

## Comparison of the Efficacy of 2% Viscous Lignocaine Gargle Over 5% Ketamine Gargle for Prevention of Postoperative Sore Throat in Patients Undergoing General Anesthesia with Endotracheal Intubation: A Randomized Control Trial

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### Abstract

Post-operative Sore Throat (POST), is unavoidable following endotracheal intubation. In our study, we compared the efficacy of 2% viscous lignocaine gargle over 5% ketamine gargle for the prevention of Post-operative Sore Throat (POST) in patients undergoing general anesthesia with endotracheal intubation. *Methodology:* 80 patients undergoing general anesthesia with endotracheal intubation were allocated into two groups lignocaine (Group L) and ketamine (Group K). Both the Groups were made to gargle five minutes with respective solutions before pre-medication. Group K were made to gargle 50 mg ketamine with 29 ml normal saline and in Group L gargling was done with 30 ml of 2% viscous lignocaine undiluted. The primary objective was to assess the incidence and severity of POST. Secondary objectives were, response to intubation every three minutes for initial 15 minutes, and cough in the post-operative period. *Results:* Incidence and severity of POST was significantly high at the end of 2<sup>nd</sup>, 4<sup>th</sup>, 6<sup>th</sup>, 12<sup>th</sup> in Group L. ( $p = < .07$ ) ( $< .001$ ) ( $< .001$ ) ( $< .04$ ). There was a significant increase in heart rate and mean arterial pressure in group at the end of 1<sup>st</sup>, 3<sup>rd</sup> and 6<sup>th</sup> minute after intubation in Group K. 4% in Group K and 12% in Group L had post-operative cough of Score 1.

**Keywords:** Gargle; Post-operative sore throat; Ketamine; Lignocaine.

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### Introduction

POST is rated as the eighth most adverse effect in post-operative period.<sup>1</sup> With the incidence after ET intubation between 15–90%.<sup>2,3</sup> sore throat is a common post-operative complaint, occurring most often following tracheal intubation. There are umpteen factors such as tracheal-tube size, cuff design, duration of surgery that have been predicted to cause POST. Routine tracheal intubation for elective surgical procedures can result in pathological changes, trauma and nerve damage

which may also account for post-operative throat.<sup>4</sup>

POST has to effectively taken care to prevent post-operative morbidity and patient dissatisfaction. There are numerous studies involving pharmacological and non-pharmacological agents to alleviate POST. These include dexamethasone,<sup>5</sup> lignocaine<sup>6</sup> magnesium,<sup>7</sup> tramadol.<sup>8</sup> There is increasing amount of experimental data showing that NMDA receptors are found not only in the CNS but also in the peripheral nerves. Anti-nociceptive and anti-inflammatory property of ketamine helps in prevention of POST.<sup>9</sup>

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## Materials and Methods

After obtaining written and informed consent, and CTRI registration (REF/2017/07/014933) 80 patients (seven dropouts) were included in the study and randomized into two Groups (40 in each Group), Group K and Group L via a computer generated random number sequence and group allocation was done by principle investigator, (Fig. 1). Along with pre-anesthesia check up all patients were screened for sore throat. Inclusion criteria includes ASA 1–2, age 18–60 years old, Mallampatti Grade 1 and 2, patients undergoing surgery under general anesthesia with endotracheal intubation. The exclusion criteria were ASA greater than three, predicted difficult intubation and patients who required more than two intubation attempts and sore throat.

Patients were kept nil per oral for *six hours* and antacid pre-medication was given as per institute protocol. All patients in the study were instructed regarding the procedure for gargling in the pre-operative holding area, that it should be done for *30 seconds* and they should not swallow or spit it immediately. Patients were instructed on the four point grades of post-operative throat pain,<sup>10</sup> where Grade 0 was no pain, Grade 1, mild pain, Grade 2, moderate pain and Grade 3, severe pain. Patients were shifted to operation room and all standard monitors were connected. Both group patients were made to sit and do the gargling for *30 seconds, five minutes* before anesthesia pre-medication according to the group allocated. Gargle preparation was done by the OT anesthesiologist, who was blinded about the group. Group K were made to gargle with *50 mg* ketamine with *29 ml* normal saline using a measuring jar (Aneket<sup>®</sup> Neon Laboratories Limited) (total volume *30 ml*). In Group L patients were made to gargle with *30 ml* of 2% viscous lignocaine undiluted. (Lox 2% Neon Laboratories Limited).

