ICOG FOGSI Recommendations for Good Clinical Practice

Female Sterilization

Chairperson:	Dr. Mandakini Parihar
Committee:	Family Welfare Committee (2004 – 2008)
Committee Members:	Dr. Behram Anklesaria
Discussed by Committee:	
Received by Core Committee:	14th March 2009 (Core Committee)
Website:	ICOG & FOGSI
Peer Reviewer:	Dr. Heema Divakar

ICOG FOGSI Recommendations for Good Clinical Practice on Female Sterilization
Outcome of the Consensus Group meeting – March 28th 2004 at Pune

Dr. Mandakini Parihar,
Chairperson Family Welfare committee FOGSI

Members of the Group Meeting

Dr. Behram Anklesaria	Dr. Sanjay Gupte
Dr. Neera Agarwal	Dr. PC Mahapatra
Dr. C N Purandare	Dr. Shyam Desai
Dr. PK Shah	Dr. PK Sekharan
Dr. Chandravati	Dr. Kamini Rao
Dr. Kurien Joseph	Dr. Hema Divakar
Dr. Nozer Sheriar	Dr. Suchitra Pandit
Dr. H P Pattnaik	Dr. Jayanth Rath
Dr. Suresh Deshpande	Dr. Dileep Walke
Dr. Jaydeep Tank	Dr. Parag Biniwale
Dr. Atul Ganatra	

Presented at FOGSI managing committee – April 16-17th 2004 at Jammu
Reviewed and revised on 14th March 2009
Members Present

Dr. C N Purandare	Dr. Usha Sariaya
Dr. Duru Shah	Dr. Sanjay Gupte
Dr. P K Sekharan	Dr. Nozer Sheriar
Dr. Madhuri Patel	Dr. Mandakini Parihar

Adopted by the ICOG-FOGSI core committee on 14th March 2009

Preamble

The National Population Policy (NPP), 2000 outlines the importance of achieving population stabilization and attaining the goal of replacement level fertility by 2010. The National Family Welfare Program provides a range of contraceptive methods including terminal and spacing methods.

For both men and women, surgical sterilization is a popular and well-established method of contraception. It offers highly effective protection against pregnancy; it carries a very low risk of complications when done according to accepted medical standards; and as a once only procedure, it eliminates the need for long-term contraceptive supplies. Male and female sterilizations can be carried out as outpatient procedures because the modern techniques are safe and simple. Since this form of contraception is permanent, informed choice and appropriate counseling is crucial.

The purpose of this document is to apprise our members about the newer standards designed by the Government of India(GOI). During the review meeting, the previous document was modified and adjusted according to the current recommendation by GOI on Standards of Female and Male Sterilization. Using the New GOI Sterilization Standards and the Quality Assurance Manual, the ICOG-FOGSI core committee has formulated these recommendations for Good Clinical Practice for all FOGSI members which have a **few differences from the GOI standards**. The ultimate goal is to improve the quality of sterilization services and looking for ways to serve growing number of clients.

The details on the criteria for eligibility, physical requirements, counseling, informed consent, pre-operative, post-operative, and follow-up procedures, and procedures for management of complications and side-effects, along with salient steps of the surgical procedures and the recommended practices for infection prevention are present in the complete original GOI document which is available for reference on the FOGSI website.

In these Recommendations for Good Clinical Practice on Female sterilization, the core committee has agreed with most of the standards for sterilization laid down by GOI as comprehensive guidelines for Sterilization. Hence, in this document we have highlighted only the important points and **also specified the areas where ICOG-FOGSI recommendations differ from the given GOI guidelines.** (Points of differences are marked in italics and our recommendations are marked in bold). We have also given the justification as to why ICOG-FOGSI's viewpoint is different from the GOI. FOGSI is the largest body of professionals dealing with women's health and we feel that these points highlighted are important as we also need to take into account a woman's right to her fertility, and we differ from some of these recommendations set by the GOI.

The annexure has the WHO eligibility criteria, a copy of the ideal consent form as per the Supreme Court guidelines and the Checklist to be signed by every operating surgeon prior to undertaking a tubal sterilization. For detailed explanations, all members are requested to read the GOI Guidelines as well as the Quality Assurance Manual, which are both available for reference on the FOGSI website.

Contents

1.1 Eligibility of Providers for Performing Female Sterilization

Female sterilization by Minilap Tubectomy should be performed by a trained and certified MBBS doctor.

Laparoscopic Sterilization should be performed by a Gynaecologist with DGO/MD/MS qualification or a Surgeon with MS degree and these doctors should have been trained and certified trained in Laparoscopic sterilization.

