Complications in a Series of 1224 Vasectomies

Philip M. Alderman, MD
North Vancouver, British Columbia

Background. The assessment of a vasectomy technique should be based on the incidence of complications resulting from the procedure. Differing diagnostic criteria for defining complications and the belated occurrence of some adverse events, however, have made such appraisals difficult. The purpose of this paper is to suggest criteria for defining vasectomy-related problems and to present the results of a long-term study of 1224 vasectomies.

Methods. The records of 1224 men who had a vasectomy performed by the same technique during a 4-year period were reviewed, and documented complications were tabulated and evaluated. Patients were referred residents of the lower mainland of British Columbia, and the majority were married. The group included a wide spectrum of ages, races, and occupations. Twelve categories of potential complications were defined, of which 10 were actually encountered in the study group. *Infection* was defined as having had antimicrobial drugs prescribed, and *regret* as having returned to discuss a reversal; all other complications were diagnosed based on a documented clinical diagnosis.

Results. Complications had been documented in 124 cases (10.6%) and included 46 minor infections (3.8%), 2 serious infections (0.16%), 23 instances of epididymitis (1.9%), 16 cases of sperm granuloma (1.3%), and 4 minor hemorrhages (0.33%). Of 3 failures, only one (0.08%) was due to recanalization. No serious hemorrhages or late failures were seen.

Conclusions. Satisfactory results were believed to be related to surgical technique and the liberal use of antimicrobial drugs. The low recanalization rate was attributed to the treatment of the ends of the vas with multiple loops of polyglycolic acid ligature.

Key words. Vasectomy; postoperative complications; intraoperative complications. *J Fam Pract 1991; 33:579-584.*

The early and midterm complications of vasectomy (defined here as those occurring within a period of 1 to 5 years following the procedure) are the subject of this paper. In 1987, the latest year for which data are available, 336,000 vasectomies were done in the United States.[1] Given the popularity of the operation, complications are bound to be appreciable. These complications are not necessarily observed by the surgeon, for adverse events can occur months or even years after a vasectomy is performed. Methods differ, and surgeons may regard their techniques and outcomes as satisfactory, but as noted by Peterson and colleagues,[2] definitions of adverse events are often lacking, with the result that comparisons cannot be made. The purpose of this paper is to describe the outcomes of a series of vasectomies while establishing some practical definitions of adverse events for use in future comparative studies.

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From the Lions Gate Hospital, North Vancouver, British Columbia. Requests for reprints should be addressed to Philip M. Alderman, MD, 940 Groverland Rd, West Vancouver, BC, V7S 1Z1 Canada.

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Methods

In the 4 years ending December 31, 1989, the author performed 1224 vasectomies, nearly all of which were done in an office setting. Complications continued to be recorded for another year, until December 31, 1990, which provided an additional period for observing possible adverse events.

Each vasectomy candidate, together with his wife or partner when possible, was interviewed at least 1 day before surgery to review the risks and alternatives, and to elicit possible unresolved misgivings. Apprehensive but otherwise well-motivated patients were offered 2 to 4 mg of sublingual lorazepam to be taken 90 minutes before surgery.

During surgery, sterile technique was observed and sterile disposable materials were used wherever feasible. The genital area was painted with a 10% povidone-iodine topical solution. Under 1% lidocaine (with epinephrine 1:100,000) anesthesia, a single, 1-cm anterior midline incision was made in the scrotum through which the vasa were delivered in turn and dissected free of

surrounding tissues; a 2- to 3-cm section was removed. No effort was made to close the sheath over vas ends, but care was taken to use blunt rather than sharp dissection. The ends of the vasa were occluded with multiple (three to four) loops and ties of an absorbable polyglycolic acid suture (Dexon, Davis & Geck, Wayne, NJ), and an athletic support was applied immediately afterward. Skin sutures were removed in 2 to 3 days. The surgical method employed is termed the *excision-ligature technique*.

Semen analysis was performed 3 months postvasectomy, and then monthly thereafter until two consecutive azoospermic specimens were obtained. This was the criterion used to determine a successful vasectomy.

The Study Population

A wide spectrum of races, ages, occupations, and incomes was seen, with white professionals especially well represented. Few members of native American groups or welfare recipients were recognized. The mean age of men in the series was 37.7 years (range 20.8 to 66.4 years); nearly all of the men were married or in a relationship, resided in the lower mainland area of Vancouver, British Columbia, and had been referred by their physicians. The mean age of men with complications was the same as for the series mean, namely 37.7 years. The mean interval between vasectomy and the end of the study period, December 31, 1990, was 2.8 years (range 1 to 5 years).

Follow-up

All patients were urged to contact the author if complications occurred, and they were seen promptly. Men returning with semen samples or for suture removal were routinely asked about problems that may have occurred since the surgery. Some complications were first mentioned at this time or by patients coming in specifically because of symptoms. One complication that occurred was reported by the patient's referring physician. Of the 1224 cases studied, 833 patients (68%) did return at least one semen sample and were therefore questioned about complications. An additional 31 patients (24%) failed to submit any semen specimens but did report problems. For these reasons, and also because nearly all members of the series had been referred and were local residents, the assumption was made that most complications that occurred during the study period had been recorded.

Table 1. Categories and Incidence of Complications in 124 of a Series of 1224 Vasectomies

Complication	No. of Complications	Percent of Total Vasectomies
Epididymitis	23*	1.9
Failure, early overt	3	0.25
Failure, technical	6	0.49
Hemorrhage, minor	4	0.33
Infection, major	2	0.16
Infection, minor	46†	3.8
Miscellaneous	18	1.5
Orchitis	2	0.16
Regret	10	0.82
Sperm granuloma	16	1.3
Total	130	10.6‡

**Includes one patient treated with antimicrobial drugs who also returned to discuss reversal.*
†Includes five patients who had an additional complication.
‡Does not match sum of column because of rounding.

Categories of Complications and Diagnosis

Twelve potential categories of complications were anticipated, of which only 10 were actually encountered in the series (no major hemorrhages or late failures were observed). Where applicable, complications were arbitrarily termed "minor" if the patient required 3 days or less off from work because of the problem, and "major" if more time was required (Table 1).

1. *Epididymitis*. Unlike the massive swelling of bacterial epididymitis or the localized nodular tumors of epididymal granulomas, vasectomy-related epididymitis was characterized by a modest inflammation of the epididymis that involved all or most of that structure and principally that structure.

2. *Early overt failure* was characterized by the presence of any motile sperm in fresh semen specimens at least 3 months and 12 ejaculations after vasectomy.

3. *Technical failure* was diagnosed when occasional nonmotile sperm ($<100 \times 10^6$/L) were found in fresh semen samples at least 5 months and 12 ejaculations after vasectomy. (*Late failure* was defined as the re-emergence in the semen of motile sperm at any time after proof of success. None were seen in this series.)

4. *Hemorrhages* occurred within 24 hours of the vasectomy, either as masses near a vasectomy site or as bleeding through the incision. Ecchymosis, the purplish discoloration of skin after local trauma, was not itself classified as a complication.

5. & 6. *Major or minor infections* commenced soon after the vasectomy (see Results), involved scrotal swelling, were prone to encroach on adjoining scrotal tissues, and were more tender and less well defined than granulomas. The cause of some early minor problems was not

always clear, but arbitrarily these were designated as infections if antimicrobial drugs were prescribed.

6. *Miscellaneous* problems did not satisfactorily fit into other categories (see Results).

7. *Orchitis* was diagnosed when postvasectomy inflammation was confined to the testes.

8. *Regret* for the purposes of this study was classified as a complication of vasectomy and was defined as returning to discuss a reversal.

9. *Sperm granulomas* occurred as persistent, hard, well-defined nodules that were only slightly or moderately tender or painful. They were found either at a vasectomy site or in the epididymis, and their median time of onset (about 100 days; see Results) was sometimes helpful in diagnosis. This study recognized only symptomatic granulomas, although in previous reports asymptomatic lesions far outnumber the others.[3,4]

Results

During the initial 4 years of the study period when vasectomies were being performed and complications recorded, 114 men (9.3%) experienced adverse effects. In the final year, when complications continued to be noted but no new vasectomies added, an additional 10 men (0.82%) reported problems. Diagnosis of some complications was aided by utilizing clinical differences and mean or median times of onset. Five men had more than one problem: thus, while there were 124 patients who experienced complications, the total number of complications was 130.

Infections

The mean time of onset of all infections was 4.1 days (range 1 to 9 days). Minor infections represented just over one third of all complications and were the most frequent problem seen (Table 1). One infection, associated with hematuria, was diagnosed as a prostatitis or seminal vesiculitis, and all but one of the remainder developed intrascrotally, at or near a vasectomy site, so that no culture material was available. The two patients with major infections were off from work for 2 and 3 weeks, respectively, and one of these, whose problem involved both the incision and one vasectomy site, was admitted to the hospital. Neither required further surgery. All infections were unilateral.

Epididymitis

The onset of epididymitis varied widely: of 23 instances, 8 reportedly began with the operation, and one did not present until more than 2 years later. In one instance the epididymitis became chronic, and removal of the organ or vasovasostomy was suggested, but to date the patient has declined this procedure. In no instance was there any suggestion that bacterial infection was involved.

Miscellaneous

There were four vasovagal reactions, two of which occurred during the procedure, the others occurred some hours later. One case of postvasectomy ejaculatory dysfunction was reported by a 66-year-old patient who was attempting nightly orgasms, and one case of transient, asymptomatic hematuria associated with vigorous physical activity was reported for which urine cultures were obtained that were negative. The remaining 12 miscellaneous problems involved intrascrotal pain with scrotal contents that were objectively normal.

Sperm Granuloma

The median time of onset of sperm granuloma was 101 days (range: 19 to 464 days). In this series the size ranged from a few millimeters to 2 cm. Only 4 of the 16 men with granulomas required treatment. In these, anti-inflammatory drugs were remarkably effective in reducing pain.

Failure, Regret, Orchitis

There were twice as many technical failures as overt failures. Of three early overt failures, one was due to recanalization, the other two to missed vasa. The incidence of regret, at least as expressed by an interest in discussing a reversal, was 0.82%, while the mean interval between such vasectomies and the termination of the study was 3.7 years.

Hemorrhage

Small hematomas occurred at a vasectomy site in three instances, one of which became infected and all of which resolved in a few weeks. No major hemorrhages were seen. A single instance of postoperative incisional bleeding was managed by advising additional dressings on the scrotum.

Discussion

Given the mobility of populations, the determination of the incidence of events such as granulomas and epid-

idymitis that occur after 5 years is probably unachievable, and for similar reasons is probably somewhat understated in this study. Vasectomy reversal may be undertaken years after the vasectomy and may be done without the surgeon who performed the vasectomy ever being notified.

In this paper vasectomy-related infections were defined as those for which antimicrobial drugs were thought to be justified (as did Schmidt in 1975[5]). The author tended to prescribe such agents in patients with early, ambiguous problems that may in fact have been due to premature activity, granulomas, or small hemorrhages; thus, the incidence of infections may be overstated. Because of the lack of culture material and the office-based nature of the follow-up, most infections were (necessarily) diagnosed on clinical grounds. For the same reasons, the choice of antimicrobial drugs was largely empirical, but oral preparations of both tetracycline and a clavulanic acid–amoxicillin combination (Clavulin, Beecham Laboratories) were virtually always associated with a good response. Since there was no control group, it is unknown how many of these would have resolved spontaneously. Only two wound infections were encountered, possibly because sutures were removed promptly. (It has been the author's experience that scrotal incisions closed by absorbable ligatures left in place for over 1 week are prone to suppurate).

The source of organisms causing infections may have been the operator, environment, or patient. The place of the operator and environment in this series has been stated. As for the patient, a 1984 report by Sheagren[6] states that colony counts of the nasopharyngeal flora consistently reveal a small group (10% to 15%) of persons with relatively large numbers of *Staphylococcus aureus* and that these organisms could spread to a wound site. It seems possible, therefore, that nasal or perineal *S aureus,* as well as coliform bacilli from the anus, could well be a source of vasectomy-related infections. On the basis of questionnaires, in 1987 Kendrick et al[7] reported a US infection rate of 3.48% (a figure quite close to that found in this study), although they offered no criteria for the diagnosis.

