Comparing the Effect of Programmed Labour and Epidural Analgesia on Vas Score before and After Intervention: A Randomized Interventional Clinical Trial

Abstract: Background: The present study was undertaken to compare the effects of programmed labour and epidural analgesia on VAS score before and after intervention. 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 therafter 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). Majority of the patients (90%) were in the age group of 20-30 years in both groups. The mean age of the women in the group 1 was 26.5 years as compared to 26.9 year in group 2. VAS Score was studied in both groups before and after intervention. In group 1 before analgesia, the VAS Score was 9.2 while after giving programmed labour the mean VAS score at 5 min was 8.1 suggestive of mild relief while at 15 minutes it improved to 4.5 suggestive of moderate pain relief. In group 2, the VAS score was 2.5 at 15 minutes and 0.00 at 30 minutes after epidural which suggest significantly low level of pain. P value was highly significant when compared with group 1 at 15 minutes and at 30 minutes. Conclusion: Both programmed labour protocol and epidural analgesia provides good pain relief among parturients but excellent results seen in group 2 receiving epidural analgesia. The VAS Score in group 2 was superior and more effective than Group 1 with significant p value.

Keywords: Comparison programmed labour, epidural analgesia, VAS score

INTRODUCTION

Perception of pain by labouring female is a dynamic process that involves both peripheral and central mechanisms. There are many factors that have an influence on the degree of pain experienced by a woman during labour, including emotional support to the parturient during labour, psychological preparation, past experience of labour pains, the patient’s expectation of labor, and induction and augmentation of labour; however, for most of the parturients, child birth is associated with very severe pain which often is worst pain they have ever experienced.1

The ideal technique for labor analgesia should; provide rapid, effective, economical and safe pain relief for all stages of labor without compromising fetal vital physiology and wellbeing. It should not hamper the normal process of labor and should be flexible enough to convert to anaesthesia for urgent operative delivery or other intervention. Such an ideal technique would leave the mother awake, alert, comfortable and able to beardown and if desired, even ambulate throughout labour.2

Programmed labour is protocol which is followed in many institutes. In this a cocktail of drugs are given, which include Injection Pentazocine 6 mg with Injection Diazepam 2 mg given I.V followed by Injection Tramadol 1-1.5mg/kg I.M, along with a single dose of Injection Drotaverine 40 mg I.V. It is a simple, easy and effective method for painless and safe delivery. It shorten all stages of labour. A significant reduction in duration of active phase of labor has been observed in women receiving programmed labor.3,4
Epidural analgesia is the most effective and least depressant method of intrapartum pain relief in current practice. Convenience of administration of programmed labor can be an alternative in rural setups where trained medical personnel may not be available most of the times.1,4

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 VAS score. Therefore current study has been designed to study and compare the effect of epidural analgesia on VAS score before and after intervention.

AIMS AND OBJECTIVES:
To study and compare the effect of programmed labour with epidural analgesia on VAS score before and after intervention.

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 4-6 cm 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 1-1.5 mg/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 30 minutes 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% -0.5 mg/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.

Maternal VAS score for pain was recorded at 0, 5, 15 minutes and then every 15 minutes till 1 hour and then every 30 minutes until delivery.

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 IM thereafter a single dose of injection Drotaverine 40 mg I.V. whereas group 2 received epidural analgesia.

| Table 1: Distribution according to age group, parity and gestational age |
|---------------------------------|-----------------|-----------------|-----------------|-----------------|-----------------|-----------------|
| Age (years)                     | Number | Percentage | Number | Percentage | Number | Percentage | p value |
| <20                            | 2      | 5%          | 2      | 5%          |        |           | 1.000             |
| 21-30                          | 36     | 90%         | 36     | 90%         |        |           |                   |
| 31-40                          | 2      | 5%          | 2      | 5%          |        |           |                   |
| Mean± S D                      | 26.5± 3.4 years | 26.9± 3.9 years |        | 0.630             |
| Parity                         |        |             |        |             |        |           |                   |
| Primigravidae                  | 24     | 60%         | 24     | 60%         |        |           | 0.999             |
| Multigravidae                  | 16     | 40%         | 16     | 40%         |        |           |                   |
| Gestational age in weeks       |        |             |        |             |        |           |                   |
| <37 weeks                      | 7      | 17.5%       | 2      | 5%          |        |           | 0.195             |
| 37-40 weeks                    | 23     | 57.5%       | 28     | 70%         |        |           |                   |
| >40 weeks                      | 10     | 25%         | 10     | 25%         |        |           |                   |
| Mean POG                       | 37.5   |             | 37.4   |             |        |           | 1.274             |

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 2: Comparison of visual analogue scale among both groups.