General anesthesia was induced and maintained according to departmental protocol. Intubation was done by a Senior Anesthesiologist to minimize airway trauma. If the patients required more than two intubation attempts they were excluded from the study. Polyvinyl endotracheal tube (high volume and low pressure cuff) was used for intubation and standard size of *7 mm* for female patients and *8 mm* for male patients were used. After intubation cuff was injected with air until a minimal audible leak was heard in the suprasternal area. Following Parameters were recorded by the OT anesthesiologist during intra-operative period. Heart rate and Mean Arterial Pressure

(MAP) were recorded at the base line and then every *3 min* till *15 min* after the intubation. After surgery, all patients were extubated and shifted to Post-operative Ward (POW). Total duration of intubation time was noted. Post-operative staff was instructed regarding the grade of POST and they noted it in the proforma. POST with 4 point scale (0 to 3) was assessed every *2 hrs* interval for first *6 hours* then every *6 hour* interval till *24 hrs*, by the staff who was not a the part of the study. Post-operative cough was assessed using three point scale (No cough at any time since the operation-0, Minimal-1, Moderate-2 Severe-3).<sup>11</sup> Patients were observed for cough at the end of *2, 4, 6, 12, 24 hours*. Those with moderate to severe sore throat were given Normal saline gargle.

## Statistical Analysis

The collected data were entered in master sheet in Microsoft excel and analysed using Statistical Package for Social Sciences (SPSS Inc, Chicago, IL, USA, version 19.0 for windows). Normality for age, weight, duration of surgery was checked with Kolmogorov-Smirnov test. Hemodynamic variables (heart rate and mean arterial pressure) between the groups were compared with *t*-test differences in the incidence of POST were compared with Fisher's exact test or Chi-square test. Mann-Whitney *U*-test was used to assess severity of POST.  $p < 0.05$  was considered statistically significant.

## Results

We included 87 patients in the study and seven were excluded. Four patients had sore throat, two patients had partially swallowed during gargling and two patients there were more than three intubations attempts. There were no significant differences between the two groups regarding age, body weight, gender distribution, duration of surgery (Table 1). Surgeries in both the groups included epigastric hernia, lymph node excision, fibroadenoma breast, and axillary lipoma.

**Table 1:** Demographic data

Sl. No	Characteristics	Group L (Mean ± SD)	Group K (Mean ± SD)
1	Age (years)	37.7 ± 8.8	35 ± 10.7
2	Weight (Kg)	61.28 ± 15.11	62.18 ± 10.42
3	Male (Female)	28:22	24:26
4	Duration of intubation (mins)	45 ± 12.75	48 ± 14.52

**Sample size calculation**

Based on a previous study by Aigbedia<sup>10</sup> considering the incidence of the moderate POST in patients who received katamine gargle as compared to control

group (44.1 vs 23.5%), with 95% confidence interval and 80% power, minimum sample size to obtain statistically significant result was calculated as 35 in each Group. Considering the dropouts we recruited 40 in each Group.

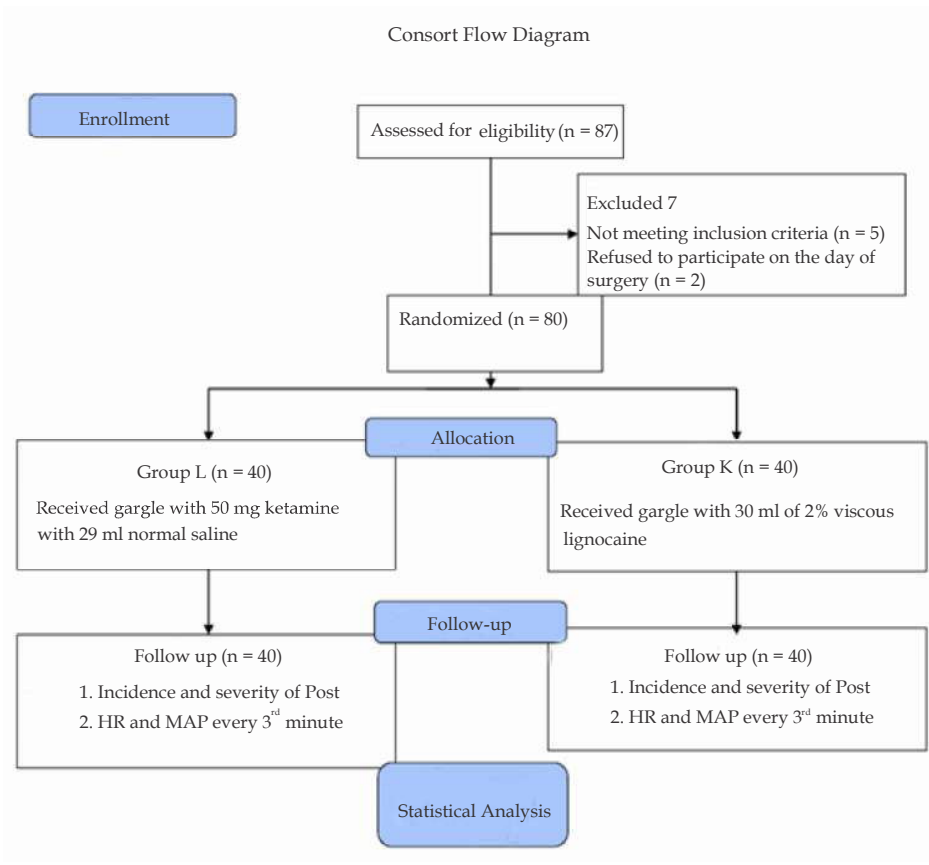


Fig. 1: Consort Flow Diagram

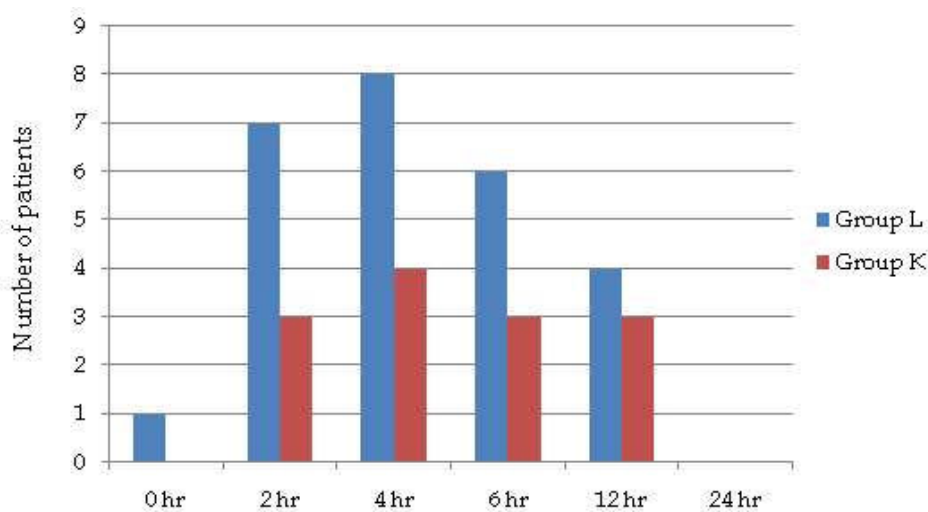


Fig. 2: Incidence of post-operative sore throat at 0, 2, 4, 6, 8, 12 and 24 h post-operatively in both the groups

