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CASE REPORT
Coronary intervention

Simultaneous therapy with pressure-controlled intermittent coronary sinus occlusion and left ventricular support during high-risk percutaneous coronary intervention: a case report

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Background Previous studies in patients with ST-segment elevation acute myocardial infarction treated with primary angioplasty and supported by the PiCSO® system have shown a modest yet significant absolute reduction in the infarcted myocardial area. However, the simultaneous use of PiCSO® and Impella CP® during high-risk percutaneous coronary intervention (PCI) procedures has not been reported.

Case summary A 76-year-old Caucasian man presented with severe and highly calcified left main coronary disease and severely depressed left ventricular function. As coronary bypass surgery was deemed prohibitive, successful PCI was performed with the simultaneous use of PiCSO® and Impella CP® to mitigate damage from distal microembolization and provide mechanical circulatory support to the left ventricle during the high-risk PCI procedure.

Discussion Our case exemplifies for the first time the simultaneous use of PiCSO® and Impella CP® during a high-risk PCI. This case suggests the feasibility and safety of combining both devices for mechanical haemodynamic and microcirculatory support simultaneously in specific cases during high-risk PCI, offering hope for reducing post-PCI myocardial damage in a selected population of patients.

Keywords Coronary sinus • Impella • PiCSO • PCI • Left main • Case report

ESC curriculum 3.1 Coronary artery disease • 3.2 Acute coronary syndrome

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Learning points

- To learn about the feasibility and potential benefit of the use of pressure-controlled intermittent coronary sinus occlusion and left ventricular haemodynamic support during high-risk PCI.
- To understand the potential benefit of pressure-controlled intermittent coronary sinus occlusion to reduce distal microembolization and post-PCI myocardial damage.

Introduction

The continuous search of diverse strategies for improving the outcome of patients during high-risk percutaneous coronary intervention (PCI) is essential. Despite an early reperfusion in acute coronary syndromes (ACS), molecular and biochemical alterations caused by the previously deprived microcirculation persist. Therefore, some studies in recent years have been focused on methods to reduce microcirculatory obstruction as an important prognostic factor during ACS or high-risk PCI.[1,2]

The pressure-controlled intermittent coronary sinus occlusion (PiCSO®, Miracor Medical SA, Awans, Belgium) is a mechanical therapy guided through a percutaneously placed balloon catheter in the coronary sinus (CS), which by cyclically inflating and deflating causes a temporary occlusion in its drainage.[3] During the inflation of the balloon, there is an increase in pressure on the CS to approximately 70 mmHg, which leads to the redistribution of the coronary flow to the border zone of the ischaemic area of the myocardium, causing vasodilation of the small arteries and capillaries and improving myocardial perfusion (*Figure 1*). After reaching a pressure plateau, the balloon deflates causing a pressure drop which leads to a washout and clearance of inflammatory and vasoconstricting mediators as well as micro-debris.[4] This case presents the use of PiCSO® and percutaneous left ventricular support during high-risk PCI.

