Impact Of Pre-Induction Inhaled Budesonide On The Severity Of Post-Operative Airway Morbidity After Endotracheal Intubation

Dr Heena Rathi[1], Dr Priyanka Rathi[2*], Dr Sampat G Rathod[3], Dr Hemant Garg[4], Dr Mohit Biyani[5], Dr Pranshu Mehtani[6]

[1]Phd Scholar, Medical Pharmacology, Nims University. Email: drheenarathi@gmail.com. Orcid: Https://Orcid.Org/0000-0002-8056-8768

[2*]M.B.B.S, M.D (Pharmacology), Professor, Nims University. Email: drpriyankarathi@gmail.com. Orcid: Https://Orcid.Org/0000-0002-6400-6888

[3]M.B.B.S, M.D (Anaesthesia), Assistant Professor, Nims University

[4]M.B.B.S, M.D (Pharmacology), Professor, Nims University

[5]M.B.B.S, M.D (Anaesthesia), Senior Medical Officer, Ruhs College Of Medical Sciences, Jaipur (Rajasthan)

[6]3Rd Year Resident, Anaesthesia, Nims University, Jaipur

Name And Details Of The Corresponding Author:

Dr. Priyanka Rathi**

M.B.B.S, M.D (Pharmacology)

Professor, Nims University

Email: drpriyankarathi@gmail.com

Orcid: Https://Orcid.Org/0000-0002-6400-6888

ABSTRACT

Introduction

Post-operative airway morbidity, including sore throat, cough, and hoarseness of voice, is a common complication following endotracheal intubation under general anaesthesia and can significantly affect patient comfort and satisfaction. Inhaled budesonide, a potent corticosteroid with local anti-inflammatory properties, may reduce airway inflammation when administered prophylactically.

Objective

To evaluate the impact of pre-induction inhaled budesonide on the severity of post-operative airway morbidity following endotracheal intubation under general anaesthesia.

Materials and Methods

This prospective, randomized, single-blind, controlled interventional study was conducted on 82 adult patients (ASA I–II), aged 20–60 years, undergoing surgery under general anaesthesia with endotracheal intubation. Patients were randomly allocated into two groups (n = 41 each). The experimental group received 200 µg inhaled budesonide, while the non-experimental group received a placebo, administered 10 minutes prior to induction of anaesthesia. Severity of post-operative sore throat, cough, and hoarseness of voice was assessed at 2 hours and 24 hours post-extubation using a standardized grading scale. Statistical analysis was performed using the Chi-square test, and a p value < 0.05 was considered statistically significant.

Results

At both 2 hours and 24 hours post-operatively, patients in the budesonide group demonstrated a significantly lower severity of post-operative sore throat, cough, and hoarseness of voice compared to the non-experimental group (p< 0.05 for all variables). At 2 hours, complete absence of sore throat was observed in 46.34% of patients in the experimental group versus none in the non-experimental group. Similar significant reductions were noted in cough and hoarseness severity. These beneficial effects persisted at 24 hours, with the experimental group showing a markedly higher proportion of patients free from airway symptoms and no cases of moderate to severe morbidity.

Conclusion

Prophylactic administration of inhaled budesonide significantly reduces the severity of post-operative sore throat, cough, and hoarseness of voice following endotracheal intubation. Inhaled budesonide represents a safe, effective, and simple preventive strategy to minimize post-intubation airway morbidity in patients undergoing general anaesthesia.

Keywords

Impact Of Pre-Induction Inhaled Budesonide On The Severity Of Post-Operative Airway Morbidity After Endotracheal Intubation

Post-operative sore throat, Inhaled budesonide, Endotracheal intubation, Airway morbidity, General anaesthesia, Corticosteroids

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INTRODUCTION

Postoperative airway complications, including sore throat, cough, and hoarseness of voice (1,2), are common adverse events following endotracheal intubation under general anaesthesia, with incidence rates ranging from 20% to 71.8% (3,4) depending on patient factors, surgical procedures, and intubation techniques. These symptoms, though generally self-limiting, can cause significant discomfort, impair early oral intake, delay recovery, and reduce overall patient satisfaction. Furthermore, POST makes the surgery an unpleasant memory for patients following discharge (5,6,7,8).The pathophysiology of post-intubation airway morbidity involves mechanical trauma to the pharyngeal and laryngeal mucosa, cuff-induced ischemia, and subsequent inflammatory responses.

