


Lithotripsy-Facilitated Transfemoral Access for Transcatheter Aortic Valve Replacement

Fernando Rivero¹  · Rosana Hernández-Antolín² · César Morís³ · Teresa Bastante¹ · Luisa Salido² · Fernando Alfonso¹

Received: 4 November 2019 / Accepted: 12 November 2019

© Springer Science+Business Media, LLC, part of Springer Nature and the Cardiovascular and Interventional Radiological Society of Europe (CIRSE) 2019

To the Editor:

A growing number of cardiovascular procedures require high-caliber femoral access devices [1], including transfemoral aortic valve replacement (TAVR) and endovascular repair of abdominal and thoracic aneurysms (EVAR, TEVAR). Unfortunately, a significant number of patients remain ineligible for transfemoral access due to peripheral arterial disease which precludes advancing large-bore delivery systems. Intravascular lithoplasty (IVL) has been shown to be an effective and safe system for the treatment of moderate and severely calcified femoropopliteal arteries [2]. However, the experience with the use of IVL on peripheral vessels to facilitate femoral access during TAVR is very scant [3]. Therefore, we sought to investigate the safety and usefulness of IVL in patients presenting complex, heavily calcified, iliofemoral vascular disease, before transfemoral TAVR (Fig. 1).

A prospective study, with inclusion of consecutive patients in three high-volume TAVR centers, was conducted to explore the feasibility and safety of systematic use of iliofemoral IVL before transfemoral TAVR. Inclusion criteria were as follows: (1) presence of severe symptomatic aortic stenosis suitable for TAVR after

assessment by the Heart Team; (2) challenging transfemoral access due to severe calcified iliofemoral arterial disease including a minimal lumen diameter (MLD) < 6 mm associated with heavily calcified lumen-protruding atherosclerotic plaques on lower limb computed tomography angiography (CTA). IVL was performed using the Shockwave lithoplasty system (Shockwave Medical Inc). All pre-intervention CTA and pre- and post-IVL invasive angiographic studies were independently analyzed in a central core-lab by a blinded operator using dedicated software (3mensio; Pie Medical). The primary endpoint of the study was IVL success, defined as a successful TAVR delivery sheath and system passage throughout the aortoiliac arteries without vascular complications. In every patient, clinical follow-up was obtained 1 month after discharge. All patients gave written informed consent in accordance with a protocol approved by the Institutional of the coordinating center.

A total of 11 consecutive patients (age: 81 ± 4 years; diabetes mellitus: 55%) were included. Most target lesions were located in the common iliac artery (64%) showing a CTA-derived MLD of 4.5 mm (IQR 3.3–6.1) and a mean calcium arch of $145 \pm 74^\circ$. In 4 patients (36%), an initial failed to cross the corresponding sheath prompted the bailout use of IVL that, eventually, proved to be successful in all these cases. All IVL procedures were performed with a 7×60 mm balloon catheter at 6.2 ± 0.6 atmospheres (126 ± 90 pulses per lesion) without the need for previous conventional balloon angioplasty in any patient. The angiographic acute lumen gain after IVL was 0.9 ± 0.2 mm. No iliofemoral arterial complication was observed, and there was no need for post-IVL angioplasty in any patient. All patients achieved successful sheath passage and TAVR intervention after IVL. Femoral

