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ORIGINAL ARTICLE

Impact of gender difference on PCI outcome in Egyptian diabetic patients: Prospective two center registry study

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KEYWORDS

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Abstract *Introduction:* Diabetes mellitus is a chronic condition with devastating cardiovascular complications. Earlier studies have reported a gender-based difference in major adverse cardiac events (MACEs) after index PCI procedures. In the drug eluting stent era, more recent studies have failed to show any differences in post-PCI outcomes between both genders. However, this finding has never been verified in Egyptian patients with diabetes.

The aim of the study: The aim of the study was to compare the impact of female gender on short- and long-term outcomes after elective PCI using drug-eluting stents (DES) in Egyptian diabetic patients.

Patients and method: The study included 100 diabetic males and 100 diabetic females, all of whom had DES deployed during elective PCI and followed up for 12 months. The clinical endpoints were death, myocardial infarction (MI), target vessel revascularization (TVR), or target lesion revascularization (TLR) at any time during 12 month follow-up period.

Results: Both diabetic females and males have a low and nearly equal incidence of adverse events following PCI using DES.

Conclusion: When all patients had DES implanted and after adjustment of demographic and risk factor/co morbidity profiles, there were no significant differences in the short- or long-term PCI outcomes of diabetic females treated with DES when compared to diabetic males.

1. Introduction

Diabetes mellitus is a chronic condition with devastating cardiovascular complications. It is estimated that the number of patients with diabetes, about 220 million by 2010 will rise to 350 million by 2025. The prevalence of diabetes was reported as 13.5% in Egypt and it is closely associated with a concomitant rise in obesity rates.[1]

Earlier studies have reported a gender-based difference in major adverse cardiac events (MACEs) after index PCI procedures thought to be related to their smaller coronary vessel

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diameters and higher rates of coronary artery dissection and femoral access-site vascular complication.[2]

In the drug eluting stent era, more recent studies have failed to show any differences in post-PCI outcomes between both genders.[3,4] However, comparative data concerning differences in clinical outcomes after drug-eluting stent implantation in diabetic patients according to gender are still not available for the Egyptian population.

2. Aim of the study

The aim of the study was to compare the impact of female gender on short- and long-term outcomes after elective PCI using drug-eluting stents (DES) in Egyptian diabetic patients.

3. Patients and methods

From August 2010 to January 2013, a total of 200 Egyptian diabetic patients (100 men and 100 women) who underwent drug-eluting stent implantation were studied prospectively. Diabetes mellitus was defined as fulfillment of at least one of hemoglobin A1c $>6.1\%$, or under treatment with anti-diabetic agents (insulin or oral hypoglycemic agents). Our study protocol was approved by the local Ethics Committee and all patients provided consent for participation in the study.

3.1. Exclusion criteria

1. Non-diabetic patients.
2. Patients treated with BMS.
3. Patients treated with primary PCI.
4. Patients with cardiogenic shock.

All patients were subjected to the following:

1. **Careful history taking and thorough physical examination**
2. **Laboratory investigations:**

Renal function tests.
Complete lipid profile.
Fasting blood sugar and hemoglobin A1c.
Complete blood picture and coagulation profile.
Creatinine kinase MB (CK-MB): measured at baseline and 8–12 h after procedure.

3. **Resting 12 lead ECG:** For assessment of cardiac rhythm and signs of myocardial ischemia (ST segment and T wave abnormalities and pathological Q waves.
4. **Echo Doppler study:** All patients were studied by transthoracic echocardiography using commercially available echocardiographic machines (Siemens), equipped with 3.5 MHz phased array transducer. M-mode echocardiography was used to assess chamber dimensions and calculation of the ejection fraction. Two dimensional echocardiography was used for the assessment of the overall left ventricular systolic function by eyeballing and biplane Simpson's rule. Pulsed wave Doppler was used to measure peak mitral E velocity, peak mitral A velocity and the E/A ratio. Continuous wave Doppler was used for the assessment of flow across cardiac valves and the right ventricular systolic pressure.
5. **Diagnostic coronary angiography:** Performed via transfemoral approach, using Seldinger's technique. The angiograms were done in all the standard views using right and left coronary catheters.
6. **Percutaneous coronary intervention (PCI):** After arterial access was obtained using standard technique, all patients received a bolus dose of heparin to reach a target Activated Clotting Time (ACT) of >300 s. The technique done was noted, as well as all data of the stent(s) used (manufacturer, type and length).

The success of the PCI procedure was defined by angiographic, procedural, and clinical criteria.[5]

a. **Angiographic success:** A successful PCI was defined as one that achieves a minimum stenosis diameter reduction to less than 20% in the presence of grade 3 TIMI flow (assessed by angiography).
b. **Procedural success:** A successful PCI should achieve angiographic success without major clinical complications (e.g., death, MI, emergency coronary artery bypass surgery) during hospitalization.
c. **Clinical success:** A clinically successful PCI includes anatomic and procedural success with relief of signs and/or symptoms of myocardial ischemia after the patient recovers from the procedure. The long-term clinical success requires that the short-term clinical success remains durable and that the patient has persistent relief of signs and symptoms of myocardial ischemia for more than 6 months after the procedure.

All patients were pretreated with 300 mg of both aspirin and clopidogrel. Patients were maintained on aspirin 100 mg daily lifelong and Clopidogrel 75 mg per day for at least 12 months. Clinical follow up comprised checking office visits and telephone contacts. All patients were observed for immediate and late complications over a period of 12 months for:

a. **Stent thrombosis:** whether acute (during the PCI procedure or within the subsequent 24 h), sub acute (between 1 and 30 days following PCI), or late (between 1 month and 1 year following PCI).[6]
b. **Cerebrovascular accidents (CVA)**
c. **Major adverse cardiac events (MACEs):** defined as a composite of all-cause death, ACS and target lesion revascularization (TLR), at anytime during 12 month follow-up period. We defined acute coronary syndrome among patients with unstable angina and acute myocardial infarction. Unstable angina was diagnosed in the presence of ischemic symptoms regardless of ST-T changes. Acute myocardial infarction was defined as the presence of ischemic symptoms and a two-fold increase in CK-MB level. TLR was defined as repeat revascularization clinically driven (recurrence of chest pain and new ECG changes) by any lesion in a stented segment ($\geqslant 50\%$ diameter stenosis with $\geqslant 5$ mm proximal or distal to the DES).[7]