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Effect of inhaled budesonide with a metered dose inhaler on post operative sore throat, voice hoarsness and cough in abdominal surgeries under general anesthesia: A randomized double blind controlled interventional study

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ABSTRACT:

The purpose of this study was to determine whether inhaling budesonide via a metered dose inhaler (MDI) reduced the incidence and intensity of POST (post operative sore throat), hoarseness, and cough in patients undergoing endotracheal intubation during abdominal surgery at 2 and 24 hours after extubation.

Methods: Patients were split into two groups of 30 each—one receiving budesonide inhaler and the other receiving an empty inhaler—in this randomized, double-blind, interventional research.

Results: The incidence of post-operative sore throat was substantially higher in Group B than in Group A at 2 and 24 hours (25 vs. 8) and (19 vs. 0), respectively (p value=0.001). At 2 hours, group B had significantly more cases of coughing (20 vs 11) and hoarseness of voice (19 vs 7), compared to group A. At 24 hours, there was, however, no discernible difference.

Conclusion: Prior to intubation, budesonide can be inhaled using a metered dose inhaler to lessen the frequency and intensity of postoperative cough, sore throat, and hoarseness.

Keywords: budesonide, metered dose inhaler, postoperative sore throat.

Introduction:

Postoperative sore throat (POST), cough, and hoarseness are the most common complaints in post-intubation patients. The prevalence of POST is 21-71.8%. It mainly occurs due to damage to the larynx and respiratory mucosa. This causes increased patient morbidity and a distressing memory of surgery in patients following discharge.[1-3]

Effective prevention and treatment of POST are recommended to improve the quality of post anesthesia care. Various methods and drugs have been tried with varying degrees of success to prevent or minimize laryngeal pathology after anesthesia.4-6

Inhaled corticosteroids (ICS) are often used in patients with breathing problems because they can be delivered directly into the airways without entering the circulatory system. Budesonide is a steroid with high glucocorticoid activity and low mineralocorticoid activity. It is used in many diseases, such as obstructive pulmonary disease and asthma.

Using a metered-dose inhaler is easier, faster, and better tolerated by patients.7-9

Given this information and its role in the treatment of respiratory disease, this study aimed to evaluate the effectiveness of inhaled budesonide (200 mcg) in preventing or reducing laryngeal pathology after intubation.

We compared the differences between the 2 groups in the proportion of patients with POST, hoarseness and cough at 2 and 24 h after extubation and determined the different correlations between groups for sore throat, hoarseness and cough. cough. The null hypothesis was that there was no significant difference between budesonide and empty inhalers in preventing sore throat after intubation.

Materials and methods:

After approval from the organization's ethics committee and approval from CTRI (CTRI/2021/04/032779), this study was conducted. All patient participants were informed of the procedure and enrolled in the study after written informed consent was obtained.
This randomized, double-blind intervention study with a calculated sample size of 30 patients in each group with a power of 80% and a 95% confidence interval was planned to detect an expected difference of 57% in the proportion of cases.

In the study group, budesonide (200 mcg) was administered 10 minutes before induction of anaesthesia with a metered-dose inhaler and with an empty (no-drug) inhaler in the control group.

The anaesthesiologist administering the inhalation is different from the person administering the anaesthesia and collecting the data.

Patients aged 20-60 years with BMI <30 kg / m2, undergoing abdominal surgery under general anaesthesia and requiring tracheal intubation, regardless of gender, were included in this study.

Patients with ASA physical status III or higher, refusing to include in the study or with pre-operative symptoms of the hyper-reactive airway (sore throat, cough) or recent respiratory tract infection, currently taking steroids (Systemic or inhaled), patients required more than two intubation attempts or suspected difficult tracheal intubation or any contraindication to corticosteroids were excluded from this study.

Patients were randomized into 2 groups of 30 patients each by the opaque sealed envelope procedure. Group-A [Budesonide Inhaler Group] - Patients were asked to inhale one 200mcg budesonide inhaler and hold their breath for 15 seconds. Group B [Empty Inhaler Group] - Ask the patient to inhale and hold the inhaler for 15 seconds. Ten minutes after inhalation, patients in both groups were anesthetized using the same anesthesia technique.

Routine monitoring, including electrocardiogram (ECG), non-invasive blood pressure (NIBP), pulse oximetry (SPO2), temperature and end-tidal carbon dioxide was started.

