International Journal of Science and Research (IJSR)
ISSN (Online): 2319-7064
Index Copernicus Value (2015): 78.96 | Impact Factor (2015): 6.391

A Comparative Study of ProSeal Laryngeal Mask Airway Cuff Pressure Changes with and without use of Nitrous oxide in Laparoscopic Surgeries

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Abstract: ***ProSeal Laryngeal mask airway is increasingly being used as an airway device for laparoscopic surgery. Nitrous oxide can diffuse into the cuff of airway devices and may further increase the intracuff pressure. The present study was designed to investigate the intracufff pressure changes during anesthesia with and without use of nitrous oxide in patients undergoing laparoscopic surgery and also note post-operative complications like sore throat, dysphagia and dyshphon. 33 patients of ASA Grade 1 and 2 were randomized and allocated to group A (receiving mixture of nitrous oxide and oxygen) and Group B(receiving oxygen). Following insertion of Proseal LMA, the cuff was inflated to an intracuff pressure of 45 mm Hg. The cuff pressure measured every 5 mins and also assessment of post-operative complications. The maximum intracuff pressure recorded in group A was 113 cm of H_20, which was 87% higher than the baseline and in group B was 71.4 cm H_20, which was 19 % percent higher than the baseline. The percentage rise in cuff pressure every 5 mins was also significant in Group A, being maximum at 20 mins. The incidence of complications in both the groups was statistically insignificant.***

Keywords: ProSeal LMA, Nitrous oxide, Cuff Pressure, Laparoscopic

1. Introduction

Intubation has been practiced following its description by Rowbatham and Magill in 1921. Several cuffed supraglottic airway devices have been introduced into clinical practice since the introduction of classic laryngeal mask airway.The laryngeal mask airway (LMA) was invented by Archie Brain in 1981 and the advantages of LMA over the endotracheal intubation include the absence of the need of muscle relaxants and a decreased risk of post-operative sore throat. A potential risk of LMA is an incomplete mask seal which causes gastric insufflation or oropharyngeal air leakage. The use of a new variant of LMA, "LMA–Proseal" (PLMA), which incorporates a second tube which is lateral to the airway tube, was intended to separate the alimentary and the respiratory tracts. Recent survey has shown the use of a supraglottic airway as a primary airway management device for general anesthesia is as high as 56.2%[1]

The ProSeal laryngeal mask airway(PLMA)is a directional perilaryngeal sealer.[2-4] Its cuff forms an oro-pharyngeal seal(≥30 mm Hg) without increasing directly measured mucosal pressure.[3,5] Excessive intracuff pressure can result in malposition, suboptimal seal and pharyngo-laryngeal morbidity, including sore throat, dysphagia and nerve injury[2]

Nitrous oxide, carbon dioxide and other gases can diffuse into the cuff of airway devices and may further increase the intracuff pressure. The Proseal laryngeal mask airway is increasingly being used as an airway device for laparoscopic surgery. There are several reports of the use of PLMA in laparoscopic surgery [6-9] but there is lack of data on the intracuff measurements of PLMA in laproscopic surgery. The present study was designed to investigate the intracuff pressure changes during anesthesia with and without use of nitrous oxide in patients undergoing laparoscopic surgery.

2. Materials and Methods

The study was done in 66 patients over duration of 5 months from May 2015 to September 2015 in patients undergoing laparoscopic surgery under general anesthesia in S.M.S. Medical College and Group of Attached Hospitals, Jaipur. With due permission from the institutional ethical committee and review board, written informed patient consent was obtained.

Sixty-six ASA grade 1 and 2 patients, of 20- 60 years with BMI <35, who underwent laproscopic surgery under general anestheisa, with anticipated duration of 30-120 mins were included in the study.

