ESC European Society of Cardiology

European Heart Journal - Case Reports (2023) **7**, 1–5
https://doi.org/10.1093/ehjcr/ytad506

CASE REPORT
Coronary intervention

First-in-human robotic percutaneous coronary intervention by the ROSES robotic system: a case report

Ciro Indolfi [1,2]*†, Alberto Polimeni [1†], Salvatore De Rosa [1], and Guido Danieli[3]

[1]Division of Cardiology, Department of Medical and Surgical Sciences, Magna Graecia University, Viale Europa snc, 88100 Catanzaro, Italy; [2]Mediterranea Cardiocentro, Via Orazio 2, 80122 Naples, Italy; and [3]Calabrian High Tech—CHT S.r.l., Rende (CS), Italy

Received 28 October 2022; revised 27 September 2023; accepted 9 October 2023; online publish-ahead-of-print 13 October 2023

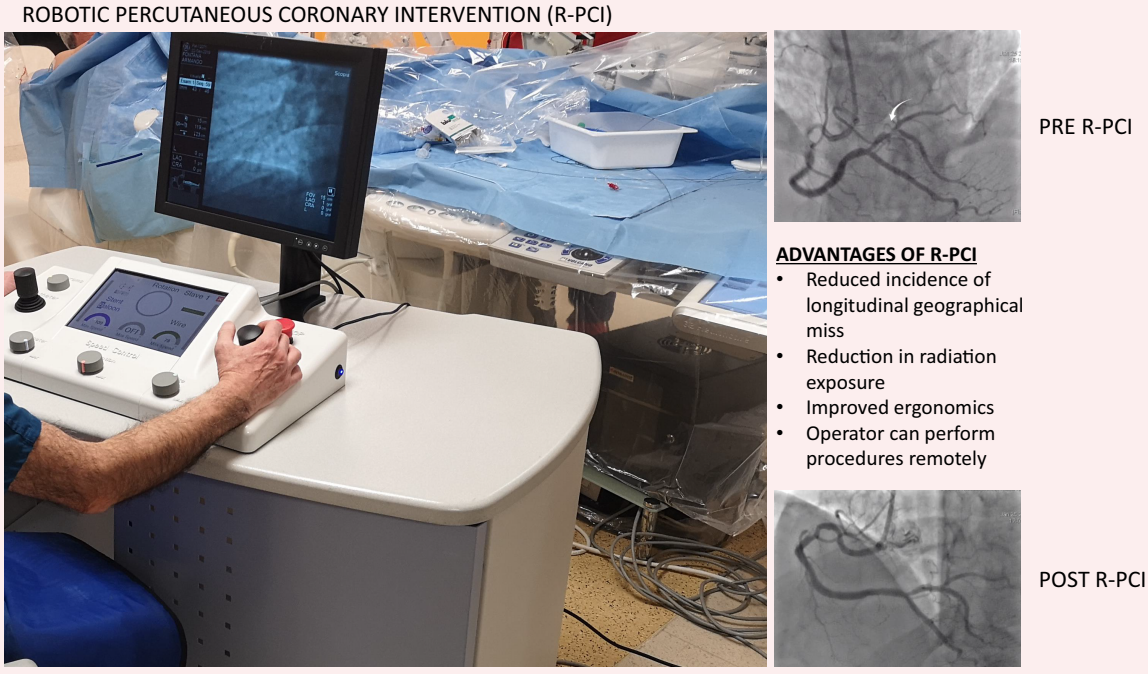
Background Robotic-assisted percutaneous coronary intervention (R-PCI) is increasingly gaining acceptance owing to several advantages.

Case summary Here, we report the first-in-human R-PCI performed with RObotic System for Endovascular Surgery (ROSES), an innovative robotic system designed to perform transcatheter angioplasty. We have reported a case of severe proximal posterolateral (PL) branch disease of the right coronary artery managed with R-PCI.

Discussion In this early clinical experience, the use of the ROSES robotic system seems to be safe and effective. However, this report still represents an early feasibility study, and the use of this technology in more challenging anatomies including the presence of severe tortuosity, severe calcification, or interventions requiring multiple wires and balloons needs to be further studied. A larger, prospective, multicentre pivotal clinical trial designed to test the ROSES robotic angioplasty system in a larger number of patients is currently ongoing.

