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Robotically-assisted percutaneous coronary intervention: Reasons for partial manual assistance or manual conversion☆

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ABSTRACT

Background: Robotically-assisted percutaneous coronary intervention (R-PCI) is feasible for simple coronary lesions.
Objectives: To determine the frequency and reasons for partial manual assistance or manual conversion during R-PCI in clinical practice.
Methods: The CorPath 200 System (Corindus, Waltham, MA) enables the operator to sit in a radiation-shielded cockpit and remotely control intracoronary devices including guidewires, balloons, and stents. Consecutive R-PCI procedures performed over 18 months were analyzed to identify reasons for planned or unplanned manual assistance or manual conversion, and categorized as due to 1) adverse event; 2) technical limitation of the robotic platform; or 3) limited guide catheter/wire support.
Results: During the study period, 108 R-PCI procedures (68.1 ± 11.0 years, 77.8% men, 69.4% elective PCI, 78.3% type B2/C lesions, and 50.3% left anterior descending/left main target lesion segment) were performed. High robotic technical success (91.7%) and clinical procedural success (99.1%) were achieved. Twenty procedures (18.5%) required either planned partial manual assistance (3.7%), unplanned partial manual assistance (7.4%), or manual conversion (7.4%). Among these procedures, manual assistance/conversion was required in 3 procedures for an adverse event (15%), 8 for technical limitation of the robotic platform (40%), and 9 for guide catheter/wire support issues (45%).
Conclusions: High clinical success with R-PCI for a complex lesion cohort is possible with only occasional partial manual assistance or manual conversion. The majority of procedures requiring manual assistance/conversion were due to limited guide catheter/wire support or robotic platform limitations, rather than occurrence of adverse events.

1. Introduction

Tremendous advances in adjunctive pharmacotherapy and device technology have been made since the initial description of percutaneous coronary intervention (PCI), but the fundamental technique of operators manually advancing intracoronary devices at the patient's tableside while wearing heavy lead aprons in close proximity to an X-ray radiation source remains largely unchanged. The heavy lead apron worn by cardiovascular interventionalists is associated with orthopedic complications while significant radiation exposure is an additional occupational hazard [1–4].

Robotically-assisted PCI (R-PCI), allowing operators to remotely manipulate intracoronary devices without lead-apron protection, can potentially limit the orthopedic and radiation-associated risks. The PRECISE (Percutaneous Robotically Enhanced Coronary Intervention) trial, in a large multicenter study consisting of 164 patients, demonstrated the safety and feasibility of robotic-assisted PCI in simple coronary lesions with approximately 1% of the cases requiring any manual assistance [5]. PCI in this study was primarily performed for simple lesions (12.3% type C), and 99% of the procedures were completed entirely robotically. The current study sought to determine the frequency of partial manual assistance or manual conversion during R-PCI, and identify the associated reasons for assistance or conversion, among subjects treated in clinical practice and with more complex coronary anatomy.

2. Methods

This study was approved by the Institutional Review Board of the University of California, San Diego. Data for all patients enrolled in the

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PRECISION registry (ClinicalTrials.gov Identifier: NCT01917682) at UC San Diego were queried. The PRECISION registry is a post-market, prospective, single-arm, multi-center registry collecting data on the use, safety and effectiveness of the CorPath 200 Vascular Robotic System for patients undergoing PCI procedures. All patients participating in this study were ≥18 years of age, underwent R-PCI using the CorPath200 system, and voluntarily agreed to participate in the study after providing informed consent.

The occurrence and reason for either partial manual assistance (planned or unplanned) or manual conversion were recorded and categorized as being due to 1) an adverse event, 2) technical limitation of the robotic platform (e.g. requirement for two balloons or stents to be inflated together, need for any over-the-wire equipment), or 3) limited guide catheter/wire support. Baseline subject characteristics, procedural details, and laboratory data were routinely measured with post-PCI creatinine phosphokinase myocardial band (CK-MB) and total creatine phosphokinase (CPK) collected every 8 h in all subjects.

2.1. CorPath 200 vascular robotic system

The CorPath 200 system has been previously described [5]. Briefly, it consists of an interventional cockpit and a robotic arm mounted on the catheterization bedside rail (Fig. 1). This robotic arm contains a drive housing a single-use sterile cassette, which is connected to the guiding catheter after manual engagement of the target coronary vessel. The interventional cockpit is located within the cardiac catheterization laboratory and is connected via cables to the bedside drive. Monitors displaying the live fluoroscopic images and hemodynamic data are mounted within the cockpit. Controls allow the operator to remotely advance, retract, and rotate a 0.014-inch guidewire. Additionally, rapid-exchange balloons and stents can be remotely advanced and retracted.

