Effectiveness of VasectomyTechniques

David C. Sokal, MD^{a,*}, Michel Labrecque, MD, PhD^b

KEYWORDS

- Vasectomy methods Contraception Recanalization
- Pregnancy Semen analysis Review

Modern vasectomy techniques were developed as a component of family planning services in the 1960s and 1970s. Since then, vasectomy has been used as a contraceptive method by millions of couples¹ (see articles by Sheynkin and by Pile and Barone elsewhere in this issue). The procedure is performed in two distinct steps (or three steps if the administration of anesthesia is included as the first step). The first step is the approach to the vas (ie, penetrating the skin and bringing a loop of the vas outside of the scrotum). The second step, which determines contraceptive effectiveness, is to occlude the vas. Many techniques for approaching and occluding the vas have been suggested over the years (see the articles by Sheynkin and by Art and Nangia elsewhere in this issue), and surgeons in the United States and around the world use a wide variety of techniques. This article presents the current knowledge on the effectiveness of the most commonly used vasectomy techniques. To understand vasectomy effectiveness, it is necessary to briefly review the definition and measurement of vasectomy outcomes.

DEFINITION AND MEASUREMENT OF VASECTOMY OUTCOMES

Vasectomy effectiveness may be defined by the absence or occurrence of pregnancy (contraceptive effectiveness) or by the results of semen analyses (occlusive effectiveness).

Contraceptive Effectiveness

Data on pregnancy outcomes have been gathered from two general settings: clinic-based studies and population-based studies. Most published data come from clinical series and family planning clinics. A few reports have provided follow-up data from large clinical series to estimate long-term failure risks.^{2–4} Clinic-based studies may underestimate pregnancy rates because of at least three limitations:

- If a pregnancy occurs 1 or more years after a vasectomy, some men may not return to the clinic where they had the vasectomy performed.
- Some women might have an abortion and not inform their partners of a pregnancy because of concerns about marital stability.
- Physicians who have more vasectomy failures are less likely to publish their data.

Only a few population-based studies on the risk for pregnancy in couples relying on vasectomy for family planning have been published. Three studies from outside the United States^{5–7} have reported high pregnancy rates (between 3% and

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^a Behavioral and Biomedical Research Department, Family Health International, PO Box 13950, Research Triangle Park, NC 27709, USA

^b Département de médecine familiale et de médecine d'urgence, Université Laval, Centre de recherche du CHUQ, D6-728, Hôpital Saint-François d'Assise, CHUQ, 10 rue de l'Espinay, Québec, Québec, Canada * Corresponding author. Family Health International, 2224 East NC Highway 54, Durham, NC 27713. *E-mail address:* dsokal@fhi.org (D.C. Sokal).

9%) 3 to 5 years after vasectomy. These studies are discussed in more detail later.

The risk for pregnancy associated with vasectomy in the United States seems to be relatively low. In a study based on the National Survey of Family Growth,⁸ failure risks for vasectomy (and tubal occlusion) were not estimated because "accidental pregnancy is rare with these methods." Based on a survey of US urologists, Deneux-Tharaux and colleagues⁹ estimated the risk for pregnancy to be 1 per 1000 procedures, with approximately half of the pregnancies occurring within the first 3 months post vasectomy. Urologists who did more than 50 procedures per year had a lower risk for failures, but no associations were seen between the risk for pregnancy and particular vasectomy techniques. The relatively low risk for pregnancy in the United States may be explained by surgeons' typical use of a combination of vas occlusion techniques.¹⁰ Another US study,¹¹ however, based on a telephone interview of 540 women whose partners had had a vasectomy, found higher pregnancy rates of 7.4 per 1000 procedures (95% CI, 0.2, 14.6) 1 year after vasectomy and 11.3 per 1000 procedures (95% CI, 2.3, 20.3) up to 5 years after vasectomy.

Although pregnancy prevention is the primary goal, it would be difficult to conduct a prospective study of different vasectomy techniques with pregnancy as the main endpoint. Therefore, prospective studies of the success rates of different vasectomy techniques are based on semen analysis data (ie, occlusive effectiveness) rather than pregnancy rates.

Occlusive Effectiveness

In clinical practice and in most research settings, vasectomy outcomes are defined by the results of one or more semen analyses. In brief, vasectomy success is defined as at least one semen analysis showing no sperm (azoospermia). If only a few nonmotile sperm are observed, most clinicians give a "cautious assurance of success." The presence of any motile sperm indicates a possible vasectomy failure and a risk for pregnancy.

