SAFETY AND OUTCOME OF SAME DAY DISCHARGE VS OVER-NIGHT STAY AFTER ELECTIVE PCI IN PATIENTS WITH STABLE CAD: A RANDOMIZED CONTROL TRIAL IN ARMY CARDIAC CENTER

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ABSTARCT

Objective: To determine and compare the safety and outcomes of same day discharge patients with over-night stay patients after elective percutaneous coronary interventions with stable coronary artery disease.

Study Design: Randomized controlled trial.

Place and Duration of Study: This study was conducted at Army Cardiac Center, Lahore from, Jun 2017 to Jul 2018.

Methodology: Hundred patients with stable CAD were recruited after their informed consent. Patients were randomized through lottery method using list of patients. Fifty patients were discharged on the same day of PCI while 50 patients stayed over-night. Inclusion Criteria was patients of either gender with age <75 years undergoing elective PCI with no acute decompensated CHF or shock, LVEF > 30%, Serum creatinine <1.5 mg/dl and no contrast allergy. While those excluded were with multi vessel disease, bifurcation disease or left main disease, saphenous vein graft or internal mammary disease, recent ACS, ≥3 stents or Femoral access. Immediate adverse cardiac and cerebral events were noted in the first 24 hours. The procedural result followed by a 6-hours observation period allowed adequate triage of patients to same-day discharge or to extended clinical observation. The one month clinical follow up was also done. Data was analyzed using SPSS 23. Confidentiality of data was maintained.

Results: Mean age of the patients was 54 ± 3.8 years, 81 male patients while 19 female patients. Most common comorbidity was hypertension in 62 patients followed by diabetes in 43, dyslipidemia in 39 patients and current smokers 20 (20%). Haematoma formation [3 (6.0% vs 4 (8.0%); *p*=0.04], allergic reaction [5 (10.0% vs 6 (12.0%); *p*=0.50] and re- hospitalization for chest pain [5 (10.0% vs 2 (4.0%); *p*=0.50] were almost the same. No cardiac death, MI, Repeat PCI, urgent CABG, stroke, re-hospitalization for bleeding or non-cardiac death were observed in both groups. When patients were asked about their preference of discharge, 47 (47.0%) patients preferred for same day discharge, 22 (22.0%) for over-night stay while 31 (31.0%) preferred whatever their doctor considered best for them.

Conclusion: Our study results yielded that same day discharge after elective PCI is a safe practice. Post-procedural outcomes are the same in same day group and over-night stay group. Same day discharge strategy is a cost effective approach and should be considered for the future.

Keywords: Coronary artery disease, Elective percutaneous coronary intervention, Myocardial Infarction, Post-procedural outcomes.

INTRODUCTION

Percutaneous coronary Intervention (PCI) is one of the most commonly performed cardiac procedure[1]. Because of the development in device technology, and pharmacotherapy, Short-and long-term outcomes after PCI have improved considerably. After elective PCI, patients are usually observed overnight in the hospital to monitor for PCI associated complications[1,2].

The increasing number of percutaneous coronary intervention (PCI) procedures has led to accumulating logistic constraints. A reduction in hospital stay and the application of day-case facilities were advocated to reduce procedure-related costs. New developments in interventional car-

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diology such as stents and adjunctive antithrombotic therapy have made PCI safer[3]. Previous studies demonstrated that short-term observation after PCI is safe. Patients could be adequately selected for additional observation to anticipate post-procedural complications[4]. Furthermore, it was shown that early ambulation after femoral-approach PCI was safe and did not add to the complication rate[5].

Many observational studies, randomized trials and meta analysis performed all over the world have demonstrated the safety of discharging patients on the same day after PCI without overnight observation. But few studies have been reported from Pakistan which compare safety and feasibility of performing coronary angioplasty as a day care procedure[6].

METHODOLOGY

This was a randomized controlled trial, conducted at Army Cardiac Center, Lahore from June 2017 till July 2018. Hundred patients with stable CAD were recruited after their informed consent. Patients were randomized through lottery method using list of patients. Fifty patients were discharged on the same day of PCI while 50 patients stayed over-night. Inclusion Criteria was patients of either gender with age <75 years undergoing elective PCI with no acute decompensated CHF or shock, LVEF > 30%, Serum creatinine <1.5 mg/dl and no contrast allergy. While those excluded were with multi vessel disease, bifurcation disease or left main disease, saphenous vein graft or internal mammary disease, recent ACS, ≥3 stents or femoral access. Immediate adverse cardiac and cerebral events were noted in the first 24 hours. The procedural result followed by a 6-hours observation period allowed adequate triage of patients to same-day discharge or to extended clinical observation. The one month clinical follow up was also done. Data was analyzed using SPSS 23. Confidentiality of data was maintained.