Exclusion criteria included Patients with ASA grade III, IV and V, Obesity(BMI < 35), Patients with anticipated difficult intubationeg. Oropharyngeal pathology, limited mouth opening (inter-incisor gap <20 mm), Patients at risk of aspiration (full stomach, previous Upper GI surgery, hiatus hernia), Patients with reactive airway diseases and history of cardiac diseases andPatients having known allergy to anaestheticagents .

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On arrival in the operation theatre, fasting status, consent and PAC was checked.Randomisation by chit in box was done by another anesthesiologist and patient allocation to respective groups was done. Routine non-invasive monitors attached and baseline parameters i.e. Heart rate (HR), Systolic blood pressure (SBP), Diastolic blood pressure (DBP), Mean arterial pressure (MAP), SpO2 & ECG was noted.

Patients were monitored throughout the period of anesthesia with electrocardiogram(ECG), Automated non-invasive blood pressure, pulse oximeter and capnography

Patients were premedicated with Inj. Ranitidine 50mg, Inj. Metoclopramide 10 mg, Inj. Glycopyrrolate 0.2mg, Inj Midazolam 1mg,Inj.Fentanyl citrate 1.5mcg/kg administered over 30 seconds. Pre-oxygenation was done with 100% oxygen for 3 minutes. Patients were induced with Inj. Propofol 2mg/kg iv. Neuromuscular blockade achieved by Inj. Atracurium 0.5 mg/kg given intravenously.

Pre-use checkup and size selection of PLMA was done as recommended by the manufacturer.[10] One anesthesiologist (out of the two anesthesiologists in the study) well versed with PLMA use, inserted and fixed the device. A hand-held cuff manometer was connected to the pilot balloon of the PLMA via a three-way stopcock. Cuff was inflated with air to an intracuff pressure of 45 mm Hg(60 cm H_2O)$^{.}$ PLMA was connected to the gas delivery circuit of the anesthesia machine. Proper placement was confirmed by Capnography, bilateral chest wall movements and absence of leakage from the drain tube with the peak airway pressure <20 cm H_2O.Position of the PLMA was evaluated by a flexible fiberoptic scope introduced into the airway tube forviewing the laryngeal structures and fiberoptic view was graded on the following scoring system;

Grade 1 – vocal cords not seen
Grade 2 – vocal cords plus anterior epiglottis
Grade 3 – vocal cords plus posterior epiglottis
Grade 4 – vocal cords only

Patients were mechanically ventilated with a tidal volume of 8 ml/kg (volume control mode) with I:E ratio of 1:2. Respiratory rate was adjusted to maintain $EtCO_2$ between 35-45 mm Hg.Then surgery was allowed to commence &anaesthesia was maintained with 0.4% V/V Isoflurane in oxygen or oxygen/nitrous oxide (FiO_2 = 0.3). Maintainence doses of Inj. Atracurium 0.1 mg/kg IV for neuromuscular blockade was given as and when required.

The intra-cuff pressure and peak airway pressure (P_{aw}) was measured at 5 mins intervals for the entire course of anaesthesia. Inj. Ondansetron 2mg IV was given as an antiemetic after end point of study. At the end of the surgery, patient was reversed with inj. Glycopyrrolate 0.5mg + Inj. Neostigmine 2.5mg I.V.Post-operatively, the patients were assessed by an independent blind observer for sore throat, dysphagia and dysphonia. If surgery lasted for more than two hours, PLMA cuff pressure was adjusted to 45 mm Hg, but data collection was terminated at that point.

NOTE: While placing ProSeal LMA, maximum of 3 attempts were allowed. If insertion failed after 3 attempts, the airway was secured by a tracheal tube.

Posterior folding of mask was ruled out by passing a gastric tube through the drain tube and its correct position was confirmed by aspiration of gastric contents or by auscultating the epigastrium while injecting air.Data was recorded intraoperatively using standardized data collection sheet and analysis was carried out using SPSS(Statistical Package for Social Studies) for Window version 20.0.

