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Two Decades of Percutaneous Transluminal Coronary Angioplasty Practice by a Single Operator in India: Insights and Long-Term Outcomes

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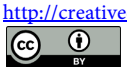

Abstract

Objectives: To explore and analyze a single operator's experience in performing percutaneous transluminal coronary angioplasty (PTCA) with respect to procedural technique, patient characteristics, and procedural outcomes. **Methods**: This retrospective analysis includes follow-up data of 3070 patients who underwent PTCA in Hyderabad, India, between 2000 and 2024. Stent implantation was performed via radial, femoral, or ulnar access with or without the aid of imaging techniques. Bare metal stents (BMS), drug-eluting stents (DES), and bioresorbable vascular scaffolds (BVS) were used to achieve reperfusion. Outcomes including repeat revascularizations, coronary artery bypass graft, and mortality were recorded. Descriptive statistics were used for analysis. **Results**: The mean age of the patients was 58.2 ± 12.1 years and 78.6% were males. Hypertension (66.25%) and diabetes (50.49%) were the most common comorbidities among patients. PTCA was performed in the LAD in 58.44% of patients. Before 2005, BMS was deployed in 100% of the cases. After 2005, there was a temporal shift from BMS to DES where DES was used in 87.3% of the cases, while BMS in 9.6%, and BVS in 0.6%. Overall, DES was the most commonly deployed stent (88.86%) and BMS was deployed only among 10.1% of the patients. The rate of overall mortality and revascularization was 6.55% and 2.08%, respectively. Revascularization (11.6% *vs.* 4.0%) and mortality (17.1% *vs.* 5.9%) were highest with BMS and lowest with DES. Follow-up data of 25% of patients were not recorded. **Conclusion**: This is the first single-operator experience using PTCA with 20-year follow-up data analyzed in India. The findings revealed a declining incidence of repeat revascularization and mortality across 20 years due to evolving stent technologies and operator expertise.

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Keywords

Angioplasty, Coronary Artery Disease, Mortality, Percutaneous Transluminal Coronary Angioplasty, Stents

1. Introduction

Coronary artery disease (CAD) is estimated to be prevalent among 315 million people globally. An 18% decrease in age-standardized prevalence has been reported over a span of 30 years (1990-2022) [1]. On the contrary, the overall prevalence of CAD in India has increased 2.3 times from 25.7 million in 1990 to 54.5 million in 2016 [2]. In the year 2017 alone, 1.2 million new cases of CAD were reported in India [3]. Further, Indians are 2 - 4 times more susceptible to hospitalization due to CAD than other populations [4].

Primary CAD manifestations include acute coronary syndromes (ACS) like unstable angina, non-ST-segment elevation myocardial infarction (NSTEMI), and STEMI [5]. Events such as stroke, heart failure, revascularization, etc., can worsen the quality of life of patients with CAD [6]. Complex clinical assessments to diagnose affected patients also incur a significant burden on healthcare infrastructure [7]. Nevertheless, there has been remarkable progress in the diagnosis and management of CAD. Primary percutaneous coronary intervention (PCI) or percutaneous transluminal angioplasty (PTCA) is the current gold standard treatment for coronary lesions, while coronary artery bypass graft (CABG) is not frequently performed due to higher surgical risks, delayed reperfusion, and reduced prognostic impact [7].

First developed in 1977, PTCA was quickly adopted widely by the 1980s. Initially reliant on balloons for dilatation, within the first two decades of its advent, the procedure evolved rapidly to employ bare metal stents (BMS), which were followed by other procedures like atherectomy and brachytherapy, finally switching to the most recent drug-eluting stents (DES). PTCA, therefore, has evolved to consider patients with complex comorbidities, ACS, and multivessel disease for interventional treatment of coronary lesions. Further, the introduction of stents has reduced the need for CABG [8].

Incomplete myocardial reperfusion has been reported as one of the common operator-related adverse events. Differences in procedural outcomes have been attributed to inter-operator variability, where an approach to treatment concerning the use of medications, type of stenting and imaging, and technical skills of the operator play an important role in procedural success [9]. Additionally, the National Cardiovascular Data Registry reported stable major adverse cardiovascular rates after the 12th case of a single operator, suggesting the role of the operator learning curve for procedural success [10].

In India, there is a lack of a single operator report on the procedural outcomes

and long-term follow-up of PTCA. Through this study, a single operator's experience of performing PTCA for over two decades and the long-term outcomes of PTCA have been presented, highlighting the clinical and technical evolution of PTCA.

