ORIGINAL ARTICLE

COMPARISON OF PROSTAGLANDIN E_2 GEL, PROSTAGLANDIN E_2 PESSARY AND EXTRA-AMNIOTIC SALINE INFUSION WITH OXYTOCIN FOR INDUCTION OF LABOUR

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Background: Induction of labour is the intentional initiation of cervical ripening and uterine contraction for the purpose of accomplishing delivery, prior to onset of spontaneous parturition. This study was conducted to compare maternal and neonatal outcome in women induced with Prostaglandin E_2 gel, Prostaglandin E_2 pessary and extra-amniotic saline infusion with oxytocin at Bishops score <5. **Methods:** It was a quasi-experimental which was conducted at the Department of Gynaecology and Obstetrics Unit-I, Mother and Child Health Care Centre, Pakistan Institute of Medical Sciences, Islamabad during one year of time. Eighty cases in each group (prostaglandin gel, prostaglandinE_2 pessary and extra-amniotic saline infusion with oxytocin) were collected. Systematic sampling was done. First woman admitted was induced with prostaglandin gel, the second one with prostaglandin pessary and the third was induced with extra amniotic saline infusion and oxytocin. **Results:** The most common indication for induction was post dates followed by PIH. The induction labour interval was less in EASI with oxytocin group (5.18±3.4) hours, as compared to prostaglandin pessary (8.81±5.60) hours and prostaglandin gel (8.32±5.18) hours. Induction delivery interval in EASI with oxytocin was (10±5.6) hours as compared to prostaglandin pessary (14±6.3) hours and prostaglandin gel (13±7.1) hours. This difference was statistically significant. The primigravidas had longer duration of labour than multigravidas. Induction labour interval in primigravidas was (8.2±5.1) hours while in multigravidas it was (6.7±5.02) hours. Induction delivery interval was also more in primigravidas (13.6±6.80) hours as compared to multigravidas (11.4±6.20) hours. Vaginal delivery rate was 89.2% while the caesarean section rate was 10.4%. The most common indication for caesarean section was foetal distress. There was no significant difference in perinatal morbidity and mortality in the three groups. **Conclusion:** EASI with oxytocin is a better method of induction than prostaglandin E_2 gel and pessary. Moreover it is more economical in our country.

Keywords: Induction of labour, Bishop score, EASI, Prostaglandin E_2

INTRODUCTION

Induction of labour is the intentional initiation of cervical ripening and uterine contraction for the purpose of accomplishing delivery, prior to onset of spontaneous parturition.[1] Induction of labour is indicated where the benefits to mother or to the foetus outweighs the benefit of continuing pregnancy.[2]

Generally, labour starts spontaneously and results in vaginal delivery at or near term. However, because of medical or obstetric complications of pregnancy, cervical ripening and labour induction is often required. This process has the potential to confer major maternal and perinatal benefits.

History of induction dates back to 1836 AD, when Hamilton advocated digital separation of membranes from lower uterine segment. Labour induction was revolutionized by introduction of prostaglandins in 1970.[3] Presently the rate of labour induction is more than 13% of live births in USA.[4] While in the local literature it has been found to vary between 20–24.2%.[5]

Mechanical methods include laminaria, extra-amniotic Foley balloon catheter, and extra amniotic sodium chloride infusion via Foley catheter. Pharmacologic methods have cantered on preparations of dinoprostone (prostaglandin E_2) delivered by variety of vehicle, concentration, dosing schedules, and routes of administration.[6]

Risk of labour induction include prolonged labour, high Caesarean rate, high rate of epidural analgesia, low APGAR score at one minute and five minute.[7] It is said that regardless of indication, induction of labour is associated with increase operative vaginal delivery rate in nulli-parous and significantly reduced spontaneous delivery rate, increased caesarean section rate, [8] and shoulder dystocia for all women[9].

This study was undertaken to determine the labour outcome in women induced with three different modes of induction, i.e., prostaglandin pessary, prostaglandin gel and EASI with oxytocin.

The rationale of the study was to focus on a common medical intervention in pregnant women, i.e., induction of labour. It is prudent to find out a method of induction of labour which doesn't lead to increased operative delivery and increased peri-natal morbidity and mortality and is cost effective. Therefore it is

important to find out safe, effective, rapid and cheap method of induction of labour.

MATERIAL AND METHODS

Singleton alive foetus, cephalic presentation, gestation at or beyond 37 weeks, Para four or less, bishop score less than five, obstetric and medical indication for induction were included.

