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Original Article

A Comparative Analysis of Epidural Butorphanol and Fentanyl for Post-Operative Analgesia in Lower Abdominal Surgeries.

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ABSTRACT

BACKGROUND: Epidural analgesia is being extensively used for post-operative pain relief and when opioids are combined with local anesthetics, it results in better postoperative analgesia, therefore we conducted prospected comparative double blind randomised study using epidural Butorphanol and Fentanyl for post-operative analgesia in Lower Abdominal surgeries.

METHODS: A comparative double blind randomized study with 60 patients randomized into two groups with 30 in group A in which epidural Fentanyl (50 microgram) followed by top up doses of 15 micrograms was administered for post-operative analgesia and 30 patient in group B in which epidural Butorphanol (2mg) followed by top up doses of 0.5 mg was administered for post-operative analgesia, was undertaken to study the duration of analgesia, quality of analgesia and side effects.

RESULTS: In our present study mean age sex ratio, weight and duration of surgery of both group patients were statistically similar. Duration of post-operative analgesia was longer with epidural Butorphanol as compared to fentanyl, both Butorphanol and Fentanyl causes sedation but it was higher in epidural butorphanol at all-time intervals. Pruritis, nausea and vomiting was more in fentanyl group.

CONCLUSION: We compared epidural butorphanol and epidural fentanyl for post-operative analgesia and observed that butorphanol is more effective analgesic with lesser side effects as compared to fentanyl.

KEYWORDS: Butorphanol, Epidural Analgesia, Fentanyl.

INTRODUCTION

Mankind has been seeking relief from pain since time immemorial. Invention of hollow needle by Alexender Wood (1855) opened the door for use of parental analgesia. At present there are various modalities available for post-operative pain management. Oral and intramuscular agents being simplest and most commonly used and reasonably effective for majority of patients. Intravenous infusion and Patient Controlled Analgesia allows more rapid adjustment of dosage and less fluctuation in blood levels. Approximately 50% patients still experience inadequate pain relief after surgery. It has finally been appreciated that cause of such suffering is not effective analgesia but the inappropriate manner in which these agents are administered. Thus in recent years there has been shift from the search of more perfect analgesic agent to the use of more perfect route of administration and delivery system. This has resulted in epidural analgesia being extensively used for post-operative analgesia, therefore in this study we are using Butorphanol and Fentanyl through epidural route for post-operative analgesia.

Fentanyl, an mu receptor agonist, has analgesic potency greater than morphine and respiratory depressant effect of fentanyl is less pronounced and of shorter duration as compared to other opioid.

Butorphanol being a mixed agonist and antagonist non-narcotic opioid analgesic, Its potency has been found greater than morphine and pethidine. Butorphanol unlike morphine exhibit a ceiling effect of respiratory depression.

Henceforth present study was conducted to access the safety and efficacy of epidural butorphanol and epidural fentanyl for post-operative analgesia.

MATERIALS AND METHODS

Approval was obtained from hospital ethic committee prior to start of study and all participating patients gave informed consent. The present study consists of 60 cases

undergoing Lower Abdominal Surgeries under Epidural anaesthesia.

Study Population

The present double blind study was conducted on about 60 patient aged between 20-60 years, belonging to ASA physical status class I or class II and scheduled for lower abdominal procedure to assess efficacy and safety of postoperative analgesia with epidural butorphanol when compared with epidural fentanyl.

Exclusion Criteria

Patients with Bleeding Disorders, systemic diseases like Diabetes, Hypertension, Anaemias, Respiratory, Cardiac, Renal, or Hepatic insufficiency and those with known hypersensitivity to local anaesthetics were excluded from study.

STUDY PROCEDURE

Premedication

All the patients were premedicated with Tab Diazepam 10mg orally night before surgery. No other premedication was administered before the start of anaesthetic procedure.

