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A COMPARISON OF EPIDURAL BUTORPHANOL AND FENTANYL FOR POSTOPERATIVE ANALGESIA USING COMBINED SPINAL EPIDURAL ANAESTHESIA TECHNIQUE

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AUTHORS' CONTRIBUTIONS

This work was carried out in collaboration among all authors. Authors PBJ and SS designed the study, performed the statistical analysis, wrote the protocol, and wrote the first draft of the manuscript. Authors SS, AG and DK managed the analyses of the study. Author AH managed the literature searches. All authors read and approved the final manuscript.

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ABSTRACT

A prospective randomized controlled clinical comparative study entitled "A Comparison of epidural Butorphanol 2 mg and Fentanyl 75 mcg for Postoperative analgesia using Combined Spinal Epidural Anaesthesia technique: A randomized double blind clinical study" was conducted in 40 patients between the ages of 18-60 for elective physical conditions at the Krishna Institute of Medical Sciences Hospital and Research Center, Karad from the year 2016-2017 and admitted for elective physical surgery. All cases were given Combined spinal epidural anaesthesia using 4 ml 0.5% bupivacaine in spinal and in the postoperative period, immediately after surgery they received epidural butorphanol 2 mg (group B) or fentanyl 75 mcg (group F) diluted to 10 ml with normal saline.

Keywords: Epidural butorphanol; fentanyl; analgesia; anaesthesia technique; spinal epidural.

1. INTRODUCTION

Pain is unavoidable following surgery. Relieving pain is also one of the basic duties of anaesthesiologist and is also the main purpose for which patients are receiving treatment. Acute postoperative pain is a complex neurological response to tissue damage, abdominal distension, or disease. Its expression of autonomic, psychological and behavioural reactions results in uncomfortable, unwanted sensory and

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emotional experience. Despite developments in the understanding of pain pathophysiology, analgesic pharmacology and the advancement of successful methods for postoperative pain management, many patients continue to encounter significant discomfort [1,2].

2. AIM AND OBJECTIVES

Aim: This study would assess the effect of Butorphanol & Fentanyl used as epidural analgesic agent in patients undergoing elective Abdomino-Pelvic and lower limb surgeries.

Objectives: Opioids as epidural adjuvants to nearby sedative improve the nature of the obstruct and give a portion saving impact. We decided to explore fentanyl, a μ-receptor agonist and butorphanol, a solid k-receptor agonist and a feeble μ-receptor agonist-enemy managed epidurally for post-operative absence of pain.

3. REVIEW OF LITERATURE

August Bier [3] is regarded as the father of intrathecal anaesthesia. He said that his technique, termed as "cocainization" of the spinal cord, can provide the relief of pain needed for major surgery.

Leonard J Corning, [4,5] a New York nervous system specialist in 1885 played out the principal epidural absense of pain coincidentally, by infusing cocaine between the spinous cycle of the second rate dorsal vertebrae, with the expectation of treating his patient's grievance of masturbation.

Resill SI et al. [6] in 1976 has described Visual analogue scale is the simplest way to assess pain severity, convenient to use, effective and can be analysed easily. It's a very sensitive way to measure pain severity. VAS will assess the effectiveness of analgesia with a certain analgesic by noting the scores before and after treatment, but the main drawback of VAS is that it assumes pain to be one-dimensional and measures only the intensity of pain, whereas the nature, location and psycho social aspect of pain are not taken into consideration.

The first epidural injection was by caudal route, introduced independently by Hean Athanase Sicard, a French neurologist and Cathelin FC, in 1901. Sicard also described "loss of resistance" technique for locating the epidural space in 1921 [7].

In 1921, Pages Mirave F, a Spanish surgeon described the mid-line approach to lumbar epidural analgesia and used it extensively for clinical work [8].

In 1931, Dogliotti, [9,10] in Italy and Massey Dawkins, in Britain popularized clinical use of epidural analgesia particularly for labour analgesia in obstetric practice.

Hingson and Edwards, [11] in 1942 introduced a malleable and flexible steel needle for continuous caudal analgesia and reported 1000 cases of continuous caudal analgesia in 1943.

Hingson and Southworth, [12] with a spinal needle, introduced a small 4F ureteric catheter into the lumbar epidural space and reported their experience of continuous lumbar epidural analgesia.

In 1977, Soloman H, Syndel HD [13] stated that several aspects of opiate actions suggested that the opiates exert those clinical effects via highly selective sites on neuronal membrane in brain. He identified opiate receptors by binding highly specific radioactive opiates to brain membranes and rapid washing of membranes removing non-specific bound drugs.

