MATERIAL AND METHODS
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The study was performed in 200 cases admitted in wards of department of Obstetrics and Gynaecology, M.L.B. Medical College, Hospital, Jhansi in the year 1993-94. Induction of labour with PGE$_2$ gel (Cerviprime) followed by intravenous oxytocin was carried out in 100 cases and results were compared with similar number of cases induced with intravenous oxytocin alone.

After interrogation with regard to name, age, parity and address detailed menstrual and obstetric history was taken in each case.

Complete general and systemic examination and complete obstetric examination with special reference to the size of the uterus, gestational age of the foetus, lie and presentation of the foetus was done and RIS was recorded in every case. Per vaginal examination was done to note the Bishop cervical score, to assess the pelvis and to confirm the integrity of membranes.

All patients had indication for induction of labour, and fulfilled the inclusion criteria for the study.

100 patients were given intracervical cerviprime (PGE$_2$) gel, 0.5 mg.

**CERVIPRIME (PROSTAGLANDINS E$_2$ GEL)**

PGE$_2$ gel for endocervical application is supplied in the form of tricosatin based gel containing 0.5 mg of
PGE\textsubscript{2} or dinoprostone marketed under the brand of cerviprime made available by Astra-IDL Limited Bangalore. It comes in prefilled sterile ready to use syringe. The syringe comprises of three components, the barrel, the plunger, the catheter. In package, the plunger is attached to the nozzle of the syringe. The entire assembly is packed sterile in a blister pack.

Before administration of the drug the syringe is assembled as follows:
1. The plunger is removed from the nozzle of the syringe.
2. The catheter packed separately is attached to the nozzle.
3. Pushing the plunger would expel the gel through the catheter.

**Metabolism and Excretion**

Dinoprostone is one of the naturally occurring prostaglandin, produced mainly in the cervical tissue. It does not get stored or accumulated in the cervical tissue. Dinoprostone is removed through the oxidative pathways that give rise to metabolites which are excreted mainly in urine.

**Drug Interactions**

Prostaglandins potentiate the action of oxytocin therefore oxytocin if required for induction of labour, should be used once the process of cervical ripening has begun, non-steroidal anti inflammatory drugs (NSAIDS) may
have effect on the action of PGE₂ hence to be used with caution.

**STORAGE AND SHELF LIFE**

It should be stored in the refrigerator at 2-8°C. It has a shelf life of 2 years from the date of manufacture. The contents of the syringe and the remaining gel if any, should be discarded after use.

**PATIENT SELECTION CRITERIA**

Antenatal patients at term (36-42 weeks) having a single fetus in cephalic presentation and vertex as the presenting part, were recruited for study if they fulfil the following inclusion criteria.

1. Gestational age of more than 36 weeks.
2. Bishop score of 5 or less than 5.
3. No contraindication for vaginal delivery like CPD, contracted pelvis.
4. No contraindications for prostaglandin.
5. Patient was not in labour.
6. Intact membranes.
7. Labour induction indicated for one or more of the following medical/obstetric reasons:
   a. Post term/post dated pregnancy.
   b. Pregnancy induced hypertension/toxemia.
   c. Chronic hypertension.
   d. Intrauterine foetal death.
e. Oligohydramnios.
f. Intrauterine growth retardation.
g. Diabetes.
h. Rh iso-immunization.

CONTRAINDICATIONS

1. Hypersensitivity to prostaglandin.
2. Previous caesarean section or major uterine surgery.
3. Cephalo-pelvic disproportion.
4. Pre-existing foetal distress.
5. Grand multipara.
6. History of difficult or traumatic labour.
7. Ruptured membranes.
8. Patients with non-existing vertex presentation.
9. Vaginal bleeding.
10. History of asthma and epilepsy.

DRUG ADMINISTRATION

After evacuation of the bladder, the patient lies supine and kept in the lithotomy position. Under full aseptic techniques, the cervix is visualized using a speculum. The polythene catheter provided with the syringe is fitted to the nozzle is inserted through external cervical os into the cervical canal until the internal os is felt. The tip of the catheter is then withdrawn slightly. The contents of the syringe, the gel is slowly injected while withdrawing the catheter so as to fill the cervical canal. Care should be taken to avoid
spilling of the gel into the extra-amniotic space or into the vaginal canal. No attempt should be made to expel the gel remaining in the catheter. The patient should be asked to remain supine for at least 30 minutes after gel instillation.

**PRECAUTIONS**

Certain precautions should be exercised while using cerviprime gel for ripening of cervix.

1. Should be used only in a well equipped obstetric hospital.

2. Care should be taken in patients with raised intraocular pressure.

3. To avoid side effects, care should be taken to ensure that the application is endocervical.

4. The uterine activity, foetal distress, cervical dilatation and effacement should be carefully monitored to detect hypertonic myometrial contractions and fetal distress.

**ADVERSE REACTIONS**

1. Occasional nausea, vomiting, and diarrhoea.

2. Intrapartum fetal heart rate change.

3. Uterine contractile abnormalities with or without fetal distress.

**OVERDOSAGE**

Applied in doses of 0.5 mg can cause hypertonic uterine contractions if gel is applied incorrectly and if
it spreads into the extra-amniotic space. If hypertonic uterine contractions are sustained possibility of uterine rupture should be considered. Beta agents like terbutaline can be used to relax the myometrium.

ONSET OF ACTION

Changes in the cervix start in about 5 hours from the time of gel application and completed in 12 hours to 24 hours.

PARAMETERS TO BE ASSESSED

Monitoring of patient during labour and two hours postpartum for pulse, blood pressure, temperature, foetal heart sound, induction priming interval, induction delivery interval, uterine contraction pattern, mode of delivery, postpartum blood loss was done. Birth weight was taken and APGAR score of baby at birth and at 5 minutes was assessed.

After 6 hours of gel applications, cervical score was assessed. If labour did not ensue by reassessment at 12 hours, a second score was assigned and oxytocin induction was commenced with 0.5 unit syntocinon in 500 ml in 5% dextrose at drip rate of 8 drops/minute in escalating dose according to uterine sensitivity. Bishop scoring was done during labour.
**INTRAVENTOUS OXYTOCIN GROUP**

In the control group, induction of labour was done by intravenous oxytocin that is syntocinon drip.

To start with 0.5 unit syntocinon in 500 ml of 5% dextrose at drip rate of 8 drops/minute in escalating dose according to uterine sensitivity was given.

**Criteria for Successful Induction**

1. Initiation of labour within 24 hours of application.
2. Not jeopardizing the foetus.
3. Foetus should be delivered vaginally.
AIMS OF STUDY

1. To find an improved method for induction of labour with unripe cervix.

2. To find out the efficacy and safety of PGE$_2$ gel (endocervical application).

3. To study the effect of PGE$_2$ gel on ripening of cervix.

4. Comparative study of endocervical application of PGE$_2$ gel and intravenous oxytocin for induction of labour.