EFFECT OF CERVIPRIME ON CERVICAL RIPENING AND INDUCTION OF LABOUR
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ABSTRACT: OBJECTIVE: Present study is undertaken with a view to study the effect of intracervical PGE2 gel for cervical ripening & induction of labour. METHODOLOGY: 52 patients with Bishop score <3 were studied for the effect of PGE2 gel for cervical ripening & induction of labour. The study was conducted in MOSC Medical Mission Hospital kolencery, Ernakulam district. RESULT: Among the 52 patients 32% delivered within 12Hrs & 34% were in the active phase of labour. 15% of patients cervical ripening had occurred. Neonatal outcome was good. CONCLUSION: This study showed that intra cervical application of prostagladinE2 Gel is effective safe & acceptable method for cervical ripening & induction of labour in women with unfavorable cervix.

KEYWORDS: Intracervical prostagladinE2 gel, unfavourable cervix, Bishop score, induction of labour.

INTRODUCTION: Ideally all pregnancies should go to term & labour should begin spontaneously. But situations arise in obstetrics where it becomes necessary to interrupt a pregnancy in the interest of mother or baby or both. The aim of induction is to perform a safe vaginal delivery. Induction is a challenge to the clinician, mother & fetus must be selected & supervised carefully.¹ Spontaneous labour & vaginal delivery is preceded by a cascade of synchronized events, which lead to ripening of cervix. Calder² said that ripening of cervix governs the ease &success of induction of labour Prins et al³ has rightly said that if ripening of cervix fails to occur, then delivery & labour may be prolonged & may at times unsuccessful. Cervical ripening is essential prerequisite for induction & is employed when the cervix is unfavorable. Cruz et al⁴ and Noah et al⁵ studied the effect of PGE2 gel as a cervical ripening agent.

Prostagladin E2 intracervical gel contains. 5mg Dinoprostone & when applied locally it induces collagen break down, dispersion, fluid absorption by stromal tissues & effective cervical ripening for induction of labour. In some cases early uterine activity may start as well. But it is relatively expensive & requires refrigeration.

METHODOLOGY: Prospective study of 6months duration in MOSC MM hospital, Kolenchery, Ernakulam district, Kerala. 52 patients were included.

| INDICATION               | NO.OF CASES | PERCENTAGE |
|--------------------------|-------------|------------|
| Postdatism               | 34          | 63         |
| Gestational HT           | 9           | 17         |
| Reduced fetal movement   | 5           | 11         |
| Others                   | 4           | 9          |

Table 1: Indication for induction
INCLUSION CRITERIA:
1. Singleton live foetus.
2. Cephalic presentation.
3. Gestational age >37wks.

EXCLUSION CRITERIA:
1. Gestational age <37 wks.
2. Previous uterine surgery.
3. Abnormal presentation.

5mg of PGE2 gel is instilled into the cervical canal for cervical priming after assessing the Bishop score. They are reassessed after 12 hrs. Accordingly they are classified into 4 groups:
Group 1: Those who delivered within 12 hours.
Group 2: Those who are in active phase of labour.
Group 3: Those with an increase in Bishop score by 3.
Group 4: No change in Bishop score after 12 hours. Cervix still in the unfavorable state.
Repeat cerviprime was not undertaken. All the patients with group 3 and group 4 are induced with pitocin. When they are in the active phase, ARM was done.

RESULTS AND OBSERVATION:

| PARITY         | NUMBER OF CASES N=52 | PERCENTAGE |
|----------------|-----------------------|------------|
| NULLIPAROUS    | 39                    | 75         |
| PARA 1         | 11                    | 21         |
| PARA 2         | 1                     | 2          |
| PARA 3         | 1                     | 2          |

Table 2: DISTRIBUTION OF CASES ACCORDING TO PARITY

| AGE IN YEARS | NULLIPAROUS | PARA 1 AND ABOVE | TOTAL | PERCENTAGE |
|--------------|-------------|-------------------|-------|------------|
| <20          | 2           | -                 | 2     | 3          |
| 21-25        | 27          | 3                 | 30    | 58         |
| 26-30        | 8           | 8                 | 16    | 13         |
| >30          | 2           | 2                 | 4     | 6          |

Table 3: AGE DISTRIBUTION

less than 20 – 2.
>35 years – elderly primi – 1 Age 41 LSCS was done for her as the cerviprime failed to induce labour.
So 66% of patients (grp 1 and grp2) – PGE2 gel has induced labour and in another 15% ripening of cervix was achieved.
MODE OF DELIVERY IN TRIAL SUCCESS GROUP:
1. Spontaneous vaginal delivery – 20.
2. Vacuum extraction – 4.
3. Forceps – 13.
   LSCS - 11%
   TOTAL VAGINAL DELIVERY - 89%

INDUCTION DELIVERY INTERVAL IN VARIOUS GPS:
   Average induction delivery interval in GP 1.
   Nullipara: 9Hrs 13mts.
   Range: 4Hrs 30mts - 11Hrs15mts.
   Para1 & above: 6hrs43mts.
   Range: 4hrs hrs30mts—11hrs55mts.

OUTCOME OF LABOUR IN GP 4 (WHERE THE CERVIX IS UNFAVORABLE AFTER 12HRS OF CERVIPRIME INSTILLATION):
1. Spontaneous vaginal delivery: 3(30%).
2. Forceps delivery: 1(10%).
3. LSCS: 6(60%).
   All these patients were given pitocin induction followed by ARM and all are associated with prolonged labour.

