

A Comparative Study Of Outcome Of Induction Of Labour In Primigravidae Women With Cerviprime Gel And Propress

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Abstract

BACKGROUND:- Induction of labour defines as artificial initiation of uterine contractions leading to progressive dilatation and effacement of cervix and delivery of baby. Includes women with intact membranes and those with spontaneous rupture of membranes but who are not in labour. Induction of labour is indicated when the risk of continuing pregnancy, for the mother or the fetus, exceeds the risk associated with induced labour and delivery. Many different methods have been used, but prostaglandins remain a preferred method for cervical ripening and labour induction. Dinoprostone is the preferred form of prostaglandin and has been shown to increase the rate of vaginal delivery within 24 h and is generally given when the cervix has a Bishop's score of \leq six.

OBJECTIVE:- comparative study of outcome of induction of labour in term primigravidae women with repeated cerviprime gel and long acting propress vaginal inserts.

METHODS:- Electronic databases and additional preserved hardcopy registers were used to identify randomized controlled trial (RCT). We included studies reporting data for nulliparous women with unfavourable cervix (Bishop <6) and intact membranes. The primary efficacy outcome was caesarean section (CS) rate. Primary safety outcome was uterine hyperstimulation requiring immediate delivery. This study emphasizes on the importance of having a proper induction protocol in place and at the same time judicious use of the agents for induction of labour.

RESULT:- Out of 166 patients, 108(65.5%) delivered vaginally within 29 hr of trial of labour. 64 patients delivered after induction with cerviprime gel and 44 patients delivered after propress induction. Average time of delivery was 21 hrs for cerviprime gel group and 29hrs for propress group.

CONCLUSIONS:- IOL with the shorter acting preparation was likely to result in a quicker delivery regardless of the mode of delivery (operative or vaginal), a feature likely to be appreciated by the women undergoing the interventions. The risk of hyperstimulation is statistically higher in nulliparous women using vaginal insert than the other ways of administration. but there was no significant difference in the caesarean section or overall (spontaneous and assisted) vaginal delivery rates.

Keywords- Induction, Cerviprime Gel, Propress, Intracervical, Dinoprostone(PGE2 Gel), Bishops Score.

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I. Introduction

Induction of labour (IOL) is one of the commonest intervention in obstetrics. Over recent decades, more pregnant women around the world have undergone labour induction to deliver their babies. In developing countries up to 25% of all deliveries at term now involve induction of labour, but in some developing countries the rate are generally lower [1]. Induction is indicated when the benefits to either the mother or the outweigh those of continuing the pregnancy.

Prostaglandins play a critical role in cervical ripening by increasing inflammatory mediators in the cervix and inducing cervical remodelling. Prostaglandin E1 (PGE1) and prostaglandin E2 (PGE2) exert different effects on these processes and on myometrial contractility. These mechanistic differences may affect outcomes in women treated with dinoprostone, a formulation identical to endogenous PGE2, compared with misoprostol, a PGE1 analog.

Dinoprostone is a Prostaglandin (PGE 2) which acts on the collagen structural network of the cervix and makes it favourable thus increasing the chances of a successful of a vaginal delivery.

Vaginal prostaglandin E2 has been shown to be efficacious to prepare the cervix for IOL [2]. Various preparations of prostaglandin are available differing in their effectiveness, side effects [3], and price [4]. The preparation most commonly used for IOL is the shorter acting Dinoprostone vaginal gel (cerviprime gel). Recently longer-acting Dinoprostone preparations (Cervidil and Propess) with retrieval system have become available which have been successfully used for IOL. Nevertheless, some studies [4] show that longer-acting preparations do not reduce time to delivery or improve any birth outcome compared to the shorter acting gel which is also considered more cost effective [5].

It has been noted [3] that more than one dose of the long acting preparation is needed to achieve amniotomy compared to the shorter acting one.

The only consistent benefit seems to be the lesser number of vaginal examinations with the long acting preparations and thus reducing the risk of ascending infections adding to it's safety along with reduced maternal anxiety associated with induction of labour.

A potential risk of IOL is failure of this intervention resulting in delivery by Caesarean section (CS) [6]. Recent findings show that following IOL the emergency CS rate may be as high as 22%. Others [7] have noted that IOL in nulliparous women at term, with or without medical or obstetric complications, significantly increases the chance of caesareans.

II. Methods

This study was conducted on 166 primigravidae women with term pregnancy at ESI Model Hospital Basai Darapur PGIMS, New Delhi, a tertiary health care centre and higher referral centre having annual delivery rate of 3500-4000. The women for this retrospective cohort study were identified from the IOL database which is an in-hospital electronic record system. The data was obtained from the hospital electronic patient record system combined with hard copy records. Information was collected on the outcome of IOL in nulliparous women induced in the six months of cerviprime gel and propess (May–October, 2017). The departmental protocol for IOL in a nulliparous woman with a singleton foetus in cephalic presentation with term gestation is described below.

