A Randomized Clinical Trial to Evaluate the Effect of Programmed Labour and Epidural Analgesia on Onset and Duration of Stages of Labour

Abstract: Background: The present study was conducted to evaluate the effect of programmed labour and epidural analgesia on onset and duration of stages of labour. Material & Methods: This randomized interventional clinical trial was conducted in department of Anaesthesia at Kamla Nehru State Hospital for Mother and Child, Indira Gandhi medical College Shimla in collaboration with Department of Anaesthesia on eighty uncomplicated pregnant women that were divided into two groups of 40 patients each by block randomization. One group received programmed labour protocol (Injection Pentazocine 6 mg + Injection Diazepam 2 mg IV + Injection Tramadol 1-1.5 mg/kg I.M thererafter a single dose of injection Drotaverine 40 mg intravenously) while the other group received epidural analgesia. They were monitored for VAS score before and after intervention. Results: The two groups were comparable in terms of patients characteristics (age, parity, period of gestation). Both groups were comparable in terms of onset of labour Spontaneous labour seen in 65-70% of subjects. Regarding the duration of active phase of labour, in our study, In group 1 duration of active phase of 1 stage of labour was 215 min, and in group 2 it was 204 minutes with standard deviation of 32 minutes in group 1 and 40.4 minutes in group 2 respectively. Using student ‘t’ test this difference was found to be significant statistically. (P value <0.005). The mean duration of second stage of labour was 24.3 in group 1 and 35.8 min in group 2 with significant p value<0.005. The mean duration of third stage of labour in our study was 5.89 minutes in group 1 and 5.7 min group 2. This difference is statistically insignificant (using student ‘t’ test (>0.005)). Conclusion: Our study concluded that there was significant difference in first and second stage of labour in both groups while there was no significant difference in third stage and onset of labour in both groups.

Keywords: Randomized Clinical Trial, programmed labour, epidural analgesia, Onset and stages of labour.

INTRODUCTION

The optimal method of labour analgesia should offer quick, efficient, cost-effective, and secure pain relief for all phases of labour without jeopardising the health and vitality of the foetus. It shouldn't interfere with normal labour and should be adaptable enough to switch to anaesthesia for a last-minute surgical birth or other intervention. The woman would be awake, alert, comfortable, and able to be down and, if desired, even walk throughout labour thanks to such a perfect approach.

The protocol of programmed labour is one that many institutions follow. In this case, a variety of medications are administered, including Injection Pentazocine 6 mg, Injection Diazepam 2 mg, Injection Tramadol 1-1.5mg/kg I.M., and Injection Drotaverine 40 mg I.V. It is a straightforward, hassle-free, and efficient technique for quick, painless delivery. All labour stages are shortened by it. In women who undergo planned labour, the duration of the active phase of labour has been found to be much shorter. The most efficient and least depressive technique of intrapartum pain management currently used is epidural analgesia.

There are many studies available in the literature regarding epidural analgesia and programmed labour but no study has been conducted at Kamla Nehru State Hospital for Mother and Child to study and compare the effect of programmed labour and epidural analgesia on Onset and stages of labour. Therefore current study has been designed to evaluate the effect of programmed labour and epidural analgesia on Onset and stages of labour.
AIMS AND OBJECTIVES:
To evaluate the effect of programmed labour and epidural analgesia on Onset and stages of labour.

MATERIAL AND METHODS:
Type of Study:
This randomized Interventional clinical trial was conducted in department of Anaesthesia at Kamla Nehru State Hospital for Mother and Child, Indira Gandhi medical College Shimla in collaboration with Department of Anaesthesia.

Inclusion Criteria:
- Age 18-40 years
- Pre pregnancy BMI- 18.5 to 24.9 Kg/m2
- Singleton pregnancy with vertex presentation with spontaneous or induced labour after 34 weeks.
- Cervix dilatation 4-6cm and effacement 20-50 percent.
- Presence of regular uterine contraction.
- Reactive NST.
- Pre rupture of membrane less than 6 hours
- Pre-eclampsia with non-severe features
- Clear liquor after Artificial Rupture Of Membrane

Exclusion Criteria:
- Malpresentation
- Cephalopelvic disproportion
- Preterm labour less than 34 weeks
- Intrauterine death
- Previous lower segment caesarean section and placenta praevia
- Medical Disorders complicating pregnancy excluding preeclampsia with non-severe feature
- Foetal compromise before epidural analgesia
- Previous back surgery, spinal deformity
- Bleeding disorders
- History of psychiatric disorders, drug allergy.

In our study, 80 parturient females fulfilling the inclusion criteria were taken. They were divided into two groups of 40 patient each by block randomization method to study and compare the effect of programmed labour with epidural analgesia on maternal and foetal outcome for a period of one year. The group 1 was administered programmed labour analgesia which included injection Pentazocine 6 mg IV +Inj Diazepam 2 mg I.V +Inj. Tramadol 1-1.5mg/kg I.M thereafter a single dose of injection Drotaverine 40 mg I.V. whereas group 2 received epidural analgesia.

Study Drug:
15 ml of ropivacaine 0.2% with 2 μg/ml fentanyl (2 μg /ml of fentanyl will be taken by using six parts from a tuberculin syringe graduated in markings to divide 1 ml (50 mcg/ml) into 10 parts and added to 15 ml of ropivacaine to achieve a final concentration of fentanyl i.e. 2 mcg/ml).

The time of injection was noted and patients were kept in supine position for 10 minutes .Effect of Epidural analgesia was recorded at 5 minutes, 15 minutes and then at every 15 minutes for 1 hour and every 30minutes till VAS Score becomes less than 3, this was noted as onset of analgesia and ambulation grading was done.

Rescue analgesia was given in the form of injection ketamine 0.25% -0.5mg/kg was given intravenously in group one only in selected cases at cervical dilation of 7-8 cm and patient complaining of pain, subsequent doses was half of the first dose and interval between two doses was 30 minutes required. The outcome of study was recorded as onset and duration of first, second and third stages of labour.

Data Analysis:
Data collected from patient's records and was transferred into MS Excel sheet for further processing and analysis. Data was further analyzed using statistical software Epi info version 7 and SPSS version 20. Qualitative variables were expressed in term of frequencies, proportion and 95% confidence interval while quantitative variables were expressed as mean and standard deviation. In order to compare results between two study groups appropriate parametric or non-parametric test of statistical significance was used. Probability value (p-value) less than 0.05 was considered statistically significant.

OBSERVATIONS AND RESULTS:
In our study, 80 parturient females fulfilling the inclusion criteria were taken. They were divided into two groups of 40 patient each by block randomization method to study and compare the effect of programmed labour with epidural analgesia on VAS score before and after intervention. The group 1 was administered programmed labour analgesia which included injection Pentazocine 6 mg IV +Inj Diazepam 2 mg I.V +Inj. Tramadol 1-1.5mg/kg I.M thereafter a single dose of injection Drotaverine 40 mg I.V. whereas group 2 received epidural analgesia.
In both groups, maximum subjects i.e., 90% were in the Age group of 21-30 years. Mean age was comparable (p>0.05) in both groups i.e., 26.5 years Vs 26.9 years. Out of total 80 parturient females recruited in the study, maximum subjects (60%) were primigravidae. The parity was comparable (p value >0.05) in both groups. In group 1, 57.5% patients were in the gestational age group between 37-40 weeks while in group 2, 70% parturients were in the gestational age group of 37-40 weeks. The mean POG was 37.5 in group 1 and 37.4 in group 2. The POG was comparable in both groups.

### Table 1: Comparison of onset of labour in both groups

<table>
<thead>
<tr>
<th></th>
<th>Group 1</th>
<th>Percentage</th>
<th>Group 2</th>
<th>Percentage</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Spontaneous</td>
<td>28</td>
<td>70%</td>
<td>26</td>
<td>65%</td>
<td></td>
</tr>
<tr>
<td>Induced</td>
<td>12</td>
<td>30%</td>
<td>14</td>
<td>35%</td>
<td></td>
</tr>
</tbody>
</table>

Both groups were comparable in terms of onset of labour. Spontaneous labour seen in 65-70% of subjects.