Cousins et al. [14] in 1984 had suggested that epidural drug dosing is complicated by anatomical and physiological factors including dural and pial penetration, absorption by epidural fat and consequent vascular uptake. A portion of the epidural dose crosses the dura, enters the CSF and penetrates spinal tissue in amounts proportional to the lipid solubility of the agent, the remainder is absorbed by the vasculature producing plasma levels comparable to that achieved with intramuscular injections and producing some degree of supraspinal analgesia. Lipid solubility appears to play the key role in determining onset of analgesia, dermatome spread and duration of activity, with highly lipid soluble drugs having rapid onset of analgesia and limited duration of activity.

Lomessy A et al. [15] in 1984 designed a study to examine the analgesic effects, plasma concentrations and ventilatory consequences of an injection of the same dose of fentanyl given epidurally or intramuscularly post-operatively in random sequence in 11 patients who had undergone an abdominal or thoracic surgery. The day after surgery, 5 of the 11 subjects were given 200 μg of epidural fentanyl diluted in 10 ml of saline. This was followed, at least 3 hours later, by an intramuscular injection of the same dose of fentanyl. Remaining six patients underwent same procedure but in the inverse order. They concluded that epidural fentanyl 200 μg provides a rapid analgesia that remains optimum during 2 hours, despite the intensity of pain stimulation.

Naulty MD et al. [16] in 1984 in Harvard Medical School, Boston, had conducted a double blind randomized dose response study of epidural butorphanol in post caesarean delivery patients, using 1, 2, 4 or 6 mg of butorphanol tartrate. After the injection, subjects were evaluated at 5, 10, 15 and 30 minutes and then at 30 minutes intervals for at least 5 hours following the injection. The onset of sensory analgesia was defined as the time elapsed when the patients had no sensory blockade detectable by pinprick and the duration of analgesia was defined as the time elapsed when the patient experienced any pain (a pain score >0 on the linear VAS). A statistically significant ($p< 0.01$) prolongation of postoperative analgesia was seen with butorphanol doses greater than 1 mg and increasing duration of analgesia seen with increasing dose. Finally, increasing doses of epidural butorphanol significantly decreased the amount of narcotic required in the first 24 hrs. Somnolence (easily arousable with a quiet verbal stimulus) of mean duration of approximately 6 hrs was the only significant side effect encountered. No patients reported pruritus, nausea, dysphoria or respiratory depression during the course of study.

Naulty JS et al. [17] in 1985 evaluated suitability of fentanyl for epidural use and the dosages required in the parturient in a double blind, randomized manner in 30 ASA 1 patients following caesarean delivery. The patients (5 each group) were randomly assigned to receive 0, 12.5, 25, 50, 70, or 100 µg of fentanyl through the epidural catheter. Level of sensory block, motor block, and pain intensity was assessed. 50 µg of fentanyl produced pain scores of 0 within 9 min and 100 µg in 3-6 min. With fentanyl 25 µg, mean duration of analgesia was 3 hrs. and higher doses produced an increase of approximately 1.5 times. They found that analgesia produced by 50 µg of epidural fentanyl was useful but if a longer duration of action is required, repeated injections will be needed.

Mok et al. [18]. in 1986 evaluated the analgesic efficacy and safety of epidural butorphanol in comparison to epidural morphine, in patients with postoperative pain, in a double blind controlled design. Post-operatively patients were divided into 2 groups in a randomized, double-blind fashion. Group A patients received, epidural butorphanol 4 mg in 10 ml normal saline and patients in Group B received morphine 5 mg in 10 ml normal saline epidurally. Onset of pain relief with epidural butorphanol appeared at 15 minutes, peaked at 30 minutes and duration of action averaged 5.4 hours; whereas with epidural morphine onset of analgesia appeared at 25 minutes, with a peak effect at 1 hour and duration of action averaged 15.2 hours. Study concluded that epidural butorphanol appears to provide efficacious pain relief without much untoward effects in patients with post surgical pain.

Lytle SA et al. [19] in 1991 did a retrospective analysis of 133 patients who received fentanyl for postoperative analgesia 5 µg/ml as continuous epidural infusions. 59.3% of the patients did not receive any additional narcotics but 26.3% did. Side effects were less, respiratory depression did not occur. Urinary retention occurred in one patient, pruritus in 4% and nausea in 25.5%. They had shown that epidural fentanyl provided good to excellent pain relief with minimal side effects.

Abe T et al. [20] in 1997 did a study to find out the efficacy of epidural fentanyl as analgesic for extracorporeal shock wave lithotripsy (ESWL). No anaesthetic and accessory drugs were used. Patients were questioned regarding the presence of postoperative nausea, vomiting, and motor disturbance. No remarkable change in blood pressure and heart rate were observed. Postoperative side effects were mild especially in the patients treated with epidural fentanyl alone.

