CGA-TAVI Registy

Published: 29-09-2014
Last updated: 21-04-2024

The purpose of this registry is to expand upon existing data sets, to identify patient characteristics and indicators related to complications and clinical benefits for patients with symptomatic severe calcific degenerative aortic stenosis that are...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON44486

Source
ToetsingOnline

Brief title
CGA-TAVI Registy

Condition

- Other condition
- Cardiac valve disorders

Synonym
Aortic Valve Narrowing/Stenosis

Health condition

Multimorbiditeit (geriatrische aandoeningen)

Research involving
Human

Sponsors and support

Primary sponsor: IPPMed - Institut für Pharmakologie und präventive Medizin GmbH
Source(s) of monetary or material Support: IPPMed - Institut für Pharmakologie und

präventive Medizin GmbH

Intervention

Keyword: Aortic Stenosis (AS), Comprehensive Geriatric Assessment (CGA), Older persons, Transcatheter aortic valve implantation (TAVI)

Outcome measures

Primary outcome

Establish predictive value of CGA (MPI, SPPB, SilverCode) for mortality and/or

hospitalization in TAVI patients

Demonstrate CGA changes within 3 months after TAVI

Secondary outcome

Establish predictive value of CGA (MPI, SPPB, SilverCode) in TAVI patients for

all-cause hospitalization, TAVI-related hospitalization, and nursing home

admission

Develop a comprehensive score for the assessment of TAVI patient prognosis

(identify variables from the MPI, SPPB and SilverCode that account for 80% of

the predictive power of the complete set)

Study description

Background summary

Senile, calcific aortic stenosis (AS) is the most common valvular abnormality in Europe. At 75 years of age 4.6% of the population have severe AS and by 85 years old this has risen to 8%. With an increasingly elderly population, this presents a major healthcare burden. Once symptoms develop, the one-year and five-year survival rates of unoperated patients are dramatically curtailed at 32% and 60%, respectively. Symptomatic, severe AS is therefore a class I indication for a surgical aortic valve replacement (sAVR) and the efficacy of aortic valve replacement (AVR) for symptomatic AS is well established

Despite this, a large proportion of this cohort remain untreated because of advanced age and multiple comorbidities * some estimates suggest that 30*40% of elderly patients that would meet the criteria for surgery are never offered it. It is in these patients that transcatheter aortic valve implantation (TAVI) has seen its most marked growth since it was first demonstrated by Cribier et al. using a transvenous, transseptal approach. There have been encouraging results in the short and longer term registries and recently a randomized controlled trial demonstrated an absolute reduction of 20% in all-cause mortality compared with medical therapy in patients unsuitable for surgery. There are currently several devices commercially available from Edwards, Medtronic, St. Jude, Symetis and JenaValve

Comprehensive geriatric assessment (CGA) is a multidimensional and interdisciplinary diagnostic process to determine the medical, psychological, and functional capabilities of an elderly person in order to develop a coordinated and integrated plan for treatment and follow-up. CGA usually includes clinical, cognitive, functional, nutritional, and social parameters and is carried out using six standardized scales and information on medications and social support network, for a total of 63 items in eight domains. A Multidimensional Prognostic Index (MPI) aggregates the total scores of the eight domains of the CGA, expressing it as a score from 0 to 1. Three grades of MPI are defined: low risk 0.0-0.33; moderate risk 0.34-0.66; and severe risk 0.67-1.0. Higher MPI scores are significantly associated with older age, female sex, lower educational level, and higher mortality. The discrimination of the MPI is good, with a ROC area of 0.751 (95%CI 0.70-0.80) at 6 months and 0.751 (95%CI 0.71-0.80) at 1 year of follow-up. Taken together the MPI is a CGA that can be routinely carried out in elderly patients in a geriatric acute ward to predict 1-year mortality.

