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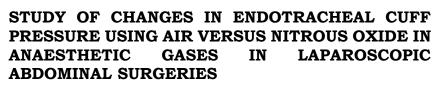
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Abstract

Background: Laparoscopic surgeries are preferred now-a days. General Anaesthesia with Endotracheal intubation and controlled ventilation is gold standard technique of anaesthesia for laparoscopy. Endotracheal cuff pressure greater than 30 cm of H2O impairs tracheal mucosal perfusion leading to necrosis of trachea and can cause sore throat, hoarseness, dysphagia. This study aimed to compare the endotracheal tube cuff pressure while using air versus nitrous oxide in the anaesthetic gas mixture during laparoscopic abdominal surgeries. Materials and Methods: Ninety patients 18-60 years of age undergoing laparoscopic abdominal surgery under general anaesthesia were randomized into 2 groups of 45 each. Group A patient's received air and oxygen mixture and group N patients received nitrous oxide and oxygen for maintenance of anaesthesia. Cuff pressure changes were measured throughout the surgery. The incidence and severity of sore throat, dysphagia and dysphonia was also evaluated postoperatively for 24 hours. Result: Two groups were comparable in demographic profile. The cuff pressure was higher in Group N compared to Group A at all times & was statistically highly significant (p value <0.05 and P <0.0001). The increase in cuff pressure in group N was associated with increased incidence of sore throat and dysphagia in group N. Conclusion: Nitrous oxide causes significant increase in endotracheal tube cuff pressure compared to air when used as anesthetic gas in laparoscopic surgery. Cuffpressure should be routinely monitored during anesthesia while using nitrous oxide for maintenance of anesthesia.

INTRODUCTION

The fundamental aspect of anesthetic practice and critical care medicine is airway management. All the goals of airway management are achieved with endotracheal Intubation.^[1] Intubation remains the gold standard procedure for airway management.

Because of benefits like less incisional pain, quicker recovery and short hospital stay, laparoscopic surgeries are commonly preferred now-a days over open abdominal surgeries. For laparoscopy general anesthesia with endotracheal intubation and controlled ventilation is a safe technique.

Cuffed endotracheal tube are used to achieve a seal between the cuff and trachea with a pressure great enough to prevent aspiration but not so high that the tracheal blood flow will be impeded. Ischemia of the tracheal wall occurs when pressure against the tracheal wall from hyperinflated cuff exceeds the pressure in the capillary blood supply. Tracheal mucosal perfusion can be impaired by cuff pressure greater than 30 cm of H2O and thus patient can experience sore throat, hoarseness, and dysphagia. ^[2,3] Intracuff pressure can be affected by anesthetic agents such as nitrous oxide which diffuse into endotracheal tube cuffs.^[4] Studies have shown that during general anesthesia with nitrous oxide, intra cuff pressure increases causing increase in tracheal injury and sore throat. ^[1,5] In modern era with emphasis on enhanced recovery after surgery, nitrous oxide remains a valuable option in view of its effect on recovery and benefits in general anesthesia.^[6] Several methods have been used to decrease the pressure exerted on the tracheal mucosa by decreasing the diffusion of nitrous oxide into the cuff like checking volume and pressure of the cuff regularly, deflating the cuff if indicated, use of normal saline or distilled water to inflate the cuff to prevent increase in cuff pressure.^[7]

The objective of this study was to evaluate changes in endotracheal tube cuff pressure during laparoscopy using air versus nitrous oxide in anesthetic gas mixture in balanced general anesthesia.

MATERIALS AND METHODS

Study Area: Patients posted for elective laparoscopic surgery under general anesthesia. **Study Population:** The study included both rural and urban population. **Study Duration:** August 2018 to May 2019 **Data Collection Method:** Simple random sampling technique **Sample Size Calculation:** Confidence level = 9 n1=45, n2=45, S1=15.40, S2=6.59Combined SD= 6=Sp

$$Sp = \sqrt{\frac{(n_1 - 1){s_1}^2 + (n_2 - 1){s_2}^2}{(n_1 + n_2 - 2)}}$$

SD = Sp = 11.84Desired margin error = E = 5%

$$n_i = 2\left(\frac{Z\sigma}{E}\right)$$

=43.08 = 43 in each group

So, we had taken 45 cases in each group in our study Study Design- A prospective randomized analytical study.

