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Fertility and Sterility, Marrakesh, October 1989

Volume 3

PROGRESS IN CONTRACEPTION

Edited by Y. Boutaleb and A. Gzouli



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Foreword

Whilst preparing for the XIIIth World Congress of Fertility and Sterility, I could not help reflecting on the possibility that perhaps the Palais de Congrès might not be completed in time – and that for the first time in the history of the IFFS, the Congress might have to be held in tents! However, I need not have worried; after a very rapid construction schedule, this splendid new building was finished shortly before the Congress opened – and provided an ideal setting for the distinguished gathering of scientists from all over the world that met in Marrakesh for the IFFS Congress.

I should like to thank all those who took part in the XIIIth World Congress: their presentations made an important contribution to our growing understanding of all aspects of reproductive medicine, an understanding which is helping to develop new approaches to therapy around the world.

Finally, I should like to pay a special tribute to Dr Jean Cohen and Professor Robert Harrison, from the IFFS Committee, who together went to so much effort to ensure the success of the scientific program. I am indebted to them for their help – and I trust that these published Proceedings will provide a useful record of this very important scientific occasion.

Y. Boutaleb
President of the Congress

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SECTION 1

Voluntary surgical contraception

SECTION 1

THEORY OF THE EARTH

Vas occlusion and reversal

A. Nirapathpongorn

INTRODUCTION

Vasectomy or vasal sterilization is a safe, simple and effective male contraception. According to the survey^{1,2} in 1988, there are at least 59 million couples using this form of contraception in 30 countries. The majority of these couples (56 million) are in the People's Republic of China, India, USA and Bangladesh. However, several countries especially in Africa and the Middle East have no reported cases of vasectomies. Acceptability of vasectomy depends on the knowledge, attitude and sociocultural make-up of each society. Furthermore, misconceptions and bad rumors about vasectomies are still covering large population groups in many countries. Fear of loss of libido and energy to work are among the most common misunderstandings that prevent many men from accepting vasectomy. Some are also concerned about surgical incision and the problem of reversal in the future.

To overcome these obstacles, a better education process and new methods of vasectomy that could eliminate the fear of surgical incision and that are highly reversible should be developed and made available to help solve some, if not all, of these problems. These developments would be most welcome by many more potential acceptors.

APPROACHES TO THE VAS DEFERENS

Incision method

When performing vasectomy, the traditional method of approaching the vas deferens in the scrotum is to make one small incision in the midline or two incisions, one on each side of the scrotum, followed by sharp or blunt dissection of the subcutaneous tissue down to the vas deferens which sometimes causes tissue trauma or blood vessel injury that can lead to infection or bleeding complications. This surgical procedure usually takes 5–10 min in good hands and is mostly performed under local anesthesia on an outpatient basis. However, as noted above, many people are still afraid of being cut and refuse to accept vasectomy just because of this.

Non-scalpel method

In 1974, Li and his associates in China developed a new method of vasectomy originally called 'Ligation of vas deferens with clamping method under direct vision'³. It is now known as the 'non-scalpel vasectomy technique' as the procedure does not need a scalpel incision. Two special instruments are essential for this method, one is the extracutaneous vas deferens fixation clamp which, as the name implies, fixes the vas deferens from outside the skin of the scrotum at the midline, and the other is the vas deferens dissecting clamp which is basically a small curved hemostat where the tips are sharpened to a needle point, and it is used for making a puncture into the skin down to the vas deferens which is fixed by the first clamp. Widening of the punctured hole with the same vas dissecting clamp will separate the skin, subcutaneous tissue and spermatic fascia from the vas without cutting blood vessels. The vas will then be elevated out of the punctured hole and several vas occlusion methods can be used to complete the vasectomy. This approach has several advantages over the traditional incision method:

- (1) It eliminates the fear of surgical incision.
- (2) Bleeding during the procedure is much less.
- (3) The wound is so small that it does not require suturing and heals rapidly.

The approach to the vas by the non-scalpel technique is widely used in China. To date, over 8 million cases of vasectomy were performed with this technique in 24 of 36 provinces of China (S.Q. Li, personal communication). The use of this technique has recently spread from China and is being used in another 12 countries (Table 1).

