Heart Valve Society Aortic Valve Database research proposal

Proposal AmsterdamUMC – Department of Cardiothoracic Surgery
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Clinical outcomes of Aortic Valvuloplasty in patients with aortic cusp fenestration, retraction or calcification: Do specific cusp characteristics affect surgical outcomes?

Introduction

Aortic regurgitation (AR) refers to the diastolic reversed blood flow from the aorta into the left ventricle. **[1]** Both the incidence and severity of AR increases with age and is found to be more common in men than women. **[2]** In severe cases, AR is treated surgically with either aortic valvuloplasty (AVP) or complete aortic valve replacement (AVR). Nonetheless, AVP is considered the favorable treatment due to its better survival rates and lower risk of valve-related complications. **[3, 4]** From a technical point of view, different surgical approaches towards AVP are possible depending on the type of AR. **[5]**

AR is classified based on assessment of the aortic leaflets and the aortic root anatomy. Patients classified as having normal-appearing aortic cusps with functional aortic annulus dilatation or cusp prolapse appear to be excellent candidates for AVP. **[6, 7, 8]** However, patients with AR can also present themselves with a wider variety of cusp characteristics that could induce more challenging AVP procedures. Important variations among these include cusp fenestration, retraction and calcification.

In literature, patients with cusp fenestration, retraction and calcification seem to be less suitable candidates for AVP and could potentially predict failure of aortic valve repair. **[9, 10, 11]** To this date, only few researchers have investigated the correlation between specific cusp characteristics and clinical outcomes of AVP. Better insight in the clinical predictive value of these specific cusp characteristics might help surgeons in deciding upon AVP feasibility.

Aim of study

This study aims to evaluate the clinical outcomes of AVP in patients with the following aortic cusp characteristics: fenestration, calcification and retraction.

Methods

Study design:
This is a retrospective study that explores the clinical outcomes of AVP in patients with specific aortic cusp characteristics using the AVIATOR registry.

Inclusion criteria
Subjects in the AVIATOR registry;
- Aged ≥18 years
- Who have undergone elective surgical AVP or AVR
- With the following cusp characteristics:

- o Calcification
- o Retraction
- o Fenestration
- Control group without cusp fenestration, retraction or calcification
  - o Normal cusps AND/OR prolapse

Exclusion criteria

Subjects in the AVIATOR database with;

- A history of cardiac surgery
- Endocarditis
- Unicuspid valve

Primary outcomes

1. Post-operative AR
   - At the end of surgical procedure
   - At hospital discharge
   - During follow-up
2. Survival
   - 30-days survival
   - 1-year survival
   - 2-year survival
3. AV related re-intervention
4. Switch to AVR after surgical indexing (despite initial intention for repair)

Secondary outcomes

1. Crossclamping and cardiopulmonary bypass duration
2. Vascular thromboembolic events (stroke, TIA, peripheral embolism)
3. Myocardial infarction after surgery
4. Arrhythmias and PM implantation
5. Post-operative hospitalization duration
6. Ejection fraction at discharge and follow-up
7. Post-operative renal failure

Statistical methods

All analyses will be performed using SPSS for Mac, version 24.0 (SPSS Inc, Chicago, IL) and results will be considered statistically significant when $p \leq 0.05$. Descriptive results will be reported as mean ± standard deviation, where appropriate. Survival curves will be constructed using the Kaplan-Meier method and compared using Log-rank testing. Univariate and multivariate cox-regression analyses will be used to explore interfering variables, whilst taking the proportional hazard assumption into account. Correlation analyses will be used to analyze differences between continuous variables, whilst ratios will be provided for analysis of non-continuous variables. Fisher exact, Chi-square or ANOVA testing will be performed to define the significance, risk ratio (RR) and 95% confidence intervals (CI).

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Variables needed

- Age
- Gender
- Comorbidity (cardiac, pulmonary etc.)
- EuroSCORE II
- Preoperative grade of AR
- Intention to repair the valve (pre-operative + operative)
- Valve and cusp characteristics (tricuspid/bicuspid/unicuspid, retraction/fenestration/ calcification, geometric height)
- Type of AV surgery (repair/replacement)
- Cusp repair and/or annuloplasty technique
- Cross-clamp time & perfusion time
- Status (alive/death)
- AV regurgitation at discharge and follow-up (ECHO)
- AV related re-intervention (main reason & type of intervention)
- Vascular thromboembolic events (stroke, TIA, peripheral embolism)
- Myocardial infarction after surgery
- Post-operative renal failure (highest post-operative creatinine value)
- Arrhythmias and PM implantation upon discharge and at follow-up
- Ejection fraction at discharge and follow-up (ECHO)
- Post-operative hospitalization duration (date of discharge)

Time schedule

September 2021	Receival of data set
September – December 2021	Data analysis
January - February 2022	Writing first draft of manuscript

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