Comparison of Extraamniotic Corticosteroids Injection versus Extraamniotic Saline Infusion for Ripening of the Cervix

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Abstract

Objective: To compare the effectiveness, safety and patient acceptability of extraamniotic corticosteroids injection versus; extraamniotic saline infusion for ripening of the cervix in induction of labour.

Study design: An interventional randomized comparative clinical study.

Patients & methods: This study was conducted in Gynaecology and Obstetric department of Al-Kadimyia teaching hospital. The study includes 100 pregnant women with a gestational age of 36-42 weeks, an unfavorable cervix and obstetric indication for induction of labour. The patients were divided into group A and group B. Group A received dexamethasone in saline solution, and group B received saline solution only with a concentration of (0.9%) administered extraamniotically through an intracervical inflated Foley's catheter.

Results: Group A achieved the higher post-ripening Bishop's score. The mean priming and the induction-delivery interval times were significantly shorter in-group A compared with those of group B (2.61 ± 0.42 h versus 4.38 ± 0.32 h with a P value = 0.0001 and 6.38 ± 1.57h versus 9.15 ± 0.99 h with a P value = 0.0001 respectively).

Conclusion: Extraamniotic corticosteroids injection was found to be superior method for induction of labour in comparison with extraamniotic saline infusion.

Key words: Induction of labour, Bishop's score, Corticosteroids

Introduction:

Planned induction of labour has become an established part of modern obstetric practice[1]. Labour induction is indicated when the benefits to either the mother or the fetus outweigh those of continuing the pregnancy [2]. The most important factors for successful induction of labour include the condition of the cervix and the level of fetal presenting part, or station [3].

One quantifiable method that is predictive of a successful labour induction is that described by Bishop in 1964 and induction of labour is usually successful with a Bishop score of seven or greater and is less successful with lower scores [4]. Other factors include gestational age, maternal health and parity, fetal health and obstetric unit facilities [5].

Cervical ripening is now seen as an essential requirement for successful induction of labour so the cervices were classified prior to induction of labour as ripe (soft, dilated and effaced) and unripe (firm, long and undilated) [6]. Induction of labour in cases with unripe cervix is frequently associated with maternal complications and induction failure [7].

One of the pre induction cervical ripening mechanical techniques is the insertion of a Balloon catheter into the extraamniotic space [5]. It can be used for induction of labour either alone, with traction or with infusion using the isotonic normal saline or corticosteroids in the form of Dexamethasone [8, 9]. Various studies demonstrate the local effect of glucocorticoid on PG production. Human amnion cells in primary monolayer cultures were found to respond to dexamethasone with an increase in PGE2 output [10]. This increase is mediated by glucocorticoid hormone receptors. Amnion contains a very active phospholipase C; hence, it is possible that dexamethasone increases lipocortin 1 formation that enhanced phospholipase C activity leading to greater release of arachidonic acid from glycerophospholipid stores that serves as substrate for increased PG biosynthesis [10].

Other studies have demonstrated that dexamethasone could also potentiate the stimulatory action of epidermal growth factor on amnion PGE2 biosynthesis. Epidermal Growth Factor can induce phosphorylation of lipocortin, an action that may attenuate the antiphospholipase activity of lipocortin [10].

This study was conducted to compare the effectiveness, safety and patient acceptability of extraamniotic corticosteroids injection versus extraamniotic saline infusion for cervical ripening in induction of labour.

Patients & Methods:

This interventional randomized comparative study was conducted at the department of Obstetrics and Gynaecology in Al-Kadimyia teaching hospital during the period from June 2003 through March 2004. Hundred pregnant women were randomly selected both primigravidae and multiparae

(para1-4) presented with obstetric indications for induction of labour. The criteria used for collection of cases include gestational age of 36-42 weeks, unfavorable cervix (Bishop's score ≤ 5), singleton pregnancy, vertex presentation and intact fetal membranes. Women with a known uterine anomaly, placenta praevia, maternal fever, intrauterine death, previous caesarean delivery and

three or more uterine contractions in 10 minutes were excluded from the study.

The indications for induction of labour includes postdate pregnancy, suspected fetal compromise (decrease fetal movements and poor biophysical profile) and hypertensive disorders. Eligible patients were informed about the purpose of the study and were requested to sign an informed consent.

After medical, surgical, drug and obstetrical history was taken from all women, they were subjected to full physical and obstetrical examination. Pelvic examination was performed to estimate pelvic capacity and assess the state of the cervix (Bishop's score) which was recorded as an initial Bishop's score. The patients were randomly divided into two groups. The first group (group A) includes 50 patients (primigravidae = 30, multiparae = 20) who have application of Foley's catheter (size 20) with extraamniotic corticosteroids injection and the second group (group B) includes 50 patients (primigravidae = 30, multiparae = 20) who have application of Foley's catheter (size 20) with extraamniotic saline infusion.

