



## Original Research Article

## Efficacy of programmed labor protocol in providing shorter, safer and a relatively pain free delivery

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## ABSTRACT

**Introduction:** Labor is a multifactorial spontaneous process, which involves myometrial contractions, cervical ripening and dilatation, expulsion of the fetus in an orderly manner with minimal aids. The thought of labor produces anguish and apprehension in women. In an attempt to overcome the same this indigenously developed protocol for parturient women was designed to make labor a pleasant experience.

**Materials and Methods:** This was a prospective randomized clinical trial. Total of 100 parturient women at term in active labor who attended labor room, GSL Medical College & Hospital, Rajahmundry were admitted between April 2013 to March 2014. The study group received programmed labor protocol and control group managed expectantly. All were low risk primigravid women. The women entered the study after taking an informed and written consent.

**Result:** Mean duration of Active phase was  $3.47 \pm .24$  hrs &  $5.61 \pm .21$  hrs in study and controls respectively. Mean cervical dilatation rate was  $3.05 \pm .58$  cm/hr in study and  $1.15 \pm .05$  cm/hr in controls. Complications seen during labor in the study group were prolonged 2<sup>nd</sup> stage in 4(8%). One had dilatation of arrest at 5cms for almost 4hrs and underwent LSCS. One had fetal distress at full dilatation and delivered by forceps. 88% had no complications.

**Conclusion:** Programmed labor group had faster cervical dilatation, shorter labors, excellent pain relief, No impact on LSCS rates, No compromise on Maternal or Neonatal safety. It reduces laboring women's anxiety, apprehension associated with labor and makes it a pleasant and memorable event. It can be used as routine protocol in low risk gravid women at least in institution.

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## 1. Introduction

Labor is a natural physiological phenomenon of childbirth. It is a multifactorial spontaneous process, which involves myometrial contractions, cervical ripening and dilatation, expulsion of the fetus in an orderly manner with minimal aids. Improper management of such a normal physiological process may lead to increased morbidity, mortality or disability of the mother and her newborn. To optimize the uterine contractions that will improve the progress of labor and subsequent outcome, the philosophy of active management of labor came into picture, the fore fathers of which were O'Driscoll<sup>1</sup> and Studd.<sup>2</sup>

Programmed labor is based on the incorporation of three principles- Active Management of Labor, synergistic application of Analgesics and Antispasmodics during active phase of labor and plotting of partogram, so as to detect early any dysfunctional labor and adopt timely measures to optimize labor.<sup>3</sup>

The thought of labor produces anguish and apprehension in women. In an attempt to overcome the same this indigenously developed protocol for parturient women was designed to make labor a pleasant experience.

In order to study its outcome in terms of duration of labor, pain relief during labor, better neonatal & maternal outcome on low risk gravid women this study was taken up.

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## 2. Objectives

To compare the duration of active phase of 1<sup>st</sup> stage, 2<sup>nd</sup> and 3<sup>rd</sup> stages of labor in study and control groups.

## 3. Materials and Methods

This was a prospective randomized clinical trial. Total of 100 parturient women at term in active labor who attended labor room, GSL Medical College & Hospital, Rajahmundry were admitted between April 2013 to March 2014. They were alternatively allocated to two groups-study and control. The study group received programmed labor protocol and control group managed expectantly. All were low risk primigravid women. After they fit into the inclusion criteria, protocol of program med labor was implemented on them as developed by Daftary SN et al<sup>4</sup> and the labor outcome was studied. Partogram was plotted for all the patients as recommended by WHO.<sup>5</sup> The women entered the study after taking an informed and written consent.

