

BREAKING THE STONE: STENTLESS CORONARY REVASCULARIZATION WITH INTRAVASCULAR LITHOTRIPSY AND DRUG-COATED BALLOON TECHNOLOGY GUIDED BY IVI

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ABSTRACT

Background: Severe coronary calcification remains a major challenge in percutaneous coronary intervention (PCI), often complicating lesion preparation and stent expansion. Intravascular lithotripsy (IVL) enables controlled plaque modification through acoustic pressure waves, while drug-coated balloons (DCB) offer antiproliferative therapy without leaving a permanent scaffold.

Case summary: We report two cases of severe calcified coronary stenosis treated with calcium modification techniques, intravascular lithotripsy, and drug-coated balloon technology. The first 73-year-old patient presented with a non-ST-elevation myocardial infarction. Coronary angiography identified a heavily calcified mid-LAD lesion. Optical coherence tomography revealed severe concentric calcification with a circumferential arc exceeding 270°, thickness 0.76 mm, length 12 mm, MLA 1.9 mm², prompting the use of intravascular lithotripsy (IVL) for lesion modification. The therapy achieved multiple calcium fractures and optimal luminal gain. As final therapeutic modality, drug-coated balloon angioplasty (DCB) was chosen, after which TIMI 3 flow was maintained with no dissection. In the second case, a 53-year-old male patient presented with cardiogenic shock and multivessel coronary artery disease. After the initial life-saving procedure, a second intervention on a heavily calcified 360° arc on the proximal LAD was performed under guidance with intravascular ultrasound (IVUS) with a cutting balloon and IVL, achieving excellent luminal gain, and DCB was used as a final treatment device. At follow-up, the patients remained asymptomatic, underscoring the safety and efficacy of a stent-less IVL + DCB strategy in complex calcified anatomy.

Discussion: IVL's excellent safety profile and uniform circumferential action make it especially suitable for thick, concentric calcification. Likewise, contemporary DCB studies in de novo lesions have shown comparable mid-term results to DES in selected patients, supporting a "leave-nothing-behind" philosophy when optimal lesion preparation and imaging guidance are achieved.

Take-home message: In appropriately selected patients, IVL-assisted plaque modification followed by DCB can achieve optimal outcomes while avoiding permanent implants and their late complications.

Keywords: Cardiovascular diseases, Coronary artery disease, Percutaneous coronary intervention, Intravascular lithotripsy, Drug coated balloons, Optical coherence tomography

INTRODUCTION

Severe coronary calcification continues to challenge interventional cardiology, often leading to suboptimal balloon expansion, incomplete stent apposition, and restenosis. While rotational and orbital atherectomy remain effective options, they are technically demanding and carry risks of distal embolization, vessel injury, and procedural complexity.

Intravascular lithotripsy offers a controlled and safer alternative, using acoustic pressure waves to fracture both superficial and deep calcium, improving vessel compliance without extensive trauma. In parallel, drug-coated balloon technology allows homogeneous drug delivery without leaving a metallic scaffold, aligning with the modern “leave-nothing-behind” approach that reduces long-term inflammation and neo-atherosclerosis.

Recent multicenter studies and latest breaking trials have further supported the safety and versatility of both IVL [1-3] and DCB [4-7] for the treatment of coronary artery disease, laying the foundation for stent-less revascularization strategies guided by intravascular imaging, even in the most complex calcified anatomy.

In calcified lesions, intravascular imaging (IVUS/OCT) enables precise calcium assessment, guides lesion modification, and significantly reduces adverse events [8, 9].

Here, we report the first cases of IVL performed in Macedonia, illustrating the feasibility,

safety, and early clinical success of a stentless revascularization approach combining IVL and DCB in patients with complex, heavily calcified coronary disease.

CASE PRESENTATION

Case 1

A 73-year-old man presented to the emergency department with chest discomfort and palpitations. His past medical history revealed well-known CAD, type 2 diabetes, dilated cardiomyopathy, permanent atrial fibrillation, hypertension, and hyperlipidemia. Initial ECG revealed atrial fibrillation without acute ischemic changes. High-sensitivity troponin I was 300 ng/L. Knowing his past medical history and increased troponin values, he was sent to the catheterization laboratory within the next 24 hours.

Coronary angiography showed heavily calcified coronary arteries: non-significant in-stent restenosis in proximal/mid RCA; 90% distal RCA calcified stenosis (treated successfully during the index admission); 80 % mid-LAD calcified stenosis, reference diameter $\approx$ 3.5 mm, TIMI 3 flow.

