

Original Research Article

Comparative evaluation of fentanyl versus nalbuphine for attenuation of hemodynamic changes during airway stimulation

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ABSTRACT

Background: Airway stimulation predictably leads to variable hemodynamic changes which can be modified by opioid premedication. The present study was aimed to compare the clinical efficacy of fentanyl with nalbuphine on hemodynamic changes during airway stimulation.

Methods: Sixty adult patients of ASA physical status I and II of either gender, were randomized into two groups of 30 patients each to receive either fentanyl 2µg/kg, Group I or nalbuphine 0.2mg/kg, Group II, 10min before induction with propofol. Direct laryngoscopy and intubation was facilitated with vecuronium bromide. Heart rate, blood pressure and ECG were recorded at baseline, after giving study drug, at intubation and then after at 1st, 2nd, 3rd, 5th, 10th and 15th minutes after intubation and noted as primary variable. Any adverse effects and complications were recorded as secondary end points.

Results: After premedication, the fall in heart rate was comparable between the groups. The fall in mean blood pressure showed statistically significant difference between the groups. After induction, there was further decrease in heart rate and blood pressure with statistically significant difference. After laryngoscopy and intubation, the increase in mean heart rate and blood pressure occurred immediately in patients of nalbuphine group and persisted up to 1 to 2min while this increase persisted up to 5 to 7min in fentanyl group. The differences in hemodynamic changes between the groups were statistically significant.

Conclusions: Nalbuphine (0.2mg/kg) could effectively attenuate the hemodynamic changes during airway stimulation when compared to fentanyl (2µg/kg), when given 10 minutes before induction.

Keywords: Airway stimulation, Fentanyl, Hemodynamic changes, Nalbuphine

INTRODUCTION

Direct laryngoscopy for endotracheal intubation is most noxious stimuli during airway management which is manifested by hypertension, tachycardia and increased catecholamine levels, hence increased cardiac workload.

The principal mechanism is reflex sympathetic stimulation, mediated by vagus and glossopharyngeal nerve. These hemodynamic changes may affect the high-

risk patients of untreated hypertension or cardiac compromised patients.¹

The magnitude of hemodynamic changes can be decreased by narcotic analgesics, α-2 adrenoreceptors agonists, intravenous lidocaine, beta-blockers, vasodilators and calcium channel blockers. These agents are associated with their inherent side effects of respiratory depression, histamine release and gastrointestinal effects.²

Fentanyl acts as agonist on μ opioid receptors and is found to be effective to suppress the pressor response of airway stimulation. Its relatively short duration of action, minimal respiratory depression and its ability to provide cardiovascular stability, made it the drug of choice for anaesthesia. Nalbuphine is agonist at κ receptor and acts as antagonist at μ receptor. It is also effective in suppressing the hemodynamic changes during airway stimulation. Its cardiovascular stability, long duration of analgesia, lack of respiratory depression and decreased incidences of nausea and vomiting, makes it an ideal analgesic during anaesthesia.^{3,4}

The present study was aimed to compare the clinical efficacy of fentanyl with nalbuphine for hemodynamic changes during airway stimulation.

METHODS

After approval from Institutional Ethical Committee and written informed consent, 60 patients of American Society of Anaesthesiologists (ASA) physical status I and II of either sex, aged between 18 to 58 years, scheduled for elective surgery under general anaesthesia were enrolled for the present double blind randomized study.

The patients suffering from cardio-pulmonary diseases, hepatic disease or renal disease, uncontrolled hypertension, any neurological disorder or endocrinal disease, obesity and patients with anticipated difficult airway or who required more than one attempt for intubation, were excluded from the studies. Patients with known hypersensitivity or drug allergies, taking antihypertensive or antidepressant drugs, were also excluded from the study.

Patients were divided into two groups of 30 patients each, according to computer generated random number table. Patients of Group I received intravenous fentanyl in dose of $2\mu\text{g}/\text{kg}$ and patients of Group II received intravenous nalbuphine in dose of $0.2\text{mg}/\text{kg}$. Both drugs were diluted in 10mL normal saline and administered, 10 minutes before induction. Study drug preparation was done by an assistant who was blinded to study protocol and was not involved for any data collection.

