DOI: https://doi.org/10.53350/pjmhs221610788

ORIGINAL ARTICLE

Patient Characteristics, Procedural Details, and Outcomes of Contemporary Percutaneous Coronary Interventions

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ABSTRACT

Background: The prevalence and success of percutaneous coronary intervention (PCI) varies widely between regions, with South Asia displaying some of the greatest regional differences.

Objectives: Examining PCI procedures and their outcomes in Pakistan over time and comparing this information to that from other countries is the goal of this study.

Methods: Throughout the course of a year, information was collected from several cardiac catheterization laboratories in Pakistan. An in-depth history of each patient was recorded, along with data on their procedures, the tools and drugs they required, their outcomes, and any complications that may have arisen.

Results: The study contained information from 22,741 patients. Their average age was 64.2 years (11.7) and they were predominantly male (70%). Acute coronary syndrome was the most prevalent symptom (57%), while ST-elevation myocardial infarction was the most common type of heart attack (28%). Multivessel disease was present in nearly two-thirds of patients, and 11% of those patients also had substantial left main stenosis. Almost half of these procedures (44.2%) opted for the transradial route. In spite of the high complexity of the lesions (56.9% class C lesion), the operative success rate was quite good at 95.2%. There was a 5.3% rate of procedure-related complications and a 2.8% rate of in-hospital deaths.

Conclusion: The collected data shed light on the state of PCI in the United States, both in terms of its implementation and its results. Despite the complexity of the lesions being treated, the success rate was high, and problems were minimal.

INTRODUCTION

Background: In Pakistan, coronary artery disease (CAD) was the top cause of death, accounting for 12.4% of all deaths in the country in 2015. 1 This is consistent with the global trend. 2. Most of these individuals are treated with percutaneous coronary intervention (PCI), which is a type of revascularization. Third, information on PCI gleaned from clinical registries has become an invaluable resource for gauging the efficacy and safety of healthcare delivery, with the ultimate goal of enhancing the quality of care provided 4-7. Real-world data of PCI in poor nations are quite scarce, in contrast to statistics from Western countries. In Pakistan, only one PCI procedure was carried out on 4,156 patients 13 years ago. Since then, the rate of PCI has skyrocketed as the government has expanded access to PCI across the country and mandated healthcare for all Pakistanis. The health national policy also increased funding for Interventional Cardiology Training Scholarships, which contributed to a rise in the number of hospitals with cardiac catheterization equipment.

Insights on PCI treatment quality should be attainable, thanks to these dramatic shifts over a decade. The primary goals of this study were to quantify PCI failure, complication, and mortality rates in Pakistan and to evaluate PCI success rates with time. This data would be an invaluable resource for healthcare officials on a global scale, as it would provide the most recent PCI practise benchmarks.

MATERIAL AND METHODS

From Nov, 2016 to Nov, 2019, information from all of Pakistan's catheterization labs was gathered from all over the country. After obtaining their informed agreement, all consecutive adult patients aged 18 or older who got PCIs at these collaborating centres were included. Relatives acting as legal representatives made decisions for persons who were unable to provide written approval.

Data collection and analysis followed the Declaration of Helsinki and the Ethical Guidelines for Human Research. We used SPSS Version 23.0 to record every detail about each patient, including demographics, procedures, tools and medications used, post-operative problems, and final hospital outcomes. The researcher kept a close eye on the quality of the collected data at every stage: collection, analysis, and reporting.

PCI success/failure, complications, hospital mortality (all causes, cardiovascular, and specific cause), repeat myocardial infarction (MI), repeat revascularization, stroke, heart failure, and bleeding were among the outcomes of interest.

Data Analysis: Patients' demographics, preexisting conditions, surgical procedures, and postoperative medication use were all described with measures of central tendency (mean or median) and dispersion (frequency and percentage) for continuous data. We estimated the frequency of clinical outcomes (i.e., PCI, success/failure, complications, and death) and their associated 95% confidence intervals (CIs). The current version (23.0) of SPSS was used for all of the statistical analysis.

RESULTS

Table 1 displays the patients' baseline characteristics. See Table 1 for details, but in brief, the average age was 64.2 (SD = 11.7), about two-thirds were 60 or older, and nearly 10% were centenarians. There were roughly 70 male patients and over half of all patients were referred cases from other hospitals. The vast majority of patients (62.8%) relied on universal coverage, followed by government services/state-owned companies (26.7%). The average BMI was 24.3 (4.2), and over 60% of people were considered overweight or obese. Nearly half of the patients were either current smokers or former smokers. About two-thirds of the participants in the study reported having hypertension and dyslipidemia. At the time of admission, the average (SD) systolic blood pressure (SBP) was 137.1 (26.8) mmHg, and the average (SD) heart rate (HR) was 76.0 (16.7) bpm. Nearly half (44.2%), and nearly a third (32.5%), of those examined had diabetes or CKD. About a third of the population had a history of CAD, and a quarter of the population had a history of a previous MI. Only 1.6% had undergone a coronary artery bypass graft (CABG) before, while 13.8% were diagnosed with heart failure (HF). Only 5.7% of people reported never having a stroke, while 1.7% had a history of PAD.

