



Original Article

GENDER IMPACT ON IN-HOSPITAL OUTCOMES AFTER PERCUTANEOUS CORONARY INTERVENTION

Atif Nazir, Abdul Rehman Abid, Tahir Abbas Shah, Habib Afzal, Naresh Kumar, Muhammad Saleem

ABSTRACT

Objective: To compare in-hospital complications between males and females after percutaneous coronary intervention (PCI).

Materials and Methods: This Cohort study was conducted at the Coronary Care Unit and Angiography Department of the Punjab Institute of Cardiology, Lahore from January to June 2010. Non-probability, purposive sampling technique was used. A total of 1243 percutaneous coronary interventions were done. Out of these 1050 patients, were selected. All the baseline procedural and biochemical characteristics were recorded. All patients were evaluated for cumulative vascular complications (access site hematoma, psuedoaneurysm, retroperitoneal bleed and blood transfusion requirements) and contrast induced nephropathy.

Results: Out of 1050 cases, (525 were males and 525 females). In terms of gender related risk, cumulative vascular complications (CVC) were significantly more often seen in females as compared to males, 48(9.14%) vs 25(4.76%) respectively ($p < 0.005$). Out of these CVC, access site hematoma was present in 31(5.90%) females as compared to 18(3.42%) males. Blood transfusion was required in 16(3.04%) females and 06(1.14%) males. There was no significant gender differences in contrast induced nephropathy, 14(2.66%) females vs 9(1.71%) males.

Conclusion: Women are at increased risk of cumulative vascular complications as compared to men but the complication of contrast induced nephropathy was similar in men and women.

Key words: Percutaneous coronary intervention, gender differences, vascular complications, contrast induced nephropathy, major adverse cardiovascular events.

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INTRODUCTION

Percutaneous coronary intervention (PCI) is the most common interventional procedure for coronary artery revascularization. The number of PCI procedures has increased in recent years due to increased awareness and improved outcomes.^{1,2} Meta-analyses of randomized clinical trials have reported that primary PCI is more cost-effective compared to fibrinolysis and reduces the incidence of death, reinfarction, and stroke.³⁻⁵ Furthermore, in stable patients and in patients with multivessel disease, PCI has become the preferred procedure in the United States,⁶ with

declining mortality in patients undergoing multivessel PCI.⁷

Similar to most invasive procedures, PCI is accompanied by a risk of peri-procedural and post-procedural complications. Potential complications include death, myocardial infarction (MI), emergency coronary artery bypass grafting (CABG), stroke, contrast-induced nephropathy (CIN), and vascular access-site complications.⁸ The possibility of these complications must be considered while assessing the risks and benefits of PCI for a given patient. Although stenting in the presence of a Glycoprotein IIb/IIIa inhibitor reduces mortality by 20% over 6–12 months compared with medical therapy in patients with unstable angina or non-ST-segment elevation myocardial infarction (NSTEMI).⁹ PCI has not been shown to significantly decrease mortality in patients with stable angina.¹⁰

Ischemic heart disease (IHD), previously regarded as middle aged male disorder, is also a major cause of morbidity and mortality in women.¹¹ Sex based differences has been area of active in-

Correspondence address:

Dr Atif Nazir, MBBS
Punjab Institute of Cardiology,
Lahore



investigation over the past two decades. Females become symptomatic at an older age than males, however the symptoms are atypical, the diagnosis is more difficult and the prognosis is less favorable.^{12,13} Several reports have revealed that invasive diagnostic procedures and invasive treatment are less frequently used in women with IHD than men.^{14,15} Percutaneous coronary intervention in females is usually more complicated due to gender related small sized coronary arteries. Thus female gender contributes to substantially worse early and late outcomes and increased mortality.¹⁴⁻¹⁷

Multiple studies have demonstrated that women are at increased risk for in-hospital mortality, stroke, vascular complications, repeat revascularization, and same-admission CABG after PCI.^{18,19} Poor outcomes post-PCI have been related to older age and a higher prevalence of risk factors in women compared to men.¹⁹ This is considered one of the reasons for less frequent use of an invasive management strategy for acute coronary syndromes (ACS) in women.²⁰

However, to date, the existence of gender-related risk in women has never been fully explored or described in Pakistan. Therefore, the purpose of this study was to examine the presence of a gender-based difference in in-hospital outcome among patients undergoing an initial PCI procedure.

This study was designed to compare the in-hospital complications after percutaneous coronary intervention between males and females.

MATERIALS AND METHODS

This Cohort study was conducted at the Coronary Care Unit and Angiography ward of the Punjab Institute of Cardiology, Lahore from January to June 2010. Non-probability, purposive sampling technique was used. Out of 1243 PCIs 1050 patients, were studied. All the baseline procedural and biochemical characteristics were recorded. These patients were evaluated for cumulative vascular complications (access site hematoma, pseudoaneurysm, retroperitoneal bleed and blood transfusion requirements) and contrast induced nephropathy.

Inclusion Criteria were PCI in male and female patients >40 yrs of age, elective PCI in patients with STEMI, NSTEMI, unstable and stable angina. PCI with either bare metal stent (BMS) or drug eluting stent (DES) were studied. PCI for single vessel disease (SVD) or multi vessel disease (MVD) and PCI through radial or femoral route were in-

cluded.

Exclusion criteria were primary PCI, previous PCI/ CABG, left main stem (LMS) PCI and plain old balloon angioplasty (POBA).

A total of 1243 PCIs were done out of these 1050 patients, (525 males and 525 females) fulfilling the inclusion and exclusion criteria were selected.

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 twice daily and clopidogrel 75mg twice daily).

