

A Prospective Study Of Induction Of Labour Versus Expectant Management For Pregnancies Beyond 40 Weeks Of Gestation

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Abstract- Introduction: Recent studies show increased incidence of perinatal morbidity and mortality with increase in gestational age but there is uncertainty on the policy concerning the timing of induction for prolonged pregnancy or impending post term pregnancy, leading to practice variation between caregivers. Managing pregnancies continuing beyond their due dates remains to be tricky situation for obstetrician. Present study aims to analyze and compare various maternal and neonatal parameters in pregnancies beyond expected date of delivery.

Study design: This was prospective observational study. 270 low risk primigravida at 40 weeks of gestation were included in the study and were divided into two groups of 135 each.

Group I- patients were admitted and induced at 40 weeks and onwards till 40+6 weeks.

Group II- comprised of patients who were expectantly managed till 40+6 weeks and then induced, if required.

Various maternal and neonatal parameters were studied in above two groups.

Result: Patients managed expectantly till 40 +6 weeks had significantly higher vaginal delivery rate compared to patients induced at 40 weeks onwards. Similarly the incidence of meconium staining of liquor, caesarean section rate and its associated morbidity was higher in induction group. Neonatal morbidity and mortality were comparable in both the groups.

Conclusion: Expectantly managing pregnancies till 41 weeks allows patients to go into spontaneous labour and reduces operative deliveries whereas early induction increases rate of operative delivery.

I. INTRODUCTION

Term pregnancy is defined as gestation from 37 completed weeks to 42 completed weeks. Thus, it is five weeks gestational age range. The research has shown that neonatal outcomes, especially respiratory morbidity vary depending on the timing of delivery within this five week gestational age range. Post term or prolonged pregnancy is one that extends to or beyond 42 weeks of gestation. Prolonged pregnancy rates vary from 9.5% to 33.7%^(1,2).

The placenta, as it ages becomes thinner, and shows increasing amounts of infarcts and fibrin deposition with calcification. Such a placenta will have reduced reserve capacity. The inadequacy of placental function under situations of stress as in labour, predispose to foetal hypoxia. The foetal growth gets restricted due to deficient placental transfer. There will be significant decrease in amount of amniotic fluid. Aging of the gut and hypoxic insult leads to release of meconium into the amniotic cavity⁽³⁾.

Pregnancies carrying beyond 40 weeks of gestation tend to develop oligohydramnios, placental insufficiency and doppler changes. Oligohydramnios and placental insufficiency tends to increase the rates of perinatal mortality and morbidity. Both antepartum foetal jeopardy and intrapartum foetal distress were the consequence of cord compression associated with oligohydramnios and placental insufficiency.

Induction of labour is defined as the process of artificially stimulating the uterus to start labour. The prerequisite for successful induction of labour is good bishop score. Mechanical methods used for cervical ripening and induction of labour are membrane stripping, laminaria tents, transcervical Foley's catheter with or without ethacridine. Medical methods used are dinoprostone gels (PGE₂), misoprostol (PGE₁) tablets orally or vaginally, antiprogesterone drug mifepristone (RU 486) and intravenous infusion of oxytocin. Surgical methods include artificial rupture of membranes which cause release of prostaglandins which helps in augmentation of labour⁽³⁾.

Induction of labour is not risk free, and many women find it uncomfortable⁽⁴⁾. In addition, labour induction for maternal indications such as oligohydramnios, polyhydramnios, maternal diabetes, foetal growth restriction, preeclampsia, antepartum bleeding and pre labour rupture of membranes at term is prevalent with an optimism that it would significantly reduce maternal and foetal morbidity⁽⁵⁾. Foetal indications for induction of labour are prolonged pregnancy, foetal growth restriction and maternal diabetes etc.

The beneficial effect of labour induction in term pregnancy has always been controversial. However, in post term pregnancy it has shown to improve maternal and foetal outcome.

An earlier induction potentially can, expose the mother to operative intervention, and its morbidity while delaying the induction increases chance of foetal distress and perinatal morbidity⁽²⁾.

This study aims to assess the foeto-maternal outcome, advantages and disadvantages of induction versus expectant management of pregnancy between group of women induced at 40+1 to 40+6 weeks of gestation with group of women that were expectantly managed upto 41 weeks of gestation and then induced.

