will require a modification of the TMVR procedural protocols.[84,86]

9 | CONCLUSIONS

The approval by the FDA of electric IVL for the treatment of artery calcification has resulted in its rapid adoption by clinicians. It is a novel and safe approach for the modification of coronary and peripheral artery calcifications. However, many controversies exist regarding its use, which have been discussed in this review in detail.

CONFLICT OF INTEREST STATEMENT

The authors declare no conflict of interest.

DATA AVAILABILITY STATEMENT

Data sharing is not applicable to this article as no new data were created or analyzed in this study.

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