

First case report of fully robotically assisted lithotripsy in heavily calcified left main stenosis

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Background

Percutaneous coronary intervention (PCI) is the standard-of-care treatment for left main stenosis as an alternative to bypass surgery. In addition, severe coronary lesion calcification can be modified by intravascular lithotripsy (IVL). However, with PCI and debulking treatment options, there are inherent limitations. PCI poses an increased health burden for the treating physician that is associated with wearing a heavy, lead-lined apron and being exposed to radiation. To overcome these issues, a robotically assisted angioplasty system (rPCI) was established that enables the operator to perform PCI remotely in routine clinical procedures. Furthermore, IVL have not been used remotely.

Case summary

Here, we report the use of this technique for treating a heavily calcified left main stenosis in an 82-year-old male with previously diagnosed two-vessel coronary artery disease, progressive symptoms of dyspnoea at high cardio-vascular risk profile. The decision of the local heart team declined surgery. To the best of our knowledge, this is the first report of successful rPCI combined with IVL.

Discussion

In the case presented, rPCI was feasible and safe even in a complex lesion of the left main coronary artery requiring IVL. rPCI is a revolutionary new technique that may be applied to various types of coronary artery lesions.

Keywords

Robotic PCI (rPCI) • Percutaneous coronary intervention • Lithotripsy • Left main stenosis • Calcified stenosis • Case report

ESC Curriculum 3.1 Coronary artery disease • 3.3 Chronic coronary syndrome • 3.4 Coronary angiography

Learning points

- Robotically assisted percutaneous coronary intervention (PCI) utilizing lithotripsy to prepare heavily calcified lesions is feasible and safe and can be used in routine practice in catheter laboratory.
- Robotic PCI is safe when used to treat left main stenosis.

Background

PCI is associated with a physical burden for the interventionalist due to radiation exposure and protection measures, leading to both orthopedic issues as well as radiation-induced brain tumors, lymphoma,

and cataracts.¹ Particularly in cases with heavily calcified lesions requiring complex PCI, the procedural time and the physician's radiation exposure and physical burden is high as great precision is required. To overcome these issues, a robotically assisted angioplasty system was implemented that allows the operator to perform PCI procedures

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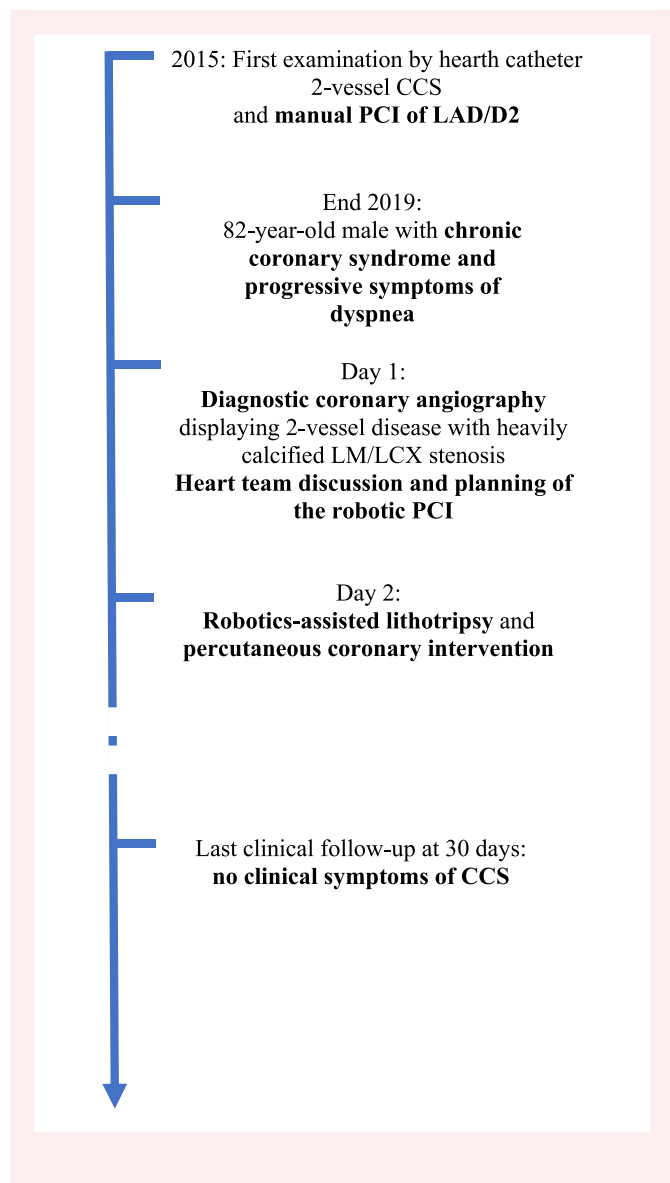
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remotely (rPCI).² Here we describe the application of rPCI and the recently introduced intravascular lithotripsy (IVL) technique for plaque modification in a heavily calcified stenotic lesion of the left main (LM) coronary artery. To the best of our knowledge, this debulking technique has not been used remotely, due to its relatively new clinical application.

