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Original Research Article

A Prospective Randomized Double Blind Study to Evaluate Efficacy of Intravenous Dexamethasone for Postoperative Sore Throat in Patients Undergoing Surgery under General Anesthesia

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ABSTRACT

Background: administration of general anesthesia is associated with endotracheal intubation which in turn causes postoperative sore throat. Our aim was to see the effectiveness of intravenous dexamethasone in prevention of postoperative sore throat.
Methods: 100 patients of ASA physical status I and II in the age group of 18 to 70 years were divided into two groups of 50 each. Group I (dexamethasone group) received intravenous dexamethasone 8 mg in 50 mL normal saline for 10 minutes after intubation and group II (placebo group) received 50 ml of normal saline for 10 minutes after intubation. Incidence and severity of sore throat and incidence of hoarseness of voice was assessed at different study intervals postoperatively.
Results: There was statistically significant decrease in sore throat and hoarseness in dexamethasone group than placebo group (p-value<0.05).
Conclusion: Dexamethasone given intravenously reduces incidence and severity of sore throat and incidence of hoarseness caused due to endotracheal intubation.

Keywords: Dexamethasone, sore throat, hoarseness, endotracheal intubation

INTRODUCTION

For administration of general anesthesia securing of airway is an important step which is usually done by placement of endotracheal tube (ETT) or laryngeal mask airway (LMA). Placement of these airway devices has often lead to postoperative sore throat and hence addition to morbidity and patient satisfaction. [1] ETT has been found with increased incidence of sore throat than LMA or facemask. [2] The postoperative sore throat is attributed to the local irritation, inflammation and edema associated with airway instrumentation and due to reduction in the mucosal blood flow in tracheal mucosa leading to ischemic damage. [3-5] Various pharmacological and non-pharmacological methods have been tried to prevent the postoperative sore throat. Pharmacological measures include steroid jellies, intravenous steroids, benzydamine hydrochloride, aspirin, steroid inhalations used with variable outcomes. Non-pharmacological measures include low cuff pressures, less airway manipulation, lubricated ETT, small sized ETT etc. Dexamethasone is a highly selective glucocorticoid and has pluripotent action

and has proven preventive for post operative sore throat. [6, 7]

We have undertaken this study to see the effectiveness of intravenous dexamethasone in preventing postoperative sore throat by comparing incidence and severity of sore throat and incidence of hoarseness with placebo (normal saline) group.

METHODS

This randomized placebo controlled study was conducted in department of anesthesiology of a tertiary care centre and 100 patients of ASA physical status I and II in age group of 18 to 70 years were included in study after proper informed consent and approval from institutional ethical committee.

Patients with prior history of cardiovascular or renal disease, respiratory tract infection, hoarseness, sore throat and allergy to study drugs were excluded from study. On day of surgery patients were shifted to operating room on trolley and all mandatory monitors like electrocardiogram (ECG), non invasive blood pressure (NIBP) and pulse oximetry were attached after placement of an intravenous line. Technique of anesthesia was standardized for all patients.

Patients were divided into two groups of 50 each. Group I (dexamethasone group) received intravenous dexamethasone 8 mg in 50 mL normal saline for 10 minutes after intubation and group II (placebo group) received 50 ml of normal saline for 10 minutes after intubation. The drugs were prepared and administered by anaesthesiologist not involved in study. Similarly postoperative findings were also noted by anaesthesiologist not involved in study. Anesthesia was induced with propofol 2mg.kg^{-1} and fentanyl 2µg.kg^{-1} and muscle relaxation by atracurium 0.5 mg.kg^{-1}. The patient was intubated and tracheal cuff pressure was kept at 20 cm H_2O using hand held pressure gauge. Anesthesia was maintained by oxygen in nitrous oxide and isoflurane and muscle relaxation by atracurium. All the patients received morphine 3 mg and intravenous paracetamol one gram 30 minutes after tracheal intubation. Intraoperative monitoring included ECG, heart rate, pulse oximetry, capnography, and non-invasive blood pressure. After completion of surgery, neuromuscular block was reversed and extubated when adequate spontaneous ventilation is established. Oropharyngeal suction was performed under direct vision to avoid trauma to the tissues before extubation and to confirm that the clearance of secretions is complete.

