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

Funding

Funding status	Public
Details	ASSISTANCE PUBLIQUE HOPITAUX DE PARIS

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 multricentric 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 CAVIAAR 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 enroliment 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