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Labour Induction with Either Oxytocin or Dinoprostone Gel in Term Pregnancy and Its Obstetric Outcome- A Prospective Comparative Study

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KEYWORDS

Labour Induction, Oxytocin and Dinoprostone Gel.

ABSTRACT:

Introduction: Child birth is such a central event in family life and culture that a good obstetric care cannot be out of tune with the attitudes and expectation of parturient women. In every country women see child birth as an experience, achievement and respect. In the traditional cultures of the developing world, successful vaginal delivery brings women marital security, family status and esteem in her community.

Aims: To assess the feto-maternal outcomes in labour induced either with oxytocin or dinoprostone gel. To compare the feto-maternal outcomes in labour induced with oxytocin versus dinoprostone gel.

Materials and Methods: The present study was a Randomised Prospective comparative study. The study was conducted in the department of Obstetrics and Gynaecology, Midnapore Medical College and Hospital, West Bengal from March 2020 to February 2021.

Result: Majority mothers delivered vaginally and findings were not statistically significant between the groups (84.3% versus 77.3%), p value= 0.29. 5.3% mothers underwent cesarean section in group A and 18.7% in group B. The difference between two groups was significant, p value 0.02 with oxytocin group undergoing more cesarean section.

Conclusion: Vaginal delivery is considered to be the success of obstetrics. Many pregnant women requiring induction of labour come with unfavorable cervix. Achieving vaginal delivery through pre-induction cervical ripening is an obstetric challenge. There are various methods which have their own merits and demerits. The most commonly used are oxytocin and prostaglandin PGE2 Dinoprostone gel (under the name of cerviprime).

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INTRODUCTION

Child birth is such a central event in family life and culture that a good obstetric care cannot be out of tune with the attitudes and expectation of parturient women. In every country women see child birth as an experience, achievement and respect. In the traditional cultures of the developing world, successful vaginal delivery brings women marital security, family status and esteem in her community.

The ultimate outcome of a good obstetric care is the delivery of the healthy baby with healthy mother. A fact that sounds so simple is actually a coveted aim achieved only after meticulous planning of antenatal care and delivery. All obstetricians who provide the best services to the parturient women should be well versed with the agents used, regarding their effects and outcome for a good success.

There are times when the benefits of delivery outweigh the continuation of pregnancy and the need for "induction of labour" arises. This process requires a comprehensive assessment of the indication, appropriate choice of the method and skilful execution to attain the final goal of obstetrics.

Induction implies stimulation of contractions before the spontaneous onset of labour, with or without ruptured membranes.[1]

When the cervix is closed and uneffaced, labour induction will often commence with cervical ripening a process that generally employs prostaglandins to soften and open the cervix.

Augmentation refers to enhancement of spontaneous contractions that are considered inadequate because of failed cervical dilatation and fetal descent- inertia uteri.

Induction of labour is one of the most common procedures during pregnancy. Data from the National Centre for Health Statistics for the last decade indicate that the rate of labour induction has increased gradually from 9% to 20%. This increase has been noted both at community Hospitals and at the university tertiary care hospitals. Explanations for this jump in the induction rate are complex and multifactorial. Better planning of birth by the physician, patient and her family is the most common reason. Other reasons include the availability of Food and Drug Administration (FDA) approved cervical ripeners, more released attitudes towards marginal or elective inductions and litigious constraints.[2]

Indications for induction of labour have essentially not changed. When concern for the wellbeing of the mother arises, primary indications for induction include active medical disorders, being well beyond the due date and prolonged ruptured membranes. Indication is also justified when the fetus is at risk.

Another general concept is the recognition that induction is associated with increased complications as compared with spontaneous labour. Complications include an increase of chorioamnionitis and increased Caesarean delivery.[3]

MATERIALS AND METHODS

The study was conducted in the department of Obstetrics and Gynaecology, Midnapore Medical College and Hospital, West Bengal from March 2020 to February 2021.

