Current and Future Use of Robotic Devices to Perform Percutaneous Coronary Interventions: A Review

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Robots are electromechanical machines that can be used to perform repetitive or dangerous tasks in place of humans. Although robots are now widely used in industrial mass production, it was not until the mid-1990s that robots were first introduced to clinical medicine. Medical robots are gaining widespread use in surgery because of advantages such as high precision and speed, reproducibility, greater access to areas under operation, and machine endurance.[1] In cardiovascular medicine, medical robots are routinely used for minimally invasive cardiac surgery, with the da Vinci system (Intuitive Surgical)[2,3] for mitral valve repair and for coronary artery bypass grafting surgery. Robots are also being evaluated for clinical use in endovascular surgery,[4–6] electrophysiology,[7,8] and percutaneous coronary intervention (PCI). Despite accumulating evidence that supports the feasibility and safety of robot-assisted PCI, robot-assisted coronary interventions are now performed only in a limited number of centers worldwide. Although the interventional cardiology community is more aware today of the many potential hazards of working in the catheterization laboratory, interventional cardiologists have been slow to accept robotic technology, given concerns about learning curves and costs. For the purpose of this narrative review, a literature search was performed using available search engines including Medline (Ovid), Web of Science (Thomson Reuters), PubMed, and Google Scholar. The search was last updated in January 2017. Keywords included terms such as *robotic percutaneous coronary intervention, robotic enhanced PCI*, and *telemedicine*. In addition, we manually searched for all manuscripts and conference abstracts that cited pivotal trials for robotic PCI.

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What Is a Robotic PCI System?

A robot-assisted PCI system enables control of coronary guide wires, balloons, and stents during PCI from a protected control console. Two robotic PCI systems (CorPath 200 and CorPath GRX, Corindus Vascular Robotics) are currently available. The CorPath 200 is the only system that was evaluated in clinical studies[9–11] and is currently in use at our institution. It is composed of 2 functional subunits: the bedside unit and the remote physician workspace (Figure). The bedside unit consists of the articulated arm, the robotic drive, and a single-use cassette in which devices including wires, balloons, and stents are loaded. The remote workspace consists of the interventional cockpit, which is surrounded by a radiation shield and houses the control console, angiographic monitors, hemodynamic monitors, and the x-ray foot pedal. During the procedure, the interventional cardiologist can sit comfortably within the shielded environment, protected from the hazards of ionizing radiation without being encumbered by lead apronwear. The operator may choose to have the cockpit "sterilized," and thereby remain in a sterile gown throughout the procedure (as was performed in the case shown in Figure), or to perform the PCI without a sterile gown. The latter approach facilitates removal of the operator's lead garments during PCI. The system allows the operator to control and manipulate guide wires, balloon, and stents using a set of joysticks and touch screens while fluoroscopy provides image guidance.[11] Axial and rotational motion are achieved by a mechanical transmission module. The balloon or stent can be guided both in a continuous motion using the joystick and in discrete highly sensitive small steps using the touch screen. Axial motion is achieved by the motored-roller pair. If the device meets resistance and the motored rollers slide, the motion-sensing rollers report malfunction and the system halts.[12] Limitations of the current system include the lack of haptic mechanical force feedback, the inability to manipulate guiding catheters during complex cases, and the inability to use over-the-wire equipment (eg, microcatheters, rotational atherectomy devices) or to control >1 wire and balloon/stent. The next-generation robot (CorPath GRX) was recently approved by the US Food and Drug Administration (FDA) and is now in clinical use in several centers in the United States. This newer generation system overcomes some of the limitations described. Specifically, it provides guide-

