Corindus
Vascular Robotics

Summary of
Clinical Research

Peer-Reviewed Publications on the Clinical Utility and Outcomes of the CorPath Vascular Robotic System
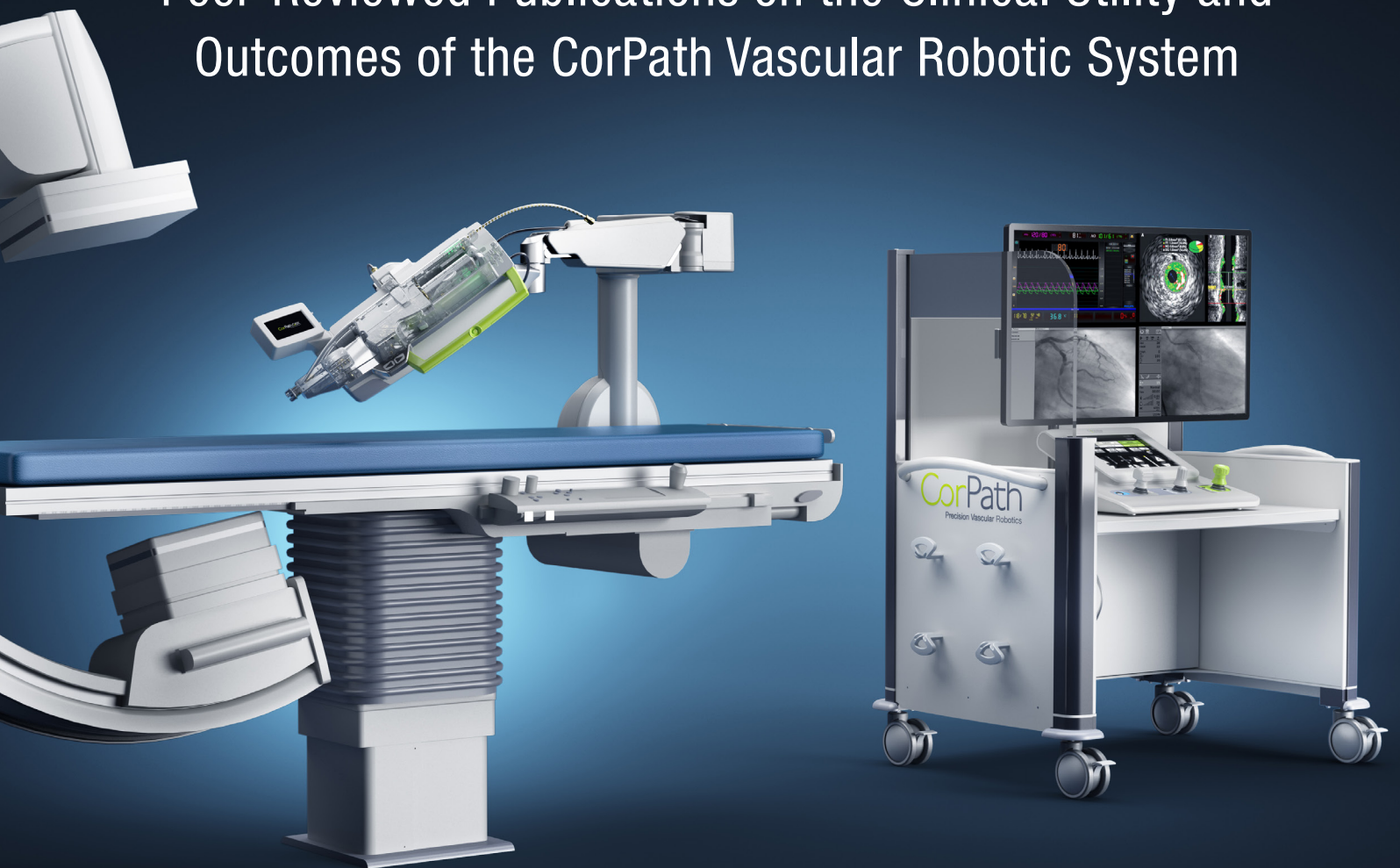
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OVERVIEW

Clinical experience with the CorPath robotic systems has continued to grow over the past several years. This compilation summarizes scientific manuscripts on clinical studies evaluating CorPath in robotic-assisted PCI and PVI. Remote robotic-assisted PCI, or telestenting, is perhaps the most groundbreaking and exciting application of CorPath.

The compilation also includes new sections for Case Reports discussing new features of CorPath GRX (e.g., Rotate on Retract), use of advanced interventional cardiology tools with the CorPath System (e.g., FFR, embolic protection devices) and new applications (e.g., transradial diagnostic angiography). In addition, the compilation includes summaries of seven review articles on robotics in interventional cardiology that have been recently published in peer-reviewed journals. These review articles underscore the breadth of evidence for CorPath as well as growing awareness of Cath Lab occupational risks, most notably radiation exposure and orthopedic injury.

Corindus Vascular Robotics is dedicated to advancing robotic-assisted vascular procedures through the publication of clinical data supporting the value and applicability of CorPath System. The latest generation of the platform, CorPath GRX, enables remote delivery and manipulation of guidewires and rapid exchange catheters as well as remote manipulation of guide catheters during percutaneous coronary and vascular procedures. CorPath provides the ability to measure anatomy and offers enhanced visualization of imaging monitors. Seated at the radiation-shielded interventional cockpit or positioned in the control room, the operator can control the interventional procedure and focus on clinical decisions without wearing lead.

Glossary

ACS	Acute coronary syndrome	**MI**	Myocardial infarction
AMI	Acute myocardial infarction	**OCT**	Optical coherence tomography
EF	Ejection fraction	**PAD**	Peripheral artery disease
FFR	Fractional flow reserve	**PCI**	Percutaneous coronary intervention
Fr	French	**PPE**	Personal protective equipment
CAD	Coronary artery disease	**PVI**	Percutaneous vascular intervention
CTO	Chronic total occlusion	**RCA**	Right coronary artery
CVA	Cerebrovascular accident	**SFA**	Superficial femoral artery
IVUS	Intravascular ultrasound	**STEMI**	ST elevation myocardial infarction
LAD	Left anterior descending	**SVG**	Saphenous vein graft
LCX	Left circumflex	**TIMI**	Thrombolysis in myocardial infarction
LMCA	Left main coronary artery	**TLR**	Target lesion revascularization
MACE	Major adverse cardiac event	**UA**	Unstable angina

Some manuscripts summarized in this compilation may discuss off-label uses or use with non-compatible interventional devices and is not intended to be used to provide medical guidance. The user should confirm all interventional device compatibility in accordance with the CorPath GRX Operator's Manual prior to use.

INSIGHTS FROM CLINICAL TRIALS AND USE

This section includes summaries of clinical trials of the CorPath 200 and CorPath GRX robotic systems used in PCI, telestenting, and PVI. Studies examining robotic-assisted PCI of complex lesions are also presented, including intermediate-term outcomes of the CORA-PCI study and analysis of reasons for manual assistance or conversion to manual PCI. Case reports using features on CorPath GRX (such as Rotate on Retract) and new applications (diagnostic angiography) provide insight into optimizing use of the robotic system. Data demonstrating the clinical value of precise measurement of anatomy are also presented. Finally, summaries of several review articles on robotic-assisted PCI that have been published over the last couple of years are presented.

ROBOTIC-ASSISTED PCI CLINICAL TRIALS

Safety and Feasibility of a Novel, Second-Generation Robotic-Assisted System for Percutaneous Coronary Intervention: First-in-Human Report

Smitson CC, Ang L, Pourdjabbar A, Reeves R, Patel M, Mahmud E.

J Invasive Cardiol. 2018;30(4):152-156.

The second-generation CorPath GRX was evaluated in a single-arm, open-label study. Compared to the first-generation robotic system, CorPath GRX has easier device exchange, faster rotation of guidewires, and an additional joystick, which enables active manipulation of the guide catheter.

Forty consecutive patients with coronary artery stenosis >70% warranting PCI were enrolled. Patients were predominantly male (72.5%), with an average age of 65.7 years. A total of 54 lesions were treated, the majority of which (77.8%) were type B2 or C. Over 13% of lesions were ostial, with 11.3% having moderate to severe calcification. A modest number of lesions (3.8%) were bifurcated. Primary lesion length averaged 19.2mm; nearly half of lesions (49.1%) were >20mm. Radial access was used in 65% of cases.

Clinical procedural success was achieved in 97.5% of patients (39 of 40), as CTO could not be crossed robotically in one patient. The technical

Clinical Success

<30% residual stenosis after robotic delivery of stent and TIMI 3 flow with no in-hospital MACE. MACE included death, MI, emergent cardiac surgery and urgent revascularization.

Technical Success

Clinical procedural success without unplanned manual assistance or conversion to manual PCI.

Select Inclusion Criteria

>70% stenosis by visual estimate and need for revascularization/PCI.

Select Exclusion Criteria

STEMI, CTO requiring a hybrid approach, need for orbital or rotational atherectomy, and bifurcation with strategy of placing two stents.

success rate was 90.0%, reflecting two instances of unplanned manual assistance and one conversion to manual PCI. The latter involved placement of overlapping stents and difficulty with advancing the second stent. Unplanned manual assistance was needed for guidewire crossing of a proximal RCA (95% stenosis) and an eccentric lesion that ultimately required orbital atherectomy.

CorPath GRX's third joystick enhanced engagement of the target vessel. It was particularly useful when the coronary artery became disengaged during the procedure. Active manipulation of the guide catheter reduced the number of complex cases that required unplanned manual assistance or conversion to manual PCI compared to that seen with the first-generation CorPath in other clinical studies. Of note, one procedure in the series used CorPath GRX to perform laser atherectomy.

Conclusion
The second-generation CorPath GRX system demonstrated high procedural and technical success rates. In addition to facilitating robotic treatment of complex and ostial lesions, CorPath GRX seems well suited for radial PCI.

> " As radial access is sometimes associated with ergonomic challenges and radiation exposure for the operator, the feasibility of radial robotic PCI with the CorPath GRX system is reassuring as active guide-catheter control is required more often with radial guide catheters. "

Percutaneous Coronary Intervention Using a Combination of Robotics and Telecommunications by an Operator in a Separate Physical Location from the Patient: An Early Exploration into the Feasibility of Telestenting (the REMOTE-PCI Study)

Madder RR, VanOosterhout S, Jacoby ME, Collins JS, et al.

Door-to-balloon time of <90 minutes or <120 minutes is rarely achieved for individuals with STEMI who are not geographically close to a hospital with PCI capabilities. Procedural delay is associated with increased infarct size and higher mortality rates.

The REMOTE-PCI study evaluated the feasibility of using the CorPath 200 robotic system and telecommunications devices to perform robotic-assisted PCI from a room physically separate from the patient. The CorPath System was located behind closed doors in a room 55 feet from the Cath

Lab where the patient was located. For most cases, telecommunications using the facility's WiFi network transmitted video feed from the procedure room to the CorPath interventional cockpit.

Twenty patients were enrolled in the study. Inclusion criteria included need for PCI in an occluded vessel amenable to robotic-assisted PCI. Individuals who were hemodynamically unstable, in cardiogenic shock, needed emergent PCI, had severe multivessel CAD, EF <35%, or a target lesion within a graft were excluded from the study.

After manually introducing a guide catheter into the target vessel, the operating physician proceeded to the robotic room. A scrub technician and nurse remained in the Cath Lab, along with a second interventional physician who remained in the room in the event of an urgent need for a physician at the bedside. Technical success was defined as advancement and retraction of intra-coronary devices by the robotic system with no conversion to manual PCI.

Remote robotic PCI was attempted in 22 target lesions, of which a plurality (45.5%) were located in the LAD artery. Thrombus was found in nearly one quarter of target lesions (22.7%). Technical success was achieved in 19 of 22 lesions (86.4%). Remote robotic delivery of a guidewire was achieved in all cases. One case involving in-stent restenosis of a previously implanted drug-eluting stent was successfully treated with remote robotic angioplasty. Remote robotic delivery was attempted in 20 of 22 vessels. Telestenting was achieved in 18 of 20 cases. Regarding the cases which could not be treated with remote robotic PCI, manual conversion was required because of the need for a stiff supportive wire in one case, intubation of a guide catheter extension, and a target vessel requiring rotational atherectomy.

Remote Robotic Success Rates

	Successful Remote Delivery/ # of Lesions Attempted	Success Rate
Predilation balloon delivery	20/21	95.2%
Stent delivery	18/20	90.0%
Postdilation balloon delivery	15/15	100.0%
Technical success achieved	19/22	86.4%

" When performed over longer distances, telestenting has the potential to increase access to PCI in geographic regions where PCI is currently unavailable. "

Radial access was used for all cases. Audio was available for all cases, enabling the operating physician to provide instructions to the scrub technician and nurse. Video was available for 18 of 20 cases which allowed the operating physician to view the bedside. Procedural time averaged 29 minutes, with mean fluoroscopy time of 15.5 minutes.

Conclusion
Telestenting using the CorPath robotic system and audiovisual devices can be safely performed in selected PCI cases. Additional study is needed to assess the feasibility of long-distance telestenting.

Feasibility of Robotic Telestenting Over Long Geographic Distances: A Pre-Clinical Ex Vivo and In Vivo Study

Madder RR, VanOosterhout S, Mulder A, Bush J et al.

A pre-clinical study evaluating the feasibility of remote robotic PCI over long geographic distances consisted of ex vivo and in vivo components. In the ex vivo model, an endovascular simulator was used to perform telestenting in two cases and three target vessels. The operator was located 7.4 kilometers (km) from the simulation room; the facility's virtual private network (VPN) was used to transmit commands from the interventional cockpit of the CorPath GRX robotic system to the simulation room. A cardiology fellow introduced the guide catheter into the target vessel and positioned a guidewire. Thereafter, the operating physician delivered the guidewire and advanced the balloon and stent catheters from the interventional console. Virtual stenting was achieved in all cases.

