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Original Research Article

Efficacy of prophylactic intravenous dexamethasone on postoperative laryngotracheal symptoms after orotracheal extubation: A randomized study

Smitha S[1,*]

[1] *Dept. of Anaesthesiology, SS Institute Of Medical Sciences, Davanagere, Karnataka, India*

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ABSTRACT

Background: Postoperative sore throat (POST) is not an uncommon complaint and has been described as one of the most undesirable outcomes during the postoperative period after orotracheal extubation, because it adversely affects the patient satisfaction and activities after discharge from hospital. Cough and hoarseness are other problems that follow intubation. The objective of this study was to determine the efficacy of prophylactic intravenous dexamethasone in reducing post postoperative sore throat, cough and hoarseness of voice in patients operated under general anaesthesia with orotracheal intubation.
Materials and Methods: After obtaining approval from hospital ethical committee and informed consent from the patients. The patients were divided in to two groups of 40 each. Group C- patients who received a placebo (normal saline) Group D- patients who received a treatment drug (dexamethasone). Assessment of patients for post-operative sore throat, cough, and hoarseness of voice at 1, 6 and, 24 hours after surgery will be carried out by the investigator and anaesthesiologist in charge of the post anaesthesia care unit, who is blinded to the group allocation, using the questionnaire.
Results : There was significant reduction in scores of postoperative sore throat and cough in 1^{st} postoperative hour ($p<0.005$) than in 6^{th} and 24 hours in comparison with placebo group (group C).
Conclusion: from the present study, it can be concluded that prophylactic iv dexamethasone administration significantly reduces postoperative sore throat, cough when compared to control groups.

1. Introduction

The trachea extends from the inferior border of the cricoid cartilage to the level of the T6, where it splits into the left and right main stem bronchus. The trachea is 12-15 cms long in the average adult and is composed of C-shaped cartilages joined vertically by fibroelastic tissue and completed posteriorly by the vertical trachealis muscle.[1]

Endotracheal intubation is a routine part of delivering anaesthetic gases and vapours to the patients undergoing surgeries, it is not without risks. Postoperative sore throat (POST) is not an uncommon complaint, and has been described as one of the most undesirable outcomesduring the postoperative period, because it adversely affects the patient satisfaction and activities after discharge from hospital.

Cough and hoarseness are other problems that follow intubation. Although these are minor sequelae, they are very distressing to the patients. The incidence of postoperative sore throat ranges from 40 to 90%.

Incidence of POST depends on various factors such as female sex, history of smoking or lung diseases, postoperative nausea, the size of the endotracheal tube, the cuff pressure and design, and the time and manipulations needed to insert the tube.

* *Corresponding author*.
E-mail address: smithamurthy.092@gmail.com (Smitha S).

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Other factors which were identified to correlate with occurrence of these complications, includes irritation and inflammation of the airway, traumatization of airway mucosa, tracheal mucosal hypo perfusion induced by pressure, tracheal tube contact with vocal cords, and lastly duration of surgery.[2]

Various interventions have been introduced to reduce postoperative throat complaints, such as use of smaller size endotracheal tubes, lower intracuff pressure, application of topical lidocaine along with steroid coated tubes like application of betamethasone gel which has a anti-inflammatory role,[3] Azulene sulphate, Ketamine gargle.[4,5]

Dexamethasone is a potent corticosteroid with analgesic, anti-inflammatory, and antiemetic effects. Recent studies indicated that prophylactic dexamethasone may be an effective method for the prevention of POST and it also showed to offer analgesic, anti-inflammatory effects and also has antiemetic action, furthermore this intervention has reduced the severity of sore throat and hoarseness in patients receiving general anaesthesia and have potential quality of recovery after tracheal extubation.

This prospective randomized clinical study aimed to determine the efficacy of prophylactic intravenous dexamethasone in reducing postoperative sore throat, hoarseness and cough during the first 24 post-operative hours after elective surgical procedures in patients under general anaesthesia after oro-tracheal extubation.

