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A Comparative Study between Intracervical Dinoprostone Gel and Intravenous Oxytocin in Induction of Labour- Fetal and Maternal Outcome

Dr. Kanak Lata[1] ,Dr. Anita Kumari[2]
[1(*MS Obstetrcs And Gynae, ,B.S.M.C.H,,W.B ,Specialist Contractual Medical Officer ,Department of Obs & Gynae , Bankura Sammilani Medical College, West Bengal university of Health & Sciences)*
[2]*(MD, Obstetrics And Gynaec,N.M.C.H, Patna , 3rd year ,senior Resident , , Department of Obs & Gynae ,ESI ,Basaidarpur ,New Delhi ,university)*
Corresponding Author: Dr. Kanak Lata

Abstract:
BACKGROUND- *Induction of Labour is the artificial initiation of labour before spontaneous onset of labour sets in. The frequency of induction varies by the different drugs used for it. The objective of this study was to study the fetomaternal outcome after induction with Intracervical Dinoprostone (PGE2 Gel) and Intravenous Oxytocin.*
METHOD-*.A prospective study was done at B.S.M.C.H, W.B, India using data of deliveries conducted during the period of Jan,2016 to Dec 2017. Eligible patients included those at term, 37 weeks of gestation . All patients had singleton pregnancy with vertex presentation. A total of 150 patients were studied. They were distributed into two groups. 85 patients were in Group A were induced with single intra-cervical application of 0.5 mg PGE2 gel and remaining 65 patients of Group B were induced with intravenous Oxytocin and efficacy of the two methods of induction was compared.*
RESULTS-*Total number of deliveries during this period was 21091. Labour was established within 24 hours in 71.4% of primigravida and 94% of multigravida in PGE2 treated group compared to 68% primigravida and 90% multigravida in the Oxytocin treaed group. The study found substantial improvement in cervical score 12 hrs after application of PGE2 gel with no major adverse effect to mother or neonate.*
CONCLUSION- *Intra-cervical PGE2 gel is safe and effective for inducing labour in patients with unfavorable cervix. In our study we had high rate of vaginal delivery with no major adverse effect to mother or neonate.*

Keywords- *Induction, Intracervical Dinoprostone (PGE2 gel) , Oxytocin.*

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I. Introduction

Induction is indicated when the benifits to either mother or fetus outweighs those of pregnancy continuation. The more common indications include postdatism, gestational hypertension, membrane rupture without labour, oligohydramnios, and various maternal medical conditions such as chronic hypertension and diabetes.[1]

The aim of induction being to achieve a safe vaginal delivery for the fetus without causing harm to mother. Failed induction may be associated with, besides a poor neonatal outcome,great physical and mental trauma to the mother. Failed induction is the failure to enter into active phase of labour after 12 hours of regular uterine contractions in a patient who has been induced[2].

The success of induction of labour depends largely on the parity and the pre-induction state of cervix. It is the prelabour softening, effacement and eventual dilatation that culminates in spontaneous labour. Important structural and biochemical changes take place during ripening of cervix. There is a gradual dissociation and scattering of previously densely packed collagen along with qualitative and quantitative changes in proteoglycan content within ground substance[3].

Local use of prostaglandin E2 (PGE2) by extra-amniotic, intravaginal and intracervical route has been found to be effective in priming the cervix and inducing labour in patients at term with poor Bishop score[4,5,6]

The intracervical use has fewer side effects. Extra-amniotic use, besides being invasive is associated with increase risk of introducing infection. The intravaginal application though less invasive and easy to use requires larger dose of the drug and hence associated with gastrointestinal side effects and uterine irritability. Besides its action is unpredictable and result often unsatisfactory[7]. Intravenous oxytocin infusion with low

amniotomy has been and is still widely practised to induce labour. However, prostaglandins used locally have been found to be successful in inducing particularly those patients who have an unfavourable cervix. It permits longer ambulation, decreased analgesia requirement and lower incidence of neonatal jaundice.

The aim of the present study was to compare the methods of induction with escalating oxytocin infusion and intracervical PGE2 gel application amongst primigravidas and multigravidas in women with unfavourable cervix.

II. Materials and Methods

The present prospective observational study was carried at Bankura Sammilani Medical College,W.B in the department of Obstetrics And Gynaecology from the period of 1st Jan 2016 to 31st Dec 2017. The annual delivery rate was 21091.

Study Design- A prospective Observational study.
Study Location- Bankura Sammilani Medical College,W.B in the department of Obstetrics And Gynaecology.
Study Duration- 1st Jan 2016 to 31st Dec 2017.
Sample Size- 150 patients.