2. Methods

2.1. Patient Characteristics

This retrospective analysis includes follow-up data of 3070 patients who underwent PTCA at various hospitals in Hyderabad, India from January 2000 to July 2024. PTCA was performed for different indications such as unstable angina, primary STEMI, non-Q wave myocardial infarction, presyncope, CAD diagnosed by computed tomography (CT), and others as presented in Figure 1. Each patient had one or more indications.

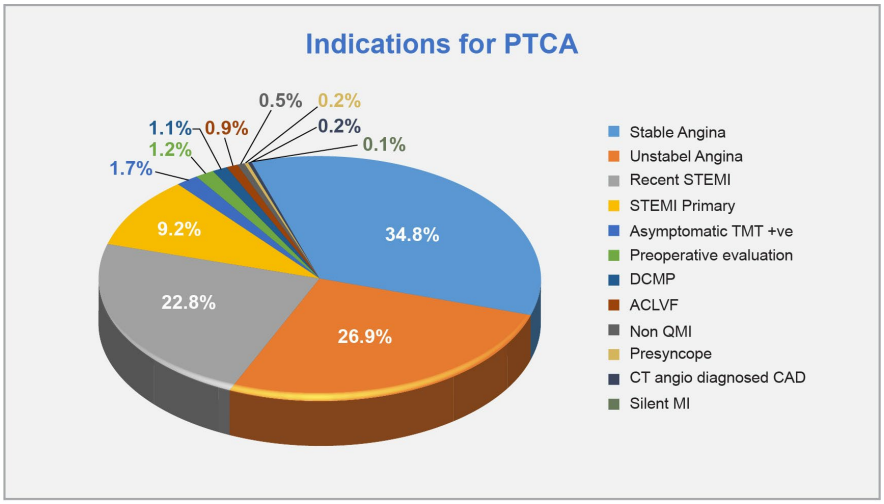

Figure 1. Indications for PTCA.

2.2. Procedure

PCI was carried out under local anesthesia and catheters were inserted via the right or left radial, femoral, or ulnar arteries, guided by various imaging techniques including contemporary methods such as intravascular ultrasound (IVUS) and optical coherence tomography (OCT). Lesion preparation was done using balloon angioplasty including plain balloons, cutting balloon, scoring balloon, or open (OPN) balloon where deemed necessary. Intra-aortic balloon pump (IABP), rotablation, and intravascular lithotripsy (IVL) were among the few recent techniques employed during the PCI. An active clotting time > 250 seconds was maintained. Following balloon inflation, stents were implanted depending on the number of vessels and lesion length. BMS and DES were used. In a few patients, bioresorbable vascular scaffolds (BVS) were used, while in others, plain old balloon angioplasty (POBA) or Drug-coated balloon (DCB) was performed.

After successful PCI, patients were monitored for adverse events in the coronary care unit for 24 hrs. Medications commonly prescribed before the procedure were aspirin 75 mg, clopidogrel 300 mg loading dose, prasugrel 60 mg, ticagrelor 180 mg loading dose, and heparin 5000 IU (70 - 100 IU per kg body weight added additionally during the procedure).

2.3. Clinical Outcomes and Follow-Up

Procedural success was defined as less than 10% residual stenosis. Mortality rates, repeat revascularizations, emergent CABG, and other adverse events across twenty years were recorded.

2.4. Statistical Analysis

Descriptive statistics were used to present the data, where continuous and categorical variables were expressed as mean with standard deviation (SD), and frequency with percentages, respectively. All analyses were performed using R software.

3. Results

3.1. Baseline Characteristics

A total of 3070 patients with a mean age of 58.2 ± 12.1 years underwent PTCA procedure while being treated for CAD. About 78.6% (n = 2413) were males and the remaining 21.3% (n = 654) were females. Among comorbidities, majority of the patients had hypertension (n, %: 2034, 66.25%), followed by diabetes mellitus (1550, 50.49%), and dyslipidemia (496, 16.16%). A few patients (10.6%) had a previous history of myocardial infarction (MI), CABG procedure, and/or PCI as outlined in Figure 2.