Postvasectomy semen analysis

Various strategies for timing and interpreting the results of postvasectomy semen analysis (PVSA) have been proposed.^{12,13} The first PVSA usually is recommended at approximately 12 weeks,¹² or at least 8 weeks after vasectomy.¹⁴ Some practitioners recommend starting as soon as 3 to 4 weeks,¹⁵ and others suggest waiting until 16 weeks.¹⁶ Reflecting the various

recommendations, clinical practice in the United States is extremely diverse.¹⁰

The rationale for an early test is that if a surgeon's vas occlusion technique is reliable, then only small numbers of nonmotile sperm should be present by 3 to 4 weeks post vasectomy, and the ability of such residual sperm to fertilize an ovum is doubtful.^{17–19} Jouannet and David wrote, "Motile spermatozoa were never observed after the 15th day following vasectomy. The reappearance of motile spermatozoa after that time was an almost certain sign of a defect in the vas block or of recanalization of the vas deferens."¹⁷

The reason that has been proposed for later testing, at 16 weeks, is to allow time for men who have slow sperm clearance to reach azoospermia and avoid the need for a second PVSA.

There is wide variation among clinicians in the number of PVSA deemed necessary to confirm vas occlusion.10,20 Based on most recent evidence, only one completely azoospermic semen specimen is sufficient to confirm occlusion.¹² Moreover, most experts classify probable success and provide "special clearance" or "cautious assurance of success" when only small numbers of nonmotile sperm are present.^{12,13,21,22} The initial article defining special clearance suggested a nonmotile sperm cutoff level of 10,000/ mL,²¹ but a description of the laboratory methods used by the investigators was never published. More recently, investigators,^{23,24} and guidelines from the British Andrology Society¹⁶ and the Dutch Urological Association²⁵ have suggested a nonmotile sperm cutoff level of 100.000/mL.

Readers can find additional information about semen analysis techniques in the World Health Organization's manual for semen analysis,²⁶ in Mortimer's Practical Laboratory Andrology,²⁷ and in other published articles.^{24,28} Although some authorities recommend centrifugation to document azoospermia,¹⁶ a recent article suggests that a careful examination of noncentrifuged specimens may be sufficient.²⁴ Mortimer provides detailed instructions on how to estimate sperm concentration in uncentrifuged wet preparations based on the volume of the drop of semen, the coverslip size, and the particular microscope's field of view. (A calculation that was cited occasionally in the older literature was that 1 sperm/ high power field [hpf] of a wet preparation is equal to 1 million sperm/mL. With modern, wide-field microscopes, however, the field of vision is larger and that estimate is probably no longer valid in most laboratories. With modern microscopes, and a small, 10-µL drop of liquefied semen under a 22-mm coverslip, 1 sperm/hpf = approximately 250,000 sperm/mL [calculated from data in Mortimer's Table 3.1, page 49, and Appendix II]).

In 2008, the Food and Drug Administration approved the first home test kit, SpermCheck Vasectomy,²⁹ for men to perform their own PVSA at home. It is similar to a home pregnancy test but uses semen rather than urine. Among 144 postvasectomy semen samples, the test was always positive (100% sensitivity) with sperm counts above 385,000 sperm/mL.²⁹ At that cutoff, the test should identify most cases of early recanalization, the most common cause of vasectomy failure. Sperm motility cannot be assessed with this test, however, requiring standard semen analysis in case of a positive result.

Recanalization and occlusive outcomes

Postvasectomy recanalization of the vas may be defined most simply as the growth of new connections between the proximal and distal cut ends of the vas, permitting the passage of sperm (This article uses the term recanalization to refer to spontaneous postvasectomy recanalization, but in some countries other than the United States, recanalization may be used to refer to vasectomy reversal surgery [ie, vasovasostomy and related procedures]). The pathophysiology of recanalization remains unclear, however. Current limited understanding is based mainly on histopathologic studies that have been conducted on specimens collected from men undergoing repeat vasectomy or vasovasostomy.³⁰⁻³⁵ Various tissues and cells, including connective tissue, spermatozoa, blood cells, smooth muscle tissue, and epithelial cells, are involved in a granulomatous reaction that bridges the gap between the cut ends of the vas deferens. Epithelial-lined microtubules proliferate through the granulomatous tissue, producing a fistula that allows the passage of sperm.

Recanalizations usually are classified as early or late. Early recanalization can be diagnosed when a man shows motile sperm on a routine PVSA at 8 to 12 weeks and may be suspected if a man shows more than 1 million nonmotile sperm/mL at that time. A late recanalization is one that occurs after a man has been declared sterile. Late recanalizations are relatively rare and usually are identified after the occurrence of a pregnancy.

