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ORIGINAL RESEARCH

Diagnosis

Safety and Usability of a Novel, Robotic Assistance System for Echocardiographic Examination

Cathy West [1], Kristyan Guppy-Coles [1], James W Armstrong [1], Matthew Johnstone,[1] Adam Scott [1] and John J Atherton [1,2]

1. Department of Cardiology, Royal Brisbane and Women's Hospital, Brisbane, Australia; 2. Faculty of Health, Medicine and Behavioural Sciences, University of Queensland, Brisbane, Australia

Abstract

Background: Transthoracic echocardiography (TTE) is essential for modern cardiac diagnostics, yet it is difficult to access in remote areas. Remotely operated robotic-assisted ultrasound may enable access to services in rural and remote locations, while also improving ergonomics for the sonographer. This study evaluated the safety, usability and patient satisfaction of a novel robotic ultrasound assistance tool (RUAT). **Methods:** This open-label, single-site, single-arm clinical trial enrolled adult participants who had recently completed a standard manual echocardiogram. A trained sonographer performed a robot-assisted TTE from a dedicated workstation in the same room as the patient. Endpoints included safety measured by adverse events, technical and clinical usability, and patient satisfaction using surveys about the participants' experience. **Results:** The trial cohort (n=30; mean age 62.9 ± 17.5 years; 70% men) all successfully completed the robot-assisted TTE and the patient satisfaction survey. There were no adverse events or adverse device effects. The functional verification checklist supporting technical usability demonstrated an average usability rate of 96.9% (95% CI [98.9–100.0]), with a 100% rate across 10 of 12 metrics. The sonographer's review of the acquired robotic images measured the clinical usability and 29 of 30 examinations met acceptable diagnostic standards (96.7%; 95% CI [88.1–100.0]). The mean participant satisfaction score was 8.3 out of 10, with 96.7% scoring ≥6. **Conclusion:** The RUAT demonstrated high technical and clinical usability, as well as high acceptance by participants. These findings indicate that robot-assisted TTE is a viable strategy to enhance remote access to TTE services.

Keywords

Robot-assisted echocardiography, collaborative robot, remote ultrasound, medical devices, sonographer ergonomics, safety and usability

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Ethics: This study was carried out in accordance with the Code of Ethics of the World Medical Association (Declaration of Helsinki). Approval was granted by the Ethics Committee of Gold Coast Hospital and Health Service Human Research Ethics Committee.

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Data availability: The data that support the findings of this study are available on request from the corresponding author. The data are not publicly available due to privacy or ethical restrictions.

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Consent: Written informed consent was obtained from all individuals included in the study. Patients provided written informed consent to publish their data and/or images.

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Correspondence: Cathy West, Department of Cardiology, Royal Brisbane and Women's Hospital, Butterfield St, Herston QLD 4006, Australia. E: Cathy.West@health.qld.gov.au

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Transthoracic echocardiography (TTE) remains a cornerstone of modern cardiac imaging as the primary modality to guide therapeutic decision-making in patients with suspected or confirmed heart failure, valvular heart disease and coronary artery disease, cardiac arrhythmia, and for rapid acute assessment within emergency and critical care pathways.[1,2] However, the application of TTE in rural and remote areas is constrained due to a lack of local specialised staff and services.[3–9]

Individuals living outside major metropolitan areas encounter barriers when they require diagnostic imaging and are often required to travel long distances for tests, which frequently delays diagnosis and treatment, leading to adverse cardiovascular outcomes.[4,6,9–12]

Collaborative robotic (COBOT) systems have emerged as a highly promising technological innovation. Advancements in robotic automation

and telecommunication hardware allow robotic manipulators to hold and position standard ultrasound transducers securely on human subjects while being directed remotely by a trained sonographer.[13] Early generation systems have demonstrated the basic technical feasibility of remote transducer positioning, although evidence of clinical implementation remains limited.[14–20]

For traditional TTE, the physical mechanics of image acquisition remain a primary challenge. When performing a traditional TTE, sonographers apply sustained static muscle loading, repetitive application of force and unsupported arm abduction, which places an immense physical burden on their bodies. As a result, up to 90% of cardiac sonographers live with pain and are prone to extensive sick leave and even premature retirement as a result of work-related musculoskeletal disorders.[21] In addition, the unmonitored, subjective and sometimes high-force pressures applied by sonographers during a manual scan commonly result in chest wall discomfort for patients.

