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### RESEARCH ARTICLE

#### EFFECT OF DISCONTINUATION OF EPIDURAL ANALGESIA LATE IN LABOUR ON ADVERSE DELIVERY OUTCOMES-A RANDOMIZED CONTROLLED TRIAL

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#### Abstract

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#### Introduction:-

Labour pain is an extremely agonising experience for most women. A painful labour has detrimental effects on the mother and foetus, often producing immense maternal suffering sustained maternal hyperventilation, elevated oxygen demand and increased mechanical work. In a foetus because of uterine hypoperfusion, it can lead to foetal hypoxia and acidosis. Various methods have been tried till date to alleviate this pain.

Epidural analgesia (EA) Epidural analgesia is a central nerve block technique achieved by injection of a local anesthetic close to the nerves that transmit pain and is widely used as a form of pain relief in labor.

Though it is the most effective treatment for pain control during labor and delivery(1, 2), there is evidence though insufficient to suggest that women who use this form of pain relief are at increased risk of having an instrumental delivery(3). It has been suggested that discontinuation of epidural analgesia late in labor might improve a woman's ability to push and reduce the rate of instrumental delivery. However, there is insufficient evidence to support the hypothesis that discontinuing epidural analgesia late in labor reduces the rate of instrumental delivery or other unwanted outcomes(4)

The purpose of this study is to review and summarize the available evidence regarding the impact of neuraxial analgesia on labour outcomes and provide clinicians with a clearer understanding of the issues.

There is lack of methodological uniformity between published studies (only 5 RCTs till date),with different interventions in early as well in control group and different dose of anaesthetics were included. We, therefore plan to

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do this study to establish whether discontinuation of epidural analgesia late in labour might reduce the incidence of adverse delivery outcomes among these women.

Also, we propose to look at the neonatal outcome which has not been reported in most studies on this topic.

#### **Aims & objectives: to evaluate:-**

- Rate of caesarean section
- Rate of Instrumental delivery (vacuum / forceps)
- Rate of Spontaneous vaginal delivery
- Duration of second stage of labor
- Level of pain relief among mothers
- APGAR score at 1 & 5 minutes.

#### **Materials and Methods:-**

- a. **Study site.** Maternity unit at St Stephens Hospital
- b. **Study period & duration.** 1 year study from April 2013 to March 2014.
- c. **Subjects**

#### **Inclusion criteria:**

Low risk primigravidae women with term ( $\geq 37$  weeks) singleton fetuses of vertex presentation receiving intermittent epidural infusion.

- Primigravidae
- Patients aged 18-35 years
- More than 145 cm tall
- Gestational age 37 weeks or more
- Singleton, term foetus with vertex presentation.
- Normal fetal heart rate pattern status on admission

#### **Exclusion Criteria:-**

- Evidence of fetal malformation or IUGR or macrosomia
  - H/o allergy to anaesthetic agents
  - The mothers have severe co-existing diseases like diabetes, severe pregnancy induced hypertension, bronchial asthma, epilepsy, ischaemic or valvular heart disease
  - Fetal malpresentations/malpositions
- a. **Study design.** Randomized Controlled Trial
  - b. **Sample size calculation.**

Based on the hospital data of last one month, of 21 nulliparous women who received epidural analgesia, 14 had caesarean section. Assuming a 40% reduction in the rate of caesarean section by discontinuation of epidural analgesia late in labor, the sample size comes out to be 29 women in each group at 80% power with alpha error of 5% .

Estimated sample size for two sample comparison of proportions

Test Ho:  $p_1 = p_2$ , where  $p_1$  is the proportion in population 1  
and  $p_2$  is the proportion in population 2

#### **Assumptions:-**

Alpha=0.0500(two-sided)

Power=0.8000

$p_1=0.6700$

$p_2=0.2700$

$n_2/n_1=1.00$

#### **Estimated required sample sizes:-**

$n_1=29$

$n_2=29$

f. Patients will be divided into two groups-Group A and Group B each having 30 women. In group A, epidural analgesia will be discontinued when the cervical dilatation is less than 8 cm. In group B, epidural analgesia will be continued till the delivery of the baby.

**Preparation:-**

Equipments and drugs- Tuohy needle 18G, syringes of 2 ml, 5ml, 20ml, needles of 18G, 23G, 18G portex<sup>R</sup> or perifix<sup>R</sup>(Broun). 0.125% Bupivacaine , 25 microgram Fentanyl , normal saline and equipments and drugs for resuscitation.

**Outcome will be monitored on the basis of following Results:-**

1. rate of caesarean section;
2. rate of instrumental delivery;
3. rate of spontaneous vaginal delivery;
4. duration of the second stage of labour;
5. level of pain relief among mothers;
6. Apgar score at one and five minutes.

