COMPARISON OF CUFF INFLATION TECHNIQUE AND CONVENTIONAL TECHNIQUE FOR NASOTRACHEAL INTUBATION USING C-MAC VIDEO LARYNGOSCOPE: A PROSPECTIVE RANDOMISED CONTROLLED TRIAL

THESIS

Submitted to

All India Institute of Medical Sciences, Jodhpur

In partial fulfilment of the requirement for the degree of

DOCTOR OF MEDICINE (MD)

(ANAESTHESIOLOGY AND CRITICAL CARE)

JUNE, 2022 **DR. VENKATA PREM KUMAR SANGAMALA**

AIIMS, JODHPUR

DECLARATION

I hereby declare that thesis titled **"COMPARISON OF CUFF INFLATION TECHNIQUE AND CONVENTIONAL TECHNIQUE FOR NASOTRACHEAL INTUBATION USING C-MAC VIDEO LARYNGOSCOPE: A PROSPECTIVE RANDOMISED CONTROLLED TRIAL"** embodies the original work carried out by the undersigned in All India Institute of Medical Sciences, Jodhpur.

The submitted thesis **"COMPARISON OF CUFF INFLATION TECHNIQUE AND CONVENTIONAL TECHNIQUE FOR NASOTRACHEAL INTUBATION USING C-MAC VIDEO LARYNGOSCOPE: A PROSPECTIVE RANDOMISED CONTROLLED TRIAL"** has been evaluated on Dupli checker software platform and the report reads that the submitted thesis has no similarity in discussion and introduction section.

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CERTIFICATE FROM THE SUPERVISORS

This is to certify that the submitted thesis titled **"COMPARISON OF CUFF INFLATION TECHNIQUE AND CONVENTIONAL TECHNIQUE FOR NASOTRACHEAL INTUBATION USING C-MAC VIDEO LARYNGOSCOPE: A PROSPECTIVE RANDOMISED CONTROLLED TRIAL"** is a record of the research work undertaken by **Dr Venkata Prem Kumar Sangamala** in partial fulfillment of the requirements for the award of the degree of **"Doctor of Medicine (MD) Anaesthesiology"** under my guidance and supervision.

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Forwarded and recommended by

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Nature of Project:	**Research Project**
Submitted as:	**M.D. Dissertation**
Student Name:	**Dr.Venkata Prem Kumar Sangamala**
Guide:	**Dr.Rakesh Kumar**
Co-Guide:	**Dr.Pradeep Kumar Bhatia, Dr.Manoj Kamal & Dr.Sadik Mohammed**

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Enclose:
1. Annexure 1

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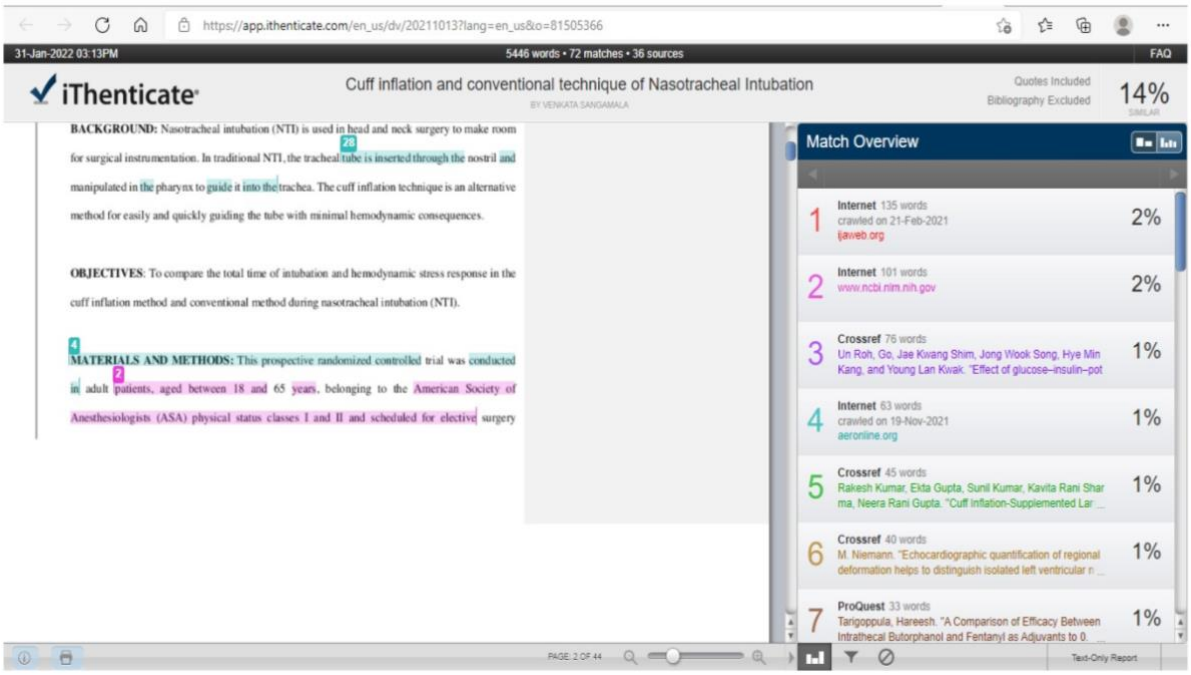
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BACKGROUND: Nasotracheal intubation (NTI) is used in head and neck surgery to make room for surgical instrumentation. In traditional NTI, the tracheal tube is inserted through the nostril and manipulated in the pharynx to guide it into the trachea. The cuff inflation technique is an alternative method for easily and quickly guiding the tube with minimal hemodynamic consequences.
OBJECTIVES: To compare the total time of intubation and hemodynamic stress response in the cuff inflation method and conventional method during nasotracheal intubation (NTI).
MATERIALS AND METHODS: This prospective randomized controlled trial was conducted in adult patients, aged between 18 and 65 years, belonging to the American Society of Anesthesiologists (ASA) physical status classes I and II and scheduled for elective surgery
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ACKNOWLEDGEMENT

"Expert Knowledge is limited Knowledge"

-Winston Churchill

First and foremost, I express my gratitude to The Almighty God for his blessing on my thesis project completion. Nothing is possible without good teachers' guidance. With these words, I'd like to express my heartfelt gratitude to **Dr Rakesh Kumar,** my MD thesis guide and Associate Professor, Department of Anaesthesiology and Critical Care, All India Institute of Medical Sciences, Jodhpur, for his unwavering trust and support. I am truly honoured and grateful for the opportunity to learn under her guidance.

I am also indebted to my Co-guides **Dr Pradeep Kumar Bhatia**, Professor, and HOD of the Department of Anaesthesiology and Critical Care, **Dr Manoj Kamal**, Additional Professor Department of Anaesthesiology and Critical Care**, Dr Sadik Mohammed** Associate Professor of the Department of Anaesthesiology and Critical Care, their continual supervision and step-by-step support have been critical in building the environment of success and quality required for a dissertation from our prestigious institute.

I would like to thank all the faculties of the Department of Anaesthesiology and Critical Care, All India Institute of Medical Sciences, Jodhpur who have been the pillars of support. I hope I have been a good friend to my co-PG's **Dr Anas V P, Dr Anjana Ramachandran, Dr Shipra Roy, Dr Priyadarshan, Dr Markandey Prasad, Dr Somya Goel**, and acknowledge their support.

My parents and brothers deserve a huge thank you for their unwavering support, love, encouragement, and sacrifices.

I appreciate the support I've received from my colleagues at the Department of Anaesthesiology. I'd also like to thank my juniors for stepping forward to aid in times of need. I would like to express my gratitude to all of the patients who took part in the trial.

-Dr Venkata Prem Kumar Sangamala

ABBREVIATIONS

NTI	Nasotracheal Intubation
ETT	Endotracheal Tube
PVC	Polyvinyl Chloride
VL	Video laryngoscopy
BURP	Back Upward Right Lateral Pressure
CL	Cormack Lehane
POGO	Percentage of Glottic Opening
GA	General Anaesthesia
SD	Standard Deviation
BMI	Body Mass Index
M	Manoeuvers
C-MAC®	C-MAC video laryngoscope
CI	Confidence Interval
OT	Operation Theater
IV	Intravenous
ASA	American Society Anaesthesiologist

CONTENT

LIST OF TABLES

LIST OF FIGURES

SUMMARY

BACKGROUND: Nasotracheal intubation (NTI) is used in head and neck surgery to make room for surgical instrumentation. In traditional NTI, the tracheal tube is inserted through the nostril and manipulated in the pharynx to guide it into the trachea. The cuff inflation technique is an alternative method for easily and quickly guiding the tube with minimal hemodynamic consequences.

OBJECTIVES: To compare the total time of intubation and hemodynamic stress response in the cuff inflation method and conventional method during nasotracheal intubation (NTI).

MATERIALS AND METHODS: This prospective randomized controlled trial was conducted in adult patients, aged between 18 and 65 years, belonging to the American Society of Anaesthesiologists (ASA) physical status classes I and II and scheduled for elective surgery requiring NTI using C-MAC video-laryngoscope (VL). Patients were divided into two groups, NTI was performed using cuff inflation technique in group I and using conventional technique in group C. The anaesthesiologist securing the airway used the POGO score and Cormack Lehane's (CL) grade for grading laryngoscopic view. In group C, the first attempt was to pass the ETT through the vocal cords without the use of any manoeuvers; however, if any difficulty was encountered while passing the tube through the vocal cords, accessory manoeuvers were used as per patient requirement -burping, neck movements, tube rotation, and finally with the use of Magill forceps. In group I, after inserting the tube into the nasopharynx, the cuff of the tube was inflated with 15mL of air by an assistant, allowing the tube to align with the laryngeal inlet before being deflated and guided through the glottis. In the event of a problem, accessory manoeuvers were used as per patient requirement.

RESULTS: The cuff inflation technique requires significantly lesser time for successful NTI compared to conventional group (27.86±4.47 sec vs. 41.11±10.98 sec respectively; $p < 0.0001$). Also, the accessory manoeuvers required, hemodynamic stress response, and complications were significantly less ($p < 0.00277$) with cuff inflation technique compared to conventional technique.

CONCLUSION: Cuff inflation technique provides successful NTI in lesser time with minimal or no accessory manoeuvers and comparative hemodynamic stability.

INTRODUCTION

Surgical procedures involving head and neck region, intraoral, maxillofacial, and dental procedures usually require nasotracheal intubation (NTI). [1] The advantage of NTI is that it better isolates the surgical field from the artificial airway so that the endotracheal tube is less vulnerable to kinking, damage due to surgical instrumentations, and good space for intraoral surgical procedures. In addition, the nasal tube is better tolerated postoperatively than the oral route and requires less sedation.

Conventionally, NTI is performed by blindly passing an endotracheal tube (ETT) through one of the patient's nostrils until the tube reaches the oropharynx after the induction of general anaesthesia (GA). The ETT usually follows the posterior pharyngeal wall during this course. To navigate through the laryngeal opening, the tip of the ETT must be brought anteriorly to enter the glottis using additional manoeuvers such as a burp, neck movement, tube rotation, the use of a bougie, or the use of Magill's/Boedeker forceps under laryngoscopic guidance. This conventional method requires more intubation time due to the need for one or more manoeuvers that result in the hemodynamic stress response. While negotiating the ETT into the trachea, instruments used during NTI may rupture the ETT cuff and injure oropharyngeal soft tissues. [2]

Gorback[3] described a technique for blind NTI called cuff inflation technique (wherein the cuff of ETT is inflated with air) in which after inflation of the cuff the ETT is lifted away from the posterior pharyngeal wall and gets aligned with the laryngeal inlet and tip of the ETT is engaged with the glottis opening. Once the tip of the ETT passes through the glottis, the cuff is deflated and the ETT is further advanced.