INDICATION FOR LSCS:
   Failed induction: 8(15.3%).
   1st degree CPD: 1(1.9%).
   PROM -Failed Induction: 1(1.9%).
   Foetal distress: 1(1.9%).

LABOUR OUTCOME IN MULTI:
   Para1 & above: N-(13).
   Trial success: 92%.
   Induction of labour: 74%.
   Ripening of cervix: 15%.
   One patient underwent LSCS. She had PROM after instillation of the gel & cervix fail to dialate even after pitocin acceleration. But the baby was preterm & that may be the reason why cerviprime fail to have any effect. All others delivered vaginally.

NEONATAL OUTCOME:

|   | 10 at 1min | 8at 1min | <8min |
|---|------------|----------|-------|
|   | 49         | 2        | 1     |

Table 7: APGAR SCORE OF BABIES
The baby with apgar < 8 had cord thrice around the neck which was very tight. No neonatal death occurred in this study.

| Birth Weight | Count |
|--------------|-------|
| <2kg         | 2     |
| 2.1—2.5     | 7     |
| 2.6—3       | 27    |
| 3.1—3.5     | 12    |
| >3.5         | 4     |

**Table 8: BIRTH WEIGHT OF BABIES**

**COMPLICATION**

**MATERNAL COMPLICATIONS:**
- Cervical tear—1(1.9%) (Bucket handle tear sutured with catgut. Bleeding was normal. Baby had apgar score 10 at 1min).
- Hyperstimulation—1(1.9%).
- Atonic PPH—3(5.7%).
- Maternal convulsion—1(1.9%).
- Maternal febrile illness—2(3.8%).
- Vomiting & diarrhea —3(5.7%).
- Manual removal of placenta—1(1.9%).

**FOETAL COMPLICATIONS:**
- Foetal distress—3(5.7%) [Mode of delivery: vacuum-1, forceps-1, LSCS-1].
- Neonatal fever-5(9.5%).
- Hypoglycemic convulsion-1(1.9%).
- Hypocalcemic convulsion-1(1.9%).
- Prematurity—1(1.9%).
- No neonatal death.

**DISCUSSION:** The aim of induction of labour is to perform safe vaginal delivery. Spontaneous labour and vaginal delivery is preceded by a cascade of synchronized events, governs the ease and success of induction of labour. Prince et al has observed that if ripening of cervix fails to occur, then delivery and labour may be prolonged and many a times it may be unsuccessful. Induction of labour in a patient with an unripe cervix is professional folly without ripening the cervix first.

From 15% to 20% of all pregnancies require induction of labour. Cervical ripening before induction is essential and Prostaglandins (PGs) are thought to play a significant role in the process of cervical ripening and initiation of labour.

Fetal membranes and decidua produce PGE2 during pregnancy and labor. Release of this hormone leads to changes in the biochemistry of the cervix and also stimulates the production of PGF2 α. In turn, PGF2α sensitizes the myometrium to oxytocin. Exogenous administration of PGE2 (Dinoprostone) is known to mimic this natural process and lead to cervical ripening or labor. Endo cervical application of prostaglandin E2 gel has become increasingly popular following studies in Sweden. However PGE1 is also a suitable preparation for softening and effacement of
cervix. The overall success rate in terms of vaginal delivery was 81% in our study. Kierse et al\(^9\) in his meta-analysis had shown that intracervical prostaglandins E2 in the form of gel compared with no treatment effectively increase Bishop’s score and the incidences of successful initial inductions. In these trials the success rate was from 72(%). The success rate of our study is comparable to study done by Rafiq-ul-Islam et al\(^8\) 84% and Warke et al 81%. The incidence of failed induction in our study was 15% which is not comparable to a study done by prince et al with incidence of 6 % & by Warke et al\(^11\) with a failure rate of 1.33%.

Various studies have shown the beneficial effects of intra cervical PGE2 gel in improving Bishop score, the improvement ranging from 3 to 7 points.\(^3,5,12\) The success of induction of labour was found to be directly proportional to the Bishop score at instillation. The mean Bishop's score was 7.1 which is comparable to the study done by Noah et al 1987. The overall mean induction delivery time was 9 hours 13 mts in Gp 1. Various studies have shown considerable variation as far as induction delivery time is concerned ranging from 9 hours Noah et al to 17.9 hours, Thiery et al\(^13\) to 20.2 hrs in a study done by Jackson Gm 1994\(^14\). The parity of the patients considered also influenced the duration of labour. PGE2 gel has shown to shorten the induction delivery interval in many studies and thus will result in less fetal and maternal morbidity and mortality.

CONCLUSIONS:

- The study showed that intra cervical application of prostaglandin E2 is an effective, safe and acceptable method for induction of labour in women with unfavorable cervix and indications for induction.
- Dinoprostone gel application resulted in improved Bishop score, facilitates the process of induction, increased number of successful inductions, shortened application delivery interval and decreased cesareans section rate.
- Fewer patients required labor induction with oxytocin.
- All these effects were achieved without increasing maternal and neonatal morbidity. Hence PGE2 gel can be recommended as a useful and potent method of induction of labor with unfavorable cervix.

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