Original Article

Efficacy of intravenous dexamethasone to reduce incidence of postoperative sore throat: A prospective randomized controlled trial

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Abstract

Background: Sore throat and hoarseness are common complications of endotracheal intubation. It may be very distressing for the patient and may lead to sleep disturbances and unpleasant memories.

Materials and Methods: This prospective double-blinded randomized control trial was aimed to determine the efficacy of prophylactic intravenous dexamethasone to reduce the incidence of postoperative sore throat at 1 hour after tracheal extubation. Ninety six patients of either sex aged between 18 to 60 years scheduled for elective surgeries needing general anesthesia with endotracheal intubation, were randomly allocated into two groups A and B. The patients received either intravenous 0.2 mg/ kg dexamethasone (group A, n = 48) or normal saline (group B, n = 47) just before induction. Trachea was intubated with appropriate size disposable endotracheal tubes for securing the airway. Follow up for the incidence of sore throat, cough and hoarseness was done at 1, 6 and 24 hours post-extubation.

Results: At 1 hour post-extubation, the incidence of sore throat in the control group was 48.9% compared with 18.8% in the dexamethasone group (P<0.002).

Conclusions: Prophylactic intravenous dexamethasone in a dose of 0.2 mg/kg can reduce the incidence of postoperative sore throat at 1 hour post-extubation by around 30%, with the efficacy being around 60%.

Key words: Intravenous dexamethasone, Intubation, Postoperative sore throat

Introduction

Sore throat and hoarseness are common complications after endotracheal intubation, with the incidence ranging from 6.6 to 90%.^[1,2] They may be distressing and leave the patient with an unpleasant memory of the operation.^[1,3] Incidence depends on various factors like age, sex, the size of the endotracheal tube, the cuff pressure, the duration for which the tube is in place, the

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time and manipulations needed to insert the tube, number of suctioning attempts^[1] and others. Studies have been performed, using azulene sulphate,^[4] ketamine gargle,^[5] steroid gels^[1] and steroid injections,^[2] to reduce the incidence of postoperative sore throat. This study was undertaken to determine the efficacy of prophylactic intravenous dexamethasone to reduce the incidence of postoperative sore throat in the population of north-east part of India.

Materials and Methods

This study was conducted over a period of around three months from June 2011 till September 2011. After obtaining the Institutional Ethics Committee's approval, 96 consenting patients of either sex, aged between 18 to 60 years, of American Society of Anesthesiologists (ASA) physical status I and II, scheduled for surgeries with an estimated duration of 45 minutes to three hours and needing general anesthesia with endotracheal intubation, were enrolled in this randomized clinical study. The enrollment was done during the preoperative check-up visit. Exclusion criteria were: 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.

A previous study found a difference in the incidence of sore throat of 30% when using dexamethasone.^[3] 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 patients were needed.

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 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 anesthesia. The drugs were prepared and administered by an anesthesiologist not involved in the study.

Anesthesia was induced with propofol 2mg/kg IV after pre-oxgenation for 3 minutes. After muscle relaxation with rocuronium, trachea was intubated by an experienced anaesthesiologist using disposable endotracheal tubes (Paramount Surgimed Ltd., New Delhi, India) (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. The number of attempts for intubation was noted. Anesthesia was maintained with nitrous oxide, oxygen and isoflurane. At the end of the operation, the oropharynx was cautiously toileted 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 1, 6 and 24 hours post-extubation, in the post-anesthesia care unit (PACU). Sore throat, cough and hoarseness were assessed using a 4-point scale [Table 1].^[1]

The satisfaction of the patient with intubation was assessed using the 7-point Likert-like verbal rating scale.^[6] All patients were followed up for 24 hours post-extubation and study ended at this time point. Patients complaining of moderate to severe sore throat after 24 hours were advised lukewarm saline gurgle and decongestant medications and those not responding to the above were referred for oto-rhino-laryngology consultation.

Data was represented as numerical (continuous and discrete) and categorical (nominal and ordinal) data. They were entered into the excel sheet and analyzed by using SPSS for windows (version 12). Independent sample *t-test* was used for analyzing numerical data and Chi-square test was utilized for analyzing categorical data.

Results

Ninety six patients were allocated into two groups of 48 each. One patient in the control group was lost to follow up as the patient was discharged on request before completing 24 hours. Forty seven patients in the group B and 48 patients in the group A were available for follow up and collection of data. Mean age of patients, sex ratio within the groups, body mass index (BMI), attempts for intubation, duration of surgery and satisfaction scores were comparable in both groups [Table 2].