Division of the patients was done using computer generated random numbers. Allocation concealment was ensured using opaque sealed envelopes.

Data was entered in Excel and statistical testing was conducted with the statistical package for the social science system version SPSS 17.0.

- Continuous variables are presented as mean  $\pm$  SD, and categorical variables are presented as absolute numbers and percentage.
- The comparison of normally distributed continuous variables between the groups was performed using Student's t test.
- Nominal categorical data between the groups were compared using Chi-squared test or Fisher's exact test as appropriate.
- $P < 0.05$  was considered as the statistically significant value.

**Results:-**

- The rate of instrumental delivery among the early group was 20% , in comparison, the rate of instrumental delivery among the late group was 17%.
- This difference of 3% may be clinically important but this value is not statistically significant.
- The rate of caesarean section among the early group was 20%, in comparison, the rate among late group was 27%.
- Likewise instrumental delivery, this difference is also not statistically significant.
- The rate of vaginal delivery was comparable among the two groups being 60% in the early group and 57% among the late group.
- A review of the indications for which caesarean sections were conducted in the two groups showed that the indications were fetal distress, cephalopelvic disproportion, meconium stained liquor and non progress of labour. When the two groups were compared in terms of the indications of caesarean sections, it was seen that there was no statistically significant difference between the two groups.
- The duration of the second stage of labour was comparable with no statistically significant difference among the two groups.
- There was inadequate pain relief among the early group as compared to the late group.
- The patients in the early group marked higher pain scores on the Visual analogue scale as compared to patients in the late group, showing inadequate pain relief among the women in the early group.
- The p value is 0.035 which is statistically significant showing that women who are administered epidural analgesia until late in labor have higher pain relief as compared to women in whom epidural analgesia is withheld at an early stage of labor.
- The APGAR score was comparable among the two groups with no statistically significant difference among the early and the late groups.

**Conclusion:-**

The conclusions drawn from the present study are as follows:

- The mode of delivery, the duration of second stage of labour and Apgar scores are not affected by continuing epidural analgesia till late in labour.
- Patients who are given epidural till late in labour have better pain relief without the mode of delivery being affected.

So the practice of continuing epidural analgesia till late in labour for better pain relief should not be withheld as it does not affect obstetric outcomes.

**Acknowledgements:-**

This thesis has been a great learning experience and has helped me in understanding the intricacies of clinical and medical research.

It has been my privilege to undertake this study under the guidance of **Dr. Naimaa Chaudhary** who has helped me every step of the way from choosing my topic, understanding it and then its execution and analysis. It has been a pleasure and I want to take this opportunity to offer my sincere thanks for her invaluable support and guidance.

I also wish to express my deepest regards and gratitude to all my family members who are my constant source of strength. I would like to add a special note of thanks to my husband **Dr. Alok Tiwari** and my brother **Mr. Markandey Tripathi** for their valuable input during formatting of this work. I am also grateful to all the subjects who consented to be part of the study.

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**Discussion:-**

In this study, no statistically significant difference was found in terms of modes of delivery, duration of second of second stage of labour and APGAR scores between the early and late groups. The patients in the late group had lower pain scores (more satisfactory analgesia).

Following is a comparison of the results of the present study with the results of few other studies done till present date.

**Studies included:-**

CHESTNUT(1987), JOHNSRUD(1988), CHESTNUT(1990), LUXMAN(1996), MARUCCI M ET AL(2007), HUI LING LEE(2008), WONG ET AL(2005), BAKHAMEES H ET AL(2007), WONG ET AL(2009), ROBERTS(2003).

**Incidence of Instrumental Delivery:-**

Of all the studies included, the only study that shows an increase in the rate of instrumental delivery in the late group is that by Chestnut et al(1987). The present study demonstrated no statistically significant increase in the rate of instrumental delivery with the p value being 0.282. The most frequent indication of instrumental delivery in this study was poor maternal efforts.

**Incidence of Caesarean section:-**

Of all the studies, the study that showed a statistically significant difference was that by Hui Ling Lee(2008) showing increased incidence of caesarean section in the early group with a p value of 0.002. The present study demonstrated no statistically significant difference between the two groups in terms of incidence of caesarean section (p value=0.282).

**Incidence of inadequate pain Relief:-**

All the studies included showed higher pain scores in the early group and lower pain scores in the late group. The present study in accordance with the earlier studies showed a statistically significant difference between the early and late groups in terms of pain scores (VAS scores) with higher pain scores in the early group with a p value of 0.035.

