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COMPARATIVE STUDY OF LIGNOCAINE NEBULISATION AND SPRAY FOR ATTENUATION OF HEMODYNAMIC RESPONSE TO LARYNGOSCOPY AND INTUBATION IN PATIENTS UNDERGOING ELECTIVE SURGERIES UNDER GENERAL ANAESTHESIA.

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ABSTACT:

BACKGROUND: Laryngoscopy & intubation is associated with adverse hemodynamic response which can lead to morbidity and mortality in susceptible patients. Suppression of this can be done by drugs like lignocaine which has anti-inflammatory, analgesic, bronchodilatory, anti-arrhythmic properties.
METHODOLOGY: This double blinded randomised comparative study was done for 2 months, after obtaining ethical committee clearance. It included 60 subjects of either sex, aged 18-60 years, with BMI 18–30kg/m^2belonging to ASA I&II, undergoing elective surgeries under general anaesthesia. Participants were divided into 2 groups randomly. Group N received 4%lignocaine nebulisation(1.5mg/kg),diluted to make 10ml,15 minutes before induction. Group S patients received 10%lignocaine spray(1.5mg/kg)applied to posterior oropharyngeal wall,soft palate,palatopharyngeal arch,base of tongue and supraglottic region 90seconds before laryngoscopy. Hemodynamic parameters assessed:Heart Rate(HR), Systolic(SBP), Diastolic(DBP), Mean BP(MAP) at baseline,3and 1 minutes before intubation,1,3,5,7,10,15 minutes after intubation.
RESULTS: Increase in HR was maximum at 3 minutes after intubation in both groups, Attenuation of heart rate was significant at 1(p=0.001),3(p=0024),7(p=0.022) minutes after intubation in group S. Maximum SBP and DBP was1 minute after intubation. Attenuation of SBP and DBP was significant in Group S at 1(p=0.017,0.035), 3(0.001,0.002), 5(0.001,0.001), 7(0.01,0.023), 10(0.009,0.018)minutes when compared to group N.

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CONCLUSION: Lignocaine 10% spray 90 seconds before laryngoscopy and intubation can control the hemodynamic changes more effectively than lignocaine 2% nebulisation.

KEY WORDS: laryngoscopy, intubation, general anaesthesia, lignocaine, hemodynamic response

INTRODUCTION:

Direct laryngoscopy and endotracheal intubation are important procedures for surgeries requiring General Anaesthesia. The responsibility lies on the anaesthesiologist to secure the airway and provide adequate ventilation throughout the procedure. But laryngoscopy and intubation are associated with hemodynamic response in the form of pressor response, that is increase in heart rate, systolic and diastolic blood pressure, sometimes even arrythmias.[2,3]

The precise mechanism for this cardiovascular pressor response is not known but it has been established that it is due to sympatho-adrenal stimulation[3] and release of catecholamines[1] in response to intense mechanical stimulation of pharynx, larynx and the trachea[4]. It has been established that both sympathetic and parasympathetic systems are involved in eliciting this response.[4,5] These pressor responses are usually transient, unpredictable and variable lasting for less than 10 minutes after intubation.

This has no consequences in healthy individuals but can lead to morbidity and mortality in patients with hypertension, coronary artery disease, raised intracranial pressure or raised intraocular pressure[6] as it may be associated with deleterious effects like increased myocardial oxygen demand, myocardial ischaemia, infarction, arrhythmias, cardiac failure, pulmonary oedema raised intracranial pressure and cerebrovascular accidents.[4,7]

Suppressing this hemodynamic response is an important part of properly administered general anaesthesia. Stoelting found that short-duration laryngoscopy (ideally <15 s) is an effective method to minimize increase in mean arterial pressure during endotracheal intubation[4]. Suppression of pressor responses can also be done by deepening the plane of anaesthesia[3], by using laryngeal mask airway, various types of laryngoscope blades like McCoy blade[2], by fibreoptic intubation, pharmacological methods like magnesium sulphate, beta blockers, gabapentin, topical local anaesthetics[8], pregabalin , opioids[7] , alpha 2 agonist, calcium channel blockers, vasodilators etc or by using advanced airway devices.[5]