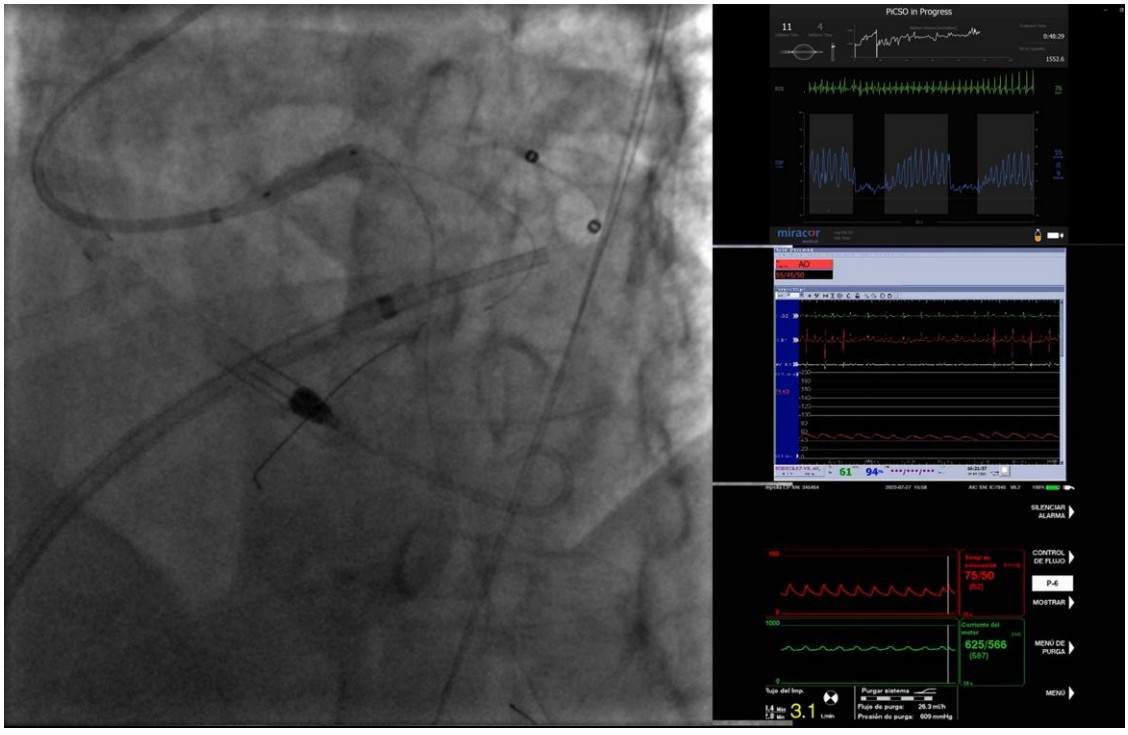
Summary figure

Case presentation

A 76-year-old Caucasian man presented to the emergency department with a 24 h history of shortness of breath, chest pain, and fatigue at rest. The patient had previously experienced similar symptoms during exercise, but he suffered an exacerbation during the last 24 h. Physical examination revealed jugular distention, pulmonary congestion, and oedema in the lower limbs.

The patient had a medical history of chronic obstructive pulmonary disease; lung cancer treated with surgery, radiation, and chemotherapy; myelodysplastic syndrome previously treated and under clinical surveillance; and stage 4 chronic kidney disease. Additionally, the patient had history of chronic coronary artery disease with an inferior ST-elevation myocardial infarction (STEMI) and a primary PCI with a bare metal stent (BMS) to the distal circumflex artery in 2009. A staged non-culprit PCI with two drug-eluting stents (DES) to the proximal and mid-right coronary artery was performed in the same year. The patient also exhibited severe left ventricular dysfunction [left ventricular ejection fraction (LVEF) of 25%].

The patient was admitted to the coronary care unit. The electrocardiogram at hospital admission showed sinus rhythm, with normal PR interval, QRS complex, and QTc interval and no alterations in repolarization. Blood test revealed an increase of cardiac biomarkers, with a peak troponin T of 336 ng/L (normal values: < 54 ng/L). No inotropes



PiCSO® and Impella CP® devices active during LM bifurcation PCI (left). Images from the PiCSO software during its activation (right).