Ranitidine 1 mg/kg, metoclopramide 0.1 mg/kg, glycopyrrolate 0.004 mg/kg, midazolam 0.02 mg/kg and fentanyl 2 mcg/kg were administered intravenously as a pre-anesthetic.

The patient was then pre-oxygenated with 100% oxygen for 3 minutes and anesthetized with sodium thiopentone 5 mg/kg (slow intravenous route). The trachea was intubated by direct laryngoscopy after full neuromuscular blockade with Atracurium 0.5 mg/kg and 3 min of IPV. We used a common PVC endotracheal tube containing a high volume and low pressure cuff. Laryngoscopy was performed by the same anesthesiologist in both groups. Inflate the cuff enough to seal any leak. Uniform cuff pressure was maintained at 20-25 cm H2O in all patients.

During the above procedure, we recorded time of intubation, number of intubation attempts, Cormack-Lehane grading of larynx, extra laryngeal pressure (needed or not), bucking or coughing and any injury during intubation.

Anesthesia was maintained with O2: N2O (40: 60) and atracurium 0.1 mg/kg and sevoflurane (1-2% end-tidal concentration). We monitored and recorded all vital signs (HR, SBP, DBP, MAP and SpO2) during the perioperative period.

After neuromuscular reversal with injection of neostigmine and glycopyrrolate, extubation was performed after proper suctioning of secretion from the oropharynx directly under the vision. During extubation, bucking or coughing, secretion or blood in the tube, and the entire intubation time were recorded.

Upon arrival at the post-anesthesia care unit, patients were enquired at 2 hours and 24 hours by a blinded investigator about sore throat, cough or hoarseness of voice.

All the collected data were entered in an excel sheet and calculate the mean and standard deviation. Percentage differences were analyzed with the chi-squared test. Mean differences were analyzed using Student's t-test. A value of $p < 0.05$ was considered significant.

Result:

Patient demographics, ASA classification and operative time were not statistically significant between the two groups and were comparable. Intubation time, number of intubation attempts, CL rating, and mean cuff pressure were also comparable between the two groups (Table 1). At 2 h after extubation, the incidence of sore throat was lower in group A (p value 8 vs 25 = 0.001; significant) and the same rate also occurred after 24 h (p value 0 0). compared to 19 = 0.001; significant). Patients with pharyngitis also had mild pain in group A. After 2 hours, stage 0 pain was found in 73.0% of group A and 7% in group B. By 24 hours, stage 0 pain was present in all patients. in the group. A, while only 36.7% of group B were able to reach stage 0 at this stage.

After 2 hours, the rates of hoarseness (group A vs B; 7 vs 19, significant p=0.004) and cough (11 vs 20, p=0.039 significant) in group B were higher than that of group B. group A, but the difference was not significant after 24 h (hoarseness Group A vs B; 0 vs 3 p=0.23; Cough Group A vs B; 1 vs 5 p=0.67) (Table 2). After 2 hours, grade 0 hoarseness was found in 76.7% in group A and 36.7% in group B. After 24 hours, all patients in group A were at grade 0, compared with 90.0 % in group B.

After 2 hours, grade 0 cough appeared in 63.3% of patients in group A and 33.33% in group B. The rate of cough decreased gradually over time. After 24 hours, grade 0 was observed in 96.6% of group A patients compared with 83.33% in group B.

Table1. Comparison of demographical and clinical parameters

S.N.	VARIABLES		GROUP A (N=30)	GROUP B (N=30)	p-value
1	AGE (in yrs) Mean±SD		36.70±13.19	35.97±13.77	0.69 NS
2	GENDER	a) MALE	19	11	0.07NS
		b) FEMALE	11	19	
3	ASA	a) 1	18	14	0.43NS

		b) 2	12	16	
4	Mean surgery Duration (in minutes) mean±SD		35.73±11.29	38.37±8.66	0.31NS
5	Mean cuff pressure (cm H2O) mean±S.D.		22.23±1.81	23.04±1.14	0.053NS

Table 2. Comparison of Postoperative Sore Throat,Hoarsness and Cough

S.No.	Variables	Time	Result	Group A (N=30)	Group B (N=30)	p-value
1	Post operative sore throat	2hr	YES	8	25	0.001
			NO	22	05	
		24hr	YES	0	19	0.001
			NO	30	11	
2	Hoarseness of voice	2hr	YES	07	19	0.004
			NO	23	11	
		24hr	YES	00	03	0.236
			NO	30	27	
3	Post operative cough	2hr	YES	11	20	0.039
			NO	19	10	
		24hr	YES	01	05	0.67
			NO	29	25	

