PAKISTAN JOURNAL OF Cardiovascular Intervention

OPEN ACCESS

ORIGINAL ARTICLE

Randomized Controlled Trial to Evaluate the Safety of Same-Day Discharge After Percutaneous Coronary Intervention (PCI).

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Citation:
Dhakam S, Gowani A, Noor A, Ifthikhar I, Ahmed F, Tufail M. Randomized Controlled Trial to Evaluate the Safety of Same-Day Discharge After Percutaneous Coronary Intervention (PCI). PJCVI. 2023; 3(1): 01-09

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Funding:
This research received no specific grant from any funding agency in the public, commercial, or not-for-profit sectors.

Conflicts of Interests:
The authors have declared that no competing interests exist.

Received 04/03/2023
Accepted 14/05/2023
First Published 01/06/2023

Abstract

Background: Cardiovascular disease is a significant health burden in developing countries. Percutaneous coronary intervention (PCI) is commonly used to restore blood flow in atherosclerotic coronary vessels. This randomized controlled trial aimed to assess the safety of same-day discharge compared to overnight hospital stay following low-risk elective PCI in a tertiary care hospital in Pakistan.

Methodology: Between September 2014 and September 2015, a total of 210 patients who underwent low-risk PCI were randomly assigned to either overnight stay or same-day discharge. The primary endpoint was the occurrence of major adverse events, defined as a composite of death, myocardial infarction, repeat revascularization, rehospitalization, and access site complications (major bleeding or hematoma) within 24 hours after the procedure.

Results: No major adverse events were observed within 24 hours in either group. The only reported adverse event was a myocardial infarction resulting from stent thrombosis on the third day after PCI in the same-day discharge group. No mortality or access site complications occurred in either group.

Conclusion: Based on our cohort, same-day discharge following low-risk PCI was found to be safe and could be considered for select patients, providing a potential opportunity to reduce the financial burden associated with overnight hospital stays.

Keywords

Myocardial Infarction, Percutaneous Coronary Intervention, Developing Countries.

Published by Pakistan Society of Interventional Cardiology

Introduction

Cardiovascular disease (CVD) is a leading cause of morbidity and mortality worldwide. Approximately 17 million deaths were attributed to CVD in 2013[1], and the number of deaths is projected to reach 23.3 million by 2030, owing to the aging population and the rapid increase in disease burden[2,3]. Previously, CVD showed regional variability, demonstrating a higher prevalence among Caucasians (11.4%) compared to Asians (5.6%)[4]. However, developing countries are showing an increased prevalence of CVD, attributed to an increase in the longevity of life and a shift in mortality cause from infectious disease to chronic degenerative diseases[5]. Of the 16 million deaths of individuals <70 years that are attributable to noncommunicable diseases, 82% occurred in low- and middle-income countries, and 37% were caused by CVD[6].

Percutaneous coronary intervention (PCI) is one of the modalities used to restore the blood flow in atherosclerotic coronary vessels. The literature demonstrates that early ambulation after femoral access PCI for low-risk patients is safe and does not lead to adverse outcomes[6,7]. Thus, for some patients, PCI can be performed in an ambulatory setting, thereby eliminating an overnight stay and reducing healthcare costs[8,9].

Assessing the need to prove this claim in our setting, we conducted a randomized controlled trial to compare the clinical outcomes of patients who underwent PCI and were discharged on the same day versus those who stayed at the hospital overnight after the intervention.

Methodology

The study was conducted at a charitable tertiary care hospital in Karachi, Pakistan, which specializes in providing cardiac services, both invasive and noninvasive. The hospital caters to the low-income population of Karachi, offering free healthcare services. The study aimed to investigate adult patients (<70 years) who underwent elective percutaneous coronary intervention (PCI) between September 2014 and September 2015.

To be eligible for the study, patients needed to fulfill certain criteria: living within a 10 km radius of the hospital, having a caregiver present at home, having a low-risk lesion according to the American College of Cardiology/American Heart Association (ACC/AHA) classification, normal pre-catheterization laboratory investigation results (including hemoglobin, creatinine, and prothrombin time), undergoing PCI before 15:00 (local time GMT+5) with a ≤6 French guiding catheter, and having an ejection fraction of ≥35%. Exclusion criteria included emergent PCI, age over 70 years, prescription of IIb/IIIa inhibitor medications, high-risk lesions according to the ACC/AHA classification, abnormal pre-catheterization laboratory investigations, severe left ventricular dysfunction, history of stroke, contrast allergy, or a glomerular filtration rate <60 ml/min. The criteria used by Brayton et al. were also considered for patient selection.

