

Chapter 7

Male Sterilization

Highlights:

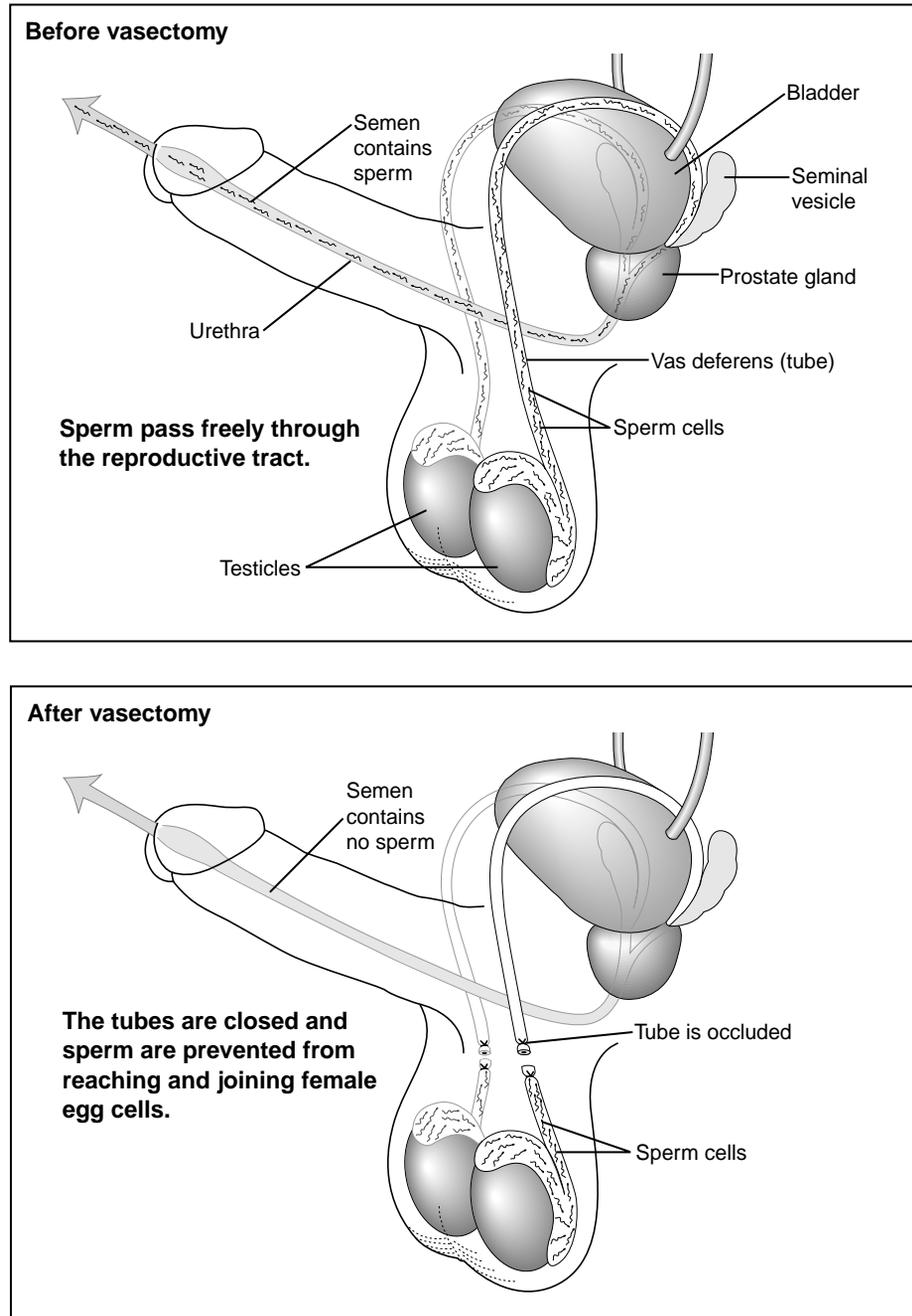
- Vasectomy is one of the safest and most effective family planning methods and is one of the few contraceptive options available for men. Failure rates are generally thought to be between two and four pregnancies per 1,000 users, although rates as high as 5% have been reported.
- Both conventional and no-scalpel vasectomies are performed almost exclusively under local anesthesia only. Sedation or regional or general anesthesia are rarely needed and unnecessarily increase the risk and the costs of the procedure.
- Compared with conventional vasectomy, no-scalpel vasectomy results in fewer complications, produces less pain during the procedure and early follow-up period, and permits couples to resume sexual activity earlier after surgery; also, the time required for the vasectomy procedure is less when skilled providers use the no-scalpel approach.
- Vasectomy does not appear to have any significant long-term negative physical or mental health effects, as well-designed epidemiological studies in men have consistently shown the procedure to be associated with no elevated risks of heart disease, testicular or prostate cancer, or immune complex disorders.

Vasectomy, a method of male sterilization, is a simple, minor surgical procedure that is performed by entering the scrotum through a small incision or puncture, locating each vas deferens (the tube that carries the sperm from the testis to the ejaculate), and blocking each vas to prevent sperm from passing (Figure 7.1, page 162). It usually takes 5–15 minutes to perform, after 5–10 minutes for preoperative preparation and administration of local anesthesia. Vasectomy is one of the safest and most effective family planning methods and is one of the few contraceptive options available for men. Failure rates are commonly quoted to be between 0.2% and 0.4%.

