ONE-YEAR CLINICAL OUTCOMES IN INDIAN PATIENTS UNDERGOING PRIMARY PERCUTANEOUS CORONARY INTERVENTION WITHOUT ON-SITE SURGICAL BACKUP

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ABSTRACT

BACKGROUND

Primary Percutaneous Coronary Intervention (PCI) has emerged as a relatively safe treatment option for acute ST elevation myocardial infarction. However, performing primary PCI at centres without surgical backup has been controversial. To the best of our knowledge, no such data has been available that represents outcomes in Indian population.

Thus, this study aims to present one year clinical outcomes in Indian patients undergoing primary PCI without on-site surgical backup.

MATERIALS AND METHODS

This was a retrospective, single centre, observational study. The study population included 192 patients, who underwent primary PCI from February 2014 to July 2015. The primary endpoint was rate of Major Adverse Cardiac Events (MACE), an agglomerate of cardiac death, myocardial infarction and Target Vessel Revascularisation (TLR) at one year after procedure.

RESULTS

The mean age of population was 57.2 years where 86.5% were males, 35.4% were diabetics and 22.4% were hypertensives. There were six cardiac deaths at 30-day follow-up and 6 (3.1%) cardiac deaths and 4 (2.1%) events of TLR at one-year follow-up.

CONCLUSION

In light of these results, it can be concluded that primary PCI can be performed safely at PCI centres without on-site surgical backup, especially in developing countries like India.

KEY WORDS

Coronary Artery Disease, Percutaneous Coronary Intervention, ST Elevation Myocardial Infarction.

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BACKGROUND

Acute ST elevation Myocardial Infarction (AMI) has been one of the major causes of death throughout the world, especially in developing countries. At inception, the procedure of balloon angioplasty for treatment of CAD was time consuming as well as associated with augmented rate of complications. Therefore, it mandated the requirement of emergency coronary artery bypass graft surgery (CABG) at the site of angioplasty.[1] However, with the elapse of time the development of new generation stents have led to decrease in reperfusion time, thus resulting in decreased infarct size and reduced incidence of Major Adverse Cardiac Events (MACE). Advancement in interventional cardiology techniques, equipment and pharmacology has contributed towards such diminution of complications, thus leading to reduction in need for emergency CABG at Percutaneous Coronary Intervention (PCI) centres.[2] Due to finesse in operators and facilities, the requirement of emergency CABG during PCI has been limited to only 0.3 to 0.6% of total cases.[1,3]

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On the darker side, 2004 American College of Cardiology/ American Heart Association practice guidelines for ST Segment Elevation Myocardial Infarction (STEMI) had recommended Class IIb for primary PCI in centres without cardiac surgery.[4] The 2011 ACCF/AHA/SCAI guidelines has suggested that primary PCI can be performed in hospitals without on-site surgical back-up, only with apt planning for program development (Class IIa).

However, without a proper plan for prompt shifting to a nearby cardiac surgery hospital or without suitable haemodynamic support capability for transfer, the guideline has recommended Class III.[5] Despite conflicting literature, the number of PCIs performed at centres without on-site surgical backup have been progressively increasing through years, such that several studies have been performed to compare the safety and effectiveness of PCI at PCI centres without on-site surgical backup and those with on-site CABG backup.[6-13] These studies reported no significant difference in outcomes of PCI between both centres at various follow-up periods. However, to the best of our knowledge, none of such study has been reported in India. Thus, this study aimed to present one-year clinical outcomes in Indian patients undergoing primary PCI without on-site surgical backup.

MATERIALS AND METHODS

Study design and patient's population.

This was a retrospective, single centre, observational study which included 192 patients who underwent primary

PCI at our institute between February 2014 and July 2015. Baseline demographics, cardiac history and angiographic data were collected from patient's medical records and follow-up data were recorded prospectively. Before the discharge of the patient from the hospital, data release consent was taken from every patient, irrespective of any study to be conducted in future. The study has been approved by the Institutional Ethics Committee.

Patients admitted with acute ST elevation myocardial infarction were included in the study. Patients with significant co-morbidities like severe renal or liver impairment with contraindications for dual antiplatelet therapy for one year with major or advanced malignancies which limit the longevity of life and those who refused to give informed consent were not included in the study.

