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ORIGINAL ARTICLE

Operational Andrology

A randomized, controlled, multicenter contraceptive efficacy clinical trial of the intravas device, a nonocclusive surgical male sterilization

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Because of unavoidable complications of vasectomy, this study was undertaken to assess the efficacy and safety of male sterilization with a nonobstructive intravas device (IVD) implanted into the vas lumen by a mini-surgical method compared with no-scalpel vasectomy (NSV). IVDs were categorized into two types: IVD-B has a tail used for fixing to the vas deferens (fixed wing) whereas IVD-A does not. A multicenter prospective randomized controlled clinical trial was conducted in China. The study was comprised of 1459 male volunteers seeking vasectomy who were randomly assigned to the IVD-A (*n* = 487), IVD-B (*n* = 485) or NSV (*n* = 487) groups and underwent operation. Follow-up included visits at the 3rd–6th and 12th postoperative months. The assessments of the subjects involved regular physical examinations (including general and andrological examinations) and semen analysis. The subjects' partners also underwent monitoring for pregnancy by monthly interviews regarding menstruation and if necessary, urine tests. There were no significant differences in pregnancy rates (0.65% for IVD-A, 0 for IVD-B and 0.21% for NSV) among the three groups (*P* > 0.05). The cumulative rates of complications at the 12th postoperative month were zero, 0.9% and 1.7% in the three groups, respectively. In conclusion, IVD male sterilization exhibits a low risk of long-term adverse events and was found to be effective as a male sterilization method, similar to the NSV technique. IVD male sterilization is expected to be a novel contraceptive method.

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Keywords: complication; male sterilization; nonobstructive intravas device; no-scalpel vasectomy

INTRODUCTION

Vasectomy is the major male contraceptive method at present, and more than 40 million men have received this operation as a method of male sterilization worldwide.[1–5] A few users are reported to endure some unavoidable complications, including bleeding, infection, congestive epididymitis and granuloma, which are believed to be caused by acute and complete vas blockage.[6] Severe complications may cause difficulty in the case of recanalization and return of fertility and could impact quality of life.

Unlike NSV's complete occlusion of the vas, intravas devices (IVDs) are designed to act as contraceptives by blocking sperm or killing and injuring sperm. Additionally, the vas deferens is not completely blocked by these devices, thereby reducing the complication rate while preserving contraceptive efficacy.

Early generations of IVD-based male sterilization used polypropylene or polytef as the shell of the IVD, the inside of which was filled with medical nylon threads, as reported by our research group.[7,8] Subsequently, small-scale clinical trials were conducted and have exhibited good safety and efficacy.[9] However, polypropylene and polytef are not ideal as implants in the vas lumen for extended periods. In addition, the material was too difficult to shape and easily caused perforation of the IVD in a few of the volunteers. Furthermore, as the exterior wall of the IVD was so smooth, it was hard to fix the device in the vas lumen.

A new generation of polyurethane IVDs was developed by our research group without the shortcomings described above. The IVD insertion procedure is simple and can be mastered easily. The IVD is designed for easy removal to restore the full luminal patency of the vas. Because the continuity of the vas is preserved during the operation, no complicated microsurgical anastomosis is needed. The animal experiments[10] were completed in previous study. Simply removing the device should restore fertility. We conducted studies to assess the efficacy, safety and reversibility of IVD sterilization in rabbits compared with vasectomy. IVD removal requires approximately half of the operating time of that required for vas anastomosis. Trauma in the reversal operations was lighter in the IVD group than in vasectomy group. The patency rate of the vas lumen achieved in reversal operations was higher in IVD removal than in vas anastomosis (unpublished).

A randomized, controlled clinical trial was performed to compare the contraceptive efficacy and safety of the new IVD with NSV as a control group.