Before recent work by Family Health International and EngenderHealth, only a few others had published data using serial semen analyses to document early recanalizations.^{36,37} By analyzing serial samples from 400 vasectomy cases, Marshall and Lyon³⁶ reported eight men who had a transient re-appearance of sperm. Similarly, Esho and coworkers³⁷ reported six cases of early recanalization. In four of the cases of early recanalization with repeat vasectomies, they reported seeing recanalization channels by histopathology and by radiographic study of the excised vas segments.

A decade of research led by Family Health International and EngenderHealth, with funding from the US Agency for International Development and assistance from many collaborators, has helped further understanding of the frequency of early and transient recanalizations, especially when ligation and excision are used for vas occlusion. In three prospective clinical trials, the investigators collected multiple semen samples beginning as early as 2 weeks post vasectomy, including data from more than 1400 men.^{38–41} Early recanalizations were more common than generally realized, as high as 25% with simple ligation and excision of a short vas segment. Approximately half of the recanalizations were subclinical or transient.

Based on the authors' work, possible vasectomy outcomes have been identified and classified into two categories, success or failure (**Table 1**). **Figs. 1** and **2** illustrate the semen clearance patterns associated with these outcomes, except for late recanalizations. Each line in the figures shows PVSA results for one man, with semen analyses done every 2 weeks.⁴¹

Occlusive outcomes without recanalization Cases 1 to 3 are successes and case 4 is a failure (see **Fig. 1**). Cases 1 and 2 show rapid achievement of azoospermia. In case 3, the sperm concentration rapidly drops below 1 million sperm/mL, but the decrease to azoospermia is much slower. This may be explained by individual differences in anatomy or sperm flow or by age. In some men, residual nonmotile sperm may take longer to dislodge from the complex folds of the ampullary region of the vas or from the passages of the seminal vesicles.⁴² Older men commonly take longer to reach azoospermia than younger men.^{39,43} In cases 1 to 3, no motile sperm were seen after the 2-week semen analysis.

Case 4 was presumed a surgical error (ie, one vas was not occluded). The sperm concentration never dropped, and all samples showed motile sperm. Such technical failures are so rare among experienced surgeons that it is difficult to estimate their frequency. A surgeon occasionally may operate twice on the same vas, thus leaving one vas unoccluded. More rarely, an anatomic variation, such as a duplicate vas deferens, may lead to a technical failure. Given the usual timing of the first semen analysis in clinical settings, it may not be possible to tell the difference between a technical/surgical failure and an early recanalization based solely on the semen analysis results.

Table 1 Possible postvasectomy occlusive outcomes	
Success	
"Normal" success (see Fig. 1, cases 1 to 3)	
Transient early recanalization	
Success before first PVSA (subclinical recanalization) (see Fig. 2, cases 5 and 6)	
Success after first PVSA (delayed success) (see Fig. 2, case 7)	
Failure	
Technical/surgical error (see Fig. 1, case 4)	
Persistent early recanalization (see Fig. 2, case 8)	
Late failure	
Persistent late recanalization	
Transient late recanalization	

Occlusive outcomes with recanalization Fig. 2 shows the PVSA results of four men who had presumed recanalization: three men had transient recanalization, with subsequent scarring of the vas lumen resulting in vasectomy success, and one man had persistent recanalization, a vasectomy failure. The recanalizations in cases 5 and 6 probably would not be recognized by a surgeon in the usual clinical setting, because the first PVSA is commonly done at 12 weeks, when both men would be azoospermic or close to azoospermic. Cases 5 and 6 probably would have been considered normal successful vasectomies (ie, subclinical recanalization). Case 7 would be identified at his first PVSA as a possible failure, but subsequent PVSA showed that he reached success (albeit delayed) after a transient recanalization. Delayed success occurs by 6 months in approximately 50% of men who have motile sperm at the time of their first PVSA and are considered to have an early recanalization.⁴⁴

Case 8 was azoospermic at 2 weeks, but the sperm concentration rapidly returned to normal levels with motile sperm and persisted. This is a persistent early recanalization and was considered a vasectomy failure at 24 weeks. This probably is the most common type of failure that surgeons see. In the research context, the authors

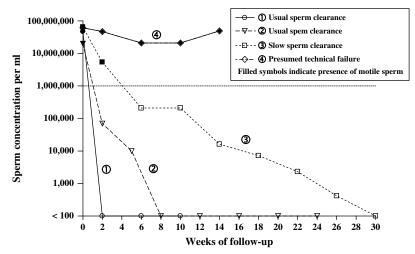


Fig.1. Semen analysis charts of four men who did not have presumed early recanalization. Sperm concentration is illustrated on a logarithmic scale. Because a logarithmic scale has no true zero, <100 on the graph was used to indicate azoospermia. The dotted line indicates low sperm cutoff (1,000,000 sperm/mL) according to reviewers' consensus. For case 2, prevasectomy sperm concentrations were not available. A count of 20,000,000 sperm/mL with presence of motile sperm was assumed. (*From* Labrecque M, Hays M, Chen-Mok M, et al. Frequency and patterns of early recanalization after vasectomy. BMC Urol 2006;6:25; under a Creative Commons license, http://creativecommons.org/licenses/by/2.0/; with permission.)