Inclusion criteria

- Singleton pregnancy
- Cephalic presentation
- Gestational age >37 weeks
- **Exclusion criteria**
- Gestational age <37 weeks
- Multiple pregnancy
- Previous uterine surgery
- Non-cephalic presentation

Planned IOL was to commence at 0400 hrs early in the morning. An initial vaginal examination was done to determine the modified Bishop's score [8]. If the score was greater than 6 then the woman was to have amniotomy followed by augmentation with oxytocin infusion if necessary. If the modified Bishop's score was less than 6, then labour was induced by placing Propess (retrievable controlled release 10mg Dinoprostone pessary releasing 0.3mg Dinoprostone/hour) into the posterior vaginal fornix. Electronic foetal monitoring was done for an hour after insertion of Propess. The next assessment would be at 1600hrs almost 12hrs after commencement of induction or earlier if there was any suggestion of active labour. If cervix was unfavourable for amniotomy then consultant advice was sought regarding further prostaglandin pessary.

Similarly IOL was commenced at 0400hrs with cerviprime gel. A 2mg dose was placed intracervically at 0400 hours followed by electronic foetal monitoring for 1 hour.

A reassessment was done six hours later, and a further 2 mg intracervical gel was inserted if the modified Bishop's score was less than 6. Amniotomy was done if this score was greater than 6. If the second dose of intracervical gel was administered then, the next examination was at 1600hrs to consider amniotomy or the need for a further third 2mg dose of intracervical gel. Regardless of the change in practice, failed IOL was defined as inability of the agent to dilate the cervix to enable amniotomy, or failure of the cervix to dilate beyond 4 cm despite at least 10 hours of a titrated oxytocin infusion. Data was entered on a Microsoft Excel spreadsheet. Statistical analysis was done using statistics software for Microsoft Excel.

The groups were compared using contingency table and chi-square analysis for categorical and binary values. Continuous variables were analysed by a t-test. Two-sided P values are reported for all tests. Values 0.05 or less were regarded as significant.

Table 1: Baseline characteristics of the women in the cerviprime gel and propess induction agent groups.

characteristics	Cerviprime gel (N=88)	Propess (N=76)	P
Age(yrs)	24.5	25.2	0.465
Gestations(weeks)	40.2	40.2	0.978
Bishops score (median)	2	2	1.000
Indications	Numbers(%)		
postdatism	48(54.5)	44(57.9)	0.936
cholestasis	4(4.5)	2(2.6)	1.000
hypertension	14(15.9)	16(21.1)	0.751
GDM	12(13.6)	10(13.2)	1.000
Growth restriction	8(9.1)	2(2.6)	0.458
social	2(2.3)	2(2.6)	1.000
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Percentage of indication of IOL

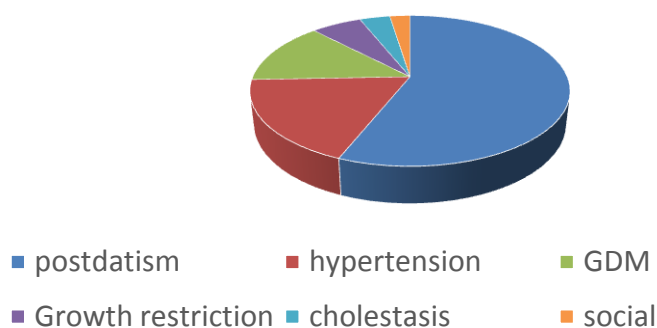


Table2:- Maternal outcome following induction of labour with cerviprime gel and propess

	Cerviprime gel N=88 Number (%)	Propess N=76	RR	95% CI	P
Failed induction	2 (2.3)	6 (7.9)	0.29	0.03-2.65	0.51
Amniotomy	54 (61.4)	48(63.2)	0.97	0.69-1.36	1.0
Oxytocin infusion	58 (65.9)	48 (63.2)	1.04	0.76-1.44	0.98
Epidural analgesia	38 (43.2)	36 (44.4)	0.91	0.57-1.47	0.87
L.S.C.S	24 (27.3)	32 (14.1)	0.65	0.35-1.19	0.24
Vaginal delivery	64 (72.7)	44 (57.9)	1.26	0.91-1.74	0.24
Instrumental delivery	28 (31.8)	8 (10.5)	3.0	1.1-8.4	0.04
Non-instrumental delivery	36 (40.9)	36 (47.4)	0.86	0.53-1.41	0.72
L.S.C.S or	52 (59.9)	40 (68.4)	1.12	0.76-1.66	0.72

Instrumental delivery					
Mean time to deliver (hrs)	21.1	29.6			0.02

III. Result

There were 166 women who were eligible for inclusion, 88 in the cerviprime gel group, and 78 in the propess group. Two cases were excluded from the propess group (n = 76) as the IOL was commenced with propess, postponed, and then recommenced 2 days later with cerviprime gel making classification impossible.

