

ORIGINAL ARTICLE

Extra-Amniotic Infusion of Corticosteroids versus Normal Saline for Cervical Ripening and Shortening of 1st Stage of Labour in Mid Trimester Termination of Pregnancy

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ABSTRACT

Background: Pregnancy termination is still a big challenge for Obstetrician specifically in case when the Cervix is not ripped. Recently it was shown that the extra amniotic infusion of corticosteroids is superior in terms of mean duration of first stage of labour and frequency of cervical Ripening to the conventional practice of extra-amniotic infusion of normal saline. However, the limited data and lack of local research material necessitated this study.

Objective: The objective of this study was to compare outcome of extra-amniotic infusion of corticosteroids versus normal saline for cervical ripening and mean duration of 1st stage of labour in mid trimester termination of pregnancy.

Material & Methods: It was a randomized controlled trial. Research was conducted at Department of Obstetrics & Gynecology Rai Medical College Teaching Hospital, Sargodha from 10/01/2022 to 09/06/2022. This study involved 100 pregnant women aged between 18-40 years undergoing termination of pregnancy between 14-28 weeks of gestation (as per dating scan). These patients were randomly allocated into two groups. Patients in Group-A were given extra-amniotic infusion of corticosteroids while those in Group-B received extra-amniotic infusion of normal saline. Outcome variables were mean duration of first stage of labor and frequency of cervical ripening which was noted and compared between the groups. A written informed consent was taken from each patient

Results: The mean duration of first stage of labor was significantly shorter in women receiving extra-amniotic infusion of steroids as compared to normal saline (178.94±34.19 vs. 237.20±24.84 minutes; p-value<0.001). The frequency of cervical ripening was significantly higher in women receiving extra-amniotic infusion of steroids as compared to normal saline (96.0% vs. 72.0%; p-value=0.001).

Conclusion: Extra-amniotic infusion of corticosteroids was found superior to conventional practice of normal saline in terms of significantly higher frequency of cervical ripening and significantly shorter mean duration of 1st stage of labor which is desirable in women undergoing mid-trimester termination of pregnancy and advocates preferred use of extra-amniotic infusion of corticosteroids in future obstetric practice

Keywords: Mid-Trimester Abortion, Cervical Ripening, Steroids, Extra-amniotic Infusion

INTRODUCTION

The termination of pregnancy (TOP) in the middle of a patient's pregnancy is a prominent worry in obstetric practise because to the complications and psychological damage that it causes to patients. This is because TOP causes patients to have their pregnancies ended in the middle of their pregnancies.¹ A missed abortion or a foetus that was born with a congenital abnormality are the two scenarios that lead most frequently to an abortion being performed during the second trimester of pregnancy. Even though it only accounts for 10-

15% of all terminations, termination of pregnancy during the middle trimester is responsible for 66-

75% of all serious difficulties associated with termination.²

The natural physiological process of cervical ripening that happens right before the start of uterine contractions is referred to as the "ripening of the cervical cervix." It is a biological process that is quite involved and difficult to understand. Inducing labour, often referred to as cervical ripening, is performed with the goal of attaining a vaginal delivery and avoiding the necessity of an operational delivery through caesarean section. The procedure is also known as cervical ripening.³ Approximately twenty percent of pregnancies end up requiring some sort of medical intervention to start labour. It is anticipated that roughly half of all women who go through the procedure of having their labour artificially induced would have an unfavourable cervix. This statistic comes from studies that looked at the outcomes of women who had their labour artificially induced.

When an induction is unsuccessful, which happens in twenty percent of pregnancies, the only option left is to deliver the baby via caesarean section.⁴ Inducing labour can be done by mechanical means as well as through the use of pharmaceutical methods. Prostaglandins PGE₁, PGE₂, and PGF₂ are examples of pharmacological approaches, whereas mechanical methods such as the Foley catheter balloon and laminarients are examples of mechanical me-

thods. In contrast, pharmacological treatments cause connective tissue softening, cervical effacement, and uterine activity. Mechanical devices remove the cervix by gaining access to the foetal membrane, whereas these effects are caused by pharmaceutical treatments. The process of the cervix becoming more dilated is referred to as cervical effacement. Even though there are a variety of methods available, there is not a single strategy for inducing labour that is universally acknowledged as being superior than the others.⁵ When it comes to figuring out whether or not an IOL will be effective, the condition of the cervix prior to induction is one of the most critical factors. According to a number of studies, glucocorticoids have the potential to hasten the process of cervical ripening and, as a consequence, reduce the amount of time that must be spent in labour. It is probable that the increased number of glucocorticoid receptors that are present on the cervix prior to the beginning of labour is the cause of the improvement in cervical effacement that occurred following extraamniotic infusion of glucocorticosteroid treatment.⁷ In the research that Fatima and her colleagues conducted, they discovered that increasing the dosage of corticosteroids that were given intramuscularly, intravenously, or extraamniotically resulted in much greater rates of successful induction of labour as well as vaginal deliveries.^{8,9,10}

