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Original Research Article

Comparison of Effectiveness of Preoperative Nebulized Dexamethasone versus Ketamine on Attenuating Occurrence and Severity of Post-Operative Sore Throat following Endotracheal Intubation in Patients Under General Anaesthesia Prospective Double Blind Randomized Control Trial

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Abstract:

Background and Objective: General Anaesthesia with endotracheal intubation is a frequent cause of airway mucosal trauma which results in the post-operative sore throat (POST) with an incidence of 21-65 %. Although minor and self-limiting complication, it produces significant discomfort and annoyance to the patient. This study was aimed to compare the efficacy of nebulized dexamethasone versus ketamine in preventing POST.

Material and Methods: Present study included 60 patients of ASA I to II, posted for general anaesthesia with endotracheal intubation. Patients were divided into two groups of 30 patients each. Around 15 min prior to the intubation, patients of Group K were nebulised with ketamine (50 mg) and patients of Group D were nebulised with dexamethasone (8 mg). Pulse rate and mean arterial pressure were recorded at specific time intervals. Occurrence and severity of POST, Occurrence of PONV and Post-operative cough were assessed post operatively at specific time intervals.

Results: occurrence of POST was significantly less in Group D as compared to Group K at 2,4 and 6th hour postoperatively (p value <0.05). severity of POST was significantly less in Group D as compared to Group K at 2nd ,4th and 6th hour post operatively (p value<0.05). Although, statistically insignificant PONV is less in Group D compared to Group K. Regarding post-operative cough, it was comparable at 0, 2nd, 4th, 12th and 24 hr post operatively. No patients have experienced hoarseness of voice. Hemodynamic parameters like pulse rate and mean arterial pressure were comparable in both the groups.

Conclusion: Pre-operative single dose of nebulized dexamethasone 8 mg effectively attenuates occurrence and severity of POST, with stable hemodynamics following GA with endotracheal intubation than nebulized ketamine 50 mg. Pre-operative single dose of nebulized dexamethasone 8 mg reduces occurrence of PONV and post-operative cough following GA with endotracheal intubation than nebulized ketamine 50 mg.

Keywords: Dexamethasone, General Anaesthesia, Intubation, Ketamine, Nebulisation, Sore throat.

Introduction

Post-operative sore throat (POST) is ranked 8th undesirable side effects by American Anaesthesiologist following general anaesthesia. [1] Post-operative sore throat is a usual complain following endotracheal intubation results into significant anguish and annoyance to the patient with incidence ranging from 21 to 65%). [2,3]

In this era of quality care factors responsible for post-operative morbidity and patient dissatisfaction have to be taken care of. Post-operative sore throat (POST) is common occurrence following general anaesthesia and although clinicians often regard it as a relatively minor complication. [4] Postoperative sore throat has the potential to not only diminish patient satisfaction, but also increase the need for adjunct pain therapy in the post anaesthesia care unit. [5] Although the symptoms resolve spontaneously without any treatment, prophylactic management for decreasing its frequency and severity is still recommended. [6]

Instrumentations of the airway (tracheal intubation) are the foremost cause of trauma to the pharyngeal and tracheal mucosa, resulting irritation and inflammation of the airway and it will cause

postoperative sore throat. [7] Lack of airway humidity, suctioning, high anaesthetic air flow rates and surgical manipulation of airway and adjacent tissue are possibly the other contributing factors for POST. The high variability of incidence (21 to 60%) is due to a large number of factors implicated in POST such as type of airway device, technique of insertion, use/type of lubricant, airway design, cuff pressure, length of procedure, anaesthesia administered, and a multitude of patient features. The occurrence is the highest with tracheal tube insertion (45.4%) followed by patients with laryngeal mask airway insertion (17.5%), while patients with facemask have the lowest occurrence of sore throat (3.3%).

