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Feto Maternal out Come in Programmed Labour Protocol

Ravi Karad¹, Vijaya Harsoor², Amrutha A V³

Vijay Nagara Institute of Medical Science Ballari, India

Abstract: Background: Labour pain is among the maximum excruciating pain experienced by all women. Labour pain impacts maternal psychology and course of labour causing apprehension, tension, and strain. Pain relief throughout labour is predicted to lessen maternal strain and improve maternal and perinatal outcome. Many Nonpharmacological & Pharmacological methods of pain relief available. In this study we are comparing efficacy & safety of Paracetamol & Tramadol as labour analgesics. Objective: To analyse the outcome of Programmed labour protocol vs expectant management of labour with respect to 1) Mean rate of cervical dilatation. 2) Mean duration of first, second, third stage of labour. 3) Pain relief in labour. 4) Mode of Delivery. 5) APGAR scores at Imin and 5min. Methods: All women admitted in the labour room, meeting the inclusion criteria and willing to participate in study are categorized into group A and group B. Programmed labor group(A) and expectant group. (B). The study group A includes primigravida at term in active phase. Admitted in labor who will receive Programmed labor protocol. And group B will be managed expectantly. After obtaining informed consent all women willing to participate will be examined according to protocol. <u>Results</u>: In our study both the groups were comparable in relation to age, gestational weeks and cervical dilatation. Most common mode of delivery was vaginal in both the groups. Duration of first stage of labour and second stage of labour is significantly reduced compared to control group. Pain relief scoring in study group moderate to complete pain relief is 85.7%. Mean cervical dilatation among the study group was 2 cm/hour which is higher compared to the control group (1 cm/hour). In study group- 11.5% underwent LSCS which is lesser compared to the control group (15.5%). All the babies had Apgar score of 7-9 at one and five minutes. 4babies 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. <u>Conclusion</u>: Programmed labor 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.

Keywords: Labour Analgesia, Primigravida, Pentazocine, Tramadol, Diazepam

1. Introduction

Pregnancy and motherhood are a major milestone in the life of a female which changes her position in the family and the society giving more self confidence and independence¹

"The delivery of the infant with conscious and pain-free mother is one of the most exciting and rewarding moments in medicine"- Moir².

The International Association for the Study of Pain (IASP) declared 2007-2008 as the "Global Year against Pain in Women - Real Women, Real Pain." The focus was to study both acute pain and chronic pain in women. Labour pain was found to be a good study model for treating acute pain³. The experience of labour is complex and subjective. Several factors affect a woman's perception of labour making each experience unique. However, as a consistent finding, labour pain is ranked high on the pain rating scale when compared to other painful life experiences⁴.

Programmed labour is indigenously developed for the labour management, developed with the objective of providing optimum pain relief and to hasten the labour process for better obstetric and neonatal outcome⁵

2. Materials and Methods

This was a prospective randomised study conducted in the department of obstetrics and gynecology vijaynagara institute of medical sciences Ballari. In the month of January

2018 to 31st December 2019.All the primigravida with single tone cephalic in the age group of 18-35 years admitted to the labour room in the active phase of labour with no medical comorbiditis are included in the study. Cephalopelvic disproportion, Malpresentations, Ante partum Haemorrhage, Evidence of I UGR, oligo or polyhydramnios, Multiple pregnancy, Pregnancy complicated by any medical illness are excluded from the study.

All women admitted in the labour room, meeting the inclusion criteria and willing to participate in study are categorized into group A and group B. Programmed labour group (A) and expectant group (B).

The study group A includes primigravida at term in active phase. Admitted in labour who will receive Programmed labor protocol. And group B will be managed expectantly.

The patient is taken up for programmed labour only after she enters active phase of labour. From this point onwards all events in labour are documented on a partogram and labour is monitored.

In study group amniotomy should be performed at 3-4 cms dilatation to ensure presence of clear liquor and satisfactory fetal heart rate pattern. At 3-4 cm of cervical dilatation, administer a small dose of 2mg Diazepam + 6mg Pentazocine diluted in 10 ml of saline, slow I/V as bolus to initiate pain relief.

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Then administer Injection Tramadol 50 mg IM in patients BMI<25, If patient's BMI >25the dose is to be increased to 1.0 mg/kg maternal body weight.

If the frequency of uterine contractions is not adequate, labour is augmented with Oxytocin infusion 5 units in 500ml of I/V fluid in escalating doses till at least 3 contractions in 10 minutes lasting 35-45 seconds is achieved.

To prevent maternal exhaustion and ketosis: IV infusion line using Ringer Lactate solution.

Along with Tramadol Injection Drotaverine 40 mg is administered I/V.

Injection Drotaverine can be repeated every 2 hours, if required, for a maximum of three doses.

The combined drug effect provides excellent pain relief and cervical dilatation. During the Third stage is managed by active management of labour Partogram is to be plotted for the progress of labour. Pain Relief Score in these women is to be noted postpartum after they were fully awake. Level of analgesia assessed using following scale.

0-No pain relief, 1-mild pain relief, 2-moderate pain relief, 3- excellent pain relief

All the parameters are compared with Primigravida with no risk factors admitted during the study period taken as controls. Appropriate statistical analysis is to be done.

Descriptive statistics were used to describe the study variables of the subjects. To compare the categorical qualitative data variables among the two study groups, Chi-square test and Fisher exact test was used and to compare the continuous quantitative data variables 't' test was used. The P-values were corrected by the Bonferroni method and a P-value <0.05 was regarded as statistically significant.

3. Results

- All pregnant women admitted in the labour room, meeting the inclusion criteria and willing to participate in study are categorized into group A and group B. Programmed labour group A (84) and expectant group B (84).mean age of distribution among the case and controls is 23.43±2.77years. mean gestational age is 38.32±1.38 weeks among the cases and 38.13±1.10 weeks in controls. Within 4 hours 92% of the study group completed their first stage .all the cases in control group took more than 5 hours to complete first stage of labour. P Value is 0.001 this is statistically significant. In study group 88.1% of the cases completed their 2nd stage with in 30min. 56% of control group completed their 2nd stage in 30-60 min. this is statistically significant (p=0.001).
- The duration of 3rd stage of delivery lasting for 6 to 10 min in both the groups. In our study mean cervical dilatation among the cases is 2cm/hour. Compared to control mean cervical dilatation is 1.0±0.4cm/hour with p value of 0.001 which is significant.

- Mean duration of labour among cases is 3.28±0.49hours. Compared to control 6.77±0.58hourswhich is statistically significant (p value is 0.002)
- In study group 53.6% of the cases had moderate pain relief, 32.1% of the cases in study group had complete pain relief,4.8% of the cases had no pain relief p value is 0.001 which is statistically significant. In our study 88.1% of the cases had vaginal delivery.
- In control group 84.5% of the cases had vaginal delivery, 11.9% of the study group underwent LSCS, 15.5% of the control group underwent LSCS .Comparison between the mode of delivery, Fishers exact test was done and the two tailed p value is 0.462 and statistically not significant. In our study 50% of the cases underwent LSCS due to fetal distress. In control group 69.2% underwent LSCS due to fetal distress. P value is 0.175 which is statistically not significant.
- In the study group, APGAR scores of all the neonates were 7-10. without being much affected by the analgesics used, The APGAR scores of 4 neonates in the control group was 4-7 who were taken up for emergency LSCS for fetal distress. The neonates required NICU admission for 1day for observation after which they showed good prognosis. (P = 0.005)

Table 1						
Comparison	of age wise	e distribu	ution among	g the two	groups	
Age group Cases Controls					P value	
	Frequency	Percent	Frequency	Percent		
21 - 25 yrs	67	79.8	73	86.9		
26 - 30 yrs	14	16.7	8	9.5		
31 - 35 yrs	3	3.6	3	3.5		
Total	84	100.0	84	100.0		
Mean \pm SD	23.43 ±	2.77	23.13 ±	2.81	0.497	

Age wise distribution of cases and control

Comparison	of gestational	age among	the two groups
	Ta	able 2	

Comparison of gestational age among the two groups						
Costation	Case	es	Contr	D volue		
Gestation	Frequency	Percent	Frequency	Percent	r value	
37 weeks	23	27.4	22	26.2		
38 weeks	38	45.2	42	50.0		
39 weeks	10	11.9	11	13.0		
40 weeks	5	6.0	4	4.7		
41 weeks	2	2.4	4	4.7		
42 weeks	6	7.1	1	1.1		
Total	84	100.0	84	100.0		
Mean + SD	38.32 +	1.38	38.13 +	1.10	0.336	

- In our study group 45.2% of the cases belongs to 38weeks
- In control group 50 % of the cases belongs to 38weeks of gestation

Duration of active stage of labour

Table 5						
Duration of labour in hours	Cases	Control	P value			
< 1	0	0				
1-2.9	2(2.4%)	0				
3-4.9	78(92.8%)	0	0.001			
>5	4(4.8%)	84(100%)				
Total	84	84				

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Duration of second stage of labour

Table 4					
Duration of II Stage	Cases	Control	P value		
<30MIN	74(88.1%)	37(44%)			
30-60MIN	10(11.9%)	47(56%)	0.001		
Total	84(100%)	84(100%)			

Duration of 3rd Stage of Labour

Table 5						
3rd stage of labour in minutes	Cases	Control	p value			
<5min	11(13.1%)	16(19.0%)				
6-10min	73(86.9%)	68(81.0%)	0.119			
Total	84(100%)	84(100%)				

Comparison of outcome variables among the two groups

Table 6					
Comparison of outco	ome variables	among the two	groups		
	Cases	Controls			
Outcome variables	(n=84)	(n=84)	P value		
	$Mean \pm SD$	Mean \pm SD			
Cervical dilatation in cm/hour	2.0 ± 0.00	1.00 ± 0.49	< 0.001		
Duration of first stage of labour in hours	3.12 ± 0.52	6.33 ± 0.55	< 0.001		
Duration of second stage in minutes	24.85 ± 7.89	31.79 ± 16.47	0.001		
Duration of third stage in minutes	6.13 ± 2.07	6.59 ± 1.63	0.119		
Pain relief score	2.13 ± 0.77	1.02 ± 0.22	< 0.001		

- In our study mean cervical dilatation among the cases is 2cm/hour.
- Compared to control mean cervical dilatation is 1.0±0.4cm/hour with p value of 0.001 which is significant.
- Mean duration of labour among cases is 3.28±0.49hours
- Compared to control 6.77±0.58hourswhich is statistically significant (p value is 0.002)

Pain relief scoring

	Table 7		
Pain score	Frequency	Percent (%)	P value
No pain	4	4.8	
Mild pain relief	8	9.5	
Moderate pain relief	45	53.6	0.001
Complete pain relief	27	32.1	
Total	84	100.0	

Mode of delivery among the cases and control groups

Table 8					
Mode of de	elivery amo	ng the ca	uses and cor	trol grou	ıps
Mode	Cases		Controls		Dyoluo
Mode	Frequency	Percent	Frequency	Percent	r value
Vaginal delivery	74	88.1	71	84.5	
LSCS	10	11.9	13	15.5	0.462
Total	84	100	84	100	

Type of instrumental delivery among the cases and control groups

Table 9						
Type of instrumental delivery among the cases and control						
	Į	groups				
Tuno	Case	s	Contr	ols	Р	
Type	Frequency	Percent	Frequency	Percent	value	
Normal vaginal delivery	58	78.4	41	57.7		
Instrumental vaginal delivery	8	10.8	14	19.3		
Forceps vaginal delivery	1	1.4	3	3.6	0.364	
Vacuum vaginal delivery	7	9.4	11	15.4		
Total	74	100.0	71	100.0		

• In our study instrumental delivery among the cases is 10.8% compared to control is 19.3%, P value is 0.364 which is statistically not significant.

Indications of LSCS among the cases and control groups

Table 10						
Indications of L	SCS among	the case	es and contr	ol group	S	
Indication	Case	es	Contr	ols	Р	
mulcation	Frequency	Percent	Frequency	Percent	value	
Fetal distress	5	50.0	9	69.2		
2nd stage arrest	3	30.0	0	0.0		
Arrest of dilatation	1	10.0	0	0.0		
NST non-reactive	1	10.0	0	0.0	0.175	
Arrest of decent	0	0.0	2	15.4		
Failure of dilatation	0	0.0	1	7.7		
DTA	0	0.0	1	7.7		
Total	10	100.0	13	100.0		

Comparison of APGAR scores after birth among the two groups

	Table 11					
	Compariso	on of AP	GAR scores	after		
	birth a	mong th	e two group	S		
APGAR	Cases		Controls		D voluo	
score	Frequency	Percent	Frequency	P value		
	APGAR s	core at 1	minute			
\geq 7 score	56	66.7	72	85.7		
< 7 score	28	33.3	12	14.2	0.005	
Total	84	100	84	100		
APGAR score at 5 minutes						
\geq 7 score	83	98.8	80	95.2		
< 7 score	1	1.2	4	4.8	1	
Total	84	100	84	100	1	

- APGAR score ≥7 in study group at 1 minute and 5 minute is 66.7% and 98.8% respectively
- APGAR score ≥7 in control group at1 minute and 5 minute 85.7% and 95.5% respectively.

4. Discussion

• In our study maximum number of cases and control are distributed in the age group of 21-25 years 79.8%.and 86.9% respectively. Mean age of distribution among the study group 23.43±2.77years.

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- This is comparable to **Meena et al**⁶ (2006) 67.3% of the women are in the age group of 21-25 years¹⁰¹. 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. In our study mean gestational age is 38.32±1.38 weeks among the cases.38.13±1.10 weeks in controls.
- In our study mean gestational age is 38.32±1.38 weeks among the cases.38.13±1.10 weeks in controls. This is similar to that observed in **Meena et al**6³ (38.3±1.2weeks) and **Shahida Mir et al** ⁷studies (38.1±1.1).
- In our study 92 % of study group completed their active stage within 5hrs &100% of control took > 5hrs .in study group active phase of labour 3.12±0.52 hours when compared with the control group 6.33±0.55hours using student t test this difference was found to be significant statistically (P value 0.001)
- In Meena et al's (2006) study, the mean duration of active phase of 1st stage of labour is 2.75 hours⁹³. When compared with the Daftary et al study⁸ (4hours) we have almost half the duration¹²³. 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 ¹⁰ (2008) and Daftary et al ⁸ (2009) studies.
- In our study 88.1% of study group completed their 2^{ND} stage within 30min &56% of control took > 30minDuration of second stage of labour in the study and the control group is 24.85 ± 7.89 min and 31.79 ± 16.47 min respectively. It is significant statistically when analyzed with student "t" test. (P value 0.001)
- In **Daftary et al** ⁸ and **veronica et al** ⁵studies, 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.
- The mean duration of third stage of labour in my study is 6.13±2.07 min in the study group and6.59±1.63 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**⁶ (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 our study duration of all three stages of labour were shortened when compared with the control. But the difference is statistically significant in first and second stage of labour when studied with student "t" test. There is no statistically significant difference in the duration of third stage of labour. **Meena et al** ⁶-study showed reduction is the duration of all 3 stages of labour.
- The study group had faster rate of cervical dilatation (2cm per hour) compared to the control group (1.0±0.4cm per hour). This difference was statistically significant when using student "t" test (p value < 0.005).
- In **Daftary et al**⁸ (2009) study, the mean rate of cervical dilatation was 2.5cm per hour while **veronica et al**¹⁰(2008) reported as 2.3cm per hour. The rate of cervical dilatation observed in my study is similar when compared with **Daftary et al**⁸ (2009) and **Veronica et al1**⁵(2008) studies.

- Pain relief score of 2 or more is seen in 53.3% of the patients in the study group. Excellent pain relief is observed in 32.1% 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 ⁶ (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 al⁷ (2009) observed excellent pain relief in labour in 26% and **Prasertsawat et al**⁹(1986) in 24%, which is consistent with our study
- 88.1% of the women in the study group and 84.5% of the women in the control group progressed smoothly and had vaginal delivery without any interventions. 11% of the study group and 15.5% of the control group had caesarean section. On analyzing the difference among them using chi-square test, they were not statistically significant.
- Our results are similar to that of Veronica et al⁵ (2008) study. In Daftary et al⁸ (2009) study only 65.5% of the women had vaginal delivery, while in Meena Jyothi et al⁶ (2008) 98% of the women had vaginal delivery.
- When compared with **Daftary et al** ⁸(2009) study, our study had higher assisted delivery (10.8%). But in **Meena at al study** ⁶(2008) 2% had assisted delivery with no caesarean section.

5. 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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