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A COMPARATIVE STUDY OF THE NO SCALPEL AND STANDARD INCISION APPROACHES TO VASECTOMY IN 5 COUNTRIES

DAVID SOKAL,* SUSAN MCMULLEN, DEB GATES, ROSALIE DOMINIK AND THE MALE STERILIZATION INVESTIGATOR TEAM†

From the Family Health International and Clinical Trials Support Services, Research Triangle Park, North Carolina

ABSTRACT

Purpose: We compare the safety, ease of use and effectiveness of the no scalpel and standard incision approaches to vasectomy.

Materials and Methods: A multicenter, randomized, partially masked controlled trial was conducted at 8 sites in Brazil, Guatemala, Indonesia, Sri Lanka and Thailand. Semen samples were collected 10 weeks postoperatively and tested to ascertain sterility using verification of no living spermatozoa.

Results: The study included 1,429 men seeking vasectomy. The efficacy of the 2 approaches was virtually identical. In the no scalpel group operating time was significantly shorter, and complications and pain were less frequent than in the standard incision group. The no scalpel group resumed intercourse sooner, probably as a result of less pain following the procedure.

Conclusions: The no scalpel approach is an important advance in the surgical approach to vasectomy, and offers fewer side effects and greater comfort compared to the standard incision technique, without compromising efficacy.

KEY WORDS: vasectomy; sterilization, sexual; methods; treatment outcome

Vasectomy is among the safest and most reliable methods of contraception but has a number of drawbacks, including the side effects associated with surgery as well as the delay between surgery and onset of sterility. In 1974 a new surgical approach to isolating the vas for vasectomy that eliminated use of the scalpel was introduced in China, reportedly resulting in a smaller wound and fewer hematomas than the standard procedure.[1,2] Use of the no scalpel technique has spread from China to developed countries. In Thailand Nirapathpongporn et al demonstrated that the no scalpel approach took less time to perform and had a lower complication rate than the standard incision approach but the study was only partially randomized.[3] A comparative study by Holt and Higgins in the United Kingdom reached the same conclusions but used historical controls.[4] Training programs in the no scalpel vasectomy technique have been conducted for physicians working in public sector clinics in the United States.[5] A 1995 survey of United States physicians revealed use of the no scalpel approach for nearly a third (29%) of vasectomies.[6] To our knowledge our study is the first to compare the no scalpel and standard incision approaches in a randomized controlled trial.

MATERIALS AND METHODS

Study design. A prospective, partially blinded, parallel group, randomized multicenter clinical trial was performed to evaluate the safety, ease of use and effectiveness of the no scalpel and standard incision approaches to vasectomy. A total of 1,429 men were admitted to the trial and assigned to the no scalpel or standard incision group. Evaluators were blinded to the surgical procedure. The trial was conducted at 8 sites in Brazil, Guatemala, Indonesia, Sri Lanka and Thailand between March 1988 and August 1991. Before initiation the study protocol was approved by the Family Health International Protection of Human Subjects Committee and the local institutional review board in each country when available. To ensure an unbiased evaluation of the outcomes a surgeon and an evaluator blinded to the approach at each center performed the trial. The surgeon admitted participants into the study and performed surgery, and the evaluator was responsible for followup care from the time of discharge from the operating room until the last followup contact.

Study population. Men in good health who had requested vasectomy were invited to volunteer. Informed consent was obtained from each participant before enrollment. A medical history was obtained and a physical examination was performed. Study participants had to meet local clinic eligibility requirements for vasectomy, be 21 years old or older, and in good physical and mental health, and have a normal physical examination. Exclusions criteria were a history of excessive pain or swelling, abnormality or congenital anomaly and previous injury to or operation on the scrotum or testes, including any previous sterilization. In Brazil participants had to be 30 to 40 years old, and have 2 or more living children, at least an eighth grade education and a minimum monthly income of 6 times the Brazilian minimum wage (approximately $360 per month). Participants at the site in Sri Lanka had to have 2 or more living children.

