

DOI: <https://dx.doi.org/10.18203/2320-1770.ijrcog20231930>

Original Research Article

A study on comparison of cerviprime and IV oxytocin in labour induction and evaluation of changes in the bishop's score with these two agents

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Received: 09 May 2023

Revised: 09 June 2023

Accepted: 12 June 2023

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ABSTRACT

Background: There are several strategies for the induction of labor (IOL), and pharmacologic agents, including oxytocin and prostaglandins, are most commonly used in clinical practice. Compared with oxytocin, the prostaglandin E2 agent, dinoprostone, has been regarded as more effective for the induction of labor of LTPs with a non-dilated cervix. Objective was to compare the PGE2 gel placed intracervically with that of oxytocin given intravenously for induction of labor in both primipara as well as multipara with the comparison of Bishop's score at the starting of induction and its improvement with both of these inducing agents in those with indications for induction with gestational age greater than 36 weeks.

Methods: Hospital based prospective observational study over a period of one year on patients attending the antenatal and high-risk pregnancy clinic and scheduled for induction of labor with Bishop score <4.

Results: The number of successful induction was low in primiparae group with low Bishop's score (1-2). There were greater number of successful inductions in both primi as well as multiparae with higher Bishop's score.

Conclusions: When a primigravida had a low cervical score or an unfavourable cervix, intracervical PGE2 gel was found to be more effective at ripening the cervix and inducing labour. Both medicines were equally effective at inducing labour in cases of multigravidae with any Bishop's score and primi with a higher Bishop's score.

Keywords: Bishop's score, Cesarean rate, Failed induction, Induction of labour, Maternal outcome, Neonatal outcome, Oxytocin, PGE2 gel, Vaginal delivery rate

INTRODUCTION

Term induction of labor means deliberate termination of pregnancy beyond 28 weeks gestation by any means or methods which aim at initiation of labor and delivery per via naturalis. Induction is justifiable if the benefits of expeditious delivery outweigh the risk of continuing pregnancy. It is common obstetric intervention occurring in approximately 15% of all deliveries.

In order to be successful, induction of labor must fulfill

three criteria. First-it should result in labor, namely adequate uterine contractions with progressive dilatation of the cervix. Second, this labor should result in vaginal delivery, as there is little purpose in bringing about labor as a mere preparation for cesarean section. Third- in viable pregnancies, these aims must be achieved with a minimum discomfort and risk to both the mother and fetus.

There are several strategies for the induction of labor (IOL), and pharmacologic agents, including oxytocin and prostaglandins, are most commonly used in clinical

practice.¹ Compared with oxytocin, the prostaglandin E2 agent, dinoprostone, has been regarded as more effective for the induction of labor of LTPs with a non-dilated cervix.^{2,3} The World Health Organisation (WHO) recommends that oxytocin alone is indicated if prostaglandins are not available.⁴ Unfortunately, due to the high cost of dinoprostone, and instability of pharmacy-prepared dinoprostone gel, oxytocin remains in use for IOL at medical centers in developing and rural areas.⁵⁻⁷

During labor, the readiness of the uterine cervix for IOL can be assessed by several methods, including the use of the Bishop's score. A recently reported cohort study that recruited LTPs with a Bishop's score of between 4-6 showed that when compared with vaginal dinoprostone, intravenous oxytocin resulted in fewer cesarean deliveries and was more effective in IOL.⁸

In patients with unripe cervix (Bishop's score <5), if measures are not taken to improve the cervical status before induction, oxytocin infusion alone may be relatively ineffective, resulting in prolonged inductions, induction failures, unacceptable high rate of cesarean sections (>40%), prolonged hospital stays and increase in maternal and fetal mortality and morbidity.

The method of administration that had been explored most thoroughly is endocervical prostaglandin E2 gel (cerviprime, ASTRA IDL) or dinoprostone. A number of controlled trials had proven that PGE2 gel to be more efficacious in cervical ripening as compared to that of oxytocin in unripe cervix improving the rate of successful inductions. In our study, we compared the efficacy of these two inducing agents in cervical ripening and induction of labor with respect to Bishop's score and its changes with these two inducing agents.

Objectives were to compare the PGE2 gel placed intracervically with that of oxytocin given intravenously for induction of labor in both primipara as well as multipara with the comparison of Bishop's score at the starting of induction and its improvement with both of these inducing agents in those with indications for induction with gestational age greater than 36 weeks

METHODS

Hospital based prospective observational study conducted at Department of Obstetrics & Gynaecology, Labour delivery and recovery (LDR) rooms from September 2019 to October 2020 for patients attending the antenatal and high-risk pregnancy clinic and scheduled for induction of labor with Bishop Score < 4. Study consisted a total of 80 subjects.

