The effects of budesonide nebulization on post-operative sore throat after general anaesthesia

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ABSTRACT:

Post-operative sore throat after general anaesthesia with endo-tracheal intubation occurs in 21% to 65% of patients.[1] It has been reported to be one of the most undesirable outcomes in the post-operative period influencing patient satisfaction.[2] Complaints range from minor throat irritation to debilitating pain, inability to swallow and temporary hoarseness of voice. Routine tracheal intubation for surgical procedures can result in pathological changes, trauma and nerve damage which may cause post operative sore throat. Several non-pharmacological methods like small sized endotracheal tubes,[3] lubricating the endotracheal intubation tube with water soluble jelly, intubation after full relaxation, minimizing intra-cuff pressure and extubation when cuff is fully deflated, the pharmacological measures include gargling and nebulization with drugs like budesonide, beclomethasone, ketamine, lignocaine etc., have been studied.[4,5] Budesonide is a non-halogenated glucocorticoid with powerful anti-inflammatory effects. It relieves congestion, reduces capillary permeability and oedema in the laryngeal mucosa. It is the only corticosteroid approved by FDA that can be used for aerosol inhalation.[5] There are no studies on Indian population to evaluate the efficacy of budesonide on post-operative sore-throat. We found that Budesonide nebulization in a dose of 1 mg, 15 minutes before endotracheal intubation reduced the incidence and severity of sore-throat, cough and hoarseness of voice in the post-operative period up to 24 hrs in patients who underwent elective middle ear surgery under general anaesthesia. There were no systemic side effects with budesonide nebulization and patient satisfaction was good.

INTRODUCTION

Post-operative sore throat after general anaesthesia with endo-tracheal intubation occurs in 21% to 65% of patients.[1] It has been reported to be one of the most undesirable outcomes in the post-operative period influencing patient satisfaction.[2] Complaints range from minor throat irritation to debilitating pain, inability to swallow and temporary hoarseness of voice. Routine tracheal intubation for surgical procedures can result in pathological changes, trauma

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Table 1 :Scoring system for sore throat, cough and hoarseness

Scores	Parameters
0	No sore throat, cough, hoarseness of voice
1	Mild sore throat, cough, hoarseness of voice
2	Moderate sore throat, cough, hoarseness of voice
3	Severe sore throat, cough, hoarseness of voice

and nerve damage which may cause post op sore throat. Several non-pharmacological methods like small sized endotracheal tubes,[3] lubricating the endotracheal intubation tube with water soluble jelly, intubation after full relaxation, minimizing intra-cuff pressure and extubation when cuff is fully deflated, the pharmacological measures include gargling and nebulization with drugs like budesonide, beclomethasone, ketamine, lignocaine etc have been studied.[4,5] Budesonide is a non-halogenated glucocorticoid with powerful anti-inflammatory effects. It relieves congestion, reduces capillary permeability and oedema in the laryngeal mucosa. It is the only corticosteroid proved by FDA that can be used for aerosol inhalation.[5] There are no studies on Indian population to evaluate the efficacy of budesonide on post-operative sore-throat.

METHODS:

A prospective randomised study was carried out on 60 patients after approval of institutional ethical committee. Written informed consent was obtained from the patients of either gender belonging to ASA class 1 and 2 scheduled for elective middle ear surgery under general anaesthesia with tracheal intubation. Patients were randomized into two groups to receive budesonide 1mg in 2 ml or saline 2ml in control group. All medications were inhaled by nebulization, 15 minutes before induction of anaesthesia. 18 G IV cannula inserted and Ringer's Lactate started. ECG, NIBP, SpO_2 monitors were connected and baseline readings noted. Injection midazolam 1mg, glycopyrrolate 0.2mg intravenously were given. All patients were preoxygenated for 3 minutes and anaesthesia induced with injection propofol 2.5mg/kg and fentanyl 2mcg/kg. Neuromuscular blockade achieved with injection vecuronium bromide 0.1mg/kg. Once adequate depth was achieved, the trachea was intubated with a 7.5mm tube in females and an 8.0mm tube in males. An effective airway was confirmed. After successful insertion, the ET cuffs were inflated with room air to a cuff pressure of 20 to 25 cm H_2O. Anaesthesia was maintained with oxygen, nitrous oxide

