Original Article

Safety and feasibility of robotic assisted percutaneous coronary intervention compared to standard percutaneous coronary intervention- a systematic review and meta-analysis

Byomesh Tripathi a, *, Purnima Sharma d, Shilpkumar Arora b, Malik Murtaza a, Aanandita Singh c, Dhanshree Solanki d, Saurabh Kapadia e, Akshat Sharma f, Ashish Pershad a

a University of Arizona College of Medicine, Phoenix, AZ, USA
b Harrington Heart and Vascular Institute, Case Western Reserve University, Cleveland, OH, USA
c Sri Guru Ram Das Institute of Medical Sciences, Amritsar, Punjab, India
d Rutgers University, New Brunswick, NJ, USA
e Jaslok Hospital and Research Center, Mumbai, India
f Florida State University, Tallahassee, FL, USA

Abstract

Objective: Robotically assisted PCI offers a great alternative to S–PCI. This has gained even more relevance during the COVID-19 pandemic era however safety of R–PCI compared to S–PCI has not been studied well. This study explores the safety and efficacy of robotically assisted PCI (R–PCI) compared to standard PCI (S–PCI) for the treatment of coronary artery disease (CAD).

Methods: PubMed, Scopus, Ovid, and Google scholar databases were searched for studies comparing R–PCI to S–PCI. Outcomes included clinical success, procedure time, fluoroscopy time, contrast use and radiation exposure.

Results: The authors included 5 studies comprising 1555 patients in this meta-analysis. Clinical success was comparable in both arms (p = 0.91). Procedure time was significantly longer in R–PCI group (risk ratio: 5.52, 95% confidence interval: 1.85 to 9.91, p = 0.003). Compared to S–PCI, patients in R–PCI group had lower contrast use (mean difference: –19.88, 95% confidence interval: –21.43 to –18.33, p < 0.001), fluoroscopy time (mean difference: –18.33, 95% confidence interval: –3.64 to –0.00, p = 0.05) and radiation exposure (mean difference: –457.8, 95% confidence interval: –707.14 to –208.14, p < 0.001).

Conclusion: R–PCI can achieve similar success as S–PCI at the expense of longer procedural times. However, radiation exposure and contrast exposure were lower in the R–PCI arm.

Keywords: Robotic PCI, Robotic assisted PCI, CorePath, Coronary artery disease, Coronary angiography, Radiation exposure, COVID-19

1. Introduction

Percutaneous coronary intervention is the dominant treatment strategy for patients with stable and unstable coronary artery disease. Occupational hazards are a prime concern for interventional cardiologists and cardiac catheterization laboratory (CCL) staff. Orthopedic injury from the wear and tear of prolonged standing with lead aprons and stochastic and deterministic effects of radiation exposure are prime concerns. Robotic assisted PCI (R–PCI) is an emerging technology with promising results in mitigating the aforementioned occupational hazards to interventional cardiologists. Reduced patient and CCL staff contact with a potentially COVID positive patient during coronary revascularization offers an advantage of R–PCI in this era. “Tele-stenting” is also a promising strategy whentime is a critical determinant of a successful outcome like during a STEMI or a stroke and access to coronary and neuro-interventional specialists is limited. Since the FDA approval of CorePath 200 robotic system (Corindus Vascular Robotics, Natick, Massachusetts) in 2012, only few studies and case reports have been published demonstrating efficacy of R–PCI in treating simple and complex coronary lesions. Strong clinical data related to efficacy and safety of R–PCI is lacking and there are no randomized...
clinical trials (RCTs) available with currently available robotic platforms. The authors conducted a meta-analysis of all existing studies comparing R–PCI to S–PCI to bridge this gap in the literature.

1.1. Overview of current robotic technology

The parts of the current Corindus GX device are:

Remote controlled cockpit
An articulated robotic arm attached to the table
Disposable cassette to which the guide catheter is connected and through which the intravascular equipment is advanced and retracted.
Encompassed within the workspace are high-resolution angiographic and hemodynamic monitors, standard foot pedal controls, and a series of joysticks for control of the cassette’s features (Fig. 1).

2. Methods

2.1. Study search and eligibility criteria

Two authors (B.T. and S.K.) independently and in duplicate searched PubMed, Scopus, Ovid and google scholar databases until the end of July 2020 to identify studies comparing R–PCI to S–PCI. A systematic search using the key words “Robotic PCI”, “Robotically assisted PCI” and “CorePath” was carried out. No search limitations by publication dates or language were set.

Studies that compared R–PCI to S–PCI for cardiac outcomes of interest were included in this metanalysis. Studies without any S–PCI comparison arm were excluded from this analysis.

2.2. Data extraction

We extracted the baseline characteristics and the treatment variables of the study population (Supplementary table 1), including the sample size of the studies, the design of the studies and exclusion criteria (Table 1). We also extracted the angiographic characteristics of the target lesions (Table 2).

2.3. Efficacy and safety outcomes

The efficacy outcomes of the analysis were separate end points of clinical success of the PCI and procedure time. Safety outcomes included separate endpoints contrast use, fluoroscopy time and radiation exposure.

2.4. Patient and public involvement

This study utilized results of already published studies to conduct the statistical analysis hence public and patient involvement is not applicable to this study. Additionally, this study was deemed exempt for IRB approval from University of Arizona ethics committee for the same reason.

Table 1

| Characteristics of included studies. | Smilowitz et al | Madder et al | Mahmud et al | Hirai et al | Patel et al |
|-------------------------------------|----------------|-------------|-------------|------------|-------------|
| Year                                | 2014           | 2016        | 2017        | 2019       | 2020        |
| System used                         | CorePath 200   | CorePath 200| CorePath 200| CorePath 200| CorePath GRX|
| R–PCI                               | 40             | 45          | 108         | 49         | 310         |
| S–PCI                               | 80             | 168         | 126         | 46         | 686         |
| Setting                             | Single center  | Single center| Single center| Two centers| Single center|
| Randomization                       | No             | No          | No          | No         | No          |
| Exclusion criteria                  | Ejection fraction <30% | None        | STEMI requiring primary PCI | Requirement for over the wire devices | Planned bifurcation stenting >2 CTO lesion |

R–PCI – Robotic assisted percutaneous coronary intervention; S–PCI – Standard percutaneous coronary intervention; AMI – Acute myocardial infarction; STEMI – ST Segment myocardial infarction; CTO – Chronic total occlusion; CABG – Coronary artery bypass grafting.
Table 2. Angiographic characteristics of target lesion in included studies.

|                  | Smilowitz et al | Madder et al | Mahmud et al | Hirai et al | Patel et al |
|------------------|----------------|--------------|--------------|-------------|-------------|
| **Target Lesion (%)** | LM 0 0 4.4 | 0.6 | 3.2 3.3 0 0 | 0.3 0.1 | 0.1 |
| **þ** | LCX 30 27.5 28.9 18.6 21 | 39.3 | 14.3 | 37 | 15.8 5.7 |
| **RCA** | 57.5 27.5 24.4 35.3 | 27.4 | 37.7 | 53.1 | 41.3 | 16.1 10.1 |
| **Grafts** | 0 0 | NA | 1.3 | 2.1 | 0 |
| **Bifurcation lesion** | 0 0 | NA | NA | 12.2 | 28.3 |
| **Chronic total occlusion** | 0 0 | NA | NA | 100 | 100 |
| **Primary lesion stenosis (%)** | 76.9 | 8.5 | 81.6 9.2 | 84.9 9.8 | 85.9 9.8 |
| **Primary lesion length (mm)** | 13.7 | 4.8 | 21.3 5.9 | 22.2 10.6 | 19.4 6.9 |
| **SYNTAX Score** | NA | NA | NA | 19.6 13.9 | 17.7 ± 10.9 |

PCI: standard percutaneous coronary intervention; LM: left main coronary artery; LAD: left anterior descending coronary artery; LCX: left circumflex coronary artery; RI: ramus intermedius branch; RCA: right coronary artery; NA: not available.

2.5. Statistical analysis

The statistical analysis was done in line with recommendations from the Cochrane Collaboration and the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines using Review Manager (RevMan) version 5.1.7 (Copenhagen, Denmark, Nordic Cochrane Centre, The Cochrane Collaboration, 2012). Risk ratios for dichotomous outcomes and mean difference for continuous outcomes using random effect model were determined. Heterogeneity was assessed using the $I^2$ statistic, defined as the proportion of total variation observed between the trials attributable to differences between trials rather than sampling error (chance), with values $<25\%$ considered as low and $>75\%$ as high. Analysis was performed on an intention-to-treat basis. We used random model. Publication bias was estimated visually by funnel plots, and/or using Begg’s test and the weighted regression test of Egger (Supplementary figure 1).

All studies reported radiation exposure in mGy except Mahmoud et al who reported radiation exposure in cGy.cm² and hence excluded from the subgroup analysis to avoid the heterogeneity. Patel et al reported outcomes in median and interquartile range (IQR) and hence Hozo methodology was applied to obtain mean and standard deviation for the purpose of meta-analysis.

3. Results

Our search strategy yielded 5 studies out of 44 articles initially screened. We included 1535 patients in the final meta-analysis, with 552 patients receiving R-PCI and 983 patients treated with S-PCI (Fig. 2). Baseline characteristics of study population is provided in supplementary Table 1. Angiographic characteristics of target lesions in included studies is presented in Table 2.

Efficacy endpoint: Clinical success of R-PCI was found to be comparable to S-PCI (Risk ratio:1.95% confidence interval: 0.98–1.02, $p = 0.91$) (Fig. 3A). Procedure time was significantly shorter with R-PCI compared to S-PCI (mean difference:5.52, 95% confidence interval: 1.82–9.19, $p = 0.003$) (Fig. 3B).

Safety endpoint: We noted an overall better safety profile with R-PCI compared to S-PCI. R-PCI was associated with lower use of contrast than S-PCI (mean difference: -19.88, 95% confidence interval: -21.43 to -18.33, $p < 0.001$) (Fig. 3C). Fluoroscopy time (Fig. 3D) was significantly lower with R-PCI compared to S-PCI arm (mean difference: -1.82 to -0.00, $p = 0.05$). Similarly, radiation exposure (Fig. 3E) was lesser among patients treated with R-PCI than S-PCI (mean difference: -457.8 to -208.5, $p = 0.0003$).

4. Discussion

The present study is the most up to date meta-analysis comparing efficacy and safety of R-PCI compared to S-PCI. The principal findings of this meta-analysis are — (1). Clinical efficacy and PCI success can be achieved with the same frequency as in S-PCI in a broad variety of lesion subsets including CTO’s, bifurcations and in high risk subsets such as left main stenosis. Procedure times were significantly longer with R-PCI compared to S-PCI. R-PCI was associated with lower contrast use and lower fluoroscopy times and radiation dose to the patient.
with a separate joystick. Intravascular imaging, laser atherectomy can be performed seamlessly and with the “retract and rotate” maneuver, side branches can also be wired. Due to the limitation of not being able to use “over the wire” systems with the current robot, manual crossover is needed to perform orbital and rotational atherectomy. For CTO PCI, the attractiveness of R–PCI is that radiation exposure to the PCI operator is reduced by almost 50%. After manual crossing of the CTO lesion, switching to R–PCI alleviates any further need for wearing a lead apron and almost eliminates further radiation exposure. R–PCI facilitates accurate stent placement by minimizing longitudinal geographic miss which is quite common in S–PCI.

Procedural time was higher with R–PCI than S–PCI. Higher procedure time with R–PCI is related to current limitations of the technology. Current generation systems are not capable of performing vascular access and placement of sheaths and guiding catheters. Every change in balloon and stent requires manual placement of the device in the cassette. While this adds additional time to the case, it is noteworthy that this extra time is not additional radiation or fluoroscopy exposure to either patient or the interventional cardiologist. As operators and catheterization laboratory staff gain more experience with current generation devices this time will most certainly decrease.

Contrast volume, fluoroscopy time and radiation dose was significantly lower with R–PCI comparison to S–PCI. These benefits result from better visualization on the high definition monitors in the cockpit resulting in precise balloon and stent positioning and reduced chances of longitudinal geographic miss. There have been prior studies in which the number of stents used per case due to precise stent positioning has translated to cost savings. A focused cost-effective analysis in a RCT would need to be performed before such claims can be validated.

