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

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Keywords: Myocardial infarction, percutaneous coronary intervention, developing countries

DOI: https://doi.org/10.21203/rs.3.rs-58169/v1

Abstract

Objective: Cardiovascular disease have a large disease burden in developing countries. Percutaneous coronary intervention (PCI) is one of the modalities used to restore the blood flow in atherosclerotic coronary vessels. The aim of this randomized controlled trial was to evaluate the safety of same-day discharge compared to overnight hospital stay after low-risk elective PCI in a tertiary care hospital in Pakistan.

Results: From September 2014 to September 2015, a total of 210 patients who underwent low-risk PCI were randomized to overnight stay or same-day discharge. Primary endpoint of the study was a major adverse event, a composite of death, myocardial infarction, repeat revascularization, rehospitalization, and any access site complications (major bleeding or hematoma) after the procedure. No major adverse events were noted within 24 hours in either group. The only reported adverse event was myocardial infarction secondary to stent thrombosis on the third day after PCI in the same-day discharge group. No mortality or access site complications occurred in either group. In our cohort, same-day discharge after low-risk PCI was safe and should be considered for certain patients to eliminate the cost of an overnight hospital stay.

clinical trial registry number: NCT02214082. Registered on 11th August 2014

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.

Methods

The study was conducted at a tertiary care hospital in Karachi, Pakistan, that offers invasive and noninvasive cardiac services. The hospital provides free of cost healthcare services to the people of Karachi and is run by a charitable trust. Most of the patients visiting this hospital belong to the low-income stratum of the society.

Adult patients (< 70 years) undergoing elective PCI from September 2014 through September 2015 and who met the inclusion criteria were invited to enroll in the study. Patients who lived within a 10 km radius from the hospital with a caregiver present at home and had low-risk lesion (according to the American College of Cardiology/American Heart Association (ACC/AHA) classification) [10], normal pre-catheterization laboratory investigation (hemoglobin, creatinine, prothrombin time), PCI performed before 15:00 (local time GMT + 5) with a ≤ 6 French guiding catheter, and an ejection fraction of ≥ 35% were eligible for inclusion in the study. Patients undergoing an emergent PCI, patients > 70 years, patients prescribed IIb/IIIa inhibitor medications, and those with high-risk lesions (according to the ACC/AHA classification) [10] abnormal pre-catheterization laboratory investigations, severe left ventricular dysfunction, stroke, contrast allergy, or a glomerular filtration rate < 60 ml/min

were excluded from the study. The induction of patients into the study was further guided by the criteria used by Brayton et al [11].

The study was a prospective randomized controlled trial with a parallel allocation of participants to the same-day discharge group or overnight stay group. Patients were recruited for the study after providing informed consent; both verbal and written consents were obtained in the local language. Confidentiality and anonymity of the participants were maintained by providing them with a study identification (ID) number. Patients were given the right to withdraw from the study at any time without risking any change in treatment plan. The Indus Hospital Institutional Review Board (IRB) approved the study (clinical trial registry number NCT02214082).

Most patients underwent PCI via bare metal stents because of economic feasibility. The decision regarding the type of the stent was based on the type, location, and characteristics of the lesion [11]. After completion of successful PCI, patients were moved to the coronary care unit for post-procedure monitoring and care. Postprocedural monitoring included 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.

After continuous cardiac monitoring for 6–8 hours post-procedure, patients were randomized into the study groups. The randomization sequence was centralized and generated by the research unit of the study setting. The group assignment was concealed in sequentially numbered, opaque, sealed envelopes. Before opening the envelope, the study coordinator wrote down the date and the patient's ID number on the envelope and signed it. The information was autoprinted to the treatment allocation paper inside [12]. The healthcare professionals imparting the intervention and the data analyst were blinded to the allocation of the patients. Because randomization occurred after sheath removal, no crossover occurred.

All patients were given comprehensive education on medication, diet, exercise, and follow-up, as well as an emergency contact number, irrespective of their group allocation at the time of discharge. All patients were prescribed dual antiplatelet therapy, consisting of aspirin 75 mg and clopidogrel 75 mg, before and after intervention.

