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Original Research Article

Comparison between Nebulization with Ketamine (50mg) and Dexmedetomidine (50mcg) To Study Incidence of Postoperative Sore Throat

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Abstract:

Background and Aim: Postoperative sore throat (POST) is a minor but distressing complication following general anesthesia. Present study was done with an aim to Study and compare efficacy of preoperative nebulization with ketamine and dexmedetomidine to reduce postoperative sore throat.

Material and Methods: Sixty patients of either sex of American society of anaesthesiologists (ASA) grade I, II or III, 18-60 years of age were randomized into two groups of 30 each by chit method. Group K received ketamine 50mg(1mL) with saline (4mL) nebulisation. Group D received dexmedetomidine $50\mu g(0.5mL)$ with saline (4mL) nebulisation. The primary objective was to compare the incidence and severity of POST, as inferred from the patient interviews at 0, 2, 6, 12, 24-h postoperatively.

Results: All the parameter, heart rate, systolic blood pressure, diastolic blood pressure and mean arterial pressure are reduced in Group D after nebulization with Dexmedetomidine while all have increased from base level in Group K after nebulization with ketamine. Group K had a significantly lower incidence and severity of POST compared to group K.

Conclusion: From this randomized control prospective double blinded study, pre-operatively administered dexmedetomidine nebulisation is as effective as ketamine nebulisation in attenuating POST We also conclude that there is decrease incidence of post-operative other complications after nebulisation with both Dexmedetomedine and Ketamine.

Keywords: Dexmeditomedine, Ketamine, Nebulisation, Postoperative sore throat.

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Introduction

Postoperative sore throat is a common, uncomfortable, distressing problem after tracheal intubation [1] It has been postulated that this is due to mucosal injury with resulting inflammation caused by the process of airway instrumentation or the irritating effects of foreign objects like endotracheal tubes on the airway.

Parts of the airway affected include the pharynx, larynx and trachea. Sore throat along with hoarseness in the first 24 hours after surgery is among the most common complications of endotracheal intubation [2]. Postoperative sore throat is a complication that remains unresolved in patients undergoing tracheal intubation. Postoperative sore throat following tracheal intubation is due to trauma to airway mucosa. The reported incidence of postoperative sore throat varies from 21% to 65% [3.4]. Because of this high incidence, postoperative sore throat is often considered synonymous with endotracheal intubation. It is commonly associated with hoarseness of voice and cough. Prophylactic management of Postoperative sore throat (POST) is recommended to improve the quality of postanesthesia care and reduce patient dissatisfaction. Throat irritation in the presence of an abdominal or thoracic incision can be very distressing especially in the presence of inadequate analgesia since any attempt to cough causes severe pain.

The etiology of postoperative sore throat is multifactorial, including patient related factors such as age, sex, smoking and intubation factors

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including technique, duration, tube size, intra-cuff pressure, lubricants on the tube, cuff design, intraoperative tube movement and suctioning.

Nebulisations are better accepted and tolerated by the patients than gargles, spray or any local applications, as it spares them from the bitter taste of the drug. The chance of aspiration is also less likely as only a reduced volume is administered when compared to the volume needed for gargle or local applications.

Ketamine [5] is an N-methyl-D-aspartate (NMDA) receptor antagonist [5], which has already been in use in the nebulised form, for attenuating Post-operative sore throat, due to its anti-nociceptive and anti-inflammatory properties. Dexmedetomidine [6] is a colourless, tasteless and odourless drug with a selective α -2 adrenergic agonistic action, which causes sedation and analgesia.

This prospective randomized controlled double blinded clinical study will be comparing the effect of preoperative nebulization with ketamine and dexmedetomidine to reduce postoperative sore throat and any other complications during the first 24 post-operative hours after surgical procedures in patients under general anesthesia with endotracheal intubation.

Materials and Methods

Sixty patients of either sex of American society of anaesthesiologists (ASA) grade I, II or III, 18-60 years of age were randomized into two groups of 30 each by chit method.

