

Perfusion Index to Assess Hemodynamic Changes and Analgesia with Premedication of Fentanyl versus Nalbuphine during General Anesthesia

Kumkum Gupta¹, Bhawana Rastogi¹, Prashant K Gupta², Manoranjan K Bansal³, Pavitra Kalra⁴, Sukhreet Kaur⁴

¹Professor, Department of Anaesthesiology and Critical care, ²Director Professor, Department of Radio diagnosis and Imaging, ³Assistant Professor, Department of Anaesthesiology and Critical care, ⁴Resident, Department of Anaesthesiology and Critical care, Subharti Medical College, Partapur Bye Pass Road, Meerut-UP, India

Abstract

Background: The hemodynamic changes are part of stress responses of airway manipulation and surgical pain, which are manifested as tachyarrhythmia and hypertension, and should be ameliorated. This study compared the hemodynamic changes and analgesia with premedication of fentanyl versus nalbuphine during general anesthesia, using perfusion index technique, a non-invasive parameter. **Subjects and Methods:** After approval, 60 patients of ASA physical status I and II aged between 26 to 56 years of either gender were randomized in two groups of 30 patients each to receive either intravenous fentanyl 2µg/kg (Group F) or nalbuphine 0.2 mg/kg (Group N), 5 min before induction with propofol. Direct laryngoscopy and intubation was facilitated with vecuronium bromide (0.1 mg/kg). Hemodynamic changes and intraoperative analgesia were recorded at specific time intervals, as primary objectives. Any side effects or complications were noted as secondary outcome. **Results:** After airway manipulation, the increase in heart rate and systolic blood pressure with decreased perfusion index occurred immediately in patients of both groups which persisted up to 6 to 10 min, thereafter the changes returned back to baseline value with statistically significant difference between both groups. At the time of surgical incision, nalbuphine showed better analgesic effect than fentanyl as assessed by perfusion index. No significant correction between perfusion index and heart rate was observed but there was statistically significant negative correlation between perfusion index and systolic blood pressure. **Conclusion:** Intravenous fentanyl was more effective for ameliorating the stress response of airway manipulation while nalbuphine was better for intraoperative analgesia as assessed by perfusion index.

Keywords: Perfusion Index; Hemodynamic changes; Fentanyl; Nalbuphine; Pain.

Corresponding Author: Prof (Dr) Kumkum Gupta, 108-109, Chanakyapuri, Shastri Nagar, Meerut-250004 U.P. India

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Introduction

During general anesthesia, airway management and surgical stimulus do affect the autonomic nervous system and increases the circulating plasma catecholamine concentrations, hence predisposing the myocardium to ischemic changes that may be life threatening in vulnerable patients.^[1] The magnitude of hemodynamic changes can be ameliorated by opioid analgesics, alpha 2- adrenoreceptors agonist, beta blockers, vasodilators and calcium channel blockers but with their integral shortcomings.

Perfusion index represents a non-invasive method to measure the peripheral perfusion, which is the ratio of the pulsatile blood flow to the non-pulsatile or static blood in peripheral tissue.^[2] Perfusion is known to be affected by vasoconstriction and vasodilation, hence may be affected by temperature, stroke volume, tone of sympathetic nervous system, pain, surgical stimulus and anesthetic agents.^[3,4]

Perfusion index can be used as valuable objective parameters

during anesthesia to predict the hemodynamic response to anesthetic drugs, techniques and intraoperative pain along with routine monitoring.^[5] The value range of perfusion index is from 0.02% to 20%. Low perfusion index (PI) suggested peripheral vasoconstriction and pain, while high perfusion index suggested peripheral vasodilation. Haken Taper et al evaluated the perfusion index technique for assessment of pain and concluded that perfusion index can be used for assessment of perioperative pain response to analgesics.^[6]

Opioid analgesics activate opioid receptors located on primary afferent neurons, resulting in the activation of pain modulating systems. Their activation may either directly decrease neurotransmission or inhibit the release of excitatory neurotransmitters. Morphine, fentanyl and other µ-opioids come under Narcotic Act, hence their availability is a major concern in many hospitals of India, while nalbuphine is easily available and devoid of side effects of nausea, pruritus and respiratory depression.