Although this study did not compare long term outcomes of R–PCI and S–PCI there is no reason to believe that major adverse cardiovascular events (MACE) rates would be different at 1 year. Prior work by Walters et al reported no difference in MACE in a study of 333 patients at 6 months and 12 months follow up. R–PCI offers obvious advantages over S–PCI that cannot be measured tangibly in this meta-analysis or for that matter with any study. The bodies of interventional cardiologists over their lifespan are subjected to wear and tear from prolonged standing at the catheterization table with heavy lead shields. These lead aprons provide only partial protection from the ill effects of radiation exposure. The incidence of radiation exposure is higher on the left side and center of the cranium and in a cohort the incidence of brain and neck tumors amongst interventional cardiologists was disproportionately higher on the left side. Fifty percent of interventional cardiologists report a job related orthopedic injury. Wearing heavy lead aprons significantly contributes to these injuries. By reducing the time spent at the table and limiting the time wearing a lead apron, R–PCI significantly reduces the radiation exposure and risk of orthopedic injuries for the interventional cardiologist.

4.1. Limitations

This study has the following limitations. The lack of any RCT’s comparing R–PCI with S–PCI limits the quality of the meta-analysis because the analysis is limited to observational data. This is a study-level and not a patient level meta-analysis. Differences in the...
Fig. 3. A: Risk estimates of clinical success. B: Mean difference in procedure time. C: Mean difference in contrast use. D: Mean difference in fluoroscopy time. E: Mean difference in radiation exposure.
impact of clinical presentations, lesion complexity and concurrent pharmacotherapy could not be assessed.

5. Conclusion

In this updated meta-analysis comparing R–PCI with S–PCI, there were no difference in outcomes between the two groups in terms of procedural success. R–PCI took longer than S–PCI but radiation dose, contrast volume and fluoroscopy times were lower with R–PCI. In addition, the non-tangible benefits of R–PCI related to occupational relief to the interventional cardiologist by not having to wear lead aprons for as long and reduced radiation exposure cannot be quantified.

Key questions

● What is already known about this subject?

Robotic assisted PCI can be safe and effective approach for simpler coronary lesions.

● What does this study add?

This study shows that Robotic assisted PCI has superior safety profile with reduced contrast and radiation exposure with comparable efficacy compared to standard PCI even for selected complex coronary lesions.

● How might this impact on clinical practice?

This study calls for greater utilization of Robotic assisted PCI to reduced occupation related hazards to operators, radiation and contrasted related injury to patients and minimize patient-catheterization laboratory staff exposure in ongoing COVID-19 pandemic.

Acknowledgement

None declared.

Funding sources

No study specific funding was used to support this work. The authors are solely responsible for the study design, conduct and analyses, drafting and editing of the manuscript and its final contents. All authors had access to the data and a role in writing the manuscript.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.ijh.2021.08.006.

References

1. Klein LW, Tra Y, Garrant KN, et al. Occupational health hazards of interventional cardiologists in the current decade: results of the 2014 SCAI membership survey. Cathet Cardiovasc Interv. 2015;86(5):913–924.

2. Orme NM, Rihal CS, Gulati R, et al. Occupational health hazards of working in the interventional laboratory: a multisite case control study of physicians and allied staff. J Am Coll Cardiol. 2015;65(8):820–826.

3. Andreassi MG, Piccaluga E, Gargani L, et al. 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. JACC Cardiovasc Interv. 2015;8(4):616–627.

4. Weisz G, Metzger DC, Caputo RP, et al. Safety and feasibility of robotic percutaneous coronary intervention. PRECISE (Percutaneous Robotically-Enhanced Coronary Intervention) Study. 2013;61(13):1596–1600.

5. Madder RD, VanOosterhout SM, Jacoby ME, et al. 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 teletesting (the REMOTE-PCI study). EuroIntervention. 2017;12(13):1569–1576.

6. Patel TM, Shah SC, Panchoy SB. Long distance tele-robotic-assisted percutaneous coronary intervention: a report of first-in-human experience. Eclinimi-cal Medicine. 2019;14:53–58.

