A 73-year-old white female, a retired nurse, presented to her primary physician with a 3-day history of dull back pain. Initially, the pain lasted 4 hours and radiated to her neck, with associated nausea, sweats and shortness of breath. The angina subsided, but returned and was intermittent until the day of admission.

This woman’s past medical history was remarkable for diabetes mellitus type 2, hypertension, and hyperlipidemia. Additional coronary risk factors included ongoing tobacco use, a family history of carotid disease in her father, and coronary bypass surgery in her mother.

Her medications included atorvastatin 40 mg daily, metformin hydrochloride 2000 mg daily, lisinopril 10 mg daily, metoprolol succinate 12.5 mg twice daily, aspirin (ASA) 81 mg daily, vitamin D 50,000 units weekly, glimepiride 2 mg daily, and nitrofurantoin 1 capsule twice daily.

Her primary physician obtained an electrocardiogram which showed an anterior Q-wave infarct. There was ST elevation from V1 to V6 and in lead 1. She was promptly transferred to the emergency room. On presentation, she had 3/10 chest pain but appeared comfortable. Her heart rate was 95 beats per minute, and blood pressure was 137/87 mmHg.

Laboratory studies showed creatinine of 0.95 mg/dL. Troponin I ES was 4.307 ug/L and hemoglobin A1C was 10%. Limited bedside echocardiogram showed a dense anterior infarct, with akinesis of the distal three-quarters of the anterior wall, apex and infero-apical wall, and reduced ejection fraction (35%). She received 180 mg of ticagrelor, 324 mg of ASA, 70 U/kg of heparin IV, and was emergently taken to the cardiac catheterization laboratory (cath lab).

A 6 Fr JR-4 diagnostic catheter was used to engage the right coronary artery. This was a dominant artery with a moderate (60-70%) stenosis in the mid segment.
Heparin was administered to achieve a goal activated clotting time (ACT) >250 sec. A Cougar wire (Medtronic) was advanced across the mid LAD occlusion and positioned in the distal LAD. A second Cougar wire was advanced into the D2. A 2.5x15 mm compliant balloon was used to cross the occluded segment and pre-dilate the mid LAD. The CorPath Robotic System was used to measure the diseased segment by performing a pull-back of the balloon. This segment measured 29 mm. A 2.75x32 mm Promus Premier drug-eluting stent (Boston Scientific) was successfully deployed across the mid LAD lesion with inflation to 12 atmospheres, and the D2 wire was withdrawn. Robotically, we re-wired the D2 through the LAD stent struts, using a BMW wire (Abbott Vascular). With this safety wire in the D2, the LAD stent was post-dilated to high pressures with a 3.0x15 mm noncompliant balloon. Due to plaque shift, the ostial D2 now had a 95% stenosis (Figure 3). We then dilated the D2 using a 1.5x15 mm compliant balloon. In order to perform simultaneous kissing balloon dilation in the LAD and D2, the balloons were sequentially advanced with the robotic system, with the D2 balloon first, and then the LAD balloon. Kissing balloon inflation was performed with a 2.0x12 mm compliant balloon across the ostial D2 and a 3.0x12 mm NC balloon in the LAD.

By alternating the main branch and side branch wires in the drive and parking tracks of the robot cassette we were able to perform this complex bifurcation PCI entirely using the CorPath System. Final angiography showed an excellent result with a residual stenosis of 0% in the mid LAD and 40% in the ostium of the D2 with TIMI 3 flow (Figure 4). There were no complications. Fluoroscopy time was 20.5 minutes, and a total of 230 mL iopamidol contrast was used for the procedure. The door-to-balloon time was 67 minutes. Dual antiplatelet therapy (ticagrelor and ASA) was to be continued for at least 12 months with lifelong ASA.

Discussion

The effects of procedures performed in the cath lab are typically measured in terms of a risk/benefit ratio to the patient, compared to more invasive surgical procedures or medical therapy. Recently, more attention is being given to the effects of procedure-related ionizing (low-dose) radiation and mechanical strain on the medical professionals who perform these procedures along with continued concerns regarding procedural costs and accuracy. In 1990, the National Council on Radiation Protection (NRC) published the “as low as reasonably achievable” (ALARA) principle governing radiation exposure while performing medical procedures. Multiple measures have been initiated to implement ALARA including use of dose optimization and increased radiation shielding. However, studies have shown that these fail to offer sufficient protection to medical professionals who regularly perform these procedures and who are exposed to radiation levels that are up to ten times higher than those experienced by medical personnel in non-interventional specialties. This exposure to recurrent low-dose ionizing radiation has no “safe level,” and can lead to stochastic health effects which are chronic and tend to become apparent many years after the exposure. These effects include cancer, damage to reproductive organs, teratogenic effects, genetic mutations, premature cataract, and thyroid disease. The occurrence of these effects correlate with operator proximity to the radiation source.

