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Original Research Article

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: Induction of labor is an artificial initiation of uterine activity before the spontaneous onset of labor with the aim of achieving vaginal delivery. To assess the effectiveness of extra amniotic saline infusion and prostaglandin E2 gel for induction of labour. ***Methods:*** A randomized, comparative study was conducted in the Department of Obstetrics and Gynaecology, Ayaan Institute of Medical Sciences over a period of 6 month. 260 patients at term with a Bishop's score ≤5 with various indications for induction were randomly allocated to group E (extra amniotic normal saline) and group P (PGE2 gel) with 130 women included in each group. ***Results:*** 61.5% of Primi delivered within 12 hrs in the extra amniotic saline infusion group compared to only 44.4% in the PGE2 gel group. 96% of Multi delivered within 12 hrs in extra amniotic saline infusion group compared to only 55.6% in the PGE2 gel. The mean Induction delivery interval in Primi with Extra amniotic saline infusion was 12.34 hrs. The mean Induction to delivery interval in Primi with PGE2 gel was 14.43 hrs. The mean Induction to delivery interval in Multi with Extra amniotic saline infusion was 10.54 hrs. The mean Induction to delivery interval in Multi with PGE2 gel was 13.64 hrs. The difference between the two group is statistically significant. ***Conclusions:*** Cervical ripening was more effective in the Extra amniotic saline infusion group when compared to PGE2 group. Oxytocin usage was lower in the Extra amniotic saline infusion group when compared to PGE2 gel group.

Keywords: Cervical ripening, Foley's catheter, Induction of labor, PGE2.

INTRODUCTION

Induction of labour can be defined as the artificial initiation of uterine contractions before its natural onset, with the purpose of delivery of the feto placental unit. It is indicated in conditions with obstetric or medical problems where the benefit of expeditious delivery outweighs the risk of continuing pregnancy.[1] The common indications are post-term pregnancy, gestational hypertension, preeclampsia, maternal diabetes mellitus, foetal compromise and for logistic reasons. The method of induction must be both safe and effective.[2]

Modified Bishops Score system is most commonly used for cervical assessment prior to induction. Cervix is considered unfavourable if the score is less than 6. There is an increased risk of caesarean section associated with induction of labour in unfavourable cervix. Cervical ripening refers to a process of preparing the cervix for induction of labour by promoting effacement and dilatation and may have a role in reducing the incidence of failed induction and caesarean delivery.[3]

Ripening of cervix may be achieved by mechanical techniques such as introduction of intracervical Foley's catheter. It causes mechanical dilatation of cervix and stimulates endogenous release of prostaglandins by stripping the foetal membranes and release of lysosomes from decidua cells [4] Local application of dinoprostone causes connective tissue softening, cervical effacement and uterine activity.[5]

Foleys catheter is cheaper than dinoprostone gel and is easily preserved at room temperature unlike

dinoprostone gel which requires preservation at a temp of 2-8 ºC. Also, use of dinoprostone gel requires caution in some conditions like asthma, glaucoma, epilepsy, compromised cardiac, hepatic or renal function.[6]

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.[7] It is in use since 1960s for cervical ripening. Local application of PGE2 causes direct softening of cervix by a number of different mechanisms. It can cause connective tissue softening, cervical effacement and uterine activity. PGE2 gel can be used in cases of heart disease, PIH and eclampsia also.[8]

MATERIALS AND METHODS

The study was conducted in the Department of Obstetrics and Gynaecology, Ayaan Institute of Medical Sciences over a period of 6 month. This randomized prospective study included 260 pregnant women attending the labor ward for induction of labor. The selection criteria were singleton live fetus in cephalic presentation between 33 and 42 weeks of gestation, with intact membranes and Bishop Score <4. Cases with antepartum hemorrhage, scarred uterus, low-located placenta, cervicovaginal infection, and history of cardiac disease, glaucoma, convulsive disorder, asthma, or jaundice were excluded from the study. Of 260 women, 130 were randomized to Group A (balloon group) and rest 130 to Group B (gel group). After detailed history and thorough clinical examination, pelvic examination was carried out to assign Bishop score.

