“COMPARISON OF THE GLOTTIC VIEW DURING INTUBATION USING AIRTRAQ AND MACINTOSH LARYNGOSCOPES IN ADULT PATIENTS UNDERGOING SURGERIES UNDER GENERAL ANAESTHESIA WITH A SIMULATED CERVICAL SPINE IMMOBILIZATION - A ONE YEAR HOSPITAL BASED RANDOMIZED CONTROLLED TRIAL”

By

REG NO. BA0114001

Dissertation

Submitted to the
KLE University, Belagavi, Karnataka

In Partial Fulfillment
of the requirements for the degree of

M. D.
in
ANAESTHESIOLOGY

DEPARTMENT OF ANAESTHESIOLOGY,
JAWAHARLAL NEHRU MEDICAL COLLEGE,
BELAGAVI, KARNATAKA

APRIL - 2017

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ENDORSEMENT

This is to certify that the dissertation entitled **"COMPARISON OF THE GLOTTIC VIEW DURING INTUBATION USING AIRTRAQ AND MACINTOSH LARYNGOSCOPES IN ADULT PATIENTS UNDERGOING SURGERIES UNDER GENERAL ANAESTHESIA WITH A SIMULATED CERVICAL SPINE IMMOBILIZATION - A ONE YEAR HOSPITAL BASED RANDOMIZED CONTROLLED TRIAL"** is a bonafide research work done by **CANDIDATE REG NO. BA0114001**.

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LIST OF ABBREVIATIONS USED

ASA	-	American Society of Anesthesiologists
BMI	-	Body mass index
BURP	-	Backward Upward Right Pressure
CBF	-	Cerebral blood flow
Cms	-	Centimeters
DF	-	Degree of Freedom
ECG	-	Electrocardiogram
ENT	-	Ear Nose Throat
EtCO2	-	End tidal carbon dioxide concentration
ETT	-	Endotracheal tube
I.V	-	Intravenous
IDS	-	Intubation Difficulty Score
IQR	-	Interquartile range
Kg/m^2	-	Kilogram per square meter
LED	-	Light-emitting diode
mg/kg	-	Milligram/Kilogram
MIAS	-	Manual inline axial stabilization
MILS	-	Manual-in-line stabilization
mins	-	Minutes
mm Hg	-	Millimeters of mercury
n	-	Total number
OELM	-	Optimal External Laryngeal Manipulation
p	-	Probability
POGO	-	Percentage of glottic opening

RCT	-	Randomized controlled trial
SD	-	Standard deviation
vs	-	versus
μg/kg/minute	-	Microgram per kilogram per minute

ABSTRACT

Background and objectives

The Airtraq is an intubation device that has been developed to aid laryngoscopy. This study was aimed to compare the glottic visualization between Macintosh laryngoscope and Airtraq video laryngoscope in patients with a simulated difficult airway posted for surgeries under general anesthesia.

Methodology

This one year randomized clinical study was conducted between January 2015 to December 2015 on 60, ASA grade I and II patients of either gender, aged between 18 - 60 years. The study population was randomly divided into two groups. Group A (n=30): intubation performed using Airtraq laryngoscope. Group L (n=30): intubation performed using Macintosh laryngoscope.

Results

In the present study 76.67% of patients in group A had a Cormack Lehane grade 1 view of glottis compared to 13.33% in group L. Most of the patients (56.67%) in group L had Cormack Lehane grade 2 view of glottis compared to 23.33% in group A. Thus Airtraq laryngoscope significantly reduced the Cormack-Lehane grade of glottic view with p value 0.001. It was observed in our study that the mean heart rate, mean systolic blood pressure, mean diastolic blood pressure, and the mean of mean arterial pressure were higher in group L compared to group A at one minute, three minute, and five minute intervals after intubation.

Conclusions

In conclusion, laryngoscopy with Airtraq video laryngocope offers better view of glottis with minimal changes in hemodynamic parameters compared to Macintosh laryngoscope in patients with a simulated cervical spine immobilization.

Keywords

Airtraq video laryngoscope; Macintosh laryngoscope; Rigid cervical collar;

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INTRODUCTION

Expertise in airway management is important for every medical professional and is a lifeline for the anaesthesiologist with patients presenting for anaesthesia and surgery being more complex. In addition, the number of patients requiring anaesthesia and airway management outside the operating room continues to increase.[1,2]

The field of airway management is constantly changing. The decision of airway management is still a challenge as eventhough a number of newer airway devices continue to be introduced into clinical practice, the incidence of difficult airway has not reduced.

General anaesthesia has undergone many refinements and advances in the last few decades. The introduction of safe, short-acting induction and maintenance agents with fewer side-effects, and airway devices such as the laryngeal mask airway, have revolutionized anaesthesia to the point where major complications and morbidity are rare occurrences.

Respiratory events are the most common anaesthetic related injuries. The three main causes of respiratory related injuries are inadequate ventilation, oesophageal intubation and difficult tracheal intubation. Difficult tracheal intubation accounts for 17% of the respiratory related injuries and results in significant morbidity and mortality. In fact up to 28% of all anaesthesia related deaths are secondary to the inability to mask ventilate or intubate.[3]

Endotracheal intubation an important component in general anesthesia requires the alignment of oral pharyngeal and laryngeal axis which is achieved by sniffing position. However in patients with suspected cervical spine injuries tracheal intubation is done after stabilization of the neck using a rigid cervical collar or by manual inline axial stabilization (MIAS) to avoid exacerbation of spinal cord injuries.[4]

It is a significant challenge even to the most experienced anaesthesiologist to intubate patients in whom the movement of the cervical spine is not desirable or restricted. In cases of cervical spine immobility or instability, the use of direct laryngoscopy is reserved: it requires flexion of the cervical spine and atlanto-occipital extension for alignment of the oral, pharyngeal and laryngeal axis to create a direct line of vision from the mouth to the vocal cords. Tracheal intubation in patients with suspected neck injuries should achieve two contradicting goals: sufficient laryngeal exposure and the least cervical spine movement. As the former involves movement of the cervical vertebrae, intubation has to be performed using cervical spine immobilization to prevent exacerbation of spinal cord injuries.

Protective measures to avoid deleterious compression forces on the spinal column include application of rigid collar, a forehead tape and manual-in-line stabilization (MILS). Application of cervical collars may reduce cervical spine movements, but it hinders tracheal intubation with the standard laryngoscope. The cervical collar also significantly reduces the mouth opening, rendering laryngoscopy difficult.[5] Besides, the neck collar lifts up the chin and tips the larynx anteriorly.[6] Removing the anterior portion of the collar can facilitate tracheal intubation. However, this jeopardizes the safety of the cervical spine. MILS that is recommended for cervical spine immobilization further impairs glottic visualization.[7,8]

Fibreoptic intubation is the most reliable method in patients with cervical trauma, but it may be difficult in patients with restricted neck movement.[9] The other drawbacks of fiberoptic intubation are lack of availability of equipment, lack of expertise in its use and difficulty in using it if the patient is not co-operative or if there is blood or secretions in the airway.

Conventionally Macintosh laryngoscope is used for tracheal intubation. But with cervical spine immobilization, it is more difficult to visualize the larynx using the Macintosh laryngoscope.[5,10]

This has prompted the development of newer alternatives to Macintosh laryngoscope to improve the glottic visualization and ease of intubation in patients with cervical spine immobilization such as Airwayscope, Glidescope, C –MAC, Airtraq.[4,10,11,12]

The Airtraq (AirTraq, Prodol Meditec, Vizcaya, Spain) is an intubation device that has been developed to aid laryngoscopy. It provides a high quality glottic view eliminating the need for alignment of the oral pharyngeal and laryngeal axis.[12]

The unique curving blade of the Airtraq® is designed to fit the oropharyngeal anatomy. It possesses considerable advantages in the setting of cervical spine immobilization[12] when direct laryngoscopy is difficult or not recommended.[13] It provides a full view of the glottis without requiring to align the airway axis. In addition, the Airtraq® laryngoscope also appears to cause less cervical spine movements during tracheal intubation when compared with the Macintosh or Mc

Coy® laryngoscopes.[14] The Airtraq facilitates tracheal intubation with the neck in neutral position, which is similar to the neck position maintained by a rigid cervical collar.[15] However, a rigid cervical collar in combination with forehead strapping and MILS virtually obliterates even the small neck movements which normally facilitate airway insertion.[8]

There are limited number of studies reported in the literature comparing glottic visualization obtained by Airtraq and Macintosh laryngoscopes. Hence an attmpt is made to compare the glottic visualization between Macintosh laryngoscope and Airtraq video laryngoscope in patients with a simulated cervical spine immobilization posted for surgery under general anesthesia based on Cormack - Lehane grading and also to evaluate the hemodynamic changes in both the groups.

AIMS AND OBJECTIVES

The aims and objectives of this study were;

Primary objective

To compare the glottic visualization by Cormack - Lehane grading between Macintosh laryngoscope and Airtraq video laryngoscope in patients with a simulated cervical spine immobilization posted for surgeries under general anesthesia.

Secondary objective

To compare the hemodynamic changes in both the groups.

REVIEW OF LITERATURE

Maintenance of patent airway in patients under general anesthesia as well as in critically ill is a lifesaving manoeuvre.[16,17] In 1943, Macintosh developed the first curved laryngoscope blade.[18] Macintosh got the idea for this curved blade after seeing the Boyle Davis mouth gag used for tonsillectomies. Since its inception, the Macintosh blade design has become perhaps the most popular throughout the world.[19]

The flexible fiberoptic bronchoscope was introduced into clinical practice in 1964 and although it was not developed for the purpose of airway management, its value as a device to facilitate endotracheal intubation was soon appreciated.[20] Following the publication of the ASA guidelines on Difficult Airway Management in 1993, the use of flexible fiberoptic intubation among anaesthesia practitioners greatly increased[17] and the technique has come to play a pivotal role in the management of the difficult airway.[21]

Currently, Fibreoptic intubation is the most reliable method in patients with cervical trauma, but it may be difficult in patients with restricted neck movement.[9] The other drawbacks of fiberoptic intubation are lack of availability of equipment, requires expertise in its use and difficulty in using it if the patient is not co-operative or if there is blood or secretions in the airway.[22]

It is a significant challenge even to the most experienced anaesthesiologist to intubate patients in whom the movement of the cervical spine is not desirable or restricted. While cervical immobilization may prevent injury of the cervical spine, it also worsens intubation conditions.[23] In particular, cervical spine immobilization may prevent adequate alignment of the oral, pharyngeal, and laryngeal axis, jeopardizing visualization of the glottis when direct laryngoscopy is attempted.[24]

With advances in technology, video laryngoscopy and optic intubation have been gaining popularity, particularly in patients with difficult airways or as rescue devices in failed intubation attempts. The 2013 ASA guidelines on Difficult Airway Management has recommended the use of videolaryngoscopes in the initial management of anticipated difficult airway.[25]

Various alternative intubation devices including videolaryngoscopes have been compared with the classic Macintosh blade in randomized controlled trials (RCTs), but it remains unclear whether these devices perform better compared with conventional laryngoscopy in patients with cervical spine immobilization.

In a study by Koh JC et al.[26] in 2010 comparing laryngeal view during intubation using Airtraq and Macintosh laryngoscopes in patients with cervical spine immobilization and mouth opening limitation, 50 patients, aged 20 to 60 years, with ASA status I-II who were scheduled to undergo surgical procedures necessitating tracheal intubation were included in the study. After a Philadelphia cervical collar was applied, patients were randomly assigned to tracheal intubation with an Airtraq (Group A, n = 25) or with conventional laryngoscopy (Group L, n = 25). They observed that the success rate of the first attempt in Group A (96%) was significantly greater than with the Group L (40%). Percentage of glottic opening (POGO) score was significantly greater in Group A (84 ± 20%) than in Group L (6 ±

11%). The duration of successful intubation at first tracheal intubation attempt and hemodynamic changes were not significantly different between the two groups.

J. McElwain and J. G. Laffey[4] in 2011 conducted a study comparing C-MAC, Airtraq and Macintosh laryngoscope in 90 patients, 30 in each group undergoing tracheal intubation with cervical spine immobilization using manual inline axial stabilization of cervical spine. All patients were intubated by one anesthetist experienced in the use of each laryngoscope. Authors observed that The Airtraq laryngoscope performed best in these patients, reducing the Intubation Difficulty Scale score, improving the Cormack and Lehane glottic view, and reducing the need for optimization manoeuvres, compared with both the Macintosh and the C-MAC. The C-MAC and Macintosh laryngoscopes performed similarly. There were no differences in success rates or hemodynamic profiles post-intubation between any of the devices tested.

Ferrando C. et al.[27] in 2011 conducted a prospective, randomized cross-over trial with 60 patients with the aim to evaluate if, in unskillful anaesthesiology residents during laryngoscopy, the Airtraq compared with Macintosh laryngoscope improves the laryngeal view, decreasing the Cormack -Lehane score. The Airtraq significantly decreased the Cormack - Lehane score(p=0.04) but there was no differences in time of laryngoscopy and intubation with no complications while using both the devices. Authors concluded that the Airtraq is useful in unskillful anesthesiology residents improving the laryngeal view and therefore facilitating tracheal intubation.

A systematic review and meta - analysis conducted by Lu, Y. et al.[28] in 2011 to compare the Airtraq with the conventional Macintosh laryngoscope included twelve randomized controlled trials (published between 2006 and 2011) with 1061 patients. They pooled the results of the intubation time, the first attempt success rate, the rate of incidence of complications and the incidence of esophageal intubation. Authors observed that the Airtraq reduced the intubation time significantly when used by both experienced anesthetists and novices and it increases the first attempt success rate only in novices($p=0.07$). The incidence of oesophageal intubation was significantly reduced by the Airtraq ($p<0.05$). They concluded that the Airtraq laryngoscope facilitates a more rapid and accurate intubation, especially when used by novices.

Tolon MA. et al.[29] in their comparative study between the use of Macintosh laryngoscope and Airtraq in 40 adult ASA I and II patients with cervical spine immobilization observed that duration of intubation was significantly longer with more optimization maneuvers in Macintosh group but there was no significant difference in intubation attempts between the groups. Both the Cormack- Lehane grading and IDS score have shown statistically significant higher values in Macintosh group. The authors concluded that the Airtraq laryngoscope offers a new approach for management of difficult airway like patients with potential cervical spine injury, gets an easy view of the larynx without moving cervical spine or causing hemodynamic stimulation.

Wasem S. et al.[30] in 2013 conducted a randomized clinical trial comparing the Airtraq with the Macintosh laryngoscope for intubation with a double-lumen tube in patients undergoing elective thoracic surgery. 60 adult patients were intubated by an anaesthesiologist with either an Airtraq (n=30) or a Macintosh laryngoscope (n=30). They concluded that there was no significant difference between the Airtraq and the Macintosh laryngoscopes regarding the time needed to insert a double-lumen tube during elective thoracic surgery. Only subtle enhancement of visualisation and a higher incidence of hoarseness were observed in the Airtraq group. The Airtraq device did not result in superior patient safety in this setting.