### 3.1. Inclusion criteria

Nullipara, Age between 17-35yrs, Gestational age 37-41wks, Singleton pregnancy with cephalic presentation, No clinical disproportion, No fetal distress, With intact membranes, Induced labors also included after reaching active labor

### 3.2. Exclusion criteria

Who are not willing to sign informed consent, Elderly primi, Malpresentations, Fetal distress, FGR, High risk cases like ante partum haemorrhage, Pre-eclampsia, Diabetes and other medical diseases complicating pregnancy, Polyhydramnios/oligohydramnios, Cephalopelvic disproportion

### 3.3. Data collection procedure

On admission to labor, detailed history was taken and thorough examination was done with reference to points as per proforma. History of allergy to any of the drugs used, contraindications to the drug used, detailed obstetric history, past history was taken. General examination of the patient was carried out including height, weight, temperature, pulse and blood pressure. She was examined for presence of pallor, icterus, cyanosis, clubbing, oedema, normal thyroid, breast and spine. Thorough examination of cardiovascular and respiratory system was done to rule out any kind of systemic disease.

Per abdomen examination was carried out by Leopold's maneuvers. Height of the uterus was noted, Lie, presentation and position of fetus were confirmed. Amount of liquor assessed clinically and station of head assessed in fifths.

Duration, intensity and frequency per 10 minutes of uterine contractions were noted. Fetal heart sounds were

auscultated with fetoscope/stethoscope/ Doppler for rate and rhythm.

Next, per vaginal examination was carried out with all aseptic precautions and following findings were noted:

Pelvic assessment was done and CPD excluded by Muller Munro Kerr method. The patient registered for the study in their active phase (3-4cm), which was marked as zero hour on the partogram.

The patients were allowed liquid or light semisolid diet only in view to reduce nausea, vomiting which could be there with drugs used in our protocol.

In women who had to be induced due to any condition, Tab Misoprostol 25mcg was inserted in the posterior fornix if the cervix was unfavourable. The dose was repeated every 4 hours if required. If misoprostol was instilled then oxytocin drip was deferred for at least 6 hours to avoid uterine tachysystole.

Once these women reach active phase or in other women who were already in active phase, amniotomy was performed and clear liquor ensured.

In jection Tramadol 1mg/kg IM and Inj. Drotaverine 40mg IV given at amniotomy.

When the women appreciated pain substantially and asked for pain relief in active phase Inj pentazocine 6mg in dilution was pushed for immediate pain relief.

Diazepam 2mg in dilution with 5cc or 10cc distilled water was given slow IV. Diazepam acts as an anxiolytic and potentiates the action of opioid.

Drotaverine 40mg IV stat was given for helping cervical dilatation. Dose of Drotaverine was repeated second hourly as required.

Pentazocine offers only short-term relief, so for longer duration of pain relief Inj Tramadol 1mg/kg body weight was given IM. Tramadol takes care of moderate pain. Since its half-life is 5-8 hours, 2<sup>nd</sup> dose is usually not required. Any side effects including alterations in the vitals were noted.

Besides this 2nd hourly PV examination with all aseptic precautions was done during labor and recorded on partogram. FHR monitoring was done electronically. Patient monitored continuously to detect any side effects immediately due to any drug used either to mother or the fetus.

On full dilatation, delivery was conducted with right/left mediolateral episiotomy whenever necessary after local infiltration with 10cc of 1% lignocaine. In case of maternal exhaustion/fetal distress, instrumental delivery done after fulfilling the pre-requisites. 0.25mg methergine given slow iv immediately after baby delivery if there is no contraindication. Any complications of labor like protraction & arrest disorders, PPH, neonatal hypoxia/depression noted.

Episiotomy if given was sutured with chromic catgut No 0. All the patients were vigilantly monitored for side effects and noted for 1 hour. Then pain relief score was done by

oral questionnaire by rupees scale method.

Maternal satisfaction was asked for and patient was monitored for all vital parameters and bleeding PV during the 4th stage of labor.

Fetal outcome: APGAR at 1 and 5min s were noted. Admission to NICU due to any cause in the first 24hrs were noted & followed till discharge from NICU.

All the mothers and babies were kept in the ward for 2-3 days and their condition at discharge was noted.

### 3.4. Statistical analysis

Descriptive statistics such as mean, SD and percentage was used. Comparison between groups was done by using t-test for continuous variable and chi-square for discrete variable. A p-value less than 0.05 were considered as significant.

## 4. Results

Majority of parturients are in the age group 17-20yrs (66%) in both groups. 30% in either groups are in between 21-25yrs, whereas only 4% in each group are in the age group 26-30. 19(38%) from the study group and 23(46%) from the control group are teenage pregnancies.

Out of 50 parturients in the study group, 37(74%) and 30(60%) out of 50 from the control group are in the height group 151-160cms. 8(16%) of the study group & 14(28%) of control group are in the height group 146-150cms. Total of 8 women (16%) are below 145cms, out of which 5(10%) from study group & 3(6%) are from control group.

Duration of active phase is a mean of  $3.47 \pm 0.24$  hrs in study group and  $5.61 \pm 0.21$  hrs in controls. Duration of 2nd stage is a mean of  $35.4 \pm 5.41$  mins in study group and  $62.06 \pm 6.27$  mins in control group. Duration of 3rd stage is a mean of  $7.84 \pm 0.45$  min in study &  $10.13 \pm 0.67$  min in control group. There is no case of retained placenta and PPH. All stages having significant reduction in the durations.

Rate of cervical dilatation in active phase in study group is  $3.05 \pm 0.58$  cm/hr and  $1.15 \pm 0.05$  cm/hr in controls. In the present study, all the patients had adequate rate of cervical dilatation except for 1 patient in the study group who had arrest of dilatation at 5cms for 4hrs inspite of adequate oxytocin and repeated doses of Drotaverine. Hence the patient had to be taken up for emergency LSCS.

Total duration of labor (from active phase to placental delivery) is a mean of  $4.03 \pm 0.23$  hrs and  $6.70 \pm 0.68$  hrs in study group and controls respectively, showing a significant reduction in duration ( $p=0.001$ ).

Out of 50 women in the study group, 44(88%) delivered normally, 3(6%) needed forceps delivery, none delivered by ventouse, 3(6%) underwent caesarean section. In the control group, 35(70%) had normal vaginal delivery, 9(18%) had forceps delivery, 3(6%) delivered with help of ventouse, 3(6%) had C-section.

44(88%) out of 50 parturients in the study group had no complications during labor whereas 4(8%) had prolonged 2<sup>nd</sup> stage. One had arrest of dilatation at 5cms for 4hrs and underwent LSCS. One had fetal distress at full dilatation and delivered by forceps.

Out of 50 women in the control group, 40(80%) had no complications of labor, two had prolonged 2<sup>nd</sup> stage and delivered by forceps, one had non-progress (arrest at 3cms for 8hrs) and another for 7hrs with fetal distress, both of which underwent LSCS. 6(12%) had fetal distress, out of which 1 underwent LSCS and 4 delivered by forceps, 1 by ventouse.

Pain score given by oral questionnaire by rupees scale method showed out of 50 parturients, 6(12%) had grade 1 relief, 38(76%) had grade 2 pain relief, 6(12%) had grade 3 relief and none had grade 0 i.e., no pain relief and none had complete pain relief i.e., grade 4.

Out of 50 women, 30(60%) had minimal side effects. Most common side effects found in order of frequency was nausea/vomiting(34%), tachycardia (26%), drowsiness (18%) and diarrhea(18%), pyrexia of  $100^{\circ}$  F(10%), transient hypertension(6%) and dryness of mouth(2%). Out of 50 women, 20(40%) had no side effects.

3(6%) babies in the study group had APGAR between 5-6 and 47(94%) had APGAR 7-8 at 1 minute after birth. In the control group, one baby had APGAR 2 at 1min due to distress and was admitted in NICU. Two (4%) had APGAR between 5-6. 47(94%) had APGAR between 7-8 at 1 min after birth.

At 5 minutes after birth, 3(6%) in the study group and 4(8%) in the control group had APGAR between 7-8 and 47(94%) in the study group and 46(92%) in the control group had APGAR between 9-10.

## 5. Discussion

In the present study, maximum patients are in the age group of 17-20 yrs. All patients are below age group of 30 years. In control group, 3 patients had age below 18 years (17yrs) & all had full term normal vaginal delivery without any complications.

