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Observational Study

**Study to Compare Effect of Butorphanol Versus Fentanyl on
Intraoperative Anaesthesia Course and Postoperative Recovery
Characteristic in Patients Undergoing Laparoscopic Surgery- A
Prospective Observational Study**

Siddhi Barodawala^{1*}, Rupal Kapadia², Sonal Shah³, Dimple Pandya⁴, Priyanka Patel⁵, Namrata Mehta⁶

1Third Year Resident, Department of Anaesthesia, SMT NHL Municipal Medical College and SVP Hospital, Ahmedabad, Gujarat, India.

2Assistant Professor and PG Guide, Department of Anaesthesia, SMT NHL Municipal Medical College and SVP Hospital, Ahmedabad, Gujarat, India.

3,4,5. Assistant Professor, Department of Anaesthesia, SMT NHL Municipal Medical College and SVP Hospital, Ahmedabad, Gujarat, India.

6. Senior Resident, Department of Anaesthesia, GMERS Medical College, Junagadh, Gujarat, India.

***Correspondence to: Dr. Siddhi Barodawala**, Third Year Resident, Department of Anaesthesia, SMT NHL Municipal Medical College and SVP Hospital, Ahmedabad, Gujarat, India.

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Abstract

Background: Opioids serve as potent central analgesics that are commonly used as a part of balanced anaesthesia. The objective of this study was to analyse and compare the effects two opioids, butorphanol and fentanyl on suppression of stress response to laryngoscopy and intubation, intra-operative hemodynamic changes, sedative effect during postoperative period, the duration of postoperative analgesia and adverse events in patients undergoing elective laparoscopic surgery performed under general anaesthesia.

Material and methods: This was a comparative, observational, and prospective study in which total 50 patients undergoing elective laparoscopic surgery were divided into two equal groups. Group-B received inj. butorphanol (dose of 20 µg/kg i.v.), and Group-F received inj. Fentanyl (dose of 2 µg/kg i.v.). Baseline preoperative values of hemodynamic parameters were recorded. Both groups were observed for hemodynamic parameters during the course of general anaesthesia. In post-operative room, patients were observed for sedation by the Ramsay's score, for pain by the VAS score, duration of post-operative analgesia and adverse events.

Result: From the observation it was found that Fentanyl had better attenuation of the stress response during laryngoscopy and intubation than butorphanol. However, there was no significant difference in hemodynamic parameters during the intraoperative course. It took around 3 hours and 6 hours to reach a VAS score of 4 in group F and B, respectively. The mean score of sedation was higher during first hour in Group-B.

Conclusion: Butorphanol (20 µg/kg i.v.) is a suitable substitute to fentanyl (2 µg/kg i.v.) as a component of balanced general anaesthesia. Butorphanol demonstrates several advantages, including prolonged analgesia and amnesia, stable vital parameters, no respiratory depression and no delay in recovery. However, fentanyl exhibits greater suppression of stress response during laryngoscopy and intubation compared to butorphanol.

Keywords: Laparoscopic surgery, General anaesthesia, Butorphanol, Fentanyl.

INTRODUCTION

Opioids serve as potent central analgesics that are commonly used as a part of balanced anaesthesia. Their inclusion can alleviate pre-operative anxiety and pain, decrease the stress response to airway manipulation, stabilise hemodynamics, decrease the need of inhalational anaesthetic agents, and offers pain relief immediately after surgery. ⁽¹⁾

Among the available opioids, fentanyl stands out as an effective and most commonly used agent. A synthetic phenyl-piperidine opioid, fentanyl citrate, exhibits analgesic properties, it is a chemical analogue of pethidine. With a potency 100 times more compare to morphine, it functions as an agonist at μ receptor and is a member of G protein coupled receptor group. Fentanyl undergoes extensive first-pass metabolism, primarily in the liver.

