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Robotic-Assisted PCI – A New Approach to the Transcatheter Treatment of Coronary Artery Disease

Author(s):

Joseph P. Carrozza Jr., MD, Steward St. Elizabeth's Medical Center and Tufts University Medical School, Boston, Massachusetts

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Introduction

Despite significant advances in the devices for percutaneous coronary intervention (PCI) in the last three decades, the basic approach to how the operator performs the procedure has experienced very little change. The operator still manually maneuvers guide wires and balloon catheters, while donning a heavy lead apron adjacent to a high dose radiation source. While PCI today is considered a safe, effective treatment for ischemic heart disease, there is an opportunity to enhance the current procedure by providing a precise, cost-effective tool to the physicians to perform PCI in a safer and ergonomic environment.



With increase in PCI procedure volume and complexity, there is increasing evidence relating interventional cardiologist time in the catheterization laboratory with orthopedic problems, cataract formation, and cancer.(1-7) The cardiac catheterization laboratory is indeed a “high-risk” work environment for the interventional cardiologist.(8)

In July 2012, the FDA cleared the first robotic-assisted system for PCI, the CorPath® 200 System (Corindus Vascular Robotics). The system is designed to provide a tool to the physician to enhance the current procedure by providing precise control of guidewires and balloon/stent catheters, while addressing the risk to the interventional cardiologist of orthopedic problems and radiation exposure, as well as potentially improve the precision and accuracy of PCI device manipulation and delivery.(9-12) The system underwent extensive testing and validation in animal laboratory and two clinical trials.(13-16)

The clinical trials: Data demonstrate safety and efficacy, while enhancing control and radiation protection

The first-in-man and pivotal PRECISE (Percutaneous Robotically-Enhanced Coronary Intervention Study) clinical trial were initiated to evaluate and compare safety and efficacy of robotic-assisted PCI (CorPath 200 System) to historical controls of traditional manual PCI performed in recent clinical trials of coronary stenting. The first-in-man trial enrolled eight patients with coronary artery disease indicated for elective PCI at the Corbic Research Institute in Envigado, Colombia. More comprehensive, the PRECISE trial was designed as a prospective, multicenter, non-randomized clinical trial. The study enrolled 164 patients at nine clinical sites, including St. Elizabeth's Medical Center in Boston.

The main criteria for inclusion were the presence of ischemic heart disease and de novo lesion less than or equal to 24 mm in length in a native coronary artery 2.5–4.0 mm in diameter treatable with a single stent. Exclusion criteria include myocardial infarction (MI) within 72 hours, staged PCI or coronary artery bypass graft surgery (CABG) within 30 days, a prior PCI within 30 days complicated by a serious adverse event, serum creatinine >2.0 mg/dl, and treatment of chronic total occlusion, bifurcation stenosis, ostial lesion location, severe calcification or angulation, and need for adjunctive treatment with atheroablative techniques.

The PRECISE trial co-primary endpoints compared 1) safety – defined as clinical procedural success in the absence of major adverse cardiac events (MACE) such as cardiac death, myocardial infarction, or clinically driven target vessel revascularization (TVR) within 48 hours of procedure or before discharge, whichever comes first, and 2) efficacy – defined as technical procedural success in the completion of the procedure without converting to manual manipulation. Secondary endpoints assessed relative reduction in radiation exposure to the operator in the cockpit compared with radiation exposure at the table site, contrast usage, procedure time, and 30-day follow-up MACE.

Of the 164 patients enrolled, slightly over one third of the treated lesions were considered complex and classified as B2 and C by an independent angiographic core laboratory. Both co-primary and all secondary endpoints were successfully met. The primary endpoint of a clinical procedural success was achieved at 97.6 percent with four peri-procedural MIs (asymptomatic post-procedure increase in CK-MB levels above 3X of upper laboratory limit) and the primary endpoint of a device technical success was achieved at 98.8 percent, with only two cases converted to manual PCI. All patients in the study achieved

Both clinical trials validated the concept of robotic-assisted PCI and demonstrated that the interventional cardiologist can successfully perform PCI with a similarly high level of efficacy when compared with historical controls.