* Corresponding author. Tel: +39 0961 364 7668, Fax: +39 0961 364 7653, Email: indolfi@unicz.it
† The first two authors contributed equally to the study.
Handling Editor: Andrew Peter Vanezis
Peer-reviewers: Muhammad Usman Shah; F Aaysha Cader
Compliance Editor: Emmanouil Mantzouranis

Graphical Abstract



Keywords Percutaneous coronary intervention • Angioplasty • Robotics • Case report

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

Learning points

- Robotic-assisted percutaneous coronary intervention (R-PCI) can overcome the limits of traditional PCI.
- The R-PCI can help physicians to reduce radiation exposure and to perform more precise PCI.
- The R-PCI with ROSES system seems to be safe and effective.

Introduction

Since the introduction of percutaneous coronary intervention (PCI), significant advancements have been made in percutaneous device technology. However, the fundamental technique of performing PCI has remained largely unchanged. Robotic-assisted PCI (R-PCI) has emerged as a promising approach, primarily due to the potential reduction in radiation exposure for operators.[1] This field has seen ongoing innovation with the aim of simplifying PCI procedures and improving precision in PCI. The concept of remote-controlled robotic PCI was initially described by Beyar *et al.*[2] and subsequent studies, such as the PRECISE (Percutaneous Robotically Enhanced Coronary Intervention) trial, have demonstrated the safety and feasibility of R-PCI in multicentre settings.[3]

While there are currently three available robotic systems in the market to address this need, namely CorPath by Corindus, Robocath, and Magellan by Hansen Medical,[2,4,5] extensive research is still ongoing. Our team has recently developed a novel robotic system called the RObotic System for Endovascular Surgery (ROSES),[6,7] specifically designed for PCI and endovascular interventions.

In this study, we present the first-in-human R-PCI performed using ROSES, an innovative robotic system designed for transcatheter angioplasty. The system consists of a simple configuration, comprising a measuring unit known as the Master (*Figure 1A*), which the physician uses to direct the operations, and an actuation device called the Slave (*Figure 1B*), located near the patient, that replicates the movements commanded by the operator at the passive Master unit. Both systems require an additional sterile element that comes into direct contact with guidewires and catheters, located on the Slave unit (*Figure 1C*). During R-PCI procedures, the interventionalist controls the robotic movement of PCI devices, such as wires, balloons, and stents, while seated at the cockpit, which can be situated either inside or outside the cath-lab, depending on convenience. This arrangement allows for the assistance of a fellow or a technologist/nurse in loading PCI devices into the system. The interventional cockpit, serving as the central control centre for the operator during a robotic-assisted procedure, offers a safe and ergonomic environment for precise control of the robotic system. Whether placed behind a mobile radiation shield within the catheterization laboratory or in a separate control room, the cockpit is strategically located to optimize performance. This setup allows

the primary operator to be in close proximity to the patient, enabling direct observation, seamless communication with the medical team, and immediate implementation of necessary interventions or adjustments during the procedure.

Within the cockpit, a high-resolution screen provides the operator with a view of the fluoroscopy screen. The controls of the robotic system are efficiently managed using individual joysticks, assigned to specific tracks. Typically, there are joysticks dedicated to manipulating the guidewire and the devices (*Figure 1A*). This integrated setup empowers the operator, transforming the cockpit into a centralized command centre within the cath-lab. It enables effective manipulation of the controls and instruments of the robotic system, facilitating precise and optimized robotic-assisted procedures.

Summary figure

Time	Events
April 2017	Acute Coronary Syndrome - Non ST elevation myocardial infarction (ACS-NSTEMI) with proximal LAD and circumflex PCI/stent
October 2017	ACS-NSTEMI with mid-LAD PCI/stent
January 2019	MPI+ and robotic PCI of posterolateral branch of RCA
July 2021	Coronary angiography for angina with good results of previous stentings

Case presentation

A 64-year-old man with a history of arterial hypertension and a previous non-ST-elevation myocardial infarction (NSTEMI) in 2017, which was treated with PCI involving the left anterior descending and circumflex arteries, presented with chronic stable angina (CCS III). This was the case despite receiving optimal medical therapy, including a RAS inhibitor, a beta-blocker, short-acting nitrates, aspirin, ranolazine, and statins at the highest tolerated dose. A myocardial perfusion imaging test showed 10% reversible ischaemia in the infero-posterior wall, with preserved left ventricular function. The patient underwent coronary angiography using the left radial access, which demonstrated a favourable angiographic outcome in the left system. The right coronary artery showed a mild lesion of the ostial posterolateral (PL) branch followed by severe proximal branch disease (type A lesion). Due to the concordance between the stenosis position and MPI data, pressure wire assessment was not performed. Therefore, the patient underwent a R-PCI of the PL to facilitate precise stent positioning and enhance accuracy.

