

Cervical ripening by using extra-amniotic dexamethasone infusion versus extra-amniotic saline infusion

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Abstract:

Background: Induction of labour is a commonly practiced obstetric intervention designed to artificially initiate the process of cervical effacement to achieve vaginal delivery.

Objective: examine the hypothesis that corticosteroids, when administered extra-amniotically, can enhance labor process and reduce the induction--delivery interval in comparison with foley's and extra-amniotic saline infusion.

Patients and methods: This, randomized case- control study was conducted on 99 women, who were referred to the AL-Batool teaching Hospital in Diyala, Iraq, for induction of labor with a Bishop score of less than or equal to 5 from January 2014-March 2016, and divided into 2 groups, 1st group consist of 58 pregnant, a 26F catheter & and 20 mg of dexamethasone mixed with 20 ml of sterile saline solution infused extraamniotically. 2nd group consist of 41 pregnant, with the same size catheter attached to 500 ml of saline solution infused into the extra-amniotic space.

Results: Administration of dexamethasone extraamniotically improve the Bishop score, reduce the time needed for expulsion of the catheter, shortening of 1st&2nd stage of labour without increasing the caesarean section rate.

Conclusion: Extraamniotic administration of dexamethasone is effective & safe method for induction of labour.

Keywords: labor, induction, corticosteroid, cervical ripening.

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Introduction:

Induction of labour is common practice obstetric intervention designed to artificially initiate the process of cervical dilatation, uterine contraction after augmentation with oxytocin and delivery of the baby(1). Labour induction when the cervix is unripe associated with a higher than normal incidence of prolonged labour, instrumental delivery and cesarean section. To prevent these complications, many of methods develop for cervical ripening and labour induction (2). Ripening of the cervix is normally physiological process that precedes uterine contraction and includes high complex biochemical process. The purpose of cervical ripening and induction of labour is to achieve vaginal delivery (3). There are multiple approaches for cervical ripening, including mechanical and non-chemical methods. Mechanical method for cervical ripening have several advantage in comparison to pharmacological methods, including low cost, can be reversible, abnormality of fetal heart and low risk of tachysystole(4). Oxytocin and prostaglandin as pharmacological methods, oxytocin is the most common agent used (5). Folly's catheter balloon is the most common mechanical method for labour induction that acts not only as a mechanical dilator for the cervix but also as a stimulator of endogenous prostaglandin release (6).

Especially with saline infusion, this technique has been reported to improve the Bishop score and decrease induction to delivery time compare with other methods (7). The mean induction to delivery time with catheter infusion was significant less than other methods also did not increase the risk of preterm labour in subsequent pregnancy (7,8). The role of corticosteroid in this process is not well understood. Several study have been reported that intramuscular or intraamniotic injection of corticosteroid result in higher rate of successful induction of labour in lambs and human. There is a possible role in parturition as being effective in a paracrine or autocrine action because amniotic fluid receptors for glucocorticoids have been found (3).

Materials and Methods:

In this double blind randomized case- control study we compared extra amniotic infusion of corticosteroids with infusion of saline solution for ripening of the cervix prior to induction of labor. The study conducted on 99 nullipara women with singleton pregnancy and a gestational age of 37 to 42 weeks, who were referred to the Al-Batool Teaching Hospital in Diyala, Iraq, for induction of labor with a Bishop score < or = 5, from January 2014-March 2016. *Inclusion criteria* for induction of labour during the study time included postdate pregnancy (83), hypertensive disorders (3), Rh incompatibility (9) and maternal diabetes (4). *Exclusion criteria* were known invasive cervical carcinoma, uterine anomaly, cephalopelvic disproportion (because of abnormal pelvic bone structures or malpresentation), known placenta

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previa or low-lying placenta, vasa previa, oligohydramnios, abruption placentae, documented episode of midtrimester or thirdtrimester bleeding, active genital herpes, intrauterine fetal death, maternal fever, three or more uterine contractions in 10 minutes and previous classical uterine incision.

An informed consent was obtained from the patients. Patients randomized to one of 2 groups:

The 1st group consist of 58 pregnant, a 26 F catheter, was inserted under direct vision through the cervix of patients using sterile technique and then inflated with 30 ml sterile water, and a total dose of 20 mg dexamethasone mixed with 20 cc of sterile saline solution infused into the extraamniotic space then the end of catheter taped to the patient's inner thigh.