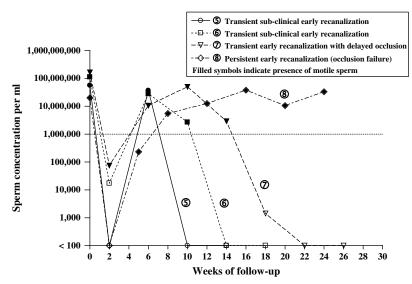


Fig. 2. Semen analysis charts of four men who had presumed early recanalization. Sperm concentration is illustrated on a logarithmic scale. Because a logarithmic scale has no true zero, <100 on the graph was used to indicate azoospermia. The dotted line indicates low sperm cutoff (1,000,000 sperm/mL) according to reviewers' consensus. For case 8, prevasectomy sperm concentrations were not available. A count of 20,000,000 sperm/mL with presence of motile sperm was assumed. (*From* Labrecque M, Hays M, Chen-Mok M, et al. Frequency and patterns of early recanalization after vasectomy. BMC Urol 2006;6:25; under a Creative Commons license, http://creativecommons.org/licenses/by/2.0/; with permission.)

defined success and failure by a man's status at 6 months, so case 8 was considered a vasectomy failure. In clinical practice, however, many surgeons might follow such a case with monthly semen analyses for more than 6 months before doing a repeat vasectomy. Such cases eventually may show a decline to azoospermia and become delayed successes. In a study that followed 36 such men,³⁹ 10 of them eventually achieved vasectomy success by 42 weeks post vasectomy.

Late recanalization Although a few surgeons³⁷ have suggested that men return for annual PVSA to identify failures due to late recanalization, subsequent research has shown that the risk for late failure after documented azoospermia is too low to justify routine annual testing. Philp and colleagues² and Davies and colleagues²¹ at the Elliot-Smith Clinic, have provided key data on long-term outcomes. Philp and colleagues reported long-term followup data on 14,047 men who had confirmed azoospermia on two rounds of PVSA and estimated that the risk for pregnancy after azoospermia was approximately 1 in 2000 men. Davies and colleagues reported long-term follow-up data on 151 men at the clinic who had been given "special clearance" based on the continued presence of small numbers of nonmotile sperm. These men were older than average patients at the clinic, with age perhaps contributing to a slower clearance of sperm. Upon semen analysis at later follow-up, at

least three or more years post vasectomy, all but one of the men were azoospermic and none of their partners had become pregnant. A single man still had small numbers of sperm present in his semen, estimated at less than 5000/mL.

Data on men requesting vasectomy reversal from infertility clinics show that even many years after vasectomy, 10% to 20% of men have small numbers of nonmotile sperm that can be detected by careful examination after centrifugation.^{45,46} This suggests another reason not to recommend annual PVSA, because results could lead to repeat vasectomies in men who have very low sperm counts and a remote risk for pregnancy.

If a postvasectomy pregnancy does occur, physicians should assume that the pregnancy is due to recanalization, even if the results of a semen analysis are negative. Transient late recanalizations resulting in pregnancy—with negative semen samples after diagnosis of the pregnancy—have been well documented by genetic testing.^{47–49} Physicians should not suggest that a man's spouse may have had another sexual partner unless genetic testing has been performed to rule out fatherhood by the vasectomized man.

EFFECTIVENESS OF VASECTOMY OCCLUSION TECHNIQUES

Many vasectomy occlusion techniques have been developed over the years, and these techniques

continue to evolve (see the articles by Sheynkin and by Art and Nangia elsewhere in this issue). The authors have reviewed the effectiveness of the vas occlusion techniques that are most commonly used in the United States.¹⁰

Most physicians use a combination of these techniques (some investigators do not classify the last four techniques as methods of vas occlusion):

- Ligation
- Cautery (intraluminal)
- Clips
- · Excision of a segment of the vas
- Fascial interposition (FI)
- Fold back one or two vasal ends
- Open-ended vasectomy (testicular end)

Details on how each of these common techniques is performed are provided (see the article by Art and Nangia elsewhere in this issue). Techniques for approaching the vas (such as the noscalpel technique) have no influence on vasectomy effectiveness and are not considered in this article.

