A Case of Critical Calcified Innominate Artery Stenosis Successfully Treated With the Shockwave Lithoplasty

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ABSTRACT

PURPOSE: The Shockwave Lithoplasty System represents a novel technology combining a balloon angioplasty catheter with the use of sound waves. Evidences suggest that it is a reliable tool to overcome calcified stenosis in both peripheral and coronary arteries. Here, we describe the case of a patient with calcified innominate artery stenosis successfully treated with the Shockwave Lithoplasty System.

CASE REPORT: A 78-year-old woman with hypertension, and dyslipidemia, came to our observation for dizziness. Instrumental examinations showed critical calcified stenosis of the innominate artery. The lesion was successfully treated with the Shockwave Lithoplasty System and subsequent stent apposition. Final angiography demonstrated excellent position of the stent, good wall apposition, and confirmed patency of the right common and right vertebral artery origins.

CONCLUSION: Our clinical experience demonstrates that Lithoplasty is safe and effective also for the treatment of supra-aortic vessels.

KEYWORDS: Lithoplasty, Innominate artery, calcification, stenting

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Introduction

Despite many advances in the field of endovascular intervention, the treatment of calcified artery stenosis still represents a significant challenge for the interventional cardiologist. Indeed, a calcified lesion is hard to treat and associates with difficulty in stent delivery or incomplete stent expansion.[1] Current techniques to overcome these lesions include standard or high-pressure non-compliant balloons, cutting/scoring balloons, or rotational atherectomy.[2] However, these techniques are encumbered by several complications such as vascular wall injury, artery dissection, or perforation.

In recent years, therapeutic armamentarium has been enriched by the Shockwave Lithoplasty System. It consists in a novel technology combining a balloon angioplasty catheter with the use of sound waves, similar to that used for treating kidney stones. Lithoplasty catheter emits sound waves that disrupt arterial calcifications before stent implantation. Preliminary evidences suggest that it is a sure and reliable tool to overcome calcified stenosis in both peripheral and coronary arteries.[3-6]

Here, we describe the case of a patient with calcified innominate artery stenosis successfully treated with the Shockwave Lithoplasty System.

Case Report

A 78-year-old woman with hypertension, and dyslipidemia, came to our observation for dizziness. Echo-Doppler examination showed retrograde right vertebral artery flow with a "post-stenotic pattern" flow in the ipsilateral subclavian and carotid arteries (Figure 1A). To deepen this finding, the patient underwent computed tomography that revealed critical calcified stenosis (90%) of innominate artery (Figure 2A). After team discussion, we decided to treat this lesion through endovascular intervention.

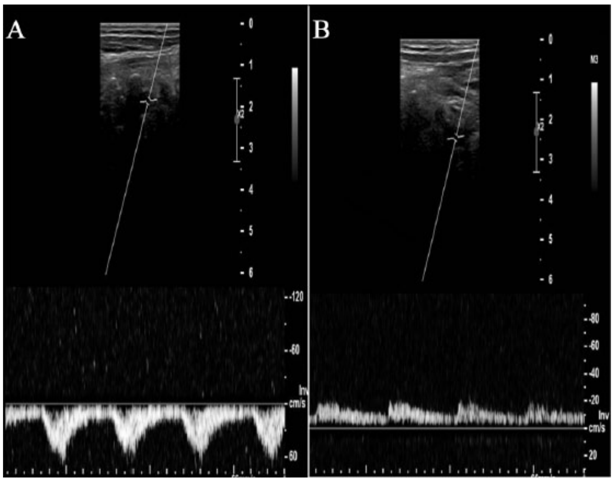

Figure 1. Echo-Doppler examination showing: (A) reversal flow in the right vertebral artery (B) recovery of normal flow after intervention.

Under local anesthesia, right femoral and radial arteries were cannulated with a 6F sheath, and a selective angiography of the brachiocephalic trunk was performed. Dual injection confirmed the presence of a critical calcified stenosis (99%) at the proximal trait of innominate artery (Figure 3A).

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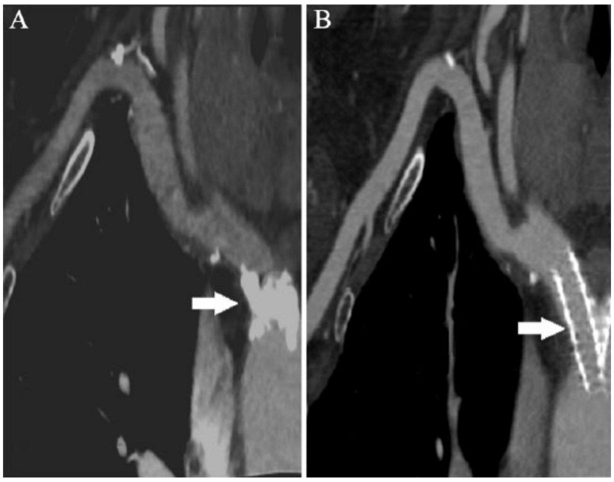

Figure 2. Computed tomography examination showing: (A) critical calcified plaque of Innominate artery; (B) patency of the Innominate artery after stenting.

