First-in-Human Evaluation of a Novel Robotic-Assisted Coronary Angioplasty System

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Objectives We aimed to evaluate the safety and feasibility of a robotic angioplasty system in delivery and manipulation of coronary guidewires, balloons, and stents in patients undergoing elective percutaneous coronary intervention (PCI).

Background A remote-control, robotic-assisted angioplasty system is under development to address some of the procedural challenges and occupational hazards associated with traditional PCI.

Methods Patients with coronary artery disease and clinical indication for elective PCI were enrolled. The coronary angioplasty procedure was performed with the CorPath 200 robotic system (Corindus, Inc., Natick, Massachusetts). The system consists of a remote interventional cockpit and a multicomponent bedside unit that enables the operator to advance, retract, and rotate guidewires and rapid exchange catheters. The primary endpoint was device clinical success (≤30% residual stenosis) without in-hospital major adverse cardiac events. Technical success was defined as the ability of the system to complete all the planned angioplasty steps on the basis of procedural segments. Patients were followed up to 30 days after angioplasty procedure.

Results A total of 8 patients were enrolled in the study. The primary endpoint was achieved in all patients (100%). The technical success of the robotic system was 97.9% in completing 47 of 48 planned steps. There were no device- or procedure-related complications and no in-hospital or 30-day major adverse cardiac events. The operators rated the robotic system performances as equal to or better than manual procedures in 97.5% of the cases. The operator radiation exposure was 97% lower than the levels found at the standard table position.

Conclusions Early clinical experience with a robotic-assisted angioplasty system demonstrated feasibility, safety, and procedural effectiveness comparable to manual operation. In addition, the total operator exposure to radiation was significantly low. A larger study is warranted to verify the safety and effectiveness of robotic-assisted percutaneous coronary intervention. (J Am Coll Cardiol Intv 2011;4:460–5) © 2011 by the American College of Cardiology Foundation.

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The current practice of percutaneous coronary intervention (PCI) still presents potential hazards for patients, operators, and the catheterization laboratory personnel (1–3). With the increasing complexity of the treated lesions and procedures, both patients and laboratory personnel are subjected to longer procedural duration and radiation exposure (3). From the operator perspective, the long hours of standing while wearing a lead apron commonly leads to orthopedic injuries that frequently results in reduced performance and loss of workdays (1).

A remote-control, robotic-assisted angioplasty system was developed to address some of the procedural challenges and occupational hazards associated with traditional PCI in addition to enhancing the degree of precision and control for the interventional procedure. We report the first-in-human experience with a novel, robotic system for PCI. The objective of the study was to evaluate the safety and feasibility of the system in delivery and manipulation of coronary guidewires, balloons, and stents in patients undergoing elective PCI.

**Methods**

This first-in-human study was designed as a single-arm, open-label, prospective investigation of a robotically assisted angioplasty system among patients undergoing PCI. All procedures were performed at the Corbic Research Institute (Corbic Institute, Envigado, Colombia). The study protocol was approved by the local ethics committee and the Ministry of Health of Colombia, South America.

**Study population.** Patients with angiographic documentation of obstructive coronary artery disease and evidence of myocardial ischemia were enrolled in the study. All patients had a single de novo coronary target lesion, up to 25 mm in length, in vessels ranging from 2.5 to 4.0 mm in diameter. Major clinical exclusion criteria included planned coronary artery bypass graft surgery or PCI within 30 days of target procedure, congestive heart failure or left ventricular ejection fraction of <30%, recent (<72 h) myocardial infarction, and recent stroke (<30 days) or bleeding diathesis. Angiographic exclusion criteria included prior stent within 5 mm of the target lesion, ostial or bifurcation lesion, total occlusion, and severe tortuosity or calcification. All patients were individually followed for clinical events for 30 days after procedure.

