

# Use of Intravenous Dexamethasone for Cervical Ripening and Labor Induction in Term Pregnancies with Pre-labour Rupture of Membranes: Randomized control trial

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## Abstract

**Background:** During the first 36 to 38 weeks of normal gestation, the myometrium is in a preparatory yet unresponsive state. Concurrently, the cervix begins an early stage of remodeling yet maintains structural integrity. Induction of labour is a complex process involving cervical ripening which undergo extensive remodeling and dynamic changes controlled by hormonal, inflammatory changes, and other biological processes.

**Aim of the Work:** to assess the effect of intravenous administration of dexamethasone on the induction delivery interval in term patients with prelabour rupture of membranes undergoing induction of labor.

**Patients and Methods:** This randomized control trial was conducted at department of Obstetrics and Gynecology at Ain Shams University Maternity Hospital (ASUMH) in the period between August 2020 and January 2021. Participants of this study were 80 full term pregnant women with pre-labor rupture of membranes attended the labor ward in El Demerdash Maternity Hospital and scheduled for induction of labor by 8 mg dexamethasone IV before starting induction by PGE1, after 4 hours oxytocin was added by 1 IU/hr with the dose increasing by 1 IU every 30 minutes till optimal contractions were reached which were three uterine contractions in 10 minutes and each lasting for 40-50 seconds.

**Results:** Fetal distress, arrest of delivery and indications of CS delivery were non-significantly less frequent among Dexamethasone group. Induction-active phase and active phase durations were significantly shorter among dexamethasone group than among control group. Second and third stages durations were non-significantly shorter among dexamethasone group than among control group. Total induction-delivery duration was significantly shorter and rate of vaginal delivery was significantly higher among dexamethasone group than among control group. Postpartum hemorrhage (PPH), postpartum endometritis, chorioamnionitis were not reported among the studied groups. No significant difference between Dexamethasone and Control groups regarding neonatal condition

**Conclusion:** Intravenous administration of dexamethasone in addition to labor induction protocol shortened the induction - active phase and active phase durations. It shortened the total induction-delivery duration and increased the rate of successful vaginal delivery. It has no effect on second and third stages durations with no increase in incidence of intrapartum, postpartum nor neonatal complications.

**Key words:** dexamethasone; cervical ripening; labor induction; term pregnancies; pre-labour rupture of membranes

## Introduction

During 36 to 38 weeks of normal gestation, the uterus is in a silent unresponsive state. While, the cervix starts remodeling and structural changes. Following this stage, the cervix undergoes ripening, effacement,

and loss of structural adhesions under effect of prostaglandins, produced in the cervix, uterus and fetal membranes [1,2].

Induction of labor is the process by which artificial stimulation of uterine contractions leads to progressive cervical effacement and dilatation, then active labor and birth [3].

Steroid substances secreted by fetal adrenal glands cause uterine contractions. The placenta may have a role by producing CRH (Corticotropin releasing hormone). During the last weeks of pregnancy, cortisol and DHEA-S (Dehydroepiandrosterone sulfate), CRH in the fetus increase, also maternal estrogens. This results in modification of the contractility of the uterus [4].

Studies have shown that corticosteroids analogues as dexamethasone could improve the Bishop score of the cervix and thus causes softening of the cervix and reduces the length of time between labor induction and delivery but further studies in that field is still needed & no studies in prelabour rupture of membranes were done [4].

This study aims to assess the effect of intravenous administration of dexamethasone on the induction delivery interval in term patients with prelabour rupture of membranes undergoing induction of labor.

### Patients and Methods

This randomized control, double blinded study was conducted during the period during the period from August 2020 to January 2021 on 80 pregnant patients with pre-labor rupture of membranes attended the labor ward in El Demerdash Maternity Hospital and scheduled for induction of labor by 8 mg dexamethasone IV under cover of broad spectrum antibiotics (3 gm ampicillin-sulbactam I.V. every 6 hours) to decrease the risk of infection according to inclusion and exclusion criteria.

The study included primipara patients with gestational age (> or equal 37 weeks) according to Naegles rule and a first-trimester ultrasound evaluation, vertex presentation, singleton fetus, prelabour Rupture of fetal membranes, cervix with a Bishop score (5-6), reactive CTG, clear liquor who are not in labor.