7. Kapur V, Smilowitz NR, Weisz G. Complex robotic-enhanced percutaneous coronary intervention. Cathet Cardiovasc Interv. 2014;83(6):915–921.

8. Granada JF, Delgado JA, Uribe MP, et al. First-in-Human evaluation of a novel robotic-assisted coronary angioplasty system. JACC Cardiovasc Interv. 2011;4(9):460–465.

9. Mahmud E, Dominguez A, Bahadorani J. First-in-human robotic percutaneous coronary intervention for unprotected left main stenosis. Cathet Cardiovasc Interv. 2016;88(4):565–570.

10. Nagaraja V, Khatri JJ. Hybrid robotic impella assisted single arterial access complex high risk percutaneous coronary intervention. Cardiovasc Revascu-larization Med. 2019;9(19):3080–30806.

11. Huggins JPT, Thompson SC, Deeks JJ, Altman DG. Measuring inconsistency in meta-analyses. BMJ. 2003;327(7414):557–560.

12. Deeks JH, Altman DG. Chapter 9: analyzing data and undertaking meta-analyses. In: Higgins JPT, Green S, eds. Cochrane Handbook for Systematic Reviews of Interventions. Version 5.0.1 (Updated September 2008). The Cochrane Collaboration. editors; 2008. Available at:www.cochrane-handbook.org. Accessed July 22, 2020. Accessed.

13. Hozo SP, Djulbegovic B, Hozo I. Estimating the mean and variance from the median, range, and of the size of a sample. BMC Med Res Methodol. 2005;5(1):13.

14. Smilowitz NR, Moses JW, Sosa FA, et al. Robotic-Enhanced PCI compared to the traditional manual approach. J Invasive Cardiol. 2014;26(7):318–321.

15. Mahmud E, Naghi J, Ang L, et al. Demonstration of the safety and feasibility of robotically assisted percutaneous coronary intervention in complex coronary lesions: results of the CORA-PCI study (complex robotically assisted percutaneous coronary intervention). JACC Cardiovasc Interv. 2017;10(13):1320–1327.

16. Hirai T, Kearney K, Kataoka A, et al. Initial report of safety and procedure duration of robotic-assisted chronic total occlusion coronary intervention. Cathet Cardiovasc Interv. 2020;95(1):165–169, 01.

17. Patel TM, Shah SC, Sora YV, et al. Comparison of robotic percutaneous coronary intervention with traditional percutaneous coronary intervention: a propensity score-matched analysis of a large cohort. Circ Cardiovasc Interv. 2020;13(5):14.

18. Madder RD, VanOosterhout S, Mulder A, et al. Impact of robotics and a suspended lead suit on physician radiation exposure during percutaneous coronary intervention. Cardiovasc Revascularization Med. 2017;18(3):190–196.

19. Campbell PT, Kruse KR, Kroll CR, Patterson JY, Esposito MJ. The impact of precise robotic lesion length measurement on stent length selection: ramifications for stent savings. Cardiovasc Revascularization Med. 2015;16(6):348–350.

20. Chakravarti J, Rao SV. Robotic assisted percutaneous coronary intervention: hype or hope? Journal of the American Heart Association. 2019;8(13), e012743-e012743.

21. Walters D, Reeves RR, Patel M, Naghi J, Ang L, Mahmud E. Complex robotic compared to manual coronary interventions: 6- and 12-month outcomes. Cathet Cardiovasc Interv. 2019;93(4):613–617.

22. Reeves RR, Ang L, Bahadorani J, et al. Invasive cardiologists are exposed to greater left sided cranial radiation: the BRAIN study (brain radiation exposure and attenuation during invasive cardiology procedures). JACC Cardiovasc Interv. Aug. 2015;8(9):1197–1206.

23. Roguin A, Goldstein J, Bar O, Goldstein JA. Brain and neck tumors among physicians performing interventional procedures. Am J Cardiol. May. 2013;111(9):1368–1372.

24. Klein LW, Tra Y, Garrant KN, et al. Occupational health hazards of interventional cardiologists in the current decade: results of the 2014 SCAI membership survey. Catheter Cardiovasc Interv. Nov. 2015;86(5):913–924.