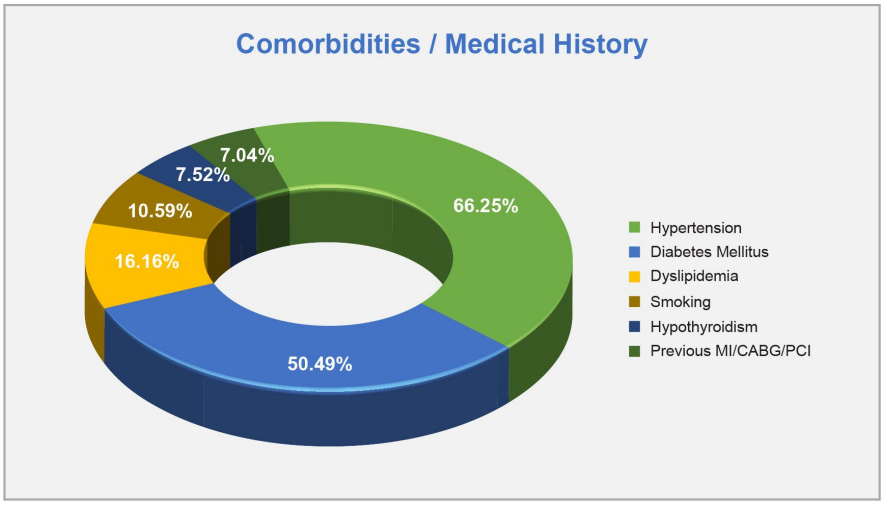

Figure 2. Comorbidities and medical history in the patient that underwent PTCA procedure.

Left ventricular ejection fraction was normal in most of the patients (n = 2284,

74.4%), mildly reduced in 12.18% (n = 374), moderately reduced in 7.13% (n = 219), and severely reduced in 4.66% (n = 143) of the patients.

3.2. Procedural and Angiographic Characteristics

Intracoronary imaging modalities were used in 233 (7.6%) patients OCT constituting 75.5% and IVUS constituting 25.5%) due to late acquisition of equipment by the hospital and affordability issues. PTCA was performed in the left anterior descending (LAD) artery in most of the patients (n=1794, 58.44%) (Figure 3).

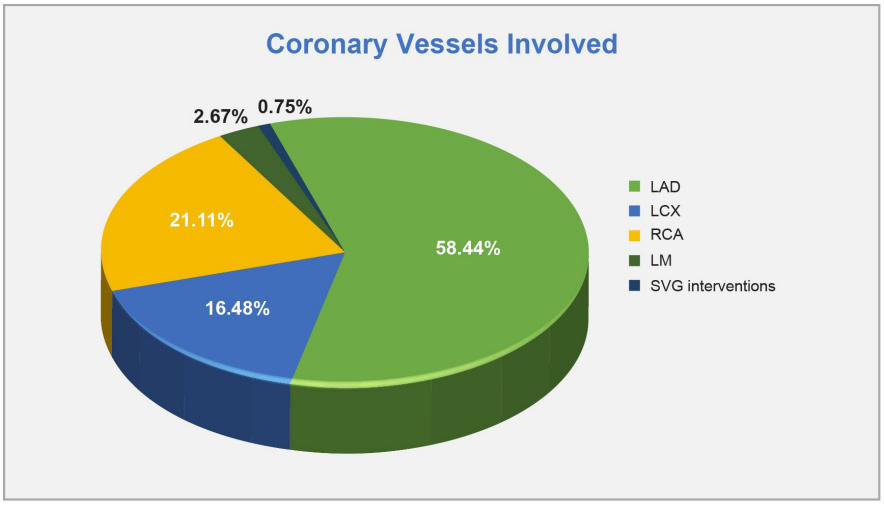

Figure 3. Coronary vessels involved.

Medications:

All patients received antiplatelet therapy following the procedure. About 97.98% (n = 3008) of patients received P2Y12 (purinergic receptor P2Y, G-protein coupled, 12-protein) inhibitors, 0.07% (n = 2) received rivaroxaban (anticoagulant), and all of them were administered aspirin (n = 3070).

Stents:

PCI procedure was performed for 4042 lesions. DES was the commonly deployed stent (3547, 87.75%), and BMS was deployed only among 10.14% (n = 410) of the lesions. IABP was employed in 0.91% (n = 28) patients. With respect to the stent used for index procedure, for vessel 1, DES was used in 86.48% of the patients followed by BMS in 10.03%, POBA in 0.91%, and BVS in 0.65%. Similarly, for vessel 2, DES was used in 27.3% of patients, BMS in 3.22%, POBA in 0.91%, and BVS in 0.10%.

3.3. Clinical Outcomes

Of the clinical outcomes, revascularization was observed in 2.08% (n = 64) of patients. Upon follow-up, the majority of the patients (n = 2099, 68.37%) were living incidence-free from revascularization. The mortality rate was low at 6.55% (n = 201). Follow-up outcomes of 25.02% (n = 768) patients could not be recorded as they were not contactable.