The amount of time that elapsed between the induction of labour and the delivery was substantially shorter in the group that was a part of the study (5.73.4 hours, P<0.01) in comparison to the group that acted as the control for the study (6.94.7 hours).¹¹

It has been shown that glucocorticoids are responsible for inducing the synthesis of surfactant protein A in human foetal membranes. It has also been suggested that surfactant protein is responsible for inducing the synthesis of prostaglandin E2 in chorionic trophoblasts. Both of these claims have been supported by scientific evidence.⁷ Because receptors for glucocorticoids have been discovered in the membranes of the amniotic sac, several hypotheses conce-

ring the possible role that glucocorticoids could play in parturition have been expected as being effective in either a paracrine or autocrine manner. This is due to the presence of glucocorticoid receptors in the amniotic membranes, which is responsible for the observed phenomenon.^{9,11} In a separate trial, it was discovered that the frequency of cervical ripening was 100% in the group that was given an extra-amniotic infusion of corticosteroid, whereas it was only 80.0% in the group that was given normal saline. This difference in frequency was found to be statistically significant.¹³

When a pregnancy is terminated in the second trimester, the process is more difficult and takes more time than it does in the first trimester because the cervix is more inflexible at this point in the pregnancy and because it has not yet begun to ripen.

Although the labour inducing drugs that are most commonly used are effective, they are also quite pricey, and their administration necessitates careful monitoring for potential complications such as uterine hyperstimulation and other concerns of a similar nature.

Because of this, we made the decision to conduct some research on the impact that glucocorticoids have on the rate at which the cervix of the cervical ripens and the length of the labour process. Inducing labour is the focus of this research project, and one of the questions that will be asked is whether or not glucocorticoids are successful in doing so. Since there is no local study available in Pakistan, extraamniotic infusion of glucocorticoids (dexamethasone) will be an inexpensive, easily available labour inducing agent with minimal side effects in the middle trimester termination of pregnancy on our local population if it proves to be effective. If it does prove to be effective, it will be able to induce labour at a low cost. This is because Pakistan does not currently have any available studies conducted on the topic.

Objective: The objective of this study was to compare outcome of extra-amniotic infusion of corticosteroids versus normal saline for cervical ripening and mean duration of 1st stage of labour in mid trimester termination of pregnancy.

MATERIAL AND METHODS

Study design: Randomized controlled trial.

Setting: Research was conducted at Department of Obstetrics & Gynecology Rai Medical College Teaching Hospital, Sargodha.

Duration of study: 6 months from 10/01/2022 to 09/06/2022.

Sample size: Sample size of 100 cases (50 cases in each group) was calculated with 95% confidence interval and 80% power of test taking expected mean duration of first stage of labor to be 10.27±4.70 hours in cases and 14.00±5.57 hours in controls.³

Sampling technique: Patients were selected by non-probability, consecutive sampling.

Sample Selection

Inclusion criteria:

1. Age between 18 and 40 years.
2. Parity less than 5.
3. Age of gestation between 14 and 28 weeks (on obstetrical scan).
4. Anomalous baby on USG
5. Intrauterine fetal death on USG.
6. Singleton fetus on USG

Exclusion Criteria

1. Uterine anomaly
2. Premalignant or malignant conditions of lower genital tract
3. Known placenta previa or low-lying placenta.
4. Rupture of membranes, (assessed by speculum examination)

Data Collection Procedure: After taking approval from ethical review board, 100 patients (50 patients in each group) fulfilling the inclusion criteria were enrolled for study from Obstetrics & Gynecology Department Rai Medical College Teaching Hospital Sargodha after taking informed consent. Patients were divided in 2 groups A & B according to lottery methods.