On arrival to operation theatre, baseline vital parameters of heart rate, non-invasive systemic arterial pressure, peripheral oxygen saturation (SpO_2) and electrocardiogram (ECG), were recorded. An intravenous line was secured with 18 Gauge intravenous cannula and lactate Ringer solution was started at the rate of 4-6 mL/kg/hr. They were premedicated with midazolam $0.02\text{mg}/\text{kg}$, glycopyrrolate 0.2mg , followed by study drug-fentanyl, $2\mu\text{g}/\text{kg}$ or nalbuphine, $0.2\text{mg}/\text{kg}$ intravenously, 10 minutes before induction of anaesthesia in double blind manner.

After pre-oxygenation, anaesthesia was induced with propofol $2\text{mg}/\text{kg}$, followed by vecuronium bromide

$0.1\text{mg}/\text{kg}$ to facilitate direct laryngoscopy and intubation. Intubation was accomplished by Macintosh curve blade laryngoscope with proper sized cuffed endotracheal tube. Anaesthesia was maintained with isoflurane, nitrous oxide 60% in oxygen and they were mechanically ventilated to keep normocapnia (EtCO_2 -35-40mmHg).

The hemodynamic parameters of heart rate, systemic blood pressure (systolic, diastolic and mean arterial pressure), peripheral oxygen saturation and any changes in ECG were recorded at baseline, after giving study drug, after induction with propofol, immediately after laryngoscopy and tracheal intubation and then at 1st, 2nd, 3rd, 5th min, 10th and 15th min after tracheal intubation. Thereafter these changes were recorded at 5min interval till the end of surgery and post extubation.

The hemodynamic changes observed as abnormal findings during the study were defined as hypotension when systolic blood pressure was less than 20% of baseline or $< 90\text{mmHg}$. Hypertension was defined when systolic blood pressure was more than 20% of baseline or $> 140\text{mmHg}$. Tachycardia was defined as heart rate more than 100 beats per minute and bradycardia was defined as heart rate less than 60 beats per minute

Patients were not stimulated during the observation period and thereafter the surgery was allowed to proceed. Hemodynamic changes occurring during study period were not treated unless these changes were sustained over a period of time and were compromising patients' safety and records of each such patient was kept.

If intraoperative hypertension and tachycardia occurred, it was managed by increasing the dial concentration of isoflurane. Hypotension was primarily treated by increasing the intravenous infusion rate of lactate Ringer solution, and additionally with vasoactive drugs. Bradycardia was treated with bolus of intravenous atropine.

At the end of surgery, isoflurane was discontinued, and residual neuromuscular blockade was antagonized with neostigmine ($0.05\text{mg}/\text{kg}$) and glycopyrrolate ($0.01\text{mg}/\text{kg}$). Ventilation was continued to eliminate volatile agents until signs of awakening appear. Both the level of consciousness and neuromuscular transmission was assessed for adequacy of reflexes. Extubation was performed when respiration became adequate in tidal volume and patient was able to obey simple commands. Patients were transferred to post anaesthesia care unit and monitored until there were no signs of any drug-induced effects. Any hemodynamic changes, respiratory depression, postoperative shivering, nausea and vomiting was noted and treated accordingly.

Sample size

Preliminary sample size was based on previous studies, which indicated that approximately 27 patients should be

included in each group in order to ensure power of 80% and alpha error of 0.05 with confidence limit of 95% for detecting clinically meaningful reduction by 20% in heart rate and mean arterial blood pressure during airway stimulation. Assuming a 5% drop out rate, a total of 60 patients were incorporated in the study for better validation of results.

Statistical analysis

The data obtained in the study was presented in a tabulated manner and variables were expressed as mean ± standard deviation (SD). The results were analysed using Stat Graphic Centurion, Version 16 (Stat point technologies INC, Warrenton, Virginia).

The parameters of both groups were compared using one-way analysis of variance (ANOVA) for intergroup comparison, the Chi square test was applied for categorical data and paired t-test was applied for intragroup comparison. A p value of < 0.05 was considered statistically significant.

RESULTS

The present study compared the clinical efficacy of fentanyl with nalbuphine for hemodynamic changes during airway stimulation on 60 adult patients of both genders. There was no protocol deviation and study were successfully completed. Data of all patients were included for statistical analysis.

The demographic data for age, weight, height, American Society of Anaesthesiologist (ASA) physical status and gender were comparable between both the groups (Table 1).

Table 1: Demographic data of the study population.

