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Original Article

Evaluation of Cuff Pressure Monitoring in Attenuating Post-Operative Laryngo-Tracheal Complications in Adults Due to Oro-Tracheal Intubation: A Prospective Randomized Controlled trial

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ABSTRACT

Introduction: The most common laryngo-tracheal complaints following General anesthesia with tracheal intubation in the postoperative period are sore throat and hoarseness of voice with an incidence varying from 24% to 90%. The tracheal mucosal damage following excess pressure by endotracheal cuff is one of the most important causative factors. This study was designed to evaluate whether monitoring the cuff pressure of the endotracheal tube intra-operatively can help in attenuating the occurrence of sore throat and hoarseness of voice.
Methodology: 100 patients posted to undergo elective procedures under general anaesthesia with oro-tracheal intubation were recruited by simple random sampling and randomized into Group A and Group B with 50 in each group. General anaesthesia was administered using standard protocol in all the patients. Patients belonging to Group A underwent cuff pressure monitoring and patients belonging to Group B were taken as controls and no such monitoring was done. The Incidence of sore throat and hoarseness of voice were noted in both the groups along with the severity of sore throat.
Results: 100 patients were analyzed for the outcomes without any dropouts. The basic parameters like age, sex, BMI, and duration of surgery were found to be statistically insignificant among the two groups. The incidence of sore throat and its severity along with that of hoarseness of voice were found to be statistically highly significant in Group B when compared to Group A ($p < 0.002^{**}$).
Conclusion: We conclude that intraoperative cuff pressure monitoring not only reduces incidence of sore throat and hoarseness of voice, but also its severity in patients undergoing general anesthesia with oro-tracheal intubation.

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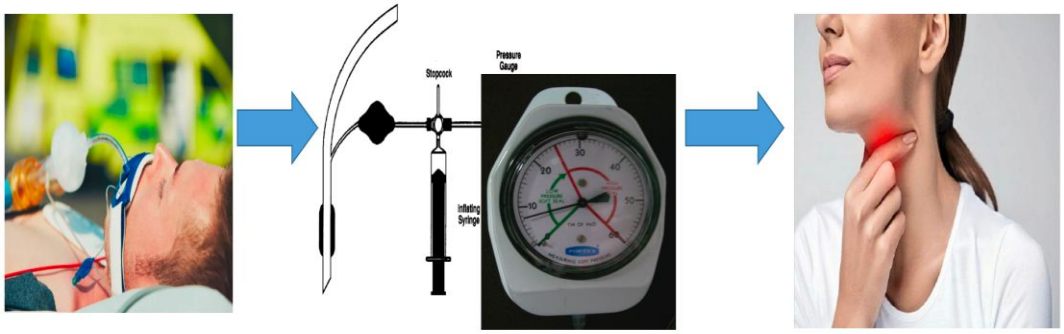
GRAPHICALABSTRACT



General anaesthesia with orotracheal intubation | Intraoperative Cuff pressure monitoring of the endotracheal tube cuff | Incidence of postoperative Sore throat and Hoarseness of voice

Introduction

General anaesthesia with tracheal intubation is the most commonly employed anaesthesia technique in day to day practice. Patients frequently complain of sore throat and hoarseness of voice after endotracheal intubation sometimes even more so than pain [1]. Various studies have documented a wide range of incidence of these complaints from a low of 24% to almost 90% [2].

The cause of these laryngo-tracheal symptoms has been attributed to the pressure effects of the inflated cuff on the tracheal mucosa [1]. Most endotracheal intubations cause damage to the mucosa of the airways even when done by experts [3]. When the endotracheal tube cuff pressure exceeds that of perfusion pressure of the tracheal mucosa (normally between 20-30 mm Hg), there is an occurrence of edema and epithelial injury [4]. This damaged epithelial lining is shed, and then heals within the next 2 to 3 days [3]. The high cuff pressures may occur due to over inflation immediately after intubation or due to the passive diffusion of nitrous oxide into the cuff over the duration of anaesthesia [1].