STUDY DURATION: 12 months

STUDY DESIGN: Randomised Prospective comparative study

STUDY PLACE: Midnapore Medical College and Hospital

STUDY AREA: East Midnapore, West Midnapore, Jhargram and catchment areas from Bihar, Jharkhand and Odisha.

STUDY POPULATION:

Study group consisted of two groups. These groups constituted of pregnant women at term admitted to MMCH. The patients were selected on the basis of inclusion and exclusion criteria. Paper chits numbered 1,2,3,4… till 150 were made and patients were asked to pick a chit. The odd numbered patients were induced with cp gel and even numbered were induced with intravenous oxytocin.

Group A- constituted the mothers who were induced with dinoprostone gel (n= 75)

Group B- constituted the mothers who were induced with oxytocin. (n= 75)

SELECTION CRITERIA

- Any primigravida/ multigravida woman with prior ≤2 successful vaginal deliveries.

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- Age- 18- 30 years
- Singleton Pregnancy
- Cephalic Presentation
- Term pregnancy (37 weeks to 42 weeks)
- Reactive fetal heart rate pattern
- No contraindication to vaginal delivery
- No cardiac disease
- No thyroid abnormality.

EXCLUSION CRITERIA

- Multiple gestation
- Breech and other abnormal presentation
- Placenta previa
- Abruptio placenta
- Pre term/ post term
- Previous LSCS or any other uterine surgery
- Severe oligohydramnios
- Cord prolapse
- Nonreasaauring fetal heart rate.

Statistical Analysis:

For statistical analysis, data were initially entered into a Microsoft Excel spreadsheet and then analyzed using SPSS (version 27.0; SPSS Inc., Chicago, IL, USA) and GraphPad Prism (version 5). Numerical variables were summarized using means and standard deviations, while categorical variables were described with counts and percentages. Two-sample t-tests, which compare the means of independent or unpaired samples, were used to assess differences between groups. Paired t-tests, which account for the correlation between paired observations, offer greater power than unpaired tests. Chi-square tests (χ^2 tests) were employed to evaluate hypotheses where the sampling distribution of the test statistic follows a chi-squared distribution under the null hypothesis; Pearson's chi-squared test is often referred to simply as the chi-squared test. For comparisons of unpaired proportions, either the chi-square test or Fisher's exact test was used, depending on the context. To perform t-tests, the relevant formulae for test statistics, which either exactly follow or closely approximate a t-distribution under the null hypothesis, were applied, with specific degrees of freedom indicated for each test. P-values were determined from Student's t-distribution tables. A p-value ≤ 0.05 was considered statistically significant, leading to the rejection of the null hypothesis in favour of the alternative hypothesis.

RESULT

DISTRIBUTION OF CASES ON THE BASIS OF INDICATIONS FOR INDUCTION

Indications	Group A (n=75)	Group B (n=75)	p value
PIH	35 (46.7%)	24 (32%)	0.06
POST DATE	21 (28.0%)	25 (33.3%)	0.47
IUGR	8 (10.7%)	8 (10.7%)	1
PROM	7 (9.3%)	13 (17.3%)	0.14
BOH	1 (1.3%)	3 (4.0%)	0.62
GDM	3 (4.0%)	2 (2.7%)	1

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DISTRIBUTION OF CASES ACCORDING TO BISHOP SCORE (on admission):

Bishop score	**GROUP A (n=75)**	**GROUP B (n=75)**	**p value**
<4 (n=2)	1 (1.3%)	1 (1.3%)	1
4-6 (n=81)	38 (58.7%)	43 (57.3%)	0.41
≥7 (n=67)	36 (49.3%)	31 (41.3%)	0.41
Total	75	75	

DISTRIBUTION OF CASES ACCORDING TO MODE OF DELIVERY

DELIVERY MODE	**GROUP A (n= 75)**	**GROUP B (n= 75)**	**P value**
VAGINAL (n=122)	64 (84.3%)	58 (77.3%)	0.29
INSTRUMENTAL (n= 10)	7 (9.3%)	3 (4.0%)	0.32
LSCS (n= 18)	4 (5.3%)	14 (18.7%)	0.02
TOTAL	75 (100.0%)	75 (100.0%)	