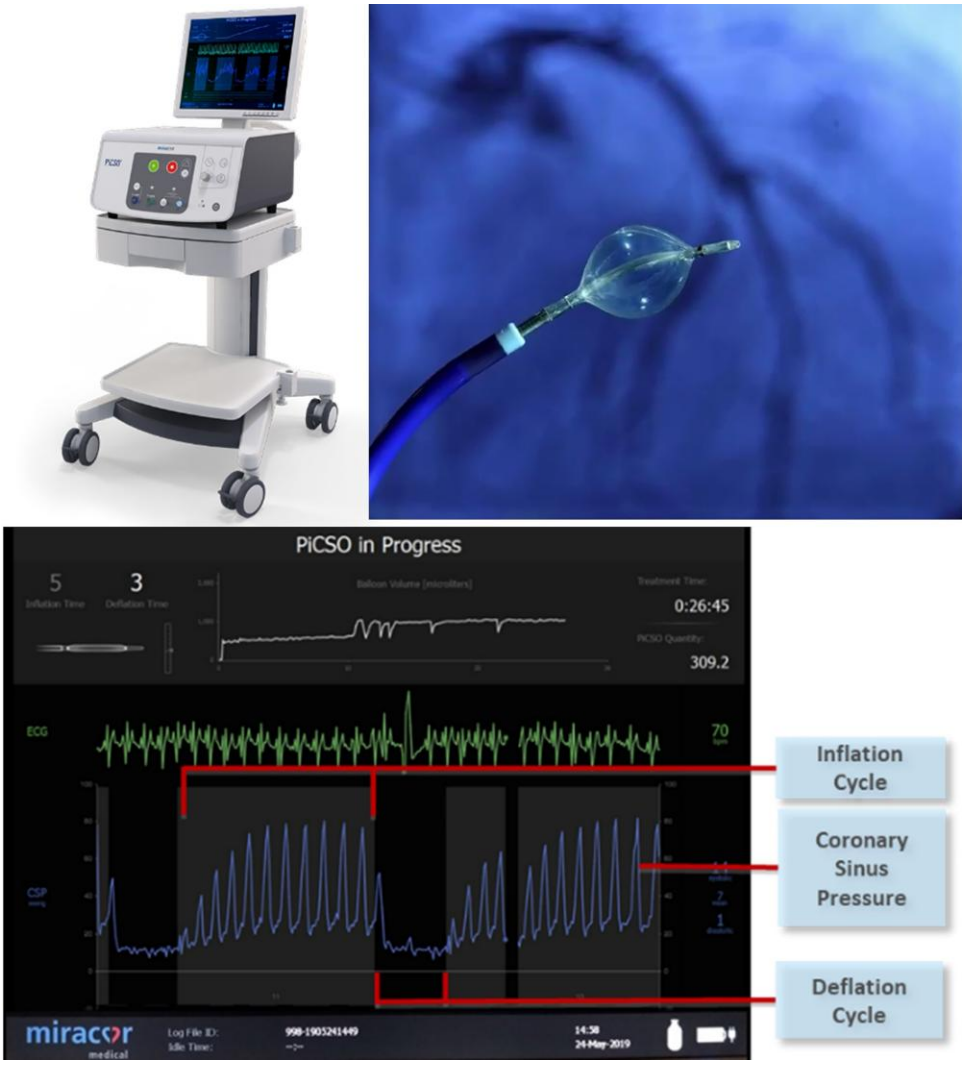


Figure 1 PiCSO® balloon and control console for recording of pressure and inflation of the PiCSO® balloon.

or vasopressors were needed with an average non-invasive blood pressure of 105/44/64 mmHg, heart rate of 73 b.p.m., and oxygen saturation of 98% during the hospitalization. Coronary angiography was conducted revealing a critical and severely calcified distal left main (LM) stenosis (Medina classification 11,1), a severe stenosis in the mid-left anterior descending artery (LAD), chronic occlusion of the right coronary artery, and patency of the BMS in the distal circumflex artery implanted in 2009. Intravascular ultrasound imaging confirmed the severity of the lesions in the LAD and LM as well as their significant degree of calcification (*Video 1*).

As coronary bypass surgery was deemed prohibitive (EuroSCORE II 15.22%) and given that the patient presented with severe left ventricular dysfunction and highly calcified LM stenosis, LM-PCI under mechanical haemodynamic support with Impella CP® (Abiomed, Danvers, MA, USA) was chosen and complemented with temporary CS occlusion using PiCSO® to potentially decrease distal microembolization, thereby limiting the extent of myocardial damage during high-risk PCI.