The clinical use of vasectomy is historically linked to the course of experimental investigation. Hunter made the first reference to the occluded vas during his dissections in 1775. The first experiment in tying the vas was reported as early as 1785, but it was not until the 19th century that several investigations into the effects of vasectomy were undertaken. In 1830, Cooper initiated the first systematic experimental work when he demonstrated that closing the duct of the testis had no effect on the production of sperm by the testis, for as long as six years after the operation. In the late 1890s, an investigation of the clinical uses of vasectomy was begun by surgeons in conjunction with therapeutic operations on the prostate gland. Ochsner performed such operations and reported that his clients experienced no change in their sexual function following a successful vasectomy.

In 1921, Simmonds noted that even in cases in which the vasa deferentia had been occluded for many years, there was no apparent injury to the sperm-producing functions of the testicles. Gosselin confirmed this in 1947. In the 1920s, Rolnick studied the regenerative power of the vas and its ability to resist trauma and to restore continuity of its lumen. He emphasized the importance of the blood supply and the sheath of the vas

Figure 7.1. Key points of male anatomy, before vasectomy and after vasectomy



(which acts as a splint) during recanalization of the vas.¹ This classic work still has pertinence today in efforts to achieve successful vas occlusion and to reduce the chance of failure, and informs us about the potential for successful vasectomy reversal.

In this chapter, we present descriptive information about vasectomy (approaches and occlusion techniques), analyze data on the effectiveness and complications associated with male sterilization, review issues related to reversal, and examine innovations that promise to improve upon current procedures.

¹ Recanalization occurs when the severed ends of the vas deferens spontaneously reconnect, and sperm resume passing through the vas.

Requirements for a Safe Procedure: An Overview

Among the key elements in providing appropriate sterilization services are assessing and screening potential vasectomy users, ensuring that they give informed consent, preventing infection, administering anesthesia adequately and safely, and giving thorough postoperative instructions.

There is no medical reason that would absolutely restrict a man's eligibility for vasectomy. Some conditions and circumstances indicate that certain precautions should be taken or that the procedure should be delayed (WHO, 1996). These include localized problems that make vasectomy more difficult to perform (such as inguinal hernia, large hydrocele or varicocele, cryptorchidism, and previous scrotal injury) or conditions that may be more likely to produce complications (such as diabetes, coagulation disorders, or AIDS). In cases of local skin infection, systemic infection, gastroenteritis, or filariasis, the provider should delay performing the vasectomy until the condition is resolved. When an intrascrotal mass is present, the vasectomy should be delayed until the cause of the mass is determined.

However, even when these conditions exist, vasectomy is safe and simple when undertaken with proper screening. Prior to vasectomy, a medical history should be taken and a limited physical examination should be given (including a genital exam); the penis, scrotum, and inguinal region should be inspected visually; and the scrotum should be palpated. Laboratory tests should not be routine but should be reserved for specific cases in which the provider suspects a condition that would make it necessary to take extra preparation or precautions.

The surgeon should verify that the vasectomy client has signed an informed consent form before beginning the procedure. Although the purpose of signing the form is to document informed consent, the principal focus should be on confirming that the vasectomy client has made an informed choice of vasectomy as a contraceptive method (see Chapter 1).

Strict adherence to good infection prevention practices at all times (before, during, and after surgery) is another crucial factor for the safety of the procedure. Proper aseptic technique is essential to prevent both immediate and long-term infectious morbidity and mortality. Inadequate infection prevention practices can lead to surgical-site infections, tetanus, and infections such as HIV/AIDS, hepatitis B, and hepatitis C (Grimes et al., 1982b; IPPF, 1997; Mangram et al., 1999). Shaving the scrotum is no longer recommended, as this significantly increases the chance of surgical-site infection (Cruse & Foord, 1980; Seropian & Reynolds, 1971).

Good anesthesia is essential for a pain-free vasectomy. Both conventional and no-scalpel vasectomies are performed almost exclusively under local anesthesia only. Pre-medication is not commonly used. Use of sedation or regional or general anesthesia is rarely needed and unnecessarily increases the risk and the costs of the procedure (Kendrick et al., 1985; Kendrick et al., 1987). However, general anesthesia may be necessary when there are scrotal abnormalities (such as large varicocele, large hydrocele, or cryptorchidism) or when vasectomy is performed along with another surgical procedure. Men who need modest sedation (e.g., those who are extremely nervous) may be given a small dose of an oral tranquilizer, such as diazepam.

Men undergoing vasectomy should receive clear instructions about postoperative care, anticipated side effects, actions to take if complications occur, sites where they can access emergency care, the need for postoperative semen analysis, and the time and place for making a follow-up visit.

Approaches

Regardless of the method of scrotal entry, the first step in the vasectomy is to identify and immobilize the vas through the skin of the scrotum. The second step is to bring the vas into the open. There are two approaches for doing this: conventional vasectomy and no-scalpel vasectomy.

Conventional vasectomy

In conventional vasectomy, the clinician uses a scalpel to make either one midline incision or two incisions in the scrotal skin, one overlying each vas deferens. Each incision is usually 1–2 cm long and is routinely closed with sutures after the vasectomy has been completed. In general, with conventional vasectomy, only the area around the skin entry site is anesthetized.

