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**Research Article**

# Study to compare effect of equipotent dose of butorphanol versus fentanyl on intraoperative anaesthesia course and postoperative recovery characteristic in patient undergoing laparoscopic surgery

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## ABSTRACT

**Background:** The recent trend for control of intraoperative and post-operative pain is towards multimodal analgesia where adequate analgesia is provided using 2 or more analgesic agents, thereby reducing undesirable side effects of each agent and improving the efficacy of each with smaller doses. Analgesic effects of butorphanol and fentanyl have been evaluated extensively for acute and chronic pain for last many years. Many of these studies have shown promising results for intra-operative and post-operative pain. They have also shown to have favourable effects on pressure response caused by laryngoscopy and intubation during general anaesthesia. The present study aimed at comparin the effect of butorphanol versus fentanyl in patients undergoing elective laparoscopic surgery with respect to degree of suppression of sympathetic response to intubation and laryngoscopy, intraoperative hemodynamics, emergence time, recovery time and post-operative sedation, time of post-operative analgesic requirement and complications if any.

**Methods:** The present study designed was a prospective single blind randomised clinical study. After meeting inclusion criteria 60 patients were selected and divide into two groups each consisting 30. Group B received butorphanol (20 µg/kg, i.v) and group F received fentanyl (1 µg/kg, i.v). Required physical parameters are monitored and baseline values were recorded. During surgery pulse rate, B.P, ETCO2, SpO2, intra-abdominal pressures were recorded. Post-operative patient were shifted to recovery room, and monitored for Ramsay score for sedation and VAS score for pain and recorded if present.

**Results:** From the results it was found that butorphanol 20 µg/kg i.v. prevents response to endotracheal intubation to a greater extent than fentanyl 1 µg/kg i.v and the difference is highly significant statistically <0.001. Both induction and maintainence dose of propofol, total dose of muscle relaxant, vecuronium used are found to be less with the group B than group F and found statistically very highly significant. The pain, measured by the VAS score and requirement of rescue analgesia after post-operative period was found to be lower in group B compared to group F and also group B showed significant levels of sedation (p=0.000), for first half hour, none of the patients had any episode of desaturation (SpO2 <95%) and did not require any further intervention. Nine patients of group B experienced nausea and 2 vomited, while it was 8 and 2 in group F. So incidences of adverse effects are comparable with both groups. These episodes were subsided after giving injection ondansetron.

**Conclusions:** It was concluded that butorphanol is an acceptable alternative opioid to fentanyl for use as a component of balanced general anaesthesia at the doses studied, because of its ability to produce prolonged analgesia and amnesia, stable haemodynamic parameters, no postoperative respiratory depression and no prolongation of the recovery room stay.

**Keywords:** Balanced anaesthesia, Butorphanol, Fentanyl, Propofol

## INTRODUCTION

Balanced anaesthesia is the technique in which a number of agents are combined to produce desired effect.[1] The intent of combining opioids with sedative-hypnotics and/or volatile anaesthetics is to produce anaesthetic conditions with stable hemodynamics prior to, as well as after, noxious stimulation. The inclusion of an opioid can reduce preoperative pain and anxiety, decrease somatic and autonomic responses to airway manipulations, improve hemodynamic stability, lower requirements for inhaled anaesthetics, and provide immediate postoperative analgesia. It is a common practice among anaesthesiologists to include a small dose of narcotic analgesic as part of anaesthetic technique. These narcotic agents in addition to providing analgesia also minimize the requirement for potent anaesthetic agent during induction and maintenance of anaesthesia. Narcotics have also been used for attenuation of pressor response during laryngoscopy and intubation and are believed to provide a comfortable recovery from anaesthesia.[2]

Many opoids drugs are available as balanced anaesthetic agents. Each drug has its own advantages and disadvantages depending upon its pharmacokinetic and pharmacodynamics profile. Many studies have compared different opoids but only few studies are carried away on butorphanol and fentanyl. Hence, the present study was conducted to compare equipotent moderate doses of above mentioned drugs, used as a part of a balanced anaesthetic technique in a patient population of healthy adults undergoing laparoscopic procedures.