All the routine blood investigations (complete blood profile, renal function tests, cardiac markers, coagulation profile, hepatitis B and C viral serology etc) were done prior to procedure.

After successful PCI, the radial or femoral sheath was removed, and a pressure bandage was applied and patients were fully ambulated after 3-4 hours of radial PCI and 6-8 hours of femoral PCI. They were observed in hospital for about 12-18 hours. Necessary blood tests (complete blood count, cardiac enzymes, renal function tests, and PT/INR) were done. If there were no complications (chest pain, vascular complications) and blood tests were normal, they were discharged after 24 hours observation. Patients were advised follow-up after 2 weeks.

Informed consent was taken from all 1050 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, address, contact numbers, and baseline characteristics, like risk factors for ischemic heart disease, diabetes, hypertension, BMI (body mass index), were collected. All procedural characteristics were also recorded like single vessel disease/multi vessel disease, GPIIb/IIIa used and the stent used. Patients were observed during their in-hospital stay and assessed regarding cumulative vascular complications i.e. access site hematoma, pseudoaneurysm, retroperitoneal bleed, blood transfusion requirements, contrast induced nephropathy i.e increase in serum creatinine concentration of >1.0 mg/dl or relative increase of >50% if pre PCI values were abnormal.

Patients were followed up for complications during their in-hospital stay until they were discharged.

Contrast induced nephropathy was impairment



of renal function manifested subsequent to contrast administration in the absence of other aetiology.

Cumulative vascular complications included atleast one of these

- Access site hematoma >8 cm
- Psuedoaneurysm confirmed by Doppler ultrasound
- Retroperitoneal bleed documented by ultrasound.
- Blood transfusion requirements: Transfusion of 1 or more than 1 pint of blood, both related or unrelated to access site bleeding.

Major adverse cardiovascular events (MACE) like mortality, post PCI myocardial infarction, heart failure and acute thrombocytopenia were also recorded.

Those patients who did not have any procedural complications were discharged on the next day.

The patients with vascular complications, contrast induced nephropathy, MACE, or increased risk for post discharge complications (suboptimal PCI result etc) were not discharged and they were followed up during their in-hospital stay until they were stable and discharged.

DATA ANALYSIS:

The collected data was entered and analyzed by using Statistical Package for Social Sciences (SPSS) Version 12 for Windows. Continuous variable (age, BMI) were expressed as mean \pm standard deviation. Risk factors for ischemic heart disease like diabetes mellitus, hypertension were expressed as frequency tables.

Categorical variables such as gender, baseline and procedural characteristics, contrast induced nephropathy, cumulative vascular complications (access site hematoma, retroperitoneal bleed, blood transfusion requirements and psuedoaneurysm) were expressed as frequencies and percentages.

RESULTS

Mean age of the male patients was 49.8 ± 9.60 years while that of female patients was 52.1 ± 8.91 years. Baseline characteristics of the patients are shown in table 1.

Out of 525 male patients who underwent PCI, 21.14% of the patients were diabetics. Hypertension was present in 45.9% of the male patients. Among the female patients the incidence of diabetes and hypertension was 29.14% and 52.95% respectively. The mean body mass index (BMI) of female patients was also higher than the male

patients i.e 28.57 ± 4.71 vs 27.17 ± 4.59 respectively.

Comparison of indications for percutaneous coronary intervention between males and females are outlined in table 1.

Procedural characteristics are shown in table 2.

Table 3 shows the difference in in-hospital complications between males and females. Cumulative vascular complications were significantly higher in female population as compared to males while there was no significant difference of contrast induced nephropathy between the groups (Table 3).

Relative Risk:

Relative risk of cumulative vascular complications is presented in Table 4. Females were 1.9 times as likely as males to develop cumulative vascular complications after percutaneous coronary intervention.

DISCUSSION

PCI is the most common interventional procedure for coronary artery revascularization. It is associated with various periprocedural and postprocedural in-hospital complications. Potential complications include death, MI, emergency CABG, stroke, CIN, and vascular access-site complications.⁸ Gender differences in in-hospital post PCI complications has been an area of active investigation over the last few years. PCI of females is usually more complicated due to gender related small sized coronary arteries. Thus female gender contributes to substantially worse early and late outcomes and increased mortality.¹⁴⁻¹⁹

Multiple studies have demonstrated that women are at increased risk for in-hospital mortality, stroke, vascular complications, repeat revascularization, and same-admission CABG after PCI.^{20,21}

Women have been shown to be at increased risk for major and minor bleeding complications including intracranial, intraocular, retroperitoneal, or clinically-overt bleeding with a drop of hemoglobin of 3 g/dl, or any drop of hemoglobin of 4 g/dl in the absence of overt bleeding, or the transfusion of 2 or more units of packed red blood cells.²²

The possibility of these complications must be considered while assessing the risks and benefits of PCI especially of female patients.

In terms of gender related risk, cumulative vascular complications (CVC) were significantly more often seen in females as compared to males, 48(9.14%) vs 25(4.76%) respectively with a P-



14(2.66%) females vs 9(1.71%) males. This may be due to the fact that all the procedures performed were elective, so the factors that contribute to contrast induced nephropathy like anemia, pre PCI renal failure, diabetes mellitus, hypotension, cardiogenic shock etc. were adequately addressed before the procedure.

CONCLUSION

This study on the effect of gender on differences in in-hospital complications in Pakistani population showed that women are at in-

creased risk for cumulative vascular complications as compared to men. But the complication of contrast induced nephropathy was similar in men and women.

Our data suggest that there exists a relationship between gender and adverse outcome of vascular complications after PCI. Consideration should be given to quality improvement efforts focused on decreasing complication rates in women. Further research to uncover the exact cause of this higher risk is warranted.

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