### Table 2: Comparison of duration of first, second and third stages of labour

<table>
<thead>
<tr>
<th>Duration</th>
<th>Group 1 Mean (Minutes)</th>
<th>Group 2 Mean (Minutes)</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>First stage of labour</td>
<td>215.0min</td>
<td>204.8min</td>
<td>0.000</td>
</tr>
<tr>
<td>Second stage of labour</td>
<td>24.3 min</td>
<td>35.8min</td>
<td>0.005</td>
</tr>
<tr>
<td>Third stage of labour</td>
<td>5.89min</td>
<td>5.7min</td>
<td>0.216</td>
</tr>
</tbody>
</table>

Active phase was taken from 4 cm dilatation of cervix. It was observed that the duration of active phase of labour was more in group 1 than group 2. In group 1 duration of active phase of 1 stage of labour was 215 min, and in group 2 it was 204.8 minutes. The mean duration of second stage of labour was 24.3 in group 1 and 35.8 min in group 2 with significant p value. This shows that the duration of second stage of labour is more in epidural analgesia group. The duration of third stage of labour was 5.89 min in group 1 and 5.7 minutes in group 2 and was comparable in both groups. This shows that labour analgesia has no effect upon duration of third stage of labour. The p value was not significant (<0.005).

**DISCUSSION:**

In our study, in group 1 duration of active phase of 1 stage of Labour was 215 min, and in group 2 it was 204 minutes with standard deviation of 32 minutes in group 1 and 40.4 minutes in group 2 respectively. Using student ‘t’ test this difference was found to be significant statistically. (P value <0.005).
Duration of the active phase of first stage of labour in Programmed labor group was similar when compared with study done by Nitin S et al.,5, Daftary et al.,5 and Rehana Nazam et al.,6. While it was less as compared to that of Konin Savita et al.,7. This can be attributed to the fact that our study included patients at 4-6 cm dilated while in Konin savita et al.,7 study, all patients were primiparæ and included at 3-4 cm dilatation. When compared to study by Veerandrakumar et al.,8, our mean duration of active phase was more when compared to their study because most of the patients in their study were augmented with oxytocin. In our study, the mean duration of active phase of labour in epidural analgesia group was 204 minutes while it was comparatively less in a study conducted by Najam R t et al.,9. In a study conducted by Dipti et al.,9, they showed increased duration of first stage of labour when compared to our study in group receiving epidural group. This may be due to the use of ropivacaine 2% and fentanyl 50ug. More concentration of drug causing relaxation of pelvic musculature in Dipti et al.,9 study. The duration of active phase of labour was more seen in Niteen arsule et al.,10 because the drug used and vidya et al.,11 because the study group were primigraividae in these studies while in our study, the primiparæ were only 60%.

Duration of second stage of labour in the group 1 and the group 2 were 24.3 min and 35.8 minutes respectively. It was significant statistically when analysed with student ‘t’ test. The mean duration of second stage in group 1 was 24.3 minutes and the result was comparable to study conducted by Shahida Mir et al.,12, Sravani et al.,13, Daftary et al.,5, Konin et al.,7 all studies. The duration of second stage in group 2 received epidural analgesia is comparable to Dipti et al.,8 while slightly shorter in duration when compared to Niteen et al.10 and Najam et al.,9 because all patients in their study were primigravidae.

The mean duration of third stage of labour in our study is 5.89 min in group 1 and 5.7 min group 2. This difference is statistically insignificant using student ‘t’ test (>0.005). The duration of third stage of labour similar results seen in study conducted by Shahida et al.,12, Veerandrakumar et al.,10, Rehana et al.,6. In group 2, the duration of third stage of labour was 5.7 minutes and it was comparable to study conducted by Rehana Njam et al.,10. It was observed that that the there was significant reduction in the duration of third stage, which was due to early separation of placenta in both groups.

CONCLUSION:
Our study concluded that there was significant difference in first and second stage of labour in programmed labour and epidural analgesia groups while there was no significant difference in third stage and onset of labour in both groups.
REFERENCES: