



# Cath Lab Robotics: Paradigm Change in Interventional Cardiology?

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## Abstract

**Purpose of Review** To review the contemporary evidence for robotic-assisted percutaneous coronary and vascular interventions, discussing its current capabilities, limitations, and potential future applications.

**Recent Findings** Robotic-assisted cardiovascular interventions significantly reduce radiation exposure and orthopedic strains for interventionalists, while maintaining high rates of device and clinical success. The PRECISE and CORA-PCI studies demonstrated the safety and efficacy of robotic-assisted percutaneous coronary intervention (PCI) in increasingly complex coronary lesions. The RAPID study demonstrated similar findings in peripheral vascular interventions (PVI). Subsequent studies have demonstrated the safety and efficacy of second-generation devices, with automations mimicking manual PCI techniques. While innovations such as telesteering continue to bring excitement to the field, major limitations remain—particularly the lack of randomized trials comparing robotic-assisted PCI with manual PCI.

**Summary** Robotic technology has successfully been applied to multiple cardiovascular procedures. There are limited data to evaluate outcomes with robotic-assisted PCI and other robotic-assisted cardiovascular procedures, but existing data show some promise of improving the precision of PCI while decreasing occupational hazards associated with radiation exposure.

**Keywords** Robotic-assisted · Percutaneous coronary intervention · Coronary angiography · Coronary artery disease

## Introduction

Robotic systems are utilized throughout multiple disciplines of medicine as a strategy to advance operative precision in a minimally invasive manner [1–9]. Interventional cardiology remains at the forefront of minimally invasive cardiovascular procedures since the inception of percutaneous coronary intervention (PCI) [10]. The addition of robotic technology to the cardiac catheterization lab (cath lab) protects operators from occupational hazards such as ionizing radiation and orthopedic injuries, and has

the potential to increase the precision of interventional procedures. Robotics in the cath lab has been applied to both PCI and peripheral vascular interventions (PVI). Data suggest robotic-assisted interventions are associated with a significant reduction in radiation exposure for operators. No randomized control trial data exists at the present time for a head to head appraisal of robotic-assisted PCI versus manual PCI. However, the current body of evidence from cohort studies and registry data suggests that short-term outcomes and MACE outcomes at 1 year are approximately equivalent between the two groups. Other small studies have suggested a potential clinical benefit for patients undergoing robotic interventions, including more precise stent selection and deployment. This review summarizes the current body of evidence surrounding the use of robotic technology in the cardiac catheterization lab.

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## Overview of Robotic PCI Technology

### Basic Concepts in Robotic-Assisted PCI Technology

The premise of robotic-assisted PCI is to allow the operator to remotely control the guidewire, balloon and stent platforms,