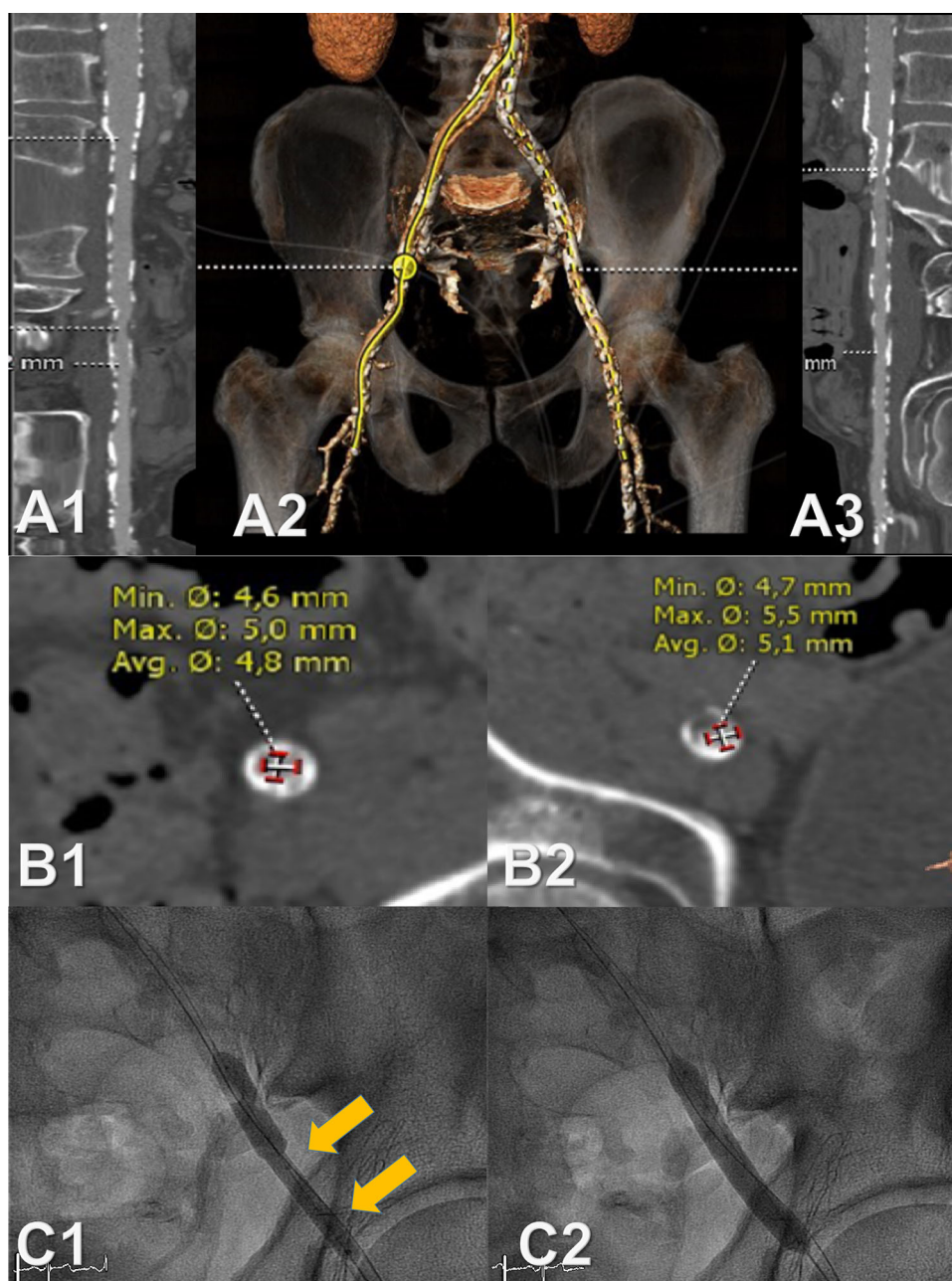
✉ Fernando Alfonso
falf@hotmail.com

¹ Cardiology Department, Hospital Universitario de La Princesa, Instituto de Investigación Sanitaria IIS-IP, Universidad Autónoma de Madrid, CIBER-CV, C/Diego de León 62, 28006 Madrid, Spain

² Department of Cardiology, University Hospital Ramon y Cajal, Madrid, Spain

³ Cardiology Department, Hospital Universitario Central de Asturias, Oviedo, Spain

Fig. 1 **A1–A3** Three-dimensional computed tomography showing severe calcified iliofemoral arteries with a minimum lumen diameter located at the level of the left and the right common femoral arteries; **B1, B2** computed tomographic analysis of the iliofemoral system revealed severe calcified lesions with smallest luminal diameter at the level of the common femoral arteries (4.6 mm for the left and 4.7 mm for the right); **C1** IVL treatment of the common femoral artery showing a balloon waist at 6 atm (arrows) before delivering the therapy; **C2** after two ultrasonic pulse cycles the initial infraexpansion of the balloon could be solved using the same pressure (6 atm), allowing successful crossing of the TAVR sheath



hemostasis was achieved in all patients using standard closure devices without any access site complication. At 1-month clinical follow-up, there were no vascular complications or complains of claudication in any patient.

Our results suggest that IVL may play an important role in the management of challenging calcified peripheral arterial disease in patients requiring TAVR, EVAR or TEVAR procedures. However, further studies, including a larger number of patients, will be required to confirm these satisfactory preliminary findings.

Funding This study was not supported by any funding.

Compliance with Ethical Standards

Conflict of interest The authors declare that they have no conflict of interest.

Ethical Approval All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. This study has been approved by the local Institutional Review Board (IRB).

Informed Consent Informed consent was obtained from all individual participants included in the study. Consent for publication was obtained for every individual person's data included in the study.

References

1. Elgandy IY, Mahmoud AN, Gad MM, Elbadawi A, Rivero F, Alfonso F. Transcatheter or surgical aortic valve replacement for low surgical risk patients: meta-analysis of randomized trials. *JACC Cardiovasc Interv.* 2019;12(14):1399–401.
2. Brodmann M, Werner M, Brinton TJ, et al. Safety and performance of lithoplasty for treatment of calcified peripheral artery lesions. *J Am Coll Cardiol.* 2017;70:908–10.
3. Di Mario C, Goodwin M, Ristalli F, Ravani M, Meucci F, Stolcova M, Sardella G, Salvi N, Bedogni F, Berti S, Babaliaros VC, Pop A, Caparrelli D, Stewart J, Devireddy C. A prospective registry of intravascular lithotripsy-enabled vascular access for transfemoral transcatheter aortic valve replacement. *JACC Cardiovasc Interv.* 2019;12(5):502–4.

Publisher's Note Springer Nature remains neutral with regard to jurisdictional claims in published maps and institutional affiliations.