

Female sterilisation: medico legal aspects

G Marcus Filshie DM FRCOG MFFP

Abstract

Contemporary methods of sterilisation are described and litigation problems, including failed procedures, are addressed. Case Law relevant to the procedure is discussed. Reasons for litigation both actual and theoretical and how to minimise these are suggested.

Keywords: female sterilisation, legal aspects, prevention of litigation

Background

Female sterilisation is a very popular procedure for couples who have completed their families. It is estimated that over 180 million couples around the world depend on female sterilisation for contraception (United Nations 1992)¹.

In the United Kingdom information collected through the General Housekeeping Survey 1986–1995 (Office of National Statistics 1997)² shows that around one in four women or their partners rely on sterilisation for family planning. By the age of 40 years the figure is nearly one in two, with slightly more couples opting for female sterilisation than male sterilisation.

Over the same period the proportion of younger women who were sterilised fell (from 25% to 18% for women aged 30 to 34, and from 42% to 32% of women aged 35 to 39). The use of oral contraception has risen in these groups.

In the United States of America more couples rely on sterilisation to avoid conception than any other method, including oral contraception (Peterson 1997 *et al*)³.

Approximately 90,000 women are sterilised in the United Kingdom each year. In Scotland, the

Filshie clip is reported as being the preferred method, being used by 67% of surgeons (Penney *et al*, 1997)⁴. In England this figure is as high as 82% (Garrud *et al*, 2000)⁵.

Falope ring, Bipolar cautery or Hulka Clip application and partial salpingectomy comprise the alternative methods.

It is not surprising that when a procedure fails if the procedure is associated with injury that litigation is often sought.

Claims have been brought in the English Courts in respect of failed sterilisations in both contract and in the tort of negligence.

The obligation of a doctor to disclose relevant information to the patient prior to surgery was decided by a majority vote in the House of Lords in the case of *Sidaway v Board of Governors of Bethnal Royal Hospital* (1985)⁶. That obligation was decided on the basis of medical evidence applying to the Bolam test (*Bolam v Friern Hospital Management Committee*, 1957)⁷, i.e. that the physician's duty to warn will be fulfilled if the patient is given advice which a substantial body of respectable doctors would also have given.

This test has been applied by the Court of Appeal to the giving of advice on contraception and sterilisation, the leading case being *Gold v Harringay Health Authority* (1987)⁸. The patient had not been clearly told that the operation could fail.

However, in 1979 there was a body of responsible doctors who were not giving warnings at that time.

Since the early 1980s a dedicated written form for consent has been developed, highlighting the possibility of failure in accordance with the Department of Health's Red Book 'A Guide to Consent for Examination and Treatment', issued by the Department in association with HC(90)22.

Reader / Honorary Consultant in Obstetrics & Gynaecology
School of Human Development
University of Nottingham
D Floor East Block
Queens Medical Centre
Nottingham NG7 2UH
Tel: (0115) 9709236
Fax: (0115) 9709234
e-mail: marcus.filshie@nottingham.ac.uk

The two cases in which the plaintiff relied on breach of contract were *Eyre v Measday* (1986)⁹ and *Thake v Maurice* (1986)¹⁰. They involved a failed clip sterilisation 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, in *Eyre v Measday* (1986)⁹ at first instance and in *Thake v Maurice* (1986)¹⁰ on appeal, that the contracts entered into by the defendants were to carry out particular operations competently and not to render the plaintiffs irreversibly sterile.

Where sterilisation fails for reason of incompetent surgery, actions brought in tort raise no particular problems. The surgeon is judged by the standards of his peers (Bolam Test).

Financial awards were incurred in the case of *Emeh v Kensington* (1984)¹¹ when a failed sterilisation involved a congenitally abnormal baby. However, in the case of *Udale v Bloomsbury Area Health Authority* (1983)¹², the cost of bringing up a normal child was rejected by the Court of Appeal. Following this, in 1988, after a failed vasectomy, the costs awarded included the child's private education (*Benarr v Kettering Health Authority*, 1988)¹³. In 1992, the High Court awarded damages of £96,697 to a woman whose daughter was born eight months after a sterilisation operation.

More recently however in a case of failed sterilisation *MacFarlane v The Tayside Health Board* (2000)¹⁴, the judgement handed down by the House of Lords ruled that in wrongful birth cases such as this the claimant cannot recover damages for the rearing of the child but that recoverable damages are limited to compensation for the physical effect of the pregnancy and birth and possibly any special damages such as loss of earnings arising from the period of the pregnancy.