The state should prepare a panel of doctors - district-wise based on their qualification for performing sterilization operations as per the above eligibility criteria. The same criteria of empanelment would also be applicable for the private accredited facilities for sterilization services. Only those doctors whose names appear in the panel would be entitled to carry out sterilization operations. The panel should be updated quarterly.

ICOG- FOGSI Recommends

Laparoscopic Sterilization should be performed by a Gynecologist with DGO/MD/MS qualification. These doctors learn Laparoscopic Tubal Ligation as part of their post-graduate curriculum and these doctors should be certified as trained in Laparoscopic sterilization without the need for additional certification of training.

Justification for this recommendation

Laparoscopic sterilization and laparoscopic procedures are routinely being done in all hospitals – public as well as private. All residents qualifying with a post-graduate diploma/ degree have had training in laparoscopic procedures as part of their routine Obstetrics and Gynecology curriculum. There should be no additional certification required for laparoscopic sterilization for a doctor holding a post graduate diploma or degree in Obstetrics and Gynecology. Most state health officials have had differences in this interpretation and hence results in difficulties. The GOI has given permission for a Surgeon with MS degree to perform Tubal Sterilization as there maybe unavailability of gynecologist in a few places.

The GOI with Oriental Insurance Company has taken a National Insurance Scheme for all the doctors across the country for Tubal Ligation. The National Insurance Scheme benefits all empanelled doctors to avail of compensation in case of any major complication or death due to TL procedure. As per the rules of the National Insurance Scheme, only doctors empanelled with state government will be eligible for the benefits under the National insurance Scheme. The Eligibility Criteria being worded as above will enable all qualified diploma and degree holders to get empanelled with their local Health Authorities.

1.2. Client Eligibility Criteria/Case Selection

(Self- declaration by the client will be the basis for this information)

1.2. 1. The clients must have been married.

1.2. 2. Female clients should be below the age of 45 years and above 22 years.

1.2. 3. The couple should have at least one child whose age is above one year unless the sterilization is medically indicated.

1.2.4. Clients or their spouses must not have undergone sterilization in the past (not applicable in the cases of failure of previous sterilization).

1.2. 5. Clients must be in a normal state of mind so as to understand the full implications of sterilization.

1.2. 6. Mentally ill clients must be certified by a psychiatrist and consent should be given by a legal guardian/spouse.

The **Medical Eligibility Criteria for Female Surgical Sterilization procedures** outlined by WHO (2004) is attached as Annexure.

ICOG-FOGSI Recommends

We recognize the right of unmarried or nulliparous women to choose female sterilization as their method of choice for contraception. However, Sterilization is a permanent method of contraception and hence adequate and proper counseling with options of other methods should be offered.

Justification

ICOG and FOGSI recognize the right of women to choose whether or not they want to have children and it is their right to choose their preferred method of contraception. As tubal sterilization is a permanent method it should be offered with adequate counseling. If even after other options being offered and counseled appropriately, if an unmarried woman or nulliparous woman choose tubal sterilization as their preferred contraceptive option, it should not be denied to them.

1.3. Clinical Processes

Preparation for surgery includes counseling, pre-operative assessment, pre-operative instructions, review of the surgical procedure and post-operative care. It is essential to ensure that the consent for surgery is voluntary and well informed and that the client is physical fit for the surgery. Pre-operative assessment can also provide an opportunity for overall health screening and treatment of RTI/STIs.

Timing of the Surgical Procedure

a. Interval Sterilization should be performed within 7 days of the menstrual period (in the follicular phase of the menstrual cycle).
b. Post-partum Sterilization should be done after 48 hours up to 7 days of delivery.
c. Sterilization with medical termination of pregnancy (MTP) can be performed concurrently.
d. Sterilization following spontaneous abortion can be performed provided client fulfils the medical eligibility criteria.

Laparoscopic tubal ligation should not be done concurrently with second trimester abortion and in the post-partum period

1.4. Counseling

Counseling is the process of helping clients makes informed and voluntary decisions about fertility. The following steps must be taken before the client signs the consent form:

1.4.1 They must be informed of all the available methods of family planning and made aware that for all practical purpose this operation is a permanent one.

1.4.2. Clients must make an informed decision for sterilization voluntarily.

1.4.3. They must be counseled in the language they understand.

1.4.4. Clients must be made to understand what will happen before, during and after the surgery, its side effects or potential complications.

1.4.5. The following features of the sterilization procedure may be explained to the client

a. It is a permanent procedure for preventing future pregnancies.
b. It is a surgical procedure that has a possibility of complications including failure requiring further management.
c. It does not affect sexual pleasure, ability or performance.
d. It will not affect the client's strength or her ability to perform normal day to day functions.
e. Sterilization does not protect against RTI/STI/HIV/AIDS.
f. Clients must be told that a reversal of this surgery is possible, but the reversal involves a major surgery and its success cannot be guaranteed.

