ORIGINAL ARTICLE

ASSOCIATION OF GENDER WITH STENT THROMBOSIS AND SHORT-TERM MAJOR ADVERSE CARDIOVASCULAR EVENTS IN PATIENTS UNDERGOING PRIMARY PERCUTANEOUS CORONARY INTERVENTION

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Objectives: Gender has been reported to be an independent predictor of stent thrombosis (ST), however, very limited data are available regarding gender disparities in the incidence of ST after primary percutaneous coronary intervention (PCI). Therefore, the objective of this study was to compare the incidence of ST among males and females after primary PCI.

Methodology: In this study, we included consecutive patients diagnosed with ST-elevation myocardial infarction undergoing primary PCI. The incidence of ST and short-term major adverse cardiovascular events (MACE) were compared between male and female cohorts.

Results: The gender distribution was 21% (368) female and 79% (1388) male patients. In the unmatched cohorts of females and males, the incidence of ST was 3.3% (12) vs. 5.3% (74); p=0.102, respectively. Short-term all-cause mortality rate was 12.2% (45) vs. 8.6% (119); p=0.032 among female and male patients, respectively. After propensity matching of the baseline characteristics, the incidence of stent thrombosis was 3.3% (12) vs. 4.9% (18); p=0.263 among females and male counterparts, respectively. The short-term all-cause mortality rate was 12.2% (45) vs. 10.6% (39); p=0.487 among female and propensity-matched male cohorts, respectively.

Conclusion: There are no gender-based disparities in the incidence of ST as well as short-term MACE after primary PCI. The gender of the patient itself does not determine the prognosis of the patient, but longer ischemic time, older age, and consequently higher burden of risk factors confound the effect of the female gender.

Keywords: STEMI, primary PCI, stent thrombosis, MACE, gender

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INTRODUCTION

Cardiovascular diseases (CVD) are the major cause of mortalities not only in males but also in females. Atherosclerotic characteristics and pathophysiology of the disease significantly differ by gender. Clinical manifestations and the epidemiological landscape of disease among males and females also differ significantly.[1] During the reproductive years of females, the occurrence rate of CVD is low in comparison to males, with around a decade of gap in presentation age. This effect is partially associated with estrogen, a sex hormone, which has a cardio-protective mechanism.[2,3] On one hand, the development and progression of diseases are relatively low, on the other hand, the female gender is believed to be an independent predictor of poor prognosis following a cardiovascular event. Different researches have been conducted that show female gender is linked to the increased risks of immediate and long-term death following cardiovascular events.[4-11] However, there is a contradiction of evidence because there are plenty of studies showing no variances in results or attributed differences in outcomes to the variations in baseline features such as a higher burden of comorbidities in females owing to advanced age at the time of presentation.[12,13]

Multiple factors associated with an increased rate of severe events in females have been depicted by studies centering on outcomes of gender disparities, such as some studies have shown that females are more likely to have the atypical medical presentation and pre-hospital delays than males leading to delay in reperfusion therapy.[7,9,10,14,15] Apart from this, another factor that has been witnessed is that females have a

lesser chance of receiving any aggressive or guideline-directed medical therapy (GDMT).[7-9]

Primary percutaneous coronary intervention (PCI) is considered the ideal choice of treatment when it comes to restoring myocardium in individuals with ST-Segment elevation myocardial infarction (STEMI), provided that it is carried out within 12 hours of symptoms.[16,17] Stent thrombosis (ST) is one of the major post-procedural complications of primary PCI associated with a higher risk of major adverse cardiovascular events.[18] Gender has been reported to be an independent predictor of ST, however, very limited data are available regarding gender disparities in the incidence of ST after primary PCI. Therefore, the objective of this study was to compare the incidence of ST among males and females diagnosed with STEMI.

METHODOLOGY

This cross sectional study was conducted between August 2020 and July 2021 at a tertiary care cardiac hospital in Karachi, Pakistan namely the National Institute of Cardiovascular Diseases (NICVD). Consecutive patients diagnosed with STEMI undergone primary PCI were included after taken informed consent from patients and approval of the ethics committee (ERC-30/2020). Inclusion criteria were all patients who presented to the emergency department of the hospital with typical symptoms, who were diagnosed with STEMI and fulfilled the current clinical practice guidelines recommended criteria of primary PCI. Non-consenting patients and patients in whom stent was not deployed or only plain old balloon angioplasty (POBA) done due to any reason were excluded from the study. Patients with unsuccessful 30-day follow-ups were also excluded from the analysis.

