



Effect Of Prophylactic Intravenous Dexamethasone In Attenuating Postoperative Sore Throat, Cough And Hoarseness In Patients Undergoing General Anaesthesia; A Randomized Controlled Trial

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Type of Publication: Original Research Paper

Conflicts of Interest: Nil

Abstract

Keywords: NIL

Introduction

Postoperative sore throat (POST), cough and hoarseness of voice after endotracheal intubation of general anaesthesia are common, uncomfortable, distressing and troublesome complications. The incidence of post ranges from 21% to 66% in accordance with different surgical and anaesthetic manipulations.^[1,2] The mean duration of postoperative sore throat has been suggested to be 16±11 hours.^[3] Even though a minor complication, POST contributes to post-operative morbidity and patient dissatisfaction.

The main culprits of increased sore throat in postoperative period are larger diameter endotracheal tubes, cuff design, over inflation of cuff, tube movement, bucking /cuffing with tube in situ, excessive oral suctioning and repeated attempts.^[4] Postoperative hoarseness and cough are the result of at least some degree of laryngeal injury. There are other factors that contribute to the increased incidence of postoperative sore throat in patients requiring endotracheal intubation like, female gender, older age group, duration of surgery, and patient's position during surgery. It was found that supine head down position is associated with more postoperative sore throat.^[5]

Various non-pharmacological and pharmacological trials have been used for attenuating POST with variable success, such as smaller-sized endotracheal tubes (ETT),^[6] lubricating the endotracheal tube with water soluble jelly,¹ intubation after full relaxation, minimizing intracuff pressure,^[7] beclomethasone inhalation, gargling with azulene sulphonate,^[8] ketamine gargles,^[9] steroid gels and steroid injection,^[10,11] inhaled fluticasone propionate, strepsils, lozenge containing amyl metacresol and 2,4-dichlorobenzyl alcohol.^[4]

Dexamethasone is a potent glucocorticoid with analgesic, antiemetic and anti-inflammatory effects. This prospective randomized placebo controlled, double-blind study was undertaken to evaluate the efficacy of prophylactic intravenous dexamethasone to reduce the incidence and severity of postoperative sore throat, cough, and hoarseness in Manipur, India.

Materials And Methods

This study was conducted over a period of around three years from October 2018 till September 2021. After obtaining the Institutional Ethics Committee's approval, ninety-six consenting patients of either sex, aged between 18 to 60 years, of American Society of Anaesthesiologists (ASA) physical status I and II, scheduled for surgeries with an estimated duration of

45 minutes to three hours and needing general anaesthesia with endotracheal intubation, were enrolled in this randomized clinical study. The enrolment was done during the preoperative check-up visit. Exclusion criteria were: Patients with ASA grade III and IV, history of allergy to study drug, any comorbidities, patients for surgeries of the oral cavity and pharynx; unpredicted or long duration surgeries (greater than three hours); anticipated difficult airways; more than three attempts needed at intubation; visible trauma during intubation; use of nasogastric tube and throat packs; patients with upper respiratory tract infections; and patients on steroid therapy. Based on the study conducted by Bagchi D *et al*¹¹ on the efficacy of prophylactic dexamethasone in decreasing the incidence of postoperative sore throat and hoarseness found a difference in the incidence of sore throat of 30% when using dexamethasone. Considering that a 20% difference in the incidence of postoperative sore throat at 1-hour post-extubation would be clinically relevant, 44 patients were required in each group [assuming α error of 0.05 and the power of the study (1- β) to be 80%]. Allowing for a dropout rate of 10%, ninety-six (96) patients were enrolled. The patients were randomly allocated into two groups to receive either dexamethasone (group A, n=48) or normal saline (group B, n = 48) with help of a computer-generated random number table. All patients received alprazolam 0.5 mg orally the night before the operation and received midazolam 0.05 mg/kg, ranitidine 50 mg and ondansetron 4 mg intravenously (IV) 15 minutes before the start of the operation. On arrival to the operating room, the patients in the group A received dexamethasone in a dose of 0.2 mg/kg IV (diluted to a total volume of 4 ml with normal saline) while patients in the group B received 4 ml of normal saline IV just before induction of anaesthesia. The drugs were prepared and administered by an anaesthesiologist not involved in the study. Anaesthesia was induced with propofol 2mg/kg IV after pre-oxygenation for 3 minutes. After adequate muscle relaxation with rocuronium, trachea was intubated by an experienced anaesthesiologist using disposable endotracheal tubes (8-8.5 mm ID for male patients and 7-7.5 mm ID for female patients). MacIntosh blade size 3 or 4 was used for laryngoscopy. Anaesthesia was maintained with nitrous oxide, oxygen and isoflurane/sevoflurane. At