II. MATERIALS AND METHODS

The present study was designed to evaluate the foeto-maternal outcome, advantages and disadvantages of induction versus expectant management of pregnancy between group of women induced between 40+1 to 40+6 weeks of gestation with group of women that were expectantly managed upto 40+6 weeks of gestation and then induced if required.

Subjects fulfilling our inclusion and exclusion criteria and willing to participate in the study were enrolled after obtaining written informed consent. The study was approved by the ethics committee of the institution.

Study design: Prospective observational study

Study duration: October 2018 to September 2020

Study centre: Obstetrics and gynaecology department of tertiary care centre in central India.

Sample size: Total 270 ie 135 in each group

1. Inclusion criteria

- a. Women attending ANC OPD and getting admitted in labour ward with confirmed 40 weeks of gestation by menstrual history and early ultrasound.
- b. Age group 18-35 years
- c. Primigravida
- d. Bishop score < 6
- e. Patients not in labour
- f. No premature rupture of membranes at the time of admission

2. Exclusion criteria

- a. Scarred uterus
- b. Non cephalic presentation
- c. Multifetal pregnancy
- d. Intrauterine growth restriction
- e. Oligohydramnios/ polyhydramnios
- f. Antepartum haemorrhage
- g. Comorbid conditions like PIH, GDM, asthma
- h. Anomalous babies
- i. Cephalopelvic disproportion
- j. Abnormal CTG

Methodology

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Women attending Antenatal care OPD of this institution who fulfilled the inclusion and exclusion criteria were enrolled for the study. During counselling patients were explained regarding nature of our study and the two groups and willingness to join either group I or group II was obtained. All patients underwent thorough clinical examination and per vaginal examination. Findings in regards to bishop score were noted on admission. Those who opted to get induced between 40+1 to 40+6 weeks of gestation were allotted group I and those who wanted to get expectantly managed till 41 weeks and then induced if required were allotted group II. Group I comprised of 135 patients and group II comprised of 135 patients. All patient belonging to group I were advised to get admitted at 40 weeks. Patients were induced next day of admission after necessary preparations as per our routine hospital protocol. All group II patients ready for expectant management till 40+6 weeks were admitted at 40 weeks and expectantly managed till 40+6 weeks. Those who did not deliver even after 40+6 weeks were induced at 41 weeks and thereafter. Thus group II was subdivided into group IIa which comprised of patients delivering spontaneously during expectant management upto 40+6 weeks and group IIb comprised of patients who required induction at 41 weeks and thereafter. All patients in group I and those requiring induction in group II were induced by transcervical Foley's catheterization No.18 and inflating balloon with 50cc of normal saline and simultaneously keeping tablet misoprostol 25 microgram in posterior fornix of vagina. Tablet misoprostol 25 microgram was repeated every four hourly for maximum 4 doses till patient starts getting good uterine contractions. Once the patients cervix becomes 3-4 centimetre dilated with good uterine contractions, artificial rupture of membranes was done to see colour of liquor and to augment the labour. Those patient who did not start uterine contractions even after 4 doses of tablet misoprostol were labelled as cases of failed induction and were taken for caesarean section in both the groups.

The following maternal and neonatal parameters were noted down:

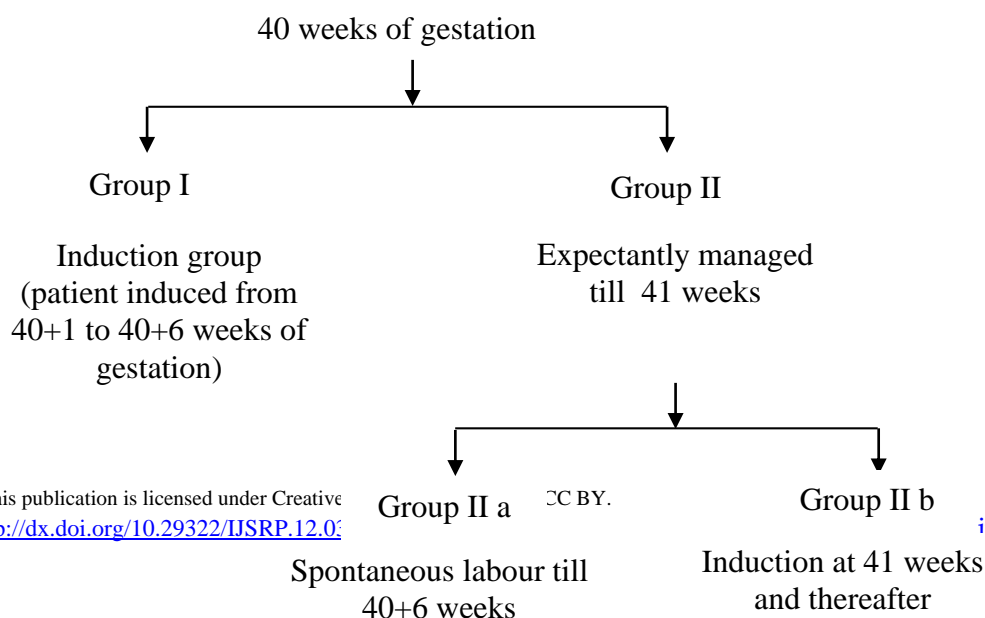
MATERNAL OUTCOME

1. Mode of delivery
 - Vaginal delivery
 - Instrumental delivery
 - Caesarean section
2. Hyperstimulation, tachysystole and foetal distress
3. Prelabour rupture of membranes
4. Colour of liquor
5. Postpartum haemorrhage

NEONATAL OUTCOME

1. APGAR score at 1minute and 5 minutes
 2. Weight of neonate
 3. NICU admission for indications like birth asphyxia, meconium aspiration syndrome, transient tachypnea of newborn and sepsis, etc
 4. Perinatal mortality (still birth, early neonatal death)
- Neonates admitted in NICU were followed up till discharge/death.

SCHEMATIC REPRESENTATION OF DIVISION BETWEEN TWO GROUPS



III. RESULTS

In present study, mean age in group I and group II was 26.17±3.08 and 26.24±3.18 respectively, the difference was statistically not significant. The mean period of gestation in group I and group II was 40.3±2.2 and 41±0.1 respectively, the difference was statistically significant between two groups.

Comparison of bishop score :

Bishop score	Group I(induced group) N=135	Group II (expectantly managed group) N=135		
		Group IIa N=96	Group IIb N=39	Total N=135
≤3	81(60%)	60(62.5%)	17(43.5%)	77(57.03%)
3-6	54(40%)	36(37.5%)	22(56.4%)	58(42.96%)

Parameters	Group I	Group II	P value
Age	26.17±3.08	26.24±3.18	Not significant
Period of gestation	40.3±2.2	41±0.1	0.0001

In our study, 81(60%) patients with bishop score ≤3 were from group I (induction group), 60(62.5%) patients belonged to group IIa (observation till 40+6 weeks) and 17(43.5%) patients were from group IIb (induction at 41 weeks and thereafter). Similarly, distribution of patients with bishop score between 3-6 for group I, group IIa and group IIb was 54 (40%), 36 (37.5%) and 22 (56.4%) patients respectively. Thus, in group II 81(60%) patients had bishop score ≤3 and 54(40%) patients had bishop score between 3-6. The p-value is 0.210 which is not significant, suggesting distribution of patients with bishop score of ≤3 in both the groups was comparable. Similarly distribution of patients having bishop score between 3-6 in both the groups was also comparable.

Comparison of mode of delivery:

Mode of delivery	Group I (induction group) N=135	Group II (expectantly managed group) N=135			P value Test performed
		Group IIa N=96 (observation till 40+6 weeks)	Group IIb (induced at 41 weeks and thereafter) N=39	Total N=135	
Vaginal delivery	90(66%)	85(88.54%)	30(76.92%)	115(85.1%)	Fischer exact test 0.001 for vaginal delivery 0.085 for caesarean section
Instrumental delivery (vacuum delivery and forceps delivery)	3(2.22%)	0	0	0	
LSCS	42(33%)	11(11.4%)	9(23.07%)	20(14.8%)	

Of 135 patients belonging to group I (induction group) 90 (66%) patients delivered vaginally, 42 (33%) required caesarean section and 3 (2.22%) were instrumental deliveries.

Similarly, out of 135 patients belonging to group II (expectantly managed group), 96 (71.1%) patients (group IIa) went into labour spontaneously out of which, 85 (88.54%) delivered vaginally while 11 (11.4%) patients required caesarean section.

Whereas, out of 39 (28.8%) patients (group IIb) who required induction at 41 weeks and thereafter, 30 (76.92%) patients delivered vaginally and only 9 (23.07%) patients required caesarean section. Thus in group II, out of 135 patients 115 (85.1%) patients delivered vaginally and 20 (14.8%) patients underwent caesarean section.