Figure 1: Distribution according to grade of Post operative Sore Throat

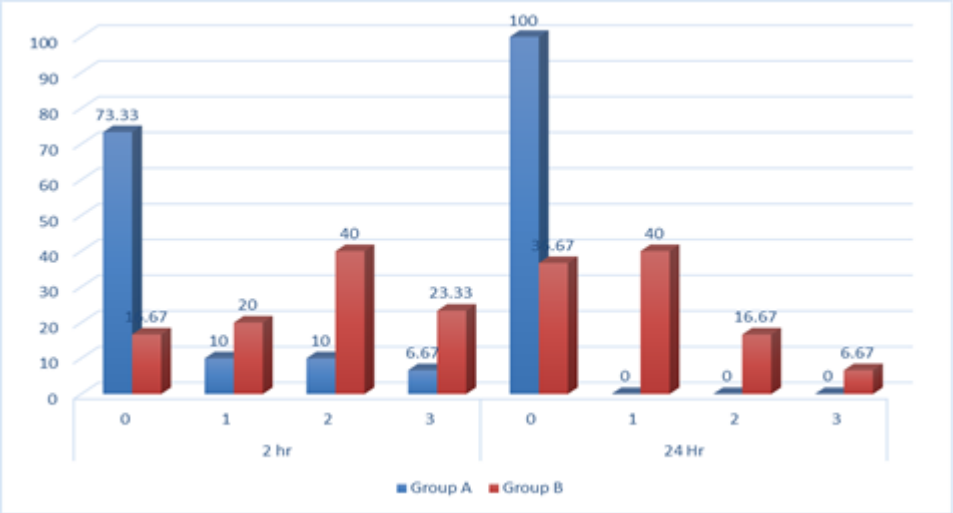


Figure 2. Distribution according to grade of Voice hoarsness

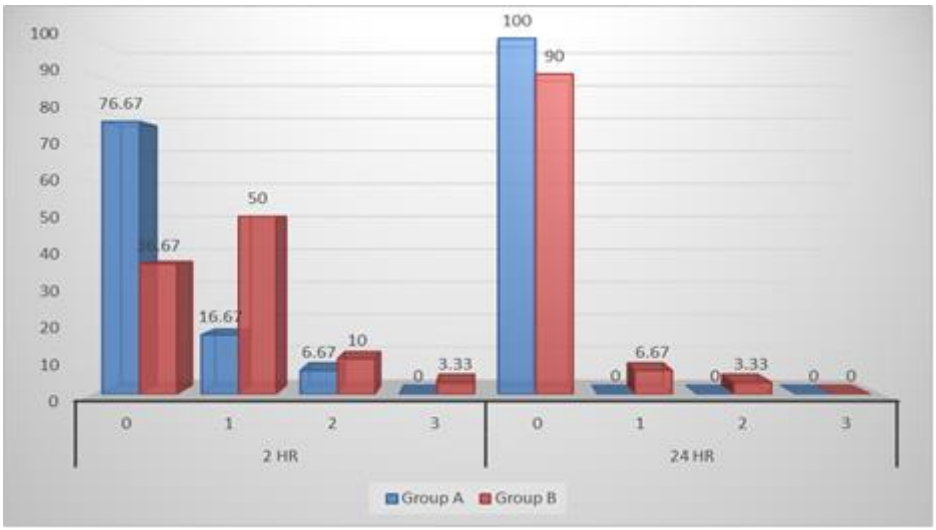
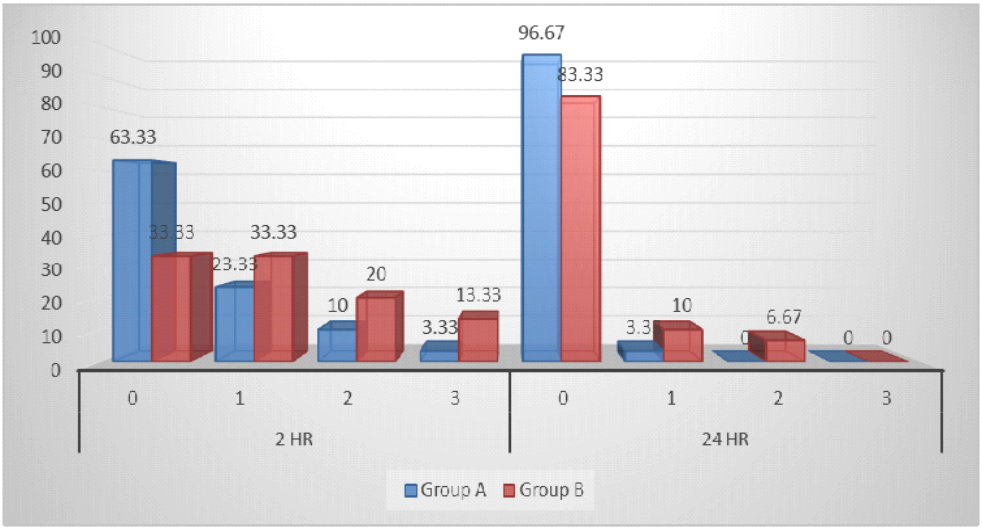