Procedure

The Pulse rate, Blood pressure were recorded before starting the case. After setting up a 18 G cannula patient was preloaded with 500 ml of Ringer lactate solution. Than patient was placed in left lateral position and under strict aseptic precaution, the epidural space was identified with a 18G Tuohy needle through L2-L3 interspace, using "loss of resistance" technique. An 18 G epidural catheter was threaded through the epidural space for up to 4cm. After negative aspiration for blood and cerebrospinal fluid, 3 ml of 1.5 % of Lignocaine 1 in 200000 adrenaline was given as a test dose. Time of injection was noted, Epidural secured in position and patient turned to supine position. After 3 minutes the intrathecal or intravascular placement was ruled out, than a standard dose of 15 ml of 1.5% Lignocaine with 1 in 200000 Adrenaline was injected through the epidural catheter. Then if needed a graded doses of 1ml to 5ml was given and blocked assessed and stabilised to T6 level, Sensory block was assessed by pinprick method and time of onset of blockade was noted. The surgeries were completed up to 1 to 2 hours after initiation of epidural blockade.

In the post-operative period, at VAS of > 4 patient in group A was administered 50 micrograms of fentanyl dissolved in 9ml of NS (total volume 10ml) and in group B 2mg of Butorphanol dissolved in 9ml of NS (total volume 10 ml) through the epidural catheter for pain relief. Incremental doses of either fentanyl (15 micrograms in 10 ml of NS) or butorphanol 0.5 mg in 10 ml of NS) were administered whenever patient had VAS >4. Timing of incremental doses, interval between injections and total doses given in 24 hours were recorded. If analgesia was inadequate even after two consecutive incremental epidural doses given 20 – 30 minutes apart, patients were given rescue medication in form of Inj. Diclofenac sodium 75 mg intramuscular and excluded from study. Patients were observed for 24 hours postoperatively.

After giving first dose of epidural opioid following variable were assessed at 1 hour, 2 hours, 4 hours, 8 hours, 12 hours and 24 hours :

A) Sedation score 0 = Alert conversant, 1 = mildly sedated, 2 = moderately sedated, 3 = asleep but arousable, 4 = asleep but not arousable.

B) Pulse rate and Blood pressure.

C) Monitoring of SpO2 was done to evaluate effects of epidural analgesics on respiration.

D) Side effects like nausea, vomiting, retention of urine , pruritis, if any were recorded.

E) At the end of 24 hours observation period, overall assessment of pain relief (good/moderate/poor) by patients was done.

At the end of study, all data were compiled and analysed statistically using paired unpaired "t" tests and chi square test.

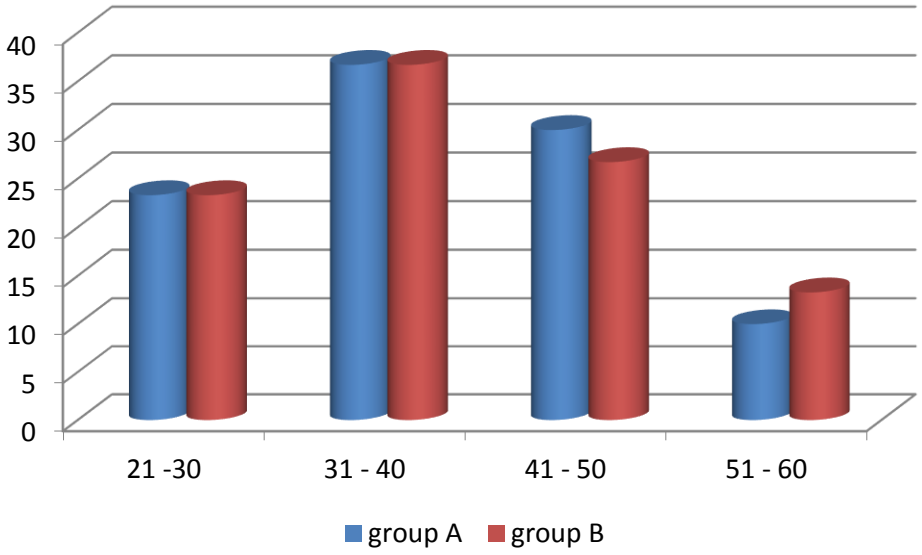
RESULTS

All patients were successfully enrolled in our study. Patients were found to be comparable with respect to demographic profile and were found to statistical similar with regards to age(p = 0.768), sex (p = 0.602), weight (Group A =63.17 Kg and Group B= 61.00 Kg) and duration of surgery (Group A = 83. 5 min. and Group B= 82.33 min) in both groups. [Table 1 – 4]

Table 1: Comparison of age in years.