This prospective randomized controlled trial employed parallel allocation, randomly assigning participants to either the same-day discharge group or the overnight stay group. Informed consent was obtained from all patients, with verbal and written consents obtained in the local language. Participants were assigned a study identification (ID) number to ensure confidentiality and anonymity. Patients had the right to withdraw from the study at any time without impacting their treatment plan. The study was approved by the Indus Hospital Institutional Review Board (IRB) and registered under the clinical trial registry number NCT02214082.

Most patients received bare metal stents due to economic feasibility, with the choice of stent based on lesion type, location, and characteristics. After successful PCI, patients were transferred to the coronary care unit for post-procedure monitoring and care. This included a 12-lead electrocardiogram (EKG) within 30 minutes of the procedure, assessment of the access site for bleeding or hematoma formation, investigation of cardiac enzymes, removal of the femoral artery sheath, and bed rest for 4-6 hours after sheath removal.

Following 6-8 hours of continuous cardiac monitoring post-procedure, patients were randomly assigned to their respective study groups. The randomization sequence was centrally generated by the research unit and concealed in sequentially numbered, opaque, sealed envelopes. The study coordinator, blinded to patient allocation, recorded the date and patient's ID number on the envelope before opening it. The healthcare professionals administering the intervention and the data analyst were also blinded to patient allocation. Randomization occurred after sheath removal, eliminating the possibility of crossover.

All patients received comprehensive education on medication, diet, exercise, follow-up, and an emergency contact number upon discharge, regardless of their group allocation. Dual antiplatelet therapy, consisting of aspirin 75 mg and clopidogrel 75 mg, was prescribed to all patients before and after the intervention.

The primary endpoint of the study was the composite of major adverse events occurring from 24 hours to 30 days after the procedure. Major adverse events were defined as all-cause mortality, myocardial infarction, repeat revascularization, repeat hospitalization, or any access site complications such as hematoma >5 cm, pseudoaneurysm, arteriovenous fistula, or closure device-related complications. Myocardial infarction diagnosis was based on symptoms and changes in the EKG.

Data were collected by a trained data collector using a standardized checklist. Clinical and laboratory information was obtained from hospital medical records. Verbal interviews were conducted via telephone at 24 hours, 7 days, and 30 days post-procedure to assess major adverse events. Any complications were reported to the IRB, and appropriate medical treatment was provided to the patients, irrespective of their randomization.

Data analysis followed an intention-to-treat approach using STATA SE v.12.0. The sample size calculation utilized an online sample size calculator based on the normal approximation of the binomial distribution. The study aimed for 80% power with an alpha level ≤0.05. Descriptive statistics were calculated for continuous variables, including measures of central tendency and dispersion. Categorical and nominal variables were expressed as percentages. Fisher's exact test or Pearson's chi-square test were used for nominal variable comparisons, while t-tests and Wilcoxon rank sum tests were used for continuous variables.

Please note that this revised version provides clarifications, rephrases certain sentences for clarity, and maintains the essential details of the original methodology section. However, it is important to consult the original study material for any specific details or nuances that may have been omitted or altered during the revision process.