In Thailand, about 7000 cases of non-scalpel vasectomy were performed since 1987. The method has gained rapid popularity there. Clinical studies of the non-scalpel vasectomy in China³ and in Thailand by Ratana-olarn⁴

Table 1 Countries where the non-scalpel vasectomy technique is being used by some vasectomists

Countries	Year introduced
People's Republic of China	1974
USA	1986
Thailand	1986
Sri Lanka	1986
Nepal	1986
United Kingdom	1987
Philippines	1988
Colombia	1988
Brazil	1988
Guatemala	1988
Pakistan	1988
Indonesia	1989
Bangladesh	1989

VAS OCCLUSION AND REVERSAL

and Nirapathpongpon (unpublished data) have shown that this method is associated with very low complication rates (Table 2). A comparative study of the incision method and non-scalpel technique at the King's Birthday Vasectomy Festival in Bangkok in 1987 by Nirapathpongpon also demonstrated a significantly lower rate of complication from the non-scalpel technique compared with the incision method (Table 3). Only three (0.4%) of 680 acceptors of the non-scalpel method developed minor complications whereas 16 (3.1%) of 523 cases using the incision technique had complications which included two big scrotal hematomas needing surgical drainage ($p < 0.001$). The same study also showed that the case turnover time of the non-scalpel method was 9.5 min compared with 16.5 min for the incisional technique.

This non-scalpel method of approaching the vas has made vasectomy procedures less frightening, easy, quick and safer. Many countries in Asia and Latin America are now expanding their training and service delivery programs of the non-scalpel vasectomy method. International training centers for non-scalpel vasectomy techniques are now established in Bangkok, Thailand and in Chongqing, China.

Table 2 Complication cases in three clinical studies of the non-scalpel vasectomy technique

Complication	Number of cases		
	Li, S.Q. (n = 534)	Ratana-olarn (n = 627)	Nirapathpongpon, A. (n = 921)
Bleeding			
hematoma (small)	—	—	1
external bleeding	—	2	—
Epididymo-orchitis	1	1	5
Congestive epididymitis	—	—	5
Wound abscess	—	3	1
Painful nodules	—	2	—
Vasocutaneous fistula	—	—	1
Total	1 (0.18%)	8 (1.2%)	13 (1.4%)

Table 3 Cases with complications of vasectomy acceptors in the comparative study of the standard incision and non-scalpel vasectomy technique (A. Nirapathpongpon, unpublished data)

Type of complication	No. acceptors with complications	
	Incision (n = 523)	Non-scalpel (n = 680)
Big scrotal hematoma needing surgical drainage	2	—
Small scrotal hematoma treated conservatively	6	1
External wound bleeding	1	1
Wound infection	4	—
Sperm granuloma	2	1
Epididymo-orchitis	1	—
Total	16	3

Percutaneous intravasal cannulation

Another approach to the vas is through a non-surgical percutaneous intravasal cannulation of the vas deferens. This method was developed in 1972 by Li and his associates in China⁵. This method is so simple that the vas deferens is first fixed with the vas fixation clamp. The skin and the vas wall are punctured by a no. 8 gauge sharp needle so that the tip of the needle enters the vas lumen. The sharp needle is removed and a blunt-ended needle, no. 6 gauge, is inserted into the punctured hole and threaded along the intravasal canal. A series of tests are performed to ensure that the needle is in the vas lumen, after which chemical agents may be injected to form a solid adhesive blockage or a plug which obstructs the vasa canal⁵. It is to be noted that, although the method may look simple, to master the technique of vasa cannulation, good training and much practice are needed. The technique can be performed effectively only by an operator with very good eyesight and a steady hand.

Over half a million vasa sterilizations using the intravasal injection approach have been performed in China since 1972⁵. Studies have shown that this approach is a very safe, effective and economical non-operative method for male contraception. Only minor complications have occurred in a few cases among these many acceptors. Pharmacokinetic and toxicology studies of the injected chemical agent were carried out and found no toxic effects in experimental animals and in humans (S.Q. Li, personal communication).

