Original Article

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Anaesthesia Section

Redefining the Role of Ketamine for Topicalisation and its Comparison with the Legend Lignocaine for Oesophagogastroduodenoscopies- A Randomised Clinical Study

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ABSTRACT

Introduction: Endoscopy is a minimally invasive procedure for visualisation of gastrointestinal tract performed under topicalisation with or without sedation. Lignocaine is one of the most popular local anaesthetic used for topicalisation for endotracheal intubation in different forms like spray, gargles, nebulisation, gel. Recently ketamine has emerged as an effective antinociceptive and anti-inflammatory agent.

Aim: To observe and compare the effect of ketamine and lignocaine gargles for decreasing sore throat, coughing and change in voice. Also to observe various side-effects following use of ketamine and lignocaine.

Materials and Methods: This prospective double-blind randomised clinical trial was conducted at Shree Krishna Hospital, Karamsad, Gujarat, India, from January 2020 to June 2021. Total 70 patients undergoing oesophagogastroduodenoscopies under sedation were included in the study. They were divided into two groups i.e, 35 patients in each group. Group L received lignocaine 2% viscous gargles 3 mg/kg and group K received ketamine gargles 3 mg/kg ideal body weight diluted in Normal Saline (NS) up to total 30 mL. Sore throat, coughing, change in voice, side-effects were observed. Student's t-test was used for continuous data.

Results: In group L, 11.4% of patients and in group K 22.9% of patients complained of mild sore throat (grade 1) immediate postprocedure but this was statistically insignificant (p-value=0.2). For both the groups, grade 1 coughing was observed in 2.9% patients (p-value >0.995). In both the groups 5.71% of patients complained about change of voice, statistically insignificant (p-value >0.995). Vomiting was observed as a side-effect in 2.9% of patients in both the groups but there were no other side-effects.

Conclusion: Gargling with ketamine was as effective as lignocaine for prevention of sore throat, coughing and change in voice in patients undergoing oesophagogastroduodenoscopies and thus improved patient compliance.

Keywords: Change in voice, Cough, Sore throat

INTRODUCTION

Oesophagogastroduodenoscopies have gained popularity over a period of time for various diagnostic and therapeutic procedures for gastrointestinal diseases [1,2]. They are advantageous over conventional open techniques as they enable direct visualisation of disease, avoidance of incision, less surgical manipulation, less painful and less hospital stay [3]. In comparison to conventional technique, they are less invasive but unpleasant procedures. During oesophagogastroduodenoscopies, endoscope is passed through upper gastrointestinal tract which causes tissue trauma and inflammation which leads to coughing, sore throat and sometimes change in voice particularly when the topicalisation of the oropharynx is inadequate [4,5]. These side-effects lead to discomfort, pain and patient dissatisfaction [6]. Hence to prevent these side-effects topicalisation of oropharynx is mandatory which can be done with nebulisation (lignocaine 4%, steroids), lignocaine spray 10%, gargles of viscous lignocaine 2% and ketamine gargles [7]. Among all topicalisation techniques, gargling is simple, easily available, provides topical effect, better tolerated by patient and cost effective. Both lignocaine and ketamine can be used for gargles because they have a topical effect on oral mucosa and hence, prevent postoperative side-effects like sore throat, coughing and change in voice [8].

Lignocaine is a local anaesthetic drug which when used for gargles, spray or nebulisation have topical anaesthetic effect over oral cavity, oropharynx, hypo pharynx and provides short duration of analgesia [9]. Most of the times these methods of or pharyngotracheal topical anaesthesia have been used for endotracheal intubation and laryngeal mask airway insertion [7,8].

Ketamine is well versed with its antinociceptive action since its introduction in an anaesthesia practice but anti-inflammatory action of ketamine has picked up stream very recently [10]. Ketamine is glutamate antagonist and agonist at opioid receptors located in oral and upper respiratory tract mucosa which provides analgesia and reduces postoperative sore throat [11]. Ketamine acts at different levels of inflammation and reduces cytokine production and regulates inflammatory mediators, hence provides anti-inflammatory action. When ketamine is used as gargles, it has antinociceptive and anti-inflammatory effect on oropharynx and hypopharynx [12]. This property of ketamine is been used for treatment of various diseases like mood disorder, major depression, bipolar disorder [13,14]. Lignocaine is been used for topicalisation since quite a long time but its efficacy is very sparsely compared with ketamine [15]. So, the primary objective of this study was to compare the effect of ketamine gargles and lignocaine gargles for prevention of sore throat, coughing and change in voice for patients undergoing oesophagogastroduodenoscopies under sedation and secondary objective was to observe the side-effects like vomiting, hypertension or hypotension, arrhythmias, hypoxia, convulsion.