Total of 8 women, 5 from the study group & 3 from the control group had height less than 145 cm. They were included in the study after ruling out cephalo pelvic disproportion and all had normal vaginal deliveries. The shortest women of study was about 141cms but she entered the study only after ruling out CPD by clinical examination and she delivered a healthy baby of 2.7kgs with no complications.

### 5.1. Duration of labor

In the present study, mean duration of active phase of labor was 3.47 hours (cases) and 5.61 hours (controls). It was statistically significant ( $p=0.001$ ).

**Table 1:** Basic characteristics

	Study group		Control group	
	Number	Percentage	Number	Percentage
Age				
17-20	33	66%	33	66%
21-25	15	30%	15	30%
26-30	02	04%	02	04%
Height (cms)				
<145	05	10%	03	06%
146-150	08	16%	14	28%
151-160	37	74%	30	60%
>161	00	00%	03	06%

**Table 2:** Active phase related parameters

	Study group	Control group	p-value
<b>Duration of each stage (Active phase of)</b>			
1 <sup>st</sup> stage	3.47 hrs	5.5 hrs	0.001
2 <sup>nd</sup> stage	35 mins	62 mins	0.001
3 <sup>rd</sup> stage	7 mins	10 mins	0.006
<b>Rate of cervical dilation in active phase (cm/hr)</b>	3.05 ± 0.58	1.15 ± 0.05	0.002
<b>Total duration of labor</b>	4.03 ± 0.23	6.70 ± 0.22	0.001

**Table 3:** Mode of delivery and complications

	Study group		Control group	
	Number	Percentage	Number	Percentage
<b>Mode of delivery</b>				
Normal Vaginal	44	88%	35	70%
Forceps	03	06%	09	18%
Ventouse	00	00%	03	06%
LSCS	03	06%	03	06%
<b>Complications</b>				
Prolonged 2 <sup>nd</sup> stage	04	08%	02	04%
Cervical dystocia (Arrest disorder)	01	02%	02	04%
Cervical dystocia & Fetal Distress	00	00%	01	02%
Fetal Distress	01	02%	06	12%
No complications	44	88%	40	80%

**Table 4:** Pain relief during labor and side effects

	Number	Percentage
<b>Grade</b>		
0	00	00%
1	06	12%
2	38	76%
3	06	12%
4	00	00%
<b>Side effects</b>		
Nausea/Vomiting	17	34%
Tachycardia > 10bpm	13	26%
Drowsiness	09	18%
Diarrhoea	09	18%
Pyrexia(1000 F)	05	10%
Transient HTN	03	06%
Dryness of mouth	01	02%
Nil side effects	20	40%

**Table 5:** APGAR score

	Study group		Control group	
	Number	Percentage	Number	Percentage
APGAR at 1 min				
<5	00	00%	01	02%
5-6	03	06%	02	04%
7-8	47	94%	47	94%
APGAR at 5 min				
7-8	03	06%	04	08%
9-10	47	94%	46	92%

Mean duration of active phase in Daftary SN et al<sup>5</sup> study was 3.5hrs. In Kshirsagar NS et al.<sup>6</sup> study including 100 primi as study and 100 as control group, the duration of active phase of labor was significantly reduced (3.42 hours in cases & 4.71 hrs in controls).

Veronica et al study including 30 primis as study group showed duration of active phase as 4hrs in the study compared to 6 hrs in the control group(30), showing similar results.<sup>7</sup> Chauhan et al found duration of first stage of labor was 3.4 hours.<sup>8</sup>

In the present study, mean duration of 2<sup>nd</sup> stage was 35.4mins in the study group and 62.6mins in the control group. There was a statistically significant difference in the two groups as seen in other studies. (p =0.001)

The mean duration of 2<sup>nd</sup> stage of labor was 27.8 min in cases & 34.2 min in Controls in Kshirsagar NS et al study.<sup>6</sup> In Veronica et al study, the mean duration of 2<sup>nd</sup> stage was 25 + 10 mins in the study group and 45 + 15 mins in the control group.<sup>7</sup> In Daftary SN et al study, the mean duration of 2<sup>nd</sup> stage was 26 mins in the study group and 48 mins in the control group.<sup>4</sup>