Procedure Foley catheter group (Group A) After asking the patient to urinate, an aseptic speculum (Cusco) examination was carried out in lithotomy position and swab was taken from the external os, for culture of any bacterial infection. After that, vaginal examination was performed to assess the Bishop score and the pelvis. If Bishop score was <4 and pelvis was adequate, then with the aid of Sim's speculum, the portio vaginalis of the cervix was cleaned with betadine solution and anterior lip of cervix was held with sponge holding forceps; prepacked sterile Foley catheter of 16 gauge size was introduced through the external os with the help of a sterile artery forceps for about 10–12 cm past the internal os. After that, catheter balloon was inflated with 30 ml of sterile normal saline and the catheter was pulled back so that the bulb got hitched back against the internal os. The outside portion of the catheter was folded and strapped loosely by adhesive tape with the medial aspect of upper thigh of the patient. Patients were observed for 10–15 min for any leakage of amniotic fluid or from catheter causing deflation of balloon and were monitored for fetal distress and uterine activity over the next 12 h.

After 12 h, the catheter was deflated and removed if not already expelled. Swab was taken from the external os for culture of any bacterial infection. Rescoring of the cervix was carried out. A note was made on spontaneous expulsion or removal of catheter, spontaneous rupture of membranes, and whether the subject was in active labor. In the absence of active labor, enema simplex was given and, after enema result, patients were prepared for further augmentation of labor with intravenous oxytocin infusion.

Initially, oxytocin was started at the dosage of 1 mIU/min and escalating doses of intravenous oxytocin, doubled everyhalf an hour, were given (e.g. 1, 2, 4, and 8 mIU/min). The intravenous oxytocin dose was titrated against the response and was increased till the patient got good contractions lasting for 40 s with a frequency of three contractions every 10 min. Intravenous oxytocin infusion was not increased above a maximum of 64 mIU/min. Amniotomy was performed as and when indicated. After delivery, placental membranes were sent for bacterial culture study.

PGE2 gel (Cerviprime) group (Group B) The patients of this group also underwent aseptic speculum examination and swab study and preinduction Bishop scoring. The cervix was swabbed clean of excess mucus and PGE2 prepacked in sterile prefilled ready-to-use syringe was instilled into the endocervix. The patients were asked to lie supine for at least 30 min and were monitored for fetal well-being and uterine activity over next 12 h. After 12 h, repeat swab was taken and vaginal examination was carried out and rescoring was assigned. Oxytocin induction or augmentation was performed as per hospital protocol. Placental membranes were sent for bacterial culture study after delivery.

RESULTS

In table 1, 61.5% of Primi delivered within 12 hrs in the extra amniotic saline infusion group compared to only 44.4% in the PGE2 gel group. 96% of Multi delivered within 12 hrs in extra amniotic saline infusion group compared to only 55.6% in the PGE2 gel group in (Table 1).

Table 1: Induction delivery interval

Duration in hours	Extra amniotic saline Infusion				PGE2 gel			
	Primi		Multi		Primi		Multi	
	No.	%	No.	%	No.	%	No.	%
6-12	52	61.5	41	96.0	40	44.4	24	55.6
12-24	35	38.5	2	4.0	49	55.6	17	44.4
Total	87	100	43	100	89	100	41	100

Table 2: Mean induction delivery interval

	Extra amniotic saline infusion		PGE2 Gel	
	Primi	Multi	Primi	Multi
IDL	12.34+3.63	10.54+2.01	14.43+4.53	13.64+3.53

The mean Induction delivery interval in Primi with Extra amniotic saline infusion was 12.34 hrs. The mean Induction to delivery interval in Primi with PGE2 gel was 14.43 hrs. The mean Induction to delivery interval in Multi with Extra amniotic saline infusion was 10.54 hrs. The mean Induction to delivery interval in Multi with PGE2 gel was 13.64 hrs. The difference between the two groups is statistically significant in (Table 2).

Table 3: Patients requiring oxytocin augmentation

Oxytocin	Extra amniotic saline infusion		PGE2 Gel		Total
	Number	Percent	Number	Percent	
Not used	73	56.1	43	33.0	116
Used	57	43.8	87	66.9	144
Total	130	100	130	100	260

This table shows the higher use of Oxytocin in the PGE2 gel group – 66.9% when compared to extra amniotic saline infusion group – 43.8%. The difference is statistically significant in (Table 3).