This observational prospective study was aimed to compare

the hemodynamic changes and analgesia with premedication of Fentanyl or Nalbuphine during general anesthesia, by using perfusion index technique.

Subjects and Methods

After approval from Institution Ethical Committee and written informed consent, this observational prospective study was performed on 60 patients of American Society of Anaesthesiologist physical status I and II of both genders, aged between 28 to 58 years with Body Mass Index between 20-25 kg.m² and scheduled for elective surgeries under general anesthesia.

After pre-anesthetic evaluation, patients with anticipated difficult intubation, known history of cardiopulmonary disease, uncontrolled hypertension, diabetes, hepatic or renal disease, obesity, peripheral vascular disease or taking any pain relieving drugs, were excluded from the study.

All patients were admitted prior to day of surgery and were given Tab Alprazolam 0.5 mg and Tab Ranitidine 150 mg, the night before surgery and their nil per oral status for 6 h was upheld on the day of surgery.

The total 60 patients were randomized into two equal of 30 patients each, according to computer generated random number table and allocation of concealment was ensured with sealed opaque envelop. Patients of Group F were given fentanyl in dose of 2µg/kg, and patients of Group N were given nalbuphine in dose of 0.2mg/kg. Both study drugs were diluted in 10 mL isotonic saline and administered intravenously, 5 min before induction.

To avoid bias, study drug was prepared by a resident who was blinded to study protocol and intraoperative parameters were recorded by another resident. Both residents were unaware of group allocation, to make the study double blind.

On arrival to operation theatre, baseline vital parameters of heart rate, non-invasive blood pressure, electrocardiogram and peripheral oxygen saturation were initiated. The perfusion index was monitored by using Masimo Radical SET monitor and probe was attached to the middle finger tip of the hand, contralateral to the site of BP monitoring.^[7] The probe was wrapped with towel to minimize heat loss and effect of ambient light. An intravenous line was secured and lactate Ringer solution was infused at rate of 4-6 mL/kg/hr. The ambient temperature of OT was maintained between 25°C-26°C.

The patients were premedicated with glycopyrrolate 0.2 mg, midazolam 0.02mg/kg followed by study drugs. They were given either fentanyl 2µg/kg or nalbuphine 0.2 mg/kg or, intravenously, 5 min before induction, according to randomization schedule in double blind manner. After preoxygenation, anesthesia was induced with propofol 2mg/kg, followed by vecuronium bromide 0.1 mg/kg to facilitate direct laryngoscopy and intubation with proper size cuffed endotracheal tube. Anesthesia was maintained with isoflurane (dial concentration of 1%), nitrous oxide (60%) and oxygen (40%). Patients were mechanically ventilated to keep the normocapnia (EtCO₂ between 35 to 40 mm Hg).

The hemodynamic parameters of heart rate, systemic blood pressure, ECG, perfusion index and peripheral oxygen saturation, were recorded at baseline, after induction and

airway management, then at every 5 min interval till end of surgery and post extubation. If intraoperative hypertension (SBP>20% of baseline), tachycardia (heart rate >100bpm) and fall in perfusion index occurred, it was managed by increasing the dial concentration of isoflurane and additionally with intravenous paracetamol (1Gm), if required. Hemodynamic changes occurring during the study period were not treated unless sustained over a time and were compromising the safety of patients. Records of each such patients was kept.

At the end of surgery, isoflurane was discontinued and residual neuromuscular blockade was antagonized by appropriate doses of neostigmine (0.05mg/kg) and glycopyrrolate (0.01 mg/kg). Extubation was performed when respiration became adequate in tidal volume and patient could obey simple commands.

Patients were transferred to post anaesthesia room to monitor the vital parameters. Any hemodynamic changes, respiratory depression, pruritus, nausea and vomiting were noted and treated accordingly.

Sample Size and Statistical Analysis

After consulting a statistician, sample size was calculated. Approximately 25 patients in each group were required 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 hemodynamic parameters. Assuming a 5% dropout rate, total 60 patients were incorporated in the study for better validation of results.

After completion of the study, the data collected and expressed as mean and standard deviation, considering the later as best predictor. The results were statistically analyzed by using Stat Graphic Centurion, version 16 (Stat point technologies INC, Warrenton, Virginia). The demographic variable were compared using unpaired 't' test and Chi square test. Mean of hemodynamic changes at different time intervals between groups, were compared by one way analysis of variance (ANOVA) and unpaired 't' test. Correlation between perfusion index and heart rate as well as systolic blood pressure was calculated using Pearson correlation coefficient. A p value of less than 0.05 was considered to indicate statistical significance.

Results

This study compared the clinical efficacy of fentanyl with nalbuphine for hemodynamic changes and analgesia of 60 adult patients of both gender who were screened for potentiation of inclusion criteria of the study. There was no protocol deviation and data of all patients were statistically analyzed.

The demographic profile of age, weight, height, gender and ASA physical status of patients was comparable between both the groups.

Heart rate in patients of both groups were comparable at base line and after premedication. Thereafter, the changes in mean heart rate showed statistically highly significant from baseline at all-time intervals till 10th min. On comparing the two groups, it was observed that increase in heart rate in patients of Group F was +15.22 % and for patients of Group N was +19.76%, from the base values, immediately after

airway manipulation. Thereafter, changes in heart rate showed decreasing trend towards normal. [Table 2]

On comparing the systolic blood pressure between the groups, there was increase in SBP immediately after airway manipulation in all patients with statistically significant difference between the groups. The maximum increase in SBP for patients of Group F was +11.09 % and for patients of Group N was + 18.78% from the base line. These changes were persisted up to 6 to 10 min, thereafter the systolic blood pressure returned back to normal values with comparable difference between the groups. [Table 3]

The diastolic blood pressure and mean arterial blood pressure were also compared between the groups at different time intervals, which showed a significant rise immediately after airway manipulation in patients of both groups. Thereafter, these values started decreasing steadily in patients of both the groups. [Table 4 & 5]

Post extubation, there was increase in mean heart rate and systolic blood pressure in patients of both groups with statistically significant difference between the groups.

The perfusion index was compared between the groups at different time intervals. Perfusion index values were decreased from baseline immediately after airway manipulation till 10 min with statistically significant difference between the groups. Thereafter, PI started increasing steadily at each time interval during intraoperative period.

Correlation between perfusion index and heart rate was statistically insignificant in patients of both groups at the base line, after premedication and induction and post airway stimulation. There was no significant correction between perfusion index and heart rate. Correlation between perfusion index and mean systolic blood pressure was statistically significant in patients of both groups and showed negative correlation, means that as systolic blood pressure was increasing, the perfusion index started decreasing.

Table 1: Demographic data of the study population

Demographic parameters	Group N	Group F	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

Table 2: Comparison of mean Heart Rate

Time Intervals	Group N	Group F	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	83.26±3.87	78.63±6.23	0.001**
Immediate post Intubation	106.11±3.16	96.60±3.22	0.001**
1 min	102.63±2.68	89.60±2.86	0.001**
2 min	99.91±3.44	87.47±3.32	0.001**
3 min	98.91±3.50	87.17±2.90	0.001**
5 min	93.97±3.52	85.66±0.61	0.001**
10 min	91.34±4.57	87.17±3.22	0.256
15 min	86.11±3.78	82.12±5.32	0.38
30 min	84.11±6.37	82.81±2.34	0.43
60 min	84.61±4.78	83.12±3.9	0.68
Post extubation	101.09± 2.35	92.17±2.90	0.007*

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

Time Intervals	Group N	Group F	P Value
Baseline	127.8±4.36	125.5±3.15	0.677
After study drug	122.69±4.36	121.46±3.13	0.214
After Induction	116.23±3.32	109.68±4.83	<0.001**
Immediate post Laryngoscopy and Intubation	148.43±4.38	136.43±3.96	<0.001**
1 min	148.68±3.36	137.11±5.43	<0.001**
2 min	139.32±4.63	135.69±4.54	<0.001**
3 min	136.7±3.68	132.6±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	119.1±4.87	117.10±4.11	0.38
30 min	116.1±4.87	115.70± 8.11	0.38
60 min	129.1±4.87	115.10±3.41	0.38
Post extubation	134.3±4.87	127.10±4.12	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