While patients with indication for cesarean section e.g. CPD (obstructed labour), placenta previa (Antepartum hemorrhage), IUGR (fetal distress), non-vertex presentation (failed induction) and previous cesarean section (rupture uterus), maternal medical disorders as diabetes mellitus and severe preeclampsia as dexamethasone increases the blood pressure and blood sugar and may cause DKA), active phase of labor (cervical dilatation of 4 cm plus 3 forceful contractions over a ten minute span) (no role for induction), multiparous women, significant vaginal bleeding as Placenta Previa, probable placental abruption, (fetal distress), fetal macrosomia > 4.5 kg estimated by U/S (may cause shoulder dystocia) and Fetal distress and non-reactive CTG (it may lead to prenatal mortality) were excluded from the study.

Factor					
Score	Dilatation (cm)	Effacement (percent)	Station (-3 to +2)	Cervical consistency	Cervical position
0	Closed	0-30	-3	Firm	Posterior
1	1-2	40-50	-2	Medium	Midposition
2	3-4	60-70	-1, 0	Soft	Anterior
3	≥5	≥ 80	+1, +2	–	–

**Table 1:** Bishop scoring system [1]

### Ethical considerations:

The study was approved from the Ethical Committee of the Department of Obstetrics and Gynecology, Faculty of Medicine, Ain Shams University. Informed written consents will be taken from all women before recruitment in the study, and after extensive explanation and clear discussion of risks and benefits.

Eighty patients were distributed into two groups: Group C (control group): 40 patients undergoing induction of labor received 2 ml of normal saline intravenous one hour before the initiation of labor induction, and labor induction was performed according to the American College of Obstetricians and Gynecologists protocol, i.e., starting by 25 mcg of PGE1 vaginally, in the form of Vagiprost®, After 4 hours oxytocin was added by 1 IU/hr with the dose increasing by 1 IU every 30 minutes till optimal contractions were reached which were three uterine contractions in 10 minutes and each lasting for 40-50 seconds. Group D (intervention group – Dexamethasone group): 40 patients undergoing induction of labor received 8 mg (2 ml) of the product dexamethasone sodium phosphate intravenous one hour before the initiation of labor induction in the form of Epidrone® ampoules which is a dexamethasone product from Epico-Egypt, and labor induction was performed according to the American College of Obstetricians and Gynecologists protocol, i.e., starting by 25 mcg of PGE1 vaginally, in the form of Vagiprost®. After 4 hours oxytocin was added by 1 IU/hr with the dose increasing by 1 IU every 30 minutes till optimal contractions were reached which were three uterine contractions in 10 minutes and each lasting for 40-50 seconds

**Blinding:** Staff members responsible for process of induction of labor (whether giving doses or follow up progression of labour) were blinded to which group the patients belonged either received intravenous dexamethasone, or saline.

**Randomization & Allocation:** b randomized numbers table designed by random allocation software (SPSS® for Windows® version 24.0).

Every patient was subjected to: Written consent. Complete history to determine the last menstrual period (LMP) to calculate the gestational age (GA) and to exclude systemic disorders, congenital fetal malformation and contraindications for vaginal delivery. General examination of the patients including pulse, blood pressure and temperature. Abdominal examination including presentation, station of fetal head, fetal heart rate, uterine contractions and exclusion of multiple pregnancy Local examination to determine cervical dilatation at the beginning of intervention, presenting part, station of fetal head, pelvis adequacy and Bishop scoring.

**Modified Bishop score:** Subtract 1 point of overall score do postdate pregnancy, no prior births, premature or prolonged rupture of membranes (water breaking). Sonographic examination including assessment of fetal well-being by biophysical profile and cardiotocography (CTG). Partographic representation of labor. The induction delivery interval, induction active phase interval and the duration of 2nd and 3rd stages of labor were determined. Follow up for 6 hours after delivery to detect postpartum hemorrhage.

The study assessed the rate of vaginal delivery in dexamethasone and prostaglandins group in comparison to prostaglandins group as primary outcome, while the secondary outcome measures were: Induction active phase interval, duration of second stage of labor, duration of third stage of labor, neonatal Outcome, occurrence of Postpartum haemorrhage or sepsis, occurrence of chorioamnionitis.

