

## Original Research Article

# Comparative study of prophylactic dexamethasone versus placebo for reducing post-operative sore throat after tracheal intubation: a prospective, randomised, double blinded clinical study

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### ABSTRACT

**Background:** Tracheal intubation for elective surgical procedures can result in pathological changes, trauma and nerve damage which may account for postoperative sore throat, hoarseness and cough. Dexamethasone is a very potent long acting glucocorticoid with analgesic, anti-inflammatory and antiemetic effects which helps to reduce post-operative sore throat.

**Methods:** A prospective double blinded randomized study was conducted involving 80 patients, dividing them into 2 groups. Group D received dexamethasone 0.1 mg/kg and group S received an equivalent volume of normal saline (placebo) intravenously before induction. Intubation was performed by an experienced anesthesiologist. Anesthesia induction and maintenance dosage were standardized for all patients. The incidence and severity of sore throat, hoarseness and cough were recorded at 1, 6 and 24 hours postoperatively by using four-point scale.

**Results:** The overall incidence of sore throat and hoarseness was significantly reduced in dexamethasone group compared to placebo (normal saline) group. Incidence and severity of sore throat and hoarseness were assessed at 1 hour, 6 hours and 24 hours interval and found out that they were reduced in dexamethasone group compared to placebo group which was statistically significant at all intervals. But incidence and severity of cough reduced significantly only in the first hour. It was comparable at 6 and 24 hours between the groups.

**Conclusions:** Dexamethasone was effective in reducing the incidence and severity of sore throat and hoarseness at 1, 6 and 24 hours. Incidence of postoperative cough was reduced significantly at 1 hour in the dexamethasone group.

**Keywords:** Dexamethasone, Postoperative sore throat, Hoarseness, Cough, Four-point scale

### INTRODUCTION

Endotracheal intubation forms an essential part of general anesthesia to control respiration, to protect the airway and to maintain anesthesia. Almost all patients who are intubated for long or short duration surgeries, have some degree of airway injury which leads to postoperative sore throat, cough and hoarseness of voice. These are common, uncomfortable and distressing sequelae with reported incidence of 21-65%.<sup>1-3</sup> Throat irritation in the presence of an abdominal or thoracic incision can be very

distressing, since any attempt to cough causes severe pain.

It is postulated that these effects are because of irritation and mucosal injury with resulting inflammation caused by the process of airway instrumentation (i.e., laryngoscopy and suctioning) or the irritating effects of a foreign object (i.e., endotracheal tube or oral airway).<sup>2</sup> Mucous membrane of the mouth, pharynx and upper airway are sensitive to the effect of un-humidified gases, the drying effect of which may also cause postoperative

sore throat. The endotracheal cuff pressure affects tracheal mucosal capillary perfusion which can also lead to sore throat.<sup>4</sup>

A search through the literature reveals that various pharmacological methods are available to reduce the incidence of post-operative sore throat. These include use of corticosteroid, benzydamine, aspirin, local anesthetic (lidocaine), magnesium sulphate, ketamine etc.<sup>1,4-8</sup> Although these are found to be effective, some of them are associated with certain side effects. So, an inexpensive, quick, convenient and easy to administer medication with less side effects is needed to reduce post-operative sore throat. Steroids are known for their anti-inflammatory action. Dexamethasone is a very potent long acting glucocorticoid with analgesic, anti-inflammatory and antiemetic effects.<sup>9</sup> This study was conducted to assess the efficacy of prophylactic dose of dexamethasone in decreasing the incidence and severity of postoperative sore throat, hoarseness and cough.

In most cases, the symptoms resolve spontaneously without intervention, but in a few cases, they may persist. When the symptoms do occur, patients perceive them as mild to severe and often discomforting. Therefore, identification of risk factors and prevention of these symptoms would add to patient satisfaction.

## METHODS

A prospective randomized double blinded study was conducted in 80 patients scheduled for elective surgeries under general anesthesia.

### *Inclusion criteria*

- Patients belonging to ASA physical status I, II
- Patients between age 18 to 65 years
- Patients belonging to both gender
- Patients scheduled for elective surgeries lasting 60-180 minutes
- Patients with fasting blood glucose <100 mg/dl or random blood sugar <140 mg/dl.

