

ENDOTRACHEAL TUBE CUFF PRESSURE MONITORING-
COMPARISON OF SAFETY PROFILE BETWEEN MANUAL
AND AUTOMATIC MANOMETER.IN SURGERIES LASTING
FOR UP TO 3 HOURS

By

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Dissertation submitted to

B.L.D.E. (DU) UNIVERSITY VIJAYAPUR, KARNATAKA



In partial fulfillment of the requirements for the degree of

DOCTOR OF MEDICINE

IN

ANESTHESIOLOGY

Under the guidance of

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KARNATAKA

2020

**“ENDOTRACHEAL TUBE CUFF PRESSURE MONITORING –
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ANAESTHESIOLOGY

ABBREVIATIONS

ASA- American Society of Anesthesiologists

ECG- Electrocardiogram

HR- Heart rate

BP- Blood Pressure

RR- Respiratory rate

I.V- Intravenous

Inj - Injection

NIBP- Non-invasive Blood Pressure

SPO₂- Oxygen Saturation

S.D- Standard Deviation

mcg- Microgram

mg- Milligram

kg- Kilogram

mL- Milliliter

hrs- Hours

mins- Minutes

cm- centimeters

mm- millimeter

p- 'p' value

Sl. No.- Serial number

ETTc – Endotracheal tube cuff

CBC- Complete blood count

HIV- Human immunodeficiency virus

H₂O- Water

Group M – Manual group

Group C – Cuff group

H/O- History of

Hg- Mercury

VAP- Ventilator associated pneumonia

C3-C6- Cervical vertebra

SLN- Superior laryngeal nerve

RLN- Recurrent laryngeal nerve

KPa-Kilopascal

ABSTRACT

Providing patients with effective anesthetic care involves evaluating the endotracheal tube cuff pressure.⁽¹⁾

In the operating room, it is routine method to correctly put an endotracheal tube (ETT) to ensure and maintain the patient's airway and ventilate them.⁽²⁾

The recommended range of cuff pressure is within 20 to 30 cm H₂O.

The vast majority of studies reveal that in order to protect the lung parenchyma against aspiration and to provide patients with the finest oxygen and ventilation, between 55% and 80% of a suitable and safe air pressure of 20 to 30 cm H₂O is frequently applied to tube cuffs.⁽³⁾

Insufficient management of the endotracheal tube cuff pressure can lead to inadequate oxygenation and complications include tracheal edema, tracheal ischemia, tracheal stenosis, sore throats, tracheal rupture, recurrent laryngeal nerve palsy, and micro aspiration.⁽⁴⁾

The signs and symptoms include hoarseness, inspiratory stridor, dyspnea, and complete obstruction. A sore throat is a frequently occurring side effect of general anesthesia with endotracheal tube and over-pressurized endotracheal tube cuffs are a crucial factor.^(3,4)

Endotracheal tube cuff pressure maintenance within the advised range is a painless, non-invasive strategy that would lessen the detrimental effects of this variable on patient outcomes⁽⁵⁾

Morbidities happen when the cuff pressure is inflated in between the threshold values, hence endotracheal cuff pressure management is essential to prevent these two extremes. ⁽⁶⁾

The requirement for enhancing patient outcomes, minimizing the risk of problems associated to perioperative therapy, and preserving patient satisfaction falls on anesthetic practitioners as well as other surgical personnel.

In the intraoperative settings, utilizing an evidence-based method for managing endotracheal tube cuff pressure has the ability to lessen variance, enhance patient health outcomes, and lower the risk of difficulties.⁽⁷⁾

AIM AND OBJECTIVE:

Endotracheal tube cuff pressure monitoring – Comparison of safety profile between manual and automatic manometer in surgeries lasting for up to 3 hours.

PRIMARY OBJECTIVE :

- To compare and evaluate the intraoperative parameters such as pulse and blood pressure as a result of changes occurring in the endotracheal tube cuff pressure.

SECONDARY OBJECTIVE:

- To compare the likelihood of post-operative complications using the two methods of maintenance of endotracheal tube cuff pressure, like hoarseness, sore throat, inspiratory stridor, dyspnea, aspiration pneumonitis and complete obstruction.

SUBJECTS -

The study population of 72 patients shall be selected in each group, by computer generated randomization, of age group between 20-70 years undergoing surgeries lasting for up to 3 hours under general anesthesia. In one group, endotracheal tube would be inflated manually, and in the other it is done using a automated manometer. Intraoperative changes in pulse and blood pressure shall be evaluated and post-operative problems such as hoarseness of voice, coughing, sore throat, stridor, laryngeal nerve palsy, aspiration pneumonitis would be observed and evaluated.

METHODS-

Two groups of patients were formed: group M, which had 72 patients, underwent manual endotracheal tube cuff inflation by a skilled anesthesiologist; group C, which also had 72 patients, underwent automatic endotracheal tube cuff inflation

by a pressure controller; group C's pressure was maintained at 20 to 30 cm H₂O throughout the surgical procedures.

In group M, air is injected into the cuff using the traditional model, which involves using a syringe. Measurement of the cuff pressure is done by anesthesiologists with at least five years of expertise by palpating pilot balloon and hearing cessation of audible air leak. In group C, automatic cuff pressure controller is used to automatically inflate endotracheal tube cuff, and pressure maintained at 20-30 cm H₂O during the surgical procedures, complications during and after surgery are both discussed.

- **RESULTS** – The two groups' demographic information was comparable, of which 93 females and 51 males studied in both comparative groups. No statistical significance noted thus complications associated with cuff pressure monitoring is not influenced by the sex of the patient. P value being 0.356 of the total 144 ASA class 1 and 2 subjects are studied. No statistical significance and complications associated with cuff pressure monitoring in both manual and automatic method is not influenced by the ASA class of the patient / subject undergoing the procedure. P value being 0.324. In Group M, procedure time was statistically significant (p value 0.001) $2.87 \pm .2996$ while group C the procedure time was 2.715 ± 0.354 . Increased in duration of surgery more is the complications associated with the same. HR , SBP , DBP was assessed among all the subjects for influencing the

effect of rise in cuff pressure in both groups . There is statistical significant p value determined. Heart rate increase was more in Manual group than automatic group as the duration of surgery increased (*p<0.05) .Standard oxygen saturation parameters were assessed for influencing effect of rise in cuff pressure in both categories. Not much significance change determined in both groups .ETTc was assessed among all the subjects for influencing effect of rise in cuff pressure in both categories. There is statistical significance p value determined. ETTc increase was more in Manual group than automatic group as duration of surgery prolonged (*p<0.05). Post-operative complications associated with cuff pressure monitoring in both manual and automatic technique was noted. 30.55% of patients had complained of sore throat in manual category compared to automatic category with 13.88% .16.66% of subjects complained of cough in manual category compared to automatic category with 12.5%.2.77% of subjects complained hoarseness of voice in manual category and none automatic category . No patients had complaints of laryngeal nerve injury, stridor, aspiration pneumonitis either of the group.

CONCLUSION- According to our research, routine use of endotracheal tube cuff pressure is most secure method to prevent cuff-related injuries to monitor endotracheal cuff pressures. This method is more novel than manual cuff inflation. This study therefore stresses the advantages of routinely using an endotracheal tube cuff pressure monitor for the patient's safety profile.

KEY WORDS- Endotracheal tubes, cuff pressures, manual, automatic, post-operative complications

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INTRODUCTION

The study provides information on endotracheal tube cuff-induced ischemia problems and aids in the use of current procedures and their corresponding tube cuff pressures. The standard of care for many surgical operations is general anesthesia, which uses endotracheal intubation and mechanical ventilation to ensure that the patient receives enough oxygen. Endotracheal intubation aids in preventing the intake of stomach contents into lungs and helps lungs receive enough oxygen. The method now used by the majority of anesthesiologists involves expanding a tube cuff until it makes proximity with the trachea's walls while applying minimal pressure on them. The endotracheal tube and trachea are properly sealed as a result.^(8,11)

Endotracheal Tube in Trachea

To provide adequate tidal volumes and avoid aspirating stomach or secretory contents into the lungs, cuff successfully seals airway while applying pressure to tracheal wall. If there is high pressure, patients may develop tracheal necrosis and substantially diminished tracheal capillary perfusion. (Seegobin & Hasselt, 1984)⁽²⁹⁾

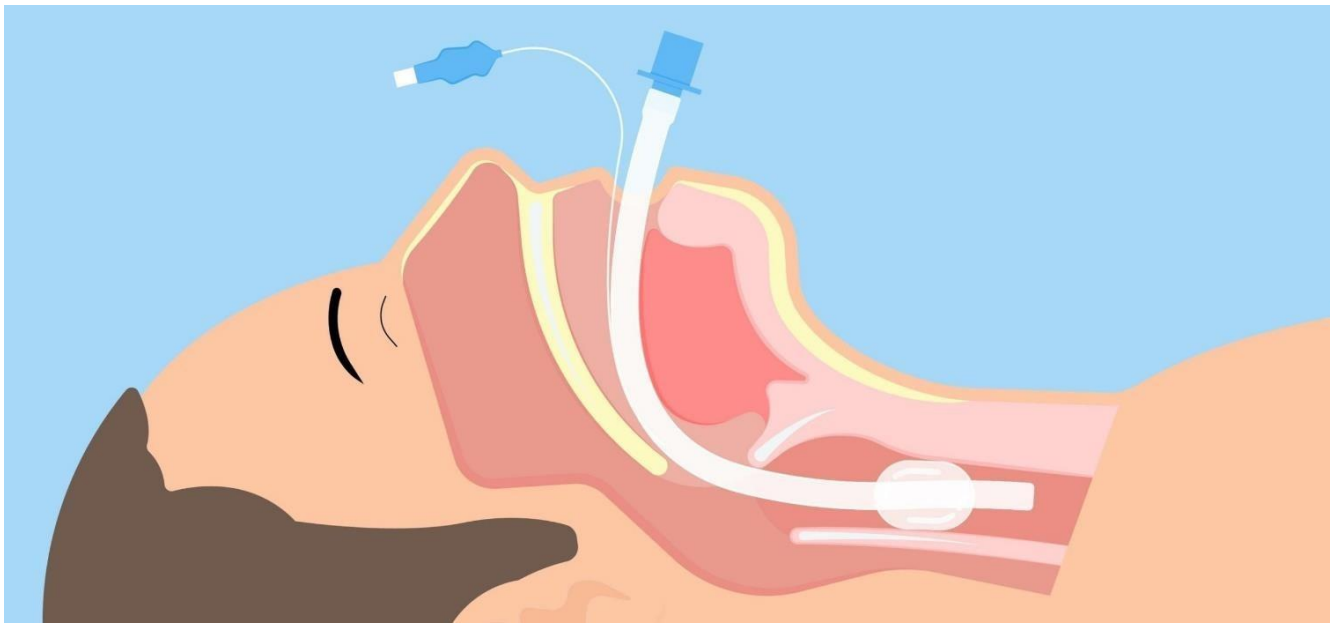


Figure 1 : Endotracheal Tube in Trachea

BACKGROUND

The best ETT should seal off the airway to enable for appropriate positive pressure breathing, shield it from stomach aspiration, and guard against tracheal injury (O Donnell, 1995).⁽²⁵⁾

Endotracheal tube ischemic complications, which can include mild sore throats, hoarseness of voice, coughing, stridor, and tracheoesophageal fistulas, are most frequently linked to increased pressure exercised by ETTs cuff on mucosa of trachea (Guyton, Barlow, & Bresselievre, 1997)⁽²³⁾. According to research done in 1984 by Seegorbin and Hasselt⁽²⁹⁾, tracheal ischemia is caused by the restriction of mucosal capillary blood flow at cuff pressures higher than 25 mm Hg. Columnar epithelium is primarily destroyed after 15 minutes of tracheal wall pressure exceeding 50 mm Hg.^(10,41,42)

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REVIEW OF LITERATURE

INTRODUCTION

Endotracheal cuff-related problems have been covered in depth in the literature. Early literature discusses advantages of low-pressure high-volume cuffs vs high-pressure, low-volume cuffs, benefits of adopting it. Following the widespread adoption of low pressure cuffs, literature revealed problems related to them. The history of the endotracheal tube will be covered in the review, along with significant studies on aspiration and ischemia caused by the cuff of the

endotracheal tube, as well as factors that can effect various problems, such as nitrous oxide and cuff inflation methods.^(9,12,13)

HISTORICAL EVENTS

Order to prevent patients' airways from being occluded by aspirating stomach contents, anesthesia professionals started placing tubes orally into the larynx in the late **1840s**. To stop aspiration of blood and debris, gauze was wrapped around these early stiff tubes before being inserted into the larynx.

Friedrich Trendelenburg created a device in 1869 used soft tube retained in place by inflating of a balloon around it to deliver an aesthetics to lungs through the trachea. Aspiration was shown to be prevented more successfully by the balloon than by gauze.

William Macewen invented and popularized an oral tracheal intubation procedure in **1880**, which made a tracheotomy unnecessary for numerous head and neck treatments. **Victor Eisenmenger created a device in 1893** device utilized a Trendelenburg-designed inflatable cuff on a broad bore semi-rigid endotracheal tube. **(Duncum, 1947)⁽²¹⁾**

Joseph O. Dyer and George Fell's joint efforts resulted in the creation of an artificial breathing device. These tools immediately became useful to surgeons because they empowered them to undertake thoracic surgery. Few thoracic surgeries were conducted prior before the invention of these devices because pneumothorax had bad consequences. Positive pressure's striking resemblance to

physiological respiration and the benefits of endotracheal anesthesia encouraged its usage which is still in existence today (**Bernard *et al*, 1979**)⁽¹⁷⁾

Endotracheal tube cuff-induced ischemia was first described pathologically by **Som, Khilnani, Keller, and Som in 1972**⁽³⁰⁾. The gradual ischemia cuff injury is brought on by pressure necrosis of the mucosa over inflexible cartilaginous rings. The fibro muscular intercartilaginous space receives transverse branches from the inferior thyroid artery which is main source of the trachea's blood supply. The horizontal vessels are connected by vertical channels. These vertical veins, which are placed between the mucosal surface on the inside and the hard cartilage on the outside, are particularly susceptible to early occlusion by inflated cuff. Crosses the intercartilaginous membrane's arteries which become squeezed under persistent pressure. These reasons explain why antero-lateral two-thirds of tracheal mucosa, which protects stiff cartilages, are initially destroyed by ischemia. The membranous tracheal wall towards the back is corrugated and extensible. There is a substantial circulatory network on this common wall with the esophagus, including tracheal and esophageal veins. Dilatation of the cuff makes these arteries, which are located between malleable mucosal surfaces, less easily obstructed. These anatomical characteristics account for the posterior tracheal wall's less frequent or later involvement in stenotic cuff lesions. Continued severe pressure can lead in necrosis of the wall's whole structure, including the cartilage (**Som *et al*, 1972**).^(30,31)

There was a considerable risk of tracheal ischemia issues at the cuff site when low-volume high-pressure ETT cuffs used. Trachea is not round and must be roughly bent to a circle by the low-volume, high-pressure cuffs before a seal is accomplished. Consequently, incredibly excessive pressures are produced. Tracheal tissue is danger of damage when cuff to tracheal wall tension is greater than mucosal capillary perfusion, which is typically 30 mm Hg. (**Seegobin & Hasselet,1984**) ^(28,29)

Columnar epithelium is destroyed after 15 minutes of tracheal wall pressure above 50 mm Hg. Within 24-48 hours, there are histologic alterations and inflammation. If the tracheal wall pressure remains high, deep ulcerations with cartilage exposure happen within a week. The tendency of high-pressure cuffs to put risky levels of pressure on tracheal wall as a result over-inflation is the most common risk they pose. Such difficulties happen when the cuff exerts pressure that is greater than the tracheal capillary perfusion pressure, which leaves little to no blood flow where the cuff meets the skin. Although the perfusion pressure of the tracheal tissue of a normotensive person is thought to be around 30 mm Hg, many critically ill patients are not hemodynamically stable, therefore their perfusion pressures are probably not typical. As a result, many people experienced hardships. Attempts were made to create very low-pressure cuff that would seal trachea at low intra-cuff pressures as a result of the numerous problems. Thin walls and a large resting diameter of low-pressure cuffs increase the area of contact with the trachea. This cuff's ultra-thin wall drapes the trachea's irregularities and applies a reasonably equal pressure on the tracheal wall, which is its prime benefit. Before

cuff wall is stretched, pressure inside cuff closely resembles that on tracheal wall. Additionally, compared to high-pressure cuffs, inflation past seal boosts tracheal wall pressure less. (**Nordin, 1977**)⁽²⁴⁾

In order to determine if low-pressure cuff pressures changed dynamically or remained static during mechanical ventilation, **Crawley and Cross (1975)**⁽¹⁹⁾ designed a study. Airway pressure was at atmospheric pressure prior to start of inspiratory phase on ventilator. Lung airway pressure rose as soon as ventilator started to inflate. Intracuff pressure finally fell behind airway pressure as ventilator pressure rose higher. Then, it applied upward pressure on cuff's front. Cuff would have retracted if it had been loose and bulky since it couldn't bear the pressure. The closed system caused the cuff's volume to decrease and its internal pressure to increase. When the intra-cuff pressure matched the airway pressure, equilibrium was once again restored. Similar to this, throughout expiratory phase, the cuff pressure declined till it approached resting cuff pressure.

Intracuff pressure consequently followed airway pressure when airway pressure was larger than resting intracuff pressure during that phase of the inspiratory cycle. The blood flow to the tracheal mucosa was thus barely affected. The tracheal mucosa at the cuff interface did not experience any additional pressure beyond that which is applied to trachea below the cuff. Study of **Crawley and Cross (1975)** ,high volume, low pressure cuffs can effectively seal trachea when airway pressures fluctuate in response to changes in ventilator pressure.

In order to determine how pressure of tracheal mucosa affected blood flow through tracheal wall of dogs who were under anaesthesia, **Dorbin and Canfield**

(1977)⁽²⁰⁾ compared pressure imposed by inflated endotracheal tube cuffs against mucosa. In contrast to compliant low-pressure, high-volume cuffs, which only needed 20 to 40 mm Hg of pressure to achieve a satisfactory seal in the trachea, this study discovered that low-volume, high-pressure cuffs needed 320 to 360 mm Hg of pressure to do so. At seal, the mucosal pressures from the high pressure, low volume cuffs ranged from 147 to 205 mm Hg, while the mucosal pressures from the low pressure, high volume cuffs were only 17 to 30 mm Hg. This showed that low-pressure, high-volume cuffs not only need less pressure to close, but also that not all of cuff's pressure is necessary.

