Recent developments in vasectomy

Kerry Wright Aradhya, Kim Best and David C Sokal

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Clinical review

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Kerry Wright Aradhya, Kim Best, David C Sokal

Field, Information and Training Services Department, Family Health International, PO Box 13950, Research Triangle Park, NC 27709, USA
Kerry Wright Aradhya *senior science writer/editor*
Kim Best *senior science writer/editor*

Clinical Research Department, Family Health International
David C Sokal *associate medical director*

Correspondence to: D C Sokal dsokal@fhi.org

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Vasectomy is one of the safest and most effective permanent contraceptive methods available. Compared with tubal ligation, which is usually done under general anaesthesia and entails surgery within a woman's peritoneal cavity, vasectomy is safer and men recover more quickly from the procedure. Vasectomies are usually done under local anaesthesia in outpatient settings, and men usually go home within an hour of the surgery. None the less, for various reasons, vasectomy procedures are less common than tubal ligation procedures in most countries.

Surgical techniques used for vasectomy vary widely throughout the world. The two main components of vasectomy are isolation of the vas deferens from the scrotum and subsequent vas occlusion. However, more than 30 different combinations of vas occlusion techniques probably exist,[1] and poor quality studies, heterogeneous study designs, and conflicting results have made it difficult to determine which are the most effective.[2]

The most common technique, especially in low resource settings, is suture ligation with excision of a small segment of the vas.[3] Few data are available on exact rates of use, but recent observations and interviews with surgeons in Asia suggest that at least 95% of all vasectomies in India, Nepal, and Bangladesh are done using ligation and excision (Michel Labrecque, Laval University, written communication, 28 May 2004). In contrast, data from 1995 indicate that only about 18% of vasectomies in the United States are done using this technique.[4] Although vasectomy has traditionally been thought to have overall failure rates of 1-3% or lower,[5–7] recent research indicates higher failure rates for ligation and excision.[8–10]

Because of a concern that vasectomy failure rates with ligation and excision could be higher than generally acknowledged, Family Health International and EngenderHealth convened a meeting of vasectomy experts in April 2001 in Durham, North Carolina. Family Health International and EngenderHealth are non-profit, non-governmental organisations devoted to improving global reproductive health. As a result of the experts' recommendations in 2001, additional research was conducted, and new data are now available. To review the latest findings, a second meeting of vasectomy experts was convened in December 2003 in Washington, DC. We describe here the outcomes of discussions from that meeting.

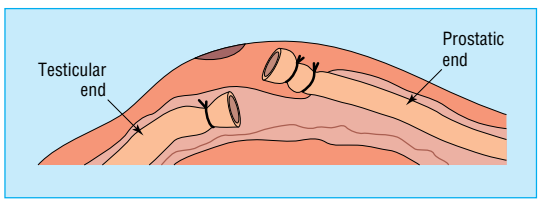

Fig 1 Fascial interposition. Adapted from EngenderHealth[20]

Summary points

In fascial interposition, the sheath covering the vas is pulled over one severed end and the sheath is closed to create a natural tissue barrier

Ligation and excision of a small segment of the vas plus fascial interposition is more effective at occluding the vas than is ligation and excision alone

Thermal cautery or electrocautery of the vas lumen is also more effective than ligation and excision alone; inexpensive, battery powered thermal cautery devices are commercially available

Recent evidence suggests that cautery plus fascial interposition is more effective than ligation and excision plus fascial interposition, but fascial interposition is technically challenging; research is needed to determine where cautery alone fits into this hierarchy

Methods

Family Health International, EngenderHealth, and EngenderHealth's ACQUIRE Project organised an expert consultation on vasectomy to review the literature and share new research findings on vas occlusion techniques, discuss programmatic implications, prioritise future research, and develop guidelines for using vasectomy techniques in diverse healthcare settings. More than 50 representatives from 24 universities and reproductive health research, service delivery, training, advocacy, and donor organisations attended the consultation. We focus here on the new clinical

P+ *Photographs of family planning clinics and a handheld cautery device are on bmj.com*

findings and evidence based "points of consensus" on the effectiveness of techniques agreed on at the meeting. These points of consensus were based on recent research results, described below; input from independent experts; and results of a formal, systematic literature review that was presented at the meeting and has since been published.[2]

Recent research results

Because pregnancy after vasectomy is relatively rare and difficult to study, the findings given below are based on results of semen analysis rather than pregnancy outcomes.