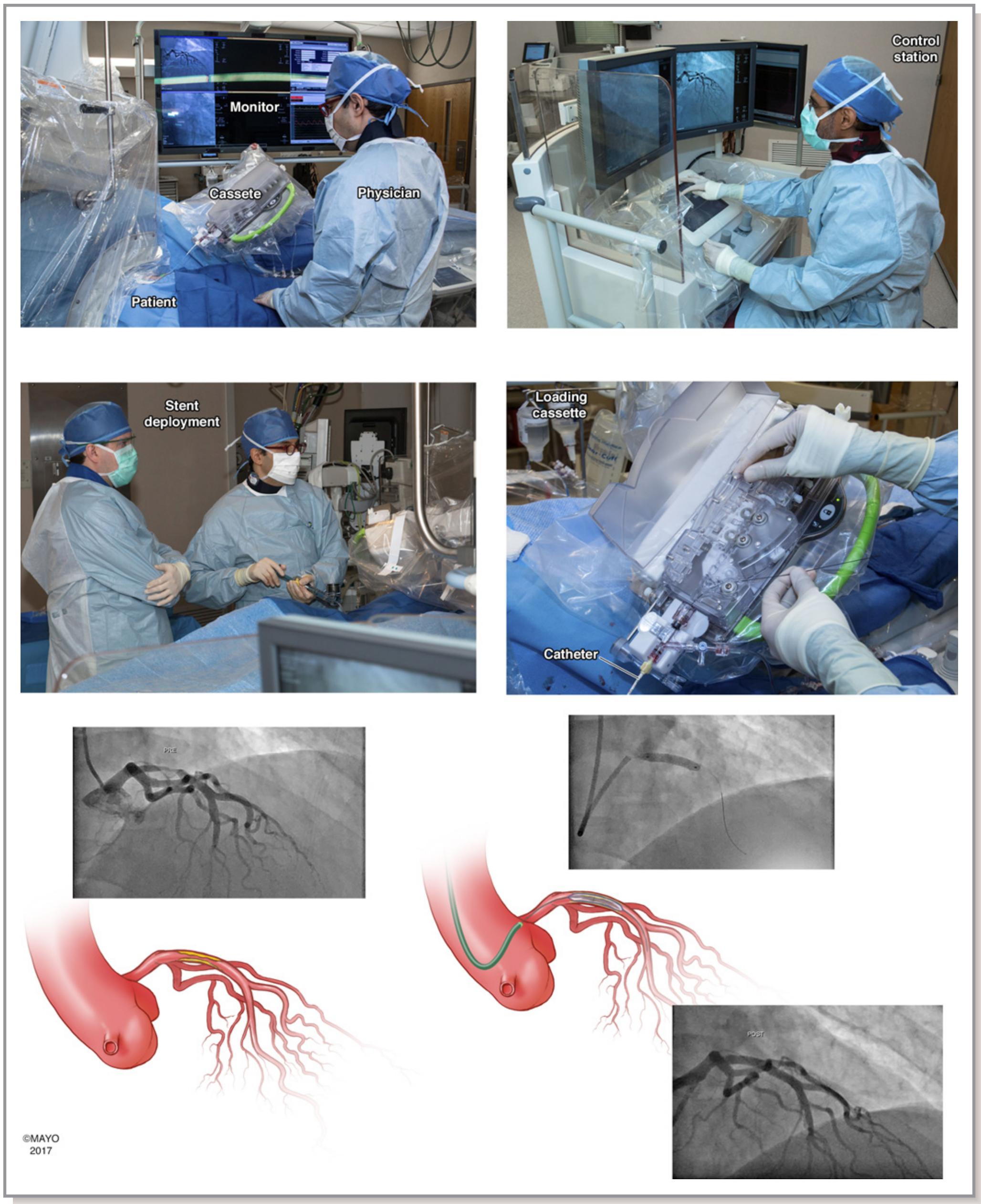

Figure. Contemporary use of robotic percutaneous coronary intervention (PCI). The figure shows a real case of a 50-year-old man with unstable angina who was transferred to our catheterization laboratory in Rochester, Minnesota, from the emergency department and underwent successful PCI with drug-eluting stent placement in the proximal left anterior descending artery. The procedure was performed through a radial approach (top left), with the consultant sitting in a protected environment controlling fluoroscopy and manipulating coronary wires, balloon and stent deployment (top right). The figure also shows how the wire and stent were inserted into the loading cassette (middle right) and how the interventional fellow and/or technician has to stay in the radiation field to inflate the balloon and deploy the stent (middle left). At the bottom, three real images and two illustrations show the proximal left anterior descending coronary lesion that was successfully treated with the robotic device. Final result is in the bottom right. Used with permission of Mayo Foundation for Medical Education and Research. All rights reserved.

catheter control, has 3 joysticks instead of 2, and increases the speed of wire rotation for challenging coronary anatomy. In addition, it includes a redesigned bedside unit with a bedside touch screen for better workflow and ease of use.

