Section: Obstetrics and Gynaecology

Original Research Article

COMPARATIVE STUDY OF EFFICACY BETWEEN FOLEY'S INDUCTION WITH MISOPROSTOL AND MIFEPRISTONE WITH MISOPROSTOL IN SECOND TRIEMESTER ABORTION

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Received *: 20/01/2026*
Received in revised form *: 07/03/2026*
Accepted *: 24/03/2026*

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DOI: 10.70034/ijmedph.2026.2.32

Source of Support: Nil,
Conflict of Interest: None declared

Int J Med Pub Health
2026; 16 (2); 181-185

ABSTRACT

Background: Termination of pregnancy in the second trimester is associated with increased maternal risks. The MTP act, 1971 (amended in 2020) defines the ideal place and person who can conduct MTP. The safest, lowcost method of inducing MTP is preferred. This study was conducted to evaluate the efficacy and outcome of 2 medical methods of MTP , i.e., use of Foley's bulb and misoprostol versus misoprostol with mifepristone.

Materials and Methods: This observational study was conducted in the Department of Obstetrics and Gynaecology, St. Peter's Medical College, Hospital and Research Institute, Krishnagiri, over 12 months period. A total of 150 patients in their second trimester eligible for MTP were included in this study. Patients were divided into 2 groups of 75 members each. Group A was induced with Foley's bulb and misoprostol and Group B was induced with mifepristone and misoprostol.

Results: most of the patients belonged to 20-30 years of age group. 86% of the study population was parous. Majority of the study patients were married and belonged to lower socioeconomic class. Most of the patients were in 17-20 weeks of gestational age. Request for MTP was the most common indication. The number of requirement of misoprostol doses was significantly decreasing with increase in the parity. The induction to abortion time interval was lower for Group B. patients of Group B had 100% success rate with minimal complications.

Conclusion: Although Foley's bulb with misoprostol is of low cost, but when compared to efficacy, it is inferior to mifepristone with misoprostol.

Keywords: Abortion, second trimester, Foley's, misoprostol, mifepristone.

INTRODUCTION

Abortion is defined as the termination of pregnancy before the period of viability. Second trimester abortions constitute 10-15% of all induced abortions worldwide but are responsible for two-thirds of major abortion-related complications like placental retention, maternal hemorrhage, uterine rupture and hysterectomy.[1,2]

According to the MTP Act, 1971 (amended in 2020), legal abortion is allowed only upto 20 weeks of gestational age. It should be performed by recognized medical practitioners in a recognized place approved by competent authority. As per the Act, abortion from 12 weeks upto 20 weeks should be performed by a registered practitioner who holds a PG degree/ diploma in Obstetrics and Gynaecology; has completed 6 months of internship in Obstetrics and Gynaecology and has a minimum of one year experience in practice of Obstetrics and Gynaecology.[3]

There are various methods available for second trimester MTP. Among the medical methods, MTP using mifepristone and misoprostol is popular, while

in mechanical methods, use of Foley's bulb for induction, either alone or in combination with misoprostol is popular.

Misoprostol is a synthetic PGE1 analogue, initially developed for the treatment of peptic ulcer but later used as an abortifacient.[4] within 24 hours of using misoprostol, the success rates typically range from 80% to 90%, with a median induction-to-abortion interval of 10–15 h.[5] Misoprostol is most effective when it is used in combination with methotrexate or mifepristone (also known as RU-486).[6] Mifepristone inhibits the signals of progesterone, eventually causing the uterine lining to detach, similar to a menstrual period, as a result of which the embryo detaches from the uterine walls. Misoprostol then dilates the cervix and induces uterine muscle contractions which clear the uterus.[7,8]

In low resource settings like our country mifepristone is not affordable always. So, in order to shorten the induction to abortion interval and also to minimize side effects of repeated doses of misoprostol, intracervical Foley's catheter inflation can be used in combination with misoprostol.[9] The Foley's catheter is inserted into the cervix and filled with sterile water or saline to gradually dilate the cervix, making it easier to perform the abortion procedure.

This study was conducted with an aim to evaluate the efficacy of using mifepristone with misoprostol versus misoprostol with Foley's catheter for inducing abortion in second trimester.

MATERIALS AND METHODS

The present comparative study was conducted in the Department of Obstetrics and Gynaecology, St. Peter's Medical College, Hospital and Research Institute, Krishnagiri, over a period of 12 months, i.e. from February 2025 to January 2026. All singleton pregnant patients aged between 18-35 years with 14-20 weeks of gestational age attending the OPD and casualty for undergoing abortion in compliance with the MTP Act 1971 and who gave a written informed consent to do so were included in the study. A total of 150 patients were included in the study during the study period.

Patients already presenting with process of abortion, or patients with multiple gestation or with underlying medical comorbidities like cardiac conditions, diabetes mellitus, bronchial asthma, and epilepsy; or with cervical incompetence or with scarred uterus or with cervical lesions or with disseminated intravascular coagulation, or any history of allergy or adverse drug reaction to prostaglandins or with genital infections were excluded from the study.

