Circulation: Cardiovascular Interventions

ORIGINAL ARTICLE

Comparison of Robotic Percutaneous Coronary Intervention With Traditional Percutaneous Coronary Intervention

A Propensity Score–Matched Analysis of a Large Cohort

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BACKGROUND: Robotic percutaneous coronary intervention (R-PCI) has been shown to benefit the operator but has not shown any significant benefit to the patient. We sought to compare a large cohort of R-PCI to traditional percutaneous coronary intervention (PCI) procedures performed at a tertiary care center in the same time frame.

METHODS: A total of 996 consecutive patients referred for PCI between December 2017 and March 2019 were studied, of which 310 (31.1%) patients were selected to undergo R-PCI and 686 (68.9%) patients underwent traditional PCI. The coprimary study outcome measures were air kerma, dose-area product, fluoroscopy time, volume of contrast, and total procedural time. Caliper propensity-matching technique was used (caliper, 0.05) to match each R-PCI patient to the nearest traditional PCI patient without replacement.

RESULTS: Air kerma (mGy; median [interquartile range]; *P*; 884 [537–1398] versus 1110 [699–1498]; *P*=0.002) and dose-area product (cGycm^2; 4734 [2695–7746] versus 5746 [3751–7833]; *P*=0.003) were significantly lower in the R-PCI group. There was no difference in fluoroscopy time (minutes; 5.51 [3.53–8.31] versus 5.48 [3.31–9.37]; *P*=0.936) and contrast volume (mL; 130 [103–170] versus 140 [100–180]; *P*=0.905). Total procedural time (minutes) was significantly higher in the R-PCI group (27 [21–40] versus 37 [27–50]; *P*<0.0005).

CONCLUSIONS: R-PCI is associated with a significant decrease in radiation exposure to the patient with no increase in fluoroscopy time, as well as contrast utilization, and a minor increase in procedure duration compared with traditional PCI.

VISUAL OVERVIEW: A visual overview is available for this article.

Key Words: cohort studies ■ fluoroscopy ■ percutaneous coronary intervention ■ robotic surgical procedures ■ tertiary care centers

See Editorial by Eleid and Gulati

Robotics in percutaneous coronary intervention (PCI) has gradually increased in utilization since its first description in 2005.[1–5] In view of the fact that the operator controls the procedural transactions from a cockpit located significantly farther away from the patient and the source of radiation, a significant decrease in radiation exposure to the operator has been observed.[6,7] Application of robotics in surgical arena has led to improved precision, as well as wider application of minimally invasive approaches, where the patient derives a major benefit.[8] In the coronary intervention domain, no discernible benefit has been demonstrated to the patient as a result of performing the procedure with robotic assistance. Most data sets comparing robotic PCI (R-PCI) to traditional PCI (T-PCI) reported thus far have been relatively small samples. We sought to comparatively evaluate

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WHAT IS KNOWN

- Robotic percutaneous coronary intervention has demonstrated feasibility in a broad array of percutaneous coronary intervention subsets and has been shown to significantly reduce radiation exposure to the operator.

WHAT THE STUDY ADDS

- This study demonstrates that robotic percutaneous coronary intervention significantly lowers the burden of radiation exposure to the patient compared with traditional percutaneous coronary intervention. Despite being a new addition to the catheterization laboratory, fluoroscopy time, and contrast use are not significantly increased, although procedure duration is increased.

Nonstandard Abbreviations and Acronyms

AK	air kerma
ALARA	as low as reasonably achievable
CK-MB	creatine kinase-MB isoenzyme
DAP	dose-area product
MI	myocardial infarction
PCI	percutaneous coronary intervention
R-PCI	robotic percutaneous coronary intervention
T-PCI	traditional percutaneous coronary intervention

T-PCI procedures performed in the same time frame as the R-PCI at a tertiary care center in India.

PATIENTS AND METHODS

The authors declare that all supporting data are available within the article and in the Data Supplement.

