POLISH HEART JOURNAL

Kardiologia Polska
The Official Peer-reviewed Journal of the Polish Cardiac Society since 1957

Online first
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ISSN 0022–9032 e-ISSN 1897–4279

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Article type: Short communication

Received: December 18, 2024

Accepted: February 7, 2025

Early publication date: February 28, 2025

The first Polish experience in robotically assisted percutaneous coronary interventions using the R-one™ medical robot

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INTRODUCTION

Robotics in surgery, including cardiac surgery, already has its place, and it is difficult to imagine its absence in everyday activities [1]. On the other hand, this form of supporting percutaneous coronary procedures is relatively young [2], but there are many indications that it will develop faster and faster.

Robotically assisted percutaneous coronary interventions (R-PCI), are a response to the need to reduce occupational risks associated with radiation exposure and the use of wearable X-ray protection.

R-One™ robotic device is a fully integrated robotic platform by Robocath that is the developer of the system. This robotic assistance platform received CE Mark approval in 2019 and is currently used in Europe, Africa, and China.

We present the summary of the first Polish experiences with this promising robotic platform.

ABOUT R-ONE

R-One consists of two parts — a robotic unit attached to the operation table and wirely or wireless connected to radioprotected control station. The multiple joints allow to adjust the arm to any position. The guiding catheter has to be manually introduced to the coronary artery. The guidewire and rapid exchange catheter have to be placed in dedicated paths of the cassette. Further steps may be performed off the table. The control station allows to steer one wire and one Rx catheter. Additional guidewire may be clamped in the cassette, but without the control option.

To date, apart from single-center communications the only study evaluating R-one was the European multicenter prospective R-EVOLUTION study [3, 4]. Key findings in R-EVOLUTION were: 1) >95% technical success, 2) no major procedural or 30-day complications, 3) 84.5% reduction in physician radiation exposure.

METHODS

This study involves 48 consecutive R-PCIs with the R-one system performed between March 2023 and April 2024 in three high-volume, experienced Polish cardiology centers according to the standard PCI protocol. Two operators in each center were designated and trained to perform robotic PCI and underwent hands-on training.

Patients with angiographic or functional criteria of significant coronary stenosis (>50% stenosis of the left main stem, >70% stenosis in a major coronary vessel, or fractional flow reserve ≤0.8) were referred to robotic PCI. High-risk PCI and CTO were considered inappropriate for robotic-assisted PCI.

Major cardiac adverse events (MACE) were defined as acute myocardial infarction, stroke, or cardiovascular death. Clinical success was defined as the absence of major intraprocedural complications, and technical success as successful treatment of target lesion (TIMI 3 flow, no MACE) without conversion to regular PCI. Population characteristics and procedure-related data were collected. Follow-up data were collected during telephone conversations with patients.

The normality of the distribution of numerical variables had been tested using the Shapiro–Wilk *W* test. The descriptive statistics was organized and displayed accordingly. Non-normally distributed variables were described by using their median, lower/upper quartiles. Normally distributed numerical traits were depicted by showing their mean, standard deviation and 95% confidence interval. All the computations were performed using Statistica™, release 13.3 (TIBCO Software Inc., Palo Alto, CA, US)

RESULTS

The R-one system was used for forty-eight procedures. Demographic, clinical, and angiographic characteristics are presented in Table 1.

The radial access was used in 38 (79.19%) patients, and femoral access in 10 (20.81%) cases. Median of administered contrast volume was 120 ml (IQR 100–150 ml). The median of the procedure time was 70 min. (IQR 50–110 min), median of fluoroscopy time 17.30 min. (IQR 14–29 min), and median of radiation dose 491 mGy (IQR 355–908 mGy)

The devices used for the procedure are listed in Table 1, but of note, intravascular ultrasound was used in 12 cases (25%), and laser atherectomy was performed once.

Technical success was achieved in 46 cases (95.83%). Conversion to regular PCI took place in two patients (4.2%) due to dissection of the target vessel. One of these cases was successfully completed manually, and the other ended in a target vessel failure. This shows that clinical success was achieved in 47 cases (97.92%).

Median of hospitalization length was one day (IQR 1–1 day). No major adverse cardiac events occurred within 30 days after the procedure.

DISCUSSION

To our knowledge, 48 percutaneous coronary interventions performed in three Polish cathlabs constitute the relatively big part of experience with R-one in general. We achieved high clinical and technical success rate (97.92% and 95.83% respectively).

Although we tried to avoid the most challenging cases at this step of our experience, more than half of our target lesions were assessed as B2 or C in American College of Cardiology/American Heart Association classification. It is important to note that the results obtained in our group cannot be simply extrapolated for high-risk or complex interventions.

In two cases dissection of target vessel forced us to convert the procedure to manual PCI. These complications occurred post inflations, and not during guidewire manipulations, so that we do not consider them as directly related to the R-one system. In both cases the decision

to convert was based on limited experience with R-one and the desire to resolve the complication as quickly as possible, and not on the limitations of the robotic system.

Apart from these cases no major adverse cardiac events occurred in 30 days follow-up period.

Clinical and technical success rates in our study are comparable with previous reports concerning R-one and other robotic systems. Durand et al. reported 100% clinical and 95.2% technical success in R-EVOLUTION study. [4] In remote navigation system (RNS) (NaviCath, Haifa, Israel), technical success was achieved in 83% of cases, and clinical success in 100%. Based on four trials with first-generation Corindus CorPath 200, technical success was achieved in 91.7-97.6% of cases, whilst clinical success in 98.8-100%. Using the CorPath GRX platform, technical success was observed in 81% to 93.3%, whilst clinical success in 98% to 100% of cases. The use of either robot was not associated with an increased rate of MACE. Data from all previous trials has been already summarized in detail by Wagener et al. [2].

Contrast agent consumption was comparable to other studies concerning robotic PCI i.e. 137 (standard deviation [SD] 62 ml) reported by Smilowitz et al. [5] and 167 (SD 89 ml) reported by Madder et al. [6].

In one fourth of our patients, intravascular ultrasound was used and was trouble free. It is particularly important in the context of the European Society of Cardiology guidelines for the use of IVUS. Solid state IVUS catheters for R-one is not recommended by the manufacturer so far. In terms of non-standard use of R-one, it is worth to mention the recently published case of robotic implantation of a left ventricular lead for a resynchronization system [7].

Relatively long fluoroscopy time may results from our initial experience, but also from differences in study population characteristics We cannot underestimate the expertise of operators taking part in R-EVOLUITION, where mean fluoroscopy time was 10.3 min (SD 5.3 min) [4].

In spite of our initial experience with robotic procedures, we were able to cross all target lesions and deliver various rapid exchange catheters (semi-compliant, non-compliant, cutting balloons, intravascular ultrasound). Particularly noteworthy is the trouble free case with the use of excimer laser catheter. We believe that precise speed control provided by R-one makes the laser atherectomy safer and effective.

Even though we managed six bifurcations, we believe that the possibility of control two guidewires and two catheters simultaneously should be taken into consideration by manufacturer.

CONCLUSIONS

The first, multicenter Polish experience, consisting of 48 robotic assisted percutaneous coronary interventions with R-one system indicates its safety and efficacy. As a product that dramatically affects the safety and well-being of medical personnel, it deserves attention and further development.

Article information

Conflict of interest: None declared.

Funding: None.

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Table 1. Study population characteristics and procedural data

Gender (males), n (%)	27 (56.25)
Age, years, Me (IQR)	70.50 (63–76)
CKD, n (%)	11 (23)
DM, n (%)	18 (37.5)
Previous MI, n (%)	13 (27.1)
Previous PCI, n (%)	20 (41.7)
Previous CABG, n (%)	5 (10.42)
LVEF, %, Me (IQR)	50.00 (40–60)
Chronic coronary syndrome, n (%)	36 (75)
Unstable angina, n (%)	3 (6.25)
NSTEMI, n (%)	5 (10.42)
STEMI, n (%)	4 (8.33)
1-vessel disease, n (%)	25 (52.08)
2-vessel disease, n (%)	14 (29.17)
3-vessel disease, n (%)	9 (18.75)
Syntax, M (SD) (95% CI)	35.35 (14.72) (24.82–45.88)
Bifurcation, n (%)	6 (12.5)
Taget vessel, n (%) • LAD • CX • RCA • Venous graft	 • 18 (37.5) • 12 (25) • 17 (35.42) • 1 (2.08)
ACC/AHA lesion classification, n (%)	

• A • B1 • B2 • C	• 6 (12.5) • 17 (35.42) • 23 (47.92) • 2 (4.17)
Number of stents per procedure, n (%)	1.36 (0.88)
Total DES length, mm, Me (IQR)	26.00 (18–34)
SC balloon, n (%)	19 (39.58)
NC balloon, n (%)	15 (31.25)
Cutting/scoring, n (%)	3 (6.25)
Intravascular imaging, n (%)	12 (25)
Laser atherectomy, n (%)	1 (2.08)

Abbreviations: ACC, American College of Cardiology, AHA, American Heart Association; CKD, chronic kidney disease; CABG, coronary artery bypass grafting; CI, confidence interval; CX, circumflex artery; DES, drug-eluting stent; DM, diabetes mellitus; IQR, interquartile range; LAD, left anterior descending artery; LVEF, left ventricular ejection fraction; MI, myocardial infarction; NC balloon, non-compliant balloon; PCI, percutaneous coronary intervention; RCA, right coronary artery; SC ballon, semi-compliant balloon; SD, standard deviation