The in vivo model consisted of remote PCI on five 50-kg female pigs with a total of eight target vessels. As with the ex vivo model, a cardiology fellow introduced the guide catheter and guidewire. For the first two in vivo cases, the operating physician was located 6.6 km from the animal laboratory. For the next three cases, the operator was located 166 km from the animal laboratory. Remote telestenting was achieved in all cases, with commodity Internet connectivity used for portions of these cases. There were no complications.

Conclusion
This study demonstrated that using the CorPath GRX robotic system, telecommunications devices, and network/Internet connectivity permits safe and effective telestenting over long geographic distances (>100 miles). Feasibility studies assessing the safety and effectiveness in human subjects are warranted.

> " Now that robotic telestenting has been demonstrated to be technically feasible in this pre-clinical research, future studies will likely be performed to test the safety and feasibility of telestenting in humans. If developed further, telestenting may eventually be tested as a means to overcome barriers to PCI access. "

Impact of Robotics and a Suspended Lead Suit on Physician Radiation Exposure during Percutaneous Coronary Intervention

Madder RR, VanOosterhout S, Mulder A, Elmore M, et al.

Because of reports of left-sided brain malignancies among interventionalists, there is a need to reduce radiation exposure to the operating physician during PCI. The prospective SHIELD study compared data from dosimeters near operating physicians' head and chest areas during one of three procedure types: 1) manual PCI with traditional PPE, 2) manual PCI with a suspended lead suit, and 3) robotic PCI with a suspended lead suit.

Identical imaging systems were used in the two Cath Labs participating in the study. Ancillary ceiling- and table-mounted lead shields were used during all procedures. Data were collected from dosimeters worn on the left anterior side of protective glasses and thyroid collar as well a badge placed on the physicians' scrub shirt. Dose area product (DAP) for each case was calculated by the imaging system and subtracted from dosimeter data to arrive at adjusted radiation exposure at the head and chest level for operating physicians in each case.

The decision to use the suspended lead suit or the CorPath 200 robotic system was at the discretion of the operating physician. Of the 336 PCIs in the study, 86.6% were performed manually. The right radial artery was the primary access point for the majority of robotic PCI and manual PCI cases using the suspended lead suit for 80.0% and 64.1%, respectively. Comparatively, in manual PCI using traditional PPE, right radial access was used in 48.0% of cases. In addition, diagnostic angiography was more frequently performed during cases involving robotic PCI (P<0.001) and manual PCI using a suspended lead suit (P<0.001) than during manual PCI with traditional PCI.

There were no significant differences in the number of vessels, or target vessel type, treated in the three groups. PCI success, defined as <30% residual stenosis in the target vessel after procedure completion, was lowest in the manual PCI group at 95% and highest in the robotic PCI group at 100%.

There were no significant between-group differences with regard to fluoroscopy time or air kerma. Robotic PCI with beside use of the suspended lead suit was associated with the lowest amount of radiation

> Accordingly, robotic PCI combined with a suspended lead suit achieved physician head-level radiation exposures that were 99% less than those of manual PCI performed with traditional lead apparel and 80% less than those of manual PCI performed with a suspended lead suit.

exposure to the head and chest. Robotic PCI with suspended lead suit resulted in adjusted dose per case of 0.1 µSv for head exposure versus 17.8 µSv for manual PCI with traditional PPE (P<0.001). Robotic PCI was also associated with significantly lower radiation to the head versus manual PCI with the suspended lead suit (0.5 µSv ; P<0.001). The adjusted dose per case for chest exposure was 0.0 µSv for robotic PCI with suspended lead suit and 0.4 µSv for manual PCI with traditional PPE (P<0.001).

Comparison of Physician Radiation Exposure

	Manual PCI with Traditional PPE	Manual PCI with Suspended Lead Suit	Robotic PCI with Suspended Lead Suit
Chest Exposure (N)	120	157	42
Dose per case (µSv)	0.4	0.0	0.0
Dose per case – normalized DAP*	0.4	0.0	0.0
Head Exposure (N)	121	156	41
Dose per case (µSv)	14.9	0.5	0.1
Dose per case – normalized DAP*	17.8	0.5	0.1

*Units shown are for $\mu Sv/(mGy \times cm^2) \times 10^{-5}$

Conclusion

Robotic PCI combined with a suspended lead suit significantly reduced the amount of radiation exposure to the operating physician's head and chest area compared to manual PCI with traditional PPE. Radiation exposure to the head was also significantly lower with robotic PCI compared to both manual PCI groups.

Safety and Feasibility of Robotic Percutaneous Coronary Intervention: PRECISE (Percutaneous Robotically-Enhanced Coronary Intervention) Study

Weisz G, Metzger DC, Caputo R, Delgado J, Marshall JJ, Vetrovec GW et al.

The PRECISE trial evaluated the safety and feasibility of using the CorPath 200 Robotic System during single-vessel PCI. The study had two primary endpoints: clinical success and device success. A secondary endpoint related to reduction in radiation exposure. Nine centers participated in PRECISE; 23 operators treated 164 patients with coronary artery disease (CAD) and myocardial ischemia. Roughly 74% of patients were male, and 57% had unstable angina (UA). The average lesion length was 12.2mm, with mean stenosis of 64.1%.

The CorPath 200 Robotic System achieved clinical success in 97.6% of patients (160 of 164), which was significantly better than the 84% performance goal set in the study protocol. There were no major clinical events related to the robot. However, four patients experienced peri-procedural modest elevations of biomarkers indicative of non-Q-wave myocardial infarction (MI). The device success rate was 98.8%, which was significantly better than the 90% performance goal. There were no dissections or perforations. Two procedures were converted to manual, as the operator experienced severe resistance during stent placement.

The secondary endpoint assumed at least a 50% reduction in radiation exposure to the operator at the cockpit. PRECISE also met this endpoint, with 95.2% lower levels of radiation exposure at the cockpit compared to that at the procedure table (p<0.0001). The time on CorPath averaged 24.4 minutes, with an average fluoroscopy time of 11.1 minutes.

Conclusion

The pivotal, multi-center PRECISE trial demonstrated the safety and feasibility of the remote-controlled CorPath 200 Robotic System for use during PCI. The study met its clinical and technical endpoints, with the operator experiencing a significant reduction in radiation exposure.

Clinical Success

<30% residual stenosis after robotic delivery of stent with no major adverse cardiovascular events (MACE) within 48 hours or before discharge. MACE included cardiac death, Q-wave or non-Q-wave MI, and target lesion revascularization.

Device Success

Revascularization with robotic manipulation of commercially available guidewires, balloons, and stents.

Select Inclusion Criteria

>50% de novo stenosis by visual estimate. Maximum lesion length of 24 mm, with diameter of 2.5-4.0mm. Single stent placement expected.

Select Exclusion Criteria

Acute MI, more than 1 stenosed artery, previous stent within 5.0mm of target lesion, and need for atherectomy devices, among others.

Staff Exposure to Radiation During Percutaneous Coronary Interventions: Randomized Comparison of Robotic versus Manual Procedures

Campbell PT, Tennis P, Bitler C, Tullis K, Warren P, Maksimenko S, Soos T, Patterson J, Esposito M.

The authors sought to assess the impact of robotic PCI (R-PCI) on exposure to scatter radiation for operating physicians and cath lab staff compared to that recorded during manual PCI (M-PCI). The Staff Exposure to X-Ray during PCI: CorPath vs. Manual trial randomized 30 prospective patients undergoing PCI at Sanger Heart & Vascular Institute to either M-PCI or R-PCI. Patients were excluded from the study in the event of STEMI, cardiogenic shock, totally occluded lesion(s), and unprotected left main disease. In addition, patients were excluded if >2 lesions required treatment or if more advanced devices than a conventional predilatation balloon were needed. Cath lab staff received training related to radiation exposure reduction principles, practices, and techniques.

Affirming results in the PRECISE multi-center single-arm trial, R-PCI significantly lowered the operating physician's exposure to scatter radiation, which measured 9.1 μSv in the M-PCI group and just 0.8 μSv in the R-PCI arm (P=0.015). Fluoroscopy time was similar at 9.6 and 10.6 minutes for M-PCI and R-PCI, respectively. Exposure to scatter radiation for cath lab staff was also similar between M-PCI and R-PCI at 1.3 μSv and 1.1 μSv, respectively.

	Manual PCI (n=15)	Robotic PCI (n=15)	P value
Lesions treated/patient	18	15	N.A.
# of Complex Lesions*	16	9	0.054
Fluoroscopy Time	9.6	10.6	0.569
PCI Time	17.0	12.0	0.638
Cardiologist Rad Expos (μSv)	9.1	0.8	0.015
Technician Rad Expos (μSv)	1.3	1.1	0.728

*ACC/AHA Lesion Classification, B2/C.

Conclusion

This randomized study showed that R-PCI significantly lowered exposure to scatter radiation to operating physicians and a 15% reduction for cath lab personnel.

Feasibility and Success of Radial-Access Robotic Percutaneous Coronary Intervention: Insights from the PRECISION Multicenter Registry

Madder R, Campbell PT, Caputo R, Kasi V, Mahmud E, Manish P, Marshall JJ, Stys T, Wohns D, Weisz G.

PRECISION is a multicenter, post-market registry of robotic PCI using the CorPath 200 Robotic System. We analyzed clinical data on transradial access (TRA) and transfemoral access (TFA) procedures included in the PRECISION Registry. Technical success was defined as successful robotic PCI of target lesions and residual stenosis of <30%. Clinical success was defined as residual stenosis of <30% and absence of MACE at discharge or 72 hours after robotic PCI, whichever occurred first.

Robotic PCI with TRA was performed in 57% of cases. Baseline characteristics were similar between the TRA (n=156, 192 lesions) and TFA (n=117, 142 lesions) cohorts, except for significantly more patients with diabetes in the TFA group. Lesion location was similar but there were significantly more type C lesions in the TFA group.

TRA technical success was higher than that for TFA at 93.7% and 85.7%, respectively (p=0.02). Clinical success was also slightly higher in the TRA group at 99.4% vs. 97.4% for TFA. On average, 1.1 stents were used in both groups. Fluoroscopy time was comparable at 14.2 minutes for TRA and 15.1 minutes for TFA but use of contrast media volume was greater in the TRA cases at 210 ml vs. 186.9 ml (p=0.07) for TFA.

Conclusion

Data from the PRECISION Multicenter Registry demonstrate that radial access for robotic PCI is common, with higher technical success than that recorded for transfemoral robotic PCI. Both access routes have high clinical success rates without post-procedural MACE.

PRECISION Multicenter Registry Robotic PCI: TFA vs. TRA

Lesion Characteristics	TFA (n=142)	TRA (n192)	P Value
ACC/AHA Lesion Classification – n/N (%)			<0.001
A	14/137 (10.2%)	27/189 (14.3%)	
B1	47/137 (34.3%)	56/189 (29.6%)	
B2	12/137 (8.8%)	50/189 (26.5%)	
C	64/137 (46.7%)	56/189 (29.6%)	

Procedure Characteristics			
Number of Stents per CorPath Lesion - Mean ± SD (N)	1.1±0.4 (120)	1.1±0.4 (178)	1.00
Total Contrast Media Volume (ml) - Mean ± SD (N)	186.9±81.0 (117)	210.1±121.0 (156)	0.07
Total Fluoroscopy Time (min) - Mean ± SD (N)	15.1±9.5 (116)	14.2±6.7 (156)	0.36

Safety and Feasibility of Robotic PCI Utilizing Radial Arterial Access

Caputo R, Lesser A, Fischi M, Simons A.

The use of TRA is increasing in the US. We sought to evaluate the feasibility and safety of using the CorPath 200 Robotic System for TRA PCI. Technical success was defined as procedural completion without conversion to manual PCI. Procedural success was PCI without post-procedure major adverse cardiovascular events (MACE) and <30% residual stenosis. We compared robotic PCI with TRA to robotic PCI with TFA in unmatched non-emergent cases at our facility.

There were no significant differences between baseline characteristics of patients in the TRA (n=36, 50 lesions) and TFA (n=32, 36 lesions) groups. Multi-vessel PCI occurred in 13.9% of the TRA patients vs. only 3% of in the TFA cases. Technical and procedural success was 96% for TRA and 100% for TFA. TRA had a longer procedure time than TFA at 45.14 minutes and 36.67 minutes, respectively (p=0.009). TRA procedures also had longer duration of fluoroscopy at 14.24 minutes compared to 10.13 minutes for TFA (p=0.003). However, the amount of contrast use did not differ. There was no MACE reported for either cohort.

Conclusion
Robotic PCI for TRA is feasible with high technical and procedural success rates without post-procedure MACE.

The Association between Experience and Proficiency with Robotic-Enhanced Coronary Intervention—Insights from the PRECISE Multi-Center Trial

Weisz G, Smilowitz NR, Metzger DC, Caputo R, Delgado J, Marshall JJ, et al.

Procedures performed in the PRECISE clinical study were analyzed for evidence of learning curve associated with robotic PCI. The first three cases performed by each operator were considered "early experience" (n=60), with subsequent cases categorized as "advanced experience" (n=104). The patients were similar in both groups, and there were no differences in clinical outcomes. Both groups had two cases of peri-procedural elevated biomarkers indicating non-Q-wave MI. Device success was 100% in the early experience group. In the advanced experience group, robotic PCI was abandoned in two cases in which severe resistance was encountered during stent placement for a device success rate of 98.1%.

Advanced experience was associated with shorter durations for the total procedure, robot use, and fluoroscopy than early experience. Total procedure time averaged 42.2 minutes for advanced experience cases—17.7% lower than early experience cases. Time on the CorPath 200 averaged 22.2 minutes for advanced operators vs. 28.5 minutes for early experience cases. Fluoroscopy duration decreased 21.7% in the advanced experience group to 10.1 minutes from 12.9 minutes in the early experience group. The use of contrast media was roughly the same at 147.5 mL for advanced experience cases and 138.4 mL for early experience cases.