MATERIALS AND METHODS

This prospective double-blind randomised clinical trial was conducted at Shree Krishna Hospital, Karamsad, Gujarat, India, from January 2020 to June 2021. This study was commenced after obtaining approval from Hospital Ethics Committee (IEC/HMPCMCE/122/FACULTY/10/191/20). CTRI registration (CTRI/2020/10/028411) and written and informed consent from all the study participants were obtained.

Inclusion and Exclusion criteria: Patients of either gender, American Society of Anaesthesiologist (ASA) grade I, II and III physical status, aged 18-60 years posted for oesophagogastroduodenoscopies under sedation were included in this study. Patients who refused to give consent, unco-operative patients, history of preoperative sore throat, asthma, upper respiratory tract infection, history of allergy to study drugs, anticipated difficult airway and intubated patients were excluded from study.

Sample size calculation: By considering incidence of sore throat as main outcome and based on the study by Dhanger S et al., it was evident that incidence of sore throat was almost zero using lignocaine gargle [8]. Thus, in this study, 70 participants were enrolled (35 in each group) to detect a 20% difference in incidence of sore throat for achieving 80% power allowing 5% type I error. Patients were allotted randomly into two groups using WINPEPI software and by using the opaque envelope method.

Patients were kept nil per oral 8 hours for solids and 6 hours for liquids. Preoperative intravenous cannula was secured and vitals like heart rate, blood pressure and pulse oximetry were noted and recorded in the case protocol. Gargles were given according to the group allotted.

- Group K (n=35): Ketamine gargles, 3 mg/kg ideal body weight diluted in Normal Saline (NS) upto total 30 mL.
- Group L (n=35): Lignocaine 2% viscous gargles, 3 mg/kg NS ideal body weight diluted in NS upto total 30 mL.

Study Procedure

Patients were asked to gargle for 60 seconds. Anaesthesia was given after 10 minutes of gargles. After shifting the patient to Operation Theatre patients were monitored with electrocardiogram, non invasive blood pressure, pulse oximetry, end tidal carbon dioxide monitoring with nasal cannula. Oxygen was started with nasal prongs. Patients were positioned in lateral position with mouth piece in situ. Induction sequence included intravenous (i.v.) fentanyl 2 mcg/kg and i.v. propofol 2 mg/kg and spontaneous respiration was maintained. After loss of eyelash reflex, patients were handed over to surgeon for endoscopic procedure. Additional dose of intravenous propanol was given if required till completion of the procedure. After completion of endoscopy, oral suctioning was done. Once patients were fully awake and were following verbal commands, they were shifted to recovery room and assessed for sore throat, coughing and change in voice by 4 point scale at 0,1,4 and 24 hours after the completion of procedure [12].

Four point scale for sore throat:

0: No sore throat,

1: Mild-Complained of sore throat only on asking,

2: Moderate-Complained of sore throat on his/her own,

3: Severe-Change of voice or hoarseness associated with throat pain.

Four point scale for coughing:

0: No cough,

1: Mild-Less than what is seen in common cold,

2: Moderate-Like what is seen in common cold,

3: Severe-More than what is seen in common cold.

Four point scale for change of voice:

0: No hoarseness,

1: Mild- No hoarseness at the time of interview but had previously,

2: Moderate- Only felt by patient at the time of interview,

3: Severe- Recognisable at the time of interview.

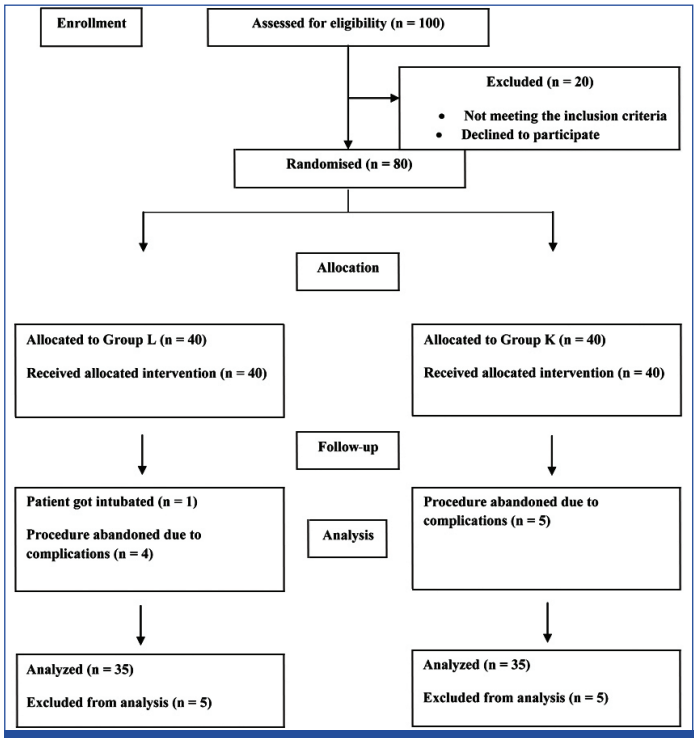
In both the groups patients were also observed for side-effects like vomiting, hypertension or hypotension, arrhythmias, hypoxia, convulsion.

STATISTICAL ANALYSIS

Descriptive statistics, mean±SD, frequency (%), was used to present the profile of study participants (age, gender, weight, ASA grading, duration of procedure). Student's t-test was used for continuous data. Test of difference between Proportions/Chi-square tests was performed to check whether the incidence of sore throat, cough and change in voice were statistically significant in group K versus group L and p-values for all parameters were derived. The analysis was performed using STATA (14.2) version.

RESULTS

Out of 80 patients, 70 patients were analysed and five patients in each group were excluded from the analysis. In group L, four patients and in group K, five patients were excluded from analysis as in these patients procedure was abandoned due to unforeseen surgical complications like large growth; large varices with high risk of bleeding and inability to negotiate endoscope due to stricture. In group L, one patient was intubated in view of variceal bleeding and excluded from the analysis [Table/Fig-1]. In this study, demographic data such as age, gender, weight, ASA status, duration of procedure were comparable between the groups [Table/Fig-2].



[Table/Fig-1]: CONSORT flow diagram.

Variables	Group L (n=35)	Group K (n=35)	p-value
Male: Female (n)	17:18	16:19	0.19*
Age in years (Mean±SD)	39.09±14.65	39.95±12.04	0.79**
Weight in Kg (Mean±SD)	59.21±6.231	58.29±8.651	0.649**
ASA grade (II:III)	7:28	9:26	0.24*
Duration of surgery (Mean±SD)	32.62±8.71	35.74±8.68	0.599**

[Table/Fig-2]: Demographic Profile.
*Chi-square test, **Student's t-test

In this study, incidence of sore throat at 0 hour was 4 (11.4%) in group L and 8 (22.9%) in group K. Severity of sore throat was grade 1 (mild) in both the groups. The incidence as well as severity was

statistically insignificant in both the groups (p-value=0.2) [Table/Fig-3]. In both the groups, 2.9% of patients complained of mild coughing (grade 1) at 0 hour, which was statistically insignificant (p-value >0.995) [Table/Fig-4]. Incidence of change of voice (grade 1) was 2 (5.71%) in both the groups at 1 hour which was also statistically insignificant as p-value >0.995 [Table/Fig-5]. None of the patients complained of sore throat, coughing and change in voice beyond one hour in both the groups. Severity of sore throat, coughing and change in voice was also mild (grade 1) in both the groups. The only side-effect observed was vomiting in 2.9% of patients in both the groups and none of the other adverse effects were observed [Table/Fig-6].

Grade of sore throat	0 hour		1 hour		4 hours		24 hours	
	Group L	Group K	Group L	Group K	Group L	Group K	Group L	Group K
0 No	31 (88.6%)	27 (77.1%)	35 (100%)	35 (100%)	35 (100%)	35 (100%)	35 (100%)	35 (100%)
1 Mlld	4 (11.4%)	8 (22.9%)	0	0	0	0	0	0
2 Moderate	0	0	0	0	0	0	0	0
3 Severe	0	0	0	0	0	0	0	0
Total percentage of patients having sore throat	11.4%	22.9%	0	0	0	0	0	0
p-value	0.2							

[Table/Fig-3]: Comparison of severity of sore throat at 0,1,4 and 24 hour postprocedure.
p-value <0.05 was considered as statistically significant; Chi-square test used

Grade of cough	0 hour		1 hour		4 hours		24 hours	
	Group L	Group K	Group L	Group K	Group L	Group K	Group L	Group K
0 No	34 (97.1%)	34 (97.1%)	35 (100%)	35 (100%)	35 (100%)	35 (100%)	35 (100%)	35 (100%)
1 Mild	1 (2.9%)	1 (2.9%)	0	0	0	0	0	0
2 Moderate	0	0	0	0	0	0	0	0
3 Severe	0	0	0	0	0	0	0	0
Total percentage of patients having cough	2.9%	2.9%						
p-value	>0.995							