The endotracheal tube cuff is usually inflated using room air and forms a closed air space. When nitrous oxide is used for maintenance of anaesthesia, it tends to slowly diffuse into the cuff causing an increase in cuff pressure [5]. This gradual increase in pressure forms the primary reason for the tracheal epithelial damage.

The diffusion of nitrous oxide into the cuff can be stopped or minimized in various ways. The recommended method is to use a cuff pressure monitor throughout the intraoperative period thus allowing the cuff pressure to be maintained below the perfusion pressure of the tracheal mucosa and preventing injury [6].

This study was designed to evaluate whether monitoring the cuff pressure of the endotracheal tube intra-operatively can help in attenuating the occurrence of sore throat and hoarseness of voice in patients postoperatively.

Materials and Methods

After obtaining the Institutional Ethical Committee approval, this prospective double blind randomized controlled trial was conducted in 100 patients who underwent surgeries with orotracheal intubation and nitrous oxide for maintenance of anaesthesia in a tertiary care center in Chennai, Tamil Nadu, India between January 2006 to December 2006 for one year.

The inclusion criteria included patients belonging to American society of Anesthesiology (ASA) grades I and II with age group of 25 to 45 years old undergoing procedures under general anaesthesia with orotracheal intubation and oxygen / nitrous oxide mixture with a FiO_2 of 33% for maintenance of anaesthesia.

The exclusion criteria were patients of ASA grading above II, presence of upper respiratory tract infections preoperatively or in the recent past, procedures involving the upper airway, surgeries involving movement of the head intra-operatively after intubation, more than one attempt at intubation, Traumatic intubation, Contraindication to the use of nitrous oxide, delayed extubations, and reintubation due to any cause and use of gastric tubes.

The cuff pressures were measured using a portex cuff pressure gauge, as displayed in Figure 1a and this gauge was equipped with pressure tubing with two ports-one to be connected to the pilot balloon of the endotracheal tube and the other to the cuff inflation syringe as shown in Figure 1b. The Mindray Anaesthesia work station with an oxygen analyzer was used to maintain a FiO_2 of 0.33.

A hundred patients who fit the eligibility criteria were included in this study using simple random sampling. After obtaining an informed consent, they were randomized into two groups using a computer program. Group A whose cuff pressure was monitored and Group B was the control group.

After routine pre-anaesthetic examination, patient was transferred to the theatre. After attaching base line monitors, an adequate intravenous access was secured and appropriate crystalloid fluid started. After preoxygenation for 3 minutes, the patient was induced with 2 micrograms /kilogram of fentanyl, 2 milligram/kilogram of propofol and paralyzed with 0.1 milligrams/kilograms of vecuronium using intravenous route. The patient was intubated with 7.5 mm sized cuffed high volume, low pressure portex endotracheal disposable tubes for females and similar 8.0 mm endotracheal tubes for males under vision. The black line was kept at the level of the cords to avoid the cuff making contact with the vocal cords. The initial cuff inflation was standardized for both the groups using the minimal leak technique [3]. Initially, the stethoscope diaphragm was placed over the laryngeal area and the cuff was inflated till no air leak was audible, and then the patient was connected to the ventilator and 0.5 ml of air was removed in stages from the cuff until a small leak was heard at the peak of inspiration. Fresh gas flow of oxygen and nitrous oxide were started at a FiO_2 of 0.33 with Sevoflurane and was maintained through the intraoperative period for both the groups.

In group A, the cuff pressure was then maintained at 20 mm Hg by checking the cuff pressure every 15 minutes and adjusting the cuff volume through the side port of the pressure gauge. In group B, besides following initial cuff inflation and maintenance fresh gas flow by the standardized protocol no further cuff pressure monitoring was done intra-operatively.

At the end of the procedure, patients were extubated following adequate reversal of neuromuscular blockade using Neostigmine (0.05 mg/kg) and Glycopyrolate (0.01 mg/kg). Adequate care was taken before extubations to avoid coughing on the tube. The duration of nitrous oxide use from initiation to cessation was noted for both the groups. The patients were interviewed 24 hours after the procedure by an anesthesiologist who was unaware of which group the patient belonged to. In patients who complained of a sore throat, its severity was graded as per the visual analogue scale (VAS) as shown in Figure 2. Hoarseness was evidenced by a change in the voice pitch. This was also recorded separately.

The unbiased anesthesiologist who evaluated the patient postoperatively and the statistician who analyzed the data were unaware of the patients group, ensuring double blinding.

Age, sex, and duration of surgery were analyzed using the T-TEST and expressed as mean and standard deviation. A p-value less than 0.05 were considered significant. The occurrence of sore throat and hoarseness of voice in both the groups was compared using the chi-square test. The relationship between the duration of surgery and the incidence and severity of sore throat and also hoarseness of voice was also compared using the chi-square test.

Results and Discussion

100 patients with 50 patients in each group were enrolled and analyzed for the results.

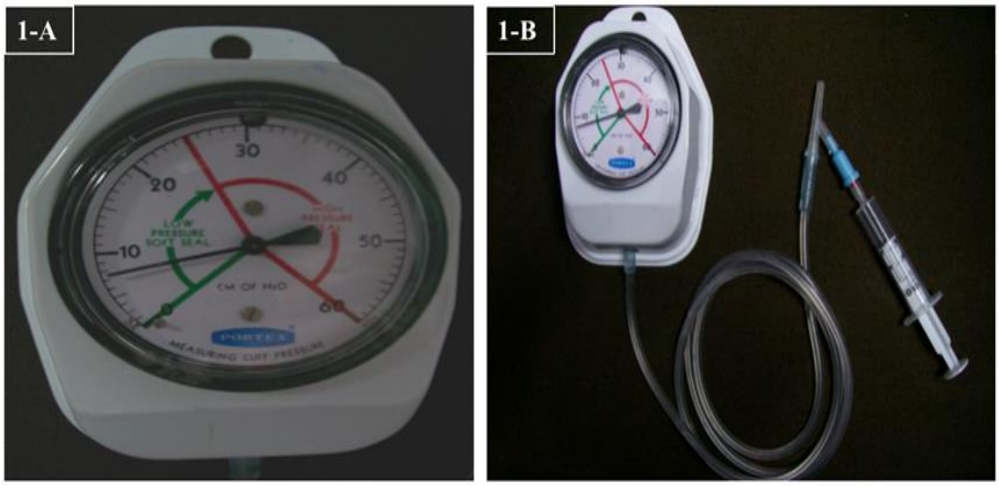


Figure 1: (a) Cuff pressure monitor gauge and (b) Cuff pressure monitor gauge equipped with connecting tubing and two ports

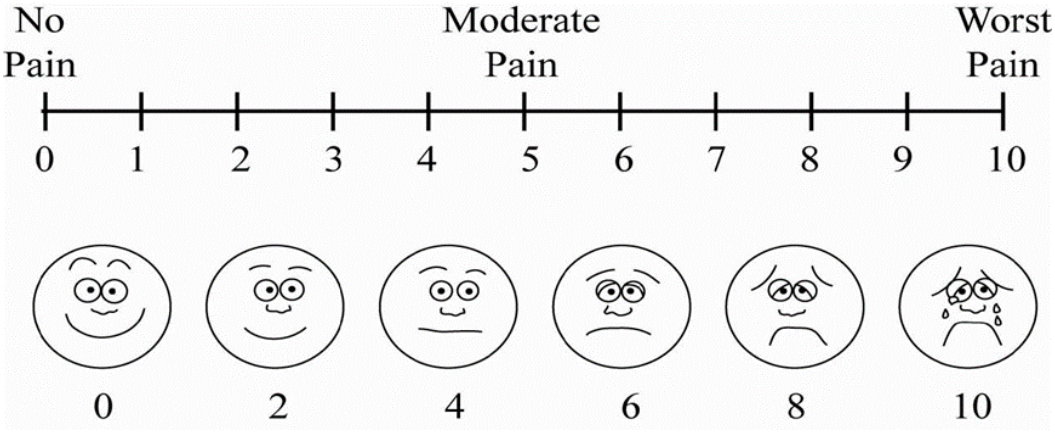


Figure 2: VAS score for assessment of severity of sore throat

There was no loss of follow up in any of the patients. The demographic parameters were comparable among the two groups. The surgeries included were laparoscopic surgeries, laparotomies, reconstructive surgeries of limbs belonging to departments of gynecology, surgical oncology, and plastic surgeries. Group A was the study group and Group B was the control group (Table 1).