Inclusion Criteria of patients

- 1. Age group: >18 years and < 60 years
- 2. ASA grade: 1 to 11
- 3. BMI < 35 kg/m2
- 4. Patient undergoing elective surgery under general anesthesia.

Exclusion Criteria of patients

- 1. BMI > 35kg/m2
- 2. ASA >II
- 3. Recurrent history of upper respiratory tract infection.
- 4. Smokers
- 5. Gastroesophageal reflux disease.
- 6. Pregnancy
- 7. Oropharyngeal pathology
- 8. Patient with anticipated difficult intubation.

Methodology

This prospective and randomized study was conducted with institutional research ethics board approval. Written informed consent was obtained from all participants.

90 patients were included in the study and patients were randomized in two groups by computer generated randomization table. (Group A) received oxygen-air while (Group N) received oxygen-Nitrous oxide for maintenance of anesthesia with Intermittent Positive Pressure Ventilation (IPPV) for general anesthesia. Allocation concealment was maintained with opaque sealed envelope. All patients were fasted for at least 6 hours before induction of general anesthesia. IV catheter was placed in a peripheral vein in patient's upper limb while in holding area & infusion of lactated Ringer's solution was started slowly. In the operation theatre routine monitoring was applied i.e., pulse oximetry, noninvasive blood pressure and electrocardiography. All patients were pre-oxygenated with 100% oxygen for 3 min, general anesthesia was induced with intravenous fentanyl (1 - 2microgram/kg) & propofol (2-3 mg/kg). Intravenous atracurium (0.5 mg/kg) was used for neuromuscular block. For tracheal intubation high-volume, low-pressure cuffs (Smiths medical, Hythe, UK) Portex®ETT was used. Internal diameter of 7 mm for females and 8 mm for males was used for intubation. ETT cuff was inflated with air with the help of a sterile 10 mL syringe, to achieve an adequate cuff seal so that there is no audible leak at peak inspiratory pressures.

To measure endotracheal tube cuff pressure, a handheld pressure manometer (COMPANY NAME PORTEX, GERMANY) was connected to the endotracheal tube pilot balloon. We recorded baseline sealing pressure in both the groups. Both the groups received balanced general anesthesia. Group A received receive oxygen and air (50:50) while Group N received oxygen and nitrous oxide (50:50) with positive pressure ventilation. Mechanical ventilation was controlled and adapted to maintain end-tidal carbon-dioxide (ETCO2) between 30and 35 mmHg. Before trocar insertion nasogastric tube was inserted in both the groups. Anesthesia was maintained with intermittent doses of intravenous fentanyl (1---2 microgram/kg), intravenous atracurium (0.1 mg/kg) and sevoflurane to maintain MAC between 1-1.2. Maintenance intravenous fluids were given as per calculation.

Endotracheal tube cuff pressure was measured subsequently at baseline and at 30 min,60 min, 90 min and every 30minutes thereafter in both the groups by an anesthesiologist. At the end of surgery, intravenous glycopyrrolate (10 microgram/kg) and intravenous neostigmine (0.05 mg/kg) were given for reversal.

After full reversal of neuromuscular blockade, patient was extubated after return of reflexes, smooth spontaneous adequate respiration, and ability to follow verbal commands. Nasogastric tube was removed after discussing with the surgeon. The patients were monitored in postoperative recovery room and discharged according to Modified Aldrete's scoring criteria from postoperative recovery room.

A predetermined questionnaire was used to collect data postoperatively by anesthesiologist who was blinded to the patient group allocation. Intraoperatively, data of possible confounders was also collected.

After the surgery, patients were assessed for sore throat, dysphonia, and dysphagia at 1,2,4 and 24 hours postoperatively. We used following definitions

for assessment of complications caused by excessive endotracheal tube cuff pressure.

Sore throat was defined specifically as "constant pain or discomfort in the throat independent of swallowing".

Dysphonia was defined specifically as "difficulty speaking or pain on speaking."

Dysphagia was defined specifically as "difficulty or pain provoked by swallowing."

