Future CARDIOLOGY

Case Report

The use of shockwave intravascular lithotripsy for the treatment of calcified renal artery stenosis in symptomatic subject

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Purpose: The use of shockwave lithotripsy for the treatment of heavily calcified atherosclerotic plaques before stenting showed great results in terms of feasibility and safety with favorable initial success. Evidence suggests that it is a useful tool to treat calcified lesions in peripheral and coronary arteries. Here, we describe the case of a patient with calcified renal artery stenosis successfully treated with the shockwave lithotripsy system. **Case Report:** We present a 76-year-old man with a known significant atherosclerotic renal artery stenosis and refractory hypertension. The patient received an angioplasty of the right renal artery in the first session and he was admitted for a second session to intervene in the left renal artery. The lesion was successfully treated with the lithotripsy system. Final angiography demonstrated an excellent position of the stent and good wall apposition. **Conclusion:** Our clinical case demonstrates that lithotripsy is safe and effective also for the treatment of the renal artery.

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There is no doubt that the treatment of calcified artery lesions represents a serious challenge despite the great advances in the endovascular interventions. Calcified plaques impact interventional outcomes by reducing stent expansion and reducing drug delivery and elution [1]. For these reasons, medical technology today offers many innovative tools to increase interventional success and reduce complications. Tools like high-pressure non-compliant balloons, rotational atherectomy and scoring/cutting balloons are current techniques used to overcome challenging lesions. The use of shockwave lithotripsy for the treatment of heavily calcified atherosclerotic plaques before stenting showed great results in terms of feasibility and safety with favorable initial success [2]. The shockwave catheter contains multiple lithotripsy emitters in an integrated balloon which allows creating sonic pressure waves for circumferential field effect. These sonic pressure waves selectively fracture calcium, altering vessel compliance, while minimizing barotrauma attributable to low inflation pressure (4 atm), thus maintaining the fibroelastic architecture of the vessel wall. The intravascular lithotripsy (IVL) catheter, available in 2.5–4.0 mm diameters and 12 mm in length, is connected via a connector cable to the generator that is preprogrammed to deliver 10 pulses in sequence at a frequency of 1 pulse/s for a maximum of 80 pulses per catheter [2]. Here, we describe the case of a patient with calcified renal artery stenosis successfully treated with the IVL system.

Case presentation

We report about a patient who was presented to our center for a planned angioplasty of the left renal artery. The patient is a 76-year-old male with multiple cardiovascular risk factors (Patient information is presented in Table 1). He has a chronic kidney disease stage 3b (with a history of urgent dialysis) and biological aortic valve replacement 6 years ago. The patient has resistant arterial hypertension despite maximal drug therapy (five antihypertensive medications including a β-blocker, calcium channel antagonist, ACE-antagonist, diuretic and α-adrenoreceptors

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Table 1. Patient information.

Patient information	
Gender	Male
Age (years)	76
BMI (kg/m^2)	34.3
Admission blood pressure (mmHg)	170/90
Discharge blood pressure (mmHg)	140/80
Creatinin (mg/dl)	1.69
GFR (ml/min)	41.96
Potassium	4.72
Sodium	136
Left ventricle ejection fraction (%)	65
Important baseline diseases	• History of stroke • History of aortic valve implantation • Sleep apnea syndrome • Chronic renal disease (G3b, A2) with a history of emergency dialysis.
Cardiovascular risk factors	• Arterial hypertension • Diabetes • Metabolic syndrome • Hyperlipidemia
Follow-up data (3 months)	
Blood pressure (mmHg)	125/75
Potassium (mmol/l)	4.48
Sodium (mmol/l)	140
Creatinin (mg/dl)	1.3
GFR (ml/min)	57.01

BMI: Body mass index; GFR: Glomelular filtration rate.