Conclusion
Robotic PCI has a short learning curve. Experience leads to shorter procedure and fluoroscopy times.

> " …experienced interventional cardiologists can quickly master robotic-enhanced PCI, with a significant decrement in procedural and fluoroscopy time after a few cases. "

Robotic-Enhanced PCI Compared to the Traditional Manual Approach

Smilowitz NR, Moses JW, Sosa FA, Lerman B, Qureshi Y, Dalton KE et al.

The PRECISE study demonstrated the safety and feasibility of robotic PCI as well as a statistically significant reduction in radiation exposure to the operator. Critics of robotic PCI have hypothesized that operator comfort from being seated at the interventional cockpit could result in greater radiation exposure to the patient as well as higher use of contrast media.

We compared procedural characteristics of the 40 patients enrolled in PRECISE with 80 consecutive patients who underwent manual PCI at our institution. The baseline characteristics of the two patient groups were similar. The characteristics of the target lesions were also similar, with the exception that the manual PCI cohort had a greater percentage of stenoses in the left anterior descending artery.

Robotic PCI was associated with a reduced duration of fluoroscopy, less contrast media, and lower radiation exposure to the patient. This trended toward statistical significance compared to the manual PCI cohort. Two patients were converted to manual PCI owing to resistance during stent deployment. Conversion was completed quickly—within seconds—and did not result in any complications. Excluding these two patients, a sensitivity analysis showed statistically significant reductions in fluoroscopy duration and radiation dose for patients treated by robotic PCI. The volume of contrast was 13% lower at 119 mL for robotic PCI vs. 137 mL for manual procedures but this reduction did not achieve statistical significance.

Conclusion
Our analysis suggests robotic PCI offers radiation protection for both the operator and the patient, with a trend toward lower contrast use. Robotic PCI compares favorably to manual procedures and could represent a paradigm shift in the cath lab.

> "
> Robotic-enhanced PCI may confer direct benefits to patients…. Simultaneous direct control over both intracoronary catheter positioning and the contrast media injector may enable reductions in fluoroscopy and total contrast delivery.
> "

Procedural Characteristics: Robotic-Enhanced and Manual PCI Comparison

Procedural Characteristics	Robotic PCI (n=40)	Manual PCI (n= 80)	P Value
Predilatation*	39 (97.5%)	57 (71.3%)	<0.001
Multiple stents inserted	5 (12.5%)	13 (16.3%)	0.59
Number of catheters	2.1 ± 1	2.7 ± 1.1	0.01
Postdilatation	13 (32.5%)	51 (51.3%)	0.05
Contrast volume (mL)	121 ± 47	137 ± 62	0.11
Fluoroscopy time (min)	10.1 ± 4.7	12.3 ± 7.6	0.05
Radiation dose (µGy)	1389 ± 599	1665 ± 1026	0.07
Device technical success	38 (95.0%)	N.A.	N.A.
Clinical procedure success	40 (100%)	80 (100%)	0.99

* Predilatation was required by robotic PCI protocol. It was not required in the manual PCI cohort.

N.A. – Not applicable.

First-in-Human Evaluation of a Novel Robotic-Assisted Coronary Angioplasty System

Granada JF, Delgado JA, Uribe MP, Fernandez A, Bianco G, Leon MB, Weisz G

Eight patients received elective PCI of a single vessel using the CorPath 200 robotic system. All lesions had stenosis of at least 50%; six lesions were type A and two were type B1. The clinical success rate was 100%, and no MACE was reported to 30 days. Of 48 planned procedural steps, 47 were completed for a technical success rate of 97.9%. There were no perforations or dissections. Use of CorPath reduced operator exposure to radiation by 97% compared to that at the procedure table (1.81 µGy and 61.57 µGy, respectively). Total procedure time averaged 43.0 minutes, with an average of 11.5 minutes of fluoroscopy. CorPath was rated as equal to or better than manual PCI in 97.5% of cases.

Conclusion

Robotic-assisted PCI is safe and feasible. Procedural effectiveness is comparable to manual PCI, and radiation exposure to the operator was low.

> "
> In our study, 1 of the most important findings was the significant (97.1%) reduction in radiation exposure to the operator performing the robotic PCI procedure.
> "

ROBOTIC-ASSISTED PCI IN COMPLEX CASES

Demonstration of the Safety and Feasibility of Robotically Assisted Percutaneous Coronary Intervention in Complex Coronary Lesions: Results of the Complex Robotically Assisted Percutaneous Coronary Intervention (CORA-PCI) Trial

Mahmud E, Naghi J, Harrison J, Bahadorani J, Ang L, Behnmafer O, Reeves R, Patel, M.

During an 18-month period, 334 procedures —108 robotically and 226 manually—were performed in 315 patients by a single operator. R-PCI on 157 lesions and M-PCI on 336 lesions were analyzed. Procedures, such as atherectomy, deemed ineligible for robotic treatment were not included in the M-PCI group. R-PCI technical success equated to robotic completion of the procedure with or without planned manual assistance and no MACE. Clinical success was completion of PCI and no MACE.

Other than significantly more patients in the M-PCI arm having angina and prior coronary artery bypass (CABG), baseline characteristics between the two groups were similar. The R-PCI group had significantly more challenging angiographic characteristics, including longer lesions (22.2 mm vs. 19.4 mm in M-PCI), lesion class B2/C (81% vs. 69% in M-PCI), and SYNTAX score (19.65 vs. 15.769).

The technical success rate for the R-PCI group was 91.7%, reflecting unplanned manual assistance or conversion to conventional PCI at the bedside. Clinical success in both groups exceeded 99%. R-PCI was associated with a significantly longer procedure time at 44:30 compared to 36:34 for M-PCI (P=0.005). However, when treating more complex lesions, the difference between R-PCI and M-PCI for lesions with intermediate complexity (43:47 and 40:06, respectively, P=0.53) and high complexity (56:27 and 57:37, respectively) was negligible. For the overall cohort, fluoroscopy time was shorter at 18.2 minutes for R-PCI vs. 19.2 minutes for M-PCI. In addition, contrast volume was significantly lower for R-PCI at 183.4 cc compared to 202.5 cc for conventional PCI (P=0.03).

Key Angiographic and Procedural Characteristics

	R-PCI (n=108)	M-PCI (n=226)	P value
Primary Lesion Length (mm	22.2	19.4	0.02
Primary Lesion Class B2/C	81%	69%	0.02
SYNTAX Score	19.65	15.769	0.01
Lesions Treated	1.47	1.49	0.87
Procedure Time (min)	44:30	36:34	0.005
Fluoroscopy Time (min)	18.2	19.2	0.42
Contrast Volume (cc)	183.4	202.5	0.03

Conclusion

R-PCI has comparable technical and clinical success rates to that for M-PCI in the treatment of patients with complex lesions and multiple comorbidities.

Complex Robotic Compared to Manual Coronary Interventions: 6- and 12-Month Outcomes

Walters D, Reeves R, Patel M, Naghi J, et al.

The CORA-PCI trial demonstrated comparable technical and clinical success rates for robotic-assisted and manual PCI of complex lesions. Patients were followed to assess the long-term safety, denoted by MACE consisting of death, stroke, MI, or TLR. There were 103 individuals treated by R-PCI and 210 patients treated by M-PCI. In total, there were 108 R-PCIs and 226 M-PCIs.

Baseline characteristics were similar. Both groups had a high percentage of patients with hypertension (>95%), dyslipidemia (>93%), diabetes (~55%), and chronic kidney disease (20%-25%). Approximately 20% of each cohort had ACS.

The primary lesion length was longer in the R-PCI arm compared to the M-PCI cohort at 22.2mm and 19.4mm, respectively (P=.02). Type B2/C lesions comprised a higher percentage of the R-PCI group than the M-PCI arm at 81% and 69%, respectively (P=.03). In

> "
> This long-term follow-up study of the original CORA-PCI study provides confirmation that robotic PCI can be performed with high technical success and leads to short- and intermediate-term outcomes which are comparable to the manual approach.
> "

addition, SYNTAX scores were higher in the R-PCI arm at 19.6, which compares to 15.7 in the manual group (P=.01).

There were no significant between-group differences in MACE at six- and 12-month follow up. The combined MACE rate was 5.8% for R-PCI and 3.3% for M-PCI (P=.51) at six months and 7.8% and 8.1%, respectively (P=.92) at 12 months. There were no significant differences in MACE components for either time period.

Safety Event Rates

SIX-MONTH FOLLOW UP

12-MONTH FOLLOW UP

Legend: R-PCI (orange), M-PCI (blue)

X-axis categories: Combined MACE, All-cause mortality, CVA, MI, TLR
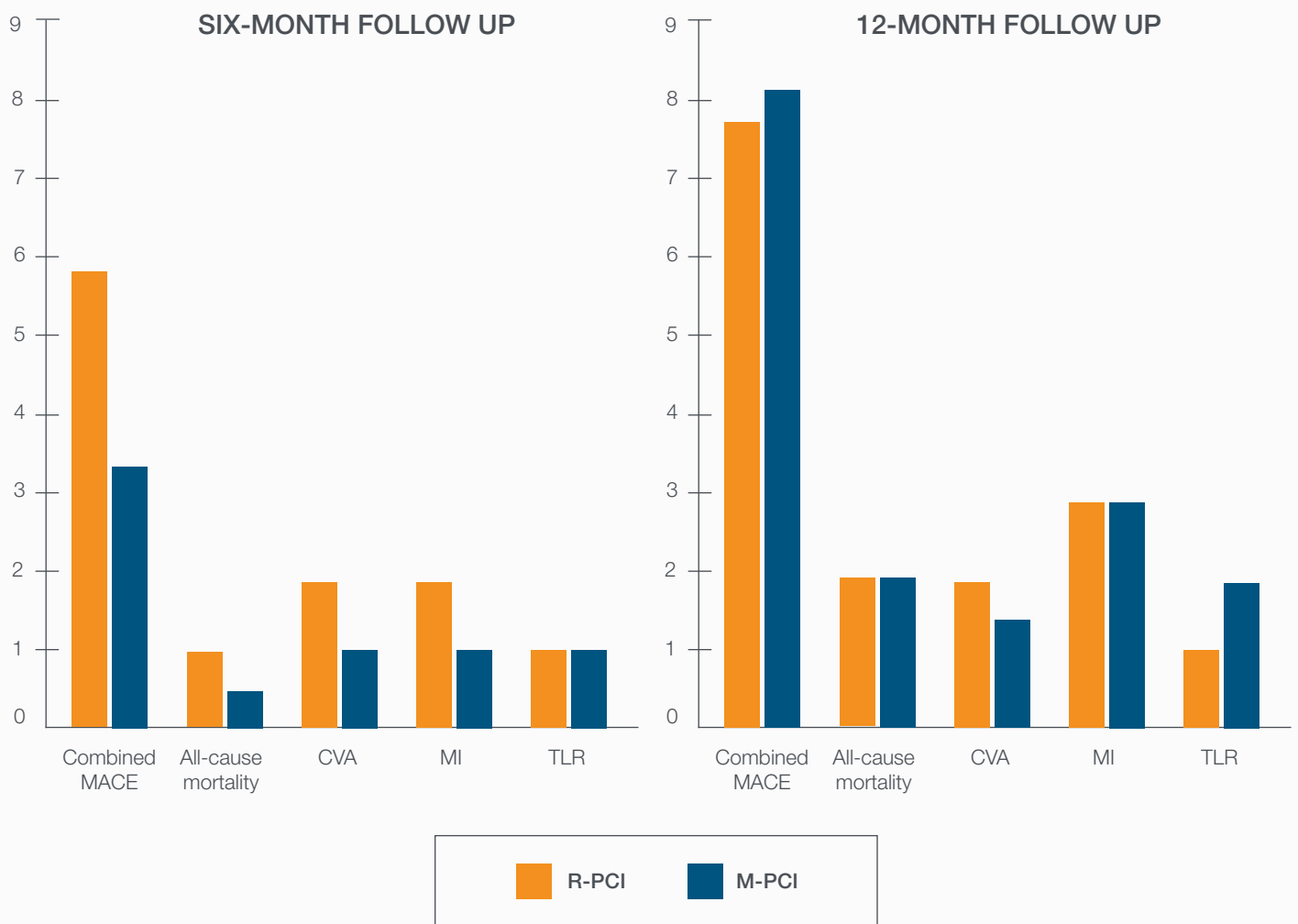
Conclusion

Intermediate follow up of the CORA-PCI study showed robotic PCI to be as safe and effective as manual PCI in the treatment of complex patients.

Robotically-assisted percutaneous coronary intervention: Reasons for partial manual assistance or manual conversion

Harrison J, Ang L, Naghi J, Behnamfar O, et al.

Partial manual assistance, either planned or unplanned, occurs during robotic PCI for a variety of reasons. This report delineates the frequency of, and reasons for, partial manual assistance or conversion to manual PCI during a single center's initial experience with the CorPath 200 robotic system.

Over an 18-month period, 108 robotic PCI procedures were performed. The average age of patients was 68.1 years. At baseline, >95% of individuals had hypertension and hyperlipidemia. Diabetes and prior MI were common, affecting more than half of the cohort. About 20% of patients had ACS. The majority of lesions (78.3%) were type B2/C. About 10% of lesions had severe calcification, and nearly 15% had severe tortuosity.

Most of the procedures (81.5%) were completed robotically; 20 cases involved manual assistance or conversion. By type, 7.4% of cases included planned manual assistance, 3.7% had unplanned manual assistance, and 7.4% were converted to manual PCI. The primary reasons for manual assistance or conversion to manual PCI related to limitations associated with the first-generation robot and insufficient guide catheter support. Fifteen percent of manual assistance or conversion cases related to adverse events, such as non-flow-limiting dissection without MACE.

The initial experience reflected learning curve with CorPath 200. Despite this, there were no clinically relevant adverse events stemming from use of the first-generation robotic system in complex PCI. The authors noted that almost half of the manual assistance or conversion cases would be able to be performed without manual assistance with the newer robotic system, CorPath GRX.