NTI can be performed using a variety of techniques, including blind intubation, conventional laryngoscopy, video laryngoscopy (VL), or under fiberoptic guidance. VL aids in the visualization of the laryngoscopic view as well as the passage of the ETT not only to the performer but also to other people in the operating room via a screen. It has also been used to manage difficult intubations and has reduced the occurrence of complications such as hypoxia, failed intubations, and airway trauma. [4]

The Cuff inflation technique has not been compared with the conventional technique Hence, we planned a study to compare these two techniques of NTI. We hypothesized that the cuff inflation technique would provide faster intubation with the requirement of lesser accessory manipulation compared to the conventional NTI technique.

AIMS & OBJECTIVES

This study aimed to compare cuff inflation technique and conventional techniques of NTI using VL.

1. **Primary outcome**: Time taken for successful NTI by two techniques.
2. **Secondary outcomes**:
    A. Comparison of types of manoeuvers used during NTI
    B. Comparison of number of manoeuvers used during NTI
    C. Comparison of hemodynamic response to intubation
    D. Comparison of Cormack–Lehane (CL) Grading
    E. Comparison of POGO score
    F. Complication if any.

REVIEW OF LITERATURE

Kasaudhan et al[5] in a prospective randomized study of 50 patients, compared the intubating conditions for NTI with standard direct Macintosh laryngoscope versus C-MAC® video laryngoscope (VL) employing ETT cuff inflation technique. They were randomly divided into two groups: group VL (n = 25): C-MAC® VL and group ML (n = 25): Macintosh laryngoscope. The primary outcome was to compare the total duration of NTI(T) and they found that it was significantly higher in group ML than group VL ($P < 0.001$). The intubation was successful with cuff inflation in all the patients in group VL, however, six patients of group ML required assistance with Magill forceps ($P = 0.022$). They concluded that the cuff inflation technique when used along with C-MAC® VL had more success rate, required lesser time and had minimal postoperative complications in comparison to the Macintosh laryngoscope

Prashant HT et al [6] conducted a prospective randomized controlled study to compare the ease of navigation of thermosoftened ETT using curvature control modification with the cuff inflation technique. 70 patients undergoing general anaesthesia with NTI were randomly divided into two groups. The primary outcome was the ease of navigation of thermosoftened ETT. Secondary outcomes were time taken for moving tube from oropharynx to glottis and incidence of epistaxis during NTI. They found that both techniques resulted in successful navigation of thermosoftened ETT in all patients with the majority of cases resulting in smooth engagement to the glottic inlet. The Cuff inflation method resulted in faster alignment to the glottis compared to the use of a modified tube (12. 39 ± 7 Vs 18.73 ± 11.5 sec; $P = 0.003$). They concluded that for thermosoftened ETT, both cuff inflation method and the technique of curvature controlled modified ETT can be used for navigation of tube to glottis with ease

Kumar et al [7] assessed the role of cuff inflation in improving oropharyngeal navigation of 3 ET tubes of varying stiffness during direct laryngoscope-guided NTI. Simultaneously, they also assessed and compared the nasotracheal navigability and incidence of nasal injury with these ET tubes during cuff inflation-supplemented, laryngoscope-guided NTI. They randomized one hundred sixty-two adults to undergo NTI with either a conventional PVC (*n* = 54), wire-reinforced (WR; *n* = 54), or a silicone-tipped WR (SWR; *n* = 54) ET tube. In their result, they found that all ET tubes could be inserted into the trachea. Seventy-one of 162 ET tubes could be inserted from the oropharynx into the laryngeal inlet without cuff inflation. Eighty-six of the remaining 91 tubes that did not enter the laryngeal inlet without cuff inflation could be inserted when using the cuff inflation technique. Thus, a total of 157 ET tubes could be inserted into the laryngeal inlet with cuff inflation (95% confidence interval of difference of proportions between a total number of tubes passed [157] and those without cuff inflation [71]: 53% [45%–61%]). The remaining 5 tubes had to be inserted with the help of Magill forceps. They concluded that the cuff inflation technique consistently improved the oropharyngeal insertion of the 3 ET tubes of varying stiffness during direct laryngoscope-guided NTI.

Lim et al [8] evaluated the use of a nasogastric tube as a guide to facilitate tracheal tube passage through the lower pathway, compared with the 'conventional' technique (blind insertion of the tracheal tube into the nasal cavity). A total of 60 adult patients undergoing oral and maxillofacial surgery were included in the study. In 20 out of 30 patients (66.7%) with the nasogastric tube-guided technique, the tracheal tube passed through the lower pathway, compared with 8 out of 30 patients (26.7%) with the 'conventional' technique (p = 0.004). Use of the nasogastric tube-guided technique

reduced the incidence and severity of epistaxis (p = 0.027), improved navigability (p = 0.034), and required fewer manipulations (p = 0.001) than the 'conventional' technique.

Abrons et al [9] evaluated a novel technique for routine asleep (i.e. post-induction) nasotracheal intubation using a bougie ('bougie technique'), which uses a nasopharyngeal airway to guide a pediatric bougie nasotracheally for use as a Seldinger tracheal intubation guide. Two hundred and fifty-seven older children (> 8 years) and adults were randomly assigned to video laryngoscopy-assisted nasotracheal intubation using either the conventional or the bougie technique. The bougie technique was associated with significantly less nasopharyngeal bleeding than the conventional technique at both 60–90 s (55% vs. 68%; p = 0.033) and 5 min (51% vs. 70%; p = 0.002). Magill forceps were needed significantly less often with the bougie technique (9% vs. 28%, p = 0.0001) and there was no difference in first attempt and overall success rates between the two techniques (p = 0.133 and p = 0.750, respectively).

Yeom et al [10] in a Randomized trial compared the effectiveness of the Magill forceps vs vascular forceps for nasotracheal intubation using the GVL. 60 patients scheduled to undergo elective surgery requiring nasotracheal intubation were assigned to one of two groups—i.e., Magill forceps (group M) or vascular forceps along with a tube exchanger (group V), by computer randomization. They found that the total intubation time was significantly less with the vascular forceps (and tube exchanger) than with the Magill forceps. Using vascular forceps also reduced the incidence of epistaxis compared with that using the Magill forceps. Using a tube exchanger and vascular forceps offers advantages overuse of Magill forceps when a GlideScope video laryngoscope is used for nasotracheal intubation.

Shah et al [11] evaluated the success rate of nasal intubation with cuff inflation technique through VL. 50 patients posted for oral cancer surgery were included in the study. After general anaesthesia induction, NTT passed up to the oropharynx; with VL NT cuff inflation with 15 ml of air done in Group I and no cuff inflation in Group D. They found that the NT tip locations were midline in 88% after cuff inflation. The duration of intubation was earlier in the inflated group (32 ± 18 s vs. 44 ± 20 s). Additional manoeuvers such as more 5 cc air or Magill forceps were more in Group D (52% vs. 22% P = 0.25). First trail intubation success without any manoeuvers was 48% in Group I and 12% in Group D (P = 0.006). Counterclockwise 180° endotracheal tube rotation (M2) was useful to pass NT to VC in 32%, 48% Group I and D, respectively (P = 0.25). The air required for cuff inflation was 16.57 ± 2.65 ml in Group I. The Cuff inflation technique had a good success rate with minimum additional assistance in video laryngoscopic nasal intubation in their study.

Tseng et al [12] compared the efficiency of video-scopes and the traditional direct laryngoscopy in NTI. One hundred and eight patients scheduled for elective oromaxillofacial surgery under nasotracheal intubation general anaesthesia were randomly allocated into one of 3 groups of GlideScope, Pentax Airway Scope, or Macintosh laryngoscope respectively. They found that the mean total intubation time and time C interval were taken with GlideScope (33.1 s and 9.7 s), Pentax (38.4 s and 12.9 s), and Macintosh (42.2 s and 14.9 s) respectively. The median score of MNIDS was significantly lower using GlideScope or Pentax compared with using Macintosh in NTI (P ¼ 0.037). Using GlideScope, intubation was successful at the first attempt in 80% of patients whereas only 65% and 72.5% with the Pentax and Macintosh (P ¼ 0.02). They concluded that the GlideScope video laryngoscope facilitated nasotracheal

intubations with shortened intubation time and reduced intubation difficulty in patients undergoing oromaxillofacial surgery as compared with the Macintosh laryngoscope.

Mishra et al [13] evaluated the suitability of King Vision video laryngoscope for nasotracheal intubation compared with TruviewPCD. Eighty American Society of Anesthesiologists Grade I and II elective surgical patients were randomized into two groups. Group T was intubated using TruviewPCD and Group K was intubated with the nonchanneled King Vision video laryngoscope. They found that seventy-one patients (88.75%) were successfully intubated in a single attempt, i.e. 35 patients (90%) in Group K and 36 patients (87.5%) in Group T. Intubation time (mean ± standard deviation) was 67.9 ± 24.1 s in Group T and 64.9 ± 20.0 s in Group K where comparison was not statistically significant (P = 0.5). The additional manoeuvers (P = 0.2) and hemodynamic changes were not clinically significant. There were no associated serious complications. They concluded that King Vision video laryngoscope is just as effective as TruviewPCD video laryngoscope for successful nasotracheal intubation.

Rajan et al[14] assessed the ease of intubation during C-MAC video laryngoscope-assisted nasal intubation using D blade and compared it with traditional Macintosh laryngoscope-aided nasal intubation. Sixty patients requiring nasal intubation were randomized into two groups, M and V. Laryngoscopy was performed using the traditional Macintosh laryngoscope in group M and with Storz® C-Mac video laryngoscope with D-blade in group V. They found that intubation was significantly easy in 70% of the patients in group V compared to only 3.3% in group M. Time to intubate was significantly shorter in group V (24 vs 68 s). Though the majority of patients were intubated in the first attempt in both groups, the number was more in group V (96.7 vs 70%). There was no case of oesophagal intubation in group V, but 2

patients (6.7%) had oesophagal intubation in group M. Mucosal trauma was significantly more frequent in group M. There was no statistically significant difference in hemodynamics in both groups. They concluded that C MAC video laryngoscope-aided nasotracheal intubation using D blade is superior because of easier, quicker, and less traumatic intubation compared to the use of traditional Macintosh laryngoscope.

MATERIAL AND METHODS

This prospective, randomized controlled study was carried out in the Department of Anaesthesiology and Critical Care at All India Institute of Medical Sciences, Jodhpur, after approval from the Institutional Ethical Committee (IEC Reg. No. AIIMS/IEC/2019-20/997) and registration with Clinical Trial Registry-India (CTRI Reg. No.2020/12/029692). One hundred and six adult patients aged between 18 and 65 years, belonging to ASA physical status class I and II and scheduled for elective surgeries requiring NTI were enrolled after exercising the following exclusion criteria.

Exclusion criteria:

1. Patient refusal.
2. Known difficult airway.
3. Mouth opening less than 2.5 cm.
4. Oropharyngeal tumors.
5. Patients that are difficult to mask ventilate.
6. History of nasal trauma or basal skull fracture.
7. History of laryngeal surgery or radiotherapy.
8. Malampatti class 3 or 4.
9. Frequent episodes of epistaxis.
10. Bleeding tendency and patients with significant systemic disease.
11. Patients having contraindications for NTI.

All patients underwent pre-anaesthesia check-ups a day before scheduled surgery and informed consent was obtained from them. They were kept fasted preoperatively, according to ASA fasting guidelines. All intubations were done with the help of C-

MAC® Video laryngoscopy (Karl Storz, Tuttlingen, Germany). The study participants were randomly allocated to either conventional group (group C) or cuff inflation group (group I) with the help of block randomization technique by using a block size of four with a 1:1 allocation ratio into study groups (Group 'C' and Group 'I') by an investigator not involved in the study. Allocation concealment was done by using an opaque sealed envelope technique. Envelop was opened only after the patient was transferred to the operating room

The patency of the nostrils was checked before anaesthesia induction by simply instructing the patient to compare their nasal airflow while alternately breathing through each nostril. The more patent nostril was chosen for NTI. In the preoperative area xylometazoline, 0.05% nasal drops were administered in the chosen nostrils 15 minutes before induction of anaesthesia.