The 2nd group consist of 41 women received the same procedure except that the infusion of 20 mg of corticosteroids was replaced by 500 ml of pure saline solution ,with a rate of 5 drop/min through the catheter into the extra-amniotic space. The patients were monitored for fetal heart rate and maternal vital sign. Gentle traction of the catheter was performed every hour to watch for expulsion of the balloon. If the balloon was not expelled within 6 hours, it was deflated and extracted. After extra ameniotic catheter expelled, intravenous oxytocin administered as an initial dose until three contractions per ten minute were achieved. The patient were re-examined for Bishop Score after a further 2 hours). Only when the patient passes to the active phase of labor, which defined as three or more contractions in 10 minutes and cervical dilatation ≥ 4 cm, the protocol was continued. Amniotomy was performed only in the active phase. If the patient did not develop the progress (Bishop Score < 5), oxytocin was stopped and failure of induction was announced.

Statistical analysis

Those data express as mean plus minus standard deviation was used unpaired t test to show the comparison between groups, while those express as frequency and percentage, the comparison done by chi square test and fisher exact test.

Results:

In this study there were no significant difference regarding maternal age, gestational age, and birth weight between the two groups. Mean maternal age was (28.53 \pm 5.38)in 1St group and the mean gestational age, birth weight were (40.82 \pm 0.67),(3.46 \pm 0.51) respectively while mean maternal age in the 2nd group was (28.8 \pm 5.71)and the mean gestational age, birth weight were (40.82 \pm 0.68), (3.58 \pm 0.43)respectively in 2nd group .Regarding gender of babies ,it was(43.1% male& 56.9%) female in 1st group, while it was about (31.71% males&68.29% females) in 2nd group, as shown in table(1) .

Table (1): Socio-demographic parameters between two study groups:

Parameters	Foly Dexamethasone N=58	+ Foly with saline N=41	p-value
Maternal age (yr)	28.53 \pm 5.38	28.8 \pm 5.71	0.813
Gestational age (wk)	40.82 \pm 0.67	40.82 \pm 0.68	0.945
Birth weight	3.46 \pm 0.51	3.58 \pm 0.43	0.222
Babygender	Male	13 (31.71%)	0.297
	Female	28 (68.29%)	

*Data are presented as mean \pm SD unless otherwise specified.
** No significant difference was found between groups in any of parameters.

Regarding Bishop score table (2) showed no statistical significance found between two groups regarding Bishop score before introduction of foley catheter P-value of (0.110) while significantly higher Bishop score after expulsion of foley catheter in the 1st group than in the 2nd group with P-value of (0.04).

Table (2): Comparison of Bishop Score before& after expulsion of catheter between the two study groups:

Drug use	Score	Foly& Dexamethasone N=58	Foly&Saline N=41	Pvalue
before use of drug	3	36(62.07%)	17(41.46%)	0.110
	4	18(31.03)	18(43.9%)	
	5	4(6.9)	6(14.63%)	
after use of drug	6	6(10.34%)	4(9.76%)	0.040
	7	21(36.21%)	25(60.97%)	
	8	31(53.45%)	12(29.27%)	

Table (3) showed the time needed for expulsion of foley catheter it mean from start of ripening of cervix till establishment of active labor was shorter in the 1st group meanof time (150.36 \pm 46.79) compared with 2nd group meanof time (223.83 \pm 40.0), with P-value of <0.001.The mean duration of 1st stage of labor was (184.53 \pm 44.6 min.) in the 1st group which is shorter than in 2nd group (222.0 \pm 47.62 min.) (P-value < 0.001). The duration of 2nd stage was also shorter in the 1st group (with mean of 33.25 \pm 9.14 min.) compared with the 2nd group (with mean of 44.02 \pm 7.0 min.). No significant difference regarding the mode of delivery between the two groups (91.38% delivered vaginally versus 8.62% delivered by caesarean section) in the 1st group, while (87.8% delivered vaginally versus 12.2% delivered by caesarean section) in the 2nd group (P-value 0.737).

