RESUME DU PROTOCOLE AVIATOR
« Aortic Valve Insufficiency and ascending aorta Aneurysm InternaTiOnalRegistry »

Or

«Observatoire International sur les Insuffisances de la Valve aortique et les Anévrismes de l'Aorte ascendante »

Including international cohorte CAVIAAR (Conservation Aortique Valvulaire dans les Insuffisances Aortiques dystrophiques et les Anévrismes de la Racine aortique)

Background :

Dystrophic aortic insufficiency and/or aneurysm of the ascending aorta is most commonly treated with prosthetic valve replacement, mounted on a Dacron® graft in case of associated aortic root aneurysm (Bentall procedure). The outcomes of this technique have been validated, but its long-term benefits are limited by inherent risks associated with long-term anticoagulation therapy for mechanical valves or reoperation in case of bioprostheses. Aortic valve repair may offer a response to these limitations, however multicenter and long-term prospective evaluation remains needed.

Objectives

On behalf of the HVS (Heart Valve Society), an international registry is proposed on a large series of patients with ascending aorta aneurysm (including root and/or supra coronary aorta) and/or isolated aortic insufficiency (including mixed congenital aortic valve disease). It is a prospective registry in order to ascertain a systematic uniform registration of patient characteristic, medical and surgical care.

Study population:

All patients, aged 18 years or older, with ascending aorta aneurysm (including root, ascending aorta and aortic dissection) and/or isolated aortic insufficiency (including congenital mixed aortic valve disease).

Inclusion criteria:

- Medically treated patients with ascending aorta aneurysm (including root and/or supra coronary aorta) and/or isolated aortic insufficiency (including congenital mix aortic valve disease)
- Patients undergoing surgery for ascending aorta aneurysm (including root and/or supra coronary aorta), and/or isolated aortic insufficiency (including congenital mix aortic valve disease):
    - Isolated aortic valve repair or replacement
    - Valve sparing root replacement or composite valve and graft replacement (Bentall)
    - Supra coronary graft replacement associated to valve repair or valve replacement

Exclusion criteria:

Patient's opposition to participate to AVIATOR Registry.

Methods:

This is a multicenter prospective international observatory (with the following participants in France: Institut Mutualiste Montsouris, Hôpital Européen Georges Pompidou, Hôpital de la Pitié-Salpêtrière, Clinique de Belledonne, CHU Grenoble, Clinique Saint-Gatien, Hôpital du Boccage,

Hôpital Saint-Joseph, Hôpital Charles Nicolle, Hôpital Rangueil, Hôpital Arnaud De Villeneuve, CHU Saint-Etienne, Hôpital Louis Pradel, CHU RENNES Pontchaillou, Institut Arnaud Tzank, CHRU Lille)**,** collecting clinical and imaging operative and follow-up data of patients with ascending aorta aneurysm (including root and/or supra coronary aorta), and/or isolated aortic insufficiency (including congenital mix aortic valve disease). Patients who were operated before
Patients operated before the inclusions could be included in retrospective, if they want to participate. The medical and clinical follow-up will be annual.
The registry will be separated in two parts:

- An observatory for each patient followed medically with ascending aorta aneurysm (including root and/or supra coronary aorta), and/or isolated aortic insufficiency (including congenital mix aortic valve disease
- An observatory for operated patients for ascending aorta aneurysm (including root and/or supra coronary aorta), and/or isolated aortic insufficiency (including congenital mix aortic valve disease

3 types of data collected :

1. Patients characteristics :
    - Patient demography
    - Cormobidity (Euroscore)
    - Diagnosis of valve and/or ascending aorta disease
    - Aorta phenotype
    - Pre-operative medical imaging
2. Procedural data :
    - Peri-procedural data
    - Per operative echographic data
    - Echographic data at discharge
    - complications at discharge
3. Follow up data (every year after surgery)
    - Clinical data
    - Treatments
    - Echographic data
    - Complications since last follow-up

Duration and organization of the study :
Start date: 01-08-2013
Number of patients (approximately): 2000
Duration of the study: 15 years
Duration of participation for each patient: at least 10 years

Location of the Aviator Registry: Telemedicine Technologies S.A.S, 102-104, avenue Edouard Vaillant, 92100 Boulogne-Billancourt.

Pre-requisites for Registry participation:

- Informed consent form
- Inclusion of patients in intention to treat including intraoperative conversions for valve replacement
  Annual follow up examinations, including clinical and echo data

Registry Dashboard:

- Annual report summarizing the contents of the database
- Dedicated studies with respect for different items
- Assessment of risk factors for the development failures of the valve repair
- Exchange of data and analysis for the comparative activities
- Scientific evaluation and publication

Data ownership and potential authorship

Each centre may use the data of its own patients which remain the property of this centre. On request all data from a participating centre will be erased from the central registry database. Scientific committee should be informed of any publications involving a single centre data and AVIATOR database should be acknowledged.

The Scientific Committee defines the basic scientific objectives and all scientific activities of the following year (distribution of areas of responsibility of scientific assessments, the allocation of part of the database for scientific working groups concerned).
In conjunction with each working group the Scientific Committee determines the sequence of authorship with special attention to the scientific impact of each participating colleague. All publications, including abstracts, will have a lead author(s) for and on behalf of the Registry. All participants, including data entry personnel, should be acknowledged. All publications must be submitted to the Scientific Committee for prior approval.

Ethics:

All data are collected, stored and used in strict accordance with current country regulation on data protection, ethics and written informed patient consent.

Administrative aspects and publication: Confidentiality & Handling and storage of data and documents: Each patient will be assigned a study number registered in the CleanWeb database. CleanWeb is compliant with Food and Drug Administration (Regulation 21 CRF part 11 regarding electronics registrations). Data will be analyzed using Microsoft Excel and SPSS software. Stored data regarding patients and personnel included in this study can only be accessed by the investigators or a person authorized by him. Any information from this study, if published in scientific journals or presented at scientific meetings, will not reveal patient identity. Data will be stored for a maximum of 15 years after ending the study. Collected data will be secured against unauthorized access and will be stored and secured by the department of Cardio-Thoracic Surgery.