

Primary Percutaneous Coronary Intervention in Elderly Patients with Acute Myocardial Infarction: A Single Centre Experience from Southern India

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ABSTRACT

Introduction: Due to increasing life expectancy, the elderly population is constantly rising globally and the number of older patients presenting with Acute Coronary Syndrome (ACS) and Acute Myocardial Infarction (AMI) is also on the rise. The treatment of choice for patients suffering from acute ST Elevation Myocardial Infarction (STEMI) is Primary Percutaneous Coronary Intervention (Primary PCI). However, Primary PCI in elderly patients is thought to carry higher mortality and morbidity when compared to general population due to multiple co-morbidities and other factors.

Aim: To evaluate the clinical outcomes of Primary Angioplasty in Myocardial Infarction (PAMI) in elderly south Indian patients, attending a single center.

Materials and Methods: This was a retrospective, non-randomised, single center observational study, conducted at a tertiary care centre in southern India, between January 2015 and December 2017. Consecutive elderly patients (aged ≥ 65 years) who underwent primary angioplasty for acute STEMI were studied. The clinical endpoint of cumulative incidence of Major

Adverse Cardiac Events (MACE), which included composite of cardiac death, Myocardial Infarction (MI) and Target Vessel Revascularisation (TVR) were analysed. The MACE during one, six and twelve months follow-up after procedure was noted as documented in the hospital records.

Results: The mean age of 103 patients was 79.23 ± 3.61 years, and 67% (69) patients were males. Amongst those enrolled patients, 58.3% (60) were hypertensive and 50.5% (52) were diabetic. Single vessel disease was present in 57.3% (59) patients and 30.1% (31) patients had isolated Left Anterior Descending (LAD) artery lesion and 53.4% (55) had combined LAD and one other vessel lesions. At 12th month follow-up, the cumulative incidence of MACE was 8.73% (9) in the form of cardiac deaths 7.77% (8) and TVR 0.97% (1). There were 3.88% (4) patients who suffered stroke.

Conclusion: The lower rate of MACE reported in the present study implies that, for the management of AMI in elderly patients, the primary angioplasty is advantageous and can be performed safely.

Keywords: Acute coronary syndrome, Major adverse cardiac events, Primary angioplasty in myocardial infarction

INTRODUCTION

The terms "elderly" or "older adults" usually reflects persons aged 65 years or above; and World Health Organisation (WHO) defines "elderly" as persons above 65 years of age [1]. The elderly population account for 5.7% of the total population of India as per 2011 census report by Govt of India. Both the share and size of elderly population is increasing over time, from 5.6% in 1961 and it is projected to rise to 12.4% of population of India by the year 2026 [2].

According to American College of Cardiology and American Heart Association (ACC/AHA) guidelines, elderly population is considered to be at higher risk for the development of Acute Coronary Syndrome (ACS) [3]. The higher prevalence, increased severity of coronary artery disease associated with higher mortality and morbidity in elderly patients may be due to advancing age, frailty, atypical presentation, undiagnosed or subclinical vascular disease, socio-economic and psychosocial issues. Additionally, co-morbidities like hypertension, diabetes, and lipid abnormalities are also more prevalent among elderly patients [4,5].

Despite the fact that the elderly population is growing, the number of elderly patients in ACS trials has not increased until 2000 [6-8]. The reason behind under representation of elderly patients in clinical trials could be due to perceived poor outcomes i.e., early mortality and morbidity and opting for less invasive management such as Medical therapy. Reasons for early mortality and morbidity

in elderly could be secondary to advancing age, frailty, multiple associated co-morbidities such as diabetes mellitus, hypertension, dyslipidemia, extensive coronary artery disease, increased calcification, late presentation due to various reasons and more prevalence of cardiogenic shock [9-12].

To date, no indicative treatment is available for elderly patients suffering from Acute Myocardial Infarction (AMI). The choice between fibrinolytic therapy and primary angioplasty is determined by the presence or absence of cardiogenic shock, time of presentation, and associated co-morbidities, which often tip the balance towards PCI in the elderly [13].

Previous retrospective studies showed that primary Percutaneous Coronary Intervention (PCI) can be considered as the treatment of choice in ST Elevation Myocardial Infarction (STEMI) patients [14-16]. Hence, the proportion of elderly patients opting for primary PCI is increasing [17,18]. Additionally, real-world trials, registries and retrospective studies have documented an extensive array of co-morbidities in the elderly [19]. Therefore, the current study was undertaken to evaluate the clinical outcomes after Primary Angioplasty in Myocardial Infarction (PAMI) in elderly patients.

MATERIALS AND METHODS

Study Design and Patient Population

This was a retrospective, non-randomised, single-center observational study conducted at a tertiary care center in Southern

India (JSS Medical College Hospital, Mysuru, Karnataka), from January 2015 to December 2017. Consecutive elderly patients (aged ≥ 65 years) who underwent primary angioplasty to treat AMI were evaluated in the study.

Patients presenting with symptoms and signs of STEMI with or without cardiogenic shock who underwent primary angioplasty were analysed. Patients who did not give consent, those not offered, those who opted for medical management including fibrinolytic therapy were excluded from the study. The study protocol was reviewed and cleared (Vide Letter No. JSSMC/IEC/1401/21NCT/2019-20) by the institutional ethics committee and an informed consent was obtained by the patient/relative for utilisation of data for research purposes.

Procedure and Data Collection

The detailed history, clinical parameters, associated co-morbidities, previous interventions, medications and baseline demographic data were noted retrospectively as per the admission records available with the hospital. The PCI procedural details such as the femoral or radial approach according to the operator's preference and patient factors as per current standard guidelines, the choice and number of stents, intracoronary glycoprotein IIb/IIIa receptor inhibitors/nicorandil/nitroglycerine or any other medication usage, Temporary Pacemaker Insertion (TPI) and use of intra-aortic balloon pump according to the indication and discretion of the operator in a given patient was noted as in the records. Coronary angiographic lesions were categorised into three types based on ACC/AHA classification [20].

1. Type A lesions-Discrete, concentric lesions with easy access, in non-angulated segment (<45 degree), smooth contour, little/no calcification, non-ostial location, and absence of total occlusion, absence of major branch involvement, and no thrombus. Risk of abrupt vessel closure is low. Anticipated success rate $>85\%$.
2. Type B lesions- Tubular lesions, eccentric, location-moderately angulated segment, moderate or severe calcification, presence of thrombus, ostial location, bifurcation lesions. Risk of abrupt vessel closure is moderate. Anticipated success rate 60-85%.
3. Type C lesions- Diffuse disease (>2 cm length), more tortuous proximal segment, location- extremely angulated segment (>90 degree) or total occlusion. Anticipated success rate $<60\%$.

Post procedure Thrombolysis in Myocardial Infarction (TIMI) flow grades were noted as mentioned in the PCI report [21]. Use of heparin type, dosage, loading doses of antiplatelet, maintenance Dual Antiplatelet Therapy (DAPT) was also noted. Unfractionated heparin was administered in all cases (70 to 100 IU/kg body weight) at the time of procedure and additional aliquots were used so as to maintain an ACT of 250-300 seconds and they continued to receive heparin during hospital stay for 3 to 5 days. All patients were started on DAPT and advised to continue for a minimum period of 12 months.

End-Points and Definitions

The clinical endpoint was cumulative incidence of MACE which was composite of cardiac death, MI and TVR at the time of discharge, one, six and 12-months after the index procedure, as noted in the follow-up records, were analysed for the MACE. Cardiac death was defined as death due to acute MI, heart failure, procedural death or death from unknown cause. MI was defined as an acute clinical event with typical electrocardiographic and/or enzymatic changes [22]. TVR was defined as any re-vascularisation required to the target vessel. Stent Thrombosis (ST) was defined as per the definition of the Academic Research Consortium (ARC) [23].

STATISTICAL ANALYSIS

Continuous variables were presented as mean \pm Standard Deviation (SD) and categorical variables such as counts as percentages.

Statistical analysis was carried out using Microsoft Excel spreadsheet (version 2007, Microsoft Corp, Seattle, Washington). All data were assessed using Statistical Package for Social Sciences Statistics (SPSS) version 16 (Chicago, IL, USA) program.

RESULTS

Baseline and Demographic Characteristics

Among 103 enrolled patients, 67% (69) were male and 33% (34) were female. The mean age of patients was 79.23 ± 3.61 years. Prevalence of single vessel disease was found in 57.3% (59) and double vessel disease in 35% (36) and triple vessel disease in 7.8% (8) respectively. Among the enrolled patients, 52.4% (54) patients were diagnosed with Anterior wall STEMI (AWMI), 35% (36) Inferior Wall MI (IWMI) and 12.6% (13) had Posterior Wall MI (PWMI), respectively. A 16.5% (17) of patients had cardiogenic shock and 24.3% (25) patients had prior history of IHD.

History of hypertension and diabetes was seen in 58.3% (60) and 50.5% (52) of the patients respectively. Other demographic and baseline characteristics of enrolled patients are shown in [Table/Fig-1].

Characteristics	n=103
Age (years), Mean \pm SD	79.23 \pm 3.61
Gender, n (%)	
Male	69 (67)
Female	34 (33)
Disease vessel, n (%)	
Single vessel	59 (57.3)
Double vessel	36 (35)
Triple vessel	8 (7.8)
Primary diagnosis, n (%)	
AWMI	54 (52.4%)
IWMI	36 (35%)
PWMI	13 (12.6%)
Medical history, n (%)	
Previous CAD	25 (24.3)
Diabetes mellitus	52 (50.5)
Hypertension	60 (58.3)
PAD	6 (5.8)
Chronic kidney disease	7 (6.8)
COPD	21 (20.4)
CVA	15 (14.6)
Creatinine, Mean \pm SD	1.23 \pm 0.80
Troponin-T, Mean \pm SD	1.64 \pm 1.05
TPI, n (%)	13 (12.6)
IABP, n (%)	9 (8.7)
POBA	5 (4.85)
Intracoronary drugs, n (%)	
Eptifibatide	1 (1.0)
Nicorandil	34 (33)
Nicorandil and eptifibatide	55 (53.4)
None	13 (12.6)

[Table/Fig-1]: Baseline and demographic characteristics of the study population. AWMI: Anterior wall myocardial infarction, IWMI: Inferior wall myocardial infarction, PWMI: Posterior wall myocardial infarction, CAD: Coronary artery disease, PAD: Peripheral artery disease, COPD: Chronic Obstructive Pulmonary Disease, CVA: Cerebrovascular accident, TPI: Temporary pacemaker insertion, IABP: Intra-aortic balloon pump, POBA: Plain old balloon angioplasty

Procedural and Lesion Characteristics

In brief, most of the lesions were located in the LAD artery 30.1% (31) in isolation or involving LAD and one other vessel 23.3% (24), respectively. A total of 63.1% of the lesions were ACC/AHA

classified Type A lesions and the rest were distributed between more complex Type B and C. The average number of stents used per patient was 1.34 ± 0.57 . Postprocedure TIMI flow grades 0 to 2 were present in 10.7% of patients and 89.3% had TIMI flow grade 3. At the time of discharge, all the patients received DAPT, of which, 78.6% (81) were prescribed aspirin plus ticagrelor and remaining 21.4% (22) with aspirin plus clopidogrel. The other procedural and lesion characteristics are shown in [Table/Fig-2].

Characteristics	n=103
Lesion type, n (%)	
Bifurcation	5 (4.9)
CTO	3 (2.9)
Calcified	34 (33)
Ostial	3 (2.9)
Restenosis	3 (2.9)
Other	55 (53.4)
ACC/AHA lesion classification, n (%)	
A	65 (63.1)
B1	15 (14.6)
B2	20 (19.4)
C	3 (2.9)
TIMI flow pre-procedure, n (%)	
0	46 (44.66)
1	23 (22.33)
2	14 (13.59)
3	20 (19.42)
TIMI flow post-procedure, n (%)	
0	2 (1.9)
1	4 (3.9)
2	5 (4.9)
3	92 (89.3)
Procedural approach, n (%)	
Right femoral	78 (75.7)
Left radial	22 (21.4)
Left radial/Right femoral	3 (2.91)
Vessels treated, n (%)	
LAD	31 (30.1)
RCA	29 (28.2)
LCx	5 (4.9)
LAD and LCx	11 (10.7)
LAD and RCA	13 (12.6)
RCA and LCx	6 (5.8)
Others (OM, Diagonal, PLV or PDA)	8 (7.76%)
Average stent used, Mean\pmSD	1.34 \pm 0.57
DAPT at baseline, n (%)	
Aspirin	26 (25.2)
Clopidogrel	13 (12.6)
Ticagrelor	4 (3.9)
No antiplatelet	60 (58.3)
DAPT at discharge, n (%)	
Aspirin+Clopidogrel	22 (21.4)
Aspirin+Ticagrelor	81 (78.6)

[Table/Fig-2]: Procedural and lesion characteristics of the study population. CTO: Chronic total occlusion; TIMI: Thrombolysis in myocardial infarction; LAD: Left anterior descending; RCA: Right coronary artery; LCx: Left circumflex; DAPT: Dual anti-platelet therapy; OM: Obtuse Marginal, PLV: Posterior Left Ventricular artery, PDA: Posterior Descending Artery.

Clinical Outcomes

The cumulative MACE at 12-month follow-up was found to be 8.73% (9), which consisted of 7.77% (8) cardiac deaths

and 0.97% (1) TVR. However, stroke was observed in 3.88% (4) patients. The detailed clinical outcomes are presented in [Table/Fig-3].

Characteristics	1 month follow-up	6 months follow-up	12 months follow-up
All-cause mortality (%)	7 (6.8%)	9 (8.73%)	14 (13.59%)
Cardiac death (%)	7 (6.8%)	7 (6.8%)	8 (7.77%)
Non-cardiac death (%)	0 (0%)	2 (1.9%)	6 (5.83%)
MI (%)	0 (0%)	0 (0%)	0 (0%)
TVR (%)	1 (0.97%)	1 (0.97%)	1 (0.97%)
Non-TVR (%)	2 (1.94%)	2 (1.94%)	2 (1.94%)
Stroke (%)	1 (0.97%)	3 (2.91%)	4 (3.88%)
ST (%)	0 (0%)	0 (0%)	0 (0%)
MACE	8 (7.77%)	8 (7.77%)	9 (8.73%)

[Table/Fig-3]: Clinical outcomes.

TVR: Target vessel revascularisation; ST: Stent thrombosis; MACE: Major adverse cardiac events

DISCUSSION

The present study confirms the favorable clinical outcomes after PAMI in elderly patients. The study population had a high prevalence of hypertension (58.3%) and diabetes (50.5%). Furthermore, the cumulative MACE rate was 8.73% and stroke rate was 3.88% at 12-month follow-up, after the procedure.

Some authors have reported that PCI in elderly patients is challenging not only because of the age as a risk factor but also due to the complex co-morbidities including multi-vessel calcific coronary disease, tortuous vascular anatomy and poor left ventricular function [24-26]. The proportion of elderly patients was relatively less in randomised ACS trials partly due to the fact that many elderly patients do not opt for revascularisation [27,28] and partly as they are selectively excluded because of high mortality [29-31]. Hence, the PCI data in elderly patients are limited which is one of the major hurdles in decision making for physicians, and patients too. As established earlier, the reference-vessel diameter and the number of stents implanted were predominant determinants as well as the risk factors for clinical and angiographic restenosis after primary or elective PCI [32,33]. Additionally, restoration of TIMI-3 flow post-procedure was the strongest predictor of early and late mortality, re-infarction, TVR and event-free survival after primary PCI [34]. The above-stated findings support the results of present study, that the primary PCI in elderly ACS patients has favorable outcomes and low MACE rate.

A subgroup analysis of PAMI-I trial conducted in elderly patients (65 years) showed a significant reduction in death and recurrent MI with no events of stroke and intracranial haemorrhage [35,36]. The Global Use of Strategies to Open Occluded Coronary Arteries in ACS (GUSTO IIb) trial showed lower one-month mortality rate of (5.7%) compared to fibrinolytic therapy (7%) in STEMI patients aged between 61 to 71 years [34]. Similar results were obtained in the subgroup analysis of the Danish multicenter randomised study, Fibrinolytic Therapy Versus Acute Coronary Angioplasty in AMI-2 (DANAMI-2). The DANAMI-2 showed results in favour of PCI when compared to fibrinolytic therapy in patients with median age of 63 years in terms of reduction in one-month mortality (6.6% vs. 7.8%), rate of re-infarction (1.6% vs. 6.3%), and stroke (1.1% vs. 2.0%) [37]. In the present study, the rate of all-cause mortality (6.8%), stroke (0.97%), and MACE (7.77%) at one-month follow-up were in accordance with the above-mentioned studies. Some other trials showed similar results in elderly (≥ 70 years) patients who underwent primary PCI for STEMI [38,39]. Furthermore, a real-world trial showed high survival rate in patients aged 75 or older after primary PCI [40].

Another retrospective study of primary PCI in elderly (>90 years) STEMI patients compared Korea Acute Myocardial Infarction

Registraz (KAMIR) and the Korean Working Group on Myocardial Infarction (KorMI). These studies reported that the proportion of nonagenarians increased to double during the period of KAMIR study to KorMI study. The rate of opting for primary PCI was increased in KAMIR to KorMI trial (62.5% vs. 81.0%) and in-hospital mortality rate decreased in KAMIR to KorMI trial (25.0% vs. 20.3%; $p=0.919$) [41]. The lower rate of MACE (8.73%) in the index study was mainly because of comparatively lower risk factors including age of enrolled patients. Furthermore, as per Western Denmark registry, TIMI flow grade 3 in octogenarians with STEMI was achieved in 86.3%, which was comparable with present study results (TIMI flow grade 3; 89.3%) [42].

In the largest trial of AMI stenting in general population, the PAMI stent pilot trial ($n=236$), the cumulative clinical outcome of death, reinfarction, TVR, or stroke was 17.8%, in addition to 14.8% TVR and 0.8% stroke, during a mean follow-up period of 7.4 ± 2.6 months [43]. In the current study, the cumulative MACE was 8.73%, TVR was 0.97% and stroke was 3.88% at 12-month follow-up. All these studies along with the results of present study support the hypothesis that primary PCI in AMI can be performed in elderly patients with a high success rate along with low rate of mortality and other adverse events.

Limitation(s)

The major limitation of the study was retrospective, single center and non-randomised design. The other limitations of the study were the relatively small sample size, short duration of follow-up and no control group. Duration of follow-up might not be enough to evaluate long-term safety and recurring events. Hence large-scale, multicenter trials with control group and longer duration of follow-up are necessary to confirm the late events after primary PCI in elderly.

CONCLUSION(S)

From the study, it can be concluded that the elderly patients undergoing primary PCI for AMI had a lower rate of MACE and stroke, which demonstrates favorable clinical outcomes and hence should be the first line of therapy in this high-risk subgroup.

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