Female Sterilization — Medicolegal Aspects

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The Female Sterilization is easily the most common operation carried out by our members & also medical officers in our country.

This operation also forms an important part of our National Family Welfare Programme.

The common methods used in our country are

1) Minilaparotomy
2) Laparotomy with tubal ligation
3) Laparoscopy

Minilaparotomy can be done as Puerperal, Concurrent or Interval Sterilization.

Medicolegal problems can arise due to following reasons.

Unqualified persons–inadequate training
Unrecognized place
Improper consent
Wrong selection of patient

Complications

1) During the procedure
2) Failure of the procedure
3) Sequel of procedure

Medicolegal problems arising out of sterilization operation can be discussed under following headings.

Qualification of the surgeon: In our country not only qualified gynaecologists but medical officers who are M.B.B.S. and in some states even those from other pathies are expected to carry out sterilization procedures.

So far our FOGSI members are concerned problem of qualification will not come in the way. Having said this I must remind our collegues who are in teaching institutes that they can still be held responsible vicariously for mistakes committed by junior trainees. Properly supervised training is therefore a must. In some states (eg: Maharashtra) government guidelines require even M.D.s to obtain phase 1 and phase 2 training certificates for carrying out laproscopic tubal ligations. Most of our members seem to be unaware of this.

Unrecognised place.: In the M.T.P. Act specific approval of the place is mentioned. Though there is no specific law governing the sterilization most of our states have formulated elaborate guidelines regarding these procedures. Specification of the requirements of operation theatre are to be found in these guidelines and in some states e.g. Maharashtra, specific approval of place for sterilization procedure is a requirement of which some of our members may still be unaware.

Improper consent: Proper informed consent and counselling should be part of any operation. More so when sterilization is being carried out, as this operation is to be carried out in a perfectly healthy patient by choice. In our country sterilisation is shrouded in myths and mispresentations. Often minor side effects are exaggerated and unrelated occurrences blamed on the sterlisation procedure. Naturally these tend to create anxieties and apprehensions not only in the minds of those who are considering sterilization but also in the minds of those who have already undergone this procedure. This makes counselling all the more important and should include discussion about other available options especially vasectomy because it is definitely less risky.

Route and method of operation should be explained to the patient. In our country this is essential because there are various misbeliefs amongst the patients especially as regards the laparoscopy procedure. It is always of importance to take into consideration the patient's own views rather than imposing any particular method on her. Such imposition can sometimes be the root cause of further litigations.

It is also important to ensure that the patient is freely willing on her own for the sterilization and no element of coercion from husband, inlaws, or anybody else is playing any part.

Next, the patient should be told about the permanent nature of the operation. Sometimes patients assume possibility of reversal. Especially in the young educated couples who tend to undertake this procedure, sometimes even with a single child, this is important.

In young patients many times postoperative "regret" is commonly observed and this should be discussed. This can become cause of dissatisfaction later. Finally and the most important, the risk of the procedure as well as possibility of failure should also be communicated to the patients. Patient should be told that in case of failure early reporting by her is required, which will keep her option of MTP open.

The patients own consent is legally adequate for carrying out sterilization operation. However, many states (again including Maharashtra) deem it necessary to take in writing from patient that she has discussed the issue with her husband.

I know of a case where patient claimed that her husband was a drunkard and would refuse to give consent for her sterilization. In such a situation advise was given to carry out the procedure with her own consent duly witnessed by a responsible person.

Selection of the patient: Medicolegal problems can arise due to improperly selected patient. Again various states have guidelines regarding age and parity of the patient as well as ages of her children. These are -

1) The client must be married and the spouse must be living
2) The male client must be below age 50, his wife must be below age 45
3) The female client must be below age 45 and above age 22
4) The number of children must not be a criterion for determining the eligibility of sterilization acceptors
5) The client or spouse must not have undergone previous sterilization (this condition may be waived in case of failure of the previous operation)
6) The client must be in the proper state of mind to understand the full implications of the sterilization surgery

Therefore, if the couple so wishes these can be overruled after due counselling. It must be emphasized that these are only govt. guidelines but not statutory laws.

