



A Comparative Study of the Effectiveness of Intravaginal Misoprostol Alone and Combined Use of Intravaginal Misoprostol and Intracervical Foley's Catheter for Termination of Mid Trimester Pregnancy in Women with Previous Cesarean Section

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Abstract

Introduction: Termination of pregnancy in 2nd trimester is one of the greatest challenges in modern obstetrics practice and is more risky than during 1st trimester. In our study, we aimed at assessing the effectiveness and safety of intracervical foleys catheter with vaginal misoprostol and comparing it with vaginal misoprostol for mid trimester abortion in patients with previous cesarean.

Methods: A hospital based comparative study was conducted on 100 women with period of gestation 13 to 20 weeks for termination of mid trimester pregnancy in women with previous cesarean section

Results: The mean induction-abortion interval for group 1 was 17.9 ± 6.7 hours and for group 2 it was 13.4 ± 5.2 hours. The mean total amount of drug required in group 1 was 1560 ± 437.05 μg and for group 2 it was 1256 ± 404.14 μg . Complete abortion was achieved in 76% (38) and 88% (44) of the patient in group 1 and group 2 respectively. No significant difference as regard occurrence of adverse effects between the two groups.

Conclusions: Intracervical foley's catheter with misoprostol is safe and more efficacious than misoprostol alone for second trimester termination of pregnancy in women with previous cesarean section with no significant increase in side effects.

Keywords: Misoprostol, foleys, cesarean section, termination of pregnancy.

INTRODUCTION

With the global trend of raised cesarean section rate, obstetricians are faced with the challenge of termination of pregnancy in women with a scarred uterus. This becomes more and more challenging as the number of previous cesarean increases and there is no consensus on the safest method of therapeutic abortion in such patients.

Termination of pregnancy is defined as elective expulsion or removal of products of conception from uterus instead of spontaneous onset of process irrespective of duration of pregnancy. Congenital abnormality and intrauterine fetal death are the most common reason of Mid-trimester termination of pregnancy. It is associated with three to five times higher risk of maternal morbidity and mortality than termination of pregnancy during first trimester^[1].

Termination of second trimester pregnancy is more-risky and as surgical methods have more morbidity, therefore the medical methods of termination of pregnancy seem to be better alternative to surgical methods^[2]. Prostaglandins (PGE1, PGE2) induce labor with cervical effacement and dilatation. They have collagenolytic property. Surgical methods are gradually getting replaced by mifepristone, prostaglandin, oxytocin and mechanical methods.

Misoprostol is a synthetic analogue of prostaglandin E1, binds to myometrial cells causing strong myometrial contractions and causes cervical softening and dilatation and then expulsion of product of conception^[3,4].

There are several advantages of using misoprostol as it is inexpensive, stable at room temperature, does not require refrigeration for storage and it has multiple routes of administration (oral, vaginal, buccal, rectal or sublingual)^[5].

Intracervical Foley's catheter is the most common mechanical method that was first described by Embrey and Mollison in 1967, where a Foley's is inserted into the cervical canal and inflated just past the internal os with mild traction outward dilating the cervix directly, as well as indirectly stimulating prostaglandin (PG) and oxytocin secretion^[6].

Foley's catheter is economical, easily available, associated with minimal complication and thus provides a readily available and efficacious method of cervical ripening^[7].

OBJECTIVES

To compare the effectiveness of intravaginal misoprostol alone with combined use of intravaginal misoprostol and intracervical foley's catheter for termination of mid trimester pregnancy in women with previous cesarean section.

To access the effectiveness, safety and acceptability of misoprostol alone versus intracervical foley's catheter and vaginal misoprostol for termination of mid trimester pregnancy in women with previous cesarean section.

METHODOLOGY

Our study was a hospital based comparative study conducted on 100 women undergoing mid trimester termination of pregnancy with previous cesarean section from April 2021 to June 2022 in the department of obstetrics and gynaecology, SMS medical college and attached groups of hospitals, Jaipur.

After approval from institutional ethical committee, patient was selected after applying inclusion and exclusion criteria.

After proper counseling regarding the purpose of the study, a written and informed consent will be taken.

Patients were divided into two groups randomly-

Group I (Misoprostol group) (n=50):

Moistened misoprostol tablets (400 µg) 4 hourly intravaginally (maximum 5 doses) was given until termination.

Group II (misoprostol and foleys combined group) (n=50):

Moistened misoprostol tablets (400 µg) 4 hourly inserted vaginally along with inserting intracervical foleys catheter (no 16 fr) inflated with 50 ml normal saline. Then 400 µg misoprostol (maximum 5 doses) were repeated 4 hrly until termination of pregnancy.

Inclusion criteria - All pregnant female with previous 1 and 2 cesarean section requiring termination between 13 to 20 weeks of gestation.

Exclusion criteria –

1. Patient with more than 2 cesarean sections
2. Women with previous history of Classical cesarean section, hysterotomy and myomectomy.
3. Multiple gestation
4. Placenta previa
5. Allergy to prostaglandin
6. Other medical comorbidities like hypertension, diabetes mellitus

Procedure efficacy, safety, dose of misoprostol required, successful abortion, side effects and complication were assessed in both the groups.

STATISTICAL ANALYSIS

Descriptive statistical analysis was used and data was expressed as frequency, percentage, mean ± standard deviation and range. Continuous variables were summarized as mean and standard deviation while nominal/categorical variables were expressed as percentages.

Unpaired t-test was used for analysis of continuous variables while chi-square test and other relevant statistical test were used for nominal/categorical variable. P-value < 0.05 was taken as significant

RESULTS

The following data were collected in the study conducted at SMS MEDICAL COLLEGE AND ATTACHED GROUP OF HOSPITALS in the DEPARTMENT OF OBSTETRICS AND GYNAECOLOGY.

TABLE 1 – Maternal characteristics

Maternal characteristics	Group I	Group II	P value
Mean age (years)	27.2±3.6	27.8±3.5	0.4
Mean gestational age (weeks)	15.9±2.1	15.5±1.9	0.3
Previous no of LSCS			
Previous 1	42	43	0.9
Previous 2	08	07	0.7

The mean age for group 1 was 27.2 years and for group 2 it was 27.8 years.

The mean gestational age for group 1 was 15.9 weeks and for group 2 it was 15.5 weeks.

We found that majority 84% women in group 1 and 86% women in group 2 had one LSCS followed by 16% women in group 1 and 14% women in group 2 with 2 LSCS.

TABLE 2 - Indication for termination –

Indication for termination	Group I	Group II	P Value
Anomalous baby	26	23	0.5
IUD	22	25	0.5
Anhydramnios	2	2	1

We found that majority 44% women in group 1 and 50% women in group 2 were of IUD while 52% women in group 1 and 46% women in group 2 had Anomalous Baby.

TABLE 3 - Total dose of misoprostol required and induction – abortion interval –

Variables	Group I	Group II	P value
Total dose of misoprostol (µg)	1560 ± 437.05	1256 ± 404.14	0.0005
induction – abortion interval (hours)	17.9 ± 6.7	13.4 ± 5.2	0.0003

Here we found that mean induction-abortion interval for group 1 was 17.9 ± 6.7 hrs. Mean induction-abortion interval in group 2 was 13.4 ± 5.2 hr.

