A study of induction of labour versus expectant management for pregnancies beyond 40 weeks a prospective comparative randomised study

Bhagyalakshmi Manthri¹, Nina. V. Kate¹ *

¹DNB Resident, ²Consultant, Dept. of Obstetrics and Gynaecology, Rajiv Gandhi Government Women & Children Hospital, Puducherry, India

*Corresponding Author: Email: drninakate@gmail.com

Abstract

Introduction: Post-term pregnancy is one that extends to or beyond 42 weeks of gestation. Patients at 40 weeks can either undergo induction or can be managed expectantly. At 41 weeks of gestation the perinatal mortality rate is 9 per 1000 live births, and it continues to rise thereafter. Labour induction at 41 weeks gestation for otherwise uncomplicated singleton pregnancies reduces caesarean delivery rates without compromising perinatal outcomes.

Study Design: 200 Low risk primigravida at 40 weeks of gestation were included and randomized into two groups. Group I=Induction group (n=100) Patients were admitted at 40 weeks and were induced at 40+0 to 40+6 Weeks. Group II the Expectant group which was further subdivided into 2 groups. Group IIa=Those who went into labour or had PROM or any ominous event during the Expectant period till 41 weeks. Group IIb=Patients who reached 41 weeks and then were induced.

Results: Expectant management till 41 weeks and then inducing labour at 41 weeks resulted in a significantly higher number of patients having vaginal delivery when compared with patients who were induced at 40 weeks. The incidence of meconium stained liquor, caesarean section, non-reassuring CTG, maternal complications and neonatal morbidity was high in Group I when compared to Group II.

Conclusion: Labour induction in uncomplicated pregnancies at 41 weeks is not associated with increased rates of operative delivery, maternal and neonatal morbidity.

Keywords: Expectant management, Labor induction, Post term pregnancy.

Introduction

Pregnancy between 41 and 42 weeks is referred as prolonged pregnancy, which varies from 9.5 to 33.7% annually¹ and needs to be closely monitored. An earlier induction can, potentially expose the mother to a greater risk of an operative intervention and its subsequent morbidity while delaying the induction increases the chances of fetal distress and perinatal morbidity. The incidence of prolonged pregnancy drops from 7.5% to 2.6% when gestation age is calculated by early ultrasound rather than menstrual dates.² Since labor induction is the commonest intervention in obstetrics, WHO recommends a policy of routine induction of labor at 41 completed weeks.³ This study aims to assess the advantages and disadvantages of inducing labor in women at 40+1/ 40+6 weeks of gestation with those expectantly managed matched group of women up to 41 completed weeks of gestation and then induced.⁴

Materials and Methods

A prospective comparative study was undertaken in our Hospital from Jan 2015 to June 2016 after obtaining clearance from the institute’s ethical committee. Women at 40 weeks of gestation satisfying the inclusion and exclusion criteria were explained the risks and benefits of the procedure and those who gave informed, written, valid consent were included in the study. They were randomised into two groups and feto-maternal surveillance was started and continued till delivery.

40 weeks of gestation (Confirmed by menstrual history and early ultra sound)

[Diagram showing the flow of patients into Group I and Group II]

Inclusion Criteria

1. Singleton Pregnancies with cephalic presentation with 40 weeks of gestation.
2. Primigravida
3. Bishops score<6
4. Patients not in labour
5. No Premature rupture of membranes at admission

Exclusion Criteria
1. Scarred uterus like previous caesarean section, myomectomy.
2. Non cephalic presentation
3. Multifetal pregnancy
4. Intra uterine growth restriction
5. Oligohydramnios/Polyhydramnios
6. Antepartum haemorrhage
7. Co morbid conditions like pregnancy induced hypertension, diabetis mellitus, asthma
8. Anamolous babies
9. Cephalopelvic disproportion
10. Abnormal Doppler studies

The following Maternal outcomes were monitored.
1. Mode of delivery
   i. Spontaneous vaginal delivery
   ii. Instrumental delivery
   iii. Caesarean section.
2. Hyperstimulation, Tachysystole, Fetal distress
3. Prolapru rupture of membranes (PROM)
4. Colour of liquor
5. Postpartum haemorrhage

The following fetal outcomes were monitored.
1. APGAR at 1 and 5 minutes
2. Weight of the baby
3. NICU admission (Neonatal Intensive care unit)
4. Other neonatal complications

Methods of Statistical Analysis: The data after entering in MS excel data sheet, was analyzed with SPSS software. Data was presented in the form of descriptive and inferential statistics. Descriptive statistics was expressed in frequencies, percentages, and appropriate measures of central tendency and dispersion like mean, standard deviation. As per the level of measurement of data, appropriate statistical test was applied like chi-square for categorical and t-test, ANOVA for continuous data to test the association and significant difference of mean wherever applicable, if any, in the given data.