Inclusion criteria

The inclusion criteria for the study were weeks of gestation >36 weeks, singleton pregnancy, cephalic presentation with intact membranes and no cephalo-pelvic

disproportion and reactive NST in cases where the baby was alive.

Exclusion criteria

The exclusion criteria were contra-indication for vaginal delivery, prior hypersensitivity to PGs, malpresentations, multiple pregnancies and antepartum haemorrhage.

Patients requiring induction were picked either from the outpatient (cases of post-datism, premature rupture of membranes, term previous section etc.) or the inpatient (cases of PIH, eclampsia, intrauterine growth retardation etc.). Patients were explained the procedure and were included in the study after their consent. Patients were examined in detail and per-vaginal examination was done for assessing the Bishop's score and with score <4 were picked up. Patients were randomly assigned to intracervical PGE2 gel group (Group A) and intravenous oxytocin group (Group B).

Group A-Once Bishop's scoring was done, intra-cervical PGE2-cerviprime gel marketed by Astra-IDL was introduced by the standard applicator taking care that the nozzle did not go beyond the internal OS under acute aseptic precautions. The Bishop's was recorded every 4 hourly interval. If the subject did not go into labor i.e., until the onset of at least 1 contraction lasting for 25-30 seconds in 5 minutes or Bishop's score remained <4 after 12 hrs of PGE2 gel insertion, reinsertion was done. If the cervical score remained <4 after 12 hrs of reinsertion, it was recorded as failure of cervical ripening. At the time of insertion the patient's pulse-rate, blood-pressure and FHR were recorded. Insertion was done in the ward or the labor room depending upon the indication. Patient was advised to lie down for 30-60 minutes following the insertion. After that, the patient was ambulatory and had light refreshment.

Patient was shifted to the labor room with onset of good uterine action i.e. 3-4 contractions lasting for 40-45 seconds in 10 minutes. Uterine action was monitored at every half-an-hour interval by palpatory method and FHR every 15-30 minutes interval with either a fetoscope or a doppler. Amniotomy was done at >3 cms of dilatation. Labor progress was closely monitored for hypertonic uterine action i.e. 5-7 contractions in 10 minutes or individual contraction lasting for more than 2 minutes duration, fetal distress i.e., tachycardia or bradycardia or variable decelerations, for signs of scar dehiscence in case of previous section. Augmentation of labor with intravenous oxytocin was done if the uterine contractions were inadequate after 4 hrs of onset of regular uterine contractions as indicated by the partogram. Reinsertion was done in subjects with inadequate response after 12 hrs. if the Bishop's score was <4 after reinsertion, it was recorded as failed induction and the subject was taken up for section.

Group B-Once the Bishop's scoring was done, intravenous

oxytocin was administered in primiparas and multiparas and the doses were titrated according to the response at regular intervals till the maximum dose was reached or uterine contractions occurring at a frequency of 3-4 in 10 minutes lasting for 40-45 seconds was achieved, whichever was earlier.

In both primiparas and multiparas 2 U of oxytocin in 500 ml of lactated Ringer at 8 drops/min i.e. 2 mU /min was started in escalating doses at 8 drops/min i.e. 2 mU/min till a maximum of 30 mU/min or uterine contractions as above is achieved, whichever was earlier.

Before the drip, the patient's vitals were recorded and the drip was started in the labor room and the labor was closely monitored, the uterine contractions every 30 minutes by palpatory method and FHR every 15-30 minutes by a fetoscope or a Doppler and change in Bishop's score every 4 hourly. Amniotomy was done at >3 cms of dilatation. Infusion was discontinued if there were hyper stimulation i.e. 5-7 contractions in 10 minutes or individual contraction lasting for 2 minutes duration, fetal distress. In case of uterine hyper stimulation, the drip was discontinued for half-an-hour and re-started at a lower dose if the FHR was normal in continuous electronic monitor. In case of continuous hyper stimulation with persistent decelerations in the monitor, the drip was discontinued and the case is labeled as failed induction and the patient is taken up for cesarean section. Induction failure was defined as no appreciable change in the cervix after 8 hrs of adequate labor as suggested by partogram or if no progress was made in active phase of labor for more than 2 hrs or if the patient did not go into labor with oxytocin infusion on 2 days and were taken up for section.

Induction-delivery interval, length of labor, doses of oxytocin and PGE2 gel used for induction with maternal side-effects and neonatal outcome, rate of vaginal deliveries and cesarean were documents and compared between the 2 groups. All this data was entered in the proforma with partogram.

