

Post PCI with stenting Follow-Up in Women for 7 Years in Public Sector Tertiary Care Cardiac Unit. Retrospective Study.

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Abstract

Introduction: Despite of the fact that there is continual improvement in diagnostic and therapeutic procedures in catheterization Lab introduction of better catheter techniques and new-generation stents and with the acquisition of knowledge from large-scale clinical trials Still women appear to have a higher in-hospital mortality after PCI with stenting and during long term follow up specially in developing countries of South Asia the, Reason could be multi-factorial in women.

The objectives: The goals of treatment in PCI with stenting in Women is to improve quality of life, to prevent CHD from becoming symptomatic, prevent myocardial infarction, cardiac death and heart failure, the approaches to achieve these goals at the societal or individual level in this regards differ among various countries, the data that have been published are often limited due to the relatively small number of western women. It is important to collect data in under developed countries on outcomes of long term follow up of women with AMI after PCI with stenting to change the global perception of treatment of women with myocardial infarction.

Material and Method: Out of 3300 patients, underwent successful PCI with stenting during 2010 to 2016 in Cath Lab of cardiology department of Dow University of Health and Sciences Karachi Pakistan , 577 patients with Sciences Karachi Pakistan, 577 patients with Myocardial infarction within 7 days were included in study and they constitute the present follow-up population. Additional data regarding noncardiac comorbid diseases and Risk factors were obtained along with crucial aspects of women's health, such as menopausal status, use of hormonal contraceptives, Follow-up was planned after 1 month and then with annually for 7 years. The primary end point of study were the long-term rate of major adverse cardiac events (i.e. death, Infarction, and repeat revascularization). The secondary end points were the individual components of the major adverse cardiac events and stent thrombosis.

Result: This observational study was conducted by reviewing the record of cases performed and getting information on follow up visits of patients for 7 years from June 2010 to June 2016, out of total 3300 procedure 577 patients were included in the study who underwent PCI with stenting with in the 7 day of Myocardial infarction consisting of 346 patient from urban and 237 people from Rural areas of Sindh Balochistan Provincie of Pakistan Revascularization with stenting was performed in 313 patients 40-50 years of age followed by 219 patients 56-70 years of age in comparison to 23 in older group > 70 years and 22 in younger age < 40 years .In 528 (91.5%)patients PCI with BMS, in 28 (4.8%)patients DES alone and in 21 (3.6%)patients with BMS and DES performed The odds of short-term mortality were significantly higher among older post-menopausal group compared to premenopausal patients <55 . 13 patients (5 patients during hospitalization) and 8 patients died within 30 days after PCI. Total 57(9.8%) patient died during 7 years follow up, 31 (58.5%) cases due to comorbid conditions, and remaining 27 patients death was due to myocardial infarction in 13 (39.4%). Arrhythmias in 5 (9.4%) and worsening of heart Failure in 8 (42.1%) elderly patients. Patient had complete Closure of Target Vessel, 28 (4.8%) had Re PCI on 7 years follow up and CABG was performed in 13 (2.2%). Patients main reason could be noncompliance of therapy in 71 (12.3%) in patients.

Conclusion: Ideally a Women patient who has undergone coronary stent implantation should be cared for by the primary cardiologist who by working closely together for long term outcomes in different developing countries of South Asia to collect the data which will change the perception about the treatment of Myocardial infarction in women globally and help in making guidelines.

Keywords: PCI: Percutaneous Coronary Intervention, BMS: Bare Metal Stent, DES: Drug-Eluting Stent, CABG: Coronary Artery Bypass Grafting, MI: Myocardial Infarction, DM: Diabetes, HTN: Hypertension, CVD: Cardiovascular disease

Introduction

Prior studies have suggested that women are at higher risk for morbidity and mortality during coronary angioplasty, although their long-term prognosis is similar after successful procedures [1]. Their higher mortality during procedure can be accounted for by their poorer clinical characteristics largely explained by their older age, comorbid conditions, and worse clinical status at the time of treatment more likely to present with atypical symptoms, delays in the administration of treatment, therefore have longer ischaemic period, leading to higher risk for mortality during procedure but not for similar long term prognosis, as women of South Asian developing countries are less likely to receive evidence-based treatments during the procedure and Later on as secondary prevention in comparison to western women [2,3]. Data that have been published are often limited in developing countries due to the relatively small number of female patients included and have generally been limited to comparisons between men and women [4]. It is important to carefully document the long-term outcome of women undergoing this procedure in developing countries of South Asia like Pakistan.