Bhandari G. and Shahi KS[31] in 2014 conducted a comparative study in tracheal intubation between Airtraq and Macintosh laryngoscopes. 80 Patients, 40 patients in each group were intubated with the respective devices after induction of general anesthesia. They found that Airtraq was better than the Macintosh laryngoscope as duration of successful intubation was shorter in Airtraq 18.15 seconds (±2.74) and in the Macintosh laryngoscope it was 32.72 seconds (±8.31) $P < 0.001$. POGO was also better in the Airtraq group 100% grade 1 versus 67.5% in the Macintosh group, $P < 0.001$. Ease of intubation was also better in the Airtraq group. It was easy in 97.5% versus 42.5% in the Macintosh group, $P < 0.001$.

Younus S. et al.[32] in 2014 conducted a randomised, cross-over, open-labelled study to evaluate the effectiveness of Airtraq in comparison with the Mc Coy laryngoscope in 60 ASA I and II patients aged between 20 and 50 years, belonging to either gender, scheduled to undergo elective surgical procedures, when performing tracheal intubation in patients with neck immobilization using rigid cervical collar and manual in-line axial cervical spine stabilization. Following induction and adequate muscle relaxation, they were intubated using either of the techniques first, followed by the other. Intubation time and Intubation Difficulty

Score (IDS) were noted using Mc Coy laryngoscope and Airtraq. The mean intubation time was 33.27 sec (13.25) for laryngoscopy and 28.95 sec (18.53) for Airtraq (*P*=0.32). The median IDS values were 4 (interquartile range (IQR) 1–6) and 0 (IQR 0–1) for laryngoscopy and Airtraq, respectively (*P*=0.007). The median Cormack Lehane glottic view grade was 3 (IQR 2–4) and 1 (IQR 1–1) for laryngoscopy and Airtraq, respectively (*P*=0.003). The authors concluded that Airtraq improves the ease of intubation significantly when compared to Mc Coy blade in patients immobilised with cervical collar and manual in-line stabilisation simulating cervical spine injury.

Yi J et al.[33] conducted a prospective randomized trial in 2015 Comparing Airtraq laryngoscope and the GlideScope for double-lumen tube intubation in patients with predicted normal airways. 70 ASA physical status I and II patients with predicted normal airway were scheduled for thoracic surgeries with double-lumen tube intubation. They were randomly assigned to one of two groups and intubated with either the Airtraq laryngoscope (group A, n = 35) or the GlideScope (group G, n=35). They found that the intubation time of group A was shorter than that of group G (36.6 ± 20.2 s vs. 54.6 ± 25.7 s, p = 0.002). The Cormack-Lehane grade (I/II/III/IV) was significantly better in group A (33/2/0/0 vs. 28/7/0/0, p = 0.042). The mean arterial pressure and heart rate rose to higher levels during intubation with the GlideScope than with the Airtraq laryngoscope. The success of the first intubation attempt and the intubation difficulty scales were comparable between the two groups. The numbers of patients who experienced postoperative sore throat were similar (6 vs. 8) in the two groups.

Gómez-Ríos MÁ et al.[34] in 2016 conducted a randomised crossover trial comparing the Airtraq® NT, McGrath® MAC and Macintosh laryngoscopes for nasotracheal intubation of simulated easy and difficult airways in a manikin. Sixty-three anaesthetists were recruited into a randomised trial in which each performed nasotracheal intubation with all laryngoscopes, in both scenarios. They found that Intubation time was significantly shorter using the McGrath MAC in both scenarios and using the Airtraq in the difficult scenario, when compared with the Macintosh laryngoscope. Both devices gave more Cormack and Lehane grade 1 or 2 views than the Macintosh in the difficult scenario ($p<0.001$). The McGrath MAC had the best first-attempt success rate (98.4% vs. 96.8% and 95.8%, $p < 0.001$ for the Airtraq NT and Macintosh laryngoscopes respectively). The number of optimisation manoeuvres, audible dental clicks and subjective assessment of the degree of force applied were significantly lower for indirect laryngoscopes versus the Macintosh laryngoscope ($p<0.001$).

Laryngoscopy and tracheal intubation are noxious stimuli that provoke a transient but marked sympathetic response, manifesting as tachycardia and hypertension. King et al.[35] in 1951 observed Laryngeal and tracheal stimulation caused tachycardia and rise in blood pressure in normotensive patients. These were interpreted as a result of reflex sympathoadrenal response. These responses are transitory, variable and are much more pronounced in hypertensive than in normotensive individuals.

Tolon MA. et al.[29] in their comparative study between the use of Macintosh laryngoscope and Airtraq in 40 adult ASA I and II patients with cervical spine immobilization observed that both heart rate and mean arterial blood pressure did not show statistically significant changes during the intubation with airtraq laryngoscope (AL) while with Macintosh laryngoscope (ML), there was statistically significant increase in heart rate and mean arterial blood pressure at all periods following intubation when compared to the preinduction values. On comparing the two groups together; the AL resulted in significantly less stimulation of heart rate and blood pressure after tracheal intubation in comparison with the ML.

BASIC SCIENCES

Anatomy of upper airway[36-40]

Pharynx

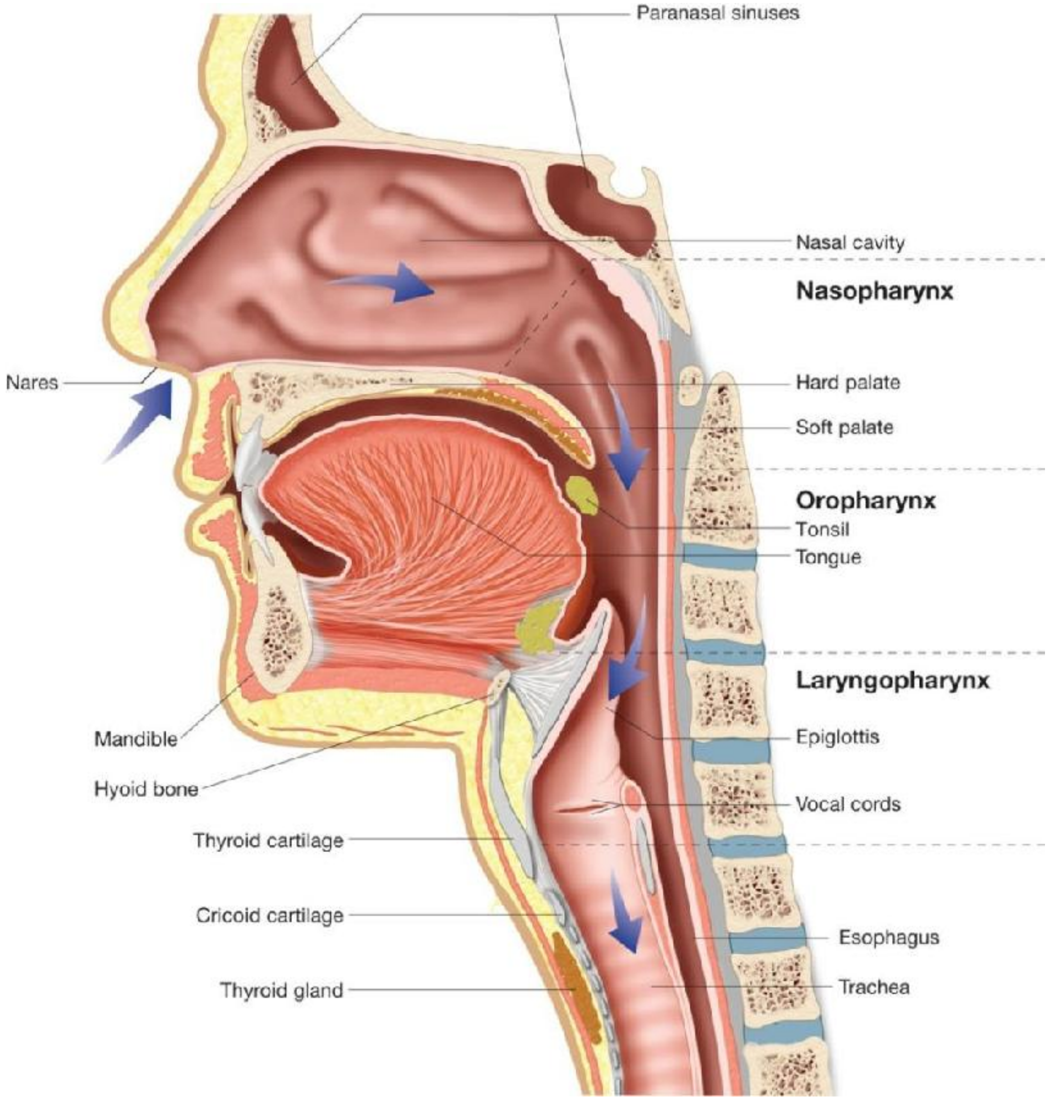


Figure 1. Anatomy of pharynx

The pharynx is a 12-14 cm long musculo membranous tube shaped like an inverted cone. It extends from the cranial base to the lower border of the cricoid cartilage (the level of the sixth cervical vertebra), where it becomes continuous with the oesophagus.

Parts of the pharynx:

The cavity of the pharynx is divided into;

1. The nasal part, nasopharynx.
2. The oral part, oropharynx.
3. The laryngeal part, laryngopharynx.

Nasopharynx

The nasopharynx lies above the soft palate and behind the posterior nares, which allow free respiratory passage between the nasal cavities and the nasopharynx. On the either side, each lateral wall receives the opening of eustachian tube.

Oropharynx

The oropharynx extends from below the soft palate to the upper border of the epiglottis. It opens into the mouth through the oropharyngeal isthmus, demarcated by the palatoglossal arch and its lateral wall consists of the palato pharyngeal arch and palatine tonsil.

Laryngopharynx

The laryngopharynx is situated behind the entire length of the larynx and extends from the superior border of the epiglottis, where it is delineated from the oropharynx by the lateral glossoepiglottic folds, to the inferior border of the cricoid cartilage, where it becomes continues with the oesophagus.

A small piriform fossa lies on each side of the laryngeal inlet, bounded medially by the aryepiglottic folds and laterally by the thyroid cartilage and thyrohyoid membrane.

Muscles of the pharynx

Beneath the mucosa of pharynx is a fibromuscular sheath, fibrous layer being dense superiorly where muscle is absent. The three constrictors: superior, middle and inferior are so arranged that the inferior overlaps middle which in turn overlaps the superior. The longitudinal muscle coat of pharynx consists of stylopharyngeus, salpingopharyngeus and palatopharyngeus.

Nerve supply

Motor: Glossopharyngeal nerve, cranial part of accessory nerve via pharyngeal plexus.

Sensory: General sensation is carried by the pharyngeal branches of glossopharyngeal nerve and palatine branches of maxillary nerve. The special sensation of taste is carried in the lesser petrosal nerve to the pterygopalatine ganglion, which also supplies secretomotor innervations to the pharyngeal mucosa.

Arterial supply

Ascending pharyngeal, superior thyroid, lingual, facial and maxillary arteries (branches of external carotid artery).

Venous drainage

Pterygoid and pharyngeal plexus of veins.

Lymphatic drainage

Retropharyngeal and upper deep cervical lymph nodes

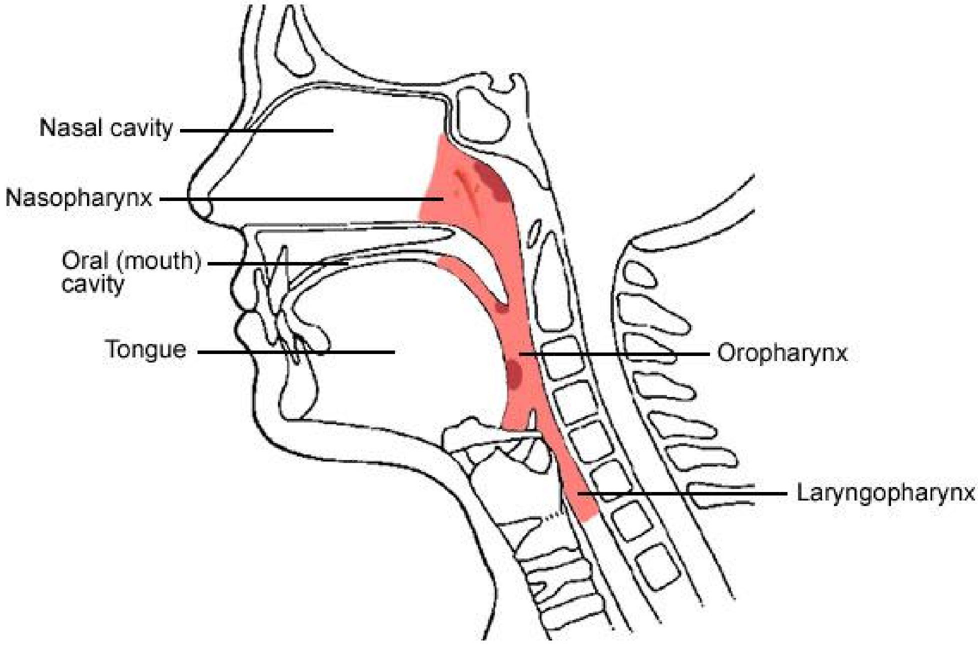


Figure 2. Anatomy of pharynx

Larynx

Situation and extent

Larynx lies in the anterior midline of the neck. It lies opposite the 4th, 5th and 6^{th} cervical vertebrae. Larynx is made up of skeletal framework of cartilages, connected by joints, ligaments and membranes. The cartilages are moved by various muscles.

The laryngeal cartilages

The principal cartilages are the thyroid, cricoid and the paired arytenoids, together with the epiglottis. In addition, there are the small corniculate and cuneiform cartilages. The thyroid cartilage is shield-like and consists of two laminae that meet in the midline inferiorly. This junction is well marked in the male, forming the laryngeal prominence or Adam‟s apple. On the inner side of this fusion line, are attached the vestibular ligaments and below them, the vocal ligament.

False and true vocal cords

The quadrangular membrane extends in the aryepiglottic fold between the arytenoids and the epiglottis. The lower free border of membrane is called vestibular ligament and forms vestibular folds or false cords. The cricovocal membrane is attached below to the upper border of the cricoid cartilage, and above is stretched between the mid-point of the laryngeal prominence of the thyroid cartilage anteriorly and the vocal process of the arytenoid behind. The free upper border of this membrane constitutes the vocal ligament, the framework of the true vocal cord.