For group A (20 mg) of dexamethasone mixed with sterile saline solution up to a volume of 20 ml was injected through the catheter into the extraamniotic space followed by continuous infusion of normal saline solution at a constant rate of 15 drops/minute into the extraamniotic space. Group B received the same treatment except that 20 mg of corticosteroids was replaced by 20 ml of pure saline solution. In both groups, gentle traction of the catheter was performed every hour to check for expulsion of the balloon. Fetal heart sounds were checked regularly.

After expulsion of the balloon pelvic examination was performed to assess changes in Bishop's score and recorded as post-ripening Bishop's score. Time between pre and post-ripening scores was recorded and uterine contractions were checked manually, if uterine action was inefficient after expulsion of the balloon, augmentation with artificial rupture of membranes was done under aseptic condition. One-hour later if uterine contractions persist to be inefficient an intravenous oxytocin infusion was started. The course of labour was followed-up by the partogram and assessed by the same investigator. The time interval from induction of labour to delivery was recorded in both groups and all newborns were handled and examined by paediatrician.

The patients were followed up for the complications of balloon application such as nausea, vomiting, uterine hypertonus and febrile morbidity. None of them received prophylactic antibiotics. The patients and the newborns were observed for the first 24 hours after delivery as the majority of them were discharged home.

The data were analyzed and presented in simple measures of frequency, percentage, mean and standard deviation. Student-t-test and chi-square test were used for testing the significance of difference for quantitative and qualitative data respectively. P value of ≤ 0.05 was used as the level of significance.

Results:

Hundred pregnant women with a gestational age of ≥ 36 weeks were studied. They were divided into two groups; group A received extraamniotic corticosteroids injection and group B received extraamniotic saline infusion. Each group includes 30 primigravidae and 20 multiparae. Maternal characteristics that included age, parity and gestational age did not differ significantly among the pregnancies.

The mean initial Bishop's score in primigravidae was 2.73 ± 0.69 in group A and 2.83 ± 0.79 in-group B. In multiparae, the mean initial Bishop's score was 3.60 ± 0.75 in-group A and 3.55 ± 0.75 in group B. There were no statistically significant differences between the two groups.

Table 1 compares the pre- and post-ripening Bishop's score; the time elapsed between them and the induction-delivery time between the two groups. It revealed that the mean post-ripening Bishop's score was higher in-group A than that in group B and the difference was statistically significant (P = 0.0001). In addition, the mean time between pre- and post-ripening Bishop's score was significantly shorter in-group A than in group B (P = 0.0001) and the mean interval from induction of labour to the delivery was significantly shorter in group A compared with group B (P = 0.0001). Table 2 demonstrates that in primigravidae the mean post-ripening Bishop's score was higher in group A than in group B. The difference was statistically significant (P = 0.028) and the mean primary time was significantly shorter in group A than in group B (p = 0.0001). The mean induction to delivery interval was shorter in group A compared with group B and the difference was statistically significant (P = 0.0001).

Table 1: The pre- and post-ripening Bishop's score and induction-delivery interval

Parameters	Group A (n=50) Mean ± SD	Group B (n=50) Mean ± SD	P-value
Initial Bishop's score	3.08 ± 0.82	3.12 ± 0.84	0.664
Post-ripening Bishop's score	7.38 ± 0.90	6.45 ± 0.69	0.0001
Time between pre- and post-ripening score (hr)	2.61 ± 0.42	4.38 ± 0.32	0.0001
Induction-delivery time (hr)	6.38 ± 1.57	9.15 ± 0.99	0.0001

Table 2: The pre- and post-ripening Bishop's score and the induction-delivery interval (Primigravidae)

Parameters	Group A (n=30) Mean ± SD	Group B (n=30) Mean ± SD	P value
Initial Bishop's score	2.73 ± 0.69	2.83 ± 0.79	0.829
Post-ripening Bishop's score	7.12 ± 0.88	6.40 ± 0.70	0.028
Time between pre- and post-ripening score (hr)	2.62 ± 0.46	4.45 ± 0.37	0.0001
Induction-delivery time (hr)	7.24 ± 1.17	9.80 ± 0.79	0.0001

Table 3 compares the mean initial Bishop's score, the mean Post-ripening Bishop's score, the mean priming time and the mean Induction-delivery interval between the two groups in multiparae. It revealed that the mean Post-ripening Bishop's score was significantly higher in group A than in group B (P = 0.0001) and the mean priming time in group A was shorter than in group B which was statistically significant (P = 0.0001), also the mean induction-delivery time was significantly shorter in group A than in group B (P = 0.0001). Table 4 compares the mode of delivery between the two groups in both primigravidae and multiparae.

