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Original Article

Safety and outcomes of day care based coronary angioplasty – First report from India



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ABSTRACT

Background: The concept of day care based coronary angioplasty might be frugal especially in countries like India where epidemic of coronary disease is enduring and healthcare delivery systems are limited. Published literature addressing the feasibility and safety of day care percutaneous coronary interventions (PCI) is lacking from our country.

Objectives: To study the safety and outcomes in stable cardiac patients undergoing day care coronary angioplasty.

Methods: A single centre nonrandomized active controlled trial of patients undergoing elective transradial coronary angioplasty and same day discharge after triaging was compared with a conventional arm of hospital overnight stay.

Results: Fifty six patients with stable coronary artery disease underwent day care angioplasty. There were no major immediate adverse cardiac and cerebral events noted in the first 24 h. The procedural result followed by a 6-h observation period allowed adequate triage of patients to same-day discharge or to extended clinical observation. Apart from one possible stent thrombosis on day 3 in the treatment arm where the patient received fibrinolytic treatment in a local hospital, there were no major adverse cardiac or cerebral vascular events in the study group. The six month clinical follow up in the day care procedure group was also unevenful for any major adverse cardiac events.

Conclusion: The study albeit small shows the feasibility and safety of day care PCI in the Indian scenario. It did not lead to additional complications compared with overnight stay. Triage of patients for an extended observation period can be performed adequately on the basis of clinical and procedural criteria.

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1. Introduction

Percutaneous coronary Intervention (PCI) is one of the most commonly performed cardiac procedures with more than 1 million episodes of care annually among Medicare recipients.^{1,2} Short- and long-term outcomes after PCI have improved because of the evolution in device technology and pharmacotherapy.² Despite this improvement, patients are usually observed overnight in the hospital after elective PCI to monitor for PCI related complications. Many observational studies and randomized studies performed in the United States and European countries have demonstrated the safety of discharging patients home after PCI without overnight observation.³

But no study has been reported from India which compares safety and feasibility of performing coronary angioplasty on day care basis.

2. Objectives

To study the safety and outcomes in stable cardiac patients undergoing day care coronary angioplasty with or without stenting.

3. Design and settings

A nonrandomized active controlled trial of patients undergoing coronary angioplasty and sent home on the same day or after overnight stay after an uncomplicated procedure. Patients scheduled to undergo elective PCI at the tertiary care referral hospital (JIPMER Hospital, Puducherry) were eligible for enrollment if they fulfilled the predefined inclusion criteria for the study. The study was conducted after the approved by the Institute Ethics Committee.

3.1. Inclusion criteria

Patients undergoing elective coronary angioplasty with.

1. Elective or ad hoc PCI for stable angina with or without positive non invasive stress testing.
2. Successful PCI with/without the use of bolus intravenous GP IIb/IIIa inhibitors
3. Absence of post-procedural chest pain/any coronary complication
4. Absence of vascular complications
5. PCI performed before 3 pm to allow 6 h of observation before discharge on the same day
6. Successful completion of a 100-m walk
7. Residence within 50 km from JIPMER

3.2. Exclusion criteria

1. Acute coronary syndrome presenting as rest angina or myocardial infarction (MI) within 3 days
2. Serum creatinine >1.5 mg/dl

3. Left ventricular ejection fraction of <30% or decompensated systolic heart failure
4. Uncontrolled diabetes mellitus (RBS >250 mg %)
5. Poor general condition/co-morbid illness requiring hospitalization
6. Continued need for hospital stay for any social reason like insurance scheme

4. Methods

The selection criteria were designed to ensure maximum patient safety. Coronary angioplasty was performed via the transradial approach. Patients were categorised into two groups.

