

Nalbuphine Compared with Fentanyl for Attenuation of Pressor Response in Laparoscopic appendicectomy-A Randomized Double blind Clinical Trial

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Abstract: *Background* In this study, our primary aim was to compare the efficacy of fentanyl and nalbuphine in attenuating the pressor response to laryngoscopy and tracheal intubation in patients undergoing laparoscopic appendicectomy under general anesthesia. The secondary aim was to observe hemodynamic response to pneumoperitoneum and to study the level of sedation using the Richmond Agitation-Sedation Scale (RASS). *Methodology* A total of 80 patients belonging to the American Society of Anesthesiologist Physical Status class I/II scheduled to undergo elective laparoscopic appendicectomy under general anesthesia were divided into two groups of 40 each. group A received intravenous nalbuphine 0.2 mg/kg and group B received intravenous fentanyl 2 µg/kg, five minutes before induction of anesthesia. *Technique of anesthesia* was standardized for all patients in the study. Heart rate (HR), systolic blood pressure (SBP), diastolic blood pressure (DBP), and mean arterial pressure (MAP) were recorded before giving the study drug; before induction; immediately after intubation; at one, three, and five minutes after intubation; before creating pneumoperitoneum; 15 minutes after creating pneumoperitoneum; and five minutes after release of pneumoperitoneum. Preoperative and postoperative sedation scoring was done using RASS. *Results* Immediately after intubation, HR was significantly higher in group A ($p = 0.02$). Both groups showed a rise in SBP immediately after intubation. Group A showed a significantly higher SBP, DBP, MAP in comparison to group B (136.58 ± 10.55 , 80.23 ± 7.88 , 99.01 ± 8.01 , and 125.23 ± 9.12 , 73.8 ± 8.86 , 94.61 ± 8.85 ;) respectively. At one, three, and five minutes after intubation, HR, SBP, DBP, and MAP were similar between the groups. Post-extubation sedation score was significantly higher in group A ($p < 0.001$). *Conclusions* We found that fentanyl was more effective than nalbuphine in attenuating the pressor response to laryngoscopy and tracheal intubation.

Keywords: Fentanyl, Nalbuphine, pressor response, laparoscopic appendicectomy, laryngoscopy, General anaesthesia, Hemodynamic response

1. Introduction

Laryngoscopy, endotracheal intubation, and other airway manipulations are noxious stimuli that may induce profound changes in cardiovascular physiology, primarily through reflex responses. The rise in heart rate and blood pressure are usually transitory, variable, unpredictable, and can have detrimental consequences such as myocardial ischemia and cerebral hemorrhage.

Laparoscopic surgeries form a crucial part of today's surgical practice but pose a challenge due to significant hemodynamic alterations contributing to elevated heart rate (HR), mean arterial pressure (MAP), and increased systemic and pulmonary vascular resistance along with reduced cardiac output. Such hemodynamic changes predispose the myocardium in vulnerable patients to ischemic changes. Hence, it wants to prevent the exaggerated hemodynamic response to laryngoscopy and intubation.

Fentanyl is a potent μ receptor agonist with rapid onset and relatively short duration of action, minimal respiratory depression, and has the ability to provide cardiovascular stability. Despite these beneficial effects, fentanyl is known to cause bradycardia, nausea, vomiting, pruritus, and muscle rigidity.

Nalbuphine is a mixed agonist/antagonist opioid being agonist at κ receptor and antagonist at μ receptor. It is reported to have a ceiling effect on respiratory depression, cardiovascular stability, longer duration of analgesia, and decreased incidence of nausea and vomiting, which makes it an ideal analgesic during anesthesia.

Aim and Objectives

Aim

To determine the effect of fentanyl and nalbuphine in attenuating the pressor response to laryngoscopy and tracheal intubation in patients undergoing laparoscopic appendicectomy under general anesthesia.

Primary Objective

To compare the effect of fentanyl and nalbuphine in attenuating the pressor response to laryngoscopy and tracheal intubation in patients undergoing laparoscopic appendicectomy under general anesthesia.

Secondary Objective

- To observe the hemodynamic response to pneumoperitoneum,
- To study the level of sedation using the Richmond Agitation-Sedation Scale (RASS).

2. Materials and Methods

Source of the data-The patients who are admitted in general surgery department of government medical college Kadapa, for elective laparoscopic appendicectomy Study design-A prospective randomized double blind trial

Sample size: 40 patients in each group.

Inclusion Criteria

The patients of 25-65 year age group of both sex who are scheduled to undergo elective laparoscopic appendicectomy under general anaesthesia belonging to (American Society of Anaesthesiologists physical status I & II).