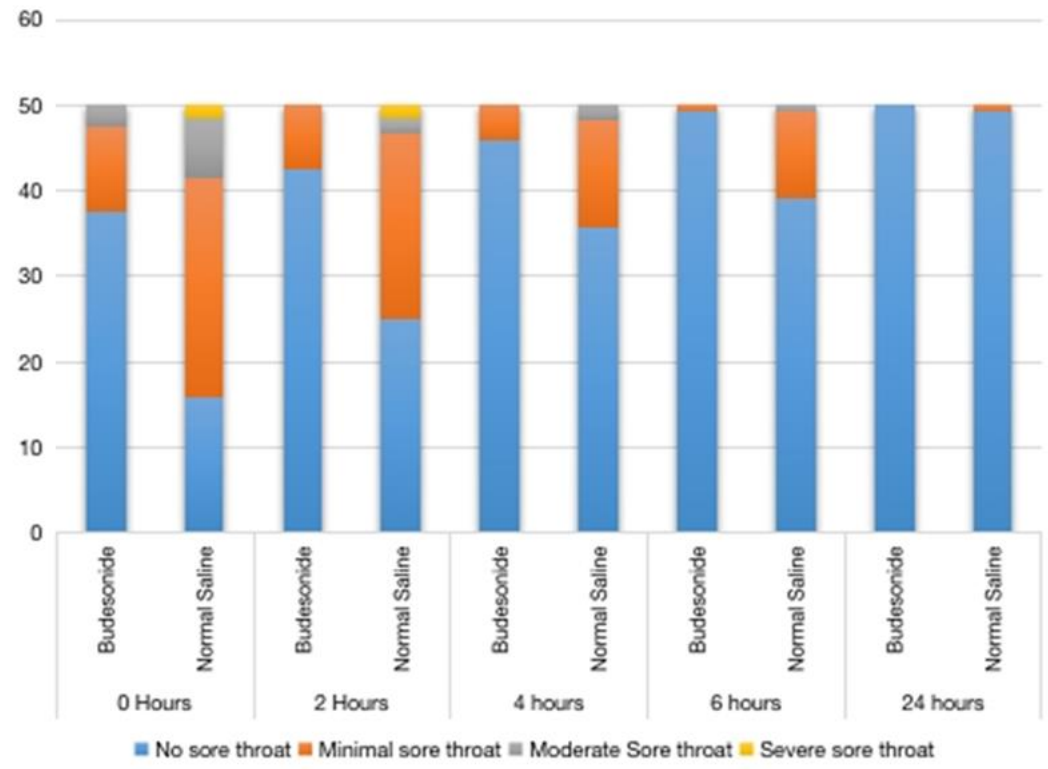

Figure 1: Distribution of the sore throat severity between the study and control groups at different time intervals

and sevoflurane and ventilated with intermittent positive pressure ventilation. At the end of surgical procedure, anaesthesia was discontinued, and the patient reversed with a standard dose of neostigmine and glycopyrrolate, and the device removed after deflating the cuff and the patients were shifted to the recovery room.

When arriving at the post anaesthesia care unit (0 hour) and thereafter at 2, 4, 6 and 24 hours, patients were assessed for the incidence and severity of sore throat, cough and hoarseness of voice using the questionnaire.

Scoring system for sore throat, cough and hoarseness was given. Statistical analysis was performed using SPSS for windows version 24 (SPSS, Chicago, IL). chi-square test, fischer exact test, student t test, any other suitable method at the time of data analysis. If the p-value was < 0.05, then the results were considered to be statistically significant otherwise it was considered insignificant statistically.

