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Efficacy and acceptability of medical abortion with mifepristone and misoprostol in early pregnancy

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ABSTRACT

Introduction: In many countries including India, the only method for termination of early pregnancy has, until recently been surgical namely vacuum aspiration. However, with the medical method, general anesthesia and surgery together with the potential complications related to their use can be avoided. To present the new procedure as an alternative to the surgical method, health care providers need to know its user potential. Valuable opinion for further development of the method can also be obtained from the opinion of women who have undergone the procedure. The success rate of medical abortion in the current study is 90.32%. This can be further increased with either higher dose of misoprostol, or with sublingual misoprostol or any of the previous routes with further follow up with misoprostol administration.
Materials and Methods: This prospective observational follow up study was conducted in a tertiary care hospital in large urban area, where back up facilities are easily available and of reasonably good quality. This study was conducted in the Department of Obstetrics and Gynaecology, I.P.G.M.E & R, Kolkata from 1st June 2010 to 31st May 2011. for the study, A group of 80 early pregnancy abortion seekers ($\leq$ 7weeks of gestation) who attended Out Patient Clinic / Medical Termination clinic of I.P.G.M.E & R / S.S.K.M Hospital, Kolkata were taken. The sample was designed according to the following mentioned inclusion and exclusion criteria. All those patients, who attended Out Patient Clinic of Department of Obstetrics & Gynaecology and satisfied the following selection criteria, were included in the study.
Results: Women who undergo medical abortion experience much more bleeding either in amount or in duration than do surgical patients. Since women's expectations may significantly affect their comfort and satisfaction with a method, medical abortion patients must receive appropriate counseling to prepare them for the method's potential side effects and to judge correctly when an unscheduled visit to the clinic is necessary. Acceptability of low dose mifepristone – misoprostol regimen in the population studied is quite high and women having past experience of surgical abortion have a preference towards surgical abortion.
Conclusion: Nevertheless medical abortion is a revolutionary technique and our study results indicate that mifepristone-misoprostol medical abortion can complement available surgical services and help meet the long standing need for safe abortion.

1. Introduction

Women provide emotional, physical and economic support for their families. The death of a mother is one of the most traumatic events that can befall a family. The United Nations International Conference on Population and Development, Cairo, 1994 recommended that, in order to improve women's reproductive health every effort should be made to reduce unwanted pregnancies. Yet, every year, millions of women are exposed to unprotected intercourse or encounter contraceptive failure, involving risk of unwanted pregnancy. These huge numbers of unwanted pregnancies are terminated by induced abortions. Unsafe abortion which can cause severe illness and death should be prevented at every cost. The safety and efficacy of induced abortion is

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therefore of global public health importance.

Termination of such an unwanted pregnancy has been legal in India (MTP Act, 1971) for more than three decades. The traditional method of termination of early pregnancy has been surgical i.e., mechanical dilation of cervix, followed by uterine evacuation by suction aspiration performed under local / general anaesthesia or sedation. Though safe in hands of expert, the surgical abortion performed by the untrained practitioner under unhygienic conditions, is associated with high maternal morbidity and mortality.

In surgical methods of termination of first trimester pregnancy, there is a likelihood of early complications like haemorrhage and shock due to trauma, incomplete abortion, uterine perforation, and the late complications like infertility due to tubal blockage, cervical incompetence and rupture uterus.

Estimated annual number of induced abortion of India is 6.7 millions. Most of these abortions are performed under unsafe and undesirable conditions, making abortion a vital reproductive health issue for Indian women. Unsafe abortion is a major cause of maternal mortality in India.[1]

Medical method of inducing abortion has always fascinated obstetricians. Mifepristone or RU-486 was invented in France in 1980 and has been used as an abortifacient for medical termination of pregnancy for over two decades.[2] The administration of mifepristone, a powerful antiprogestin, coupled with a prostaglandin (misoprostol) is a highly effective medical method of terminating early pregnancy.

