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Original article

The effect of dexamethasone therapy on prolonged latent phase of labor: a randomized double-blind clinical trial

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Abstract

Background: [illegible] both mothers and fetuses. The aim of the study was to investigate the effect of dexamethasone on the augmentation and the duration of labor in prolonged latent phase of labor.

Method: The design of the study was a randomized double-blind clinical trial design, which was conducted in delivery center of Rouhani hospital in Babol (Iran). A total 121 nulliparrous women 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 Then, the augmentation of labor with the use of intravenous oxytocin infusion (Caspian Tamin Company Iran) (2.5 m units/ per minute) began in both groups. The primary outcome was the duration of time between the onset of augmentation and the second stage of labor.

Results: The duration of time between the onset of labor augmentation and the second stage of labor (hours) was 5.6±1.9 in the study group, whereas it was 7.7±1.5 in controls with a significant difference ($p \leq <0.001$). In the study group, the duration of time between the onset of labor augmentation and the active phase of labor was lower than that of the control group ($p= 0.02$). In addition, 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.

Conclusion: It is imperative that midwives administer dexamethasone to improve the prolonged latent phase in women during the labour.

Keywords: Labor, Augmentation, Dexamethasone, Caesarean section

Introduction

It is generally assumed that some women who undergo cesarean are likely to experience a prolonged latent phase of labor (1- 2). The prolonged latent phase could be associated with an increased risk of labor consequences such as postpartum hemorrhage, chorioamnionitis and operative delivery, and further maternal and newborn hospital stays (3-5). In addition,

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infants who are exposed to thick meconium stained amniotic fluid also need to receive neonatal intensive care (6).

One proposed method to accelerate the delivery process is the administration of corticosteroids. As a matter of fact, the activation of the hypothalamic-pituitary - adrenal – placenta axis in human embryo is regarded as one of the important components of natural childbirth (7-9). Some studies reported that the administration of corticosteroids could improve the induced labor in women (10-14). Kavanagh, however, indicated in two separate studies that the effectiveness of corticosteroids for the induction of labor was not certain (15- 16). The results of some other studies demonstrated that only the interval from the induction to the active phase in dexamethasone group was shorter, and that the active phase duration remained unchangeable (13, 17). It is worth mentioning that the augmentation of labor is known as a method for shortening the prolonged latent phase (6).

This study was designed based on the assumption that the administration of corticosteroids was an important component of natural childbirth. Our aim was to explore the impact of dexamethasone on labor augmentation and the duration time of labor in prolonged latent phase of labor.

Materials and Methods

This double-blind randomized controlled clinical trial study was approved by the ethic committee of Babol University of Medical Science (protocol number: 30/4419), and was also registered in Iranian Registry of Clinical Trials (IRCT ID: 201401221760N29). The study protocol was based on the declaration of Helsinki. The population for the study was selected from among the healthy nulliparrous women who were hospitalized in the labor unit of Ayatollah Rouhani Hospital in Babol (Iran). All the participants were diagnosed to have prolonged latent phase at the gestational age of 40-42 weeks. The study was conducted over the period between June 2012 and June of 2013. It should be noted that we selected only the patients who had been prenatally trained for normal vaginal delivery; thus, they knew everything about latent phase or prolonged latent phase.

Prolonged latent phase for nullipara women is defined as the perceived regular spontaneous uterine contractions (women's report) ≥20 hours with any cervical dilatation and/or the effacement until the active phase of labor begins (18). The inclusion criteria for the study were: the singleton pregnancy, fetus cephalic presentation at 40–42 gestational weeks, intact membranes, and normal amniotic fluid. Pregnant women with maternal systemic diseases, fetal distress in the third trimester, Intrauterine growth retardation (IUGR), fetus abnormality, and macrosomia (babies weighing more than 4 kgs) were excluded from the study.

