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Original Research Paper

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COMPARISON OF PRE-INTUBATION LARYNGEAL SPRAY WITH KETAMINE, LIDOCAINE AND DEXAMETHASONE ON INCIDENCE AND SEVERITY OF POST-OPERATIVE SORE THROAT IN ADULT PATIENTS UNDERGOING SURGERY UNDER GENERAL ANAESTHESIA – A PROSPECTIVE RANDOMISED DOUBLE BLINDED STUDY.

Dr. Gaddam Sravya Junior Resident, Department of Anaesthesiology, Mallareddy institute of medical sciences, Hyderabad.

Dr. M. Keerthi Reddy Junior Resident, Department of Anaesthesiology, Mallareddy institute of medical sciences, Hyderabad.

Dr. Suresh Chander HOD, Department of Anaesthesiology, Mallareddy institute of medical sciences, Hyderabad.

KEYWORDS :

INTRODUCTION:

Postoperative sore throat (POST) is a common complaint after endotracheal intubation, incidence of POST varies between 21%-65%[1] . Various pharmacological and non-pharmacological methods have been used for attenuating postoperative sore throat with no proven single modality. Pharmacological methods include use of various drugs in different formulations like gel, spray & nebulization for reducing incidence and severity of POST and spraying is the easiest and least time consuming technique. Several studies have proved the effeciency of using lignocaine to reduce incidence of POST[4].

Comparitive studies of lignocaine with ketamine and dexamethasone are sparse. Hence we wanted to compare the efficacy of 4% Lidocaine, 25mg Ketamine and 4mg Dexamethasone on incidence and severity of POST[2] .These drugs are routinely used and easily available in most operation theatres and hence the outcome of our study can help safe anaesthetic practice even in resource limited settings.

Our primary objective was to compare the effectiveness of ketamine , lidocaine & dexamethasone as pre-intubation laryngeal spray on incidence and severity of postoperative sore throat over 24hrs post-extubation in patients receiving general anaesthesia.

Our secondary objectives were to note the heamodynamic changes after laryngoscopy and intubation, postoperative alterations in voice and adverse effects of study drugs like emergence delerium.

METHODS:

We conducted a prospective double blind randomized controlled trial from March 2021 – August 2022 at Mallareddy institute of medical sciences, Hyderabad. Ethical clearence was obtained from institutional ethical committee at Mallareddy institute of medical sciences.

Inclusion Criteria

- Age 18 – 60 years of Either sex
- ASA Status I & II
- Surgery in supine position under GA for up to or less than 2 hours - Mallampatti Grade I & II

Exclusion Criteria

- Patient using steroids or NSAIDS
- Patients with Chronic obstructive pulmonary disorder, asthma, reactive airway disease - Patients with greater than 2 attempts of intubation
- Pregnant patients
- Recent Upper respiratory tract infection (<2 weeks) - Patients allergic to study drug
- Patients requiring Nasogastric tube, throat pack Oral and nasal surgeries
- Patients and his/her legally accepted representatives not willing to provide their voluntary written informed consent for participation in the study
- Patients with IHD/Rhythm abnormalities.

Sampling Technique :

- Sampling was done using opaque sealed envelope technique.
- Calculation of the sample size was based on the prevalence in previous studies, of postoperative sore throat in patients undergoing surgeries under general endotracheal anaesthesia.
- Sample Size: Z2pq/d2
- Z: Standardizes normal deviation (1.96)
- P: Proportion of prevalance (Ketamine, Lidocaine, Dexamethsone) which is 0.5
- q: 1-p which is 0.5
- d: margin of error (10%)
- sample size= (1.96)2(0.5)(0.5)/(0.1)(0.1) = 96
- i.e 32 in each group. Considering the dropouts, we considered the sample size to be 35 in each group. Hence, we observed a total of 105 subjects.

Methodology :

After receiving approval by the Ethics Committee of our hospital & written informed consent, 105 patients belonging to ASA physical class I-II in the age group of 18-60 years of either sex, undergoing elective surgery in supine position under general endotracheal anaesthesia of <2hrs duration were selected for the study. Thorough pre-anaesthetic evaluation was done on the day before surgery and the required pre-anaesthetic orders were given.

Patients were randomized into 3 groups with the help of shuffled opaque sealed envelopes prepared by an anaesthesiologist who was also involved in preparing the study drugs and who did not take part further. Another anaesthesiologist performed the pre-intubation spray of study drug and was also the observer. Thus the observer & the patient were blinded for the study drug. The enlisted 105 patients were randomly allocated into 3 groups of 35 each.

- 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 anaesthesia protocol was followed for all patients. Basic monitoring included continuous electrocardiography, heart rate, non-invasive blood pressure, oxygen saturation, end tidal carbon dioxide. Baseline values of heart rate(HR), &

mean arterial pressure(MAP) were recorded. The patients were preoxygenated with 100% O2 for 3mins & then premedicated with injection midazolam 0.01mg/kg; and injection fentanyl 1mcg/kg and then induced with injection propofol 2mg/kg and relaxed with injection vecuronium 0.1mg/kg. Direct laryngoscopy was done after confirming effective muscle paralysis with train Of four (TOF) count 'Zero' of ulnar nerve. Using appropriate sized blade, and upon visualisation of vocal cords, test drug was sprayed by using 25G Quincke's spinal needle connected securely to 5cc syringe.

Patients were intubated with appropriate size oral cuffed endotracheal tube, once the air entry was confirmed to be bilaterally equal, cuff was inflated with air and cuff pressure maintained between 20-25cm H2O throughout surgery. The anaesthesia was maintained using isoflurane 0.6 -1% N2O : O2 in 66:33 ratio & inj.vecuronium 0.01mg/kg as required. HR & MAP were recorded immedietly after propofol injection , 1min, 3mins, 5mins, 10mins, after laryngoscopy & endotracheal intubation.

The head was kept in neutral position through out the surgery & not turned to one side after intubation. If there were >2 attempts at intubation or if inj.dexamethasone IV 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 haemodynamically stable and when they fulfilled the extubation criteria.

20mins before extubation inj.ondansetron 4mg IV was given for prevention of postoperative nausea and vomiting (PONV). In the recovery room, the patient received humidified oxygen at 5lts/hr through face mask for 4hrs. The intensity of sore throat was recorded at 0 hour, 1 hour, 6 hours, 12 hours, 24 hours postoperatively.

Incidence of sore throat was assessed by asking for the presence/absence of throat discomfort at 1hr after extubation using YES/NO questionnaire. Severity of Sore throat was measured on 4 point scale 0 – 3

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 institutional protocol.If patient had hallucinations , then Inj.Midazolam 1mg IV was given. Hallucinations/emergence delerium was assessed using Richmond Agitaion Sedation Scale (RASS).

		t Drugs						P value
		Dexamethasone		Ketamine		Lidocaine 4%		
		Count	%	Count	%	Count	%	
Age	20 - 30 Years	3	8.6%	8	22.9 %	7	20.0 %	0.248
	31 - 40 Years	18	51.4%	12	34.3 %	13	37.1 %	
	41 - 50 Years	14	40.0%	12	34.3 %	11	31.4 %	
	> 50 years	0	0.0%	3	8.6%	4	11.4 %	
	Age (years)	39.00	5.63	38.77	9.62	39.89	10.53	0.857
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/mt sq		24.34	2.41	24.49	2.69	24.17	2.27	0.867

There was no significant difference in the three groups with respect to age, gender, ASA classification and BMI.

			Drugs						P value
			Ketamine		Dexamethasone		Lidocaine 4%		
			Count	%	Count	%	Count	%	
At 0hrs	Grade	0	35	100.0 %	35	100.0 %	35	100.0 %	-
	Mean	0	0	0	0	0	0	-	
At 1hrs	Grade	0	31	88.6%	33	94.3 %	29	82.9%	0.570
		1	3	8.6%	2	5.7%	4	11.4%	
		2	1	2.9%	0	0.0%	2	5.7%	
	Mean		0.14	0.43	0.06	0.24	0.23	0.55	0.244
At 6hrs	Grade	0	32	91.4%	34	97.1 %	30	85.7%	0.517
		1	2	5.7%	1	2.9%	4	11.4%	
		2	1	2.9%	0	0.0%	1	2.9%	
	Mean		0.11	0.4	0.03	0.17	0.17	0.45	0.259
At 12hrs	Grade	0	33	94.3%	35	100.0 %	32	91.4%	0.230
		1	2	5.7%	0	0.0%	3	8.6%	
	Mean		0.06	0.24	0	0	0.09	0.28	0.235
At 24hrs	Grade	0	35	100.0 %	35	100.0 %	35	100.0 %	-
	Mean		0	0	0	0	0	0	-

At 0 hr, all the 3 groups had no POST.