No-scalpel vasectomy

No-scalpel vasectomy (also known as NSV) was developed and first performed in China in 1974 (AVSC International, 1997; Li et al., 1991). This technique uses a vasal nerve block, created by first anesthetizing the scrotal skin and then making a deep injection of anesthetic alongside each vas. This provides better anesthesia than simply anesthetizing the skin around the entry point (AVSC International, 1997; Skriver, Skovsgaard, & Miskowiak, 1997; Sokal et al., 1999). Instead of a scalpel, two specialized instruments—a ringed clamp and a dissecting forceps (a sharp, curved hemostat)—are used (Figure 7.2). Because the scrotal skin puncture made with the dissecting forceps is so small, sutures are not needed.

No-scalpel vasectomy offers several advantages over conventional vasectomy: fewer complications (see Table 7.1), less pain during the procedure and early follow-up period, and earlier resumption of sexual activity after surgery (AVSC International, 1997; Skriver et al., 1997; Sokal et al., 1999). Because it requires no scrotal incision, no-scalpel vasectomy is believed to decrease men's fears about vasectomy (AVSC International, 1997). Neither conventional nor no-scalpel vasectomy is time-consuming, but it has been reported that the vasectomy procedure time is shorter when skilled providers use the no-scalpel approach (Li et al., 1991; Nirapathpongpon, Huber, & Krieger, 1990). Further details on no-scalpel vasectomy can be found in the book *No-Scalpel Vasectomy: An Illustrated Guide for Surgeons* (AVSC International, 1997).

Occlusion Techniques

Once the vas has been brought into the open, it is then occluded using a variety of methods, including ligation with sutures, division, cautery, application of clips, excision of a

Figure 7.2. In no-scalpel vasectomy, the clinician delivers the vas for ligation by piercing the skin of the scrotum with the medial blade of the dissecting forceps

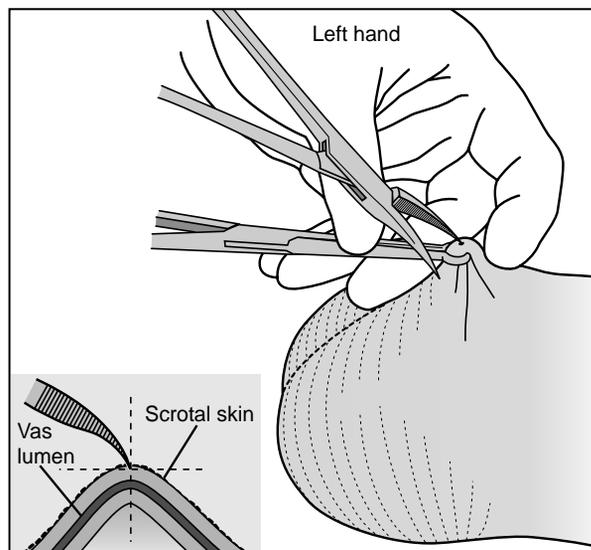


Table 7.1. Percentage of vasectomies in which infection or hematoma or bleeding occurred, by type of vasectomy and study

| Study | No. of vasectomies | % with infections | % with hematoma/bleeding |
|-----------------------------------------|--------------------|-------------------|--------------------------|
| Incisional vasectomy | | | |
| Philp, Guillebaud, & Budd, 1984 | 534 | 1.3 | 4.5 |
| Kendrick et al., 1987 | 65,155 | 3.5 | 2.0 |
| Nirapathongporn, Huber, & Krieger, 1990 | 523 | 1.3 | 1.7 |
| Alderman, 1991 | 1,224 | 4.0 | 0.3 |
| Sokal et al., 1999 | 627 | 1.3 | 10.7 |
| No-scalpel vasectomy | | | |
| Nirapathongporn, Huber, & Krieger, 1990 | 680 | 0.2 | 0.3 |
| Li et al., 1991 | 179,741 | 0.9 | 0.1 |
| Li et al., 1991 | 238 | 0.0 | 0.0 |
| Sokal et al., 1999 | 606 | 0.2 | 1.7 |
| Arellano et al., 1997 | 1,000 | 0.0 | 2.1 |

segment of the vas, fascial interposition, or some combination of these. The same techniques are used to occlude the vas in both conventional and no-scalpel vasectomy.

Ligation is the most widely used technique. It involves tying the vas deferens with suture material, cutting it, and in many cases, removing a section of the vas.

Cautery—electrosurgical (electrical coagulation) or thermal—is done by inserting a needle electrode or a cautery device into the vas lumen to create a firm scar that will occlude the vas. Sometimes a segment of the vas is removed as well. With this method, only the inner layer of the vas is sealed closed; the muscle wall of the vas remains intact.²

Clips can be applied to the vas to compress a narrow segment and block the passage of sperm. After division of the vas, a clip is applied to both of the cut ends. Sometimes a segment of the vas is removed before the clips are applied.

Fascial interposition places a tissue barrier between the two cut ends of the vas. This is done by suturing (or securing with a clip) the thin layer of tissue that surrounds the vas (called the fascial sheath) over one end of the vas (Figure 7.3, page 166).

In some cases, these techniques are combined; for example, cautery may be used with clips, or ligation may be used with cautery. Ligation without division and division alone are not recommended, as the potential for failure due to recanalization is high. Some practitioners remove a section of the vas; others do not. Data to support the superiority of any of these vas-disruption techniques had been lacking, but several recent studies have suggested that there are some differences in effectiveness among different occlusion techniques (see Effectiveness).

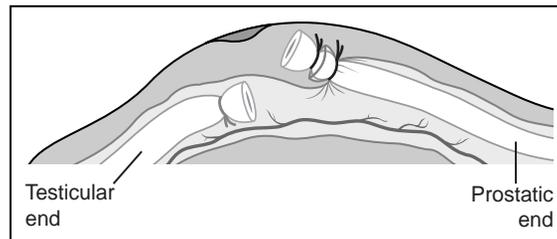
Although open-ended vasectomy—not sealing the testicular end of the cut vas—has been tried, it is not commonly used. Data have shown that this technique causes less pressure-induced damage to the epididymis (Silber, 1977). Thus, it is possible that vasectomy reversal will be more successful following an open-ended vasectomy. However, no studies on open-ended vasectomy and the success of reversal efforts have been reported in the literature.

Effectiveness

The contraceptive effects of vasectomy are not immediate, because viable sperm must be cleared from the vas. Thus, the vasectomy user and his partner(s) must practice alternate methods of contraception for some time after the procedure.

² This differs from the cautery method of tubal occlusion for women, whereby an entire segment of the fallopian tube is destroyed.

Figure 7.3. With fascial interposition, the fascial sheath (the thin layer of tissue that surrounds the vas) is sutured over one end of the cut vas



Ideally, vasectomy success can be routinely confirmed by demonstrating the absence of sperm (azoospermia) from one or more semen samples taken after the vasectomy, but there is little consistency in vasectomy follow-up protocols. Some providers ask men to return based on the time since the vasectomy, while others use the number of ejaculations since vasectomy, and yet others use some combination of both time and number of ejaculations (Alderman, 1988; Babayan & Krane, 1986; Haws et al., 1998; Rajfer & Bennett, 1988; Schmidt, 1987). In addition, providers vary in the number of azoospermic samples they require before they will tell a man it is safe for him to rely on his vasectomy for contraception (Babayan & Krane, 1986; Haws et al., 1998). This variety in postvasectomy follow-up protocols reflects the limited data available on determinants of azoospermia, including the time and number of ejaculations after vasectomy, as well as uncertainty over whether azoospermia is the best endpoint for vasectomy.

While the standard accepted endpoint of vasectomy has traditionally been achievement of azoospermia, some have discussed whether azoospermia is a necessary condition for the contraceptive effectiveness of vasectomy. A number of studies examining changes in sperm function after vasectomy, including fertilizing competence and sperm motility, have suggested that the duration of risk of pregnancy after vasectomy is shorter (and in some cases, much shorter) than the time necessary to reach azoospermia (Bedford & Zelikovsky, 1979; Cortes et al., 1997; Edwards, 1993; Jouannet & David, 1978; Lewis, Brazil, & Overstreet, 1984; Richardson, Aitken, & Loudon, 1984; Sivanesaratnam, 1985). A number of reports have shown that men with low numbers of nonmotile sperm remaining after vasectomy are at low risk of causing pregnancy (Alderman, 1989; Davies et al., 1990; De Knijff et al., 1997; Edwards, 1993; Edwards & Farlow, 1979; Philp et al., 1984; Thompson et al., 1991); some have suggested that these men can rely on their vasectomy for contraception even before reaching azoospermia (Davies et al., 1990; De Knijff et al., 1997; Edwards, 1993; Edwards & Farlow, 1979; Philp et al., 1984).

Endpoints of vasectomy other than azoospermia, however, have not been widely accepted. It is generally recommended that men have a semen analysis; in many cases, the suggested time for the semen analysis is a long time after the vasectomy (e.g., 12 weeks). During this time, couples must use an alternative method of contraception. If sperm are found in the semen at the first visit, additional visits are necessary. In many low-resource settings, it is impossible or impractical for men to have a semen analysis: Men may have no access to a facility that can do a semen analysis, they may be far from such a facility, or they may not have the money to pay for the analysis. In the United States and Europe, where semen analysis is widely available and more easily accessible, compliance with postvasectomy follow-up has been shown to be poor, with anywhere from 5% to 45% of men not returning for any follow-up (Belker et al., 1990; Derwin, Barnett, & Stone, 1982; Maatman, Aldrin, & Carothers, 1997; Smucker et al., 1991). This suggests that current follow-up protocols do not work very well, even under favorable circumstances.

In general, vasectomy is highly effective and one of the most reliable contraceptive methods available. Usually, vasectomy failure rates are quoted to be between 0.2% and 0.4%; however, a thorough review of the literature reveals published rates as high as 5% (Li et al., 1994; Schmidt & Free, 1978; Shapiro & Silber, 1979; Temmerman et al.,

1986). Vasectomy failure rates are generally believed to be similar to those for female sterilization, and they are lower than those for reversible methods. However, it is difficult to directly compare failure rates for vasectomy with those of other contraceptive methods, including female sterilization, since in most reports on vasectomy, rates are presented as failures per 100 procedures, while for other methods the measure most often used is failures per 100 person-years of use. Interpreting the literature on vasectomy failure rates is difficult for several reasons: Most published studies are retrospective reviews of individual physicians' experiences; follow-up has been relatively short-term and varies from one study to another; studies use different occlusion methods and different definitions of failure; and some studies are difficult to interpret because of limited details on the follow-up procedure that was used or on the numbers of men who did not return for follow-up.

