Comparison between Induction of Labor and Expectant Management in Post-Date Pregnancy

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Abstract:

Background: Post-date pregnancy is associated with increased perinatal morbidity and mortality. Therefore post-date pregnancy is considered as a high-risk condition which requires specialist surveillance and induction of labor at some stage. **Purpose:** to evaluate if a policy of induction of labor at 41 GW is superior, in terms of neonatal and maternal outcomes, as compared to expectant management in healthy women with a low risk singleton pregnancy. **Materials and Methods**: a case control study. The study included 2 groups: group 1 (n = 50) including women who waited for spontaneous labor till 42 weeks (expectant management); group 2 (n=50) including women who had induction of labor at 41^{+0} to 41^{+6} weeks. **Results:** This study shows that MAS occurred in significantly more neonates in the expectant group as compared to the induction group. There were no significant differences between the two groups regarding APGAR score and other perinatal outcomes. Also, this study shows that the rate of CS was significantly higher in the induction group than in expectant group, also the need for analgesia was significantly higher in the induction group as compared to the expectant group. **Conclusion:** it can be concluded that induction of labor at 41 completed weeks carries no increased risk of perinatal mortality or morbidity when compared to expectant management until 42 completed weeks. The policy of labor induction may be associated with an increase rate of CS and the need for analgesia.

Keywords*:* Post-date pregnancy – Induction of labor – Post-term pregnancy

Abbreviations:

GW: gestational week

MAS: meconium aspiration syndrome

CS: Caesarean section

Introduction

According to World Health Organization (WHO), post-date or post-term pregnancy is defined as pregnancy duration of 294 days or longer i.e. gestational week (GW) 42 and 0 days (42+0) or more measured from the first day of the last menstrual period.

Post-date pregnancy is associated with increased perinatal morbidity and mortality [1]. Therefore post-date pregnancy is considered as a high-risk condition which requires specialist surveillance and induction of labor at some stage.

The etiology of post-date birth is largely unknown. Some rare, known causes of post-date birth are fetal anencephaly, fetal adrenal hypoplasia or insufficiency and placental sulphatase deficiency. Risk factors for post term birth include: primiparity, advanced maternal age, maternal obesity, heredity, previous post term pregnancy, and a male fetus [2].

Perinatal mortality (PNM) is defined as the prevalence of stillbirth (after GW 28+0) and neonatal mortality within 7 days after birth ***[3]***. PNM is increased in women with post-date pregnancies as compared to women with term pregnancies **[4].**

The risk of perinatal complications such as meconium aspiration syndrome (MAS), umbilical cord complications, asphyxia, pneumonia, sepsis, convulsions, shoulder dystocia, traumatic injuries and peripheral nerve damage is higher in post-date deliveries than in deliveries at term **[4].** Also a higher risk of neonatal encephalopathy is noted in children born post-date [5].

Maternal complications increase from GW 40. The risk of puerperal infections, postpartum bleeding, disproportion, labor dystocia, emergency caesarean sections, and cervical lacerations was higher for post-date than for term pregnancies **[4].**

From the present study, it can be concluded that induction of labor at 41 completed weeks carries no increased risk of perinatal mortality or morbidity when compared to expectant management until 42 completed weeks.

The policy of labor induction may be associated with an increase rate of CS and the need for analgesia.

It is therefore recommended to offer induction of labor at 41 completed weeks to low risk women.

If the woman chooses to wait for spontaneous labor onset it would be prudent to have regular fetal monitoring.

Patients and Methods

Design:

The prospective study was performed at Shebin El-kom Teaching Hospital during the period between September 2016 and October 2017.

Sample size justification:

A total number of 100 pregnant women were included in the study and were divided into 2 groups:

1- ***Group (1):*** consists of 50 women who underwent expectant management and awaited for spontaneous onset of labor until 42 weeks
2- ***Group (2):*** consists of 50 pregnant women who underwent induction of labor at 41^{+0} or 41^{+6} weeks

Inclusion criteria:

1- Obstetrical low risk women ≥ 18 years with a singleton pregnancy in stable cephalic presentation.
2- Gestational age of ≥ 41 weeks without contra-indications for expectant management until 42 weeks. Gestational age was calculated from the first day of last normal menstrual cycle (if reliable) or by using data from early ultrasound (if present).

- **Exclusion criteria:**

1- Age <18 years
2- Uncertain gestational age
3- High risk pregnancy (e.g. hypertension, Proteinuria (≥3 g/L), Pre-existent maternal heart or kidney diseases, gestational diabetes,
4- Previous Caesarean section
5- Multiple pregnancy, intra-uterine growth retardation and non-reassuring fetal status (no fetal movements, abnormal fetal heart rate, known fetal abnormalities which could influence perinatal outcome, including abnormal karyotype, ruptured membranes at time of randomization and a non-reassuring fetal status at time of randomization).

