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Induction of labor with three different techniques at 41 weeks of gestation or spontaneous follow-up until 42 weeks in women with definitely unfavorable cervical scores

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Abstract

Objective: To compare the obstetric outcome of induction of labor at 41 weeks and of follow-up until 42 weeks and induction if the patient has still not given birth at 42 weeks.

Study design: Six hundred women at 287 ± 1 days of gestation with definitely unfavorable cervical scores were randomized to labor induction ($N = 300$) or spontaneous follow-up ($N = 300$) with twice-weekly nonstress testing and amniotic fluid measurement and once-weekly biophysical scoring. The treatments used in the induction group were (1) vaginal administration of 50 μg misoprostol ($n = 100$), (2) oxytocin induction ($n = 100$), and (3) transcervical insertion of a Foley balloon ($n = 100$). The primary outcome measures were the cesarean delivery rate, whether or not the normal hospital stay had to be extended, and the neonatal outcomes. Secondary outcome measure included number of emergency cesarean deliveries performed for abnormalities of the fetal heart rate (FHR).

Results: The abdominal delivery rate was 19.3% in the induction group and 22% in the follow-up group ($p = 0.4$). The mean length of hospital stay in the two main groups was 1.4 ± 0.8 days and 1.3 ± 1 days, respectively ($p = 0.1$). Significantly higher rates of macrosomia and shoulder dystocia were seen in the follow-up group (24.6 and 2.3%) than in the induction group (7.6%, $p < 0.001$; 0.3%, $p = 0.03$). Meconium-stained amniotic fluid and meconium aspiration syndrome were observed significantly less frequently in the induction group (9.3 and 1.3%) than in the follow-up group (20.3%, $p < 0.001$; 4%, $p = 0.03$). Rates of emergency abdominal delivery in response to worrying FHR traces, neonatal intensive care unit admission, and low umblical artery pH were similar in the two groups. There was one intrauterine fetal death in the follow-up group.

Conclusion: Induction of labor at 41 weeks of gestation does not increase the cesarean delivery rate or cause a longer stay in hospital than follow-up until 42 weeks, and neonatal morbidity is also lower after induction.

Keywords: Post-term pregnancy; Misoprostol; Foley catheter; Oxytocin; Follow-up

1. Introduction

Post-term pregnancy is defined as gestation lasting beyond 42 full weeks (>294 days) [1]. Post-term pregnancies involve increased fetal morbidity, including meconium aspiration, dystocia, and fetal or neonatal mortality. One large survey showed that the odds ratio for stillbirth increases at 41 completed weeks in nulliparas and at 42 completed weeks in multiparas [2]. Also, compared with deliveries at 40 weeks of gestation, the risk of macrosomia, operative delivery, admission to neonatal intensive care units, and neonatal sepsis increases with every further gestational week [3].

A comprehensive review of randomized controlled trials in 1994, before the era of misoprostol, concluded with the recommendation that labor should be routinely induced once pregnancy has continued beyond 41 full weeks of gestation

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[4]. Many clinicians adopted this practice, and the number of births at or beyond 42 weeks declined significantly [5]. On the other hand, elective induction of labor at or beyond term has been blamed for the increased costs of cesarean delivery and labor in retrospective studies in which oxytocin, misoprostol, or other prostaglandins were used for labor induction [6–8]. Furthermore, Menticoglou and Hall, in their recent commentary, describe induction at 41 weeks of gestation as unacceptable, illogical, and unsupported interference with a normal physiological situation [9].

The purpose of this study, was to compare the fetal and maternal outcomes and lengths of hospital stay after induction on day 287 of gestation (i.e., after 41 completed weeks) and after follow-up until day 294 of gestation (42 completed weeks). It was also our intention to evaluate and compare the efficacy of oxytocin plus membrane sweeping, Foley catheter insertion plus membrane sweeping, and 50 μg vaginal misoprostol administration for induction of labor.

