Official Tittle of the study:

Prospective Study On Novel Usage of Airway Ultrasound To Detect Subglottic Secretion Above Endotracheal Tube (ETT) Cuff

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Objective:

To our knowledge, there is limited studies on the use of ultrasound to visualise subglottic secretions in intubated patients. The main objective of our study is to compare the performance of ultrasound in detecting subglottic secretion above the ETT tube cuff in comparison to computed tomography (CT) scan.

Design:

This is a prospective controlled trial. The study was conducted from March 2021 to August 2021 in Emergency Department, Raja Permaisuri Bainun Hospital, Perak, Malaysia

Methods:

Consecutive patients admitted to the Emergency Department of Raja Permaisuri Bainun Hospital from November 2020 to April 2021 who are emergency or semi-electively intubated and planned for cervical computed tomography (CT) scan will be enrolled.

Airway ultrasound will be performed on all intubated patients who fulfilled the inclusion and exclusion criteria prior to cervical computed tomography. The procedure performed by the critical care and emergency physicians who have been trained in critical care sonography with minimum of 5 years experienced. Findings of the CT scan is examined by a radiologist with more than 10 years experienced, and then are compared with the ultrasound findings. The investigator radiologist is blinded to the ultrasound findings done beforehand.

Ethical approval from Medical Research and Ethics Committee of Malaysia Ministry of Health had been granted [Research ID: 58284]. Written informed consent was obtained from patient whenever possible or from the next of kin. An external data monitoring committee supervised data collection.

Participants

All patients who are emergency or semi-electively intubated and planned for cervical computed tomography(CT) scan will be enrolled. Endotracheal intubation or placement of the endotracheal tube (ETT) is a medical procedure in which a tube is placed in the trachea through the mouth or the nose.

Patient inclusion criteria were:

(1) 18-years and older, (2) ETT in situ (3) indicated for cervical CT scan.

Patients were excluded if they had any of the following:

(1) neck subcutaneous emphysema, (2) neck scar or surgical dressing around the neck which can lead to difficulty in obtaining an optimal ultrasound image.

Study End Points

To determine the sensitivity and specificity of upper airway ultrasound in the detection of subglottic secretion, in comparison to CT scan.

Sample Size

We calculate the sample size to determine whether an area under the curve (AUC) of ≥ 0.75 was achieved for a receiver operator characteristic

(ROC) plot of neck ultrasound for detecting subglottic secretions versus cervical CT scan as a gold standard. The null hypothesis is set as AUC 0.5 (meaning no discriminating power), Type 1 error of 0.05 and power of 80%. Based on the unpublished data from our own experience, with a precision of 10%, and an expected proportion of subglottic secretions on chest CT scan of 80%, the sample size required was 45. Taking into account the potential for 10% incomplete data from neck ultrasound or cervical CT scans, we included 49 patients for the final analysis. AUROC sample size calculation was performed using MedCalc for Windows, version 19.4 (MedCalc Software, Ostend, Belgium). (13)