

PERSONAL VIEW

Review of the complications and medicolegal implications of vasectomy

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The operation of vasectomy is a commonly performed procedure for male sterilisation. It should normally be a straightforward day case procedure undertaken by a competent medical practitioner under local anaesthesia. But how is competence assessed? General practitioners (GPs) have increasingly undertaken minor surgical procedures, and guidance to ensure an appropriate standard of care for patients undergoing such surgery in general practice has been published.¹ Vasectomy, however, is not specifically mentioned though problems relating to vasectomy are the main cause of claims against GPs for medical negligence related to minor surgery.²

Litigation against secondary care practitioners, mainly urologists and general surgeons undertaking vasectomy in the hospital setting or in private practice, is also highly prevalent. Neither the Royal College of Surgeons of England³ nor the Joint Committee for Higher Training in Urology⁴ mentions vasectomy in their curricula. The most common reason for complaint is that the operation failed to render the patient sterile, but failure to warn patients of possible complications such as pain, haematoma, and infection are also prominent causes of patient dissatisfaction. In this article we outline the potential pitfalls in offering a vasectomy service and suggest ways of avoiding them. In so doing we aim to provide guidance for best clinical practice in this litigious area.

Counselling and consent

There should be a standard protocol for the performance of vasectomy after referral which

incorporates counselling and informed consent. Written documentation which records the details discussed at the consultation is essential. The provision of a booklet for the couple is strongly recommended (table 1) and the fact that this has been done recorded in the notes. Any man may request a vasectomy and it is not a legal requirement for his partner to sign the consent form. It is, however, advisable wherever possible, that this is undertaken. The general aim of counselling both partners is that the full implications of vasectomy are explicit in the context of the family concerned. Occasionally the female partner is pregnant at the time of vasectomy counselling and it is as well to establish whether the vasectomy should be deferred until the outcome of the pregnancy is known. If the couple have a young baby then the possibility of a cot death in the first six months should be considered and if there is concern in this respect the vasectomy can be deferred to a later date.

Nevertheless variations occur. Men claiming to be in the process of marital divorce may sometimes request vasectomy because of the requirements of a new partner. This may be accompanied by a request for professional secrecy. The latter may also be requested by men claiming to be locked into loveless marriages and wishing to continue a liaison with a partner having the same difficulty. Childless couples determined to remain so are not uncommon. In such couples it is sometimes reasonable to have a pre-vasectomy sperm test performed in order to be certain that the male partner is not already infertile.

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Table 1 Example of patient information leaflet

YOUR VASECTOMY OPERATION

Before the operation

It is important that you have a full pubic and scrotal shave.

Bring with you a clean pair of underpants of the "Y" front type (not boxer shorts) to hold a small dressing in place.

After the operation

The local anaesthetic lasts for over 1 hour but when it wears off you will experience some discomfort. This is usually slight, not severe and should be controlled by taking painkillers.

Keep the dressing in place until the following evening when you should bathe or shower. You will not need a dressing after this and a daily bath or shower will keep the area clean and help the stitches to dissolve.

You may notice some bruising in the skin and slight swelling around the stitches. If you develop increasing discomfort, pain, swelling, redness and/or discharge you should consult your doctor without delay. Infection is uncommon but can be a complication of any operation and so can excessive bruising. For 48 hours after the operation it is best to avoid physical activities, straining, or heavy lifting as this reduces the risk of developing troublesome bruising. There is a small possibility of chronic pain or discomfort after vasectomy even after a straightforward, uncomplicated operation.

You should resume intercourse as soon as you feel comfortable to do so making sure that you continue to use your usual method of contraception. There are still active sperm "upstream" from the site of the operation and these need to be ejaculated away.

Try and ensure that you have two ejaculations per week in order to get rid of these before the first sperm test 3 months after the operation and the second test 1 month later. If these tests are clear then you will receive a letter telling you this so that you can discontinue contraception.

There is the possibility that even after being given the "all clear" the operation may fail to keep you sterile but this is very rare and the risk of this happening is remote.

