Evaluation of the worlds smallest multiplane Micro Transesophageal Echocardiographic Probe in infants scheduled for Cardiac Surgery for Congenital Heart Disease

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In this study we want to evaluate the clinical and diagnostic ability of the micro TEE transducer (7.5 - 5.5 mm diameter tip, 18.5 mm length tip with a 5.2 mm diameter shaft) (Figure 1,2), the smallest multiplane TEE in the world, in pediatric...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Congenital cardiac disorders
Study type	Observational invasive

Summary

ID

NL-OMON33069

Source
ToetsingOnline

Brief title
Micro TEE probe in infants

Condition

- Congenital cardiac disorders
- Cardiac and vascular disorders congenital
- Cardiac therapeutic procedures

Synonym
Congenital heart defect

Research involving

Human

Sponsors and support

Primary sponsor: Philips Research
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Cardiac surgery, Congenital Heart Defect, Micro TEE Probe, Pediatric patients

Outcome measures

Primary outcome

clinical and diagnostic image quality.

Secondary outcome

none

Study description

Background summary

The role of transesophageal echocardiography (TEE) during surgery for congenital cardiac disease to define complex anatomical structures, functional abnormalities, and to monitor hemodynamics is well established [1,1,2]. Until 1990, intraoperative evaluation of infants and children undergoing congenital heart surgery was not feasible with TEE because probe sizes were too large [1]. It is not surprising that inability to pass the TEE probe and complications as esophageal trauma, airway compromise, and aortic compression occur predominantly in smaller children [3]. The subsequent development of miniaturized single- and bi-plane probes (from 9 mm down to 3.3 mm diameter) has generated a number of studies, which have demonstrated that TEE can be performed safely in the pediatric population [4-6]. A multiplane TEE probe for neonates and small children, which obtains images in several planes, is an obvious advantage, certainly considering the complexity of the intracardiac defects [7-9]
However, the use of a mini multiplane TEE probe (10.7 - 8.0 mm diameter tip with a 7.4 mm diameter shaft) is still limited to children above the weight of 5 kg [10], until today the smallest available multiplane TEE probe on the market.
In the Thoraxcentrum Rotterdam intaoperative TEE, with the Oldelft

Micromultiplane TEE (8.2 - 7 mm diameter tip, 24.0 mm length tip with a 5.2 mm diameter shaft) (Oldelft, Delft, The Netherlands) connected to a Philips iE 33 ultrasound system (Philips, Andover, MA. USA) is since January 2006 standard practice in all infants above a weight of 2.5 kg scheduled for cardiac surgery for congenital heart disease [11].
In this study we want to evaluate the clinical and diagnostic ability of the micro TEE transducer (7.5 - 5.5 mm diameter tip, 18.5 mm length tip with a 5.2 mm diameter shaft) (Figure 1,2), the smallest multiplane TEE in the world, in pediatric patients greater than 2.5 kg undergoing cardiac surgery to provide data on imaging quality.

Study objective

In this study we want to evaluate the clinical and diagnostic ability of the micro TEE transducer (7.5 - 5.5 mm diameter tip, 18.5 mm length tip with a 5.2 mm diameter shaft) (Figure 1,2), the smallest multiplane TEE in the world, in pediatric patients greater than 2.5 kg undergoing cardiac surgery to provide data on imaging quality.

Study design

This study is designed as a prospective, single centre study.

Intervention

TEE during operation

Study burden and risks

No risks other than the standard risks of a TEE.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

Pediatric patients with body weight > 2,5 kg
Open heart surgery
Congentital heart defect

Exclusion criteria

Pediatric patients with body weight < = 2,5 kg

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruiting

Start date (anticipated):	29-10-2009
Enrollment:	40
Type:	Actual

Medical products/devices used

Registration:	No

Ethics review

Approved WMO Date:	24-09-2009
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	NL27602.078.09