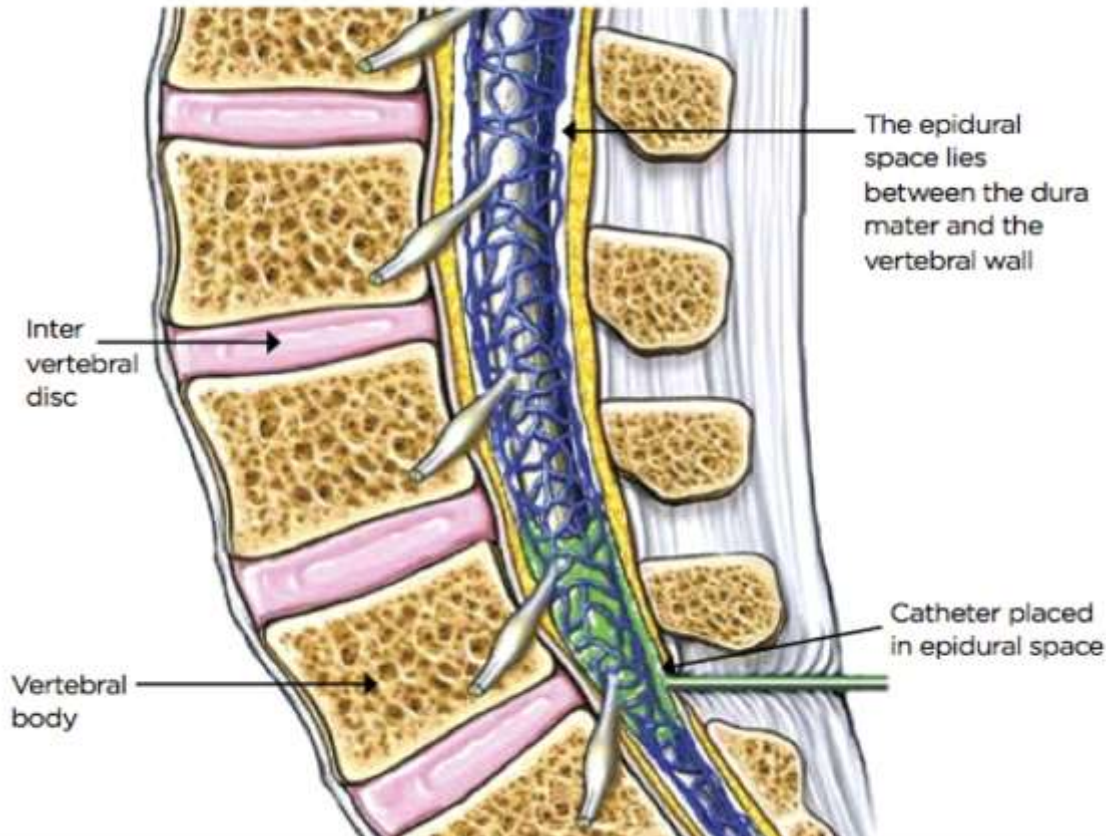
**Incidence of increased duration of second stage of labour:-**

None of the studies showed increased duration of second stage of labour in the late group as compared to the early group. The present study in accordance with the earlier studies showed no statistically significant difference between the two groups with a p value of 0.673.

**Incidence of low APGAR scores:-**

Not much studies included APGAR score as one of the outcomes. The studies that took APGAR scores into consideration showed no statistically significant difference between the early and the late groups. The present study in accordance with the earlier studies showed no statistically significant difference between the two groups with a p value of 0.59.

**FIG 1. POSITION OF THE EPIDURAL CANNULA**



**Tables**

Mode of delivery	Group E		Group L		P Value
	Frequency	%	Frequency	%	
Forceps	3	10%	0	0%	0.282
LSCS	6	20%	8	27%	
NVD	18	60%	17	57%	
Vaccum	3	10%	5	17%	
Total	30	100%	30	100%	

Indications of LSCS	Group E (n=6)		Group L (n=8)		P Value
	Frequency	%	Frequency	%	
FD	4	66.7%	6	75.0%	1.000
CPD	3	50.0%	3	37.5%	1.000
MSL	1	16.7%	0	0.0%	0.429
NPOL	2	33.3%	0	0.0%	0.165

Duration of second stage of labour	Group E (n=24)		Group L (n=22)		P Value
	Frequency	%	Frequency	%	
<30 min	14	58.3%	12	54.5%	0.967
30 - 45 min	7	29.2%	8	36.4%	
>45 min	3	12.5%	3	13.6%	

	Group E	Group L	P Value
	Mean ± Sd	Mean ± Sd	
Duration of second stage of labour(minutes)	29.38 ± 11.19	30.14 ± 12.26	0.673

	Group E	Group L	P Value
	Mean ± Sd	Mean ± Sd	
Evaluation of pain relief using VAS score	7.67 ± 1.29	7.07 ± 0.80	<b>0.035</b>