2. Materials and method

This was a randomized, controlled trial performed in a tertiary training center in Turkey. The local Clinical Research Ethics Committee approved the study protocol. Criteria for enrollment included (1) singleton live pregnancy with vertex presentation and intact membranes, (2) gestational age 287 ± 1 days (41 completed weeks of gestation confirmed by first-trimester ultrasound), (3) Bishop score [8] of <5 (assigned by E.O.), (4) absence of spontaneous uterine contractions (i.e., fewer than four spontaneous contractions per hour), (5) estimated fetal body weight < 4500 g, (6) a reactive nonstress test (NST), and (7) amniotic fluid index ≥ 5 cm. The exclusion criteria applied were known hypersensitivity to the use of prostaglandins, previous cesarean delivery or other uterine surgery, noncephalic presentation, body mass index (BMI) ≥ 30 before conception, parity ≥ 5, any previous attempt at induction of labor during the current pregnancy, and low-lying placenta. In our institution, labor is induced at 40 weeks of pregnancy in women with known diabetes mellitus, so that no patients with diabetes were included in the study.

Women who fulfilled the inclusion criteria were invited to take part in the study, and those who gave written informed consent were enrolled. The investigators, who were not involved in the clinical care of the patients, carried out the randomization by opening sealed opaque envelope. Six hundred identical envelopes were prepared, with one of the protocols named in each. Spontaneous follow-up was named in 300 envelopes and labor induction with 50 μg vaginal misoprostol, labor induction with oxytocin, and labor induction with Foley catheter, in 100 envelopes each.

Spontaneous follow-up (follow-up group, $N = 300$) involved nonstress testing and amniotic fluid measurement twice weekly and biophysical scoring on a single occasion 3–5 days after randomization. Labor was induced in 34 patients in the follow-up group before the 294th day following the observation of oligohydramnios and/or persistent nonreactive nonstress tests. The outcomes in these women were analyzed with those in the rest of the follow-up group. If patients did not give birth until the 294th day (42 completed weeks) of gestation ($n = 73$) induction of labor was attempted with 50 μg vaginal misoprostol every 6 h. If misoprostol failed to induce labor within 24 h cesarean delivery was performed.

Throughout the study period, the prevailing obstetric practice was to perform sonography to document fetal presentation, weight, and amniotic fluid index. Prior to the induction of labor, the admitting staff physicians performed a vaginal examination to assess the cervix, and an NST was routinely performed before administration of the medication. Staff members in charge of labor were not blinded to the type of medication used for induction.

In each patient in the misoprostol group ($N = 100$) a 50-μg dose of misoprostol was placed intravaginally at the posterior fornix for the induction of labor. Each 50 μg dose was prepared by quartering a 200-μg misoprostol tablet in the hospital pharmacy. The misoprostol dose was repeated every 6 h, and if this procedure failed to induce labor within 24 h cesarean delivery was performed. Prior to every dose, we performed a fetal cardiotocography for at least 20 min to confirm fetal well being and a vaginal examination to assess the cervical score. A further intervention was performed if the patient was experiencing contractions more than three times in 10 min. Any patient who progressed into labor or had a cervical Bishop score ≥ 8 was transferred to the labor unit for artificial rupture of the membranes and for administration of oxytocin if indicated. Oxytocin was not administered earlier than 4 h after the last dose of misoprostol, as specified in the American College of Obstetricians and Gynecologists (ACOG) guidelines [10]. After transfer to the labor unit, patients in the active phase of labor (at least 4 cm dilatation with regular uterine contractions) in whom arrest of dilatation was subsequently observed (no change in cervical dilatation >2 h) received oxytocin augmentation [11].

In the oxytocin group ($N = 100$) with a low-dose protocol with an initial dose of 1 mU/min was used to induce labor. The oxytocin dose was increased by 1 mU/min every 15 min until contractions of 200–250 Montevideo units were achieved.

