Original Article

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Maternal and Perinatal Outcomes in Planned Labour: A Prospective Interventional Study

Obstetrics and Gynaecology Section

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ABSTRACT

Introduction: Labour, especially in primiparas, is associated with intense pain. Patients labouring without analgesia may experience longer durations in all stages, along with the suffering associated with labour pains. The study was conducted to determine whether a programmed labour regime provided adequate pain relief and accelerated the labour process.

Aim: To compare the maternal and perinatal outcomes in patients who underwent conventional labour with those who received programmed labour analgesia.

Materials and Methods: This prospective interventional study was conducted in the Department of Obstetrics and Gynaecology at Netaji Subhash Chandra Bose Medical College and Hospital in Jabalpur, Madhya Pradesh, India. The study duration was one year and five months, from March 2021 to August 2022. A total of 100 patients, including 50 low-risk primiparas in each group with cervical dilatation of 3 to 4 cm, were randomly allocated to the case and control groups. The case group received a programmed labour regime, which involved administering small doses of various drugs such as pentazocine, drotaverine, diazepam, and tramadol. No analgesia was given to the control group. Pain relief assessment was conducted using a Visual Analogue Scale (VAS). The duration of the various stages of labour and the rate of cervical dilatation were assessed in both groups. Data analysis was performed using Statistical Package for Social Sciences (SPSS) version 23.0.

Results: The mean age of the study subjects in the control group was 24.14±2.39 years, and in the case group, it was 24.26±2.49 years. Compared to the control group, 29 (58%) cases experienced mild pain, and 21 (42%) experienced moderate pain. The rate of cervical dilatation was 2.57±1.41 cm/hour in the case group compared to 1.41±0.36 cm/hour in the control group (p-value <0.001). The mean duration of the first (cervical dilatation from 3-4 cm onwards), second, and third stages of labour was 140.2±35.06 minutes, 25.22±9.41 minutes, and 3.56±0.91 minutes, respectively, in the case group. The duration of all stages of labour was significantly reduced in the case group (p-value <0.001). Minimal side effects were observed, with nausea being the most common side effect in 16% of cases.

Conclusion: Programmed labour resulted in shorter and more comfortable labour with minimal adverse effects. This method does not require a trained anaesthetist; thus, it can be easily administered in low-resource settings.

Keywords: Cervical dilatation, Labour analgesia, Nausea, Pain relief

INTRODUCTION

Labour is a physiological phenomenon that occurs during the process of childbirth. It is considered to be one of the most painful events that women experience [1]. Over the years, with the progress of civilisation, education, eradication of poverty, the evolution of modernisation, and the assumption of a more positive role of women in today's society, women are standing up for their rights and demanding the benefits of technological advances involving modern analgesic methods to be made widely available during childbirth [2]. Labour analgesia ensures adequate pain relief and controls alterations of placental circulation, thereby safeguarding the foetus against hypoxia and depression at birth. Optimal pain relief also prevents hyperventilation and excessive muscle efforts that exhaust the mother [3]. Many methods of providing pain relief in labour have been used in the past, such as regional anaesthesia, spinal anaesthesia, epidural anaesthesia, and the use of nitrous oxide. Analgesia with various drugs such as pethidine has also been used in the past [4]. Among them, epidural analgesia has proven to be beneficial and has significantly contributed to pain relief and improved obstetric outcomes. However, due to limited resources in India, it is not feasible to provide epidural analgesia in all clinical settings.

In 1973, O'Driscoll K et al., reported that, active management of labour results in the shortening of labour, improved obstetric outcomes, and a lower rate of caesarean sections [5]. The programmed labour protocol incorporates these principles advantageously. The protocol of programmed labour was developed by Daftary SN et al., in India, with the dual objective of providing adequate pain relief during labour and achieving the goals of safe motherhood, thus optimising obstetric outcomes [3]. It is based on three pillars:

- Ensuring adequate uterine contractions by following the active management of labour protocol.
- Providing optimum pain relief through the use of analgesics and antispasmodics.
- Close clinical assessment of labour events by maintaining a partogram.

The present study was designed to evaluate the efficacy of the programmed labour regime while keeping all the above objectives in mind.

MATERIALS AND METHODS

A prospective interventional study was conducted in the Department of Obstetrics and Gynaecology at Netaji Subhash Chandra Bose Medical College and Hospital in Jabalpur, Madhya Pradesh, India. The duration of the study was one year and five months, from March 2021 to August 2022. The study was approved by the Institutional Ethical Committee on 5th September 2022 No. (IEC/2022/8629-146).

Sample size calculation: The minimum sample size calculated was 29 for both cases and controls. The sample size calculation was performed using G*power software version 3.1.9.2. A total of 50 cases and 50 controls were enrolled in the study. Participants were included in the cases based on patient preference (consent), while others were taken as controls.

Inclusion criteria: The study included all primiparas between 18-30 years with a full-term singleton pregnancy and cephalic presentation, with an estimated fetal weight of more than 2.5 kg. Inclusion was also based on reactive cardiotocography.

Exclusion criteria: Patients with presentations other than vertex were excluded from the study. Additionally, patients with obstetric and medical complications such as hypertensive disorders, previous caesarean sections, severe anemia, diabetes mellitus, asthma, and heart disease, as well as, patients with cervical dilation of more than 4 cm upon admission, were excluded from the study.

Study Procedure

In the cases, all women were started on an intravenous line of Ringer's Lactate (RL) at a rate of 15 drops per minute. If uterine contractions were not adequate, oxytocin was initiated at a rate of 1 mIU/minute and increased by 1 mIU every 30 minutes until 3 to 5 contractions in 10 minutes were achieved. One ampule of pentazocine 30 mg (1 mL) and one ampule of diazepam 10 mg (2 mL) were diluted with 7 mL of distilled water to obtain a diluent of 10 mL. A 2 mL portion of the diluent containing 6 mg of pentazocine injection and 2 mg of diazepam injection was slowly administered intravenously (IV) once the patient achieved adequate contractions. Injection tramadol 1 mg/kg (body weight) was given intramuscularly (IM). Injection drotaverine hydrochloride 40 mg was given IM and repeated every two hours until full cervical dilation, up to a maximum of three doses. Ketamine, as described in the regime by Daftary SN et al., was not used in the present study due to the unavailability of a trained anaesthetist in the labour room [3]. A 10 mL dose of 1% lignocaine was locally infiltrated before episiotomy, if required. Injection oxytocin 10 IU was given intramuscularly within one minute of delivery of the baby, following the active management of the third stage of labour. The progression of labour was recorded and assessed using the simplified World Health Organisation (WHO) partogram [6].

Pain scores were assessed using the VAS method [7]:

- No pain: 0
- Mild pain: 1-3
- Moderate pain: 4-7
- Severe pain: 8-10

All controls were started on an intravenous line of RL. If uterine contractions were not adequate, oxytocin was initiated at a rate of 1 mIU/minute and increased by 1 mIU every 30 minutes until 3 to 5 contractions in 10 minutes were achieved. After the delivery of the baby, 10 IU of oxytocin injection was given intramuscularly within one minute, following the active management of the third stage of labour. After following the procedure, pain relief scores, duration of various stages of labour, rate of cervical dilatation, maternal side effects, and Appearance, Pulse, Grimace, Activity, and Respiration (APGAR) scores were assessed.

STATISTICAL ANALYSIS

The data were entered into an Excel sheet and analysed using SPSS version 23.0. Pearson's Chi-square test and independent t-test were applied for statistical analysis.

RESULTS

The mean age of subjects in the present study was 24.14±2.39 years in the control group and 24.26±2.49 years in the cases. In the cases, the mean gestational age was 39.41±1.17 weeks, while in the controls it was 39.26±1.22 weeks. Most of the patients achieved mild to moderate pain relief [Table/Fig-1]. Among the cases, 29 (58%) experienced mild pain, while 21 (42%) had moderate pain. None of the patients in the regime group achieved complete pain relief. The rate of cervical dilatation was significantly higher in the cases compared to the controls (p-value <0.001) [Table/Fig-2]. The duration of all stages of labour was significantly reduced in the cases compared to the controls [Table/Fig-3].

Pain assessment with VAS	Case n (%)	Control n (%)	p-value
Severe	0	48 (96)	<0.0001
Moderate	21 (42)	2 (4)	
Mild	29 (58)	0	
No pain	0	0	

[Table/Fig-1]: Pain assessment using Visual Analogue Scale (VAS). Chi-square test was used.
n: Number of patients; %: Percentage. (N=100)

Groups	Rate of cervical dilatation (cm/hr)	p-value
Case	2.57±1.41	<0.0001
Control	1.41±0.36	

[Table/Fig-2]: Rate of cervical dilatation in cm/hr.
*Independent t-test was used

Stages of labour	Case (n=50) Mean±SD	Control (n=50) Mean±SD	p-value
1st stage of labour (from cervical dilatation 3-4 cm)	140.2±35.06	234.00±61.51	<0.0001
2nd	25.22±9.41	44±13.68	<0.0001
3rd	3.56±0.91	5.18±1.38	<0.0001

[Table/Fig-3]: Duration of various stages of labour in minutes. Independent t-test was used.
(N=100)

The most common adverse effect observed was nausea in 8 (16%) cases, followed by tachycardia in 2 (4%) cases, and vomiting 1 (2%) cases, respectively [Table/Fig-4].

