International Journal of Science and Research (IJSR)
ISSN: 2319-7064
Impact Factor (2018): 7.426

Evaluation of Maternal and Neonatal Outcome in Conventional Labour Vs Programmed Labour in Low Risk Woman

S. S. Gayathri[1], M. Ajeetha Banu[2]

[1]Senior Assistant Professor, Department of O & G, Madurai Medical College, Madurai, India

[2]Assistant Professor, Department of O & G, Madurai Medical College, Madurai, India

Abstract: ***Introduction: Objective of the study is to compare the effects of programmed labour protocol with the conventional labour protocol with regards to adequacy of pain relief, duration of labour, blood loss, maternal and neonatal adverse effects. Material and methods: This was a prospective, monocentric clinical trial. Total of 300 women who attended Government Rajai Hospital, Madurai, were included in the study. All were low risk gravid women. After they fit into the inclusion criteria, protocol of programmed labour was implemented on them as developed by Daftary SN etal and the labour outcome was studied. Partogram was plotted for all patients recommended by WHO. Results: In the study group 4.7% had outlet forceps delivery and 4% had caesarean section. Of the study group 26% had excellent pain relief as compared to 0% in control group. The mean rate of cervical dilation was 3.71cm/Hr in the study group and 1.53cm/Hr in the control group. The mean duration of active phase 1st stage, 2nd stage, 3rd stage of labour were 116.95mins, 21.23mins, 4.36mins respectively in the study group as compared to this 236.44mins, 23.57mins, 4.83mins respectively in the control group. Maternal and fetal outcome were comparable in both groups. Conclusion: Programmed labour protocol provides adequate labour analgesia, augments the process of labour thereby shortens the duration of labour reduces blood loss during labour without adverse maternal and fetal effects.***

Keywords: Programmed labour; Labour analgesia; Partogram

1. Introduction

Pain relief during labour is need of the hour. The International Association for the study of pain (IASP) declared 2007-2008 as the "Global year against pain in women – Real Women, Real Pain'. Although epidural analgesia is excellent at pain relief, it demands technical expertise.

2. Aim

Objective of the study is to compare the effects of programmed labour protocol with the conventional labour protocol with regards to adequacy of pain relief, duration of labour, blood loss, maternal and neonatal adverse effect

To alleviate the women of her sufferings, various labour analgesics have been tried.

LABOUR ANALGESIA

An ideal analgesic technique should therefore take into consideration maternal wishes and preferences, available expertise, support staff and facilities. Practices in various countries may vary from culture to culture. The technique used should be cheap, easy to administer, produce good and reliable relief from pain, but not impair consciousness or cooperation. It should be nontoxic to mother and fetus and should not produce cardio respiratory depression in the fetus. The technique must have no tocolytic action and should not delay labour.

Programmed Labour[24]

Definition

It is an indigenously developed protocol by Shirish Daftary and his colleagues in 2003 for labour management. Dual objectives are: Providing optimum pain relief. Optimizing obstetric outcome to reach the goal of safe motherhood. Programmed labour incorporates the 3 principles of active management of labour advantageously. Pain relief is utmost importance in programmed labour. Concept of programmed labour rests on 3 pillars (Daftaryetal 1993), Ensuring adequate effective uterine contractions, Active management of labour, Providing pain relief, Use of analgesics and antispasmodics, Close monitoring of labour events. Using partograph **Benefits of pain relief** , As the fear and anxiety in the mother is relieved, uteroplacental circulation is maintained thereby baby is protected against hypoxia. Maternal exhaustion is prevented by providing adequate rest and sleep. As the cervical dilatation is facilitated, duration of the labour is shortened. Less operative deliveries and cervical tears. As the duration of labour is shortened, intrapartum infections are reduced. **Drugs Used In The Programmed Labour Protocol**, Injection oxytocin 2.5 U in RL (augmentation of labour).10 U IM for active management of third stage of labour, Injectionpentazociine 6mg in dilution slow IV, Injectiontramadol 1mg/kg body weight IM, Injection Diazepam 2mg in dilution slow IV, Injection Drotaverine hydrochloride 40mg IM, every 2 hours (maximum 120mg). Injection Ketamine 0.25 mg/kg body weight in dilution slow IV

3. Materials and Methods

Subjects: This study was conducted in the Department of Obstetrics and Gynaecology, Madurai Medical College FromDecember 2014-December 2015. 300 parturient women in their active phase of labour were included in the study.

Inclusion criteria: Age: 18-35 yeas, Primigravida, Gestational age: 37-41 weeks, Singleton gestation, Vertex presentation, Clear liquor, NST Reactive

Exclusion criteria: Elderly, primi, Cephalopelvic disproportion, Medical complications in pregnancy, Hydramnios / IUGR, Multiple pregnancy, Antepartum Hemorrhage, Previous uterine surgeries

Methods of study
Three hundred low risk parturient women satisfying the above criteria were included in the study. They were alternately allocated into 2 groups.

Group 1: 150 women received programmed labour protocol

4. Study Group

Minutes lasting 35-40 seconds) 1 ampoule of pentazocine 30mg in 1ml and 1 ampoule of diazepam 10mg in 2ml is diluted with 7ml distilled water to get diluents of 10ml. 2ml of the diluents containing 6mg injection pentazocine and 2mg of injection diazepam is given slowly intravenously. Injection Tramadol 1mg/kg (body) is given intramuscularly. Injection drotaverine hydrochloride 40mg is given intravenously. 2nd hourly drotaverine is repeated till full cervical dilatation to a maximum of 3 doses. Drotaverine helps cervical dilatation and also pain relief. Antispasmodic and analgesics are synergistic. Injection Tramadol have longer duration of action and it takes care of mild to moderate pain. On 7-8 cm dilatation of cervix, injection Ketamine 0.25 mg/kg body weight diluted with distilled water is given slowly intravenously over 10 minutes. If needed injection ketamine is repeated after 30 minutes in the half of the above dose. 10 ml of 1% lignocaine is infiltrated locally before episiotomy if required. Injection oxytocin 10U IM is given within one minute of delivery of the baby, as per active management of III stage of labour. Blood loss is estimated by PPH drape/mop count. Pain relief score was asked by rupees scale method, No pain relief: score zero, Mild pain relief: score one, Moderate pain relief: score two, Excellent pain relief: score three.

Group 2: 150 women were observed expectantly **Control group:**

All women were started an intravenous line of Ringer lactate. If uterine contractions are inadequate, injection oxytocin 2.5U in 500ml of Ringer lactate is started at the rate of 12 drops per minute and titrated to achieve effective uterine contractions. On delivery of the baby, 10 units of oxytocin injection is given intramuscularly within one minute as per Active management of III stage of labour. Blood loss is estimated.

The time when they entered into the active phase was marked as zero hour in the partogram. Partogram was plotted and progress of labour monitored in all the patients. Only liquid or semisolid diets were allowed to reduce nausea or vomiting.
Parameters studied are, Mean duration of all 3 stages of labour ,Active phase of I stage, IIstage, III stage ,Mode of delivery :Pain relief score Blood loss.

Maternal outcome : Ability to cooperate at 2nd stage**,**Ability to feed her baby at 30 minutes**,** Maternal adverse effects**,** Maternal satisfaction score**, Neonataloutcome:** Birth weight APGAR score at 1minute and 5 minute. NICU admission.

5. Results of the Study

Table 1: Age Distribution

Age	Study		Control	
	(n=150)	*(100%)*	*(n=150)*	*(100%)*
Below 20yrs	26	17.3%	23	15.3%
21 to 25yrs	101	67.3%	100	66.7%
26 to 30yrs	23	15.3%	23	15.3%
31 to 35yrs	0	.0%	4	2.7%

Table 2: Gestational Age

Gestational Age In Days	Study		Control	
	(n=150)	*(100%)*	*(n=150)*	*(100%)*
259 to 266	40	26.7%	39	26.0%
267 to 273	46	30.7%	47	31.3%
274 to 280	43	28.7%	38	25.3%
281 to 287	21	14.0%	26	17.3%

Mean Gestational age of the patients in the study group and control group were 272.73 and 272.93 days respectively.The mean age of the patients in the study group and the control group is 22.91 years and 23.18 years respectively. In the study group the age of patients ranged from 18-30 years and in the control group from 18-34years. Majority of the women in the study and the control group were 21-25 years.

Table 3: Mode of Onset of Labour

		Study	Control	
Spontaneous	114	76.0%	125	83.3%
Induced	36	24.0%	25	16.7%

83 .3% of the control group and 76.0% of the study group had spontaneous onset of Labour.

Table 4: Rate of Cervical Dilatation

Rate of cervical Dilatation	Study	Control
cm/hr	3.71 ±1.64	1.53±0.64

The mean rate of cervical dilatation in the study and the control group were 3.71cm/hr and 1.53 cm/hr respectively.

Table 5: Duration of 3 Stages of Labour

Duration (min)	Study		control	
	mean	SD	mean	SD
Active phase I stage	116.95	45.679	236.44	90.933
II stage	21.23	9.292	23.57	12.404
III stage	4.36	.979	4.83	1.589

The mean duration of active phase of I stage of labour in the study and the control group were 116.95 min (1.95hr) and

236.44 min (3.94 hr) respectively. The mean duration of II stage of labour in the study group and control group were 21.23 & 23.57 min respectively. Mean duration of the III stage of labour in the study group and the control group were 4.36min and 4.83min respectively.

Table 6: Total Duration of Labour

	Study	Control
Mean (min)	144.92 ± 55.799	263.59 ± 99.928

Total duration of labour in the study and the control group were 144.92 min (2.415 hr) and 263.59 min (4.39hr) respectively.

Table 7: Mode of Delivery

MOD	Study		Control	
	(n=150)	*(100%)*	*(n=150)*	*(100%)*
Normal delivery	137	91.3%	126	84.0%
Outlet forceps	7	4.7%	10	6.7%
LSCS	6	4.0%	14	9.3%

91.3% of the women in the study group and 84% of the control group had normal vaginal delivery 4.7% of the study group and 6.7% of the control group have outlet forceps delivery. 4% of the study group and 9.3% of the study control group have undergone caesarean section.

Table 8: Pain Relief Score

Pain Relief score	Study		Control	
	(n=150)	*(100%)*	*(n=150)*	*(100%)*
No pain relief	0	0%	50	33.3%
Mild relief	21	14.0%	90	60%
Moderate relief	90	60.0%	10	6.66%
Excellent relief	39	26.0%	0	0%

All the parturient in the study group had pain relief, out of which 26% had excellent pain relief and 60% had moderate pain relief. In the control group 33.3% of the patients had no pain relief, 60% of them had mild pain relief.

Table 9: Inability to Cooperate at 2nd Stage of Labour

Study	Control
5(3.3%)	4(2.7%)

Five women in the study group were not able to cooperate in the second stage of labour. While in the control group four women did not cooperate because of maternal exhaustion.

Table 10: Meconium Stained Liquor

Study		Control	
8	5.3%	10	6.6%

5.3 percentage of the study group and 6.6 percentage of the control group had meconium Stained Liquor.

Table 12: Maternal Complication

Maternal complication	Study		Control	
	(n=150)	*(100%)*	*(n=150)*	*(100%)*
No	111	74.0%	138	92%
Nausea/Vomiting	15	10.0%	12	8.0%
Tachycardia	9	6.0%	0	0%
Drowsiness	11	7.3%	0	0%
Dryness of mouth	7	4.7%	0	0%
Hyper salivation	3	2%	0	0%

Most common complication in the both groups was nausea and vomiting. No patient in either group had serious complication

Table 13: Maternal Satisfaction Score

Maternal satisfaction	Study		Control	
	(n=150)	*(100%)*	*(n=150)*	*(100%)*
Unsatisfied	0	.0%	111	74.0%
Just satisfied	20	13.3%	37	24.7%
Good satisfaction	92	61.3%	2	1.3%
Excellent satisfaction	38	25.3%	0	.0%

With the programmed labour protocol 100% of the women were satisfied. Majority of the women (61.3%) had good satisfaction with 25.3% of them had excellent satisfaction, nobody were unsatisfied. while in the control group 74% were unsatisfied.

Table 14: Birth Weight of the Babies

BW	Study		Control	
	(n=150)	*(100%)*	*(n=150)*	*(100%)*
Below 2 Kg	7	4.7%	2	1.3%
2.1 to 2.5 Kg	52	34.7%	63	42.0%
2.6 to 3 Kg	74	49.3%	64	42.7%
3.1 to 3.5 Kg	17	11.3%	21	14.0%

Majority of the babies in the study and control group are in the range of 2 to 3 kg .The mean birth weight of the babies in the study group is 2.70±0.32 kg and in the control group 2.69±0.31 kg.

Table 15: NICU Admission

Study	Control
13	15

13 Babies in the study group and 15 babies in the control group are admitted in NICU. All babies recovered well and discharged within 24 to 48 hours.

Table 16: APGAR Score

APGAR	Study		Control	
	Mean(ml)	*SD*	*Mean(ml)*	*SD*
1 min	7.97	0.7	8.06	0.69
5 min	8.75	0.48	8.82	0.46

Mean apgar of the babies at 1 min and 5 min were 8 and 9 respectively

6. 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 in the study group was 22.91 ± 2.35 years as compared to 23 years in Meena et al[47] (2006) study.

