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Overdue pregnancies in India: An observational study comparing induction with expectant management

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Abstract
Background of the Study: This research compared elective induction of labor (e-IOL)* in overdue pregnancies (40 1/7 to 40 6/7 weeks) with expectant management (EM)* up to 41 weeks, and it was designed as a prospective observational study. The major focus was to examine the variance in the frequency of cesarean sections between the two groups. methodological framework Women who met the study's inclusion and exclusion criteria were sought out when they had reached the 40th week of pregnancy. There were 112 people in the sample. Group 1 (e-IOL) comprised 56 people who were induced between weeks 40.1-60.7 of their pregnancies, while Group 2 (EM) had 56 people who were provided expectant management until week 41 of their pregnancies. Women in Group 2 were further classified into Group 2a if they went into labor on their own while under expectant care, and Group 2 b if they were induced for maternal/fetal reasons or because they were beyond 41 weeks and 7 days pregnant.
Result: The risk of spontaneous labor was raised by expecting management through 41 weeks of gestation beyond the due date without compromising perinatal outcome. In the EM group, 78.2% of women had birth vaginally after going into labor spontaneously. In our research, the rate of caesarean sections was lower for EM (37.5%) than for e-IOL (58.9%) (p=0.002).
Conclusion: Compared to elective induction of labor, expectant management resulted in a lower rate of caesarean sections for women with postdate pregnancies. There was no difference in perinatal outcomes across the groups. Births that occurred vaginally were more common among participants who went into spontaneous labor while under expectant management.

Keywords: Overdue pregnancies, observational, expectant management

1. Introduction
Post term pregnancy refers to a pregnancy that has reached or extended beyond 42 weeks of gestation from last menstrual period (LMP*) [1]. The perinatal deaths and neonatal morbidity increases gradually after 41 weeks of pregnancy with a steeper increase after 42 weeks [2]. The clinical management of women who remain pregnant past their expected due date (EDD*) is a contentious issue. The foetal risk associated with such pregnancy is small but real. An earlier induction of labour (IOL*) can potentially expose the mother to a risk inherent to induction of labor which includes a possible higher operative intervention a [3, 4] and its subsequent morbidity while delaying it increases the chances of stillbirth, foetal distress and perinatal morbidity.
Most guidelines recommend delivery at 42 weeks of gestation and offer induction of labour between $41^{0/7}$ – $41^{6/7}$ weeks with antenatal surveillance [1]. The duration of pregnancy does show variation according to the ethnicity of mother. The median gestational age at delivery for the Black and Asian population is around 39 weeks [5]. Hence, many obstetricians in our country prefer to induce the pregnant women as soon as they are over date (40 $^{1/7}$– 40 $^{6/7}$ weeks).
Available evidences comparing induction of labour with expectant management have demonstrated that Caesarean section rates are in fact reduced with induction of labour, however bulk of these studies have been conducted at 41 weeks of gestation [6-7]. In our teaching hospital, pregnancies that progress beyond their due date are managed either with induction of labour or expectant management. Different teaching units have different standards of care. Therefore there is no consensus regarding their exact management. As there is a paucity of data comparing induction of labour with expectant management amongst Indian pregnant women who go over date, the present study was planned to evaluate the rates of Caesarean section and also compare perinatal and maternal outcome between the two mentioned groups.

2. Materials and Methods

We intended to study pregnancies continuing beyond their due date in this prospective observational study. Cases were studied from April 2016 to December 2017. Pregnant women who were admitted to our hospital at 40 weeks of gestation satisfying the inclusion and exclusion criteria were recruited for the study after taking an informed consent. The study being an observational study, no intervention was done for the purpose of study and clinical management was done as per different unit protocol. The sample size of 112 was based on the statistical calculation of the data from the past records of the hospital over 2 months, keeping primary objective in view (Caesarean section rates) {Two sided confidence level(1-alpha) – 95; Power (% chance of detecting) - 80}.

2.1 Inclusion criteria

All pregnant women at or beyond 40 $^{0/7}$ weeks (overdate) admitted in the hospital.