Statistical Analysis: Data analysis was done using the SPSS (Statistical Package for the Social Science) Version 17 for window by using appropriate test of significance like t test, chi - square test, proportion test etc. A probability value of 0.05 was accepted as the level of statistical significance.

RESULTS

In Group A mean age of patients was 45.98 ± 13.53 years. In Group N mean age of patients was 44.42 ± 13.24 . Mean age of the patients in 2 group was compared using Z test and showed no significant difference (P value >0.05). **[Table 1]**

There were 18 males and 27 females in Group A, 14 males and 31 females in group N. The difference in the two groups was not statistically significant. (Chi square test P value >0.05). [Table 2]

In Group A BMI of the patients was 29.13 ± 3.207 . In Group N BMI of the patients was 29.08 ± 2.88 . Mean BMI of the patients in two groups was compared using Z- test and showed no significant difference (p value>0.05). [Table 3]

In Group A amount of air used to insufflate ETT cuff was 5.18 ± 0.65 In Group N amount of air used to insufflate ETT cuff was 5.29 ± 0.76 Mean amount of air used to insufflate the ETT cuff was compared using Z test and showed statistically insignificant difference (p value>0.05). **[Table 4]**

Comparison for intraoperative ETT cuff pressure was done between Group A and Group N till the end of surgery. The initial cuff pressure in Group A was 30.04-mmhg & Group N was 30.17-mmhg which was compared between the two groups & was found to be statistically insignificant. The cuff pressure in Group A at 30min increased to 35mmhg.At 60min & 90min its was found to be 37mmhg & 39mmhg.Thereafter maintained at 40mmhg throughout the surgery.

In Group N the initial cuff pressure increased from 30-mmhg to 45-mmhg at 30min.The cuff pressure gradually kept on increasing throughout the duration of the surgery. The cuff pressure was higher in Group N compared to Group A at all times & was statistically highly significant (p value <0.05 and P <0.0001). **[Table 5]**

Group A and Group N were compared for postoperative sore throat at 1hr,2hr 4hr and 24-hour using Z test. Group N showed significantly higher sore throat than group A (P value <0.05) **[Table 6]**

None of patients reported dysphonia in both the groups. Group N showed more incidence of dysphagia compared to group A. The difference was statistically insignificant.

Table 1: Comparison of age in group A and group N									
Parameter	Group A (n=45)		Group N (n=45	5)	Z	P Value			
	Mean	SD	Mean	SD	Value				
Age (Yrs.)	45.98	13.53	44.42	13.24	0.55	0.58			

Table 2: Gender wise distribution of cases in Group A and group N

Sex	Group A	Group N	Total	
Male	18	14	32	
Female	27	31	58	
Total	45	45	90	

Chi-square = 0.78, P = 0.38

Table 3: Comparison of Body Mass Index in group A and group N

Parameter	Group A (n=45)		Group N (n=45	5)	Z	P Value
	Mean	SD	Mean	SD	Value	
BMI	29.13	3.20	29.08	2.883	0.08	0.93

Table 4: Comparison of amount of air used to insufflate in group A and group N

Amount of air used to	Group A (n=45)		Group N (n=45	5)	Z Value	P Value
	Mean	SD	Mean	SD		
Insufflate (ml)	5.18	0.65	5.29	0.76	0.75	0.46

Table 5: Comparison of Intraoperative ETT cuff pressure in group A and group N

ETT cuff pressure	Grou	Group A			Group N			P Value
(cmH20)	no	Mean	SD	no	Mean	SD		
At 0 min	45	30.04	1.24	45	30.17	1.33	1.95	0.623
At 30 min	45	35.47	1.72	45	45.02	1.98	24.38	< 0.0001
At 60 min	44	37.82	1.35	45	54.18	2.28	40.94	< 0.0001
At 90 min	28	39.93	1.27	35	56.91	1.83	41.55	< 0.0001
At 120 min	20	40.80	1.00	30	67.20	1.24	79.2	< 0.0001
At 150 min	3	40.67	1.15	3	70.00	0		