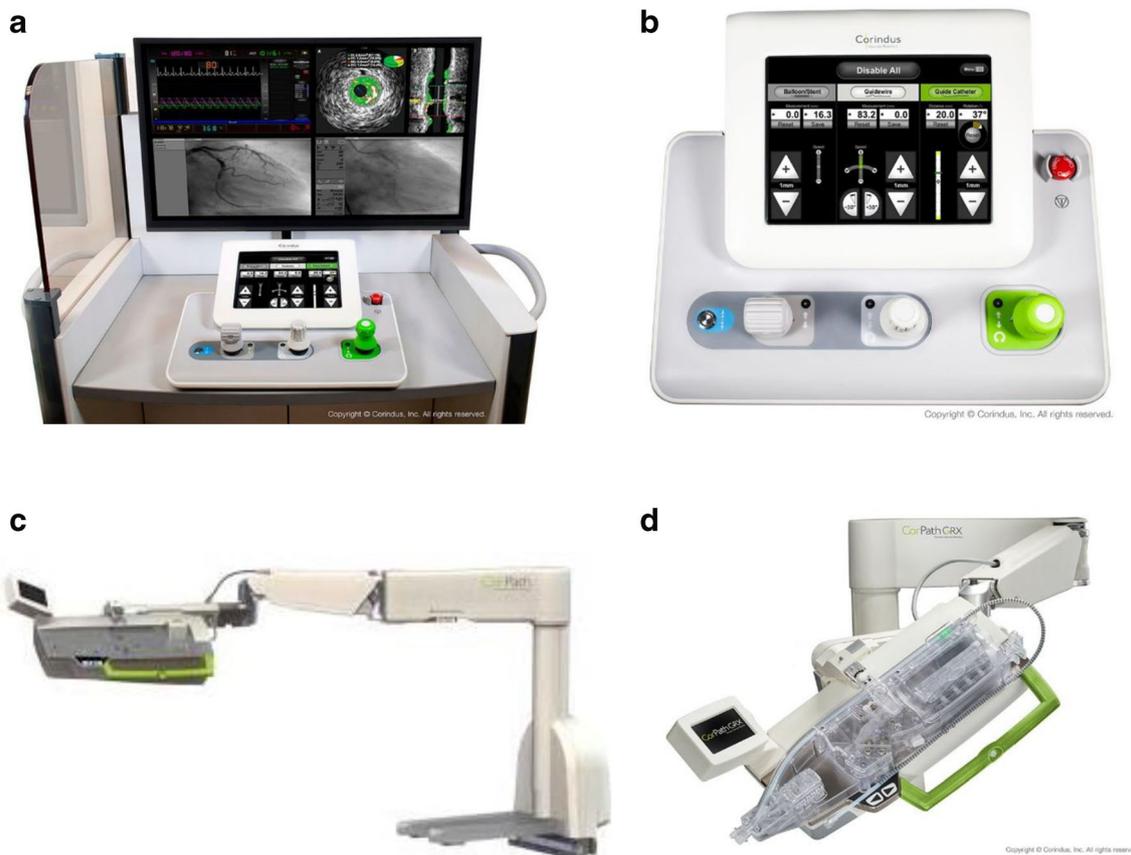
and the guide catheter used during PCI from a shielded cockpit away from the X-ray system and table. The three main components are a remote control cockpit, an articulated robotic arm attached to the cath lab table, and a disposable cassette to which the guide catheter is connected and through which the intravascular equipment is advanced and retracted (Fig. 1). The remote control cockpit is a radiation-shielded control panel where the operator can sit without the need for further radiation protection to complete the procedure. Encompassed within the workspace are high-resolution angiographic and hemodynamic monitors, standard foot pedal controls, and a series of joysticks for control of the cassette's features. The remote control cockpit is mobile and can be positioned as far away from the radiation source as desired.

Cabling connects the remote control cockpit and the mounted, articulated robotic arm. The robotic arm allows for the rapid deployment of robotic PCI technology when desired and is maneuverable for either radial or femoral access [11, 12, 13, 14]. This interfaces with the disposable cassette used with each case. The cassette is the sterile point of contact with the guide catheter, coronary guidewires, and intracoronary balloon and stent platforms. Importantly, current robotic systems

are only compatible with rapid exchange designs; over-the-wire equipment cannot be used with the robotic cassette.

### Evolution of Robotic-Assisted PCI Technology and Practice

Beyar et al. reported both preclinical results and the first in human use of robotic-assisted PCI in 2006. Their work utilized the Remote Navigation System (RNS, NaviCath, Haifa, Israel), consisting of a remote control station and bedside robotic drive system for manipulation of intracoronary equipment, including balloon and stent platforms [11]. With this system, the remote control station was not radiation shielded. It consisted of a computer touch screen control panel and a single joystick for control of the intracoronary equipment. This allowed for continuous movement of either the guidewire, intracoronary balloon or stent platform via the joystick and discrete movement (fixed distances or rotational movement) via the touch screen. The first preclinical study included navigating a transparent coronary glass model with both a guidewire and stent platform [11]. Subsequently, the group performed robotic-assisted PCI in a coronary sheep



**Fig. 1** The Corindus CorPath GRX system demonstrates the representative components robotic-assisted PCI platforms. **a** A representative view from within the radiation-shielded remote control cockpit. **b** The remote control panel including joystick and touch screen

controls. **c** The articulated robotic arm which is mounted to the cath lab table. **d** The sterile cassette attached to the robotic arm. (The images in this figure were used with permission from Corindus Vascular Robotics)

model. Device malfunction was detected in two runs, which required manual conversion. A total of 8 stents were deployed using the robotic system, without a case of edge dissection [11]. Thereafter, the team proceeded to in human testing, with the first in human study involving 18 patients. In 17 of 18 patients, the guidewire was successfully navigated across a lesion, with the one failed case being successfully navigated after conversion to manual operation. In 15 of 17 cases, the stent was successfully delivered using the robotic system, with the remaining 2 cases requiring conversion to manual operation. Two patients in the series required additional stents due to inadequate lesion coverage or distal edge dissection. When compared with a case control group, there was no significant increase in procedural time [11].

The first robotic-assisted PCI device clinically tested and brought to commercial use in the USA was the Corindus CorPath 200 (Corindus Vascular Robotics, Waltham, MA) [12, 15]. This system consisted of the same three parts described above and represented in Fig. 1. The interventional cockpit is radiation shielded and contains touch screen controls and two joysticks, one for control of coronary guidewires and one for control of intracoronary balloon and stent platforms. Guide catheter control was not available on this iteration. This system was first tested in humans as part of the PRECISE study published in 2013, a single arm, multicenter, nonrandomized study measuring device technical and clinical success. Device technical success was measured as successful navigation of lesions and retraction of equipment without bail out to manual operation. Clinical success was measured as < 30% residual stenosis and absence of MACE at 48 h post-PCI or at discharge. Technical device success was achieved in 162 of 164 cases (98.8%). Coronary guidewires were advanced successfully in every case. In the 2 cases of device failure, procedures were converted to manual operation due to severe resistance with robotic advancement of the stent platform. With both of these cases, stent delivery was reportedly also difficult via manual delivery and required use of guide catheter extensions to complete the PCI. There were no adverse events associated with use of the robotic PCI system in this study. Clinical success was achieved in a majority of cases; all procedures achieved the endpoint of < 30% residual stenosis and MACE was only detected in 4 of 164 cases (2.4%). All four events were due to periprocedural MI without ECG changes. There were no deaths or Q-wave MI in the study group [12].

One major limitation of the PRECISE study is the study population only had single vessel disease in large diameter vessels [12]. The CORA-PCI study was designed to address the issue of whether robotic-assisted PCI was applicable to higher risk cases [13•]. The study enrolled all comers presenting for elective and urgent coronary angiography at a single center with one or more complex coronary lesions amenable to PCI. Complex lesions were defined as bifurcation disease, chronic total occlusion (CTO), unprotected left main stenosis, multivessel disease, mild

to moderate calcification, or left ventricular dysfunction with or without hemodynamic support. Excluded cases included ST elevation myocardial infarction (STEMI), planned bifurcation stenting, CTO requiring a hybrid approach, and calcified lesions requiring atherectomy. Cases performed with robotic assistance were compared with controls undergoing manual PCI at the same center. Technical procedural success was measured as completion of the procedure entirely with robotic assistance or minimal manual assistance, as well as clinical success (< 30% residual stenosis and absence of an adverse outcome). Of the 157 robotic-assisted PCI attempted, 81.5% were completed entirely with robotic assistance and an additional 11.1% with minimal manual assistance, with only one procedure related MI. The manual conversion rate was 7.4% and the technical success rate was 91.7%. Clinical success was 99.1%, equivalent to the manual PCI group [13•]. As such, robotic-assisted PCI appears safe and feasible in a broad range of simple and complex coronary lesions compared with manual PCI.

The Corindus CorPath GRX is the second-generation robotic system. Advancements from the CorPath 200 include the addition of a third joystick with the ability to remotely control the guide catheter [14]. Clinical safety and feasibility of use in humans were demonstrated in a 40-patient study. Technical procedural and clinical success were defined in the same manner as in CORA-PCI, and were 90% (36 of 40) and 97.7% (39 of 40), respectively [14].

Subsequent software upgrades to the Corpath GRX system have implemented specific algorithms that mimic manual techniques used to facilitate wire crossing of complex lesions in tortuous vessels [16]. One example includes the optional “rotate on retract” automation. This rotates the guidewire any time that the wire is retracted, facilitating wire redirection into branch vessels. The algorithm is based on a technique that operators use when manually attempting to engage a side branch with a guidewire [16]. Although this has been shown to reduce wiring times in a porcine coronary model, whether it reduces procedure time or increases procedure success remains unknown [17].

### Acquisition of Robotic-Assisted PCI Skill

The learning curve for robotic-assisted PCI skills appears to show operators rapidly acquire proficiency in using robotic technology. One analysis from the PRECISE trial showed that after only three robotic-assisted procedures, operators were able to perform subsequent robotic-assisted PCI with significantly shorter procedure and fluoroscopy times [18]. Additionally, there was no measurable increase in adverse events during this lead in period. While this was a secondary analysis of a small study, it is the only study published that examines the time to acquisition of operator proficiency, albeit by surrogate markers. Further studies are needed to delineate the true learning curve with robotic-assisted interventional systems.

## Application of Robotic Technology to Peripheral Vascular Intervention

Robotic-assisted endovascular interventions for treatment of peripheral arterial disease are beginning to emerge. The RAPID trial assessed the safety and feasibility of the Corindus CorPath 200 robotic system for PVI on femoropopliteal arterial disease in 20 patients [19]. Technical procedural success, safety, and clinical success were all 100% [19]. Fluoroscopy time and total contrast volumes compared favorably with historical cohort studies of manual PVI [19]. Robotic-assisted PVI has also been performed in arteries below the knee [20]. While these studies were all nonrandomized and involved small patient populations, they demonstrate the feasibility of robotic-assisted PVI.

Other robotic technology systems have been applied to the endovascular treatment of peripheral and aortic vascular disease [2–4]. Hansen Medical's Vascular Control Catheter (Hansen Medical, Mountain View, CA) allows for remote control of a proprietary deflectable endovascular catheter and is intended for use in cannulating challenging locations in the arterial tree [2]. This system currently limits operators' choice of devices for treatment through their catheter system.

## Benefits of Robotic PCI in Clinical Practice

### Potential Benefits to Patients

There are limited data available to clearly demonstrate a benefit to patients from robotic-assisted PCI. This is partly driven by the lack of randomized control trials comparing robotic-assisted PCI with manual PCI. As such, there are no head to head safety and outcomes data comparing these two modalities. The data available are drawn from relatively small sample sizes and are from a limited number of centers. A recent meta-analysis by Allencherril et al. provides the largest analysis of composite data regarding patient safety in robotic-assisted PCI thus far, with no apparent differences in fluoroscopy time [21]. There are conflicting data across studies regarding total contrast use, but the same meta-analysis suggests no significant difference in contrast use per procedure between robotic-assisted and manual PCI [21]. More recent registry studies have shown equivalent rates of MACE between robotic-assisted and manual PCI over a longer follow-up period. Walters et al. showed that cohorts of patients undergoing robotic-assisted PCI and manual PCI contemporarily at a single center had equivalent rates of MACE at 6- and 12-month follow-up periods [22]. Additionally, there are signals of potential benefits within the existing literature that warrant further investigation.