Subjects & selection method- 150 women with modified Bishop score of 3 or less and requiring induction were randomly assigned into two groups viz A (n=85) and B (n=65). Primigravidas and multigravidas were included at different periods of gestation.
Group A-Total 85 patients ,primigravida (n-35) ,multigravida (n-50).
Group B- Total 65 patients, primigravida (n-25) ,multigravida (n-40).

INCLUSION CRITERIA:
1- Gestational age ≥ 37 wks.
2- Singleton pregnancy.
3- Amniotic Fluid Index ≥ 5.
4- Intrauterine growth retardation.
5- Gestational Diabetes (uncomplicated).

EXCLUSION CRITERIA
1-Gestational age < 37 wks.
2-Severe Oligohydramnios.
3-Inrauterine fetal death.
4-Prelaboure Ruture of Membranes.
5-Past history of any uterine surgery

PROCEDURE AND METHODOLOGY

Patients of group A were administered intracervical PGE2 containing 0.5 mgm per 3.0 gm in gel form (Dinoprostone gel- Cerviprime) available in pre filled sterile syringe with catheter just below level of internal Os taking aseptic precautions. Ambulation was permitted 60 minutes after instillation. Cervical score before and after 12 hours of administration were noted.

Group B patients were assessed in the morning of induction and intravenous oxytocin infusion begun at 2 mu/mt at 0800 hrs. The oxytocin infusion was escalated by doubling technique till a maximum of 60 mu/mt or till good uterine contractions were achieved. All patients in this group were re-evaluated after 12 hours if they had not delivered and delivered by caesarean section if labour was not established by then.

Group A patients too were re-evaluated next morning at 0800 hrs if not delivered by then and their cervical scores noted. Those who were yet to go into labour were induced with oxytocin as in Gp B.

Amniotomy was done in all cases in labour at 3.0 cm cervical dilatation. Informed written consent was obtained prior to induction in all cases. Induction was considered having failed if inspite of oxytocin at 64 mu/mt patient failed to go into active labour. Good uterine contractions were considered achieved when there were 3/4 contractions in 10 mts lasting 45-60 sees each. The definition of excessive uterine activity was considered as advocated by Sanchez Ramos et al. Tachysystole was defined as at least six contractions in 10 mts for two consecutive periods of time and hypersystole as a single contraction lasting for two minutes. Hyperstimulation syndrome was defined as either tachysystole or hypersystole associated with fetal tachycardia. bradycardia or irregularity.Mode of delivery. birth weight, Apgar score at 5 mts afterbirth and evidence ofneonatal jaundice (more than 8 mg %) within first seven days of birth were also noted.

III. Results

There were total 150 patients. Patients of group A were administered intracervical PGE2 containing 0.5 mgm per 3.0 gm in gel form. Group B patients were assessed in the morning of induction and intravenous oxytocin infusion begun at 2 mu/mt at 0800 hrs. The oxytocin infusion was escalated by doubling technique till a maximum of 60 mu/mt or till good uterine contractions were achieved.

Patient characteristics are summarised in Table I . Both the group were comparable as regards their age, weight gestational age and initial cervical score calculated as per modified Bishops score.70.1% of induction were for postdatism (Table 2). Other reasons were intrauterine growth retardation , hypertensive disorders of pregnancy, unexplained still birth in previous pregnancy and diabetes.

TABLE NO 1-

	Group A (PGE2 Gel) (n-85)		Group B (Oxytocin) (n-65)	
Mean	Primi (n-35)	Multi (n-50)	Primi (n-25)	Multi (n-40)
Mean age in yrs	22	30	23	31
BMI	22.8	23.4	22.5	31
GA	37.5	38.2	38	38.4
Bishop Score(Initial)	2.0	2.4	2.7	2.3
Cervical Length	1.2	1.3	1.3	1.5

GA-Gestational Age , BMI-Body Mass Index.

