FOGSI FOCUS

Medical Abortion

The Federation of
Obstetric & Gynaecological
Societies of India

A FOGSI - MTP Committee Publication

About the cover

The cover depicts all those faceless women who have suffered and continue to suffer the stigma of unsafe abortion.

About the design

This depicts woman empowerment. Empowerment to take unbiased, confident, proactive decision on contraception and abortion.

Unless you perforate the uterus
you cannot be called as a gynaecologist
- An old saying

For years gynaecologist's have been performing MTP's
For years gynaecologist's have been perforating the uterus
This FOGSI focus is dedicated to all the gynaecologist's
who have perforated the uterus
&
To all the women who had their uteri perforated,
their intestines resected & anastomosed
&
To those unfortunate who could not make it
due to haemorrhage & sepsis

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A FOGSI - MTP Committee Publication

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The Federation of
Obstetric & Gynaecological Societies of India

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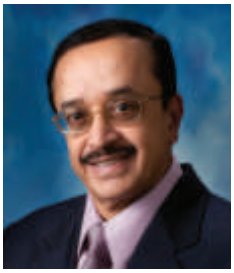
Presidential Message

Dr. P. C. Mahapatra
Professor, O & G
S.C.B. Medical College, Cuttack
President, FOGSI – 2011

Unsafe Abortion has been recognized as one of the significant causes of maternal mortality and morbidity in the developing countries in general and India in particular. After the legalization of abortion in India, we have not able to reduce the abortion related death to bare minimum in spite of safe surgical techniques and trained personnel. Fortunately, with the advent of development of clinical research in newer drugs in the last decade, the concept of medical abortion emerged as one of the safe and effective method for termination of pregnancy. In spite of the fact that this method will be misused in the community, the health care providers have expressed their deep concerns as regards selection criteria, the type of drugs, the dose, its complications and post abortion care.

I am very happy to know that the FOGSI Focus is going to be released in the AICOG 2011 where various aspects of medical abortion has been dealt with in greater detail so as to reach at a consensus out of many many controversial aspects. I am sure this focused booklet under the FOGSI-PSI Partnership – PEHEL initiated by the Chairperson, MTP Committee FOGSI Dr. Kiran Kurtkoti will be a landmark review for the Hon'ble members of FOGSI. I congratulate the committee for this brilliant scientific endeavor.

Presidential Message



Dr. Sanjay Gupte
President FOGSI - 2010

Dear Friends,

It indeed gives me a great pleasure to bring forth the FOGSI focus on Safe Abortions by the MTP Committee. Maternal health has become an extremely sensitive health issue for India and the high maternal mortality a glaring revelation of failure at various social, governmental, economical levels. Yes; we agree that the issue of women dying in India is multifactorial in origin but we as FOGSI have regularly endeavored towards trying to help the situation. The efforts have been small but the urge has always been there.

The various national surveys have revealed that contraception, safe abortions, later age of marriage are important interventions which can help change the maternal health related scenario dramatically. The very poor contraceptive usage of the Indian woman has to be changed. We need to empower women with the knowledge of spacing and each one of us as members must strive to empower them thus.

The FOGSI focus on safe abortions, am very glad to mention is a detailed update on the subject of medical abortions. The advent of Misoprostol in Obstetric practice; has drastically changed the situation favorably and no wonder it is identified as the molecule of the millennium. Likewise the RU 486 (mifepristone) has indeed increased the safety of abortions. However a lot of scientific information as far as the pharmacokinetics are concerned are essential for a practitioner. I am sure that the focus will help guide all regarding this in a scientific manner.

Save the Mother and Newborn Initiative is targeted at reducing the maternal mortality of India and you all as members of FOGSI should actively participate in these projects with great enthusiasm. We have to make a mark and help our mothers. We need to take the step and I am sure with all of us working towards this goal we shall definitely be able to deliver.

Every member should also be in touch with the FOGSI website at a regular basis and use the various Policy statements of FOGSI as reference points in practice. This year we have strived hard to put in place important policy statements & have updated the older ones. I am grateful to all the members who contributed in the drafting of the same and the members of the Managing Committee for their active inputs and participation.

Wish you all a pleasant reading.

Presidential Message

Dr. C. N. Purandare
President - FOGSI 2009

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FRCOG (U.K.), P.G.D.M.L.S., (Law)
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Dear FOGSIANS,

It gives me the great pleasure to present to all of you the FOGSI FOCUS on "Medical Abortion".

Every year approximately 210 million women become pregnant and as many as 80 million of these pregnancies are unplanned. Unintended pregnancies continue to be a major problem that affects not only the individual, but the larger society as well. These occur due to failure of contraceptive method or because the contraceptive method is difficult for the women to use consistently and correctly.

The advent of Medical Abortion has made a great impact on the life of women all over the world.

Medical Abortion has a great potential of being the modern, reliable, safe and non-invasive method of termination of pregnancy which can serve large number of women particularly in developing countries like India. So far the results of Medical Abortions are encouraging however, it is the duty of each and every gynecologist & obstetrician that this method is neither overused nor misused.

The aim of family welfare is to improve maternal and child health by reducing the number of children, spacing of the children and to offer the safest method of abortion in cases of unwanted pregnancies which can drastically reduce the maternal mortality and morbidity.

The topics of this FOGSI FOCUS are very carefully selected and contributors are highly experienced and expert in the field of Medical Abortion. I congratulate Dr. Kiran Kurtkoti, Chairperson, Medical Termination of Pregnancy Committee, FOGSI for doing this wonderful job.

I am sure that this issue of FOGSI FOCUS will make an interesting reading as well as throw lights on the new development in medical abortion and will serve as useful resource to all concerned whose Mission is to reduce Maternal Mortality and Morbidity.

Secretary General's Message

Dr. P. K. Shah
Secretary General - FOGSI
President FOGSI - 2012

I am glad to know that Dr. Kiran Kurtkoti, Chairperson - Medical Termination of Pregnancy Committee of FOGSI & his team have come out with FOGSI Focus on "Medical Abortion". I am confident that the information provided in this FOGSI Focus will tremendously help FOGSI members know and understand all related to Medical abortion.

I congratulate Dr. Kiran Kurtkoti and his team for publishing very informative reading material for FOGSI members.

Treasurer's Message

Dr. Hrishikesh Pai
Treasurer - FOGSI

Medical Abortion has a great potential of being the modern, reliable, safe and non-invasive method of termination of pregnancy which can serve large number of women particularly in developing countries like India. So far the results of Medical Abortions are encouraging however, it is the duty of each and every gynecologist & obstetrician that this method is neither overused nor misused.

It is a fantastic job done by Dr. Kiran Kurtkoti & his team by releasing FOGSI Focus on "Medical Abortion". I am sure the topics written by experts in the field of Medical Abortion will be informative to FOGSI members.

I congratulate Dr. Kiran Kurtkoti, Chairperson, Medical Termination of Pregnancy Committee, FOGSI & his team.

Editorial

Dr. Kiran Kurtkoti

Chairperson-MTP Committee,FOGSI
Member - Pune Obstetric & Gynaecological Society

"No woman can call herself free who does not own and control her body. No woman can call herself free until she can choose consciously whether she will or will not be a mother." - Margaret Sanger

Worldwide maternal mortality due to abortions remained static, at 70 000 deaths per year. Most deaths still occur in sub-Saharan Africa (38 000) and south-central Asia (24 000). This tragic and unnecessary toll follows from an unchanged rate of unsafe abortions: 14 per 1000 women of childbearing age, currently at 20 million annually. Thus, somewhere in the world a woman dies every 8 minutes because of an unsafe abortion.

Unsafe abortions and related complications occur almost exclusively in the developing world, the report states. A poor woman in a rural area is more prone to turn to traditional practitioners and unsafe abortion methods, and is thus three times more likely to experience complications of unsafe abortion and half as likely to receive medical treatment compared with a well-off woman in an urban area. Worldwide, 8 million women have complications from abortion, but only 5 million receive the necessary care.

That access to safe abortion is still highly restricted for women in the developing world . In India , three decades after legalisation, two safe abortions are performed for every three unsafe ones simply because most abortion clinics are located in urban centres while 70% of Indian women live in a rural setting.

Medical Abortion has come a long way since it was first introduced to the world. The worth of the technology has withstood political, medical, legal, media and activist opposition and only emerged the stronger for it.

Reaching the fifth UN Millennium Development Goal—a 75% reduction of maternal mortality worldwide by 2015—will be impossible without successfully addressing unsafe abortions. The focus on abortion should be urgent, immediate, and multidimensional. In the few minutes it has taken to read this text, a woman will have died from an unsafe abortion—the time to act is now.

FOGSI is committed to saving women's lives and the cause of providing safe abortion. Several activities have been undertaken and bought to successful conclusion. We hope that this Focus on Medical Abortion will help in disseminating knowledge about this powerful technology and enable improved access through this to the end users.

The "FOCUS" in the title refers to the fact that a single subject is taken up for a thorough and complete discussion. The concept of the focus was initiated to offer to the health care providers a diverse and wide ranging view on a given topic.

My thanks are due to the experts who have contributed to the preparation of this FOCUS .I would also like to place on record appreciation for Population Services International for making this issue of the focus possible through a generous sponsorship.

Foreword

Dr. Shirish N. Daftary

MD DGO FICOG FICS

Emeritus Professor of Obstetrics & Gynaecology
Former Dean – Nowrosji Wadia Maternity Hospital
Former Medical Advisor N. Wadia Maternity Hospital
Past President – Bombay Obstetric & Gynaec. Society
Vice -President – Indian Academy of Juvenile Ob & Gyn
Former Jt. Associate Editor of Journal Obst. Gyn. India
Past President Fed. Obst. Gynec India (F.O.G.S.I.)
Former Chairman – MTP Committee of FOGSI

The MTP act liberalizing abortions in our country came into force in the year 1972. The objective of the act was to reduce maternal deaths from criminal abortions and safeguarding maternal health. The law indirectly complements and promotes the national family planning programme for population control.

It is timely that FOGSI MTP committee has considered it imperative to publish this FOGSI FOCUS on the subject of MTP to update FOGSI members about the present day practices.

Nearly 15 million abortions are estimated to be taking place in our country every year. Of these 10 million risk their lives by approaching quacks or untrained abortion providers, almost 15,000 to 20,000 women die because of complications.

Rao (2001) estimated that in India, almost 10-11 illegal abortions take place for each legal abortion inspite of having one of the most liberal law prevailing in the country.

The cause of maternal mortality is a result of a complex of medical, cultural, logistic and socioeconomic factors and the available healthcare infrastructure existing in the community. Prominent amongst these are uncontrolled fertility, inaccessibility or non-utilization of health care facilities and the high prevalence of ignorance, low education, cultural inhibitions, mistaken ideas about family pride and the low social status of women in developing countries.

FOGSI under the guidance of President Dr. C.G.Saraiya (1976), established subcommittees to study important health care issues in Obsterics and Gynaecology in our country. Dr. Anusaya Das (New Delhi) was appointed as the first convener. During her 6 year tenure, she collected basic data of MTP from Institutions. I had the privilege of chairing this committee from 1983 onwards for 5 years. During this tenure, the committee collated data from Institutions and private practitioners. Conducted over 40 workshops in various parts of the country to increase awareness, teach safe MTP procedures and collect data for FOGSI. The committee published the first FOGSI publication entitled Handbook of MTP for use of our members.

MTP practices have undergone a sea change over the years. WHO (2003) postulated that all countries should have accessible and safe services in place to provide abortion as permitted under the law. In developing countries where the majority of the people live in rural areas, accessibility to health care facilities gets limited, as also the number of trained healthcare providers authorized to provide safe care abortions falls far short of the optimum numbers required in the country.

