

Emergence of a new technique to treat calcified coronary lesions

Ha surgido una nueva técnica para el tratamiento de lesiones calcificadas

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Over the last few years, the risk profile of patients referred to receive a coronary angiography has deteriorated and angiographic findings as well. Therefore, the progressive aging of the population and the development of better techniques to address the complexity of the different angiographic scenarios have conditioned the current situation of percutaneous coronary interventions. The balance between demand and supply in this field is in an ongoing expansion. The management of these delicate situations—which is often competence of cardiac surgery—requires profound knowledge of dedicated techniques and a precise clinical judgment.¹⁻³ This population is often discarded for coronary artery bypass graft surgery. There are times that even percutaneous treatment is denied because of a high clinical risk or unfavorable angiographic profile.

According to different series,⁴ to this day complex calcified coronary lesions are a common finding in up to 25% to 30% of all percutaneous coronary interventions. De Maria et al.⁵ published a review on the management of calcified lesions. They portrayed an accurate, contemporary big picture on the treatment of these lesions. The review basically focused on the technologies in intravascular imaging and tools available to solve today's technical complexities. The authors emphasize that today the objective of percutaneous coronary intervention when treating these lesions is to modify the plaque. If it fails to do so, the procedure is more likely to fail also in the clinical and technical aspects. Clinically because there would be more major complications, and technically because the result would compromise stent expansion and apposition, with the resulting increase in the rates of in-stent restenosis and thrombosis, etc.^{6,7}

Intracoronary lithotripsy (ICL) is the latest technology available for the management of severely calcified lesions. Its mechanism of action has been well described in the document. Basically, ultrasound energy interacts with the atherosclerotic plaque causing vibrations that crack and tear the calcified components of superficial and deep layers. Compared to ablation techniques, since it is based on balloons, it is easy to use and there is a short learning curve. This, together with an early apparent evidence of efficacy, suggests that it will soon become the standard of care for the management of many severely calcified lesions. Similarly, this effect on deep calcium is an important benefit of ICL compared

to other plaque-modifying techniques. Compared to rotational and orbital atherectomies, both of which reduce the plaque burden, ICL does not ablate or reduce it but cracks it supposedly improving stent apposition and expansion. The long-term follow-up will confirm whether this is enough to see long-term benefits.

In a recent article published in *REC: Interventional Cardiology*, Vilalta del Olmo et al.⁸ commented on their first experience with an ICL device in a high-risk population. Their data provide useful information to assess the role, safety, and feasibility profile of ICL in high-risk patients not included in other studies. The authors report on procedural success and the short-term clinical outcomes of a non-randomized registry. The data published show the utility of ICL improving the clinical and angiographic results of complex patients with advanced, diffuse, multivessel, and calcified atherosclerotic disease. Their patients often presented with critical conditions such as acute coronary syndrome or left ventricular dysfunction.

Since they recruited their first patient, many things have changed and new information has come to light. By performing OCTs in 31 patients, Ali et al.⁹ confirmed that ICL cracks the calcified arch in 43% of the patients with multiple fractures caused in over 25% of the cases. According to these authors, the efficacy of this technique is proportional to the burden of calcium with a higher rate of calcium fractures (77%) in cases with a higher degree of coronary calcifications. Serious safety issues or technical complications (coronary perforations, important dissections or slow flow/no reflow) have not been reported in the studies. Unlike former reports,¹⁰ Vilalta del Olmo et al.⁸ share encouraging data on a high-risk population with results that are as good as those from other authors.

Although the use of ICL has grown rapidly, the experience published on this device is limited, especially that coming from randomized clinical trials, and some considerations should be made on this regard. The first one is that the navigation capabilities of the device are an important limitation of this technique. Although Vilalta del Olmo et al.⁸ reported that the ICL balloon crossing rate was 100%, our data show that 89% of the lesions required preconditioning with balloon angioplasty (62%) or rotational atherectomy (27%). Therefore, with the current design of the

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Online: 19-03-2020.

