



## Randomised comparative study of Fentanyl versus Butorphanol on recovery characteristics and analgesic efficacy under total intravenous anaesthesia for laparoscopic cholecystectomy.

### KEYWORDS

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**ABSTRACT** Background: The study aimed to compare the analgesic efficacy and recovery characteristics of Fentanyl and Butorphanol under TIVA (Total Intravenous Anesthesia) for laparoscopic cholecystectomy and find out the better analgesic along with Propofol.

*Patients and methods:* Seventy two patients of ASA grade I and II of either sex in the age group of 20-60 years undergoing laparoscopic cholecystectomy were allocated to one of the two groups of 36 each. Group I received Inj. Fentanyl in the doses of 2 µg/kg while patients in group II received Butorphanol in doses of 25µg/kg. All the patients were induced with Inj. propofol 2 µg/kg and intubated with 100 µg/kg Vecuronium. Anaesthesia was maintained by Oxygen, Nitrous oxide and Propofol. Intra-operative hemodynamic parameters (HR, MAP) were noted. Recovery time, post operative sedation, duration of analgesia using visual analogue pain score and post operative complications were noted. Results were compared among the groups using the unpaired t test and chi square test. In all cases,  $p < 0.05$  was considered statistically significant.

*Results:* Demographic characteristics as well as duration of surgery, baseline pulse rate, systolic blood pressure and diastolic blood pressure were comparable in both the groups. Intraoperative and post operative hemodynamics in butorphanol group were more stable when compared to Fentanyl group. All the patients in butorphanol group were sedated but arousable and had analgesia for 3 hours post operatively while in case of Fentanyl group, patients required rescue analgesia within 30 minutes after extubation and patients were not sedated. No significant intra operative complication was observed in both the groups. The incidence of nausea and vomiting was slightly more in butorphanol group. No incidence of respiratory depression was noted in both the groups.

*Conclusion:* Both Butorphanol and Fentanyl are cardio stable. Less haemodynamic variations are observed in the Butorphanol group. Recovery time in Butorphanol group was more (5.86 min) when compared to that in Fentanyl group (3.33 min) which is not clinically significant. Post operative sedation and analgesia remained for longer duration in Butorphanol group. Thus we can conclude that butorphanol is better alternative to Fentanyl in terms of haemodynamic stability and prolonged analgesia.

### Objectives of the study

Primary—To compare the analgesic efficacy and recovery characteristics of Fentanyl and Butorphanol

Secondary—To compare the incidence of nausea, vomiting, sedation and respiratory depression

### Material & Method

Study population

Patients of 20 to 60 yrs posted for laparoscopic cholecystectomy surgery

### Sample size & sample technique

Sample size of the study population is 72. Here my study parameter is analgesic efficacy. In order to achieve the difference in mean pain scores between the two groups to be significant, with 5% (0.05) level of significance and 90% power of the test, the sample size is 72. Approximately 80 patients were enrolled in the study to arrive at 72 evalu-

able cases assuming a dropout rate of 10%. These 72 patients were divided into two groups of 36 each.

### Data collection technique and tools

Data was collected by noting the demographic details(Age, Sex, ASA physical status, duration of surgery), pre operative vital parameters (BP, PR and SpO<sub>2</sub>), intraoperative vital parameters (baseline, post intubation, post extubation), recovery time, and in the post operative period (pain scores, sedation score, occurrence of complications like nausea, vomiting, respiratory depression

### Data analysis

The collected data was summarized by calculating the mean and standard deviation and presented in the form of tables and diagrams. Paired't' test and analysis of variance for repeated measures were used for the analysis of significance. Chi Square test was used to obtain other possible associations.

### Discussion

#### DURATION OF SURGERY, RECOVERY TIME AND DURATION OF ANALGESIA

	Group B	Group F	t Value	p Value	Statistical Significance
Duration of Surgery (Min)	71.66 ± 16.38	72.08 ± 20.22	-0.09	0.78	Not significant
Recovery Time (Min)	5.86 ± 1.31	3.33 ± 0.89	9.55	< 0.0001	Statistically significant
Duration of Analgesia(Min)	248.97 ± 45.98	83.97 ± 19.40	19.83	< 0.0001	Statistically significant

The mean duration of surgery in group B was  $71.66 \pm 16.38$  min and in group F was  $72.08 \pm 20.22$  min, which was comparable ( $p > 0.05$ ). Recovery time in group B was  $5.86 \pm 1.31$  and in group F was  $3.33 \pm 0.89$ , which was statistically highly significant ( $p < 0.0001$ ). The duration of analgesia in group B was  $248.97 \pm 45.98$  and in group F was  $83.97 \pm 19.40$  which was statistically highly significant ( $p < 0.0001$ ).