2. Objectives

To determine the efficacy of prophylactic intravenous dexamethasone in reducing postoperative sore throat, cough and hoarseness of voice in patients operated under general anaesthesia with orotracheal intubation.

3. Materials and Methods

3.1. Study Design

Prospective, randomized, comparative study.

3.2. Study area

Department of Anaesthesia,

3.3. Study Period

Aug. 2016 – July 2020.

3.4. Study population

Patient between 18 to 55 years' age group of both genders, scheduled to undergo elective surgery under general anesthesia.

3.5. Sample size

Study consisted a total of 80 cases.

3.6. Inclusion criteria

Adults with

1. Age group: 18- 55 years.
2. Physical status ASA class I-II.
3. Undergoing elective surgeries under general anaesthesia with endotracheal intubation.
4. Duration of surgery <120 minutes.

3.7. Exclusion criteria

1. Surgeries of oral cavity and pharynx or with anticipated difficult airway.
2. More than 2 attempts at intubation.
3. Use of nasogastric tube or throat packs
4. Patients with sore throat, cough, hoarseness of voice.
5. Patients on steroid therapy.
6. Obstetrics patients.
7. Surgeries more than 120 minutes.

3.8. Ethical consideration

Institutional Ethical committee permission was taken prior to the commencement of the study.

3.9. Study tools and data collection procedure

Randomization was done by generating random numbers using computer software, the generated random number will be written on chits of similar size and shape, which are labelled with treatment (dexamethasone) group and control (placebo) group alternatively, these chits was placed in a sealed envelope, and Patient was asked to pick the chit and hand over to the nursing assistant who was not blind to the study, and the same nursing assistant helped in loading treatment drug (dexamethasone) and placebo (normal saline) in 2 different syringes which was not labelled and the same was handed over to the investigator who is blind, to administer preoperatively to the patient who is blind as per allocation , Thus randomization of study subjects into treatment group and control group by allocation concealment and double-blind was achieved. The patients have received either dexamethasone or normal saline as per allocation.

The patients were allocated in to two groups of 40 each (group C and group D).

Group C- patients who received a placebo (normal saline).

Group D- patients who received a treatment drug (dexamethasone).

Patients were explained about the procedure and informed consent/written consent was obtained. During routine preanesthetic evaluation patients were told that postoperatively sore throat, Cough and hoarseness would be assessed at 1st, 6 and 24 hours.

3.10. Statistical analysis

All statistical procedures were performed with SPSS 16 statistical software. Descriptive statistics were used to characterize the basic data of the sample. Difference in the two groups on clinical details were assessed using student t test(unpaired t test). Statistical level of significance was set at P <0.005 and P<0.001 as highly significant.

4. Observations & Results

There was no significant difference in age distribution between the groups. The mean age in both the study group was 39 and 38.75 years, respectively. There was no statistically significant difference in terms of age between the two groups. Similar findings were seen with the duration of surgery, with mean being 85 and 78 years in group D and C, respectively, which was not significant.Table 2

Regarding gender, both groups showed similar distribution.

Out of 80 samples, about 54 (67.5%) were ASA 1 and 26 (32.4%) of them were ASA 2. There was no statistically significant difference in ASA grading between the groups.Table 3

In the post-operative period first hour, patients in the dexamethasone group had no or minimal sore throat as compared to the control group. These results were statistically significant. 15 patients (37.5%) in group D had minimal sore throat when compared with that of 28 patients (70%) in group C who had minimal sore throat at 1st postoperative hour.Table 4

At the end of 6 hours postoperative, 30(75%) patients in the dexamethasone group had no sore throat, as compared to 21(52.5%) in the control group. Minimal sore throat was seen among 10(25%) in the dexamethasone group and 19(47.5%) patients in the control group. None of the patients in either group had moderate or severe sore throat at the end of 6 hours. However, these values were not statistically significant.Table 5

There was no statistically significant difference in the incidence of sore throat in both dexamethasone and control group (group C) where 40 patients (100%) in group D had no sore throat compared with that of control group. Only 3 patients (7.5%) in group C had minimal sore throat at 24^{th} postoperative hour.Table 6

The Table 6, depicts that 34(85%) of patients in the dexamethasone group had no cough at the end of first hour. However, in the control group, the number of patients with no cough was 18(45%). These values were statistically significant.

