Study of Foley’s Bulb for Cervical Ripening in Induction of Second Trimester Abortion

Authors
Dr Alla Satyanarayana Reddy, MD DGO FICMCH¹, Dr Harish Babu B G, MD²
¹Professor and HOD, Department of Obstetrics and Gynaecology, Vinayaka Missions Medical College and Hospital, Karaikal, Puducherry, INDIA
²Assistant Professor, Department of Obstetrics and Gynaecology, Vinayaka Missions Medical College and Hospital, Karaikal, Puducherry, INDIA

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 in to 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:

| Age  | Subjects |
|------|----------|
| <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

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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, ofetalanomalies  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
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

| Study                        | Method                                  | Induction abortion interval |
|------------------------------|-----------------------------------------|-----------------------------|
| Ansa Islam et al             | Foley’s catheter alone                  | 22.93 +/- 3.30 hours        |
| Ansa Islam et a              | Foley’s catheter + PGF2 Alfa injections | 25.97 +/- 2.63 hours        |
| Ayman Shabana et al          | 10.8 +/- 3.9 hours                      |                             |
| Mohammed Abd Allah Rezk et al| 7.5 +/- 1.25 hours                      |                             |
| Present study                | 11.79 +/- 3.12 hours                    |                             |

Method: Foley’s catheter with Misoprostol 400 mcg 4 th hourly
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

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