Age in years	Group A		Group B	
	Number	percentage	Number	Percentage
21 – 30	7	23.3	7	23.3
31 – 40	11	36.7	11	36.7
41 – 50	9	30.0	8	26.7
51 – 60	3	10.0	4	13.3
Total	30	100.0	30	100.0
Mean +/- SD	38.30 +/-8.41		39.00 +/- 9.82	

Samples are age matched with P = 0.768



X axis – Age in years, Y axis – Percentage

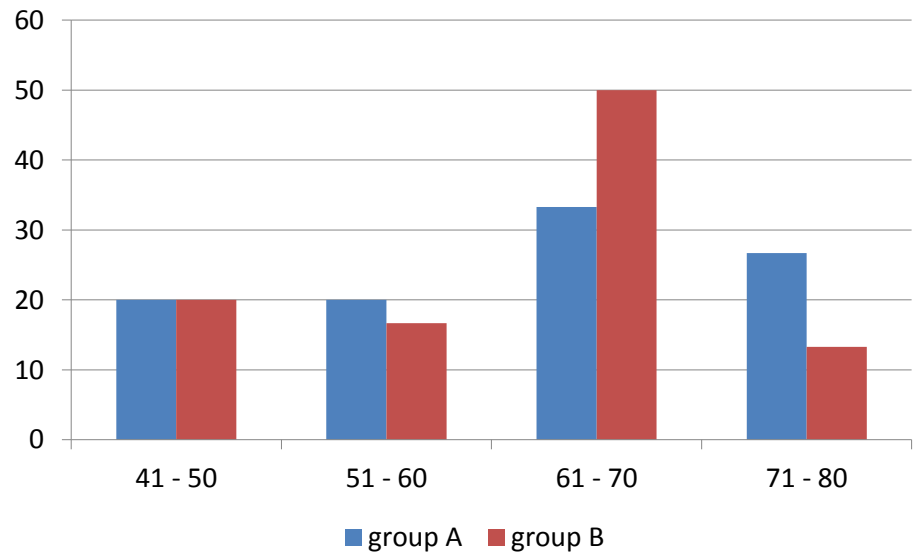
Table 2: Gender distribution of patients studied

Gender	Group A		Group B	
	number	percentage	number	Percentage
Male	16	53.3	18	60.0
Female	14	46.7	12	40.0
Total	30	100.0	30	100.0

Samples are gender matched with P = 0.602

Table 3: Comparison of Weight distribution

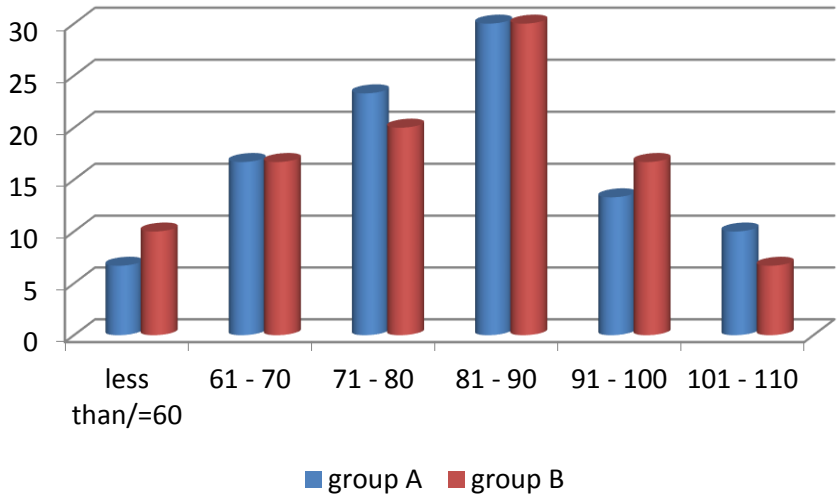
Weight (kg)	Group A		Group B	
	number	percentage	number	Percentage
41 -50	6	20.0	6	20.0
51 -60	6	20.0	5	16.7
61 -70	10	33.3	15	50.0
71 -80	8	26.7	4	13.3
Total	30	100.0	30	100.0
Mean +/- SD	63.17+/-11.40		61.00+/-9.71	



X axis: Weight in kg, Y axis: Percentage

Table 4: Comparison of duration of surgery (min)