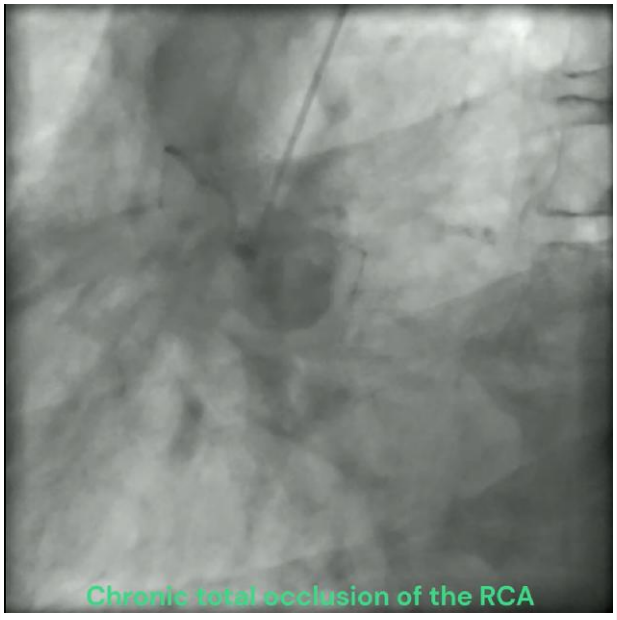
The PiCSO® balloon (*Figure 2*) was placed into the CS via the left femoral vein and was activated throughout the entire procedure producing an intermittent occlusion of the CS (see Supplementary material online, *Video S1*). The Impella CP® was placed into the left ventricle via left femoral artery. Non-compliant balloons, cutting balloon, and intravascular lithotripsy (Shockwave Medical, Santa Clara, California) were used as plaque-modifying devices to successfully implant one DES in mid-LAD and two DES on the LM-LAD circumflex with the T-and-small protrusion stenting technique (*Video 2*). The PiCSO® activity and Impella CP® were enhanced during LM-PCI, thus leading to increased CS and mean arterial pressure (see Supplementary material online, *Video S2*). The final result was optimal and without complications (*Figure 3*; *Video 3*), achieving a PiCSO® quantity of circa 1800 mmHg, which is associated with increased myocardial salvage in values above 800 mmHg during primary PCI.[5] The total procedure time was 114 min, 200 mL of contrast was used, and the peak of high-sensitivity troponin I increased to 211 ng/L.

Impella CP® device and PiCSO® were removed immediately after PCI. Closure of the Impella CP arterial access was performed with two ProGlide devices, and closure of the PiCSO venous access was done with one ProGlide device. There were no vascular complications, and the hospital stay was uneventful. During the hospitalization and at hospital discharge, the main pharmacological therapy consisted of double antiplatelet treatment with acetylsalicylic acid 100 mg once a day (QD) and clopidogrel 75 mg QD, bisoprolol 5 mg QD, atorvastatin

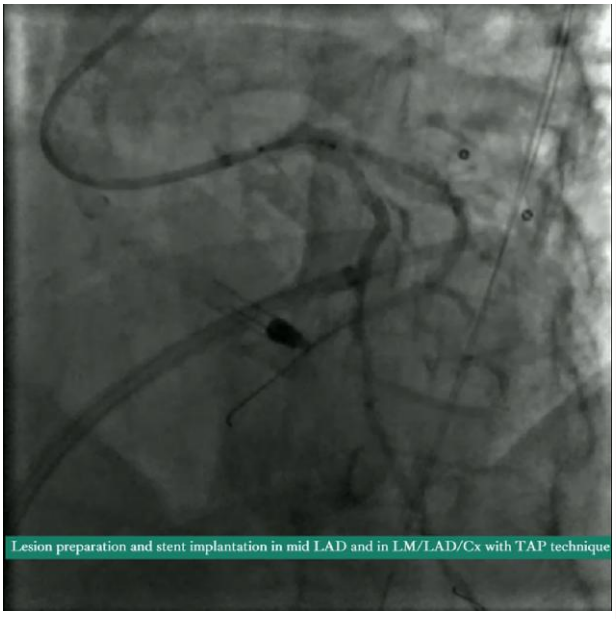
40 mg QD, empagliflozin 25 mg QD, and spironolactone 25 mg QD. Due to the history of myelodysplastic syndrome and high bleeding risk (Academic Research Consortium for High Bleeding Risk (ARC-HBR) scale with two major and two minor criteria; PRECISE-DAPT score of 42), clopidogrel was chose as a $P2Y_{12}$ inhibitor. During the clinical follow-up, the patient was free from angina at 6 months after the PCI, and the LVEF improved to 42% on the 6-month transthoracic echocardiogram.