There are many challenges to interpreting published data on the effectiveness of vasectomy techniques, including incomplete follow-up (discussed previously). Another challenge is that few studies have been performed on any particular technique, and those studies that have been performed primarily are retrospective reviews of individual physicians' experiences. Moreover, study details often are lacking; definitions of techniques and outcomes vary; failure is based mostly on semen analysis but without defining the laboratory methods or criteria explicitly; and follow-up data often are relatively short-term and unsystematic.

The following summaries of vasectomy occlusion technique effectiveness are based on a systematic review of comparative studies of vasectomy techniques published in 2004 by Labrecque and colleagues⁵⁰ and on a Cochrane review of randomized clinical trials updated in 2007.⁵¹ To find more recent comparative studies to include in this article, the authors searched MEDLINE for articles published between June 2003 and February 2009, using the keywords, "vasectomy" and "humans"; 349 articles were identified, but only one new study compared two vasectomy occlusion techniques.⁵²

In what follows, level A evidence refers to randomized controlled trials or meta-analyses, and level B evidence refers to other types of studies.

Ligation and Excision

Ligation and excision of the vas is the most common method of vas occlusion in developing

countries,^{6,44} although the data documenting this are limited. Suture material or metal clips can be used to ligate the vas. In the United States, only approximately 6.9% of surgeons use simple ligation and excision with suture material and 6.8% use simple ligation and excision with metal clips (based on data from Barone and colleagues: [16.9% of surgeons use ligation alone] \times [100 -59.3% of those surgeons not using FI = 6.9% for suture ligation alone; $[8.8\% \times (100 - 22.2\%)]$ = 6.8% for clip ligation alone).¹⁰ Some practitioners who use clips, however, report using more than one clip on each end of each vas. Most surgeons excise a vas segment from between the ligatures-usually between 0.5 cm and 4 cm but most commonly approximately 1 cm.

How the vas is ligated may affect the likelihood of failure. Applying too much pressure when putting sutures or clips on the vas deferens, which is a smooth muscle, is common. Too tight a ligature creates ischemia and eventually causes necrosis and sloughing of the ligated stump, leading to recanalization. Alternatively, if the ligature is too loose, occlusion will fail. For these reasons, many investigators have recommended not putting any sutures or clips on the vas deferens.^{4,53,54}

The risk for vasectomy failure with this technique traditionally has been considered to be high, between 1% and 5%.⁵⁵ Recent, more rigorous studies, however, have shown that the risk could be much higher, ranging from 8% to 13% based on data from semen analyses.^{38,39,56} The risk for recanalization is even higher. In the authors' study assessing the frequency and patterns of recanalization, the risks for vasectomy failure and early recanalization were estimated to be 13% and 25%, respectively, among 416 men who provided serial postvasectomy semen samples up to 6 months after vasectomy (**Table 2**).⁴¹

The risk for contraceptive failure also may be high, as illustrated in studies in which most vasectomies were done by simple ligation and excision.⁴⁴ In a population-based cross-sectional study of family planning conducted in China, the cumulative pregnancy rate among 1555 couples relying on vasectomy was 9.5% at 5 years.⁵ A population-based study of 1052 men in Nepal⁶ estimated a cumulative pregnancy rate of 4.2% at 3 years or 3% at 3 years excluding pregnancies occurring within the first 3 months post vasectomy. The Nepal study is unique among population-based studies in that Nazerali and colleagues (1) collected semen samples and (2) they were able to obtain limited data on surgical techniques. A similar pregnancy rate (4.1%) was found in Vietnam after more than 5 years of follow-up.⁷ Finally, in a retrospective clinic-based

Table 2 Risk for occlusive failure and early recanalization according to vasectomy occlusion techniques							
	Ligation a	nd Excision	Cautery				
Outcomes	FI —	FI+	FI —	FI +			
	N = 414	n = 410	n = 197	n = 192			
Occlusive failure (%) ^a	13	5	1	0.5 ^b			
Recanalization (%)	25	10	9	0			

Abbreviations: FI-, without FI; FI+, with FI.

^a Occlusive failure was defined as 10 million sperm/mL at 12 weeks or later.