Objectives

Although the causes of CVD in women are common to all parts of the world, the approaches to its secondary prevention at the societal or individual level differs among countries for cultural, social, medical, and economic reasons [4,5]. Whether we are achieving target goals of Coronary angioplasty in women which are to improve quality of life, to prevent CHD from becoming symptomatic due to heart failure and angina, in particular to prevent Myocardial infarction and cardiac death due to restenosis on follow up, the achievement of these goals requires a combination of drug treatment for secondary prevention, lifestyle changes, and reduction of cardiovascular risk factors. Low socioeconomic conditions and less awareness of women for CVD status have impact on the goals of coronary angioplasty in this part of world [6,7]. This article is concerned only with the follow-up data of patients who have undergone interventional therapy (coronary stent implantation) to change the perception of the treatment of women with CVD, who are too often under-diagnosed and under-treated hence less included in the research studies than the women of western countries to develop a global position statement including immediate procedural success as well as early and late outcomes [8-11].

Materials and Methods

The Base line features of a database includes demographic, clinical and procedural outcome details of 578 (25.4) women patients from total procedures 3378 (74.6%) who had undergone successful stenting in native arteries treated with PCI within 7 days of myocardial infarction in Cath Lab of Cardiology Department of Dow university of Health and Sciences Karachi Pakistan from March 2010 to March 2016 were identified and assessed retrospectively to evaluate 7 years out comes. Patients with a prior PCI or CABG were excluded for accurate identification of those who required any repeat revascularization. The following clinical covariates were included in the adjusted model: age, smoking status, history of Diabetes mellites, Hypertension, Dyslipidaemia, Cerebrovascular

disease, Congestive heart disease, (Left ventricular ejection fraction), peripheral vascular disease, Pulmonary and liver disease Malignancy, Dialysis, as well as peri-procedural variables, procedure urgency, disease severity (3-vessel or left main vs. rest) and to evaluate crucial women's health such as menopausal status. Use of hormonal contraceptives. Patients were followed up regularly on one month, (every three to six months) for one year and on yearly basis for 7 years. Follow up of all patients dismissed from the hospital was maintained in outdoor patients department on card for visits or obtained by an experienced data technician by telephone 6 and 12 months after the initial procedure and continued annually thereafter up to 7 years yearly if they were unable to come for visit due to long distance. In follow up visits clinical history taking on secondary stabilization, which was defined as freedom from recurrence of angina, compliance of drugs if patient was not achieving adequate symptomatic relief, h/o Myocardial infarction, coronary artery bypass grafting, and use of target lesion-percutaneous coronary intervention (TL-PCI) and death was sought. All Patients were grouped as follows: <40. 40-54 years, 55-69 years and ≥ 70 years old, and PCI with stent placement were assessed accordingly (BMS or DES). Survival probabilities in one month, one year and 2year, 5year and 7years were estimated by using the Kaplan-Meier method. Cox hazards regression models were used to Test results with a p-value < 0.05 where needed. The primary end point of study was the long-term rate of major adverse cardiac events (i.e., death, Infarction, and repeat revascularization). The secondary end points were the individual components of the major adverse cardiac events and stent thrombosis.

Results

Baseline characteristics and the indications for coronary stenting were similar in women of all ages, Amongst 3300 revascularized patients 577 (25.4%) women who underwent native coronary arteries revascularization 7days of AMI were included in this study, 347(60.1%) from urban and 289 (35.2%) from rural areas of Sindh and Baluchistan province of Pakistan. PCI with stenting performed along with antiplatelet drug of the glycoprotein 11b/111a inhibitors class Tirofiban or eptifibatide or fractionated heparin in 363(62.9%). 97(19.9%) and 119 (19.9%) respectively.

