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ROBOTIC PCI: FUTURE OF CORONARY INTERVENTION?

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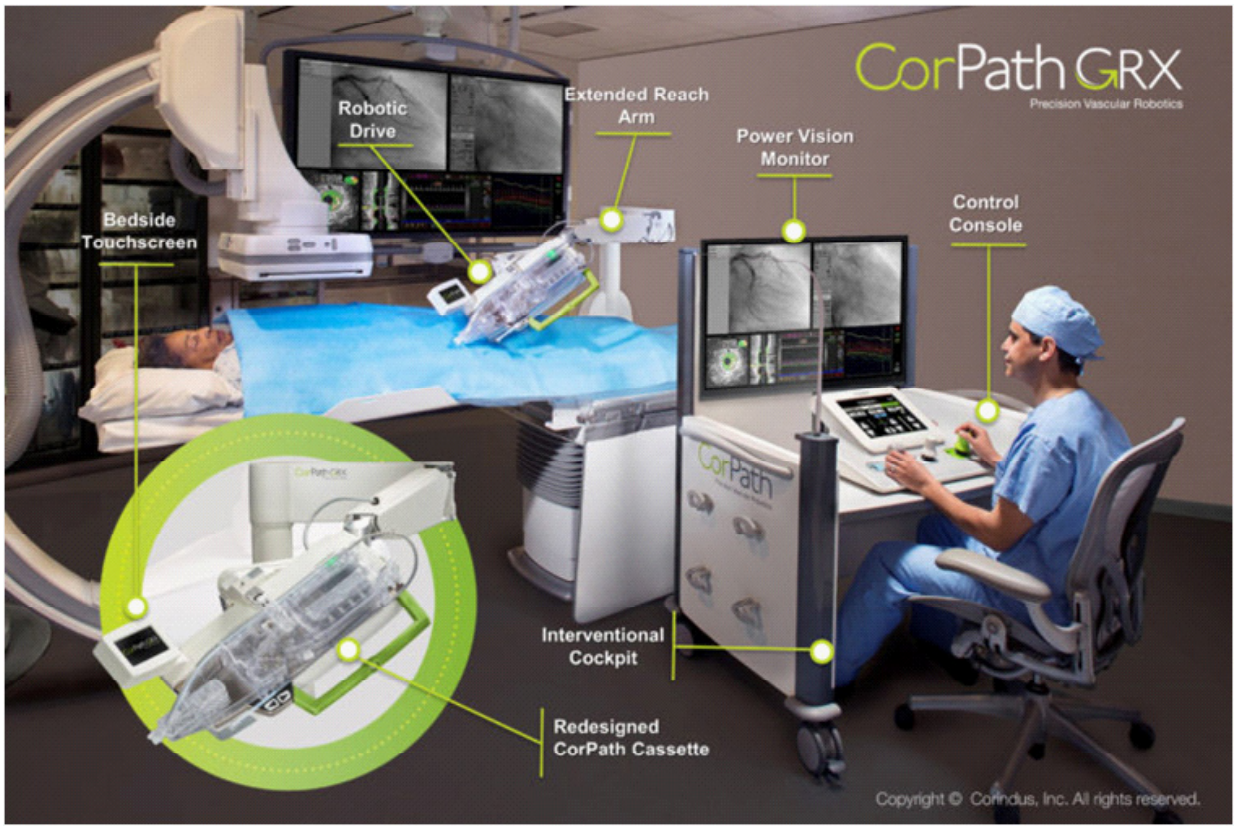
INTRODUCTION:

Interventional cardiology has come a long way since the first plain balloon angioplasty was performed in 70s. The initial results of balloon angioplasty were very encouraging but the subsequent recoil of vessels resulting in restenosis resulted in development of stents. Initially bare metal stents were developed which had high incidence of restenosis due to neo intimal proliferation. To overcome this problem cytotoxic drug coated stents were developed called drug eluting stents (DES). First generation DES were coated with sirolimus and paclitaxel. Subsequent 2nd generation stents are coated with everolimus and zotarolimus. While the intervention equipment and techniques have refined a lot over the years, one hazard is still there of radiation exposure. And since PCIs are being performed increasingly every year, it means incremental exposure of operator to these hazardous radiations. The interventionalist has to wear heavy leaded protective equipment to ward off these radiations, which can also lead to orthopedic injuries.[1] To overcome this occupational hazard, robotically assisted intervention was developed by Beyar and colleagues in 2006. This platform laid foundation of the Corindus CorPath® 200. (Corindus Vascular Robotics) the first true robotically assisted mechanism of delivering guide wires and devices into coronaries while operator sits safely in a shielded cockpit, away from hazardous radiations. Diagnostic angiogram is performed in the conventional way then PCI can be performed while sitting in the cockpit using a joy stick to maneuver the guide wire. CorPath GRX (Corindus Vascular Robotics) is the improved and latest version. It allows guide catheter manipulation and has built in rotate and retract algorithms for wiring. It comprises of two subunits: a bed side robotic arm, drive and a cassette on which devices are mounted for delivery. Other unit is a shielded cockpit where operator sits and it can be installed in the same room or in a separate room.