Various pharmacological and non-pharmacological strategies have been explored to minimize postoperative airway symptoms, including careful intubation technique, smaller endotracheal tube sizes, local anaesthetic sprays, systemic anti-inflammatory drugs, and inhaled corticosteroids. Budesonide is an anti-inflammatory corticosteroid that exhibits potent glucocorticoid activity and weak mineralocorticoid activity (9). Budesonide, offer targeted anti-inflammatory effects on the airway mucosa, reducing edema, irritation, and inflammatory mediator release. Budesonide's rapid onset and local action make it a potentially effective prophylactic intervention to prevent post-intubation airway morbidity without systemic side effects.

Despite its theoretical advantages, limited studies have systematically evaluated the prophylactic use of inhaled Budesonide to reduce postoperative sore throat, cough, and hoarseness following general anaesthesia. Understanding its effectiveness could enhance perioperative care, improve patient comfort, and optimize recovery.

Therefore, this study was conducted to assess theimpact of Pre-Induction Inhaled Budesonide on the Severity of Post-Operative Airway Morbidity After Endotracheal Intubation.

MATERIALS AND METHODS

It is a randomized controlled, single blind, prospective interventional study.A randomized control study by Madhura et.al. 2020is with the two ratios of 17.5% and 45% (10).

$$N = (Z_{1-\alpha/2} + Z_{1-\beta})^2 \frac{p_1(1-p_1) + p_2(1-p_2)}{(p_1-p_2)^2}$$

using above formula for calculating the sample size of two proportions (10) at an alpha error of 5% power of 80%. We have arrived at a sample size in total of 40.62, in round of we have taken total 41. 41 in each group.

INCLUSION CRITERIA:

1. Patient of either sex of age group between 20 to 60 years.
2. Patients who are willing to give informed consent.
3.Patients undergoing surgery under general anaesthesia requiring endotracheal intubation.
4.Non smoker
5.Patients belonging to ASA (American Society of Anaesthesiogists) Class I and II.

EXCLUSION CRITERIA:

1.Patients with a history of pre-operative sore throat, cough and hoarseness of voice.
2.Patients with recent upper and lower respiratory tract infection or any other respiratory disease.
3.Patients with chronic respiratory disease.
4.Patients who are be allergic to test drug.
5.Patients who are already on analgesics or steroids (systemic or inhaled)
6.Patients who will require more than two attempts for intubation.
7.Patients with anticipation of difficulty in endotracheal intubation.
8.Patients with contraindications to corticosteroid.

TECHNIQUE

After obtaining Institutional Ethics Committee and Research Review Board's approval and informed written consent, 82 patients undergoing surgery under general Anaesthesia with endotracheal intubation fulfilling inclusion and exclusion criteria will be included in this study.

The patients were randomly divided in 2 groups, each of 41 patients by systemic sampling technique. Patient

were divided in odd number group and even number group. Odd group received test drug and even received placebo.

Informed written consent were taken after complete explanation regarding the study. Patients were asked to inhale a single puff of 200 mcg budesonide and empty inhaler according to group allocation in the pre-anaesthesia room.

After 10 minutes the patient was taken for anaesthesia. Necessary drugs were given as premedication by the anaesthesiologist. During the operation an endotracheal tube of appropriate internal diameter were used by the anaesthesiologist. Laryngoscopy were performed by the same anaesthesiologist in both the groups. Time of intubation, attempt for intubation, coughing and any trauma during intubation will be recorded. During the perioperative period vital parameters (HR, SBP, DBP, MAP, and SpO2) were noted by the anaesthesiologist. Extubation was performed. During extubation coughing, blood in secretion or in tube and intubation period also recorded. After arrival in the post anaesthetic care unit the patient were questioned at 2hr. and 24 hr. whether he/she had experienced any sore throat, cough or hoarseness.

STASTICAL ANALYSIS

All the data obtained were compiled and analyzed using **Statistical Package for the Social Sciences (SPSS) software**. Descriptive statistics were used to summarize the demographic and baseline characteristics of the study population. Continuous variables such as age were expressed as **mean ± standard deviation (SD)**, whereas categorical variables such as gender and incidence of postoperative sore throat were expressed as **frequency and percentage**.

The **Chi-square test (χ^2 test)** was applied to compare the **severity of postoperative sore throat** between the test group and the control group at various postoperative time intervals. This test was used to determine the association between treatment groups and categorical outcomes.

