Section A-Research Paper
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Comparison of Nitroglycerine spray and Lignocaine spray for attenuating the pressor response during laryngoscopy and endotracheal intubation in patients undergoing elective surgery under general anaesthesia

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Abstract
Background: To attenuate the pressor response during laryngoscopy and endotracheal intubation many studies have done, but the intention of this study is to observe the impact of oral nitroglycerine spray and oropharyngeal lignocaine spray in diminishing the haemodynamic response during laryngoscopy and intubation. **Methods:** 70 patients were selected who are planned for elective general anaesthesia were divided into 2 groups, Group L (n=35) and Group N (n=35). Haemodynamic parameters like heart rate, SBP, DBP, Rate pressure product, MAP and sore throat were recorded in both groups. P value < 0.05 is considered as statistical significance. **Results:** Nitroglycerine spray group was significantly more effective than lignocaine spray group in attenuating the pressor response and were also statistically significant (P valve <0.05). There was statistically significant difference between two groups in HR, DBP, MAP at 1,2,3 minutes after intubation. Both the groups effectively decreases the haemodynamic response. **Conclusions:** This study concludes that both lignocaine spray and nitroglycerine spray are simple, effective and comfortable means in attenuating the pressor response to laryngoscopy and endotracheal intubation, but nitroglycerine spray was significantly more effective than lignocaine spray.
Keywords: endotracheal intubation, spray, laryngoscopy, general anaesthesia, attenuate.

Introduction: Magill and Row Bottom in 1921 introduced modern endotracheal anaesthesia and intubation during first world war. Ever since, tracheal intubation has turned as an airway management in elective and emergency situation.
In 1951, circulatory effects such as tachycardia and hypertension in response to sympathetic stimulation due to direct laryngoscopy and tracheal intubation was reported under light anaesthesia. The rise in blood pressure and heart rate is usually transient, variable and unpredictable.[1] The pressor response include 40-50% rise in blood pressure, 20% rise in heart rate and elevation of epinephrine and norepinephrine levels. These effects occur within 30 seconds of intubation and last less than 10 min and highly compatible in healthy patients.[2]
In normal individual these changes are well tolerated, but in individuals with systemic hypertension, coronary artery disease or intracranial hypertension these changes are fatal.

This is mainly due to reflex sympathetic discharge in regards to endotracheal stimulation thereby leads to increase in plasma concentration and rise in blood pressure.[3]

Endotracheal intubation creates modification in catecholamine concentration and impulsive surge in sympathetic activity due to hypertension, arrhythmia and tachycardia. Short term pressor response with deleterious effect on coronary and cerebral flow in greater risk patients specifically in systemic hypertension, coronary artery or cerebrovascular disease.[4]

The factors that cause difficult intubation are[5]

- Anterior of larynx
- Prominent upper teeth
- Backwards displacement of tongue
- Elevation of epiglottis.

Intravenous anaesthetic agents alone cannot suppress the circulatory response occurring due to tracheal intubation. Therefore prior to initiating laryngoscopy and endotracheal intubation additional pharmacological responses should be taken to obtund these responses.[6]

Lignocaine is an amide local anaesthetic and is metabolized (N-dealkylation and hydroxylation) by microsomal p450 enzymes in the liver. Intravenous lignocaine (1.5mg/kg) and lignocaine spray attenuates arterial and intracranial pressure that accompanies laryngoscopy and endotracheal intubation. It is available as oral spray, intravenous injection or topical application. It depresses the circulatory response to Endotracheal Intubation.[5-6]

Nitroglycerine or Glyceryl Trinitrate (NTG) is an organic nitrate which exerts its effect being converted to nitric oxide in the body by mitochondria aldehyde dehydrogenase. It relaxes vascular smooth muscle with venous dilatation predominantly over arterial dilatation.[8] NTG can be administered intranasally, intravenously, oral spray, topical application or oral tablet to lessen pressor response due to laryngoscopy and intubation. Studies have shown that nitroglycerine can be used to prevent stress induced ischemia and relieve constriction of coronary arteries. However, administration of NTG alone during pre-intubation may not be sufficient to decrease hemodynamic response due to its tendency of producing tachycardia.[9,10]

These anaesthetic drug are easily accessible and its spray form can be used in a conscious patient in order to anaesthetise glottis area for laryngoscopy and intubation.[10]

The intention of this study is to observe the interference of oral nitroglycerine spray and oropharyngeal lignocaine spray in diminishing the pressor response during direct laryngoscopy and endotracheal intubation.