Recent advancements in COBOT frameworks offer a pathway to address these issues by allowing the sonographer to be removed from the physical delivery of transducer pressure. In replacing the manual manipulation of the probe by the sonographer with a workstation-guided graphical user interface, COBOT systems enable the sonographer to continue to use their highly developed fine motor skills without the muscular strain. The integration of internal force-torque tracking loops in the COBOT allows for quantifiable, regulated force parameters and enables the delivery of a pre-programmed force that is appropriate for the individual patient. Clinical data evaluating the technical usability and patient tolerability of these automated force regulation loops during human examination remain sparse.

Aims

This study aimed to formally evaluate the safety profile, technical and clinical usability, and participant acceptance of a novel robotic ultrasound assistance tool (RUAT).

Methods

Equipment

The investigational device evaluated was the RUAT (RMI Oceania). The RUAT functions as a COBOT system that enables operators to steer an ultrasound transducer through remote-controlled operation of a robotic arm. The RUAT is compatible with commercially available ultrasound equipment (Aplio i900, Canon Medical Systems).

The system is divided into a remote patient system and a local sonographer workstation, which was connected via hardline Ethernet in this study. The remote patient system comprises the robotic arm, force sensor and proprietary probe holder and is monitored by specialised dual-camera tracking (a close-up probe positioning camera and a wide-angle patient camera). It also includes a screen to allow audiovisual communication between the patient and the operator, and emergency stop features including a hand-held buzzer for the patient and trolley-mounted stop button for the clinician. The sonographer's workstation has a proprietary graphical user interface and is used to manipulate the ultrasound probe, define force limits and view the images streamed from the camera.

Study Design

This study was conducted as a single-site, open-label, single-arm feasibility clinical trial in Australia at the Royal Brisbane and Women's Hospital in Brisbane, Queensland. All participants provided written informed consent prior to screening and enrolment. Each participant had previously undergone a clinically indicated traditional TTE. Two sonographers were present in the same room as the participant for each robot-assisted TTE; one scanning sonographer to operate the RUAT via the dedicated remote workstation and one observing sonographer to ensure safety and to support the participant.

Participants

The study population comprised patient volunteers aged 18 or older, who had already undergone a clinically indicated traditional TTE. Major exclusion criteria included pregnancy, acute cardiac symptoms or highly restricted mobility that may have prevented the patient from lying down on their left-hand side for the duration of the procedure.

Operators

Before the trial started, three senior cardiac sonographers completed a novel robot-assisted TTE training programme, requiring completion of virtual environment modules and practical simulation using the RUAT with an ultrasound simulator. This allowed for familiarisation with the graphical user interface, the trajectories of the robotic arm and development of the fine motor skills required to adjust the probe using the controller.

Study Endpoints and Usability Metrics

Primary endpoints focused on evaluating safety, technical usability, clinical usability and patient-reported acceptance. Safety parameters included incidence of adverse events (AEs), serious adverse events, adverse device effects (ADEs) and serious adverse device effects from consent until 72 hours post-procedure. Technical usability was evaluated using a 12-item functional verification checklist completed by the observing sonographer during or immediately after each robot-assisted TTE procedure to log mechanical, electronic and software performance. Clinical usability was determined by the performing sonographer who assessed the diagnostic quality of robot-assisted TTE images. Sufficient diagnostic quality was defined as on-axis images that were suitable to form a clinical assessment. Participant experience and device acceptance were assessed using a satisfaction survey containing four subscales scored on a 10-point Likert scale (1 indicating extreme disagreement/dissatisfaction, 10 indicating perfect agreement/satisfaction).

Statistical Analysis

The trial sample size was determined using exact single-proportion CI formatting. Assuming a robot-assisted TTE success rate of 80%, a sample size of 30 participants was calculated to provide a two-sided 95% CI width of 30.9% [61.4–92.3] using the exact Clopper-Pearson formula. Statistical analyses were performed using SAS version 9.4 or higher (SAS Institute).

Continuous demographic attributes, verification rates and satisfaction subscale parameters are expressed as either mean + standard deviation (SD) or median with interquartile range (IQR) and absolute minimum/maximum bounds. Categorical variables are reported as absolute counts and percentages. Two primary analysis sets were defined as the full analysis set (FAS), consisting of all enrolled participants meeting selection criteria, and the safety analysis set (SAS), comprising all subjects with any physical exposure to the RUAT device.