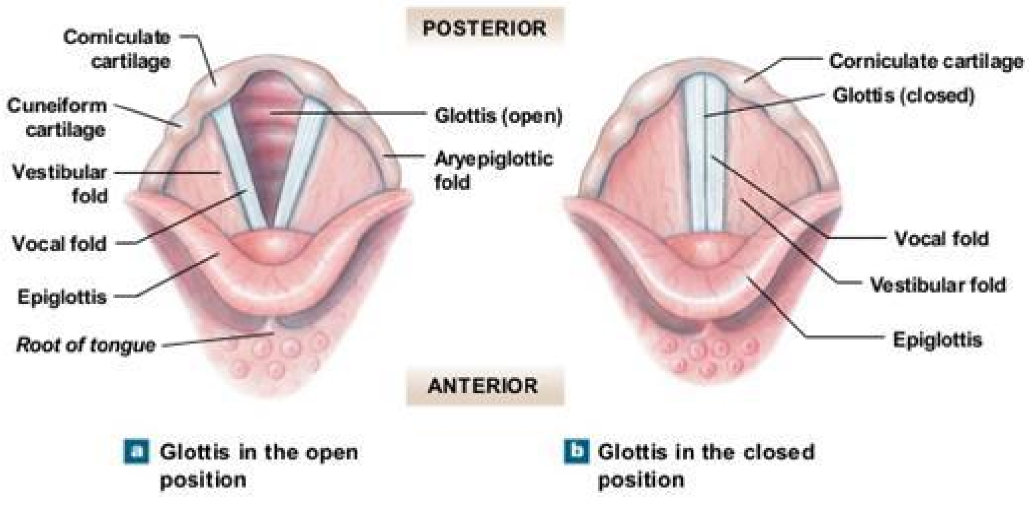


Figure 3. Vocal cords

Cavity of larynx

It is bound anteriorly by the epiglottis, posteriorly by interarytenoid fold of mucous membrane, and on each side by aryepiglottic fold. The area extending from the laryngeal inlet to the vestibular folds is known as vestibular or supraglottic larynx. The laryngeal space from the free border of cords to inferior border of cricoid is called infraglottic or subglottic space. The region between vestibular folds and vocal cords is termed as ventricle. The piriform sinus lies lateral to the aryepiglottic fold within the inner surface of the thyroid cartilage.

Nerve supply

The nerve supply of the larynx is from the vagus via its superior and recurrent laryngeal branches. The superior laryngeal nerve passes deep to both the internal and external carotid arteries and divides into a small external branch, which supplies the cricothyroid muscle, and a larger internal branch that pierces the thyrohyoid membrane to provide the sensory supply to the interior of the larynx as far down as the vocal cords. The internal laryngeal nerve runs beneath the mucosa of the piriform fossa. In this position it can easily be blocked by the topical application of local anesthetic to provide anesthesia for laryngoscopy and bronchoscopy.

The recurrent laryngeal nerve, on the right side, crosses the right subclavian artery; it then loops under the artery and ascends to the larynx in the groove between the esophagus and trachea. On the left side, it crosses the aortic arch; the nerve then passes under the arch to reach the groove between the esophagus and the trachea. Once it reaches the neck, the left nerve assumes the same relationships as on the right. The recurrent laryngeal nerves provide the motor supply to the intrinsic muscles of the larynx apart from cricothyroid, as well as sensory supply to the laryngeal mucosa inferior to the vocal cords.

Autonomic innervation of pharynx: Nerve supply to pharynx is derived from pharyngeal plexus which is formed from the branches of glossopharyngeal, vagus and sympathetic (from superior cervical ganglia) nerves

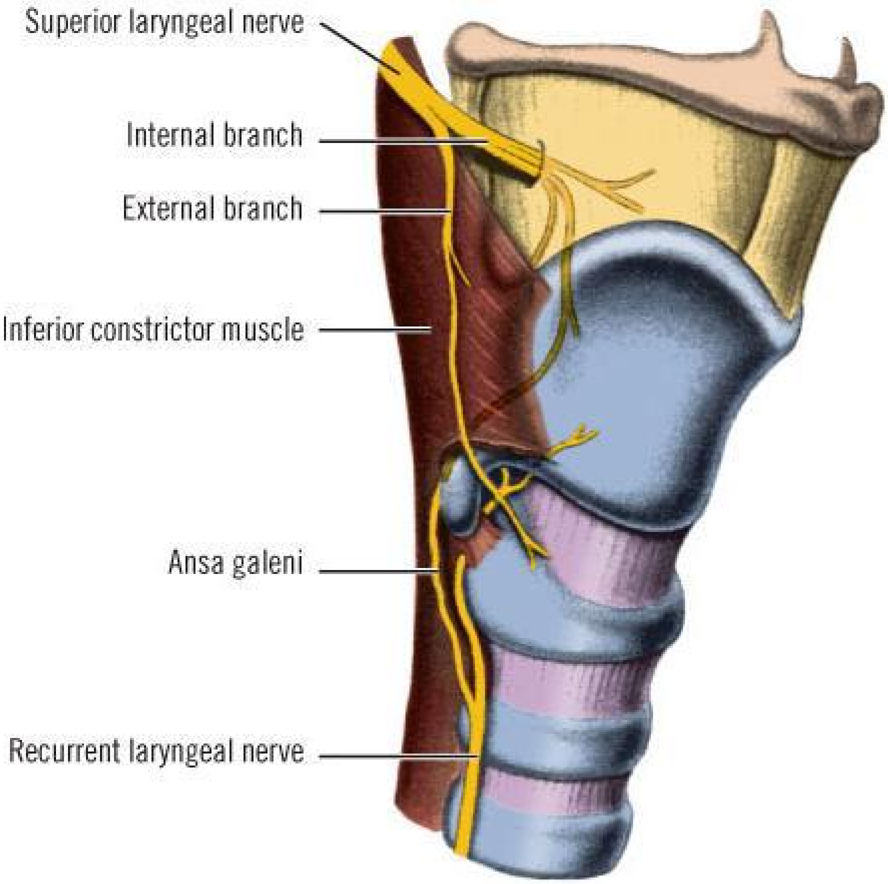


Figure 4. Nerve supply of larynx

The larynx is an air passage, a sphincter and an organ of phonation, and extends from the tongue to the trachea. Above it opens into the laryngopharynx and forms its anterior wall; below, it continues into trachea. It is mobile on deglutition.

At rest, the larynx lies opposite the third to sixth cervical vertebrae in adult males; it is somewhat higher in children and adult females.

The skeletal framework of the larynx is formed by a series of cartilages interconnected by ligaments and fibrous membranes, and moved by a number of muscles.

Cartilages of larynx

Unpaired cartilages

1. Thyroid
2. Cricoid
3. Epiglottis

Paired cartilages

1. Arytenoids
2. Corniculate
3. Cuneiform

Laryngeal joints (Synovial joints)

1. Cricothyroid joint
2. Cricoarytenoid joint

Laryngeal ligaments and membranes

Extrinsic

1. Thyrohyoid membrane

2. Hyo- and thyroepiglottic ligaments
3. Cricotracheal ligament

Intrinsic

1. Quadrate membrane (Fibroelastic membrane of the larynx)
2. Cricothyroid membrane and Conus elasticus

Cavity of larynx

Two folds of mucous membrane divide the cavity of the larynx into three parts

1. Vestibule of the larynx
2. Ventricle of the larynx
3. Infraglottic part

Intrinsic muscles of larynx

1. Oblique arytenoid and Aryepiglotticus – Sphincter action at the laryngeal inlet
2. Transverse(Inter) arytenoids – adductor of vocal cords.
3. Posterior cricoarytenoid – opens the glottis.
4. Lateral cricoarytenoid – adducts the vocal cords.
5. Cricothyroid – lengthens and affects tension in the vocal cords.
6. Thyroarytenoid and Vocalis – relaxes the vocal cords.
7. Thyroepiglotticus – opens the inlet of the larynx

Extrinsic muscles of larynx

Include the intrahyoid strap muscles, thyrohyoid, sternohyoid and the inferior constrictor of the pharynx.

Nerve supply

Motor: Vagus nerve via recurrent laryngeal nerve to all intrinsic muscles except cricothyroid (supplied by external laryngeal nerve).

Sensory: Mucosal membrane is supplied by internal laryngeal nerve upto the level of vocal cords and recurrent laryngeal nerve below the level of the vocal cords.

Taste fibres from the epiglottis are carried in the vagus nerve.

Arterial supply

1. Superior laryngeal artery and cricothyroid artery (branches of superior thyroid artery)

2. Inferior laryngeal artery (branch of inferior thyroid artery)

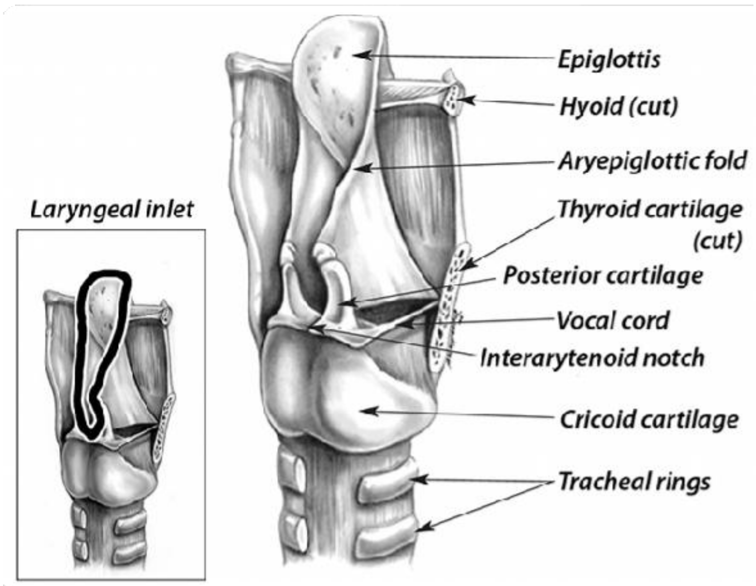


Figure 5. Anatomy of larynx

Venous drainage

Via superior and inferior laryngeal veins to superior and inferior thyroid veins respectively.

Lymphatic drainage

The lymph vessels draining the supra glottic part of the larynx end in the upper deep cervical lymph nodes and below the vocal cords, lymph vessels reach pre and para tracheal lymph nodes and join the lower deep cervical lymph nodes.

PHYSIOLOGY OF HAEMODYNAMIC RESPONSE[41-43]

Sympatho-adrenal system regulates the body's response to combat any stress. Noradrenaline and adrenaline are the neurotransmitters of the sympathoadrenal system. Normal basal secretion by adrenal medulla of adrenaline is 0.2µg/kg/minute and that of noradrenaline is 0.05µg/kg/minute which are adequate to maintain the body physiology. The sympathoadrenal system is stimulated by hypothalamus in situations of stress, resulting in an increase in the catecholamine secretion.

The sympathetic system in response to stress acts to increase heart rate, blood pressure, cardiac output, dilates bronchial tree and shunts blood away from skin and viscera to muscles.

A powerful noxious stimulus like laryngoscopy and tracheal intubation induces hypothalamic activity and results in an increased outflow in the sympathetic tracts. Consequently norepinephrine is released by post ganglionic sympathetic fibers and increased secretion from adrenal medulla. Several attempts have been made to assess sympathetic activity directly by measurement of plasma catecholamine concentrations with the use of radio enzymatic assays and high pressure liquid chromatography, by various authors. Russell WJ and Mortis RG found that the magnitude of increase in blood pressure paralleled the increase in plasma noradrenaline concentration. The adrenergic response was maximum by one minute and had diminished by 5 minutes. This hemodynamic response was due to activation of sympatho-adrenal system mediated increase in heart rate, blood pressure and these serve as indirect indices to measure the response. Thus heart rate and blood pressure have been used as indirect indices to measure levels of sympathetic activity clinically.

In addition to activation of the autonomic nervous system, endotracheal intubation also stimulates central nervous system activity as evidenced by increase in electroencephalographic activity and basal metabolic rate. In patients with compromised intracranial compliance, the increase in cerebral blood flow (CBF) may result in elevated intra cranial pressure which in turn may result in herniation of brain contents and severe neurologic deterioration.

Laryngoscopy alone, without intubation provides a supraglottic pressure stimulus with significant increases in both systolic and diastolic pressures above the pre-induction control levels.

The act of intubation and placement of an endotracheal tube in the trachea stimulates infraglottic receptors and evokes an additional cardiovascular response with a further increase in catecholamines. The pressor response is much greater, increasing by 36% from pre-induction control levels. The heart rate also significantly increases by about 20% with the act of tracheal intubation.

The most common adverse cardiovascular problem related to intubation is myocardial ischemia in patients with coronary artery insufficiency. The major determinants of myocardial oxygen demand are heart rate and blood pressure and when endotracheal intubation causes marked increase in arterial pressure and heart rate, the increase in myocardial oxygen demand must be met by an increase in supply of oxygenated blood through coronary circulation. When one or more occlusive coronary lesions results in relatively fixed coronary blood flow, ability to increase myocardial oxygen supply during periods of increased demand is minimal and abrupt increase in myocardial demand results in tissue ischemia that can result in myocardial dysfunction or overt tissue infarction. Furthermore, ischemia induced by arterial hypertension may be compounded by increase in left ventricular end-diastolic pressure resulting in further compromise of perfusion to subendocardial tissue. These circumstances are responsible for episodes of ST segment depression in ECG and increased pulmonary artery diastolic pressure in patients with atherosclerosis. Occasionally these episodes predispose to the occurrence of perioperative myocardial infarction. Patients with vascular anomalies that cause weakening of lining of major arteries are at risk during endotracheal intubation. Integrity of cerebral and aortic aneurysms is largely a function of transmural pressure; a sudden increase in blood pressure can lead to rupture of vessel and abrupt deterioration of patient's status.

Predictors of difficult intubation

Unanticipated difficult intubation can be challenging to anesthesiologists. Numerous investigators have attempted to predict difficult intubation by using a simple bedside physical examination. In 1985 Mallampati introduced a currently well-known screening test that classifies visibility of the oropharyngeal structures. The distance from the thyroid notch to the mentum (thyromental distance), the distance from the upper border of the manubrium sterni to the mentum (sternomental distance),and a simple summation of risk factors (Wilson risk sum score) are widely recognized as tools for predicting difficult intubation. Nevertheless, the diagnostic accuracy of these screening tests has varied from trial to trial, probably because of differences in the incidence of difficult intubation, inadequate statistical power, different test thresholds, or differences in patient characteristics.[47]

Modified Mallampati test

Mallampati test is the most commonly employed bedside test for airway assessment. It indicates the amount of space within the oral cavity to accommodate the laryngoscope and endotracheal tube. This is performed by having the patient head in neutral position with mouth open as wide as possible and protrude the tongue without phonation. The observer‟s eye should be at the level of patient‟s mouth. The degree to which faucial pillars, uvula, soft palate and hard palate are visible is observed. Samsoon and Young modified Mallampati grading to 4 grades.[45,46] As per modification of Mallampati grading, following 4 grades may be noted:

Class I:Faucial pillars, uvula, soft and hard palate visible

Class II: Uvula, soft and hard palate visible

Class III: Soft and hard palate visible

Class IV: Hard palate visible.

Class III and IV are associated with difficult intubation.

