Original Article

“Comparative study of medical abortion by Mifepristone with vaginal Misoprostol in women < 49 days versus 50 - 63 days of amenorrhoea”

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Abstract

Objectives: To compare the outcome with Mifepristone and vaginal Misoprostol combination in women having amenorrhea ≤ 49 days (group-A) verses 50-63 days. (Group-B) **Methods:** We administered 200 mg of mifepristone to 200 women willing for medical abortion within 63 days of amenorrhea. After 48 hours they were assigned to receive 400 microgram of misoprostol vaginally. At the end of 4 hours, if required, reinstallation of 400 microgram misoprostol vaginally was done. **Results:** Complete abortion rate in women with amenorrhea ≤ 49 days verses 50-63 days were 99.16% and 98.75% respectively. Average duration of bleeding was 6.26 (S.D. 2.43 days) and 6.98 days (2.26 days) respectively and the difference is statistically significant ($p < 0.05$). The proportion of women with induction abortion interval ≤ 4 hours in the two groups as 83.33% and 72.25% respectively. This difference is statistically not significant (Chi-square=3.47, $P > 0.05$). The success rate at the end of 14 days in group A and B was 99.16% and 98.75% respectively and this difference is statistically not significant. (Chi-square = 0.19, $P > 0.05$) **Conclusions:** The combination of oral mifepristone and vaginal misoprostol is currently approved for medical abortion in women with amenorrhoea up to 49 days (7 weeks gestation). Our study has demonstrated that the use of this combination can be effectively and safely extended for inducing abortions in women with amenorrhoea up to 63 days (9 weeks gestation).

Keywords: medical abortion, mifepristone and misoprostone.

Introduction

Abortion is one of the most fundamental health care need of a woman!

In spite of legislation of abortion, the incidences of il-

legal & unsafe abortion have not come down in our country & quality & coverage of MTP services remain poor. Septic abortion contributes to 10% of maternal mortality. So high quality safe abortion services should be available even at grass root levels to avoid the risk of women turning to un-authorized personnel. Significant advances have occurred during last 15 years in the development of medical methods for pregnancy termination. Use of drugs to induce abortion is safe and non-invasive alternative. The training is simpler and complications are minimum. This can be an attractive option for healthcare systems of developing countries where limited resources and trained personnel are available to carry out surgical abortions. Medical abortion with a combination of Mefipristone and Misoprostol is safe and effective alternative to Suction & Evacuation

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Table I: Baseline Characteristics.

Characteristics	Gestational age ≤ 49 days (Group A) (n=120)	Gestational age 50-63 days (Group B) (n=80)	Statistical Analysis
1. Age in years Mean $\pm$ SD Range	26.53 $\pm$ 4.11 18-44	26.93 $\pm$ 5.19 18-44	RD=0.57,P>0.05
2. Parity Primigravidas Multigravidas	10(8.33%) 110(91.77%)	4(5%) 76(95%)	Chi-square=0.39,P>0.05
3. Previous MTP	8(6.67%)	5(6.25%)	Chi-Square=0.03,P>0.05
4. Previous LSCS	6(5%)	4(5%)	Chi-Square=0.11,P>0.05

Table II: Induction abortion Interval.

Induction Abortion Interval (In Hours)	Gestational age ≤ 49 days (Group A) (n=120)	Gestational age 50-63 days (Group B) (n=80)
≤ 4	100 (83.33%)	57(72.25%)
> 4	20 (16.67%)	23(28.75%)

Chi-Square: 3.47, P >0.05

Table III: Additional Dose of Misopostol

Gestational age (In Days)	Women required Additional Dose of Misoprostol
≤ 49 (Group A)	20 (16.67%)
$> 50-63$ (Group B)	23(28.75%)

Chi-Square: 3.47, P >0.05

Table IV: Average duration of bleeding.

Gestational age (In Days)	Average duration of bleeding
≤ 49 (Group A)	6.26 SD= $\pm$ 2.43
50-63 (Group B)	6.98 SD= $\pm$ 2.26

R.D. 2.14, P<0.05

Table V: Adverse Effects.

Adverse Effect	Gestational age ≤ 49 Days (Group A)	Gestational age 50-63 Days (Group B)
Abdominal pain requiring Analgesia	18(15%)	30(37.50%)
Nausea	12(10%)	25(31.11%)
Vomiting	4(3.33%)	4(5%)
Diarrhea	-	1(1.22%)

Table VI: Outcome

Gestational Age (In Days)	Success Rate
≤ 49 (Group A)	119(99.16%)
50-63 (Group B)	79(98.75%)
Chi-square=0.19, P>0.05	

up to 9 weeks of gestation.

The present study aims to conduct prospective comparative clinical study using Mefipristone and vaginal misoprostol combination in women having amenorrhea ≤ 49 days and 50-63 days.

Aims and Objective of the study :

To Compare

- The success rate of abortion in group A and group B.
- Induction abortion interval
- Average duration of bleeding

To study the side effects of the drugs.

