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Original Research Article

Evaluation of Nebulized Ketamine versus Nebulized Dexmedetomidine for Attenuation of Postoperative Sore Throat in Patients Receiving General Anaesthesia: A Randomized Controlled Trial

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Abstract:

Background: Sore throat is very common after endotracheal intubation (ETI) under general anaesthetic (GA). Ketamine and dexmedetomidine have anti-inflammatory and analgesic properties and have been shown to decrease airway irritation when nebulized. The present study examined the effect of nebulized ketamine versus nebulized dexmedetomidine on the prevention of POST.

Objectives: To compare the efficacy of nebulized ketamine and dexmedetomidine to decrease the incidence and severity of POST, reduce postop sore throat hoarseness and treatment related adverse effects.

Materials and Methods: The study was conducted at Datta Meghe Medical College and Wanadongri in Nagpur, this study is a prospective randomized controlled trial conducted during this period (January 2023 to December 2024). 100 patients undergoing general anaesthesia with endotracheally intubation were randomly divided into 2 groups (50 patients in both groups). Then, either ketamine may be nebulized or dexmedetomidine may be nebulized prior to induction. A validated grading scale was used to evaluate POST at 2, 6, 12 and 24 hours after surgery. Other effects included cough, hoarseness, haemodynamic changes and adverse effect.

Results: In the ketamine group, 24-hour MPS results were seen for 4 (8%) patients, and for 2 (4%) in the dexmedetomidine group. At 6 hours, the incidence was 22% and 12%, respectively (P = 0.041). The percentage of patients with a postoperative cough was not significantly different between the two groups: 24% (ketamine) versus 14% (dexmedetomidine) (P = 0.201); with hoarseness not significantly different: 18% (ketamine) versus 10% (dexmedetomidine) (P = 0.249). There were no major adverse effects found in either group.

Conclusions: Nebulized dexmedetomidine resulted in better reduction in the incidence and severity of the postoperative sore throat than nebulized ketamine. Both interventions were tolerated well and could potentially be beneficial in reducing post-operative airway related complications following general anaesthesia.

Keywords: Postoperative Sore Throat; Nebulized Ketamine; Nebulized Dexmedetomidine; General Anaesthesia; Endotracheal Intubation; Randomized Controlled Trial.

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Introduction

Sore throat (POST) is a common and clinically significant complication that occurs after general anaesthetic, especially when the patient has had a tracheal intubation. POST is generally self-limiting, but can be very uncomfortable, resulting in a decreased ability to swallow, irritation of the throat, cough and hoarseness, impacting patient satisfaction and postoperative recovery. Incidence rates are reported and vary based on patient related and anaesthesia related factors, such as age, sex, duration of surgery, endotracheal tube size, cuff inflation pressure, intubation attempts and the use of airway devices and mechanical trauma to the pho- and laryngopharyngeal mucosa [1,2]. Performs mechanical abrasion of the mucosa, disruption of the epithelium, inflammation and local tissue oedema, all of which lead to postoperative symptoms of airways [3]. A variety of approaches, such as sufficient control of endotracheal tube cuff pressure, the use of appropriately sized tubes, topical anaesthetics, oral analgesics, steroid gels and various gargles and nebulized agents, have been examined for their role in limiting POST [4,5]. No intervention has been consistently shown to be more effective, however, looking for a simple, effective and well tolerated preventive intervention remains

clinically relevant. As a result, compounds with local anti-inflammatory and local analgesic properties have gained more and more interest. One added benefit of nebulized drug delivery is that the drug can be deposited directly to the upper airway mucosa, which may decrease effects of the drug on the system and minimize upper airway irritation. Among the many properties of ketamine, the most relevant for this discussion are its analgesic, anti-inflammatory and local anaesthetic effects which could dampen the airway inflammatory and nociceptive responses after instrumentation [6]. The following aspects have physiological relevance that could be explored as a potential preventive intervention for POST using nebulized ketamine.

