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TO STUDY THE LABOUR AND PERINATAL OUTCOME OF EPIDURAL ANALGESIA IN ACTIVE PHASE OF LABOUR

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ABSTRACT

Introduction: The delivery of an infant into the arms of a conscious and pain free mother is one of the most exciting and rewarding moments in life of a woman1. Analgesia during labour is a basic component of a relaxed childbirth experience and can influence subsequent pregnancy desire4. Numerous strategies both pharmacologic and non pharmacologic, have been used as treatment of labour pain7. Regional analgesia remains the gold standard of pain relief during labour. It includes epidural analgesia, combined spinal epidural, and spinal analgesia. Epidural analgesia is a central nerve blockade technique which involves the injection of a local anaesthetic into the lower region of the spine. The injected agent gradually diffuses across the dura into the subarachnoid space. Blocking of the painful impulses becomes apparent within 10-20 minutes of administration13. However despite being so popular, epidural analgesia is not without complications, with hypotension being the most common. Other complications include accidental dural puncture, infection, intravascular placement, high block, postpartum backache and epidural hematoma. The advantages of epidural analgesia in labour are numerous but in our country this option is not widely available to the parturients. In the view of above, we plan to conduct a study in our set up to provide pain free delivery to parturients and to see the effect of epidural analgesia on labour and perinatal outcome. **Aims And Objectives:** To study labour and perinatal outcome of epidural analgesia in active phase of labour. **Materials And Methods:** A prospective interventional study was conducted in the Department of Obstetrics and Gynaecology in collaboration with Department of Anaesthesiology at Dr.RPGMC Kangra at Tanda after the approval of protocol review committee and ethical committee of the institution. Parturients reporting to labour room in early active phase of labour fulfilling the inclusion criteria were explained about the study and counselling regarding epidural analgesia was done. Those who were willing to participate in the study formed Group 1/Epidural group after taking informed written consent and Group 2/Non epidural group included women immediately next to epidural case with similar demographic characteristics who did not want epidural analgesia. These women received pain relief as per the standard protocol of our institution. **Results:** The two groups were similar with respect to demographic profile. There was no significant difference in age, socioeconomic status, BMI between the two groups. There was no statistical significant difference in the mode of onset of labour in both the groups (p value=0.297). Percentage of women who needed augmentation of labour was significantly higher in group 1 as compared to group 2 (p value=0.002). There was no statistical difference in the mode of delivery in the two groups. There was no statistical significant difference in duration of first stage of labour (p value=0.551) as well as in duration of second stage of labour (p value=0.45) in both the groups. The mean VAS score after administration of epidural analgesia at 15 minutes as well as during second stage of labour was significantly higher in Group 2 as compared to Group 1 (p value<0.0001). **Conclusion:** From the present study it was observed that women with epidural analgesia during labour had significant pain relief as compared to women who were given conventional pain relief as per the institutional protocol. There was no prolongation of first and second stage of labour in the epidural group compared with control group, though more augmentation of labour with oxytocin was required in the epidural group. Also no significant increase in the incidence of operative vaginal delivery or caesarean section was observed due to epidural analgesia.

KEYWORDS :

INTRODUCTION

The delivery of an infant into the arms of a conscious and pain free mother is one of the most exciting and rewarding moments in life of a woman[1]. Childbirth is a normal life event yet it is considered one of the most painful experience a woman ever encounters. The physical and the cultural birth environment and the degree of emotional support provided by clinical care givers and the woman's birth companions also affect perceptions of pain[2].

There is evidence that labour pain is more severe in humans than almost all other mammalian species, partly due to changes in the pelvis brought about by the upright posture and partly due to prolonged gestation resulting in increased foetal weight[3]. Therefore management of labour pain is a crucial moment not only in providing more comfort to the woman in labour but also in relieving their stress and suffering.

Analgesia during labour is a basic component of a relaxed childbirth experience and can influence subsequent pregnancy desire[4]. According to American Society of Anaesthesiology and American college of Obstetricians and Gynaecologists "in the absence of medical contraindication, maternal request is sufficient indication for pain relief during labour"[5]. Adequate labour analgesia should significantly decrease delivery associated pain, be comfortable for the parturient woman, enable active labour participation and ensure satisfactory progress of labour[6].