Aim:

The goal of the research was to compare the intensity of attenuating the pressor response during laryngoscopy and endotracheal intubation between oral nitroglycerine spray and oropharyngeal lignocaine spray in patients underwent elective surgery under general anaesthesia.

Objectives:

- To compare the hemodynamic responses such as Heart rate (HR), Systolic Blood Pressure (SBP), Diastolic Blood Pressure (DBP) and Mean Arterial Pressure (MAP), rate pressure product (RPP) between two groups.
- To compare the incidence of sore throat after extubation between two groups.

Materials and Methods

This study was performed in the Department of Anaesthesiology, in our institute.

Study population: Patients scheduled for elective surgery under general anaesthesia requiring intubation and who met the inclusion criteria.

Study design: Prospective, Randomized, Double blinded study.

Sample size: Sample size was calculated based on a previous observation made by Madhuri Gopal., (2017) using Epi-info software 7, with two – sided confidence interval of 99% with the power 90%, the required sample size was 70 with 35 participants in each group.

Randomization and binding: Selected 70 patients were randomly divided into two groups (35 patients in each group) using computer generated randomization code. Blinding was achieved using a sealed envelope technique.

Study duration and Ethical consideration: The data collection for the study was done from December 2018 to February 2021. After obtaining approval from Institutional Human Ethics Committee IHEC NO: 153/ IHEC/ 9-18, dated 27.10.2018, written informed consent were obtained from 70 patients, who underwent elective surgeries under general anaesthesia in our institution meeting the following selection criteria will be included in the study. The risks and benefits involved in the study and voluntary nature of participants were explained to the participants before obtaining the consent.

Inclusion criteria:

1) Patients of both sex scheduled for elective surgery under general anaesthesia requiring tracheal intubation.
2) Age 18-60 years.
3) American Society of Anaesthesiologists (ASA) Grade I & II.

Exclusion criteria:

1) Pregnant patients.
2) Patients with history of cardiovascular disorders.
3) Patients with history of hepatic and renal disorders.
4) Patients who are allergic to the test drugs.
5) Patients with BMI more than 30.
6) Patients with anticipated difficult airway.
7) Hypertensive patients on antihypertensive medications.

Study methodology:

After a complete pre-anaesthetic evaluation and a valid informed consent from the patients, they were randomized according to computer generated codes to one of the study groups. They were premedicated with Tab.Alprazolam 0.5mg and Tab. Ranitidine 150mg the night before the day of surgery and at 6am on the day of surgery.

GROUP L – 35 patients received oropharyngeal 10% Lignocaine 10mg/puff (2 puffs).

GROUP N – 35 patients received oral Nitroglycerine – 400mcg/puff – (1 puff).

After an arrival of the patient to the operation theatre, 18-gauge IV line were secured. Standard monitoring including non-invasive arterial blood pressure (NIBP), Electrocardiogram (ECG), Oxygen saturation (SpO2) by pulse oximetry and neuromuscular monitoring (TOF- WATCH SX) were applied and monitored continuously. The base line parameters of the patient like heart rate, systolic and diastolic blood pressure and mean arterial pressure were noted.

After pre oxygenation with 100% O_2 for 3 minutes, Inj Midazolam 1.0 mg and Inj. Fentanyl 2mcg/kg iv were given following which the patient has been induced with Inj Propofol 2mg/kg iv. After the loss of verbal response, the ulnar nerve was stimulated at the wrist with supramaximal stimulus using TOF – WATCH SX. Supramaximal stimulus was obtained by adding 25% of the strength of current required for maximal stimulation followed by which Inj Vecuronium 0.1 mg/kg iv were given.

