

# Will inducing low-risk women at 40 weeks improve the outcomes of mothers and babies? A retrospective cohort, observational, single-centre study

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## Abstract

**Objective** We compared maternal and foetal outcomes between termination gestational age at 40 0/7-40 6/7 and 41 0/7-41 6/7 weeks. **Design** Retrospective cohort, observational, single-centre study. **Setting** Jiangsu Province Hospital, China: January 2020-December 2020 **Population** 1569 low-risk pregnancies. **Methods** Maternal medical records and neonatal delivery data were analysed retrospectively. **Main outcome measures** Difference in adverse outcomes of mothers and babies between termination gestational age at 40 0/7-40 6/7 and 41 0/7-41 6/7 weeks. **Results** The study included 1569 pregnancies, with 1107 (70.6%) delivered at 40 0/7-40 6/7 weeks and 462 (29.4%) delivered at 41 0/7-41 6/7 weeks. Intrapartum caesarean section (8% versus 16%,  $P<0.001$ ), meconium-stained amniotic fluid (13% versus 19%,  $P=0.004$ ), episiotomy (41% versus 49%,  $P=0.011$ ), and macrosomia (13% versus 18%,  $P=0.026$ ) were significantly lower at 40 0/7-40 6/7 weeks. The premature rupture of membranes rate (22% versus 12%,  $P<0.001$ ), spontaneous labour rate (54% versus 20%,  $P<0.001$ ), vaginal delivery rate of artificial rupture of membrane induction (83% versus 71%,  $P=0.006$ ) and balloon catheter combined with oxytocin induction (88% versus 79%,  $P=0.049$ ) were significantly higher at 40 0/7-40 6/7 weeks. **Conclusions** Low-risk women who delivered at 40 0/7-40 6/7 weeks showed better outcomes in terms of the mother's and baby's health, such as decreased rates of intrapartum caesarean section, meconium-stained amniotic fluid, episiotomy, and macrosomia, compared with those who delivered at 41 0/7-41 6/7 weeks. **Tweetable abstract** Induction at 40 weeks will decrease adverse outcomes of mothers and babies.

## Introduction

The appropriate time for termination of pregnancy has always been a concern of medical staff. Foetal lung maturity gradually increases with gestational age, and premature termination of pregnancy may lead to neonatal respiratory disease syndrome (RDS), whereas late termination may increase maternal and neonatal risks. Neonates delivered at 36 to 38 weeks after confirmed foetal lung maturity are at higher risk of adverse outcomes than those delivered at 39 to 40 weeks<sup>1</sup>. Pulmonary maturity generally occurs after full-term birth (39 0/7-40 6/7 weeks)<sup>2</sup>. Therefore, inducing pregnancy at 39 0/7-40 6/7 weeks may be proper from the angle of foetal lung maturity.

At present, elective labour induction is commonly performed after 41 weeks in low-risk women without labour onset<sup>3,4</sup>. However, with increases in gestational weeks, increases are observed in foetal weight, the probability of macrosomia, the rate of cephalopelvic disproportion, and the occurrence of shoulder dystocia, caesarean section, neonatal asphyxia and birth injury<sup>5-8</sup>. Thus, we sought to determine whether inducing low-risk

pregnant women in advance at 40 weeks will lead to improved maternal and foetal outcomes. Therefore, the goal of this study was to compare maternal and foetal outcomes between termination gestational age at 40 0/7-40 6/7 and 41 0/7-41 6/7 weeks.

## Materials and methods

### Study population

This retrospective cohort study assessed data from the obstetrics department of Jiangsu Province Hospital from January 1<sup>st</sup> to December 31<sup>st</sup>, 2020. These data included all maternal medical records and neonatal deliveries. The inclusion criteria were a low-risk singleton pregnancy delivered at 40 0/7-41 6/7 weeks of gestation at our hospital. Low risk was defined as the absence of any condition that might be a maternal or foetal indication for delivery in a short time, such as any antepartum hypertensive disorder, cardiac disease or renal insufficiency<sup>9</sup>. Cases with electing caesarean delivery, vaginal birth after caesarean section (VBAC) and partial data loss were excluded. We divided pregnancies meeting the inclusion criteria into a full-term group (40 0/7-40 6/7 weeks) and a late-term group (41 0/7-41 6/7 weeks)<sup>10</sup>. This study was approved by the Ethics Committee of Jiangsu Province Hospital [Ethics Committee 2020-SR-256].

