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Original Article

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The Effect of Epidural Analgesia on Labour, Mode of Delivery and Neonatal Outcome in Nullipara of India, 2011-2014

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ABSTRACT

Aims: This study aimed to evaluate the effect of ropivacaine epidural analgesia on duration and outcome of labour in nulliparous parturients of India with parturient not receiving any analgesia.

Settings and Design: One hundred and twenty nulliparous parturient in established labour at full term with a singleton vertex presentation were assigned to the study. Parturients who request epidural analgesia were allocated in the epidural group (n=60), whereas those not enthusiastic to labour analgesia were allocated in the control group (n=60).

Materials and Methods: Epidural analgesia was provided by a bolus injection of 10 ml of ropivacaine 0.2% and 50µg fentanyl and maintained by using a continuous infusion of ropivacaine 0.1% with fentanyl 2µl/ml at a 10ml/hour rate. The outcomes were duration of labour, incidence of cesarean sections and instrumental vaginal delivery and neonatal outcome.

Statistical Analysis used: Statistical analysis was conducted using unpaired student t-test and chi-square test as required. All tests of significance were performed using two-tailed probability tests. Differences were considered significant when p-value was <0.05.

Results: The two groups were comparable in terms of socio-demographic data. The mean duration of first stage of labour was shorter in epidural group (4.83 ± 1.59 h) compared with control group (5.48 ± 1.56 h) while the duration of second stage of labour was prolong in epidural group (33.13 ± 12.78 min) as compared to control (27.53 ± 11.73 min). Instrumental vaginal or caesarean delivery rate did not increase in the epidural group. The APGAR scores at 5 min were statistically similar in both groups.

Conclusion: Epidural analgesia by ropivacaine in Indian nulliparous resulted in shorter duration of first stage and prolongs duration of second stage of labour compared with parturients without analgesia; however, instrumental vaginal or caesarean delivery rate does not increase in the epidural group.

Keywords: Epidural analgesia, Labour, Nulliparous, Parturient, Ropivacaine

INTRODUCTION

The pain of labour has been known since Garden of Eden. Labour may be the most painful experience many women ever encounter. The experience is different for each woman and the different methods chosen to relieve pain depend upon the techniques available locally and the personal choice of the individual. Pain relief in labour has always been surrounded with myths and controversies. Hence, providing effective and safe analgesia during labour has remained an ongoing challenge. Numerous strategies, both pharmacologic and non-pharmacologic, have been used as treatment of labour pain [1].

In the early 1960s, the lumbar epidural replaced caudal analgesia as the preferred technique. In 1967 Beazley et al.,[2] published a classic study of the efficacy of different forms of analgesia in labour. Since then epidural analgesia has been widely introduced for pain relief in labour even for routine practice [3].The use of lumbar epidural catheters in the 1970s permitted administration of pain relief early in labour, rather than only at the time of delivery. Several improvements in epidural analgesia occurred in the 1970s and 1980s [1]. The use of epidural analgesia in the United States has tripled between 1981 and 2001, with 60% of parturient using this technique currently in large hospitals [4]. About a fifth parturient women in England and Wales received epidural analgesia [5]. In developing countries like India national average acceptance of epidural analgesia for labour pain relief is almost negligible though sporadically few centre have a comprehensive labour analgesia program [6].

Epidural analgesia effectively relieves pain during labour and delivery [7,8]. However, controversy exists as to the effect of epidurals on the progress of labour, mode of delivery and effects on the fetus and neonate.

This study aimed to evaluate the effect of ropivacaine epidural analgesia on duration and outcome of labour in nulliparous parturients of India with parturients not receiving any analgesia.

MATERIALS AND METHODS

The study protocol was developed in collabouration with aestheticians at Department of Obstetrics and Gynecology, Batra Hospital and Medical Research Centre, New Delhi, India, and approved by the local ethics committee. One hundred twenty nulliparous parturient who presented in spontaneous labour were enrolled in this study after a written informed consent was signed.