A **p-value < 0.05** was considered **statistically significant**, indicating a meaningful difference between the compared groups.

All results were presented in tabular and graphical formats for better clarity and interpretation.

RESULTS

The severity of post-operative airway morbidity, including post-operative sore throat (POST), cough, and hoarseness of voice, was compared between the non-experimental (control) and experimental (budesonide) groups at 2 hours and 24 hours following endotracheal extubation. Intergroup comparisons were performed using the Chi-square test, and a p value < 0.05 was considered statistically significant.

Table1: Comparing severity post operative sore throat, cough and hoarseness of voice of patient at 2 hrs. between non-experimental and experimental group groups by using chi-square test

Variables (At 2 Hrs.)		Non-Experimental	Experimental	Chi-Square test	P - Value	Significance
Post Operative Sore Throat	0	4 (9.76%)	19 (46.34 %)	26.989	< 0.0001	All are Significant
	1	7 (17.07%)	15 (36.59 %)			
	2	16 (39.02%)	7 (17.07 %)			
	3	14 (34.15%)	0			
Cough	0	10 (24.39%)	27 (65.85 %)	17.32	0.00017	
	1	15 (36.59%)	11 (26.83 %)			
	2	13 (31.71%)	3 (7.32 %)			
	3	3 (7.32%)	0			
Hoarseness of Voice	0	11 (26.83%)	16 (39.02 %)	13.04	0.00147	
	1	13 (31.71%)	22 (53.66 %)			
	2	8 (19.51%)	3 (7.32 %)			
	3	9 (21.95%)	0			

According to Table 1 the chi-square analysis at 2 hours postoperatively shows a significant difference in the severity of sore throat, cough, and hoarseness of voice between the non-experimental and experimental groups ($p < 0.05$ for all variables). Patients in the non-experimental group demonstrated markedly higher symptom severity, with a greater proportion experiencing moderate to severe sore throat (grades 2 and 3), whereas the experimental group had more patients with absent or mild symptoms. Similarly, cough severity was higher in the non-experimental group, while the experimental group showed a larger number of patients with no cough or only mild cough. Hoarseness of voice followed the same trend, with moderate to severe grades more common in the non-experimental group and absent or mild hoarseness predominating in the experimental group. Overall, these results indicate that prophylactic budesonide significantly reduced the severity of postoperative sore throat, cough, and hoarseness at 2 hours following surgery.

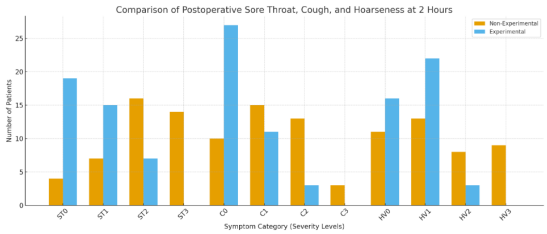

Fig1:Severity of Post-Operative Airway Symptoms at 2 Hours

Post-Operative Sore Throat

At 2 hours post-operatively, a significantly greater proportion of patients in the experimental group experienced lower severity grades or complete absence of sore throat compared to the non-experimental group. Grade 0 sore throat was reported in 46.34% of patients in the experimental group, whereas none in the non-experimental group were symptom-free. Conversely, moderate to severe sore throat (grades 2 and 3) was predominantly observed in the non-experimental group.

The intergroup difference in severity distribution was highly statistically significant ($\chi^2 = 26.989$, $p < 0.0001$).

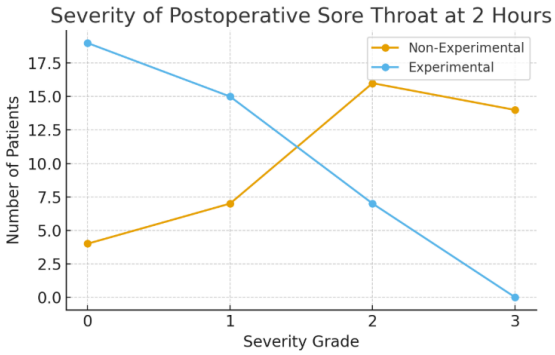

Fig 2: Severity of postoperative sore throat at 2 hours

Cough

The severity of cough at 2 hours was significantly reduced in the experimental group, with 65.85% of patients reporting no cough compared to 24.39% in the non-experimental group. Higher severity grades were more frequent in the non-experimental group, and no patient in the experimental group reported severe cough.

