Assessment tools of the tricuspid valve using volumetric ultrasonic recordings as an alternative to traditional CT imaging approaches

A Data Management Plan created using DMPonline.be

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Grant number / URL: C3/23/026

ID: 203487

Start date: 01-10-2023

End date: 30-09-2025

Project abstract:

Characterization of the tricuspid valve (TV) is a crucial step within the planning of transcatheter TV replacement operations. While CT scans are the traditional golden standards for this process, they entail limitations that impede their use in daily practice and might even compromise patient's health. In contrast, ultrasonic echocardiography represents a logistically simpler and more risk-free alternative, but is restricted to the unavailability of analysis tools. This project aims to build on our recently proposed ultrasound segmentation solution and to automatically extract clinically relevant measures of the peri-annular region for interventional planning. Within this project, the developed methods will be embedded in a user-friendly interface and will be validated against CT recordings.

Last modified: 11-12-2023

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Research Data Summary

List and describe all datasets or research materials that you plan to generate/collect or reuse during your research project. For each dataset or data type (observational, experimental etc.), provide a short name & description (sufficient for yourself to know what data it is about), indicate whether the data are newly generated/collected or reused, digital or physical, also indicate the type of the data (the kind of content), its technical format (file extension), and an estimate of the upper limit of the volume of the data.

Dataset name / ID	Description	New or reuse	Digital or Physical data	Data Type	File format	Data volume	Physical volume
		Indicate: ***N****(ew data) or* ***E****(xisting data)*	Indicate: **D**(igital) or **P**(hysical)	Indicate: **A**udiovisual **I**mages **S**ound **N**umerical **T**extual **M**odel **SO**ftware Other (specify)		Indicate: <1GB <100GB <1TB <5TB >5TB NA	
Patient characteristics	Demographic and clinical data	N	D	T/N	xls/ReDCap	< 1 TB	NA
3D echodata	TEE recordings	N	D	I	DICOM	< 5 TB	NA
CT scan data	CT scan images	N	D	I	DICOM	< 5 TB	NA
Segmentation software	Developed software	N	D	SO	NA	< 1 TB	NA

If you reuse existing data, please specify the source, preferably by using a persistent identifier (e.g. DOI, Handle, URL etc.) per dataset or data type:

NA

Are there any ethical issues concerning the creation and/or use of the data (e.g. experiments on humans or animals, dual use)? If so, refer to specific datasets or data types when appropriate and provide the relevant ethical approval number.

- Yes, human subject data (Provide SMEC or EC approval number below)

EC approval will be applied for.

Will you process personal data? If so, please refer to specific datasets or data types when appropriate and provide the KU Leuven or UZ Leuven privacy register number (G or S number).

- Yes (Provide PRET G-number or EC S-number below)

EC approval will be applied for.

Does your work have potential for commercial valorization (e.g. tech transfer, for example spin-offs, commercial exploitation, …)? If so, please comment per dataset or data type where appropriate.

- Yes

The software developed for automatic segmentation of the tricuspid valve has potential for commercial valorization.

Do existing 3rd party agreements restrict exploitation or dissemination of the data you (re)use (e.g. Material or Data transfer agreements, Research collaboration agreements)? If so, please explain in the comment section to what data they relate and what restrictions are in place.

- No

Are there any other legal issues, such as intellectual property rights and ownership, to be managed related to the data you (re)use? If so, please explain in the comment section to what data they relate and which restrictions will be asserted.

- Yes

The software developed might contain intellectual property rights and ownership. The data used for the development of the software not.

Documentation and Metadata

Clearly describe what approach will be followed to capture the accompanying information necessary to keep data understandable and usable, for yourself and others, now and in the future (e.g. in terms of documentation levels and types required, procedures used, Electronic Lab Notebooks, README.txt files, codebook.tsv etc. where this information is recorded).