On the other hand, butorphanol, a synthetic opioid derivative, possesses both narcotic antagonist and analgesic agonist properties. Limited to parenteral administration, it is five to eight times more potent than morphine. Butorphanol acts as an agonist on the κ receptor and exhibits mixed activity as agonist and antagonist on the μ receptor. While it maintains plasma half-life of 2 to 3 hours with an analgesic effect lasting 3 to 4 hours, which is comparable to morphine. ⁽²⁾

Laparoscopic procedures constitute a cornerstone of modern surgical practice, owing to their advantages such as magnification, precision, reduced blood loss and cosmetic scarring, diminished post-operative pain, and shorter duration of hospital stays due to lower morbidity and mortality rates. ⁽³⁾ However, positioning adjustments (the reverse Trendelenburg position) and pneumoperitoneum, which is used for visualising intra-abdominal organs, have significant effects on respiration and hemodynamics. ⁽⁴⁾

The primary objective of the study was to analyse and compare the effects two opioids, butorphanol and fentanyl on suppression of stress response to laryngoscopy and intubation, to compare sedative effect during postoperative period and duration of postoperative analgesia. The secondary objective of the study was to compare intra-operative hemodynamics and any adverse events in a patient population of healthy adults posted for elective laparoscopic surgery performed under balanced general anaesthesia.

MATERIALS AND METHODS

Study design

This was a comparative, observational, and prospective study conducted in SVP Hospital, NHL Municipal Medical College, Ahmedabad, India. After receiving an approval letter from ethical committee of the institute, 50 patients planned for the laparoscopic surgery were enlisted in the study. The sample size was obtained based on previous studies. Patients between 18 to 60 years age group, ASA grade of I / II posted for elective surgeries under general anaesthesia like laparoscopic appendectomy, laparoscopic hernia repair, and laparoscopic cholecystectomy were included in this study. The duration of surgery was approximately 2 hours. This study excluded patients less than 18 years and more than 60 years of age; an ASA grade of III / IV; pregnant females; patients having hypersensitivity to thiopentone, fentanyl, or butorphanol; or patients with known systemic diseases such as uncontrolled diabetes mellitus, uncontrolled hypertension, altered coagulation profile, or deranged renal function.

All the patients in this study received general anaesthesia as per routine protocol of the institute by the consultant anaesthesiologist of the hospital and all the parameters were observed and noted. Hospital had 2 operation theatres allocated for laparoscopic surgeries. Patients scheduled for surgery in OT-1 received butorphanol and OT-2 received fentanyl and divided into two groups, Group B and Group F, respectively.

- Group-F: received inj. fentanyl (2 µg/kg) intravenously.
- Group-B: received inj. butorphanol (20 µg/kg) intravenously.

Prior to scheduled surgery, all the patients had a thorough pre-anaesthetic assessment following protocol of the institute. They were well-informed about the nature of study, potential consequences, and Visual Analogue Scale (VAS) for assessment of intensity of pain. Well-informed and written consent was obtained. Nil per oral for 8 hours was kept in all patients. Peripheral venous cannulation was established using 18 / 20 G intravenous cannula, and intravenous fluid was initiated at 4 ml/kg/hr rate. Basal parameters such as blood pressure, oxygen saturation, and heart rate were noted using a pulse oximeter, non-invasive blood pressure monitor, and electro-cardiography monitor.

They received inj. ondansetron (0.08 mg/kg i.v.), inj. glycopyrrolate (0.004 mg/kg i.v.), and inj. diclofenac sodium (1.5 mg/kg i.v.) as premedication. Subsequently, either inj. butorphanol (20 µg/kg i.v.) or inj. fentanyl

(2 µg/kg i.v.) was administered intravenously over 30 seconds, with concurrent monitoring of blood pressure and heart rate. Pre-oxygenation with the 100% O₂ for the duration of 3 minutes was done, followed by the induction with inj. thiopentone sodium (6-8 mg/kg i.v.). Following confirmation of mask ventilation, inj. succinylcholine (1-2 mg/kg i.v.) was administered. A laryngoscopy was done within 90–120 seconds and blood pressure and heart rate were recorded thereafter. Heart rate and B.P. were monitored 5 minutes after intubation and afterwards at 30-minute interval till end of surgery. An adequate depth of anaesthesia was maintained by using sevoflurane and 50% N₂O in oxygen, as assessed by pulse rate and blood pressure with controlled ventilation. Injection vecuronium was used to maintain muscle relaxation, administered at loading-dose (0.08 mg/kg i.v.), followed by maintenance dose (0.02 mg/kg i.v.) as required. Following completion of the surgery, patients underwent a complete neuro-muscular blockade reversal by inj. glycopyrrolate (0.008 mg/kg i.v.), inj. neostigmine (0.06 mg/kg i.v.). After the establishment of adequate spontaneous and regular breathing, as well as the restoration of adequate muscle tone, power, and all protective reflexes, patients were extubated. They were then shifted to the postoperative area, where they were observed for sedation (until Ramsay's score 3 was achieved) as well as for pain and analgesic requirements. Inj. tramadol 1 mg/kg i.v. administered for rescue analgesia upon reaching a visual analogue score (VAS) of 4. Any side effects of drugs or complications were identified, documented, and analysed.