The study drug was sprayed at a TOF value of 2. Both the study drugs were covered with a black sheet for blinding and the anaesthesiologist who sprayed the study drug was not a part of this study. The study drug either 10% lignocaine spray - 2 puffs (10mg per puff) was sprayed oropharyngeally or nitroglycerine spray (400 mcg/puff) orally were sprayed. The

patient was ventilated again till the TOF value reached 0. Then the patient were intubated by an experienced anaesthesiologist with the appropriate size endotracheal tube and fixed.
The parameters were noted down immediately after intubation, at an interval of 0,1,2,3,4 and 5 minutes and then every 5 minutes for the first half an hour and then every 10 minutes till the end of the surgery.
Anaesthesia was maintained with oxygen, air and isoflurane to reach a Mac of 1 to 1.5. Inj Vecuronium 0.05mg/kg were given as required. At the end of the surgery patient was reversed with Inj.Glycopyrrolate 0.01mg/kg and Inj.Neostigmine 0.05mg/kg and extubated.
Vitals were also noted immediately after extubating the patient. If an anaesthesiologist failed to intubate at the first attempt or required a bougie or stylet for intubation or if he required a change in the size of the laryngoscope blade for intubating, those patients were excluded from the study. Postoperatively the patient were assessed for sore throat after one hour in recovery room and noted. These study drugs were used in elective surgeries of less than 2 hours procedure under general anaesthesia.

Scoring for post-operative sore throat (post): [12]

SCORE	DESCRIPTION
0	No sore throat
1	Mild sore throat (complains of sore throat only on asking)
2	Moderate sore throat (complains of sore throat on his/her own)
3	Severe sore throat (change of voice or hoarseness associated with throat pain)

Figure 1: Nitroglycerin spray [17] Figure 2. Lignocaine spray [18]

Results

This study concludes that both lignocaine oropharyngeal spray and nitroglycerine oral spray are elementary, efficacious and convenient means in attenuating the pressor response to laryngoscopy and endotracheal intubation.

Table 1: Comparison of Heart Rate (HR) between study groups (N=70)

Heart Rate (HR)	Study Group		Independent Sample t-test P value
	Group N (N=35) Mean ± SD	Group L (N=35) Mean ± SD	
Baseline	77.57±13.8	76.6±17.8	0.799
0 min	89.37±13.8	80.57±15.6	0.015
1 min	93.51±12.4	79.23±16.6	<0.001
2 min	96.83±14.2	77.91±16.8	<0.001
3 min	94.57±14.9	78.63 ±17.2	<0.001
4 min	93.14±16.1	77.15±16.3	0.001

5 min	91.9±17.2	77.34±17.07	0.001
10 min	88.8±16.8	77.91±16.2	0.008
15min	85.17±17.3	76.03±16.5	0.027
20 min	81.34±13.8	73.49±14	0.019
25 min	79.11±10.8	72.49±13.9	0.03
30 min	78.54±11.8	71.83±14.4	0.037
40 min	78.38±13.8	71.06±15.0	0.039
50 min	76.3±16.9	70.76±14.5	0.148
60 min	76.2±14.9	69.69±13.5	0.076
70 min	75.67±16.3	69.67±14.1	0.154
80 min	75.29±16.2	71.56±14.06	0.408
90 min	77.56±15.8	71.52±13.2	0.191
100 min	78.69±16.0	71.42±12.8	0.146
110 min	79.08±18.7	73.92±14.8	0.444
120 min	71.83±10.3	78.3±13.1	0.208
After extubation	87.31±16.1	80±11.2	0.031

