



DAY CARE CORONARY ANGIOPLASTY: SAFETY AND FEASIBILITY IN A TERTIARY CARE HOSPITAL OF INDIA

Cardiology

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ABSTRACT

Background:The present study was done mainly to demonstrate the safety and feasibility of the same-day discharge after elective coronary angioplasty in a selected group of patients with stable cardiac status in the Indian context. Same-day discharge PCI can potentially reduce the hospital cost of PCI and improve bed utilization, but there are concerns about the risk of entry site complications and occlusion of the target vessel post-discharge with this strategy. These methods will be highly beneficial for the society with a developing economy, the limited number of hospitals with lagging bed strength and manpower may all would make the daycare procedures significantly cost-effective in high volume PCI doing hospitals. Very limited data's regarding daycare angioplasty is available from our country. **Objective:** To study the safety and feasibility of day care coronary angioplasty in a tertiary care hospital of India. **Methods:** A single centre nonrandomized active controlled trial of patients undergoing elective transradial coronary angioplasty and same day discharge was compared with a conventional arm with 2-3 days of hospital stay. **Results:**Fifty six patients with stable coronary artery disease underwent day care angioplasty. Six patients were excluded from the study due to intra procedural or post-procedural complications during 6hr observation period. Out of remaining 50 patients who were discharged on day care basis showed no major immediate adverse cardiac and cerebral events noted in the first 24 h. The six month clinical follow up in the day care procedure group was also uneventful for any major adverse cardiac events. **Conclusion:**Our study showed that day care coronary angioplasty via the transradial approach is feasible and safe in the majority of patients selected for day-care PCI in Indian scenario.

KEYWORDS

Daycare Angioplasty, Safety, Feasibility

INTRODUCTION:

Percutaneous coronary Intervention (PCI) is one of the most commonly performed cardiac procedures for coronary artery disease. Generally, patients are kept under observation for a few days after the procedure for monitoring PCI related complications. The clinical basis of this practice is rooted in the short history of PCI when acute ischemic events from abrupt vessel closure or vascular access complications were common and occasionally life-threatening. Technological advances, such as improvement in stent quality and techniques of stent implantation, along with improvements in adjunctive pharmacotherapy, have addressed the risk of acute ischemic events. Many observational studies and randomized studies performed in the United States and European countries have demonstrated safety in discharging patients after PCI without overnight observation.¹⁻³ But very limited data are available from developing country like India, regarding safety and feasibility of performing coronary angioplasty on a daycare basis.

OBJECTIVE:

To study the safety and feasibility of day care coronary angioplasty in a tertiary care hospital of India.

METHODS:

Patient selection:

It was a single centre nonrandomized active controlled trial, where patients after elective transradial coronary angioplasty were discharged on the same day of the procedure or after 2-3 days of hospital stay. Patients scheduled to undergo elective PCI at the tertiary care hospital (IPGME&R &SSKM Hospital, KOLKATA) were eligible for enrollment if they fulfilled the predefined inclusion criteria for the study mentioned below. The study was conducted after being approved by the Institute Ethical Committee.

Inclusion criteria:

Patient undergoing elective coronary angioplasty with

1. Type A and B lesion on coronary angiography. (Type A lesions-discrete i.e. <10mm, concentric, readily accessible, nongulated segment i.e. <45 degrees, smooth contour, little or no calcium, less than total occlusive, not ostial in locations, no major side branch involvement, absence of thrombus).

Type B lesions - tubular i.e 10 to 20 mm in length, eccentric,

moderate tortuosity of proximal segment, moderately angulated segment i.e. ≥ 45 degrees and < 90 degrees, irregular contour, moderate to heavy calcification, total occlusion <3 months old, ostial in locations, bifurcation lesion requiring double guidewire, some thrombus present).

