

# **Research Article**

# Labor induction with dinoprostone or oxytocin versus expectant management for late-term pregnancies

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## Abstract

Objective: To compare outcomes between those who underwent labor induction at 41 weeks gestation with either dinoprostone or oxytocin and those expectantly managed until 42 weeks.

Methods: Chart review was performed. 202 women were either induced at 41 weeks with dinoprostone or oxytocin (depending on favorability of the cervix) or managed expectantly. Baseline characteristics and maternal/neonatal outcomes were compared.

**Results:** Baseline characteristics between groups were similar. Intrapartum course duration (23.6 vs. 11.0 hours, p<0.0001), cesarean delivery rate (68% vs. 14.9%, p<0.0001) and estimated blood loss loss (611 vs. 414 milliliters, p<0.01) were significantly higher in those induced with dinoprostone versus expectantly managed. These outcomes were similar between those induced with oxytocin and expectantly managed (12.6 vs. 11.0 hours, 17.6% vs. 14.9%, 470 vs. 414 milliliters, p=NS). Incidence of fetal heart rate abnormalities was significantly lower (38.3% vs. 63.3%, p<0.001) in those induced at 41 weeks, irrespective of induction agent, than expectantly managed.

**Conclusion:** Labor induction at 41 weeks gestation with oxytocin is associated with similar intrapartum course duration, cesarean delivery rate and estimated blood loss and a lower incidence of fetal heart rate abnormalities when compared to expectant management.

# Introduction

Post-term pregnancy is defined as a pregnancy that has reached 42 weeks gestation. Many practitioners elect to induce labor at 41 weeks gestation given the risks associated with post-term pregnancy such as increases in the incidence of labor dystocia, intrauterine infection, cesarean delivery and perinatal death [1]. However, the management of late-term pregnancies is controversial as it is currently unclear if induction of labor prior to 42 weeks decreases the risk of adverse maternal and neonatal outcomes. Several studies have supported a policy of induction of labor at 41 weeks gestation citing it as being cost-effective and leading to a lower rate of adverse obstetric outcomes including neonatal demise, shoulder dystocia, meconium aspiration and severe perineal lacerations without increasing the cesarean delivery rate when compared to a policy of expectant management until 42 weeks gestation [2]. However, other studies have compared outcomes from induction at 41 weeks gestation and expectant management until 42 weeks gestation and found not only an increased risk of interventions but a higher cesarean delivery rate in the group that underwent induction at 41 weeks [3,4].

Other studies have specifically looked at outcomes in relation to agents used for induction. One study used one of three labor induction techniques (administration of intravaginal misoprostol, administration of oxytocin or placement of intracervical ripening balloon) at 41 weeks gestation and compared these outcomes to that of expectant management until 42 weeks [5]. No increase in the cesarean delivery rate or neonatal morbidity was noted. Another used one of two labor induction techniques (administration of dinoprostone gel or amniotomy) and found results similar to the one mentioned [6]. However, no study to date has examined maternal and neonatal outcomes associated with labor induction at 41 weeks gestation versus expectant management until 42 weeks when the sustained-released 10 milligram dinoprostone vaginal insert and oxytocin are specifically used as labor induction agents, a common regimen in many institutions.

## Methods

This study was an Institutional Review Board-approved retrospective cohort study in concordance with World Medical Association Declaration of Helsinki regarding ethical conduct of research involving human subjects and/or animals. Charts of 202 women who had presented to the Labor and Delivery Unit at Staten Island University Hospital from 2010-2014 were reviewed. All subjects were between 41 and 42 weeks gestation with parity  $\leq$  3, cephalic presentation and no condition requiring urgent delivery. Exclusion criteria were previous uterine surgery, uterine anomaly, exposure to oxytocin, receipt of any cervical ripening agent or tocolytic within 7 days prior to presentation, fetal malpresentation or suspected cephalopelvic disproportion, evidence of fetal compromise at presentation, any condition in which vaginal delivery was contraindicated (*i.e.*, placenta

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previa) and known or suspected allergy to misoprostol, dinoprostone or any other prostaglandin.

Baseline characteristics also recorded were group B streptococcus status (based on rectovaginal culture done at 36 weeks gestational age), ethnicity and body mass index. Gestational age was based on the date of last menstrual period and prenatal ultrasonographic examination at less than 20 weeks.

Group assignment was determined by the initial course of management undertaken: routine induction at 41 weeks gestation or expectant management until 42 weeks gestation with induction as necessary. In the group who underwent routine induction at 41 weeks gestation, dinoprostone was used for induction in those with an unfavorable cervix (Bishop score  $\leq$  4) and oxytocin was used in those with a favorable cervix (Bishop score > 4). Calculation of the Bishop score was based on cervical dilation, effacement, station, position and cervical consistency. The maximum Bishop score was thirteen. Dinoprostone was administered Dinoprostone was removed in the presence of fetal heart rate abnormalities, tachysystole or upon entering active phase of labor. Participants remained in bed for at least two hours after prostaglandin insertion and were continuously monitored for uterine activity and fetal heart rate until delivery. Oxytocin was used for augmentation when unsatisfactory progress of labor occurred. In those who were induced with oxytocin, the infusion was started at 2 mU/min and increased by 2 mU/min every 20 minutes until contractions were 2 minutes apart.

In the expectant management group, women at more than 41 weeks gestation were sent for weekly biophysical profiles. Provided that no abnormalities were found, they were sent home with labor precautions. In case of abnormalities either in the fetal heart rate evaluation or in the biophysical profile, labor was induced. Labor was also induced in all cases of pregnancy exceeding a gestation of 41 weeks and 6 days. Induction was performed in the same way as described in the induction group.

Tachysystole was defined as >5 contractions within 10 minutes averaged over a 30-minute period. Information regarding fetal heart rate tracing abnormalities (recurrent variable decelerations, recurrent late decelerations, prolonged decelerations and absent variability) were obtained from clinical staff notes written every fifteen to thirty minutes during the entire intrapartum course. Cesarean delivery was performed for standard obstetric indications at the discretion of the attending obstetrician.

Mode of delivery (vaginal versus cesarean), estimated blood loss, use of oxytocin for labor augmentation, presence of meconium, adverse outcomes (intrapartum fever, fetal heart rate abnormalities, tachysystole) and neonatal outcomes (birth weight, Apgars at 1 and 5 minutes, NICU admission and arterial cord pH) were also recorded. Diagnoses of arrest of dilatation and descent were made based on the absence of cervical change or fetal descent over two hours in the presence of adequate contractions.

The primary outcome was cesarean delivery rate. Secondary outcomes were intrapartum course duration and estimated blood loss. Student t-test was used to compare continuous variables and the Chisquare test was used to compare proportions between the groups. A p value of less than 0.05 was considered significant.

#### Results

No significant differences were noted between the groups with respect to baseline characteristics (Table 1).

Maternal outcomes are outlined in Table 2. Labor induction at 41 weeks gestation with dinoprostone was associated with a significantly longer intrapartum course duration (p<0.0001), greater estimated

Table 1. Baseline Characteristics.

	Induction (n=101)		Expectant Management (n=101)	P value
	Dinoprostone (n=50)	Oxytocin (n=51)		
Age	27.4 ± 4.7	$27.5\pm4.0$	26.3 ± 5.1	0.08
Parity				0.14
0	43	25	57	
1	6	13	17	
≥2	1	13	27	
Gestational Age	41 ± 0.1	$41 \pm 0.1$	41.6 ± 0.4	0.09
Body mass index	27 ± 5.4	$27 \pm 6.2$	25.4 ± 6.6	0.13
Group B Streptococcus				
Positive	9	12	31	
Negative	39	38	69	
Unknown	2	1	1	
Ethnicity				0.12
Caucasian	31	37	70	
African-American	4	5	14	
Hispanic	5	1	13	
Other	10	8	4	
Initial Bishop Score	2.4 ± 2.2	6.8 ± 1.7	6.3 ± 3.1	

Age, gestational age, initial Bishop score presented as mean ± standard deviation. Categorical factors presented as number of patients.

#### Table 2. Labor Outcomes.

	Induction (n = 101)		Expectant Management (n = 101)	P value
	Dinoprostone ( $n = 50$ )	Oxytocin $(n = 51)$		
Intrapartum course duration (hours)	23.6 ± 9.4	$12.6 \pm 7.2$	11 ± 7.7	< 0.0001* 0.22**
Estimated blood loss (milliliters)	611 ± 301	$470\pm286$	414 ± 208	< 0.01* 0.30**
Fetal heart rate abnormalities	16	23	64	< 0.05
Cesarean delivery Indications for cesarean:	22	9	15	<0.0001* 0.66**
Failed induction	9	1	2	
Non-reassuring fetal heart rate tracing	8	2	7	
Arrest of descent	3	2	2	
Arrest of dilatation	2	4	2	
Not documented			2	
Oxytocin use for labor augmentation	32		17	< 0.01
Amniotomy	69		54	< 0.01
Epidural use	91		88	0.55
Intrapartum temperature	6		9	0.43
Meconium staining	19		27	0.19

Bishop score and estimated blood loss are presented as mean ± standard deviation. Categorical factors presented as number of patients.

#### Table 3. Neonatal Outcomes.

	Induction (n = 101)	Expectant Management (n = 101)	P Value
Birth weight (kg)	3.7 ± 0.4	3.5 ± 0.4	0.09
Number of patients with Apgar score $\ge 9$ at:			
1 minute	98 (97%)	100 (99%)	0.31
5 minutes	98 (98%)	100 (99%)	0.56
Cord pH (arterial)	$7.2 \pm 0.1$	7.1 ± 0.1	0.68
Admitted to NICU	5 (4.9%)	6 (5.9%)	0.78

Birth weight and Cord pH are presented as mean ± standard deviation. Categorical factors are presented as number of patients.

blood loss (p<0.01) and higher cesarean delivery rate (p<0.0001) when compared to expectant management. Labor induction at 41 weeks gestation with oxytocin was associated with a similar intrapartum course duration (p=0.22), estimated blood loss (p=0.30) and cesarean delivery rate (p=0.66) when compared to expectant management. Expectant management was associated with a significantly greater incidence of fetal heart rate abnormalities (p<0.05) and a lower incidence of amniotomy (p<0.01) when compared to labor induction at 41 weeks gestation irrespective of induction agent used. Labor induction at 41 weeks gestation at dinoprostone was associated with a greater incidence of oxytocin use for augmentation when compared with expectant management (p<0.01).

Neonatal outcomes were not significantly different between the two groups (Table 3).

#### Discussion

Post-term pregnancy refers to a pregnancy that has reached or extended beyond 42 weeks gestation. A late-term pregnancy is defined

as one that has reached between 41 weeks and 41 weeks and 6 days gestation [7]. In 2011, the overall incidence of post-term pregnancy in the United States was 5.5% [8].

The etiology of late-term and post-term pregnancies is currently unknown but several risk factors have been proposed including nulliparity, male fetus, maternal obesity and prior post-term pregnancy [9]. Evidence supports that there is an increase in maternal and neonatal morbidity and mortality associated with late-term and post-term pregnancies. In one cross-sectional study of birth registry data between 1978 and 1993 in Denmark, the overall risk of perinatal death was 0.4% in the post-term pregnancy group and 0.3% in the term pregnancy group [10]. Maternal risks include severe perineal lacerations, shoulder dystocia and especially in the presence of an unfavorable cervix risks include prolonged labor, cesarean delivery and postpartum hemorrhage. Given these issues, the management of late-term pregnancies is controversial with multiple studies presenting conflicting results.

A recent Cochrane review analyzed outcomes from 22 trials

and concluded a policy of labor induction compared with expectant management was associated with fewer perinatal deaths and cesarean sections. But, in the face of a very low absolute risk of perinatal death, women should be appropriately counseled in order to make an informed choice between scheduled induction for a late-term pregnancy and expectant management [11]. However, of the many studies that have been performed examining maternal and neonatal outcomes associated with induction and expectant management for late-term pregnancies, only a handful have assessed these measures in relation to induction agent used. However, no study to date has investigated outcomes between routine induction at 41 weeks gestation and expectant management until 42 weeks gestation when the dinoprostone vaginal insert and oxytocin are specifically used as labor induction agents.

In our study, we found that induction of labor in the presence of an unfavorable cervix with dinoprostone was associated with a significantly longer intrapartum course duration and a higher cesarean delivery rate and estimated blood loss when compared with expectant management. Of those patients who underwent cesarean delivery in the dinoprostone group, 45% were nulliparous. This is in contrast to findings by Cheng et al. [12], in which induction of labor in low-risk women at term is not associated with increased risk of cesarean delivery. However, this study did not assess delivery in outcomes in relation to favorability of the cervix unlike a study by Johnson et al. [13] in which the cesarean delivery rate was found to be as high as 31.5% among patients whose Bishop score was less than 5. However, intrapartum course duration, cesarean delivery rate and estimated blood loss were similar between those induced in the presence of a favorable cervix with oxytocin and those expectantly managed. Although, fetal heart rate abnormalities were significantly higher in those who were expectantly managed than those who were induced, ultimately, cord arterial pH, Apgar scores and incidence of NICU admissions were not significantly different between these two groups. This lack of difference in neonatal outcomes is analogous to that found in a meta-analysis performed by Wennerholm et al. [14] in which elective induction of labor was not associated with lower risk of perinatal mortality compared to expectant management. These results are compelling to those proponents of expectant management who cite routine induction as potentially increasing the risk of cesarean delivery and in adding clarity to this point of view. Our study provides data indicating that there is a role in routine induction at 41 weeks gestation in the presence of a favorable cervix thus providing obstetricians valuable information in the process of patient counseling. Additionally, our institution carries a cesarean delivery rate of approximately 20%, one that is lower than the current national cesarean rate of 33% [15] and these results provide key points in minimizing this cesarean delivery rate even further. Supporters of routine induction at 41 weeks regardless of favorability of the cervix will also find these results intriguing in that the intrapartum course duration in those induced with an unfavorable cervix was twice as long as those who were expectantly managed and the cesarean delivery was approximately 4.5 times higher.

The major limitation of this study is its retrospective design. Patients were allocated to a particular course of care by their attending obstetrician, rather than being randomly assigned. Since an individual clinician's management style affects their decision to induce or not to induce as well as the decision to proceed to cesarean delivery, this may have introduced selection bias and influenced our results. However, at our institution the majority of obstetricians practice in groups that share Labor and Delivery coverage. This aids in reducing the impact of any one obstetrician's management style on our results.

A prospective clinical trial will need to be performed in order to elucidate and subsequently generalize the findings from this study. However, data from this observational study do indicate that induction of labor in the presence of an unfavorable cervix is associated with a longer intrapartum course and higher cesarean delivery rate and estimated blood loss when compared to expectant management while induction of labor in the presence of a favorable cervix is associated with a similar intrapartum course duration, cesarean delivery rate and estimated blood loss compared to expectant management.

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