Timeline



Case summary

An 82-year-old Caucasian male patient with progressive symptoms of dyspnoea was referred to our center. Known cardiovascular risk factors were arterial hypertension, hyperlipoproteinaemia, and persistent nicotine use. Renal function was normal. Echocardiography showed normal left ventricular ejection fraction without regional wall motion abnormalities or valvular diseases. PCI of LAD/D2 had been performed previously within the context of chronic coronary syndrome in 2015. At admission to our department, the patient was in age-appropriate

physical condition (>4 MET). Physical examination at rest including auscultation appeared unremarkable and at exertion there was no evidence of angina (CCS 0) but dyspnoea (NYHA III).

Renewed coronary angiography at the first day showed coronary two-vessel disease with intermediate stenosis in the left main (LM) and high-grade ostial stenosis of the left circumflex artery (LCX). Intravascular ultrasound (IVUS) of the LCX to LM showed a minimal lumen area of 1.8 mm² of the ostial LCX with a distal reference vessel diameter of 3.7 mm and severely eccentric stenosis showing a 270° arc of calcium (Figure 1A–C). The resting full-cycle ratio of the ostial LCX was 0.82. The reference vessel diameter of the LM was 4.4 mm. The decision of the local heart team was to use rPCI (CorPath GXR, Corindus Inc., Natick, MA, USA) (Figure 1D and E) with addition of IVL (Shockwave Medical, Inc., Santa Clara, CA, USA) to allow high-precision, thorough lesion preparation followed by a provisional stent strategy.

The LM was intubated manually with an EBU 3.75 (Medtronic, Dublin, Ireland) (Figure 1F) using a radial approach. Then the robotic system was connected to a 7-French guiding catheter. After robotically assisted wiring of the LCX and left anterior descending (LAD) (each Runthrough-NS, Terumo, Eschborn, Germany; see [Supplementary material online, Videos S1 and S2](#)), the lesion preparation was initiated with inflation of a coronary IVL balloon (3.5/12 mm, Shockwave Medical) at 4 atm. A total of 7 cycles at 80 Hz were applied (Figure 1G). Thereafter, extensive postdilation was performed with a non-compliant balloon (3.5/20 mm NC Emerge, Boston Scientific, Marlborough, United States), and a drug-eluting stent (DES) (PROMUS Premier Select 3.5/28 mm, Boston Scientific) was implanted by robotic assistance from ostial LM crossover to the LCX. The balloon-expandable stent was inflated to 14 atm for 15 sec (Figure 1H). Angiography showed a sufficient expansion of the stent balloon. After robotically assisted rewiring of the LAD through the distal stent struts of the implanted stent (see [Supplementary material online, Video S3](#)), a kissing-balloon maneuver was performed (both balloons: NC Emerge 3.0/15 mm, Boston Scientific) (Figure 1I). The procedure was finalized with a proximal optimization technique using a non-compliant balloon (NC Emerge 4.5/12 mm, Boston Scientific) that was inflated to 12 atm in the distal LM (Figure 1J). The final angiography and manually performed IVUS (Minimal lumen area [MLA] LM: 13.2 mm²; MLA ostial LCX: 7.5 mm²) showed a good stent result (Figure 1K). From the first wiring to the final dilation, all steps were fully robotically assisted. The vessel-access as well as the intubation of the LM-ostium was done manually. Follow-up at 30 days post rPCI showed a reduction of subjective symptoms (NYHA < II) and an improvement of life quality.