Exclusion Criteria

- Patients having severe systemic illness (cardiac, hepatic, renal pulmonary, endocrinal, neurological, or psychiatric disease),
- Patients who have anticipated difficult airway
- Patients with substance abuse disorder,
- Patients having body mass index >35 kg/m²,

- Patients with known allergic reactions to study drug
- Pregnant and lactating mothers

Parameters Measured

Primary outcome

Heart rate (HR), systolic blood pressure (SBP), diastolic blood pressure (DBP), and mean arterial pressure (MAP) were recorded before giving the study drug;

Before induction;

Immediately after intubation;

At one, three and five minutes after intubation.

Secondary outcome

HR, SBP, DBP and MAP were recorded before creating pneumoperitoneum; 15minutes after creating pneumoperitoneum; Five minutes after the release of pneumoperitoneum Pre-induction and post-extubation sedation scoring were assessed using Richmond-Agitation-Sedation Scale Agitation-Sedation Scale Agitation-Sedation Scale (RASS)

RESULTS

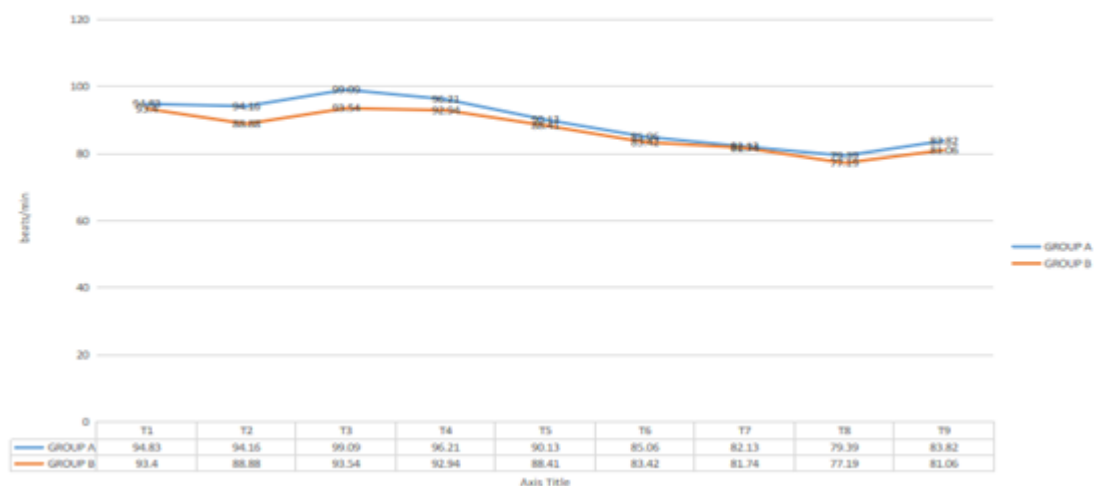
The demographic characteristics and ASA PS grade

PARAMETER	Group A (Nalbuphine) (n = 40)	Group B (Fentanyl) (n = 40)	P-Value
Age(mean \pm SD)	35.61 \pm 9.79	35.79 \pm 10.3	0.931
Sex female(%)	91.1	92.2	0.787
BMI (kg/m ²) mean \pm SD	24.33 \pm 4.02	24.68 \pm 3.6	0.608
ASA PS I/II(n)	83/7	86/4	0.536

BMI: body mass index; **ASA PS:** American Society of Anesthesiologist Physical Status;
SD: standard deviation

Table 1 There is no significant difference between Group A and Group B patients in age, gender, BMI, ASA level distribution

comparison of mean heart rate



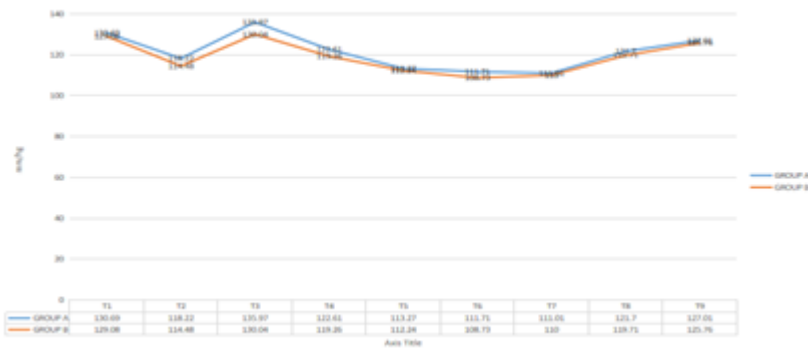
Line Graph 1: Compares the mean heart rate between group A and group B of patients and the P value of T2 & T3 IS 0.0001 & 0.0002 respectively and statically significant

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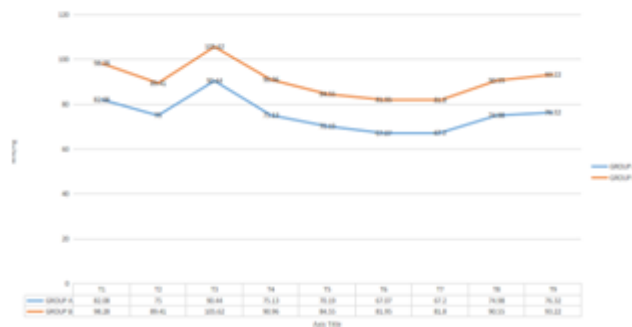
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comparison of mean systolic blood pressure.