A total of 150 patients were selected after inclusion and exclusion criteria. Patient details and general and obstetric examination was done. All routine hematological investigations were done. Ultrasound examination was used to confirm the gestational age and their eligibility for MTP.

All the patients were counseled regarding the need for termination of pregnancy and a written informed consent was taken.

Patients were assigned equally into 2 groups. Group A patients: Induction was done using Foley's bulb followed by insertion of intra-vaginal misoprostol 400mcg every 4th hourly till a maximum of 4 doses.

Group B: Induction was done with 200mg of oral Mifepristone, 36-48 hours after which, 400mcg of intra-vaginal misoprostol was inserted every 4th hourly until a maximum of 4-5 doses.

Appropriate methods of statistical analysis were applied to study the efficacy of each method of induction. Means, frequencies were calculated and S.D Chi square test were used to compare categorical variables of significance, the student's t- test was used to test the significant differences between numerical variable.

RESULTS

A total of 150 patients were included in the study. 75 patients were allotted to Group A who were induced with Foley's bulb and misoprostol (400mcg) while the other 75 patients were allotted into Group B who were given mifepristone (200mg) and misoprostol (400mcg).

Most of the patients in both groups belonged to 20-30 years of age (40%). Parous women constituted the majority of the study population in both groups (86%). Primigravid women constituted of 14% of the study population. Among the parous women, multiparous women with above 3 pregnancies (G3) were most common (30%), followed by G2 (27%).

Most of the women in both groups were married. 6.6% of the patients in Group A and 10.6% of the patients in Group B were unmarried. Most of the patients belong to the lower socioeconomic status in both groups.

About 60% (n=45) of the patients in Group A and 50.6% (n=38) of patients in Group B were between the gestational age of 17- 20 weeks.

The most common indication for MTP in both groups was request for MTP, followed by intrauterine death of fetus.

Table 1: Indications of MTP

INDICATIONS	Group A (Foley's induction and misoprostol)	Group B (Mifepristone and misoprostol)	Total
Request for MTP	50 (66.7%)	49 (65.3%)	99(66%)
Presence of fetal anomalies	6 (8%)	9 (12%)	15 (10%)
Anhydramnios	7 (9.3%)	7 (9.3%)	14 (9.3%)
Intra-uterine fetal death	12 (16%)	10 (13.3%)	22 14.6%)
Total	**75**	**75**	**150**

Table 2: N0. of misoprostol doses

PARITY	No. of doses of 400mcg of misoprostol required									
	1 dose		2 doses		3 doses		4 doses		5 doses	
	Group A	Group B	Group A	Group B	Group A	Group B	Group A	Group B	Group A	Group B
Primi	0	0	0	3	8	4	5	7	1	1
G2	0	2	3	6	15	8	1	1	1	0
G3	1	4	14	13	2	2	0	1	1	0
G4	2	5	10	9	2	1	0	0	0	0
>G4	3	5	5	3	1	0	0	0	0	0
Total	6 (8%)	16 (21.3%)	32 (42.6%)	34 (45.3%)	28 (37.3%)	15 (20%)	6 (8%)	9 (12%)	3 (4%)	1 (1.3%)

No. of misoprostol doses decreases with increasing gestational age and the P- value by chi-square tests is highly significant which is 0.001.

Table 3: Induction to Abortion Interval (I-A-I)

PARITY	Group A (Foley induction + Misoprostol (Mean hours))	Group B (Mifepristone + Misoprostol (Meanhours))
Primi	12.7	11
G2	11.8	10.2
G3	8.9	8.1
G4	7.5	6.9
>G4	7.1	6.1

Induction to abortion interval decreases with increasing parity. Induction to abortion interval is relatively lower for Group B (Mifepristone with Misoprostol) in comparison to Group A (Foley induction with Misoprostol). However, the induction to abortion interval on comparing both the methods was found to be statistically insignificant (P-value is >0.050 by chi-square test).

22% of patients in Group A and 21% of patients in Group B had severe abdominal pain, which was the most common side effect observed, followed by fever with chills and rigor (10% in Group A and 6.1% in Group B). Two patients in Group A had diarrhoea. 8% of patients in Group A and 3.1% of patients in Group B had complaints of vomiting.

Table 4: Analysis of complete abortion

POST ABORTAL USG	Group A (Foley induction and Misoprostol)	Group B (Mifepristone and Misoprostol)	Total
Nil products left	70 (93.3%)	75 (100%)	145 (96.6%)
Retained products of conception	5 (6.7%)	0	5 (3.3%)
Total	75	75	150

All patients in Group B had complete evacuation on ultrasound examination (100%) while only 93.3% of patients in Group A had complete evacuation. The rest 6.7% of patients in Group A had retained products of conception for which check curettage was done for complete evacuation. The success rate of complete abortion was 100% for Group B which is statistically significant (p-value = <0.050), while for Group A the success rate was 93.3%.

