

Study Protocol

Comparative Evaluation of Macintosh and Airtraq Laryngoscopes for Laryngeal View During Endotracheal Intubation: A Study Protocol

ABSTRACT

BACKGROUND: Intubating trachea is a routine procedure for anaesthesiologists, but during surgeries, protecting the airway remains a challenge. Intubation failure in anaesthetic and emergency cases remains a big cause of mortality and morbidity. The Macintosh laryngoscope remains most widely used of various inventions and numerous advancements in the airway used for endotracheal intubation. Airtraq laryngoscope is a novel video laryngoscope which aids the procedure for intubation of patients with difficult or normal airways. Airtraq blade curvature and the precise internal arrangement of the optical components are made in such a way that enables visualization of the glottic field with minimal manipulation of the pharyngeal, oral and tracheal axis. This study aims to compare Airtraq and Macintosh Laryngoscope for Laryngeal view.

METHODS: This will be a prospective comparative randomised study that will include total 80 patients. Patients posted for surgery under general anaesthesia will be randomized into two groups (i.e. 40 in each groups): **Group M-E** patients will be intubated with Macintosh Endotracheal Intubation whereas **Group A-E** patients will be intubated with Airtraq Endotracheal Intubation. Patients will be evaluated for Ease of intubation, duration of induction, successful number of attempts and hemodynamic parameters. Data will be compiled and analysed with appropriate statistical programme.

EXPECTED RESULTS: Significant results are expected to support that, Airtraq can be secured easily and with lesser number of attempts compared to Macintosh and duration of insertion is less.

CONCLUSION: Intubation with Airtraq is easier in relation to intubation ease and duration compared to Macintosh with less post-operative complications.

KEYWORDS: Endotracheal intubation , Airtraq, Macintosh , Laryngoscope, General Anesthesia.

INTRODUCTION:

Intubating trachea is a routine procedure for anaesthesiologists, but during surgeries, protecting the airway remains a challenge. ⁽¹⁾ Intubation failure in anaesthetic and emergency cases remains a big cause of mortality and morbidity. ⁽²⁾ The Macintosh laryngoscope remains most widely used of various inventions and numerous advancements in the airway used for endotracheal intubation. ⁽³⁾ It is known to be the “gold standard” for endotracheal intubation

and on basis of which other airway devices are compared. Before the induction of anaesthesia, difficult airways are not identified as it depends on many factors.⁽⁴⁾ Airtraq laryngoscope is a novel video laryngoscope which aids the procedure for intubation of patients with difficult or normal airways. Airtraq blade curvature and the precise internal arrangement of the optical components are made in such a way that enables visualization of the glottic field with minimal manipulation of the pharyngeal, oral and tracheal axis.⁽⁵⁾ Compared to regular Macintosh laryngoscopes, less cervical spine movement will be needed for subsequent indirect laryngeal exposure.⁽⁶⁾

Two side streams consist of the Airtraq blade, With a wide-angle view, one is of high quality for the insertion of endotracheal tubes (ETT) and the other for a series of lenses, prisms and mirrors that move the image from the illuminated tip, the glottis and the neighboring laryngeal structures and the tip of the tracheal tube. The structure of Airtraq resembles to that of the normal anatomy and hence can be used with standard ETTs.⁽⁷⁾

RATIONALE:

Airtraq laryngoscope has many advantages over the macintosh laryngoscope, such as sore throat is less observed in airtraq intubation group of individuals than in macintosh. There is no visual obstruction in Airtraq during endotracheal intubation, and any variety of endotracheal tubes can be used. Hoarseness of voice and laryngospasm are also observed less from airtraq.

AIM AND OBJECTIVES

AIM

The Aim is to compare Airtraq and Macintosh Laryngoscope for Laryngeal view.

OBJECTIVES:

Primary objective :-

To compare study the ease of intubation in accordance with intubation difficulty score.

Secondary objectives :

1. To compare duration of intubation among the two groups.
2. To compare Hemodynamic response between the two groups.
3. To assess successful intubation at first attempt .
4. To compare post op complications among the two groups, if any.

MATERIALS AND METHODS

Study design:

1. Study period :2 years
2. Study area : department of anaesthesiology JNMC &AVBRH.
3. Study design : prospective comparative randomised study.
4. Study population: Patients, 20-60yrs of age of either gender.

Study Settings

After the approval of the ethics and screening committee of Jawaharlal Nehru Medical College, DMIMS (DU), Acharya Vinoba Bhave Rural Hospital (AVBRH), Datta Meghe Institute of Medical Sciences, Sawangi (M), Wardha. This study will be conducted on 60 individuals.