Planned Manual Assistance

Anticipated temporary disengagement of robotic control of guidewire or guide catheter to perform an aspect of the procedure; robotic system used to complete PCI

Unplanned Manual Assistance

Unanticipated temporary disengagement of robotic control of guidewire or guide catheter; robotic system used to complete PCI

Conversion to Manual:

Disengagement of robotic drive; PCI completed manually.

Results:
- 88 procedures (81.5%) performed robotically
- 4 procedures (3.7%) with planned partial assistance
- 8 procedures (7.4%) with unplanned partial assistance
- 8 procedures (7.4%) with manual conversion

High-risk PCI is becoming more common in individuals who are not surgical candidates. These procedures are associated with longer procedure times, increased complexity, and higher radiation exposure for patients and interventional physicians. Even with limitations of the first-generation robot, physicians receive significant reduction in radiation exposure.

Conclusion

The high clinical success rate with CorPath 200 may require instances of manual assistance or conversion. Improvements in CorPath GRX should increase the percentage of individuals with complex anatomy who can be treated with robotic PCI.

> "
> Although efforts to reduce radiation dose and contrast volume are made, these factors often limit the degree of revascularization that can be safely achieved during a single procedure. R-PCI for complex coronary anatomy has the potential to address this issue…
> "

Complex Robotic-Enhanced Percutaneous Coronary Intervention

Kapur V, Smilowitz NR, Weisz G.

Kapur et al report of their experience using the CorPath 200 robotic system for four complex coronary cases at New York-Presbyterian Hospital/Columbia University Medical Center. Cases included treatment of a multi-lesion coronary artery, multi-vessel disease, a saphenous venous graft, and acute ST-elevation MI (STEMI).

All cases were completed with the CorPath robotic system. Commercially available guidewires, rapid exchange balloons, and stents were used. Guidewire manipulation at the interventional cockpit was intuitive, and lesion crossings were successful even in the case of the acute STEMI patient who had a thrombotic occlusion. Multiple balloon types (high pressure, scoring, etc.) were used during pre-dilation and post-dilation. According to the authors, CorPath offers superior lesion measurement and advances intravascular devices in 1 mm increments, facilitating precise stent positioning and placement. As the operator sits in the interventional cockpit near a fluoroscopy monitor, CorPath enhances

visualization in addition to offering protection from radiation exposure and a more ergonomic procedure.

Conclusion

Remote control of various off-the-shelf intravascular devices is safe and easy even in complex coronary cases. Image visibility is enhanced, and the operator is protected from radiation and also benefits from a more ergonomic position.

The CorPath 200 Robotic System in the Cath Lab

> " Robotic-enhanced PCI has multiple apparent clinical advantages. Precise measurement of lesions using the robotic system….allows for appropriate lesion sizing and can prevent the placement of unnecessary stents. "
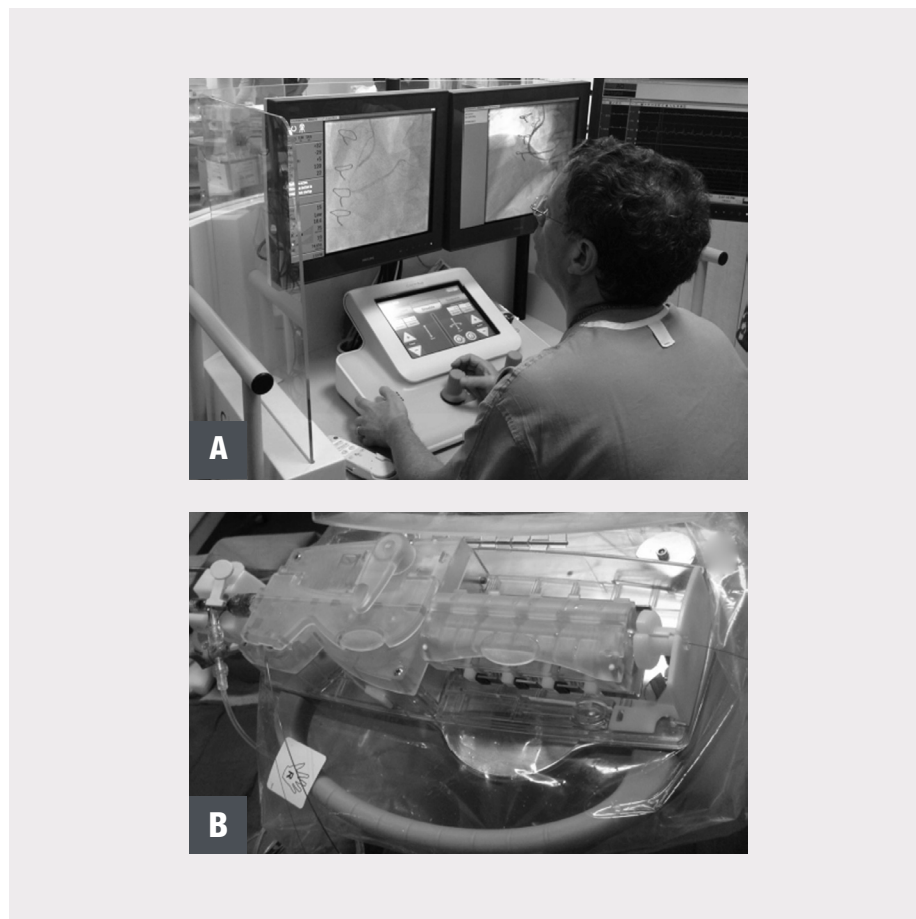
A) Operator performs the PCI while seated at shielded interventional cockpit and controlling intravascular devices attached to the cassette in the robot's arm.

B) Commercially available guidewires, balloons, and stents are connected to the sterile cassette and can be manipulated simultaneously or independently.

CASE REPORTS

Rotate-on-Retract Procedural Automation for Robotic-Assisted Percutaneous Coronary Intervention: First Clinical Experience

Al Nooryani A, Aboushokka W.

Advancing, retracting, and rotating a guidewire to reach a target vessel is a time-consuming aspect of PCI procedures involving complex anatomy. The CorPath GRX robotic system has a new "Rotate-on-Retract" feature that, once activated, changes the orientation of a guidewire tip when retracted by the operator.

We first used the Rotate-on-Retract feature in a case involving a staged treatment approach for a 62-year-old male presenting with symptoms of AMI. The first procedure was manual PCI with stent placement in the RCA. The patient returned three weeks later for robotic-assisted PCI of the LAD coronary artery, which had 90% stenosis in the mid and proximal segments.

The guide catheter was manually introduced via radial access and connected to a Y-connector, which was loaded into the CorPath GRX robotic drive. A guidewire was introduced into the guide catheter through the Y-connector. After this was completed, the primary physician used the joystick controls in the interventional console to advance the guidewire. The Rotate-on-Retract feature was enabled.

The guidewire entered first one side branch and then another before reaching the LAD. In each instance, the robot rotated the tip on retraction, and the guidewire was then advanced using controls in the cockpit. A rapid-exchange catheter was then loaded into the CorPath GRX robotic drive. A 3.00mm x 23mm stent was robotically advanced and positioned in the mid-LAD, with a 3.50mm x 28mm stent robotically positioned in the proximal LAD. There were no perforations, dissections, or other adverse events. TIMI 3 flow was achieved post procedure.

The Rotate-on-Retract feature can be used when treating a variety of vessels, including side branches and highly angled LADs, among others. A presentation at the 2017 Transcatheter Cardiovascular Therapies (TCT) conference showed that Rotate-on-Retract shortened

> " In our view, the principal advantage of the feature is that it automates a common maneuver, essentially combining the time usually required for two separate steps— retracting the guidewire and then rotating it— into one. "

robotic wiring times of experienced interventionalists by 53% (P=0.03).

Conclusion

CorPath GRX's Rotate-on-Retract feature is safe and effective. It enhances the maneuverability of guidewires, which could reduce wiring times and expedite PCI procedures.

Robotic-Assisted Percutaneous Coronary Intervention of a Saphenous Vein Graft Stenosis using a FilterWire EZ Embolic Protection

Anuwatworn A, Stys T, Stys A.

PRECISE, the pivotal trial for CorPath 200, demonstrated the safety and efficacy of robotic-assisted PCI of low-risk patients with simple lesions. In many case studies and series, physicians have shown that CorPath 200 can be used to perform complex PCI, such as unprotected left main disease, STEMI arising from proximal RCA occlusion, and multi-vessel cardiac allograft vasculopathy, among others. We report on robotic PCI of an SVG with 99% occlusion to the first obtuse marginal artery in an elderly male with NSTEMI, EF of 25%, and elevated heart rate.

A guide catheter was manually introduced and engaged the SVG. A guidewire and balloon catheter were loaded into the robotic cassette. A FilterWire EZ embolic protection device was positioned distal to the lesion, following ACC guidelines for embolic protection when performing PCI on an SVG, and loaded into the robotic cassette's auxiliary device track.

Thereafter, the operating physician used controls at the interventional cockpit to advance and position the intracoronary devices. There were no difficulties crossing the lesion with a 2.25mm x 15mm balloon and a 3.25mm x 23mm stent. There were no adverse events.

Conclusion

The CorPath 200 robotic system can be used to assist with PCI of many complex cases, including occluded SVGs. The new CorPath GRX System, which enables robotic manipulation of guide catheters, may expand the number of high-risk complex lesions that could be treated with robotic-assisted PCI.

> "
> Our case illustrates the feasibility of performing complex PCI on acute SVG stenosis with the robotic system.
> "

Robotic-Assisted Transradial Diagnostic Angiography

Swaminathan RV, Rao SV.

CorPath GRX's Active Guide Management feature enables advancement and rotation of 5Fr-7Fr guide catheters by using the third joystick at the interventional cockpit. This reduces the need for conversion to manual PCI that was common with the first-generation CorPath 200. The robotic system is most often used for PCI. We explored use of the system to assist in diagnostic procedures in two patients.

The first case involved a 69-year-old man with atypical chest pain; cardiac markers were somewhat elevated. A sheath was inserted in the right radial artery, and a J-wire was manually introduced and advanced to the ascending aorta. A 6Fr diagnostic catheter, which was connected to a hemostatic valve, was also manually introduced and positioned above the aortic cusp. The catheter with hemostatic valve was loaded into the robotic cassette. The diagnostic catheter was engaged by turning the guide control joystick and robotically positioned in the left main coronary artery. The catheter was dislodged during patient respiration but robotically repositioned in the left main artery. Angiographic images were taken of the left coronary arteries; no significant occlusions were found. The operating physician retracted the diagnostic catheter by rotating the guide control joystick in a counter-clockwise motion. The guide catheter was then advanced into the right coronary cusp. By slightly retracting the catheter and turning the joystick in a clockwise motion, the catheter was engaged in the RCA. Images showed minor irregularities in the RCA. The catheter became soft, and the operating physician used the joystick to retract the catheter backward. The catheter was manually removed.

The second case involved a 70-year-old man referred for angiography prior to implantation of pacemaker. The patient had a CTO in the RCA and previous stents in the LAD and circumflex arteries. Stress test results were abnormal (chronotropic incompetence and exertional hypotension). Right radial access was used for the procedure. After manual introduction of a guidewire and 6Fr diagnostic catheter and positioning in the left main artery, the physician used the guide control at the interventional console to engage the diagnostic catheter in the left coronary system. Images showed moderate in-stent restenosis of the circumflex artery, with patent stents in the LAD. The operating physician then used the joystick to retract, advance, and rotate the catheter, which was then positioned at the right cusp. Images of the

CTO in the RCA were taken. The catheter was then retracted to the right subclavian artery. The case was ended.

CorPath GRX is compatible with 5Fr-7Fr catheters. Small catheters may be prone to inadequate tracking by the robotic drive and could become soft after many rotations. The system can retract to the level of the subclavian artery, which suggests that PCI of coronary bypass grafts arising from the ascending aorta could be amenable to robotic-assisted PCI. Use of left radial access in manual PCI has had limited use because of strain placed on the physician's lower back while manipulating catheters. Set-up time, e.g., loading devices into the robotic cassette, was minimal.

Conclusion

CorPath GRX enables the robotic manipulation of universal diagnostic catheters. Catheters can be advanced, rotated, and retracted from the control console. Combining transradial access and robotic assistance provides benefits to both the patient and operating physician.

A Case of Robotic Assisted Percutaneous Coronary Intervention of the Left Main Coronary Artery in a Patient with Very Late Baffle Stenosis after Surgical Correction of Anomalous Left Coronary Artery from the Pulmonary Artery

Hirai T, Jacob D, Main ML.

Anomalous left coronary artery from the left pulmonary artery (ALCAPA), which occurs in 1 in 30,000 births, is corrected by Takeuchi repair or coronary translocation. Takeuchi repair is associated with late complications, such as baffle leak, pulmonary stenosis, mitral regurgitation, and impaired EF.

We performed robotic-assisted PCI on a 34-year-old woman with a history of Takeuchi repair of ALCAPA who was found to have akinesis in the anterior wall in a work up following a recent acute stroke. Angiography revealed 90% stenosis in the ostia of the LMCA.

A guidewire and 6FR guide catheter were manually introduced. The guide catheter engaged the LCMA and connected to CorPath GRX. Using controls at the control console, the guidewire was advanced to the LCX. An IVUS catheter, which was advanced along the guidewire, showed the diameter to be 3.5mm; there was no calcium. However, the baffle had severe stenosis and did not have typical characteristics (i.e., no three-layer appearance).

Pre-dilation was performed using a 3.5mm x 15mm cutting balloon, which was selected in the event the baffle had scarring or sutures. Lesion length measurement was calculated by CorPath GRX. The distal marker on the cutting balloon was positioned at the distal lesion and pulled back robotically to the LMCA ostia. CorPath GRX measured the lesion length to be 15mm. A 3.5mm x 16mm drug-eluting stent was introduced and then robotically advanced to the LMCA ostia. The stent was advanced distal to the lesion. With the guide catheter positioned at the proximal edge of stent, the stent, guide catheter, and guidewire were retracted as a unit to the ostia. IVUS showed stent positioning and apposition to be excellent. Post-dilation of the proximal lesion was performed using a 4.0 noncompliant balloon; the ostia was post-dilated with a 5.0 compliant balloon. Angiography showed a good flow, and the patient was discharged the following day. At three months, she reported significant symptom improvement.