Providing effective and safe analgesia for labour has always been a challenge more so because of the myths and controversies surrounding labour. Numerous strategies both pharmacologic and non pharmacologic, have been used as treatment of labour pain[7]. Non pharmacological methods include massage and warm bath, relaxation in form of music or meditation, Aromatherapy, birthing balls, hypnosis, Transcutaneous electrical nerve stimulation (TENS) and acupuncture therapy[8]. In the pharmacological methods there are options like Non Opioid analgesics, systemic opioid analgesia, nitrous oxide and Regional analgesia. The technique selected from a wide range of available techniques is aimed to relieve pain and depends on the mode of delivery, personal choice, and doctor's recommendations[9].

Non pharmacological methods of analgesia are non invasive

maybe useful for mild labour pain. They are generally inexpensive, easy to administer and low risk, however their efficacy is unclear due to limited evidence. Pharmacological options in labour are limited because they have dose dependant maternal and foetal side effects. Opioids in neonates exacerbate acidosis, depresses APGAR scores and respiration. Nitrous oxide in form of Entonox acts as a very weak anaesthetic at high concentrations and as an analgesic and anxiolytic at lower concentrations[10].

Regional analgesia remains the gold standard of pain relief during labour. It includes epidural analgesia, combined spinal epidural, and spinal analgesia. It was introduced by Spanish military surgeon, Fidel pages in 1921[11]. It was then popularized by John Bonica, an American Anaesthesiologist. Since the 1960s epidural analgesia had been widely introduced as pain relief in labour in developed countries. Epidural analgesia is a central nerve blockade technique which involves the injection of a local anaesthetic into the lower region of the spine. The injected agent gradually diffuses across the dura into the subarachnoid space. The anaesthetic inhibits nerve conduction by blocking sodium channels in nerve membranes and thus preventing the propagation of nerve impulses along these fibres[12], yet it allows mother to fully participate in the process of childbirth without being sedated.

Blocking of the painful impulses becomes apparent within 10-20 minutes of administration[13]. Lumbar epidural analgesia aims to produce a selective sensory block from T10 to L1 while at the same time sparing the motor supply to the lower limbs (L2 to L5) and it is called mobile epidural or walking epidural. However despite being so popular, epidural analgesia is not without complications, with hypotension being the most common. Severe sudden hypotension may result in significant decrease in uteroplacental blood flow, which could potentially affect delivery of oxygen to the baby. Other complications include accidental dural puncture, infection, intravascular placement, high block, postpartum backache and epidural hematoma.

The use of epidural analgesia during childbirth is continually being refined, and much of its success depends on the skill with which it is administered. There is still a wide gap between desire for labour analgesia and its provision. Good communication and a team effort are needed to reap the benefits of pain free labour. The advantages of epidural analgesia in labour are numerous but in our country this option is not widely available to the parturients. In the view of above, we plan to conduct a study in our set up to provide pain free delivery to parturients and to see the effect of epidural analgesia on labour and perinatal outcome.

AIMS AND OBJECTIVES

AIM: To study labour and perinatal outcome of epidural analgesia in active phase of labour.

Primary Outcome

To compare the incidence of operative deliveries (abdominal or vaginal) in parturients with or without epidural analgesia.

Secondary Outcome

1. To compare the duration of active first and second stage of labour in women receiving epidural and those not receiving epidural analgesia.
2. Foetal outcome in terms of APGAR score at 1 and 5 min and NICU admissions.
3. Side effects and complications of epidural analgesia
4. Patient satisfaction

MATERIALS AND METHODS

A prospective interventional study was conducted in the Department of Obstetrics and Gynaecology in collaboration with Department of Anaesthesiology at Dr.RPGMC Kangra at Tanda after the approval of protocol review committee and ethical committee of the institution. The women who were in early active phase of labour and met the inclusion criteria were explained about the study in detail and those women who were willing to participate were included in the study.