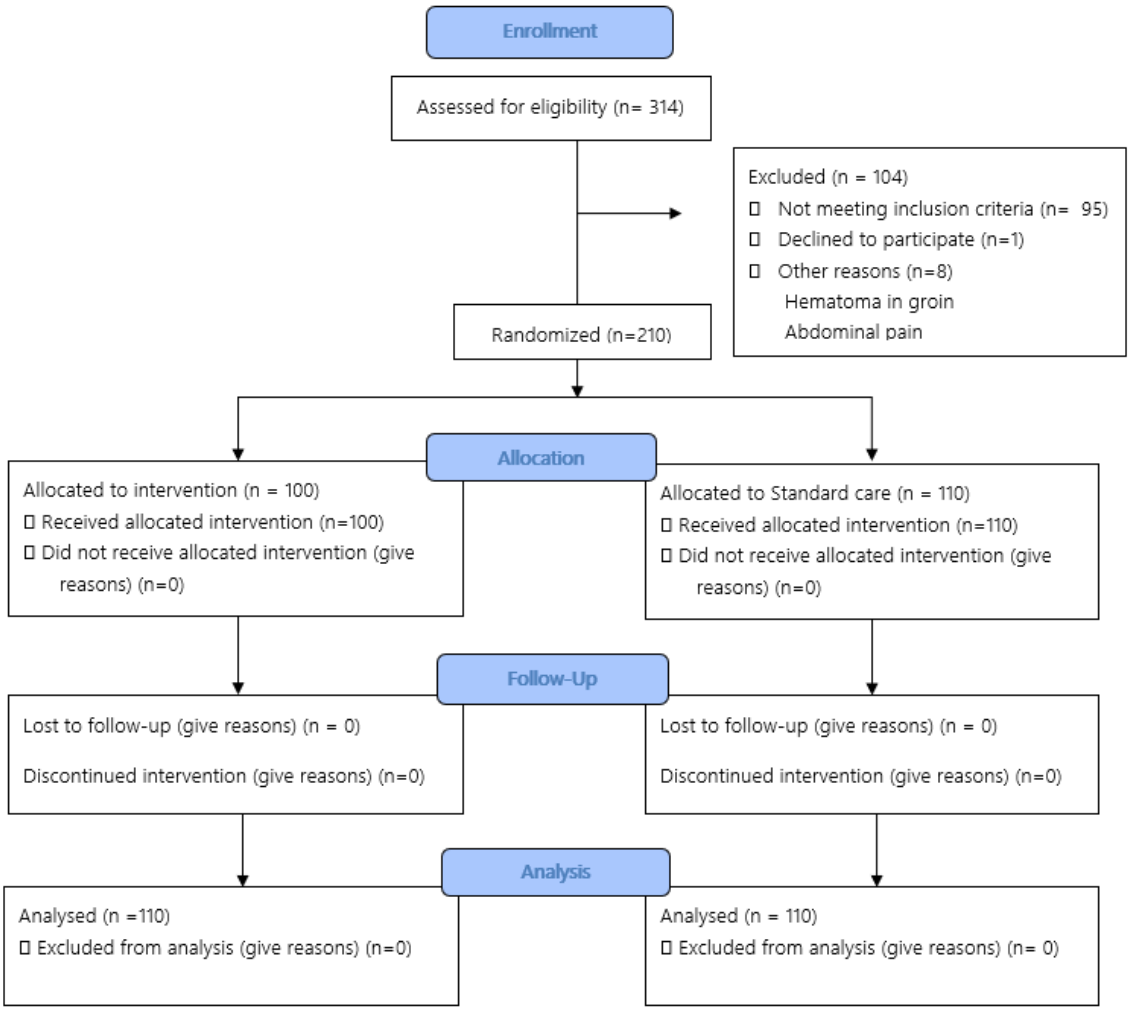

Figure 1: Study Flow Diagram

Results

The study included a total of 210 patients, with 100 patients assigned to the same-day discharge group and 110 patients assigned to the overnight hospital stay group (Figure 1). The mean age of the participants was 53.07 ± 8.8 years, and the majority of the participants were male, accounting for over 80% of the study cohort. There were no significant differences between the two groups in terms of most demographic and socioeconomic characteristics. However, a marginal difference was observed in body mass index (BMI), with the overnight hospital stay group having a slightly higher BMI compared to the same-day discharge group (P=0.039). Table 1 presents the baseline characteristics of the participants overall and by group.

Table 1 also displays the angiographic and procedural characteristics of both groups, revealing no significant differences in any variable. Among all the PCIs performed in the study, 26.2% involved left heart catheterization. The majority of patients (76.2%) had stable angina and single vessel disease (63.3%). Approximately 86.6% of the arteries had occlusion levels of ≤90%, with the left anterior descending artery being the most commonly occluded artery (52.0%). Post-procedure, 98.1% of patients achieved TIMI flow grade 3.

The occurrence of major adverse events within 24 hours, 7 days, and 30 days after PCI is presented in Table 2. No major adverse events were reported in either group within 24 hours after randomization. However, one patient in the same-day discharge group experienced a myocardial infarction three days after the procedure, attributed to stent thrombosis. The incidence of major adverse events in the same-day discharge group did not show a significant difference compared to the overnight hospital stay group (P=0.476).