The mean gestational age of our study group is 272.73±7.316 days. This is similar to that observed in Meena et al[47] (272.3 days) and shahida Mir et al[48] studies (271.6 days).

In my 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]

In Meena et al's[47] (2006) study, the mean duration of active phase of 1st stage of labour is 165 min. When compared with the Daftary et al study[24] (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[47] (2006) and veronica et al[49] (2008) and Daftary et al[24] (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 with student "t" test.

In Daftary et al[24 and] veronica et al [49]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 [47]study, the duration of second stage is 17.46minutes, this value is lower than that observed in my study.

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 al[47] (4.94min) and Shahida Mir et al[48] (4.8min) studies. In Daftary et al[24] (2009) study, the duration of 3rd stage is still lower 3.5 min.

In our 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[47] 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 al[49] (2008) reported as 2.3cm per hour. The rate of cervical dilatation observed in my study is faster when compared with Daftary et al[24] (2009) and Veronica et al[49] (2008) studies.,114 women in the study group and 125 women in the control group had spontaneous onset of labour. Both groups were comparable regarding the 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. 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[24] (2009) observed excellent pain relief in labour in 26% and Prasertsawat et al[50] (1986) in 24%, which is consistent with our 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. Our results are similar to that of Veronica et al's[49] (2008) study. In Daftary et al [24] (2009) study only 65.5% of the women had vaginal delivery, while in Meena jyothi et al[47] (2008) 98% of the women had vaginal delivery. When compared with Daftary et al[24] (2009) study, our study had decreased assisted delivery (4.7%). But in Meena at al study[47] (2008) 2% had assisted delivery with no caesarean section, 4% of our parturient had caesarean section which was consistent with the veronica et al[49] (2008) study.

Mode of delivery

Mode of delivery	Study	Daftary[24]	Meena[47]	Veronica[49]
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.

Incidence of nausea and vomiting is similar to that in Meena jyothi et al (2008) and shahida M and Razia A[48] (2011) studies.Our 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.

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.

All the babies had Apgar score of 7-9 at one and five minutes. 2 babies 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.

In their study, Sameer Dixit et al [51] (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 no statistically significant difference between them.

Shahida M and Rafia A [48] (2011) reported the mean birth weight of the neonates 2.85kgs in the study group and 2.84kgs in the control group.

Comparison of Various Studies on Programmed Labour

Outcome	My Study	Daftary[24]	Shahida[48]	Veronica[49]	Meena Jothi [47]
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	21.23 Mins	26Mins	29.6Mins	25Mins	17.46 Mins
3rd stage	4.36 Mins	3.5Mins	4.5Mins	3 to 5 Mins	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

7. Summary

Study design

Three hundred uncomplicated nulliparous women were included in the study when they were in active phase and were alternately allocated to two groups. One group (study) received programmed labour protocol while the other group (control) were observed expectantly. They were monitored for adequacy of labour analgesia, progress and duration of labour, maternal and fetal outcome.

Statistical methods

Value of significance was found using cross tabulations of the study with reference to pain relief score, rate of cervical dilatation, duration of all three stages of labour, maternal and neonatal outcome.

- On comparing the age, gestational age, mode of onset of labour, there was no statistically significant difference between the study and the control group.
- Regarding pain relief, in the study group 86%had pain relief score of two and above, while in the control group 6.66% had pain relief score of two. This was statistically significant.
- The mean rate of cervical dilatation was 3.71cm per hour in the study group. It was significantly faster than that in the control group of 1.53 cm per hour.
- Total duration of labour in the control group (263.59 minutes or 4.39 hour) is significantly higher that observed in the study group (144.92 minutes or 2.42 hour).
- 9.3% of the women in the control group had caesarean section as compared to 4% in the study group. This is not statistically significant.
- In the study group blood loss was 103.8 ±36.55 ml as against 139.94 ±76.33 ml, the difference was found to be statistically significant.
- There were no serious maternal or neonatal adverse effects in either group.

8. Conclusion

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

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Author Profile

Dr. S.S. Gayathri M.D (OG), DNB(OG) is Senior Assistant Professor Of O&G, Madurai Medical College, Madurai

Corresponding Author: Dr. M. Ajeetha Banu, M.D (OG) is Assistant Professor Of O&G, Madurai Medical College, Madurai