Remote control PCI benefits patients and interventional cardiologists.

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In the last several years, clinical robotic systems have entered almost every medical field, with increasing recognition of their potential benefits. Most current systems are passive robotic devices that convert movements from an operator’s hands into subtle or powered movements with increased precision and accuracy. Robotic systems give the operator additional “hands” (ie, support) with increased stability. These machines have movements that are accurate and executed within the precision of a submillimeter. Robotic systems also benefit the operator by reducing occupational hazards and physical fatigue, which may lead to better patient care.

In the interventional cardiology arena, Rafael Beyar, MD, invented the first true remote navigation system (Navicath) to address the procedural challenges and occupational hazards associated with conventional percutaneous coronary intervention (PCI). Dr. Beyar postulated that robotic intervention could improve the stability, precision, and accuracy of coronary interventions. The earliest remote navigation system consisted of a joystick-controlled operator module tethered to a tabletop-mounted motorized drive used to advance and retrieve intravascular devices. Early preclinical studies in animal and humans demonstrated the feasibility of the concept of remote control intravascular device manipulations.

The intravascular manipulation of wire has been attempted by using magnetic forces. The operator could change the orientation of the powerful magnetic field, manipulating the direction and movement of magnet-tipped guidewires, using software support of a three-dimensional reconstruction of the coronary angiogram. This enabled potential wire navigation without additional contrast media and fluoroscopy. Hansen Medical developed another robotic system (Magellan), but it focused on catheter manipulation rather than on intravascular devices and targeted the peripheral vasculature. The Magellan system has since been discontinued.

THE CORPATH GRX SYSTEM

The most advanced robotic PCI technology is the new-generation CorPath GRX system (Corindus Vascular Robotics). The system consists of two major components: the interventional cockpit console (Figure 1) and a bedside unit (Figure 2). The interventional cockpit is a radiation-shielded, mobile workstation that is usually positioned at the corner area of the catheterization laboratory away from the procedure table, but the system’s control console could also be positioned in the control room (Figure 3). The operator is seated in the cockpit and performs the PCI by manipulating designated joysticks or touchscreen buttons at the control console. The joystick and touchscreen commands from the control console are delivered as electrical signals via a communication cable that runs from the control console to the robotic drive (bedside unit). These signals generate mechanical operations in an attached single-use cassette, which translate into linear and rotational movements that control the intravascular device that is loaded with a guiding catheter.

The guidewire and the interventional devices (balloon or stent) are then introduced through the guide catheter. The bedside unit can be positioned so that robotic PCI can be performed using either femoral or radial access on either side of the patient. The operator controls the robotic drive by using three console joysticks or touchscreen buttons that enable linear and rotational motions, so the devices can be advanced, retracted, and rotated within the blood vessel. Fluoroscopic, electrocardiographic, and hemodynamic images are duplicated on monitors inside the cockpit, enabling the operator to view them from a close distance and at eye level.

The robotic-assisted system is compatible with all commercially available 5- to 7-F guiding catheters, 0.014-inch guidewires, rapid-exchange balloon angioplasty and stent delivery systems, and all standard catheterization lab products and imaging systems.
There is no need for special catheters, guidewires, balloon, or stents. Every off-the-shelf standard rapid-exchange interventional device can be used. A new feature of the GRX model, which did not exist in the previous CorPath 200 system, is the active control of the guiding catheter, which enables adjustment, repositioning, and even deep-seated support of the guiding catheter.

**EXPERIENCE WITH ROBOTIC-ASSISTED PCI**

**What Is the Evidence Base?**

The first-in-human study using the CorPath 200 robotic system demonstrated a technical success rate of 97.9%, with no adverse events. The PRECISE study, a prospective, single-arm, multicenter, open-label registry that enrolled 164 patients at nine sites, was the major study that demonstrated the safety, efficacy, and technical performance of the CorPath200 system and led to regulatory clearance. PCI was successfully completed using the robotic system without conversion to manual operation, and device technical success was achieved in 162 of 164 patients (98.8%). There were no device-related complications. Clinical procedural success was achieved in 160 of 164 patients (97.6%), while four patients (2.4%) had periprocedural non–Q wave myocardial infarction. No death, stroke, Q wave myocardial infarction, or revascularization occurred in the 30-day postprocedure period.

A thorough review of the PRECISE data yielded additional insight into the safety and effectiveness of the robotic system. Forty patients who were enrolled in the PRECISE study and underwent PCI with the CorPath 200 were compared to 80 consecutive patients who underwent conventional (manual) PCI.
and met the same inclusion/exclusion criteria. Robotic PCI was associated with trends toward lower duration of fluoroscopy (10 vs 12 minutes; \( P = .05 \)), lower radiation dose (1,389 vs 1,665 mGy; \( P = .07 \)), and less contrast volume (121 vs 137 mL; \( P = .11 \)). These findings demonstrated that robotic PCI was not associated with increased radiation and contrast media exposure to patients and compares favorably to the traditional approach.\(^6\)

The PRECISE study evaluated relatively simple coronary lesions that needed treatment with a single stent. Complex lesions (eg, left main, aorto-ostial, bifurcations, severe calcifications) were excluded. With increased experience, more complex coronary lesions were also treated with the robotic system.\(^7\) In a large single-center report of 315 patients who underwent robotic-assisted PCI, technical success was 92%. Manual assistance was needed in 11% of cases, and the operators converted to manual operation in 7% of cases. When compared to manual PCI, robotic PCI resulted in similar clinical success (both 99%) and similar fluoroscopy duration (18 vs 19 minutes; \( P = .39 \)). Propensity-matched analysis showed that the procedure time was longer in the robotic group (43 vs 34 minutes; \( P = .007 \)).\(^8\)