### Outcome measures

#### *Maternal complications*

The main variable exposed in our analysis was gestational age at delivery. The maternal complications were mainly episiotomy, instrumental delivery, intrapartum caesarean section (ICS), postpartum haemorrhage (PPH), shoulder dystocia, obstetric anal sphincter injury (OASIS), meconium-stained amniotic fluid (MSAF), intrapartum cervical laceration, epidural analgesia, amniotic fluid embolism and labour progression duration. An episiotomy performed at the time of crowning was defined as a surgical incision made to widen the vaginal opening for the delivery of the foetus<sup>11</sup>. Instrumental delivery was defined as vacuum extraction or forceps delivery<sup>12</sup>. In our hospital, it mainly referred to vacuum extraction. An international uniform standard of labour onset has not been established. Based on our combined physician experience, we defined ICS as emergency caesarean after regular uterine contractions, cervical canal flattening and cervix opening by 2+ cm for women who were attempting a vaginal delivery. According to the medical indication, the cephalopelvic disproportion group and foetal distress group were mainly compared. PPH was defined as blood loss in excess of 500 ml after vaginal delivery and in excess of 1000 ml after caesarean delivery in the first 24 hours after labour, and it was divided into mild PPH (estimated blood loss > 500 ml) and severe PPH (estimated blood loss > 1000 ml)<sup>13</sup>. The total amount of blood loss was measured by weighing soaked materials and by use of the suction system and collector bags in the operating room. Shoulder dystocia was defined as the inability of the foetus to be delivered by traditional midwifery methods when the symphysis pubis obstructed the anterior descending of the shoulder or the posterior shoulder of the foetus was impacted on the maternal sacral promontory<sup>14</sup>. OASIS, including third- and fourth-degree vaginal tears, damages the anal sphincter complex and anorectal mucosa<sup>15</sup>. Intrapartum cervical laceration was defined as laceration with abnormal vaginal bleeding or requiring cervical suturing<sup>16</sup>. Amniotic fluid embolism was defined as the abnormal activation of proinflammatory mediator systems triggered by entrance into the maternal circulation of material from the foetal compartment<sup>17</sup>. The first stage of labour was defined as beginning from maternal perception of regular contractions to dilation. The second stage of labour was defined as the time from full dilation to delivery of the neonate<sup>3</sup>.

#### Neonatal complications

The neonatal complications were mainly neonatal birth weight, neonatal intensive care unit (NICU) admission, 1-minute Apgar score [?]<sup>7</sup>, newborn respiratory distress, subgaleal haemorrhage, glyopenia, neonatal jaundice, digestive syndrome and clavicle fracture. Newborn respiratory distress manifested as dyspnoea, shallow and rapid breathing, moaning, and low pulse oxygen. We also diagnosed respiratory distress for umbilical artery pH <7.2, chest X-ray abnormal and white blood cells >20\*10<sup>9</sup>/L<sup>18</sup>. Hypoglycaemia was defined as a neonatal blood glucose <2.5 mmol/L<sup>19</sup>. A paediatric professional doctor diagnosed neonatal

jaundice requiring treatment through clinical examination and bilirubin levels due to the different peak serum bilirubin levels of neonates of different races.

## Statistical analysis

All statistical analyses were conducted using Excel and SPSS 26.0. Qualitative data were expressed as percentages (%), differences between groups were assessed by  $\chi^2$  test, and Fisher's exact test was used to test significance. Normally distributed data were expressed as the mean  $\pm$  standard deviation, and differences between groups were analysed by one-way analysis of variance. Nonnormally distributed data were expressed as the median (minimum, maximum), and differences between groups were tested using the Mann–Whitney U test. Statistical significance was reached at  $P < 0.05$ .