Table (3): Comparison of time of catheter, duration of (1st & 2nd) stage the mode of delivery between the two study groups

Parameters	Foly+ Dexamethasone N=58	Foly&Saline N=41	P_value
Time of catheter (min)**	150.36±46.79	223.83±40.0	< 0.001
Duration of 1st stage (min)**	184.53±44.6	222.0±47.62	< 0.001
Duration of 2nd stage (min)**	33.25±9.14	44.02±7.0	< 0.001
Mode of delivery	Vaginal 53(91.38%) Cesarean section 5(8.62%)	36(87.8%) 5(12.2%)	0.737

*Data are presented as mean±SD unless otherwise specified.
**Significant difference was found between groups in any of parameters, (p value < 0.001).

Apgar score at 1minute & 5minute in this study showed no statistically significant difference in Apgar score between the two groups with P-value of(0.844),(0.087) in 1st and 2nd group respectively .as in table(4).

Table (4): Comparison of Apgar Score at 1&5 minute between the two study groups

Drug use	Score	Foly& Dexamethasone N=58	Foly&Saline N=41	P-value
Apgar score at 1 min	6	4 (6.9%)	4(9.76%)	0.844
	7	41 (70.69%)	29 (70.73%)	
Apgar score at 5 min	8	13 (22.41%)	8(19.51%)	0.087
	9	55 (94.83%)	34 (82.93%)	

Discussion:

Induction of labour and delivery considered as the most common practices in modern obstetrical care but it is associated with maternal and/or fetal complications (7, 8). The most important characteristic features of agents used in cervical ripening are adequacy in decreasing time to delivery, its safety, and capability in increasing the possibility of vaginal delivery (9, 10). In this study a foley’s catheter with extra-amniotic infusion of steroid was used , which is a simple, cheap method with minimal complications. It has been shown that induction of labour with foley's catheter and extra-amniotic dexamethasone improve the bishop score & shortening the time needed to the active labor compared to induction by intracervical saline infusion (10) . Corticosteroids role in initiation of labour still not well known. Studies done in animals showed that cortisol secretion by the fetal adrenal

gland is important in establishing sheep labour. Premature labour after infusion of glucocorticosteroid in sheep fetuses was observed according to these studies it has been hypothesized that induction of labour in women will promote by corticosteroids (11). In this study there is no significant difference in the age of patient , gestational age and parity in both 1st and 2nd group, this in agree with many researchers like Mansouri et al.(12)and Zafarghandi et al. (13) who used the same methods for ripening of the cervix. After expulsion of the catheter Bishop score was higher with high statistical significance p- value 0.040 in group receiving extra-amniotic dexamethasone than group received extra- amniotic saline infusion, this in agreement with Maha A (14) who applied her study on pregnant women in Baghdad and found that post ripening Bishop score was higher in group receiving extra-amniotic corticosteroid than extra-amniotic saline infusion. The most important findings in this study that the mean time interval between establishment of ripening of cervix till start of active labour was significantly shorter in 1st group compared with 2nd group with p-value of (< 0.001) these findings in concordance with Zafarghandi et al. (13) and Hajivandi et al (15) who also concluded shorter interval between induction of labour with corticosteroid comparing with other group used extra-amniotic saline infusion.In this study also we found that adding dexamethasone extra amniotically to intracervical catheter decrease the duration of 1st&2nd stage of labor without any significant risk to the mother or her fetus, this agrees with Maryam et al(16) who approved the same findings. Currently, several randomized controlled trails are comparing use of a foley catheter with extra-amniotic saline infusion, prostaglandin E2 (PGE2) or currently corticosteroid, these studies concluded that cervix will effectively ripe by using all of these methods and each has equal effect on the rate of caesarean section delivery in females with an unfavorable cervix (17). Mode of delivery in this study had no significant difference between two groups and these findings agree with most of the researches in the same field (12, 13, and 14). This study found that there is no significant difference in 1 minute and 5 minute Apgar score between the 1st and 2nd group this in agree with Fatemeh et al. (18). All these findings disagree with review of researches done by Kavanagh et al. (11) who concluded from his review that the potency of corticosteroid for induction of labour is unreliable. This method of cervical ripening and induction of labour is not widely used and further research in this field is presumably unreasonable. So on the other hand the results of this study demonstrate the effectiveness of extra-amniotic dexamethasone in ripening of the cervix prior to induction of labour but this concluded from limited number of data so further study required to reach to exact route and dose required to produce this effect.

Conclusion:

Extraamniotic administration of dexamethasone is effective, cheap & safe method for induction of labour.

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Dr. Sawsan Talib Salman: data collector & writer
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Dr. Inaam Faisal Mohammed: data collector & writer

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