Table 1: Demographic and baseline characteristics.

Characteristics	Data
Male gender	15,708 (69.1)
Mean age (years), mean (SD)	64.2 (11.7)
<50 years, number (%)	2,630 (12)
50–59 years, number (%)	5,537 (24)

60–69 years, number (%)	7,351 (32)
70–79 years, number (%)	5,124 (23)
≥80 years, number (%)	2,099 (9)
Refer case, number (%)	12,350 (54.3)
Payment for PCI, number (%)	
Universal coverage	14,349 (63.1)
Civil service	6,106 (26.9)
Social security service	1,557 (6.8)
Self-pay, private insurance, and others	729 (3.2)
BMI (kg/m^2), mean (SD)	24.3 (4.2)
Normal (18.5 to 22.99)	7,505 (33.0)
Underweight (<18.5)	1,474 (6.5)
Overweight (23.0 to 24.99)	5,007 (22.0)
Obese (≥25)	8,753 (38.5)
Admission SBP (mmHg), mean (SD)	137.1 (26.8)
Admission HR (bpm), mean (SD)	76.0 (16.7)
Known CAD, number (%)	7,723 (34.0)
Previous MI (>7 days), number (%)	5,366 (23.6)
Previous PCI, number (%)	6,737 (29.6)
Previous CABG, number (%)	373 (1.6)
Previous CVA/TIA, number (%)	1,296 (5.7)
Prior heart failure, number (%)	3,131 (13.8)
Prior valve surgery/procedure, number (%)	101 (0.4)
Chronic renal failure, number (%)	7,398 (32.5)
Dialysis, number (%)	814 (3.6)
Peripheral arterial disease, number (%)	389 (1.7)
Family history of CAD, number (%)	2,058 (9.0)
Hypertension, number (%)	15,322 (67.4)
Dyslipidemia, number (%)	14,862 (65.4)
Smoking status, number (%)	
Current	5,286 (23.2)
Previous	7,239 (31.8)
Never	10,216 (44.9)
Diabetes mellitus, number (%)	10,050 (44.2)

Most patients (57%) were diagnosed with acute coronary syndrome, which included ST-elevation myocardial infarction (STEMI) in 28.0% and non-ST elevation myocardial infarction (NSTEMI) in 29.9%. While angiography revealed that 26% of patients had single vessel disease, 28% had double vessel disease, and 33% had triple vessel illness, 11% had substantial left main coronary artery stenosis.

Table. 2 Details of PCI protocols. The transfemoral artery was the most common site of initial access (53.7%), while the transradial route accounted for 44.2%. A small percentage of patients (1.9%, to be exact) required more than one vascular access strategy (e.g., bifemoral access), and this was most commonly seen during difficult PCI operations. Fluoroscopy lasted for a median (range) of 12.6 (0.1, 910.0) minutes, while air kerma was 925.0 (80.0, 25810.6) mGy, and dose area product (DAP) was 77.4 (20.0, 2939.0) Gy cm2. It was found that the most common volume of contrast medium administered was 100.0 (10.0, 600.0) ml. In general, 1.1 catheters, 1.6 wires, 2.0 balloons, and 1.5 stents were used per procedure.

Table 2: Procedural details of data collected.