Time Intervals	Group N	Group F	P Value
Baseline	87.62±7.8	83.42±8.44	0.57
After study drug	82.61±12.49	80.81±9.66	<0.001*
After Induction	76.12±13.36	74.97±10.51	<0.001*
Immediate post Intubation	91.45±14.27	89.84±12.10	<0.001*
1 min	89.97±14.19	88.33±14.98	<0.001*
2 min	85.41±14.57	83.02±7.96	0.40
3 min	84.10±12.86	87.31±12.72	0.92
5 min	82.48±14.62	79.01±10.69	0.10
10 min	80.76±15.02	78.97±11.64	0.81
15 min	78.71±15.11	77.80±11.32	0.77
30 min	78.12±17.34	77.48±9.13	0.68
60 min	81.12±19.13	79.80±11.37	0.77
Post Extubation	89.79±9.81	84.42±8.44	0.57

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

Time intervals	Group N	Group F	P Value
Baseline	98.95±10.4	94.6±10.74	0.32
After study drug	94.79±13.11	90.45±10.69	0.001**
After Induction	87.69±14.66	79.95±11.92	0.001**
Immediate post Intubation	106.69±15.06	102.37±14.32	0.04*
1 min	105.86±16.06	100.24±14.05	0.07
2 min	104.61±15.11	96.98±14.26	0.03*
3 min	101.79±13.41	92.87±12.62	0.13
5 min	98.44±15.57	92.44±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	0.08
30 min	93.14±15.11	86.24±11.89	0.07
60 min	94.14±15.11	89.24±11.89	0.18
Post Extubation	103.98±10.4	97.6±10.74	0.06

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

Table 6: Changes in Perfusion Index

Time Interval	Group N	Group F	P values
Baseline	3.0± 1.0	2.9 ± 1.3	0.685
After study drug	3.7±1.2	3.7±1.2	1.000
After induction	3.9±0.7	3.9±1.8	0.673
Immediately post intubation	1.8±0.6	2.3±1.3	0.034*
1min	2.2±1.6	3.1±1.9	0.001*
2 min	3.0±1.7	4.3±2.0	0.018*
3min	3.0±1.0	4.0±2.0	0.006*
5 min	5.0±1.0	5.0±1.0	1.000
10 min	5.4±1.1	6.0±1.3	0.005*
15 min	5.9±1.6	6.0±1.5	0.874

Data are presented as mean ±SD; *P value <0.05 is statistically significant.

Discussion

The major stimuli to intraoperative hemodynamic changes are due to forces exerted by laryngoscope blade on the base of tongue during airway manipulation, leading to upsurge of circulating catecholamine concentrations. These exacerbated hemodynamic response can cause unexpected adverse effects of cardiac dysrhythmias, amplified blood pressure, left ventricular failure or even pulmonary edema which should be ameliorated for better outcome of patients.

Several pharmacological methods are used to ameliorate the magnitude of these hemodynamic responses of airway manipulation and surgical pain. Opioid analgesics and inhalation agents can also attenuate the hemodynamic pressor responses by deepening the anaesthesia. Many studies have shown that fentanyl and nalbuphine were effective for attenuating the hemodynamic pressor responses of airway manipulation and surgical pain.^[8]

Ko SH et al designed their study to scrutinize the optimal time to administer fentanyl to suppress the hemodynamic responses to laryngoscopy and intubation and concluded that the optimal time is 5 min before intubation.^[9] Chawda PM et al studied the effect of nalbuphine on hemodynamic pressor responses to tracheal intubation and concluded that nalbuphine in doses of 0.2 mg/kg, should be given 3 to 5 min before laryngoscopy to prevent the stress response to tracheal intubation.^[10] Hence in the present study, nalbuphine and fentanyl were given 5 min before induction.

In present study, after administration of study drugs, mean heart rate in patients of fentanyl group decreased while it increased in patients of nalbuphine group. The mean heart rate after intubation showed significant increase in all patients with statistically significant difference. The heart rate and systolic blood pressure gradually decreased in both the groups.