After being admitted for NSTEMI and intervention to the RCA, a staged PCI to the LAD was performed. Pre-intervention OCT revealed a severely calcified segment with calcium arc $> 270^\circ$, max. calcium thickness of 0.76 mm, lesion length 12 mm, and MLA 1.9 mm².

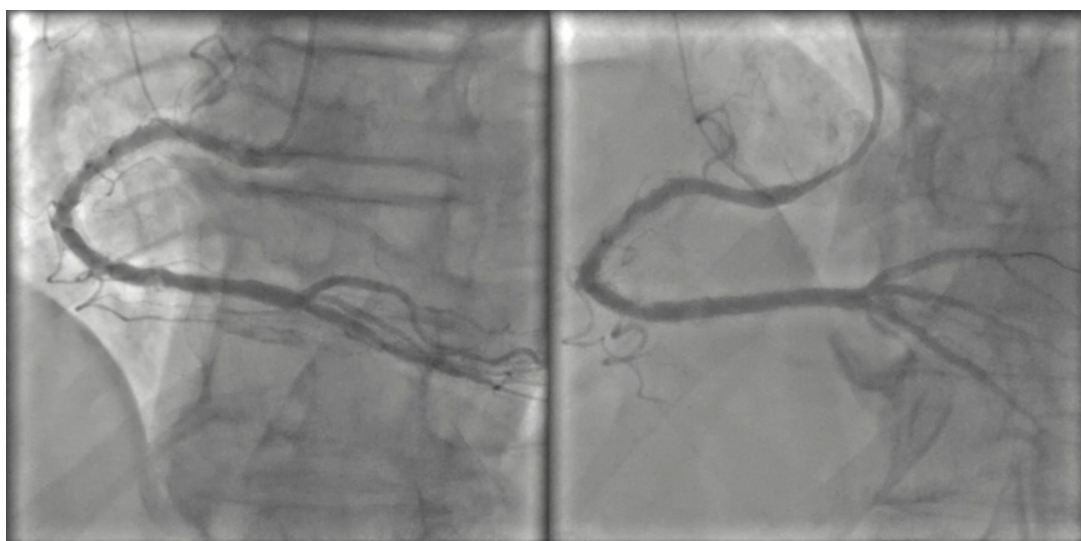


Figure 1. Initial coronary angiogram of RCA (left) and angiogram of RCA post-PCI (right)

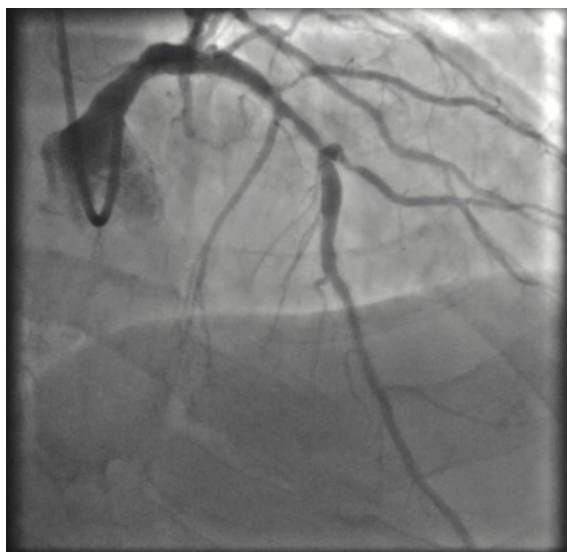


Figure 2. Initial coronary angiogram of LAD

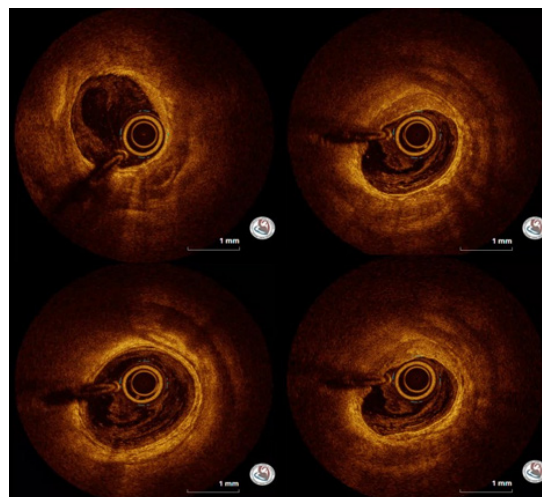


Figure 3. OCT imaging assessment before PCI

After OCT assessment of a large, calcified arc and a big side branch at the place of the lesion, the decision was to start with IVL modification. A 3.5×12 mm IVL balloon was inflated at nominal pressure (4atm), delivering 20 pulses. Post-IVL OCT showed multiple calcium fractures and sufficient luminal gain without a flow limiting dissection.