the end of the operation, the oropharynx was cautiously toiletted with a 14Fr disposable soft suction catheter and trachea extubated after standard reversal of muscle relaxation with neostigmine and glycopyrrolate. Outcome assessment for the incidence of sore throat, cough and hoarseness was carried out by a resident not involved in the study process, at 15 min, 1, 6 and 24 hours post-extubation, in the post-anaesthesia care unit (PACU). Sore throat, cough and hoarseness were assessed using a 4-point scale [Table 1].

All patients were followed up for 24 hours post-extubation and study ended at this time point. Patients who complained of moderate to severe sore throat after 24 hours were advised lukewarm saline gargle and decongestant medications and those not responding to the above were referred for otorhinolaryngology consultation.

Data was represented as numerical (continuous and discrete) and categorical (nominal and ordinal) data. The data were analysed by using SPSS for windows version 21.0 (Armonk, NY: IBM Corp). Independent sample t-test was used for analysing continuous data and Chi-square or Fischer exact test was utilized for analysing categorical data. Statistical significance was defined as p value < 0.05.

Results

Ninety-six patients were allocated into two groups of 48 each. Forty-eight patients in both the groups A and B were available for follow up and collection of data. Mean age of patients, sex ratio within the groups, mean weight and ASA grade were comparable in both groups [Table 2].

The overall incidence of POST in 24 hours was significantly lower in Dexamethasone group 14 (29.17%) compared to Normal saline group 27 (56.25%), chi square test, p value=0.007[Table 3]. The incidence of POST were 36(37%), 41(43%) and 38(40%) at 1 hour, 6 hour and 24 hour respectively in the total study population. Incidence of POST at 15 min was 0(0%) in both the groups. There was more number of patients complaining of POST in Group B than Group A at 1 hour, 6 hour and 24 hours. In Group A, incidence of POST was 11(23%), 14(29%) and 14(29%) at 1 hour, 6 hour and 24 hours respectively. In Group B, incidence of POST was 25(52%), 27(56%) and 24(50%) at 1 hour, 6 hour and

24 hours respectively. Incidence of POST for patients in Group A was lower at all hours post-operative period when compared to Group B. Overall, less number of patients in the dexamethasone group suffered from minimal and moderate grades of sore throat at 1, 6 and 24 hours post-extubation. [Table 4] The incidences of cough at 1, 6 and 24 hours post-

extubation were lower in the dexamethasone group but were statistically not significant [Table 5]. The incidences of hoarseness in group A were significantly lower than group B at 6 and 24 hours [Table 6]. No patients from both the groups developed severe degree of sore throat, cough or hoarseness of voice.

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

SCORE	SORE THROAT
0	No sore throat at any time since operation
1	The patient answered in the affirmation when asked about sore throat (minimal)
2	The patient complained of sore throat on his/her own (moderate)
3	The patient is in obvious distress (severe)
SCORE	COUGH
0	No cough at any time since the operation
1	Mild cough
2	Moderate cough
3	Severe cough
SCORE	HOARSENESS OF VOICE
0	No complaint of hoarseness at any time since the operation
1	Minimal change in quality of speech. Patient answers in the affirmative only when enquired about (minimal hoarseness)
	Moderate change in quality of speech which the patient complaints

2	on his/her own (moderate hoarseness)
3	Gross change in the quality of voice perceived by the observer (severe hoarseness)

Table 2: Patient characteristics

	Group A (n=48)	Group B (n=48)	p-value
Age in years (mean±SD)	37.58±9.94	37.90±10.05	0.88
Male: Female	21:27	20:28	0.84
Weight in kg (mean±SD)	54.25±6.73	53.98±7.68	0.86
ASA I: ASA II	26:22	29:19	0.54