The primary endpoint of the study was the composite of major adverse events, defined as all-cause mortality, myocardial infarction, repeat revascularization, repeat hospitalization, or any access site complication occurring from 24 hours to 30 days after the procedure. The diagnosis of myocardial infarction was made based on symptoms and changes in the EKG [13]. Access site complication was defined as a hematoma > 5 cm at the access site or pseudoaneurysm; arteriovenous fistula; or any closure device-related complications such as abrupt closure, dissection, thrombosis requiring invasive vascular intervention, or surgery [14].

Data were collected by a trained data collector using a standardized checklist prepared by the research team. Hospital medical records were accessed to obtain clinical and laboratory information of the patient. Verbal interviews via telephone were conducted at 24 hours, 7 days, and 30 days postprocedure to assess for major adverse events. All complications were reported to the IRB, and the necessary medical treatment was provided to the patient regardless of the randomization.

The data were analyzed using an intention-to-treat approach through STATA SE v.12.0. The sample size calculation was based on the principle of normal approximation of binomial distribution from the online sample size calculator [15]. The major adverse events rate in the same-day discharge group was estimated to be 8.5%, and the incidence of major adverse events in the overnight hospital stay group was estimated to be 0.5%. The power of the study was adjusted at 80%, with alpha defined as ≤ 0.05. Measures of central tendency and dispersion were calculated for all continuous variables according to the distribution followed by the data. The categorical and nominal variables were expressed as percentages. Fisher exact test or Pearson chi-square test were used to compare nominal variables between the groups; *t* test and Wilcoxon rank sum test were used to compare continuous variables.

Results

The total cohort included 200 patients, with 100 patients allocated to the same-day discharge group and 110 patients allocated to the overnight hospital stay group (Fig. 1). The mean age of the participants in the study was 53.07 ± 8.8 years. More than 80% of the study participants were male. No significant differences were present across the two groups with regard to all but one of the demographic and socioeconomic characteristics. A marginally significant difference in body mass index (BMI) was seen, with patients in the overnight hospital stay group having a higher BMI than the patients in the same-day discharge group ($P = 0.039$). Baseline characteristics overall and by group are presented in Table 1.

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 Female	172 (81.9) 38 (18.1)	82 (82) 18 (18)	90 (81.8) 20 (18.2)	0.973
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 coronary intervention	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

Data are presented as n (%) unless otherwise indicated

Variable	All Patients	Same-Day Discharge Group	Overnight Hospital Stay Group	*P* Value
	n = 210	n = 100	n = 110	
Indication	160 (76.2)	75 (75.0)	85 (77.3)	0.757
Stable angina		17 (17.0)	16 (14.5)	
Unstable angina	33 (15.7)	8 (8.0)	8 (7.3)	
NSTEMI	16 (7.6)	0	1 (0.9)	
Asymptomatic	1 (0.5)			
Heparin dose, units/kg	1 (0.5)	1 (1.0)	0	0.695
30	9 (4.3)	3 (3.0)	6 (5.5)	
50	150 (71.4)	72 (72.0)	78 (70.9)	
70		24 (24.0)	26 (23.6)	
100	50 (23.8)			
Stenosis before percutaneous coronary intervention	182 (86.7)	87 (87.0)	95 (86.4)	0.892
≤ 90%		13 (13.0)	15 (13.6)	
> 90%	28 (13.3)			
TIMI flow before procedure	25 (11.9)	13 (13.0)	12 (10.9)	0.893
0		2 (2.0)	3 (2.7)	
1	5 (2.4)	11 (11.0)	15 (13.6)	
2	26 (12.4)	74 (74.0)	80 (72.7)	
3	154 (73.3)			
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

Data are presented as n (%) unless otherwise indicated

Variable	All Patients	Same-Day Discharge Group	Overnight Hospital Stay Group	*P* Value
	n = 210	n = 100	n = 110	
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	110 (52.4)	48 (48.0)	62 (56.4)	0.366
Left anterior descending artery	60 (28.6)	33 (33.0)	27 (24.5)	
Left circumflex artery	40 (19.0)	19 (19.0)	21 (19.1)	
Right coronary artery				
Number of diseased vessels	133 (63.3)	70 (70.0)	63 (57.3)	0.121
1	60 (28.6)	22 (22.0)	38 (34.5)	
2	17 (8.1)	8 (8.0)	9 (8.2)	
3				
Data are presented as n (%) unless otherwise indicated				

Angiographic and procedural characteristics in both groups shown in Table 1 were also similar, with no significant differences seen in any variable. Of the total PCIs in the study, 26.2% were performed along with left heart catheterization. Most patients (76.2%) had stable angina and single vessel disease (63.3%). The majority of arteries (86.6%) had ≤ 90% occlusion. The most commonly occluded artery was the left anterior descending artery (52.0%). Postprocedure, 98.1% of patients had TIMI flow grade 3.

Table 2 shows major adverse events reported 24 hours, 7 days, and 30 days after PCI. None of the patients in either group experienced any major adverse event within 24 hours after randomization. One patient in the same-day discharge group had a myocardial infarction 3 days after the procedure that was attributed to stent thrombosis. The occurrence of the major adverse event in the same-day discharge group was not significant ($P = 0.476$).

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 has one of the highest burden of CVDs worldwide, with a high percentage of health expenditure spent on the management of myocardial infarction [16,17]. To our knowledge, ours is one of the first randomized trials to evaluate the safety of same-day discharge in a developing country where most of the population lives below the poverty line and many patients have to bear the cost of healthcare at their own expense. Our study shows that same-day discharge after elective PCI in low-risk patients does not lead to the occurrence of major adverse events, a finding with particular significance in a developing country such as Pakistan.

The results of our study are consistent with a randomized control trial conducted by Heyde et al showing that the same-day discharge group did not differ significantly from the overnight hospital stay group in terms of complications. However, Heyde et al defined a time period of 4 hours for observation (triage period) after the procedure that was absolutely crucial for clearly defining the clinical fate of the patient [6]. A similar trial conducted in the United States found no significant difference in the rate of complications between the same-day discharge and overnight hospital stay group. However, this study included individuals undergoing PCI through both radial and femoral access, while our trial only included patients undergoing PCI through femoral access [19]. Perret et al concluded that discharging patients the same day after an ad hoc PCI is safe, and the characteristics of the participants in that study were similar to ours [20]. A retrospective cohort study on the occurrence of adverse outcomes in patients undergoing same-day discharge after PCI for treatment of stable angina found no statistical significance in the occurrence of long-term adverse events after 1 year, further validating the safety of the intervention employed in the study [21]. A multicenter cohort analyzing the outcomes of older patients undergoing same-day discharge after elective PCI found no significant complications in the group, indicating that same-day discharge can be employed in all age groups [22]. A systematic review of studies comparing same-day discharge with overnight hospital stay in patients undergoing elective PCI exhibited a low incidence of complication rates in most of the studies, but the authors of the review pointed out the unmet need of a large sample size and multicenter data to provide concrete evidence. Overall, however, they concluded that same-day discharges are safe in patients undergoing elective PCI with low-risk lesions [23].

A study conducted in Norway concluded that same-day discharge of patients following elective PCI can reduce healthcare costs by as much as 50%, made possible using access site closure devices and the availability of anticoagulants [24].

STUDY LIMITATIONS

The study has several limitations, including the lack of a comparison of the economic burden of the patients in the overnight hospital stay group vs those in the same-day discharge group. No assessment of quality of life or patient satisfaction after the procedure was performed in either group. This study only included patients coming to one tertiary care hospital in Karachi, and we recruited patients who lived within 10 km of the hospital with a caregiver at home. These factors could have affected the results of the study. Only patients who underwent PCI during the day were included for the ease of data collection. Further, the assumption of the safety of same-day discharge can only be applied to patients undergoing elective PCI through the transfemoral approach. The study did not assess the safety of this practice in patients with acute myocardial infarction or in high-risk individuals.

The literature, as well as the findings from the current study, suggest that same-day discharge is a safe clinical practice after elective PCI in low-risk patients. This finding is especially applicable to our setting—a developing country that is burdened by a high prevalence of CVD and mortality attributable to CVD, as well as the associated costs.

Abbreviations

PCI
Percutaneous coronary intervention
CVD
Cardiovascular disease
ACC
American College of Cardiology
AHA
American Heart Association
ID
Identification
IRB
Institutional Review Board
EKG
Electrocardiogram
BMI
Body Mass Index
TIMI
Thrombolysis in Myocardial Infacrction
STEMI
ST elevation myocardial Infarction

Declarations

Ethical approval and consent to participate

The study was approved by IRB of the Indus Hospital. Authors obtained written informed consent from all the participants in the study.

Availability of data and material

All the data obtained in the study is presented in this paper. Any additonal material required will be provided by the corrsponding author based on the ethical guidelines.