Congenital anomalies, multiple pregnancies, mal-presentation, gestation less than 37 weeks, CPD, placenta praevia or APH, previous caesarean section, and pre-labour rupture of membranes were excluded from the study. It was an analytic study. Eighty women were included in each group. They were given systematic allotment for method of induction after admission to antenatal ward. The confirmation of gestational age, pelvic adequacy and bishop score were done prior to admission. Induction was done at twelve midnight in the ward after filling the induction Performa and taking informed written consent. The patients were shifted to labour room when the contractions started. Pre and post induction CTG was done for every patient and IV line was maintained. Each patient was reassessed after six hours.

In the case of failure in improvement of modified bishop score (<5), a second prostaglandin E2 gel/pessary was applied and patient reassessed again after six hours. If still there was no improvement in bishop score (<5) a third prostaglandin E2 gel/pessary was applied.

If the modified bishop score was 5 or >5 ARM was done and oxytocin infusion was started at 2mu/min and the dose was doubled at half hourly interval up to maximum dose of 40mu/min until 3–4 effective uterine contractions of 40–60 seconds per 10 minutes were established.

In the patients induced with extra-amniotic saline infusion with concurrent oxytocin infusion, an intra-cervical Foleys catheter of 24 or 26 Fr was inserted with visualization of the cervix by sterile speculum examination. After proper placement was ensured the catheter balloon was inflated with 45 ml of distilled water. Traction was applied to the catheter until the balloon was taut against the internal os, and then saline infusion was started extra-amniotically at 30 ml per hour for 12 hours. Along with it oxytocin infusion was started at 2 mU/min and the dose was doubled at half hourly interval up to the maximum dose of 40 mU/min until 3–4 effective uterine contractions of 40–60 seconds per 10 minutes were established.

Patients were reassessed after 12 hours and if the catheter had not been expelled spontaneously, it was removed by deflating and ARM was done.

For the purpose of this study, failed induction was considered when the cervix failed to dilate >3 cm despite of optimal uterine contraction. Primary arrest was defined as cessation of dilatation before 7 cm dilatation, while secondary arrest was declared when no further dilatation occurred from 7 cm to full dilatation.

Abnormalities of FHR or uterine contraction pattern were corrected by giving oxygen inhalation, left lateral position of the patient and intravenous crystalloid therapy.

Maternal outcome measures include induction labour interval, induction delivery interval and mode of delivery, which were measured by resident doctor on duty on partogram. Neonatal outcome measures include Apgar score at one and five minutes, and neonatal morbidity and mortality including intensive care unit admission.

Data was recorded on the enclosed induction Performa and partogram by collecting observational facts. It was entered and analysed on SPSS-10. For numerical data which includes labour duration and Apgar score in three groups, ANOVA (a test that measures the difference between the means of two or more groups) was applied. For duration of labour in primigravidae versus multigravidae students t test was utilised. For categorical data, i.e., mode of delivery, indication of caesarean section, indication of instrumental delivery neonatal mortality and morbidity chi square was used. *p*-value of <0.05 was considered as significant.

RESULTS

This study was done to compare labour outcome in women induced with three different modes, namely vaginal prostaglandin pessary, intra-cervical prostaglandin gel and extra-amniotic saline infusion with IV Oxytocin infusion.

The most common indication of induction was post dates followed by PIH. There was a significant difference in induction-labour interval and induction-delivery interval in three groups. Women induced with EASI with oxytocin had less induction-labour interval and induction-delivery interval as compared to the other two methods as shown in Table 1 and 2.

Induction labour interval is 8.22±5.14 and 6.72±5.05 while induction-delivery interval is 13.64±6.85 and11.42±6.24 in primigravida and multigravida respectively. There was no significant difference in Bishop Scores at the time of admission, in women of the three groups. The mean Bishop score is 2.93±0.94. Similarly there was no difference in mode of delivery. The main indication for Caesarean section and instrumental delivery was foetal distress.

Overall 89.6% of women delivered vaginally and the caesarean section rate was 10.4%. In primigravidae vaginal delivery rate was 86.1% and caesarean section rate was 13.9% while in multigravidae the vaginal delivery was 92.8% and caesarean section rate was 7.2%

Neonatal mortality is similar in all the three groups. The causes of neonatal mortality are birth asphyxia, meconium aspiration syndrome and septicaemia. The peri-natal mortality rate is 0.029%.