## METHODS

### *Study design*

The study was a prospective single blinded, randomized and comparative clinical study conducted in Lokmanya Tilak Municipal Medical College and General Hospital, Mumbai, India. After taking approval of institutional ethics committee, this study included 60 ASA-I and II patients of either sex, between age group 18-60 years undergoing elective laparoscopic surgery under general anaesthesia based on the eligibility. Stratified randomisation of the patients was done in to 2 groups depending on pelvic or upper abdominal surgeries. Each group consisted of 30 patients.

- Group F: Patients receiving fentanyl 1 µg/kg i.v
- Group B: Patients receiving butorphanol 20 µg/kg i.v

### *Exclusion criteria*

Patients with age group <18 years and >60 years, ASA grade: grade III and above, patients with systemic diseases like diabetes mellitus, severe hypertension, deranged renal function, deranged coagulation profile, pregnant females and known hypersensitivity to propofol, butorphanol or fentanyl were excluded from the study.

Patients scheduled for laparoscopic surgery were thoroughly evaluated and assessed. They were explained about the nature and consequences of the study and also about the visual analogue scale for grading of pain intensity. Informed and written consent was obtained from all the patients. After selection, patients were randomised in to the 2 said groups.

A diclofenac suppository of 100 mg was inserted per rectum in all patients 1 hour prior to taking the patient on operation table. After the patient came inside operation theatre, monitors namely pulse oximeter, cardioscope, blood pressure cuff were attached and baseline values were recorded. They were premedicated with inj. glycopyrrolate: 0.004 mg/kg, injection ranitidine: 1 mg/kg., injection metoclopramide: 0.2 mg/kg, injection midazolam: 0.02 mg/kg. 1 min after premedication pulse rate, blood pressure, $SpO_2$ readings was recorded.

Later inj. fentanyl (1 µg/kg) or injection butorphanol (20 µg/kg) was given i.v. over a period of 30 seconds. After 2 min induction of anaesthesia was started using inj. propofol (2-3 mg/kg) till loss of eyelash reflex. Pulse rate, BP were recorded. After checking ventilation, intubating dose of succinylcholine 1.5 mg/kg i.v was administered. Within 90-120 seconds laryngoscopy was done, pulse rate, BP were recorded. Intubation was done with appropriate size PVC cuffed endotracheal tube within 60-120 seconds after giving succinylcholine pulse, B.P were recorded after every 1 min from the time of intubation for 5 min, then every 5 min till 15 min and then every 10 min till end of surgery. Anaesthesia was maintained with 60% nitrous oxide in oxygen and propofol infusion at 4-6 mg/kg/hr dose to maintain adequate depth of anaesthesia as judged by pulse rate, B.P with controlled ventilation.

Muscle relaxation was maintained with inj. vecuronium using loading dose of 0.08 mg/kg and top-ups of 0.02 mg/kg as needed. Pulse rate, BP, $ETCO_2$, $SpO_2$ were monitored throughout the surgical procedures every 5 min and recorded every 10 min. Intra-abdominal pressure was monitored and noted down. After complete reversal of N-M blockade with inj. neostigmine 0.06 mg/kg and inj. glycopyrrolate 0.008 mg/kg, patients were extubated when adequate, spontaneous and regular respiration was established. Time was noted between discontinuation of propofol infusion and extubation and between time of last dose of vecuronium and extubation.

Post-operative patient were shifted to recovery room, where patients were monitored for sedation till Ramsay score of 3 was achieved and they were also monitored for pain and analgesic requirement 1 hourly. At visual analogue score of 4, rescue analgesia was given with inj. tramadol 1 mg/kg. At the end of observation period, patients were asked to express their opinion concerning efficacy of pain relief. Opinion was graded as excellent, good, fair and poor. Any adverse drug reaction or complications noted were recorded and analysed.

***Statistical analysis***

The data thus obtained was statistically analyzed using paired and unpaired student t' test and Chi-square test. For all statistical comparisons, P<0.05 was taken as significant.

