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# **Original Research Article**

# Programmed labour compared with expectant management: is it truly a need of new millennium?

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#### **ABSTRACT**

**Background:** The mechanism triggering the initiation of human parturition is still an enigma. At term a series of complex physiological, biochemical and physical processes cascade resulting in delivery of the fetus. This study deals exclusively with comparison of normal labour, induction of labour with prostaglandin, and with augmentation by intracervical insertion of PGE2 tablets, amniotomy and smooth muscle relaxant. Advantages and disadvantages of each of the above methods are compared with expectant management of labour. Aim of this study was to compare pros and cons of programmed labour that to with expectant management.

**Methods:** Study was conducted in Department of Obstetrics and Gynaecology, Bharati Hospital and Research Centre, Pune. It was a prospective randomized clinical trial. 100 pregnant full term women, were selected for each group. At 0 hour primiprost tablet is inserted into the vagina close to the cervix. Frequency of repetition of tablet will be at three hours interval. Patient will be monitored.

**Results:** The youngest one being of age 17 years and the eldest being of age 29 years. In this, we observed those primi and 2<sup>nd</sup> gravida patients 2-2 tablets each in latent phase and 1-1 tablets in active phase. The induction delivery Interval in primigravida was observed to be of average of 9 hours. While in II Gravida was 6.5 hours, in III Gravida 5.5 hours and in IV Gravida 4 hours.

**Conclusions:** It has been proved beyond doubt that by programmed labour, the patient definitely can get the benefit of decrease in duration of labour.

**Keywords:** Expectant management, Programmed labour, Prostaglandins

#### INTRODUCTION

The mechanism triggering the initiation of human parturition is still an enigma. At term a series of complex physiological, biochemical and physical processes cascade resulting in delivery of the fetus. 1

Until recently the approach to labour has been passive. This approach has led to unduly prolonged labour with its attendant risks and complications like obstructed labour, rupture of uterus, sepsis, post-partum hemorrhage and therefore a higher rate of maternal with foetal morbidity and mortality. However recently a more active approach

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to labour has been adopted and this approach consists of prostaglandins.<sup>2,3</sup>

Prostaglandins and oxytocin have been used for inducing labour as well as augmenting uterine contractions during labour.<sup>3</sup> This approach allows deliveries to be conducted in a well-organised and streamlined fashion ensuring rapid delivery with reduced maternal and fetal stress. The process of induction of labour has been well studied in several excellent reviews and is now widely accepted.<sup>4</sup>

In this jet age, when almost everything is planned then why not a planned delivery? It is a worthwhile therapeutic option when the benefits to either the mother or fetus outweigh those of expectant management.

This study deals exclusively with comparison of normal labour, induction of labour with Prostaglandin, and with augmentation by intracervical insertion of PGE2 tablets, amniotomy and smooth muscle relaxant. Advantages and disadvantages of each of the above methods are compared with expectant management of labour.

The objective of this study was to study is it worthwhile therapeutic option when the benefits to either the mother or fetus outweigh those of expectant management.

#### **METHODS**

Department of Obstetrics and Gynaecology, Bharati Hospital and Research Centre. Pune. Study was conducted between June 2015-May 2016. Total number of deliveries during this period was 1260. Out of which 100 pregnant full term women were selected for programmed labour that fulfills inclusion criteria and 100 cases as control by stastical analysis (method of confidence level and confidence interval).

Patients were selected in each group by sytematic random sampling- every  $2^{nd}$  patient came to OPD will be included in programmed labour and every  $3^{rd}$  patient will be included in control group who fulfills inclusion criteria.

#### Inclusion criteria

- Gestational age >37 weeks
- Longitudinal lie, cephalic presentation
- Adequate pelvis
- Ready to participate after consent.

### Exclusion criteria

- Inadequate pelvis
- Any medical, obstetric, surgical complication
- Not willing after consent
- Precious pregnancy like conception after long infertility, IVF conception, elderly primi.

This is a prospective randomized clinical trial.

#### **Participants**

#### For programmed labour

100 pregnant full term women, without any obstetrical, medical, surgical complications with confirmed maturity and adequate pelvis will be selected.

#### Control cases

100 pregnant full term women, without any obstetrical, medical, surgical complications with confirmed maturity and adequate pelvis admitted in labour ward in latent phase of labour.

