

**Predictors of Death in Patients with Aortic Stenosis Not Eligible To Participate In a Trial Evaluation of Transcatheter Aortic Valve Implantation**

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Background: Transcatheter aortic valve implantation (TAVI) is currently evaluated in patients (Pts) with severe aortic stenosis (AS) who are considered high risk surgical candidates. This study aimed to detect incidence, cause and correlates of mortality in Pts who were not eligible to participate in the TAVI study.

Methods: A cohort of 362 pts with severe AS were screened and did not meet the inclusion/exclusion criteria to participate in the TAVI trial. These pts assigned into two groups: I medical arm 274 (75.7%) treated medically 97 (35.4%) or by balloon aortic valvuloplasty (BAV) 177 (64.6%) and II surgical arm 88 (24.3%). Clinical follow-up was obtained by telephone or office visit

Results: The medical/BAV group had significantly higher risk compared to the surgical group, with significantly higher STS  $12.8 \pm 7.0$  vs.  $8.5 \pm 5.1$ ,  $p < 0.001$  and logistic Euroscore  $42.4 \pm 22.8$  vs.  $24.4$ ,  $p < 0.001$ . The medical/BAV group had higher NYHA functional class, incidence of renal failure, and lower ejection fraction. During median follow up of 377 days the mortality in the medical /BAV group was 102 (37.2%) and during median follow up of 386 days the mortality in the surgical group was 19 (21.5%). The cause of death in the medical/BAV group and surgical groups was cardiac in 44 (43.1%) and 9 (47.3%), non-cardiac in 37 (36.2%) and 10 (52.6%), and unknown in 21 (20.6%) and 0 patients respectively. Multivariate adjustment analysis identified renal failure, HR 5.88, NYHA HR 4.16 and aortic systolic pressure HR 0.98 as independent predictors for mortality in the medical group while renal failure HR 7.45, STS score HR 1.09 and Euroscore HR 1.45 were correlates of mortality in the in the surgical group

Conclusion: Pts with severe symptomatic AS who are not included in the TAVI trials are doing poorly with extremely high mortality rate, especially in the non-surgical group and loss of quality of life in the surgical group. Renal failure, NYHA class and low blood pressure correlates of mortality in this population