**Robotic PCI system.** The CorPath 200 System (Corindus, Inc., Natick, Massachusetts) is a novel robotic system that was developed for coronary and endovascular procedures (Fig. 1). The system consists of 2 major components: the interventional cockpit and a bedside unit. The interventional cockpit is a radiation-shielded mobile workstation that can be positioned anywhere in the catheterization laboratory. It allows the interventional cardiologist to perform the PCI procedure remotely from the control console while sitting at the cockpit unit. The robotic system is an open-architecture system that is compatible with 0.014-inch guidewires, rapid exchange catheter systems, and other standard catheterization laboratory hardware and imaging systems (Fig. 1B). The system allows manipulation of the guidewire, balloon, and/or stent catheter with 1 hand with the possibility of operating the automatic contrast media injector with the other hand. Manipulation is achieved through the designated joysticks at the control console (Fig. 2A). The fluoroscopy and electrocardiography and hemodynamic monitors are “slaved” to duplicate monitors inside the cockpit, enabling visualization from a closer distance (Fig. 2B). The bedside unit includes the bedrail-mounted articulated arm supporting the robotic drive with the attached single-use cassette. The robotic drive is connected to the control console with a communication cable.

**Robotic-assisted angioplasty procedure.** Baseline angiograms and the suitability of the target lesion for robotically assisted PCI were analyzed before intervention. The procedure was started by obtaining vascular access through conventional percutaneous catheterization techniques. A standard guiding catheter was manually introduced, and the target coronary artery was selectively cannulated by the operator with standard interventional techniques. The guide catheter is manually connected to the Y-connector, which—in its turn—is placed manually into the Y-connector holder of the cassette. A part of the guide catheter between the Y-connector and incision site was supported by the adjustable robotic extension arm. The coronary guidewire was manually introduced through the Y-connector into the guiding catheter and loaded the distal end of the guidewire into the cassette. From this point forward, the operator, via the control console joysticks is capable of controlling the cassette, which offers linear and rotational motions, so the devices can be advanced, retracted, and rotated. After coronary guidewire introduction with the robotic system, the operator loaded a rapid exchange coronary angiography balloon into the system and advanced the device with the robotic system to perform pre-dilation of the target lesion by a standard technique. Thereafter, the angioplasty balloon was retracted with the robotic system and then exchanged for a rapid exchange stent delivery system. The procedure for stent insertion, deployment, and retrieval was performed with the robotic system in a similar fashion. Final angiography was performed from the cockpit to assess the efficacy of stent implantation and rule out the presence of any associated complications.

**Study endpoints.** The primary endpoint was device clinical success, defined as <30% final diameter stenosis after using the robotic angioplasty system to deliver a balloon and deploying a stent to the target lesion, and successfully retracting the delivery system without in-hospital major adverse cardiac events (MACE). Major adverse cardiac events were defined as cardiac death, Q-wave or non-Q-wave myocardial infarction, or clinically driven target vessel revascularization. Technical success was defined as the ability of the
Figure 1. CorPath 200 System

Description of the CorPath 200 System. (A) Typical set up of the equipment in the catheterization laboratory: bedside unit mounted on a bedrail, and the Interventional Cockpit is positioned at the foot of the procedure table. (B) The bedside unit is composed of: 1—an articulated arm containing 2—the robotic drive; and 3—a single-use cassette. The 4—single-use cassette, shown with 5—attached guide catheter supported with guide catheter arm and 6—loaded balloon catheter.
system to complete all the planned technical steps on the basis of the number of procedural segments required to complete the introduction and retrieval of all devices. Radiation exposure to the operator at the cockpit and at the procedure table—a site of traditional operator—was monitored with the electronic direct dosimeters (EDD-30, Unfors, Billdal, Sweden). The robotic-system procedural attributes were recorded immediately after the procedure and were rated by all operators as better, equal, or worse than manual separately for the guidewire, balloon catheter, and balloon/stent catheter in 5 performance categories: introduction, tractability, pushability, crossing lesion, and withdrawal.