At 1 hr, Incidence of POST in ketamine group was 11.5%, in dexamethasone group was 5.7% and in Lidocaine 4% group was 17.1%. There was no significant difference in POST incidence between 3 groups at 1 hrs.

At 6 hr, Incidence of POST in ketamine group was 8.6%, in dexamethasone group was 2.9% and in Lidocaine 4% group was 14.3%. There was no significant difference in POST incidence between 3 groups at 6 hrs.

At 12 hr, Incidence of POST in ketamine group was 5.7%, in dexamethasone group was 0% and in Lidocaine 4% group was 8.6%. There was no significant difference in POST incidence between 3 groups at 12 hrs.

At 24 hr, all the 3 groups had no POST.

DISCUSSION :

In our study, all patients in the three groups (n=105) were similar in age, gender, BMI. No statistical difference was observed in the 3 groups regarding demographic criteria.

There have been several factors recognised in previous studies contributing to POST, like patient age, sex, size of ET tube, cuff design of ET tube, intracuff pressure etc. In our study, comparison was done in the 3 groups in distribution of ASA class and duration of surgery and duration of anaesthesia and were proved statistically insignificant and hence there was no correlation was noted with sore throat.

This study was designed to study the effectiveness of pre-intubation laryngeal spray of ketamine, dexamethasone and 4% lidocaine in decreasing the incidence and severity of POST, following general endotracheal anaesthesia. Spray

form of ketamine, dexamethasone and 4% lidocaine were used in this study because it's safe, quick, convenient, relatively inexpensive and can be administered to the patient with ease and also spares the patients from the bitter taste of the drug especially seen with gargling[1].

Since most of authors have recommended an optimum dosage of 25 mg of ketamine, 4mg of dexamethasone and 4% lidocaine. we have also selected such doses.

Ayatollahi V et al conducted a study in 68 patients who were divided into 2 groups one received ketamine spray and other received 2ml saline spray were sprayed after laryngoscopy before intubation in pharyngeal space by syringes with insulin needle under laryngoscopic direct vision and observed presence of the incidence and severity of sore throat and hoarseness were recorded at 2, 6, 12, 18, and 24 h after the surgery and in that 17 patients in ketamine group and 21 patients in saline group developed POST and concluded that after anesthesia, pre-intubation splashing with ketamine can efficiently attenuate post, with no adverse effects.[1]

Novel features of this study :

1. Spraying is the easiest and convenient way of administration with least systemic side effects.
2. Dexamethasone wasn't used in the form of spray before, according to literature and the minimal 4mg can be even used in well controlled diabetic patients via local administration.
3. Drugs used in this study are routinely used and readily available in most operation theatres.

Post-operative complications due to the study drug :

- There was no incidences of oropharyngeal irritation, increased salivation, laryngospasm, cough, dry mouth, hoarseness, stridor, dyspnoea, tachypnoea, aspiration, cardiac dysrhythmias, or desaturations during or after ketamine administration
- Adverse effects, including wound healing delays, infection susceptibility, gastrointestinal bleeding, peptic ulcers, and electrolyte imbalances that come from using dexamethasone were not seen.
- Lignocaine toxicity effects like circumoral numbness, tinnitus, systemic hypotension, myocardial depression, seizures, unconsciousness, apnea, coma and cardiovascular depression were not seen in any patient.

Limitations Of The Study :

1. Study was limited to ASA class 1 & ll
2. Serum Ketamine and nor ketamine levels were not measured so the systemic effects were not assessed .
3. Patients' subjective descriptions of their sore throat are used to evaluate the condition and it's difficult to develop objective indices for sore throat.

CONCLUSION :

In patients undergoing surgeries under general endotracheal anaesthesia, a prophylactic spray of either Ketamine, Dexamethasone, or Lidocaine 4% significantly reduces the incidence of post-operative sore throat at 1, 6, and 12 hours post-operatively without the study drugs causing any reported side effects however there was no statistically significant difference between the three study drugs but clinically it was observed that patients receiving dexamethasone spray has lesser incidence and severity of POST compared with the other two drugs. This can probably be attributed to the anti inflammatory action of dexamethasone.

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