Data Collection

Patients referred to Apex Heart Institute, Ahmedabad, India, undergoing PCI procedures by 2 experienced operators between December 2017 and March 2019 were retrospectively studied. The study was approved by the Institutional Review Board at the Apex Heart Institute, and patients provided written informed consent. Patient-related demographic data, such as age, sex, comorbidities, height, weight, and indication of the procedure, were collected from the electronic health records maintained at the Apex Heart Institute. Procedural and angiographic data, such as lesion severity and SYNTAX score (Synergy Between PCI With Taxus and Cardiac Surgery), were collected. Contrast volume, number of cineangiography acquisitions, fluoroscopy time, air kerma (AK), dose-area product (DAP), and total procedural time were also collected. Major adverse cardiovascular events defined as a composite of target vessel revascularization, nonfatal myocardial infarction (MI) defined as post-PCI CK-MB (creatine kinase-MB isoenzyme) level of >3× the upper limit of normal or clinical presentation with MI, and death were recorded at 30 days. Patients were divided into 2 groups: group I consisted of patients who underwent R-PCI, and group II consisted of patients who underwent T-PCI.

Study End Points

The coprimary study outcome measures were AK, DAP, fluoroscopy time, volume of contrast, and total procedural time.

Robotic PCI

R-PCI was performed using the CorePath GRX developed by Corindus Vascular Robotics, Inc. The setup consisted of a radiation-shielded interventional cockpit located within the cardiac catheterization laboratory and comprised of monitors, which display fluoroscopic images and hemodynamic data. The interventional cockpit is connected to a robotic arm mounted on the cardiac catheterization bedside rail via cables. The robotic arm consists of a sterile single-use cassette. As with the T-PCI, the operator gains access manually, advances the guide catheter, and engages the coronary artery. The operator then attaches the guide catheter into single-use cassette mounted on the robotic arm. Sitting inside the interventional cockpit, the operator then performs the intervention using the controls mounted on the cockpit console, which allows the operator to precisely manipulate guide catheters, balloons, and stents by applying longitudinal or rotational displacement to the control knobs. The robotic arm is shown in Figure 1. All R-PCIs at the Apex Heart Institute were performed by 2 highly experienced operators.

Traditional PCI

T-PCIs were performed after manually obtaining vascular access. The operator and the assisting technician stand next to the cardiac catheterization table. The guide catheter is then manually advanced through the introducer sheath, and coronary artery is engaged. Through the guide catheter, guidewire is advanced beyond the site of lesion. Coronary intervention is then performed by manually advancing coronary balloons and stent catheters to the site of lesion through the guide catheter.

Figure 1. Robotic arm and cassette.
The caption of the current version of the robotic arm and cassette that houses the catheters and wire and is controlled by a console placed at a distance.

Statistical Analysis

All statistical analyses were performed using SPSS Statistics software, version 26 (IBM Corporation, Armonk, NY). Baseline patient-related characteristics including sex, history of hypertension, diabetes mellitus, hyperlipidemia, smoking, previous MI, previous PCI, previous coronary artery bypass graft surgery, and acute coronary syndrome presentation, as well as procedural characteristics including target vessel, presence of chronic total occlusion, bifurcation, and presence of severe tortuosity, were expressed as proportions and were compared using Pearson χ^2 test. Continuous variables including age, left ventricular ejection fraction, height, weight, SYNTAX score, and the number of cineangiograms were expressed as median and interquartile range and were compared using Mann-Whitney *U* test. Procedural outcome variables including AK, DAP, fluoroscopy time, procedure time, and contrast volume were expressed as median and interquartile range and were compared using Mann-Whitney *U* test. Clinical outcome variables including death, nonfatal MI, and target vessel revascularization were expressed as proportions and were compared using Pearson χ^2 test. A *P* of <0.05 was considered statistically significant.

Propensity score–matched analysis was performed. Binary logistic regression was performed to calculate the propensity score. Age, sex, hypertension, diabetes mellitus, previous MI, previous PCI, previous coronary artery bypass graft, hyperlipidemia, smoking, presentation with an acute coronary syndrome, left ventricular ejection fraction, height, weight, SYNTAX score, and the number of cineangiogram acquisitions were included in the binary logistic regression to estimate the probability. We used the nearest-neighbor greedy caliper match technique using caliper size equal to one-quarter of the SD of the propensity score (caliper, 0.05) to match each R-PCI patient to the nearest T-PCI patient without replacement.[9] In the propensity score–matched cohort, comparisons were performed using Mann-Whitney *U* test for numeric variables and χ^2 test for categorical variables.

RESULTS

A total of 1022 consecutive patients who underwent PCI at the Apex Heart Institute were collected, of which 26 T-PCI procedures were performed by low experienced operators and hence were excluded. Twenty-two patients from R-PCI group needed crossover to T-PCI. They were analyzed in an intention-to-treat fashion and were included in the R-PCI cohort. Of 996 patients included in the final analyses, 310 (31.1%) patients underwent R-PCI and 686 (68.9%) patients underwent T-PCI.

Table 1 demonstrates baseline patient characteristics. Patients who underwent R-PCI were younger and were more likely to be male, hypertensive, diabetic, and were more likely to have had previous PCI procedure and coronary artery bypass graft surgery. There were no significant differences in previous MI, smoking status, hyperlipidemia, height, and weight between the 2 study groups. Left ventricular ejection fraction (%) was significantly higher in patients who underwent R-PCI compared with T-PCI.

Table 1. Baseline Demographic Characteristics of the Study Population

Characteristics	T-PCI (n=686)	R-PCI (n=310)	*P* Value
Age, y*	60 (53–67)	58 (51–64)	0.022
Sex			0.082
Male	519 (75.7)	250 (80.6)	
Female	167 (24.3)	60 (19.4)	
Hypertension	404 (58.9)	229 (73.9)	<0.0005
Diabetes mellitus	290 (42.3)	181 (58.4)	<0.0005
Previous MI	349 (50.9)	148 (47.7)	0.360
Previous PCI	121 (17.6)	77 (24.8)	0.008
Previous CABG surgery	29 (4.2)	25 (8.1)	0.013
Hyperlipidemia	22 (3.2)	15 (4.8)	0.207
Smoker	50 (7.3)	29 (9.4)	0.264
Acute coronary syndrome	416 (60.6)	145 (46.8)	<0.0005
LVEF, %*	50 (40–60)	58 (45–60)	0.005
Height, cm*	165 (159–171)	165 (160–171)	0.911
Weight, kg*	70 (64–80)	70 (64–79)	0.274

Values are n (%) or median (interquartile range). CABG indicates coronary artery bypass graft; LVEF, left ventricular ejection fraction; MI, myocardial infarction; PCI, percutaneous coronary intervention; R-PCI, robotic PCI; and T-PCI, traditional PCI.

All continuous variables were compared using Mann-Whitney *U* test (*), and the rest of the categorical variables were compared using Pearson χ^2 test.

Table 2 demonstrates procedural and angiographic characteristics between the 2 groups. Patients who presented with acute coronary syndrome were more likely to undergo T-PCI procedure. Patients who underwent R-PCI were more likely to have a lower SYNTAX score compared with patients who underwent T-PCI. There were no significant differences in the rates of chronic total occlusions and the presence of severe tortuosity between the 2 groups. Patients with severe coronary calcifications were more likely to receive T-PCI compared with R-PCI. Number of cineangiogram acquisitions was significantly higher in T-PCI group.

Table 3 depicts unadjusted coprimary outcomes of the study population. AK (mGy; median [interquartile range]; *P*; 1235 [793–1873] versus 833 [521–1378]; *P*<0.0005), DAP (cGycm^2; 6313 [4049–9574] versus 4465 [2644–7389]; *P*<0.0005), fluoroscopy time (minutes; 6.29 [4.23–9.68] versus 5.39 [3.17–9.03]; *P*<0.0005), and contrast volume (mL; 150 [120–190] versus 130 [100–170]; *P*<0.0005) were significantly higher in the T-PCI group. Compared with the T-PCI group, total procedure time (minutes) was significantly higher in the R-PCI group (36 [26–49] versus 31 [21–42]; *P*<0.0005).

Propensity score–matched cohort included a total of 560 patients (280 patients in each group). There were no significant differences in baseline demographics and

Table 2. Angiographic and Procedural Characteristics of the Study Population

Characteristics	T-PCI (n=686)	R-PCI (n=310)	*P* Value
Target vessel			<0.0005
LM	1 (0.1)	1 (0.3)	
LAD	565 (82.4)	205 (66.1)	
LCX	39 (5.7)	49 (15.8)	
RCA	69 (10.1)	50 (16.1)	
Grafts	2 (0.3)	2 (0.6)	
Bifurcation	10 (1.5)	3 (1.0)	
Chronic total occlusions	38 (5.5)	11 (3.5)	0.179
Severe calcification	66 (9.6)	4 (1.3)	<0.0005
Severe tortuosity	14 (2.0)	2 (0.6)	0.105
SYNTAX score*	11 (7–18)	8 (6–13)	<0.0005
No. of cineangiogram acquisitions*	22 (16–28)	16 (10–23)	<0.0005

Values are n (%) or median (interquartile range). LAD indicates left anterior descending coronary artery; LCX, left circumflex coronary artery; LM, left main coronary artery; R-PCI, robotic PCI; RCA, right coronary artery; SYNTAX, Synergy Between PCI With Taxus and Cardiac Surgery; and T-PCI, traditional PCI.

All continuous variables were compared using Mann-Whitney *U* test (*), and the rest of the categorical variables were compared using Pearson χ^2 test.

angiographic and procedural characteristics between the 2 matched groups (Tables 4 and 5).

Table 6 and Figure 2 demonstrate coprimary outcomes in the propensity score–matched cohort. AK (mGy; median [interquartile range]; *P*; 884 [537–1398] versus 1110 [699–1498]; *P*=0.002) and DAP (cGycm^2; 4734 [2695–7746] versus 5746 [3751–7833]; *P*=0.003) were significantly lower in the R-PCI group. There was no difference in fluoroscopy time (minutes; 5.51 [3.53–8.31] versus 5.48 [3.31–9.37]; *P*=0.936) and contrast volume (mL; 130 [103–170] versus 140 [100–180]; *P*=0.905). Total procedural time (minutes) was significantly higher in the R-PCI group (27 [21–40] versus 37 [27–50]; *P*<0.0005). Table I in the Data Supplement depicts 30-day major adverse cardiovascular event rates in the study population. There were no differences in the rates of target vessel revascularization, nonfatal MI, and death between the 2 groups.

Table 3. Unadjusted Coprimary Outcomes in the Study Population

Characteristics	T-PCI (n=686)	R-PCI (n=310)	*P* Value
AK, mGy	1235 (793–1873)	833 (521–1378)	<0.0005
Dose-area product, cGycm^2	6313 (4049–9574)	4465 (2644–7389)	<0.0005
Fluoroscopy time, min	6.29 (4.23–9.68)	5.39 (3.17–9.03)	<0.0005
Contrast volume, mL	150 (120–190)	130 (100–170)	<0.0005
Total procedural time, min	31 (21–42)	36 (26–49)	<0.0005

Values are median (interquartile range). All continuous variables were compared using Mann-Whitney *U* test. AK indicates air kerma; R-PCI, robotic percutaneous coronary intervention; and T-PCI, traditional percutaneous coronary intervention.

Table 4. Baseline Demographic Characteristics of the Propensity Score–Matched Cohort

Characteristics	T-PCI (n=280)	R-PCI (n=280)	*P* Value
Age, y*	58 (51–66)	59 (51–65)	0.910
Sex			1.0
Male	220 (78.6)	220 (78.6)	
Female	60 (21.4)	60 (21.4)	
Hypertension	206 (73.6)	201 (71.8)	0.635
Diabetes mellitus	150 (53.6)	156 (55.7)	0.611
Previous MI	141 (50.4)	135 (48.2)	0.612
Previous PCI	58 (20.7)	57 (20.4)	0.917
Previous CABG surgery	20 (7.1)	18 (6.4)	0.737
Hyperlipidemia	11 (3.9)	11 (3.9)	1.0
Smoker	21 (7.5)	23 (8.2)	0.753
Acute coronary syndrome	153 (54.6)	138 (49.3)	0.205
LVEF, %*	58 (45–60)	57 (45–60)	0.748
Height, cm*	166 (160–171)	165 (160–171)	0.849
Weight, kg*	70 (65–80)	70 (64–79)	0.680

Values are n (%) or median (interquartile range). CABG indicates coronary artery bypass graft; LVEF, left ventricular ejection fraction; MI, myocardial infarction; PCI, percutaneous coronary intervention; R-PCI, robotic PCI; and T-PCI, traditional PCI.

All continuous variables were compared using Mann-Whitney *U* test (*), and the rest of the categorical variables were compared using Pearson χ^2 test.

DISCUSSION

Our data indicate that patients selected to undergo R-PCI are exposed to a significantly lower burden of radiation compared with those undergoing T-PCI. Despite being a

Table 5. Angiographic and Procedural Characteristics of the Propensity-Matched Cohort

Characteristics	T-PCI (n=280)	R-PCI (n=280)	*P* Value
Target vessel			0.171
LM	0 (<0.1)	1 (0.4)	
LAD	205 (73.2)	187 (66.8)	
LCX	24 (8.6)	43 (15.4)	
RCA	46 (16.4)	44 (15.7)	
Grafts	1 (0.4)	2 (0.7)	
Bifurcation	4 (1.4)	3 (1.1)	
Chronic total occlusions	13 (4.6)	11 (3.9)	0.676
Severe tortuosity	1 (0.4)	2 (0.7)	0.5
SYNTAX score*	14 (10–21)	13 (9–17)	0.433
No. of cineangiogram acquisitions*	18 (14–24)	17 (11–24)	0.2

Values are n (%) or median (interquartile range). LAD indicates left anterior descending coronary artery; LCX, left circumflex coronary artery; LM, left main coronary artery; R-PCI, robotic percutaneous coronary intervention; RCA, right coronary artery SYNTAX, Synergy Between PCI With Taxus and Cardiac Surgery; and T-PCI, traditional percutaneous coronary intervention.

All continuous variables were compared using Mann-Whitney *U* test (*), and the rest of the categorical variables were compared using Pearson χ^2 test.

Table 6. Coprimary Outcomes in the Propensity Score–Matched Cohort

Characteristics	T-PCI (n=280)	R-PCI (n=280)	*P* Value
AK, mGy	1110 (699–1498)	884 (537–1398)	0.002
Dose-area product, cGycm²	5746 (3751–7833)	4734 (2695–7746)	0.003
Fluoroscopy time, min	5.51 (3.53–8.31)	5.48 (3.31–9.37)	0.936
Contrast volume, mL	130 (103–170)	140 (100–180)	0.905
Total procedural time, min	27 (21–40)	37 (27–50)	<0.0005

Values are median (interquartile range). All continuous variables were compared using Mann-Whitney *U* test. AK indicates air kerma; R-PCI, robotic percutaneous coronary intervention; and T-PCI, traditional percutaneous coronary intervention.

new addition to the catheterization laboratory, fluoroscopy time was not statistically significantly different between the groups, albeit was numerically lower in R-PCI compared with T-PCI. As expected, procedure duration was significantly higher with R-PCI, with an average of 10 more minutes spent during the procedure while using the robot. No excess contrast utilization was observed in the R-PCI group compared with the T-PCI group.

Radiation exposure during PCI, although a necessity, exposes the patient and the operators to several health risks. Most high-quality facilities follow the principle of as low as reasonably achievable (ALARA), with continuous efforts to use the minimum necessary radiation exposure during the procedure. The exposure to the patient is inevitable, and the operator exposure is largely dependent on the patient exposure, as well as shielding used by the operator. Based on the principles of optics and radiation physics, certain maneuvers have been shown to lower patient radiation exposure. Raising the table and hence the patient away from the radiograph source is one of the maneuvers associated with a lower dose to the patient, although a higher dose to the operator is observed with this maneuver.[10] The table height is limited by the maximal height at which the operator can ergonomically work on the sterile field. It is likely that maximizing the principles of ALARA, during R-PCI, the catheterization team likely was able to elevate the height of the table and the patient to the maximum allowable limit hence lowering the patient exposure significantly compared with T-PCI. As the operator is sitting far away from the radiograph source, the table, and the patient, the inherent ergonomic disadvantage and the increase in operator radiation exposure associated with this maneuver becomes irrelevant when using a robotic setup. This alignment of patient safety, as well as operator safety, from a radiation exposure standpoint is a unique advantage of the robotic approach and is difficult to achieve in a traditional setup.