Based on the results of the PRECISE study, a single-arm, multicenter, open-label, nonrandomized study evaluating the safety and efficacy of robotic percutaneous coronary intervention (PCI), Corindus Vascular Robotics received FDA 510(k) clearance for the CorPath System. The goal of the CorPath System is to address some of these aforementioned occupational hazards associated with traditional manual PCI and to improve precision of PCI.

Reduction in radiation exposure. It is known that maximizing distance of operator from the X-ray source and the patient reduces radiation to the operator. PRECISE found that the median radiation exposure to the operators at the interventional cockpit was 95.2% lower than at the procedure table (0.98 vs. 20.6 Gy, \(P=0.0001\)). Further, this improved protection to the operator was not associated with increased radiation or contrast exposure to the patient. The study authors reported a mean fluoroscopy time of 11.1±6.2 min. The mean patient cumulative radiation dose was 1.5±0.8 Gy, and the mean contrast media volume used was 144.2±70.4 ml, all comparable to findings in other studies using traditional PCI. In our patient, who presented with a subacute infarct, the door-to-balloon time was 67 minutes, indicating that this system can be safely and efficiently used in the setting of an acute ST-elevation myocardial infarction (STEMI).
Reduction in mechanical strain. Musculoskeletal problems, including orthopedic and spinal injury are commonly noted among interventionalists. One report noted prevalence of musculoskeletal problems of up to 85% among those who had been in practice for at least five years. Factors contributing to these problems include the weight of the lead aprons and the need to hold uncomfortable postures for extended periods in order to view images around protective lead shields. The use of the robotic system where the interventionalist comfortably sits in the shielded interventional cockpit, while performing PCI, could be beneficial in the long term, possibly leading to fewer musculoskeletal problems.

Precision of anatomic measurement. The STLLR trial evaluated the frequency and impact of suboptimal PCI on long-term outcomes. The procedures were scrutinized by an independent core laboratory to determine the occurrence of geographic miss, which included both longitudinal and axial mismatch. They found that longitudinal geographic miss occurred in 47.6% of procedures evaluated and was associated with increased risk of target vessel revascularization (two-fold) and myocardial infarction (three-fold) at 1 year. Pre-dilation balloons are often used to estimate the length and diameter of stents, but these estimates are subjective and may be inaccurate. Visual estimates of lesion length have been reported to be inaccurate in up to 51% of cases. The CorPath System can be used to measure lesion length while pulling back a wire or balloon. This can potentially reduce costs by initial selection of a single stent of proper length (rather than two or more inappropriately short stents) and improve outcomes by reducing longitudinal geographic miss.

Procedure success. In the PRECISE trial, among 164 patients treated by 23 operators, there were no system-related complications and no major clinical events. One criticism of the PRECISE study was that lesions treated in the study were largely type A (simple), and required only single vessel angioplasty. Bifurcation lesions and total occlusions were excluded. Our patient had a sub-acute total occlusion and also required bifurcation PCI. With relative ease, using the CorPath System, we were able to advance a regular workhorse wire (BMW) through side cells of the stent to rescue a “jailed” side branch with a 95% ostial stenosis. We were also able to pass a balloon into the side branch without the need to provide extra guide support. Another concern that operators may have is the lack of tactile feedback; the PRECISE trial suggests that the absence of this tactile feedback does not increase procedure-related complications.

Economics. No trial has investigated the cost-benefit ratio of use of this equipment. However, the potential improvement in patient outcomes may contribute to long-term cost savings.

This case presentation suggests that complex robotic bifurcation PCI with final kissing balloon angioplasty can be accomplished with similar efficacy and risk to the patient compared with standard PCI techniques. Our total fluoroscopic time of 20.5 minutes and 230 ml contrast is comparable to results from the Nordic I and
the Nordic-Baltic III side branch study arm where they reported mean fluoroscopy times of 21 and 16 minutes and contrast doses of 283 and 235 ml respectively.\textsuperscript{21,22} With operator radiation doses dropping as a function of the square of the distance from the camera, this suggests robotic PCI has no additional “costs” to the patient with respect to radiation and contrast use while affording a benefit to the operator. Additional studies will be required to determine if this cost/benefit can be maintained.

**Summary**

Any practice that reduces mechanical strain and fatigue along with radiation exposure and its associated risks to the cath lab operator should be adopted; especially if it is not detrimental to the performance of the procedure or the safety of the patient. The use of robotic-assisted PCI systems will help address some of the long-term occupational hazards associated with working in the cath lab. We have presented a case of a subacute thrombotic total mid LAD occlusion, requiring bifurcation PCI with side branch balloon dilation through stent struts, successfully performed using the CorPath robotic system. It remains to be seen how the CorPath system performs in more complex PCI procedures, as well as the potential economic implications of using the system.

**References**