Study procedures. While experience using the no scalpel and standard incision approaches varied among surgeons, all were experienced with the latter before this study. Of the surgeons 3 had considerable experience with the no scalpel vasectomy approach (Brazil, Sri Lanka, Thailand) and 5 had relatively little experience (Indonesia, Guatemala). Surgeons from Indonesia and Guatemala underwent training in the no scalpel technique before the study. The usual surgical proce-

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* Requests for reprints: Family Health International, P. O. Box 13950, Research Triangle Park, North Carolina, 27709.
†Marcos de Castro, PROPATER, Brazil; Roberto Santiso, APROFAM, Guatemala; H. Azrul Azwar, PKMI, Indonesia; A. M. L. Beligaswatte, AVSC International, Sri Lanka, and Apichart Nirapathpongporn, Population and Community Development Association, Thailand.

dures for the standard incision approach were used at each site. A double vertical incision was used in Guatemala and Semarang, Indonesia, and at all other centers a single vertical incision was used. It is noteworthy that the single vertical incision technique is a modification of the standard incision procedure which was introduced following the introduction of the no scalpel technique. For both procedures the surgeon excised a small segment of the vas and ligated both ends of the cut vas.

Participants were asked to return between 3 and 15 days postoperatively to gather data on postoperative complications, and 10 weeks postoperatively for semen analysis. No live spermatozoa was considered proof of sterility. Participants were encouraged to return whenever they had a problem related to surgery and until the semen test results showed no live spermatozoa or sterilization was declared a failure. Failures were determined at surgeon discretion and criteria were not standardized among centers. Contacts during the first 15 days after sterilization were considered early and those after 15 days were considered long-term followup.

Statistical methods. Results are presented for the analysis population, which included all participants who underwent vasectomy even if they did not undergo the assigned method. Participants with protocol violations, random allocation errors or technical failures are included in this primary analysis population. Men who underwent a different approach from that assigned due to intraoperative obstacles were considered to have technical failure. Efficacy analyses were repeated after excluding data for participants with protocol violations, random allocation errors or technical failures. All analyses were performed based on surgical approach. For all tests of differences between treatment groups $p \leqq 0.05$ was considered statistically significant. Center by treatment group interaction was tested at the 0.10 significance level. Differences in the operating time (available only as an ordered categorical variable) between treatment groups were tested using the mean score chi-square test.[7] Sterility status at the last followup visit was the main efficacy outcome of interest. The exact counterpart of the Mantel-Haenszel test was used.[8,9] Consistency of the odds ratios across centers was tested using Zelen's exact homogeneity test.[10]

Differences between the treatment groups in the number of participants with specific types of surgical difficulties, surgical injuries and complications during early followup, any complication during long-term followup and any hospitalization during followup were tested using Fisher's exact test. The mean score chi-square test was used to test for differences in degree of pain during surgery and degree of scrotal pain at early followup between the 2 groups. Kaplan-Meier estimates of the survival distributions for days to resumption of intercourse were calculated and compared using the log rank test.[11] This outcome was only assessed at early followup visits. Participants who reported at early followup that they had not yet had sexual intercourse were censored from the analysis on the date of the visit. The difference in the degree of satisfaction with vasectomy was tested using the mean score chi-square test. Differences in the number of men who would recommend vasectomy to a friend were analyzed using Fisher's exact test.

RESULTS

Of the 1,429 men admitted to the study 715 were randomized to the no scalpel and 714 to the standard incision group (fig. 1). Various errors resulted in 705 men undergoing the no scalpel and 723 undergoing the standard incision procedure. Figure 2 shows the disposition of men during the study. All procedures were performed by a urologist (79%) or general surgeon (21%). Operating time was shorter for the no scalpel group ($p < 0.01$). The majority of the procedures took 6 minutes or less in 59.9% of no scalpel and 7 or more in 61.7% of

