Patient Noncompliance with Postvasectomy Semen Examination Protocol

John V. Dervin, MD, Richard C. Barnett, MD, and David L. Stone
San Francisco, and Santa Rosa, California

This study determined the degree of patient compliance with postvasectomy semen examination protocol for verbal instructions as compared with verbal augmented by written instructions. The addition of written instructions did not improve patient compliance, and for a significant majority of patients (68 to 76 percent) there was no laboratory verification of the effectiveness of the vasectomy procedure. Results of the study raise serious concerns about physician reliance on patient compliance for postvasectomy semen examination protocol as assurance of successful vasectomy. When the potential for fertility among vasectomized men is uncertain, the complication of an unwanted pregnancy will fall on the woman. Educating physicians in the problems and strategies for gaining patient compliance is as essential as education in competent surgical technique.

Vasectomy is a popular form of sterilization in the United States. The effectiveness of this procedure has traditionally depended on demonstration of a sperm-free state (aspermia) postoperatively. Although various medical protocols have been established to ensure achievement of aspermia and to detect early recanalization of the vas deferens, the efficacy of these protocols is critically dependent on patient compliance in returning semen specimens for laboratory testing. This study determined the degree of patient compliance with postvasectomy semen examination protocol for verbal instructions as compared with verbal augmented by written instructions.

From the Division of Family and Community Medicine, University of California School of Medicine, San Francisco, and the Family Practice Program, Community Hospital of Sonoma County, Santa Rosa, California. Requests for reprints should be addressed to Dr. John V. Dervin, Family Practice Program, Community Hospital, 3325 Chanate Road, Santa Rosa, CA 95402.

Methods

The Family Practice Center is the outpatient facility of Community Hospital of Sonoma County, Santa Rosa, California. Patients desiring vasectomy are initially evaluated by a resident physician. At this time, information, instructions, and clinical evaluation are accomplished. This activity is augmented by written materials supplied by the US Department of Health and Human Services, which the patient is required to read and sign.

Patients are scheduled for vasectomy by the resident physician under the supervision of family practice or urology faculty. All vasectomies are

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performed in the outpatient surgery area under local anesthesia using the fulguration method described by Schmidt.[1]

The postvasectomy protocol for assurance of aspermia requires that patients provide semen specimens for analysis at one and two months with 15 to 20 ejaculates before the first analysis and an additional 15 to 20 ejaculates before the second specimen. Postvasectomy semen specimens are obtained by the patient by ejaculation directly into specimen containers or into a condom with transfer to the specimen container. Within a few hours after collection, the specimens are examined uncentrifuged under a microscope. The criterion for a negative specimen requires total absence of sperm in all examined fields. Presence of any sperm (motile or nonmotile) is considered positive and not meeting the criterion for sterility. Criteria for demonstration of successful sterilization are two consecutive sperm-free specimens (two negative specimens).

This study compared patient compliance with postvasectomy semen examination protocol according to (1) the standard protocol in use during phase 1 and (2) the modified protocol applied during phase 2. A posttest only, static group comparison design was used. To determine patient compliance, the number of semen specimens returned by patients, ascertained by chart review, during phase 1 was compared with the number returned during phase 2.

In phase 1 patient records were reviewed to determine patient compliance with postvasectomy protocol in use during the period of August 1, 1975, to December 31, 1977. During this period, patient instructions were entirely verbal and given by the family practice residents. Patients were asked to return to the clinic two semen specimens in the containers provided according to the collection methods described. Specimens were examined by residents or family nurse practitioners and results were entered by them into the patient's record. For phase 1 the records of 454 postvasectomy patients were reviewed, representing the total number of vasectomies done during phase 1.

For phase 2, the previous patient instruction method was modified to incorporate features that could possibly increase patient compliance with postvasectomy protocol and the accuracy of medical record keeping. The time frame for phase 2 was January 1, 1978, to December 31, 1979. Verbal instructions were given by the residents and augmented by written follow-up instructions given to the patient postoperatively. This was done by a specially trained nursing assistant who also served as the vasectomy nursing assistant. The patient was given two specimen containers and laboratory slips to return with the specimens. Returned specimens were examined by laboratory technologists, and the results were entered into the patient's chart using standard medical records procedures. For phase 2, records of 279 postvasectomy patients were reviewed, which represented the total number of vasectomies done during phase 2.

A control group was not utilized during the actual phase 2 period. This decision was made as a result of a concern regarding the extremely poor compliance rate discovered during record review in phase 1, when it was discovered that a large minority of patients returned no semen specimen at all. It was thought to be of most patient benefit to modify the standard protocol for all patients and compare compliance in phase 1 with compliance in phase 2, using phase 1 as the "control."

Results

The number and percentage of patients returning semen specimens according to the number of semen specimens received is shown in Table 1. A large percentage, 46 percent of patients in phase 1 and 43 percent in phase 2, returned no postvasectomy specimens. Only one postvasectomy specimen was returned by 30 percent of patients in phase 1 and 25 percent in phase 2. The remaining patients, 24 percent in phase 1 and 32 percent in phase 2, returned at least two specimens.