At 1 hour, 6 hours and 24 hours post-extubation, the incidences of sore throat was lower in the dexamethasone group compared to control [Table 3]. 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. Though one patient had moderate sore throat at 6 hours post-extubation in the dexamethasone group compared to no patient in the control group, the difference was not significant on analysis [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 both the groups were comparable [Table 6]. No patients from both the groups developed severe degree of sore throat, cough or hoarseness of voice.

The reduction in the incidence of sore throat at 1 hour postextubation was found to be approximately 30% when using IV dexamethasone prophylactically [Table 3]. The efficacy of prophylactic IV dexamethasone to reduce sore throat at 1 hour post-extubation was calculated to be 61.2%. Positive outcome of this study can also be expressed as the number needed to treat (NNT) which was calculated to be 3.3 at 1 hour postextubation. These implied that three extra patients would need to be treated with prophylactic IV dexamethasone to prevent postoperative sore throat in one patient after 1 hour of extubation.

Discussion

The present study demonstrates that prophylactic IV dexamethasone results in a reduction of the incidence of

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

Score

Sore throat

- 0 No sore throat at any time since the operation
- 1 The patient answered in the affirmative when asked about sore throat (minimal sore throat)
- 2 The patient complained of sore throat on his/her own (moderate sore throat)
- 3 The patient is in obvious distress (severe sore throat)

Cough

- 0 No cough at any time since the operation
- 1 Minimal cough
- 2 Moderate cough
- 3 Severe cough

Hoarseness

- 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)
- 2 Moderate change in quality of speech of which the patient complains 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 <i>A</i> (<i>n</i> = 48)	Group B (n = 47)	<i>P</i> -value
Age of patient (years)	37.1±10.0	36.0±9.9	0.615
Male: Female*	16:32	17:30	0.772
BMI (kg/m2)	23.0±1.6	22.5 ± 2.0	0.185
Intubation attempts	1.3	1.3	0.982
Duration of surgery	117.4±19.9	111.8±19.3	0.17
Satisfaction scores (7-point scale)	6.0	5.9	0.758

*Categorical data, analyzed by Chi-square test. The rest are numerical data, analyzed by Independent sample t-test. Data presented as mean \pm SD.

Table 3: Incidences of sore throat between two groups at1, 6 and 24 hours post-extubation

	Group A (<i>n</i> = 48)	Group B (<i>n</i> = 47)	P-value
Incidence of sore throat at 1 hour	9 (18.8%)	23 (48.9%)	0.002
Incidence of sore throat at 6 hours	13 (27.1%)	24 (51.1%)	0.017
Incidence of sore throat at 24 hours	14 (29.2%)	21 (44.7%)	0.117

Numerical data, analyzed by Independent sample t-test.

sore throat at 1, 6 and 24 hours post-extubation. The incidences of minimal sore throat were significantly less in the dexamethasone group in first 6 hours but became comparable at 24 hours postoperatively with the control group. There was no incidence of moderate sore throat at 1 hour and 24 hours post-extubation in the dexamethasone group. Although one patient suffered from moderate sore throat at 6 hours, it was statistically insignificant. Incidence of severe degree sore throat was not found among both groups. Thus it was apparent that, even though dexamethasone caused a reduction in the

Table 4: Incidence of different grades of sore throat			
	Group A (<i>n</i> = 48)	Group B (n = 47)	<i>P</i> - value
At 1 hour post extubation			
Minimal sore throat	9 (18.8%)	20 (42.6%)	0.012
Moderate sore throat	0	3 (6.4%)	0.075
Severe sore throat	0	0	
At 6 hours post extubation			
Minimal sore throat	12 (25.0%)	24 (51.1%)	0.009
Moderate sore throat	1 (2.1%)	0	0.320
Severe sore throat	0	0	
At 24 hours postextubation			
Minimal sore throat	14 (29.2%)	14 (29.8%)	0.947
Moderate sore throat	0	7 (14.9%)	0.005
Severe sore throat	0	0	

Categorical data, analyzed by Chi-square test

	Group A $(n = 48)$	Group B $(n = 47)$	<i>P</i> - value
Incidence of cough at 1 hour	4 (8.3%)	9 (19.1%)	0.125
Incidence of cough at 6 hours	9 (18.8%)	15 (31.9%)	0.140
Incidence of cough at 24 hours	10 (20.8%)	14 (29.7%)	0.315

Numerical data, analyzed by Independent sample t-test

Table 6: Incidence of hoarseness between two groups			
	Group A (n = 48)	Group B (n = 47)	<i>P</i> - value
Incidence of hoarseness at 1 hour	1 (2.1%)	2 (4.3%)	0.545
Incidence of hoarseness at 6 hours	9 (18.8%)	6 (12.8%)	0.424
Incidence of hoarseness at 24 hours	14 (29.2%)	15 (31.9%)	0.771

Numerical data, analyzed by Independent sample t-test

incidence of sore throat at 1 and 6 hours post extubation, it did not reduce the incidence of minimal sore throat after 24 hours. However, it reduced the severity of sore throat at 24 hours post-extubation. The incidences of cough and hoarseness were also lower at all points of observation, except at 6 hours when the incidence of hoarseness increased apparently, but it was not statistically significant when analyzed. Although, we did not include patients more prone to sore throat, due to a greater degree of insults to oropharyngeal or tracheal mucosa, the observations may extend to such cases where sore throat/ hoarseness etc. may be expected, as in patients having head and neck surgery, change of position, difficult intubation with repeated attempts at intubation and bronchoscopy.

The incidence of postoperative sore throat, cough and hoarseness of voice is distressingly high (6.6-90%).^[1,2] The incidence of these post-extubation sequelae is known to be higher with the larger diameter of the tracheal tube, low volume-high pressure cuff, difficult intubation procedure or

repeated attempts, movement of the tracheal tube during the surgery, bucking/cuffing on the tube and excessive pharyngeal suctioning during extubation.^[7] Postoperative sore throat is probably mediated by an aseptic inflammatory process caused by irritation of the pharyngeal mucosa during laryngoscopy, the tracheal mucosa by the cuff of the endotracheal tube and the trauma to tissues during the process of intubation and extubation.^[3,8,9] The prophylactic use of steroids was found to reduce the incidence of sore throat and cough during recovery, probably by modifying the inflammatory process caused by tissue injury. This anti-inflammatory process includes inhibition of leukocyte migration to the inflammation site and inhibition of release of cytokines probably by maintaining cellular integrity. Fibroblast proliferation may also be inhibited.^[3,5,7,10] Dexamethasone also inhibits arachidonic acid metabolism and the production of leukotriene-B4 leading to the inhibition of interleukin-2 and moderating the inflammatory process.[11]

Park *et al.*^[3] found a decrease in incidence of sore throat at 1 hour post-extubation by 22% and 42% with prophylactic IV dexamethasone in doses of 0.1 mg/kg and 0.2 mg/kg respectively with a decrease of 30% in the incidence of sore throat at 24 hours post-extubation with IV dexamethasone 0.2 mg/kg. Thomas *et al*^[12] reported a 36.3% decrease in overall incidence of sore throat at 24 hours post-extubation with IV dexamethasone 8mg preoperatively. Others reported a decrease in incidence of sore throat at 2 hours post-extubation to the extent of 56.7% when using 0.1 mg/kg dexamethasone preoperatively.^[13] A reduction of postoperative sore throat at 6 hours have also been observed with 10mg IV dexamethasone preoperatively.^[14]

Although, there were reports of beneficial effect of steroid gel application and inhaled steroids, studies did not consistently confirm their results. Our study found a decrease in overall incidence of postoperative sore throat during first 24 hours, especially in the first hour post-extubation. We also found that the severity of postoperative sore throat was lower after prophylactic IV dexamethasone. Our study also justified the use of prophylactic IV dexamethasone for prevention of postoperative sore throat at 1 hour post-extubation (NNT = 3.3).

The limitation of this study was that we couldn't measure the cuff pressure and did not use fibre optic bronchoscope to assess the amount of tissue damage. Our study was not designed for extended follow up beyond 24 hours, as the process of acute inflammation usually peaks by 24 hours.^[15] Sore throat, hoarseness and cough cannot be assessed objectively and there are inter-individual variations and hence, a chance of bias always exists. The BMI of our patients in the two groups were comparable and we used standard sized tubes of the same manufacturer to ameliorate the possible error due to different tube size and quality.

To conclude, prophylactic intravenous dexamethasone in a dose of 0.2 mg/kg can reduce the incidence of postoperative sore throat at 1 hour post-extubation by around 30% and its efficacy to prevent sore throat is about 60%.

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