Statistical analysis

The data was entered into MS-Excel, and the statistical analysis was carried out with IBM SPSS Version 25.0. The data values for categorical variables are expressed as numbers and percentages. The connection between the groups was tested using the chi-square test. The data values for continuous variables are shown as mean and standard deviation. A student's t-test was used to compare the mean differences between groups. All P-values less than 0.05 are considered statistically significant.

RESULTS

The youngest patient in both the groups was 19 yrs old, while the oldest patient in both the groups was 32 yrs old. The highest no. of patients in both the groups was found in

the age group of 21-25 yrs. 60% in cerviprime group and 65% in oxytocin group (Table 1).

Table 1: Distribution in relation to age.

Patient age	Cerviprime		Oxytocin		Total
	No.	%	No.	%	
16-20 yrs	8	20	4	10	12
21-25 yrs	24	60	26	65	50
26-30 yrs	6	15	7	17.5	13
31-35 yrs	2	5	3	7.5	5
Total	40	100	40	100	80

Among 40 m cases of cerviprime group, 18 (45%) were primigravida and in oxytocin group 16 (40%) were primigravida (Table 4).

Table 2: Distribution according to gestational age.

Gestational age in weeks	Cerviprime		Oxytocin		Total
	No.	%	No.	%	
36-38 wks	3	7.5	3	7.5	6
38-40 wks	17	42.5	18	45	35
40-42 wks	20	50	19	47.5	39
Total	40	100	40	100	80

The highest number of cases was in 40-42 weeks of gestation, 50% in cerviprime group and 47.5% in oxytocin group (Table 2).

Table 3: Indications for induction.

Indications	Cerviprime n=40		Oxytocin N=40		P value
	No.	%	No.	%	
Post-datism	23	57.5	18	45	NS
Hypertensive disorders	4	10	4	10	NS
PROM	9	22.5	13	32.5	NS
Oligohydramnios	2	5	2	5	NS
Others	2	5	3	7.5	NS

Others include 2 cases of IUGR, 1 case of Diabetes mellitus, and 2 cases of abnormal antepartum testing. Hypertensive disorders include pre-eclampsia, eclampsia and chronic hypertension. Indications were similar in both groups and did not differ significantly. Post-dates formed the largest group in indication for induction (Table 3).

The initial Bishop's score had its influence on the percentage of success of inductions. There was greater numbers of successful inductions with a score 3-4 in both primiparae as well as multiparae in both the groups. The number of successful inductions in primiparae with low cervical score (1-2) was greater in the cerviprime group with 66.67% when compared with those in the oxytocin group with 33.3% only through statistically not significant. The rate of successful inductions in primiparae with score

3-4 and those of multiparae with any Bishop’s score (low with score 1-2 or with score 3-4) were comparable in both the groups (Table 4).

Table 4: Initial Bishop’s score and its success rate.

Group & initial Bishop’s score	Number	Success rate	%
Cerviprime group	n=40 (18±22)		
Primiparous			
score< 1-2	6	4	66.67
score> 3-4	12	10	83.33
>Para 1			
score<1-2	9	8	88.89
score>3-4	13	12	92.3
Oxytocingroup	N=40 (16±24)		
Primiparous			
score< 1-2	6	2	33.33
score> 3-4	10	7	70
>Para 1			
score< 1-2	9	7	77.78
score> 3-4	15	13	86.67

Table 5: Change in the Bishop’s score after 12 hrs.

Group	Initial score (Mean)	After 12 hrs (Mean)	Difference (Mean)
Cerviprime	2.9	8.9	6.0
Oxytocin	3.2	4.8	1.6

Table 6: Response to treatment.

Group	Vaginal delivery		Cesarean section	
	No.	%	No.	%
Cerviprime primiparous	14/18	77.78	4	22.2
> Para 1	20/22	90.9	2	9.09
Total	34/40	84.3	6	15.6
Oxytocin primiparous	9/16	56.2	7	43.75
>Para 1	20/24	83.3	4	16.67
Total	29/40	69.7	11	30.2

The Bishop’s score in the cerviprime group had a greater rise of 2-3 pts every 6 hrs with a more favorable cervix by the end of 12 hrs than that of the oxytocin group who didn’t show much rise in the score by the end of 12 hrs (Table 5).

Data presented as no. and percentages and rate of cesarean i.e., 84.3 is the mean of the above 2 values and similarly done in other groups (P value-NS). The rate of vaginal deliveries in the cerviprime group was higher when compared with that of the oxytocin group and the cesarean rate was also much less in the cerviprime group than that of the oxytocin group. The number of primi with successful vaginal deliveries after 24 hrs was higher in the cerviprime group with 77.78% and the rate of cesarean was

less with 22.2% when compared with that of the oxytocin group where the rate of vaginal delivery after 24 hrs among primi being 56.2% with greater cesarean rate of 43.75% through statistically not significant (Table 6).

