Journal or p OF	RIGINAL RESEARCH P	PAPER	Anaesthesiology
ARIPET INSI	STUDY THE EFFECT OF M PHATE NEBULISATION AND ULISATION FOR PREVENT RATIVE SORE THROAT FO ERTION DURING GENERAL	IAGNESIUM D KETAMINE 'ION OF POST- LLOWING I-GEL L ANAESTHESIA''.	KEY WORDS: Magnesium sulphate(Mgso4),General anaesthesia(GA),Post operative sore throat(POST),Verbal rating scale(VRS)
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INTRODUCTION: Post operative sore throat (POST) is a frequent complaint with I-gel for general anaesthesia. Irritation and inflammation of		gender sexes, aged between 20-60 years, belonging to ASA I and II, posted for elective surgeries were included in the study.	
the airway are considered to be the causes of POST. Although considered a minor complication it may cause significant		Patients with history of frequent sore throat, bronchial asthma, chronic obstructive pulmonary disease, oral surgeries, head	

hospital stay thus should be prevented⁽¹⁾. I-Gel is a relatively new and unique supraglottic airway with non-inflatable cuff made of a soft gel like medical grade thermoplastic elastometer and used in anaesthesia during spontaneous or intermittent positive pressure ventilation⁽²⁾.

patient morbidity, dissatisfaction, and increased length of

After I-Gel insertion, the incidence of sore throat varies from $21-65\%^{(3)}$.

Various non-pharmacological and pharmacological measures have been tried to decrease the incidence of POST with variable success rate⁽¹⁾.

Non-pharmacological methods like careful airway instrumentation, minimizing the number of laryngoscopy attempts, I-gel insertion after full relaxation, gentle oropharyngeal suctioning and Pharmacological methods like use of beclamethasone gel, gargling with azulenesulphonate, ketamine, magnesium sulphate and local spray of benzydaminesulphonatehave been reported to decrease the incidence of post operative sore throat⁽²⁾.

It is known that N methyl D aspartate (NMDA) receptors have a role in nociception and inflammation. NMDA receptors are found in peripheral nerves and in the central nervous system⁽⁴⁾. Hence NMDA antagonists such as Magnesium sulphate and ketamine work on peripheral nerve endings in pharyngeal mucosa and can reduce the incidence of sore throat hence this study is aimed at using the aerosol route of magnesium sulphate and ketamine to find its effectiveness in preventing POST⁽⁶⁾.

In this background, the aim of the study was to compare the efficacy of Magnesium sulphate nebulization and ketamine nebulization in prevention of post operative sore throat with I-gel for general anaesthesia.

Research question: In patients undergoing general anaesthesia with i-gel, weather 'Magnesium sulphate nebulization is better than ketamine nebulization in prevention of POST.

MATERIALS AND METHODS:

A prospective, randomized, comparative study was approved by the Institutional Ethics Committee (Reference No: EC-141) and registered with Clinical Trail Registry Of India, no. CTRI/2022/09/045879. The study was conducted between February 2021 to January 2022. Written Informed consent was taken and the study was conducted in 100 patients of either

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Patients with history of frequent sore throat, bronchial asthma, chronic obstructive pulmonary disease, oral surgeries, head and neck surgeries, mallampatti grade 3 and above, known allergies to study drug, those who received non-steroidal antiinflammatory drugs recently were excluded from the study.

Patients who fulfilled the inclusion criteria were randomly divided into two groups, Group M and Group K using computer generated random numbers.

After obtaining informed written consent, all enrolled patients underwent detailed pre-anaesthetic evaluation and routine laboratory investigations.

All patients were kept fasting overnight and pre-medicated with oral alprazolam 0.25mg and ranitidine 150mg the night before surgery.

On the day of surgery after arrival to the operation theatre, intravenous line was secured and preloaded with ringer lactate 500ml.

Multichannel monitors were connected to monitor pulse rate, oxygen saturation, electrocardiogram, non-invasive blood pressure and base line vitals were recorded.

Prior to induction with general anaesthesia, patients in Group M received nebulization with magnesium sulphate 225 mg diluted in 5ml NS for 15 minutes and patients in Group K received nebulization with 50 mg ketamine in 5ml NS for 15 minutes.

This study aimed at comparing the incidence and severity of POST with Magnesium sulphate nebulization and ketamine nebulization following use of I-gel.

All patients were preoxygenated, pre-medicated with intravenous glycopyrolate 0.005mg/kg IV, ondansetron 0.1mg/kg IV, fentanyl 2mcg/kg IV and midazolam 0.05mg/kg IV. Anaesthesia induction was done with intravenous injection of propofol 2mg/kg followed by I-GEL insertion with appropriate size facilitated by injection atracurium 0.5mg/kg, maintenance of anaesthesia was achieved with 66% nitrous oxide in oxygen and isoflurane and injection atracurium 0.1mg/kg as and when required. Tidal volume was set at 6-10ml/kg body weight and end tidal carbon-di-oxide was maintained around 35mmHg.