## Results

### Study population

In 2020, a total of 6046 women were booked for delivery in our hospital and 1868 low-risk singleton deliveries at 40 0/7–41 6/7 weeks were included in the study. Of these, 299 pregnancies were excluded based on the following factors: elected caesarean delivery ( $n = 295$ ), VBAC ( $n = 3$ ) and partial data loss ( $n = 1$ ). Ultimately, a total of 1569 pregnancies met the inclusion criteria. Among them, 1107 (71%) pregnancies delivered at 40 0/7–40 6/7 weeks and 462 (29%) delivered at 41 0/7–41 6/7 weeks (Fig. 1).

Maternal characteristics in the study groups are compared in Table 1. A total of 1262 (approximately 80%) were nulliparous, and 73 (<5%) were assisted reproductive pregnancies. Approximately 60% of women had complications, including anaemia, hypothyroidism, diabetes and other unusual complications. Statistical significance was not observed in the cases of anaemia or hypothyroidism between the two groups. The risk of premature rupture of membranes (PROM) in the full-term group was significantly higher than that in the late-term group (22% versus 12%,  $P < 0.001$ ). The prevalence rate of gestational diabetes mellitus (GDM) in the full-term group was significantly higher than that in the late-term group (16% versus 8%,  $P < 0.001$ ).

Different modes of labour are compared in Table 2. The spontaneous labour rate was significantly higher than that in the late-term group (54% versus 20%,  $P < 0.001$ ). The full-term group was lower than the late-term group in terms of the rate of induction of balloon catheter combined with oxytocin (BCCO) (9% versus 46%,  $P < 0.001$ ), the rate of oxytocin induction (22% versus 27%,  $P = 0.012$ ) and artificial rupture of membrane (AROM) induction (21% versus 31%,  $P < 0.001$ ). The Bishop score of parturients with BCCO induction was not statistically significant ( $P = 0.055$ ). However, the late-term group had a higher final vaginal delivery rate of BCCO (88% versus 79%,  $P = 0.049$ ) and AROM (83% versus 71%,  $P = 0.006$ ). Significant differences were not observed in the vaginal delivery rate of oxytocin induction (80% versus 76%,  $P = 0.431$ ).

### Maternal outcomes

Maternal outcomes in the study groups are compared in Table 3. The successful vaginal delivery rate in the full-term group was significantly higher than that in the late-term group (90% versus 80%,  $P < 0.001$ ), and the rate of episiotomy was also significantly decreased (41% versus 49%,  $P = 0.011$ ). The risk of ICS in the full-term group was significantly lower than that in the late-term group (8% versus 16%,  $P < 0.001$ ). Significant differences were not observed between the full-term and late-term groups in cephalopelvic disproportion (6% versus 10%,  $P = 0.073$ ) or foetal distress (29% versus 39%,  $P = 0.133$ ). The rate of MSAF in the late-term group was significantly higher than that in the full-term group (19% versus 13%,  $P = 0.004$ ). The epidural analgesia rate during labour in the full-term group was lower than that in the late-term group (76% versus 81%,  $P = 0.034$ ). Significant differences were not observed in labour duration, postpartum haemorrhage, shoulder dystocia, or intrapartum cervical laceration rates between the two groups.