The right coronary artery (RCA) was the dominant vessel and exhibited proximal tortuosity, along with multiple side branches in the mid-segment. A 6 Fr JR4 guiding catheter was used to engage the RCA, and a balance middleweight (BMW) 0.014″ guidewire (Abbott Vascular, USA) was introduced into the guiding catheter for the PCI procedure. The further advancement of the guidewire was performed robotically using the guidewire joystick.

Subsequently, a 2.0 × 12 mm Euphora balloon (Medtronic, USA) was robotically advanced into the lesion, and pre-dilatation was carried out at 12 atm. The same balloon was used for precise stent length measurement. A 2.5 × 15 mm Resolute Onyx® drug-eluting stent (Medtronic, USA) was then robotically advanced into position and deployed at 14 atm. StentViz (GE Healthcare, USA), enhanced stent visualization system, confirmed optimal stent expansion, while angiography revealed a well-deployed stent with a favourable angiographic outcome.

Following the completion of the procedure, the guidewire was robotically retracted (see Supplementary material online, video *S1*). The entire procedural duration was 35 min, utilizing a contrast volume of 110 mL. The patient was effectively discharged following a single day's hospitalization, with a recommended six-month regimen of dual antiplatelet therapy. The main steps of R-PCI are depicted in *Figure 2*. At a follow-up of 2.5 years, the patient underwent a repeat coronary angiogram due to recurrent angina, which demonstrated satisfactory angiographic results of the previously implanted stents (*Figure 3*).

Discussion

Despite the significant advancements in interventional device technologies, the procedural methodology and workflow in the catheterization laboratory have remained largely unchanged in the past years. Robotic-assisted percutaneous coronary intervention represents the

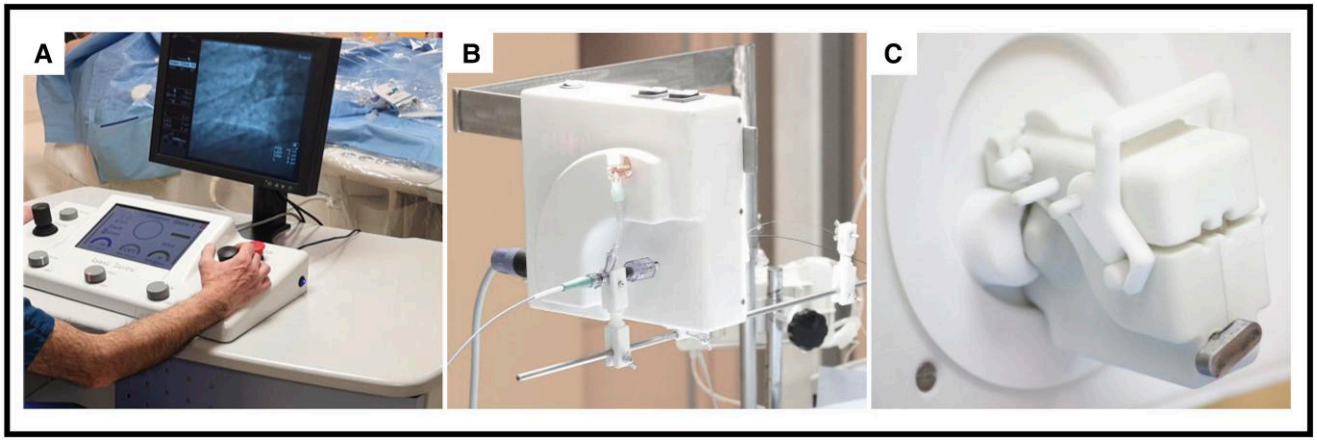


Figure 1 (*A*) The interventional cardiologist performing robotic percutaneous coronary intervention from the robotic console. (*B*) The SLAVE, the power unit of the robot. (*C*) The functional unit of the robot that takes direct contact with guidewires and catheters.

