

EVALUATION OF THE ANALGESIC AND ADVERSE EFFECTS OF TRAMADOL IN COMBINATION WITH LOW DOSE BUPIVACAINE FOR PAINLESS EPIDURAL DELIVERY

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ABSTRACT

Objective: To evaluate the analgesic and adverse effects of Tramadol in combination with low dose Bupivacaine for painless epidural delivery.

Study Design: Quasi-experimental study.

Place and Duration of Study: The study was carried out at department of anaesthesiology Military Hospital Rawalpindi from August 2004-July 2007.

Material and Methods: Fifty ASA-I uncomplicated full term primiparous were selected. Epidural analgesia was given with 15ml of 0.1% Bupivacaine plus 0.5% Tramadol when labour was established and was repeated on patient's demand. Pain was assessed by using verbal analogue scale 0-10 in first stage as well as in second stage of labour. Adverse effects on mother and baby were noted. Overall satisfaction about the procedure was also assessed.

Results: Forty two (84%) rated first stage of labour pain free (VAS-0) and Eight patients (16%) rated it as good pain relief (VAS-3). Thirty four (68%) patients in second stage of labour rated it pain free while sixteen (32%) patients rated it as good pain relief (VAS-3). One patient developed hypotension. Two patients complained of nausea. No patient complained of vomiting and none of them developed sedation. Three (6%) newborns had Apgar score nine and forty seven (94%) had ten after five minutes of delivery. Forty four patients described the experience as excellent; five described it as good and one as satisfactory.

Conclusion: Tramadol used in epidural painless delivery in combination with low dose Bupivacaine is very effective analgesic with less adverse effects on mother and baby and can be used as an alternative to fentanyl/pethedine.

Keywords: Analgesic effects, Bupivacaine, Painless delivery, Tramadol

INTRODUCTION

Labour is the most painful experience in a woman's life. It is not simply the physical pain that can be explained on physiological, chemical and neurological basis but it is associated with anxiety and fear also. Agony and stress that a woman suffers is beyond description. If pain is not adequately controlled, it can lead to maternal and fetal adverse outcome because of maternal sympathetic activation, which in turn predisposes to dysfunctional labour and compromises fetal oxygenation.

Effective pain relief in labour prevents the sympathetic activation and exhaustion of mother and improves obstetric outcome as well as it shortens the duration of labour due to

forceful and effective maternal timely coordinated voluntarily push.

In developed countries demand for painless delivery is at rise, in United States it was more than 50% in late 90's¹ and now increased to 70-80%.

In Pakistani women the knowledge about pain free labour is very low due to multiple factors², but it is now at increase and more and more women request for painless labour.

Many studies conducted in past have attempted to evaluate the effects of epidural analgesia during labour on obstetric outcome. Most of them have concluded that epidural analgesia during labour lead to increase rate of cesarean section and instrumental deliveries, and also increases the duration of labour 3, 4. Due to better understanding of drug pharmacology and trials with newer drugs, and more experience with combination of local

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anaesthetic and opioid, the obstetric outcome has improved^{5,6}.

It is now well established that the only consistently effective method of pain relief during labour is lumbar epidural analgesia. Use of only local anaesthetics in higher concentrations keep the patient paralyzed and leads to longer duration of labour and increases the rate of instrumental deliveries and cesarean section. The common practice is to use low concentration of local anaesthetics with combination of opioids. The most common opioid used worldwide is fentanyl family but in Pakistan fentanyl is not freely available so we tried the use of synthetic centrally acting mu agonist opioid Tramadol which is freely available and cheaper also. Tramadol is frequently used parenterally to reduce labour pains in this part of world but yet not commonly used for epidural painless deliveries^{7,8}.

This study was carried out to evaluate the analgesic and adverse effects of Tramadol in combination of low dose Bupivacaine for painless epidural delivery.

MATERIAL AND METHODS

This quasi-experimental study was carried out at department of anaesthesiology Military Hospital Rawalpindi from August 2004-July 2007. After obtaining approval from hospital ethic committee, all patients and their husbands were interviewed in antenatal period. They were explained about procedure, discussed the technique, shortcomings and possible problems/complications and written consent was taken. Consecutive 50 patients all primiparous ASA-I, requesting for painless delivery were included in this study. All patients were well educated and related to medical profession (Doctor, wife of a doctor or related to doctor) they all were highly keen to get epidural painless delivery. All patients selected for this study were with uncomplicated pregnancy without any mal-rotation or cephalo-pelvic disproportion. Epidural analgesia was given by consultant anaesthesiologist and all deliveries were conducted by consultant gynaecologist.