**Statistical analysis.** Data were manually entered in Excel spreadsheet (Microsoft, Redmond, Washington), and with Excel software, the following values were calculated: average (mean), SD, and median. The radiation exposure for the operator at the intervention cockpit and at the procedure table as well as creatine kinase-myocardial band values from before and 24 h after procedure were analyzed with Wilcoxon paired nonparametric test, due to a small sample size (n = 8).

**Results**

A total of 8 patients who met inclusion and exclusion criteria and had signed the informed consent form underwent PCI with the robotic system. Table 1 summarizes the demographic and baseline characteristics of all included patients. The left anterior descending artery was treated in 1 patient (12.5%), the right coronary artery was treated in 4 patients (50%), and the left circumflex artery was treated in 3 (37.5%). Six selected lesions were classified as type A, and 2 were classified as Type B1 lesions, in accordance with American College of Cardiology/American Heart Association grading criteria. The mean lesion length was 11.4 ± 6.1 mm, mean reference vessel diameter was 3.0 ± 0.74 mm, and the mean diameter stenosis was 63.1 ± 15%. All procedures were performed with a 6-F guide catheter and a single type 0.014-inch balanced middleweight wire (Abbott Vascular, Santa Clara, California). Pre-dilation was done with the monorail Maverick2 balloon (Boston Scientific,
Natick, Massachusetts). The stents used were either bare-metal (Liberté, 75%) or the everolimus-eluting stent (Promus, 25%) (both Boston Scientific). At the end of the procedures, all patients had final residual stenosis of <10% with Thrombolysis In Myocardial Infarction flow grade 3.

All PCI procedures were completed with the robotic system without any periprocedural complications. An example of the lesions treated is shown in Figure 2B. The mean procedure time was 43.0 ± 18.6 min with mean robotic-system procedure time of 26.5 ± 8.0 min and with a mean fluoroscopy time of 11.5 ± 3.7 min. In all patients the robotic-assisted procedure included successful navigation and crossing the target lesion. The advancements of the guidewire proceeded smoothly, without any dissection or perforation. In all patients the pre-dilation balloon was successfully delivered to the lesion, inflated as clinically indicated, and successfully retrieved by the robotic system back into the guiding catheter. In all the patients the stent was successfully delivered to the lesion by the system. After stent deployment, in all patients, the stent delivery system was successfully retrieved into the guiding catheter. In all but 1 patient, the guidewire was successfully retrieved into the guiding catheter. In 1 patient, the guidewire was retrieved by the robotic system to the distal part of the guiding catheter, but because of a partial system malfunction, the rest of the retrieval was performed manually. This conversion to manual operation was immediate and not associated with myocardial ischemia, hemodynamic compromise, or any other complications. In summary, 100% of the interventional components were successfully delivered, and 95.8% (23 of 24) were successfully retrieved, for an overall technical success rate of 97.9% (47 of 48). There were no clinical adverse affects related to the use of the robotic system. Thus, the primary endpoint defined as device clinical success (≤30% residual stenosis) without in-hospital MACE was achieved in all 8 patients (100%). At 24 h after procedure, no patient had increase in the creatine kinase-myocardial band levels (mean levels changed from 14.6 ± 3.2 at baseline to 16.1 ± 3.6 at 24 h, p < 0.35). There were no instances of in-hospital MACE, and at 30-day follow-up, all patients remained asymptomatic with no MACE. Total radiation exposure to the operator at the cockpit was 97% lower than at the procedure table (1.81 ± 1.93 μGy vs. 61.57 ± 54.95 μGy, p < 0.012).

The robotic system performance during PCI procedure was rated as equal to that of the manual procedure in 92.5% of the cases for all devices and procedural steps. In 2 cases, the guidewire advancement/retrieval was rated as better than manual, and in the single case of guidewire retrieval failure, it was rated as worse than manual.