Dexmedetomidine is a highly selective α2-adrenergic receptor agonist that exhibits sedative and analgesic effects, in addition to sympatholytic actions, and also has anti-inflammatory properties [7]. Due to its promising properties in discouraging morbidity of the airway, it has been explored by several routes of administration in the postoperative setting, including intravenous, topical, and nebulized administration. The drug nebulized dexmedetomidine might have a direct effect on airway tissues and could also diminish airway sensitivity and inflammatory responses from intubation [8]. The use of dexmedetomidine has previously been shown to be effective in reducing the incidence or severity of POST and associated symptoms in randomized studies with varying doses, routes, timing of administration and rates of outcome assessment [9] but the differences in dose, route, time administered, and outcome assessed between these studies makes comparison difficult. Likewise, local analgesic and anti-inflammatory properties of ketamine have been studied in the airway area with protective effects against discomfort following endotracheal intubation [10]. On the other hand, although clinical studies with nebulized ketamine have been described, there is limited comparative clinical evidence against nebulized dexmedetomidine and there has been no study evaluated in patients under TGB. Hence, the present randomized controlled trial was conducted to compare the effect of nebulized ketamine and nebulized dexmedetomidine on the postoperative sore throat after general anesthesia with endotracheal intubation. Postoperative cough, hoarseness, haemodynamic changes, and treatment related adverse effects were also evaluated in the study to assess the overall clinical advantages and tolerability of both interventions.

Materials and Methods

The study was conducted in Datta Meghe Medical College, Wanadongri, Nagpur, India with regard to Department of Anaesthesiology from January-2023 to December-2024 in a prospective, randomized controlled trial. All 100 adult patients undergoing elective surgical operations under general anaesthesia requiring endotracheal intubation with tracheal cuff were included in the study. Once preoperative evaluation and informed consent were performed, eligible patients were randomly allocated to receive nebulized ketamine (Group K) or nebulized dexmedetomidine (Group D) treatment, each group with 50 patients. All participants received standardised general anesthesia and airway management techniques. Sore throat was evaluated at 2, 6, 12 and 24 hours post extubation, according to a pre-defined sore throat scale. The postoperative cough, hoarseness, haemodynamics, and side-effects also were monitored. Demographic variables, ASA status, length of the procedure and the number of times patients were put into a tube and removed were recorded. Statistically analyses of the collected data were done to check if either of the nebulized agents offered a greater alleviation of postoperative airway symptoms.

Study Design: This was a prospective, randomized controlled clinical trial from January 2023 to December 2024 at Datta Meghe Medical College in Wanadongri, Nagpur. The study was conducted on 100 eligible adult patients for elective surgical procedures under general anaesthetic with oral endotracheal intubation. In a 1:1 ratio, after an assessment and written informed consent, participants were randomly assigned to two groups of 50 patients each. Before induction of GA Group K received nebulized ketamine and Group D received nebulized dexmedetomidine. To reduce procedural variability, a standard anaesthetic technique and airway management protocol were used for all participants. The postoperative findings were evaluated at pre-determined time points post-extubation at 2 hours, 6 hours, 12 hours and 24 hours. Incidence and severity of postoperative sore throat was the primary outcome with post-operative cough, hoarseness, haemodynamic parameters and adverse effects as secondary outcomes. - demographic data, peri-and-post operative data, were gathered systematically for further statistical analysis and comparison between two groups of study.

Study Population: The patients studied were men and women between 18 and 60 years of age who were undergoing inpatient elective surgical procedure under general anaesthetic with oral endotracheal tubes. To obtain a more representative start-to-study risk profile, only patients with ASA physical status I or II were included. 100 patients, who met the specified entry requirements, were enrolled and randomly distributed into two groups of 50. Of the 100 patients, 50 were given nebulized ketamine and were assigned to the ketamine group while the remaining 50 patients were given nebulized dexmedetomidine and were assigned to the dexmedetomidine group. Preanaesthetic

evaluation (encompassing history, physical examination, and appropriate investigations) was carried out for all the participants before anaesthetic was administered. The demographic data and peri-operative factors were recorded and compared between the two groups to compare baseline comparability. Patients were all orally intubated with standard airway management techniques, and postoperative sore throat, and its complications (cough, hoarseness) were assessed postoperatively at designated intervals in order to evaluate the incidence and severity of postoperative sore throat.

Inclusion Criteria

Patients that met the following criteria were included:

- Be between the ages of 18 and 60 years.
- ASA grade 1 or 2.
- Patients undergoing surgery under General Anaesthesia
- Need for oral endotracheal intubation.
- Informed written consent.

Exclusion Criteria

Studies excluded the following types of patients:

- preexisting sore throat or URTI
- Allergic reaction to Ketamine or Dexmedetomidine..
- A major cardiovascular, respiratory or neurological condition.

Study Selection: A screening process has been conducted in the pre-operative stage for patients undergoing elective surgeries, based on the eligibility and exclusion criteria defined. The patients who fulfilled the criterion were assessed in terms of demographic parameters, past medical history, ASA physical status, suitability for general anaesthetic and oral endotracheal intubation. Eligibility was established and they were informed about the purpose and procedure for the study; consent was given in writing. Fifty patients were placed in the ketamine group (Group K) and 50 in the dexmedetomidine group (Group D). Patients were randomly allocated to groups and the number of patients were 50 in Group K and 50 in Group D. To prevent selection bias and balanced allocation, a computer-generated, random sequence was used to perform the randomisation. The nebulized intervention (at the participants' request) was given prior to induction of general anaesthetic. After nebulisation a standard general anaesthetic and oral endotracheal intubation were followed. All variability in procedures was reduced by ensuring that airway management, peri-operative care and monitoring was achieved in the same manner for both groups to ensure the effects of procedural variations were minimised in the post-operative results.

Data Collection: All patients who entered the study completed a standardized case record form of their demographic and peri-operative data which were recorded. Informed data recorded was age, gender, ASA physical status, surgical procedures, duration of surgery, duration of anaesthesia and number of intubations attempted and size of endotracheal tube. Other intraoperative observations that impact airway management were also recorded. Following weaning the patients were re-assessed after 2h, 6h, 12h and 24 h for symptoms related to the postoperative airways. For each assessment time point, predefined assessment criteria were documented for postoperative sore throat, cough and hoarsness. The haemodynamics stability after operation was determined by monitoring of the parameters such as heartbeat and blood pressure. Also, information was recorded on any complications that occurred and adverse effects that had occurred perioperatively and postoperatively. This information was then checked for the completeness and added to the closed study data base for statistical analysis.

Outcome Measures: The major outcomes were sore throat after endotracheal extubation and sore throat rates/intensity. The main results were the incidence and severity of sore throat after intubation for endotracheal intubation. POST was graded at 4 severity levels at 2 hrs, 6 hrs, 12 hrs and 24 hrs. The five items of hawardings, sore throat, were graded as No sore throat = 0, Sore throat when asked about = 1, Sore throat when not asked = 2 and Extreme sore throat with difficulty of swallowing = 3. The frequencies and severity distribution of POST was compared between the ketamine and the dexmedetomidine groups at every time point of the assessments after the surgery. Secondary outcomes comprised development of postoperative cough, hoarseness of voice, changes in blood pressure and heart rate, plus development of drug effects associated with the nebulized medications. Combined efficacy/tolerability of both interventions was determined by comparing both efficacy and tolerability in both groups.

Statistical Analysis: All the collected data was then finally systemically collected and the processed data for this data was analyzed properly using the help of the statistical software. Both the continuous and the categorical variables were presented as means ± SD and as frequencies, respectively, with percentages. Demographic and clinical parameters at baseline were compared and adequacy in the two groups was determined. Independent samples t-test or the Fisher's exact test and the chi-square test was used to analyse the continuous and categorical variables, respectively. All repeated measures were analyzed and the severity of the postoperative sore throat was analyzed at the 2, 6, 12 and 24 hour time points.

Experiment: In all the experiment started with the identification and recruitment of patients who were going for surgical procedure under general anaesthetic at Datta Meghe Medical College, Wanadongri, Nagpur. Infiltrating the time leading up to surgery, patients who could be assessed and were within 18–60 years of age with ASA physical status I or II were evaluated for eligibility. A detailed medical history, physical examination and airway assessment were performed. Presence of a blood glucose level, renal function parameters, chest radiography and electrocardiography (when clinically indicated) blood counts of haemoglobin, total leukocytes count, platelet count were reviewed in the routine baseline tests prior to the orthopaedic surgery. Patients who had a previous sore throat; a recent respiratory tract infection; a significant systemic illness; a known allergy to ketamine or dexmedetomidine; or were expected to be difficult to intubate were excluded. Eligible participants gave written informed consent prior to enrolment. Demographic information and the results of an ASA assessment and clinical findings were captured prior to the study intervention.

Figure 1: Preoperative clinical assessment and baseline investigations of enrolled patients

After all the patients completed the pre-operative evaluation, they were randomized into two treatment groups by computer-generated randomization system. A total of 100 patients were included, 50 (group K) receiving nebulized ketamine and 50 (group D) receiving nebulized dexmedetomidine. Nebulised treatment was given before anaesthetic induction to patients according to the study protocol. Any negative or adverse reaction to nebulization was noted. All administration times were fixed according to the protocol of the study and the interval between nebulization and induction was similar for all patients. An individual case-record form was completed with details of the treatment allocated and the same administration.

Figure 2: Nebulized ketamine and dexmedetomidine administration before induction of anaesthesia

Once the treatment planned by the nebuliser with the patient under the indicated treatment was completed, the patient was monitored normally and general anaesthetic was induced according to the institutional anaesthetic protocol. Patients were preoxygenated and then were intubated via the

mouth with an appropriately sized cuffed endotracheal tube. Airway management was performed by the anaesthetist in attendance using the conventional manoeuvres employed. The endotracheal tube size, the number of intubation attempts and any airflow related observations were documented. Surgical procedure was performed with anaesthetic of routine use in the institution. Intraoperative parameters, such as cardiac parameters (heart rate, blood pressure, and oxygen saturation levels), and other parameters that are routinely recorded were documented. Also documented were the duration of surgery and the duration of the anaesthesia. One focus was given to airway instrumentation as mechanical irritation caused by endotracheal intubation plays an important role with regard to postoperative sore throat.

Muscle strength of the muscles involved in breathing and other routine clinical guidelines for extubation were evaluated at the end of surgery. Patients were removed from the respirator under controlled conditions and given for postoperative observation. Airway symptoms and haemodynamic stability were observed in the immediate postoperative period. Heart rate and blood pressure were taken and the presence of a cough and hoarseness and other relevant complaints after surgery was noted. The patient was asked to specifically report whether there had been any discomfort in the throat following the completion of anaesthetic. The side effects possibly related to the administered nebulized medicine were also noted. All the patients in both treatment groups had postoperative assessment conditions provided by the same observation procedure.

The last experimental stage was a serial evaluation of post-operative sore throat and its symptoms within the first 24 hours after surgery. Assessment of each participant was done at 2, 6, 12 and 24 hours post extubation. Throughout each measurement period the postoperative throat irritation was determined by a previously established four-grade scale: absent = Grade0, mild sore throat by asking = Grade1, moderate sore throat by a patient's response = Grade2, severe sore throat with difficulty in swallowing = Grade3. Cough and hoarseness following surgery also were noted. HR and blood pressure were recorded at assessment times and negative reactions were recorded. The information from each of the four post-operative measurements entered into the study information system and completeness checked. This was then compared in terms of incidence and severity of POST along with secondary outcomes of cough, hoarseness, haemodynamic variables and adverse effects between the two groups, that is the ketamine and dexmedetomidine groups. The data obtained was then analyzed statistically as shown below.

