ICOG FOGSI Recommendations for Good Clinical Practice

Consensus Statement for Medical Termination of Pregnancy

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Committee:	Medical Termination of Pregnancy Committee. (2004 – 2008)

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Consensus group meeting at Pune March 2004.

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Chairperson's Note

"Turn your face to the sun and the shadows fall behind you. "

Maori proverb

The MTP Committee would like to place on record its appreciation for the move to have a FOGSI consensus on vital issues. It is felt that the consensus will help promote the activities of FOGSI by stating clearly the stand of the Federation in issues which come up for discussion in many forums medical and non medical.

It should be clearly understood that 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.

Background

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.

Of the 210 million pregnancies which occur each year about 46 million (22 %) end in induced abortion. (Alan Guttmacher Institute 1999). The vast majority of women are likely to have at least one abortion by the time they are 45. About 20 million or nearly half of the induced abortions annually are estimated to be unsafe. Ninety five percent of these occur in developing countries (WHO 1998). Even in societies and areas where effective contraception methods are available the abortion rate has not declined to zero although it sharply declines (Bongaarts and Westoff 2000).

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 (GOI – MOHFW 1990) – 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% - WHO 1998) as a standard for calculating maternal deaths from unsafe abortion this would mean 9.1 million maternal deaths for a 18 year period!!

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1. Acknowledgement of the Problem

FOGSI acknowledges the magnitude of the problem of unsafe abortion.

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.

Context:

Unsafe abortion is a major problem as has already been emphasized in the background section. 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. (Alan Guttmacher Institute 1999). In developing countries the risk of death following complications of unsafe abortions is several hundred times higher (WHO 1998 WHO/RHT/MSM/97.16). 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.

Nepal is the only one of our neighboring countries where abortions services are legalized. The MTP committee of FOGSI recently contributed to the first ever safe abortion workshop held by the Nepal Obstetrics and Gynecological Society. The response of the society and the Government of Nepal was very appreciative of our inputs and we have been invited to take an active part in further training programs.

2 . Surgical abortion

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.

Context:

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 inconviencing 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

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. (Form C and the supplementary informed consent form is attached as annexure)

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

Context:

This section seeks to emphasize certain important but not always well known 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. To facilitate this, a suggested form for informed consent is attached as Annexure 1.

3.3 seeks to emphasize 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

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

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

Context:

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. However a few points need to be highlighted:

- There is increasing evidence to show that pre testing before the administration of local anesthesia may not be mandatory.
- Lidocaine 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. (Thonneau et al 1998 – Eur J Ob Gyn Rep Bio 81:59-63).

5 Method

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.

Context:

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. (Greensdale et al 1993 Ipas Advances in Abortion care 3(2):1-4, Westfall et al J Womens Health 7:991 - 995).

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 (Cates et al Am J Prev Med 2000; 19(Suppl 1): 12 – 17, Grimes et al 1977 Abortion in the seventies NAF, Grimes and Cates 1979 Ob Gyn Survey 34:177-191, Lean et al 1976; Int J Obs Gyn14:481-486). 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 performed effectively with the use of prostaglandins or their analogues.

6.2 In exceptional cases mechanical priming may have to be resorted to.

Context:

Cervical priming is recommended by some associations for nulliparous women wishing to undergo a termination of a pregnancy more than 9 weeks of gestation, for women younger than 18 years old and all women with a duration of pregnancy over 12 completed weeks. (RCOG evidence based guideline No 7. 2000, WHO Technical report series 871, 1997). Using agents to ripen the cervix prior to performing a surgical abortion 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, mifeprisotne and injectable PGF2 alfa. In the event that these drugs are not available osmotic dilators may have to be used.

7. Antibiotics

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

Context:

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.

8. The Role of Ultrasound

8.1 It is not mandatory to do an ultrasound before a surgical MTP.

8.2 There are certain exceptional situations where ultrasound may be helpful before, during and after an abortion.

Context:

The statement is meant to convey that ultrasound scanning is not necessary for the provision of early abortion services (RCOG evidence based guideline No 7. 2000).

However some providers may choose to use it at any stage of the procedure.

9. Post abortion care

9.1 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.

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

9.3 A follow up visit within 7 days is recommended. The patient should report if she misses her periods beyond six weeks after the termination of pregnancy.

10. Medical abortions

FOGSI statement on medical abortions.

- FOGSI recognises the universal evidence on the safety & effectiveness of mifepristone-misoprostol for MTP up to 49 days as approved for use by the Drug Controller
- It is stressed that under existing laws these methods can only be administered by gynecologists & RMPs recognised for performing MTPs by the MTP Act of 1971
- FOGSI recommends close monitoring of distribution & that the medical profession & the pharmaceutical industry exercise due diligence in their promotion & use
- It is also vital that consumers be educated & counselled regarding its advantages, drawbacks, risks & limitations FOGSI, April 2002

Context:

Medical Methods of abortion have been proven to be safe and effective. (WHO Technical and Policy Guidance for Health Systems 2003).

The current recommendations for use up to 7 weeks since LMP are 200 mg Mifepristone followed after 36 – 48 hours by 800 micrograms of vaginal misoprostol, or 400 microgram oral misoprostol.

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

However the MTP Act as it stands today allows for use only up to 49 days after LMP.

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.

11. Second trimester abortions

11.1 FOGSI strongly supports the rules and regulations in the amendment made to the MTP act in 2003.

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

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

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

12. Complications

Where abortion is performed by skilled service providers complications are rare, but not unknown. They include incomplete abortion, failed abortion, hemorrhage, infection, uterine perforation and anesthesia related complications.

"There is one thing even more vital to science than intelligent methods;
And that is, the sincere desire to find out the truth, whatever it may be."

– Charles Sanders Pierce