Comparative Study of the Effect of Early Versus Late Initiation of Epidural Analgesia on Labour

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Abstract: *Background:* Epidural analgesia also known as regional analgesia has been established as a safe and an effective method of pain relief during labor. It was thought that epidurals may possibly interfere with labor and consequently increase the rate of cesarean deliveries or instrumental deliveries or other adverse effect. A more recent review concluded that epidural analgesia is not associated with such a risk. But, the timing of placement of epidural analgesia has been a controversial issue and how early laboring women can benefit from epidural analgesia is still debated. Hence this comparative study determines the effect of early versus late initiation of epidural analgesia on labor.

Objective: To compare the effect of early versus late initiation of epidural analgesia on the duration of labour and the mode of delivery.

Methodology: A randomized trial in which 100 term women in early labor at less than3 cm of cervical dilatation were assigned to either immediate initiation of epidural analgesia at first request (50 women) or delay of epidural until the cervix was dilated to at least 4 cm (50 women).

Results: At initiation of the epidural, the mean cervical dilatation was 3.1 cm in the early epidural group and 4.4 cm in the late group (P value 0.0000). The mean duration from initiation to full dilatation was significantly shorter in the early compared to the late epidural group: 5.57 hours and 6.3hours respectively amongst primigravida (P = 0.0001) and 3.04 hours and 4.07 hours respectively amongst multigravida. The rates of cesarean section were not significantly different between the groups *i.e.* 6% and 6% in both early and late groups (P = 0.82) which was not significant. When questioned after delivery regarding their next labor, the women indicated a preference for early epidural.

Conclusion: Epidural analgesia in the early labour, following the first request for epidural at cervical dilation of 2-3 cm does not prolong the progression of labor and does not increase the rate of Cesarean deliveries , instrumental vaginal deliveries , and other adverse effects in laboring women compared with the delayed analgesia at the cervical dilation of 4.0 cm or more. Furthermore, it was associated with shorter duration of the first stage of labor and was clearly preferred by the women.

Keywords: Epidural, Painless labor, Instrumental deliveries, Cesarean section.

INTRODUCTION

"Pain is Inevitable. Suffering is Optional" – Buddha

There is always a fear of pain of childbirth that haunts every expectant mother almost from the time she gets pregnant. For years women have been tolerating this suffering. A prolonged and painful process of childbirth can have adverse effects on the mother and the unborn baby. The McGill Pain Questionnaire ranks labour pain in the upper part of the pain scale between cancer pain and amputation of a digit [1]. Pain relief in labour remained a myth; till recent years when epidural analgesia emerged as the most widely accepted safe choice. While concerns have been raised that epidural may possibly interfere with labour and consequently increase the rate of cesarean deliveries [2, 3]. A more recent review concluded that epidural analgesia is not associated with such a risk [4]. An additional issue of controversy is the effect of timing of epidural placement on the progress and outcomes of labour.

Previously it was recommended that physicians delay administration of epidural analgesia in nulliparous parturients until cervical dilatation reaches 4-5 cm to avoid prolonged labour and reduce the risk of a required cesarean section [5, 6]. In 2005, Wong et al. published a paper clarifying that pain relief early in labor with neuraxial analgesia at the cervix dilated 2.0 cm or more does not increase the risk of Cesarean delivery [7]. This combined with Ohel's report contributed to the change in recommendation on Epidural Analgesia in labor pain control from the American College of Obstetricians and Gynecologists in June 2006 [8, 9]. The National Institute for Health and Clinical Excellence guidelines suggest that "women in labor who desire regional analgesia should

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not be denied it, including women in severe pain in the early labor [10, 11]. The purpose of the present study was to compare the effect of early versus late initiation of epidural analgesia on the duration of labour and obstetric outcome in terms of mode of delivery.