In addition to proving safety and efficacy of the technology, both trials also demonstrated unambiguously significant radiation reduction in radiation exposure to the primary operator (the first-in-man – 97.1 percent and PRECISE – 95.2 percent reduction in median radiation exposure to the operator when compared to a radiation exposure at the table) without prolonging total procedure time or negatively affecting any other procedural characteristics. It is a significant advancement to potentially reducing the deleterious effects of long-term radiation exposure and the orthopedic issues that are inherent in the cath lab.

Catheterization laboratory environment

The CorPath 200 System is composed of a bedside unit mounted on the table and an interventional cockpit positioned at the foot of the table (Figure 1). The bed-side unit has an articulated arm that mounts on a procedure table and houses a robotic drive with a single-use cassette. The radiation-shielded interventional cockpit is a workstation housing a control console, and duplicate angiographic and hemodynamic monitors. The cockpit has a low profile and does not require any additional construction to fit into the cath lab — it can be rolled in and out of the treatment room. The interventional cardiologist, when seated in a radiation-protected cockpit, is in close proximity to the eye-level-positioned monitors, and controls the commercially available angioplasty guide wires, balloons, and stent delivery systems by joysticks or touch screen on the control console. The devices can be advanced and withdrawn continually or in precise 1-mm increments. Guide wires can also be rotated continually or in 30° increments. The Y-adapter connected to a guiding catheter is attached to the cassette. The measurement function built into the system allows precise quantification of the distance the guide wire or balloon/stent catheter travels, facilitating precise measurements of important anatomic relations in the coronary arteries.



Figure 1. CorPath 200 System in the catheterization laboratory of St. Elizabeth's Medical Center.

The cockpit protects the operator from radiation exposure. Results of both clinical trials showed no radiation exposure to the operator as long as the physician remained seated at the cockpit for the duration of the interventional part of the procedure. Initial concern that placing the operators in a safe and comfortable environment will make them less aware of radiation to which patient and cath lab staff are exposed were unfounded. The results of both trials showed that overall procedure time, radiation dosage, contrast media usage, and radiation exposure to the second operator (cath lab technologist or fellow) compared favorably with the historical data.(17)

In addition, the results of animal studies demonstrated that the CorPath 200 PCI overall procedure time, x-ray time, contrast media usage, and radiation exposure to the animal were similar when compared to the animals which underwent traditional, manually performed PCI procedures.(18) There was a 30 percent reduction in contrast media usage in robotic-assisted PCI in the first-in-man trial(13) and nearly 40 percent in the PRECISE trial(14) when compared to historical controls.(17)

While operating the robotic-assisted system, the interventional cardiologist can elect to wear a protective apron under a sterile gown, and perform functions at the bedside and the

interventional cockpit, or he/she may elect not to scrub and manipulate the PCI devices from the control console, thus allowing a fellow or a cath lab technologist to load PCI devices into the cassette. In both situations, the operator is seated at the cockpit during the interventional part of the procedure, utilizing the cockpit monitors for visualization and robotic controls for PCI device manipulation (Figure 2).



Figure 2. CorPath 200 system set-up: (A) for a case with physician scrubbed and operating at the patient's site at the table and at the cockpit (sterile draping of the console and chair is required); (B) for a

case where physician is only operating at the cockpit.

Robotic-assisted PCI is designed to enable a hybrid approach to the robotic procedure. The robotic-assisted system allows the physician to easily switch to traditional manual delivery if desired. The operator can easily alternate between robotic and manual operation by simply opening the cassette, removing the guide wire and catheter, and proceeding manually to manipulate the PCI devices. Later, if desired, the operator may reload them back into the cassette and continue the robotic procedure.

Robotic PCI: A learning curve?

