| Frequency of Same Day Discharge and its | Feasibility after Transradial Percutaneous Coronary | Intervention

1. Muhammad Salman Dawood 2. Saqib Shafi Sheikh 3. Abdul Rehman Abid 4. Muhammad Khan 5. Muhammad Azhar

 Med. Officer, Kot Khwaja Saeed Hospital Lahore 2. Assoc. Prof. PIC, Lahore 3. Sen. Registrar of Cardiology, PIC, Lahore 4. Sen. Registrar of Cardiology, PIC, Lahore 5. Prof. and Chief of Cardiology, Punjab Institute of Cardiology, Lahore

ABSTRACT

Objective: To observe the frequency of same day discharge and its feasibility after transradial percutaneous coronary intervention (PCI).

Study Design: Observational Study.

Place and Duration of Study: This study was conducted at the Coronary Care Unit and Angiography ward of the Punjab Institute of Cardiology, Lahore from January 2007 to June 2007.

Materials and Methods: Non-probability purposive sampling technique was used to enroll 100 subjects. A total of 790 PCIs were performed from January 2007 to June 2007 at the Punjab Institute of Cardiology, Lahore via transradial approach. Out of these 790 patients, one hundred patients (12.66%) had same-day discharge after transradial PCI. These patients were evaluated and information was obtained regarding entry site complications and adverse cardiovascular events at the time of discharge and at one month follow up after the procedure.

Results: Out of 100 patients, who had same day discharge, 2(2%) patients had hematoma at the time of discharge, 1(1%) had asymptomatic loss of radial pulse and 6(6%) patients had weak but palpable radial artery. At one month follow up 4(4%) patients had asymptomatic loss of radial pulse. However, none of these patients had major access site complications which required blood transfusion or admission to the hospital. Only 1(1%) patient had repeat coronary angiogram for chest pain, which revealed patent stent and TIMI III flow in distal vessel. One patient had repeat PCI but it was done to another vessel and previously placed stent was patent. There was no death and none of the patients underwent coronary artery bypass grafting (CABG).

Conclusion: The radial artery is the route of choice for most coronary procedures. The radial approach virtually eliminates access site complications after PCI, and allows rapid mobilization of the patient. Same-day discharge after radial PCI is a safe and feasible strategy.

Key words: Transradial percutaneous coronary intervention, same-day discharge, angioplasty, access site complications, adverse cardiovascular events.

INTRODUCTION

There is increasing data in the literature that same-day discharge is a safe approach for certain low-risk patients undergoing percutaneous coronary intervention (PCI) via radial approach, 1-5 but overnight stay is still considered the standard approach for the majority of patients. In recent years, the practice of intracoronary techniques stenting using modern developments in antiplatelet therapies have made percutaneous coronary intervention procedures much safer, with a diminished risk of complications such as acute/subacute stent thrombosis. These observations along with limited health care resources have led many invasive cardiologists to consider the feasibility of PCI to be carried out on an outpatient basis. It has been shown that a few hours observation period is safe after elective PCI,6 and pilot studies suggest that outpatient PCI performed via the transradial route is feasible in selected patient populations. 1,4 Major advantages of radial PCI are earlier ambulation of the patient and lower rates of access site complications. ⁷⁻⁹

However as in this study, the previus studies also excluded subjects who received platelet glycoprotein IIb/IIIa inhibitors. As these potent antiplatelet agents are increasingly used in clinical practice, this is clearly a major issue that needs to be clarified as they are often given an intravenous infusions of 12–18 hours duration, which would limit the feasibility of same-day discharge. Although the beneficial effects of these agents in PCI have been well documented in a number of large randomized placebo-controlled trials, it remains controversial if all patients undergoing PCI should receive these antiplatelet agents. The benefit of these drugs is greatest in Troponin positive or diabetic subjects.

Over the past 30 years, dramatic improvements have been achieved in the safety of percutaneous coronary intervention procedures, despite the increasing complexity of clinical and anatomic conditions treated. The rate of vascular complications has declined dramatically as techniques have improved and procedural experience has increased. Several previous investigators have explored the safety of same-day discharge after low-risk elective coronary intervention, and almost all have supported the safety of the practice.

As the burden of IHD is increasing and the number of patients undergoing PCI is increasing, there is a need for better utilization of hospital resources. It has been reported that same-day-discharge PCI is safe in certain low risk patients and is preferred by patients. But data on this at national level is lacking so this study was designed to evaluate the feasibility and safety of same day discharge after transradial PCI.