It was concluded that modifying the protocol to include written instructions did not substantially increase patient compliance in patients returning none or one semen specimen. There was a slight increase (8 percent) in the number of patients returning two or more specimens in phase 2, suggesting that the modified protocol was helpful in increasing compliance among a few patients. The clinically important finding was that a significant majority of patients did not return at least two

Table 1. Percentage of Patients Who Returned Semen Specimens According to Number of Specimens Received for Phase 1 and Phase 2

Number of Semen Specimens Received	Percent of Patients Returning Semen Specimens: Phase 1 Standard Protocol (N=454)	Phase 2 Modified Protocol (N=279)
None	46	43
One	30	25
Two or more	24	32
Total	100	100

specimens (76 percent for phase 1 and 68 percent for phase 2); consequently, there is no laboratory verification of the effectiveness of the procedure in these cases. The quantitative risk of potential fertility for these patients is not known.

Comment

Results of this study indicate that noncompliance with postvasectomy semen examination protocol for assurance of successful sterilization is a major problem in this patient population, which was minimally affected by a protocol modification to influence compliance. Compliance did increase in those patients who were probably already somewhat compliant. The behavior of the least compliant group of patients, the patients who return no specimens, did not improve, however. For this group, noncompliance is an unresolved major problem that raises questions concerning semen examination protocols, vasectomy surgical technique, and resident and patient education.

Compared with other authors, this experience in noncompliance with postvasectomy protocol is most disturbing. Schmidt reported obtaining follow-up semen specimens on all of his 432 patients within five months and had only a 3 percent noncompliance rate with a request for a repeat specimen at one year.[1] Rees reported that only 53 of 903 patients (6 percent) failed to provide a semen specimen, and that an additional 5 percent failed to provide a second specimen as required.[2] The staff of the Margaret Pyke Centre indicated that only 7 percent of their 1,000 patients failed to supply any specimen, but that 252 of 460 patients (55 percent) asked to supply a specimen at one year failed to do so.[3] Other authors have reported less optimistic results, with noncompliance rates of 12 percent, 18 percent, and 22 percent in supplying even a single specimen.[4-6]

While less optimistic, results of this study are more consistent with compliance rates reported in other areas of health care. Rosenstock states that "a variety of studies have shown non-compliance rates that vary between 30% and 70% over a wide range of conditions and recommended actions, but apparently average about 50%; ie, 50% of your patients will not follow prescribed regimen precisely as ordered or for a full period of time of the prescription."[7] Whether the noncompliance rate in this study is better explained by general noncompliance rates or whether there are factors unique to this patient population and setting that particularly hamper compliance in the postvasectomy patient is not known.

Whatever the reasons, such a high noncompliance rate for a common procedure is a source of concern and raises serious doubts about physician reliance on any postvasectomy semen specimen

protocol, no matter what the timing or frequency of required specimens. Measures must be taken to enhance compliance, and given that this is difficult to do, innovations must also be considered to ensure the success rate of the procedure, which depends more on physician vasectomy technique than on patient compliance.

One approach pertinent to the problem of noncompliance is the attempt to render the semen sterile immediately postvasectomy and thus decrease the risk from noncompliance particularly related to slow clearance of sperm. All such techniques have used irrigation of the vas deferens at the time of vasectomy. Central to reliance on irrigation techniques is the demonstration that nonmotile sperm are not fertile (several authorities consider nonmotile sperm to be safe[3,8,9]). Urquhart-Hay used a nonirritant spermicidal solution in 81 patients. Semen were analyzed within 30 minutes of ejaculation in 88 percent of cases, and specimens were centrifuged. No motile sperm were seen in any of the specimens. Eighty-two specimens contained a few (5 million) sperm, and eight contained moderate (5 to 20 million) sperm.[8] Craft and McQueen irrigated the vas deferens with 20 cc of sterile saline. In a comparison of 125 patients done routinely and 111 patients receiving irrigation, none of the semen specimens in the irrigated group showed motile sperm.[9]

Irrigation of the vas deferens should be most effective in eliminating risk of fertility from those sperm stored above the vasectomy sites. The risk, however, of fertility related to duplication of the vas deferens, failure to identify the vas deferens properly at the time of surgery, and recanalization cannot be reduced by the irrigation method. Therefore, the most conservative stand is that aspermia be demonstrated before resumption of otherwise unprotected intercourse postvasectomy. Persons using this criterion would consider the presence of even nonmotile sperm as indicative of potential fertility and would not rely on irrigation of the vas deferens for assurance of sterility.

The availability of the irrigation technique raises the question, Should the technique be used in selected populations or patients at risk for low compliance with postvasectomy protocol? If so, how does a physician identify potentially noncompliant patients? Even more perplexing is the question, What is the fertility risk of the noncompliant patient? In this study of approximately 1,000 vasectomies over a period of eight years, only one patient reported the complication of pregnancy and that patient was already knowledgeable about his potential fertility. This suggests that the postvasectomy semen examination protocol may require closer scrutiny in terms of costs and benefits.

Another explanation for an apparently low pregnancy complication rate is that these pregnancies are not reported. When the potential for fertility among vasectomized men is uncertain, the complication of an unwanted pregnancy will fall on the woman. Postvasectomy pregnancy secondary to the lack of compliance or overconfidence in the technique may have devastating effects on personal relationships, with the spectre of infidelity in the background. Most popular methods of birth control place a compliance burden on the woman over many years. The adherence to postvasectomy semen examination protocol on the part of the man seems minor in comparison.

Physicians performing vasectomy must be cognizant of the issues raised by low patient compliance for postvasectomy semen examination protocol. Unfortunately, vasectomy itself is a procedure with high potential for noncompliance because the patient may be unaware of failure to achieve sterility until pregnancy occurs. Education of the resident in the problems and strategies for gaining patient compliance is as essential as education in competent surgical technique.

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