Informed and written consent will be procured from all the patients prior to procedure.

PARTICIPANTS

Inclusion criteria:

1. Patients aged between 20- 60years of either gender.
2. Elective surgical cases requiring GA.
3. ASA Class I & II patients.
4. All the patients willing to give informed written consent

Exclusion criteria:

1. ASA Class III and above
2. Parents /Guardian's refusal
3. Patients with bleeding disorders ,CVS,RS, hepatic, renal disease patients
4. Patients who could require rapid sequence induction.
5. Age : <20years & > 60 years (male or female).
6. Patients having allergy to drugs.

MATERIALS REQUIRED:

1. Airtraq laryngoscope 3 and 4
2. Macintosh laryngoscope 3 and 4
3. Endotracheal tubes #7.0 cuffed, #7.5 cuffed
4. Drugs- glycopyrrolate, midazolam, butrium, propofol, vecoronium, isoflurane/sevoflurane, ondansetron.

Data measurement:

1.INSERTION CONDITIONS:

- EASE OF INTUBATION -easy/difficult/impossible
- Number of attempts -<2 attempts
- TIME TAKEN FOR INSERTION (time from picking up device until attaching to breathing system)

AIRTRAQ LARYNGOSCOPE (18 seconds)

MACINTOSH ARYNGOSCOPE (29 seconds)

2. HEAMODYNAMIC PARAMETERS: Heart Rate, systolic and diastolic BP,

3. COMPLICATIONS

- SORE THROAT Y/N
- HOARSENESS OF VOICE Y/N

Sample Size & Design:

Sample size is calculated using WWW.OpenEpi.com. The mean MAP after 10 mins of induction is taken to be 88.30 (+or -) 6.77 keeping power at 80% an alpha of 0.05, and a 10% difference in Mean MAP between the two groups, requiring a sample size of 80 patients. The patients selected will be divided into two groups of 40 each randomly.

n=80 number of Patients between the ages of 20 and 60 that meet both the inclusion and exclusion requirements and patients are split into two groups posted for surgery under general anaesthesia (i.e. 40 in each group) as follows:

Group M-E(n1=40) intubated with Macintosh Endotracheal Intubation

Group A-E (n2=40) intubated with Airtraq Endotracheal Intubation

PREOPERATIVELY:

For all the patients, a brief history and a comprehensive general examination will be performed.. All the patients will be kept fasting overnight prior to the scheduled day of operation Vital parameters such as respiratory rate, heart rate, saturation of oxygen (SpO₂), blood pressure and ECG changes in the preoperative room will be assessed for patients. The selected patients will be randomly assigned to two subsequent groups of n=40 each based on a computer generated randomization table and will be allotted the same by sealed envelope technique.

METHODOLOGY

Patients will receive standardized premedication in the form of inj. Glycopyrrolate 0.2mg, inj. Ondansetron 0.1mg/kg and normal monitoring with the assistance of pulse oximetry, electrocardiography and non-invasive arterial blood pressure will be done once in the operating theatre and 100% oxygen (2 L/min) will be administered. Induction will be done with propofol 2-2.5 mg/kg and muscle relaxation will be assisted with vecuronium 0.1 mg/kg and bag mask ventilation was facilitated with a mixture of oxygen, nitrous oxide, and Sevoflurane for 3 minutes. In the ME group, Macintosh will be practiced first, and in the AE group, Airtraq will be practised first. Tracheal intubation will be carried out in the second laryngoscopy with the device used. Intubation duration attempt is characterized as the time elapsed between the dental arches from the insertion of the blade until ETT is inserted through vocal cords and verified by capnography of chest rise, auscultation, and square wave. Once entering the trachea, intubation will be confirmed using capnography. The endotracheal tube will be fixed. In both groups, general anaesthesia would be administered with propofol 1 mg/kg and vecuronium 0.1 mg/kg injection.

Anesthesia maintenance will be done using a controlled oxygen sevoflurane anaesthetic procedure and incremental doses (0.025 mg/kg) of inj. After neuromuscular block reversal with neostigmine (0.05 mg/kg) and glycopyrrolate (0.2 mg/kg), extubation is performed at the end of the procedure. The research will examine the airway and other factors that can affect laryngoscopy, including steps to predict difficult tracheal intubation, such as beard, dental prosthesis, or obstructive sleep apnoea syndrome (Mallampati score, thyromental distance, and

cervical movement). This study will document the laryngoscopy period (time elapsed from the insertion of the laryngoscope into the dental arch before the glottis was visualised) and the intubation time in all laryngoscopies: the score for Cormack-Lehane (from the insertion of the laryngoscope into the dental arch, time elapsed before the investigator reported tracheal intubation by lung auscultation).

The patients will be then transferred to the recovery room. Failed intubation is described as an attempt in which the user was unable to intubate the trachea at all or which took > 120 seconds to intubate the trachea perform the operation, even with optimization manoeuvres. In the event of an intubation failure, intubation with another laryngoscope is allowed.

Any complications during laryngoscopy and intubation (desaturation, injuries to the lip, injury to the teeth, and/or tongue) or after extubation complications like laryngospasms , hoarseness of voice , and sore throat will be recorded. Any need for assistance in laryngoscopy will also be recorded.

STATISTICAL METHODS:

Statistical analysis could be done by using descriptive statistics i.e mean, standard deviation(SD), standard error of mean & by using inferential statistics like chi-square test, students unpaired t test. All the results will be tested at 5% level of significance.

EXPECTED OUTCOME/ RESULTS:

Expecting that compared to Macintosh , Airtraq can be secured easily and with lesser number of attempts and duration of insertion is less. Airtraq is hemodynamically ore stable with minimal or no-postoperative complications.

DISCUSSION

McElwain et al (2011) conducted a prospective study with the objective to compare the performance of C-MAC, Airtraq and Macintosh laryngoscopes when tracheal intubation is performed in patients undergoing neck immobilization using manual inline axial stabilization of the cervical spine. The study concludes that in patients undergoing cervical immobilization, the Airtraq laryngoscope performed better than the C-MAC and Macintosh laryngoscopes.⁽⁶⁾

C.H. Maharaj et al(2006) conducted a prospective study with the goal of this study to determine the efficacy of this new system in patients considered to be at low risk of difficult intubation for use by experienced anaesthetists. The study concludes that the Airtraq Laryngoscope introduces a new approach to traditional airway control. In this first randomized clinical trial with this product, Airtraq decreased the complexity of tracheal intubation and the degree of haemodynamic stimulation compared with the Macintosh laryngoscope in patients at low risk for difficult laryngoscopy and intubation.⁽⁷⁾

Dr. Geeta Bhandari et al,(2007) A Prospective study aimed to observe that as a successful intubation period, Airtraq was better than the Macintosh laryngoscope. It was found that as the active intubation time was shorter, Airtraq was better than the Macintosh laryngoscope in Airtraq 18.15 seconds (± 2.74) than Macintosh laryngoscope 32.72 seconds (± 8.31) $P < 0.001$.

POGO (percentage of glottic opening) is also better in the Airtraq group 100% grade 1 versus 67.5% in Macintosh group, $P < 0.001$. In the Airtraq category, the ease of intubation was also better. In the Macintosh party, $P < 0.001$, it was simple at 97.5 percent versus 42.5 percent. Both the laryngoscopes are equally successful in regular airways for tracheal intubation. The study concludes that the duration of successful tracheal intubation was shorter in the Airtraq group which was statistically significant.⁽⁸⁾

Carlos Ferrando, et al,(2011) A prospective study aimed to demonstrate that the Cormack-Lehane score ($P = 0.04$) has been substantially reduced by Airtraq. On the other hand, there were no variations between the two instruments in laryngoscopy times ($P = 0.645$; IC 95 percent 3.1, +4.8) and intubation ($P = 0.62$; IC95 percent -6.1, +10.0). During the intubation manoeuvres using both instruments, no relevant complications were identified. The study concludes that the Airtraq is a helpful laryngoscope that improves the laryngeal view in unskilled anesthesiology residents, thereby promoting tracheal intubation.⁽⁹⁾

Tuna Ertuk ,et al. (2013)In this single-center, prospective randomised, clinical study on 80 patients under general anaesthesia, ASA I-II, aged 18-65 years, was conducted. Using two separate tools for endotracheal intubation, patients were intubated. The Macintosh (direct and classic) laryngoscope was used to intubate Group A, while the Airtraq laryngoscope was used to intubate Group B. In terms of C-L scores, The variations between the groups were statistically important ($p=0.041$. In Macintosh, rate of Mallampati scoring "difficult" was 4/6 and in Airtraq laryngoscopy groups, 2/11 ($p=0.553$). In cases with apparently difficult intubation, the study concludes that the Airtraq laryngoscope has a benefit over the Macintosh laryngoscope, in addition to promoting intubation in patients with minimal head extension due to its clearer view of the oropharyngeal and glottic regions.⁽¹⁰⁾ Few of the related studies on endotracheal intubation were reviewed⁽¹¹⁻²⁹⁾.

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