4.1. Group I (day care group)

Patients were enrolled for study group only if they fulfilled inclusion criteria. Routine pre procedural care and counseling of patients were done in outpatients department one week prior to planned procedure. Patients were advised to come to cardiology ward one day prior to planned procedure with required investigation reports (Hemoglobin %, Bleeding time, Clotting time, Random blood sugar, blood urea, serum creatinine). All the pre procedural catheterization instructions with antiplatelet loading dosages (as per protocol) were given to patients one day prior to planned procedure. Patients were sent home and advised to come to catheterisation laboratory on the day of procedure. On this day pre procedural check list was scrutinized and verified. All patients underwent elective coronary angioplasty via radial artery route with 6 French size sheath.

4.2. Group II: (prior admission)

We selected a matched control group among the patients who underwent elective coronary angioplasty as per hospital protocol (Admitted one day prior to procedure and discharged after overnight hospital stay). Patients were enrolled in control group only if they satisfied the inclusion criteria. Pre procedural protocols were followed in the same way as for the treatment arm. Repeat pre procedural check list scrutiny was done prior to procedure as per the protocol. All patients in this group underwent elective coronary angioplasty via radial artery route with 6 French sheath as well.

4.3. Procedure

After the decision to perform a PCI but before the start of the PCI, patients were non randomly assigned to discharge the same day as PCI or to overnight hospital stay after PCI. Patients were pre-treated with aspirin 150 mg and clopidogrel 150 mg. According to a previously described protocol, a single dose of 5000 IU heparin was given after insertion of the arterial sheath, and an additional dose of 2500 IU heparin was given if the procedure lasted 90 min. The arterial sheath was removed immediately after the percutaneous coronary intervention and an occlusive tourniquet was applied at the puncture site for 4 h. Pressure was gradually released after 4 h and a light pressure bandage is continued for another 12 h.

4.4. Post-procedure care

All patients had a 12-lead electrocardiogram done immediately following the PCI and then before the discharge. After PCI, the patients were observed in the post-procedure cath care unit. Post-interventional therapy included dual anti-platelet treatment and other secondary prevention drugs.

4.5. Ambulation

All patients were ambulated after 2–3 h of procedure. The ambulation protocol involved ambulation for 5 min, with a walking distance of 200 m before discharge. Any patient who failed to accomplish the set ambulatory targets was deemed unsuitable for same-day discharge. Vital signs check, vascular access site, were done immediately after ambulation with a comprehensive check list analysis before discharge.

4.6. Pre-discharge evaluation

Suitability for discharge required freedom from symptoms, absence of electrocardiogram changes, absence of puncture site abnormalities and successful ambulation. Written instructions and oral explanation of all possible events were given to all the patients. Before discharge, patients were instructed on how to achieve hemostasis by local pressure for an unexpected puncture site bleeding/oozing. In case of an emergency, patients were instructed to contact the general practitioner, their referring cardiologist, the interventionalist, or the nearest emergency department. All patients received pre-discharge counseling on diet and lifestyle modifications. The management of medication compliance was repeatedly highlighted by the interventionalist as well as the nurse practitioner directly involved in the patient care. Formal triage was done to determine whether the patient was deemed suitable for early discharge. Suitability included freedom from symptoms and the absence of ECG changes and puncture site abnormalities.

4.7. Extended observation

Directly after the PCI, patients requiring extended clinical observation, cardiac monitoring, or additional treatment were identified from the following predefined clinical and angiographic criteria derived from an earlier reported study⁴ viz. occluded coronary artery, suboptimal angiographic result, dissection type C to E, residual dissection after stent implantation, occlusion of (major) side branch, angiographic thrombus, no-reflow/slow-flow phenomenon, perforation with guidewire, persistent or recurrent chest pain, ECG changes, congestive heart failure, and complicated hemostasis after PCI. The remaining patients were observed for 6 h without cardiac monitoring in a dedicated care unit of the cardiac catheterization laboratory as described previously.

4.8. Follow-up

Patients were given the contact phone number of hospital emergency services (24 × 7) for any emergency need. All patients were advised to be reviewed two days after the procedure with renal function test reports. Evidence for contrast

induced nephropathy and radial artery patency were checked. Thereafter, the patients were followed up in outpatient department monthly for six months.

