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COMPARATIVE EVALUATION OF EPIDURAL TRAMADOL VERSUS EPIDURAL BUPRENORPHINE FOR POSTOPERATIVE ANALGESIA IN PATIENTS UNDERGOING LOWER ABDOMINAL SURGERIES: A PROSPECTIVE RANDOMIZED DOUBLE BLIND STUDY

Anaesthesiology

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ABSTRACT

Introduction: Aim of this study is to evaluate and compare the efficacy between epidurally administered Tramadol and Buprenorphine in providing postoperative analgesia in terms of onset and duration of analgesia, haemodynamic parameters and side effects.
Material and Methods: This double blind, prospective, randomized hospital study was conducted after taking ethical committee approval of a total of 60 patients scheduled for elective lower abdominal surgeries. Patients were randomly allocated into two equal groups of 30 each: Group A patients received Injection Tramadol 50 mg and Group B patients received Injection Buprenorphine 150 mcg through epidural catheter.
Result: The mean onset of analgesia was 12.42 minutes in Group A whereas it was 19.19 minutes in Group B. The mean duration of analgesia was longer in Group B(689.52 +- 74.22 mins) compared to Group A(359.02 +- 83.85 mins). Nausea and vomiting were the side effects seen in Tramadol group whereas drowsiness was seen in Buprenorphine group.
Conclusion: Epidural Buprenorphine provides a longer duration and better quality of analgesia as compared to epidural Tramadol.

KEYWORDS

Epidural analgesia, Tramadol, Buprenorphine

INTRODUCTION

Pain is an inevitable component of the peri operative period. It is an unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage[1]. Postoperative pain is self limiting which gradually starts decreasing in 24 hours. It is a type of acute pain which occurs due to surgical trauma resulting in an inflammatory reaction and afferent neuronal barrage[2]. A stress free postoperative period attenuates detrimental physiological response hence decreases morbidity[3].

Tramadol, a centrally acting analgesic is a synthetic analogue of codeine with moderate affinity for mu receptors and weak affinity for delta and kappa opioid receptors. Its analgesic potency is 5 to 10 times less than that of morphine. Clinically relevant respiratory depression is not seen following epidural tramadol as compared to epidural morphine owing to different mechanisms of their analgesic action[4]. It also enhances the function of spinal descending inhibitory pathways by inhibition of neuronal reuptake of norepinephrine and 5-hydroxytryptamine as well as presynaptic stimulation of 5-hydroxytryptamine release.

Buprenorphine, a newer semi-synthetic opioid, is a thebaine derivative which has both agonist as well as antagonist properties. It is highly lipid soluble with a higher affinity for mu opioid receptor thus minimum chances of side effects and addiction and can be safely used epidurally[5]. It also acts as an antagonist on kappa receptor, as an agonist on delta receptor and as a partial agonist on opioid-receptor-like 1(ORL-1). It is metabolized via the cytochrome p450 3A4 system thus has the potential for interacting with drugs that induce or inhibit this pathway. Epidural analgesia is a safe technique for relief of post operative pain and is equivalent to various traditional analgesic methods[6]. It is considered to be the gold standard analgesic technique in major surgeries. Since they can be given repeatedly through the indwelling epidural catheter thus they can be used to provide prolonged analgesia in postoperative period. In this study we compared the efficacy of epidurally administered Tramadol and Buprenorphine in providing postoperative analgesia in terms of onset and duration of analgesia, requirement of rescue analgesic, hemodynamic parameters and side effects.

MATERIALS AND METHODS

This prospective, randomized, double blind study was conducted after taking ethical committee approval of a total of 60 patients scheduled for elective lower abdominal surgeries under general anesthesia. This study was done in ASA Grade I and II patients and age between 18 to 60 years while non-consenting patients, ASA Grade III and IV patients and all contraindications for epidural anesthesia were excluded.

Following approval of the ethical committee and obtaining written informed consent from the patients, all patients posted for elective lower abdominal surgeries under general anaesthesia were subjected to a thorough pre-anaesthetic evaluation on the day previous to surgery. They were given Tablet Alprazolam 0.5 mg orally as an anxiolytic the night before the surgery and kept fasting from the night prior to surgery. Patients were divided into two groups as follows: Group A patients received Injection Tramadol 50mg and Group B patients received Injection Buprenorphine 150micg through epidural catheter . 60 patients were randomly allocated into two equal groups of 30 each using chit box method.

