

Optimizing outcomes in vasectomy: how to ensure sterility and prevent complications

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Abstract: Vasectomy provides a long-term effective sterilization for men and is performed on nearly 500,000 men annually in the United States. Improvements in technique have led to a decreased failure rate and fewer complications, although significant variations in technique exist. Use of cautery occlusion with or without fascial interposition appears to have the least failures. A no-scalpel approach lowers risk of hematoma formation, infection and bleeding post-operatively. A patient can be considered sterile when azoospermia is achieved or the semen analysis shows less than 100,000 non-motile sperm per milliliter. Incorporating these principles may allow the physician to optimize outcomes in vasectomy.

Keywords: Postoperative complication; sterilization; vasectomy

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Introduction

Vasectomy is the most common non-diagnostic office based procedure performed by urologists. Within the United States, the basic principles of a minimally invasive scrotal opening, vas identification and vas transection are universal but the methods for performing these steps vary by practitioner. Unfortunately most of these surgical variances have not been evaluated with prospective randomized trials to provide an evidence based approach with the highest success rate and fewest complications. Many studies have been underpowered or lacked adequate follow-up. The definition of sterile differs between studies making direct comparisons difficult. The aim of this mini-review is to provide background information for the practitioner to determine which approach will be most effective in their patient population.

Vasectomy is commonly seen as an underutilized contraceptive method (1). Currently vasectomy is more common among non-Hispanic white men, among men with higher education levels, and among men with private insurance. For vasectomy to become more widely utilized, the risk of complications needs to be viewed as minimal.

Men commonly discuss the procedure with others they know that underwent vasectomy. Therefore many patients may present for consultation with an inaccurate expectation regarding pain, failure, risk of complications or recovery period. Additionally minimizing complications and maximizing success will limit exposure to potential litigation. Vasectomy no longer appears to be the most commonly litigated urologic procedure but a patient's view of a complication from a "simple" procedure is likely to generate a more negative feeling toward the physician (2).

Defining success

Utilizing pregnancy as the outcome to determine success following vasectomy is not feasible. Identifying failures prior to conception is critical due to the high cost of an unwanted pregnancy. Post-vasectomy semen analysis has become the surrogate test to define success. Failure may occur due to four scenarios. The first scenario is a failure of the occlusive mechanism during the procedure or one vas being addressed twice with failure to treat the contralateral side. The second scenario is due to early recanalization which often occurs prior to completed semen

analysis testing (3). Another type of failure occurs when sperm reappear in the ejaculate following a prior finding of azoospermia due to late recanalization. Finally, patients may fail if they do not follow precautions and use alternative contraceptive methods immediately after the procedure when sperm would still be expected in the ejaculate. Due to the location of the vasal occlusion, vasectomy does not produce immediate sterility. To determine success, there is a time component to be evaluated plus the ultimate goal of azoospermia. Neither a fixed number of ejaculations nor a standardized elapsed time following the procedure is adequate to universally ensure azoospermia. Both the American Urological Association and European Association of Urology guidelines suggest informing a patient that 100% sterility cannot be guaranteed (4,5). These guidelines now suggest a patient be considered sterile when the semen analysis shows no sperm or has less than 100,000 non-motile sperm per milliliter. Traditionally two samples have been requested but this is not considered necessary currently. A single well done semen analysis performed within 2 hours of ejaculation is recommended by the American Urological Association (4). A sample with less than 100,000 non-motile sperm per milliliter has been shown to subsequently become azoospermic in 75% of men and only became a failure with motile sperm in 1% of men (6). Another study found that utilizing the special clearance guideline for men with less than 100,000 non-motile sperm per milliliter allowed nearly 45% of men to be given clearance at 3 months post-procedure and no pregnancies had occurred with greater than 1 year follow-up (7).

Ensuring sterility

There are two basic steps to ensuring sterility. The first step regards the method to perform the procedure and relies on the physician to properly occlude the vasa. The second step requires the patient to wait a defined period of time or ejaculations and submit the requested semen sample. Approximately half of patients are non-compliant with providing the semen analysis (8). Men with a higher number of children and younger men were more likely to be non-compliant. Being married did not improve patient compliance. Therefore physicians must be confident in their chosen surgical technique.

A Cochrane review evaluating vasectomy occlusion techniques found only six studies that met inclusion criteria (9). This review concluded that studies evaluating the use of clips to seal the vas as opposed to transection

and suture ligation were of poor quality and suggested a similar rate of success between these two approaches. The Cochrane review did suggest use of fascial interposition reduced vasectomy failures. This conclusion came from one large study by Sokal and colleagues (10). In this study the investigators performed a randomized controlled trial using time to azoospermia as the primary outcome. Patients were randomized to ligation and excision of the vas with or without fascial interposition. The study was stopped after the interim analysis revealed a decrease in failures from 12.7% to 5.9% with the use of fascial interposition. The fascial interposition did add difficulty in 13% of the cases based on physician reports and added approximately 2 minutes to the surgical time. Sokal and colleagues later used this study data to compare ligation and excision with fascial interposition versus cautery (11). This study was not randomized but used the success rates determined previously for the ligation and excision group. The cautery group was not standardized as two institutions used cautery with fascial interposition and two other sites did not use fascial interposition. Another factor not standardized was the use of thermal cautery at two sites versus electrocautery at two sites, and the length of vas to which cautery was applied was not identified. This study did conclude that cautery with or without fascial interposition was associated with fewer failures than ligation and excision with fascial interposition. A larger retrospective study refuted the assertion that lumen cautery provided an improvement in sterility rates (12). Based on the inconclusive nature of the studies comparing occlusion techniques, the American Urological Association vasectomy guidelines suggest one of three occlusion methods; mucosal cautery with fascial interposition, mucosal cautery without fascial interposition, or open ended vasectomy with mucosal cautery of the abdominal end and fascial interposition (4). These approaches should allow for a failure rate of 1% or less. The guidelines do allow alternative methods of occluding the vas provided the surgeon's training or experience enables them to consistently obtain satisfactory results. The European Association of Urology guidelines suggest use of luminal cautery, interposition of tissue or excision of a segment of vas deferens and ligation with sutures or clips (5).

Other methods to ensure sterility have been attempted without providing sufficient evidence to recommend their use at this time. Intraoperative distal vasal flushing with 30 mL of sterile water has been shown to hasten time to azoospermia in one prospective, randomized controlled trial (13). In this trial, 80% of patients were azoospermic at

8 weeks in the sterile water flushing group compared with 50% in the standard technique, however by 12 weeks there was no significant difference in azoospermia rates. Taking into account other trials evaluating the use of a distal vasal flush to improve success rates, a Cochrane review concluded there was insufficient evidence to determine utility of this approach (9). For those physicians excising a segment of vas deferens, pathologic examination of this segment may provide reassurance of vasal transection but due to risk of recanalization still does not provide assurance of sterility.

Patient compliance with post-vasectomy semen analysis is poor. Multiple studies have suggested upwards of 50% of patients will not complete a single post-vasectomy semen analysis (8,14-16). By defining sterility as less than 100,000 non-motile sperm per milliliter, there has been a decrease in the number of repeat testing that has been performed and allows greater success rates at the first post-vasectomy semen analysis. Requesting multiple semen analyses leads to overall worse patient compliance (14). It has been suggested that a longer wait time following vasectomy may decrease compliance and expert opinion has suggested a post-procedure time of 8–16 weeks is appropriate (4). This opinion is in agreement with a prior systematic review that showed 80% of patients were azoospermic at 3 months following vasectomy or after 11–20 ejaculations (17). This time frame allows identification of early recanalization as well. Written and verbal instruction should be provided to the patient but has not been shown to improve compliance (6,8). In regards to ensuring sterility, physicians are limited by the patient's willingness to return for the semen analysis. For medicolegal reasons, providing a written instruction sheet to the patient and documenting in the chart that the patient received this information is beneficial.

Any patient with motile sperm at 6 months post-vasectomy should be considered a failure (4,5).

Minimizing complications

Failure is only one of a number of potential complications associated with vasectomy. Bleeding, hematoma formation, infection, sperm granuloma, chronic pain or orchitis, fistula and psychological distress have all been reported following vasectomy (18-22). There has been a concern that vasectomy is associated with a higher risk of prostate cancer, testicular cancer, mortality or cardiovascular risk, but expert review of these publications and follow-up studies have concluded these risks are not substantially increased following vasectomy (4,22). Guidelines suggest informing

the patient of a risk of 1–2% for surgical complications to occur and 1–2% risk of chronic scrotal pain (4). Uncommon complications such as Fournier's gangrene, endocarditis, vasovenous fistula and vasocutaneous fistula have been reported in a very small group of patients (19). Due to the very rare nature of these complications, methods to decrease their occurrence are based on opinion rather than publications. The more common complications will be addressed here with potential methods to limit occurrence of each complication.

Bleeding and hematoma

Hematoma formation is the most common complication immediately following vasectomy. Hematoma and bleeding are documented to occur in 0–29% of patients with an acceptable rate of 2% (4,5,18). Physicians performing fewer than ten vasectomies annually have a reported 3 times greater rate of hematoma compared to physicians performing more than 50 vasectomies annually (23). Surgical technique has been shown to affect the incidence of hematoma as well. A 2014 Cochrane review evaluated an incisional vasectomy technique with the no-scalpel technique (24). Only two randomized controlled trials were available for evaluation. Both studies showed lower rates of hematoma formation with the no-scalpel technique and the larger study revealed lower rates of bleeding, surgical pain, and infection in the no-scalpel treatment group. When the data was pooled, infection, scrotal pain and hematoma risk showed a significantly lower rate in the no-scalpel procedure than in the incisional procedure, but these findings were predominantly dictated by the larger trial. Sokal and colleagues showed similar rates of hematoma formation between studies using fascial interposition and studies not using this technique (10). Regardless of surgical approach or occlusion technique, conservative measures may reduce risk of bleeding. Scrotal elevation and compression can minimize bleeding and hematoma by providing a tamponade effect. Scrotal support when patients return to activities may decrease risk of delayed bleeding as well.

Infection

The quoted risk for an infection following vasectomy is 3.4% (18,19). Antibiotics are not indicated for the standard vasectomy (4). Most infections are localized and easily treated with antibiotics. As noted previously, a no-scalpel approach has been shown to decrease the risk of infection

in the few randomized controlled trials available (24). Consistent with other bodily locations, risk of infection may be minimized with hair removal at the time of the procedure, a surgical prep and limiting skin injury.

Sperm granuloma

Sperm granuloma is a common finding at the time of vasectomy reversal. Sperm granulomas may occur as a result of an open-ended vasectomy or due to leakage of sperm from the vas into the surrounding interstitium. Sperm elicit an immune response leading to chronic inflammation in this region. Most of these lesions are non-painful, however approximately 2–3% of patients may have pain at the site of the sperm granuloma. For patients undergoing a closed-ended vasectomy, delaying ejaculation for one week after surgery may decrease risk of a sperm granuloma forming.

Post-vasectomy pain

Most patients experience pain initially following the vasectomy that will improve over the first few weeks post-operatively. Chronic pain following vasectomy is rare and occurs in less than 1% of men. The etiology of this process is not fully known but may relate to epididymal congestion, vascular stasis, sperm granulomas and nerve impingement (20). Pressure within the epididymis rises until compensatory mechanisms are unable to prevent a blowout of the epididymis or obstructed vas. Performing an open-ended vasectomy is suggested to decrease the risk of post-vasectomy pain related to congestive epididymitis (18). Nerve impingement may lead to post-vasectomy pain as well, consistent with a similar process seen following herniorrhaphy. Pain mainly with ejaculation may be due to fluid passing from the distal epididymis into an obstructed vas leading to distension of the epididymal and vasal wall. Regardless of etiology, post-vasectomy pain is treated conservatively initially. Scrotal elevation, scrotal support, sitz baths and limiting activity may allow resolution of persistent inflammation. Oral medications such as tricyclic antidepressants or gabapentin may be utilized. When a patient fails the conservative approach, surgical treatment with vasovasostomy, spermatic cord denervation or epididymectomy may result in pain resolution.

Psychological distress

Most complications following vasectomy are physical

in nature. Depression following vasectomy has been reported (21). Psychological distress is more common in patients with marital or sexual difficulties, pre-existing mental illness, older age, higher income and negative views about the operation. The most common predictor of distress however is poor pre-operative counseling. Patients may fear the procedure due to a limited understanding of anatomy and a sense of vulnerability. Pre-operative counseling should provide the patient with an understanding of pain he may experience during the procedure, post-operative recovery expectations, and when he may return to normal activities including sexual activity. Patients can be reassured that sexual function does not change or improves for the majority of men (25). In fact, men with a prior vasectomy have on average one more sexual encounter per month than nonvasectomized men (26).

Conclusions

Vasectomy is a safe and effective long-term contraception method for men. Few randomized controlled trials exist to directly compare techniques, however no-scalpel vasectomy and utilization of fascial interposition appear to have contributed the largest improvements in maximizing sterility and minimizing complications.

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Footnote

Conflicts of Interest: The author is a consultant for American Medical Systems & Coloplast Corp.

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