2. Absence of post procedural chest pain/arrhythmias/any coronary complication such as slow flow/no flow, dissection, side branch occlusion.
3. Absence of vascular complication.
4. PCI will be performed in early hours to have an observation period of 6 hours post procedure.
5. Residence within 100 km of SSKM hospital.
6. LVEF $\geq 40\%$.

Exclusion criteria:

1. Acute coronary syndrome presented as unstable angina or myocardial infarction (MI) within 3 days.
2. Serum creatinine >1.5 mg/dl
3. Left ventricular ejection fraction of <40% or decompensated systolic heart failure.
4. Uncontrolled diabetes mellitus.
5. Poor general condition/co-morbid illness requiring hospitalization.
6. Continued need for hospital stay for any other reason.

Patients were categorized in two groups:

1. Same-day discharge group :

Patients were enrolled only if they fulfilled the inclusion criteria. All the routine pre-procedural investigations and counselling was done on OPD basis one to two week prior to procedures. Patients were advised to visit the cardiology ward on the day of procedure with the required investigation reports (Hemoglobin %, Bleeding time, Clotting time, Random blood sugar, blood urea, serum creatinine and serology).

All the pre-procedural catheterization instructions with antiplatelet loading dosages (as per protocol) were given to the patients in morning on the day of procedure. All patients had undergone elective coronary angioplasty via transradial artery route.

2. Control population:

A matched control group of the patients was selected who had undergone elective coronary angioplasty (discharged at least after two-three days of hospital stay). Patients were enrolled in the control group

only if they satisfy the inclusion criteria. Pre-procedural protocols were followed in the same way as for the treatment arm. Pre-procedural check list scrutiny was done prior to procedure as per the protocol. All patients in this group had undergone elective coronary angioplasty via trans-radial artery route.

Procedure:

After the decision to perform a PCI but before the start of the PCI, patients were non-randomly assigned to the same day discharge group and to second group to be discharged after 2-3 days of hospital stay after PCI. Patients were pre-treated with loading dose of aspirin and clopidogrel/ticagrelor/prasugrel. All the procedure were done through the radial access. Patients received the unfractionated heparin according to bodyweight along with heparin and verapamil, immediately after radial sheath insertion (6Fr).The arterial sheath was removed immediately after the percutaneous coronary intervention and TR band was applied at the puncture site for 4 hr. Pressure was gradually released until hemostasis was achieved and a light pressure bandage was applied and to be removed on next day.

Post-procedure Care:

After PCI, the patients were observed in the post-procedure cath care unit for minimum period of 6hr prior to discharge in the day care arm. All patients had a 12-lead electrocardiogram done following the PCI and prior to discharge. Post-interventional therapy included dual antiplatelet treatment and other secondary prevention drugs. 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.

Pre-discharge evaluation:

Formal triage was done to determine whether the patient was deemed suitable for early discharge. 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 to the nearby hospital or to us (doctor's phone number were provided to each patient). All patients received predischARGE counseling on diet, lifestyle modifications and on prescribed medication compliance.

Follow up:

We had telephonic consultation with the patients on the same day of the discharge as well as on the next day of discharge. Patient were asked to attend cardiology opd after 7 day and then monthly visit for next 6 months.

End points:

Primary end point:

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.

Secondary end points:

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

Results:

From 1st September 2018 to 31st October 2019, 56 patients were enrolled for day care percutaneous coronary intervention after getting the informed consent. However 50 cases of coronary artery disease were included in the study who undergone PTCA and was discharged on day care basis after meeting the inclusion and exclusion criteria.

Out of these 56 patients, two patients were converted into femoral route and four patients were unfit for same day discharge after procedure and hence were excluded from analysis. Fifty patients who had PCI with conventional hospital stay formed the control arm. The mean age of the population in the case group was 56.9±8.27yr and in the control group it was 57.08± 8.33yr, out of 50 patients 64% of the

cases were male and rests were female, risk factor in the form of hypertension,T2DM and Smoking in the case arm was around 36%, 34% and 34% respectively. No incidence of major adverse cardiac or cerebral events occurred in both the groups of patient. Few case related complications such as radial hematoma, radial artery occlusion developed in both group which was statistically non significant.