Given the excellent result and preserved flow in both main and side branch, a stent-less approach was selected. A 3.5×15 mm paclitaxel-coated balloon, matched to the distal reference vessel, was used with a 60 seconds inflation, achieving full expansion and TIMI 3 flow. The final angiogram confirmed good luminal gain and absence of recoil or dissection.

The patient was discharged on single anti-platelet therapy with Clopidogrel and Rivaroxaban, due to his permanent atrial fibrillation.

Follow-up angiogram was performed at 3 months, revealing no restenosis and visual vessel enlargement, indicating favorable healing. Although it was the patient's third coronary angiography in a row and sixth in the past fifteen years, preferred right artery access was maintained every time, performed with patent hemostasis after the procedure. At nine-month clinical follow-up, the patient was asymptomatic with a complete return to daily activities. OCT follow-up is scheduled at 12 months for further detailed long-term assessment.

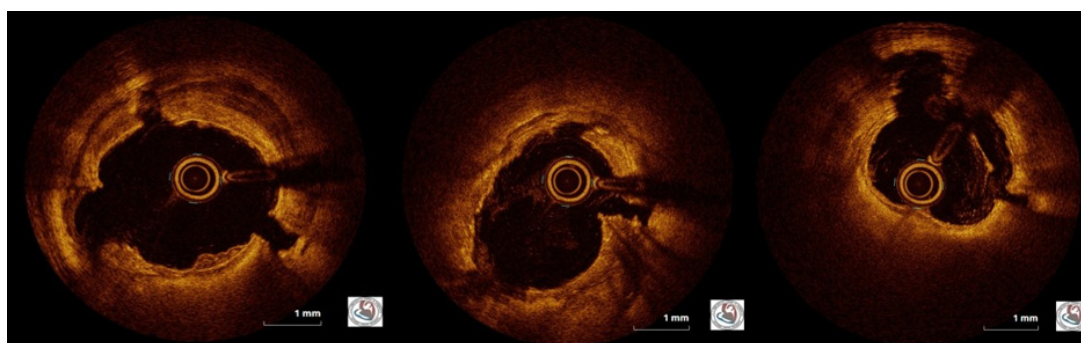


Figure 4. OCT imaging after IVL showcasing multiple calcium cracks and improved MLA after IVL

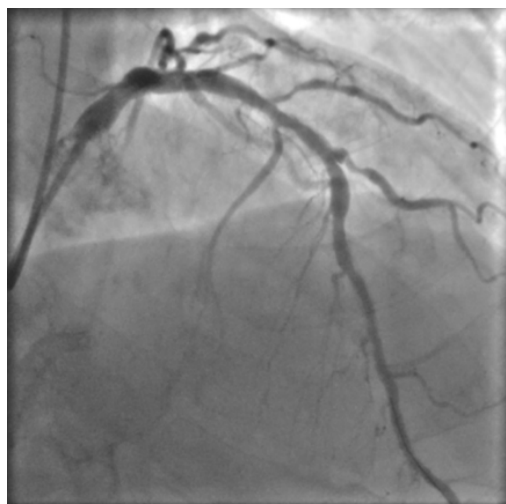


Figure 5. *Final coronary angiogram assessment*

Case 2

In the second case, a 53-year-old male patient presented with cardiogenic shock and multivessel coronary artery disease. He had hyperlipidemia and was a heavy smoker. His father had a myocardial infarction at a young age. The patient was taken to the catheterization laboratory for emergency coronary angiography. Before the procedure, he was given a loading dose of Aspirin, Ticagrelor, and UF Heparin.

After the initial life-saving procedure, on an occluded dominant circumflex artery and a large diagonal artery, a second intervention on a heavily calcified 360° arc on the proximal LAD was performed under guidance with intravascular ultrasound (IVUS).

Lesion modification was performed with a specialized cutting balloon and intravascular lithotripsy balloon 3.0/15 inflated at nominal pressure (4atm), delivering 120 pulses, achieving excellent

luminal gain. A paclitaxel drug-coated balloon 3.0/30mm over 8 atm. was used as a final treatment device.