#### Methodology

#### For programmed labour

- Counseling of patients who are fit for programmed labour be carried out after 37 weeks of gestation
- After obtaining a verbal consent patient will be called for admission to the hospital between gestations at 6 am
- On admission informed written consent will be taken and a thorough examination and preparation will be done
- At 0 hour primiprost tablet is inserted into the vagina close to the cervix. Frequency of repetition of tablet will be at three hours interval
- Patient will be monitored with the help of partogram for maternal pulse, blood pressure, uterine contractions (frequency, duration, intensity), fetal heart rate, progressive dilatation of cervix and descend of the presenting part
- Amniotomy will be done at 4cm dilatation.
- Followed by injection buscopan at half hourly interval (total 3 doses).

## Control cases

- Cases getting admitted in labour ward after thorough examination will be selected for comparative study
- From the latent phase of labour, the patient will be monitored partographically, in order to study progress of labour.

## **RESULTS**

## Following factors will be looked for in study group

- Induction delivery interval
- Any other medication apart from the standard protocol required
- Any operative intervention required
- Maternal and neonatal clinical outcome.

#### Following factors will be looked for in control group

- Total duration of labour
- Any complication during labour
- Maternal and neonatal clinical outcome.

#### **Observations**

In this study authors observed that majority of patients fell into Age group of 21-25 years. The youngest one being of age 17 years and the eldest being of age 29 years (Table 1).

Table 1: Age distribution.

Age (yrs)	Study group	Control group
15-20	4	20
21-25	84	73
26-30	12	7
>30	-	-
Total	100	100

In this, authors observed that primi and 2<sup>nd</sup> gravida patients required 2-2 tablets each in latent phase and 1-1 tablets in active phase. All primigravidas required the set of total doses of Inj. Buscopon (total 3) while the 4<sup>th</sup> gravida required only 1 Inj. of Buscopon (Table 2).

Table 2: Number of tablets required in latent and active phase of labour with respect to parity.

Dowitz	Average tablets required		
Parity	Latent phase	Active phase	
Primigravida	2	1	
II Gravida	2	1	
III Gravida	1	1	
IV Gravida	1	Nil	

It was also observed that the induction delivery Interval in primigravida was observed to be of average of 9 hours. While in II Gravida was 6.5 hours, in III Gravida 5.5 hours and in IV Gravida 4 hours (Table 3) and (Figure 1).

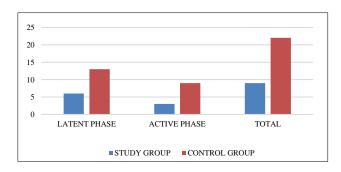


Figure 1: Duration of laboure in primigravida in hours.

Table 3: Duration of labour with respect to parity in study group.

Parity	Duration		Industion delivery interval
	Latent	Active	Induction delivery interval
Primigravida	6 hours	3 hours	9 hours (Max. 12 hours Min. 7 hours)
II Gravida	4 hours	2.5 hours	6.5 hours (Max. 8 hours Min. 5 hours)
III Gravida	3.5 hours	2 hours	5.5 hours (Max. 7 hours Min. 5 hours)
IV Gravida	3 hours	1 hours	4 hours (Max. 5 hours Min. 3 hours)

Table 4: Total duration of labour in control group (including latent and active phase).

Parity	Duration
Primigravida	22 hours
II Gravida	17 hours
III Gravida	13 hours
IV Gravida	10 hours

The average duration of latent phase in primigaravida of control group was 13 hours while of IV Gravida was 5 hours. The average duration of active phase of labour in primigravida was 9 hours and that of IV Gravida was 5 hours. Thus, the total duration of labour (including latent and active phase) in primigravida was 22 hours and that of IV Gravida was 10 hours (Table 4)and (Figure 1).

Also it was found that in study group one patient had hypertonic uterine actions (primigravida), one had precipitate labour (IV Gravida) one had post partum hemorrhage who was III Gravida. While in control group 2 had second degree perianal tear (III Gravida). While 3 had PPH of which one was II gravida and 2 were III gravida. While 2 patients (primigravida) had ghypotonic uterine action.

In this study 1 patient from study group required oxytocin from study group and 4 cases from control group due to hypotonia. Ventouse was required for 6 cases of control group due to prolongrd 2<sup>nd</sup> stage. Emergency LSCS was required in study group due to hypertonia with fetal distress (Table 5).

Table 5: Medical instrumental and operative intervention.