Table 3: Overall incidence of postoperative sore throat

	GROUP A n = 48	GROUP B n = 48	P value
Incidence of sore throat within 24 hours	14 (29.17%)	27 (56.25%)	0.007

Table 4: Incidence of postoperative sore throat at 1, 6 and 24 hours

Sore Throat Assessment Grading	Number of patients N=96 (N%)							
	15 min		1hr		6hr		24hr	
	A n=48 (%)	B n=48 (%)	A n=48 (%)	B n=48 (%)	A n=48 (%)	B n=48 (%)	A n=48 (%)	B n=48 (%)

0 (Sore throat)	48(100)	48(100)	37(77)	23(48)	34(71)	21(44)	33(69)	24(50)
1 (Mild Sore throat)	0(0)	0(0)	11(23)	21(44)	13(27)	25(52)	14(29)	18(38)
2(Moderate Sore throat)	0(0)	0(0)	0(0)	4(8)	1(2)	2(4)	0(0)	6(12)
3 (Severe Sore throat)	0(0)	0(0)	0(0)	0(0)	0(0)	0(0)	0(0)	0(0)
Total number of patients having POST	0(0)	0(0)	11(23)	25(52)	14(29)	27(56)	14(29)	24(50)
	0(0)		36(37)		41(43)		38(40)	
P value	--		0.003		0.007		0.037	

Table 5: Incidence of postoperative cough at 1, 6 and 24 hours

Incidence of postoperative cough	Group A (n=48)	Group B (n=48)	p-value
At 15 mins	0	0	--
At 1 hour	5	10	0.160
At 6 hours	10	16	0.168
At 24 hours	11	15	0.358

Table 6: Incidence of postoperative hoarseness at 1, 6 and 24 hours

Incidence of postoperative hoarseness	Group A (n=48)	Group B (n=48)	p-value
At 15 mins	0	0	--
At 1 hour	2(4.1%)	3(6.3%)	0.646
At 6 hours	3(6.3%)	12(25%)	0.011
At 24 hours	5(10.4%)	13(27%)	0.036

Discussion

The present study demonstrates that prophylactic IV dexamethasone results in a statistically significant reduction in the incidence of sore throat at 1, 6 and 24 hours post-extubation than the control group. The overall incidence of sore throat in the first 24 hours post-extubation was found to be lesser in comparison to the control group, which is found to be statistically significant. At 15 min post-extubation none of the patients complained of sore throat. The incidence of mild and moderate sore throat at 1, 6 and 24 hours post operatively were found to be lower than that in the control group. Incidence of severe degree sore throat was not found among both groups. The incidence of hoarseness was observed to be significantly attenuated in dexamethasone group at 6 and 24 hours postoperatively. The incidences of cough and hoarseness were also lower at all points of observation in the dexamethasone group, but found to be statistically not significant on analysis.

Post-operative sore throat and hoarseness are common complications after endotracheal intubation, with a distressingly high incidence from 21% - 66% in earlier studies.^[1,2] It can lead to dissatisfaction and discomfort after surgery, and also it prolongs the postoperative stay by 14 minutes ($p < 0.05$) and discharge time by 51 minutes ($p < 0.05$).^[12] There are many studies done emphasizing the benefits of dexamethasone in attenuating the postoperative sore throat, cough and hoarseness, where dexamethasone was used in different routes, doses, combinations and time. In previous studies dexamethasone was used in intracuff, nebulisation, intravenous at doses of 0.1 mg/kg and 0.2 mg /kg and in both pre induction and post induction time.^[10,13,14]

In a study conducted by Shalini S et al,^[15] found that the incidence of POST after 24 hrs with 8mg of IV dexamethasone as 30.8% which is slightly higher than our finding. They also observed the incidence of hoarsness as 40.3%, whereas in our study incidence of hoarsness after 24 hrs was 27%.