2.2. Key definitions

Clinical success was defined as R-PCI completion (final flow TIMI 3 and residual stenosis <30%) without an in-hospital major adverse cardiovascular event (MACE: myocardial infarction, urgent target vessel revascularization, emergent coronary artery bypass grafting, all-cause death). Clinically-relevant post-PCI myocardial infarction was defined as rise in CK-MB >5× upper limit of normal (ULN) with evidence of myocardial injury or an asymptomatic CK-MB >10× ULN [6]. Data for the universal definition of myocardial infarction (CK-MB >3× ULN) were also collected. Robotic technical success was defined as clinical success and the completion of the PCI procedure entirely robotically or with partial manual assistance in the absence of MACE.

Manual assistance was defined as temporary disengagement of the robotic drive in order to utilize bedside manipulation of either the guide catheter or wire, with ultimate completion of the procedure utilizing the re-engaged robotic drive. Planned manual assistance was defined as anticipated temporary disengagement of the robotic drive in order to utilize bedside manipulation of either the guide catheter or wire, with ultimate completion of the procedure utilizing the re-engaged robotic drive (e.g. deployment and retrieval of a distal embolic protection device during vein graft PCI). Unplanned manual assistance was defined as unanticipated temporary disengagement of the guide catheter or wire, with ultimate completion of the procedure utilizing the re-engaged robotic drive. Manual conversion was defined as the disengagement of the robotic drive in order to utilize bedside manipulation of either the guide catheter, wire, or stent, which was required until the end of the procedure. An example of such a case is presented (Figs. 2 and 3).

3. Results

During the 18-month study period, a total of 108 R-PCI procedures (157 lesions) were performed. Subjects undergoing R-PCI had a high prevalence of diabetes mellitus, hypertension, dyslipidemia, prior myocardial infarction, and prior coronary artery revascularization (Table 1). A high proportion of complex coronary lesions (78.3% type B2/C lesions) were treated within this cohort (Table 2) predominantly via femoral arterial access (88.0%). Overall subject characteristics were similar between procedures completed entirely robotically ($n = 88$, 81.5%) versus those utilizing any manual aspect.

Among the 20 procedures requiring any manual aspect, planned partial manual assistance was performed in 4 procedures (3.7%), unplanned partial manual assistance in 8 procedures (7.4%), and manual

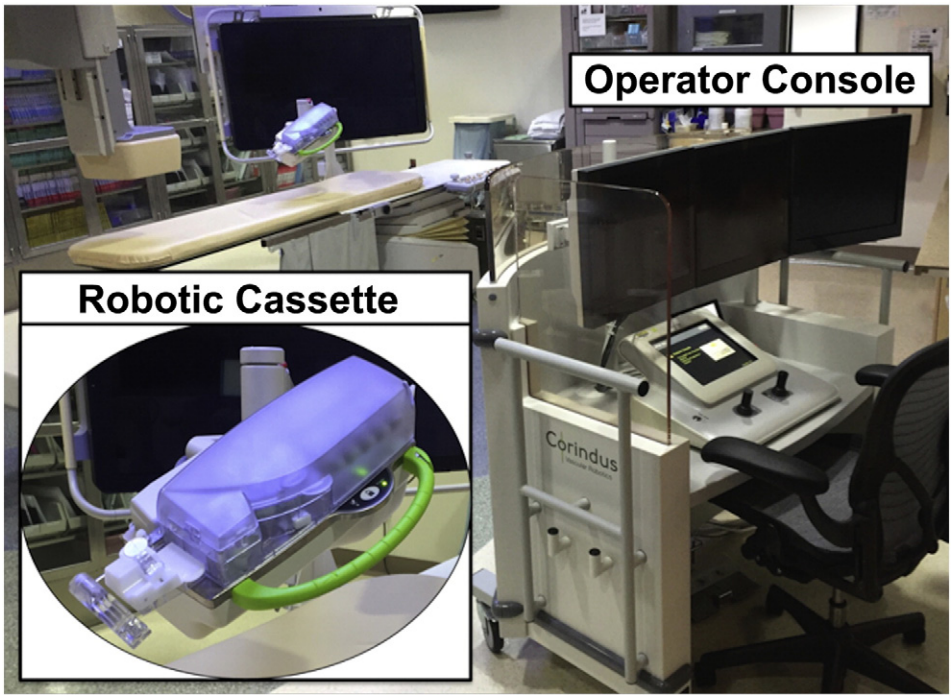

Fig. 1. Robotic PCI platform. (A) Robotic console and tableside drive (CorPath 200, Corindus, Waltham, MA) with robotic cassette (inset).

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