## RESULTS

The demographic data of both groups were recorded and are given in Table 1. The mean age and mean weight of the patients in group B and group F were found statistically not significant. The sex and ASA grades of both groups were compared with Chi-Square test and the values are statistically insignificant. Group B had 2 lap hernia repair, 7 lap appendecectomies, and 21 lap cholecystectomies, while group F had 1, 7, and 22 respectively. The 'p' values by t- test applied independently for each type of surgery i.e. lap hernia repair, lap appendecectomy, lap cholecystectomy were 0.94, 1, 0.95 respectively, which statistically were not significant as given in Table 2.

**Table 1: Demographic data.**

| Parameters | Group B (n=30) | Group F (n=30) | 'p' value |
|---|---|---|---|
| **Age (Years)** | 38.63±11.76 | 41.43±12.33 | 0.37 |
| **Weight (Kg)** | 57.43±7.65 | 57.96±7.92 | 0.79 |
| **Sex( M:F)** | 16:14 | 19:11 | 0.6 |
| **ASA I:II** | 25:5 | 23:7 | 0.88 |

**Table 2: Comparison of type of surgery.**

| Type of Surgery | Group B (n=30) | Group F (n=30) | 'p' value |
|---|---|---|---|
| **Lap cholecystectomy** | 21 (70%) | 22 (73.33%) | 0.95 |
| **Lap Appendecectomy** | 7 (23.33%) | 7 (23.33%) | 1 |
| **Lap hernia repair** | 2 (6.66%) | 1 (3.33%) | 0.94 |

Table 3, Table 4 shows the comparison of intubation response in both groups by measuring pulse and systolic blood pressure. Pulse and systolic blood pressure of both the groups were comparable till 1 min after premedication. There were no statistically significant differences between values of both the groups. However both pulse and systolic blood pressure dropped to a greater level with group B than group F after administration of butorphanol or fentanyl.

**Table 3: Comparison of pulse rate.**

| Time | Group B | Group F | 'p' value |
|---|---|---|---|
| **Preoperative** | 88.33±10.06 | 88±10.80 | 0.9 |
| **Premedication** | 88.53±9.82 | 88.4±10.65 | 0.95 |
| **1 min after premedication** | 95±11.02 | 94±11.23 | 0.79 |
| **After Butorphanol/Fentanyl** | 80.93±9.75 | 88.13±10.25 | 0.007 |
| **At induction** | 76.8±8.73 | 84.13±10.14 | 0.003 |
| **At laryngoscopy** | 80.13±8.77 | 91±10.79 | 0.000 |
| **At intubation** | 84.06±9.46 | 96.86±10.2 | 0.000 |
| **1 min after intubation** | 81.86±9.36 | 94.66±10.28 | 0.000 |
| **2 min after intubation** | 80.13±9.37 | 92.33±10.21 | 0.000 |
| **3 min after intubation** | 78.73±8.92 | 90.53±10.27 | 0.000 |
| **4 min after intubation** | 76.06±8.85 | 88.4±10.16 | 0.000 |
| **5 min after intubation** | 74±8.42 | 86.06±10.19 | 0.000 |

The 'p' values are highly significant after butorphanol/fentanyl and at the time of induction. The 'p' values from the time of laryngoscopy till 5 minutes after intubation are <0.001 (i.e. very highly significant). So

there was a statistically significant difference between both groups. From the above data it is clear that butorphanol 20 µg/kg i.v. prevents response to endotracheal intubation to a greater extent than fentanyl 1 µg/kg i.v. Table 5 explains the anaesthetic requirement during surgery. Both induction dose of propofol and maintenance dose are found to be less with the group B than group F. The 'p' values for both are very highly significant. Total dose of muscle relaxant, vecuronium used is found to be reduced with group B which is also statistically very highly significant.

**Table 4: Comparison of blood pressure.**

| Time | Group B | Group F | 'p' value |
|---|---|---|---|
| **Preoperative** | 121.4±10.03 | 121.33±10.09 | 0.97 |
| **Premedication** | 121±9.25 | 121.33±10.09 | 0.89 |
| **1 min after premedication** | 120.8±9.24 | 121.33±10.09 | 0.83 |
| **After Butorphanol/Fentanyl** | 108.73±6.93 | 116.33±9.3 | 0.0007 |
| **At induction** | 105±6.31 | 111.6±9.01 | 0.0017 |
| **At laryngoscopy** | 108.4±6.2 | 117.33±9.04 | 0.000 |
| **At intubation** | 112±6.19 | 122.73±8.6 | 0.000 |
| **1 min after intubation** | 109.8±6.22 | 120.82±9.12 | 0.000 |
| **2 min after intubation** | 108.26±5.79 | 118.6±8.61 | 0.000 |
| **3 min after intubation** | 106.53±5.75 | 116.86±8.6 | 0.000 |
| **4 min after intubation** | 105.13±5.57 | 115.13±8.57 | 0.000 |
| **5 min after intubation** | 104.07±5.26 | 113.46±8.91 | 0.000 |

**Table 5: Comparison of anaesthetic requirement.**

| Parameters | Group B | Group F | 'p' value |
|---|---|---|---|
| **Propofol Induction dose (mg)** | 115.66 ±18.51 | 154.66 ±25.56 | 0.000 |
| **Propofol maintenance dose (mg)** | 105.16 ±21.02 | 159.5 ±28.47 | 0.000 |
| **Total vecuronium used (mg)** | 6.9 ±0.99 | 7.96 ±0.92 | 0.000 |

**Table 6: Comparison of time interval from end of propofol to extubation and VAS score.**

| | Group B | Group F | 'p' value |
|---|---|---|---|
| **Time to extubation from end of propofol infusion** | 34.16 ±8.1 | 26 ±5.9 | 0.000 |
| **VAS Score at 30 min** | 0 ±0 | 3.13 ±1.00 | 0.000 |

**Table 7: Comparison of mean VAS scores at various time periods.**

| Time (Hrs) | Group B | Group F | 'p' value |
|---|---|---|---|
| **1** | 0.2 ±0.6 | 1.6 ±1.92 | 0.0003 |
| **1.5** | 1.8 ±1.21 | 0.26 ±1.01 | 0.000 |
| **2** | 2.86 ±1.54 | 0 ±0 | 0.000 |
| **3** | 1.06 ±1.72 | 0 ±0 | 0.000 |
| **4** | 0.13 ±0.73 | 0 ±0 | 0.32 |
| **5** | 0 ±0 | 0 ±0 | 0.32 |
| **6** | 0.06 ±0.36 | 1.06 ±1.14 | 0.000 |
| **12** | 3.93 ±0.36 | 4 ±0 | 0.32 |
| **18** | 1.86 ±0.89 | 3.46±0.89 | 0.000 |
| **24** | 4 ±0 | 4 ±0 | 1 |

Table 6 showed that time interval between end of propofol infusion and extubation was less in group F. The 'p' value is <0.001 signifying that patient receiving fentanyl are extubated earlier and mean VAS Score was 3.13. Seventeen out of 30 patients i.e. (56%) required rescue analgesia in the group F while no one from group B required rescue analgesia in first half hour postoperative period.

Table 7 shows the fact that pain, as measured by the visual analogue scale score was found to be lower in group B when compared with group F till 1 hr postoperatively. As the group F patients received rescue analgesia during first hour their VAS score decreased while that of group B patients' increased during subsequent period. However at the end of 12 hours both groups had high VAS score with p value of 0.32 that means there is no statistically significant difference.

As shown in Table 8 number of patients requiring rescue analgesia during the first postoperative hour was found to be 0 in group B while it was 28 in group F. Rescue analgesia (injection tramadol 1 mg/Kg IV) was administered when the visual analogue scale score was ≥4 on a scale of 0 to 10. The mean number of rescue analgesic doses required in both groups did not differ substantially.