### Discussion

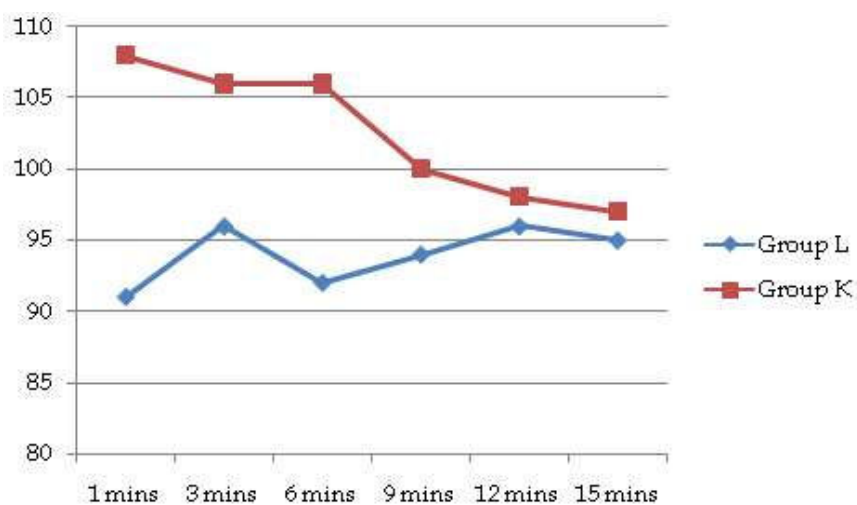
Ketamine hydrochloride is an intravenous induction agent and a potent NMDA receptor antagonist. It has been recently studied in attenuating POST because of its ant nociceptive property and anti-inflammatory property. The incidence of POST in lignocaine group was 62% (24 patients) and in Group K was 33% (13 patients) (Fig. 2). Of 24 patients in Group L, 15 had POST score one, nine had score two. In Group K, 11 had a POST score of one and two patients had a score of 2, (Table 2). None of the patients in both Group had severe sore throat. (Score 3). This was similar to the study done by Aigbedia, KU Tobi, FE Amadasun<sup>11</sup> who compared ketamine gargle and lidocaine jelly application for the prevention of POST with endotracheal Intubation and proved that ketamine gargle had more protection against moderate to severe post-operative pain compared to topical lidocaine jelly. Rudra, Suchanda Ray, and S Ghosh *et al.*<sup>12</sup> Shrestha *et al.*<sup>13</sup> in their study proved that gargling with ketamine attenuates the Post-operative Sore Throat without any drug related adverse effects. Ahuja V, Mitra S, Sarna R<sup>14</sup> had justified that nebulized ketamine decreases incidence and severity of post-operative sore throat. All the above studies are concordant with our study that ketamine is more potent in attenuating POST.

**Table 2:** Grading of POST between Groups

Time	Group L (n = 40)	Group K (n = 40)	p - value
0 hr	0	1	< .07
	1	0	
	2		
	3		
2 hr	0	3	** < .001
	1	4	
	2		
	3		
4 hr	0	5	** < .001
	1	3	
	2		
	3		
6 hr	0	5	** < .001
	1	1	
	2		
	3		
12 hr	0	4	** < .04
	1	1	
	2		
	3		
24 hr	0	6	** < .04
	1		
	2		
	3		

\*\* p - value significant

There was a significant increase in heart rate and in Group K at 1<sup>st</sup> (114 ± 28.5 min), 3<sup>rd</sup> (112 ± 24.50) 6<sup>th</sup> (102 ± 14.55) minute after intubation compared with



**Fig. 3:** Change in mean arterial pressure between groups

Group L at 1 (96 ± 18.5 min), 3<sup>rd</sup> (94 ± 22.45), 6<sup>th</sup> (96 ± 12.5), (Table 3). There was a significant increase in mean arterial pressure in Group K at 1<sup>st</sup> (108 ± 8.5), 3<sup>rd</sup> (106 ± 11.50), 6<sup>th</sup> (106 ± 14.50) minute compared to Group L at 1<sup>st</sup> (91 ± 5.5), 3<sup>rd</sup> (93 ± 7.50), 6<sup>th</sup> (92 ± 16.50), (Fig. 3). We hypothesize that is increase in heart rate and MAP might be due to prominent action of ketamine on the sympathetic nervous.<sup>15</sup>

There are established studies proving that lignocaine in various forms such as nebulization,<sup>16</sup> intravenous,<sup>17,18</sup> spray<sup>19</sup> have been used for obtunding intubation response which was also observed in our study. 4% in Group K and 12% in Group L had post-operative cough of Score 1.

**Table 3:** Change in heart rate between groups

Time	Group L (Mean ± SD)	Group K (Mean ± SD)	P - value
1 mins	96 ± 18.5	114 ± 28.5	** < .003
3 mins	94 ± 22.45	112 ± 24.50	** < .002
6 mins	96 ± 12.5	102 ± 14.55	** < .05
9 mins	90 ± 10.5	94 ± 14.5	< .057
12 mins	88 ± 11	92 ± 12.0	< .061
15 mins	88 ± 9	90 ± 10.5	< .12

\*\* p - value significant

### Limitations of the study

Cuff pressure was not monitored during the study which plays an important role in POST. Systemic effect of ketamine might have contributed towards analgesia which might be compounding factor for ketamine gargle.

### Conclusion

Ketamine gargle remarkably lessened the incidence and severity of POST but less effective in obtunding the intubation response compared to lignocaine gargle.

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