Dorbin and Canfeild (1977)⁽²⁰⁾ tracheal tube cuffs were inflated to shut in trachea while blood flow through trachea was also examined. They arrived to conclusion that the low-volume, high-pressure cuffs decreased mucosal blood flow by 20% to 40%. When inflated to shut in trachea, low pressure, high volume cuffs reduced mucosal blood flow by just 2%.

Experiment demonstrated , reduced tracheal wall blood flow is caused by increased mucosal pressure. The tracheal blood vessels' caliber is reduced as a result. ⁽²⁶⁾

The authors caution readers, emphasising that each increase in cuff pressure was accompanied by commensurate increase in mucosal pressure, even if study's results preferred low-pressure, high-volume cuffs. Since these cuffs are low pressure, high volume, and compliant, little resistance exists to inflation, and excessive inflation may significantly reduce mucosal blood flow. (**Dorbin & Canfeild, 1977)⁽²⁰⁾**

In related study, **Tonnesen, Vereen, and Arens (1981)** discovered cuff pressure was always higher than wall pressure and that if cuff pressure was regularly monitored kept below 20 to 30 mm Hg, wall pressure would be lower than ideal capillary pressure. ⁽³²⁾

Studies using animals or model tracheas, **Seegobin and Hasselt⁽²⁹⁾** first observed effect of lateral wall pressure on human mucosal blood flow in 1984. In this study, cuff inflation pressure was adjusted while mucosal blood flow was monitored using fiber optic bronchoscopes. Study comprised 40 normotensive people who had undergone surgery (mean arterial pressure, 85mm Hg) Above 22 mm Hg, mucosal capillary blood flow is impaired, mucosal capillary blow flow is interrupted beyond 37 mm Hg, and intermittent flow along mucosal arterioles occurs above 75 mm Hg, according to Seegobin and Hassle (1984). Although large capacity cuffs may offer a clinical seal at low intracuff pressure, researchers found that inflation past point of seal, with modest increments of air, rapidly generates excessive intracuff pressure, and consequently lateral wall pressure (**Seegobin & Hasslet, 1984**).

Rashkin's (1986)⁽²⁷⁾ According to studies on endotracheal intubation complications, persistently high cuff pressures—defined as pressures greater than 25 mm Hg—were linked to significant problems such tracheomalacia and posterior pharyngeal abscess. Nine out of the 29 patients in this study had cuff pressure readings that were higher than 25 mm Hg at least once, and five patients had readings that were raised three times or more. In later group, there were two patients (or 40%) who had tracheolarygeal problems. Rashkin's research showed

that low-pressure cuffs can nevertheless cause damage to the tracheal mucosa since excessive inflation of any cuff can significantly increase intracuff pressure.

Mandoe H, Mandoe H, Nikolajsen L, Lintrup U, Jepsen D, Mlgaard J(1992)⁽¹⁾

It has been proven that nitrous oxide, which diffuses into endotracheal tube cuffs during tracheal intubation, can cause mucosal damage by pressing the cuff against the tracheal wall. The Brandt Anesthesia Tube is an endotracheal tube that successfully reduces intracuff pressure rises caused by nitrous gas. They tested whether utilizing this tube could lower the occurrence of postoperative sore throat. The study comprised 48 female patients between the ages of 18 and 50. Either a Brandt anesthesia tube or a Mallinckrodt endotracheal tube was used for endotracheal intubation. After 20–30 hours, all patients underwent postoperative interviews with people who had no idea which tube had been utilized. In the Mallinckrodt group, 10 patients had intracuff pressures greater than 25 mmHg, and 12 of the 20 patients experienced sore throats. In Brandt group, there were just 3 sore throats among the 20 patients. They discovered that Brandt Anesthesia Tube might significantly lower the occurrence of sore throats following intubation.

D C Guyton , M R Barlow, T R Besselievre(1997) ⁽²³⁾

Based on relationship between peak inflation pressure and lowest occlusive pressure, it has been shown that doctor can identify patients who may be at a high risk for cuff-induced tracheal ischemia issues, such as tracheoesophageal fistula and tracheal stenosis. In their series, cuff pressures ranging from 25 millimetres of mercury to 35.3 millimetres of mercury were recorded (48 cm H₂O). Danger of

ischemia tracheal injury may still arise in patients with higher peak inflation pressures even after using acceptable cuff inflation techniques.

Papiya Sengupta , Daniel I Sessler, Paul Maglinger, Spencer Wells, Alicia Vogt, Jaleel Durrani, Anupama Wadhwa(2004)⁽⁹⁾

They demonstrated that the optimal range for cuff pressure in endotracheal (ET) tubes is between 20 and 30 cm H₂O. They investigated the hypothesis that in the absence of manometers, the tube cuff is not adequately inflated.

Patients in morphometrics, a reputable institution, and a skilled anaesthesia practitioner did not let the diameter of the tube affect how much cuff pressure was measured. Only 27% of the 93 individuals had pressures between 20 and 30 cm of H₂O, while 27% had pressures above 42 cm of H₂O. Although the results diverse greatly, amount of air needed to achieve cuff pressure of 20 cm of H₂O was consistent across all tube sizes. They advise using a manometer to set and track the ET cuff pressure.

Jianhui Liu, Xiaoqing Zhang, Wei Gong, Shitong Li (2010)⁽¹⁶⁾ –Elective surgery under general anesthesia was planned for 500 individuals. They were split into two study groups, one receiving endotracheal tube cuff pressure adjustments and measurements, and the other serving as a control group. In between 120 and 180 minutes, the operation took place. Research group and control group experienced significantly different rates of post-procedural sore throat, hoarseness, and expectoration with blood streaks. While severity of

tracheal mucosa injuries in both groups varied, a fibre optic bronchoscopy performed on 20 patients revealed that control group's injuries were more severe than the study group's. Incidence of sore throat and blood-streaked expectoration in the control group rose along with the procedure's duration and endotracheal intubation.

Mukul Kumar Jain, Chander Bhushan Tripathi(2011)⁽¹⁵⁾- 100 patients divided into two groups, correlations between manual techniques of pressure evaluation , a skilled anesthesiologist and analysis with the maintenance of pressure within the normal range by an automated pressure controller system discovered. A competent anesthesiologist manually inflated an endotracheal tube cuff in Group M, and its pressure was checked hourly until the surgery was complete. In Group C, pressure on the endotracheal tube cuff was automatically maintained at 25 cm H₂O throughout the operations.

When the endotracheal tube cuff was manually inflated, the pressure was noticeably high. If cuff pressure controller device is placed, the recognized difficulties associated with a increased endotracheal tube cuff pressure could be prevented. Manual techniques cannot be trusted to maintain the pressure within the suggested ranges.

Pervez Sultan, Brendan Carvalho, Bernd Oliver Rose and Roman Cregg(2011)⁽¹³⁾

Over 500 patients were analyzed in a prospective trial in China using a conventional anaesthetic approach, and problems in the first 24 hours following surgery were assessed. Endotracheal tube cuffs in control group were inflated by

anesthesiologist using their own judgment and no pressure gauge. The study group's patients had their cuff pressure adjusted using a pressure manometer to fall between 20 and 34 cm H₂O. The 273 patients in the control group displayed a higher incidence of post-operative sore throat, hoarseness, and blood-streaked expectorations when compared to the 236 patients in the study group. It was demonstrated that the incidence of these symptoms increased in both the control and study groups with longer endotracheal intubations.

At the conclusion surgery, a fibre optic evaluation of 20 randomly chosen patients from each group revealed more severe tracheal mucosal damage in the control group.

Dr.Manjulata Tandan, Dr.A.M. Lakra, Dr.Uttam Roshan Tigga in (2018)⁽²⁸⁾

Conducted a study on 60 randomly chosen patients with ASA grade I/II , Mallampati grade I/II who were between ages of 20 and 50. Patients registered for general anesthesia operations. Endotracheal tube cuff in Group M (30 patients) was manually inflated by skilled anesthesiologists, while in Group C (30 patients), the cuff was automatically inflated by a cuff pressure controller, and pressure was maintained at 25 cm H₂O during procedure. In group M patients, painful throat, cough, hoarseness of voice, and laryngeal nerve palsy was observed in 15 patients, whereas in group C, cough and sore throat were experienced by 7 patients.

Michael A Turner , Monika Feeney, LTC Jacob L Deeds in June (2020),⁽¹⁸⁾

Conducted a study that was finished in three stages 1) Staff members use assessment techniques to determine the proper endotracheal tube cuff inflation pressure 2) Staff familiarity with recommended procedures for assessing

endotracheal tube inflation pressure 3) Randomly checking the patients' blood pressure while they are under general endotracheal anesthesia 40 endotracheal tube cuff pressure measurements were compared before and after adoption. Cuff pressure started out at 11% and then climbed to 53%. Knowledge of an accurate cuff pressure (20–30 cm of water) among anesthesia physicians increased from 35% to 87%.

Chandra M. Kumar¹ · Edwin Seet¹ · Tom C. R. V. Van Zundert² (2020)⁽¹⁴⁾

The frequency of endotracheal tube cuff pressure measurements, both in intensive care unit and during anesthesia, varies greatly amongst clinical settings worldwide. In intensive care, he advised measuring the cuff pressure at least three times per day. He carried out an observational research on 72 ICU patients. They discovered that there were 4 cases of an underinflated cuff and 5 cases of an overinflated cuff during the first four hours, and 7 cases of intra-cuff pressures 30 cm H₂O during the fifth and eighth hours. 22 incidents of underinflated cuffs and 4 cases of overinflated cuffs occurred in the last four hours. They recommended taking an intra-cuff pressure reading every 8 to 24 hours because the air inside the cuff could leak out of the endotracheal tube.

ANATOMY OF UPPER AIRWAY

Upper airway has a major role in normal respiration which is a highly detailed neurophysiological process. Both the anatomy and the functions influence the exchange of inspired and expired air. Upper airway is from mouth to trachea which comprises of mouth, nose, palate, uvula, pharynx, and larynx. Knowledge about functional anatomy of the airway is important to the anesthesiologist to maintain the normal airway.⁽³³⁾ The airway is divided into:-

Upper airway is subdivided in to nasal cavity, oral cavity, pharynx and larynx.

Lower airway which includes tracheobronchial tree⁽³⁴⁾.

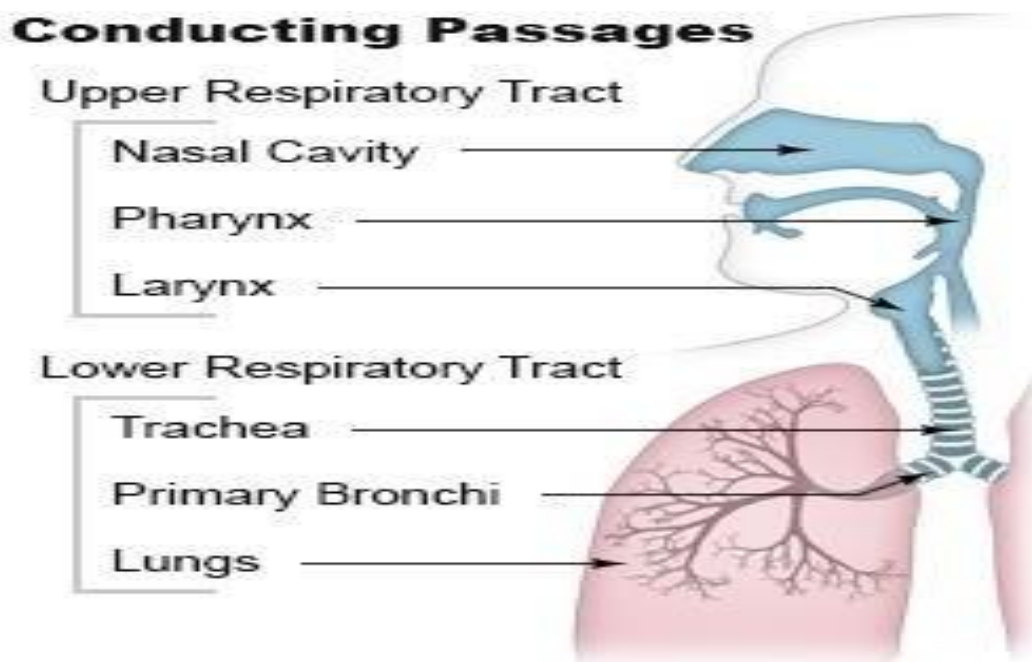


Figure 2 : Showing anatomical structures in upper and lower airway

UPPER AIRWAY

NOSE

External part of nose is made up of nasal bones, upper and lower lateral cartilages, cartilaginous part of nasal septum, and skin. Columella ,flexible section of nasal septum separate the two nostrils. Two nasal bones together create the skeletal framework of the upper part of nose. Vomer makes up inferior and ethmoid's perpendicular plate makes up the superior portions of the posterior septum's bones. The bottom lower anterior section of nose is braced by cartilage.^(35,36)

NASAL CAVITY

Two channels are established in the nasal cavity by nasal septum. Nasal septum is composed of vomer, septal cartilage, and ethmoid's perpendicular plate. Although it typically has a midline structure, this is not a must. Each nasal fossa made up of roof, floor, medial wall, lateral wall, the nasal septum as the medial wall, and is opened anteriorly by anterior nares and posteriorly by choana into nasopharynx. Anterior portion of nasal cavity, which found above each anterior nare, is known as nasal vestibule. Nares and vestibule are encircled by medial and lateral crura of alar cartilage. The connective septum anterior part of cartilaginous septum comprise vestibule's medial wall, whereas the lateral portion is covered in coarse hairs- the vibrissae in the skin which guards nasal entrance and assist in air

filtration^(35,37)

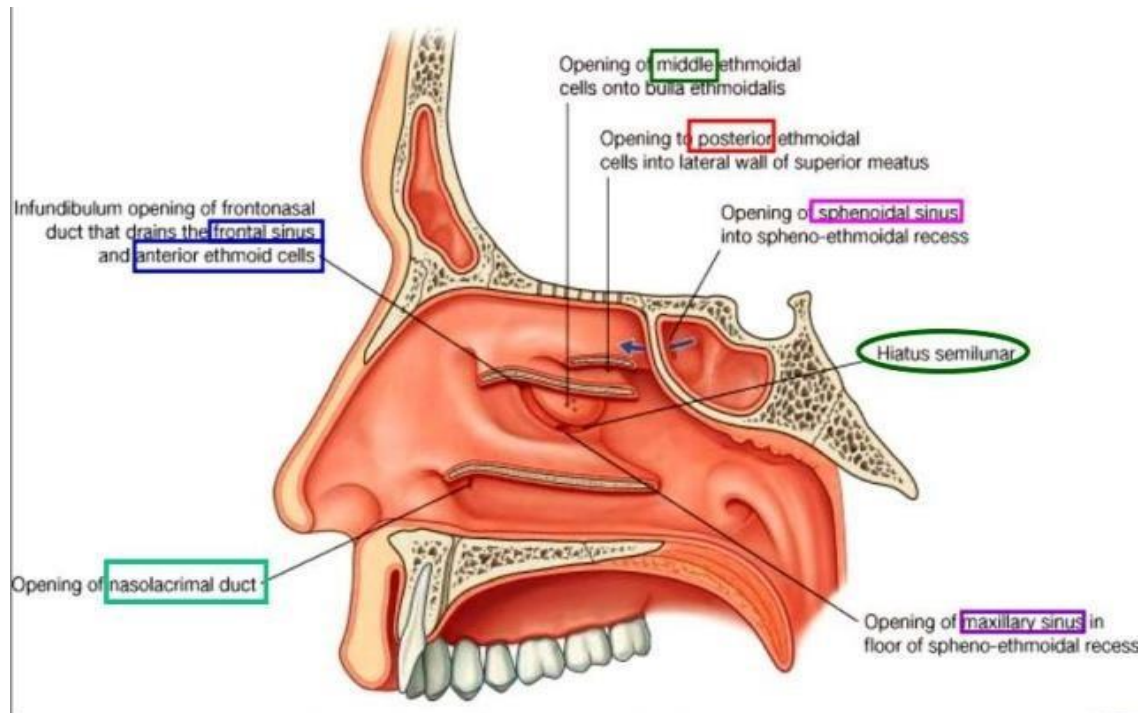


Figure 3: Shows the opening of all sinuses in the lateral wall of nose.