This difference was statistically significant ($\chi^2 = 17.32$, $p = 0.00017$).

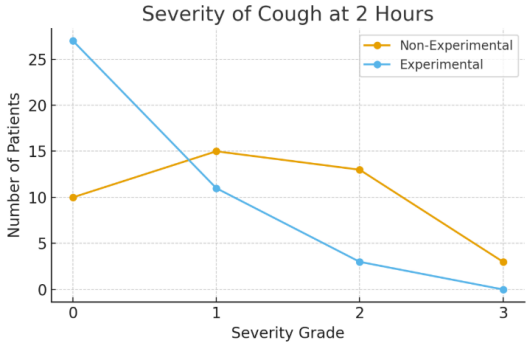

Fig 3: Severity of Cough at 2 hours

Hoarseness of Voice

Patients receiving inhaled budesonide demonstrated a significantly lower severity of hoarseness of voice at 2 hours. Severe hoarseness (grade 3) was observed exclusively in the non-experimental group, whereas none of the patients in the experimental group reported grade 3 symptoms.

The difference in severity distribution was statistically significant ($\chi^2 = 13.04$, $p = 0.00147$).

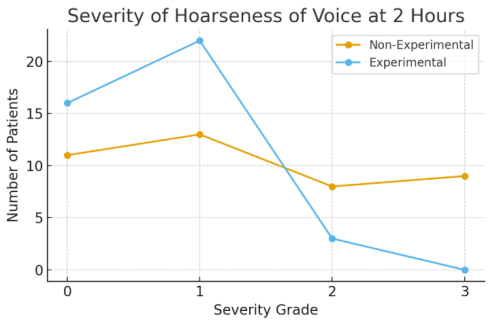

Fig 4: Severity of Hoarseness of Voice at 2 hours

Table 2: Comparing severity of post operative sore throat, cough and hoarseness of voice of patient at 24 hrs. between non-experimental and experimental group groups by using chi-square test

Variables (At 24 Hrs.)		Non-Experimental	Experimental	Chi-Square test	P - Value	Significance
Post Operative Sore Throat	0	3 (7.32%)	19 (46.34 %)	15.903	< 0.0001	All are Significant
	1	26 (63.41%)	22 (53.66 %)			
	2	12 (29.27%)	0			
	3	0	0			
Cough	0	9 (21.95%)	27 (65.85 %)	16.044	< 0.0001	
	1	28 (68.29%)	14 (34.15 %)			
	2	4 (9.76%)	0			
	3	0	0			
Hoarseness of Voice	0	10 (24.39%)	18 (43.90 %)	9.673	0.00794	
	1	21 (51.22%)	22 (53.66 %)			
	2	10 (24.39%)	1 (2.44 %)			
	3	0	0			

According to table 2 the chi-square analysis at 24 hours demonstrates a significant difference in the severity of postoperative sore throat, cough, and hoarseness between the non-experimental and experimental groups ($p < 0.05$ for all variables). In the non-experimental group, a considerable proportion of patients continued to report mild to moderate sore throat (grades 1 and 2), whereas the experimental group showed a much higher percentage of patients with no sore throat and no cases of moderate severity. Cough severity followed a similar pattern, with the non-experimental group showing more patients with mild to moderate cough, while the experimental group had a markedly higher number of patients who remained cough-free. Hoarseness of voice was also more common and more severe in the non-experimental group, whereas the experimental group predominantly demonstrated absent or only mild hoarseness. Overall, these findings indicate that prophylactic inhaled budesonide significantly reduced the severity of postoperative airway symptoms at 24 hours, providing sustained symptomatic relief compared to the non-experimental group.

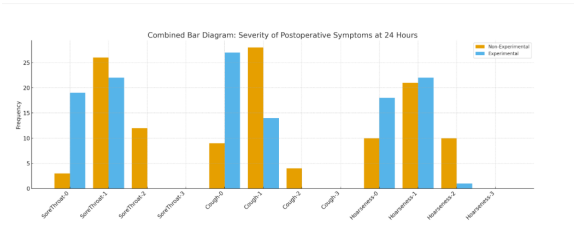

Fig 5: Severity of Post-Operative Airway Symptoms at 24 Hours

Post-Operative Sore Throat

At 24 hours post-operatively, the beneficial effect of inhaled budesonide persisted. Complete absence of sore throat (grade 0) was observed in 46.34% of patients in the experimental group compared to 7.32% in the non-experimental group. Moderate sore throat (grade 2) was reported in 29.27% of patients in the non-experimental group, while no patient in the experimental group experienced grade 2 or grade 3 symptoms.