The visual analogue scale (VAS) was employed to quantify pain relief, ranging from 0 -no pain to 10 -worst pain. Ramsay's sedation score was used to assess sedation postoperatively as follows:

- 1- awake; agitated, restless, or both.
- 2- awake; cooperative, oriented, and tranquil.
- 3- awake but responds to commands only.
- 4- asleep; brisk response to a light glabellar tap or loud auditory stimulus.
- 5- asleep; sluggish response to a light glabellar tap or loud auditory stimulus.
- 6- asleep; no response to a light glabellar tap or loud auditory stimulus.

Statistical analysis

Statistical analysis was conducted by the paired and unpaired student t-tests and the Chi square test by using EPI INFO software, with a significance threshold set at 'p' value <0.05.

RESULTS

Table-1 presents demographic information of both groups. Statistical analysis revealed that the mean weight and mean age of Group-B and Group-F did not exhibit significant differences statistically. Similarly, comparison of sex and ASA grade between the two group using the Chi Square test yielded statistically insignificant results.

Parameters	GROUP-B	GROUP-F	P-VALUE
Age In Years	41.20±10.92	38.64±12.41	0.59
Weight In Kg	60.25±8.12	61.12±8.62	0.71
Sex (Male:Female)	13:12	16:9	0.39
Asa Grade (I:II)	21:4	19:6	0.47

Table-2 displays the distribution of surgical procedures performed in each group. Group-B comprised 2 laparoscopic hernia repair, 6 laparoscopic appendicectomy, and 17 laparoscopic cholecystectomy, while Group-F comprised 1 laparoscopic hernia repair, 6 laparoscopic appendicectomy, and 18 laparoscopic cholecystectomy. The p-value obtained from the chi-square test was 0.834, indicating no statistically significant difference between two groups regarding different surgeries.

Surgery Name	GROUP-B	GROUP-F	P-VALUE
Laparoscopic Cholecystectomy	17(68%)	18(72%)	0.834
Laparoscopic Appendicectomy	6(24%)	6(24%)	
Laparoscopic Hernia Repair	2(2%)	1(4%)	

Table-3 and table-4 demonstrate the comparison of stress responses to intubation and intraoperative hemodynamic changes between both groups, assessed by the heart rate and mean arterial blood pressure.

Following administration of butorphanol or fentanyl, heart rate and mean arterial blood pressure exhibited greater reductions in the Group-F compared to Group-B. The p-value was <0.001 (statistically extremely significant) during induction, during laryngoscopy, and at 5 minutes and 30 minutes post-intubation. These results indicate significant statistical difference between two groups. Specifically, fentanyl (2 µg/kg) intravenously demonstrated superior attenuation of hemodynamic response during induction and laryngoscopy compared to butorphanol (20 µg/kg) intravenously. However, statistically insignificant differences observed in hemodynamic parameters between both groups during intraoperative course.

TABLE- 3: COMPARISON OF HEART RATE AT DIFFERENT TIME PERIOD

Time Period	Group-B	Group-F	P- Value
Pre-Operative	125.00±8.21	127.16±7.76	0.323
After Butorphanol/Fentanyl	126.72±7.776.48	115.00±8.08	<0.001
At Induction	124.04±9.77	111.76±8.40	<0.001
At Laryngoscopy	129.76±11.48	112.84±9.54	<0.001
5 Min After Intubation	126.76±13.77	112.40±8.03	<0.001
30 Min	124.12±5.50	118.04±6.20	<0.001
1 Hr	127.00±5.65	122.00±5.65	0.365
1.5 Hr	120.33±4.04	123.75±5.36	0.272
2 Hr	124.52±6.48	122.64±4.63	0.233
At Extubation	125.60±8.88	125.40±3.86	0.914