Heart rate, mean arterial pressure, oxygen saturation was monitored every 5 minutes till the end of the surgery. Neuromuscular blockade was reversed by injection neostigmine 0.05mg/kg and injection glycopyrolate 0.01mg/kg. During emergence from anaesthesia any cough

was noted. Upon completion of surgery, I-GEL was removed by careful suctioning when adequate recovery is observed. The total duration of surgery and anaesthesia were observed and recorded.

Hemodynamic recording were done at pre-nebulization (baseline parameters before nebulization of patient), preinduction (parameters after nebulization and just before induction of general anaesthesia).

After extubation patients were shifted to postoperative care unit for observation and the patients were assessed regarding the incidence and severity of POST at 0,2,4, and 24 hours. Any side effects like cough, nausea and vomiting were also noted.

Incidence of POST, was assessed on a Verbal Rating Scale(VRS) and the severity was assessed by 4-point scale(0-3) as follows

- 0=no sore throat
- l=mild discomfort or sore Throat (complains only on questioning)
- 2=moderate degree of sore throat (complains of his/her own)
- 3=severe sore throat (change in voice, hoarseness and throat pain).

Statisical Analysis And Sample

The duration of anaesthesia was between 30min to 2hrs, incidence and severity of sore throat assessed up to 24hours, by keeping the power at 80% and confidence interval at 95%, a sample of 48 will be required in each group, to detect a minimum of 25% difference in the duration of anaesthesia between two groups. In order to compensate for possible dropouts, 50 patients were studied in each group.

The data was coded and entered into Microsoft Excel spreadsheet. Analysis was done using SPSS version 20 (IBM SPSS Statistics Inc., Chicago, Illinois, USA) Windows software program. Descriptive statistics included computation of percentages, means and standard deviations. The unpaired t test (for quantitative data to compare two independent observations) was applied. The chi square test was used for quantitative data comparison of all clinical indicators. Level of significance was set at p < 0.05.

RESULTS:



Figure 1: Consort chart

Evaluation Of Incidence Of POST

- In group M patients who received mgso4 nebulization 4 of them had incidence of POST at 0 and 2 hrs, 3 at 4hrs and none complained of POST at 24hours.
- In group K patients who received ketamine nebulization, 8 patients complained of POST upto 4hrs and 1 had complaints at 24hrs.
- There was no significant difference between the 2 groups with a P value of >0.05.

Table 1 : shows time of incidence of POST sore throat.



Graph 1: shows time of incidence of POST sore throat

Evaluation Of Severity Of Post

In our study, 4 patients with Mgs04 nebulisation and 8 with ketamine nebulisation complained of mild sore throat, which is statistically not significant.

Table 2 : shows severity of post operative sore throat



Graph 2: shows severity of post operative sore throat

Cough At Different Time Intervals (0-3) Table 3: Shows incidence of cough at different time intervals



Graph 3: Shows incidence of cough at different time intervals

None of the patients complained of nausea and vomiting.

DISCUSSION:

POST and cough remains the major complaints among most of www.worldwidejournals.com

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the patients who undergo GA. It is even more common with prolonged surgeries.

Modern anaesthesia is multifaceted, secure, and requisite to the patient therefore anaesthesiologists doing their efforts to minimize the occurrence and severity of anaesthesia related complications like POST.

Tracheal intubation is associated with a greater risk of postoperative sore throat when compared to either a supraglottic airway device is used and several risk factors have been identified like female sex , pre-existing lung disease, duration of anaesthesia and the presence of a blood-stained tracheal tube on extubation were all associated with the greatest risk of postoperative sore throat⁽³⁾.

Vast majority of current literature suggest that the incidence of POST is lower with I gel due to the incorporation of a thermoplastic elastomer cuff instead of the usual inflatable cuff which hence exerts less pressure on the hypopharynx.

Prophylactic management of POST is recommended to improve the quality of anaesthesia care of duration of time a patient stays in the post-anesthesia care unit as POST increases the cost of care⁽¹³⁾.

Prophylactic administration of nebulized Magnesium or Ketamine can decrease incidence and severity of POST within the first 24 hours following I gel insertion.

The suggested mechanism for the attenuation is the antinociceptive and anti-inflammatory properties of NMDA receptor antagonists. Typically, POST occurs following noxious stimulation provoked by inflammation that results from mucosal injuries. Excitatory amino acids such as glutamate and inflammatory mediators are released after such mucosal injuries or following stretch of pharyngeal muscles by instrumentation. Prior occupation of NMDAR by Ketamine or Magnesium molecules prevents glutamate mediated central sensitization and sensation of POST⁽¹³⁾.

