JOURNAL OF CLINICAL AND DIAGNOSTIC RESEARCH

How to cite this article:
SHARMA R , VERMA U, KHAJURIA B. MEDICAL TERMINATION OF PREGNANCY WITH MIFEPRISTONE – MISOPROSTOL IN RURAL INDIA. Journal of Clinical and Diagnostic Research [serial online] 2008 June [cited: 2008 June 2];3:901-904
Available from
http://www.jcdr.net/back_issues.asp?issn=0973-709x&year=2008&month=June &volume=2&issue=3&page=901-904&id=182b

LETTER TO EDITOR

Medical Termination Of Pregnancy With Mifepristone – Misoprostol In Rural India

SHARMA R *, VERMA U*, KHAJURIA B ***MD.

***Rashmi Sharma** MD.DMCH, Clinical Pharmacologist, Govt Hospital Vijay- Pur, J and K Health Services, Jammu.
****Ujala Verma MD** Drug and Food Control Organisation, Jammu, Jand K- India.
*****Bhupesh Khajuria MD**
Dept of Forensic Medicine and Toxicology, Govt Medical College***, Jammu- J and K- India.

Corresponding Author: Dr Rashmi Sharma MD, DMCH, Clinical Pharmacologist, Govt Hospital Vijay- Pur, J and K Health Services- Jammu, 216-A, Last-Morh, Gandhi-Nagar, Jammu. E.mail: drrashmi@india.com

Sir,

Mifepristone was approved on 28th September 2000 by the FDA for the termination of early pregnancy (49 days or less from the beginning of the last menstrual period)[1]. Mifepristone prevents receptor binding of endogenous or exogenous progesterone, resulting in abortion. Mifepristone softens the cervix and sensitizes the myometrium to the contraction-inducing activity of prostaglandins. It also has antiglucocorticoid and weak antiandrogenic activity. The FDA-approved regimen for medica[1]. abortion consists of taking 600 milligrams (three 200 milligrams tablets) of mifepristone orally on Day 1 in the provider's office, and 400 micrograms (two 200 micrograms tablets) of misoprostol orally on Day 3, also in the provider's office[2]. However, rigorous randomized controlled trials by the World Health Organization have demonstrated similar efficacy with lower doses (200 milligrams) of mifepristone[3]. Mifepristone was licensed for use in India in 2002[4]. Misoprostol has been available as a medication for gastric ulcer treatment. However, both these drugs can be sold only on prescription (as Schedule H drugs, Drug and Cosmetics Rules, 1945)[4]. In addition, the Drug Controller of India registration for mifepristone requires product packaging to mention that it to be used under the supervision of a gynaecologist[4]. However, there are reports of the increased trend of medical termination of pregnancy (MTP) among Indian women[5]. We conducted a pilot study to analyse the pattern of use of Mifepristone – Misoprostol for MTP in rural Indian women.

In the present study, all the women with the history of intake of Mifepristone – misoprostol pills (MAP) within the last one-month attending the Gynaec Out Patient Department of a Government Rural Hospital (GRH) on two fixed days of the week, were included after taking their well informed consent. GRH is located at about 30 kilometers away from the tertiary care hospital, and it caters to the rural population of more than one lac. The study was conducted over a period of six months with effect from 1st February 2007 to 30th September 2007, and a total of 160 women were included in the study. The women visited GRH either for some complication related to MAP use, or to confirm success of medical termination of pregnancy. Ninety (56.25%), 20 (12.50%) and 50 (31.25%) women reported between 10-20 days, 21-30 days, and 2-9 days after administration of mifepristone. All the women were interviewed regarding their

demographic characteristics (gravida, qualification, profession, age, duration of pregnancy at which MAP were taken, income of the family), source of information about MAP, MAP taken as self medication or under a doctor's supervision, concomitant use of other drugs (antibiotics, NSAIDs (anti-inflammatory drugs, iron/calcium, herbal/ayurvedic/homeopathic drugs) and complications or side effects experienced after use of the MAP. All the women were examined for outcome of MAP. Outcome and complications of MAP between self medication and drugs used under the doctor's supervision group were compared using chi-square test, and P-values less than 0.05 were considered as statistically significant.