Table-1: Induction Labour Interval (Hrs)

Groups	N	Mean	SD
Prostaglandin pessary	80	8.81	5.60
Prostaglandin Gel	80	8.32	5.36
EASI with Oxytocin.	80	5.18	3.46
Total	240	7.477	5.14

Table-2: Induction Delivery Interval (Hrs)

Groups	N	Mean	SD
Prostaglandin pessary	80	14.04	6.38
Prostaglandin Gel	80	13.38	7.11
EASI with Oxytocin	80	10.03	5.66
Total	240	12.48	6.62

DISCUSSION

Approximately 20–30% of all pregnant women are induced making labour induction a frequent medical intervention. Ripening of an unfavourable cervix has become an integral part of the labour induction process. Labour induction remains a significant clinical challenge. Options for cervical ripening and induction are numerous and varied. Each induction method has advantages and disadvantages.

The choice of a particular inducing agent depends not only on safety and efficacy but also on local practice pattern, cost, and availability and physicians preference. In our study there is no statistically significant difference in labour outcome in PGE_2 pessary and PGE_2 gel. Similar observations were seen by Shetty A.[10] in a retrospective analysis. Use of dinoprostone vaginal pessaries did not shorten time to delivery or improve any other birth outcome measured compared to dinoprostone intra-vaginal gel was also observed in another study by Kho EM.[11] Current RCOG guidelines suggest that vaginal PGE_2 tablets are as effective as gel and in the absence of clinical benefits offer more financial savings than gel.

The cervical ripening mechanism of the extra-amniotic balloon is probably two fold, firstly by direct pressure and over stretching of the lower uterine segment and cervix, secondly local secretion of prostaglandin. Three randomised controlled trials[12–14] compared EASI to intra-vaginal or intra-cervical prostaglandin for cervical ripening in women with an unfavourable cervix. It showed significantly fewer ripening failure occurred in the catheter group. Moreover the patients who received EASI had a shorter induction to delivery interval. There was no significant difference in mode of delivery.

In a study by Al-Taani MI[15] women with singleton pregnancies (235 nulli-parous and 201 multi-paras) were recruited if they had a clinically unfavourable cervix, and indications for induction. The mean (standard deviation) interval from initiation to delivery was statistically significantly shorter in multi-paras than nulli-parous 13.5 hours (SD 1.8) versus 15.5 hours (SD 2.4).

Rayburn[16] analysed the cumulative experience of more than three thousand pregnancies in 59 prospective clinical trials in which prostaglandin gel was used for cervical ripening. He found that the local application of prostaglandin was superior to placebo in enhancing the cervical score, reducing induction failure, shortening the induction to delivery time, reducing oxytocin use and decreasing the caesarean section rate.

An early meta-analysis by Keirse[17] of 44 published controlled trials comparing vaginal PGE_2 with placebo found no significant influence of treatment with PGE_2 on incidence of caesarean deliveries. Overall, the use of prostaglandin improves the cervical score in 80–90% of patients and significantly reduces the frequency of induction failure and caesarean section.

Neonatal outcomes compare favourably with those achieved by oxytocin induction. The likelihood of a low Apgar score, need for resuscitation, admission to an intensive care nursery, or peri-natal death is not increased with prostaglandin E_2. In our study 89.5% women were delivered vaginally out of which instrumental deliveries were 8.3% and Caesarean section rate was 10.4%. Our caesarean section rate is low as compared to other studies (21–25%) done by Buccellato CA *et al*.[6] This could be due to more number of multi-gravidas in the study population as caesarean section rate is more in primi-gravidas.

In a study by Dublin *et al*[11] 19% of the induced nulli-parous women underwent caesarean section when compared to multi-parous, in which the caesarean rate was only 4%. In our study, 14% of nulli-parous and 7% of multi-parous women ended up in caesarean section.

A valid indication for induction of labour, accurate determination of gestation, parity, bishop score, appropriate timing and selection of best method for an individual patient can reduce the risk of labour induction.

The limitations of study include high cost of prostaglandin gel and pessary. Considering the poor socioeconomic state of our patients, this was a factor which kept the sample size small in each of the study group. Admittedly, a sample size larger than our study would have been more of a value to establish the safety and efficacy of the three modes of induction of labour. Furthermore the reliability of cold-chain for the drugs couldn't be ensured which may have affected the efficacy of drugs and biased results.

CONCLUSION

Cervical ripening with extra-amniotic saline infusion with oxytocin possesses the advantage of simplicity, low cost and reversibility. Maternal outcome variables, i.e.,

induction-labour interval and induction-delivery interval are less in EASI with oxytocin as compared to prostaglandin pessary and gel. Moreover there is no difference in caesarean section rate, neonatal mortality and morbidity when compared to prostaglandins. Also, it can safely be used in patients where prostaglandins are contraindicated.

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