Discussion

Prior investigations involving patients with STEMI who underwent primary angioplasty and received assistance from the PiCSO® system have demonstrated a modest yet significant absolute reduction in the infarcted area. This reduction amounted to 6.9% within the initial 5 days (14.2% vs. 21.2%, $P = 0.023$) compared with a propensity score–matched control cohort[5] and 7.0% over the course of 5 months (26.0% vs. 33.0%, $P = 0.006$), as evaluated through cardiac magnetic resonance imaging (MRI), in comparison with a control group derived from a historical cohort of STEMI patients.[6] Another trial involving 30 patients with ACS who were treated with primary PCI and 90 min of PiCSO® therapy during the reperfusion period reported greater myocardial salvage (baseline vs. 4 months) in the PiCSO group compared with matched controls, as measured by cardiac MRI ($41.6 \pm 8.2\%$ vs. $27.7 \pm 9.9\%$, $P < 0.04$).[7] In a recently published trial, 145 patients with anterior STEMI and thrombolysis were randomized to receive PiCSO-assisted primary PCI vs. conventional primary PCI. The primary endpoint was the difference in infarct size at 5 days, measured by cardiac MRI. This trial was prematurely discontinued by the sponsor with



Video 1 Baseline coronary angiography and intravascular ultrasound imaging of lesions in left main and mid-left anterior descending artery.



Video 2 Pre-dilatation of coronary lesions and stent placement.

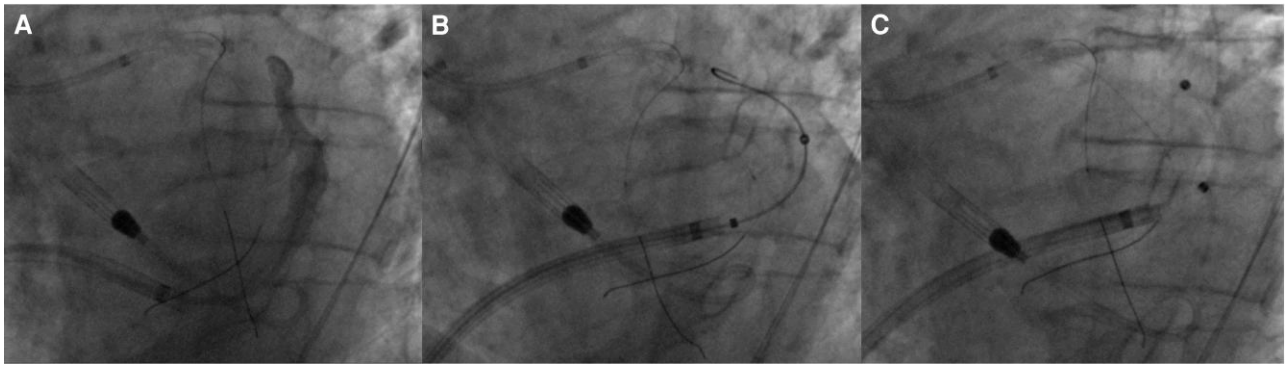


Figure 2 Coronary sinus angiography, cannulation, and PiCSO® balloon positioning (*A*–*C*).