However, relevant medical conditions should be looked for by the doctor himself. Though these may not be absolute contraindications they may add to the operative risk and such should be communicated to the patient.

Obesity, previous laparotomies or L.S.C.S. in otherwise healthy patient can also add to the operative risk and this must be remembered and conveyed to the patient.

Preoperative investigation: Minimum haemogram and urine examination should be a basic requirement which should not be overlooked.

Complications:

During surgery -

1) Due to local or general anaesthesia: hyper sensitivity to local anaesthesia or aspiration or cardiac arrest during general anaesthesia are remote but real possibilities and mention of these rare, but serious complications, during taking of consent, is always of help.
2) Inadvertent injuries to bowels, blood vessels, bladder etc. during access to the tube during laparotomy or laparoscopy are known to occur

The total complication rate of laparoscopic interval tubal sterilization in a large section from several institutions was found to be 1.7 per 100 (De Stefanof et al, 1983).

The surgeon should try to identify the complication as far as possible during the procedure. If it is possible, in a given setup, he should proceed to deal with the same himself. However if this is not possible the patient should be shifted to proper referral center. In such a case the doctor should as far as possible accompany the patient.

Sometimes the complication eg injury to bowel may not be apparent immediately and it may come to notice only when further signs develop. In this

situation postoperative followup becomes important and whenever such a delayed complication is noticed steps should be taken to deal with the problem immediately and adequately.

Documentation: It is always important to document steps of operation and post ---operative care. In case of complication, this can go a long way in saving the doctor before the courts.

Mortality

Female sterilization is a safe procedure but even then mortality may occur. Peterson et al (1983) from US has reported mortality between 1-2 per 100,000 procedures in a large series. National data from the Association for Voluntary Surgical Contraception shows mortality rate of 4.7 deaths per 100,000 procedures from developing countries (Khairulla et al 1992)

Failure of Sterilization

This happens to be the most important medico-legal issue regarding the procedure of sterilization. Most of the cases in our consumer fora against the doctors are due to failure of the operation.

All sterilization procedures have definite failure rate even in the best of hands. This ranges between 1-4 pregnancies per 1000 women sterilized. The difference in the risk has been demonstrated between laparotomy or laparoscopy with exception of Irving and Uchida techniques.

Failure may occur due to the following reasons:

1) **Patient may already be pregnant when procedure is carried out.**
It is important to counsel regarding use of contraceptions before tubal ligation. Farguarson (1996) has reported that as many as 5% women are pregnant at the time of tubal ligation. Sometimes the patients do not give proper history or may insist on carrying out sterilization in luteal phase because of time convenience. This situation should be avoided as far as possible and, if pressurized, the possibility of existing pregnancy and it's responsibility should be mentioned in the consent itself.

2) **Operation may fail because of**

i) a correctly employed technique which was followed by a re-canalisation or the development of a proximal tuboperitoneal fistula

ii) a procedure which was inappropriately or inadequately performed leading to the continuance of fertility, eg: structures other than a fallopian tube may be operated upon eg the round ligament or a fold of peritoneum between the round ligament and the fallopian tube may be clipped, ringed or cauterized. Also, a tube could be incompletely cauterized or incompletely clipped or ringed. If a failure of a tubal ligation occurs prior to one year it is more likely to be associated with a misapplication although this is not a proof of negligence. Failures after this time are more likely to be associated with natural causes. The decision as to whether negligence has occurred will depend upon whether standard precautions, methods and care was used just as in any other procedure.

Claims have been brought in English courts in respect of failed sterilizations in both contract and in the tort of negligence. The two cases in which the plaintiff relied on breach of contract were Eyre v Measday [1986] and Thake v Maurice [1986]. They involve a failed clip sterilization and vasectomy respectively. In both cases the plaintiffs sought to argue that there was breach of collateral warranty on the part of the defendant to render the plaintiff irreversibly sterile. This argument failed. The courts held that the contracts entered into by the defendants were to carry out particular operations competently and not to render the plaintiffs irreversibly sterile.

In our courts this issue of failure of sterilization came up before Delhi S.C.R.F. in case of Jaiwati Vs Pariwar Seva Sanstha where complainant had asked for Rs. 3,00,000 as compensation for sterilization failure. In one of the very precisely worded judgement Delhi S.C.R.F. (1999) ruled as follows.

