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COMPARISON OF PRE-INTUBATION LARYNGEAL SPRAY WITH KETAMINE, LIDOCAINE AND DEXAMETHASONE ON INCIDENCE AND SEVERITY OF POST-OPERATIVE SORE-THROAT.

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ABSTRACT **Background & Aims:** Postoperative sore throat (POST) is a common complaint after endotracheal intubation. We wanted to compare the efficacy of lignocaine, dexamethasone and ketamine as pre-intubation laryngeal spray for attenuation of POST. Hence this study was undertaken. **Materials And Methods:** 105 patients of ASA class I & II were randomized sssssusing closed sealed envelope technique into Group K: received 25mg (0.5ml) Ketamine spray made to 2ml with normal saline; Group L: received 2ml of 4% Lidocaine spray; and Group D: received 4mg of dexamethasone, made to 2ml with normal saline. Endotracheal tube (ET) cuff pressure was maintained at 18-20cm of H2O throughout the surgery. The patient was assessed for the incidence and severity of POST, hoarseness, voice changes and any other complications at 0, 1, 6, 12 and 24 hours after extubation. **Results:** There was no significant difference in incidence and severity of POST between the three groups at all intervals of follow-up and also at any given interval. However, it was clinically observed that patients of dexamethasone group had lesser incidence of POST compared to the other groups, though this was not statistically significant. No complication or adverse effects were noted due to any study drug. **Conclusion:** Prophylactic spray with either Ketamine, Dexamethasone or Lidocaine 4% spray significantly decreases the incidence of POST at 1, 6, 12 and 24 hours post operatively in patients undergoing surgeries under general endotracheal anesthesia without any reported adverse effects of the study drugs.

KEYWORDS : Postoperative sore-throat, Ketamine, Dexamethasone, Lidocaine.

INTRODUCTION

Post operative sore throat (POST) is a common problem encountered in post operative period affecting 10-62% of surgical patients undergoing intubation. Besides throat irritation, it can also cause sleep impairment, increase morbidity and prolong the patients' return to normalcy. [1] No wonder it stands at the sixth place among the undesirable effects of general anesthesia. POST occurs as a result of the injury and inflammation induced by the passage of the endotracheal tube (ET) exerting pressure and causing irritation to the laryngeal mucosa; mucosal dehydration and stretching of cervical muscles and ligaments. [1,2] Several drugs such as lignocaine, ketamine, dexamethasone, benzydamine hydrochloride, beclomethasone have been used. Various routes such as nebulisation, gargling, spraying the ET or the vocal cords, coating/ dipping the ET with the drug, intravenous administration have been tried with varying success.[3] Pre-intubation laryngeal spraying is an easy method requiring minimum preparation. Ketamine, dexamethasone and lignocaine are universally available drugs in most of the operation theatres. There are no studies specifically comparing these three drugs, namely, lignocaine 4%, dexamethasone 4mg and ketamine 25mg. Hence a study to compare the efficacy of these three easily available drugs in reducing the incidence and severity of POST, when administered as pre intubation laryngeal spray was undertaken. The outcome of this study can affect the practice even in resource limited settings.

METHODS

After obtaining approval from the institutional ethics committee and registering the study under Central Trial Registry of India (CTRI number: REF/2021/10/048393), 105 patients who gave informed consent were enrolled for the study. These were patients belonging to American Society of Anesthesiologists (ASA) I and II, aged between 18-60 years of either sex who were posted for surgery lasting less than two hours, under general anesthesia in supine position. Only patients with Mallampati Class I and II were included for the study. Patients using steroids or non-steroidal anti-inflammatory drugs or with recent upper respiratory tract infection (less than two weeks), chronic obstructive pulmonary disorder, asthma and reactive airway disease were excluded from the study. Similarly, patients requiring more than two attempts of intubation or placement of nasogastric tube or throat pack; allergic to study drug, undergoing oral and nasal surgeries, pregnant patients and those with ischemic heart disease / rhythm abnormalities were excluded from the study.

Thorough pre-anesthetic evaluation was done on the day before surgery and the required pre-anesthetic orders were given. Patients were randomized into three groups of 35 each, with the help of shuffled opaque sealed envelopes prepared by an anesthesiologist who was also involved in preparing the study drugs and who did not participate further. Another anesthesiologist performed the pre-intubation spraying of the study drug and was also the observer. Thus the observer & the patient were blinded for the study drug. Group K received 25mg (0.5ml) Ketamine spray made to 2ml with normal saline. Group L received 2ml of 4% Lidocaine spray. Group D received 4mg (1ml) of dexamethasone, made to 2ml with normal saline.