In the Foley group ($N = 100$) an 18-G Foley catheter balloon was inserted to above the internal cervical os. The balloon was inflated to 50 mL with sterile normal saline. After moderate traction the Foley catheter was taped to the patient's knee. After expulsion of the Foley catheter an oxytocin infusion was started at a rate of 1.0 mU/min, which was increased at 15-min intervals until an adequate uterine contraction pattern was achieved.

Membrane sweeping was routinely performed before misoprostol induction ($n = 93/100$), oxytocin induction

(n = 88/100), or Foley catheter insertion (n = 92/100), and before labor induction in the follow-up group (n = 73/73). Six patients in the Foley group had cervical dilatation that permitted the Foley catheter but not a finger, while the remaining two patients needed mechanical cervical dilatation for Foley catheter placement. Early amniotomy was performed in all patients when the cervix was dilated to $\geq$3 cm. Continuous external fetal monitoring was performed, and intrapartum fetal heart rate (FHR) patterns were classified according to Kubli et al. [12]. Tachysystole was defined as six or more uterine contractions in 10 min for two consecutive 10-min periods. Uterine hyperstimulation was defined as the presence of tachysystole associated with fetal tachycardia, late decelerations, or loss of beat-to-beat variability. Hyperstimulation was treated with one or all of the following: maternal change of position (to left lateral decubitus or knee-chest position), an i.v. fluid bolus, oxygen supplementation (8 L/min oxygen by face mask), cessation of oxytocin infusion, removal of the remainder of the misoprostol tablet and vaginal irrigation, or ritodrine hydrochloride 0.50 mg i.v. After delivery, an investigator blinded to the group assignments reviewed the fetal monitor strips of each expectant mother to assess the frequency and duration of tachysystole and the hyperstimulation syndrome. Epidural anesthesia was not used, but intravenous narcotics were freely available to all patients throughout the study period. If labor and delivery were uneventful patients were discharged within 24 h after vaginal delivery and on the second postoperative day after abdominal delivery.

The primary outcome measures were cesarean delivery rate, length of hospital stay, and neonatal outcomes, including rate of macrosomia, incidence of meconium-stained amniotic fluid, arterial cord blood pH values, number of infants with fetal acidemia (pH $<$ 7.16 in an umbilical cord arterial sample), and rate of admission to neonatal intensive care units (NICU). A cut-off value of $<$ 7.16 was chosen for the umbilical artery pH because a value of 7.15 is 2 S.D. below the mean [13]. Secondary outcome measures included number of emergency cesarean deliveries performed for FHR abnormalities and incidence of adverse effects, such as tachysystole and hyperstimulation syndrome.

Statistical analysis of the data was performed with the aid of readily available statistical software (Statistical Package for the Social Sciences, SPSS Inc., Chicago, IL, USA). Results were reported as mean $\pm$ standard deviation or numbers and percentages. All analyses performed were two-tailed, and $p < 0.05$ was accepted as indicating statistical significance. Categorical variables were analyzed either by a Chi-square test or by Fisher's exact test whenever appropriate. Since the distribution was not skewed (as confirmed by tests of normality), the analysis of variance and Tukey tests were used to analyze continuous variables among groups. For comparison of the induction (N = 300) versus spontaneous follow-up (N = 300) groups the independent samples t-test, Fisher's exact test, or Chi-square tests were used, as appropriate.

3. Results

The four groups were similar in terms of maternal age, body mass index, gravida, nulliparity, history of abortion, previous dilatation and curettage, maternal anemia, and Bishop Score at the day of randomization (Table 1). Two women in the misoprostol group, one in the oxytocin group, and none women in the Foley group were enrolled in the study at 288 days of gestation. Labor induction was performed in 73 women in the follow-up group (24.3%) because their pregnancies had continued to 294th days.