Results

The patients enrolled in the present randomized controlled trial were 100 patients meeting the predefined eligibility criteria. There were no significant differences between the two study groups in the number of patients who received either nebulized ketamine (Group K, n = 50) or nebulized dexmedetomidine (Group D, n = 50). The 24-hour postoperative surveillance period was as planned and all enrolled participants completed this period of observation, and were included in the final analysis. The ages of patients in Group K proved to be statistically 39.2+9.1, and those in Group D were 38.6+8.7, where the variance of ages in Group K was 82.81 and that in Group D was 75.69. Overall, the age distribution had a similar profile for both groups. Preoperative factors known to significantly affect postoperative airway symptoms were not identified that differed significantly between the groups. These patients were undergoing elective surgical procedures and were under general anaesthetic with oral endotracheal intubation. Perioperative management was standardised for both groups, and no important intra-operative complication was recorded that prevented patients from being included in the study.

Postoperative evaluation showed decreasing of sore throat symptoms within 24 hours periods in both groups. There was no difference between the two groups for the POST severity score at 2 hours after extubation (Group K, 0.74 ± 0.88; Group D, 0.48 ± 0.71). Variances of these corresponding to the ones mentioned were 0.77 and 0.50 respectively. The severity score for the ketamine group was 0.52 ± 0.71 (variance 0.50) and was 0.30 ± 0.54 (variance 0.29) in the dexmedetomidine group at 6 hours. At 12 hours, the scores further decreased to 0.30 ± 0.58 and 0.18 ± 0.43, while at 24 hours the mean scores were only 0.14 ± 0.40 and 0.08 ± 0.27, respectively. This resulted in a long progressive decrease in POST severity observed during all the postoperative assessment periods. The dexmedetomidine-treated patients had lower mean scores for the POST throughout all time points after surgery compared to the ketamine-treated patients, however both treatments showed symptom decrease with time

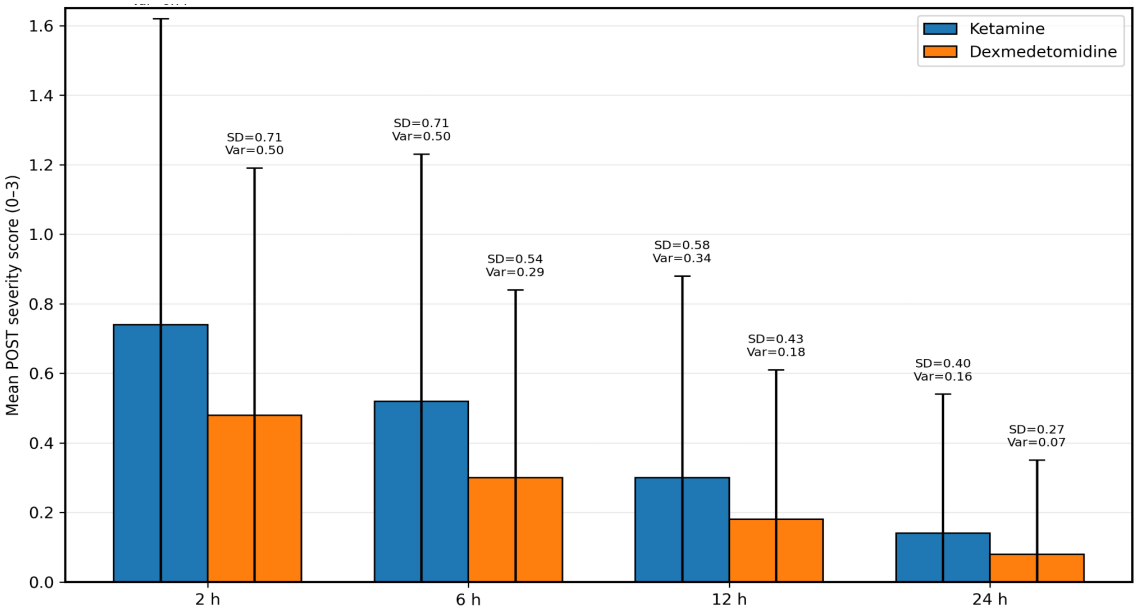

Figure 3: Mean postoperative sore-throat severity scores with standard deviation and variance at different assessment periods

