



## Marie Stopes Society, Pakistan: 1000 cases of quinacrine sterilization (QS)

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### Abstract

**Objectives:** To evaluate the safety, efficacy and acceptability of QS in Karachi, Pakistan. **Methods:** 1000 women who had chosen sterilization during the 4-year period 1994 to 1997 inclusive were offered QS at both stationary clinics and in a mobile van at 23 sites in the outskirts of Karachi. The protocol involved transcervical insertion to the uterine fundus of 252 mg quinacrine in 7 pellets and 55 mg of ibuprofen in 3 pellets through an IUD inserter, during the proliferative phase of the menstrual cycle. Two doses were administered one month apart. A temporary method of contraception was provided for 3 cycles, usually DMPA. Follow-up was scheduled: monthly for 3 months, quarterly for 1 year and then every 6 months for 4 years. **Results:** The crude pregnancy rate after 4 years was 2.0%. Minor complications and complaints were reported by 59% of the patients. There was one ectopic pregnancy and no major complications. **Conclusions:** QS was found to be safe and effective and has become the most popular method of sterilization in our area of Pakistan.

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**Keywords:** nonsurgical sterilization, quinacrine sterilization, female sterilization

### 1. Introduction

For some time surgical sterilization has been needed outside cities in Pakistan, but it is not an available option. In July 1993, *The Lancet* published an article by Dr. Do Trong Hieu and his colleagues on a 31,781 case series of quinacrine nonsurgical female sterilizations (QS) in Vietnam [1]. The commentary appearing in that issue of the journal was most supportive of the study [2]. Under development since 1977, QS uses the long-established antibiotic and antimalarial drug quinacrine to initiate inflammation in a short segment of the fallopian tubes [3]. This reaction leads to the formation of 2 plugs of scar tissue that block the tubes, preventing the passage of eggs and sperm through them. According to Hieu there had been no deaths in this series and the rate of serious complications was only 1/50 of that seen with surgical sterilization. They found that the failure rate was higher than with

surgical sterilization but acceptable. The cost of the procedure in Vietnam was less than US\$1. Vietnamese women showed a strong preference for QS over surgical sterilization. In 1993, in an effort to offer sterilization in areas in Pakistan where it is currently unavailable, the Marie Stopes Society, Pakistan, decided to undertake a clinical trial of 1,000 cases to evaluate QS for possible inclusion in our service program.

### 2. Materials and methods

QS involves the transcervical insertion of 252 mg of quinacrine in the form of 7 pellets (Sipharm, Sisseln, Switzerland). In 1993, there was evidence that the antiprostaglandin, ibuprofen, served to relax the tubal ostia, thus allowing the quinacrine to enter the tube, and enhancing the successful outcomes of the

method. A recommended dose of 55 mg of ibuprofen in the form of 3 pellets was inserted along with the quinacrine pellets. The procedure was performed during the proliferative phase of the menstrual cycle, using a modified CuT IUD inserter. Two doses were administered one month apart. A temporary method of contraception was provided for three menstrual cycles. Most of the clients chose depot medroxyprogesterone acetate (DMPA) as a back-up method. The follow-up visit schedule was: monthly for three months, quarterly for one year and six-monthly for four years. From 1994 to 1997, 1000 women were enrolled in this study. Early in the first year, hysterosalpingography was performed on 14 patients 100 days after insertion, on 10 after a single insertion and on 4 after two insertions of quinacrine. Initially QS was performed at stationary clinics. Later it was offered in the outskirts of Karachi in a mobile van equipped for that purpose. Service was provided at the doorstep of the women. Knowing where they lived obviously helped in their follow-up. These 1000 cases were performed at 23 sites.

### 3. Results

Among the 10 women who had a single insertion of quinacrine followed by a hysterosalpingogram 100 days later, there were 9 who had bilateral tubal occlusion and one with unilateral tubal occlusion, while all 4 patients who had 2 insertions had bilateral occlusion.

Table 1 shows the number of QS cases performed during each of the 4 years. All the women had 4 years of follow-up. The gross failure rate for each of the 4 cohorts of women is also shown in Table 1. Among the 1000 women there were 20 pregnancies, for a

Table 1  
Quinacrine sterilization (QS) procedures performed annually 1994–1997 and the failure rate for each of the four cohorts with 4-year follow-up, Karachi, Pakistan

Year	Cases (N)	Pregnancies (N)	Gross failure rate (%)
1994	174	7	4.2
1995	231	9	3.9
1996	246	3	1.2
1997	349	1	0.2
Total	1000	20	2.0

gross pregnancy rate of 2.0% at 4 years. The failure rate fell with each new cohort from 4.2% in 1994 to 0.3% in 1997. One was an ectopic pregnancy.

Minor side effects were experienced by 59% of the patients. These included yellow discharge and itching, pain in the lower abdomen, backache, amenorrhea, fever, allergy (local and generalized), loss of weight (approximately 1–2% of patients), and post-insertion infection. There were no major complications or deaths.

### 4. Discussion

We found QS to have many advantages over surgical sterilization. It does not involve invasive surgery and yet it is permanent; low cost makes it affordable to clients; it does not require a physician; it is quickly carried out and easy to deliver. Serious complications are rare and the risk of death extremely small. It is much more cost effective than surgical sterilization.

The greatest deterrent to offering QS is that this use of quinacrine is not authorized by the United States Food and Drug Administration (FDA) and not registered by the Government of Pakistan. Because the method is unapproved, it is more difficult to market. Women were often not confident in accepting QS since it was not a registered product. Another disadvantage is that long-term side effects are unknown. In our experience, follow-up was expensive and time consuming.

In this study the major referral source was the general practitioner. However, some of these doctors were reluctant to refer the cases for lack of FDA approval and Pakistani registration. This caused a major obstacle in the marketing of the method, as well as its utilization. Consequently, the majority of QS cases were generated in camps organized for the purpose of sterilization in general. After women were informed and counseled on both surgical sterilization and QS, many of them chose QS.

Since this method has the potential to replace surgical female sterilization, the following measures are suggested for improving a QS program:

- There should be an initiative creating awareness of this method. An effective marketing program needs to be developed.
- A comprehensive training program for staff should be implemented.

- Most important, there should be training workshops for private practitioners.
- A proper kit for QS should be provided with pre-loaded inserters in order to reduce the chances of infection and re-use of the inserters.
- Sterile packs should be made available.

In our series, the failure rate fell with each new cohort. This diminution may have been due to the increasing experience of the clinicians and the staff. We found QS to be safe, effective and acceptable in Karachi. Indeed, QS is the most popular method of sterilization in our area of Pakistan, which has a large unmet need for this service.

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