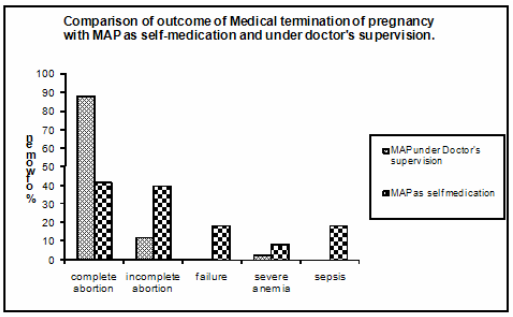
Out of 160 women, 90 (56.25%), 30 (18.75%) and 40 (25%) women were multi-gravida, primi-gravida and grand- multi (>5 pregnancies) respectively. A majority of women were undergraduates and non-working [Table/Fig 1]. A majority of women were from the middle socioeconomic group, and about 90 (56.25%) women were above 30 years of age [Table/fig 1]. Duration of pregnancy was less than 6 weeks, 6-8 weeks, 9-10 weeks, and 11-12 weeks in 90 (56.25%), 40 (25%), 20 (12.50%) and 10 (6.25%) of women, respectively. However, 110 (68.75%) women had taken drugs as self-medication, and brought it without a doctor's prescription. Fifty (31.25%) women, who used drugs under doctor's supervision, requested themselves to the doctors to prescribe them MAP. Doctors and pharmacists/chemists/health workers (female) were found to be the common source of information regarding MTP-pills among women.

Table/Fig 1: Demographic characteristics, complications and outcome of medical termination of pregnancy on study women (n=160).

Patients characteristics	Number (%)	Patients characteristics	Number (%)
Gravida		*Marital status*	
Primi	30 (18.75%)	Married	130 (81.25%)
Multi	90 (56.25%)	Unmarried	30 (18.75%)
Grand multi	40 (25%)		
Qualification			50 (31.25%)
Undergraduate	100 (62.5%)	*Drug taken under doctor's supervision*	
Graduate	40 (25%)		
Postgraduate	20 (12.50%)		
Profession			110 (68.75%)
Housewife(non-working)	110 (68.75%)	*Drug taken as self medication*	
Working	30 (18.75%)		
Student	20 (12.5%)		
Socioeconomic status		*Concomitant use of drugs*	60 (37.5%)
Low	30 (18.75%)	Antibiotics	100 (62.50%)
Middle	100 (62.5%)	NSAIDs	40 (25%)
High	30 (18.75%)	Iron/calcium	80 (50%)
		Ayurvedic/herbal/homeopathic drugs	
Age in years		*Outcome*	90 (56.25%)
<20	20 (12.50%)	Complete	
20-30	50 (31.25%)	Incomplete	20 (12.50%)
>30	90 (56.25%)	Clinically diagnosed	30 (18.75%)
		USG diagnosed	20 (12.50%)
		Failure	
Duration of pregnancy in weeks		*Complications*	
<6	90 (56.25%)	Excessive bleeding	90 (56.25%)
6-8	40 (25%)	Pain	130 (81.25%)
9-10	20 (12.50%)	Mild to moderate anemia	70 (43.75%)
11-12	10 (6.25%)	Severe anemia	10 (6.25%)
		Sepsis	20 (12.50%)
		Nausea/vomiting	80 (50%)

Low socioeconomic class= <1000 per capita per month income, Middle socioeconomic class=Rs 1000-2000 per capita per month income, High socioeconomic class= >2000 per capita per month income, NSAIDs = non-steroidal anti-inflammatory drugs.

NSAIDs and Ayurvedic/herbal/homeopathic drugs were most commonly used, along with MTP-pills in 100 (62.50%) and 80 (50%) of women, respectively. Ninety (56.25%), 50 (31.25%) and 20 (12.50%) women had complete termination of pregnancy, incomplete termination of pregnancy and failure, respectively. The most common side effects reported were pain, excessive bleeding, anaemia and nausea/vomiting [Table/Fig 1]. More women in the self-medication group resulted in incomplete abortion [44(40%) Vs 6 (12%)], failure [20 (18.18%) Vs 0], severe anaemia [9(8.18%) Vs 1(2%)] and sepsis [20(18.18%) Vs 0] than those who used MAP under a doctor's supervision (P<0.001) [Table/Fig 2].



Table/Fig 2

Suction and evacuation was done in 50 (31.25%) women, and pregnancy was continued

in 10 (6.25%) women. Antibiotic cover and iron / calcium supplements were prescribed in 70 (43.75%) and 80 (50%) women, respectively.

