Introduction

While the overwhelming majority of pregnancies terminate safely, in some instances, however, early termination of pregnancy becomes desirable.\(^1\,^2\)

Termination of pregnancy by medical or surgical methods, especially in the presence of unfavorable cervix may lead to additional difficulties and complications. Cervical ripening, before induction of labor, is needed to increase the success of labor induction, to reduce complications and to diminish the rate of cesarean section and duration of labor.\(^2\,^5\,^6\)

Prostaglandin \(\text{E}_2\) (\(\text{PGE}_2\)) suppositories, as a medical method, and Foley catheter balloon inflated at the cervical internal os, as a mechanical method, can be used in ripening of the cervix.\(^6\,^{10}\)

There are only a few clinical studies comparing the efficacies as well as the complication rates of the aforementioned techniques. Given the diversity of results by different investigators on conventional methods of cervical ripening before induction of labor, we conducted this study to determine and compare the efficacy, induction to delivery time and complication rates of two earlier-mentioned techniques, i.e., \(\text{PGE}_2\) suppositories and inflated Foley catheter, in pre-induction cervical ripening.

Patients and Methods

In a quasi-experimental study conducted between the years 2000 and 2001 at the Emam Reza Hospital in Mashhad, 70 women with a gestational age of 14-28 weeks and unfavorable cervix (Bishop score \(\leq 4\))\(^7\) requiring induction of labor, were randomly allocated into two groups. Subjects with asthma, epilepsy, heart diseases, diabetes, severe hypertension, placenta previa, uterine bleeding, uterine contractions, mal-presentation and uterine cicatrices were excluded from the study.

For each mother, a digital cervical examination was performed to determine the Bishop score. A skilled obstetrician performed all examinations. One group received vaginal suppository containing 3 mg dino-prostone inserted in the posterior fornix and re-administered after 6 hours, if necessary.

For the other group, a G16 Foley catheter balloon was inserted in the cervical internal os that was filled with 30 ml sterile normal saline and kept under mild traction by a 500 g scale stone. Oxytocin augmentation was routinely given to both groups after 12 hours, i.e., 15 drops/min of 20 U oxytocin in 1000 ml Ringer’s solution. The outcome variables including the change in cervical Bishop score, beginning of uterine contractions and complications during and after labor were assessed. Personal characteristics and other information were gathered and recorded in a questionnaire. Student’s \(t\) test was used for normally-distributed, and Chi-square test was used for categorical data. Statistical tests with \(p<0.05\) were considered significant.

Results

Table 1 shows the demographic characteristics of participants. Considering the parameters studied and using Student’s \(t\) test, no significant difference was observed between the two groups. No participant failed to complete the protocol or requested to be withdrawn from the study.

Table 2 shows a summary of parameters measured during labor and after delivery. The two interventions used, resulted in successful onset of uterine activity in all but seven cases. Abruptio of placenta occurred in two patients (one in each group). Nine patients (5 from Foley catheter and 4 from \(\text{PGE}_2\) group) underwent hysterotomy. Induction to delivery time varied from 2 to 36 hours and was significantly \((p<0.01)\) shorter in Foley catheter group compared to \(\text{PGE}_2\) group. In 15 patients, residuals of placenta were detected by sonography. They underwent curettage, however, no significant difference was observed between rates of

### Table 1: Characteristics of participants

<table>
<thead>
<tr>
<th>Variables</th>
<th>Foley catheter (n=37)</th>
<th>(\text{PGE}_2) (n=33)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Maternal age (yr)</td>
<td>28.1±7</td>
<td>26.2±5.4</td>
</tr>
<tr>
<td>Gestational age (wk)</td>
<td>22.5±5.2</td>
<td>21.7±5.2</td>
</tr>
<tr>
<td>Number of pregnancies</td>
<td>2.9±1.8</td>
<td>3.06±1.7</td>
</tr>
<tr>
<td>Number of deliveries</td>
<td>1.36±1.5</td>
<td>1.5±1.4</td>
</tr>
<tr>
<td>Interval between two latest pregnancies (m)</td>
<td>32.8±17.1</td>
<td>23.2±15.7</td>
</tr>
</tbody>
</table>
Comparing the efficacy of PGE2 suppository and cervical Foley catheter in pre-induction ripening of cervix