Figure 3: Distribution according to grade of Post operative Cough



DISCUSSION:

POST is one of the most common subjective complaints by post-surgical patients after recovery from general anesthesia with endotracheal intubation. It causes patient dissatisfaction during the postoperative period, unpleasant memory and delay in discharge, which might be because of trauma induced by laryngoscopy, introduction of endotracheal tube and irritation with aseptic inflammation of airway mucosa resulting from the pressure of the endotracheal tube cuff.

The occurrence and severity of POST increase in various situations. A few examples are when the duration of the surgery is too long or patient position during surgery is changed too frequently, when multiple intubation attempts are performed, when an inexperienced person is performing intubation etc.[10,11]

Cough and hoarseness of voice are the most common symptoms often associated with POST. Although prolonged hoarseness is a rare finding, hoarseness is a common complaint following extubation. Frequent assessment of cuff pressure significantly decreases the chances of mucosal damage and thereby hoarseness and postoperative cough.

The causes of cough, hoarseness, and sore throat after laryngoscopy and endotracheal intubation can be caused by local irritation, inflammation, and edema in some parts of the upper and lower airways.

In prior studies, various techniques and preoperative administration of different drugs via multiple routes are effective in reducing POST. As systemic administration of drugs is not devoid of side effects, topical administration of drug at the desired site of action is preferred wherever feasible.[12-14]

Many steroids such as dexamethasone, beclomethasone, hydrocortisone, methylprednisolone etc are used in different doses and routes for their anti-inflammatory actions.

Topical corticosteroids decrease the incidence and severity of sore throat and cough without systemic side effects. Budesonide has potent glucocorticoid and weak mineralocorticoid action. It has shown effective local anti-inflammatory activity. Its usefulness in the prevention of POST has been investigated with favorable results. [15-16]

In our study, we administered Budesonide via metered dose inhaler which is easy and less time-consuming with high acceptance and, at the same time, the maximum concentration of the drug will be present at the site of action, therefore decreasing the side effects.

In our study, all of the 60 patients completed the study with no dropouts. Patient characteristics were comparable. The incidence of post operative sore throat was significantly less in the budesonide group at 2 and 24 hrs postoperatively in our study. Also, the grade of POST severity was significantly less in the group which received budesonide inhalation. Rajan et al also found that twice inhalation of budesonide (before surgery and 6 hours after extubation) resulted in a lower incidence of POST at 2, 6, 12, and 24 h in patients undergoing through endoscopic surgery. Their results were in good agreement with the results of our study, but we did not repeat inhalation of budesonide in the period after extubation.17

Postoperative cough and hoarseness were also significantly less in the budesonide group after 2 hours, but there were no significant differences between the groups after 24 hours.

There were no local or systemic side effects. Paul et al found in their study found that pre-induction nebulization with budesonide was more efficacious than dexamethasone in patients undergoing surgery in prone position in reducing the incidence of POST, hoarseness of voice and cough. They attributed their findings to the half-life of dexamethasone (t1/2-36 hours) and budesonide (t1/2-3 hours).[18]

Chen et al. conducted a study of 120 patients admitted for thyroid surgery under general anaesthesia and confirmed the efficacy of prophylactic inhaled budesonide for postoperative sore throat, but they used repeated doses of budesonide at different times during the perioperative period.19

CONCLUSION :

Therefore, our study supports the efficacy of inhaled budesonide by metered-dose inhaler at a dose of 200 mcg 10 min prior to intubation. It significantly reduces the incidence and severity of postoperative sore throat, hoarseness, and postoperative cough and thus may play a potential role in the prevention of post-intubation airway pathology.

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nil

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