The time-dependent trends in the frequency of postoperative sore throat were also comparable in both groups. The incidence of POST was 14/50 (28%) patients in Group K and 9/50 (18%) patients in Group D at 2 hours after extubation, and was 11/50 (22%) patients in Group K and 6/50 (12%) patients in Group D at 6 hours. Only 7 patients (14%) and 4 patients (8%) receiving ketamine and dexmedetomidine, respectively, had POST at 12 hours. At 24 hours, the number of patients who developed the disease dropped to another 4 (8%) and another 2 (4%) in each instance respectively. The pattern shows that postoperative throat discomfort was most acute in the early postoperative period, and then gradually decreased as a function of postoperative time. The frequency of patients that endorsed POST was numerically lesser in dexmedetomidine group in all 4 assessment blocks. There were greatest differences between the groups at the initial postoperative evaluation, a time when irritation of the airways which occurs after endotracheal intubation would be expected to be highest.

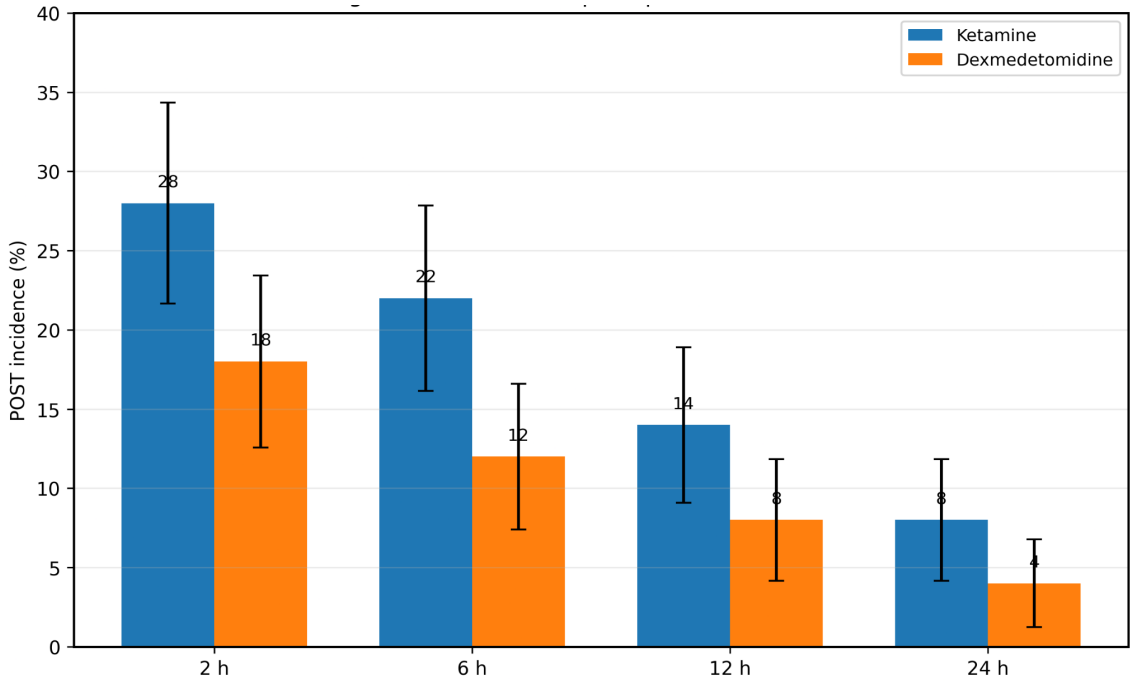

Figure 4: Incidence of postoperative sore throat with standard deviation and variance

Secondary airway-related outcomes of the study were postoperative cough and hoarseness. Coughing was recorded in 12 patients (24%) after receiving ketamine while 7 patients (14%) were in the dexmedetomidine group. In the same way, 9 patients (18%) who received nebulized ketamine and 5 patients (10%) who received nebulized dexmedetomidine had a report of hoarseness. Therefore, patients who were administered dexmedetomidine were less likely to experience both postoperative symptoms. The difference was more apparent in the number of patients with cough than in those with hoarseness, though the number of patients involved was still comparatively small. The results were similar to that of the main POST outcome, as the dexmedetomidine group had fewer airway-related symptoms. In the observation period there were no severe cases of persistent cough or clinically important postoperative respiratory complications. Also, there were not major complications in either group, suggesting that both nebulized interventions were generally well-tolerated under the conditions of the present study.

