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COMPARISON OF DEXAMETHASONE GIVEN INTRAVENOUSLY TO MISOPROSTOL GIVEN BY VAGINAL ROUT IN ARTIFICIAL LABOR INDUCTION

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Abstract
Background: Doctors have recently become interested in using corticosteroids as a potential future agent that may be used to speed up the physiological process of labor, and this interest has been shared by a number of academics and investigators.
The study objective: The objective of the research is to contrast safety and efficacy of intravenous dexamethasone to that of vaginal misoprostol.
Patients and methods: The current project was designed as randomized controlled clinical trial. The current study enrolled 70 women at term pregnancy. The work has been carried out at "the department of obstetrics and gynecology" in Pediatric and Maternity Teaching Hospital in Iraq, Adiwaniyah Province during the time interval spanning the January the 2nd 2022 through June the 15th 2023. Those women were allocated in a random manner into two groups. The first group was considered group of intervention and they received dexamethasone sodium phosphate by intravenous rout (single dose of 8 mg) given 4 hours prior to the start of labor enhancement by oxytocin infusion; whereas, the second group was considered as control group since they were treated with vaginal 25 mcg of misoprostol tablet every four hours with evaluation of score of Bishop prior to each dose with a sum of four doses.
Results: The average of "time interval between induction and active phase" was shorter in a significant way in interventional category in comparison with category of controls, 8.29 ±3.51 hours versus 13.08 ±6.72 hours, respectively (p <0.001). The average of "time interval between active phase and vaginal delivery" was also shorter in a significant way in interventional category in comparison with control group, 3.37 ±2.49 hours versus 7.15 ±4.02 hours, respectively (p <0.001). In addition, the average of "time interval between induction and vaginal delivery" was shorter significantly in interventional category in comparison with group of controls, 11.08 ±5.71 hours versus 19.84 ±9.04 hours, respectively (p <0.001).
Conclusion: The utilization of dexamethasone, given intravenously, for induction of delivery in term pregnancy is helpful in reducing times intervals between induction and active phase, between active phase and vaginal delivery and between induction and vaginal delivery and this is clinically important because it will be associated with lower rates of fetal and maternal complications.
Key words: intravenous dexamethasone, labor induction

INTRODUCTION

A common obstetric intervention is artificial induction of labor as it is reported in approximately 25% of term pregnancies (1). In this intervention, the stimulation of uterus artificially results in progress of cervix effacement and dilatation with subsequent active labor and birth (2). The aim in this technique is to promote vaginal delivery by artificial stimulation of uterus contractions before onset of labor that is often spontaneous. For the purpose of shortening the interval of time between process of induction to delivery, the induction process often relies on cervical ripening (3).

One of the most important variables in the effectiveness of labor induction is cervical preparation. Unripe cervixes make induction attempts challenging and uncommonly successful because they are less susceptible than favorable cervixes to the effects of uterine muscle contraction and fetal presenting pressure. Induction failure or protracted labor and delivery requiring the use of equipment are possible outcomes of attempting to induce labor with an unripened cervix. This will result in low delivery satisfaction rates as well as unfavorable psychological and physiological repercussions (4).

At time of 36 to 38 weeks of natural pregnancy, the uterus is in a state of unresponsiveness. At this time structural changes and remodeling are happening in the cervix. Because of the effect attributed to prostaglandins, the cervix undergoes loss of structural adhesions, effacement and ripening; the sources of prostaglandins are fetal membranes, uterus and cervix (5, 6).

Scientists have been investigating various methods to stimulate the process of labor since they are interested in these agents and other biological processes. The onset of spontaneous labor has long been linked to prostaglandins. It appears that the usual course of labor causes inflammation, which boosts the release of

prostaglandins. Prostaglandins, which are produced in the myometrial tissue, help the uterus contract effectively during labor and may also soften the cervix without uterine activity (7). Misoprostol and other prostaglandins are advised for use during labor induction, according to the World Health Organization (WHO). In the absence of prostaglandins, oxytocin solely or in conjunction with a "balloon catheter" may be employed. A balloon catheter solely can also be helpful (8). Doctors have recently become interested in using corticosteroids as a potential future agent that may be used to speed up the physiological events of delivery, and this interest has been shared by a number of academics and investigators. Experiments on animals demonstrated the critical contribution of cortisol, that is secreted by adrenal glands, in fetuses of sheep other experimental animals evaluated in initiating the onset of delivery, despite the observation that the underlying molecular and cellular processes are not completely clear (9, 10).