Compared with the late-term group, the full-term group had a higher risk of PROM (RR 2.04; 95% CI 1.49–2.79), spontaneous labour (RR 4.58; 95% CI 3.55–5.92), GDM (RR 2.11; 95% CI 1.46–3.07) and vaginal delivery (RR 2.33; 95% CI 1.72–3.15) and a lower risk of episiotomy (RR 0.73, 95% CI 0.58–0.93), as shown in Fig. 2. Compared with the full-term group, the late-term group had a higher risk of balloon catheter

combined with oxytocin induction (RR 8.54; 95%CI 6.49-11.24) but lower success risk (RR 0.51, 95%CI 0.26-1.01), a higher oxytocin induction risk (RR 1.38; 95%CI 1.07-1.77), a higher AROM induction risk (RR 1.64; 95%CI 1.28-2.09) but lower success risk (RR 0.50, 95%CI 0.31-0.83), a higher MSAF risk (RR 1.53, 95%CI 1.14-2.04) and a higher ICS risk (RR 2.19; 95%CI 1.63-2.94), as shown in Fig. 3.

## Neonatal outcomes

Neonatal outcomes in the study groups are compared in Table 4. The average neonatal birth weight of the late-term group was higher than that of the full-term group ( $P < 0.001$ ), and the macrosomia rate was also significantly higher than that of the full-term group (18% versus 13%,  $P = 0.026$ ). The main difference was in the range of 4000-4499 g (16% versus 12%,  $P = 0.042$ ). Significant differences were not observed in the rates of NICU admission, 1-minute Apgar score [?], newborn respiratory distress, subgaleal haemorrhage, glyopenia, neonatal jaundice, swallowing syndrome or clavicle fracture between the two groups. Compared with the full-term group, the late-term group had a higher risk of macrosomia (RR 1.40, 95% CI 1.04-1.88), as shown in Fig. 3.

## Conclusions

At present, the timing of pregnancy termination is controversial, and many studies are exploring more suitable timings. Studies have shown that elective induction before 39 weeks increases the rate of NICU admission, prolongs the neonatal hospitalization time, results in a high readmission rate within two weeks after delivery, and increases emergency department visits<sup>20,21</sup>. A large multicentre RCT along with some retrospective studies showed that elective induction at 39 weeks reduced the caesarean section rate, vaginal delivery rate, pregnancy hypertension risk, perinatal infection, neonatal adverse perinatal outcomes (respiratory complications, NICU admission, perinatal death) and did not affect neonatal early literacy and numeracy ability<sup>9,22,23</sup>. Therefore, elective induction after 39 weeks in low-risk nulliparous women is recommended. However, there is little evidence for elective induction between 40 0/7 and 40 6/7 weeks.

Nowadays, elective labour induction is commonly recommended after 41 weeks in low-risk women without labour onset. The reason for inducing until 41 weeks is to wait for the maturity of the cervix and to have higher chances of spontaneous labour and PROM. However, our study showed no difference in the Bishop scores in the two groups and less opportunity for spontaneous labour and PROM after 41 weeks. If we need to induce these women by AROM or balloon catheter, then there is a higher rate for vaginal delivery at 40 0/7-40 6/7 weeks. Furthermore, we also found decreased intrapartum caesarean section, meconium-stained amniotic fluid, episiotomy and macrosomia rates at 40 0/7-40 6/7 weeks. Studies have shown that the incidence of MSAF increases with gestational age<sup>24,25</sup>, which is consistent with our findings. Therefore, our study indicated that waiting until 41 weeks in low-risk women was not necessarily beneficial; however, our study is retrospective and needs to be further proven by prospective studies.

An international cohort study showed that after 39 weeks, the risk of PPH increased with gestational age<sup>26</sup>. Our results did not reflect this obvious difference, although preliminarily observations indicated that the rate of PPH in the late-term group was slightly greater than that in the full-term group (17% versus 14%,  $P = 0.226$ ). If we increased the amount of data, statistical significance might be obtained. In our study, the prevalence rate of GDM in the full-term group was significantly higher than that in the late-term group. This might be because ACOG recommended that for women with GDM that was controlled with only diet and exercise, it was appropriate to control the gestation period within 40 6/7 weeks<sup>27</sup>. Those persisted beyond 41 weeks were due to lack of medical compliance. There was one case of amniotic fluid embolism in our study, which occurred during spontaneous vaginal delivery at 40 3/7 weeks. One hour after delivery, the patient experienced dyspnoea, a sudden drop in blood pressure (86/42 mmHg) and oxygen saturation (80%). After a series of rescue measures, such as open veins, oxygen inhalation, blood pressure boosting, and anti-allergic measures, the final prognosis was good.