There was no statistically significant difference in cough between the two groups at the end of six hours. Only 3 patients (7.5%) in group D had minimal cough when compared with that of five patients (12.5%) in group C who had minimal cough at 6^{th} postoperative hour.Table 7

At post-operative 24 hours, the incidences of cough between the two groups were similar. It was not significant. There was 1 patient in group C who had minimal cough at postoperative 24 hours.Table 8

The occurrence of hoarseness of voice at the end of first hour was reduced in the dexamethasone group (92.5%), as compared to the control group (70%). However, these results were not statistically significant. There were 3 patients (7.5%) in group D who had no hoarseness at the time of interval when compared with that of 12 patients (30%) in group C who had no evidence of hoarseness at 1^{st} postoperative hour at the time of interval.Table 9

There was no statistically significant difference in hoarseness in either group at the end of one, 6 and 24 hours postoperatively, where 39(97.5%) patients in group D had no hoarseness compared with that of control group, with 38(95%). There was 1 patient (2.5%) in group D had no hoarseness at the time of interval when compared with that of 2 patients (5%) in group C who had no evidence of hoarseness at 6^{th} postoperative hour at the time of interval.

There was no difference in hoarseness of voice in both the groups after 24 hours.

5. Discussion

Endo tracheal intubation is the placement of a flexible tube into the trachea to maintain an open airway or acts as a conduit through which to administer anaesthetic gases and vapours.

The most frequent side effect of intubation is sore throat with a reported incidence ranging from 24% to 90%. The important factors which affect the incidence of post intubation sore throat are irritation and inflammation of the airway, trauma to the airway mucosa, cuff design, cuff pressure, tube size and lubricants used. The other common side effects are postoperative cough and hoarseness of voice. Although the exact pathophysiologic mechanism responsible for post intubation throat complaints are not elucidated, mucosal damage to the trachea and pressure induced tracheal mucosal capillary hypo perfusion are thought to be the causative factors for tracheal morbidity.[5]

Coughing during emergence from general anaesthesia is a big concern and the goal of an anaesthesiologist should be smooth emergence with minimal coughing. Coughing during emergence probably results from irritation of the respiratory mucosa by the endotracheal tube and its cuff. Coughing could result in sore throat, tachycardia, increased BP, arrhythmias and precipitation of myocardial ischemia in patients with coronary artery disease. It also causes increased intra thoracic, intraabdominal pressure with consequent increase in venous pressure which in turn leads to increased bleeding from wound site, increased intra cranial and intra ocular pressure.[5,6]

Hoarseness is another problem which makes the patient distressed. It indicates some amount of vocal cord injury

Table 1: Showing age distribution

Age (in years)	Drug/Placebo		Total	p value
	Group D	Group C		
<20	3 7.5%	4 10.0%	7 8.8%	0.216
21-30	10 25.0%	6 15.0%	16 20.0%	
31-40	10 25.0%	13 32.5%	23 28.8%	
41-50	6 15.0%	12 30.0%	18 22.5%	
51-60	11 27.5%	5 12.5%	16 20.0%	
Total	40 100.0%	40 100.0%	80 100.0%	

Table 2: Showing sex distribution

Sex	Drug/Placebo		Total	p value
	Group D	Group C		
Male	13 32.5%	15 37.5%	28 35.0%	0.639
Female	27 67.5%	25 62.5%	52 65.0%	
Total	40 100.0%	40 100.0%	80 100.0%	

Table 3: Sorethroat at post operative 1^{st} hour

Sore Throat Postoperative1st hour	Group		Total	p value
	Group D	Group C		
No Sore Throat	25 (62.5%)	11 (27.5%)	36 (45.0%)	0.002
Minimal Sore Throat	15 (37.5%)	28 (70.0%)	43 (53.8%)	0.003
Moderate Sore Throat	0 (0.0%)	1 (2.5%)	1 (1.3%)	0.314
Severe Sore Throat	0	0	0	-

