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COMPARISON OF TWO DIFFERENT DOSES OF BUTORPHANOL FOR POST OPERATIVE ANALGESIA IN TOTAL ABDOMINAL HYSTERECTOMIES.

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ABSTRACT

INTRODUCTION Postoperative pain especially in abdominal surgeries is an important reason for increased morbidity, prolonged hospital admission and patient dissatisfaction. Epidural analgesia with opioids has advantage over systemic opioids by providing adequate analgesia with lesser doses and less incidence of cardiovascular, respiratory or thromboembolic complications.

AIMS This study was done to compare effectiveness of two different doses of butorphanol when used epidurally for postoperative analgesia. Safety and side effect profile was also compared.

MATERIALS AND METHODS This prospective, randomized controlled, double-blinded study was carried out at a tertiary care hospital. 60 patients belonging to ASA I, II aged between 30 to 60 years scheduled for total abdominal hysterectomy under General Anaesthesia were enrolled for the study into two groups A and B. Group A patients received epidural butorphanol 1mg diluted till 10ml in normal saline (NS) while as Group B patients received epidural butorphanol 2mg diluted till 10 ml of NS. Observed parameters were changes in vital parameters like heart rate, respiratory rate and systolic blood pressure. The time taken for onset, peak effect and duration of analgesia was compared between the two groups. Mean pain scores at different time intervals were recorded and compared, side effects if seen were noted.

RESULTS Onset of analgesia was similar in group A (17.83 + 5.97 min) when compared with group B (17.83 + 2.62 min). Peak onset of analgesia was achieved significantly earlier in group B (43.17+ 5.72 min) than in group A (54.83 + 19.02). Duration of analgesia was also significantly longer in group B (317.6 + 38.86 min) than in Group A (266.3 + 101.15 min). Mean pain scores when compared over the time until weaning showed that pain scores were significantly lower at30 min to 1 hour interval. Side effects like sedation and nausea/vomiting was seen more in group B patient.

CONCLUSION Epidural butorphanol 2mg is an effective dose for postoperative analgesia for abdominal surgery like total abdominal hysterectomy and provides good analgesia with early peak and prolonged action.

KEYWORDS :

INTRODUCTION

Postoperative analgesia is one of the important aspects of Anaesthesia. Postoperative pain especially in abdominal surgeries is an important reason for increased morbidity, prolonged hospital admission and patient dissatisfaction[1]. So effective management of postoperative pain remains an important concern. Systemic analgesics have long been used and include NSAIDs and opioids, however their use has been limited due to their side effects.[2] Other methods have been used and includes epidural analgesia or nerve blocks. Epidural analgesia is a safe method and is effective for postoperative pain relief.[3] The epidural analgesic technique for major abdominal surgeries provides effective pain relief with lesser side effects and hence higher levels of patient satisfaction. It also obtunds central sensitization and pain-induced organ dysfunction, resulting in an improved outcome. Epidural analgesia results in early recovery as patients can be mobilized earlier with less postoperative complications.[4]

Epidural analgesia with opioids has advantage over systemic opioids by providing adequate analgesia with lesser doses and less incidence of cardiovascular, respiratory or thromboembolic complications. However, they may also be associated with troublesome side effects such as pruritus, nausea, vomiting, urinary retention, and respiratory depression. These side effects are more commonly seen with morphine.[5,6]

Butorphanol is a lipid-soluble opioid with strong κ-receptor agonist and weak μ-receptor agonist/antagonist activity[7]. The analgesic efficacy of epidural butorphanol is comparable to that of morphine, with less respiratory depression, pruritus, and nausea and vomiting.[8]

Aim of this study was to compare effectiveness of two different doses of butorphanol when used epidurally for postoperative analgesia.

Effect of these two commonly used doses on hemodynamics and their safety profile was also compared.

MATERIAL AND METHODS

This randomized double blinded prospective study was carried out at a tertiary care hospital, Government Medical College Srinagar for a period of 1 year from December 2019 to December 2020. Following approval of local ethics committee and obtaining written informed consent from patients, 60 patients belonging to ASA I, II aged between 30 to 60 years scheduled for Total Abdominal Hysterectomy under General Anaesthesia were enrolled for the study.

Exclusion criteria included patient's refusal, spinal deformity, bleeding diathesis, sepsis, significant cardiorespiratory and hepatic, renal and neurological disease. Patients were randomly allocated into two groups, Group A and Group B. Randomization was done through computer generated random numbers.

