EchoNavigator 3D Models

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON28303

Source
Nationaal Trial Register

Health condition

Structural Heart Disease procedures

Sponsors and support

Primary sponsor: Philips Medical Systems Nederland B.V
Source(s) of monetary or material Support: Philips Medical Systems Nederland B.V

Intervention

Outcome measures

Primary outcome

The primary endpoint is a qualitative and quantitative assessment by comparing the distances between annotations genered automatically by the model with manual annotated structures and/or validating the
position of the annotations by contrast enhanced X-ray angio or the location of X-ray opaque structures (e.g. devices) on the X-ray image.

Secondary outcome

Secondary endpoints are qualitative feedback on the user interfaceto improve the investigational device, recorded anonymized raw Echo and X-ray data to tune algorithm

parameters and qualitative to improve future versions of the EchoNavigator device.

Study description

Background summary

Structural Heart Disease (SHD) procedures are routinely guided by real-time 3D transesophageal echocardiography (RT3D TEE) during cardiac catheterization to visualize the soft tissue anatomy of the heart, which cannot be defined clearly by fluoroscopy. Although this pivotal role of 3DTEE is undisputed, there are challenges in the peri-operational setting, such as discrepant communication conventions between the intervention cardiologist and echocardiographist that may cause maneuvering errors and decrease procedure efficiency. In particular, valve replacement and device defect closures require better peri-procedure imaging and image guidance. The EchoNavigator assists the interventional cardiologist and echocardiographer with image guidance during treatment of cardiovascular disease for which the procedure uses both live X-ray and live Echo guidance. EchoNavigator uses image analysis to automatically find and track the position and orientation of the head of the TEE probe in three dimensions. During fluoroscopy, the silhouette of the head of the 3D TEE probe is used to determine its position in space and the direction of the 3D TEE imaging cone. This results in a 3D TEE image that is automatically coregistered in real-time as the TEE probe is moved. EchoNavigator is particularly appreciated in procedures involving the atrial septum as is the case with interventions requiring a precise transseptal puncture or in the presence of multi-fenestrated ASD .

Features of the EchoNavigator R2.0 product are:

· Real-time fusion of live echo and live X-ray images for intuitive guidance

· Markings placed on soft-tissue, in echo, are displayed in the X-ray image

· Echo and X-ray images move in sync in the same orientation when the C-arm is repositioned

· Up to 3 perspectives of TEE imaged anatomy are simultaneously displayed in real time

· Table side interrogation of echo data, e.g. change the viewing direction

· 3D TEE field of view (cone) visible on the X-ray image for additional reference

A disadvantage of image fusion is an excess of visual information that could distract the operator during the intervention. Furthermore, manual annotation of anatomical structures in echo can be time consuming and cumbersome. The sometimes “noisy” low resolution 3D

echo images may be difficult to interpret by the less experienced operators. To facilitate 3D TEE image fusion provided by EchoNavigator, Philips Healthcare has developed a 3D model investigational device of EchoNavigator. The new functionality of the investigational device creates and overlay of 3D anatomical models and automatic annotations of cardiac structures based on 3D TEE imaging. The aim of this study is to determine the clinical value and usefulness of 3D model overlays for SHD procedures.

Study objective

Primary objective:
to determine the clinical value and impact of 3D TEE models for image guidance during SHD interventions in both a qualitative and quantitative approach.

Study design

not applicable, participation ends at the end of the procedure.

Intervention

Structural Heart Disease procedures:

-MitraClip placement on the mitral valve (TMVR), -left atrial appendage closure (LAAC),

-trans catheter aortic valve implantation (TAVI)

Contacts

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Eligibility criteria

Inclusion criteria

-Patients that require one of the following SHD interventions for which routine fluoroscopy and TEE guidance is used: MitraClip placement on the mitral valve (TMVR), left atrial appendage closure
(LAAC), trans catheter aortic valve implantation (TAVI)

- Subject is 18 years of age or older, or of legal age to give informed consent per state or national law

Exclusion criteria

-Patients who are unsuitable to accept TEE imaging during a SHD intervention (indications when not to include specified in protocol)

-Subject participates in a potentially confounding drug or device trial during the course of the study

- Subject meets an exclusion criteria according to national law (e.g. Age, pregnant woman, breast
feeding woman)

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-04-2016
Enrollment:	30
Type:	Anticipated

Ethics review

Positive opinion

Date:	08-03-2016
Application type:	First submission

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
NTR-new	NL5611
NTR-old	NTR5717
Other	Philips Medical Systems Nederland B.V : DHF248565

Study results