### *Exclusion criteria*

- Patients who are not willing to give consent for participation in the study
- Patients with anticipated difficult airway
- Patients who are allergic to steroids
- Patients with ASA physical status III, IV
- Diabetic patients.
- Patients on steroids
- Patients requiring nasogastric tube or throat pack
- Patients posted for head and neck surgeries
- Obese patients with BMI >35
- Pregnant patients
- Patients with preexisting upper respiratory tract infection

- Surgeries in prone position (flexometallic ETT, throat pack)
- Patients with other systemic infection in whom steroids are contraindicated.

After obtaining approval from Institutional ethical and scientific committee, 80 patients scheduled for elective surgery under general anesthesia satisfying inclusion and exclusion criteria were included in the study and a written informed consent was obtained. Patients were randomly divided by computer generated randomization into 2 groups. Group D received dexamethasone 0.1 mg/kg and Group S received an equivalent volume of normal saline (placebo) intravenously before induction. Study drug was loaded as a 4 ml clear solution in identical syringes by an anesthesiologist who was not involved in the study. Monitoring and data entry was done by the principal investigator who was blinded to the drug.

All patients were assessed pre-operatively and were kept nil per oral for solids for 8 hours and for clear fluids for 2 hours prior to surgery and pre-medicated with oral ranitidine 150 mg and diazepam 5 mg the previous night and 2 hours before surgery. Patients were monitored by a multiparameter monitor having pulse oximetry, electrocardiograph (ECG) and non-invasive blood pressure (NIBP). Test drug was given before induction. Patients were given Inj. Glycopyrrolate 0.01 mg/kg, Inj. midazolam 0.05 mg/kg, Inj. Fentanyl 1 microgram/kg and Inj. ondansetron 4 mg/kg and induced with Inj. propofol 2 mg/kg. Orotracheal intubation was facilitated by Inj. vecuronium 0.1 mg/kg. Male patients were intubated using size 8.0 mm internal diameter (ID) ETT and female patients using size 7.5 mm ID ETT. Three minutes after induction, laryngoscopy and intubation was performed by an anesthesiologist of more than 2 years' experience, using standard 3 or 4 Macintosh metal blades. The cuff was inflated just to the point of obtaining a seal in the presence of positive airway pressure. Intracuff pressure was adjusted every 30 minutes to maintain pressure of 20-30 cm H<sub>2</sub>O by using a hand held cuff inflator with pressure gauge to limit nitrous oxide-related intracuff pressure increase. Anesthesia was maintained with N<sub>2</sub>O:O<sub>2</sub> (66%:33%), isoflurane, Inj. fentanyl and Inj. vecuronium. At the conclusion of surgery, residual neuromuscular blockade was reversed with mixture of Inj. neostigmine 0.05 mg/kg and Inj. glycopyrrolate 0.01 mg/kg. Extubation was done when patients were able to maintain their airway and obey verbal command. The number of intubation attempts, external laryngeal pressure, duration of intubation and any episode of coughing or straining on the tube at the time of intubation and extubation were recorded. It was proposed that patients requiring bougie guided intubation or more than two attempts would be excluded from the study.

The incidence and severity of sore throat, hoarseness and cough were recorded at 1, 6 and 24 hours postoperatively by using four-point scale (0-3):

**Scoring system for assessment of sore throat (Harding and Mcvey)<sup>1</sup>**

- 0: No sore throat at any time since the operation
- 1: Minimal sore throat (complains of sore throat only on asking)
- 2: Moderate sore throat (complains of sore throat on his/her own)
- 3: Severe sore throat (change in voice or hoarseness, associated with throat pain).

**Scoring system for assessment hoarseness<sup>10</sup>**

- 0: No complaint of hoarseness
- 1: Minimal change in quality of speech (noted by patient)
- 2: Moderate change in quality of speech (obvious to observer)
- 3: Gross change in the quality of speech (aphonia).

**Scoring system for assessment of cough<sup>11</sup>**

- 0: No cough or scratchy throat

- 1: Minimal scratchy throat or cough, less than noted with a cold
- 2: Moderate cough, as would be noted with a cold
- 3: Severe cough, greater than would be noted with a cold.

**Statistical analysis**

Data was entered in Microsoft excel and descriptive analysis was done for frequencies. Chi-square tests were done for the for comparison of incidence of sore throat, hoarseness of voice, cough. Mean and SD were calculated for age, BMI etc. p-value is considered significant when  $p \leq 0.05$ . Data was analyzed using SPSS version 19.0 (statistical packages for social sciences).

