Heart Valve Society
Aortic Valve
Database

Heart Valve Society Aortic Valve Database research proposal

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Aortic valve repair and replacement in patients affected by infective endocarditis: short and mid-term results from the AVIATOR Registry.

Introduction

In the past decades, aortic valve (AV) repair surgery has evolved to become an important treatment alternative to AV replacement (AVR) in selected patients affected by aortic regurgitation (AR). [1] Patients with AVR have been exposed to the typical prosthesis-related complications, risks of thrombo-embolism, valve thrombosis and anticoagulation-related haemorrhage. Whereas, AV repair surgery has not only been succeeded by lowering the incidence of valve related complications, but has also been given the advantage of freedom from anticoagulation. [2]

Active infective endocarditis (AIE) is a major cause of the acute AR, which is associated with high mortality and severe complications. Complicated AIE requires surgical approach that can improve the prognosis, which is otherwise dismal. AV replacement is now standard surgical treatment in IE, although the surgical outcome seems to be less optimal in comparison with AR from other causes. [1] According to previous literature studies, mitral valve repair is a preferred technique in mitral regurgitation due to degenerative valve disease. However, uncertainty remains on more challenging clinical conditions such as mitral AIE. It has been observed that the long term results in mitral valve repair were significantly superior as compared to mitral valve replacement. [3-5]

More recently, the refining and standardization of aortic valve repair techniques has lead some surgeons to adopt this strategy in aortic valve IE cases as well. Unfortunately, there is still too little evidence for AV repair for IE, mainly limited to few case reports and one single-center series specifically addressing this topic. According to results from the Euro Heart Survey on Valvular Heart Disease, patients with tricuspid or bicuspid dystrophic aortic insufficiency

(AI) account for approximately two-thirds of the AI cases and are usually good candidates for AV repair. [6] Reports from experienced centers in aortic valve repair surgery have evidenced good mid-term and long-term results, underlying at the same time possible limitations in selected aortic valve morphotypes (BAV) and with too big replacing patch size. [1, 7]

Objective

The objective of this study is to evaluate the short and mid-term results of aortic valve repair and replacement in patients with acute and chronic aortic valve infective endocarditis. If comparison with aortic valve replacement is, due to limitations impossible, we expect to give an up-dated overview of the role of valve repair surgery in the setting of aortic IE.

Study design

We propose a retrospective cohort study with the inclusion of patients with acute or chronic ('healed') aortic valve infective endocarditis as indication for surgery. The surgical approach whether repair or replacement of the affected valve, and the short and mid-term results are going to be analyzed in terms of mortality and morbidity. We sought to pay attention to neurological outcome, recurrence of endocarditis and valve-related complications.

Study design: Multicentric, retrospective analysis of prospectively collected data.
Source of data: Patients enrolled in AVIATOR register
Inclusion criteria: patients with aortic valve endocarditis acute and chronic ('healed')
Exclusion criteria: Acute aortic dissection, previous aortic valve surgery or replacement
Primary outcome:

- Survival

Secondary outcome:

- Freedom from recurrence of endocarditis
- Freedom from reintervention
- Freedom from valve regurgitation grade >2/4.

Statistical analysis:

Continuous variables will be expressed as means ± standard deviation (SD), or median with range as appropriate. Comparison among two groups (repair vs replacement and acute vs chronic) will performed using two-sample t-tests or nonparametric Mann Whitney U-test as appropriate. Categorical variables are expressed as frequencies (%) and compared using chi-squared test or Fishers exact test. Freedom from long-term adverse events (all-cause

mortality, cardiac- and valve-related mortality, cardiac reintervention, stroke, endocarditis) will be estimated with the Kaplan-Meier method. The differences in freedom from these adverse events between two cohorts were assessed with the Log rank test. Patients who had reoperations or other adverse events will be continued to be followed up with an intention-to-treat approach.

If possible (see limitations), 1:1 propensity score (PS) matching (between replacement and repair) will be performed to adjust for potential confounders. Gender, age, body mass index (BMI), renal function, New York Heart Association (NYHA) score, chronic obstructive pulmonary disease (COPD), pulmonary hypertension, dialysis, insulin-dependent diabetes mellitus (IDDM), extracardiac arteriopathy, preoperative left ventricular ejection fraction (LVEF), heart rhythm, EuroSCORE II, urgency, concomitant surgery, and concomitant arch surgery will be the criteria used for PS calculation. Patients will be matched using the nearest neighbor method, without replacement and a caliper width of 0.15 standard deviations of the PS. The balance was evaluated using standardized mean differences (SMD). Statistical significance at p-values <0.05.

Limitations:

It might be that in the Aviator database valve replacement for infective endocarditis is under-reported. At that point the participating centers will be asked to revise their patients and upload patients who underwent aortic valve replacement for infective endocarditis. If impossible, the study will be limited to a description of the aortic valve repair group.

We believe it is not possible to correct for potential bias due to the fact that patients undergoing repair might have less aggressive disease. This because of the description of 'endocarditis' is very limited within the database: no description of extensiveness of disease, type of bacteria, antibiotic treatment etc.

Variables needed

Pre-operative

- Age
- Sex
- Aortic dissection
- AV endocarditis
- Rheumatic disease
- Height
- Weight
- Prosthesis failure
- NYHA class
- CCS class IV
- Rhythm
- Previous cardiac surgery

- Arterial hypertension
- COPD
- IDDM
- NIDDM
- Creatinine
- Dialysis
- Extra-cardiac arteriopathy
- Recent MI
- Critical state
- Pulmonary hypertension
- Connective tissue disease
- Urgency of operation
- Intention to repair the valve (based on pre-op echo findings)

Operative

- Date of surgery
- Aortic valve
- Cusp analysis
- Intention to repair the valve (based on cusp analysis)
- Left ventricular ejection fraction
- Left ventricular end-diastolic diameter
- Left ventricular end-systolic diameter
- Ascending aorta diameter
- Aortic root diameter
- Aortic annulus diameter
- Sinus Valsalva diameter
- Sinotubular junction diameter
- Grade of aortic regurgitation
- Jet eccentricity
- Transvalvular peak pressure (mmHg)
- Procedure
    - VSRR technique (Remodeling/ Reimplantation)
    - Graft size
    - Graft type
    - Annuloplasty
    - Cusp repair
    - If patch, type
    - Type of valve replacement
    - Aortic arch surgery
    - Concomitant procedures
        1. Mitral valve repair

2. Mitral valve replacement
3. Other valve repair or replacement
4. Coronary artery bypass grafting
5. Other

- Duration crossclamping
- Cardiopulmonary bypass time
- More than one clamp session

Complications and status at discharge

- Mortality
- Reintervention
  - Aortic valve related
  - Non-aortic-valve-related
- Embolism (stroke, TIA, peripheral)
- Major bleeding (non cardiac)
- PM implantation
- Myocardial infarction
- Acute kidney injury
- Endocarditis
- Other complication
- Rythm at discharge
- Antiplatelets at discharge
- Oral anticoagulation at discharge

Late outcome

- Mortality
- NYHA
- Reintervention
  - Aortic valve related
  - Non-aortic-valve-related
- Aorta complication
- AV endocarditis
- AV thrombosis
- Embolism
- Major bleeding
- PM implantation
- Other complicaiton

Echo

- Pre OP
- Intra OP, pre repair

- Intra OP, post repair
- At discharge
- At follow-up

References

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