TABLE-4: COMPARISON OF MEAN ARTERIAL BLOOD PRESSURE AT DIFFERENT TIME PERIOD

Time Period	GROUP-B	GROUP-F	P- VALUE
Pre-Operative	93.76±5.63	94.96±5.72	0.267
After Butorphanol/Fentanyl	95.28±6.26	84.52±5.97	<0.001
At Induction	93.72±8.60	83.56±4.27	<0.001
At Laryngoscopy	102.12±10.05	85.88±4.15	<0.001
5 Min After Intubation	98.32±10.33	85.40±3.81	<0.001
30 Min	95.72±3.52	88.80±6.16	<0.001

1 Hr	109.00±7.07	100.00±1.41	0.694
1.5 Hr	102.67±8.62	96.83±3.85	0.046
2 Hr	96.12±4.24	94.96±4.45	0.380
At Extubation	99.88±5.90	95.32±4.21	0.002

Figure-1 illustrates that post-operative pain, assessed by VAS (visual analogue scale), was significantly low in Group-B in comparison to Group-F. Patients in Group-F reached a VAS score of 4 approximately 3 hours postoperatively, while those in Group-B took around 6 hours to reach the same score.

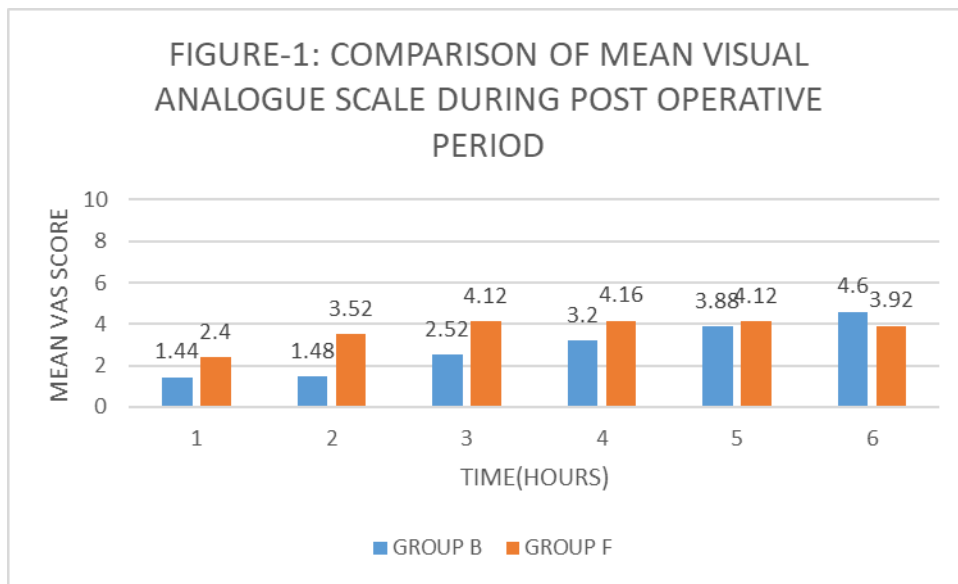


Figure 1

Table-5 highlights that 16 patients in Group-F needed the first rescue analgesia during 1st hour after the surgery, whereas nobody in Group-B required rescue analgesia during this time frame. Additionally, all 25 patients in Group-F needed their first rescue analgesia dose in a span of 3 hours after surgery, whereas in Group-B, it took around 6 hours.

Time Interval	GROUP-B	GROUP-F
0.5 Hour	0	9

1 Hour	0	7
1.5 Hour	1	3
2 Hour	3	4
3 Hour	4	2
4 Hour	2	0
5 Hour	5	0
6 Hour	10	0

In this study, postoperative sedation among patients in the postoperative room was evaluated by the Ramsay's sedation score. Figure-2 shows, the mean score for sedation was notably greater in Group-B during initial 1 hour postoperatively, a finding that was extremely significant. However, subsequent mean scores for sedation were comparable between the two groups. Notably, although Group-B patients exhibited significant sedative effect during the first hour after surgery, no one experienced desaturation ($SpO_2 < 94\%$ on room air) which required any additional intervention.

