

Comparison of two ultrasound techniques in identifying the cricothyroid membrane in patients with abnormal necks

Submission date 23/01/2017	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 31/01/2017	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 06/10/2022	Condition category Signs and Symptoms	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

The cricothyroid membrane (CTM) is a band of tissue located at the front of the neck, which can be used to access the airways to provide oxygen. In patients who cannot be intubated (having a tube passed through their mouth into their lungs to provide breathing support), inserting the tube through the front of the neck is recommended (cricothyroidotomy). Locating the CTM is vital for placing the tube in the right place is vital, however the traditional technique of “feeling” where it is is not always accurate. Ultrasound is a technique which uses the way sound waves bounce off different types of tissue inside the body to produce a picture on a screen of the inside of the body. The use of ultrasound in locating the CTM could help improve accuracy, especially when a patient has some kind of neck deformity. The aim of this study is to find out whether using ultrasound is able to improve the rate of accuracy in locating the CTM in anesthesiology trainees.

Who can participate?

The participants of this study are trainee anesthesiologists (doctors who specialize in anesthetizing people), and the study is performed on one healthy volunteer, two patients with neck deformities.

What does the study involve?

Three patients take part in this study, one who is healthy and two who have neck abnormalities. The participants of this study (trainee anesthesiologists) perform the standard technique of using fingers to feel the neck and using two ultrasound techniques to scan the front of the neck, in order to locate the CTM. At the start of the study, the healthy patient is used to help “train” the participants in the different techniques. They then perform each technique of each patient with neck abnormalities in a random order. The time taken to perform each assessment is recorded, and at the end of the study, the accuracy of the assessments is calculated.

What are the possible benefits and risks of participating?

There are no direct benefits to the patients taking part. The anesthesiologists may benefit from receiving training of identifying the cricothyroid membrane using the ultrasound which would be

useful in their when they are working with patients with neck deformities. There are no risks involved for anyone taking part.

Where is the study run from?
Royal Surrey County Hospital NHS Trust (UK)

When is the study starting and how long is it expected to run for?
January 2016 to December 2017

Who is funding the study?
National Institute of Academic Anaesthesia (UK)

Who is the main contact?
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Contact information

Type(s)

Public

Contact name

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Additional identifiers

Protocol serial number

32960

Study information

Scientific Title

Comparison of sagittal versus transverse ultrasound techniques in identifying the cricothyroid membrane in subjects with neck pathology: A diagnostic accuracy study

Study objectives

The aim of this study is to compare both ultrasound technique and also the landmark technique the time and accuracy in identifying the cricothyroid membrane in subjects with neck pathologies.

Ethics approval required

Old ethics approval format

Ethics approval(s)

London Central Research Ethics Committee, 06/12/2016, ref: 16/LO/2068

Study design

Randomised; Both; Design type: Process of Care, Imaging, Case-controlled study

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Specialty: Anaesthesia, perioperative medicine and pain management, Primary sub-specialty: Anaesthesia, Perioperative Medicine and Pain Management; UKCRC code/ Disease: Respiratory/ Other diseases of upper respiratory tract

Interventions

Three subjects are to be recruited. The first subject is a healthy adult subject with normal BMI as the 'training' subject. The other two subjects are adults with neck pathology who is otherwise medically stable as the 'study' subjects. The 'study' subjects with neck pathology would ideally be patients who have a deviated trachea or neck mobility issues (e.g. post radiotherapy or surgery) that is known by the head & neck surgeons in RSCH. Subjects will be lying supine with the neck extended. The borders of the cricothyroid membrane will be demarcated with an invisible UV pen by a Consultant Radiologist and a transparent dressing applied over the front of the neck. The demarcated line will only be visible when exposed to UV light.

Participants (anaesthetists from the anaesthetic department) will provide written consent before completing a pre-study questionnaire. Training will be provided to all participants in identifying the cricothyroid membrane with both ultrasound techniques on the 'training' subject.

All participants will be required to complete the assessments on both 'study' subjects and will be randomized to a subject to start with. Participants (anaesthetists) perform three interventions of each subject (1 'training' subject and 2 'study' subjects).

1. Landmark technique: It is a touch technique with fingers on the subject's front of neck.
2. Transverse ultrasound technique: Using the ultrasound probe in the transverse plane (out of plane) on the subject's front of neck.
3. Sagittal ultrasound technique: Using the ultrasound probe in the sagittal plane (in plane) on the subject's front of neck.

Each anaesthetist would have assessed both 'study' subjects with all three techniques by the end of the study.

Each participant should take no longer than 30 minutes to complete the training and assessments. On completing the study, participants will be asked to complete a post-study questionnaire.

Intervention Type

Other

Primary outcome(s)

Time taken in successful identification of the cricothyroid membrane with each technique is measured in seconds throughout the performance of each technique.

Key secondary outcome(s)

1. Accuracy in identifying the cricothyroid membrane with each technique is assessed by comparing results to subject status immediately after each technique is performed (the borders of the cricothyroid membrane has been pre-marked with UV pen)
2. Confidence in identification of the cricothyroid membrane with each technique is measured using a numerical rating scale from 1-10 immediately before and after performing all 3 techniques on all 3 subjects
3. Ease of learning and performing techniques is assessed by a post-study questionnaire designed for the purpose of this study immediately after performing all 3 techniques on all 3 subjects

Completion date

31/12/2017

Eligibility

Key inclusion criteria

Training subjects (n = 1):

1. Between the ages of 18-80 years old either male or female
2. Able to give informed consent
3. Healthy volunteer

Study subjects (n = 2):

1. Between the ages of 18-80 years old either male or female
2. Able to give informed consent
3. Has neck pathology/ previous neck surgery or irradiation

Research Participants (n = 45):

1. Anaesthetic trainees (ST3 and above), NCCG and consultants proficient in handling the ultrasound either for vascular access or regional anaesthesia.
2. Between the ages of 18-80 years old either male or female
3. Able to give informed consent

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Upper age limit

80 years

Sex

All

Key exclusion criteria

Training subjects (n1):

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

Study subjects (n2):

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

Research Participants (n45):

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

Date of first enrolment

01/02/2017

Date of final enrolment

31/03/2017

Locations**Countries of recruitment**

United Kingdom

England

Study participating centre

Royal Surrey County Hospital NHS Trust

Egerton Road

Guildford

United Kingdom

GU2 7XX

Sponsor information**Organisation**

Royal Surrey County Hospital NHS Foundation Trust

ROR

<https://ror.org/050bd8661>

Funder(s)

Funder type

Research organisation

Funder Name

National Institute of Academic Anaesthesia

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication.

IPD sharing plan summary

Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Abstract results			17/08/2022	No	No
Basic results		07/01/2019	15/01/2019	No	No
HRA research summary			28/06/2023	No	No
Poster results			17/08/2022	No	No
Protocol file	version 4	12/08/2016	06/10/2022	No	No