Possible Benefits of Robot-Assisted PCI

The major benefits of robot-assisted PCI are summarized in Table and include improved operator safety and procedural precision. Scatter radiation is especially concerning because

Table. Benefits of Robot-Assisted PCI

Reduction of ionizing radiation exposure by 95%[9]	
	Cancer (left sided brain tumors, melanoma, and breast cancer)[13,14]
	Lens opacities[15]
	Accelerated subclinical atherosclerosis[16]
Potential reduction of orthopedic injuries[17]	
Potential improvement of stent-length selection[18]	

PCI indicates percutaneous coronary intervention.

interventional cardiologists have the highest radiation exposure among health professionals, with an exposure per person per year that is 2 to 10 times higher than that of diagnostic radiologists. Cumulative doses after 30 years of working are in the range of 50 to 200 mSv, with a projected professional lifetime attributable excess cancer risk in the order of magnitude of 1 in 100.[19] Robot-assisted PCI can reduce radiation exposure by 97%.[11] Although the association between radiation exposure and cancer is based on the Japanese atomic bomb survivors,[20] it is difficult to establish a direct causal link between long-term, low-dose radiation exposure in the catheterization laboratory and cancer. Head and hands are the least protected parts of the body of the interventional cardiologist. Roguin and colleagues collected self-reported data on 31 brain tumors among physicians exposed to ionizing radiation, the majority of whom were interventional cardiologists. They found that in 85% of the cases, the brain tumors were left-sided.[13] Their data are supported by the BRAIN (Brain Radiation Exposure and Attenuation During Invasive Cardiology Procedures) study, which confirmed that radiation exposure to the cranium is higher on the left side during interventional cardiology procedures.[21] The concern about increased cancer risk is further increased with the widespread use of radial access, through which interventional cardiologists are exposed to small but significantly higher doses of ionizing radiation.[22] Increased risk of cancer is not limited to brain tumors: A prospective cohort demonstrated a mild increase in the risk of melanoma and breast cancer among 90 957 technologists who performed fluoroscopically guided interventional procedures.[14] Radiation exposure also increases the risk of early cataracts. In a study that included 106 interventional cardiologists and 99 unexposed controls, posterior subcapsular lens opacities were almost 4 times more frequent among interventional cardiologists (17% versus 5%, P=0.006).[15] A similar study demonstrated lens changes characteristic of ionizing radiation exposure in 50% of interventional cardiologists and 41% of nurses and technicians compared with findings of similar lens changes in <10% of controls.[23] A third hazard associated with chronic exposure to low-dose radiation is excess cardiovascular risk: carotid intima–media thickness (an early marker of atherosclerosis and a strong predictor of cardiovascular risk) was measured in 223 catheterization laboratory personnel and 222 unexposed participants. The study showed increased left carotid intima–media thickness as well as telomerase-length shortening, providing further support for a causal connection to left-sided radiation exposure.[16]

By allowing the operator to sit in a protected environment, robot-assisted PCI holds the potential to reduce the risks of scattered radiation, as described. In the prospective PRECISE (Percutaneous Robotically Enhanced Coronary Intervention) study, which included 164 patients that were treated by 23 operators, the secondary effectiveness end point of a minimum 50% reduction in operator radiation exposure was successfully met. The median radiation exposure to the operators at the interventional cockpit was 95.2% lower than at the procedure table (0.98 versus 20.6 μGy, P<0.0001).[9]

Orthopedic Injuries

As interventional cardiology procedures are becoming more and more complex, it is expected that interventional cardiologists will be spending more time standing with leaded personal protective equipment that exerts continuous force on the musculoskeletal system. Indeed, in a recent survey of Society for Cardiovascular Angiography & Interventions members, 153 (50%) of 314 responders reported at least 1 orthopedic problem. The most common orthopedic problems were cervical and lumbar injuries, and injuries were strongly correlated with case load and operator age.[17] This survey extends previously reported data suggesting an association between back pain and lead apron use among radiologists.[24] By remotely controlling the procedure and sitting comfortably without lead apronwear, robotic PCI holds the potential to minimize back discomfort and interventional cardiologists' orthopedic injuries.

Lesion Coverage Accuracy

When using robot-assisted PCI, the interventionalist can use a special measurement feature by advancing the balloon markers to the distal and proximal edges of the lesion of interest. The distal edge is marked as "0" on the touch screen display. Next, by withdrawing the marker to the proximal edge of the lesion, measurement of the distance traveled by the marker provides the lesion length. The robot-assisted PCI system can make submillimeter measurements, potentially improving accuracy compared with the visual estimates interventionalists use today. Target-vessel revascularization continues to be a concern in contemporary interventional cardiology practice.[25] A major modifiable risk factor for target-vessel revascularization is accurate stent selection, which is influenced by operator experience and procedural technique. In a study of sirolimus-eluting stents that included

1557 patients in 41 US hospitals, incomplete coverage of the entire length of the injured coronary lesion was observed in 46.5% of patients. Incomplete lesion coverage (geographic miss) was associated with higher rates of target-vessel revascularization at 1 year, independent of clinical or anatomical risk factors. The authors concluded that there is a need for improvement in contemporary PCI practices and technologies.[26] These conclusions are supported by the observation that visual assessments of experienced interventional cardiologists are highly variable and may be inaccurate. In a recent study of 40 interventional cardiologists, visual lesion length was underestimated by 51% and overestimated by 19%.[27] Similar numbers were shown when compared with objective robotic measurement.[18,28] Although this information needs to be confirmed with prospective clinical data, by improving accuracy of lesion-length assessment, robot-assisted PCI hold the potential to reduce the risk of in-stent restenosis and to improve patient outcomes.[29] The impact of precise robotic lesion-length measurement on stent length selection was studied in 60 consecutive patients by Campbell and colleagues. In their study, visual estimates of lesion length and stent selection by treating physicians were compared with measurements made using the robotic system. The study showed that, compared with robotic measurement, only 35% of visually estimated lesions resulted in accurate stent selection, whereas 33% of stents were long (25 ± 13 versus 18 ± 11, P=0.002) and 32% were short (20 ± 9 versus 23 ± 11, $P<0.001$).[18]

Clinical Evidence and Contemporary Use

Beyar and colleagues were the first to show in-human use of a robot-assisted system in which the operator remotely, safely, and precisely navigated the procedure during PCI.[12] In their first-in-human pilot study of a remote navigation system, published in 2006, robot-assisted PCI was performed in 18 highly selected patients with simple coronary lesions and showed 100% clinical success, 94% guide wire success, and 83% overall success of the robot-assisted procedure. More recently, Weisz and colleagues evaluated the safety and clinical effectiveness of the CorPath 200 robotic system in the PRECISE study.[9] The PRECISE study enrolled 164 patients at 9 sites. The population included highly selected patients with relatively simple lesions. PCI was completed successfully without conversion to manual operation in 162 of 164 patients (98.8%). There were no device-related complications. No deaths, strokes, Q-wave myocardial infarctions, or need for revascularization occurred in the 30 days after the procedures. As expected, radiation exposure for the primary operator was 95.2% lower than the levels found at the traditional table position.

Importantly, the investigators of the PRECISE study clearly showed that the learning curve for robot-assisted PCI is surprisingly short. In a subanalysis of the original trial, a total of 164 robotically enhanced PCI procedures were analyzed, with 60 early experience cases.[30] After performing only 3 cases, interventionalists could complete robotically enhanced PCI faster, with reduced radiation, and without compromising safety. Following the first 3 cases, both procedure duration (51.3 ± 25.5 versus 42.2 ± 16.4 minutes) and fluoroscopy time (12.9 ± 7.8 versus 10.1 ± 4.8 minutes) were reduced significantly compared with early experience cases.

The use of transradial access is rapidly increasing in the United States. Case reports and registry data support the clinical use of robot-assisted PCI during transradial procedures.[31,32] Madder and colleagues compared transradial and transfemoral procedures in the PRECISION study and showed that the technical success rate was higher with a transradial approach, with similar rates of clinical success and fluoroscopy time. Similar conclusions were reported in an analysis by Caputo and colleagues, who evaluated 50 lesions that were treated transradially and 36 lesions that were treated transfemorally. Although their report also showed similar success rates for both approaches, it showed that transradial robot-assisted PCI took significantly longer (45 versus 37 minutes).

