INDUCTION OF LABOR
COMPARISON OF CERVICAL FOLEY’S CATHETER AND PROSTAGLANDIN E-2 AT TERM

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ABSTRACT…background: Labor can be induced through a myriad of ways. The aim of this study was to compare the effectiveness of the intracervical Foley balloon catheter and intra vaginal 3 mg prostaglandin E2 tablet(s) in preinduction cervical ripening at term. Methods: Prospective analytic study of a cohort of 280 women selected through non probability sampling admitted in Obstetrics units, in two private hospitals one at Rawalpindi and the other at Mirpur (Azad Kashmir), from January 2009 to March 2010. All women were randomized to receive an intracervical Foley catheter or prostaglandin E2 tablets. The primary measured outcome was ripening of the cervix as measured with the Bishop score. Results: There were no differences in mean Bishop Scores between the prostaglandin and the Foley catheter groups. Bishop scores (mean ± S.D.) after ripening were 6.6±0.81 and 6.7±0.86 for the Foley catheter and prostaglandin groups, respectively (P=0.54). The prostaglandin group showed a statistically shorter induction to delivery time compared with the Foley catheter (16.5±2.2 and 20.51±3.89 h, respectively (P<0.01). Both the groups showed no statistically significant difference between the occurrences of spontaneous vaginal delivery. Labor was established in 72% cases of cervical Foley group. On the other hand induction occurred in 76% cases in prostaglandin group. There was no statistical difference between the need of oxytocin infusion for labor augmentation between the two groups and fetal distress was equally frequent in both the groups. Conclusions: Foley catheter was as effective as Prostaglandin E-2 at term for induction of labor with additional advantage of being cheaper, readily available and had no systemic side effects.

INTRODUCTION
Labor is accomplished with transformation in the biochemical connective tissue and with gradual effacement and dilatation of the uterine cervix on account of rhythmic uterine contractions of adequate frequency, force and extent. Prolonged labor carries the increased risks of operative deliveries and maternal morbidities.

Induction of labor is an intervention intended to artificially start uterine contractions leading to progressive effacement and dilatation of the cervix and delivery of the fetus. It attempts to induce two interlinked components of labor, cervical ripening and uterine contractility. Cervical ripening is the conversion of rigid cervical sphincter associated with maintenance of pregnancy to a readily dilating structure that allows passage of the fetus with comparative ease. Induction of labor is only performed upon specific indications. Labor is now considered as an intensive care situation and obstetrics emergencies can arise suddenly. For feto-maternal safety, active management is superior to expectant management and should be the routine management of choice.

A variety of techniques for induction of labor have been developed. Prostaglandins have been used for induction of labor since the 1960s. PGE2 increases successful vaginal delivery rates in 24 hours and cervical favorability with no increase in operative delivery rates. Currently the most commonly used method is intra-cervical application of Prostaglandin E2. However, systemic absorption of this agent is common resulting in nausea, vomiting and initiation of uterine contractions which may lead to uterine hyperactivity, especially in women with an unfavorable cervix and even placental abruption. Depicting a woman with high likelihood for cervical ripening failure with prostaglandins will help selecting the most favorable technique for labor induction in such cases.

Cervical Foley has been used for induction of labor to ripen the cervix by mechanical means without causing hypertonic uterine contractions. It also stimulates the release of endogenous prostaglandins in the cervix. Efficacy of Foley catheter to ripe the cervix may be objectively assessed through transvaginal ultra-
sonography and it helps predict the probability of success to induce labor in a woman who need preinduction ripening. Such Mechanical methods are advantageous in terms of reversibility and reduced expenditure. But Foley catheter is linked with a possibility of infections in larger studies. Thus, tremendous attention should be drawn towards carrying aseptic measures while inserting it to avoid maternal and probable neonatal infections.

Induction of labor in the presence of unripe cervix may result in many complications. This study was conducted to determine the efficacy and role of cervical Foley catheter in ripening and dilatation of unfavorable cervix for induction of labor at term and to compare it with intra-vaginal application of Prostaglandins E-2, meanwhile comparing the cost effectiveness of two methods and any complications.

PATIENTS AND METHODS
This prospective randomized study was carried out at two private hospitals at Mirpur (AJ&K) and Rawalpindi. Between January 2009 to March 2010, 294 women at term who presented with unfavorable cervix indicating for labor induction were recruited for the study. Inclusion criteria to recruit the patients were singleton pregnancy, vertex presentation, intact membranes and normal fetal heart tracings. Patients with the history of previous caesarean section, ruptured membranes, any contraindications for vaginal birth, suspected cephalopelvic disproportion or unexplained antepartum hemorrhage were excluded.

A written consent was taken from all the patients. They were randomized to one of the 2 techniques, using a random number table. In the first group, 150 women were tried with PGE2 3 mg vaginal tablet, inserted in the posterior vaginal fornix. This was repeated at 6-hour intervals, if needed. For the second method, 144 women an attempt with a 20 size Foley catheter, introduced into cervix so as to go by the internal os via a sterile speculum method. Its balloon was filled with 50 ml distilled water and then it was tied to the inner side of the thigh to create a small traction.

