ISRCTN66168037 https://doi.org/10.1186/ISRCTN66168037

Endotracheal tube cuff pressure estimation techniques: safety and reliability among women undergoing general anaesthesia with intubation for cesarean section

Submission date
01/07/2021

Recruitment status
No longer recruiting

Registration date
16/07/2021

Overall study status
Completed

Last Edited
10/11/2021

Condition category
Pregnancy and Childbirth

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
An endotracheal tube is a flexible plastic tube that is placed through the mouth into the windpipe (trachea). The use of an endotracheal tube has become routine for women undergoing general anaesthesia for a cesarean section. Its insertion can damage the trachea due to excessive pressure in the cuff. This study aims to compare the techniques involve in cuff inflation and its corresponding pressure estimations as well as associated complications among parturients undergoing general anaesthesia with intubation for cesarean section at the obstetric unit of the Tamale Teaching Hospital.

Who can participate?
Pregnant women aged 18 to 40 undergoing cesarean section under general anaesthesia with intubation

What does the study involve?
An anesthesiologist inflates the endotracheal tube cuff and determines the cuff pressure using either of the following techniques: standard manometer, predetermined volume of air (10 - 15 ml), or manual palpation of the endotracheal tube pilot balloon immediately after intubation. Before extubation, the pressure gauge is used to measure the actual pressure generated using manual palpation of the pilot balloon or the predetermined volume of air (10 - 15 ml).

What are the possible benefits and risks of participating?
The findings of this study will provide information on endotracheal tube cuff pressure procedures and will influence anaesthesia clinical policies, the monitoring of endotracheal tube cuff pressure and its estimation. Cuff pressure associated complications (cough, sore throat, hoarseness, and blood-streaked expectoration) may result.

Where is the study run from?
Tamale Teaching Hospital (Ghana)

When is the study starting and how long is it expected to run for?
December 2020 to November 2021

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Dr Sylvanus Kampo
sylvanuskampo@yahoo.com

Contact information

Type(s)
Scientific

Contact name
Dr Sylvanus Kampo

Contact details
C.K. Tedam University of Technology and Applied Sciences
Navrongo
Ghana
00233
+233 (0)559355229
skampo@cktutas.edu.gh

Type(s)
Scientific

Contact name
Dr Tamale Winsum Anabah

Contact details
Habana Medical Services
Tamale
Ghana
+233
+233 (0)242186766
thomas.anabah@uds.edu.gh

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
UHAS REC A.9[114]20-21

Study information

Scientific Title
Endotracheal tube cuff pressure estimation techniques: safety and reliability among parturients undergoing general anaesthesia with intubation for cesarean section at the obstetric unit of the Tamale Teaching Hospital. A prospective randomized comparative study

Study objectives
The experience in cuff pressure estimation by the anaesthesia providers correlates poorly within therapeutic limits. The manual palpation of the pilot balloon technique is associated with a high incidence of cough, sore throat, hoarseness, and blood-streaked expectoration among parturients. The standard manometer technique is the ideal and should routinely be used to estimate endotracheal tube cuff pressures among parturients undergoing cesarean section under general anaesthesia

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 01/06/2021, the ethical committee of the University of Health and Allied Sciences (PMB 31, Ho Volta Region, Ghana; +233 (0)362196193; rec@uhas.edu.qh), ref: UHAS REC A.9[114] 20-21

Study design
Prospective randomized comparative study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Diagnostic

Participant information sheet
Not available in web format, please use the contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Elective cesarean section

Interventions

All parturients are prospectively assessed and classified according to the American Society of Anesthesiologists (ASA) physical status classification. Basic intraoperative monitoring (ECG, SpO_2, temperature, and non-invasive blood pressure) is applied, and the baseline vital signs are checked and recorded. The individual parturient is advised not to eat any solid food for at least 6-8 hours before surgery. An independent anesthesiologist is assigned to perform the intubation and monitor the patient till discharge from the hospital.

In the supine position, the parturient is anaesthetized with propofol 1.5-2 mg/kg, succinylcholine 1.0 mg/kg, and then intubated with the appropriate endotracheal tube size (internal diameter of 6.5 or 7 mm with a cuff type of high-volume low pressure). Successful insertion of the endotracheal tube is confirmed by the presence of equal bilateral breath sound. The vital signs (pulse rate, blood pressure, oxygen saturation, and respiratory rate) of the individual parturient are monitored and recorded every 5 minutes for the first 30 minutes and then for every 15 minutes. Any estimated deficit of fluid or blood loss is replaced accordingly. An independent anesthesiologist blinded to the study is asked to inflate the endotracheal tube cuff and determine the cuff pressure using either of the following techniques; standard manometer, predetermined volume of air (10 - 15 ml), or manual palpation of the endotracheal tube pilot balloon immediately after intubation. Again, prior to extubation, the pressure gauge is used to measure the actual pressure generated using the manual palpation of the pilot balloon, or the predetermined volume of air (10 - 15 ml).

Intervention Type
Device

Phase
Not Applicable

Primary outcome measure
1. Endotracheal tube cuff pressure determined using a standard manometer, predetermined volume of air (10 - 15 ml), or manual palpation of endotracheal tube pilot balloon immediately after intubation or prior to extubation. The technique used and the cuff pressure estimated in each group is recorded
2. Cuff pressure associated complications (cough, sore throat, hoarseness, and blood-streaked expectoration) determined during an interview after 24 hours of extubation

Secondary outcome measures
Overall perioperative satisfaction, evaluated as 4 = excellent, 3 = good, 2 = satisfactory, 1 = poor, during an interview on the day of discharge

Overall study start date
01/12/2020

Completion date
30/11/2021

Eligibility

Key inclusion criteria

1. Parturients scheduled for elective cesarean section under general anaesthesia with endotracheal intubation
2. Aged 18 to 40 years
3. American Society of Anesthesiologists Physical Status (ASA-PS) score 1-2

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
40 Years

Sex
Female

Target number of participants
Between 380 and 400 respondents

Total final enrolment
389

Key exclusion criteria
1. Patients with a history of difficult intubation or multiple attempts (more than three attempts) during intubation
2. Parturient requiring emergency intubation
3. Parturient with a higher risk for aspiration
4. Intubation performed by non-anaesthesia staff
5. Parturient with known anatomical laryngotracheal abnormalities
6. Those expected to remain intubated beyond the operation room period

Date of first enrolment
01/06/2021

Date of final enrolment
30/11/2021

Locations

Countries of recruitment
Ghana

Study participating centre

Tamale Teaching Hospital
Post Office Box 16
Tamale
Ghana
00233

Study participating centre
Habana Medical Center
Tamale
Tamale
Ghana
+233

Sponsor information

Organisation
Habana Medical Services

Sponsor details
Tamale Northern Region
Tamale
Ghana
00233
+233 (0)554470555
habanamedicalservice@gmail.com

Sponsor type
Hospital/treatment centre

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan

Current publication and dissemination plan as of 22/10/2021:
Planned publication in a high-impact peer-reviewed journal.

Previous publication and dissemination plan:
The researchers will publish the findings of this study in an SCI journal. No additional documents are available.

Intention to publish date
10/12/2021

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Sylvanus Kampo (sylvanuskampo@yahoo.com).

IPD sharing plan summary
Available on request