The baseline characteristics were similar amongst both groups as shown in Table 1 including maternal age, mean gestational age at IOL, and the modified Bishop’s score at the commencement of IOL. As expected, the commonest indication for IOL in both groups was prolonged pregnancy beyond 40 weeks of gestation. Other common indications for IOL were hypertensive diseases in pregnancy, gestational diabetes mellitus and intrahepatic cholestasis of pregnancy.

Outcome of IOL in the two groups is detailed in Table 2. The number of women requiring amniotomy and oxytocin infusion to cause effective contractions and delivery did not differ between the two groups. The incidence of epidural analgesia use during labour did not vary between the two groups either. Eight women were recorded as having a failed IOL, two in the cerviprime gel group and six in the propess. group (RR 0.29, 95% CI 0.03–2.65, P = 0.51), but this difference was not significant. There was no difference in the incidence of caesarean section (RR 0.65, 95% CI 0.35– 1.19, P = 0.24) between the cerviprime gel and propess groups. There was also no statistically significant difference in the number of women needing an operative delivery (either a caesarean section or assisted vaginal delivery) between the two groups (RR 1.12, 95% CI 0.76–1.66, P = 0.72).

However, there was a significant difference in the number of women requiring instrumental delivery, with those receiving cerviprime gel more likely to need assisted vaginal delivery (RR 3.0, 95% CI 1.1–8.4, P = 0.04). The mean time to delivery for all women also showed a significant difference, with women receiving cerviprime gel delivering earlier on average than those having propess (21.1 versus 29.6 hrs P = 0.018) irrespective of the mode of delivery.

IV. Discussion

IOL is a common obstetric intervention. Moreover, failed induction of labour results in caesarean section leading to cause bad obstetric history in primipravias; hence, judicious use and selection of agents apart from using strict criteria for IOL should underpin this intervention. It is argued that IOL can place more strain on birthing suite workload than spontaneous labour [11]. Therefore, timing of IOL is also of importance which again is related to the induction delivery interval. It appears from this small retrospective study that Cerviprime gel is more likely to achieve a quicker delivery, regardless of the mode of delivery, in nulliparous women following IOL than Propess. This was not observed by others [5] who however, used a different proprietary long-acting retrievable preparation. The finding from this study is likely to have a favourable impact especially for elective IOL which is known to affect the workload in birth suite. The concern amongst women undergoing IOL about the length of labour is well known [9]. Hence, it is believed [10] that women are likely to value a reduction in the interval between induction and delivery.

Therefore the finding that the preparation which is associated with a significant reduction in the delivery time irrespective of the mode of delivery being used in their care is likely to go down favourably with the women undergoing IOL. Rate of caesarean section in primiparous women, does not appear to be increased with either cerviprime gel or propess, and hence there was no impact on the overall performance. The indications for caesarean sections in both groups included acute foetal bradycardia not responding to intrauterine resuscitative measures, arrest of labour in the first stage despite augmentation with oxytocins, uterine hypercontractions and failed assisted vaginal delivery apart from failed induction.

This study, however, shows that using Cerviprime gel for IOL is more likely to be associated with assisted vaginal delivery than Propess though the overall incidence of operative deliveries (assisted vaginal delivery and caesarean section) is no different with the use of either agent. This greater incidence of assisted vaginal delivery with Cerviprime gel compared to Propess was not addressed in a previous study [4].

During the study period, there was only two instances of failed assisted vaginal delivery which resulted in a caesarean section at full dilatation in case of cerviprime group. Incidentally, most of the caesarean sections done in the 6 months of Cerviprime gel use were done in the first stage of labour and hence less likely to have been influenced by operator skill.

This study nevertheless has several limitations. The numbers are small, and the data relates to a single birthing unit in one hospital. The time frame used in this study is only six months. The study is not a randomised trial but retrospective data analysis. It is also difficult to explain why women having IOL with Cerviprime gel

achieved an earlier delivery than those who were induced with propress. The basic mechanism of action with either preparation is essentially the same being mediated through a combination of reduced collagen concentration and dissociation of collagen fibrils by activation of the collagenase enzyme apart from the alterations in glycosaminoglycan composition and hydration. One reason may be the additive effects of repeated doses of Cerviprime gel compared to the slow-release Propress preparation that allowed an earlier amniotomy and oxytocin augmentation. This would have allowed a diagnosis of failed IOL or an operative delivery earlier.

V. Conclusion

In conclusion, this is a small study comparing the outcome of IOL in nulliparous women following use of a long-acting vaginal prostaglandin E2 and a shorter-acting preparation. IOL with the shorter acting preparation was likely to result in a quicker delivery regardless of the mode of delivery (operative or vaginal), a feature likely to be appreciated by the women undergoing the intervention. The risk of hyperstimulation is statistically higher in nulliparous women using vaginal insert than the other ways of administration. This was associated with a higher assisted vaginal delivery rate, but there was no significant difference in the caesarean section or overall (spontaneous and assisted) vaginal delivery rates.

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