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Original Research Article

Prospective Study of Programmed Labour Protocol at a Tertiary Care Centre

Seema Gurjar[1], Preeti Sharma[2], UrmilaTripathi[3]

[1]PG 3rd year, Department of Obstetrics and Gynaecology, Kamla Raja Hospital, G.R. Medical College, Gwalior (M.P.)

[2]M.S., Associate Professor, Department of Obstetrics and Gynaecology, Kamla Raja Hospital, G.R. Medical College, Gwalior (M.P.)

[3]M.S., Professor, Department of Obstetrics and Gynaecology, Kamla Raja Hospital, G.R. Medical College, Gwalior (M.P.)

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Corresponding author: Dr. Preeti Sharma

Conflict of interest: Nil

Abstract:

Introduction: A Prospective randomized Clinical study of outcome of labour following. "Prospective study of programmed labour protocol at a tertiary care centre was done at Department of Obstetrics and Gynaecology, Kamla Raja Hospital, G.R. Medical College, Gwalior M.P. The Protocol was aimed with dual. Objective of Providing Pain relief during labour and teaching the goal of safe motherhood by optimizing objective outcome.

Aims and Objectives: Shortening of duration of labour. Effect of labour analgesia, monitoring of the events during labour, lowering the incidence of operative deliveries.

Methods: 140 cases primi pregnant women admitted in labour room are randomly selected. It is designed to apply to low risk primiparous, singleton cephalic presentation without evidence of CPD and spontaneous onset of labour.

Results: Shortened duration of all the stages of Labour, especially significant reduction in duration of active phase of labour.

Conclusion: The programmed labour is simple easy and effective method for painless and safe delivery.

Keywords: Programmed labour, oxytocin, Amniotomy, Pain relief, Prostaglandins analgesics, antispasmodics and Partogram.

Introduction

Labour begins with the onset of regular uterine contractions and ends with delivery of the newborn and expulsion of the placenta. Pregnancy and birth are physiological processes, and thus, labor and delivery should be considered normal for most women.[1] Labour is physiological but painful event. Labour analgesia ensures pain relief, controls alteration of placental circulation thereby safe guarding the fetus against hypoxia.[2]

Programmed labor concept: This concept rest on three pillars;

1. Providing optimum pain relief: Use of analgesics and antispasmodics.
2. Ensuring adequate uterine contractions: Active management of labor
3. Close clinical monitoring of labor events: Maintaining a PARTOGRAM[2]. In a civilized society freedom from pain is one of the basic rights of a person. Programmed labour protocol is based on incorporation of labor analgesia, active management of labor and monitoring events of labor by a partograph.[3]Programmed labor is an indigenously developed protocol for labor management (Daftary et al, developed with the dual objective of providing pain relief during labor and reaching the goals of safe motherhood by optimizing obstetric outcome.[4]Although Epidural Analgesia offers the best method of providing pain relief, one must accept the fact that services of trained anesthesiologists are not universally available, and beyond the reach of a large section of our population. Hence, the adoption of an analgesia protocol which can be easily followed by the attending obstetrician has much to recommend.[5] The aims of the study to evaluate the effect of programmed labour on duration of labour. To assess efficacy of analgesics in reducing severity of labour pains and to find out any maternal and fetal neonatal complications.

Materials and Methods

Study Design: Prospective study

Study Setup

The study will be carried out in the Department of

Obstetrics and Gynaecology, Kamla Raja Hospital, G.R.M.C, Gwalior (M.P.)

Duration: The study will be conducted with data collection for a period of two years from November 2020 to October 2022.

Study Population: 140 Cases
For two comparison group:

$$N = \frac{(Z\alpha_2\sqrt{2PQ} + Z_{1-\beta}\sqrt{P_1Q_1+P_2Q_2})^2}{(P_1-P_2)^2}$$

At 5% level of significance $Z\alpha_2=1.96$

At 95% power of test $Z_{1-\beta} = 1.64$

P_1= Proportion of pain relief among intervention group

P_2 = Proportion of pain relief among control group

$P=\frac{P_1+P_2}{2}$ =47%

P1 = 62%
P2 = 32%

n1 = n2 = 69 (70)

Minimum sample size in each group 69 i.e. increased up 70 so for each group intervention and control group 70 patients will be taken. So sample size for current study is 140.