In recent years, the aging of the population together with advances in biomedical engineering have led to increasingly complex coronary interventions. In addition, new devices are constantly introduced to percutaneous coronary procedures and interventions. Some of these contemporary changes have already been tested in the robot-assisted environment. Kapur and colleagues demonstrated the capabilities of robot-assisted PCI to perform complex interventions. In their report, they successfully used the CorPath 200 system in complex procedures such as multilesion, multivessel coronary disease, saphenous venous graft disease, and an ST-segment–elevation myocardial infarction.[33] In addition, registry data show that robot-assisted PCI is not associated with prolonged procedural time in intermediately and highly complex coronary lesions (43 versus 40 minutes and 56 versus 57 minutes, P=0.53 and P=0.83, respectively) and that only a small minority of the procedures are converted to manual PCI.[34,35] Al-Nooryani and colleagues recently described implantation of 2 bioresorbable vascular scaffolds in 2 coronary stenosis lesions. In their report, robot-assisted PCI was used not only for stent placement but also for comprehensive physiologic (fractional flow reserve) and intravascular morphologic (optical coherence tomography) assessment of the coronary lesions.[36] In a subanalysis of the PRECISION registry, 6 cases were identified in which robot-assisted PCI was successfully used to treat unprotected left main disease. Clinical success was 100%, with 3 of the cases performed without hemodynamic support.[37]

The data of the PRECISE study and PRECISION registry are further supported by multicenter postmarketing data showing that robot-assisted PCI during routine clinical use is associated with high clinical success and low rates of major adverse cardiac events.[10]

In summary, a robot-assisted PCI system offers better safety to operators, holds the potential to improve procedural accuracy, and is associated with high procedural success rates in clinical registries. In addition, these systems are not limited to simple coronary lesions; multiple case reports describe their potential use in complex and high-risk coronary interventions.

Limitations and Reasons for Slow Adoption of Current Systems

Robot-assisted PCI, even though approved for use by the FDA in 2012, has been limited by its slow adoption. Several challenges are limiting the utilization of robot-assisted PCI, even in developed countries. First, strong clinical data are still lacking, and there are no randomized clinical trials with the currently available systems. Most of the data that were described are based on small and medium-sized clinical registries of highly selected patients with relatively simple coronary lesions. There is a need for clinical evidence from large-scale randomized clinical trials showing improved radiation safety for the operators and noninferior angiographic results for patients.

Second, in an environment that is resource minded, interventional cardiologists are concerned about the costs of installing and operating a robot-assisted PCI system. The current system is stationary and can be installed only in a single room in the catheterization laboratory—this limits its use in high-volume centers, where multiple procedures are performed simultaneously. Moreover, the robotic system and disposable cassettes add cost per patient. Unfortunately, no well-designed studies have examined the economics of robot-assisted PCI systems. In the context of limited resources and costs, it is important to point out that robot-assisted PCI can be associated with prolonged procedural time compared with traditional manual PCI. This is especially true during early use experience and for advanced coronary interventions that require conversion to manual PCI.

Third, the currently available robotic systems (CorPath 200 and GRX) lack tactile sensation. Although the PRECISE registry reported procedural success of 98%, many interventionalists feel that tactile sensation of wires and catheters is important for procedural success in challenging cases. A haptics interface that allows the interventional cardiologist to feel and interact during wiring and catheter manipulation can help in increasing adoption rates of robotic PCI systems among operators.

Fourth, the currently available robotic systems do not support over-the-wire coronary interventions. Examples of such interventions include microcatheters for chronic total occlusions, rotational atherectomy for calcific lesions, and aspiration devices during ST-segment–elevation myocardial infarction. In addition, the current system does not support planned coronary bifurcation stenting with a 2-device approach. With advanced coronary interventions becoming more common, this limitation means that a major portion of the procedure needs to be performed manually.

Finally, robotic PCI does not eliminate scattered radiation risk. Although the interventional cardiologist sits within a shielded environment protected from ionizing radiation, technicians and fellows are still required to stay in the radiation field during the procedure to inflate the balloon and stents and therefore are less motivated to adopt this new technology. In addition, diagnostic angiograms represent a significant portion of the work performed by many interventional cardiologists. Because robotic PCI does not currently offer the operators a means to decrease radiation exposure during diagnostic catheterizations, scattered radiation risks will remain a problem, even at centers where robotic PCI is available.

Future Directions

With growing widespread experience with robot-assisted PCI, robotic systems hold the potential to dramatically change interventional cardiology practice and to make coronary interventions available in remote and underprivileged locations.

Interventional Cardiology Telerobotics

In the contemporary robotic PCI system, the very short distance between the controllers and the robot allows almost immediate real-time feedback and control over the PCI process. Any change in guide wire, balloon, or stent location is almost instantaneously transmitted to the controller screen and allows the interventionalist to respond accordingly. A major future direction for robot-assisted PCI systems is overcoming the time-lag challenge to allow treating patients who are in geographically distant locations. For patients who otherwise could not be transported in time to a PCI-capable hospital, this approach holds the potential to reduce door-to-balloon time and possibly render emergency procedures when weather conditions restrict air transport of patients.