MATERIALS AND METHODS

The study was approved by the Ethics Committee of our hospital and was conducted at Acharya Vinobha Bhave Rural Hospital, Wardha. In the study, 100 women in labour, on their first request for regional analgesia, ones who fulfilled the inclusion criteria after excluding the exclusion criteria were offered participation. A complete relevant history was obtained and a thorough clinical examination was done by the team of obstetricians and anesthetists. An informed written consent was taken from parturient and relatives who were willing for epidural analgesia. Whole of the procedure was explained to them including its advantages and disadvantages. Inclusion criteria included low risk pregnancies, singleton term pregnancy (37-40 weeks), vertex presentation with established labor (spontaneous onset), as diagnosed by regular uterine contractions and cervical dilatation of more than 2-3 cms and normal fetal heart rate. Exclusion criteria included patient's refusal for labour analgesia, high risk pregnancies (preeclampsia, Gestational and insulin-dependent diabetes), multiple pregnancies, contraindications to epidural analgesia and abnormal fetal heart rate tracing. Parturient on their first request for labour analgesia were randomized to receive either early or late epidural Analgesia. We broadly divided them in two groups, GROUP A (early initiation of epidural analgesia) and GROUP B (late initiation of epidural analgesia). In GROUP A, the epidural was started immediately following the women's request, and when cervical dilatation was of 2-3 cm. In GROUP B, epidural analgesia was started when the cervical dilatation was >= 4 cm. The obstetric management, apart from the timing of initiation of epidural analgesia, was similar in the two groups. The epidural insertion followed intravenous pre-hydration with 500-1000 ml of Ringer's lactate solution. The lower lumbar epidural space was identified by the loss- of-resistance technique with 18 gauge Tuohy needle with parturient in sitting position. If no signs of intravascular or subarachnoid puncture were observed, the catheter was secured 4-5 cm into the epidural space. A test dose of 3ml lignocaine 2% with adrenaline was given to confirm epidural placement of the catheter as indicated by non development of tingling and numbness. At 0 min 10 ml solution of ropivacaine 0.2% with 2micgm/cc of fentanyl was given. Ropivacaine is an amino amide local anesthetic agent that is structurally similar to bupivacaine, but because of its greater selectivity for block of sensory fibers, it is associated with less motor block. Top up doses were given every 60-90 minutes after confirming two segment regressions of sensory level or on patient request, until delivery of the baby. Following parameters were recorded -Maternal Heart Rate And Blood Pressure , Sensory Level (using pin prick method), Pain Score using verbal analogue scale for patients , Motor Block (using Bromage Scale) , Fetal Heart Rate (using Fetal Doppler) ,Progress of labour (partograph), Occurrence Of Adverse Events ,Maternal Satisfaction Following Delivery.

Statistical analysis was done by using descriptive and inferential statistics using Chisquare test and Student's unpaired t test. The software used in the analysis were SPSS 17.0 and Graph Pad Prism 5.0 version and $p<0.05$ is considered as level of significance ($p<0.05$).

RESULTS

The study group comprised 100 gravidas: with 55 primigravida and 45 multi gravida in whom labor was spontaneous onset. The pre-labor characteristics of patients in groups 1 and 2 are shown in Table **1**.

The mean dilatation at the time of epidural analgesia initiation in GROUP A was 3.15±0.30 and in GROUP B was 4.45±0.40. As p-value was 0.000 the difference was statically significant. The cervical effacement improved drastically after the initiation of epidural. In GROUP A the mean cervical effacement was 89.40±3.73 and 87.20±4.53 in GROUP B p- value was 0.009. This difference is statistically significant. 22% of the patients in GROUP A and 24% of the patients in GROUP B required augmentation of labour by oxytocin. As p-value was 0.86, The difference was not statistically significant. The mean duration of labour amongst primigravida in GROUP A was 5.57±0.24 hours and in GROUP B was 6.30±0.21hours. As p-value was 0.0001 the difference was statistically significant. The mean duration of 1st stage of labour after the onset of epidural analgesia was 33 minutes shorter amongst the primigravida of GROUP A than GROUP B. The mean duration of 1st stage labour from the onset of epidural analgesia amongst multigravida in

