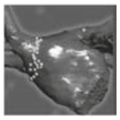
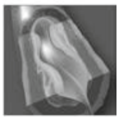
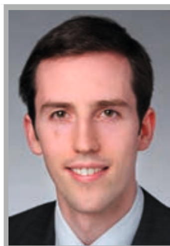




Evaluating the use of robotically assisted percutaneous coronary intervention: a matter of being precise

> *"Remote-control robotic navigation systems are poised to launch a new era of interventional cardiology, with reduced operator radiation exposure and fewer orthopedic injuries among interventionalists."*

KEYWORDS: coronary artery disease ▪ ionizing radiation ▪ percutaneous coronary intervention ▪ remote-control navigation ▪ robotic angioplasty



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Since the advent of catheter-based coronary intervention three decades ago, steady technological progress has led to the development and refinement of intracoronary devices [1]. Despite technological advances, the fundamental workflow of coronary procedures remains unchanged. Interventionalists still wear heavy protective lead aprons, stand at the bedside for long hours and manually manipulate catheters and intravascular devices under direct fluoroscopic guidance. As the field has matured, greater attention has been paid to the long-term occupational hazards of this antiquated interventional approach [2]. A striking prevalence of orthopedic injuries and spinal disc disease has been reported following hours of standing under heavy lead aprons [3,4]. Although radiation badges worn by interventional personnel can help track and limit exposure, any radiation exposure may be harmful, and risks of solid or hematologic malignancy continue to be a significant concern [5,6]. A high prevalence of posterior lens radiation injuries leads to earlier cataracts among interventionalists and provides additional incentive to minimize ionizing radiation exposure [7].

Given the clear risks of modern practice, remote-control robotic catheter-based systems were first proposed to mitigate occupational hazards in percutaneous coronary interventions (PCIs). Beyar *et al.* developed the first-generation 'Remote Navigation System' for PCI (Remote Navigation System, NaviCath, Haifa, Israel), consisting of a joystick controlled operator module and motorized drive to advance and retrieve intravascular devices mounted on the procedure table. A small clinical pilot study demonstrated the feasibility and safety of this robotic system for single-vessel PCI [8,9]. Following this early study, the Robotic Navigation System was redesigned as the CorPath System (Corindus Vascular Robotics, MA, USA).

The CorPath 200 system allows interventionalists to perform remote-control PCI while comfortably seated in a radiation-shielded interventional cockpit. Operators control wires and devices using joysticks, a touch-screen control console and a remote-control contrast delivery system. Fluoroscopic images, electrocardiography and hemodynamic parameters are displayed on cockpit monitors. A robotic drive mounted on the bedrail manipulates standard 0.014 inch rapid-exchange intravascular equipment and angioplasty devices that can be controlled in 1 mm increments. The first-in-man study evaluating the CorPath 200 robotic system yielded promising results [10]. Among eight patients with single vessel *de novo* coronary artery disease, the robotic system achieved successful stent placement and Thrombolysis in Myocardial Infarction grade 3 flow in all cases. The CorPath system demonstrated 95.8% success in device retrieval and an overall technical success rate of 97.9%. No in-hospital or 30-day major adverse cardiac events were reported. Radiation exposure to the operator in the cockpit was 97% lower than at the conventional position at the procedure table (1.8 vs 61.6 μGy; p = 0.012), while patient radiation exposure remained within usual limits.

The follow-up PRECISE study is a 164-patient, prospective, single-arm, multicenter registry to further evaluate the performance of the CorPath 200 robotic PCI system. The study includes adults with obstructive coronary artery disease, a single *de novo* target lesion and indications for revascularization. The primary end points are clinical and technical procedural success. The results of this study are expected to be published soon.

Based on prior experience, robotic PCI should have no difficulty fulfilling its original purpose

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to reduce occupational hazards. A shielded cockpit set far from the x-ray source can substantially decrease operator radiation exposure. The seated position eliminates most orthopedic concerns. In the early CorPath study by Granada *et al.*, operators rated robotic performance equal to or better than the conventional manual approach in nearly all procedural steps [10]. In fact, remote robotic technology may substantially improve the PCI experience for the technologically savvy interventional cardiologist.

"Robotic percutaneous coronary interventions could prompt the incorporation of endovascular simulators in training and assessment."

Benefits to patients remain less certain, although robotic technology offers tantalizing possibilities. Recent studies have identified increased target-vessel revascularization and higher rates of myocardial infarction following stent placement with 'geographic miss' [11]. High-precision robotic systems may facilitate more accurate stent placement and reduce adverse outcomes following PCI. Robotic catheter manipulation may allow for improved lesion assessment to minimize stent length, which has been associated with rates of restenosis and thrombosis [12]. Since operators have direct control over both intracoronary catheter positioning and the contrast injector, robotic systems may permit reductions in fluoroscopy and total contrast delivery [13]. Dose-dependent contrast media administration is associated with contrast-induced nephropathy, with a high rate of morbidity and mortality [14].Finally, improved ergonomics, closer distance to the monitors and decreased physical strain should translate into fewer procedural errors.

While long-term outcomes will not be initially available, strong short-term safety and efficacy data from the PRECISE study will be necessary for the success of the current generation of robotic PCI systems. Still, even with encouraging results, we believe that widespread adoption of this exciting technology is likely to be limited by the highly selective patient populations included in current set of clinical trials. Additional large studies will be needed to validate the efficacy of robotic PCI in patients with multivessel disease, ostial lesions, bifurcations, chronic total occlusions, bypass grafts and other high-risk lesions.

"Patients may benefit from a standardized procedure with more accurate stent placement, reductions in contrast-media exposure and less operator fatigue."

The rise of robotics and remote control interventions may also fundamentally change methods of training. Robotic PCIs could prompt the incorporation of endovascular simulators in training and assessment [15]. Simulators designed to mimic the remote control interface of robotic PCI would permit standardization of technical skills using a realistic training environment. Simulated training could allow novice operators to rapidly achieve technical competency without risks to patients and could improve operator proficiency and patient safety in the long term.

Conclusion

Remote-control robotic navigation systems are poised to launch a new era of interventional cardiology, with reduced operator radiation exposure and fewer orthopedic injuries among interventionalists. Patients may benefit from a standardized procedure with more accurate stent placement, reductions in contrast-media exposure and less operator fatigue. Forthcoming results from the PRECISE study will guide future trial design and may determine the adoption and development of robotic PCI technology for years to come.

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