Indian Heart Journal xxx (2018) xxx–xxx

Contents lists available at ScienceDirect

Indian Heart Journal

journal homepage: www.elsevier.com/locate/ihj

Original Article

Gender disparities with the use of percutaneous left ventricular assist device in patients undergoing percutaneous coronary intervention complicated by cardiogenic shock: From pVAD Working Group

Rajkumar Doshi*, Krunalkumar Patel, Dean Decter, Rajiv Jauhar, Perwaiz Meraj

Department of Cardiology, North Shore University Hospital, Northwell Health, Manhasset, NY, United States

ARTICLE INFO

Article history:
Received 1 February 2018
Accepted 21 April 2018
Available online xxx

Keywords:
Mechanical circulatory device
Cardiogenic shock
High-risk PCI
Gender

ABSTRACT

Background: Hemodynamic support with Impella (Abiomed Inc., Danvers, MA) devices is becoming a more prevalent treatment option for patients with cardiogenic shock (CS) undergoing percutaneous coronary intervention (PCI). There exists only limited published data regarding outcome differences between male and female patients. Therefore, the objective of this paper is to analyze these gender differences between short-term survival and in-hospital outcomes in those undergoing PCI with CS.
Methods: Between January 2011 and July 2016, patients undergoing PCI with simultaneous use of Impella were identified. Only patients presenting with CS were included in the analysis. All-cause in-hospital mortality was the primary outcome. Using SAS 9.4 for propensity score matching, additional secondary outcomes were also compared.
Results: The primary outcome was comparable between males and females (39.5% vs. 26.3%, p = 0.33) in CS patients. Secondary outcomes were also comparable and included: myocardial infarction, stroke, CS, heart failure, dialysis requirement, bleeding within 72 h, blood transfusion, dysrhythmia, composite of all complications, major adverse cardiac events. Survival at 30 days was equal in both groups. A reduced mortality in males was noted for pre-PCI initiation of Impella. Additionally, both genders who received pre-PCI Impella support, experienced a significant reduction in inotrope use.
Conclusions: Despite the small number of cohorts, this study did not reveal any significant differences among gender with the use of percutaneous left ventricular assist devices for PCI in patients with acute myocardial infarction complicated by CS. However, initiation of Impella prior to PCI may be associated with improved mortality and morbidity in both genders.

1. Introduction

The incidence of cardiogenic shock (CS) in patients presenting with acute myocardial infarction (AMI) is nearly 10%.[1,2] The incidence of CS increased two-fold between 2004 and 2014.[3] Even after prompt percutaneous coronary intervention (PCI) and other adjunctive therapies, mortality rates for these patients reaches nearly 70%.[1,2] It should be noted that mortality has mildly decreased from 2004 to 2014; however, it still hovers around 50%.[3] Trans-valvular mechanical circulatory support (MCS) has been associated with improved hemodynamics and myocardial recovery by unloading the left ventricle and decreasing myocardial oxygen demand.[4] Guidelines have recommended the use of MCS, in addition to early revascularization and pharmacological management, in patients with AMI complicated by CS (AMI-CS).[5] When looking at gender differences, females are more likely to have worse comorbidities and less likely to be treated with intraaortic balloon pump (IABP) in the setting of CS due to a myriad of reasons.[6,7] Hence, females, compared to males, are likely to have higher mortality rates in the setting of CS.[8,9] However, the SHOCK registry showed no gender differences in in-hospital mortality, and revealed similar benefits for males and females after PCI for AMI-CS.[6]

Although Joseph et al. compared outcomes in males and females undergoing PCI for AMI-CS with Impella 2.5 support, the conclusion reached from the investigation was limited by their lack of adjustment and by the utilization of only smaller pumps.[10]

Abbreviations: CS, cardiogenic shock; PCI, percutaneous coronary intervention; AMI, acute myocardial infarction; MCS, mechanical circulatory support; IABP, intraaortic balloon pump; pLVAD, percutaneous left ventricle assist device; EKG, electrocardiogram.

* Corresponding author at: Department of Cardiology, North Shore University Hospital, 300 Community Dr, Manhasset, NY 11030, United States.
E-mail address: raj20490@gmail.com (R. Doshi).

https://doi.org/10.1016/j.ihj.2018.04.009

Moreover, there is no gender difference in patients undergoing high-risk procedures using Impella; however, gender differences for patients with CS when using Impella is not clear.[11] This data sought to analyze the differences in short-term survival and in-hospital outcome between males and females undergoing PCI for AMI-CS in a "real-world" patient cohort. Our analysis included the clinical outcomes up to 30-days for both Impella 2.5 and Impella CP. Furthermore, as shown by a previous article for only left main disease, this discussion assessed whether the placement of percutaneous left ventricular assist device (pLVAD) prior to PCI was beneficial to either gender.[12]

2. Methods

2.1. Study design and data collection

Data were obtained from two high volume tertiary care centres in New York City between January 2011 and July 2016. Data were collected at both sites using the USpella registry form to record baseline, clinical and procedural characteristics. Follow-up records were also recorded and were obtained from the electronic medical records. At both sites, all patients receiving Impella 2.5 or Impella CP support during PCI for AMI-CS were identified. From the total 35,910 patients who underwent PCI, 241 were supported with Impella devices. 160 patients were considered "high-risk", but without CS, and were analyzed differently due to their different risk profiles. The remaining 81 patients who underwent PCI for AMI-CS supported with Impella were included in this study [Supplementary Fig. S1]. The timing of Impella insertion was decided by the operating physician's discretion. Crude mortality rates in patients with Impella support prior to PCI were compared to post-PCI in both genders.