4.9. End points

4.9.1. Primary end point

1. Composite of major adverse cardiac and cerebral events until 24 h after PCI. Major adverse cardiac and cerebral events defined as cardiac death, myocardial infarction, stroke, urgent coronary artery bypass grafting, and repeat PCI. The diagnosis of myocardial infarction was based on symptoms and typical ECG changes combined with creatine kinase-MB isoenzyme elevations 3 time the upper limit of normal.

4.9.2. Secondary end points

1. Vascular and puncture site complications
2. Contrast induced nephropathy
3. Composite of major adverse cardiac and cerebral events 24 h -six months after PCI

4.10. Statistical analysis

Descriptive analyses were done and also comparisons of baseline characteristic among the same day discharge and overnight stay. The absolute difference between the rates of the primary outcome was used to test elective PCI in a same-day discharge setting versus an overnight-stay setting. Comparison of clinical end points was done with the absolute risk difference with 95% CI; categorical data were analyzed with χ^2 test. Continuous variables were described as mean and mean difference. A value of $p < 0.05$ was considered statistically significant, and 95% CIs were used. Statistical analysis was done with the IBM SPSS 22 version software package for Windows.

5. Results

5.1. Patients

From 1 March 2013 to 31 December 2013, 710 elective coronary angioplasty were performed in our centre, out of them 60 patients were enrolled for day care percutaneous coronary intervention after getting the informed consent. Major reason for exclusion were, residence more than 50 km from the treatment hospital JIPMER (64.2%) followed by primary PCI (12.4%) and patients changing their wish for same day discharge after deemed fit for the same (8.6%) (Fig. 1). Out of these 60 patients two patients were converted into femoral route because of negative allen test and two patients were unfit for same day discharge after procedure and were hence excluded from analysis. Fifty six patients who had PCI with conventional overnight stay formed the control arm. The mean age of the study population was 55.9 years (Table 1). Fig. 2 shows the age distribution of patients. Left ventricular ejection fraction, patients with previous ACS (including ST elevation myocardial infarction) and NYHA class were equally distributed among case and control groups (Table 2). However