Inside the operation theatre, monitoring including electrocardiography (ECG), non-invasive blood pressure (NIBP), and oxygen saturation (SpO2) was attached to patients. In both groups, a standardized protocol of GA was followed in all the patients. Patients were induced with injection IV fentanyl 2 mcg/kg and IV propofol 2.5 mg/kg. After assessing the adequacy of the bag and mask ventilation, muscle relaxation was facilitated with IV rocuronium 0.6 mg/kg. After ensuring adequate muscle relaxation, chosen nostril was lubricated with lignocaine jelly and appropriate size lubricated wire reinforced fully deflated cuffed ETT (Mallinckrodt-Covidien, Dublin, Ireland) (7.5 mm internal diameter for males and 6.5 mm for females) was inserted through the floor of the nostril with the concavity facing caudad until its tip reached the oropharynx. Then laryngoscopy was performed by using C-MAC® VL to obtain a laryngeal view and ETT was advanced further in the laryngeal opening using either of two techniques

according to group allotment. To avoid inter-user variation, all the intubations were performed by two experienced anaesthesiologists, who have performed at least 50 successful nasal intubations with C-MAC VL and who were not part of the study. POGO score and Cormack-Lehane (CL) grading of the laryngoscopic view were done by the anaesthesiologist securing the airway. In those patients in which CL grading was found to be III or more was excluded from the study and another airway modality was used for securing the airway.

In group C, the initial attempt was to pass the ETT through the vocal cords without the help of any manoeuvers (M0) under C-MAC guidance. If difficulty persisted while passing the ETT through vocal cords, accessory manoeuvers were used including BURP [M1], neck movements [M2], anticlockwise rotation of tube [M3], and finally use of Magill's forceps [M4] as per the requirement.

In group I, once the ETT had reached into the oropharynx, the cuff of the tube was inflated with 15 mL of air by an assistant such that the tube gets aligned with the laryngeal inlet (cuff inflation technique) and gets engaged in it. Thereafter, the cuff was deflated and the ETT was guided through the glottis (M0). If difficulty was encountered in passing the ETT through vocal cords, the same accessory manoeuvers were followed as per the requirement.

Successful placement of the ETT was confirmed by three successive end-tidal CO2 waveforms. Duration of NTI was defined as the time taken after the confirmation of the tip of the ETT in the nasopharynx by C-MAC VL to the appearance of three successive end-tidal CO2 waveforms. Duration of NTI more than 150 seconds, more than 3 attempts of intubation fall in SpO2 below 92% during the procedure was considered as failed NTI then intubation was attempted via the oral route. During the intubation

procedure, HR, SBP, DBP, MBP, and SpO2 were recorded every minute for the initial 5 min after induction of anaesthesia, and thereafter at 5 min intervals for the next 10 minutes.

The following parameters were measured during the study:

- **CL Grading-**

1. Full view of the glottis
2. Only posterior extremity of glottis seen or only arytenoid cartilages
3. Only epiglottis seen, none of the glottis seen
4. Neither glottis nor epiglottis seen

- **POGO score**

1. 100% Glottis view
2. 50% Glottis view
3. 0% Glottis view

- **Duration of NTI** was defined as the time taken after the confirmation of the tip of the ETT in the nasopharynx by C-MAC VL to the appearance of three successive end-tidal CO2 waveforms.
- **Number and type of manoeuvers** (M0–M4) used

  M0- If ETT advanced into laryngeal inlet without any manoeuvers

  M1- BURP (Backward, Upward and Rightward Pressure) was applied

  M2- Neck movement was done to enhance the alignment of the larynx and the Glottis

  M3- If the ETT tip got stuck in the laryngeal vestibule, it was rotated clockwise

  M4- If the above manoeuvers were unsuccessful, Magill's forceps were used
- Hemodynamic parameters including HR, SBP, DBP, MBP, and SpO2
- Complication if any

Figure: 1.

Conventional method

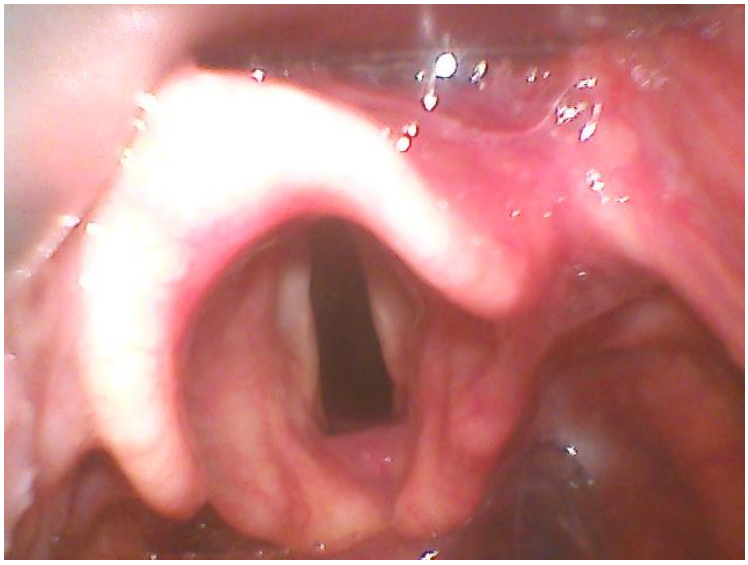
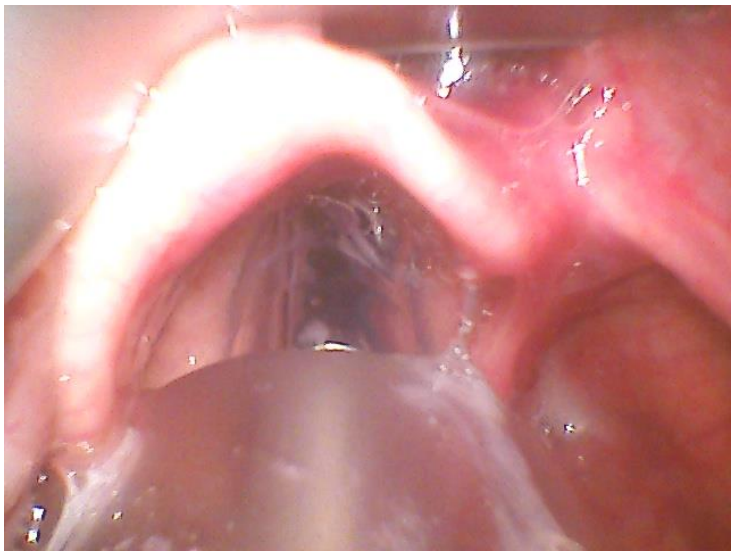


Figure: 2.

Cuff inflation method



Statistical Analysis

The sample size was calculated based on a previously published study done by Shah et al. [15] Assuming a clinical meaningful mean difference of 12 seconds and a standard deviation of 2 in intubation time in two treatment groups, with 90% power and 5% significance, the sample size was estimated to be 53 per treatment group. As it is a one-time point study, there were no dropouts, we recruited 53 patients per treatment group. For a total of two groups, 106 patients were recruited.

$$\text{Sample Size (n)} = \frac{[Z(1-\alpha) + Z(1-\beta)]^2 \, 2 \, Sp^2}{\mu 2d}$$

Sp = Pooled Variance, μd = Mean Difference between two groups;

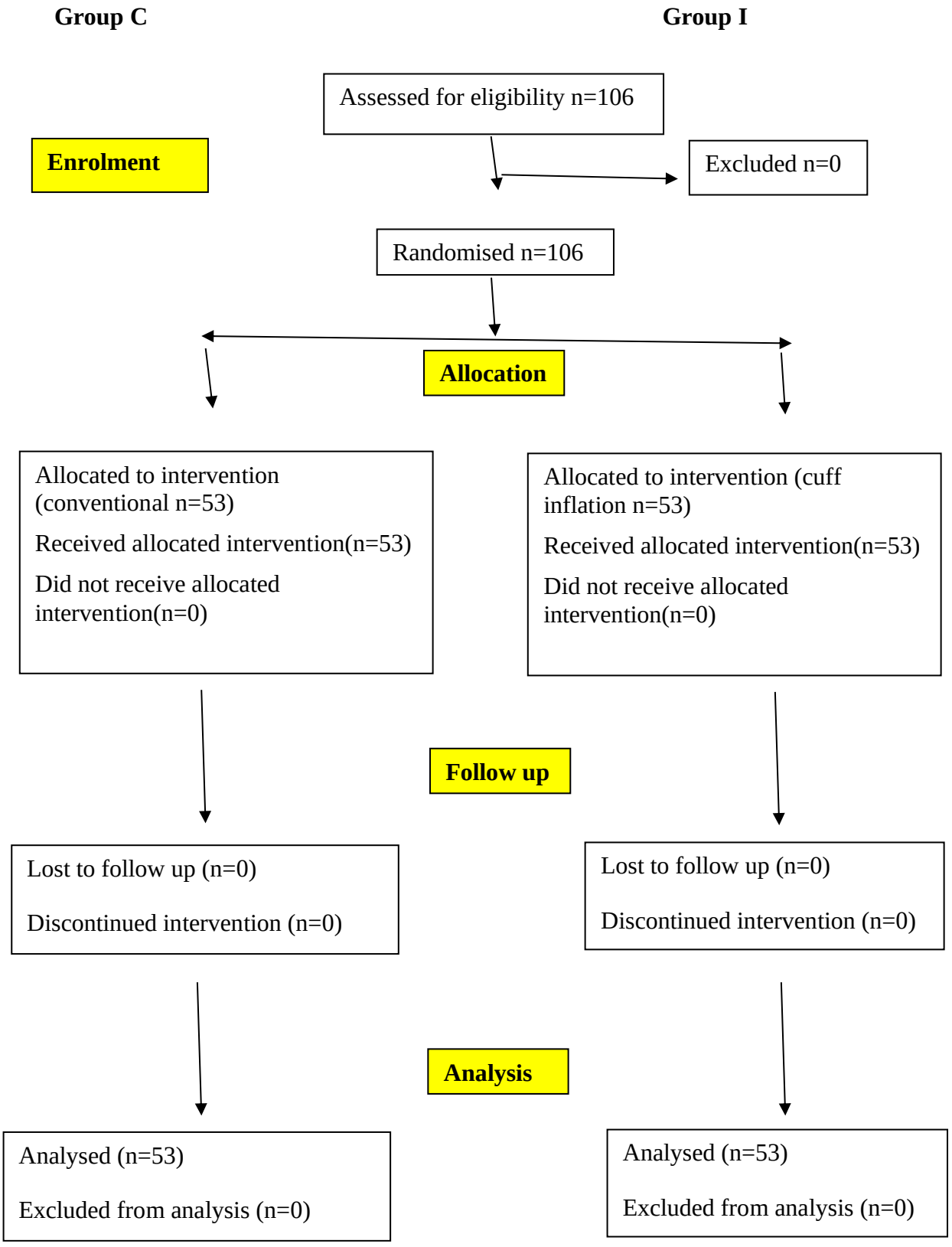
Z (1-β) = 1.28 as Power is 90%.

Z (1-α) = 1.96 as the significance level of 95%

N = 53 per treatment group.

The recorded data was stored in a Microsoft Excel spreadsheet and analyzed using SPSS version 23 (IBM Corp. Ltd, Newark, USA). Categorical data were presented as a ratio or percentage. Continuous data were expressed as mean ± standard deviation. Chi-square test was used to analyze the categorical variables while the intergroup comparison of mean changes in outcomes was evaluated by an unpaired t-test. The difference was considered significant if $p<.05$ was obtained.

Figure: 3. CONSORT figure representing the enrolment and analysis of data.