1. Patient characteristics are stored in RedCap. From RedCap data can be exported to files for review and/or statistical analysis (.txt or .xls). RedCap runs on the servers of KU Leuven.
2. 3D TEE data are anonymized and exported from the echocardiography machine to a local drive; data on the local drive are transferred to a KU Leuven computer on which the developed software is loaded; data are backed up to the KU Leuven servers.
3. CT scan data are anonymized and exported from the UZ PACS system to a KU Leuven computer on which analytic software is loaded for further analysis; data are backed up to the KU Leuven servers.
4. Experimental and developed software is stored on a KU Leuven computer; software is backed up to the KU Leuven servers.

Will a metadata standard be used to make it easier to find and reuse the data?
If so, please specify which metadata standard will be used.

If not, please specify which metadata will be created to make the data easier to find and reuse.

- Yes

DataCite.

Data Storage & Back-up during the Research Project

Where will the data be stored?

- OneDrive (KU Leuven)
- Shared network drive (J-drive)
- Large Volume Storage

Patient characteristics, numeric, and analytic data are stored at the KU Leuven OneDrive.
3D and CT images are stored on the Large Volume Storage.

The developed software is stored on the shared network drive.
Data transfer (not for storage) will be done by using an external hard drive.

How will the data be backed up?

- Standard back-up provided by KU Leuven ICTS for my storage solution

Is there currently sufficient storage & backup capacity during the project?

If no or insufficient storage or backup capacities are available, explain how this will be taken care of.

- Yes

How will you ensure that the data are securely stored and not accessed or modified by unauthorized persons?

Computers that are used are password protected.
Software the is developed, is password protected.
Networks are password protected.
Files on KU Leuven servers are password protected.

What are the expected costs for data storage and backup during the research project? How will these costs be covered?

Expected costs are 750 Euro/year and are covered by existing research funds.

Data Preservation after the end of the Research Project

Which data will be retained for 10 years (or longer, in agreement with other retention policies that are applicable) after the end of the project?

In case some data cannot be preserved, clearly state the reasons for this (e.g. legal or contractual restrictions, storage/budget issues, institutional policies...).

- All data will be preserved for 10 years according to KU Leuven RDM policy

Where will these data be archived (stored and curated for the long-term)?

- Large Volume Storage (longterm for large volumes)

What are the expected costs for data preservation during the expected retention period? How will these costs be covered?

Imaging data will be compressed and stored on one of the KU Leuven servers according to the size.
Yearly cost is estimated 250 Euro/year and will be covered by research funds.

Data Sharing and Reuse

Will the data (or part of the data) be made available for reuse after/during the project?
Please explain per dataset or data type which data will be made available.

- Yes, as open data

Clinical data will be made available.
Analytic data and statistics on 3D echo images and CT scan recordings will be made available.
Original images and videos clips will be considered as restricted data.
The developed software will not be open accessible.

If access is restricted, please specify who will be able to access the data and under what conditions.

Restricted data will be available for the research team and if requested for a review team.
Software data will be not open accessible, except for the research team or a collaborative research group.

Are there any factors that restrict or prevent the sharing of (some of) the data (e.g. as defined in an agreement with a 3rd party, legal restrictions)?

Please explain per dataset or data type where appropriate.

- No

Where will the data be made available?

If already known, please provide a repository per dataset or data type.

- KU Leuven RDR (Research Data Repository)

When will the data be made available?

- Upon publication of research results

Which data usage licenses are you going to provide?

If none, please explain why.

- MIT licence (code)
- CC-BY 4.0 (data)

For software: MIT licence
For datasets: CC-BY 4.0

Do you intend to add a persistent identifier (PID) to your dataset(s), e.g. a DOI or accession number? If already available, please provide it here.

- No

What are the expected costs for data sharing? How will these costs be covered?

N/A.

Responsibilities

Who will manage data documentation and metadata during the research project?

Researcher who generates the data is responsible for storage as long as the project is running.
Promotor (and co-promotor) are responsible for long-term storage of data.

Who will manage data storage and backup during the research project?

Will be done automatically by KU Leuven server management.

Who will manage data preservation and sharing?

Promotor of the project.

Who will update and implement this DMP?

Promotor of the project.