This difference was highly statistically significant ($\chi^2 = 15.903$, $p < 0.0001$).

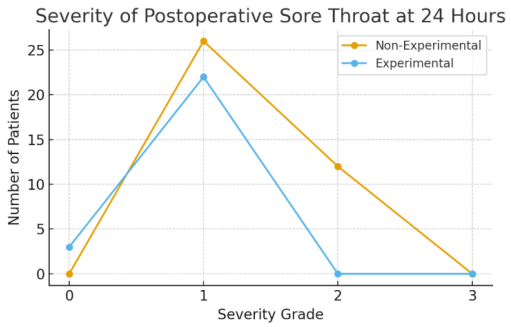

Fig 6: Severity of postoperative sore throat at 24 hours

Cough

A significantly greater proportion of patients in the experimental group were free from cough at 24 hours (65.85%) compared with the non-experimental group (21.95%). Residual moderate cough was observed only in the non-experimental group.

The intergroup difference remained highly significant ($\chi^2 = 16.044$, $p < 0.0001$).

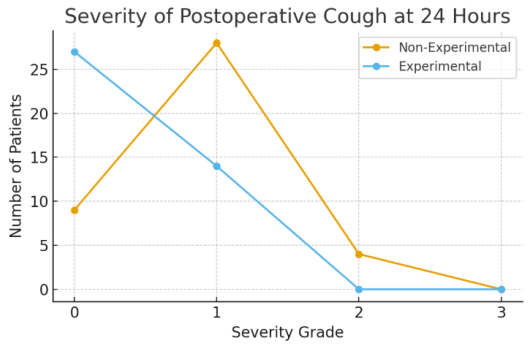

Fig 7: Severity of cough at 24 hours

Hoarseness of Voice

At 24 hours, 43.90% of patients in the experimental group reported no hoarseness of voice compared to 24.39% in the non-experimental group. Moderate hoarseness persisted in 24.39% of non-experimental patients but was present in only 2.44% of experimental patients.

This difference was statistically significant ($\chi^2 = 9.673$, $p = 0.00794$).

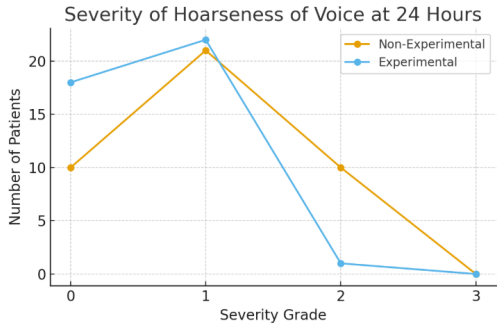

Fig 8: Severity of hoarsness of voice at 24 hours

DISCUSSION

The present study demonstrates that prophylactic inhalation of budesonide significantly reduces the severity of post-intubation airway morbidity, including post-operative sore throat, cough, and hoarseness of voice, in patients undergoing general anaesthesia with endotracheal intubation.

Early post-operative assessment at 2 hours revealed a marked shift toward lower severity grades among patients receiving budesonide, indicating effective attenuation of acute airway inflammation caused by mechanical trauma during laryngoscopy and intubation. The absence of severe airway symptoms in the experimental group further supports the protective role of inhaled corticosteroids in minimizing mucosal edema and inflammatory responses.

At 24 hours, the sustained reduction in symptom severity observed in the experimental group suggests a prolonged local anti-inflammatory effect of budesonide. These findings are consistent with the pharmacological properties of inhaled corticosteroids, which reduce vascular permeability, suppress inflammatory mediator release, and promote mucosal healing.

Given its ease of administration, minimal systemic absorption, and favorable safety profile, inhaled budesonide represents a practical prophylactic intervention to improve post-operative airway comfort. Incorporation of this strategy into routine anaesthetic practice may enhance patient satisfaction and reduce post-operative morbidity associated with endotracheal intubation.

CONCLUSION

Prophylactic administration of inhaled budesonide significantly reduces the severity of post-operative sore throat, cough, and hoarseness of voice at both early and late post-operative periods following endotracheal intubation. Inhaled budesonide may be considered an effective and safe preventive measure for reducing post-intubation airway morbidity in patients undergoing general anaesthesia.

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