The most commonly used method is usage of intravenous lignocaine[8]. Lignocaine is an amide local anaesthetic[10]. It has both anti-inflammatory and analgesic properties and it is available in multiple dosage forms[9]. The added advantage of lignocaine is its bronchodilatory and anti-

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arrhythmic properties.[6] Lignocaine can be administered by different routes like intravenous (i.v), local nerve blocks, nebulisation, viscous gargling, instillation into endotracheal tube cuff, oropharyngeal topical spray, laryngotracheal instillation etc[11]

OBJECTIVES:

To compare the attenuation of hemodynamic response in the form of heart rate (HR), systolic BP(SBP) and diastolic BP(DBP),mean arterial pressure(MAP) to laryngoscopy and intubation between lignocaine spray and lignocaine nebulisation before (-3 and -1 minutes) and after intubation(+1,3,5,7,10,15 minutes)

MATERIALS & METHODS:

This is a double blinded, prospective randomised comparative study conducted for a period of 2 months at Shridevi Institute of Medical Sciences and Research Hospital, Tumkur on patients undergoing Orthopaedic, General Surgery, Neurosurgery, ENT and Gynaecological elective surgeries under General Anaesthesia. Institutional ethical committee clearance was taken before the start of study.

Inclusion criteria: Patients of either sex aged 18-60 years, with BMI 18kg/m^2 – 30kg/m^2, belonging to American society of Anaesthesiologists (ASA) Grade I and Grade II.

Exclusion criteria: Patients with history of allergy or hypersensitivity to Lignocaine or its preservatives, anticipated difficult intubation; Mallampatti Grade III or IV, patients with history of laryngeal or tracheal pathologies and patients with cardiovascular diseases, uncontrolled hypertension, cerebrovascular diseases, liver disease.

The sample size was calculated using 2 studies conducted in 2020 and 2022 considering the mean arterial pressure (MAP) at similar time intervals. In the 1st group at 6 minutes mean±SD was 101.43±11.65, 2nd group mean±SD was 97.07±12.46 and 3rd group mean±SD was 98.03±10.4. At 80% confidence level and an absolute allowable error of 5%, the sample size was calculated using the following formula:

$$\text{Sample size(n)} = \frac{z^2\left(1-\frac{\alpha}{2}\right)+sD2}{d^2}$$

Where $z^2(1-\alpha/2)$=standard normal deviate for 80% confidence, SD=Standard deviation of Mean Arterial Pressure, d=marginal error=5% The sample size was calculated with the help of software G*Power version 3.1. where the sample size estimated was 60 that is 30 in each group.

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METHODOLOGY:

Preoperative evaluation of the patients for fitness for surgery were conducted a day before the surgery. Patients satisfying the eligibility criteria and giving informed written consent were randomly allocated to Group N(nebulization), or S(spray) by simple randomisation by closed envelope method.

Once the patient was shifted into the preoperative ward and into the operation theatre, they were connected to monitors including non-invasive blood pressure monitoring (NIBP), Heart rate(HR), peripheral oxygen saturation(SPO2), 5 lead Electro Cardiogram(ECG) with standard lead II display, end tidal carbon dioxide(ETCO2). All the base line values of HR, SBP, DBP, MAP, ECG were recorded.

Patients of Group N received 4% lignocaine nebulisation (1.5 mg/kg), diluted to make 10ml solution by simple face fitting face mask with Compressor Nebulizer (Beurer) 15 minutes before induction of anaesthesia and then shifted into the operation theatre and connected to monitor. As a part of double blinding, they received saline spray just after induction of anaesthesia.