2.2 Exclusion criteria

1. Over date pregnancies with diabetes, hypertensive disorders of pregnancy, cardiac or renal disease, congenital anomalies, fetal growth restriction, obesity, oligohydramnios.
2. Women with suboptimal dating of pregnancy (Unsure LMP and non availability of early sonography).
3. Those who refuse to give consent for the study.

The two groups to be compared were labelled as

1. **Group 1:** Elective Induction of labour between $40^{1/7}$ to $40^{6/7}$ weeks of gestation.
2. (e-IOL).
3. **Group 2:** Expectant management till 41 weeks of gestation (EM).
4. Group 2 was further subdivided to assess the outcome of different lines of management in the expectant group.
5. **Group 2a:** Who went into spontaneous labour while on expectant management.
6. **Group 2b:** Who were induced while on expectant management for maternal / fetal reasons or ≥ $41^{0/7}$ weeks of gestation.

The Elective induction group 1 was observed for the method of induction used, mode of delivery and neonatal outcomes. All the participants in the elective induction group were offered IOL at $40^{1/7}$ to 40 $^{6/7}$ weeks. The Expectant Management group 2 was monitored with the antenatal fetal surveillance in the form of twice weekly Non-stress test (NST)* and Amniotic fluid index (AFI)*. Expectant management group was further observed for spontaneous onset and progress of labour, need for IOL for maternal or fetal reasons, the mode of delivery and the neonatal outcome. All participants in the expectant management group were offered induction at or immediately after $41^{0/7}$weeks of gestation.

Other intrapartum events such as abnormal cardiotocography (CTG)*, meconium passage and labour progress disorders were noted. Fetal outcomes evaluated were Apgar score at 1 and 5 minutes, baby weight, need for NICU* admission and neonatal problems.

2.3 Statistical analysis

Data entry was done in MS* Excel 2010 and was analyzed using professional statistics package EPI Info 7.0 version for Windows. Descriptive data was represented as mean ± SD for numeric variables, percentages and proportions for categorical variables. Appropriate tests of significance was used depending on nature & distribution of variables like Chi square test, Fisher exact test for categorical variables, independent t test for numerical variables. Values of $p<0.05$ was considered statistically significant.

3. Results

A total of 112 participants were recruited in the study in accordance to sample size calculation. Group 1 had 56 patients who underwent elective induction of labour at 40 1/7to 40 $^{6/7}$ weeks (e-IOL). Group 2 also had 56 participants who were given expectant management till 41 weeks of gestation (EM).

The mean age of participants in e-IOL group 1 was 26.6±3.34 years and EM group 2 was 25.55±2.75 years respectively. Both the groups were comparable (p=0.067). Primigravida and multigravida were comparable in both groups (Table 1).

In the e-IOL group 1, all the 56 participants were induced, whereas in EM group 2, 41 (73.2%) went into spontaneous labour and 15 (26.8%) were induced (Figure 1). In the e-IOL group 1, maximum were induced at 40 $^{2/7}$ weeks of gestation (16 participants, 28.5%) and 40 3/7 weeks of gestation (16 participants, 28.5%). Among the 41 participants in the EM group who went into spontaneous labour (group 2a), 24.4% went into spontaneous labour at 40 $^{2/7}$ weeks (10 participants) followed by 21.9% (9 participants) at 40 $^{1/7}$ weeks of gestation. Amongst EM group 2b (15 participants, 26.8%), 3 participants were induced in view of maternal / fetal reasons and 12 (80%) were induced at 41 weeks of gestation as they did not go into spontaneous labour.

Table 1: Distribution of participants according to gravidity in elective induction group 1 and expectant management group 2

Gravida	Group 1	Group 2
Primigravida	62.5%	71.4%
Multigravida	37.5%	28.6%

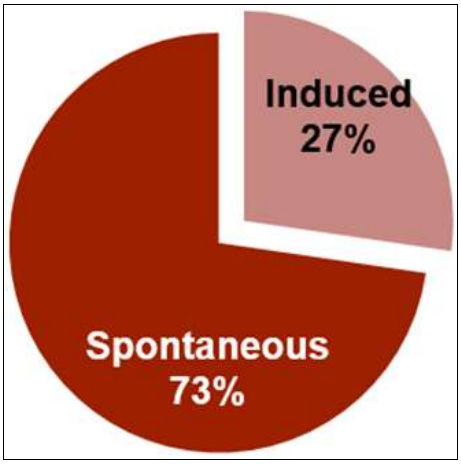

Fig 1: Distribution of participants according to the type of labour in expectant management group 2

In the e-IOL group 1, 23 participants (41.07%) delivered vaginally and 33 underwent caesarean section (58.93%). Whereas in EM group 2, 35 participants delivered vaginally (62.5%) and 21 participants underwent caesarean section (37.5%). There is statistical difference in the mode of delivery (p=0.002) (Figure 2).

In the EM group 2a, 32 participants (78%) delivered vaginally and 9 participants (22%) underwent Caesarean section. Among the 15 participants in the EM group 2b who underwent IOL, 8 of

12 (66.6%) who underwent induction at 41 weeks of gestation ended in Caesarean delivery while one amongst the 3 (33.3%) participants induced due to oligohydramanios on fetal surveillance, underwent Caesarean section.

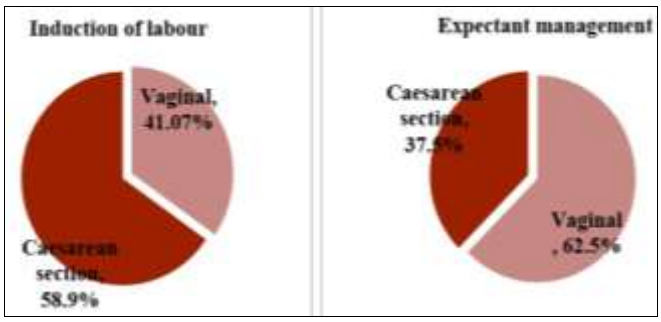

Fig 2: Distribution of mode of delivery in elective IOL group 1 and expectant management group 2

Most participants in the e-IOL group 1 were induced with foley catheter (n 31, 55.3%), followed by 0.5 mg of endocervical dinoprostrone gel (n 17, 30.35%), vaginal misoprostol 25 mcg (n 4, 7.14%), dinoprostone vaginal pessary 10 mg (n 1, 1.78%) and oxytocin infusion (n3,5.35%). Amongst 31 participants induced at 40 weeks of gestation with foley catheter, 15 (48.3%) delivered vaginally while only 3 (17.6%) delivered vaginally after dinoprostrone gel induction. In the EM group 2b, 8 participants who were induced at 41 weeks of gestation with foley catheter, 50% delivered vaginally. 3 participants were induced with dinoprostrone vaginal pessary, all of them underwent Caesarean section for delivery.

In e-IOL group 1 most common indication of Caesarean section was non-progress of labour followed by failure of induction and meconium-stained amniotic fluid (MSF)* and in EM group 2, refusal for further continuation of IOL was the most common indication for Caesarean section.

12 of 56 participants in the e-IOL group 1 had meconium stained liquor. 2 delivered vaginally and 10 underwent Caesarean section. In EM group 2a, 8 participants had meconium stained liqour, out of which 2 delivered vaginally and 6 underwent Caesarean section. And in EM group 2b, 3 patients had meconium stained liquor, and all 3 underwent Caesarean section (Table 2).

Most women had babies weighing between 2.5 and 3.5 kg in e-IOL group 1 (85.7%) and similarly in EM group 2 (87.5%). Only one baby in the EM group 2 had birth weight more than 4 kg (p=0.9) and was delivered vaginally after foleys induction at 41 weeks of gestation. In the e-IOL group 1, 4 neonates were admitted to NICU for tachypnoea; out of which 3 had intrapartum MSF. In the EM group 2, 4 neonates were admitted to NICU, of whom 2 had neonatal tachypnoea, however they did not have intrapartum MSF. No other neonatal problems and neonatal deaths were noted (p=1).

Table 2: Analysis of meconium stained amniotic fluid in elective induction of labour group 1 and expectant management group 2 with the mode of delivery

	Elective induction of labour (group 1)		**Expectant management spontaneous (group 2a)**		**Expectant management induced (group 2b)**	
MSF	Count	N %	Count	N %	Count	N %
Vaginal	2	16.67%	2	12.5%	0	0%
LSCS	10	83.33%	6	75%	3	100%
Total	12	100.0%	8	100.0%	3	100.0%

4. Discussion

The timing of delivery is an important determinant of perinatal outcome. Early induction of labour is thought to expose the mother to a higher risk of operative intervention (Caesarean section) especially in an environment where patience in labor is not the common approach [8]. On the other hand delaying induction in postdate pregnancy increases the incidence of stillbirth, perinatal morbidity and mortality. There is uncertainty on the timing of induction for pregnancies past their due date, leading to practice variation between obstetricians [9]. Formulating the best possible time to deliver a pregnancy necessarily involves balancing risks and benefits. The present study aimed to answer the research question whether induction of labour as compared to expectant management increases Caesarean section rates in pregnancies past their due date in a real-life situation. This observational study was done on 116 participants satisfying inclusion and exclusion criteria. They were recruited at 40 weeks of gestation, 56 participants were recruited in e-IOL group 1 and the other 56 in EM group 2.

The mean age of participants amongst the two groups in the study was comparable. Maximum participants in both the groups were primigravida with no statistical difference amongst the two groups. Nulliparity is a known risk factor for post term pregnancies [10]. Most participants were induced in the first few days of being overdate in the e-IOL group 1 and also in the EM group 2 most went into spontaneous labour in the first few days of being overdate.

Although many past observational studies (Vrouenraets *et al.*) [11] have found a higher risk for adverse outcomes with elective induction, these studies are suggested to have a methodological flaw. Such studies have been designed to compare IOL with spontaneous labor at the same gestational age, a comparison that is not clinically relevant and is potentially misleading. The actual clinical alternative comparator to IOL is not spontaneous labor but rather allowing the pregnancy to progress to a greater gestational age with expectant management [12]. Today, there are many randomized controlled trials (RCTs) which have compared routine IOL at 41 weeks and expectant management. They have found no differences in Caesarean section rates [13-14].

In the present study which compared elective induction of labour at 40 weeks versus expectant management, expectant management till 41 weeks and then inducing labour at 41 weeks of gestation resulted in a significantly higher number of patients having vaginal delivery (62.5%) when compared with patients who were induced at 40 weeks (41.07%).

In the present study foley catheter, dinoprostone gel, vaginal misoprostol or oxytocin alone were the different methods of induction in the e-IOL group 1 whereas foley catheter or dinoprostone vaginal pessary in EM group 2. Foley catheter was used for maximum patients in both the groups. Participants who underwent IOL by foley catheter followed by oxytocin both in the e-IOL and in the EM group were more likely to deliver vaginally compared to prostaglandins.

Waiting till 41 weeks and then inducing labour did not have an effect on meconium staining of liquor in our study. No significant difference in perinatal outcome was noted amongst

those whose labour was induced as compared to those who were expectantly managed.

In the present study we found, expectant management till 41 weeks of gestation increases the likelihood of spontaneous labour without adversely affecting the perinatal outcome with lesser chances of Caesarean section.

5. Limitations

The present study has the limitations of a real-life study where individual consultants had different approaches to clinical situations different methods of induction, different clinical decisions regarding oligohydramnios, but it had the advantage of better representation and assessment of what we normally deal in clinical practice. These results should be seen as an attempt to understand clinical practice in a particular setup.

6. Abbreviations

e-IOL Elective induction of labour; EM: Expectant management; LMP: Last menstrual period; EDD: Expected due date; IOL: Induction of labour; CTG: Cardiotocography; NICU: Neonatal intensive care unit; MSF: Meconium -stained amniotic fluid

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