Variables	Data
Indications for PCI, number (%)	
STEMI	6,373 (28)
NSTEMI	6,808 (30)
Stable CAD	9,562 (42)
Clinical settings for PCI, number (%)	
Elective	13,926 (61.2)
Urgent	3,527 (15.5)
Emergent	5,288 (23.3)
Extent of coronary disease	
1-Vessel	6,011 (26.4)
2-Vessel	6,529 (28.7)
3-Vessel	7,495 (33.0)
Left main stenosis >50%	2,706 (11.9)
Access sites, number (%)	
Femoral	12,199 (53.6)
Radial	10,062 (44.2)
Brachial	29 (0.1)
Combination	433 (1.9)
Other	18 (0.1)
More than one attempt for vascular access, number (%)	1,354 (6.0)
Require cross-over of vascular access, number (%)	683 (3.0)
Vascular closure device, number (%)	1,095 (4.8)
Number of treated lesions, mean (SD)	1.2 (0.5)
Number of treated lesions, number (%)	
1	18,059 (79.4)
2	3,925 (17.3)
3	700 (3.1)
4	48 (0.2)
5	9 (0.04)
6	0 (0.0)
Fluoroscopy time, min, median (range)	12.6 (0.1, 910.0)
Air kerma dose, mGy, median (range)	925.0 (80.0, 25810.6)
Dose area product (DAP), Gy.cm^2, median (range)	77.4 (20.0, 2939.0)
Total volume of contrast, ml, median (range)	100.0 (10.0, 600.0)
Type of contrast used, number (%)	
Ultravist	17,069 (75.1)
Optiray	4,504 (19.8)
Visipaque	1,241 (5.5)
Others (Iopamiro, Hexabrix)	24 (0.1)
Cardiogenic shock before PCI	1,812 (8.0)
IABP used, number (%)	772 (3.4)
Other mechanical support, number (%)	14 (0.1)
Number of guiding catheters used, mean (SD)	1.1 (0.4)
Number of guide wire used, mean (SD)	1.6 (1.0)
Number of balloons used, mean (SD)	2.0 (1.4)
Number of stents used, mean (SD)	1.5 (0.9)
Lesion complexity (N = 28,246), number (%)	
A	1,504 (5.4)
B1	4,978 (17.8)
B2	5,617 (20.0)
C	15,946 (56.9)
Lesion length, mm, median (range)	24 (1, 100)
IVUS, number (%)	3,161 (13.9)
FFR, number (%)	451 (2.0)
OCT, number (%)	226 (1.0)
Rotablator, number (%)	489 (2.15)

Patients had PCI performed in 1 lesion on average (79.4%), with a maximum of 5 lesions treated per patient. Most PCI lesions in the Data were categorised as type C lesions (56.9%), and in those cases, 13.9% used intravascular ultrasonography (IVUS), 1.0% used optical coherence tomography (OCT), and 2.0% used fractional flow reserve (FFR). The intra-aortic balloon pump (IABP) and Rotablator were also employed in 3.4% and 2.2% of cases, respectively.

Table. 3 provides information on medication use. Unfractionated heparin (UFH) was the periprocedural anticoagulant of choice for the vast majority of patients (91.3%). Antiplatelet medications were most commonly recommended as aspirin (97.2%), and clopidogrel (92.4%). Ticagrelor (9%).

Table 3: Medications used

Cardiac medications	Data Collected
Aspirin	22,362 (99.2)
Clopidogrel	20,983 (92.4)
Ticagrelor	2,013 (9.0)
Fondaparinux	121 (0.5)
LMWH	2,685 (12.1)
UFH	20,726 (91.3)
GP2 b/3 a inhibitors	1,391 (6.3)
Home medications**	
ACEIs	8,118 (36.7)
ARBs	3,308 (15.0)
Beta blockers	13,655 (61.7)
Statins	20,750 (93.8)
Non-statin lipid drugs	482 (2.2)
ASA	21,743 (98.3)

Clopidogrel	17,852 (80.7)
Ticagrelor	3,181 (14.4)
Vitamin K antagonist	540 (2.4)
NOACs	203 (0.9)

Table. 4 summarizes the results of percutaneous coronary intervention procedures. The operative success rate was as high as 95.2% (94.9%, 95.5%), whereas the complication rate was 5.3% (4.9%, 5.6%) and the in-hospital mortality rate was 2.8% (2.5%, 3.0%). Bleeding was the most prevalent consequence, occurring in 4.8% (4.6%, 5.1%) of patients and necessitating blood transfusions in 1% (0.9%, 1.2%) of those 237 patients. Moreover, the frequencies of heart failure (12.1–12.6%), cardiogenic shock (17.5–8.2%), and myocardial infarction (6.1–6.9%) were, respectively, 11.7–12.6%, 7.9–8.2%, and 5.6–6.1%. Stroke affected just 84 people, or 0.4% (0.3%, 0.5%), and of those, roughly two-thirds suffered ischemic stroke. In-hospital CABG occurred at a 0.3% (95% CI: 0.2%, 0.4%) incidence rate, with a median length of stay of 2 days.