Methods:

After obtaining an informed consent to participate in the study that was approved by ethical community of Shebin El-Kom Hospital. It was allocated to either induction of labor or wait for spontaneous onset of labor until 42 weeks, the following assessment was done for every woman in the study:

I- History:

Detailed history including:

- Personal history:

Maternal age and socioeconomic state.

- Obstetric history: details of each previous pregnancy and delivery, Gravidity and parity, Antenatal period, Labor onset, Mode of delivery, Outcome

(maternal and perinatal) and history of past-date pregnancy.

- Menstrual history:

- Regular cycles before pregnancy.
- 1st day of LMP.

- *Family history.*
- *Maternal medical history:*

DM, Hypertension, Coagulopathies.

II- Examination:

- General examination:

Full general examination was done with special concern to:

- Vital signs (BP, pulse, temperature, and respiratory rate).
- Chest and heart examination.
- Height, weight to calculate the BMI.

- Abdominal examination:

For assessment of the gestational age, fetal size, amount of liquor, fetal lie and presentation, fetal heart sound, uterine contractions, scar of previous surgeries.

- Vaginal examination:

- To exclude cephalopelvic disproportion, to identify the presenting part, to exclude any cause making vaginal delivery contraindicated.
- Assessment of the cervix by modified Bishop Score (based on cervical dilatation, effacement, consistency, and position plus head station).

III- Routine laboratory investigations:

e.g. CBC, RH, urine analysis and RBS.

IV- Obstetric ultrasound and fetal biophysical profile.

V- NST to document reassuring fetal heart rate.

VI- Intervention

In induction group, 50 women with GA ≥ 41 weeks were randomly selected & referred to the labor ward for induction of labor.

Women with a cervix that is judged to be 'ripe' at vaginal examination (Bishop Score of 6 or more), had labor induced with amniotomy followed by intravenous oxytocin. In case of unripe cervix, cervical ripening will be accomplished by vaginal dinoprostone tablet 3 mg (repeated after 6-8 hours with a second tablet if patient didn't respond to the first dose with a maximum dose of 6 mg) followed by augmentation by oxytocin.

- In expectant group, 50 women who were allocated to expectant management awaiting spontaneous onset of labor until 42 weeks were admitted to the inpatient ward, and they were followed up by daily fetal movement count, NST every other day and biophysical profile every 3 days.

During the follow up if a non-reassuring fetal status is found termination of pregnancy was done. In this group if the woman didn't deliver by 42 weeks she was subjected to cesarean section.

Data on first, second and third stage of labor were collected through the partogram. Perinatal and maternal mortality and morbidity were recorded.

Outcome measures

Primary outcome was a composite of perinatal mortality and neonatal morbidity (meconium aspiration syndrome, birth trauma, and perinatal asphyxia and/or NICU admission).

Secondary outcomes were maternal outcomes such as operative delivery (operative vaginal delivery, Caesarean section), need for analgesia (epidural, remifentanil, pethidin), post-partum hemorrhage and severe perineal injury (third- or fourth-degree perineal tear).

Statistical analysis:

Data will be collected, tabulated, then analyzed on a personal computer using IBM SPSS© Statistical version 21 (IBM© Corp., Armonk, NY).

The Kolmogorov-Smirnov goodness of fit test will be used to test the normality of numerical data distribution. Normally distributed numerical data will be presented as mean and SD and differences between the two groups will be compared with the independent- sample t test.

Skewed numerical data will be presented as median and interquartile range and inter group differences will be compared non-parametrically using the Mann-Whitney U test. Qualitative data will be presented as number and percentage and the chi square test or Fisher's exact test, when appropriate, will be applied for comparison of the two groups. All P values will be two-tailed. If P value is less than 0.05, it will be considered statistically significant.

RESULTS

This case-control study was performed on 100 pregnant women attending casualties and outpatient clinics of Shebin El-Kom Teaching Hospital. The study was performed to assess if induction of labor at 41 weeks results in better perinatal and maternal outcomes than expectant management until 42 weeks.

The study included 2 groups: group 1 (n = 50) including women who waited for spontaneous labor till 42 weeks (expectant management); group 2 (n=50) including women who had induction of labor at 41^{+0} to 41^{+6} weeks.