However, several recent studies suggest differences in the effectiveness of certain vas occlusion techniques. A study conducted in Mexico on time to azoospermia following vasectomy using ligation and excision alone showed a prolonged risk of continued fertility in an unexpectedly large percentage of men. Thirteen percent of men (28 of 217) showed potential fertility (defined as a sperm concentration of 3 million or more sperm per ml of semen) six months after the vasectomy. This finding suggests that recanalization was occurring more frequently than expected (Nazerli et al., 2002). Similar results were seen following an interim analysis of a randomized controlled trial of fascial interposition conducted at eight sites in seven countries: Only 76–86% of men reached azoospermia by 34 weeks after vasectomy in the group in which only ligation and excision was performed (Sokal et al., 2001).

A Canadian study indicates that failure is also higher than expected when clips are used instead of sutures. A retrospective review of computerized records of more than 2,500 men who had vasectomy with occlusion by clips or by cautery and fascial interposition found failure rates (based on semen analysis) of 8.7% for clips but only 0.3% for cautery and fascial interposition, a highly significant difference (Labrecque et al., 2001).

While fascial interposition has been promoted as a way to further reduce vasectomy failure rates, reported success rates have varied. Some studies have shown good results (Denniston, 1985; Esho & Cass, 1978; Schmidt, 1995), while others have found failure rates similar to those attained without use of the technique (Li et al., 1994; Philp et al., 1984). One survey of U.S. physicians found that 48% reported using fascial interposition (Haws et al., 1998).

Preliminary results from a randomized controlled trial found that use of fascial interposition with ligation and excision led to a more rapid decrease in sperm counts than when ligation and excision were used alone. When fascial interposition was used along with ligation and excision, about 93% of men had reached a low sperm count (less than 100,000 sperm per ml of semen) by 22 weeks after surgery, compared with only 81% of men when fascial interposition was not used. The results demonstrate that fascial interposition significantly improves the effectiveness of vasectomy by ligation and excision (Sokal et al., 2001).

Data comparing failure rates of open-ended and closed-ended vasectomy have varied, with some showing comparable failure rates (Denniston & Kuehl, 1994; Errey & Edwards, 1986; Moss, 1992) and some showing higher failure rates with open-ended vasectomy (Goldstein, 1983; Shapiro & Silber, 1979; Temmerman et al., 1986).

Besides the studies demonstrating higher-than-expected failure rates for vasectomy by ligation and excision or for vasectomy with clips, two provide evidence that post-vasectomy pregnancies are indeed more common than expected in general. The first, an analysis of Chinese vasectomy data from the 1988 National Demographic and Family Planning Survey, which used a nationally representative sample of more than 2 million respondents, found surprisingly high cumulative failure rates. Life-table methods indicated that among the more than 28,000 women who reported that their husbands had had a vasectomy, pregnancy rates after the vasectomy were 2.7 pregnancies per 100 women after one year and increased to 9.2 per 100 after 10 years (based on the women's reports

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of pregnancy). Further analysis showed that lower-level hospitals, where the majority of male sterilizations were performed, had higher failure rates. In addition, husbands of younger women had much higher failure rates than husbands of older women. Unfortunately, no information is available on what occlusion methods were used for the vasectomies (Chen, 1999).

In the other analysis, a retrospective follow-up study, more than 1,000 Nepalese men were interviewed 1–4 years after vasectomy. The sample was randomly selected from more than 30,000 men in the hill districts of Nepal who had a vasectomy between 1996 and 1999. The estimated first-year pregnancy rate was 1.7 per 100 among wives of men having ligation and excision vasectomies. The cumulative probability of pregnancy at three years was 4.2 per 100 (Nazerali et al., 2001).

It is important to note that despite these recent findings, vasectomy remains a highly effective method of contraception. In addition, it is difficult to make general statements about vasectomy failure because of the wide variety of occlusion methods used. It is becoming clearer that some occlusion methods or combinations of occlusion methods are likely to be more effective than others.

There are two causes of vasectomy failure: user failure and failure of the technique itself. User failure is defined as when a pregnancy occurs before sperm have been cleared from the male reproductive tract postvasectomy. User failure could be related either to inadequate instruction or to the vasectomy user's failure to comply with instructions to use alternate contraceptive methods until azoospermia is confirmed.

Spontaneous recanalization of the vas is the most common cause of failure of the vasectomy technique itself, yet it is not well understood (Alderman, 1988). Recanalization occurs when a sperm granuloma forms at the vasectomy site, linking the two cut ends of the vas (Esho, Ireland, & Cass, 1974; Pugh & Hanley, 1969). In the case of vasectomy by ligation and excision, it is thought that failure may occur when the cut ends of the vas at the site of the ligature die and are sloughed off. A similar mechanism could be involved in recanalization following the use of clips.

When recanalization occurs in the first few months after vasectomy and before azoospermia has been achieved, it is called early recanalization. On the other hand, late recanalization occurs when sperm appear in the ejaculate after azoospermia has been demonstrated (Alderman, 1988; Philp et al., 1984). Late recanalization is usually identified when the partner of a vasectomized man becomes pregnant, and may occur several years after a seemingly successful vasectomy.

Rare causes of failure include congenital duplication of the vas that went undetected at surgery and a failure to identify and occlude the correct structure during the procedure (Alderman, 1988).