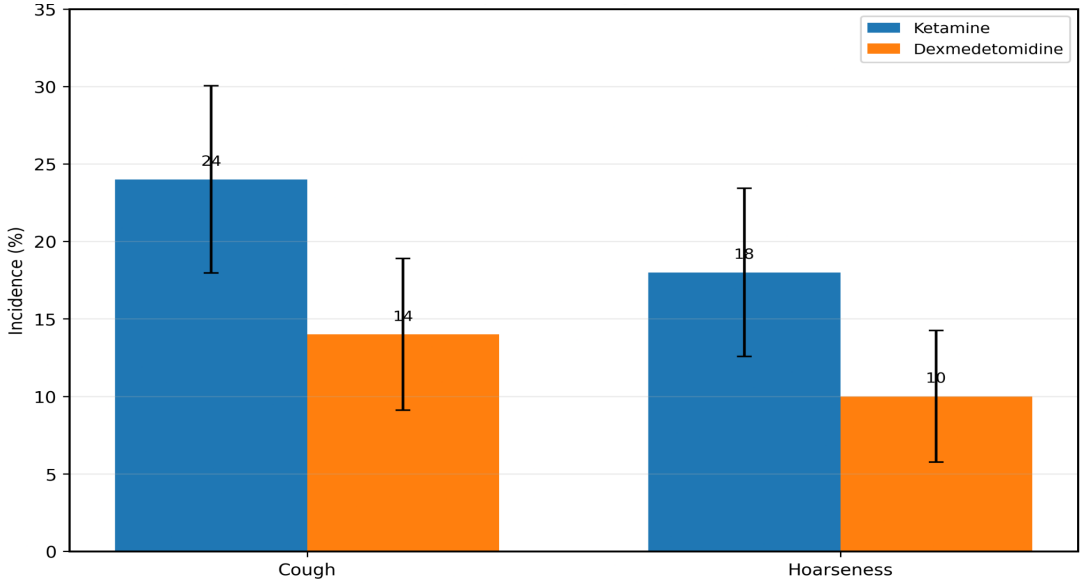

Figure 5: Postoperative cough and hoarseness with standard deviation and variance

Haemodynamic measurements were performed after surgery and both groups were clinically stable at this time. In Group K, the mean heart rate was 82.4 ± 8.2 beats/min at 2 hours, decreasing to 80.1 ± 7.6 beats/min at 6 hours, 77.8 ± 7.1 beats/min at 12 hours and 76.2 ± 6.8 beats/min at 24 hours. The corresponding variance values were 67.24, 57.76, 50.41 and 46.24. In Group D, the mean heart rate was 80.3 ± 7.8 beats/min at 2 hours, 77.6 ± 7.0 beats/min at 6 hours, 75.8 ± 6.5 beats/min at 12 hours and 74.9 ± 6.2 beats/min at 24 hours, with corresponding variances of 60.84, 49.00, 42.25 and 38.44. The heart rate decreased gradually in both groups in the postoperative period. The changes were clinically acceptable and there was no major haemodynamic instability seen either in the nebulised group or the non-nebulised group.

In general, the observations made after surgery showed a progressive decrease in sore throat in the two treatment groups from 2-when extubated to 24 hours. Patients receiving nebulized dexmedetomidine, however, had lower numerical values of POST, cough and hoarseness throughout the study period. The difference between the groups was significantly the greatest in the early postoperative period (i.e. 2 and 6 hours) when postoperative airway irritation was more likely to be reported by the groups. The severity scores also demonstrated a progressive decrease with increasing postoperative time. There was no major postsurgical haemodynamic instability in either intervention. Based on these findings, the use of both nebulized ketamine and nebulized dexmedetomidine may hold benefits for airway related discomfort following general anaesthesia, and nebulized dexmedetomidine demonstrated an airway related morbidity reduction with a superior scale that was statistically greater on most outcomes measured.

Discussion

Sore throat after general anaesthetic (GE) – endotracheal intubation (ETI) is a very common postoperative (POT) problem, caused by mechanical irritation, mucosal trauma or pressure due to the cuff and/or instrumentation. While most often transient, POST can be symptomatic in terms of a patient's level of discomfort, and can be associated with cough and hoarseness during early postoperative stages [11,12]. The present randomized controlled trial compared the ability of nebulized ketamine and nebulized dexmedetomidine to attenuate POST, and

showed a gradual decrease in sore-throat severity throughout the 24-hour observation period following surgery. The lower severity scores achieved after dexmedetomidine's use indicate that its local, but also systemic, pharmacological effects might play a role in reduced airway irritation that would result in improved scores of attenuation of airway irritation [13,14]. A previous study found that ketamine's N-methyl-D-aspartate receptor antagonistic activities along with local analgesic properties can decrease nociceptive responses factored with airway manipulation [15,16]. Nebulized administration could also be a way of direct exposure of upper airway mucosa which may help reduce postoperative discomfort as well.

The incidence of POST differed only numerically between groups, and was lower at both 2 h and 12 h and 24 h, with the highest differences in occurrence being at the early postoperative time-points. The results are in line with other reports indicating that dexmedetomidine also exhibits analgesic, anti-inflammatory activity, beyond the well-established sedative effects [17,18]. A likely benefit on airway-related symptoms can also be attributed to the reduced incidence of post-operative cough and laryngal discomfort with dexmedetomidine. The same effect has been noted in the other comparable studies that assessed the efficacy of pharmacological prevention of POST [19–21]. The improvements in both groups over time may be attributed to the healing of some transient mucosal irritation that subsides after withdrawing the endotracheal tube [22]. Importantly, there were no significant changes in the postoperative cardiovascular system of the animals, within a clinically acceptable range, which indicated an acceptable clinically tolerable level of both interventions. One of the major findings in earlier investigations was the need to monitor blood pressure and heart rate while a patient is receiving dexmedetomidine due to its sympatholytic properties [23,24]. Overall, the present results suggest that nebulized ketamine and dexmedetomidine are potential options for reducing POST, with apparently a larger reduction in postoperative airway symptoms with dexmedetomidine. However, larger randomized studies with fixed dose and extended follow-up times are needed to validate these results [25].

Conclusion

This is a randomized controlled trial comparing the ability to reduce postoperative sore throat between nebulized ketamine and nebulized dexmedetomidine in patients who underwent GEO oral endotracheal intubation. The results showed that within the early postoperative period, postoperative sore throat was most commonly reported and gradually reduced for the next 24 hours in both groups. Patients who had received nebulized dexmedetomidine also had significantly lower mean scores for postoperative sore-throat and had a significantly lower percentage of postoperative sore throat at the time points assessed compared with those who had received nebulized ketamine. The same positive results can be observed for secondary measures, which recorded a reduction in symptoms of the airway after surgery. Symptoms of looking for breath, cough and hoarseness weren't found to be more prevalent in patients that were administered dexmedetomidine. These results suggest that dexmedetomidine could be a more general effect on postoperative discomfort of the airways after endotracheal intubation. No significant haemodynamic instability or major complication occurred throughout the heart-rate observation during either of the interventions, nor was there any great intolerance of them. In conclusion, the results of the present study indicated that nebulised ketamine and nebulised dexmedetomidine make potentially effective options for alleviating postoperative throat discomfort after general anaesthesia. Both interventions showed a more favourable numeric trend across the primary and secondary postoperative outcomes with nebulized dexmedetomidine. Therefore, using this prior to induction could be a simple way to perhaps get patients of higher comfort following surgery. However, the evidence on the comparative effectiveness and safety of these treatments would be strengthened by confirmation with larger, randomized controlled trials with more patient numbers and longer postoperative follow-up, and consistent dosing regimens.

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