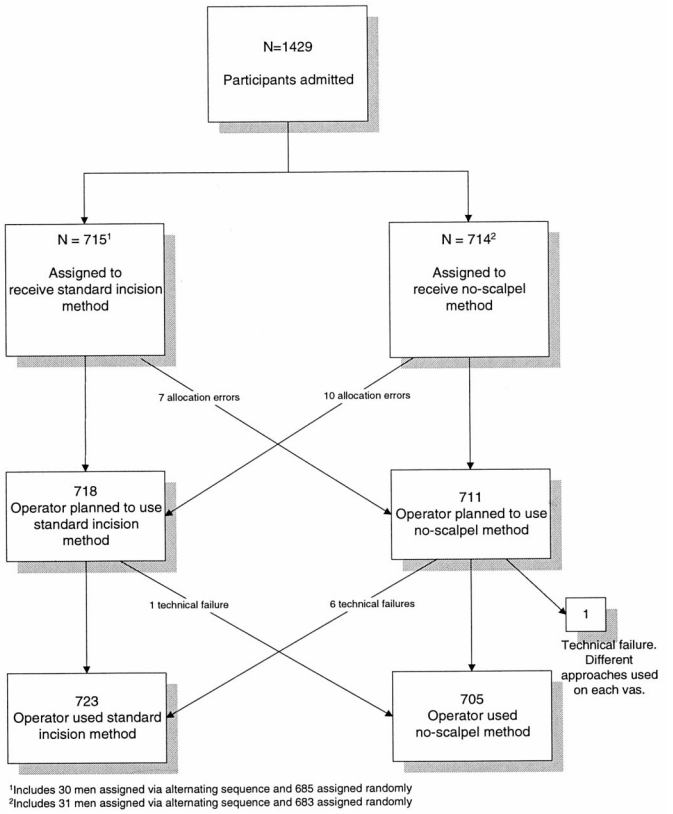

FIG. 1. Determination of primary analysis population

standard incision cases. Only 13.9% of no scalpel procedures took 11 minutes or more, compared to 22.6% of standard incision procedures. The vasal occlusion technique was ligation in 99.8% of no scalpel and 99.6% of standard incision procedures. Excision of the vas segment was completed for most participants in both groups (99.7% no scalpel and 99.9% standard incision). Ligation of both ends of the vas was performed in 99.7% of both groups. Sutures were used for wound closure in 2.2% of no scalpel and 28.9% of standard incision procedures.

Followup and disposition of cases. The numbers of men with early and/or late followup visits and final status, that is success or failure, are shown in figure 2. At least 1 clinic or home visit for an early followup was performed in 547 no scalpel (77.6%) and 549 standard incision (75.9%) cases. During long-term followup 635 no scalpel (90.1%) and 662 standard incision (91.6%) cases had at least 1 followup contact. Long-term followup ranged from 16 to 511 days for the no scalpel and 16 to 498 days for the standard incision group. Semen analyses were available for 608 no scalpel and 631 standard incision cases.

Efficacy and power analyses. Sterility status at last followup visit is presented in table 1. The effectiveness of the 2 techniques was virtually identical. Of the 40 cases not declared sterile as of the last semen test result (ranging from 70 to 406 days after sterilization) 11 no scalpel and 10 standard incision were considered vasectomy failure (1.8 and 1.6%, respectively). No declaration of vasectomy failure or sterilization was made in 8 no scalpel and 11 standard incision cases by the end of the study. Although the proportion of men declared sterile varied across centers, there was no evidence of any surgical procedure group by center interaction (Zelen's homogeneity test $p = 0.55$). Nearly identical results were obtained after excluding 108 subjects with protocol violations, random allocation errors or technical failures who also had semen test data from this analysis. Assuming that the true success rate for the standard incision group was 96.8%