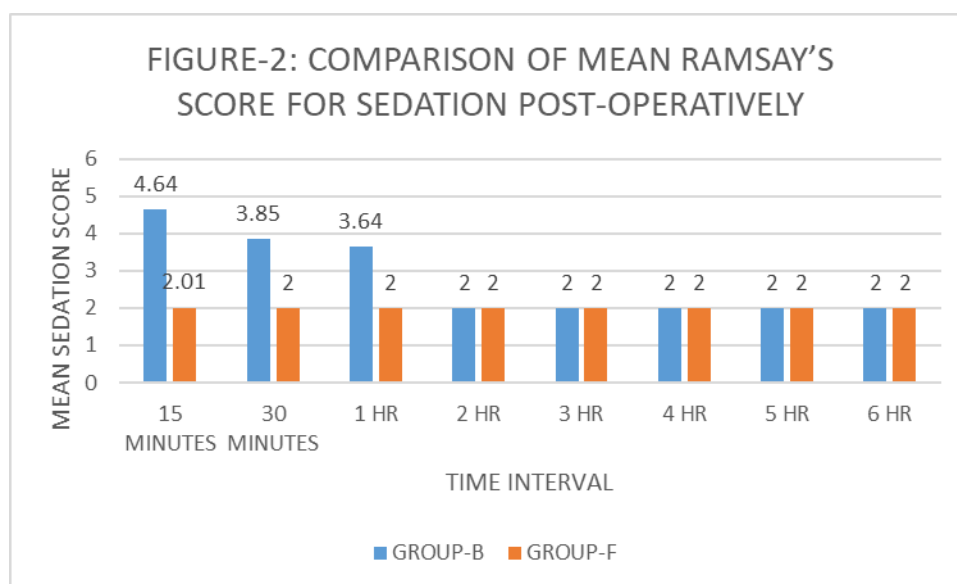


Figure 2

As demonstrated in Table-6, 8 patients in Group-B reported nausea, with 3 patients had vomiting, while 7 patients in Group-F reported nausea, with 3 patients had vomiting. Therefore, the occurrence of side effects was comparable among both group. Inj. ondansetron effectively alleviated these symptoms.

Symptoms	GROUP-B	GROUP-F
Nausea	8	7
Vomiting	3	3

DISCUSSION

Two opioids, butorphanol and fentanyl, were included as a part of balanced anaesthesia and compared in this study, aiming to identify their efficacy in inhibiting undesirable responses to different stimuli, minimizing additional requirements, preserving cardiovascular function, and providing postoperative pain relief with minimum side effect. Butorphanol and fentanyl, both demonstrated ability to reduce the dose of other anaesthetics, has hemodynamic stability, provide analgesia and sedation, and were cost-effective. Therefore, fentanyl and butorphanol were selected for assessing their analgesic and post-operative recovery characteristics.

Many opioid agents are available. Every opioid has its own pros and cons depending on its pharmacokinetic and pharmacodynamics. So far only few studies have compared butorphanol and fentanyl. Previous studies have used different doses of butorphanol (20 -40 µg/kg i.v.) and fentanyl (1-3 µg/kg i.v.).

Our findings align with previous research. Pandit et al. reported greater drowsiness in the group butorphanol and a greater incidence of post operative pain in group fentanyl when compared butorphanol (40 µg/kg i.v.) and fentanyl (2 µg/kg i.v.). In each group, 40% of patients needed antiemetic therapy. ⁽⁵⁾

Similarly, Wetchler concluded that butorphanol (20 µg/kg i.v.) and fentanyl (2 µg/kg i.v.) seem appropriate as narcotic analgesics before induction, while a higher dose of butorphanol (40 µg/kg i.v.) led to longer durations of adverse effects such as nausea and dizziness and time to achieve APARS of 10- delayed discharge indicates that butorphanol (40 µg/kg) seems unsatisfactory. ⁽⁶⁾

Rao Satyanarayana et al. compared fentanyl v/s butorphanol in laparoscopic surgeries. 50 patients of ASA I/II were randomised and divided into fentanyl and butorphanol groups. Compared to butorphanol, fentanyl group had observed rise in blood pressure following intubation, which was significant. ⁽⁷⁾

R.K. Verma et al. compared fentanyl v/s butorphanol in TIVA (total intravenous anaesthesia) in lap cholecystectomy. Patients were given an injection of either fentanyl (2 µg/kg i.v.) or butorphanol (25 µg/kg i.v.). Patients received propofol for induction. Anaesthesia was maintained by infusion of propofol and O₂. Compared to fentanyl, butorphanol was found to be more effective in suppressing the stress response during laryngoscopy and intubation. ⁽⁸⁾