RESULTS

This thesis entitled "**Comparison of Cuff inflation technique and Conventional technique for nasotracheal intubation using C-MAC video laryngoscope-A prospective randomized controlled trial**" was carried out in the Department of Anaesthesiology and Critical Care, All India Institute of Medical Sciences, Jodhpur in between November 2020 to December 2021. In this prospective randomized control trial, 106 patients scheduled to undergo NTI were studied. Patients were randomly allocated into two groups in a 1:1 ratio using block randomization

1. Group C
2. Group I

The results obtained were as follows:

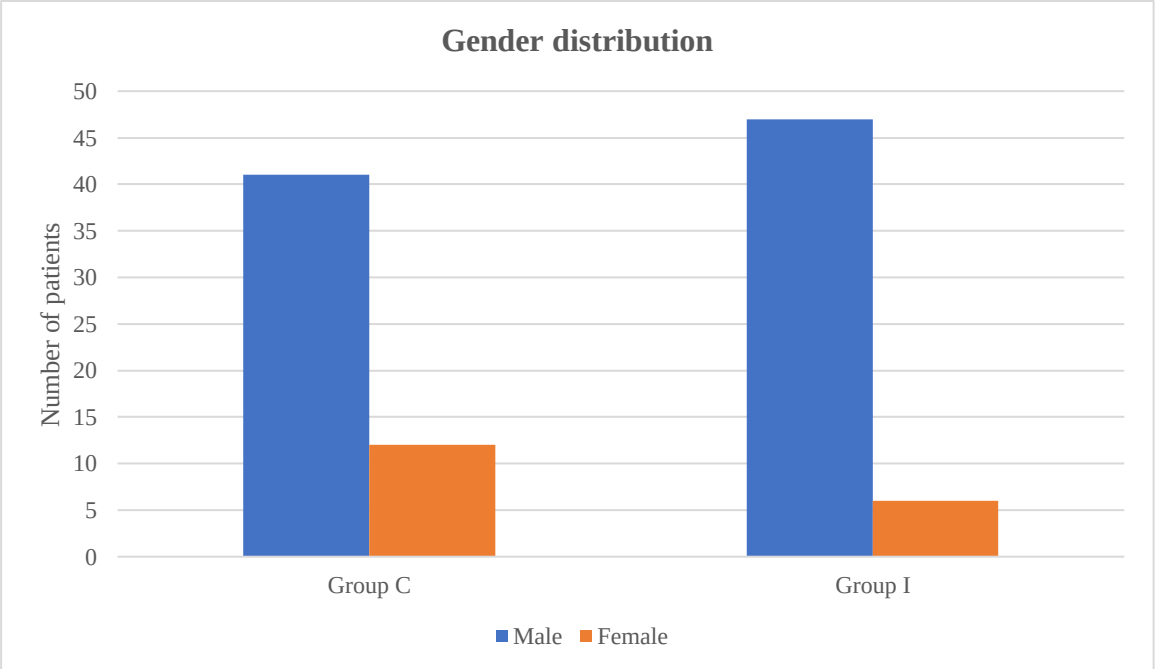
ENDER DISTRIBUTION

Table-1: Comparison of gender distribution between study groups

Gender	Group C (n=53)	Group I (n=53)	p-value
Male	41(77%)	47(88%)	0.1380
Female	12(22%)	6(11%)	

The above table shows the gender distribution of patients between **Group C & Group I.** There were 41(77%) males and 12 (22%) females in the Conventional group vs 47 (88%) males and 6(11%) females in the Cuff inflation group. The chi-square test was applied, which gave a $\chi 2$ value of 2.200 The corresponding p-value was 0.1380; which was statistically non-significant i.e., both the study groups were comparable with respect to the gender of patients enrolled.

Figure-4: Comparison of gender distribution between study groups



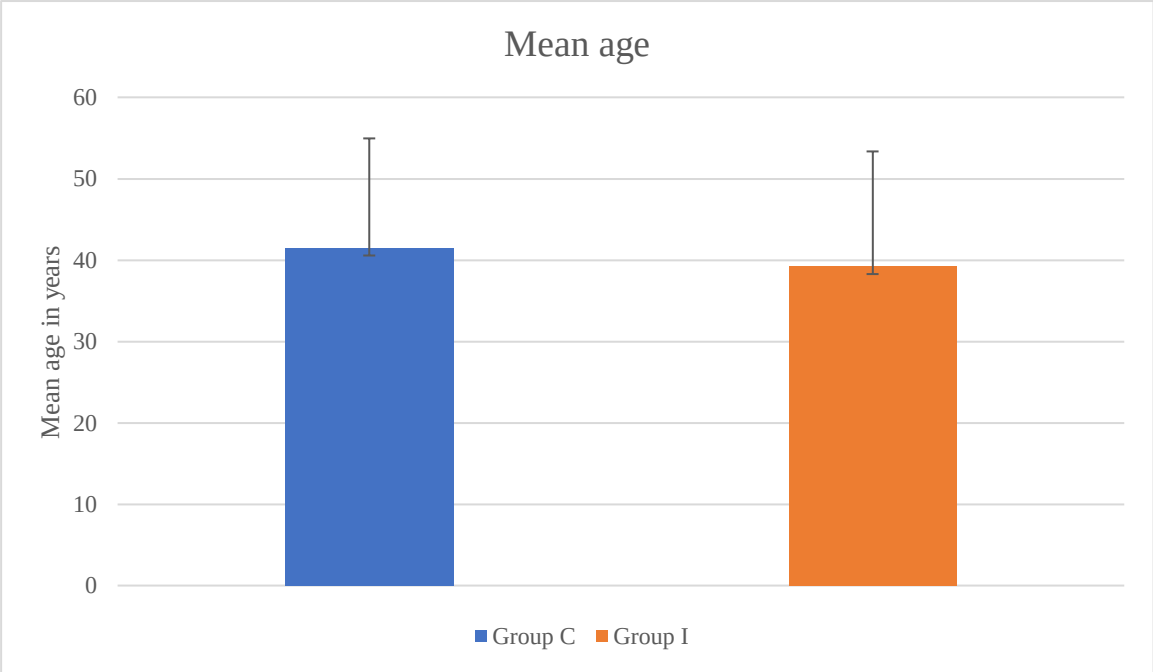
AGE:

Table-2: Comparison of mean age between study groups

Age (Years)	Group C (n=53)	Group I (n=53)	p-value
Mean ±SD	41.56±13.39	39.28±14.07	0.394

The mean age in group C and group I was 41.56±13.39 years and 39.28±14.07years, respectively (p-value = 0.394). The unpaired student 't-test' was used to compare the age between study groups, which showed a p-value of 0.394, which was statistically non-significant i.e., both the study groups were comparable with respect to the age. (Table 2, Figure5)

Figure-5: Comparison of Mean age between study groups



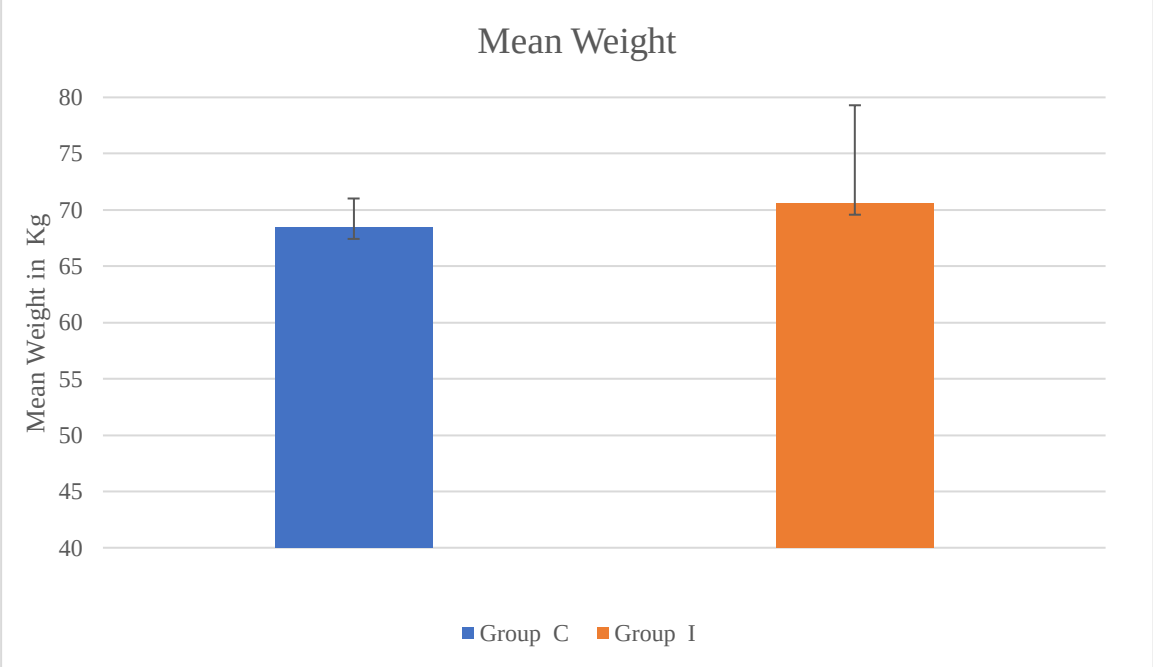
WEIGHT:

Table-3: Comparison of patients' mean weight in Kg between the study groups.

Weight (kg)	Group C (n=53)	Group I (n=53)	p-value
Mean ± SD	68.43±2.59	70.58±8.72	0.088

The above table shows weight distribution and comparison of mean ± SD of weight between study groups. The mean ± SD of weight (kg) in group C and group I was 68.43±2.59 and 70.58±8.72 respectively. The unpaired student 't-test' was used to compare the weight between the groups, which showed a p-value of 0.088, which was statistically non-significant. That means both the study groups were comparable with respect to the weight of the patients (Table 3, Figure 6)

Figure 6: Comparison of patients mean weight in Kg between the study groups



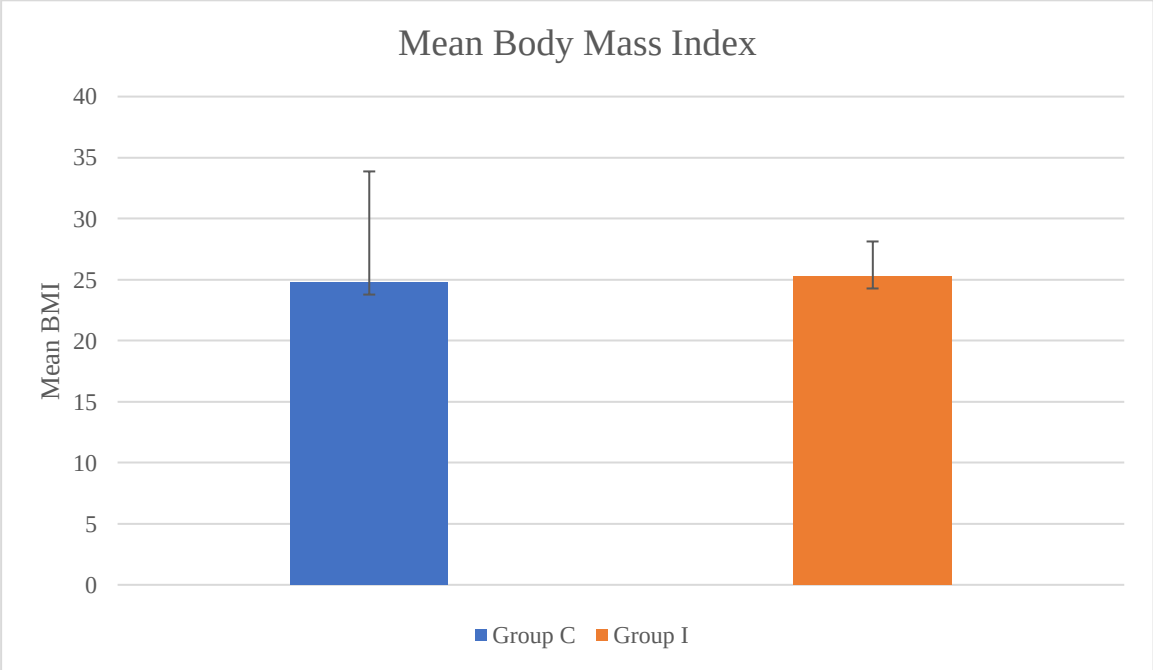
BMI

Table-4: Comparison of patients' mean BMI between the study groups.