In April 2001 at the Court of Appeal (*Parkinson V St. James and Seacroft University Hospital NHS Trust*)¹⁵ a mother who had undergone a sterilisation which was negligently performed was entitled to recover damages for the cost of providing for the special needs and extra expenses of her son who was conceived after the operation and was born with significant disabilities. However, she could not recover any sum in respect of the basic cost of his maintenance.

Methods of Female Sterilisation

There are many routes and techniques for female sterilisation in the UK but the most popular methods incorporate the use of clips (Penney *et al*, 1998⁴ & Garrud *et al*, 2000⁵)

However, the choice of route and technique of sterilisation must be that of the gynaecologist concerned. The gynaecologist should use the route and technique with which he is most comfortable. He should listen to what the patient asks for but in respect of method his view should prevail after explaining the reasons for his choice. If the patient wishes a route or technique which is not favoured by the gynaecologist, she should be referred appropriately.

Laparotomy provides the best route for sterilisation when the use of the closed technique of laparoscopy provides less than ideal conditions, or the surgeon is insufficiently skilled or experienced.

Often laparotomy requires a cautious entry to the abdominal cavity, especially in women who have had previous Caesarean section or other pelvic operations, because the commonest injury is to the bladder, especially with a low small suprapubic incision.

Mini-laparotomy, which involves a small transverse suprapubic incision (3–5cm long), is popular. The surgeon should be skilled and experienced in the use of this approach and take account of the limited view and access to the uterine tubes that such an approach provides.

The *Madlener* technique in which a loop of tube is crushed with forceps and ligated with an unabsorbable suture has a high failure rate. It has been abandoned and should not be used.

The *Pomeroy* operation, so called, is probably the most widely used method worldwide. It is carried out at an open operation when there is a lesser risk that the surgeon will mistake some other structure for the uterine tube or, as with clips and rings, inadequately occlude the tube. A loop of the isthmic portion of the tube is pulled up and ligated with an absorbable suture and the isolated loop of the tube is excised. When the suture is absorbed the divided ends of the tube should not only be occluded, but also fall apart to separate them (Bishop and Nelms 1930)¹⁶. Histological examination of the excised parts of the uterine tubes provides evidence that the operation has been carried out properly.

Fimbriectomy is claimed to be a reliable technique, but the remaining tubal ampulla has been shown to regenerate microfimbriae giving rise to an unacceptable failure rate and should not be used (*Pitkin v Zlatnik* 1982)¹⁷.

The *Uchida* and *Irving* techniques of sterilisation involve more complicated procedures with increased morbidity which is not offset by a significant increase in effectiveness.

Hysterectomy, either by the abdominal or vaginal route, has been used as a method of sterilisation. This is acceptable and also indicated, particularly when the patient also has gynaecological symptoms such as menorrhagia or the uterus is enlarged by fibroids. It is also used in Catholic countries where sterilisation is not acceptable, but hysterectomy is for the cure of gynaecological symptoms. Nevertheless, even hysterectomy according to a report in the literature has been followed by 24 pregnancies (*Meizner et al*-1983)¹⁸.

Removal of the ovaries although effective is not an acceptable method of sterilisation, since it precipitates the menopause which would generally require hormone replacement therapy subsequently.

Laparoscopy requires much greater skill and experience to provide a safe and effective technique of sterilisation (*Chamberlain and Brown* 1978)¹⁹. At laparoscopy three main techniques of tubal occlusion have been used:

1. *Diathermy coagulation* is a method that has rightly been abandoned by a majority of gynaecologists since the early 1980s because of the risk of inadvertent damage to organs other than the uterine tubes, as well as the high failure rate associated with inadequate coagulation (*Howkins & Hudson* 1983)²⁰.

Unipolar diathermy for coagulation of the uterine tubes was abandoned in the mid-1970s because the associated mortality rate was in the range of 8-10 per 1000,000 operations (*Chamberlain & Brown* 1978)¹⁹. Serious illness or death was attributable either to life-threatening internal haemorrhage from direct burns of blood-vessels or to faecal peritonitis from burns to the bowel causing perforation. Unipolar diathermy generates temperatures between 200 and 300°C, but heat may spread to sites distant from the application of the forceps so that injuries may not be noticed.

Textbooks of the 1970s stressed the need to apply the diathermy current for a sufficient time

and in more than one site to achieve effective tubal occlusion. There was never any consensus about the practice of dividing the burnt tubes.

Bipolar diathermy generates similar temperatures, but significantly reduces, though does not eliminate, the risk of distant thermal injury. This is because the electric current passes only between the jaws of the coagulation forceps and not outwards from a single point, as with unipolar diathermy, through the patient's body to the 'negative' plate applied either to the thigh or the buttock. *Semm* (1983)²¹ has advocated the use of so called 'cold' coagulation diathermy as being safer, using temperatures of about 120°C. However, to be certain of occluding the tubes he advises cauterization at three sites for a minimum length of time so that a great deal of the tube is destroyed and reliability depends on the patience of the surgeon. This technique has not been widely used in the UK.