The induction to delivery interval was 554 $\pm$ 206 min in the oxytocin group, and this was significantly shorter than in the misoprostol group (718 $\pm$ 486 min; p = 0.009) or the Foley group (635 $\pm$ 230 min; p = 0.002). The frequency of oligohydramnios and that of pre-eclampsia were similar in the four groups, but meconium-stained amniotic fluid was observed significantly more frequently in the follow-up group than in the misoprostol, oxytocin, and Foley groups (p = 0.002, Table 2). Similar incidences of tachysystole, hyperstimulation, and vaginal delivery were observed in all

Table 1
Distribution of selected variables among the groups

Variable	Misoprostol group (N = 100)	Oxytocin group (N = 100)	Foley group (N = 100)	Follow-up group (N = 300)	p
Age (years)	25.9 $\pm$ 5.9	26 $\pm$ 4.9	24.4 $\pm$ 4.1	25.6 $\pm$ 5	0.1[a]
Body mass index (kg/m^2)	27.8 $\pm$ 3.9	27.5 $\pm$ 3.3	28 $\pm$ 5	27.5 $\pm$ 3.3	0.7[a]
Gravida	2.3 $\pm$ 1.6	2 $\pm$ 1.2	1.9 $\pm$ 1	2 $\pm$ 1.2	0.1[a]
Nulliparous	46 (46)	51 (51)	47 (47)	135 (45)	0.7[b]
Abortion $\geq$1	13 (13)	16 (16)	16 (16)	50 (16)	0.3[b]
Dilatation and curettage $\geq$1	7 (7)	5 (5)	3 (3)	21 (7)	0.4[b]
Maternal anemia (Hb $<$ 10 g/dL)	2 (2)	1 (1)	2 (2)	3 (1)	0.4[b]
Bishop score on day of randomization	1.6 $\pm$ 1	1.5 $\pm$ 1	1.8 $\pm$ 0.9	1.5 $\pm$ 1	0.1[a]
Mean gestational age at delivery (days)	287	287	287	290 $\pm$ 3.2	

Data are presented as mean $\pm$ standard deviation or number and (percentage).
[a] No statistically significant difference ($p > 0.05$), Chi-square test.
[b] No statistically significant difference ($p > 0.05$), ANOVA, Tukey test.

Table 2
Intrapartum variables and obstetric outcome

Variable	Misoprostol group ($N = 100$)	Oxytocin group ($N = 100$)	Foley group ($N = 100$)	Follow-up group ($N = 300$)	p
Oligohydramnios	11 (11)	15 (15)	13 (13)	56 (18.7)	0.2
Preeclampsia	–	1 (1)	–	2 (0.7)	0.6
Meconium stained amniotic fluid	8 (8)	13 (13)	7 (7)	61 (20.3)	0.002[a]
Tachysystole	5 (5)	3 (3)	1(1)	7 (2.3)	0.3
Hyperstimulation	3 (3)	2 (2)	–	5 (1.6)	0.2
Vaginal delivery	83 (83)	76 (76)	83 (83)	234 (78)	0.4
Emergent abdominal delivery for worrying FHR	12 (12)	13 (13)	6 (6)	24 (8)	0.01[a]
Failed induction of labor	4 (4)	8 (8)	3 (3)	5 (1.7)	0.003[a]
Fetal macrosomia (>4000 g)	9 (9)	7 (7)	7 (7)	74 (24.7)	<0.001[a]
Birthweight (g)	3567 ± 384	3426 ± 408	3454 ± 380	3607 ± 464	<0.001[b]
Hospital stay (days)	1.4 ± 1.1	1.3 ± 0.5	1.4 ± 0.8	1.3 ± 1	0.2

Data are presented as mean ± standard deviation or number and (percentage).
[a] Significantly different ($p < 0.05$), Chi-square test.
[b] Significantly different ($p < 0.05$), ANOVA, Tukey test.

four groups. Emergency abdominal delivery as a result of a worrying FHR and failed induction of labor was significantly more frequent in the oxytocin group than in the follow-up group (Table 2). Fetal macrosomia was observed significantly more frequently in the follow-up group than in the other groups ($p < 0.001$). The mean birthweight was significantly higher in the follow-up group ($p < 0.001$). The mean numbers of patients for whom hospital stay was extended were similar in the four groups.