In the multigravidae the rate of vaginal deliveries Vs cesarean within 24 hrs were comparable among both the groups.

The mode of vaginal delivery either spontaneous or operative with either outlet or the ventouse was comparable in both the groups without much significance.

Table 7: Bishop’s score and induction delivery interval.

Group	Number	Induction-delivery Interval (S.D)
Cerviprime		
Primipara		
Score < 1-2	6	18.5±6.8
Score > 3-4	12	10.1±4.3
> Para 1		
Score < 1-2	9	9.3±4.2
Score >3-4	13	7±3.1
Oxytocin		
Primipara		
Score < 1-	6	23.5±5.2
Score > 3-4	10	12.1±-3.0
> Para 1		
Score < 1-2	9	10.2±4.1
Score >3-4	15	8.2±4.0

Table 8: Indications for cesarean delivery.

Indication	Cerviprime n=6		Oxytocin n=11		P value
	No.	%	No.	%	
Fetal distress	2	33.3	2	18.18	NS
Failure to progress					
Deep transverse arrest	1	16.67	1	9.09	NS
Secondary arrest of dilatation	1	16.67	1	9.09	NS
Failure to descend	1	16.67	1	9.09	NS
Failed induction	1	16.67	6	54.54	

In a case of primi with initial low score i.e. 1-2 the I-D interval was comparatively less than that of the cerviprime group. But where the score was greater than 3-4 in primis and any score in case of multigravidae the induction-delivery interval was comparable in both the groups (Table 7). In case of indications for the cesarean the fetal distress rate, rate of patients who failed to progress were comparable. But the rate of failed induction was much higher in the oxytocin group when compared with the cerviprime group (Table 8). In case of complications occurring during labor

the complication rates of both the groups were comparable and the rates of fetal distress, tachysystole and hyperstimulation were bit higher in the oxytocin group but not significant. Similarly, the rate of meconium stained liquor was bit high in the cerviprime group but not significant.

The neonatal outcome was comparable in both the groups though the 5 min Apgar was slightly less in the oxytocin group compared with the cerviprime group but not significant (Table 9).

Table 9: Neonatal outcome.

	Cerviprime, n=40		Oxytocin, n=40		P value
Birth weight (kgs)	2.86±0.587		2.841±0.394		NS
Apgar at 5 min	8.8		7.8		NS
Meconium stained liquor	6	15%	5	12.5%	NS
NICU admission	4	10%	5	12.5%	NS
Still birth	Nil		Nil		NS

Data presented as Mean±S.D, mean, no. and percentages. NS – nil significant, NICU – Neonatal intensive care unit

DISCUSSION

Membrane rupture prior to labour is a typical sign that labour should be induced. PROM clinical management during pregnancy is still debatable. Many researchers think that the lengthened time between PROM and birth is linked to a rise in the frequency of both maternal and perinatal infections. In the group of women who appear with an unfavourable cervix and preterm membrane rupture, prostaglandin induction of labour has the benefit of enhancing both cervical softening and myometrial contractility. PGE1 and PGE2 are frequently utilised prostaglandins. Misoprostol is linked to increased foetal discomfort and hyperstimulation. PGE2 successfully induces labour in patients with unfavourable cervixes.

In this study 80 women were studied, out of which 40 were induced with intracervical PGE2 gel (cerviprime) and remaining 40 were induced with intravenous oxytocin.

The initial Bishop's score at the time of insertion had greater influence over the success of induction. Success rate was 66.67% when the score was low i.e. 1-2 in cerviprime group when compared with only 33.33%. at the same score in the oxytocin group in case of primigravidae. The success rate soared to 83.3% and 70% in the same groups when the score was 3 or 4. In case of multigravidae the initial Bishop's score had no significant influence on the success of induction be it cerviprime or oxytocin as the inducing agent. A gradual change in the Bishop's score of 2-3 pts every 6 hrs occurred when success was met in case of cerviprime induction group with no significant change in the oxytocin group.

In a Cochrane review of 58 clinical trials, prostaglandins were shown to be more effective in IOL than oxytocin and resulted in fewer cesarean sections.⁷ However, oxytocin also reduced the rate of unsuccessful vaginal delivery when compared with expectant management. The findings from the present study showed that the subgroup with a Bishop's score of between 4-6 showed no superiority for dinoprostone over oxytocin.

