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THE PERCUTANEOUS ELECTROCOAGULATION  
VASECTOMY TECHNIQUE - A COMPARATIVE TRIAL  
WITH THE STANDARD INCISION TECHNIQUE  
AT MARIE STOPES HOUSE, LONDON

89-30

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ABSTRACT

One-hundred-and-one men requesting vasectomy in 1985 for the purpose of limiting family size were admitted to a study of standard incision and monopolar diathermy, and a new percutaneous electrocoagulation vasectomy procedure. Semen specimens were tested at 10 and 12 weeks after surgery. Men were telephoned at 2, 12 and 24 weeks post-surgery to elicit complications and complaints.

Half of the men having the standard incision procedure and about one-third of the men undergoing the percutaneous procedure complained of discomfort during the surgery. At the two-week telephone contact, 23% of those having the standard incision and 66% of those having the percutaneous procedure reported complications.

There were few complications or complaints reported at the long-term follow-up contacts with either method; although twice as many men in the percutaneous group were not declared sterile by the end of the study period. Failure rates were 2.0% for the standard incision procedure and 7.8% for the percutaneous approach.

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# CONTRACEPTION

## Introduction

Despite the obvious advantages of vasectomy over female sterilization, female sterilization remains the overwhelming method of choice. This bias probably results from a mixture of cultural and psychological factors in providers as well as in acceptors of the operation. The Marie Stopes Clinic has developed an incisionless vasectomy technique aimed at improving acceptability as well as removing the most common cause of significant complications - the skin wound.

Although the vas deferens can be isolated just beneath the scrotal skin, attempts to secure a reliable transcutaneous occlusion for male sterilization have been elusive in the West. Goldsmith, Edelman and Zatushni have reported on animal and human experiments using various chemicals including intraepididymal or intravasal injections of formaldehyde, methyl cyanoacrylate and quinacrine dihydrochloride (1). They also report that over 500,000 transcutaneous chemical male sterilizations have been performed in The People's Republic of China with "satisfactory results".

The first reported use of transcutaneous electrocoagulation was by Lee in 1964 (2). In 1970 an attempt to minimize complications and secure "greater mass appeal", Sekhon in India experimented with percutaneous diathermy (3). He used a wire passed through the skin and around the vas as a "diathermy snare". There were five failures in the ten cases performed. More recent Indian experiments by Agarawal and colleagues used special diathermy needles on 28 patients after perfecting the technique on men undergoing prostatectomy (4). The needles were insulated with an acrylic resin connected to an unspecified source of electrocautery. There was only one minor complication but there were two failures (7%). They concluded the method used was safe, simple and quicker than conventional techniques and advocated a large-scale trial.

The Marie Stopes organization performs some 700 - 800 outpatient laparoscopic female sterilizations and 5000 vasectomies annually. Although the organization has evolved a simplified, local anesthetic bipolar occlusion technique for female sterilization, it remains a 10 to 14 minute operating theatre procedure requiring highly specialized skills and a 1-1/2 - 2 hour post-operative stay. In contrast, the Stopes vasectomy procedure, in which the exposed vas is diathermied through a small single incision, is a four to five minute "office" procedure requiring minimal skill and a 20 minute recovery period.

The Stopes percutaneous procedure has evolved to develop a more "marketable" vasectomy which is simpler, quicker and less physically and psychologically traumatic. It would be particularly suited to Third World conditions where the incision wound is the commonest cause of complications and the only potentially lethal hazard is tetanus infection.

The first step in the evolution of the new technique was the use of a modified Schmidt technique in which about a centimeter of undivided vas is pulled out through a small scrotal incision and electrocoagulated(5).