Table 4: Sorethroat at post operative 6^{th} hour

Sore Throat Postoperative 6 hours	Group		Total	p value
	Group D	Group C		
No Sore Throat	30 (75.0%)	21 (52.5%)	51 (63.8%)	0.036
Minimal Sore Throat	10 (25.0%)	19 (47.5%)	29 (36.3%)	0.036
Moderate Sore Throat	0	0	0	-
Severe Sore Throat	0	0	0	-

Table 5: Sorethroat at post operative 24 hours

Sore Throat Postoperative 24 hours	Group		Total	p value
	Group D	Group C		
No Sore Throat	40 (100.0%)	37 (92.5%)	77 (77.3%)	0.077
Minimal Sore Throat	0	3 (7.5%)	3 (3.8%)	0.077
Moderate Sore Throat	0	0	0	-
Severe Sore Throat	0	0	0	-

Table 6: Cough at post operative 1^{st} Hour

Cough Postoperative1st hour	Group		Total	p value
	Group D	Group C		
No Cough	34 (85.0%)	18 (45.0%)	52 (65.0%)	0.001
Minimal Cough	6 (15.0%)	22 (55.0%)	28 (35.0%)	0.001
Moderate Cough	0.00	0.00	0.00	-
Severe Cough	0.00	0.00	0.00	-

Table 7: Cough at post operative 6 hours

Cough Postoperative 6 hours	Group		Total	p value
	Group D	Group C		
No Cough	37 (92.5%)	35 (87.5%)	72 (90.0%)	0.456
Minimal Cough	3 (7.5%)	5 (12.5%)	8 (10.0%)	0.456
Moderate Cough	0.00	0.00	0.00	-
Severe Cough	0.00	0.00	0.00	-

Table 8: Cough at post operative 24 hours

Cough Postoperative 24 hours	Group		Total	p value
	Group D	Group C		
No Cough	40 (100.0%)	39 (97.5%)	79 (98.8%)	0.314
Minimal Cough	0 (0.0%)	1 (2.5%)	1 (1.3%)	0.314
Moderate Cough	0.00	0.00	0.00	-
Severe Cough	0.00	0.00	0.00	-

Table 9: Hoarseness at post operative 1^{st} hour

Hoarseness Postoperative 1st hour	Group		Total	p value
	Group D	Group C		
No hoarseness	37 (92.5%)	28 (70.0%)	65 (81.3%)	0.009
No evidence of hoarseness at the time of interview	3 (7.5%)	12 (30.0%)	15 (18.8%)	0.009
Hoarseness at the time of interview noted by patient only	0.00	0.00	0.00	
Hoarseness easily noted at the time of interview	0.00	0.00	0.00	

Table 10: Hoarseness at post operative 6 hours

Hoarseness Postoperative 6 hours	Group		Total	p value
	Group D	Group C		
No hoarseness	39 (97.5%)	38 (95.0%)	77 (96.3%)	0.556
No evidence of hoarseness at the time of interview	1 (2.5%)	2 (5.0%)	3 (3.8%)	0.556
Hoarseness at the time of interview noted by patient only	0.00	0.00	0.00	-
Hoarseness easily noted at the time of interview	0.00	0.00	0.00	-

Table 11: Hoarseness at post operative 24 hours

Hoarseness Postoperative 24 hour	Group		Total	P value
	Group D	Group C		
No hoarseness	**40 (100.0%)**	**40 (100.0%)**	**80 (100.0%)**	**-**
No evidence of hoarseness at the time of interview	0.00	0.00	0.00	-
Hoarseness at the time of interview noted by patient only	0.00	0.00	0.00	-
Hoarseness easily noted at the time of interview	0.00	0.00	0.00	-

because of tracheal tube size. Blocking of these receptors can decrease the postoperative sore throat, cough and other post intubation problems.[7,8]

Dexamethasone, with its potent immunomodulatory effects, has been used to reduce inflammation and tissue damage in a variety of clinical settings.[9] The efficacy of dexamethasone in reducing pain and inflammation after surgery has also been explored.[10] Previous studies demonstrated that dexamethasone can be safely used for the prevention of postoperative nausea and vomiting (PONV).

Our effort was to study the efficacy of prophylactic intravenous dexamethasone (8mg) on postoperative larngotracheal symptoms after orotrachealextubation., and we found that there is significant reduction of sorethroat and cough in postoperative 1^{st} hour than in 6 and 24 hours compared to control groups.Study byDipanjanBagchi et al[11] also showed that prophylactic administration of IV dexamethasone at 0.2mg/kg has shown beneficial analgesic, anti-inflammatory andantiemetic actions. Its prophylactic use significantly decreased the incidence of sore throat after extubation in dexamethasone group in comparison with control groups who received normal saline in a randomized controlled study.

The demographic profile of the patients was similar in both groups. There wasno difference between both the groups with respect to the type of surgery, duration of surgery and the anaesthetic management.

Our study showed there was a significant decrease in the mean scores for sore throat and cough in the dexamethasone group at 1^{st} postoperative hour than in 6, and 24 hours in comparison to control groups [P value <0.05], indicating a decrease in the severity of postoperative sore throat in the dexamethasone group mainly in 1^{st} postoperative hour parameters were considered significant when p value is <0.05.

Previous studies by Shiji Thomas et al[12]who did a randomized study and found that overall incidence of postoperative sore throat during first 24hr following surgery was lower in group who received preoperative intravenous dexamethasone 8mg compared to control group. postoperatively at one hour, six hours,12 hours and 24 hours, the VAS scores for postoperative sore throat at rest and during effort were lower in the dexamethasone group compared to control group(p<0.01) at corresponding time interval.

In our study we used iv dexamethasone in comparison with control groups who received normal saline, where patients who received dexamethasone had significant reduction of sorethroat and cough in postoperative 1^{st} hour.

MasoomehTabari et al[13] conducted a study to compare the effectiveness of betamethasone gel applied to the tracheal tube and intravenous Dexamethasone on postoperative sore throat.

Soltani and Agadhavoudi et al (2002)[14] conducted a study to evaluate the effectiveness of various ways of lidocaine application in reducing postoperative sore throat and coughconcluded that the most effective methods to decrease postoperative sore throat and cough were intra cuff lidocaine and IV Lidocaine. Lubrication with 2 % lidocaine jelly was associated with highest frequency of cough and sore throat which was greater than that in the control group.

Asif Kazemi et al (2007)[15]conducted a study to evaluate the effectiveness of betamethasone gel in reducing sore throat cough and hoarseness after laryngotracheal intubation, recommended lubrication of all parts of tracheal tube that is in contact with posterior pharynx, larynx and trachea with betamethasone gel in order to reduce cough, hoarseness and sore throat.

Shiji Thomas et al[16] found that overall incidence of postoperative sore throat during first 24hr following surgery was lower in group who received preoperative intravenous dexamethasone 8mg compared to control group.PA Sumathi et al (2008)[17] concluded that betamethasone gel applied widely over endotracheal tube effectively mitigates postoperative sore throat, cough and hoarseness compared with lidocaine jelly. Sang-Hyun et al (2008)[18] found that the prophylactic use of 0.2mg/kg of dexamethasone significantly decreases the incidence and severity of sore throat at1hr and 24hr after tracheal extubation with double-lumen tube. Dipanjan Bagchi et al(2012)[11]concluded that prophylactic intravenous dexamethasone in a dose of 0.2 mg/kg can reduce the incidence of post-operative sore throat at 1-hour post extubation by around 30%, with the efficacy being around 60%. The role of dexamethasone in our study made a significant reduction of vas scores in postoperative sore throat and cough similar to the above mentioned studies.

6. Conclusion

From the present study, it can be concluded that prophylactic iv dexamethasone administration significantly reduces postoperative sore throat and cough when compared to control groups in postoperative 1^{st} hour.

7. Conflict of Interest

There are no conflicts of interest in this article.

8. Source of Funding

None.

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Author biography

Smitha S, Critical Care Fellow

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