**Table 8: Comparison of number of patients and dose requiring rescue analgesia in the first post-operative hour.**

| | Group B | Group F | 'p' value |
|---|---|---|---|
| **Number of patients** | 0 | 28 | 0.000 |
| **Mean number of rescue analgesia dose required** | 8.27±11.7 | 10.27±12.4 | 0.702 |

**Table 9: Comparison of time duration for requirement of first dose of rescue analgesia.**

| Hours | Group B | Group F |
|---|---|---|
| **0.5** | 0 | 17 |
| **1** | 0 | 11 |
| **1.5** | 4 | 2 |
| **2** | 18 | 0 |
| **3** | 7 | 0 |
| **4** | 1 | 0 |
| **5** | 0 | 0 |
| **6** | 0 | 1 |
| **12** | 29 | 30 |
| **18** | 2 | 22 |
| **24** | 30 | 30 |

**Table 10: Comparison of mean post operative Ramsay's sedation score.**

| Time | Group B | Group F | 'p' value |
|---|---|---|---|
| **15 min** | 2.63±0.49 | 2 | 0.000 |
| **30 min** | 2.4±0.49 | 2 | 0.000 |
| **1 Hour** | 2 | 2 | 1 |
| **2 Hour** | 2 | 2 | 1 |
| **3 Hour** | 2 | 2 | 1 |
| **4 Hour** | 2 | 2 | 1 |
| **5 Hour** | 2 | 2 | 1 |
| **6 Hour** | 2 | 2 | 1 |
| **12 Hour** | 2 | 2 | 1 |
| **18 Hour** | 2 | 2 | 1 |
| **24 Hour** | 2 | 2 | 1 |

Table 9 shows the fact those 28 patients of the group F required the first dose of rescue analgesic within the first postoperative hour, as compared to none from group B. All 30 patients in the group F received their first dose of rescue analgesia within one and half postoperative hour, while in the group B this time duration was extended up to fourth postoperative hour. In the study, throughout their stay in post anaesthesia care unit, patient's postoperative sedation was assessed using Ramsay's sedation score. As shown in Table 10 mean sedation score were higher in the first half hour in group B which was statistically very highly significant. Subsequently mean sedation scores were equal. Though patients in group B showed significant levels of sedation, for first half hour none of the patients had any episode of desaturation ($SpO_2$ <95%) and did not require any further intervention.

**Table 11: Comparison for occurrence of adverse events.**

| Adverse Effects | Group B | Group F |
|---|---|---|
| **Nausea** | 9 | 8 |
| **Vomiting** | 2 | 2 |

As illustrated in the Table 11 nine patients of group B experienced nausea and 2 vomited, while it was 8 and 2 in group F. So incidences of adverse effects are comparable with both groups. These episodes subsided after giving injection ondansetron.

## DISCUSSION

The present study included and compared two opioids - butorphanol and fentanyl as a component of balanced anaesthesia. An ideal opioid successfully prevent unwanted responses to various stimuli, requires little supplementation, does not depress cardiovascular function and produce post-operative analgesia with minimal side effects. Both the group of drugs has haemodynamic stability, analgesia, sedation and decreases the requirement of other anesthetic drugs and are available at low cost. So we have chosen butorphanol and fentanyl to study the analgesia and adequate post-operative recovery characteristics of the same drugs.

Many of the earlier studies have used varying doses of butorphanol (20 µg/kg-40 µg/kg) and fentanyl (1-3 µg/kg). Pandit et al compared butorphanol 40 µg/kg with fentanyl 2 µg/kg and reported a higher incidence of pain in fentanyl group and more drowsiness in butorphanol group. 40% of patients in each group required anti-emetic therapy.[2] Hammad Usmani compared the same doses of butorphanol and fentanyl, but the incidence of drowsiness was not significantly different in both groups.[3] In a study conducted by Wetchler, he compared Butorphanol 20 µg/kg, butorphanol 40 µg/kg, and fentanyl 2 µg/kg and concluded 20 µg/kg butorphanol and 2 µg/kg of fentanyl appears to be suitable to use as a preinduction narcotic analgesic.[4] Whereas Butorphanol 40 µg/kg appears to be unsuitable due to increased duration of nausea, dizziness, time to reach a score of 10 on APARS and discharge-ready status.

From these studies we concluded higher doses of Butorphanol (40 to 60 µg/kg) resulted in prolonged sedative effects and delayed discharge and increased doses of Fentanyl as the opioid component also been shown to prolong recovery. Hence, we chose to limit the doses of opioids, and add instead propofol to complete the balanced general anaesthetic.