Fascial interposition

Fascial interposition is a technique in which the sheath covering the vas is pulled over one severed end and the sheath is closed to create a natural tissue barrier. Figure 1 shows the testicular end of the vas within the sheath and the prostatic end outside, but many practitioners prefer the reverse—that is, keeping the prostatic end inside the sheath and the testicular end outside.

Recent results from a large randomised controlled trial conducted in eight outpatient clinics in Brazil, El Salvador, Mexico, Nepal, Panama, Sri Lanka, and the United States (see figures A and B on bmj.com) showed that ligation and excision plus fascial interposition is significantly more effective than ligation and excision alone.[11] An interim analysis of 552 men suggested that fascial interposition significantly reduced vasectomy failure rates, leading to early termination of the study.[12] Final results, which included data from 841 men receiving vasectomies between December 1999 and June 2002, confirmed these findings. The study included frequent semen analyses, at two weeks after vasectomy and every four weeks until either vasectomy success (defined as the complete absence of sperm—azoospermia—in two consecutive semen samples) or vasectomy failure (defined as more than five million motile sperm/ml at 14 weeks or later, or more than 100 000 sperm/ml with any motility at 26 weeks or later). Fascial interposition reduced failure rates by approximately 50%, from 12.7% to 5.9%.

This trial supported the results of several smaller studies suggesting the superiority of fascial interposition and helped to resolve conflicting results from previous studies.[2] Although ligation and excision alone is considered safe and effective, the experts agreed that these findings had important implications for improving vasectomy services. Efforts are now under way to train vasectomy providers on fascial interposition, especially in low resource settings.[13]

Cautery

Another technique to improve the effectiveness of vasectomy is cautery, in which heat or an electric current is used to cauterise the lumen of the vas (fig 2). Cautery is the most common vas occlusion technique in the United States; it was used in 71% of vasectomies done in 1995,[4] up from 50% in 1991.[14] Data reviewed from several large case series and comparative studies suggest that failure rates are lower with cautery than with simple ligation and excision, with consistent failure rates of less than 1% when cautery is used in combination with fascial interposition.[2] Although most surgeons cauterise both ends of the vas, some prefer to cauterise only the prostatic end. This is called an open ended vasectomy, and some researchers have suggested that leaving the testicular end open reduces side effects from the procedure.

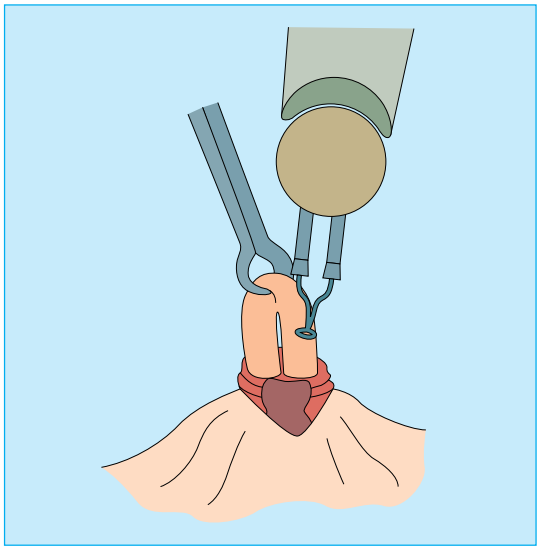

Fig 2 Thermal cautery. Adapted from EngenderHealth[20]

Recent results from a six month prospective non-comparative study of 400 men having vasectomies in Brazil, Canada, the United Kingdom, and the United States seem to confirm the low failure rate when cautery is used.[15] In this multicentre study, the rate of failure (defined as more than 10 million sperm/ml at 12 weeks or later, without subsequent success) among 364 participants who completed follow up was 0.8%. This study also included frequent semen analyses, beginning at two weeks and continuing through 24 weeks.