### Discussion

In this study we report the first-in-man experience with the CorPath 200 System, a novel robotic-assisted angioplasty system. The system achieved a technical success rate of 97.9%, completing 47 of 48 procedural segments, and there were no MACE or any other adverse events associated with the system. All patients were discharged home within 24 h after intervention. In 1 case, at the end of the procedure after successful deployment of the stent and at the time of the final wire retrieval, there was a recoverable cassette failure, and the operator decided not to complete the procedure with the robotic-assisted system and removed the remainder of the wire (approximately 2 cm) manually. This system malfunction was considered minor and did not compromise the overall performance and safety of the procedure at any given point. Except for this 1 case, the operators consistently scored the robotic-assisted system at least equal to manual operation. All the patients completed the 30-day follow-up without MACE.

Robotic systems have been suggested to enhance the precision of cardiovascular procedures with increased accuracy (4–10). One of the technical features of the robotic system is the capability to control and accurately position (1-mm steps) the stent delivery system. The recent STLLR (Stent deployment Techniques on cLinicalL outcomes of patients treated with the cypherRestent) trial highlighted the impact on clinical outcomes of geographic miss and stent misplacement (11). Although endovascular imaging guidance is likely necessary to improve the precision of stent placement, the robotically assisted system facilitates the positioning of the stent delivery system with a high degree of accuracy. In addition, robotic systems have been suggested to reduce radiation exposure (12,13). The RELID (Retrospective evaluation study of lens injuries and dose) study revealed that interventional cardiologists have cataract-type eye opacities 3 times more often than age-matched controlled group (2). The mean fluoroscopy time from this study compares favorably with the results of the study of 9,650 patients undergoing single-vessel PCI (11.5 min vs. 18.3 min) (14) and with a subgroup of 7,242 patients whose fluoroscopy time was ≤23 min (11.5 min vs. 12.7 min) (14). Shorter fluoroscopy time translated into...
reduced radiation exposure for the patient and the operator and reduced contrast fluid usage. In our study, 1 of the most important findings was the significant (97.1%) reduction in radiation exposure to the operator performing the robotic PCI procedure. The patient radiation exposure was within the normal reported limits: 2.1 Gy versus 1.9 Gy (14). Also, although the study was not designed to show differences in contrast volume usage, the total volume of contrast agents used in this study seemed to be less, compared with what has been reported in other clinical series (14). The lower contrast usage might be attributed to the complete procedure control enabled by the interventional cockpit environment (Fig. 2). Another subjective but still important finding was the level of technical “comfort” expressed by the operators. Although no specific measurement of this variable was used in this study, both operators perceived this system to be more comfortable compared with the typical technique used for coronary intervention. Most of the cases were performed under a controlled environment, in which the operator had the opportunity to focus on the performance of the procedure, having a close proximity of the monitors and not distracted by the physical strain of the lead apron and standing position.

Despite the significant evolution in interventional device technologies, the actual procedural methodology and workflow in the catheterization laboratory has remained unchanged in the last 25 years. As the current practice of interventional cardiology evolves into more complex PCI procedures, interventional cardiologists, the professional societies (15), U.S. Food and Drug Administration, and International Atomic Energy Agency called for enhanced catheterization laboratory safety by reducing radiation exposure to both patients and operators (16–17) and making the overall catheterization laboratory environment more ergonomically friendly through technological innovations (3). Incorporating a remote-control, robotic-assisted PCI system into the catheterization laboratory might address some of the procedural deficiencies and occupational hazards associated with traditional PCI in addition to contributing to a higher degree of precision and control for the interventional procedure.

In this early clinical experience, the use of the robotic system seems not to reduce the overall periprocedural times compared with manual PCI of single lesions (14). However, we believe that, as this technology underwent initial clinical evaluation, the rigor of the study procedure in addition to the time required to register the data added additional procedural time. In addition, from the operator point of view, there was an initial learning and technology adaptation curve that we believe will improve over time, leading to shorter procedural times. However, this study still represents an early feasibility study in a small cohort of patients, 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, multicenter pivotal clinical trial designed to test the robotic angioplasty system in a larger number of patients is underway.

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REFERENCES


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