MicroTEE guided lead extraction.

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

Summary

ID

NL-OMON42044

Source
ToetsingOnline

Brief title
MicroTEE

Condition

- Cardiac arrhythmias

Synonym
defibrillator or pacemaker lead removal; comparing two types of oesophgeal heart echo's

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: extraction, lead adhesion, MicroTEE, Transoesophageal echocardiography, tricuspid valve

Outcome measures

Primary outcome

- Covering of the lead by the shadow of the TEE probe on fluoroscopic X-ray (in AP view). Score: no covering, slight covering (no pullback needed), significant covering (probe pull back necessary).

- Image quality assessment of intraoperative microTEE, sufficient for detection of complications such as pericardial effusion, tamponade, myocardial perforation and vascular laceration (score: good or bad. If bad: switch probe if microTEE was used).

- Time delay to first pull back (in min, from first attempt to pull the lead after insertion of a normal stilet).

- The number of TEE probe pull backs and reinsertions.

- Quantification of image quality of 3D MicroTEE reconstructions, compared to 3D TTE and conventional 3D TEE images. (Image quality score of the 3D MicroTEE reconstructions compared to 3D TTE/conventional 3D TEE : better, similar, worse)

Secondary outcome

- Location of assumed lead adhesions in preoperative 3D TTE/TEE (subclavian vein, innominate vein, superior caval vein, atrial or ventricular wall, tricuspid valve).

- Severity of pre- and post-procedural TR (score: 0: no TR, 1: mild TR, 2: moderate TR, 3: moderate to severe, 4: severe) and calculation of increase in severity of TR.

- Correlation between the surface of the tricuspid valve tissue present on the lead after extraction and (1) pre- and periprocedural TEE assumed lead adhesions, (2) attempts made to adapt the extraction technique, and (3) the increase in the severity of the TR.

Study description

Background summary

Lead extraction can be a complex procedure, associated with multiple periprocedural complications due to significant lead adhesions to the surrounding tissues. The large x-ray shadow of the conventional adult-TEE probe (S7-2t Omni or 3D X7-2t) often requires pull back of the probe in order to obtain an optimal fluoroscopic view on the leads during extraction. Such pull backs can be potentially harmful for the patient as it implicates that potential critical complications, such as tamponade, might not be observed immediately. In addition, retracting and reinserting of the probe can cause oesophageal abrasion or even perforation. Furthermore, intraoperative 3D TEE imaging may be an excellent modality to visualize adhesions, especially at fast moving structures such as the tricuspid valve (TV), potentially enabling the physician to adapt his/her extraction technique and to avoid additional valvular damage or other complications.

Study objective

The study is intended to (1) confirm the reduced x-ray shadow of the MicroTEE (S8-3t) probe, and to asses whether this results in a more delayed first pull back or a reduction in the number of pull backs or not; and (2) to evaluate the feasibility and additional value of both 2D and 3D MicroTEE (S8-3t) images in determining focal regions of lead wire adhesion, diagnosing complications, and assessing or reducing the deterioration of tricuspid valve regurgitation in adults.

Primary Objectives:
- To confirm the reduced fluoroscopic X-ray shadow of the MicroTEE (S8-3t) probe on the underlying structures/tissues when compared to the conventional 3D TEE (X7-2t) probe.
- To determine if using the MicroTEE (S8-3t) probe results in a more delayed first pull back and/or a reduced number of probe pull backs when compared to the conventional 3D TEE (X7-2t) probe.
- Reconstruction of 3D images from 2D MicroTEE data sets and quantification of

image quality of 3D reconstructions, compared to 3D TTE and 3D TEE.

Secondary Objectives:
- To evaluate the feasibility and additional value of both 2D and 3D MicroTEE (S8-3t) images in determining focal regions of lead wire adhesion, diagnosing complications and assessing deterioration of TR in adults.
- To determine if, while pulling the lead after liberating it from any vascular adhesions, TEE assessment of tricuspid valve adhesion results in an adapted extraction technique and a consequently reduced severity of the post procedural TR.
- Determining any correlation between tricuspid valve tissue present on the lead after extraction (score: small, medium, large) and (1) pre-procedural 3D TTE and peri-procedural 2D/3D TEE assumed lead adhesions, (2) attempts made to adapt the extraction technique, and (3) the increase in the severity of the TR.

Study design

A prospective, randomized, controlled pilot study.
Patients will be randomized between the conventional 3D adult-TEE (X7-2t) or the MicroTEE (S8-3t) probe.
A study period of 18 months is intended.

Study burden and risks

Patients will be receiving standard care besides the introduction of two different TEE probes prior to extraction. The additional imaging time will be less than 15 minutes. Because the MicroTEE prove (S8-3t) is smaller than the conventrional 3D TEE (X7-2t) probe, we do not expect any additional or more severe gastrointestinal complications than previously mentioned with the conventioneel probe (cfr. E9). Up to now, no complicaties have been reported regarding the MicroTEE probe. The patiënt will not be aware of any probe changes or additional imaging time as he/she will be under general anesthesia. There will be no other medical devices or medications than otherwise used during the intervention for this study.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- subjects who require extraction of (one or more) pace/sense or shock leads.
- age > 18 years

Exclusion criteria

- incapacitated adults
- contraindication for TEE: dysphagia, odynophagia, mediastinal radiation, recent upper gastrointestinal surgery, recent esophagitis, thoracic aortic aneurysm and esophageal pathology (stricture, tumour, diverticulum, varices).

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel

Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	23-07-2015
Enrollment:	40
Type:	Actual

Medical products/devices used

Generic name:	transoesophageal echocardiography (TEE)
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	09-06-2015
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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
CCMO	NL52070.078.15