Results

Cohort Distribution and Demographic Profiles

A total of 30 eligible participants were enrolled in the study (30% women, mean age 62.9 ± 17.5 years, mean weight 86.9 ± 18.8 kg, mean height 173.3 ± 12.2 cm). All 30 participants successfully completed a robot-

Table 1: Functional Usability and Verification Checklist Outcomes (n=30)

Functional Usability Evaluation Parameter	Positive Outcome, n (%)	95% CI
Q1: Did the robotic arm and cameras activate when turned on?	29 (96.7%)	[88.1–100.0]
Q2: Did the robotic arm move into home position when instructed?	27 (90.0%)	[87.2–100.0]
Q3: Did the robotic arm move into the preset positions correctly?	29 (96.7%)	[88.1–100.0]
Q4: Could the sonographer move the robotic arm onto the patient's chest from each preset position?	30 (100.0%)	[88.4–100.0]
Q5: Could the sonographer move the robotic arm from the end of the preset movement to the correct location on the patient's chest?	30 (100.0%)	[88.4–100.0]
Q6: When in the correct location, could the robotic arm be instructed to the correct angulation so that an image could be acquired?	29 (96.7%)	[88.1–100.0]
Q7: Did the force sensor work within its pressure range?	30 (100.0%)	[88.4–100.0]
Q8: Did the probe holder hold the probe correctly for the scan?	30 (100.0%)	[88.4–100.0]
Q9: Could the robotic arm move freely, without restriction caused by the cables?	28 (93.3%)	[87.7–100.0]
Q10: Could the sonographer move the robot trolley as required during the scan?	30 (100.0%)	[88.4–100.0]
Q11: Did the patient telehealth screen provide adequate image and audio?	28 (93.3%)	[87.7–100.0]
Q12: Was the sonographer satisfied that the images could be used for reporting?	29 (96.7%)	[88.1–100.0]
Combined functional verification success rate	349 (96.9%)	[98.9–100.0]

assisted TTE and the 72-hour safety phase analysis, resulting in no early withdrawals, investigator-driven discontinuations or dropouts. The FAS and SAS were identical (n=30).

Safety and Tolerability Analysis

Safety outcomes were optimal across the study with no reported AEs or ADEs. None of the participants reported local thoracic skin injury, bruising, localised soreness or chest wall discomfort during the examination or within the 72-hour post-procedure window.

Technical and Clinical Usability Outcomes

The 12-item functional verification metrics completed across the 30 procedures demonstrated a combined positive success rate of 96.9% (95% CI [98.9–100.0]). The system achieved >95% across nine out of the 12 technical indices, as shown in *Table 1*. Technical limitations were identified through Question 2 ('Did the robotic arm move into home position when instructed?'), which recorded three negative outcomes (10.0% failure rate; 90.0% success; 95% CI [29.2–100.0]). Evaluation of clinical usability identified that robot-assisted TTE was of sufficient diagnostic quality to generate a qualitative or quantitative clinical assessment in 29 of the 30 cases, yielding a clinical adequacy success rate of 96.7% (95% CI [88.1–100.0]).

Participant Experience and Satisfaction Feedback

Subjective feedback from the participants demonstrated an overall mean score of 8.3 (SD 1.0) across all aggregated satisfaction evaluations on the 10-point scale, with individual entries ranging from a minimum score of 5.5 and a maximum of 10.0. Twenty-nine out of 30 participants (96.7%; 95% CI [88.1–100.0]) recorded an overall satisfaction score equal to or greater than 6.0; detailed analysis of the individual satisfaction subscales is provided in *Table 2*. Subscale 1 (procedural movement speed and comfort) and subscale 2 (safety perception during active transducer adjustments) achieved the highest scores, with a mean of 9.3 and 9.2, respectively. Comfort regarding physical chest wall compression (subscale 3) achieved a mean score of 8.2. Subscale 4 (Could you clearly see the video of the sonographer via the integrated screen?) was the lowest performing, recording a mean score of 6.3 and an absolute minimum score of 1.0 due to physical obstruction in the line of sight.