Recently, quality assurance of anaesthesia has become increasingly important for improving postoperative sore throat so various pharmacological and non-pharmacological trials have been used for attenuating postoperative sore throat with variable success. Pharmacological measures include use of beclomethasone inhalation, gargling with azulene sulfonate, and local spray with lidocaine and intracuff administration of alkalized lignocaine, topical methylprednisolone, diclofenac patch, transdermal ketoprofen, and application of triamcinolone acetonide paste. [8] Non pharmacological measures include use of smaller sized endotracheal tubes, lubricating the endotracheal tube with water soluble jelly, careful airway instrumentations, intubation after full relaxation, gentle oropharyngeal suctioning, minimizing intra-cuff pressure and extubation when the tracheal tube cuff is fully deflated. [9]

It is well known that NMDA (N-Methyl-D-Aspartate) receptor plays key role in inflammation and nociceptive pathway. [10] Ketamine is an NMDA receptor antagonist which is used for decreasing POST because of its anti-inflammatory and anti-nociceptive pathway action as gargle as well as in nebulised form.

The topical effect of ketamine nebulisation that attenuated the local inflammation and also due to peripheral analgesic effect. Ketamine is bitter in taste so nebulised ketamine is well tolerated and is convenient to the patient. Ketamine in gargle form requires large dose as compared to nebulised form. Steroids are preferred in common practice because of its potential anti-inflammatory activity. The inhaled corticosteroids deliver the drug to the site of action where it is used in patients with airway diseases without producing systemic effects. [11,12]

Dexamethasone is a potent synthetic glucocorticoid anti-inflammatory drug. It is a potent, long-acting synthetic steroid with anti-inflammatory effects, superior to other steroids. It has been reported that dexamethasone is effective in the treatment of sore throat. [12] In the prospective randomised clinical trial, we try to compare the effectiveness of both these drugs in reducing incidence and severity of post-operative sore throat and to conclude that which drug is better or having same effect.

Material and Methods

The Present Prospective Double blind Randomized control trial was conducted at Sir Takhtasinhji hospital, Bhavnagar for the duration of 1 year. The necessary permission of Institutional Ethics committee (IEC), Government medical college, Bhavnagar was obtained prior to the commencement of study. The study was registered in Clinical Trials Registry (CTRI) India. Total 60 patients were screened for eligibility to participate in the study considering the inclusion and exclusion criteria.

Inclusion criteria: The study included total of 60 patients undergoing general anaesthesia following endotracheal intubation age range from 18 to 65 years of either sex with ASA I and II.

Exclusion criteria:

- Patients with pre preoperative sore throat, upper respiratory tract infection, chronic obstructive pulmonary disease (COPD), bronchial asthma.
- Immunocompromised patients or patients on long term use of immunosuppressants
- Current use of corticosteroids or NSAIDS
- Patient with risk factor for post-operative aspiration like obese, diabetic patients.
- Allergy to study drug
- Patient with preoperative cough, hoarseness of voice, require > 1 attempt of intubation, Mallam Pati grade > 2 were excluded from the study.

All the patients were provided with patient information sheet and written informed consent was taken from patients. They were divided into two group Group-K or Group-D by computer generated programmes. Randomisation was performed using a computer-generated programme to allocate patients to various study groups.

Group-K: Thirty (n=30) patients were administered ketamine 50 mg (1 ml) preservative free with 4 ml of normal saline (NS) total volume of 5 ml for nebulisation.

Group-D: Thirty (n=30) patients were administered dexamethasone 8 mg (2 ml) with 3 ml of normal saline (NS) total volume of 5 ml for each nebulisation.

Both group patients were nebulised 15 minutes prior to the induction. After shifting the patients to pre anaesthetic room, 20 G intravenous catheter was inserted on non-dominant hand. Baseline parameters such as Heart rate (HR), non-invasive

blood pressure (NIBP) , mean arterial pressure (MAP) and pulse oximetry for oxygen saturation (SPo2) were recorded .

Patients were shifted to operation theatre after 15 minutes of giving nebulisation. Patients were premedicated with inj. Ondansetron 0.08 mg/kg, inj. Glycopyrrolate 4mcg/kg, inj. Midazolam 0.02 mg/kg and inj. Fentanyl 1 mcg/kg and preoxygenated with 100 % oxygen for 3 minutes. General anaesthesia technique was generalized for both the groups. Patient was induced with inj. propofol 2-2.5 mg/kg IV slowly and inj. Succinyl chloride 2mg/kg till loss of eyelash reflex, jaw relaxation, absence of movements and apnoea. Patients were ventilated with bain's circuit. Following laryngoscopy and endotracheal intubation, HR, BP (SBP, DBP, and MAP), SPO2 were recorded before induction and then every 15 minutes till the end of surgery. Patients were maintained with O2, nitrous oxide, sevoflurane, intermittent positive pressure ventilation and inj. vecuronium/ inj. atracurium as maintenance anaesthesia.