Inclusion and exclusion criteria

The inclusion criteria included nulliparity, age 20-35 y, body weight < 80 kg, at least 36 completed wk (and less than 42 wk) of gestation (confirmed by ultrasound), established labour, single fetus in vertex presentation, cervical dilatation of equal or more than 4 cm, and request for analgesia. The exclusion criteria included multiparity, age <20 or >35 y, gestation age <36 or >42 wk, probable cephalopelvic disproportion or malpresentation on pelvic examination, cervical dilatation of less than 4 cm, presence of medical complications (preeclampsia, eclampsia, diabetes, etc), presence of contraindications for epidural analgesia (coagulopathy, marked hypovolemia, neurological disorders, allergies to local anaesthetics, etc), and patients refusal or inability to cooperate for epidural analgesia.

Nulliparous parturients (n=60) who desired epidural analgesia were allocated in the Group I (epidural group), whereas those (n=60) were not desired any labour analgesia were allocated in the Group II (Control or non-epidural group).

Characteristics	Epidural Group (n=60)	Control Group (n=60)	p-value
Mean Age (year)	28.13 ± 3.83	26.95 ± 3.79	0.092
Mean weight (kg)	65.06 ± 4.84	64.65 ± 5.46	0.659
Mean height (cm)	163.1 ± 8.31	162.4 ± 8.33	0.685
Mean Gestation age (weeks)	37.76 ± 1.24	38.10 ± 1.24	0.126

[Table/Fig-1]: Maternal demographic characteristics of both groups
Values are expressed as "Mean ±SD"

	Epidural Group (n=60)	Control Group (n=60)	p-value
Duration of Labour			
First Stage (hours)	4.83 ± 1.59	5.48 ± 1.56	0.025*
Second stage (minutes)	33.13 ± 12.78	27.53 ± 11.73	0.0137*
Mode of Delivery			
Normal Vaginal Delivery	44 (73.3 %)	52 (86.67 %)	0.162
Instrumental Delivery	10 (16.7 %)	4 (6.67 %)	
Cesarean Delivery (LSCS)	6 (10 %)	4 (6.67 %)	
Apgar Score			
>7	52	54	0.569
<7	8	6	

[Table/Fig-2]: Maternal and neonatal outcomes in both groups
*Significant

Epidural group

Thorough pre-anaesthetic check up was carried out in the epidural group. Once cervical dilatation reached 4 cm, 500 ml of Ringer lactated solution was administered intravenously, and the patient was seated in the upright position for epidural placement. The low back was prepared and draped in a sterile fashion. The epidural space, at the L2-L3 or L3-L4 intervertebral space, was identified with the use of the loss of resistance technique with 17-gauge Tuohy needle. An epidural catheter was inserted 4-5 cm into the epidural space, and a test dose of 3ml lidocaine 2% was followed 5 minutes later by a bolus injection of 10 ml of ropivacaine 0.2% and 50µg fentanyl. Analgesia was maintained using a continuous infusion of ropivacaine 0.1% with fentanyl 2µl/ml at a 10ml/hr rate. Further boluses of 5-10ml ropivacaine 0.2% were given upon patients' request.

Following epidural analgesia, maternal blood pressure, heart rate and sensory blockage levels were assessed throughout labour. Episodes of hypotension (systolic blood pressure below 100 mm/Hg or <70% of baseline) were managed by rapid intravenous fluid infusion, left uterine displacement or intravenous boluses of 5mg ephedrine, and bradycardia with 0.5 mg of intravenous atropine, as required. An anaesthetist managed all parturient women in epidural group.

Control group

In this group, patients did not request any analgesia.

Obstetric management

The obstetric management was similar in both groups. The progress of labour was recorded on WHO Modified Partograph. All pregnant women were managed according to the study protocol by trained medical staffs under the direct supervision of an obstetrician. Routine intrapartum management of all pregnant women included intravenous fluid administration and continuous external electronic fetal heart rate monitoring. Pelvic examination was performed every hour to evaluate the progress of labour.

Decisions regarding instrumental vaginal or operative deliveries were made by the obstetrician according to maternal or fetal indications.

Outcomes of interest

The primary outcome was duration of labour (first and second stage of labour). Secondary outcome measures were the incidence of caesarean sections and instrumental vaginal delivery and neonatal outcome in form of APGAR score at 5 min.