<table>
<thead>
<tr>
<th></th>
<th>At 0 min</th>
<th>At 5 min</th>
<th>At 15 min</th>
<th>At 30 min</th>
<th>At 5 hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>Group 1</td>
<td>9.2</td>
<td>8.1</td>
<td>6</td>
<td>4.5</td>
<td>3.4</td>
</tr>
<tr>
<td>Group 2</td>
<td>9.7</td>
<td>7.7</td>
<td>2.5</td>
<td>0</td>
<td>0.9</td>
</tr>
<tr>
<td>P value</td>
<td>&gt;0.05</td>
<td>0.047</td>
<td>0.000</td>
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</tbody>
</table>

In our study all the parturient females were assessed on the basis of visual analogue scale (VAS) on a scale of 0 to 10, 0 being no pain and 10 was worst pain possible.

The VAS Scale before analgesia was 9.2 in group 1 while in group 2, it was 9.7 which suggest worst pain in labouring patients in both groups and was comparable in both groups. After that there was highly significant difference between the VAS of both the groups, the highly significant difference continued till 300 minutes.

After analgesia, the VAS score improved in both groups however it was better in group 2 compared to group 1 as shown in table 2 with significant P value. In group 2, the VAS score was 2.5 at 15 minutes and 0.00 at 30 minutes after epidural which suggest significantly low level of pain. P value was highly significant when compared with group 1 at 15 minutes and at 30 minutes.

DISCUSSION:

Pregnancy and labour are physiological processes which are part of woman’s life. Labour should be remembered with pleasure rather than with dismay at the agony which invariably accompanies it. While a majority of the patients who have undergone successful labour reflect at its outcome with satisfaction, it should be obstetrician’s duty to minimize the severe pain accompanying labour.

In this study, 80 pregnant women in labour were taken. All of them entered in the study in active phase of labour. Group 1 received programmed labour in active phase of labour while Group 2 received epidural analgesia.

Majority of the patients in our study (90%) were in the age group of 20-30 years in both groups. The mean age of the women in the group 1 was 26.5 years as compared to 26.9 year in group 2. The mean age in our study is comparable to other studies conducted by Vidya et al.,5 study, Anjuman et al.,6 study and Rehana Nazam et al.,7 study in which mean age was 25 years, 24.8 years and 24 years respectively in programmed labour group. While in group 2 who received epidural analgesia, the mean age of the subjects were comparable to that of study conducted by Desai pankaj et al.,8 Rehana Nazam et al.,7 and Angeliki et al.,9 in which mean age was 24.9 years, 25.6 years and 25.9 years respectively.

In the present study, 60% participants were Primigravidae in group 1, which was comparable to study conducted by Mir Shahida et al.,10. In other studies, this parameter was not taken into consideration.
Similar pattern was observed in study conducted by Sadia et al.,11 and Yogesh et al.,12 in epidural analgesia group. Present study shows 60% were primigravidae while lower into other studies conducted by Yogesh et al.,12, Sadia et al.,11 probably because of inclusion of patients at the time of study.

In present study, the mean gestational age of group 1 was 37±5 weeks. This was similar to that observed by Veronica Irene et al.,13, Veerendra Kumar et al.,14 and Rehana Nazam et al.,1. Similar pattern was observed in gestation in group 2 when compared to study conducted by Desai Pankaj et al.,8, Angeliki et al.,9 and Rehana Nazam et al.,7 where the average gestational age is >37 weeks.

In our study all parturient females were assessed on the basis of visual analogue scale (VAS) on a scale of 0 to 10, 0 being no pain and 10 was worst pain possible. In group 1, before analgesia, the VAS score was 9.2 while after giving programmed labour the mean VAS score at 5 min was 8.1 suggestive of mild relief while at 15 minutes, it improved to 4.5 suggestive of moderate pain relief. In our study after giving analgesia, the VAS score was 5 suggestive of moderate pain relief in 87% of parturients among group 1 and similar results seen in studies conducted by Meena et al.,15 and Shahida et al.,10. In another study conducted by Niteen Arsules6, Varsha Deshmukh et al.,16, Yogesh Shetty et al.,12 the VAS score was comparable with our study in epidural analgesia group.

Both programmed labour protocol and epidural analgesia provides good pain relief among parturients but excellent results seen in group 2 receiving epidural analgesia.

CONCLUSION:

Both programmed labour protocol and epidural analgesia provides good pain relief among parturients but excellent results seen in group 2 receiving epidural analgesia. The VAS Score in group 2 was superior and more effective than Group 1 with significant p value.

REFERENCES: