

Ensuring Vasectomy Success: What Is the Standard?

Androlog Summary

ANTOINE A. MAKHLOUF AND
CRAIG S. NIEDERBERGER

From the Department of Urology, University of Illinois at Chicago, Chicago, Illinois.

Vasectomy is one of the oldest and most commonly performed surgical procedures worldwide. Yet, as this thread on *Androlog* shows, there is no general agreement on the best approach to ensure contraceptive success.

Jay Sandlow (United States) started the discussion by asking a seemingly simple question:

I have a question for those that perform vasectomies. Does anyone know what the standard of care is in regard to sending vas specimens after a vasectomy? In the event that motile sperm are present at some point, there could potentially be a question as to whether or not one side was missed, although it certainly would not change the treatment. A review that was published in the *Journal of Urology* (Griffin et al, 2005) suggested that routine histologic exam was not necessary, but it was a study from Australia. I would be interested in other peoples' thoughts.

Jacqmin Didier (France) replied that he routinely sends the specimen to a pathologist:

Personally, and this is a general policy in my department, I do send a vas specimen to the pathologist. This is an important issue from a legal point of view. I also, of course, ask the patient to provide a sperm sample 3 months after surgery to be sure of the success.

Stuart Howards (United States) then pointed out that the American Urological Association (AUA) has a policy on this particular topic.

Several years ago I asked the AUA to establish a policy that it is not necessary to send a specimen. They did that so the official AUA policy is that a specimen is not necessary.

Sidney Glina (Brazil) agreed with the AUA policy:

To send the vas specimen to the pathologist is unnecessary care that is good only for lawyers and increases the costs of medical care.

So did Jerry Yuan (United States), who also detailed his approach for avoiding the pitfall of dividing the same vas twice and for ensuring azoospermia on follow-up:

As per Dr Stuart's comment, I do not submit vas segments for histology unless it is an unusual case. For example, for two recent cases with histories of undescended testes in whom I could not palpate the vas associated with the pexed testes, I proceeded with in-office unilateral vasectomies. Both men had positive post vas semen with extremely low but motile sperm. Both turned out to have tiny, "angel hair" like vas on the undescended side. The lesson learned is that patients such as these should have exploration or be fully consulted regarding the possibility of needing exploration if unilateral vasectomy fails. I obtain semen at 3 and 6 months post vas; in my experience, about 1 in 10 failures occurs between 3 and 6 months as evidenced by an initially negative 3-month sample and a positive 6-month sample; these men tend not to revert to azoospermia despite extended observation. The likelihood of transecting a structure other than the vas is distinctly low in experienced hands. The possibility of vasectomizing the same vas twice does exist, I *always* perform the vasectomy the same way, ie, the left, then the right, and verify having the intended vas by gently lifting the clamp once the vas is isolated and observing the testis lifting as well. Proper patient consultation and repeated re-enforcement regarding the need for post vas semen will eliminate most medicolegal headaches; as long as patients are well aware of the potential failure, there should be no "unpleasant" surprises. I repeat all vasectomies for free. A phrase I use when informing patients about the need for a repeat vasectomy is "Mr Smith, as it turns out, you are a better man than most..." essentially putting the ball back in his court.

Peter Burrows (United States) further supported the position that pathologic examination of the vas is of little value. Rather, he stressed the importance of postoperative semen analysis testing:

It was my understanding that sending vas specimens or even saving them in your office in the event of a paternity lawsuit provides little liability protection, as not even the best pathologist can discriminate laterality of the vasal segments. That is, perhaps both segments came from the same side. We include as part of the vasectomy a 2-month semen analysis, and if that is azoospermic we recommend a 6-month specimen. If the initial semen analysis is anything but azoospermic, we have them return monthly with the request for frequent ejaculations. When the semen analysis finally clears, a 6-month follow-up is once again recommended. Of course, we have the standard disclaimers for failure, consents, and follow-ups.

Eric Seamen (United States) commented on the variability of urologic practice regarding histologic examination of the vas. More importantly, he raised

the question of counseling patients regarding post-operative semen analysis results:

I have read the posts on this subject with some interest. Certainly, other than initiating a survey, I do not think you will have representation of what most urologists are doing. Many urologists send the vas, just as many of us send hydrocele sacs to the pathologist, and many general surgeons send hernia sacs. I have a question for those who obtain a 6-months semen analysis. When do you tell the patient that it is OK for them to have unprotected relations? As soon as they are azoospermic? Or do you have them wait the full 6 months?

Phillip Wise (United States) stressed the importance of informed consent and provided an excerpt of the question/answer consent form he uses:

I had an occasion to talk with a general surgeon who had just defended a malpractice case against a colleague for pain after a cholecystectomy. This was before laparoscopic cholecystectomies were the norm. In his defense was the office consent form on which the patient had answered some questions regarding the material he had read, supplied by the defending surgeon. Obviously the "informed consent" was obtained because the patient has answered correctly that one of the complications of the surgery was pain. I incorporated that idea when making my information brochure for vasectomies. I have 4 questions at the end of the paper that the patient must answer correctly and sign. If any of the answers are not correct, I explain the rationale behind the question and ask the patient to cross out the incorrect answer and circle the correct one and initial it. The brochure explains the risks, procedures, and alternatives to vasectomy, can be folded in thirds, and sent to the patient prior to the first visit.