Conclusion

This is the first report of robotic-assisted PCI of a patient with surgically corrected ALCAPA. The benefits of robotic-assisted PCI—measurement of lesion length and precise positioning—may be more marked in treatment of ostial lesions.

First-in-Human Robotic Percutaneous Coronary Intervention for Unprotected Left Main Disease

Mahmud E, Dominguez A, Bahadorani J.

High-risk PCI for complex coronary artery disease (CAD) is increasingly being performed for patients who are poor candidates for CABG. Complex PCI is associated with longer procedure times, increasing physician fatigue and exposure to scatter radiation. In addition, use of assist devices—intra-aortic balloon pumps (IABPs) or Impella—typically needed in the presence of unprotected left main disease. However, these devices also add to procedure time and operator exposure.

Of 102 robotically assisted PCIs performed at University of California San Diego (UCSD) and reported in the post-market PRECISION Registry, 6 patients had unprotected left main (LM) disease. All patients were successfully revascularized (0% stenosis in LM). On average, 1.8 stents were used and 2.2 vessels were treated. The mean fluoroscopy time was 26.8 minutes. Half of the patients required hemodynamic support, with Impella 2.5 used in two of the procedures and an IABP used in one.

> " This study demonstrates the feasibility of performing high-risk unprotected left main PCI robotically in the presence or absence of percutaneous hemodynamic support. This was possible with either femoral or radial access approaches. "

Angiographic and Procedural Characteristics of the Robotic Left Main Study Population

Case	Baseline LM Stenosis	LM Lesion Length (mm)	Stents (#)	Fluoroscopy Time (min)
1	80%	18	4	45.9
2	80%	28	1	32.6
3	70%	15	2	18.9
4	70%	8	1	23.6
5	70%	34	1	13.1
6	Ostial LCX 90%, ostial LAD 90%	20 mm LAD, 12 mm LCX	3	26.7

Bifurcated lesions can be treated using a provisional approach or by implanting stents sequentially. The CorPath casette has a second wire port, which can be used to support a guidewire while the primary port is used to advance a balloon. Thus, minor manual bedside assistance is needed for kissing techniques with the current iteration of CorPath.

Conclusion

This study demonstrates that robotically assisted PCI of unprotected LM disease with or without mechanical hemodynamic support is feasible.

ROBOTIC-ASSISTED PERIPHERAL VASCULAR INTERVENTIONS

Feasibility and Safety of Robotic Peripheral Vascular Interventions: Results of the RAPID Trial

Mahmud E, Schmid F, Kalmar P, Duetschmann H, Hafner F, Rief P, Brodmann M.

Peripheral vascular interventions (PVIs) have been largely unchanged over the last 30 years. Use of robots to assist PCI has been well studied. RAPID was the first trial to evaluate the feasibility of using a robotic system in PVIs in the superficial femoral (SFA) and popliteal arteries (SFA). This prospective, single-center study enrolled 20 patients with stenosis of >50% in the SFA and popliteal, with lesion lengths of up to 50 mm. The majority of patients (60%) had severe claudication (Rutherford Class 3) or moderate (30%) claudication (Rutherford Class 2). The primary endpoints were technical and device safety. Other endpoints included clinical success, procedure time, fluoroscopy time, amount of contrast volume used, and adverse events.

Of the 29 treated lesions, 89.7% were located in the SFA, with the remainder in the popliteal artery. More than half of lesions (55.2%) had moderate to heavy calcification. The average lesion length was 33.1 mm. Prior to intervention, the average stenosis was 85.5%.

All lesions were successfully cannulated for a 100% technical success rate. Provisional stenting was needed in 10 lesions (34.5% of total), which is comparable with that typically needed for manual angioplasty in the lower limbs. There were no device-related adverse events. After intervention, the average stenosis was 7.2%, equating to 100% clinical success. Total procedure time averaged 45.5 minutes, with a mean fluoroscopy time of 6.8 minutes.

Conclusion
Robotic PVI for the treatment of PAD is feasible and safe. The technical success rate was 100%, and all vessels were successfully revascularized. There were no adverse events related to the robotic system.

> " It is likely that a robotic-assisted PVI system could facilitate more precise lesion measurement and accurate device selection, reducing longitudinal geographic miss in PVI procedures. "

Lesion Characteristics and Procedure Outcomes	Mean + SD (N) (Min, Median, Max) Or # (%)
Lesion Characteristics	**N=29**
Lesions Treated	
Superficial Femoral	89.7%
Popliteal	13.8%
Lesion Length (mm; mean ± SD)	33.1 ± 15.5
Vessel Tortuosity	
Mild	93.1%
Moderate	6.9%
Severe	0%
Calcification	
Mild	44.8%
Moderate	27.6%
Heavy	27.6%
Pre-Intervention Percent Stenosis (Mean ± SD)	85.5 ± 11.0
Post-Intervention Percent Stenosis (Mean ± SD)	7.2 ± 11.1
Procedure Characteristics	
Total Procedure Time – min (Mean ± SD)	45.5 ± 6.2
CorPath Procedure Time – min (Mean + SD)	23.4 + 14.0
Contrast Media Volume – ml (Mean ± SD)	73.3 ± 9.2
Fluoroscopy Time – min (Mean ± SD)	6.8 ± 3.4
Provisional stenting required	34.5%
CorPath Technical Success	100%
CorPath Clinical Procedural Success	100%

* One lesion covered the distal superficial femoral artery and the proximal popliteal artery.

Robotic Percutaneous Vascular Intervention with Drug Coated Balloons Is Feasible and Reduces Operator Radiation Exposure: Results of the Robotic-Assisted Intervention for Peripheral Artery Disease (RAPID) Study II

Mahmud E, Hafner F, Rief P, Cain C, Ang L, Brodmann M.

RAPID II enrolled 20 patients with 24 lesions, of which 75% had Rutherford class 3-4 claudication. Over 90% of lesions were located in the SFA. Use of a drug-coated balloon was part of the study protocol. RAPID II assessed the effect of robotic-assisted PVI on radiation exposure for the operating physician. The primary outcome was clinical success, which was defined as <50% residual stenosis with no device-related serious adverse events. Using the CorPath robotic system, all lesions achieved clinical success; one lesion had provisional stenting. There were no adverse events related to CorPath.

Fluoroscopy time averaged 7.3 minutes. A dosimeter placed at the patient table served as the control and was compared to radiation exposure for the operating physician at the CorPath interventional cockpit as well as for the table-side operator. Use of CorPath significantly reduced radiation exposure for the operating physician who had a recorded exposure of 1.9 µSv, which compares to 4.1µSv for the assisting physician and 95.8 µSv for control. This equated to 96.9% radiation exposure reduction for the operating physician.

Conclusion

RAPID II demonstrated that robotic-assisted PVI with drug-coated balloons can safely treat complex lesions in the SFA, with a corresponding benefit of a significant reduction in radiation exposure for the operating physician.

> "This corresponded to a 96.9±5.0% and 95.4±7.8% reduction in radiation exposure (p<0.0001 for both [operating physician dose and table-side operator dose])."

First Case of Robotic Percutaneous Vascular Intervention for Below-the-Knee Peripheral Vascular Disease

Behnamfar O, Pourdjabbar A, Yalvac E, Reeves R, Mahmud E.

The RAPID Study demonstrated the safety and feasibility of using the CorPath robotic system to perform PVI in the SFA and popliteal artery. We present the first reported case of robotic-assisted PVI for below-the-knee occlusions.

A 56-year-old male with PAD and a previous stent implanted in the left SFA developed bilateral Rutherford class 3 claudication in the lower extremities. Guidewires and catheters for angiography were introduced and manipulated manually. Angiography showed the right anterior and posterior tibialis to have 100% occlusion, with 90% focal stenosis in the tibioperoneal trunk and 80% occlusion of the proximal peroneal artery.

A 300-cm, 0.014" guidewire and a 3.0mm x 20mm rapid exchange balloon were introduced and connected to the robotic drive. The devices were advanced to the right peroneal artery using the controls at the control console. Balloon angioplasty was performed. The balloon catheter was then repositioned in the tibioperoneal trunk where the balloon was re-inflated. Angiography showed a good result but with substantial elastic recoil. A 3.5mm x 20mm rapid exchange balloon was inserted and advanced robotically to the target vessels. Balloon angioplasty was repeated. Angiography confirmed <30% residual stenosis in both lesions.

Procedure times for PVI tend to be longer than those for PCI. Radiation exposure is typically higher than that associated with PCI, and physicians have to maintain awkward positions, particularly when advancing devices around the iliac horn. The use of the CorPath robotic system enables the physician to perform PVI while seated behind a lead-shielded interventional cockpit. The ability to use atherectomy and other devices used in PVI would expand the robot's utility in PVI.

Conclusion

PVI is an emerging area for use of robotic technology. This case demonstrates that robotic-assisted PVI is safe and effective. Further study in a larger number of patients is warranted.

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> Using the CorPath Robotic System, this case demonstrates the ability to remotely cannulate and treat below-the-knee atherosclerotic disease with balloon angioplasty.
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> "

Feasibility of Robotic Percutaneous Renal Artery Vascularization

Caputo RP, Lesser A, Simons A.

Restenosis occurs in up to 21% of stented renal arteries. Optimized stent placement could reduce restenosis and enhance patient outcomes. We used CorPath 200 in five consecutive patients requiring a stent in the renal artery. Technical success was defined as completion of PCI without conversion to manual PCI or deployment of a second stent because of geographic miss. Procedural success was defined as residual stenosis of <30% and no post-PCI adverse events.

Radial access was used in 3 (60%) patients. CorPath's millimeter positioning tool was used in all cases. Procedure time averaged 57.5 minutes with mean fluoroscopy time of 23.3 minutes. There were no major post-procedural adverse events. All five cases achieved technical and procedural success.

Conclusion:
Robotic revascularization of the renal artery and renal stent implantation is safe and feasible.

PRECISION

The Impact of Precise Robotic Lesion Length Measurement on Stent Length Selection: Ramifications for Stent Savings

Campbell PT, Kruse KR, Kroll CR, Patterson JY, Esposito MJ

Following results of the STLLR trial, there is greater focus on addressing procedural factors, such as longitudinal geographic miss (LGM), which could affect patient outcomes. Robotic PCI could address three procedural elements that are associated with worse clinical outcomes: inaccurate assessment of lesion length, selection of inappropriately sized stent, and suboptimal stent deployment. The authors sought to evaluate whether robotic PCI offered advantages over manual (visual) assessment for the first two procedural factors.

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> Robotic PCI can more precisely measure lesion length in 0.1mm increments, which in turn would lead to the appropriate selection of both overall stent length and the correct number of stents thereby reducing both under- and over-stenting.
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> "

Stent length selection based on visual assessment made by interventional cardiologists were compared to robotic measurement performed using the CorPath 200 Robotic System for 60 consecutive patients. The treating physician estimated the lesion length from orthogonal diagnostic angiographic images and proposed a stent length that would provide optimal lesion coverage. The initial selection of stent length was then compared to the intra-procedure measurement taken by CorPath.

The majority (65%) of visual estimates did not match CorPath's measurement of the lesion length, with 32% of visual assessments being short and 33% being long. Of the 35% accurate visual assessments, most tended to be short but the selected stent length was sufficient to cover the lesion. Of the 20 visual assessments categorized as long, CorPath measurement resulted in fewer stents used in five instances, representing 8.3% of all cases (see table).

Stent Savings from Robotic Measurement

Case	Visual Assessment (mm)	CorPath Measurement (mm)	Initial Stent Length Selection (mm)	Stent Length Chosen after CorPath Measurement (mm)
1	38	34.9	23 + 18	38
2	46	38.0	24 + 24	38
3	52	37.7	24 + 28	38
4	44	28.0	24 + 20	32
5	40	35.1	18 + 23	38

Conclusion

Visual assessment resulted in accurate lesion length estimates in only 35% of images. Objective robotic measurement can reduce LGM, optimize stent selection, and negate the use of extra stents.

Longitudinal Geographic Miss (LGM) in Robotic-Assisted versus Manual Percutaneous Coronary Interventions

Bezerra H, Mehanna E, Vetrovec G, Costa M, Weisz G

This study evaluated whether robotic-assisted PCI (RA-PCI) reduced the incidence of LGM compared to visual assessment of lesion length performed during manual PCI (M-PCI). This retrospective study analyzed data from two clinical trials: PRECISE (n=164), which assessed safety and technical feasibility of RA-PCI using the CorPath 200 Robotic System, and STLLR (n=1509). The latter trial was selected because it demonstrated the relationship between LGM and worse clinical outcomes.

The PRECISE and STLLR trials had similar inclusion and exclusion criteria. However, from the STLLR trial, we only included patients who had at least one stent implanted and for which LGM could be evaluated. In our study, LGM was denoted by the stent length not fully covering the target lesion.

There was a statistically lower overall incidence of LGM in the RA-PCI group than the M-PCI cohort at 12.2% and 43.1%, respectively (p<0.0001). This represents a 72% improvement in favor of robotic measurement and stent deployment. RA-PCI demonstrated lower LGM rates than M-PCI regardless of lesion type (simple or complex). For simple lesions, LGM was 10.7% for RA-PCI compared to 28.7% for M-PCI (p=0.0002). For complex lesions, RA-PCI had an LGM rate of 15.4%, significantly lower than 48.0% in the M-PCI group (p<0.0001).

> "Robotic measurement is associated with a significantly lower LGM rate than visual assessment and manual stent deployment. The reduced LGM may reflect several factors, including improved accuracy of lesion measurement."