At 180 min	2	41.00	1.41	2	71	1.41		
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Sore Throat	Group A(n=45)	Group N(n=45)	Z Value	P Value	
At 1 hr	7(15.56)	25(55.56)	4.36	< 0.0001	
At 2 hr	6(13.33)	25(55.56)	4.70	< 0.0001	
At 4 hr	3(6.67)	6(13.33)	1.06	0.29	
At 24 hr	1(2.22)	3(6.67)	1.03	0.31	

Table 6: Distribution of cases in Group A and group N according to incidence of sore throat

DISCUSSION

Laparoscopic surgeries are commonly preferred now-a days over open abdominal surgeries because of benefits like less incisional pain, quicker recovery and short hospital stay. General anesthesia with endotracheal intubation high volume and lowpressure endotracheal tube is safest technique of anesthesia for laparoscopy.

The cuff of an endotracheal tube provides seal between the tube and tracheal wall. This seal ensures positive pressure ventilation by avoiding gas leaks and prevents passage of pharyngeal contents into the trachea.^[6]

Excessive ETT cuff pressure is associated with several postoperative complications such as cough, sore throat, dysphagia. So routine ETT cuff pressure measurement has been recommended as a means of minimizing tracheal trauma. Various methods have been advocated to prevent the rise in ETT cuff pressure during N2O anesthesia. To prevent excessive increase in endotracheal cuff pressure, foam filled cuffs, pressure-relief valve, rediffusion systems have been used intraoperatively.^[7,8]

In present study, significant increases in cuff pressure were observed at various time intervals of pneumoperitoneum and change in patient position during surgery. In group A at 0 min cuff pressure was 30±1.24, at 30 min cuff pressure increased to 35 cm of H2O and at 60 minutes and 90 minutes, it was 37 cm of H2O and 39 cm of H2O respectively. The initial increase in cuff pressure can be attributed to CO2 pneumoperitoneum and change in present position.

This is consistent with the findings of Zeynep Baysal Y et al (2012), Chun-Yu Wu et al (2014) and Guiqi Geng (2015).^[9-11]

In Group N, the initial cuff pressure increased from 30 cm of H2O to 45 cm of H2O at 30 min. At 60 min, 90 min and 120 min, it was found to be 54 cm of H2O, 56 cm of H2O and 67 cm of H2O respectively. Thus, cuff pressure was higher in Group N always as compared to Group A and the difference was statistically highly significant. This significant increase in cuff pressure can be attributed to CO2 pneumoperitoneum, change in patient position and continuous diffusion of nitrous oxide into the ETT cuff. Thus, findings of our study correlate with the findings of Gajal Lakhe (2017),^[12] Amruta Pooja Kannadkar (2017),^[13] Rosero et al (2018),^[14] and Shweta Sarjerao M (2018).^[6]

The incidence of sore throat in group A was 15.56% 13.33%, 6.67% and 2.22% at 1 hour, 2-hour, 4 hour and 24 hours respectively. In Group N, it was 55.56%, 55.56%, 13.33% and 6.67% at 1 hour, 2hour, 4 hour and 24 hours respectively. The incidence was compared using chi square test and found to be statistically significant at 1 hour, 2 hours but not at 4 hour and 24 hours. Thus, incidence of sore throat was much higher in Group N than Group A. Thus findings of our study correlates with the study of Xavier Combes et al (2001),^[15] K, EI-Boghdadly(2016),^[16] and Gajal Lakhe (2017).^[12]

The higher incidence of sore throat in the immediate recovery in Group N can be explained by excessive pressure in the cuff of the endotracheal tube, which is mainly generated by the diffusion of nitrous oxide leading to mucosal hypoperfusion.

CONCLUSION

From our study we can conclude that nitrous oxide causes significant increase in endotracheal tube cuff pressure compared to air when used as anesthetic gas in laparoscopic surgery. The regular monitoring of endotracheal tube cuff pressure should be a part of regular safe practice of anesthesia and we recommend use of manometer to measure ETT cuff pressure and maintain between it between 20-30 cm of H2O in all patients as a 'Standard of Care'. Limitations:

- 1. The sample size was small.
- 2. Nitrous oxide and static table position could have been a control.
- 3. Our findings are only for abdominal laparoscopic surgery and further studies will be needed for other types of laparoscopic procedures.

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