Provision of safe abortion to the full extent of the law[3] is an important component of reproductive health services. In developing countries, where the demand for abortion services is high, such as India, the need for safe and effective alternatives to surgical abortion is great.

Currently, antiprogesterone mifepristone orally followed two days later by prostaglandin analogue misoprostol (orally/vaginally) for this purpose is very promising. This combination is registered as a non-surgical alternative to surgical termination of early intrauterine pregnancy.

The recommended dose of mifepristone in USA is 600mg, but it has been shown by the World Health Organization and others that a lower dose of mifepristone (200 mg) is just as effective as the 600-mg dose.[4] This is especially important for reducing the cost of medical abortions, as it would mean taking only one 200-mg tablet instead of three 200-mg tablets.

There are a few small studies regarding safety, efficacy and acceptability of medical abortion in India. Here we have carried out a study regarding Efficacy and acceptability of medical abortion with mifepristone and misoprostol in early pregnancy. In our study we administered misoprostol orally or vaginally as per abortion seeker's choice. Regarding Indian context WHO's recently published reports dealt mainly with safety and efficacy of medical abortion.[5,6] However, there is very little information available regarding it's acceptability in Indian women.[7]

The current study was planned to evaluate the efficacy and acceptability of medical abortion with low dose mifepristone (200mg) and oral or vaginal 400 mcg misoprostol in early pregnancy ($\leq$ 7weeks of gestation) in Indian women.[8]

1. To evaluate the efficacy of mifepristone-misoprostol regimen for medical abortion in early pregnancy of $\leq$ 7 weeks of gestation. The regimen included 200 mg of oral mifepristone on Day 1 followed by 400 mcg of misoprostol (orally or vaginally administered according to patient's preference) on Day 2-3 (as per national guide lines[8]).
2. To study acceptability of medical method of abortion among abortion seekers in early pregnancy ($\leq$ 7 weeks gestation).
3. To explore the perception of the women regarding the experience of medical abortion procedure. This is particularly to record their satisfaction with medical abortion to assess its acceptability in our set-up.
4. To compare efficacy and acceptability of medical abortion with that of surgical method.

2. Materials and Methods

A total of 80 early pregnancy abortion seeking women with amenorrhoea of less than or equal to 7 weeks(49 days) from the first day of last menstrual period were taken and counseled to participate in the study. All women received standardized counseling about the procedure and their most common side effects. An informed consent form was signed regarding participation in the study. Once they decided regarding the choice of method (medical or surgical) the abortion procedure was carried out according to the chosen method. Those who accepted medical method, were given a choice regarding route of administration of misoprostol (vaginal or oral) and the reason for choosing a particular route of administration was recorded. The participants were also explained about the types of surgical abortion available at the clinic and that this method was nearly 100% effective. Explicit comparisons between medical and surgical abortion were avoided, however, so as not to bias women's selection. For each case, a case record form was completed which included personal details, communication address including telephone no, detailed records of clinical history(obstetric, medical, surgical and gynecological) examination findings(general clinical, abdominal, speculum and vaginal examination) and investigations, procedure carried out and follow-up (refer case record form).

Patients who chose surgical abortion had the procedure in accordance with the clinic's regular standard practice. Reasons for choosing medical abortion (with mifepristone-

misoprostol regime) as well as reasons for refusing medical abortion and choosing surgical abortion were recorded.

Before they proceeded for abortion detailed information was taken regarding the current practice of contraception. They were also counseled regarding future contraception.

Once they accepted abortion, irrespective of the procedure carried out, each of them was followed up until 15 days after abortion.

This study was conducted in the Department of Obstetrics and Gynaecology, I.P.G.M.E & R, Kolkata from 1st June 2010 to 31st May 2011. for the study, A group of 80 early pregnancy abortion seekers ($\leq$ 7weeks of gestation) who attended Out Patient Clinic / Medical Termination clinic of I.P.G.M.E & R / S.S.K.M Hospital, Kolkata were taken. The sample was designed according to the following mentioned inclusion and exclusion criteria. All those patients, who attended Out Patient Clinic of Department of Obstetrics & Gynaecology and satisfied the following selection criteria, were included in the study.