Result
The mean period of gestational age in Induction Group was 23.55±2.805 and 22.66±2.547 respectively and this was not statistically significant whereas period of gestation in both groups was significant (p=0.001) (Table 1).

<table>
<thead>
<tr>
<th>Parameters</th>
<th>Induction group</th>
<th>Expectant group</th>
<th>Significance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>23.55±2.805</td>
<td>22.66±2.547</td>
<td>NS</td>
</tr>
<tr>
<td>Period of gestation</td>
<td>40.3±2.8</td>
<td>41.0±0.2</td>
<td>P=0.001</td>
</tr>
</tbody>
</table>

In Group I, all the patients were induced at 40+0 to 40+4 weeks of gestation where as in Group IIa, all patients went into spontaneous labor without any induction and in Group IIb, 94.2% were induced at 41 weeks, 5.7% were induced at >41weeks and this was statistically significant (p=0.001).

64% of Group I patients had caesarean section, 3% had instrumental delivery and 33% had normal vaginal delivery. Where as in Group II, 65 patients delivered before 41weeks, out of which 15.3% had caesarean section and 84.6% had normal vaginal delivery. Out of 35 patients who reached 41 weeks and were induced, 34.2% had caesarean delivery and 65.7% had normal vaginal delivery. There was statistical significance between mode of delivery in Group I and Group II (p=0.001) (Table 2).

Table 2: Comparison of mode of delivery in both groups

<table>
<thead>
<tr>
<th>Mode of delivery</th>
<th>Group I (100)</th>
<th>Group II (100)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Observation till 41weeks (N=65)</td>
<td>Induction at 41weeks (N=35)</td>
</tr>
<tr>
<td>SVD</td>
<td>33 (33%)</td>
<td>55 (84.6%)</td>
</tr>
<tr>
<td>Vacuum-forceps</td>
<td>3 (3%)</td>
<td>0</td>
</tr>
<tr>
<td>LSCS</td>
<td>64 (64%)</td>
<td>10 (15.3%)</td>
</tr>
<tr>
<td>Total</td>
<td>100</td>
<td>65</td>
</tr>
</tbody>
</table>

29 patients of group I had MSL out of which 2 delivered vaginally and 27 underwent caesarean section, where as in group IIa, 6 had MSL out of which 2 delivered vaginally and 4 underwent LSCS. In group IIb, 5 had MSL and all 5 underwent LSCS (P=0.001) (Table 3).
Table 3: Mode of delivery and colour of liquor

<table>
<thead>
<tr>
<th>Colour of liquor</th>
<th>Group I (N=100)</th>
<th>Group II(N=100)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>SVD (33)</td>
<td>Operative delivery (67)</td>
</tr>
<tr>
<td>Clear liquor</td>
<td>31</td>
<td>40</td>
</tr>
<tr>
<td>MSL</td>
<td>2</td>
<td>27</td>
</tr>
<tr>
<td>Total</td>
<td>33</td>
<td>67</td>
</tr>
</tbody>
</table>

In Group I only 36 had favourable bishops score. In Group IIa out of 65, 40 had Bishops score >3 and in Group IIb out of 35, 20 had bishops score >3. In Group I, 68 patients had reactive CTG (Cardiotocography) and remaining had Nonreactive CTG. In Group IIa out of 65 patients, 57 had reactive CTG, and out of 35 in Group IIb, 30 had reactive CTG and this was statistically significant. Only 14 patients in Group IIa had Prelabor rupture of membranes (PROM). 41 babies in Group I, 11 babies each in Group IIa and Group IIb were admitted in NICU (Table 4).

Table 4: Comparision of Bishop score, CTG, PROM and NICU admissions in both groups

<table>
<thead>
<tr>
<th></th>
<th>Group I (N=100)</th>
<th>Group IIa (N=65)</th>
<th>Group IIb (N=35)</th>
<th>Significance (p)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bishop Score &gt;3</td>
<td>36</td>
<td>40</td>
<td>20</td>
<td>0.002</td>
</tr>
<tr>
<td>CTG (Reactive)</td>
<td>68</td>
<td>57</td>
<td>30</td>
<td>0.02</td>
</tr>
<tr>
<td>PROM</td>
<td>0</td>
<td>14</td>
<td>0</td>
<td>0.001</td>
</tr>
<tr>
<td>NICU admissions</td>
<td>41</td>
<td>11</td>
<td>11</td>
<td>0.05</td>
</tr>
</tbody>
</table>

Maternal Complications like hyperstimulation (2 patients), Uterine atony (1 patient), Chorioamnionitis (1 patient) were noted in Group I. While in Group II, only one patient had hyperstimulation and no other complications were noted. When compared to Group I, Group II had less maternal complications.