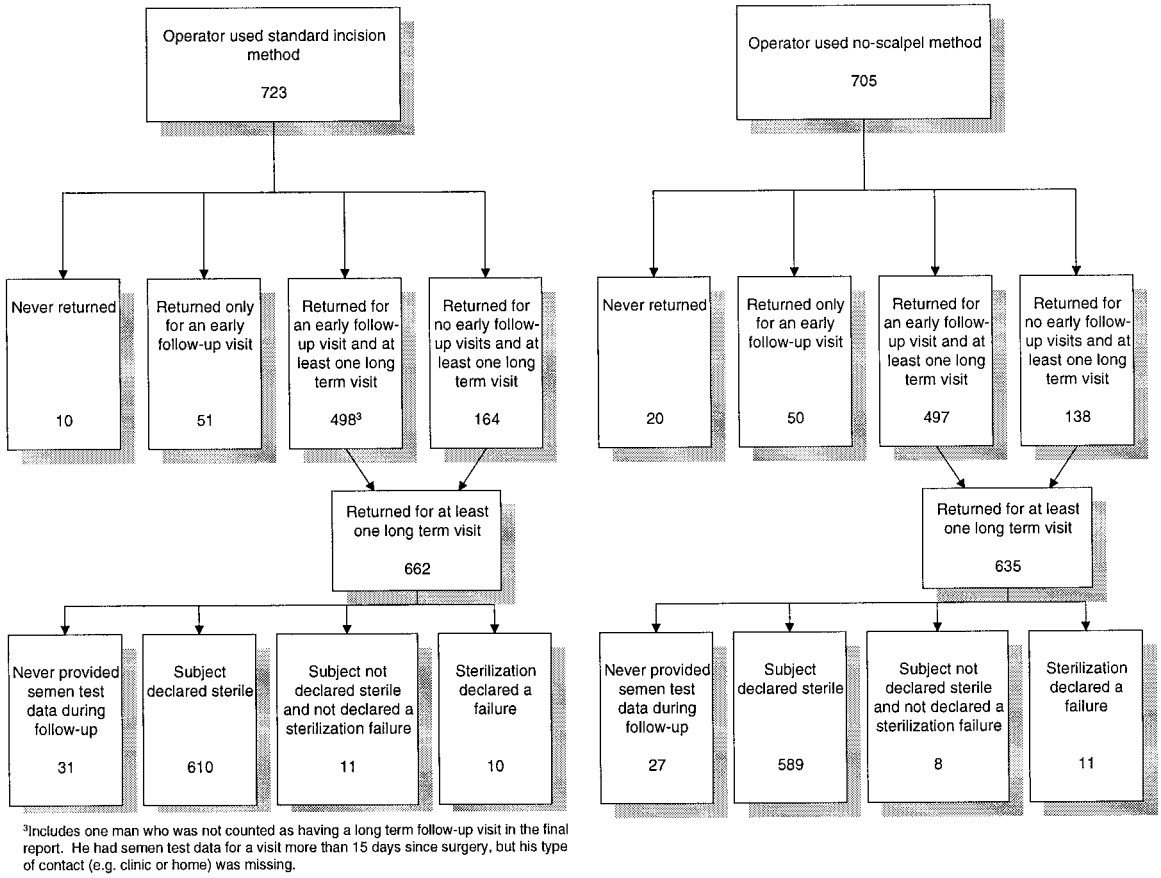

FIG. 2. Disposition of participants

TABLE 1. *Sterility status at latest visit at which a semen test was performed*

	No. No Scalpel (%)	No. Standard Incision (%)
Sterile (p = 0.76*)	589 (96.9)	610 (96.7)
Not declared sterile†	19 (3.1)	21 (3.3)
Totals	608	631

* Calculated using exact Mantel-Haenszel test, controlling for center.
† Of these patients 11 in the no scalpel and 10 in the standard incision group had vasectomy failure (1.8 and 1.6%, respectively).

