

EACTS 2019 Annual Meeting Lisbon, Portugal

Date: Thursday, 3 October 2019

Time: 12:45 - 14:15

Location: Room 1.05

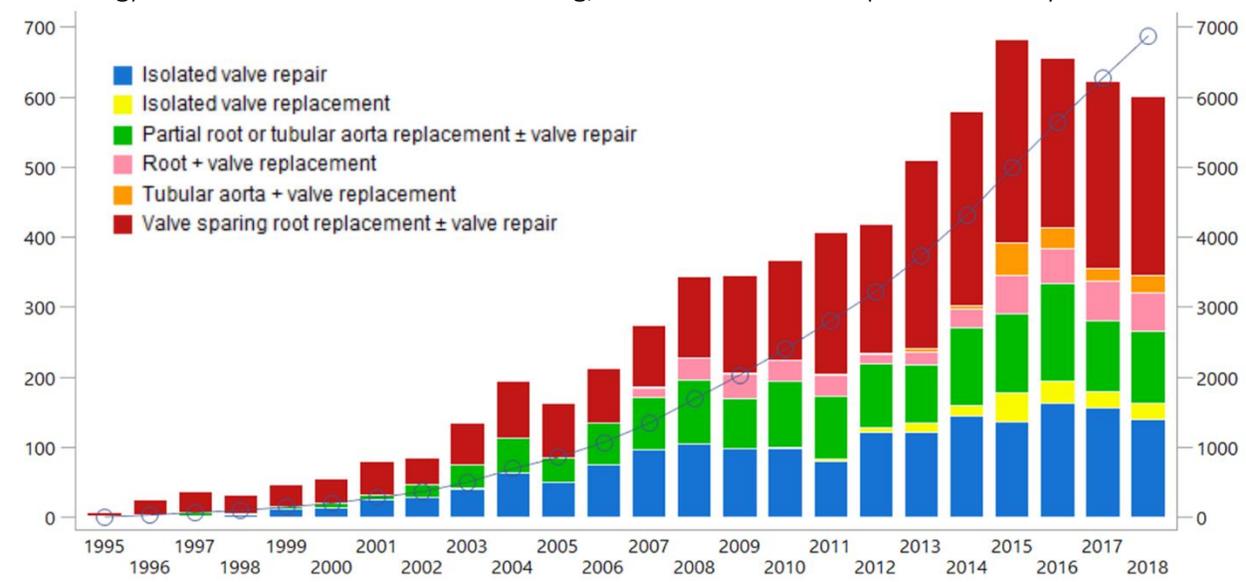
MINUTES

In attendance:

1. Update on the Database (Frederiek de Heer)

Inclusion

Frederiek updated the group on the data base noting that there was 2 large data uploads one from Brussels which has been completed and the other in progress from Homburg. Till 2019 there are now 7000 patients included in the database (this is including the new upload from Homburg). Inclusion rate has been increasing, there are about 600 patients each year.



AVIATOR data manager

An AVIATOR data manager has been hired: *Nienke Adriaens*. She will work full time from Amsterdam UMC. She will be responsible for reporting data completeness to the centers, actively encourage centers to increase data completeness and follow-up, send newsletters, and update the website. She will be the first contact for database issues.

HVS Aortic Valve Data Platform

It was decided in Sitges to enlarge the database to include aortic stenosis. Dr. Lansac added that it will be an aortic base but the people who want to only participate in AVAITOR, which includes replacement in AI patients, can continue just that. There will be an option for participating in the whole database or just AI patients.

2. Update on LEOPARD an aortic HVS database (Thierry Bourguignon and Bart Meuris)

HVS aortic base

"The HVS Aortic Valve Data Platform is aimed to improve outcomes for non-elderly patients – below 65 years – with aortic valve stenosis or regurgitation"

Patient population

AR
surgical indication

- no: AR > grade 1 (mild AR) and/or aortic diameter \geq 40 mm
- yes: operated for AR and/or aortic aneurysm

AS
Indication for AVR

- no: mean gradient <40mmHg, EOA >1cm²
- yes: surgical or transcatheter AV replacement

Aortic Valve Data Platform

AVIATOR

LEOPARD

The heart valve society

Aviator is focused on Aortic valve regurgitation and LEOPARD will focus on replacement and add AV stenosis and more details of the implanted prostheses. Leopard will also focus on safety and performance, like AVIATOR.

Test database

LEOPARD is a compliment to the AVIATOR database, a standalone database poses some complications. The goal is to have the database operational by the end of October.

Management of database – accessing will remain the same. But there is a new patient population so centers will have to make an amendment to inform the patients and their

Institutional Ethical Board that some criteria has changed (if they decide to participate in LEOPARD as well)

There is a lively discussion whether there should be an age limit for LEOPARD. From scientific point of view most people suggest not to have an age limit. Several examples are given. But as it is a voluntary data base, some raise the question how complete the data will be. In case of no age limit, all TAVI's in a center must be included. This will be huge and difficult for some. Besides, the addition of LEOPARD includes several extra variables, which will be also extra work (if a center decides to participate in LEOPARD as well).

