Gender-specific outcomes after balloon aortic valvuloplasty: Inhospital and long-term outcomes

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Background Increasing numbers of balloon aortic valvuloplasty (BAV) are performed in the management of symptomatic aortic stenosis as bridge and therapeutic challenge in the work-up for transcatheter aortic valve replacement. However, the significance of gender in outcomes following BAV remains controversial.

Methods We retrospectively reviewed 664 consecutive patients who underwent BAV from January 2005 to December 2012. Patients were stratified according to gender. Clinical and procedural characteristics as well as in-hospital outcomes and 1-year mortality were collected. Cumulative survival curves for women and men were constructed using the Kaplan-Meier method and were compared by the log-rank test. Cox regression analysis was performed to identify the independent effect of sex on 1-year mortality.

Results Of the 664 patients, 333 (52%) were women. Women had lower body surface area, tended to be frailer and were less likely to have history of coronary artery disease. Women were more likely to present with heart failure whereas men presented more commonly with chest pain. In hospital death was significantly higher in women compared to men, mainly driven by the difference in cardiac death (8.1% vs 3.9%, $P = .02$ and 6.3% vs 2.6%, $P = .02$ respectively). One-year mortality rates were similar in women and men (25.4% vs 29.4%, $P = .42$) and after multivariate analysis gender had no association with 1-year mortality (HR = 0.9, $P = .65$).

Conclusions Significant differences exist in baseline characteristics and presentation between genders. Although in hospital mortality after BAV was significantly higher in women, 1-year mortality was similar between women and men. (Am Heart J 2015;170:180-6.)

Surgical and transcatheter aortic valve replacement improves symptoms and survival in patients with severe, symptomatic aortic stenosis (AS).[1-3] However, even with the expanded use of transcatheter aortic valve replacement (TAVR) in high-risk patients, it still remains that a portion of patients are ineligible for either procedure due to high risk clinical features or unfavorable vascular anatomy.[4,5]In these patients, balloon aortic valvuloplasty (BAV) may be offered as a standalone palliative procedure or as a bridge to valve replacement. Although BAV has been shown to have an early positive impact on clinical and hemodynamic parameters,[6] procedural complications are common and long term outcomes remain poor.[7,8] Of note, studies examining the prognostic determinants in patients undergoing BAV have consistently shown that outcomes are primarily influenced by patient baseline characteristics rather than procedural variables.[9]

Women represent a significant proportion of the population with severe AS[10] and comprise approximately half of the total patients undergoing aortic valve procedures.[3,11] While female gender has been associated with poor prognosis after coronary interventions,[12-14] its impact on outcomes following aortic valve procedures remains controversial. The EuroSCORE includes female gender as a high risk feature for patients undergoing cardiac surgery[15] whereas female gender is associated with favorable outcomes after TAVR.[16,17] However, no previous study has examined gender-related differences in patients undergoing BAV in detail, and previous reports in gender-specific outcomes following BAV have been conflicting.[7,8] This study therefore aims to compare the baseline characteristics, treatment, and short and long term outcomes in women and men undergoing BAV in this contemporary context.

Materials and methods

We conducted a single-center retrospective review of 644 consecutive patients with severe symptomatic AS who underwent a total of 771 BAV procedures from January 2005 to December 2012. The decision to proceed with BAV was made by the treating physician after consultations with interventional cardiology and cardiothoracic surgery. After 2010, select patients who became eligible for TAVR post-BAV, either due to improved clinical status with respect to decompensated heart