**Statistical analysis:**

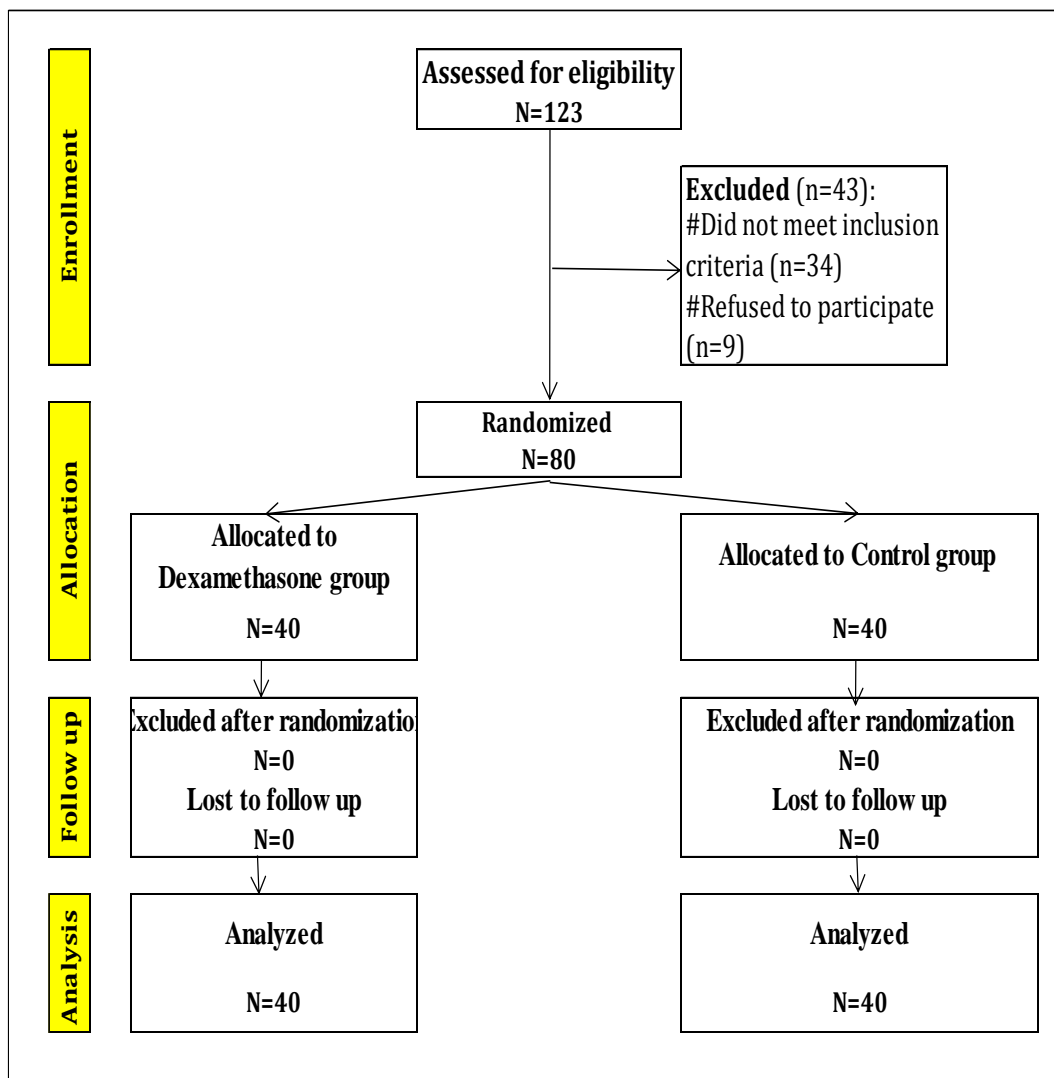
Descriptive statistics for measured variables were expressed as range, mean and standard deviation (for metric data); range, median and

interquartile range (for discrete data); and number and proportions (for categorical data). Demographic data, and primary and secondary outcomes of both groups were compared using t-test (for quantitative parametric measures), Mann-Whitney’ s U-test (for quantitative non-parametric measures) and Chi-squared and Fischer’ s Exact tests (for categorical measures). Pearson’ s correlation coefficient (for metric variables) and Spearman’ s correlation coefficient (for rank variables) were used to estimate association between variables. Microsoft® Excel® (version 2007) and SPSS® for Windows® version 24.0 were used for data presentation and statistical analysis.