Khan and Hameedullah conducted a similar study and observed a significant decrease in heart rate response in fentanyl group after induction, tracheal intubation and incision. In their study, the heart rate in nalbuphine group remained significantly high 15 min post intubation while in present study, the heart rate gradually settled after intubation.^[11] Bhandari et al,^[12] and Ahsan et al,^[13] also support the present study.

Priti M Chawda et al studied the efficacy of nalbuphine to attenuate the increase of heart rate and blood pressure in response to intubation and observed significant rise in heart rate in control group (20.4%) after intubation at 2 min when compared to nalbuphine (16.66%). The heart rate and mean arterial pressure gradually decreased after 3 to 8 min, thus concluded that nalbuphine could attenuate the hemodynamic pressor response to laryngoscopy and intubation.^[10] The observations of present study is in consistence with their study.

Perfusion index is an assessment of the pulsatile strength at a specific monitoring site. It is calculated by means of pulse oximetry by expressing the pulsatile signal during arterial flow, as a percentage of non-pulsatile signal. Perfusion index could assess the intraoperative pain during general anesthesia, consequently helps to manage the perioperative pain when patient is unable to communicate their

discomfort.^[14,15] Various studies are done to evaluate the role of perfusion index as one of the markers of hemodynamic responses of laryngoscopy and surgical pain stimulus.^[16]

In the present study, the perfusion index was correlated with heart rate and systolic blood pressure at different time intervals in patients of both groups. The study showed no significant correlation with mean heart rate changes in patients of both groups, which indicated that any change in heart rate did not affect the perfusion index. The changes in mean systolic pressure from baseline, did affect the perfusion index value with negative correlation, in patients of both groups.

H Hager et al measured perfusion index by a pulse oximeter to indicate pain stimuli in anesthetized volunteers. They were induced with propofol (2mg/kg) and anesthesia was maintained with varying concentration of Sevoflurane. The standard painful stimuli were provided by two 25 G electric needles inserted into the lower part of anterior thigh bilaterally and a 65-70 mill-ampere, 100 Hz tetanic electric current was maintained for 10 sec. They observed that heart rate and mean arterial blood pressure increased under the influence of painful stimuli and the perfusion index showed a statistically significant decrease during painful stimuli. They concluded that the perfusion index is able to independently indicate a pain stimulus in anesthetized volunteers with different concentrations of Sevoflurane.^[17]

Kowalezyk et al noted the perfusion index at different time intervals. They stated that perfusion index increased significantly from the start to the end of surgery in all patients of study. They found significant correlation between perfusion index and end tidal desflurane concentration, but there was no correlation between propofol or remifentanyl concentration and perfusion index, thus concluded that Sevoflurane and Desflurane increases the perfusion index.^[17]

Haidry et al compared hemodynamic response to tracheal intubation with Macintosh and McCoy laryngoscopes and concluded that McCoy laryngoscope is safer alternative for intubation. They also stated that perfusion index can replace the conventional parameters to assess hemodynamic stress response during laryngoscopy and intubation since it has good negative correlation with mean arterial pressure.^[18]

Choudhary et al compared the hemodynamic responses to tracheal intubation with Macintosh versus McCoy laryngoscopes along with perfusion index and concluded that the McCoy laryngoscope elicits lesser hemodynamic response to laryngoscopy and tracheal intubation. They also concluded that perfusion index can also serve as an additional parameter to assess hemodynamic responses as it showed negative correlation with mean arterial pressure.^[19]

The present study is in consistence with these study.

Conclusion

Perfusion index could serve as an additional and independent parameters to assess intraoperative hemodynamic changes during airway manipulation and surgical pain in anesthetized patients. Perfusion index has a negative correlation with changes in mean systolic blood pressure, but no correlation with changes in heart rate. Intravenous premedication with fentanyl was more effective for ameliorating the stress

responses of airway stimulation, while nalbuphine premedication was better for intraoperative analgesia as assessed by perfusion index.

However, larger sample can throw better light before it can be recommended as a routine monitoring parameter and its clinical applicability and importance.

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