Preanesthetic checkup was done day before surgery. Details and vitals of patient were recorded. Patients were made familiar with Visual Analogue Scale and taught to grade their pain according to VAS. Pre-operative counseling was done to gain the confidence of the patient, thereby minimizing the emotional component of pain.

On the day of surgery, basic monitors for ECG, Spo2 and BP were connected. an intravenous (IV) line was obtained with the 18-gauge cannula in all patients. Intravenous fluid ringer lactate was started before the procedure.

The patients were placed in sitting position. Under all aseptic precautions, a skin wheal was raised in the L2-L3 or L3-L4 interspace with 2 ml 2% lignocaine. An 18-gauge Tuohy needle was passed through space about 1 cm. The stylet was removed, and a 10 ml loss of resistance (LOR) syringe with 5 ml air was firmly attached to the hub of the Tuohy needle. The needle was slowly advanced until it enters the epidural space, which was identified by the LOR technique. The LOR syringe was disconnected. The absence of blood or cerebrospinal fluid was verified by negative aspiration. An 18-gauge epidural catheter was passed through the epidural space with the catheter tip 3-5 cm into space. Three milliliters of 2% lignocaine with epinephrine 1:200,000 was given as test dose. Hemodynamic parameters were monitored for 5 min. Patients were put in supine position.

Patients were induced with iv Propofol (2ml/Kg), Succinylcholine (2mg/Kg) was given for muscle relaxation and tracheal intubation. For intraoperative analgesia iv Fentanyl (2ml/Kg) was give. Towards end of surgery, in Group A 1mg of Butorphanol diluted to 10ml with NS was given through epidural catheter, in Group B 2mg of Butorphanol diluted to 10ml was given.

Patients were observed for period of 24 hours. Assessment of pain was done using linear Visual Analogue Scale Score (VAS). It involved use of a 10cm line on a piece of white paper, which represented the patient's opinion for the degree of pain. It was explained to all the patients preoperatively that one end of the line i.e., '0' represents no pain at all while the other end i.e., '10' represents worst pain he/she ever felt. Patient rated the degree of pain by making a mark on the linear scale. Thus, the pain score was obtained by measuring the distance from the '0' end to the indicated mark.

Vital parameters and pain score recorded at regular time intervals (at the time of injection, at 15 minutes, 30 minutes, 1hour, 2 hours and then till the effect of drug wore off.) Patient asked for maximum pain relief he/she felt during the duration of drug effect, and side effects observed and noted. After completion of the study, data analysis was done with appropriate statistical tests. Results were tabulated.

RESULTS

The demographic variable between the two groups is shown in Table 1, the difference between the two groups is non-significant and hence two groups are comparable.

Table 1: Demographic Variables.

		Group A	Group B	P value
Height		160.45 ± 11.45	160.47 ± 11.25	0.995
Weight		55.90 ± 13.30	56.80 ± 13.40	0.796
ASA	ASA I		43.33%	60.00%
	ASA II		56.66%	40.00%
Duration of Surgery		138.5 ± 37.95	134 ± 31.27	0.359

Postoperative baseline vitals including Pulse, Systolic BP, Respiratory rate are compared in Table 2. The difference between the two groups is insignificant.

Table 2: Postoperative Baseline Vitals.

	Group A	Group B	P value
Pulse (bpm)	93 ±11.12	92.4 ± 12.72	>0.05
Systolic B.P (mmHg)	132 ± 19.53	135.2 ± 15.7	>0.05
RR (pm)	15.47 ±1.59	14.83 ± 1.39	>0.05

Table 3: Comparison Of Mean Of Onset, Peak And Duration Of Analgesia.

	Group A (Epidural 1mg)	Group B (Epidural 2mg)	P Value	S or NS
	Mean ± SD (minutes)	**Mean ± SD** (minutes)		
Onset	17.83 ± 5.97	17.83 + 2.62	1.000	NS
Peak	54.83 ± 19.02	43.17+ 5.72	**0.0021**	**Significant**
Duration	266.3 ± 101.15	317.6 + 38.86	**0.0120**	**Significant**

Mean **Onset of analgesia** in Group A is 17.83 ± 5.97 minutes and in Group B 17.83±2.62 minutes, after applying unpaired t-test this difference is not significant**.**

Mean **Peak of analgesia** in Group A is 54.83 ± 19.02 minutes and in Group B is 43.17+ 5.72 minutes, after applying unpaired t-test this difference is highly **significant** (t = -3.216 & P= .0021).

