INFORMED CONSENT FORM
Version 1.0 of 12/02/2024

"Transcatheter aortic valve replacement in severe low flow low gradient aortic stenosis: the multicenter LOW-TAVR registry"

Principal Investigator:
Participating Center:

INTRODUCTION

Dear patient, the Investigating Doctor has proposed that you participate in a clinical study. In order to decide whether or not you want to take part in this study, you must receive sufficient information to understand the associated risks and benefits, so that you can provide "informed consent," i.e., a conscious decision.

Please read this document carefully and take all the time you need to decide; you may consult a family member or another trusted physician before deciding. If you have any doubts, feel free to ask the Investigating Doctor. This is a multicenter study, meaning that several hospitals and care centers are involved, in accordance with good clinical practice guidelines (ICH/GCP) and the Declaration of Helsinki for the protection of subjects participating in clinical studies.

DESCRIPTION OF THE STUDY AND PROCEDURES

This is a multicenter, retrospective and prospective observational study initiated by the Principal Investigator. The study will enroll patients with low flow low gradient aortic stenosis undergoing transcatheter aortic valve replacement (TAVR) and will collect data related to the patient's clinical history, instrumental examinations, procedural characteristics, outcomes, and extra-hospital clinical and instrumental follow-up.

PURPOSE OF THE STUDY

Although criteria for diagnosing LFLG-AS have been developed, the clinical and anatomical characteristics, procedural strategies, and prognosis of patients with LFLG-AS undergoing TAVR in large patient cohorts are still not well defined. There are many questions related to risk stratification, the accurate selection of patients for TAVR, and the prognostic assessment of this high-risk population.

The study aims to examine the clinical characteristics, incidence, risk factors, comorbidities, anatomical features, procedural factors, in-hospital complications after TAVR, gender differences, and short- and long-term prognosis of patients with LFLG-AS undergoing TAVR, as well as the specific characteristics of different forms of LFLG-AS.

POPULATION, PARTICIPATING CENTERS, AND STUDY DURATION

The study will enroll patients from approximately 10 clinical centers in Italy. The doctor will assess whether you are eligible to participate, and you will be enrolled only after signing this informed consent form.

BENEFITS AND RISKS OF PARTICIPATING IN THE STUDY

It cannot be guaranteed that you will benefit from participating in this study. However, the knowledge gained from your participation may benefit others in the future. Your participation helps expand the knowledge base regarding the best treatment for patients with your condition and may assist doctors in treating future patients.

The study will not modify your diagnostic or therapeutic pathway, which will adhere to the best known clinical practice.

CONFIDENTIALITY OF YOUR MEDICAL RECORDS

As of May 25, 2018, the European Union's General Data Protection Regulation (GDPR) has been in effect. If you decide to participate in this study, the study doctor will collect personal data directly from you and/or your medical records. "Personal data" refers to any information that identifies you or through which you can be identified, such as your name, identification numbers, health information, and other data that could lead to your identification.

Under the GDPR, all patient health information, such as weight, height, age, medical condition, treatment, and treatment dates, are also considered personal data, even if identifying the patient based on such information is difficult. If you decide to participate in this study, your medical records and personal data will be kept confidential to the extent permitted by European and local laws.

Before being used in this clinical study, your personal data will be coded using a unique patient number so that only the nurses and doctors at your hospital can identify you. When we refer to "personal data," we are only referring to these coded personal data. Your first and last name, or your identification numbers, will never be collected as part of this study.

If you decide to participate, your personal data may be used for the following reasons:

- To analyze and draw conclusions from the study and to prepare scientific presentations;
- To report adverse events to governmental health agencies;
- For the processing, monitoring, auditing, and control of the study or for inspections by competent authorities;
- To reanalyze study results in the future or to combine information about you with data obtained from other studies;

- To develop new medical products and procedures and to engage in activities related to product development.

By signing this informed consent form, you authorize the Investigating Doctor to use anonymized information obtained from this study for scientific communications and publications in medical journals. "Anonymized" means that your name and any other information that could be used to identify you will not be disclosed.

You also consent to your general practitioner being informed of your participation in this study, unless you have expressly indicated otherwise.

COSTS

You will not receive any compensation for participating in the study. You will not have to pay anything for the standard procedures to which you will be subjected.

CONTACTING STUDY STAFF

If you have any questions about this study (e.g., risks or side effects) or if you believe you have been injured as a result of the study, you may contact the Principal Investigator at the Coordinating Center: Prof. Gennaro Galasso: +39-89-965-060
Email: ggalasso@unisa.it

VOLUNTARY PARTICIPATION/WITHDRAWAL

Participation in the study is entirely voluntary. You may refuse to participate or withdraw from the study at any time without suffering any disadvantages or loss of benefits to which you are entitled. If you wish to withdraw, please contact the Investigating Doctor listed above.

The Study Doctor may discontinue your participation at any time if it is believed that continuing the study may result in significant adverse events. You will be informed and the reasons explained.

It may be helpful to inform your general practitioner about your participation in the study.

INFORMED CONSENT FOR THE PATIENT

By signing below, you certify the following:

I have understood the information regarding the Study. I have been provided with sufficient information about the procedures and devices that will be used in the Study, and all my questions have been satisfactorily answered.

I freely agree to participate in this Study and to return for follow-up visits.

I confirm that I have had enough time to consider my participation and have received my copy of the information and the consent signature page.

I understand that my participation in the Study is voluntary, and that my refusal to participate will not affect the medical care provided to me. I agree to participate and understand that I

can withdraw my consent at any time, before or during the Study, without needing to explain my reasons, and without any legal consequences, disadvantages, or loss of benefits to which I am entitled. If I decide to withdraw or need further information at any time, I will discuss this with the Investigating Physician.

I agree to adhere to the Study guidelines and to provide the Investigating Physician with information about my medical history, medications, or other clinical aspects, as well as any unexpected events that occur during this Study.

I consent to the use of my data for the purposes of the Study. Therefore, I consent to provide direct access to my medical records to representatives of regulatory authorities and other individuals and entities involved in the Study, as specified in the Information.

I consent to my family doctor being informed of my participation.

I agree to participate in the Study.

Patient (or legal representative if the patient is unable to give consent):

_____

Printed Name of the Subject

_____

Signature of the Subject Date Time

_____

Investigator I have conducted the informed consent discussion.

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Signature of the person obtaining consent Date

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