The availability of Medical methods of MTP, the expanding role of vacuum aspiration beyond the first trimester, and the role of prostaglandin derivatives has changed the face of MTP. Although second trimester MTPs have reduced in numbers, there is great need to promote conception control to reduce MTP Load.

FOGSI-PSI Pehel Project

Dr. Kiran Kurtkoti
Chairperson-
MTP Committee,
FOGSI

Dr. Ritu Joshi
Chairperson-
Family Welfare Committee,
FOGSI

With a commitment to reduce maternal deaths by preventing unintended pregnancy, The Federation of Obstetric and Gynaecological Societies of India (FOGSI) and Population Services International (PSI), a non-profit entity entered into a partnership for improving maternal health through long term family planning and safe abortions. The launch of FOGSI-PSI partnership –PEHEL was formally announced on October 24th, 2009 in New Delhi.

As part of , Women's Health Project-PEHEL, PSI India is working on two areas – long term spacing methods and medical abortion (MA). The overall objective of the program is as follows.

1. Provide quality IUD services to over 500,000 women and facilitate over 192,000 safe abortions using MA.
2. Increase access and enhance quality of IUD & MA services – by strengthening capacity of existing providers and increasing the provider base.
3. Increase provider and women's access to high quality products for IUD and MA.
4. Implement demand generation and Behavior Change Communication focusing on target audiences and influencers.

Details of proposed activities

1. Orientation and Advocacy workshops at District level

PEHEL is an initiative for addressing family planning needs of the urban poor, in states with the highest population, poor indicators and high need, i.e. Uttar Pradesh, Rajasthan and Delhi. The PSI-FOGSI partnership is geared towards improving access to affordable and high quality IUD services, products and specialized counseling by obstetricians and gynecologists for low and middle income population in these states. The initial workshops have covered Jaipur, Alwar, Jodhpur, Ganganagar, Delhi, Agra, Lucknow, Varanasi, Kanpur, Gorakhpur. We appreciate the efforts of these Societies in organizing the workshops.

FOGSI-PSI Pehel Project

2. **Technical update on IUDs and MA in FOGSI's magazine 'FOGSI FOCUS'**
3. **Research Proposals**

   A KAP survey is a web based survey. We appeal to all FOGSIANS to please take this survey .The statistics that are obtained would be of immense benefit from the point of view of data collection, knowledge dissemination & explaining the benefits of Medical Abortion & IUCD insertion amongst FOGSIANS. Please complete the survey by pressing the link
   http://www.abcofobg.com/demo_MA/welcome.html
   http://www.abcofobg.com/demo_IUD/welcome.html
   which will take through a few simple multiple choice questions .

Phase II

As we launch our partnership in phase II, we would like to thank and congratulate all the esteemed members without whose support we could not have achieved success in our endeavors.

Under PEHEL Phase II, the program is being implemented in 10 districts of U.P viz. – Lucknow, Agra, Gorakhpur, Varanasi, Kanpur, Firozabad, Barabanki, Bareilly, Mirzapur, Ghaziabad and 8 districts of Rajasthan Alwar, Jaipur, Jodhpur, Sriganganagar, Bharatpur, Pali, Kota, Ajmer and in Delhi.

On going Advocacy, Knowledge and skills workshops are going to be organized in all the districts mentioned above under the leadership of the FOGSI Society President & Secretary.

This workshop will orient the members on the details of the project, discuss technical updates, as well as share information material .

Abortion - Global Scenario

Dr. Milind R. Shah

MD, DGO, DFP

2nd Vice President FOGSI (2011)
Past Chairman-Rural Obstetrics Committee of FOGSI (2004-08)
Past President- Solapur OBGY Society (2001-2002)
Executive committee member- ISOPARB
Managing committee member - IAGE
Steering committee member - Asia Safe Abortion Partnership

An estimated 41.6 million abortion occur annually and nearly 19 million (55%) of them are unsafe.[1] Almost there is one unsafe abortion for every 10 pregnancies or one abortion every 7 live births worldwide.[2]

There is almost one unsafe abortion per every woman in developing world.[3] Risk of death from unsafe abortion is highest in sub-Saharan Africa (Middle, Western and Eastern Africa) ranging from 850-900 per 100,000 births.[4]

About 13% of pregnancy related deaths have been attributed to complications of unsafe abortions. Worldwide 70,000 women die each year due to unsafe abortion, 8 million suffer from some or other complications including infertility and only 5 million out of these receive medical care.[5] Complications rate is higher by 100 times if abortion is illegal or unsafe.[6]

This is mainly because of restrictive abortion laws and globally almost 40% of women of childbearing age live in countries with highly restrictive abortion laws.[7] Since 1997, 19 countries have significantly reduced abortion restrictions but three have substantially increased restrictions.[8] By now, in almost all countries the law permits abortion to save the women's life and in most countries abortion is allowed to preserve the physical and mental health of the woman.

At the special session of the United Nations General Assembly in June 1999, governments agreed that "In circumstances where abortion is not against law, health systems should train and equip health service providers and should take other measures to ensure that such abortion is safe and easily accessible. Additional measures should be taken to safeguard women's health."

Table 1: Milestones in the worldwide approval of mifepristone

Year of approval	Countries
1988	France and China
1991	Great Britain
1992	Sweden France changed the approved regimen
1998	Germany

1999	Austria, Belgium, Denmark, Finland, Germany, Greece, Israel, Luxembourg, The Netherlands, Spain and Switzerland
2000	Georgia, Norway, Russia, Taiwan, Ukraine and USA
2001	Tunisia becomes the first African country to approve mifepristone and is soon followed by South Africa
2002	India and Vietnam
2003	Guyana

Conclusion

Safe abortion services, as provided by law, therefore need to be available, provided by well-trained health personnel supported by policies, regulations and a health system infrastructure, including equipment and supplies, so that women can have rapid access to these services. This picture needs to come in reality to nullify the ugly picture of one woman dying per seven minute worldwide due to unsafe abortion.[9]

The global experience with medical abortion also suggests that we should explore alternative protocols that would improve accessibility of medical abortion and its acceptability to women and providers alike. An increased role of mid-level providers in provision of medical abortion, extended gestational age, lower dose of mifepristone and home administration of misoprostol holds the potential to improve access to medical abortion services and increase satisfaction levels of women obtaining abortion services in India.

References:

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2. WHO, "Unsafe Abortion: Global and Regional Estimates of the Incidence of Unsafe Abortion and Associated Mortality in 2003," p.14
3. Asian Congress on Women's Health and sare Abortion, January 2010.
4. WHO, p.19.
5. Ibid, pp.4-5.
6. www.who.int / reproductivehealth / publications / unsafe_abortion_estimates_04 / estimates.pdf
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8. Ibid
9. http://www.womenonweb.org

Medical Method of Termination-Indian Scenario

Dr. Usha Krishna

President, Family Planning Association of India (FPAI) Chairperson, Scientific Advisory Group - Reproductive Health and on Scientific

Advisory Board, Indian Council of Medical Research Hon. Gynecologist, Governor of Maharashtra. Trustee & Member Scientific Advisory Committee, KEM Hospital Research Society, Pune.

On Advisory Committee of Population Foundation of India. President, Federation of Obstetric & Gynecological Societies of India (1993)

President, Mumbai Obstetric & Gynecological Society (1994)

In India, medical method of termination was approved only in 2002 upto 49 days after the last menstrual period. **The Drug Controller has approved the use of Combipack upto 63 days .**

The statistics of abortions are grossly inadequate, as only legal abortions are reported and the ratio of legal to illegal abortions vary from 2:1 (ICMR) to 10:1 (Khan et al). The maternal mortality attributed to abortion in India is 12% - 18% in different states.

Indian Contribution:

Prof. Sune Bergstrom, the noble laureate, set up a WHO prostaglandin task force and included 4 centres in India in 1972. In 1990 we started the study of Mifepristone (RU 486) followed by different PG analogues. Misoprostol PG E1 which is stable at room temperature and has long shelf life is therefore most suitable and is effective orally, vaginally and sublingually. Over the years the author and her colleagues studied about 2500 cases through WHO, ICMR, FPAI, Gynuity Health Project, etc. and later could acquire the drug through the market. The success varied from 88% to 97%. The facilities of medical method of termination was set up at KEM Hospital, Bhatia Hospital, L&T Health Centre and in private clinics. Dr. Coyaji of KEM Hospital, Pune, contributed immensely by doing these studies not only in the FP research centre but in rural areas too. The success rates in urban centre was 94.7%, in research centre it was 96.8% and in rural centre 95.9%, with no significant difference.

Year	Mifepristone 200 mg	Annual Sales
2006 - 2007	3.51 million tablets	Rs. 976 million
2007 - 2008	5.18 million tablets	Rs. 1452 million
2008 - 2009	6.36 million tablets	Rs. 1832 million

Role of FOGSI:

The awareness regarding the safety and efficacy of this method has increased because of various programmes for providers as well as for the community by Government, NGOs, FOGSI, FPAI, IPAS, Gynuity, etc. In April 2002, a statement on medical abortion was presented at Meerut by FOGSI . Later in the same year, a FOGSI Focus was published on Making Abortion Safer. The importance of MVA was emphasized by multi-centric study. A survey of medical abortion use by FOGSI members, was possible with the help of Population Council 2006 and Ipas 2007. There was a comprehensive

Medical Method of Termination-Indian Scenario

Abortion Care Project Consortium, SIDA 2007 where other NGOs such as FPAI contributed. In 2008, FOGSI published a statement on mid-level providers and promoted the project of medical abortion with PSI. Finally, this year there is an excellent Comprehensive Abortion Care Guidelines published by Ministry of Health and Family Welfare, Govt. of India. There were contributions from NGOs such as Parivar Seva Sanstha (PSS) IPAS, ICMR, FOGSI, PSI ,AIIMS and advisors and programme coordinators of Govt. of India. These activities have been conducted under our dynamic chairpersons of MTP committee - Nozer Sheriar, Jaydeep Tank and Kiran Kurtkoti.

FOGSI Statement - April 2002

In a proactive response to the introduction, anticipating allegations of resistance from the profession and recognizing responsibility issues for providers, users and industry, FOGSI adopted and circulated a Statement on Medical Abortion articulating it's official position.FIGO working group on unsafe abortions conducted situational analysis in India in 2008. Cehat, FOGSI, FPAI, Ipas, Lawyer's Collective, SoMI, UNFPA contributed and there were discussions on abortion (facilitated by WHO).

Contribution of FPAI:

FPAI actively participated to reach the message of safe abortion all over India through their 40 branches and various training programmers .

Laxmi Ramachandran studied the impact of cost of abortion (FPAI 2007). She felt that Govt. institutions have questionable quality and women preferred private institutions which cost Rs. 500 - 1000 for 1st trimester and Rs. 5070 for 2nd trimester in Karnataka. The lowest cost was from Rs. 50 - 100 from unqualified providers.

Global Comprehensive Abortion Care Project in India (GCACP) was set up by FPAI with an anonymous and substantial grant to create access for safe abortion services in the need based areas of the country. Medical officers, counselors, nursing staff and volunteers were sensitized and underwent special training to improve the quality of the service and infrastructure of the clinics. Introduction of safe abortion services in 5 new locations and upgradation of 7 clinics as well as introduction of second trimester abortion in two clinics was possible. In one year of 7373 abortions, 1568 were by medical method.

In Tonk district - Rajasthan, training was given to the service providers - 36 medical officers and 36 support staff with the help of 4 master trainers. Dr. Bhargav and her team from Jaipur medical college were very helpful in this SIDA project.

