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Original Research Article

Clinical Efficacy of Two Different Doses of Intranasal Nitroglycerine Spray in Attenuating the Haemodynamic Response to Pneumoperitoneum in Laparoscopic Surgeries

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Abstract

Background: Increase in heart rate and blood pressure in response to pneumoperitoneum produced during laparoscopic surgeries is a challenging situation for a practicing anaesthesiologist. Without adequate control of sympathetic response there is a chance of increase in morbidity of the patient during the perioperative period hampering the speedy recovery of the patient.

Objectives: this study aimed to investigate the effect of two different doses of nitroglycerine (400 µg versus 800 µg) on haemodynamic changes associated with pneumoperitoneum.

Materials and Methods: A total of 90 patients of either sex, with age group 18 to 65 years belonging to ASA Grade I & II, undergoing laparoscopic surgeries under general anaesthesia were enrolled for our study. The study population was randomly divided into two groups with 45 patients each using sealed envelope method. Group LN (n=45) – low dose nitroglycerin group received 0.4 mg (400 µg) intranasal nitroglycerin spray. Group HN (n=45) - high dose nitroglycerin group received 0.8 mg (800 µg) intranasal nitroglycerin spray.

Results: 800 µg NTG spray had significantly lower blood pressures (SBP, DBP, MAP) compared to those receiving 400 µg NTG spray, after creation of pneumoperitoneum.

Conclusion: Haemodynamic variables like systolic, diastolic and mean arterial pressure were more stable with 800 µg compared to 400 µg of intranasal nitroglycerine after the creation of pneumoperitoneum. Hence, use of intranasal 800 µg nitroglycerine helps better in suppressing the hypertensive response to pneumoperitoneum.

Keywords: Pneumoperitoneum, Nitroglycerine, Intranasal Spray.

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Introduction

Laparoscopic surgery has its advantages over open surgery which includes reduced surgical trauma, less postoperative pain, shorter hospital stays, and faster recovery. [1] CO_2 pneumoperitoneum increases intra-abdominal pressure, leading to reduced venous return, reduced cardiac output, decreased lung compliance, impaired ventilation and increased systemic vascular resistance.

These changes, compounded by CO_2 absorption and hypercarbia, result in sympathetic activation manifested as tachycardia and hypertension. [2] In addition, laryngoscopy and endotracheal intubation provoke an acute stress response due to stimulation of the laryngeal and tracheal structures, causing abrupt increases in heart rate and arterial blood pressure. Such haemodynamic fluctuations may be detrimental, particularly in patients with limited cardiovascular reserve. Without adequate control of sympathetic response there is a chance of increase in morbidity of the patient during the perioperative period hampering the speedy recovery of the patient. [3] Pharmacological agents such as alpha-2 agonists, β-blockers, and opioids can attenuate the haemodynamic changes associated with pneumoperitoneum to provide haemodynamic stability, though they have their own disadvantages. Use of propofol, fentanyl, esmolol and midazolam has been tried with varying degree of success. [4]

Nitroglycerine, an organic nitrate is a venous and arteriolar dilator that releases nitric oxide and causes relaxation of vascular smooth muscles. Dilation of larger veins promotes peripheral pooling of blood thereby reducing preload. At higher doses, arterial relaxation reduces systemic vascular resistance and hence, the afterload. [5] Literature search revealed studies done on intranasal Nitroglycerine, to attenuate hypertensive response of laryngoscopy and intubation. [6] Although Nethra et al. demonstrated that 800 µg intranasal nitroglycerine was more effective than 400 µg in attenuating the haemodynamic response to pneumoperitoneum in patients undergoing laparoscopic cholecystectomy, evidence from other surgical populations remains limited. The present study was therefore undertaken to evaluate these two doses in a broader population of patients undergoing elective laparoscopic surgeries. Our primary objective was to compare 400 µg and 800 µg of intranasal Nitroglycerine spray to attenuate hypertensive response associated with pneumoperitoneum in laparoscopic surgeries. Secondary objective was to look for any side effects of the study drug.

Materials and Methods

This hospital based, prospective randomized double-blind controlled study was conducted in the Department of Anaesthesiology, Jawahar Lal Nehru Medical College and the associated group of hospitals, Ajmer. It was approved by Institutional Ethics Committee (letter no – 4215/Acad-III/MCA/2024, dated-8/10/2024) and registered at Clinical Trials Registry of India (CTRI/2025/9/94367). 0200

Inclusion Criteria: Patients who were ready to give consent, aged 18–65 years, of either gender, belonging to ASA physical status I and II, scheduled to undergo elective laparoscopic surgeries under general anesthesia.