The second was to coagulate the immobilized vas in situ through a small scrotal incision, using a specially insulated electrocautery needle with an exposed ball tip which was inserted into the lumen of the vas through a small longitudinal incision. This technique, used in over a thousand procedures, proved to have only a marginally higher re-operation rate (1.2%), but a similar incidence of complications to the standard vasectomy procedure. It was also slightly quicker enabling a typical case to be performed in 3-1/2 to 4 minutes (quickness being desirable since it minimizes the procedure psychologically). Most importantly, it demonstrated that the vas could be sealed by a monopolar electrode inserted either into the lumen, or more significantly even alongside it. The observation that it was not necessary to actually penetrate the lumen of the vas in order to secure occlusion with monopolar diathermy spurred the development of the prototype percutaneous monopolar needle.

From March to November 1985, men seeking vasectomy at the Marie Stopes London Clinic were given the opportunity of volunteering for the percutaneous vasectomy, which was offered free of charge, or to have the standard procedure for which there was a fee. The principal author (T.R.L.B.) performed the percutaneous procedures; another equally experienced surgeon performed the standard procedures.

### MATERIALS AND METHODS

In the standard incision technique, the unshaved scrotum is swabbed with Hibbiscrub (chlorhexidine gluconate) and the right vas is located beneath the surface of the scrotum with thumb and first two fingers. Xylocaine 1% or 2% with 1:200,000 adrenaline is infiltrated subcutaneously and then around the vas (no premedication is used). A small, three-quarter to 1 cm incision is made through which the right vas is grasped with a Soonawalla forceps. A small longitudinal incision is made between the jaws of the forceps through the covering tissues and the vas teased out from the scrotum with a second forceps into a loop. A standard Birtcher 716 needle is then used to coagulate about a centimeter of the vas on either side of the forceps holding the exposed loop using monopolar diathermy from a Birtcher Hyfrecator. No segments are excised or ties used. The vas is then released and the same procedure repeated on the left side through the original skin incision. The small bleeders in the superficial tissues are coagulated and the wound closed between the jaws of a mosquito forceps. Starch powder (corn flour) is sprinkled on the wound and a bulky dressing applied which is held in place by tight underpants. The client is advised to sit in the waiting room for 20 minutes and to keep the wound dry for as long as possible. They are free to have intercourse when they like and are advised to use another form of contraception until declared sterile.

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The percutaneous technique follows essentially the same steps but uses a prototype 22-gauge hypodermic needle with an insulated barrel and uninsulated tip. Following infiltration of the local anesthetic, the vas is separated from the cord and then grasped in the Soonawalla forceps within a skin fold rather than through an incision. A centimeter of the percutaneous needle is then introduced through the skin and superficial tissues alongside, but not necessarily within the vas. This is then diathermied, using the standard hyfrecator. This produces a visible spark and when this is seen the needle is slowly withdrawn so as to cauterize at least a centimeter or so of the adjacent vas. The same procedure is repeated on the other side through the same puncture. The protocol for this study required that a small incision be made on completion of the operation in order to visually confirm coagulation of the vas.

One-hundred-and-one men requesting vasectomy in 1985 for the purpose of limiting family size were admitted to the study. Fifty men were sterilized by standard incision and monopolar diathermy technique used in the Stopes' clinics, while the remaining fifty-one men underwent the new percutaneous procedure. The procedures were not randomly allocated. Data was collected by the clinic staff on standard forms and sent to Family Health International (FHI) for processing and analysis to evaluate the safety, ease of use and efficacy of percutaneous vas occlusion. The Fisher's exact test was used to calculate the statistical significance of differences.

All the men had approached the Stopes clinic expecting to be fee-for-service patients; some had traveled a long way to central London. It was not possible for the Stopes staff, nor convenient for the clients, to conduct a follow-up physical examination, therefore the men were given two postal specimen containers for mailing semen samples at 10 and 12 weeks after the procedure, as is standard practice at Stopes. They were also telephoned by the Project Nurse Coordinator at 2, 12, and 24 weeks post-vasectomy to elicit complications and complaints. Conducting follow-up contacts by telephone is standard practice at the clinic where over 40,000 vasectomies have been performed.