Table 4: Mode of delivery distribution

Mode of delivery	Extra amniotic saline infusion		Pge2 Gel		Total
	Number	Percent	Number	Percent	
Labour natural	93	71.5	83	63.8	176
LSCS	28	21.5	36	27.6	64
Forceps/ vacuum	9	6.9	11	8.4	20
Total	130	100	130	100	260

71.5% of patients in extra amniotic saline infusion delivered vaginally compared to only 63.8% in the PGE2 gel. LSCS was 27.6% in the PGE2 gel group whereas it was only 21.5% in the extra amniotic saline infusion. The difference is statistically significant in (Table 4)

Table 5: Indication for cesarean section

Indication	Extra amniotic saline infusion		PGE2 Gel		Total
	Number	Percent	Number	Percent	
Fetal distress	8	61.5	11	68.75	19
CPD	3	23.0	1	6.25	4
Failed induction	1	7.6	3	18.75	4
others	1	7.6	1	6.25	2
total	13	100	16	100	29

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 7.6% compared to 18.75% in PGE2 gel group. The difference is statistically significant in (Table 5).

DISCUSSION

Labour induction is one of the most commonly performed obstetric procedures in patients undergoing inpatients cervical ripening. Recently, induction of labour by use of prostaglandins is very common due to the rise of maternal or fetal reasons. [9] Induction of

labour with prostaglandins offers the advantage of promoting both cervical ripening and myometrial contractility. A drawback of prostaglandin is their ability to induce excessive uterine contractility which can increase perinatal morbidity. [10] Prostaglandins are highly efficacious cervical ripening agents used to shorten induction to delivery intervals, improve induction success, and reduce morbidities associated with prolonged labour induction. According to Mohamed and Jayaguru extra amniotic saline infusion for induction of labour is a cost effective method worthy of wider use. [11] EASI is successful in inducing labour in antepartum fetal deaths after 20 weeks of gestation. This method has been shown to be safe and well tolerated by the women and should be considered in areas with limited resources. [12]

A sample of 130 pregnant women was taken in this study. The mean induction delivery interval in PGE2 was 14.43 hrs and in the EASI group was 12.34 hrs. The baseline characteristics taken in the study were age, parity and gestational age. Among the three baseline characteristics we found significant difference in age parity and gestational age among two groups. PGE2 is associated with less oxytocin augmentation and lesser caesarean section operations for failed induction Bartha et al. [12] (2000). Our study also indicates that PGE2 was linked with less need of oxytocin augmentation. Caesarean section was lesser in group I. Many studies reported that hyperstimulation were found more in patients who were induced with PGE2. It may be due to the reason there is less risk of hyperstimulation with lower dose of PGE2 but at the same time reducing the effectiveness of labour induction.

Overall, the present study showed that both EASI using Foley's catheter and PGE2 gel appeared to be effective agents for cervical ripening and labor induction. There was no significant difference in ripening efficacy and perinatal and neonatal outcomes. As more patients are induced for postdatism and other indications, the question of the best method of preinduction cervical ripening remains controversial. [13] The current study supports both the EASI using Foley's catheter and the use of exogenous prostaglandins as effective and safe. However, in specific patient populations, such as those with vaginal births after cesarean section, the use of a Foley's catheter is a safer option. No common side effects (intrapartum or postpartum fever and vaginal bleeding, the quite rare rupture of membranes, along with displacement of the presenting part and umbilical cord prolapse) have been seen with this simplified insertion technique in this study.

Moreover, PGE2 gel cannot be used in patients with medical disorders like bronchial asthma, epilepsy, and glaucoma in which Foley's catheter can be used safely for cervical ripening. Therefore, considering the side effects of PGE2 gel, its irreversible effect on uterine contraction, cost, and requirement of proper monitoring of fetus and mother, it is better to use Foley's catheter with EASI than PGE2 gel. It avoids the need for continuous monitoring in a health care facility. Hence, Foley's catheter is safe in contrast to PGE2 gel. [14] Foley's catheter causes less fetal distress. The safety profile of Foley's catheter is such that it can be used on an outpatient basis, but not PGE2 gel. These results make Foley's catheter comparable or even superior to PGE2 gel for cervical ripening, especially in developing countries. Thus, it is concluded that cervical ripening with EASI using Foley's catheter has the advantages of simplicity, low cost, reversibility, and lack of serious side effects. [15-17]

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. Oxytocin usage was lower in the extra amniotic saline infusion group when compared to 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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