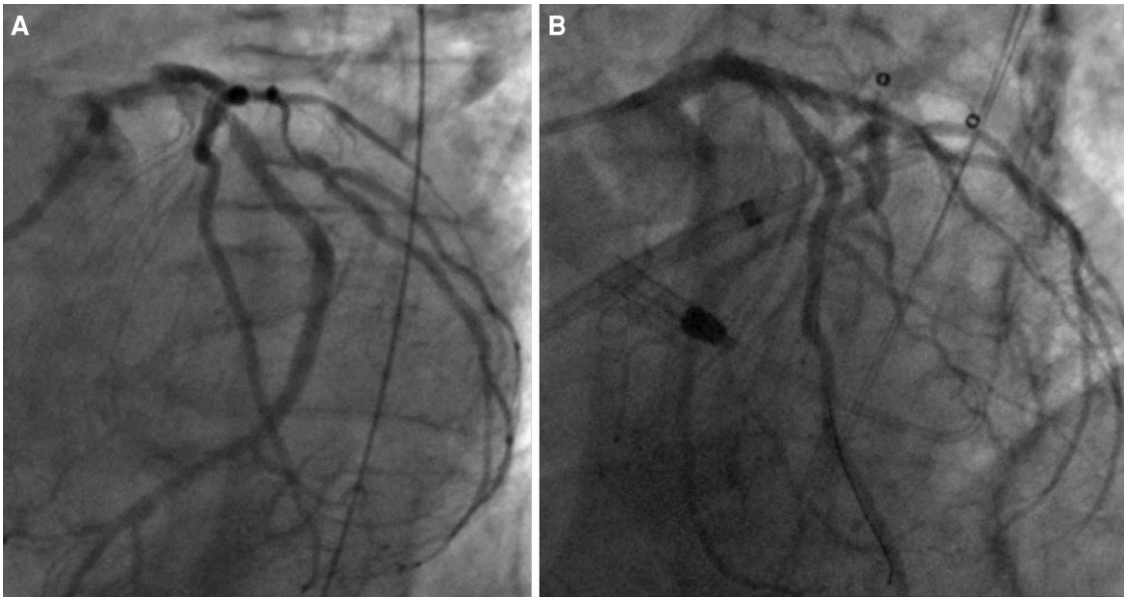
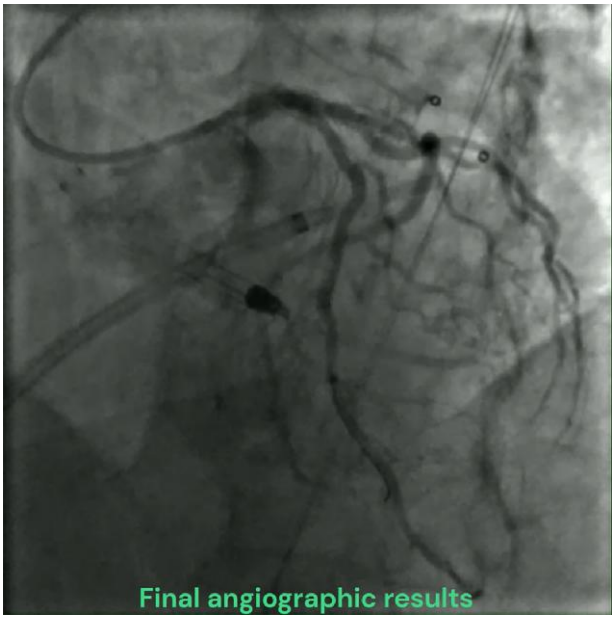


Figure 3 Baseline coronary angiography (*A*) and final result after LM-PCI (*B*).



Video 3 Final angiographic results.

no follow-up beyond 6 months. No differences were observed in infarct size at 5 days (27.2 ± 12.4% vs. 28.3 ± 11.45%; $P = 0.59$) or at 6 months (19.2 ± 10.1% vs. 18.8 ± 7.7%; $P = 0.83$).[8] There is no reported experience of the simultaneous use of PiCSO® to decrease the risk of debris embolization to the microcirculatory system and no-reflow phenomena and Impella CP® to provide short-term circulatory support during high-risk PCI. Our case exemplifies for the first time the simultaneous use of PiCSO® and Impella CP® during a high-risk PCI, unveiling a hope in a selected population of patients to reduce post-PCI myocardial damage. Due to its mechanism of action, the PiCSO® system may offer potential benefit to a population of patients susceptible to reperfusion injury or in whom relevant distal microembolization is anticipated during primary angioplasty or high-risk coronary angioplasty[9] (*Figure 4*). The simultaneous use of PiCSO® and Impella CP® may be considered for patients undergoing high-risk PCI, such as those with multivessel disease, LM disease, or last patent conduit interventions, particularly if the patient is inoperable or has severely decreased LVEF, or in whom the occurrence of microembolization and the no-reflow phenomenon is highly predictable. In this case, PiCSO potentially helped by improving coronary pressure, as there is less risk of debris embolization when using intravascular lithotripsy for calcium modification compared with other plaque modification tools,[10] thereby limiting coronary ischaemia during LM intervention in a patient with severe left ventricular dysfunction.