BISHOP SCORE AND INDUCTION DELIVERY INTERVAL:

Induction to delivery interval (hrs)	**Groups**	**Mean± sd (Hrs)**	**P value**
Bishop score <6	A (n= 22)	9.19± 1.59	
	B (n= 24)	12.97± 2.12	<0.01
Bishop score ≥*6*	A (n= 53)	7.16± 2.13	
	B (n= 51)	8.33± 2.91	0.23

INDICATION FOR C-SECTION:

INDICATION	**GROUP A (n= 75)**	**GROUP B (n= 75)**	**p value**
FETAL DISTRESS	1 (1.3%)	4 (5.3%)	0.36
HYPERTONIC UTERUS	1 (1.3%)	1 (1.3%)	1
DEEP TRANSVERESE ARREST	1 (1.3%)	1 (1.3%)	1

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INDICATION	GROUP A (n= 75)	GROUP B (n= 75)	p value
FAILED INDUCTION	1 (1.3%)	8 (10.7%)	0.033

POST-PARTUM COMPLICATIONS IN MOTHER

COMPLICATIONS	GROUP A (n= 75)	GROUP B (n= 75)	p Values
PPH	3 (4%)	7 (9.3%)	0.32
UTERINE HYPERSTIMULATION	3 (4%)	1 (1.3%)	0.62
RETAINED PLACENTA	1 (1.3%)	3 (4%)	0.62
CCU ADMISSIONS	1 (1.3%)	2 (2.7%)	1
WOUND INFECTION	1 (1.3%)	3 (4%)	0.62

PIH was the major cause for labour induction approximately 39.3% cases followed by post dated pregnancy in 30.7% followed by premature rupture of membranes, fetal growth restriction, gestational diabetes mellitus and bad obstetric history. No statistically significant difference was observed in the distribution between study groups with regards to indication for induction, p value= 0.36

52% mothers had bishop score ≤6 at the time of admission in group A versus 58.7% in group B.

Mean Bishop score was 6.44± 1.42 in those induced with dinoprostone gel and 6.33± 1.27 in those with oxytocin. It was comparable and had no statistical significance, p value= 0.717.

Majority mothers delivered vaginally and findings were not statistically significant between the groups (84.3% versus 77.3%), p value= 0.29.

5.3% mothers underwent cesarean section in group A and 18.7% in group B. The difference between two groups was significant, p value 0.02 with oxytocin group undergoing more cesarean section.

Induction delivery interval was shorter in dinoprostone gel group (9.19+/- 1.59 hrs) as compared to oxytocin group (12.97+/- 2.12 hrs) and was statistically significant in cases where cervix was unfavourable i.e bishop score <6 with p value <0.01, whereas the interval difference was not statistically significant where bishop score was >6 i.e favourable cervix (7.16± 2.13hrs vs 8.33± 2.91hrs), p value= 0.23

6% cases underwent caesarean section due to failure of induction followed by fetal distress (3.3%) in both groups. Cases of failed induction were more common in oxytocin receiving group (1.3% vs 10.7%) and the findings were statistically significant, p value= 0.033

No statistical significance was observed between study groups with regards to maternal complications like PPH (4% vs 9.3%; p value= 0.32), uterine hyperstimulation (4% vs 1.3%; p value= 0.62), wound infections (1.3% vs 4%; p value= 0.62), retained placenta (1.3% vs 4%; p value= 0.62). Critical care admission rate was also comparable (1.3% vs 4%; p value= 1.0).

DISCUSSION

Induction of labor refers to iatrogenic stimulation of uterine contractions to accomplish delivery prior to the onset of spontaneous labor. Labor induction is one of the most frequently used procedures in pregnant women. The prevalence of labor induction has doubled over the past two decades. This increase is partly related to a rise in the number of medically and obstetrically indicated inductions; however, it appears that marginally indicated and elective inductions account for a large proportion of this increase. Indications vary, but

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most obstetricians use labor induction for prolonged pregnancy because it has been shown to reduce perinatal mortality when used after 41 weeks of gestation [4].