The p value of the table was 0.085 for caesarean section which is significant, suggesting that there is statistically significant difference between number of caesarean section in above two groups.

Indications of caesarean section in different groups

Indication of LSCS	Group I (induction group) N=42	Group II (expectantly managed group)		Total N=135
		Group IIa (observation till 40+6 weeks) N=11	Group IIb (induction at 41 weeks) N=9	
Meconium stained liquor	16(38.09%)	6(54.5%)	1(11.1%)	7(35%)
Non progression of labour	10(23.8%)	0	4(44.4%)	4(20%)
Failed induction	13(30.9%)	Not applicable	0	0
Foetal distress	3(7.1%)	5(45.4%)	4(44.4%)	9(45%)

In present study, out of 135 patients in group I, 42 patients required caesarean section of which 16 (38.09%), 10 (23.8%), 13 (30.9%) and 3 (7.1%) underwent caesarean section for meconium staining of liquor, non-progression of labour, failed induction and foetal distress respectively.

Similarly, out of 135 patients in group II, 20 patients required caesarean section of which 7 (35%), 4 (20%) and 9 (45%) underwent caesarean section for meconium stained liquor, non progression of labour and foetal distress respectively.

Comparison of maternal parameters:

Maternal parameters	Group I(induction group)	Group II(expectant managed group)
PROM	4(2.9%)	13(9.6%)
Tachysystole and hyperstimulation	3(2.2%)	2(1.4%)
Post partum haemorrhage	10(7.4%)	8(5.9%)
Prolonged labour	23(17.03%)	8(5.9%)
Fever	12(8.8%)	4(2.9%)
Wound infection	5(3.7%)	1(0.7%)

The above table shows comparison of different maternal parameters in two groups. Incidence of prolonged rupture of membranes was only 2.9% in group I compared to 9.6% in group II. The difference was statistically significant (p value- 0.04) suggesting higher incidence of prolonged rupture of membranes in expectantly managed group. Similarly, incidence of prolonged labour was 17.03% in group I compared to 5.9% in group II (pvalue-0.004) suggesting more incidence of prolonged labour in group I. 8.8% and 2.9% in group I and group II respectively had fever. The p value is 0.037 which is significant suggesting the incidence of fever is more in group I compared to group II. Incidence of wound infection in group I and group II was 5(3.7%) patients and 1(0.7%) patient respectively. The p value for table is 0.03 which is significant.

Comparison of colour of liquor:

Colour of liquor	Group I(induction group)	Group II(expectantly managed group)
Clear liquor	116(85.3%)	120(88.8%)
Meconium stained liquor	19(14.07%)	15(11.1%)

The above table shows that 19 (14.07%) patients in group I and 15 (11.1%) in group II had meconium staining of liquor, out of 15 patients of group II 11(11.4%) belonged to group IIa and 4 (10.2%) were from group IIb. In present study, incidence of meconium staining liquor was more in induction group than expectant group. Incidence of meconium staining of liquor could be because of unripe cervix and frequent tablet misoprostol instillation.

Comparison of neonatal parameters:

Neonatal parameters	Group I	Group II
NICU admission	15(11.1%)	16(11.8%)
APGAR score >7	103(76.2%)	110(81.4%)
Birth weight >2.5kg	97(71.8%)	101(74.8%)

Out of total 135 patients in each group, 15 (11.11%) neonates required NICU admission in group I (induction group) and 16 (11.8%) neonates required NICU admission in group II (expectantly managed group). Similarly, 107 (79.25%) neonates and 118 (87.4%) neonates had APGAR score >7 at 5 minutes in group I and group II respectively. 97 (7.8%) and 101 (74.8%) neonates had birth weight >2.5 kg in group I and II respectively.

Out of 15 neonates admitted in NICU in group I 5(33.3%) , 4(26.6%), 3(20%), 2(13.3%) and 1(6.67%) were admitted in view of meconium aspiration syndrome , transient tachypnea of newborn, birth asphyxia, sepsis and respiratory distress syndrome respectively. Similarly out of 16 neonates admitted in group II 6(37.5%) were admitted due to meconium aspiration syndrome of which 4(36.3%) were from group IIa and 2(40%) were from group IIb. 5(31.5%) neonates were admitted for transient tachypnea of newborn of which 4(36.3%) neonates belonged to group IIa and 1(20%) neonates were from group IIb. Out of 3(18.7%) neonates admitted for birth asphyxia 2(18.1%) were from group IIa and 1(20%) belonged to group IIb.