STATISTICAL ANALYSIS

The data was collected on a predesigned performa. Statistical analysis was conducted using unpaired student t-test and chi-square test as required. All tests of significance were performed using two-tailed probability tests. Differences were considered significant when p was <0.05.

RESULTS

The study group comprised 120 nulliparous parturients. Age of the patient varies between 20 and 35 y in epidural group and between 21 and 34 y in control with mean age 28.1 and 26.9 y respectively. Maximum numbers of patients were in gestation age between 38-39 wk in both the groups (mean gestation age 37.76 ± 1.24 for epidural group and 38.10 ± 1.24 wk for non-epidural). Both groups were similar in obstetric and maternal demographic character like age, height, weight and gestation age [Table/Fig-1].

The mean duration from the time of randomization to full dilatation (first stage of labour) was significantly shorter in epidural group (4.83 ± 1.59 h) compared with control group (5.48 ± 1.56 h) (p-value = 0.025). The duration of second stage of labour was prolong in epidural group (33.13 ± 12.78 min) as compared to control (27.53 ± 11.73 min) (p-value = 0.0137) [Table/Fig-2].

There was no statistically significant difference in the rate of caesarean section deliveries between the two groups (10% patients in the epidural group versus 6.67% in the control). Although, the number of instrumental deliveries (forceps or vacuum assisted deliveries) looked to be greater in epidural group (16.7% patients in the epidural group versus 6.67% in the control) but was not statistically significant. Incidence of normal vaginal deliveries were also not statistically different in both groups (73.3% patients in the epidural group versus 86.67% in the control) (p-value = 0.162). The APGAR scores at 5 min were also statistically similar in both groups (p-value = 0.569).

DISCUSSION

Epidural analgesia provides significantly more analgesia, as measured by visual analog scale in both the first and second stage of labour than parenteral opioid [7]. Although regional anaesthesia has been associated with a reduction in anaesthesia related maternal mortality, there is continuing controversy over whether epidural analgesia impedes the progress of labour by causing dystocia and increasing operative delivery rates [9-11].

We chose 0.2% ropivacaine with fentanyl for comparison because ropivacaine and bupivacaine are equally effective for epidural pain relief during labour while ropivacaine may have an advantage over bupivacaine regarding neurobehavioral performance during the first few hours after delivery, and cause less motor block and less cardio- and neurotoxic analgesic agent [12,13].

In current study, epidural analgesia was given in late stage of labour (after cervical dilatation of 4 cm). American college of obstetrician and gynecologists recommends that "when feasible obstetrician should delay the administration of epidural analgesia in nulliparous parturients until the cervical dilatation reaches at least 4 cm [14].

Many studies have found that epidural analgesia as compared with systemic opioid analgesia or no analgesia is associated with a prolonged first stage of labour while some studies showed no effect on first stage [Table/Fig-3]. In current study, the duration of

first stage of labour was shorted in epidural group as compared to control group. The studies done by Wong et al., [15] in 2005 and Fyneface-Ogan et al.,[16], stated that epidural analgesia was associated with shorter first stage of labour as was noted in current study [Table/Fig-3]. Short duration of first stage may be because of better analgesia with epidural resulting to decrease inhibitory effect of catecholamines on uterine contractility hence faster cervical dilatation. With combined spinal-epidural (CSE), and its resultant benefits of decreased motor block, a study demonstrated

S. No.	Author	year	No. of patients	First stage with epidural	Second stage with epidural
1	Thorp et al., [18]	1993	93	Prolong	Prolong
2	Bofill et al., [19]	1997	100	No effect	No effect
3	Halpren et al., [20]	1998	2369	Prolong	Prolong
4	Zimmer EZ et al., [21]	2000	847	-	Prolong
5	Barbara et al., [7]	2002	-	No effect	Prolong
6	Sharma et al., [22]	2004	2703	Prolong	Prolong
7	Liu [23]	2004	2962	-	Prolong
8	Fernandez-Guisasola [24]	2004	4364	Prolong	Prolong
9	Sienko J et al., [25]	2005	1334	Prolong	Prolong
10	Anim Souman et al., [8]	2005	6664	Prolong	Prolong
11	Wu CY et al., [26]	2005	412	Prolong	Prolong
12	Zhang et al., [27]	2005	722	Prolong	Prolong
13	Wong et al., [15]	2005	750	Short	No effect
14	Shahram Nafisi [28]	2006	395	No effect	No effect
15	Liang [29]	2007	583	Prolong	Prolong
16	Fyneface-Ogan et al., [16]	2009	50	Short	Short
17	Raja [30]	2009	156	-	Prolong
18	Anwer et al., [31]	2010	70	-	Prolong
19	Anim-Somuah et al., [32]	2011	9658	-	Prolong
20	Mousa et al., [33]	2012	160	No effect	No effect
21	Present study	2014	120	Short	Prolong