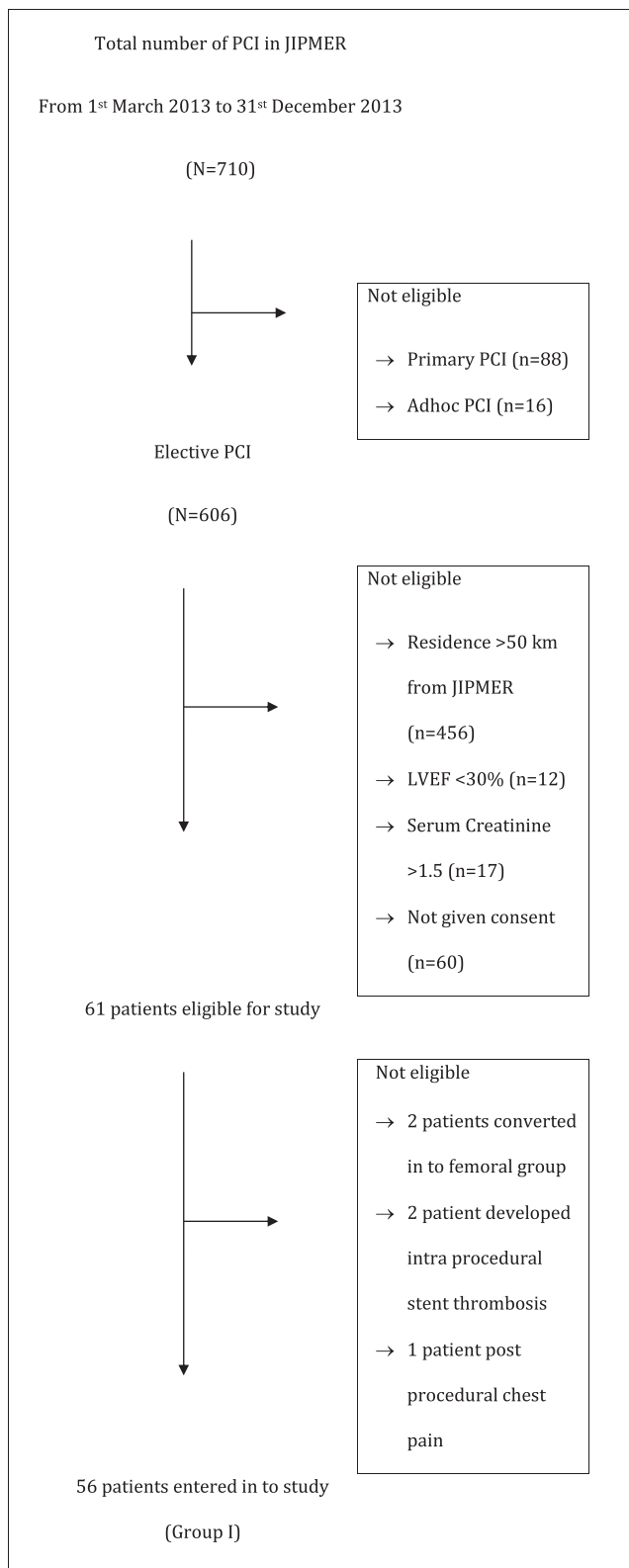


Fig. 1 – The Flow chart depicting enrollment of patients.

patients with chronic stable angina were more frequent in group I. Although number of patients with single vessel disease were more common in the day care group this was statistically non significant (Table 3).

Table 1 – Demographic characteristics.

Demographics	Group I (N = 56)	Group II (N = 56)	P value
Age in years (mean±SD)	55.91 ± 10.02	54.91 ± 9.59	0.591
Male (%)	87.5	85.7	0.78
Smoking (%)	32.14	46.43	0.12
Diabetes mellitus (%)	55.36	44.64	0.257
Hypertension (%)	42.86	33.92	0.33

Group I = Day care angioplasty, Group II= Control arm with overnight hospital stay.

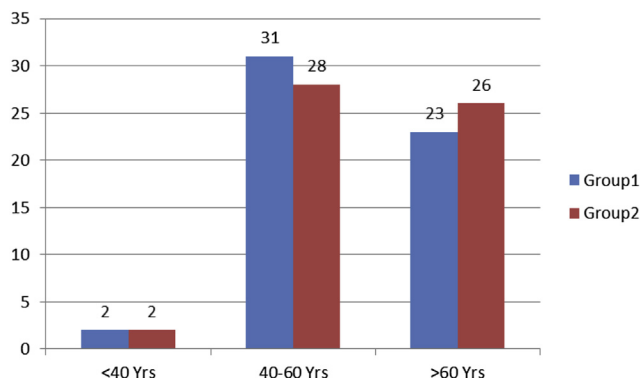


Fig. 2 – Comparison of patient age in the day care and control groups.

We performed all types of complex PCI including chronic total occlusions, except left main disease. Procedural success in this study was 100 percent. Procedural characteristic of case and control group were equally distributed (Table 4).

5.2. Observation and discharge

Two patients from day care group were kept for extended observation and were excluded from study (one patient developed intraprocedural stent thrombosis, managed by

Table 2 – Clinical characteristics of study and control groups.

Clinical characteristic	Group I (N = 56)	Group II (N = 56)	P value
LVEF (mean ± SD)	54.51	54.73	0.95
Previous STEMI (%)	44.64	48.21	0.84
Previous NSTEMI (%)	5.35	7.14	1
Previous UA (%)	17.85	28.57	0.26
CSA (%)	32.14	16.07	0.076
Previous PCI (%)	7.14	5.35	0.69
NYHA angina classification			0.507
I	0	0	
II	50	55.36	
III	50	44.64	
IV	0	0	

Group I = Day care angioplasty, Group II = Control arm, LVEF = left ventricular ejection fraction, STEMI = ST elevation myocardial infarction, NSTEMI = Non ST elevation myocardial infarction, UA = Unstable angina, CSA = chronic stable angina, PCI = Percutaneous coronary intervention NYHA = New York Heart Association.