Comparison of RA-PCI and M-PCI Pre- and Post-Procedure Lesion Characteristics and LGM

Lesion/Procedure Characteristics	RA-PCI (n=164)	M-PCI (n=1509)	P value
Pre-Procedure			
Lesion Length (mm)	13.4 ± 4.0	14.8 ± 9.2	0.0007
Lesion diameter stenosis (%)	78.1 ± 10.0	61.7 ± 12.5	<0.0001
Lesion minimal lumen diameter (mm)	0.95 ± 0.33	1.00 ± 0.39	0.1717
Lesion reference diameter (mm)	3.04 ± 0.40	2.61 ± 0.53	<0.0001
Post-Procedure			
Lesion diameter stenosis (%)	4.9 ± 7.9	16.7 ± 10.8	<0.0001
Lesion minimal lumen diameter (mm)	2.59 ± 0.43	2.28 ± 0.50	<0.0001
Lesion reference diameter (mm)	2.73 ± 0.46	2.73 ± 0.45	0.9654
LGM Overall and by Lesion Classification			
Overall	20/164 (12.2%)	650/1509 (43.1%)	<0.0001
Simple	12/112 (10.7%)	105/366 (28.7%)	0.0002
Complex	8/52 (15.4%)	539/1124 (48.0%)	<0.0001
Unclassified		6/19 (31.6%)	

To address differing baseline characteristics, propensity scores were applied to create a subset of better matched M-PCI patients (n=329). The RA-PCI group had a significantly lower incidence of LGM than this M-PCI cohort at 9.3% and 55.0%, respectively (p<0.0001). In addition, propensity-matched cohorts of 39 patients with similar baseline characteristics from both groups were identified. In this comparison, the incidence of LGM for RA-PCI was 10.3%, significantly lower than the 64.1% recorded in the M-PCI group (p<0.0001).

Conclusion

Robotic measurement is associated with a significantly lower LGM rate than visual assessment and manual stent deployment. The reduced LGM may reflect several factors, including improved accuracy of lesion measurement, ability to advance catheters in precise increments, feedback from the robotic system on catheter movement and anatomic measurements, more comfortable distance from fluoroscopic monitor, and reduced operator fatigue related to performing the procedure in a seated position.

REVIEW ARTICLES

Robotic-Assisted Percutaneous Coronary Intervention: Concept, Data, and Clinical Application

Walters D, Omran J, Patel M, Reeves R, et al

Robotic technology for PCI and PVI reduces occupational hazards of interventional fluoroscopy, namely health risks stemming from chronic exposure to ionizing radiation and use of heavy PPE. The BRAIN study showed that interventional cardiologists are subject to significantly higher radiation exposure to the left side of head and neck than the right side, with other studies showing left-sided brain and neck tumors among interventionalists. Almost half of interventional physicians have a work-related musculoskeletal injury. There is a need to address these occupational hazards, as procedural complexity and radiation exposure has increased over the past 40 years.

The CorPath robotic system, which can be used in most PCI cases, distances the operating physician from the radiation source. The robotic arm is located at the bedside and connected to the interventional console by cables. Guidewires and catheters are manually introduced via femoral or radial access and then loaded into the single-use cassette on the robotic arm. The operating physician advances and manipulates devices using controls at the lead-shielded interventional console. CorPath's turbo feature rapidly advances devices. The operator can also take measurements of anatomy to determine lesion length by zeroing out the counter on the touchscreen, positioning a balloon catheter past the distal target, and retracting the balloon. CorPath is compatible with 0.014" wires and rapid exchange catheters. The system cannot be used with over-the-wire catheters that do not have a rapid exchange port. Laser atherectomy devices with rapid exchange ports can be used with CorPath; rotational and orbital atherectomy devices cannot. Inflation and deflation of balloons is performed manually at the bedside by an assistant.

There are several ways to address guidewire or catheter resistance in difficult-to-cross lesions. For instance, torque response and tip support of the guidewire can be bolstered by advancing a rapid

exchange catheter toward the tip of the guidewire. For difficulty advancing a rapid exchange catheter, subtly changing the position of the guidewire can enable catheter crossing after several attempts. Alternatively, angioplasty with a low-profile balloon can facilitate crossing by the therapeutic catheter. Of note, quickly moving the joystick controlling the balloon catheter up and down mimics jiggling that is performed manually. Retracting the guidewire while advancing the balloon catheter is similar to the manual rail guidewire position. CorPath GRX has a joystick to advance and manipulate guide catheters. As its name implies, the system's Rotate on Retract feature automatically rotates a wire during retraction.

There have been several clinical studies or registries of CorPath in PCI, including PRECISE, CORA-PCI, PRECISION, the CorPath GRX feasibility study, and RAPID. All studies have shown CorPath-assisted percutaneous interventions to have high technical and clinical success rates. In addition, the REMOTE-PCI study demonstrated that the CorPath robotic system can assist in PCI performed in a separate location from the interventional cockpit.

Conclusion

Robotic systems have had a positive effect on PCI efficiency as well as a reduction in fluoroscopy-related occupational hazards. Compatibility with additional devices for PCI and other minimally invasive procedures will position robotic technology to have a major role in ever-evolving interventional cardiology.

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> The recent application and advancement of robotic systems have made an impressive impact on interventional cardiology in regard to procedural efficiency, operator radiation reduction, and safety.
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Major CorPath Clinical Trials

	PRECISE	CORA-PCI	PRECISION Registry	CorPath GRX Feasibility	RAPID
	PCI	PCI	PCI	PCI	PVI
System Used	CorPath 200	CorPath 200	CorPath 200	CorPath GRX	CorPath 200
Enrollees	164	103/108	949 lesions	40 (54 lesions)	20
% complex lesions	12.8%	78.3%	63.4%	77.3%	N.A.
Technical success	98.8%	91.5%	88.6% - Radial 82.4% - Femoral	90.0%	100%
Clinical success	97.6%	99.1%	98.9% - Radial 94.9% - Femoral	97.5%	100%

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

Maor E, Eleid MF, Gulati R, Lerman A, et al.

Robotic technology has gained widespread adoption in several surgical areas but its uptake has been limited in interventional cardiology despite the accumulating clinical data demonstrating the safety and efficacy of robotic-assisted PCI. Concern over cost and learning curve are barriers to greater uptake. However, robotic technology offers important benefits, including a significant reduction in operator exposure to scatter radiation, lower risk for musculoskeletal problems for interventional physicians, and improvement in stent-length selection.

Interventional cardiologists have the most exposure to medical radiation compared to other specialists, with a lifetime excess risk for cancer of 1%. Chronic exposure to fluoroscopy in PCI has led to reports of brain tumors, the majority of which were left-sided, among interventionalists. The BRAIN study documented the higher radiation exposure to the left side of interventional cardiologists' heads and necks. Other radiation-associated risks include posterior subcapsular lens opacities (precursors of cataracts) and excess cardiovascular risk. Orthopedic injury is a known adverse effect of wearing leaded PPE to reduce radiation exposure: Approximately 50% of interventional cardiologists have a musculoskeletal injury.

CorPath 200 and GRX are the only robotic systems that have been cleared for use in PCI. The PRECISE study (N=164) demonstrated a 98.8% technical success rate for CorPath 200 in the treatment of simple lesions while lowering radiation exposure by 95.2% for the operating physician. By analyzing procedure and fluoroscopy time, the learning curve for performing robotic-assisted PCI with CorPath 200 was calculated to be three cases. There have been numerous reports of CorPath 200 assisting complex PCI, including treatment of STEMI, multivessel CAD, and unprotected left main disease. In addition, CorPath 200 has been used with FFR and OCT in the implantation of bioresorbable vascular scaffolds.

Regarding lesion coverage, studies have shown that physicians' visual estimation of lesion length is often inaccurate, which can lead to adverse events and need for revascularization. In one

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> 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.
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study, 46.5% of lesions had incomplete coverage. Another study showed that physicians overestimated the length of 19% of lesions and underestimated the length of 51% of lesions. The CorPath robotic systems can measure anatomy to determine lesion length by positioning the balloon marker at the distal lesion, zeroing out the counter on the interventional monitor, and retracting the balloon until the marker reaches the proximal end of the lesion. A study comparing the lesion length estimated by CorPath and that estimated by physicians showed that visual estimation led to selection of the appropriate stent size for only 35% of lesions.

To drive greater adoption of robotic systems in the Cath Lab, large randomized trials confirming significant radiation exposure reduction for operating physicians are needed. Cost-benefit and resource utilization analyses may also assist in spurring increased uptake of robotic technology for PCI. A haptics interface, compatibility with a greater array of intracoronary devices, and ability to perform planned dual-stent PCI would address other barriers to use. Robotic technology, possibly with one operator manipulating robots at several geographically distant facilities, could enable remote locations to offer PCI.

Conclusion
Robotic-assisted PCI reduces radiation exposure for the operating physician and thereby addresses an ongoing occupational hazard in the Cath Lab.

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> 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.
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Robotic Technology in Interventional Cardiology: Current Status and Future Perspectives

Mahmud E, Pourdjabbar A, Ang L, Behnamfar O, et al.

Robotics in interventional cardiology was developed to enhance precision and efficiency. However, the immediate advantage has been reducing radiation-related and orthopedic risk for interventionalists. Strategies and tools, such as collimation, to limit radiation dose during percutaneous procedures cannot eliminate all the risk associated with cumulative exposure to ionizing radiation. However, robotic technology can reduce operator radiation exposure by >95%.

The first-generation CorPath 200 and second-generation CorPath GRX robotic systems have been cleared for use in both PCI and PVI. Numerous studies and reports have demonstrated CorPath 200 to be safe and effective in the treatment of both simple and complex lesions. Of note, the CORA-PCI trial did not show a difference in procedure time for complex lesions treated with CorPath 200 compared to those performed manually. CorPath 200 also demonstrated a technical success rate of 86.4% in a feasibility study of telestenting. Regarding the CorPath GRX System, the ability to manipulate the guide catheter from the interventional console should facilitate catheter advancement through tortuous vessels, enable treatment of ostial lesions, and reduce the incidence of conversion to manual PCI.

The Magellan Robotic System, which uses a proprietary 6Fr delivery catheter, has also been approved for use in PVI (but not PCI). Magellan can advance and manipulate 0.035" guidewires; standard therapeutic catheters are inserted into the proprietary catheter to reach the target lesion. Magellan, which also demonstrated high technical success rates in small studies, is no longer commercially available.

Robotic systems need to be evaluated in several common clinical scenarios, including treatment of STEMI and CTO as well as planned dual stenting. In addition, studies assessing clinical outcomes associated with more precise lesion length measurement would be informative. A large study of telestenting over long geographic distances is needed to validate promising feasibility results. Greater compatibility with devices used in PCI and PVI, along with dual advancing robotic drives, would enable robotic systems to assist in the treatment of a broader array of complex PCI and PVI cases.

Conclusion

Robotic-assisted PCI is safe and effective in both simple and complex cases. Robotic technology limits the risk associated with physicians' chronic exposure to ionizing radiation; telestenting represents an exciting frontier in interventional cardiology.

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The development and refinement of robotic systems represents the dawn of a new era in the field of interventional cardiology.

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Robotic-Assisted Percutaneous Coronary Intervention: Rationale, Implementation, Case Selection and Limitations of Current Technology

Ragosta M, Singh KP.

While tools and techniques for PCI have evolved since the first coronary angiogram in 1958, the process for performing percutaneous diagnostic and interventional procedures has not changed. Interventional cardiologists have occupational radiation exposure that is 2x-3x higher than that for radiologists. Chronic exposure to ionizing radiation increases the risk of cancer, results in premature development of cataracts, has negative effects on the reproductive organs, accelerates vascular aging, and impairs short-term memory. Orthopedic hazards are another occupational risk for interventional cardiologists, given prolonged periods of standing with heavy PPE. The effect of physician fatigue on patient outcomes has not been assessed.

Robotic-assisted PCI lowers the primary physician's radiation exposure and alleviates orthopedic strain. It has had high technical success rates and is associated with lower contrast use and decreased fluoroscopy time.

Physicians and institutions implementing a robotic PCI capability need to embrace a philosophy of safety and clinical accuracy. While performing robotic-assisted PCI does not permit tactile feedback from catheters, the operating physician can view nonverbal feedback from the patient and observe fellows and interventional staff performing tasks at the bedside via a closed-circuit camera located at the patient table.

Physicians will also need to accept a small learning curve. It's advisable that the first five cases of robotic-assisted PCI be performed on "straightforward" lesions, with increasingly complex cases being treated during the next 5-10 cases. After the learning curve has been surmounted, the time for robotic-assisted PCI is not materially different than that for manual PCI.

Robotic-assisted PCI shouldn't be viewed as applicable to all cases or no cases. Cases that are ideal for robotic-assisted PCI evolve with operator experience. Hybrid cases are common, with robotic technology used for some aspects of PCI and manual assistance performing other parts of PCI.

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> The limitations of manual PCI—such as radiation, ergonomics, and safety—are otherwise accepted as 'costs of business', but with the advent of robotic PCI we are now able to challenge the notion that these mature techniques are immutable. Now we have an alternative.
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Interventional cardiologists may be resistant to a technology that in the beginning takes longer to perform a routine task. Implementing robotic PCI requires a commitment to safety and reducing operator fatigue, which has largely been overlooked. Additional ports and other refinements to the robotic technology (e.g., easier treatment of bifurcated lesions) would be beneficial.

Robotics in Percutaneous Cardiovascular Interventions

Pourdjabbar A, Ang L, Behnamfar O, Patel MP et al.

