

# Identifying the Cricothyroid Membrane (CTM) with Ultrasound, Laryngeal Handshake and Conventional Palpation Study Protocol

## Study Personnel

James Bowness<sup>123</sup>, Alasdair Taylor<sup>2</sup>, Alexander Le Saint-Grant<sup>3</sup>, Andrew Dalton<sup>2</sup>, Simon Crawley,<sup>2</sup> Fraser Chisholm<sup>3</sup>, Ourania Varsou<sup>4</sup>, Wendy Teoh<sup>5</sup>, Michael Kristensen<sup>6</sup>, Barry McGuire<sup>2</sup>

- 1) Institute of Academic Anaesthesia, University of Dundee, Scotland
- 2) Department of Anaesthesia, Ninewells Hospital, Dundee, Scotland
- 3) School of Medicine, University of St Andrews, Scotland
- 4) Anatomy Facility, School of Life Sciences, University of Glasgow, Scotland
- 5) Private Anaesthesia Practice, Singapore
- 6) Department of Anaesthesia, Rigshospitalet, University Hospital of Copenhagen

## Roles

Mr Fraser Chisholm - local lead and permanent member of staff in St Andrews, data collection/secure storage, image preparation

Dr Alexander Le Saint-Grant - project management, recruit volunteers (operators and simulated patients), co-ordinate data collection/preparation

Dr James Bowness - project lead, data collection/analysis, presentation/write up

Drs Alasdair Taylor, Andrew Dalton & Simon Crawley - NHS Tayside anaesthetists (local expertise in ultrasound assessment of the front of neck, to assist with data collection)

Dr Ourania Varsou - data analysis, write-up

Drs Michael Kristensen, Wendy Teoh & Barry McGuire - international experts on airway management and ultrasound, study design/critique, presentation/write-up

## Aims

- Compare the accuracy, confidence and speed in assessing the CTM of simulated patients with three different techniques (conventional palpation, laryngeal handshake, ultrasound) by two groups of operators (anaesthetists vs medical students)
- Determine the distance from the suprasternal notch to the CTM, size of CTM, and whether skin markings of the CTM (when identified and marked by experts using ultrasound) maintain their position with respect to the CTM after time, manipulation and changing position of the neck

## Data Collection

- Assessment of the front of the neck of simulated patients

## Primary Outcomes

- Which technique allows operators to identify the CTM most accurately?
- Which technique allows operators to identify the CTM most confidently?
- Which technique allows operators to identify the CTM most quickly?

## Secondary Outcomes

- Is there a difference in accuracy, confidence and speed of identifying the CTM between groups of operators (anaesthetists and medical students)?
- Do the skin markings of the CTM maintain their position with respect to the CTM after time, manipulation and changing position of the neck?
- What is the distance from the suprasternal notch to the CTM midpoint in the eFONA position?
- What is the vertical height of the CTM as measured on ultrasound?

## Background and Rationale

The situation of 'can't intubate, can't oxygenate' (CICO) is a life-threatening emergency in airway management, from which patients die every year throughout the world. The final step in managing a patient's airway in this situation is 'emergency front of neck access' (eFONA), where the anaesthetist attempts to oxygenate the patient by accessing the trachea via the CTM at the front of the neck. This is not always successful, due to an inability to correctly identify the CTM or inability to access the trachea after appropriate identification of structure (1,2). Such cases have a high mortality.

As eFONA is a life-threatening, time-critical emergency to save a patient's life in the event of CICO, stress levels are understandably high amongst all staff managing such situations. Therefore, strategies to simplify the technique and improve success are vital. The most commonly used techniques to identify airway structures at the front of the neck are:

- Conventional palpation:
  - Anaesthetists are taught to palpate the thyroid eminence, cricoid ring and then the shallow depression between them (the CTM)
- Laryngeal handshake (3):
  - The index finger and thumb grasp the top of the larynx (greater cornu of the hyoid bone) and roll it from side to side
  - The fingers and thumb slide down over the thyroid laminae
  - Middle finger and thumb rest on the cricoid cartilage
  - The index finger palpates the cricothyroid membrane

However, these techniques are not 100% accurate (4). Recent accounts of ultrasound assessment of the front of neck describe more successful identification of these structures by two methods: longitudinal (string of pearls) and transverse (Thyroid Cartilage - Airline - Cricoid Cartilage - Airline: TACA) (2,5). The use of ultrasound to identify the CTM, and mark structures on the overlying skin, is recommended for use prior to commencing airway management (2). Such a strategy aims to improve the identification of structures and target eFONA techniques in the event of unsuccessful methods of oxygenation using the patient's upper airway. However, a potential criticism of such a technique is the lack of evidence as to whether the skin markings still reflect the position of the underlying CTM after movement of the neck and instrumentation of the upper airway (6).

This prospective pilot study aims to evaluate these methods of identifying the CTM in simulated patients, when performed by experienced operators (anaesthetists) and novice operators (medical students). It also aims to assess the distance from the suprasternal notch to the midpoint of the CTM, size of the CTM, and whether the position of the skin and CTM move in relation to each other after the neck has been manipulated.

## Study Design

The first stage of this study involves training a group of volunteers, hereafter referred to as 'operators'. The operators (anaesthetists and medical students) will attend a three hour educational tutorial. During this tutorial, experts will provide a summary of the relevant anatomy (using models and cadavers) and the three techniques to identify the CTM. These techniques will subsequently be demonstrated using teaching images, videos and performed in real time on members of the group. Finally, the operators will gain extensive practise identifying the CTM on other members of the tutorial group (under supervision) multiple times for each technique. Then three operators from each group (anaesthetists and medical students) will be offered the chance to take part in stage two of the study, where experts assess their performance for these techniques. During training we aim to reach the top of the learning curve with each technique so that, during the assessment phase, the inherent success rate of the technique is being assessed (not the operator's proficiency or learning with that technique). If more than three for either group (anaesthetists or medical students) wish to undertake this, all names will be taken and three from each group will be drawn at random.

The second stage will recruit a second group of volunteers, hereafter referred to as 'Simulated Patients' (SPs). The recruitment process will particularly encourage the engagement of female patients with BMI >30, as the traditional methods of palpation and laryngeal handshake are known to carry the lowest success rate in this group of patients (as well as those with airway pathology/ abnormal anatomy) (2). The SPs will have the front of their neck assessed by two experts. These experts will position the volunteer in the position recommended for eFONA by the Difficult Airway Society guidelines for unexpected difficult intubation in adults (3). They will identify the CTM and measure the distance between its superior and inferior boundaries on ultrasound. Then they will mark its superior/inferior margins and central point on a transparent mouldable dressing placed over the skin of the anterior neck (with its position and orientation indicated by identifier markings on the edges of the dressing and surrounding skin of the neck). The distance from suprasternal notch to the midpoint of the CTM and size (distance between upper and lower borders) of the CTM will be measured.

The SP will subsequently move through a series of six stations where their neck is assessed by the operators selected from stage one (three anaesthetists and three medical students), again whilst in the eFONA position. The SP will go through this series of stations three times, so each operator will assess the neck of each SP three times (once with each technique: palpation, laryngeal handshake or ultrasound). Ultimately, each SP will have their neck assessed 18 times (each of the six operators using all three techniques). By this method, as an SP revisits the series of stations, the operators will be assessing the necks of other SPs (using different techniques) between each assessment of the same participant. This is designed to avoid the operator serially assessing the same neck and 'getting used' to that neck (which may influence the second and third assessment). With each assessment, when the operator has identified what they believe to be the CTM, they will be asked to mark the centre of each using a 5 mm sticker. The transparent dressing will then be applied to the front of the SP's neck (aligned with the identifier markings), so the sticker position can be compared to the experts' markings. If the centre of the 5 mm sticker lies within the experts' marks of the upper and lower boundaries of the CTM, this will be accepted as successful. Also, if the central point of the sticker lies within 5 mm of the midline over the CTM, this will again be accepted. In all cases, the distance from the centre of the sticker to the central point of the CTM

(as identified by the expert) will be measured. The operator will be asked to assess their confidence in each technique using a visual analogue scale (0 = no confidence, 10 = extremely confident). Each time the neck is assessed, the operator will be timed from the point they touch the SP's neck (with their hand or the ultrasound probe) to the time they place the second sticker on the skin.

Finally, the same experts will re-position the SP into the position for eFONA once again, and reassess the distance between the suprasternal notch and CTM, and mark the central point of the CTM. This point will be compared to the initial expert assessment in the same manner as above.

### **Ethical Considerations**

Approval for this study will be sought from the University of St Andrews Teaching and Research Ethics Committee.

### **Sample Size**

This is a pilot study to assess the three techniques described, as performed by anaesthetists and medical students. Recent similar work on the palpation and laryngeal handshake techniques determined a success rate of 33% for palpation and 62% for laryngeal handshake (4). A study demonstrated the success of ultrasound: in a randomised cross-over comparison undertaken by this group showed 90% success using two different ultrasound techniques (5). These figures are consistent with earlier preliminary data collected by members of this group during an audit in Ninewells Hospital: 37.5% success for palpation and 100% for ultrasound (with a mean  $\pm$ SD distance (mm) from the expert's central point of  $8.75 \pm 7.92$  and  $1.5 \pm 1.93$ ). A priori calculation of sample size for detection of a statistically significant difference between any two assessments, with Alpha (type I) error = 0.05 and Beta (type II error) = 0.8 was performed, comparing ultrasound (90% success) to palpation (33%) and then ultrasound (90%) to laryngeal handshake (62%). Based on this, a minimum of 20 (ultrasound:palpation) or 35 (ultrasound:laryngeal handshake) assessments are required for each arm of the study. We are therefore projecting to recruit 12 SPs (up to a maximum of 50) until a satisfactory power is achieved. The SPs will each be assessed three operators from each group (anaesthetists and medical students) by each technique. We will therefore have 36 assessments by each group of operators for each technique (and 72 in total for each technique). SPs will be recruited by e-mail, presentation and/or poster advertising to take part in this part of the study.

### **Inclusion and Exclusion Criteria (Operators)**

Inclusion criteria:

- Anaesthetists at Ninewells Hospital, Department of Anaesthesia
- Medical students at St Andrews University, School of Medicine

Exclusion criteria:

- Non-attendance at the initial study tutorial
- (After the initial tutorial, participation in the neck assessment study will be sought from the operators, if more than three of either anaesthetists or medical students wish to participate, all names will be taken and three drawn at random)

### **Inclusion and Exclusion Criteria (Simulated Patients)**

Inclusion criteria:

- Male and female
- Adults (aged >17 years, most will be students/staff/simulated patients from the University of St Andrews, but no restriction will be made e.g. assessment of the investigators themselves)
- Ability to consent

Exclusion criteria:

- Previous surgery, radiation or major pathology of the neck anterior to the vertebral column that distorts the soft tissue anatomy (e.g. thyroid tumour, but not dermatitis/abrasions)
- Inability to extend neck
- Inability to identify the CTM or trachea by the experts prior to assessment by operators

### **Data to be Collected**

Operator background:

- Age
- Sex
- Designation of operator (e.g. medical student, anaesthetist)
- Prior experience/training of operator using ultrasound? (Please describe.)
- Prior experience/training of operator in identifying CTM for eFONA:
  - Specific training (if so, what?)
  - Use of ultrasound?
  - Simulation or clinical setting? (If so, how many numbers for each?)
- Years of training/work in anaesthesia (if any)

Simulated Patient data:

- Age
- Sex
- Height, weight and BMI
- Size of the CTM on ultrasound as measured by expert (in millimetres; distance between lower border of thyroid cartilage and upper border of cricoid cartilage)
- Distance from suprasternal notch to centre of CTM as measured by expert (in millimetres)
- Operator identification of centre of CTM within boundaries marked by experts (yes/no)
- Distance between the two CTM locations marked (in millimetres, in vertical and horizontal planes)
- Confidence of operator in their identification of the centre of the CTM
- Duration from start of operator's assessment of SP's neck to time at which the sticker is applied to identify the centre of the CTM
- Centre of CTM identified in second expert assessment within boundaries marked on first assessment (yes/no)
- Distance between first and second expert assessments of the CTM (in millimetres, in vertical and horizontal planes)

### **Data Management**

SPs will be allocated a unique identifier to ensure anonymity. Data will be entered onto a spreadsheet with only the unique identifier and demographic details on it. All data will be recorded and stored in an anonymised format within the secure Anatomy Act drive of the University of St Andrews School of Medicine that has restricted and monitored access rights. Mr Fraser Chisholm will act as the custodian for the data ensuring appropriate data collection and management, and

will ensure that the data get destroyed at the appropriate time. Consent forms will be stored in a secure and locked cabinet, with only the custodian having access to these. All data and signed consent forms will be destroyed after 5 years as described in the ethics application.

### **Statistical Results and Analysis**

Anonymised data will be coded in SPSS and initially checked for normality using a three-stage approach: basic descriptive statistics (e.g. mean, median, skewness, etc.), plotting of data on a histogram with a superimposed normality curve and a visual check; and finally using the Kolmogorov-Smirnov Test and the Shapiro-Wilk Test. Dichotomous independent data (i.e. yes/no) will be analysed using the Chi-square test. Continuous numerical data will be log transformed, if not normally distributed, and then ANOVA will be employed, to assess for statistically significant differences amongst the means of the different groups.

### **Dissemination of Results**

This study will be written up and a manuscript submitted to an appropriate peer-reviewed journal. It will also be presented at relevant clinical meetings.

## References

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2. Kristensen MS, Teoh WH, Rudolph SS. Ultrasonographic identification of the cricothyroid membrane: best evidence, techniques, and clinical impact. *Br J Anaesth* 2016; 117 (S1): i39-i48.
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4. Drew T, McCaul CL. Laryngeal handshake technique in locating the cricothyroid membrane - a non-randomised comparative study. *Br J Anaesth* 2018, 121 (5): 1173-1178.
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6. Dixit A, Ramaswamy KK, Perera S, Sukumar V, Frerk C. Impact of change in head and neck position on ultrasound localisation of the cricothyroid membrane: an observational study. *Anaesthesia* 2019; 74: 29-32.