One may question the type of training necessary to become proficient in robotic-assisted PCI, because often, new technologies and products are challenged by extensive training and routine-breaking, challenging workflow. There were 23 investigators in the PRECISE clinical trial, with 18 subjected to hands-on training in the animal laboratory, while the other 5 were trained with an acrylic vascular model. The clinical outcomes and procedural characteristics from the cases performed by these two groups showed no difference, validating use of an acrylic vascular model as a sufficient and acceptable paradigm for training operators in robotic-assisted PCI with the CorPath 200 System. The first three patients of every investigator in the PRECISE trial were considered as 'roll-ins.' When procedural characteristics of roll-in cases were compared with the rest of the patients in the trial, a gradual improvement in the total procedure time (51.1 ± 25.5 vs. 42.3 ± 16.4 min) and x-ray time (12.8 ± 7.9 vs. 10.2 ± 4.8 min) was noted as part of a learning curve that leveled off after the 'roll-in' patients; i.e., there were no difference in the procedural characteristics between next three patients and the rest of the patients. PRECISE confirmed a quick learning curve in the development of operating proficiency of the CorPath 200 System.

Cath lab staff

During the PRECISE trial at St. Elizabeth's, the catheterization laboratory staff also underwent training in robotic-assisted PCI with the CorPath 200 System. The training was focused primarily around setting up a system for a case: connecting the robotic drive to the control console, powering the system up, draping the robotic drive, control console and chair for sterile operation,

attaching the cassette to the robotic drive, testing the system, loading PCI devices into the cassette (Figure 3), exchanging devices, completing the case, etc.



Figure 3. Loading a guidewire into a cassette: (A) guidewire is loaded into the linear drive; (B) guidewire is fully loaded into both the linear and a rotary drives.

Now that the CorPath 200 System has been cleared by the FDA for marketing, the Steward St. Elizabeth's Medical Center will become the first medical institution in Boston area to employ it as part of its interventional cardiovascular program. The staff in the cath lab was excited to be one of the first hospitals in the world to treat patients with this breakthrough technology. They found it quite easy to incorporate into the traditional workflow of the cath lab.

Improving patient outcomes

The first-in-man and PRECISE studies established the benefits of robotic assistance for the interventional cardiologist; however, it is equally important that robotic PCI demonstrate improvements to patient care. Further post-marketing studies are needed to validate the initial positive, encouraging results, but one potential benefit of robotic-assisted PCI is the ability to reduce contrast media usage. High levels of contrast media in patients can affect kidney function.¹⁹ If further validated in post-marketing studies, it could represent a significant opportunity to reduce contrast-related complications in patients.

There are a number of functions and features in the robotic-assisted system that have the potential to minimize adverse events and to improve clinical outcomes such as accurate measurement of lesion length, precise PCI device manipulation (1-mm increment movements when necessary), accurate device placement to avoid longitudinal geographic miss, and fixation of the PCI devices (when not manipulated). According to one study, 47.6 percent of the PCI cases encountered a longitudinal geographic miss that is associated with increased risk of target vessel revascularization (TVR) and MI at one year post-procedure.²⁰ If robotic guidance can facilitate more accurate placement of devices such as stents, reduce the possibility of inadvertent dislodgement of the guide wire, and decrease patient radiation exposure and contrast use, this will significantly increase the possibility of improved clinical outcomes.

Also, by improving the ergonomics and comfort of the procedure, a more relaxed and efficient operator may be less likely to commit errors resulting from fatigue, musculoskeletal pain, and eye strain.

Reducing costs

The technology may also demonstrate economic benefits as well. If all the benefits to the patient and cardiologist are confirmed in the post-market studies, the hospital may benefit economically

from lower physician absenteeism and reduced number of stents per case, and elicit better clinical outcomes and reductions in readmissions.

Conclusions

The new robotic-assisted system presents a major step on the way to revolutionizing the way vascular interventional procedures are performed. The first-in-man and PRECISE clinical trials support its safety and efficacy for the patient, and have identified a multitude of potential benefits to the patient, interventional cardiologist and the hospital.

Corindus, in collaboration with the medical institutions that acquired this technology for everyday use, plans to continue conducting clinical trials and collecting data to validate potential clinical advantages, expand clinical indications, and improve performance, focusing on accuracy in the delivery of PCI devices, stent deployment precision, radiation exposure and contrast media usage, and operator satisfaction.