All women attended OPD/MTP Clinic seeking termination of pregnancy up to 7 weeks period of gestation (49 days from 1st day of last menstrual period in women with a regular cycle of 28 days or best estimate) were counseled. Medical abortion was offered with due respect to frame of mind of patient (acceptability of minimum 3 visits, ready for surgical procedure if failure or excessive bleeding occurs), family support, permission of guardian in case of minor as per M.T.P Act, 1971. As per national guidelines 8, women with anaemia (Hb % $<$8 gm %), suspected /confirmed ectopic pregnancy, udiagnosed adnexal mass, associated medical conditions such as coagulopathy, chronic adrenal failure, uncontrolled hypertention with BP $>$160/100mmHg, cardiovascular disease, liver or respiratory diseases, seizure disorder., allergy or intolerance to mifepristone or misoprostol were excluded from our study. It was a prospective observational follow up study. For medical abortion, on first visit (Day 1) and second visit (day 2-3) mifepristone 200 mg orally and misoprostol 400 microgram given orally or vaginally (as per patient's choice) respectively. On third visit (Day 15), assessment of completeness of abortion was done by history and pelvic examination, ultrasonography, if needed. Assessment of side effects and blood loss during the abortion process was done from patient's history. Additional visits in between scheduled visit or after the third visit, were made when required. Counseling was carried out regarding contraception and appropriate contraceptive was prescribed. Investigations such as hemoglobin estimation, ABO grouping and Rh typing, ultrasonography were done accordingly and follow up for confirmation of complete abortion was done by taking the history of cramping, passage of clots with products of conception, small uterus on clinical examination. Success was additionally defined as completing this process without need for a surgical intervention (a suction evacuation / any other procedure).

The efficacy as well as Side-effects and complication rate of the combination of low dose mifepristone (200mg) and oral/vaginal misopristol (400mcg) in induction of early abortion was compared with that of surgical abortion. Any surgical evacuation / curettage performed in the group of medical abortion, was considered as failure of medical abortion. Continuation of pregnancy (presence of gestational sac with cardiac activity two weeks following drug administration) was also considered as failure. Side effects of misoprostol for oral and vaginal route of administration were compared. Acceptability was assessed by overall experience of the women regarding their chosen method of abortion was assessed on a 10 point scale (0-10) by structured questions related to service provision, concordance/discordance between expectation and experience including subjective perception of patient, and further recommendation to others. Each response was allotted 1 or 0 point (except Q. no. 7- allotted point 2/1/0). Summation of all points provided total score which is subdivided in 3 categories (ordinal scale) $\rightarrow$ a) highly satisfied (score $\geq$ 8) b) satisfied (score 5-7) c) not satisfied($\leq$ 4). Final acceptability was reported with combining the outcome of highly satisfied and satisfied categores.7 Satisfaction rates between surgical and medical methods were compared. Response to structured questionnaire regarding acceptability, side-effects, efficacy and satisfaction with medical / surgical method of induced abortion was noted.

Data were analysed using Microsoft Excel 2007 and the statistical software used was Statistical version 6 [Tulsa, Oklahoma: StatSoft Inc., 2001] and MedCalc version 11.6 [Mariakerke, Belgium: MedCalc Software, 2011].