RESULTS: Distribution of the sore throat severity between the study and control groups: Immediately after extubation, 15 patients in test group had sore throat compared to 41 patients in control group

(p<0.001); at the end of 2 hours postoperatively, only 9 patient had sore throat in test group as compared to 40 patients in control group (p<0.001); after 4 hours postoperatively, 5 patients in test group had sore throat as compared to 17 minimum sore throat as compared to 13 patients in control group (p=0.002); at the end of 24 hours, no patient had sore throat in test group and 1 patient had sore throat in control group (p=0.5)patients in control group (p=0.014); at the end of 6 hours, 1 patient in test group had sore throat in control group.

Table 2: Distribution of the sore throat severity between the study and control groups

		Budesonide (test) n= 60	Saline (control) n=60	Total n=120	p-value
0 Hours	No sore throat	45 (37.5 %)	19(15.8%)	64 (53.3%)	*<0.001*
	Minimal sore throat	12 (10.0%)	31 (25.8%)	43 (35.7%)	
	Moderate Sore throat	3 (2.5%)	8 (6.8%)	11(9.2%)	
	Severe sore throat	0	2(1.7%)	2(1.7%)	
2 Hours	No sore throat	51 (42.5%)	30 (25.0%)	81 (67.5%)	*<0.001*
	Minimal sore throat	9 (7.5%)	26(21.7%)	35 (29.2%)	
	Moderate Sore throat	0	2(1.7%)	2(1.7%)	
	Severe sore throat	0	2(1.7%)	2(1.7%)	
4 hours	No sore throat	55 (45.8%)	43 (35.8%)	98(81.7%)	*0.014*
	Minimal sore throat	5(4.2%)	15(12.5%)	20(16.7%)	
	Moderate Sore throat	0	2(1.7%)	2(1.7%)	
	Severe sore throat	0	0	0	
6 hours	No sore throat	59(49.2%)	47(39.2%)	106(88.4%)	*0.002*
	Minimal sore throat	1(0.8%)	12(10.0%)	14(10.8%)	
	Moderate Sore throat	0	1(0.8%)	1(0.8%)	
	Severe sore throat	0	0	0	
24 hours	No sore throat	60(100.0%)	59(49.2%)	119(99.2%)	0.5
	Minimal sore throat	0	1(0.8%)	1(0.8%)	
	Moderate Sore throat	0	0	0	
	Severe sore throat	0	0	0	

Table 3: Distribution of the side effects between the study and control groups

Side effects	Budesonide (test) n=60	Saline (control) n=60	Total n=120	p-value
Nausea	6 (5%)	8 (6.6%)	14(11.7%)	1.00
Vomiting	1(0.8%)	1(0.8%)	02(1.6%)	1.00
Numbness of tongue	3(2.5%)	0(0.0)	03(2.5%)	0.122

Chi square test, sig.2 tailed, p<0.05

Demographic data between the study and control groups were comparable with p values of 0.226, 0.584, 0.015, 0.974, 0.020, 1 for parameters like age, gender, weight, height, BMI, ASA classification respectively.

Distribution of the cough severity between the study and control groups at different time intervals: Immediately after extubation, 15 patients in test group had cough as compared to 24 patients in control group (p=0.039); at the end of 2 hours postoperatively, only 1 patient had cough in test group as compared to 12 patients in control group (p=0.017); after 4 hours postoperatively, no patient in test group had cough as compared to 10 patients in control group (p<0.001); at the end of 6 hours, no patient in test group had cough as compared to 1 patient in control group (p=0.874); at the end of 24 hours, no patient had cough in both test and control groups (p=1)

Distribution of the hoarseness of voice severity between the study and control groups at different time intervals: Immediately after extubation, 3 patients in the test group had hoarseness of voice compared to 20 patients in the control group (p<0.001); at the end of 2 hours postoperatively, only 2 patients had compared to 17 patients in control group (p=0.031); after 4 hours postoperatively, 2 patients in test group had hoarseness of voice as compared to 13 patients in the control group (p=0.044); at the end of 6

control group (p=0.874); at the end of 24 hours, no patient had hoarseness of voice in both the test and control groups (p=1)

Distribution of the patient's satisfaction between the study and control groups: At 24 hours after surgery and extubation, all the patients in the test group were satisfied and comfortable compared to 37 patients in the control group.