After revascularization the echocardiography showed a mildly reduced ejection fraction. Due to the newly discovered diabetes mellitus the patient was put on oral anti-diabetic medications. He was discharged home on dual anti-platelet therapy with Aspirin and Ticagrelor.

At two-month follow-up, the patient remained asymptomatic, returning to his regular physical activities.

DISCUSSION

These cases illustrate the efficiency of combining intravascular lithotripsy and drug-coated balloon angioplasty for the management of

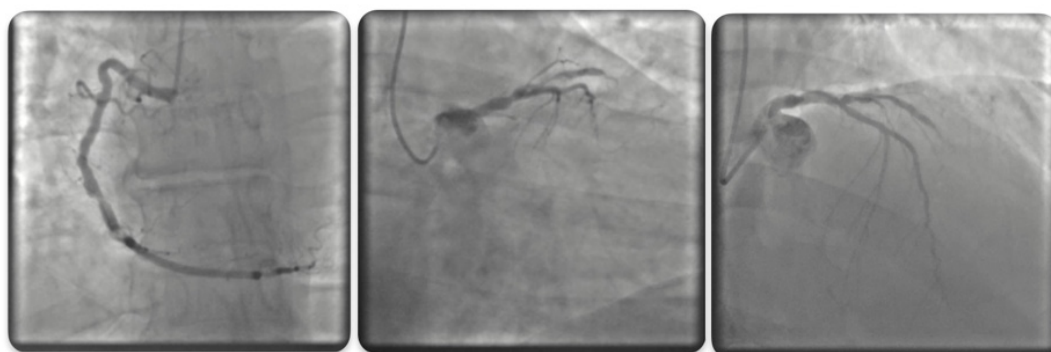


Figure 6. *Initial angiography - case 2*

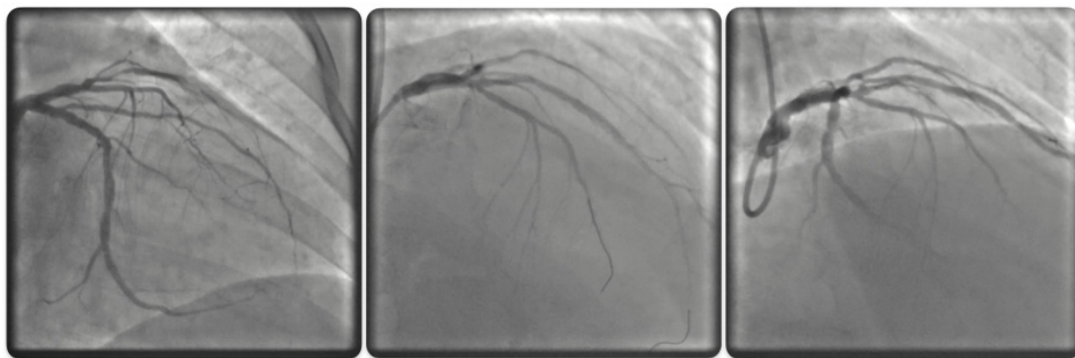


Figure 7. After revascularization of the Circumflex and Diagonal artery. The white arrow shows a severely calcified stenotic segment on the proximal LAD.