Discussion

Heavily calcified lesions are common (10–30% of all lesions) but are difficult to treat.^{3,4} To the best of our knowledge, this is the first report of a case utilizing rPCI for IVL in a severely calcified LM lesion.

In the past few decades, there has been tremendous development in interventional cardiology with an increase in procedure complexity and duration; however, this has been accompanied by only marginal development and optimization of catheter laboratory workflows. Due the greater complexity of lesions being treated, the procedure time has been extended and as a result the radiation dose and workload have increased, resulting in a greater risk of multiple health hazards for the operators.⁵ In addition to its benefits for the cardiologist, rPCI also seems to improve the precision and accuracy of intervention.⁶ This is a result of various technical features such as the option to accurately position the catheter material in 1-mm steps, which offers very precise navigation in coronary arteries. Accurate balloon and stent positioning are mandatory for the best-possible interventional success and

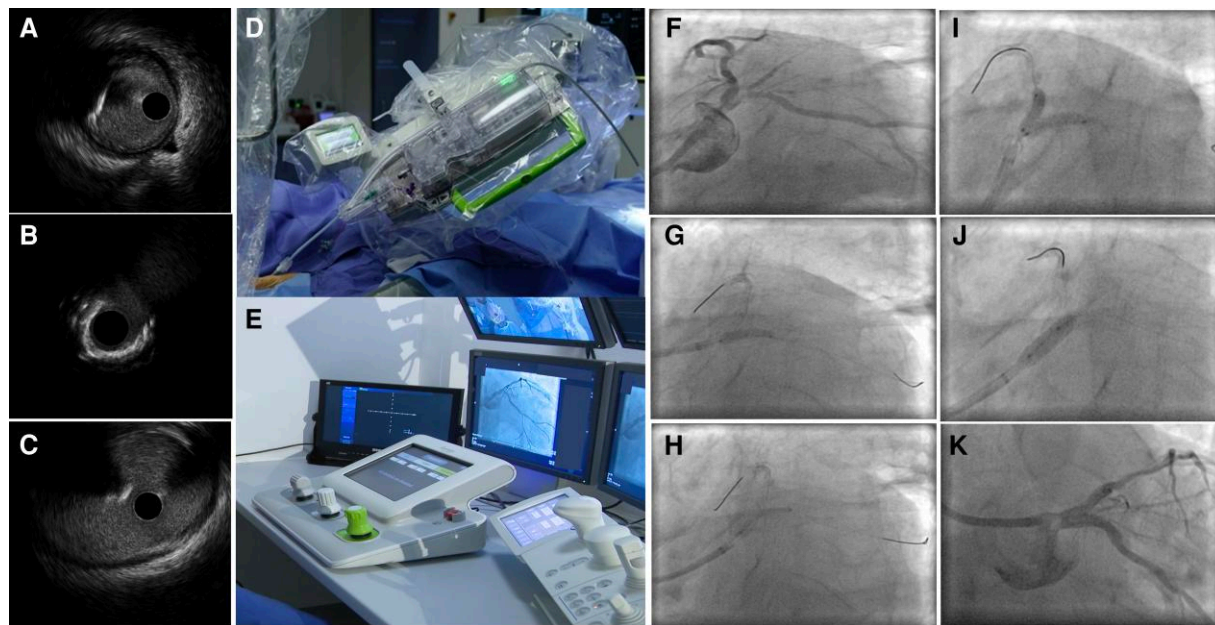


Figure 1 Intravascular ultrasound demonstrating stenosis of the ostial LCX: (A) distal LCX with diffuse, punctate calcification; (B) ostial LCX stenosis with heavy calcification covering 270° of the vessel circumference and minimal lumen area of 1.8 mm²; (C) left main. Setup of CorPath GXR System: (D) robotic console with a guiding catheter placed in the right radial artery; (E) remote control station. Procedural angiograms: (F) Diagnostic angiography; (G) Spider view showing lesion preparation with intravascular lithotripsy balloon (3.5/12 mm) with wires in LAD and LCX inflated; (H) DES implantation into the left main and LCX; (I) kissing-balloon maneuver with 3.0/15 mm each balloon; (J) proximal optimization in the left main coronary artery with 4.5/12 non-compliant balloon; (K) final procedural result.

prognosis.⁷ Moreover, the available robotics software add-ons, which offer different longitudinal and rotational movement options for lesion crossing, seem to optimize wiring results (technIQ, Siemens).^{2,8}

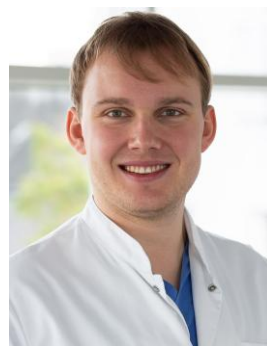