Reported factors contributing to post-operative sore throat after surgery includes gender (female), age (elderly), use of succinylcholine, large tracheal tube, cuff design (low volume high pressure cuff),^[16] intra-cuff pressure, difficult intubation, repeated attempts, movement of the tube during surgery, bucking/cuffing on the tube, excessive pharyngeal

suctioning during extubation, duration of surgery and patient's position during surgery.^[4,5,12] The pathological cause of sore throat is thought to be aseptic inflammatory process because of the irritation of the pharyngeal mucosa during laryngoscopy, the damage of tracheal mucosa by the cuff of the endotracheal tube, and the trauma to tissues during the processes of intubation and extubation.^[2,10] In our study, we did not find any association between age and gender with POST. As age, gender and weight were comparable in both the groups, appropriate sized tubes of same manufacturer were used for all cases to avoid the possible error due to different tube size and quality.

Dexamethasone is a potent drug with analgesic and anti-inflammatory effects, and also have a prophylactic effect on postoperative nausea and vomiting. This anti-inflammatory process includes inhibition of leukocyte migration to the site of inflammation, inhibition of release of cytokines probably by maintaining cellular integrity and attenuation of lysosome release. Fibroblast proliferation may also be inhibited.^[4,7,10] Dexamethasone can reduce the synthesis of inflammatory mediators, leukotrienes and prostaglandins by inhibiting phospholipase A₂ through production of Annexins (calcium dependent phospholipid binding proteins) and by inhibition of arachidonic acid metabolism and cyclooxygenase-2 during inflammation.^[17]

Anish S et al,^[18] also conducted a study to compare the effect of dexamethasone and dexamethasone with lignocaine in attenuating POST. In their study the incidence of POST was 36% in dexamethasone group and 25% in patient receiving dexamethasone and lignocaine together which is higher than our findings.

In his study Park SH et al,^[10] found that at 24 hours post-extubation the incidence and severity of POST and hoarseness to be significantly lower in Group D2 (27% and 15%) compared to Group D1 (47% and 31%) and Group P (57% and 45%), where they received dexamethasone 0.2 mg/kg, 0.1 mg/kg and normal saline respectively. Bagchi D et al^[11] observed that at 1, 6 and 24 hours after extubation there was a significant reduction in incidence of POST in Dexamethasone group by 30%, 24% and 15.5% respectively. In a study conducted by Thomas S et al^[14] found a significant decrease in the overall

incidence of postoperative sore throat in group D by 36.3% after prophylactic administration of dexamethasone 8 mg.

Yaofei J *et al*,^[19] also conducted an updated systematic review and meta-analysis on impact of prophylactic dexamethasone on post operative sore throat and found that dexamethasone ≥ 0.2 mg/kg had a statistically greater impact on reducing the incidence of POST than dexamethasone 0.1-0.2mg/kg, while dexamethasone ≤ 0.1 mg/kg did not.

In our study, we did tracheal suctioning, gently under direct vision, before giving reversal, after giving reversal and before extubation. Utmost care was taken to minimize any trauma to the pharyngeal mucosa with the suction catheter. But this may have contributed to the incidence of mild POST in our study.

The limitation of our study was not measuring the cuff pressure and not using fiber optic bronchoscope to assess the amount of tissue damage. Duration of surgery was not included in the present study. Sore throat, hoarseness and cough cannot be assessed objectively and there are inter-individual variations and therefore, a chance of bias is unavoidable. As the process of acute inflammation usually peaks by 24 hours, it is a limitation that this study was not designed for an extended follow up beyond 24 hours.

Dexamethasone is associated with potential side effects like hyperglycemia, peptic ulcer, increased susceptibility to infection, electrolyte imbalance, adrenal suppression and vascular necrosis of hip and other joints. Although a single dose of dexamethasone is considered safe and no such side effects were reported in our study, further studies of longer follow-ups are required.

Conclusion

In conclusion, prophylactic intravenous dexamethasone in a dose of 0.2 mg/kg can effectively reduce the incidence of postoperative sore throat and hoarseness at 1, 6 and 24 hours and 1 and 6 hours respectively, in patient undergoing elective surgery under general anaesthesia using endotracheal tube.

The results observed in my study strengthen the conclusion of other studies conducted in different parts of the world that dexamethasone effectively decreases the incidence and severity of sore throat

and hoarseness in the postoperative period after endotracheal intubation.