In our study, the incidence of sore throat and hoarseness of voice were found to be statistically significantly higher in Group B when both groups were compared, as shown in Table 2 ($p<0.002^{**}$). The severity of sore throat was also found to be statistically significantly higher in Group B when both groups were compared, as listed in Table 3 ($p=0.001^{**}$).

Analysis showed that Hoarseness of voice occurred with greater frequency in patients with higher sore throat VAS scores showing a co-relation between severity of sore throat and hoarseness of voice, as listed in Table 4.

A positive correlation was found between higher sore throat VAS score and longer duration of surgery. It was found that longer exposure to nitrous oxide there was an increase in severity of sore throat, as provided in Table 5.

Oro-tracheal intubation is associated with numerous complications, the commonest ones being sore throat and hoarseness of voice. Studies done by Christenson *et al.* had postulated various causative factors for this. Some of those implicated variables were anaesthetic drugs like suxamethonium, longer and numerous attempts in intubation, use of nasogastric tubes, female gender, and those surgeries involving movement of the head and neck intraoperatively [7].

Table 1: Demographic parameters among the groups

Serial No.	Demographic parameters	Group A (n=50)	Group B (n=50)	P- Value
1	Age (years)	33.8 ± 8.1	33.6 ± 7.7	0.89
2	Sex (M/F)	25(50%) / 25(50%)	20 (40%) / 30(60%)	0.42
3	ASA I / II	36(72%) / 14(28%)	40(80%) / 10(20%)	0.56
4	BMI (kg per square meter)	28.2 ± 1.8	27.4 ± 2.2	0.77
5	Duration of surgery (minutes)	109.5 ± 37.2	114.7 ± 47.1	0.54

Table 2: Incidence of sore throat and hoarseness of voice in the groups

Serial No.	Parameters	Group A (n=50)	Group B (n=50)	P-value
1	Incidence of Sore Throat (%)	23/50 (46%)	34/50 (68%)	0.002**
2	Incidence of Hoarseness of Voice (%)	10/50 (20%)	27/50 (54%)	0.000**

Table 3: Severity of sore throat in the two groups

Serial No.	VAS score for Severity of Sore throat	Group A (n=50)	Group B (n=50)	P-value
1	VAS ≥ 5	5/50 (10%)	20/50 (40%)	0.001**
2	VAS < 5	45/50 (90%)	30/50 (60%)	

Table 4: Association of severity of sore throat and incidence of hoarseness of voice among the two groups

Serial No.	Severity of Sore throat	Patients with Hoarseness of voice		Patients without Hoarseness of voice	
		Group A	Group B	Group A	Group B
1	Mean VAS Score	3.61	5.9	1.1	2

Table 5: Association between severity of sore throat and duration of exposure to nitrous oxide

Serial No.	Duration of Surgery (Minutes)	Group A		Group B	
		Incidence	Mean VAS	Incidence	Mean VAS
1	60 to 120	31.5 %	1.02	56.2 %	3.3
2	121 to 180	88.8 %	3.6	85.7 %	5
3	181 to 240	100 %	6.3	100 %	7

As these may be considered as confounding variables, this study specifically excluded most of these factors so that a direct causal relationship may be established between cuff pressure and post tracheal intubation sore throat and hoarseness of voice.