TABLE NO-2 Indications for Induction in 150 patients with PGE2 gel and IV Oxytocin-

	Group A(PGE2 gel) (n-85)		Group B (Oxytocin) (n-65)		
	Primi(n-35)	Multi (n-50)	Primi(n-25)	Multi (n-40)	Total %
Postdatism	24	33	17	33	107 (71.33 %)
IUGR	3	9	4	2	18 (12.0 %)
Hypertensive disorders	8	6	4	3	21 (14.0 %)
H/O Unexplained still births	-	1	-	1	2 (1.33 %)
GDM	-	1	-	1	2(1.33 %)
Total	35	50	25	40	150

TABLE NO 3- It shows results of Induction. By 24 hours , however. 71.4% of primigravidas and 90.0 % of multigravidas had delivered vaginally in the prostaglandin group A in contrast to 60.0 % of primigravida and 85.0 % of multigravidas in oxytocin Group B. 13 primigravidas and 8 multigravidas in the PGE2 gel applied

group required acceleration of labour. 37.14 % of primigravidas (13 out of 35) and 16.0 % of multigravidas (8 out of 50) did not go into labour after 12 hours of PGE2 intracervical application and required oxytocin infusion. The mean induction delivery interval in PGE2 group was longer in both primigravidas and multigravidas compared to the oxytocin group. The mean amniotomy delivery interval was more in primigravidas in the PGE2 group but almost similar amongst PGE2 and oxytocin group in multigravidas

TABLE NO3-

	Group A (PGE2 gel) (n-85)		Group B (IV Oxytocin) (n-65)	
	Primi (n-35)	Multi (n-50)	Primi(n-25)	Multi(n-40)
1)Labour Established	25 (71.4%)	45 (90%)	15 (60 %)	34 (85%)
a) In 12 hrs	7 (20%)	30 (60%)	3 (12%)	20 (50%)
b) In 24 hrs	25 (71.4 %)	47 (94%)	17 (68%)	36 (90%)
2)Oxytocin used in Group A	13	8	-	-
3)induction Delivery mean in hrs	16 hrs	12 hrs	15hrs	10hrs
4)Amniotomy +Delivery Mean in hrs	9	5	7	6
5)Falied Induction	10 (28.57%)	5 (10%)	10 (40%)	6 (15%)

TABLE NO 4- The improvements in cervical score at 12 hours after PGE2 application in both primigravidas and multigravidas against the oxytocin group is evident from Table 4.

TABLE NO 4-CERVICAL SCORE AFTER 12 HRS-

	Group A (n-85) PGE2 gel		Group B(n-65) IV Oxytocin	
	Primi (n-35)	Multi (n-50)	Primi (n-25)	Multi (n-40)
Initial Score	2	2.5	2.6	2.4
After 12 hrs (Mean)	6	7	4.2	5

TABLE 5-Table 5 depicts the average birth weights and Apgar Score 5 minutes after birth. Only one male child was born with severe birth asphyxia due to meconium aspiration in a post-term primigravida in the oxytocin induced group. There were no perinatal deaths. Three cases of neonatal jaundice were observed between second and third day. The jaundice disappeared following conservative management within seven days. The single case of neonatal jaundice in the prostaglandin group was not born of mother given oxytocin infusion either for acceleration or induction.

TABLE 5- FETAL OUTCOMES BIRTH WEIGHT, NEONATAL JAUNDICE & APGAR SCOR

	Group A (n-85) PGE2 gel		Group B(n-65) IV Oxytocin	
	Primi (n-35)	Multi(n-50)	Primi (n-25)	Multi (n-40)
Mean Birth Weight (kg)	2.6	2.8	2.5	2.2
Neonatal Jaundice	1	-	1	1
Apgar Score at 5 Min				
a) 7-10	32	45	20	35
b) 4-6	3	5	4	5
c) 5-3	-	-	1	-

TABLE NO 5- MATERNAL OUTCOMES MODE OF DELIVERY AND INDICATIONS OF LSCS

	Group A (n-85) PGE2 gel		Group B (n-65) IV Oxytocin	
	Primi (n-35)	Multi(n-50)	Primi (n-25)	Multi (n-40)
Normal Vaginal Delivery	23	44	12	34
Forceps Delivery (outlet)	1	1	1	1
Ventouse	1	0	1	1
Total Vaginal Delivery	25	45	14	36
LSCS	10	5	11	4
Indication of LSCS				
a) Failed Indication	10	4	8	4
b) Foetal Ditsress	-	1	2	0
c) Failure to Progress	-	-	1	-

In the present study 80.0 % delivered vaginally and remaining underwent abdominal delivery. 44.0 % oxytocin induced primigravidas underwent LSCS delivery as compared to 28.57 % in prostaglandin induced group (Table 6). The LSCS rates amongst multigravidas in both the groups were similar, for Group A 10.0 % and for Group B 11.7 % respectively. 25 of the 30 (83.33 %) caesarean deliveries were for failed induction while the remaining were for either intrapartum fetal distress or failure to progress. The incidence of failed induction in the oxytocin group were 32.0 % among primigravidas and 10.0 % among multigravidas. The prostaglandin group had a rate of 28.57 % and 8.0 % of failed induction amongst primigravidas and multigravidas respectively.

