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Comparative study of extra amniotic saline infusion through intracervical balloon catheter and prostaglandin E2 gel for induction of labour

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Abstract

Introduction: Using mechanical techniques such as the implementation of the trans-cervical Foleys catheter, ripening of the cervix can be achieved. The use of a catheter is related to decreased induction delivery interval, decreased rate of caesarean section, increased spontaneous vaginal delivery rate.

Aims: To assess the effectiveness of extra amniotic saline infusion and prostaglandin E2 gel for induction of labour.

Materials and Methods: It is a comparative prospective study carried out in the department of obstetrics and gynaecology at tertiary care center for a period of one year, 120 participant were included in the study and they were divided into two groups. Each group 60 patients were randomly allocated to either Foley's catheter (group F) or PGE2 gel (group P) method.

Results: The mean Induction to active labour interval in primi with extra amniotic saline infusion was 6.1 hrs. The mean Induction to active labour interval in primi with PGE2 gel was 8.2 hrs. The mean Induction to active labour interval in multiparous with Extra amniotic saline infusion was 4.8hrs. The mean Induction to active labour interval in multiparous is statistically significant when compared in 2 groups. 71.6% of patients in extra amniotic saline infusion group were delivered vaginally compared to only 65% in the PGE2 gel. LSCS was 30% in the PGE2 gel group whereas it was 25% in the extra amniotic saline infusion group which is statistically significant. Incidence of Cesarean section was lower in extra amniotic saline infusion group compared to PGE2 gel group. Failed induction in extra amniotic saline infusion group was only 1.6% compared to 5 % in PGE2 gel group which is statistically significant. Only 8% neonates were admitted in NICU in the extra amniotic saline infusion group compared to 10% admissions in PGE2 gel. The cause for admission was Birth asphyxia, meconium aspiration.

Conclusion: In the extra Amniotic Saline Infusion group, cervical ripening was more successful than in the PGE2 group. In the extra amniotic saline infusion group, induction to the active labour interval (ILI) was shorter relative to the PGE2 gel group.

Keywords: Extra amniotic saline infusion, induction active labour, foley's catheter

Introduction

For a majority of women, labour starts spontaneously at term or near term. In modern obstetrics induction of labour is mandatory, because of medical or obstetric complications of pregnancy. For many reasons, there are several cases that require labour induction. Labour induction is the involuntary activation of uterine contractions before natural childbirth starts, primarily to facilitate successful vaginal uterine delivery within 24 to 48 hours. Cervical ripening is the process used by pharmacological or other means to relax or dilate the cervix to improve the probability of vaginal delivery. There are many cervical ripening procedures, such as natural non-invasive (hot water, Castrol oil), mechanical (balloon catheter, hygroscopic dilators, EASI), surgical techniques and pharmacological agents (prostaglandins).

Instillation methods are not frequently used at present, largely because of alternative methods, including surgical options, have fewer side effects, lower risk of complications, and more rapid completion times. These invasive procedures require special skills to minimize risks such as a bloody tap and maternal intravascular injection, introduction of infection, and rupture of membranes.

Intra-cervical application of PGE2 gel is also found to be effective for ripening of cervix as it can have a combined contraction inducing and cervical ripening effect^[1]. It is in use since 1960s for cervical ripening. Local application of PGE2 causes direct softening of cervix by a number of different mechanisms.

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It can cause connective tissue softening, cervical effacement and uterine activity [2, 3]. PGE2 gel can be used in cases of heart disease, PIH and eclampsia also. Since no method is free from complications, this study is carried out with the aim of finding out the effective method of induction with least complications. The study is carried out to assess the effectiveness of extra amniotic saline infusion and prostaglandin E2 gel for induction of labour.