1.4.6. Clients must be encouraged to ask questions to clarify her doubts, if any.

1.4.7. Clients must be told that they have the option of deciding against the procedure at any time without sacrificing their right to other reproductive health services.

1.5. Pre-operative Instructions as for any standard surgical procedure

1.6. Clinical assessment and screening of clients

Prior to the surgery medical history, menstrual and obstetrics history, physical examination and laboratory investigations as needed should be done to ensure the eligibility of the client for surgery.

1.7. Informed Consent

1.7.1. Consent for sterilization operation should not be obtained under coercion or when the client is under sedation.

1.7.2. Client must sign the consent form for sterilization before the surgery (see Annexure). The consent of the spouse is not required for sterilization. ***The Consent Form should be in English and in local language.***

ICOG-FOGSI Recommends

Consent of spouse is not mandatory but desirable, so that the recent Supreme Court ruling is not violated. (SC judgment was for any surgery which can affect the spouse's reproductive capacity)

1.8. Surgical Technique

ICOG-FOGSI Recommends

a. General Requirements – as per all pelvic surgery to be followed.
b. Minilaparatomy – Modified Pomeroy's technique is the preferred method but any standard method of tubal sterilization is permitted
c. Laparoscopy – **Fallope rings** should be the **preferred method** of ligation during a laparoscopic tubal ligation. However, bipolar cauterization with cutting of the tubes is also an acceptable option for tubal sterilization.

Justification

In many instances, accessing the tube by Pomeroy's method or Fallope rings may not be feasible and hence any standard method of tubal ligation is acceptable.

It is not essential to send the tubes for histopathology evaluation.

1.9. Post-operative care and instructions

The standard instructions and care should be followed as per any surgical procedure. A detailed discharge summary mentioning all relevant details should be given with strict instructions on what to do if she misses her period. Both written and verbal post-operative instructions must be provided in the local language. Special instructions for wound care to be followed. The client must be asked to Return to the clinic, if there is missed period/ suspected pregnancy within two weeks of missed period.

1.10. Certificate of Sterilization

Certificate of sterilization should be issued after the second follow up after ruling out any pregnancy.

1.11. Complications of Female Sterilization

1.11.1. INTRA-OPERATIVE COMPLICATIONS

a. Nausea and vomiting
b. Vaso-vagal attack
c. Respiratory depression or arrest
d. Cardiac arrest
e. Uterine perforation
f. Bleeding from the mesosalpinx
g. Injury to the urinary bladder
h. Injury to intra-abdominal viscera - small or large bowel and blood vessels
i. Convulsions and toxic reactions to local anaesthesia

1.11.2. POST OPERATIVE COMPLICATIONS

a. Wound sepsis
b. Haematoma in the abdominal wall
c. Intestinal obstruction, paralytic ileus and peritonitis
d. Tetanus
e. Incisional hernia

ICOG-FOGSI Recommends

ALL COMPLICATIONS, MAJOR OR MINOR, ARISING DURING SURGERY OR POST-SURGERY MUST BE REPORTED TO THE DISTRICT QUALITY ASSURANCE COMMITTEE.

All complications arising intra-op or even post-op, should be evaluating and managed as per the standard surgical guidelines.

1.4.13. Failure of operation, leading to pregnancy

This may be due to either technical deficiency in the surgical procedure or spontaneous re-canalization. The patient should be offered MTP or be medically supported throughout the pregnancy. She should be offered repeat surgery. Ectopic pregnancy must be ruled out as tubectomy predisposes this condition.

Annexure

Medical Eligibility Criteria for Female Sterilization

(Source: Medical Eligibility Criteria for Contraceptive Use, Third Edition, WHO, 2004)

A	Accept	There is no medical reason to deny sterilization to a person with this condition
C	Caution	The procedure is normally conducted in a routine setting, but with extra preparation and precautions
D	Delay	The procedure is delayed until the condition is evaluated and/or corrected. Alternative temporary methods of contraception should be provided
S	Special	The procedure should be undertaken in a setting with an experienced surgeon and staff, equipment needed to provide general anesthesia, and other back-up medical support. For these conditions, the capacity to decide on the most appropriate and anesthesia regimen is also needed. Alternative temporary methods of contraception should be provided, if referral is required or there is otherwise any delay.

Parity

Unmarried or Nulliparous women, like all women, should be counseled about the permanency of sterilization and the availability of alternative, long-term, highly effective methods.