The optimal regimen for preinduction cervical ripening and labor induction has not been established. Although local application of prostaglandin E2 (PGE2) has been considered effective for cervical ripening and shortening delivery time [5], this procedure is however expensive and thus unavailable to obstetricians in many developing or underdeveloped countries. Oxytocin is the agent most frequently used for the induction of labor [6]. Its use is relatively cheap and is more accessible in a country like us.

In present study, we thus aimed to compare the efficacy of labour induction with either oxytocin or Dinoprostone (a PGE2 gel, which comes under the name of cerviprime) in term pregnancy and its obstetric outcome.

A total of 150 patients admitted in the maternity ward were selected, of these 75 were induced with intracervical cerviprime gel (Group A) and 75 cases received intravenous oxytocin (Group B) for induction of labour.

Age wise distribution has shown that the majority of females were in age group less than 25 years i.e. around 82.6% and the distribution between the two groups was not statistically significant, p value= 0.8. Mean age was approximately 21 years, with no statistically significant difference between study groups (p value= 0.58).

Study groups were also comparable with respect to socio-economic status (p value= 0.87). A total of 10% cases were from lower socio-economic status, 84% were from middle strata and 6% were from upper strata.

Mean BMI was 20.64 kg/ m2 in group A while it was 21.04 kg/m2 in group B (p value= 0.27).

Analysis of parity has shown that primigravida were in majority in both the groups accounting to 69.3%. In group A, 74.7% mothers were primigravida and in group B, 64%. The distribution of cases on the basis of parity was not significant, p value= 0.21.

All were term pregnancy. The group A and group B were similar with respect to gestational age (39.29±1.26 weeks vs 39.56± 1.35 weeks; p value= 0.205).

Both groups were comparable to each other in terms of age, socio-economic status, obstetric history, anthropometry and gestational age signifying the homogeneity between the groups.

In my study common Indications for Induction were PIH (39.3%), Post-datism (30.7%), PROM (13.3%) and IUGR (10.7%).

No statistical significant difference was observed between study groups with regards to indication for Induction (p value= 0.36).(Table 7)

Yurtsever S et al.[7] in a similar study observed common indications as: post-datism (40.1%), PROM (18%), PIH (12.4%) and IUGR (9.5%).

Wei Y et al.[8] in their study also observed post-datism, PIH and PROM as common indications for induction of labour.

Induction to labour onset interval was significantly lesser in dinoprostone gel group as compared to Oxytocin group (4.74± 2.08 hrs vs 7.62± 2.83 hrs; p value <0.01). (Table 9)

Induction delivery interval was also less in mothers induced with dinoprostone gel as compared to those induced with oxytocin (9.19± 1.59 hrs vs 12.97± 2.12 hrs; p value <0.01) with unfavourable cervix and the findings were statistically significant.

The interval difference was not statistically significant where bishop score was >6 i.e. favorable cervix. In group A the interval was 7.16± 2.13 hrs, in group B it was 8.33± 2.91 hrs, p value= 0.23. (Table 14)

Akay NÖ et al.[9] on the contrary observed longer induction to delivery interval with dinoprostone (13.3 hrs and 10.3 hrs; p value <0.05).

Wei Y et al.[8] in a similar study observed that the interval between induction to delivery (9.5 hrs vs 11.7 hrs; p value <0.01) was significantly reduced in cases who were given dinoprostone in cases with unfavourable cervix. No difference was observed between cases with favorable cervix.

Kulhan NG et al.[10] observed no difference between the groups in terms of induction to delivery interval (12.5 ±1.15 hrs vs. 12.83 ±2.30 hrs, p value= 0.078).

