

POST-OPERATIVE SORE THROAT: INCIDENCE AND SEVERITY AFTER NEBULIZATION WITH KETAMINE AND SALINE

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ABSTRACT

BACKGROUND

Postoperative sore throat is a common complication of general anaesthesia with endotracheal intubation that affects the patient's satisfaction after surgery. Post-operative sore throat (POST) following tracheal intubation is due to the trauma to the airway mucosa. The reported incidence of post-operative sore throat varies from 21%- 65%. Our study was undertaken to assess the efficacy of ketamine nebulization for attenuating POST in patients undergoing elective surgeries under general anaesthesia with endotracheal intubation. Ketamine is N methyl D aspartate (NMDA) receptor antagonist, involved in anti-nociception and anti-inflammatory cascade.

METHODS

200 patients aged 20-60 years belonging to ASA PS I-II, scheduled for elective surgeries under general anaesthesia with endotracheal intubation satisfying the inclusion criteria were assigned into 2 groups of 100 each. Group 1: Patients received nebulization with 50 mg ketamine in 4 ml normal saline. Group 2: Patients received 5 ml normal saline; they were given nebulization 10 minutes prior induction.

RESULTS

In our study, the overall incidence of POST was less in ketamine group when compared to saline group. Our study also revealed that duration of intubation is a significant risk factor for postoperative sore throat in patients undergoing surgeries under general anaesthesia with endotracheal tube.

CONCLUSIONS

From our study we conclude that ketamine nebulization had significant impact on both reductions in incidence as well as severity of postoperative sore throat in patients undergoing surgeries under general anaesthesia with endotracheal intubation.

KEYWORDS

Post-Operative Sore Throat, Endotracheal Intubation, General Anaesthesia.

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BACKGROUND

Today general anaesthesia (GA) with endo-tracheal tube (ETT) is very commonly employed.¹ To enable mechanical ventilation, an endotracheal tube (ETT) is used, although there are alternative devices that can assist respiration.¹ Post-operative sore throat (POST) is a common complication of anaesthesia that affects the patient satisfaction after surgery.^{1,2} POST was recently ranked by American anesthesiologist's as the eighth most important problem of current clinical anesthesiology. The pharmacological methods include beclomethasone inhalation and azulene sulfonate, ketamine or licorice gargle.^{3,4} Ketamine is shown to be a promising agent to reduce POST by few authors.^{4,5,6}

Ketamine is a noncompetitive inhibitor at the N- methyl D- aspartate (NMDA) receptor. It has been shown that NMDA receptors are present not only in the CNS but also in peripheral nerves. It has been further reported that peripherally administered NMDA receptor antagonists are involved with anti-nociception and anti-inflammatory cascade.

Postoperative sore throat (POST) is a frequent side effect following endotracheal intubation.⁸ the injury varies from epithelial loss, glottis haematoma, glottis oedema, submucosal tear to contact ulcer granuloma⁵. He aetiology of postoperative sore throat is thought to involve mucosal erosion caused by endotracheal tube, trauma from intubation, bucking or coughing and dryness of mucosa^{2,6,7}. Several factors contribute to the occurrence of postoperative sore throat after endotracheal intubation. These include-

- Larger-sized non-lubricated cuffed endo-tracheal tube.
- Prolonged intubation.
- Surgeries requiring extreme positioning and airway manipulation.
- Multiple attempts of intubation.
- Ryle's tube insertion and suctioning.
- Blood and secretions causing mucosal irritation.

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- Peri-pharyngeal muscle fasciculation due to succinylcholine.
- High intra-cuff pressure.⁸
- Use of throat packs.
- Cuff design.
- High anaesthetic gas flows.

Ozaki et al. (2001)⁹ conducted a prospective study to evaluate the effect of transdermal ketoprofen on postoperative sore throat, in 63 patients undergoing surgeries under general anaesthesia. They found that the pain caused by tracheal intubation was relieved by intra-operative topical use of transdermal ketoprofen³⁶. Levy et al. (2003)¹⁰ conducted a randomized prospective study on 60 patients belonging to ASA PS I-II undergoing tracheal intubation for dental surgery, who received either topical lignocaine 5% or aerosolized methyl prednisolone 80 mg. The patients receiving methyl prednisolone showed slightly better score for sore throat and cough 1 h after surgery compared to topical lignocaine. Agarwal A, et al¹⁹ in 2006 compared the efficacy of dispersible aspirin gargle to benzydamine hydrochloride gargle to 60 consecutive female patients aged 16- 60 yrs., ASA PS I and II undergoing elective modified radical mastectomy under general anaesthesia. They found that the Aspirin gargle reduced the incidence of POST for 4 h whereas benzydamine hydrochloride gargle reduced POST for 24 h. Sumathi PA, Shenoy T, Ambareesh M, et al (2008)¹¹ conducted prospective randomized double blinded controlled study on 150 subjects. They found that the Betamethasone gel applied over tracheal tube cuff was more effective in reducing POST, cough and hoarseness when compared to lignocaine and a control group Park et al 2008¹² conducted a randomized prospective double blinded placebo controlled study to evaluate the efficacy of dexamethasone for reducing the incidence and severity of POST and hoarseness on 166 patients aged 18-75 yrs. undergoing thoracic surgery with DLT. They found that the prophylactic use of 0.2 mg/kg of dexamethasone significantly decreased the incidence and severity of sore throat and hoarseness after tracheal extubation. In 2008, Canbay et al¹³ published a prospective randomized controlled single-blinded study that examined the effects of a ketamine gargle on POST on 46 patients undergoing septo-rhinoplasty under general anaesthesia with endotracheal intubation. Researchers found that both the incidence and severity of POST was significantly reduced in the ketamine gargle group. In 2009, Rudra et al,¹⁴ designed a prospective, randomized placebo-controlled single blinded study by assigning 40 ASA 1 patients undergoing abdominal and pelvic surgery under general anaesthesia. He found that the patients having ketamine gargle effectively attenuated POST. In 2010, Shrestha et al,¹⁵ compared ketamine gargle with placebo by assigning 40 ASA I- II patients undergoing elective abdominal and orthopaedics surgery under general anaesthesia. Ketamine group showed reduced incidence and severity of POST after endotracheal intubation. Chan et al in 2011¹⁶ conducted double-blind randomized control study by assigning 44, ASA

I-II patients who were undergoing elective gynaecological procedures under general anaesthesia with endotracheal intubation. They concluded that pre-induction ketamine gargle can attenuate POST in the early postoperative period and they also found that the topical use is effective than oral/ parenteral to attenuate POST. In 2015, Vanita Ahuja, Sukanya Mitra, Rashi Sarna et al⁴ conducted a prospective randomised controlled trial by assigning 100 patients belonging to ASA I-II groups aged 20–60 years, of either sex undergoing surgery under general anaesthesia (GA). Ketamine nebulisation attenuated POST at 2 h and 4 h postoperatively.

METHODS

Department of Anaesthesiology, Government Medical College, Kottayam Study population Patient aged 20-60 years belonging to ASA PS I – II undergoing elective surgical procedure under general anaesthesia with endotracheal intubation.

Study Groups

200 patients were allotted into 2 groups of 100 each.
 Group 1: Patients received nebulization with 50 mg ketamine in 4 ml normal saline.
 Group 2: Patients received nebulization with 5 ml normal saline.

Inclusion Criteria

1. ASA physical status I–II.
2. In the age group of 20 and 60 years.
3. Of either sex.
4. Patients undergoing surgery in supine position.

Exclusion Criteria

1. Patient refusal.
2. Surgeries involving oral cavity, airway, head and neck surgeries.
3. Anticipated difficult airway.
4. More than 2 attempts at intubation, 1 episode of bucking while extubation.
5. Use of nasogastric tube or throat packs.
6. Patients with upper respiratory tract infection, bronchial asthma.
7. Patient on steroid therapy.
8. Patients requiring nasal intubation.
9. ASA PS III-IV.

Sample Size

Minimum sample size required for the study is calculated using the formula-

$$n = \frac{(Z\alpha + Z\beta)^2 \{P1(1-P1) + P2(1-P2)\}}{(P1-P2)^2}$$

Zα = Z value of α error at 5% = 1.96
 Zβ = Z value of β error with 80% power = 0.84
 P1 = proportion of sore throat among normal saline group = 46%
 P2 = proportion of sore throat among ketamine group = 20%

$$n = \frac{(1.96 + 0.84)^2 \{0.46(1-0.46) + 0.2(1-0.2)\}}{(0.46-0.20)^2} = 47.36$$

Hence study was conducted in minimum of 100 subjects in each arm.

Study Procedure

All the patients were pre-medicated with Tab Ranitidine 150 mg, Tab Metoclopramide 10 mg, Tab Alprazolam 0.25 mg Patient was fasted for 8 hrs. Patients were allotted into two groups randomly. General anaesthesia was induced within 10 min after completion of nebulization Premedication Inj. Fentanyl 2 mcg/kg i/v, Inj. Midazolam 0.02 mg/kg i/v and Inj. Glycopyrrolate 10 mcg/kg i/v. After 3 minutes of pre oxygenation, anaesthesia was induced with 2 mg/kg propofol and intubation was done after vecuronium 0.1 mg/kg with appropriate sized cuffed endotracheal tube. Cuff was inflated with air. The minimum volume needed to prevent leak around the tube as confirmed by palpation and auscultation. Anaesthesia was maintained with nitrous oxide: oxygen in the ratio 4:2. The intraoperative monitoring includes continuous ECG, NIBP, pulseoximetry (SpO₂), and end tidal carbon dioxide. At the completion of surgery, neuromuscular block was reversed with iv neostigmine 50 µg/kg and glycopyrrolate 10 µg/kg while awaiting the return of spontaneous ventilation. During extubation, if a patient has excessive coughing, IV lignocaine 1.5 mg/kg was administered. After patient becoming fully conscious; trachea was extubated after deflating cuff.

Assessment of POST

Assessments for POST at 2, 4, 8 and 12 hours after extubation, in post anaesthesia care unit. Assessed using 4 scales and taking average of the 2 having similar pain score. 4 scales were as follows Visual analogue scale(0-3) using 100 mm measuring scale; Sore Throat Pain Intensity Scale:¹⁷

- 0 = no sore throat (0-4 mm)
- 1 = mild sore throat (5-44 mm)
- 2 = moderate sore throat (45-75 mm)
- 3 = severe sore throat (76 mm-100 mm)

Numerical Rating Scale

A patient select a whole number (0-10 integers) that best reflects the intensity of their pain⁵

- 0 = no sore throat
- 1 = mild sore throat (1-3)
- 2 = moderate sore throat (4-6)
- 3 = severe sore throat (7-10)

Melzack's Pain Intensity Scale: Is one part of McGill Pain Questionnaire that measures the intensity of pain on the following scale,¹⁸

- 0 = no pain
- 1 = mild pain
- 2 = discomforting /distressing
- 3 = horrible / excruciating

* Four Point Scale:¹⁹

- 0 = No sore throat
- 1 = Mild sore throat (complains of sore throat only on asking).

- 2 = Moderate sore throat (complains of sore throat on his / her own)
- 3 = Severe sore throat (change of voice / hoarseness, associated with throat pain).

RESULTS

| Group | Age | | | | Total |
|---------|-----------|--------|------------|--------|--------|
| | <40 Years | | > 40 Years | | |
| | Number | % | Number | % | |
| Group 1 | 60 | 60% | 40 | 40% | 108 |
| Group 2 | 48 | 48% | 52 | 52% | 92% |
| Total | 100 | 100.0% | 100 | 100.0% | 100.0% |

Table 1. Age

Found no statistical significance in age distribution.

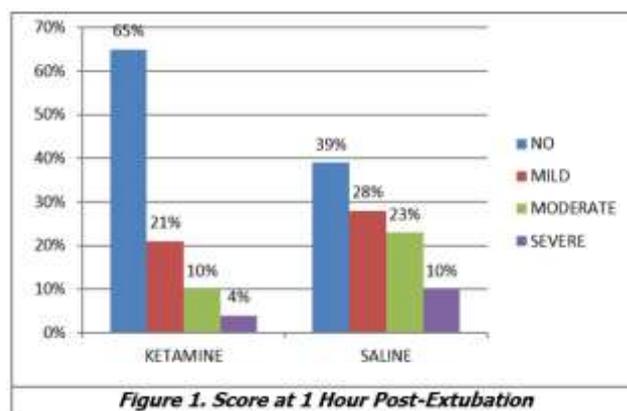


Figure 1. Score at 1 Hour Post-Extubation

At 1 hour 65% of patients among the ketamine group did not develop sore throat. Ketamine group had statistically significant lower incidence of POST.

| Group | Postoperative Sore Throat | | | | | | | |
|---------|---------------------------|-------|------|-------|----------|-------|--------|------|
| | No | | Mild | | Moderate | | Severe | |
| | No. | % | No. | % | No. | % | No. | % |
| Group 1 | 67 | 67% | 25 | 25% | 7 | 7% | 1 | 1% |
| Group 2 | 35 | 35% | 38 | 38% | 19 | 19% | 8 | 8% |
| Total | 102 | 51.0% | 63 | 31.5% | 26 | 13.0% | 9 | 4.5% |

Table 2. Score at 2 Hours Post-Extubation

Chi square test value= 23.705,
p-value = .0001

At 2 hour 67% of patients among the ketamine group did not develop sore throat. Ketamine group had statistically significant lower incidence of POST.

| Group | Postoperative Sore Throat | | | | | | | |
|---------|---------------------------|-------|------|-------|----------|-------|--------|------|
| | No | | Mild | | Moderate | | Severe | |
| | No. | % | No. | % | No. | % | No. | % |
| Group 1 | 66 | 66% | 27 | 27% | 6 | 6% | 1 | 1% |
| Group 2 | 38 | 38% | 28 | 28% | 23 | 23% | 11 | 11% |
| Total | 104 | 52.0% | 55 | 27.5% | 29 | 14.5% | 12 | 6.0% |

Table 3. Score at 4 Hours Post-Extubation

Chi square test value= 25.856
p-value =0.0001

66% of patients among the ketamine group free of sore throat. Ketamine group had statistically significant lower incidence of POST.

| Group | Postoperative Sore Throat | | | | | | | |
|---------|---------------------------|-------|------|-------|----------|-------|--------|------|
| | No | | Mild | | Moderate | | Severe | |
| | No. | % | No. | % | No. | % | No. | % |
| Group 1 | 73 | 73% | 21 | 21% | 4 | 4% | 2 | 2% |
| Group 2 | 32 | 32% | 41 | 41% | 21 | 21% | 6 | 6% |
| Total | 105 | 52.5% | 62 | 31.0% | 25 | 12.5% | 8 | 4.0% |

Table 4. Score at 8 Hours Post-Extubation

Chi Square Test Value= 36.021,
p-value = 0.0001

Ketamine group had statistically significant lower incidence of POST.

| Group | Postoperative Sore Throat | | | | | | | |
|---------|---------------------------|-------|------|-------|----------|------|--------|------|
| | No | | Mild | | Moderate | | Severe | |
| | No. | % | No. | % | No. | % | No. | % |
| Group 1 | 91 | 91% | 7 | 7% | 2 | 2% | 0 | 0% |
| Group 2 | 43 | 43% | 45 | 45% | 9 | 9% | 3 | 3% |
| Total | 134 | 67.0% | 52 | 26.0% | 11 | 5.5% | 3 | 1.5% |

Table 5. Score at 12 Hours Post-Extubation

Chi square test value= 52.418,
p-value = 0.0001

Ketamine group had statistically significant lower incidence of POST.

In our study the overall incidence of POST was less in ketamine group when compared to saline group which is statistically significant with Pearson chi-square value of 15.193 and p value of <0.002 At 1 hour, 65% of patients of ketamine group were free of sore throat while 39% patients were free in saline group. At 2 hour, 67% among ketamine group were free of POST. At 4 hour, 66% among ketamine group did not have POST comparable to 38% patients in saline group. At 8 hour, 73% of patients among ketamine group didn't develop sore throat while only 32% patients of saline group were free of POST. At 12 hour 91% of patients among ketamine group were free from POST compare to 43% of saline group.

DISCUSSION

In our study the incidence of POST was less in ketamine group with 17.5% when compared to saline group 30.5% which is statistically significant with Pearson chi-square value of 15.193 and p value of <0.002. In our study bilinear logistic regression was done and Nagelkerke R Square was obtained at 16.9%. It was found that the duration of intubation is the significant risk factor for POST. In an earlier study, Vanita Ahuja, Sukanya Mitra, Rashi Sarna et al⁴ in 2015 conducted a prospective randomised double blind placebo controlled trial by assigning 100 patients belonging to ASA PS I-II in the age group 20-60 years, of either sex undergoing surgery under general anaesthesia (GA). The POST was observed immediately on reaching post-anaesthesia care unit and at 2, 4, 6, 8, and 12h postoperatively. They found that ketamine nebulisation

attenuated the incidence and severity of POST significantly, especially in the early post-operative period, with no adverse effects. Canbay et al found that ketamine gargle was effective in reducing the incidence and severity of POST due to its anti-inflammatory effects. However, there are a few demerits of gargle ketamine over nebulization due to its bitter taste and large volume for gargle with risk of aspiration if swallowed. Honey is added to ketamine to mask the bitter taste.¹³ Our rationale of using the nebulized form of ketamine rather than its other forms (oral, IV, gargle) was primarily oriented for safety and ease of administration to the patient in the immediate pre-operative period.

CONCLUSIONS

Ketamine nebulization had significant impact on both reduction in incidence as well as severity of postoperative sore throat in patients undergoing surgeries under general anaesthesia with endotracheal intubation. Duration of intubation is a significant risk factor for post-operative sore throat in patients undergoing surgeries under general anaesthesia.

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