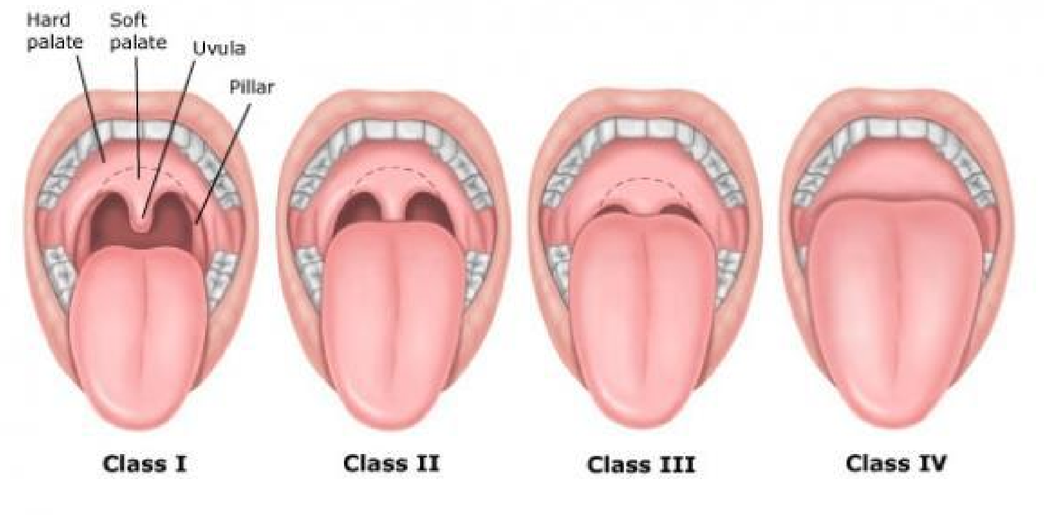


Figure 6. Modified Mallampati Classification[45,46]

Assessment of intubation difficulty

The efficacy of direct laryngoscopy is measured in terms of the best view of the vocal cords which can be achieved. The degree of difficulty encountered during direct laryngoscopy and intubation is most commonly assessed using Cormack and Lehane grading. The other indicators include POGO (Percentage Of Glottic Opening) and Intubation Difficulty Scale (IDS) score, a quantitative scale of difficult intubation with seven variables assessing the complexity of tracheal intubation, developed by Adnet et al.[47]

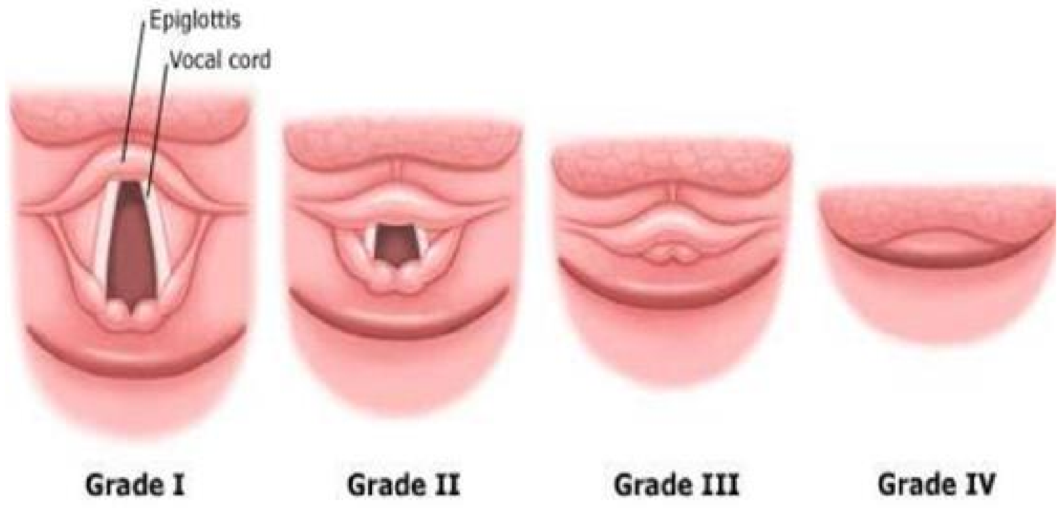
Cormack and lehane classification

Cormack and Lehane classification helps in assessing the quality of glottic opening visualization during conventional laryngoscopy and intubation. It is also the measure of efficacy of direct laryngoscopy in terms of the best view of the larynx achieved. The Cormack and Lehane grading system, although originally designed to compare glottic views at direct laryngoscopy, provides useful comparison of the direct and indirect laryngoscopic views achieved.[48]

Cormack and Lehane classification

- Grade I: Visualization of entire vocal cords.
- Grade II: Visulization of posterior part of the laryngeal aperture.
- Grade III: Visulization of epiglottis
- Grade IV: No glottic structure seen
- Cook (1999) has further subdivided Cormack and Lehane‟s Grade II and III as IIa, IIb, IIIa and IIIb where
- IIa - visualization of posterior part of vocal cord
- IIb – visualization of arytenoids only
- IIIa - epiglottis liftable
- IIIb - epiglottis adherent or only tip visible.

As per Cook, Grade I and IIa patients can be directly intubated, IIb and IIIa would require intubating aids like bougie ,stylet, lightwand., while IIIb andIV cannot be intubated using conventional laryngoscope but would require alternative specialized techniques and equipments.[49]



Figurre 7. Cormack and Lehane grading[49]

Macintosh laryngoscope[19]

The Macintosh curved laryngoscope is a type of rigid laryngoscope described in 1943 and is the most commonly used laryngoscope in day to day practice. The blade is curved, the cross section is a right angled Z section, tip is atraumatic. Macintosh's key innovation was his novel technique of indirect elevation of the epiglottis, achieved by tensioning the hyoepiglottic ligament after the laryngoscope tip has been positioned in the vallecula.

<u>Handle</u>

The handle is the part held in the hand during use. Disposable batteries in the handle provide the power source to the light. Handle accepts the blade making a metallic contact, which completes an electrical circuit when the handle and blade are in working position. Handles are available in several sizes. The surface is usually rough for improved grip. Short handles may be advantageous for patients in whom the chest and/or breast contact the handle during use, when cricoid pressure is being applied, or when the patient is in a body cast.

Although most blades form right angle with the handle when ready for use, the angle may also acute or obtuse. An adapter may be fitted between the handle and the blade to allow the angle to be altered.

<u>Blade</u>

The blade is the component that is inserted into the mouth. the blades are numbered, the number increasing with size. The blade is composed of several parts including the base, heel, tongue. flange, web, tip and the light source. The base is the part that attaches to the handle. it has a slot for engaging the hinge pin of the handle. The end of the base is called the heel. The tongue (spatula) is the main shaft. It serves to compress and manipulate the soft tissues especially the tongue and lower jaw. In Macintosh blade the tongue has gentle curve that extends to the tip. In cross section, the tongue, web and the flange forms a reverse.

The flange projects off the side of the tongue and is connected to it by the web. It serves to guide instrumentation and deflect the tissues from the line of vision.

The tip contacts the vallecula and indirectly elevates the epiglottis. It is usually blunt and thickened to decrease the trauma.

The blade has a lamp (bulb) which screws into a socket that has a metallic contact. When the blade is in the working position, electrical contact with the power source in the handle is achieved. The socket is subject to soiling by fluids that can affect the electrical contacts, causing the light to fail.

Numerous modifications have been suggested to the conventional Macintosh blade like Left handed Macintosh blade, English Macintosh, Polio blade, Improved vision Macintosh blade, Tull(suction) Macintosh blade.[50]

Figure 8. Laryngoscope handle [19]

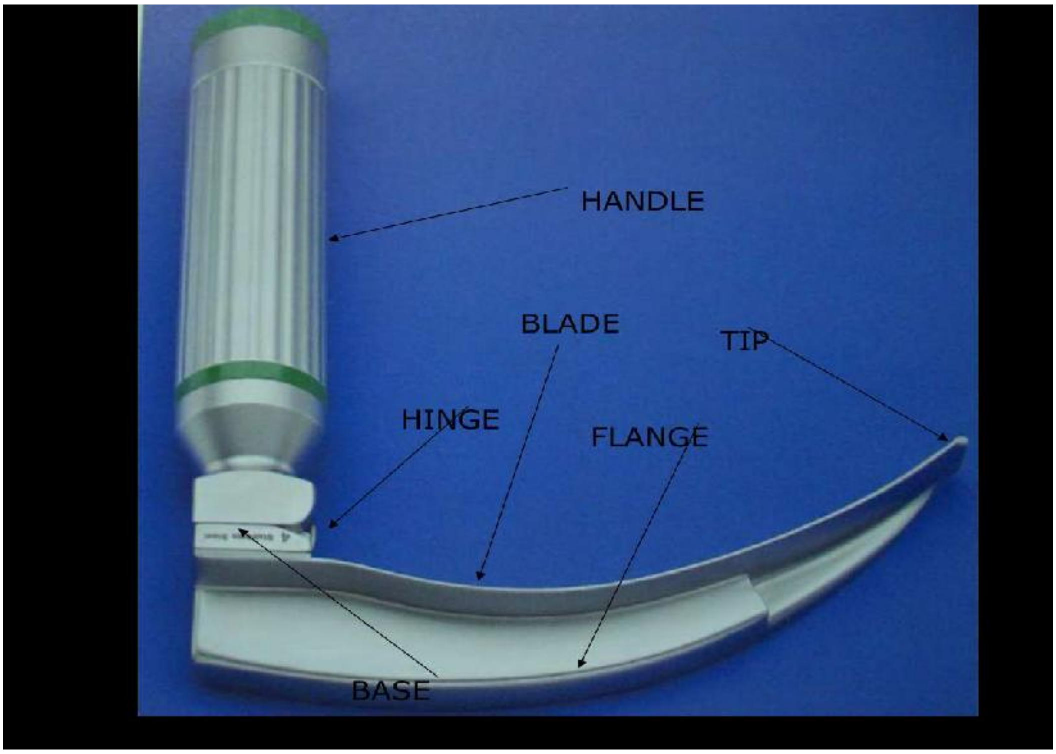


Figure 9. Macintosh laryngoscope handle and blade

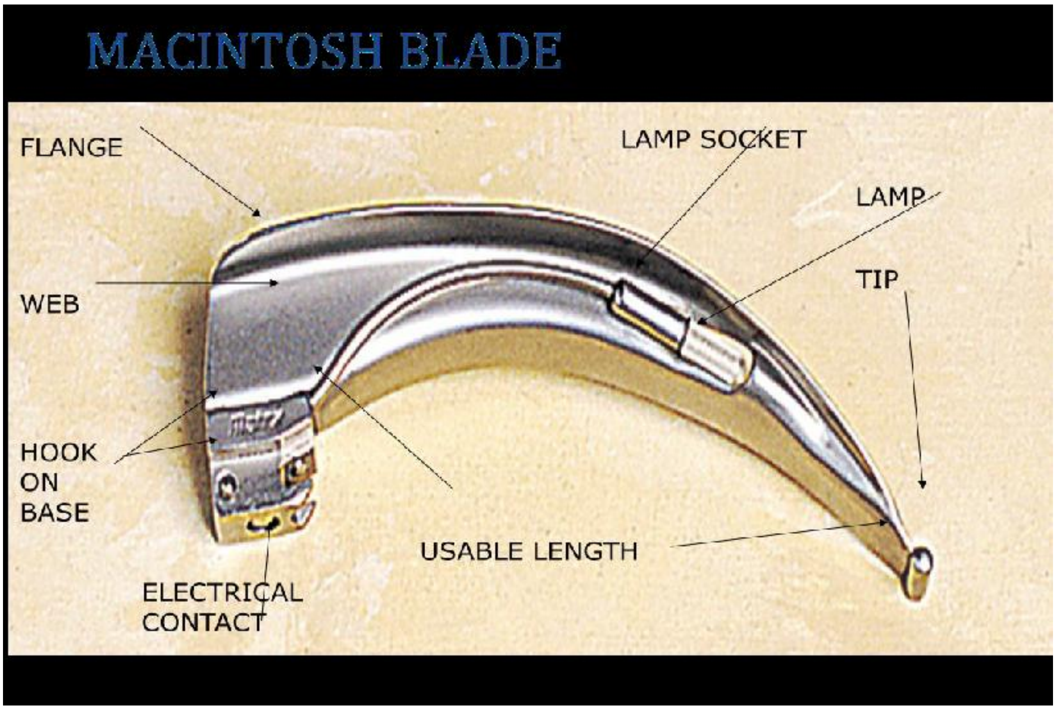


Figure 10. Laryngoscope blade[19]

Positioning for direct laryngoscopy

The optimum position for direct laryngoscopy has long been controversial. The concept of 'SNIFFING' position was introduced by Magill.[51] The triple axis alignment was first proposed by Bannister (an anesthetist) and MacBeth (an ENT surgeon) in 1944.[52] They suggested that positioning with flexion at lower cervical spine and extension at atlanto occipital joint aligned the axis of oral cavity, pharynx and larynx.

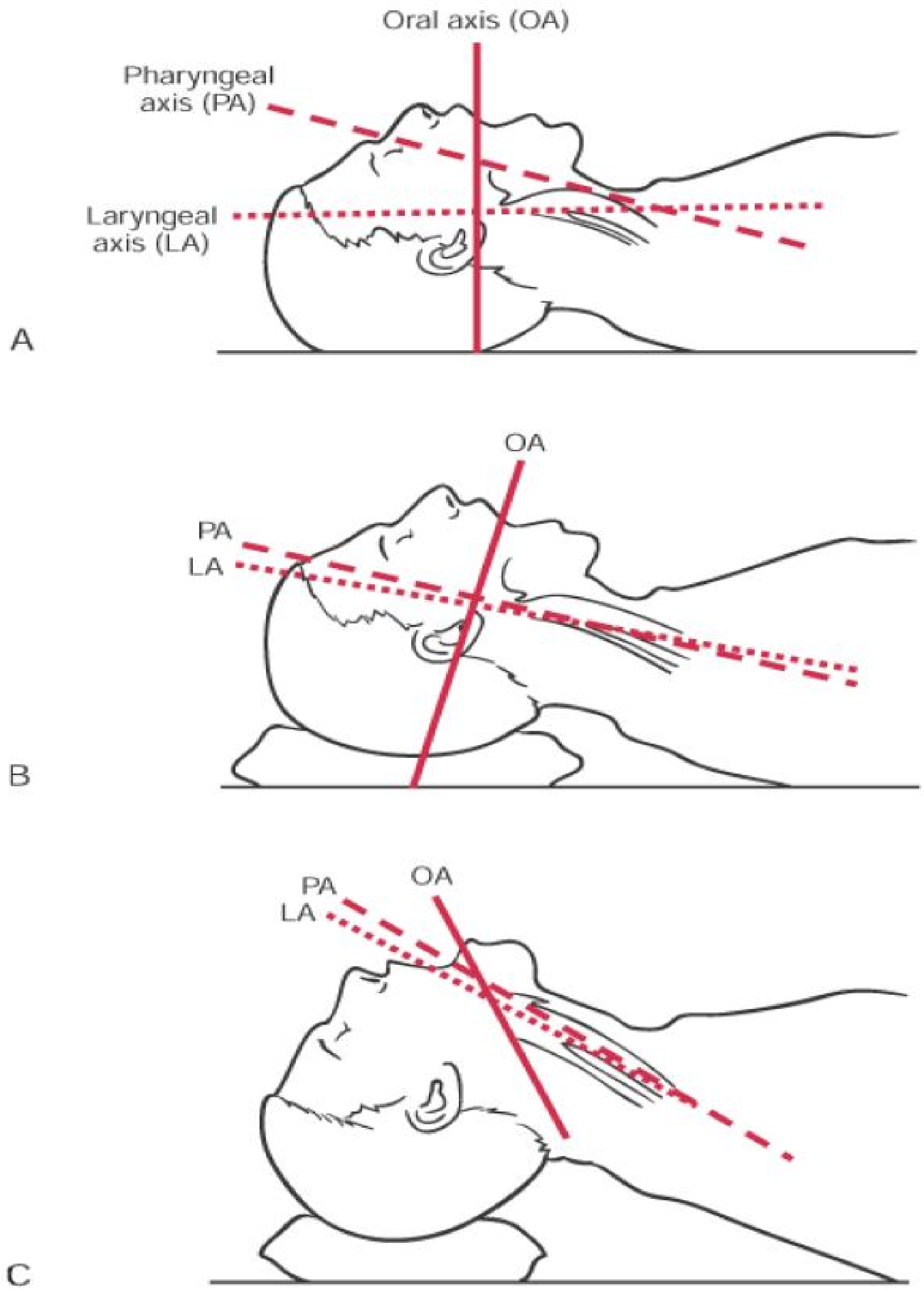


Figure 11. Positioning for direct laryngoscopy[15]

Macintosh laryngoscopy technique

The patient's head and neck are correctly positioned so that the three axis of the airway have been established and the patient has assumed the "sniffing" position.