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Cesarean section rate was more in oxytocin group as compared to dinoprostone group (18.7% vs 5.3%; p<0.01) and was statistically significant. (Table 11)

Low bishop score (<6) i.e. unfavourable cervix was associated with cesarean deliveries in both the groups with more i.e 13.3% in oxytocin group compared to 4.4% in dinoprostone group (p value= 0.047).

However, the difference between groups was not statistically significant where bishop score was >6 i.e. favorable cervix. (Table 13)

A statistically significant association was observed between number of doses required of intracervical dinoprostone and mode of delivery. Of the 30 antenatal mothers who received 1 dose of dinoprostone gel 96.7% of them underwent vaginal delivery. 42 of 75 cases required 2 doses of dinoprostone gel out of which 41 (97.6%) delivered vaginally. Only 3 mothers needed dose 3 or more and in them 66.7% had to be taken for cesarean section (p value <0.01). (Table 22)

A significant association was observed between amount of oxytocin required and mode of delivery. Maximum mothers received ≥30mU/min of oxytocin i.e 90.7%, of which 83.8% delivered vaginally and 16.2% underwent cesarean section.

In a Cochrane review, **Kelly J et al.[11]** reported that comparing oxytocin alone with intracervical prostaglandins: Oxytocin alone was associated with an increase in unsuccessful vaginal delivery within 24 hours when compared with intracervical PGE2 (51% versus 35%, RR 1.49, 95% CI 1.12,1.99). For all women with an unfavourable cervix regardless of membrane status, the caesarean section rates were increased (19.0% versus 13.1%, RR 1.42, 95% CI 1.11, 1.82). However, the difference was non-significant in cases with favourable cervix.

Wei Y et al.[8] observed cesarean section rate as 9% and 4.5% in oxytocin and dinoprostone group (p value= 0.001) in cases with bishop score 1-3 and 7.95% and 5.94% (p value= 0.181) in cases with Bishop score ≥4 which was similar to findings in my study where low bishop score (<6) i.e. unfavourable cervix was associated with cesarean deliveries in both the groups with more i.e 13.3% in oxytocin group compared to 4.4% in dinoprostone group (p value= 0.047). (Table 13)

Akay NO et al.[12] in their study observed overall vaginal delivery rates as 75% (54/72) for the dinoprostone group and 80.6% (58/72) for the oxytocin group, with no difference between the two (p value= 0.32).

No statistically significant difference was observed between study groups A and B with regards to adverse drug reactions like nausea/ vomiting (6.7% vs 1.3%; p value= 0.12), fever (4% vs 1.3%; p value= 0.62), dyspnea (1.3%in both groups; p value= 1.0), hypertonic uterus (4% vs 1.3%; p value= 0.62) and hypotension (0% vs 2.7%; p value= 1.0). (Table 17)

Yurtsever S et al.[7] in their study observed no difference between the two drugs in terms of adverse reactions like GI disturbances (5% vs 3.3%) or fever (5% vs 5.3%).

Kulhan NG et al.[10] observed fever in 28.6% and 37.5% cases and uterine hypertonicity in 7.1% and 8% cases of dinoprostone and oxytocin respectively.

Akay NÖ et al.[12] also observed similar adverse drug profile between the two groups.

No statistically significant difference was observed between study groups with regards to maternal complications like PPH (4% vs 9.3%; p value= 0.32), uterine hyperstimulation (4% vs 1.3%; p value= 0.62), wound infections (1.3% vs 4%; p value= 0.62).Critical care admission rate was also comparable (1.3% vs 2.7%; p value= 1.0). (Table 16)

Mean birth weight was comparable between both the groups A and B (2.87± 0.45kg vs 2.69± 0.76kg; p value= 0.87). (Table 18)

Mean APGAR score at 1 min (9.1± 1.12 vs 8.22± 1.65; p value= 0.12) and 5 mins (9.56±1.09 vs 9.38± 1.12; p value= 0.67) was comparable between groups A and B respectively. (Table 19)

SNCU admission rate was 5.33% and 14.67% in group A and B respectively (p value= 0.099) and birth asphyxia was seen in 8% and 9.3% babies of group A and B respectively (p value= 1.0). (Table 20)

No statistical significance was observed between study groups with regards to fetal complications like Sepsis (1.3% each; p value= 1.0) and MAS (2.7% vs 1.3%; p value= 1.0).

