

Comparison between epidural tramadol and epidural fentanyl for post operative analgesia in caesarean section patients.

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Abstract: Pain is a distressing feeling often caused by intense or damaging stimuli. The study is conducted with the aim to relieve pain postoperatively in patients undergoing caesarean section. A comparative study is being carried out between epidural tramadol and epidural fentanyl in 60 patients. In one group, 1mg/kg body weight of Inj Tramadol along with 9 ml of 0.125% bupivacaine was administered. The other group received 1µg/kg body weight of Fentanyl with 9 ml of 0.125% bupivacaine. Patients were given epidural Tramadol or Fentanyl when patient complained of pain postoperatively with VAS score of 2 or 3. Vitals were monitored every 30 min for 2 hours and every 2 hourly till patient complained of pain. Rescue analgesia was given when patient complained of pain and no monitoring done thereafter. Assessment of pain relief was done using VAS and side effects were noted.

Keywords: Analgesia, epidural, tramadol, fentanyl, VAS.

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I. Introduction

Pain is defined as an unpleasant sensory and emotional experience associated with actual or potential tissue damage¹. It is a universal experience that can span an enormous spectrum of intensity from mild discomfort to excruciating agony. Often the patients may fear of an operation mainly due to pain that follows rather than the mortal risks of operation itself. Many adverse physiological and psychological effects are caused due to post operative pain². Hence, proper control of post operative pain is important to avoid certain post operative complications in addition to provide comfort to the patient. The post operative pain can be relieved by various means as regional blocks, systemic medications and epidural analgesics. Any method of post operative analgesia must meet three basic criteria i.e. it must be effective, safe and feasible. Several studies have been conducted to evaluate the efficacy and safety of various opioids in providing post operative analgesia especially for caesarean section when given epidurally. These include morphine, pethidine, pentazocine, tramadol, fentanyl. All these drugs are associated with side effects such as respiratory depression, pruritus, nausea, vomiting, urinary retention, sedation etc. Because of these side effects the search continues for a better drug in caesarean section that will provide effective post operative analgesia with minimal side effects when given epidurally. This has prompted us to undertake this study of epidural tramadol and epidural fentanyl for post operative analgesia in caesarean patients. In this study, we have compared efficacy and safety of tramadol with fentanyl, both belonging to opioids group of drugs.

II. Materials And Methods

This study was a prospective type of study. After approval of ethical committee of our hospital and informed, written consent taken from the patient, the study was conducted. All patients were investigated routinely and kept NPO for 6 hours preoperatively. Each patient was explained about the procedure and also about visual analogue scale pain assessment. All the necessary drugs, monitoring equipments, resuscitation drugs were kept ready in wards. Inclusion criteria: pregnant women, ASA II, age 20 to 40 years, elective cases. Exclusion criteria: ASA III and ASA IV, emergency cases, patient refusal, patient on anticoagulation, patient with neurological deficits.

Sixty patients of ASA II undergoing elective caesarean section were randomly divided into 2 groups of 30 each. Group A (n=30) received epidural tramadol 1mg/kg along with 9 ml of 0.125% bupivacaine. Group B (n=30) received epidural fentanyl 1µg/kg and 9 ml of 0.125% bupivacaine.

All surgeries were conducted under combined spinal epidural anaesthesia. Epidural anaesthesia was given using epidural needle (Touhy) no.18 and 20G size of epidural catheter under all aseptic precautions using lignocaine 2% for local anaesthesia. Patients were given epidural tramadol or epidural fentanyl when patients

complained of pain postoperatively with VAS of 2 or 3. Vitals (Pulse rate, respiratory rate, blood pressure, oxygen saturation, onset of pain, onset of analgesia, duration of analgesia by VAS, occurrence of side effects like nausea, vomiting, itching, urinary retention) were monitored every 30 min for 2 hours and every 2 hourly till patients complained of pain. Rescue analgesia was given when patient complained of pain and further monitoring not done. Assessment of pain relief done using VAS and side effects noted.

III. Result

Onset of analgesia in fentanyl group was 7.9 min while in tramadol it was 10.76 min. When compared, onset of analgesia was greater with fentanyl than tramadol and this is statistically significant by 'Z' test. Duration of analgesia in fentanyl was 2.55 hours while in tramadol, it was 5 hours. When compared, duration of analgesia was more with tramadol than with fentanyl and this is statistically highly significant by 'Z' test. Change in respiratory rate after giving epidural tramadol in group A is statistically not significant by paired 't' test. SaO₂ rises after epidural tramadol in group A which is statistically significant by paired 't' test. Change in respiratory rate after giving epidural fentanyl in group B is statistically not significant by paired 't' test.