Endpoints of the Study

The primary endpoint of the study was occurrence of MACE, an agglomerate of cardiac death, myocardial infarction and target vessel revascularisation at one year after primary PCI. Furthermore, the occurrence of stent thrombosis was also evaluated. Any death because of MI, low-output failure, fatal arrhythmia, unwitnessed death and death due to unknown reason and all procedure-related deaths, encompassing those associated to concomitant treatment were categorised as cardiac death.[14] The MI was described as increase of cardiac troponin (cTn) levels {>5 × 99th percentile of Upper Reference Limit (URL)} in patients with normal baseline levels (≤ 99th percentile URL) or rise of cTn levels > 20% when baseline values are high and stable or decreasing.[15] Pathological Q-waves are defined with reference to amplitude, location and depth in minimum two contiguous leads. A TLR was referred to restenosis within stent or within 5 mm distal or proximal segment.[14]

PCI Procedure

The PCI was performed by a standard percutaneous technique through the radial or femoral artery. Aspirin (325 mg upon arrival and then 100 mg daily), clopidogrel (loading dose of 300 or 600 mg and then 75 mg daily) were administered to every patient and an IV bolus of unfractionated heparin (100 U/kg body weight or 60 U/kg body weight if also GP IIb/IIIa inhibitors was given) was also given. The choice of treatment modality between Drug-Eluting Stent (DES) versus Bare Metal Stent (BMS) or Plain Old Balloon Angioplasty (POBA) and the use of an intra-aortic balloon pump or glycoprotein IIb/IIIa inhibitors was left to the discretion of the interventional cardiologist. Moreover, thrombectomy was performed in each patient.

Follow-Up

Follow-up data up to one-year post PCI were collected through the medical records, clinical visit to hospital or telephonically. Follow-ups were carried out to establish the major cardiac adverse events at 30 days, 6 months and one year.

Statistical Analysis

Means and Standard Deviations (SD) were calculated for quantitative variables. Categorical variables were reported as counts and percentages. Cumulative incidences of events were calculated using Kaplan-Meier method. All statistical analyses were completed using the Statistical Package for Social Sciences Software (Version 15.0, SPSS, Chicago).

RESULTS

Out of 192 patients, 166 (86.5%) were males and mean age of all patients was 57.2 years. Sixty-eight (35.4%) patients were diabetics and 43 (22.4) were hypertensives. The average ejection fraction was 50.6 ± 11.0%. Glomerular filtration rate was less than 60 mL/min/1.73 m^2 in 20 (10.4%) patients. The baseline characteristics have been detailed in Table 1.

There were total 195 lesions in 192 patients, of which 102 (52.3%) lesions were located in left anterior descending artery, 70 (35.9%) in right coronary artery, 22 (11.3%) in left circumflex artery and 1 (0.5%) in left main artery. Forty-nine (25.5%) patients had triple vessel disease (Table 2). Right femoral route was the most preferred approach for PCI (97.9%). Direct stenting was performed in 26 (13.3%) lesions. Drug Eluting Stents (DES) were implanted in 143 (73.3%) lesions, BMS in 25 (12.8%) and POBA was performed in 27 (13.8%) lesions. TIMI 3 flow was achieved in 182 (93.3%) lesions (Table 3).

Six (3.1%) cardiac deaths occurred within 30 days of procedure. At one-year follow-up MACE rate was 5.2%, which included 6 (3.1%) cardiac deaths and 4 (2.1%) TLR. There were total 4 incidences of stent thrombosis at one year follow-up (Table 4). Kaplan-Meier curve for cumulative incidences of cardiac deaths and MACE at one year have been depicted in Figure 1 and Figure 2.

Characteristics	Patients (N= 192)
Age (mean ± SD, years)	57.2 ± 12.1
Male, n (%)	166 (86.5%)
BMI (mean ± SD, kg/m^2)	21.8 ± 1.8
SBP (mean ± SD, mmHg)	138.6 ± 33.1
DBP (mean ± SD, mmHg)	83.5 ± 16.5
Random Blood Sugar (mean ± SD, mmol/L)	174.6 ± 79.8
Diabetes mellitus, n (%)	68 (35.4%)
Hypertension, n (%)	43 (22.4%)
Hypercholesterolaemia, n (%)	5 (2.6%)
Smoking, n (%)	37 (19.3%)
Cardiogenic shock, n (%)	7 (3.6%)
Complete heart block, n (%)	11 (5.7%)
VT or VF, n (%)	8 (4.2%)
AF, n (%)	2 (1.0%)
Ejection fraction (mean ± SD, %)	50.6 ± 11.0
Reinfarction, n (%)	3 (1.6%)
Bleeding, n (%)	4 (2.1%)
Renal insufficiency at screening, n (%)	12 (6.3%)
Cerebral vascular accident, n (%)	1 (0.5%)
Pericarditis, n (%)	1 (0.5%)
LVF pulmonary oedema, n (%)	5 (2.6%)
GFR < 60 mL/min/1.73 m^2, n (%)	20 (10.4%)

Table 1. Baseline demographic characteristics of Patients

BMI- Body Mass Index, SBP- Systolic Blood Pressure, DBP- Diastolic Blood Pressure, VT- Ventricular Tachycardia, VF- Ventricular Fibrillation, AF- Atrial Fibrillation, LVF- Left Ventricular Failure, GFR- Glomerular Filtration Rate.