Data for the study were collected on a predefined proforma which consisted of patients' clinical and demographic characteristics, procedural and post-procedural characteristics, and follow-up data. All primary PCI procedures were performed by an on-call team of consultant cardiologists as per guidelines and institutional policies. In accordance with Academic Research Consortium (ARC) definition, ST was defined as definite (confirmed on angiography), probable (30-days unexplained mortality or re-infarction of the stented vessel), or possible (sudden mortality without autopsy confirmation after 30 days of procedure). Occurrence of ST within 24 hours of the index procedure was categorized as acute ST while ST events after 24 hours were labeled as sub-acute ST. All patients were followed post-discharge and along with ST, the occurrence of major adverse cardiovascular events (MACE) was recorded. MACE comprises all-cause mortality, re-infarction, re-hospitalization due to heart failure, and stroke/ cerebrovascular accident (CVA).

The IBM SPSS version 19 and statistical software R were used for the analysis of data. Patients were categorized by gender and the outcome of interest, i.e. ST, was compared between male and female patients. Clinical and demographic characteristics, procedural and post-procedural characteristics, and follow-up data between male and female patients were compared by conducting independent sample t-test or Chi-square test. In order to eliminate the confounding effect of differences in baseline characteristics, the two cohorts were propensity-matched in a 1:1 ratio based on the distribution of age, total ischemic time, killip class, hypertension, diabetes, prior myocardial infarction (MI), type of MI, left ventricular ejection fraction (LVEF), multi-vessel disease, high thrombus burden, vessel diameter, and lesion length. After propensity matching, well-balanced cohorts were formed except for the distribution of total ischemic time which was found to be significantly higher for female patients. A p-value of ≤ 0.05 was the statistical significance criteria.

RESULTS

The gender distribution of our study sample was 21% (368) female and 79% (1388) and male patients. On average female patients were older than the male patients with a mean age of 57.77 ± 11.41 years vs. 55.01 ± 11.12 years; p<0.001, respectively. The total ischemic time was significantly longer for female patients in comparison to the male patients with a median time of 405 [270-590] minutes vs. 330 [230.5-461.5] minutes; p<0.001, respectively. Hypertension and diabetes were more common among female patients as compared to male patients with the frequency of 74.5% (274) vs. 51.8% (719); p<0.001 and 54.6% (201) vs. 32.1% (446); p<0.001, respectively, while, smoking and prior history of MI were more common among male patients, 39.6% (549) vs. 1.9% (7); p<0.001 and 8.3% (115) vs. 5.2% (19); p=0.045, respectively. Female patients also have a higher tendency of incidence of multi-vessel disease than their male counterparts, 67.7% (249) vs. 62.1% (862); p=0.049, respectively. Similarly, there was a lower tendency of final TIMI III flow among female patients as compared to male patients with a frequency of 85.6% (315) vs. 90.6% (1258); p=0.005, respectively. A lower tendency, but statistically

insignificant, of incidence of stent thrombosis was observed among females as compared to male patients with a frequency of 3.3% (12) vs. 5.3% (74); p=0.102, respectively, however, short term all-cause mortality rate was significantly higher for female patients as compared to male counterparts, 12.2% (45) vs. 8.6% (119); p=0.032, respectively. Comparison of clinical and demographic characteristics, procedural and post-procedural characteristics, and follow-up data between female and male cohort are presented in Table 1.

Table 1: Comparison of clinical and demographic characteristics, procedural and post-procedural characteristics, and follow-up data between female and male cohort