3.4. Trends in the Type of Stents Used Pre- and Post-DES Era

Before the year 2005, BMS was commonly used. After the introduction of DES in India (after 2005), it was predominantly deployed for most cases, followed by other stents including BMS, POBA, DCB, drug-eluting balloons (DEB), and BVS (Table 1).

Table 1. Trends in the type of stents used over time.

Stents used	Before 2005, n (%), N = 16	After 2005, n (%), N = 3054
BMS	16 (100.0)	294 (9.6)
DES	0 (0.0)	2667 (87.3)
DES + BMS	0 (0.0)	19 (0.6)
DES + DCB/DEB/POBA	0 (0.0)	22 (0.7)
BVS	0 (0.0)	20 (0.6)
DCB/POBA	0 (0.0)	32 (1.1)

BMS: Bare metal stent; BVS: Bioresorbable vascular scaffold; DCB: Drug-coated balloon; DEB: Drug-eluting balloon; DES: Drug-eluting stent; POBA: Plain old balloon angioplasty; n (%): frequency (percentage). Data presented as the number of patients with percentages.

3.5. Outcomes Based on Stent Type

Of the individual stent types used, the highest incidence of repeat revascularizations and CABG (11.6%) and deaths (17.1%) was observed with BMS. The lowest incidence was with DES (revascularization and CABG, 4.0%; deaths, 5.9%) (Table 2).

Table 2. Deaths, repeat revascularizations, and CABG based on stent type.

Stent used	No. of patients (N = 3070)	Repeat revascularizations and CABG, n (%)	Deaths, n (%)
BMS	310	36 (11.6)	53 (17.1)
BVS	20	2 (10.0)	2 (10.0)
DES	2667	107 (4.0)	158 (5.9)
POBA	32	2 (6.3)	4 (12.5)
DES + BMS	19	1 (5.3)	7 (36.8)
DES + DCB/DEB/POBA	22	1 (4.6)	2 (9.1)

BMS: Bare metal stent; BVS: Bioresorbable vascular scaffold; CABG: Coronary artery bypass graft; DCB: Drug-coated balloon; DEB: Drug-eluting balloon; DES: Drug-eluting stent; POBA: Plain old balloon angioplasty.

3.6. Trends in Clinical Outcomes across Cohorts of Patients

The outcomes were roughly assessed across 3070 patients with 1000 patients in each of the three cohorts. A declining incidence of repeat revascularizations and mortality was observed in the second and third cohorts of patients (Figure 4).

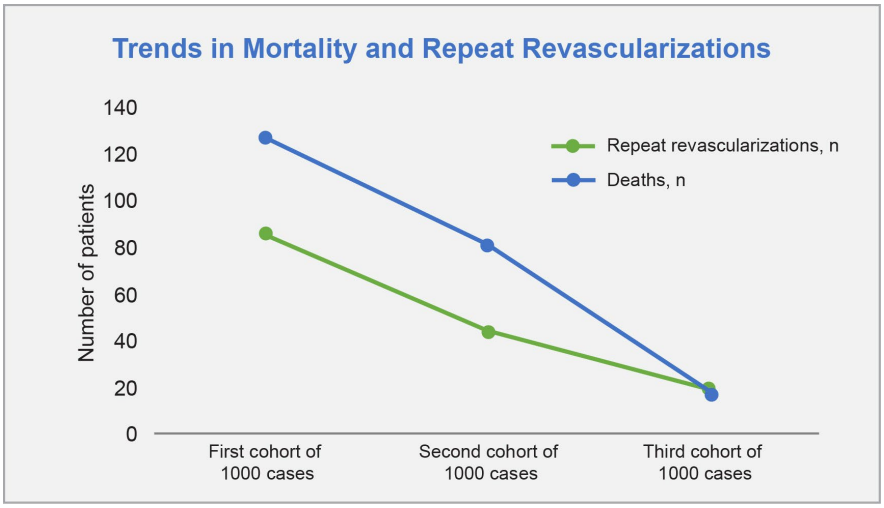

Figure 4. Trends in mortality and repeat revascularizations with time (first, second, and third cohorts of 1000 cases each).