2. *Clips* devised by *Hulka* (spring loaded - *Hulka et al* 1979)²² and by *Filshie* (made of titanium and silicone rubber - *Filshie et al* 1981)²³ have been safely and acceptably used and are the most widely used method at the present time in the UK. The clips should normally be placed over the isthmus of the uterine tubes, since this is the thinnest part of the tube. Application elsewhere, where it is thicker (e.g. the ampulla) may not completely occlude the tubal lumen and is not recommended. Most failures associated with the application of clips are due to faulty technique, either because the wrong structure has been clipped or because the tube has not been completely occluded.

3. *Falope rings* (*Yoon et al* 1977)²⁴ made of silicone rubber are easy to place over thin tubes, but if an attempt is made to place the ring too near to the uterus, or if the tube is too thick, the tube may be avulsed (transected) leading to haemorrhage. Failures may occur because a fistulous connection forms between the two arms of a correctly placed ring, or a fistula forms in the proximal end of the transected tube. Failure may also occur if only part of the tube is occluded because the whole tube has not been pulled into the applicator and only part of the tube has been ringed (*Yoon et al* 1977)²⁴. Cases have been reported of rings

'wriggling off' the tube by vigorous peristalsis. Yoon recommends that sexual intercourse and pelvic examination, should be avoided in the first month after placement of the rings (Yoon *et al* 1975)²⁵. If doubt occurs as to the correct application of the ring, then a second one should be applied close to the first.

Should there be a large gap between two rings, then a hydrosalpinx may occur. This applies equally to the placement of clips.

Counselling & Consent

Prior to an operation the patient should be given sufficient information about the operation for her to be able to give proper, informed consent. The following headings should be dealt with during the counselling interview:

1. **Alternatives:** Check that alternative methods of family planning (including vasectomy) have been discussed and thought about.
2. **Type of operation:** The type of operation, e.g. laparoscopy or laparotomy, clips or rings, should be explained to the patient.
3. **The failure rate of each operation** should be discussed and the patient should be clear in her mind that the operation is not 100% guaranteed.
The guidelines recommended by the Royal College of Obstetricians & Gynaecologists (RCOG) quote a failure rate of 1:200. This is a general figure and is recognised as being higher than the Filshie clip but lower than other methods, for example, bipolar cautery. When a procedure fails the ensuing pregnancy could be intrauterine or ectopic (over 60% of the pregnancies are ectopic when the tubes are cauterised and approximately 4 to 5% with clips). When discussing vasectomy, both early and late failures should be mentioned. Although late failures are almost unheard of, some published work has suggested that they may be up to one % (Philip *et al* 1984²⁶; Hendry 1991²⁷).
4. **Permanency:** The patient should be aware of the permanent nature of the operation. Reversal procedures should not be an integral part of the counselling process. However, should enquiries be made, it is recognised that up to 80% return of fertility can be anticipated if the methods used have included rings or clips (Owen 1984)²⁸. This is dependent upon the age of

patient at reversal.

5. **Risks:** Patients should be reminded that there is a surgical and anaesthetic risk of the procedure. Some surgeons offer a local anaesthetic procedure, which removes the risks associated with general anaesthesia (Mackenzie *et al* 1987)²⁹. From a safety point of view this should be encouraged.
6. **Condition of the patient:** Patients who are overweight or underweight or who have previous abdominal scars, or who have serious medical conditions, have an increased risk of having medical or surgical complications.
7. **Alternative procedures:** It should also be explained that the laparoscopic approach may fail and permission to resort to mini-laparotomy should always be sought pre-operatively.
8. **Procedure done at pregnancy:** Patients having the procedure performed at the time of pregnancy, eg postpartum or post-abortion should be informed of the possibility of a higher failure rate.
This has been quoted as two to three times the interval rate, although a ten-year follow-up study conducted in the United States under the auspices of the Centres of Disease Control (Peterson *et al* 1996)³ has completely reversed this spurious statistic as partial salpingectomy postpartum has one of the lowest failure rates with 7.5 per thousand over a 10 year period.
9. **Regret:** Patients must be made aware that the regret rate is more prevalent when the operation is performed when the patient is young (arbitrarily under 25 years of age) and that it is also high when associated with pregnancy. This does not necessarily mean that the operation should not be performed under these circumstances, but that extra care should be exercised when making the final decision. In this context, it must be remembered that approximately 50% of cases in the USA employ postpartum tubal ligation and postpartum sterilisation is popular in the developing world because of the ease of access and also for economic purposes.
10. **Contraception prior to the procedure.** Patients should be encouraged to use adequate contraceptive methods up to and including the period immediately following the operation.
Following counselling the patient should sign a

consent form. This should be a dedicated consent form which should include reference to the appropriate risks and failure rate. The practice is endorsed by the Department of Health in the red book 'A Guide to Consent for Examination and Treatment' issued by the Department of Health in association with HC (90)22.