At the end of surgery, analgesia was supplemented with inj. Paracetamol 10 mg/kg and oropharynx was suctioned with care, using a soft, disposable suction catheter. Neuromuscular blockage was reversed with Inj. Neostigmine 50mcg/kg IV and Inj. Glycopyrrolate 10 mcg/kg IV. The endotracheal tube was deflated properly and tube was removed after the patient regained complete consciousness. After adequate recovery, patients were shifted to post anaesthesia care unit (PACU). After shifting, the both group patients were assessed for various parameters. Both group patients were assessed for the occurance and severity of post-operative sore throat at 0, 2,4,6,12 and 24 hours using 4-point scale. Patients were also assessed for occurrence of post-operative nausea and vomiting, cough and hoarseness of voice. The time for extubation was taken as 0.

Post-operative sore throat (POST) was graded on a Likert 4 (four) point scale (0-3). The recorded data was compiled and entered in a spreadsheet computer program (Microsoft Excel 2007) and then exported to data editor page of SPSS version 15 (SPSS Inc., Chicago, Illinois, USA). Quantitative variables were described as means and standard deviations or median and interquartile range based on their distribution. Qualitative variables were presented as count and percentages. For all tests, confidence level and level of significance were set at 95% and 5% respectively.

Results

Table1: Distribution of Age of subjects

Group	Number of patients	Age (years)		P value
		Mean	SD	
Group D	**30**	**35.4**	**10.66**	**0.482**
Group K	**50**	**37.4**	**12.52**	

Mean age in both the groups were comparable and it was non-significant. P>0.05

Table 2: Results of Gender of subjects

Gender	Groups		Total	P value
	Group D	Group K		
Male	13	13	26	0.68
Female	17	17	34	
Total	**30**	**30**	**60**	

P value for gender distribution in both the groups is 0.68 (p value>0.05) and is not statistically significant.

Table 3: Results of Occurrence of post-operative sore throat

Time	Sore Throat	Group D	Group K	p-value
0 hr	Absent	21	18	**0.68**
	Present	9	12	
2hr	Absent	23	20	**0.045**
	Present	7	10	
4 hr	Absent	24	20	**0.041**
	Present	6	10	
6 hr	Absent	26	22	**0.03**
	Present	04	8	
12hr	Absent	27	25	**0.72**
	Present	3	5	
24hr	Absent	27	25	**0.72**
	Present	**3**	**5**	

Occurrence of post-operative sore throat at0, 12th, and 24thhrs postoperative hrs was comparable in both the groups (p value>0.05). Occurrence of post-operative sore throat at 2nd, 4th and 6th hrs was significantly less in

group D compared to group K (p value<0.05). Occurrence in Group D 30 % (9 patients experienced sore throat) and occurrence in Group K 40 % (12 patients experienced sore throat) in the immediate post-operative hour.

Table 4: Results of severity of post-operative sore throat

Post OP Hour	Group	Grad E 0	Grade 1	Grade 2	Grade 3	P Value
0 hr	D	21	8	1	0	
	K	18	8	4	0	**0.07**
2 hr	D	23	6	1	0	
	K	20	8	2	0	**0.04**
4 hr	D	24	5	1	0	
	K	20	8	2	0	**0.04**
6 hr	D	26	4	0	0	
	K	22	7	1	0	**0.03**
12 hr	D	27	3	0	0	
	K	25	5	0	0	**0.62**
24 hr	K	27	3	0	0	
	N	**25**	**5**	**0**	**0**	**0.62**

In immediate post-operative hour 21 patients in Group D and 18 patients in Group K had no sore throat. At immediate post-operative hour, severity of post-operative sore throat was comparable in both the groups (p value>0.05). At 2nd post-operative hour 23 patients in Group D and 20 patients in Group K had no sore throat.