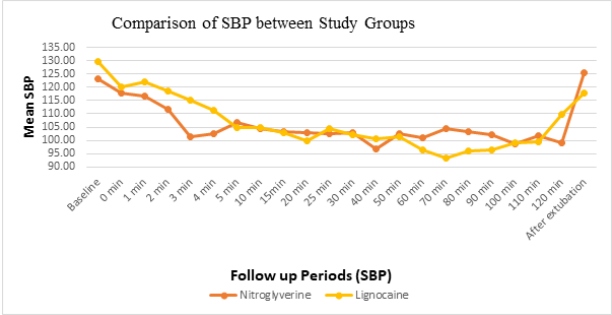

Figure 4: Line Graph for the comparison of SBP between Study Groups

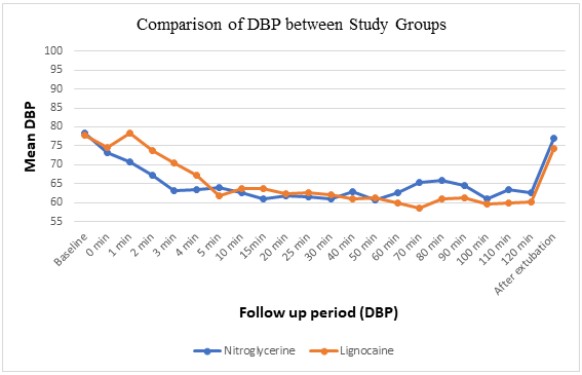

Figure 5: Line Graph for the comparison of DBP between Study Groups

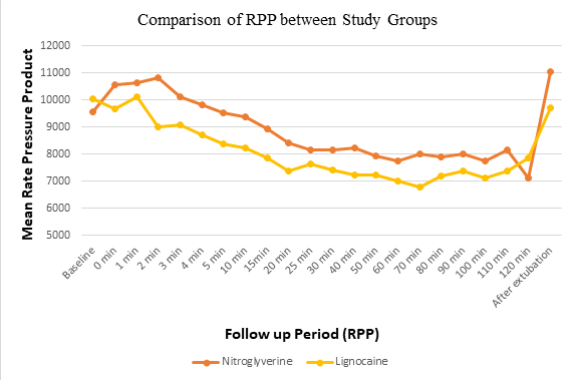

Figure 6: Line Graph for the comparison of RPP between Study Groups

Table 2: Comparison of Sore Throat Assessment between study groups (N=70)

Sore Throat Assessment	Study Group		Chi square	P-value
	Group N (N=35)	Group L (N=35)		
Yes	1 (2.9%)	13 (37.1%)	50.400	0.149
No	34 (97.1%)	22 (62.9%)		

Discussion

Tracheal intubation produces marked short term response on coronary and cerebral circulation in high-risk patients those with systemic hypertension, coronary artery disease or cerebrovascular disease. Activation of sympathetic nervous system causes coronary artery vasoconstriction reducing the supply of oxygen to the myocardium which will predispose to myocardial ischemia.

A wide variety of pharmacological methods were available, which are used to reduce the pressor response to laryngoscopy and endotracheal intubation such as appropriate premedication, topical application of local anesthetics, infiltration or nerve blocks, beta blockers, calcium channel blockers, clonidine, magnesium sulphate, etc. Nonpharmacological methods include smooth, rapid, and gentle intubation has been used to attenuate the response. But no single drug or technique is satisfactory.

Various studies have been conducted with different methods and technique to attenuate the pressor response to endotracheal intubation and laryngoscopy. In our study we compared topical drugs like oropharyngeal 10% lignocaine 2 puff (10mg/puff) with oral nitroglycerine spray 1 puff (400mcg/puff) given before intubation with TOF- WATCH SX monitor to blunt the sympathetic response to laryngoscopy and endotracheal intubation. Hence the effects of nitroglycerine spray and lignocaine spray for suppression of hemodynamic response to laryngoscopy and intubation was studied.

Figure 3: TOF monitor for ulnar nerve

Demographic profile: The two study groups were matched regarding patient's age, sex, and anthropometric indices.
Age: The median age was 40 (IQR 30 to 44.6) of group N and 43(IQR 30 to 50.8) of group L, the difference in the age between study group was statistically not significant (P Value 0.746).
Among the Group N, majority of the participants belonged to age group 21 years to 30 years of age 14(40%) followed by 13(37.1%) participants belonged to age group 31 years to 40 years of age.
Among the Group L, 14(40%) participants belonged to age group 21 years to 30 years of age, 7(20%) participants belonged to age group 31 years to 40 years of age, 7(20%) participants belonged to age group 41 years to 50 years of age. The difference in age groups between study group was statistically not significant (P value 0.355).

Gender: Among the Group N, 16 (45.7%) participants were male, and 19 (54.3%) participants were female while in Group L, 18 (51.4%) participants were male, and 17 (48.6%) participants were female. The difference in gender between two groups was statistically not significant (P value 0.632).