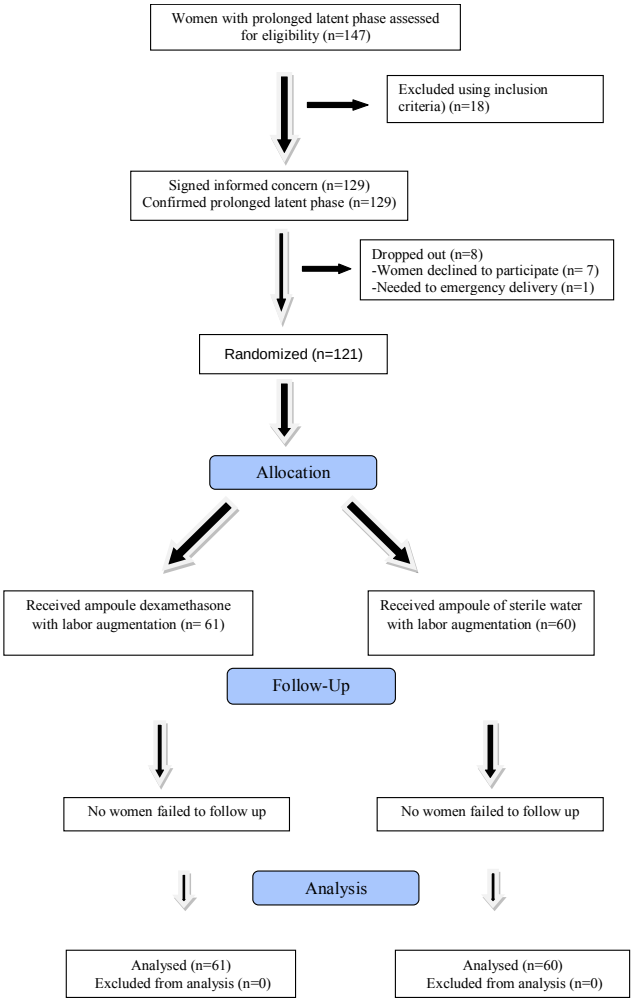

Fig. 1: The chart of selection of participants in the study.

The gestational age was calculated based on the last menstrual period (LMP) confirmed by ultrasonography in the first trimester.

A total number of 147 women with prolonged latent phase were assessed for eligibility, based on the inclusion/exclusion criteria. 18 women were excluded as they did not meet the criteria, and 129 women were

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Table 1. Characteristics of patients in study and control groups.

Variables	Dexamethasone (n=61) (Mean±SD)	Control (n=60) (Mean±SD)
Age(yr)	24.2±3.9	23.9±4.1
BMI(Kg/m2)	24.2±2.9	23.9±3.3
Gestational age(Week)	39.5±0.9	39.4±1.1
Primary Bishop Score	7.1±0.2	7.1±0.3

asked to sign the informed written consent. Seven women declined to participate, and one woman needed urgent cesarean section. Finally, a total number of 121 young women with prolonged latent phase were randomly divided into two groups. We used the blocked randomization with a block size of 4 and 6 possible arrangements as a way to randomly allocate a participant to a study or control group (Figure 1). First, 2 ml ampoule dexamethasone phosphate (produced by local pharmaceutical company Iran hormone Pharmaceutical Lab., Tehran, Iran) 4 mg/mL (study group) and 2 ml ampoule of sterile water (control group), which were both intramuscularly administered. Then, the augmentation of labor with the use of intravenous oxytocin infusion (Caspian Tamin Company Iran) (2.5 m units/ per minute) began in both groups. It should be noted that both the researchers and the participants were blinded to the treatment throughout the course of this research. To avoid the probable side effects, a midwife, as a third person, was aware of the treatment throughout the labor. Every 15 minutes, the dose of oxytocin was increased, and amniotomy was also done for both groups.

The primary outcome was the duration of time between the onset of labor augmentation and the second stage of labor. Determining the interval between the onset of labor and delivery, the duration of the active phase of labor, the duration of the second stage of labor, and the duration of the third stage of labor and the Apgar score of infants at the first and five minutes after birth were the secondary outcomes of this study. The modified Bishop score was used as the cervical assessment system in clinical practice in two stage of labor (administration and following augmentation. This score system was based upon the station of the presenting part and four features of the cervix: dilatation, effacement, consistency, and position (19). After the treatment phase, we decided to apply strategies (ITT) for the participants who did not receive the intervention, or may have missed the follow up.

Statistical analysis

All the data were analyzed through SPSS (version 18). The Chi-square and Fisher-exact tests were used to determine the relationship between qualitative variables. For quantitative variables, the t-test was used. The P-value < 0.05 indicated a statistical significant difference.

Results

The figure demonstrates the participation process of the pregnant women in the study. After the allocation phase, one woman in the dexamethasone group did not receive the intervention (declined to participate). None of the women failed to follow up. Finally, 61 women in the study group were compared with 60 women in the control group. 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 (Table1).

As a whole, 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 meconial cases, and four arrest cases. Among 13 women who had caesarean section in the control group, the reasons for the cesarean section included five cases of arrest in the labor stages, four cases of not responding to augmentation of labor, two meconial cases, and two fetal distresses.

Table 2 illustrates participants' vaginal delivery process in different phases of labor among 97 women (50 women in the study and 47 women in the control group) who had vaginal delivery. The duration of time between the onset of labor augmentation and the second stage of labor (hours) was 5.6 ± 1.9 in the study group, whereas it was 7.7 ± 1.5 in controls with a significant difference ($p \leq <0.001$). In the study group, the duration of time between the onset of labor augmentation and the active phase of labor was lower than that of the control group ($p= 0.02$). In addition, 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.

