Comparison of 2 ultrasound techniques

Comparison of sagittal versus transverse ultrasound techniques in identifying the cricothyroid membrane in subjects with neck pathology

Sponsor:	Royal Surrey County Hospital Foundation Trust
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Trial Management Group

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Glossary

AE	Adverse Event
CTM	cricothyroid membrane
G-CUT	Guildford Cricothyroid membrane Ultrasound Technique
GCP	
RSCH	Royal Surrey County Hospital NHS Foundation Trust

1. Protocol Summary

TITLE:	Comparison of sagittal versus transverse ultrasound techniques in identifying the cricothyroid membrane in subjects with neck pathology
SHORT TITLE	Comparison of 2 ultrasound techniques
SPONSOR	Royal Surrey County Hospital NHS Foundation Trust
FUNDER REFERENCE	WKR0-2016-0008
CLINICAL TRIALS GOV	
DESIGN:	Prospective controlled cross-over observational study
OVERALL AIM:	Transverse ultrasound technique is quicker and accurate to identify the cricothyroid membrane
PRIMARY OBJECTIVES;	• Time taken in successful identification of the cricothyroid membrane with both ultrasound techniques
SECONDARY OBJECTIVES:	• Accuracy in identifying the cricothyroid membrane with both ultrasound techniques • Confidence in identifying the cricothyroid membrane with each ultrasound technique • Which ultrasound technique is easier to learn and perform • Usage of ultrasound to identify the cricothyroid membrane in the future
Target Accrual	
Inclusion criteria	• Subjects: 1 healthy adult (18-80 years old) with normal BMI (18.5-25) as the 'training subject' and 2 adults with neck pathology but otherwise medically stable as the 'study subjects'. • Participants: Anaesthetic trainees (ST3 and above), staff grade and consultants from the anaesthetic department, RSCH. They have to be proficient in handling the ultrasound either for vascular access or regional anaesthesia.
Exclusion criteria	• Subjects: Medically unstable, unable to tolerate lying flat or extending the neck for a prolonged period of time. • Participants: Have used the ultrasound in identifying the cricothyroid membrane within 1 year of study.
Number of sites	1
Duration of recruitment	1-2 months
Duration of patient follow-up	Not required
Definition of end of trial	Following completion of the trial period, expected 2-3 days

2. Background

The cricothyroid membrane (CTM) is an alternative access to the airway to provide oxygenation. During a 'can't intubate, can't oxygenate' situation, the front of neck airway access, also known as cricothyroidotomy is advocated [1,2]. However, it is associated with high failure rate if not performed correctly [3].

Literature review

The classical way of identifying the CTM is landmark technique by digital palpation. Studies have shown this technique is inaccurate (24-72%)[4,5,6,7,8,9,10], even more inaccurate in obese subjects (0-46%)[6,7,9,11]. Ultrasound has shown to increase the accuracy of identifying the CTM (62.5-100%)[4,8,11]. In identifying the CTM accurately with ultrasound, the complication rate of performing cricothyroidotomy could be decreased [4]. However, the ultrasound technique is associated with a longer time to perform compared to the landmark technique [4,8]. Kristensen described an ultrasound technique in identifying the CTM in the sagittal plane [12].

Rationale for study

We have recently developed the Guildford Cricothyroid membrane Ultrasound Technique (G-CUT), which is an ultrasound technique in identifying the CTM in the transverse plane. This new technique is accurate in identifying the CTM and also relatively easy and quick to perform [13,14]. Recent studies that used human subjects have only been conducted on healthy human subjects with no neck pathology apart from obesity [5,6,7,8,9,10,11]. Only a handful of case reports demonstrated the value of ultrasound in identifying the CTM in patients with neck pathology or potential difficult airway [15,16,17,18]. Hence, we propose conducting a prospective controlled cross-over observational study of comparing the time taken and accuracy to identify the CTM using the landmark technique and ultrasound techniques, both in sagittal and transverse planes in two subjects with different neck pathologies.

3. Trial Objectives

Primary

Time taken in successful identification of the CTM (within the demarcated line of the CTM).

Secondary

Accuracy of identification of CTM with each ultrasound technique.

Confidence of identification of CTM with each ultrasound technique, which ultrasound technique is easier to learn and perform and usage of ultrasound to identify the CTM in the future.

4. Trial design

Randomised study

5. Participant Population

The research will require 3 participate populations;

Training subject (n1)
Training subject will be identified from healthy volunteers

Research subjects (n2)
Research subjects will be identified from healthy volunteers

Research Participants (n45)
Anaesthetists from RSCH anaesthetic department

Both populations will be eligible if they fit the following inclusion/ exclusion criteria;

Training subjects (n1)

Inclusion

Between the ages of 18-80 years old
Able to give informed consent

Exclusion

Have neck pathology
Previous neck surgery or irradiation.
Medically unstable
Unable to tolerate lying flat or extending the neck for a prolonged period of time

Research subjects (n2)

Inclusion

Between the ages of 18-80 years old
Able to give informed consent

Has neck pathology/ previous neck surgery or irradiation

Exclusion
Medically unstable
Unable to tolerate lying flat or extending the neck for a prolonged period of time

Research Participants (n45)
Inclusion
Anaesthetic trainees (ST3 and above), NCCG and consultants proficient in handling the ultrasound either for vascular access or regional anaesthesia.
Able to give informed consent

Exclusion
Have used the ultrasound in identifying the cricothyroid membrane within the past 1 year.

6. Patient Recruitment

Subjects:

Training subject will be identified from the NHS staff population as per the inclusion/ exclusion criteria. Potential training subjects will be given a patient information sheet to review. They will be given time to consider their involvement in the project and ask questions. If happy to do so the participant will be asked to give written consent.

Study subjects will be identified from the patient population by the Head & Neck surgical team, who will highlight patients who have the appropriate neck pathology as per the eligibility criteria. The surgical team will approach all potential patients and give them a patient information sheet to review. Potential participants will be given the opportunity to ask questions.

Participants:

Anaesthetic trainees (ST3 and above), NCCG and consultants from RSCH will be invited to participate in this study. Invitation letter will be circulated across the department approximately 1 month before the study day. Participants who are interested in participating in the study will be given the participant information sheet to review. Consent will then be taken on the study day itself. Following that, a training session will be delivered to all participants before conducting the assessments on the study subjects.

7. Trial Treatment

There is no active treatment in this trial.

Subjects' neck will be scanned using the ultrasound probe to identify the CTM.

Ultrasound scanning of the neck is a non-invasive procedure.

8. Assessments

All study assessments listed below will take place for 2-3 days.

Preparation for study

Subjects will be asked to lay supine with the neck extended ready to participate in the trial.
A consultant radiologist will demarcate the boarders of the CTM: superior, inferior and lateral, with an invisible UV pen. The pen will only be visible when exposed to UV light.

A transparent dressing will be applied on the area to protect the UV markings left by the radiologist. Any markings marked by the participants on the transparent dressing will be easier to be wiped away after each attempt without smearing the initial UV marking.

The following assessments will be performed on each of the subjects to collect the baseline data;

- Height
- Weight
- Neck circumference
- Cricothyroid membrane depth, height and width would be measured by research team using ultrasound

Training session
On giving consent participants will be asked to complete a pre-study questionnaire.

All participants will be given training on the following techniques;

- Transverse ultrasound technique in identifying the cricothyroid membrane.
- Sagittal ultrasound technique in identifying the cricothyroid membrane.

The training subject will be used for participants to practice the techniques.

Investigation

Participants will be timed completing the following assessments on the study subjects. Time starts when the transducer touches the skin and stops when the area marked with the marker pen.

- Mark CTM using the landmark technique
- Mark CTM using the sagittal technique
- Mark CTM using the transverse technique

The areas marked will be analysed against the pre-demarcated line of the CTM with UV light. Only if it is within the borders without touching the line is considered accurate identification of the CTM.

All participants will be required to complete the assessments on both study subjects and will be randomly allocated a subject to start with.
On completing the study assessments participants will be asked to complete a post study questionnaire.

Follow up Assessments

No follow up required.

Adverse events

No adverse events are expected in this trial. However, in the event of an adverse event, the trial will be immediately stop and reported. Both subjects and participants will be assessed immediately and if required admit to the Emergency Department, RSCH.

9. Data Management

Data Analysis

Pre-study

Statistical analysis is required in determining the number of participants required in comparing the accuracy and time taken of both ultrasound techniques. Based on the recent study by Kristensen et al [11], with the mean (SD) 55.4 (24.1) s to locate the CTM, 40 participants are required to detect a one-third difference in time to identification of the CTM, with a power of 90% and a significance level of $p < 0.05$. 42 participants were involved in their recent study [19]. We aim to recruit 45 participants from the anaesthetic department in case of dropouts.

Post study

Data collected from the study will be analysed. The time taken and accuracy for each technique will be analysed and compared. Our main objective will be time difference in successful identification of the CTM in the sagittal and transverse planes if it will be statistically significant. Statistical analysis will be required in comparing the data collected. The time taken can be compared using paired student's t-test and the accuracy of identification of the CTM can be compared using two-tailed Fisher's exact test as used in the previous study [19].

10. Adverse Events

Any untoward medical occurrence or effect in a patient treated with the trial protocol, which does not necessarily have a causal relationship with trial treatment. An adverse event (AE) can therefore be any unfavourable symptom or disease temporarily associated with the trial treatment, whether or not it is related to the trial treatment.

Serious adverse event (SAE):
An AE that

- Results in death
- Is life-threatening
- Requires in-patient hospitalisation or prolongs existing hospitalisation
- Results in persistent or significant disability/incapacity
- Is otherwise considered to be medically significant by the investigator

Reporting procedures

11. Trial monitoring

The CI will facilitate any local monitoring by the R&D quality manager, REC review and provide access to source data as required.

Following any monitoring a report will be provided which will summarise the visit and documents, along with any findings. The CI will be responsible for ensuring that all findings are addressed appropriately.

Additional monitoring will be scheduled where there is evidence of suspicion of non-compliance with the Trial protocol.

12. Withdrawal of a patient

Patients can withdraw their consent from the trial at any stage. If a patient explicitly states that they no longer wish to take part or contribute to the trial, their decision must be respected. The patients withdrawal from the trial will be recorded in the patient's notes. All data collected up to the point of withdrawal will be included in the trial analysis. However if the patient withdraws consent for their data to be used the data will be destroyed immediately.

If a patient is considered no longer to be eligible or the responsible clinician feels it is no longer appropriate for the patient to take part then this must be documented, indicating the reason for withdrawal, in the patient notes.

13. Trial closure

End of Trial

Upon the end of trial a "declaration of end of trial" form will be submitted to REC, as required.

Archiving trial documents

Following the end of trial arrangements for non-essential confidential documents will be destroyed. Essential documents will be securely archived for 5 years.

Early closure of the trial

The trial may be stopped early upon recommendation.

14. Sponsorship

Royal Surrey County Hospital NHS Foundation Trust

15. Indemnity

Royal Surrey County Hospital Foundation Trust holds professional liability insurance to meet the potential legal liability of the sponsor and employees for harm to participants arising from the design and management of the research.

Indemnity to meet the potential legal liability of the investigators/collaborators for the harm of participants arising from the conduct of the research is provided by the NHS Indemnity scheme or through professional indemnity.

16. Publication

The results of this study will be published by peer-reviewed journals and presented at international surgical, anaesthetic and perioperative medicine conferences.

17. References

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