A uniform anesthesia protocol was followed for all patients. Basic monitoring included continuous electrocardiography, heart rate, non-invasive blood pressure, oxygen saturation and end tidal carbon dioxide. Baseline values of heart rate (HR), & mean arterial pressure (MAP) were recorded. The patients were preoxygenated with 100% oxygen for three minutes and premedicated with intravenous (IV) injection midazolam 0.01mg/kg and injection fentanyl 1microgram/kg and then induced with injection propofol 2mg/kg and relaxed with injection vecuronium 0.1mg/kg. During laryngoscopy after visualizing the vocal cords, test drug was sprayed by using 25G Quincke's spinal needle connected securely to 5ml syringe. Patients were intubated with appropriate size oral cuffed endotracheal tube. After confirming bilaterally equal air entry, cuff was inflated with air and cuff pressure maintained between 20-25cm H2O throughout surgery. Anesthesia was maintained using isoflurane 0.6-1% with nitrous oxide and oxygen. HR & MAP were recorded immediately after propofol injection, at 1, 3, 5 and 10 minutes after laryngoscopy and endotracheal intubation. The head was kept in neutral position throughout the surgery and not turned to one side after intubation. If there were more than two attempts at intubation or if injection dexamethasone was given intra-operatively due to other reasons, then such a patient was excluded from the study. At the end of the surgery the effect of muscle relaxant was reversed with injection neostigmine 0.05 mg/kg, injection glycopyrrolate 0.01 mg/kg. The patients were extubated once they were hemodynamically stable and fulfilled the extubation criteria. Twenty minutes before extubation, injection ondansetron 4mg IV was given for prevention of postoperative nausea and vomiting (PONV). Postoperatively the intensity of sore throat was recorded at 0, 1, 6 ,12 and 24 hours.

Incidence of sore throat was assessed by asking for the presence / absence of throat discomfort one hour after extubation using YES/NO questionnaire.

Severity of Sore throat was measured on a 4 point scale from 0 – 3[4]

0 – No sore throat
1 – mild sore throat (complains of sore throat on asking)
2 – moderate sore throat (complains of sore throat on his/her own)
3 – severe sore throat (change in voice or hoarseness associated with throat pain)

Postoperative analgesia & PONV were managed according to the institutional protocol.

If patient developed hallucinations, then injection Midazolam 1mg IV was given. Hallucinations/emergence delirium was assessed using Richmond Agitation Sedation Scale (RASS). [5] Patients with POST severity 2 or greater were given a benzydamine gargle and intravenous Paracetamol and observed carefully for any other side effects.

At the end of the study, all data was compiled and analysed using Statistical Package for Social Sciences (SPSS) version 22.0 software. Categorical data was represented in the form of frequencies and proportions. Chi-square test or Fischer's exact test (for 2x2 tables only) was used as a test of significance for qualitative data. Continuous data was represented as mean and standard deviation. ANOVA (Analysis of Variance) or Kruskal Wallis test was the test of significance to identify the mean difference between more than two groups for quantitative and qualitative data respectively.

RESULTS

All patients completed the study (figure 1). There was no statistical difference with respect to the age, gender, hemodynamic changes, and duration of surgery. Surgeries in three groups included fibroadenoma breast, laparoscopic cholecystectomies, laparoscopic appendicectomies and total laparoscopic hysterectomies.

Overall incidence of POST was 22.85% (24 patients), with minimum incidence in Group D over all the time frames (8.5%) though this was not significant statistically. (Table 2). At any interval there was no significant difference in mean POST comparison between three groups.

While comparing the severity of POST, Grade 2 severity was seen in group L (8.5%) followed by group K (5.7%) and none in group D. None of the patients had severe sore throat (Grade 3). However, there was no statistically significant difference seen in grade of POST between three groups at all the intervals of follow-up.

No adverse effects were observed, like emergence delirium, hallucinations, increased salivation or hemodynamic changes with ketamine; delayed wound healing/infections with dexamethasone; toxicity effects with lignocaine.

DISCUSSION

A problem like POST, which is not related to the operative site can be distressing and irritating to the patient. Hence effective measures to avoid this problem becomes imperative to improve the quality of care and patient satisfaction. Many drugs in different routes have been studied to avoid POST with variable results. The use of easily available drugs in a route which requires minimum preparation and time will be very useful in a wide variety of settings ranging from a sophisticated tertiary care centre to a resource limited setting. Hence we conducted our study in a tertiary care centre using lignocaine, dexamethasone and ketamine which are ubiquitous in most operation theatres (OT), using the spray route which doesn't add up to the patient cost or OT turn over times.

In this study overall incidence of POST was 22.85% (24 patients) with 25.7% (9 patients) in Group K, 8.5% (3 patients) in Group D and 34.28% (12 patients) in Group L.

There have not been any studies of Dexamethasone as pre-intubation spray. Hence, we conducted this study and found an incidence of 5.7% at one hour, 2.9% at six hours and 0% from 12 hours onwards. None of the patients had Grade 2 or 3 severity of POST. These results concur with the results of previous studies where dexamethasone was given prophylactically by topical (soaking of the tube cuff in dexamethasone) and IV route and was found to reduce the incidence of POST significantly.[1,6-8] Dexamethasone has shown promising results in attenuating POST because of its anti-inflammatory action. It effectively modifies the inflammatory process by inhibiting leukocyte migration and release of cytokines; preserving membrane integrity and inhibiting fibroblast proliferation. [6,8] Studies have also documented better efficacy of dexamethasone when administered before the actual injury occurs as elucidated by Sun-young Park et al in their study where 10mg of the drug was given IV 30 minutes prior to or after intubation in two groups and the pre-intubation group was found to have better results. [6] The direct action on the pharyngeal and laryngeal mucosa resulting in an immediate effect has been well noticed with use of ketamine spray for POST and the same mechanism can probably be extrapolated to topical pre-intubation of dexamethasone as well. [9] Hyperglycemia, peptic ulcer, infection, and electrolyte imbalance are known side effects but unlikely to occur with a single dose. [6] In our study too, none of these were noticed.

It has been observed that N-methyl-d-aspartate (NMDA) has a role in nociception and inflammation. Ketamine by the virtue of its antagonizing action at NMDA receptor has been found to be effective in attenuating POST when nebulized, gargled or sprayed. [4,10] In our study, Ketamine group had an incidence of 11.5% at one hour, 8.6% at six hours, 5.7% at 12 hours and none at 24 hours. Ayatollahi et al too observed significant reduction in POST and hoarseness when they used ketamine splash and compared it with normal saline splash.[4] Similar to their findings, we too did not detect any side effects like hallucinations. Chan et al in their study noted low serum ketamine levels intraoperatively when they used ketamine gargle for decreasing POST. They concurred that this is due to its topical action, rather than a systemic effect. [11] This explains its efficacy in reducing POST by means of local anti-inflammatory action and observed lack of systemic side effects. The above analysis also explains the positive result of ketamine in reducing POST noticed in our study.

Lignocaine has been used extensively for prevention of POST in various routes and concentrations. Tanaka et al in their meta-analysis of multiple studies in Cochrane database have revealed a significant reduction in POST (risk ratio=0.64) with lignocaine. They however advise caution while interpreting the results as various factors like study quality, concentration and route of drug administration, study population can all impact the result. [12] Studies have shown that lignocaine has multiple benefits like obtunding the stress response to laryngoscopy and intubation, and reducing cough, hoarseness, POST after extubation. [12,13] We found an incidence of 17.1% at one hour, 14.3% at six hours, 8.6% at 12 hours and none at 24 hours in this group. The severity of POST was similar to that found in other two groups. The efficacy of lignocaine can be attributed to its anti-inflammatory action brought about by inhibition of ion exchange by the membrane channels; decreasing the release of neuropeptides and by direct central suppression. Thereby it counters the sensory C fibre excitation brought about by intubation and reduces the ensuing tissue damage. [14]

Several factors have been recognized in previous studies contributing to POST like patient age, sex, size and cuff design of ET tube, and intracuff pressure.[15] In our study, the comparison was done in the three groups in distribution of age, gender, body mass index, ASA class, and duration of surgery and was found to be statistically insignificant. One of the major causes of POST is the ET tube cuff causing tracheal mucosal damage and it has been found that a smaller ET tube and adequate cuff pressure, attenuates POST by decreasing the area of cuff trachea contact. Thus in our study cuff pressure was maintained between 20-25 cm of water. [15]

Our study showed efficacy in reducing both the incidence and severity of POST with all the three study drugs and there was no significant difference statistically. However clinically we noted slightly better response with dexamethasone which can be attributed to its more potent anti-inflammatory action compared to the other two drugs.