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

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Table 2. Participants' vaginal delivery process in different phases among women who had vaginal delivery*

Delivery Phase	Dexamethasone (n=50) (Mean±SD)	Control (n=47) (Mean±SD)	P-value
Bishop score following augmentation	8.2±0.5	7.5±0.6	<0.001
The first minute Apgar Score of infants	8.7±0.5	8.6±0.5	0.39
The fifth minute Apgar Score of infants	9.8±0.4	9.6±0.5	0.09
Duration time between the onset of labor augmentation until the beginning of the active phase (hours)	2.1±1.9	3.1±1.3	0.02
Duration of active phase of labor (hours)	2.9±0.9	4.9±8.1	0.1
Duration of the second stage of labor(minute)	35.4±11.6	49.2±16.9	<0.001
Duration of the third stage of labor(minute)	4.3±29	6.4±3.3	<0.001
Duration between time of the onset of labor augmentation until the second stage of labor (hours)	5.6±1.9	7.7±1.5	<0.001

* 11/61women in the study group and 13/60 women in the control group had cesarean section.

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.

Discussion

The most obvious finding to emerge from the analysis is that the duration between augmentation and the second stage of labor in the patients receiving dexamethasone was less against patients receiving the placebo. The related p-value indicates that there is only 0.001 probability that chance produced through the dexamethasone effect. In addition, the calculated effect size of the study with 95% confidence coefficient was 1.2 with confidence Interval (0.84-1.62). Accordingly, there is a considerable effect of dexamethasone on improving the duration between the augmentation and the second stage of labor.

The findings of the current study are consistent with the results of studies by Ziaee et al (20) and Kashanian et al. (13). However, kavanagah reported that the effect of corticosteroid in the augmentation of labor was ambiguous. This difference could be due to the limitations in the studies conducted by Kavanghah (16).

Contrary to expectations, we found that the duration between the augmentation and the onset of the second stage of labor was reduced significantly with the addition of dexamethasone, while the duration of the active phase of labor was reduced, but was not significant. In other words, dexamethasone only improved the prolonged latent phase with no significant shortening of the active phase.

These findings are also in line with the ideas of Laloha and Hajvandi. Even though the patients had primary bishop score ≥7 in the present study, it was ≤4 in their study. Kashanian also reported such conclusion, while her participants had the Bishop score ≥7. She, however, suggested the need for further studies for more tangible results (13). When we calculated the effect size to describe the strength of the effect of dexamethasone on the duration of active phase of labor, the conclusion was 0.3 with 95% CI (-0.03-0.7), which represented an effect but was weak. Future studies with larger samples are required to clarify this discrepancy.

In this study, the mean duration of the second and third phases of delivery was significantly lower in the women receiving dexamethasone compared with that of the control group. In Kashanian's study, a significant difference was seen in the duration of the second stage of labor between the two groups; however, no difference was seen in the third stage (13). Such a difference in the third stage may be attributed to the difference in the age, the lower mean gestational age, and also the sample size in both studies.

In this study, the obtained mean Bishop score of patients in the group receiving dexamethasone following was significantly higher than that of the control group. Such a finding was also seen in Hajivadi's study (7.2 vs. 2.8) (14). We did not find other modified Bishop score after the injection of dexamethasone in previous studies. Naturally, as the duration time between the start of augmentation of labor and the delivery was lower in dexamethasone group than in the controls, the Bishop score after the

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injection should be probably higher in the dexamethasone group than in the control group.

In our research, the rates of vaginal delivery in the two groups were compared with each other. Such conclusions seem to be consistent with the results of other studies (11, 13, 17). Even in Zafarghandi et al.'s study, the majority of women in both groups had vaginal delivery (21), while in Hajjvandi et al.'s study, the vaginal delivery rate was lower in the control group versus the group receiving dexamethasone, which may be due to the lower Bishop score of the participants in Hajjvandi's study compared to the present study (Bishop score considered in Hajjvandi study was less than 4, and it was more than 7 in the current study) (14). No differences were seen in the Apgar score afterbirth between the two groups' infants in this study. The same results were also reported by Kashanian, Hajjvandi and Mati. (13, 14, 22).

Conclusions

The administration of dexamethasone, which can reduce the time between augmentation and delivery through improving the Bishop score in women, needed more stimulation in our study, although the final rate of vaginal delivery in the two groups were compared with one another. As the use of oxytocin is regarded as the first line method for augmentation, which may cause postpartum atonia (16), dexamethasone, as a helpful option, can improve labor and the process of delivery. Experts in midwifery and obstetricians may consider the administration of dexamethasone during the labor in accelerating labor in women with prolonged latent phase.

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Conflict of interest

None declared.

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