Complications

Intraoperative complications of vasectomy, such as vasovagal reaction, lidocaine toxicity, and excessive bleeding, are unusual. Staff can prevent vasovagal reaction by explaining the procedure to the client in advance, ensuring an effective anesthetic block, using gentle surgical technique, and reassuring the client during the procedure. Lidocaine toxicity and excessive bleeding can be prevented if providers follow appropriate vasectomy guidelines and procedures for administering local anesthesia and for the surgical technique.

Most postoperative vasectomy complications are minor, subsiding within 1–2 weeks. Common complaints after surgery are swelling of the scrotum, bruising, and pain. Minor bleeding under the skin is common. Some men experience tenderness or a dragging sensation in the scrotum for up to a week after vasectomy. A scrotal support, mild pain medication, and local application of ice are usually sufficient treatment.

More significant complications, such as heavy bleeding, hematoma (a collection of blood underneath the skin), or infection, are generally quite rare. The incidence of hematoma is related to the provider's experience with vasectomy: Physicians who per-

form larger numbers of vasectomies have lower hematoma rates than do those who perform fewer procedures (Kendrick et al., 1987).

Importantly, rates of heavy bleeding, hematoma, and infection vary depending on the approach taken to the vas. Numerous studies have demonstrated that the no-scalpel approach consistently results in lower rates of hematoma and infection than does conventional vasectomy (Table 7.1).

In most cases, using good surgical technique to minimize tissue trauma and limit bleeding, practicing aseptic technique, and giving clients good postoperative instructions can prevent bleeding, hematoma, and infection. Because the loose scrotal tissue allows injured blood vessels to continue bleeding, it is important to maintain good hemostasis during the procedure if hematoma formation is to be prevented. Many hematomas can be prevented if men avoid physical activity for a few days after the procedure; clients should be carefully instructed in this regard.

Sperm granulomas can occur either at the site of vas occlusion or in the epididymis. These small nodules form when sperm leak out of the vas or the epididymis, inducing an inflammatory reaction. While the true incidence of sperm granulomas following vasectomy is not known, they are seen in 15–40% of men having vasectomy reversal (Balough & Argenyi, 1985; Peterson, Huber, & Belker, 1990). This provides a reasonable estimate for incidence in men following vasectomy, in that rates of granuloma formation are likely to be similar in men having a reversal and in the general population of vasectomized men.

The majority of sperm granulomas are asymptomatic. Only 2–3% of vasectomized men have sperm granulomas that are painful or in some way symptomatic; most of these occur in the second or third week after the procedure (Kendrick et al., 1987; Peterson et al., 1990; Rajfer & Bennett, 1988). The factors that lead to the formation of sperm granulomas are not well understood; thus, there are no measures known to prevent or decrease their occurrence.

Long-Term Effects

Potential physiological effects and long-term sequelae of vasectomy have been the subject of extensive research over the past two decades. This research provides reassurance that vasectomy does not have any significant long-term negative physical or mental health effects. Results of large-scale, well-designed epidemiological studies in men have consistently shown no adverse effects of vasectomy in terms of heart disease, testicular or prostate cancer, immune complex disorders, and a host of other conditions. Vasectomy appears to be a largely safe and highly effective method of contraception, certainly with risks no greater than those for any of the contraceptive methods used by women.

Comprehensive studies of disease incidence

Five large-scale retrospective cohort studies have examined the incidence of a number of diseases in thousands of vasectomized and nonvasectomized men (Goldacre et al., 1978; Goldacre & Vessey, 1979; Massey et al., 1984; Nienhuis et al., 1992; Petitti et al., 1983; Schuman et al., 1993; Walker et al., 1981). For the disease categories or organ systems studied, vasectomized men were no more likely to be hospitalized or to develop a disease than were controls. In these studies, there were large numbers of cases of disease among both vasectomized and nonvasectomized men in all categories. Thus, taken together, the studies are reassuring that vasectomy does not increase the risk of adverse physical or mental health outcomes.

Effects on cardiovascular function

Reports that vasectomized monkeys developed atherosclerosis more rapidly than unvasectomized controls (Alexander & Clarkson, 1978; Clarkson & Alexander, 1980) led to

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extensive research into the potential effects of vasectomy on cardiovascular disease in men. Since the early 1980s, most of the cohort, case-control, and cross-sectional studies that were conducted have found no association of vasectomy with acute myocardial infarction, other ischemic heart disease, stroke, peripheral vascular disease, hypertension, coronary artery disease, or hypertensive and atherosclerotic retinal vascular changes (Giovannucci et al., 1992; Goldacre et al., 1978; Goldacre & Vessey, 1979; Massey et al., 1984; Nienhuis et al., 1992; Petitti et al., 1983; Rimm et al., 1983; Rosenberg et al., 1986; Schuman et al., 1993; Walker et al., 1981).

Antisperm antibodies

The number of circulating antisperm antibodies increases after vasectomy: Antisperm antibodies are found in 50–80% of vasectomized men (Bernstein et al., 1979; Hellema & Rumke, 1978; Lenzi et al., 1997), but in only 8–21% of men in the general population (Gubin, Dmochowski, & Kutteh, 1998). The theoretical concern that these antibodies may have adverse health consequences has led to numerous studies, the results of which have shown no evidence of any immunological or other diseases related to the formation of antisperm antibodies after vasectomy (Coulson et al., 1993; Giovannucci et al., 1992; Goldacre, Holford, & Vessey, 1983; Lepow & Crozier, 1979; Massey et al., 1984; Petitti et al., 1982; Rimm et al., 1983; Walker et al., 1981). However, antisperm antibodies may play a role in decreased fertility after vasectomy reversal.