Characteristics	Patients (N= 192) / Lesions (N= 195)
Myocardial Infarction	
STEMI, n (%)	192 (100%)
Target Vessel	
LM, n (%)	1 (0.5%)
LAD, n (%)	102 (52.3%)
LCX, n (%)	22 (11.3%)
RCA, n (%)	70 (35.9%)
Number of Diseased Vessel	
SVD, n (%)	76 (39.6%)
DVD, n (%)	67 (34.9%)
TVD, n (%)	49 (25.5%)
Table 2. Lesion characteristics of Patients	

STEMI- ST-Elevation Myocardial Infarction, LM- Left Main, LAD- Left Anterior Descending Artery, LCX- Left Circumflex Artery, RCA- Right Coronary Artery, SVD- Single Vessel Disease, DVD- Double Vessel Disease, TVD- Triple Vessel Disease.

Characteristics	Patients (N=192)
Right femoral approach, n (%)	188 (97.9%)
Right radial approach, n (%)	4 (2.1%)
Intra-aortic balloon pump, n (%)	2 (1.0%)
Procedure time (mean ± SD, mm)	67.0 ± 23.9
Fluoroscopy time (mean ± SD, mm)	52.6 ± 21.8
Direct stenting, n (%)	26 (13.3%)
Temporary pacemaker implant, n (%)	26 (13.5%)
Stent	
BMS, n (%)	25 (12.8%)
DES, n (%)	143 (73.3%)
POBA, n (%)	27 (13.8%)
Average stent length (mean ± SD, mm)	25.3 ± 7.1 mm
Average stent diameter (mean ± SD, mm)	3.2 ± 0.3 mm
Post TIMI flow	
TIMI 0, n (%)	0 (0%)
TIMI 1, n (%)	5 (2.6%)
TIMI 2, n (%)	8 (4.1%)
TIMI 3, n (%)	182 (93.3%)
Table 3. Procedural characteristics of Patients	

POBA- Plain Old Balloon Angioplasty, BMS- Bare Metal Stents, DES- Drug Eluting Stents, TIMI- Thrombolysis In Myocardial Infarction.

Clinical Outcomes	At 30 Days Follow-up	At 6 Months Follow-up	At 1 Year Follow-up
Death from any cause, n (%)	6 (3.1%)	6 (3.1%)	7 (3.6%)
Cardiac death, n (%)	6 (3.1%)	6 (3.1%)	6 (3.1%)
Non-cardiac death, n (%)	0 (0%)	1 (0.5%)	1 (0.5%)
Myocardial infarction, n (%)	0 (0%)	0 (0%)	0 (0%)
Target lesion revascularisation, n (%)	1 (0.5%)	3 (1.6%)	4 (2.1%)
Target vessel revascularisation, n (%)	3 (1.6%)	5 (2.6%)	9 (4.7%)
Stent thrombosis, n (%)	2 (1.0%)	2 (1.0%)	4 (2.1%)
Major adverse cardiac events, n (%)	7 (3.6%)	9 (4.7%)	10 (5.2%)
Table 4. Clinical outcomes of 192 patients after Primary PCI			

