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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
Definition of induction of labour
Stimulation of regular uterine contractions in a viable pregnancy before the onset of labour using mechanical or pharmacological methods in order to generate progressive cervical dilatation and subsequent delivery after fetus maturity.
Aim of study
The study is carried out to assess the effectiveness of extra amniotic saline infusion and prostaglandin E2 gel for induction of labour.
Objectives of the study
To study the effect of cervical ripening
To study the oxytocin augmentation need
To see the effect on the labour outcome
To study the response difference in primi and multi
To assess the maternal and fetal outcome
Methodology
Study centre
The study was undertaken in the Institute of Obstetrics and Gynecology, Egmore, Chennai
Study design
Prospective randomized control study conducted between August 2014 - August 2015
Sample size
200 antenatal mothers admitted in the hospital were included in this study
Results: The 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.
Conclusion: 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.

Keywords: Saline Infusion, PGE2 gel

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.

Definition of induction of labour
Stimulation of regular uterine contractions in a viable pregnancy before the onset of labour using mechanical or pharmacological methods in order to generate progressive cervical dilatation and subsequent delivery after fetus maturity.
Induction of labour is as old as Soraners of Greece, who was the first person to induce labour in 100 A.D. From the days of Soraners to the modern days of obstetrics, induction of labour has gone through different methods over different periods by different people. Steamens started inducing labour electively for the convenience of obstetricians or the expectant mother, the indication being for social one.
Induction is accepted as an option in the management of selected cases of high risk pregnancies in which the continuation of pregnancy is likely to affect adversely the maternal health or the perinatal outcome.

Ideally the patient to be induced should be term or near term with adequate pelvis, favorable cervix & with a viable fetus.
Failed induction is termed when the uterus to fail to contract after recommended attempts of stimulation, or the uterus contracts abnormally, or cervix does not dilate, or the fetus is in jeopardy.
Stimulation of uterine contractions by means of non-pharmacological agents administered intracervical to the patients with the aim of starting labour constitutes "Mechanical induction of labour".
Stimulation of uterine contractions by means of pharmacological agent given to the patients by any route with the aim of inducing labour is "Medical induction of labour". Oxytocin is the drug that is being employed with considerable success for induction of labour for many years. It has been associated with uterine hypertonus fetal bradycardia, also fluid retention in patients with eclampsia, hypertension, heart & kidney disease.
Unripe cervix was one of the biggest drawbacks in induction of labour. There was revolutionary change after introduction of prostaglandins.
Bygdemans first used prostaglandins & their use in induction of labour is very effective and well appreciated. Cole *et al*., showed that under proper conditions, the advantage of inducing labour outweighs its disadvantages.
Though induction of labour is aimed at vaginal delivery, increased risk of caesarean section. Individual variation is more and hence each patient needs to be viewed in the context of her past obstetrical history and complications in the present pregnancy before deciding on the mode of induction.

Risks of induction of labour

1. Operative delivery: In both primi and mutiiol increases risk of caesarean section. About 3 fold increase in primi compared to those labouring spontaneously. In muti it is doubled from 3.4% to 8.5%

2. Uterine hypercontractility: any agent used in IOL can over stimulate the uterus leading to prolonged or tonic uterine contractions, fetal compromise and abnormal FHR patterns.

3. Uterine rupture: rare but occurs in patients with uterine scar like caesarean section or uterine perforation

4. Failed induction: rates of failed induction is about 3%

5. Iatrogenic prematurity

6. Pain

No method of induction is free from complications, aim of this study is to find the effective method with least complications. The study was undertaken with the objective of observing difference in the responses of mechanical & medical induction of labour. The Study was conducted in Institute of Obstetrics & Gynecology, Egmore Chennai.

Aim of study

The study is carried out to assess the effectiveness of extra amniotic saline infusion and prostaglandin E2 gel for induction of labour.