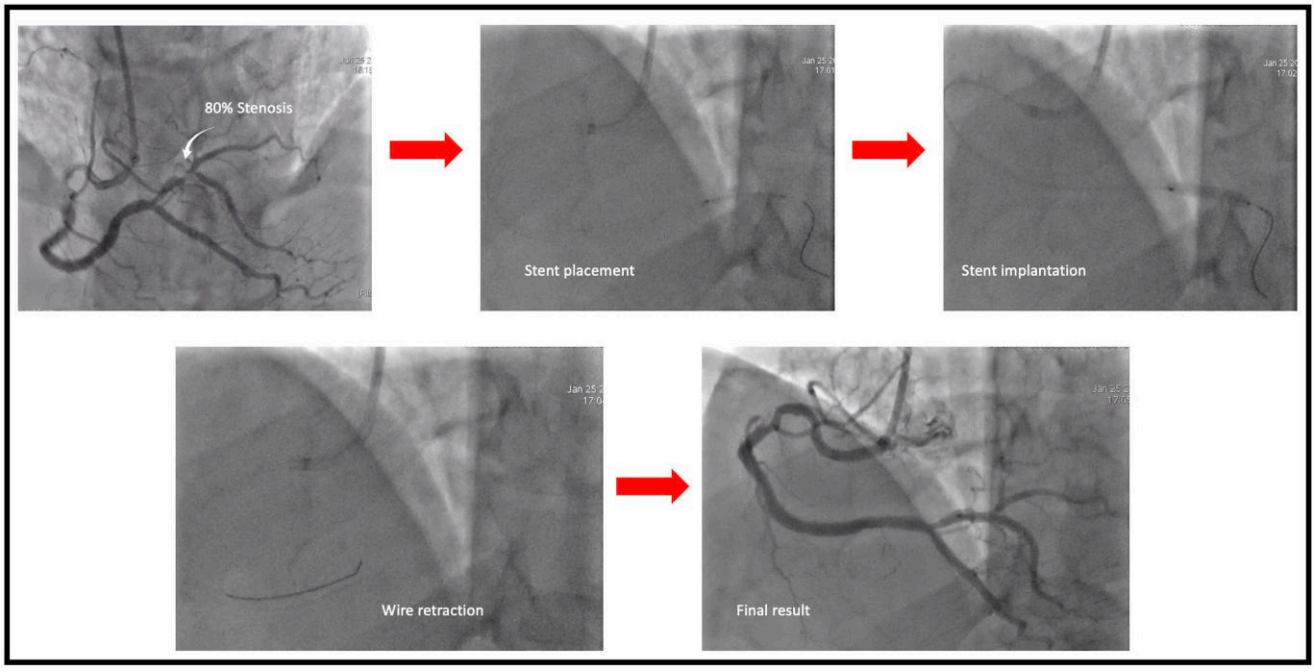


Figure 2 Step-by-step robotic PCI procedure.

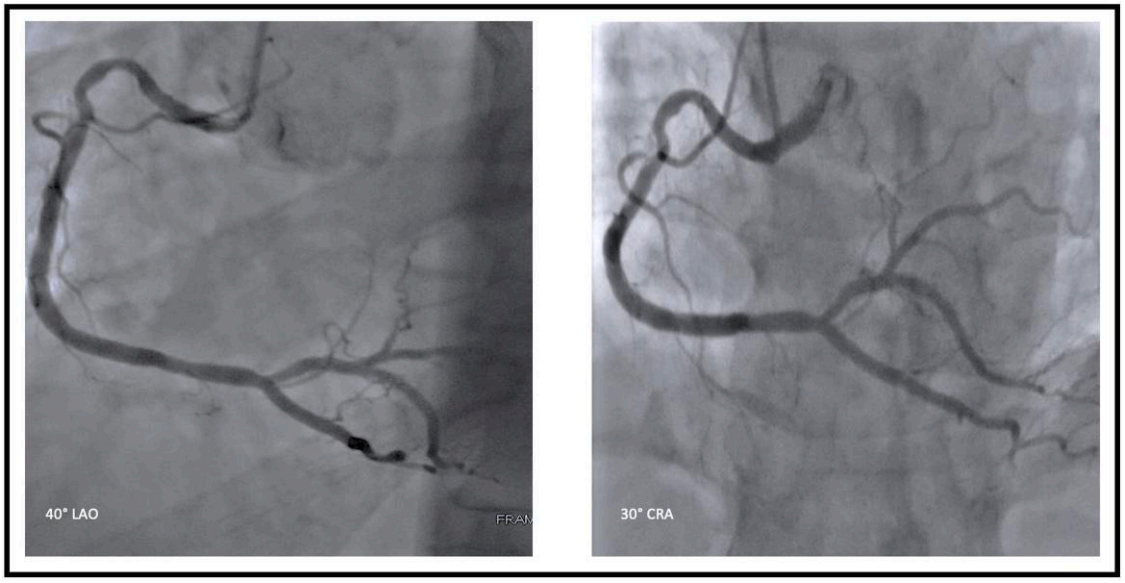


Figure 3 Angiographic follow-up images.

next frontier in the field of interventional cardiology. The advantages of R-PCI are numerous. These include a reduction in radiation exposure, enhanced precision in coronary angioplasty and wire positioning, the potential to improve lab efficiency and increase procedural throughput, as well as the ability to work remotely. Robotic-assisted percutaneous coronary intervention can significantly enhance procedural accuracy for patients while improving radiation exposure for both patients and operators. Integrating a remote-controlled, robotic-assisted PCI system within the catheterization laboratory could potentially tackle procedural shortcomings and workplace risks linked to conventional PCI. This is especially true regarding the precise manipulation of devices (such as wires, balloons, and stents) during interventional procedures.