Table 4: Outcomes of PCI and in-hospital events

Clinical outcomes	Data
Procedural success	21,650 (95.2)
Procedural complications	1,199 (5.3)
Vascular complications required treatment	69 (0.3)
Bleeding complications	1,102 (4.8)
Bleeding complication requiring transfusion	237 (1.0)
Myocardial infarction	1,375 (6.1)
Bypass surgery	78 (0.3)
Stroke	85 (0.4)
Ischemic	52 (61.9)
Hemorrhagic	25 (29.8)
Tamponade	36 (0.2)
Cardiogenic shock	1,785 (7.8)
Heart failure	2,758 (12.1)
Renal failure	NA
New onset of dialysis	119 (0.52)
Death	626 (2.8)
Cause of death	
Cardiac death	460 (73.5)
Non-cardiac death	166 (26.5)

Trends and Temporal Changes of PCI Practice and Outcomes: In comparison to the PCI Data from 2006, contemporary practise and clinical outcomes have evolved. Patients in the current data set were on average older (64.2 vs. 62.7%), and more likely to have healthcare universal coverage (63.1 vs. 23.7%), current/ex-smokers (55.0 vs. 41.4%), a history of percutaneous coronary intervention (29.6% vs. 24.7%), chronic renal failure (32.5 vs. 6.6%), and diabetes (44.2 vs. 37.2%), but less likely to be overweight or obese.

Clinical manifestations were also different; the current Datacontained a greater incidence of STEMI/NSTEMI (57.9% vs 51.3%), cardiogenic shock (8.0% vs 6.2%), and left main disease (11.9% vs 4.5%) comparison to the previous Data (see Table 1). In addition, procedures have evolved throughout time, with a smaller percentage of elective cases (61.2% vs 79.0%) and a lower rate of IABP usage (3.4% vs 5.3%), but a higher rate of radial access (44.2% vs 9.4%) and a higher rate of vascular closure devise use (4.8% vs 3.5%) in the present Data. The trend in antiplatelet medicine use had been changed, that is, lower use of Clopidogrel (92.4% vs 96.4%) and Ticlopidine (0.3% vs 7.6%) but higher use of new generation pharmaceuticals, which were not available in the preceding Data in 2006 including Prasugrel (1.7%) and Ticagrelor (9.0%) (see Table 3). Finally, the present approach of PCI obtained a greater success rate (95.2% vs. 92.5% in 2006) in clinical results compared to the old technique in 2002.

DISCUSSION

This information sheds new light on PCI in its current form, including the demographics of patients, the nature of lesions, the tools and medicines used, and the outcomes achieved in Pakistan.

Demographic and Patient Characteristics: Our patients' ages were comparable to those reported for PCI patients in Vietnam [(9)], Korea [(10)], and Hong Kong [(11)], but much higher than those reported for Malaysia [(11)] and Singapore [(11)].

According to the hub and spoke strategy employed by the Ministry of Health of Pakistan, more than half of the PCI patients were referred from other institutions. This could be an indication of the uneven distribution of cardiac catheterization laboratories across the country and the scarcity of cardiac catheterization laboratories in some regions.

These high-risk patients undergoing PCI in Pakistan warrant special consideration. This was in line with the prevalence of diabetic patients in the UK [(13)], the USA [(14)] and Japan [(15)], and Malaysia [(11)], and significantly higher than the overall prevalence of 9.9% in the general population in Pakistan [(12)]. Very high rates of renal insufficiency were found at baseline (32.5%), far greater than those seen in the Data 2006 (6.6%) or in other regions in Brazil (16.5%), Australia (17.5%), or the United States (18.5%). Also, our sample had a much higher rate of cardiogenic shock (8%) and STEMI (28%), both of which were much greater than in other registries.

There was an increase from 14% in 2006 to 28% in 2010 in the percentage of STEMI PCI procedures performed in Pakistan. The government's initiative to build strong STEMI networks across the country may be to thank for this. In this paper, the prevalence of cardiogenic shock prior to PCI rose from 6.2% in 2006 to 8% in 2017. When compared to other national data sets, this was the highest total ever recorded for PCI patients. The prevalence of STEMI and urgent care patients may be to blame for this.

Compared to other registries, the prevalence of multivessel disease was high, affecting around two-thirds of the population. The prevalence of left main illness was recorded at 11.9%, which was close to the most recent report from Vietnam [19] but higher than other registries.

Procedural Details: The percentage of Pakistani households using radial access has grown from 9.4 percent in 2006 to 44.2 percent in 2018-2019, with an accompanying increase in the frequency with which the primary access point is relocated. It's consistent with patterns seen all throughout the world. It has been reported that radial access has increased from 18.16% in 2011 [20] to 56.57% in 2017 [21] according to ANCALAR data from Austria, and from 6.9% in 2010-2011 [18] to 25.2% in 2014 [22] and 44.2% in 2017 [23] according to CathPCI data from the United States. The key rationale driving this worldwide trend towards radial initial vascular access is the well-documented benefits of radial access compared to femoral access. The national recommendations also support radial access, but its clinical efficacy relative to femoral access has yet to be established using local data from any region of the world. Over the coming decade, we anticipate a rise in the frequency of transradial interventions in Pakistan.