3. Results

Complete data obtained from all the patients. Both groups were comparable with respect to Age (years), Sex, Weight (Kg), ASA grade, Duration of surgery, Number of attempts for PLMA placement and Fiberoptic grading.

Table 1: Demographic characteristics

Variables	Group A	Group B	P value
Age (Yrs)	38.3±14.3	34.5 ± 11.3	0.2373
Sex(M:F)	24:9	24:9	0.609
Weight (Kg)	56.5 ± 10	56.2 ± 9.6	0.8711
ASA grade -I	30	33	0.76
ASA grade -II	3	0	
Duration of surgery (mins)	64.94 ± 4.14	67.7 ± 4.72	0.0143
No of Attempts (1/2/3)	31/2/0	32/1/0	0.555
Fiberoptic Grading (4/3/2/1)	24/9/0/0	21/11/1/0	0.637

Table 2: Intra Cuff Pressure Changes of PLMA

Time (in mins)	Group A	Group B	% rise from baseline in Group A (Mean)	% rise from baseline in Group B (Mean)	P value for rise in intracuff pressure
0	60	60			
5	64.2 ± 2.3	60.7 ± 0.7	7.1	1.1	<0.001
10	69.2 ± 3.2	61.5 ±1.3	15.3	2.4	<0.001
15	74.1 ± 3.9	62.2 ± 1.7	23.5	3.6	<0.001
20	78.1 ± 5.1	62.9 ± 2.1	30.2	4.8	<0.001
25	83.6 ± 6.5	63.8 ± 2.5	39.3	6.3	<0.001
30	87.9 ±7.6	64.8 ±2.9	46.6	8.0	<0.001
35	92.6 ±8.4	65.4 ±2.7	54.3	8.9	<0.001
40	96.5 ±9.5	66.5 ± 3.4	60.8	10.8	<0.001
45	98.9 ±9.0	68.1 ± 3.7	64.8	13.4	<0.001
50	102.1 ± 9.4	68.8 ± 4.0	70.1	14.6	<0.001
55	104.7 ± 7.9	69.1 ± 3.7	74.5	15.1	<0.001
60	107.5 ± 7.7	69.3 ± 3.5	79.2	15.6	<0.001
65	112.2 ± 16.1	70.1 ± 3.5			<0.001
70	109.0 ± 2.5	71.4 ± 3.5			<0.001

In Group A, there was consistent and progressive rise in the intracuff pressure, with the maximum of 112.2 cm of H20, which was 87% higher than the baseline and remained highly statistically significant throughout. In Group B also, there was a consistent rise in intracuff pressure over time with the maximum of 71.4 cm H20, which was 19 % percent higher than the baseline. However, the rise in intracuff pressure seen was much less as compared to Group A and hence, the difference in rise of intracuff pressure between both the groups remained highly significant throughout the anesthesia