	Male	Female	P-value
Total (N)	**1388 (79%)**	**368 (21%)**	**-**
Age (years)	55.01 ± 11.12	57.77 ± 11.41	<0.001*
<45 years	16.1% (224)	9.2% (34)	<0.001*
45 to 64 years	61.7% (857)	58.4% (215)	
≥ 65 years	22.1% (307)	32.3% (119)	
Total ischemic time (minutes)	330 [230.5-461.5]	405 [270-590]	<0.001*
Killip class			
I	76.4% (1061)	72% (265)	0.209
II	12.8% (178)	14.1% (52)	
III	7.1% (98)	8.2% (30)	
IV	3.7% (51)	5.7% (21)	
Hypertension	51.8% (719)	74.5% (274)	<0.001*
Diabetes mellitus	32.1% (446)	54.6% (201)	<0.001*
Smoking	39.6% (549)	1.9% (7)	<0.001*
Prior myocardial infarction (MI)	8.3% (115)	5.2% (19)	0.045*
Type of MI			
Anterior	57.2% (794)	48.9% (180)	0.078
Inferior	15.8% (219)	18.2% (67)	
Inferior with RV	17.3% (240)	21.7% (80)	
Inferio-posterior	8.1% (113)	9.2% (34)	
Lateral	1.6% (22)	1.9% (7)	
LV ejection fraction (%)	39.4 ± 9.1	40 ± 9.7	0.263
Multi-vessel disease	62.1% (862)	67.7% (249)	0.049*
Pre-procedure TIMI 0 flow	62.4% (866)	64.1% (236)	0.54
High thrombus grade (>3)	79.2% (1099)	82.3% (303)	0.179
Mean vessel diameter	3.5 ± 0.3	3.4 ± 0.3	<0.001*
Total lesion length	27.9 ± 11.8	27.7 ± 12.5	0.844
Post-procedure TIMI III flow	90.6% (1258)	85.6% (315)	0.005*
Stent thrombosis	5.3% (74)	3.3% (12)	0.102
Acute	1.2% (17)	1.4% (5)	0.132
Sub-acute	4.1% (57)	1.9% (7)	
Type stent thrombosis			
Definite	63.5% (47)	91.7% (11)	0.151
Probable	31.1% (23)	8.3% (1)	
Possible	5.4% (4)	0% (0)	
Short-term outcomes			
Follow-up duration	186.19 ± 63.78	183.28 ± 67.02	0.442
All-cause mortality	8.6% (119)	12.2% (45)	0.032*
Stroke/CVA	0.5% (7)	0.3% (1)	0.556
Hospitalization due to HF	6.1% (84)	7.6% (28)	0.277
Re-MI	4.4% (61)	3.3% (12)	0.333
MACE	14.9% (207)	18.8% (69)	0.072

*MI=myocardial infarction, HF=heart failure, RV=right ventricular, LV=left ventricular, TIMI=thrombolysis in myocardial infarction, CVA=cerebrovascular accident, MACE=major adverse cardiovascular event, *=significant*

After propensity matching, well-balanced cohorts of male and female patients were achieved, except for the total ischemic time which was significantly higher for female patients as compared to the male patients with a median time of 405 [270-590] minutes vs. 360 [257.5-530] minutes; p=0.012, respectively. Even after matching the baseline characteristics, a lower tendency of incidence of stent thrombosis, but statistically insignificant, was observed among females as compared to male patients with a frequency of 3.3% (12) vs. 4.9% (18); p=0.263, respectively, however, short term all-cause mortality rate is now no longer significant between female and male patients with a rate of 12.2% (45) vs. 10.6% (39); p=0.487, respectively. Comparison of clinical and demographic characteristics, procedural and post-procedural characteristics, and follow-up data between propensity-matched female and male cohorts are presented in Table 2.

Table 2: Comparison of clinical and demographic characteristics, procedural and post-procedural characteristics, and follow-up data between propensity-matched female and male cohorts

	Male	Female	P-value
Total (N)	**368 (50%)**	**368 (50%)**	**-**
Age (years)	57.79 ± 10.46	57.77 ± 11.41	0.984
<45 years	7.3% (27)	9.2% (34)	0.103
45 to 64 years	66% (243)	58.4% (215)	
≥ 65 years	26.6% (98)	32.3% (119)	
Total ischemic time (minutes)	360 [257.5-530]	405 [270-590]	0.012*
Killip class			
I	71.2% (262)	72% (265)	0.856

II	14.9% (55)	14.1% (52)	
III	9.2% (34)	8.2% (30)	
IV	4.6% (17)	5.7% (21)	
Hypertension	73.6% (271)	74.5% (274)	0.801
Diabetes mellitus	54.9% (202)	54.6% (201)	0.941
Smoking	1.9% (7)	1.9% (7)	>0.999
Prior MI	5.4% (20)	5.2% (19)	0.869
Type of MI			
Anterior	51.6% (190)	48.9% (180)	0.610
Inferior	17.4% (64)	18.2% (67)	
Inferior with RV	17.9% (66)	21.7% (80)	
Inferio-posterior	10.1% (37)	9.2% (34)	
Lateral	3% (11)	1.9% (7)	
LVEF (%)	39.6 ± 9.3	40 ± 9.7	0.565
Multi-vessel disease	68.2% (251)	67.7% (249)	0.874
Pre-procedure TIMI 0 flow	63.3% (233)	64.1% (236)	0.818
High thrombus grade (>3)	80.7% (297)	82.3% (303)	0.569
Mean vessel diameter	3.4 ± 0.4	3.4 ± 0.3	0.979
Total lesion length	27.3 ± 11.5	27.7 ± 12.5	0.581
Post-procedure TIMI III flow	84.8% (312)	85.6% (315)	0.756
Stent thrombosis	4.9% (18)	3.3% (12)	0.263
Acute	0.8% (3)	1.4% (5)	0.177
Sub-acute	4.1% (15)	1.9% (7)	
Type stent thrombosis			
Definite	66.7% (12)	91.7% (11)	0.271
Probable	27.8% (5)	8.3% (1)	
Possible	5.6% (1)	0% (0)	
Short-term outcomes			
Follow-up duration	189.9 ± 69.21	183.28 ± 67.02	0.188
All-cause mortality	10.6% (39)	12.2% (45)	0.487
Stroke/CVA	0.3% (1)	0.3% (1)	>0.999
Hospitalization due to HF	7.6% (28)	7.6% (28)	>0.999
Re-MI	4.1% (15)	3.3% (12)	0.556
MACE	17.7% (65)	18.8% (69)	0.702

*MI=myocardial infarction, HF=heart failure, RV=right ventricular, LV=left ventricular, TIMI=thrombolysis in myocardial infarction, CVA=cerebrovascular accident, MACE=major adverse cardiovascular event, *=significant*

DISCUSSION

To the best of our knowledge, this study is one of the largest studies on the assessment of gender-based differences in the incidence of ST in the Pakistani population. The incidence rate of ST reported in various studies ranges from 2% to 5.9%.[19-22] In our study, the incidence of ST among females was observed to be 3.3% of which 1.4% were acute events and the remaining 1.9% were sub-acute events. While among male patients, the incidence of ST was 5.3% with 1.2% acute and 4.1% sub-acute events. Additionally, female patients were observed to have a higher rate of short-term all-cause mortality as compared to male patients with a frequency of 12.2% vs. 8.6%; p=0.032. However, such differences in short-term all-cause mortality rate by gender can be attributed to the differences in the demographic and clinical construction of male and female cohorts. Such as females were observed to be older with longer total ischemic time, higher frequency of hypertension and diabetes, a higher tendency of incidence of multi-vessel disease, and a lower tendency of final TIMI III flow as compared to their male counterparts. Upon matching the two genders for baseline differences, the differences in outcomes including ST and short-term all-cause mortality were no longer evident. Hence, the gender of patients itself does not determine the prognosis of the patient, but longer ischemic time, older age, and consequently higher burden of risk factors confound the effect of the female gender as observed by various studies in the past.[5-9,23] One of the major determinants of adverse outcomes in patients with STEMI is the pre-hospital delays. The timeline in the management of STEMI is different in females compared to their male counterparts, females experience longer gaps not only in symptoms to hospital arrival but also from hospital arrival to the procedure time, causing a delay in the reinstatement of myocardium on time.[4,9,24] Multiple studies have reported a higher risk of adverse outcomes and complications following the procedure, for example, no-reflow and hospital deaths.[4,5,8,9,23,24] Similar to our observations the major cause of variations in outcomes was reported to be confounded by the high-risk profile of female patients such as old age, diabetes, hypertension, obesity, and exposure to the longer untreated ischemia.

Regardless of gender, various patient and system-related features and factors are reported to be determinants of stent thrombosis such as kidney failure, diabetes, anemia, reduced left ventricular ejection fraction, no-reflow, average stent diameter of less than 3.0 mm, reperfusion time ≤2 hours, baseline platelet count, higher Killip classes, history of congestive heart failure, the extent of disease, number of stents implanted, low baseline TIMI flow, angiographic aneurysm, peri-procedure use of clopidogrel, low baseline TIMI flow, and bifurcation lesion are some of the most commonly reported factors associated with stent thrombosis.[19-22,25]

The generalizability of the study findings may be limited due to certain limitations such as the observational nature of the study design, secondly data

regarding certain factors with potential confounding effects were not available for matching of the male and female cohorts such as anatomical complexities, a number of stents per patient, stenting techniques, strut fracture, polymer hypersensitivity, new plaque rupture, delayed arterial wall remedial, and adherence to the dual antiplatelet therapy (DAPT).

CONCLUSION

There are no gender-based disparities in the incidence of ST as well as short-term MACE after primary PCI. The gender of the patient itself does not determine the prognosis of the patient, but longer ischemic time, older age, and consequently higher burden of risk factors confound the effect of the female gender.

AUTHORS' CONTRIBUTION

AK and RK: Concept and design, data acquisition, interpretation, drafting, final approval, and agree to be accountable for all aspects of the work. MM, RA, KR, GR, MFHT, AA, AB, MS, SY, AW, YK, RR, and MNS: Data acquisition, interpretation, drafting, final approval and agree to be accountable for all aspects of the work.

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