Home administration of Misoprostol has been tried by FPAI in 559 cases through Gynuity Health Projects. Out of 559 seeking termination of pregnancy, 88.4% choose to take Misoprostol at home. There was no statistical difference in the success rate between home and clinic users. Mundle showed 95% efficacy in 99 cases in home use.

At Larsen & Toubro Health Centre more than 400 first trimester medical abortion were carried out (4 studies) including 100 cases with home use. The last study compared sublingual, vaginal and oral administration with comparable results.

Alok Banerjee et al reported medical abortions in 4 clinics in Delhi & Kolkata in 676 women with pregnancy duration of 56 days .400μg of Misoprostol was given orally or sublingually after Mifepristone. The success rate was 92.5 % and 99.3 % respectively.

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Role of NGOS in Facilitating MA Services

Dr. Jyoti Vajpayee
Senior Technical Advisor, Population Services International

Her Choice - Her Voice
I am a woman, my person is my own.
i must decide alone, when my body I share with children I may bear.
I am a woman, I urge you not to see my feminity, as my fecundity!
'Her's is the task, it is her voice which must prerail, about her choice'.
Loella Lobo-Prabhu

Of the 45 million abortions that take place globally every year, about 19 million are unsafe and more than 68,000 deaths annually. Inspite of having a legal and liberal law in India for over three and a half decades, an average of about 11 million abortions take place annually and around 20,000 women die every year due to abortion related complications.

Expanding women's access to safe and legal abortion is a global responsibility and on the agenda of any organization working on Women's Reproductive Health and Rights. There is ample evidence and experience to share that Medical Method of abortion is safe and effective to terminate pregnancies .The NGOs have a role and responsibility in facilitating Medical Abortion (MA) services across the private and public health care sectors.

- Advocacy-To engage with global partners and local governments, organizations and Ministries of Health to promote and advocate for access to safe and legal abortion to every woman who needs it.
- Work with Ministry of Health and Policy makers, legal professional bodies, doctors, lawyers, associations of Obstetricians and gynaecologists, to amend laws/policies that govern the MTP Act.
- Assist MoH in developing and updating standards, guidelines and protocols for implementing MA services.
- To strengthen the efforts of the government in expanding choices of abortion services and trainings including follow up for service providers.
- Share current information and hold conferences/workshops for policy makers, programmers and providers to advance MA in the framework of safe abortion services.
- Carry out communication and media advocacy activities on MA to create awareness in communities about the availability of MA as an option to surgical abortion. There exists a need for early detection of pregnancy and early decision to continue or discontinue the pregnancy. If the option of discontinuing the pregnancy is made early consultation with a trained medical provider is essential.
- Influence Policy makers and key government officials for procurement of Misoprostol and Mifepristone as essential drugs in the Essential drug list.
- Policies to educate chemists /pharmacists on the legal issues around abortions including Medical Abortions. They should also be oriented to MA drugs, dose, importance of completing

the full course and warning signs when clients should seek the services of trained doctors. A study conducted by PSI on chemists revealed that more than 70% MA drugs are dispensed through Chemists without prescriptions.

Currently many NGOs like PSI, Ipas, ICMA, MSI, IPPF,Janani, FPAI are working towards facilitating MA services across the health sector of India and supporting efforts to amend laws to ensure access to all appropriate technologies, including Medical abortion. It is the responsibility of every NGO working for the cause of Women to effectively advance Medical abortion services.

Pharmacology of Misoprostol and Mifepristone

Dr Sujata Misra
MD, FICOG
Associate Professor S.C.B.Medical College Cuttack Chairperson, Medical Disorders in Pregnancy Committee, FOGSI Council Member, Asia Pacific Society for Infectious Diseases in Gynaecology & Obstetrics (APSIGO) Academic Counsellor. Post Graduate Diploma in Maternal and Child Health (PGDMCH) Course ,Indira Gandhi National Open University

&

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MISOPROSTOL

Misoprostol is a synthetic methyl analog of Prostaglandin E1 (15-deoxy-16-hydroxy-16-methyl PGE1) discovered in 1967 by Robert et al. It contains equal amounts of the two diastereomers presented below with their enantiomers indicated by +/-. The structural modifications include

(i) The additiion of CH3 Ester group at C1 which increases the potency and duration of its anti-secretory activities.

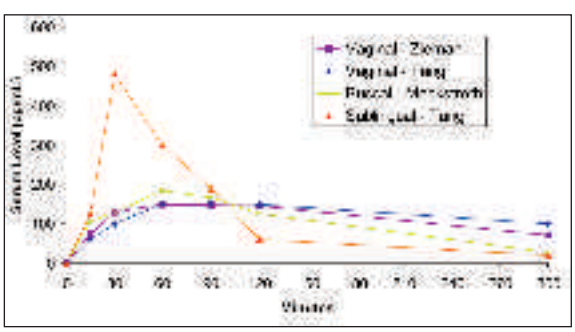
(ii) The transfer of 04 group from C15 to C16 and addition of CH3 group at C-16 improves its oral activities, duration of action and improves its safety profile.

Pharmacodynamics:

- PGE1 Causes myometrial contractions by interacting with the C specific receptors on myometrial cells due to change in calcium concentration, mediated by GI pathway by decreasing cyclic AMP. This results in cervical softening and uterine contractions thus causing expulsion of the uterine contents.

Pharmacokinetics:

- This drug is extensively absorbed and undergoes rapid de-esterification. Thus, the compound is a lipophilic methyl ester prodrug and is readily metabolized to free acid which is the biologically active form.
- Following oral administration, plasma Misoprostol level increases rapidly achieving peak values at 30 minutes and delivers rapidly by 120 minutes remaining low thereafter.
- In contrast, vaginal application of Misoprostol results in slower gradual increase, attaining maximal concentration at 70-80 minutes with values detectable even after 6 hours.



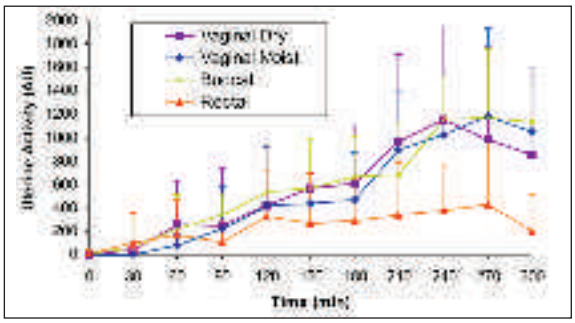
Serum Level Comparison after 400 mcg misoprostol in Four Studies

The serum levels are comparable with all routes. Sublingual route causes a rapid surge & fall in the serum levels of misoprostol.

Action on Uterus:

- Effect of Misoprostol on uterus contractility has been well studied by Gemzell - Damilsson et al and by Aronsson et al. The mean time to increase tonus is 8 min , 11 mins, 20 mins and 103 minutes for oral, sublinqual, vaginal and rectal administration respectively.

Uterine Activity Over 5 Hours :



- Studies on uterine contractility have shown that a sustained level, rather than high serum level is required for development of regular uterine contractions. This depends on the prostaglandin receptors in the uterus which again is related to the gravid state of the uterus and the duration of pregnancy.

Action on Cervix

- Misoprostol causes. cervical ripening by
  - Decreasing total collagen content.
  - Increasing collagen solubility
- Increasing collagenolytic activity.

Indication of Misoprost In OBS And GYN.

1. Medical Abortion
2. Cervical ripening prior to Uterine instrumentation.
3. Cervical ripening prior to induction of labour
4. Prevention and treatment of Post - partum hemorrhage.

Contra Indications ;

- Known hypersensensitivity to Misoprostol or other prostaglandins.
- Co-administration of Misoprost + Mifepristone contraindicated in confirmed or suspected ectopic pregnancy or undiagnosed adnexal mass.
- Hemorrhagic disorder or concomittant anticoagulant therapy.
- Inherited porphyrias.

Adverse Effects : (Incidence is 1-2%)

- GI side effects like Diarrhoea, Abdominal pain Nausea, Flatulence, Dyspepsia.
- Vomitting
- Shivering
- Hyperthermia

Pharmacology of Misoprostol and Mifepristone

PHARMACOLOGY OF MIFERPRISTONE

Description :

- Mifepristone is a synthetic steroid (an anti-progestin RU 486) which was discovered by researchers at Roussel Uclaf of France in 1980.
- Sturcture Mifepristone is a 19-nor steroid with a bulky p-(dimethylamino)phenyl substituent above the plane of the molecule at the 11?-position responsible for inducing or stabilizing an inactive receptor conformation and a hydrophobic 1-propynyl substituent below the plane of the molecule at the 17?-position that increases its progesterone receptor binding affinity. In the presence of progesterone, mifepristone acts as a competitive receptor antagonist at the progesterone receptor (in the absence of progesterone, mifepristone acts as a partial agonist). It effectively competes with both progesterone and gluco-corticoid receptors. Mifepristone was initially thought to be a pure Anti-progestin, but it has some agonistic activity as well, so now aptly considered as Progesterone Receptor Modulator (PRM).

Pharmacodynamics:

- In presence of progestins, Mifepristone acts as a competitive receptor antagonist for both progesterone receptors. **When administered in early pregnancy, it causes decidual breakdown by blockade of uterine progesterone receptors, which leads to detachment of blastocyst resulting in decrease in hCG production. This is turn decreases the progesterone secretion from the corpus luteum which further accentuates decidual breakdown.** This, further enhances uterine contractility. It also causes softening of cervix, which facilitates expulsion of the detached blastocyst.
- Mifepristone also binds to Glucocorticoid and Androgen receptors and exerts Anti-glucocorticoid and Anti-androgenic actions.

Pharmacokinetics:

Absorption :

Rapidly absorbed after oral administration. Peak plasma concentration attained 90 minutes after ingestion. Plasma t ½ = 20 - 40 hours.

Metabolism :

Metabolised in liver to N-di des methyl and N- mono des methyl compound. CYP450 3A4 is primarily responsible for metabolism.

Indications :

1. **Termination of pregnancy upto 63 days.**
2. **Cervical Ripening :** 200 mg mifepristone orally, 24 hours before attempting surgical abortion or induction of labour.
3. **Post coital contraceptives :** 600 mg Mifepristone given within 72 hours of unprotected intercourse interferes with implantation and can be used as an emergency contraceptive.
4. **Once - a - month contraceptive :** Single 200mg Mifepristone given 2 days after mid-cycle each month, prevents conception. But this method is not popular.

5. **Induction of Labour :** By blocking the relaxant action of progesterone on uterus in late pregnancy, Mifepristone can induce labour. It may be tried in cases of IUD to deliver abnormal fetuses.
6. **Other uses :**
   (i) Cushing Syndrome - Palliative. Effect due to blockade of Gluco-corticoid receptors. May be used for inoperable cases.
   (ii) Mifepristone has been studied as Antiretroviral for its in vivo interference with HIV regulator protein (Vpr).
   (iii) Trials continuing for its use in Endometriosis, breast cancer, Ovary cancer, prostrate cancer, fibroid Meningiomas, Major depression with pschyotic features.

Contraindications:

Administration of Mifepristone + Misoprostol for termination of pregnancy in contraindicated in following conditions.

- h/o of Allergy / hypersensitivity to Mifepristone, Misoprostol or other prostaglandins.
- Confirmed or suspected ectopic pregnancy or undiagnosed adnexal mass.
- Chronic Adrenal failure.
- Hemorrhagic disorders or concurrent anti coagulant therapy.
- Inherited porphyries.