## RESULTS

### Patient Characteristics

Selected sociodemographic characteristics of the men entering the trial are shown in Table I. The mean age at the time of sterilization was 37.6 years in the percutaneous group and 36.8 years in the standard incision group. The mean number of children fathered were identical (2.0) in both groups. In the percutaneous group, the mean number of years of education was 14.1 years compared to a mean number of 12.5 in the standard incision group. Nearly one-third of the men in both groups had partners who used oral contraceptives during the three months prior to sterilization (data not shown).

TABLE I

Selected Sociodemographic Characteristics of Men Undergoing Standard and Percutaneous Vasectomies

| Characteristics                    | Standard Incision<br>(N=50) |      | Percutaneous<br>(N=51) |      |
|------------------------------------|-----------------------------|------|------------------------|------|
|                                    | No.                         | %    | No.                    | %    |
| <u>Age (years)</u>                 |                             |      |                        |      |
| < 25                               | 0                           | -    | 1                      | 2.0  |
| 25 - 29                            | 6                           | 12.0 | 3                      | 5.9  |
| 30 - 34                            | 15                          | 30.0 | 16                     | 31.4 |
| 35 - 39                            | 13                          | 26.0 | 17                     | 33.3 |
| 40+                                | 16                          | 32.0 | 14                     | 27.4 |
| Mean                               | 36.8                        |      | 37.6                   |      |
| <u>Number of children fathered</u> |                             |      |                        |      |
| None                               | 4                           | 8.0  | 9                      | 17.6 |
| 1 - 2                              | 36                          | 72.0 | 28                     | 54.9 |
| 3 - 4                              | 10                          | 20.0 | 13                     | 25.5 |
| 5+                                 | 0                           | -    | 1                      | 2.0  |
| Mean                               | 2.0                         |      | 2.0                    |      |
| <u>Education (years)</u>           |                             |      |                        |      |
| 7 - 9                              | 0                           | -    | 1                      | 2.0  |
| 10 - 12                            | 33                          | 66.0 | 16                     | 31.4 |
| 13+                                | 17                          | 34.0 | 34                     | 66.7 |
| Mean                               | 12.5                        |      | 14.1                   |      |

**Surgical Difficulties and Complications**

Surgical difficulties were defined as problems the operator experienced during the sterilization procedure. In the percutaneous group, there was one difficulty (2.0%) in identifying the site of vas occlusion after the first post-diathermy incision. No difficulties were reported during the standard incision procedures.

Surgical complications were defined as problems which the patient experienced during the sterilization procedure. One man (2.0%) in the percutaneous group complained of feeling faint during the procedure. There was one case (2.0%) of excessive bleeding in the standard incision group. Sixteen men (31.3%) in the percutaneous group experienced some discomfort during sterilization compared to 25 men (50.0%) who reported discomfort in the standard incision group (not statistically significant,  $p > 0.05$ ).

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### Follow-up Complications and Complaints

A total of 49 men (96.1%) in the percutaneous group and 48 men (96.0%) in the standard incision group were contacted by telephone at two weeks post-vasectomy.

As shown in Table II more patients in the percutaneous group than in the standard incision group reported complications. The difference is statistically significant ( $p < 0.05$ ). Eleven men (23.0%) in the standard incision group reported early follow-up complications when contacted at two weeks after surgery. These included three cases (6.3%) of serous discharge from the wound, three cases (6.3%) of superficial wound infection and five cases (10.4%) of hematoma. In the percutaneous group, 32 men (65.3%) reported complications which included eleven cases (22.4%) of serous discharge, four cases (8.2%) of superficial incision infection, nine cases (18.4%) of hematoma, two incidences (4.1%) of fever and six cases (12.2%) in which the incision was slow to heal.

