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Demonstration of the Safety and Feasibility of Robotically Assisted Percutaneous Coronary Intervention in Complex Coronary Lesions

Results of the CORA-PCI Study (Complex Robotically Assisted Percutaneous Coronary Intervention)

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ABSTRACT

OBJECTIVES The aims of this study were to evaluate the feasibility and technical success of robotically assisted percutaneous coronary intervention (R-PCI) for the treatment of coronary artery disease (CAD) in clinical practice, especially in complex lesions, and to determine the safety and clinical success of R-PCI compared with manual percutaneous coronary intervention (M-PCI).

BACKGROUND R-PCI is safe and feasible for simple coronary lesions. The utility of R-PCI for complex coronary lesions is unknown.

METHODS All consecutive PCI procedures performed robotically (study group) or manually (control group) over 18 months were included. R-PCI technical success, defined as the completion of the procedure robotically or with partial manual assistance and without a major adverse cardiovascular event, was determined. Procedures ineligible for R-PCI (i.e., atherectomy, planned 2-stent strategy for bifurcation lesion, chronic total occlusion requiring hybrid approach) were excluded for analysis from the M-PCI group. Clinical success, defined as completion of the PCI procedure without a major adverse cardiovascular event, procedure time, stent use, and fluoroscopy time were compared between groups.

RESULTS A total of 315 patients (mean age 67.7 ± 11.8 years; 78% men) underwent 334 PCI procedures (108 R-PCIs, 157 lesions, 78.3% type B2/C; 226 M-PCIs, 336 lesions, 68.8% type B2/C). Technical success with R-PCI was 91.7% (rate of manual assistance 11.1%, rate of manual conversion 7.4%, rate of major adverse cardiovascular events 0.93%). Clinical success (99.1% with R-PCI vs. 99.1% with M-PCI; $p = 1.00$), stent use (stents per procedure 1.59 ± 0.79 with R-PCI vs. 1.54 ± 0.75 with M-PCI; $p = 0.73$), and fluoroscopy time (18.2 ± 10.4 min with R-PCI vs. 19.2 ± 11.4 min with M-PCI; $p = 0.39$) were similar between the groups, although procedure time was longer in the R-PCI group (44:30 ± 26:04 min:s vs. 36:34 ± 23:03 min:s; $p = 0.002$). Propensity-matched analysis confirmed that procedure time was longer in the robotic group (42:59 ± 26:14 min:s with R-PCI vs. 34:01 ± 17:14 min:s with M-PCI; $p = 0.007$), although clinical success remained similar (98.8% with R-PCI vs. 100% with M-PCI; $p = 1.00$).

CONCLUSIONS This study demonstrates the feasibility, safety, and high technical success of R-PCI for the treatment of complex coronary disease. Furthermore, comparable clinical outcomes, without an adverse effect on stent use or fluoroscopy time, were observed with R-PCI and M-PCI. (J Am Coll Cardiol Intv 2017;10:1320–7)

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Percutaneous coronary intervention (PCI) has evolved tremendously since its inception, with refinement in pharmacotherapy and improvement in interventional devices. However, the fundamental technique of manually advancing intracoronary guidewires, balloons, and stents at the patient's tableside in relative close proximity to the x-ray radiation source, while wearing heavy lead aprons, remains largely unchanged (1,2). As a result, occupational hazards inherent to performing the PCI procedure expose the operator to both orthopedic and radiation-related adverse effects (3–5).

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Robotic PCI (R-PCI) (CorPath 200, Corindus, Waltham, Massachusetts) can potentially mitigate both the orthopedic and radiation-related occupational hazards associated with the practice of interventional cardiology. The ability to perform remote-controlled R-PCI was initially described by Beyar et al. (6), followed by small in-human feasibility studies (7). Subsequently, the PRECISE (Percutaneous Robotically Enhanced Coronary Intervention) trial demonstrated the safety and feasibility of R-PCI in a multicenter registry study of 164 patients (8) without an increase in patient radiation or contrast use (9,10). However, in that trial, the majority of lesions treated were simple (mean lesion length 12.2 ± 4.8 mm, only 12.8% American College of Cardiology/American Heart Association type C lesions) and not reflective of clinical practice. Although there have been reports of complex cases treated with R-PCI (11,12), no systematic evaluation of R-PCI for complex coronary anatomy has been performed. Hence, we designed this study to 1) evaluate the feasibility and technical success of R-PCI for the treatment of coronary artery disease in clinical practice, especially in complex lesions; and 2) determine the safety and clinical success of R-PCI compared with manual PCI (M-PCI).

METHODS

The study protocol was approved by the University of California, San Diego, Human Subjects Protection Program and designed by the investigators (E.M., J.N., J.H., R.R., M.P.), who verify the authenticity of the data, and all authors participated in drafting the manuscript. Consecutive PCI procedures performed robotically or manually over 18 months by a single operator were included.

ROBOTIC PLATFORM. The robotic system consists of an interventional cockpit and a robotic arm mounted on the catheterization bedside rail (8). This robotic arm contains a drive housing a single-use sterile cassette, which is connected to the guiding catheter after manually engaging the coronary artery. The interventional cockpit is located within the cardiac catheterization laboratory and is connected via cables to the bedside drive (**Figure 1**). It contains monitors that display the live fluoroscopic image and hemodynamic data. The robotic system enables the operator to remotely advance and retract rapid exchange balloons and stents. Additionally, the operator can rotate and advance the guidewire, transmitting torque and permitting guidewire manipulation. Passive control of the guiding catheter is possible with guidewire and balloon manipulation. The fluoroscopy and cine pedal is controlled by the seated primary operator, and contrast injection is performed by the tableside team. Once streamlined, the robotic setup takes approximately 5 min and is performed simultaneously as preparation for ad hoc PCI is undertaken or as a part of the room setup for planned interventions. The robotic system has a capital cost and a disposable cassette cost of approximately $900 per procedure (capital cost depreciated over 6 years with an estimated R-PCI volume of 250 procedures per year).

STUDY GROUP. Data for R-PCI (study group) were prospectively collected as part of the ongoing PRECISION (Post-Market CorPath Registry on the CorPath 200 System in Percutaneous Coronary Interventions) registry (NCT01917682), and all R-PCI procedures at this center since the introduction of the technology constituted the study group. The PRECISION registry is a post-market, prospective, single-arm, multicenter registry collecting data on the use, safety, and effectiveness of the CorPath 200 system for PCI procedures. All patients participating in this study must be ≥18 years of age, have coronary artery disease revascularized with robotically assisted PCI using the CorPath 200 system, and voluntarily agree to participate in the study after providing informed consent.

CONTROL GROUP. Data for M-PCI (control group) were simultaneously collected as a part of the National Cardiovascular Data Registry CathPCI registry. The CathPCI registry is an initiative of the American College of Cardiology Foundation and the Society for Cardiovascular Angiography and Interventions. Details of the CathPCI registry have been previously described (13). The registry collects demographic, clinical, and procedural data elements for consecutive PCI procedures at each participating center.

ABBREVIATIONS AND ACRONYMS

CK = creatine kinase
MA = manual assistance
MACE = major adverse cardiovascular event(s)
MC = manual conversion
MI = myocardial infarction
M-PCI = manual percutaneous coronary intervention
PCI = percutaneous coronary intervention
PT = procedure time
R-PCI = robotic percutaneous coronary intervention
ULN = upper limit of normal