4. Discussion

The present study provides valuable insights into the evolution of PTCA over a span of 24 years and a single operator's experience with PTCA. The study highlights the progressive improvement of stent technology, as evidenced by the transition from BMS and POBA to modern stent systems including DES and BVS, and its impact on clinical outcomes. Furthermore, this study is the first in India to analyze a single operator's experience of PTCA with a substantial follow-up rate of nearly 75%. The analysis also reveals a declining trend in both repeat revascularizations and mortality with a lower incidence among the most recent cohort of patients.

The evolution of interventional cardiology has been well-documented in the literature [11] [12]. Balloon angioplasty was the minimally invasive approach used initially for the management of narrowed vessels. However, limitations such as abrupt vessel closure and restenosis led to the development of BMS. BMS offered structural support to prevent abrupt vessel closure, but it had its limitations with an increased risk of in-stent restenosis that resulted in failed stent placement or the need for reintervention using another stent [12]. To address these challenges, DES was introduced in the early 2000s, which consisted of a stent scaffold that delivered antiproliferative drugs locally [11]. DES is proven for its efficacy and long-term safety with low risk of thrombosis and improved revascularization [13] [14]. Recently, BVS has been introduced with the advantage of stenting followed by gradual dissolution of the scaffold aimed at reducing long-term complications that may arise due to metal implants. Despite the improved compatibility, a few disadvantages of BVS with respect to poor healing and deliverability, platelet deposition, and risk of scaffold fracture have been reported, necessitating further refinement in improving stent technology [11] [12]. Nevertheless, the changing landscape of stent technologies has improved clinical outcomes, which was also evident in the current analysis, where newer generation stents such as DES im-

proved long-term survival with a decrease in repeat revascularizations, CABG, and mortality compared to older techniques such as POBA and BMS.

In the present analysis, the use of DCB/DEB along with DES resulted in lower rates of revascularization and mortality compared to traditional POBA and BMS. Decreased all-cause mortality rates (2.4% *vs.* 3.9%) and target lesion revascularization (3.5% *vs.* 8.6%) with DES compared to BMS have been reported previously [15]. This was in line with the findings of the present study, where revascularization (4.0% *vs.* 11.6%) and mortality (5.9% *vs.* 17.1%) were lower with DES than BMS. On the contrary, comparable follow-up outcomes with respect to survival, but varying rates of revascularization at 5-year follow-ups have been previously reported for BMS and DES in the MISSION! and the Norwegian Coronary Stent (NORSTENT) trials [16] [17]. The MISSION! trial revealed comparable survival rates (94.3% with DES and 92.8% with BMS; $p = 0.57$) and clinically driven target lesion revascularization (6.6% with DES and 9.5% with BMS; $p = 0.30$) [16]; and the NORSTENT trial reported a non-significant difference in composite of death between DES and BMS (16.6% *vs.* 17.1%; $p = 0.66$) but a significantly higher rate of revascularization with BMS compared to DES (19.8% *vs.* 16.5%; $p < 0.001$) [17]. Further, a recent retrospective study from India reported similar rates of freedom from repeat revascularization ($p = 0.97$), in-stent restenosis ($p = 0.36$), and all-cause mortality ($p = 0.69$) among patients who received either BMS or DES after 5, 10, and 14-year follow-up [18]. DCBs consist of a lipophilic matrix with antiproliferative drugs directly carried to the vascular wall eliminating the need for a polymer or metallic implants [19]. They are non-inferior to DES in terms of major adverse cardiac events (MACE) but are associated with higher rates of repeat revascularization while being superior to POBA [20] [21]. They are potential alternatives to DES, offering the advantage of avoiding in-stent restenosis, stent thrombosis, or vessel damage [19]. Although a recent observational study conducted in India demonstrated the safety and efficacy of DCB (paclitaxel and sirolimus) in patients with in-stent restenosis [22], larger comparative studies are needed to establish the long-term safety and efficacy of DCB among the Indian population. Furthermore, BVS was deployed in 20 patients in the current analysis and a revascularization and mortality rate of 10% was noted, which was further higher than those who received DES. Although BVS offers improved compatibility without any metal residue, previous studies have reported a higher incidence of target lesion revascularization (16.3% *vs.* 13.7%) [23] and MACE (21.4% *vs.* 12.9%) compared to DES [24].