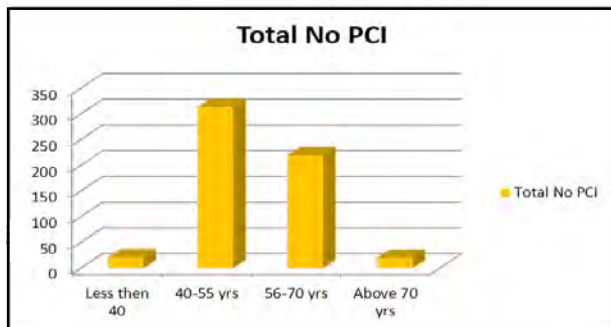
Area of living; n (n%)	Urban	347 (60.1)
	Rural	230 (39.9)
Age; mean \pm SD	Age	54.84 \pm 9.56
Medication; n (n%)	Tirofiban	363 (62.9)
	Clexane	97 (16.8)
	Eptifibatide	115 (19.9)
EF; n (n%)	< 35% (Severely below Normal)	25 (4.3)
	35% to 39% (Moderately below Normal)	64 (11.1)
	40% to 54% (Slightly below Normal)	429 (74.4)
	55% to 70% (Normal)	59 (10.2)

Table 1: Demographics and other study characteristics (Total Patients =577) On 2D Echocardiography assessment 429(74.4%) pa-

tients of <54 years of age had mild LV dysfunction then 64 (11.1%) patients had moderate LV dysfunction and 25(4.35%) with Severe LV dysfunction mostly in older women with co morbid conditions (Table 1), Revascularization with stenting was performed in 313 patients of age group 40-50 years followed by 219 patients in age group of 56-70 years in comparison to 23 in older group > 70 years and 22 in younger age < 40 years.

Age	Total No PCI(n=577)
Less than 40	22
40-55 years	313
56-70 years	219
Above 70 years	23

Table 2: Revascularization ratio in different age groups. (Total No of Patients 577)

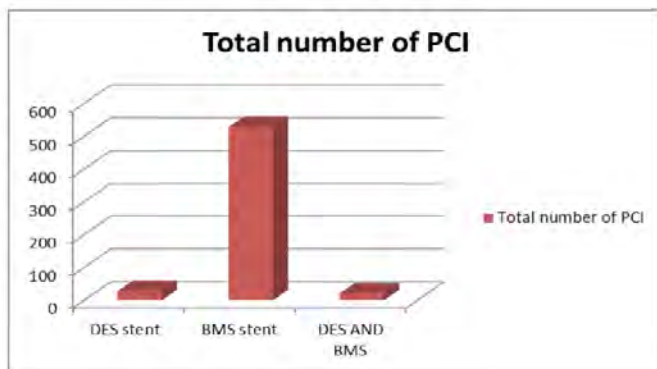


In 528 (91.5%) patients PCI with BMS, in 28 (4.8%) patients DES alone and in 21 (3.6%) patients with BMS and DES performed (Table 3).

Table 3: Revascularisation with DES AND BMS

Type of stent PCI.	Total number of Patients .577
DES stent	28(4.8%)
BMS stent	528(91.5%)
DES AND BMS	21(3.6%)

Table 3: Types of Stent used during revascularization



Differences in outcomes have been observed and may be explained

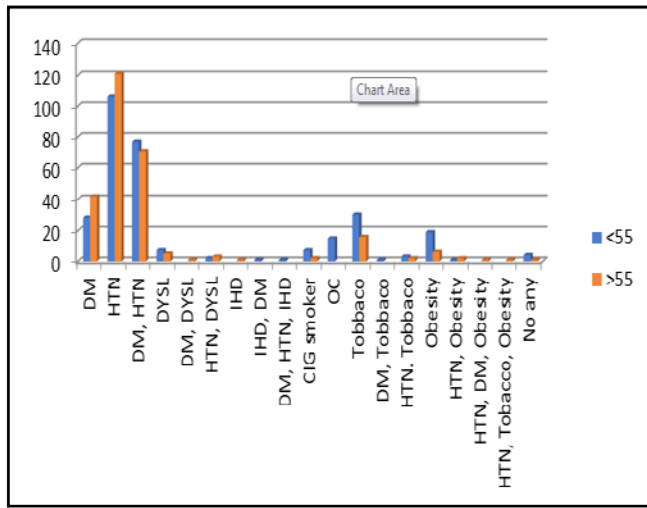
by Vessels involved and higher prevalence of risk factors diabetes mellitus in 38(15.1% P<0.001). Hypertension in 138 (41.3% P=0.006) in older age group (55-69years) and high modifiable risk factors such as smoking in 7(3.2%), tobacco use in 33(9.9%), obesity in 19(5.7%) and oral contraceptives in 15(4.2%) younger patients of age group < 54 years. (Table 4).