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MATERIALS AND METHODS

The IVD

The shell of the IVD was composed of polyurethane and barium sulfate, the interior of the IVD was filled with 2.5 mg of 9/0 medical grade nylon thread and nothing was placed in its tail. The IVD was 1 mm in outer diameter, 0.6 mm in inner diameter and 17 mm in length. IVDs were categorized into two types: IVD-B has a tail used for fixing the device to the vas deferens (fixed wing), whereas IVD-A does not (**Figure 1**). The device was patented in China in 2003.

Subjects

The inclusion criteria for volunteers were as follows: aged 24–45 years and having fathered at least one healthy child without contraindications for male sterilization. It was vital to ensure that the volunteers and their partners exhibited normal reproductive potential before the procedure and maintained a stable relationship during the study. The subjects were sexually active. They were with the partner with whom they had fathered a child. All subjects had normal medical histories, physical examinations and laboratory test results, including hematology, urinalysis and semen analysis. All subjects demonstrated normal reproductive function, as evidenced by a basal sperm concentration greater than 2×10^7 ml^{-1}, sperm motility greater than 50% (grades a + b), morphology (normal form) greater than 30%, having fathered at least one healthy child, and testicular volume more than 12 ml for each side. The current study was approved by the Ethics Committee of the National Research Institute for Family Planning, China. Informed consent was obtained from all volunteers upon admission to the trial.

Grouping and follow-up

This was a prospective, open-label, randomized and controlled multicenter clinical trial. A total of 1464 men ($\alpha = 0.05$, 85% power) seeking vasectomy were enrolled in Putian city, Fujian Province, Qingxin County, Guangdong Province, Weishi County and Xiayi County, Henan Province, China, according to the entry criteria and were randomly assigned to the IVD-A, IVD-B or NSV group (488 men per group). The random allocation sequence was generated according to a computer-generated random number list. The random allocation sequences were closed in opaque and sealed envelopes, concealing the sequence until the interventions were assigned. The technicians performing the sperm counts were blinded to the procedure. The evaluating physicians were asked not to palpate the vas when assessing congestive epididymitis to blind them to the technique used.

To ensure an unbiased evaluation of the outcomes, the standard operation procedures were followed, and the training course was undertaken, including the screening of subjects, operation of IVD and follow-up for the investigators and doctors.

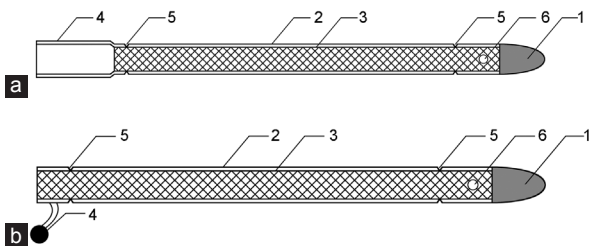

Figure 1: Schematic diagram of the intravas device (IVD). (**a**) IVD-A: 1, substantial head; 2, shell; 3, medical-grade nylon thread; 4, dilated tail; 5, sulcus; 6, hole. (**b**) IVD-B: 1, substantial head; 2, shell; 3, medical-grade nylon thread; 4, tail (fixed wing); 5, sulcus; 6, hole.

Volunteers were instructed to abstain from ejaculation for 2 weeks post-operation. Condoms were used for 3 months to avoid pregnancy caused by residual sperm in the distal reproductive tract, and then volunteers entered the exposure period without any additional intervention except for the IVD or NSV contraception.

Follow-up included visits at the 3rd–6th and 12th months post-operation. The assessments of the subjects involved regular physical examinations (including general and andrological examinations) and semen analysis. A post-vasectomy sperm count to document azoospermia was performed for the first time at the 3rd postoperative month. The partners also underwent monitoring for pregnancy by monthly interviews regarding menstruation and if necessary, urine pregnancy tests. Semen analysis was performed according to the World Health Organization (WHO) Laboratory Manual (1999).[11]

The pregnancy rate was the primary outcome of contraceptive efficacy. Sperm concentration was a reliable indicator of the filtration effect of the IVD.