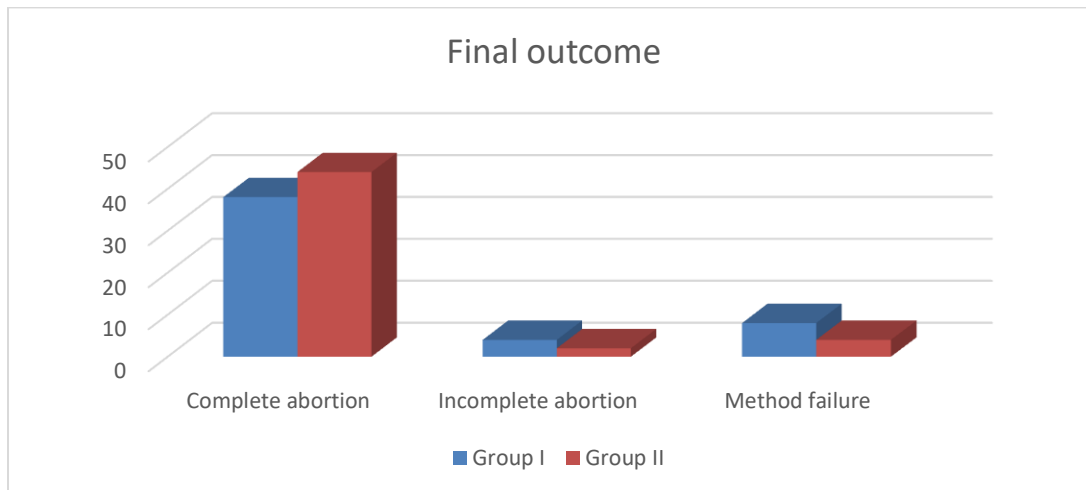
Mean total amount of drug required in group 1 was 1560 ± 437.05 µg and for group 2 it was 1256 ± 404.14 µg.

There was significant difference found between these group as p value was <0.05.

TABLE 4 - Distribution of patients according to side effects –

Side effects	Group I	Group II	P value
Pain	13	14	0.8
Nausea/vomiting	15	10	0.2
Headache	08	06	0.5
Diarrhoea	08	06	0.5
Fever	09	08	0.7
Ruptured uterus	01	00	0.8

We found that most common side effect in Group 1 and Group 2 was pain (26% and 28% respectively) followed by nausea & vomiting (30% and 20% respectively).

Final outcome in our study –

Complete abortion was achieved in 76% (38) of the patient in group 1. Complete abortion was achieved in 88% (44) of the patient with group 2. Incomplete abortion was noted in 8 % (4) and 4% (2) in group 1 and group 2 respectively and the dilatation and evacuation were done in those cases. Method failure was noted in 16 % (8) and 8% (4) in group 1 and group 2 respectively and hysterotomy was done in those cases. There was one case of uterine rupture in Group-1, laparotomy was done in that case.

DISCUSSION

With the increasing global trend in cesarean section and limited evidence available on safe second trimester pregnancy termination in these women and therefore, the decision to attempt pregnancy termination in the 2nd trimester in cases with previous uterine scar should be made on a case-by-case basis, after consideration of the number of previous cesarean sections and gestational age, and availability of facilities to tackle emergency. In our study the overall dose of misoprostol required in combination with intracervical foley's catheter was significantly reduce in comparison to the doses required in case of misoprostol alone. Induction-abortion interval was also reduced in combined group in comparison to misoprostol alone group.

Mid-trimester termination of pregnancy (TOP) has a global incidence of 10-15%. Most of the time it is unavoidable. There is a gradual increase in incidence because of wide scale introduction of prenatal screening programme^[8].

The most efficacious regimen for medical termination of second trimester pregnancy appears to be use of mifepristone followed by misoprostol. This regimen has an abortion rate of 97-99% in first 24 hours^[9,10].

Termination of pregnancy in second trimester despite being costly procedure and associated with higher risk as compared to first trimester abortion, is a necessity in today's time as due to advances in antenatal diagnosis, the decision to terminate gets delayed. There are the many methods, two popular methods used by modern obstetricians are vaginal misoprostol alone or use of cervical Foley's catheter combined with misoprostol.

CONCLUSION

In this study we found that with the combined use of intravaginal misoprostol and intra cervical Foley's catheter; there was significant reduction in the induction-abortion interval as compared to intravaginal misoprostol alone. The total required dose of misoprostol for termination of pregnancy was significant less with Foley's and misoprostol combination as compared to misoprostol alone. However, the side effects were almost same in both the groups.

After proper selection of the patients by careful history and clinical examination, in low-resource settings, combined use of intravaginal misoprostol and intracervical foley's catheter was found to effective method for termination of pregnancy in women with previous cesarean section.

Intracervical foley's catheter with misoprostol is safe and more efficacious than misoprostol alone for second trimester termination of pregnancy in women with previous cesarean section with no significant increase in side effects.

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Conflict of interest: None declared

Ethical approval: The study was approved by the Institutional Ethics Committee

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