TABLE II

#### Early\* Follow-up Complications and Complaints

| Complications/Complaints**              | Standard Incision<br>(N=48) |                | Percutaneous<br>(N=49) |                |
|---|-----------------------------|----------------|------------------------|----------------|
|   | No.                         | %              | No.                    | %              |
| <b>Complications</b>                    |                             |                |                        |                |
| Serous discharge                        | 3                           | 6.3            | 11                     | 22.4           |
| Incision infection                      | 3                           | 6.3            | 4                      | 8.2            |
| "Hematoma"                              | 5                           | 10.4           | 9                      | 18.4           |
| Fever                                   | 0                           | -              | 2                      | 4.1            |
| Wound slow to heal                      | 0                           | -              | 6                      | 12.2           |
| <b>Total men with 1+ complications</b>  | <b>11</b>                   | <b>23.0***</b> | <b>32</b>              | <b>65.3***</b> |
| <b>Complaints</b>                       |                             |                |                        |                |
| Lower abdominal pain                    | 0                           | -              | 3                      | 6.1            |
| Scrotal pain                            |                             |                |                        |                |
| Mild                                    | 29                          | 60.4           | 23                     | 46.9           |
| Moderate                                | 5                           | 10.4           | 15                     | 30.6           |
| Severe                                  | 6                           | 12.5           | 1                      | 2.0            |
| <b>Total men with 1+ complaints****</b> | <b>40</b>                   | <b>83.3</b>    | <b>39</b>              | <b>79.6</b>    |

\*Two week post-vasectomy.

\*\*Reported by patient/not confirmed by physician.

\*\*\*Significant at  $p < 0.05$ .

\*\*\*\*Men may have reported more than one complaint.

On the other hand, complaints were more frequently reported in the standard incision group. Forty men (83.3%) experienced scrotal pain compared to 39 men (79.6%) who experienced pain in the percutaneous group; six of those having the standard procedure described the pain as severe; there was one complaint of severe pain in the experimental group. The difference is, however, not statistically significant ( $p > 0.05$ ).

The mean number of days from procedure to resuming intercourse was 3.3 days for the percutaneous patients and 4.8 days for the standard incision patients (data not shown).

The patients were telephoned again at three and six months post-procedure to solicit information on any long-term follow-up events. All men in both groups were contacted at least once during this interval and the findings are shown in Table III. Complications in the standard incision group included one case (2.0%) of unspecified scrotal swelling and one case (2.0%) of wound infection. Among the percutaneous patients, there was one case (2.0%) of granuloma, one incidence (2.0%) of wound discharge and one case (2.0%) of adhesions. Complaints were minimal in both groups but included one case (2.0%) of testicular discomfort, one case (2.0%) of unspecified pain and one report (2.0%) of discomfort at the cauterization site in the standard incision group. One case (2.0%) of testicular pain and one case (2.0%) of tenderness were reported by men in the percutaneous group.

At the end of the study, nine men were not considered sterile, nor were they declared failures (Since there had not been two consecutive sperm-free or sperm-evident semen analyses, neither sterility nor failure were concluded.); three were from the standard incision group, six had had the percutaneous procedure. There was one case in each group in which the sterilization procedure was declared a failure (motile or numerous dead sperm present in two consecutive semen tests). In the percutaneous group, the patient had motile sperm present on repeated tests. In the standard incision group, one man had numerous dead sperm present in tests recorded between three and six months post-vasectomy. Subsequently three of the percutaneous procedures were declared failures. Thus, the failure rates have been computed as 2% for the standard procedure, and 7.8% for the percutaneous procedure. Three of the five men whose procedures failed were re-operated.