Objectives of the study

- To study the effect of cervical ripening
- To study the oxytocin augmentation need
- To see the effect on the labour outcome
- To study the response difference in primi and multi
- To assess the maternal and fetal outcome

Methodology

Study centre

The study was undertaken in the Institute of Obstetrics and Gynecology, Egmore, Chennai

Study design

Prospective randomized control study conducted between August 2014 - August 2015

Sample size

200 antenatal mothers admitted in the hospital were included in this study

Inclusion criteria

1. Singleton pregnancy
2. Cephalic presentation
3. Absence of infection
4. Bishop score <5
5. Term / Post term pregnancies
6. Intact fetal membrane

Exclusion criteria

1. Low lying placenta
2. Malpresentation
3. Maternal infection
4. Rupture of membranes
5. Maternal comorbid illnesses like Gestational diabetes, Heart disease, Chronic kidney disease

Induction indications

- Post EDD pregnancies
- oligohydramnios
- Intra uterine growth restriction
- Gestational hypertension

Before inducing EDD confirmed with regard to LMP, Regularity of menstrual cycles, Early Ultrasonogram scan. Then general examination and obstetric examination carried out.
After ruling out low lying placenta by ultrasonogram, pelvic examination done and Bishop Score calculated.

It is a time-honored fact that Bishop Score is a sensitive indicator that predicts successful induction of labour.

Bishop Score

	0	**1**	**2**	**3**
Dilatation	0	1-2	3-4	5-6
Effacement	0-30	40-60	60-70	80+
Station	-3	-2	-1/0	+1/+2
Consistency	Firm	Medium	Soft	
Os position	Posterior	Mid position	Anterior	

Observation and analysis

- The aim of this study was to demonstrate the effectiveness of extra amniotic saline induction (EASI) & PGE2 gel for cervical ripening and inducing labour.
- 200 mothers selected for the study were analysed using various parameters

Table 1: Induction delivery interval

Duration in hours	Extra amniotic saline Infusion				PGE2 gel			
	Primi		Multi		Primi		Multi	
	No.	%	No.	%	No.	%	No.	%
6-12	44	62.0	28	97.6	31	44.8	17	55.6
12-24	27	38.0	1	2.4	39	55.2	13	44.4
Total	71	100	29	100	70	100	30	100

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.

Table 2: Mean induction delivery interval

	Extra amniotic saline infusion		PGE2 Gel	
	Primi	Multi	Primi	Multi
IDL	11.21+2.72	9.30+1.71	13.94+3.32	12.78+2.38

The mean Induction delivery interval in Primi with Extra amniotic saline infusion was 11.2 hrs. The mean Induction to delivery interval in Primi with PGE2 gel was 13.94 hrs.
The mean Induction to delivery interval in Multi with Extra amniotic saline infusion was 9.30hrs. The mean Inductio to delivery interval in Multi with PGE2 gel was 12.78 hrs.
The difference between the two group is statistically significant.

Table 3: Patients requiring oxytocin augmentation

Oxytocin	Extra amniotic saline infusion		PGE2 Gel		Total
	Number	Percent	Number	Percent	
Not used	57	57	28	28	85
Used	43	43	72	72	115
Total	100	100	100	100	200

This table shows the higher use of Oxytocin in the PGE2 gel group – 73% when compared to extra amniotic saline infusion group – 43%. The difference is statistically significant.

Table 4: Mode of delivery distribution

Mode of delivery	Extra amniotic saline infusion		Pge2 Gel		Total
	Number	Percent	Number	Percent	
Labour natural	76	76	67	67	143
LSCS	19	19	27	27	46
Forceps/ vacuum	5	5	6	6	11
Total	100	100	100	100	200

76% of patients in extra amniotic saline infusion delivered vaginally compared to only 67% in the PGE2 gel.
LSCS was 27% in the PGE2 gel group whereas it was only 19% in the extra amniotic saline infusion.
The difference is statistically significant.