Table 5: Complications

COMPLICATIONS	Group A (Foley induction and Misoprostol)	Group B (Mifepristone and misoprostol)	Total
Sepsis	0	0	0
Uterine rupture	0	0	0
Failure of method	5 (6.7%)	0	5 (3.3%)
Need for blood transfusion	12 (16%)	10 (13.3%)	22 (14.6%)
Nil	60 (80%)	65 (86.6%)	125 (83.3%)
Total	75	75	150

5 cases in Group A had failure ie had retained products of conception even after 5 doses of Misoprostol. 16% of patients in Group A and 13.3% of cases in Group B had need for blood transfusion. A total of 83.3% of all study population didn't have any complications.

DISCUSSION

This observational study was conducted over 150 patients in their second trimester to evaluate the efficacy of combination of mifepristone and misoprostol with combination of Foley's bulb induction and misoprostol.

Most of the women in both the groups were in the age group of 20-30 years (40%), which is similar to the study done by Maninder Kauer et al,[10] and Holla R et al.[11]

86% of the women were parous and 14% were primi. Multiparous women with above 3 pregnancies (G3) were most common (30%), followed by G2 (27%) which is similar to the study by Veena et al,[12] who had most of the women G3 and above (53%) and 17.8% primigravid patients in their study.

In the present study, most of the patients were married in both the groups. 6.6% of the patients in Group A and 10.6% of the patients in Group B were unmarried This is similar to study by Maninder Kauer et al,[10] who had 5.6% unmarried females in their study.

Most of the patients in both the groups were between the gestational age of 17- 20weeks in our study unlike in the study by Shanthi Rani Bala Subramanian et al,[13] where majority (56%) of the women were between the gestational age between 13- 16weeks.

In the present study, most common indication for MTP in both groups was request for MTP. However, in the study by Mohamed Rezk et al,[14] and Veena et al,[12] the group of patients who had abortion induced by Foley's, IUFD and Fetal anomaly were the most common indications for MTP , respectively. Shanthi Rani Bala Subramanian et al,[13] in their study had the request for MTP as the most common indication for MTP in group of patients induced with mifepristone and misoprostol, which is similar to present study.

In present study, most of the patients required 2 doses of misoprostol, which is similar to study done by Fathalla MM et al.[15]

The induction to abortion interval is defined as interval from prostaglandin administration to the expulsion of products of conception. In the present study, average induction to abortion interval in foley's induction with misoprostol group is 8.4 hours which is comparable to the study by Mohamed Rezk et al,[14] (8.16hours). In mifepristone with misoprostol method, average induction to abortion interval is 7.9 hours which is comparable to the study by Shanthi Rani Balasubramanian et al,[13] (7hours)

Unsuccesful abortion is defined as evidence of retained products of conception. If the placenta is not expelled in 2hrs, post abortion curettage is required. In the present study, success rate with Foley's induction is 93.3% and success rate with mifepristone is 100%. Mohamed Rezk et al,[14] had a success rate of 100% with Foley's induction. Patel U et al,[16] had also a similar success rate but Shanthi Rani Balasubramanian et al,[13] had a success rate of 98% with mifepristone and misoprostol method.

SIDE EFFECTS:

In the present study, severe abdominal pain is the most common side effect in both groups followed by fever with chills. However in study by Mohamed Rezk et al14 fever with chills and rigor was the most common side effect in Foley's induction group. In study by Shanthi Rani Balasubramanian et al,[13] severe abdominal pain was the most common side effect in patients induced with mifepristone and misoprostol, which is in concordance with present study.

Complications

In present study, no cases of uterine rupture were reported in both grousp. In Group A (Foley's and misoprostol) failure of method occurs in 6.7% of cases where as study by Mohamed Rezk et al3 showed 100% success rate without any failure. In Group B (mifepristone with misoprostol), there were no cases of uterine rupture or failures, however, 13.3% of cases required blood transfusion. This is in concordance with study done by Maninder Kauer et al10 who also reported 0% of uterine rupture, whereas only 4% needed blood transfusion

CONCLUSION

Mifepristone- Misoprostol is an effective procedure for second trimester abortion with less induction-abortion interval and high rates of complete abortion. However, the mifepristone and misoprostol combination is expensive than Foley's induction. The study concludes that mifepristone-misoprostol combination is an effective method for second trimester abortion where cost is not a consideration. In places where mifepristone is not affordable, intracervical foley's catheter and vaginal misoprostol is a safe and effective method for second trimester abortion which is comparable to mifepristone-misoprostol group in terms of effectiveness but less expensive than mifepristone.

Acknowledgment: The authors would like to thank the entire staff of Department of Obstetrics and Gynaecology for providing all the facilities for conducting this study.

Conflicts of Interest: Nil

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