3. Results

We have performed a prospective observational study on early pregnancy abortion seekers ($\leq$49 days gestational age) in a teaching hospital. A total of 80 women were counseled regarding abortion services during the study period. Out of 80, 62 women (77.5%) had chosen medical method and 18 women (22.5%) had chosen surgical method of abortion. Women who opted for medical abortion were younger than those who opted for surgical abortion (26.8 $\pm$ 4.8 years vs 31 $\pm$ 5.7). This difference is statistically significant ($p < 0.05$). Out of 80 abortion seekers 78(97.5%) were married. Among the married women 60 women (75%) had chosen medical method of abortion and 18 women (23.07%) chose surgical method. All the nullipara had opted for medical abortion. There was only one unmarried and one widow among the abortion seekers. Both of them opted for medical abortion. Two groups of abortion seekers were comparable in terms of marital status. Both the groups sought to terminate their pregnancies quite early, and the mean gestational age was similar among those two groups

(43 ± 4.2 days vs 45.2 ± 4.1 days). There were no definite relation between the age of women and their gestational at which they were seeking termination of pregnancy. Mean hemoglobin of the medical abortion group was 10.8 ± 0.91 g/dl and surgical abortion group was 10.4 ± 0.96 g/dl. There was no significant difference of hemoglobin level between the two groups.

Several women had expressed more than one reason for choosing mifepristone-misoprostol regimen for their abortion. Therefore, the percentage in parenthesis cannot be added to make hundred percent. At the time of participating in the study all women in this group were asked to give reasons for choosing medical method. 34% women selected medical method as this involved only oral intake of medication. Privacy, no need for hospital admission and no surgical procedure involved, were the three reasons cited by all the women (100%) for choosing the medical method. Substantial proportion also chose the method as they expected less pain (77.4%) and also for possibility of better fertility prognosis in future (35.4%). None of them had any previous medical abortion experience which could influence their decision making. Only two (3.2%) women selected medical method as they had previous bad surgical abortion experience. Furthermore, only three (4.8%) women wanted to try new method of abortion. Several women had expressed more than one reason for choosing surgical method for their abortion. Therefore, the percentage in parenthesis cannot be added to make hundred percent.

Large proportions of women (72%) choosing surgical abortion said they did so because they perceived it to be a faster procedure. Similar proportions of women chose this method and rejected medical method for fear of prolonged and persistent bleeding per vagina. Six of eighteen women (33%) also decided to undergo surgical abortion because they had good surgical abortion experience in the past. 66% of women opted for surgical method because it is a single step procedure and involves fewer visits. Five women (27%) refused medical abortion because of possibility of failure of this method and need for surgical evacuation in the follow up visits. As the medical abortion seekers had chosen their method to avoid surgery, any woman who underwent a surgical procedure for any reason, was considered as medical method failure. Three types of failure 7 can occur among medical abortion seekers: user's choice, provider choice (or error) and medical failure. User choice failure occurs when a woman seek surgical intervention before the end of the study. Provider failure occurs when a provider performs or recommends medically unwarranted surgical interventions (either out of impatient or in reaction to a concern with no clear medical basis). Medical failure results from an adverse event requiring medically indicated surgical intervention during the study period or an abortion that is not complete by the end of the designated study period, in this case 15 days.

In our study, of 62 women who had chosen medical abortion, 56 women (90.32%) had complete abortion and remaining 6(9.68%) required surgical intervention. So the success rate was quite high and failure rate was very low (9.68%). All failed cases (9.68%) had incomplete abortion at the end of the study and they underwent surgical evacuation later to complete the abortion process. There was no provider failure or user failure in this study. All women were followed up till the end of the study.