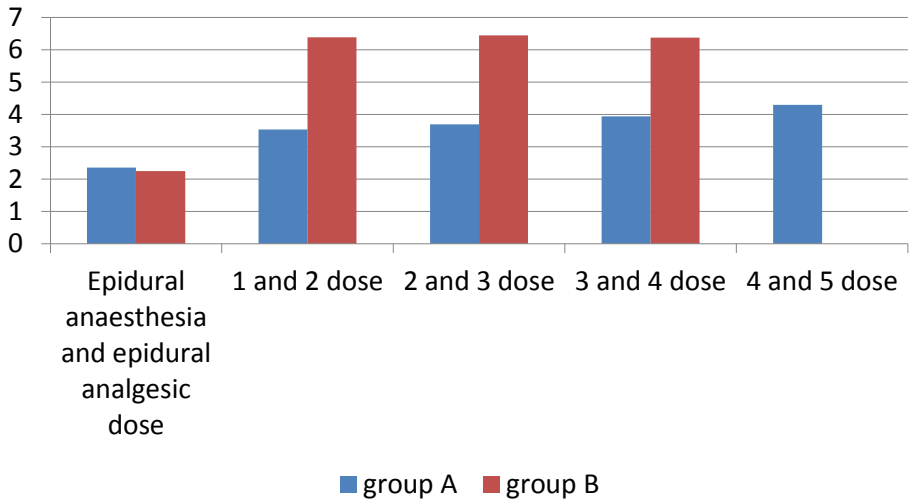
Duration of surgery (min)	Group A		Group B	
	number	percentage	number	Percentage
Less than/= 60	2	6.7	3	10.0
61 - 70	5	16.7	5	16.7
71 - 80	7	23.3	6	20.0
81 - 90	9	30.0	9	30.0
91 - 100	4	13.3	5	16.7
101 – 110	3	10.0	2	6.7
Total	30	100.0	30	100.0
Mean +/-SD	83.50+/-14.14		82.33+/-14.25	



X axis – duration of surgery, Y axis – percentage

Table 5: Comparison of time interval in hours between epidural analgesic doses between two groups.

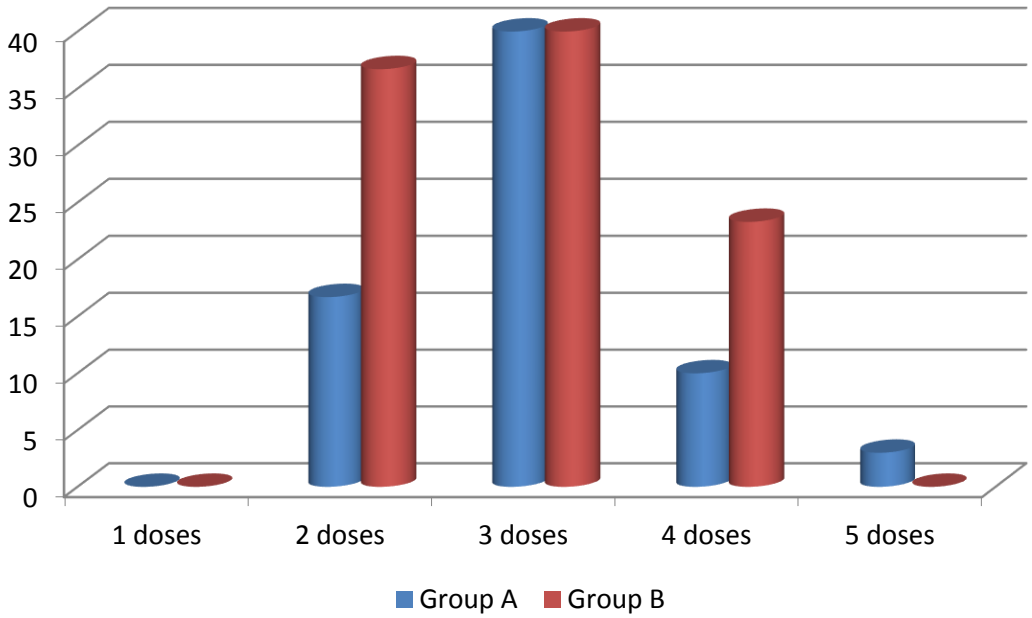
Time interval between Epidural Analgesic doses	Group A	Group B	Significance
Epidural anaesthesia and epidural analgesic dose	2.36+/-0.36	2.25+/-0.25	t=1.313;p=0.194
1 and 2 dose	3.53+/-0.73	6.39+/-0.69	t=15.583;p < 0.001
2 and 3 dose	3.69+/-0.43	6.44+/-0.62	t=17.302;p < 0.001
3 and 4 dose	3.94+/-0.44	6.38+/-0.47	t=11.512;p < 0.001
4 and 5 dose	4.34+/-0.23		