There is credibility as you wouldn't need as many centers, but you do need centers that input their data and follow up. As participation is a voluntary basis, centers need to commit to include consecutive patients.

In discussion with industry, it was decided to set up a partnership to help to develop the database and provide them with the platform. Bart noted that we are not there yet, and that adding all patients is just not feasible. The limit should be at 65 and focus on non-elderly patients, in order for centers to be able to participate. Entering all TAVI will be impossible. It is not a database for surgery versus TAVI.

Thierry Bourguignon noted that the implant files have been implemented.

Conclusion

Enlarging the age limit, will be too risky for now. Decided is that the initial limit of patients below 65 years will be set at the start.

AVIATOR – repair (no age limit)

LEOPARD – replacement (65 age limit)

3. Update on research projects

Former proposals

discussed at HVS 2017 in Monaco, EACTS 2017 in Vienna, EACTS 2018 in Milan

1. Aortic valve repair using external aortic ring annuloplasty: a multicentric analysis of outcomes (Emmanuel Lansac, IMM). -> data is provided and analysis started.
2. The Role of Aortic Root Remodeling with Annuloplasty for the Management of Patients with Connective Tissue Disorders (Vincent Chauvette, Montreal). -> data received, results presented at AV repair summit, Paris 2018. Completed manuscript and internal reviewing is almost finished. Thereafter it will be send to the authors for review and to the scientific committee. It will be submitted to JACC.
3. Annular Stabilization in Aortic Root Remodeling – Comparison Between External Aortic Ring Annuloplasty and PTFE Suture Annuloplasty (Jochen Schäfers, Homburg). -> data received, due to data incompleteness decided not go further with the analysis.

4. Determinants of conversion to aortic valve replacement in patients selected for valve repair (Frederiek de Heer, Amsterdam). -> No news, data is not provided yet. New investigation of data completeness will be done.
5. Early and mid-term clinical and echocardiography outcomes in patients undergoing aortic valve repair / replacement for isolated aortic regurgitation from AVIATOR database (Maciej Matuszewski, Wolverhampton, UK). -> No news, data is not provided yet. New investigation of data completeness will be done.
6. Valve related outcome after aortic valve and/or root repair and valve replacement: short term follow-up on the AVIATOR registry. The coordinating investigator Bardia Arabkhani (Leiden UMC, Netherlands) and the PI is Prof. Robert Klautz (Leiden UMC and Amsterdam UMC). Data is provided and abstract is submitted for HVS.

Extraction

Communicate with Frederiek and Nienke Adriaens in order to ensure a double check extraction. Of course, if it is your own data, you can do whatever you want. But for any multi center project, it must be discussed by the AVIATOR Scientific Committee.

How to submit a research study

Send proposal to aviator@heartvalvesociety.org

1 month before EACTS or HVS

Proposals will be reviewed by the scientific committee

Presentations of proposals should be at EACTS/HVS

Discussion, approval then data extraction.

4. Publications

1. AVIATOR manuscript is accepted by JTCVS (please find enclosed by these minutes or follow the link <https://www.ncbi.nlm.nih.gov/pubmed/30553597>).
2. A position statement on the database to include issues of aortic valve surgery in nonelderly patients is also published in JTCVS (please find enclosed by these minutes or follow the link <https://www.ncbi.nlm.nih.gov/pubmed/31229691>).

5. Financial issue

Tomorrow there is a meeting with Edwards to discuss industry support in the amount of \$100,000 EUR, \$50,000 for the database and \$50,000 for a fellow to work on the database. There are other companies that have been approached and they will continue to be asked to participate in some capacity.

NIH Grant

Frederiek noted that the deadline is in 2 weeks (15 October). Jolanda, Steve Marvis and Catalyze are working on the grant. The goal is to use innovative IT-based solutions in analysis of AVIATOR data to result in an e-health tool for assistance in therapeutic decision making.

USA: Joe Bavaria, Nemish Desai

EU: Rotterdam, Amsterdam, Paris

Then finally, will need to determine how to involve the pediatric cases.

Laurent noted that he is applying for H2020 trial. It is difficult to get, but there are 2 rounds, one is at the end of this year and if chosen, need to prepare the final grant application.

HVS Annual Meeting – February 15-16, 2020 in Abu Dhabi

AVIATOR will likely met on February 14, 2020, and also on Saturday February 15th and optionally Sunday 16th lunch. Please save the date. Agenda will be address shortly.

Schedule a call of the AVIATOR Scientific Committee at least 1 month prior to the meetings at EACTS and HVS to discuss any research proposals, etc.