More commonly, but again infrequently, the sperm count may fail to clear and a reoperation is advised.

Occasionally it becomes clear during a consultation that one partner is much keener on the prospect of vasectomy than the other. The authors have also experienced vasectomy requests from men who had developed extra-marital liaisons but who did not wish to abandon their wives.

The outcome of such situations is clearly a matter of discretion for the doctor concerned. While there may be requests to acquiesce to professional secrecy it should be pointed out that there may be practical difficulties with regard to the administrative correspondence for sperm tests and other appointments. Many requests for vasectomy do not involve the person's GP and there may even be a request that the latter is not informed. While this is not generally felt to be a desirable scenario, it is again a matter which is at the discretion of the doctor concerned. The latter should counsel the applicant regarding the potential disadvantages of such clandestine arrangements. Pre-vasectomy counselling may sometimes be undertaken by someone other than the surgeon undertaking the vasectomy itself. In such circumstances the surgeon must obviously be responsible for the skill and thoroughness with which the counselling is given and with which the consent forms are completed. The surgeon must check that this has been done in each individual case before actually proceeding with the vasectomy. Though not a legal necessity, to undertake a vasectomy without obtaining an appropriate signed consent form is foolish, since litigious patients may claim that they had not been adequately counselled. There should be an interval of at least a few days between pre-vasectomy counselling and the operation. This allows the man to undertake a pre-vasectomy scrotal shave which makes the operation easier. It also allows him to select a day when he can take a few days rest from his occupation, should he get more postoperative discomfort than is usual. The wording of the consent form is critical and must include the statement "I understand that I may not become or remain sterile" (box 1). The reason that this statement is so important is that early recanalisation was first described in 1969 and is recognised by the fact that the first post-vasectomy sperm count may be clear or reduced and then increase rapidly again. Late recanalisation became recognised after six such failures were reported in 1984 and which presented with unexpected pregnancies sometime after clearance after two consecutive azoospermic samples.⁵ The chance of this occurring has been estimated to be one in 2900 (0.03%).⁶ Although the risk is slight, it is therefore not negligible and failure to have warned the patient of this possibility in any vasectomy performed after 1984 is difficult to defend in a court of law.

If there is no *written* record of the warning having been given then it is the surgeon's word against the patient's (and often his partner) and the judge then has a difficult choice in deciding who to believe in this respect. In practice it is common for patients to discuss sterilisation with the family doctor who is able to discuss

Box 1: Consent for sterilisation by vasectomy

I [name of patient] of [address] consent to undergo the operation of bilateral vasectomy, the nature and effects of which have been explained to me. I have been told that the intention of the operation is to render me sterile and incapable of parenthood. I understand that this operation may not be effective for several months and that two negative sperm counts should be obtained before contraceptive precautions are discontinued. I understand that vasectomy can sometimes fail and that there is a very small chance that I may become fertile again after some time. I also understand that it may not be possible later to reverse the effect of the operation.

I consent to the administration of a local anaesthetic.

[Date and signature of patient]

I [name of patient's partner] of [address] understand the operation of bilateral vasectomy being carried out on my husband/partner, the nature and effects of which have been explained to me.

[Date and signature of patient's partner]

I confirm that I have explained the procedure and the anaesthetic required to the patient in terms, which in my judgment, are suited to his understanding.

[Signature of consultant urological surgeon]

the advantages and disadvantages of the couple's choice before referring them on for surgery.

In the event of litigation, the GP's records may be of considerable importance.

It is important to determine methods of contraception used and presently employed in view of the continued fertility for a variable period of time after the operation when contraception needs to be maintained.

It is relevant to record the general health of the man, his partner, and children and to inquire directly regarding any regular medication as a routine.

Can operative difficulties be anticipated and avoided?

Needle phobia is quite common and inquiry regarding apprehension or adverse reaction to dental injections is helpful. Having a patient who faints and has a convulsion during the operative procedure can usually be screened out by such questioning. Such patients are best advised to undergo vasectomy under general anaesthesia.