**Sample size justification:**

Assuming an effect size of 0.9 for induction of labour between the 2 groups, a sample size of 39 patients in each group would be enough to detect such effect if true at 0.01 2 sided alpha error & 0.90 power of the test

**Results**



**Figure 1:** Flow chart of the studied cases

Table (2) shows that: No significant difference between **Dexamethasone** and **Control** groups regarding **age, BMI, gestational age and BISHOP score**.

Variables		Dexamathasone (N=40)	Control (N=40)	^P-value
Age (years)	Mean±SD	25.8±3.8	25.3±4.4	0.571
	Range	19.0– 34.0	18.0– 36.0	
BMI (kg/m <sup>2</sup> )	Mean±SD	26.7±1.9	26.1±1.8	0.217
	Range	21.7– 31.8	22.9– 30.4	
GA (weeks)	Mean±SD	39.3±0.7	39.4±0.8	0.285
	Range	38.0– 41.0	37.0– 41.0	
BISHOP score	Mean±SD	5.4±0.5	5.4±0.5	0.821
	Range	5.0– 6.0	5.0– 6.0	

BMI: Body mass index. GA: Gestational age. ^Independent t-test

**Table 2:** Baseline characteristics among the studied groups

Table (3) shows that: **Fetal distress, arrest of delivery and CS delivery** were non-significantly less frequent among Dexamethasone group.

Findings	Dexamathasone (N=40)	Control (N=40)	P-value	Effect size Relative risk (95% CI)
<b>Mode of delivery</b>				
Ceasean	5 (12.5%)	8 (20.0%)	#0.363	0.63 (0.22– 1.75)
Vaginal	35 (87.5%)	32 (80.0%)		
<b>Indications of cesarean section</b>				
Arrest of delivery	2 (5.0%)	6 (15.0%)	§0.263	0.33 (0.07– 1.55)
Fetal distress	3 (7.5%)	4 (10.0%)	§0.999	0.75 (0.18– 3.14)
Chorioamnionitis	0 (0.0%)	0 (0.0%)	Not applicale	

#Chi square test. §Fisher’ s Exact test. CI: Confidence interval. Effect size: Value of Dexamethasone over Control

**Table 3:** Mode of delivery and indications of cesarean section among the studied groups

Table (4) shows that: **Induction-Active phase duration** was significantly shorter among **Dexamethasone** group than among **Control** group.

Measures	Dexamathasone (N=35)	Control (N=32)	^P-value	Effect size Mean±SE 95% CI
Mean±SD	4.6±0.6	5.3±0.6	<0.001*	-0.7±0.2
Range	2.9– 6.1	3.7– 6.7		-1.0– -0.4

^Independent t-test. CI: Confidence interval. \*Significant. Effect size: Value of Dexamethasone over Control

**Table 4:** Induction-Active phase duration (hours) among the studied groups

Table (5) shows that: **Active phase duration** was significantly shorter among **Dexamethasone** group than among **Control** group.

Measures	Dexamathasone (N=35)	Control (N=32)	^P-value	Effect size Mean±SE 95% CI
Mean±SD	3.4±0.2	4.7±0.4	<0.001*	-1.3±0.1
Range	2.8– 3.8	3.5– 5.5		-1.4– -1.1

^Independent t-test. CI: Confidence interval. \*Significant. Effect size: Value of Dexamethasone over Control

**Table 5:** Active phase duration (hours) among the studied groups

Table (6) shows that: **Second stage duration** was non-significantly shorter among **Dexamethasone** group than among **Control** group.

Measures	Dexamathasone (N=35)	Control (N=32)	^P-value	Effect size Mean±SE 95% CI
Mean±SD	42.4±5.2	45.3±6.8	0.060	-2.8±1.5
Range	33.0– 54.0	34.0– 66.0		-5.8– 0.1

**Table 6:** Second stage duration (minutes) among the studied groups

Table (7) shows that: **Third stage duration** was non-significantly shorter among **Dexamethasone** group than among **Control** group.