Table 5: Indication for cesarean section

Indication	Extra amniotic saline infusion		PGE2 Gel		Total
	Number	Percent	Number	Percent	
Fetal distress	12	63.3	19	70.3	31
CPD	3	15.7	1	3.7	4
Failed induction	3	15.7	6	22.3	9
others	1	5.3	1	3.7	2
total	19	100	27	100	46

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 3% compared to 6% in PGE2 gel group.
The difference is statistically significant.

Table 6: Fetal outcome

Admission in NICU	Extra amniotic saline infusion		PGE2 gel		Total
	Number	Percent	Number	Percent	
Yes	7	7	12	12	19
No	93	93	88	88	181
Total	100	100	100	100	200

Only 7% neonates were admitted in NICU in the extra amniotic saline infusion group compared to 12% admissions in PGE2 gel. The cause for admission was Birth asphyxia, meconium aspiration.

Table 7: Maternal outcome

	Extra amniotic saline infusion	PGE2 gel
	Number	Number
Hyper stimulation	-	6
Post-partum hemorrhage	5	11
Puperal pyrexia	7	5
Total	12	22

No hyperstimulation was noted in extra amniotic saline infusion whereas 6 had hyperstimulation in PGE2 gel group. PPH was also more in PGE2 gel. Puperal pyrexia was comparable in both the groups.

Discussion

- The study was conducted in Institute of Obstetrics and Gynecology, Egmore to compare the efficacy of extra amniotic saline infusion and PGE2 gel for induction of labour.
- The study was carried out in 200 patients. 100 patients were induced with extra amniotic saline infusion and 100 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 Janet *et al* (1999) Sharami (2005) Showed that the maximum number of patients belonged to 20-30 years of age.
- Majority of the patients were PRIMI GRAVIDA. The study of Janet *et al* and Guinn *et al* (2004) also had maximum number of primi patients.
- Majority of the patients induced were between 40-41 weeks. The study of Karjane *et al* (2006) also showed that post datism was the most common reason for induction.

Change in bishop score

- Both the groups were induced with almost similar Bishop Score initially. The mean Bishop score at 0 hrs was 2.26 in Primis induced with Extra amniotic saline infusion and PGE2 gel was 2.25
- The mean Bishop score at 6 hrs was 6.62 in Primis induced with Extra amniotic saline infusion whereas PGE2 gel was 5.51
- The mean Bishop score at 12 hrs was 9.27 in Primis induced with Extra amniotic saline infusion whereas PGE2 gel was

8.08
- The mean Bishop score at 6 hrs was 8.57 in Multis induced with Extra amniotic saline infusion whereas PGE2 gel was 6.91
- The mean Bishop score at 12 hrs was 10.40 in Multis induced with Extra amniotic saline infusion whereas PGE2 gel was 9.41
- Mean Bishop Score improved in higher rate in extra amniotic saline infusion group when compared to PGE2 gel group.
- The difference is statistically significant (P<0.01)

Induction to active labour interval
- Majority of the patients induced with extra amniotic saline infusion established active labour within 6 hrs whereas in PGE2 gel active labour established in 6-12 hrs.
- The 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.
- The difference between the two groups were statistically significant.(P<0.01)
- Extra amniotic saline infusion was found to be more effective in causing cervical ripening than PGE2 gel.
- Oxytocin augmentation
- Oxytocin use in extra amniotic saline infusion was only 43% whereas in PGE2 gel group was about 72%. More number of patients in the PGE2 gel group required oxytocin for further progress of labour.
- The difference is statistically significant (P<0.01)

Induction to delivery interval
- Majority of the patients induced with the extra amniotic saline infusion delivered within 12 hrs when compared to PGE2 gel.
- The mean Induction delivery interval in Primis induced with extra amniotic saline infusion was 11.2hrs and in PGE2 gel group was 13.35 hrs.
- The mean Induction delivery interval in Multis induced with extra amniotic saline infusion was 9.30hrs and in PGE2 gel group was 12.78 hrs.
- The difference between the two groups were statistically significant.(P<0.01)