Maternal side-effects	Case n (%)	Control n (%)	p-value
Nausea	8 (16)	0	<0.015
Vomiting	1 (2)	0	
Tachycardia	2 (4)	5 (10)	
No side-effects	39 (78)	45 (90)	

[Table/Fig-4]: Maternal side-effects. Chi-square test was used.
n: Number of patients; %: Percentage. (N=100)

The majority of the patients delivered vaginally, with a caesarean delivery rate of 2% in the cases and 4% in the controls. The p-value was 0.603, which was not significant [Table/Fig-5]. The APGAR scores of the newborns in both groups did not show any significant difference [Table/Fig-6]. Perinatal outcomes were observed in both groups. Five newborns among the cases and 11 newborns among the controls were admitted to the Neonatal Intensive Care Unit (NICU) for observation. Among them, one newborn from the control group was admitted for respiratory distress. There were no cases of newborn mortality in either group.

Mode of delivery	Case n (%)	Control n (%)	p-value
Vaginal	49 (98)	48 (96)	0.603
LSCS	1 (2)	2 (4)	

[Table/Fig-5]: Mode of delivery. Chi-square test was used.
LSCS: Lower segment caesarean section; p-value <0.005: Non significant

APGAR score	Case	Control	p-value
At one minute (0-3)	1	1	0.603
At one minute (4-6)	48	49	
At one minute (7-10)	1	0	
At five minute (0-3)	0	0	1.00
At five minute (4-6)	2	2	
At five minute (7-10)	48	48	

[Table/Fig-6]: Appearance, Pulse, Grimace, Activity and Respiration (APGAR) score at 1 and 5 minutes. Chi-square test was used.
p-value <0.005: Non significant

DISCUSSION

Pentazocine and tramadol provide pain relief thereby preventing excessive maternal exhaustion [8]. Drotaverine is a spasmolytic drug that also acts on the female genital tract, releasing cervical spasms and promoting optimal cervical dilation [9].

In the case group of the present study, none of the participants achieved complete pain relief. Out of the participants, 29 (58%) experienced moderate pain relief, while 21 (42%) had mild pain relief. In a study conducted by Daftary SN et al., they observed excellent pain relief in 24% of their study group, substantial pain relief in 62%, and insufficient pain relief in 14% [3]. Jyoti M et al., assessed pain relief using a grading scale ranging from 0 to 3 (0 - no pain relief, 1 - mild relief, 2 - moderate relief, 3 - good relief) [10]. In their study, 54% of the participants had good pain relief, 32% had moderate relief, and 14% had mild pain relief. Yuel VI et al., reported that, 70% of their study participants had total pain relief, 16.7% had substantial relief, and 13.3% had some relief, although not as much as desired [11]. In a study by Puri S et al., 84% of the patients experienced pain relief, with 18% having mild relief, 28% having moderate relief, and 38% having excellent pain relief [12]. The difference in pain relief outcomes could be attributed to the non-use of ketamine in the present study.

The present study showed a significant reduction in the duration of all stages of labour, which may be attributed to the drugs used. The mean duration of the first stage of labour was 140.2±35.06 minutes in the programmed labour (case) group. This finding is comparable to the studies conducted by Jyoti M et al., Manoj A et al., and Madhvi KN et al., where the mean durations in the study groups were 147±33 minutes, 140.41 minutes, and 147±24 minutes, respectively [10,13,14]. In the original study conducted by Daftary SN et al., the mean duration of the first stage of labour was 210 minutes in the programmed labour group and 312 minutes in the expectant management group, which was slightly longer than the present study [3]. The mean duration of the second stage of labour in the study was 25.22±9.41 minutes in the programmed labour group. These results are comparable to other studies conducted by Yuel VI et al., Puri S et al., Madhvi KN et al., Cm V and Chikkagowdra S, where the mean durations in the study groups were 25±10 minutes, 25.3±6.2 minutes, 25.52±8.60 minutes, and 27.2±5.46 minutes, respectively [11,12,14,15].

The mean rate of cervical dilatation was 2.57±1.41 cm/hour in the cases and 1.41±0.36 cm/hour in the controls. In the study conducted by Daftary SN et al., the mean rate of cervical dilatation was 2.5 cm/hour in the study group and 1.2 cm/hour in the control group [3]. Madhvi KN et al., reported a mean rate of cervical dilatation of 2.44±0.29 cm/hour in the study group and 1.18±0.43 cm/hour in the control group [14].