Table 3 – Angiographic characteristics of study and control groups.

Characteristic	Group I (N = 56)	Group II (N = 56)	P value
Single vessel disease N (%)	31 (55.35)	31 (55.35)	0.28
Double vessel disease N (%)	19 (33.92)	23 (40.07)	0.56
Triple vessel disease N (%)	6 (10.71)	2 (3.57)	0.9

Group I = Day care angioplasty, Group II = Control arm.

thrombosuction and GP IIb/IIIa inhibitors, the other patient developed chest pain 1 h after procedure, Acute Coronary syndrome was ruled out by ECG and CK-MB level at six and 12 h. These patients were discharged after 48 h of observation). From control group one patient developed intraprocedural stent thrombosis, in three patients PCI was done through femoral approach and were excluded from study.

5.3. Follow-up and events

One patient in same day discharge group developed anterior wall myocardial infarction three days after discharge. The patient had two drug eluting stents deployed in proximal-mid LAD. Patient was thrombolysed with streptokinase in a local hospital. Coronary angiogram was done one day after AAMI showed recanalised LAD. Patient was put on Prasugrel and did well thereafter in the follow up. No other events including contrast induced nephropathy and radial artery occlusion were noted in six months of follow up.

6. Study limitations

This was a nonrandomized, single centre study. So possible selection bias could not be ruled out. The trial failed to reach

Table 4 – Procedural characteristics.

Characteristic	Group I (N = 56)	Group II (N = 56)	P value
Multilesion intervention N%	9 (16.07)	7 (12.6)	0.92
Multivessel intervention N%	4 (7.14)	5 (8.92)	0.12
Stent deployment N%	54 (96.42)	53 (94.64)	0.93
Plain balloon angioplasty N %	0	2 (3.57)	0.97
Drug eluting balloon N %	2 (3.57)	1 (1.78)	0.3
Procedural success N%	56 (100)	56 (100)	0.99
Stents per procedure (mean±SD)	1.12 ± 0.33	1.27 ± 0.41	0.08
Location of target lesion, N (%)			
Left anterior descending	34 (60.71)	29 (51.78)	0.63
Circumflex coronary artery	9 (16.07)	9 (16.07)	0.06
Right coronary artery	15 (26.78)	23 (41.07)	0.72
Ramus Intermedius	2 (3.57)	0	0.32
ACC/AHA lesion morphology, N (%)			
A	28 (50)	21 (37.5)	0.43
B	22 (39.28)	32 (57.14)	0.06
C	12 (21.42)	12 (21.42)	0.08
Restenotic lesion	2 (3.57)	2 (3.57)	0.35
Chronic total occlusion	2 (3.57)	3 (5.3)	0.78

Group I = Day care angioplasty, Group II = Control arm, ACC/AHA = American College of Cardiology/American Heart Association.

the anticipated event rate. The low event rate in both the groups could possibly due to improvement in angioplasty and stent techniques and the improved care for the arterial puncture site (radial access). The very low event rates precluded a relative risk difference calculation among the two strategies.

7. Conclusion

Same-day discharge after elective PCI via the transradial approach is feasible and safe in the majority of patients selected for day-case PCI in India. It did not lead to additional complications compared with overnight stay. Triage of patients for an extended observation period can be performed adequately on the basis of clinical and procedural criteria. However the number of patients involved in this study is small and hence so a larger randomised trial is needed to confirm the finding of this study.

