Corbotics' pivotal trial: Revolutionizing TTEs Through Robotics.

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Ethical review	Approved WMO
Status	Pending
Health condition type	Cardiac disorders, signs and symptoms NEC
Study type	Observational non invasive

Summary

ID

NL-OMON56962

Source
ToetsingOnline

Brief title
BBE-BedBasedEcho

Condition

- Cardiac disorders, signs and symptoms NEC

Synonym
heart defects, heart diseases

Research involving
Human

Sponsors and support

Primary sponsor: Corbotics B.V.
Source(s) of monetary or material Support: Corbotics B.V.

Intervention

Keyword: autonomous, cardiac, robotic, sonography

Outcome measures

Primary outcome

The primary endpoint of the study is the percentage of clinically usable autonomous TTEs compared to the percentage of clinically usable manual TTEs using the same ultrasound system, where clinically usable is defined as reaching Likert Scores 3 and higher in a 5-point Likert scale.

Autonomous and manual TTEs of each participant will together be randomly assigned to one of ten independent EACVI certified cardiologists who will review the clinical usability based on the baseline criteria and application form as presented to the judging cardiologists. This could be, for example, shortness of breath or a murmur. They will assign 1 to 5 points to each TTE, 1 point reflecting a very poor quality, and 5 points reflecting an excellent quality (a 5-points Likert scale, see also Appendix 1). If an TTE is rated 3 points or more, the TTE is qualified as *sufficient for diagnostics*.

The clinical usability of the clips is rated considering the specifications of the ultrasound system integrated in the BBE. The rating cardiologists will be introduced to the specifications of the ultrasound system prior to TTE evaluation.

Secondary outcome

The secondary endpoint of the study is the difference in Likert scale ratings

per clip between the autonomous and manual clips. The clips will be randomly and equally assigned to one of ten independent EACVI cardiologists who will review the quality. They will assign 1 to 5 points to each clip, 1 point reflecting a very poor quality, and 5 points reflecting an excellent quality (a 5-points Likert scale). If a clip is rated 3 points or more, it is qualified as *clinically usable*. This will result in a separate success rates per clip in Table 1Table 1, both for the autonomously acquired clips, as well as for the manually acquired clips.

The Likert scale ratings will be supported by a quantitative comparison using the results from measurements done on both the manual and autonomously acquired clips during phase 2. These quantitative results will be compared to highlight differences between manual and autonomous clips in the measurements resulting from the TTE, which might in a clinical setting also be used to perform diagnosis.

Study description

Background summary

There is a worldwide shortage of transthoracic echocardiography (TTE) sonographers. A recent study has quantified these shortages for the United States [3]. Furthermore, recent data from the UK suggest that 40% of hospitals failed to meet the standard of >=90% of patients presenting with acute heart failure undergoing echocardiography [4]. Lastly, the Bureau of Labour Statistics states a projected percent change in employment of medical sonographers and cardiovascular technologists and technicians from 2022 to 2032 of 10% (while the average is 3%), resulting in a need for a growth of 14,200 employees by 2032 [5].

Performing TTEs is repetitive and physically strenuous work, performed by skilled professionals. A study in 2009 has shown that 90% of Diagnostic Medical Sonographers suffer from work-related muscoskeletal disorders (an increase of 9% since the last large-scale survey in 1997) [6]. Across all demographics, shoulder pain is most common, with older and more experienced sonographers having more finger, hand, and wrist pain than other groups. Pain continues to be related to pressure applied to the transducer, abduction of the arm, and twisting of the neck and trunk. Robots are ideally suited to support jobs characterized by repetitive, safe and precise movements, and found their way to surgery settings. Their introduction to the field of echocardiography could be part of the solution to the shortage of sonographers and even increase the capacity for routine TTE examinations. Our hypothesis is that robots, in combination with artificial intelligence (AI), are capable of performing high quality, standard protocol TTEs, that produce clinically usable images without the need for a sonographer and can be deployed in clinical practice to expand TTE capacity.

Echocardiography is the main diagnostic imaging tool for the diagnosis, follow-up or ruling out of a broad spectrum of heart disease. Since the majority of patients visiting the outpatient cardiology department have an indication for a TTE, a large capacity is required (both in terms of cardiac ultrasound machines and qualified sonographers).
The WHO reports that in 2016, there was an estimated global needs-based shortage of health care workers in general, of about 17.4 million [6].
For the Netherlands, data regarding the increasing demand for echocardiograms are not available. However, in the hospitals where the current study will be performed, finding enough qualified sonographers to fulfil the demand is difficult. The American Ultrasound Technician Centre also speaks about a growing demand for cardiovascular sonographers [8].

In the near future, the demand for TTEs will increase further. One of the main indications to perform a TTE is the suspicion of heart failure, and up to 2019, there has been an increase in hospital admittance due to heart failure (hartstichting.nl). It is expected that with an ageing population, the prevalence of heart failure will increase, and concomitantly, the demand for TTEs. This was already seen in the UK, where an increase in the prevalence of cardiovascular disease and increase in prevalence of heart failure was reported, which led to an annual growth of approximately 3% in the number of echocardiograms performed [10].

The shortage of cardiac sonographers results in long waiting times and subsequent undesirable treatment delays. To overcome the shortage in cardiac sonographers and the problems related to it, a product like the BedBasedEcho (BBE) would be very useful. Less (qualified) personnel would be needed to guide the patient through a TTE.
Delays in diagnostics can result in preventable cardiovascular events, and additional capacity can reduce such delays.