Elective PCI for Day care coronary angioplasty (N=56)

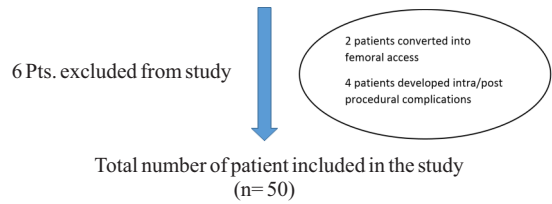


Table 1: clinical characteristics

Characteristics	Case group	Control group	P value
Age(YR)	56.94±8.27	57.08±8.33	0.933
Male	32	28	0.414
smoking	17	15	0.66
hypertension	18	10	0.0747
diabetes	17	14	0.516
LVEF	53.784.90	55.94±6.33	0.062
CCS II	16	20	0.567
CCS III	34	30	0.696
Previous STEMI	18	19	0.888
Previous NSTEMI	15	14	0.870
UA	9	10	0.833
CSA	8	7	0.809
Previous PTCA	6	5	0.749

Table 2. Procedural characteristics

Characteristics	Case group	Control group	Pvalue
Single vessel disease	27	32	0.605
Double vessel disease	19	14	0.450
Triple vessel disease	4	4	1
Single vessel intervention	27	32	0.31
Multivessel intervention	23	18	0.31
Multilesional intervention	10	8	0.61
Plain balloon angioplasty	0	0	
Drug eluting balloon	2	1	0.56
Stent per procedure	1.7+0.6145	1.58+0.6417	0.3419
LAD	39	38	0.88
LCX	18	16	0.89
RCA	20	18	0.89
RI	0	0	
Type A lesion	38	37	0.836
Type B lesion	49	43	0.857
Everolimus eluting Stent	63	58	0.965
Sirolimus eluting Stent	10	14	0.353
Zotarolimus eluting Stent	13	8	0.382
IVUS	8	7	0.779
OCT	6	9	0.575
Aspirin	50	50	
clopidogrel	22	26	0.423
Ticagrelor	18	14	0.391
Prasugrel	10	10	1
Abciximab	2	1	0.557

Table 3: Complications in case and control group:

Complications	Case group	Control group	P value
MACCE	0	0	
AKI	1	1	1
Stent thrombosis and ISR	0	0	
RAO	2	4	0.4
Radial Hematoma	3	3	1

Observation and discharge:

During observation period, four patients were kept for extended observation and were excluded from study (one patient developed tachyarrhythmia(VT) during the procedure and two patient complained of chest pain during observation period of 6hours and one

patient had single episode of hemoptysis after the procedure during observation period).

Follow-up and events

Post-discharge coronary angiogram was done only in one patient of case arm on day care basis, who complained of effort angina (CCS II) after 5 months of discharge. However, his coronary angiogram was normal and the stent (mid-LAD) was patent

DISCUSSION:

The improvement in the PCI techniques, skills of the operators, use of imaging techniques and newer anti-platelet agents have reduced the incidence of procedural complications and stent thrombosis. Nevertheless, despite appropriate care, other risks including intracranial haemorrhage and thrombo-embolic stroke still remains.

In most western countries, there is a trend towards discharging patients on the same day after elective PCI.⁶⁻¹² In our setup there are various limitations apart from health care such as lower literacy rate, social diversity and poor transportation system and poor economy, all are the hindrance to day care procedures. So the safety data from the western or developed country cannot be implemented here. However, at the same time poor economy, the limited number of healthcare resources such as the low number of hospitals compared to our population, lagging bed strength and manpower may all would make the day care procedures significantly cost-effective in high volume PCI hospitals.¹³⁻¹⁴

