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CASE REPORT
Other

The conundrum of endovascular common femoral artery treatment: a case report of lithoplasty as a viable solution

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Background Highly calcific stenosis located in common femoral artery (CFA) represents a difficult target for endovascular treatment due to the possible need for stent implantation in that area.

Case summary A 63-year-old man with history of coronary artery disease and previous multiple percutaneous transluminal angioplasties for peripheral artery disease (PAD) was admitted for recent onset left lower limb pain at rest with severe activity restriction (Leriche-Fontaine Class III and Rutherford Class III–IV). The angio-computed tomography scan showed a highly calcific stenosis of left CFA. The patient underwent lithoplasty balloon angioplasty followed by drug-eluting balloon inflation with excellent angiographic result and complete blood flow restoration. No procedural complications occurred.

Discussion Highly calcified stenosis in PAD represents a huge challenge for endovascular treatment as not all lower extremity arteries are suitable for stenting because of compressive and torsional forces associated with stent fracture and restenosis. Lithoplasty is a new technology allowing effective blood flow restoration while minimizing vessel injury.

Keywords Lithoplasty • Common femoral artery • Peripheral artery disease • Case report • Highly calcified vessels

Learning points

- Highly calcific stenosis located in common femoral artery (CFA) represents a huge challenge for endovascular treatment.
- Stent positioning in CFA may be limited by the compressive or torsional forces leading to stent fracture and/or restenosis.
- Lithoplasty balloon angioplasty is an effective treatment for calcific vessels and may represent a safe tool also for CFA.

Introduction

Endovascular approach has become the first choice treatment for lower extremity artery disease (LEAD), as recommended by the European Society of Cardiology guidelines on the diagnosis and treatment of peripheral artery disease (PAD).[1] However, common femoral artery (CFA) still represents an almost forbidden target for endovascular treatment due to the reluctance to implant a stent in

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that area if needed. Moreover, highly calcified lesions represent a challenging subset as technical success and patency rates are poor, affecting both short- and long-term outcome.[2–4] Circumferential distribution of calcium is the most negative influencing factor[5] and increases the occurrence of flow-limiting dissections[2] and acute vessel recoil after percutaneous transluminal angioplasty (PTA). Furthermore, stenting itself may be impaired due to subexpansion, malapposition, and fractures.[6]

Directional atherectomy followed by drug-eluting balloon (DEB) inflation showed positive results in small studies,[7,8] although data are still controversial.[9,10] Alternatively, scoring balloon has been demonstrated to be safe and effective for both femoropopliteal and infrapopliteal lesions, but data are still limited.[11,12]

Recently, a new device, the Shockwave Medical Peripheral Lithoplasty System, has demonstrated its safety and efficacy in the treatment of calcified, stenotic infrainguinal peripheral arteries. It integrates two functions:

- the intermittent pulsatile mechanical energy of lithotripsy disrupt the calcium; and
- the integrated balloon dilates the lesion restoring the blood flow.

It has been tested in a two-phase, single arm, prospective, multicentre study, DISRUPT PAD I and II[13] where high rates of procedural success, patency, and freedom from target lesion revascularization at 30 days and at 6 months were reported. As regards safety outcomes no vascular complications occurred and no stents were implanted. Distal embolic filters were used in six patients and thrombus was found in only one filter. Consequently, it may play an important role in severely calcific LEAD management.

Timeline

Past cardiovascular history	Left superficial femoral artery percutaneous transluminal angioplasties + stenting and coronary artery bypass grafting
One month prior to admission	Left lower limb pain at rest with severe activity restriction
In-hospital management	Lithoplasty balloon angioplasty in common femoral artery
Six-month follow-up	Patient still asymptomatic for limb pain and no activity restriction occurrence

Case presentation

A 63-year-old man with history of coronary artery disease treated by coronary artery bypass graft was admitted for recent onset left lower limb pain at rest with severe activity restriction (Leriche-Fontaine Class III and Rutherford Class III–IV). He had already undergone PTA with stent implantation on the left superficial femoral artery several years before.

Figure 1 (*A* and *B*) Computed tomography scan image before treatment.

An angio-computed tomography was performed showing highly calcific stenotic left CFA, (*Figure 1A* and *B*). Despite the high calcium burden no severe calcific stenosis was found on the right side. After in-depth discussion with the patient and upon his strong preference, a decision to attempt endovascular treatment was taken. Patient gave inform consent.

Access site

Shockwave balloons from 3.5 to 6 mm are 6-Fr introducer sheath-compatible with 110 cm length so a right femoral approach with crossover technique was selected.

In order to increase precision, ultrasonographic guidance was adopted for the right common femoral puncture. A 6-Fr sheath was placed and left common iliac artery access was obtained through a Judkins right guiding catheter. A subtraction angiography of the left iliac-femoral axis was then performed confirming highly calcific stenosis of the CFA (*Figure 2*).

Angioplasty technique

Severely calcific stenosis was crossed with 300 cm Choice PT Extra-Support guidewire (Boston Scientific). Lithotripsy catheter (Shockwave Medical Inc.) was advanced to the lesion site, so the manufacturer's instructions were followed:

- lithoplasty balloon (6 × 60 mm) inflation to 4 atm (*Figure 3*).
- Shockwave treatment (30 pulses).

Figure 2 Common femoral artery angiogram.