^b Including one technically failed vasectomy.

study in India, 3% to 5% of couples using vasectomy had a pregnancy after 5 years.⁵⁷

Metal clips do not seem to increase effectiveness when compared with any of the suture materials used in the few comparative studies available.⁵⁰ A recently published retrospective comparative case series showed that ligating the vas with Vicryl results in a significantly higher failure rate in achieving azoospermia (10.1% of 1088 men) than does ligating with chromic catgut (3.5% of 1038 men).⁵²

Failure is rare when a 4-cm or larger vas segment is excised.^{58–62} Excising such a long segment, however, requires extensive dissection of the vas and may be associated with a higher risk for surgical complications. Moreover, it may preclude successful vasovasostomy. Excising a longer segment within the range of 0.5 cm to 2 cm is not associated with a lower risk for failure.⁶³

VasClip, which is a single clip system that does not require cutting the vas, had been proposed as an alternative occlusion method. The risk for failure for VasClip seems similar or higher than that for simple ligation and excision, based on two published reports.^{64,65} The VasClip company has apparently stopped marketing the device due to the high failure rate. (The VasClip Web site, vasclip.com, is no longer active, and the company's phone number is no longer in service.)

In brief, simple ligation and excision (with no other techniques) is associated with a relatively high risk for failure and no longer recommended.^{14,66}

Fascial Interposition

To increase the effectiveness of vasectomy, some physicians have recommended creating a tissue barrier between the severed ends of the vas by pulling the internal spermatic fascia (the sheath covering the vas deferens) over one of the vas stumps. This technique is named fascial interposition (FI). The fascia can be sealed over the testicular or the prostatic end using suture materiel or a metal clip.

Five studies comparing vas occlusion techniques with FI versus without FI were reported in a systematic review published in 2004.⁵⁰ **Table 3** presents the risk for occlusive failure reported in these five studies.^{39,67–71} Although the specific occlusion techniques differed among the studies, all used some form of ligation and excision, with the exception of one study in which the vas was only transected.⁶⁸ Only three studies clearly described how the FI was performed. The fascia was sealed over the prostatic end in one study⁶⁷ and over the testicular end in the other two.^{39,69} Although the risk for failure varied largely from one study to the next, all of the studies showed fewer failures with FI.

Mainly based on the single large randomized trial by Sokal and colleagues,³⁹ there is good evidence that FI reduces the risk for occlusive failure of vasectomy performed with ligation and excision. Even in this study, however, the risk for failure (5%) and of presumed early recanalization (10%) were unacceptably high (see **Table 2**).

Cautery (Thermal or Electrical)

Intraluminal thermal (hot-wire) or electrical cautery of the vas lumen has been advocated as an effective vas occlusion technique, used alone or combined with FI.

Cautery without fascial interposition

Ligation and excision with or without FI and cautery without FI were compared in six studies.^{41,69–74} Results have not been not consistent (**Table 4**). The largest study, which was performed in the United Kingdom with electrical cautery, did not find any difference between the techniques.⁷⁴ Three of the studies found better results with ligation and excision,^{69,72,73} and two found better results with cautery.^{70,71,75} It is thus difficult to draw definitive conclusions on the effectiveness

Table 3

Risk for occlusive failure in studies comparing vasectomy performed with simple ligation and excision versus ligation and excision combined with fascial interposition

Study	Study Design	Sample Size		Side of Fascial	Occlusive Failure (%) ^a	
		LE	LE + FI	Interposition	LE	LE + FI
Schmidt, 1973	Ш	150	135	Prostatic	3.3	0
Rhodes, 1980	111	28	12	Unspecified	21.4	16.7
Li, 1994	11	183	186	Testicular	7.5	0.6
De los Rios, 1994 and 2003	III	550	302	Unspecified	29.1	2.6
Sokal 2003		422	419	Testicular	12.7	5.9

Study design. I: randomized clinical trial or quasirandomized clinical trial. II: nonrandomized parallel group trial, beforeand-after trial (prospective experimental study of different techniques conducted over different time periods), or prospective cohort study. III: case-control study, retrospective cohort study, or retrospective case series with historical or concurrent controls.

Abbreviations: FI, fascial interposition; LE, ligation and excision.

^a Definitions of occlusive failure are not uniform across studies.

of cautery, especially because none of these studies provide level A evidence (see **Table 4**).

Cautery with fascial interposition

Seven studies have compared the risk for occlusive failure with ligation and excision with or without FI versus cautery with FI (**Table 5**).^{4,41,56,67,76–82} Although none of the studies provides level A evidence, all seven studies found a small risk for occlusive failure with cautery combined with FI (0.5% or less in six of the seven studies). In all seven studies, the risk for occlusive failure was much lower for cautery than for ligation and excision.