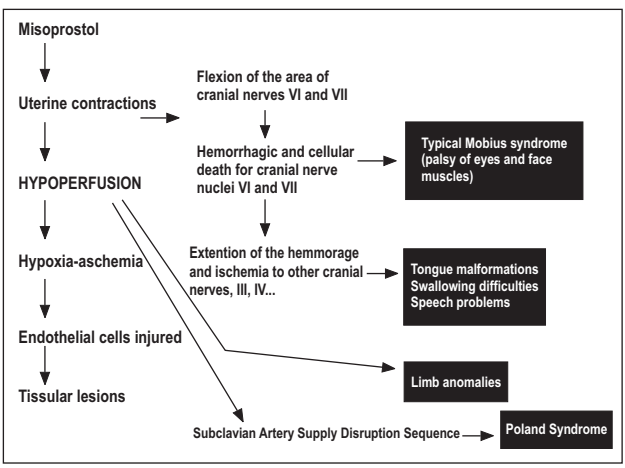
Drug Interaction :

- Ketoconazale, Itraconazole, Erythromycin, may inhibit metabolism of Mifeprisotone.
- Rifampin, Dexamethasone, Anti Convulsant may induce metabolism of Mifepistone.

Teratogenicity of Mifepristone & Misoprostol :

- Mifepristone : One case mentioned sirenomelia - anomaliesfound were (complete lack of amniotic sac; no fetal stomach, gallbladder, or urinary tract;) possibly associated with mifepristone administration in early pregnancy (400 mg at 5 weeks' gestation).
- Misoprostol: Known teratogenic. Causes teratogenicity by mechanical & vascular reasons.

Table: Mechanism of anomalies.



Medico-Legal Aspects of Medical Abortion

Dr. Dilip Walke
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Director, Medipoint Hospital,Pune

Introduction :

The Medical Termination of Pregnancy (MTP) Act that legalizes termination of pregnancy on specified grounds was passed by the Parliament in 1971 & came into effect in 1972.One of the main objectives of introducing the Act was to reduce mortality & morbidity due to illegal abortions. The act was amended in the year 2002, and was notified in the gazette in June 2003.

Q No 1 : Who can prescribe these drugs for termination with medicines?

Ans : The drugs can be prescribed only by registered medical practitioner fulfilling following criteria's under the MTP act 1971

- Has a postgraduate degree or diploma in Obstetrics & Gynaecology
- Registered before the commencement of Act and having experience of 3 yrs in Obstetrics & Gynaecology
- Registered after commence of Act with :
  a) 6 month house post in Obstetrics & Gynaecology or,
  b) More than 1 yr experience in any hospital in Obstetrics & Gynaecology, or
  c) Assisted 25 or more MTP's in a Govt hospital or recognized training centre-out of which 5 or more should have been done independently. This recognizes him/her only for performing 1st trimester MTP.

A registered Medical Practitioner is the one who has a recognized medical qualification under The Indian Medical Council Act no 102 of 1956, section 2 clause h and has his/her name in the State Medical Register This means that prescription for MTP by medicines can never be given by a non-allopathic doctor.

So it is important to remember that only a doctor who is duly qualified under MTP Act can use these drugs.

Q No 2 : Can the drugs be prescribed in a place (e.g. our consulting rooms) which is not registered as a MTP center?

Ans : Doctors who fulfill the above mentioned criteria's can prescribe the drugs at any place (like a

consulting room) which may not be registered as MTP center. However following points need to be confirmed :

- Possession and display of a certificate from the owner of a recognized MTP center allowing the concerned practitioner to report the cases and perform evacuation in case of incomplete MTP
- The consent for (form C), Form I and Form II are maintained for every case and a monthly report sent to the owner of the center affiliated for further reporting.
- It must be understood that all the obligations, liabilities & punishments are equally applicable to the medical termination of pregnancies with drugs, as they would be for any other first trimester MTP.

Q No 3 : What is the maximum gestation age which can be recruited for this method?

Ans : Presently the DCGI approve the use of RU - 486 with Misoprostol (Combipack) only upto 9 weeks or 63 days of amenorrhea.

Tips and tricks to avoid medicolegal problems?

- Consent should be an informed consent. A printed information booklet can be given to the women for reading and a signature is taken to that effect. The information should include following :
- The method is possible for intrauterine pregnancies of less than 9 weeks. It does not terminate ectopic pregnancy.
- 1% women may need surgical evacuation for heavy bleeding
- 2-3% may need surgical evacuation due to incomplete abortion
- 1% may fail to abort. In such a case since there is a possibility of congenital malformation in the fetus a surgical MTP by suction evacuation is advisable.
- 1-2 per thousand may need blood transfusion due to heavy bleeding
- There is a need for three follow-ups (day1, day3 and day 15)and SOS USG in case of excessive bleeding to rule out incomplete abortion
- Next period after the procedure may get delayed by 1-2 weeks but subsequent periods will be on time. It is advisable to use contraceptives till the onset of the next period and report if it is missed for more than 6 weeks.
- More frequent follow ups may be needed in case the bleeding is heavy

Conclusion :

Medical termination of pregnancy with drugs is now legally included under the MTP Act. Hence, it is important to understand & follow all the legal provisions mentioned and also follow the guidelines mention in the "Comprehensive Abortion Care" of the Ministry of Health, Government of India.

Clinical Workup

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Yawatmal MBBS, MD, FICMCH

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Recipient of Dr. Anandibai Joshi Award – Govt. of Maharashtra

Consultant, Sukhakarta Hospital

The following aspects have to be considered while offering medical abortion:

1. **Patient's frame of mind –**
   - acceptibility of minimum 3 follow-up visits.
   - should understand and follow the instructions
   - should give informed written consent
2. **Family support**
   - during emergency family members should be available
   - care of transport to hospital should be looked after by family members.
3. **Easy access to appropriate healthcare facility.**
4. **Guardian's consent is needed if the patient is a minor as per MTP act.**
5. **Should be ready for surgical abortion(intervention) in case of failure or excessive bleeding**
6. **Should have no absolute or relative contraindications.**[1.]

Contraindications

1. Anemia – Hb <8gm% .
2. Suspected / confirmed ectopic pregnancy / undiagnosed adnexal mass
3. Women having a coagulopathy or if she is on anticoagulant therapy.
4. Chronic adrenal failure
5. Uncontrolled seizure disorder
6. Lack of access to 24hrs emergency services
7. Porphyria

The drug needs to be used with caution in:

1) pregnancy with IUCD in situ – *iucd must be removed before medical abortion
2) pregnancy with large submucous fibriod *may cause heavy bleeding

Preabortion Workup and Investigations

I. A comprehensive history

A detailed history regarding the following should be taken

- Menstrual history as LMP is important for gestational dating, which is more important in a 28 day cycle.
- Obstetric history
- Medical disorders

II. A detailed physical examination

- A thorough general examination is necessary to check for anaemia ,icterus, pulse & blood pressure. Systemic examination should be performed to rule out cardiovascular and respiratory problems.
- Bimanual examination usually gives a rough estimate of the gestational age.[1]

III. Pregnancy Testing : Modern urine pregnancy tests using monoclonal antibodies to the subunit of hCG can detect as low as 25mIU/ml. At about the time of missed menses, these tests are positive in 98% of women.

IV. Investigations

- Haemoglobin (Hb%)
- Blood group & Rh typing
- Urine for sugar & proteins

V. Role of Ultrasound [2] (Ref. Chapter on Role of Imaging)

A . It is not mandatory to do perform ultrasound before a medical termination of pregnancy.

B. There are certain situations where ultrasound may be helpful before, during and after a surgical abortion.

C. Ultrasound may be performed for dating a pregnancy with irregular cycles, lactation amenorrhoea, clinical discrepancy or uncertainty in examination and to exclude an ectopic gestation before a medical termination of pregnancy.

References

1. Guidelines for medical officers, WHO-CCR, FOGSI, UNFPA GOI &ICMR,2002
2. FOGSI-ICOG GCPR Guidelines

Role of Imaging - in Medical Abortions

Dr. Manish Machave
MBBS. MD. DNB. MNAMS (OBGYN)
Dip. Endoscopy (Germany)
Consulting Obstetrician, Gynaecologist & Gynaec Endoscopist at Pune

The technology of ultrasound lends itself to being useful to obstetricians and gynecologists for safer practice. This technology can be of value at all stages in a Medical Termination of Pregnancy.

It is important to stress here that by no means should it be considered that the procedure of an MTP is deficient if an USG is not done.

How an ultrasound may help pre-procedure :

- Documentation of pregnancy when there is a doubt about the presence of a pregnancy.
- Dating of pregnancy when it is felt that the patient is not sure of her dates or the clinical examination does not correspond to history.
- Localization of co-existing IUCD
- Diagnosis of co- existing mass
- Ultrasound can confirm co-existing fibroid, its size & location. Though the gestational period & exact size of embryo or fetus is smaller, clinically uterus may be larger.
- Diagnosis of congenital uterine anomalies
- Diagnosis of abnormal pregnancy
- Ectopic pregnancy, Vesicular mole & Missed abortion.

A study from the USA (1) included 1016 women seeking medical abortion. Before women underwent ultrasound scanning, experienced clinicians assessed gestation using a combination of clinical history and bimanual pelvic examination. Clinicians correctly assessed gestational age as no more than 63 days in 87% of women. In only 1% of their assessments did clinicians underestimate gestational age (ie.assess women as under 63 days when they were actually greater than 63 days), which might have increased the woman's chance of failure of medical abortion and requirement for surgical intervention. The investigators concluded that "medical abortion can be safely performed without sonography".

Ultrasound for follow up

The main goal of the ultrasound examination is only the determination of the presence or absence of the gestational sac.

1. Incomplete evacuation :

The major concern for the provider after a medical MTP.

One can see hyperechogenic shadows inside the uterine cavity with collection of fluid (bleeding) as an hypoechoic area. However when a medical abortion has been performed this finding should be interpreted with the clinical situation as the backdrop.

There is some evidence to suggest that an ultrasound done too early can actually increase the rate of surgical procedures required to complete the abortion. There is therefore a learning curve attributed to dealing with the aftermath of the medical abortion. As the provider gains in experience the incidence of surgical intervention reduces.

One must REMEMBER that the mean endometrial thickness 24 hours after using misoprostol in women with a complete medical abortion may range from 7.6 to 29 mm..One week after the abortion, the mean thickness was 11.3 mm but ranged from 1.6 to 24.9 mm. A thickness of more than 15 mm as suspicious for incomplete abortion. However if the thickness is more that 15 mm & the patient is clinically asymptomatic with no P/V bleeding she need not be subjected to vacuum aspiration even if the endometrial thickness is more than 15 mm.. It is normal to visualize clot and debris in the uterus (Harwood et al.)

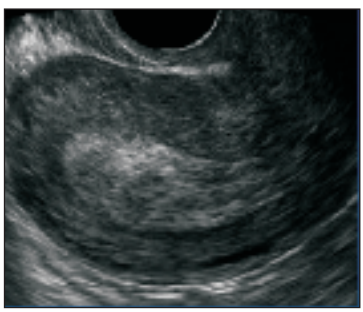


Figure-1-Transvaginal sonogram showing absence of a gestational sac and thickening of the endometrial lining. This thickening, visible as echodense tissue, extends into the lower uterine cavity.

This amount of intrauterine debris is normal and resolves spontaneously without intervention

2. Intact Gestation Sac :

Occassionally an intact sac is found on day 14 without cardiac activity. Management in this situation can be expectant, or may involve a repeat dose of misoprostol or aspiration curettage.

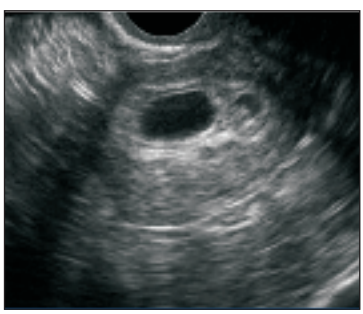


Figure-2- Transvaginal sonogram taken during a follow-up visit after medical abortion with mifepristone/misoprostol. The study shows an empty gestational sac. The edges of the sac are somewhat ragged in appearance, and there is a small hemorrhage in the choriodecidual area.

