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Fetomaternal Outcome in Postdated Primigravida Delivered at Bankura Sammilani Medical College by Induction of Labour with Intracervical Dinoprostone Gel: A Descriptive Study

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ABSTRACT

A pregnancy that produces a healthy child and a mother who has the least amount of trauma is the aim of obstetrics. Preventing cesarean delivery and all of its risks is a delicate balance that is at the heart of competent obstetric care. The typical definition of labor is the periodic contraction and relaxation of the uterine muscles along with the cervix's progressive dilatation and effacement, which result in the expulsion of the resulting reproductive products. The fetus transitions from the intrauterine to the extrauterine environment during labor. The typical progression of cervical ripening precedes the commencement of myometrial contractions. Fetomaternal Outcome in Postdated Primigravida Delivered at Bankura Sammilani Medical College by Induction of Labour with Intracervical Dinoprostone Gel. A Descriptive Study. It was a descriptive observational study this study was conducted in a large tertiary care maternity centre with a time frame of 18 months from the acceptance of synopsis at the Department of Obstetrics and Gynaecology, BSMCH, Bankura. It was seen that most of the postdated primigravida mothers 80 (66.67%) have got 2 times application of Intracervical Dinoprostone gel whereas only 40 (33.33%) postdated primigravida mothers have got 1 times. This study reflected that most of the postdated primigravida mother's i.e. 69 (57.5%) post- induction bishop score was within 2-5, whereas only 1(0.83%) postdated primigravida mother's post-induction bishop score was not obtained due to LUCS. The mean bishop score of post induction was higher than pre induction bishop score, with Standard Deviation 0.54 and 1.41, which was found to be statistically significant relationship as evident from "r" value (0.293) at df 118 at 0.05 level of significance and $p < 0.001$. Maximum postdated primigravida mother 119 (99.17%) have delivered baby with >7 Apgar score within 1 min whereas only 1 (0.83%) mother have delivered a baby with <7 Apgar score within 1 min. So the fetal outcome was satisfactory. We conclude that goes beyond 40 weeks should be considered as high risk. So, proper management should be done to decrease the rate of perinatal morbidity and mortality. The emotional impact as well as peripartum complications of a mother should also be taken into consideration while allowing a pregnancy to prolong. So, a policy should be made to intervene in pregnancy at an optimum gestational period so that a proper balance could be made between the risk of induction and that of ongoing pregnancy.

INTRODUCTION

A pregnancy that produces a healthy child and a mother who has the least amount of trauma is the aim of obstetrics. Preventing cesarean delivery and all of its risks is a delicate balance that is at the heart of excellent obstetric care^[1]. The usual definition of labor is the rhythmic contraction and relaxation of the uterine muscles along with the increasing cervical dilatation and effacement that result in the expulsion of the resulting products of conception^[2]. The fetus transitions from the intrauterine to the extrauterine environment during labor. The typical progression of cervical ripening precedes the commencement of myometrial contractions^[3]. Delivery occurs at the term as a result of a complex cascade of physiological, biochemical and physical processes. Steroids involved in humoral transmission, local hormones and neuroendocrine pathways all influence several processes. The cervical resistance lowers as the cervix grows shorter and softer as labor approaches^[4]. Cervical ripening is the term for this procedure. Selecting a technique that will allow the cervix to mature and ensure a successful planned induction of labor is crucial^[4]. The majority of the time, labor begins on its own but for a variety of obstetrical and medical reasons, it must be induced when the advantages of going into labor for the mother or the fetus exceed the risks^[4].

Normal labour is a process that sets in spontaneously. Mechanism of initiation of normal labour in humans is still obscure^[5]. However endocrine, biochemical and mechanical stretch pathways as obtained from animal experiments, however, put forth the following hypothesis uterine distension causing uterine stretch which results in increasing gap junction proteins, activation of fetal hypothalamic pituitary adrenal axis, alteration of estrogen progesterone ratio likely resulting in release of prostaglandins, release of oxytocin and increase in number of oxytocin receptors^[6]. The first stage of labour starts with dilatation, effacement of the cervix and formation of the lower uterine segment. Effacement of cervix is the process by which the muscular fibres of the cervix are pulled upward and merges with the fibres of the lower uterine segment^[7]. During labour the demarcation of an active upper segment and a relatively passive lower segment is more pronounced. The wall of the upper segment becomes progressively thickened with progress thinning of lower segment. This becomes maximum in second stage of labour^[7].

MATERIALS AND METHODS

Study design: A descriptive observational study.

Study setting and time line: The study was conducted in a large tertiary care maternity centre with a time frame of 18 months from the acceptance of synopsis.