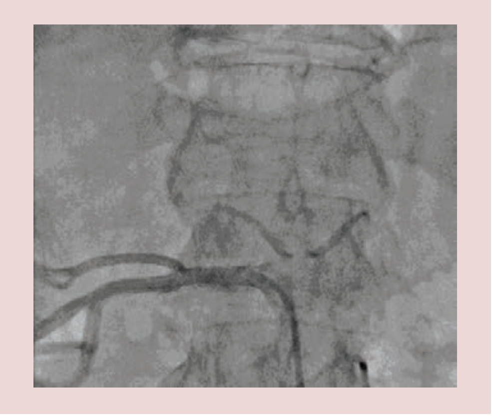

Figure 1. Right rental artery after angioplasty.

antagonist). The therapy was administered in different centers and the maximal dose of all drugs was successfully applied but unfortunately without a significant, clinically important reduction of the systolic blood pressure. After a complete workup, a significant bilateral renal artery stenosis discovered using different diagnostic methods (Doppler and CT-angiography). In the first session, angioplasty of the right renal artery a month before the admission was successfully performed. He presented this time for angioplasty of the left renal artery. After the last procedure, the patient reported better controllable blood pressure values and improvement of the renal function (creatinin and GFR have improved).

The second procedure was performed using a femoral approach (right femoral artery). Under local anesthesia, the right femoral artery was cannulated with a 6F sheath. The angiographic evaluation of the right renal artery postprocedure showed a good result after the first angioplasty (Figure 1). Thereafter we attempted to selectively perform angiography of the left renal artery, but because of high-grade exit stenosis with strong calcified proximal lesion the process was very difficult and we could perform just a nonselective angiography as shown in Figure 2.

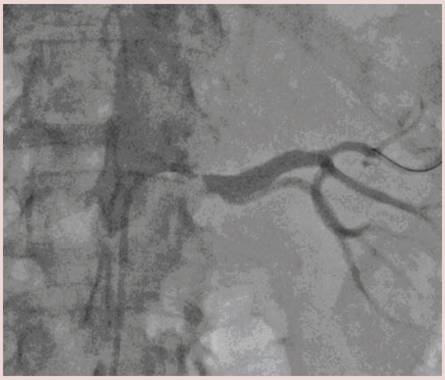

Figure 2. Left renal artery before the angioplasty showing a high grade exit stenosis.

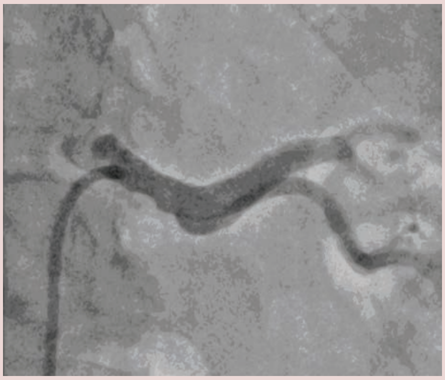

Figure 3. Left renal artery after angioplasty.

Table 2. Procedural data.

Procedural data	
Procedure date	31.07.2019
Procedure duration (min)	66
Fluoroscopy time (min)	19.3
Total surface dose (μGy $\times$ m^2)	2920
Contrast agent volume (ml)	210
Access site	Right femoral artery
Sheath size	6F
Heparin dose (I.E.)	10000
Balloon type and length pressure and time	EMERGE MR 3.00 × 15.0012 Bar, 12 sec
Lithotripsy catheter	M5 peripheral, IVL, 5.00 × 60 mm
Stent type and length	Herculink plus 7 × 15 mm

Contrast agent injection confirmed the presence of critical calcified stenosis (99%) at the proximal part of the left renal artery. After the diagnostic angiography, we proceeded with the treatment of the lesion. We crossed the lesion with a guidewire 0.014 (Hi-Torque BMW 0.014 /190 cm) and performed a predilatation with a 3.0 cm balloon (EMERGE MR, 3.00 × 15 mm, 12 Bar). As a next step, we did a plaque modification using a shock wave lithotripsy balloon (5.0/60 mm). It was inflated to 4 bar and 30 pulses of ultrasound energy of 10 sec were applied. Once the lithotripsy treatment is completed, a 7.0 × 15 mm drug-eluting stent (Herculink) was deployed at 10 Bar. Final angiography demonstrated an excellent position of the stent, good wall apposition and confirmed patency of the left renal artery origins (Figure 3). The procedural data is represented in Table 2. There were no in-hospital complications observed. The patient reported in the 3 months-follow-up a significant reduction of the

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systolic blood pressure, leading to a reduction of the medication dose. Furthermore, the patient did not experience any symptomatic blood pressure elevation at the next month following the intervention. The blood pressure was controlled with routine home measurements and 24-h ambulatory monitoring.