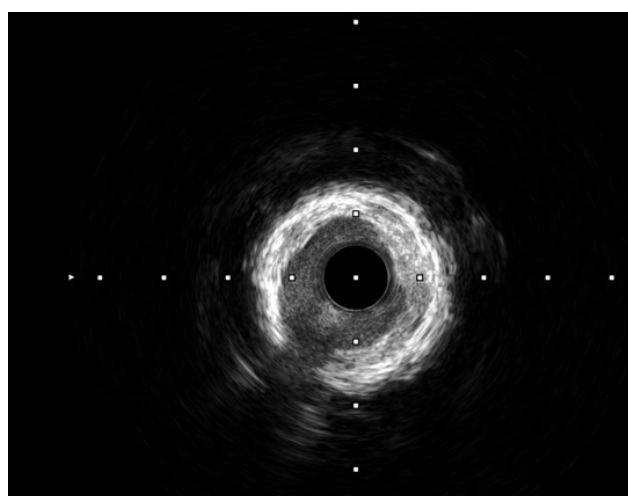


Figure 8. Severely calcified 360° arc on the proximal LAD on IVUS

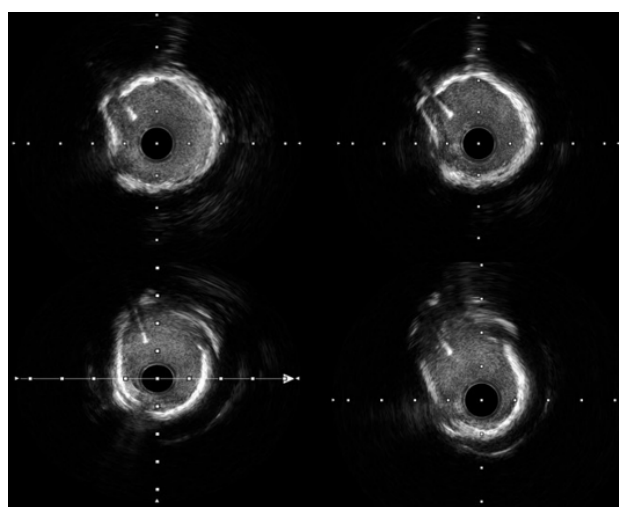


Figure 9. Modified calcium ring with cracks in multiple segments

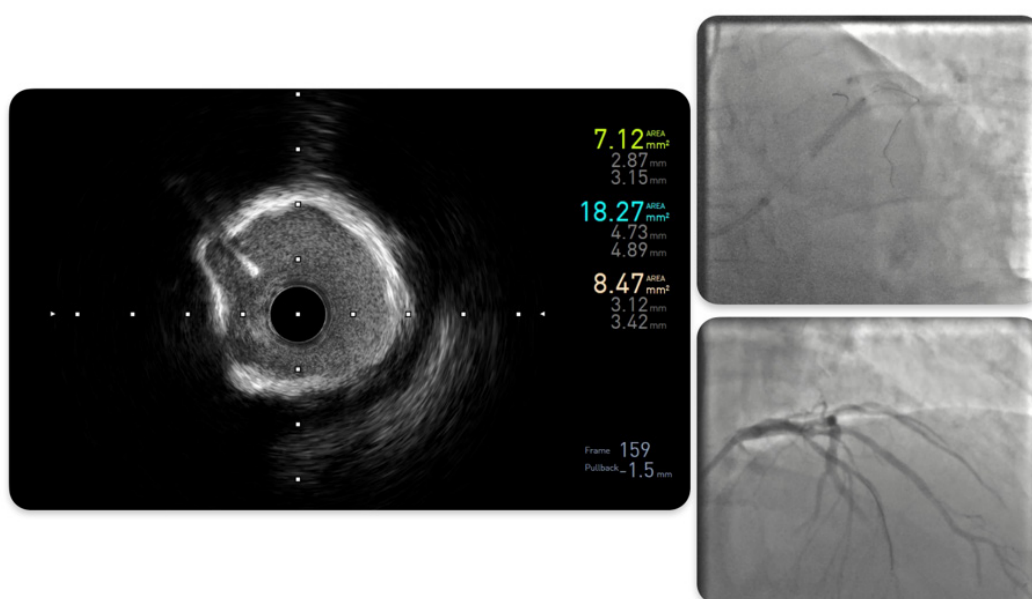


Figure 10. DCB treatment and final angiographic result with IVUS run

severely calcified lesions where conventional stenting may be suboptimal or undesirable.

A recent Japanese study by Misawa et al. [10] was first to publish the results of 45 cases with severely calcified de-novo coronary lesions treated with IVL and DCB as the final device. The TLF rate in this study was similar to IVL treatment followed by DES in other published studies. The significance of this technique will be seen in the long-term follow-up of these cases.

Severe calcification defined on OCT predicts poor compliance and underexpansion with standard balloons and scaffolds. Although recent comparative late-breaking trials reported no superiority of IVL over cutting [11] or super-high-pressure [12] balloons regarding luminal area or expansion, the controlled energy release of IVL minimizes barotrauma, dissection, and distal embolization. Its circumferential effect— independent of wire bias — makes it particularly advantageous in eccentric or concentric thick calcium, as observed in this patient [3,13].

After achieving an adequate lumen area, the use of DCB as the final therapeutic device provided local antiproliferative drug delivery without introducing permanent metal. Contemporary DCB trials in de novo lesions suggest comparable target-vessel outcomes to modern DES in well-selected, imaging-guided cases [3-7,14,15]. This evidence supports individualized, stent-less strategies, particularly when avoiding potential late events due to malapposition or neoatherosclerosis.