Table 4: Risk factors distribution among age groups.

Risk factors	(n=577)	
	< 55 years n (n%)	55 & above years n (n%)
Hypertension (HTN)	99(41.6%)	138(41.3%)
Diabetes Mellitus (DM)	37 (11.1%)	36 (15.1%)
HTN and DM	73(23.4%)	78 (30,7%)
Dyslipidemia	7 (2.1%)	6 (2.5%)
Obesity	19 (5.7%)	6 (2.5%)
Smoking	7 (2.1%)	2 (0.8%)
Use of hormonal contraceptives	15 (4.5%)	-
Oral tobacco users	33 (9.9%)	16 (6.7%)
Total	334 (57.9%)	243 (42.1%)

Risk Factors	Pre-menopausal	Post-menopausal
Age	<55 years	>55 years
DM	35(10.1%)	38(15.1%)
HTN	99(41.3%)	138(41.3%)
DM, HTN	70(28.8%)	78(33.2%)
Dyslipidemia	7(0.2%)	5(2.0)
DM, Dyslipidemia	30(8.8)	32(13.2)
HTN, Dyslipidemia	2(0.5)	3(1.2)
obesity	19(5.7%)	6(2.5%)
obesity DM	1(0.2%)	-
HTN, Tobacco, Obesity	1(0.2%)	1(0.4%)
Smoker	7(3.2%)	2(1.2%)
Oral contraceptive	15(4.2%)	-
Oral Tobacco	33(9.9%)	16(6.6%)
DM, Tobacco	2(1,2%)	-
HTN, Tobacco	3(1.2%)	2(1.2%)
HTN, Obesity	3((1.8%)	2(1.2%)
HTN, DM, Obesity	1(0.2%)	1(.8%)

Table 4: Risk Factor Profile of Patients



The more prevalence of 3-vessel coronary artery disease observed in 15(14.4%) out of 60 women of older age group >70 followed by 53(51.0%) out of 286womens of 55-70 years age after controlling for baseline characteristics,

Table 5: Distribution of number of vessels diseases among age groups (n=577)

Age groups	Total	SVD	2VD	3VD
30-54 years	231 (40.0)	110 (43.3%)	85 (38.8%)	36(34.6%)
55-69 years	286 (49.6%)	119 (46.9%)	114 (52.1%)	53 (51.0%)
> 70 years	60 (10.4)	25 (9.8%)	20 (9.1%)	15 (14.4%)

The odds of short-term mortality were significantly higher among older age group and post-menopausal compared to premenopausal patients <55. 13 patients (5 patients during hospitalization) and 8 patients died within 30 days after PCI.

Table 6: Mortality (n=53)

Within 1 month	13(2.2%)
Within 1years	18(3.1%)
Within 2year	9(1.5%)
Within 5years	13(2.3%)
Within 7years	4.(.8%)
Total	57(9.8%)



Table 7: Conditions underlying cause for death (n = 57)

Cause of Death	n (n%)
Comorbid conditions*	31 (58.5)
ACS (MI)	13 (39.4)
Arrhythmias	5 (9.4)
Heart Failure	8 (42.1%)

During hospitalization sudden cardiac death occurred in 2 patients due to arrhythmias and in 3 patients with re - myocardial infarction with shock in first month after PCI. high mortality observed during 1st year after PCI ,18 patients in comparison to other years. Total 57((9.8%) patient died during7 years follow up , 31 (58.5%) cases due to comorbid conditions like cerebrovascular accidents, Peripheral arterial diseases ,Renal failure. Cirrhosis of liver. lung disease and breast cancer ,in remaining 27 patients death was due to myocardial infarction in 13 ((39.4%). Arrhythmias in 5(9.4%) and worsening of heart Failure in 8(42.1%) elderly patients. Restenosis rates were high in 5th years of follow up .out of 17 patient 11 patient had Successful Re PCI PCI. While in 7 years follow up 13 patients more had restenosis out of those 10 cases had successful Re- PCI with stenting and 7 patients under went CABG in 5th year of follow up. 15 (2.5%) patient had complete Closure of Target Vessel ,28 (4.8%)had Re PCI on 7 years follow up and CABG was performed in 13 (2.2%) patients main reason could be noncompliance of therapy in 71 (12,3%) in patients.