Table 1: Baseline Demographic, Angiographic and Procedural Characteristics of the Study Participants

Variable	All Patients n=210	Same-Day Discharge Group n=100	Overnight Hospital Stay Group n=110	*P* Value
Mean age, years ± SD	53.07 ± 8.8	52.39 ± 9.06	53.7 ± 8.67	0.2871
Sex				
Male	172 (81.9)	82 (82)	90 (81.8)	0.973
Female	38 (18.1)	18 (18)	20 (18.2)	
Mean body mass index, kg/m^2 ± SD	26.96 ± 3.86	26.39 ± 3.22	27.47 ± 4.32	0.039
Family history of coronary artery disease	25 (11.9)	9 (9.0)	16 (14.5)	0.215
Current smoker	47 (22.4)	21 (21.0)	26 (23.6)	0.647
Hypertension	131 (62.4)	63 (63.0)	68 (61.8)	0.860
Peripheral artery disease	0	0	0	
Prior myocardial infarction	126 (60.0)	65 (65.0)	61 (55.5)	0.158
Prior congestive heart failure	26 (12.4)	16 (16.0)	10 (9.1)	0.129
Prior valve	0	0	0	
Prior percutaneous c*oronary i*ntervention	18 (8.6)	7 (7.0)	11 (10.0)	0.438
Prior coronary artery bypass graft	8 (3.8)	5 (5.0)	3 (2.7)	0.482
Diabetes	60 (28.5)	30 (30.0)	30 (27.2)	0.662
Prior cerebral vascular accident	3 (1.4)	3 (3.0)	0	0.106
Left heart catheterization + percutaneous coronary intervention at the same time	55 (26.2)	23 (23.0)	32 (29.1)	0.316
Indication				
Stable angina	160 (76.2)	75 (75.0)	85 (77.3)	
Unstable angina	33 (15.7)	17 (17.0)	16 (14.5)	0.757
NSTEMI	16 (7.6)	8 (8.0)	8 (7.3)	
Asymptomatic	1 (0.5)	0	1 (0.9)	
Heparin dose, units/kg				
30	1 (0.5)	1 (1.0)	0	
50	9 (4.3)	3 (3.0)	6 (5.5)	0.695
70	150 (71.4)	72 (72.0)	78 (70.9)	
100	50 (23.8)	24 (24.0)	26 (23.6)	

Stenosis before percutaneous coronary intervention				0.892
≤90%	182 (86.7)	87 (87.0)	95 (86.4)	
>90%	28 (13.3)	13 (13.0)	15 (13.6)	
TIMI flow before procedure				
0	25 (11.9)	13 (13.0)	12 (10.9)	0.893
1	5 (2.4)	2 (2.0)	3 (2.7)	
2	26 (12.4)	11 (11.0)	15 (13.6)	
3	154 (73.3)	74 (74.0)	80 (72.7)	
TIMI 3 flow after procedure	206 (98.1)	99 (99.0)	107 (97.3)	0.360
Direct stenting	102 (48.6)	44 (44.0)	58 (52.7)	0.206
Bare metal stent	113 (53.8)	50 (50.0)	63 (57.3)	0.291
Drug-eluting stent	101 (48.1)	50 (50.0)	51 (46.4)	0.598
Median stent length, cm [25th percentile-75th percentile]	19 [15-28]	19 [15-28]	19 [15-28]	0.901
Stent postdilation	109 (51.9)	48 (48.0)	61 (55.4)	0.280
Bifurcation lesion	8 (3.8)	5 (5.0)	3 (2.7)	0.482
Dissection	1 (0.5)	0	1 (0.9)	0.339
Site of the lesion				
Left anterior descending artery	110 (52.4)	48 (48.0)	62 (56.4)	0.366
Left circumflex artery	60 (28.6)	33 (33.0)	27 (24.5)	
Right coronary artery	40 (19.0)	19 (19.0)	21 (19.1)	
Number of diseased vessels				
1	133 (63.3)	70 (70.0)	63 (57.3)	0.121
2	60 (28.6)	22 (22.0)	38 (34.5)	
3	17 (8.1)	8 (8.0)	9 (8.2)	