References

1. 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(2):215-8.
2. Huang YS, Hung NK, Lee MS, Kuo CP, Yu JC, Huang GS, *et al*. The effectiveness of benzydamine hydrochloride spray on the endotracheal tube cuff or oral mucosa for postoperative sore throat. *Anesth Analg* 2010;111(4):887-91.
3. Biro P, Seifert B, Pasch T. Complaints of sore throat after tracheal intubation: a prospective evaluation. *Eur J Anaesthesiol* 2005;22:307–11.
4. Scuderi PE. Postoperative sore throat: More answers than questions. *Anesth Analg* 2010;111(4):831-2.
5. Ahmed A, Abbasi S, Ghafoor HB, Ishaq M. Postoperative sore throat after elective surgical procedures. *J Ayub Med Coll Abbottabad* 2007;19:12-4.
6. Al-Qahtani AS, Messahel FM. Quality improvement in anesthetic practice – incidence of sore throat after using small tracheal tube. *Middle East J Anaesthesiol* 2005;18(1):179–83.
7. Liu J, Zhang X, Gong W, Li S, Wang F, Fu S, *et al*. Correlations between controlled endotracheal tube cuff pressure and post-procedural complications: A multicenter study. *Anesth Analg* 2010;111(5):1133-7.
8. Ogata J, Minami K, Horishita T, Shirashi M, Okamoto T, Terada T, *et al*. Gargling with sodium azulene sulfonate reduces the postoperative sore throat after intubation of the trachea. *Anesth Analg* 2005;101(1):290-3.
9. Rudra A, Ray B, Chatterjee S, Ahmed A, Ghosh S. Gargling with ketamine attenuates the postoperative sore throat. *Indian J Anaesth* 2009;53(1):40-3.

10. Park SH, Han SH, Do SH, Kim JW, Rhee KY, Kim JH. Prophylactic dexamethasone decreases the incidence of sore throat and hoarseness after tracheal extubation with a double lumen endobronchial tube. *Anesth Analg* 2008;107(6):1814-8.
11. Bagchi D, Mandal MC, Das S, Sahoo T, Basu SR, Sarkar S. Efficacy of intravenous dexamethasone to reduce incidence of postoperative sore throat: A prospective randomized controlled trial. *J Anaesthesiol Clin Pharmacol* 2012;28(4):477-80.
12. Higgins PP, Chung F, Mezei G. Postoperative sore throat after ambulatory surgery. *Br J Anaesth* 2002;88(4):582-4.
13. Salama AK, El-badawy AM. Does nebulized dexamethasone decrease the incidence of postextubation sore throat? A randomized controlled study. *Ain-Shama J Anaesthesiol* 2016;9(1):104-7.
14. Thomas S, Beevi S. Dexamethasone reduces the severity of postoperative sore throat. *Can J Anaesth* 2007;54(1):897-901.
15. Shalini S, Vatika B, Shailja S, Shelly R. Dexamethasone to decrease post anaesthesia sorethroat(POST) and hoarseness- Which is the most effective route : intravenous, topical or nebulization? A prospective randomized trial. *Ain- Shams J of Anaesthesiology* 2021; 1186(10):144-8.
16. Stenqvist O, Nilsson K. Postoperative sore throat related to tracheal tube cuff design. *Can Anaesth Soc J* 1982;29(4):384-6.
17. Goodwin JS, Atluru D, Sierakowski S, Lianos EA. Mechanism of action of glucocorticosteroids inhibition of T cell proliferation and Interleukin 2 production by hydrocortisone is reversed by Leukotriene B₄. *J Clin Invest* 1986;77(4):1244-50.
18. Anish S, Mukesh T, Krishna K, Sindhu K. Effect of intravenous Lidocaine, Dexamethasone and their combination of post operative sore throat: A randomized controlled trial. *Anaesth Analg* 2019;129(1): 220-225.
19. Yaofei J, Ruoxi C, Sumin X, Jiayi L, Fangi Y, Lingdong K, et al. The impact of prophylactic dexamethasone on post operative sore throat: an updated systematic review and meta-analysis. *Journal of pain research*. 2018;11: 2463-2475.