In our study we compared butorphanol 20 µg/kg and fentanyl 2 µg/kg. As per our observation fentanyl was more potent in suppressing stress response to laryngoscopy and intubation. These results are in accordance with the study conducted by Rekhi BK et al. They compared butorphanol, nalbuphine and fentanyl in attenuating hemodynamic stress response in lap cholecystectomy. Butorphanol (25 µg/kg i.v.) and fentanyl (2 µg/kg i.v.) were administered to patients. Fentanyl was highly efficient than butorphanol in blunting hemodynamic stress response, whereas butorphanol had good postoperative analgesic and sedative properties with no depression of respiration or side effects such as nausea, vomiting. ⁽⁹⁾

Patel, H.M. and Kantharia, B.N. compared fentanyl and butorphanol as premedication in general anaesthesia, and they found that inj. butorphanol (20 µg/kg i.v.) had more hemodynamic stability during intubation, prolonged period of analgesia without causing more sedation, and less adverse events when compared to inj. fentanyl (1 µg/kg i.v.). ⁽¹⁰⁾ Here again, results are contrary to our observation as they have used half dose of fentanyl compared to our study.

Philip, B.K., Scott, D.A., and Freiburger compared butorphanol 20 µg/kg and fentanyl 1 µg/kg in laparoscopic surgery. In their study, they found significantly less hemodynamic alteration in group butorphanol immediately after intubation in comparison to group fentanyl, and patients who received butorphanol experienced more sedation than fentanyl. However, the need for postoperative analgesics was the same for both opioid groups. ⁽¹¹⁾

Similarly, Ahire, S.S., and Laheri, V. compared butorphanol (20 µg/kg i.v.) and fentanyl (1 µg/kg i.v.). Butorphanol produced longer duration of analgesia, hemodynamic stability, and good sedation without any postoperative respiratory depression, while fentanyl had insufficient effect on blunting the stress response during laryngoscopy and decreasing anaesthetic drugs requirement. ⁽¹²⁾

From the above studies we concluded that higher doses of butorphanol ($> 20 \mu\text{g}/\text{kg}$) resulted in prolonged sedation while low dose of fentanyl ($< 2 \mu\text{g}/\text{kg}$) was not sufficient to suppress the stress response to intubation. So in our study we have chosen the dose of butorphanol ($20 \mu\text{g}/\text{kg}$) and fentanyl ($2 \mu\text{g}/\text{kg}$).

From table 4 and 5 it was observed that the pulse and mean blood pressure were intraoperatively stable in both the groups while fentanyl was superior in suppressing stress response to laryngoscopy and intubation.

In this study, postoperative sedation among patients in the postoperative room was evaluated by the Ramsay's sedation score. Figure-2 shows, the mean score for sedation was notably greater in Group-B during initial 1 hour postoperatively, a finding that was extremely significant. None of the patient in group B had experienced desaturation in spite of higher sedation score in first post operative hour. This can be explained by butorphanol's kappa agonist effect. Kappa receptor is thought to mediate analgesia and sedation but not respiratory depression. Post-operative side effects like nausea and vomiting were comparable in both the groups and were statistically insignificant.

Thus in our study, observations suggest that butorphanol is an acceptable substitute to fentanyl for use as a component of balanced anaesthesia. However, observations in our study were from healthy patient population undergoing laparoscopic surgery. Whether these changes would occur or be beneficial in sicker patients or patients undergoing other types of surgery cannot be determined from this data. Other limitation of this study is that, it cannot determine the effect of this two opioid drug in opioid addicted patients.

CONCLUSION

Based on our study findings, we concluded, butorphanol $20 \mu\text{g}/\text{kg}$ is a suitable substitute to fentanyl $2 \mu\text{g}/\text{kg}$ in laparoscopic surgery as balanced anaesthesia. Butorphanol demonstrates several advantages, including prolonged analgesia, effective sedation and absence of respiratory depression in postoperative period. However, it's important to note that fentanyl exhibits superior attenuation of the hemodynamic response during induction and laryngoscopy compared to butorphanol. Despite this difference, our study found insignificant difference in hemodynamic parameters among both groups during intraoperative course.

To summarize, while fentanyl may offer advantages in certain aspects of intraoperative management, such as hemodynamic stability, butorphanol emerges as a compelling option for providing effective pain relief and promoting smooth post-operative recovery for use in anaesthesia for laparoscopic surgery.

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