Group-1 (A): In this group, a 16F catheter with a 30 ml balloon was inserted through the cervix of patients. The balloon

was inflated with 30 ml of sterile water and 20 mg of dexamethasone diluted in 15ml sterile water was injected through the catheter into the extra-amniotic space, followed by infusion of normal saline @ rate of 1ml/min by means of an infusion pump for 06 hours.

Group-2 (B): In this group, women received 20ml of saline solution injected in extra-amniotic space.

Gentle traction of the catheter was performed every hour to watch for expulsion of the balloon. Cervical ripening through bishop score was assessed every 6 hours. If the balloon was expelled within 12 hours, we augmented patient with oxytocin until delivery of baby. We measured total duration of first stage of labour (as per operational definition). If the balloon was not expelled within 12 hours, it was deflated and extracted. Failure of induction was announced and some other method of induction was used. All this information was recorded by researcher herself on a predesigned proforma (attached).

Data analysis: All the data was entered into and analyzed through SPSS version 22.0.

1. Numerical variables i.e age, gestational age, BMI and duration of first stage of labor have been presented by mean±SD. Independent sample t-test has been applied for comparison of mean duration of first stage of labor between the groups taking p-value ≤0.05 as statistically significant.

2. Frequency has been calculated for parity.

3. Categorical variables i.e cervical ripening has been presented as frequency and percentage. Chi-square test has been applied to compare the frequency of cervical ripening between the groups taking p-value ≤0.05 as statistically significant.

4. Data has been stratified for age, gestational age, BMI and parity to address effect modifiers. Post stratification independent sample t-test has been applied for comparison of mean duration of first stage of labor and chi-square test has been applied to compare the frequency of cervical ripening between the groups taking p-value ≤0.05 as statistically significant.

RESULTS

The mean age of the patients was 27.75±6.78 years while the mean gestational age was 20.76±4.50 weeks. 27 (27.0%) women were primiparas and 73 (73.0%) women were multiparas. The mean BMI of these patients was 27.56±4.29 Kg/m² and 29 (29.0%) patients were obese. The mean duration of first stage of labor was significantly shorter in women receiving extra-amniotic infusion of steroids as compared to normal saline (178.94±34.19 vs. 237.20±24.84 minutes; p-value<0.001). The frequency of cervical ripening was significantly higher in women receiving extra-amniotic infusion of steroids as compared to normal saline (96.0% vs. 72.0%; p-value=0.001). Similar significant difference was noted between the groups across various subgroups based on patient's age, gestational age, parity and BMI.

Table 1: Baseline Characteristics of Study Sample

Characteristics	Participants n=100
Age (years)	27.75±6.78
• 18-29 years	59 (59.0%)
• 30-40 years	41 (41.0%)
Gestational Age (weeks)	20.76±4.50
• 14-20 weeks	51 (51.0%)
• 21-28 weeks	49 (49.0%)
Parity	2.60±1.18
• Primiparas	27 (27.0%)
• Multiparas	73 (73.0%)
BMI (Kg/m ²)	27.56±4.29
• Non-Obese	71 (71.0%)
• Obese	29 (29.0%)

Table 2: Baseline Characteristics of Study Groups n=100

Characteristics	Corticosteroid n=50	Normal Saline n=50	P-value
Age (years)	27.78±6.47	27.72±7.14	0.965
• 18-29 years	30 (60.0%)	29 (58.0%)	0.839
• 30-40 years	20 (40.0%)	21 (42.0%)	

Gestational Age (weeks)	20.80±4.37	20.72±4.66	0.930
• 14-20 weeks	25 (50.0%)	26 (52.0%)	0.841
• 21-28 weeks	25 (50.0%)	24 (48.0%)	
Parity	2.68±1.17	2.52±1.20	0.501
• Primiparas	13 (26.0%)	14 (28.0%)	0.822
• Multiparas	37 (74.0%)	36 (72.0%)	
BMI (Kg/m ²)	27.77±4.15	27.35±4.46	0.620
• Non-Obese	35 (70.0%)	36 (72.0%)	0.826
• Obese	15 (30.0%)	14 (28.0%)	

Chi-square test and independent sample t-test, observed difference was statistically insignificant

Table 3: Comparison of Mean Duration of 1st Stage of Labor (minutes) between the Study Groups n=100

	Corticosteroid n=50	Normal Saline n=50	P-value
Duration of 1 st Stage of Labor (mean±SD)	178.94±34.19	237.20±24.84	<0.001*