Another competitor has emerged on the market. The R-One robotic system. It is the first European robotic system developed by Robocath to have attained CE mark for intervention in cardiology in 2019.

BENEFITS:

Not only does R-PCI provide some safety benefits and better ergonomics to the primary operator but it also has some potential advantages for the patients. It is a well-known fact that interventional cardiologists are exposed to cumulative doses of radiations over the years. On average primary operator is exposed to 2 to 10 times the dose of radiation as compared to a diagnostic radiologist. The hands and the head are less protected parts of the operator and are more exposed to radiation scatter. It is theorized that these cumulative radiation dosage increases the risk of certain health issues in the operators. Although never proven to have an actual causative link between prolonged low dose radiation exposure and development of malignancies, it has been inferred from the study of Japanese atomic bomb survivors. A carrier spanning 30yrs would result in exposure to approx. 50 to 200mSv and an increased cancer risk of 1 in 100.[2] BRAIN study showed that left side of cranium, is more exposed to radiations than right side and hence more tumor of left side. This observation was also made in study by Roguin and colleagues who collected data on 31 physicians, most of which were interventional cardiologists and 85% had left sided tomors.[3] Apart from brain tumors, increased risk of melanoma, breast tumors, lens opacites and accelerated subclinical atherosclerosis has also been liked to radiation exposure. The main benefit of R-PCI to operator seems to be rendered by shielding them from these adverse effects of radiation. PRECISE study showed that R-PCI offers a reduction in radiation exposure by 95.2% to the operator[4]. 164 patients were treated by 23 operator who didn't wear lead aprons and performed the procedure sitting in shielded cockpit thereby also reducing some orthopedic hazards.

R-PCI also provides interventional cardiologist with better ergonomics. With continual advancements in intervention equipment and techniques, more and more complex lesions are being addressed percutaneously, meaning longer procedures that not only increase radiation exposure time but also operators have to wear heavy lead gowns for longer periods. A survey by society for cardiovascular angiography and interventions members showed 50% operators had at least 1 orthopedic problem mostly linked with cervical and lumbar spine and incidence paralleled case load and increasing operator age.[5]

Now let's see if R-PCI offers any benefits to the patients too. Target vessel revascularization remains a complication of PCI that is still a thorn in the interventional cardiologist's side. Many risk factors are at play here, geographical miss being one of them. During PCI most operators assess the stent size and diameter based in visual assessment. It has been proved in different registries that this method isn't very accurate. Just to give you an idea, a recent study of 40 operators showed an underestimation of lesion length by 51% and overestimation by 19% by visual assessment only.[6] R-PCI helps in accurate assessment of lesion length. A balloon Is advanced beyond the distal part of lesion. Marker Is labeled on screen and then balloon is withdrawn to proximal end of lesion. The length is measured with software. It can do submillimeter measurements. Hence the observer bias seen especially in tortuous or curved vessels is mitigated. The incidence of longitudinal geographic miss was assessed by Bezerra et al in a retrospective analysis which showed incidence of LGM to be 43.1% in M-PCI versus 2.2% in

Table 1: Robotic-assisted Percutaneous Coronary Intervention Trial Data

	Granada et al. 2011[6]	Weisz et al. 2013[4]	Mahmud et al. 2017[23]	Madder et al. 2017[28]
Study design	Prospective, single-arm, single-centre, non-randomised study	Prospective, single-arm, multicentre, non-randomised study	Prospective, single-arm, single-centre, comparative study	Prospective, single-arm, single-centre, non-randomised study
Study size (n)	8	164	108	20
Number of lesions	8	164	157	22
Technical success (%)	97.9	98.8	91.7	86.4
Type B2/C lesions, n (%)	0	52 (32)	122 (78)	11 (50)
Lesion length (mm), mean ± SD	11.4 ± 6.1	12.2 ± 4.8	22.2 ± 10.6	–
In-hospital MACE	0	4 (4.2)	6 (5.6)	0
Operator radiation reduction (%)	97	95.2	–	–

MACE = major adverse cardiac events.

R-PCI[7]. Hence the accurate assessment not only results in full coverage of lesion and hence reduced TLR incidence, but also reduces the need of extra stents at time of procedure and in the long run.

A recent study has shown that R-PCI also reduced radiation exposure to the patient. Tejas M patel et al concluded in a comparative analysis that total radiation dosage to patients was reduced in R-PCI group although total procedure time was prolonged while contrast volume was aporximately same in both manual PCI and robotic PCI arm.[8]

LIMITATIONS:

Since its approval by FDA back in 2012, one would have hoped that in a decade R-PCI would be adopted on a larger scale especially in the developed countries. Unfortunately, it isn't the case. Despite the earlier success rate being very encouraging with a safety profile for operators being much better than M-PCI, there are still some constraints to its widespread adoption.