IV. Discussion

Epidural block with pharmacological drugs is a safe and common method for postoperative pain relief in caesarean section patients. Tramadol is centrally acting analgesic introduced in 1977. It acts on opioid receptors and its analgesic potency is 5-10 times less than morphine³. Fentanyl is a phenylpiperidine derivative, synthetic opioid agonist⁴. As an analgesic, it is 75 to 125 times more potent than morphine. In our study, both epidural tramadol and epidural fentanyl produce excellent analgesia. Duration of pain relief was longer in tramadol group as compared to fentanyl group. We have used a method to measure pathological pain which is known as VAS (visual analogue scale)⁵. The reliability of linear analogue scale was observed by Revill S.I et al in 1976⁶. In our study, the onset of analgesia was quicker with epidural fentanyl (7.90±1.47) than epidural tramadol (10.76±1.77) and this is statistically significant by using 'Z' test. Fu Y P et al in their study of postoperative analgesia with 75 mg of epidural tramadol noted a mean deviation of pain relief of 12±5 hours. Torda et al used 60 mcg fentanyl epidural for postoperative analgesia. They found mean duration of pain relief to be longer in epidural tramadol (5.00±1.64) when compared to epidural fentanyl (2.55±0.93) and this is statistically significant by 'Z' test. Before giving epidural tramadol and fentanyl, pulse rate and blood pressure was above the baseline readings due to pain. After giving epidural tramadol and fentanyl these parameters came down to baseline in both the groups which is statistically significant by paired 't' test. In our study, 3 patients in fentanyl group, but no patient in tramadol group complained of itching. Chaney Mark A in 1995 observed that nausea and vomiting was approximately 30% with the use of epidural opioids⁷. In our study we found that no patients had nausea in fentanyl while 30% of patients in tramadol group had nausea. The incidence of vomiting was 10% in tramadol group and no such cases found in fentanyl group. In our study, 1 patient from the tramadol group and 1 patient from fentanyl group complained of urinary retention which is statistically non-significant by using 'Z' test. Respiratory depression is the most feared side effect of intrathecal and epidural opioids. Stoelting R.K in 1980 observed that tramadol doesn't produce respiratory depression⁸. In our study, we have found that the respiratory rate decrease in both groups after administration of epidural drugs. Thus, in this study we found that the onset of analgesia was faster with epidural fentanyl but with significant occurrences of itching. The duration and degree of analgesia was better with epidural tramadol however there was significant increase of nausea and vomiting in this group.

V. Tables And Figures

Table 1: Distribution and comparison of onset time & duration of analgesia in the two groups

Parameters	Fentanyl group (n=30) Mean±SD	Tramadol group (n=30) Mean±SD	Statistical test value or 't' value	P value and inference
Onset of analgesia in minutes	7.90±1.47	10.76±1.77	6.81	0.000 significant
Duration of analgesia in hours	2.55±0.93	5.00±1.64	7.08	0.000 significant

Table 2: Distribution & comparison of side effects in the two groups

Side effects	Fentanyl group (no of patients)	Tramadol group (no of patients)	Statistical test value or Chi square value	P value & inference
Nausea	Yes=0 No=30	Yes=9 No=21	10.58	0.001 (significant)
Vomiting	Yes=0 No=30	Yes=3 No=27	3.15	0.08 (not significant)
Itching	Yes=3 No=27	Yes=0 No=30	3.15	0.08 (not significant)

Urinary retention	Yes=1 No=29	Yes=1 No=29	0.00	1.00(not significant)
Respiratory depression	Yes=0 No=30	Yes=0 No=30	*****	*****

Table 3:Distribution & comparison of VAS Score (0 to 10 cm)in the two groups before giving rescue analgesic

Time points	Fentanyl group VAS Score(mean±SD)	Tramadol group VAS Score (mean±SD)	Statistical test value or 't' value	P value & inference
0 min	2.50±0.51	2.37±0.49	1.03	0.31(not significant)
30 min	0	0		
1 st hour	0	0		
2 nd hour	0.57±0.50	0.06±0.25	4.85	0.00(significant)
4 th hour	3.63±0.49	1.26±0.40	19.48	0.00(significant)
6 th hour	***	2.36±0.42		
8 th hour	***	3.87±0.79		
10 th hour	***	***		

*** Rescue analgesic has been given and study end points has crossed.

VI. Conclusion:

- 1) Onset of analgesia with epidural fentanyl(7.90± 1.47) was quicker as compared to epidural tramadol(10.76±1.77) which is statistically significant by 'Z' test.
- 2) The mean duration of analgesia by comparing VAS pain score for epidural tramadol was 5.00±1.64 hours and for epidural fentanyl was(2.55±0.93) hours
- 3) After giving epidural drugs ,VAS pain score in first 30 to 60 minutes was 0 in both the groups.

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