Independent sample t-test, * observed difference was statistically significant

Table 4: Comparison of Mean Duration of 1st Stage of Labor (minutes) between the Study Groups across Various Subgroups n=100

Subgroups	Duration of 1 st Stage of Labor (mean±SD)		P-value
	Corticosteroid n=50	Normal Saline n=50	
Age			
• 18-29 years	177.37±31.62	234.24±27.47	<0.001*
• 30-40 years	181.30±38.46	241.29±20.59	<0.001*
Gestational Age			
• 14-20 weeks	181.68±37.36	236.58±26.21	<0.001*
• 21-28 weeks	176.20±31.24	237.88±23.80	<0.001*
Parity			
• Primiparas	178.54±27.27	238.64±25.45	<0.001*
• Multiparas	179.08±36.65	236.64±24.93	<0.001*
BMI			
• Non-Obese	178.80±35.73	236.39±25.38	<0.001*
• Obese	179.27±31.49	239.29±24.18	<0.001*

Independent sample t-test, * observed difference was statistically significant

Table 5: Comparison of Frequency of Cervical Ripening between the Study Groups n=100

Cervical Ripening	Corticosteroid n=50	Normal Saline n=50	P-value
Yes	48 (96.0%)	36 (72.0%)	0.001*
No	2 (4.0%)	14 (28.0%)	
Total	50 (100.0%)	50 (100.0%)	

Chi-Square test, * observed difference was statistically significant

Table 6: Comparison of Frequency of Cervical Ripening between the Study Groups across Various Subgroups n=100

Subgroups	Cervical Ripening n (%)		P-value
	Corticosteroid n=50	Normal Saline n=50	
Age			
• 18-29 years	29/30 (96.7%)	21/29 (72.4%)	0.010*
• 30-40 years	19/20 (95.0%)	15/21 (71.4%)	0.045*
Gestational Age			
• 14-20 weeks	24/25 (96.0%)	19/26 (73.1%)	0.024*
• 21-28 weeks	24/25 (96.0%)	17/24 (70.8%)	0.017*
Parity			
• Primiparas	12/13 (92.3%)	8/14 (57.1%)	0.037*
• Multiparas	36/37 (97.3%)	28/36 (77.8%)	0.011*
BMI			
• Non-Obese	34/35 (97.1%)	28/36 (77.8%)	0.014*
• Obese	14/15 (93.3%)	8/14 (57.1%)	0.023*

Chi-square test, * observed difference was statistically significant

DISCUSSION

The time that passes after a diagnosis of antepartum foetal compromise or death and before the delivery of the baby is an extremely trying period of time for everyone involved. After hearing the devastating news that their unborn child has been injured or has passed away, which can be determined by an ultrasound examination, it is important for women to have time to grieve and adjust. It is essential that women be made aware of the numerous options that are available to them in today's society. If labour is to be induced, the cervical ripening and labour induction processes should be as physiologically comparable to the processes of spontaneous ripening and labour as is humanly possible. If labour is to be induced, the cervic

al ripening and labour induction processes should be used.^{1,2} Some of the methods that have been developed for cervical ripening prior to labour induction include the use of prostaglandins (PGE₁, PGE₂, and PGF₂), mechanical dilators such as laminaria, Foley catheters, extra-amniotic saline infusion (EASI), oxytocin, and relaxin. Other methods include extra-amniotic saline infusion (EASI). Inducing labour can result in a number of difficulties, which led to the development of these treatments, which were created in an effort to lessen those issues.² The use of extraamniotic saline infusion as an effective adjuvant can be beneficial for inducing labour throughout the third trimester or at term. This is the case especially when labour is being induced.^{3,5,12}

Extraamniotic normal saline infusion has a number of advantages, some of the most notable of which are that it is reversible, that it does not result in any systemic adverse effects, and that it is easily accessible to patients at public institutions and is provided at no cost to them.^{3,5} Because of its lower overall cost, its ease of administration and care, and the comfort with which it may be stored, the standard practise of utilising it is followed by many obstetric centres in Pakistan. This is due to the fact that it costs less overall. Corticosteroids are thought to play a role in the initiation of labour; however, this aspect of their function is not fully understood. Studies conducted on animals found that the production of cortisol by the fetal adrenal gland is a key role in the commencement of the labour process in sheep. This process begins when the sheep are in the uterus.³

