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Efficacy of dexamethasone in reducing the incidence of postoperative sore throat: a double blind randomized study

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ABSTRACT

Introductions: Postoperative sore throat (POST) is a commonly seen adverse event after general anesthesia with endotracheal intubation. Dexamethasone, a potent corticosteroid with anti-inflammatory action is the most popular steroid studied in this regard with positive results.

Methods: This randomized, prospective, double-blinded, placebo-controlled study was conducted on one hundred and ten adult patients of either sex, American Society of Anesthesiologists physical status I & II, undergoing elective surgeries requiring endotracheal tube intubation. After obtaining written informed consent, they were randomly divided into Control (A, n=55) and Dexamethasone (B, n=55) groups and received either an injection of Dexamethasone (Group B) 8 mg intravenously or an equivalent volume of Normal Saline (Group A) just before entering the operating theatre. All the patients received a similar anesthesia with endotracheal tube intubation and at the end of surgery, extubated and transferred to the post-anesthesia care unit. The incidence and severity of sore throat were assessed at 1, 6 and 24 hours post-extubation. Severity of sore throat were graded on a 4 point scale, $p < 0.05$ was considered significant.

Results: Incidence of POST in Dexamethasone group was found significantly low compared to the control group up to six hours ($p < 0.05$) but was comparable at 24 hours post extubation. Severity of POST in the study group was of lower grade in compare to control group.

Conclusions: Prophylactic intravenous Dexamethasone 8 mg administered to patients undergoing elective surgeries requiring endotracheal tube intubation significantly reduces the incidence and severity of POST up to six hours post-extubation.

Keywords: dexamethasone, general anesthesia, post-operative sore throat (POST)

INTRODUCTIONS

Postoperative sore throat (POST) is a common adverse event after general anesthesia with endotracheal tube intubation. It has a reported incidence in various studies ranging from 21 to 65%.¹⁻⁹ It eventually leads to unpleasant memories and dissatisfaction in patients.² mediated by an aseptic inflammatory process due to localized trauma to the pharyngeal, laryngeal and tracheal mucosa during the process of airway instrumentation leads to POST.⁴

Endotracheal tube (ETT) cuff designs,^{6,8} smaller sized tubes,⁷ topical lidocaine,⁹ steroid coated ETT,¹⁰ inhalation of steroid,¹¹ gargling with sodium azulene sulphate,¹² ketamine gargle^{13,14} steroid gels¹⁵ and steroid injections¹⁶⁻¹⁹ such as dexamethasone, a potent corticosteroid with anti-inflammatory property have been studied to prevent POST.

We conducted this study to determine the efficacy of prophylactic intravenous 8.0 mg of dexamethasone in attenuating POST in Nepalese population.

METHODS

This prospective, double blind, randomized, placebo-controlled study was carried out at National Academy of Medical Sciences (NAMS), Nepal, over the period of six months from January till June 2014. Study was conducted on adult subjects of 18 years of age and older of either sex; American Society of Anesthesiologists (ASA) physical status I and II; undergoing elective surgeries requiring endotracheal tube (ETT) intubation lasting 60-180 minutes.

Exclusion criteria were patients with a history of recent respiratory tract infection, difficult intubation requiring more than 3 intubating attempts with conventional laryngoscopy, oral cavity surgery, patients on steroid therapy, any contraindication/allergy to corticosteroid medications and use of nasogastric tube and throat packs.

Assuming dexamethasone reduces the incidence of POST to half¹⁸ and taking confidence interval of 95% and power of 80%, sample size was estimated as 50 patients in each group. Allowing for a dropout rate of 10%, 55 patients in each group were taken.

After pre-anesthetic check-up done by one of the researchers, informed written consent was obtained for the study. Study subjects were pre-medicated with oral diazepam (5 mg for patients weighing up to 50 kgs and 10 mg for patients more than 50 kgs) night before the surgery.

The patients were randomly divided into two groups as A (Control group, n=55) and B (Dexamethasone group, n=55) by lottery method. Randomization was done by preparing 110 sealed envelopes with 55 slips of A or 55 slips of B. All the envelopes were placed in a box and on the day of surgery one slip was withdrawn from the box for each patient to assign group A or B accordingly.

Anesthetic resident, not participating in postoperative patient evaluations, prepared the study drugs as a 4 ml clear solution in identical 5 ml syringes. Due to unavailability of trained manpower in the pre-anesthetist checkup (PAC) room, we had to take help of anesthetic resident. According to the sealed randomization code, only accessible to the anesthetic resident, patients received either an injection of Dexamethasone (Group B) 8 mg I.V. or an equivalent volume of Normal Saline (Group A) in PAC room just before entering to operation theatre. The resident was asked to maintain confidentiality and record in a note book the administered drug to the patient according to the sealed randomization code in case de-blinding was necessary. The randomized process and the identity of the study drugs were blinded from the patients, the primary researcher anesthesiologist, and the investigator who collected the postoperative data till the data analysis was started.