The laryngoscope handle is normally held in the left hand. The laryngoscope is inserted into the right side of patient's mouth, with pushing the tongue towards left. Care is taken in that the lips are not trapped between the laryngoscope blade and the teeth. The laryngoscope is advanced and simultaneously moved medially into the midline to displace entire tongue to the left of midline. Visualization of anatomical structures are essential to minimize the risk of trauma. The first anatomical landmark is the epiglottis. The tip of the blade of the laryngoscope is applied to the posterior surface of the epiglottis, and when the tip of the blade is at the valeculla (the space between base of tongue and pharyngeal surface of epiglottis) a forward and upward movement of the handle of the laryngoscope causes the epiglottis to move upwards and vocal cords are visualized.

Manoeuvres to improve the glottic view

First, it is necessary to check for proper positioning, adjustments to the depth of insertion of laryngoscope. The lifting force applied to the laryngoscope should be adjusted in the direction and magnitude to optimise the view. The most important additional manoeuvre is external laryngeal manipulation. Benumof found that the technique, which he called Optimal External Laryngeal Manipulation (OELM),[53] could consistently improve the laryngeal grade by one grade. He stressed the importance of the manipulation being performed with the right hand of airway practitioner, who then guides an assistant to provide identical manipulation.

Backward Upward Right Pressure (BURP)[54] applied to the larynx is of proven value in improving the glottic view. OELM describes the technique better as the force and direction are adjusted by the airway practitioner. The better term is probably Bimanual laryngoscopy as it emphasizes the coordinated internal movement of the laryngoscope with the external manipulation of the larynx.

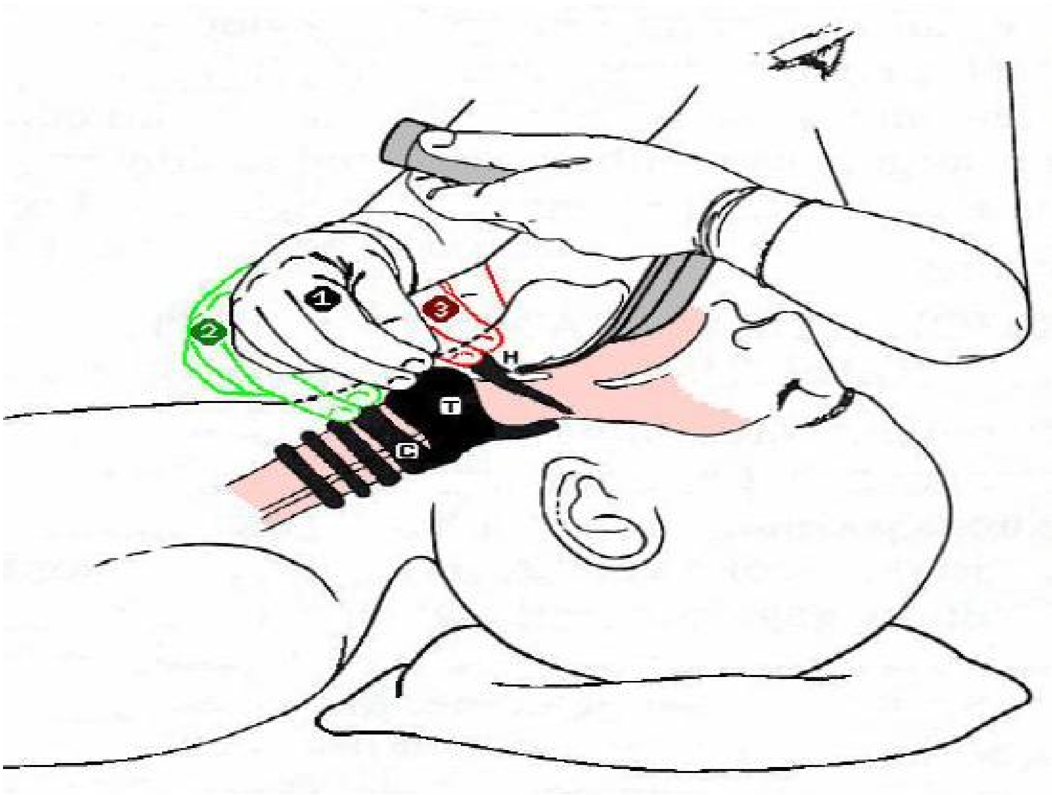


Figure 12. Optimum external laryngeal manipulation[19]

Airtraq layngoscope[29,55]

The Airtraq (Prodol Meditec SA, Spain) laryngoscope is designed to facilitate tracheal intubation in patients with normal and difficult airways. It is an anatomically shaped optical laryngoscope with two separate channels: the optical channel, which contains a high definition optical system and the guiding channel, which holds the endotracheal tube and guides it through the vocal cords. A battery-operated low temperature LED at the tip of the blade provides illumination. It is available in different sizes. The image is transmitted to a proximal view finder through a combination of lenses and a prism which allows the visualization of the glottis, surrounding structures and tip of the tracheal tube. An optional colour videocamera clips onto the proximal viewfinder and transmits the image to a display via a lightweight cable. An anti-fogging system for the lenses is activated by turning on the LED. For the anti-fogging system to be effective, the LED must be switched on at least 30 seconds before use. The airtraq disposable laryngoscope blade is available in following sizes:

- **Regular: Size 3, Blue** (A-511) For use with ETT 7.0 – 8.5. Minimum mouth opening: 17 mm
- **Small: Size 2, Green** (A-521) For use with ETT 6.0 – 7.5. Minimum mouth opening: 17 mm

As a result of exaggerated curvature of blade and an internal arrangement of optical components, a high quality view of glottis and surrounding structures is provided without sniffing position. The Airtraq requires a minimal mouth-opening of 18 mm for the regular size and 16 mm for the small size. To use the Airtraq device, the blade must be inserted into the mouth in the midline, over the centre of the tongue, the tip of the blade is positioned in the vallecula. The epiglottis can be lifted by elevating the blade into the vallecula. The endotracheal tube does not obstruct the view of the vocal cords during intubation. Once the view of glottis has been optimised, the tracheal tube is passed through the vocal cords. the endotracheal tube is then moved lateraly to remove it from the channel, the device is withdrawn and tracheal tube is secured.

The Reverse manoeuvre may facilitate the insertion of Airtraq in morbidly obese patients. For this manoeuvre, the Airtraq is inserted 180° opposite to that recommended and once in place, rotated into the conventional pharyngeal position.

Figure 13. Airtraq video laryngoscope[29,55]

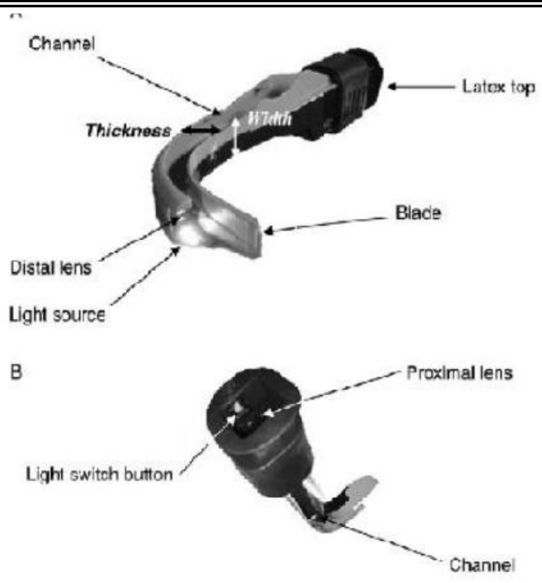


Figure14. Airtraq video laryngoscope[29,55]

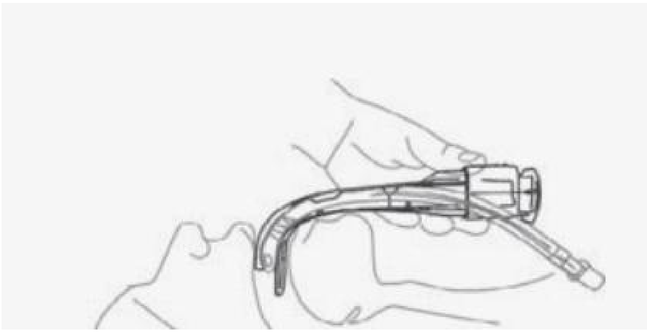


Figure 15. Airtraq video laryngoscope[29,55]

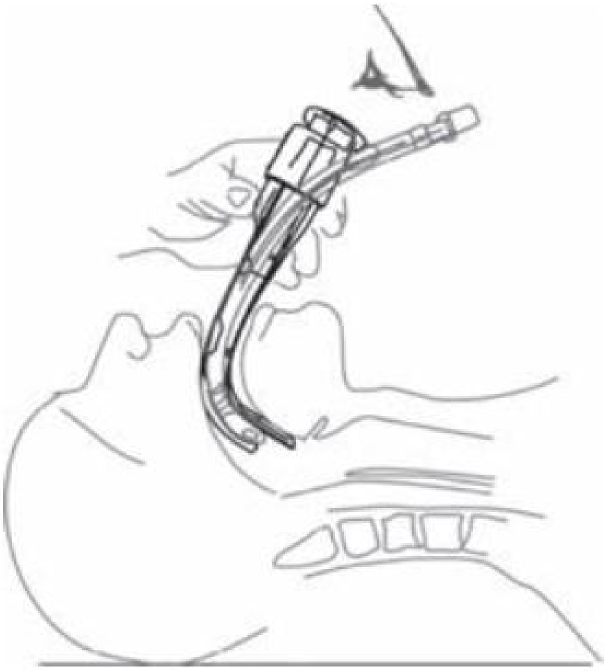


Figure 16. Airtraq Laryngoscopy technique[20,55]

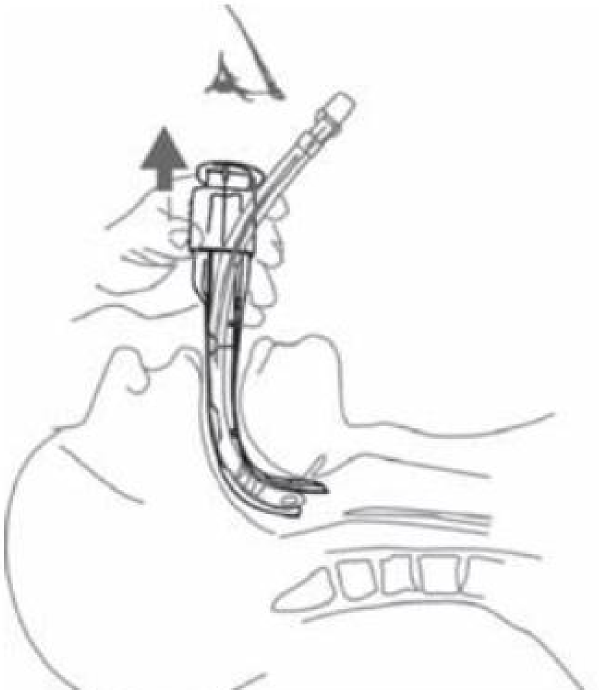


Figure 17. Airtraq Laryngoscopy technique[20,55]

METHODOLOGY

The present study titled “Comparison of the glottic view during intubation using airtraq and macintosh laryngoscopes in adult patients undergoing surgeries under general anaesthesia with a simulated cervical spine immobilization - a one year hospital based randomized control trial” was conducted in the Department of Anaesthesiology, KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, for the period of one year from January 2015 to December 2015.

Selection Criteria

Inclusion criteria

- Patients with ASA physical status I and II.
- Patients of either gender aged between 18 to 60 years.
- Patients undergoing elective surgeries under general anesthesia with oral endotracheal intubation.

Exclusion criteria

- Patient refusal.
- Patients with ASA grade 3 and 4.
- Patients with risk of pulmonary aspiration of gastric contents, pregnant patients, and patients with cervical spine pathology.
- Patients with body mass index (BMI) >30.

Sampling size and sampling method

The sample size was calculated considering the percentage of grade 1 Cormack Lehane views obtained in airtraq group as 86% (p^1) and Macintosh group as 20% (p^0) with type I error rate α = 0.05 and type II error rate β = 0.2 using the following formula

$$\text{Sample Size (n)} = \frac{2 \text{ X } (Z\alpha + Z\beta)^2 \text{ pq}}{(P_0 - P_1)^2}$$

$$\text{Therefoer } n = \frac{2 \text{ X } (1.96 + 0.84)^2 \text{ } 53*47}{(86 - 20)^2}$$

$$n = 8.966$$

With the above mentioned values, the minimum sample size was obtained was 9 for each group. As the sample size obtained by the formula is very low, by thumb rule 30 patients were taken in each group.

Ethical clearance

Prior to the commencement, the ethical clearance was obtained from Institutional Ethics Committee, Jawaharlal Nehru Medical College, Belagavi.

Informed Consent

The patients posted for elective surgeries in supine position, under general anaesthesia in whom tracheal intubation is indicated, and fulfilling selection criteria were briefed about the nature of the study and interventions and a written informed consent was obtained (Annexure I).

Data collection

Demographic data of the patients like name, age, sex and history was obtained through an interview. Visualization of pharyngeal structures and larynx as per Cormack and Lehane grading and hemodynamic response to endotracheal intubation with Airtraq optical laryngoscope, and Macintosh laryngoscope was analyzed. These findings were recorded on predesigned and pretested proforma. The physical and medical examination was conducted. (Annexure-II).

Investigations

Patients underwent following investigations

1. Complete blood picture
2. Mini renal profile
3. Electrocardiogram
4. Chest x ray

Randomization

Patients were randomized based on computerized generated randomization into two groups.