8. Discussion

The present study demonstrates that same-day discharge after elective PCI can be performed safely in selected patients with stable cardiac status in Indian context. Day care PCI did not lead to unattended cardiac events or to more complications. Furthermore, it was found that the procedural result followed by a 6-h observation period allowed adequate triage of patients to same-day discharge or to extended clinical observation. This is the first study of same-day discharge after elective PCI in India. The protocol had only a few exclusion criteria, and none were angiographic. The patients included in our study represent a general elective PCI population, with a sufficient proportion of patients with complex coronary lesions such as type B2 to C lesions, and total occlusions.

Our study shows that patients at risk for postprocedural complications can be identified effectively in a day-case setting on the basis of predefined clinical and angiographic criteria. The present study shows that triage of 6 h after PCI is pivotal for the safety of a same-day discharge protocol. After PCI, 3 patients developed an indication for extended hospital stay during the 6-h observation period. One patient developed chest pain 1 h following PCI and two patients developed intraprocedural stent thrombosis. Therefore, a definitive decision for same-day discharge can be made only after an uncomplicated clinical course of at least 6 h, which is in line with previous reports.

Primary end points achieved in both groups. No major adverse cardiac and cerebral events were noted in the first 24 h. Only one patient from day care group developed anterior wall myocardial infarction three days after PCI. The lower incidence of major adverse cardiac cerebral events may be explained by the exclusion of acute coronary syndrome patients and further reconfirms the appropriateness of the selection criteria implemented in the current study. Moreover, the present study demonstrates that this can be achieved without compromising the quality-of-care or safety in the patient population with a higher-risk profile.

With improvements in the surgical techniques and safety over the past several years, there has been a movement

toward performing a large and wide spectrum of noncardiac surgeries in the outpatient setting. It is now estimated that over 65% of surgeries performed in North America are done so in the outpatient setting. On the contrary, despite significant improvement in interventional technologies in recent years, there has been only marginal reduction in the post-PCI length of stay (LOS). The LOS following PCI is one of the major determinants of hospital cost and quality-of-care assessment. Reimbursement policies governing the LOS for elective PCI may possibly contribute to unwarranted hospitalizations causing logistic constraints on healthcare resources. In the EASY (Early Discharge After Transradial Stenting of Coronary Arteries) trial, it has shown that same-day home discharge after uncomplicated transradial PCI and resulted in a 50% relative reduction in medical costs. There have been few appraisals of same-day discharge in a real-world spectrum of practice due to extreme variations in the LOS between countries, regions, and hospitals. Length of stay shows a decreasing trend over time, and shorter LOS does not appear to affect health outcomes adversely as demonstrated in various other day care procedures.^{4–10}

The first study on same-day discharge reported by Kiemeneij et al¹¹ clearly demonstrated safety of early ambulation after transradial PCI. This was followed by the study on 922 patients reported by Koch et al¹² that showed short-term triage of 4 h as sufficient and safe for same-day discharge. However, this was a highly selective study with guiding catheter size restricted to 6-F and only 20% use of stents. Because these patients underwent PCI using the femoral approach without the use of closure devices, a sizable number of patients were discharged back to the referring hospital for overnight care. Slagboom et al¹³ later reported safety of transradial PCI with 6-F guiding catheters and 40% usage of stents in the OUTCLAS (Outpatient Coronary Low-Profile Angioplasty Study) trial. Previous investigators have shown that the radial approach is a suitable technique for same-day discharge PCI because it enables immediate ambulation.¹⁴ Largest study of same day discharge following which included 2400 patients done by Mehul Patel et al has shown that When appropriately selected, with strict adherence to the set protocol, same-day discharge after uncomplicated elective PCI is in a wide spectrum of patients.^{15,16}

All the above studies were done in Western and developed countries. Outcomes of the studies done in developed countries cannot be extrapolated in developing countries like India. Lack of patient education system, social diversity and poor transportation system are all impediments to day care procedures. But at the same time poor economy, limited number of hospitals with lagging bed strength and man power may all would make the day care procedures significantly cost effective in high volume PCI hospitals. Our study albeit small showed the safety and feasibility of day care PCI in the Indian context.

Conflicts of interest

All authors have none to declare.

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