In reviewing the medical literature, *Population Reports,* a publication of Johns Hopkins University, indicated that epididymitis occurs in "less than 1% of vasectomies."[3] In the series reported here, however, it was nearly twice that (1.8%) and was, after infection, the most common problem seen. Possibly these lesions occurred because sperm production exceeded absorption. Paradoxically, in all but two cases the epididymitis occurred unilaterally, and it was not evident why only one side was affected. "Congestive epididymitis," perhaps an aptly descriptive term, has been used to describe this condition.[4] Only 2 of the 23 patients with epididymitis were given antimicrobial drugs, and all resolved satisfactorily, suggesting that infection was not a significant factor for most. Indomethacin, when indicated by symptoms, was effective in relieving symptoms.

Among the "miscellaneous" group were 12 men with scrotal pain but objectively normal scrotal contents. Only one of these was offered medication; he improved quickly on indomethacin. It was postulated that nonpalpable granulomas, nerve entrapments, or low pain thresholds might explain some of these problems. The two men with intraoperative vasovagal reactions were, at the time, pale, sweaty, and nauseated. They may well have had bradycardia, but their reactions were deemed insufficiently serious to abandon sterile technique in order to determine this. It was the author's impression that such reactions were mitigated by preoperative lorazepam (where indicated) plus rhythmical intraoperative exercise by the patient of his hands and feet.

Sperm granulomas are inflammatory masses containing sperm, epithelial cells, and lymphocytes, and are due to the leakage of sperm into scrotal tissues.[8] Schmidt has affirmed that "proper [fulguration-fascial interposition, as opposed to ligature] sealing of the testicular end of the vas at vasectomy will prevent formation of a granuloma,"[9] although he later acknowledged a 1% incidence of sperm granulomas in his own series (personal communication, S.S. Schmidt, December 18, 1986). All vasectomies in this series were performed using ligatures to occlude the vas, and the granuloma rate was 1.3%. Kendrick and associates reported an overall sperm granuloma rate in the United States of 2.46%, with surgeons using a variety of closure techniques.[7] In any case, it appears that at least within an average of 2.8 years after vasectomy there may be little difference in granuloma rates between excision-ligature and fulguration-fascial interposition vasectomies.

Two of the three early overt failures were due to missed vasa: in one patient one vas could not be identified at surgery, at which time it was thought to be absent, and the second missed vas involved a testicle that had been the subject of an orchiopexy. The third failure was associated with the usual bilateral postoperative nodules at the vasectomy sites, identifying it as a recanalization. With but a single exception, such failures are seen in every substantial series of vasectomies that has been reported, however done. The exception is the series of Stanwood S. Schmidt, a respected California urologist who has reported 5000 failure-free vasectomies.[10] Dr Schmidt attributes his unique success to the fulguration of the lumen of the vas deferens and the closing of the sheath over the free ends. Others report less favorable results: Denniston, "using the Schmidt technique" in

2500 cases, reported a failure rate of 0.24%, although his criteria for failure or success are not clearly defined.[11] Philp and colleagues,[12] using various techniques, reported 81 overt failures (0.48%) in 16,796 vasectomies. The authors concluded that "the [early recanalization] rate was not influenced by the operative technique used, but varied markedly between individual surgeons."

The three early overt failures in this series represented a failure rate of 0.25%; the single instance of recanalization, a rate of 0.08%. An earlier and substantially larger series of vasectomies reported by the author,[13] which were performed identically but with, in most cases, only a single coil of absorbable suture closing the vas ends, had within the same time frame a recanalization rate 7.5 times greater (0.60%). The lower rate in the present series may therefore be attributable to the serendipitous use of multiple coils of polyglycolic acid ligature at the ends of the divided vasa, which could provoke a usefully occlusive foreign body reaction. (This change in technique was prompted by an attempt to extend the area of viability of the vas beneath the suture by gradually increasing the tightness of successive adjacent loops of ligature.)