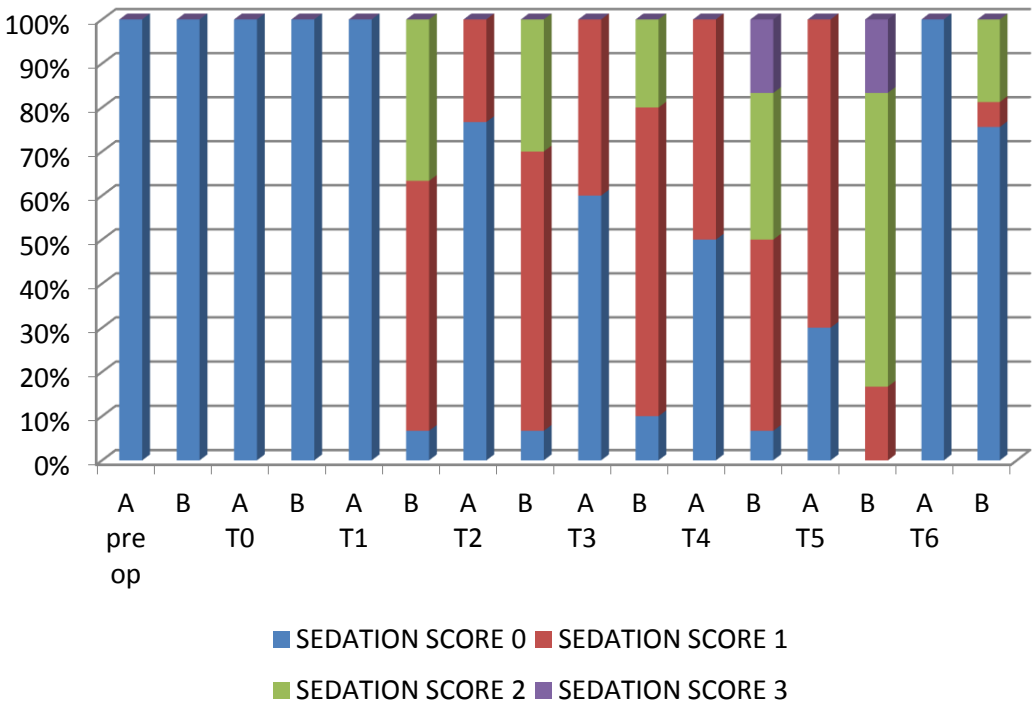
X axis – Number of epidural doses, Y axis – Time in hours

Table 6: Comparison of number of doses between two groups

Number of epidural doses	Group A	Group B	P value
1 doses	0	0	--
2 doses	5(16.7%)	11(36.7%)	0.080+
3 doses	12(40%)	12(40%)	1.000
4 doses	10(33.3%)	7(23.3%)	0.390
5 doses	3(10%)	0	0.237