Role of Imaging - in Medical Abortions

3. Failure of Medical abortion

Presence of cardiac activity 2 weeks after the dose of misoprostol indicates failed medical abortion. If patient complains of continuation of amenorrhoea or pregnancy symptoms USG can confirm or rule out continuation of pregnancy

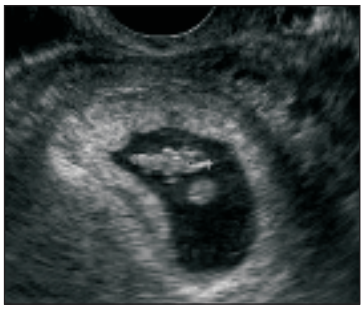


Figure-3- Transvaginal sonogram showing an 8-week fetus with limb buds. The round structure in the center of the gestational sac is the yolk sac. If these findings were obtained 2 weeks after a medical abortion, and cardiac activity were visible, the outcome would be a continuing pregnancy (failed abortion), and aspiration curettage would be indicated.

- Missing an ectopic- This is a uncompounded fear amongst many service providers However a large study done by Gynuity Health Projects, New York showed that ectopic pregnancy was diagnosed very infrequently following medical abortion procedures, occurring in only 10 of 44,789 (0.02%) women. This eliminates the need of mandatory ultrasound before all medical abortions.However if the patient does not bleed 6 hrs. to 8 hrs. after the misoprostol dose then a suspicion of ectopic pregnancy must be made & appropriate diagnostic facility should be restored to.

Ultrasound scanning is not considered to be an essential prerequisite of abortion in all cases.When ultrasound scanning is undertaken, it should be done in a setting and manner sensitive to the woman's situation. It is inappropriate for pre-abortion scanning to be undertaken in anantenatal department alongside women with wanted pregnancies (2).

Role of Ultrasound [3]

A . It is not mandatory to do perform ultrasound before a medical termination of pregnancy.

B. There are certain situations where ultrasound may be helpful before, during and after a surgical abortion.

C. Ultrasound may be performed for dating a pregnancy with irregular cycles, lactation amenorrhoea, clinical discrepancy or uncertainty in examination and to exclude an ectopic gestation before a medical termination of pregnancy.

References:

1. Fielding SL, Schaff EA, Nam N. Clinicians' perception of sonogram indication for mifepristone abortion up to 63 days. Contraception 2002;66:27-31.
2. RCOG Evidence based guideline No 7 Sept 2004.
3. FOGSI-ICOG GCPR Guidelines

Counseling for Medical Abortion

Dr. Basab Mukherjee
MD MRCOG

Consultant Gynecologist Calcutta Medical Research Institute

Introduction

An abortion, besides being a physical experience is also an emotional one for care seekers.Counseling includes advice, information, support, education and therapy. It offers women a nonjudgmental opportunity to work through her feelings.Proper counseling should be offered by a trained health care provider to help her understand the situation and make her own choice.

Counseling for a medical abortion to include :

1. Ensure eligibility

Before offering the option of terminating a pregnancy by medical means it is necessary to check out that there are no contraindications for the same.

Gestational age calculated from the first day of the last menstrual period is often reliable, especially if the preceding menstrual cycles were regular. It is advisable to reconfirm the duration of pregnancy by a pelvic examination. Legally in India, the drug controller has permitted the use of medical abortion drugs (combipack) till 63 days of pregnancy.

It is also important to assess her hemoglobin level and check blood for ABO grouping and Rh typing. Rh - negative women will need a dose of Anti-D Immunoglobulin at the time of first dose during the course of abortion.

The few absolute contraindications are previous allergic reaction, inherited porphyria, chronic adrenal failure and known/suspected ectopic pregnancy.

2. Choosing between abortion methods

Medical abortion may be a preferred option in cases of obese women, those with fibroids or uterine malformations and those with cardiovascular risk factors making surgery risky.

Information should be provided in a non-coercive and unbiased manner.

3. Drug schedule

Clinic administration of mifepristone on day 1 and vaginal misoprostol on day 3 is the usual practice followed by many practitioners. The schedule of drug intake must be clearly explained to the patient. While explaining the drug schedule, schematic diagrams on the prescription are

useful and the use of combination kits (one mifepristone and four misoprostol tablets) convenient. In 5 - 10% of cases, spotting may be noticed, after mifepristone intake and may be mentioned. Misoprostol is preferably administered through the vaginal route, 36 - 48 hours after mifepristone intake.Oral administration, though less effective may be considered at gestational ages less than 49 days. A follow up visit is usually recommended at 15 days to check for completion, advise hematinics and discuss future contraception.

The initial bleeding, soon after misoprostol use, needs to be explained will in most cases be heavy. Women should be aware that spasmodic abdominal pain would usually precede the passing of clots and products of conception for which she may need anti-spasmodics. The bleeding may stay heavy for a few days similar to menstruation but would decrease with time and ultimately stop in a couple of weeks. The chance of an emergency admission in hospital during the evacuation process is remote if counseled adequately.

In case of vomiting of the abortion medicines within 2 hours of ingestion, the dose needs to be repeated again.

4. Possible outcomes & Confirming Success

The success rates for termination done in the first 7 weeks is about 98 - 99% & about 95% when done around 9 weeks.

Typically the abortion process starts with bleeding slightly heavier than periods, which gradually decrease over time. In some cases spotting may persist for two to three weeks. A clinical history of reduced flow/spotting & a pelvic examination at the follow up visit is helpful to confirm completion. It may be mentioned that urine pregnancy test may be positive up to six weeks after the abortion and is misleading in determining success.

Confirming Success

- Progressive decrease of bleeding
- Disappearing pregnancy symptoms
- Pelvic exam at follow up visit
- Ultrasonography
- Serial serum ß-hCG

Partial or incomplete evacuation may be suspected when there are prolonged or intermittent heavy episodes of bleeding, usually lasting for more than two weeks. If a sonography after two weeks suggest retained products, which need to be removed surgically ,the need of antibiotic cover and possible need of blood transfusion would have to be considered.

5. Warning signs and contact numbers

Warning signs

- Persistent/Intermittent heavy bleeding

- Purulent/Foul-smelling vaginal discharge
- Fever with chills
- Giddiness with syncopal attacks
- Severe abdominal pain
- Medical abortion is generally safe.Urgent medical attention should be sough tincase of warning signs.Contact number and address of clinics which provide 24X7 services and the woman should be given.

6. Future Contraception

During the counseling of medical abortion, it is imperative that discussion on future contraception starts at the same time & all options explained .

Suggested Reading :

1. Frequently asked clinical questions about medical abortion. Conclusions of an International Consensus Conference on Medical Abortion in Early First Trimester, Bellagio, Italy. World Health Organization
2. National evidence-based clinical guideline: the care of women requesting induced abortion, London. Royal college of Obstetrics and Gynaecologists, 2004.

Drug Regime

Dr.Kiran Kurtkoti
Chairperson-MTP Committee, FOGSI

Over 30 million abortions are performed every year throughout the world.[1] Medical abortion requires active patient participation and offers several advantages over suction curettage; success with surgery or anesthesia, similar to a "natural abortion" and a more private and proactive patient experience

Studies on Misoprostol Used alone for medical abortion :

To date eight studies written in English have examined the efficacy of misoprostol alone for inducing early abortion. These studies have proved that success rate with misoprostol alone is not satisfactory.

Table 1

The use of misoprostol alone for early termination of pregnancy

Author (year)	Location	Number	Route of administration of Misoprostol	Gestational age	Success rate
Norman, Thong, and Baird (1991)[2]	Lothian, Scotland	40	Oral	<56 days	5%
Creinin and Vittinghoff (1994)[3]	San Francisco, US	30	vaginal	<56 days	47%
Bugalho, Faundes, Jamisse, Usfa; Maria, and Bique (1996)[4]	Maputo, Mozambique.	Ia 45 Ib 57	vaginal	5-7 wk 8-1 1 wk	9% 25% 37%
Koopersmith and Mishell (1996)[5]	California, US	Iia 87 Iib 46	vaginal	5-7 wk 8-11 wk	30% 50% 100%
Carbonell, Varela, Velazco, and Fernandez (1997)[6]	Havana, Cuba	I 10 II 3 III 15 IV 5	vaginal	<10 wk	60% 60%

Carbonell,. Varela, Velazco, Fernandez, and Sanchez (1997)[7]	Havana, Cuba	141 175	vaginal	<70 days	94%
Carbonell, Varela, Velazco, Cabezas, Tanda, and Sanchez (1998)[8]	Havana, Cuba	120	vaginal	<63 days	92%
Jain, Mishell, Mekstroth, and Lacarra (1998)[9]	Los Angeles, US	30	vaginal	64-84 days	87% 97%

The Turning Point (Discovery of Mifepristone)

Mifepristone is an anti-progesterone drug . The anti-progestational activity of mifepristone results from competitive interaction with progesterone at progesterone-receptor sites. It inhibits the activity of endogenous or exogenous progesterone, thereby causing termination of pregnancy. However, it became clear that mifepristone had a maximal effectiveness of 80% when used alone, which was not sufficiently effective to be used as an abortifacient drug in clinical routine.

The final breakthrough came with the discovery that mifepristone increased the sensitivity of the pregnant myometrium to prostaglandins, which allowed use of a reduced dose of prostaglandin. This led to the development of a combined treatment using mifepristone followed by misoprostol.

Combination of Mifepristone and Misoprostol:

Numerous studies have shown the **efficacy** of various regimes of mifepristone and misoprostol or intravaginal gemprost in the termination of early pregnancy upto 49 or 63 days duration, when followed 48 hours later by oral misoprostol or vaginal gemprost.

Reference	Duration of pregnancy (no. of patient)	Mifepristone & PG doses	Outcome (%)	Adverse effect
WHO Task Force Multicenter[10]	<56 days (1182)	200-600mg + 1 mg gemeprost vaginally	94	Pain requiring medication 26% vomiting 23%, dizziness 19%
Peyron et al.[11]	<60 days (890)	600mg + 400ug misoprostol orally	96	Pain requiring medication 13-16%, vomiting 15-17%, diarrhoea 10-14%
McKinley et al.[12]	<63 days (220)	200-600mg + 600ug misoprostol orally	94	Pain requiring medication 46%, opiate 8%, NSAID 38%

Safety and efficacy data from U.S. clinical trails[13] and two French trails[14] are reported. Success was defined as complete expulsion of the products of conception without need of surgical intervention.

Table -2

Outcome Following Treatment with Mifepristone and Misoprostol in the U.S. and French Trials

	U.S.Trials[13]		French Trials[14]	
	N	%	N	%
Complete medical abortion	762	92.1	1605	95.5
Timing of expulsion Before second visit	52	(6.3)	89	(5.3)
During second visit - less than 4 hrs after misoprostol	365	(44.1)	846	(50.3)
After second visit - greater than 4 hrs but less than 24 hrs after misoprostol - greater than 24 hrs after misoprostol	155 370	68 145	(18.7) (22.0)	(8.2) (8.6)
Time of expulsion unknown	122	(14.8)	155	(9.2)
Surgical intervention	65	7.9	76	4.5
Reason for surgery - Medically necessary interventions during the study period	13	(1.6)	NA	NA
Patient request	5	(0.6)	NA	NA
Treatment of bleeding during study	NA	NA	6	(0.3)
Incomplete expulsion at study end	39	(4.7)	48	(2.9)
Ongoing pregnancy at study end	8	(1.0)	22	(1.3)
Total	**827**	**100**	**1681**	**100**

Adverse reactions

	U.S. trials (%)	French Trials (%)
Abdominal Pain (cramping)	96	N. A.
Uterine cramping	N. A.	83
Nausea	61	43
Headache	31	2
Vomiting	26	18
Diarrhea	20	12
Back pain	9	N. A.
Fever	4	N. A.
Decrease in hemoglobin < 2 g/dl	N. A.	6

Regime of Medical Abortion:

A) Upto 49 days :

Day 1: Mifepristone 200 mg orally
Inj. Anti-D to Rh -negative patient

Day 3: Misoprostol 400 μg vaginally or orally

Day 14: Follow-up visit to assess for completion of abortion.