Intervention	Study group	Control group
Oxytocin	1 (Hypotonia) (Primi)	4 cases (Hypotonia) (Primi)
Ventouse	-	6 cases (Prolonged II stage)
Forceps	-	-
Emergency L.S.C.S.	1 (Primigravida) (Hypertonic uterine action)	-

#### **DISCUSSION**

In recent years, systematic attempt has been made by many workers to study the duration of labour, to achieve this the progress of labour should be regulated to ensure that every women should be delivered within 10 to 12 hour. This can be achieved, provided the obstetrician assumes direct responsibility and forsakes the role of passive observer for that of active director, controlling the course of labour instead of waiting in the hope that it may conclude within a reasonable time.<sup>5</sup>

Outcomes after induction of labor in term singleton pregnancies from 2006 to 2010 were retrospectively evaluated by accessing data from the National Vital Statistics System. Results were stratified by parity and the clinical variables of maternal and gestational age assessed. Among 4,341,289 deliveries, vaginal and cesarean delivery rates were significantly different when grouped by maternal age and gestation with induction success declining as maternal age increased and gestational age approached 42 weeks (P<0.001). The lowest cesarean delivery rate identified was 8% for multiparous women younger than 30 years who delivered at 39 weeks of gestation. The relative risk of cesarean delivery increased even for women aged 30-34 years and was highest among women 40 years and older regardless of parity. Although the relative risk of cesarean delivery increases with age, high induction success rates exist for multiparous women. The effect of age can be seen in women as young as 30-34 years.6

As was seen, both in study and control group major patients fell into age group of 21-25 years. A maximum being of 29 years and minimum of 17 years. Age parameter has no significance in relation to induction or augmentation of labour. Nor does the pain threshold has any relationship to progress of labour.

In this multicenter trial, authors randomly assigned lowrisk nulliparous women who were at 38 weeks 0 days to 38 weeks 6 days of gestation to labor induction at 39 weeks 0 days to 39 weeks 4 days or to expectant management. A total of 3062 women were assigned to labor induction, and 3044 were assigned to expectant management. The primary outcome occurred in 4.3% of neonates in the induction group and in 5.4% in the expectant-management group [relative risk, 0.80; 95% confidence interval (CI), 0.64 to 1.00]. The frequency of cesarean delivery was significantly lower in the induction group than in the expectant-management group (18.6% versus 22.2%; relative risk, 0.84; 95% CI, 0.76 to 0.93). Induction of labor at 39 weeks in low-risk nulliparous women did not result in a significantly lower frequency of a composite adverse perinatal outcome, but it did result in a significantly lower frequency of cesarean delivery.<sup>7</sup>

In this study it was observed in healthy nulliparous women at term with a ripe cervix, expectant management resulted in very few induction and no increase in instrumental deliveries, and maternal and neonatal morbidity.

Johnson N, Lilford R, Thornton J, ST JAMES University Leeds University, UK. studied elective amniotomy in uncomplicated labour at term result no measurable advantage over selective amniotomy for Parous women (difference 4 minute) but shortened labour in nulliparous by 1 hour, P <0.05. There was suggestion of higher LSCS rate. Conclusion routine amniotomy may shorten the 1st labour but not subsequent ones, and may be harmful by increasing the risk of LSCS.

Alcalay M, Hocruitz A, Chaim Sheba medical centre, Israel. Bishop's score versus gest age All patients in study group were selected in such a way that all had a Bishop's Score of 8 and above. Thus all patients with inducible cervix was taken into study to ensure a rapid induction and augmentation. For an inducible cervix, patients were selected at 38, 39 and 40 weeks of gestation i. e. near term, since near term. The cervix has its natural tendency to become favorable for parturition. ARM at term versus expentant management. Study group had 154 women. Observation was expectant management in patient with ARM at term is safe and reduces the frequency of operative vaginal delivery. Thus to summarise only the total duration of labour in study group: primi by 13 hours, 2<sup>nd</sup> gravida by 10.5 hours, 3<sup>rd</sup> gravida by 7.5 hours, 4<sup>th</sup> gravida by 6 hours.

Gudex G, National women's Hospital Auckland performed a prospective audit of induction of labour with prostaglandin 123 patients were induced with prostaglandin. Hyper stimulation 3% Failed induction 5% LSCS rate 29%. Induction delivery interval mean 27 hours.<sup>9</sup>

Amano K, Sarto K, Kitasato University Kanagawa, Japan. Elective induction of labour at 39 weeks a prospective randomized trial. Objective was to clarify

safety of elective induction at 39 weeks. Uncomplicated nulliparous (N=194) labour induced in 63 patients at 39 weeks in the active management weeks of gestation in the expectant group (E group) a significantly higher incidence of meconium stained annios (19.4% vetsus 3.2%) and fetal resuscitation (16.7% versus 4.8%) was found in the E group than in the I group. A high incidence of epidural analgesia was noted in I group (89%) than the E group (54%). The duration of 1st stage was shortened in I group and duration of 2nd stage was not significantly different. No different was observed in two groups in C section and blood loss. 10