Mode of delivery
- LSCS rate was only 19% in extra amniotic saline infusion group when compared to about 27% in the PGE2 gel group.
- 76% of patients delivered vaginally in the extra amniotic saline infusion group whereas only 67% had labour natural in the PGE2 gel group.
- The difference in the mode of delivery was statistically significant (P<0.01)

Indication for cesarean delivery
- Incidence of Cesarean delivery was significantly lower in the extra amniotic saline infusion when compared to the PGE2 gel group.
- Incidence of failed induction was only 3% in the extra amniotic saline infusion group whereas it was 6% in the PGE2 gel group.
- Incidence of fetal distress was only 12% in the extra amniotic saline infusion group whereas it was 19% in the PGE2 gel group.
- Buccellato *et al* (2000) reported that failure to progress and non- reassuring fetal heart rate were common cause for Cesarean deliveries.
- Guinn *et al* (2004) reported that fetal distress was the most frequent indication for Cesarean section.
- Sharami *et al* (2005) reported that cervical dystocia was the most common cause for Cesarean section.

Fetal outcome
- Only 7% of neonates were admitted in NICU in Extra amniotic saline infusion group whereas it was about 12% in the PGE2 gel group.
- The common cause for admission was Birth asphyxia, meconium aspiration.
- Guinn *et al* reported no significant maternal or neonatal morbidities.

Maternal outcome
- 6 patients had hyperstimulation in the PGE2 gel group. The patients were put in left lateral position. Oxygen was given by face mask & IV fluids were given. No hyperstimulation was seen in the extra amniotic saline infusion group.
- Puperal pyrexia was comparable in both the groups.
- There was no technical difficulty in Foley catheter insertion.
- Janet *et al* reported technical difficulty in one patient because of cervix position.
- Schreyer *et al* reported mild bleeding (6%) shortly after Foley catheter.
- Sherman *et al* reported rupture of membrane at the time of insertion (2%)

Summary
- Improvement in Bishop Score was more in the extra amniotic saline infusion group when compared to PGE2 gel group. P<0.01
- Mean Induction to active labour interval (ILI) was shorter in the extra amniotic saline infusion group when compared to PGE2 gel group. P<0.01
- Mean Induction to delivery interval was shorter in the Extra amniotic saline infusion group hen compared to PGE2 gel group. P<0.01
- The Mean Induction to active labour interval (IDL) and Mean Induction to delivery interval were shorter in Multis of both groups as compared to Primis of both the groups. P<0.01
- Oxytocin usage was higher in the PGE2 gel group when compared to Extra amniotic saline infusion group P<0.01
- Regarding Age, Parity, Gestational age and the indication for induction there was no significant difference in both the groups.
- 76% of patients in the extra amniotic saline infusion had labour natural when compared to 67% in the PGE2 gel.
- LSCS incidence was about only 19% in the extra amniotic saline infusion when compared to 27% in the PGE2 gel group.
- Incidence of LSCS for failed induction in the extra amniotic saline infusion was only 3% when compared to 6% in the PGE2 gel group.
- Hyperstimulation of uterus was higher in the PGE2 gel when compared to the extra amniotic saline infusion. P<0.01

- Neonatal admissions were comparatively more in the PGE2 gel group than extra amniotic saline infusion.
- Extra amniotic saline infusion was found to be more effective, cheaper and readily available method for cervical ripening and induction of labour.

Conclusion

- 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.
- Mean Induction to delivery interval (ILI) was shorter in the extra amniotic saline infusion group when compared to PGE2 gel group.
- Oxytocin usage was lower in the extra amniotic saline infusion group when compared to PGE2 gel group.
- Response to Multis are better than Primis in both the groups.
- Fetal and Maternal outcome were better in the extra amniotic saline infusion group than PGE2 gel group.
- Extra amniotic saline infusion was found to be more effective, cheaper and readily available method for cervical ripening and induction of labour.

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