DISCUSSION:

Our study shows that pre-operative nebulization with 1 mg of budesonide, 10 minutes before oro tracheal intubation was effective in reducing the incidence and severity of postoperative sore throat up to 6 hours, cough and hoarseness up to 4 hours with good patient satisfaction and without any complications in patients undergoing elective middle ear surgeries under general anaesthesia.

POST is a well-recognized minor distressing complaint after oro tracheal intubation. It may be caused by pharyngeal, laryngeal, or tracheal irritation and might even occur in the absence of endotracheal intubation.[6] It is difficult to differentiate whether POST is secondary to laryngoscopy alone, or is caused by insertion of an endotracheal tube, or is a combined effect of the two can result in pathological changes, trauma and nerve damage which may cause POST. Complaints range from minor throat irritation to debilitating pain, inability to swallow and temporary voice changes.

POST can be accompanied by cough, laryngitis, tracheitis, dysphagia or hoarseness. POST has multifactorial aetiology which includes mechanical injury as stated above during laryngoscopy and intubation causing local inflammation of airway,[7] suctioning,[8] increased duration of surgery, movement of tracheal tube and cuff during position change, airway damage during intubation, and prone position.[9]

The other contributing factors for POST include sex, age, use of succinylcholine, larger tracheal tubes, cuff design, and intracuff pressures.[10,,11]

Budesonide is a non-halogenated glucocorticoid with a powerful anti-inflammatory effect. It relieves congestion, reduce capillary permeability and reduces oedema in laryngeal mucosa.[5] We used budesonide nebulization in a dose of 1 mg which was similar to what Saeed Abbasi et al used in their study as it is an easy way to administer the drug, no bitter or metallic taste, smaller volume required, no risk of aspiration if accidentally swallowed, better patient cooperation is likely and cost effective method to decrease post-operative sore throat.[12] Nebulization ensures that the drug is equally and effectively distributed all over the pharynx and the respiratory tract. The nebulization produces large particles which deposit in mouth and throat and smaller particles deposit in a transition from mouth to airway. Sunil R et al evaluated the effectiveness of inhaled budesonide suspension 200 microgram using metered dose inhaler 10 minutes before intubation.[13] The budesonide receiving group had significantly lower incidence of sore throat compared to the other group.[14]

Shreesh M et al and colleagues compared nebulization with ketamine 50mg, lidocaine

4% 40 mg, budesonide 250 micrograms and distilled water for reducing post-operative sore-throat. They observed that incidence of sore throat with ketamine was less in early post op period at 1 hr, lignocaine was efficacious in reducing cough at 24hrs, whereas long term outcome was better with budesonide even at 48hrs.[5]

Yan Q et al compared the effect of budesonide inhalation suspension with placebo for post-operative sore throat in patients undergoing elective thyroid surgery. One group received 200 micrograms of budesonide nebulization 10 minutes prior to tracheal intubation while the other group received 200 micrograms after extubation. And last group received 2 ml of normal saline. The group which received budesonide before intubation showed less post op sore throat incidence than the other two groups.[15]

A Sinha et al compared the effect of aerosolized budesonide and L- epinephrine on post-operative sore throat, hoarseness and stridor secondary to intubation. One group received L- epinephrine 1% 0.25ml in 2ml normal saline. The other group received budesonide 1000 micrograms through nebulization. The need for re nebulization and re intubation at any time between 20 min to 24 hours was less in the group receiving study drugs although the efficacy of both the drugs is found to be the same.[16]

CONCLUSION:

Budesonide nebulization in a dose of 1 mg, 15 minutes before endotracheal intubation reduces the incidence and severity of sore-throat, cough and hoarseness of voice in the post-operative period up to 24 hrs in patients who underwent elective middle ear surgery under general anaesthesia.