Anthropometry: Among the Group N, the mean height was 159.09±8.21 while in Group L the mean height was 159.11±10.04. Among the Group N, the mean weight was 60.51±11.3 while in Group L the mean weight was 61.03±10.2. Among the Group N, the mean BMI was 23.91±4.14 while in Group L the mean BMI was 24.19±4.07. There was no statistically significant difference between two groups in anthropometric parameters like height, weight, and BMI. (P value >0.05)

Hemodynamic Responses
Heart rate: The difference between the two groups was statistically significant for heart rate at follow up periods of 0 min, 1 min, 2 min, 3 min, 4 min, 5 min, 10 min, (P value< 0.05).
Ajay kumar singh et al[8] has studied in 100 adult patients belonging to ASA grade 1; aged 20 to 40 years were randomly allotted into 4 groups of 25 each. Group 1- acted as control group (not receiving any pre-treatment), group 2- Nitroglycerine intranasal group, group 3- Nitroglycerine topical group, group 4-Nitroglycerine intravenous group. The study reported that with sublingual nitroglycerine, heart rate remained increased for a longer duration than the control group. The study also found a statistically significant difference between the study groups in relation to heart rate. ($p<0.05$) which is similar.
Kotwani Et al al[11] has done a study in 50 patients comparing intravenous magnesium sulphate and sublingual nitroglycerine reported that there was significant rise in the HR ($p<0.001$) from the baseline values after giving the study drugs. Mean HR values were significantly high from the baseline, in both the groups after laryngoscopy and intubation and at 2 and 5 minutes thereafter. There was significant rise in systolic blood pressure in both the groups but limited in sublingual nitroglycerine groups from the baseline after intubation.
Varsheney et al.[15] has studied in 90 patients comparing NTG spray and lignocaine spray with control group, and he found that there was a significant reduction in mean HR at 3-5 minutes in both groups compared to the control group.
Manjunath et al.[13] has done a study, where 10% Lignocaine one metered dose was sprayed 3-5 minutes before intubation to 39 Patients aged between 20- 60 years of age, belonging to ASA Grade I and II, undergoing elective surgery requiring general anesthesia. There was a highly significant finding observed between the baseline to laryngoscopy and intubation values. There was significant rise in heart rate after intubation. SBP, DBP, RPP decrease

following laryngoscopy and intubation. It blunts the cardiovascular response. The effect of lignocaine spray was more marked on blood pressure than heart rate changes.

In the current study, both lignocaine group and nitroglycerine group exhibits an increase in heart rate after intubation till 5 minutes. In comparable to lignocaine group, nitroglycerine group shows a greater increase in heart rate due to reflex tachycardia produced due to peripheral vasodilatation.

Blood pressure: The difference between the two groups was not statistically significant for systolic blood pressure and diastolic blood pressure ($p>0.05$).

Kotwani et al[11] reported that there was fall in SBP after giving Nitro-glycerine spray (-7.69% from baseline). Mean SBP at all the points after laryngoscopy and intubation was higher than the baseline values.

Sunil et al[15] has reported that, there was a maximum systolic pressure noted at 1 minute after NTG spray. Thereafter the systolic pressure started coming down and returned to near baseline values by 6th minute after extubation.

Varsheney et al.[15] has studied in 90 patients comparing NTG spray and lignocaine spray with control group, which shows a lower increases in MAP at 1-3 minutes after intubation. There was a significantly greater decrease in mean SBP in the NTG group at 2-4 minutes, compared to the other groups.

In this study, SBP and DBP was significantly reduced after intubation at 0-5 minutes in both the groups and was not statistically significant ($p>0.05$).

Mean arterial pressure: There was a statistically significant difference between two groups in mean arterial pressure at 1 minutes to 3 minutes and at 70 minutes as the p value calculated to be statistically significant. ($p<0.05$)

Binod pegu et al[14] reported that maximum rise in mean blood pressure was seen at 1 minute post-intubation. Significant attenuation of mean blood pressure was observed in NTG group during the post-intubation period in comparison to control group.

In the present study, after laryngoscopy and endotracheal intubation, nitroglycerine group decreases the MAP more effectively than lignocaine group between 1-3 min and was statistically significant ($p<0.05$).

Rate pressure product: Varshney et al.[16] studied that, there was a greater decrease in mean rate pressure product (RPP) response at 1-5 minutes in the NTG group compared to the lignocaine groups. Present study reported a significant decrease in mean RPP in lignocaine group followed by nitroglycerine group as p value was not statistically significant.

Sore throat assessment: In the present study, among the group n, 1 (2.9%) participant had sore throat while in group l, 13 (37.1%) participants had sore throat. The difference in the proportion of sore throat between study groups was statistically not significant (p value 0.149).

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