Table 1: Pre-labour Characteristics

Variables	GROUP A	GROUP B	P-value
1.Maternal age	23.90	23.41	0.64,NS
2.Maternal BMI [meanS/D]	28.76±1.30	28.48±0.67	0.18, NS
3.Gestationalweeks [meanS/D]	38.63±1.10	38.48±1.17	1.000, NS
4.Pain score	8.75±0.50	8.81±0.43	0.440 NS

No differences were observed in pre-labor characteristics between the two groups. The two groups were similar in respect to maternal age, BMI, gestational weeks and pain score at the time of admission to the labour room.

Table 2: Shows the Labour Characteristics

Variables	Early	Late	P-value
1.Dilatation at start of Epidural(mean SD)	3.15±0.30	4.45±0.40	0.000,S
2.effacement at start of Epidural(mean SD)	89.40±3.73	87.20±4.53	0.009,S
3.oxytocin	22%	24%	0.86 NS
4.Duration of 1st stage of labour from Initiation			
a. Primigravida	5.57±0.24	6.30±0.21	0.0001,S
b. Multigravida	3.04±1.20	4.07±0.40	0.003,S
5. Duration of 2nd stage labour(<60min)	94%	92%	0.05,NS
6.NICU admission	4(8%)	7(14%)	0.33 NS
7.Pain score 20 min after giving drug	1.06±0.61	1.10±70	0.05NS

GROUP A was 3.04±1.20 and was 4.07±0.40 in GROUP B. As p- value was 0.003 the difference was statistically significant. Duration of second stage of labour was less than 1 hour in 94% and 92% of patients in Group A and Group B respectively. The effect of epidural analgesia on newborns and NICU admissions showed 4 (8%) babies in GROUP A and 7 (14%) babies in GROUP B. p value is 0.33 the difference is statistically not significant. At 20 minutes all the patients in both the groups were absolutely pain free. Distribution of visual analogue scale at various intervals in both the groups was comparable and showed no statistical significance.

The distribution of patients according to mode of delivery in both the groups is shown in Table no **3**. 42 (84%) patients in Group A and 40 (80%) patients in GROUP B delivered by normal vaginal delivery. 5 (10%) patients in Group A and 7 (14 %) patients in Group B delivered by using outlet forceps. 3 (6%) patients in Group A and 3(6%) patients in Group B delivered by LSCS. There was no statistically significant difference in both the groups. (p=0.82)

The indications of instrumental delivery and cesarean sections are mentioned in Table **3**.

DISCUSSION

The present study was conducted in the Department of Obstetrics and Gynaecology, Acharya Vinoba Bhave Rural Hospital, Wardha to study the effect of early versus late initiation of epidural analgesia on duration of labour and mode of delivery. A total of 100 women fulfilling the inclusion criteria were enrolled in the study. Out of which 50 participants were given epidural in early stage of labour (cervical dilatation of 2-3 cm) after consent and 50 were given epidural at a late stage of labour (cervical dilation of >=4 cm). Demographics of both the groups were comparable. The observations of this study have been discussed and compared with other studies. The mean age of women in the study group was 24.08 ± 2.67 years which was comparable to the study done by Desai P *et al.* [12] where mean age was 24.97±3.90 years in epidural group and 25.18±4.08 years in control group. The mean age in a study done by Paddalwar *et al* was 23.30 in the epidural group. The mean age in study

Table 3: Mode of Delivery

Mode of Delivery	Early	Late	P-value
Spontaneous vaginal delivery	42(84%)	40(80%)	0.82 NS
Instrumental deliveries Indications	5(10%)	7(14%)	0.82 NS
Fetal distress	2(4%)	3(6%)	0.81 NS
Prolonged 2nd stage	1(2%)	2(4%)	0.81 NS
Failure to bear down	2(4%)	2(4%)	0.81 NS
Cesarean Section Indications	3(6%)	3(6%)	1.0 NS
Fetal distress	1(2%)	1(2%)	
Prolonged 2ns stage	2(4%)	2(4%)	

done by Gambling *et al.* [13] was 32.7 ± 0.74 years in PCEA group. This difference in age group could be understood by fact that the later study was carried out in a western country where age at marriage and child-bearing is higher compared to our country. The two groups were comparable with respect to physical parameters. Mean BMI was 28.76 with SD of 1.30 in the GROUP A and 28.48 with SD of 0.67 in the Group B. The statistical difference between the two groups was statistically not significant. This data was compared to other studies (ohel *et al.*) [14] Where the BMI in early group was 28.5 (3.5) and late group 28.5 (4.0). The mean gestational weeks in our study was 38.63 which was comparable to other studies like (Desai P *et al.* [12], Parween S *et al.* [15]). In our study parity status and their distribution among the population was also studied which showed 55(55%) primigravida and 45(45%) multigravida. Thus the numbers of patients demanding epidural analgesia were more of primigravidae as compared to multigravidae.

There have been a lot of controversies regarding use of epidural analgesia with respect to risks of caesarean delivery, vaginal delivery requiring use of forceps or vacuum extraction, use of oxytocin and progress of labour and thus has been extensively studied. The present study showed duration of labour of 5.57 hours in the Group A and 6.30 hours in the Group B amongst primigravida and 3.04 hours in the Group A and 4.07 hours in amongst Group B in multigravida and p-values of 0.0001 in primigravida group and 0.003 in the multigravida were statistically significant indicating that early initiation epidural analgesia was associated with shorter duration of first stage of labour in both primigravida and multigravida.

According to Hui-Ling Lee *et al.* [16] the duration of active phase of first stage in vaginal delivery with early epidural analgesia was shorter than that of late analgesia. Mean duration of active phase of first stage labour from initiation of epidural analgesia being 246±197 in early group and 368±221 minutes in late group. Studies in the past (Thorp *et al.* [17] ,Bofill *et al.* [l8]) proved that duration of labour is prolonged with it .This might be attributed to the fact that in the past higher concentration of local anaesthetic agents were used as an intermittent bolus which led to significant motor blokade and eventually instrumentation . Data from a 5 year study (Wang *et al.* [19]) demonstrate that epidural analgesia in the latent phase of labour at cervical dilation of 1.0 cm or more does not prolong the progression of labour and does not increase the rate of caesarean in nulliparous women compared with the delayed analgesia at the cervical dilation of 4.0 cm or more. Similar findings were proved by Chestnut DH *et al.* [20], Wassen *et al.* [21], Wageih *et al.* [22]. In our hospital careful attention is paid to correct inefficient uterine action early in labour with oxytocin infusion. Following this policy, 22 % patients in Group A and 24 % patients in Group B required augmentation of labour by oxytocin. The difference was statistically insignificant. Studies done by (Parween S *et al.* [15], Nafisi S *et al.* [23], Wang F *et al.* [24] Costley *et al.* [25]) gave similar review where they did not find any difference in oxytocin augmentation.

In present study, the cesarean delivery as well as instrumental delivery rates was not significantly different between both the groups. 10% patients delivered by outlet forceps in Group A and and 14% in Group B. 6% patients in Group A and 6% in Group B delivered with cesarean section. All cesarean sections

EFFECT OF EPIDURAL ANALGESIA ON MATERNAL AND FETAL OUTCOME IN DIFFERENT STUDIES

Thorp *et al.* [17] Am J ObstetGynecol 1993	Significant prolongation in the first and second stages of labour and a significant increase in the frequency of cesarean delivery, primarily related to dystocia.
Bofill *et al.* [18] Am J Obstet Gynecol 1997	No increase in dystocia-related cesarean delivery with epidural analgesia.
Somuah. A [26] The Cochrane Database of Systematic Reviews 2005	No statistically significant impact on the risk of cesarean section
Sharam nafisi [23] BMC Anesthesiology 2006	Epidural analgesia with 1% lidocaine does not prolong the active-first and second stages of labour and does not increase vacuum-assisted or cesarean delivery rate.
Wang *et al.* [19] A Five-year Randomized Controlled Trial Anesthesiology: October 2009	Early labour analgesia in the latent phase of labour do not have an increased risk of prolonged labour or Cesarean section compared to women who are assigned to wait for a cervical dilation of at least 4.0 cm.
Wageih *et al.* [22] Evidence Based Women's Health Journal.August 2012.	Epidural analgesia in the latent phase of labour does not differ from its application in the active phase in terms of progress of labour or fetal outcome.
PRESENT STUDY	Early initiation of epidural analgesia does not increase instrumental or cesarean delivery rate. Rather early initiation of epidural analgesia shortens the duration of first stage of labour.

were done for obstetric indications. In 2 patients instrumental delivery was performed due to meconium stained liquor with persistent fetal bradycardia, one patient had instrumental delivery because of prolonged second stage and 2 patients had failure to bear down. Only one patient had cesarean section for fetal distress. While in 2 patients cesarean section was done for prolonged second stage of labour in GROUP A.While in Group B instrumental delivery was performed in 3 paitents due to fetal distress and 2 patients had prolonged second stage labour and 2 patients failed to bear down. Only one patient had cesarean section for fetal distress. While in 2 patients, cesarean section was done for prolonged second stage of labour.

A Cochrane review [26] of 20 trials involving a total of 6534 women estimated that the relative risk of cesarean delivery with epidural analgesia as compared with other methods or with no analgesia was 1.07 (95% confidence interval, 0.93 to 1.23) which means no evidence of a significant difference in the risk of cesarean section. However it was associated with an increased risk of instrumental delivery.

In our study the total number of babies admitted to NICU were comparable in both the groups (4 babies in group A and 7 babies in Group B). Thus present study demonstrated no significant difference in neonatal outcome between the GROUP A and GROUP B which was supported by Wang *et al.* [19] who compared early verses late epidural analgesia and results expressed early epidural analgesia does not exert significant influence on neonatal APGAR ratings. Hill *et al.* [27] have proved that epidural analgesia may actually be beneficial to the foetus as it reduces stress related effects in the mother.

Women's satisfaction with epidural analgesia is correspondingly high in various studies. In present study 76% of women had excellent satisfaction in terms of pain relief. Number of studies has proved that epidural analgesia offers superior pain relief as compared to other forms of pharmacological or non-pharmacological methods. In a study done by Sharma *et al.* [28] involving 2703 nulliparous women, 95% of women in epidural group reported their satisfaction as excellent.

In present study, majority of the patients belonged to rural areas and a low socioeconomic stratum of the society where level of acceptance was found to be significantly low due to lack of education, lack of awareness, fear of delivery complications. Factors such as the woman's involvement in decision making, social and cultural factors, the woman's relationship with her caregivers, and her expectations regarding labour may be equally, if not more, are important in opting for epidural analgesia.

Creating awareness by giving proper and full information about epidural analgesia would surely improve the acceptance level among the parturients.

Good communication and a team effort are needed to reap the benefits of pain free labour, while minimizing the potential effect of epidural analgesia on labour outcome.

CONCLUSION AND RECOMMENDATIONS

Epidural analgesia in the early labour, following the first request for epidural at cervical dilation of 2-3 cm does not prolong the progression of labor and does not increase the rate of Cesarean deliveries, instrumental vaginal deliveries, and other adverse effects in laboring women compared with the delayed analgesia at the cervical dilation of 4.0 cm or more. Furthermore, it was associated with shorter duration of the first stage of labor and was clearly preferred by the women. with above results we recommend and conclude that early inititation of epidural analgesia is safe and beneficial for the parturient .

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