Hannah ME, Huh C, HEWSON, SA of the Canadian multicenter post term pregnancy trial (CMPPT) enrolled 3407 women of which 1701 were for expectant management. Assuming that administration of prostaglandin could reduce likelihood of LSCS rate by 12 to 15 percent, LSCS rate was reduced in the induction group from 21.2% to 20.8 to 20.9% and in Expectant group from 24.5% 23.3 to 24.2%, if labour was induced as a part of a policy of expectant management, the LSCS rate was much higher 33.5%, than if labour was either spontaneous or induced. <sup>11</sup>

Int J Gynaecal obstet 1996 April compared induction versus expectant care for PROM. Levenburg hospital, Netherlands found more women in induction group (23%) than in the expectant group (10%) had operative vaginal delivery.

## Timing of delivery

A retrospective cohort study of women who delivered at Danderyd Hospital, Stockholm, Sweden, 2002-2006, comprising 1940 women induced by Dinoprostone [PGE(2) or transcervical balloon catheter (BARD)]. Risks for night-time delivery were calculated as absolute risk and odds ratios by unconditional logistic regression using induction of labor in the morning as reference. For nulliparae with Bishop score 0-3 induced by BARD, odds ratios for night-time delivery were 0.42 (95% C.I. 0.19-0.93) and 0.09 (95% C.I. 0.02-0.47) when inductions started in the afternoon and evening, respectively, compared to inductions starting in the morning For multiparae, however, the risk of night-time delivery was highest if induction started in the evening. Compared to inductions started in the morning, odds ratios for nighttime delivery were 3.53 (95% C.I. 2.57-4.83) and 8.49 (95% C.I. 4.45-16.19) for induction starting in the afternoon and evening, respectively. Starting time of labor induction affects the risk of giving birth at night. For nulliparae induced by BARD, starting the induction in the evening instead of during the day may reduce the number of night-time deliveries substantially. For multiparae, however, our data suggest that induction of labor should take place in the morning.<sup>12</sup>

In this study group the patients were carefully selected and were induced on a pre scheduled time and delivered during the specific period of time, while control group had no barrier for day and time were admitted into spontaneous labour at any time. Thus all study group patients could be delivered during day time as per convenience of doctor and patient and could definitely get a benefit of having maximum efficiency of obstetrician and all resources at reach.

Maternal morbidity and mortality Study group could not prove any upper hand in better maternal outcome. On the other hand one patient had to undergo LSCS on emergency grounds solely due to adverse effect of the Dinoprostone leading to hypertonic uterine contractions leading to fetal distress and needing LSCS. While one patient had mild PPH due to atony of uterus which probably could be due to effect of prostaglandin and same needed oxytocin drip in II stage labour due to uterine hypotonia. One patient had precipitate labour which was attributed by Dinoprostone and had a III rd degree tear. On the other hand control group had no operative interference. But had 6 ventouse delivery which were solely due to maternal exhaustion in 2<sup>nd</sup> stage labour leading to poor bearing down efforts. While 3 patients had mild to moderate PPH and 3 required Oxytocin in 2nd stage due to poor bearing down, maternal exhaustion.

#### Neonatal outcome

Randomised trials completed to date have provided very little information about longer-term outcomes for children and cohort studies have shown inconsistent results as to whether post-term birth has a negative, positive or null impact on childhood development. A large cohort study from Denmark has suggested that more children born at 41 weeks' gestation or more achieved developmental milestones compared with children born at earlier term gestations (39 to 40 weeks). In this study there was no difference in neonatal outcome of study group and control group. All newborn had good apgar score in both study and control group. Thus study group could not prove any upper hand in neonatal outcome.

#### **CONCLUSION**

It has been proved beyond doubt that by programmed labour, the patient definitely can get the benefit of decrease in duration of labour. But it is worth giving a logical thought about, this decrease in duration of labour is at the cost of how many significant hours? And is it worth getting the benefit at the cost of unnecessary expenditure taking socioeconomic status into consideration.

The only benefit being that the protocol can be followed, for convenience of Doctor and as per convenience and requirements of patient and of coarse, one getting delivered during office timings can get the benefit of getting delivered, when efficiency of obstetrician is maximum and all resources are at reach.

Thus to conclude, programmed labour does not have any upper hand over expectant management. It is definitely not a worthwhile therapeutic option to ensure rapid delivery in a streamline fashion, to save just few hours, and for the convenience sake, at the cost of operative interference and unnecessary expenditure and should be practiced only in indicated and selected patients only, especially taking women's positive approach towards elective inductions.

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Ethical approval: The study was approved by the

Institutional Ethics Committee

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