Patients in Group S received normal saline nebulisation and 10% lignocaine spray (lignocaine pump oropharyngeal spray 10% 50ml, 10mg/puff, max dose 300mg) applied to posterior oropharyngeal wall mucosa, soft palate, palatopharyngeal arch, base of tongue and supraglottic region with the mouth widely open and tongue out just after induction of anaesthesia.

Each patient received injection Midazolam 1 mg, injection Glycopyrrolate 0.2mg and injection Ondansetron 4 mg as a part of regular premedication. After preoxygenation with 100% oxygen for 3 minutes, induction was done with injection propofol(2mg/kg), injection fentanyl(2mcg/kg) with adequate mask ventilation and intubation was facilitated by injection succinyl choline (2mg/kg).

Direct laryngoscopy was performed using appropriate size Macintosh blade. Under visualisation of vocal cords, intubation was performed with the appropriate sized, disposable, high volume, low pressure, cuffed endotracheal tube and fixed appropriately after 5 point auscultation. This procedure of laryngoscopy and endotracheal intubation was done in a span of 15 to 20 seconds.

All the vital parameters (Heart rate, Systolic / Diastolic blood pressure, Mean arterial pressure, ECG changes) were recorded at

1. Baseline: before giving the premedication or any study drug.
2. At 3 and 1 minute before laryngoscopy (-3 and -1 minutes)
3. At 1,3,5,7,10 and 15 minutes post laryngoscopy and intubation.

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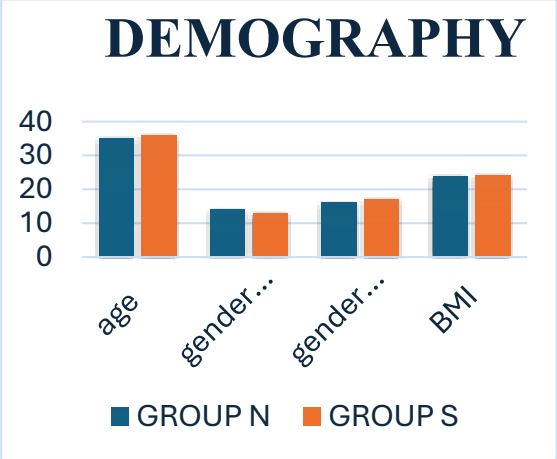
The patients were then connected to mechanical ventilator and the anaesthesia was maintained throughout the surgery. At the end of the surgery, the patient was extubated.

STATISTICAL ANALYSIS: The Quantitative variables are presented in Mean with SD and Graphs. The statistical tests were analysed using statistical software R- 4.1.3 version or Epi-Info version 7.2. ANOVA (one way analysis of variance), unpaired 't' test, chi–square test were used where deemed necessary. P value of < 0.05 are considered statistically significant.

RESULTS:

The demographic characters that is age, gender, BMI were comparable among the 2 groups

CHARACTERISTICS		GROUP S	GROUP N
AGE		36.00 ± 11.85	35.8±11.06
GENDER	MALE	14	13
	FEMALE	16	17
BMI		24.10±3.458	23.80±3.156



The distribution of age among the four groups was fairly balanced, with no significant difference observed. The mean of age was 36.00 ± 11.85 in group S and 35.8±11.06 in group N, suggesting a predominance of middle-aged patients in our study. The male-to-female ratio was not significantly different across the groups (p = 0.69). The proportion of females was slightly higher in both the groups. BMI values were also comparable, 24.10±3.458 in Group S and 23.80±3.156 in Group N

HEMODYNAMIC VARIABLES:

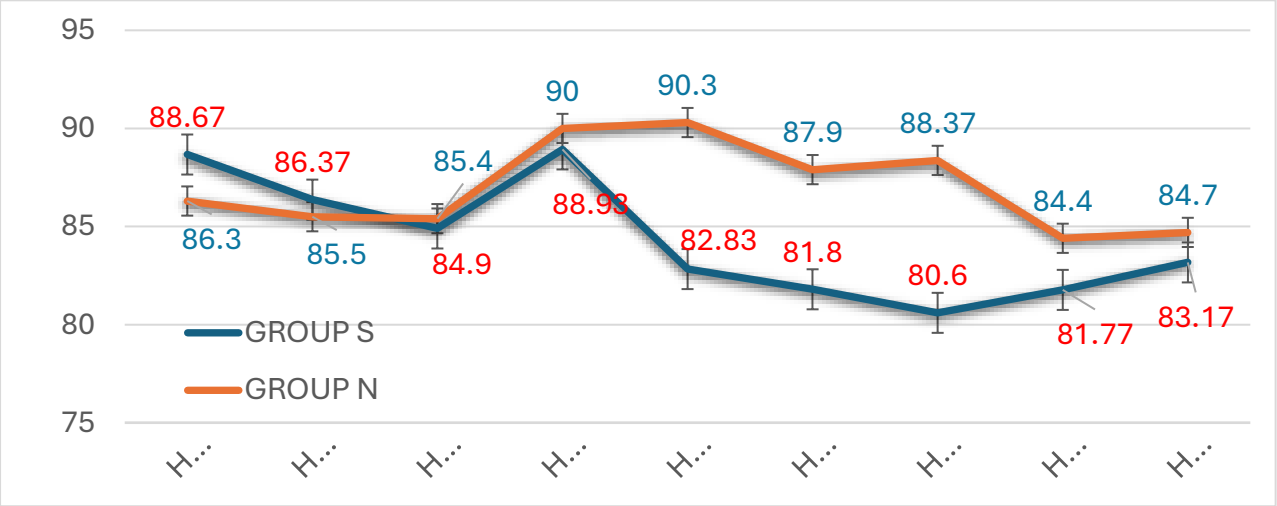
1)HEART RATE

HR	Baseline	-3min	-1min	+1 min	+3 min	+5 min	+7 min	+10 min	+15 min
GROUP S Mean± SD	88.67±15.02	86.37± 15.12	84.9± 14.44	88.93± 15.06	82.83± 13.95	81.8± 13.10	80.6± 11.22	81.77± 13.45	83.17± 13.45
GROUP N Mean± SD	86.3± 10.97	85.5± 10.54	85.4 ± 10.94	90 ± 1.017	90.3 ± 10.70	87.9± 12.51	88.37± 14.09	84.4± 12.54	84.7± 12.29

P value	0.48	0.79	0.88	**0.01**	**0.02**	0.07	**0.02**	0.43	0.63

Table 1

Figure 1



At baseline, there was no significant difference in heart rates across groups (p = 0.48). However, after intubation, Group N exhibited a marked increase in HR, peaking at 90.3 bpm at +3 min. In contrast, Group S showed the most stable HR response, reaching only 88.8 bpm at +1 min ($p < 0.05$). there is statistically significant reduction in heart rate at +1, +3,+7 minutes in group S when compared to Group N indicating that lignocaine spray effectively blunted the tachycardic response to laryngoscopy.

SBP	**Baseline**	**-3min**	**-1min**	**+1 min**	**+3 min**	**+5 min**	**+7 min**	**+10min**	**+15 min**
GROUP S Mean±SD	120.37± 10.73	120.57± 9.74	118.47± 9.18	114.23± 11.79	105.67± 11.53	101.80 ± 9.13	103.0 ± 12.53	109.93± 12.69	116.53± 12.16
GROUP N Mean±SD	120.4 ± 10.64	122.07± 10.12	119.3± 10.04	121.63± 11.42	120.43± 11.31	121.20± 11.97	117.40± 17.15	118.63± 12.12	121.27± 12.68