Complications were diagnosed according to the diagnostic criteria for Complications of Contraceptive Operations issued by Ministry of Health and the National Population and Family Planning Commission of the People's Republic of China (1989).

Insertion of IVD

The insertion of the IVD into the vas lumen was conducted with the sharp hemostat and ringed forceps used in the NSV.[12] One vas was fixed subcutaneously by hand at the midline of the scrotum and at a level of approximately 15–20 mm above the upper pole of the testis. Next, 1% lidocaine was injected through the skin into the vasal sheath. The sharp hemostat was used to pierce the skin and spread the wound to expose the vas. Ringed forceps were used to isolate and extract the vas. The sheath was fully incised using the sharp hemostat to expose a mobile vasal section of 2 cm. With a scalpel, a longitudinal incision (approximately 1 mm in length) was made in the vasal wall, through which the IVD was inserted completely into the distal lumen. The inserted IVD was then fixed with 1-0 nylon suture around the vas at the sulcus positions (position 5, **Figure 1**). Before repositioning the vas, gentle compression was applied to the vasal incision for several seconds to close it, rather than suturing. These procedures were repeated for the contralateral vas through the same scrotal wound.

NSV

The NSV procedure was conducted as recommended by the Chinese Medical Association and WHO.[13,14]

Data analysis

Data processing included double input of the data in the programmed data bank. 'Double input' means that two individuals input data into two computers (the programmed data bank) separately. All analyses were performed with the Statistical Package for Social Sciences software (V11.0, SPSS, Inc., Chicago, IL, USA). Qualitative and quantitative data were tested using the Chi-square test and one-way analysis of variance (ANOVA), respectively. A value of $P < 0.05$ was considered statistically significant.

RESULTS

Allocation and follow-up

There were 487 (IVD-A), 485 (IVD-B) and 487 (NSV) male volunteers who received either IVD-A, IVD-B or NSV operation, respectively. The follow-up rates in the three groups were all greater than 92% (**Table 1**),

which fulfilled the needs of the project design. Some of the volunteers were followed up at the 12–month post-vasectomy timepoint, but not at the 3–6-month post-vasectomy timepoint. Consequently, the follow-up rate at 12-months post-vasectomy was higher than that at 3–6-months post-vasectomy.

Demographic information and semen analysis for the three groups of subjects

The demographic information and semen analysis for the three groups of subjects is presented in **Table 2**.

Surgery

There were no significant differences regarding the mean operating time between the IVD-A and IVD-B groups **(Table 3),** but both of these groups took more time than the NSV group ($P < 0.05$). There were no significant differences in the methodological failure rates among the three groups ($P < 0.05$).

Pregnancy rates

Twelve pregnancies (four in the IVD-A group, five in the IVD-B and three in the NSV group) occurred within 3 months postoperatively because of noncompliance with the instructions of using condoms, with the exception of one pregnancy that occurred before the operation; these data were excluded from the efficacy analysis. Semen analyses for these 11 men were available when the pregnancies were diagnosed and indicated sperm counts ranging from 0.6 to 4.9 × 10^7 ml^{-1} for the four subjects in the IVD-A group, from 0.3 to 2.5 × 10^7 ml^{-1} for the five subjects in the IVD-B group and from 0.3 to 4.6 × 10^7 ml^{-1} for the three subjects in the NSV group. Twelve pregnancies were user failures but not method failures. No additional pregnancies occurred during the exposure period.

Pregnancy rates within 12 months post-operation are presented in **Table 4**. There were no significant differences in the pregnancy rates ($P > 0.05$) among the three groups.

