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# A COMPARATIVE STUDY OF SECOND TRIMESTER TERMINATION OF PREGNANCY WITH MIFEPRISTONE AND MISOPROSTOL VS MISOPROSTOL ALONE IN 50 CASES

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**Abstract**

**The aim:** To study the efficacy and safety of combined mifepristone and misoprostol used in second-trimester abortion (≥ 12 and ≤ 20 weeks) in comparison with only vaginal misoprostol.

**Materials and methods:** This study was a prospective comparative randomised clinical study in women attending hospitals in need of a second-trimester abortion, i. e., 12–20 weeks of pregnancy were taken up and divided as Group A – 50 women with mifeprisptone and misoprostol, Group B – 50 women with misoprostol alone Results were analysed according to age, parity, gestational age, average dose of misoprostol required for complete abortion, Induction abortion interval, completeness of abortion, side effects and mean days of hospital stay.

**Results:** Demographic details are comparable and insignificant in the comparison. The average dose of misoprostol (mcg) required for the completeness of abortion in group A is 596±28.28 mcg, and in group B, it is 1148±160.66 mcg ($p<0.001$) which is statistically significant. In the present study, the induction abortion interval is significantly less in group A compared to group B, with $p<0.001$. In addition, 10 out of 50 patients in group A aborted within 7 hours, whereas none in group B. Mean duration of hospital stay in group A is 24 hours. In group B, it is 34.82 hours which is statistically significant with a p-value of <0.001. 12 patients in group A and 26 in group B had side effects like nausea, vomiting, fever, headache and diarrhoea. 8 % of group A and 20 % of group B had a fever. These patients were treated with antipyretics. 6 % in group A and 14 % in group B had nausea and vomiting and were treated with antiemetics. 4 % in group A and 8 % in group B had diarrhoea and were treated with antimotility drugs. 6 % in group A and 10 % in group B had a headache; these patients were treated with NSAIDs.

**Conclusions:** The combination of mifepristone and misoprostol is a highly effective and safe method for second-trimester termination of pregnancy. The amount of misoprostol needed to accomplish the abortion, and the severity of the adverse effects are lower in the mifepristone-primed group than in the misoprostol-alone group. Since there are fewer difficulties, this approach can be employed in hospitals with high patient density.

**Keywords:** mifepristone, misoprostol, medical termination of pregnancy, induction abortion

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## 1. Introduction

According to the MTP Act, medical termination of pregnancy (MTP) in India is allowed for up to 20 weeks. However, there is no ideal or best method for MTP between 13 and 20 weeks

leading to varied complications. Second-trimester abortion forms a small fraction (10–15 %) of total induced abortions. Two-thirds of major abortion-related complications and half of the abortion-related mortality occur in pregnancies terminated after 13 weeks of gestation [1]. Worldwide, 42 million legal abortions and 10 to 12 million illegal abortions occur annually, of which 10 % to 15 % are performed in the second trimester. In India alone, 6.7 million induced abortions occur annually, of which late abortions constitute 10.7 % to 15 % [2–4].

Previously, medical and surgical methods, either alone or in combination, were used to perform MTP in the second trimester with their respective complications. However, there is a constant search for an ideal method for the second-trimester medical termination of pregnancy. A regimen should be characterised by a short induction abortion interval (I-A-I), devoid of serious side effects, high acceptability, easy to perform and cost-effective. The medical method in the second trimester of MTP is found to be effective.

The objective is to investigate the effectiveness of oral mifepristone plus vaginal misoprostol and compare it with only vaginal misoprostol in second-trimester induced abortions (≥12 and ≤20 weeks).

## 2. Materials and methods

This study was a prospective comparative randomised clinical study in 100 pregnancies from January 2015 to august 2016 conducted in a Government maternity hospital, Sultan Bazar, Osmania medical college, Hyderabad.

Women attending the Government maternity hospital, Sultan Bazar, who needed a second-trimester abortion, i.e., 12–20 weeks of pregnancy, were taken up for study. Ethical clearance was obtained.

**Inclusion criteria**: 12–20 weeks of pregnancies that fulfilled indications of MTP, if the pregnancy would involve a risk to the life of the pregnant woman or of the grave injury to her physical or mental health, if there is a substantial risk, that if the child were born, it would suffer physical or mental abnormalities as to be seriously handicapped, pregnancy caused by rape and pregnancy resulting from contraceptive failure.

**Exclusion Criteria**: scarred uterus, ectopic pregnancy, grand multipara and contraindications to misoprostol and mifepristone.

Group A – 50 women with mifepristone and misoprostol

Group B – 50 women with misoprostol alone

All routine investigations were done on all subjects who were subjected to the study.