Frailty is a geriatric syndrome that is characterized by increased vulnerability to stressors because of diminishing physiological function. Stressors may include illness or surgery, and frailty is associated with an increased risk of co-morbidities and mortality. Currently, measures of physical disability, in particular five-meter gait speed, are emerging as the most accurate parameters for assessing frailty. This is because there is a strong association between gait speed, which can be objectively measured, and dependence on outside help in activities of daily living. Moreover, it was shown that while frailty was not related with increased periprocedural complications, it was associated with a longer post-TAVI hospital stay and with increased 1-year mortality . Thus, it has been suggested that multidimensional risk prediction (involving cognition, nutrition, mobility, activities of daily living, and frailty index) could be useful for establishing global risk scores in this population. Ultimately, the incorporation of these measures into clinical decision-making related to TAVI candidates is essential for providing the best possible care to this vulnerable group of patients. However, so far, there remains a lack of consensus on the definition of frailty, and decision-making can be difficult because frailty is not included in either the

STS or the EuroSCORE scores for calculating surgical risk.
There are two recent publications on the value of a Multidimensional Geriatric Assessment (MGA) as predictor of mortality and major adverse cardiovascular and cerebral events (MACCE) after transcatheter aortic valve implantation (TAVI). Stortecky et al. assessed the impact of an MGA on mortality and MACCE rates in 100 consecutive patients of at least 70 years undergoing TAVI. Global risk scores (Society of Thoracic Surgeons [STS] score, EuroSCORE) and MGA-based scores (cognition, nutrition, mobility, activities of daily living [ADL], and frailty index) were evaluated as predictors of all-cause mortality and MACCE 30 days and 1 year after TAVI in regression models. Bivariable analyses, including STS score or EuroSCORE suggested independent associations of MGA-based scores (e.g., OR of frailty index: 3.29, 95% CI: 1.06 to 10.15, for 1-year mortality in a model including EuroSCORE). Because the patient number was too low to allow multivariable adjusted prediction, they concluded that larger investigations are needed for the development and validation of improved risk prediction models. Schoenenberger et al. [
25] aimed to assess predictors of functional decline in the elderly. Functional decline was observed in 22 (20.8%) of 106 surviving patients. EuroSCORE (OR per 10% increase 1.18, 95% CI: 0.83-1.68, P = 0.35) and STS score (OR per 5% increase 1.64, 95% CI: 0.87-3.09, P = 0.13) weakly predicted functional decline. In contrast, the frailty index strongly predicted functional decline in univariable (OR per 1 point increase 1.57, 95% CI: 1.20-2.05, P = 0.001) and bivariable analyses (OR: 1.56, 95% CI: 1.20-2.04, P = 0.001 controlled for EuroSCORE; OR: 1.53, 95% CI: 1.17-2.02, P = 0.002 controlled for STS score). Overall predictive performance was best for the frailty index [Nagelkerke's R(2) (NR(2)) 0.135] and low for the EuroSCORE (NR(2) 0.015) and STS score (NR(2) 0.034). They concluded that the frailty index, but not established risk scores, was predictive of functional decline. Refinement of this index might help to identify patients who potentially benefit from additional geriatric interventions after TAVI.

Study objective

The purpose of this registry is to expand upon existing data sets, to identify patient characteristics and indicators related to complications and clinical benefits for patients with symptomatic severe calcific degenerative aortic stenosis that are undergoing treatment with the commercially available Edwards SAPIEN XT Transcatheter Heart Valve.

Study design

This is an international, multi-center, prospective, observational registry in 20 sites across Europe with consecutive patient enrollment. A total of 200 patients across Europe are to be enrolled in the registry during the enrollment period by contributing sites.

Study burden and risks

Execution of the CGA involves negligible risks, and the burden involves approximately five hours time-investment: three to four-hour visit to the outpatient clinic of the AMC inclusing comprehensive medical history, questionnaires and short physical examination, spread over three months. The rest of the time consists of answering telephone questions (to partner or family members, if necessary) about mortality and hospitalization at 12 months after surgery.

Contacts

Public
IPPMed - Institut für Pharmakologie und präventive Medizin GmbH

Osterstrasse 15
Cloppenburg 49661
DE
Scientific
IPPMed - Institut für Pharmakologie und präventive Medizin GmbH

Osterstrasse 15
Cloppenburg 49661
DE

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

All Patients scheduled for transcatheter valve implantation with commercially available Edwards SAPIEN XT Transcatheter Heart Valve in participating sites.
Compliance with the indications of the instructions for use (Appendices 12.1 / 12.2):
- symptomatic severe calcific aortic stenosis requiring aortic valve replacement
- estimated operative/procedural mortality risk * 15% as assessed by a risk tool such as the Logistic EUROSCORE or STS-PROM
Age of at least 80 years
Written informed consent

Exclusion criteria

Presence of contraindications as to the Instructions for Use
No possibility for a follow-up

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	03-10-2014
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO

Date:	29-09-2014
Application type:	First submission
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
ClinicalTrials.gov	NCT01991444
CCMO	NL49383.018.14