MATERIALS AND METHODS

This observational study was conducted at the Coronary Care Unit and Angiography ward of the Punjab Institute of Cardiology, Lahore.

Non-probability purposive sampling technique was used to enroll 100 subjects. A total of 790 PCIs were performed from January 2007 to June 2007 at the Punjab Institute of Cardiology, Lahore via transradial approach. Out of these 790 patients, one hundred patients (12.66%) had same-day discharge after transradial PCI.

Inclusion Criteria were age 30-70 years, positive Allen's test, any indication for elective percutaneous coronary intervention.

Exclusion Criteria were age >70, primary PCI, administration of glycoprotein IIb/IIIa inhibitors, prolonged chest pain and ECG changes (Fresh ST segment elevation or depression of 1mm or more and any new T wave inversion) after the procedure, prolonged resuscitation, intracoronary thrombus and access site complications.

Local complications were, hematoma, asymptomatic loss of radial pulse, pseudo aneurysm, arteriovenous fistula, dissection of artery.

Adverse cardiovascular events were myocardial infarction, cardiac death, repeat PCI and coronary artery bypass grafting. Stent thrombosis was defined as partial or total thrombotic occlusion of stent, documented by coronary angiography after stent implantation. Acute Stent Thrombosis was stent occlusion intraprocedural or within 24 hrs of stent implantation. Subacute Stent Thrombosis was stent occlusion after 24 hrs till 30 days following stent implantation.

All patients were given antiplatelet therapy (aspirin 150mg and 600mg clopidogrel) 2–4 hours before angioplasty as loading dose. Following angioplasty, all patients were prescribed antiplatelet therapy (aspirin 150mg once daily and clopidogrel 75mg twice daily).

After successful PCI, the radial sheath was removed and a pressure bandage was applied and patients were fully ambulated after 3-4 hours. If there were no complications (chest pain, entry site complications) after 1 hour of ambulating, they were allowed to leave the hospital. Patients were asked to remove the pressure bandage the next morning and to visit for follow-up after 2-4 weeks.

Informed consent was taken from all patients included in the study. A detailed history and clinical examination was done. All the information was collected on a predesigned proforma regarding sociodemographic profile i.e. name, age, and socioeconomic background, risk factors for ischemic heart disease, history of previous myocardial infarction, procedure to be performed; procedure time, hemostasis time, time for ambulation, time for discharge and local complication profile. Patients were followed up after 4 weeks and were assessed regarding puncture complications i.e. hematoma, asymptomatic loss of radial pulse, pseudo aneurysm, arteriovenous fistula, and dissection of artery and information was obtained about adverse cardiac events like myocardial infarction, need for repeat PCI, coronary artery bypass grafting and cardiac death. Patients who were discharged on the same day during the study period were those with stable and unstable angina, single or multivessel disease and undergoing single or multivessel PCI. The patients with access site complications, administration of IIb/IIIa inhibitors, or increased risk for post discharge complications (suboptimal PCI result etc) were not discharged. Some patients were not discharged for social reasons like coming from distant areas.

Statistical Analysis: The collected data was entered and analyzed by using Statistical Package for Social Sciences (SPSS) Version 10 for Windows. Demographic profile, risk factors for ischemic heart disease like diabetes mellitus, smoking, hypertension, family history of ischemic heart disease and elevated lipid profile were presented as frequency tables. variables **Oualitative** such as occupation, socioeconomic status and variables of the history were presented as frequency tables showing proportions. Variables in examination and local complications were presented as frequency distribution tables. Continuous variables are presented as mean \pm SD.

RESULTS

A total of 790 PCIs were performed from January 2007 to June 2007 at the Punjab Institute of Cardiology, Lahore via transradial approach. Out of 790, 100(12.66%) patients had same-day discharge after transradial PCI within 14 hours of procedure.

Descriptive Statistics of the patients who underwent same day discharge after radial PCI are shown below in table 1. Mean age of the patients was 53.04 ± 10.05

years, mean procedure time was 31.30±13.1 minutes and these patients remained admitted in hospital for a mean duration of 11.44±2.01 hours. Pulse, blood pressure, temperature and respiratory rate and heparin dosage given during PCI are shown in table 1.