The study was approved by the ethical committee of Osmania medical college, Hyderabad. The study was conducted on the women attending a Government maternity hospital (date 10/2/2016: Registration. No: M140714047) Sultan Bazar in need of second-trimester abortion, i. e., 12–20 weeks of pregnancies (as per the definition of second-trimester abortion by MTP Act 1971) that fulfilled indications of MTP, as per guidelines of MTP Act of 1971.

Informed consent was obtained from 100 cases; they were randomly selected and divided into 50 each. A detailed history of all the patients was taken. A thorough clinical examination was done, including general, per abdominal, and vaginal examination. All the patients were informed about the success rate of medical termination methods and explained that they may need surgical intervention if it fails. After confirming the GA by ultrasound and written informed consent, medications were given for termination of pregnancy, and they were followed up.

Group A: 50 randomly selected cases received Mifepristone tablet 200 mg orally on an empty stomach. They were allowed to go home half an hour after the mifepristone administration with instructions to return to the gynaecology ward after 48 hours. Women were also informed that, in some cases, abortion might occur at home following mifepristone administration. After 48 hrs, they were admitted, and a 400 mcg tablet misoprostol was placed vaginally under strict aseptic conditions. Then every 6-hour Misoprostol tablet 200 mcg was placed vaginally up to a maximum of five doses, including the first dose.

GROUP B: 50 randomly selected cases were admitted and received the Misoprostol tablet, as mentioned in Group A, without the prior tablet mifepristone. For both groups, monitoring was done $4^{th}$ hourly for Temperature, Pulse rate, BP, and the onset of uterine action. In addition, per vaginal examination was done $6^{th}$ hourly to know the status of the cervix. Side effects of drugs were observed and, if present, were treated accordingly.

After an abortion, the products of conception (fetus and placenta) were examined to see whether the abortion was complete. After fetal expulsion, if the placenta is not expelled in 15–20 minutes, 20 units of oxytocin in 500ml of Ringer lactate solution at 125 ml/hr is started until delivery of the whole placenta or pieces, if any. Surgical evacuation under general anaesthesia was performed if the placenta is retained partially or completely for more than 2 hours. Completeness of abortion was confirmed by USG scan after abortion. Both groups received Inj TT. Rh antibody was given to Rh-negative mothers. Antibiotics were given to those women who underwent surgical intervention.

Success: was defined as the complete expulsion of products of conception within 24 hrs of the first dose of misoprostol.

Failure: was defined as incomplete or those who required surgical evacuation. Induction Abortion Interval (IAI) is the period between the first dose of misoprostol and the complete expulsion of products of conception.

**Statistical Analysis**

Data were entered using Microsoft Excel 2010 and analysed using Epi-Info version 7. Data were summarised in percentages and proportions. Categorical data were analysed using the Chi-square test and numerical data using the 't'-test. $P<0.05$ is considered statistically significant.

## 3. Results

Results were analysed according to age, parity, gestational age, average dose of misoprostol required for complete abortion, Induction abortion interval, completeness of abortion, side effects, and mean days of hospital stay.

All the women in group A were between 20 and 36 years, whereas in group B they were between 19 and 34. Most cases in group A and group B were aged between 20 and 25. The mean age distribution in both groups is almost equal. A maximum number of women in groups A and B belongs to 2nd gravida. In the present study, most of the cases in group A belong to 16 weeks of gestational age and in group B belong to 20 weeks of gestational age. The mean gestational age in groups A and B are 15.86±2.53 and 16.82±2.32, respectively. Both groups are comparable and insignificant (**Table 1**).

**Table 1**

The demographic distribution between the two groups

| Age group (years) | Group A | | Group B | |
|---|---|---|---|---|
| | N | % | N | % |
| <20 | -- | - | 01 | 2 % |
| 20–25 | 33 | 66 % | 26 | 52 % |
| 26–30 | 13 | 26 % | 20 | 40 % |
| >30 | 04 | 8 % | 03 | 6 % |
| Total | 50 | | 50 | |
| Mean±SD | 25.14±3.29 | | 25.22±3.21 | |
| **Gravida** | | | | |
| Primi | 06 | 12 | 13 | 26 |
| G2 | 19 | 38 | 20 | 40 |
| G3 | 18 | 36 | 09 | 18 |
| G4 | 07 | 14 | 08 | 16 |
| **Gestational age in weeks** | | | | |
| 12 | 07 | 14 | 01 | 2 |
| 13 | 03 | 6 | 01 | 2 |
| 14 | 07 | 14 | 08 | 16 |
| 15 | 03 | 6 | 06 | 12 |
| 16 | 11 | 22 | 10 | 20 |
| 17 | 05 | 10 | 04 | 8 |
| 18 | 07 | 14 | 05 | 10 |
| 19 | -- | - | 04 | 8 |
| 20 | 07 | 14 | 11 | 22 |
| Total | 50 | | 50 | |
| Mean Gestational Age | 15.86±2.53 | | 16.82±2.32 | |