The results of the present study demonstrated the safety and feasibility of the same-day discharge after elective coronary angioplasty in a selected group of patients with stable cardiac status in the Indian context. Apart from the inclusion and exclusion criteria, the use of post procedural observational period for 6hr allowed adequate triage of patients to same day discharge, which is in accord with previous studies¹⁵⁻¹⁶. Out of the 56 patients who were enrolled for day care coronary angioplasty, 6 patients were excluded from the study due to intra procedural or post-procedural complications as mentioned above. No incidence of major adverse cardiac or cerebral events may be explained by the exclusion of high-risk patients such as acute coronary syndrome patients or patients with decompensated heart failure. This further reconfirms the appropriateness of the selection criteria implemented in the current study. In the majority of the study done related to same-day discharge coronary angioplasty had not included acute coronary syndrome patients. As all the procedures were performed through transradial access, there were few complications related to access. In both control and case groups, the incidence of radial hematoma was the same and it was statistically not significant (p value=1). Out of the three (6%) incidences of radial hematoma in the case group, two were of Easy grade I and one was of Easy grade II. Radial hematoma in both groups was managed conservatively. Garg et al had shown that forearm hematomas occur in about 10% of patients undergoing TRA-PCI.¹⁷ In their study, most hematomas occur near the puncture area (grade I and II) and are related to access site-related issues. Only about 4% of patients develop hematoma in the proximal forearm and arm (grade III and IV). Thus in our study, the incidence of radial hematoma is the same as compared to the Garg et al study. All the above patients were managed conservatively with a radial bandage and ice compression.

Apart from hematoma, two (4%) patients developed the complication in the form of Radial artery occlusion (RAO) in the case arm and four (8%) cases of RAO were detected were detected in the control arm, which was again statistically not significant (p value=0.4). No symptoms of hand ischemia developed in both case and control group, thus no active intervention was done for it. In the literature, it is mentioned that radial artery occlusion (RAO) is one of the most common complications after transradial catheterization, with incidence varying between 1% and 10%.¹⁸

Apart from access related problems one (2%) patient in both case and control arm suffer from acute kidney injury (p value=1), consultation with the nephrology department was done for both cases, no hemodialysis was required. Their renal functions got normal on follow up. In the literature, the incidence of CI-AKI ranges from 2% in low-risk patients to 12% to 50% in patients with diabetes and known chronic kidney disease (CKD).¹⁹

Post-discharge coronary angiogram was done only in one patient of case arm on day care basis, who complained of effort angina (CCS II)

after 5 months of discharge. However, his coronary angiogram was normal and the stent (mid-LAD) was patent.

One previous study of same-day discharge after PCI in India was done by Singh et al. In Singh et al¹⁵ study and our study one most important inclusion criterion was the distance of residence of the patient from the hospital, in Singh et al. study it was kept 50 km and in our study, we had kept it at 100km. Our study shows that patients at risk for post-procedural complications can be identified effectively in a day-care setting on the basis of predefined clinical and angiographic criteria. Our study albeit small showed the safety and feasibility of day care PCI procedure in the Indian context.

Study limitations

This was a nonrandomized, single centre study. So possible selection bias could not be ruled out

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.