**RESULTS**

The age, sex, height, weight, body mass index (BMI), ASA status of the patients, smoking history, number of attempts, size of ETT, external laryngeal pressure, duration of intubation and coughing on ETT were noted and were comparable among two groups (Table 1).

**Table 1: Baseline characteristics.**

Parameters		N	Mean	Std. deviation	p-value
Age	Group D	40	40.05	11.1	0.195 (NS)
	Group S	40	43.35	11.5	
BMI	Group D	40	27.3	4.0	0.240 (NS)
	Group S	40	26.2	4.2	
Weight	Group D	40	69.2	9.8	0.075 (NS)
	Group S	40	65.2	10.1	
Height	Group D	40	159.5	6.9	0.326 (NS)
	Group S	40	158	6.4	
Duration of surgery in minutes	Group D	40	113.25	42.6	0.653 (NS)
	Group S	40	117.38	39.0	

**Table 2: Incidence of sore throat.**

	Score-sore throat		Total	p-value
	Yes	No		
Group D	13 (32.5%)	27 (67.5%)	40	0.000 (S)
Group S	29 (72.5%)	11 (27.5%)	40	
Total	42 (52.5%)	38 (47.5%)	80	

**Incidence of sore throat**

Total incidence of sore throat was 52.5% in this study group. The overall incidence of sore throat was significantly reduced in dexamethasone group (32.5%) compared to placebo (normal saline) group (72.5%) ( $p = 0.000$ ) (Table 2).

**Incidence of hoarseness of voice**

Total incidence of hoarseness was 48.8% in this study group, out of which 25% was in dexamethasone group and 72.5% was in normal saline group ( $p = 0.000$ ) as shown in Table 3.

**Table 3: Incidence of hoarseness.**

	Hoarseness		Total	p-value
	Yes	No		
Group D	10 (25%)	30 (75%)	40	0.000 (S)
Group S	29 (72.5%)	11 (27.5%)	40	
Total	39 (48.8%)	41 (51.3%)	80	

**Table 4: Incidence of cough.**

	Cough		Total	p-value
	Yes	No		
Group D	4 (35%)	36 (90%)	40	0.007 (S)
Group S	14 (65%)	26 (65%)	40	
Total	18 (22.5%)	62 (77.5%)	80	

**Table 5: Incidence comparison of sore throat, hoarseness and cough.**

Incidence	Dexamethasone group	Saline group
Sore throat	32.5%	72.5%
Hoarseness	25%	72.5%
Cough	35%	65%

**Table 6: Incidence of sore throat, hoarseness and cough at 1, 6 and 24 hours.**

Incidence	Dexamethasone group			Saline group		
	1 hour	6 hours	24 hours	1 hour	6 hours	24 hours
Sore throat	12.5%	32.0%	17.5%	55.0%	65.0%	50.0%
Hoarseness	12.5%	22.5%	12.5%	48.0%	62.5%	33.0%
Cough	5.0%	7.5%	2.5%	28.0%	20.0%	10.0%

### ***Incidence of cough***

Incidence of cough (22.5%) was less in this study compared to other postoperative airway symptoms. Only 10% of patients in dexamethasone group had cough, where as 35% of patients in normal saline group had cough postoperatively (p=0.007) as shown in Table 4.

Incidence of sore throat, hoarseness and cough was more in saline group than in dexamethasone group at 1, 6 and 24 hours. Severity was maximum at 6 hours of study period in both the groups and it gradually decreased by 24 hours.

### **DISCUSSION**

The overall incidence of sore throat was significantly reduced in dexamethasone group compared to normal saline group. Incidence of sore throat was assessed at 1, 6- and 24-hours interval and authors found that the incidence of sore throat was reduced in dexamethasone group compared to placebo group which was statistically significant at all intervals. Final outcome was comparable to the literature.

In the study done by Gupta A et al, though the overall incidence of sore throat was reduced in dexamethasone group compared to normal saline group, it was not statistically significant at 1, 6 and 24 hours.<sup>1</sup> However their study methodology did not standardize the dose of thiopentone (5-7 mg/kg), fentanyl (1-2 mcg/kg) or the size of ETT (8-8.5 mm for males and 7-7.5 mm for females) among them.

Lee SH et al, studied the effectiveness of dexamethasone in reducing incidence of sore throat and concluded that dexamethasone reduced the incidence compared to normal saline at 1, 6 and 24 hours (p 0.015, <0.001, 0.038). In this study patients were in prone position; hence the overall incidences were higher than this study population. Incidence was maximum at 1 hour, which gradually decreased by 24 hours.