Table 1: Number of volunteers undergoing operation at the four centers and the follow-up rate

Group	*n*	*Clinic follow-up rate % (n)*		*Semen analysis rate % (n)*	
		3–6 month	*12 month*	*3–6 month*	*12 month*
IVD–A	487	95.28 (464)	93.84 (457)	92.40 (450)	92.20 (449)
IVD–B	485	95.67 (464)	92.16 (447)	92.99 (451)	92.37 (448)
NSV	487	94.25 (459)	97.13 (473)	92.81 (452)	97.13 (473)
Total	1459	95.07 (1388)	94.38 (1378)	92.74 (1354)	93.90 (1371)

IVD: intravas device; NSV: no-scalpel vasectomy

Sperm concentration and sperm motility

There were significant differences in the azoospermic rates between the IVD-A and the NSV groups, as well as the IVD-B and NSV groups in the 3rd–6th and 12th month post-operation **(Table 5).** Most of the patients who had sperm in their semen exhibited oligoasthenozoospermia to different degrees. There were significant differences in the percentage of subjects with sperm concentrations above 2 × 10^7 ml^{-1} among the three groups.

The percentages of sperm without progressive motility for IVD-A, IVD-B and NSV were 32.96% (59/179), 35.20% (69/196) and 60.66% (37/61), repsectively in those subjects who had sperm in their semen at the 3rd–6th month post-operation for the three groups **(Table 6).** There were 49 cases, 36 and 6 cases in the IVD-A, IVD-B and NSV groups, respectively, with progressive sperm in the 12th month post-operation, including one subject from the NSV group who was diagnosed with spontaneous recanalization.

General conditions

The differences in the total testis volume and body weight among the pre-operation, 3rd–6th and 12th month post-operation timepoints, as well as among the three groups, were not significant.

Complication

No serious adverse events or hospitalizations related to male sterilization occurred during the study period. No subjects withdrew from the study due to complications. No serious incision bleeding or hematomas were identified, and no incision or urogenital tract infections were observed. Most of the complications were slight and recovered spontaneously or with simple nonsurgical treatments.

Short-term complications such as bleeding and infection are presented in **Table 7**. There was no significant difference among the groups ($P > 0.05$). The long-term complication (granuloma and congestive epididymitis) rate of the NSV group was higher than that of the IVD group ($P < 0.05$).

DISCUSSION

The new type of IVD is characterized by easy insertion into the vas lumen, and the marker line on the surface of the IVD used for suture, ligation and fixation can be observed clearly through the vas wall. The size of the IVD is suitable for most Chinese men. Only experienced doctors can find the IVD by palpation. The daily life and sex activity of the subjects were not influenced by IVD male sterilization. The location of the IVD in the vas lumen can be easily confirmed by ultrasonic examination for monitoring post-operation.

Table 2: Demographic information for the three groups of subjects

	IVD-A	*IVD-B*	*NSV*	*P value*
Age (year)[a]	31.0 (30.6–31.3)	30.8 (30.5–31.1)	30.9 (30.5–31.2)	>0.05
Occupation				>0.05
Worker	37 (7.60)	20 (4.12)	19 (3.90)	
Peasant	432 (88.71)	445 (91.75)	458 (94.05)	
Soldier	0 (0)	1 (0.21)	0 (0)	
Businessman	4 (0.82)	8 (1.65)	2 (0.41)	
Cadre	5 (1.03)	5 (0.82)	1 (0.21)	
Intelligentsia	3 (0.62)	3 (0.62)	4 (0.82)	
Other	6 (1.23)	4 (0.82)	3 (0.62)	
Number of children[a]	2.1 (2.0–2.1)	2.1 (2.0-2.1)	2.1 (2.0-2.1)	>0.05
Sperm concentration (×10^6 ml^{-1})[a]	56.9 (54.1–59.6)	60.3 (57.3-63.2)	56.1 (53.4-58.7)	>0.05
a+b motility (%)[a]	56.73 (55.58, 57.88)	57.13 (56.09, 58.18)	55.18 (54.72, 57.00)	>0.05

IVD: intravas device; NSV: no-scalpel vasectomy. [a]Numbers in parentheses represent the 95% confidence interval

Before the project, the doctors undertook training courses on the IVD insertion operations. The key steps include complete opening of the sheath to ensure the extrusion of the vas, precise incision into the vas lumen and firm fixation of the device. The operations were all performed by experienced surgeons. All surgeons were previously proficient in the NSV operation.

