Heart Valve Society
Aortic Valve
Database

Heart Valve Society Aortic Valve Database research proposal

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Comparison of bicuspidization and the Ross procedure in adults with unicuspid aortic valve – Insight from AVIATOR registry

Introduction

Unicuspid aortic valve (UAV) is a rare malformation of aortic valve often presenting in childhood or in young adulthood with aortic regurgitation or stenosis. On contrary to bicuspid aortic valve, the valve repair is rather difficult, the mid-term results are less favourable and thus this procedure is performed only in highly specialized centres. That is why most of the patients undergo valve replacement with mechanical prosthesis and are exposed to valve related complications. However, valve replacement with autograft has been recently shown favourable outcomes regarding the survival, risk of reoperation or other valve related complications.

Aortic valve repair (bicuspidization)

Surgical principle of UAV repair is bicuspidization which has been proposed by HJS [1]. Not all patients with UAV are candidates for this procedure and inclusion criteria are as follows [2]:

- The larger part of each cusp should be composed of a native cusp tissue.
- The corresponding cusp tissue should have sufficient mobility
- Native cusp geometric height of 20 mm or higher in adults
- Isolated regurgitant UAVs are generally good substrates for valve repair
- Stenotic UAVs may be suitable for this procedure when cusp tissue is not calcified or calcification is limited to the part resected for bicuspidization

The diseased part of the valve (in the region of the two residual commissures) is resected and replaced with autologous pericardium, bovine pericardium, or alternative materials, to create two identical leaflets and a new commissure. There are very few data dealing with at least mid-term results of this procedure [1, 3-5]. In the largest published cohort from highly specialized centre, the freedom from aortic valve reoperation was only 59% at 10 years [6].

This procedure is currently considered in adult patient as some form of "palliation" to postpone further treatment (valve replacement or Ross procedure).

The Ross procedure

In the last decade, a number of papers were published showing excellent results of the Ross procedure in adult patients [7-10]. These publications demonstrated excellent long-term survival, freedom from valve related complication, optimal quality of life and acceptable durability. This was proved especially in of tricuspid aortic valve stenosis. There are some concerns regarding durability of the pulmonary autograft in patients with aortic insufficiency and/or congenitally malformed aortic valve [11]. This relates to UAV also because of significant aortic annulus dilatation present in most of the patients, and its asymmetry.

Aim of study

To compare the mid-term results of the aortic valve repair (AVIATOR data) with the Ross procedure (our data) in patients with UAV.

Methods

The study will be a multi-centre retrospective observational cohort study.

Group 1 (our data – The Ross procedure in patients with UAV)

We will provide long-term data of the Ross procedure from two closely collaborating institutions from Czech Republic (Department of Cardiac Surgery, University Hospital Hradec Kralove; Institute of Cardiovascular and Transplant Surgery, Brno). Both these centres have large experience with aortic valve repair and the Ross procedure. Since 2009, the Ross procedure has been performed in 301 patients. Of those, 112 had UAV pathology. Preoperative transoesophageal echocardiography was re-evaluated in all of these patients by a cardiac surgeon experienced with bicuspidization and an echocardiographer. The intention was to identify the patients who fulfilled the criteria for aortic valve repair, as stated above (except the geometric height criterion which could not be measured by ultrasound). After this, a group of 42 patients was deemed potentially eligible for bicuspidization as well.

Group 2:

AVIATOR data – patients after bicuspidization of UAV

Inclusion criteria

UAV repair using bicuspidization technique with use of patch material (any available)

Complete follow-up of at least 1 year postoperatively

Exclusion criteria

Patients operated for active endocarditis, for aortic dissection, rheumatic disease or connective tissue disease.

Primary outcome

Freedom from reoperation

Secondary outcome

Freedom from valve regurgitation grade ≥ III

Statistical methods

Kaplan Meier analysis, Multivariate Logistic Regression, eventually Propensity Score Matching

Variables needed

Preoperative clinical data: Age, gender, height/weight, NYHA class, rhythm, previous cardiac surgery, COPD, IDDM, dialysis, poor mobility, extra-cardiac arteriopathy, recent MI critical state, creatinine value, pulmonary hypertension.

Pre operative echocardiographic: EF, LVEDD, LVESD, AV regurgitation degree,

AoV Mean gradient, annulus size, sinus size, STJ size, ascending aorta size.

Operative data: Hegar dilator size, Patch type (autologous pericardium (glutaraldehyde), fresh autologous pericardium, xeno pericardium, other patch materials), patch used for cusp belly/ commissural reconstruction/ cusp extension, annuloplasty type (external ring, internal ring, suture

annuloplasty, STJ ring, Cabrol stitches, other aortic annuloplasty), additional procedures performed, duration of first crossclamping, more than one clamp session needed.

Complications at discharge data: AV related reintervention, non-AV related reintervention (for bleeding or tamponade, mediastinitis, other cardiac, non-cardiac), vascular thromboembolic event (stroke, TIA, peripheral embolism), PM implantation, myocardial Infarction

Postoperative echocardiographic Follow-Up data: EF, LVEDD, LVESD, AV regurgitation O-IV grade, AoV Mean gradient, annulus size, sinus size, STJ size, tubular size.

Follow up data: mortality, **N**YHA I-IV, rhythm, AV related reintervention, other cardiac reoperation, aortic complication, AV endocarditis, vascular thromboembolic event (stroke, TIA, peripheral embolism), major bleeding, PM implantation, myocardial Infarction.

Time schedule

March - April 2021: acquisition of the data

May - June 2021: data analysis

July - September 2021: writing of a manuscript

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