In the present study, the trend of MAP use was seen more in the multi-gravida, middle income group, undergraduates and non-working group, with an overall 56.25% success rate. In an earlier retrospective analysis of 25 cases with 9-12 weeks of pregnancy, who underwent medical termination (using a regime of mifepristone followed 48 hours later by a course of vaginal gemeprost), complete abortion was achieved in 96% of cases[6]. Only one woman underwent surgical evacuation in view of heavy bleeding.

In another study on Vietnamese women, the success rate for MAP was extremely high (96%), with incidence of the most commonly reported side-effects like cramping, prolonged bleeding and nausea. Moreover, 32% of women who had previously undergone surgical abortion, selected medical abortion. However, the low success rate in the present study with MAP (56.25%) could be because of use of MAP as self- medication (inappropriate dosage) in 68.75% women. There are a few earlier reports of the use of MAP as OTC (over the counter) drugs also, from various other parts of India[4]. In a study from rural Tamil Nadu, India, 12 of the 37 private doctors who were providing medical abortion to 70-80% of their patients, reported widespread OTC sale of mifepristone[5]. In the present study, multi-gravida women were more likely found to select MAP for termination of pregnancy. However, according to a study from New Zealand, out of total 390 MTP, gravida 1 and nulliparous women were significantly more likely to choose MAP[8].

The use of medical abortion is subject to the provisions of the Medical Termination of Pregnancy Act 1971, which limits legal abortion provision to obstetrician-gynaecologists or generalist providers (those holding an MBBS degree) who have been certified[4]. However, the Medical Termination of Pregnancy Rules were modified in 2003, so that, unlike with surgical abortions, site certification is not required, provided the certified doctor has a demonstrable referral link to a certified centre for back-up care, should the need arise[4].

Serious complications (severe anaemia and sepsis), failure and incomplete abortion were reported more in women taking drug as self-medication than under a doctor's supervision in the present study ($p< 0.001$). Confirmed or suspected ectopic pregnancy or undiagnosed adnexal mass, intrauterine device in place, chronic adrenal failure, concurrent long-term corticosteroid therapy, history of allergy to mifepristone, misoprostol, or other prostaglandin, haemorrhagic disorders or concurrent anticoagulant therapy and inherited porphyries, are some of the contraindications to MAP. These conditions could remain undetected if MAPs are used without the doctor's supervision, and may endanger the life of consumers. Hence, there is need to educate chemists and consumers regarding the complications and contraindications of MAP through print and electronic media; as well as laws regarding OTC sale of drugs should be strictly enforced.

References:

[1] Baird DT. Mode of action of medical methods of abortion. JAMWA 2000;55: 121-6. Center for Drug Evaluation and Research, Food and Drug Administration. NDA 20-687 MIFEPREX (mifepristone) Population Council [drug approval memorandum]. Washington, DC: Department of Health and Human Services; September 28, 2000

[2] World Health Organization. Medical methods for termination of pregnancy. WHO technical report series 871. Geneva: World Health Organization; 1997Manning, Vinoj; Gana tra, Bela; Pallipamulla, Suranjeen Prasad. Availability of medical abortion pills and the role of chemists: a study from Bihar and Jharkhand, India. Reproductive Health Matters 2005. http://goliath.ecnext.com/coms2/gi_0199-5062483/Availability-of-medical-abortion-pills.html#abstract, assessed on 10- 09-20007.

[3] Ramachandar L, Pelto PJ. Medical Abortion in Rural Tamil Nadu, South India: A Quiet Transformation . Reproductive Health Matters 2005; 13: 54-64.

[4] Vyjayanthi S, Piskorowskyj N. Medical termination of pregnancy at 9-12 weeks of gestation. Journal of Obstetrics Gynaecol 2000 ; 22: 669 –671.

[5] Ngoc BNTN, Winikoff B, Clark S, Ellertson C, Ngoc Am K, Hieu DT, et al. Safety, Efficacy and Acceptability of Mifepristone-Misoprostol Medical Abortion in Vietnam. International Family Planning Perspectives 1999; 25:10-4.

[6] Goodyear-Smith F, Knowles A, Masters J. First trimester medical termination of pregnancy: An alternative for New Zealand women. The Australian and New Zealand Journal of Obstetrics and Gynaecol 2006; 46 (3):193–8