According to the findings of a number of studies, a much higher percentage of successful labour induction can be achieved when a corticosteroid injection is given either intramuscularly or intramniotically to either lambs or humans.^{6,10}

Because receptors for glucocorticoids have been found in amniotic fluid, it is possible that steroids have a role in parturition, either in a paracrine or autocrine capacity. This is the case because glucocorticoid receptors have been found in amniotic fluid.^{6,8}

Extraamniotic infusion of corticosteroids has recently been shown to be superior to the traditional practise of extraamniotic infusion of normal saline when compared in terms of shorter mean duration of the first stage of labour and higher frequency of cervical ripening. This finding was made public in a study that was published in the journal *Obstetrics and Gynecology*. This discovery was made available to the general public in a study that was written up and presented in the medical journal *Obstetrics and Gynecology*.^{3,13} The evidence that was accessible, on the other hand, was insufficient, and there was no similar locally published data, which is what made it necessary to conduct the current study. In the current study, women who received an extraamniotic infusion of steroids had a significantly shorter mean duration of the first stage of labour compared to women who received normal saline than women who received the placebo. This difference was significant enough to indicate a statistically significant difference between the two groups.

In addition, the incidence of cervical ripening was much higher in women who got extra-amniotic infusions of steroids as compared to those who received normal saline in women who received extra-amniotic infusions of steroids.

It was discovered that there was a substantial difference between the groups notwithstanding the subgroup that was based on the patient's age, gestational age, parity, or body mass index. This was the case despite the fact that there was no difference in the parity of the patients (BMI). Our discovery is in line with the results of another study that was carried out in a manner that was comparable to how we did things here. In the study by Salman et al. (2017), Iranian women who were having labour induction at term and were given either extraamniotic steroids or normal saline had a significantly shorter mean length of the first stage of labour with extraamniotic steroids as compared to normal saline. The results of our investigation are in line with these findings. Our discovery is in line with the findings of Zafarhandi et al. (2004), who discovered a similar significantly higher frequency of cervical ripening in Iranian women who

were given extra-amniotic steroids as opposed to normal saline (90.9% vs. 81.8%; p -value = 0.05). Our discovery is in line with the findings of Zafarghandi et al. (2004), who discovered a similar significantly higher frequency of cervical ripening in

This conclusion was reached after contrasting the impact of the two therapies on the progression of cervical ripening. In another Iranian study, which was carried out by Keshavarz et al., the frequency of cervical ripening was reported to be 100.0% when steroids were used, whereas it was only 80.0% when normal saline was used (2012). The findings of these researchers indicated that there was a significant disparity between the two therapy options. Asghar et al. (2019) conducted a study in Islamabad and found that the frequency of cervical ripening with extraamniotic normal saline was 74.2%. This was reported by the authors of the study. On the other hand, Kumar et al. (2018) found that the prevalence of this condition was 60.0% in India¹⁵. The results of our investigation are consistent with the findings of the previous local research.

The new study is the first of its kind to be undertaken in a local population, and it adds to the relatively modest amount of scientific information that has already been published on the subject. In the current study, it was discovered that extraamniotic infusion of corticosteroids was superior to the conventional practice of normal saline in terms of significantly higher frequency of cervical ripening and significantly shorter mean duration of the first stage of labour. This was the case because extraamniotic infusion of corticosteroids significantly shortened the mean duration of the first stage of labour. This is ideal in women who are going through the process of having their pregnancy terminated in the middle of the first trimester, and it advocates for the preferred use of extra-amniotic infusion of corticosteroids in future obstetric practice. Infusion of cortisol outside of the amniotic sac

The examination included a number of key strengths, including a randomised study design, which was used in the current study, and the stratification of results for effect modifiers, which was used. We did not take into account the various fetomaternal outcome markers such as infection, preeclampsia, uterine rupture of a frightened uterus, and the necessity for surgical intervention. These are all indicators that could have shed light on the safety of this one-of-a-kind method.

This is a very severe limitation of the study that is currently being conducted. It is strongly recommended that further research that is comparable to this one be carried out as soon as possible.

CONCLUSION

Extra-amniotic infusion of corticosteroids was found superior to conventional practice of normal saline in terms of significantly higher frequency of cervical ripening and significantly shorter mean duration of 1st stage of labor which is desirable in women undergoing mid-trimester termination of pregnancy and advocates

preferred use of extra-amniotic infusion of corticosteroids in future obstetric practice.

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