Robotic-assisted PCI has the potential benefit of more precise stent deployment through reductions in longitudinal

geographic miss (LGM). LGM is associated with an increased number of stents placed per procedure, overlapping stents, increased target vessel revascularization, myocardial infarction (MI), in-stent thrombosis, and death [23–25]. Rates of LGM were measured in a secondary analysis of the PRECISE cohort compared with a cohort of patients who underwent manual PCI in the STLLR cypher stent trial from a contemporary time period [25, 26]. LGM rates for the two cohorts were assessed by a core lab both overall and as a propensity matched cohort. Robotic-assisted PCI was associated with significantly lower rates of LGM [25]. One may be tempted to infer robotic PCI may be associated with decreased rates of target vessel revascularization and future MI; however, this has yet to be demonstrated in a randomized trial to date.

Current robotic systems include advanced measurement systems for more precisely estimating lesion length. Studies have demonstrated significant inter-reader and intra-reader variability in interventional cardiologists' estimations of lesion length, leading to LGM from selection of overly short stents as well as excessive stenting by overestimation of stent length needs [27–30]. In a study by Campbell et al. comparing operators' visual stent length estimate with the robotic quantitative measurement, only 35% of visual estimates were accurate [23]. Of the 65% inaccurate estimates, 32% were too short and 33% were overestimated with the differences in the estimates reaching statistical significance [23]. This paper also highlights an 8.3% reduction in stent usage as the initial two-stent strategy changed to one stent based on the more accurate robotic measurement of lesion length.

### Decreased Radiation Exposure for Operators

Interventional cardiologists and cath lab staff accrue a substantial lifetime radiation exposure. Studies suggest the lifetime exposure for interventional cardiologists is up to 200 mSv, or 10,000 chest x-rays [31–33]. Ionizing radiation has two classic types of effects on the body, deterministic and stochastic effects. Deterministic effects occur once a threshold dose of radiation has been reached, whereas stochastic effects can occur at any radiation dosage.

Robotic-assisted PCI reduces radiation exposure for interventional cardiologists without significant changes in fluoroscopy time to patients. In the PRECISE study, radiation was measured on body dosimeters worn by interventionalists working in the interventional cockpit and staff at the cath lab table. There was a 95.2% median reduction in radiation exposure to interventionalists, with a 50% minimum radiation reduction in all cases [12]. These data are similar to findings in the first-in-human report of the Corindus CorPath 200, which showed a 97% reduction in radiation exposure for operators compared with the standard table position [15]. There is a theoretical possibility of reduced radiation exposure for staff at the cath lab table as well by being able to stand further from

the radiation source and being able to better position radiation shields. However, this has not been well studied and merits further evaluation.

### Reduction in Orthopedic Injuries

Associated with occupational radiation exposure is the need to wear lead aprons for protection from deleterious effects of ionizing radiation. Lead aprons are heavy, and over time contribute to loading injuries on operators' spines and other joints [34–37]. Interventional cardiologists, along with interventional radiologists, have the highest rates of orthopedic injuries among physicians, with half of interventional cardiologists noting spine problems and one-quarter noting problems with other joints during their careers [35–37]. Given the radiation shielding of the interventional cockpit, operators have the option of being seated and removing their lead aprons while still achieving appropriate radiation protection. There are no direct comparisons between this robotic-assisted PCI format and conventional PCI with respect to long-term outcomes on orthopedic injuries.

## Current Limitations and Future Directions

### Limitations of Robotic PCI Technology

There are several limitations of current robotic-assisted PCI systems. These can be summarized as limitations to the current technology of robotic-assisted PCI systems and limitations in the current body of evidence regarding robotic-assisted PCI. The largest limitation of robotic-assisted PCI currently is the lack of randomized control trial data for evaluation of outcomes compared with conventional PCI. While numerous studies have looked at the safety and feasibility of robotic-assisted PCI, these have been small studies at a limited number of centers.

There are multiple limitations to current robotic-assisted PCI technology compared with manual PCI. These include the need for operators to obtain arterial access and manually engage guide catheters prior to utilization of robotic-assisted PCI systems. Secondly, robotic cassettes are only compatible with 0.014" wires, so any part of the procedure that requires larger wires (e.g., 0.035" wire for advancing the guide catheter into the aorta) or smaller wires (e.g., rotational or orbital atherectomy) cannot be performed with robotic assistance. On the other hand, laser atherectomy can be performed with a standard 0.014" wire and can be used with robotic assistance [38].