Technical failures may be due to the development of microfistulae that span the divided vas ends on one side or the other, the characteristics of which debilitate the few sperm that still manage to pass. While representing a less than fully satisfactory outcome, the tiny numbers of nonmotile sperm associated with technical failure were not deemed significant. The six patients with such failures were given a "cautious" assurance of success, and after an average of 3.6 years following vasectomy, none have reported an associated pregnancy. Described elsewhere, and further supporting the irrelevance of these sperm, is a series of 59 such men, none of whom had reported an associated pregnancy over an average of nearly 15 years after vasectomy.[14]

While no late failures were seen in this series, they have been reported in other papers.[12,13] It was suggested to patients that if this small risk is of particular concern, periodic semen analysis may offer reassurance and reduce the chance of an unplanned pregnancy.

All men manifesting regret had established or were considering a new domestic relationship, and several proceeded with having a vasovasostomy. Even retrospectively, it was not evident from the history that these individuals might fall into this group. The mean age of the men in the regret group (34.5 years), however, was 3.2 years less than that for the series as a whole (37.7 years), corroborating Clarke and Gregson's observation that younger men are more likely to want a reversal.[15] This point could be of interest to counselors.

Based on an extensive review of the medical literature, in 1983 *Population Reports*[3] recounted an overall incidence of vasectomy-related hematoma of "less than one percent." A 1987 report by Kendrick et al[7] gave an overall rate in the United States of 1.95%, at the same time (and not surprisingly) noting an inverse relationship between surgical experience and incidence. No definitions were offered in either paper.

Adverse psychosexual problems, while not seen in this series, have on rare occasions been encountered by the author in the past. Although nevertheless desirable, preoperative screening interviews have not been found to be reliable predictors of this event, the treatment of which can be unsatisfactory, to say the least.

A novel method of accessing the vas (the so-called no-scalpel or percutaneous technique) is claimed to reduce the risk of bleeding and infection. In a 1991 report by Li and colleagues,[16] however, only 238 US patients had been followed, and neither data-gathering methods nor definitions of complications were described. A smaller series, reported by Black and colleagues in 1989,[17] had significantly more complications using the percutaneous approach than with a conventional technique.

The absence of major bleeding in this series is attributed to the use of a single small incision, blunt dissection wherever possible, careful hemostasis, generous "bites" when closing the wound in order to compress the sides of the incision against each other, and the use of an elasticized scrotal support postoperatively.

Vasectomy and Tubal Sterilization: A Comparison

Often implicit in the decision to undertake the risks and discomfort of a vasectomy is the patient's recognition that his wife has been primarily responsible for contraception in the past, that she has borne the burdens of pregnancy and parturition, and that their relationship is a partnership with equivalent responsibilities. Indeed, husbands commonly and gratuitously acknowledge that "it's my turn." Among vasectomy accepters, at least, it is also widely believed that male sterilization is simpler and safer than its female counterpart. This view is corroborated in a 1985 study by Smith et al,[18] which concluded that "male sterilization procedures were found to have zero attributable deaths and significantly less major complications when compared to female sterilization procedures. No less than 14 deaths per year can be attributed to female sterilization procedures in the United States." The financial costs of female sterilization are notably higher, largely because of the use of general anesthesia and hospital facilities.[18] As for failures, Trussell and colleagues[19] in 1990 reported "typical" US accidental preg-

nancy rates during the subsequent year as nearly three times higher for female than for male sterilizations (0.4% for female sterilization vs 0.15% for vasectomy). Beyond this, failures after female sterilization result in a relative increase in ectopic pregnancies,[20] not reported after vasectomy failure. Finally, the determination of (at least early) vasectomy failure is by the simple examination of semen specimens, whereas tubal ligation failures, unhappily, are revealed by the occurrence of an unplanned pregnancy. The female operation does have one advantage: unlike vasectomy, it is effective immediately.

Conclusions

With the fairly broad definitions of adverse effects used in this study of a series of excision-ligature vasectomies, the overall incidence of vasectomy complications exceeded 10%. Few were major, however, and the two potential hazards that can result in lengthy disability (major hemorrhages and serious infections) were thought to have been minimized by the liberal use of blunt dissection and antimicrobial drugs. There is evidence that the low failure rate (only one recanalization in over 1200 cases) was related to the treatment of the ends of the vasa with multiple loops of polyglycolic acid suture. Whether other vasectomy techniques can improve on the results of this rather simple method remains to be determined.

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