There is evidence that interventional cardiologists develop posterior lens opacities and cataracts earlier and at higher rates than other professionals.¹ Furthermore, a recent report indicated a higher risk of left-sided brain tumor in interventional cardiologists exposed to radiation.⁹ The most recent studies show a decrease in operators' radiation exposure when using rPCI, whereas patients' exposure remains mostly the same. Nonetheless, even orthopedic problems are common with catheter laboratory personnel due to the need to wear heavy lead aprons for hours.¹⁰

To achieve an optimal interventional result and a good clinical outcome, adequate lesion preparation is mandatory.¹¹ Therefore, IVL was introduced when conventional techniques were shown to be insufficient, especially in eccentrically calcified lesions. The IVL catheter emits pulsatile sonic pressure waves delivered circumferentially to the vessel wall and offers a unique chance to modify plaque structure with a more homogeneous result combined with other debulking devices (e.g. a cutting/scoring balloon, rotational/orbital atherectomy).¹² As demonstrated by the present case, rPCI is feasible and safe even in a complex lesion. Additionally, as shown here, it can be applied to new devices such as an IVL or IVUS catheter. However, the current robotic systems are limited to digital IVUS catheter systems such as Eagle Eye (Philips).

Nevertheless rPCI has some limitations. Since now it is poorly investigated, whether the rPCI influences the clinical outcome. Furthermore, there is an inherent need for an operator to perform the vessel access, the cassettes are not compatible with any available device, and a rapid exchange of the devices is limited, resulting in longer procedural times.^{2,13} As bail-out option manual conversation is possible at each time of the procedure.

The combination of rPCI with sophisticated tools for plaque modification such as IVL is feasible and safe. However, the benefit of using both techniques in terms of clinical outcome should be further investigated in large-scale randomized controlled trials.

Lead author biography



Felix J. Hofmann is an assistant doctor for cardiology and internal medicine at the Department of Cardiology and Angiology at the University Hospital of Giessen and Marburg, Giessen, Germany. He is interested in interventional strategies, new therapy options as well as artificial intelligence in cardiology.

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: In accordance with COPE guidelines the patient gave informed consent for publication of the case.

Conflict of interest: H.M.N., H.M.: Speaker honoraria Shockwave Medical and Siemens Healthineers.

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