X axis-- number of epidural doses, Y axis – percentage



SEDATION SCORE

X axis – time in hours, Y axis -- percentage

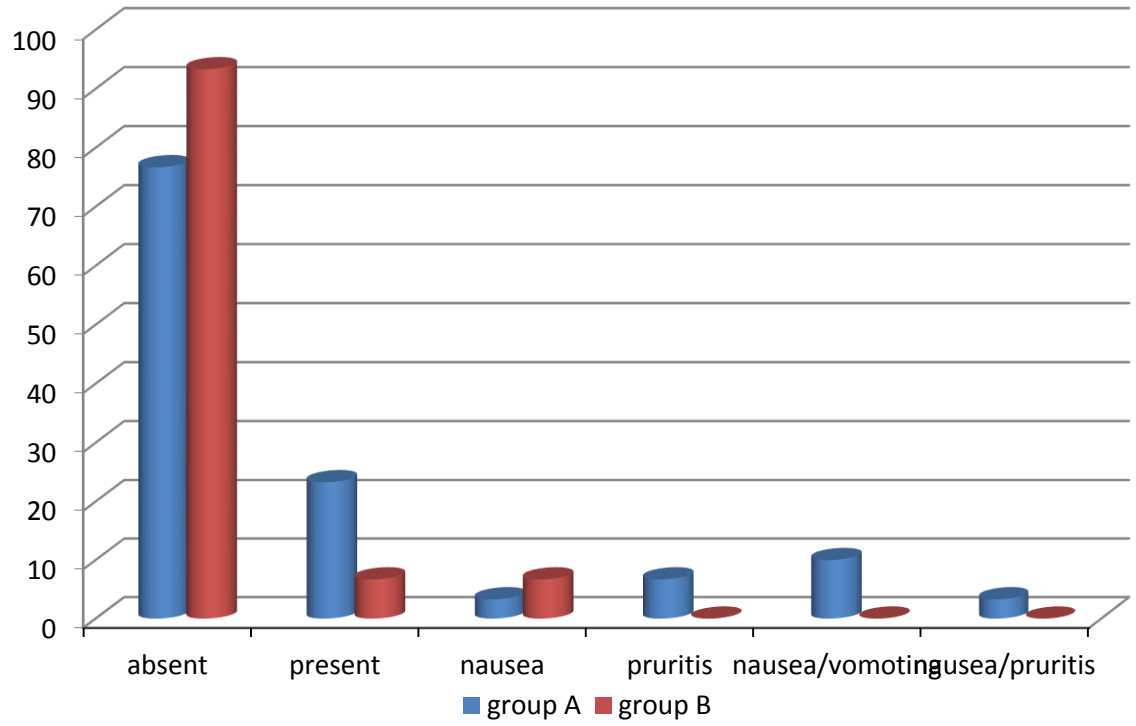
Table 7: Comparison of Sedation Score between two groups

	Group	Number of patients	SEDATION SCORE				P value
			0	1	2	3	
Pre Op	A	30	30(100%)	--	--	--	1.000
	B	30	30(100%)	--	--	--	
T0	A	30	30(100%)	--	--	--	1.000
	B	30	30(100%)	--	--	--	
T1	A	30	30(100%)	0	0	0	<1.000
	B	30	2(6.7%)	17(56.7%)	11(36.7%)	0	
T2	A	30	23(76.7%)	7(23.3%)	0	0	<1.000
	B	30	2(6.7%)	19(63.3%)	9(30%)	0	
T3	A	30	18(60%)	12(40%)	0	0	<1.000
	B	30	3(10%)	21(70%)	6(20%)	0	
T4	A	30	15(50%)	15(50%)	0	0	<1.000
	B	30	2(6.7%)	13(43.3%)	10(33.3%)	5(16.7%)	
T5	A	30	9(30%)	21(70%)	0	0	< 1.000
	B	30	0	5(16.7%)	20(66.7%)	5(16.7%)	
T6	A	30	30(100%)	0	0	0	< 1.000
	B	30	4(13.3%)	25(83.3%	1(3.3%)	0	

Table 8: Comparison of side effects between two groups

Side effects	Group A(n =30)	Group B (n = 30)
Absent	23(76.7%)	28(93.3%)
Present	7(23.3%)	2(6.7%)
Nausea	1(3.3%)	2(6.7%)
Pruritis	2(6.7%)	0
Nausea/Vomiting	3(10.0%)	0
Nausea/Pruritis	1(3.3%)	0

Inference: Side effects are more in group A with P= 0.145



X axis – side effects, Y axis – percentage.

Similarly time interval between epidural anaesthesia and first analgesic dose was similar in both groups but time interval in subsequent doses was found to be higher in butorphanol group (group B) with $p < 0.001$. [Table 5]
Number of epidural doses required for pain relief was found to be less in Butorphanol group (group B) as compared to Fentanyl group (Group A).[Table 6]
Sedation was found to be higher in Butorphanol group as compared to fentanyl group at all-time intervals but none of the patients required post-operative oxygen as spo2 never fall below 94%. [Table 7] Side effects were slightly higher in fentanyl group with 7 patients as compared with 2 in butorphanol group. [Table 8]

DISCUSSION

Post-operative pain relief results in reduction of various deleterious effects of pain on various organ systems and henceforth decreases the morbidity and allows early ambulation of patient.