On the day of surgery on arrival in the operating room standard monitors like pulse oximetry, blood pressure monitoring, electrocardiogram were connected and an intravenous line was secured with a wide bore cannula and fluid started. Under strict aseptic precautions T11-12/L1-2 space was identified by palpation. After local infiltration an epidural puncture was made by loss of resistance technique using 18G Tuohy needle. Epidural catheter was passed through the needle and thereafter the needle withdrawn and catheter secured. Injection 2% xylocaine with adrenaline was given as a test dose to rule out intrathecal or intravascular placement of epidural catheter. All patients were induced with Propofol 2mg/kg IV. Midazolam 0.05mg/kg IV was given for sedation and Fentanyl 2micg/kg IV and Paracetamol 15mg/kg IV for intraoperative analgesia. Tracheal intubation was facilitated with Succinylcholine 2mg/kg IV. Intratracheal tube placement was confirmed by auscultation of the capnography and auscultation of the chest. Anaesthesia was maintained with intermittent Vecuronium 0.05mg/kg IV, isoflurane, nitrous oxide and oxygen. The lungs were ventilated to maintain end-tidal carbon dioxide between 32-35 mmHg. Neuromuscular reversal was achieved with Neostigmine 0.05mg/kg IV and Glycopyrrolate 0.01 mg/kg IV and the patient extubated.

In the postoperative ward when the patient first complained of pain, VAS score was noted. Patients were now divided into two groups as follows: Group A patients received Injection Tramadol 50mg diluted to 10ml with normal saline and Group B patients received Injection Buprenorphine 150micg diluted to 10ml with normal saline through the epidural catheter.

VAS score for intensity of pain, onset and duration of analgesia, vital signs were recorded from the administration of first dose at the following time intervals: after 30 mins, 1 hour, 3 hour, 6 hour, 12 hour and 24 hour. Side effects if any were also noted. Injection Paracetamol 1 gram intravenously was given as a rescue analgesic if they again complained of pain with a VAS Score > 4 and then the study abandoned. The total duration of postoperative analgesia was taken from the time of giving epidural drug till the patient first complained of pain with a VAS score > 4. P-value of less than 0.05 was considered significant. The results obtained were compared with those of the existing studies to arrive at a conclusion.

RESULTS:

Table – 1 :demographic Distribution, Onset Of Analgesia And Duration Of Analgesia.

	Group A		Group B		Result (p value)
	Mean	SD	Mean	SD	Result(p-value)
Age (years)	47.48	5.25	49.45	3.65	0.594
Onset of analgesia (mins)	12.42	2.85	19.19	4.10	p<0.001
Duration of analgesia(mins)	359.02	83.85	547.52	94.22	P<0.001

Table – 2 : Comparison Of Vas Scale

	Group A	Group B	Result (p value)		
	Mean	SD	Mean	SD	
After 30 min	0.00	0.00	0.00	0.00	-
After 1 hr	0.00	0.00	0.00	0.00	-
After 3 hr	0.00	0.00	0.00	0.00	-
After 6 hr	6.58	1.08	0.10	0.54	p<0.001
After 12 hr	5.26	1.12	5.01	1.32	0.3
After 24 hr	3.16	1.29	3.23	1.33	0.6

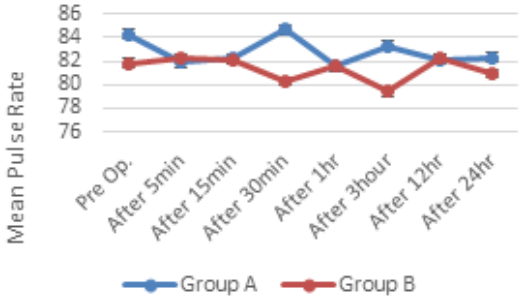

Figure 1: Comparison Of Mean Pulse Rate

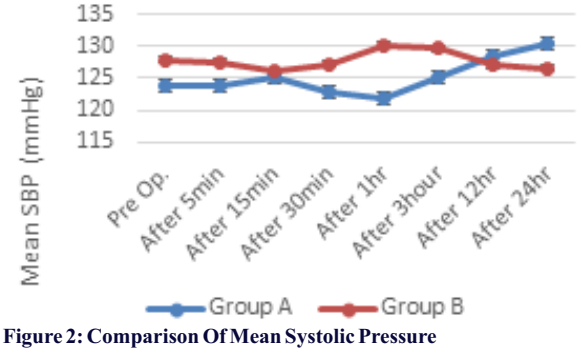

Figure 2: Comparison Of Mean Systolic Pressure

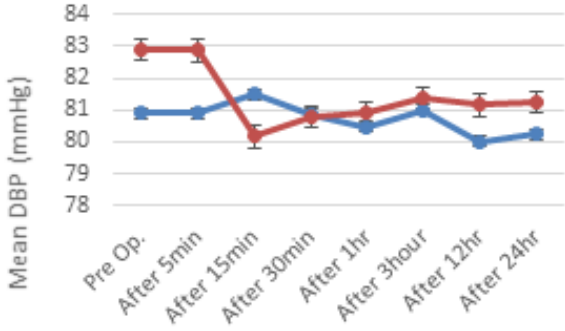

Figure 3: Comparison Of Mean Diastolic Pressure

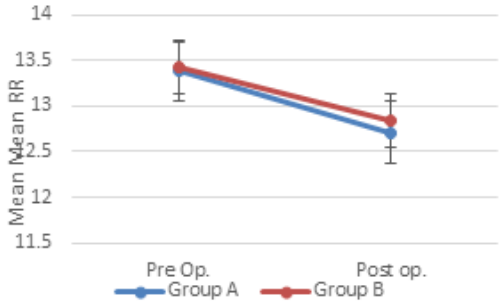

Figure 4: Comparison Of Mean Respiratory Rate

Table 3: Comparison Of Side Effects

SIDE EFFECTS	GROUP A	GROUP B
Nausea and vomiting	3	-
Hypotension	-	-
Respiratory depression	-	-
Drowsiness	-	1
Pruritis	-	-
Total	3	1