Pre-analgesia evaluation was done through history, systemic examination, examining spine and routine investigations including coagulation profile in all cases.

With the consultation of consultant gynaecologist induction of labour in early morning was planned in all cases. Cardiac monitor with noninvasive blood pressure, heart rate and pulse oximetry and cardiotocography (CTG) monitor were attached to the patient and basic parameters were recorded. Intravenous line was maintained with 18G cannula, patient was preloaded with Ringer's lactate solution 500ml. When labour was established and cervix dilatation was 3-4 cm, Epidural catheter was passed through 18G Tuohy's needle with bevel cephalad at L2-3 interspace. Loss of resistance technique with normal saline was used under aseptic conditions, in sitting position with midline approach. Epidural catheter having 5-6 cm in space was fixed with adhesive plaster at back. Analgesia was established with injection 0.1% (01mg/ml) Bupivacaine plus preservative free 0.5% (05mg/ml) Tramadol (Tramal), 15ml in supine position. Top up dose of 10ml was given on patient's demand intermittently. When cervical dilatation was about 8cm, 15ml of analgesic mixture was given in sitting position for second stage of labour. Patient was monitored for blood pressure with non invasive blood pressure monitor, heart rate and peripheral oxygen saturation by pulse oximetry, and fetal wellbeing was monitored by cardiotocography (CTG). Analgesia was assessed after 15 minutes of giving drug by monitoring pain free uterine contraction. Motor power was assessed using modified Bromage scale in both legs (0=No paralysis, full flexion of knees and feet; 1= Inability to raise extended legs; 2= Inability to flex knees; 3= Inability to flex ankle joints). Patients with full motor strength (Modified Bromage scale-0) were allowed to walk around accompanied with attendant. Pain was assessed using verbal analogue scale (VAS) 0-10 during first and second stage of labour. Zero verbal analogue score means complete pain relief and was considered excellent analgesia. Three verbal analogue score means seventy percent pain

relief and was considered good analgesia. Verbal analogue score more than three was considered as inadequate analgesia. Adverse effects of the drug on mother nausea, vomiting, sedation and hypotension were noted. Apgar score of baby was also noted at one minute and at five minutes after delivery. No prophylactic antiemetic was given to any patient.

Maternal satisfaction about the method of delivery was assessed on five point scale.

All data was analyzed by using statistical package for social sciences version-10 (SPSS-10).

Descriptive statistics were used to describe the data.

RESULTS

Fifty pregnant females were included in the study during the study period. Demographic description of the patients is given in table-1

Out of fifty parturients forty two (84%) rated the first stage of labour verbal analogue scale zero (VAS-0) means pain free and eight patients (16%) rated the first stage of labour as good pain relief (VAS-3). Thirty four (68%) parturients rated the second stage of labour pain free (VAS-0) while sixteen (32%) patients rated it as good pain relief (VAS-3) (Table-2). One (2%) patient developed hypotension and was managed with rapid intravenous ringer's solution infusion and injection ephedrine 05mg intravenously. Two (4%) patients complained of nausea and managed by reassurance and deep breathings. No patient complaint of vomiting and none of them developed sedation. Sixteen (32%) babies had Apgar score of eight and thirty four (68%) babies had ten at one minute after delivery. Three (6%) newborns had Apgar score nine and forty seven (94%) had ten after five minutes of delivery (Table-3). Forty four (88%) patients described the experience as excellent; five (10%) described it as good and one (2%) as satisfactory (Figure).

DISCUSSION

Pain relief is the basic right of a person and labour pain is one of the most severe pain that woman can experience, if any woman request for labour pain relief it is a duty of health care provider to arrange for labour pain relief. Different methods of pain relief depends upon

Table-1: Demographics description of patients (n=50)

| Variables | Mean(SD) |
|-------------|---------------|
| Age (years) | 26.54 (3.79) |
| Weight (kg) | 64.62 (5.75) |
| Height (cm) | 157.44 (3.48) |

Table-2: Description of verbal Analogue Scale (VAS) at two stages (n=50)

| Verbal analogue scale | First stage/ number of patients | Second stage/ number of patients |
|-----------------------|---------------------------------------|--|
| VAS-0 | 42 (84%) | 34 (68%) |
| VAS-3 | 08 (16%) | 16 (32%) |

Table-3: Description of score of babies at 1 min and 5 min (n=50)

| Apgar score | At one minute | At five minutes |
|-------------|---------------|-----------------|
| 08 | 16 (32%) | 00 |
| 09 | 00 | 03 (6%) |
| 10 | 34 (68%) | 47 (94%) |

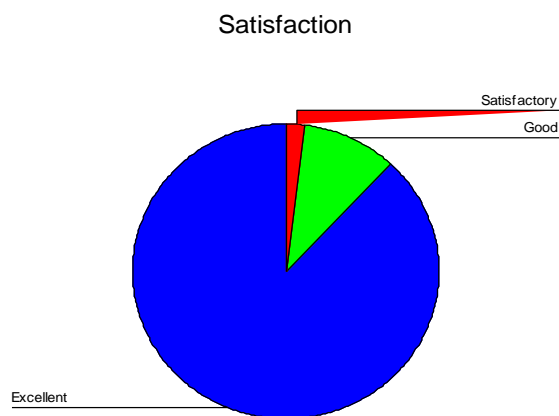


Figure: Patients satisfaction (n=50)

the technique locally available and the choice of the individual. Many drugs are being used to relieve labour pain. We studied the analgesic and adverse effects of Tramadol in relation to painless epidural delivery.

Tramadol is a synthetic centrally acting drug that binds the mu opiate receptors and inhibits nor epinephrine and serotonin reuptake. In epidural analgesia Tramadol is more effective than Bupivacaine, for labour pains it is as effective as pethedine with less sedation and respiratory depression of mother as well as newborn^{9,10}. Tramadol has less effect on gastric emptying. Chakraborty¹¹ and

colleagues compared the analgesic effects of intrathecal Bupivacaine and Bupivacaine plus Tramadol and concluded that later group had longer duration of analgesia 380 versus 210 minutes and no difference in blood pressure or respiratory depression.

Turker¹² and colleagues compared the effects of morphine and Tramadol in epidural analgesia and concluded that Tramadol results less sedation and less decrease in oxygenation. Baraka¹³ has also compared the analgesic and adverse effects of Tramadol and morphine in epidural analgesia and concludes that Tramadol can provide adequate and prolong postoperative epidural analgesia without any sedation or respiratory depression. Frikha¹⁴ has compared sufentanyl versus Tramadol in combined spinal epidural analgesia for labour and concludes that Tramadol has longer duration of action 114 as compared to 54 minutes of sufentanyl but has an adverse effect of vomiting.

Kuti¹⁵ and colleagues compared the analgesic efficacy and side effects of intramuscular (I/M) Pentazocine and Tramadol during labour analgesia and found that Pentazocine has better analgesic efficacy at sixty minutes after injection 47.7% as compared with 30.9% experienced moderate to good pain relief and 34.1% patients in Pentazocine group and 14.3% in Tramadol group rated their pain as mild after sixty minutes of drug administration. Maternal drowsiness was 22.7% in Pentazocine group as compared 14.3% in Tramadol group, Apgar score was less than seven in 11.4% babies in Pentazocine group as compared to 7.1% in Tramadol group at one minute after delivery and only one patient vomited in each group.

Jianjing¹⁶ and Yun compared the efficacy of Tramadol as patient control intravenous analgesia (PCIA) with combined spinal epidural analgesia (CSEA) plus patient control epidural analgesia (PCEA) and concluded that combined spinal epidural was more effective and has got rapid onset of action but the Apgar score was higher in patient control intravenous analgesia with Tramadol and recommended it as an alternative for painless delivery when

patient is not a good candidate for combined spinal epidural analgesia.

Tramadol has been used for long for parenteral labour analgesia and established its efficacy^{9,10,16} it has also been used in epidural/spinal for postoperative analgesia and established as a good analgesic with less side effects¹²⁻¹⁴ but in epidural labour analgesia it is used in very few studies¹⁵ that also not in this region of world where fentanyl and its family is not freely available. We tried Tramadol for epidural painless delivery and find it very effective and safe for mother as well as baby.

In our study forty two (84%) patients had VAS-0 in first stage of labour and eight (16%) patients rated the first stage of labour as good pain relief (VAS-3). Thirty four (68%) patients in stage second have excellent analgesia (VAS-0) while sixteen (32%) patients rated it as good pain relief (VAS-3) (Table-2). None of our patients had sedation, respiratory depression or any other adverse effect on mother as well as on baby. Only two patients developed nausea and one hypotension and these results are comparable with other international studies^{9,10,12-14}. Regarding patient's satisfaction, 88% patients rated the procedure as excellent, 10% rated it as good and 2% as a satisfactory.

As this study is a small study, there is a need for large and multicenter study to establish efficacy of Tramadol for painless epidural delivery as an alternative to or even better than fentanyl. We have planned a multicenter study.

CONCLUSION

Tramadol used in epidural painless delivery in combination with low dose Bupivacaine is a very effective analgesic with less adverse effects on mother and baby and can be used as an alternative to fentanyl/pethidine.

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