There were no systemic side effects with budesonide nebulization and patient satisfaction was good.

REFERENCES:

1. Loeser EA, Stanley TH, Jordan W, Machin R. Postoperative sore throat: influence of tracheal tube lubrication versus cuff design. Can Anaesth Soc J 1980;27:156–8
2. Sumathi PA, Shenoy T, Ambareesha M, Krishna HM: Controlled comparison between betamethasone gel and lidocaine jelly applied over tracheal tube to reduce postoperative sore throat, cough, and hoarseness of voice. Br J Anaesth 2008;100:215-8
3. Al- Qahtani AS, Messahel FM. Quality improvement in anaesthetic practice – Incidence of sore throat after using small tracheal tube. Middle East J Anesthesiol 2005;18:179-83
4. Ayoub CM, Ghobashy A, Koch ME, McGrimley L, Pascale V, Qadir S. Widespread application of topical steroids to decrease sore throat, hoarseness, and cough after tracheal intubation. Anesth Analg 1998;87(3):714-6
5. Shreesh Mehrotra, Nidhi Kumar, Gurjeet Khurana, Bist S.S. Incidence after nebulization with ketamine, lidocaine and budesonide. Int J Med Clin 4(6):2994-2998,2017

6. Surajit Chattopadhyay, Anjan Das, Sabyasachi Nandy, Sandip Roy Basunia, Tapobrata Mitra, Partha Sarathi Halder, Subinay Chhaule and Subrata Kumar Mandal. Postoperative sore throat prevention in ambulatory surgery: A comparison between preoperative aspirin and magnesium sulphate gargle – A prospective, randomized, double-blind study. Anesth Essays Res 2017;11(1):94–100
7. Patel RI, Oh TH, Chandra R, Epstein BS. Tracheal tube cuff pressure. Anaesthesia 1984;39:862–4
8. Stout DM, Bishop MJ, Dwersteg JF, Cullen BF. Correlation of endotracheal tube size with sore throat and hoarseness following general anaesthesia. Anaesthesiology 1987;67(3):419-21
9. Ratnaraj J, Todorov A, McHugh T, Cheng MA, Lauryssen C. Effects of decreasing endotracheal tube cuff pressures during neck retraction for anterior cervical spine surgery. J Neurosurg 2002;97:176-9
10. Higgins PP, Chung F, Mezei G. Postoperative sore throat after ambulatory surgery. Br J Anaesth 2002;88:582-4
11. Rameshkumar E, Ajaya kumar P. Postoperative sore throat in patients undergone head and neck surgeries under endotracheal intubation and laryngeal mask anaesthesia. Int J Otorhinolaryngol Head Neck Surg 2017;3:371-5
12. Saeed Abbasi, Siamak Moradi, Reihanak Talakoub, Parviz Kashefi, Ali Mehrabi Koushki. Effect of nebulized budesonide in preventing postextubation complications in critically ill patients: A prospective, randomized, double- blinded, placebo- controlled study. Adv Biomed Res 2014;3:182-184
13. Sunil Rajan, Pulak Tosh, Jerry Paul, Lakshmi Kumar. Effect of inhaled budesonide suspension, administered using a metered dose inhaler, on post-operative sore throat, hoarseness of voice and cough. Indian J Anaesth 018;62:66-71
14. Upadhyay N, Gupta R, Prakash S, Bhalla S. Controlled comparison between betamethasone gel and lignocaine jelly applied over endotracheal tube in reducing postoperative sore throat, cough, and hoarseness of voice. Indian Anaesth Forum 2018;19:65-72
15. Chen Y-Q, Li J-P, Xiao J. Prophylactic effectiveness of budesonide inhalation in reducing postoperative throat complaints. European Archives of Oto-rhino-laryngology 2014;271:1667-68
16. Sinha A, Jayashree M, and Singhi S. Aerosolized L- epinephrine vs budesonide for post extubation stridor: a randomized control trial. Indian Pediatr 2010;47:317- 322