Mean **duration of analgesia** in Group A was 266.3 ± 101.15 minutes & in Group B it was 317.6 + 38.86 minutes. The difference was found statistically **significant** (t = -2.5931 & P= .0120) with unpaired t-test.

Table 4: Comparison Of Mean Pain Score At Regular Time Intervals.

Time	Group A (Epidural 1mg)	Group B (Epidural 2mg)	P value	Significant
15 minutes	5.12	5.02	0.217	NS
30 minutes	4.85	2.00	0.000	**Significant**
1 hour	2.7	0.13	0.006	**Significant**
2 hours	2.3	0.13	0.17	NS
Weaning	7.55	4.50	0.312	NS

Comparison of mean pain score at regular time intervals between the groups showed significant difference at **30 min, and 1 hour** with above mentioned values in Table 5.

In rest of the time intervals there was no statistical difference in the pain score observed.

Table 5: Side Effects & Group Distribution

Side effects	**Group A** (Epidural 1mg) n=30		**Group B** (Epidural 2mg) n=30	
	No. of patients	**%**	**No. of patients**	**%**
Sedation	03	10	07	23.33
Somnolence	00	0	0	0
Nausea/vomiting	00	0	1	3.33
Pruritus	01	3.33	01	3.33

The incidence of all the side effects were observed in a greater number of patients in Group B as compared to group A.

DISCUSSION

Neuraxial opioids differ from their systemic administration, the quality of analgesia is better, with lesser sedation and preserved function and action is prolonged. The side effects with epidurally given opioids are less frequent and not much severe as compared to systemic opioids. Also, the dose required to produce equivalent analgesia is lesser.[9]

Epidural analgesia in postoperative period provides greater satisfaction and accelerated recovery. This Anaesthesia approach is labeled as 'postoperative rehabilitation'.[10]

We tried to study optimal dose of epidurally given opioid butorphanol in this study. 1mg dose of epidural butorphanol was compared with dose of 2mg. The two groups were comparable in demographical variables and baseline vitals. In both the groups epidurally given butorphanol resulted in stable hemodynamic parameters. Respiratory depression with butorphanol was not seen in the study, though it can occur but the dose-response curve is bell-shaped and it is not dose related.[11]

Onset of analgesia was fast and comparable in two groups. Similar findings were seen in one study where 2mg and 4mg of drug was compared.[12] Faster onset of analgesia is due to its lipid solubility. Peak onset of analgesia was achieved significantly earlier in group B (43.17+ 5.72 min) than in group A (54.83 + 19.02). Duration of analgesia was also significantly longer in group B (317.6 + 38.86 min) than in Group A (266.3 + 101.15 min). Hence with Epidural butorphanol 2mg, analgesia was more prolonged and peak analgesia was achieved more quickly.

The difference in mean pain scores was statistically significant at 30 min to 1 hour interval. Pain scores were significantly lower in Group B at these times while after 1 hour pain scores were comparable between two groups until analgesic effect weaned off. Analgesic effect weaned off much earlier in group A (266.3 ± 101.15 min) than in group B (317.6 + 38.86 min).

Side effects were slightly more frequent in Group B patients, sedation was observed more frequently in Group B patients, one patient in Group B also had nausea and vomiting while it was not seen in Group A patients.

Not many studies have been done comparing these two doses of epidural butorphanol. Better quality of analgesia was achieved in group of patients where 2mg of butorphanol was given epidurally postoperatively. The side effects were comparable, though sedation and nausea/vomiting were seen more frequently in 2mg group. Due to its longer duration of analgesia lesser number of doses will be required over time and hence over period of time it would result in effective analgesia with lesser side effects and hence better patient satisfaction and accelerated recovery.

Limitation of this study is that butorphanol is less readily available and hence may limit its application.

CONCLUSION

Epidural analgesia relieves postoperative pain and reduces the physiological changes that are associated with pain. However, selection of individual drug and its dose must balance the efficacy of analgesia against the occurrence of side effects. From this study we conclude epidural butorphanol 2mg is an effective dose for postoperative analgesia for abdominal surgery like total abdominal hysterectomy and provides good analgesia with early peak and prolonged action.

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Conflicts of interest
There are no conflicts of interest.

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