Another limitation of current robotic-assisted PCI technology is systems are limited to rapid exchange devices for coronary intervention. Over-the-wire systems are noncompatible and preclude the use of numerous advanced PCI technologies with robotic-assisted PCI. This includes orbital and rotational

atherectomy devices as well as guide catheter extensions and microcatheters. The inability to use guide catheter extensions and microcatheters is one cause of manual conversion due to the inability to achieve adequate guide catheter support [39]. Intracoronary physiologic and anatomic assessments with fractional flow reserve (FFR) and intravascular ultrasound (IVUS) are also not generally compatible with the current iteration of robotic cassettes, although reports of rapid exchange microcatheter-based flow reserve devices and IVUS catheter delivery have been reported [40].

### Future Directions

Although robotic-assisted PCI was initially tested in patients with stable ischemic heart disease with relatively simple lesions, it is utilized in increasingly complex and acute cases. Robotic-assisted PCI is currently used in cases of acute coronary syndrome and reports exist of using it for treatment of patients with STEMI [41]. There are limited to no data on the use of robotic-assisted PCI on patients presenting for emergent PCI and unstable patients. Further investigations are needed to understand the safety and efficacy of robotic-assisted PCI; this is particularly true as it is applied to increasingly complex and unstable patients, such as patients with STEMI and cardiogenic shock.

One theoretical advantage of robotic-assisted PCI is the potential to expand access to interventional cardiology services via telemedicine and robotic interventions, a concept known as telestenting. In the REMOTE-PCI study, 20 patients were enrolled and underwent robotic PCI with the interventional operator controlling a robotic platform from a separate room using the remote control cockpit and telecommunication devices providing real-time audio and video communications [42••]. Procedural success was achieved in 19 of 20 patients (95%) and technical success in 19 of 22 identified lesions (86.4%) [42••]. While this study enrolled a very small number of patients, it demonstrated the feasibility of telestenting. Lay press reports exist of further telerobotic interventions over increasing distances, but formal case reports have yet to be published in the medical literature. Given limitations of current robotic technology, an invasive cardiologist is still needed on site to gain arterial access and position the guide catheter into the coronary arteries prior to engaging the robotic equipment. As such, telestenting remains limited in practice and faces significant hurdles in bringing it to scale until future iterations of robotic-assisted PCI technology allow for larger portions of the procedure to be performed without an onsite interventional cardiologist. However, telestenting has the potential to improve access to revascularization capabilities for patients with stable and acute ischemic heart disease as well as peripheral vascular and cerebrovascular disease in the future.

## Conclusions

Robotic technology has been successfully applied to PCI and PVI. While no randomized trials have been performed demonstrating the safety and outcomes of robotic PCI against manual PCI, there are a number of case-control and cohort studies which have demonstrated the safety and efficacy of robotic PCI. The PRECISE and CORA-PCI studies showed very low rates of complications while maintaining high rates of procedural and clinical success. Additional studies demonstrating longitudinal patient outcomes would add to the body of data, as would randomized trials in comparison with manual PCI. Future innovations are needed to integrate other advanced PCI technologies with robotic-assisted PCI and robotic-assisted PVI, including IVUS, and rotational and orbital atherectomy devices. This will allow for a broader range of procedures to be performed. At the present time, the cath lab paradigm has not shifted, but robotic-assisted interventions demonstrate promise in continuing to innovate and improve percutaneous interventions.

## Compliance with Ethical Standards

**Conflict of Interest** Zachary K. Wegemann and Sunil V. Rao declare that they have no conflict of interest. Rajesh V. Swaminathan reports personal fees and nonfinancial support from Corindus Vascular Robotics.

**Human and Animal Rights and Informed Consent** This article does not contain any studies with human or animal subjects performed by any of the authors.

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