When neonatal outcomes were analyzed, no significant difference was observed between any pair of groups in the frequency of shoulder dystocia, meconium aspiration syndrome, fetal anomaly, low first or fifth minute Apgar scores, umbilical artery pH < 7.16, or neonatal intensive care unit admission (Table 3). One intrauterine fetal death occurred in the follow-up group on day 292 of gestation.

The cumulative analysis of the data is illustrated in Table 4. The induction group ($N = 300$) was compared with the follow-up group ($N = 300$). The rates of abdominal delivery and emergency abdominal delivery for worrying fetal heart rate traces were similar in the two main groups. On the other hand, macrosomia, shoulder dystocia, meconium-stained amniotic fluid, and meconium aspiration syndrome had significantly higher incidence rates in the follow-up group than in the induction group. However, frequencies of umbilical artery pH < 7.16, neonatal intensive care unit admission, and extended hospital stays were similar in the two groups.

4. Discussion

The mechanism responsible for the spontaneous onset of labor in women is still not fully understood. Besides an intact fetal hypothalamic–pituitary–adrenal axis and maternal–fetal communication, ongoing research has revealed that appropriate and timely synthesis of prostaglandins, oxytocin, their receptors, ion channels, and other cytokines are all essential for the onset of labor [14]. Diagnosis of every pathological risk that might delay labor is not yet possible, but delay in this physiological event can cause serious fetal and maternal problems. Large surveys have shown that 1.86 and 2.26 per 1000 deliveries are stillbirths at 41 and 42 completed weeks of gestation, respectively [2]. Hence, 1 fetus out of 300 died during follow-up after 40 weeks despite the availability of surveillance tests.

The main concerns about elective induction of labor today are focused on maternal and fetal risks caused by more frequent cesarean delivery and the increased costs of hospitalization these involve. Because the limited resources available should be used in the most efficient way possible that will result in a favorable obstetric outcome with

Table 3
Neonatal outcomes in the four groups

Variable	Misoprostol group ($N = 100$)	Oxytocin group ($N = 100$)	Foley group ($N = 100$)	Follow-up group ($N = 300$)	p
Shoulder dystocia	1 (1)	–	–	7 (2.3)	0.1[a]
Meconium aspiration syndrome	1 (1)	2 (2)	1 (1)	12 (4)	0.2[a]
Fetal anomaly	1 (1)	–	–	1 (0.3)	0.5[a]
Low 1st minute Apgar score (< 7)	4 (4)	8 (8)	1 (1)	16 (5.3)	0.1[a]
Low 5th minute Apgar score (< 7)	2 (2)	1 (1)	–	3 (1)	0.4[a]
Umbilical artery pH < 7.16 (%)	2 (2)	1 (1)	1 (1)	7 (2.3)	0.7[a]
Neonatal intensive care unit admission (%)	5 (5)	5 (5)	3 (3)	15 (5)	0.8[a]

Data are presented as mean ± standard deviation or number and (percentage).
[a] No statistically significant difference ($p > 0.05$), Chi-square test.