Discussion

To the best of our knowledge, we present the first case of critical calcified stenosis of the renal artery treated successfully with the shockwave lithotripsy system. It is well known that the angioplasty of renal artery represents a big challenge due to the large diameter. The presence of a calcified plaque increases the difficulty of this percutaneous intervention. Since it was impossible to overcome the lesion with common techniques, we decided to employ this novel shockwave lithotripsy system. Patients with symptomatic atherosclerotic and hemodynamically significant renal artery stenosis and no success of medical therapy in addition to a declining renal function and cardiac destabilization syndromes seem to benefit from renal artery stenting [3]. Balloon angioplasty alone is reported ineffective because of the bulky aorto-ostial plaque and the recoil associated with it [4]. In unexperienced hands, the complication rate approaches 2% [5]. Different techniques have been proposed to reduce complications. Using IVL helps to treat the lesion in the first place followed with easier stent implantation. The system integrates an angioplasty balloon catheter device with calcium-disrupting power of sonic pressure waves. In each catheter are multiple lithotripsy emitters incorporated, which can be activated with a button. A small electrical discharge at the emitters vaporizes the fluid creating 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. After the modification of the lesion, the vessel can be dilated with low pressures [6]. The system received the US FDA approval in 2016. It is employed for the treatment of calcified lesions in various arteries. Different clinical trials like DISRUPT CAD I and Disrupt Below-the-Knee demonstrated good results in terms of safety and success using the method to treat calcified lesions in coronary and infrapopliteal arteries [7]. Our case demonstrated the benefit of using the lithotripsy system in a very challenging lesion. Treating the lesion with the system simplified the procedure and provided us with support in an anatomical difficult lesion. Great stent position with perfect wall apposition was also achieved.

Conclusion

Renal artery stenting with optimal stent size is the revascularization procedure of choice in lesions where hemodynamic significance has been confirmed. Overall the procedure is considered to be a safe and effective treatment in a selected patient group [8]. The use of a shockwave IVL is already known to be a very helpful and safe tool to manage challenging high calcified lesions in the coronary, popliteal and femoral arteries. In our case, the use of lithotripsy seems to be a helpful method in treating challenging lesions also in the renal arteries. Calcified lesions represent a hard obstacle to overcome. Thanks to the lithotripsy system, we were able to modify the plaque by disrupting calcium deposits and then facilitate the correct stent apposition. Future clinical trials are required to study the safety and efficacy of this method and to extend this observation in the general population.

Summary points

- Calcified artery lesions present today a big challenge for the interventional cardiologists. Insufficient treatment of those lesions impacts the procedure outcomes which can lead to insufficient stent expansion and the reduction of the drug delivery.
- The intravascular shockwave lithotripsy system represents a new technology to overcome calcified stenosis.
- In our case, we describe the case of a patient with calcified right renal artery stenosis successfully treated with shockwave lithotripsy system.
- The angiography of the left renal artery in our case showed critical calcified stenosis. Treating the lesion with the shockwave lithotripsy system simplified the stent implantation and provided a good apposition of the stent.
- The current clinical case demonstrates that the use of the shock wave lithotripsy system is safe and effective in the treatment of calcified renal artery stenosis.
- Randomized trials are needed to study the safety and efficacy of this method in treating calcified lesions.

Financial & competing interests disclosure

The authors have no relevant affiliations or financial involvement with any organization or entity with a financial interest in or financial conflict with the subject matter or materials discussed in the manuscript. This includes employment, consultancies, honoraria, stock ownership or options, expert testimony, grants or patents received or pending, or royalties.

No writing assistance was utilized in the production of this manuscript.

Ethical conduct of research

The authors state that they have obtained verbal and written informed consent from the patient/patients for the inclusion of their medical and treatment history within this case report.

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