Funding

The authors did not receive nay funding for the study.

Acknowledgement

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

Consent for publication

All the authors consent for publication of this manuscript.

Competing Interests

The Authors declare that they have no competing interest

Authors' Contribution

SD conceived the idea, performed cornary interventions and contributed to publication . AG developed protocol, designed data collection forms, procured IRB approval, analyzed the results and contributed to publication, AN and Il performed interventions with SD, assessed patients and contributed to manuscript. FA supervised the study, performed randomization, collected and entered data for statistical analysis, managed data and constributed to manuscript. MT constributed to manuscript.

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Figures

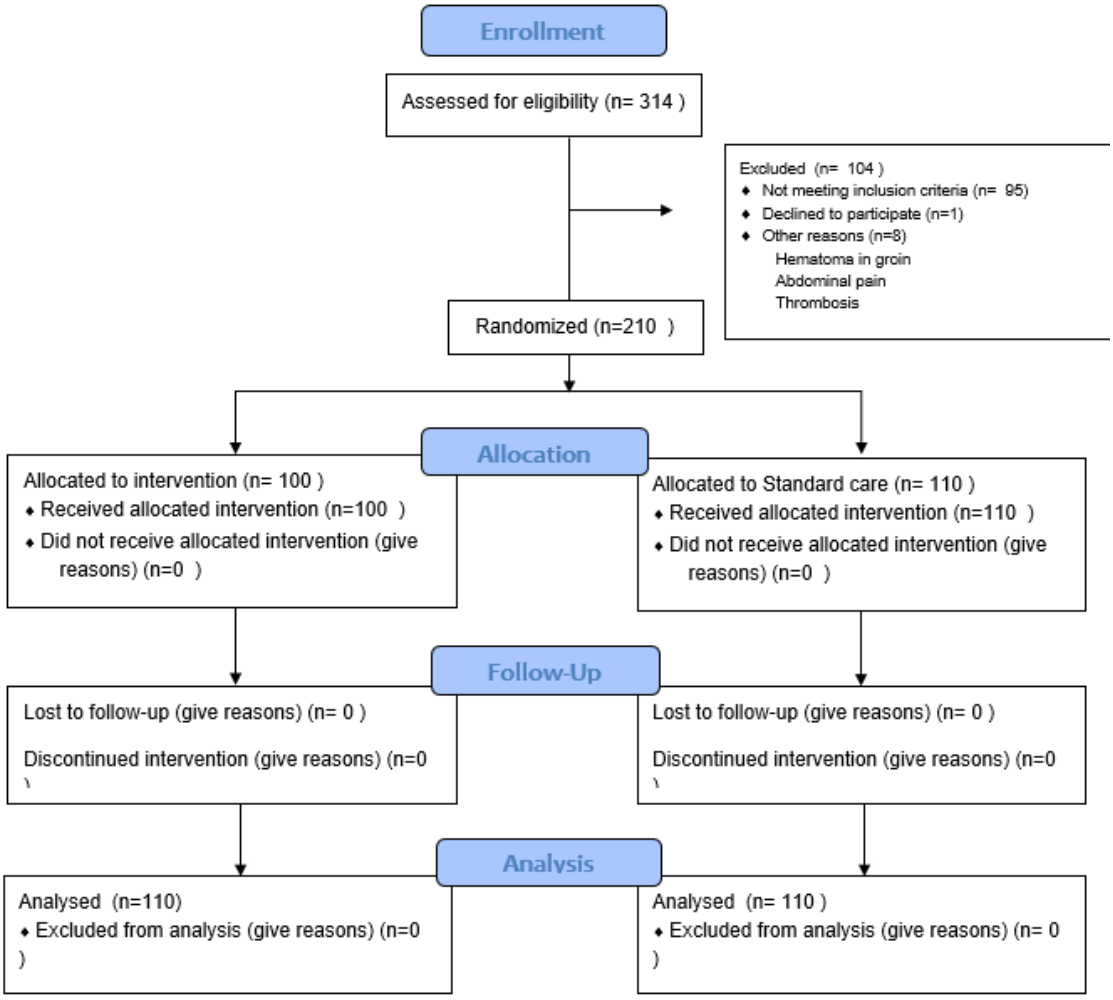

Figure 1

Study Flow Diagram