Patients have higher expectations than ever before and they require more technical information to satisfy their need for knowledge and to prevent the emotional consequences of unexpected complications.

It is becoming popular to complement the counselling/consent interview with the handing out of a leaflet summing up the nature of the operation.

Reasons for litigation relating to female sterilisation

Litigation relating to sterilisation procedures is compiled under four main headings. (Table 1)

1. The patient was pregnant at the time of the operation

It has always been recognised that if the procedure is performed in the luteal phase of the menstrual cycle the patient could already have conceived. An ectopic or an intrauterine pregnancy may follow.

1. That the patient was already pregnant at the time of sterilisation procedure and it was not recognised by the surgeon.
2. That there was failure of appropriate counselling leading to a failure to achieve proper informed consent.
3. That the operation failed because of:
 - (i) a correctly employed technique which was followed by a re-canalisation, or the presence of a proximal tuboperitoneal fistula;
 - (ii) a procedure which was inappropriately or inadequately performed, leading to the continuance of fertility.
4. That there was inadvertent injury during access to the tubes (eg laparoscopy or laparotomy), or injury relating to the method of the occlusive technique, eg bowel perforation due to cautery.

Table 1:

Although it would be ideal to perform the procedure during the proliferative phase of the menstrual cycle, this is logistically very difficult as administrative problems such as variable menstrual cycle and busy gynaecology services would prohibit its appropriate use.

However, every effort should be made to ascertain the patient's last menstrual period and to seek any evidence of pregnancy should it be there. Farquarson (1996)³⁰ has reported that as many as 5% of women are pregnant at the time of a tubal ligation. This suggests that a significant number of women are not using a reliable method of contraception prior to the procedure. It also suggests a high degree of irresponsibility in some patients immediately prior to the operation and may also reflect poor counselling.

In a recent case (*Crouchman v Burke 1997*)³¹ a patient was sterilised on the anticipated day that her period was due even though there was a note stating that she had irregular periods. Despite a tubal ligation and a dilatation and curettage the patient continued the pregnancy.

The judge ruled that the defendant was responsible for the misunderstanding which led to the patient believing that she would not be pregnant after the operation and he ruled that the defendant was liable for pain and suffering and also for the upbringing of the child. The plaintiff was awarded approximately £113,000. Although the judge intimated that the judgement should not affect clinical practice, the judge's direction can only have one message, and that is that the doctor is responsible for diagnosing any pregnancy when it may be present.

The safest course of action is to assume that all women are potentially pregnant at the time of the operation and to perform a sensitive pregnancy test on every patient. It is the author's belief that the consent should include a statement that the patient accepts full responsibility for any pregnancy which could have been conceived prior to the sterilisation operation.

2. Inadequate Counselling

Failure to warn adequately about the risks and failure rates are the basis of many legal claims. The counselling checklist should be adhered to and it should be documented in the notes. The

overall failure rate of the different procedures are difficult to interpret as long-term failure rates appear to be higher than expected particularly in relationship to Bipolar Cautery and to Hulka clips and Falope rings. Short term failure rates are often quoted and it may be between 1 and 10 per thousand (Chi *et al* 1980³², Vessey *et al* 1983³³). The Royal College of Obstetricians and Gynaecologists Handbook on male and female sterilisation quotes a failure rate of 1 in 200 and this is an overall figure and does not relate to any one particular method. Clinical governance is becoming a part of self audit, it may be necessary not to quote published figures (which may be high or low) but to quote one's own personal lifetime risk and also the personal rate of inadvertent injury.

3. Failure of Sterilisation

This subject needs further elaboration.

A sterilisation procedure may fail because of one of three mechanisms. The first is when there is the presence of a tubo-peritoneal fistula. This may be directly at the end of the proximal tubal stump, or it may possibly involve a fistula which emerges from the side wall of the fallopian tube, often secondary to endosalpingeosis. The resultant pregnancy may be intrauterine or ectopic. Fistulas are more common following cautery procedures but have been rarely described with mechanical methods. Rock *et al* 1981³⁴ reported that 46% of cases of tubal cautery healed up with a tubo-peritoneal fistula compared with 11% of Pomeroy procedures and 0% of Falope rings. This may explain the high failure rate and ectopic pregnancies quoted in the Crest study (Peterson *et al* 1996)³.