Contemporary communication systems already allow physicians to perform surgeries on patients who are not physically in the same location. The first true and complete remote robotic surgery was conducted in 2001 across the Atlantic Ocean by a French surgeon located in New York who performed cholecystectomy on a 68-year-old woman in Strasburg, France.[38] With constantly improved communication infrastructures, telerobotic remote surgery is now in routine use, providing high-quality laparoscopic surgical services to patients in rural communities.[39] Although robotic PCI has not yet been performed with an operator located off-site, the recently published REMOTE-PCI study demonstrated the feasibility of such an approach.[40] In this study of 20 patients, the interventional cockpit of the CorPath 200 system was removed from the procedure room housing the patient and placed behind the closed doors of an isolated separate room having no direct line of visual or audio contact with the patient or personnel in the catheterization laboratory. Communication between the operators and the laboratory personnel occurred via telecommunication devices providing real-time audio and video connectivity, with a technical success rate of 86% (19 of 22 lesions).

To achieve robotic PCI with a remote operator location, additional data including video displays similar to those used for telemedicine would be needed to allow the operator to observe the patient and the procedure room environment. In addition, added controls would be needed on the console such as camera controls, table and C-arm controls, dye injectors, and, ideally, a microphone with headset so that the operator could communicate directly with those in the procedure room in real time. Although this off-site approach is promising, there will still be a need for a local experienced operator who would be able to address procedural complications. Another significant hurdle is regulatory challenges across states and countries that might limit the widespread and global use of the robotic system.

Single Operator, Multiple Robot Sites

Physicians are an important driving force in healthcare costs, and this is especially true in the field of interventional cardiology.[41] From the human resources perspective, to allow primary PCI capabilities in remote areas, catheterization laboratories need an experienced operator to be available 24 hours a day, 7 days a week. This usually translates to a minimum of 3 or 4 interventionalists at each center. As robots become cheaper and more capable, robotic systems can help reduce the costs of catheterization laboratories in remote areas by allowing 1 experienced interventionalist to support and control multiple remote sites using telemedicine. With the help of local technicians and noninvasive cardiologists, robot-assisted PCIs could be performed in remote areas with the operator sitting in a control room at a different site. Although this model is routinely implemented today in diagnostic radiology, similar models might be applied to interventional procedures across multiple specialties in the future.

Arterial Access and Diagnostic Angiograms

Although currently available coronary robotic systems allow manipulation of balloons, 2 important steps of the procedures are still performed manually: gaining arterial access and manipulating the guiding catheters. Real-time ultrasound-guided arterial access is becoming more common today, and studies demonstrated that it can reduce number of attempts, time to access, risk of venipunctures, and vascular complications in femoral and radial arterial access.[42–44] In addition, there are commercially available, hand-free, voice-activated ultrasound systems for central line placements. Combining these commercially available ultrasound technologies with robot-assisted coronary catheter manipulation will allow the interventional cardiologist to perform arterial access and diagnostic coronary angiogram using remote-control systems.

Remote Training: “Telementoring”

Robot-assisted PCI holds the potential to assist in remote training and proctoring. Live cases have become an integral part of interventional cardiology conferences and help the interventional community share expertise and knowledge. Nevertheless, hands-on training is still required for future interventional cardiologists and for proctoring of practicing interventional cardiologists with new technologies. In the United States, subspecialization in electrophysiology and interventional cardiology is common; however, in many areas of the world, emigration of highly trained physicians prevents highly skilled interventional cardiology mentors to emerge.[45] Combining remotely controlled robot-assisted PCI with high-speed video-conference capabilities might eventually allow high-volume experienced mentors in the United States and elsewhere to remotely educate, train, and proctor future-generation interventional cardiologists. This approach of “telementoring” is already used in surgery and other fields of medicine and holds the potential to help medical centers in underprivileged areas where education in interventional cardiology is lacking.

Summary

In conclusion, contemporary robot-assisted PCI systems improve operator safety by reducing ionizing radiation exposure and can improve procedural quality and outcomes by offering better accuracy in stent selection. Telerobotic PCI systems hold the potential to reduce costs and improve global access to coronary care by allowing interventional cardiologists to perform off-site procedures in remote locations.

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