Lateral wall: It is made up of sporadic bony projections that are covered in mucous membrane and soft tissue. Inferior, medium, superior, and supreme nasal conchal turbinates are these projections. Each turbinate's meatus is located there, and its name matches that of the turbinate next to it. Ethmoid bone provides structure for supreme, superior, and middle turbinates, whereas a separate bone provides the framework for the inferior turbinate. Lateral wall contains ostia of paranasal sinuses and nasolacrimal duct. External nasal opening is positioned about 3 cm posterior to opening of nasolacrimal duct, which contained within the inferior meatus. Middle meatus is where middle turbinate, maxillary sinus, and nasofrontal duct entrance are located. The superior meatus contains entrance for

posterior ethmoid cells. Sphenoid opening is in anterior wall of sphenoid sinus in area of sphenoethmoidal recess.^(36,38,39)

Posterior Nares (Choana): Each choana circular-shaped roughly 2.5 cm tall 1.5 cm wide. It is surrounded by bone and has mucoperiosteum on top of it. Rare incidence of congenital choanal atresia and traumatic bone deviations are found, which might result in posterior blockage of the septum. Posterior section of septum is often present.^(33,40)

FUNCTION OF THE NOSE:

It serves as the passageway to the lower respiratory system and, while turbulently moving over membrane lining nasal passages, heats, humidifies, and purifies the inspired air. The nasal passage can increase or contract based on level of vascular engorgement thanks to its abundant vascular supply, however damage to nasal airway can lead to profuse bleeding. Olfaction and phonation are other functions.^(33,34,41)

THE PHARYNX

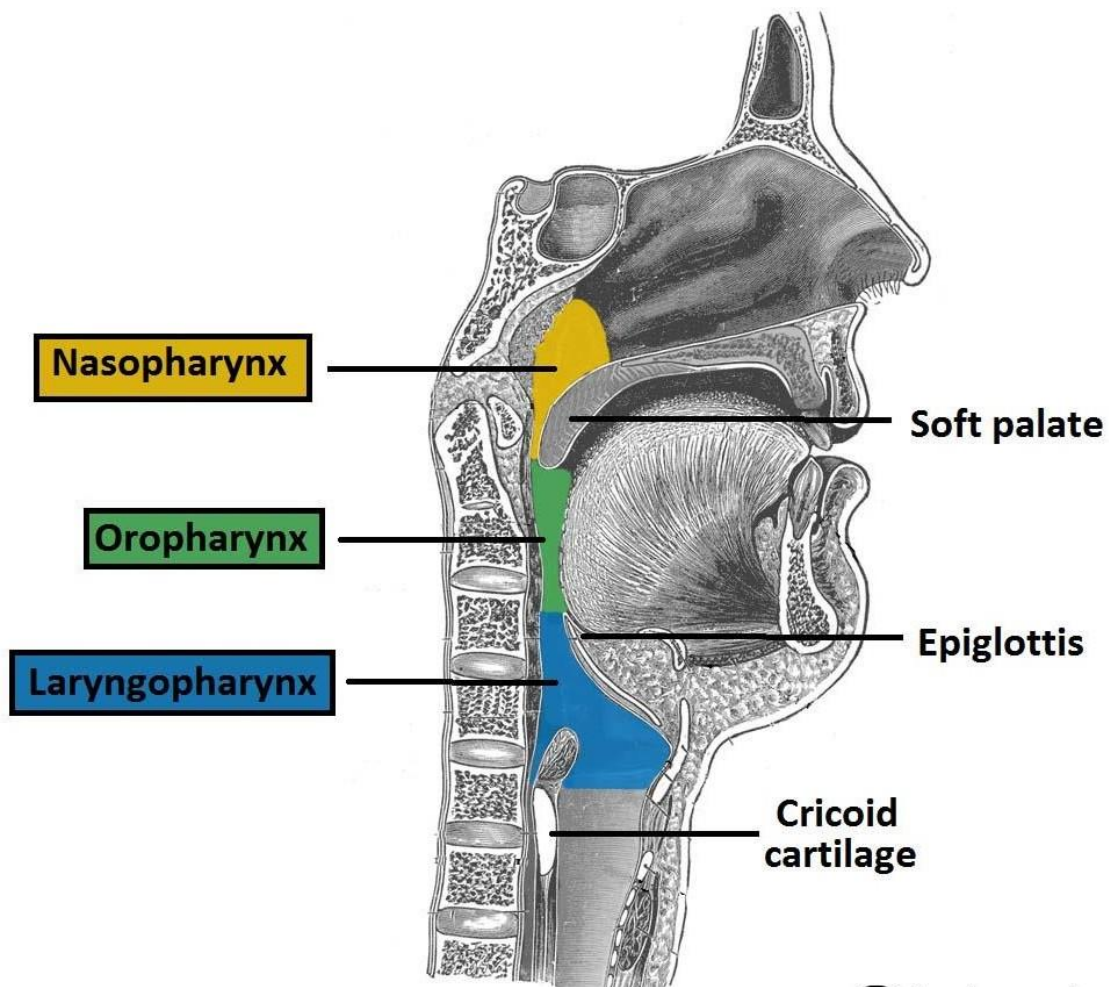
The nasal and mouth canals are connected to the larynx and esophagus by this musculofacial tube. The pharyngeal tube's thin outer fascial layer that has grown is called the buccopharyngeal fascia. It connects superiorly to the skull bone and inferiorly to the adventitia of the esophagus.

Muscle constrictors: The intermediate layer of muscles is made up of three pharyngeal constrictor muscles. Muscles are superior, middle, and inferior constrictor.

Superior constrictor inserts at hyoid bone, cricoid cartilage, and base of the skull. The lower esophageal sphincter, or inferior, also contributes cricopharyngeus, a muscular band. Every segment connects to the tendinous median raphe.^(33,34,35)

DIVISIONS OF PHARYNX :

Nasopharynx, oropharynx, and hypopharynx make up its three sections. It is vulnerable to lacerations, retropharyngeal dissection, and iatrogenic development of fake channels because it's sensitive muscular architecture. Therefore, before trying endotracheal intubation, anesthesiologists must have this knowledge.



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Figure 4: Sagittal section through head and neck showing subdivisions of pharynx.

NASOPHARYNX:

Two nasal choanae, two Eustachian tube orifices, and an inferior channel to the oropharynx are the five openings that communicate with the nasopharynx. Sphenoid and occipital bones of base of skull make up roof, which has its inferior boundary at level of soft palate. It is contiguous with back wall of nasopharynx. Prevertebral fascia, which includes longus capitis muscle, deep prevertebral

musculature, and arch of first cervical vertebrae, separates the posterior wall from the spine.

The palate muscles open the eustachian tube, which balances the middle ear and ambient pressure.

The tube's orifice is located medial torus tubarius, a lateral cartilaginous protrusion. Rosenmullar's Fossa is a recess above and behind the torus.

The lymphoid tissue in the mucous membrane of the roof and posterior walls is known as an adenoid tonsil. Its enlargement may cause a persistent nasal blockage, sleep apnea, and abnormal carbon dioxide levels. ^(34,35,36)

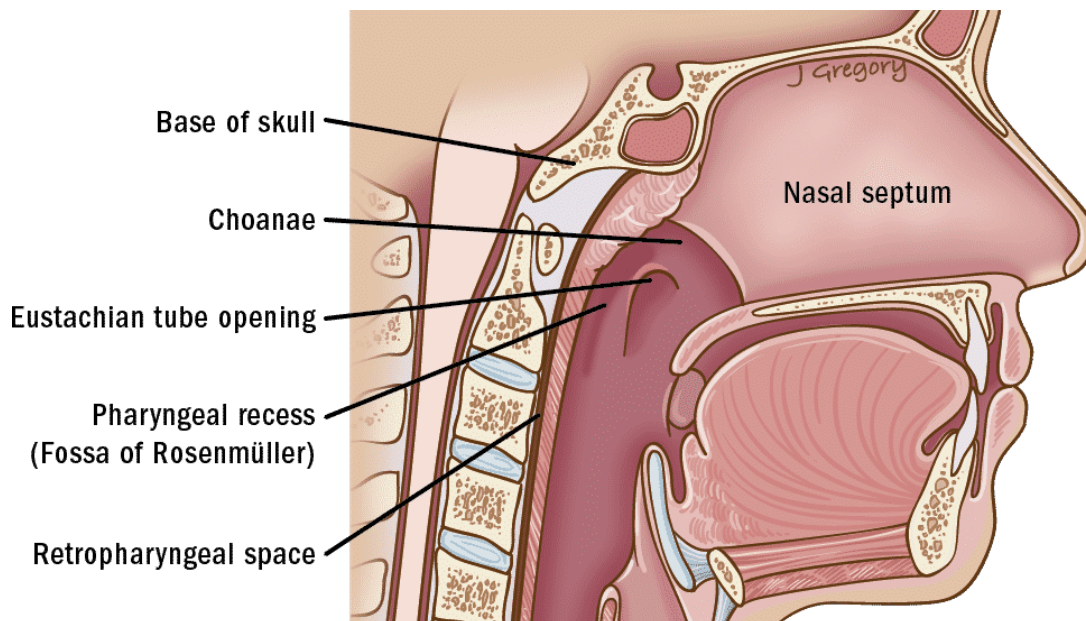


Figure 5 : Sagittal section showing parts of nasopharynx.

OROPHARYNX:

It is located behind oral cavity and reaches epiglottis posterior aspect and the soft palate superiorly. Posterior wall of the oropharynx made up of paravertebral fascia

and bodies of second and third cervical vertebrae. Paired tonsillar fossae are located within the lateral wall. The palatine tonsils are located in the palatopharyngeal folds, which is the posterior pillar of these fossae. The anterior pillar is the palatoglossal folds.

The root of the tongue is positioned medially to the tonsillar fauces. The single median glossoepiglottic fold and the paired lateral glossoepiglottic folds connect the tongue base to the epiglottis. Lingual tonsils are located in back of tongue. There are two main categories of tongue musculature: muscles that are linked the styloglossus, genioglossus, hyoglossus, and palatoglossus. Transverse, superior, inferior longitudinal, and vertical muscles all freely move throughout the tongue. The paired myohyoid muscles that emerge from mandible and insert into hyoid bone form base.

Airway obstruction can develop from cellulitis that affects the submandibular and submental areas, such as Ludwig's angina. Tracheostomy can be performed in certain circumstances to protect the airway.^(43,44,45)

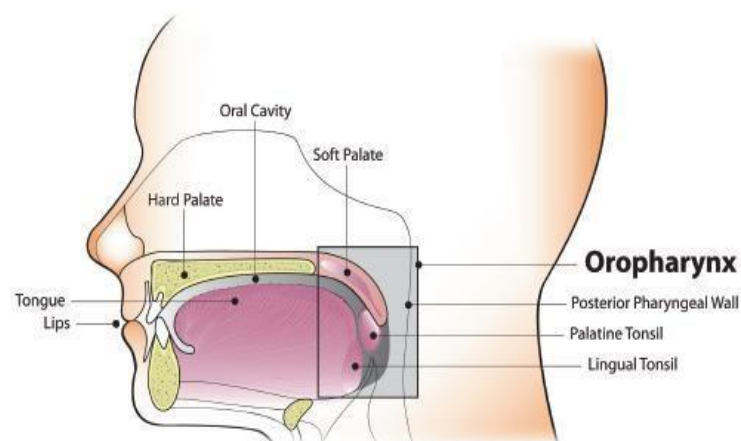


Figure 6 : Sagittal section showing various parts of oropharynx.

HYPOPHARYNX:

The fourth through sixth cervical vertebrae are located where the hypopharynx is located. It extends inferiorly from the epiglottis' tip to the cricoid cartilage's inferior surface. The oropharynx, laryngeal inlet, and oesophagus are where it starts. The pyriform fossa is located either side of hypopharynx and is superiorly bordered by lateral glossopharyngeal folds. Buccopharyngeal and prevertebral fascia, as well as deep prevertebral musculature, form posterior border.^(41,44)

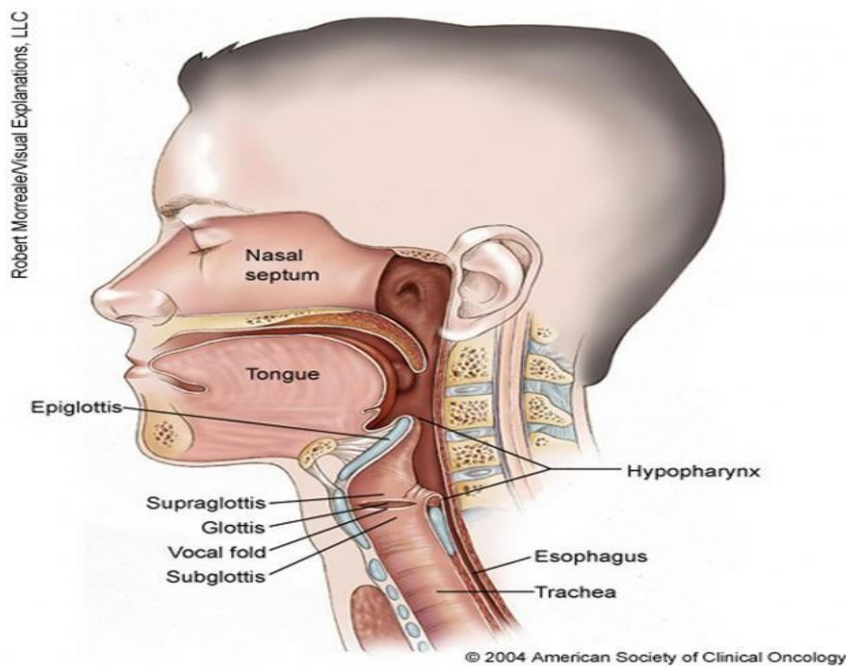


Figure 7: Sagittal section of hypopharynx.

THE LARYNX

It serves as the respiratory tract's protective sphincter, keeping the trachea and upper digestive tract apart to prevent aspiration during swallowing. Houses vocal

cords, which necessary for coughing and valsalva manoeuvre as well as for successful speech. (41,44)

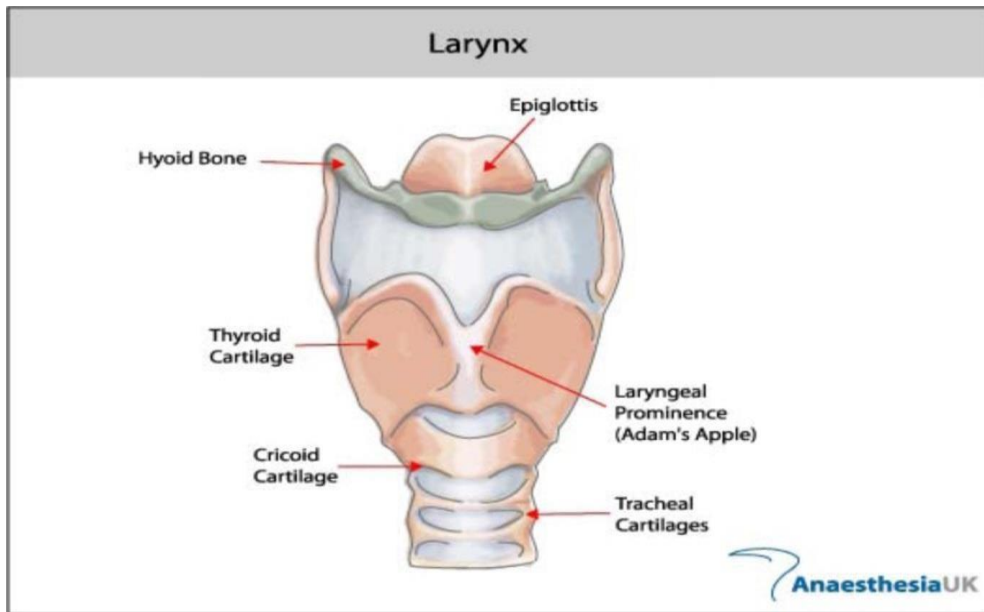


Figure 8: Anterior view of laryngeal cartilages

The larynx is situated in the front of the laryngopharynx, C4-C6 vertebral bodies, and the anterior region of the neck. On either part of larynx are carotid sheath and one thyroid gland lobe. Thyroid isthmus, which is located over the second to fourth tracheal rings, connects the thyroid gland anteriorly. Further anterior are the platysma muscle, the superficial fascia, and the deep fascia.

The laryngeal skeleton is made up of nine cartilages that are connected by a number of ligaments and membranes. Thyroid, cricoid, and epiglottis are three of the unpaired cartilages, while the other three are paired cartilages (arytenoid, corniculate, cuneiform). (35,36)

The hyoid bone (level with C3) is joined to thyroid cartilage by thyrohyoid membrane. The three unpaired cartilages are below this.

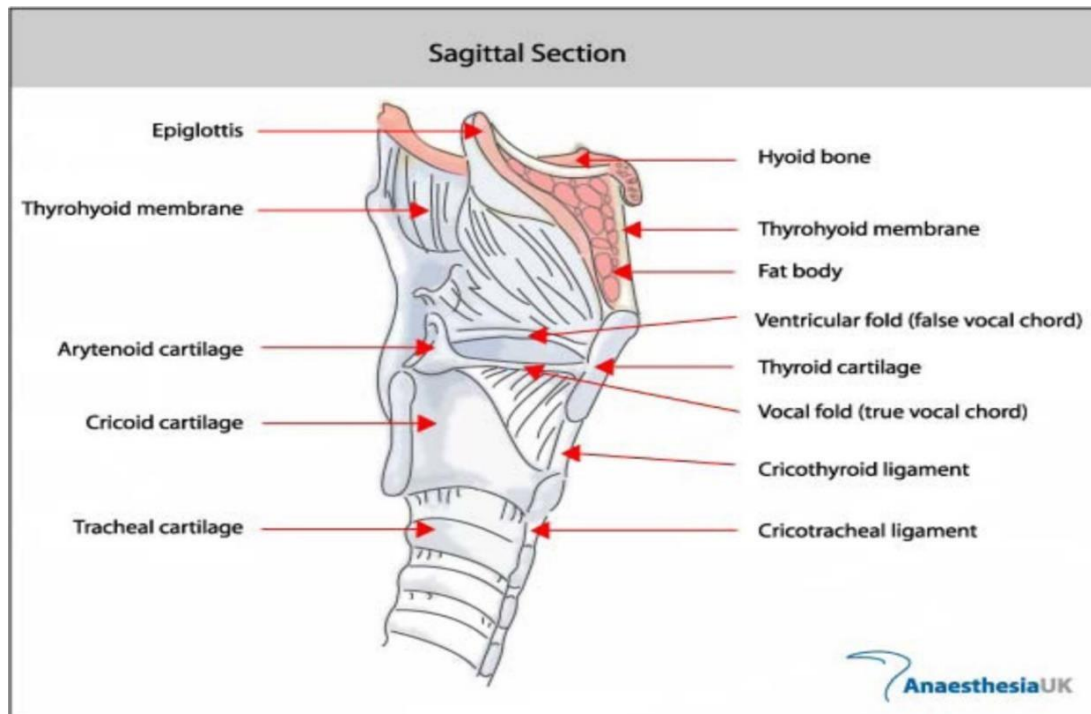


Figure 9: Lateral view of laryngeal cartilage

Thyroid cartilage- The largest and most shield-like of laryngeal cartilages is thyroid cartilage. Adam's apple, a subcutaneous laryngeal protrusion most seen in men, is composed of two laminae united in midline at an angle of 90° in males and 120° in females. Superior and inferior cornua make up the top border of (C4) and the lower border of (C5) borders (horns). The superior edge of the hyoid bone is attached by thyrohyoid membrane.⁽⁴⁵⁾

The inferior cornua and cricoid cartilage articulate

Cricoid cartilage- At the level of the C6 vertebra, the cartilage is a full ring. Its anterolateral arch is smaller, and its posterior lamina is broader. It communicates laterally with inferior thyroid cornua, which is attached to inferior border of thyroid cartilage by cricothyroid ligament, and posteriorly with arytenoid cartilages. Cricotracheal ligament connects cornua to upper border of first tracheal ring.