The authors did not find any studies comparing cautery without FI and cautery with FI. The risk for occlusive failure was lower, however, on average, in the seven studies of cautery with FI than in the five studies of cautery without FI (see **Tables 4** and **5**). In addition, in the authors and colleagues' study of frequency and patterns of recanalization,⁴¹ no recanalization was observed

Table 4

Risk for occlusive failure in studies comparing vasectomy performed with ligation and excision combined or not with fascial interposition and simple cautery

	Study	Sample	Size		Occlusive Failures (%) ^a	
Study	Design	LE/LE + FI	с	Type of Cautery	LE/LE + FI	c
Bangstrup, 1977	II	324	254	Electrical	2.7	3.5
Shapiro, 1979		262	148	Thermal	0.4	3.1
Philp, 1984		4500	12,300	Electrical	0.5	0.3
Li, 1994	II	427/186	442	Electrical	1.4/0.6	4.8
De Los Rios, 1994 and 2003	III	550/302	131	Thermal	29.1/2.6	1.2
Labrecque, 2006 ^b	II	414/410	197	Electrical	12.7/4.9	1.0

Study design. I: randomized clinical trial or quasirandomized clinical trial. II: nonrandomized parallel group trial, beforeand-after trial (prospective experimental study of different techniques conducted over different time periods), or prospective cohort study. III: case-control study, retrospective cohort study, or retrospective case series with historical or concurrent controls.

Abbreviations: C, cautery; FI, fascial interposition; LE, ligation and excision.

^a Definitions of occlusive failure are not uniform across studies.

^b Combines data from two studies. Original data were reported by Sokal and colleagues³⁹ and Barone and colleagues.⁴⁰

Table 5

Risk for occlusive failure in studies comparing vasectomy performed with ligation and excision combined or not with fascial interposition and cautery combined with fascial interposition

	Study	Sample Size			Occlusive Failures (%) ^a	
Study	Design	LE/LE + FI	C + FI	Type of Cautery	LE/LE + FI	C + Fl
Moss, 1972,1976, and 1992	III	551	6184	Thermal	0.5	0.03
Schmidt, 1973, 1978, and 1995	Ш	150/135	6248	Thermal	3.3	0
Esho, 1978		497	820	Electrical	6.5	0.5
Simcock, 1978	III	790	1649	Electrical	1.4	0.3
Labrecque, 1998	111	545	322	Thermal	2.8	1.2
Labrecque, 2002	-	1453	1165	Thermal	8.7	0.3
Labrecque, 2006 ^b	II	414/410	192	Thermal	12.7/4.9	0.5

Study design. I: randomized clinical trialor quasirandomized clinical trial. II: nonrandomized parallel group trial, beforeand-after trial (prospective experimental study of different techniques conducted over different time periods), or prospective cohort study. III: case-control study, retrospective cohort study, or retrospective case series with historical or concurrent controls.

Abbreviations: C, cautery; FI, fascial interposition; LE, ligation and excision.

^a Definitions of occlusive failure are not uniform across studies.

 $^{\rm b}$ Combines data from two studies. Original data were reported by Sokal and colleagues 39 and Barone and colleagues. 40

in patients who had their vasectomy performed with intraluminal cautery combined with FI (see **Table 2**).

Based on these comparative studies, there are no apparent differences in the risks for failure for thermal and electrical intraluminal cautery. Only one clinical study actually compared the two types of cautery. The difference in the risk for occlusive failure was not statistically significant (3.1% for thermal cautery and 6.1% for electrical cautery).⁶⁹ When the sealing of the vas was assessed by the number of cases of vasitis nodosa and spermatic granuloma at the time of vasectomy reversal, however, thermal cautery showed better results than electrical cautery.⁸³

In 2002, Marie Stopes International published a case series of 45,123 men who were vasectomized using an electrocautery technique without cutting the vas.⁸⁴ Electrocautery was used to access the vas (a no-scalpel approach) and to destroy the vas almost completely for a distance of 2 to 3 cm, leaving intact only a thin portion of the posterior wall of the vas. The reported failure rate was 0.7%. An attempt to use intraluminal thermal cautery without cutting the vas, however, proved to be associated with a high risk for failure. In a cohort of the 135 men who provided at least one sample for PVSA, 30% had motile sperm at the time of the first PVSA. The incidence of possible or confirmed occlusive failure in these men was 15%.⁸⁵

Folding Back a Vas Segment

Folding back one or both vas segments on themselves and maintaining them in place with a suture has been advocated to increase vasectomy effectiveness. Five studies have compared vas ligation with folding back and vas ligation (with or without excision) without folding back.⁵⁰ Two of the studies found a similar risk for occlusive failure between vas ligation with and without folding back when clips were used in the comparison group.86,87 Two studies found fewer occlusive failures with folding back,^{70,71,81} and one found more occlusive and contraceptive failures with folding back.⁶⁹ One population-based study⁶ found fewer failures by a single surgeon who used a fold-back technique compared with others using simple ligation and excision. Considering the overall results of the studies and their methodologic quality, there was no clear advantage of folding back in terms of increasing effectiveness.