Akay et al reported that both oxytocin and dinoprostone for IOL had similar obstetric outcomes in LTPs, but that oxytocin showed significant superiority for a shorter delivery period.⁹ The cohort studied by Koc et al included only women with a Bishop's score of between 4-6 and showed similar results to those of the present study.⁸ Also, this previous study showed no difference in the rates of cesarean delivery between dinoprostone and oxytocin, for either primiparous or multiparous pregnancies.⁸

The behavior of the cervix is now accepted to be a cardinal factor in deciding the success of an induction. Bishop's scoring system is an objective way of evaluating cervical status and response in induction.

The change in the Bishop's score was gradual, consistent and smooth when labor was induced successfully was also shown by Kar et al in a study comparing intracervical PGE2 gel and intravenous oxytocin where the difference in the improvement of the Bishop's score with PGE2 gel was statistically significant (t value 5.14) compared to oxytocin.¹⁰

The number of primiparae who delivered vaginally in the cerviprime group after 24 hrs was 77.7% Vs 56.2% in oxytocin group. The induction to delivery interval was shorter in the cerviprime group with low Bishop's score in primi than that of oxytocin group with a range of 11-26 hrs with mean of 18.5±6.8 hrs in cerviprime group to 17-29 hrs with a mean of 23.5±5.2 hrs in oxytocin group. The induction to delivery interval in case of multigravidae was comparable in both the groups. In this study, failed induction in the cerviprime group was 2.55 compared with oxytocin there was 15% of failed inductions.

No significant difference was reported in the number of operative vaginal deliveries in both the groups. 8.82% vs 6.89% in cerviprime and oxytocin groups respectively. Fetal distress in the cerviprime group occurred in the late 1st or 2nd stages of labor resulting in operative vaginal deliveries whereas fetal distress in oxytocin group occurred in early 1st stage resulting in more cesarean deliveries.

Cesarean delivery in cerviprime group was high in primi with low scores compared with highrate in oxytocin group with similar score as deducted from Table 6 and 8. In case multigravidae at any score the rate did not differ significantly in both the groups. The rate of tachysystole and hyper stimulation, though slightly higher in case of oxytocin group was comparable with that of cerviprime group. The rate of meconium stained liquor and PPH were comparable in both the groups with no significant difference. Observations regarding the neonatal outcome were comparable in both the groups; no significant differences existed for birth weight, 5 minute Apgar requirement for resuscitation or NICU admission. No difference is seen regarding meconium aspiration syndrome between the two groups.

Also, the present study's design was different from earlier LTP research in that it examined a subset with Bishop's scores between 0 and 3, where dinoprostone was more beneficial than oxytocin. The various effects of dinoprostone and oxytocin in LTPs as indicated by the various Bishop's scores may be explained by the various modes of action. In order to start or intensify uterine contraction, both oxytocin and dinoprostone can attach to certain receptors in the myometrium.^{11,12} The extracellular matrix (ECM) and fibroblast activity are also modulated by dinoprostone with functional prostaglandin E2 to induce cervical softening, which may be more significant for an unfavourable cervix even before uterine contractions start.^{13,14}

Both oxytocin and dinoprostone were declared safe for IOL of LTPs with a Bishop's score of between 4-6 when maternal and neonatal problems were taken into account. Dinoprostone did, however, prevent postpartum bleeding and greatly shorten the time intervals for women with a Bishop's score between 0 and 3, which was likewise a finding in the group with a Bishop's score between 4-6. Consequently, caution should still be advised for the use of this vaginal prostaglandin reagent with control of the dose despite the lack of sufficient positive cases to confirm the effect of dinoprostone overstimulation.

The limitations of the study are limited sample size localized to a particular hospital. The method of induction may vary depending on maternal, neo-natal, patient demographics and other variables that can complicate clinical trial design. These are further limited by not adhering to uniform protocols, inconsistent and incomplete report of the outcomes, variation in calculating Bishop's Score including observer bias.

CONCLUSION

When a primigravida had a low cervical score or an unfavourable cervix, intracervical PGE2 gel was found to be more effective at ripening the cervix and inducing labour. Both medicines were equally effective at inducing labour in cases of multigravidae with any Bishop's score and primi with a higher Bishop's score. Also, the initial

Bishop's score had an impact on how well the labour went, and higher scores are linked to better results. The impact of parity was more noticeable with lower Bishop's scores.

Funding: No funding sources

Conflict of interest: None declared

Ethical approval: The study was approved by the Institutional Ethics Committee

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Cite this article as: Swapna DL, Sree RS. A study on comparison of cerviprime and IV oxytocin in labour induction and evaluation of changes in the bishop's score with these two agents. *Int J Reprod Contracept Obstet Gynecol* 2023;12:2170-6.