The incidence and severity of postoperative sore throat and hoarseness was assessed by an anesthesiologist unaware of the group allocation, on arrival in the post anesthesia care unit at 0 h, and at 1 h, 6 h, 12 h, and 24 h thereafter. The severity of postoperative sore throat (POST), hoarseness and cough was graded on a four point scoring system (0–3) as follows:

Severity score	**Description**
Sore throat	
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 of voice, associated with throat pain).
Hoarseness	
0	No complaint of hoarseness
1	Minimal change in quality of speech (minimal hoarseness)
2	Moderate change in quality of speech (moderate hoarseness)
3	Gross change in the quality of speech (severe hoarseness)

Any complication associated with the use of dexamethasone was also assessed.

Statistical Analysis

The data thus obtained was entered into computer using Microsoft Excel. Data was analyzed using students' t-test, chi- square

test and ANOVA. A p-value of <0.05 was considered statistically significant.

RESULTS

The groups were comparable with respect to age, gender distribution and ASA status of patient [Table 1].

Table 1. Comparison of patient characteristics in two groups

Patient characteristics	Group I (n=50)	Group II (n=50)	P-value
Age(years)	47.9 ± 14.56	44.8±13.54	0.513
Gender (M/F)	24/26	29/21	0.601
ASA-PS(I/II)	35/15	41/9	0.352

Value expressed as mean ± SD, ASA-PS: American society of anesthesiologist's physical status, SD: standard deviation

At 0 hour after extubation, patients in group II (72%) had significantly higher incidence of sore throat as compared to those in group I (44%). Severity of sore throat was also more in group II and the difference was statistically significant (p value-00.015) as compared to group I [Tables 2, 3 and Fig 1]. At 1 hour after extubation, incidence of sore throat was again statistically higher in group II (72%) as compared to other group (40%) with p values of 0.001 [Table 2]. Severity of sore throat was also higher in group II than group I with a p value of 0.014 [Table 3]. Similar results were observed at rest of the study stages i.e., at 6, 12 and 24 hours after extubation [Tables 2, 3 and Fig 2,3,4]. Thus at all study stages, incidence of sore throat was less in patients receiving dexamethasone than those receiving placebo. Also, patients who developed sore throat even after receiving dexamethasone have a lesser severity of sore throat than those receiving placebo.

Table 2 Incidence of sore throat in groups at different intervals of time

Time	Group I (Dexamethasone)	Group II (Placebo)	p-value
0 h	22 (44%)	36 (72%)	0.005*
1 h	20 (40%)	36 (72%)	0.001*
6 h	14 (28%)	32 (64%)	<0.001*
12 h	8 (16%)	28 (56%)	<0.001*
24 h	4 (8%)	23 (46%)	<0.001*

Value shown as number (percentage) in which sore throat is present, *=statistically significant

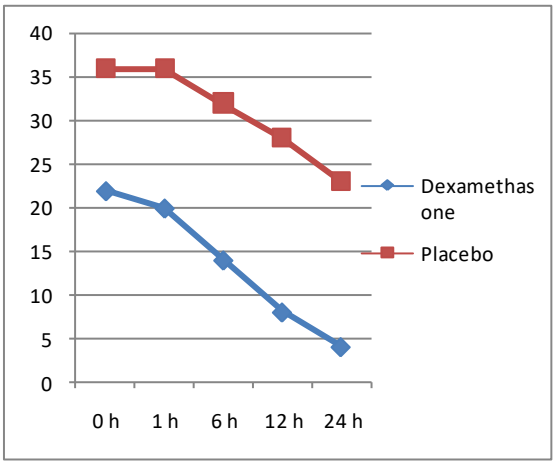

Figure 1 Incidence of sore throat in two study groups

Table 3. Comparison of severity of sore throat in two groups at different study intervals

Time	Severity	Group I (Dexamethasone)	Group II (Placebo)	p-value
0 h	Mild	14 (28%)	7 (14%)	0.015*
	Moderate	7 (14%)	17 (34%)	
	Severe	1 (2%)	12 (24%)	
1 h	Mild	13 (26%)	7 (14%)	0.014*
	Moderate	6 (12%)	17 (34%)	
	Severe	1 (2%)	12 (24%)	
6 h	Mild	11 (22%)	9 (18%)	0.023*
	Moderate	3 (6%)	15 (30%)	
	Severe	0 (0%)	10 (20%)	
12 h	Mild	6 (12%)	9 (18%)	0.044*
	Moderate	2 (4%)	14 (28%)	
	Severe	0 (0%)	8 (16%)	
24 h	Mild	3 (6%)	8 (16%)	0.041*
	Moderate	1 (2%)	14 (28%)	
	Severe	0 (0%)	6 (12%)	