Leaving the Testicular End Open (Open-ended Vasectomy)

Leaving the testicular end open has been proposed to decrease the back pressure on the epididymis and reduce the risk for postvasectomy chronic pain. A reduction in damage to the epididymis has been demonstrated in animal models.⁸⁸ Based on current clinical evidence, however, no firm conclusions can be made about the potential benefit of the open-ended technique in reducing the risk for postvasectomy chronic pain in humans.⁵⁰ Another potential advantage of the open-ended technique is that it might increase the probability of success after vasectomy reversal, but the authors are not aware of any comparative studies measuring this outcome.

A major advantage of using an open-ended vasectomy technique is that it reduces the time to perform the surgical procedure. Some clinicians are reluctant to leave the testicular end open, however, fearing the increased occurrence of sperm granuloma associated with this technique and subsequent pain^{78,89} and occlusive failure. Results from studies comparing the open-ended technique to a technique in which the testicular end is closed suggest that the open-ended technique does not increase the risk for chronic pain and occlusive failure when the prostatic end is adequately occluded using FI and cautery (**Table 6**).^{56,69,73,78,82,89}

SUMMARY AND RECOMMENDATIONS

In the United States and other high-resource settings, there seem to be fewer vasectomy failures and fewer postvasectomy pregnancies than in low-resource settings. This is probably due mainly to differences in vas occlusion methods and subsequent recanalizations.

Given the number of vasectomy procedures performed annually around the world, there is surprisingly little high-quality evidence on the relative effectiveness of various techniques for vas occlusion. Nonetheless, taking into account the limitations of the available studies, the authors propose the following conclusions and recommendations:

- Recanalization is the most common reason for vasectomy failure (evidence level B). As a randomized trial to study this outcome does not seem feasible, level B evidence probably will remain the best level of evidence available.
- 2. Simple ligation and excision, with suture material (evidence level A) or surgical clips (evidence level B), is associated with an unacceptably high risk for failure and should not be used as a vasectomy occlusion technique.
- 3. Adding FI to ligation and excision significantly reduces the risk for failure (evidence level A).
- Techniques that include cautery seem to have a lower risk for failure than techniques that do

Table 6

Risk for occlusive failure in studies comparing vasectomy performed with testicular end left open versus close end

	a. 1	Samp	le Size	Type of Occlusion on Prostatic End	Occlusive Failures (%) ^a	
Study	Study Design	Open	Close		Open	Close
Goldstein, 1978	III	4	387	тс	50	0.3
Shapiro, 1979	III	23	91	LE or TC	2.1	0
Errey, 1986	III	3867	4330	EC + FI + FB	0.02	0.08
Moss, 1992	111	3103	3081	TC + FI	0.03	0.03
Li, 1994	11	415	2298	LE + FI	4.1	3.1
Labrecque, 1998	III	322	545	TC + FI	1.2	2.8
Labrecque, 2002	-	1165	1453	TC + FI	0.3	8.7

Study design. I: randomized clinical trial or quasirandomized clinical trial. II: nonrandomized parallel group trial, beforeand-after trial (prospective experimental study of different techniques conducted over different time periods), or prospective cohort study. III: case-control study, retrospective cohort study, or retrospective case series with historical or concurrent controls.

Abbreviations: EC, electrical cautery; FB, folding back; FI, fascial interposition; LE, ligation and excision; TC, thermal cautery.

^a Definitions of occlusive failure are not uniform across studies.

not include cautery (evidence level B). There is insufficient evidence to recommend a particular standardized cautery technique, but adding FI to cautery seems to be associated with the lowest risk for failure.

- 5. Open-ended vasectomy does not increase the risk for failure when the prostatic end is adequately closed using FI and cautery (evidence level B).
- 6. Additional research is needed to a) clarify the importance of including FI with thermal or electrical cautery (the Indian Council of Medical Research is planning to conduct a randomized controlled trial to compare ligation and excision combined with FI [the current government-recommended method in India]; thermal cautery and excision; and thermal cautery and excision combined with FI. In all three groups, surgeons plan to use the no-scalpel vasectomy approach to the vas and to excise approximately 1 cm of the vas); b) document any potential benefits of the open-ended technique; and c) explore new ideas for quicker and easier methods of vas occlusion.

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