Study conducted by Haider H et al, used a single dose of dexamethasone (8 mg IV) and found that 9 (22.4%) patients in the dexamethasone group had postoperative sore throat, compared to 23 (57.5%) patients in the control group (p<0.01). In this study incidence was maximum at 1 hour which gradually decreased by 24 hours.

This study showed that administration of dexamethasone (0.1 mg/kg) prophylactically considerably reduced the total incidence of sore throat at all time periods. However, the incidence of sore throat was maximum at 6 hours times period in this study population. Though most of the literature showed a definite higher incidence of sore throat at 1 hour authors were not able to observe it.<sup>2,4</sup> This could be due to the effect of potent narcotics (fentanyl and pethidine) used in this study setup which might have masked the post-operative symptoms in the immediate post-operative period.

Park SH et al, concluded that sore throat at 1 and 24 hours was reduced in dexamethasone (31%, 47%) compared to normal saline (53%, 57%).<sup>3</sup> However at 24 hours, this difference was not statistically significant. The high incidence of sore throat in this study may be due to the use of DLT which is bigger than single lumen ETT causing more airway trauma. However, the lesser incidence at 1 hour could be due to peri operative sedation and analgesia in their study.

Park SY et al, had studied the effectiveness of prophylactic and post intubation dexamethasone and showed that severity scores of sore throat and hoarseness at 1 hour and 6 hours after the operation were significantly lower in the prophylactic group than in the post intubation group ( $p=0.106$ ).<sup>12</sup> In this study also dexamethasone was given prophylactically before induction which probably helped to reduce the incidence of sore throat.

Total incidence of hoarseness was 48.8% in this study group, out of which 25% was in dexamethasone group and 72.5% was in normal saline group ( $p=0.000$ ). Considering incidence of hoarseness at different time intervals, this study had shown that the incidence of hoarseness of voice was 12.5%, 22.5% and 12.5% in dexamethasone group at 1, 6 and 24 hours compared to normal saline (48%, 62.5% and 33%) ( $p=0.000$ ) which was statistically significant.

The incidence of hoarseness of voice was comparable between dexamethasone and saline group at all time periods in the study done by Gupta A et al.<sup>1</sup> But was definitely less at 6 hours in the study conducted by Sang Lee H et al.<sup>2</sup> Maximum incidence of hoarseness of voice was at 6 hours in this study in contrast to the study conducted by Gupta A et al, and Lee SH et al, who showed maximum incidence at 1 hour. This may be also due to the effect of analgesic drugs which might have masked the post-operative symptoms in the immediate post-operative period in this study. Both the studies showed that the incidence of hoarseness reduced in both groups at 24 hours ( $p<0.05$ ) which is similar to this study.

In contrast, the study conducted by Park et al, showed maximum incidence of hoarseness at 24 hours. This may be due to the use of DLT which is bigger than ETT causing more airway trauma.

Incidence of cough (22.5%) was less in this study compared to other post-operative airway symptoms. Only 10% of patients in dexamethasone group had cough, whereas 35% of patients in normal saline group had cough post-operatively ( $p=0.007$ ). Incidence of cough was definitely less in the 1<sup>st</sup> hour in dexamethasone group ( $p=0.00$ ) and comparable between both groups in 6 and 24 hours adding more credibility to the anti-inflammatory action of dexamethasone. However, studies conducted by Gupta A et al, and Lee SH et al, showed that incidence of cough was comparable at 1, 6, and 24 hours between the groups.

Authors also compared the severity of cough using Harding and Mcvey severity grading system between two groups at 1, 6 and 24 hours and found that dexamethasone group had less severe cough at 1 hour ( $p=0.022$ ) compared to saline group. As none of the authors had studied the severity of cough in their studies, authors were unable to compare this result.

## CONCLUSION

Dexamethasone was effective in reducing the incidence and severity of sore throat and hoarseness at 1, 6 and 24 hours. Incidence of postoperative cough was reduced significantly at 1 hours in the dexamethasone group. Overall favorable outcome was comparable and better than the recent studies mentioned in the literature. Authors recommend prophylactic dexamethasone for general anesthesia cases which require tracheal intubation as it had reduced the incidence of postoperative complications like sore throat, hoarseness and cough.

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