4. MATERIALS AND METHODS

Prospective, randomized double blind comparative study was planned. The study was conducted at KIMS, Krishna Hospital and Research Centre, Karad, Maharashtra during 2015- 2017. The study population was randomly divided into two groups, each group containing 20 patients. Computer generated codes and closed envelope technique was used for randomization and double blinding. Group B: Patients received 2 mg Butorphanol in 10 ml Normal Saline. Group F: Patients received 75 mcg Fentanyl in 10 ml Normal Saline. Forty patients of either sex, scheduled for elective Abdomino-Pelvic surgeries (Gynaecologic & Surgery procedures) and Lower Limb surgeries under CSEA technique, belonging to physical status of American Society of Anaesthesiologist class I and II were included in the study. Assuming type I error of 0.05 and a type II error of 0.1 to detect 30 min difference in post-operative analgesia so as to yield a power of 90%, a sample size of 16 patients was calculated for each group.

5. OBSERVATION AND RESULTS

This comparative clinical research was performed to study effectiveness dependent on length of analgesia, consistency of analgesia, frequency of epidural doses, effect on haemodynamic parameters and side-effects.

Table 1. Age distribution

Age Distribution	Group B		Group F		Total
	No.	%	No.	%	
<30	5	25	3	15	8
31-40	5	25	6	30	11
41-50	6	30	5	25	11
51-60	4	20	6	30	10
Total	20	100	20	100	40

Table 2. Haemodynamic parameters - heart rate

Descriptive Statistics

	GROUP	Mean	Std. Deviation	N
0 Min	GROUP B	78.65	9.724	20
	GROUP F	81.75	8.717	20
	Total	80.20	9.249	40
5 Min	GROUP B	77.30	9.493	20
	GROUP F	76.40	8.720	20
	Total	76.85	9.009	40
10 Min	GROUP B	75.45	9.087	20
	GROUP F	77.65	8.368	20
	Total	76.55	8.694	40
15 Min	GROUP B	76.80	8.679	20
	GROUP F	79.35	8.171	20
	Total	78.08	8.420	40
20 Min	GROUP B	78.40	8.035	20
	GROUP F	79.30	8.646	20
	Total	78.85	8.251	40
30 Min	GROUP B	79.20	8.276	20
	GROUP F	79.40	8.338	20
	Total	79.30	8.200	40

Tests of Between-Subjects Effects
Measure: Heart Rate
Transformed Variable: Average

Source	Type III Sum of Squares	df	Mean Square	F	Sig.	Partial Eta Squared	Noncent. Parameter	Observed Power[a]
Intercept	1471570.204	1	1471570.204	3551.893	.000	.989	3551.893	1.000
GROUP	108.004	1	108.004	.261	.613	.007	.261	.079
Error	15743.625	38	414.306					

a. Computed using alpha = .05

The above Table 1 the mean age of patients in group B was 39.9 ± 11.6 (Range: 18-60 yrs.) and in group F was 41.40 ± 11.4 (Range: 18-60 yrs.). Majority of the patients, about 50% in group B and 50% in group F belonged to age group between 31- 50 yrs. Samples in both groups were not significantly different (p=0.781) and were age matched.

It can be seen from the above Tables 2 that there was no difference in the heart rate observed up to 30 min. after administration of the study drugs. Heart rate was monitored every 4th hourly for 24 hours post-operatively. Heart rate remained stable throughout up to 24 hours. The Heart rate variation between the two groups was compared by General Linear Model for Repeated Measures. The test showed no significant difference. (p = 0.613)

6. DISCUSSION

Postoperative pain is an acute pain, which starts with the surgical trauma and usually ends with tissue healing. It diminishes with time after surgery and responds to analgesics. Severe pain can result in splinting, with resultant atelectasis and hypoxia. In addition, poor control of pain may result in increased

catecholamine secretion in response to pain, which may in turn increase myocardial oxygen demand. Since the discovery of opioid receptors in the spinal cord, the action of narcotics through opioid receptors has become more clearly understood. One of the opioid receptors, kappa are mainly involved with the mediation of visceral pain. After this, achieving satisfactory postoperative analgesia with epidural and intrathecal administration of narcotics has been the subject of much research.

All surgeries were done under combined spinal epidural anaesthesia. In the postoperative period, immediately after surgery was over, patients in group B received epidural butorphanol 2 mg diluted to 10ml in NS and patients in group F received epidural fentanyl 75 mcg diluted to 10ml in NS. It was discovered that all patients encountered some relief from discomfort. However, the duration and quality of absence of pain was discovered to be variable as a result of contrasts in the kind of medication utilized, severity of pain, pain threshold, type of surgery, etc.

7. CONCLUSION

It can be inferred from the aforementioned analysis that epidural butorphanol offers longer period of analgesia, higher consistency of analgesia with less epidural doses and less side effects such as sedation, which are statistically important relative to epidural fentanyl. In consideration of the protection profile, epidural butorphanol may be regularly used for various surgical procedures in the management of postoperative pain relief. It is healthy and effective in the supply of postoperative analgesia.

ETHICAL APPROVAL

The Institute Ethical Committee approved the study.

COMPETING INTERESTS

Authors have declared that no competing interests exist.

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