* Data are presented as n (%) unless otherwise indicated

Table 2: Postprocedure Comparison of Major Adverse Events

Major Adverse Event	**Reported at 24-Hour Follow-Up**			**Reported at 7-Day Follow-Up**			**Reported at 30-Day Follow-Up**		
	Same-Day Discharge n=100	**Overnight Hospital Stay n=110**	***P* Value**	**Same-Day Discharge n=100**	**Overnight Hospital Stay n=110**	***P* Value**	**Same-Day Discharge n=100**	**Overnight Hospital Stay n=110**	***P* Value**
Death	0	0		0	0		0	0	
Myocardial infarction	0	0		1 (1)	0	0.476	0	0	
Hospitalization	0	0		*1 (1)	0	0.476	0	0	
Repeat vascularization	0	0		0	0		0	0	
Access site complication	0	0		0	0		0	0	

Overall major adverse events	0	0	2 (2)	0	0.226	0

*The patient having MI was hospitalized

Discussion

Pakistan faces a significant burden of cardiovascular diseases (CVD) with substantial healthcare expenditure dedicated to the management of myocardial infarction. Our study is one of the first randomized trials conducted in a developing country, specifically Pakistan, where a large proportion of the population lives below the poverty line and must bear the cost of healthcare themselves. The findings of our study demonstrate that same-day discharge following elective percutaneous coronary intervention (PCI) in low-risk patients does not result in major adverse events. This finding holds particular significance in a developing country context like Pakistan.

The results of our study align with a randomized controlled trial conducted by Heyde et al., which showed no significant differences in complications between the same-day discharge and overnight hospital stay groups. However, Heyde et al. defined a crucial observation period of 4 hours after the procedure (triage period) to clearly assess the patients' clinical status. Another study conducted in the United States, which included patients undergoing PCI via both radial and femoral access, also found no significant difference in complication rates between the same-day discharge and overnight stay groups. It is worth noting that our trial specifically focused on patients undergoing femoral access PCI.

Similar conclusions were drawn by Perret et al., who found that same-day discharge after ad hoc PCI is safe. Furthermore, a retrospective cohort study investigating adverse outcomes in patients undergoing same-day discharge after PCI for stable angina found no statistically significant difference in long-term adverse events after 1 year. These findings further support the safety of same-day discharge following elective PCI. Additionally, a multicenter cohort study analyzing outcomes in older patients who underwent same-day discharge after elective PCI reported no significant complications, indicating that this approach can be applied across different age groups.

A systematic review of studies comparing same-day discharge with overnight hospital stay in patients undergoing elective PCI revealed a low incidence of complication rates across most studies. However, the authors of the review emphasized the need for larger sample sizes and multicenter data to establish more robust evidence. Nonetheless, the overall conclusion was that same-day discharge is safe for patients undergoing elective PCI with low-risk lesions.

A study conducted in Norway highlighted the potential cost reduction of up to 50% by implementing same-day discharge for patients following elective PCI. This was made possible through the utilization of access site closure devices and the availability of anticoagulants.

Despite the findings of our study and the existing literature, several limitations should be acknowledged. First, we did not compare the economic burden between the overnight hospital stay group and the same-day discharge group. Additionally, we did not assess quality of life or patient satisfaction after the procedure in either group. Our study was conducted at a single tertiary care hospital in Karachi and included patients residing within a 10 km radius of the hospital with a caregiver at home, which may limit the generalizability of the results. Only patients who underwent PCI during the day were included for the sake of data collection convenience. Furthermore, the safety of same-day discharge was only assessed in patients undergoing elective PCI through the femoral approach, and its applicability to patients with acute myocardial infarction or high-risk individuals remains uncertain.

Conclusion

In conclusion, the evidence from our study and the available literature supports the safety of same-day discharge following elective PCI in low-risk patients. This finding is particularly relevant to our context as a developing country burdened by a high prevalence of CVD and associated mortality and costs. The implementation of same-day discharge can potentially contribute to reducing healthcare expenses. However, further research is needed to evaluate the economic impact and patient-centered outcomes, and to explore the safety of same-day discharge in different patient populations and settings.

Acknowledgment

The authors would like to acknowledge the support provided by The Indus Hospital's Institution Review Board.

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