Sellick's manoeuvre, commonly known as cricoid pressure, Because of the full ring-like structure of the cricoid cartilage, applying pressure from above will squeeze oesophagus that is lying posteriorly. This method is utilised during rapid sequence intubation of anaesthesia to prevent aspiration and regurgitation of gastric contents.^(41,43,46)

Epiglottis- It is an elastic cartilage that has the shape of a "leaf." The thyroepiglottic ligament connects the thyroid cartilage's inferior, narrower end to it (to back of the laryngeal prominence). The hyoepiglottic ligament anchors to hyoid bone anteriorly. Top border end is free expand upwards and depression between mucous membrane and posterior section of tongue with epiglottis is called vallecula.^(40)

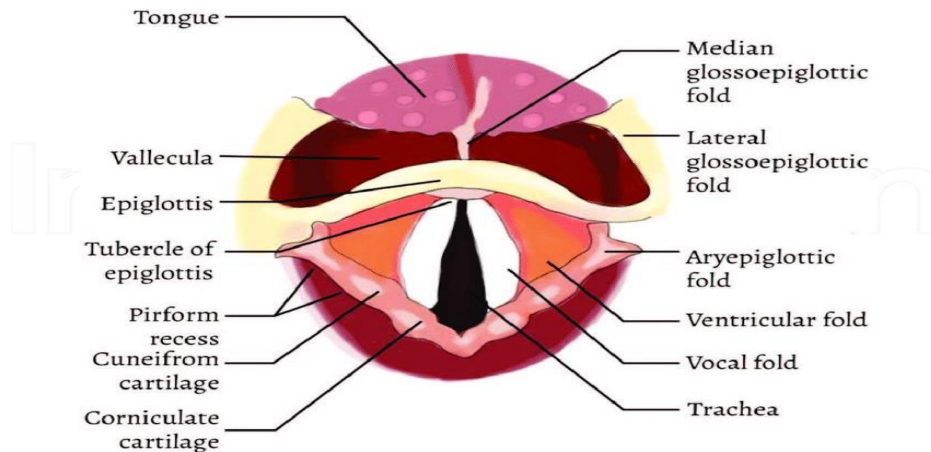


Figure 10: Showing the paired cartilages

Below are the three unpaired cartilages

Arytenoids- These are two pyramid-shaped cartilages that attach to superior border of cricoid. Each cartilage has an apex to which corniculate cartilages articulate, a lateral muscular process to which cricoarytenoid muscles articulate, and an anterior vocal process to which the vocal ligament is attached posteriorly. The only vocal cord components that can be seen in a "anterior" airway are the arytenoids because they are most posterior parts of vocal cords.

Cuneiforms and corniculates- Small cartilages found in aryepiglottic folds

(35,36)

Ligaments and membranes

The larynx contains a range of ligaments and membranes. The membrane and ligaments combine to create the vocal structures by joining the cartilages together. Thyrohyoid membrane connects thyroid cartilage and hyoid bone. The lower end of the hyoid bone is connected to the epiglottis by the hypo-epiglottic ligament. Cricothyroidotomy is done on the cricothyroid membrane, which connects cricoid and thyroid. First ring of trachea is attached to the cricoid by the cricotracheal ligament.

Cricovocal membrane – connects the thyroid cartilage's laryngeal prominence and the arytenoid's vocal process to upper border of cricoid. Vocal ligament, which is formed by the top border and gives the genuine vocal cord its strength.⁽³⁶⁾

Arterial supply to larynx- Superior laryngeal artery, a branch of superior thyroid artery, and inferior laryngeal artery, a branch of the inferior thyroid artery, deliver blood to larynx.

Innervation of larynx - Larynx is contribute by branches from vagus (X) nerve: High up in the neck, superior laryngeal nerve leaves vagus and divides into external branch provides cricothyroid muscle, the tensor of the vocal folds, with its motor supply, while internal branch supplies sensory to glottis, supraglottis, ,cricothyroid. All intrinsic laryngeal muscles, with the exception of the cricothyroid, receive motor input from recurrent laryngeal nerve and subglottis

receives input. Glossopharyngeal nerve supplies sensory input to the tongue base and vallecula, which together constitute the upper border of epiglottis. ^(35,45)

APPLIED ANATOMY OF LARYNX

Laryngeal nerves can get damaged in numerous ways, including thyroid, carotid, lung, cardiac surgery, cancers of the lung, oesophagus, or lymph nodes, a dilated right atrium, an enlarged thyroid, trauma to cervical region, insertion of laryngeal mask Airways, and after endotracheal intubation.

SLN -Due to its proximity to the superior thyroid arteries, the external branch of the thyroid **SLN** is susceptible to injury during thyroid surgery. Hoarseness and loss of vocal cord function are brought on by loss of cricothyroid function and may be transient because the opposing cricothyroid generally makes up for it.

RLN, due to its proximity to the inferior thyroid arteries, it might be injured during thyroid surgery. Due to its longer course, it is susceptible to damage from aneurysms of aorta, enlarged right atrium, lung and esophageal cancers, and large lymph nodes.

The vocal cord will adopt a midline position if only one **RLN** is damaged, which can cause hoarseness, an ineffective cough, and even recurrent aspiration of gastric contents. Vocal cord function may completely disappear in the event of bilateral **RLN** damage, creating a potentially fatal airway obstruction.

^(35,36,37,41)

ENDOTRACHEAL INTUBATION – AN OVERVIEW

The positioning of pliable plastic tube into the trachea through larynx is known as endotracheal intubation. Regularly followed is orotracheal route which remains gold standard procedure for airway management.

Aims of intubation: For process of transmitting gases to and from lungs, maintaining a patent airway, guarding against lung aspiration, and enabling leak-free ventilation during mechanical ventilation. A tracheostomy, combitube cricothyrotomy, or a laryngeal mask airway can all be used in place of endotracheal intubation.⁽⁴⁶⁾

Airway resistance

Tracheal tubes gives rise to resistance and increased breathing labour when breaths are taken spontaneously.

Factors governing airway resistance

– **Internal diameter of tube:** One of the key deciding factors is the relationship between airway resistance and tube inner diameter, which is inversely proportional. Secretions lining the inner portion of the tube, passing suction catheters, and fiberoptic scope resistance are other factors that increase resistance..

– **Endotracheal tube length:** airway resistance is directly proportion to length of ETT

→ **The tube's configuration:** Curves and kinks in the tube increase resistance.

The resistance of the tube is also increased by connectors..

→ **Dead spaces of the tube:** natural airway is bypassed by ETT and hence dead space is reduced but mechanical dead space is formed by the ETT and connector.⁽⁴⁷⁾

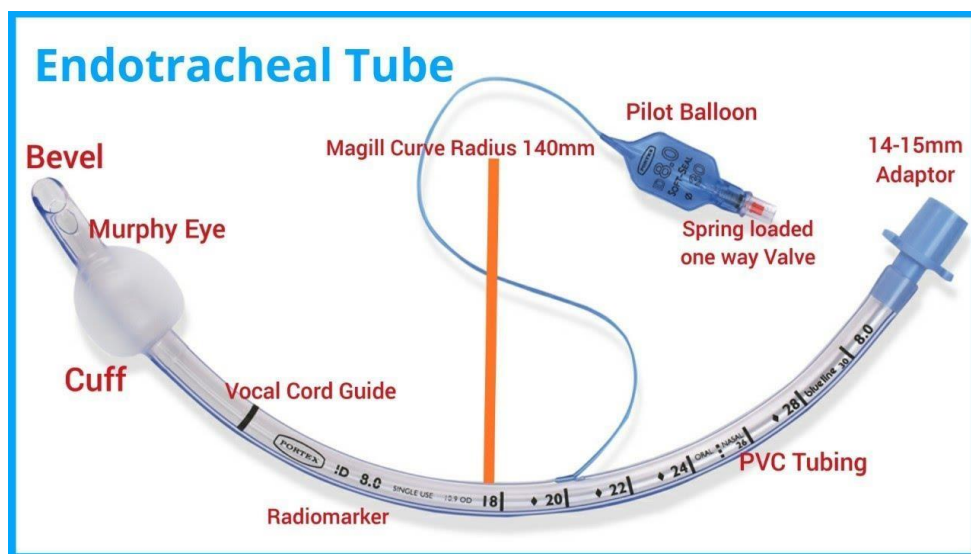


Figure 11: Design of Endotracheal tube

Available versions of endotracheal tube –

Currently ETT's are being made from Polyvinylchloride. They are cost effective, expendable and biocompatible. It has an even surface and conforms to upper airway, bronchoscope and suction catheter can pass through comfortably. Secretions and aspirated material can be seen through due to its transparent nature. Silicone tubes are costly, can be sterilised and used multiple times. ETT there are

other high volume, low pressure polyurethane cuffs with micro thin walls on the market. They lack a murphy's eye and have a short bevel⁽⁴⁸⁾

Endotracheal tube design ^(49,50)

“There are International standard recommendations for material of tube, internal diameter, length of tube, radius of curvature, inflation system, cuff, markings, labelling and packaging.

– The internal and external wall of tracheal tube should be circular.

– Machine end or proximal end receives the connector and projects from the patient. Tube can be cut short to decrease the dead space at this end.

– Patient end or distal end is inserted into the trachea.

– Endotracheal tube have slanted portion at patient end called bevel which faces to left when tube is viewed from its concave aspect.

– Some tubes have hole opposite to bevel called murphy's eye which provides alternate pathway for gas flow if bevel becomes occluded.

– Tubes which lacks murphy's eye are called Magill type tube.

– Radiopaque marker is placed along entire length of tube to determine tube position after intubation.”

Uncuffed endotracheal tube (47,48,49,52)

- These are cost effective.
- Monitoring of cuff pressure is not required in them.
- Internal diameter of the tube generally determines the resistance and the external diameter determines the mucosal injury, Uncuffed tubes provide a greater cross section and minimal resistance to mechanical ventilation, spontaneous breathing.
- Chances of occlusion of tube with secretion is comparatively less.

Cuffed endotracheal tube (49,51)

- Cuffed tubes offer enhanced precision in end-tidal gases estimation, tidal volume, lung compliance, and oxygen intake, which is beneficial in patients at higher risk of aspiration.
- Gases are prevented from escaping as the cuff seals, it decreases the contamination of atmosphere
- Chances of tube getting occluded is comparatively more Resistance is more due to smaller size. “Poiseuille law governs resistance to laminar flow through a tube, which states that resistance is proportional to the length of the tube and inversely proportional to fourth power of radius” (52)

→ Mucosal ischemia is caused by an increase in cuff pressure from excessive cuff inflation over an extended period of time.

→ Trachea oesophageal fistula are occluded by these.



Figure 12 : Cuffed vs Uncuffed endotracheal tube

Microcuff endotracheal tube

It was designed to manage the limitations of paediatric cuffed tube⁽⁴²⁾ For good accommodation in paediatric airway the high volume ,more distally positioning the low pressure cuff lowers the likelihood of endobronchial intubation.. Minimal cuff fold are formed with uniform contact and it provides tracheal sealing with ultrathin polyurethane low pressure cuff. Murphy's eye is absent here. ^(45,50) Cost is one of the major concern as it is three times costlier than regular ETT.⁽⁵²⁾ Kinking of tube is seen when tube warms up and becomes soft. Some studies have portrayed that microcuff tubes have lesser sealing pressures than conventional cuff⁽⁴⁵⁾ and few of them have reported that the re-intubation represents 1.6% of all

intubations and post intubation croup 0.4%.⁽⁴⁴⁾ Establishment of safety of these tubes needs to show in bigger cohort study .



Figure 13: Microcuff endotracheal tube

Endotracheal tube size

Age, height and weight of patient are some of the parameters by which ETT size can be calculated. At 20-30 cm H₂O inflation pressure if leak is detected around the tube, it has to be replaced by one size smaller tube. If lateral wall pressure reaches this, subglottic mucosal ischemia may result⁽⁴⁹⁾

Nitrous oxide effects

The ability of nitrous oxide to diffuse into a catheter's cuff 34 times faster than gas will diffuse out causes a rise in cuff volume and intracuff pressure (Patel, Oh, & Epstein, 1983).^(53,54)

Technique improved with increasing inhalation general anaesthetic exposure time, ablated cuff thickness, and inhalation general anaesthetic galvanised partial pressure. Inhalation general anaesthetic diffusion would be reduced if the cuff material's thickness were increased. A thick, non-compliant cuff, on the other hand, won't conform properly to shape of trachea, causing unequal pressure and creation of channels, which raises risk of aspiration. O'Donnell showed in 1995 using an inhalation general anesthesia may increase an endotracheal cuff that is correctly inflated to a pressure sufficient to cause cartilaginous tube anemia (more than 25 metric linear unit Hg) in little as eight minutes (median time). To lessen the general effects of inhalation, many procedures and design modifications have been created.⁽²⁵⁾

In order to prevent over-inflation when using inhalation general anesthesia throughout the case, the endotracheal cuff is inflated using the drug. The cuff will deflate, hence increasing the risk of aspiration, but once inhalation general anesthesia is no longer available. Inflating cuff with a combination of air also inhaled general anesthesia is a further recommended approach. The issue with this is that depending on the dose of inhalation general anesthesia utilized during the case, the cuff could deflate or rise in pressure (Revenas & Lindholm, 1976).⁽²⁸⁾

In order to distribute some of the inhalation general anesthetic into the environment and prevent a rise in catheter cuff pressure, endotracheal tubes with large external reservoirs (pilot balloon) are introduced. The issue with the inhalation general anesthetic spreading from external reservoir was that it increased amounts of inhalation general anesthetic in the anaesthetists' breathing space, probably beyond and beyond the permitted regulatory requirements (Fill, Dosch, & Bruni, 1994).

Mechanical devices are created which give continuous endotracheal cuff pressure and minimize effects inhaling general anesthesia. Due to their high price as well as the fact that they temporarily raise tube cuff pressures during coughing and positive pressure breathing, these devices are no longer in fashion. Few of those tools or methods are used by physiological state suppliers in the clinical context.

Latest techniques to minimize risk of over inflation

Prevalence and severity problems brought on by catheter cuffs have reduced since the introduction of high-volume, passive endotracheal cuffs (Crawley & Cross, 1975)⁽¹⁹⁾. However, excessive cuff inflating will significantly raise intracuff pressure. The endotracheal cuff may experience associated intracuff pressure changes of greater than thirty torr if it is inflated with two to three extra millilitres of air on the opposite side from what is required for a sufficient seal. Various methods have been devised to reduce the likelihood of the catheter cuff being overinflated. The most widely utilized approaches include direct intracuff pressure

measurement, meteorological balloon touch by physiological condition, use of a negligible leak technique, and use of a negligible occlusive volume methodology.^(55,56)

When inflating the catheter cuff, providers United Nations agency employ a preset volume technique and inject cuff with predetermined volume of air, such ten cube-like centimetres (cc s). Problem with this is that anesthesiologist frequently is unable to identify precise pressure that a predetermined volume of air can impose on trachea; it may either be too low, posing a risk of aspiration, or too high, posing a risk of injury to the cartilaginous tube.⁽⁵⁷⁾

In order to use the touch technique, air must be injected into cuff until meteorological balloon is stiff enough to tip over. According to a 1990 study, there is no disputing the low accuracy of finger touch cuff pressure assessment, and supplier experience had little bearing on the study's results (Fernandez, Blanch, Mancebo, Bonsoms, & Artigas, 1990).

When using minimal leak approach, air is first introduced into cuff to create a seal before being gradually removed until a minimal leak is visible at peak inspiration. One of method's downsides is that cuff has a propensity to move around inside trachea, which could injure the cartilaginous tube. Additionally, the danger of aspiration increases when the cuff occupies the trachea (O Donnell, 1995).⁽²⁵⁾

When using negligible occlusive volume technique, which is a variation of negligible leak technique, cuff is inflated until a seal is achieved at very peak of inspiration, a very small amount of air is then removed until a leak is detected, at which point the cuff is inflated with least amount of air possible to stop leak.

Although the aforementioned method resulted in less catheter movement and a lower risk of aspiration, one study found that utilizing it can actually increase aspiration rates by up to 38%. (Benard et al, 1979).

Directly measuring pressure within the catheter cuff as a sign of a good seal is one of the most effective methods for protecting it. When inflation and cuff pressures set to appropriate levels in manner, a pressure gauge is attached to the weather balloon. The biggest drawback of this method is absence immediately available manometers for anaesthesia care (O Donnell, 1995).⁽²⁵⁾

Rationale and Significance of the Problem

To prevent or reduce tracheal ischemia problems brought on by endotracheal tube cuff pressures, a variety of tools and methods are available. The safest anaesthetic feasible must be provided by an anaesthesiologist per professional responsibility. In recent study including 44 patients, 35% of endotracheal cuffs were over-inflated, increasing risk of ischemia issues; 43% of cuffs were under-inflated, boosting risk of aspiration in patients; and only 19% were inflated to recommended cuff pressure (O Donnell, 1995)⁽²⁵⁾. This variance in safe cuff pressures emphasises need comparing endotracheal cuff inflation methods utilised by anaesthesia providers and increases the risk of patient morbidity.