- Group L (n=30) – Macintosh group
- Group A (n=30) – Airtraq group

Procedure

Anaesthetic techniques were standardized for all patients. Preanaesthetic check up was done one day prior to the surgery. Before shifting to the operation theatre Overnight fasting status was confirmed, I.V access was obtained with 18 Gauge I.V cannula. Standard monitoring devices were attached before induction of anaesthesia, including non-invasive arterial blood pressure, ECG, and pulse oximeter saturation. After five minutes of pre oxygenation with a face mask (for adequate oxygen reserve), patients were pre - medicated with injection glycopyrollate -0.005mg/kg, midazolam -0.05mg/kg, pentazocine -0.5mg/kg, and general anaesthesia was induced with thiopentone -5mg/kg and vecuronium-0.1mg/kg. A rigid cervical immobilization collar was applied. The patients were allocated randomly to tracheal intubation with an Airtraq (Group A) or Macintosh laryngoscope (Group L). The randomization was based on computer-generated randomization codes. Three minutes after vecuronium administration, tracheal intubation was performed using one of the study devices.

Tracheal intubation

<u>Group A</u>

In patients allocated to Group A, appropriate size of Airtraq based on the size of ETT to be used was selected. Light was turned on, and time was given for activation of the antifogging system. Appropriate sized ETT with cuff fully deflated was lubricated and placed into the lateral channel of the Airtraq. The tip of the ETT was aligned with the end of the lateral channel. Airtraq was lubricated without contacting the lens. The Airtraq blade was inserted into the mouth in the midline, over the center of the tongue, the tip positioned in the valecula and the laryngoscope was lifted straight up to expose the glottis .Once the view of the glottis has been optimized, the tracheal tube was passed through the vocal cords, tracheal tube was held in place and the device removed. The endotracheal tube was connected to closed circuit. Intubation was confirmed by square wave capnography.

Group L

In patients belonging to group L Macintosh laryngoscope no3. and no.4 was used to obtain the best possible view of the glottis. Tracheal tubes with a 7.5 and 8.5 mm internal diameter for women and men, respectively, were used.

During the procedure heart rate and mean blood pressure at baseline, 1,3, and 5 mins after the intubation were recorded. The best glottic view obtained in both groups were noted according to Cormack – Lehane grading.

Photograph 1. Intubation with Macintosh laryngoscope in patient with rigid cervical collar

Photograph 2. Intubation with Airtraq laryngoscope in patient with rigid cervical collar

Whenever the first attempt for intubation failed, the intubation attempt was terminated and a second attempt was made after mask ventilation for one minute. In the event of failed second attempt, the rigid cervical collar was removed and the patients were intubated under direct vision using a conventional laryngoscope.

No other medications were administered, or procedures performed, during the 5 min data collection period after tracheal intubation. Subsequent management was left to the discretion of the anaesthetist providing care for the patient.

Outcome variables

Cormack and Lehane glottic view obtained by laryngoscopy[56]

Cormack and Lehane grading was done as below

- Grade I: Visualization of entire vocal cords.
- Grade II: Visulization of posterior part of the laryngeal aperture.
- Grade III: Visulization of epiglottis
- Grade IV: No glottic structure seen

Laryngoscpy view

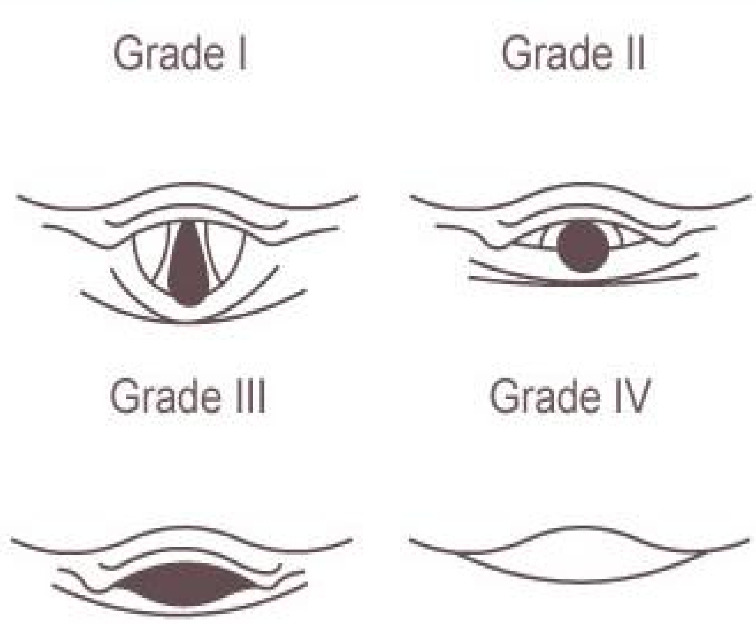


Figure 18. Cormack and Lehane glottic view[56]

Secondary end points were

- Hemodynamic profiles of both the groups including systolic blood pressure, Diastolic blood pressure, Mean arterial pressure and Heart rate were recorded at baseline 1, 3, and 5 minutes after intubation.

Statistical Methods

The data was tabulated on excel spreadsheet and master chart was prepared (Annexure III). The data was analysed using SPSS version 20.0 statistical software. The categorical data was expressed in terms of rates, ratios and percentages and the continuous data was expressed as mean ± standard deviation Significance was tested with allowable error of five percent. Independent sample ‘t’ test was used to find the significance of study parameters on continuous scale between two groups. Chi-square test was used to find association between the classes of variables. A probability value (p value) of less than or equal to 0.050 at 95% confidence interval was considered as statistically significant.

RESULTS

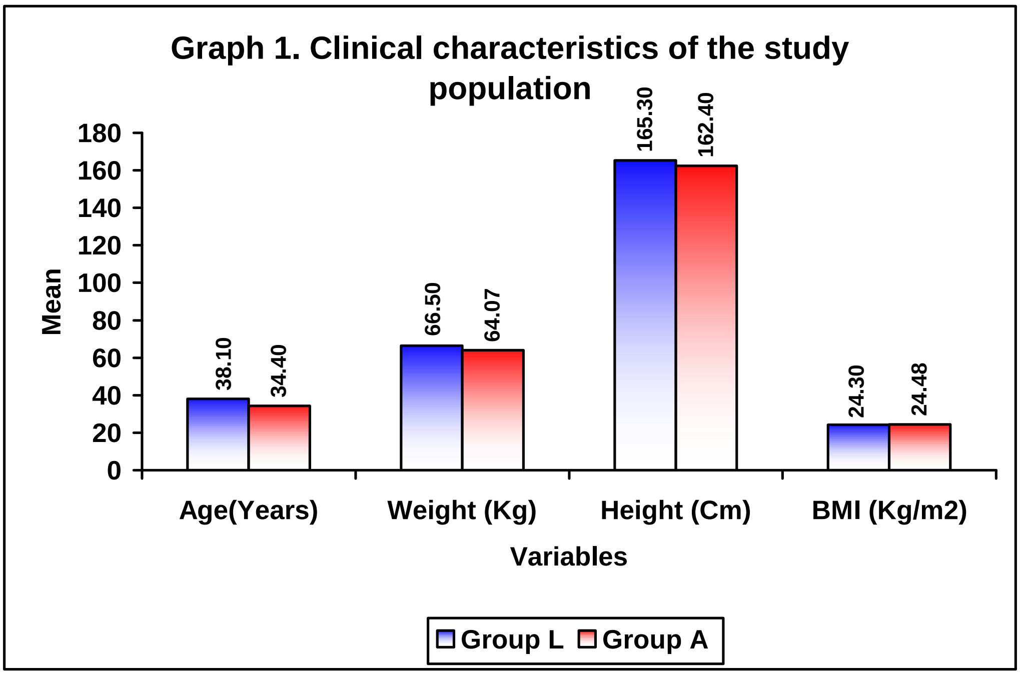
This one year hospital based randomized controlled trial was conducted in the Department of Anaesthesiology, KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, for the period of one year from January 2015 to December 2015. A total of 60 Patients were randomized based on computer generated randomization into two groups as:

- Group L (n=30) – Patients in this group underwent tracheal intubation using Macintosh laryngoscope,
- Group A (n=30) – Patients in this group underwent tracheal intubation using Airtraq video laryngoscope.

The data obtained was coded and entered into the master chart. The data was analyzed and the final results and observations were tabulated as below.

Table 1. Clinical characteristics of the study population

Variables	Group L (n=30)		Group A (n=30)		t	DF	P
	Mean	SD	Mean	SD			
Age (Years)	38.10	9.84	34.40	12.56	1.292	58.00	0.201
Weight (Kg)	66.50	7.51	64.07	4.08	3.178	58.00	0.126
Height (Cm)	165.30	6.83	162.40	6.03	1.783	58.00	0.080
BMI (Kg/m^2)	24.30	2.05	24.48	1.76	2.418	58.00	0.705

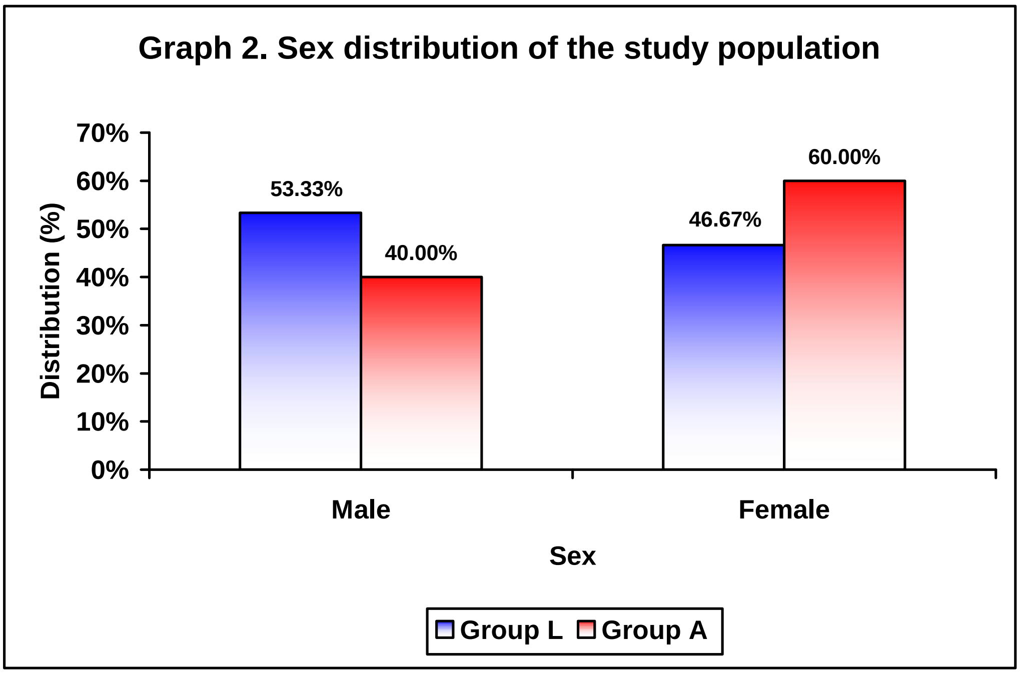


In this study the mean age (38.10 ± 9.84 vs 34.40 ±12.56 years p=0.201), mean weight (66.50 ± 7.51 vs 64.07 ± 4.08 Kg; p=0.126), mean height (165.30 ± 6.83 vs 162.40 ± 6.03 cms; p=0.080) and body mass index (24.30 ± 2.05 vs 24.48 ± 1.76 kg/m^2; p=0.705) were comparable in group L and group A.

Table 2. Sex distribution of the study population

Sex	Group L (n=30)		Group A (n=30)	
	No.	%	No.	%
Male	16	53.33	12	40.00
Female	14	46.67	18	60.00
Total	**30**	**100.00**	**30**	**100.00**

$x^2 = 1.071$ p = 0.301

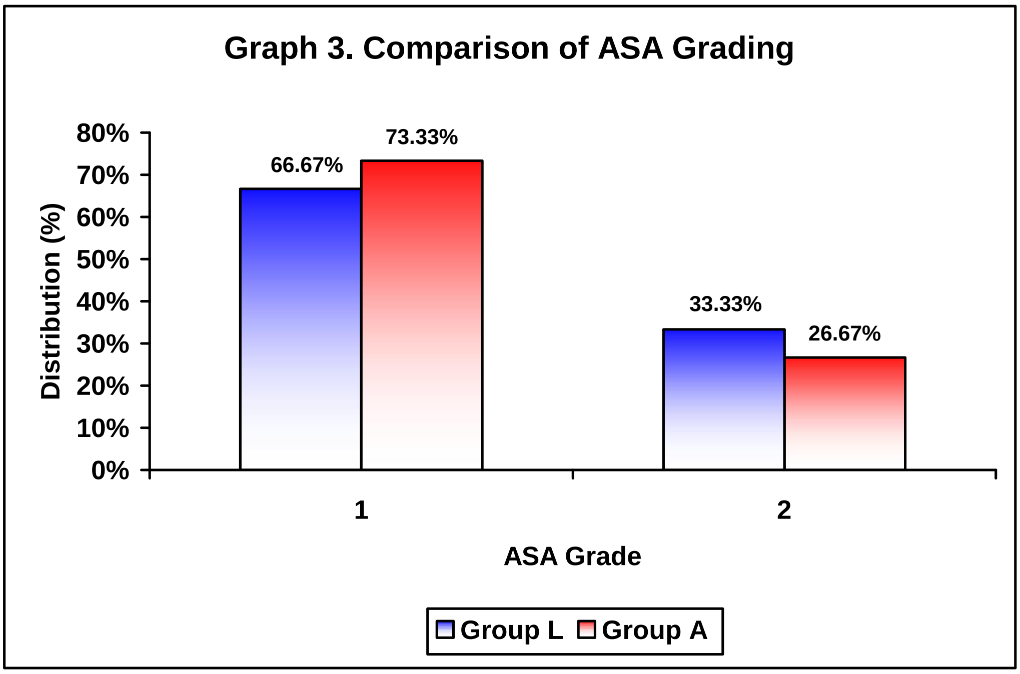


In the present study 53.33% of the patients in group L were males compared to 46.67% in group A. However this difference was statistically not significant (p=0.301).

Table 3. Comparison of ASA Grading

Grade	Group L (n=30)		Group A (n=30)	
	No.	%	No.	%
1	20	66.67	22	73.33
2	10	33.33	8	26.67
Total	**30**	**100.00**	**30**	**100.00**

x^2=0.317 DF=1 p=0.573

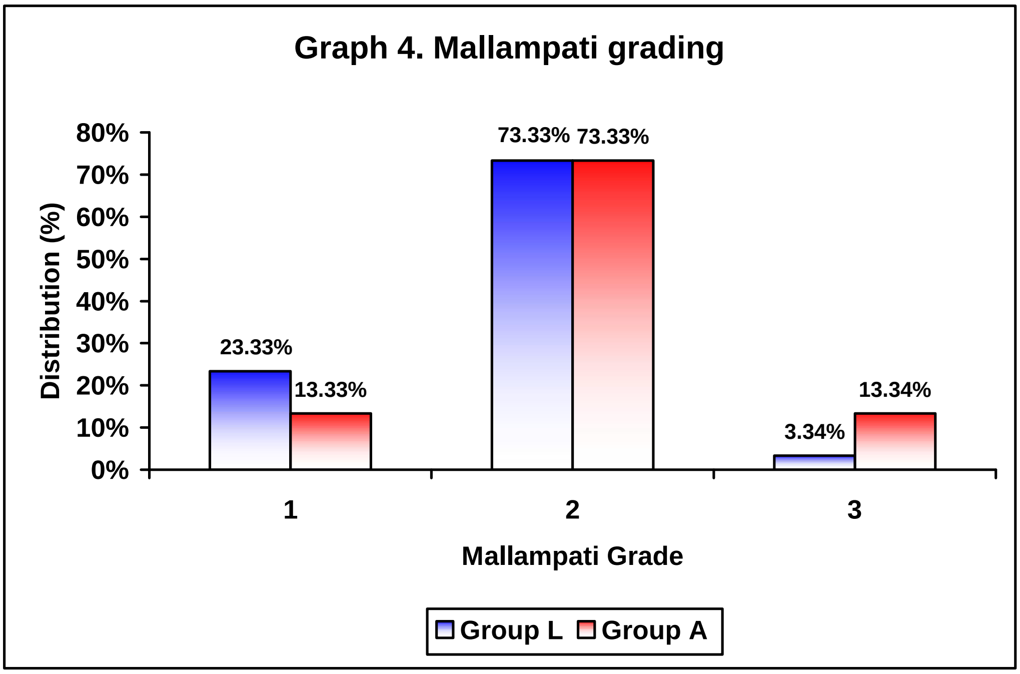


In the present study 66.67% of the patients in group L had ASA status 1 compared to 73.33% in group A. However this difference was statistically not significant (p=0.573).