Table (1): Demographic data of the studied cases

		No. = 100
Age (years)	Range	18 – 42
	Mean ± SD	26.34 ± 6.82
	< 35 years	82 (82%)
	> 35 years	18 (18%)
BMI (kg/m^2)	Range	19 – 32
	Mean ± SD	23.70 ± 3.32
	< 25	61 (61%)
	> 25	39 (39%)
Parity	Primiparous	49 (49%)
	Multiparous	51 (51%)
History of past date pregnancy among multiparous	No	21 (41.2%)
	Yes	30 (58.8%)

Table (2): Comparing maternal demographics in expectant group and induction group

		Expectant No. = 50	Induction No. = 50	Test value	P-value	Sig.
Age(years)	Range	18 – 42	18 – 39	2.087•	0.039	S
	Mean ± SD	27.74 ± 7.14	24.94 ± 6.24			
	< 35 years	38 (76%)	44 (88%)	2.439*	0.118	NS
	> 35 years	12 (24%)	6 (12%)			
BMI(kg/m^2)	Range	19 – 30	19 – 32	1.703•	0.092	NS
	Mean ± SD	24.26 ± 3.31	23.14 ± 3.27			
	< 25	26 (52%)	35 (70%)	3.405*	0.065	NS
	> 25	24 (48%)	15 (30%)			
Parity	Primiparous	18 (36%)	31 (62%)	6.763*	0.009	HS
	Multiparous	32 (64%)	19 (38%)			
History of past date pregnancy among multiparous	No	14 (43.8%)	7 (36.8%)	0.235*	0.628	NS
	Yes	18 (56.2%)	12 (63.2%)			

Table (3): Comparing neonatal outcomes between the expectant group and the induction group

		Expectant		Induction		Test value *	P-value	Sig.
		No.	%	No.	%			
APGAR score at 5 min	Range	3 – 10		3 – 10		-1.158ǂ	0.247	NS
	Median (IQR)	9 (8 – 10)		9 (8 – 10)				
Perinatal mortality	No	49	98%	50	100%	1.010	0.315	NS
	Yes	1	2%	0	0%			
MAS	No	43	86%	49	98%	4.891	0.027	S
	Yes	7	14%	1	2%			
Birth trauma	No	49	98%	50	100%	1.010	0.315	NS
	Yes	1	2%	0	0%			
Perinatal asphyxia	No	49	98%	48	96%	0.344	0.558	NS
	Yes	1	2%	2	4%			
NICU admission	No	43	86%	46	92%	0.919	0.338	NS
	Yes	7	14%	4	8%			

Table (4): Comparing maternal outcomes between the expectant group and the induction group

		Expectant		Induction		Test value *	P-value	Sig.
		No.	%	No.	%			
Mode of delivery	spontaneous vaginal delivery	38	76.0%	30	60.0%	2.941	0.086	NS
	Operative vaginal delivery	4	8.0%	3	6.0%	0.154	0.694	NS
	Cesarean section	8	16.0%	17	34.0%	4.32	0.037	S
Need for analgesia	No	39	78%	28	56%	5.473	0.019	S
	Yes	11	22%	22	44%			
PPH	No	46	92%	46	92%	0.000	1.000	NS
	Yes	4	8%	4	8%			
Severe perineal injury in vaginal delivery	No	41	97.6%	32	97.0%	0.030	0.862	NS
	Yes	1	2.4%	1	3.0%			