Firstly, there is lack of robust clinical data especially RCT to back up the observed benefits of this platform. Modern cardiology being an evidence-based medicine requires some solid results from carefully structured trials with unequivocal results to extensively apply new technologies.

Secondly there are some technical and procedural issues. Currently it can only handle one wire and one device at a time. Also, not all the currently used devices are compatible with this platform. OTW systems including OTW balloons, microcatheters, intravascular imaging devices, and rotabolator systems can't be used with it. This curbs its use to type A or type B coronary lesions at the best. As complex PCIs may require multiple guide wires and devices simultaneously. Intravascular atherectomy is also quite often required in these calcified type C lesions. Currently only laser atherectomy is compatible with this platform but it hasn't been extensively preformed yet. This issue also limits its usage in bifurcation PCI, where two stents are to be placed at the same time. Some operators have also objected on the lack of haptic feedback via robotic PCI. This tactile feel is quite important for experienced operators especially as it helps in the assessment of lesion characteristics. Also, it doesn't completely ward off the radiation exposure as diagnostic angiogram has to be performed manually and this also has some implications in its usage in PPCI setting. Despite the fact that it has proven to be safe and effective in ACS setting, it could take considerable time to switch from manual diagnostic procedure to robotically assisted angioplasty especially in setups where it is still a new upgradation. Since ACS is a time sensitive scenario, this little extra time used could prove to be critical for the patient. Also, thrombus aspiration although not as widely performed in STEMI cases now a days. Still as a bail out procedure in heavy clot burden would mean operator will have to resort to M-PCI. Any acute complication like dissection, arrythmia, perforation would also require transition to manual procedure.

Thirdly there is still a learning curve to it. Many experienced operators who have years of M-PCI experience would be reluctant to go into a learning phase again. This learning curve would result in longer procedural time that in high-volume institutions could result in fewer case performed each day.

Lastly, probably the most critical factor in its widespread adoption is the cost of installing this platform on already established Cath labs. This factor could have more impact in setups where multiple labs are working simultaneously, as one platform can work with one lab only, multiple labs would require multiple R-PCI setups. This would in turn also increase the procedural cost for the patients. More studies are required to understand the actual cost impact of this system. This could require some convincing. In addition, the fact that it doesn't fully ameliorate the radiation exposure risk, as some member of the Cath team will have to stay at table side to inflate the balloon and stents, also diagnostic angio needs to be performed manually, means that it doesn't provide the Cath team 100% radiation safety.

FUTURE DEVLEOPMENTS:

As a child I often used to hear robots will take over the world someday. That might get to be true some day or may be it will remain a fiction limited to movies. But robotics science certainly has played a pivotal role in the progress of our manufacturing industry and now is successfully being applied in medical field with loads of promising data coming in from different fields especially surgery. Its application in interventional cardiology is not something new as it has been here for almost a decade now. But its growth and applications in our field has arguably lagged behind when compared to other industries. The expected improvement in R-PCI platform is in its ability to successfully address complex PCI procedures. With new iterations hopefully It will be possible soon. CORA-PCI study is first of its kind t to directly compare R-PCI with M-PCI in complex lesions. Most of the robotic procedures were completed with

limited manual assistance. R-PCI had technical success of 91.7% (rate of manual assistance 11.1% requiring manual assistance, while 7.4% had to be converted to M-PCI. Although procedural time was prolonged with R-PCI, Clinical success was same in both groups i.e., 99.1. Another scenario of interest is improvements in the platform while addressing P-PCI. R-PCI hasn't been applied extensively to STEMI patients yet. Although some limited data exists of successful procedures. TREAT GRX STUDY is a multi-center observational study, currently underway in STEMI pts using CorPath® GRX System.

Telerobotics is the most ambitious and anticipated usage of this technology. If it becomes reality, timely intervention could be provided to patients in very remote areas thereby curtailing door to balloon time. Telerobotics is already being applied in surgical field where procedures like robotic laparoscopic surgeries have been successfully performed without complications or need to convert to open surgeries. A telerobotic service was established in CANADA between St. Joseph's Hospital in Hamilton and North Bay General Hospital 400 km away in 2003 using ZEUS-TS surgical system.[9] Different laparoscopic surgeries have been successfully performed there.

REMOTE-PCI study successfully demonstrated the feasibility of performing PCI by an operator from a separate location. Operator was seated in a separate room while communication between the operator and lab personnel was via telecommunication. Technical success was achieved in 19 of 22 lesions. (86.4%).[10] Patel et al. described successful telerobotic PCI performed on 5 pts with type A lesion located 20miles away.[11]

A probable application with heaps of benefit could be in neurological interventions as skilled operators in this field are still limited. Combining the skill of remotely located neuro interventionalist with telerobotics could provide remote care to populations lacking such skilled operators. A single operator sitting miles away could potentially operate multiple labs at different times, located at various remote locations.

CONCLUSION:

There are a lot of challenges in making R-PCI widely available. A major constraint in widespread adoption is lack of ability to conduct complex PCIs which comprise a significant number of procedures these days. Still the potential benefits to both patients and the operator will be stupendous.

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