Chauhan R. et al<sup>8</sup> reported on their experience of 75 cases, 25 primiparae and 50 multiparae. The mean duration of the first stage of labor was 3.4 + 1.55 hrs and in multiparae it was 2.50 + 1.25 hrs which was significantly lower than in controls observed as 4.50 + 1.20 hrs in primis and 3.58 + 1.47hrs in multis. In their study, 92% of primiparae and 98% of the multiparae had normal vaginal delivery. The duration of the third stage was 3-5 mins. The total blood loss was much reduced. The APGAR scores were satisfactory in all patients in the treatment group.

In the present study all the stages have a significant reduction in durations similar to other studies.

### 5.2. Rate of cervical dilatation in active phase (CM/HR)

The cervix dilated at a faster rate (3.05 cm/hr) in programmed labor than in controls (1.15 cm/hr). It resulted in shorter labors. In present study, all the patients had adequate rate of cervical dilatation except for one patient in the study group who had arrest of dilatation at 5cms and taken up for emergency LSCS. Two women in the control group had no progress beyond 3 cms and taken up for LSCS.

Veronica study noticed that rate of cervical dilatation was nearly double (2.3 cm/ hr) in subjects and (1.2 cm/hr) in controls.<sup>7</sup>

According to Mishra et al<sup>9</sup> and Singh et al,<sup>10</sup> rapid dilatation is the effect of Drotaverine.

The study group had faster cervical dilatation rates than the control groups.

### 5.3. Total duration of labor (Hrs.Mins)

Total duration of labor (from active phase to placental delivery) is a mean of 4.03± 0.23 hrs and 6.70 ± 0.68 hrs. in study and controls respectively, showing a significant reduction in duration(p-value of 0.001). In comparison with Daftary SN study the present study had similar results.<sup>4</sup>

Majority of parturients in the study group i.e., 37% delivered in between 2-4 hrs and 34% in between 4-6 hrs, whereas majority i.e., 42.5% in controls delivered in 6-8 hrs, only 1parturient in study group took >8hrs and 1 went for LSCS due to arrest of dilatation at 5cms. Two parturients in the control group had slow dilatation rates (active phase >8hrs) and were taken up for LSCS. None of the patients in either group crossed 10hrs. Principle of active management of labor is to deliver a laboring woman within 12 hrs once she enters active phase. Using the protocol of programmed labor whose important component is partogram, none of the patient had to undergo the anguish of prolonged labor and its aftermath.

Sadler LC<sup>11</sup> in their meta analysis of active management of labor, showed that active management shortens the first stage of labor (p 0.02) & reduced the relative risk of prolonged labor (RR 0.39-95%). No difference in the fetal outcome was seen, maternal satisfaction was 77%, but did not reduce the rate of C-section(9.4% V/s 9.7%).

Peaceman AM<sup>12</sup> had 2 randomized trials with both showing that labor was shortened by approximately 2 hours and maternal infectious morbidity was decreased by approximately 50% by active management of labor.

### 5.4. Mode of delivery

Out of 3 women who underwent C-section in the study group, one was due to prolonged 2<sup>nd</sup> stage for 2hrs, 2<sup>nd</sup> was due to DTA & 3<sup>rd</sup> due to arrest of dilatation at 5cms for 4hrs.

Out of 3 LSCS from the control group, one was due to fetal distress and 2 were due to non progress (for 8hrs) and fetal distress.

Daftary et al in their study of 200 primis, 97% had vaginal delivery, in that 90% had normal delivery, 5.5% ventouse, 1.5% forceps & 3% c. section.<sup>4</sup>

Programmed labor did not have any significant impact on LSCS rates. (6% in both the groups. Majority of the patients in both groups delivered vaginally (94% in study & 94% in controls) although, assisted vaginal deliveries were more in the control group. Majority of them were due to maternal exhaustion due to pain. This was in accordance with the findings of Veronica,<sup>7</sup> Daftary,<sup>4</sup> Kshirsagar<sup>6</sup> studies.