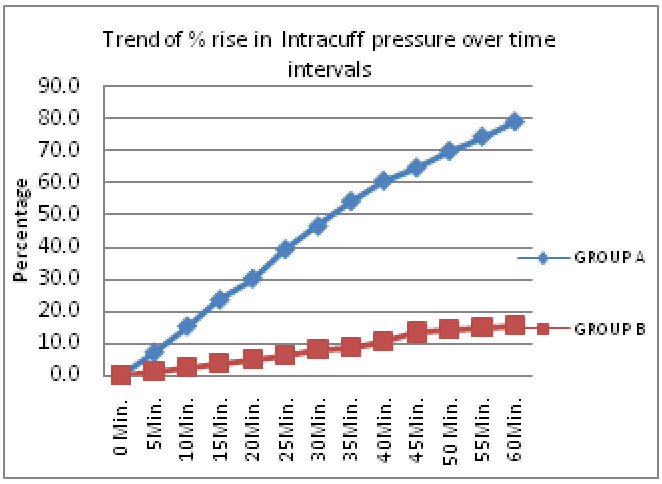

Figure 1: The Trend of Increase in Intracuff Pressure From Baseline

Due to difference in duration of anesthesia in different procedures, there were inadequate number of data to obtain P value beyond 60 mins. Hence, the P value of trend of intracuff pressure was obtained till 60 mins. The percentage rise in cuff pressure from baseline every 5 mins was highly significant in Group A($P<0.001$), with the highest (9 %) rise in between 20-25 mins, decreasing eventually. In Group B, the highest rise (6.4%) was seen in between 35-40 mins and was statistically significant. However, the difference in percentage rise of intracuff pressure between both the groups was also highly significant ($P<0.001$).

Postoperative Complication

Complications	Group A		Group B		
	No	%	No	%	
Sore throat	9	27.3	1	3.0	0.0060
Hoarseness of voice	3	9.1	0	0.0	0.1192
Dyshpagia	0	0.0	0	0.0	

In the post-anesthesia period, nine patients (27.3%) in group A as compared to one patient (3%) in group B had complained of sore throat. Hoarseness of voice was reported in three patients(9.1%) in Group A and none in Group B and no incidences of dysphagia in either group.

4. Discussion

In our study, we found significant rise in intracuff pressure in Group A over time when nitrous oxide was used during anesthesia as compared to rise in intracuff pressure in Group B where nitrous oxide was not used. The difference in rise in intra cuff pressure between both the groups was also highly significant ($P<0.001$). The maximum rise of 9.1 % at 20 to 25 min interval can be attributed to the increased pressure gradient of Nitrous oxide at initial low intracuff volume. This rise declined eventually as the pressure gradient of Nitrous oxide across the cuff of PLMA decreased with further diffusion of nitrous oxide into the PLMA cuff. Our results are comparable with results of **Bimla et al 2013**[11] wherein they measured intracuff pressure in 100 patients undergoing laproscopic surgery and found significant rise in intracuff pressure in Nitrous oxide group reaching 103 mm Hg, i.e. an increase of 129% from baseline at the end of the 120 min study period but the air and oxygen mixture group remained stable. Similar results were obtained in a study conducted by **Chen BZ Et al 2011**[12] with 50% N_2O in oxygen and sevoflurane in one group and50% air in oxygen and sevoflurane in the other group and concluded that PLMA intracuff pressure increased significantly during 50% N_2O anesthesia.**Lumb AB Et al 1992**[13] studied the effect of nitrous oxide on the cuff pressure of a laryngeal mask both in vitro and in vivo and found that nitrous oxide and carbon dioxide diffuse across the cuff wall much more rapidly than nitrogen and oxygen. Differing partial pressures of these gases across the cuff wall give rise to changes in volume and pressure within the cuff. Above mentioned studies validated the findings in our study. The rise in intracuff pressure in group A can be attributed to the diffusion of nitrous oxide which is more diffusible than carbon dioxide.

The significant rise in intracuff pressure in the Group B was attributed to the carboperitoneum created during laporoscopy. Carbondioxide used during the laporoscopic procedures gets absorbed into the blood to increase the PaCo2 as well as the end tidal carbondioxide and may diffuse into the cuff to increase intracuff pressure. This inference was supported by study of **J.Mues Et al 2005**[14] wherein they measured the CO_2 content of the gas in the cuff of 38 different sized LMA at the start of the anesthesia and immediately after removal from patients by using carbon dioxide analyser to obtain a value for the concentration of CO_2. The CO_2 in the cuff increased over time towards the end-tidal CO_2 value and the uptake of CO_2 remained unaffected by the type of breathing mixture (AIR:O_2/N_2O:02/PURE AIR). **Lu et al 2002**[15]recorded peak airway pressures in cLMA and PLMA immediately before and after carbo-peritoneum to 2.0 kPa. There was a significant increase in peak airway pressure after carboperitoneum for both devices ($P<0.001$). However, we did not find many studies directly correlating carboperitoneum with Proseal LMA cuff pressure and we believe remains an area of exploration to establish the above hypothesis.

Airway devices have cuffs which are permeable to a variety of gases depending on their partial pressure, and solubility. Nitrous oxide and other gases diffuse into air filled cuffs of tracheal tubes and supraglottic devices, increasing their volume and pressure.[16,17,18] The addition of plasticizers to the polyvinyl chloride cuff material of the tracheal tubes and disposable LMAs softens it and renders it less permeable to nitrous oxide.[19,20] The reusable cLMA and PLMA cuff are made up of silicone. The elastance for the Proseal has been reported to be lower than that of cLMA, probably due to its larger cuff size.

In our study, the incidence of sore throat was more when nitrous oxide was used as compared to when nitrous oxide was not used ($p<0.05$). Similar results were found in the study of **Chen BZ Et al**[12]. The incidence of hoarseness of voice in both the groups was not significant. Dysphagia was not reported in either group.

The rise in the intracuff pressure of the supraglottic devices is known to increase the ischemic damage to the surrounding pharyngolaryngeal mucosa.[21-25]A progressive reduction in the pharyngeal mucosal perfusion has been reported when mucosal pressure increases from 25 to 60 mmHg while using a cuffed oropharyngeal airway.[23] The cuffs of PLMA exert pressure on the pharyngeal mucosa causing a concomitant decrease of pharyngeal perfusion and increase in the incidence of post-operative complications including sore throat, dysphonia, and nerve damage.[23-25].

Since we had limited our study to two hours duration, no conclusion can be drawn regarding the incidence of sore throat being related to the duration of anesthesia. As the device is being increasingly used for procedures longer than two hours, vigilance is required during its use and excessive gas should be regularly removed from the cuff.

The trend of hemodynamic variables i.e. heart rate, systolic blood pressure and diastolic blood pressure remained comparable between both the groups throughout the duration of anesthesia and was statistically insignificant ($P < 0.05$)

5. Future Scope

***Tekin* et al.** [26] recommended inflating the PLMA cuff with nitrous oxide and oxygen mixture to avoid further increase in cuff pressure when nitrous oxide was a part of general anesthesia technique.

Our study had a few limitations. We did not record the end tidal carbondioxide and intra-abdominal pressure caused due to carboperitoneum during the course of anesthesia. We did not record the pharyngeal mucosal pressure or analyze the intracuff gas mixture due to non-availability of the appropriate equipment (microchip sensors or gas analyzer). Since the number of attempts at insertion also has significant relationship with the incidence of postoperative sore throat, the study cannot relate exclusively sore throat with the rise in intracuff pressure.

6. Conclusion

In this study, it was seen that intracuff pressure of Proseal LMA increased much more when the breathing mixture contained nitrous oxide as compared to when nitrous oxide was not used during anaesthesia. Carboperitoneum created during laporoscopy causes escape of carbondioxide into the PLMA cuff which also contributes to increase in PLMA cuff pressure. However, this rise is much less compared to the rise seen with nitrous oxide. There was also slightly higher incidences of postoperative complications like sore throat, dysphonia when nitrous oxide was used during anesthesia. Further studies confined to the single attempt of PLMA insertion would be necessary to evaluate the relationship of sore throat with prolonged duration of nitrous oxide based anesthesia.

Proseal LMA is being increasingly used due to its ease of insertion and relatively stable intraoperative and smooth extubation hemodynamic profile. It is more favored as compared to endotracheal tube for shorter duration procedures. To avoid increase in the PLMA cuff pressure, inflate it with nitrous oxide and oxygen mixture when nitrous oxide is to be used as a part of general anesthesia technique.

As for use in longer surgeries with nitrous oxide, it is advisable to use a cuff pressure monitor during inflation and intraoperatively. And if the cuff pressure increases significantly, this pressure can be released and cuff re-inflated.

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