Discussion

The primary focus of this clinical investigation was to evaluate the safety profile, technical and clinical usability, and patient-reported acceptance of a robot-assisted TTE. The study met its predefined success criteria across all major fields. The system demonstrated a strong safety profile, with no recorded adverse events or device-related complications. This safety profile confirms that integrating automated, internal force-torque tracking loops can enable safe robot-assisted TTE on humans while appropriately managing the physical interactions required during a TTE investigation. Sonographers selected the appropriate maximum force threshold required for each acoustic window per patient, which was determined by image quality and balanced with patient comfort.

Technical performance was high, with a combined success rate of 96.9%. The robotic manipulator tracking and probe positioning performed reliably in almost all cases, while the performance of the force sensor was 100%. Similarly, the clinical usability was also very high, with sonographers judging the tele-robotic images as meeting diagnostic requirements in 96.7% (29 out of 30) of the examinations. This success rate significantly exceeds the trial's pre-specified minimum usability threshold of 80.0%. Initial home positioning failures in 10% of cases were resolvable via standard workstation resets without interrupting the overall robot-assisted TTE procedure or compromising patient safety.

In contrast to traditional TTE, a key finding in this research is the clinical and technical usefulness of the regulation of force applied by the RUAT system. Traditionally, sonographers performing manual scans will exert unmonitored and variable physical forces to optimise image acquisition. This increases when scanning technically difficult patients or navigating complex anatomical variations. During a manual scan, there is no feedback mechanism to measure force in real time, so excessive pressures can be maintained for a long time, which frequently results in chest wall discomfort, bruising to the patient and musculoskeletal pain for the sonographer.

The RUAT's automated internal force-torque tracking loop is a significant advantage. For most of the trial cohort, a conservative default of 2 kg was applied to acquire diagnostic images in 96.7% of cases. This demonstrates

Table 2: Participant Satisfaction and Experience Subscale Breakdown (n=30)

Satisfaction Experience Domain	Mean (SD)	Median (Q1, Q3)	Range
Subscale 1: comfort with the speed of automatic movements when the probe was off the chest	9.3 (1.3)	10.0 (9.0, 10.0)	4.0–10.0
Subscale 2: perception of safety during active probe positioning adjustments	9.2 (0.9)	9.0 (9.0, 10.0)	7.0–10.0
Subscale 3: comfort with mechanical pressure applied to the chest wall	8.2 (1.9)	8.0 (8.0, 10.0)	3.0–10.0
Subscale 4: visual clarity of the sonographer video via the integrated screen	6.3 (3.1)	7.0 (5.0, 9.0)	1.0–10.0
Overall aggregated satisfaction score	8.3 (1.0)	8.4 (7.8, 9.0)	5.5–10.0

that excessive and continuous force is not required when using this system. A 5 kg ceiling is a safety mechanism to prevent accidental overshoot by the operator or sudden surges in pressure when the patient moves. The ability to reduce pressure to as low as 1 kg while scanning sensitive anatomy, such as the suprasternal notch or subcostal windows, enables a nuanced control of the pressure applied by the RUAT system. This changes the model of scanning from unmonitored operator pressure to regulated and quantifiable force parameters. This precision explains the complete lack of soreness in the chest wall or skin injuries within the 72-hour safety window. This also provides a framework for future protocols for automated imaging where the force applied can be programmed.

This study demonstrates high levels of participant satisfaction with the procedure, indicating acceptance of the device, particularly in relation to the pressure applied by the probe. This will be particularly important when the technology is used for truly remote scanning where the sonographer and patient are in separate locations, benefiting patients who live in rural or remote locations and are currently required to travel long distances to undertake an echocardiogram. Lower satisfaction scores regarding the obscurity of the sonographer video (mean 6.3 ± 3.1) highlighted the practical limitation of the location of a fixed patient viewing screen by the bedside. Ensuring clear, uninterrupted audiovisual communication is important for reducing patient anxiety and maintaining high satisfaction, particularly when using these systems in fully remote and regional telecommunication networks where the sonographer is not physically in the room.

From a service access and equity perspective, robot-assisted TTE can enable diagnostic studies to be completed from centralised workstations, improving access to underserved, geographically isolated communities.[13,22–24] Democratising access to cardiac imaging is likely to expedite diagnosis and the implementation of treatment strategies for patients in remote locations, which will improve cardiovascular outcomes. The successful validation of the RUAT system has potentially significant implications in improving service provision for patients in geographically isolated areas. In demonstrating that a sonographer can safely and effectively control the RUAT system from a workstation to acquire diagnostic-quality images in 96.7% of scans, this trial establishes a scalable model for decentralised cardiac care. This can help to enable sonographers based in centralised metropolitan locations to service a network of robotic systems positioned across rural locations and deliver specialised TTE across geographically distant locations much quicker than traditional outreach services. This capability assists in addressing the disparity in access to healthcare between urban and rural communities.