Success rate in gestational age <5weeks is 100%. In women with gestational age 5 to ≤ 6 weeks success rate is 92.6%. Success rate is slightly lower (87.8%) in 6 to ≤ 7 weeks gestational age group. So the Success rate decreased or failure rate increased with advancing gestational age. Out of 62 women who had chosen medical method, 56 women had complete abortion at the end of the study. So, the success rate of medical abortion is 90.32%. Only 6 women of medical abortion group had incomplete abortion or medical method failure at the end of the study and the failure rate is 9.68%. Surgical evacuation was done to complete the abortion process in all 6 women who had incomplete abortion. In contrast to the medical abortion group, all the women (100%) of surgical abortion group had complete abortion. There was no case of surgical abortion failure in this study. The p value is 0.328 and the difference between the two groups is not statistically significant. Misoprostol was administered vaginally in 30 women (48.39%) among 62 medical abortion clients and in 32 women (51.61%) misoprostol was administered by oral route. Eleven women (17.74%) among 62 medical abortion clients could not identify any reason for their misoprostol administration route. They were given misoprostol randomly either through vaginal or oral route (6-vaginal and 5-oral). 41.6% women who opted for vaginal route of misoprostol administration felt this route to be more effective than oral route and 58.3% women had chosen this route because of fear of nausea and vomiting with oral administration. Overwhelming majority of women (88.8%) had chosen the oral route of misoprostol administration because of privacy followed by easy administration (25.9%). In our study, 27(90%) out of 30 women who took misoprostol vaginally for their medical abortion had complete abortion or successful medical method. The method failure was seen only in 3 women (10%). The same outcome was seen with oral route of misoprostol administration where 29 (90.62%) out of 32 women had successful complete abortion and only 3 women (9.38%) had incomplete abortion requiring surgical evacuation.

Vaginal bleeding and gastrointestinal symptoms were two major side effects. Vaginal bleeding is a potentially serious complication of medical abortion. A total of 41women (66%) had heavy-moderate bleeding and they

were mostly managed with oral methyl ergometrine except in cases of incomplete abortions where they were managed by surgical evacuation. 19.3% women had heavy bleeding and 46.7% women had moderate vaginal bleeding. Assessment of bleeding was quite subjective; although many women reported heavy bleeding, none of the observed side effects represented a serious medical risk. Abdominal cramp which is a common side effect of prostaglandin, was encountered in 37(60%) women. They were managed with paracetamol 500mg tablets three to four times daily. Nausea, though did not cause much problem occurred in 24 % of women. The incidence of vomiting was low (6%). Nausea and vomiting were managed by oral ondansetron tablets twice daily. Diarrhoea and fever, two common side effects of prostaglandin were not seen in this study. Sixty one percent of women who had chosen surgical abortion experienced pain during the procedure. Seven women (38.8%) out of 18 surgical abortion seekers had moderate vaginal bleeding. No women of this group had heavy vaginal bleeding. Vaginal bleeding usually started after misoprostol administration. The mean interval was 98.8±39 minutes. The bleeding continued for average one week with a range from 4 to 19 days. No women required hospital admission or blood transfusion. Moderate to heavy vaginal bleeding were significantly higher in medical abortion group. Moderate bleeding was seen in 29 women (46.7%) in medical abortion group whereas it occurred in 38.8% women of surgical abortion group. Heavy bleeding was a potentially troublesome side effect (19.3%) of medical abortion group but none of the women in surgical group experienced heavy vaginal bleeding. Medical abortion patients reported more blood loss than did surgical patients. The difference between the two groups is statistically significant ($P < 0.05$). Occurrence of moderate to heavy vaginal bleeding was similar among those who took misoprostol by vaginal route and those who took by oral route (70% vs 62.4%). Gastrointestinal symptoms were more among women who took misoprostol by oral route. But there was no significant difference between the two groups except nausea which was significantly higher among oral misoprostol group (58% in oral vs 20% in vaginal group).p value for nausea is <0.01.

Overall experience of the women regarding their chosen method of abortion was assessed on a 10 point scoring system by structured questions related to service provision, concordance/discordance between expectation and experience, including subjective perception of patients, and further recommendation to others. Each response was allotted 1or 0 point (except Q.no.7-alloted point 2/1/0). Summation of all points provided total score which was subdivided into three categories: highly satisfied (score$\geq$ 8), satisfied (score 5-7) and not satisfied (score$\leq$4). Majority of women (79.03%) in the medical abortion group rated their experience as "highly satisfied" and in surgical abortion group also this experience was quite high(72.22%). Seven women (11.29%) in the medical method group and four women (22.22%) in the surgical abortion group rated their experience as "satisfied". A smaller proportion of women (9.68% of medical patients and 5.56 % of surgical patients) were "not satisfied" with either medical or surgical method of abortion. There was no significant difference of the level of satisfaction between the two groups.