Measures	Dexamathasone (N=35)	Control (N=32)	^P-value	Effect size Mean±SE 95% CI
Mean±SD	7.1±0.9	7.5±1.1	0.059	-0.5±0.2
Range	5.0– 8.0	6.0– 10.0		-1.0– 0.0

^Independent t-test. CI: Confidence interval. \*Significant. Effect size: Value of Dexamethasone over Control

**Table 7:** Third sage duration (minutes) among the studied groups

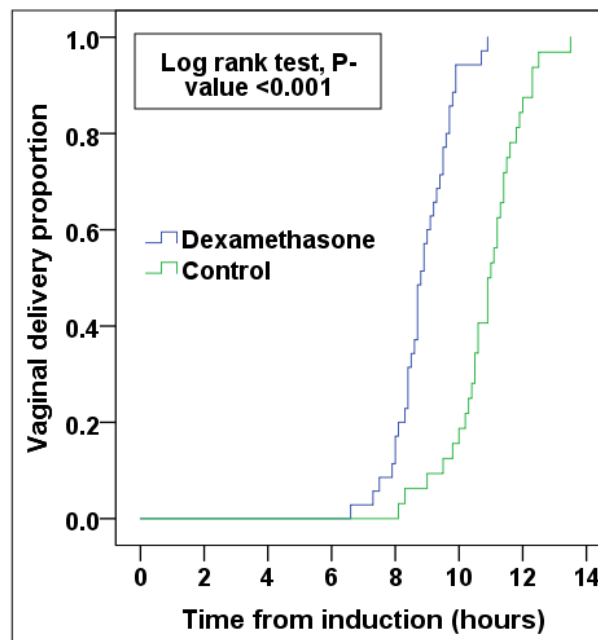
Table (8) shows that: **Total Induction-delivery duration** was significantly shorter among **Dexamethasone** group than among **Control** group.

Measures	Dexamathasone (N=35)	Control (N=32)	^P-value	Effect size Mean±SE 95% CI
Mean±SD	8.9±0.9	10.9±1.2	<0.001*	-2.0±0.3
Range	6.6– 10.9	8.1– 13.5		-2.5– -1.5

^Independent t-test. CI: Confidence interval. \*Significant. Effect size: Value of Dexamethasone over Control

**Table 8:** Total induction-delivery duration (hours) among the studied groups

Figure (2) shows that: **Rate of delivery** was significantly higher among **Dexamethasone** group than among **Control** group.



**Figure 2:** Kaplan meier curve for vaginal delivery since induction among the studied groups

Table (9) shows that: No significant difference between **Dexamaethasone** and **Control** groups regarding **neonatal condition**.

Findings	Dexamathasone (N=40)	Control (N=40)	#P-value	Effect size Mean±SE 95% CI	
<b>Birth weight</b>					
Mean±SD	3.3±0.2	3.3±0.2	^0.776	0.0±0.0	
Range	3.0– 3.6	2.8– 3.8		-0.1– 0.1	
<b>APGAR 1</b>					
Mean±SD	6.9±1.0	6.8±1.1	^0.524	0.1±0.2	
Range	4.0– 9.0	4.0– 9.0		-0.3– 0.6	
<b>APGAR 5</b>					
Mean±SD	7.9±0.9	7.8±1.2	^0.598	0.1±0.2	
Range	5.0– 10.0	5.0– 10.0		-0.3– 0.6	
<b>NICU admission</b>				<b>Relative risk (95% CI)</b>	
Needed	1 (2.5%)	2 (5.0%)	§0.999		0.50
Not needed	39 (97.5%)	38 (95.0%)			(0.05– 5.30)

^Independent t-test. §Fisher's Exact test. CI: Confidence interval. Effect size: Value of Dexamethasone over Control

**Table 9:** Neonatal condition among the studied groups

Table (10) shows that: **Post partum hemorrhage (PPH) and endometritis** were not reported among the studied groups.

Findings	Dexamathasone (N=40)	Control (N=40)
Post partum hemorrhage	0 (0.0%)	0 (0.0%)
Endometritis	0 (0.0%)	0 (0.0%)

**Table 10:** Post partum complications hemorrhage among the studied groups

Induction of labor represents a chance to control pregnancy as regards delivery timing for either maternal or fetal benefit. Much literature has been published and continues to be published on both the maternal and fetal safety of induction of labor, especially if related to decrease the incidence of cesarean section rates [5].