The technique for IVD male sterilization is simple and easy to learn, and the methodological failure rates were low. The longer operative time course ($P < 0.001$) for IVD male sterilization was due to the additional procedures during the IVD insertion.

According to results from our animal experiment (unpublished data), most of the sperm were blocked and deposited in the proximal end of the IVD after IVD male sterilization, and only the epididymal fluid and a small number of sperm that had lost their motility and exhibited abnormal morphology passed through the IVD. Therefore, we believe that the mechanism of contraceptive efficacy caused by IVD male sterilization is due in part to the destruction of sperm motility and fertilization capacity following the injury of sperm morphology and function.

The pregnancy rate was the primary endpoint for assessment of the contraception efficacy in this study. The pregnancy rates in the IVD group were not higher than those of the NSV group ($P > 0.05$).

Table 3: Mean operating time and the methodological failure rates

Group	*Operating time (min)*	*Technical failure rate, % (n)*
IVD-A	12.53±2.59	0.20 (1)
IVD-B	12.38±2.65	0.41 (2)
NSV	9.80±3.59	0 (0)
P value	<0.05	>0.05

IVD: intravas device; NSV: no-scalpel vasectomy

Table 4: Pregnancy rates

Group	*3 month (n)*	*12 month (n)*	*Cumulative rate, % (n)*
IVD-A	4	3	0.65% (3/457)
IVD-B	5	0	0.00% (0/487)
NSV	3	1	0.21% (1/473)
Total	12	4	*P*>0.05

IVD: intravas device; NSV: no-scalpel vasectomy

Although a few motile sperm existed in the ejaculation post-operation in some subjects of the IVD group, pregnancies were not found in their spouses, which are speculated to be due to dysfunction of fertilization capacity for those motile sperm.

Twelve pregnancies due to residual sperm in the distal reproductive tract were diagnosed within 3 months in the three groups postoperatively because of failure to following instructions to use barrier contraceptive methods. This result highlights the importance of using temporary contraception during the early stages of either IVD or NSV contraception. There was a 0.65% pregnancy rate in the IVD-A group within 12 months postoperatively. The possibilities for contraception failure in the IVD-A group were explained as follows: motile sperm in epididymal liquid that were transported through IVD and passage of some motile sperm through the interspaces between the device and the wall of vas deferens because of unfirm ligation and fixation. The possibility of the existence of unilateral double vas deferens in subjects could not be excluded. There were no pregnancies in the IVD-B group within 12 months postoperatively, which may be attributed to the superiority of the IVD-B with fixed wing. One pregnancy case from the NSV group was due to recanalization.

The azoospermic rates at 3rd–6th and 12th month post-operation both in groups IVD-A and IVD-B were lower than those in the NSV group in this study because of the different contraceptive mechanisms. Most of those who exhibited sperm in the semen were oligoasthenozoospermic to different degrees due to dysfunction of sperm motility and fertilization capacity. In addition, the proportion of motile sperm at 3rd–6th and 12th month post-operation in the IVD-A and IVD-B groups was higher than that in the NSV group, which is different from the results from the early small-sample study due to the difference in the sample size.[15] We also observed that epididymal liquid and a few spermatozoa were transported through the device at 12 months post-operation due to the slow blocking process of IVD.