**Learning Curve**

A subanalysis of the PRECISE data compared early experience cases with advanced experience procedures to assess whether operator learning curve was associated with improved procedure and fluoroscopy times. Advanced experience cases were associated with shorter procedure duration as compared to early experience cases (42 vs 51 minutes; \( P = .008 \)) and shorter fluoroscopy time (10 vs 13 minutes; \( P = .009 \)). After performing three cases, interventionalists were able to complete robotic-enhanced PCI faster, with a reduced duration of radiation and without compromising safety. The learning curve highlights the easy adoption of remote-control robotic technology for PCI.\(^9\)

**Benefits to Patients**

Robotic PCI provides several potential advantages for patients. During the procedure, the robotic system enables superior stabilization of the intravascular devices with an arm designed to stabilize the guiding catheter, in addition to manipulating the wire and balloon/stent. A locking mechanism differentiates between the wire and the balloon/stent movements, enabling additional stability of the wire while advancing the interventional devices over it, avoiding telescopic slippage.

One of the limitations of current practice is visual estimation ("eyeballing") of the diseased segment length that requires treatment. There is a high degree of inter- and intraoperator variability,\(^10\) and the STLLR multicenter study demonstrated that longitudinal geographic miss occurs in more than 47% of cases and is associated with an increased risk of adverse outcomes.\(^11\) With the robotic system, intravascular devices can be advanced or retracted in steps as small as 1 mm to control linear movements, enabling precise measurements of the lesion length unrelated to the angio- graphic view or foreshortening. Using the same methodology and using the STLLR data as controls, robotic-assisted PCI had a significantly lower incidence of longitudinal geographic miss (12% vs 43%; \( P < .0001 \)).\(^12\)

When lesion length was visually estimated, followed by precise measurement of the lesion with the robotic system, 32% of the cases were estimated to be shorter than measured.\(^13\) Thus, use of the robotic system for accurate stent selection in avoiding longitudinal miss and preventing the use of a second stent to fully cover the disease segment may improve long-term clinical outcomes.

**Benefits to Operators**

Much like their predecessors decades ago, currently practicing interventional cardiologists must stand at the bedside to manipulate catheters and intravascular devices under direct fluoroscopic guidance and therefore must wear heavy protective lead aprons. This workflow poses substantial long-term occupational hazards to interventional cardiologists and catheterization laboratory staff.\(^14\) Hours of standing while wearing heavy protective lead aprons can lead to orthopedic injuries, spinal disc disease, reduced performance, and missed work days.

Exposure of operators to ionizing radiation is of immense concern. Interventional cardiologists perform complex procedures that often require long fluoroscopy times, high radiation doses, and unfavorable angiographic views that increase operator exposure. Although radiation dosage is routinely monitored with radiation badges worn by interventional personnel, any radiation exposure has the potential to induce solid or hematologic malignancy, and no lower safety threshold has been identified. Anecdotal evidence and literature reviews raise concerns that interventional cardiologists with prolonged exposure to ionizing radiation may have an increased risk of brain malignancies. Personnel working with fluoroscopy are also at risk for cataracts and lens radiation injuries. In response to these concerns, the US Food and Drug Administration, the International Atomic Energy Agency, and professional
societies have called for reductions in radiation exposure to patients and operators.

Robotic catheter-based systems that enable remote control interventions have been proposed to mitigate some of the hazards of practicing interventional cardiology. In the first-in-human experience, patient radiation exposure remained within normal reported limits at 2.1 µGy, but total radiation exposure to the operator in the cockpit was 97% lower than the conventional position at the procedure table (1.8 vs 61.6 µGy; P = .012).4

In the PRECISE registry, the median radiation exposure to operators in the interventional cockpit was 95.2% lower than at the procedure table (0.98 vs 20.6 µGy; P < .0001).5 Currently, this is the highest level of protection compared to other measures to reduce operator radiation exposure.

The main protective gear that interventionists use is the lead-based apron. For the operator, an advantage of a vascular robotic system is a comfortable ergonomic working environment. Sitting during the procedure without the need for prolonged use of the heavy lead apron frees the interventional cardiologist from cumulative radiation exposure and the growing burden of spine problems that are common among interventional cardiologists. The fluoroscopic monitors, imaging, and hemodynamics are slaved into the interventional cockpit, which is located closer to the eyes and enables better vision of the angiographic images, which allows for a potential reduction in the radiation exposure of the patient.

**Remote Control Procedures**

A pilot study demonstrated the feasibility of remote tele-PCI.6 Patients underwent robotic-assisted PCI with the physician operator located in an isolated separate room outside the procedure cath lab housing the patient. Communication between the operating physician and laboratory personnel was via telecommunication devices, providing real-time audio and video connectivity. With the scarcity of cath labs in rural areas, the use of robotic-assisted PCI may enable urgent intervention by experts without the need for long-distance transportation.

**THE FUTURE**

There is wide agreement that there is an unmet need for standardization and improved precision in PCI, as well as a need to protect interventional cardiologists from the accumulating harm of ionizing radiation. Vascular robotic technology addresses both issues and carries the promise of a refreshing revolution in the way we practice interventional cardiology. With an increasing number of interventional cardiologists and cath labs using robotic vascular technology, experience and collection of evidence-based knowledge is growing regarding the benefits and advantages of the technology. The current CorPath GRX vascular robotic system focuses on the 0.014-inch rapid-exchange system, but with the growth of the interventional cardiology field, we can expect robotic developments to expand to proximal large vessel peripheral interventions, intracranial thrombectomy, and valve procedures. The development and introduction of robotic technology is a long journey, but by combining enthusiasm, creativity, and resources, it will become the standard of practice.

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