Hence in our study we have chosen equipotent doses of butorphanol (20 µg/kg) and fentanyl (1 µg/kg) to limit the doses of opioids, and instead added propofol to complete the balanced general anaesthetic as done by Philip.[5]

In our study both pulse and systolic blood pressure dropped to a greater level with group B than group F after administration of butorphanol or fentanyl. The ‘p’ values are highly significant after giving opioids and at the time of induction (<0.001).

From the above data it is clear that butorphanol 20 µg/kg i.v. prevents response to endotracheal intubation to a greater extent than fentanyl 1 µg/kg i.v. These results are in accordance with the studies conducted by Usmani et al.[3] He compared the effect of butorphanol and fentanyl in attenuating the pressure response to laryngoscopy and intubation and demonstrated better protection against autonomic stimulation to tracheal intubation and surgical incision in butorphanol group. Philip et al also found anesthetic maintenance more satisfactory in butorphanol group.[5] In present study from Table 5, we found that propofol requirement in fentanyl group is significantly more, both for induction as well as maintenance to maintain stable hemodynamics as compared to butorphanol group and also total dose of muscle relaxant, vecuronium used is found to be reduced in group B.

From Table 3 and Table 4 it was observed that the pulse and systolic blood pressure intraoperatively remained consistently lower in Group B and determines Butorphanol is an acceptable alternative opioid to Fentanyl to use as a component of balance general anaesthesia.

Post-operative sedation was assessed by Ramsay score. In our study we found that mean sedation score were higher in the first half hour in group B which was statistically very highly significant (p=0.001). Subsequently mean sedation scores were equal. Though patients in group B showed significant levels of sedation, for first half hour none of the patients had any episode of desaturation ($SpO_2$ <95%) and did not require any further intervention. This is may be due to kappa agonist effect of butorphanol. Usmani et al found that incidence of drowsiness in fentanyl group was as comparable as in butorphanol group.[3]

This was due to higher concentration of halothane required for maintenance of anaesthesia in Fentanyl group as compared to butorphanol group. The same result was observed in a study conducted by Pandit et al.[2] He found that there was significant drowsiness in 44% patients of butorphanol group as compared to 16% in fentanyl group.

Post-operative pain was analysed by VAS score. In our study, during the first 30 minute in the postoperative period, patients receiving butorphanol had not complained of any pain whereas mean VAS Score was 3.13 in patients receiving fentanyl. Seventeen out of 30 patients (56%) required rescue analgesia in group F while no one from group B required rescue analgesia in first half hour postoperative period and the VAS score was found to be lower in group B when compared with group F till 1 hour postoperatively.

After receiving rescue analgesia in group F during first hour their VAS Score was decreased while that of group B patients’ increased during subsequent period. However at the end of 12 hours both groups had high VAS Score but it was statistically insignificant. But complaint of postoperative pain was far less frequent in butorphanol group as compared to fentanyl group. This difference may due to rapid redistribution of fentanyl.

Post-operative side effects were compared in both groups. In our study nine patients of group B experienced nausea and 2 vomited, while it was 8 and 2 in group F. Findings of Pandit et al also demonstrated that nausea and vomiting were the most common side effects in 55%

patients of butorphanol group and 61% in the Fentanyl group.[2] A similar observations were also stated by Philip with no significant difference in side effects in both groups except sedation which was statistically significant in butorphanol group.[5] Other side effects included nausea, vomiting, excitement, headache, light headedness, dizziness were comparable in both groups. Thus in the present study, results suggested that butorphanol is an acceptable alternative opioid to fentanyl for use as a component of balanced general anaesthesia at the doses studied.

## CONCLUSION

From our clinical study it was concluded that butorphanol at a dose of 20 µg/kg is an acceptable alternative opiod to fentanyl for use as a component of balanced general anaesthesia for ambulatory laparoscopic surgery because of its ability to produce prolonged analgesia stable hemodynamic parameters, no post-operative respiratory depression and no prolonging of the recovery room stay.

Fentanyl 1 µg/kg is insufficient to avoid hemodynamic response to intubation and laryngoscopy, to reduce requirement of induction, maintenance of anaesthesia and analgesia.

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