The experts concluded that the results of this study should be interpreted with caution, because it was not a randomised trial and because different methods of cautery were used at each of the four centres. Providers at two centres used thermal cautery, and those at the remaining two used electrocautery. Other technical variations also occurred between sites, in particular the use of fascial interposition at only two of the sites. However, the experts did agree that, on the basis of these results and those of other published studies, cautery is more effective than ligation and excision alone, but not enough data exist to determine whether thermal cautery or electrocautery is more effective. Some surgeons prefer thermal cautery over electrocautery, because it may produce fewer granulomas and less nodular thickening of the vas.[16] Furthermore, thermal cautery can be done using potentially reusable, cheap, battery powered, handheld devices practical for use in remote locations or where electricity is unreliable.[17] See bmj.com for photographs of such a device.

Fascial interposition versus cautery

To compare cautery with fascial interposition, experts compared failure rates from the multicentre randomised controlled trial with those from the observational cautery study described above. Overall, cautery was associated with significantly fewer early vasectomy failures than was ligation and excision plus fascial interposition, when failure was defined as more than 10 million sperm/ml at 12 weeks or later (1% *v*

5%).[18] The experts concluded that it was reasonable for vasectomy providers to consider switching from ligation and excision to cautery if it was feasible and sustainable in their settings.

Points of consensus

Overall, the recent research suggests a hierarchy of increasing contraceptive effectiveness with the following techniques: ligation and excision alone, ligation and excision with fascial interposition, and cautery with fascial interposition. The position of cautery alone in this hierarchy is unclear. On this basis, the experts at the meeting developed points of consensus in the form of a brief document for vasectomy providers and programme managers, to inform them of the latest research and to provide practical recommendations for the use of various techniques (box).

These points of consensus are meant to provide guidance to vasectomy providers and programme managers but should not be considered a mandate for change, for several reasons. Firstly, data are still limited on the effectiveness of cautery alone compared with ligation and excision plus fascial interposition. Secondly, some vasectomy providers might be encouraged to abandon ligation and excision prematurely because of the notion that cautery is a superior technique. However, vasectomy with ligation and excision alone is still very effective compared with most other contraceptive options, and cautery may be difficult to implement and sustain in some settings. Thirdly, training is advisable before adopting any new surgical technique, as the details of a particular cautery technique are important in determining efficacy.

Future research priorities

The expert consultation identified several future research priorities. Of highest priority was a three armed randomised controlled trial to compare ligation and excision with fascial interposition versus cautery alone versus cautery with fascial interposition. The exact surgical techniques used in such a study need to be carefully defined and standardised, and postvasectomy pain should be monitored. A small percentage of patients (less than 10%) have chronic testicular pain after vasectomy, but this has been poorly defined and can cause diagnostic and therapeutic challenges for physicians.[19] For these reasons, systematic assessment of such pain should be incorporated into future vasectomy studies. A related question that deserves further research is whether an open ended vasectomy technique would result in less postvasectomy pain than would a vasectomy technique in which both ends of the vas are cauterised, as some researchers have suggested.[2] The participants at the meeting also agreed on the importance of determining the optimal methods of cau-

Points of consensus on the effectiveness of different vas occlusion techniques

Vasectomy can be thought of as both an approach to the vas and a vas occlusion technique. With respect to approach, strong, high quality evidence shows that the no-scalpel vasectomy technique has significantly fewer side effects and complications than does the standard incisional approach. The no-scalpel vasectomy approach to the vas is therefore recommended. The remainder of this consensus document considers different techniques of vas occlusion, for which high quality data are limited. However, some recent evidence indicates that certain occlusion techniques can further increase the effectiveness of vasectomy.

Research findings

Because postvasectomy pregnancies are rare and difficult to study, the vasectomy research findings described below are based mainly on data from semen analysis.

Fascial interposition—Several observational studies and a recent randomised controlled trial indicate that fascial interposition, when used with ligation and excision, reduces the likelihood of vasectomy failure.