This randomized control trial was conducted at department of obstetrics and gynecology at Ain Shams University Maternity Hospital (ASUMH) in the period between August 2020 and January 2021.

This study assessed the effect of intravenous administration of dexamethasone on the induction delivery interval in term patients with prelabour rupture of membranes undergoing induction of labor.

Statistical analysis of current study showed that there were no significant differences between women of both groups regarding age, BMI, gestational age and BISHOP score.

Pahlavan et al studied total 121 nulliparous women in Iran with a singleton pregnancy and cephalic presentation at 40– 42 gestational weeks in prolonged latent phase were randomly assigned to receive 2 ml ampoule dexamethasone 4 mg/mL (the intervention group) and 2 ml ampoule of sterile water for injections (the control group), which were both intramuscularly administered. Then, the augmentation of labor with the use of intravenous oxytocin infusion (2.5 m units/ per minute) began in both groups. They agreed with current study and stated that there were no significant differences were seen in the mean age, body mass index, the gestational age and the Bishop score at the baseline in both groups. He found the duration of time between the onset of augmentation and the second stage of labor was 5.6 ± 1.9 in the study group, whereas it was 7.7 ± 1.5 in controls with a significant difference (p ≤ <0.001).The duration

of time between the onset of labor augmentation and the active phase of labor was lower in the study group than that of the control group (p= 0.02) [6].

Laloha et al determined the effect of intravenous Dexamethasone on preparing the cervix and on labor induction. A randomized, clinical, double – blind trial was conducted on 172 women divided into a control and an experimental group., each woman was intravenously injected with eight milligrams of Dexamethasone or eight milligrams of distilled water.. They agreed with current results and stated that there were no statistically significant differences between the two groups in terms of their age, period of pregnancy, and Bishop score. at the start of the study. Following our results, stated that the interval between the start of induction and the beginning of the active phase in case and control groups was different significantly (P<0.001) but the interval between the start of the active stage and the beginning of the second stage of childbirth between case and control groups was not different significantly (P<0.3), also the frequency of NVD (Normal Vaginal Delivery) improved and its rate compared with C/S didn't different significantly between case and control groups (P<0.69) [4].

Elmaraghy et al evaluated the efficacy of intramuscular dexamethasone injection prior to induction in improving progression and duration of labor phases. 100 Nulliparous Pregnant women who were conducted at the labor wards of Ain Shams Maternity Hospital. He stated that use of dexamethasone intramuscularly prior to induction significantly shortens duration of normal labor with minimal complications [7].

This study differs from ours that there was no change on rate of normal vaginal delivery as ours which showed that the rate of normal delivery was significantly higher among Dexamethasone group than among



control group, this difference may be due to use of dexamethasone intramuscular, induction of labor was in term pregnancies (GA 40-42 weeks) with intact membranes [7].

Ahmed et al conducted case-controlled trial study was conducted in the labor ward of El Hussein University Hospital and El-Shiekh Zaid Specialized Hospital to evaluate the effect of dexamethasone infusion administration on the duration of induction of labor on 100 pregnant women with full term pregnancy. They agreed with current results and showed no significant difference between dexamethasone and saline groups regarding basal maternal and fetal characteristics as age, BMI, GA, also induction-active, active-second and induction-second durations were shorter among dexamethasone group than among saline group, but the differences were statistically significant only in induction- active and induction-second durations. Rate of normal delivery was significantly higher among dexamethasone group than among saline group [8].

Elsayed et al assessed the efficacy of intramuscular administration of dexamethasone on the induction delivery-interval in full term women undergoing induction of labor. This study was carried out between July 2018 and January 2019, at the labor ward of Ain Shams university maternity hospital, they stated that there was significant statistical difference between the two groups as regard induction-delivery interval ( $P<0.05$ ), there was significant statistical difference between the two groups as regard induction-active phase interval ( $P<0.05$ ). There was no significant statistical difference between the two groups as regard duration of active phase of labor [9].

Statistical analysis of current study showed that second and third stages durations were non-significantly shorter among dexamethasone group than among control group [9].