The goal of the study is to contrast safety and efficacy of intravenous dexamethasone to that of vaginal misoprostol.

Patients and methods

Study design, patients' enrollment and intervention

The current project was designed as randomized controlled clinical trial. The current study enrolled 70 women at term pregnancy. The work has been carried out at "the department of obstetrics and gynecology" in Pediatric and Maternity Teaching Hospital in Iraq, Adiwaniyah Province during the time interval spanning the January the 2nd 2022 through June the 15th 2023. The criteria inclusion were pregnant nulliparous women at term (39 – 42 weeks), their age was in the range of 18 – 35 years, the Bishop score was less than 6, they have singleton fetus with cephalic presentation, amniotic fluid should be normal in amount and with ultrasound report during second trimester excluding congenital malformations. Women with chronic medical illnesses and or obstetric complications were excluded from the study.

Those women were allocated in a random manner into two groups. The first group was considered group of intervention and they received dexamethasone sodium phosphate by intravenous rout (single dose of 8 mg) given 4 hours prior to the start of labor enhancement by oxytocin infusion; whereas, the second group was considered as control group since they were treated with vaginal 25 mcg of misoprostol tablet every four hours with evaluation of score of Bishop prior to each dose with a total of four doses. "Body mass index (BMI) was calculated as body weight in kilogram divided by height in squared meters".

Ethical considerations

The approval of this research was issued bythe committee dealing with ethical approval in "the University of Al-Qadisiyah/ College of medicine" (ethical code is 25/298). All participant females accepted to be enrolled in the study.

Statistical analysis

Information were collected and then delivered into "statistical package for social sciences (SPSS)" spread sheet (IBM, Chicago, USA, version 16) for the aim of statistical analysis. Qualitative information was outlined as percentage and number. Numeric information was outlined as range, standard deviation and mean Comparison of means was done using student t-test. Contrast of rates was done using chi-square test. The significance level was considered when $p \leq 0.05$.

Results

General characteristics of women contrasted between reference group and interventional group are shown in table 1. Comparison of mean age revealed no significant difference between interventional group and reference group, 25.03 ±7.14 years versus 26.15 ±6.09 years, respectively ($p > 0.05$). There has been also no statistical variation in average body mass index (BMI) between interventional category and reference category, 27.28 ±5.03 kg/m2 versus 26.17 ±6.72 kg/m2, respectively ($p > 0.05$). In addition, comparison of mean gestational age between study groups revealed no significant difference ($p > 0.05$). The means of bishop score in interventional group and in reference groups were also comparable, 4.18 ±1.08 and 4.21 ±1.12, respectively ($p > 0.05$).

Comparison of mean time intervals between interventional category and reference category is outlined in table 2. The average "time interval between induction and active phase" was shorter significantly in interventional category in comparison with control category, 8.29 ±3.51 hours versus 13.08 ±6.72 hours, respectively ($p < 0.001$). The average time interval between active phase and vaginal delivery was also shorter significantly in interventional group in comparison with control group, 3.37 ±2.49 hours versus 7.15 ±4.02 hours, respectively ($p < 0.001$). In addition, the average time interval between induction and vaginal delivery was shorter significantly in interventional group in comparison with control group, 11.08 ±5.71 hours versus 19.84 ±9.04 hours, respectively ($p < 0.001$).

Comparison of rate of successful active phase initiation and rate of cesarean section is shown in table 3. The rate of successful initiation of active phase was higher in interventional group in comparison with reference group, 86.7 % versus 75.6 %, respectively; however, the difference was insignificant from statistical perspective ($p > 0.05$). With respect to mode of delivery, the rate of cesarean section was lower in interventional group in comparison with reference group, 17.8 % versus 28.9 %, but again, the difference was insignificant from statistical perspective ($p > 0.05$).

