

Ultrasound versus landmark identification of the CTM in emergency department patients undergoing computed tomography of the cervical spine: a randomised, single blind, clinical trial.

Short title: Ultrasound or landmark for identification of the CTM.

Lay description:

A small number of patients who are brought to the emergency department need a general anaesthetic. This lets us help them by keeping their airway open and breathing for them, and allows us to perform tests and provide further treatment. In very rare cases, the breathing tube cannot be passed through the mouth. This is a life threatening emergency, and an emergency procedure called a cricothyroidotomy then has to be performed. This involves making a cut in the front of the neck, directly into the windpipe, so that the breathing tube can be put directly into the airway. This is similar to a tracheostomy.

The area of the neck where the cut is made is called the cricothyroid membrane, and it is usually identified by feeling the front of the neck with a finger. Recently, it has become clear that ultrasound scans can be used to locate the membrane, but it is not clear if this is more or less accurate than locating it by feel, and whether using an ultrasound takes more or less time.

The study aims to compare two groups of patients. One group will have their cricothyroid membrane identified by touch, and the other group will have it identified by ultrasound. The participants in the study, will be randomly assigned (like tossing a coin) into one of these two groups.

Immediately before having a CT scan, a doctor will try and locate the patients' cricothyroid membrane using either touch or ultrasound (depending on the group they are randomised to), and then place a marker (a small metal cross) on the neck, which will be held in place with adhesive tape.

After the CT scan, an x-ray specialist will then be able to see whether or not the marker has been placed accurately. We will then compare whether one method is more accurate than the other, as well as how long it took to place the marker.

Except for placing a marker on your neck, the rest of the participants' care will be carried out as normal.

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1. INTRODUCTION

Cricothyroidotomy is a rarely performed rescue technique in a ‘can’t intubate, can’t oxygenate (CICO) situation¹. Traditionally, the technique is performed using digital palpation to identify the cricothyroid membrane (CTM), but with increasing use of bedside ultrasound in emergency medicine, the use of ultrasound for this purpose has been advocated by enthusiasts²⁻⁴.

Given that the procedure is time-critical and that the CTM is usually readily palpable, it is possible that ultrasound may be no more accurate than the traditional landmark technique. Ultrasound may lengthen the time taken to identify the CTM and to complete the procedure.

This study aims to compare the speed and accuracy of ultrasound versus landmark technique of identifying the CTM and to secondarily assess the confidence of providers in the method that they have undertaken.

2. BACKGROUND

Cricothyroidotomy is an important but rarely performed rescue technique in a ‘can’t intubate, can’t oxygenate’ (CICO) situation with an incidence in the emergency medicine literature as low as 0.06%¹. Traditional teaching is that the procedure is simple, whilst the decision to perform it may be less so. The technique is typically performed using digital palpation to identify the CTM, however despite the superficial and easily palpable landmarks accurate localisation may be as low as 30% even in healthy volunteers⁵. Ultrasound guidance has been demonstrated to improve the rate of first-pass puncture as well as puncture accuracy in intensive care patients requiring elective tracheostomy⁶. With the increasing utilisation of bedside ultrasound in emergency medicine, the use of ultrasound for cricothyroid localisation has been advocated by enthusiasts²⁻⁴.

Ultrasound has previously been used as the gold-standard in CTM identification when assessing the accuracy of landmark palpation^{5,7}. Several studies have

investigated the accuracy of ultrasound-guided localisation of the CTM over landmark techniques^{2,4,8-9}. To date, these have largely been performed on healthy volunteers and have yielded mixed results. Interestingly, ultrasound itself was frequently used as the gold-standard comparator in the hands of study authors or a 'local expert'^{2,10}. There are also multiple cadaveric studies comparing digital palpation and ultrasound-guided cricothyroidotomy^{3,11-14} demonstrating improved accuracy in the ultrasound group. The outcomes in these studies were measured by an additional modality, being bronchoscopy, neck dissection or computed tomography.

To the best of the authors' knowledge there has not been an investigation into the accuracy of digital palpation and ultrasound-guided CTM localisation in live patients determined by an additional imaging modality.

It remains possible that ultrasound may be no more accurate than the traditional landmark technique. It could also potentially lengthen the duration of time taken to identify the CTM, and thus complete the procedure. This study aims to compare the speed and accuracy of ultrasound versus landmark technique of identifying the CTM, and to secondarily assess the confidence of providers in the method that they have undertaken.

3. Aims of the study

3.1.- Primary aims

To assess whether ultrasound or landmark technique is more accurate for the identification of the CTM.

3.2.- Secondary aims

To assess if ultrasound identification of the CTM is quicker than a landmark technique in all patients, and in the subgroups of patients who are overweight (body mass index \geq 25).

To assess the level of confidence of the assessing doctor in each technique.

4. Objectives

4.1.Primary objectives

To measure the percentage of patients in whom the CTM is accurately identified, as determined by the placement of the centre of a radio-opaque marker within the CTM, as identified by computed tomography, by landmark and ultrasound techniques.

4.2.Secondary objectives

To determine if this percentage differs in patients with a BMI \geq 25, and if treating doctors have a higher level of confidence in one technique.

5. Hypothesis

5.1.Primary hypothesis

Ultrasound is more accurate than the landmark technique in identifying the CTM.

5.2.Secondary hypothesis

Ultrasound is no accurate than landmark technique in identifying the CTM in obese patients.

Doctors are not more confident to identify the CTM using an ultrasound, rather than landmark technique.

There is no difference in time taken to identify the CTM using either technique.

6. Study Design

This is a single blind, randomised clinical trial. As this study aims to determine if one intervention is more accurate than another, a randomised study is the method of choice.

7. Study Setting

This is a single centre study, set in the Emergency and Radiology Departments of Liverpool Hospital.

8. Study Duration

Study protocol completion: Mid May 2016
NEAF submission: End July 2016
Ethical approval: Mid-October 2016
Training of study medical staff: October 2016
Study commencement: November 1st, 2016.
Recruitment closes: End January 2017.
Data analysis complete: End February 2017.
Write-up complete: End March 2017.
Submission: April 2017.

9. Study population

9.1 Recruitment process:

Doctors trained in the study protocol will during the time that they are on duty in the department, identify patients requiring CT scan of their cervical spine.

Following screening against inclusion and exclusion criteria, patients will be approached and given written and verbal information on the study, and asked to provide informed consent.

9.2 Inclusion criteria

Aged ≥ 18 years, requiring computed tomography of the cervical spine for any indication.

9.3 Exclusion criteria

GCS < 15 , inability to provide informed consent, haemodynamic instability, anterior neck wound or cellulitis, Cervical spine injury excluded by use of clinical decision rule (ie. NEXUS or Canadian C-spine Rule).

9.4 Potential for risk, burden or benefit.

As this is a study of a non-invasive procedure, with no further intervention, there is no foreseeable additional risk to participants.

The procedure involves either palpation of the neck, or an ultrasound, both of which may involve moderate pressure over the anterior neck, but are not painful.

There is no specific benefit to participants.

10. Study outcomes

10.1 Primary outcome: The primary outcome will be met if the centre of a radio-opaque marker is within the boundaries of the CTM as identified by computed tomography.

10.2 Secondary outcomes: Time from commencement to final placement of marker, clinician confidence in the accuracy of marker placement & clinician preference for ultrasound or landmark technique (both on a 10-point numerical rating scale).

11. Study Procedures

11.1. Recruitment and consent of participants

Study staff will screen patients within the ED in order to identify potential participants during their duty periods. Patients will then be screened against an eligibility checklist, and those who are eligible for participation will be provided with written and verbal information on the study.

Patients who agree to participate will then provide written consent.

Patients who do not speak English will still be eligible to participate if they can undergo a verbal consent process utilising a trained medical interpreter.

Patients who lack capacity to consent will be excluded.

This research does not target any specific groups such as Aboriginal or Torres Strait Islander people, but their participation may occur by chance.

11.2. Withdrawal of consent.

Patients may withdraw from the study at any time, and if they choose to do so, a withdrawal from consent form will be signed.

Patients who decide not to proceed with the study, will have any data collected to the point of withdrawal included, unless they specifically request otherwise, and this will be explained on the patient information sheet. This is in order to maintain a transparent consort diagram of all screened patients.

11.3. Randomisation.

Randomisation will occur following the provision of informed consent, using an online randomisation tool, sealedenvelope.com. Patients will be randomised in blocks of four.

It will not be possible to blind either the doctor who is carrying out the identification of the CTM, or the patient. However, the radiologist who assesses placement of the marker will be blinded to group allocation.

11.4. Measurement tools used

11.4.1

Two radiologists will independently identify the CTM, and determine whether the centre of the radiopaque marker lies with its boundaries. CT imaging of the cervical spine is performed using either Siemens

Definition AS 128 slice or Siemens Definition 64 slice CT scanners.

Helical acquisition acquired at 0.6mm and reconstructed to 1mm (soft tissue window) and 0.75mm (bone window setting).

Identification of the CTM is made using AquariusNet V.4.4.11.82 which will allow for multi-planar reconstructions of the soft tissue data set to be performed by the reading radiologists.

The CTM is identified as the mid distance between the inferior margin of the thyroid cartilage and superior margin of the cricoid cartilage in the median plane.

The position of the marker is extrapolated directly posteriorly to intersect the CTM.

11.4.2

If both radiologists independently agree that the centre of the marker overlies the CTM, the primary outcome will have been met.

11.4.3

If there is disagreement between radiologists with regard to the primary outcome, a third radiologist will independently measure the distance, and a majority verdict will prevail.

11.4.4

If both radiologists find the centre of the marker is not over the CTM, the primary outcome will not have been met.

11.4.5

The time taken to mark the CTM will be measured in seconds, using the stopwatch facility on a smartphone.

11.4.6

The level of certainty that the doctor feels that they identified the centre of the CTM will be measured on a 10-point numerical rating scale anchored on 0 (not at all confident) and 10 (completely confident).

11.4.7

The patient will supply data on patient height and weight.

11.5

Study involvement by participants

Following randomisation, whilst on the CT table immediately prior to their scan, patients will have either ultrasound or landmark identification of their CTM, and then have a radiopaque marker applied to their anterior neck in the position that the participating

doctor feels equates to the centre of the CTM. The marker will be held in place using micropore tape.

They will then undergo computed tomography as per normal department practice, after which the marker will be removed, and the remainder of their care will continue as normal, with no further participation in the study.

As this study involves a single discrete intervention, no further follow up of patients will occur, beyond routine care. If their CT scan identifies any abnormality, their treating doctor will arrange continued care.

11.6 Data management and storage.

Data will be collected on a paper case-report form (CRF), which will then be stored in a file in the principle investigators (locked) office.

De-identified data will then be transferred to an electronic database (password protected).

Following completion of the study, data will be maintained for a period of 15 years in a locked filing cabinet and on the hard drive of a password protected computer. After 15 years, the data will be destroyed.

11.7 Safety considerations/patient safety.

All patients will be undergoing computed tomography of their cervical spine, but the study will not expose patients to any additional radiation or other risks.

If any safety risk is identified to any participant, the treating doctor, who will also arrange any necessary follow up care, will provide immediate care.

It is not anticipated that participation in the study would have any psychological effects on patients, but if this eventuality arose, the principal investigator undertakes to arrange onward referral for assessment and/or treatment.

7. Data monitoring

As this is a small study, no formal data safety and monitoring board is required. If there is any adverse event, the principle investigator will inform the Human Research and Ethics Committee. If there is a serious adverse event, this notification will occur within one working day.

2. Sample size and statistical power

Data from previous studies suggests that landmark technique identifies the CTM successfully in approximately 40%^{4,5,13} of patients, whereas ultrasound identifies it correctly in 80%^{4,8,12}.

Using a significance level of 0.05, and power of 80%, 28 patients are required in each arm; to allow for dropouts, a target of 31 patients in each arm (62 in total) is intended.

3. Ethical considerations

This study will occur as part of participants' care within the emergency department, and it is not anticipated that any specific ethical issues will arise.

All clinical care will be provided in a tertiary emergency department, and supervised by consultant emergency physicians.

Radiological care will be provided within an accredited department of radiology, and accredited practitioners will undertake ultrasound.

Patients will be given the choice of participation, and if they choose not to do so, or withdraw consent to continue, their clinical care will continue without prejudice. This will be explicitly stated within the Patient Information Sheet.

4. Dissemination of results

It is intended that the results of the study will be published in a peer-reviewed journal, and will also be submitted for presentation at any relevant conferences.

5. Outcomes and significance

It is possible that the results of this study will improve clinical practice, by either identifying a technologically superior technique, or by preventing the utilisation of a technique that does not add value to patient care, and may be deleterious if the time taken to identify the CTM is prolonged.

6. Budget

This study will be run using no additional budget. Emergency physicians and registrars will complete study duties within their normal clinical duties or clinical support time.

7. Glossary of abbreviations

The following abbreviations have been used:

CTM - CTM
CICO - Can't intubate, Can't Oxygenate
ED - Emergency Department

8. References

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