Materials and Methods

It is a comparative prospective study carried out in the department of obstetrics and gynaecology, for a period of one year extending from November 2019 to October 2020 at tertiary care center. All the cases fulfilling the inclusion and exclusion criteria and willingness to participate in the study were included in the study and they were divided into two groups. There were total 120 cases and 60 patients were randomly allocated to either Foley's catheter (group F) or PGE2 gel (group P) method. The Bishop's score was determined earlier. Each patient was questioned in detail and examined thoroughly.

Inclusion criteria: Singleton pregnancy, Cephalic presentation, Term / Post term pregnancies and Bishop score <5.

Exclusion criteria: Maternal infections, Low lying placenta, Malpresentation, Rupture of membranes, Maternal comorbid illnesses like Gestational diabetes, Heart disease, Chronic kidney disease.

Extra amniotic saline infusion through intra cervical Foley's catheter procedure Prophylactic antibiotic injection Ampicillin 1 gm iv given after test dose patient placed in the lithotomy position. Under good light supervision, perineum and vagina

cleansed with Betadine solution. Under strict asepsis, Foley's catheter NO.16 introduced through the cervix under direct vision. Bulb inflated with 40 ml of distilled water and bulb is hitched against the internal os. Patient repositioned to left lateral, isotonic saline solution (0.9% Sodium chloride) was instilled through the catheter at the rate of 40ml/hr through infusion pump. Patient examined for progress of labour after 6 hours. If cervical ripening was observed augmentation of labour was done by Amniotomy and IV oxytocin or else infusion continued for another 6 hrs.

Prostaglandin E2 gel instillation procedure prophylactic antibiotic injection Ampicillin 1 gm iv given after test dose. Patient placed in the lithotomy position and under good light supervision, perineum and vagina cleansed with Betadine solution strict asepsis, cerviprime gel which contains 0.5mg of PGE2 instilled intracervically. Patient examined for progress of labour after 6 hours, If cervical ripening was observed augmentation of labour was done by Amniotomy and IV oxytocin or else second dose of gel applied.

Monitoring parameters are Maternal pulse rate, temperature, blood pressure, Uterine contractions for their frequency, duration and strength, Fetal heart rate, interval between induction and cervical dilatation of 3-4cm. Mother and babies were observed for three days and watched for any puerperal infections and neonatal infections. If there was any evidence of infection, it was treated accordingly.

Statistical Analysis: The results were analyzed using t-test and chi-square test.

Results

Table 1: Demographic details in study

Age intervals in years	Extra amniotic saline infusion	PGE2 gel	Total
<20 years	4(6%)	3(5%)	7(5.8%)
21-25	37(61.6%)	36(60%)	73(60.8%)
26-30	16(6.4%)	17(28%)	33(27.6%)
>30	3(5%)	4(6%)	7(5.8%)
Total			
Gravida			
1	43(71.6%)	44(73.4%)	87(72.5%)
2	13(21.7%)	12(20%)	25(21%)
3	3(5%)	2(3.3%)	5(4%)
4	1(1.7%)	2(3.3%)	3(2.5%)
Gestation in weeks			
37-40	8(13.3%)	8(13.3%)	16(13.3%)
>40	52(86.7%)	52(86.7%)	104(86.7%)
Indication			
Post EDD	48(80%)	47(78.3%)	95(79.2%)
Oligo	7(11.6%)	6(10%)	13(11.0.4%)
Mild PIH	5(8.4%)	5(8.4%)	10(8.4%)

Most common age group is 21-25 years with primigravida. Majority of patients in both the groups had gestational age

greater than 40 weeks. Both groups are statically insignificant when compared in age, gravida and gestational age.