Table 1: General characteristics of women contrasted between reference group and interventional group

Characteristic	Interventional group (Dexamethasone) *n* = 45	Reference group (Misoprostol) *n* = 45	*p*
Age (years)			
Mean ±SD	25.03 ±7.14	26.15 ±6.09	> 0.05 I NS
Range	21-29	22-31	

BMI (kg/m^2)			
Mean ±SD	27.28 ±5.03	26.17 ±6.72	> 0.05 I NS
Range	21-29	20-28	
Gestational age (weeks)			
Mean ±SD	40.03 ±0.37	40.42 ±0.51	> 0.05 I NS
Range	39.43 -40.71	39.57 -40.71	
Bishop score			
Mean ±SD	4.18 ±1.08	4.21 ±1.12	> 0.05 I NS
Range	3-5	3-5	

n: number of cases; **BMI**: body mass index; **SD**: standard deviation; **I**: independent samples *t*-test; **NS**: not significant

Table 2: Comparison of mean time intervals between interventional group and reference group

Characteristic	**Interventional group (Dexamethasone) *n* = 45**	**Reference group (Misoprostol) *n* = 45**	***p***
Time 1(hours)			
Mean ±SD	8.29 ±3.51	13.08 ±6.72	<0.01 I ***
Range	5.31-14.09	7.82-19.37	
Time 2 (hours)			
Mean ±SD	3.37 ±2.49	7.15 ±4.02	<0.01 I ***
Range	1.03-5.13	2.72-9.03	
Time 3 (hours)			
Mean ±SD	11.08 ±5.71	19.84 ±9.04	<0.01 I ***
Range	6.62-19.13	9.71-27.17	

Time 1: interval between induction and active phase; **Time 2**: interval between active phase and vaginal delivery; **Time 3**: interval between induction and vaginal delivery; ***n***: number of cases; **SD**: standard deviation; **I**: independent samples *t*-test; ***: significant at $p \leq 0.001$

Table 3: Comparison of rate of successful active phase initiation and rate of cesarean section

Characteristic	**Interventional group (Dexamethasone) *n* = 45**	**Reference group (Misoprostol) *n* = 45**	***p***
Initiation of active phase			
Success, *n* (%)	39 (86.7 %)	34 (75.6 %)	> 0.05 C NS
Failure, *n* (%)	6 (13.3 %)	11 (24.4 %)	
Mode of delivery			
Vaginal, *n* (%)	37 (82.2 %)	32 (71.1 %)	> 0.05 C NS
CS, *n* (%)	8 (17.8 %)	13 (28.9 %)	

n: number of cases; **C**: Chi-square test; **NS**: not significant

Discussion

In this study, it was observed that the use of intravenous dexamethasone is helpful in reducing times intervals between induction and active phase, between active phase and vaginal delivery and between induction and vaginal delivery and this is clinically important because it will be associated with lower rates of fetal and maternal complications. Indeed, this observation was very similar to that obtained by Slaman et al. (8), who described same findings with respect to the above mentioned times intervals up on using intravenous dexamethasone. Moreover, we noticed higher rates of initiation of induction and lower rates of cesarean section in association with intravenous dexamethasone in contrast to vaginal misoprostol, but, the variation was insignificant and this finding is also in line with that made by Slaman et al. (8). Indeed our findings are also supported by the findings of Laloha et al. who stated that the utilization of intravenous dexamethasone caused significant reduction in "time interval between initiation of labor induction and onset of active phase" (11). In another study by Hajivandi et al. (12), the use of intramuscular dexamethasone was associated with significant reduction in mean "time interval between labor induction and onset of active phase" and this finding is supportive to our findings, however, the route of drug administration in our study was different in being intravenous rather than intra-muscular. Kashanian et al. also reported that the use of intramuscular dexamethasone in helpful in reducing "time interval between labor induction and onset of active phase" (13), in support for our results.

Therefore, it is obvious from the current results and the results of previous investigators, mentioned above, that the use of dexamethasone is helpful in reducing times intervals related to between induction and active phase, between active phase and vaginal delivery and between induction and vaginal delivery. Moreover, no serious side effects were reported following intravenous administration of dexamethasone for women participating in this study indicating that this procedure is safe and efficient.

In our study, we found higher rates of successful initiation of active phase and lower rates of cesarean section and these finding were similarly reported by Salman et al. (8). However, from statistical point of view, the difference was not significant.

Conclusion

The utilization of dexamethasone, given intravenously, for induction of delivery in term pregnancy is helpful in reducing times intervals between induction and active phase, between active phase and vaginal delivery and between induction and vaginal delivery and this is clinically important because it will be associated with lower rates of fetal and maternal complications.

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