Inclusion Criteria

1. Age, between 21-35 years.
2. No identifiable medical or obstetric complications present.
3. Primigravida with singleton pregnancy with cephalic presentation with spontaneous onset of labor.
4. No clinical evidence of cephalopelvic disproportion.
5. Gestational maturity of 37-41 week.
6. Admission NST-reactive.
7. Active phase of labor with cervical dilatation 4cms and 50% effaced.
8. Liquor should be clear after ARM.

Exclusion criteria

1. High risk cases like antepartum haemorrhage, preeclampsia, diabetes complicating pregnancy, polyhydramnios, oligohydramnios, cephalopelvic disproportion, malpresentation, and pre labor rupture of membranes.
2. Patient who are not willing to sign informed consent will be excluded from the study.

Methods

The present prospective randomized study will be undertaken at Department of Obstetrics and Gynaecology, Kamla Raja Hospital, Gajra Raja Medical College, Gwalior. It will be approved by Ethical Committee of the Institute.

The patients in active labor will be divided into two groups by simple randomization.

Group I: 70 (cases) for programmed labor.

Group II: 70 (controls) for routine management of labour.

On admission to Labor room detailed history will be taken and a thorough physical and general examination will be done. Obstetrical examination including per vaginal examination will be done and pelvic assessment will be done to rule out cephalopelvic disproportion. After confirmation that the subject is in active labor, ARM will be done for confirmation of colour of liquor, cases will be selected for study. All subjects will be subjected for routine investigation.

Every women will be counseled regarding the protocol of programmed labor and after counseling written informed consent will be taken.

Level of analgesia assessed using following visual analogues scale:

0 - No pain relief
1 - Mild pain relief
2 - Moderate pain relief
3 - Excellent pain relief

Protocol

- The cervix should be 3.0- 5.0 cm dilated, >50% effaced and head is at 0 or -1 station
- Amniotomy is performed at 3 - 5 cm dilatation.
- Start an intravenous infusion line with 5% Ringer Lactate solution @ about 20 drops/min
- Ensure that pains are optimal that is 3-4 contraction/35-45”/10’.
- If needed, half an hour after amniotomy , Oxytocin drip 2 units in 500ml RL started at 8-10drops / min and titrated every 30 mins till adequate contractions (3-4 contraction / 35-45”/10’) are achieved.
- Inj. Tramadol I/M 1 mg/kg and inj. Drotaverine Hydrochloride 40 mg I.M. single dose is given at amniotomy.
- 2 mg of Diazepam + 6 mg Pentazocine given i.v. at amniotomy and repeated 2 hourly on patient demand.
- Progress of labour monitored by partogram and p/v examination done every 2 hours after amniotomy.
- 10 unit I/M oxytocin given in mother’s right shoulder at the delivery of the anterior shoulder of fetus.
- Duration of active phase of labor, 2nd stage and 3rd stage of labor will be noted.
- Neonatal assessment is done with APGAR score at 1min and 5 min.
- Maternal pain relief will be assessed with the help of visual analogue scale in the immediate postnatal period.

Control group

- Partographic monitoring of labor will be done.
- Inj. Diazepam, Pentazocine should not used for labour analgesia

Assessment

1. Duration of labor.
2. Pain relief during labor.
3. APGAR score at 1 minute and at 5 minutes.
4. Perinatal morbidity and mortality.
5. Side effects to the mother and child.

Statistical Analysis

Data will be collected compiled and analyzed. The different statistical tests as percentage proportions and chi square will be applied.

Observations Tables

Table 1: General characteristic of patients

Age	Study		Control	
	(n=70)	(100%)	(n=70)	(100%)
Below20yrs	33	4.3	6	8.6
21to25yrs	51	72.9	49	70
26to30yrs	16	22.9	14	20
31to35yrs	0	0	1	1.4
Gestational age in days				
259 to266	7	10	9	13
267 to273	44	62.9	22	31.9
274 to280	19	27.1	22	31.9
281 to287	0	0	16	23.2
Mode of onset of labour				
Spontaneous	49	70	45	64.3
Induced	21	30	25	35.7
Mode of Delivery				
Normal vaginal delivery	67	95.7	61	87.1
LSCS	3	4.3	9	12.9
Pain relief score				
No pain relief	0	0	32	45.7
Mild relief	13	18.6	34	48.6
Moderate relief	40	57.1	04	5.7
Excellent relief	17	24.3	00	00