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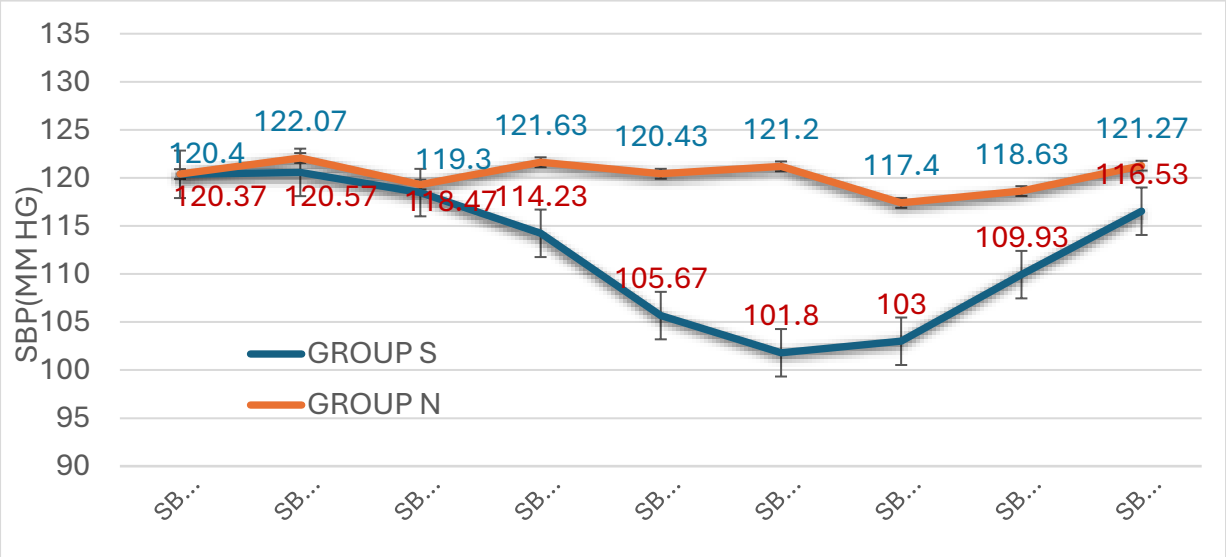
P value	0.99	0.56	0.739	**0.017**	**0.001**	**0.001**	**0.002**	**0.009**	0.146

2)SYSTOLIC BLOOD PTRESSURE(SBP)

Table 2:

Figure 2:



Baseline SBP values were comparable (p = 0.99). Group N maintained SBP almost close to the baseline but in Group S, there was reduction in baseline SBP especially at +1, +3, +5,+7, +10 min($p<0.05$). This suggests that Group S provided the best suppression of hypertensive response following laryngoscopy.

3)DIASTOLIC BLOOD PRESSURE(DBP)

Table 3:

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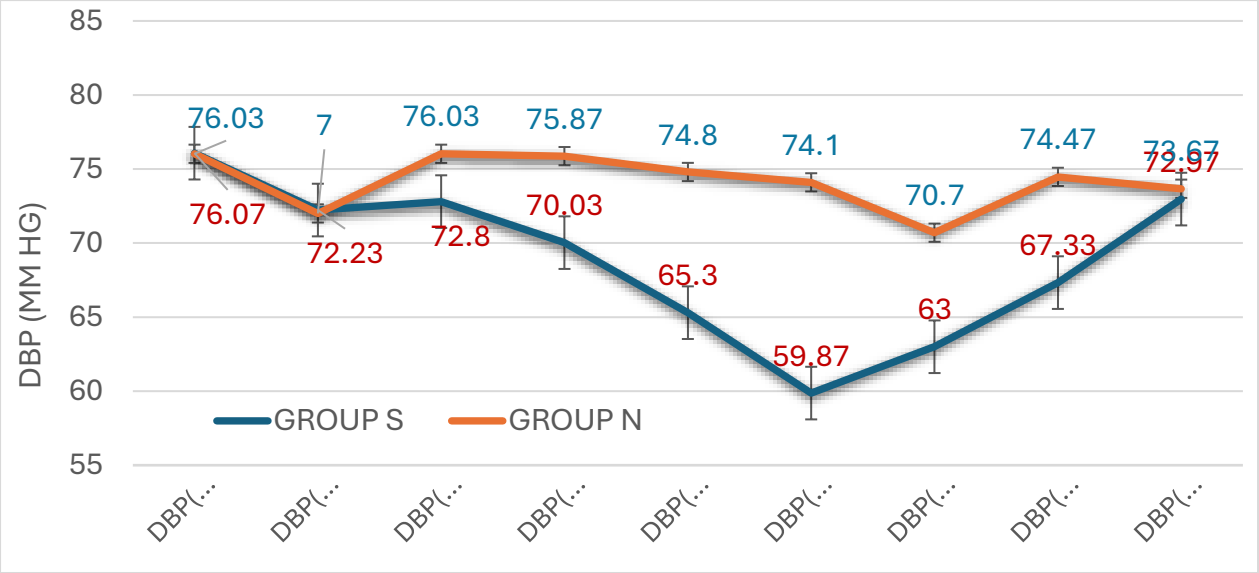
DBP	Baseline	-3min	-1min	+1 min	+3 min	+5 min	+7 min	+10min	+15 min
GROUP S mean±SD	76.07± 10.02	72.23 ± 9.46	72.8± 7.75	70.03± 11.53	65.30± 9.61	59.87± 10.69	63.0± 12.93	67.33± 11.701	72.97± 14.38
GROUP N mean±SD	76.03± 6.89	72.0 ± 7.95	76.03± 10.82	75.87± 9.32	74.80± 10.26	74.10± 9.79	70.70± 12.68	74.47± 10.98	73.67± 10.97
P value	0.98	0.74	0.43	0.035	0.00	0.01	0.02	0.01	0.83

Figure 3:



DBP followed a similar pattern, with Group N maintaining DBP close to baseline levels, whereas there was reduction in DBP after using Spray in Group S which was statistically significant at +1, +3, +5,+7, +10 minutes(p value<0.05) This statistically significant difference throughout the observation period, confirming that lignocaine spray was the most effective in maintaining stable diastolic pressures.

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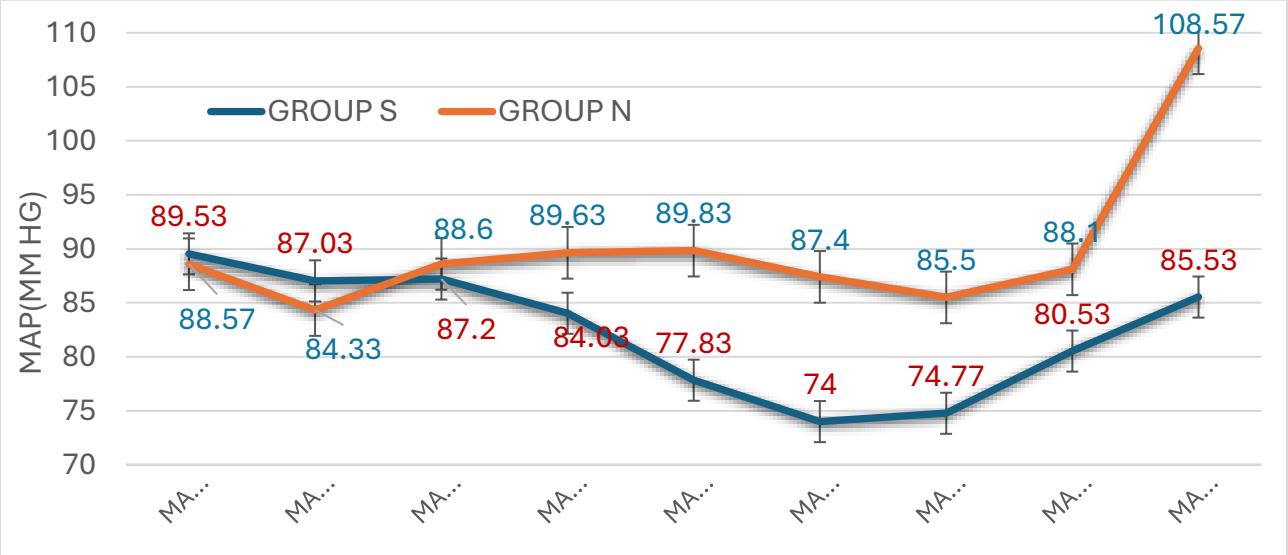
3)MEAN ARTERIAL PRESSURE(MAP)