All patients underwent general, systemic and pelvic examination and vital signs were recorded. Blood samples were drawn for complete blood count and cross-match. Fetal heart rate was monitored. Abdominal and cervical assessments were taken at 4–6 hour intervals to establish the start of labor and to gauge Bishop Score variations, except in some instances when it was indicated earlier. Amniotomy was carried out as soon as clinically possible.

The advancement of labor was watched every 2 hours. Friedman’s criteria was used to identify labor abnormalities. In such occurrences for these cases, labor was augmented by oxytocin infusion as according to the manual described by O’Driscoll and Meagher. Intrapartum fetal heart rate was constantly monitored.

The primary outcome measures were the route of delivery and the time required from start of the induction to delivery. The secondary outcome measures were the change in Bishop Score, intrapartum complications or the requirement for oxytocin for labor augmentation.

Student t-test was used to compare the constant variables. Categorical variables were compared using the chi-squared or Fisher exact test. P < 0.05 was considered to designate a significant difference.

RESULTS
There were no significant differences in presenting characteristics between the 2 study groups (Table I) and both groups had similar indications for labor induction (Table II). Postdates and pre-eclampsia were the most frequent indications in both groups. The frequency of postdate pregnancies was significantly higher in the catheter group than the PGE2 group (P = 0.028).

As shown in Table III, the changes in Bishop score were similar in the PGE2 group and the Foley catheter group (mean 6.6 ± SD 0.81 versus 6.7 ± 0.86) (P =0.54). Similarly no statistically significant difference was found in the need of oxytocin for labor augmentation in the catheter group (80.55%) and in the PGE2 group (76.66%) (P =0.083).
The time from initiation of the induction method to delivery was significantly shorter in the PGE2 group compared with the catheter group (16.5 ± 2.2 versus 20.51 ± 2.2 hours) (P < 0.01). Of women that were randomized to use PGE2, 61.33% delivered within 16 hours after initiation of induction compared with 41.66% of those randomized to use the Foley catheter. This was a statistically significant difference (P < 0.01). There were 42 women who delivered after 24 hours in the catheter group, compared with 10 women in the PGE2 group. This difference was highly statistically significant (P < 0.001).

There were no significant differences between the groups in intrapartum complications or in type of delivery (Table III). In addition, there were no statistically significant differences in fetal outcomes (Apgar scores at 5 minutes, birth weight, admissions to the neonatal intensive care unit or meconium aspiration) between the 2 groups (Table IV). No more than 2 × 3 mg PGE2 vaginal tablets were needed to achieve a clinically feasible cervix for amniotomy. No woman needed a blood transfusion. All women and their babies were discharged home in good condition.

**DISCUSSION**

This study reveals that both PGE2 and Foley catheter are safe when used for cervical ripening as well as labor induction at term. Both methods were effective in view of the induction to delivery interval and labor augmentation with oxytocin. The current study is in agreement with other reports regarding the use and safety of PGE2 vaginal tablets and Foley catheter for labor induction.

Induction of labor for planned delivery has become an established part of modern obstetrics. Many studies have been done on different methods of induction and comparison of these methods. Mechanical methods were the earliest techniques devised to ripen the cervix.
### Table III. Labor and delivery outcomes of women treated with Foley catheter or prostaglandin E2 (PGE2) vaginal tablet for induction of labor

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Catheter group (n=144)</th>
<th>PGE2 group (n=150)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>No.</td>
<td>%</td>
<td>No.</td>
</tr>
<tr>
<td>Bishop score after ripening Mean ± (SD)</td>
<td>6.6±0.81</td>
<td>6.7±0.86</td>
<td>0.64</td>
</tr>
<tr>
<td>Oxytocin required</td>
<td>116</td>
<td>80.55</td>
<td>115</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Time from induction to delivery</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;16 hours</td>
</tr>
<tr>
<td>16-24 hours</td>
</tr>
<tr>
<td>&gt;24 hours</td>
</tr>
<tr>
<td>Mean ± SD</td>
</tr>
</tbody>
</table>

#### Intrapartum complications

- Fetal distress
- Failure to progress
- Delivery type
  - Spontaneous vaginal
  - Forceps
  - Caesarean section

*SD = Standard deviation
n = number of patients

### Table IV. Fetal outcomes of women treated with Foley catheter or prostaglandin E2 (PGE2) vaginal tablet for induction of labor

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Catheter group (n=144)</th>
<th>PGE2 group (n=150)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>No.</td>
<td>%</td>
<td>No.</td>
</tr>
<tr>
<td>Mean ± SD birth weight (g)</td>
<td>3499±581</td>
<td>3457±532</td>
<td>0.76</td>
</tr>
<tr>
<td>Apgar score &lt;6 at 5 min</td>
<td>08</td>
<td>5.55</td>
<td>7</td>
</tr>
<tr>
<td>Admission to NICU</td>
<td>12</td>
<td>8.33</td>
<td>10</td>
</tr>
<tr>
<td>Meconium present</td>
<td>25</td>
<td>17.33</td>
<td>30</td>
</tr>
</tbody>
</table>

*NICU = Neonatal intensive care unit
SD = Standard deviation
N = Number of patients
or to induce labor. Tools which were used include a range of variety of catheters and of laminaria tents, introduced into the cervical canal or into the extra-amniotic space. Mechanical methods were never completely discarded, but were replaced with by pharmacological ways during latest decades. Advantages of mechanical methods over pharmacological methods would be, less need of preservation, lesser expenditure and decreased side effects. Nevertheless, extraordinary consideration should be paid to contraindications (e.g. low-lying placenta), hazard of infection and maternal distress when putting in these tools. 