Table No1: Descriptive Statistics

Variables	Mean± SD
Age in Years	53.04±10.05
Pulse in minutes	80.26±6.7
Systolic BP	126.4±24.6
Diastolic BP	78.68±13.3
Respiratory	16.04±1.4
Temp	98.328±0.46
Heparin dose	7625.00±2172.34
Procedure time (in minutes)	31.30±13.1
Hemostasis time (in minutes)	10.81±2.85
Hospital Stay time(in hours)	11.44±2.01

Table No.2: Baseline characteristics

Characteristics	Frequencies(%)
	n=100
Age mean years	53.04±10.05
Sex	
Men	74(74%)
Women	26(26%)
Hypercholesterolemia	21(21%)
Smoking current/previous	39(39%)
Diabetes mellitus	29(29%)
Hypertension	36(36%)
Previous MI	13(13%)
Family history of IHD	20(20%)
Chest pain symptom	75(75%)
NYHA angina classification	
I	4(4%)
II	18(18%)
III	68(68%)
IV	10(10%)
Single vessel disease,	82(82%)
Multivessel disease	18(18%)
Obesity	23(23%)

n=number of patients, MI=myocardial infarction, IHD=ischemic heart disease, NYHA=New York Heart Association

Table No.3: Puncture site complications at discharge

Tubic I tote I ameture bite compressions at ansenarge		
Puncture Site Complications	Frequencies (%) n=100	
Hematoma	2(2%)	
Asymptomatic loss of radial pulse	1(1%)	
Radial artery palpable	91(91%)	
Radial artery palpable but weak	6(6%)	

Baseline characteristics of the study population are shown in table 2. The study comprised of 100 patients out of which 74(74%) were males and 24(24%) were females. Ninety three percent of the patients were taking both aspirin and clopidogrel. Eighty two percent

patients had single vessel PCI and 18% had multivessel PCI. Right radial approach was used in 95% of the patients and in 5% of the patients left radial approach was used.

Table No.4: Puncture site examination and adverse cardiovascular events at follow up

Follow-Up Events	Numbers (%) n=100
Puncture site complications	
Asymptomatic loss of radial pulse	4(4%)
Radial artery palpable	96(96%)
Adverse cardiovascular events	
Repeat angiogram	1(1%)
repeat PCI	1(1%)
None	98(98%)

Cannulation was done smoothly in 87% patients and 13% had difficulty during cannulation. In 68% patients cannulation was done in the first attempt, in 22% in the second attempt, in 9% in the third attempt and in one patient it was done in fourth attempt. Verapamil alone was used in 16% of the patients and both verapamil and glyceryl trinitrate was used in 81% patients and in 3% paitens only glyceryl trinitrate was used.

At the time of discharge hematoma was observed in 2% patients but it was minor, there was weak but palpable pulse in 6% of the patients and in 1% there was asymptomatic loss of radial pulse. Table 3.

At one month follow up physical examination showed palpable radial pulse in 96% patients and in 4% patients there was loss of radial pulse. In terms of adverse cardiovascular events only one patient had repeat coronary angiogram for chest pain, which revealed patent stent and TIMI III flow in distal vessel. One patient had repeat PCI but it was done to another vessel and previously placed stent was patent. Table 4.

DISCUSSION

Same-day discharge is an attractive approach for PCI due to more efficient utilization of hospital resources. Transradial PCI has been demonstrated to be a safe and effective method of percutaneous revascularization.

After transradial PCI, patients have significantly less vascular complications compared to the transfemoral approach and can mobilize earlier. For this reason, the radial approach makes same-day discharge PCI feasible and safe. The use of the radial approach also leads to improved quality of life after the procedure compared to the femoral approach, and is preferred by the majority of patients.

Several studies have reported the effect of PCI on patients' quality of life. Expansion of the indications for PCI, including the elderly patients and primary PCI for acute myocardial infarction, and increasing utilization of stents, coupled with improved procedural success rates, has resulted in increasing

patient volumes in many catheterization laboratories. Management of this large number of patients, often with no increasing resources, is a challenge for many centers. Same-day discharge PCI can potentially reduce hospital cost of PCI and improve bed utilization. However, the major concerns for same-day discharge PCI are the risk of entry site complications and adverse cardiovascular events especially related to occlusion of the target vessel after discharge. Our study shows that same-day-discharge PCI is feasible and safe for the patients regarding post-discharge access site complications and adverse cardiovascular events.

In the current study in terms of adverse cardiovascular events only 1 had repeat coronary angiogram but it did not reveal any evidence of in-stent restenosis and stent was patent with TIMI III flow in the distal vessel. One patient had repeat PCI but it was done to another vessel and previously placed stent was patent.