The average dose of misoprostol (mcg) required for the completeness of abortion in group A is 596±28.28 mcg, and in group B, it is 1148±160.66 mcg (p<0.001) which is statistically significant. In the present study, the induction abortion interval is significantly less in group A compared to group B, with p<0.001. In addition, 10 out of 50 patients in group A aborted within 7 hours, whereas none in group B. Maximum number of patients in group A aborted between 8–10 hours and in group B between 21–24 hours (**Table 2**).

**Table 2**

Average dosage and abortion interval of misoprostol in both groups

| Average dosage of misoprostol required (mcg) | Group A | Group B | P value |
|---|---|---|---|
| Mean | 596 | 1148.0 | <0.001* |
| Standard Deviation (SD) | 28.28 | 160.66 | |
| Induction Abortion Interval (hours) | | | |
| Mean | 8.72 | 26.32 | <0.001* |
| Standard Deviation (SD) | 1.32 | 5.06 | |

In the present study, 1 case in group A had an incomplete abortion which required evacuation to complete the abortion, whereas, in group B, 6 patients had an incomplete abortion, where evacuation was done. 98 % of group A and 88 % of group B had complete abortions (**Table 3**).

**Table 3**

Comparison of outcome of abortion between the groups

| Outcome of abortion | Group A | | Group B | | P value |
|---|---|---|---|---|---|
| | N | % | N | % | |
| Complete | 49 | 98 | 44 | 88 | 0.03* |
| Incomplete | 01 | 2 | 06 | 12 | |
| Total | 50 | | 50 | | |

The above table shows Mean duration of hospital stay in group A is 24 hours, and in group B, it is 34.82 hours which is statistically significant with a p-value of <0.001 (**Table 4**).

**Table 4**

Mean duration of hospital stay among the groups

| Duration of hospital stay (hours) | Group A | Group B | P value |
|---|---|---|---|
| Mean | 24 | 34.82 | <0.001* |
| Standard Deviation (SD) | -- | 6.08 | |

In the present study, 12 patients in group A and 26 in group B had side effects like nausea, vomiting, fever, headache and diarrhoea **(Table 5**).

**Table 5**

Comparison of side effects between the groups

| Side effects | Group A | | Group B | | P value |
|---|---|---|---|---|---|
| | N | % | N | % | |
| Yes | 12 | 24 | 26 | 52 | 0.003* |
| No | 38 | 76 | 24 | 48 | |
| Total | 50 | | 50 | | |

In the present study, 8 % of group A and 20 % of group B had a fever. These patients were treated with antipyretics. 6 % in group A and 14 % in group B had nausea and vomiting and were treated with antiemetics. 4 % in group A and 8 % in group B had diarrhoea and were treated with antimotility drugs. 6 % of group A and 10 % of group B had a headache, and these patients were treated with NSAIDs (**Table 6**).

**Table 6**
Type of side effects among the groups

| Type of side effects | Group A | | Group B | |
|---|---|---|---|---|
| | N | % | N | % |
| Fever | 04 | 8 | 10 | 20 |
| Nausea & vomiting | 03 | 6 | 07 | 14 |
| Diarrhoea | 02 | 4 | 04 | 8 |
| Headache | 03 | 6 | 05 | 10 |

**4. Discussion**

The study was conducted in the government maternity hospital, Sultan Bazar. The present study includes a total of 100 cases which were randomly divided into two groups of 50 each. Group A received mifepristone and misoprostol, whereas patients in group B received only misoprostol. In the present study, the age of the patients in both the groups ranged between 19 and 35 years, the average being 25.14±3.29 in group A and 25.22±3.21 years in group B. There was not much difference between the groups for maternal age, which was similar to a study done by Saxena et al. [5].

In a study by Madhuri N. et al. [6] age groups ranged between 19 and 35 years. In a study by Jahagirdar SS et al. [7], the mean age distribution was 26.77 years. In a study by Kulkarni K. K. [8] mean age distribution was 20–38 years in both groups. In a study done by Farhadifar, F et al. [9], there is no difference in the distribution of age groups. In a study done by Nagaria et al. [10] mean age distribution in the mifepristone-primed misoprostol group was 30.7 and 28.8 years in the misoprostol-only group.