Table 2: BISHOP score at 0, 6 and 12 hours after induction

BISHOP score	Extra amniotic saline infusion	PGE2 gel	Total
At zero hour			
0			-
1	7(11.6%)	8(13.3%)	15(12.5%)
2	23(38.3%)	31(51.6)	54(45%)
3	27(45%)	19(31.6%)	46(38.3%)
4	3(5%)	2(3.3%)	5(4.1%)
At 6 hour			

<5	15(25%)	25(41.6%)	40(33.3%)
6-10	44(73.3%)	35(58.3%)	79(65.8%)
>10	1(1.6%)		1(0.8%)
At 12 hour			
Delivered	38(63.3%)	2(3.3%)	40(33.3%)
>10	11(18.3%)	9(15%)	19(15.8%)
6-10	10(16.6%)	44(73.3%)	54(45%)
<5	1(1.6%)	5(8.3%)	6 (5%)

Bishop score <5 taken as indication for induction. Majority of the patients in both groups had bishop score 2 or 3. 73% of patients induced with extra amniotic saline infusion had favorable Bishop score within 6 hours. Only 58% of patients induced with PGE2 gel had favorable Bishop score within 6

hours. 63% of patients in the Balloon dilatation with extra amniotic saline infusion group delivered within 12 hours. Only 3% of patients in the PGE2 gel group delivered within 12 hours. The difference is statistically significant.

Table 3: Induction to active labour interval

Duration in hours	Extra amniotic saline infusion	PGE2 gel
<6	17(28%)	10(16.6%)
6-12	18(30%)	4(6.6%)
>12	1(1.6%)	0
Induction delivery interval		
6-12	22(36.6%)	14(23.3%)
12-24	13(21.6%)	1(1.6%)

Most of the patients in the extra amniotic saline infusion group established active labour within 6 hours. Whereas most of the patients in the PGE2 gel group established active labour between 6- 12hrs. 62% of Primi delivered within 12 hrs in the extra amniotic saline

infusion group compared to only 44.8% in the PGE2 gel group. 97.6% of Multi delivered within 12 hrs in extra amniotic saline infusion group compared to only 55.6% in the PGE2 gel group. The difference is statistically significant.

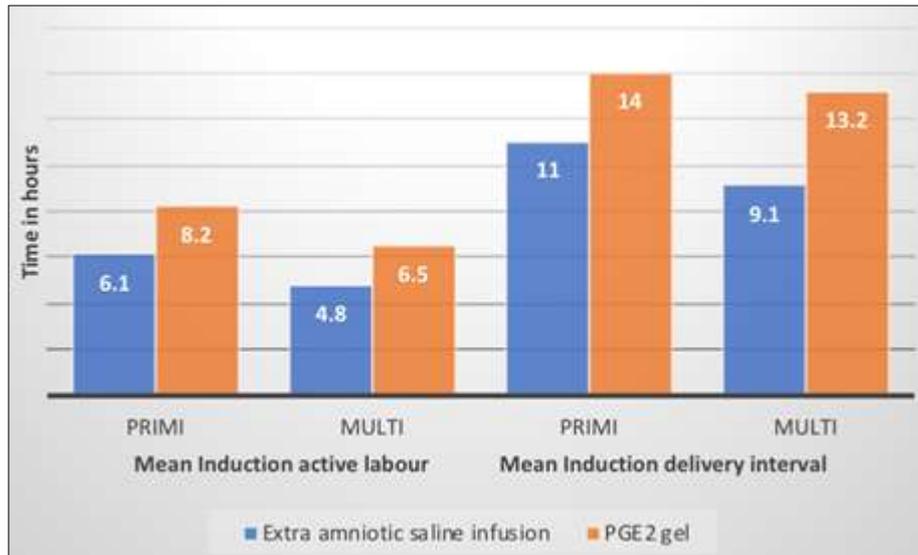


Fig 1: The mean Induction active labour interval and delivery interval

The mean Induction to active labour interval in primi with extra amniotic saline infusion group was 6.1 hrs. The mean Induction to active labour interval in primi with PGE2 gel group was 8.2 hrs. The mean Induction active labour interval in multiparous with extra amniotic saline infusion was 4.8hrs. The mean Induction to active labour interval in multiparous with PGE2 gel group was 6.5 hrs. The difference between the two groups is statistically significant.

The mean Induction delivery interval in Primi with extra amniotic saline infusion group was 11hrs. The mean Induction to delivery interval in Primi with PGE2 gel group was 14 hrs. The mean Induction to delivery interval in Multi with extra amniotic saline infusion was 9.1 hrs. The mean Induction to delivery interval in Multi with PGE2 gel group was 13.2 hrs. The difference between the two group is statistically significant.

Table 4: Mode and indication of delivery distribution

Mode of delivery	Extra amniotic saline infusion	PGE2 gel	Total
Labour natural	43(71.6%)	39(65%)	82(68%)
LSCS	15(25%)	18(30%)	33(27.5%)
Forceps/vacuum	2(3.3%)	3(5%)	5(4.2%)
Indication			
Fetal distress	6(10%)	11(16.6%)	17(14.2%)
CPD	1(1.6%)	0	1(0.8%)
Failed induction	1(1.6%)	3(5%)	4(3.3%)
Others	1(1.6%)	0	1(0.8%)
Total	9(11%)	14(23.3%)	23(19.2%)

71.6% of patients in extra amniotic saline infusion group delivered vaginally compared to only 65% in the PGE2 gel group. LSCS was 30% in the PGE2 gel group whereas it was 25% in the extra amniotic saline infusion group. The difference is statistically significant.

Incidence of Cesarean section was lower in extra amniotic saline infusion group compared to PGE2 gel group. Failed induction in extra amniotic saline infusion group was only 1.6% compared to 5 % in PGE2 gel group. The difference is statistically significant.

Table 5: Fetal and maternal outcome

Admission in NICU	Extra amniotic saline infusion	PGE2 gel	Total
Yes	5(8%)	6(10%)	11(9%)
No	55(92%)	54(90%)	109(91%)
Maternal outcome			
Hyper stimulation	-	3(5%)	3(2.5%)
Postpartum haemorrhage	2(3.3%)	6(10%)	8(6.6%)
Puperal pyrexia	3(5%)	2(3.3%)	5(4.2%)

Only 8% neonates were admitted in NICU in the Extra amniotic saline infusion group compared to 10% admissions in PGE2 gel group. The cause for admission was Birth asphyxia, meconium aspiration.

No hyperstimulation was noted in extra amniotic saline infusion whereas 5% had hyperstimulation in PGE2 gel group. PPH was also more in PGE2 gel. Pupal pyrexia was comparable in both the groups.

Discussion

The study was carried out in 120 patients. 60 patients were induced with extra amniotic saline infusion and 60 patients were induced with PGE2 gel. Both the groups had patients of almost similar age, parity and gestational age. Majority of the patients induced were belonged to the 20- 25 years group. Study of Rouben D, *et al.* [4] showed that the maximum number of patients belonged to 20-30 years of age.

Majority of the patients were primi gravida. Deb A Guinn [5] and Divya Rouben *et al.* [4] also had maximum number of women as primigravida. Majority of the patients induced were between 40-41 weeks. The study of Karjane *et al.* (2006) also showed that post-dated was the most common reason for induction [6].

In our study Bishop score <5 taken as indication for induction. Majority of the patients in both groups had bishop score 2 or 3. 73% of patients induced with extra amniotic saline infusion had favorable Bishop score within 6 hours. Whereas only 58% of patients induced with PGE2 gel had favorable Bishop score within 6 hours. 63% of patients in the Balloon dilatation with extra amniotic saline infusion delivered within 12 hours. Only 3% of patients in the PGE2 gel delivered within 12 hours. Our study is very much in similar with study of V Vijayalakshmi *et al.* [7] Mean Bishop score at 0 hrs was 2.26 in Primis induced with Extra amniotic saline infusion and with PGE2 gel was 2.25, mean Bishop score at 6 hrs was 6.62 in Primis induced with Extra amniotic saline infusion whereas with PGE2 gel was 5.51 and mean Bishop score at 12 hrs was 9.27 in Primis induced with Extra amniotic saline infusion whereas in PGE2 gel group was 8.08. The mean Bishop score at 6 hrs was 8.57 in Multis

induced with extra amniotic saline infusion group whereas in PGE2 gel group was 6.91. The mean Bishop score at 12 hrs was 10.40 in Multis induced with extra amniotic saline infusion group whereas with PGE2 gel it was 9.41. Mean Bishop Score improved in higher rate in extra amniotic saline infusion group when compared to PGE2 gel group.

