

# CAVIAAR - Conservative Aortic Valve Surgery for Aortic Insufficiency and Aneurysms of the Aortic Root

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## General

### Identification

Detailed name Conservative Aortic Valve Surgery for Aortic Insufficiency and Aneurysms of the Aortic Root

Sign or acronym CAVIAAR

CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation Accords CNIL, CPP

### General Aspects

Medical area Cardiology

Health determinants Genetic

Keywords operative mortality, thromboembolic or haemorrhagic stroke, re-operation, placement, ascending aorta, valve endocarditis, Health episodes, valve, death

### Scientific investigator(s) (Contact)

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Organization	ASSISTANCE PUBLIQUE HOPITAUX DE PARIS

## Collaborations

Participation in projects, networks and consortia	Yes
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## Funding

Funding status	Public
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Details	ASSISTANCE PUBLIQUE HOPITAUX DE PARIS
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## Governance of the database

Sponsor(s) or organisation(s) responsible	APHP
Organisation status	Public

## Additional contact

## Main features

### Type of database

Type of database Study databases

Study databases (details) Cohort study

Database recruitment is carried out by an intermediary A selection of health institutions and services

Database recruitment is carried out as part of an interventional study Yes

Details Performed at group level (clusters)

Additional information regarding sample selection. Inclusion method: Prospective

### Database objective

Main objective

General objective: to demonstrate in a prospective open and multicentric cohort study that aortic valve sparing for patients with aortic root aneurysms and/or dystrophic aortic insufficiency is associated with a 45% increase of 3 year, 5 year, 10 year, 15 year and 20 year-survival rate without increased mortality or morbidity events when compared to mechanical valve replacement (surgical treatment reference). Morbidity and mortality is defined as the occurrence of at least one of the composite endpoint events: death, re-operation and/or re-hospitalisation for infection, bleeding event, thromboembolic event or heart failure

Secondary objectives:

- To evaluate and compare between both patient groups: the rate of immediate post-operation complications associated with a 3 year, 5 year, 10 year, 15 year and 20 year-survival rate without mortality or morbidity events when evaluated on composite criteria, the changes in quality of life during follow-up using a standardised questionnaire, validated by cardiac surgery, modified SF12 Questionnaire
- to evaluate the impact of a teaching programme for a new standardised surgical technique on morbidity and mortality from each investigating surgeon's learning curve and on long-term outcomes (programme combining theoretical and video-assisted surgical procedure training on heart anatomy, first patient surgical mentoring)
- To set predictive sonographic criteria: the feasibility of valve repair with promising

immediate and long-term postoperative results from early diagnosis of criteria composite outcome: To evaluate the sensitivity and specificity of ultrasound parameters, notably on the risk of reoperation and valvular complications - To assess the impact of clinical monitoring and imaging on operated patients with aortic root dystrophy in order to propose a post-operative care protocol that meets cost-benefit objectives

#### Inclusion criteria

- over 18 years of age; - aortic root aneurysms without aortic insufficiency or with dystrophic aortic insufficiency regardless of stage (including Marfan and bicuspid diseases), with indications for surgery conformed to American Heart Association or European Society of Cardiology guidelines or dystrophic aortic insufficiency (bicuspid or tricuspid valves) with no aortic root aneurysm with indications for surgery conformed to American Heart Association or European Society of Cardiology; - scheduled valve repair surgery with annuloplasty according to mechanical valve replacement CAVIAR study protocol; - Signed information letter and informed consent; - covered by social security insurance or access to CMU (beneficiary or assignee).

#### Population type

Age  
Adulthood (19 to 24 years)  
Adulthood (25 to 44 years)  
Adulthood (45 to 64 years)  
Elderly (65 to 79 years)  
Great age (80 years and more)

Population covered Sick population

Gender  
Male  
Woman

Geography area National

Detail of the geography area France

#### Data collection

#### Dates

Date of first collection (YYYY or MM/YYYY) 05/2007

#### Size of the database

Size of the database (number of individuals) < 500 individuals

Details of the number of individuals 77:- 46 conservations valvulaires- 19 remplacements prothétiques mécaniques- 12 exclusions

## Data

Database activity Data collection completed

Type of data collected  
Clinical data  
Declarative data  
Paraclinical data  
Biological data

Clinical data (detail) Direct physical measures  
Medical registration

Declarative data (detail) Paper self-questionnaire  
Face to face interview

Paraclinical data (detail) Imaging

Biological data (detail) Type of peri-operative and enrolment samples taken: full blood count, haemostasis, blood creatinine, INR, APTT and troponins During follow-up: INR if patient is under AVK

Presence of a biobank No

Health parameters studied Health event/morbidity  
Health event/mortality  
Quality of life/health perception

## Procedures

Data collection method Self-administered questionnaire: Input from paper questionnaire (Manual input) with double data entry  
Interview: Input from paper questionnaire (Manual input) with double data entry  
Clinical Examinations: handwritten (Manual input) with double data entry  
Biological Analysis: handwritten (Manual input) with double data entry

Participant monitoring Yes

Details on monitoring of participants Follow-up duration: 20 years

Links to administrative sources No

## Promotion and access

## Promotion

Link to the document <http://caviaar.com/de/Home/Presentations/Presentations-2014.html>

Link to the document <http://www.ncbi.nlm.nih.gov/pubmed/?term=CAVIAAR>

Description List of publications in Pubmed

## Access

Terms of data access (charter for data provision, format of data, availability delay) To be decided if data may be used by academic teams To be decided if data may be used by industrial teams

Access to aggregated data Access on specific project only

Access to individual data Access on specific project only