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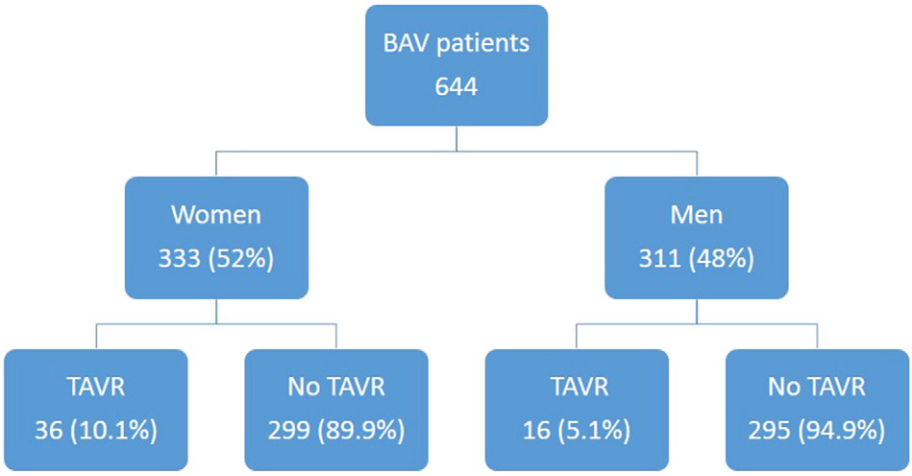
Figure 1



Flow chart of BAV patients from 2005 to 2012.

failure, frailty or general weakness, or after treatment of a concomitant non-cardiac condition post-BAV, went on to receive TAVR in the following months (n = 52, Figure 1). All patients provided written informed consent for clinical follow-up.

This study was approved by the hospital institutional review board. No extramural funding was used to support this work. The authors are solely responsible for the design and conduct of this study, all study analyses, the drafting and editing of the paper and its final contents.

Data collection

Patient baseline characteristics, medical history, treatment information and source documentation for any in-hospital clinical events were collected from the medical records. Deaths and date of deaths were ascertained via medical record review and supplemented with the Social Security Death Index. All in-hospital clinical events were adjudicated by an independent clinical events committee.

Device and procedure

A detailed description of BAV performance at our center including the concurrent right heart catheterization, procedural medications, arterial access and hemostasis techniques has been previously published.[18] In brief, using sterile technique, left heart catheterization was performed via femoral access in almost all procedures; in one case brachial access was used. After crossing the aortic valve with a wire, a valvuloplasty balloon was advanced across the valve. The balloon diameter choice and performance of rapid ventricular pacing during balloon inflation were at the operator's discretion. The residual gradient was then obtained, and occasionally subsequent dilatations were performed with a larger balloon during the same procedure. An aortogram was performed immediately post BAV to assess aortic regurgitation. After 2007, more than 90% of the patients received bivalirudin instead of heparin at the operator's discretion. Further decisions regarding the procedure, such as simultaneous revascularization of obstructive coronary disease, were also on the discretion of the operator. Hemostasis was obtained either with "Preclosure" technique utilizing one or two Perclose Proglide devices (Abbott Vascular, Santa Clara, CA) or, when the former technique was not possible, with manual compression.

Study endpoints and definitions

The primary endpoint of this study was all-cause mortality at 1 year. Secondary outcomes were in-hospital adverse outcomes including cardiovascular death, myocardial infarction (MI), stroke, acute kidney injury (AKI), vascular complications, bleeding and the composite outcome MACE (major adverse cardiovascular events; all-cause mortality, MI, and stroke) and NACE (Net adverse cardiovascular events; MACE or major bleeding). Bleeding was defined using the Bleeding Academic Research Consortium (BARC) criteria[19] with major bleeding considered as BARC $\geq$3. The remaining study endpoints were defined using the Valve Academic Research Consortium criteria.[20] Chronic kidney disease was defined as estimated glomerular filtration rate <60 mL/min per 1.73 m^2 as calculated with the Modification of Diet in Renal Disease (MDRD) formula.[21] Frailty was defined as at least one of the following: moderate to severe dementia, bedbound, nursing home resident, or dependence for all activities of daily life.

Statistical analysis

Categorical variables are presented as frequencies and percentages. Continuous variables are presented as mean ± SD. Differences between continuous variables were