Severe untoward effects either in the form of gastrointestinal symptoms or pyrexia were not noticed in the present study. One PGE2 induced multigravida who underwent oxytocin augmentation in labour, however, developed hyperstimulation syndrome. She was managed with discontinuation of drip and sedation following which she progressed normally. Tocolytic drugs were not required in the case.

IV. Discussion

We compared the efficacy of PGE2 gel applied intracervically with escalating oxytocin dosage and observed that only 28.57 % of patients in the former failed to progress to labour as compared to 32.0 % of patients in the latter amongst primigravidas. Amongst multigravidas, however, we noted that only 8.0 % in the prostaglandin group and 10.0 % in the oxytocin group failed to progress to labour. Our results are at variance to findings of Arulkumaran et al (1985) who noted that 45.8% of primigravidas and 7.7% of multigravidas of cervical score 3 or less when induced with oxytocin failed to go in labour and required caesarean delivery3. They concluded that cervical priming methods may improve chances of successful induction. We noted lesser failure of induction and lesser operative deliveries amongst the prostaglandin group. Our study corroborates the findings of Ulmstein et al8 and Shepherd et al9 that intracervical PGE2 gel results in improvement of cervical score facilitating oxytocin initiation of labour and often initiates labour per se. The improvement of cervical score from a mean of 2.0 to 6.0 in primigravidas and from mean of 2.5 to 7.0 in multigravidas 12 hours after PGE2 gel application intracervically is similar to that observed by Trofatter et al10. The authors in their study of 30 patients with poor cervical score of 3 noted an improvement of cervical score from 1.2 to 6.7, 12 hours after intracervical PGE 2 application10. Our improvements of cervical score resulted in successful initiation of labour by escalating oxytocin dose amongst 60.0 % of primigravidas and 85.0 % of multigravidas.• 28.57 % of primigravidas and 10.0 % of multigravidas in the present study failed to go in active labour even after oxytocin infusion following single application of PGE 2 gel. As it was not wise to delay delivery due to fetal

considerations in the present study, a repeat dose of PGE 2 gel was not tried. The effect of second repeat dose of intracervical PGE2 gel requires further evaluation and may bring down the failure rates further. 71.4% of primigravidas and 94.0 % of multigravidas in the prostaglandin group delivered vaginally within 24 hours with a mean induction delivery interval of 16 hours and 12 hours respectively. Trofatter et al had also observed a mean induction delivery interval of 13.3 hours. Our findings are at variance with that of Ulmsten and coworkers8 who reported only 53% of delivery in first 24 h but similar to Mishra et al11 reporting delivery rate of 73.8% among primigravidas in the PGE2 intracervically treated group within first 24 hrs . Our policy of selectively augmenting labour as of Mishra et al11 accounted for our high success rates The failure to observe any adverse reaction after PGE2 application makes it safer for use. The single case of hyperstimulation syndrome was consequent to excessive oxytocin stimulation in prostaglandin treated multigravida. There was no adverse perinatal outcome. Neonatal jaundice observed was comparable in both groups1 Prostaglandin E 2 is commonly used for ripening the cervix and for inducing labour in patients with intact membranes. Prostaglandin E2 gel intracervical1y applied improved the inducibility score of cervix and initiates labour in significant number of cases with predictable outcome. It is safe for both mother and fetus and allows ambulation unlike oxytocin induction. The reasonably good success rate with resultant decrease in caesarean sections without adverse maternal effects and neonatal outcome make PGE2 gel applied intracervical1y a preferred method of induction of labour than oxytocin alone. We advocate close monitoring and judicious use of oxytocin for labour augmentation in those treated with PGE2 gel especial1y in multigravidas. Further trials are required to compare the advantages if any for repeat PGE2 gel in patients who do not respond to single dose therapy for labour induction.

V. Conclusion

From this study, the use of intra-cervical PGE2 gel for induction of labour is accompanied by a high vaginal delivery (82.35%) and minimal complications. The use of PGE2 significantly reduced the need for oxytocin and was highly successful independently in inducing labour, with nearly 88.0 % of the patients not requiring oxytocin . So it is concluded that intracervical PGE2 gel is safe and a good option for those requiring inductionof labour.

VI. Limitations of the Study

1) It was a prospective observational study.
2) Single dose of PGE2 gel was applied in this study.

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