In the operation theatre, standard monitors including pulse oximeter, noninvasive blood

pressure, 3 lead Electrocardiogram were applied and baseline parameters recorded.

All the patients received a similar anesthesia involving premedication with midazolam 0.05mg/kg and Fentanyl 2 mcg/kg just before induction with Propofol 2 mg/kg. Orotracheal intubation was facilitated by Vecuronium Bromide 0.12 mg/kg with a single lumen high volume, low pressure ETT. Male patients received 7.5 mm internal diameter (ID) ETT and female patients received a 7 mm ID ETT. Laryngoscopy and intubation were performed by using standard 3 or 4 Macintosh laryngoscope blades. The intubation difficulty felt intubating anesthetist was recorded.

The cuff was inflated just to the point of obtaining a seal in the presence of positive airway pressure and maintaining intracuff pressure of <30 cm H₂O every 30 minutes by using a handheld cuff inflator with pressure gauge. Intraoperatively, anesthesia was maintained with O₂, Isoflurane, Fentanyl and Vecuronium. At the end of surgery, residual neuromuscular blockade was reversed with mixture of Neostigmine 0.05 mg/kg and Glycopyrrolate 0.01 mg/kg. After oropharyngeal suctioning under direct vision, extubation was done when patients could maintain their airway and obey verbal command. Any episode of coughing or straining on the tube during extubation were recorded and patient transferred to post-anesthesia care unit, where incidence and severity of sore throat were assessed at 1, 6 and 24 hours postoperatively. Severity of post-extubation sore throat was graded on 4 point scale,¹⁵ as given in the table 1.

Postoperative analgesia was provided with 15mg/Kg body wt. of intravenous

paracetamol 6 hourly and intramuscular pethidine 1 mg/kg as needed and the number of analgesic doses given was recorded. All patients were followed up for 24 hours post-extubation.

Data were represented as numerical (continuous and discrete) and categorical (nominal and ordinal) data. Data was analyzed by using SPSS ver16.0. Independent sample *t*-test were used for analyzing numerical data and Chi-square test for analyzing categorical data. P values <0.05 were considered statistically significant.

RESULTS

There were 55 patients in group A and B with no dropout in both groups. In our study, there was no significant difference in two groups, no sore throat was seen in 45 (81.8%) in group A and 47 (85.5%) group B, duration of ETT in situ was 78.60 and 76.05 mins in group A and B. Patient characteristics including factors associated with postoperative sore throat were comparable in both groups, (Table 2).

The incidence of POST was less in the Dexamethasone Group than Control. The decrease was statistically significant only up to the first 6 hours (Table 3). Regarding the severity of POST, a significant number of patients in the Dexamethasone Group had no

sore throat at all up to 6 hours post extubation. Even those who had POST in that group were of less severity than the Control Group (Table 4). None of the patients had severe sore throat during study time in the Dexamethasone Group.

Table 1. Scoring system for assessment of severity of sore throat

Score	Grading	Description
0	No sore throat	No complaint at any time since the operation
1	Minimal sore throat	Patient answers in the affirmative when asked about sore throat
2	Moderate sore throat	Patient complains of sore throat on his/her own
3	Severe sore throat	Patient is in obvious distress

Table 2. Patient characteristics including factors associated with postoperative sore throat

Variables		Group A (n=55)	Group B (n=55)	p value
Age in years (mean±SD)		42.78±10.83	46.04±7.58	0.07
Sex	Male	33 (60%)	27 (49.1%)	0.251
	Female	22 (40%)	28 (50.9%)	
ASA	I	33 (60%)	35 (63.6%)	0.695
	II	22 (40%)	20 (36.4%)	
Weight in Kg (mean±SD)		56.45±8.36	55.15±9.76	0.452
postoperative pethidine doses required in 24 hours	1 dose	0	0	0.845
	2 doses	34 (61.8%)	33 (60%)	
	3 doses	21 (31.8%)	22 (40%)	
Size of ETT	7.5 mm ID	33 (60%)	27 (49.1%)	0.251
	7.0mm ID	22 (40%)	28 (50.9%)	
No. of attempts of intubation	1	51 (92.7%)	51 (92.7%)	0.264
	2	2 (3.6%)	4 (7.3%)	
	3	2 (3.6%)	0	
Intubation difficulty encountered	No	51 (92.7%)	51 (92.7%)	1.0
	Yes	4 (7.3%)	4 (7.3%)	
Duration of ETT in situ in mins (mean±SD)		78.60±9.11	76.05±9.36	0.151
Coughing or straining during extubation	No	45 (81.8%)	47 (85.5%)	0.606
	Yes	10 (18.2%)	8 (14.5%)	

Table 3. Incidence of post-operative sore throat at 1, 6 and 24 hours post-extubation

Incidence of POST at	Group A (n=55)	Group B (n=55)	p value
1 hr	28 (50.9%)	16 (29.1%)	0.020*
6 hrs	32 (58.2%)	17 (30.9%)	0.004*
24 hrs	27 (49.1%)	18 (32.7%)	0.081

Table 4. Severity grading of post-operative sore throat at different time intervals

Severity Grading of POST	Group A (n=55)	Group B (n=55)	p Value	
at 1 hr	No sore throat	27 (49.1%)	39 (70.9%)	0.020*
	Minimal sore throat	16 (29.1%)	7 (12.7%)	0.035*
	Moderate sore throat	9 (16.4%)	9 (16.4%)	1.000
	Severe sore throat	3 (5.5%)	0	0.079
at 6 hrs	No sore throat	23 (41.8%)	38 (69.1%)	0.004*
	Minimal sore throat	26 (47.3%)	15 (27.3%)	0.030*
	Moderate sore throat	6 (10.9%)	2 (3.6%)	0.142
	Severe sore throat	0	0	
at 24 hrs	No sore throat	28 (50.9%)	37 (67.3%)	0.081
	Minimal sore throat	26 (47.3%)	18 (32.7%)	0.119
	Moderate sore throat	1 (1.8%)	0	0.315
	Severe sore throat	0	0	

DISCUSSIONS

In the present study, the incidence of POST in control group without Dexamethasone were 50.9%, 58.2% and 49.1% at 1, 6 and 24 hours post extubation respectively, similar to other studies.¹⁶⁻¹⁹ This is quite high leading to patient distress and dissatisfaction.

This study demonstrated that prophylactic intravenous dexamethasone 8 mg is effective

in reducing the incidence of POST significantly till 6 hours post extubation (29.1% in 1 hour and 30.9% in 6 hours) but had no difference at 24 hours postoperatively with the control group. Severity scores were also of less grade in the Dexamethasone group at all study periods.

Different researchers have compared the effect of various doses of dexamethasone on

POST with the control groups. Similar to our study, Bagchi D, et al.¹⁹ showed a significant reduction (approximately 30%) in the incidence of POST with prophylactic 0.2mg/kg of dexamethasone (48.9%) compared to placebo (18.8%) in the first hour of extubation. Similarly, Park et al.¹⁶ found a significant decrease in incidence of POST at 1hour post-extubation by 22% and 42% with prophylactic IV dexamethasone 0.1 mg/kg and 0.2 mg/kg respectively when compared to placebo and a 30% decrease at 24 hours post-extubation with IV dexamethasone 0.2 mg/kg. Thomas S, et al.¹⁸ reported a 36.3% decrease in incidence of sore throat at 24 hours post-extubation with IV dexamethasone 8mg preoperatively. However, in contrast to our study, Park, et al.¹⁷ found a nonsignificant difference in POST incidence but the severity was significantly less in patients receiving prophylactic dexamethasone (10 mg) 30 minutes before intubation in comparison to post intubation dexamethasone. Various rate of incidence of POST among the above mentioned studies might be due to the use of different doses of dexamethasone (0.2 mg/kg to 10.0 mg) and anesthetic techniques used such as use of double lumen tubes, constant monitoring and maintaining of ETT cuff pressure less than 30 cm of H₂O, administration of dexamethasone pre or post intubation. We standardized the contributing factors of POST,⁴ including ETT cuff design, intra-cuff pressure, type of operation, coughing or bucking on the ETT and duration of tracheal intubation. The type and dose of analgesics used during the study period were comparable between the study groups.

The mechanism of reduction of POST with systemic prophylactic steroid is probably based on its anti-inflammatory activity which includes inhibition of leukocyte migration to the inflammation site and stabilization of cell membrane integrity.^{20,21}

Single dose of systemic dexamethasone has the added benefit of prophylaxis from post-operative nausea vomiting²² but its administration might be associated with adverse events, such as glucose intolerance,

susceptibility to infections, delayed wound healing and adrenal suppression.

Sore throat is a very subjective entity resulting in a high chance of biased assessment which could be one of our limitations. Various factors such as ethnic groups, enrolled subjects level of education must be considered before objectively generalizing the incidence of POST.

CONCLUSIONS

Prophylactic administration of intravenous dexamethasone 8.0 mg can significantly reduce the incidence of POST following 24 hours of tracheal extubation. Subsequently, the severity of POST can also be reduced till six hours following extubation.

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