Robotic technology is a novel, safe tool for performing PCI or PVI while lowering occupational risks for operating physicians. Although the risk associated with chronic exposure to ionizing radiation cannot be eliminated, studies have quantified the radiation exposure reduction afforded by the CorPath robotic system to be 95%-97% for the primary physician. The CORA-PCI study demonstrated that CorPath can assist in the treatment of complex lesions, which comprised 78% of the robotic group and 69% of the manual PCI cohort. Clinical success, stent utilization, and contrast use were similar between the robotic-assisted and manual PCI arms. Although procedure time was longer for robotic-assisted PCI in CORA-PCI, there was no difference in procedure time when treating complex lesions. The newest application of robotic technology in PCI is the possibility of performing robotic-assisted PCI when the control console is in a different location than the patient table. Technical and procedure success rates were 86.4% and 95%, respectively, in a feasibility study.

PVI is performed in a similar manner as PCI but represents greater occupational hazards for operating physicians, given higher radiation exposure and non-ergonomic positions that physicians must maintain over the course of PVI. PVI of infrapopliteal lesions uses guidewires and balloons that are the same size as those used in PCI. The RAPID trial, which assessed the CorPath 200 in PVI, demonstrated technical and clinical success rates in 29 lesions. Since then, CorPath has been used to assist in below-the-knee angioplasty of the tibiperoneal trunk and proximal peroneal artery.

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> The most important innovation associated with the field of robotic PCI and PVI is the ability to remotely perform an interventional cardiovascular procedure, limiting the associated risks of the orthopedic and radiation-related occupational hazards.
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Conclusion

Robotic technology has heralded a new era in interventional cardiology. It reduces occupational risks for operating physicians and can be used to treated the majority of patients who require PCI, while providing similar outcomes as that afforded by manual PCI. Robotic technology also may expand the number of patients who have access to treatment through telestenting.

Robotic-Assisted Percutaneous Coronary Intervention

Lo N, Gutierrez JA, Swaminathan RV.

Exposure to radiation can result in deterministic or stochastic effects. Deterministic effects include damage to skin and, in the case of interventional cardiologists, the development of posterior lens opacities, which are precursors to cataracts. Stochastic effects represent damage to DNA, and chromosomal abnormalities, from which cancer can arise. Because of these radiation-risks, interventionalists wear PPE, which has led to a high rate of spinal disc disease among interventional cardiologists.

The CorPath robotic system addresses these occupational hazards by distancing the operating physician from the radiation source. The physician can manipulate intracoronary devices from a console protected by a leaded shield. Of note, the robotic arm at the bedside is located near the patient's left side, which facilitates left radial access.

For patients, robotic-assisted PCI could reduce the frequency of geographic miss. There is great variability in physicians' ability to accurate estimate lesion length, with one study showing that physicians were accurate only 30% of the time. Underestimation can result in incomplete lesion coverage and increased risk for TLR and MI. Overestimation is associated with increased risk for restenosis. CorPath enables physicians to measure anatomy to calculate lesion length and thereby select an appropriately sized stent.

Conclusion

Robotic technology offers benefits to both physicians and patients. As the system adds greater functionality and compatibility, it will be applicable to a broader array of anatomy and clinical scenarios.

Robotic-Assisted Percutaneous Coronary Intervention

Mangels DR, Giri J, Hirshfeld J, Wilensky RL.

Robotic technology is the only radiation-reduction method that distances the primary physician from the radiation source. This is imperative, given the risks associated with chronic exposure to ionizing radiation as well as the increase in radial-access PCI. The latter is associated with a 51% increase in radiation exposure for the operating physician compared to femoral access.

CorPath, the only robotic system that has gained traction for PCI, has been evaluated in several clinical studies. PRECISE (N=164) showed a technical success rate of 98.8% for CorPath-assisted PCI. There have been several case reports of robotic-assisted PCI of more complex cases, including STEMI, left main disease, CTOs, and SVG lesions, among others. The feasibility of telestenting using CorPath was also demonstrated in the REMOTE-PCI study. Robotic-assisted PCI has shorter use of fluoroscopy, but longer overall procedure times, compared to those for manual PCI. Physicians more experienced with robotic-assisted PCI record shorter procedure times than less experienced operators.

Use of CorPath has shown radiation reduction of 95%-97% for the operating physician. In addition, the SHIELD study compared radiation exposure for manual PCI with conventional PPE, manual PCI using a suspended leaded suit, and robotic-assisted PCI combined with a suspended leaded suit at the bedside. Robotic-assisted PCI with a suspended leaded suit had the greatest reduction in radiation exposure: 99.3% lower than that recorded for manual PCI with conventional PPE. Robotic-assisted PCI with a suspended leaded suit had an 80% reduction in radiation dose compared to manual PCI with a suspended leaded suit.

Conclusion

Initial studies of robotic-assisted PCI are promising, particularly with regard to the reduction in radiation exposure for the primary physician. Additional trials comparing robotic-assisted and manual PCI are needed to collect data on outcomes with more complex lesions and in various clinical scenarios, such as ACS. Should robotic technology demonstrate similar outcomes, more Cath Labs are likely to adopt robotic-assisted PCI.

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> Robotic-assisted PCI is a novel approach to PCI that utilizes remote-controlled technology to manipulate catheters thereby significantly reducing radiation exposure to the operator and catherization laboratory staff.
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CATH LAB CHALLENGES

This section presents technical challenges in PCI, such as visual estimation of lesion length. It also discusses the many health risks associated with continued exposure to fluoroscopy. Data from the Healthy Cath Lab Study Group showed alarming hazard ratios for several conditions, including orthopedic problems, cataracts, thyroid disease, and early vascular aging for interventionalists compared to healthcare professionals not routinely exposed to fluoroscopy. In addition, the BRAIN study revealed that the left side of interventionalists' heads receive 4.7x the amount of radiation than the right side. Editorials on the use of robotic technology are also presented.

CLINICAL CHALLENGES

Interoperator and Intraoperator (In) Accuracy of Stent Selection Based on Visual Estimation

Campbell PT, Mahmud E, Marshall JJ.

Catheter Cardiovasc Interv. 2015 Dec 1;86(7):1177-83.

Longitudinal geographic miss (LGM), or incomplete stent coverage of the diseased segment, can lead to restenosis. There are several causes of LGM, including inaccurate lesion length measurement, a corresponding inappropriate stent length, and imprecise stent placement. Interventional cardiologists routinely perform visual assessments of lesion length to inform stent selection. We examined the accuracy of visual assessment and selection of stent length by experienced interventional cardiologists (n=40) compared to quantitative coronary angiography (QCA) values. Optimal coverage was defined as 2-4 mm stent overlap of the distal and proximal edges of the lesion.

The majority of interventional cardiologists (80%) who participated in this prospective study had been in practice for ≥11 years. Participants evaluated 25 orthogonal angiographic

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> This study shows that there is a high degree of variability in the assessment of coronary artery lesion length and corresponding stent length selection by experienced interventional cardiologists…visual estimates of lesion length measurements were frequently too short which led to selection of stent lengths that were suboptimal for adequate lesion coverage…
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images of 20 single de novo lesions with stenosis of >50% to <100%; five images were repeated to evaluate variability between visual assessments.

More than half of visual assessments (51.1%) were short of the QCA measurement, with 29.9% of images underestimated by >4 mm.

Visual assessment was inline with QCA measurement for 29.9% of the images, with the remainder (19.0%) being long, i.e., >+4 mm from QCA value. Selected stents were short of optimal coverage for 55% of the images, and 23.8% of selected stents were shorter than the lesion length. For 22.8% of images, the selected stent was excessively long, i.e., $\geq$8 mm longer than the target lesion.

Comparison of visual assessments and stent selections for the five repeated images showed that there was variability of >3 mm in 38.5% of lesion length assessments and 37.5% of stent selections. In addition, it was found that time of day affected the accuracy of visual assessment, with statistically significant (p=0.033) greater accuracy in the morning (35%) compared to that in the evening (27.0%).

Conclusion

Visual assessment is highly variable and frequently leads to inaccurate estimate of lesion length, which could result in suboptimal stent coverage. Methods that improve accuracy of lesion length assessment should be used to lower the incidence of LGM and enhance patient outcomes.

Impact of Stent Deployment Procedural Factors on Long-Term Effectiveness and Safety of Sirolimus-Eluting Stents (Final Results of the Multicenter Prospective STLLR Trial)

Costa MA, Angiolillo DJ, Tannenbaum M, Driesman M, Chu A, et al.

The prospective, multicenter STLLR trial enrolled 1,557 patients who received sirolimus-eluting stents (SESs) and evaluated need for target vessel revascularization (TVR) in the context of Geographic Miss (GM). More than 90% of patients could be assessed for GM. In these patients (n=1,419), the incidence of GM was high at 66.5%: 47.6% were LGM and 35.2% were axial GM. Both LGM and axial GM was found in 16.5% of patients. There were no significant differences in baseline characteristics between patients with GM and those without GM.

TVR rates at 1 year were doubled in patients with GM at 5.1% compared to 2.5% in patients without GM (P=0.025). LGM was associated with a TVR rate of 6.1% compared to 2.6% for patients who did not have LGM (P=0.001). Analysis showed GM to be independently associated with TVR, with a hazard ratio of 2.0. In addition, individuals with GM had a threefold increase in the incidence of MI at 1 year compared to patients without GM.

Conclusion
GM was a frequent occurrence in STLLR and associated with heightened risk of TVR and MI. Improvement in PCI techniques and practices is needed in order to reduce the incidence of GM.

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> Although the high frequency of GM observed in the present study was alarming, our results provided an opportunity to improve the way we currently perform percutaneous coronary intervention. Of all variables associated with outcomes of patients treated with drug-eluting stents, deployment technique represents 1 of the few modifiable risk factors.
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OCCUPATIONAL HAZARDS

Occupational Health Risks in Cardiac Catheterization Laboratory Workers

Andreassi MG, Piccaluga E, Guagliumi G, Del Greco M, Gaita F, Picano E.

The authors sought to assess the prevalence of health risks associated with working in a cardiac catheterization or electrophysiology (EP) lab and correlate adverse health effects with length of time (years) working with fluoroscopy. Questionnaires were completed by 466 healthcare professionals working in cath or EP labs (218 physicians, 191 nurses, and 57 technicians) and 280 control subjects. The average age in the interventional arm was 44 years old; the median length of time working in a cath or EP lab was 10 years. More than 40% of interventional physicians performed over 200 procedures each year; 31% had an annual caseload of 100-200.

Prevalence of Medical Conditions

	Interventional	Control	P value
Skin lesion	8.6%	2.0%	0.002
Orthopedic problem	30.2%	5.4%	<0.001
Cataract	4.7%	0.7%	0.003
Thyroid Disease	7.5%	3.6%	0.03
Cancer	2.6%	0.7%	0.09
Hyperlipidemia	12.0%	4.0%	<0.001
Hypertension	12.9%	7.5%	0.02

Compared to the control group, the interventional cohort had significantly higher prevalence of many medical conditions, including skin lesions, orthopedic problems, cataracts, thyroid disease, hypertension, and hyperlipidemia. Anxiety or depression was somewhat common, affecting 12.4% of interventionalists compared to 2.1% of control (P<0.001). The prevalence of cancer was nonsignificantly higher in the internventional group than control at 2.6% and 0.7%, respectively. The prevalence of medical conditions increased in tandem with the length of time working with fluoroscopy

(e.g., <5 years, 6-15 years, >16 years). Within the interventional group, there was a significantly higher prevalence of skin lesions and cataracts among physicians compared to nurses or technicians.

Odds ratios (ORs), adjusted for age, gender, and smoking status, showed that interventionalists were 7.1x more likely to have orthopedic problems (P<0.001), 6.3x more likely to develop cataracts (P=0.01), and 3.1x more likely to have hyperlipidemia (P=0.001). Assessing the interventionalists with the highest cumulative exposure to scatter radiation, the ORs for cataract development and cancer were 9.0 and 4.5, respectively, compared to the control group.

Conclusion

Healthcare professionals participating in fluoroscopically guided procedures have a higher risk of developing many adverse health effects related to low-dose ionizing radiation compared to healthcare professionals not exposed to occupational fluoroscopy. Greater awareness of the risks associated with continued exposure to scatter radiation as well as the development of a "culture of safety" is needed to safeguard cath lab healthcare staff.

Occupational Hazards of Interventional Cardiology

Smilowitz NR, Balter S, Weisz G

With technological advancements in catheter-based tools and imaging modalities, interventional cardiologists can perform complex coronary cases that several decades ago would have been unimaginable. However, the fundamental technique—with the physician standing at the procedure table—has not changed dramatically. Complex coronary cases often involve longer procedure times as well as fluoroscopy duration, which represent significant occupational hazards for interventional cardiologists.

Orthopedic and ergonomic hazards

Interventional cardiologists are subject to spinal disc disease and musculoskeletal back pain from cumulative hours of standing with protective aprons, which can exert pressure of up to 300 lbs/square inch on intervertebral disc space. A survey of interventional cardiologists published in 2004 revealed heavy caseloads and a corresponding orthopedic toll. Over 50% of respondents performed >500 procedures/

year, with 87% having a caseload of >300 PCIs annually. Forty-two percent of respondents had spine problems or back pain: 70% of those with back pain had lumbosacral complaints and 40% had cervical disc disease. Over one-third of these physicians reported missing work because of musculoskeletal problems.

Radiation exposure hazards

Chronic radiation exposure can lead to increased micronuclei frequencies in peripheral blood cell division, a sign of chromosomal abnormalities and somatic DNA damage. A case-control study showed that interventional cardiologists had a higher rate of micronuclei frequencies than clinical cardiologists, with the number of years in the cath lab correlated with micronuclei frequency. Although scientific evidence has demonstrated conflicting results, there have been recent case reports of interventionalists developing left hemisphere brain malignancies, adding to work environment safety concerns. Separately, a correlation between radiation exposure and cataract development has been proven. The RELID trial showed a 45% rate of posterior subcapsular lens opacities among interventionalists vs. just 12% for the control group (p<0.0001).

The International Commission on Radiological Protection (ICRP) recommends a threshold dose of 20 mSV per year, averaged over five years, to the eye. However, the amount of radiation exposure that is deemed "safe" is controversial, and some literature suggests that a threshold to avoid lens opacities may not exist.

