Original Research Article

Comparative study of safety and efficacy of programmed labour against natural progression of labour in primigravida women at a tertiary hospital

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Abstract

Background: Programmed labour protocol was developed with principles as ensuring adequate uterine contractions, providing optimum pain relief and close clinical monitoring of labor events. Present study was conducted to evaluate the safety and efficacy of Programmed Labour protocol in a study group as against Spontaneous progression of labour in primigravida patients. **Material and Methods:** The present study was a hospital based randomized prospective clinical study, conducted in primigravidae at term with cephalic presentation, adequate liquor and no high risk factors and in active phase of first stage of labour or Cervical dilatation ≥ 3cm, ≥ 80% effacement and intact membranes, Reactive stress Test. 200 primigravida's were alternately allocated into 2 groups. as study group (100 women received programmed labour protocol) and control Group (100 women were observed expectantly and underwent spontaneous labour). **Results:** Mean age of patients in the study group was 23.13 ± 2.46 years and 23.74 ± 2.58 years in the control group. Among patients of the study group; period of gestation was 38.87 ±1.00 weeks and 38.74 ± 1.12 weeks in the control group. We compared various labour related parameters such as duration of active phase of labour (hours), rate of cervical dilatation (cm/hr), duration of 2nd stage of labour (mins), duration of 3rdstage of labour (mins), total duration of labour (min) and average blood loss (ml) between study and control group. All above parameters were favourable in study group and difference was highly significant statistically ($p<0.001$). Perception in degree of pain relief among patients of the study and control group was found be highly significant statistically. ($p<0.001$) i.e. pain relief was significantly much higher among patients of the study group than pain relief in control group patients. The difference in degree of maternal satisfaction in the study and control group was found be statistically significant ($p<0.001$). **Conclusion:** Programmed labour is safe, effective providing labour analgesia; facilitating cervical dilation and shortening duration of labour with good maternal and fetal outcomes.
Keywords: Programmed labour, labour analgesia, duration of labour, abnormal uterine actions.

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INTRODUCTION

Programmed labour protocol was developed by Daftary *et al.*[1] at a tertiary care hospital in Mumbai, Maharashtra over a period of 9 years(1992-2001) rests on three pillars of: Ensuring adequate uterine contractions , Providing optimum pain relief and Close clinical monitoring of labor events. The burden of maternal and perinatal deaths is disproportionately higher in low- and middle income countries (LMICs) compared to high-income countries (HICs). Over 70% of maternal deaths and approximately

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50% of all stillbirths and a 25% of neonatal deaths result from complications during labour and childbirth.[2] As trained anaesthesiologists are not universally available adoption of an analgesia protocol which can be easily followed by the attending obstetrician is needed. In India majority of women are cared in small community hospital and private maternity home facilities for providing epidural analgesia continues to remain a distant dream and in modern obstetrics has no place for prolonged labor with all hazardous accompaniments, including maternal infection ,obstructed labor, uterine rupture and postpartum hemorrhage which at times may end with maternal mortality.[3,4] Today we strive to minimize the duration and inconvenience of labor both for patient as well as for obstetrician. Thus, the present study was conducted to evaluate the safety and efficacy of Programmed Labour protocol in a study group as against Spontaneous progression of labour in primigravida patients.

MATERIAL AND METHODS

The present study was a hospital based randomized prospective clinical study. The study was conducted from Jan 2019- July 2020, in Obstetrics and Gynecology department of a tertiary care hospital, Maharashtra. Institutional Ethical committee clearance was obtained prior to commencement of the study.

Inclusion Criteria:

Primigravidae at term with cephalic presentation, adequate liquor and no high risk factors and in active phase of first stage of labour or Cervical dilatation ≥ 3cm, ≥ 80% effacement and intact membranes, Reactive stress Test were taken in to the study.

Exclusion Criteria:

1. Premature rupture of membranes
2. Teenage pregnancies and Elderly Primi
3. Cephalopelvic disproportion, Malpresentations
4. Ante partum Haemorrhage, Evidence of IUGR, Oligohydramnios
5. Multiple pregnancies
6. Medical illness like Diabetes mellitus, Bronchial Asthma, Hypertension, Cardiac disease, Liver diseases.
7. Primi in latent labor

Written informed consent was taken from the patients prior to enrolment in the study. The time of entry into the active phase was marked as zero hour in the partogram. Investigations such as CBC, Blood Group, HIV, HBsAG, VDRL, Urine Routine Microscopy, Random Blood Sugar, USG abdomen and pelvis were done for all patients.