At 2nd post-operative hour, severity of post-operative sore throat was not comparable in both the groups (p value<0.05). At 4th post-operative hour 24 patients in Group D and 20 patients in Group K had no sore throat. At 4th post-operative hour, severity of post-operative sore throat was not comparable in both the groups (p value<0.05). At 6th post-operative hour 26 patients in Group D and 22 patients in Group K had no sore throat. At 6th post-operative hour, severity of post-operative sore throat was not comparable in both the groups (p value<0.05). At 12th post-operative hour27 patients in Group D and 25 patients in Group K had no sore throat.

At 12th post-operative hour, severity of post-operative sore throat was comparable in both the groups (p value>0.05) At 24th post-operative hour 27 patients in Group D and 25 patients in Group K had no sore throat. At 24th post-operative hour, severity of post-operative sore throat was comparable in both the groups (p value>0.05).

Table 5: Results of occurrence of post-operative Nausea and Vomiting

Time	PONV	Group D	Group K	p value
	Absent	28	23	
0 hr	Present	2	7	**0.0750**
	Absent	30	27	
2hr	Present	0	3	**0.0814**
	Absent	30	28	
4 hr	Present	0	2	**0.1607**
6 hr	Absent	30	28	
	Present	0	2	**0.1607**
12 hr	Absent	30	28	
	Present	0	2	**0.1607**
24 hr	Absent	30	29	
	Present	0	1	**0.3337**

In Group D at 0 post-operative hr 2 patients and at 2 nd, 4 th ,6 th 12th , and 24th post-operative hr no patients have experienced post-operative nausea and vomiting. In Group K at 0 post-operative hr 7 patients, at 2nd post-operative hr 3 patients, at 4th post-operative hr 2 patients, at 6th post-operative hr 2 patients, at 12th post-operative hr 2 patients, at 24th post-operative hr 1 patient have experienced post-operative nausea and vomiting. Occurrence of post-operative nausea and vomiting at 0, 2nd, 4th, 6th 12th and 24th postoperative hrs were comparable in both the groups (p value>0.05).

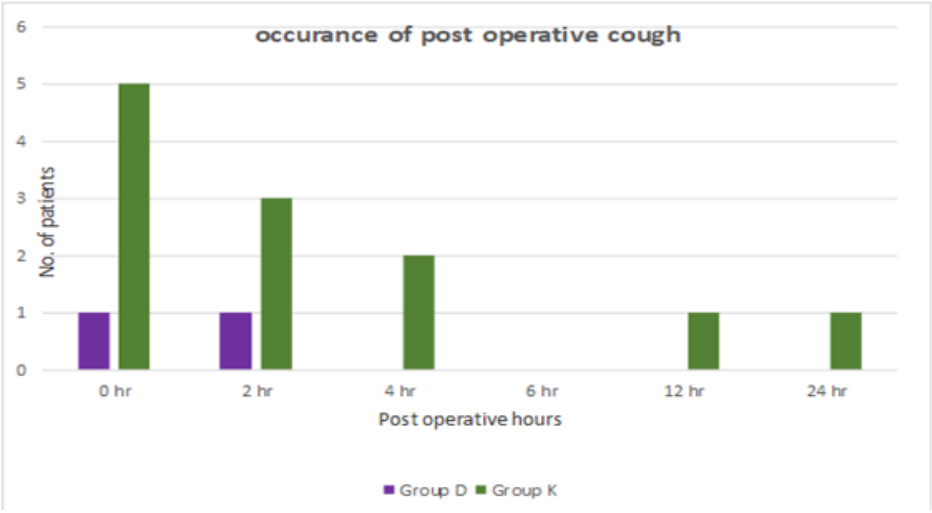

Figure 1: Occurrence of post-operative cough

In Group D at 0 & 2nd post-operative hr 1 patient and at 4th, 6th, 12th and 24th post-operative hr no patients have experienced post-operative cough. In Group K at 0 post-operative hr 5 patients, at 2nd post-operative hr 3 patients, at 4 th post-operative hr 2 patients, at 6th post-operative hr no patients, at 12th post-operative hr 1 patients, at 24th post-operative hr 1 patient have experienced post-operative cough. Occurrence of post-operative cough at 0, 2nd, 4th, 12th, and 24th postoperative hrs were comparable in both the groups (p value>0.05). Statistically insignificant differences were seen in pulse rate between the patients of group D and group K before induction and throughout the surgery till the end of surgery (p>0.05) statistically insignificant differences were seen in Mean arterial pressure between the patients of group D and group K before induction and throughout the surgery till the end of surgery (p>0.05)

