Heart Valve Society
Aortic Valve
Database

Heart Valve Society Aortic Valve Database research proposal

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Comparison of valve sparing root replacement (VSRR) and personalised external aortic root support (PEARS) in patients with a syndromic aortic root aneurysm

Introduction

A major, life-limiting feature of syndromic aneurysmal diseases (e.g. Marfan syndrome, Loeys Dietz syndrome) is the presence of ascending aortic aneurysms, with a high risk of dissection. Cardiovascular interventions have improved the life expectancy of those patients. Three forms of surgery are now available: total root replacement (TRR) with a valve conduit, valve sparing root replacement (VSRR) and personalized external aortic root support (PEARS) with a macroporous mesh sleeve [1]. TRR with a mechanical valve is associated with thromboembolic and bleeding risks. VSSR offers freedom from anticoagulation and attendant risks of bleeding, but is mainly performed in high-volume centers. There are some concerns about reoperation for aortic regurgitation, despite the fact that a meta-analysis showed comparable reintervention rate as TRR [2]. PEARS, in which a bespoke fabric mesh is positioned around the aortic root and ascending aorta with or without cardiopulmonary bypass, conserves the aortic root anatomy. This is a more recent technique with limited follow-up and mainly advocated in patients on average at an earlier stage in the natural history [3].

Objectives

The objective of this study is to evaluate and compare the short and mid-term results of VSRR and PEARS in syndromic aortic root aneurysms.

Study design

We propose a retrospective cohort study with the inclusion of VSRR and PEARS. Patients will be included on an intention-to-treat principle. Therefore all syndromic patients with an aortic root aneurysm (less than 60mm), without dissection, and less than moderate aortic regurgitation (<2/4) will be evaluated. Propensity score (PS) matching will be performed to correct for potential confounders.

Study design: Multicenter, retrospective analysis of prospectively collected data.

Source of data: Patients enrolled in AVIATOR register and PEARS database (UZ/KUL Ethical committee approved project S63787).

Inclusion criteria: patients with syndromic aortic root aneurysm (<60mm) and no or mild AR (<2/4).

Exclusion criteria: Acute aortic dissection, endocarditis

Primary outcome:

- Survival

Secondary outcome:

- 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 the two study groups 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 the 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.

Further, 1:1 propensity score (PS) matching 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 rescue valve replacement due to unexpected replacement of the aortic valve is under-reported. We are well aware of the limitations of retrospective studies (especially using two different databases) but using a very specific study population and propensity score matching we do believe we might help our patients towards the best course of action.

Variables needed:

Pre-operative and operative:

- Center size
- Age

- Sex
- NYHA class
- Rhythm
- Previous cardiac surgery
- COPD
- IDDM
- Dialysis
- Extra-cardiac arteriopathy
- Critical state
- Creatinine level
- Pulmonary hypertension
- Body mass index
- Preoperative NYHA class
- Aortic valve morphology
- Disease etiology
- Connective tissues disorder
- Previous cardiac intervention
- 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
    - External ring annuloplasty (+ type and ring size)
    - Suture annuloplasty
    - Internal ring annuloplasty (+ type and size)
    - Leaflet repair
    - 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

Complications at discharge:

- Mortality
- Reintervention
    - Aortic valve
    - Aortic root
    - Non-aortic-valve-related cardiac
    - Reexploration for bleeding
- PM implantation
- Myocardial infarction
- Endocarditis
- Thromboembolism
- Cerebrovascular accident (CVA)
- Postoperative aortic regurgitation grade
- Postoperative transvalvular peak pressure (mmHg)
- Postoperative left ventricular ejection fraction

Late outcome

- Mortality
- Reintervention
    - Aortic valve
    - Aortic root
    - Non-aortic-valve-related cardiac
    - Reexploration for bleeding
- Myocardial infarction
- Endocarditis
- Thromboembolism
- Cerebrovascular accident (CVA)
- Postoperative aortic regurgitation grade
- Postoperative transvalvular peak pressure (mmHg)
- Postoperative left ventricular ejection fraction

TIME SCHEDULE

- June – July 2021: acquisition of the data
- July – October 2021: data analysis
- November 2021 – February 2022: writing manuscript

References

1 Treasure T, Takkenberg JJM, Golesworthy T, *et al.* Personalised external aortic root support (PEARS) in Marfan syndrome: analysis of 1-9 year outcomes by intention-to-treat in a cohort of the first 30 consecutive patients to receive a novel tissue and valve-conserving procedure, compared with the publishe. *Heart* 2014;**100**:969–75. doi:10.1136/heartjnl-2013-304913

2 Flynn CD, Tian DH, Wilson-Smith A, *et al.* Systematic review and meta-analysis of surgical outcomes in Marfan patients undergoing aortic root surgery by composite-valve graft or valve sparing root replacement. *Ann Cardiothorac Surg* 2017;**6**:570–81. doi:10.21037/acs.2017.11.06

3 Treasure T, King A, Hidalgo Lemp L, *et al.* Developing a shared decision support framework for aortic root surgery in Marfan syndrome. *Heart* 2018;**104**:480–6. doi:10.1136/heartjnl-2017-311598