## Letters to the Editor

## Quo vadis, coronary lithoplasty

# Quo vadis, litoplastia coronaria

### To the Editor.

Urbano Carrillo et al. have reported the excellent outcome of dilation with a coronary lithoplasty balloon for severe stent underexpansion due to the inadvertent presence of circumferential calcium deposit. We share the enthusiasm for this new technique with a lone, single-arm feasibility study in 60 patients with 6-months' follow-up and published as a research letter<sup>2</sup>-both within the labelled indications for its use<sup>3</sup> and in early off-label use. Among the latter is stent underexpansion, which has 5 reported cases to date.<sup>4</sup> For this serious complication, associated with a risk of acute or late device failure, the available options have been prolonged dilation with nondistensible balloons at high atmospheres (plaque stress), rotational atherectomy of the stent,<sup>5</sup> or coronary laser atherectomy.<sup>6</sup> The indications for these procedures are also off-label, and they are not free of complications, are technically complex, and have limited availability, particularly laser atherectomy. Based on this background and because off-label use of coronary lithoplasty balloon dilation will likely become more widespread, we believe the following important observations should be considered: 1) the crossing profile is  $0.044 \pm 0.002$  inches, and this size may make advancement through an underexpanded device difficult; 2) use of coronary lithoplasty within a stent (recently implanted or endothelialized) is a formal contraindication in the device label<sup>7</sup>; there are no available in vivo data on the effects of mechanical energy cycles on the device scaffold or polymer, or on the stability or kinetics of antiproliferative drug release; nor is there available evidence on the use of more than 1 coronary balloon lithoplasty for breaking plaque or its possible cumulative effects on the device or the vascular architecture; 3) there are no clinical, angiographic, or intracoronary imaging data in these patients, and no data on whether there are late effects on the vessel or the device; 4) restenosis is not a negligible scenario, given the uncertainty about the above concerns and the abundant presence of calcium; 4) imaging studies are mandatory in this context, at least until additional clinical data become available; both StentBoost and optical coherence tomography provide adequate information on proper device expansion, apposition, and structural

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integrity; 5) in the absence of related evidence and given that the kinetics of drug release may be affected, we believe that posterior dilation with a drug-eluting balloon should be a measure to consider; and 6) in our opinion, when there are doubts or evidence of stent fracture, implantation of a new device within the stent is needed.

Despite the currently limited evidence, we believe that in the near future coronary lithoplasty will become the treatment of choice for severe, undilatable stent underexpansion because of its favorable results, availability, and technical simplicity.

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# Quo vadis, coronary lithoplasty. Response Quo vadis, litoplastia coronaria. Respuesta



We greatly appreciate the interest and comments expressed by Arroyo-Úcar et al. regarding our publication. Calcified coronary



lesions are a major challenge for interventional cardiologists, as they are associated with poor short- and long-term outcomes. The presence of calcium complicates the procedure by interfering with preparation of the lesion and restricting final expansion of the stent. An underexpanded stent in a patient with an acute coronary syndrome can have dramatic effects by favoring restenosis, and acute or late stent thrombosis. There are few available resources within this scenario, the most common and widespread being dilation with a noncompliant balloon at very high pressure or rotational stent atherectomy. Nonetheless, various complications have been associated with rotablation in these patients: stent deformation, dissection or

perforation of the vessel, embolization with metallic material, slowflow, and periprocedure infarction.<sup>2</sup> Furthermore, it is a technique that requires adequate training and a learning curve. Coronary lithoplasty is a novel, simple technique, with little reported experience as yet, but holds great promise. The available case series guided by optical coherence tomography have described its effects on calcified plaque and have reported a small percentage of complications.<sup>3</sup> These studies have shown that the energy emitted with this technique interacts with atherosclerotic plague and causes vibrations that fracture the calcium present in both the superficial and deep layers of the vessel wall.<sup>4</sup> We believe that the effect of coronary lithoplasty on deep calcium may be its greatest advantage over other ablative techniques. In this line, we would like to underscore the importance of using optical coherence tomography to evaluate the extent of calcium and its depth and enable individualized treatment for each case. However, additional studies are needed to define the clinical effects of coronary lithoplasty and its impact on the stent structure.

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# Scientific evidence and expert opinion. Why is TAVI different?



Evidencia científica y opinión de expertos. ¿Por qué el TAVI es diferente?

## To the Editor,

We read the article by Jiménez Quevedo et al. on the disparity between scientific evidence and expert opinion regarding the need for on-site cardiac surgery in centers performing transcatheter aortic valve implantation (TAVI), and we would like to thank the working group for underscoring the importance of scientific data in this debate.

The situation in Spain is worthy of analysis, not only for the strikingly diverse initial interpretations of the need for cardiac surgery in these centers, but also for the continuous inconsistencies in relation to this issue. Some examples include ceasing the activity in Andalusia, Catalonia, and Castile and León without having analyzed the outcomes, which in the end, turned out to be very good, maintaining the activity in Castile-La Mancha and Madrid, and later, resuming the activity in Andalusia. To further complicate things, the future suppression of a cardiac surgery service in Basque Country in a center where TAVI is performed will make this situation even more convoluted. Although a part of this haphazardness can be due to fragmentation of the health system, there are other origins.

Up to now, the reasons given have been the potential to resolve complications by having on-site cardiac surgery, and in the recent refusal to reopen 2 centers in Catalonia, not the protection afforded by surgery, but the argument that treatment decisions should be made by a cardiology team.

If there is one specialty that can boast of scientific evidence, it is cardiology. We have very robust data in this line from the AQUA registry of 17 979 patients,<sup>3</sup> which shows no significant differences in mortality rates between centers with and without on-site surgery. These results were confirmed in 1822 cases in Austria and 384 procedures in Spain.<sup>2</sup> Furthermore, in one registry in Europe<sup>4</sup> with 27 760 patients and another in the United States<sup>5</sup> with 47 546 patients, urgent conversion to surgery was required in 0.76% and 1.17% of the total, respectively, with decreasing values over the years. Moreover, many of these procedures were carried out using outmoded techniques, and in both registries half of the small number of patients who required surgery did not survive hospitalization.

The argument about the desirability of decision-making by the cardiology team is very appropriate, but medical-surgical sessions have been conducted in centers without on-site surgery for years, either face-to-face or using one of the many currently available options that do not require personal contact. That said, the recommendation should also be for ischemic heart disease, and therefore, should be implemented in centers where it is not being

We would like to point out the importance of the consequences of the present situation. First, it limits patients' access to treatment, with the subsequent increase in mortality. Second, the Spanish Society of Cardiology should be aware that the professional development of many interventional cardiologists and that of our cardiology services is limited. Advanced imaging is not progressing, and private funding for computed tomography facilities is decreasing, which is crucial given the limited access of cardiology patients to this resource. This has led to the flight of solidly trained professionals to other centers. Third, the Spanish Society of Cardiology should determine whether it is realistic to face the huge demand only with cardiac surgery in the