- Group K received ketamine 50mg (1mL) with saline (4mL) nebulisation
- Group D received dexmedetomidine 50µg (0.5mL) with saline (4mL) nebulisation

Inclusion Criteria

- 1. Age group: 18- 60 years.
- 2. Physical status ASA class I-III
- 3. Undergoing elective surgeries Under General Anaesthesia
- 4. Duration of surgery 30-180 minutes.

Exclusion Criteria

Adults with

- 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 upper respiratory tract infection.
- 5. Patients on steroid therapy.
- 6. Pregnant patients
- 7. Any associated diseases like cardiovascular disease, respiratory disease, Diabetes mellitus and central nervous system diseases

8. Adverse drug reactions especially to local anaesthetics

All patients were assessed for their preoperative condition a day before surgery. Patient's demographic data like age, sex, height and weight, vitals like heart rate, Systolic Blood Pressure (SBP), Diastolic Blood Pressure (DBP) and SpO2 was recorded. Thorough clinical history and findings of the examination of airway, cardiovascular, respiratory and other systems was recorded. Routine investigations like Complete Blood Count, Random Blood Sugar (RBS), Serum Creatinine, Chest X ray, ECG will be done in all patients. Patients were fasted for 6 hrs before time of operation.

Preoperative Preparation:

In all patient's intravenous access was secured and after shifting of patient into the operating room, monitors like NIBP, ECG, and pulse oximeter was attached, vital data like SBP, DBP and SpO2 was recorded before giving premedication. Patients were nebulised with either Ketamine or Dexmedetomidine before 15 minutes of induction in sitting position.

All patients of group K and group D were given the following premedication

- INJ Glycopyrrolate (4µg/kg) IV
- INJ Ondansetron (80 µg/kg) IV
- INJ Midazolam (20µg/kg) IV

Technique: [General Anaesthesia]

After giving premedication, pre-oxygenation was done with 100% oxygen for 3 min.

Induction was done with Inj. Propofol 2.0mg/kg IV slowly and endotracheal intubation will be facilitated with Inj. Succinylcholine 1.5 mg/kg IV.

All intubations were performed by an anaesthesiology resident, who was blinded to group allocation. Endotracheal intubation was done with disposable single use oral cuffed portex (low pressure high volume cuff) endotracheal tube of appropriate size.

Immediately after intubation, the tracheal tube cuff was inflated with just enough room air to prevent an audible leak. Neuromuscular relaxation was achieved with INJ. Atracurium 0.5mg/kg IV. For pain relief, paracetamol 15mg/kg IV was administered during surgery.

Each patient then received nitrous oxide (N2O) 60% in Oxygen (O2) 40% with mechanical controlled ventilation by tidal volume of around 7 ml/kg. The inspired concentration of the inhalational anaesthetic drug (Sevoflurane 1-2%) adjusted so that blood pressure (BP) remained at $\pm 20\%$ of baseline values. Additionally Inj. Atracurium was given as needed intravenously.

At the beginning of the skin closure, Sevoflurane was discontinued. Intra operative monitoring includes continuous temperature, Electrocardiography, Pulse oximetry, non-invasive BP. After completion of surgery and adequate suctioning of oropharynx, reversal of neuromuscular blockade was done with intravenous Inj.Neostigmine 50µg/kg and Inj. Glycopyrrolate 8µg/kg. Once patient is oriented to time, place and person with good spontaneous breathing and head lift for 30 seconds, patient was extubated and time was noted.

Monitoring

Total duration of surgery is noted. Each patient was also checked for the presence and severity of sore throat at 0 hr, 2 hr, 6 hr and 24 hrs post-extubation. Severity of sore throat is categorized by VAS Score

The visual analog scale (VAS) is a validated, subjective measure for acute and chronic pain.

Scores are recorded by making a handwritten mark on a 10-cm line that represents a continuum between "no pain" and "worst pain." Post-operative pain was managed by INJ Paracetamol (10mg/kg) as and when required.