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Jaundice was seen more in cases of group B as compared to group A (12% vs 1.3%; p value= 0.018). (Table 21)

Akay NÖ et al.[12] observed uterine hyperstimulation rate as 7.4% in dinoprostone as compared with 6.8% in oxytocin group (p value = 0.8), and abnormal fetal heart rate was 26.4% compared with 18% (p value= 0.2), respectively. No difference was observed between the groups with regards to other maternal complications, birth weight, NICU admission and APGAR score.

Yurtsever S et al.[13] observed no significant difference in maternal outcome between the two groups regarding postpartum hemorrhage or uterine hyperstimulation. No significant differences were observed in incidence of fetal complications between the groups (p value >0.05). No maternal death or uterine rupture occurred. Neonatal weight, admission to the neonatal unit, and 1- and 5-minute Apgar score < 7, did not differ significantly between the two groups (p value >0.05).

Wei Y et al.[8] observed that for late term pregnancies with a Bishop's score between 0–3, subgroup B1 given dinoprostone, showed reduced rates of postpartum hemorrhage but an increased hyperstimulation rate (p value<0.05). However, there was no difference in these incidences between subgroups with a Bishop's score between 4–6. No differences in neonatal birth weight and Apgar scores at 1 minute and 5 minutes were observed between the groups.

Kulhan NG et al.[10] observed higher incidence of uterine hyperstimulation with dinoprostone (22.3% vs 7.14%), however no difference was observed in the incidence rate of other maternal complications (p value >0.05). NICU admission was required in 14.3% and 7.14% cases while LBW rate was 6% and 8% cases of oxytocin and dinoprostone group respectively (p value >0.05).

Thus to summarize, we observed that, dinoprostone is more effective in achieving vaginal delivery as compared to oxytocin when Bishop Score ≤6. Also, time intervals from induction to onset of labour and induction to delivery intervals were significantly shorter and failure of induction was significantly less with dinoprostone in mothers with unfavourable cervix. (Table 13, 14 and 15)

However, the difference between the groups, in induction to delivery interval and cesarean sections was not statistically significant in cases with favorable cervix (Bishop score > 6). (Table 14 and 15)

Both oxytocin and dinoprostone seem to be comparable in terms of maternal and perinatal complications and adverse drug reaction profile.

In developing areas like us, where dinoprostone is unavailable, oxytocin could be considered for induction of labour as a safe and effective alternative, especially for women with favorable cervix.

CONCLUSION

Vaginal delivery is considered to be the success of obstetrics. Many pregnant women requiring induction of labour come with unfavorable cervix. Achieving vaginal delivery through pre-induction cervical ripening is an obstetric challenge. There are various methods which have their own merits and demerits. The most commonly used are oxytocin and prostaglandin PGE2 Dinoprostone gel (under the name of cerviprime).

In present study, we observed that, dinoprostone is more effective in achieving vaginal delivery as compared to oxytocin.

Time intervals from induction to onset of labour and induction to delivery intervals were significantly shorter and failure of induction was significantly less with dinoprostone compared to oxytocin when Bishop score <6.

However, the difference in induction to delivery interval and rate of cesarean sections were not observed in cases with favorable cervis (Bishop score ≥ 6).

Both oxytocin and dinoprostone seem to have similar obstetric/ fetal outcomes and adverse reaction profile.

Present study thus conclude that, dinoprostone is superior to oxytocin for labour induction with a lower rate of cesarean delivery in mothers with unfavourable cervix, but both agents had a similar outcome for women with a Bishop's score of >6.

Hence, in developing areas where dinoprostone is unavailable, oxytocin should be considered, rather than a cesarean section, especially for women with favorable cervix.

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