There was no significant difference between them. Regarding the perinatal outcome, this study revealed no statistical significant differences between the two groups and there was no recorded significant maternal infection or other complications during the antepartum, intrapartum and the immediate postpartum period.

Table 3: The pre- and post-ripening Bishop's score and induction-delivery interval (Multiparae)

Parameters	Group A (n=20) Mean ± SD	Group B (n=20) Mean ± SD	P value
Initial Bishop's score	3.60 ± 0.75	3.55 ± 0.75	0.999
Post-ripening Bishop's score	7.80 ± 0.78	6.50 ± 0.71	0.0001
Time between pre- and post-ripening score (hr)	2.60 ± 0.34	4.30 ± 0.26	0.0001
Induction-delivery time (hr)	5.93 ± 0.96	8.50 ± 0.71	0.0001

Table 4: The mode of delivery in group A and group B

Mode of delivery	Group A primigravidae		Group B primigravidae		Group A multiparae		Group B multiparae	
	No.	%	No.	%	No.	%	No.	%
SVD	26	52	28	56	19	38	18	36
AVD	1	2	0	0	0	0	0	0
C/S	3	6	2	4	1	2	2	4
Total	30		30		20		20	

SVD (Spontaneous vaginal delivery), AVD (Assisted vaginal delivery), C/S (Caesarean section)

Discussion:

Kossman et al explained the role of corticosteroids in cervical ripening. He found that at term the amniotic membranes in the human placenta express receptors for glucocorticoid [11]. In the amniotic fluid, the levels of cortisol rise throughout the pregnancy and more sharply before the appearance of regular contractions at term [7].

In this study induction of labour by the extraamniotic corticosteroids injection (group A) revealed that the mean induction to delivery time interval was 6.38 ± 1.57 h which was shorter than that reported by Barkai et al[7] as the mean induction to delivery time interval was 11.9 ± 3.0 h.

Regarding the induction of labour by the extraamniotic saline infusion (group B), the mean post-ripening Bishop's score was 6.4 ± 0.7 in primigravidae and 6.5 ± 0.71 in multiparae. This is lower than that reported by Schreyer et al [6] study which revealed 7.8 ± 0.9 for multiparae and that reported by Al-Dahhan study [12] which revealed 6.9 ± 0.9 for primigravidae and 7.3 ± 1.2 for multiparae.

The mean priming time was 4.45 ± 0.37 h in primigravidae and 4.30 ± 0.26h in multiparae which is shorter than that reported by Al-Dahhan study which revealed 6.1 ± 2.5 h for primigravidae and 5.7 ± 2.3 h for multiparae, but it is longer than that reported by Schreyer et al (2.81 for multiparae).

The mean induction to delivery time was 9.8 ± 0.79 h in primigravidae and 8.5 ± 0.71 h in multiparous. Which is shorter than that reported by Barkai et al study which revealed 14.5 ± 4.8 h but it

is longer than that reported by Schreyer et al (first stage = 5.84 ± 3.63 h and the second stage = 0.5 ± 0.3 h for multiparae) and that reported by Al-Dahhan study which revealed 7.5 ± 1.7 h for primigravidae and 5.8 ± 2.5 h for multiparae.

The differences between the results of our study and the results of Schreyer et al and Al-Dahhan studies could be due to the difference in sample size being 30 primigravidae, 20 multiparae in this study while 52 multiparae in Schreyer et al study and 11 primigravidae, and 18 multiparae in Al-Dahhan study.

In this study, we found that induction of labour by extraamniotic corticosteroids injection was more effective than extraamniotic saline infusion with respect to improvement in cervical score; shorter priming and induction to delivery times, and the differences were statistically significant between both groups. This study revealed that the antepartum, intrapartum, and the immediate postpartum periods were uneventful in both groups. Al-Dahhan also reported no significant maternal complications; however, Schreyer et al reported one case of early postpartum haemorrhage. Barkai et al reported febrile morbidity and uterine hypertonus in 14.3% and 7.1% respectively in the extraamniotic corticosteroids injection group and 12.5% and 7.5% respectively in the extraamniotic saline infusion group.

The main argument against the use of Foley's catheter for induction of labour was the risk of introduction of infection and accidental rupture of fetal membranes; these risks were reduced if not eliminated by aseptic precautions and the gentle application of Foley's catheter. None of our patients had accidental rupture of the membranes or pyrexia attributable to the use of Foley's catheter.

In conclusion, we found that the application of Foley’s catheter with extraamniotic corticosteroids injection is a successful method for induction of labour and it is superior to the induction of labour with extraamniotic saline infusion. It was found to be safe, easily applied, inexpensive, more rapid, more effective and acceptable by the patient as it is associated with little maternal discomfort and no recorded adverse perinatal outcome.

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