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Labour Analgesia and Epidural Labour Analgesia in Controlling Labour Pain-A Randomized Clinical Trial Study

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Abstract **Original Research Article**

Background: Labour analgesia has evolved from 18th century with the use of ether to present day practice of regional techniques. Variety of regional techniques, non-pharmacological methods and systemic analgesia had remodeled pain management in parturient resulting in better satisfaction. ***Objectives:*** To assess the labour Analgesia and epidural labour analgesia in controlling labour pain. ***Methods:*** This randomized interventional clinical trial was conducted in the department of Anaesthesia at Shaheed Ziaur Rahman Medical College Hospital, Bogura, Bangladesh from January to June 2022. A total of 72 parturients in active labour were allocated into two equal groups by using random allocation software. Group (G1) was given epidural injection of 15 ml of Bupivacaine 0.2% with 2mcg/ml fentanyl. Top up was given with same dose regimen in graded manner. Group (G2) was given programmed labour analgesia with Inj. Pentazocine 6mg IV+Inj. Diazepam 2mg IV+Inj. Tramadol 1mg/kg deep i.m and thereafter Inj. Drotaverine 40mg IV half hourly (maximum of 3 doses). Inj. Ketamine 0.25-0.5 mg/kg IV was given as resque analgesia. Quality of pain relief was assessed with VAS score. ***Results:*** Labour analgesia was better in epidural group (G1) with VAS decreased significantly at 5 min (p 3 and they required resque analgesia with ketamine. There were no significant changes in hemodynamics. Side effects were mild without needing any intervention. There was no effect on ambulation in group (G1). Local anaesthetics were needed for episiotomy in all cases in group (G2). No adverse effects were seen on neonate in either group. ***Conclusion:*** Epidural labour analgesia is a better option than programmed labour analgesia for pain relief in labour. In programmed labour satisfactory pain relief was not achieved and duration of analgesia was for shorter period. It does not affect mode of delivery and neonatal outcome. In programmedlabour pain relief is not satisfactory, remains for shorter duration and requires rescue analgesia.

Keywords: Labour Pains, Epidural Labour Analgesia, Programmed Labour.

INTRODUCTION

Labour analgesia has evolved from 18th century with the use of ether to present day practice of regional techniques. Variety of regional techniques, non-pharmacological methods and systemic analgesia had remodeled pain management in parturient resulting in better satisfaction [1]. Maternal pain relief benefits both the mother and her neonate. Hence option of labor analgesia should be given to all pregnant females. Numerous physical and psychological factors may influence the intensity and duration of labour pain and suffering [2]. Foetal outcome without any adverse maternal effect is the chief goal of pain relief during labor and lumbar epidural analgesia is the most efficient and widely employed modality for this. After initiation of epidural analgesia by bolus dose, many techniques have evolved for subsequent maintenance of analgesia such as intermittent boluses by the clinicians, midwives or patient herself and continuous epidural infusion. Maternal pain relief benefits both the mother and her neonate. Maternal and fetal effects of analgesia during labour remain central to discussions among patients, anaesthesiologists and obstetricians [3]. The aim should be maternal safety and pain relief without any adverse effects on progress of labour or on fetus. Central neuraxial analgesia is the gold standard technique for pain relief in labour. Epidural analgesia with less