Table 4:

MAP	Baseline	-3min	-1min	+1 min	+3 min	+5 min	+7 min	+10min	+15 min
GROUP S mean±SD	89.53± 9.54	87.03± 9.40	87.20± 7.93	84.03±1 1.75	77.83± 10.19	74.00± 10.15	74.77± 11.91	80.53± 11.53	85.53± 13.35
GROUP N mean±SD	88.57± 10.06	84.33± 15.71	88.60± 12.14	89.63±1 0.97	89.83± 9.67	87.40± 10.52	85.50± 13.04	88.10± 10.73	108.57± 11.32
P value	0.70	0.42	0.59	0.06	0.00	0.01	0.00	0.11	0.273

Figure 5:



The MAP showed a similar trend to SBP and DBP, with Group N reaching the highest MAP at +15 min (108.57 mmHg), while Group S had the lowest at +5 minutes. (74 mmHg, $p < 0.05$.)These results highlight that Group S demonstrated the best attenuation of MAP fluctuations.

DISCUSSION:

Laryngoscopy and endotracheal intubation are considered as the most critical events during general anaesthesia as they provoke transient but marked sympathoadrenal response manifesting as hypertension and tachycardia. Lignocaine is one of the drugs used to blunt this response as evidenced by previous studies, but there are limited studies comparing usage in nebulised form and spray form.

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All of our study patients had successful intubation in the first attempt, with duration of laryngoscopy and intubation lasting for less than 30 seconds. No complications were reported in either groups confirming the safe administration of lignocaine in these forms.

The age distribution among the two study groups was balanced, with no statistically significant difference ($p = 0.766$). The mean of age was 36.00 ± 11.85 in group S and 35.8±11.06 in group N, suggesting a predominance of middle-aged patients in our study. Similar findings were reported by Kashyap OP et al.[12], where the mean ages in Group A (Placebo), Group B (Nebulized Lignocaine) and Group C (IV Lignocaine) were 33.00±7.31, 31.27±6.87, and 31.70±8.82 years, respectively. Additionally, Shweta P et al [13] reported age-matched groups with no significant differences (Group A: 38.20 ± 10.63 years, Group B: 39.80 ± 12.45 years).

Gender distribution across groups was not significantly different ($p = 0.69$). The proportion of females was slightly higher in both the groups. A similar trend was noted in Kashyap OP et al's study, with female participation rates of 76.7%, 90%, and 86.7% in Groups A, B, and C respectively[12] . Conversely, Mahajan A et al reported a male majority (56% and 53% in Groups I and II, respectively)[14]. Shweta P et[7] al and Roy et al also found no significant gender distribution differences. [12]

BMI values were also comparable, 24.10±3.458 in Group S and 23.80±3.156 in Group N. Kashyap OP et al. reported BMI values within the normal range (Group A: 19.80 ± 1.4, Group B: 19.64 ± 1.5, Group C: 20.55 ± 1.5)[12] . Shweta P et al reported no significant weight differences between study groups.[13]

Heart Rate Response: Baseline heart rates were comparable across groups ($p = 0.48$) Following intubation, Group S demonstrated the most stable HR response (81.8 bpm at +5 minutes, $p < 0.05$). Groups N also showed HR reduction post intubation indicating that lignocaine effectively mitigated tachycardia post-laryngoscopy. But at 1, 3, 7 minutes post intubation, the difference in heart rate was statistically significant in group S (p value:0.01,0.02,0.02)