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## TABLE III

Long-term\* Follow-up Complications and Complaints

| Complications/Complaints                         | Standard Incision<br>(N=50) |            | Percutaneous<br>(N=51) |             |
|--|-----------------------------|------------|------------------------|-------------|
|  | No.                         | %          | No.                    | %           |
| <b>Complications</b>                             |                             |            |                        |             |
| Scrotal  | 1                           | 2.0        | 0                      | -           |
| Granuloma  | 0                           | -          | 1                      | 2.0         |
| Wound infection                                  | 1                           | 2.0        | 0                      | -           |
| Wound discharge                                  | 0                           | -          | 1                      | 2.0         |
| Adhesions  | 0                           | -          | 1                      | 2.0         |
| <b>Total men with 1+ complications</b>           | <b>2</b>                    | <b>4.0</b> | <b>3</b>               | <b>6.0</b>  |
| <b>Complaints</b>                                |                             |            |                        |             |
| Testicular pain                                  | 1**                         | 2.0        | 1                      | 2.0         |
| Unspecified pain                                 | 1                           | 2.0        | 0                      | -           |
| Tenderness                                       | 0                           | -          | 1                      | 2.0         |
| Discomfort at cauterization site                 | 1                           | 2.0        | 0                      | -           |
| <b>Total men with 1+ complaints</b>              | <b>3</b>                    | <b>6.0</b> | <b>2</b>               | <b>4.0</b>  |
| <b>No. of men not declared sterile/failed***</b> | <b>3</b>                    | <b>6.0</b> | <b>6</b>               | <b>11.8</b> |
| <b>No. of failed procedures****</b>              | <b>1</b>                    | <b>2.0</b> | <b>4</b>               | <b>7.8</b>  |

\*12 and 24 weeks post-vasectomy.

\*\*Reported at 24 weeks post-vasectomy; all other complaints were reported at 12-14 weeks post surgery.

\*\*\*By end of study.

\*\*\*\*Motile or numerous dead sperm present in 2 consecutive semen tests; includes 3 percutaneous cases which had not been declared failures at study's end.

## DISCUSSION

The level of complications for both groups is significantly higher than normally experienced at the Stopes clinics. The reported incidence of "hematomas" at the London clinic is just over one percent. Of the 14 reported hematomas here (by telephone), subsequent inquiry established that only three were confirmed by a physician; one of these resulted from unrelated trauma (a child's kick) in the post-operative period. The remaining eleven men did report post-operative scrotal swelling and discomfort but it is doubtful on the basis of later questioning if any of these were true hematomas. The reported superficial infection rate is also high and again this is based on the client's own assessment. The unsutured wound usually develops a dry "scab" within days. Clinical experience, however, indicates that men in sedentary occupations tend to have a moist sweaty wound somewhat longer. This delayed formation of a "scab" is sometimes interpreted as a superficial infection. Some 21 (or 65.6%) of the 32 complications in the percutaneous group reported at early follow-up were wound related. In non-trial use of this technique, no incision would be made.

The overall re-operation (a second vasectomy performed after four positive sperm tests) rate for the Marie Stopes vasectomy programme using the standard procedure has been 0.7 percent in recent years. It is evident from this trial and from previous experience with 85 cases, that while the percutaneous technique requires no more than the normal skills of a good vasectomist, the failure rate of 4 out of 5 (7.8%) is unacceptably high. Whether this is due to the fact that the percutaneous procedure was performed blindly and only the outside of the vas was cauterized needs further study.

On the basis of the reported and continuing experience with percutaneous diathermy, the Marie Stopes staff are confident that a further reduction of failure rates to acceptable levels of under one percent is possible. It is evident that the simple and highly reliable Birtcher Hyfrecator is a suitable power source for monopolar coagulation. The problem remains of developing a suitably fine insulated percutaneous needle capable of delivering the high output of the Hyfrecator to an uninsulated tip. The 22-gauge prototype needle used in this trial is far from ideal. A 25-gauge insulated needle would greatly facilitate the ease and accuracy with which the area of coagulation could be focused.

Our experience confirms the quickness and comparative simplicity of the percutaneous procedure but suggests that further trials could be justified only if the electrocautery needle technology can be improved to ensure failure rates comparable to existing techniques. When perfected, this electro-percutaneous occlusion of the vas could offer very significant surgical, programming and marketing advantages to existing techniques, particularly in Third World settings.

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