Inclusion Criteria

1. Primigravida with full term singleton pregnancies (37-42 weeks) with vertex presentation.
2. No obstetric or medical risk factors contraindicating epidural analgesia.
3. Normal fetal heart rate before the time of induction of epidural labour analgesia.
4. Women in early active phase of labour (3-4cm dilation of cervix)

Exclusion Criteria

1. Multiparity
2. Prematurity and postmaturity
3. Any contraindication for vaginal delivery like CPD or malpresentation.
4. Patient in latent phase of labour
5. Non reassuring fetal heart rate
6. Contraindication for epidural analgesia (coagulopathy, infection at local site, spine deformity, allergy to the study drug)

Sample Size

In order to calculate sample size, the incidence of operative and caesarean deliveries in Group 1 (cases) assumed 33% and 5% in Group 2 (controls) with 80% confidence interval and 5% level of significance. Total sample size calculated =60.

Parturients reporting to labour room in early active phase of labour fulfilling the inclusion criteria were explained about the study and counselling regarding epidural analgesia was done. Those who were willing to participate in the study formed Group 1/Epidural group after taking informed written consent and Group 2/Non epidural group included women immediately next to epidural case with similar demographic characteristics who did not want epidural analgesia. These women received pain relief as per the standard protocol of our institution.

Complete detailed history was obtained and thorough clinical examination including general physical examination, systemic examination and obstetric examination (including per abdomen, per speculum and per vaginal examination) was done. All the investigations were recorded and any additional investigations were done as per requirement. The contraindications for epidural analgesia and vaginal delivery were ruled out. Cases consisted of 30 participants who underwent epidural analgesia and controls consisted of 30 participants in whom standard method of pain relief was used as per our institutional protocol.

Epidural Group

After counselling, an informed written consent was taken from parturient who were willing for epidural analgesia. Thorough preanaesthetic check-up was carried out in the epidural group by the anaesthesia team. A 500 ml of Ringer lactate solution was started intravenously slowly. She was seated in upright position/left lateral position for epidural placement under all aseptic precautions. Epidural space was identified at L2-3 or L3-4 space and skin was infiltrated with 2ml of 2% Xylocaine. An epidural catheter was threaded through 18G Tuohy needle. Epidural drug was prepared by taking two 10 ml syringes. In each syringe 5ml of 0.2% Ropivacine with 3.5 ml of 0.9% normal saline and 1.5 ml of Fentanyl (10 g/ml) was added to it. Thus a total of 20 ml of drug was prepared with a final concentration of 0.1% Ropivacaine and 1.5 micrograms/ml of Fentanyl for loading the epidural space. The prepared drug was given in increments of 3 ml and each increment was considered as the test dose given after negative aspiration of

blood and CSF and time the increment was given. The adequacy of analgesia was assessed 5 minutes after the increment of drug was administered. Onset of analgesia was defined as duration from injection of first initial epidural bolus dose to attainment of VAS <3. In case of inadequate analgesia (VAS<3) during labour, epidural top-ups were given in 3ml increments of same drug till sufficient block was achieved.

Pain relief was recorded as per VAS (Visual analogue scale) score which ranged from 0-10 where 0 being no pain and 10 being maximum pain. Presence of motor block in lower extremities was assessed using a modified Bromage scale shown below:

Score	Criteria
1	Complete block (unable to move feet or knees)
2	Almost complete block (able to move feet only)
3	Partial block (just able to move knees)
4	Detectable weakness of hip flexion while supine (full flexion of knees)
5	No detectable weakness of hip flexion while supine
6	Able to perform partial knee bend

Pain score (VAS), sensory and motor block characteristics and vital parameters (pulse, mean arterial pressure, respiratory rate) were recorded at 0 (before epidural), 5, 15 min and then every 15 minutes till 1 hour and then every 30 minutes until the delivery.

All parturients were given trial walk in the presence of attendant to assess their ability to ambulate. Patient was instructed to pass urine every hour. Any adverse effects of epidural analgesia like hypotension, bradycardia if occurred were recorded by the anaesthetist.

Obstetric Management

The obstetric management was similar in both the groups as per the protocol of our institution. Throughout the procedure maternal heart rate, blood pressure, motor and sensory blockage levels were assessed. Maternal, foetal condition and progress of labour were monitored partographically. Foetal heart rate was monitored using CTG and any evidence of foetal heart rate and liquor abnormalities were recorded. Level of pain was graded according to VAS score. Augmentation of labour was done by Oxytocin infusion if uterine contractions were inadequate (less than 3 in 10 minutes for 45 seconds). Decision regarding operative deliveries or instrumental vaginal was made according to maternal or foetal indications. Mode of delivery (normal vaginal/instrumental vaginal/ caesarean) was noted. Duration of first stage of labour was calculated as the time interval between patient entering the active stage of labour and full dilatation of cervix. Duration of second stage of labour was calculated from full dilatation of cervix to delivery of the baby from the birth canal. Neonatal assessment was performed by assessing the APGAR score at 1 and 5 min and any NICU admission was noted. Labour and postpartum period was managed as per the standard protocol.

OBSERVATIONS

Majority of the women in both the groups were between 20-25 years. Mean ± SD age (years) in group 1 was 25.13 ± 3.62 and group 2 was 25.33 ± 3.25 with no significant difference between them. (p value=0.823). Education status of women was comparable in both the groups (p value=0.210). Mean BMI in Group 1 was 20.52 ± 1.73 and in Group 2 was 20.35 ± 2.05, which was comparable in both the groups. In Group 2, 19 (63.3%) women out of 30 had spontaneous onset of labour whereas only 15 (50%) women in Group 1 had spontaneous labour. Induction was done in 15 (50%) women in group 1 whereas only 11 (36.67%) women had induction of labour in Group 2.There was no statistical significant difference in the mode of onset of labour in both the groups (p value=0.297)

All women in Group1/Epidural Group (100%) required augmentation of labour whereas in Group 2/ Non Epidural Group, 20 (66.6%) out of 30 women required augmentation of labour. Percentage of women who needed augmentation of labour was significantly higher in group 1 as compared to group 2 (p value=0.002)

The table 1 shows the need for augmentation of labour during various stages in both the groups.

Table 1 Need For Augmentation Of Labour (N=60)

Augmentation	Group 1(N=30)	Group 2(N=30)	P value
Required			0.002‡
a. Early 1st stage (3-6 cm)	23(76.6%)	15(50%)	
b. Late 1st stage (>=7 cm)	4(13.33%)	4(13.33%)	
c. Second stage	3(10%)	1(3.33%)	
Not Required	0 (0%)	10 (33.33%)	

‡ Fisher's exact test

In present study, 26 (86.6%) women in Group 1 and 25 (83.3%) women in Group 2 had vaginal delivery. Emergency LSCS was done in four (13.3%) women of Group 1 and five (16.66%) women of Group 2. There was no statistical difference in the mode of delivery in the two groups. Duration of first stage of labour ranged from 390-480 minutes with mean of 450± 31.24 in Group 1 and it ranged from 390-540 minutes with mean of 445.21 ± 36.16 in Group 2.There was no statistical significant difference in duration of first stage of labour in both the groups. (p value=0.551) Though the mean of duration of second stage of labour was slightly more in Group 1(38.54 ± 19.04) as compared to Group 2 (33.52 ± 10.77), none of the patients had prolonged second stage of labour in both the groups. There was no statistically significant difference in both the groups regarding the duration of second stage of labour (p value=0.45) There was no statistically significant difference in both the groups regarding the complications in intraoperative/ intrapartum period. Distribution of neonatal complications was comparable between Group 1 and 2.

Mean of VAS score at 15 minutes after analgesia in Group 1 was 3.3 ± 0.95 and in Group 2 was 7.77 ± 0.5.Similarly VAS score during second stage of labour in Group 1 was 4.47 ± 1.38 and in Group 2 was 8.77 ± 0.86. So the mean VAS score after administration of epidural analgesia at 15 minutes as well as during second stage of labour was significantly higher in Group 2 as compared to Group 1 (p value<0.0001). Table 2 shows VAS score at different time intervals between both the groups.