DISCUSSION

Postoperative pain relief is one of the major goals of perioperative patient care. A stress free postoperative period attenuates detrimental physiological responses and decreases morbidity[7]. Epidural opioids have been commonly administered to reduce pain associated with surgical procedures and to relieve anxiety. The pharmacodynamic response is based upon the receptor to which the opioid binds, the affinity of binding and whether it is an agonist or antagonist. In our study the age wise distribution was similar in both the groups.

Onset of analgesia: The onset of analgesia was shorter in Group A when compared to Group B and was statistically significant. The mean onset of analgesia was 12.42 minutes in Group A whereas it was 19.19 minutes in Group B. Buprenorphine, unlike other opioids, has slow rates of association and dissociation with the opioid receptors and takes about 30 minutes for the receptor binding to achieve an equilibrium[8]. This slow rate of association with the opioid receptors explains the late onset of action of Buprenorphine in comparison to faster onset of action of Tramadol. In a study done by Debashish Mondal et al(2017) in which they compared epidural Buprenorphine and epidural Tramadol for post-operative analgesia in patients undergoing lower abdominal surgeries. They found the mean onset of analgesia with epidural Tramadol to be 9.85 +- 2.86 minutes and 15.71 +- 5.85 minutes with epidural Buprenorphine. Siddik-Sayyid et al[9] studied the analgesic effect of epidural Tramadol in patients undergoing elective caesarean section. They concluded that epidural Tramadol provided post-operative analgesia for a period of 4.5 +- 3.1 hours.

Duration of analgesia: In Group A the mean VAS score was > 4 at 6 hour and 12 hour interval whereas it was > 4 in Group B only at 12 hour. The mean duration of analgesia was longer in Group B(689.52 +- 74.22 mins) compared to Group A(359.02 +- 83.85 mins). This longer duration of action of Buprenorphine could be due to its high affinity for opiate receptors and its high lipid solubility. D Kumar, N. Dev et al[10] compared the effectiveness and duration of analgesia between epidural ketamine and epidural buprenorphine and found that although both the drugs produced analgesia without any significant side effects, the analgesia produced by buprenorphine was relatively longer(13.1 hours) compared to ketamine. A study done by Jose DE, Ganapathi P et al (2016) [11] to compare the postoperative pain relief with epidural Buprenorphine versus epidural Butorphanol in laparoscopic hysterectomies found Buprenorphine had a longer duration of analgesia compared to butorphanol(586.17 +- 73.64 vs 342.53 +- 47.42).

Side effects: In our study nausea and vomiting was observed in 3 patients in Group A. The probable reason could be increased sensitivity of the patient to Tramadol as it has a direct effect on the chemoreceptor trigger zone in the brain thus resulting in vomiting even when anti-emetic was administered before epidural drug administration. Drowsiness was seen in 1 patient in Group B. Koshi T et al[12] in 1994 compared epidural Morphine with epidural Buprenorphine for postoperative analgesia and side effects. They compared 4mg of

epidural Morphine with 0.12mg of epidural Buprenorphine for postoperative analgesia. They found that the incidence of side effects were much less with epidural Buprenorphine compared to epidural Morphine. Hypotension, however was seen in 1 case in Buprenorphine group. A study done by Rathie P et al[13] to study the effectiveness and duration of post operative pain relief by epidural Tramadol found that nausea and vomiting were the common side effects with epidural Tramadol. There was no statistically significant difference in the mean pulse rate, mean blood pressure and mean respiratory rate among both the groups at pre-defined time intervals. L. Giridhar Naik, B. Venkateswar et al[14] conducted a study to compare postoperative analgesia among epidural Tramadol, Fentanyl and Buprenorphine over the first 24 hours in patients undergoing elective lower limb or lower abdominal surgeries and found no significant difference in hemodynamic parameters among the three groups except an increase in respiratory rate in the Fentanyl and Tramadol group compared to Buprenorphine group at 6 hrs and 7 hrs. Ichiishi N, Hiraishi T et al[15] studied the effects of epidural Buprenorphine on post-operative respiratory function using respiratory inductive plethysmography. They observed a decrease in respiratory rate and increase in tidal volume, however no severe respiratory depression was seen.

CONCLUSION:

From our study it can be concluded that epidural Buprenorphine provides a longer duration and better quality of analgesia compared to epidural Tramadol. However, the onset of analgesia was shorter with epidural Tramadol. No serious side effects and hemodynamic disturbances were seen post epidural drug administration both with Buprenorphine and Tramadol groups. Thus, epidural Buprenorphine is better in providing prolonged satisfactory postoperative analgesia as compared to epidural Tramadol.

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