Erwan Salaun and **Ismail El-Hamamsy**

One-year clinical and hemodynamic outcomes in patients treated for aortic insufficiency and ascending aorta aneurysm. The one-year flight of AVIATOR.

Introduction

The Aortic Valve Insufficiency and ascending aorta Aneurysm InternATiOnal Registry (AVIATOR) is the first longitudinal observational multicenter and international cohort study enrolling patients with ascending aorta aneurysm and/or aortic insufficiency.(1) Retrospective inclusions from 1995 to 2013 were made and prospective inclusions started from January 2013.(1) The registry contains 2 separate entities: 1. AVIATOR medical registry to evaluate the natural history of non-operated patients; and 2. AVIATOR surgical registry to evaluate outcomes after surgical treatment (repair or replacement).(1) Baseline data of AVIATOR surgical registry and encouraging early results and survival were recently reported.(2) However, in order to further support the current recommendations for early surgical therapy in aortic regurgitation (3), real-world evidence from multiple centers supporting aortic valve repair should be provided. (1) Finally, repair/sparing of the aortic valve may lead to better aortic transvalvular hemodynamic compared to implantation of a valve prosthesis. We propose to examine one-year clinical and hemodynamic outcomes after aortic valve repair/sparing surgery from the AVIATOR registry participating sites.

Aim of the study

The aim of this study is to determine the one-year outcomes of patients included in AVIATOR surgical registry.

Methods

Data will be extracted from the more recent iteration of the AVIATOR surgical registry database. For the analysis all patients between 1995 and December 2018 will be selected.

Inclusion criteria

Patients who are operated on because of AR (including congenital mixed AV disease) and/or aortic aneurysm (root or tubular ascending aorta) and eligible for the surgical database will included. Both patients who undergo AV repair including valve-sparing root replacement as well as AV replacement—including composite graft replacement—are included.

Exclusion criteria

Patients:

- younger than 18 years;
- without a registered operation date or procedural specification;
- operated for active endocarditis;
- operated for aortic dissection (type A);
- with insufficient follow-up or missing data to conclude at the occurrence of primary end-point at one-year;
- with pure aortic stenosis

Primary outcome

Composite primary endpoints:

- Clinical primary endpoint: All-cause mortality and/or Aortic (valve or ascending aorta) Reintervention at 1 year;
- Hemodynamic and anatomic primary endpoint: Increase in transaortic mean gradient ≥ 10 mmHg (associated to significant decrease in AVA and/or DVI), and/or worsening aortic regurgitation ≥ 1 grade, and/or Increase in proximal aortic (sinus or STJ or tubular aorta) >3 mm, from discharge to 1 year or severe patient prosthesis mismatch or aortic regurgitation≥ moderate at discharge.

Secondary outcome

Composite clinical secondary endpoints at 1 year:

- Cardiovascular mortality and/or Aortic (valve or ascending aorta) Reintervention

Composite Hemodynamic and anatomic secondary endpoints:

- Postoperative hemodynamic endpoints: Severe patient prosthesis mismatch or aortic regurgitation ≥ moderate at discharge.
- Hemodynamic and anatomic endpoint at 1-Year: Increase in transaortic mean gradient ≥ 10 mmHg (associated to significant decrease in AVA and/or DVI), and/or worsening aortic regurgitation ≥ 1 grade, and/or Increase in proximal aortic (sinus or STJ or tubular aorta) >3 mm, from discharge to 1 year.

Others secondary endpoints at 1 year:

- Cardiovascular deaths
- Valve or ascending aorta-related deaths
- Valve or ascending aorta-related reintervention
- Valve or ascending aorta-related reintervention for structural dysfunction
- Valve or ascending aorta-related reintervention for non-structural dysfunction
- Other cardiac intervention (PCI; other cardiac operation)
- Aorta complication (thoracic or abdominal)
- Aortic valve endocarditis (all, non-operated, operated)
- Aortic valve thrombosis (all, non-operated, operated)
- Systemic embolism (Stroke, TIA, peripheral embolism)
- Major bleeding
- Pacemaker implantation
- Change in NYHA class from discharge to 1 year
- Sinus rhythm at 1 year
- Severe patient prosthesis mismatch at discharge
- Aortic mean gradient ≥ 15 mmHg at discharge
- Aortic regurgitation ≥ moderate at discharge
- Increase in transaortic mean gradient ≥ 10 mmHg (associated to significant decrease in AVA and/or DVI) from discharge to 1 year
- Worsening central artic regurgitation ≥ 1 grade from discharge to 1 year
- Increase in proximal aortic (sinus or STJ or tubular aorta) >3 mm from discharge to 1 year

- Change in left ventricle ejection fraction from discharge to 1 year
- Change in left ventricle end-diastolic diameter from discharge to 1 year
- Change in left ventricle end-systolic diameter from discharge to 1 year

Statistical methods

1. Report rates of primary and secondary outcomes in whole AVIATOR cohort and separately in aortic valve repair / sparing and in aortic valve replacement sub-cohorts.
2. Comparison of patients with aortic valve repair versus replacement in the whole AVIATOR surgical registry.
3. Comparison between patients with aortic valve repair versus replacement in each subgroups of patients: i. Isolated AV surgery; Partial root and/or tubular aorta replacement with AV surgery; Root replacement with AV surgery.
4. Comparison using inverse probability of treatment weighting (IPTW) method between patients with aortic valve repair versus replacement in the whole AVIATOR surgical registry using inverse probability of treatment weighting (IPTW) method.
5. Comparison using IPTW method between patients with aortic valve repair versus replacement in each subgroups of patients: i. Isolated AV surgery; Partial root and/or tubular aorta replacement with AV surgery; Root replacement with AV surgery.

Variables needed

Data from Case Report Form (CRF):

- Form 1,
- Form 2,
- Form 3, and
- Form 4.

Time schedule

6 months

References

1. Lansac E, Youssefi P, de Heer F et al. Aortic Valve Surgery in Nonelderly Patients: Insights Gained From AVIATOR. Semin Thorac Cardiovasc Surg 2019;31:643-649.
2. de Heer F, Kluin J, Elkhoury G et al. AVIATOR: An open international registry to evaluate medical and surgical outcomes of aortic valve insufficiency and ascending aorta aneurysm. J Thorac Cardiovasc Surg 2019;157:2202-2211 e7.
3. Baumgartner H, Falk V, Bax JJ et al. 2017 ESC/EACTS Guidelines for the management of valvular heart disease. Eur Heart J 2017;38:2739-2791.