Furthermore, one of the limitations of traditional PCI is the risk of radiation-induced adverse effects due to radiation exposure. A recent

study has demonstrated a significant reduction in radiation exposure with R-PCI compared to traditional PCI.[8] This highlights the potential of R-PCI to mitigate the risks associated with radiation exposure during coronary interventions.

In this early clinical experience, the use of the ROSES robotic system seems to be safe and effective. In selecting this patient for R-PCI, we initially opted for a simple case in order to assess the feasibility and safety of the robotic system in a standard scenario during the first-in-man procedure. This approach allowed us to evaluate the basic functionalities and performance of the system in a controlled setting. However, it is important to note that R-PCI holds potential benefits that extend beyond simple cases. While our presented case was relatively straightforward, the utilization of robotic assistance can also be advantageous in more complex scenarios. However, this report still represents an early feasibility study, and the use of this technology in more challenging anatomies including the presence of severe tortuosity, severe calcification, or interventions requiring multiple wires and balloons needs to be further studied. A larger, prospective, multicentre pivotal clinical trial designed to test the ROSES robotic angioplasty system in a larger number of patients is currently ongoing.

Lead author biography

Ciro Indolfi is full Professor of Cardiology, Director of the Regional Centre of Excellence for the Endovascular Treatment of Cardiovascular Diseases at the Campus Germaneto, UMG, Past Director, Department of Surgical and Medical Sciences, and Director, URT of Consiglio Nazionale delle Ricerche, University 'Magna Graecia', Catanzaro, Italy. From 1986 to 1987, he was an assistant at the Division of Cardiology University of California, La Jolla, USA, directed by Dr John Ross Jr., President of the Italian Society of Cardiology and Director of the Cardiovascular Research Center of the UMG.

Supplementary material

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

Acknowledgements

Drs Carmen Spaccarotella and Annalisa Mongiardo for helping us to the setup of the robot.

Consent: The authors confirm that written consent for submission and publication of this case report including images and associated text has been obtained from the patient in line with COPE guidance.

Conflict of interest: None declared.

Funding: This research was funded from 2013 to 2017 by the PONREC, grant number PON02_PON03PE_00009_4 Optima Cardiopaths, and ever since by Calabrian High Tech.

Data availability

The data underlying this article are available in the article and in its online supplementary material.

References

1. Reeves RR, Ang L, Bahadorani J, Naghi J, Dominguez A, Palakodeti V, *et al.* Invasive cardiologists are exposed to greater left sided cranial radiation: the BRAIN study (brain radiation exposure and attenuation during invasive cardiology procedures). *JACC Cardiovasc Interv* 2015;**8**:1197–1206.
2. Beyar R, Gruberg L, Deleanu D, Roguin A, Almagor Y, Cohen S, *et al.* Remote-control percutaneous coronary interventions: concept, validation, and first-in-humans pilot clinical trial. *J Am Coll Cardiol* 2006;**47**:296–300.
3. Weisz G, Metzger DC, Caputo RP, Delgado JA, Marshall JJ, Vetrovec GW, *et al.* Safety and feasibility of robotic percutaneous coronary intervention: PRECISE (percutaneous robotically-enhanced coronary intervention) study. *J AmColl Cardiol* 2013;**61**:1596–1600.
4. Robocath. Available online: https://www.robocath.com (accessed on 03 October 2022).
5. Riga CV, Bicknell CD, Rolls A, Cheshire NJ, Hamady MS. Robot-assisted fenestrated endovascular aneurysm repair (FEVAR) using the Magellan system. *J Vasc Interv Radiol* 2013;**24**:191–196.
6. Danieli G, Indolfi C, De Rosa S, Battaglia D, De Gaetano G, Fragomeni G, *et al.* "Robotic System for Angioplasty and Endovascular Surgery" PCT/IT2018/050209 deposited 26.10.2018.
7. Danieli G, Greco PF, Larocca G, De Rosa S, Indolfi C, Polimeni A, *et al.* Development of disposables and accessories for ROSES and their in vitro experimentation. *Appl Mech* 2022;**3**:956–973.
8. Patel TM, Shah SC, Soni YY, Radadiya RC, Patel GA, Tiwari PO, *et al.* Comparison of robotic percutaneous coronary intervention with traditional percutaneous coronary intervention: a propensity score-matched analysis of a large cohort. *Circ Cardiovasc Interv* 2020;**13**:e008888.