Demographic parameters	Group I	Group II	P value
Age (years)	48.51±9.2	47.44±7.6	0.06
Weight (kg)	59.17±5.5	60.43±9.3	0.525
Height (cm)	154.97±3.8	155.83±4.5	0.48
Gender (m/f)	18/11	19/11	0.78
Asa (I/II)	21/9	22/8	0.75

Data are presented in Mean ±SD or absolute numbers. P value >0.05 is statistically insignificant

Hemodynamic changes

At baseline, the mean systolic blood pressure, diastolic blood pressure and heart rate in patients of Group I was 125.8±4.36mmHg, 79.62±9.8mmHg and 86.8±4.43 beats/min respectively, while in patients of Group II, it was 125.5±3.15mmHg, 80.42±8.44mmHg and 86.69±3.71beats/min respectively. Both groups were comparable and there was no statistically significant difference in the preoperative baseline values.

After the administration of nalbuphine or fentanyl, the changes in mean heart rate did not show any significant difference between the groups. There was fall in systolic blood pressure (Group I-122.69±4.36mm Hg, Group II-119.46±3.13mmHg), diastolic blood pressure (Group I-66.11±12.49mmHg, Group II-78.81±9.66mmHg) and mean arterial pressure (Group I-77.90±13.11mmHg, Group II-90.45±10.69mmHg) and the difference was statistically significant (p<0.05) between the groups.

After induction with propofol, there was further decrease in mean heart rate (Group I-80.26±3.87b/m, Group II-78.63±6.23b/m), systolic blood pressure (Group I-109.23±3.32mmHg, Group II 104.68±4.83mmHg), diastolic blood pressure (Group I-65.12±13.36mmHg, Group II 70.97±10.51mmHg) and mean arterial pressure (Group I-75.69±14.66mmHg, Group II- 89.95±11.92mm Hg), with statistically significant difference (p = <0.0001) between the groups.

After airway stimulation in patients of fentanyl group, the increase in mean heart rate (102.11±3.16b/m), systolic blood pressure (148.43±4.38mmHg), diastolic blood pressure (91.45±14.27mmHg) a mean arterial pressure (101.69±15.06mmHg) occurred immediately after laryngoscopy and intubation and persisted up to 5 to 7minutes, thereafter the changes returned back to baseline values.

After airway stimulation in patients of nalbuphine group, the increase in mean heart rate (90.60±3.22b/m), systolic blood pressure (139.43± 3.96mmHg), diastolic blood pressure (88.84±12.10mmHg) a mean arterial pressure (98.37±14.32mmHg) occurred immediately after laryngoscopy and intubation and persisted up to 1to 2 minutes, thereafter the changes returned back to baseline values (Tables 2-5).

Table 2: Comparison of mean heart rate.

Heart rate (beats/min)	GROUP I	Group II	P value
Baseline	86.82±4.43	86.69±3.71	0.902
After study drug	87.69±4.73	87.09±5.10	0.638
After induction	85.26±3.87	78.63±6.23	0.001**
Immediate post intubation	102.11±3.16	90.60±3.22	0.001**
1 min	101.63±2.68	88.60±2.86	0.001**
2 min	99.91±3.44	84.77±3.32	0.001**
3 min	98.91±3.50	84.17±2.90	0.001**
5 min	93.97±3.52	85.66±.61	0.001**
10 min	88.34±4.57	84.17±3.22	0.256
15 min	86.11±3.78	88.12±2.32	0.38

Data are presented in Mean ±SD or absolute numbers; *P value <0.05 is statistically significant; **P value <0.001 is statistically highly significant

Table 3: Comparison of mean Systolic Blood Pressure.

SBP (mm hg)	Group I	Group II	P value
Baseline	125.8±4.36	125.5±3.15	0.677
After study drug	122.69±4.36	119.46±3.13	0.214
After induction	121.23±3.32	104.68±4.83	<0.001**
Immediate post laryngoscopy and intubation	148.43±4.38	139.43±3.96	<0.001**
1 min	148.68±3.36	137.11±5.43	<0.001**
2 min	138.32±4.63	136.69±4.54	<0.001**
3 min	136.7±3.68	135.6±3.98	0.270
5 min	132.23±3.20	125.06±2.75	0.032*
10 min	128.34±4.28	118.43±3.71	0.04*
15 min	129.1±4.87	117.10±4.11	0.38

Data are presented in Mean ± SD or absolute numbers. *P value <0.05 is statistically significant, **P value <0.001 is statistically highly significant

Table 4: Comparison of mean diastolic blood pressure.

Diastolic blood pressure (mmHg)	Group I	Group II	P value
Baseline	79.62±9.8	80.42±8.44	0.57
After study drug	66.11±12.49	78.81±9.66	<0.001*
After induction	65.12±13.36	70.97±10.51	<0.001*
Immediate post intubation	91.45±14.27	88.84±12.10	<0.001*
1 min	89.97±14.19	82.33±14.98	<0.001*
2 min	75.41±14.57	79.02±11.96	0.40
3 min	74.10±12.86	77.31±12.72	0.92
5 min	76.48±14.62	76.01±10.69	0.10
10 min	78.76±15.02	76.97±11.64	0.81
15 min	78.12±15.11	77.80±11.32	0.77

Data are presented in Mean ± SD or absolute numbers. *P value <0.05 is statistically significant. **P Value <0.001 is statistically highly significant

Table 5: Comparison of average mean arterial pressure.

Mean arterial pressure (mmHg)	Group I	Group II	P value
Baseline	93.95±10.4	94.6±10.74	0.32
After study drug	77.90±13.11	90.45±10.69	0.001**
After induction	75.69±14.66	89.95±11.92	0.001**
Immediate post intubation	101.69±15.06	98.37±14.32	0.04*
1 min	98.86±16.06	96.24±14.05	0.87
2 min	96.61±15.11	91.98±14.26	0.3
3 min	90.79±13.41	92.87±12.62	0.13
5 min	90.44±15.57	88.44±11.65	0.35
10 min	92.74±16.69	90.1±12.51	0.26
15 min	93.14±15.11	89.24±11.89	0.78

Data are presented in Mean ± SD or absolute numbers. *P value <0.05 is statistically significant, **P value <0.001 is statistically highly significant

The differences in hemodynamic changes between the groups were statistically significant ($p < 0.001$).

DISCUSSION

Airway stimulation leads to a hemodynamic change due to intense sympathetic discharge and release of catecholamine.

The therapeutic armamentarium to counteract the cardiovascular responses to laryngoscopy and intubation includes a wide variety of drugs, techniques and route of administration. Nalbuphine, a synthetic opioid and a potent agonist/antagonist analgesic with a low side effect profile and low abuse potential, can effectively control the hemodynamic responses of laryngoscopy and intubation and prevent many unwanted deleterious

cardiovascular side effects, occurring during the critical period of laryngoscopy and intubation.⁵⁻⁸

Fentanyl is more potent at μ opioid receptor than commonly used opioid analgesics and its ability to suppress the stress response to airway stimulation with cardiovascular stability, has made fentanyl the mainstay analgesics during anesthesia. The rapid onset of action with relatively shorter duration, minimal respiratory depression and wide safety margin made it suitable for premedication.⁹

In the present study, clinical efficacy of fentanyl and nalbuphine was compared for hemodynamic changes during airway stimulation. The significance of the study lies in the fact to select the better drug for premedication which could attenuate the hemodynamic pressor response during airway stimulation. Besides minimizing the hemodynamic pressor response, anaesthesia induction for patients at risk, drugs should not affect the duration or modality of the anesthetic technique and should not affect the recovery profile. Therefore, these premedicants were selected for the present study.

Large doses of fentanyl can lead to various adverse effects such as muscular rigidity, bradycardia, nausea and vomiting. Even postoperative respiratory depression was observed in short duration surgical procedures. So, in the present study fentanyl in dose of 2 μ g/kg was selected. Nalbuphine was used in doses of 0.2mg/kg, to prevent the marked rise in heart rate and blood pressure during airway stimulation. Nalbuphine in this dose possess less side of nausea, vomiting and postoperative respiratory depression.

In present study, there was a significant rise of heart rate in fentanyl group immediately after intubation till 5th minute while in patients of nalbuphine group, the rise in heart rate was till 1st minute only. These changes in heart rates were statistically highly significant ($p < 0.001$).

Sharma and Parikh found that changes in heart rate between fentanyl and nalbuphine group did not show statistically significant difference at any time interval ($p > 0.05$).¹⁰ Khan FA et al found significant increase in heart rate in patients of nalbuphine group (25%) as compared to fentanyl group.¹¹ BKY et al in their study, compared the effects of fentanyl and nalbuphine and found significant rise in heart rate in patients of nalbuphine group, as compared to patients of fentanyl group.⁹

Bhandari et al stated that mean heart rate after intubation showed significant increased value of 88 ± 11.45 beats/min in fentanyl group and 102.68 ± 16.04 beats/min in nalbuphine group with statistical difference.¹² Khan and Hameedullah conducted a similar study and observed a significant decrease in heart rate response in fentanyl group.¹¹ Their study was not in concurrence of present study.

In the present study, an increase in systolic, diastolic blood pressure and mean arterial pressure was observed in all patients. On comparison, both groups showed statistically highly significant difference from baseline after laryngoscopy and intubation. The rise in systolic blood pressure, diastolic blood pressure and mean arterial pressure was highest in patients of fentanyl group immediately after laryngoscopy and intubation.

Bhandari and Rastogi et al observed fall in mean systolic blood pressure from baseline value of in patients of both groups after administration of study drugs with no statistically significant difference. After laryngoscopy and intubation, there was significant attenuation of the hemodynamic changes in patients of nalbuphine group as compared to patients of fentanyl group. Thereafter, the fall in mean systolic blood pressure was comparable.¹² Contrary to the present study, Khan and Hameedullah observed that nalbuphine provided lesser hemodynamic stability as compared to fentanyl when used as an intraoperative analgesic during total intravenous anesthesia with propofol.

Aftab et al compared the fentanyl/isoflurane and nalbuphine/isoflurane in patients undergoing elective coronary artery bypass surgery. In contradiction to the present study, they showed that fentanyl/isoflurane provided better hemodynamic stability than nalbuphine/isoflurane ($p < 0.05$).¹³

Channaiah et al studied the effect of low dose fentanyl on hemodynamic response to endotracheal intubation in normotensive patients and found greatest attenuation in systolic blood pressure and diastolic blood pressure during intubation with statistically significant difference from the control group ($p < 0.001$).¹⁴ Khan and Hameedullah also observed fall in diastolic blood pressure after induction. After tracheal intubation, the diastolic blood pressure significantly rose to a maximum of 13% in nalbuphine group and 3% in fentanyl group. In contrast to their study, the present study showed a better and more prolonged control of diastolic blood pressure in nalbuphine group. Chung et al also observed the significant changes in diastolic blood pressure at 10th and 20th min after nalbuphine injection when compared to control group.¹⁵

In the present study, there was a fall in mean arterial pressure from baseline in patients of both groups with no significant difference. After endotracheal intubation, the mean arterial pressure in patients of both groups showed significant fall till 5th min after intubation, thus showing better control of mean arterial pressure after laryngoscopy and intubation with nalbuphine premedication when compared to fentanyl premedication.

Chawda et al showed that nalbuphine in the dose of 0.2mg/kg, given 3 to 5min before laryngoscopy and intubation prevented its associated hemodynamic response while patients in placebo group exhibited

significant increase in heart rate and mean arterial pressure.¹⁶ Channaiah et al observed that mean arterial pressure yielded significant attenuation in patients of fentanyl group for all recorded time periods.

Ahsan and colleagues also compared nalbuphine 0.2mg/kg with placebo. They noticed rise in heart rate and mean arterial pressure just after induction in placebo group which was significant from baseline while nalbuphine prevented this rise, as observed in the present study.¹⁷ Chestnut et al had also studied effects of nalbuphine, pethidine and placebo and noticed excellent control of hemodynamic response in minor gynaecological surgery in nalbuphine as well as pethidine group, but noticed nausea and vomiting at the end of surgery which was more in pethidine group.¹⁸ Kothari and Sharma also used nalbuphine in dose of 0.2mg/kg and noticed effective reduction in heart rate and mean arterial pressure as compared to pentazocine.¹⁹ The present study also supports their results.

Chung et al observed that pure agonists can cause complications such as respiratory depression which can be dangerous in the recovery room. On the other hand, nalbuphine is an agonist-antagonist opioid and causes less respiratory depression by activating the supraspinal and spinal kappa receptors.

Fentanyl and nalbuphine, both offered a unique pharmacological profile with sedation, analgesia and intraoperative cardiovascular stability. They provide hemodynamic stability by attenuating the stress induced sympatho-adrenal responses to airway stimulation.

CONCLUSION

The present study concluded that premedication with nalbuphine 0.2mg/kg, could more effectively attenuate the hemodynamic pressor response to airway stimulation than fentanyl 2µg/kg, when administered 10minute before induction. Nalbuphine provides more stable hemodynamics without any deleterious effects on patients and anaesthetic technique. Moreover, the nalbuphine does not come under the Narcotic Act, so can be utilized more freely for premedication to attenuate the hemodynamic changes during laryngoscopy and intubation and for perioperative analgesia.

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