Statistical analysis

The recorded data was compiled and entered in a spread sheet 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

Table 1: Age wise distribution of patients			
Age (Years)	Group D	Group K	
18-25	8 (26.67%)	10 (33.33%)	
26-35	6 (20.00%)	6 (20.00%)	
36-45	7 (23.33%)	6 (20.00%)	
46-55	6 (20.00%)	6 (20.00%)	
56-65	3 (10.00%)	2 (6.67%)	
Total	30 (100%)	30 (100%)	
Mean in Years \pm SD	37.46 ± 13.54	35.26 ± 13.08	
P value	0.525		

There were total 30 patients in each group whose age ranged between 18 to 60 years mean 37.46 ± 13.54 in group D and mean age 35.26 ± 13.08 in group K. Table 1 and chart 1 shows the age wise distribution of patients in both groups. There is no statistical significance between age group in both groups (p=0.525).

Table 2: Gender wise distribution of patients Sex GROUP D (%) GROUP K(%) Male 11 (36.67%) 19 (63.33%) Female 19 (63.33%) 11 (36.67%) Total 30 (100%) 30 (100%)

There were 11(36.67%) male patients and 19(63.33%) female patients in group D whereas There were 19(63.33%) male patients and 11(36.67%) female patients in group K

The weights (in kg) in group D (mean 59.50 \pm 8.23) and in group K (mean 59.67 \pm 6.42) were comparable.

Table 3: Comparison of hemodynamic parameters of before nebulization and after nebulization/before induction

Variable		Before Nebulization	Before Induction	P Value
Pulse Rate	GROUP D	89.53±8.31	85.33±7.76	0.04
	GROUP K	85.57±7.25	89.92±8.74	0.04
SBP	GROUP D	126.53±11.41	120.46±11.41	0.04
	GROUP K	120.07±8.85	125.46±8.33	0.03
DBP	GROUP D	79.33±8.27	75.20±7.64	0.04
	GROUP K	76.57±15.29	79.71±5.89	0.04
MAP	GROUP D	95.06±9.05	90.02±86.10	0.04
	GROUP K	91.07±6.49	95.02±6.10	0.03

Table 3 shows comparison of hemodynamics parameters of both the group before nebulization and after nebulization. All the parameter, heart rate, systolic blood pressure, diastolic blood pressure and mean arterial pressure are reduced in Group D after nebulization with Dexmedetomidine while all have

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increased from base level in Group K after nebulization with ketamine. There is significant difference in changes in mean pulse rate between both groups at all point of study except basal value. Basal SBP were comparable in both groups and there is significant difference in both groups after nebulisation except baseline SBP. The basal mean DBP were comparable in both groups also there is

significant difference in DBP after nebulisation in both groups. The basal mean MAP values were comparable in both groups.

Statistical evaluation between the groups showed a significant difference in MAP in both groups. There is no statistical significant difference in changes in SPO₂ in both groups at all point of study.

Table 4: Intergroup comparison of Duration of Surgery in all groups

0			
Variables	Group D	Group K	p-value
Duration of Surgery	134.66 ± 47.61	121.66 ± 44.10	0.277
	1	. 0.05	

There is no statistical difference between duration of surgery in both groups as p > 0.05

Table 5: Incidence of post op sore throat in patients				
Variables	Total No. of patients	No. of patients develop POST	Incidence (%)	
Group D	30	7	23.33	
Group K	30	3	13 33	

Table shows overall incidence of post op sore throat in both groups, which is less in Group K than Group D

Table 6: Incidence of post op sore throat in patients				
Variables	Sore throat	Sore throat		P VALUE
	Yes	No		
After extubatio	n			
Group D	3	27	0.218	0.640
Group K	2	28		
At 2hrs				
Group D	2	28	0.351	0.553
Group K	1	29		
At 6hrs				
Group D	1	29	0	1.0
Group K	1	29		
At 12hrs				
Group D	1	29	1.017	0.313
Group K	0	30		
At 24hrs				
Group D	0	30	0	1.0
Group K	0	30		

Table 6 shows comparison of incidence of sore throat in both groups at different intervals, which shows incidence of sore throat is less in ketamine than Dexmedetomidine at each interval but not significant. No complication in both the groups after extubation was noted.

Discussion

Postoperative sore throat is a common, uncomfortable, distressing problem after surgery during emergence from anaesthesia. and Postoperative sore throat following tracheal intubation is due to trauma to airway mucosa. The reported incidence of postoperative sore throat varies from 21% to 65%. [3] The etiology of postoperative sore throat is multifactorial. Nebulisation, Sprays, aerosols and lubricants applied over endotracheal tube is helpful in reducing these complications. The basis of present study is aimed to compare the effect of preoperative

nebulization with ketamine and dexmedetomidine to reduce postoperative sore throat and any other complications during the first 24 post-operative hours after surgical procedures in patients under general anesthesia with endotracheal intubation. The basis of present study is aimed to compare the effect of preoperative nebulization with ketamine and dexmedetomidine to reduce postoperative sore throat and any other complications during the first 24 post-operative hours after surgical procedures in patients under general anesthesia with endotracheal intubation. In our study, the overall incidence of post-operative sore throat was 36.66%. POST was seen in four patients (13.33%) in Group K and seven patients (23.33%) in Group D. There was a significant reduction in the severity of sore throat noticed in both groups at all-time points during the first post-operative day but no such statistically significant difference in the incidence of POST between the two groups at 0, 2, 6, 12 and 24hrs postoperatively. Our study is comparable to study done by Derlin Thomas, Lini Chacko, and Paul O Raphael. [7] Dexmedetomidine, a super-selective alpha 2 agonist, reduces the transmission of nociceptive signals at the dorsal horn of the spinal cord. The mechanism of action of topically applied dexmedetomidine and topical analgesic preparations of the drug is still under research.

Recently, Thomas et al [7] used dexmedetomidine as preoperative nebulization and it was equally efficacious as ketamine nebulization in reducing the incidence and severity of POST at 0, 2, 6, 12, 24 h postoperative time point. Nebulizations would act more locally at the desired site, and also are, likely to have a much lower concentration in the blood, hence containing the possible systemic adversities. Cardiorespiratory depression following intravenous dexmedetomidine is supported by a study conducted by Kim et al. [8] which evaluated the efficacy of intravenous dexmedetomidine and compared it with remifentanil infusion. The sore throat was better controlled with dexmedetomidine, however, the use of an intravenous route for both the drugs brought about systemic effects of cardiorespiratory depression. Ketamine is an N-methyl D-Aspartate (NMDA) receptor antagonist that acts peripherally on the sensory afferent nerve endings and also has anti-inflammatory effects.

Following nebulisation, a marked increase in the pre induction values of haemodynamic parameters such as HR, SBP and DBP was recorded in the ketamine group in our study, which may be because of the systemic absorption of ketamine. Similar results were also obtained by Derlin Thomas, Lini Chacko, and Paul O Raphae [7] who concluded that Preadministered operatively dexmedetomidine nebulisation is as effective as ketamine nebulisation in attenuating POST, with less haemodynamic derangement. Hence, nebulised dexmedetomidine may be considered as a safe alternative to nebulised ketamine for decreasing POST. Also, study done by Satyajeet Misra et al [9] concluded that Nebulized dexmedetomidine at 1 µg/kg attenuated the increase in HR, SBP, DBP and MAP following laryngoscopy and reduced the intraoperative anesthetic and analgesic consumption.

Also there was no incidence of any other post op complications like coughing, bucking, hoarsness of voice, dysphonia, dysphagia or post-operative nausea /vomiting, other anaesthetic complications like dizziness, sedation, hallucinations in both the groups. Our study is also comparable to study done by Jaya Lalwani, Rashmi Thakur, Manju Tandon and Sandeep Bhagat [10] who studied the Effect of Ketamine Gargle for Attenuating Post-Operative Sore Throat, Cough and Hoarseness of Voice in which they inferred that gargling with ketamine decreases the incidence and severity of POST, hoarseness of voice and cough.

Our study had certain limitations. We did not measure the blood concentrations of the study drugs; this would have helped to understand the pharmacokinetics of the nebulized drug and the mechanism of reduction of POST.

Conclusion

From this randomized control prospective double blinded study, pre-operatively administered dexmedetomidine nebulisation is as effective as ketamine nebulisation in attenuating POST We also conclude that there is decrease incidence of postoperative other complications after nebulisation with both Dexmeditomedine and Ketamine.

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