VAS OCCLUSION

Ligation

Once the vas deferens in the scrotum is identified and freed from other structures, it is then divided and a segment may be removed. The vasa stumps can now be occluded by one of many methods. The most common and most practical method being used in many countries is the vas ligation with non-absorbable suture. This method has stood the test of time as a simple, inexpensive and effective vas occlusion⁶. In general, this method will produce azoospermia in 96-98% of cases. Fascial interposition between the two ligated vasa stumps may add some protection against spontaneous recanalization.

Cautery

Electric cautery has also been used for vas occlusion. Schmidt reported no failures in more than 4600 vasectomies with this method⁷. Unfortunately, the bipolar electric cautery equipment, that precisely regulates the amount of electric current and limits the cautery to only the mucosa and a few layers of muscular wall of the vas, is not available commercially. The unipolar electric cautery commonly used in surgical facilities may damage the vas

more than necessary and produces poor results. Goldstein⁸ and Belker⁹ use battery-operated hot wire to cauterize the lumen of the divided vas. The effectiveness of vas occlusion using hot wire is being investigated. It is worth noting here that cautery of the vasal lumen needs great skill from the operating surgeon in regulating the correct amount of heat to be applied to the vas avoiding overheating them.

Clips

Metal clips are used for vas occlusion by some vasectomists with very good results⁸. The clips are applied to the open ends of the vasal stumps. It is advisable that two or more clips should be applied on each vasal stump to ensure complete blockage. The clips on the vas may be palpable like a nodule in the scrotum. Questions have been raised on the use of the clips concerning the practicality and the cost of the procedure in less-developed countries.

Intravasal injection with chemical agents

Vas occlusion with intravasal injection of chemical agents needs special attention because of its potential impact on the new trends in male contraception.

The technique of intravasal cannulation is a very delicate maneuver that needs not only great skill but also the precision of an operating surgeon to successfully place the needle in the lumen of the vas. Injection of the chemical agent also needs a special approach and specific timing during the procedure. It will need a lot of practice before one can be competent in this technique.

Two chemical agents are currently used for vasal sterilization in China. Carbolic acid-*n*-butyl cyanoacrylate mixture (CABCM) is a sclerosing agent which will be solidified in 20's after injection into the vasal lumen and produces complete blockage of the vas deferens by adhering permanently to the luminal surface of the vas. It is referred to as adhesive blocking agent or superglue. To date, this chemical agent has been used in over 600 000 cases of vasal sterilization in China with good results. Li reported an azoospermic rate of 96.3% and a 99.13% rate of pregnancy prevention in his follow-up study 8 years after the injection⁵. Complications among these cases were rare. Studies on pharmacology, toxicity and clinical effects of adhesive blocking agent for vas deferens have shown that this agent has no toxic or carcinogenic effects in experimental animals. A small fraction of the injected drug is absorbed but does not accumulate in the organs or body and is excreted in the urine and feces. A 10-year follow-up of 822 cases found no long-term complications except one man who had a painful nodule at the site of the injection. Another study of 3073 cases of vasal sterilization using intravasal adhesive blocking agent found 62 children born in 60 cases. These children were well-developed with normal intelligence (S.Q. Li, personal communication).

Another chemical agent used for vasal sterilization is polyurethane elastomer which is a mixture of two solutions (Solution A, formed by the co-polymerization of polytetra-methylene-ether-glycol (molecular weight 1000) with toluene-2,4-diisocyanate to form a pre-polymer linked by carbamate; Solution B, a chain extender made from methylene-bis-ortho-chloro-aniline, a catalyst and a solvent) that will form a spindle-shaped solid plug in 1-3 min after the injection (S.C. Zhao, personal communication). This plug, however, will not adhere to the luminal surface of the vas nor will it be migrated by peristaltic movement of the vas and it can be surgically removed at a later date to restore patency of the vas. This method of vas occlusion is referred to as vas obliteration and has been used for vasal sterilization in 82 000 men in China since 1983. The method is very effective and very safe. Of the 12 000 men followed-up during the first year after the injection, only 56 cases developed minor complications (0.47%). Of these, 47 had local infections and nine had local hematomas. There were no long-term complications in the groups of 2600 and 1000 sterilized men followed-up for 3 and 5 years, respectively. The azoospermic rate among 500 men after 1 year of vas occlusion with this method was 98%. Follow-up sperm count on 100 men collected after 2 and 3 years of vasal sterilization showed similar results. It is interesting to note that 86 men who were sterilized with this method had their plugs removed surgically and 51 had consequently impregnated their wives. This will be discussed in more detail later.