B) Regime from 49 days to 63 days

Day 1: Mifepristone 200 mg orally
Inj. Anti-D to Rh negative patient

Day 3: Misoprostol **800 μg** vaginally or orally

Day 14: Follow-up visit to assess for completion of abortion

Surgical termination is recommended if a viable pregnancy is detected at follow up , because the pregnancy may continue and there is a risk of foetal malformation.

Contraindications

- Confirmed or suspected ectopic pregnancy/undiagnosed adnexal mass.
- Chronic adrenal failure.
- Concurrent long term steroid therapy.
- History of allergy to other prostaglandins.
- Hemorrhagic disorders or concurrent anticoagulant therapy.
- Inherited porphyries
- Because it is important to have access to appropriate medical care if an emergency develops, the treatment is contraindicated if a patient does not have an access to medical facilities equipped to provide emergency treatment of incomplete abortions.

Complications of Medical Abortion and Management

a. Persistent Gestational Sac

If the woman has not expelled the pregnancy by the time of her follow-up visit and the pregnancy is nonviable, she can be offered the following:

1. Expectant management- This means that she will wait for the pregnancy to be expelled naturally; with time, this usually occurs without further intervention. To choose expectant management, the woman must be willing to return to the clinic in approximately one week to ensure that the process is complete.

ii. Administer an additional dose of misoprostol to women who have persistent nonviable gestational sacs.

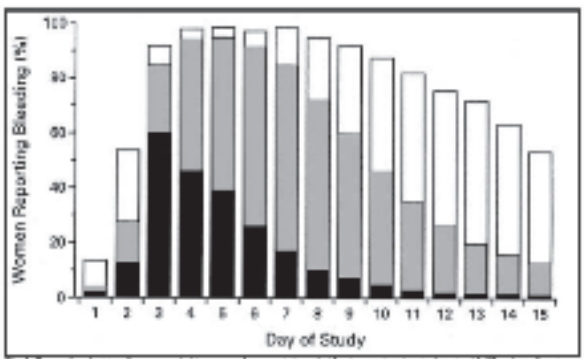
iii. If the woman prefers not to make return visits or is experiencing uncomfortable symptoms, such as heavy bleeding, vacuum aspiration to remove the products is preferred.

b. Continuing Pregnancy

Presence of cardiac activity 2 weeks after misoprostol dose indicates failure of medical abortion . The Mifepristone-Misoprostol combination is effective in 92-97% cases.1-2% may require surgical evacuation due to heavy bleeding, 1-2% may fail to abort, and 2-3% have incomplete abortion for which surgical methods are to be used;0.1 -0.2% may have profuse bleeding requiring blood transfusion.

In this case, the abortion must be completed, preferably using vacuum aspiration.

c. Hemorrhage



Women tend to bleed or spot longer after medical abortion than after abortion using vacuum aspiration. Studies indicate an average duration of bleeding with medical abortion of nine to16 days, though a minority of women may have some bleeding for extended periods of time (Davis et al., 2000). Providers must have clearly documented procedures for assessing and managing abnormally heavy bleeding (> 2 pads per hour for more than 2 hrs.). Acute hemorrhage associated with medication abortion assuming there is no physical trauma to the pelvic organs-is likely to require vacuum aspiration along with fluid replacement and, in some instances, blood transfusion. A US-based study found that out of 80,000 women who received mifepristone and misoprostol for medical abortion, only 13 received blood transfusions (Hausknecht, 2003).

d. Infection

Infection of the uterus is rarely associated with medication abortion. If POC are retained and the woman displays signs and symptoms of uterine infection, uterine evacuation with vacuum aspiration should be performed as soon as broad-spectrum antibiotic treatment has been established. Routine use of antibiotics is not recommended in Medical Abortion. If a woman has vaginal infection, she may be asked to take buccal dose of misoprostol. Researchers (Planned Parenthood Foundation) found that the infection rate dropped 73 percent (from 0.93 to 0.25 per 1,000 abortions) with the adoption of buccal administration of misoprostol, and then

dropped another 76 percent (from 0.25 to 0.06 per 1,000 abortions) after introduction of the screening and antibiotic treatment protocols. Antibiotic prophylaxis is beneficial in patients with vaginal infections. - NEJM 2009.

Antibiotics should cover chlamydial infections & bacterial vaginosis which are commonest organisms infecting the vaginal tract. Doxycycline 100 mg BD x 7 days & Metronidazole 400 mg TDS x 7 days can be the choice of antibiotics to cover the vaginal infection

e. Undiagnosed Ectopic Pregnancy

Ectopic pregnancy was diagnosed very infrequently following medical abortion procedures, occurring in only 10 of 44,789 (0.02%) women. Ectopic pregnancy may go undiagnosed when a woman seeking a medication abortion undergoes clinical assessment before the procedure or an ultrasound before 6 weeks. One should remember ,if the patient does not start P/V bleeding within 6 hrs. to 8 hrs. after the misoprostol dose then a suspicion of ectopic pregnancy must be made & appropriate diagnostic facility should be restored to.

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Post Abortion Contraception

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"Contraceptives should be used at every conceivable occasion." - Spike Milligan

India's population by the year 2050 is projected to reach 1.53 billion, making it the most populous country in the world. As per NFHS-3, the contraceptive prevalence in India is 56.3%, which varies widely among different states and the unmet need for family planning is higher at 13% (6% for spacing).

An Informed Choice Strategy

The principle of informed choice refers to decisions that people can make for themselves-not to a process that family planning programs and providers carry out .Gynaecologists are the service providers and we can help by providing a "cafeteria approach" and allow them to make their choice.

1. Give our patients their desired family planning method unless it is medically inappropriate.
2. Provide clear, unbiased information on the advantages and disadvantages of the various contraceptive methods and explain correct use of the chosen method.
3. Tailor counseling and advice to each patient's expressed needs and personal situation.
4. Refrain from judging the patient and from holding preconceived perceptions about what is best for them.
5. Respect the patient's decision even if they choose a less effective method than your advise.
6. Respect the patient's decision to switch from one method to another.
7. Respect the patient's decision to refuse any or all services

Post – Abortion Contraception

A women's fertility can return quickly after an abortion or miscarriage- as soon as two weeks after (Bongaarts 1983). Post abortion contraception choice is given below in the table -

Method	Time of administration	Advantages	Remarks
OCPills Combined and progestin-only	May be given immediately after abortion using vacuum aspiration or confirmation of completed medical abortion	• Highly effective • Can be started immediately, even if infection is present • Can be provided by non-physicians • Does not interfere with intercourse	• Requires continued motivation and daily use · • Resupply must be available • Effectiveness may be lowered with long-term use of certain medications, including rifampin, dilantin, and griseofulvin
Progesterone only contraception DMPA, NET-EN	May be given immediately after abortion using vacuum aspiration or confirmation of completed medical abortion May be appropriate for use if the woman wants to delay choice of a longer-term method	• Highly effective • Can be started immediately, even if infection is present • Can be provided by non-physician • Does not interfere with intercourse • Not user-dependent, except for remembering to come for injection every two or three months • No supplies needed by user	• May cause irregular bleeding, especially amenorrhea; excessive bleeding may occur in rare instances • Delayed return to fertility after stopping use • Must receive injections every two or three months
Intra-Uterine Device	IUD can be inserted after abortion using vacuum aspiration or after next cycles	• Highly effective Long-term contraception; effective for five to 10 years,depending on the type • Immediate return to fertility following removal • Does not interfere with intercourse • No supplies needed by user • Requires only monthly checking for strings by user • Only one follow-up visit needed unless there are problems	• May increase menstrual bleeding and cramping during the first few months. • May increase risk of pelvic inflammatory disease (PID) and subsequent infertility for women at risk for RTIs and STIs (HBV and HIV/AIDS) • Trained provider required to insert and remove

Post Abortion Contraception

Tubal Ligation	It is to be performed after next menstrual cycles.	• Permanent effective method • Does not interfere with intercourse • No change in sexual function • No long-term side effects	• Adequate counseling and fully informed consent are required before VS procedures • Slight possibility of surgical complications • Requires trained staff and appropriate equipment
Condoms	As soon as she resumes her sexual activity	• Prevents STDs, including HIV/AIDS • Can be used without seeing a health care provider first	• Latex condoms may cause itching for a few people • Small possibility that condom will slip off or break during sex
Vasectomy	This procedure can be done independent of the abortion procedure	• Very effective • Permanent • No interference with sex • No supplies to get, and no repeated clinic visits required • No apparent long-term health risks	• Not immediately effective. At least the first 20 ejaculations after vasectomy may contain sperm. The couple must use another contraceptive method for at least the first 20 ejaculations or the first 3 months-whichever comes first • No protection against sexually transmitted diseases (STDs) including HIV/AIDS.
Emergency Contraceptive Pills	May be used immediately after abortion using vacuum aspiration or confirmation of completed medical abortion	• Important back-up method when contraception fails for example, condom breaks), when no method is used or when sex is forced	• Providing emergency contraceptive pills in advance as a back-up method may help prevent future unwanted pregnancies • No protection from STIs/HIV • Generally less effective than other contraceptive methods • May have side-effects such as nausea and vomiting

* This information applies to methods after first trimester abortion.

Conclusion : Every year India adds the population of Sub-Saharan Africa to the earth. Contraception should become a people's movement rather than be forced upon the people. Family planning should come to mean 'Fewer babies- But better babies'.

FOGSI-ICOG - GCPR Guidelines

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FOGSI ICOG Good Clinical Practice Recommendation Medical Termination of Pregnancy

Consensus Group Meeting at Pune on March 28, 2004 Presented and adopted at FOGSI Managing Committee Meeting at Jammu on April 16, 2004

President, FOGSI :
Dr. Behram Anklesaria

Vice President, FOGSI and Convenor for Consensus statement :
Dr. Sanjay Gupte

Treasurer, FOGSI and Co -Convenor for Consensus statement :
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Chairman MTP Committee, FOGSI (2004-2008) :
Dr. Jaydeep Tank

Core Group Meeting at Pune on October 24, 2010 to discuss revised guidelines

President FOGSI :
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Dr. Kiran Kurtkoti

The recommendations and guidelines in this consensus statement should not be misconstrued as mandatory rules to be followed by all gynecologists. Rather they should serve as a base upon which to build good practice with adequate leeway for specific situations, patients and providers.

The consensus is presented in the following format:

The statement is presented first and if required the context is placed after it. The section context was included as an explanation of the scientific logic behind the statement.

Introduction

The price that women pay simply for being women is unfortunately a nightmare which is appallingly true. The demands of procreation and childbirth take a heavy toll on women's life. One of the most preventable tragedies for womankind is the problem of unwanted pregnancy and unsafe abortion.

Each year about 42 million induced abortions are estimated to be performed worldwide Of these an estimated 20 million abortions are unsafe with developing nations burdened with 97%. The vast majority of women are likely to have at least one abortion by the time they are 45. Even in societies and areas where effective contraception methods are available the abortion rate has not declined to zero although it sharply declines.

In India the annual estimates of abortion vary from 3.9 to 6 million with some projections claiming upwards of 12 million. Even a conservative 3.9 million annual abortions resulted in 70 million abortions in the initial 18 years since 1971 compared to official reported figures of 6.3 million abortions - a gross underestimate - suggesting that a majority of abortions are either not reported or take place illegally. If one takes the reported rate of pregnancy related deaths due to abortions (13%) as a standard for calculating maternal deaths from unsafe abortion this would mean 9.1 million maternal deaths for a 18 year period.

1. Background Situation

1.1. FOGSI acknowledges the magnitude of the problem of unsafe abortion.

1.2. It promotes the services offered for safe abortion and is willing to do whatever possible for the cause of safe abortion in India and wherever legally permitted abroad.

Unsafe abortion is a major problem as has already been emphasized. Almost all the deaths and complications from unsafe abortions are preventable. In countries where women have access to safe abortion services their likelihood of dying as a result of an abortion is no more than one per 200,000 procedures. In developing countries the risk of death following complications of unsafe abortions is several hundred times higher.

It is not surprising that most interventions for safe abortions tend to be those which make safe abortion services easily accessible. Therefore the need to promote training and increase the pool of trained personnel.

2. Evaluation

2.1. Determining the length of the pregnancy

Bimanual pelvic examination and recognition of other symptoms of pregnancy is usually adequate.

Laboratory or ultrasound testing to confirm pregnancy / gestational age is not mandatory but may be used as per the clinician's discretion.

2.2. Investigations

Hemoglobin, blood group, Rh typing, urine sugar and protein testing may be the minimum investigations that are to be performed.

There is much discussion about this aspect of providing safe abortion. The central issue is how much is enough to ensure the safety of the patient without inconveniencing her both in terms of cost and time.

The most basic of all investigations have been recommended. However it is important to keep in mind that as per the WHO technical and policy guidelines, the lack of even the investigations recommended should not be a cause to deny the woman a safe abortion.

It is recognized that there are situations wherein unexpected conditions may be encountered which cannot always be anticipated by investigations. The recommended investigations in no way place the onus on the service provider.

3. Consent for Medical Termination of Pregnancy

3.1. Consent as per form C of the MTP Act is mandatory.

3.2. FOGSI suggests that an informed consent be obtained in a supplementary form.

3.3. An adult woman who is not mentally ill can undergo MTP with only her own consent as provided under the MTP Act.

This section seeks to emphasize certain important but not always appreciated aspects of the MTP act of India. Whilst recognizing that it is essential to be true to the entire act certain issues regarding the consent were chosen to be highlighted.

This statement emphasizes the need to obtain consent for MTP in the required format. The informed consent is not a part of Form C and as such may be obtained separately in a suitable format.

It is emphasized that spousal consent or consent of partner is not required in case a major woman who has no mental illness desires to terminate an unwanted pregnancy.

4. Anesthesia for surgical methods for early abortion

4.1. The choice of the anesthesia should be at the discretion of the attending physician provider.

4.2. Local anesthesia is a feasible method of providing pain relief during a surgical MTP.

The choice of anesthesia should be made taking into consideration the availability of staff and equipment necessary to handle adequately any problems arising from its use. Anesthesia is a specialty discipline and the mode of anesthesia should be decided by adopting a team approach.

It has been accepted now that local anesthesia is a viable choice of anesthesia. There is increasing evidence to show that pre testing before the administration of local anesthesia may not be mandatory. Lignocaine 1 or 2 percent solution can be used taking care not exceed the maximum dose. Injection of local anesthetic must be done so as to avoid intravenous injection. The use of local anesthesia has been proven to be safe and effective.

5. Surgical Methods for Early Abortion

5.1. Vacuum aspiration, manual or electric is the preferred method of choice for first trimester surgical termination.

5.2. Manual vacuum aspiration and electrical vacuum aspiration are both equally effective.

5.3. Manual aspiration has advantages where maintenance of equipment and reliable source of electricity are not available.

5.4. FOGSI recommends against the routine use of D&C in first trimester terminations. However clinical discretion may be exercised in its occasional use.

It is now generally accepted that Vacuum aspiration should be the method of choice right through for first trimester surgical abortion. It has replaced D&C in routine use in most countries. Complete abortion rates to the tune of 95 to 100% are reported after vacuum aspiration with equal efficacy rates for electric and manual aspiration.

FOGSI recognizes that a reliable electric supply, lack of maintenance facilities, and poor portability may pose problems for the use of electric vacuum and therefore considers MVA as advantageous in these respects.

Dilatation and curettage is less safe than vacuum aspiration, is more painful, takes longer to perform and has a two to three fold higher rate of complications. Where D&C is practiced all possible efforts should be made to replace it with vacuum aspiration.

Where no abortion related services are currently offered, vacuum aspiration should be

introduced rather than D&C. However the absence of vacuum aspiration should not be used as an excuse to deny a woman a safe abortion when D&C is available.

6. Pre- Procedure Priming of Cervix.

6.1. It is not mandatory to perform pre procedure priming for all patients. However in selected cases this may be effectively performed with the use of prostaglandins or their analogues.

6.2. FOGSI recommendations 400 micrograms of oral, sublingual or vaginal misoprostol 2 to 4 hours before the procedure for pre procedure priming of the cervix.

6.3. In exceptional cases mechanical priming may be resorted to and is effective.

Pre procedure cervical priming is recommended to ripen the cervix prior to performing a surgical abortion and may help in facilitating the procedure by making the dilatation less traumatic and reducing the amount of hemorrhage. The drugs which can be used are misoprostol and injectable PGF2 alfa. In the event that these drugs are not available osmotic dilators may have to be used.

Cervical priming is not contraindicated prior to performing a surgical abortion in previously scarred uteri.

7. Medical Methods for Early Abortions

7.1. FOGSI recognises the universal evidence on the effectiveness and safety of combining mifepristone - misoprostol for inducing abortion up to 63 days as approved for use by the Drug Controller of India

7.2. Under existing laws medical methods can only be administered by Gynecologists and Registered Medical Practitioners recognized for performing MTPs by the MTP Act of 1971.

7.3. FOGSI recommends that the medical profession and the pharmaceutical industry exercise due diligence in their promotion and use.

7.4. It is vital that consumers be educated regarding this recently introduced method its advantages, drawbacks, risks and limitations.

7.5. The current recommendations for medical methods for early abortions are 200 mg mifepristone followed after 36 - 48 hours by 400 micrograms of oral or vaginal misoprostol up to 7 weeks or 800 micrograms of oral or vaginal misoprostol over 7 weeks .

Medical methods of abortion have been proven to be safe and effective.

There is enough evidence to show that these drugs can be safely used right up to 20 weeks of gestation (the legal limit in India for a MTP).

In the event that vomiting ensues within 30 minutes of oral misoprostol the medication should be repeated. It is clear from evidence available that there is no need to keep a woman in the facility till she aborts.

The need for follow up should be stressed. If possible the client should follow up once after 7 days or in the event of a problem.

Due to the risk of teratogenesis it is advisable to recommend surgical termination of a pregnancy that continues.

8. Role of Antibiotics

8.1. Routine use of antibiotics at the time of the surgical abortion procedure reduces the risk of post procedural infection.

8.2. While routine use of antibiotics is not mandated with medical methods of abortion their use may be beneficial in nulliparas, in the presence of active vaginal infections and in high risk situations.

It is accepted that the routine use of prophylactic antibiotics reduces the incidence of post abortion infection. However adequate disinfection of the instruments used for performing the termination of pregnancy and maintaining the adequate levels of cleanliness are vital to preventing post abortion infection.

Suitable doses of antibiotic prophylaxis or therapy with ampicillin, amoxicillin, cephalosporins or doxycycline are all effective.

9. Role of Ultrasound

9.1. It is not mandatory to do perform ultrasound before a medical termination of pregnancy.

9.2. There are certain situations where ultrasound may be helpful before, during and after a surgical abortion.

9.3. Ultrasound may be performed for dating a pregnancy with irregular cycles, lactation amenorrhoea, clinical discrepancy or uncertainty in examination and to exclude an ectopic gestation before a medical termination of pregnancy.

The statement is meant to convey that ultrasound scanning is not necessary for the provision of early abortion services. However some providers may choose to use it at any stage of the procedure.

10. Methods for Second Trimester Abortions

10.1. FOGSI supports the rules and regulations in the amendment made to the MTP act in 2003 delinking facilities for first and second trimester abortions.

10.2. **Abortions beyond the second trimester are more technically demanding procedures than early abortions. Complication rates are also higher.**

10.3. **Therefore any program which promotes safe abortion must try to underline the need for safe second trimester abortions.**

10.4. **Ethacridine lactate has a long history of use in our country and its safety has been well documented.**

10.5. **The prostaglandins and their analogues can be used as adjuncts to bring about safe abortion if the need arises.**

10.6. **The use of mifepristone - misoprostol for second trimester termination is yet not approved in India. However international evidence shows that it is a safe and effective method for termination of second trimester pregnancies.**

10.7. **The suggested protocol for mifepristone - misoprostol for second trimester termination is 200 mg mifepristone followed after 36 - 48 hours by 400 micrograms of oral, sublingual or vaginal misoprostol every 3 - 6 hours up to 5 doses.**

Abortions during the second trimester are more technically demanding procedures than early abortions with higher complication rates. Therefore any program which promotes safe abortion must try to underline the need for safe second trimester abortions.

Recommendations for second trimester abortions are as per national and international guidelines.

11. Late Termination of Pregnancy

11.1. **FOGSI recognizes the right of a woman to terminate the pregnancy beyond 20 weeks when there exists a fetal abnormality that is either incompatible with life or would require major medical or surgical intervention to permit survival.**

11.2. **These late terminations should be undertaken for specific medical reasons.**

11.3. **FOGSI takes into account the current position of law and strongly recommends necessary amendment to the law.**

There will always be pregnancies which need to be terminated. The existing MTP Act section 3 recognizes the risk of fetal abnormality as a valid reason for the medical termination if the gestational age is below 20 weeks.

FOGSI contrasts this from pregnancies involving fetuses with diagnosed and proven fetal abnormalities that are either incompatible with life or requiring major medical or surgical intervention to permit survival irrespective of the gestational age and considers it ethical to terminate these. This is in line with the ethical guidelines of FIGO on the subject.

12. Post Abortion Care and Contraception

12.1. Post abortion care should emphasize in providing women with information to recognize early the complications of surgical abortion and instructing them to report early in case of such an event occurring.

12.2. It is equally important to counsel the woman regarding the choice of contraception available.

12.3. All contemporary contraceptive methods both temporary and permanent may be used at or immediately after surgical and medical abortion after confirming acceptance and suitability.

12.4. A follow up visit within 7 days is recommended.

12.5. The patient should report if she misses her periods beyond six weeks after the termination of pregnancy.

All methods of contraception including intrauterine devices and hormonal contraceptives can be considered for use after abortion.

Concomitant female sterilization at the time of surgical abortion is safe and may be undertaken after adequate pre procedure counseling.

13. Complications of Abortion

13.1. Where abortion is performed by skilled service providers complications are rare, but not unknown.

13.2. Possible complications include incomplete abortion, hemorrhage, infection, uterine perforation and anesthesia related complications.

13.3. Failure to achieve abortion with continuation of pregnancy though rare can occur in women who have undergone surgical or medical methods of abortion.

As with any medical therapy or procedure surgical and medical abortions are associated with occasional complications.

Women should be counseled to report persistent postabortion amenorrhoea. If at the follow up visit or at a later date the pregnancy is found to be continuing, termination of pregnancy should be offered and undertaken.