Table 4
Distribution of outcome variables by induction versus follow-up

Variable	Induction group ($N = 300$)	Follow-up group ($N = 300$)	p
Abdominal delivery rate (%)	58 (19.3)	66 (22)	0.4
Emergency abdominal delivery for worrying FHR (%)	31 (10.3)	24 (8)	0.3
Macrosomia (%)	23 (7.6)	74 (24.6)	<0.001[a]
Shoulder dystocia (%)	1 (0.3)	7 (2.3)	0.03[a]
Meconium stained amniotic fluid (%)	28 (9.3)	61 (20.3)	<0.001[a]
Meconium aspiration syndrome	4 (1.3)	12 (4)	0.03[a]
Umbilical artery pH < 7.16 (%)	4 (1.3)	7 (2.3)	0.3
Neonatal intensive care unit admission (%)	13 (4.3)	15 (5)	0.5
Hospital stay (days)	1.4 ± 0.8	1.3 ± 1	0.1

[a] Statistically significant difference ($p < 0.05$), Chi-square test.

minimum fetal morbidity, elective induction was evaluated in this study. After induction at 41 weeks there was a lower incidence of neonatal morbidity without any significant change in abdominal delivery rates or duration of hospital stay. Our findings are at odds with those of other studies, which indicate extension of hospital stay and more treatment, higher costs, and higher cesarean delivery rates following elective induction of labor [6–8]. Our study differs from these retrospective studies in that our sole indication for elective labor induction was 41 weeks of gestation, which excluded other possible causes of an increased cesarean delivery rate. Another point of difference from other studies is that we recruited women with strictly unfavorable cervical scores, who we believe are the ones that obstetricians should really be concerned about if their pregnancies extend to 41 completed weeks. Maslow and Sweeny [8] found that in their study the time from admission to delivery was longer when labor was induced labor than when it was not, which raised the average cost. This is also true for elective induction at 41 weeks of gestation in our study, but tests carried out between the 41st and 42nd completed weeks to check on fetal well being and the higher neonatal morbidity were factors that are bound to have increased costs in the follow-up group.

In 18–31% of women whose pregnancies persist for 41 full weeks of gestation they will continue until completion of 42 weeks and beyond if not induced [5,15]. In our study 24.3% of the follow-up group requested labor induction when they reached 42 completed weeks. Alexander et al. [16] found by comparing women in whom spontaneous labor started between the 287th and 293th days of gestation with women in whom labor was induced at 294 days that it was risk factors intrinsic to the patient, rather than the induction of labor itself that led to excess cesarean deliveries in women with prolonged pregnancies. These data provide an explanation for the similar cesarean delivery rates in induction and follow-up groups in our study.

The method of induction also affects the outcome of elective induction. The meta-analysis culminating in the recommendation of routine induction of labor after 41 weeks of gestation was conducted when oxytocin was the main agent used for labor induction [4]. On the other hand, a more recent meta-analysis revealed that misoprostol use was followed by a lower overall cesarean rate than other prostaglandins or oxytocin when labor was induced because of maternal or fetal indications [17]. In addition, transcervical Foley catheter placement was found to be about as efficacious as intravaginal misoprostol in accelerating cervical ripening but to be accompanied by a lower rate of uterine contractile abnormalities [18,19]. When the induction groups were compared against each other, higher rates of vaginal deliveries were found to have been achieved with a misoprostol and Foley catheter use than with oxytocin induction. Failed induction was more frequent in the oxytocin group than in the other induction groups. Uterine contractile abnormalities were most frequent in the misoprostol group and least frequent in the Foley group, but none of the differences mentioned reached statistical significance. All induction methods had similar cesarean delivery rates after labor induction at 41 weeks of gestation.

We believe that use of the Foley catheter may be preferable to the other methods, as it produces high vaginal delivery rates and low rates of contractile abnormalities. Uterine contractile abnormalities have been shown to increase the risk of an adverse fetal outcome [20], which may also explain the lower frequency of FHR abnormalities observed in the Foley group in this study. Misoprostol may be an option for women who refuse this painful vaginal intervention.

We conclude that when labor is induced at 41 weeks of gestation the neonatal morbidity rate is lower, the cesarean delivery rate is no higher, and hospital stay is no longer than when such pregnancies are monitored until 42 weeks.

5. Condensation

Induction of labor at 41 weeks of gestation decreases neonatal morbidity without higher cesarean delivery rate or longer hospital stay than with follow-up until 42 weeks.

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