Place of study: The study was carried out in the inpatient Department of Obstetrics and Gynaecology, BSMCH, Bankura.

Study period: 18 Months.

Sample population: Postdated primigravida in-patients with Bishop score less than or equal to 4 in Department of Gynaecology and Obstetrics, Bankura Sammilani Medical College, Bankura during the data collection phase.

Sample size: Sample size of the proposed study was calculated according to $n = (Z/e)^2$, where $Z = 1.96$ and $e =$ allowable error around the predicted/reported incidence of event of interest (here it is fetal distress). Assuming $e = 20\% = 0.2$ Now putting the values in the formula $n = (1.96/0.2)^2 = 96$ Considering 10% non response the revised sample size would be 106.

Sampling design: The data collection for the study will be done over a period of 10 months i.e. 43 weeks approximately. It was planned that data collection will be carried out on the basis of once a week schedule. This one day of the week was selected at the beginning of each week with help of simple random sampling (SRS) technique using lottery method. To achieve the sample size within the stipulated time of 43 weeks was planned that 2 or 3 study subjects will be included in alternate week starting unbiasedly by help of simple random sampling.

Inclusion criteria:

- Singleton pregnancy
- cephalic presentation
- 40 completed weeks of gestation
- Bishop Score less than or equal to 4
- No genital tract infections

Exclusion criteria:

- The women who have major medical and surgical problems
- The women with malpresentations, cephalopelvic disproportions, multiple pregnancy, Antepartum hemorrhage
- Altered Doppler findings
- Non reassuring fetal heart pattern
- IUGR
- Oligohydramnios

RESULTS

Most of the postdated primigravida mothers i.e. 58 (48.33%) out of 120 were illiterate whereas only 19 (15.83%) postdated primigravida mothers have studied up to H.S. Maximum postdated primigravida mothers 110 (91.67%) were House wife whereas only 2 (1.67%) postdated primigravida mothers were Teacher.

Table 1: Distribution of all parameters

| Participant's Characteristics | Participant's Characteristics | Frequency | Percentages (%) |
|-------------------------------|---|-----------|-----------------|
| Participant's Characteristics | Educational status | | |
| | Illiterate | 58 | 48.33 |
| | Primary | 43 | 35.83 |
| | H.S. | 19 | 15.83 |
| | Occupation | | |
| | House wife | 110 | 91.67 |
| | Teacher | 2 | 1.67 |
| | Daily labour | 4 | 3.33 |
| | Service | 4 | 3.33 |
| | Socio Economic Status | | |
| Upper middle | 39 | 32.5 | |
| Middle | 7 | 5.83 | |
| Lower middle | 41 | 34.17 | |
| Lower | 33 | 27.5 | |
| Items | Pre-induction bishop score | | |
| | <2 | 98 | 81.67 |
| | >3 | 22 | 18.33 |
| | No. of application of Intracervical Dinoprostone Gel | | |
| | 1 times | 40 | 33.33 |
| | 2 times | 80 | 66.67 |
| | Post-induction bishop score | | |
| | 2-5 | 69 | 57.5 |
| | >5 | 50 | 41.67 |
| | NA (LUCS) | 1 | 0.83 |
| Maternal outcomes | PPH | 2 | 1.67 |
| | Augmentation | 86 | 71.66 |
| | Not required | 17 | 14.17 |
| | Amniotomy | 17 | 14.17 |
| | Oxytocin infusion | | |
| | Retained Placenta | 1 | 0.83 |
| | Failed Induction | 11 | 9.16 |
| | Birth weight | | |
| | >2.5 kg. | 116 | 96.67 |
| | <2.5 kg. | 4 | 3.33 |
| Fetal characteristics | APGAR Score within 1 min | | |
| | <7 | 1 | 0.83 |
| | >7 | 119 | 99.17 |

Table 2: Frequency and percentages distribution of fetal maternal outcome according to bishop score

| Feto-maternal Out come | Bishop score 2-5 | Bishop score 6-8 |
|-------------------------|------------------|------------------|
| Vaginal delivery | 51 | 50 |
| C-section | 18 | 1 |
| Failed induction | 11 | 0 |
| Foetal distress | 4 | 1 |
| Meconium stained liquor | 5 | 0 |

Table 3: Mean value of active phase and post-induction bishop score of postdated pregnant mother

| Bishop score | Mean |
|----------------|-------|
| Active phase | 10.75 |
| Post-induction | 5.28 |

This Table also depicted that most of the postdated primigravida mothers i.e. 41 (34.17%) were belongs to lower middle class. Whereas only 7 (5.83%) postdated primigravida mothers were belongs to middle class. We depicted that, most of the postdated primigravida mother's 98 (81.67%) pre-induction bishop score was <2 whereas 22 (18.33%) postdated primigravida mother's pre induction bishop score was >3.