In a review of a series of studies comparing mechanical methods with placebo/no treatment, only one study with 48 participants reported on vaginal delivery not achieved in 24 hours (69% with mechanical methods versus 77% with placebo/no treatment). The risk of caesarean section, reported in six studies including 416 women, was similar between groups. Comparing mechanical methods with vaginal PGE2, only one trial (109 women) reported on vaginal delivery not achieved in 24 hours. The use of mechanical method reduced the risk of hyper stimulation with fetal heart rate changes when compared with prostaglandins: vaginal PGE2, intracervical PGE2. There was no difference in the risk of caesarean section between mechanical methods and prostaglandins. Serious neonatal (three cases) and maternal morbidity (one case) were infrequently reported. When compared with oxytocin, use of mechanical methods reduced the risk of caesarean section. These results are similar whatever specific mechanical method was used, except with extra-amniotic infusion. When comparing extra-amniotic infusion with any prostaglandins, women were more likely to not achieve vaginal delivery within 24 hours; the risk of caesarean section was increased, without a reduction of the risk of hyper stimulation.

Currently one of the commonest methods is the intra vaginal application of prostaglandin E-2. There is convincing evidence that Prostaglandin E-2 is essential for the initiation and normal progress of labour. Its low temperature storage requirement is itself a problem and experienced medical staff is mandatory for its use and storage.

Our analytic study showed that an inflated Foley Catheter placed in extra amniotic space is an effective method of ripening unfavorable cervix and there was no significant difference from Prostaglandin E-2, rather its results were better in many ways. It has a mechanical action of ripening away the fetal membranes from the lower uterine segment. This result in the release of lytic enzymes from lysosomes including phospholipase A, which acts on phospholipids to form arachidonic acids which in turn is converted into Prostaglandin E-2.

Observation made by Atad-et al from Israel revealed that double balloon Foley catheter was significantly better in improving the Bishop’s score than Prostaglandin E-2 and Oxytocin. Similarly Pennell and associates found that the single balloon catheter offers the best combination of safety and patient comfort had similar efficacy when compared with double balloon catheter and PGE2.

The main argument against the Foley Catheter was the risk of infection and accidental rupture of membranes. Maslovitz study of 1,083 women have shown that complications associated with trans-cervical ripening through Foley catheter with extra-amniotic saline infusion occurred in 7.6% and included acute febrile reaction, pain, vaginal bleeding and altered fetal presentation.

Heinemann noticed while reviewing randomized controlled trials that maternal infection rates were similar for patients who underwent ripening with extra amniotic saline solution infusion, Laminaria, or hygroscopic dilators. When compared with the use of pharmacologic agents alone, maternal and neonatal infectious morbidity came out to be high when mechanical agents were used for cervical ripening.

During our study aseptic precautions were carried out and policy of active management after expulsion of catheter was adopted. It was well tolerated by women in our study group. There were only two women in which accidental rupture of membranes occurred and both of them delivered after augmentation. This method is very cost effective in the third world and developing countries.

There lies a major risk of rupture of uterus whenever
labor is induced with prostaglandins which may be depicted when risk factors like multiparity, use of oxytocin and the condition of the cervix are taken into account. We did not come across any major complications in the present study. Comparison of intrapartum complications between groups showed no significant differences. Labor augmentation was carried out with oxytocin in 80.55% and 76.66% of the Foley and PGE2 groups, respectively. End result of labor and delivery matched up favorably well in both sets. This exhibits a comparable safety of both techniques that parallels the observations by others²⁴,²⁵.

In the view of these findings, it can be deduced that cervical priming as well as labor induction at term is safe and efficient when using PGE2 tablets or Foley catheter, together with oxytocin infusion, if required for labor augmentation, excluding any contraindications to induction. Prostaglandin E2 vaginal tablets is more efficacious to the intracervical Foley catheter in terms of shorter induction to delivery interval.

CONCLUSIONS
It is concluded that cervical Foley Catheter allows successful induction of labor as good as Prostaglandin E-2. However it has the additional advantage of being readily available, cost effective and a low frequency of systemic side effects.

REFERENCES
8. Crane JM, Butler B, Young DC, Hannah ME. Misoprostol compared with prostaglandin E2 for labour induction in women at term with intact membranes and unfavorable cervix: a systematic review. BJOG. 2006 Dec; 113(12):1366-76.


PREVIOUS RELATED STUDIES

Maimoona Hafeez, Waseem Talib, Saadia Siddique. Induction of labour; comparison of efficacy of different methods.