Table 8: Noncompliance of drugs and coronary events.

Duration	NOC	Closed STENT	RE PCI	CABG
1 Month	8	1	2	0
1 Year	19	3	4	3
2 Year	14	1	1	1
5 Year	22	7	11	7
7 Year	8	3	10	2
Total	71(12.3%)	15(2.5%)	28(4.8%)	13(2.2%)

In the adjusted analyses, the risk of recurrent AMI leading to Re-PCI, there was no significant difference in the use of further angioplasty procedures between women of premenopausal and post-menopausal. Urban and rural women. Except non follow up mainly in rural area patients.

Table 9: Survival and death percentage of women in different follow-up periods (n=577)

Follow-up Duration	Death n (n%)	Follow-up n (n%)	Non-Follow-up n (n%)
< 1 month	13(2.2%)	555(96.1%)	19(3.2%)
< 1 year	18(3.1%)	514(89%)	25(4.5%)
< 2 years	9(1.5%)	489(84.7%)	6(1.1%)
<5 years	13(2.3%)	469(81.2%)	7(1.4%)
<7 years	4(.8%)	459(79.5%)	6(1.2%)
Total	57(9.8)	459(79.5%)	65(11.2%)

Compares survival and death in women, shows out of 577 the probability of survival was in 459 (79.5%) patients who were in follow up for 7 years and Death occurred in 57 patients (11.2%) more in elderly patients. 65 (11.2 %) not followed the visits. over all women of age >70 had slightly lower survival than women of young age. The Probability of survival at 7years was 73% in premenopausal women versus 78% post-menopausal (P=.06) after adjustment for important baseline variables, and there was no significant survival difference between women of two classes (relative mortality risk, 0.94; CI, 0.76 to 1.15. except comorbid condition and type of stent used death was more observed in Patients with BMS then DES.

Table 10: Mortality rate among stent type and follow-up duration (n=53)

Follow up duration	Type of stent		
	PCI with BMS stent n (n%)	PCI with DES stent n (n%)	PCI with DES and BMS n (n%)
Up to 1 month	10 (30.3%)	1 (5.3%)	-
< 1 year	2 (6.1%)	1 (5.3%)	-
< 2 year	13 (39.4%)	8 (42.1%)	-
< 5 years	5 (15.2%)	7 (36.8%)	-
< 7 years	2 (6.1%)	1 (5.3%)	1 (100.0%)
7 years and above	5 (15.2%)	1 (5.3%)	-
Overall death	37 (65.3%)	19 (35.8%)	1 (1.9)

Discussion

There is evidence to suggest that women with Myocardial infarction are less likely to receive evidence-based treatments and less likely to undergo revascularisation Worldwide [12,13]. In this observational study we found, out of 3300 performed PCI only 577 (17.4%) women underwent revascularization with stenting, this correlates with a large French registry of 74,389 consecutive patients (30% women) demonstrated a lower rate of PCI with stenting in women having an acute MI (14.2% versus 24.4%; p<0.001). In the same study, in-hospital mortality was significantly higher in women (14.8% versus 6.1%; p<0.0001). in hospital mortality after PCI was slightly higher 5(8.7%) patients vs 57 patients in 7 years. Urban women underwent more PCI then the rural women (347(60.1%) VS 230 (30.9%) due to long distance and logistic problems.