*-statistically significant, values shown as number (percentage)

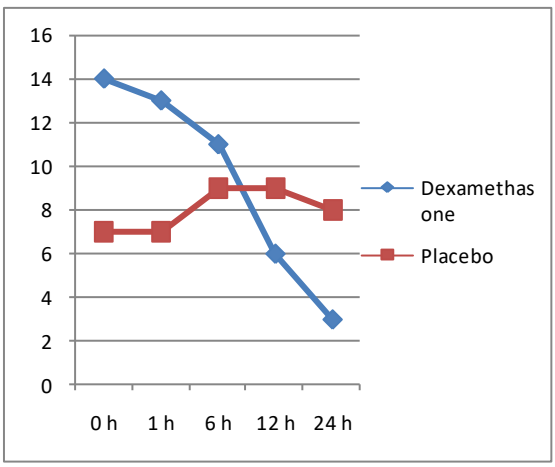

Figure 2 Number of patients having mild sore throat at different study intervals in two groups.

Incidence of hoarseness at 0 hour post-extubation was less in patients receiving dexamethasone (50%) than those receiving placebo (76%) and was statistically significant with p-value of 0.007 [Table 4].

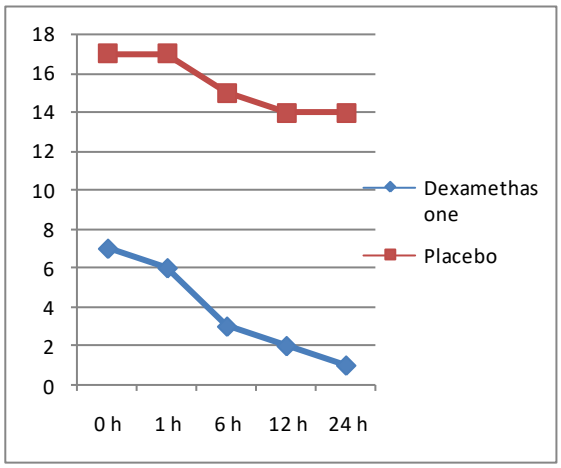

Figure 3 Number of patients having moderate sore throat at different study intervals in two groups.

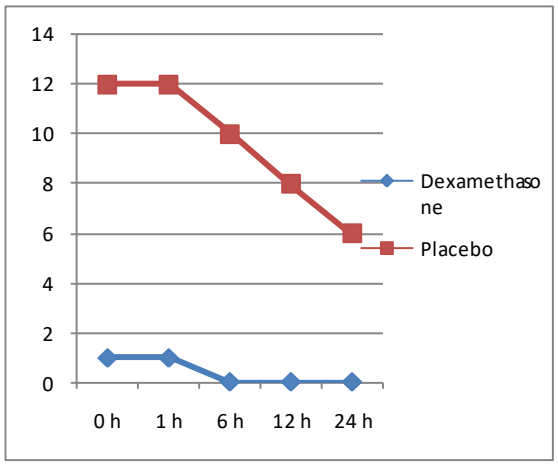

Figure 4 Number of patients having severe sore throat at different intervals in two groups.

Similar results were seen at rest of study stages with incidence of hoarseness being higher in placebo group at all stages than dexamethasone group [Table 4 and Fig 5]. The results suggest that dexamethasone is effective in reducing incidence of post-extubation hoarseness of voice.