This case suggests the feasibility and safety of PiCSO® and Impella CP® combination as mechanical haemodynamic and microcirculatory support simultaneously in selected cases during high-risk PCI and decreased LVEF. While the safety of PiCSO® has been established in earlier studies, the potential cost implications of using both devices in combination could present a significant limitation to their broader adoption in high-risk PCI cases. Randomized clinical trials should be encouraged in this context to determine the efficacy of these procedures, elevate their guideline indications, and ensure their availability in experienced centres for eligible patients.

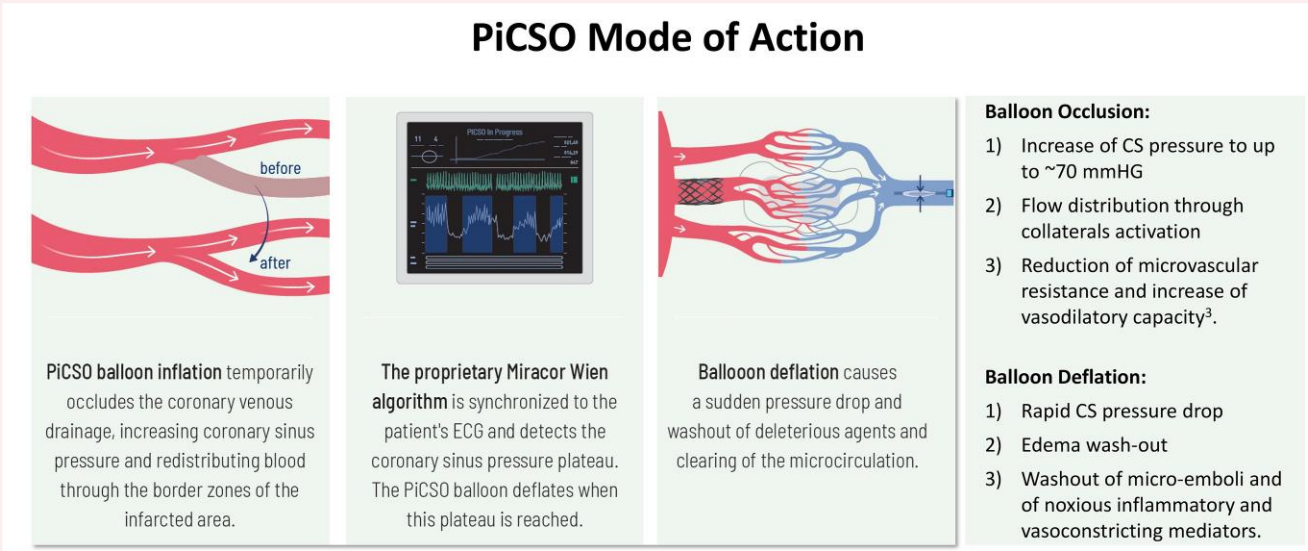


Figure 4 PiCSO® physiologic mode of action.

Lead author biography

Born in Monterrey, Mexico, Erick Martinez is a cardiologist currently training as an interventional cardiologist in the Cardiology Department of the Vigo University Hospital Complex 'Álvaro Cunqueiro' (CHUVI) in Vigo, Spain. He obtained his medical degree at the Nuevo León Autonomous University (UANL) in Mexico. His main research interest is acute coronary syndromes and drug-coated balloon angioplasty.

Supplementary material

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

Consent: The authors confirm that written consent for submission and publication of this case report was obtained from the patient.

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Data availability

The data underlying this article will be shared on reasonable request to the corresponding author.

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