Conclusion

Advancements in catheter-based tools are enabling more complex procedures that typically have a prolonged duration of fluoroscopy. New adjunctive technologies, such as a remote-controlled robotic system, could significantly lower interventional cardiologists' orthopedic injuries as well as substantially reduce their radiation exposure risk.

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Robotic remote-control angioplasty allows operators to work from a seated position at a shielded workstation and can drastically reduce both orthopedic injuries and radiation risks associated with current practice.

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Occupational Health Hazards of Interventional Cardiologists in the Current Decade: Results of the 2014 SCAI Membership Survey

Klein LW, Tra Y, Garratt K, Powell W, Lopez-Cruz G, Chambers C, Goldstein JA.

Since the previous survey of SCAI members in 2004, PCI patterns have changed. Complex PCI is performed on a routine basis, with both more difficult patients (older) and lesions being treated by PCI. In addition, radial access, which is often associated with longer fluoroscopy times, is increasingly being adopted. Surveys related to certain occupational health risks were sent to current SCAI members. Respondents (n=314) perform an average of 200 interventional and 380 diagnostic cases each year.

Approximately half (49%) of respondents reported orthopedic injury (cervical spine, lumbar spine, or hip/knee/ankle). Injury was correlated with the annual number of cases performed as well as age. After controlling for age, there was a strong association between orthopedic injury and caseload. Of the respondents with an orthopedic problem, 85% had been in practice >5 years. Despite the high incidence of musculoskeletal complaints, <10% of respondents took a health-related absence from work, a decrease from the 2004 survey.

The survey also showed other adverse occupational health effects, including cataracts (5.5%), hematologic diseases and cancer (4.8%), and skin damage (4.8%). The incidence of cancer and other adverse health effects may be underreported, as the survey was sent to current SCAI members and does not capture the health of retired physicians.

Of note, 28.6% of respondents indicated they never wear dosimeters, and 18.5% reported variable use of dosimeters. Underuse may reflect concern for losing lab privileges because of recorded radiation doses. The survey also found that the majority of respondents do not wear radio-protective scrub caps.

Conclusion

Orthopedic injuries are common among SCAI members and are related to age and annual case volume. Although the incidence of cancer was low, it remains concerning and, perhaps, is underreported.

> "The interventional community, including both operators and staff, is dedicated to providing the best quality patient care. However, the inherent risks from fluoroscopic imaging and body-worn shielding require recognition from the health care community, with concerted effort to ameliorate these hazards."

Invasive Cardiologists Are Exposed to Greater Left Sided Cranial Radiation: The BRAIN Study (Brain Radiation Exposure and Attenuation During Invasive Cardiology Procedures)

Reeves RR, Ang L, Bahadorani J, Naghi J, et al.

Following the first reports of head and neck malignancies among interventionalists in 2012, a total of 35 cases have been established, with the majority of malignancies located on the left side. This has heightened concern that brain malignancy is a potential occupational hazard of interventional labs. The BRAIN study quantified the level of radiation to which the cranium is exposed during PCI. Dosimeters were placed in three areas on the outside of a lead-free cap: left (OL), center (OC), and right (OR). Dosimeters were placed outside the cath lab to be a proxy for ambient radiation and represent the control in the study.

The average number of procedures performed by the 11 partipicants over the study period was 66.2. Radiation exposures to the OL (106.1 mrad) and OC (83.1 mrad) were significantly higher than the 50.2 mrad recorded at the OR (p<0.001). Excluding ambient radiation, the exposure to the OL was 4.7x that of the OR. Compared to control, the OL and OC recorded significantly elevated radiation exposure of 177% and 117%, respectively.

Conclusion

While It is difficult to assess the risk of brain malignancy related to radiation exposure, this study showed that the left side and center of the cranium receive significantly higher exposure compared to the right side of head and ambient radiation. Further studies are needed to assess brain malignancy as a potential occupational hazard for interventionalists.

> " …although a direct causal link between operator exposure and the risk of brain cancer may be impossible to establish….this study adds to the theoretical validity that long-term, low-dose exposure from cardiovascular catheterization procedures increases the risk of the development of left-sided brain malignancy. "

Subclinical Carotid Atherosclerosis and Early Vascular Aging from Long-Term Low-Dose Ionizing Radiation Exposure: A Genetic, Telomere, and Vascular Ultrasound Study in Cardiac Catheterization Laboratory Staff

Grazia Andreassi M, Piccaluga E, Gargani L, Sabatino L, et al.

Excess cardiovascular (CV) risk is a possible consequence of chronic exposure to low-dose ionizing radiation. This study used carotid intima-media thickness (CIMT) and leukocyte telomere length (LTL) to assess the presence of subclinical carotid atherosclerosis and evidence suggesting premature vascular aging among interventional staff (n=223) exposed to ionizing radiation compared to unexposed individuals (n=222). Both cohorts were young, with an average age of 45 in the interventional arm and 44 in the control group.

An occupational radiological risk score (ORRS) was calculated based on years in the cath lab, annual number of cases, and worker distance from radiation source (i.e., physician versus nurse). The average number of years of occupational radiation exposure was 12.2 among interventional staff.

CIMT was significantly higher for high-volume interventional staff (n=91) compared to low-volume interventional staff (n=80). There was a significant correlation between left-sided CIMT and ORRS (p=0.001). For a subset of interventional staff who had recorded lifetime effective doses (n=57), there was a significant effect on left-sided CIMT (p=0.006).

The median LTL was significantly shortened in the interventional group compared with control. Analysis showed LTL shortening was correlated with high ORRS. Using linear regression analysis, two variables were found to have a significant impact on LTL: radiation exposure (p=0.03) and age (p=0.003).

Conclusion
Both CIMT and LTL had significant associations with ORRS. Subclinical atherosclerosis and premature vascular aging may be associated with chronic exposure to ionizing radiation.

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> ...a significant association with increasing dose was found only on the left side, but not the right, providing further support for a causal connection between occupational radiation exposure and early signs of subclinical atherosclerosis.... Additionally, shorter LTL has been demonstrated to predict cardiovascular disease and mortality.
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Radiation-Associated Lens Opacities in Catheterization Personnel: Results of a Survey and Direct Assessments

Vano E, Kleiman NJ, Duran A, Romano-Miller M, Rehani MM.

Reports of lens opacities among interventional cardiologists and radiologists began to be published in 2010. In 2011, the International Commission on Radiological Protection (ICRP) lowered its threshold for annual radiation dose exposure to the eye from 150 mSv to 20 mSv owing to demonstrated tissue effects.

As part of the ongoing RELID study, 127 participants (58 physicians, 69 nurses/technicians) received ocular examinations at the SOLACI interventional cardiology meeting in Buenos Aires, Argentina. Interventional physicians and staff completed a survey of 90 questions related to years in the cath lab, annual case load, average fluoroscopy time, etc. The control group was comprised of age-matched, unexposed, nonmedical individuals.

Half of the interventional cardiologists and 41% of nurses/technicians had evidence of posterior subcapsular lens changes compared to <10% of the control group. The estimated cumulative eye dose averaged 8.3 Gy for physicians who had a lens opacity compared to 3.0 Gy for physicians without a lens opacity. A smaller percentage of physicians with a lens opacity routinely used protective eyewear compared to physicians who did not have a lens opacity at 46% and 59%, respectively. There was a correlation between the severity of opacity and cumulative career radiation exposure for physicians. Nurses and technicians with a lens opacity had less severity than physicians.

Conclusion

There is a high incidence of posterior subcapsular lens changes among interventional cardiologists, indicating an urgent need for radiation safety education, use of personal dosimetry, and protection tools.

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> Lens radiation injuries can be easily avoided by the appropriate use of radiation protection tools, and such tools would further ensure the safety of individuals working in catheterization laboratories.
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EDITORIALS

Robotically Assisted Percutaneous Coronary Intervention: Benefits to the Patient and the Cardiologist

Hasan F, Bonatti J.

Innovation has enabled the percutaneous treatment of ever-growing complex coronary lesions and other indications, such as PAD and structural heart disease. However, the health of pioneers in interventional cardiology has been negatively impacted by proximity to fluoroscopy and wearing heavy protective aprons and other PPE. This has created a high-risk work environment for interventional cardiologists. The risks are likely to increase, given the growing complexity of PCI and longer procedure times. As a result, the fundamental way that PCI is performed—with the primary physician at the bedside—needs to change.

Despite monitoring dosimeters, there is no threshold that can be considered "safe". DNA damage is significantly higher for interventional cardiologists compared to clinical cardiologists. While lead aprons are routinely worn by interventionalists, the head, neck, and hands are often exposed to scatter radiation. In addition, leaded PPE can exert pressure of 300 lbs/square inch on vertebrae, which leads to orthopedic injury. Nearly 60% of interventional physicians with >20 years of experience have spinal disc disease.

The CorPath 200 robotic system distances the operating physician from the bedside. The primary physician sits at a radiation-shielded, mobile interventional cockpit and moves controls and joysticks to manipulate intracoronary devices that are loaded into the single-use cassette on the bedrail-mounted robotic arm. The robot can be quickly and easily disabled if necessary.

CorPath is engineered to be complementary to interventional cardiology techniques and training. While the learning curve for simple lesions is low at three to five cases, 15-20 cases are needed to become proficient with using CorPath to assist with more complex cases. Of note, the value of CorPath is likely to increase for long and/or complex cases, during which the operating physician is subject to prolonged standing and higher radiation exposure if performing manual PCI. The PRECISE clinical trial demonstrated that the physician at CorPath's

> " Robotics has the potential of converting the current 'high-risk' catherization laboratory into a safe, physician- and patient-friendly environment. "

interventional cockpit had significantly lower radiation exposure (95%) than that recorded at the bedside.

Robotic technology may also benefit patients and outcomes. Studies have shown that a physician's visual estimate of lesion length is often incorrect, which can lead to inappropriate stent sizing. Geographic miss, which can occur when stent sizing is inaccurate, is associated with higher rates of revascularization and MI. CorPath can measure anatomy to determine lesion length, and devices can be advanced by 1 mm increments to precisely position a stent. Other potential benefits include lower radiation exposure for the patient and decreased risk for contrast-induced nephropathy, resulting from less operator fatigue and better technical procedural efficiency that may translate to reduced used of fluoroscopy and contrast injections.

Conclusion

Robotic technology could become the new standard of care in PCI if the technology can demonstrate the ability to integrate seamlessly into the treatment of more complex lesions, such as ostial, bifurcated, and CTOs.

Robotic Percutaneous Coronary Intervention: Time to Focus on the Patient

Bezerra HG, Simon DI.

There over more than 2 million PCIs performed worldwide each year. Advancements in tools, such as FFR and OCT, as well as in antithrombotic therapy have led to high procedural and clinical success of >95%; complication rates are very low.

Robotic technology reduces the radiation exposure for operating physicians and enhances precision of catheters. The PRECISE clinical trial demonstrated the feasibility of using the CorPath robotic system to assist in PCI of simple lesions. More recently, the CORA-PCI "all comers" trial showed CorPath to be effective in treating complex lesions (78.3% of lesions in the robotic arm were type B2/C). The technical success rate was 91.7% in the robotic group, with 11.1% of cases requiring manual assistance and 7.4% of cases needing manual conversion. The CORA-PCI trial used the first-generation system, CorPath 200. The second-generation system, CorPath GRX, will likely reduce the need for manual

assistance or conversion because of added functionality related to guide catheter support.

A downstream effect of the CorPath robotic system is increased awareness of occupational radiation exposure in the Cath Lab. There are many ways that interventional staff can lower radiation-related risk through the use of filters, using pulsatile fluoroscopy, not acquiring cine images, and avoiding magnification, among others. Improvements in PPE may reduce orthopedic strain for healthcare providers.

Thus far, robotic technology for PCI has primarily focused on reducing occupational hazards for operating physicians. It needs to transition to a focus on benefits for the patient. This will require the ability to integrate other interventional tools, such as FFR and atherectomy devices, with the robot. Since CorPath enables precision catheter positioning and lesion measurement, it's possible that it could reduce the frequency of geographic miss, which would have a beneficial impact on patient outcomes.

> We believe that to harness the true potential of robotic PCI, our focus needs to move from the operator to the patient.

Don't Hang Up Your Lead, Yet

Smilowitz NR, Weisz G.

Cardiovasc Revasc Med. 2018;19(5 Pt A):477-479.

Robotic technology is a major advancement for interventional cardiology. Clinical studies have shown robotic-assisted PCI to have high technical and clinical success rates in simple and complex lesions. While the majority of procedures can be performed from the CorPath interventional console, some types of PCI and anatomy require manual assistance or conversion to manual PCI.

An analysis of 108 robotic-assisted procedures performed at one center examined the causes of manual assistance or conversion. Of the 20 cases (18.5% of total) that involved manual assistance or conversion, 11.1% had planned or unplanned manual assistance and 7.4% had conversion to manual PCI. Need for additional support or manipulation of guidewire or guide catheter was the reason for manual assistance or conversion in nine cases. Technique (such as kissing balloons) or additional intracoronary device (embolic protection and intravascular imaging) was the reason for manual assistance or conversion in eight cases. Adverse events requiring manual assistance or conversion was rare at three cases.

> The current second generation robotic PCI system (CorPath GRX) addresses the issue of guide catheter manipulation and is an important step toward more complete robotic PCI.

Although 20% of cases could not be completed robotically, operating physicians had the benefits of reduced exposure to scatter radiation and less time wearing PPE while standing at the bedside. Patients received the benefit of precision afforded by robotic-assisted PCI.

About half of the procedures with manual involvement stemmed from the inability of CorPath 200 to manipulate the guide catheter or guidewire. As a result, the availability of the CorPath GRX could minimize the frequency of manual assistance. However, certain devices, such as orbital and rotational atherectomy devices, embolic protection devices, and intravascular imaging, cannot be used with CorPath GRX or require some manual assistance. Future iterations of the CorPath robotic system may offer greater functionality with regard to devices used in complex procedures.

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