Our study indicated that the macrosomia rate was higher at 41 0/7-41 6/7 weeks. No differences in adverse neonatal outcomes were noted in either group, which is consistent with a previous study<sup>21</sup>. However, many studies have revealed the risks of macrosomia, such as shoulder dystocia, clavicle fractures, breathing

problems, decreased 5-minute Apgar score, hypoglycaemia, meconium aspiration, and more<sup>5-8</sup>. From this point of view, it is a wise choice to induce at 40 weeks to reduce the risk of macrosomia.

Our conclusion is not to overrule termination timing after 41 weeks. We found that PPH and NICU admission did not increase due to expectations; therefore, termination after 41 weeks cannot be considered inappropriate. For low-risk pregnant women without suspicious macrosomia, we can expect up to 41 weeks according to their willingness. The limitations of our study should also be noted. This study was a single-centre retrospective study, which was small in scale, so increasing the sample size might lead to more significant results.

In conclusion, deliveries at 40 0/7-40 6/7 weeks had better outcomes for low-risk mothers and their babies, such as decreased rates of intrapartum caesarean section, meconium-stained amniotic fluid, episiotomy, and macrosomia, compared with deliveries at 41 0/7-41 6/7 weeks. From our results, we suppose that elective termination at 40 weeks of gestation might be superior to that at 41 weeks in terms of certain maternal and neonatal outcomes. However, in clinical practice, the appropriate termination timing should be discussed and choose a personalized delivery plan. Moreover, the conclusions remain to be further proven by prospective studies.

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**Table1. Maternal baseline characteristics in two groups**

**Baseline characteristics**

Maternal age /years

Maternal body mass index (kg/m<sup>2</sup>)

Nulliparous –no. (%)

Gestational age/w–median (min, max)

Gravity–median (min, max)

Parity–median (min, max)

Assisted reproduction–no. (%)

Complications–no. (%)

GDM–no. (%)

Hypothyroidism–no. (%)

Anemia–no. (%)

PROM–no. (%)

mesns significant difference between groups; <sup>T</sup>one-way analysis of variance; <sup>ψ</sup>Mann-Whitney U-test; GDM: gestational diabetes

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**Table2. Comparison of different mode of labor**

**Mode**

Spontaneous labor–no. (%)

BCCO–no. (%)

Bishop score

Vaginal delivery–no. (%)

Oxytocin–no. (%)

Vaginal delivery–no. (%)

AROM–no. (%)

Vaginal delivery–no. (%)

mesns significant difference between groups; BCCO: balloon catheter combined with oxytocin, AROM: artificial rupture of membranes

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**Table3. Maternal outcomes in two groups**

**Outcomes**

Vaginal delivery–no. (%)

Instrumental delivery—no. (%)

Episiotomy—no. (%)

ICS—no./total no. (%)

Cephalopelvic disproportion—no. (%)

Fetal distress—no. (%)

Postpartum hemorrhage/ml—no. (%)

500-999—no. (%)

1000—no. (%)

Epidural analgesia—no. (%)

Shoulder dystocia—no. (%)

MSAF—no. (%)

OASIS—no. (%)

Intrapartum cervical laceration—no. (%)

Amniotic fluid embolism—no. (%)

Labor duration in nullipara /h

The first stage (analgesia)

The second stage (analgesia)

The first stage (non-analgesia)

The second stage (non-analgesia)

Labor duration in multipara/h

The first stage (analgesia)

The second stage (analgesia)

The first stage (non-analgesia)

The second stage (non-analgesia)

mesns significant difference between groups; <sup>T</sup>one-way analysis of variance; ICS: intrapartum cesarean section; MSAF: meconium aspiration syndrome

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