RESULTS

Mean age of the patients was 54 ± 3.8 years, 81 male patients while 19 female patients. Most common comorbidity was hypertension in 62 patients followed by diabetes in 43, dyslipidemia in 39 patients and current smokers 20 (20%) as shown in table-I & II.

As far as comparison between the same day group vs over-night group was concerned, Haematoma formation [3 (6.0% vs 4 (8.0%); *p*=0.04], allergic reaction [5 (10.0% vs 6 (12.0%); *p*=0.50] and re- hospitalization for chest pain [5 (10.0% vs 2 (4.0%); *p*=0.50] were almost the same. No cardiac death, MI, Repeat PCI, urgent CABG, stroke, re-hospitalization for bleeding or non-cardiac death were observed in both groups. When patients were asked about their preference

Table-I: Showing demographics and co-morbids of the patients.

Variables	Same Day Group	Over-Night Group	*p*-value
Age			
<40 years	2 (4.0%)	-	0.220
40-60 years	25 (50.0%)	31 (62.0%)	
>60 years	23 (46.0%)	19 (38.0%)	
Gender			
Male	40 (80.0%)	41(82.0%)	0.500
Female	10 (20.0%)	9 (18.0%)	
Smoker			
Current Smoker	14 (28.0%)	6 (12.0%)	0.125
Ex-Smoker	13 (26.0%)	14 (28.0%)	
Non-Smoker	23 (46.0%)	30 (60.0%)	
Diabetes Mellitus			
Yes	20 (40.0%)	23 (46.0%)	0.343
No	30 (20.0%)	27 (54.0%)	
Hypertension			
Yes	36 (72.0%)	26 (52.0%)	0.032
No	14 (28.0%)	24 (48.0%)	
Dyslipidemia			
Yes	25 (50.0%)	14 (28.0%)	0.020
No	25 (20.0%)	36 (72.0%)	
Pervious Cardiac History			
Previous Unstable Angina	4 (8.0%)	-	0.04
STEMI	19 (38.0%)	17 (34.0%)	
NSTEMI	14 (28.0%)	10 (20.0%)	
CSA	13 (26.0%)	23 (46.0%)	
Previous PCI			
Yes	3 (6.0%)	4 (8.0%)	0.500
No	47 (94.0%)	46 (92.0%)	
Previous CABG			
Yes	2 (4.0%)	-	0.247
No	48 (96.0%)	50 (100%)	

of discharge, 47 (47.0%) patients preferred for same day discharge, 22 (22.0%) for over-night stay while 31 (31.0%) preferred whatever their doctor considered best for them (figure).

Table-II: Showing clinical characteristics and procedural outcomes of both groups.

Echocardiography			
Good	28 (56.0%)	24 (48.0%)	0.500
Mild Dysfunction	15 (30.0%)	14 (28.0%)	
Moderate Dysfunction	7 (14.0%)	11 (22.0%)	
Severe Dysfunction	-	1 (2.0%)	
Angina CSS Class			
CSS 1	1 (2.0%)	-	0.132
CSS 2	12 (24.0%)	16 (32.0%)	
CSS 3	27 (54.0%)	31 (62.0%)	
CSS 4	10 (20.0%)	3 (6.0%)	
NYHA Heart Failure Class			
NYHA 2	24 (48.0%)	37 (74.0%)	0.002
NYHA 3	20 (40.0%)	13 (26.0%)	
NYHA 4	6 (12.0%)	-	
No. of Diseased Arteries			
SVCAD	27 (54.0%)	22 (44.0%)	0.002
DVCAD	13 (26.0%)	21 (42.0%)	
TVCAD	10 (20.0%)	7 (14.0%)	
Arterial Dominance			
R	45 (90.0%)	39 (78.0%)	0.050
L	4 (8.0%)	6 (12.0%)	
CO	1 (2.0%)	5 (10.0%)	
No. of Arteries Stented			
1	44 (88.0%)	35 (70.0%)	0.024
2	6 (12.0%)	15 (30.0%)	
No. of Stents			
1	39 (78.0%)	30 (60.0%)	0.044
2	11 (22.0%)	20 (40.0%)	
Type of Lesion			
Type A	32 (64.0%)	36 (72.0%)	0.223
Type B	18 (36.0%)	14 (28.0%)	
Type of Access			
Right Radial	46 (92.0%)	45 (90.0%)	0.500
Left Radial	4 (8.0%)	5 (10.0%)	