Probability of Caesarean Section among various studies

Studies	Group I	Group II
Macer et al(7)	14.6%	11.1%
Hermus et al(5)	19.4%	16.3%
Sanchez-ramos et al(8)	20.1%	22%
Donald et al(9)	22%	18%
Ambreen et al(10)	28.2%	10.25%
Hannah et al(11)	66.3%	33.9%
Dublin et al(12)	19.4%	9.9%
Augensen et al(13)	82.2%	30.8%
Bhagyalaxmi et al(2)	64%	22%
Present study	33%	14.8%

The above table shows the rate of caesarean sections in induced and expectant groups in various studies. Incidence of caesarean section is more in group I (induced group) compared to group II (expectantly managed group) and difference is statistically significant in all above studies which substantiates findings of present study.

IV. DISCUSSION

Currently WHO recommends induction of labour at 41 weeks in women with favourable cervixes and cervical ripening and foetal surveillance in women with unfavourable cervixes, but recognizes that management of women beyond 40 completed weeks of gestation is unclear.

In **present study**, mean age in group I and group II was 26.17±3.08 and 26.24±3.18 respectively, the difference was statistically not significant. The mean period of gestation in group I and group II was 40.3±2.2 and 41±0.1 respectively, the difference was statistically significant between both groups.

Incidence of vaginal delivery in **present study** was 66% in group I while in group II it was 85.1% and rate caesarean delivery in group I was 33% and 14.8% in group II. Incidence of instrumental delivery was 2.22% in group I. Findings of present study were comparable with the studies by **Dobariya et al(14)**, **Prabha singh et al(15)** and **Indumathi et al(16)**.

Expectantly managing pregnancies till 41 weeks allows patients to go into spontaneous labour and reduces operative deliveries whereas early induction increases rate of operative delivery which also substantiates our study.

In **present study**, meconium stained liquor was seen in 14.07% patients in group I while in group II it was seen in 11.8% patients. Waiting till 41 weeks and then inducing did not have any effect on meconium staining of liquor as seen in our study and in studies by **Bhagyalaxmi et al(2)**, **Dobariya et al(14)** and **Janhvi et al(17)**.

In our study, APGAR score was >7 in 79.25% neonates in group I and in 82.05% neonates in group II. In a retrospective study by Swati et al(18), (62) APGAR score was >7 in 75.9% neonates in group I and 80% neonates in group II. In a study by Dobariya et al(14), (60) APGAR score was >7 in 87.8% neonates in group I and in 88.73% in group II. The findings were comparable with our study. In present study, 7.4% patients had post-partum haemorrhage in group I and 5.9% patients in group II. The p-value was 0.059 which was non-significant suggesting that the incidence of PPH was comparable in both the groups. The findings of studies by Dobariya et al, Bhagyalaxmi et al and Sargunam et al(19) related to incidence of post-partum haemorrhage between two groups were comparable with present study.

In present study, 2.9% patients had PROM in group I and 9.6% in group II. The p value 0.04 was significant which suggest increased incidence of PROM in group II. Incidence of PROM was more in group II in our study and findings of above studies are comparable with present study. Incidence of tachysystole and hyperstimulation was comparable in both the groups.

In present study, 11.1% neonates were admitted to NICU in group I and 11.8% in group II. The p value was not significant. Findings of present study were comparable with the studies by Sargunam et al, Alexander et al, Dobariya et al, Srah J stock et al and Sugnathi et al.

V. CONCLUSION

Pregnancy beyond dates is one of the most frequent clinical dilemma faced by the obstetrician. Whether to choose expectant management with antepartum foetal surveillance or to prescribe induction of labour is the question. The correct choice of management remains controversial. Foetal well being after 40 weeks is still worrying, foetal jeopardy increases after 40 weeks itself.

Our study, suggests that induction of labour should be reserved for cases where maternal and perinatal benefits outweigh the risk of complications. Elective induction of labour with an unfavourable cervix should be discouraged and waiting till 41 weeks with proper foeto-maternal surveillance and then inducing improves maternal and neonatal outcome.

Therefore, induction of labour optimally in otherwise uncomplicated pregnancies at 41 weeks and thereafter is associated with reduced maternal morbidity with comparable perinatal outcome.

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