Prostate cancer

Since the mid-1980s, more than a dozen epidemiological studies of the risk of prostate cancer after vasectomy have been reported in the literature. Results have been difficult to interpret because of conflicting study findings, lack of a convincing biological mechanism for an association between vasectomy and prostate cancer, and generally weak associations when they have been found. Also, the potential for bias in some studies was high and likely led to an overestimation of any effect (Bernal-Delgado et al., 1998).

Based on the results of the research published to date, there is little evidence for a causal association between vasectomy and prostate cancer (Peterson & Howards, 1998). A panel of experts gathered by the U.S. National Institutes of Health in 1993 concluded that no change in the current practice of vasectomy was necessary nor should vasectomy reversal be done as a measure to prevent prostate cancer (Healy, 1993). Studies published after the expert panel report support these conclusions (Bernal-Delgado et al., 1998; Peterson & Howards, 1998).

Postvasectomy pain syndrome

A small percentage of vasectomized men have reported chronic pain in the testis following vasectomy (Choe & Kirkemo, 1996; Ehn & Liljestrang, 1995; McMahon et al., 1992). While up to one-third of men have reported occasional testicular discomfort following vasectomy, only around 2% of all vasectomized men said that the pain had negatively affected their life or that they regretted having had the vasectomy because of chronic pain (Choe & Kirkemo, 1996; McMahon et al., 1992). Conservative therapy such as nonsteroidal anti-inflammatory drugs, sitz baths, antibiotics, or spermatic cord blocks is sufficient treatment in most cases. When this fails, there is some evidence that vasectomy reversal or denervation of the spermatic cord may be helpful (Ahmed et al., 1997; Myers, Mershon, & Fuchs, 1997).

Mortality

Mortality following vasectomy has generally been very low. The few reports from the literature have demonstrated minimal mortality associated with vasectomy (Grimes et al., 1982a; Grimes et al., 1982b; Khairullah, Huber, & Gonzales, 1992; Strauss et al.,

1984). The most comprehensive study, based on data from more than 400,000 vasectomies worldwide, reported a mortality rate of 0.5 deaths per 100,000 vasectomized men (Khairullah et al., 1992). In addition, since 1990, EngenderHealth has become aware of only one vasectomy-related death (due to a postoperative infection at the surgical site) from among the more than 200,000 vasectomy procedures reported between 1990 and 2000 in EngenderHealth-supported programs around the world. Although reporting of mortality related to sterilization services is voluntary and complications are known to be underreported, vasectomy-related mortality clearly is quite low.

Vasectomy Regret and Reversal

Regret

Regret following a vasectomy is more common among men who at the time of the vasectomy were in an unstable marriage, were younger than 31, or had no children or had very young children, or among men who made the decision to have a vasectomy during a time of financial crisis or for reasons related to a pregnancy (Clarke & Gregson, 1986; Howard, 1982; Kjersgaard, Thranov, & Rasmussen, 1987; Shain, 1986). Providers should use risk factors for regret to identify men who may need more in-depth counseling to ensure that vasectomy is right for them at the time, but not to deny vasectomy to men who want it. In addition, the fact that regret is often seen when vasectomy users have an adverse health effect that is either caused by the procedure or perceived to be caused by it underscores the importance of good counseling prior to the procedure (see Chapter 5 for more information about regret).

Reversal

The most common reasons for reversal requests are remarriage after divorce or after the death of a partner, the death of one or more children, a desire for more children, or problems of either a physiological or psychological nature that the vasectomized man or his provider believe will be alleviated by vasectomy reversal (Belker et al., 1991; Howard, 1982; Myers et al., 1997; Owen & Kapila, 1984).

Vasovasostomy (reattaching the cut ends of the vas) is the most common procedure for reversing a vasectomy. In some situations, it may be necessary to attach the vas directly to the epididymis; this procedure is known as vasoepididymostomy. Both procedures are complex, technically demanding, and expensive; most importantly, there is no guarantee that fertility can be restored. This highlights the importance of carefully screening, counseling, and selecting vasectomy users.

Both macroscopic and microsurgical techniques for vasovasostomy and vasoepididymostomy have been used for vasectomy reversal; the current consensus is that microsurgical techniques are more successful (Belker et al., 1991; Belker, 1998; Fox, 1997). Reported rates of patency (evaluated by the presence of sperm in the ejaculate) following vasovasostomy range from 74% to 92% for macroscopic reversal and from 75% to 100% for microsurgical reversal (Belker et al., 1991; Cos et al., 1983; Huang et al., 1997; Kessler & Freiha, 1981; Lee, 1986; Mason et al., 1997). Reported pregnancy rates are lower, however, ranging from 35% to 57% for macroscopic and from 38% to 82% for microsurgical vasovasostomy approaches (Belker et al., 1991; Fallon, Miller, & Gerber, 1981; Lee, 1986; Owen & Kapila, 1984; Takihara, 1998). Vasoepididymostomy is generally less successful than vasovasostomy, and while pregnancy rates as high as 42–55% have been reported (Kolettis & Thomas, 1997; Marmar, 1995; Silber, 1989; Thomas, 1993), most are lower, ranging from 10% to 30% (Berardinucci, Zini, & Jarvi, 1998; Jarow, 1995; Matthews, Schlegel, & Goldstein, 1995; Takihara, 1998).