**Incidence of Instrumental delivery.**

AUTHOR(YEAR)	INCIDENCE OF INSTRUMENTAL DELIVERY		INFERENCE
	EARLY GROUP	LATE GROUP	
CHESTNUT(1987)	28%	53%	INCREASED IN THE LATE GROUP
	P<0.05		
JOHNSRUD(1988)	25.5%	25.5%	NO STATISTICALLY SIGNIFICANT DIFFERENCE
	P>0.05		
CHESTNUT(1990)	15%	21%	NO STATISTICALLY SIGNIFICANT DIFFERENCE
	P>0.05		
LUXMAN(1996)	OVERALL 15%		NO STATISTICALLY SIGNIFICANT DIFFERENCE
MARUCCI M ET AL(2007)	P=0.56		NO STATISTICALLY SIGNIFICANT DIFFERENCE
HUI LING LEE(2008)	16.4%	17.4%	NO STATISTICALLY SIGNIFICANT DIFFERENCE
	P=0.816		
<b>PRESENT STUDY</b>	20%	17%	NO STATISTICALLY SIGNIFICANT DIFFERENCE
	P=0.282		

**Incidence of Caesarean section.**

AUTHOR(YEAR)	INCIDENCE OF CAESAREAN SECTION		INFERENCE
	EARLY GROUP	LATE GROUP	
CHESTNUT(1987)	13%	13%	NO STATISTICALLY SIGNIFICANT DIFFERENCE
	P>0.05		
JOHNSRUD(1988)	P>0.05		NO STATISTICALLY SIGNIFICANT DIFFERENCE
CHESTNUT(1990)	10%	8%	NO STATISTICALLY SIGNIFICANT DIFFERENCE
	P>0.05		
LUXMAN(1996)	P>0.05		NO STATISTICALLY SIGNIFICANT DIFFERENCE
WONG ET AL(2005)	17.8%	20.7%	NO STATISTICALLY SIGNIFICANT DIFFERENCE
	P>0.05		
BAKHAMEES H ET AL(2007)	P>0.05		NO STATISTICALLY SIGNIFICANT DIFFERENCE
MARUCCI M ET			NO STATISTICALLY

AL(2007)	P=0.78		SIGNIFICANT DIFFERENCE
HUI LING LEE(2008)	16.4%	7.7%	INCREASED INCIDENCE IN THE EARLY GROUP
	P=0.002		
WONG ET AL(2009)	32.7%	31.5%	NO STATISTICALLY SIGNIFICANT DIFFERENCE
	P>0.05		
PRESENT STUDY	20%	27%	NO STATISTICALLY SIGNIFICANT DIFFERENCE
	P=0.282		

**Incidence of inadequate pain relief.**

AUTHOR(YEAR)	INCIDENCE OF INADEQUATE PAIN RELIEF	
	EARLY GROUP	LATE GROUP
CHESTNUT(1987)	INADEQUATE PAIN RELIEF	SATISFACTORY ANALGESIA
JOHNSRUD(1988)	INADEQUATE PAIN RELIEF	SATISFACTORY ANALGESIA
CHESTNUT(1990)	INADEQUATE PAIN RELIEF	SATISFACTORY ANALGESIA
LUXMAN(1996)	INADEQUATE PAIN RELIEF	SATISFACTORY ANALGESIA
ROBERTS(2003)	INADEQUATE PAIN RELIEF	SATISFACTORY ANALGESIA
<b>PRESENT STUDY (VAS score)</b>	7.67 ± 1.29	7.07 ± 0.80
P = 0.035		

**Incidence of increased duration of second stage of labour.**

AUTHOR(YEAR)	DURATION OF SECOND STAGE OF LABOUR		INFERENCE
	EARLY GROUP	LATE GROUP	
CHESTNUT(1987)	94±54 MINUTES	124±74 MINUTES	NO STATISTICALLY SIGNIFICANT DIFFERENCE
	P>0.05		
JOHNSRUD(1988)	P>0.05		NO STATISTICALLY SIGNIFICANT DIFFERENCE
CHESTNUT(1990)	63 MINUTES	53 MINUTES	NO STATISTICALLY SIGNIFICANT DIFFERENCE
	P>0.05		
LUXMAN(1996)	P>0.05		NO STATISTICALLY SIGNIFICANT DIFFERENCE
HUI LING LEE(2008)	93±57 MINUTES	102±70 MINUTES	NO STATISTICALLY SIGNIFICANT DIFFERENCE
	P=0.113		
PRESENT STUDY	29.38±11.19 MINUTES	30.14±12.26 MINUTES	NO STATISTICALLY SIGNIFICANT DIFFERENCE
	P=0.673		