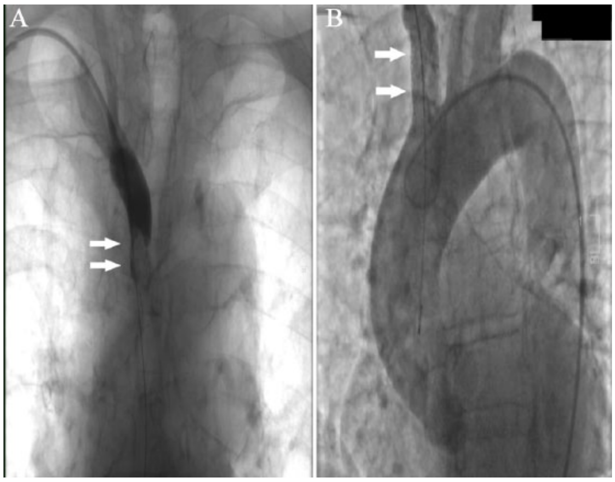

Figure 3. Angiography showing: (A) critical calcified plaque of Innominate artery; (B) patency of the Innominate artery after stenting.

Once diagnostic angiography is performed, we proceed with the treatment of the lesion. Via radial access, we crossed the lesion with a guidewire 0.018 inch (V18 ControlWire, Boston Scientific, Marlborough, MA, USA) and performed a pre-dilation with a 4 mm × 60 mm semi-compliant balloon (Sterling, Boston Scientific) inflated at 20 atm.

Afterward, using a 0.014 inch guidewire (Luge, Boston Scientific), a 4.0 mm × 12 mm Lithoplasty balloon (Shockwave Medical, Fremont, California) was conducted at the lesion level. It was inflated to 4 atm and 6 pulses of ultrasound energy of 10 seconds were applied. Once the lithoplasty treatment is completed, a semi-compliant balloon (Alvipro, 8 mm × 40 mm, Alvimedica, Istanbul, Turkey) inflated at 8 atm was used to further dilate the lesion. Finally, a 9 mm × 29 mm stent (Isthmus, CID) was deployed at 10 atm and post dilated with a 10 mm × 20 mm non-compliant balloon (Mustang, Boston Scientific) inflated at 8 atm.

Final angiography demonstrated excellent position of the stent, good wall apposition, and confirmed patency of the right common and right vertebral artery origins (Figure 3B).

Subsequent echo-Doppler and computed tomography confirmed the recovery of normal flow in the right vertebral, carotid, and subclavian arteries (Figures 1B and 2B).

Discussion

To the best of our knowledge, we described the first case of a critical calcified stenosis of innominate artery successfully treated with the Shockwave Lithoplasty System.

It is well recognized that percutaneous transluminal angioplasty of innominate artery is very challenging due to its large diameter, short length, and the proximity to the origin of the right common carotid artery (CCA).[7] In our case, the presence of a calcified plaque added another important difficulty to the percutaneous intervention. Given the impossibility to overcome this lesion with the common endovascular devices, we decided to employ Shockwave Lithoplasty.

The Lithoplasty System integrates angioplasty balloon catheter devices with the calcium-disrupting power of sonic pressure waves. Each Lithoplasty catheter incorporates multiple lithotripsy emitters activated with the touch of a button after the balloon is inflated. In detail, the balloon is inflated to 4 atm using a mixture of saline and contrast solution to achieve balloon-vessel wall apposition. Subsequently, a small electrical discharge at the emitters vaporizes the fluid and creates a rapidly expanding bubble within the balloon. This bubble generates a series of sonic pressure waves that are highly tissue-selective, passing through the balloon and soft vascular tissue, to selectively disrupt calcium. Once the calcium has been modified, the vessel can be dilated using low pressures. The Lithoplasty system received Food and Drug Administration (FDA) approval in 2016 and has been available in Europe since 2015. To date, Lithoplasty system is employed for the treatment of calcified lesion in various vascular districts such as coronary, iliac, femoral, popliteal, infra-popliteal, and renal arteries. Safety and performance are supported by clinical data from results of DISRUPT CAD I, a pre-market, prospective multi-center single-arm study conducted at 7 centers in Europe and Australia. The study evaluated the use of the Shockwave Medical Coronary Lithoplasty System as a treatment for calcified coronary arteries prior to stent implantation. In a recent study using optical coherence tomography, Ali et al[3] demonstrated that Lithoplasty creates micro-fracture in the calcium deposits and further demonstrated efficacy in the achievement of significant acute area gain and favorable stent expansion.

The Disrupt Below-the-Knee (BTK) study was a prospective, nonrandomized, multicenter pilot study conducted at 3 sites in Austria, Germany, and New Zealand. This investigation was aimed to explore the utility of Lithoplasty in treating calcified infrapopliteal stenosis. The results of this pilot study demonstrated that calcified, stenotic infrapopliteal arteries can be safely and successfully treated with intravascular lithotripsy.[5]

The novelty highlighted in our article relates to the use of Lithoplasty also in the treatment of calcified stenosis in a vascular district such as innominate artery. Traditionally, surgical intervention was the preferred way to treat these types of lesions. Over the years, with the development of endovascular techniques, surgical approach has been increasingly shelved. Despite these progresses, calcified lesions represent a hard obstacle to overcome. Thanks to the Lithoplasty technology, we were able to enhance plaque compliance by disrupting calcium deposits and then facilitate the correct stent apposition. Of note, in contrast to the other devices (ie, rotational atherectomy, cutting balloons) which generate microparticles that embolize distally, large calcium fragments generated by lithoplasty remained in situ, reducing the risk of embolization.

In conclusion, our clinical experience demonstrates that Lithoplasty is safe and effective also for the treatment of supra-aortic vessels. Future clinical trials are warranted to extend our observation in the general population.

Author Contributions

CT and EJT drafted the manuscript. PG performed endovascular procedure. GM contributed to the acquisition of the clinical data. BM and DM provided a detailed review of the contents and structure of the manuscript. All of the authors have read and approved the final manuscript.

Informed Consent

Informed consent has been obtained from the patient for publication of the case report and accompanying images.

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