[Table/Fig-4]: Comparison of severity of cough at 0,1,4 and 24 hour postprocedure.
p-value <0.05 was considered as statistically significant; Chi-square test used

Grade of change of voice	0 hour		1 hour		4 hours		24 hours	
	Group L	Group K	Group L	Group K	Group L	Group K	Group L	Group K
0 No	35 (100%)	35 (100%)	33 (94.29%)	33 (94.29%)	35 (100%)	35 (100%)	35 (100%)	35 (100%)
1 Mild	0	0	2 (5.71%)	2 (5.71%)	0	0	0	0
2 Moderate	0	0	0	0	0	0	0	0
3 Severe	0	0	0	0	0	0	0	0
Total percentage of patients having change of voice	0	0	5.71%	5.71%	0	0	0	0
p-value			>0.995					

[Table/Fig-5]: Comparison of severity of change of voice at 0,1,4 and 24 hour postprocedure.
p-value <0.05 was considered as statistically significant; Chi-square test used

Side-effects	Group L (n, %)	Group K (n, %)
Vomiting	1 (2.9)	1 (2.9)
Hypertension	0	0
Hypotension	0	0
Arrhythmia	0	0
Convulsion	0	0
Hypoxia	0	0
No side-effects	34 (97.1)	34 (97.1)

[Table/Fig-6]: Assessment of side-effects.

DISCUSSION

Oesophagogastroduodenoscopies are less invasive, less time consuming and offers less morbidity to the patients that is why they are preferred over conventional technique. They can be performed as day care procedure, so they provide better patient compliance and enhances recovery after surgery [3,4]. Though they have some disadvantages like postprocedure aspiration, bleeding, perforation and they can not be used in unstable patients, patients with coagulopathy, still they are well versed technique for most of the diagnostic and therapeutic procedures of upper gastrointestinal tract [5].

When endoscope is passed through upper gastrointestinal tract, it causes discomfort, activates gag reflex, causes localised tissue trauma which leads to release of inflammatory markers (Interleukins, interferons, cyclooxygenase and tumour necrosis factor-alpha) which causes coughing, postoperative sore throat and sometimes change in voice [16]. Various studies have been performed to study the effect of ketamine and lignocaine gargles for prevention of sore throat in endotracheal intubation or laryngeal mask airway insertion but till now none of the studies were performed to prevent sore throat in patients posted for oesophagogastroduodenoscopies [6-8,16-22]. There are various factors which can affect the incidence of sore throat like age, gender, duration of surgery [16,17]. But in present study both the groups were comparable in terms of demographic profile and results of this study were in accordance with the study performed by Kamble NP and Gajbhare MN [16].

In the study performed by Dhanger S et al., incidence and severity of postoperative sore throat was compared using 4-point scale in patients undergoing Laryngeal Mask Airway insertion under general anaesthesia. They concluded that incidence as well as severity of

Authors with year of publication	No. of patients	Place of study	Gargles	Sore throat	Coughing	Change of voice	Conclusion
Dhangar S et al., [8] 2018	90	Uttarakhand, India	• Group L-Lignocaine 30 mL, • Group K-Ketamine 50 mg	• Group K-15% • Group L-17.5%	Not studied	Not studied	Lignocaine is better than Ketamine
Lalwani J et al., [12] 2017	200	Raipur, India	• Group K-Ketamine 50 mg • Group C-Normal saline 30 mL	• Group K-43,38,25,20% • Group C-78,72,60,56%	• Group K-32,28,20,15% • Group C-69,65,58,51%	• Group K-36,28,25,18% • Group C-61,68,60,54%	Ketamine is effective
Kamble NP and Gajbhare MN, [16] 2015	60	Pune,India	• Group K-Ketamine 50 mg, • Group C-Distilled water	• Group K-66.7,46.7,23.3,13.3%, • Group C-90,86.7,66.7,50%	-	-	Ketamine is better
Rabbani MW et al., [6] 2015	60	Multan	• Ketamine • Normal saline	• Ketamine-13.3% • Normal saline-46.7%	Not studied	Not studied	Ketamine is better than placebo
Shetty SR et al., [19] 2015	100	Mangaluru, India	• Ketamine (50 mg) • Lignocaine (50 mg) • Chlorhexidine 30 mg • Sterile water	-	-	-	Ketamine and Lignocaine are better than other two
Kudva S and Hegde R, [21] 2020	42	Mangaluru, India	• Ketamine (50mg) • Tramadol (100mg)	• Ketamine -19% • Tramadol-28.6%	Not studied	Not studied	Both are comparable
Altiparmak B and Turan M, [20] 2018	122	Turkey	• Ketamine 0.5 mg/kg • Bensydamine 15 mL	• Ketamine-2.8 • Bensydamine-3.3			Ketamine is better
Kumar MS et al., [18] 2014	150	Bengaluru, India	Ketamine 40 mg, Aspirin (350 mg), Lignocaine Spray 10% (300 mg)	• K-20% • A-24%, • L-22%	K-20%, A-12%, L-11%	K-4% A-4% L-6%	All three are effective
Present study, 2022	70	Gujarat, India	Ketamine 3 mg/kg Lignocaine 3 mg/kg	• K-22.9% • L-11.4%	K-2.9% L-2.9%	K-5.71% L-5.71%	Both are effective