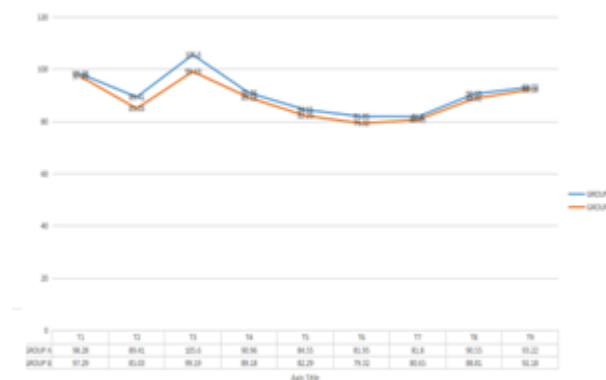


Line Graph 2, 3 & 4 compares mean SBP, DBP & MAP between group A and group B of patients and the P value of T2 & T3 is 0.0001 & 0.0002 respectively and statically significant

comparison of mean diastolic blood pressure.



comparison of mean arterial pressure.



Comparison of RASS score before induction

RASS score	Group A (Nalbuphine) n(%)	Group B (Fentanyl) n(%)	P-Value
-2	17 (18.89%)	18 (20.00%)	0.928
-1	19 (21.11%)	17 (18.89%)	
0	54 (60.00%)	55 (61.11%)	
Total	90 (100%)	90 (100%)	

RASS: Richmond Agitation–Sedation Scale

Comparison of RASS score after extubation			
RASS score	Group A (Nalbuphine) n(%)	Group B (Fentanyl) n(%)	P-Value
-2	49 (54.44%)	0 (0.00%)	<0.0001
-1	29 (32.22%)	12 (13.33%)	
0	12 (13.33%)	78 (86.67%)	
Total	90 (100%)	90 (100%)	
RASS: Richmond Agitation–Sedation Scale			

Table 2 & 3 shows: There is significant difference between Group A and Group B patients in RASS score before induction and after extubation.

3. Discussion

Tracheal intubation is still the gold standard of airway management for general anesthesia. Intubation preceded by laryngoscopy are intense nociceptive stimuli that induce sympathetic response which is responsible for tachycardia, hypertension, and arrhythmias.

In the absence of any measures to prevent the hemodynamic response, the HR and BP can increase much above acceptable limits. These changes are maximum one minute after intubation and last for around five to ten minutes. Fentanyl attenuates the cardiovascular response by its action on opioid receptors and by decreasing sympathetic outflow.

The desirability of agents with partial antagonist activity lies in the possibility of a decrease in abuse potential and a limitation to the extent of side effects, particularly respiratory depression. The analgesic potency of nalbuphine equals that of morphine on a milligram basis.

The greatest advantage with nalbuphine is its ceiling effect on respiratory depression when compared to pure opioid agonists. The baseline HR was comparable between the groups. HR in fentanyl group was significantly lower than nalbuphine group at (T2) with a p-value of 0.015. The mean SBP, DBP, and MAP before administration of study drugs were comparable between the groups. SBP was significantly lower in the fentanyl group compared to the nalbuphine group five minutes after administration of the study drug. Thereafter throughout the study period (T4-T9), the SBP was significantly lower than the baseline in both the groups.

In our study, hemodynamic parameters were comparable between the two groups after creation of pneumoperitoneum. RASS scores after administration of study drugs were comparable between the groups.

However, at 30 minutes after extubation, 54.4% of patients in the nalbuphine group had a RASS score of -2 compared to none in the fentanyl group, reflecting the sedative effect of nalbuphine due to kappa agonistic action.

There were no significant side effects between the two groups.

The limitations of our study were that we only studied ASA PS I/II patients, stress mediators such as endogenous plasma catecholamines were not measured, invasive arterial blood pressure monitoring was not done, and the study was limited to patients undergoing laparoscopic appendectomy.

4. Conclusion

In our study, we found that fentanyl was more effective than nalbuphine in attenuating the pressor response to laryngoscopy and tracheal intubation in patients undergoing laparoscopic appendectomy under general anesthesia.

There was no significant difference observed between nalbuphine and fentanyl in the hemodynamic response to pneumoperitoneum. The depth of sedation post extubation was significantly greater with nalbuphine.

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