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Valve related outcome after aortic valve and/or root repair and replacement: short term follow-up from the AVIATOR registry

Introduction

The gold standard for surgical treatment of aortic root aneurysm, with or without regurgitation, has been aortic root replacement by either a mechanical or biological valve substitute for decades. However, in the past twenty years several surgical approaches aimed at preserving the aortic valve have been introduced and progressively gained popularity, such as valve-sparing aortic root replacement and root remodelling technique. Several studies have described surgical outcome after valve-sparing aortic root replacement (VSARR) and some have posed to compare VSARR with valve/root replacement techniques, showing superiority of valve-sparing procedures regarding valve-related events.

After the Bentall procedure average bleeding and thrombo-embolic event rates of 0.64%, and 0.77% per patient-year respectively are reported, while endocarditis rates are 0.39%

Additionally, estimated annual occurrence rates of major bleeding, thrombo-embolism and endocarditis for one of the most commonly used stentless bioprostheses (Medtronic Freestyle stentless bioprosthesis) are 0.28%, 2.9% and 0.45% per patient year respectively.

In comparison, haemorrhagic and thromboembolic event rates are estimated to be 0.41% and 0.25% per patient-year, respectively, and endocarditis rate of 0.21% per patient-year is reported after valve-sparing root replacement . Similarly, in marfan patients that compared total root replacement with valve sparing root replacement, has shown a reintervention rate of 0.3%/year versus 1.3%/year while thromboembolic events rate was 0.7%/year versus 0.3%/y, respectively.

However, it is important to realize that patient outcome after surgical treatment of aortic regurgitation is determined by patient related factors, timing of surgery and procedural factors which are often interrelated. Furthermore, it is challenging to compare the differences in (valve related) outcome in these studies, because of the heterogeneity of the patient cohorts.

Moreover, the etiology of disease may be different in studies that reported on replacement of the aortic valve with more degenerative aortic stenosis, while valve-sparing root replacement is probably described in studies with dilated aortic root disease (with or without aortic regurgitation).

Both the European and the US guidelines state that when it comes to choosing any of these options, this should be a shared decision-making process that accounts for the patient's values and preferences, with full disclosure of the indications for and risks of anticoagulant therapy and the potential need for and risk of reoperation.

The observed lack of standardization in data reporting concerning outcomes after valve sparing aortic root replacement, and the sparsity of available outcome data after VSARR have led to an international prospective multicenter registry for aortic valve-sparing/repair and replacement surgical procedures, i.e. AVIATOR, which attempts to provide sufficient patient numbers with comparable operation indication, namely potentially repairable aortic valve/root, and to address key epidemiological and therapeutic issues and standardize indications for surgery as well as the place of repair versus replacement in aortic valve surgery.

Aim of study

Using these data we aim to provide an overview of (short term) valve-related outcome -i.e. mortality, reintervention, endocarditis, haemorrhagic and thromboembolic events - after valve-sparing root replacement and, moreover, to compare these outcome to "conventional" aortic root replacement with biological or mechanical prosthesis. However, the main focus will be on short term (mean of 1 year) valve-related outcome.

Methods

There will be 2 groups of patients:

1) Patient with valve-sparing aortic root replacement or valve repair

2) Patients with biological or mechanical root/valve replacement

Inclusion criteria

- All patient from group 1 and 2

Exclusion criteria

- Patients with poor LVF (may have poor outcome and higher chance of TE event a priori)
- Age > 70 years (higher risk of haemorrhagic and TE event)
- Any type of coagulopathy
- (acute) type A aortic dissection

Primary outcome

- Tromboembolic event
- Hemorrhagic event
- Endocarditis

Secondary outcome

- Early and late mortality
- Reintervention on aortic root/valve
- Perioperative outcome (especially in patients with “converted” repair to replacement)

Statistical methods

Continuous data awill be presented as means (standard deviation; range). Comparison between groups will be performed using the unpaired t-test unless data were not normally distributed (Mann-Whitney U-test in these cases). Categorical data will be presented as proportions, and comparison by chi-square test or the Fisher-exact test, where appropriate. Univariable logistic regression analysis was used to study potential variables affecting early mortality (hospital and/or 30 day mortality).The Cox proportional hazards model will be used for univariable analyses of time-related events, and survival analyzed using the Kaplan-Meier method. Combines valve-related events will be presented using the cumulative incidence function, from a competing risk analysis. Tests will be performed two-sided and a p-value of 0.05 was considered statistically significant.

Variables needed

- Age
- Sex
- Date of birth
- Comorbidity (cardiac, pulmonary etc.)
- Etiology of disease (connective tissue, idiopathic, aneurysm, regurgitation, dissection)
- LVF
- NYHA class
- Type of operation (VSARR and type, Biological prosthesis, Mechanical prosthesis)
- Conversion to replacement (intraoperative) when initially repair was planned
- Concomitant procedure
- Cross clamp time
- Perfusion time
- Early mortality
- Late mortality
- Thromboembolic event
- Haemorrhagic event
- Endocarditis

Time frame

- Data analysis: 1 month after receiving the data
- Writing the article: 1 to 2 months
- Presentation at the next AVIATOR meeting

Reference

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