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Original Research Article

The Assessment of the Outcome of Drug Induced Medical Abortion: A Clinic-Observational Study

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Abstract

Aim: To assess the outcome of drug induced medical abortion.

Materials and Method: The present prospective clinic-observational study was conducted in the Department of Obstetrics and Gynaecology, Netaji Subhas Medical College and Hospital, Bihta, Patna, Bihar. 110 women who fulfilled the criteria for the investigation were interviewed. After confirming gestational age by ultrasound the following regimen was followed mifepristone 200 mg stat dose and then after 24 h admitted and started on misoprostol 600 mcg in the posterior vaginal fornix, followed by 400 mcg sublingually until abortion or a maximum of five doses.

Results: Majority of the women were multiparous (83.6%) and the average duration of bleeding was found to be 6.23 days. Majority of the women (89.1%) had Induction Abortion Interval of less than 4 hr. the success rate reported was 98.2%.

Conclusions: Mifepristone-misoprostol medical abortion can complement available surgical services and help meet the pressing need for safe, effective and acceptable abortion services in the developing country like India.

Keywords: MTP, Medical Abortion, Drug.

Introduction

Medical Termination of Pregnancy (MTP) Act was passed by the Indian Parliament in 1971 and came into force from April 1, 1972, and revised again in 1975. Under this Act, termination of pregnancy can be performed up to 20 weeks of gestation where the pregnancy exceeds 12 weeks and not more than 20 weeks (second trimester abortion), the opinion of two registered medical practitioners is required to terminate the pregnancy.

Over the past two decades, the health evidence technologies and human rights rationale for providing safe, comprehensive abortion care have evolved greatly. Medical methods of abortion have been proved to be safe and effective.[1] 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.

Only two studies, however, have focused on the potential use of mifepristone and

misoprostol for medical abortion in developing countries, and only one of these measured the method's acceptability to clients.[2,3] Given the potential of medical abortion to improve conditions for women in developing countries, these women's perceptions of the method in general and of the mifepristone-misoprostol regimen in particular is critical to its acceptability. Patient's attitudes, expectations and tolerance of side effects influence surgical intervention rates; ultimately, for the method to work successfully, women must complete the regimen and wait while the treatment takes its course. Hence the present study was undertaken to assess the outcome of drug induced medical abortion.

Materials and methods

Study Design

The present prospective clinic-observational study was conducted in the Department of Obstetrics and Gynaecology, Netaji Subhas Medical College and Hospital, Bihta, Patna, Bihar. The study protocol was reviewed by the Ethical Committee of the Hospital and granted ethical clearance. After explaining the purpose and details of the study, a written informed consent was obtained.

Inclusion Criteria

- Patients above 18 years of age
- Patients who have signed the informed consent.
- Patients who are willing to undergo surgical abortion if failure or excess bleeding.
- Patients having legal indication for termination of pregnancy and official approval.

Exclusion criteria

- Patients who have not signed the informed consent.
- Patients in which mifepristone and misoprostol is contraindicated.
- Patients suffering from any kind of systemic and neurologic disorder.
- Hemoglobin <8mg/dl

Sample selection

The sample size was calculated using a prior type of power analysis by G* Power Software Version 3.0.1.0 (Franz Faul, Universitat Kiel, Germany). The minimum sample size was calculated, following these input conditions: power of 0.80 and $P \leq 0.05$ and sample size arrived were 106 participants. The final sample achieved was 110.

Methodology

Women who fulfilled the criteria for the investigation were interviewed. A pelvic ultrasound examination was performed to confirm the gestation and to exclude multiple pregnancy and missed abortion. After confirming gestational age by ultrasound the following regimen was followed mifepristone 200 mg stat dose and then after 24 h admitted and started on misoprostol 600 mcg in the posterior vaginal fornix, followed by 400 mcg sublingually until abortion or a maximum of five doses. The side effects including nausea, vomiting, diarrhea and fever were recorded. The blood pressure, pulse, temperature and frequency of uterine contractions are monitored every 3rd hourly. After abortion, the products of gestation (fetus and placenta) were examined to see whether the abortion was complete. After fetal expulsion if placenta is not expelled within 15–20 min, 20 units of oxytocin in 500 ml of lactated Ringer solution at 125 ml/hr is started until delivery of whole placenta or pieces if any. If placenta partial or complete is retained for more, then 2 hr surgical evacuation under general anesthesia was performed. Rh antibody was given to Rh negative mothers.

Statistical analysis

The data was entered in the form of a data matrix in Microsoft Excel® and analysed statistically using IBM® SPSS® version 20.0.0. Descriptive statistics were

calculated as frequencies for categorical variables and means and standard deviation for continuous variables.

Results

Table 1: Demographic and Clinical profile

Age (Years)	**26.14±2.26**
Duration of Bleeding (Days)	6.23±1.48
Gravidity	
Primigravidas	18 (16.4%)
Multigarvida	92 (83.6%)
Induction Abortion Interval	
< 4hr	98 (89.1%)
> 4hr	12 (10.9%)
Additional dose of misoprostol	18 (16.4%)

Table 2: Distribution of adverse effects in study population

Adverse effects	**N (%)**
Pain requiring Analgesia	16 (14.5%)
Nausea	10 (9.1%)
Vomiting	6 (5.5%)
Diarrhea	2 (1.8%)

Table 3: Outcome observed in the study population after intervention

Outcome	**N (%)**
Complete Abortion	108 (98.2%)
In-complete Abortion	2 (1.8%)

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.

Nearly all the women in our study aborted before 24 h like in other similar studies conducted by Elami et al.[4], Dickinson et al.[5], Borgatta and Kapp[6] reported a success rate of 95 % within 24 h. Similarly Peyron et al.[7] also found a success rate of 98.7% with additional dose of misoprostol.

In our study, the average duration of bleeding was found to be 6.23 days. 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 clinically insignificant. Hemorrhage requiring transfusions occurs in only about 1 in 1000 cases of medical abortions as reported by Grimes et al.[8] in 1997 . There are no reports in the literature of laparotomy or hysterectomy for hemostasis after medical abortions. However, the possibility of hemorrhage with medical abortion highlights the need for vigilance and early access to medical help.

In the present investigation the majority of the women (89.1%) had Induction Abortion Interval of less than 4 hr. Wildschut et al.9 in their review article on medical methods for midtrimester termination of pregnancy suggested that mifepristone plus misoprostol is the most efficient regimen and 3-hourly intervals of misoprostol administration are more effective than 6-hourly intervals. Mifepristone enhances the action of misoprostol there by reducing the induction to abortion interval and dose of misoprostol.[10]

In the present study majority of the women were multiparous (83.6%), Heini et al.[11] in their study of clinical efficacy of mifepristone and misoprostol in second trimester termination showed majority of the women were also multiparous and women with early gestation completed medical termination faster.

Conclusion

Our results indicate that the method's success rate in our study was 98.2% and this is the highest documented rate in a developing country and is comparable to the rate found in developed countries. Mifepristone-misoprostol medical abortion can complement available surgical services and help meet the pressing need for safe, effective and acceptable abortion services in the developing country like India.

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