In the case group of the present study, 16% of the study subjects experienced nausea as a side effect, followed by tachycardia in 4% and vomiting in 2%. All side effects subsided within 6-8 hours after delivery, and all women were discharged after receiving regular postnatal treatment. In the study conducted by Daftary KN et al., minor side effects such as nausea, vomiting, drowsiness, and malaise were reported in 25.5% of cases [3]. Yuel VI et al., noted that, tachycardia was the most common maternal morbidity observed in 80% of women in the study group, followed by nausea and vomiting in 10%, and a rise or fall in blood pressure in 5% each [11]. Manoj A et al., observed nausea in 30% of cases and vomiting in 20% of cases [13].

Although, these drugs may have minimal benefits, they can also have life-threatening side effects if used excessively. However, in the present study, minimal side effects were observed. Nausea and vomiting could be attributed to the use of pentazocine and tramadol. Drotaverine may also lead to maternal tachycardia, in addition to common side effects such as nausea and vomiting. It is worth noting that, pentazocine can cross the placenta and, in high doses, may cause respiratory depression in the baby. In the present study, the authors used minimal doses of pentazocine to prevent this side effect.

Limitation(s)

The present study was a single-center study; therefore, the results cannot be generalised to the entire population. The vaginal delivery rate is likely to be higher in the programmed labour group compared to the conventional group, but the authors did not find a significant difference in the caesarean rate between the two groups in the present study. This may be due to the small sample size. A study with a larger sample size would be required to determine if such a difference exists.

CONCLUSION(S)

The programmed labour regime used in the present study significantly reduces the duration of labour and accelerates the rate of cervical dilatation, with minimal side effects. Patients experience sufficient pain relief, leading to a reduced demand for caesarean delivery. This method does not require a trained anaesthetist, making it easy to administer in low-resource settings.

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REFERENCES

[1] Shirzad M, Shakibazadeh E, Hajimiri K, Betran AP, Jahanfar S, Bohren MA, et al. Prevalence of and reasons for women's, family members', and health professionals' preferences for cesarean section in Iran: A mixed-methods systematic review. Reprod Health [Internet]. 2021;8(1):03.
[2] Sravani GG, Rao KS. A clinical study of programmed labour and its maternal and fetal outcome. JMSCR. 2014;2:672-81.
[3] Daftary SN, Desai SV, Thanawala U, Bhide A, Levi J, Patki A, et al. Programmed labor-indegenous protocol to optimize labor outcome. Journal of SAFOG with DVD [Internet]. 2009;1(1):61-64.
[4] Lam K, Leung MK, Irwin MG. Labour analgesia: Update and literature review. Hong Kong Med J [Internet]. 2020;26(5):413-20.
[5] O'Driscoll K, Stronge JM, Minogue M. Active management of labour. Br Med J [Internet]. 1973;3(5872):135-37.
[6] Dalal AR, Purandare AC. The partograph in childbirth: An absolute essentiality or a mere exercise? J Obstet Gynaecol India [Internet]. 2018;68(1):03-14.
[7] Wewers ME, Lowe NK. A critical review of visual analogue scales in the measurement of clinical phenomena. Res Nurs Health. 1990;13(4):227-36.
[8] Shetty J, Vishalakshi A, Pandey D. Labour analgesia when epidural is not a choice: Tramadol versus Pentazocine. ISRN Obstet Gynecol. 2014;2014:930349.
[9] Mukhopadhyay G, Das A. The effect of drotaverine on cervical dilatation--A comparative study with hyoscine in first stage of labour. Journal of Evolution of Medical and Dental Sciences [Internet]. 2018;7(30):3369-73.
[10] Jyoti M, Singhal P, Choudhary D. Programmed labour. J Obstet Gynecol India. 2006;56(1):53-55.
[11] Yuel VI, Kaur V, Kaur D. Programmed labour for optimizing labor and delivery. JK Science. 2008;10(2):62-64.
[12] Puri S, Sunil I, Jaggi R. Programmed labour: A comparative study. JK Science. 2019;21(3):130-33.
[13] Manoj A, Sivashanmugam T, Ghose S, Gowda M, Maurya DK. Maternal outcome in programmed labour-A randomized control trial. Indian Medical Gazette. 2012;145(10):405-09.

[14] Madhavi KN, Anuradha C, Chandra Sekhar P. A clinical study of programmed labour and its maternal and foetal outcome. IOSR Journal of Dental and Medical Sciences. 2015;14(2):23-26.

[15] Cm V, Chikkagowdra S. A clinical study on the effect of programmed labor on feto maternal outcome. International Journal of Reproduction, Contraception, Obstetrics and Gynecology [Internet]. 2016;5(10):3357-60.

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