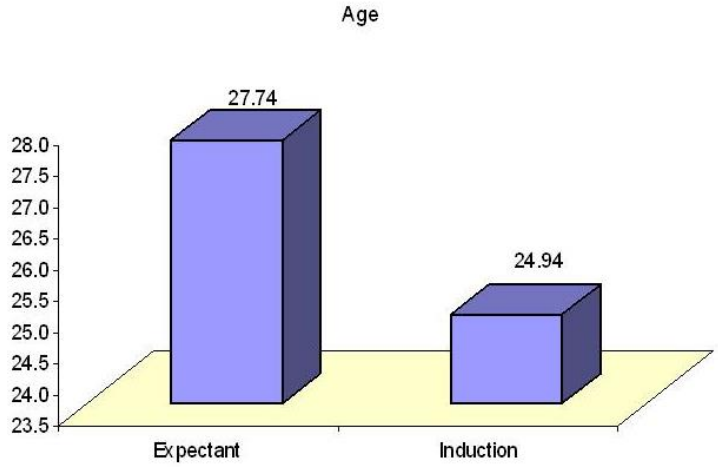

Figure (1): Comparison between expectant and induction regarding age

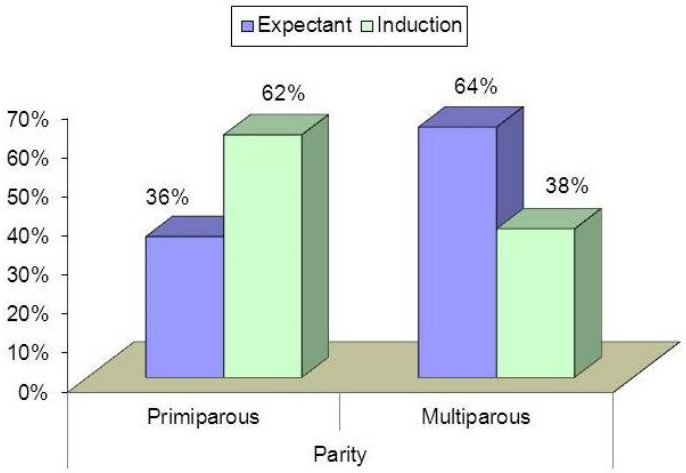

Figure (2): Comparison between expectant and induction regarding parity

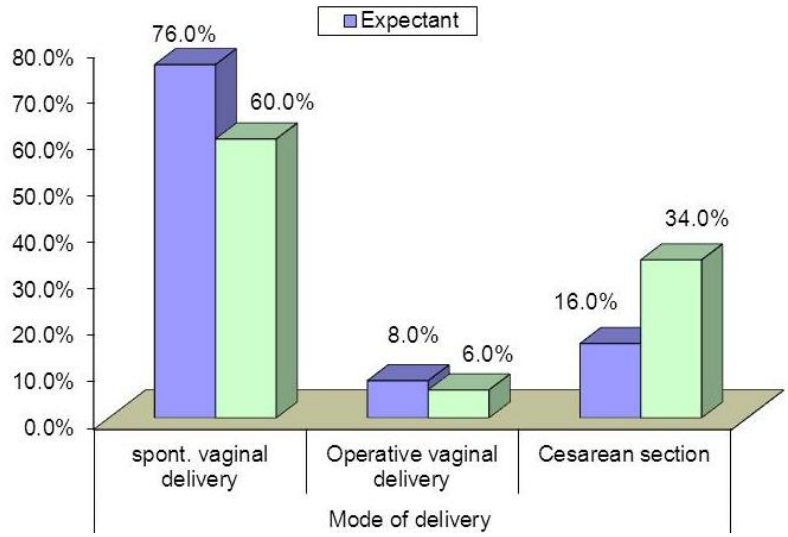

Figure (3): Comparison between expectant and induction regarding mode of delivery

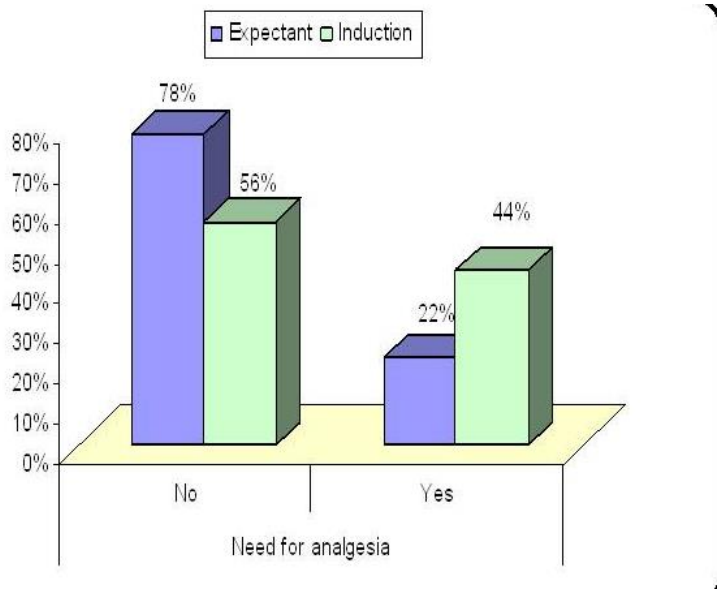

Figure (4): Comparison between expectant and induction regarding need for analgesia

Discussion

This randomized controlled clinical trial was performed at Shebin El-Kom Teaching Hospital during the period between (Sept. 2016 & Oct. 2017). One hundred pregnant women with gestational age 41 weeks or more were included in the study and were divided into two groups:

- 1st group (induction group):50 patients randomized to induction of labor.
- 2nd group (expectant group):50 patients allocated to expectant management

waiting for spontaneous onset of labor until 42 week.

The study aimed at comparing perinatal and maternal outcomes in both policies.