Frequently Asked Questions (FAQ) About Medical Abortion

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-Director Dr Ganatra 's Nursing Home
-Member MTP Comm , Family Welfare Comm FOGSI
-Member Managing Council IAGE

1. Will a medical abortion affect Obstetric Outcome in future Pregnancies ?

Medical abortion does not cause future infertility, preterm delivery, ectopic pregnancy, breast cancer or severe psychological reactions .A large study of 11,814 pregnancies in women who had had a previous first-trimester medical abortion (2710 women) or surgical abortion (9104 women) were studied .There were 274 ectopic pregnancies (respective incidence rates, 2.4% and 2.3%),1426 spontaneous abortions (12.2% and 12.7%), 552 preterm births (5.4% and 6.7%), 478 births with low birth weight (4.0% and 5.1%) 20.

2. Safety profile of Medical abortion related to :

a. Age- Neither adolescence nor older age (e.g. over 35 years) should be regarded as a contraindication to medical abortion.

b. Anaemia- This need not be regarded as a contraindication. However, anaemia detected at the time of abortion should be treated. Average blood loss in medical abortion may be more than that in surgical abortion (1), and the incidence of heavy bleeding may be higher.

c. Breastfeeding - It is likely that mifepristone passes into breast milk. Studies investigating the endocrine effects of mifepristone on the fetus have found increased levels of adrenocorticotropic hormone and cortisol . The clinical implications of these changes are unclear. Small amounts of misoprostol also enter breast milk soon after administration, but it is not known whether this could have any effect on the infant. As misoprostol levels decline rapidly, it has been recommended that misoprostol should be taken immediately after a feed and the next feed given after four hours in case of oral administration . After vaginal administration, misoprostol levels stay high for longer, and the feed should preferably be given more than six hours later.

d. Insulin-dependent diabetes or thyroid disorder- There is no evidence that abortion causes particular problems in women with these disorders.

e. Multiple pregnancy (current gestation)-There is no evidence that the failure rate of medical abortion is increased or that a different dosage regimen is required in the case of multiple pregnancy.

f. Obesity-There is no evidence that the failure rate of medical abortion is increased or that a different dosage regimen is required in obese women.

g. Previous Caesarean section- There is NO contraindication for use of Medical abortion in previous caesarean section or myomectomy. A study by Xu et al showed that in thirty-three out of 35 cases with uterine scar achieved complete abortion (94.29%).There were no obvious complications e.g. uterine rupture, serious haemorrhage and shock in the scar group.

h. Smoking-There is no evidence of interaction between the risks of smoking and Uterine malformations, congenital and acquired; previous cervical surgery. There is no evidence that these represent contraindications.

I. Bronchial asthama - Mifepristone & Misoprostol can be used

3 . How should pregnancy be confirmed and gestation estimated ?

In most cases, pregnancy can be confirmed and its length estimated on the basis of the woman's history and a physical examination. Occasionally, laboratory tests may be needed when the typical signs of pregnancy are not clearly present and the health-care provider is unsure whether the woman is pregnant.Ultrasound scanning is not necessary for the provision of medical abortion.

4. Can I give the medicines in my consulting room / clinic ?

The clinic does not require an approval as a place PROVIDED the RMP has access to a place approved for termination of pregnancy under the MTP Act. A board must be displayed in the clinic stating the name of the place approved under MTP Act where the patient should reach incase of emergency.

5. If a woman has an incomplete abortion, is it necessary to evacuate the uterus surgically?

On average, vaginal bleeding gradually diminishes over about two weeks after a medical abortion, but in individual cases spotting can last up to 45 days.

If the woman is well, neither prolonged bleeding nor the presence of tissue in the uterus (as detected by ultrasound) nor a endometrial thickness > 15 mm is an indication for surgical intervention. The mean endometrial thickness 24 hours after using misoprostol in women with a complete medical abortion was 17.5 mm, but ranged from 7.6 to 29 mm. One week after the abortion, the mean thickness was 11.3 mm but ranged from 1.6 to 24.9 mm. It is normal to visualize clot and debris in the uterus - Harwood et al

Surgical evacuation of the uterus may be carried out :

I) on the woman's request

ii) if the bleeding is heavy (>2 pads/hour for 2 hrs.) or prolonged or causes anaemia

iii) if there is evidence of infection. Antibiotic treatment should be initiated prior to surgery

Combipack approval certificate

F.No.4-193/2005-DC(Pt-SYN)
Government of India
Central Drugs Standard Control Organisation
Directorate General of Health Services
FDA Bhawan, New Delhi – 110 002 (India)

Form-46

(See rules 122-B and 122-D and 122-DA)

Permission/approval for manufacture of new drug formulation

****

Number of the permission and date of issue **MF-193/09**

M/s. Pharmaceuticals Ltd., _____(address) is hereby granted permission/approval to manufacture the following new drug formulation under rule 122-B/122-D/ 122-DA of the Drugs and Cosmetics Rules-1945, namely:

(1) Name of the drug	:	FDC of combipack of Mifepristone + Misoprostol Tablet.
(2) Dosage Form	:	Combipack.
(3) Composition	:	Each combipack contains:- (A) Mifepristone Tablet .....1 tablet Uncoated tablet contains:- Mifepristone 200mg (B) Misoprostol .....4 tablets. Each uncoated tablet contains Misprostol 200mcg.
(4) Indication	:	For medical termination of intrauterine pregnancy (MTP) of up to 63 days gestation based on the first day of the last menstrual period.

Date: 19 MAR 2009

Signature: _____

(Dr.Surinder Singh)
Drugs Controller General (India)
(Name & Designation of Licensing Authority)

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Knowledge, Attitude and Practices (KAP) Survey on Medical Abortion

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FOGSI and Population Services International (PSI) have come together to conduct this survey on Knowledge, Attitudes and Practices (KAP) of OBGYNs in India towards providing medical abortion to Indian women. This survey will specifically study the approach of OBGYNs towards Medical Abortion and attempts to find out if any knowledge gaps need to be addressed in prescribing the use of MA in your patients.

The results of this survey will help FOGSI and PSI formulate policy decisions and guidelines to better the use of MA in Indian women.

We will start the survey by filling in your identification details.

Q No.	Questions	Responses	Code	Skip
	Please provide the following details:			
i.	Please provide your full name.	FIRST NAME: _____ LAST NAME: _____		
ii.	Please provide your email id. **ENTER YOUR FULL EMAIL ID. FOR EXAMPLE: fogsi2007@gmail.com**	_____		
iii.	Please give your mobile no.	MOBILE PHONE NO.: _____		
iv.	Please tell me which state you belong to:	NAME OF THE STATE: _____		
v.	Please tell me your qualification. **PLEASE CIRCLE ALL RESPONSES THAT MAY APPLY**	MBBS	1	
		MD	2	
		MRCOG	3	
		DGO	4	
		Others (specify) _____	5	
vi.	Please tell me the type of practice you currently have.	Private	1	
		Institutional	2	
		Others _____ (specify)	3	
vii.	Generally how many clients in a day do you see? **PLEASE TRY TO SPLIT THEM BY AGE AND GENDER**		Adult / Children	
		Female		
		Male		

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Q No.	Questions	Responses	Code	Skip

SECTION : MEDICAL ABORTION

The following questions will talk about the abortion services that you provide and specifically will explore issues related to Medical Abortion. Please read through each question carefully and provide answer that holds most appropriate according to you.

PLEASE CIRCLE ALL RESPONSES THAT MAY APPLY.

201.	What are the safe methods to end 1st trimester pregnancy?	Vaccum aspirartion (MVA or EVA)	1	
		Medical Abortion	2	
		Dilatation and curettage (D&C)	3	
		Don't know / Cannot say	4	
		Other **(PLEASE SPECIFY)** _____ _____	5	
202.	Does medical abortion (MA) fall under the purview of MTP Act?	Yes	1	
		No	2	
		Don't know / Can't say	3	
203.	What are the recommended best drugs for medical abortion?	1. _____ 2. _____ 3. _____ 4. _____ 5. _____		
204.	Code the conditions in which you will not provide MA drugs	Suspected ectopic pregnancy	1	
		Faild IUD with pregnancy	2	
		Women who don't have access to emergency services	3	
		Women on corticosteroid or anticoagulants therapy	4	
		Bronchial asthma	5	
		Diabetes - mellitus	6	
205.	For upto how many weeks of pregnancy has the Drug Controller General of India (DGCI) approved the use of Mifepristone and Misoprostol?	Weeks of pregnancy ☐☐		
206.	Effectiveness of Medical abortion is…	95-99%	1	
		80%	2	
		82-83%	3	
		Don't know / can't say	4	

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Q No.	Questions	Responses	Code	Skip
207.	Fertility can return within how many days/months of an abortion?	1 month	1	
		90 days	2	
		10 days	3	
		Don't know / cannot say	4	
208.	Do you take written consent of the woman seeking medical abortion in the prescribed format?	Yes, always	1	
		Yes, when women in literate	2	
		Yes, but ask husband to provide written consent if woman if not literate	3	
		I would take verbal consent	4	
		No, I will not ask for writtten consent	5	
209.	What dosages of Mifepristone and Misoprostol you provide to woman seeking medical abortion?	Dose of Mifepristone ☐☐☐ Dose of Misoprostol ☐☐☐		
210.	Do you provide information about both medical and surgical abortion to the clients who want to terminate the pregnancy?	Yes	1	
		No	2	
211.	Do you tell your clients during counseling about what should they expect in MA, like heavy bleeding and cramping?	Yes	1	
		No	2	
212.	Do you admit your client in the hospital / nursing home / clinic for taking MA from you?	Yes	1	
		No	2	
213.	**[IF YOU ANSWERED YES IN Q212 THEN ANSWER THIS QUESTION]** For how long do they stay in the facility?	Days ☐☐		
214.	After how many days do you ask MA client to return to your clinic for assessing the completion of abortion process?	Days ☐☐		
215.	Do you advice to start contraception immediately after confirming that the abortion is complete?	Yes	1	
		No	2	
216.	What percentage of clients seeking abortion opts for medical abortion?	Percentage of clients ☐☐ %		

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Q No.	Questions	Responses	Code	Skip
217.	What are the main reasons for which they choose MA over vacuum aspirations?	_____ _____ _____ _____ _____		
218.	In your clinical practice, what percentage of MA clients requires vacuum aspirations / surgical evacuation for completing the abortion?	Percentage of clients ☐☐ %		
219.	What percentage of abortion seeking clients wants abortion due to contraceptive failure?	Percentage of clients ☐☐ %		

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Please fill up the survey & send to :
Dr. Kiran Kurtkoti ,Chairperson MTP Committee ,FOGSI

Address:
Kurtkoti Nursing Home,
Right Bhusari Colony, Behind Honda Showroom, Paud Road,
Pune-411038, Maharashtra State.

OR You may fill the survey, scan it &
send the scanned document to :
kirankurtkoti@yahoo.com

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Healthy lives. Measurable results.

Products

Reproductive Health

A family of products that provides couples with a variety of safe choices

Safe Abort Kit

Combipack of Mifepristone & Misoprostol with Client Information Leafet for Medical Abortion

Freedom 5

Intra Uterine Device

Emergency Goli

Emergency Contraceptive Pill

Injectible Contraceptives

Pearl

Oral Contraceptive Pill

Masti

Male Condoms

Maternal and Child Health

Products that improve health during pregnancy and protecting children under five against some of the leading causes of morbidity and mortality

Vitalet-Preg

Iron and Folic Acid Tablets

Neotral

Oral Rehydration Solution

Zinc

Dispersible Vanilla-favoured Tablets

Safewat

Safe Water System

Aquatabs

Home-based Water Treatment Tablets

For more information please contact:
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