<https://doi.org/10.24875/RECICE.M19000093>

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ICL device, in most cases a coadjuvant technique is required prior to the ICL so it can be used effectively which increases the cost of both procedures. Secondly, since the population of the Disrupt CAD II clinical trial¹⁰ included stable patients with concentric lesions, the role of this technique in unstable patients and eccentric calcified lesions should be studied in a randomized controlled trial. Although it is a registry with a small sample size, the data from Vilalta del Olmo et al.⁸ are encouraging on this regard. In the third place, life often outruns science. Although it is a friendly, easy to use technique, randomized clinical trials should be performed to select the patients and establish the indications. For instance, because of the simultaneous presence of compression and decompression forces (pull and push) and the fact that flow is compromised with ICL, its role should be studied in detail in different clinical and angiographic contexts like ST-segment elevation myocardial infarction, chronic total coronary occlusion via subintimal pathway, patients with pacemakers, etc. Other contexts suggested are patients with in-stent restenosis or to facilitate transfemoral access in patients with transcatheter aortic valve implantation. The fourth consideration to make is closely associated with the previous one and is inherent to any new technique: the lack of data on its use and long-term benefit. With the ICL rapid expansion we run the risk of using it in non-studied settings making it a useless and unsafe technique that may increase the rate of complications or lead to worse results. For example, a few isolated clinical cases have been reported on the role of ICL on in-stent restenosis due to stent underexpansion. The study conducted by Vilalta del Olmo et al.⁸ did not report on any of this. Maybe the underlying mechanism of restenosis may explain the observed differences (underexpansion, malapposition, neoatherosclerosis, etc.). Nevertheless, we still need time to study these issues in randomized and controlled clinical trials. ICL balloon tears have also been reported with the resulting added risk.¹¹ In the fifth place, a very important aspect is that ICL may complement other plaque-modifying techniques; its use is feasible and safe with different angioplasty balloons (non-compliant balloons, cutting balloons, and other), rotational atherectomy, etc.¹²

In conclusion, the ICL is a new, attractive, easy-to-learn and use technique for the management of calcified lesions. Randomized clinical trials and further data are needed to establish its indications and benefits. In the coming future this technique will probably simplify the complex procedures associated with percutaneous coronary interventions and improve the outcomes of patients.

CONFLICTS OF INTEREST

None reported.

REFERENCES

- Hahn JY, Chun WJ, Kim JH, et al. Predictors and outcome of side branch occlusion after main vessel stenting in coronary bifurcation lesions (COBIS II registry). *J Am Coll Cardiol.* 2013;62:1654-1659.
- Burzotta F, Trani C, Todaro D, et al. Prospective Randomized Comparison of Sirolimus- or Everolimus-Eluting Stent to Treat Bifurcated Lesions by Provisional Approach. *JACC Cardiovasc Interv.* 2011;4:327-335.
- Dahdouh Z, Roule V, Dugué AE, Sabatier R, Lognoné T, Grollier G. Rotational Atherectomy for Left Main Coronary Artery Disease in Octogenarians: Transradial Approach in a Tertiary Center and Literature Review. *J Interv Cardiol.* 2013; 26:173-182.
- Khattab AA, Otto A, Hochadel M, Toelg R, Geist V, Richardt G. Drug-eluting stents versus bare metal stents following rotational atherectomy for heavily calcified coronary lesions: late angiographic and clinical follow-up results. *J Interv Cardiol.* 2007;20:100-106.
- De Maria GL, Scarsini R, Banning AP. Management of Calcific Coronary Artery Lesions. Is it time to change our interventional therapeutic approach? *JACC Cardiovasc Interv.* 2019;12:1465-1478.
- Lassen JF, Burzotta F, Banning AP, et al. Percutaneous coronary intervention for the left main stem and other bifurcation lesions: 12th consensus document from the European Bifurcation Club. *EuroIntervention.* 2018;13:1540-1553.
- Barbato E, Carrié D, Dardas P, et al. European expert consensus on rotational atherectomy. *EuroIntervention.* 2015;11:30-36.
- Vilalta del Olmo V, Rodríguez-Leor O, Redondo A, et al. Intracoronary lithotripsy in a high-risk real-world population. First experience in severely calcified, complex coronary lesions. *REC Interv Cardiol.* 2019. <https://doi.org/10.24875/RECICE.M19000083>.
- Ali ZA, Brinton TJ, Hill JM, et al. Optical coherence tomography characterization of coronary lithoplasty for treatment of calcified lesions: first description. *JACC Cardiovasc Imaging.* 2017;10:897-906.
- Ali ZA, Nef H, Escaned J, et al. Safety and effectiveness of coronary intravascular lithotripsy for treatment of severely calcified stenoses. The Disrupt CAD II Study. *Circ Cardiovasc Interv.* 2019;12:e008434.
- López-Lliva MT, Jurado-Román A, Sánchez-Pérez I, Abellán-Huerta J, Lozano Ruíz-Poveda F. Shockwave: Useful But Potentially Dangerous. *JACC Cardiovasc Interv.* 2019;12:500-501.
- Jurado-Román A, González A, Galeote G, Jiménez-Valero S, Moreno R. RotaTripsy: Combination of Rotational Atherectomy and Intravascular Lithotripsy for the Treatment of Severely Calcified Lesions. *JACC Cardiovasc Interv.* 2019;12:e127-e129.