Table 2: Inability to Cooperate at 2nd Stage of Labour

Study		Control	
No.	**Percentage**	**No.**	**Percentage**
67	95.7	66	94.3
3	4.3	04	5.7
Meconium Stained Liquor			
68	97.1	65	92.9
2	2.9	5	7.1

Table 3: Clinical Characteristic Features

Maternal Complication	Study		Control	
	(N=70)	*(100%)*	*(N=70)*	*(100%)*
No	53	75.17	47	67.1
Nausea/Vomiting	09	12.9	14	20.0
Tachycardia	02	2.9	02	2.9
Drowsiness	00	0.0	02	2.9
Dryness of mouth	04	5.7	05	7.1
Hypersalivation	02	2.9	00	00
Maternal Satisfaction Score				
Unsatisfied	0	07	18	25.7
Just satisfied	16	8.6	49	70
Good satisfaction	46	65.7	03	4.3
Excellent satisfaction	18	25.7	00	0
Birth Weight Of the babies				
Below2 Kg	2	2.9	2	2.9
2.1to2.5Kg	25	35.7	27	38.6

2.6to3Kg	31	44.3	38	54.3
3.1to3.5Kg	12	17.1	3	4.3

Table 4: NICU Admission

Study		Control	
No.	**Percentage**	**No.**	**Percentage**
69	98.6	64	91.4
1	1.4	6	8.6

Table 5: APGAR Score

APGAR	Study		Control	
	Mean(ml)	**SD**	**Mean(ml)**	**SD**
1min	7.81	0.82	7.31	1.21
5min	8.66	0.59	8.21	1.15

Results and Discussion

67.3% of the women are in the age group of 21-25 years. Mean age of the women in both the groups are comparable. Mean age of the women inthe study group was 22.91 ± 2.35 years as compared to 23 years in Meena et al [6] (2006) study. The mean gestational age of present study group is 272.73±7.316 days. This is similar to that observed in Meena et al [6] (272.3 days) and shahida Mir et al [7] studies (271.6 days). (Table -1)

In present study, the study group had reduced duration of Active phase of I stage of labour (116.95±45.67) min, when compared with the control group (236.44 ± 90.33 min). Using student "t" test this difference was found to be significant statistically. [P value < 0.005] (Table -2)

In Meena et al's [6] (2006) study, the mean duration of active phase of 1st stage of labour is 165 min. When compared with the Daftary et al study [8] (240 min) we have almost half the duration. Duration of the active phase of first stage of labour is much lesser when compared with Meena et al [6] (2006) and veronica et al [9] (2008) and Daftary et al [8] (2009) studies.

Duration of second stage of labour in the study and the control group is 21.23 ± 9.29 min and 23.57 ± 12.404 min respectively. It is not significant statistically when analysed withstudent "t" test. (Table -2)

In Daftary et al8 and veronica et al [9] studies, the duration of second stage of labour were 26min and 25 min respectively. This value is comparable to that observed in my study. In Meena et al [6] study, the duration of second stage is 17.46 minutes, this value is lower than that observed in my study. (Table -2)

The mean duration of third stage of labour in my study is 4.36 min in the study group and 4.83 min in the control group. This difference in statistically insignificant on using student "t" test.(> 0.005) This is similar to that observed in Meena et al6 (4.94min) and Shahida Mir et al [7] (4.8min) studies. In Daftary et al [8] (2009) study, the duration of 3rd stage is still lower 3.5 min.

In present study duration of all three stages of labour were shortened when compared with the control. But the difference is statistically significant in first stage of labour when studied with student "t" test. There is no statistically significant difference in the duration of II and third stage of labour. Meena et al [6] study showed reduction is the duration of all 3 stages of labour.

Total duration of labour is 144.92 ± 55.799 min in the study group and 263.59 ± 99.928 min in the control group. This difference is statistically significant on analysing with student "t" test.

The study group had faster rate of cervical dilatation (3.71cm per hour) compared to the control group (1.53cm per hour). This difference was statistically significant when using student "t" test (p value < 0.005).

In Daftary et al [24] (2009) study, the mean rate of cervical dilatation was 2.5cm per hour while veronica et al9 (2008) reported as 2.3cm per hour. The rate of cervical dilatation observed in my study is faster when compared with Daftary et al [8] (2009) and Veronica et al [9] (2008) studies.