Initial vascular access was successful in nearly all cases (97%). Type C ACC/AHA classification was used for 56.9% of PCI procedures, which is higher than the percentages reported by other registries. As compared to other foreign registries, where IVUS use was below 5%, with the exception of the PCI Data from Korea, where IVUS use was above 27%, this may be explained in part by the high rate of IVUS use in our population (13.9%). The Public Health policy of Pakistan, which allowed complete coverage of IVUS in all three major healthcare schemes covering >97% of PCI patients in this Data, is a primary reason for the high IVUS usage in Pakistan. OCT use was also lower than expected but consistent with data from other PCI registries. The high proportion of people with renal failure in this Data may be to blame for this.

Amongst Muslim countries, Pakistan had the highest rotablator usage (2.15 percent). Using a rotablator was recorded in less than 2% of PCI patients in all registries except Japan (3.7% of 15). More than half of the lesions in Pakistan that were treated

required a rotablator, and this was consistent with the high complexity of these lesions.

PCI Outcomes: Our PCI success rate was 95.2%, despite the fact that many of our patients had very difficult lesions to treat. The overall rate of complications was 5.3%, with bleeding being the most prevalent type of problem (4.8%). Due to differences in patient characteristics and definition of bleeding, the incidence of bleeding from earlier registries varied considerably, from 0.3% 15 to more than 10% 25. Our data showed a transfusion rate of 1%, which is low but in line with the 1-2% seen in other registries [10, 18, 25].

Despite an increase in higher risk patients and more complex lesions, the post-PCI stroke rate was not significantly different from the incidence in 2006. The CABG rate after PCI was 0.3%, significantly lower than the 0.8% rate in 2006. This was despite an increase in the number of cardiac surgeons and CABG-capable hospitals across the country. This may be because most PCI facilities are now able to use percutaneous intervention as a rescue bailout method, thanks to advancements in angioplasty technology. Assuming an efficient CABG referral system to a nearby center, this low number may suggest that in-house CABG teams are not essential for the establishment of new PCI centers.

With higher risk patients, the PCI in-hospital mortality rate in Pakistan was 2.8%, which was identical to the rate in 2006. This seems to be greater than the reported in-hospital death rate of around 1% that has been found in various registries [9, 22, 25]. The large proportion of patients with ST-elevation myocardial infarction and cardiac arrest in our Data may account for this. Similar rates of in-hospital death (2.3% vs. 2.2%, respectively) were reported by the Data of Melbourne Intervention Group, Australia, whose data included 17 patients with STEMI (30.1% vs. 30.2%, respectively).

Strength and Limitations: The Data provided a more accurate depiction of how PCI is now being used and the consequences it produces in Pakistan. The data was both comprehensive and precise. Data in this Data were acquired prospectively using well-constructed CRF and eCRF, in contrast to some retrospective registries. All variables and their definitions were standardized, and all principal investigators and their co-investigators were given frequent and in-depth training. In order to catch input mistakes and discrepancies, a specialised web-based data input tool was developed.

The Data had a few caveats. Firstly, like with all PCI registries, participation was entirely optional, and not all hospitals in Pakistan participated in the Data. Thankfully, the majority of the significant PCI hubs consented to take part. The overall number of PCIs in Pakistan was estimated to be around 35,000 during the Data's time period, based on existing literature. A total of 22,741 PCI patients were enrolled in this Data, which is around two-thirds of the total number of PCI procedures performed in the country. Second, some lines of information (such as the percentage of normal coronary angiography, the usage of FFR in non-PCI patients, and the fraction of ad hoc angioplasty) were unavailable because this Data did not gather data of a patient undergoing coronary angiography without PCI. Third, not all parameters' details were acquired because of the Data's heavy load and the nation's already strained services. Furthermore, some of the gathered characteristics (such as lesion length, TIMI flow, and SYNTAX score) were site-reported, and there was no central laboratory for the interpretation of Coronary angiograms.

CONCLUSION

This research of 22,741 patients who had coronary angioplasty was done to shed light on the state of the art and clinical outcomes. Despite the high risk of the patient's baseline characteristics and the high complexity of treated lesions, the success rate was quite high, and the complication rate was very low. Compared to other international data, the proportion of octogenarians with STEMI and cardiogenic shock was higher in this Data. There has also been a significant rise in the use of radial access and coronary imaging for PCI in Pakistan, both of which are on the rise around the world.

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