It is important to note the potential ergonomic value of RUAT technology for cardiac sonographers. Traditional TTE places a significant physical burden on operators, with up to 90% of sonographers experiencing work-related musculoskeletal disorders resulting in pain, extended sick leave and potential early retirement.[25,26] This is attributed to sustained muscle loading and repetitive awkward scanning postures while performing diagnostic ultrasound in a clinical environment. The RUAT system fundamentally alters the biomechanical risk factors that have plagued sonographers for decades. The RUAT reduces the risk of occupational injury by removing prolonged abduction of the sonographer's scanning hand, traditionally required for probe manipulation and pressure, and replacing it with an interface that can be guided from a workstation. The RUAT system removes the need for the physical delivery of angulation and force, allowing probe manipulation from a workstation, enabling the sonographer to use fine motor skills to operate the system but eliminating the physical burden. This allows the sonographer to operate from a more ergonomically sound posture and reduces the physical strain associated with traditional scanning, presenting a viable strategy for reducing musculoskeletal injuries.[26] Ultimately, this system has the potential to significantly reduce the occupational injury rate among sonographers.

Considering the potential downstream effects of protecting the workforce, robot-assisted TTE may also increase capacity and prove to be an invaluable resource in the diagnosis and monitoring of conditions which require frequent check-ups to assess the effectiveness of guideline-directed medical therapies. Heart failure, in its many forms, is one of these. The use of echocardiography in the diagnosis and monitoring of heart failure is well established due to its ability to phenotype the diagnosis and longitudinally assess structural change.[27,28] Laborante et al. discuss how technological advances in heart failure monitoring have enabled early intervention strategies to potentially prevent decompensation, and robot-assisted TTE would complement this strategy.[29]

It is known that early and rapid uptitration of heart failure therapies improves patient outcomes and reduces readmission rates.[30] The provision of more accessible serial TTE monitoring to provide updated assessments on filling pressures in patients with preserved ejection fraction, assess the authenticity of reverse remodelling and monitor responsiveness to guideline-directed medical therapy is a potential area of interest in future research into robot-assisted TTE.[31–33] The provision of services closer to home builds capacity for more personalised care plans, which is particularly important for older people, those with frailty and exacerbated symptoms where timely intervention may preclude further decompensation.[34] As heart failure nurses become more common in primary care settings, robot-assisted TTE performed by a trained echocardiographer at a central location could be used to supplement clinical findings and be beneficial even in metropolitan centres.[35] Further studies are required to look at the potential applications of robot-assisted TTE and evaluate its longer term impact.

Study Limitations

There were several study limitations that require consideration when interpreting the findings. This investigation was designed as a single-site, single-arm feasibility trial with a modest sample size of 30 participants,

limiting the ability to generalise the safety and usability findings across broader, unselected clinical populations. While the performing sonographer operated the system via a dedicated workstation, they were in the same room as the patient. This arrangement allowed for direct, verbal communication and may not reflect the technical and interpersonal dynamics of a long-distance regional telecommunications network. The RUAT was directly connected to the workstation via an Ethernet cable; therefore, this study aims to test the technology in its purest form, prior to introducing the potential limitations of network induced instability and latency issues, which may be experienced in truly remote applications.

Conclusion

This clinical trial demonstrates that robot-assisted TTE using a novel RUAT is safe, highly functional and clinically useful. It is also well tolerated by patients. Robot-assisted ultrasound represents a viable technological solution to improve echocardiographic access in geographically isolated populations, while simultaneously addressing occupational safety for sonographers by reducing the physical strain of prolonged manual positioning. Future trials should evaluate the clinical deployment of the system across large, distributed regional telecommunication networks in larger, unselected clinical populations. ❑

Clinical Perspective

- Transthoracic echocardiography (TTE) facilitates diagnosis and management of patients with cardiovascular disease.
- Access to TTE is limited in geographically isolated populations.
- Robot-assisted TTE is feasible and can be safely performed by experienced sonographers and has high participant acceptance.
- Robot-assisted TTE has the potential to reduce the musculoskeletal burden on sonographers.
- Future studies should investigate its practical application in remote settings.

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