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

Corindus Vascular Robotics is dedicated to advancing robotic-assisted PCI through the publication of clinical data supporting the value and applicability of the CorPath® 200 System. CorPath enables controlled manipulation and placement of guidewires and rapid exchange catheters, ability to measure anatomy, and enhanced visualization of imaging monitors. Seated at the radiation-shielded Interventional Cockpit, the operator can control the interventional procedure and focus on clinical decisions without wearing lead.

Scientific evidence is accumulating on the value and applicability of CorPath in interventional procedures. Since 2013, more than 20 peer-reviewed publications and abstracts have been published on CorPath. Early publications focused on results from the safety and feasibility study of CorPath in PCI (PRECISE), learning curve, and benefits to the operator.

Recent contributions to the clinical evidence include CorPath's potential role in lowering adverse event rates and revascularization procedures. Data suggest CorPath's measurement tool could reduce the incidence of geographic miss and overstenting. In addition, data from CorPath's PRECISION Multicenter Registry compare lesion and procedural characteristics of femoral versus radial access in the real-world setting.

CorPath has shown additional value and applicability for complex and radial PCI procedures by enabling robotic precision and protecting physicians from the added radiation exposure and time in lead. Finally, CorPath is being evaluated in new areas, such as peripheral vascular interventions (PVIs).

NEED FOR ROBOTICS IN THE CATH LAB

This section highlights recent evidence that demonstrates the need to improve technical aspects of catheter-based interventions and reduce occupational hazards. CorPath provides precise measurement of anatomy, augments stability of intra-luminal and intra-cardiac devices, and enables controlled catheter manipulation. CorPath allows operators to perform procedures while seated at a shielded interventional cockpit, thereby minimizing exposure to scatter radiation and relieving pressure on the musculoskeletal system.

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

Campbell PT, Mahmud E, Marshall JJ,

Catheter Cardiovasc Interv. 2014;Dec 15. doi: 10.1002/ccd.25780

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 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., >8 mm longer than the target lesion.

> " 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…"

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.

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.

JACC Cardiovasc Interv. 2015;8:1197-206.

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.

> " ...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. "

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.

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.

JACC Cardiovasc Interv. 2015;8:616-27.

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).

> “ …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. ”

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.

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.

J Vasc Interv Radiol. 2013;24:197-204

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.

> " 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. "

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.

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.

Catheter Cardiovasc Interv. 2015;00:00-00.

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. "

INSIGHTS FROM CLINICAL TRIALS AND USE

This section highlights scientific publications related to the occupational hazards of today's cath lab practice and the benefits that robotic-assisted PCI can bring to both operators and patients by reducing radiation exposure, increasing operator comfort, and enabling precise anatomy measurement and stent positioning.

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.

TCT conference, October 13, 2015; San Francisco, CA

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.

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 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.

J Am Coll Cardiol, 2015; 65(10_S).

The use of transradial access (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 transfemoral arterial access (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.

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, Reisman M, Waksman R, Granada JF, Novack V, Moses JW, Carrozza JP.

J Am Coll Cardiol, 2013;61:1596-600

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 (MI). 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 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.

> " Incorporating a remote-controlled, robotic-assisted PCI system into the catheterization laboratory addresses some of the occupational hazards associated with PCI, without affecting procedural performance and patient safety. "

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.

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, Vetrovec G, Reisman M, Waksman R, Pichard A, Granada JF, Moses JW, Carrozza JP.

Acute Cardiac Care Journal, 2014;16:37-40

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 CorPath 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.

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

Conclusion

Robotic PCI has a short learning curve of only three cases. Experience leads to shorter procedure and fluoroscopy times.

Robotic-Enhanced PCI Compared to the Traditional Manual Approach

Smilowitz NR, Moses JW, Sosa FA, Lerman B, Qureshi Y, Dalton KE, Privitera LT, Canone-Weber D, Singh V, Leon MB, Weisz G.

Journal of Invasive Cardiology, 2014;26:318-321

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.

Complex Robotic-Enhanced Percutaneous Coronary Intervention

Kapur V, Smilowitz NR, Weisz G.

Catheter and Cardiovascular Interventions, 2014;83:915-21

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).

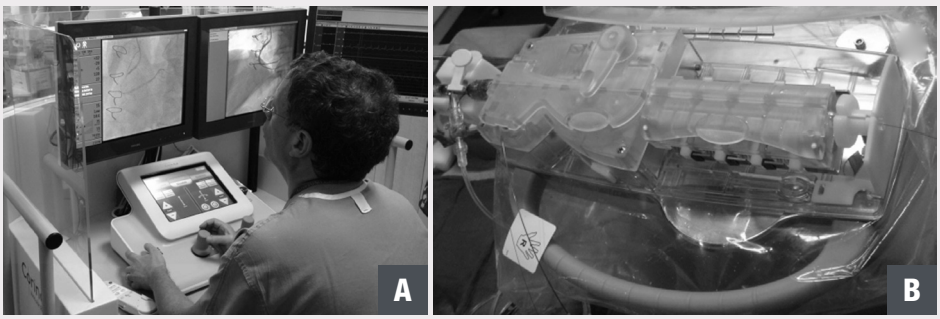
All cases were completed with the CorPath Robotic System. Commercially available guidewires, rapid exchange balloons, and stents were used. Guidewire manipulation at the interventional cockpit was intuitive, and lesion crossings were successful even in the case of the acute STEMI patient who had a thrombotic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

> " 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. "

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



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.