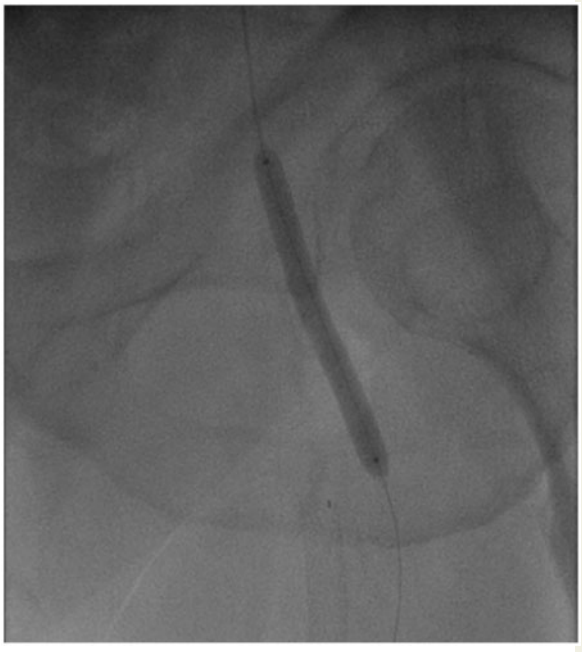

Figure 3 Lithoplasty balloon inflation in common femoral artery.

- Lithoplasty balloon deflation in order to re-establish blood flow (30 s).
- Further lithoplasty balloon inflation to 6 atm (30 s).
- The same sequence was repeated for six times for a total of 180 pulses in the same segment.

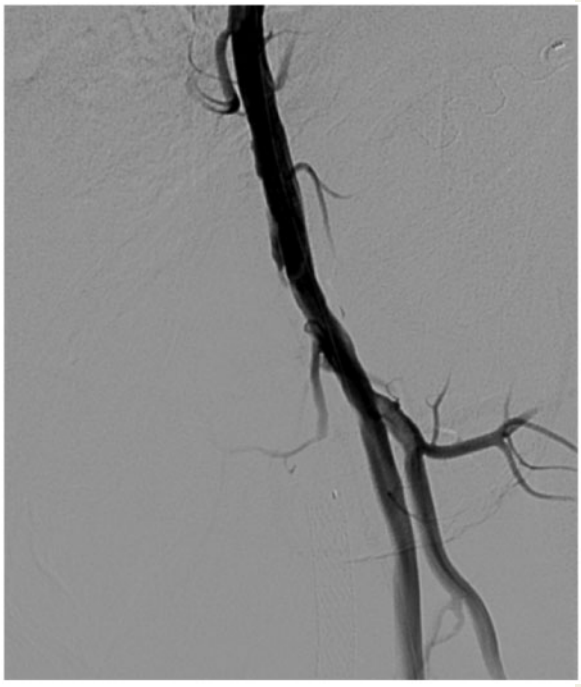

Figure 4 Final angiography.

After the entire shockwave treatment was completed an angiogram was performed in order to assess post-intervention result (*Figure 4*). After calcifications disruption, the lesion was finally dilated with a 7 × 60 mm DEB and the final arteriogram showed a good angiographic final result with completely restored flow and no residual vascular calcium.

The patient was discharged the day after the procedure and after 9-month follow-up, no symptoms/activity restriction were reported.

Discussion

Although the true prevalence of vascular calcification in symptomatic PAD patients may vary a lot, we know that it represents a significant challenge for current endovascular device strategies. Indeed, it increases the procedure-related adverse events from early elastic recoil to dissections, perforations, and embolization, which, in some cases, lead to bailout stenting. However, not all lower extremity arteries are suitable for stenting as subject to compressive or torsional forces and consequently associated with stent fracture and restenosis.

In this perspective, the use of innovative techniques may help in the treatment of severely calcific lesions.

Lithotripsy is a well-established treatment adopted for calcified renal calculi, in which calcifications are fragmented by high-power acoustic shockwaves. Lithoplasty is a new technology based on lithotripsy where the circumferential pulsatile energy disrupting the calcified plaque is combined with the balloon inflation force. It is

effective to restore blood flow into the highly calcified stenotic artery, minimizing vessel injury.

The case we described is the first case of lithoplasty applied to the CFA as the previous studies (PAD I and II) were focused on superficial femoral artery and popliteal lesions and some reports exist on iliac treatment.[14] Although a recent paper[15] showed positive results for stenting, CFA is usually considered not suitable for stenting consequently PTA in this segment needs to be very careful. In a retrospective analysis, Guo *et al.*[16] have recently demonstrated that atherectomy might be better than angioplasty for CFA atherosclerotic obstructive lesions, especially in bifurcations. However, this technique might be limited by the high rates of dissection and consequent need for stenting. Angioplasty and provisional stenting were also compared in 96 patients undergoing isolated percutaneous revascularization of CFA. In more than one-third of patients undergoing angioplasty, stent placement became necessary, with a restenosis 14%.[17]

In our case, lithoplasty balloon was highly effective as shown by the pre- and post-procedural angiograms (*Figures* 2 and 4), and was safe as no early/late vascular complication occurred. Although larger studies are needed to confirm our result, peripheral lithoplasty seems a promising system for the treatment of highly calcified lesions not only in the superficial femoral artery and popliteal segments but also in CFA.

Lead author biography

Professor Carlo Trani is the Head of Cath Lab at Catholic University of the Sacred Heart in Rome.

Supplementary material

Supplementary material is available at *European Heart Journal - Case Reports* online.

Slide sets: A fully edited slide set detailing this case and suitable for local presentation is available online as Supplementary data.

Consent: The author/s confirm that written consent for submission and publication of this case report including image(s) and associated text has been obtained from the patient in line with COPE guidance.

Conflict of interest: F.B. discloses to have been involved in advisory board meetings or having received speaker's fees from Medtronic, St Jude Medical, Abiomed, and Biotronic. C.T. discloses to have been involved in advisory board meetings or having received speaker's fees from St Jude Medical, Abiomed, and Biotronic. C.A. has been involved in advisory board activities by Biotronic. G.R. has no conflict of interest to declare.

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