Most of the postdated primigravida mothers 80 (66.67%) have got 2 times application of Intracervical Dinoprostone gel whereas only 40 (33.33%) postdated primigravida mothers have got 1 times. This Table also reflected that most of the postdated primigravida mothers' i.e. 69 (57.5%) post-induction bishop score was within 2-5, whereas only 1 (0.83%) postdated primigravida mother's post-induction bishop score was not obtained due to LUCS.

This Table depicted that most of the postdated primigravida mothers i.e. 17 (14.17%) out of 120 have required augmentation of labour by amniotomy and another 17 (14.17%) postdated primigravida mother have required augmentation of labour by Oxytocin infusion. Augmentation was done when partograph showed crossing of alert line to prevent non progression of labour and to avoid adverse fetomaternal outcome and to decrease rates of caesarean section.

This Table also depicted that the very few postdated primigravida mother i.e. 1 (0.83%) out of 120 have suffered from Retained Placenta, which was managed in operation theatre by manual removal under general anaesthesia. Depicted that most of the postdated primigravida mother i.e. 116 (96.67%) out of 120 have delivered baby with >2.5 kg. weight whereas only 4 (3.33%) mothers have delivered baby with <2.5 kg. weight.

This Table also reflected that maximum postdated primigravida mother 119 (99.17%) have delivered baby with >7 Apgar score within 1 minute whereas only 1(0.83%) mother have delivered a baby with <7 Apgar score within 1 min. So the fetal outcome was satisfactory. No incidences of fetal death due to the induction process was recorded even when followed up in SNCU.

Most of the postdated primigravida mother i.e. 51 out of 120, delivered their baby vaginally and whose bishop score was within 2-5. Whereas 50 mothers delivered their baby vaginally but bishop score was within 6-8. The difference was not significant. This Table also shown that 18 mother, delivered their baby by C-section whose bishop score was 2-5 but only 1 mother who has delivered her baby by C-section and her bishop score was within 6-8. The difference was not significant.

This Table reflected that 11 mother's induction was failure whose bishop score was 2-5. No one was under 6-8 bishop score whose induction was failure. The difference was not significant. The Table also described that 4 mothers, baby was suffering from foetal distress whose bishop score was within 2-5 and only 1 mother's baby was suffering from fetal distress but her bishop score was within 6-8. The difference was not significant.

The Table also described that 5 mothers, baby was suffering from meconium stained liquor whose bishop score was within 2-5 $t_{119} = 0.195$, Significant. The data presented in Table 6 showed that the mean bishop score of post induction was higher than pre-induction bishop score, with Standard Deviation 0.54 and 1.41, which was found to be statistically significant relationship as evident from "r" value (0.293) at df 118 at 0.05 level of significance and $p < 0.001$.

Hence Research hypothesis H_1 had been accepted and the null hypothesis H_{01} had been rejected. In order to identify the relationship between the post induction and active phase bishop score of postdated primigravida mother who received the Intracervical Dinoprostone gel. H_2 There is relationship between post induction bishop score and active phase bishop score at 0.05 level of significance. The data presented in table 3 showed that the mean bishop score of active phase was higher than post induction bishop score.

DISCUSSIONS

Keeping in mind the increasing rates of caesarean section nowadays and at an attempt to reduce incidence of caesarean section, dinoprostone gel was tested in 120 postdated primigravida patients to see the fetomaternal outcome after induction of labour with dinoprostone gel. After taking informed consent from the patients for induction of labour with dinoprostone gel, cardiotocography was done to assess fetal wellbeing. Ultrasonography was done for all patients to exclude intrauterine growth retardation, oligohydramnios or altered Doppler study. Pre induction bishop score calculated. Intracervical Dinoprostone gel applied at 6 hourly intervals, maximum of 2 doses as per response of the patient. Post induction bishop score calculated once at 6 hours

and next in active phase. The pre, post and active phase bishop score is then compared to see the effectiveness of the gel. The post induction phase fetal well being was again seen by cardiotocography at 6hrs post application. Modified WHO Partograph plotting started at 4 cm cervical dilatation in labour room in all cases. Augmentation was done when partograph showed crossing of alert line to prevent non progression of labour and to avoid adverse fetomaternal outcome and to decrease rates of caesarean section. Progress of labour is monitored with the partograph. Any signs of fetal distress, fetal bradycardia or meconium stained liquor noted. All cases of fetal distress are detected promptly and prepared with consent for emergency caesarean section. If induction failed, we discuss this with the woman and provide support. The woman's condition and the pregnancy in general is fully reassessed and fetal wellbeing assessed using electronic fetal monitoring. The subsequent management options is caesarean section, with consent of patient.

From the study we had the target of knowing the following 1. Average time and onset of labour pain 2. Proportion of women needing amniotomy 3. Proportion of women requiring of oxytocin augmentation 4. Prostaglandin instillation delivery interval (in min) 5. Mode of delivery 6 .Preinduction, postinduction and active phase Bishop score 7. Proportion of women with 3rd stage complications 8. Percentage of maternal and fetal favourable or unfavourable outcome.

We found that ,in the study most of the postdated primigravida mother's 98 (81.67%) pre induction bishop score was < 2 whereas 22 (18.33%) postdated primigravida mother's pre induction bishop score was > 3 as in case of study of Warke *et al.*^[8] where pre induction bishop score was < 3 and was 1-6 in case of study of Basutheen *et al.*^[9]

This study showed that most of the postdated primigravida mothers 80 (66.67%) have got 2 times application of Intracervical Dinoprostone gel whereas only 40 (33.33%) postdated primigravida mothers have got 1 times. Reinduction rates were 41.5% in case of study of Basutheen *et al.*^[9], 72% in case of study of Gupta *et al.*^[10], 8% in case of study of Warke *et al.*^[8] therefore our study results were consistent with study of Gupta et al and was inconsistent with the other two studies.

It also reflected that most of the postdated primigravida mothers i.e. 69 (57.5%) post-induction bishop score was within 2-5 and > 5 in 41.67%, which improved to 11-14 in 52.48% mothers and 7-10 in 47.52%, thus resulting in a $p < 0.001$ which is statistically significant. This means that there was significant improvement of bishop score after gel application,

though majority required reinduction. Improvement in bishop score in postinduction phase was also noted in study of Gupta *et al.*^[10] and significant p value was obtained. Post induction bishop score was consistent with the study of Basutheen *et al.*^[9] where post induction bishop score at 12 hrs was 9.5 and at 24 hrs was 10.26.

In our study, 16% underwent lucs, most common indication being induction failure in 57.89% of those undergoing lucs followed by fetal distress in 26.31% of mother undergoing lucs. Percentage of mothers undergoing caesarean section was consistent with the study findings of Gupta *et al.*^[10], where it was 16% and Warke *et al.*^[8] with caesarean rate of 17%. Result findings were inconsistent with the studies of Basutheen *et al.*^[9] which had caesarean section rate of 38.5%.

In 11 (57.89%) mothers indication of LUCS was Induction Failure whereas only 3 (15.79%) postdated primigravida mother's indication was Meconium stained Liquor (MSL). Rest underwent vaginal delivery. In studies of Warke *et al.*^[8], Karmakar *et al.*^[11] and most common indication of caesarean section was fetal distress which is inconsistent with our study.

Lucs for fetal distress and meconium stained liquor were done promptly to avoid any adverse effect to fetus. Thus our study proves that it is possible to reduce rates of caesarean section and promote vaginal delivery even in cases of postdated primigravida with unfavourable cervix. Average induction delivery interval was 4-8 hrs in 57%, 8-12 hrs in 37% and more than 12 hrs in 6% in our study. The induction delivery interval was 14.72 hrs, 23.8 hrs in study of Basutheen *et al.*^[12]

APGAR score at 1min was >7 in 99.17% which was significantly good as in case of the study of Ramesh *et al.*^[34] where 93% of cases had APGAR score of 7 at 5 min after birth, thus ruling out adverse effect of dinoprostone gel on fetus. Augmentation was done when partograph showed crossing of alert line to prevent non progression of labour and to avoid adverse fetomaternal outcome and to decrease rates of caesarean section. 17 (14.17%) out of 120 have required augmentation of labour by amniotomy and another 17 (14.17%) postdated primigravida mother have required augmentation of labour by Oxytocin infusion. The percentage requiring augmentation of labour was less than that in the study of Warke *et al.*^[8] where augmentation was required in case of 68.1% of patients with oxytocin infusion.

CONCLUSION

We conclude that goes beyond 40 weeks should be considered as high risk. So, proper management should be done to decrease the rate of perinatal

morbidity and mortality. The emotional impact as well as peripartum complications of a mother should also be taken into consideration while allowing a pregnancy to prolong. So, a policy should be made to intervene in pregnancy at an optimum gestational period so that a proper balance could be made between the risk of induction and that of ongoing pregnancy. Dinoprostone gel has been seen to be quite a safe and effective method for induction of labour in postdated pregnancy cases. However the strive towards an even more safe option of labour induction continues. There are a few studies which shows positive role of hyaluronidase injection with few side effects. In view of increasing number of caesareans we should explore more and more options for induction of labour other than prostaglandins.

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