(based on that observed in our study), this study had approximately 65% power to detect a 3% difference in success rates between the 2 groups (2-sided test $\alpha = 0.05$).[12]

Safety analyses. Surgical Difficulties: Almost identical proportions of the 2 groups (no scalpel 11.4% and standard incision 11.2%) had surgical difficulties. However, difficulty isolating the vas, short scrotum/thin deferens and adhesions were more common in the no scalpel group. Difficulty isolating the vas was reported in 57 no scalpel (8.1%) and 33 standard incision (4.6%) cases ($p < 0.05$). However, of these 90 cases 64 (71%) were reported by 1 surgeon. Short scrotum/thin deferens was reported in 25 no scalpel (3.6%) and 13 standard incision (1.8%) cases ($p < 0.05$), and adhesions were reported in 19 (2.7%) and 7 (1.0%), respectively ($p < 0.05$). Bleeding was more common with the standard incision (31 cases, 4.3%) than with the no scalpel (15, 2.1%) approach ($p < 0.05$). Equipment difficulties were noted for 12 standard incision (1.7%) and 3 no scalpel (0.4%) cases ($p < 0.05$). No statistically significant differences were observed between the 2 treatment groups for percent with difficulty entering the scrotum, closing the incision, occluding the vas, difficulties due to fatty, adipose or fibrous tissue, chronic infection, pain or patient restlessness ($p > 0.05$).

Pain During Surgery: Intensity of pain during surgery varied significantly by treatment group ($p < 0.05$). While 4.8% of both groups reported moderate or severe pain, the no scalpel group reported no pain more often and mild pain less frequently. No pain was reported by 66.8% of the no scalpel versus 60.2% of the standard incision group, and mild pain was reported by 28.4 and 35.0%, respectively.

Complications and Complaints After Discharge Home: Data on complications between discharge home and early followup (less than 15 days after vasectomy) were available for 547 no scalpel and 549 standard incision cases. No significant differences were observed in the number of participants reported to have congestive epididymitis, excessive bleeding/exudate, fever, sub-incisional induration, backache, discomfort in lower abdomen, unspecified infection or scrotal abscess. However, significant differences between treatment groups were observed for hematoma, intensity of scrotal pain and incision infection (table 2). The standard incision group was more likely to have a hematoma ($p < 0.01$), mild or moderate pain at early followup ($p < 0.01$) and incision infections ($p = 0.04$).

Hospitalizations and Resumption of Intercourse: Hospitalizations were reported for 5 men during early and 1 during long-term followup (3 in each group). Of the 6 hospitalizations 3 were clearly related to vasectomy procedures, including 2 scrotal hematomas that required drainage (1 in each group). The no scalpel group resumed intercourse sooner than the standard incision group ($p < 0.05$), that is 6 days after vasectomy 34% of the no scalpel had had intercourse versus only 22% of the standard incision group (fig. 3).

Long-Term Followup and Patient Satisfaction: Data on complications or complaints during long-term followup were available for 627 no scalpel and 649 standard incision cases. There were no complications or complaints for 94.7% of the

TABLE 2. *Hematoma, scrotal pain and incision infection during early followup*

	No. No Scalpel (%)	No. Standard Incision (%)
Hematoma (p <0.01 Fisher's exact*):		
None	537 (98.1)	482 (87.8)
Small/superficial	1 (0.2)	4 (0.7)
Small/deep	1 (0.2)	18 (3.3)
Large/deep	0 (0.0)	4 (0.7)
Size unspecified	8 (1.5)	41 (7.5)
Total	547 (100.0)	549 (100.0)
Scrotal pain (p <0.01 mean score chi-square):		
None	298 (54.7)	237 (43.3)
Mild	215 (39.5)	251 (45.8)
Moderate	28 (5.1)	51 (9.3)
Severe	4 (0.7)	9 (1.6)
Total	545 (100.0)	548 (100.0)
Incision infection (p = 0.04 Fisher's exact):		
Yes	1 (0.2)	8 (1.5)
No	546 (99.8)	541 (98.5)
Total	547 (100.0)	549 (100.0)

Includes visits 1 to 15 days after sterilization.
* Any versus none.