There are very few studies in the literature that report PCI outcomes for up to 10 to 20 years, primarily because long-term data collection is challenging. The Synergy between PCI with Taxus and Cardiac Surgery (SYNTAX) and the Bypass Angioplasty Revascularization Investigation (BARI) trials have recorded the 10-year follow-up of patients who underwent CABG *vs.* PCI [25] [26]. The SYNTAX trial recorded higher but non-significant all-cause death at 10-year follow-up with PCI compared to CABG (28% *vs.* 24%; $p = 0.066$); the BARI trial reported similar

survival rates with CABG (73.5%) compared to PTCA (71%), but a significantly higher incidence of repeat revascularization was noted with PCI than CABG (76.8% *vs.* 20.3%) [25] [26]. A higher 5-year incidence and adjusted risk for death, MI, and stroke with PCI (34.5%) compared to CABG (24.1%) was also reported by the Clopidogrel for the Reduction of Events During Observation (CREDO)-Kyoto registry [27]. While the present study design was not comparative, the mortality rate recorded with PTCA over a span of two decades was low at 6.55%. However, nearly 25% of the patients were lost to follow-up, which might slightly impact the survival/mortality rates.

The Swedish Coronary Angiography and Angioplasty Registry (SCAAR) reported a decreasing trend of 1-year mortality after PCI adjusted for age and indication over the course of 20 years from 1990 to 2010 [28]. Similarly, in the present study, a declining trend of mortality and repeat revascularizations were observed with time.

Diabetes is considered an independent predictor of mortality after coronary stenting [29] [30]. The presence of both diabetes and hypertension is associated with poor prognosis compared to either condition alone in patients undergoing coronary interventions [30]. Moreover, prediabetes and higher low-density lipoprotein levels are also considered independent risk factors for MACEs and repeat revascularizations after PCI [31] [32]. In the present study, more than half of the patients had comorbid conditions such as diabetes and hypertension, which may also have been the driving factors of repeat revascularization or mortality following PTCA. The BARI and the Future Revascularization Evaluation in Patients with Diabetes Mellitus: Optimal Management of Multivessel Disease (FREEDOM) trial reports CABG to be a better approach than PCI for patients with diabetes, offering a better survival rate and freedom from MI, nevertheless, the 5-year stroke rates were lower with PCI (2.4%) compared to CABG (5.2%) procedure [26] [33].

The nature of the current analysis offers a unique perspective of a single operator's experience of PTCA and its outcomes. Over the two decades, the decline in mortality and repeat revascularization rates may also be attributed to the operator's growing proficiency and expertise. The impact of early career interventionalists on predicting mortality risk and other complications, compared to their experienced counterparts, has been previously reported [34] [35]. A ten-year follow-up data of complex PCI performed by experienced *vs.* less experienced operators reported a significantly lower risk of cardiac death or target vessel myocardial infarction. Operator experience was reported as an independent predictor of cardiac death [36]. The incidence of in-hospital mortality and MACE decreased with increasing operator experience with a learning curve of 12 cases, following which the incidence is said to remain stable [10]. As observed in the present study, improving consistency and reducing variability in procedural approaches may contribute to favorable outcomes. Additionally, since the procedures were conducted across different centers, variations in infrastructure, equipment, hospital guidelines, and supporting team dynamics could influence procedural outcomes. Furthermore, no single study perfectly tracks 20-year PCI outcomes; studies like the

present analysis and a few real-world registries like SCAAR provide a close approximation. Long-term follow-up remains challenging due to patient attrition, evolving techniques, and changes in medical therapy.

Limitations

The study has limited generalizability, as the outcomes reflect the performance and experience of a single operator and can differ depending on the operator's skill levels and training. The follow-up data for nearly 25% of the patients were not recorded. Additionally, since electronic medical records were introduced only a decade ago, the dependency on older medical records may have introduced some inaccuracies in the data.

Multi-operator comparisons to understand the difference in outcomes and prospective studies focusing on the learning curve of early career interventional cardiologists could provide insights into their clinical skills. Although all procedures were performed by a single operator, they were conducted across different centers, which may have introduced variability in resources and facilities. Intracoronary imaging guidance was employed in fewer than 8% of the procedures. Additionally, based on the skillset and gaps, training programs can be introduced as part of a professional course. Further, long-term follow-up studies assessing the safety and effectiveness of new-generation stents and BVS are necessary.

5. Conclusion

This study presents a single operator experience involving a large cohort of patients with CAD who underwent PCI in India, with follow-up extending over two decades. The findings demonstrate a progressive decline in repeat revascularization rates and all-cause mortality over 20 years, likely attributable to advancements in stent technology and the refinement of procedural expertise.

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Author's Contributions

All activities related to this publication are performed by me.

Conflicts of Interest

The authors declare no conflicts of interest regarding the publication of this paper.

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