In this observational study we found worse prognosis in older women specially >55 with AMI following revascularization compared to premenopausal women <55 years of age .Observed differences in death , risk of recurrent MI, RE-PCI and heart failure were due to co morbid conditions ,severity of coronary Disease, type of stent used and no compliance of drugs due to Lack of awareness about the Problem in women and low socio-economic status , Our findings of non-significant short-term mortality 13 (2.2%) patients in 1st month following PCI correlates with to a recent study finding where the rates of short term all-cause and cardiac mortality following PCI were lower in Asian patients (Singapore, Hong Kong, and Malaysia) compared to their counterparts from Western Europe [14]. This correlation is may be due to the fact that our population of AMI is compared to a lower risk unselected coronary disease population in the study above. Moreover, we directly compared outcomes in women's within a single health care system despite the fact that we included the women of the rural area who may have had arrived later to the emergency department resulting in less effectiveness of the procedures or more extensive myocardial damage at time of PCI. But in our study use of glyco protein 11b /111a inhibitors and direct thrombin inhibitors, prior to PCI in majority of patients lead to less significant short-term mortality However, in our study, we extensively adjusted for differences in baseline prognostic characteristics and extent of coronary disease. while no significant difference between two populations was observed for mortality, except older age group which was found to have comparatively at increased risk of -fatal adverse cardiovascular events following PCI compared to younger age group premenopausal and non-significant difference in non-fatal events specially, While several studies of unselected coronary disease patients have revealed no difference in fatal cardiac outcomes in South Asian and White patients in a study following PCI, during the 2 years after the initial procedure or after the last TL-PCI, was achieved in 373 patients (92%) overall. Only 6 patients (1.7%) underwent TL-PCI [15]. After the initial 12years period, 20 women underwent repeat cardiac catheterization, revealing similar rates of restenosis, in 91 patients at 7 years similarly, the annual incidence of stent thrombosis was less than 1%, but as many as 80% of persons with stent

thrombosis had myocardial infarction, and as many as half of these persons died. Where as in our study Total 57(9.8%) patient died, 31 (58.5%) cases died due to comorbid conditions, in rest of 27 patients death was due to myocardial infarction in 13 (39.4%). Arrhythmias in 5(9.4%) and worsening of heart Failure in 8 (42,1%) cases. restenosis observed in 17 patients at 5 years of follow up, out of these patients 11 patient had successful PCI. while up to 7 years follow up 13 more patients had restenosis and amongst them 10 cases had successful revascularization, symptomatic improvement was much better in younger age group women after successful coronary angioplasty. In 7 years follow up total 15 (2.5%) patient had complete Closure of Target Vessel, 28 (4.8%) had Re PCI and CABG was performed in 13 (2.2%) patients (TABLE 7) main reason could be noncompliance of therapy in 71 (12.3%) in patients and the tendency to underestimate the problem by women themselves due to lack of awareness and they have roles to play in maximizing adherence to optimal primary and secondary prevention measures. To decrease the risk of RePCI and CABG with the latest drug coated stents, the numbers of stent thrombosis and rePCI and CABG can be even more lower [16-21]. Recently published data demonstrates the safety and efficacy of the use of contemporary DES in 2,176 women after acute MI [22]. In our study due to low socio economical condition of the patient and in a tertiary care public sector set up DES was less used in Study and that had insignificant impact on primary end points and on survival of patients as most patient had bare metal stents specially in diabetic women.

Our study represents a direct comparison of women of rural and urban population with varying age according to premenopausal and menopausal age suffering from of AMI patients in a single health care system using extensive adjustment for prognostic factors including severity of coronary disease. However, several study limitations should be noted. First, this study is an observational study and the ideal study design for determining efficacy of these procedures following AMI would be a randomized trial. This study is thus susceptible to treatment-selection bias although we did adjust for multiple potential confounding factors, we were not able to control for risk behaviours, dyslipidaemia or extent of infarct (non-ST elevation MI, or peak cardiac enzyme level) that could explain the observed difference in outcomes.

Conclusion

Evaluation in the use of PCI for the management of coronary artery disease have been shared commonalities of the disease process globally in women's by their unique pathologic process and responses to interventions and therapeutics, despite their greater baseline risk profile, women are significantly less likely to have received effective treatment, the use of including drug-eluting stents and use of glycol protein 11b /111a inhibitors and direct thrombin inhibitors, these behind-the scenes risk factors, plays a role that add up to a higher mortality risk on follow up women after PCI due to the numerous bearer to heart health in women chief among mainly due to socio economic reasons non-compliance to drugs and non-adherence to follow up .Which are not taken care of in this part of the world [23].

This study found Observed socioeconomic and age related disparities in outcomes which were present despite adjustment for demographic, and clinical characteristics. We believe the presence of awareness programs for the importance of adherence to secondary prevention medication, and timely seek of care, along with equitable access to health care, may help further regional disparities in post revascularization outcomes.

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