Discussion

Post-operative sore throat (POST) is a frequent complain after endotracheal intubation, which resulting in significant anguish and annoyance to the patient, with a varying incidence of 21-65 % (2,3) Various causes have been attributed to the occurrence of POST such as trauma to the mucosa during laryngoscopy, repeated attempts at intubation, mechanical irritation of the airway with inflammation, and high intracuff pressures. [11]

The present study was undertaken to evaluate and compare the effectiveness of nebulized dexamethasone versus ketamine in alleviating POST following GA with endotracheal intubation. The comprehensive occurrence of POST was 35 % in present study. Nine (9) patients (30%) in Group D and 12 patients (40%) in Group K contacted POST at one point of study. Our findings are in consonance with the study by Osama et.a [13], compared the effects of nebulized Dexamethasone versus nebulized Ketamine on post-operative sore throat after Thyroid surgeries, where they showed an incidence of 20.8 % in Group D and 50 % in Group K at one point of study.

In the study done by Altef K. Salma et al [5] concluded that a single dose of 8 mg dexamethasone nebulization reduces overall incidence of POST. This is consistent with our study where the incidence of post-operative sore throat in the patients nebulized with dexamethasone is 20 % which is lesser than the reported incidence of 21-65 %.Lee et. Al [14] found that the incidence of POST was reduced to 27 % in their study on the effects of topical dexamethasone on a POST, whereas in our study, nebulized dexamethasone resulted in a much lower incidence of 20 % due to its topical effects.

In the present study, Occurrence of POST were comparable in both the groups at 0 ,12th and 24th post-operative hours (p value>0.05), while occurrence of POST was significantly less in Group D as compared to Group K at 2,4 and 6th hour postoperatively. This result was in consonance with a previously done study by Kumari et.al [15] Another study by Osama et.al [13], compared the effects of nebulized Dexamethasone versus nebulized Ketamine on post-operative sore throat after Thyroid surgeries, Occurrence of POST were comparable in both the groups at 12th and 24th post-operative hours (p value>0.05), while occurrence of POST was significantly less in Group D as compared to Group K at 0,2nd and 6th hour postoperatively.

In the present study, severity of POST was comparable in both the groups at 0,12th and 24th post-operative hours (p value>0.05), while severity of POST was significantly less in Group D as compared to Group K at 2 nd ,4th and 6 th hour postoperatively (p value <0.05). This may be due to the topical analgesic, anti-inflammatory and NMDA receptor antagonistic effect of ketamine.

(2) This result was in consonance with a previously done study by Kumari et al [15], in severity of POST was significantly less in Group D as compared to Group K at 2nd, 4th,6th and 12th hour postoperatively.

Regarding PONV, Two (2) patients (6.6%) in Group D and 7 patients (23.3%) in Group K had PONV. Although, statistically insignificant PONV is less in Group D compared to Group K. These findings are in consonance with the study by Veena et al [16] where they have compared nebulized ketamine and saline nebulization.

Regarding post-operative cough, it was comparable at 0,2nd, 4th, 12th and 24 hr post operatively. These findings are in consonance with the study by Veena et al [16], where they have showed post-operative cough was comparable at 12th and 24 hr postoperatively. In the Present study, Hemodynamic parameters like mean pulse rate and mean arterial pressure were comparable in both the groups (p value>0.05).

These findings were in consonance with a study done by Osama et al [15]. There were no significant side effects observed post operatively in both the group during study.

Conclusion

Pre-operative single dose of nebulized dexamethasone 8 mg effectively attenuates occurrence and severity of POST, with stable hemodynamics following GA with endotracheal intubation than nebulized ketamine 50 mg. Pre-operative single dose of nebulized dexamethasone 8 mg reduces occurrence of PONV and post-operative cough following GA with endotracheal intubation than nebulized ketamine 50 mg.

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