Post-vasectomy testing to confirm sterility

Post-vasectomy testing is carried out to check that a vasectomy has been successful. A vasectomy is a surgical procedure undertaken to render a man sterile (unable to father children). The procedure involves cutting the tubes (vas deferens) that carry sperm from the testicles (see figure 1), preventing it from mixing with semen, the fluid produced in the seminal vesicles and then ejaculated. ASERNIP-S has reviewed the available published evidence to determine how testing should be conducted to confirm sterility.

Figure 1: Male anatomy
What does post-vasectomy testing involve?

Vasectomy is considered a very safe and effective method of contraception, with failure rates generally quoted as between 0% and 2%. The success or failure of a vasectomy can be determined after the operation by testing the semen ejaculated by the patient to see whether it contains sperm. If the vasectomy has been successful, there will be no sperm in the semen. Testing for sperm after a vasectomy is called post-vasectomy semen analysis (PVSA). In an alternatively test procedure, a small piece of vas deferens is cut away and examined under a microscope to check that it has been divided. PVSA is, however, considered a much better indicator of vasectomy success than the vas deferens test procedure.

Current questions concerning PVSA

There is a lack of agreement amongst practitioners concerning some aspects of PVSA testing.

- **The number and timing of tests**
  Traditionally, two PVSA tests have been recommended at between 12 and 16 weeks post-vasectomy and after at least 20 ejaculations. However, many practitioners recommend only one test, in some cases after a much shorter time, such as four weeks.

- **How to measure vasectomy success**
  A vasectomy is considered to be a success if it leads to azoospermia (the absence of sperm in the semen). However, studies suggest that sperm can lose their ability to fertilise a female egg before azoospermia is reached. In these cases the sperm are non-motile or unable to move independently to the female egg and are therefore unlikely to cause pregnancy. Thus patients may be able to rely on vasectomy for contraception before PVSA testing confirms azoospermia.
What is the available published evidence?

In order to make recommendations on testing to confirm sterility after vasectomy, the review group considered:

1. The appropriate endpoint of vasectomy (azoospermia or loss of sperm motility?)

   Azoospermia appears to be a more reliable measure than loss of sperm motility, which can only be measured if the sample is delivered to the laboratory and examined within a certain time.

2. The time taken, or number of ejaculations needed, to clear the vas deferens of existing sperm after vasectomy

   - The percentage of patients reaching azoospermia by their first test varied greatly depending on when the test took place e.g. 51% to 98% of patients reached azoospermia when first tested at three months.
   - In more than half the studies, at least 80% of men reached azoospermia when first tested from three months onwards.
   - For patients undergoing a second test, there was always an increase in the percentage of patients reaching azoospermia between the first and second test. When first tests were performed later, this increase got smaller.
   - Between 11 and 20 ejaculations were required to reach azoospermia in 80% of patients.

   The evidence suggests that approximately 80% of patients are azoospermic after three or four months and after about 20 ejaculations.

3. The reappearance of sperm (motile or non-motile, permanent or temporary).

   - One study reported temporary reappearance of motile sperm in seven patients (up to four months post-vasectomy), but azoospermia was reached again in all cases.
   - The reappearance of non-motile sperm after azoospermia was reported in seven studies, up to 22 months post-vasectomy and up to 17 months after azoospermia had been demonstrated.
Motile sperm can reappear in the semen due to recanalisation (see point 4 below). Reappearance of non-motile sperm can result from sperm being stored in the vas deferens or the failure to detect sperm in an earlier test. The reappearance of sperm will only be detected if a second test is performed. Only a small proportion of patients demonstrate the reappearance of sperm, and in many cases it is temporary with azoospermia eventually reached.

4. **Recanalisation (early and late).**

- Uncommonly the ends of the vas deferens rejoin (called recanalisation). In the studies in this review, recanalisation was diagnosed in patients as early as one month and as late as 12 years after vasectomy (but this can be difficult to distinguish from cases where azoospermia was never reached).

Although we cannot tell when early recanalisation is likely to occur, in most cases motile sperm had been detected in the initial post-vasectomy semen tests. Late recanalisation can occur at any point after azoospermia has been reached.

5. **Pregnancies**

There were 69 pregnancies reported in 20 studies, regardless of the PVSA protocol employed. In the 13 studies that reported on the number of vasectomies, 60 pregnancies were recorded out of 92,184 vasectomies (0.07%). Of the total 69 pregnancies, 27 patients had demonstrated azoospermia in at least one PVSA test; however, only 7 of these (25.9%) had paternity confirmed by DNA analysis. Further semen analyses were reported for 22 patients after pregnancy was confirmed: motile sperm was found in 10 cases, non-motile sperm in 2 cases and 10 were azoospermic.
What are the conclusions and recommendations?
After considering the evidence presented in this review, the review group recommended the following PVSA plan or protocol (see figure 2):

- **Post-vasectomy** testing occurs with only one *azoospermic* test at three months and after a minimum of 20 *ejaculations* (an earlier test cannot be recommended on the poor evidence available).

- If the *semen* sample is *azoospermic* at three months (i.e. the test is negative), the patient can be considered sterile and no further follow-up is necessary.