200 primigravidas were included in the study after obtaining consent applying the inclusion and exclusion criteria. They were alternately allocated into 2 groups.

1. Study group: 100 women received programmed labour protocol.
2. Control Group:100 women were observed expectantly and underwent spontaneous labour.

Partogram was plotted and progress of labour monitored in all the patients. Only liquid or semisolid diets were allowed to reduce nausea or vomiting. On delivery of the baby, 10 units of oxytocin injection was given intramuscularly. Blood loss was estimated by PPH drape/mop count.

Group 1: Study Group: (Programmed Labour) - If the uterine contraction were not adequate, oxytocin 2.5Units in Ringer lactate infusion were started at the rate of 12drops/minutes and increased every 15-30 minute to get effective uterine contractions (3-5 /10 minutes lasting 35-40 seconds). 30mg (1ml) pentazocine and 10 mg (2 ml) diazepam was diluted with 7ml distilled water to get diluents of 10ml. 2ml of the diluents containing was given slowly intravenously. Injection Tramadol 1mg/kg (body) was given intramuscularly. Injection drotaverine hydrochloride 40mg was given intravenously. 2nd hourly drotaverine was repeated till full cervical dilatation to a maximum of 3 doses. Control group: (Spontaneous Labour) If uterine contractions were inadequate, injection oxytocin 2.5U in 500ml of Ringer lactate was started at the rate of 12 drops/ minute and titrated to achieve effective uterine contractions. Parameters studied were duration of all 3 stages of labour, Mode of delivery, Pain relief score, Blood loss, Maternal satisfaction score, Neonatal outcome (Birth weight, APGAR score at 1minute and 5 minute and NICU admission).

Pain relief score was asked by visual analogue scale in the immediate postnatal period. Maternal satisfaction in the immediate postnatal period was assessed verbally on the scale of excellent satisfaction, good satisfaction, insufficient satisfaction and no satisfaction. Data entry was done using MS Excel. Statistical analysis was carried out using Statistical Package for Social Sciences (SPSS) Version 23.0. Descriptive statistics were expressed as frequencies and proportions. Continuous variables were expressed as Mean (±standard deviation). Unpaired t test was used for comparison of numerical variables between the study and control groups. Fishers exact test or chi square test was used for comparison in between categorical variable between the study and control groups s. For all the tests performed, a P value of < 0.05 was considered significant and <0.001 as highly significant.

RESULTS

The present study was conducted to assess the outcome of programmed labour (Study group 100) as compared to spontaneous labour (Control group 100) in term primigravidas. Mean age of patients in the study group was 23.13 ± 2.46 years and 23.74 ± 2.58 years in the control group. Among patients of the study group; period of gestation was 38.87 ±1.00 weeks and 38.74 ± 1.12 weeks in the control group. The difference in mean age, period of gestation of the study and control group was not found be statistically significant. (p>0.05).

Table 1: Mean age and period of gestation

Mean ± SD	Study group (N=100)	Control group (N=100)	P Value
Age (years)	23.13 ± 2.46	23.74 ± 2.58	>0.05
Period of gestation (weeks)	38.87 ±1.00	38.74 ± 1.12	>0.05

In the study group; mode of onset of labour was spontaneous in majority 74(74%) patients and labour was induced in 26 (26%) patients. In the control group; mode of onset of labour was spontaneous in 77(77%) patients and labour was induced in 23(23%) patients. The difference in mode of onset of labour among patients of the study and control group was not found be statistically significant.

Table 2: Mode of onset of labour among patients of the study and control group

Mode Of Onset Of Labour	Study Group (N=100)		Control Group (N=100)		P Value
	N	%	N	%	
Spontaneous	74	74	77	77	>0.05
Induced	26	26	23	23	

We compared various labour related parameters such as duration of active phase of labour (hours), rate of cervical dilatation (cm/hr), duration of 2nd stage of labour (mins), duration of 3rdstage of labour (mins), total duration of labour (min) and average blood loss (ml) between study and control group. All above parameters were favourable in study group and difference was highly significant statistically (p<0.001).