Material and Methods :

1. Design: Prospective clinical trial.
2. Number of Patients : 200.
Group A: 120 Women with Amenorrhea ≤ 49 days.
Group B: 80 Women with Amenorrhea 50-63 days.
3. Duration of study period : April 2007- September 2007.

Inclusion Criteria:

Gestational age up to 63 days, Commitment to complete the process, adhering to the protocol, Emergency preparedness, Willingness to undergo surgical abortion if failure or excess bleeding.

Exclusion Criteria:

Anemia. Hb < 8 gm%, Suspected / confirmed Ectopic pregnancy/ undiagnosed adnexal, mass, Coagulopathy or anticoagulant therapy, Chronic adrenal failure or steroid therapy, Cardiovascular , renal , liver ,respiratory disease, Glaucoma , uncontrolled seizure disorder, Lack of access to emergency services.

Investigations :

Hb %, Urine, Blood group, USG (TVS), BT, CT .

Methods:

The study was approved by the ethical committee, Government Medical College, Aurangabad. After confirming gestational age by ultrasound, and after written informed consent, following regimen was followed

while prescribing the study drugs.
Mifepristone standard regimen.

Day 1

Women 200 mg Mifepristone orally. Anti-D was given to Rh negative mothers.

Day 3

400 µg Misoprostol vaginally. Schedule was completed even if the woman aborted with mifepristone only. At the end of 4 hrs if patient didn't abort reinsertion of 400 µg vaginally. Women were asked to note onset of bleeding, timing of passage of product of conception, duration of bleeding and side effects.

Day 14

Women were called for follow-up and clinical and ultrasound evaluation was done.

Success was defined as complete expulsion of products of conception with no need for surgical intervention. The induction abortion interval was defined as, "The interval from the administration of prostaglandin to the passage of products of conception". Side effects like abdominal pain requiring analgesia, nausea, vomiting, Diarrhea were noted.

Failure was to be considered if:

- Surgical curettage performed for any reason.
- Cardiac activity persisting 2 weeks following standard protocol.

In present study, continuous variables were presented as mean with standard deviation and ranges. Differences in continuous variables were analyzed with Test of Significance of Difference between Two Means. The differences in proportion were tested with Chi-square test. The demarcating level of statistical significance was probability level of 0.05.

Results

Table I shows the baseline data of the 200 women enrolled in the study. The two groups were comparable in age, parity, previous MTP and previous LSCS.

83.33% women in group A and 72.25% women in group B aborted within 4 hours (Table II). The difference was not found to be statistically significant.

Table III shows requirement of additional dose of Misoprostol in both the groups. 16.67% women in group A and 28.75% women in group B required additional dose. The difference was not statistically significant.

The average duration of bleeding (Table IV) was significantly longer in women with 50-63 days of gestation (6.98 ± 2.26) days as compared with women with gestational age ≤ 49 days (6.26 ± 2.43), $P < 0.5$.

Table V shows adverse effects observed in the two groups.

Table VI shows treatment outcome in the two groups. Complete abortion occurred in 99.16% women in group A and 98.75% women in group B. The difference in the treatment outcome was statistically not significant.

Discussion:

Researchers continue to modify medical abortion regimens to provide optimal alternatives for women seeking early pregnancy termination. The addition of vaginal misoprostol may extend the use of medical abortion up to 9 weeks. The complete abortion rate in our study is in agreement with that of Peyron et al¹. They found a success rate of 98.7% with additional dose of misoprostol. However, they conclude that the addition of second dose of misoprostol does not necessarily increase the overall efficacy.

Ashok et al² reported a high (96.7%) rate of abortion in 1072 women with 50 to 63 days of gestation. Schaff et al³ in their study of 933 women at less than or equal to 56 days of gestation reported a success rate of 97%. Pyamar and Creinin⁴ proved the efficacy of vaginal misoprostol in achieving complete abortion between 7 to 9 weeks of gestation.

There was no statistically significant difference in induction-abortion interval and requirement of additional dose of misoprostol between both the groups in our study. Aubeny et al⁶ reported in his study that the second dose of misoprostol did not improve the efficacy in comparison with the standard regimen.

In our study, the average duration of bleeding was found to be statistically significantly higher in women with higher gestational age. None of the women required blood transfusion. In most of the studies, women bled for median 9 to 13 days yet total blood loss was clini-

cally insignificant. Hemorrhage requiring transfusions occurs in only about 1 in 1000 cases of medical abortions as reported by Grimes et al⁷ in 1997. There are no reports in the literature of laparotomy or hysterectomy for hemostasis after medical abortions⁸. However, the possibility of hemorrhage with medical abortion highlights the need for vigilance and early access to medical help.

Conclusion:

The combination of oral mifepristone and vaginal misoprostol is currently approved for medical abortion in women with amenorrhoea up to 49 days (7 weeks gestation). Our study has demonstrated that the use of this combination can be effectively and safely extended for inducing abortions in women with amenorrhoea up to 63 days (9 weeks gestation).

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