ICOG-FOGSI recognizes the right of the women, even if unmarried or nulliparous, in choosing sterilization as an option provided adequate counseling has been done and it is an informed choice made by her.

Sterilization concurrent with caesarean section

Concurrent sterilization does not increase the risk of complications in a surgically stable client.

Annexure

Check List for all operating surgeons prior to surgery as per the superme Court Ruling

To be filled by the operating surgeon

5. Checklist before conducting surgery

Client is within eligible age	Yes	No
Client is ever married	Yes	No
Client has at least one child more than one year old	Yes	No
Lab investigations (Hb, urine) undertaken are within normal limits	Yes	No
Medical status as per clinical observation is within normal limits	Yes	No
Mental status as per clinical observation is normal	Yes	No
Local examination done is normal	Yes	No
Informed consent is given by the client	Yes	No
Explained to the client that consent form has authority as legal document	Yes	No
Abdominal/pelvic examination has been done in the female and the finding are within normal limits (WNL)	Yes	No
Infection-prevention practices followed as per laid down standards	Yes	No

Annexure

Informed consent form for sterilization operation / Re-sterilization

1. Name of the Client: Shri/Smt _____

2. Husband/Wife's Name _____

Address _____

3. Father's Name and address _____

_____

4. Religion _____

5. Educational Qualifications _____

6. Business/Occupation _____

7. Operating Centre _____

I am married and my husband/wife is alive. My age is _____ years and my husband/wife's age is _____ years. We have _____ male and _____ female living children. The age of my youngest living child is _____ years.

My spouse has not been sterilized previously. I am aware that I have the option to decide against the sterilization procedure at any time without sacrificing my rights to other reproductive health services.

a. I have decided to undergo the sterilization/re-sterilization operation on my own without any outside pressure, inducement or force.
b. I am aware that other methods of contraception are available to me.
c. I know that for all practical purpose this operation is permanent and I also know that there are still some chances of failure of the operation for which the operating doctor and health facility will not be held responsible by me or by my relatives or any other person whomsoever
d. I am aware that I am undergoing an operation, which carries an element of risk.
e. I have been explained the eligibility criteria for the operation and I affirm that I am eligible to undergo the operation according to the criteria.
f. I agree to undergo the operation under any type of anesthesia, which the doctor/health facility thinks suitable for me, and to be given other medicines as considered appropriate by the doctor/health facility concerned.
g. If after the sterilization operation, there is any missed menstrual cycle of mine/my spouse, then I/my spouse shall report within two weeks of missed menstrual cycle to the doctor/health facility and will avail the choice to get the MTP done free of cost.
h. In case of complications following sterilization operation including failure, I will accept the compensation as per the existing provisions of the Government of India Family Planning Insurance Scheme as full and final settlement.
i. That if I/my wife gets pregnant after failure of sterilization operation and I will not be able to get the pregnancy aborted within two weeks, then I will not be entitled to claim any compensation

over and above the compensation under Family Planning Insurance Scheme from any court of law in this regard or any compensation for upbringing the child.

j. I agree to come for follow-up to the Hospital/Institution/Doctor/health facility as instructed, failing which I shall be responsible for consequences, if any.

I have read the above information. /*The above information has been read out and explained to me in my own language and that this form has the authority of a legal document.

Name & Signature/Thumb
of the Acceptor

Impression Signature of Witness:

Full Name

Full Address

* (Only for those beneficiaries who cannot read and write).

Applicable to cases where the client cannot read and the above information is read out.

Shri/Smt

have been fully explained about the contents of the Informed Consent Form in his/her local language.

Signature of Counselor**

Full Name

Full Address

I certify that I have satisfied myself that –

1. Shri/Smt

is within the eligible age group and is medically fit for the sterilization operation.

2. I have explained all clauses to the client and also explained that this form has the authority of a legal document.
3. I have filled out the medical record-cum-checklist and followed the standards for sterilization procedures as laid down by the Government of India.

Signature of Operating Doctor	Signature of Medical Officer in-charge of the Facility
Seal (Name and address)	Seal (Name and address)

References

1. Standards of Male and Female Sterilization. GOI, Division of Research Studies & Standards, Ministry of health and Family Welfare. 2006.
2. Quality Assurance Manual for Male and Female Sterilization. GOI, Division of Research Studies & Standards, Ministry of Health and Family Welfare, 2006.
3. Huezo, C Organization (WHO)..M. and Carignam, C. S. 1997. Medical and Service guidelines for Family Planning – 2nd Edition. International Planned Parenthood Federation (IPPF) and World Health
4. World Health Organization, 2004. Medical Eligibility Criteria For Contraceptive Use. Geneva.