### 5.5. Pain relief

Pain relief plays a vital role in maternal well being. Pain and fear retards the progress of labor. Pain relief prevents maternal hyperventilation, undue muscular efforts and exhaustion. Hence, pain relief was one of the important objectives of the study.

In the present study, pain score given by oral questionnaire by rupees scale method showed out of 50 parturients, 6(12%) had grade 1 pain relief, 38(76%) had grade 2 pain relief, 6(12%) had grade 3 relief.

Meena Jyoti et al noticed that 54% achieved good and 32% achieved moderate pain relief.<sup>13</sup> In Veronica et al<sup>7</sup> study, 13.3% had grade -1 relief, 16.7% had grade-2 relief, 70% had grade-3 relief. Kshirsagar et al<sup>6</sup> observed that 73% cases had pain relief. Out of them 47% experienced excellent pain relief while in controls, only 22% had pain relief with tramadol alone.

Chauhan R, Gupta A<sup>8</sup> reported the mean time for onset of analgesia to be around 16 minutes. Satisfactory pain relief was experienced by 88% of primiparae and 92% of multiparae.

In this study, rupee scale method was used because majority of our women were illiterates. The other methods for scoring the pain relief are visual analogue scale (VAS) and others. It also helped in preventing the complications to the mother and the baby due to excessive pain.

### 5.6. Maternal outcome

None of the patients had any major complications of labor. In the study group, 4 women had prolonged 2<sup>nd</sup> stage.

With the use of so many drugs (analgesics, antispasmodics & oxytocics) side effects were inevitable. Some drug related side effects like nausea, vomiting (34%), tachycardia (26%), drowsiness (18%), diarrhea (18%), pyrexia (10%), transient hypertension (6%) were seen. All the side effects subsided by 12 hours after delivery.

Kshirsagar et al<sup>6</sup> in programmed labor group, drug related side effects like nausea, vomiting, drowsiness, tachycardia were seen. Five cases developed hypertonic

uterine contractions. Only one of them required LSCS for fetal distress.

Veronica et al<sup>7</sup> had similar findings. Tachycardia in 80% was the commonest side effect followed by nausea and vomiting in 10%, rise in blood pressure & fall in blood pressure in 5% each.

### 5.7. Neonatal outcome

Majority of the babies were in between 2.6-3kgs (60% of the study and 52% of the control group) 4 babies in the study group and 5 babies in the control group were admitted to NICU. 2 babies in the study group had mild respiratory depression at birth, but recovered after resuscitation and were healthy at discharge.

One baby in study group had drowsiness, this was probably due to the effect of sedative i.e. diazepam used. But at discharge baby was healthy. One baby in the control group had APGAR 2 at 1min after birth and was admitted to NICU due to thick meconium stained liquor and aspiration but recovered at 5mins after resuscitation. Baby was kept in NICU for 3 days and was healthy at discharge. One baby had mild birth asphyxia but recovered after resuscitation in NICU and discharged on 3<sup>rd</sup> postnatal day and was healthy at discharge. Most of the babies in both groups had good APGAR scores and had no significant difference in the neonatal outcomes similar to other studies. There was no neonatal mortality or morbidity. This protocol in spite of the usage of multiple drugs (Opioid analgesics, sedatives, antispasmodics, oxytocics) was relatively safe in healthy term fetuses, since all the drugs were used at the minimum doses recommended.

Usage of these drugs makes continuous and strict vigilance of this fetus through CTG a must.

## 6. Conclusion

Programmed labor group had faster cervical dilatation, shorter labors, Excellent pain relief, No impact on LSCS rates, No compromise on Maternal or Neonatal safety. It reduces laboring women's anxiety, apprehension associated with labor and makes it a pleasant and memorable event. Presence of neonatologist, Anesthetist is necessary. Strict vigilance on patient's vital parameters although no pulse oximetry monitoring is required. It can be used as routine protocol in low risk gravid women at least in institution. This protocol also is of advantage to the obstetricians since it keeps the laboring women at ease with substantial pain relief and decreases unnecessary intervention.

## 7. Source of funding

None.

## 8. Conflict of interest

None.

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