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Left head rotation as an alternative to difficult intubation: a randomized clinical trial

Submission date
02/09/2022

Recruitment status
No longer recruiting

Registration date
05/09/2022

Overall study status
Completed

Last Edited
20/06/2023

Condition category
Other

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Background and study aims
Tracheal intubation is a life-saving intervention not only for physicians but also for allied health workers. Optimizing the patient's head and neck position for the best glottic view is a crucial step that accelerates tracheal intubation. Several head and body positions are employed to facilitate tracheal intubation. The sniffing position is the preferred position among anesthesiologists and is the current gold standard in the intubation process. Several studies have reported attaining an optimal head position for direct laryngoscopy and intubation with the normal airway in the sniffing position. However, in some studies sniffing position did not improve glottic visualization, the success rate on first intubation, or intubation time. The left head rotation maneuver has been recently described as an innovative approach to tracheal intubation with marked improvement in glottic visualization and can be an alternative before proceeding to a surgical airway. In this randomized open-label clinical trial, we aimed to compare the glottic view and intubating conditions with left head rotation versus the conventional sniffing position during direct laryngoscopy of patients undergoing elective surgery and evaluate if the left head rotation maneuver is a viable alternative for difficult endotracheal intubation.

Who can participate?
Adult patients admitted for an elective surgical procedure requiring tracheal intubation under general anesthesia

What does the study involve?
This randomized, open-label clinical trial enrolled fifty-two adult patients admitted to the Baguio General Hospital & Medical Center from September to December 2020 for an elective surgical procedure requiring tracheal intubation under general anesthesia. Intubation was done using a 45-degree left head rotation in the experimental group, while the control group was intubated using the conventional sniffing position. Glottic visualization and intubation difficulty with left head rotation and sniffing position were assessed using Cormack-Lehane Grade and Intubation Difficulty Scale, respectively. Successful intubation is measured by observing a capnographic waveform in the end-tidal CO2 monitor after placement of the endotracheal tube.

What are the possible benefits and risks of participating?
Left head rotation maneuver may be a practical noninvasive alternative approach to improve the glottic view among anesthetized patients requiring tracheal intubation. The potential outcome of this study can benefit patients by providing quicker airway access during intubations and fewer intubation attempts, thereby improving patient safety. The protocol and informed consent forms were reviewed and approved by the institutional ethics board of Baguio General Hospital & Medical Center. The researcher obtained written informed consent the day before the scheduled operation. The anesthesiologist-in-charge prioritized the patient's comfort and safety, and any changes in vital signs such as hypotension and bradycardia were actively looked out for. Patients who failed to be intubated using left head rotation or standard sniffing position received an appropriate standard point of care based on Difficult Airway Society guidelines. Untoward reactions were included in the report, and a close follow-up was advised.

Where is the study run from?
Baguio General Hospital & Medical Center (Philippines)

When is the study starting and how long is it expected to run for?
December 2019 to January 2021

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Dr Danya Chan
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Contact information

Type(s)
Principal investigator

Contact name
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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
BGHMC-ERC-2020-27

Study information

Scientific Title
Left head rotation as an alternative to difficult tracheal intubation: a randomized open-label clinical trial

Acronym
LEHER

Study objectives
Left head rotation manoeuvre is a viable alternative to the sniffing position for difficult endotracheal intubation.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 09/23/2020, Baguio General Hospital & Medical Center Ethics Review Committee (Governor Pack Road, Baguio City, 2600 Benguet CAR, Philippines; +63 442-3765; bghmc.erc@gmail.com), ref: BGHMC-ERC-2020-27

Study design
Randomized open-label clinical trial

Primary study design
Interventional

Study type(s)
Other

Health condition(s) or problem(s) studied
Alternative head position for difficult tracheal intubation

Interventions
Enrolled participants who met the inclusion criteria were randomized by drawing lots into the experimental (intubated with left head rotation; n=26) and control groups (intubated in the sniffing position; n=26). The consultant or senior anesthesiology resident opened the papers drawn prior to the induction of anesthesia to determine group assignment. Thus, the consultant or senior anesthesiology resident served as the observer, and the researcher was blinded during data collection.

Intubation was done using a 45-degree left head rotation in the experimental group, while the control group was intubated using a sniffing position by placing a cushion under the head such that the external auditory meatus and sternal notch are on the same horizontal plane. Glottic

visualization and intubation difficulty with left head rotation and sniffing position were assessed using Cormack-Lehane Grade and Intubation Difficulty Scale, respectively, which were evaluated by the consultant or senior anesthesiology resident in charge.

Alternative techniques were used to facilitate intubation in case intubation was unsuccessful with left head rotation or the sniffing position alone and included a change of blade or tube, the addition of a stylet, change to nasotracheal intubation, applying pressure on the cricoid cartilage, and use of fiberoptic intubation or intubating laryngeal mask airway. In addition, if the intubation was deemed unsuccessful after two attempts, an alternative position was used (change to sniffing position if difficulty intubating with left head rotation, and vice versa). The duration of each intubation attempt was no longer than 10 minutes. A carbon dioxide/flow sensor measured end-tidal carbon dioxide, the gold standard for confirming successful tracheal intubation. The study protocol ended once the airway was secured, and the intended surgical procedure proceeded as planned.

Intervention Type
Procedure/Surgery

Primary outcome(s)
Success rate of intubation measured by observing a capnographic waveform in the end-tidal CO2 monitor after placement of the endotracheal tube at a single time point

Key secondary outcome(s))
Measured at a single time point:
1. Laryngeal exposure measured using Cormack Lehane Grade
2. Intubation ease measured using Intubation Difficulty Scale

Completion date
25/01/2021

Eligibility

Key inclusion criteria
1. 18-65 years old
2. BMI 18.5-35 kg/m²
3. ASA Classification I to III
4. Mallampati III

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
65 years

Sex
All

Total final enrolment
52

Key exclusion criteria
1. Mallampati IV
2. Sternomental distance <12 cm
3. Thyromental distance <6 cm
4. Small mouth opening <3 fingerbreadths
5. Limited head rotation or neck extension
6. BMI >35 kg/m²
7. Known gastroesophageal reflux
8. Presence of anterior neck mass
9. Facial fractures obstructing the airway

Date of first enrolment
23/09/2020

Date of final enrolment
05/01/2021

Locations

Countries of recruitment
Philippines

Study participating centre
Baguio General Hospital & Medical Center
Governor Pack Road
Baguio City
Philippines
2600

Sponsor information

Organisation
Baguio General Hospital and Medical Center

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study will be published as a supplement to the subsequent results publication.

IPD sharing plan summary
Published as a supplement to the results publication

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		19/06/2023	20/06/2023	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Protocol file		09/05/2022	05/09/2022	No	No