The main finding in this study is that there was no significant difference in perinatal mortality between induction of labor at 41 weeks' gestation or later as compared to expectant management (test value 1.010, P value 0.315), there was only one perinatal death in this study 2ry to asphyxia in the expectant group. This results is in accordance with the results obtained there is no significant difference between the two groups regarding stillbirths as the percent of stillbirths in their 2 groups was 0.02. [6] However in 2016 a paper published in ELSEVIER Sexual & Reproductive Healthcare journal titled (Has perinatal outcome improved after introduction of a guideline in favor of routine induction and increased surveillance prior to 42 weeks of gestation?) showed that the perinatal mortality rate remained steady in 2009, 2010 and 2011 (0.10 %), but was reduced from 10 cases in 2010 to three cases in 2012(60% reduction). However, this reduction was not statistically significant (p = 0.10**)** [7]**.**

In the current study, it was found that induction of labor compared with expectant management was associated with a significantly lower risk of meconium aspiration syndrome (test value 4.891, P value 0.027). This result is in keeping with the results reported that induction of labor was associated with fewer infants with meconium aspiration syndrome compared with expectant management (RR: 0.43; 95% CI: 0.23_0.79). [8] However, meconium aspiration syndrome is a poor indicator of neonatal stress, and most newborns with meconium aspiration syndrome recover and remain healthy. So, there was no significant difference in intensive care unit admissions between induction of labor or expectant management groups (test value 0.919 P value 0.338). These results are in keeping with results reported no significant difference between the two groups regarding admission of the newborn to NICU. [9, 10]

This study shows no significant difference between the two groups regarding perinatal asphyxia (test value 0.344, P value 0.558), APGAR score less than 7 at 5th minute after delivery (test value -1.158ǂ, P value 0.247) or the rate of birth trauma (test value 1.010, P value 0.315) these results are in keeping with results that there is no significant difference between the two groups regarding perinatal asphyxia, APGAR score at 5 minute and the rate of birth trauma in

women who completed 41 weeks and 42 weeks.[11]

The rate of cesarean section in this study is significantly higher in the induction group than the expectant group (test value 4.320, P value 0.038) and these results are similar to the rate of cesarean deliveries was significantly higher in the induction group (33.8% vs. 21.1%, P value 0.001).[12] These results also are in keeping with results found that the incidence of CS was significantly higher in the induction group, 22.2% versus 12.1% (OR 2.06; 95% CI 1.93–2.2).[6] Results were also similar to the current study results regarding the higher cesarean delivery rate (p<0.0001) when compared to expectant management. [10] However, results that compared expectant management and induction at 42 week with induction of labor at 41 week and found that the rate of caesarean sections in the two groups were 14.1% and 11.4%, respectively (p = 0.01).[9]

The present study showed significant difference between the two groups regarding the need for analgesia (epidural, remifentanil, pethidin), there were higher need for analgesia in the induction group (44%) compared with (22%) in the expectant group (test value 5.473, P value 0.019). These results are in keeping with results showed significant difference in the epidural use between the induction and expectant groups (33.5% versus 21.9%),[6] but differ from results showed no significant difference between the two groups regarding epidural use (P value 0.55).[10]

The other maternal outcomes in the current study showed no significant difference between the two groups: operative vaginal delivery (test value 0.154, P value 0.695), PPH (test value 0.000, P value 1.000) and perineal injury (test value 0.000, P value 1.000). These results apart from perineal lacerations are in keeping with results showed no significant difference between the two groups regarding PPH and operative vaginal delivery but they showed significantly higher perineal injuries in the induction group (38.1%) compared with (26.4%) in the expectant group(P value 0.002).[12] Also, results showed no significant difference between the two groups regarding PPH and 3rd or 4th degree perineal tear and this is similar to the present study results.[6] Also, results showed no significant difference between the two groups regarding instrumental deliveries (P value 0.69).[9] There was no significant difference between the two groups regarding Vacuum extraction (p value 0.15). [7] The results of the present study regarding PPH and operative vaginal delivery were also

similar to results that showed no significant difference between the two groups as regard assisted vaginal delivery (P = 0.65) or PPH (P = 0.99).[11]

Conclusion

From the present study, it can be concluded that induction of labor at 41 completed weeks carries no increased risk of perinatal mortality or morbidity when compared to expectant management until 42 completed weeks.

The policy of labor induction may be associated with an increased rate of CS and the need for analgesia.

It is therefore recommended to offer induction of labor at 41 completed weeks to low risk women.

If the woman chooses to wait for spontaneous labor onset it would be prudent to have regular fetal monitoring.

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