Table 4. Mallampati grading

Grade	Group L (n=30)		Group A (n=30)	
	No.	%	No.	%
1	7	23.33	4	13.33
2	22	73.33	22	73.33
3	1	3.34	4	13.34
Total	**30**	**100.00**	**30**	**100.00**

$x^2 = 2.618$ p = 0.270

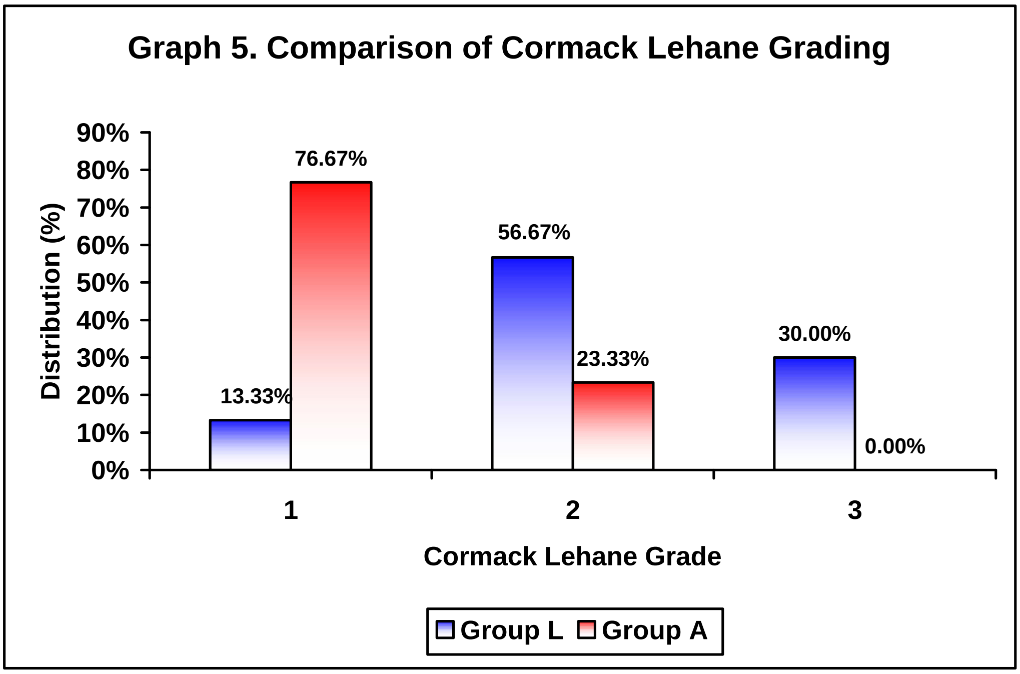


In this study the Mallampatti grades of patients in group L and group A were almost similar with no statistically significant difference.

Table 5. Comparison of Cormack Lehane Grading

Grade	Group L (n=30)		Group A (n=30)	
	No.	%	No.	%
1	4	13.33	23	76.67
2	17	56.67	7	23.33
3	9	30.00	0	0.00
Total	**30**	**100.00**	**30**	**100.00**

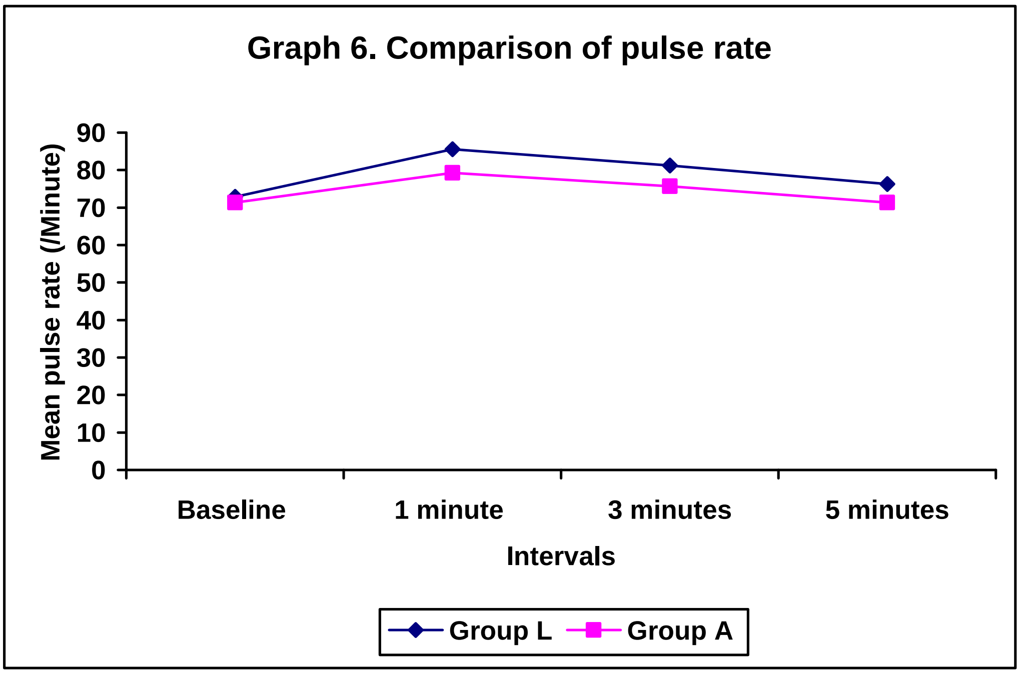
x^2 = 26.53 DF = 2 p = 0.001



In this study significantly higher number of patients in group A (76.67%) had Cormack Lehane grade 1 compared to patients in group L (13.33%). This difference was statistically significant (p=0.001).

Table 6. Comparison of pulse rate

Intervals	Group L (n=30)		Group A (n=30)		t	P
	Mean	**SD**	**Mean**	**SD**		
Baseline	72.83	6.67	71.30	7.57	1.287	0.203
1 minute	85.60	7.63	79.30	7.56	3.286	**0.002**
3 minutes	81.20	7.41	75.70	7.07	2.942	**0.005**
5 minutes	76.30	7.43	71.30	7.18	2.63	0.011

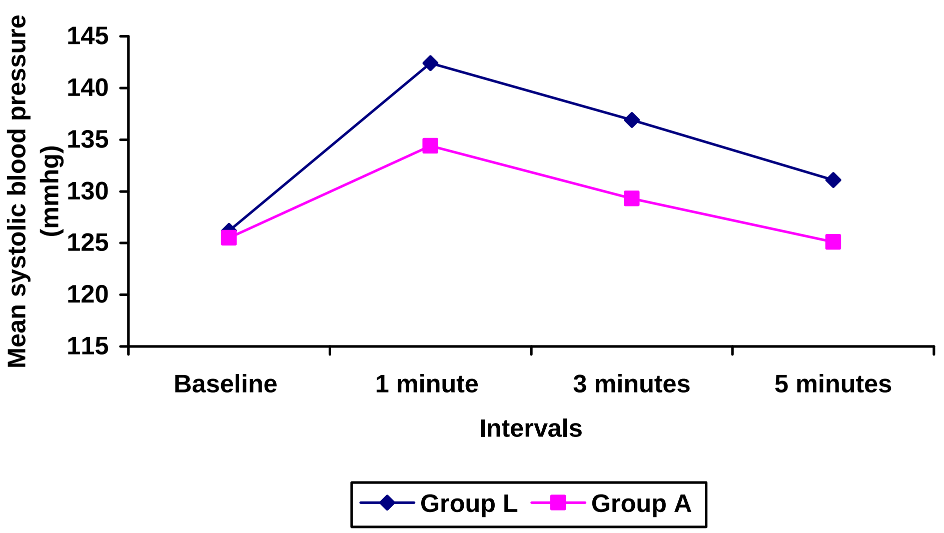


In this study mean pulse rate at baseline was comparable in group L and A (p=0.203) while at one minute (85.60 ± 7.63 Vs 79.30 ± 7.56 per minute; p=0.002), at three minutes (81.20 ± 7.41 vs 75.70 ± 7.07 per minute; p=0.005) and at five minutes interval (76.30 ± 7.43 vs 71.30 ± 7.18 per minute; p=0.011) it was significantly higher in group L compared to group A.

Table 7. Comparison of systolic blood pressure

Variables	Group L (n=30)		Group A (n=30)		t	P
	Mean	SD	Mean	SD		
Baseline	126.17	7.41	125.50	11.11	1.555	0.125
1 minute	142.40	9.32	134.40	10.16	3.163	**0.002**
3 minutes	136.90	8.86	129.30	9.66	3.160	**0.003**
5 minutes	131.10	9.11	125.10	9.35	2.545	**0.014**

Graph 7. Comparison of systolic blood pressure

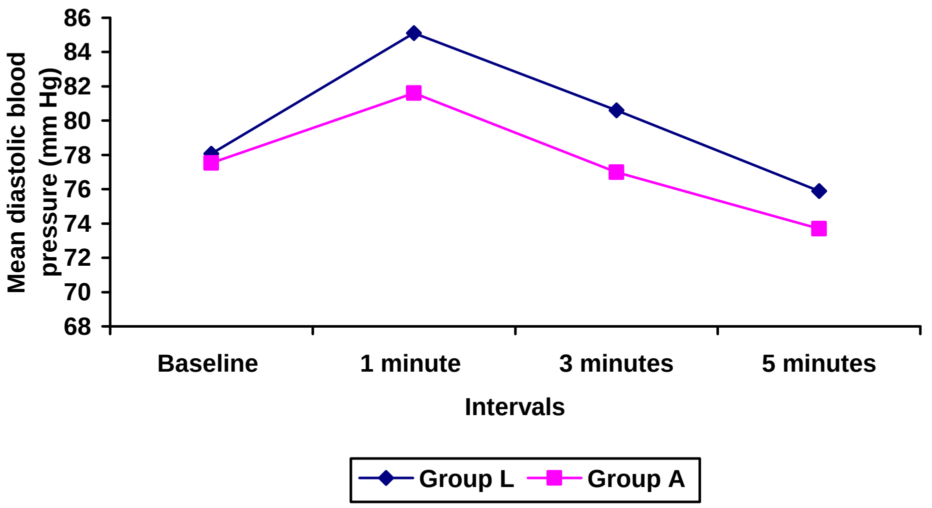


In the present study mean systolic blood pressure at baseline was comparable in group L and A (p=0.125) but, at one minute interval the mean systolic blood pressure was significantly high in group L (142.40 ± 9.32 mm Hg) compared to group A (134.40 ± 10.16 mm Hg) (p=0.002) Similar statistically significant differences were noted at three minutes interval (136.90 ± 8.86 vs. 129.30 ± 9.66 mm Hg; p=0.003) and five minute interval (131.10 ± 9.11 vs. 125.10 ± 9.35 mm Hg; p=0.014) respectively.

Table 8. Comparison of diastolic blood pressure

Intervals	Group L (n=30)		Group A (n=30)		t	P
	Mean	SD	Mean	SD		
Baseline	78.07	5.23	77.53	11.11	1.181	0.242
1 minute	85.10	4.81	81.60	4.83	2.864	**0.006**
3 minutes	80.60	4.17	77.00	5.12	2.956	**0.004**
5 minutes	75.90	3.95	73.70	4.71	1.99	0.051

Graph 8. Comparison of diastolic blood pressure

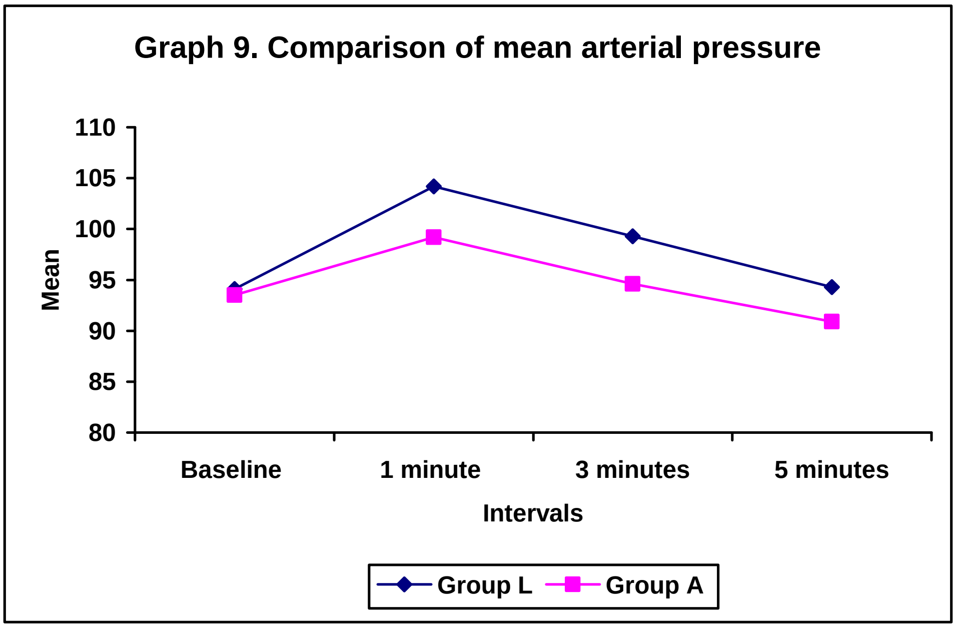


In this study mean diastolic blood pressure at baseline and five minutes interval was comparable in group L and A (p=0.242) but, at one minute interval the mean diastolic blood pressure was significantly high in group L (85.10 ± 4.81 mm Hg) compared to group A (81.60 ± 4.83 mm Hg) (p=0.006). Similar statistically significant differences were noted at three minutes interval (80.60± 4.17 vs 77.00 ± 5.12 mm Hg; p=004) respectively.