It has been reported that the long-term complications of conventional vasectomy are partly attributable to acute and complete obstruction of the vas lumen,[16] which leads to sharply increased intraluminal pressure, dilated lumen and sperm extravasations and subsequently to congestive epididymitis, granuloma, spontaneous recanalization and antisperm antibody reactions.[6] In the present study, long-term complications such as congestive epididymitis and granuloma

Table 5: Sperm concentration at the 3rd–6th and 12th month post operation

Group	*3-6 month, % (n)*					*12 month, % (n)*				
	Follow-up (n)	*0*	*>0 to <5 × 10⁶ ml⁻¹*	*5-20×10⁶ ml⁻¹*	*≥20×10⁶ ml⁻¹*	*Follow-up (n)*	*0*	*>0 to <5 × 10⁶ ml⁻¹*	*5–20×10⁶ ml⁻¹*	*≥20×10⁶ ml⁻¹*
IVD-A	450	60.22 (271)	14.89 (67)	16.44 (74)	8.44 (38)	449	79.96 (359)	4.45 (20)	8.46 (38)	7.13 (32)
IVD-B	451	56.54 (255)	13.75 (62)	20.84 (94)	8.87 (40)	448	84.15 (377)	5.13 (23)	7.59 (34)	3.13 (14)
NSV	452	86.50 (391)	6.64 (30)	2.88 (13)	3.98 (18)	473	95.98 (454)	1.90 (9)	0.85 (4)	1.27 (6)
P value		<0.05	<0.05	<0.05	<0.05		<0.05	<0.05	<0.05	<0.05

IVD: intravas device; NSV: no-scalpel vasectomy

Table 6: Motility rates at 3rd–6th and 12th month post operation

Group	*3-6 month, % (n)*					*12 month, % (n)*				
	With sperm (n)	*0*	*>0 to <10%*	*10 to <50%*	*≥50%*	*With sperm (n)*	*0*	*>0 to <10%*	*10 to <50%*	*≥50%*
IVD-A	179	32.96 (59)	7.82 (14)	53.63 (96)	5.59 (10)	90	45.56 (41)	4.44 (4)	43.33 (39)	6.67 (6)
IVD-B	196	35.20 (69)	9.69 (19)	50.51 (99)	4.59 (9)	71	50.70 (36)	4.23 (3)	40.85 (29)	4.23 (3)
NSV	61	60.66 (37)	3.28 (2)	27.87 (17)	8.20 (5)	19	68.42 (13)	5.26 (1)	26.32 (5)	0
P value		<0.05	<0.05	<0.05	>0.05		>0.05	>0.05	<0.05	<0.05

IVD: intravas device; NSV: no-scalpel vasectomy

Table 7: Cumulative rate of complications

Group	*Short-term complication % (n)*			*Long-term complication % (n)*		
	Bleeding	*Infection*	*Cumulative rates*	*Granuloma*	*Congestive epididymitis*	*Cumulative rates*
IVD-A	0.21 (1)	0.43 (2)	0.64 (3)	0	0	0
IVD-B	0.00	0.43 (2)	0.43 (2)	0.67 (3)	0.22 (1)	0.89 (4)
NSV	0.00	0.00	0.00	0.64 (3)	1.06 (5)	1.70 (8)
P value			>0.05			<0.05

IVD: intravas device; NSV: no-scalpel vasectomy

were significantly less common in the IVD group than in the NSV group. Moreover, our previous animal experimental study also indicated that lesions in the testis and epididymis after IVD male sterilization were less serious.[10] Therefore, the most likely explanation for the differences in the long-term complication rates is that the IVD prevented the intraluminal pressure from sharply rising by filtering the epididymal fluid.

In conclusion, IVD male sterilization provides good contraceptive efficacy with fewer complications, despite the slightly increased operative time. Furthermore, IVD male sterilization is advantageous due to its low cost and simple surgical procedures, which will facilitate its popularization for clients in clinics, although further follow-up is needed to observe the long-term contraceptive efficacy.

AUTHOR CONTRIBUTIONS

WHL carried out semen analysis and data analysis. XWL carried out semen analysis. YQG, WXW, LWB and TGZ carried out assessing the subjects involved regular physical examinations (including general and andrological examinations) and the IVD and NSV operation. ZWC carried out the training including the screening of subjects, operation of IVD, and follow-up for the investigators and doctors.

COMPETING INTERESTS

All authors declare no competing interests.

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