BMI (kg/m^2)	Group C (n=53)	Group I (n=53)	p-value
Mean ± SD	24.78±9.09	25.28±2.85	0.703

The above table shows the distribution of BMI and the comparison of mean ± SD of BMI between study groups. The mean ± SD of BMI in group C and group I was 24.78±9.09 and 25.28±2.85 respectively. The unpaired student 't-test' was used to compare the BMI between the groups, which showed a p-value of 0.703, which was statistically non-significant. That means both the study groups were comparable with respect to the BMI of the patients (Table 4, Figure7)

Figure-7: Comparison of patients' mean BMI in between the study groups.



MEAN HEART RATE

Table 5: Comparison of mean Heart rate in beats/min between the study groups

Heart rate	Group C (n=53)	Group I (n=53)	p-value
H1	76.83±9.89	75.43±9.48	0.458
H2	79.05±13.92	79.0±12.90	0.984
H3	83.05±16.55	79.60±12.46	0.228
H4	89.75±16.64	79.64±11.61	0.000
H5	87.96±14.46	78.54±11.40	0.000
H6	82.37±11.10	77.33±10.67	0.019
H7	76.83±7.76	75.33±9.83	0.385
H8	73.79±9.30	73.69±10.22	0.958

The above table shows the comparison of the mean heart rate between the study groups at different time intervals. Unpaired 't-test' was used to compare the mean heart rate at different points of measurement between the study group, which showed that the p-value was statistically significant at the 3rd,4th, and 5th minute of measurement. (Table 5, Figure 5) (H1-preoperative Heart rate, H2- Heart rate at 1minute, H3- Heart rate at 2minutes, H4- Heart rate at 3minutes, H5- Heart rate at 4minutes, H6- Heart rate at 5minutes, H7- Heart rate at 10minutes, H8- Heart rate at 15minutes)

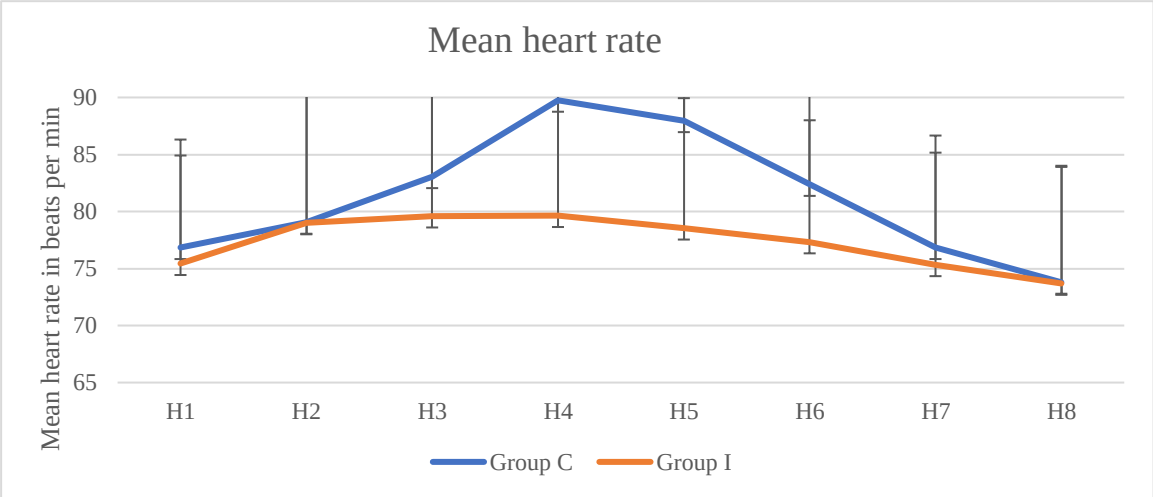


Figure-8: Comparison of mean heart rate in beats/min between the study groups.

SYSTOLIC BLOOD PRESSURE

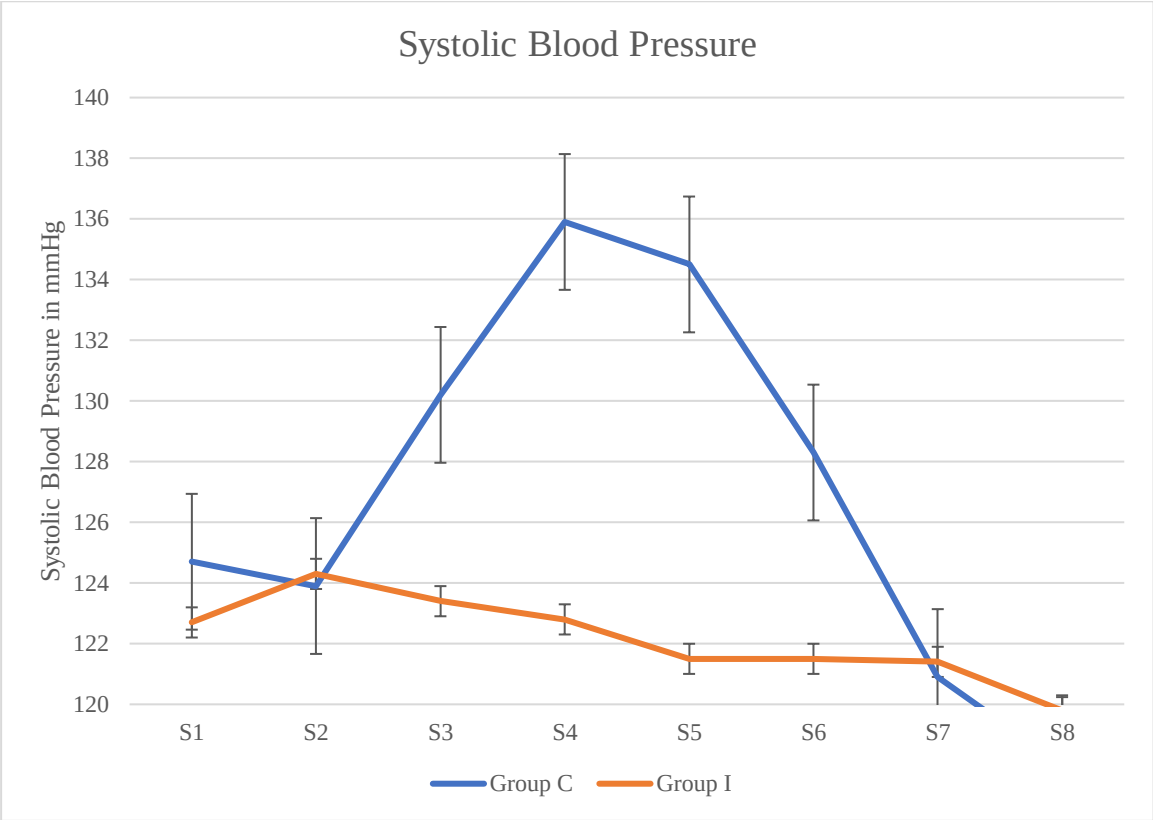
Table 6: Comparison of Systolic Blood Pressure in mmHg between the study groups

Systolic BP	**Group C (n=53)**	**Group I (n=53)**	**p-value**
S1	124.7±9.44	122.7±10.50	0.304
S2	123.9±12.93	124.3±13.07	0.812
S3	130.2±13.62	123.4±9.22	0.003
S4	135.9±14.96	122.8±9.83	0.000
S5	134.5±14.98	121.5±7.88	0.000
S6	128.3±12.47	121.5±7.67	0.001
S7	120.9±6.2	121.4±8.76	0.735
S8	118.0±6.69	119.8±8.24	0.219

The above table shows the comparison of Systolic Blood Pressure between the study groups at different time intervals. Unpaired t-test was applied to compare the Systolic Blood Pressure at different points of measurement between the study groups, which showed that the p-value was statistically significant at the 2^{nd},3^{rd},$4^{th,}$ and 5^{th} minute of measurement. (Table 6, Figure8)

(S1-preoperative Systolic Blood Pressure, S2- Systolic Blood Pressure at 1minute, S3- Systolic Blood Pressure at 2minutes, S4- Systolic Blood Pressure at 3minutes, S5- Systolic Blood Pressure 4minutes, S6- Systolic Blood Pressure at 5minutes, S7- Systolic Blood Pressure at 10minutes, S8- Systolic Blood Pressure at 15minutes)

Figure-9: Comparison of Systolic Blood Pressure in mmHg between the study groups.



DIASTOLIC BLOOD PRESSURE

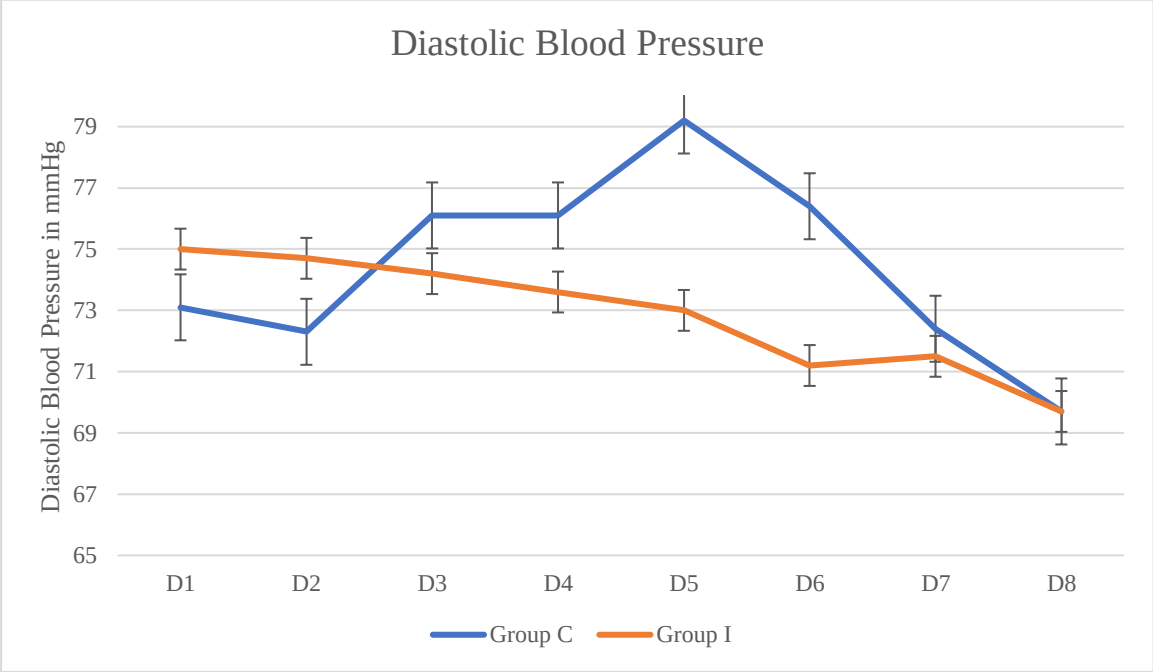
Table 7: Comparison of Diastolic Blood Pressure in mmHg between the study groups

Diastolic BP	**Group C (n=53)**	**Group I (n=53)**	**p-value**
D1	73.1±7.65	75.0±7.78	0.207
D2	72.3±9.94	74.7±8.28	0.179
D3	76.1±9.81	74.2±6.46	0.241
D4	79.2±10.77	73.6±6.14	0.001
D5	79.0±10.36	73.0±6.61	0.000
D6	76.4±8.79	71.2±7.30	0.001
D7	72.4±7.51	71.5±8.52	0.565
D8	69.7±7.21	69.7±10.21	1.000

The above table shows the comparison of Diastolic Blood Pressure between the study groups at different time intervals. Unpaired 't-test' was applied to compare the Diastolic blood pressure at different points of measurement between the study groups, which showed that the p-value was statistically significant at the 3rd,4^{th,} and 5th minute of measurement. (Table 7, Figure10)

(D1-preoperative Diastolic Blood Pressure, D2- Diastolic Blood Pressure at 1minute, D3- Diastolic Blood Pressure at 2minutes, D4- Diastolic Blood Pressure at 3minutes, D5- Diastolic Blood Pressure 4minutes, D6- Diastolic Blood Pressure at 5minutes, D7- Diastolic Blood Pressure at 10minutes, D8- Diastolic Blood Pressure at 15minutes)

Figure-10: Comparison of Diastolic Blood Pressure in mmHg between the study groups.



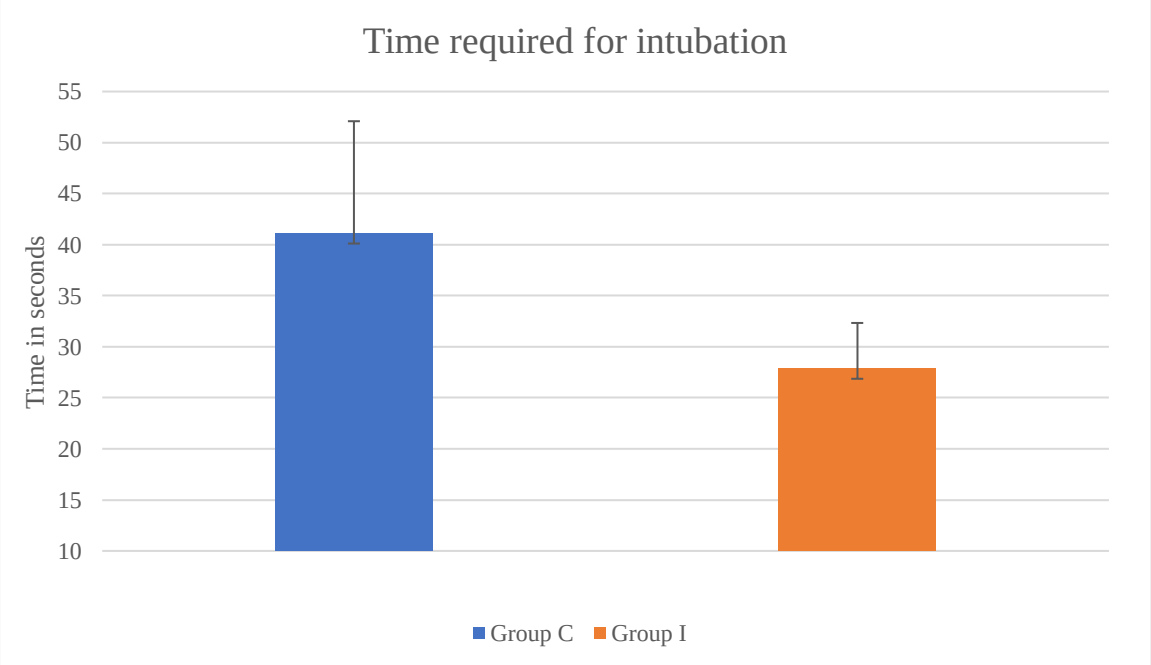
TIME REQUIRED FOR INTUBATION

Table 8- Comparison of Time required for intubation between the study groups

Time required for intubation (Seconds)	Group C (n=53)	Group I (n=53)	p-value
Mean ±SD	41.11±10.98	27.86±4.47	<0.0001

The above table shows the comparison of mean ± SD of insertion time between the groups. Group C and Group I. The mean ± SD of time of intubation in Group C and Group I was 41.11±10.98 seconds and 27.86±4.47 seconds, respectively. The unpaired student 't-test' was used to compare insertion time between study groups, which showed a p-value of 0.0001, which was statistically significant, i.e., both the study groups were not comparable with respect to time of intubation insertion between the study group. (Table 8, Figure 11)

Figure-11 Comparison of Time required for intubation between the study groups.



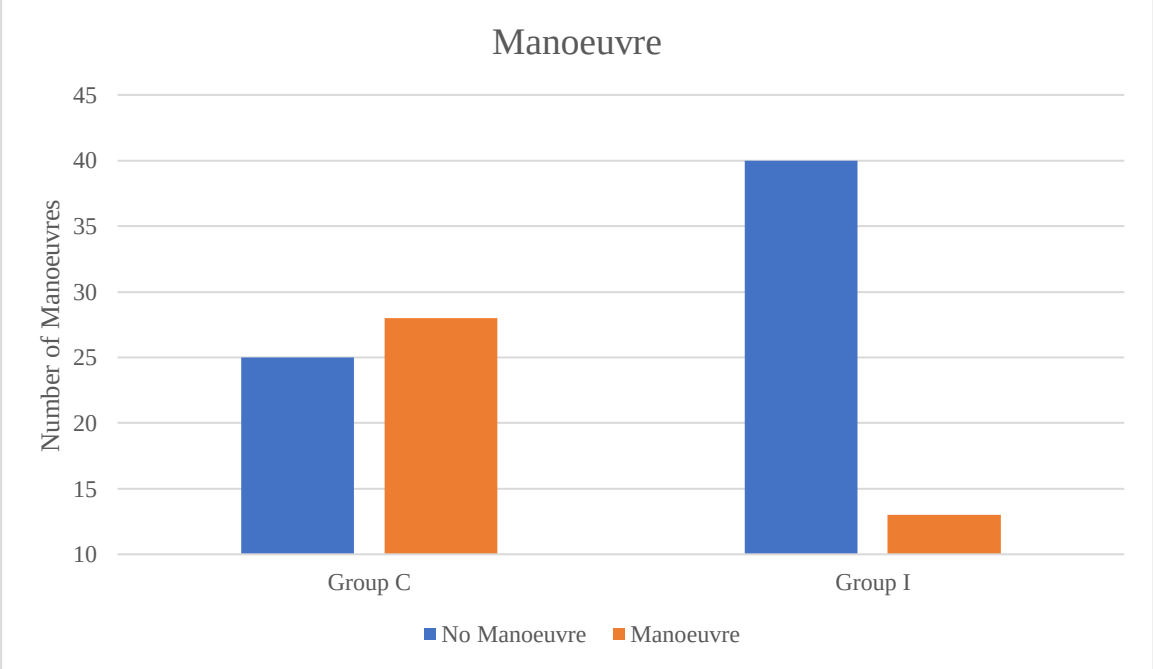
NUMBER OF MANOEUVRES REQUIRED

Table 9 Comparison of the number of manoeuvers required between the study groups

	Group C (n=53)	**Group I (n=53)**	**p-value**
No Manoeuvers	25	40	0.00277
Manoeuvres	28	13	

The above table shows the distribution of the number of manoeuvers in patients between groups C & I. There were 25 patients with no manoeuvers and 28 patients with manoeuvers in group C vs 40 patients with no manoeuvers and 13 patients with manoeuvers in group I. The chi-square test was applied, which gave a $\chi 2$ value of 8.949 The corresponding p-value was 0.00277; which was statistically significant i.e., both the study groups were not comparable with respect to the manoeuvers required (Table-9, Figure12)

Figure-12 Comparison of number of manoeuvers used between the study groups.



TYPE OF MANOEUVRE (M1–M4) USED

Table 10 - Comparison of type of manoeuvers (M1–M4) used between the study groups

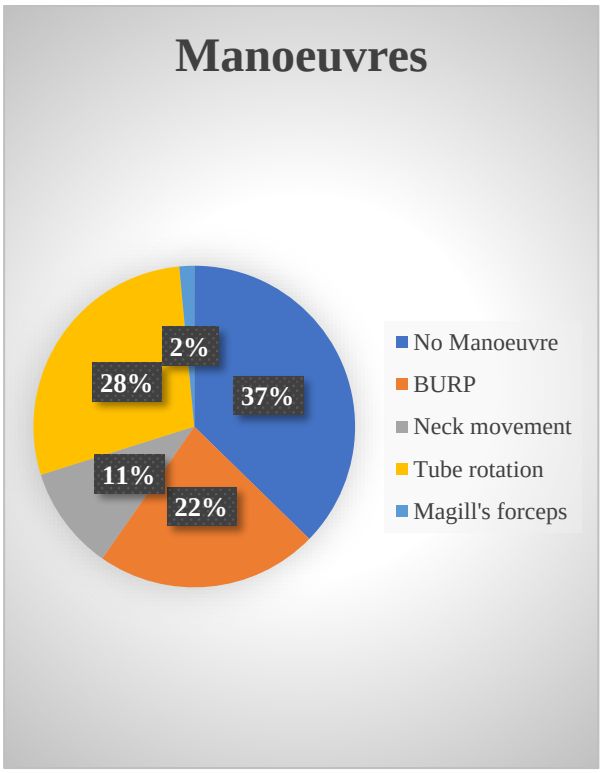
Manoeuvres	**Group C (n=53)**	**Group I (n=53)**
No Manoeuvre[M0]	25	40
BURP[M1]	15	4
Neck movement [M2]	7	5
Anti-clockwise tube rotation [M3]	19	8
Use of Magill forceps [M4]	1	0

The above table shows the type of manoeuvers (M1–M4) used between the study groups which were categorized as no manoeuvers [M0], burp[M1], neck movement[M2], tube rotation[M3], use of Magill forceps [M4]. some subjects needed more than one maneuver and combined manoeuvers were given in required subjects.

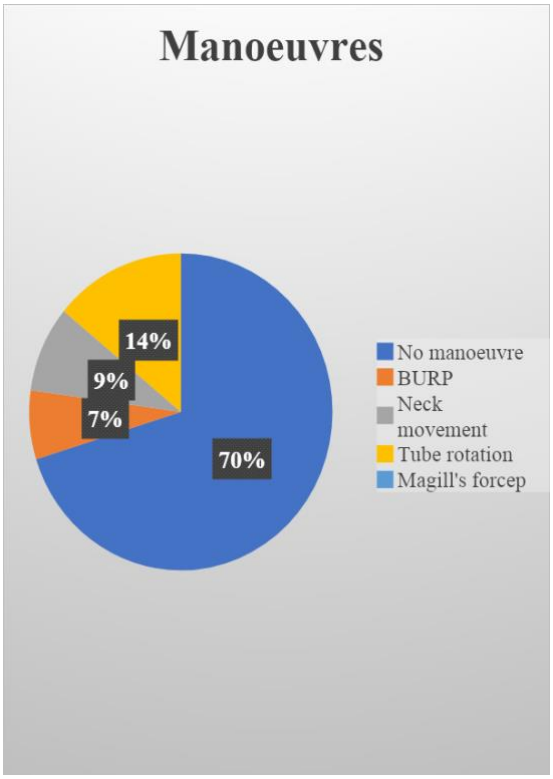
In group C no manoeuvers [M0] was required in 25 patients, rest 28 patients needed manoeuvers 1- burp[M1] was required in 15 subjects(out of these 15 patients, 3 patients needed only burp, 10 patients needed burp [M1] + tube rotation[M3] ,1 patient needed burp[M1] + use of Magill forceps [M4] and 1 patient needed burp[M1]+ neck movement[M2]+ tube rotation[M3]), 2-neckmovement [M2] was required in 7 patients(out of these 7 patients, 3 patients needed only neck movement[M2], 3 patients required neck movement[M2]+ tube rotation[M3] and 1 patient needed burp[M1]+ neck movement[M2]+ tube rotation[M3]), 3-tube rotation[M3] was required in 19 subjects(out of these 19 patients, 5 patients needed only tube rotation[M3],rest 14 were involved in combined manoeuvers M1+M3= 10; M2+M3=3; M1+M2+M3=1. use of Magill's forceps [M4] was required in 1 subject (M1+M4=1).

In the group C, no maneuver [M0] was required in 40 patients, the rest 13 patients needed manoeuvers. Burp[M1] was required in 4 patients (out of these 4 patients, 3 patients needed only burp, 1 patient needed burp + tube rotation[M3]) neck movement[M2] was required in 5 subjects (out of these 5 patients, 2 patients needed only neck movement[M2], 3 patients required neck movement[M2] + tube rotation[M3]), tube rotation[M3] was required in 8 subjects (out of these 8 patients, 4 patients needed only tube rotation[M3], rest 4 were involved in combined manoeuvers M1+M3= 1; M2+M3=3. use of Magill's forceps [M4] was required in no subject.

Figure 13 - Comparison of type of manoeuvers (M1–M4) used between the study groups



Group C



Group I

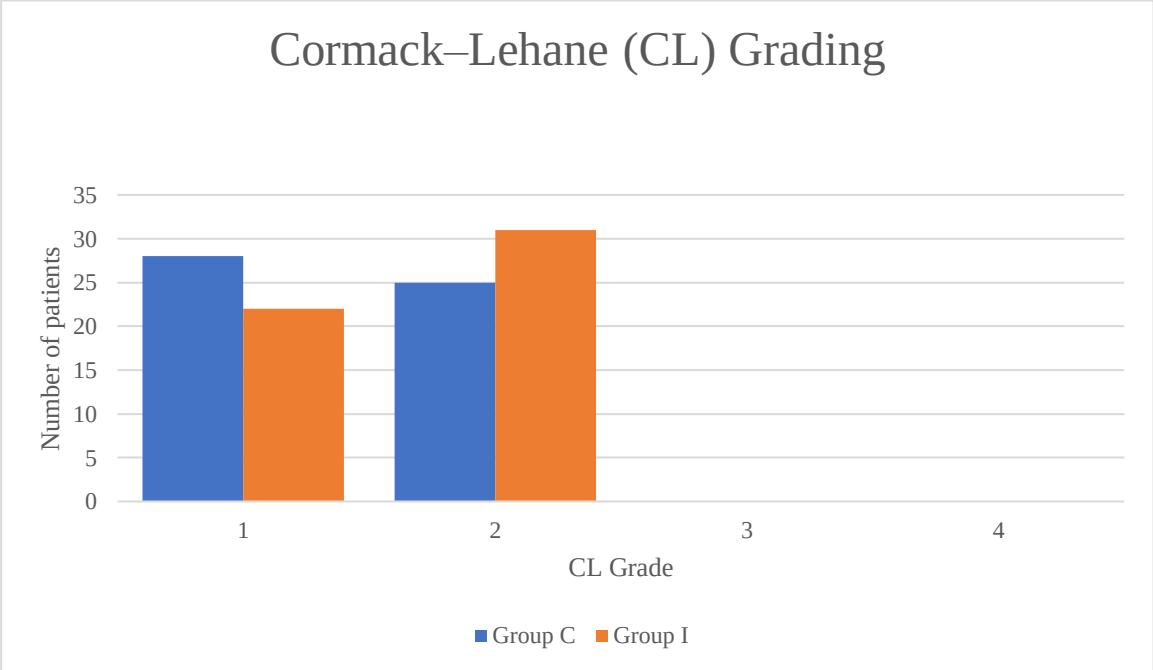
Cormack–Lehane (CL) Grading

Table 11 - Comparison of Cormack–Lehane (CL) Grading between the study groups

Cormack-Lehane (CL) Grading	Group C (n=53)	Group I(n=53)	p-value
1	28	22	0.2460
2	25	31	
3	0	0	
4	0	0	

Mann-Whitney U test was used to compare Cormack–Lehane (CL) Grading between the study groups, which showed a p-value of 0. 2460, which was statistically non-significant, i.e., both the study groups were comparable concerning the Cormack–Lehane (CL) Grading. (Table-11, Figure14)

Figure-14 Comparison of Cormack–Lehane (CL) Grading between the study groups.



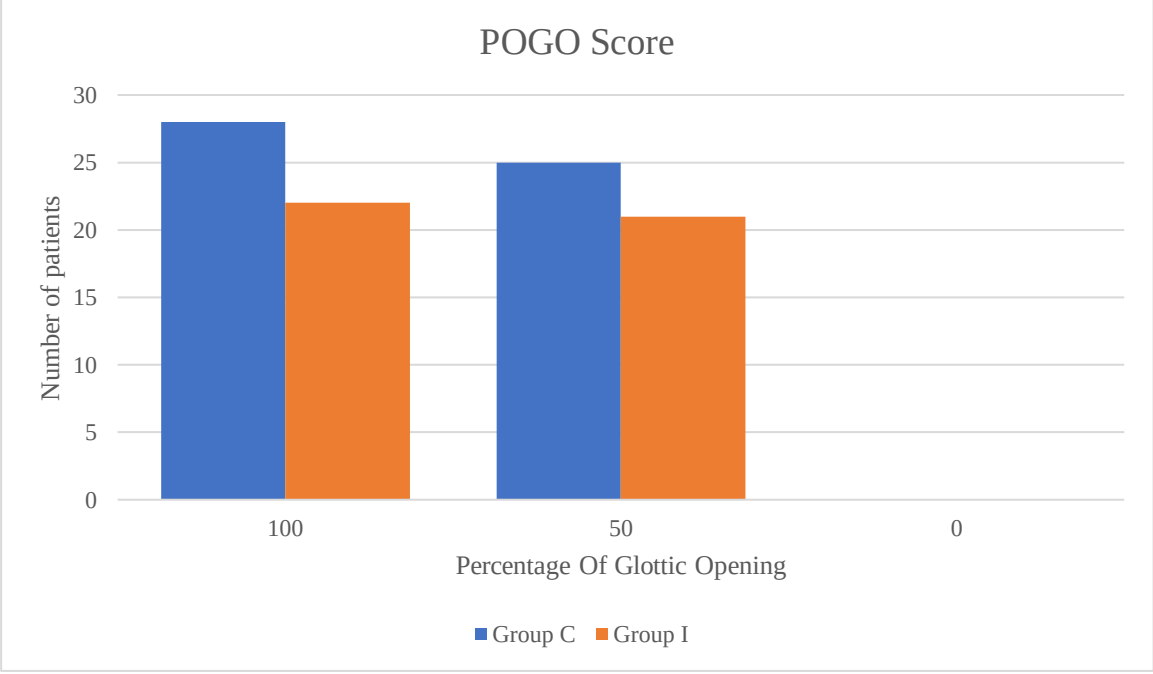
POGO SCORE

Table 12 - Comparison of POGO score between the study groups

POGO score	Group C (n=53)	Group C (n=53)	p-value
100	28	22	0.31732
50	25	31	
0	0	0	

Mann-Whitney U test was used to compare the POGO scores between the study groups, which showed a p-value of 0. 3172, which was statistically non-significant, i.e., both the study groups were comparable concerning the POGO score. (Table-12, Figure15)

Figure15 - Comparison of POGO score between the study groups



DISCUSSION

Nasotracheal intubation is commonly used in the operating room for head and neck surgery, orofacial maxillary surgery, and otorhinolaryngologic surgery. While performing NTI, the difficulty in aligning the tip of the flexometallic ETT with the glottic inlet poses a challenge. The use of different manoeuvers or any instruments like Magill's forceps to guide the tip of the ETT into the glottis may result in a longer intubation time, hemodynamic changes due to prolonged laryngoscopy, and trauma to the oropharyngeal tissue.

The ‘conventional technique involves blind nasal passage and external manipulation of the tube through the glottis. A ‘simple cuff inflation technique’ eliminates the need for manipulations or instrumentation, as well as the complications that come with them. When the cuff is inflated, the tube is lifted away from the posterior pharyngeal wall, allowing the tip to be aligned in the axis of the vocal cord opening and allowing for faster intubation. Previous studies have shown that the cuff inflation technique is consistently found to improve the alignment of the ETT tip into the glottis inlet.

In patients undergoing NTI, we conducted a randomized controlled trial comparing conventional technique and cuff inflation technique. We compared the time required for ETT placement using CMAC® VL, the type and number of manoeuvers used, the hemodynamic response to intubation (HR, SBP, DBP, MBP, and SpO2 were recorded every minute for the first 5 minutes after anaesthesia induction, and then at 5minute intervals for the next 10 minutes), and complications if any were noted.

DEMOGRAPHIC PROFILE:

Age:

The mean age of patients enrolled in our study was 41.56±13.39 years and 39.28±14.07 years in group C and group I respectively, which was comparable (p-value = 0.394). Similarly, in a study conducted by **Prashant et al[6]**. the mean age in the Curvature control group was 35.13±9.32 years and in the Cuff inflation group was 35.0±10.54 years which is comparable to our study. **Kasaudhan S et al[5]**. also found similar ages in their study. Our findings on age were also consistent with the findings of the study done by **Kumar R et al[7]**.

Weight:

The mean weight of patients enrolled in our study was 68.43±2.59kg and 70.58±8.72kg in the Conventional group and Cuff inflation group respectively, which was comparable (p-value = 0.088). Similarly, in a study conducted by **Prashant et al[6]**. the mean age in the Curvature control group was 59.716.8kg and in the Cuff inflation group in thermo-softened ETT was 57.62±7.36kg respectively, which is comparable to our study. In their study, **Kasaudhan S et al[5]**. discovered a similar weight. Our findings on weight were also consistent with the findings of the study done by **Kumar R et al[7]**.

Gender Distribution:

Most of the patients in our study were males in group C and group I, (41 vs 47) and comparatively less number of females in group C and group I (12 vs 6) respectively. Our finding might be due to the higher incidence of oral cancers and dental procedures in males.

BMI:

The mean BMI of patients enrolled in our study was 24.78±9.09 (kg/m2) and 25.28±2.85 (kg/m2) in the group C and group I respectively, which was comparable (p-value = 0.703). Similarly, in a study conducted by **Kasaudhan S et al[5]**. the mean BMI in Macintosh laryngoscope group was 22.73±1.32kg and in the C-MAC® video laryngoscope group was 23.53±3.53kg which is comparable to our study.

Primary outcome source

In both study groups, the duration of NTI was calculated by measuring the time from the confirmation of the tip of the endotracheal tube in the nasopharynx by C-MAC Video laryngoscope to the appearance of three successive end-tidal CO2 waveforms. In our study, the time taken for intubation in group C and group I was 41.11±10.98 seconds and 27.86±4.47 seconds, respectively, with a statistically significant p-value of 0.0001. Intubation time was shorter in group I. Our findings were consistent with those of **Kasaudhan S et al[5]**. who compared the time taken for ETT navigation from the oropharynx to the cords by cuff inflation method using Macintosh laryngoscope and C-MAC® video laryngoscope and discovered that the time taken by cuff inflation method in the C-MAC® video laryngoscope group was significantly less than that of cuff inflation method in the Macintosh laryngoscope group. Our research results were also consistent with those of **Prashant et al[6]**. who compared the cuff inflation method to curvature control modification in a thermo-softened endotracheal tube during NTI and discovered that the cuff inflation method resulted in significantly faster alignment to the glottis when compared to the use of a modified tube.

Secondary outcome measures

Cormack–Lehane (CL) Grading:

In our study, the CL grade 1 was seen in 28 patients, the CL grade 2 was seen in 25 patients, and there were no patients with the CL grade 3 or 4 of the 53 study participants in the group C. CL grade 1 was seen in 22 of the 53 study participants in the group I, CL grade 2 in 31 patients, and no patient with CL grade 3 or 4. The p-value for CL grading between the groups was 0.2460, which was statistically insignificant. Similarly, in a study conducted by **Kasaudhan S et al[5]**. the Macintosh laryngoscope group had CL grade 1 in 18 patients, CL grade 2 in 7 patients, and the C-MAC® video laryngoscope group had CL grade 1 in 16 patients, CL grade 2 in 9 patients with a p-value of 0.544, which is statistically insignificant, which is similar to our study.