Table 2 Mean Vas Score (N=60)

VAS SCORE	Group 1(N=30)	Group 2(N=30)	P value
Before analgesia			
Mean ± SD	7.67 ± 0.71	7.57 ± 0.5	0.753†
Range	7-9	7-8	
15 minutes after analgesia			
Mean ± SD	3.3 ± 0.95	7.77 ± 0.5	<.0001†
Range	3-8	7-9	
Second stage of labour			
Mean ± SD	4.47 ± 1.38	8.77 ± 0.86	<.0001†
Range	3-10	7-10	

† Mann Whitney test

DISCUSSION

In the present study, the two groups were comparable as the mean age of patients in Group 1 was 25.13 ± 3.62 and in Group 2 was 25.33 ± 3.25. The mean age in a study conducted by Deshmukh et al and Decca L et al was slightly lower than the present study whereas the mean age was slightly higher in a study conducted by Agarwal D et al which was 28.13±3.83 in

Group 1 and 26.95±3.79 in Group 2.In these studies also the mean age was comparable between the two groups.

The BMI was within normal range in the study of Deshmukh V et al (Group 1=22.35 and Group 2=21.98) and Antonakou A et al (Group 1=22.3± 1.9 and Group 2=21.9±1.9) which was comparable with our study. The mean BMI of the women in two groups were within normal range but was slightly higher in the studies conducted by Newnham E et al (Group 1=25.1± 4.8 and Group 2=23.5± 3.9) and Wang L et al (Group 1=23.48±0.46 and Group 2=23.42±0.58) as compared to our present study.

In the present study, onset of labor was spontaneous in 50% of women in Group 1 and induction of labour was done in remaining 50% whereas in Group 2, 63.3% women had spontaneous onset of labour and 36.67% had induction of labour. Similar to our study, Malevic A et al and Hung T et al showed that spontaneous onset of labour was more in women of Group 2 as compared to Group 1. Decca L et al showed equal percentage i.e. 22.7% of women in both the groups had spontaneous onset of labour which is in contrast to our study.

In the present study, all the 30 women (100%) in Group 1 and two third women (66%) of Group 2 required augmentation of labour with Oxytocin. In the various other studies also, more women in Group 1 required augmentation with oxytocin as compared to Group 2. However the difference in the need of augmentation of labour between the two groups was significant in our study and Thorp J et al, and not significant in studies by Nafisi S et al, Mousa et al and Sawant V et al.

In the present study, the rate of normal vaginal delivery was comparable between Group 1 and Group 2 (Group 1=70% Vs Group 2=76.6%). The rate of caesarean delivery was also comparable in both the groups (Group 1=13.33% Vs Group 2=16.66%). All of the mentioned studies, showed results similar to our study with maximum number of patients having normal vaginal delivery and also the rate of normal vaginal delivery was slightly higher in Group 2 as compared to Group 1. All these studies showed no significant difference between Group 1 and Group 2 in terms of operative vaginal delivery although a higher incidence was seen in Group 1(epidural group) as compared to Group 2(non epidural). Similarly, the rate of caesarean section was also comparable between Group 1 and Group 2 in various studies. Contrasting results were observed by Thorp J et al where the rate of caesarean delivery was significantly higher in Group 1 (25%) as compared to Group 2 (2.2%). Table 3 shows mode of delivery in various studies.

Table 3: Mode Of Delivery (%)

Authors	Normal vaginal		Operative vaginal		Emergency LSCS	
	Group 1	Group 2	Group 1	Group 2	Group 1	Group 2
Deshmukh Vet al	84%	88%	10%	4%	6%	8%
Agarwal D et al	73.3%	86.67%	16.7%	6.67%	10%	6.67%
Sawant V et al	83.33%	86.66%	10%	3.33%	6.66%	10%
Thorp J et al	56.2%	86.7%	18.7%	11.1%	25%	2.2%
Mousa et al	87.5%	90%	5%	5%	7.5%	5%
Present study	70%	76.6%	16.6%	6.66%	13.33%	16.66%

In the present study, the mean duration of first stage of labour in Group 1 was 450 ± 31.24 min and in Group 2 was 445.8 ± 35.52 min with no significant difference between both the groups (p value=0.55). Similar results were observed in various studies with no significant difference in the duration of first stage of labour between Group 1 and Group 2. Contrasting results were found by Agarwal D et al. In their study the duration of first stage of labour in Epidural group (289.8 ±95.4 min) was significantly shorter as compared to control group (328 ±93.6 min) (p value=0.025%). Table 4 shows the duration of first stage of labour in various studies.

Table 4: Mean Duration Of First Stage Of Labour

Authors	Duration of first stage of labour		P value
	Group 1	Group 2	
Agarwal D et al	289.8 ±95.4 min	328 ±93.6 min	0.025
Sawant V et al	381.16 ±61.75 min	370.03 ±79.33 min	0.54
Decca L et al	254 ±96 min	251 ±103 min	NS
Mousa et al	535.80±13.21 min	537.24±11.71 min	0.35
Present study	450 ± 31.24 min	445.8 ± 35.52 min	0.551

In the present study as well as the other studies mentioned below in table 30, the duration of second stage was more in Group 1 as compared to Group 2. The mean duration of second stage of labour in Group 1 was slightly more (38.54 ± 19.04 min) as compared to Group 2 (33.52 ± 10.77 min) but the difference was not significant statistically. Similarly, study by Mousa et al showed no significant difference in mean duration of second stage in both the groups (Group1=61.3±5.53 min; Group 2=61.02±6.43 min) with p value=0.41. This is attributed to adequate hydration of parturients and appropriate dose of analgesics. Though similar to our study, the duration of second stage of labour in Group 1 was more as compared to Group 2 in the studies by Agarwal D et al, Sawant V et al and Decca L et al, but the results of these studies were statistically significant whereas the difference between the two groups was not significant in our study. In these studies, the probable cause of prolonged second stage was attributed to motor blockade which reduces effective maternal pushing. Table 5 shows the mean duration of second stage of labour in various studies.

Table 5: Mean Duration Of Second Stage Of Labour

Authors	Duration of second stage of labour		P value
	Group 1	Group 2	
Agarwal D et al	33.13±12.78 min	27.53±11.73 min	0.013
Sawant V et al	71.63 ±10.11 min	23.00 ±10.30 min	<0.001
Decca L et al	41±21 min	32±18 min	0.005
Mousa et al	61.3±5.53 min	61.02±6.43 min	0.41
Present study	38.54 ± 19.04 min	33.52 ± 10.77 min	0.45

The percentage of neonates admitted in NICU was higher in Group 2 (6.66%) in our study as compared to Group 1 (3.33%) which was similar to the study of Hung T et al (Group 1=.1.5% and Group 2=1.8%). Contrasting results were observed in a study by Antonakou A et al where Group 1 (4.7%) had more NICU admission compared to Group 2 (3.7%).

Before administration of epidural analgesia, pain VAS score was comparable among the two groups. At 15 minutes after epidural analgesia, in our study there was significant decrease in VAS score in Group 1 from Group 2. During the second stage of labour, in our study the mean VAS score was significantly higher in Group 2 (8.77 ± 0.86) as compared to Group 1 (4.47± 1.38). Similarly VAS score in study by Deshmukh V et al was significantly higher in Group 2 (8.62±1.06) as compared to Group 1(1.94±0.61). Table 6 shows mean VAS Score at different stages of labour in the two studies

Table 6: Mean Vas Score

Authors	Before analgesia		At 15 minutes		During second stage	
	Group 1	Group 2	Group 1	Group 2	Group 1	Group 2
Deshmukh V et al	7.94± 0.91	7.80± 0.88	2.68± 0.86	7.92± 0.92	1.94± 0.61	8.62± 1.06
Present Study	7.67 ± 0.71	7.57 ± 0.5	3.3 ± 0.95	7.77 ± 0.5	4.47 ± 1.38	8.77 ± 0.86

CONCLUSION

From the present study it was observed that women with epidural analgesia during labour had significant pain relief as compared to women who were given conventional pain relief as per the institutional protocol thereby ensuring better comfort to the women during labour. Epidural analgesia showed no evidence of detrimental effects on maternal and neonatal outcome during labour and postpartum period. There was no prolongation of first and second stage of labour in the epidural group compared with control group, though more augmentation of labour with oxytocin was required in the epidural group. Also no significant increase in the incidence of operative vaginal delivery or caesarean section was observed due to epidural analgesia.

As effective management of labour pain plays an important role in woman's satisfaction with childbirth, epidural analgesia has become the gold standard for pain relief during labour. Though the sample size in the present study was small but it can be concluded that epidural analgesia is a safe and effective method of pain relief during labour and can be considered for labour analgesia especially in nulliparous women who are more anxious regarding labour and delivery compared to multiparous women.

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