The Questions are:

- 1) True or False. The ejaculate can contain sperm for 2 months or longer after the vasectomy.
- 2) True or False. Complications due to vasectomy can include bleeding, infection, or pain.
- 3) True or False. A semen analysis is necessary 2 months after a vasectomy to determine whether the vasectomy was successful or not.
- 4) True or False. Pregnancies can occur months or years later even after a successful vasectomy.

These 4 questions cover the majority of reasons a patient might be unhappy with the results or the surgeon. Even the best can have complications so if the patient returns with a pregnant wife after a successful vasectomy and you send the vas for pathology testing (having saved it in formaldehyde for 11 years), no one is really helped by such a policy. Why did I mention 11 years? Well, a neighbor and his 42-year-old wife announced her pregnancy just last weekend, 11 years after his vasectomy. What a surprise. Anyone interested in my consent form for vasectomy, just let me know and I will either fax or e-mail you a copy. You can use it if you find it helpful—it is not copyrighted. I would be glad to entertain any suggestions to improve mine too.

Mac Van den Bergh (Switzerland) provided a reference to the policy he uses:

I have been following the debate about vasectomy for quite a while. We are performing weekly about 5 to 6 post vasectomy controls and do observe residual sperm on a regular basis. We have adopted the guidelines published in 2002 by the British Andrology Society (Hancock et al, 2002). We are quite happy with those guidelines especially when we explain them to the patient.

Charles Shapiro (United States) brought up the related issue of late-term failures noted at the time of vasectomy reversals:

As an aside, I do a lot of vasectomy reversals and have adopted the practice of having the patients submit a semen sample ahead of time. So far, I have data on 51 consecutive patients and have found 2 with detectable sperm: one with 14 million and one with only a few. While hardly statistically significant, it does suggest that the long-term failure rate of vasectomy might be higher than we suspect. It would be great if we could collect data like this in an organized fashion to get a better idea of the incidence of long-term detectable sperm (but below the level of pregnancy) in patients after vasectomy. The other potential benefit to the patient and to the surgeon thinking about doing a vasectomy reversal is that if there are a few sperm, there is the option of intracytoplasmic sperm injection. Plus if a few are getting through, it means that at least one side is at least partially open and this might influence the character and amount of intraoperative fluid coming from the testicular end and therefore might have some bearing on the decision to proceed to epididymovasostomy rather than a straightforward vasovasostomy.

Marc Goldstein (United States) replied with a reference to his published work on the significance of the presence of spermatozoa at the time of vasectomy reversal:

Regarding Dr Shapiro's finding of sperm in prereversal semen samples and its implication for reversal: We found sperm or identifiable sperm parts in the centrifuged ($200 \times g$ for 15 minutes) pellets in 9.7% of 229 prereversal men (Lemack and Goldstein, 1996). We found sperm in the vasal fluid intraoperatively on at least one side in 94% of men with sperm in the spun pellet. As per Dr Shapiro's suggestion, presence of sperm in the spun pellet is indeed a predictor of the presence of sperm in the vasal fluid on at least one side.

After some requests by posters looking for the official policy, Lawrence Ross (United States) posted it to the thread:

I have been following the discussions regarding standard of care for vasectomy patients with interest. The issue of whether one needs to send a specimen of vas deferens has been considered by the AUA and resulted in the following policy statement:

Routine histologic confirmation unnecessary in performing vasectomy. The American Urological Association, Inc. (AUA) recommends that physicians in practice and that residency training programs no longer require histologic confirmation of the vas deferens as a measurement of vasectomy success. The finding of azoospermia

after a bilateral vasectomy is the standard for success. The persistence of sperm in the semen after a bilateral vasectomy is a surgical failure regardless of a pathologic confirmation that two segments of the vas were removed. The lack of clinical value makes the routine histologic evaluation of surgical specimens obtained by a surgeon experienced in performing vasectomies clinically unnecessary. The surgeon should decide whether a histologic evaluation is warranted. The surgeon should document in the patient's record comprehensive preoperative counseling, careful patient selection, meticulous surgical technique, and whether azoospermia was achieved in the postoperative semen.

Board of Directors, February 1998

Board of Directors, February 2003 (Reaffirmed)

I believe this policy clearly states the accepted standard and as noted has been reviewed and reaffirmed at a 5-year interval as required by the Board of Directors of the AUA.

This thread raised several questions regarding the standard of care for vasectomies.

The first question is whether a vas specimen should be routinely sent for histologic confirmation. As several posters clearly stated, this would not necessarily ensure surgical success. Surgical failure due to incorrect identification of the vas is easily detected by the presence of millions of motile sperm in the postoperative semen examination. Thus, the one scenario in which histologic examination affects management is when the surgeon misidentifies the vas *and* the patient is noncompliant with postoperative semen exam. Unfortunately, it is difficult to estimate the likelihood of such an occurrence, as there are no large contemporary series of vasectomies that report the rate of vas misidentification (Griffin et al, 2005). In experienced hands, as Dr Yuan pointed out, this should be a very rare occurrence. Our approach is to confirm vas identification by cannulating the lumen just before ligation.

The second, and more important, question is how to confirm azoospermia postoperatively. The AUA guidelines quoted above declare azoospermia as the standard of success, without specifying how many exams are necessary. Protocols vary significantly, although most appear to involve either 1 or 2 examinations (Halls et al, 1998). More frequent testing, including annual exams to detect late failures, is rarely used because of extremely low compliance and dubious utility in preventing a pregnancy (Maatman et al, 1997). Several series have documented that patient compliance decreases with each additional test (Belker et al, 1990; Maatman et al, 1997; Badrakumar et al, 2000). In a comparison of compliance with a 1-test vs 2-test protocol, Badrakumar and colleagues found an 84% compliance with a single semen analysis at 4 months vs 71% compliance with 2 tests at 3 and 4 months. The rate of confirmed azoospermia was identical in both arms, and they

concluded that a single test is equally effective (Badrakumar et al, 2000). Surveys of patients reveal that inconvenience is a more common cause of noncompliance than lack of understanding or forgetfulness (Smucker et al, 1991). Thus, we feel that repeated testing after a first azoospermic sample, while desirable, is impractical and not cost effective.

The presence of rare nonmotile sperm after vasectomy has bedeviled urologists for quite a while, and this was the topic of a previous *Androlog* column (Meacham, 2003). The half-life of residual sperm after vasectomy is approximately 2 ejaculations (Freund and Davis, 1969), and most protocols recommend approximately 20 ejaculations prior to a semen analysis. Several investigators have attempted to speed up the onset of azoospermia by flushing the vas at the time of vasectomy. Unfortunately, flushing the vas with water (Mason et al, 2002) or saline (Leungwattanakij et al, 2001; Pearce et al, 2002; Eisner et al, 2004) did not lead to any shortening of the time to azoospermia, possibly because of deposition of sperm within the seminal vesicles (Sukapiriya et al, 2005). While flushing with spermicidal agents has been explored (Slome, 1975; Albert and Seebode, 1977), we are not aware of any recent randomized trials addressing this issue. Thus repeated postoperative testing is the only management option for men with rare nonmotile sperm, unless the patient and surgeon are willing to take the unknown, but presumably extremely small, risk of failure (Hancock et al, 2002).

The posts by Drs Shapiro and Goldstein raise the issue about vasectomy failure rates. Their series reveal a nonazoospermia rate of 5% to 10%, a value that is significantly higher than what is often quoted to patients during consent (Meacham, 2003). Studies of vasectomy success and failure rates are obviously complicated by the large variety of surgical techniques (Haws et al, 1998). Surgeons differ significantly in their use of cautery, clips, ties or fascial interposition among others (Haws et al, 1998). Unfortunately, there are virtually no randomized controlled trials comparing the efficacy of these various modifications (Cook et al, 2004). One exception, however, was an international multicenter trial of vasectomy with and without fascial interposition that demonstrated a 2-fold reduction in failure rates with the use of fascial interposition, although the failure rate was still a high 5.9% (Sokal et al, 2004).

Overshadowing the entire *Androlog* thread is the topic of medicolegal risk. Thus, no discussion of vasectomy is complete without mentioning this topic. Vasectomy-related cases have long been recognized as a leading source of malpractice claims against urologists (Koontz

and Russell, 1977; Kahan et al, 2001). Awareness of this problem increased in the late 1970s, when claims of “wrongful life/wrongful birth” started to be considered by the courts, which were moving away from the view that the birth of a child, even if unwanted, is a blessing and not grounds for a complaint (Mark, 1976; ANM, 1982). This prompted *Urology* to publish recommendations by a legal consultant on lowering the risk of malpractice liability in the case of vasectomies (Beal, 1978). These recommendations still apply today and stress the importance of proper informed consent, preferably validated by a lawyer, and of careful documentation of follow-up. The author recommended that physicians be proactive in ensuring compliance, including the use of certified mail reminders for delinquent patients, a sentiment echoed by Belker and colleagues (Beal, 1978; Belker et al, 1990).

In conclusion, there is little standardization of vasectomy management. The AUA guideline recommendations, namely not sending the vas for histologic examination and using postoperative azoospermia as the criterion of success, appear close to the consensus of most *Androlog* posts and the urologic literature in general. Other questions such as dealing with rare nonmotile sperm and optimizing vasectomy technique await future studies.

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