In our study Most of the patients in the extra amniotic saline infusion group established active labour within 6 hours. Whereas most of the patients in the PGE2 gel group established active labour between 6-12hrs. 62% of Primi delivered within 12 hrs in the extra amniotic saline infusion group compared to only 44.8% in the PGE2 gel group. 97.6% of Multi delivered within 12 hrs in extra amniotic saline infusion group compared to only 55.6% in the PGE2 gel group. Our study is in agreement with V Vijayalakshmi *et al.* [7] Active labour established within 6 hrs in extra amniotic saline infusion group whereas in PGE2 gel group active labour established in 6-12 hrs and mean Induction active labour interval in Primis induced with extra amniotic saline infusion was 6.35 hrs and in PGE2 gel group was 8.35 hrs. The mean Induction active labour interval in Multis induced with extra amniotic saline infusion was 4.98 hrs and in PGE2 gel group was 6.55 hrs.

In present study 71.6% of patients in extra amniotic saline infusion group delivered vaginally compared to only 65% in the PGE2 gel. LSCS was 30% in the PGE2 gel group whereas it was 25% in the extra amniotic saline infusion group. The difference is statistically significant. Incidence of Cesarean section was lower in extra amniotic saline infusion group compared to PGE2 gel group. Failed induction in extra amniotic saline infusion group was only 1.6% compared to 5 % in PGE2 gel group. The difference is statistically significant. In study done by Alam *et al.* [8] rate of LSCS in Group F was 21% and 19% in Group P (p = 0.88). The most common indication for LSCS in Group F was fetal distress. Group F had 9 cases for FD and Group P had 11

cases of FD. The rate of LSCS in our study is agreeable^[9, 10]. There was no association of increased rate of cesarean section with the Foley's catheter or PGE2 gel use.

In our study only 8% neonates were admitted in NICU in the extra amniotic saline infusion group compared to 10% admissions in PGE2 group. The cause for admission was Birth asphyxia, meconium aspiration. No hyperstimulation was noted in extra amniotic saline infusion group whereas 5% had hyperstimulation in PGE2 gel group. PPH was also more in PGE2 group. Pupal pyrexia was comparable in both the groups. In study done by Alam *et al.*^[8] study fetal outcome data showed no significant difference between Group F and Group P with respect to birth wt (2.57 ± 0.44 and 2.58 ± 0.48) and MAS (4 and 4 respectively), NICU admission rate is 20 and 18 respectively.

So Cervical ripening was more effective in the Extra amniotic saline infusion group when compared to PGE2 group. Mean Induction to active labour interval (ILI) was shorter in the Extra amniotic saline infusion group when compared to PGE2 gel group.

Conclusion

Compared to the PGE2 group, cervical ripening was more successful in the extra amniotic saline infusion group. In the extra amniotic saline infusion group, the induction to the active labour interval (ILI) was shorter relative to the PGE2 gel group. In the extra amniotic saline infusion group, the mean induction to delivery interval (ILI) was shorter than in the PGE2 gel group. In the extra amniotic saline infusion group, the use of oxytocin was lower compared to the PGE2 gel group. In both groups, the response of Multigravida was higher than Primigravida. In the extra amniotic saline infusion group, foetal and maternal outcomes were better than in the PGE2 gel group. extra amniotic saline infusion has been found to be more effective, cheaper and more readily available for cervical ripening and labour induction.

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