Study of Foley`S Bulb for Cervical Ripening in Induction of Second Trimester Abortion

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Abstract
To evaluate the efficacy and safety of Foley’s bulb along with Misoprostol in the management of second trimester abortion with special emphasis on cervical injury, a study was done on fifty six women who came for termination of pregnancy between 14 and 20 weeks of gestational age. Inflated Foley’s bulb with traction pressure over internal cervical os and Misoprostol 400 mcg vaginally every four hours is the method adopted. Induction abortion interval, doses used, additional techniques adopted, side effects, complications encountered were recorded. 100 percent success rate with minimal side effects, no major complications, no cervical damage was observed. The findings are compared with the similar studies from literature

Keywords: Mid trimester abortion, Misoprostol, Foley’s catheter, Cervical injury.

Introduction
Mid trimester is the period ranging between 14-28 weeks of gestation. In India medical termination of pregnancy is permitted up to 20 weeks on indication, not later. Even though MTP services are widely available in all corners of India, and first trimester MTP is an outpatient procedure, some women especially from remote places, women with failed inefficient techniques of abortion, single women come late in pregnancy for termination. With availability of ultrasonography, congenital anomalies, unviable foetuses, Intrauterine deaths are diagnosed and need termination. These two major groups of women form the bulk of the present study. Midtrimester abortion is an inpatient procedure ,so it should be quick, employ an easily followed protocol, cheap, without additional infrastructure, without compromising safety, both short time and long time.

Prostaglandins are proven abortifacients with primed and unprimed myometrium. Prostaglandins are known to cause cervical tears both vertical and bucket handle type. The immediate and late complications of cervical injury can be prevented by cervical ripening.

Cervical ripening before or at termination of pregnancy can be achieved by slow mechanical dialatation, osmotic dialators Viz Laminaria tents: by using prostaglandins oral or intracervically. The use of Foley’s catheter has been recommended in many developing countries. The reports from Turkey, Egypt, Ethiopia, Israel, Nigeria have mentioned excellent results with the
use of Foley’s catheter either alone or in combination.
Although the exact mode of action of Foley’s catheter is not fully understood, it has been postulated that the catheter stimulates various unspecified regions of the uterus, elevates its excitability and causes regular uterine contractions. Several studies have described the utility of Foley’s catheter in cervical ripening. Obed and Adwole showed that it increased the Bishop’s score in women with unripe cervices in a way comparable to that of prostaglandins. The drawback of using singly to induce abortion is, it takes long time and needs additional techniques later to complete abortion.
Combining prostaglandins and Foley’s catheter can reduce the abortion time, minimising complications.

Materials and Methods
The study involves 56 women, attending Balaji Nursing Home, Sirpur Kaghaznagar, Adilabad district, Telangana state, India, between July 2014 and October 2016, for termination of pregnancy of 14-20 weeks.
Inclusion criteria: pregnancies of 14-20 weeks gestational age, needed termination on a medical indication or for MTP fulfilling the criterion of MTP act
Patient in the process of spontaneous abortion, scarred uterus, cervical incompetence, genital tract infections, associated general medical conditions which are contraindicated for prostaglandins, DIC, women who are allergic to or had previous adverse reactions to prostaglandins are excluded from the study.
Routine antenatal investigations undertaken. Ultrasound examination done to confirm the age of the pregnancy, reconfirm the medical indication for termination like IUD, congenital anomalies. Patients were admitted and discharged 6-24 hours after completed abortion. Informed consent was taken after counselling the patient regarding the need for termination, technique used, expected complications.

In lithotomy position, under aseptic precautions, the anterior lip of cervix was held with ring forceps. No 14 Foley’s catheter was held with another ring forceps and introduced into the cervix beyond the internal os. The balloon was inflated with 30 ml of normal saline, and the catheter was pulled back to snugly fit against internal os and taped to the inner aspect of thigh to maintain the pressure over internal os. 400 mcg of Misoprostol tablet inserted high in the vagina. Prophylactic antibiotics given.
Every four hours general condition of the patient, uterine action, cervical state was assessed by PV examination by one of the authors. If there is no imminent abortion 400 mcg of Misoprostol was inserted till a maximum of four doses at 0,4,8,12 hours. At 16 hours if there is no expulsion of fetus, additional methods are resorted to. The additional method used are additional doses of Misoprostol or 20 units of Oxytocin in 500 ml of Ringer’s solution run at 20 drops per minute.
After expulsion of fetus, bleeding PV and placental expulsion observed. If there is no placental expulsion one hour after fetal expulsion, digital or instrumental evacuation of placenta done. After expulsion of placenta uterine cavity is explored manually for cervical tears and completion of placental expulsion. In doubt, speculum examination and instrumental evacuation done. Observed for post abortal bleeding and discharged 6-24 hours after abortion.

Results
Demography of the subjects
Age:
<20 years 12
20-25 years 9
25-30 years 23
30-35 years 10
>35 years 2
Total 56

Legend for demography chart
Age in years: <20,20-25,25-30,30-35,>35
Gravida: Primi, multi, grand multi
Gestational age in weeks: 14-16, 16-18, 18-20
Marital status: Married, single
Indication: Failure of contraception, IUD, congenital anomalies, triplets

Marital status:
Married 39
Single (unwed, divorced, widow) 17
Total 56
Gestational age:
14-16 weeks 23
16-18 weeks 14
18-20 weeks 19
Total 56
Indication for induction:
Failure of contraception 27
Intrauterine foetal demise 14
Medical indication, of fetal anomalies 14
Triplets 1
Total 56
Mean induction abortion interval:
Total 11.79 hours
Primis 13.0 hours
Multis 11.34 hours
14-16 weeks gestation 12.60 hours
16-18 weeks gestation 10.64 hours
18-20 weeks gestation 12.37 hours

Average of misoprostol used:
Total 1336 mcgs
Primis 1378 mcgs
Multis 1347 mcgs
14-16 weeks 139 mcgs
16-18 weeks 1257 mcgs
18-20 weeks 1347 mcgs
Three women did not abort at 16 hours post induction. For one woman an additional single dose of 400 mcg of misoprostol was used. For another woman an additional dose of misoprostol, oxytocin drip resulted in spontaneous abortion at 23 hours. After additional dose of misoprostol, oxytocin drip at 24 hours there was breech abortion with head stuck up. Crushing the head with sponge holder and oxytocin resulted in abortion at 25 hours. Digital exploration of uterine cavity for non expulsion of placenta one hour after expulsion of foetus revealed a separated placenta in the cavity which was evacuated digitally – in seven cases. Instrumental evacuation was done in four patients. No excessive post abortal bleeding necessitated blood transfusion. Prophylactic methergine was given for two women, one women had Injection Prostodin. In two women 400 mcg of misoprostol was inserted rectally for slight extra bleeding. Vomiting in 11 women, rigor and sweating in 7 women, aseptic pyrexia in 5 women was seen in a total of 15 women; only assurance and symptomatic treatment was given for these women. None of the women had any cervical tear.

**Discussion**

Sixty one percent of women had complete spontaneous abortion at twelve hours, reaching to 95 percent at 16 hours. Women with 14-16 weeks of gestational age lagged behind in abortions at 12 hours compared to others: 16-18 weeks of pregnancy fared well in abortion during corresponding period. Every one aborted at 25 hours. Except these, no significant difference was noticed in induction abortion interval in gravidity and weeks of pregnancy.

A brief comparison of some frequently quoted studies is presented in the table.

<table>
<thead>
<tr>
<th>Study</th>
<th>Method</th>
<th>Induction abortion interval</th>
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<tbody>
<tr>
<td>Ansa Islam et al</td>
<td>Foley’s catheter alone</td>
<td>22.93+/-3.30 hours</td>
</tr>
<tr>
<td>Ansa Islam et al</td>
<td>Foley’s catheter+PGF2 Alfa injections</td>
<td>25.97+/-2.63 hours</td>
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Method: Foley’s catheter with Misoprostol 400 mcg 4 th hourly

<table>
<thead>
<tr>
<th>Study</th>
<th>Induction abortion interval</th>
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<tbody>
<tr>
<td>Ayman Shabana et al</td>
<td>10.8 +/-3.9 hours</td>
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<tr>
<td>Mohammed Abd Allah Rezk et al</td>
<td>7.5+/-1.25 hours</td>
</tr>
<tr>
<td>Present study</td>
<td>11.79+/-3.12 hours</td>
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</table>
Conclusion
Termination of pregnancy in second trimester is relatively safe with low complication rate
Medical methods are non invasive, anaesthesia is not required, patient compliance and acceptance is excellent.
Use of mechanical dialators like Foley’s catheter is easy, no special training is required for medical personnel.
Combination of Foley’s catheter and Misoprostol lowers the dose of misoprostol required; induction abortion interval is drastically reduced to less than half than when used alone.
The side effects are not significant, minimal; cervical tears can be prevented
It is inexpensive, easily available; less hospital stay, cost effective and is ideally suited to low resourceful countries

Draw backs and limitations of the study:
The sample size is small
Intra cervical inflation of Foley’s bulb needs strict aseptic precautions and use of antibiotics
The risk of infection is masked by routine antibiotic usage

References