Table 3: Labour related parameters among patients in study and control group

Labour related parameters	Study Group (Mean ± SD)	Control Group (Mean ± SD)	P Value
Duration of active phase of labour (hours)	3.43 ± 0.51	5.12 ± 0.61	<0.001**
Rate of cervical dilatation (cm/Hr)	2.58 ± 0.54	1.43 ± 0.40	<0.001**
Duration of 2nd stage of labour (mins)	24.0 ± 5.90	38.0 ± 11.96	<0.001**
Duration of 3rdstage of labour (mins)	4.0 ± 0.94	10.5 ± 2.19	<0.001**
Total duration of labour (Min)	233.4 ± 31.4	355.3 ± 37.0	<0.001**
Average Blood Loss (ml)	62 ± 13.59	120 ± 20.70	<0.001**

Perception in degree of pain relief among patients of the study and control group was found be highly significant statistically. (p<0.001) i.e. pain relief was significantly much higher among patients of the study group than pain relief in control group patients.

Table 4: Pain relief among patients of the study and control group

Pain Relief	Study Group (N=100)		Control Group (N=100)		P Value
	N	%	N	%	
Excellent	30	30	0	0	<0.001*
Substantial	56	56	23	23	
Insufficient	14	14	58	58	
No relief	0	0	19	19	

Among patients of the study group; majority 91(91%) patients had spontaneous vaginal delivery and 9(9%)patients underwent LSCS. Among patients of the control group; majority 81(81%) patients had spontaneous vaginal delivery and 19(19%) patients underwent LSCS. Difference in mode of delivery of patients of the study and control group was not found to be statistically significant. (p>0.05).

Table 5: Mode of delivery of patients of the study and control group

Mode Of Delivery	Study Group (N=100)		Control Group (N=100)		P value
	N	%	N	%	
Vaginal Delivery	91	91	81	81	>0.05
LSCS	9	9	19	19	

Two neonates in the study group and 13 neonates in the control group were admitted in NICU for observation .All recovered well and were discharged after 24-48 hrs. In the study group; mean neonatal Apgar score at 1 minute and 5 minutes was 7.88 ± 0.56 and 8.98± 0.14 respectively. In the control group the mean neonatal Apgar score at 1 minute and 5 minutes was 7.56 ± 0.54 and 8.97± 0.17 respectively and difference was not found be statistically significant.

Table 6: Neonatal APGAR scores in the study and control group

APGAR Score	Study group (N=100)	Control group (N=100)	P Value
1 minute	7.88 ± 0.56	7.56 ± 0.54	>0.05
5 minutes	8.98 ± 0.14	8.97 ± 0.17	

The difference in degree of maternal satisfaction in the study and control group was found be statistically significant (p<0.001).

Table 7: Maternal satisfaction in the study and control group

Maternal Satisfaction	Study Group (N=100)		Control Group (N=100)		P Value
	N	%	N	%	
No Satisfaction	0	0	75	75	<0.001*
Sufficient Satisfaction	12	12	24	24	
Good Satisfaction	61	61	1	1	
Excellent Satisfaction	27	27	0	0	