Table 4. Incidence of hoarseness in groups at different intervals of time

Time	Group I (Dexamethasone)	Group II (Placebo)	p-value
0 h	25 (50%)	38 (76%)	0.007*
1 h	23 (46%)	37 (74%)	0.004*
6 h	19 (38%)	35 (70%)	0.002*
12 h	9 (18%)	28 (56%)	<0.001*
24 h	5 (10%)	24 (48%)	<0.001*

Value shown as number (percentage) in which hoarseness is present, *=statistically significant

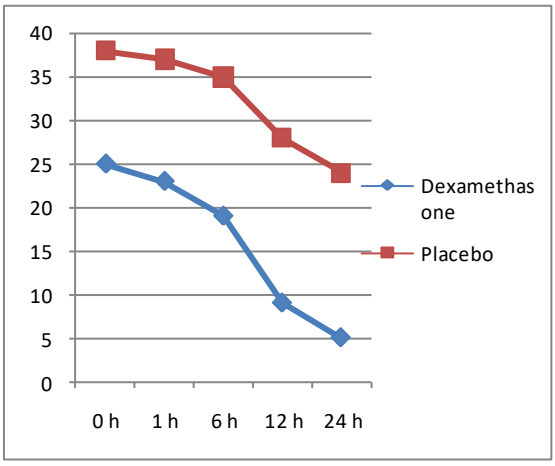

Figure 5 Incidence of hoarseness of voice in two study groups

DISCUSSION

Attenuation of postoperative sore throat (POST) is an important goal in postoperative period as it effects the satisfaction of patient and quality of life at the time of discharge from hospital. [2,8,9] So, various measures are tried to prevent it.

In our prospective, randomized, double blind, placebo controlled study two groups were comparable with respect to age, gender distribution and ASA status of patients (Table 1). Similar results were in studies done by Park JH et al (2015), [10] Bagchi et al. (2012), [11] Park SH et al. (2008) [6] and Thomas S et al (2007). [7]

Incidence and severity of sore throat in placebo group was much more than dexamethasone group and was statistically significant at 0 h, 1 h, 2 h, 6 h, 12 h and 24 h. This shows dexamethasone 8 mg is effective in reducing incidence and severity of postoperative sore throat and is superior to normal saline given as placebo.

Our results are also in concordance with the study conducted by Park SH et al (2008). [6] They conducted a prospective, randomized, double blind, placebo controlled study to evaluate the efficacy of dexamethasone for reducing the incidence and severity of postoperative sore throat and hoarseness. One hundred and sixty-six patients (aged 18-75years) were included in the study. They concluded that prophylactic use of 0.2mg/kg of dexamethasone significantly decreases the incidence and

severity and hoarseness at 1hr and 24 hrs after extubation as compared to the placebo group.

Our results also correlate with studies by Bagchi D et al (2012) [11] who concluded that prophylactic intravenous dexamethasone in a dose of 0.2mg/kg can reduce the incidence of postoperative sore throat as compared to the placebo group. Our findings are also similar to study conducted by Thomas S et al (2007) [7] who in their randomized, double blind and placebo controlled study, they concluded that preoperative administration of dexamethasone 8mg intravenously reduces the incidence and severity of postoperative sore throat in patients receiving general anesthesia with endotracheal intubation as compared to the placebo group. Another meta-analysis conducted by Sun L et al (2014) [12] suggested that intravenous dexamethasone reduces the risk and severity of postoperative sore throat from intubation at 24 hours. They suggested that effective dose of dexamethasone for prevention of POST to be 0.1mg/kg.

In our study we found hoarseness of voice was less in dexamethasone as compared to placebo group. So we found that dexamethasone 8 mg is efficacious in reducing the incidence of hoarseness as compared to normal saline used as placebo. Our results are in concordance with the study conducted by Park JH et al (2008) [10] who found dexamethasone and magnesium sulphate to be effective for prevention of post extubation hoarseness. Results also correlate with the study conducted by Park SH et al (2008) [6] who found that prophylactic use of 0.2 mg/kg dexamethasone significantly decreases the incidence of postoperative hoarseness at 1 and 24 hours after extubation. Lee SH et al (2016) [13] also found that dexamethasone in a dose of 0.2 mg/kg decreased the incidence of hoarseness in patients undergoing prone position surgery.

Limitations: our study parameters were to be enquired from the patients and hence subject to bias. Also long term follow up of patients was not done.

CONCLUSION

Postoperative sore throat and hoarseness of voice are associated with endotracheal intubation. Intravenous dexamethasone 8 mg reduces the incidence and severity of postoperative sore throat compared to placebo. It also reduces the incidence of postoperative hoarseness compared to placebo.

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Conflicts of interest: There are no conflicts of interest.

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