concentration of local anaesthetics combined with opioids, provides good analgesia with little motor blockade known as"walking epidural" [4]. Pain relief starts sooner and lasts longer than either drug alone. Bupivacaine has advantage of more sensory blockade, less motor blockade than bupivacaine and decreased risk of systemic toxicity. We will also discuss the main complications and contraindications for this method of analgesia. Programmed labour is a method of providing labour analgesia which is easily available and the obstetrician can give it to the parturient. In this review, epidural analgesia refers to local anesthetics and adjuvants injected into the epidural space. Spinal anesthesia refers to local anesthetic, with or without adjuvants, injected into the subarachnoid space. Combined spinal–epidural analgesia includes analgesia initiated with an intrathecal injection and placement of an epidural catheter to provide a route for additional drug. To resolve various controversies we conducted this study to compare epidural labour analgesia and programmed labour analgesia. Epidural blockade comes close to being the ideal analgesic technique in labour. It provides continuous analgesia for an unpredictable period of time and to convert analgesia to anaesthesia if an operative intervention becomes necessary. Nowadays, less concentrations of local anaesthetics combined with opioids provides good analgesia with little motor blockade known as "walking epidural" [5]. The pain relief starts sooner and lasts longer than either drug alone. It allows both the drugs to be used in lower concentration, thereby reducing the risk of local anaesthetic systemic toxicity as well as opioids side effects [6]. Programmed labor is simple, easy and effective method for painless delivery. In programmed labor a cocktail of drugs are given to provide labor analgesia.6 Basic principles of Programmed labor are providing pain relief using analgesics and antispasmodics, ensure adequate uterine contractions and monitoring of labor events [6-8].

MATERIAL AND METHODS

This randomized interventional clinical trial was conducted in the department of Anaesthesia at Shaheed Ziaur Rahman Medical College Hospital, Bogura, Bangladesh from January to June 2022. Study participants included 72 parturients of ASA1 and ASA2 with uncomplicated pregnancy with vertex presentation was calculated anticipating a minimum of 20% decrease in VAS score at the time of delivery considering significance level of 96% (alfa=0.05) and 80% power of the study (beta=0.2). Randomization was done to allocate 72 parturients fulfilling the inclusion criteria. Various independent variables (eg. age, study group, drugs, dosing, baseline vitals) and dependent variables (vitals, VAS score, ambulation, APGAR, side effects) of interest were recorded on proforma for further analysis.

Inclusion Criteria

- Parturients requesting labour analgesia, in active labour, singleton pregnancy with vertex with spontaneous or induced labour, cervical dilatation 4-6 cm, 20-50% effaced, reactive NST, preruptured membranes less than 6 hrs, pre-eclampsia with non-severe features.

Exclusion Criteria

- Hypersensitivity to study drugs, bleeding disorders, decreased platelet count, spine surgery or deformity, mal presentations, cephalo-pelvic disproportion, previous LSCS, placenta previa, height<150 cm.

Thorough preanaesthetic evaluation was done on parturients. After taking informed consent, IV line was secured with 18G cannula and Ringer lactate started. Monitors were attached and baseline vitals and VAS Score recorded.

Study Group (G1): 36 parturients were subjected to epidural labour analgesia. Under all aseptic conditions (sitting/lateral position) 0.2% lignocaine local anaesthesia was infiltrated. With 18G TOUHY needle epidural spaces was approached through L3-4/L4- 5 intervertebral space using loss of resistance technique and hanging drop technique and 18G catheter was threaded and fixed at 5 cm from the epidural space. 3ml of study drug was given as test dose after negative aspiration for blood and cerebrospinal fluid. The catheter was secured and woman was placed in supine position. Five minute after test dose if she is able to move her legs and absence of hypotension, additional 12 ml of study solution was given. This dose was initial bolus and its time noted. If catheter was intravascular, it was removed and reinserted at another interspace. Intradural placement of catheter was removed from the study.

Study Group (G2): After complete physical examination by obstetrician, conventional programmed labour analgesia was given as practiced in SZRMCH, at cervical dilatation 4-6 cm. Parturient received Inj. Pentazocine 6mg i.v+Inj. Diazepam 2mg i.v+Inj. Tramadol 1mg/kg deep i.m and thereafter Inj. Drotaverine 40 mg i.v half hourly(max imum of 3 doses).Inj. Ketamine 0.25 mg- 0.5mg/kg was given as rescue analgesia if required at cervical dilatation of 7-8 cm. Time of inj. was noted and VAS score checked. Partographic monitoring of fetal heart rate was done throughout the labour. Following data were recorded at 0,5,15 minute and then every 15 minute till 1 hour and then every 30 minute until deliver. Heart rate, blood pressure, oxygen saturation, VAS score and fetal heart rate.