Aspiration

⁽¹⁸⁾Cottrell, Bernard, Sivakumaran, Patel, and Turndorf (1977) conducted their research in an effort to determine least intracuff pressure necessary to prevent aspiration around high-volume, low-pressure cuffs. After 12 patients had had a standardised anaesthetic induction, two different types of cuffs were inflated with air. Intracuff pressure for high-volume, low-pressure cuffs was set at 15 or 18 torr, or minimal occlusive volume, whereas the intracuff pressure for low-volume, high-pressure cuffs was set at minimal occluding volume. A column of blue dye rising 5–10 cm above the larynx was created by injecting 10 ml of blue dye into the posterior oropharynx while under direct vision. After procedure, bronchoscopy was done to check for dye distal to cuff. There was no dye aspiration in the 12 intubated patients who received low-volume, high-pressure cuffed tubes that were only occlusive in volume. More than 35 mm Hg of lateral wall pressure was present in these cases. Additionally, none of the 21 mechanically ventilated patients or the 20 patients who were intubated with high-volume, low-pressure cuffed tubes and were spontaneously breathing aspirated while intracuff pressure was maintained at 18 torr. Aspiration of dye occurred in 7 out of 12 patients when the intracuff pressure in high-volume, low-pressure cuffs was maintained at 15 torr. Cuffed high-volume, low-pressure tubes that were hardly occlusive aspirated were used to intubate six out of the eleven patients. Nothing said that the least occlusive volume was greater than or equal to 18 torr. Authors came to conclusion

that high-volume, low-pressure cuffed tracheal tubes could avoid aspiration and suggested carefully regulating the intracuff pressure to at least 18 torr.^(19,20)

Similar findings were made by Bernard et al. (1979)⁽¹⁷⁾ in study including 133 adult patients. Researchers discovered that number and size of folds pressing on tracheal mucosa as well as potential channels through which liquids may enter trachea are all influenced by the cuff diameter, wall thickness, and intracuff pressure. When it was feasible, they advised employing endotracheal tubes with broad, thin-walled cuffs. In large diameter thin-walled cuffs, considerable aspiration should be avoided by maintaining intracuff pressure between 19 and 26 mm Hg while yet allowing appropriate capillary mucosal blood flow. Pressure-regulating valve or routine intracuff pressure and volume changes can be used to accomplish this.

Nitrous Oxide Diffusion

In blood, nitrogen is 34 times less soluble than nitrous oxide. This means that the capacity of an air-filled room can increase because nitrous oxide can diffuse into it 34 times faster than nitrogen can.⁽⁵³⁾

According to Stanley's (1973) research, nitrous oxide would permeate into endotracheal tube's cuff and expand in volume in response to exposure time and nitrous gas concentration.

In patients who were given 70% nitrous oxide, Revanas and Linholm (1976) showed that the endotracheal tube's capacity might rise by 3.3 times its initial value.

Patel et al. (1983) investigated endotracheal tubes exposed to 70% nitrous oxide and 30% oxygen as well as different temperatures to establish which component most significantly influenced the change in cuff volume. The research discovered that nitrous oxide's inward diffusion was responsible for 76–88% of the volume change and oxygen was responsible for 2-10%. The volume of the cuff changed, but temperature barely made a difference.^(17,26)

Intracuff pressure is raised from 19 mm Hg to above 25 mm Hg by 50-70% nitrous oxide on average in eight minutes, according to a 1995 study by O'Donnell. This shows that care must be taken to regularly check the endotracheal cuff pressure in order to prevent volume fluctuations brought on by nitrous oxide.⁽¹⁸⁾

Inflation Techniques

One of the most popular techniques for estimating cuff pressure, according to Fernandez and colleagues in 1990, is palpation of pilot balloon on endotracheal tube. This study evaluated the capacity of 20 critical care workers to calculate cuff pressure using pilot balloon palpation. If the cuff was overinflated, 69% of participants could tell; if it was inflated to appropriate levels, 58% could tell; and if it was underinflated, 73% could tell. Because of physical characteristics of tubes and subjectivity of observers, the study came to the conclusion that manual estimation is an unsuitable technique for measuring cuff pressure. To prevent negative consequences brought on by aberrant cuff pressures, reliable measurement systems should be utilised.^(47,57,58)

O'Donnell (1995) found that when the minimal occlusive volume strategy was utilised, 7% of patients were danger for tracheal ischemia (cuff pressure more than 25 mm Hg), 80% of patients were risk for aspiration, and 13% of patients were in the optimal range (cuff pressure less than 18 mm Hg). When utilising the palpation method, 33% of the patients were within ideal range, 22% had a risk of aspiration, 45% had a risk of tracheal ischemia, and the remaining 22% had a risk of both. Only 15% of patients were within the optimal range when predefined volume technique was used, 25% of patients were danger for aspiration, and 60% of patients were at risk for tracheal ischemia.⁽²⁵⁾

Endotracheal intubation related complications (38,39,40,43)

Present with various complications some of which are debilitating to life. Often encountered in pediatric age group due to their anatomical variation.

During intubation:

Unsuccessful intubation: Cannot ventilate cannot intubate (CVCI) may cause hypoxic brain injury leading to death. Cricothyrotomy or tracheostomy can be lifesaving in such situations.

→ Esophageal intubation

→ Endobronchial intubation: can cause hyperinflation and barotraumas in the intubated lung or it can lead to hypoxia due to inadequate ventilation of the other lung. Once recognized ETT should be fixed out by few centimeters.

→ Laryngospasm: occurs when intubation is tried in lighter planes of anesthesia leading to hypoxia. This can be overcome by suboptimal dose of muscle relaxant, deepening the plane of anesthesia and Larson's maneuver.

→ Bronchospasm: produced by mild anesthesia and extremely sensitive airways. Topical or intravenous lignocaine, steroids, beta 2 agonists, anticholinergics, and narcotics may have previously lessened its effects.

→ Pressor response: In course of laryngoscopy and intubation, there may be an increase in catecholamine that causes tachycardia, hypertension, myocardial ischemia, decrease of myocardial contractility, ventricular arrhythmias, an

increase in intraocular pressure, and intracranial hypertension. A lengthier laryngoscopy may result in an increased response. Beta blockers like esmolol, lignocaine (1–5 mg/kg), and fentanyl (3–4 micrograms/kg) all dampen these responses.

– Trauma to respiratory tract during laryngoscopy and intubation chances which increases with the use of stylet. Cord avulsions, fractures and dislocation of arytenoids are also seen.

– Perforation of esophagus or trachea: rare complication but can occur with repeated attempts which presents as subcutaneous emphysema. There may be mediastinitis, which could result in sepsis and possibly death. Bronchoscopic identification has to be done and necessary intervention has to be done.

– When cervical injury is suspected manual inline stabilization of head must be done during intubation, if not spinal cord and vertebral column injury can be encountered. Blindness, central retinal artery blockage, and corneal abrasion are also common.

Complication with ETT insitu ⁽⁴¹⁾

– Tension pneumothorax: caused by IPPV which can lead to barotraumas or airway perforation during intubation. If it is leading to cardiopulmonary distress, it has to be decompressed using intercostal drain or wide bore cannula.

→ Incomplete seal: can be due to ill-fitting size tube, cuff leak, inflation valve leak and improper position of ETT. Inadequate breathing and aspiration of stomach contents are the results.

→ Obstruction of tube can be caused by biting, kinking, blood clots, or secretions. It raises the resistance and pressure in airways.

→ Fire during laser surgery.

Complications during extubation^(41,43)

→ Suturing of tube to trachea or bronchus can be encountered during pneumonectomy. In this situation, a direct or fiberoptic examination should be performed.

→ Laryngospasm and airway blockage can happen during extubation.

→ Laryngeal edema: Cricoid cartilage is thinnest least extendible portion in children that age range. Therefore subglottic edema is often seen in children which presents as inspiratory stridor and causes total airway obstruction later. Humidified oxygen, racemic epinephrine and dexamethasone can be used to treat the same. Reintubation is done if airway obstruction persists.

Complications post extubation⁽⁴²⁾

→ **Sore throat:** The most frequent side effect following extubation, particularly in recovery room, is sore throat. Following extubation, a sore throat can develop that includes pain, discomfort, and hoarseness of voice, dysphagia, and dry throat. This

condition is hypothesized to be brought on by laryngeal inflammation and edema. Main cause is damage to airway mucosa during treatment. Severity of injury is influenced by forces used during laryngoscopy, number of attempts necessary for effective intubation, and length of procedure .It usually resolves in 48 hrs. Management strategies include nebulized racemic epinephrine, heliox, glucocorticoids, and reintubation.^(2,3,54)

→ Edema of larynx

→ Aspiration of stomach contents or oral fluids

→ Laryngeal granuloma: presents as chronic cough and hemoptysis which resolve spontaneously with strict voice rest. Surgical intervention is needed if pedunculated lesion is present.

→ **Vocal cord paralysis and stridor** : All the intrinsic muscles of larynx are supplied by anterior branch of recurrent laryngeal nerve which enters the larynx between cricoid and thyroid cartilage. Over inflated cuff compresses the nerve at this region which can lead to nerve palsy. In unilateral injury to the nerve cords remain in adducted position as abduction of cords is restricted and hoarseness of voice is present. Airway compromise requiring reintubation or tracheostomy is seen in bilateral nerve palsy. It typically heals on its own in a matter of days to months.^(7,59)

→ Tracheal membrane of the larynx - Leads to respiratory compromise after 24-72 hrs after extubation. Removal of membrane through suction under vision can

be done. – Tracheal stenosis: Ischemia of lateral walls of trachea caused when tracheal cuff pressure more than 25mm Hg leads to destruction of structural integrity of trachea. Fibrous stricture may be formed during the healing process which causes stenosis.

–**Cough and hoarseness of voice** - Coughing is an intricate reflex that has three main phases: inspiration, which draws a lot of air into the lungs; compression, which involves forcing air out against a closed glottis and can reach high intrathoracic pressures (up to 40 kPa); and expulsive, during which the glottis opens and allows quick expiratory flow throughout the respiratory tract. Inflation of an inflatable cuff can cause tracheal morbidity, loss of mucosal cilia, ulceration, bleeding, and tracheal stenosis. Patients also have sore throat, hoarseness, and dysphagia in days and weeks following surgery.^(55,59,60)

CUFF MANOMETERS

Subjects using endo tracheal tubes often have their cuff pressure measured during both surgical procedures and medical aid. Preventing hyperinflation, which can damage cartilaginous tube membranes, suction of settled secretions from higher airways, and tracheal membrane injuries are the two main objectives. Therefore, recommend cuff pressures between 20 and 30 cmH₂O. It could be challenging to apply these constraints in a clinical setting while maintaining constant cuff pressures.⁽⁶⁰⁾

Topic and cuff positions, the cuff volume, and consequently the body heat all have an impact on the stability of the cuff pressure. The trachea's compliance and, therefore, the cuff, are also affected.

Even a little intracuff pressure excess for a short period of time can compromise the cartilaginous tube wall at the cuff contact space and result in congestion and bleeding.

However, it is crucial to maintain the tube cuff pressure above 20cmH₂O to stop contaminated supraglottic secretions from leaking past the cuff. Ventilator-associated respiratory disease (VAP) is caused by a variety of factors, which include compromised host defense and mucociliary clearance, organ and higher tract organization, and organism virulence. However, some authors contend that main cause of VAP is escape of contaminated secretions past cuff. VAP is one of the most common infections in patients in intensive care units with a prevalence of between ten and twenty-seven .Controlling metabolic secretions from the

supraglottic area and keeping an eye on cuff pressure are two tried-and-true ways for preventing VAP. ^(22,27,49)

The cuff pressure gauge, which has historically been used in clinical settings, is recommended tool measuring tube cuff pressures. However, some institutions with limited resources don't have the equipment due of its high cost. Because of their affordable pricing and portability, these new devices quickly became commonplace among medical staff.

AG Cuffill Description & Indication for Use

The Laryngeal Masks Airways, Tracheostomy Tubes, and Endotracheal Tube Cuff Pressure are all measured and controlled by the Hospitech AG Cuffill. Cuff by Hospitech AG is intended for use by physicians and qualified ventilation care givers under medical supervision in hospitals, and any other facilities where ventilated patients are taken care of (i.e. Extended care institutions, outpatient clinics, and pre-hospital (EMS)). By following the cleaning and disinfection instruction in this manual, the AG Cuffill can be reused up to 100 times on the same patient or different patients (multiuse, multipatient).



Figure 14: AG Cuffill manometer

Precautions - The AG Cuffill should only be used with an air-filled cuff and not with liquids as this could harm the instrument.

→ Continuous monitoring cannot be performed with the AG Cuffill. After use, it should be taken off each time.

→ Whenever possible, the AG Cuffill it should be stored and transported in a dry environment.

→ The cuffill's tip's luer (connection) is free of any secretions or obstructions and is exposed to atmospheric pressure.

Size: 13 cm in length, 15 mm in diameter, and 18 gm in weight.

Volume delivered: 0-10 cc in 1cc graduations.

Storage/Operation: Temperature +10... +30°C (50...85°F), Relative air humidity without condensation:

Instructions for Use-

→ Activate the atomic switch. By clicking the facilities button on the sharp right of the display, Cuffill. The display can blink twice to indicate how many readings are still available before displaying "00."

→ Push the syringe plunger till it stops blinking.

→ Inflate the cuff on the airway using the Cuffill, then check the pressure reading.

→ If necessary, cuff pressure can also be decreased by depressing the plunger until the desired pressure is reached.

→ After the reading and pressure adjustment, detach the Cuffill from the cuff inflate line.

Cleaning: → Soak a clean pad with Alconox 1 Chronicles (diluted with distilled water) or body part Scrub four-dimensional Chloroxidine resolution.

→ Wipe the device surfaces (barrel and plunger) and clean totally till product is clean from contamination. Repeat a minimum of four times.

→ Soak a clean pad with water. Wipe and clean the device surfaces.

→ Wipe the device surfaces with a dry pad and ensure to go away to dry for one hour on a clean surface within the area.

Disinfection: → Soak a clean pad with either: Alcohol IPA seventieth or a oxide one.4 %.

→ Wipe the device surfaces (barrel and plunger) and clean totally till product is clean from contamination. Repeat a minimum of four times.

→ Wipe the device surfaces with a dry pad and ensure to go away to dry for two minutes on a clean surface within the area.

→ When finishing the cleansing method and therefore the medical care method, insert the plunger back to the syringe barrel. The Cuffill is prepared to be used once more.

METHODOLOGY

SOURCE OF DATA:

The Department of Anesthesiology at B.L.D.E. (Deemed to be University) Shri was where this study was carried out. B M PATIL Medical College and Hospital, Vijayapura.

METHOD OF COLLECTION OF DATA:

Study Design:

Prospective randomized comparative study.

Study Period:

One and half years from January 2021 - June 2022.

Sample Size:

The study would need a sample size of 72 people per group to account for anticipated 20 and 8 percent post-procedural problems for manual vs. automatic cuff pressure monitor, respectively. (i.e., a total sample size of 144, assuming equal group sizes), to reach a power of 80% for detecting a difference in proportions between 2 groups at a two-sided p-value of 0.05.

Formula used:

$$n = \frac{(z_{\alpha} + z_{\beta})^2 \cdot 2 \cdot p \cdot q}{MD^2}$$

Where Z= Z statistic at a level of significance

MD= Anticipated difference between two proportions

$P = \text{Common Proportion}$

$q = 100 - p$

Total sample size = $72 + 72 = 144$

Randomization:

Study population of 72 patients was randomly selected in each group, by computer generated randomization, of age group between 20-80 years undergoing surgeries lasting for up to 3 hours under general anesthesia. In one group, endotracheal tube was inflated manually, and in the other it was done using a automated manometer. Intraoperative changes in pulse and blood pressure shall be evaluated and post-operative complications such as sore throat, hoarseness of voice, cough, stridor, laryngeal nerve palsy, aspiration pneumonitis would be observed and evaluated.

Group M: In these patients endotracheal tube cuff was inflated manually by an experienced anesthesiologists

Group C: In these patients endotracheal tube cuff was inflated by using automatic cuff manometer.

To provide conclusive results using statistical analysis, observations that were made were noted and tallied.

Criteria for inclusion:

- * Patients between the ages of 20 and 70, regardless of their sex
- * Patients with ASA grade 1 & 2 , Malampatti grade 1 & 2
- * Surgeries posted under general anesthesia lasting for up to 3 hours
- * High volume, low-pressure cuff, single use, oral Portex tube with an internal diameter of 7.0-8.5 mm.

Exclusion Criteria:

- * Pregnant patients, trauma cases involving anterior cervical spine injuries, and all emergency intubations.
- * Patients with difficult airway
- *Patients with hepatic or renal insufficiency.
- *Patients with neurologic and psychiatric disease.
- *Patient refusal.
- *Patient having bleeding disorders.
- *Patients with H/o Cardio- Respiratory disorders

Preanaesthetic evaluation:

All study participants underwent full pre-anesthesia evaluations, which were completed as follows:

History:

We enquired about past surgical history, anesthesia exposure, hospitalization, and history of underlying medical conditions.

Physical examination:

In addition to evaluating the patient's overall health and documenting his vital signs (HR, BP, RR), his height and weight were taken. The respiratory, cardiovascular, central nervous, and spinal systems were all thoroughly examined in addition to the airway assessment.

Investigations:

The following standard investigations were necessary for this study:

CBC, Coagulation profile, chest x-ray, ECG, random blood sugar, renal function test, HbSAg, HIV, and urine analysis

PROCEDURE:

- Two groups, Group M (manual) and Group C, each with 72 patients, were randomly chosen from 72 patients who had been advertised for elective procedures (cuff manometer)
- The day before surgery, all patients underwent full examinations in accordance with institute protocol. They were also given advice on the procedure and anesthesia.

- Informed consent was obtained from patients who met the selected criteria and they were asked to participate in study. The patient was told to fast for 6 to 8 hours.
- In the operating room, all resuscitation and monitoring tools, including bag-valve-mask system, laryngoscope, endotracheal tubes, and emergency medications, available for use in case of a bad event.
- The patient was brought into operating room on day of the procedure. Blood pressure, heart rate, and SpO₂ baseline values are recorded.
- To gain intravenous access, a 20G cannula is used.

PROCEDURE: INTRAOPERATIVE PERIOD

The patient was shifted to operation table, good IV access shall obtained on forearm and Ringer's lactate solution 10ml/kg/hr was infused intravenously. Baseline heart rate, non-invasive blood pressure, SPO₂, respiratory rate and ECG was recorded using multi-parameter monitor, before starting the procedure.

Patients was divided to two groups:

Group M- 72 patients, a experienced anesthesiologist manually inflated the endotracheal tube cuff of minimum of 5 years of experience and pressure was monitored every hourly without altering the pressure recorded

In group C- 72 patients, Automatic cuff pressure controller was used to maintain the endotracheal tube's cuff pressure at 25 cm H₂O during the surgical procedures.

After pre oxygenating the patient for 3 mins. Premedication was done with ondansetron (0.15 mg per kg body weight), glycopyrrolate (0.008 - 0.15 mg per kg body weight) and midazolam (0.08 – 0.1 mg per kg body weight). Analgesic was given using fentanyl (1 – 2 ug per kg body weight). Anaesthesia was induced using propofol (1-2 mg per kg body weight) and succinyl choline(1 - 1.5 mg per kg body weight) given. The proper size endotracheal tube was used for oral endotracheal intubation. Atracurium (0.5–0.8 mg per kg of body weight) is a muscle relaxant used .

Group M, the typical method of cuff inflation was injecting air into the cuff with a syringe. Anesthesiologists with at least five years of experience can determine the cuff pressure by palpating external pilot balloon and listening for the elimination of audible air leak.

Group C, The pressure in the endotracheal tube cuff was kept at 25 cm H₂O throughout the procedures using an automated cuff pressure controller. Patients were maintained by using isoflurane, fentanyl, atracurium, oxygen + nitrous oxide (1:2), and both.

ASSESSMENT OF COMPLICATIONS:

- Assessment of intraoperative changes in pulse and blood pressure secondary to changes in endotracheal tube cuff pressure.
- Assessment of complications in immediate postoperative period, like cough , sore throat , hoarseness of voice, laryngeal nerve palsy,

stridor shall be noted, and aspiration pneumonitis (due to under inflation) if any.

Late complications such as , tracheal wall damage with blood stained expectoration , larygomalacia, tracheomalacia, tracheal stenosis , subglottic scarring and stenosis , tracheoesophageal fistula due to over inflation , are likely to occur. But are not included in the study.

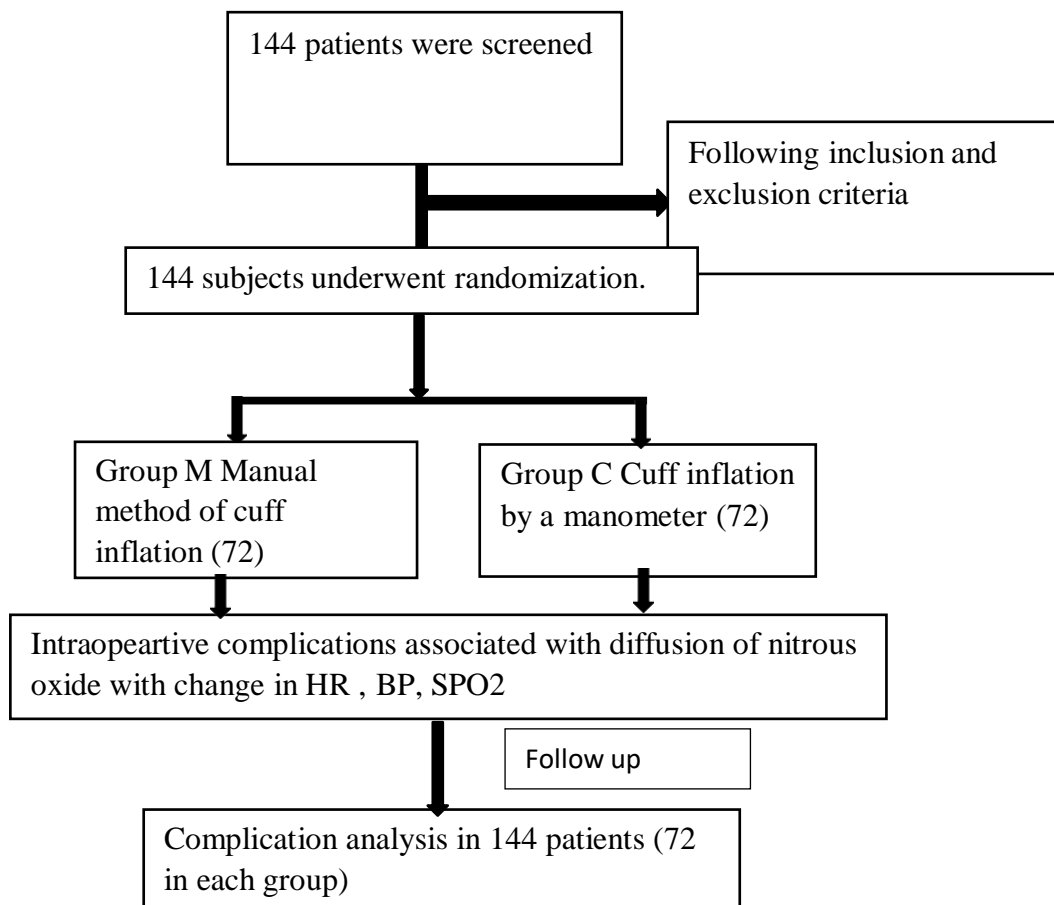


Figure 15: Flow chart illustrating patient inclusion.



(a)

(b) Figure 16 : Cuff manometer recordings



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OBSERVATION AND RESULTS

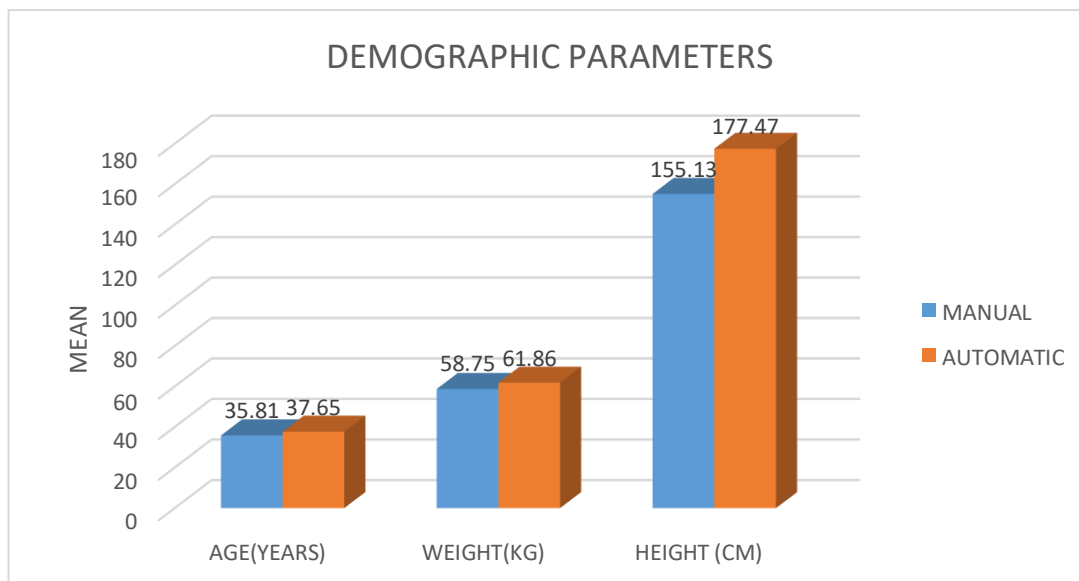
During the study's one and a half years, general anesthesia for procedures lasting up to three hours was administered to patients between the ages of 18 and 80.

The information needed to generate the findings for the study's objectives was appropriately collected, tabulated, and analyzed.

The following findings were recorded:

DEMOGRAPHIC PARAMETERS	MANUAL		CUFF		MANN-WHITNEY	P VALUE
	MEAN	SD	MEAN	SD		
AGE(YEARS)	35.81	15.210	37.65	15.279	2363.500	.361
WEIGHT(KG)	58.75	10.035	61.86	10.929	2162.500	.084
HEIGHT (CM)	155.13	6.065	177.47	158.173	1717.000	0.01

TABLE 1 : Distribution of patients according to age , weight, height in study groups

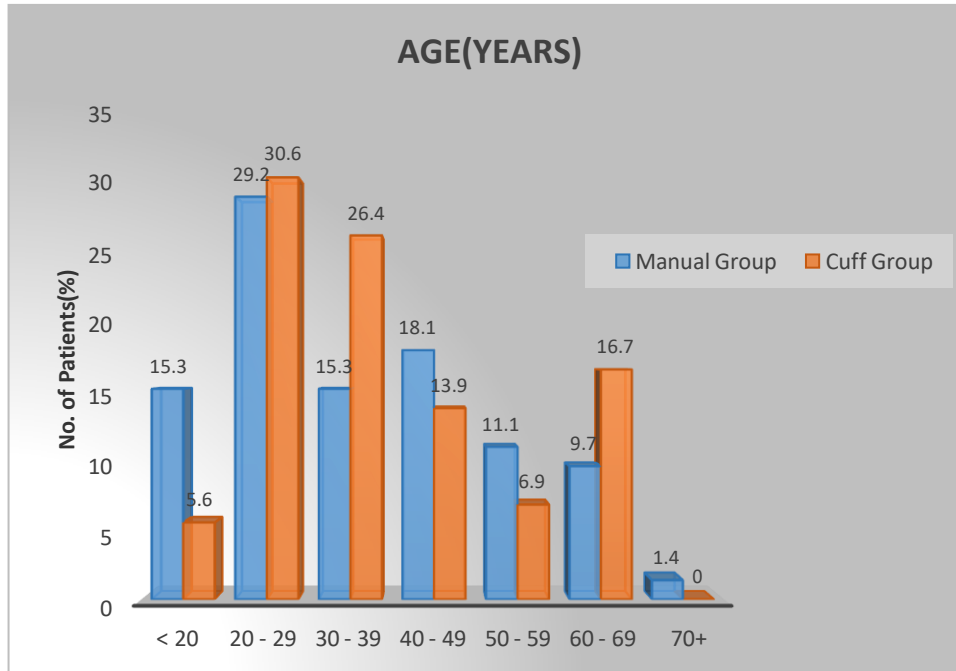


GRAPH 1 : Distribution of patients according to age , weight, height in study groups

- In our investigation, both groups had comparable age, weight, height . Cases ranged in age from 18 to 80 years old, with a mean of 35.81 15.210 for Group M and 37.651 15.279 for Group C, with a p value Of .361
- With p value of .084 , mean weight of the patients in Group M is 58.75 10.035 kg and in Group C is 61.86 10.929 kg. Weights of patients in two groups are comparable, and no statistically significant difference exists between them.
- With p value of .001, mean height of patients in Group M is 155.83 6.035 cm and in Group C is 177.47 158.173 cm. The height of the patients in the two groups are comparable, and no statistically significant difference exists between them.

Age(Years)	Manual Group		Cuff Group	
	No. of patients	Percentage	No. of patients	Percentage
< 20	11	15.3	4	5.6
20 - 29	21	29.2	22	30.6
30 - 39	11	15.3	19	26.4
40 - 49	13	18.1	10	13.9
50 - 59	8	11.1	5	6.9
60 - 69	7	9.7	12	16.7
70+	1	1.4	0	0
Total	72	100.0	72	100.0

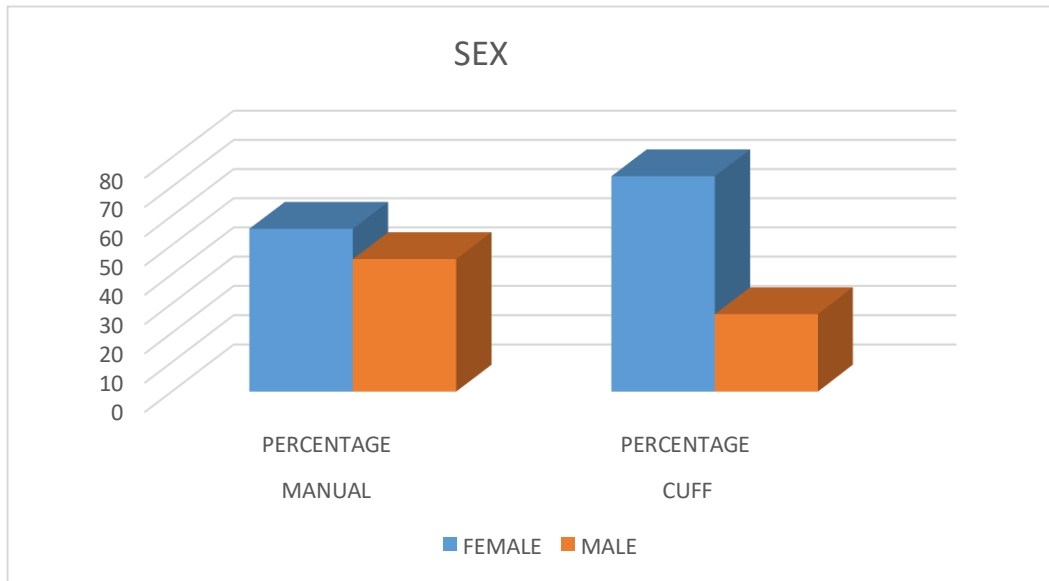
TABLE 2 : Distribution of patients according to age in percentage in study groups



GRAPH 2 : Distribution of patients according to age in percentage in study groups

Sex	Manual Group		Cuff Group		P value
	No. of patients	Percentage	No. of patients	Percentage	
Female	40	55.6	53	73.6	0.356
Male	32	44.4	19	26.4	
Total	72	100.0	72	100.0	

TABLE 3 : Distribution of patients based on gender in percentage between study groups

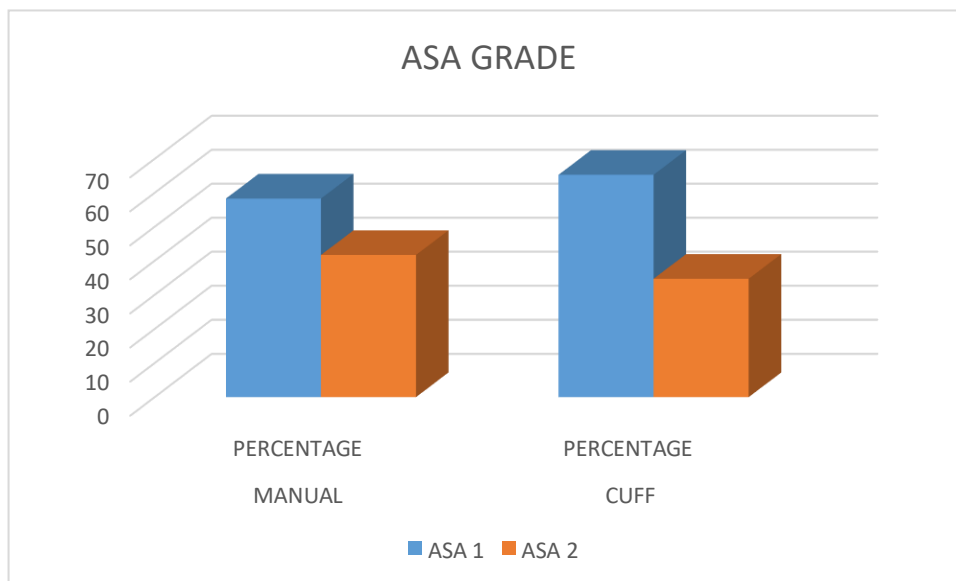


GRAPH 3 : Distribution of patients based on gender in percentage in study groups

- Out of 93 females and 51 males studied in both comparative groups . No statistical significance noted thus complications associated with cuff pressure monitoring is not influenced by the sex of the patient subject . P value being 0.356.

ASA GRADE	Manual Group		Cuff Group		P value
	No. of patients	Percentage	No. of patients	Percentage	
ASA 1	42	58.3	47	65.3	0.324
ASA 2	30	41.7	25	34.7	
Total	72	100.0	72	100.0	

TABLE 4 : Distribution of patients based on ASA grading in percentage between study groups

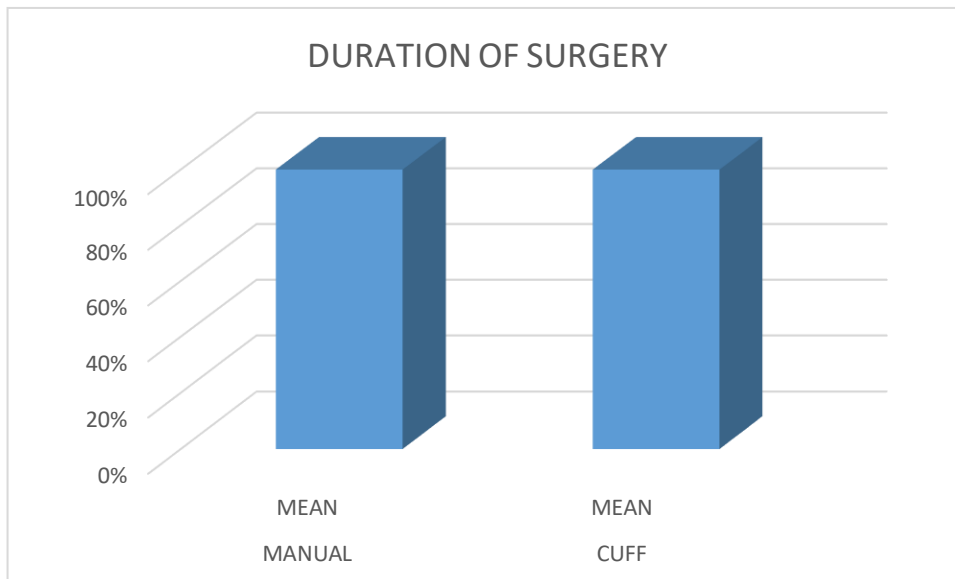


GRAPH 4: Distribution of patients based on ASA grading in percentage between study groups

- Total 144 ASA class 1 and 2 subjects are studied. No statistical significance noted in any group. Complications associated with cuff pressure monitoring in both manual and automatic method is not influenced by the ASA class of the patient / subject undergoing the procedure. P value being 0.324

DURATION	MANUAL		CUFF		MANN-WHITNEY	P VALUE
	MEAN	SD	MEAN	SD		
TOTAL DURATION OF SURGERY	2.875	.2996	2.715	.3543	1914.000	0.001

TABLE 5 : Comparison of mean duration of surgery between the study groups

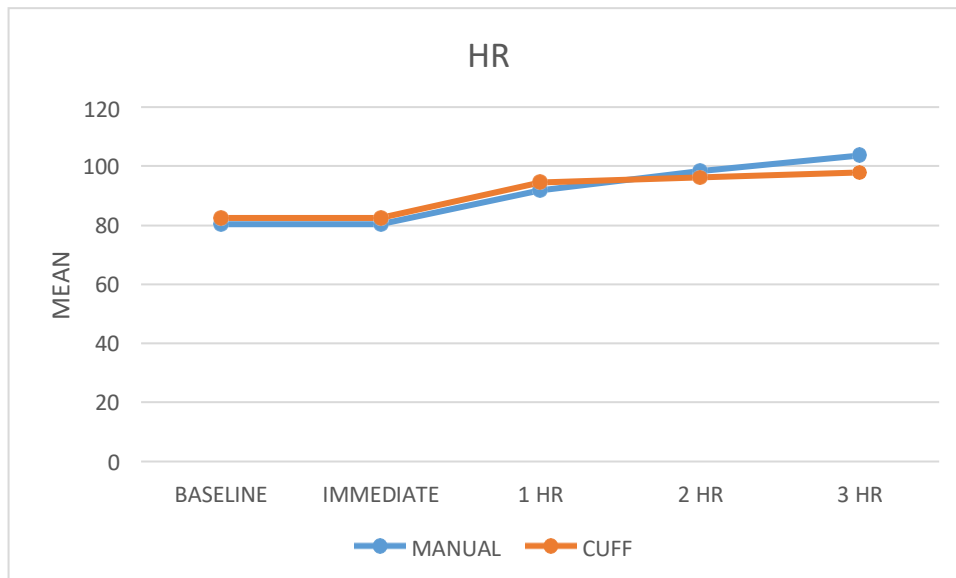


GRAPH 5: Comparison of mean duration of surgery between study groups

- Procedure time was statistically significant (p value <0.001) in Group M procedure time was $2.87 \pm .2996$ while group C the procedure time was 2.715 ± 0.354 . Increased in duration of surgery more is the complications associated with it in manual than cuff group.

Heart Rate	MANUAL		CUFF		MANN-WHITNEY	P VALUE
	MEAN	SD	MEAN	SD		
BASELINE	80.33	8.88	82.4	9.8	1656.400	0.001
IMMEDIATE	80.33	8.88	82.4	9.8	1664.500	0.001
1 HR	91.83	8.944	94.53	10.022	2185.000	0.103
2 HR	98.29	9.338	96.08	9.988	2190.000	0.107
3 HR	103.60	15.542	97.83	8.439	1252.000	0.00

TABLE 6 : Comparison of mean heart rate according to time in both study groups

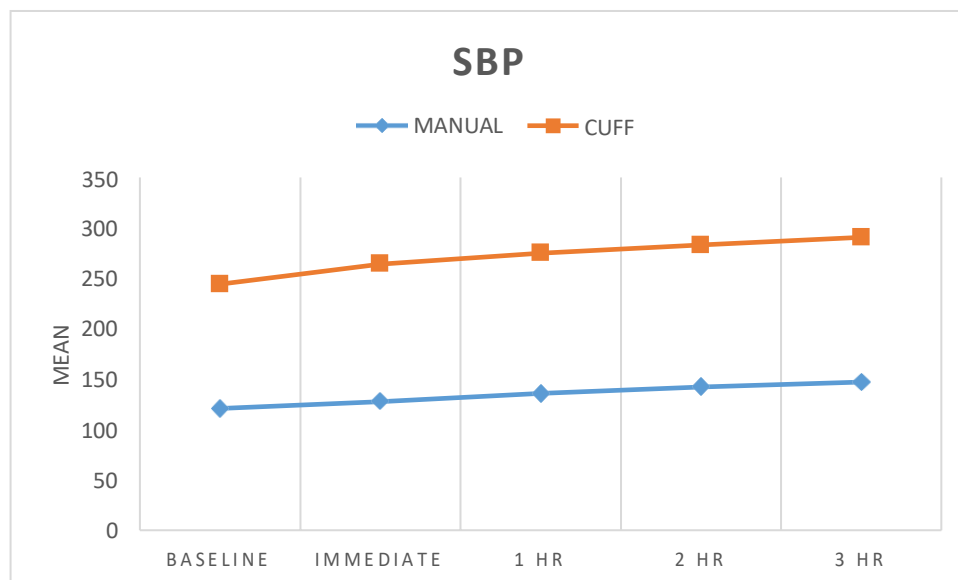


GRAPH 6 :Comparison of mean heart rate according to time in both study groups

- Heart rate was assessed among all the subjects for influencing the effect of increase in cuff pressure in both groups. There is statistical significant p value determined. Heart rate increase was more in Manual group than automatic group as the duration of surgery increased. (* $p < 0.05$)

SBP	MANUAL		CUFF		MAN-WHITNEY	P VALUE
	MEAN	SD	MEAN	SD		
BASELINE	120.8	8.4	123.4	9.5	1326.000	0.323
IMMEDIATE	127.71	10.754	136.44	10.472	1456.000	0.001
SBP 1 Hr	135.69	9.779	139.29	9.224	1912.000	0.002
SBP 2 Hr	142.36	9.371	140.60	9.168	2351.500	0.000
SBP 3 Hr	147.00	9.943	143.63	8.932	2362.400	0.004

TABLE 7: Comparison of SBP according to time in both study groups

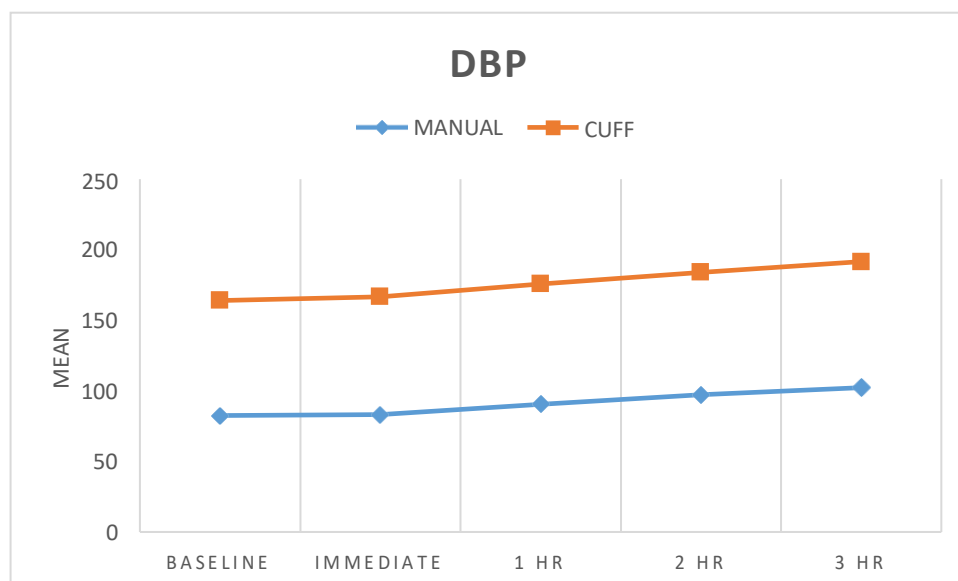


GRAPH 7: Comparison of SBP according to time in both study groups

- SBP was assessed among all the subjects for influencing effect of increase in cuff pressure in both groups. There is statistical significant p value determined. SBP increase was more in Manual group than automatic group as the duration of surgery increased. (*p<0.05)

DBP	MANUAL		CUFF		MANN-WHITNEY	P VALUE
	MEAN	SD	MEAN	SD		
BASELINE	82.5	8.1	81.5	10.9	2466.502	0.023
IMMEDIATE	83.08	8.505	83.68	10.922	2496.500	0.001
DBP 1 Hr	90.56	7.455	85.19	12.842	1769.500	0.001
DBP 2 Hr	97.07	7.590	86.97	14.002	1755.500	0.000
DBP 3 Hr	102.27	7.540	89.30	11.871	2351.500	0.000

TABLE 8: Comparison of DBP according to time in both study groups

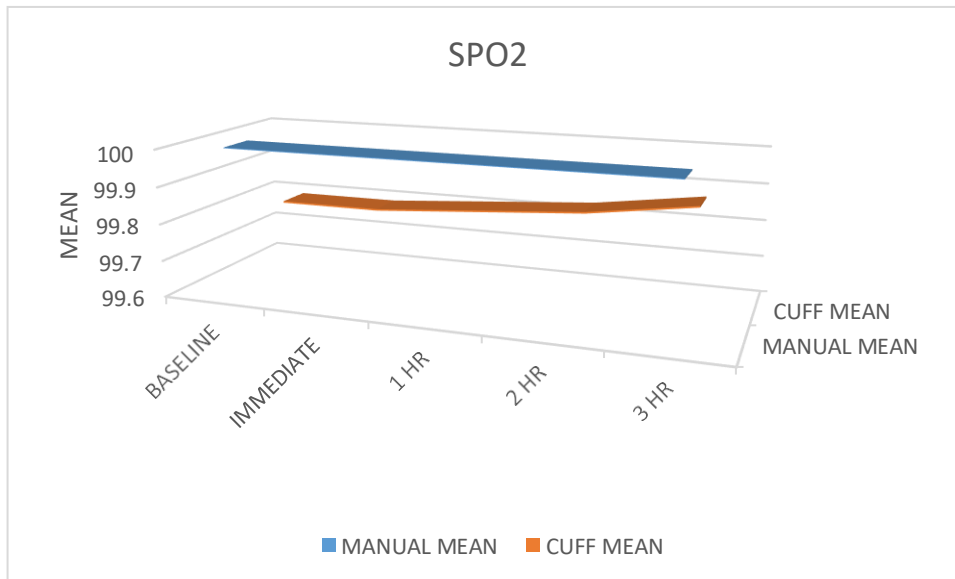


GRAPH 8: Comparison of DBP according to time in both study groups

- DBP was assessed among all the subjects for influencing effect of increase in cuff pressure in both groups. There is statistical significant p value determined. DBP increase was more in Manual group than automatic group as the duration of surgery increased. (*p<0.05)

SPO2	MANUAL		CUFF		MANN-WHITNEY	P VALUE
	MEAN	SD	MEAN	SD		
BASELINE	100.00	.000	99.79	.442	2089.00	0.000
IMMEDIATE	100.00	.000	99.79	.442	2088.000	0.000
SPO2 1 HR	100.00	.000	99.81	.399	2088.000	0.000
SPO2 2 HR	100.00	.000	99.83	.375	2160.000	0.000
SPO2 3 HR	100.00	.000	99.87	.338	1782.000	0.003

TABLE 9: Comparison of SPO2 according to time in both study groups

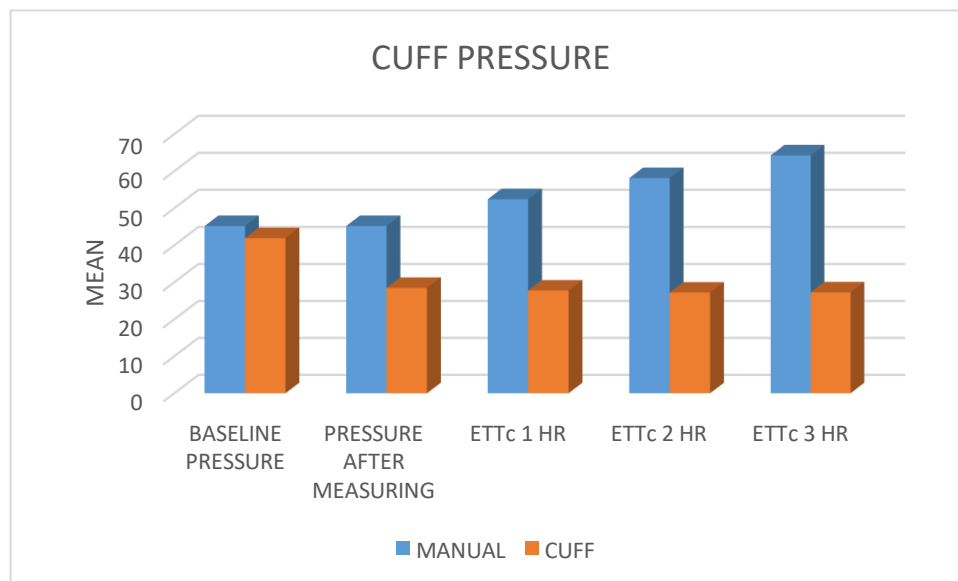


GRAPH 9: Comparison of SPO2 according to time in both study groups

- Standard oxygen saturation parameters were assessed for influencing effect of increase in cuff pressure in both groups. Statically p value determined. Not much significant change determined in both groups.

CUFF PRESSURE	MANUAL		CUFF		MANN WHITNEY	P VALUE
	MEAN	SD	MEAN	SD		
BASELINE PRESSURE	45.21	2.313	41.93	4.923	1438.000	0.000
PRESSURE AFTER MEASURING	45.21	2.313	28.50	1.627	0.000	0.000
ETTc 1 HR	52.43	3.179	27.77	1.466	0.000	0.000
ETTc 2 HR	58.14	3.955	27.22	1.778	0.000	0.000
ETTc 3 HR	64.26	4.721	27.29	1.507	0.000	0.000

TABLE 10: Comparison of ETTc according to time in both study groups

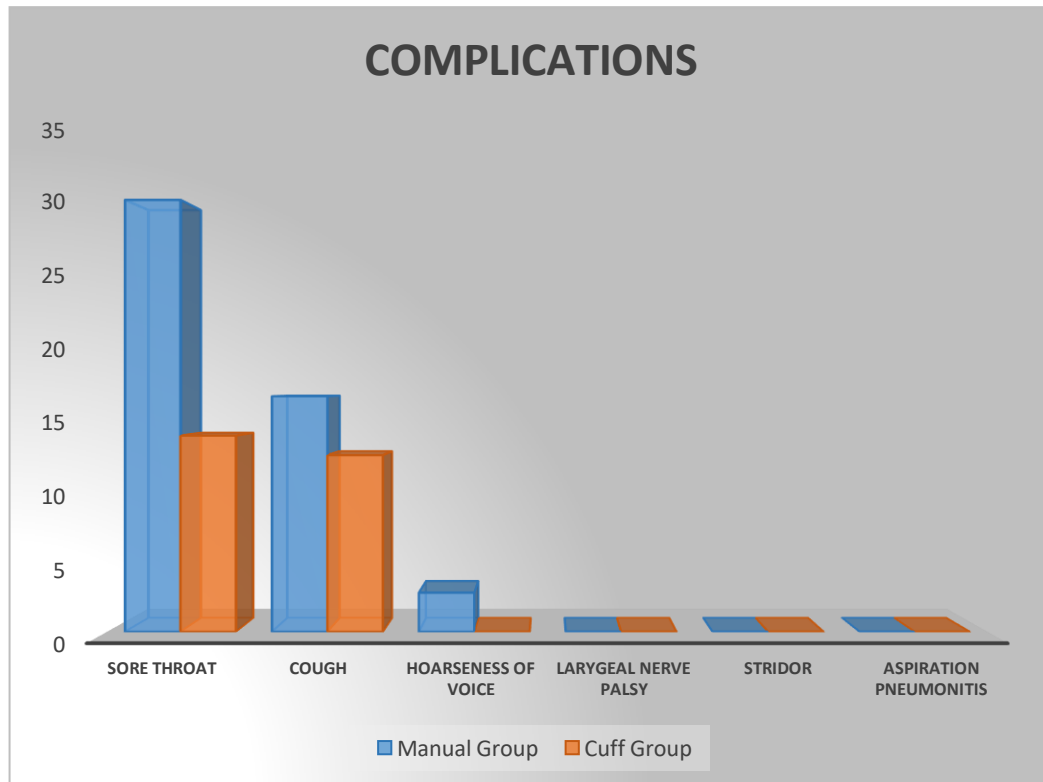


GRAPH 10- Comparison of ETTc according to time in both study groups

- ETTc was assessed among all the subjects for influencing effect of increase in cuff pressure in both groups. There is statistical significant p value determined. ETTc increase was more in Manual group than automatic group as the duration of surgery increased. (*p<0.05)

COMPLICATIONS	Manual Group		Cuff Group	
	No. of patients	Percentage	No. of patients	Percentage
SORE THROAT	22	30.55	10	13.88
COUGH	12	16.66	9	12.5
HOARSENESS OF VOICE	2	2.77	0	0
LARYGEAL NERVE PALSY	0	0	0	0
STRIDOR	0	0	0	0
ASPIRATION PNEUMONITIS	0	0	0	0
Total	72	100.0	72	100.0

TABLE 11: Distribution of patients based on post-operative complications in percentage noted in study groups



GRAPH 11 : Distribution of patients based on post-operative complications in percentage noted in study groups

- Total 144 subjects are studied .Post-operative complications associated with cuff pressure monitoring in both manual and automatic method was note. 30.55 percentage of patients had complained of sore throat in manual group compared to automatic group with percentage of 13.88.
- 16.66 percentage of subjects complained of cough in manual group compared to automatic group with percentage of 12.5
- 2.77 percentage of subjects complained of hoarseness of voice in manual group and none in automatic group.
- No patients had complaints of laryngeal nerve injury, stridor, aspiration pneumonitis in either of the group.

STATISTICAL ANALYSIS

The details of each quality were provided. For continuous variables, summary statistics of mean and standard deviation (SD) were used. Numbers and percentages were employed for data summaries and the diagrammatic representation of categorical data. Chi-square test was used as a qualitative data significance test for the link between two categorical variables. Numerical variables were presented as Mean and SD, whereas categorical variables were given as frequency (%) and graphs. Chi square/Exact Fisher's test was used to compare categorical variables, while unpaired t test/Mann-Whitney U test was used to compare numerical variables between groups. Chi-square statistic used in the chi square test has the following formula:

$$\chi_c^2 = \sum \frac{(O_i - E_i)^2}{E_i}$$

c- degrees of freedom

O-observed value

E- expected value

Formula for unpaired t test is

t statistic to test whether means are different can be calculated as follows:

$$t = \frac{(\bar{x}_1 - \bar{x}_2) - (\mu_1 - \mu_2)}{\sqrt{\frac{s_1^2}{n_1} + \frac{s_2^2}{n_2}}}$$

where \bar{x}_1 = mean of sample 1

\bar{x}_2 = mean of sample 2

n_1 = number of subjects in sample 1

n_2 = number of subjects in sample 2

$$s_1^2 = \text{variance of sample 1} = \frac{\sum(x_1 - \bar{x}_1)^2}{n_1}$$

$$s_2^2 = \text{variance of sample 2} = \frac{\sum(x_2 - \bar{x}_2)^2}{n_2}$$

The formula for Mann -Whitney u test was

For large samples: When n_1 and n_2 given by >10 , it is given by

$$Z = \frac{U - \mu_U}{\sigma_U}$$

$$\sigma_U$$

$$\mu_U = \frac{n_1 n_2}{2}$$

$$\sigma_U = \sqrt{\{(n_1 n_2) (n_1 + n_2 + 1)\} / 12}$$

$$U_1 = n_1 n_2 + \frac{n_1(n_1 + 1)}{2} - R_1$$

$$U_2 = n_1 n_2 + \frac{n_2(n_2 + 1)}{2} - R_2$$

To create several sorts of graphs, such as bar diagrams and line diagrams, Microsoft Word and Excel were employed. In order to analyse the data, SPSS version 22 (IBM SPSS Statistics, Somers NY, USA) was utilized. Data were entered into a Microsoft Excel data sheet.

If the p value was less than 0.05, the results were deemed statistically significant; otherwise, they were deemed insignificant.

DISCUSSION

While we continue to experiment with different types of intubating techniques, endotracheal intubation is a crucial life-saving skill that an anesthetist must learn and master, same way providing safe anesthesia practice to the patient also becomes a primary modality. Anesthetist always keep the long term complications in mind and there is always a grey area which goes unnoticed. All the meticulous concerns should also be taken care of so to provide safe anesthesia practice to both intraoperative and postoperatively and preventing its untoward complications.

This randomized clinical trial demonstrated that usage of cuff manometer intraoperatively provides effective care for patients undergoing surgeries under general anesthesia. It reduces the intensity of post-operative complications, by providing a shorter stay and by not hindering in the overall recovery of the patient and inadvertent usage of unnecessary medications. ⁽⁶¹⁻⁶³⁾

The standard regimens used in our hospital setting was usage of manual inflation of the cuff by a experienced and trained anesthesiologist and the inflated cuffs where checked with pilot balloon palpation technique. None of cuff pressures obtained were found to be in acceptable range of 20 to 30 cm of H₂O.

Many at times the inflated cuff pressures will be below minimum value required to prevent aspiration and on other hand, several times there will be over inflation of the cuff leading to increase chance of tracheal ischemia with other post operative complications .Many at times there will be enormous increase in cuff pressure leading to occlusion of mucosal capillaries and arterioles .

In manual group, there is statistical significant p value determined. ETTc increase was more in Manual group than automatic group as the duration of surgery increased. In manual group the cuff was inflated by an experienced anesthesiologist with a minimum of 5 years' experience and confirmed by palpating the pilot balloon and looking for it approximation and also by hearing for any audible leak . Many at times nitrous oxide is used which causes enormous diffusion of gas which causes over inflation of the cuff leading to tracheal damage.

In the manual group the set pressure from the beginning of the procedure until the end of the procedure is not altered instead the pressure is recorded every hourly and no attempts are made to alter the pressures. In the intraoperative period vital parameters where observed and was found to have increased in both heart and systolic blood pressure with a significant $P < 0.05$ value with a mean of 103.60 and standard deviation of 15.542. Patients were assessed in the postoperative period and risk of sore throat, cough, hoarseness of voice was more in manual group than automatic group . Of the total of 72 patients there was 30.55 % of patients with sore throat, 16.66 % with cough and 2.77% of patients with hoarseness of voice.

In study group (cuff) pressure is set by a automatic manometer and the pressure is adjusted within ideal range of 20 – 30 cm H₂O. Pressures where recorded every hourly and if there was increase in the pressure more than the ideal range pressure was adjusted to required range. In intraoperative period vital parameters where observed and was found to have increased in both heart and systolic blood pressure with a significant $P < 0.05$ value but reduced when pressure was adjusted to the optimal range with a mean of 97.83 with standard deviation of 8.439. Patients were assessed in the postoperative period and risk of sore throat, cough, and hoarseness of voice was comparatively less in automatic group in contrast to manual group. Of the total of 72 patients there was 13.88 % of patients with sore throat and 12.5 % of patients with cough and no patients with stridor , hoarseness of voice , laryngeal nerve injury . Intubated and mechanically ventilated patients who are critically unwell should maintain a cuff pressure of about 25 cm H₂O.

Tracheal discomfort or stridor can result from mucosal blood flow being impeded when ETTc pressure is greater than the tracheal mucosa's capillary perfusion pressure ⁽⁶⁶⁾

In addition to nerve palsy, tracheoesophageal fistula, tracheal wall injury, subglottic scarring or stenosis, hoarseness, overinflation of cuff are other problems.

Aspiration of secretions and insufficient delivery of the appropriate tidal volume are both related to under-inflation of the ETTc. ⁽⁶⁸⁾

91% of postoperative nitrous oxide anesthesia patients and 45% of patients receiving other anesthetics reported pressures more than 40cm H₂O.

According to a study by Mukul Kumar Jain et al⁽¹⁴⁾., manually inflating the endotracheal tube cuff resulted in noticeably high pressure. If the cuff manometer device is utilized, the difficulties of increased endotracheal tube cuff pressure can be prevented. Manual methods cannot be trusted to maintain the pressure within the prescribed limit.

The maximum cuff inflation pressure recommended by Seegobin and Hasselt is 30 cm H₂O It is crucial to maintain cuff pressures between 20 and 30 cm H₂O Seegobin and Hasselt also found that a number of variables, most importantly blood pressure, will determine precise pressure at which a person may experience obstructed or impaired tracheal mucosal blood flow. They also found that adjusting cuff inflation for altitude, positioning the patient's head and neck correctly during intubation, avoiding infection involving patient secretions, preventing severe respiratory failure, and avoiding prolonged intubation are other important precautions to take in order to prevent damage⁽²⁹⁾.

Regardless of anaesthetic providers' experience, Sengupta et al. Found that in 27% of instances, ETTc pressure reaches 40 cm H₂O. Due to the fact that our safe limit was more conservative, we were able to demonstrate a larger occurrence of ETTc pressure surpassing the safe limit. (25cm H₂ O).

This study shows that an ETTc could not be inflated to a safe pressure limit even by skilled anesthesiologists.⁽⁹⁾

Manual methods, such as palpating pilot balloon and waiting for audible air leak to stop, are imprecise ways to determine a sufficient ETTc pressure, and they frequently lead to an ETTc pressure that is higher than the safe limit. Other researchers have addressed the issue of clinicians being unable to detect ETTc pressure using the conventional standard approach of palpating the pilot balloon. By lowering the risk of harm from endotracheal intubation, using standardized tools to measure cuff pressures may help to promote safety.⁽⁶⁴⁻⁶⁸⁾

CONCLUSION

Endotracheal intubation is utilized during many surgical operations that need for general anesthesia in order to keep patients ventilation adequately. Ideal cuffed endotracheal tube should offer an airway seal that permits positive pressure breathing, guards against gastric contents being inhaled, and prevents tracheal damage. Certain aspiration or trachea damage hazards can be reduced even if they cannot be entirely removed. All methods of inflating were linked to insufficient cuff pressures. The most secure method to prevent cuff-related injuries may involve customary use of manometers to monitor endotracheal cuff pressures which becomes most novel method of practice. This study therefore, emphasizes the benefits of Usage of endotracheal tube cuff pressure monitor routinely for safety profile of patient.

Recommendations of practice

As a result of technology, anesthesiology professionals are constantly able to access new and enhanced technologies which can increase safety of patient. Advent of high-volume, low-pressure endotracheal cuff did reduce dangers of tracheal ischemia in patients, but anesthesia physician must maintain constant watch to avoid accidents. All methods of inflating were linked to insufficient cuff pressures. Several of the anesthesia professionals should make use of manometers. The most secure method to prevent cuff-related injuries may involve routine use of manometers to monitor endotracheal cuff pressures.

SUMMARY

“ENDOTRACHEAL TUBE CUFF PRESSURE MONITORING – COMPARISON OF SAFETY PROFILE BETWEEN MANUAL AND AUTOMATIC MANOMETER. IN SURGERIES LASTING FOR UPTO 3 HOURS”

was carried out from January 2021 to June 2022 in the Department of Anesthesiology at B.L.D.E (Deemed To Be University) Shri. B. M. Patil Medical College and Hospital, Vijayapur.

The study was designed to compare the two techniques manual method of inflating the endotracheal tube vs automatic method of inflating the endotracheal tube cuff using a manometer with respect to following parameters: intraoperative complications with respect to heart rate , blood pressure and oxygen saturation and post operative complications .

For the purpose of this study 144 patients were recruited and divided by computer generated random number tables into two groups of 72 each. The patients were aged 18-80 years and belonged to ASA grade I and II. Both groups consisted of patients posted for general anesthesia for surgeries lasting for upto 3 hours **Group M:** In these patients endotracheal tube was inflated manually by an experienced anesthesiologists

Group C: In these patients endotracheal tube was inflated by using automatic cuff manometer

Observations made during the study period were recorded, tabulated and analyzed. They were as follows:

- Demographic data of the two groups was comparable.
- Out of 93 females and 51 males studied in both comparative groups . No statistical significance noted thus complications associated with cuff pressure monitoring is not influenced by the sex of the patient subject . P value being 0.356.
- Total 144 ASA class 1 and 2 subjects are studied. No statistical significance noted in any group. Complications associated with cuff pressure monitoring in both manual and automatic method is not influenced by the ASA class of the patient / subject undergoing the procedure . P value being 0.324
- Procedure time was statistically significant (p value <0.001) in Group M procedure time was $2.87 \pm .2996$ while group C the procedure time was 2.715 ± 0.354 . Increased in duration of surgery more is the complications associated with the same
- Heart Rate , SBP , DBP was assessed among all the subjects for influencing the effect of increase in cuff pressure in both groups . There is statistical significant p value determined. Heart rate increase was more in Manual group than automatic group as the duration of surgery increased.(*p<0.05)
- Standard oxygen saturation parameters were assessed for influencing effect of increase in cuff pressure in both groups. Statistical p value determined. Not much significant change determined in both groups
- ETTc was assessed among all the subjects for influencing effect of increase in cuff pressure in both groups. There is statistical significant p value determined.

ETTc increase was more in Manual group than automatic group as the duration of surgery increased. (* $p < 0.05$)

- Total 144 subjects are studied .Post-operative complications associated with cuff pressure monitoring in both manual and automatic method was note. 30.55% of patients had complained of sore throat in manual group compared to automatic group with 13.88%
- 16.66% of subjects complained of cough in manual group compared to automatic group with 12.5%
- 2.77% of subjects complained of hoarseness of voice in manual group and none in automatic group.
- No patients had complaints of laryngeal nerve injury, stridor , aspiration pneumonitis in either of the group.

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ANNEXURES

I. INSTITUTIONAL ETHICAL COMMITTEE CLEARANCE **CERTIFICATE**



B.L.D.E. (DEEMED TO BE UNIVERSITY)

(Declared vide notification No. F.9-37/2007-U.3 (A) Dated. 29-2-2008 of the MHRD, Government of India under Section 3 of the UGC Act, 1956)

The Constituent College

SHRI. B. M. PATIL MEDICAL COLLEGE, HOSPITAL AND RESEARCH CENTRE

IEC/NO:09/2021
22-01-2021

INSTITUTIONAL ETHICAL CLEARANCE CERTIFICATE

The Institutional ethical committee of this college met on 11-01-2021 at 11 am to scrutinize the synopsis of Postgraduate students of this college from Ethical Clearance point of view. After scrutiny the following original/corrected and revised version synopsis of the Thesis has been accorded Ethical Clearance

Title: Endotracheal tube cuff pressure monitoring comparison of safety profile between manual and automatic manometer. In surgeries lasting for upto 3 hours.

Name of PG student: Dr Divya M, Department of Anaesthesiology

Name of Guide/Co-investigator: Dr Vidya.A.Patil, Professor & HOD of Anaesthesiology


DR .S.V.PATIL
CHAIRMAN,IEC
Institutional Ethical Committee
B L D E (Deemed to be University)
Shri B.M. Patil Medical College,
VIJAYAPUR-586103 (Karnataka)

Following documents were placed before Ethical Committee for Scrutinization:

1. Copy of Synopsis / Research project
2. Copy of informed consent form
3. Any other relevant documents.

II. SAMPLE INFORMED CONSENT FORM

TITLE OF THE PROJECT:

**“ENDOTRACHEAL TUBE CUFF PRESSURE MONITORING –
COMPARISON OF SAFETY PROFILE BETWEEN MANUAL AND
AUTOMATIC MANOMETER. IN SURGERIES LASTING FOR
UPTO 3 HOURS”**

PRINCIPAL INVESTIGATOR : DR. DIVYA M

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Email:vidyapatila@gmail.com

I have been informed that this study is “ENDOTRACHEAL TUBE CUFF PRESSURE MONITORING – COMPARISON OF SAFETY PROFILE BETWEEN MANUAL AND AUTOMATIC MANOMETER. IN SURGERIES LASTING FOR UPTO 3 HOURS” I have been explained about this study in the language which I understand. I have been explained about the reason for doing this study and selecting me/my ward as a subject for this study. I have been told that my participation in the above study is voluntary and I am aware that I can opt out of the study at any time without having to give any reasons for doing so. I am also informed that my refusal to participate in this study will not affect my treatment by any means.

I agree to participate in the above study and cooperate fully. I agree to follow the Doctor's instructions about my treatment to the best of my ability.

CONFIDENTIALITY:

I understand that medical information produced by this study was come a part of this Hospital records and was subjected to the confidentiality and privacy regulation of this hospital. Information of a sensitive, personal nature will not be a part of the medical records, but was stored in the investigator’s research file and identified only by a code number. The code key connecting name to numbers was kept in a separate secure location.

If the data are used for publication in the medical literature or for teaching purpose, no names was used and other identifiers such as photographs and audio or video tapes was used only with my special written permission. I understand that I may see the photograph and videotapes and hear audiotapes before giving this permission.

REQUEST FOR MORE INFORMATION:

I understand that I may ask more questions about the study at any time and Dr.Divya M available to answer my questions or concerns. I understand that I was informed of any significant new findings discovered during the course of this study, which might influence my continued participation.

If during this study, or later, I wish to discuss my participation or concerns regarding this study with a person not directly involved, I am aware that the social worker of the hospital is available to talk with me and that a copy of this consent form was given to me for my careful reading.

REFUSAL OR WITHDRAWL OF PARTICIPATION:

I understand that my participation is voluntary and I may refuse to participate or may withdraw consent and discontinue participation in the study at any time without prejudice to my present or future care at this hospital.

I also understand that Dr.Divya M will terminate my participation in this study at any time after she has explained the reasons for doing so and has helped arrange for my continued care by my own physician or therapist.

INJURY STATEMENT:

I understand that in the unlikely event of injury to me/my ward, resulting directly to my participation in this study, if such injury were reported promptly, then medical treatment would be available to me, but no further compensation was provided.

I understand that by my agreement to participate in this study, I am not waiving any of my legal rights.

I have been explained about the purpose of this research, the procedures required and the possible risks and benefits, in my own language.

I have been explained all the above in detail and I understand the same. Therefore I agree to give my consent to participate as a subject in this research project.

Patient's Signature:

Witness Signature

Name:

Date:

Dr.VIDYA PATIL

(Guide)

DR. DIVYA M

(Investigator)

III. SCHEME OF CASE TAKING PROFORMA

**STUDY -- “ENDOTRACHEAL TUBE CUFF PRESSURE MONITORING –
COMPARISON OF SAFETY PROFILE BETWEEN MANUAL AND
AUTOMATIC MANOMETER. IN SURGERIES LASTING FOR UPTO 3
HOURS”**

Patient name -

Date -

Address-

I.P. number -

Age

Sex-

Male/Female

Weight -

Height -

Diagnosis -

Proposed Surgery -

Proposed duration of
surgery-

ASA -

Consent -

Medical and surgical history -

Examination in brief -

General Physical Examination-

Vitals -:

Pulse-

B.P. -

Respiratory
rate:

Systemic examination -:

R.S. -

C.N.S. -

Airway assessment by

Malmpatti grading -

C.V.S. -

P/A -

PREOPERATIVE INVESTIGATIONS -:

Hb% -

TLC/DLC -

Platelet count –

BT/CT -

RBS - mg/dl

Blood Urea :

Serum Creatinine :

Chest X ray if required :

ECG:

Other investigations:

Monitors Attached:

Pulse :

B.P :

SpO2 :

Parameters observed during intraoperative period

ETTcuff pressure(Approximate)	N (Sample)	Group M	Pulse	BP
Manual pressure (H₂O), Baseline	72			
Pressure set after measuring by palpating experienced anaesthiologist of at least 5 years experience	72			
ETTc pressure after 1hrs(cm of H₂O)	72			
ETTc pressure after 2hrs(cm H₂O)	72			
ETTc pressure after 3hrs(cm of H₂O)	72			
ETTc pressure after 4hrs(cm of H₂O)	72			
ETTc pressure after 5hrs(cm of H₂O)	72			

ETT cuff pressure	N (Sample)	Group C	Pulse	BP
Baseline pressure (cm H₂O)	72			
Pressure set after measuring by cuff pressure monitor (cm H₂O)	72			
ETTc pressure after 1hrs(cm of H₂O)	72			
ETTc pressure after 2hrs(cm H₂O)	72			
ETTc pressure after 3hrs(cm of H₂O)	72			
ETTc pressure after 4hrs(cm of H₂O)	72			
ETTc pressure after 5hrs(cm of H₂O)	72			

PARAMETERS OBSERVED POST EXTUBATION**Group M**

TIME►	5	10	15	20	25	30	2	6	12	24
PARAMETER	mins	mins	mins	mins	mins	mins	hrs	hrs	hrs	hrs
▼										
Sore throat										
Cough										
Hoarseness of voice										
Laryngeal nerve injury										
Stridor										
Aspiration pneumonitis										

PARAMETERS OBSERVED POST EXTUBATION**Group C**

TIME►	5	10	15	20	25	30	2	6	12	24
PARAMETER	mins	mins	mins	mins	mins	mins	hrs	hrs	hrs	hrs
▼										
Sore throat										
Cough										
Hoarseness of voice										
Laryngeal nerve injury										
Stridor										
Aspiration pneumonitis										

SIGNATURE

**IV . MASTER CHART-GROUP M – MANUAL AND
AUTOMATIC GROUP**

Table with columns: SLNO, PRESENT NAME, P.FAMILY, GROUP, AGE, SEX, HEIGHT, WEIGHT, HAIR COLOR, DIRECTION OF SUNSHINE, ANGLELINE PRESSURE, PRESSURE AFTER 20 MINUTES, etc. It contains a large grid of data points for various individuals.