'As already stated, the present case as put forth by the complainant is a case of 'sterilization failure' and the point to be considered by us is that whether it

can be stated that the opposite parties were guilty of such an error which no doctor of reasonable competence would commit. One of the most commonly used methods of sterilization is laparoscopic sterilization which was adopted in the case of the complainant. The said method involves passing of a ring or band over the fallopian tubes. There are numerous medical studies which testify to the fact that all methods of female sterilization, including tubal ligation have a certain failure rate since the risk of failure is inherent in the procedure. And therefore, it cannot be said that the opposite parties were, in any way guilty of negligence merely because the procedure has failed. As such assuming that sterilization failure took place in the case of the complainant it cannot be said that the same is indicative of any negligence on part of the opposite parties.'

In another case Andhra state C.D.R.C. (1999) in case of Sandhya rani Vs Kalpana has also given similar verdict. This was a case of Appeal against the judgement of district forum. Here pregnancy occurred 2 years and 6 months after the operation of tubectomy. The district forum has held the doctor guilty but in appeal state forum acknowledged that there is 0.2% failure rate and hence the doctor cannot be said to be negligent.

In one more interesting case Janaki Vs Saifunissa Kerala S.C.R.C. (2000) has held the doctor liable for carrying out sterilization without patient's consent and Rs.75000/- compensation is awarded to the complainant.

Some special situations

1) **Tubectomies in 'Camp' Setup**

   Many times our members are requested to carry out tubectomies in camp setups by government authorities and our members do so on charitable basis but even then precautions have to be taken.

   There are central government guidelines for such camps which should always be followed.

   Proper preoperative screening of patients is required. Proper sterility precautions have to be taken and especially postoperative care should be designated to a qualified and competent medical officer. Otherwise the surgeon may be faced with vicarious responsibility. I know of a case where damage to small intestines occurred during laproscopic sterilization at a camp. It went unnoticed post-operatively for 3 days and patient developed peritonitis. Though not his negligence, the surgeon had to face difficulties.

2) Sterilization in case of mentally handicapped patients - In these cases it is important to involve a psychiatrist, patient's guardians and one more competent colleague for second opinion. Onus of proving the need for such an operation may befall the surgeon.

Recently Supreme Court of India has given a very important & far reaching decision in case of Santra Vs. Govt. of Harayana. In this judgement the Honourable Court has held the doctor liable for performing the sterilization negligently & also held the State Govt. liable to pay compensation to the patient which includes expenses to bring up the child upto puberty. Unfortunately this landmark judgement has been only partially reported in most of the newspapers leading to lot of apprehension amongst our members. Most of them are now under the misconception that any failure of Sterilization Operation would make them liable for huge payments. Let me make it very clear that the honourable court has very correctly held the doctor liable for carrying out the family planning operation negligently & rightly held the Govt. liable vicariously for paying the compensation.

The facts of the case are as follows: when she conceived she contacted the C.M.O. & other doctors of the General Hospital, she was informed that she was not pregnant. Two months later when the pregnancy became apparent, she again approached the doctors who then told her that her sterilization operation was not successful. The doctor who had carried out the operation himself told the court that he had only operated on the right Fallopian tube & had not touched the left tube at all, which indicates that complete sterilization operation was not done. However, she was informed that the operation was successful that she would not conceive in future. She requested for an abortion, but was advised not to go in for it as the same would be dangerous to her life.

In this judgement the courts have rightly considered Family Planning work to be of utmost importance to the country. Secondly, courts have also made the State Government liable for compensation. Thirdly, for the first time in our country, the supreme court has ruled on compensation for bringing up the "unwanted" child. Lastly in this case the courts have not denied the possibility of the failure of the sterilization due to natural recannalisation of the tubes in which cases it will not come under the definition of negligence at all.

Conclusion

Tubectomy is an everyday procedure. It is a need of patient's as well as our nation. But it has certain rare but definite complications.

A gynaecologist has a duty to inform the patients of the risk of failure, to carry out operation in accordance with accepted practice and to avoid foreseeable complications. This will help in avoiding future litigations.

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