Incidence of stent thrombosis varies between 2-10 % in literature. This difference could be due to the fact that our study population was small. Patients were considered suitable for same-day discharge, based on certain criteria already mentioned, which were also negatively related to acute stent thrombosis and low risk for access site complications. Another factor was that the majority of patients undergoing stenting in our hospital were pretreated with clopidogrel several days before the procedure. Thus, in this stable group of patients with low risk of stent thrombosis, same-day discharge did not culminate in any increase in patient risk.

Complications at the angioplasty access site (radial artery) in current study were minor. None of the patients had major access site complications. At the time of discharge hematoma was observed in 2% of the patients but it was minor and no blood transfusion was required, there was weak but palpable pulse in 6% of the patients and in 1% there was asymptomatic loss of radial pulse.

At one month follow up physical examination showed palpable radial pulse in 96% of the patients and in 4% of the patients there was loss of radial pulse.

The absence of major access site complications substantiates the safety of same-day discharge. Significant radial bleeding or hematoma after discharge does not occur with any frequency in patients selected to be eligible for same-day discharge.

In OUTCLAS study same day discharge was applied to 106 patients while in current study same day discharge was applied to 100 patients. The largest study so far in this respect was the study by Ziakas et al, where same-day-discharge PCI was applied to 943 patients. Larger catheters were used in study by Ziakas et al, 7F in half of the procedures, whereas only 6F were used in the OUTCLAS and in current study. Another safety and feasibility study is RADICAL

study which was conducted on 150 patients. Baseline characteristics of patients were similar in all three studies and are comparable to current study. The results of all these studies show that same-day PCI can be applied to larger variety of patients.

In current study none of the patients had major access site complications or required admission to the hospital. In the study by Ziakas et al within 24 hours from discharge only 1(0.1%) required a repeat angiogram, which did not show target vessel occlusion while in this study none of the patients underwent repeat angiogram within 24 hours. In study by Ziakas et al during the first month, 11(1.3%) underwent a repeat angiogram, out of which 4 had subacute vessel closure and 3 underwent a new PCI (performed in a lesion that was also present at the first procedure but was left untreated, while in this study only 1 patient underwent repeat angiogram but it did not show any evidence of in-stent restenosis.

In study by Ziakas et al, ¹⁷ 27(2.8%) visited their doctor and/or the hospital within 24 hours after discharge because of entry site complications, and 38(4%) patients visited within 1 month. However, none of the patients had major access site complications or required admission to the hospital. In our study at the time of discharge hematoma was observed in 2% patients but it was minor, there was weak but palpable pulse in 6% of the patients and in 1% there was asymptomatic loss of radial pulse.

It is obvious that same-day discharge can not be applied to all patients undergoing PCI. In our study, 12.66% patients undergoing PCI (100 of 790 patients) were discharged on the same day of the procedure. Some patients have clinical (PCI for acute myocardial infarction, and so forth) or social reasons that make same-day discharge not possible and other patients are considered at high risk for post-discharge complications. Same-day discharge is also not feasible for patients receiving glycoprotein IIb/IIIa inhibitors, as these agents require an at least 12-hour infusion. Recent clinical trials have shown the benefit of glycoprotein IIb/IIIa inhibitor administration in patients undergoing PCI. 4,6,19,20 Although the beneficial effects of these agents in PCI have been well documented in a number of large randomized placebo-controlled trials. 12,13 It remains controversial if all patients undergoing PCI should receive these antiplatelet agents. The benefit of these drugs is greatest in Troponin positive or diabetic subjects. 12,13

One of the issues in same-day-discharge PCI is that it does not allow serial measurement of cardiac enzymes, and so it is possible that patients discharged home may have undetected enzyme elevation. In our study, patients who were most likely to have enzyme elevation were not discharged the same day (patients with

prolonged chest pain or electrocardiographic changes after the procedure, prolonged resuscitation, major side branch occlusion, intracoronary thrombus, poor intracoronary flow).

CONCLUSION

The radial artery is the route of choice for most coronary procedures. The radial approach virtually eliminates access site complications after PCI, and allows rapid mobilization of the patient.Same-day discharge after radial PCI is a safe and feasible strategy.