Exclusion Criteria: Age < 18 years and > 5 years, ASA grade III and IV, patients not willing to participate in the study, patients with chronic pre-existing disease like Asthma, Renal or Hepatic dysfunction, diabetes mellitus, neuro muscular diseases, severe respiratory diseases etc. Anticipated difficult intubation, SBP <90 mm Hg and MAP <50 mm Hg, allergy to study drugs, unanticipated difficult intubation requiring more than one attempt or ≥ 30 seconds for successful intubation. [6]

Randomization: was done by sealed envelope method. A total 90 envelopes, 45 per group were made, each envelope mentioning a particular study group.

Blinding: This trial is so planned that neither doctor nor the patient were aware of the groups and drugs.

Study Groups:

Group LN (n=45) – low dose Nitroglycerine group received 0.4 mg (400 mcg) intranasal Nitroglycerine spray.

Group HN (n=45) - high dose Nitroglycerine group received 0.8 mg (800 mcg) intranasal Nitroglycerine spray.

Procedure

Patient was identified, PAC, informed written Consent & Fasting status checked. Patients were premedicated with Inj. Glycopyrrolate 0.2 mg IV. and inj. Midazolam 0.01mg/kg IV and inj. Fentanyl 2 mcg/kg. Induction was done with Inj. Propofol 2 mg/kg IV and tracheal intubation with Inj. vecuronium 0.1 mg/kg IV. Injection 2% preservative-free lignocaine 40 mg IV was given 90 seconds prior to laryngoscopy. Maintenance was with 50% oxygen and air, isoflurane (1 - 1.4 minimum alveolar concentration) with intermittent doses of injection vecuronium 0.03 mg/kg IV.

According to group allocation, Group LN received one metered spray (400 µg) of Nitroglycerine intra nasally and group HN received two metered sprays (800 µg) of Nitroglycerine intra nasally. The spray was administered 2 min prior to the creation of pneumoperitoneum in the nostril where the nasogastric tube was not inserted. The rate of insufflation of CO^2 by surgeons was initiated at 1 liter/minute, then increased up to 5 liters/minute and maintained to achieve an intra-abdominal pressure of 15 mm Hg throughout the procedure. Heart rate (HR), systolic blood pressure (SBP), diastolic blood pressure (DBP), Mean Arterial Pressure (MAP), and peripheral oxygen saturation (SpO2) were recorded at the following time intervals: Baseline, After induction, after intubation and then at 1, 3, 5,10,15,20,25,30,45,60,75,90, 120 minutes then at 1,2,3,4,6,12,18 and 24 hours postoperatively. At the end of the surgery patients were reversed with Inj. Neostigmine (0.05 mg/kg iv) and Inj. Glycopyrrolate (0.008 mg/kg iv) and extubation was done.

Statistical analyses: Data collected was compiled in MS Excel spread sheet as master chart. Data was presented as tables, figures and charts. Nominal / categorical variables were summarized as frequencies and percentage and was analysed using Chi square test. Continuous variables were summarized as mean and standard deviation and was analysed using independent sample t test for comparison between 2 groups. A p value ≤ 0. Was taken as statistically significant. All statistical analyses were done using Epi info version 7.2.1.0 statistical software.[5]

Results

Table 1: Comparison of demographic parameters between the two groups

Parameters	Group LN (n = 45)	Group HN (n = 45)	p value
Age (years) (Mean ±SD)	41.61 ± 4.3	42.2 ± 5.3	0.503 (NS)
Weight (kg) (Mean ±SD)	67.10 ± 5.68	69.10 ± 5.46	0.092 (NS)
Male: Female	28:17	22:23	0.205 (NS)
ASA I: ASA II	33:12	31:14	0.643 (NS)
Duration of surgery (min) (Mean ±SD)	75.23 ± 11.64	76.36 ± 10.95	0.636 (NS)

Table 1 shows that both groups were comparable in terms of demographic variables.

Table 2: Comparison of intraoperative mean heart rate between the two groups

Time point	Group LN (400 µg)	Group HN (800 µg)	Intergroup significance
Baseline	78.56	80.40	NS ($p > 0.05$)
After intubation	85.46	86.16	NS ($p > 0.05$)
After NTG	88.79	90.06	NS ($p > 0.05$)
2 min after pneumoperitoneum	92.56	93.70	NS ($p > 0.05$)
4 min	92.54	94.83	NS ($p > 0.05$)
6 min	94.68	96.10	NS ($p > 0.05$)
8 min	95.20	96.78	NS ($p > 0.05$)
10 min	94.56	95.25	NS ($p > 0.05$)
12 min	92.65	94.16	NS ($p > 0.05$)
15 min	92.68	94.56	NS ($p > 0.05$)
30 min	90.87	92.67	NS ($p > 0.05$)
45 min	88.65	90.65	NS ($p > 0.05$)
60 min	87.23	89.35	NS ($p > 0.05$)
90 min	88.62	90.62	NS ($p > 0.05$)

Table 3: Comparison of intraoperative mean systolic blood pressure between the two groups

Time point	Group LN (400 µg)	Group HN (800 µg)	Intergroup significance
Baseline	120.30	119.26	Comparable/initial response
After intubation	122.53	121.64	Comparable/initial response
After NTG	116.83	110.13	$p < 0.0001$ after NTG
2 min after pneumoperitoneum	112.13	106.12	$p < 0.05$ up to 60 min after pneumoperitoneum
4 min	114.85	107.58	$p < 0.05$ up to 60 min after pneumoperitoneum
6 min	112.65	108.85	$p < 0.05$ up to 60 min after pneumoperitoneum
8 min	114.63	111.50	$p < 0.05$ up to 60 min after pneumoperitoneum
10 min	114.45	110.13	$p < 0.05$ up to 60 min after pneumoperitoneum
12 min	115.70	113.54	$p < 0.05$ up to 60 min after pneumoperitoneum
15 min	117.30	114.20	$p < 0.05$ up to 60 min after pneumoperitoneum
30 min	118.13	114.69	$p < 0.05$ up to 60 min after pneumoperitoneum
45 min	118.69	116.23	$p < 0.05$ up to 60 min after pneumoperitoneum
60 min	119.23	116.62	$p < 0.05$ up to 60 min after pneumoperitoneum
90 min	120.62	118.62	Comparable/initial response

Table 4: Comparison of intraoperative mean diastolic blood pressure between the two groups

Time point	Group LN (400 µg)	Group HN (800 µg)	Intergroup significance
Baseline	80.20	81.16	Comparable/initial response
After intubation	83.03	82.07	Comparable/initial response
After NTG	70.83	65.41	$p < 0.0001$ after NTG
2 min after pneumoperitoneum	73.93	68.43	$p < 0.05$ up to 60 min after pneumoperitoneum
4 min	71.53	67.36	$p < 0.05$ up to 60 min after pneumoperitoneum
6 min	70.20	66.53	$p < 0.05$ up to 60 min after pneumoperitoneum
8 min	70.53	65.02	$p < 0.05$ up to 60 min after pneumoperitoneum
10 min	68.90	62.69	$p < 0.05$ up to 60 min after pneumoperitoneum
12 min	67.46	63.28	$p < 0.05$ up to 60 min after pneumoperitoneum
15 min	66.46	62.16	$p < 0.05$ up to 60 min after pneumoperitoneum

30 min	70.50	65.90	$p < 0.05$ up to 60 min after pneumoperitoneum
45 min	70.53	66.03	$p < 0.05$ up to 60 min after pneumoperitoneum
60 min	75.23	72.53	$p < 0.05$ up to 60 min after pneumoperitoneum
90 min	77.62	75.52	Comparable/initial response

Table 5: Comparison of intraoperative mean arterial pressure between the two groups

Time point	Group LN (400 µg)	Group HN (800 µg)	Intergroup significance
Baseline	86.45	85.62	Comparable/initial response
After intubation	88.53	87.23	Comparable/initial response
After NTG	79.03	73.90	$p < 0.0001$ after NTG
2 min after pneumoperitoneum	78.35	74.53	$p < 0.05$ up to 60 min after pneumoperitoneum
4 min	80.53	74.23	$p < 0.05$ up to 60 min after pneumoperitoneum
6 min	80.63	74.90	$p < 0.05$ up to 60 min after pneumoperitoneum
8 min	81.35	75.53	$p < 0.05$ up to 60 min after pneumoperitoneum
10 min	82.90	76.69	$p < 0.05$ up to 60 min after pneumoperitoneum
12 min	83.46	77.28	$p < 0.05$ up to 60 min after pneumoperitoneum
15 min	83.66	76.16	$p < 0.05$ up to 60 min after pneumoperitoneum
30 min	82.03	75.90	$p < 0.05$ up to 60 min after pneumoperitoneum
45 min	84.35	78.53	$p < 0.05$ up to 60 min after pneumoperitoneum
60 min	83.56	78.63	$p < 0.05$ up to 60 min after pneumoperitoneum
90 min	85.62	84.62	Comparable/initial response