The procedure also emphasizes the role of intravascular imaging (IVI) as OCT and IVUS in decision-making: quantifying calcium (arc, thickness, length), identifying which lesions will benefit from IVL, verifying fracture success, and ensuring safety before final DCB application. Imaging also defines suitability for a stent-less approach— adequate luminal gain and absence of flow-limiting dissection [16,17].

In the era of advanced calcium-modification tools and expanding DCB technology, individualized, imaging-driven treatment can optimize both immediate and long-term results. While randomized trials will determine the definitive place of IVL + DCB compared with DES, real-world experiences like these highlight its potential in high-risk patients with multiple comorbidities and heavily calcified vessels.

CONCLUSION

In high-risk patients with severely calcified LAD lesions, intravascular lithotripsy followed by drug-coated balloon angioplasty provided excellent results and sustained early patency without the need for a permanent stent. Despite the recent comparative studies showing similar mechanical outcomes among various calcium-modification devices, IVL maintains a unique safety and versatility profile. When guided by intravascular imaging and applied to suitable anatomy, the combination of IVL + DCB represents a safe and effective alternative aligned with the “leave-nothing-behind” paradigm.

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Резиме

КРШЕЊЕ НА КАМЕНОТ: РЕВАСКУЛАРИЗАЦИЈА БЕЗ СТЕНТОВИ СО ИНТРАВАСКУЛАРНА ЛИТОТРИПСИЈА И БАЛОНИ ОБЛОЖЕНИ СО ЛЕКОВИ ВОДЕНИ СО ИНТРАВАСКУЛАРНИ СЛИКОВНИ ТЕХНИКИ

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Вовед: Изразените калцификации на коронарните крвни садови остануваат голем предизвик во перкутаните коронарни интервенции (ПКИ), често комплицирајќи ја подготовката на лезијата и експанзијата на стентот. Интраваскуларната литотрипсија (ИВЛ) овозможува контролирана модификација на плаката преку акустични притисочни бранови, додека балоните обложени со лекови (DCB) аплицираат антипролиферативна терапија без да остават траен метален скафолд.

Прикази на случаи: Опишуваме 2 случаја на изразено калцифицирани коронарни стенози третирани со техники за модификација на калциум, интраваскуларна литотрипсија и технологија со балони обложени со лекови. Првиот, 73-годишен пациент, беше примен со дијагноза на миокарден инфаркт. Коронарната ангиографија покажа изразено калцифицирана стеноза на левата коронарна артерија. Со оптичка кохерентна томографија се идентификува изразена концентрична калцификација со обрач на калцификација со 270°, дебелина од 0,76 mm, должина 12 mm, MLA 1,9 mm², поради што имаше потреба за користење интраваскуларна литотрипсија за модификација на плаката. Аплицираната терапија овозможи мултипли фрактури на калциумот и оптимално проширување на луменот. Како финален терапевтски модалитет беше избрана ангиопластика со балон обложен со лекови. На 3-месечната контролна ангиографија и 9-месечното клиничко следење пациентот е без симптоми, со позитивно ремоделирање на коронарниот крвен сад.

Во вториот случај се работи за 53-годишен пациент со повеќесадовна коронарна болест во кардиоген шок. По почетната животоспасувачка процедура, се изврши втора интервенција на изразено калцифицирана проксимална ЛАД со калцификација од 360°, под водство на интраваскуларен ултразвук. Таа се изврши со помош на посебен засекувачки балон и интраваскуларна литотрипсија, постигнувајќи добар лумен и како последен уред беше нанесен балон обложен со лекови. При следењето пациентите останаа асимптоматски, без тегоби, што укажува на безбедноста и на ефикасноста на стратегија IVL+DCB кај комплексната коронарна анатомија.

Дискусија. Одличниот безбедносен профил на ИВЛ ја прави да биде соодветна за изразени, концентрични калцификации. Истовремено, објавените студии за DCB кај лезиите *denovo* покажаа еднакви резултати со ДЕС кај селектирани пациенти, поддржувајќи ја филозофијата „да не се остава ништо“ во крвниот сад, во случаи каде што е обезбедена максимална подготовка на лезијата и водење на процедурата со сликовни техники.

Заклучок: Кај соодветно селектирани пациенти модификацијата на плака со DCB помогната со ИВЛ постигнува оптимален исход, избегнувајќи траен метален имплант и неговите подоцнежни компликации.

Клучни зборови: кардиоваскуларни заболувања, коронарна артериска болест, перкутана коронарна интервенција, интраваскуларна литотрипсија, балони обложени со лекови, оптичка кохерентна томографија