POGO score:

In our study, in the group C among 53 study participants, the POGO score of 100% was seen in 28 patients, the POGO score of 50% was seen in 25 patients, and no patient with a POGO score of 0%. In the group I among 53 study participants, the POGO score of 100% was seen in 22 patients, the POGO score of 50% was seen in 31 patients, and no patient with a POGO score of 0% with a p-value of 0.3173 which was statistically insignificant.

Hemodynamic parameters:

Hemodynamic parameters were also measured during intubation, and group C had higher blood pressure and heart rate than group I at 3 to 6 minutes of anaesthesia induction. This can be attributed to the sympathetic stimulation due to the excessive manipulation of the airway during intubation in group C. Similarly, in a study conducted by **Kasaudhan S et al[5]**. Macintosh laryngoscope group had all

hemodynamic parameters significantly higher at 3 minutes than that of the C-MAC® video laryngoscope group.

Number and type of Manoeuvre (M1–M4) used:

The type of maneuver required was categorized as No Manoeuvre [M0], BURP [M1], Neck movement [M2], Tube rotation [M3], Use of Magill forceps [M4]. Some subjects needed more than one maneuver and combined manoeuvers were given when required subjects.

The percentage of patients who required no manoeuver in the conventional and cuff inflation technique group were 47.16% vs 75.47%, who required BURP manoeuver were 28.3% vs 0.07%, who required neck movement were 13.2% vs 0.09%, who required tube movements were 35.8% vs 15% and those in whom Magill's forceps were used for manipulation were 0.01% vs 0% respectively. The p-value between the group was statistically significant (0.0027) with the group I requiring almost nil/lesser manoeuver for intubation compared to the group C. This could be due to the alignment of the tube tip in the glottis on inflation of the cuff requiring no manoeuvers or minimal external manipulation for intubation. No patient in either group was impossible to intubate or who required other techniques like fiberoptic intubation.

To summarize, the cuff inflation technique is a very good alternative to the conventional NTI technique in normal airways and it requires minimal or no external manipulations and manoeuvers. It also not only allows for quicker, easier, and less traumatic intubation but also maintains hemodynamic stability by reducing the intubation stress response. It also avoids airway trauma, cuff rupture, and other complications due to instrumentation.

CONCLUSION

Therefore, after the study, we hereby conclude that

1. The cuff inflation method required a statistically significant (p-value <0.0001) reduced time of NTI compared to the conventional method with a mean ± SD of time of intubation of 27.86±4.47 seconds and 41.11±10.98 seconds, respectively.
2. The cuff inflation method of NTI required no/lesser manoeuvers compared to the conventional method with a p-value of 0.00277; which was statistically significant
3. A greater number of patients required either a single or combined manoeuvers during NTI using the conventional method compared to the cuff inflation method of NTI.
4. The hemodynamic responses (HR, BP) to intubation were statistically significantly higher at 3 to 6 minutes in the conventional group than the cuff inflation group.
5. The Cormack–Lehane (CL) Grading was comparable between the groups with a p-value of 0.2460
6. The POGO score was comparable between the groups with a p-value of 0.317
7. There were no complications noted in both groups.

The Cuff inflation method has the advantages of providing faster alignment with the glottis inlet, lower hemodynamic response, little to no maneuverability, and no complications.

LIMITATIONS OF THE STUDY:

First, the patients in our study had a CL of 1 or 2 on laryngoscopy, and none of the participants had a higher CL grade (3 or 4). As a result, the study's findings cannot be extrapolated to patients with higher CL grades or those with difficult airways.

Second, we allowed an experienced anaesthesiologist who had performed at least 50 successful C-MAC nasal intubations to participate in our study; thus, the results could differ if an inexperienced anaesthetist had no experience with C-MAC video laryngoscope guided intubations would intubate.

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ANNEXURE 1

All India Institute of Medical Sciences, Jodhpur, Rajasthan.

Informed Consent Form

Title of the project: COMPARISON OF CUFF INFLATION TECHNIQUE AND CONVENTIONAL TECHNIQUE FOR NASOTRACHEAL INTUBATION USING C-MAC VIDEO LARYNGOSCOPE. A PROSPECTIVE RANDOMISED CONTROLLED TRIAL.

Name of the Principal Investigator: DR Venkata Prem Kumar Sangamala

Tel. No. 8099661696

Patient/Volunteer Identification No. : _____

I, _____ S/o or D/o _____

R/o _____

give my full, free, voluntary consent to be a part of the study "_____ _____", the procedure and nature of which has been explained to me in my own language to my full satisfaction. I confirm that I have had the opportunity to ask questions. I understand that my participation is voluntary and am aware of my right to opt out of the study at any time without giving any reason. I understand that the information collected about me and any of my medical records may be looked at by responsible individual from _____ (Company Name) or from regulatory authorities. I give permission for these individuals to have access to my records.

Date: _____ _____

Place: _____ Signature/Left thumb impression

This to certify that the above consent has been obtained in my presence.

Date: _____ _____

Place: _____ Signature of Principal Investigator

Witness 1

_____

Signature

Name: _____

Address: _____

2. Witness 2

_____

Signature

Name: _____

Address: _____

ANNEXURE 2

अखिल भारतीय आयुर्विज्ञान संस्थान जोधपुर, राजस्थान.

सूचित सहमति प्रपत्र

थीसिस / निबंध का शीर्षक: सी-मैक वीडियो लैरिंगोस्कोप का उपयोग करके नासोट्रेचल इंटुबलेशन के लिए कफ मुद्रास्फीति तकनीक और पारंपरिक टेकिक की तुलना। एक संभावित रामडोमीकृत नियंत्रित परीक्षण.

पीजी छात्र का नाम: डॉ वेंकट प्रेम कुमार संगमला टेल न: 8099661696

रोगी / स्वयंसेवक पहचान संख्या: _____

मैं, _____ पुत्र / पुत्री _____

पता_____

अध्ययन "_____ " का एक भाग बनने के लिए मेरी पूर्ण, स्वतंत्र, स्वैच्छिक सहमति दें, जिसकी प्रक्रिया और प्रकृति मुझे अपनी पूरी संतुष्टि के लिए अपनी भाषा में समझाई गई है। मैं पुष्टि करता हूं कि मुझे प्रश्न पूछने का अवसर मिला है।

मैं समझता हूं कि मेरी भागीदारी स्वैच्छिक है और मुझे किसी भी कारण दिए बिना किसी भी समय अध्ययन से बाहर निकलने के मेरे अधिकार की जानकारी है।

मैं समझता हूं कि मेरे और मेरे मेडिकल रिकॉर्ड के बारे में एकत्रित की गई जानकारी को _____ (कंपनी नाम) या विनियामक प्राधिकरणों से जिम्मेदार व्यक्ति द्वारा देखा जा सकता है। मैं इन व्यक्तियों को अपने अभिलेखों तक पहुंच के लिए अनुमति देता हूं I

तारीख: _____ _____

जगह: _____ हस्ताक्षर / बाएं अंगूठे का छाप

यह प्रमाणित करने के लिए कि मेरी उपस्थिति में उपरोक्त सहमति प्राप्त की गई है I

तारीख: _____ _____

जगह: _____ पीजी छात्र के हस्ताक्षर

गवाह 1 गवाह 2

_____ _____

हस्ताक्षर हस्ताक्षर

नाम_____ पता_____

नाम_____ पता_____

ANNEXURE 3

All India Institute of Medical Sciences Jodhpur, Rajasthan

PARTICIPANT INFORMATION SHEET (PIS)

1. Risks to the patients: No interventions or life-threatening procedures will be done.

2. Confidentiality: Your participation will be kept confidential. Your medical records will be treated with confidentiality and will be revealed only to doctors/ scientists involved in this study. The results of this study may be published in a scientific journal, but you will not be identified by name.

3. Provision of free treatment for research-related injury. Not applicable.

4. Compensation of subjects for disability or death resulting from such injury: Not Applicable

5. Freedom of individuals to participate and to withdraw from the research at any time without penalty or loss of benefits to which the subject would otherwise be entitled.

6. You have complete freedom to participate and to withdraw from the research at any time without penalty or loss of benefits to which you would otherwise be entitled.

7. Your participation in the study is optional and voluntary.

8. The copy of the results of the investigations performed will be provided to you for your record.

9. You can withdraw from the project at any time, and this will not affect your subsequent medical treatment or relationship with the treating physician.

10. Any additional expense for the project, other than your regular expenses, will not be charged from you.

ANNEXURE 4

रोगी सूचना पत्रक

1. रोगियों के लिए जोखिम: कोई हस्तक्षेप या जीवन-धमकी प्रक्रिया नहीं की जाएगी।

2. गोपनीयता: आपकी भागीदारी को गोपनीय रखा जाएगा। आपके मेडिकल रिकॉर्ड को गोपनीयता के साथ इलाज किया जाएगा और केवल इस अध्ययन में शामिल डॉक्टरों / वैज्ञानिकों को पता चलेगा। इस अध्ययन के परिणाम एक वैज्ञानिक पत्रिका में प्रकाशित हो सकते हैं, लेकिन आपको नाम से पहचाना नहीं जाएगा।

3. अनुसंधान संबंधी चोट के लिए नि: शुल्क उपचार की व्यवस्था। लागू नहीं।

4. ऐसी चोट से उत्पन्न विकलांगता या मृत्यु के लिए विषयों का मुआवजा: लागू नहीं है

5. किसी भी समय दंड या लाभों के नुकसान के बिना किसी भी समय भाग लेने के लिए व्यक्ति को स्वतंत्रता लेने और अनुसंधान से वापस लेने के लिए स्वतंत्रता, जिसके तहत विषय अन्यथा हकदार होगा

6. आपको जुर्माना या लाभ के नुकसान के बिना किसी भी समय भाग लेने और अनुसंधान से वापस लेने की पूरी आजादी है, जिस पर आप अन्यथा हकदार होंगे।

7. अध्ययन में आपकी भागीदारी वैकल्पिक और स्वैच्छिक है।

8. प्रदर्शन की जांच की परिणामों की प्रति आपके रिकॉर्ड के लिए आपको उपलब्ध कराई जाएगी।

9. आप किसी भी समय परियोजना से वापस ले सकते हैं, और यह आपके बाद के चिकित्सा उपचार या उपचार चिकित्सक के साथ संबंध को प्रभावित नहीं करेगा।

10. परियोजना के लिए कोई भी अतिरिक्त व्यय, आपके नियमित खर्चों के अलावा, आपसे शुल्क नहीं लिया जाएगा।

ANNEXURE 5

Modified Cormack–Lehane (CL) Grading

Grade	Description
1	Full view of the glottis.
2a	Partial view of the glottis.
2b	Only posterior extremity of glottis seen or only arytenoid cartilages.
3	Only epiglottis seen, none of the glottis seen.
4	Neither glottis nor epiglottis is seen.

ANNEXURE 6

POGO Score

Grade	Description
1	100% Glottis view
2	50% Glottis view
3	0% Glottis view

ANNEXURE 7

Proforma

Name

Age Sex

Weight BMI

Procedure

Hemodynamic parameters

	Preop.	1min	2min	3min	4min	5min	10 min	15min	
HR									
BP									
SPO2									

Cormack–Lehane (CL) grading

POGO scoring

Time required for intubation (seconds)

Need of any maneuver (yes/no)

Type of maneuver	
NO MANOEUVRE [M0]	
BURP[M1]	
NECK MOVEMENT[M2]	
TUBE ROTATION[M3]	
USE OF MAGILL FORCEPS [M4]	

No of intubation attempts

Complications

ANNEXURE 8

MASTER CHART