The most common indication for Caesarean section in Group I and Group II was fetal distress, followed by failed induction. There was no statistical significance in relation to indication of operative interference (P=0.19), Birth weight (P=0.48), Apgar score in both groups (P=0.19).

Table 5: Probability of caesarean section among primigravida randomized to the induced group (Group I) and the expectant group (Group II)

<table>
<thead>
<tr>
<th>Studies</th>
<th>Induction Group (Group I)</th>
<th>Expectant Group (Group II)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Macer et al(^6)</td>
<td>14.6%</td>
<td>11.1%</td>
</tr>
<tr>
<td>Hermus et al(^10)</td>
<td>19.4%</td>
<td>16.3%</td>
</tr>
<tr>
<td>Sanchez-Ramos et al(^11)</td>
<td>20.1%</td>
<td>22%</td>
</tr>
<tr>
<td>Donald et al(^12)</td>
<td>22%</td>
<td>18%</td>
</tr>
<tr>
<td>Ambreen et al(^13)</td>
<td>28.2%</td>
<td>10.25%</td>
</tr>
<tr>
<td>Hannah et al(^14)</td>
<td>66.3%</td>
<td>33.9%</td>
</tr>
<tr>
<td>Alexander et al(^15)</td>
<td>7%</td>
<td>10%</td>
</tr>
<tr>
<td>Dublin et al(^16)</td>
<td>19.4%</td>
<td>9.9%</td>
</tr>
<tr>
<td>Prysak et al(^17)</td>
<td>8.7%</td>
<td>5.0%</td>
</tr>
<tr>
<td>Augensen et al(^18)</td>
<td>82.2%</td>
<td>30.8%</td>
</tr>
<tr>
<td>Present Study</td>
<td>64%</td>
<td>22%</td>
</tr>
</tbody>
</table>

Discussion
Managing pregnancies expectantly till 41 weeks and then inducing reduces the rate of caesarean section, intrapartum and postpartum complications and neonatal morbidity and mortality. Though recent studies show increased incidence of perinatal morbidity and mortality with increase in gestational age, 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 a tricky situation for the obstetrician.

The mean age of patients in Group I and Group II was 23.55±2.805 and 22.66±2.547 respectively which was not significant statistically. In the present study the mean period of Gestation in Induction Group and Expectant Group was 40.3±2.8 and 41.0±0.2 respectively (Table 1) where as in a study by Johnson et al\(^5\) and Macer et al\(^6\) the mean period of gestation in
induction Group and expectant Group was 39.8±1.35 and 39.5±1.15 and 39.0±1.02 and 39.32±0.9 respectively.

It is well known that the successful induction of labour is related to cervical ripeness. Compared with spontaneous onset of labour, elective induction of labour in primigravida at term with an unfavourable Bishop score is associated with an increased risk of caesarean delivery. Most studies that do include the Bishop score find an increased risk of caesarean delivery when labour is induced with a low Bishop score. Present study showed that Bishops score drastically improves as the period of gestation increases. Bishops score was <3 in 64% of patients in Group I and 40% in Group II, whereas Bishops score was 3-6 in 36% and 60% of patients in Group I and Group II respectively, similar to studies conducted by Johnson et al7 and Vrouenraets et al.7

Waiting till 41 weeks and then inducing did not have an effect on meconium staining of the liquor as seen in our study (Table 3) and as documented in studies by Cole et al8 and Heimstad et al.9

In our study, Abnormal Fetal heart rate patterns also showed significant differences (p=0.02) between early induction of labor to expectancy managed pregnancies (15% vs 5%) which indirectly increases the operative interference.

Expectantly managing pregnancies till 41 weeks allows patients to go into spontaneous labour and reduces operative deliveries whereas early induction increases the rate of operative delivery which is also substantiated in the studies as shown in Table 5.

No statistical significance was noted in Birth weight and Apgar score in both groups.

Though 41 babies in Group I and 22 babies in Group II needed NICU admissions, no major neonatal complications were noted and was not statistically significant.

**Conclusion**

Our study suggests that Induction of labor should be reserved for cases where maternal and perinatal benefits outweigh the risk of complications.

Elective induction of labor with an unfavourable cervix should be discouraged and waiting till 41 weeks with proper fetomaternal surveillance and then inducing improves maternal and neonatal outcome.

**Limitations of the study**

Since it is not a double blinded study, subjective variation in the observations noted may be present.

The period of study is short hence many outcomes like long term neurodevelopmental outcomes and maternal side effects may not have surfaced.

Hence well designed randomized double blinded studies are recommended further for improving level of evidence.

**Acknowledgements**

We are thankful to our patients and colleagues for their contribution to the work.

**Conflict of Interest:** None declared

**Funding:** No funding sources

**References**