Table 9. Comparison of mean arterial pressure

Intervals	Group L (n=30)		Group A (n=30)		t	P
	Mean	SD	Mean	SD		
Baseline	94.10	5.38	93.52	7.45	1.385	0.171
1 minute	104.20	5.96	99.20*	6.13	3.201	**0.002**
3 minutes	99.30	5.27	94.60#	6.17	3.150	**0.003**
5 minutes	94.30	5.29	90.90$	5.89	2.351	**0.022**

***p<0.001 compared to baseline; #p<0.001 compared to 1 minute $p<0.001 compared to 3 minutes**



In the present study mean of mean arterial pressure at baseline was comparable in group L and A (p=0.171) but, at one minute interval the mean arterial pressure was significantly high in group L (104.20 ± 5.96 mm Hg) compared to group A (99.20 ± 6.13 mm Hg) (p=0.002) and Similar statistically significant differences were noted at three minutes interval (99.30± 5.27 vs 94.60 ± 6.17 mm

Hg; p=0.003) and five minutes (94.30 ± 5.29 vs 90.90 ± 5.89 mm Hg; p=0.022) respectively.

In the present study no complications were noted in both the groups.

DISCUSSION

During the airway management procedures, the degree of cervical spine motion varies according to the intubation techniques.[57-59] Oral intubation with neck immobilization is an accepted feasible method in trauma patients suspected of having cervical injuries.[60] However, this neck immobilization has been shown to worsen the laryngoscopic views and decrease the inter-incisor distance.[5]

The manual in-line stabilization is a widely accepted neck immobilization technique.[61] The reports that this method increases the risk of subluxation[62,63] and the requirement of a method-acknowledged assistant makes the value of this method doubtful. A Philadelphia cervical collar is used for neck immobilization because patients with a suspected cervical spine injuries are transported to the operating room with this device and removing this device can cause considerable spinal movement.

The development of laryngoscopes that reduce tracheal intubation difficulty in these patients would represent a real advance. The Airtraq has demonstrated promise in a number of settings including simulated easy[13,64-66] and difficult[13,64-66] laryngoscopy and in patients at low[55] and higher risk[12,67-68] for difficult tracheal intubation.

The Airtraq (AirTraq, Prodol Meditec, Vizcaya, Spain) is an intubation device that has been developed to aid laryngoscopy. The curvature of the Airtraq blade and the special internal arrangement of the optical components allow visualization of the glottic plane without alignment of the oral, pharyngeal, and laryngeal axis.[19]

The present one year hospital based randomized control trial was undertaken in the Department of Anaesthesiology, KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, from January 2015 to December 2015 for the period of one year. A total of 60 Patients posted for surgeries under general anesthesia were randomized based on computerized generated randomization table into two groups of 30 each as group L (Patients in this group underwent tracheal intubation using Macintosh laryngoscope) and Group A (Patients in this group underwent tracheal intubation using Airtraq video laryngoscope).

There was no significant difference in the demographic profile and airway characteristics of patients in the two groups.

In the present study 76.67% of patients in group A had a Cormack Lehane grade 1 view of glottis compared to 13.33% in group L. Most of the patients (56.67%) in group L had Cormack Lehane grade 2 view of glottis compared to 23.33% in patients of group A. Thus Airtraq laryngoscope significantly reduced the Cormack- Lehane grade of glottic view with p value 0.001. These findings are consistent with a study by Koh JC et al.[26]. They assessed that the POGO score was significantly greater in Group A (84 ± 20%) than in Group L (6 ± 11%). However Philadelphia cervical collar was used in the study.

Similar results were observed in a study conducted by Marwa A et al.[29] comparing the use of Macintosh Laryngoscope and Airtraq in patients with cervical spine immobilization. They found that 90% of the patients intubated with the Airtraq laryngoscope had a grade I Cormack and Lehane glottic view and 10% had grade 2, compared with 50% grade 1 view, 35% grade 2 view, and 15% grade 3 view in the Macintosh laryngoscope group. The results of the present study are also similar to the study by Bhandari G. and co-workers comparing Airtraq and macintosh laryngoscopes for tracheal intubation with better POGO scores in the Airtraq group (100%) versus 67.5% in the Macintosh group, $P < 0.001$.

The Airtraq has advantages in both limited mouth opening and poor laryngeal view settings.[12,69] Exaggerated curvature of the Airtraq blade eliminates the requirement of neck extension to align the oral, pharyngeal and laryngeal axis. The internal arrangement of the high definition optical components including a series of lenses, prisms and mirrors with antifogging system transfer the image from low temperature illuminated tip to the proximal view finder, giving a high quality and wide angle view of glottis, surrounding structures and the tip of the endotracheal tube.[26]

During administration of general anaesthesia, laryngoscopy and tracheal intubation are considered most critical events as they trigger transient but marked sympathoadrenal response which can be detrimental in patients particularly with underlying cardiac diseases.[70]

It was observed in our study that the mean heart rate, mean systolic blood pressure, mean diastolic blood pressure, and the mean of mean arterial pressure were higher in group L compared to group A at one minute, three minute, and five minute intervals. These findings suggest that, tracheal intubation with Airtraq offers better view of glottis with minimal changes in hemodynamic parameters in patients with a simulated cervical spine immobilization compared to Macintosh laryngoscope.

The hemodynamic findings in our study were comparable to those described by Marwa A et al,[29] in their comparative study between the use of Macintosh laryngoscope and Airtraq in patients with cervical spine immobilization. There was a statistically significant increase in both heart rate and mean arterial pressure in Macintosh group than Airtraq group.

This could be due to exaggerated anatomical curvature of the blade of Airtraq laryngoscope which does not require alignment of oral, pharyngeal and laryngeal axis with less lifting force required during laryngoscopy and lesser trauma caused during intubation.

Koh JC et al.[26] reported that, mean blood pressure before intubation was significantly decreased as compared with the baseline value in both groups. Mean blood pressure after intubation was also decreased compared to baseline value in both the groups. Heart rate after intubation was significantly increased as compared with those of baseline and before intubation in both groups which was consistent with the present study. But In contrast to the findings of the present study, there were no significant differences between the two groups, which can be due to the usage of remifentanil throughout the procedures which has been proved to prevent the hemodynamic changes during airway management.[71-73]

An important potential advantage of the Airtraq is that it is a single-use device, reducing the chance of prion transfer.[26,72,73] These concerns arise from the difficulties in ensuring that all proteinaceous material has been removed from reusable laryngoscope blades during cleaning and sterilization.[65,73]

Limitations

There were some limitations in our study.

- Anesthesiologist was not blinded to the devices used.
- The laryngoscopic glottic view grading, were subjective in nature.
- The results may also vary among anaesthetists with differing expertise in the use of the devices.

CONCLUSION

In conclusion, the Airtraq videolaryngoscope produced a superior laryngeal view (CL grading) over the Macintosh laryngoscope during intubation in patients with a rigid cervical collar with lesser variation in hemodynamic parameters.

SUMMARY

The Airtraq is an intubation device that has been developed to aid laryngoscopy. It provides a high quality glottic view eliminating the need for to alignment of the oral pharyngeal and tracheal axis. However, the efficacy of the Airtraq has not been determined in the setting of simulated cervical spine immobilization. The aim of the present study was to compare the glottic visualization between Macintosh laryngoscope and Airtraq video laryngoscope in patients with a simulated difficult airway posted for surgery under general anesthesia based on Cormack - Lehane grading and also to evaluate the hemodynamic changes in both the groups.

This one year hospital based randomized controlled trial was conducted in the Department of Anaesthesiology, KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, from January 2015 to December 2015 for the period of one year. A total of 60 Patients with a simulated difficult airway posted for surgery under general anesthesia were randomized into two groups of 30 each based on computerized generated randomization as group L (Patients in this group underwent tracheal intubation with Macintosh laryngoscope) and Group A (Patients in this group underwent tracheal intubation with Airtraq video laryngoxscope).

Demographic parameters and airway characters were comparable between the groups. Significantly higher number of patients in group L had Cormack Lehane grade 1 (76.67%) compared to 13.33% in group A (p=0.001). It was observed in our study that the mean heart rate, mean systolic blood pressure, mean diastolic blood pressure, and the mean of mean arterial pressure were higher in group L compared to group A at one minute, three minute, and five minute intervals. These findings suggest that, laryngoscopy with Airtraq offers better view of glottis with minimal changes in hemodynamic parameters during intubation in patients with a simulated cervical spine immobilization compared to Macintosh laryngoscope.

Based on the results of this study it may be concluded that, the Airtraq offers superior laryngeal view over the Macintosh laryngoscope in patients with a rigid cervical collar with lesser variation in hemodynamic parameters.

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ANNEXURE I – CONENT FORM

Mr./Mrs./Miss. ______________________________ we are requesting you to enroll yourself in study titled “COMPARISON OF THE GLOTTIC VIEW DURING INTUBATION USING AIRTRAQ AND MACINTOSH LARYNGOSCOPES IN ADULT PATIENTS UNDERGOING SURGERIES UNDER GENERAL ANAESTHESIA WITH A SIMULATED CERVICAL SPINE IMMOBILIZATION - A ONE YEAR HOSPITAL BASED RANDOMIZED CONTROLLED TRIAL”

Conducted by

Dr. **** *******. Post Graduate in M.D. Anaesthesiology under the guidance of Dr. **** ****** , M.D. Professor & Head, Department of Anaesthesiology, Jawaharlal Nehru Medical College, Belagavi under KLE University, Belagavi.

Respected Sir/Madam,

We request you to enroll yourself to participate in our study as you are eligible for participating in the study. During the study you will be asked some questions regarding your present complaint and you are supposed to answer to the best of your knowledge.

Purpose of the study

The purpose of the study is to compare the glottic view obtained during intubation using Airtraq and Macintosh laryngoscopes in patients with a simulated cervical spine immobilization undergoing surgeries under general anaesthesia.

Procedure Involved

If you agree to enroll yourself in our study, you will be interviewed regarding your present, past and family history. Then you will be clinically examined in detail and investigated accordingly. You will be allotted into one of the two groups randomly using computer generated randomization table. Then you will be induced with general anaesthesia. Then an appropriate size cervical collar will be applied. Then you will be intubated either with Macintosh laryngoscope or Airtraq laryngoscope.

Benefits and Risks

The benefits with intubation using Airtraq are better chances of successful intubation, lesser trauma and better homodynamic stability. There are no observable risks associated with the study.

Voluntary Participation/Withdrawal

Taking part in the study is voluntary. You may choose not to enroll in this study. Your decision will not change present or future health care services offered to you at KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belagavi

Alternatives

Even if you decline the participation in the study, you will get the routine line of management.

Privacy and Confidentiality

The only person to know that you are a research subject is you and members of the research team. No information about you, or information provided by you during the research will be disclosed to others without your written permission except:

In emergency to protect your rights and welfare. If required by law.

Authorization to Publish Results

When the results of the research are published or discussed, in a conference, no information will be displayed that would disclose your identity. Any information that is obtained in connection with this study and that can be identified with your identity remains confidential.

Financial Incentives for participation

No financial incentives are being offered to enrolled patients. It is purely being done with the idea of research and all the cost of the study will be borne by the investigator.

Compensation

In the event of injury related to the study, treatment will be made available through KLES Hospital & MRC, Belagavi. There is no compensation or payment for such medical treatment by law.

Queries/ Contact details

In case you have any questions related to the study, in future or in case of study related injury or illness, you can contact Dr. **** ****, Department of Anaesthesiology, KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belagavi, phone number: **** ****** . Or Dr. **** ***** Professor, Dept. of Anaesthesiology, KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belagavi, Belagavi Ph: **** ***** .

If you have any queries about your rights as a study subject, you may call Dr. *** ****** , Professor, Department of Pathology and Chairman, J. N. Medical College Institutional Ethical Committee for Human Subjects Research, Phone number- ***** ****, or extension ***** at J.N. Medical College, Belagavi.

CONSENT FOR PARTICIPATION IN RESEARCH TRIAL

"COMPARISON OF THE GLOTTIC VIEW DURING INTUBATION USING AIRTRAQ AND MACINTOSH LARYNGOSCOPES IN ADULT PATIENTS UNDERGOING SURGERIES UNDER GENERAL ANAESTHESIA WITH A SIMULATED CERVICAL SPINE IMMOBILIZATION - A ONE YEAR HOSPITAL BASED RANDOMIZED CONTROLLED TRIAL"

I, Mr. /Ms. /Mrs. ________________________________ voluntarily agree for the participation as a subject of study. By signing this consent form I am not giving up any of my legal rights, I may withdraw from the study anytime. I am signing the consent form after having read or been read for me in vernacular language, including the risks and the benefits and having all my questions answered.

Subject Name : ____

Signature or the Left Thumb Print of

Subject : ____

Date : _____________________

Witness Name : _____________________

Signature : _____________________

Date : _____________________

Investigators Name: ________________

Signature : _____________________

Date : _____________________

Place : _____________________

ANNEXURE II PROFORMA

"COMPARISON OF THE GLOTTIC VIEW DURING INTUBATION USING AIRTRAQ AND MACINTOSH LARYNGOSCOPES IN ADULT PATIENTS UNDERGOING SURGERIES UNDER GENERAL ANAESTHESIA WITH A SIMULATED CERVICAL SPINE IMMOBILIZATION - A ONE YEAR HOSPITAL BASED RANDOMIZED CONTROLLED TRIAL"

Name & Address of the patient:

____

____

Age of the Patient : ____________

In patient number : ____________

Weight of Patient : ____________

Sex : ____________

Anaesthesiologist : ____________

Surgeon : ____________

Pre anaesthetic evaluation

Chief Complaints

<u>Past History</u>

History of Diabetes Mellitus :

Hypertension :

Asthma :

Tuberculosis :

<u>Drug Therapy</u>

Previous Anaesthetic procedure :

Previous surgeries :

History of renal disease :

Hepatic disease and neurological diseases:

Family History

General Physical Examination

Pallor	:	Icterus	:
Clubbing	:	Cyanosis	:
Lymphadenopathy	:	Edema	:
Pulse	:	Blood Pressure	:
Temperature	:	Airway Assessment	:
Teeth	:	Jaw Movements	:
Mallampatti Grading	:		

Systemic examination

Cardiovascular System:		Respiratory System	:
Per Abdomen	:	Central Nervous system	:
Spine assessment	:		

Investigations

Heamoglobin % :

Any Other :

American society of anaesthologist status

Grade 1 / 2

Diagnosis

Proposed Surgery	:	Pre operative baseline values:	
Heart rate	:	Blood Pressure	:
Monitors attached	:	Pulse oximetry	:

Non invasive blood pressure : Ecocardiogram :

Observations

Readings will be recorded in the following manner:

Intubating device used: ______________________________

Group: ____

No. of attempts to intubation	
Cormack and Lehane glottic view	

Intra – Op Vital Parameters

TIME	H.R	NIBP

Any intra – op complications

Signature of staff in charge

ANNEXURE III – KEY TO MASTER CHART

ASA	-	American Society of Anesthesiologists
bpm	-	beats per minute
Cms	-	Centimeters
DBP	-	Diastolic blood pressure
F	-	Female
HR	-	Heart rate
Intra Op	-	Intra operative
Kg/m^2	-	Kilograms per square meter
Kgs	-	Kilogram
M	-	Male
MAP	-	Mean arterial pressure
min	-	minute
mm Hg	-	Millimeters of mercury
MPG	-	Mallampatti grading
SBP	-	Systolic blood pressure