In the present study, most cases in group A and group B belong to 2nd gravida. There is not much difference in parity distribution between the two groups, which was similar to a study done by Farhadifar F et al. [9], where there was a similar distribution of parity in both groups. In a study done by J.E. Dickinson et al. [5], there is not much difference in parity between the two groups. In a study done by Madhuri N et al. [6], there was no statistical difference in parity between the two groups. In a study done by Kulkarni K.K. [8], most of the cases in the study group and control group were 3rd gravida.

In the present study, the mean gestational age in both groups A and B was 15.86±2.53 and 16.82±2.32 weeks. Most of the patients in both groups belong to 15 – 17 weeks of gestational age. There was no statistical difference in the mean gestational age distribution between the two groups, similar to a study done by Madhuri N et al. [6], where the mean gestational age was 16.5 weeks in group I and 15.9 weeks in group II.

In a study done by Nagaria et al. [10] mean gestational age was 16.04±2.57 weeks in the misoprostol group compared to 16.04±2.57 weeks in the mifepristone primed misoprostol group. In a study by Saxena P. et al. [5], the mean gestational age in the isosorbide mononitrate and misoprostol group was 15.9 weeks and 16.6 weeks in the misoprostol-only group.

The average dose of misoprostol required in the present study is 596 mcg in group A and 1148 mcg in group B with a p-value of <0.001, which is statistically significant and is comparable to a study done by Kulkarni K.K. [8] where an average dose of misoprostol required in the group received mifepristone prior to misoprostol is 600 mcg, and 1600 mcg in the group received only misoprostol. There was a significant reduction in the dose of misoprostol required for completeness of abortion in mifepristone-primed misoprostol cases.

In a study by Akkenapally P.L. [11], the mean dose of misoprostol required in the mifepristone-induced group was significantly less, with a p-value < 0.01. In a study done by Nagaria et al. [10] showed there is a significant reduction in the dose of misoprostol required for completeness of abortion in a mifepristone-primed group with a p-value of <0.001. In a study by Patel U et al. [12], the dose required for the mifepristone pre-induced group was 122 mcg, and in the misoprostol alone group, it was 696 mcg.

In the present study, there was a significant difference in the IAI in both the groups; the mean IAI of 8.72 hours in group A, whereas, in group B, it was 26.32 hours, which is comparable to a study done by Saxena et al. [5] where the mean IAI was 14.8±4.16 hours while in group B the mean induction abortion interval was 12.45±3.9 hours in the misoprostol group.

In a study by Akkenapally P. L. [11], the mean IAI was 6.19 hours in the mifepristone-primed group compared to 10.69 hours in the misoprostol group. In a study done by Madhuri N et al. [6],

mean IAI was 6.2±3.1 hours in a group of patients receiving mifepristone + vaginal misoprostol compared to 11.6±5.4hours in a group receiving mifepristone + oral misoprostol. In a study done by Jahadirdar SS et al. [7], the mean IAI was 13hrs. In a study by Kulkarni K.K. [8], the mean IAI in the mifepristone primed group was 8.15 hours, and in the misoprostol alone group, it was 24 hours. In a study by Patil SB et al. [13], the mean IAI in the mifepristone primed group was 8.25±3.93 hours, and in the misoprostol group, it was 10.99±3.22 hours.

In the present study, 98 % of group A and 88 % of group B had a complete abortion which is statistically significant with a p-value < 0.03 and is comparable to a study done by Akkenapally P. L. [12] where 96 % had a complete abortion in mifepristone primed group and 89 % in misoprostol alone group. In a study by Patel U et al. [13], the complete abortion rate was 100 % in the mifepristone-induced group and 84 % in the misoprostol-alone group. In a study by Nagaria et al. [10], the complete abortion rate was 95 % in the mifepristone-primed group and 90 % in the misoprostol-alone group. In a study by Patil S. B. et al. [13], 96.7 % had a complete abortion in the mifepristone primed group and 90 % in the misoprostol alone group. Finally, in a study done by Madhuri N et al. [6], 83 % had a complete abortion in a group of patients who received misoprostol by vaginal group and 80 % in the group of patients who received misoprostol by the oral group.

Most current guidelines [14] recommend a time interval of 36–48 hours of administration between mifepristone and misoprostol. The mechanism for this basis is due to uterine muscle having maximum sensitivity to prostaglandins and their analogues following such an interval. Sindhuri et al. [15], Hemalatha et al. [16], and Trivedi et al. [17] found that the combination had shorter induction delivery intervals as compared to the misoprostol-only regimen, and the difference was found to be statistically significant.