REFERENCES

- 1. Slagboom T, Kiemeneij F, Laarman GJ, et al. Actual outpatient PCI: results of the Outclas pilot study. Cathet Cardiovasc Intervent 2001;53: 204–208.
- 2. Knopf WD, Cohen-Bernstein C, Ryan J, et al. Outpatient PCI with same day discharge is safe and produces high patient satisfaction level. J Invasive Cardiol 1999;11:290–295.
- 3. Wilentz JR, Mishkel G, McDermott D, et al. Outpatient coronary stenting: femoral approach with vascular sealing. Herz 1999;24:624–633.
- 4. Kiemeneij F, Laarman GJ, Slagboom T, et al., Outpatient coronary stent implantation. Am J Coll Cardiol 1997;29:323–327.
- 5. Laarman GJ, Kiemeneij F, Van der Wieken LR, et al. A pilot study of coronary angioplasty in outpatients. Br Heart J 1994;72:12–15.
- 6. Koch KT, Piek JJ, Prins MH, et al., Triage of patients for short term observation after elective coronary angioplasty. Heart 2000; 83:557–563.
- 7. Kiemeneij F, Laarman GJ, Odekerken D, et al. A randomized comparison of percutaneous transluminal coronary angioplasty by the radial, brachial and femoral approaches: the access study. J Am Coll Cardiol 1997;29:1269–1275.
- 8. Mann T, Cubeddu G, Bowen J, et al. Stenting in acute coronary syndromes: a comparison of radial vs. femoral access sites. J Am Coll Cardiol 1998;32:572–576.
- Mann T, Cowper PA, Peterson ED, et al. Transradial coronary stenting: comparison with femoral access closed with an arterial suture device. Cathet Cardiovasc Intervent 2000;49: 150–156.
- 10. The EPIC Investigators. Use of a monoclonal antibody directed against the platelet glycoprotein IIb/IIIa receptor in high-risk coronary angioplasty. N Engl J Med 1994; 330:956–961.
- 11. The Epistent Investigators. Randomized placebo controlled and balloon angioplasty controlled trial to assess safety of coronary stenting with use of platelet glycoprotein IIb/IIIa blockade. Lancet 1998;352:87–92.

- 12. Hamm CW, Heeschen C, Goldmann B, et al. for the CAPTURE Study Investigators. Benefit of abciximab in patients with refractory unstable angina in relation to serum Troponin T levels. N Engl J Med 1999;340:1623–1629.
- 13. The Prism Study Investigators. Troponin concentrations for stratification of patients with acute coronary syndromes in relation to therapeutic efficacy of tirofiban. Lancet 1999;354:1757–1762.
- 14. Bertrand OF, De Larochelliere R, Rodes-Cabau J, Proulx G, Gleeton O, Nguyen CM, et al. A randomized study comparing same-day home discharge and abciximab bolus only to overnight hospitalization and abciximab bolus and infusion after transradial coronary stent implantation. Circulation 2006; 114:2636–2643.
- 15. Slagboom T, Kiemeneij F, Laarman GJ, van der Wieken R. Outpatient coronary angioplasty: feasible and safe. Catheter Cardiovasc Interv 2005;64:421–427.
- 16. Kumar S, Anantharaman R, Das P, Hobbs J, Densem C, Ansell J, et al. Radial approach to day case intervention in coronary artery lesions (RADICAL): a single centre safety and feasibility study. Heart 2004;90:1340–1341.
- 17. Ziakas AA, Klinke BP, Mildenberger CR, Fretz DE, Williams EM, Kinloch FR, et al. Safety of same-day-discharge radial percutaneous coronary intervention: a retrospective study. Am Heart J 2003;146:699–704.
- 18. Gilchrist IC, Nickolaus MJ, Momplaisir T. Sameday transradial outpatient stenting with a 6-hr course of glycoprotein IIb/IIIa receptor blockade: a feasibility study. Catheter Cardiovasc Interv 2002;56:10–13.
- 19. Carere RG, Webb JG, Buller CE, Wilson M, Rahman T, Spinelli J, et al. Suture closure of femoral arterial puncture sites after coronary angioplasty followed by same-day discharge. Am Heart J 2000;139:52–58.
- Wilentz JR, Mishkel G, McDermott D, Ravi K, Fox JT, Reimers CD. Outpatient coronary stenting using the femoral approach with vascular sealing. J Invasive Cardiol 1999;11:709–717.
- 21. Kuchulakanti PK, Chu WW, Torguson R, Rha SW, Clavijo LC, Kim SW, et al. Correlate and long term outcome of angiographically proven stent thrombosis with sirolimus and paclitaxel eluting stents. Circulation 2006;113:1108-13.

Address for Corresponding Author: Dr Abdul Rehman Abid,

Senior Registrar Cardiology, Punjab Institute of Cardiology, Lahore. E mail: drarehman@gmail.com

Cell: 03336015574