DISCUSSION

The present study demonstrates that same-day discharge after elective PCI can be performed safely in most patients. Same-day discharge after PCI did not lead to unattended cardiac events or to more complications at the femoral access site. Furthermore, it was found that the procedural result followed by a 4-hour observation period allowed adequate triage of patients to same-day discharge or to extended clinical observation. Thus far, nonrandomized studies have reported same-day discharge after PCI in highly selected patients with either the femoral or the radial approach[7-10]. The patients included in our study represent a general elective PCI population, with a sufficient proportion of patients with complex coronary lesions. Our study shows that patients at risk for post-procedural 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 4 hours after PCI is pivotal for the safety of a same-day discharge protocol. Therefore, a definitive

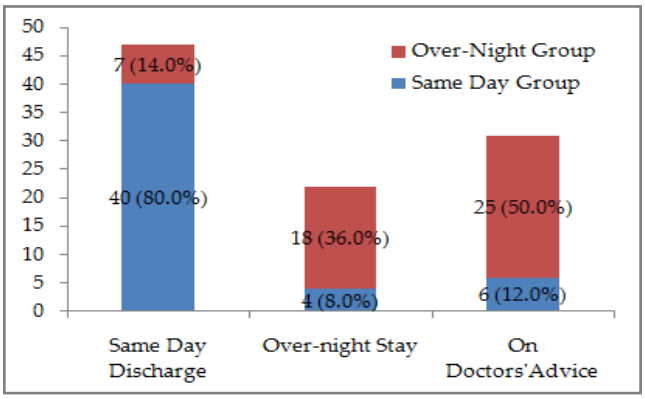

Figure: Bar chart showing patients' preferences.

decision for same-day discharge can be made only after an uncomplicated clinical course of at least 4 hours, which is in line with previous reports[12]. Previous investigators have shown that the radial approach is a suitable technique for same day discharge PCI because it enables immediate ambulation[13].

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 non-cardiac surgeries in the outpatient setting[14]. It is now estimated that over 65% of surgeries performed in North America are done so in the outpatient setting[15,16]. 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 length of stay following PCI is one of the major determinants of hospital cost and quality of care assessment. There have been few appraisals of same-day discharge in a real world spectrum of practice due to extreme variations in the length of saty between countries, regions, and hospitals. Length of stay shows a decreasing trend over time, and shorter length of stay does not appear to affect health outcomes adversely as demonstrated in various other day care procedures[17,18]. The first study on same day discharge reported by Kiemeneij *et al*[18]. clearly demonstrated safety of early ambulation after transradial PCI. This was followed by the study on 922 patients reported by Koch *et al*[19]. that showed short-term triage of 4 hours 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 al*[20]. 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. The current study has a limited number of exclusions and used more device variations such as larger guide catheters, complex interventions requiring rotablation, a uniform use of stents, and various closure devices. The patients included in our study had diverse demographics, comorbidities, and risk factors with complex coronary lesions that match the real-world setting of a tertiary referral center. There were very few post-PCI cardiac events or vascular access complications even in the elderly population (<65 years). The 6 to 8 h observation in the recovery unit with the necessary post-PCI care and education seems adequate to triage patients for either same-day discharge or extended over- night in-hospital admission. The 30 day major adverse cardiac cerebral events along with 30-day vascular complications for same-day discharge PCIs were low and comparable to the other studies reported to date. 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. Our study in a diverse patient population supports the importance of careful selection guidelines for determining the suitability of same-day discharge so that in-hospital resources can be predictably allocated. Based on the current study, the factors considered favorable for same-day discharge are outlined in table-II, which can safely be applied to a large number of patients undergoing elective PCI. Moreover, the present study demonstrates that safety of procedure can be achieved without compromising the quality-of-care or safety in the patient population with a higher-risk profile. Also, once the protocol[21,22] for ambulatory PCI is set in place, it does not incur extra costs on the hospital system to follow these patients and it does not add any costs to the physicians.

CONCLUSION

Our study results yielded that same day discharge after elective PCI is a safe practice. Post-procedural outcomes are the same in same day group and over-night stay group. As Pakistan is a resource deficient country so same day discharge is a cost effective approach and should be considered for the future.

CONFLICT OF INTEREST

This study has no conflict of interest to be declared by any author.

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