DISCUSSION

The experience of labour is unique, complex and subjective. Yet, labour pain is consistently ranked high on the pain rating scale when compared to other painful life experiences even though the memory is short-lived .The pattern of labour pain differs between nulliparous and multiparous women and pain scores are higher in the nulliparous.[5] Programmed labour protocol incorporates utility of a variety of drugs in minimal sub anesthetic doses with the objective of providing pain free short labour while at the same time decreasing significantly morbidity to mother and fetus. In the present study, mean age of patients in the study group was 23.13(±2.46) and 23.74(+-2.58) years in the control group. In the study by Jyoti M *et al.*[6] mean age of women in the study group was 23 years and 22.9 years in the control group. Mean gestational age was 38.9 weeks in subjects. In the study by Puri S *et al.*[7] the mean age in study group was 27.52 ± 4.68 years. The present study was conducted in primigravidas which explains the younger mean age. Differences in mean age of patients compared to other studies may due to different inclusion criteria (inclusion of both primi and multi gravidas). Daftary SN *et al.*[1] had reported active phase duration to be 3.5 hours in cases and 5.2 hours. In the study by Sravani G *et al.*[8] maximum number of patients had mean duration of active phase for 1- 2.9 hrs. In the study by Madhavi KN *et al.*[9] duration of Active Phase of Labour was 2.45 + 0.40 hrs and 4.97 + 1.05 hrs in controls. In the study by Puri S *et al.*[7] the duration of first stage was 3.36 hrs as compared to 5.25 hours in control group which was significantly lower. Similar findings were noted in present study. In the present study; who underwent programmed labour; the mean rate of cervical dilatation was 2.58(±0.54)cm/hr and in patients of the control group it was 1.43(±0.40) cm/hr. Rate of cervical dilatation among patients of the study group was significantly more than in patients in the control group. Similar findings were noted by Daftary SN *et al.*[1], Madhavi KN *et al.*[9], Jyoti M *et al.*[6] Sravani g *et al.*[8], Gupta K. *et al.*[10] In the study by Daftary SN *et al.*[1] mean duration of 2nd stage of labor in women who underwent programmed labour was 26 minutes and in controls it was 48 minutes. In the study by Madhavi KN *et al.*[9] mean duration of Second Stage of Labour In study group was 25.52 + 8.60 min and 57.00 + 6.44 min (P <0.0001) in controls. In the study by Gupta K *et al.*[10] duration of II stage of labor was 27.4 min in cases and 34.0 min in controls (P <0.001). Similar findings were noted in present study. The partogram has been used to monitor of the progress of labour in the present study and other similar studies. The partogram is an excellent modality of documenting labour events.[11] Partogram is a simple and inexpensive tool to monitor labor in a cost-effective way. Further studies incorporating e-partographs may be helpful. In the present study; in women who underwent programmed labour; majority 91(91%) patients had a vaginal delivery and 9(9%) patients underwent LSCS. Among patients of the control group; majority 81(81%) patients had a vaginal delivery and 19(19%) patients underwent LSCS. Difference in mode of delivery of patients of the study and control group was not found to be statistically significant. Similar findings were noted by Daftary SN *et al.*[1], Madhavi KN *et al.*[9], Jyoti M *et al.*[6], Sravani g *et al.*[8], Gupta K. *et al.*[10] Pain relief plays a vital role in maternal well-being. Pain and fear retard the progress of labor. It prevents maternal hyperventilation, undue muscular efforts and exhaustion. In the present study; pain relief was significantly much higher among patients of the study group than in control group. Other similar studies have reported variable findings in context of pain relief with majority of studies documenting substantial to excellent pain relief experienced by patients: S.N. Daftary *et al.*[1](86% substantial-excellent pain relief), Sravani g *et al.*[8] (66% mild pain relief), Madhavi KN *et al.*[9] (92% moderate-excellent pain relief), Jyoti M *et al.*[6] (54 % good pain relief), Gupta K *et al.*[10]; (86% patients), Jain A *et al.*[12] (81.25% had moderate-total pain relief), Puri S *et al.*[6] (38% excellent pain relief). In the study by S.N.Daftary *et al.*[1] maximum number of neonates (84%) had APGAR

Score 7-8 at 1 min. 96% had APGAR Score 9-10 at 5 mins. In the study by Madhavi KN *et al.*[9] 2 babies born to the women in the study group had APGAR score of <7 at one and five minutes. In the study by Gupta K *et al.*[10] 94% of neonates of cases had APGAR score (8-9) at 5 minutes. APGAR score of babies in both groups were good (>7 in 94% cases and in 90% controls). Similar findings were noted in present study. Newer advances in the field of labour analgesia include introduction of newer techniques like combined spinal epidurals, low-dose epidurals facilitating ambulation, pharmacological advances like introduction of remifentanil for patient-controlled intravenous analgesia, introduction of newer local anaesthetics and adjuvants like ropivacaine, levobupivacaine, sufentanil, clonidine and neostigmine, use of inhalational agents like sevoflourane for patient-controlled inhalational analgesia using special vaporizers, have revolutionized the practice of pain management in labouring parturients.[13]

CONCLUSION

Programmed labour is safe, effective providing labour analgesia; facilitating cervical dilation and shortening duration of labour with good maternal and fetal outcomes. It helps to alleviate fear, anxiety about natural, physiological process of labor and decrease incidence of LSCS on demand in view of unbearable pain in labor and abnormal uterine actions.

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