Several factors affect the success of vasectomy reversal: the technical demands of the surgery itself; the type of vasectomy procedure performed; the length of time between the vasectomy and the reversal procedure; the levels of antisperm antibodies that may

have developed after the vasectomy or the reversal; and changes in the epididymis or partial obstruction of the vas after reversal that prevent sperm from moving through the vas.

The time that has elapsed between vasectomy and reversal is a major factor in the success of reversal: The longer the interval between vasectomy and reversal, the less likely the man is to be fertile after reversal. Reversal is usually more successful when it is done within 10 years of the vasectomy; pregnancy rates drop to less than 50% when vasectomy reversal is performed more than 9–10 years later (Belker et al., 1991; Huang et al., 1997; Takihara, 1998).

Reports of the effect of antisperm antibodies on fertility following vasectomy reversal vary; some studies have shown decreased pregnancy rates due to antisperm antibodies, while others have not (Huang et al., 1997; Meinertz et al., 1990; Newton, 1988; Thomas et al., 1981). The consensus is that fertility following vasectomy reversal is inhibited only by high levels of antisperm antibodies (Lea, Adoyo, & O'Rand, 1997).

Partial obstruction of the vas after vasectomy reversal (e.g., because of a sperm granuloma or adhesions from the surgery) has been shown to affect the success of reversal (Carbone et al., 1998; Fox, 1997; Thomas et al., 1981). In these cases, semen quality may be poor in terms of sperm numbers, sperm motility, or both. When partial obstruction is the cause for failure of reversal, repeat vasectomy reversal has produced good pregnancy results (Belker et al., 1991; Fox, 1997).

Assisted reproduction technologies have been successful in vasectomized men who want children but who either do not want to attempt a vasectomy reversal or have had one or more unsuccessful reversal surgeries. Sperm can be retrieved from the epididymis or testis and then used in a procedure known as intracytoplasmic sperm injection (ICSI), in which sperm are injected directly into the ova in a laboratory. Pregnancy rates following ICSI with epididymal sperm are reported to be between 25% and 36% (Aboulghar et al., 1997; Craft et al., 1995a; Craft et al., 1995b; Dohle et al., 1998). Pregnancy rates ranging from 17% to 36% have been reported when testicular sperm are used (Aboulghar et al., 1997; Abuzeid, Sasy, & Salem, 1997; Craft et al., 1995a; Meniru et al., 1997; Watkins et al., 1997).

Research continues on methods of vasectomy reversal that produce better success rates. Additionally, new assisted reproduction techniques are also being explored that might be applied in the cases of vasectomized men who are interested in having children. However, there is no guarantee that pregnancy will occur following vasectomy reversal or use of assisted reproduction techniques, and these procedures are expensive and not widely available—especially in low-resource settings. Thus, vasectomy should be considered a permanent contraceptive method.

Innovations

New methods of vas occlusion are unlikely to become available in the near future, but investigators have explored several alternatives to surgical sterilization in men. Experimental methods of occluding the vas include injecting chemicals into the vas percutaneously (through the skin), to scar the vas closed or physically block the passage of sperm through the vas. In theory, percutaneous occlusion of the vas could offer several potential advantages over vasectomy as a male contraceptive, as it would be less invasive and thus might have a lower rate of complications. Such a procedure might also be quicker or easier to perform. In addition, some types could be reversed more easily, and the approach may be more acceptable, since it does not involve surgery.

Studies on occluding the vas for contraceptive purposes by injecting chemicals percutaneously began in the 1970s in China (Xiao, 1987; Zhao, 1990). This technique was easily performed and led to high rates of azoospermia and low pregnancy rates, although reversal was no easier than for vasectomy because the occluded portion of the vas needed to be excised and reanastomosis of the vas performed (Xiao, 1987; Zhao, 1990). Concerns about the safety of these chemicals have limited exploration of this approach. It is possible that a suitable method for chemically scarring the vas may be found in the future, and although reversal may not be any easier than for vasectomy, the technique

may offer other advantages over vasectomy in terms of ease of procedure, number of complications, or cost.

Formed-in-place plugs use a liquid material that is injected into the vas and forms a solid plug to block the vas lumen; such plugs have been examined as a method of vas occlusion. A formed-in-place polyurethane plug had low rates of complications, was highly effective, and was easily reversible (Zhao, 1990; Zhao et al., 1992a). However, uncertainty regarding the safety of the polyurethane product led to an investigation of medical-grade silicone plugs. Variable rates of success have been reported for a formed-in-place silicone plug known as Vasoc (Soebadi, Gardjito, & Meurik, 1995, Zambon et al., 2000; Zhao, Zhang, & Yu, 1992b). Vasoc vas occlusion does not appear to be suitable for use as a male contraceptive at this time: Not only are there questions about efficacy, but given the complex and technically demanding nature of the technique, the need for specialized and costly equipment and supplies (including refrigeration or freezing for the materials), and the need for three people to perform the procedure, service-delivery constraints would likely limit the method's utility in low-resource settings.

Researchers have also attempted to develop devices that can be placed in the vas to obstruct sperm but then later can be removed or opened to allow sperm to pass. Such devices have had several problems, however; for example, the surgery has been difficult and the devices have not consistently stayed in place within the muscular vas.

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