[Table/Fig-7]: Comparison of Results of different study [6,8,12,16,18-21].

postoperative sore throat were significantly less in the lignocaine group (17.5% grade 1) in comparison to ketamine group (15% grade 2 and 25% grade 1) [8]. This incidence of postoperative sore throat in their study was comparable to present study (group L 11.4% and group K 22.9%) but severity of sore throat was less in present study as all the patients in both the groups were having only grade 1(mild) sore throat. Also the incidence of sore throat was limited to immediate postoperative period (only at 0 hour) in both the groups.

Kamble NP et al., studied the effect of ketamine gargles 50 mg in 29 mL distilled water and placebo with 30 mL distilled water in 60 patients undergoing endotracheal intubation for surgeries. They concluded that incidence of sore throat was significantly less in ketamine group (66.7%, 46.7%, 23.3%, 13.3% at 0, 4, 8 and 24 hour postsurgery) compared to placebo group (90%, 86.7%, 66.7%, 50%) [16]. Results of their study were consistent with present study in terms of both severity and incidence of postoperative sore throat in ketamine gargle group. Ketamine is an N-Methyl D-Aspartate receptor antagonist and is involved in pain pathway and anti-inflammatory pathway. Ketamine diminishes the production of various inflammatory markers like cytokines, interleukins, tumour necrosis factor-alpha and gamma-interferon when given before or after proinflammatory insult and thus helps in reducing inflammation and complication related to it like sore throat [13,16]. Similarly in different studies performed by Rabbani MW et al., [6] Shetty SR et al., [19], Kudva S and Hegde R, [21] Altiparmak B and Turan M [20] incidence of sore throat varied from 13% to 60% in Ketamine group and 20-90% in placebo group.

Kumar MS et al., in their study observed and compared the effect of ketamine gargles (40 mg), aspirin gargles (350 mg) and 10% lignocaine spray in reducing the incidence and severity of postoperative sore throat, coughing and change in voice in patients undergoing endotracheal intubation. In their study incidence of coughing was 20% in group L, 14% in group K and 10% in group A after 2 hours postestuation, grade 1 coughing in 4% of patients at the end of 24 hours in group L and group K, grade 3 change in voice in 6% patients in group L and grade 2 change of voice in 4% of patients in group K at the end of 4 hours [18]. In the present study incidence of mild coughing (grade 1) was 2.9% in both the groups which was limited to immediate postprocedure period. Incidence of change in voice was also 5.71% (grade 1) in both the groups. In comparison to present study incidence and severity of coughing and change in voice were higher in study performed by Kumar MS et al., [18]. They used a fixed dose of ketamine (40 mg) and three puffs of 10% lignocaine spray for their study whereas in present study, a flexible dose (3 mg/kg ideal body weight) of ketamine and lignocaine had been used. This could be a likely cause for reduced incidence and severity of coughing and change in voice in present study. Lalwani J et al., had found higher incidence of coughing and change in voice than present study. They also used fixed dose of ketamine (50 mg) which could be a cause of this discrepancy in results [12].

In the present study patients were also observed for side-effects. Incidence of vomiting was 2.9% in both the groups immediate post-procedure but there were no other side-effects noted. None of the other studies have observed these side-effects. [Table/Fig-7] is showing the comparison of results of different study [6,8,12,16,18-21].

Limitation(s)

In the present study, instead of using subjective method for patient's and surgeon's satisfaction, objective scoring system could be used and their statistical analysis could be included.

CONCLUSION(S)

Oesophagogastroduodenoscopies are the future of microsurgery. Using topical anaesthesia with sedation makes it an agreeable experience for both, patients as well as surgeons. From this study it was observed that both ketamine and lignocaine gargles were having promising results for reducing the incidence of sore throat, coughing and change in voice without evident side-effects in oesophagogastroduodenoscopy patients.

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