Our study is not without limitations. The study was limited to ASA class I & II, serum ketamine and norketamine levels were not measured and so the systemic effects could not be assessed properly and the patients subjective descriptions of their sore throat were used to evaluate the condition as objective indices are difficult to develop. Though a tube of a larger diameter is a known risk factor for development of POST, we do not have a uniform tube size for all the patients in our study since we included patients of both genders.

CONCLUSION

We observed that dexamethasone, ketamine and lignocaine can be used effectively to reduce the incidence and severity of POST by administering them as pre-intubation spray on the vocal cords. This

method is not only efficacious but also cost and time effective, easy to perform, and without any side effects.

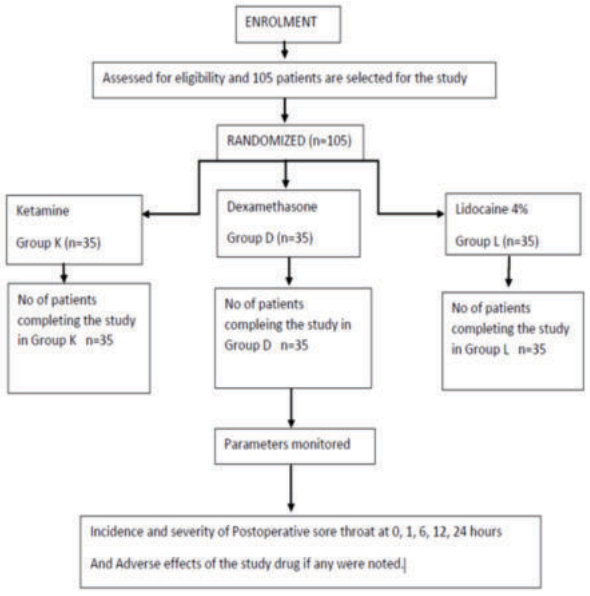

Figure 1: Consort flow chart

Table 1: Profile of subject's distribution between three groups

		Drugs						P value
		Dexamethasone		Ketamine		Lidocaine 4%		
Age (years) Mean ± SD		40.2±10.18		38.77±9.63		39.89±10.54		0.168
Gender	Female	24	68.57%	27	77.14%	24	68.57%	0.657
	Male	11	31.43%	8	22.86%	11	31.43%	
ASA	1	28	80.00%	27	77.14%	29	82.86%	0.836
	2	7	20.00%	8	22.86%	6	17.14%	
BMI (kg/mt2) Mean ± SD		24.34	2.41	24.49	2.69	24.17	2.27	0.867
Duration of surgery (mins) Mean ± SD		64.71±5.93		63.43±3.79		64.29±5.31		0.562
Duration of anaesthesia (mins) Mean ± SD		76.57 ±5.91		74.29±4.56		76.14±5.43		0.168
Cuff pressure in cm of water	22	1	2.86%	0	0.00%	0	0.00%	0.364
	25	34	97.14%	35	100.00 %	35	100.00 %	
HR (bpm) Mean ± SD		73.71±8.81		69.83±6.26		73.37±9.72		0.106
MAP (mmHg) Mean ± SD		89.56±8.110		88.81±7.079		89.86±6.67		0.827

Table 2: Incidence and Severity of POST at different periods of follow-up comparison between three groups

			Drugs						p value
			Dexamethasone		Ketamine		Lidocaine 4%		
			Count	%	Count	%	Count	%	
At 0hrs	Incidence of POST	0	35	100.0 %	35	100.0 %	35	100.0 %	-
At 1hrs	Incidence of POST		4	11.5 %	2	5.7%	4	17.1 %	0.570
	Severity of POST		4 (0-2)		2 (0-1)		6 (0-2)		
At 6hrs	Incidence of POST		3	8.6%	1	2.9%	5	14.3 %	0.517
	Severity of POST		3 (0-2)		1 (0-1)		5 (0-2)		
At 12hrs	Incidence of POST		2	5.7%	0	0.0%	3	8.6%	0.230
	Severity of POST		2 (0-1)		0		3 (0-1)		
At 24hrs	Incidence of POST	0	35	100.0 %	35	100.0 %	35	100.0 %	-

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