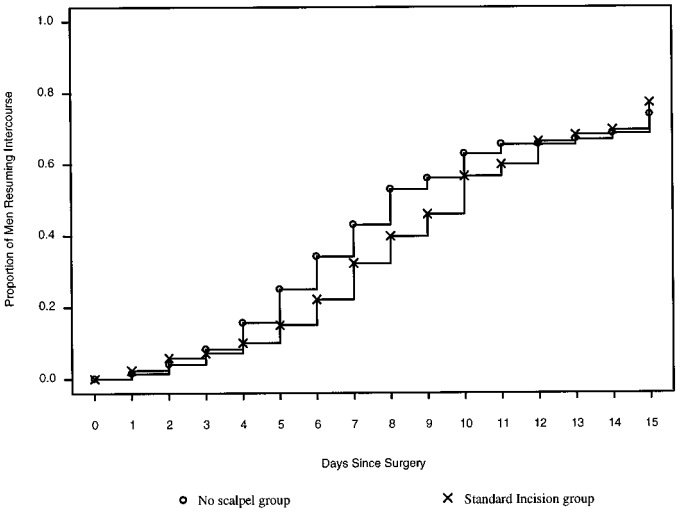

FIG. 3. Kaplan-Meier estimates of cumulative proportion of men resuming intercourse by approach.

no scalpel and 94.1% of the standard incision group. Pain/tenderness was the most common complaint in both groups, and was reported in 25 no scalpel (4.0%) and 33 standard incision (5.1%) cases. The difference in the proportion of participants with complications or complaints at long-term followup was not statistically significant (p = 0.24). No statistically significant differences between the 2 treatment groups were observed for satisfaction with vasectomy (p >0.05). Nearly 90% of the participants in both groups reported that they were satisfied or very satisfied.

DISCUSSION

While use of the no scalpel approach has become more widespread in recent years, to our knowledge this is the first randomized controlled trial that documents its advantages, which include less bleeding during surgery, shorter operating time, fewer hematomas, reduced pain during and after surgery, and more rapid resumption of sexual activity. No scalpel procedures were significantly shorter to perform than standard incision procedures. The shorter duration may have been partly due to the fact that only about 2% of wounds in the no scalpel group were closed with sutures compared to about 29% in the standard incision group.

Difficulties with bleeding during surgery were significantly less common among the no scalpel group (15 versus 31 cases), which is probably because the dissecting action of the no scalpel puncture technique is less likely to cut small subcutaneous blood vessels than an incision with a scalpel. Difficulty isolating the vas was significantly more frequent in the no scalpel group (57 versus 33 standard incision cases), which could be an indication of a potential problem for some surgeons. However, since 64 of these reports were from 1 surgeon, the problem is likely to be related to surgeon level of experience with the no scalpel method or to reporting bias.

There were significantly fewer hematomas during early followup in the no scalpel (1.8%, 10 cases) than in the standard incision (12.2%, 67) group, which is an 85% reduction in the frequency of hematomas. Since hematomas were responsible for 2 of the 3 hospitalizations related to the vasectomy procedure, this may be an important advantage. In the no scalpel group significantly less pain during surgery, and significantly fewer reports of scrotal pain and incision infection during the early followup period were noted. The no scalpel group was significantly more likely to resume intercourse sooner than the standard incision group, which may be related to the presence of less pain during and following the procedure.

The efficacy of vasectomy for the 2 approaches to isolating the vas was virtually identical. Vasectomy failure was noted in 10 patients (1.6%) in the no scalpel and 11 (1.8%) in the standard incision group of 631 and 608, respectively, who returned for semen testing. Many of the failures were attributed to recanalizations. While there were differences in failure rates between surgeons, those who had failures had similar numbers with the no scalpel and standard incision approaches. This study did not evaluate the effect of different occlusion techniques on success or failure of the procedure. A recent study in Mexico[13] and the diversity of techniques currently used in the United States[6] suggest that additional research is needed to evaluate the relative efficacy of different occlusion techniques.

CONCLUSIONS

The no scalpel approach offers significant advantages compared to the standard incision approach. Especially notable was the reduction in bleeding during surgery and the subsequent 85% reduction in the frequency of hematomas, an occasionally serious complication of vasectomy. Also, participants who underwent the no scalpel approach reported less pain during the procedure and at early followup, and resumed sexual intercourse sooner after surgery.

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