Bernard *et al.* postulated there were two ways in which the cuff pressure may increase [8]. During the initial inflation of the cuff, the anaesthesiologist usually relied on tactile feel of the tenseness of the pilot balloon to ensure adequate cuff pressures. As this is subjective and not quantified, this method had serious limitations. Thus, to standardize both the groups to a common starting point, it was decided to use the minimal leak technique to initially inflate the cuff. Secondly, the slow diffusion of nitrous oxide into the cuff can also significantly contribute to the increase in cuff pressures over the entire duration of exposure to nitrous oxide. Perbe *et al.* postulated that the cuff pressure needs to be monitored regularly throughout the intraoperative period to prevent this and to keep the cuff pressure below the tracheal mucosal perfusion pressure [6]. Seegobin *et al.* studied the effect of cuff pressure on the tracheal mucosal perfusion [2]. They postulated that the tracheal mucosal perfusion stops at 30 mm Hg causing ischemic damage. They recommended that to avoid mucosal damage, the cuff pressure needs to be kept below 20 mm Hg [2]. We decided to follow their recommendation this in our study. Thus, by eliminating the confounding variables and standardizing the study methodology, our

study aims to prove a direct causal relationship between cuff pressures and post endotracheal intubation sore throat and hoarseness of voice.

In our study the incidence of sore throat was 46% in the study group and 68% in the control group which was statistically significant showing that cuff pressure monitoring can reduce the incidence of sore throat. The incidence was found to be in the higher limit of the range mentioned in literature by Ayoub *et al.* who cited an incidence of 21% to 65% [9]. We attribute this to be probably due to the difference in the height to weight ratios between the Indian and the western population with the Indian population being comparatively smaller. The use of smaller size tubes than those routinely used probably would have been more appropriate in our setting.

We tried to quantify the severity of sore throat using a simple bed side Visual Analog Scale as a measure of patient's symptoms as these complaints can have a huge impact on patient satisfaction. Quantification of tracheal mucosal injury by bronchoscopic evaluation as done by TU *et al.* found that tracheal injury correlated to cuff pressures [10].

In our study, analysis of the VAS scores in the study and control groups revealed a distinctly lower severity of sore throat in the study group. Hence, monitoring of cuff pressure decreases both the occurrence of sore throat and its severity, as presented in Tables 1 and 2.

Seegobin *et al.* [2] and Christenson *et al.* [7] found no correlation between the duration of nitrous oxide use and the occurrence of sore throat. Unlike this, we found that the occurrence of sore throat increases with an increase in duration of surgery with an apparent ceiling effect being reached by 120 minutes, as shown in Table 5. Cuff pressure monitoring was found to decrease the occurrence of sore throat only when the duration of surgery was between 1 to 2 hours. Surgeries lasting for less than 1 hours and more than 2 hours did not show any change in occurrence of sore throat between the two groups. Seegobin *et al.* postulated that the prolonged contact of the tracheal mucosa with the cuff increased the occurrence of sore throat in surgeries lasting for more than 4 hours [2].

On analysis a positive correlation between hoarseness of voice and the severity of sore throat was found. Patients with hoarseness of voice had higher sore throat VAS scores (1.17 vs. 3.61 in the study group and 2.03 vs. 5.94 in control group), as indicated in Table 4. The occurrence of hoarseness of voice in the study group was 20% and in the control group was 54% with a highly significant p-value of 0.00. This showed that the monitoring of cuff pressure can have a larger impact on reducing the occurrence of hoarseness of voice than sore throat which only had a p-value of 0.03. This suggests that monitoring cuff pressure will decrease the intensity of sore throat even in patients who develops one.

Our study was not devoid of limitations. Firstly, our study is single centric study with smaller sample size done in Asian population. Hence, multicentric study done in patients belonging to different ethnicity and with bigger sample size should be done in future. Secondly, we did not standardize the anesthesiologists who performed the laryngoscopy and intubation. Hence, studies involving anesthesiologists of varying experience should be performed in future.

Conclusion

We conclude that monitoring of cuff pressure using a cuff pressure monitor significantly reduced the incidence as well as the severity of sore throat and incidence of hoarseness of voice in patients undergoing orotracheal intubation.

Conflict of Interest

No potential conflict of interest was reported by the authors.

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Authors' Contributions

All authors contributed to data analysis, drafting, and revising of the paper and agreed to be responsible for all the aspects of this work.

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