<table>
<thead>
<tr>
<th>Table 2: Labor and delivery characteristics</th>
</tr>
</thead>
<tbody>
<tr>
<td>Groups Variables</td>
</tr>
<tr>
<td>-------------------------------------------</td>
</tr>
<tr>
<td>Primary Bishop Score</td>
</tr>
<tr>
<td>Secondary Bishop Score</td>
</tr>
<tr>
<td>Bishop score changes</td>
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<tr>
<td>Induction-to-delivery interval</td>
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<tr>
<td>Vaginal delivery</td>
</tr>
<tr>
<td>Hysterotomy</td>
</tr>
<tr>
<td>Post-partum curettage</td>
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</tbody>
</table>

NS = Not Significant

post-partum curettage in the two groups (Table 2).

Other complications observed included nausea and vomiting in 1 case, diarrhea in another one, headache in 1, and hot flashes (<37.8 °C) in 7 cases of PGE$_2$ group. Post-partum infectious complications were similar in both groups; two cases of PGE$_2$ and three of Foley catheter group developed post-partum infection. They were hospitalized and treated accordingly; all these cases underwent hysterotomy.

The mean±SD time between insertion and reescape of Foley catheter from the cervix was 6.4±4.2 hours. In two patients, the catheter did not escape. In these cases, the catheters were removed manually after 12 hours. Twenty-four (75%) of 33 patients in PGE$_2$ group required two PGE$_2$ suppositories to ripen the cervix.

Discussion

We found that intracervical insertion of inflated Foley catheter balloon or intravaginal administration of suppository of PGE$_2$ have excellent efficacy with minimal side effects and can promote the cervical Bishop score and prepare the cervix for induction of labor by oxytocin. The induction to delivery interval in Foley catheter group was significantly shorter than PGE$_2$ group. The rate of failure was also equal in both groups.

Prostaglandins E and F in the form of oral, intravaginal and intramuscular, intra-myometrial as well as vaginal and cervical jelly are suggested for induction of labor and abortion.$^{26,7,11-21}$ Vaginal suppositories (Dino-prostone) are preferred by some investigators, since its absorption is lower than PGE$_2$ jelly (3 mg/h) and the systemic complications (nausea, vomiting, and diarrhea) are less severe.$^7$

One in 1995, found no difference between the efficacy of intra-cervical Foley catheter and prostaglandin vaginal jelly, and also between their side effects when were used in cervical ripening.$^{22}$

Sherman et al. (1996) suggested that inflated Foley catheter balloon is more effective and has lower side effects compared to other mechanical and medical methods of cervical ripening.$^{23}$ In a study conducted by Atlas et. al. (1998), the use of combined methods of Foley catheter and cervical PGE$_2$ jelly in comparison to two doses of cervical prostaglandin PGE$_2$ jelly, resulted in higher cervical Bishop score and lower rate of induction failure. In this study complications such as cesarean section, uterine hyper-stimulation and post-partum infection were similar in the two groups.$^{10}$

In another study, Scisclone et al used Foley catheter for ripening of cervix before induction of labor by oxytocin, and had excellent efficacy and minimal side effects.$^{24}$ Considering our findings, the use of internal Foley catheter in ripening and termination of pregnancy is as effective as intravaginal administration of PGE$_2$. It can shorten the induction-to-delivery interval with minimal side effects. Foley catheter is easy to use, and is more accessible at lower cost, therefore, as a mechanical method, can be used instead of prostaglandin in ripening of unfavorable cervixes.

Acknowledgements

The authors appreciate the help and contribution of residents of Obstetric and Gynecology Ward, especially Dr. M. Nayebi and Dr. F. Shooride and the personnel of delivery room of Emam Reza Hospital.

References