Patients were treated with drug-eluting stents (DES) and/or bare metal stents (BMS) and/or percutaneous transluminal coronary angioplasty according to individual operator's discretion. Furthermore, the number of vessels and lesions treated, and the use of adjunctive therapies was also decided by the operating physician. Patients with other types of cardiac support such as tandem heart, IABP, extra-corporeal membrane oxygenation were excluded. The investigators had full access to the data and control of the data analysis. Institutional review board approval was obtained for this paper.

2.2. Endpoints and definitions

The primary endpoint was all-cause in-hospital mortality. Secondary endpoints included in-hospital AMI, stroke, CS, heart failure, dialysis requirement, bleeding within 72 h, blood transfusion, dysrhythmia, composite of all complications, major adverse cardiac events (MACE), and status of the patient at 30 days. MACE was a composite of all-cause in-hospital mortality, AMI, and stroke. AMI was defined as a creatine kinase-MB fraction greater than three times the upper limit of normal, or the development of a new pathological q wave on the electrocardiogram (EKG). Major bleeding events were defined as a hemoglobin drop of $\geq$3 g/dL, blood transfusion, or blood loss requiring a procedural intervention to stop the bleeding. The diagnosis of CS was based on the definition from the USpella registry: (1) systolic blood pressure $<$90 mmHg for $>$30 min or the need for vasopressor and/or inotropic therapy and/or IABP to maintain a systolic blood pressure greater than 90 mmHg; (2) signs of organ hypoperfusion such as oliguria/anuria, altered mental status, or cold extremities. In-hospital mortality is reported as the proportion of patients who died during their hospital stay.

2.3. Device details

The Impella 2.5 and Impella CP (Abiomed Inc., Danvers, MA) devices have been explained previously.[13,14] Briefly, Impella 2.5 is a 12 Fr pLVAD, which generates up to 2.5 L/min of forward flow into the ascending aorta. Impella CP is a 14 Fr pLVAD device, which provides a forward flow up to 3.5 L/min. Both devices are inserted through the femoral artery using a modified Seldinger technique.

2.4. Statistical analysis

Continuous data are expressed as the mean $\pm$ standard deviation (SD) and categorical data are expressed as frequencies and percentages. Continuous variables were computed using the student's *T*-test. Categorical data were evaluated using a Chi-square test. Statistical analysis was done using SAS 9.4 (SAS Institute, Cary, NC). To adjust for the baseline characteristics and procedural details, a propensity score matched analysis using logistic regression model was performed, which also reduced selection bias. First, a propensity score was generated for each patient using an automated step-wise logistic regression method. Covariates in the matching model included baseline demographics, cardiovascular risk factors, relevant comorbidities, procedural characteristics, and in-hospital outcomes. Next, patients were matched based on their propensity scores keeping the calliper width 0.2. We utilized 1:2 matching protocol without replacement. Next, unmatched patients were excluded from the analysis. Then, outcomes were compared using McNemar's test and Wilcoxon signed rank test as appropriate. The absolute standardized difference is below 10% after matching to ensure the small difference between groups after matching.[15] Statistically significant results were considered at p-value $<$ 0.05. All tests performed were two-sided.

Table 1
Baseline characteristics in cardiogenic shock patients with Impella use: stratified by gender (unmatched cohorts).

Variable name	Male (N = 62)	Female (N = 19)	P value
Age (years)	61.1 $\pm$ 13.1	67.3 $\pm$ 15.1	0.08
Body mass index (kg/m^2)	28.2 $\pm$ 5.6	25.6 $\pm$ 5.4	0.08
Race:			
White	30 (48.4%)	9 (47.4%)	0.71
Black	6 (9.7%)	4 (21.1%)	
Asian	17 (27.4%)	4 (21.1%)	
Other	9 (14.5%)	2 (10.5%)	
Baseline characteristics:			
Hypertension	47 (75.8%)	16 (84.2%)	0.44
Renal failure	7 (11.3%)	1 (5.3%)	0.44
Dialysis	2 (3.2%)	1 (5.3%)	0.68
Diabetes mellitus	24 (38.7%)	9 (47.4%)	0.50
Smoker	19 (30.6%)	2 (10.5%)	0.08
Peripheral vascular disease	5 (8.1%)	1 (5.3%)	0.68
Myo/endocarditis	2 (3.2%)	0 (0%)	0.43
Hyperlipidemia	32 (51.6%)	9 (47.4%)	0.75
Chronic lung disease	2 (3.2%)	2 (10.5%)	0.20
Prior myocardial infarction	14 (22.6%)	4 (21.1%)	0.89
Dysrhythmia	4 (6.4%)	1 (5.3%)	0.85
Cerebrovascular disease	1 (1.6%)	0 (0%)	0.58
Prior coronary artery disease	30 (48.4%)	10 (52.6%)	0.75
Congestive heart failure	25 (40.3%)	7 (36.8%)	0.79
Valvular disease	4 (6.4%)	0 (0%)	0.26
Ischemic cardiomyopathy	20 (32.3%)	1 (5.3%)	0.02
Prior CABG	11 (17.7%)	1 (5.3%)	0.18
Prior PCI	19 (30.6%)	4 (21.1%)	0.42

CABG – coronary artery bypass grafting, PCI – Percutaneous Coronary Intervention. Frequencies are in number (%) or mean $\pm$ standard deviation.

Please cite this article in press as: R. Doshi, et al., Gender disparities with the use of percutaneous left ventricular assist device in patients undergoing percutaneous coronary intervention complicated by cardiogenic shock: From pVAD Working Group, Indian Heart J (2018), https://doi.org/10.1016/j.ihj.2018.04.009