RAPID (Robotic-Assisted Peripheral Intervention for Peripheral Arterial Disease) Study

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

TCT conference, October 13, 2015; San Francisco, CA

Peripheral vascular interventions (PVIs) have been largely unchanged over the last 30 years. Use of robots to assist PCI has been well studied. RAPID is the first trial to evaluate the feasibility of using a robotic system in PVIs in the superficial femoral artery (SFA). This prospective, single-center study enrolled 20 patients with stenosis of >50% in the SFA, 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 successful cannulation of the target vessel using the CorPath 200 Robotic System and incidence of procedural 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. There were no device-related adverse events. After intervention, the average stenosis was 7.2%, equating to 100% clinical success. Time on CorPath averaged 23.4 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.

Lesion Characteristics and Procedure Outcomes	Mean + SD (N) (Min, Median, Max) Or # (%)
Lesion Characteristics	**N=29**
Lesions Treated	
Superficial Femoral	89.7%
Popliteal	10.3%
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
CorPath Technical Success	100%
CorPath Clinical Procedural Success	100%

*This information concerns a use that has not been cleared by the FDA. The CorPath 200 System has not been evaluated in Peripheral Vascular Interventions by the FDA. Corindus Vascular Robotics, Inc. sponsored the RAPID Trial.

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

JACC Cardiovascular Interventions, 2011;4:460-5

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. "

CorPath 200 System

A) Control console: 1–Touch screen controls, 2–Guidewire joystick, and 3–Balloon stent joystick.

B) Operator seated in interventional cockpit. Angiographic and hemodynamic monitors are positioned at eye level.

C) A guidewire was deployed. Then the robotic arm advanced a 2.5 X 9mm balloon through a proximal posterior descending artery for pre-dilation. The robotic system then delivered a 2.5 X 16mm stent to the target lesion.

BENEFITS OF ROBOTIC-ASSISTED PCI

This section highlights scientific publications related to the occupational hazards of today's cath lab practice and the benefits that robotic-assisted PCI can bring to both operators and patients by reducing radiation exposure, increasing operator comfort, and enabling precise anatomy measurement and stent positioning.

Occupational Hazards of Interventional Cardiology

Smilowitz NR, Balter S, Weisz G

Cardiovascular Revascularization Medicine, 2013;14:223-8

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

> " 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. "

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.

Robotic-Assisted Percutaneous Coronary Intervention—Filling an Unmet Need

Carrozza JP

Journal of Cardiovascular Translational Research, 2012;5:62-6

Despite the quantum leaps in the utility and performance of intravascular coronary devices, the typical procedure has changed very little since 1997. Interventional cardiologists face two major health risks during each procedure—exposure to ionizing radiation and on-going stress to the musculoskeletal system—making the cath lab a high-risk work environment. A remote navigation system was proposed in 2005 to address these health risks. A modified system, the CorPath 200 Robotic System, had promising first-in-human results: a technical success rate of 97.9% and radiation exposure reduction of 97% for the operator at the control console. There could also be benefits to patients via CorPath's precise measurement of lesion length and stent placement as well as reduced patient exposure to radiation and contrast media.

> " Also, by improving the ergonomics and comfort of the procedure, a more relaxed and efficient operator may be less likely to commit errors resulting from fatigue, musculoskeletal pain, and eye strain. "

Robotic-Assisted Angioplasty: Current Status and Future Possibilities

Smilowitz NR, Weisz G

Current Cardiology Reports, 2012;14:642-6

The development of a remote-controlled robotic system for PCI heralds a new era in interventional cardiology. With complex coronary cases, interventionalists are often exposed to long periods of fluoroscopy. The early remote navigation system conceived by Beyer et al has been further developed and is now available as the CorPath 200 System, which significantly reduces the radiation exposure to the operator. Intravascular devices are connected to a sterile cassette embedded in the robotic articulating arm, which is mounted on the bedside. Data shown on monitors at the procedure table are slaved to monitors in the radiation-shielded cockpit. Joysticks on the control console permit the operator to manipulate guidewires and other intravascular devices (e.g., balloons and stents) in 1mm increments. A locking mechanism, which can differentiate between guidewires and other devices, provides stability and averts "telescopic slippage". The amount of contrast media can also be controlled from the cockpit.

Proposed Benefit to Patients

In the STLLR study, stent misplacement, or geographic miss, occurred in 66.5% of patients. This was associated with a three-fold increase in MI and high target lesion revascularization rates. Robotic systems with precise measurement, controlled advancement of intracoronary devices, and guidewire stabilization could prevent geographic miss. Robotic PCI could also augment accuracy of anatomy measurement, perhaps leading to shorter stent lengths and, thus, reduced incidence of stent thrombosis and restenosis. Patients could also benefit from reduced radiation exposure, which averages 7 mSv for conventional angiography and can increase five-fold for complex procedures. Patient risk of contrast-induced nephrotoxicity could also be reduced.

Future Directions

Real-time three-dimensional coordinates of intravascular devices could be incorporated into current systems, and robotics could also be used in peripheral vascular procedures.

> " Robotic technologies reduce operator exposure to ionizing radiation and decrease occupational hazards. . . . These systems may substantially improve standardization, precision, safety, and success of PCI. "

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

Cardiovascular Revasc Med. 2015;pii:S1553-8389

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.

Stent length selection based on visual assessment made by interventional cardiologists were compared to robotic measurement performed using the CorPath 200 Robotic PCI 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

Transcatheter Cardiovascular Therapeutics (TCT) conference, October 13, 2015; San Francisco, CA

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.

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Precision Vascular Robotics

Corindus Vascular Robotics is dedicated to continually advancing robotic-assisted PCI through the publication of clinical data supporting the value and applicability.

CorPath 200 Robotic-assisted PCI System is intended for use in the remote delivery and manipulation of coronary guidewires and balloon/stent catheters during PCI procedures.

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