Statistical analysis of current study showed that fetal distress, arrest of delivery and indications of CS delivery were non-significantly less frequent among Dexamethasone group. The reasons for cesarean section in the 5 women in the study group included two arrest of labour, three fetal distress. Among 8 women who had cesarean sections in control group, the reason for the cesarean sections included six arrest of labour, two fetal distress.

Pahlavan et al stated that 50 cases (82.0%) in the study group and 47 cases (78.3%) in the control group had vaginal delivery. The reasons for the caesarean section in the 11 women in the study group included four fetal distress, three meconium liquor cases, and four labour arrest cases. Among 13 women who had caesarean section in the control group, the reasons for the caesarean section included five cases of arrest in the labor stages, four cases not responding to augmentation of labor, two meconium cases, and two fetal distresses with no significant difference [6].

Laloha et al stated that the frequency of C/S (Caesarian Section) in case and control group was 9.9% and 8.1%, respectively with no significance, this follows our results [4].

Kavanagh et al aimed to determine the effects of corticosteroids for third trimester cervical ripening or induction of labor in comparison with other methods. They disagreed with us and stated that the primary outcome vaginal birth within 24 hours was not reported. No benefit of intramuscular administration of corticosteroids with intravenous oxytocin was found when compared with oxytocin alone. However, given the small size of this trial this result should be interpreted cautiously. This method of induction of labor is not commonly used [10].

In contrast to our study, Pahlavan et al mentioned that the duration of the second stage of labor ( $p < 0.001$ ) and the third stage ( $p < 0.001$ ) was lower in the study group compared with that of the control group that may be due to different methodology. As his study he used Dexamethasone intramuscular, induction of labor was in term pregnancies (GA 40-42 weeks) with intact membranes [6].

Similar to current study, Elsayed et al stated that there were no statistically significant differences between the two groups as regard duration of 2nd and 3rd stages of labor [9].

Statistical analysis of current study showed that there were no significant differences between dexamethasone and control groups regarding neonatal condition as birth weight, APGAR 1 and 5 minutes and need for NICU admission. Postpartum hemorrhage (PPH), also postpartum endometritis, chorioamnionitis were not reported among the studied groups.

While Pahlavan et al stated that the fetal complications in the study group included one infant admitted in the neonatal intensive care unit (NICU) for respiratory distress and one infant for fetal heart rate variation. Also, in the control group, two infants were admitted in the NICU for respiratory problems. Regarding maternal complications, 4 (6.5%) women with nausea were observed in the dexamethasone group, while there were 3 (5.0) cases of nausea in the control group, all non significant statistically [6].

Laloha et al agreed with us and stated that there was no significant difference in the first and fifth minute Apgar score between case and control groups ( $P<0.98$ ,  $P<0.79$ ) [4].

Elmaraghy et al stated that there were no significant statistical differences between the two studied groups as regards fetal heart rate [7].

Ahmed et al goes with our results and stated that there was no significant difference between dexamethasone and saline groups regarding neonatal condition as birth weight, APGAR 1 and 5 minutes and need for NICU admission [8].

Points of strength of the study:

Double blinded RCT study, randomization, allocation and concealment of study population were done.

Assessment of study outcomes was done by the same observer, the study included women with term pregnancies with pre-labour rupture of membranes with no studies done before in this area.

Limitations of the study:

Exclude women with medical disorder and Great variation in Gestational age and Bishop score.

## Conclusion

From the results of current study we can conclude that: Intravenous administration of dexamethasone in addition to labor induction according to the American College of Obstetricians and Gynecologists protocol shortened the induction - active phase and active phase durations. It shortened the total induction-delivery duration and increased the rate of successful vaginal delivery, but has no effect on second and third stages' durations, incidence of intrapartum complications as fetal distress, arrest of delivery process, rate of emergency CS, chorioamnionitis. Use of

dexamethasone didn't alter neonatal condition as regards birth weight, APGAR 1 and 5 minutes and need for NICU admission, also didn't increase the incidence of postpartum complication as postpartum hemorrhage or postpartum endometritis.

#### *Compliance with ethical standards:*

#### **Disclosure statement**

No potential conflict of interest was reported by the authors.

**Informed consent:** Informed consent was obtained from all individual participants included in the study.

**Ethical approval:** All procedures performed in studies involving human participants were in accordance with ethical standards of the Ethical committee of the department of obstetrics and gynecology faculty of medicine, Ain Shams University.

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