Table 6: Tabular summary of haemodynamic findings

Variable	After NTG spray	After pneumoperitoneum	Interpretation
Heart rate	Increased slightly in both groups	Increased in both groups; Group LN slightly lower	No significant intergroup difference ($p > 0.05$)
SBP	Decreased in both groups ($p < 0.0001$)	Lower in Group HN up to 60 min ($p < 0.05$)	800 µg showed better attenuation
DBP	Decreased in both groups ($p < 0.0001$)	Lower in Group HN up to 60 min ($p < 0.05$)	800 µg showed better attenuation
MAP	Decreased in both groups ($p < 0.0001$)	Lower in Group HN up to 60 min ($p < 0.05$)	800 µg showed better attenuation

Note: Graphical presentations have been converted to tables using the numerical values provided in the original manuscript; no new numerical data were introduced.

Discussion

The stress response to pneumoperitoneum during laparoscopic surgeries can have deleterious effects due to alteration in haemodynamics. Maintaining heart rate and blood pressure near baseline levels with the advancements in anaesthetic techniques and dosing regimens is the need of the hour. Drugs used should preferably have short duration of action as the trend is moving towards enhanced recovery protocols in terms of both surgical and anaesthetic techniques. Nitroglycerine which is known to have a short half-life and quicker onset has been utilized in our study. [9]

Literature search revealed studies done on intranasal Nitroglycerine, to attenuate hypertensive response of laryngoscopy and intubation. [10] But there are very less studies which have used intranasal Nitroglycerine to prevent haemodynamic response of pneumoperitoneum. Hence, we have done this study to investigate the effect of two different doses of Nitroglycerine on haemodynamic changes associated with pneumoperitoneum.

Both Group LN (400 mcg NTG spray) and Group HN (800 mcg NTG spray) patients were comparable regarding age, sex, weight and duration of surgery with no statistically significant difference ($p > 0.05$).

After creation of pneumoperitoneum, heart rate increases in both groups from baseline value. On comparison between the groups, heart rate was slightly lower in Group LN patients as compared to Group HN patients after pneumoperitoneum with statistically non-significant difference in intraoperative period. ($p > 0.05$).

Our study results were supported by Nethra SS et al (2022), [7] in their study, there was no significant difference in mean heart rate between the two groups at all the intervals except at the 6th and 10th min after pneumoperitoneum. Within both the groups, there was increase in mean heart rate from the baseline throughout.

The baseline SBP, DBP and MAP were comparable in both groups. At intubation SBP, DBP and MAP

increases in both groups. After NTG spray, SBP decreases in both groups with statistically highly significant difference. ($p < 0.0001$). After creation of pneumoperitoneum, SBP was significantly lower in Group HN patients as compared to Group LN patients up to 60 minutes with statistically significant difference. ($p<0.05$).

Our study results were supported by the study done by Nethra SS et al (2022), [7] in their study, there was significant difference in mean SBP between the two groups at all intervals after administration of the study drug, being on much lower side in group N8 compared to Group N4.

In the study done by Kumari I et al (2016) [6] mean value of SBP, DBP and MAP showed a significant rise as compared to baseline, following intubation in control group that persisted up to 5 min, while no significant rise was observed in Group N1(400 mcg) and N2 (800 mcg). Mean value of SBP, DBP and MAP was significantly higher in Group C than in Group N1, which was in turn greater than Group N2 (Group C> N1> N2), with statistically significant difference.

Meena JK et al (2025) [8] did their study to determine the effectiveness of Nitroglycerine (NTG) administered intranasally in attenuating the pressor response via rapid absorption and vasodilatory effects.

The group receiving 1200 µg demonstrated a higher peak heart rate compared to those receiving 400 µg or 800 µg. Conversely, systolic, diastolic, and mean arterial pressures decreased more pronouncedly with the 1200 µg dose compared to the lower doses.

There were no statistically significant differences in mean oxygen saturation between Group LN and Group HN at any of the time intervals. ($p>0.05$). Both groups are comparable regarding postoperative haemodynamics (HR, SBP, DBP and MAP) without any significant difference. Adverse effects in perioperative period were comparable between the groups.

Conclusion

Intranasal nitroglycerine 800 µg provided better attenuation of the hypertensive response to pneumoperitoneum than 400 µg, with significantly lower systolic, diastolic and mean arterial pressures during the intraoperative period. No significant intergroup difference was observed in heart rate. Based on the findings of this study, 800 µg intranasal nitroglycerine was more effective than 400 µg in attenuating the haemodynamic pressor response to pneumoperitoneum.

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