Study Drug: 15 ml of Bupivacaine 0.1% with 2 mcg/ml fentanyl (using 6 parts from a tuberculin syringe containing 50 mcg in 10 parts). Adequacy of analgesia checked after 5 min. If VAS score <3

analgesia was considered adequate. Onset of analgesia was from 1st bolus to time of achieving VAS <3.If analgesia was not adequate after 15 min, 2nd graded dose of 15 ml of study drug was given. If still analgesia was not attained, case was withdrawn and classified as epidural failure. An assisted trial of walk was given to assess ambulation. An additional graded dose of Bupivacaine (5ml+5ml+5ml) was given as top- up on patient request. Hypotension was defined as systolic blood pressure <90mmHg and treated with 6mg ephedrine. Bradycardia was defined as heart rate <60 bpm and was treated by inj. Atropine.

RESULTS

Out of total 72 parturient females recruited in the study, in group G1, 21 (58.3%) were primiparous and 15 (41.6%) were multiparous. The mean age (years) was 26.72 ± 4.26 years in group G1 and 25.17±4.17 years in group G2. Whereas in group G2, 19 (52.7%) were primiparous and 17 (47.2%) were multiparous. The mean period of gestation was 37.97±1.14 weeks in group 1 and 38.25±1.25 weeks in group 2. Mean cervical dilatation at time of entry in study was in group 1 was 4.95 ± 1.01 cm in group 1 and 5 ± 0.78 cm in group 2. Mean age, parity distribution, period of gestation and mean cervical dilatation was comparable (p>.05) in both groups. Maternal hemodynamic parameters were monitored. At 15 min the mean SBP started to increase in group 2 as compared to group 1 and the difference between the mean SBP became highly significant (p<.001) till 150 min. The mean oxyhemoglobin saturation was comparable (p value>.05) in both the groups. APGAR score at 1 min and 5 min were comparable in 2 groups. Duration of labour since starting of labour analgesia was 289.02±28.3min in Group (G1) and 295.02±24 min in Group(G2), which was comparable(p-value>.05). Visual analogue scale (VAS): Baseline mean VAS was 6.12±1.01 in Group (G1), At 5 minute it was 2.8±.68, which is highly significant (p value <.00001) and remained< 3 till the end of delivery. In Group (G2), mean VAS was 6.22±.91 at 0 minute, at 5 minute it decreased significantly(p value<00001) and was 3.62±.49.It remained low till only 270 minutes and that too was mostly > 3. The mean SBP significantly decreased (p value=.0002) at 5 min in Group (G1) and remained decreased till 180 min. After that it started increasing. In Group2 mean SBP started decreasing after 5 min and was significantly less than baseline (p value=.03) at 15 min and it remained decreased, significantly till 150 min (p value <.001). Then it started increasing. But if we compare mean systolic BP between the two groups, it was not significant. Mean maternal heart rates in Group (G1) decreased significantly from baseline (p value<.006) from 5 min till 60 min duration. Then it increased. In Group (G2) maternal heart rate decreased significantly from baseline at 5 min (p value=.004) and remained significantly low till 45 min, there after started increasing. But in between the Group (G1) and G2 decrease in maternal heart rates was comparable. Side effects: Out of 40 parturients in Group (G1), two subjects (5.5%) had pruritus and two (5.5%) had hypotension. In Group (G2), seven (19.4) had nausea /vomiting and three (8.3%) had drowsiness. In Group (G2) all parturients needed local anesthetic for episiotomy whereas in Group (G1) none needed local anesthetic. There was no effect on ambulation in either group. Mode of delivery: In Group(G1), 34(94.4%) parturients delivered by normal vaginal delivery, 2(5.6%) delivered by Caesarean section for non-progress of labour and deep transverse arrest. In Group (G2), 35(97.2%) delivered by normal vaginal delivery and 1(2.3%) delivered by caesarean section for foetal distress.