114 women in the study group and 125 women in the control group had spontaneous onset of labour. Both groups were comparable regardingthe mode of onset of labour. Pain relief score of 2 or more is seen in 66% of the patients in the study group. Excellent pain relief is observed in 26% of the patients in the study group and none in the control group. When using chi-square test, there was statistically significant difference among the two groups. (Table -1)

Meena jyothi et al [46] (2008) observed excellent pain relief in 54% of the study group, moderate pain relief in 32% and mild pain relief in 14%. Shirish N Daftary et al [8] (2009) observed excellent pain relief in labour in 26% and Prasertsawat et al [10] (1986) in 24%, which is consistent with present study.

91.3% of the women in the study group and 83% of the women in the control group progressed smoothly

and had vaginal delivery without any interventions. 4% of the study group and 10% of the control group had caesarean section. On analysing the difference among them using chi-square test, they were not statistically significant. (Table - 1)

Present results are similar to that of Veronica et al's 49 (2008) study. In Daftary et al [8] (2009) study only 65.5% of the women had vaginal delivery, while in Meena jyothi et al [6] (2008) 98% of the women had vaginal delivery. When compared with Daftary et al [8] (2009) study, present study had decreased assisted delivery (4.7%). But in Meena at al study [6] (2008) 2% had assisted delivery with no caesarean section. (Table -1) 4% of our parturient had caesarean section which was consistent with the veronica et al [9] (2008) study.

Mode of delivery

Table 6:

Mode of delivery	Study	Daftary [8]	Meena [6]	Veronica [9]
Vaginal delivery	91.3%	65.5%	98%	86.66%
Forceps	4.7%	7%	2%	6.67%
Ventouse	0%	15.5%	0%	0%
LSCS	4%	12%	0%	6.67%

8 women in the study group and 10 women in the control group had meconium-stained liquor. This was not statistically significant.

The commonest complication observed in both the study group and the control group was nausea and vomiting. Other complications noted in the study group were tachycardia, dryness of mouth. No patients in either group had serious adverse effects. (Table - 3)

Incidence of nausea and vomiting is similar to that in Meena Jyothi et al [6] (2008) and Shahida M and Razia A7 (2011) studies.

Present women in the study group (103.8 ml) had lesser blood loss compared to their controls (139.94ml). Using student "t" test, the difference was found to be statistically significant. In Meena et al study, the mean blood loss was 110ml, that was consistent with my study. (Table - 3)

Daftary et al observed blood loss of only 60ml. In Veronica et al study, he observed blood loss of 75ml.

There was no neonatal mortality in either group. Neonatal outcomes were comparable in both the groups. There was no statistically significant difference between the study and the control group. (Table - 4)

All the babies had Apgar score of 7-9 at one and five minutes. 2babies in the control group had Apgar score of six at one minute and on resuscitation, they had Apgar score of 8-9 at 5 minutes. Mean Apgar of the babies at one and five minutes in both the groups were comparable. (Table 5)

In their study, Sameer Dixit et al 11 (2005) reported Apgar score of 8-10 in all neonates at one and five minutes. My study is consistent with his study.

The mean birth weight of the babies in the study group and in the control group was

2.70 ± 0.32 kgs and 2.69 ± 0.31 kgs respectively. Using student "t" test, there was nostatistically significant difference between them. (Table -3)

Shahida M and Rafia A [7] (2011) reported the mean birth weight of the neonates 2.85kgs in the study group and 2.84kgs in the control group

.**Table 7: Comparison of Various Studies on Programmed Labour**

Outcome	My Study	Daftary [8]	Shahida [7]	Veronica [9]	MeenaJothi [6]
Vaginal Delivery	91.3%	65.5%	93%	86%	98%
Duration of Labour					
1st stage	1.95Hrs	3.5Hrs	2.98Hrs	4Hrs	2.45Hrs
2nd stage	21.23Mins	26Mins	29.6Mins	25Mins	17.46Mins
3rd stage	4.36Mins	3.5Mins	4.5Mins	3 to 5Mins	4.94 Mins
Excellent Pain Relief	26%	24%	37%	70%	54%
Rate of Cervical Dilation	3.71cm/Hr	2.5cm/Hr	-	2.3cm/Hr	-
Blood loss	103 ml	60ml	-	75ml	110ml

Conclusion

Programmed labour is an easier, safer means for ensuring less painful delivery. It reduces the duration of the labour without serious maternal and neonatal side effects Pain relief is effective with minimal maternal side effects due to the drugs used. Labour and childbirth are cherished by the mother and her family. It can be adapted safely in all Maternity hospitals in low-risk gravid woman.

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