[Table/Fig-3]: Effect of epidural analgesia on duration of first and second stage of labour

a decreased duration of first-stage labour with CSE compared to conventional epidural analgesia [17].

In current study, the second stage was found to be prolonged in epidural group as compared to control. Several retrospective studies consistently demonstrated an association between epidural analgesia and increased durations of second stages of labour, but few randomized, prospective studies could not find any significant relation regarding the effects of epidural analgesia on the duration of labour as compared to non-epidural analgesia [Table/Fig-3]. Prolonged labour seems to occur more frequently when a higher dose of local anaesthetic agent is used [34].

In this study, no statistically significant difference was found between epidural group and control group when comparing the rate of caesarean sections, instrumental vaginal (forceps or vacuum assisted) deliveries and normal vaginal deliveries. Few early studies have reported significantly higher incidences of caesarean or instrument deliveries with epidural analgesia as compared with systemic opiate drugs [Table/Fig-4]. In the late 1980s and early 1990s, several retrospective trials demonstrated an association between the use of epidural and increased cesarean rate [35].

S. No.	Author	year	No. of patients	Instrumental delivery	Cesarean section
1	Carli [36]	1993	1250	Higher	
2	Thorp et al., [18]	1993	93	-	Higher
3	Bofill et al., [19]	1997	100	Higher	No difference
4	Halpren et al., [20]	1998	2369	Higher	No difference
5	Zimmer EZ et al., [21]	2000	847	Higher	Higher
6	Howell et al., [37]	2002	369	Higher	-
7	Barbara et al., [7]	2002	-	No difference	No difference
8	Sharma et al., [22]	2004	2703	Higher	No difference
9	Liu [23]	2004	2962	Higher	No difference
10	Sienko J et al., [25]	2005	1334	No difference	No difference
11	Anim Souman et al., [8]	2005	6664	Higher	No difference
12	Wu CY et al., [26]	2005	412	Higher	lower
13	Shahram Nafisi [28]	2006	395	No difference	No difference
14	Liang [29]	2007	583	Higher	Higher
15	Bakhamees [38]	2007	861	Higher	No difference
16	Fyneface-Ogan et al., [16]	2009	50	-	No difference
17	Raja [30]	2009	156	Higher	-
18	Anim-Somuah et al., [32]	2011	9658	Higher	No difference
19	Mousa et al., [33]	2012	160	No difference	No difference
20	Present study	2014	120	No difference	No difference

[Table/Fig-4]: Effect of epidural analgesia on mode of delivery

The main pitfalls of these retrospective trials were that the patients who requested for epidural usually have an associated increased risk of cephalo-pelvic disproportion or fetal malposition, both of which increased the risk of caesarean delivery. Recent randomized, population based studies do not show such increase as in current study. Instrumental births declined over time [Table/Fig-4]. This decline in the strength of association between epidural analgesia and instrumental birth may reflect improved epidural techniques and management of epidural labour [11].

Our results demonstrated no significant difference in neonatal outcome (APGAR score) between epidural and control groups as in almost all other studies [7,8,16,20,25,26,28].

In summary, result of current study and review of related article reveals that use of newer epidural analgesic agent like ropivacaine having minimal motor blockage, addition of opioids like fentanyl, use advanced techniques and given epidural analgesia at late stage of labour (cervical dilatation of more than 4 cm) provides better analgesic effect with minimal motor blockade of abdomino-pelvic muscles encourages parturients to actively participate in expulsion of fetus under active obstetric management resulting short duration of labour and lower rate of operative deliveries.

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