#### PAIN SCORE—VISUAL ANALOGUE SCALE

		GROUP -B	GROUP -F	P Value
Post Operative	Immediate	$0.58 \pm 0.73$	$4.30 \pm 0.82$	$<0.001$
	15 min	$1.50 \pm 0.84$	$4.77 \pm 0.42$	$<0.001$
	30 min	$2.75 \pm 0.65$	$5 \pm 0$	$<0.001$
	1 hour	$3.22 \pm 0.59$	$5 \pm 0$	$<0.01$
	2 hour	$3.72 \pm 0.84$	$5 \pm 0$	$<0.01$
	3 hour	$4.66 \pm 0.47$	$5 \pm 0$	$>0.05$
	4 hour	$5 \pm 0$	$5 \pm 0$	$>0.05$

VAS SCORE<sup>35</sup>, rescue analgesia- inj. Tramadol hydrochloride 1.5mg/kg IV.

The duration of analgesia was significantly more in group B in comparison to group F. (After 2 hours postoperatively VAS of group B is  $3.72 \pm 0.84$  and group F is  $5 \pm 0$  ( $P < 0.001$ )).

All the patients in group B were having analgesia for 3 hours post-operatively while in case of group F patients required rescue analgesia within 30 min after extubation.

Recovery time in group B ( $5.86 \pm 1.31$ ) is more than that in group F ( $3.33 \pm 0.89$ ).

#### SEDATION SCORE

	GROUP -B	GROUP -F	P Value
Immediate	$3.36 \pm 0.53$	$2.27 \pm 0.44$	$<0.001$
15 min	$3.08 \pm 0.36$	$2.19 \pm 0.40$	$<0.001$
30 min	$2.88 \pm 0.32$	$2 \pm 0$	$<0.001$
1 hour	$2.41 \pm 0.5$	$2 \pm 0$	$<0.05$
2 hour	$2 \pm 0$	$1 \pm 0$	$>0.05$
3 hour	$2 \pm 0$	$1 \pm 0$	$>0.05$
4 hour	$2 \pm 0$	$1 \pm 0$	$>0.05$

All the patients in group B were sedated but arousable for upto 2 hours post-operatively while in case of group F patients were not sedated.

#### POST-OPERATIVE COMPLICATIONS

	GROUP -B		GROUP -F	
	NO.	%	NO.	%
NAUSEA	2	5.5%	1	2.7%
VOMITING	1	2.7%	0	0%
RESPIRATORY DEPRESSION	-	-	-	-

No significant intra-operative complication was observed in both the groups. The incidence of nausea and vomiting was more in case of group B (nausea-5.5% and vomiting-2.7%) as compared to group F (nausea-2.7% and vomiting-0%). No incidence of respiratory depression is noted in both the groups.

#### Salient findings

- In my study both Fentanyl and Butorphanol group were comparable with respect to demographic data (Age, Sex, ASA physical status, duration of surgery)
- The mean duration of surgery in group B was  $71.66 \pm 16.38$  min and in group F was  $72.08 \pm 20.22$  min, which was

comparable.

- Base-line pulse rate, systolic blood pressure and diastolic blood pressure were comparable in both the groups.
- Intraoperative and post operative haemodynamics in group B are more stable when compared to group F.
- All the patients in group B were sedated but arousable and had analgesia for 3 hours post-operatively while in case of group F, patients required rescue analgesia within 30 min after extubation and patients were not sedated.
- No significant intra-operative complication was observed in both the groups. The incidence of nausea and vomiting was more in case of group B (nausea-5.5% and vomiting-2.7%) as compared to group F (nausea-2.7% and vomiting-0%). No incidence of respiratory depression is noted in both the groups.

### Conclusions

Both Butorphanol and Fentanyl are cardio-stable. When compared to fentanyl group, less haemodynamic variations are observed in the butorphanol group. Recovery time in butorphanol group (5.86 min) when compared to that in fentanyl group (3.33 min) is approximately 2 to 3 minutes more. Though the difference in recovery time is statistically significant it can be clinically acceptable. Post-operative sedation remained for longer duration in Butorphanol group up to 1 hour when compared to fentanyl group, but is

not associated with any respiratory depression. Analgesia in butorphanol group patients lasted for 120 to 150 minutes more when compared to that in fentanyl group which is statistically very highly significant. Butorphanol group showed more incidences of side effects like nausea and vomiting, but they are easily amenable to rescue antiemetic.

### Recommendations

Butorphanol at a dose of 25 mcg/kg is a better alternative to Fentanyl (2 mcg/kg) for use in laparoscopic surgeries because of its ability to produce haemodynamic stability and prolonged analgesia.

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