In the present study, 12 out of 50 patients had side effects in group A, and 26 out of 50 patients in group B had side effects, which got subsided by medication. Most of the patients with side effects in both groups were 2nd gravidas. In a study done by Jahagirdar SS et al. [7], 80 % had no side effects, and 17 % had minor side effects. In a study done by Madhuri N et al. [6], 30 % had side effects in a group of patients receiving misoprostol by the vaginal route and 83.4 % in patients receiving misoprostol by the oral group. In a study by Patel U et al. [13], 4 % in the mifepristone-primed group and 56 % in the misoprostol group had adverse effects. In a study by Partha Mukhopadhyay et al. [9], 90 % in the mifepristone-primed group and 80.7 % in the misoprostol group had no adverse effects. In a study by Nagaria et al. [10], 40 % in the mifepristone-induced group and 52 % in the misoprostol-alone group had side effects. In the misoprostol group, side symptoms like fever and shivering were more common than in the combined therapy group. [17, 18]. According to Panda et al. [19], the two groups did not differ significantly regarding complications suffered during labour and delivery.

In the present study mean duration of hospital stay in group A is 24 hours and 34.82±6.08 hours in group B, which is similar to a study done by Kulkarni K. K. [8] where it is 32 hours in the mifepristone group and 36–72 hours in the misoprostol group.

In the present study, the complication rate was significantly less in the mifepristone-primed group compared to the misoprostol alone group, which was comparable to the study done by Akkenapally P. L. In a study done by Nagaria et al. [10, 11] complication rate was 5 % in mifepristone primed group and 10 % in misoprostol alone group (**Table 7**).

**Table 7**

Comparison of results of the present study with other studies

| AUTHOR | Average dose of misoprostol required(mcg) | | Induction of abortion | | Outcome (complete abortion) | | Side effect | | Complications | | Mean duration hospital stay | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 |
| | A | B | A | B | A | B | A | B | A | B | A | B |
| | 596 | 1148 | 8.72 | 26.32 | 98 % | 88 % | 24 % | 52 % | 2 % | 12 % | 24 | 34.8 |
| Patel U et al[12] | 122 | 696 | 18.9 | 24.29 | 100 % | 84 % | 4 % | 56 % | – | 16 % | less | more |

**Continuation of Table 6**

| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Kulkarni K K[8] | 600 | 1600 | 8.15 | >24 | 100 % | 90 % | 33 % | 63 % | – | 10 % | 32 | 36.7 |
| Jahagirdar SS et al[7] | – | – | 13 | – | 60 % | – | 19 % | – | 6 % | – | – | – |
| Akkenapally P L [11] | 1046 | 1610 | 619 | 10.67 | 96 % | 89 % | 33 % | 33 % | 4 % | 11 % | – | – |
| Present study | 596 | 1148 | 8.72 | 26.32 | 98 % | 88 % | 24 % | 52 % | 2 % | 12 % | 24 | 34.8 |

*Note: group A – Group of women received mifepristone prior to misoprostol; group B – Group of women received only misoprostol*

Hoda A et al. [20] compared to misoprostol alone, the combination of mifepristone and misoprostol was more effective for the induction of labour in IUFD in terms of less misoprostol dosage, oxytocin augmentation, improvement in Modified Bishops score, and shorter induction labour and the delivery interval.

**Study limitations:** As this study was carried out on a small scale with small sample size, further studies with larger sample sizes are required to draw definitive conclusions on the efficacy of misoprostol with or without mifepristone. Therefore, whenever possible, the combined regimen should be used until further studies are available to support misoprostol's efficacy without mifepristone. But both regimens are feasible as far as results are concerned, and a misoprostol-only regimen can be used when mifepristone is not available or affordable.

**Prospects for further research:** Extensive studies, including many patients, are needed to get more information on pre-induction with mifepristone in second-trimester termination of pregnancy.

## 5. Conclusion

The combination of mifepristone and misoprostol is a highly effective and safe method for second-trimester termination of pregnancy. A combination of mifepristone and misoprostol reduces induction abortion interval and dose of misoprostol required and has fewer side effects with fewer surgical and anaesthetic complications. In the present study, there is a shorter induction abortion interval. The dose of misoprostol required for completeness of abortion and side effects are less in the mifepristone primed group compared to the misoprostol alone group. This method can be used in high-density hospitals since the complications are fewer.

## Conflict of interest

The authors declare that there is no conflict of interest in relation to this paper, as well as the published research results, including the financial aspects of conducting the research, obtaining and using its results, as well as any non-financial personal relationships.

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