- If a sample contains *sperm* at the three month test (i.e. the test is positive), further tests are required.

- If *motile sperm* are present, the *vasectomy* is probably a failure and another test one month later will confirm this (and a decision can be made about re-*vasectomy*).

- If *non-motile sperm* are present, further tests should be performed monthly until either an *azoospermic* sample is provided or “special clearance” (due to persistent *non-motile sperm*) can be given. Special clearance could be given when the patient has provided two samples in a row containing < 100,000 *sperm*/ml (non-motile) at least seven months post-vasectomy.

- Approximately 80% of patients would be cleared after one test and the remaining 20% can continue follow-up until cleared, as described above.

- **Vasectomy** failures will be detected at the three month test, and hence histological testing of the *vas deferens* is not necessary (however, it may be useful in a training situation).
Figure 2: Flow chart of the proposed post-vasectomy testing protocol

† The proposal of monthly testing after a positive sample is not evidence-based. It is an arbitrary time period chosen to potentially allow enough time and ejaculations to clear the vas deferens of any remaining sperm.
‡ The pre-requisites for special clearance in this proposal have been based on those in the British Andrology Society guidelines of post-vasectomy semen analysis.

Vasectomy

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Single test at 3 months and after at least 20 ejaculations

~ 80% of patients

Negative
No further testing required

~ 20% of patients

Positive
Further testing required

Non-motile sperm
Monthly† testing required

Motile sperm
Probably vasectomy failure. A 2nd test performed 1 month later will confirm

Positive
“Special clearance” if:
- 2 consecutive tests show no motile sperm
- concentration of non-motile sperm < 100,000/ml
- at least 7 months post-vasectomy‡

Negative
No further testing required (only 1 negative test required)

Motile sperm
Vasectomy failure confirmed
According to the ASERNIP-S Classification System, the evidence available on PVSA protocols was of poor quality. The ASERNIP-S review group considers that more research is required to further improve the protocol of post-vasectomy semen testing.

Acknowledgments
Figure 1 was prepared by Kathrin Hohloch.

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Important note The information provided is based on up-to-date research. However, it is not intended to replace the advice of your medical practitioner. Please ask your doctor if you have any further questions about the management of this condition.

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POST-VAESECTOMY TESTING TO CONFIRM STERILITY

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Evidence Rating

The evidence (i.e. studies included in the review) for ASERNIP-S systematic reviews is rated as Good, Average or Poor, according to the:

- quality of the evidence. High quality evidence comes from a study that has a low risk of bias and no other major flaws (such as lack of enough follow-up data or big differences between the patients selected for the groups).
- availability of the evidence. This refers to how much evidence there is to obtain.

Good

Most of the evidence is either from:

- a high quality systematic review of all relevant randomised controlled trials, or
- at least one large high quality randomised controlled trial.

Average

Most of the evidence is from:

- high quality quasi-randomised trials, and/or
- comparative studies, without major flaws, in which the patients are placed into groups without being randomized, and/or
- an inconclusive systematic review based on small randomised controlled trials, and/or
- randomised controlled trials that are of moderate or uncertain quality.

The results of these studies are more likely to be influenced by other factors compared to high-quality randomised controlled trials. However, these studies show to some extent that there is still a reasonable chance (moderate probability) that outcomes are valid.

Poor

Most of the evidence is from:

- case series
- studies mentioned above, with major flaws or a high risk of bias
- studies in which there is not enough evidence.
Glossary

**Azoospermia**: the absence of sperm in the semen

**Bias**: The influence of other factors, i.e. those not being measured, on the results of a study.

**Case series**: A series of single patients, usually treated at the same centre within a particular timeframe. This often reflects the historical experience of that centre.

**Ejaculation**: semen is expelled from the male urethra

**Evidence**: the studies included in the review

**Motile sperm**: sperm that can move towards and fertilize the female egg

**Non-motile sperm**: sperm that cannot move independently towards the female egg

**Post-vasectomy**: after the vasectomy

**PVSA**: post-vasectomy semen analysis

**Quasi-randomised trial**: A trial using a method which is not completely randomised of placing patients into treatment groups. There is a greater risk of selection bias in quasi-random trials where placement is not adequately concealed compared with randomised controlled trials with adequate allocation concealment.

**Randomised controlled trial**: A study in which researchers randomly place participants in groups. The new surgical procedure will be performed on one group of patients, while the other group of patients will undergo the conventional operation. Researchers measure and compare the outcomes of the patients from the different groups.

**Semen**: fluid produced in the seminal vesicles

**Sperm**: male reproductive cells which combine with the female reproductive egg to form an embryo

**Systematic review**: ASERNIP-S conducts literature reviews on the safety and effectiveness of new surgical techniques before they are widely accepted into the health care system. Each review collects all relevant information, or evidence, on new and standard techniques used to treat a medical condition. The quality of evidence is assessed. ASERNIP-S then makes recommendations on the safety and effectiveness of the procedures that are then endorsed by RACS.

**Vas deferens**: tubes that carry sperm from the testicles
Vasectomy: a surgical procedure to cut the tubes (vas deferens) that carry sperm from the testicles