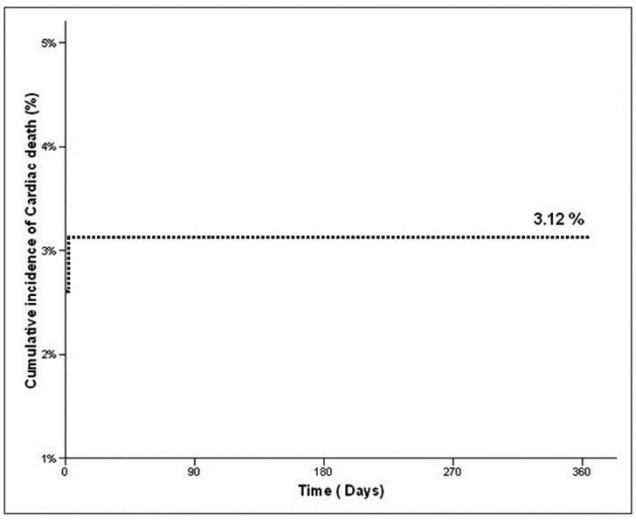

Figure 1. Cumulative Incidence of Cardiac Death upto 1 Year

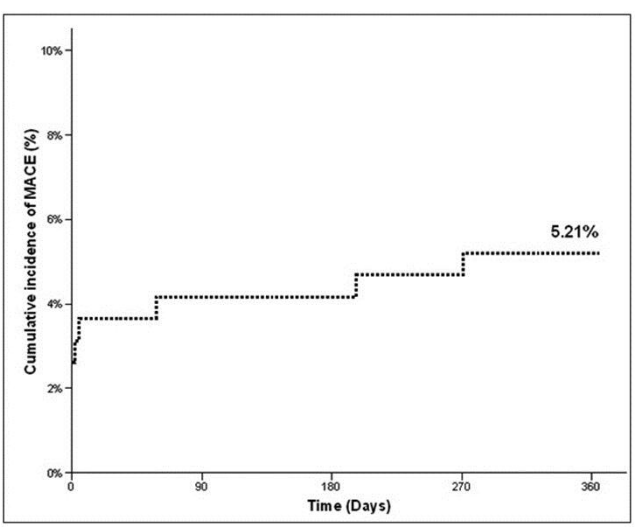

Figure 2. Cumulative Incidence of MACE at 1 Year

DISCUSSION

The developments in PCI have been a crucial boon as these have eliminated the complications due to balloon angioplasty, thus leading to wane the role of surgical backup. Major concern related to PCI without on-site surgical backup was the early mortality rate, i.e. in-hospital mortality and 30-day mortality rate. Various studies have compared the early mortality rates at on-site PCI centres and centres without on-site surgical backup. Recently, Koolen et al had compared MACE rates between the off-site PCI and on-site PCI procedures at 30 days and 6 months follow-up. Cardiac deaths within 30 days for the off-site PCI group and on-site PCI group were 2.3% and 1.8%, respectively (p= 1.000). While, the cardiac deaths at six months were 2.4% and 1.8%, respectively.[16] However, there are studies which have reported range of in-hospital deaths without surgical backup

to be widespread between 4% and 9.8%.[9,17] A study in United Kingdom had reported the favour of off-site surgical cover in terms of 30-day mortality (HR: 0.87; 95% CI: 0.71 - 1.06; p= 0.16) and at 1 year mortality (HR: 0.92; 95% CI: 0.71 - 1.06; p= 0.26) in patients with any indication, but lacked statistical significance.[18] Similarly, a report from National Cardiovascular Data Registry had stated observance of similar procedure's success, morbidity, emergency cardiac surgery rates and mortality in PCI centres without on-site surgical backup and in cases that required emergency surgery.[19] In a meta-analysis, Simard T et al had observed that primary PCI as well as elective PCI could be performed safely at PCI centres without on-site surgical backup, without an increase in mortality rates or other complications.[2] In present study, the mortality rate at 30 days was 3.1%, which was parallel to the results of clinical trials for primary PCI which represent early death rates of < 5%.[20-22] While the real world registries (irrespective of on-site procedures or procedures without on-site surgical backup) exhibit higher mortality rates ranging from 7% to 10.5%.[23-25] Thus, it can be conferred that the availability of surgical backup does not chiefly affect the early mortality rates.

Furthermore, the literature states that coronary reperfusion should be achieved at the earliest as mortality is closely allied to the time delay between symptom onset and reperfusion.[26] Thus, mortality has been a major dependent of time delay rather than availability of surgical backup. In view of this, a door-to-balloon time of ≤ 90 mins is recommended to achieve optimal results.[27] Accordingly, in developing countries like India where it has been difficult for rural population to reach out at the hospitals during emergency, in such cases the availability of PCI centres at community hospitals without on-site surgical backup would be of immense benefit in terms of avoiding delay in reperfusion time. Establishment of such PCI centres will enable more patients to utilise the benefits of PCI. On the other hand, taking into consideration the finesse of operator and patient's selection is also equally important, such that the patients could get full benefit of the facilities.

Limitations

There are some limitations of this study. First of all, it lacks a comparative arm. Secondly, this study represents a retrospective data. Third, the data are derived from a single centre.

CONCLUSION

In light of these results, it can be concluded that primary PCI can be performed safely at PCI centres without on-site surgical backup, especially in developing countries like India. However, adequate facilities at centres, availability of skilled operators and apt patient selection must be taken into consideration.

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