Following counselling the man must be examined to ascertain that the operation can be undertaken easily and painlessly under local anaesthesia. Previous inguinal or scrotal surgery may have resulted in thickening of the spermatic cord. The presence of a hydrocoele, epididymal cysts, a varicocele, or horizontal lie testes may not necessarily prejudice surgery under local anaesthetic but their presence

should be noted and recorded. In order to assess a varicocele and horizontal lies accurately the patient needs to be examined standing up as well as lying down. Some men have a particularly thick walled scrotum with testes held high against the abdomen so that it is difficult to “get above” the testicle and palpate the vas easily. A warm room and the application of a warm pack to the scrotum may well resolve the problem but if the vas cannot be palpated with confidence and brought to the surface, and fixed by the examining fingers and thumb immediately below the scrotal wall, then the patient is not suitable for vasectomy under local anaesthesia.

It is painful for the patient and difficult for the surgeon to “go looking” for the vas via a small skin incision. Prolonged dissection may lead to an increased risk of haematoma formation, infection, and occasionally vascular impairment of the testicle with subsequent atrophy and occasionally, loss. Such an outcome is difficult to defend. It is no shame to admit to the patient that the procedure cannot be undertaken easily and painlessly under local anaesthesia and that a general anaesthetic is required.

Does the technique of vasectomy matter?

Schmidt, in a series of 6248 consecutive vasectomies performed over a period of 38 years with a section-fulguration fascial interposition technique reported no post-vasectomy pregnancies.⁷ Is the success due to sealing the ends of the divided vasa with diathermy or the fascial interposition or both? If the vasa are simply divided and ligated the failure rate is as high as six per 1000.⁸ It would seem prudent therefore to utilise a technique whereby the ends of the vasa after ligation or diathermy are separated by viable tissue to minimise the risk of failure.

Should men have a written warning about postoperative complications?

Postoperative haematomata are a sufficiently common occurrence for the patient to be warned of the possibility (table 1). Infection, usually with a skin staphylococcus, may also occur and patients should be warned about this possibility so that prompt and appropriate antibiotic therapy can be given.

The problem of chronic testicular pain after vasectomy has become increasingly recognised and is common enough to mention during counselling.⁷⁻¹³ It is certainly the subject of litigation and a difficult clinical problem to investigate and treat. Painful and clinically tender post-vasectomy nodules can be excised and epididymectomy to include the lower vas segment may be successful if the pain persists.¹⁴⁻¹⁵ Orchidectomy should only be a very last resort. If this course is pursued the patient may well then present with pain in the other testicle.

Choe and Kirkemo found post-vasectomy scrotal pain to be the commonest late complication in 34 out of 182 patients (18.7%), which adversely affected the quality of life in four (2.2%).¹² Thirteen men (9.3%) were dissatisfied with the decision to undergo vasectomy

and 10 of these listed chronic scrotal pain as the reason. McMahon *et al* are clear in their advice regarding chronic testicular pain⁹: “Those performing a vasectomy are under an obligation to ensure that patients requesting the operation are aware of the risk, albeit with the reassurance that in the majority of cases the pain is comparatively mild and only rarely requires further medical or surgical intervention”.

We agree that the evidence is such that men should be warned about the small possibility of chronic testicular pain after vasectomy and that this is sometimes difficult to treat successfully. Referral to a pain clinic for management may be necessary when it occurs.

Postoperative sperm counts and the problem of persisting non-motile sperm

By convention in the UK, two post-vasectomy samples are normally examined before clearance to stop contraception is given. All vasectomised men should be clearly warned that contraceptive measures must be continued until two consecutive samples have confirmed the complete absence of sperm. Compliance with post-vasectomy testing is often poor.¹⁶⁻¹⁸ It is advisable to write to such patients warning them that they should not consider the operation to have been successful in rendering them sterile until such tests are undertaken. A copy of this letter should be sent to the referring GP.

If testing is undertaken three and four months after vasectomy then 87% will be clear,¹⁹ whereas if testing is started too soon then many more men will have to be inconvenienced by providing more than two samples.

A significant number of men on repeated testing have persisting non-motile sperm. Philp *et al* reported no pregnancies after “special clearance” of 310 such men (2%) after vasectomy.⁷ Davies *et al* confirmed this finding in 151 men (2.5%) followed up for three years after vasectomy.²⁰ Edwards and Farlow also gave special clearance to 200 men with non-motile sperm,²¹ and there were no pregnancies in 190 of these that were followed up for 12–15 months. In one study 96% of patients with small numbers of non-motile sperm were azoospermic within two years.²² One pregnancy has been reported, however, where semen analyses showed a small number of non-motile sperm despite two initial azoospermic samples.²³ It seems then that men with small numbers of non-motile sperm have the same risk of late recanalisation as all vasectomised men.

It is wise to note the warning of Smith that the decision to discontinue contraception should be with the patient rather than the doctor.²⁴ In patients with persisting so called non-motile sperm in their ejaculate after vasectomy it is important that arrangements are made with the laboratory that a fresh specimen is examined to ensure that the sperm are truly non-motile. The presence of even a few motile sperm requires that the vasectomy should be repeated.²⁵

Why are doctors sued post-vasectomy?

Doctors are sued after vasectomy for several reasons:

- (1) Failure of the operation to render a man sterile resulting in an unwanted pregnancy.
- (2) Significant postoperative haematoma formation +/- infection requiring operative intervention.
- (3) Chronic scrotal pain sometimes requiring further surgery which is not always successful.
- (4) Atrophy or loss of a testicle following 2 and sometimes 3.
- (5) Failure to inform the patient of a positive postoperative semen sample.

With regard to 2, 3, 4 and 5, claims for compensation will continue to be decided on the familiar issues of duty of care, breach of duty, and causation. In the case of an unwanted pregnancy, successful claims for compensation in the past have included the substantial expense of bringing up a child to the age of maturity. However, following a ruling by the UK House of Lords in 1999,²⁶ it is no longer possible to succeed in a claim for compensation under this heading when a healthy child is the result. Nevertheless, claims relating to the pain, suffering, and expense of an unwanted pregnancy and the additional costs of a disabled child may still be pursued. It is appropriate to point out that at the present time, and for the foreseeable future, the increasingly high marriage breakdown rate does not imply that the surgeon/hospital carrying out the vasectomy has a duty of care towards the patient's future sexual partners.²⁷

Conclusion

We consider that there is a need for a national standard for training in vasectomy to safeguard patients, and to protect medical practitioners from medical negligence claims. It is clear that there are no well controlled comparisons between different methods of vasectomy and long term studies which relate to the technique of vasectomy to failure rates.

In those cases where there is a dispute about consent and counselling, the parties may decide to proceed to a court action. The outcome of the case depends very much on whether the doctor's word or the plaintiff's account of events is believed by the judge. Contemporaneous notes, consent forms, and letters written by the surgeon are invaluable.

It is the responsibility of the surgeon undertaking the vasectomy to notify the patient about the result of the semen analysis and not the laboratory. It is probably wise to reiterate the possibility of late failure in the letter advising the man of the success of the operation as Plaintiffs have used such an omission as the basis of litigation in cases of late failure.

There can be few operations so simple to carry out under local anaesthesia on an outpatient basis which carry so much potential for criticism, complaint, and allegations of incompetence. The counselling and consent, combined with an accurate recording of such disciplines, the written communications, conduct and circumstances of the procedure, the

laboratory assessment of samples, early and late failures resulting in continued fertility, and postoperative complications all demand a highly disciplined approach to the management of the patient during and after surgery.

If one step in the protocol is overlooked it may not be possible to correct the omission retrospectively and a claim for negligence, whether justified or not, may well follow. For the majority of men, with a low risk of complications, vasectomy is an acceptable and effective method of permanent contraception. For the unfortunate few, however, in whom the operation fails to render them sterile or who have significant postoperative complications, litigation is an increasingly popular method of obtaining compensation and causing considerable distress to the unfortunate doctor concerned. Much of this distress is avoidable by good communication, accurate and comprehensive note keeping, and a sound surgical technique.

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