The second is regeneration of a tubo-tubal fistula. This is common with bipolar coagulation and the pregnancy may be intrauterine or ectopic. A third cause of failure is failure of the operator to perform a satisfactory procedure. 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 the clip equipment is not assembled or maintained correctly incomplete closure may occur leading

to failures, eg the Filshie Clip applicator may not close clips sufficiently if not assembled and maintained correctly, although there is no detailed scientific analysis concerning this in scientific literature to date.

The top jaw should always be noted to be flat following application. A curved upper jaw, known as 'the Sydney Harbour Bridge curve' denotes incomplete compression of the upper jaw.

Also, on balance, 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 proof of negligence. Failures after this time are more likely to be associated with natural causes. The decisions as to whether negligence has occurred is based upon the Bolam test. If an intrauterine pregnancy occurs the patient has the prerogative of seeking a termination of pregnancy, or continuing with the pregnancy. If she elects for a re-sterilisation procedure it is recommended that another doctor perform the operation, or is at least present during the operation and, if possible, histological evidence should be obtained to confirm the cause of mechanical failure. Should histological evidence not be available, then a careful description of the fallopian tubes should be clearly documented by both observers.

4. Long-term failure rates

There are remarkably few reports relating to long-term failure rates following female sterilisation. The most notable study has emerged from the Centers of Disease Control in the USA, known as the CREST study, when 10,685 women participated (Peterson *et al* 1996)³.

At ten years post-operation the life table probability of pregnancy was 24.8 per 1000, for bipolar cautery and 36.5 per 1000 for Hulka clip sterilisation (Figure 1). For women under 28 years of age this figure was 54.3 per 1000 and 51.1 per 1000 respectively. This is considerably higher than that expected.

Surprisingly, unipolar diathermy had a 10 year life table probability of pregnancy of 7.5 per 1000, and postpartum partial salpingectomy was also 7.5 per 1000 which is relatively low and contradicts the belief that there is a higher rate of pregnancy following a post-partum procedure.

In a series of over 400 patients receiving the Filshie clip under local anaesthesia, in patients recruited between 1982 and 1992 from the Family Planning Association clinic in Nottingham, only one failure has been observed (Filshie *et al* 1998)³⁵, which represents a long term failure rate of less than 0.25% which is very low and similar to that reported by Penfold 2000³⁶.

Laparoscopic Techniques: Results of the CREST study (Peterson 1996)

Ectopic pregnancy is possible following a sterilisation procedure, and, of the failures, over 60% could be ectopic when tubal cautery is employed; this reduces to approximately 5% when mechanical methods of ligation are employed. Patients undergoing bipolar coagulation under the age of 30 years were 30 times more likely to have an ectopic pregnancy than patients who had a postpartum salpingectomy (Peterson *et al* 1997b)³⁷.

Inadvertent injury during the procedure

Puncture of blood vessels or viscera during the insertion of the Veress needle or trocar and cannula have been described. The relationship of the major vessels to the umbilicus is very variable and must not be assumed. Most vascular injuries can be avoided, but bowel perforation, particularly by the Veress needle, is often unavoidable.

Obese patients, thin patients and patients who have lower abdominal scars are more at risk.

Open laparoscopy (Hassoon 1974)³⁸ is designed

to reduce inadvertent injury to visceral structures (Peterson *et al* 1983)³⁹. Mechanical methods of sterilisation eliminate electrical and thermal injuries. Anaesthesia always has its risks. The increased use of local anaesthetic is recommended by some surgeons.

Checking for tubal patency after sterilisation

There is general consensus that there is no need to check that the tubes have been effectively occluded before the couple resume sexual relations. Obviously, if the surgeon was in any doubt at the time of his operation that the tubes may not have been occluded then he would be wise to say so and to arrange for a hysterosalpingogram to check the situation. Contraception should be employed until tubal blockage has been confirmed.

Managing a failed sterilisation

The patient should be seen as soon as possible for counselling. If possible a senior member of the team should give advice.

In particular, the doctor should be frank in his explanation, whilst being sensitive to the patient's feelings and natural consternation. The doctor should proceed circumspectly to ascertain whether or not the woman would wish the pregnancy to be terminated. If she does, arrangements should be made to do so expeditiously, whilst allowing proper time for her to arrive at her decision with her partner.

If the decision is that the pregnancy should continue to the full term, the gynaecologist

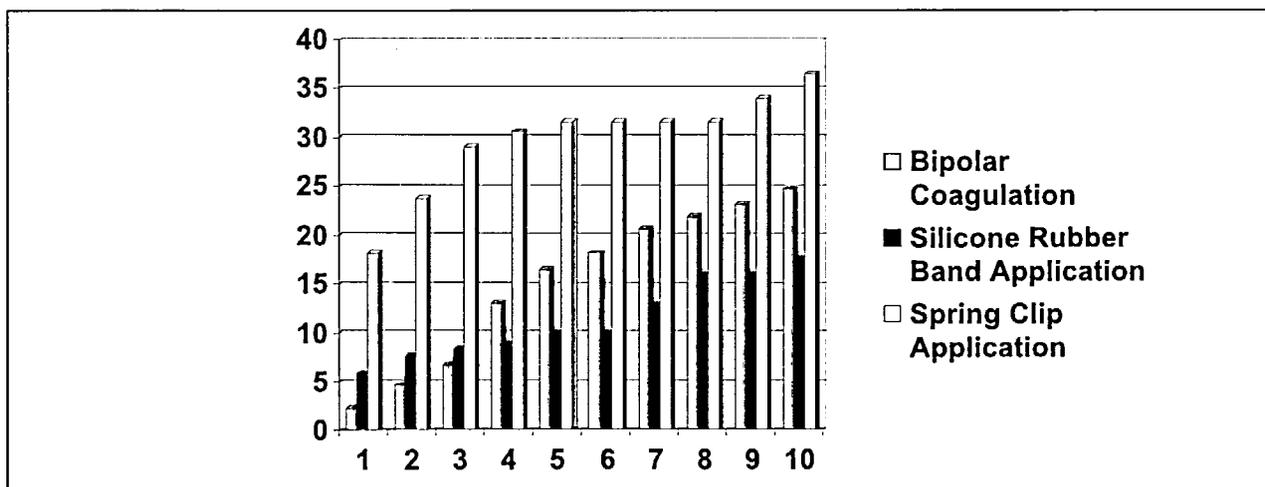


Figure 1: Life table probability of pregnancy in CREST Study

should accept this.

The question of repeat sterilisation obviously arises and requires time for discussion. It may not be appropriate to do this until the decision has been made concerning the future of the pregnancy. In any case consideration must be given to the time of re-sterilisation. There are certainly reasons for not combining repeat sterilisation with abortion or soon after full-term delivery, including the small increase in morbidity and difficulties with the laparoscopic application of clips or rings. Time should be taken to explain these problems.

A further problem is finding the cause of the failure at a repeat operation. This is often a dilemma for the patient that needs to be spelled out. The apparently simplest, and maybe the safest, option is often a repeat laparoscopic procedure but this will not always be necessary and usually does not provide forensic evidence of the reason for failure.

Many women believe that the cause will be found at the second operation. This may be true if it is obvious that on one or both sides, the tube had not been occluded because some other structure had been dealt with at the first operation. However, it is not usually the case, especially if no portion of the tube is removed for histological examination. Rarely, either hysterosalpingography prior to the second operation or the injection of blue dye to the uterine cavity at the time of the second operation may demonstrate a tubal fistula or patent tube.

If a repeat laparoscopic sterilisation is required photo documentation is useful. However if the clip or ring or area of cautery appears to be satisfactory a partial or complete salpingectomy could provide scientific evidence of why the procedure failed. Laparoscopic salpingectomies are now commonly performed. If the patient has a repeat procedure then a colleague should either take-over the case or should be present at the repeat procedure. A histopathologist should be fully informed of the clinical picture and the pathologist should be skilled in attempting to find a fistula or other cause of failure.

Potential Litigation

1. Clip Migration

Innocent migration of clips following a normal application are commonplace and it is estimated that the incidence is over 25%. The pathophysiology is related to the speed at which peritoneal-like tissue forms over the clip anchoring it to the fallopian tube. If the peritonealisation is quick, the clip remains *in situ*, if it is slow, the tube may become transected with both ends of the tube healed over to form a cul-de-sac. The clip will have no covering tissue to maintain its position and the clip will fall off and migrate.

The clip usually migrates to the omentum but, less commonly, may remain in the pouch of Douglas, paracolic gutters or at any other site. In a prospective study involving over 6000 patients which was presented to the FDA panel hearing in 1996, three clips were noted to have been expelled from the body via the vagina, urethra and rectum but in no case was any morbidity observed on examination. If a pelvic abscess occurs then the clip may be expelled abdominally when the abscess bursts or is incised (Robson and Kerin 1993)⁴⁰. Both Filshie clips and Hulka clips have been known to migrate (Gooden *et al* 1993)⁴¹. Considering that in excess of three million pairs of Filshie clips have been used, only a handful of cases with such problems have been reported in the literature.

A review of migration of clips is provided by Amu & Husemayer (1999)⁴².

If a migrated clip is noted incidentally, eg when x-rays have been taken because of urinary or skeletal problems, reassurance is normally all that is warranted. To inform the patient to use another method of contraception, or to resort to laparoscopy or indeed laparotomy, is not indicated in the overwhelming majority of cases as the morbidity of such procedures is significantly in excess of leaving the clip, whether it be open or closed.

Equipment Maintenance

2. The sterilisation equipment be it the Filshie clip, Yoon ring, Hulka clip applications or cautery forceps, all need to be kept in first class working order. The hospitals, surgeons, theatre sisters and Central Sterile Supply Departments have a duty to their patients to ensure the equipment is

well kept. In particular the Filshie clip applicator should be able to flatten the upper jaw. If a clip is observed to have an upper jaw curved when fully compressed the applicator needs checking. Firstly the handle number of the applicator should match the shaft number. Secondly, the handle and the stem should be fully screwed together. There is a checking device available to insert into the jaws which can confirm whether the jaw closes appropriately. It is recommended that the batch number of the clips or rings should be recorded in the notes as should be the serial number of the applicator.

Photo Documentation

Photo documentation whether it be videos or photographs serve two purposes, the first is that every procedure is carefully checked not only by the surgeon and his assistant but also by the theatre staff. Secondly, in cases of failure documentation could provide reassuring information for the surgeon.

Conclusions

Sterilisation is an operation frequently used as a method of contraception, which is permanent. However, the associated failure rate dictates that gynaecologists should:

- ensure that the women they advise are properly informed, which involves taking the time necessary during preoperative counselling;
- ensure that proper skill is employed and the chosen method of sterilisation is carried out;
- and deal with failures, taking account of the circumstances that led to failure, and the consequent needs of the individual woman.

Practice Points

- * More than 1 in 4 couples rely on sterilisation (either male or female)
- * A dedicated consent form for the procedure is considered good practice encompassing the contraceptive alternatives, permanency, type of procedure, associated risks and the failure rate
- * Litigation for sterilisation relates to 4 main areas; unrecognised pre-existent pregnancy, failure of counselling, operation failure, and inadvertent injury
- * In the event of failed sterilisation, the patient should be seen as soon as possible by a senior clinician. The doctor should re-address the failure rate, enquire about how the women wishes to proceed with the pregnancy and discuss the issues regarding the repeat sterilisation and potential difficulties in establishing why the initial procedure failed.

References

1. United Nations. Levels and trends of contraceptive use as assessed in 1988. New York, 1992.
2. Office of National Statistics 1995 Birth Statistics. Series FMI No. 24 London: HMSO. 1977.
3. Peterson HB, Xia Z, Hughes JM, Wilcox LS, Taylor LR, Trussell J. The risk of pregnancy after tubal sterilisation: findings from the US collaborative review of sterilisation. *Am J Obstet Gynecol* 1996; **174**: 1161-1168.
4. Penney CG, Soutar V, Glasier A, Templeton AA. Laparoscopic sterilisation: opinion and practice among gynaecologists in Scotland. *Br J Obstet Gynaecol* 1997; **104**: 71-77.
5. Garrud P, Sheard C, Filshie G, Beattie A. Elective female sterilisation: a survey of UK gynaecological practice. *CME Bulletin Gynaecology* 2000; **2** (1):13-17.
6. Sidaway v BRHG. 1 All ER 643, (1985) AC871, (1985) 2 WLR. 1985.
7. Bolam v FPMC. 1957 2 All ER 118, (1957) 1 WKR 82.
8. Gold v HHA. 1 QB 481, (1987) 2 All ER 888, (1987) 3 WLR 649, (1988) 1 FLR 55. 1988.
9. Eyre v M. 1 All ER 488. 1986.
10. Thake v M. 1 All ER 497. 1986.
11. Emeh v K, Chelsea & Fulham Area Health Authority. 3 All ER 1044. 1984.

12. Udale v BAHA. 2 All ER 522. 1983.
13. Benarr v KHA. NLJR 179. 1988.
14. MacFarlane v THB. 2000.
15. Parkinson v St. James and Seacroft University Hospital NHS Trust.
16. Bishop E, Nelms WF. A simple method of tubal sterilisation. *NY State J Med* 1930; 30: 214-216.
17. Pitkin RM, Zlatnic FJ. The year book of obstetrics and gynaecology. Chicago, London, 1982.
18. Meizner I, Glezerman M, Harroch D, Leventhal H. Abdominal pregnancy following hysterectomy. *Isr J Med Sci* 1983;19 (3):283-285.
19. Chamberlain G, C B. Gynaecological laparoscopy - the Report of the Working Party of the Confidential Enquiry into Gynaecologic Laparoscopy: Change after tubal sterilisation. Royal College of Obstetricians and Gynaecologists. *Am J Obstet Gynecol* 1978; 147: 830-836.
20. Howkins J, Hudson C. Shaw's Textbook of Operative Gynaecology 5th Edition. London: Churchill Livingstone, 1983.
21. Semm K. Endocoagulation: a nearly 99% effective method of tubal sterilisation. In: Philips J, editor. Endoscopic Female Sterilisation. A comparison of Methods. California: Downey: *Am Ass Gynaecol Laparosc* 1983: 89-104.
22. Hulka J, Omran K, Leiberman B, Gordon A. Laparoscopic sterilisation with the spring clip: instrumentation development and current clinical experience. *Am J Obstet Gynecol* 1979; 135 (8):1016-1020.
23. Filshie GM, Casey D, Pogmore JR, Dutton AGB, Symonds EM, Peake ABL. The titanium/silicone rubber clip for female sterilisation. *Br J Obstet Gynaecol* 1981; 88: 655-662.
24. Yoon IB, King TM, Parmley TH. A two-year experience with the Falope ring sterilisation procedure. *Am J Obstet Gynecol* 1977; 127(2):109-112.
25. Yoon IB, King TM. A preliminary and immediate report on a new laparoscopic tubal ring procedure. *J Reprod Med* 1975; 15(2): 54-56.
26. Philip T, Guillebaud J, Budd D. Late failure of vasectomy after two documented analyses showing azoospermic semen. *BMJ* 1984; 289: 77-79.
27. Hendry WF, editor. Vasectomy and vasectomy reversal. London: Butterworth-Heinemann, 1989.
28. Owen E. Reversal of female sterilisation. A review of 252 microsurgical salpingo salpingostomies. *Med J Aus* 1984; 25: 276-280.
29. MacKenzie IZ, Turner E, O'Sullivan GM, Guillebaud J. Two hundred outpatient laparoscopic clip sterilisations using local anaesthesia. *Br J Obstet Gynaecol* 1987; 94: 449-453.
30. Farquarson RG. Value of preoperative pregnancy test in risk management. *Lancet* 1996; 547: 1271.
31. Crouchman v B. RSC Ord 59, r (1)(f), Ord 68, r (1)(1990) 2 All ER 1024. 1997.
32. Chi I, Laufe L, Gardner Sea. An epidemiologic study of risk factors associated with pregnancy following female sterilisation. *Am J Obstet Gynaecol* 1980; 136 (768-771).
32. Vessey M, Huggins G, Lawles M. McPherson K, Yeates D. Tubal Sterilisation: Findings in a large prospective study. *Br J Obstet Gynaecol* 1983; 90: 203-209.
34. Rock J, Parmley T, King T, Laufe L, Su B. Endometriosis and its development of tuboperformed fistulas after tubal ligations. *Fertil Steril* 1981; 35(1):6-20.
35. Filshie GM, Helson K, Teper S. Day case sterilization with the Filshie Clip in Nottingham. 10 year follow up study: the first 200 cases, pp 145-158, 7th. Annual Meeting of the International Society for Gynecologic Endoscopy, Eds. Kruger, Gomiel & van der Wat, Publisher: Monduzzi Editore International Proceedings Division.
36. Penfield AJ. The Filshie clip for female sterilisation: a review of world experience *Am J Obstet Gynecol* 2000 182 485-489.
37. Peterson HB, Xia Z, Hughes JM, Wilcox LS, Tylor LR, Trussell J. The risk of ectopic pregnancy after tubal sterilisation. *N Eng J Med* 1997b; 336: 762-767.
38. Hassoon H. Open laparoscopy: a report of 1590 cases. *J Reprod Med* 1974; 12: 234-238.
39. Peterson HB, DeStefano F, Rubin GL, Greenspan JR, Lee NC, Ory HW. Deaths attributable to tubal sterilization in the United States 1977-1981. *Am J Obstet Gynecol* 1983;146(2): 131-136.
40. Robson S, Kerin J. Recurrence of pelvic abscess associated with a detached Filshie clip. *NZ J Obstet Gynaecol* 1993; 33(4): 446.
41. Gooden MD, Hulka JF, Christman GM. Spontaneous vaginal expulsion of Hulka Clips. *Obstet Gynaecol* 1993; 81(5 part 2): 884-886.
42. Amu O, Husemeyer RP. Migration of sterilisation clips: case report and review. *Br J Fam Plann* 1999; 25(1):27-28.