Table-1: Demographic and obstetric data were comparable in both the groups (N=72)

Characteristics	**G1**	**G2**	**p-value**
Mean Age (years)	26.72±4.26	25.17±4.17	.104
Parity			
Primi	21 (58.3)	19 (52.7)	.653
Multi	15 (41.6)	17 (47.2)	
Mean Cervical dilatation (cm)	4.95±1.01	5±0.78	.805
Mean POG(weeks)	37.97±1.14	38.25±1.25	.30
Duration of labour	289.02±28.3min	295.02±24 min	>.05
Side Effects On site effect Pruritus Hypotension Nausea /Vomiting Drowsiness	 32 (88.8) 2 (5.5) 2 (5.5) 0 0	 26 (72.2) 0-0% 0.0 7 (19.4) 3 (8.3)	
Mode of delivery Normal vaginal delivery Caesarean section	 34(94.4%) 2(5.6%)	 35(97.2%) 1(2.3%)	

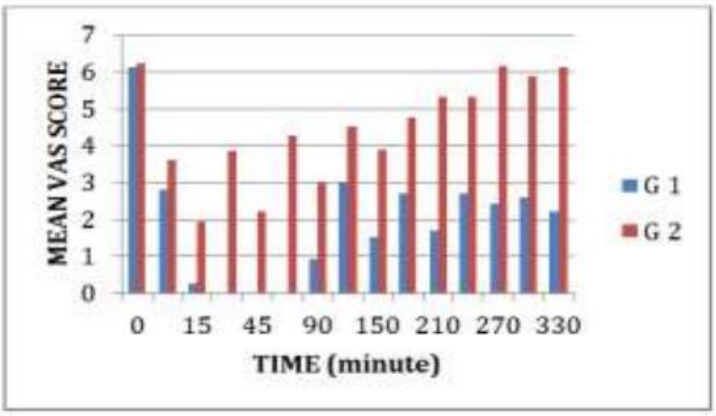

Fig-1: Mean Maternal VAS.

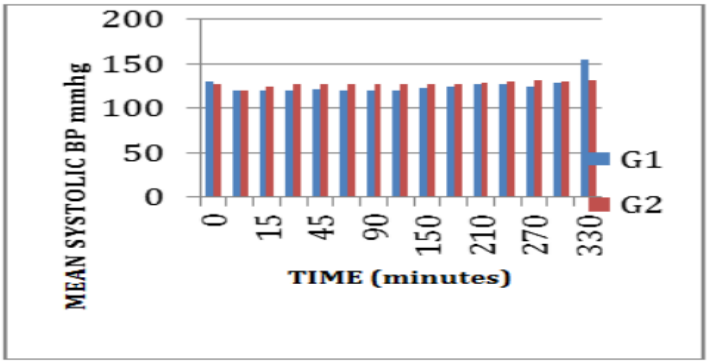

Fig-2: Mean maternal systolic blood pressure.

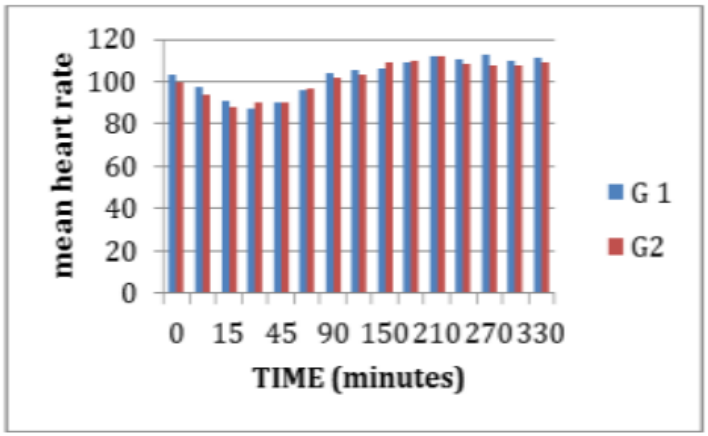

Fig-3: Mean maternal heart rate.