Open-ended vasectomy

This method of vasectomy has been tried but has not gained wide acceptance. Since the vas occlusion is not performed on the proximal (testicular) vasal stump (as sperm granuloma will form and the result of future reversal will be better), the failure rate of open-ended vasectomy is higher than that of conventional methods. Attempts have been made to improve the efficacy of the method by employing better sealing of the abdominal vasal stump and fascial interposition techniques⁸. The results of this study are necessary before this method can be recommended further.

VAS REVERSAL

After vasectomy, there will always be a small number of acceptors who request reversal later on. The most common reason for such a request is remarriage or the death of a child. As the number of vasectomy acceptors continues to increase, it is reasonable to assume that the demand for vasectomy reversal will increase. Furthermore, the acceptors are having the procedure performed at an increasingly younger age and lower parity. These people will be the potential requestors of the reversal.

According to the data collected at the meeting of experts on the issue of sterilization reversal organized by the World Federation for Voluntary Surgical Contraception in 1988, the demand for vasectomy reversal is between

1 and 3 individuals per 1000 vasectomies and this demand has a tendency to increase over time (J.M. Pile, personal communication).

Vasectomy reversal following vas occlusion by ligation, clipping, or cautery is performed by division of the obstructed segments and reanastomosis of the vas deferens under naked eye (macroscopic), or with a magnifying lens or microscope (microsurgery). The successful rate of the reversal depends on many factors including the time interval since vasectomy, site of vasectomy and occlusion method, presence or absence of sperm granuloma and antisperm antibody, quality of vas fluid, the skill of the operating surgeon, age of female partner and availability of microsurgical reanastomosis⁸⁻¹⁰.

Reviews of the literature on reported cases of vasectomy reversal have found the technical success in macroscopic procedures to be 35-92% while pregnancy rates range from 19 to 78%. Procedures performed with a microscope have the vas patency rate of 75-100% and pregnancy rate of 43-83%. With advances in microsurgical technique and the skill of operating surgeons, the chance of successful restoration of fertility is increasing. Unfortunately, the service of microsurgical techniques is available only in some countries. The majority of vasectomy clients will find it difficult to obtain such a service, especially in less-developed areas. Training of more microsurgery surgeons and the establishment of more vasectomy reversal centers are required to help solve this problem. The alternative is to develop vas occlusion methods that are highly reversible without having to use high-cost and very sophisticated surgical procedures for restoring continuity or patency of the vas deferens.

The vas obliteration by polyurethane elastomer plugs, as already mentioned above, seems to provide some hope in this regard. Zhao Sheng-cai of Shanxi Provincial People's Hospital in China has extensive experience in this method. Among his 12000 vasal sterilization clients, Zhao had removed the plugs from 86 men who had the polyurethane elastomer injected into the vas for 3 months to 4 years. These 86 men were grouped according to the duration of time after the plugs were removed. Group 1 consisted of 31 men whose plugs were removed for a duration of over 1 year. In this group, all 31 men were capable of impregnating their wives, a 100% pregnancy rate.

In group 2, 55 men had their plugs removed for 1-12 months. Pregnancy had occurred in the wives of 20 men, a 36% pregnancy rate. However, more pregnancies may be expected from wives of the rest of the 35 men in this

Table 4 The recovery of sperm in the ejaculates of two groups of men from whom the polyurethane plugs have been removed for more than and less than 1 year and occurrence of pregnancy in their partners

Group	n	Duration (years)		Sperm concentration (million/cm ³)			Pregnancy	
		Occlusion	Removal	5	5-20	20-100	no.	%
1	31	2-4	1-2		6	25	31	100
2	55	3/12-1	1/12-1	11	26		20	36

Source: Zhao Sheng-cai, Shanxi Provincial People's Hospital, Taiyuan, People's Republic of China (with permission)