Cautery—Available data suggest that cautery is more effective than ligation and excision for vas occlusion. Furthermore, some data suggest that cautery is more effective than ligation and excision with fascial interposition. Data are insufficient to determine if either of the cautery techniques—thermal cautery or electrocautery—is more effective than the other. A preliminary evaluation of a battery powered, handheld cautery device indicates that the thermal cautery tips can be effectively resterilised and safely reused; they can be inexpensively manufactured.

Recommendations

- Training of vasectomy providers should emphasise the potential increased effectiveness of adding fascial interposition to the standard technique of ligation and excision. Providers now using simple ligation and excision should consider adopting fascial interposition, with appropriate training as needed
- Where resources, training, and logistical support are available, cautery is recommended as an effective and safe vas occlusion technique
- Further research is needed on simple ways to learn how to do fascial interposition and on the feasibility of using cost effective cautery devices in low resource settings

Additional educational resources

Royal College of Obstetricians and Gynaecologists. *National evidence-based clinical guidelines: male and female sterilisation.* London: Royal College of Obstetricians and Gynaecologists, 2004. www.rcog.org.uk/guidelines.asp?PageID=108&GuidelineID=30

EngenderHealth. *Contraceptive sterilization: global issues and trends.* New York: EngenderHealth, 2002. www.engenderhealth.org/res/offc/steril/factbook/index.html

Sokal DC. Recent research on vasectomy techniques. *Asian J Androl* 2003;5:227-30. www.asiaandro.com/1008-682X/5/227.htm

Cook LA, Van Vliet H, Pun A, Gallo MF. Vasectomy occlusion techniques for male sterilization. *Cochrane Database Syst Rev* 2004;(3):CD003991

Information for patients

Sterilisation for women and men: what you need to know (www.rcog.org.uk/mainpages.asp?PageID=1420)—Patient information document produced by the Royal College of Obstetricians and Gynaecologists

Vasectomy: questions and answers (www.engenderhealth.com/wh/fp/cvas2.html)—Vasectomy facts from the US based non-governmental organisation EngenderHealth, including links for accessing additional information

Vasectomy information (www.vasectomy-information.com/indexie.asp)—Personal experiences of men who have had vasectomies; frequently asked questions about the procedure; vasectomy news from around the world

tery for low resource settings, including further research on developing simple, acceptable, and low cost approaches for sterilisation and reuse of cautery tips.

The experts also discussed programmatic research, including prospective evaluations of different techniques, studies to determine the feasibility of implementing and training providers on various techniques, and research to identify practical differences between the techniques and perhaps to make recommendations for providers depending on the number of vasectomies done in a particular clinical setting. Future research should clarify the appropriate use of cautery and fascial interposition in low resource settings.

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Lesson of the week

Carbamazepine and false positive dexamethasone suppression tests for Cushing's syndrome

Ronald C W Ma, Wing Bun Chan, Wing Yee So, Peter C Y Tong, Juliana C N Chan, Chun Chung Chow

The clinical features of Cushing's syndrome may be subtle to begin with, and they resemble those of patients with metabolic syndrome. The key to diagnosing Cushing's syndrome is a high index of suspicion and the use of screening tests. The 1 mg overnight dexamethasone suppression test is commonly used. Subsequent biochemical evaluation often uses higher doses of dexamethasone. The overnight dexamethasone suppression test is also increasingly used in the functional evaluation of incidental adrenal masses.

We describe two patients, both of whom were suspected of having Cushing's syndrome based on abnormal results from overnight dexamethasone suppression tests. Subsequent evaluation excluded Cushing's syndrome in both patients. The false positive suppression tests were because of accelerated metabolism of dexamethasone caused by carbamazepine. Awareness of this potential pitfall in the diagnosis of Cushing's syndrome is important to avoid unnecessary investigations and anxiety.

Drugs that induce metabolism of dexamethasone can lead to misdiagnosis of Cushing's syndrome

Correspondence to:
R C W Ma
rcwma@cuhk.edu.hk

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Case reports

Case 1

A 24 year old woman was referred to the clinic for investigation of her weight gain. She had noticed progressive weight gain in recent years. She had a known history of depression, for which she has been prescribed alprazolam, sertraline, and propranolol. She had no history of steroid use. She was a non-smoker and was teetotal. On examination, she was