REFERENCES

- Rubimbura V, Rostain L, Duval AM, et al. Outcomes and safety of same-day discharge after percutaneous coronary intervention: a 10-year single-center study. 2019 Jul 1;94(1):105e111.
- Kiemeneij, G.J. Laarman, T. Slagboom, R. van der Wieken. Outpatient coronary stent implantation. J Am Coll Cardiol, 1997 Feb;29(2):323-327.
- Koch KT, Piek JJ, Prins MH, et al. Triage of patients for short-term observation after elective coronary angioplasty Heart, 2000 May;83(5):557-63
- Slagboom T, Kiemeneij F, Laarman GJ, Van der Wieken R, Odekerken D. Actual outpatient PTCA: results of the OUTCLAS pilot study Catheter Cardiovasc Interv. 2001 Jun;53(2):204-8.
- Patel M, Kim M, Karajigkar R, Kodali V, Kaplish D, Lee P, Moreno P, Krishnan P, Sharma SK, Kini AS. Outcomes of patients discharged the same day following percutaneous coronary intervention. JACC Cardiovasc Interv. 2010 Aug;3(8):851-8.
- Madan M, Bagai A, Overgaard CB, Fang J, Koh M, Cantor WJ, Garg P, Natarajan MK, et al. Same-Day Discharge After Elective Percutaneous Coronary Interventions in Ontario, Canada. Journal of the American Heart Association. 2019 Jul 2; 8(13): e012131.
- Nascimento FO, Pineda AM, Benjo A, Mas I Jr, Podesta C, Heimowitz TB, Kirtane A, Beohar N. Same-day discharge or overnight stay after percutaneous coronary intervention: comparison of net adverse cardiovascular events. J Invasive Cardiol. 2014 May;26(5):204-8.
- Heyde GS, Koch KT, de Winter RJ, Dijkgraaf MG, Klees MI, Dijkman LM, Piek JJ, Tijssen JG. Randomized trial comparing same-day discharge with overnight hospital stay after percutaneous coronary intervention: results of the Elective PCI in Outpatient Study (EPOS). Circulation. 2007 May 1; 115(17):2299-306.
- Elfandi A, Safirstein J.G. Transradial PCI and Same Day Discharge. Curr Treat Options Cardiovasc Med. 2018 Feb 24;20(2):10.
- Abdelaal E, Rao SV, Gilchrist IC, et al. Same-Day Discharge Compared With Overnight Hospitalization After Uncomplicated Percutaneous Coronary Intervention: A Systematic Review and Meta-Analysis. JACC: Cardiovascular Interventions. 2013 Feb;6(2):99-112.
- Koutouzis M, Agelaki M, Maniotis C et al. Predictors of same day discharge after percutaneous coronary interventions. Cardiovascular Revascularization Medicine. 2017 Jun;18(4):241-244.
- Koutouzis M, Karatasakis A, Brilakis ES et al. Feasibility and safety of same-day discharge after complex percutaneous coronary intervention using forearm approach. Cardiovascular Revascularization Medicine. 2017 Jun;18(4):245-249.
- Khatri S, Webb JG, Carere RG et al. Safety and Cost Benefit of Same-Day Discharge After Percutaneous Coronary Intervention. The American Journal of Cardiology 2002 Aug 15;90(4):425-7.
- Amin AP, Pinto D, House JA, et al. Association of Same-Day Discharge After Elective Percutaneous Coronary Intervention in the United States With Costs and Outcomes. JAMA Cardiol. 2018 Nov 1;3(11):1041-1049.
- Singh VR, Jayaraman B, Saatheesh S, et al. Safety and outcomes of day care based coronary angioplasty – First report from India. Indian Heart Journal 2015 Mar-Apr; 67(2): 108–113.
- Jabara R, Gadesam R, Pendyala L et al. Ambulatory discharge after transradial coronary intervention: Preliminary US single-center experience (Same-day TransRadial Intervention and Discharge Evaluation, the STRIDE Study). American Heart Journal. 2008 Dec;156(6):1141-6.
- Garg N, Umamaheswar KL, Kapoor A, Tewari S, Khanna R, Kumar S, Goel PK. Incidence and predictors of forearm hematoma during the transradial approach for percutaneous coronary interventions. Indian Heart J. 2019 Mar - Apr;71(2):136-142.
- Avdikos G, Karatasakis A, Tsoumeleas A, Lazaris E, Ziakas A, and Koutouzis M. Radial artery occlusion after transradial coronary catheterization Cardiovasc Diagn Ther. 2017 Jun;7(3): 305–316.
- Mehran R. and Dangas G.D. Coronary Angiography and Intravascular Imaging. Braunwald's Heart Disease. A Textbook of Cardiovascular Medicine 11th edition. Zipes, Libby, Bonow, Mann, Tomaselli; pp.375-376.