In our study patients who were given Mgso4 nebulization, 4 of them had incidence of POST at 0 and 2 hrs, 3 at 4hrs and none complained of POST at 24hours. While with ketamine nebulisation ,8 patients complained of POST upto 4hrs and 1 had complaint at 24hrs. There was no significant difference between the 2 groups, with a P value of >0.05.

In study done by Essam Mostafa et al observed that incidence of POST was significantly lower in magnesium group compare to ketamine group at 2hr(p=0.023), 4hr(p=0.001), and 8hr(p=0.044). Severity of sore throat was also significantly lower in magnesium group at 4hr(p=0.002) and 8hr(p=0.038). Magnesium sulfate nebulization reduces incidence and severity of POST more effectively than ketamine nebulization⁽⁶⁾.

Borazan et al also conducted a similar study with magnesium sulfate lozenges and found that The incidence of POST at 4 h was higher in control group than in magnesium group (95% CI: 26%, 14-42%; P=0.032). The highest incidence of POST occurred at the second hour after surgery, with the rate of 23% in the magnesium group and 57% in the control group (95% CI: 34%, 20-51%; P=0.007). The severity of POST was significantly lower in the magnesium group at 0 (P=0.007) and 2 h (P=0.002). it significantly reduced the incidence and severity of POST⁽⁷⁾.

Study done by Narinder p singh on Role of topical magnesium in post-operative sore throat: A systematic review and metaanalysis of randomised controlled trial with Seven trials involving 726 study participants were included in the final analysis showed that the Incidence of POST at 24 hours was significantly lower in magnesium group (26/363) in comparison to active and non-active control group (89/363);P = 0.00- RR 0.22 (95%CI = 0.12-0.39, I2 = 0%). No significant adverse events were reported with the use of topical magnesium⁽⁶⁾.

Study done by Gupta et al also assessed the efficiency of preoperative nebulization of magnesium sulfate and found that the incidence and severity of POST were reduced at rest and on swallowing at all-time points (P<0.05)⁽⁶⁾.

Yadav et al evaluated the effect of magnesium sulfate nebulization on POST at rest and swallowing and found that it significantly decreased the incidence of POST at 4 and $24h^{(10)}$.

In contrast to our study Shalini jain et al observed that incidence of sore throat was was 37.3% (56/150); 60% in normal saline group (30/50), 30% in magnesium sulfate group (15/50), 22% in ketamine group (11/50) (p<0.05 for both GK and GM on comparing with GS), least with GK but insignificant on comparison with GM (p=0.37). Haemodynamic response to laryngoscopy was signicantly (p<0.05) attenuated in GK.hence concluded that the incidence of POST is significantly less with ketamine and Mgso4 nebulisation⁽¹¹⁾.

Study done by Neepa patel et al on incidence of sore throat observed at 0hr, 2hr, 4hr, 12hr, and 24hrs showed that there was statistically significant reduction in sore throat in group k compare to group m at 0hr (p=<0.01), 2hr (p=<0.01), and 4hr (p=<0.01). there was also decrease in incidence of sore throat in group k compare to group M at 12hr and 24hr but it was statistically insignificant (p=>0.05) hence concluded that the ketamine nebulization was superior than magnesium sulphate nebulization in prevention of sore throat⁽⁴⁾.

Ahuja et al evaluated the effectiveness of nebulized ketamine on the severity of POST which occurred in 44.03 percent of patients overall, with 41 patients in group S (61.19 percent) and 18 patients in group K (26.86 percent) experiencing POST throughout the study period. (0.001) (P = 0.001). At 2, 4, 6, 12, and 24 hours postoperatively, the use of ketamine nebulization significantly reduced POST (P 0.05). At 2 h (P=0.04) and 4 h (P = 0.002) postextubation, the severity of sore throat was also greater in the saline group than in the ketamine group, hence concluded that Preoperative nebulized ketamine is helpful at reducing the occurrence and severity of postoperative sore throat without causing any adverse effects⁽¹⁾.

In our study, pre-operative nebulization with Mgso4 and ketamine was used to prevent the incidence and severity of POST and it was found to be effective in preventing the incidence and severity of POST during first 24hrs without any significant side effects. The incidence and severity of POST in the magnesium sulfate group was decreased but not statistically significant when compared to ketamine group.

CONCLUSION:

In our study we concluded that there was a statistically significant decrease in incidence and severity of POST with preoperative nebulisation of Magnesium sulphate compared to ketamine nebulisation in prevention of POST.

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