The finding of lack of increase in fluoroscopy time with an actual numeric decrease in the R-PCI group in the propensity score–matched cohort despite inclusion of all patients treated with R-PCI, including the initial subset that likely accounted for the learning curve for the operators, leads to the speculation that in future cohorts, a measurable decrease may be possible. Although residual confounding may have led to this observation, a true effect driven by the precision delivered by the robotic platform may be operational. No difference in contrast utilization was observed, despite an inherent sense of lower confidence while performing R-PCI in view of its novelty, once again raising hope that with increased training, the operator might be able to further improve patient safety by a potential decrease in contrast utilization in future cohorts.

As expected, procedure time was significantly increased with R-PCI compared with T-PCI. This was likely driven by the necessity to load equipment in a sequential fashion in the robot cassette, although the short duration of 4 minutes implies a well-trained catheterization laboratory staff facile with equipment exchanges in the cassette. To our knowledge, this is the first report demonstrating a patient benefit associated with R-PCI compared with T-PCI in a well-balanced propensity score–matched analysis where patient-related, procedural, and operator-related covariates were aggressively adjusted.

Limitations

In view of the retrospective nature of our study, despite utilization of sophisticated statistical methodologies such as caliper propensity score matching using an aggressive caliper distance, residual confounding is possible. Our data set also included every patient who underwent R-PCI since its inception at our institution, and hence the effect of the learning curve of the operators is likely operational

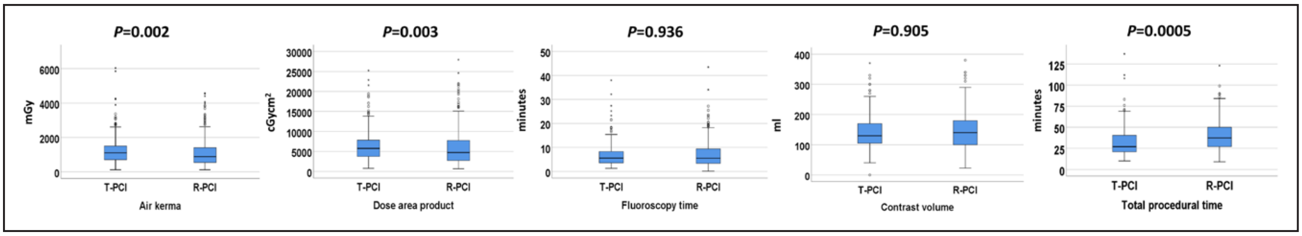

Figure 2. Comparison of coprimary outcome measures between robotic percutaneous coronary intervention (R-PCI) and traditional percutaneous coronary intervention (T-PCI).
Air kerma and dose-area product were significantly lower in the R-PCI group. Total procedural time was marginally higher in the R-PCI group. There were no differences in contrast volume utilization and fluoroscopy time between the 2 groups.

as shown by our analysis, although the effect of learning curve should dilute the difference in favor of T-PCI. Those procedures where R-PCI was converted to T-PCI were analyzed as a part of R-PCI cohort. A continuing registry-based data collection at our institution is ongoing to reevaluate the comparative performance of the 2 approaches with a larger sample and likely free of learning curve influences in the future. An appropriately powered randomized controlled trial comparing R-PCI versus T-PCI is necessary to evaluate the potential patient advantage and other differences between the 2 approaches.

Conclusions

R-PCI is associated with a significant decrease in radiation exposure to the patient with no increase in contrast utilization and a minor increase in procedure duration compared with T-PCI.

ARTICLE INFORMATION

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