4. Discussion

The women who had chosen medical medical method of abortion in this study were young. All the nulliparous women opted for medical method as also the only unmarried and widow. This is probably because there is no surgical risk and hospital stay. They also believed this method to be more private. Selection of medical abortion more by the unmarried was also seen in the previous study.[8] After proper counseling 77.5% women overall had chosen medical method, this suggests a huge number of surgical abortions, many of which are unsafe, can be avoided in our country by proper information, education and communication. The acceptability of medical abortion can depend heavily on patients' expectations. Women in this study received careful explanations of both medical and surgical abortion methods before they chose their methods. Virtually all women reported that the method chosen had been properly explained. In this study the woman had the option of choosing their method. Nearly 80% of women had chosen medical procedure, which in concordance with Indian arm of population council study.[7] Here the women belonged to wide range of age groups, all socioeconomic strata with varying educational status. Therefore, the results of our study could be extrapolated to a wider population of our country. In previous studies where acceptability was taken into account women chose medical method mainly because it was noninvasive, safer method with less pain and without any hospital stay.[7,8] In our study reasons cited by the women for selecting medical method were similar. However there were few other reasons recorded in our study- the women like oral administration of drugs; better prognosis of fertility in future and intention to try a new method. In our institution surgical abortion is provided free of cost. However, the drugs for medical abortion was not provided by the hospital. This inability to afford the cost of the drugs was one of the reasons for refusing medical abortion and choosing surgical method, because majority of the women came from poor socioeconomic background.

The final acceptability of the method of abortion among clients was assessed by the level of satisfaction with the procedure. Women rated their overall abortion experience as "highly satisfied", "satisfied" and "not satisfied" depending on a 10 point scale (0-10) by structured questions related to service provision, concordance/discordance between expectation and experience, including subjective perception

of patients, and further recommendation to others.

Vast majority of women in the medical abortion group (79.03%) and surgical abortion group (72.22%) rated their experience as "highly satisfied". 11.29% women in medical and 22.22% in surgical group rated their experience as "satisfied". The proportion of "highly satisfied" women is more in medical group. So, the combination of the two categories of "highly satisfied" and "satisfied" gives the final acceptability (90.32%) of medical abortion in our study. All the "not satisfied" clients had method failure in medical abortion group. This high acceptability (90.38%) of medical method of our study was also seen in previous studies.[7–9] Acceptability of surgical abortion in surgical abortion group was also quite high in our study(94.4%) combining the "highly satisfied" and "satisfied" categories. In the Vietnam study and in the Indian arm of population council study overwhelming majority of all women were either satisfied or highly satisfied with their abortion experience regardless of the method.

5. Conclusion

This study shows that the medical abortion using low dose mifepristone followed by oral or vaginal misoprostol has high efficacy (90.32%). It is a safe procedure and though side effects are more common among medical abortion clients than among surgical clients, but they do not jeopardize the safety of the medical abortion regimen and are tolerable for the vast majority of women who choose this method. With appropriate counseling, majority of women (77.5%) had preferred, and ultimately chosen this method of abortion to avoid surgery, anaethesia and hospital admission. Most of the women were either highly satisfied or satisfied with the medical abortion procedure and the proportion of highly satisfied women was higher in medical group than in surgical abortion group suggesting that medical abortion is a highly acceptable method of early pregnancy abortion among our study population. Thus, the results of this study suggest that mifepristone-misoprostol medical abortion is a safe, effective and highly acceptable method of abortion among women asking for early pregnancy legal abortion. This study also suggest that a medical abortion regimen using mifepristone and misoprostol would meet the need for an effective nonsurgical technique in developing countries like India.

6. Source of funding

None.

7. Conflict of interest

none.

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