Kashyap OP et al.[12] found HR differences to be significant ($p < 0.05$) at 5-15 minutes post-intubation. The control group had significantly increased HR compared to nebulized and IV group. Mahajan A et al[14]. reported a gradual HR decline after intubation in IV Lignocaine group though it did not return to baseline within 5 minutes. In spray group, HR increased post-intubation but returned to baseline within 5 minutes. Similar findings noted by Shweta P et al.[13], where the IV lignocaine group had a significantly lower HR rise compared to the nebulized lignocaine group. However, Agarwal A et al[15]. reported no statistically significant HR differences between nebulized and IV lignocaine groups over a 16-minute observation period. Roy et al[16]. with nebulised vs spray lignocaine and comparison of hemodynamic parameters 1,2 and 5 min post intubation showed statistically significant reduction in heart rate at 1, 2 and 5 minutes in nebulised group

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Blood Pressure Response: Baseline SBP values were comparable across groups ($p = 0.99$). At +1 minute post-intubation, Group N exhibited a SBP rise (121.63 mmHg), while Group S had the lowest increase (114.23 mmHg, $p < 0.05$). This trend continued at +5 minutes, with Group N peaking at 121.20 mmHg and Group S maintaining a significantly lower SBP (101.8 mmHg, $p < 0.05$. Similar trends were observed for DBP, where Group N reached 74.10 mmHg at +5 minutes, whereas Group S remained lowest at 59.87 mmHg , where DBP was significantly lower in group S at +1 to +10 minutes($p<0.05$).

Also the SBP and DBP were maintained somewhere near to the baseline with slight increase in Group N whereas there was significant reduction in BP in Group S from the baseline suggesting lignocaine spray not only attenuates, but also reduces the hypertensive response to laryngoscopy and intubation.

Agarwal A et al[15]. found no significant SBP or DBP differences between IV and nebulized lignocaine groups over 16 minutes. However, Shweta P et al[13]. reported significantly lower SBP and DBP increases in the IV lignocaine group (3.0 mmHg and 2.41 mmHg, respectively) compared to the nebulized group (9.60 mmHg and 20.44 mmHg). Mahajan A et al[4]. also found topical xylocaine 10% to be more effective than IV lignocaine 2% in blunting pressor responses. But Roy et al found statistically significant reduction in SBP and DBP in nebulisation group than spray group[16] .

Mean Arterial Pressure Response: The MAP showed a similar trend to SBP and DBP, with Group N having high MAP readings at +3,+5,+7 minutes which were significantly higher than group S. These results highlight that Group S demonstrated the best attenuation of MAP fluctuations

In the study by Shweta P et al[13], in nebulisation group the MAP was found to be 22.30 mm Hg and in iv group the maximal increase in the MAP was found to be 4.77 mm Hg .In study by Roy et al, nebulisation group had statistically less MAP values which is opposite to our study findings.[16]

CONCLUSION:

- Across all measured parameters, Group S (10% lignocaine spray) exhibited the most stable haemodynamic response, with significantly lower HR, SBP, DBP, and MAP variations. Groups N (nebulized lignocaine) also showed some attenuation of hemodynamic response, but Group S consistently had the best control over cardiovascular responses post-intubation.
- Topical lignocaine spray is significantly better as it provides targeted airway desensitization, reducing sensory input and attenuating stress responses. Furthermore, this technique is a simple effective way to suppress the hemodynamic response without additional cost and with no patient discomfort

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LIMITATIONS:

- The droplet size, drug output from the nebuliser and respiratory rate of patient could not be standardized. There can be loss of a significant amount of lignocaine during nebulisation in the form of aerosol and residual volume.
- We did not measure plasma lignocaine concentrations to find a clinical relevance of plasma lignocaine levels, effect of lignocaine on other organ systems such as suppression airway reactivity and reduction of intracranial hypertension.

STRENGTH:

- Simplicity in terms of medications, route of administration and the effectiveness of the procedure which can be easily replicated.

Conflict of interest: None

Financial support: None

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