Corbotics B.V. is the developer of the BBE. The goal of Corbotics B.V. is to robotically perform a TTE fully autonomously. The robot is mounted under a specially designed bed providing access to the thorax by a specific opening. Using the opening, the robot can access the anterior and anterolateral side of the thorax of the patient (lying in a prone position or on the left side). The ultrasound system and ECG system are off-the-shelf certified ME Equipment. Corbotics B.V. develops the mechanical steering of the probe and the embedded software.
Artificial intelligence (AI) is used to develop view-finding algorithms. This AI is developed to find the precise locations on the thorax for obtaining the standard echo views (parasternal long axis, parasternal short axis, apical views, and subcostal views including measurements). For now, the suprasternal view is not (yet) included, since it is impossible to perform these with the BBE in a prone position. The indication for the suprasternal view is limited to certain specific questions (i.e., severe aortic valve insufficiency and/or coarctation).

Study objective

The goal of the study is to evaluate the quality of TTEs produced autonomously by the BBE. The primary endpoint will be the percentage of TTEs obtained autonomously by the BBE that are usable in clinical practice, compared to the percentage of clinically usable TTEs obtained manually using the BBE, as reviewed by ten EACVI (European Association of Cardiovascular Imaging) certified cardiologists.

This will be the first study to examine the feasibility of cardiac echocardiography through robotics with fully independent control. Previously, studies have been performed using a remotely controlled robot for echocardiography, however, this was mainly to timely diagnose patients in remote areas at a distance, and thus with use of a remote operator [3].

Study design

Study type and setting
This is a multicentre, single blinded, non-randomized feasibility study carried out in six Dutch clinical centres; the LUMC (Leiden University Medical Centre, academic hospital), UMC Utrecht, HagaZiekenhuis, OLVG, Isala and Catharina (the latter four are cardiac referral centres in The Hague, Amsterdam, Zwolle and Eindhoven, respectively; hospitals that perform triage for a wide array of their cardiac interventions, based on ultrasound in daily practice).

During the study, at most two centres will concurrently be collecting data for the study. Two BBE*s are available for data collection, which will be placed at different centres throughout the study based on the centre*s availability of resources.

During the study, no additional space/room in the study centre is needed. The BBE can be placed in the same room as existing TTE modalities that are used for conventional TTEs outside of this study. The BBE can be used as bed for these conventional TTEs if required.

Study phases
It was decided to perform the study in two phases in order to be able to use the study results of the first phase (including participant satisfaction) to further develop the BBE and optimize its performance before commencing phase 2. This means that the study may be temporarily halted between phase 1 and phase 2 if the performance of the BBE is insufficient or if BBE performance can be further improved by the findings of phase 1.

Study duration
The total duration of the study is highly dependent on the availability of participants and sonographers. A minimum of fifteen (15) participants per week is targeted from each study centre for the duration that a BBE is installed at their location. If a centre is not able to meet this target, the sponsor might decide to relocate the BBE to another centre that is able to meet this target at that point in time. With this target, the first phase will effectively take 4 weeks (100 participants, 2 BBE*s operating in parallel at two different centres). Phase 2 will take 9 weeks (250 participants). Taking into account the time needed to install the BBE, train personnel, analyse the data and write a clinical trial report, the expected duration of the study is nine (9) months. The study will start on 01-07-2024, and the study will end on 01-04-2025.

Intervention

Each participant will first undergo a TTE performed manually by a sonographer using the manual probe of the BBE, and then a TTE performed autonomously by the BBE. The data resulting from the manual TTE will be used as a comparator to assess the quality of the data resulting from the autonomous TTE. These TTEs will be performed on the same day.

Study burden and risks

Use of the BBE, if working and used according to the intentional use, entails minimal risk for the participant. Risks are further minimized by building algorithms in the software, that for example, prevent the BBE from applying too much force on the thorax (minimizing the experience of pain or discomfort). Also, heat development from the robot arm (not the probe itself) is limited; the arm can only reach a temperature of 44.6°C. The arm is unable to come in contact with the participant by itself, but the participant might touch the arm intentionally. A temperature of 48°C is able to produce skin burns, but only after 17 minutes of contact to the source [1] [2]. The BBE stays below that temperature.

Participants may be injured climbing on and off the bed, just like in the case of a standard TTE made by a sonographer, but risks are minimized using trained personnel to guide the participant through the examination.

Contacts

Public
Corbotics B.V.

Molengraaffsingel 12
Delft 2629JD
NL
Scientific
Corbotics B.V.

Molengraaffsingel 12
Delft 2629JD
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- Listed to undergo a standard TTE
- Age >= 18 years

Exclusion criteria

• BMI>35
• patients who are unable to lie in a prone position (unable to lay in the positions required for complete TTE and BBE exams)
• patients with breast amputation or implants in the left breast
• patients with known congenital heart disease
• patients suffering from pectus excavatum/carinatum
• patients with injuries on the torso that would hinder examination
• unable to sign or understand informed consent
• patients who are already known not to be accessible to echocardiography (i.e., very poor quality TTE images)
• patients who are scheduled for a TTE with baseline criteria and application form that require clips not listed in Table 1 of the research protocol (i.e. baseline criteria where suprasternal clips are required to be clinically usable)

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-07-2024
Enrollment:	311
Type:	Anticipated

Medical products/devices used

Generic name:	BedBasedEcho
Registration:	No

Ethics review

Approved WMO Date:	21-08-2024
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl

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	NL86788.000.24