DISCUSSION

Out of various methods for labour analgesia, epidural anaesthesia satisfies the basic requirements of labour analgesia. It decreases the pains of labour without affecting the tone of pelvic floor muscles. It also retains the sensation of baby's head in vagina thus allowing labour to progress unaffected. In present study, there was no increase in caesarean section rate with epidural labour analgesia. Availability of Bupivacaine revolutionised the labour analgesia in terms of its reduced systemic toxicity and less motor blockade. Lipid soluble fentanyl exerts its effect only in 5 min and lasts for 60 to 90 min. Synergy between Bupivacaine and Fentanyl enhances duration of analgesia from 2.5 to 3 hours. Mean VAS scores were significantly less in group 2 than in group 1 at 5, 60, and 90 min. There were no significant changes in hemodynamics, nor adverse effects related to neonatal or maternal outcomes in both groups. There are misconceptions among obstetricians that epidural labour analgesia prolongs the labour and leads to more instrumentation in comparison to programmed labour. In our study VAS was <3 in all cases who were given epidural labour analgesia which were in accordance with study done by Chetty *et al*., [9] who found VAS <3 in all 72 parturients who were given Bupivacaine 0.2% with Fentanyl 2 mcg/ml. VAS was >3 in

programmed labour group. VAS was highly significant in two groups in our study (p<.00001). G. Sravani *et al*., [10] in a study on programmed labour found no pain relief in 5 patients, mild relief in 33 patients, moderate pain relief in 12 patients and no patient had complete pain relief. S. N. Daftary [11] concluded that only 70% patients get pain relief by programmed labour. There was 10% decrease in mean SBP from baseline and 12% decrease in heart rate in Group (G1) but no parturient had bradycardia. Dr Tushar Majumder *et al.*, [12] did not find hypotension with different concentrations of Bupivacaine and Fentanyl in 60 parturients. In Group (G2) no parturient developed hypotension or bradycardia in concordance with study by Priyanka Kadakia *et al*., [13]. No rescue was required in group (G1) but all parturients needed Ketamine as resque analgesic in Group (G2). No adverse effect on APGAR in both the groups, in consistence with study done by Millicent Anim-Somuah *et al*., [14]. There was no increase in caesarean rate with epidural labour analgesia group (G1), it was only 5% and in programmed labour group (G2) it was 2.5%. Chetty *et al*., [6] had 95% vaginal deliveries and 2.5% caesarean rate and 2.5% had forceps delivery. Agarwal *et al*., [15] in their study observed that instrumental delivery does not relate to epidural analgesia. Duration of labour was slightly less in Group (G1) but statistical significance was not seen in duration of labour between the two groups. Halpern and Leigton [16] found no increase in duration of labour in epidural group versus systemic opioids. Side effects were not significant in group (G1). No intervention was required by them. Incidence of hypotension is known in 10% cases of neuraxial analgesia during labour and pruritus in 30-100% cases after neuraxial opioids. In programmed labour nausea/vomiting occurred in17.5% and drowsiness in 7.5 % cases. In study by Veronica *et al*., [11] nausea /vomiting was seen in 10 % cases. We observed failure in one case and it was excluded from the study. Epidural analgesia has minimum effect on maternal haemodynamics, while parturients in programmed labour group did not show any adverse effect on maternal haemodynamics. Duration of labour in epidural group was slightly less than programmed labour group, but there was no significant difference between the two. Epidural as well as programmed labour do not prolong duration of labour. There was no effect on ambulation in either group as assessed by giving assisted trial walk, no adverse effect on neonatal APGAR score at 1min. and 5min. and no significant effect on mode of delivery in both the groups.

CONCLUSION

Epidural labour analgesia is a better option than programmed labour analgesia for pain relief in labour. In programmed labour satisfactory pain relief was not achieved and duration of analgesia was for shorter period. It does not affect mode of delivery and neonatal outcome. In programmed labour pain relief is not satisfactory, remains for shorter duration and requires rescue analgesia.

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Conflicts of interest: There are no conflicts of interest.

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