The traditional management of post-operative pain by intramuscular administration of narcotics has been previously limited by elaborate array of checks and counter checks the administrated dose has its inherent delayed onset and erratic absorption pattern resulting in under treatment of discomfort and frequent over sedation of patient.[1-3]

Post-operative analgesia techniques have evolved over a long period of time starting from parenteral administration of various analgesics to injection of local anaesthetic solutions with or without adjuvants into spinal, epidural or nerve plexus.

The opioid occupy the prime place among the adjuvants administered along with local anaesthetics because of effective early onset and increased duration of analgesia and better quality of pain relief.

Butorphanol is a synthetic compound of opioid agonist-antagonist drug which was introduced in west in 1978. The side effects of Butorphanol when compared with morphine or Fentanyl were less since dose response curve for Butorphanol is bell shaped i.e. higher doses producing lesser effects than lower doses. Butorphanol induced respiratory depression was minimal and was reversible with moderate doses (0.8mg) of Naloxone. When compared to Morphine it has no dependent tendency. For woman in labour pain, Butorphanol 1-2mg and pethidine 40-80mg IM provided similar pain relief and there was no significant change in maternal and foetal blood gases. The new APGAR scores were slightly higher for Butorphanol than with pethidine.

Butorphanol is a useful addition to strong analgesic drugs presently available. It is relatively effective when compared with another analgesic Buprenorphine a similar opioid agonist-antagonist which has more respiratory depressant effect. Local infusion of Butorphanol into nerve plexus proved to be superior to intravenous continuous infusion as per the study conducted by Z Wajjin, Y Nakijima et al.[4] In there study there was no major complication and side effects such as respiratory depression, nausea, vomiting, and slight drowsiness did occurred. They postulated three possible mechanisms of action for prolonged analgesia produced by peripheral administration, these were:

1. Primary afferent tissues (dorsal roots) have been found to contain mu binding sites. Young and colleagues demonstrated the opioid receptors and various macromolecules in the neuron undergo axon flow. Laduron later showed bidirectional axonal transport of opioid binding proteins.
2. Opioids may diffuse from brachial plexus sheath to extradural and sub arachnoid spaces and bind with opioid receptors in the dorsal horn.
3. Possible centripetal axonal transport of opioids into the substantia gelatinosa after perineural injection.

In our present study mean age sex ratio, weight and duration of surgery of both A and B group patients were statistically similar.

In our study duration of post-operative analgesia was longer with epidural Butorphanol as compared to fentanyl. Similarly ,Abboud et al.[5] observed mean duration of pain relief by the first dose of 2mg epidural butorphanol to be 5.53 hours and after second dose to be 5.06 hours. Palacios et al.[6] observed median time of analgesia with 2 mg butorphanol as 2.5 hours with a range of 1.5 to 6 hours. Nauty et al.[7] observed that duration of analgesia with epidural fentanyl was 285 minutes but they used 100 microgram instead of 50micrograms used in our study.

The results of this study suggest that both Butorphanol and Fentanyl cause sedation but it was higher in epidural butorphanol at all-time intervals. None of the patients have excessive sedation (sedation score > 4). Abboud et al.[5], Ackerman et al.[8]and Gunter et al.[9] also observed sedation to be major side effect of epidural butophanol. The use of epidural opioid carries inherent risk of respiratory depression. In our study we also observed for respiratory rate and spo2, none of the group showed respiratory rate< 10/minute and never did the saturation was < 90%, study asserted absence of respiratory depression with both groups, as also confirmed by Palacios et al.[6], Nauty et al.[7], Ackerman et al.[8]

In our study pruritis was observed in 10% of cases in fentanyl group and none in butorphanol group, Ackermann et al.[8] found incidence of pruritis to be 6.7% in epidural fentanyl group. Palacios et al.[6] noted incidence of pruritis to be 1.4% with butorhanol group.

In our present study 1 patient had nausea and 3 patient experienced nausea and vomiting and required 4mg

ondensetron in fenatnyl group whereas butorphanol group only 2 patients has mild nausea which required no treatment. Abboud et al and Nauty et al reported no nausea with butorphanol group and 9% incidence of nausea with fentanyl group and no urinary retention were noted with either study in accordance with our studies.

CONCLUSION

We compared epidural butorphanol and epidural fentanyl for post-operative analgesia and observed that butorphanol is more effective analgesic with lesser side effects as compared to fentanyl.

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