



## Quinacrine sterilization (QS) among high-risk women: a study of 134 cases

A.R. Sarin<sup>a,\*</sup>, R.K. Sarin<sup>b</sup>

<sup>a</sup>Department of Obstetrics & Gynecology, Government Medical College, Patiala, India

<sup>b</sup>Aastha Medical Center, Patiala, India

### Abstract

**Objective:** To determine if quinacrine sterilization (QS) is safe and effective in women at high risk for surgery. **Methods:** A trial was initiated at the Government Medical College in Patiala, India, in December 1993. Patient intake was terminated in July 1999 and the cut-off date for this analysis was March 31, 2003. Using a modified IUD inserter, seven 252 mg quinacrine pellets with 50 mg of diclofenac were transcervically inserted into the uterus. DMPA 150 mg was administered IM at the time of the first insertion as a back-up contraceptive. This same combination was inserted a month later. A total of 134 women underwent QS. Of these, 92 were considered to be at high risk for surgery, 27 were afraid of surgery or voluntarily opted for QS, and 15 had had failed surgical sterilization or surgery was found not to be technically feasible. Follow-up was scheduled for 1, 3, 6 and 12 months, and then annually after the second insertion or whenever side effects or complications were experienced. **Results:** Mean follow-up was 7.2 years. No pregnancies or serious complications were experienced. **Conclusion:** QS is a safe and effective option for women at high risk of surgical complications.

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**Keywords:** quinacrine sterilization, nonsurgical sterilization, high-risk women

### 1. Introduction

Jaime Zipper discovered the potential of quinacrine [1] as a sclerosing agent that causes fibrosis and occlusion of the fallopian tubes. Dr. Zipper published the first human studies on QS in 1970 [2]. Since 1977, quinacrine pellet sterilization (QS) has been used by tens of thousands of women in many different countries [3].

The logistics of offering any method of fertility regulation is influenced by the medical infrastructure and circumstances. One of us (ARS) till recently was

heading a tertiary care facility at a Punjab medical school (Government Medical College, Patiala).

The following aspects of our situation are worth consideration:

- Our government advises against surgical female sterilization for women with hemoglobin less than 7 g/dl, but 57% of women in our area are this anemic [4].
- Since we work at a referral center, we see mothers whose lives would be endangered by another pregnancy, and who are very poor risks for surgery.
- Patients who have experienced sterilization failures are often referred to us, and it is well known that previous pelvic surgery increases the risk of serious complications of a surgical sterilization by a factor of 2.7 [5].
- Finally, we are committed to promote and pro-

\* Corresponding author. Tel.: +91-175-2213703, 2215887.

E-mail address: sarinrajashi@yahoo.co.in

Correspondence address: Department of Obstetrics & Gynecology, Aastha Medical Center, 7, Bank Colony, Patiala-147001, India

vide choices of contraception among well-informed women.

The general situation of our women and children also prompted us to undertake this trial. Fifty-two percent of women in Punjab are illiterate; the mean number of years of schooling is 2.0. They have an average of 2.9 children. Forty-six percent of children younger than 4 years of age in Punjab are underweight and 40% are stunted [6]. Fewer than half of the women who say that they want no more children are actually protected by sterilization.

Currently, the standard technique for female sterilization requires abdominal surgery. In developing countries, it is often difficult to meet the demand for the operation while still maintaining the necessary quality of surgical services. Also, some women who need sterilization have special problems such as high risk of complications due to concomitant medical conditions. Others who desire sterilization refuse it out of fear of surgery. Again, in some cases, surgical sterilization may not be technically feasible.

Most quinacrine sterilizations have been conducted among healthy women, or at least women of average health in a particular area. There have been no reports of QS trials focused on high-risk women. So to meet their special needs, we initiated a trial of QS. In a developing country such as India, QS seems to be a promising method and from the user's immediate perspective, it is a 'woman friendly' procedure. Before embarking on this clinical trial, we carried out our own studies on hysterectomy specimens following transcervical quinacrine pellet insertion in cases of elective hysterectomies [7]. Also, we reviewed the published reports showing the safety and reasonable efficacy of QS [8–10]. This trial was designed especially for high-risk women. Earlier, we published a brief account of this experience [11]. The present report is an update after a longer follow-up (maximum, 10.3 years).

## 2. Materials and methods

This research was carried out from December 1993 through July 1999 when the Drug Controller of India banned the use of quinacrine for this purpose as a

Table 1  
Clinical features of high-risk women undergoing QS in Patiala, India, 1993–1999 (N = 134)

Indication	QS cases (N)
High risk for surgery (N = 92)	
severe anemia (Hb <7 g/dl)	61
cardiovascular disease	11
bronchial asthma	8
pelvic inflammatory disease	12
Non-feasibility of surgery (N = 15)	
previous surgical failure	7
technical problems	8
tubo-ovarian mass, 2	
thickened tubes, 4	
marked obesity, 2	
Voluntary choice	27
Total	134

result of an article in the *Wall Street Journal* [12]. However, we are still monitoring the women who had undergone QS. The cut-off date for this analysis was March 31, 2003.

We studied 134 women of reproductive age who had two transcervical insertions of 7 quinacrine pellets (252 mg; Sipharm, Sisseln, Switzerland) with 2 diclofenac pellets (50 mg) a month apart during the proliferative phase of the menstrual cycle. A modified IUD inserter was used to place the pellets at the fundus following the standard protocol [13]. One 150-mg injection of depot medroxyprogesterone acetate (DMPA) was given with the first insertion as a back-up contraceptive.

Table 1 describes the clinical features of our cases: 92 women were at high risk of surgery; 27 had voluntarily chosen a non-surgical procedure; and 15 included those who had experienced earlier surgical sterilization failure or for whom the operation was not technically feasible. All of these women gave their informed consent to undergo QS.

Follow-up was scheduled for 1, 3, 6 and 12 months, and then annually, after the second insertion or whenever side effects or complications were experienced. Home visits were made when the women did not report to the clinic. Three additional patients were lost to

follow-up and are not included in this analysis. Thus, all 134 women reported on continued to be followed.

### 3. Results

No pregnancies or serious complications were reported. The mean follow-up to date is 7.2 years (range 3.9 to 10.3 years). Table 2 summarizes the side effects and complications. The main complaint was transient menstrual irregularity, due probably to the DMPA injection. Other side effects included transient lower abdominal pain, oligomenorrhea or amenorrhea and mild post-insertion bleeding.

Table 2  
Side effects and complications after QS among 134 high-risk women in Patiala, India, 1993–1999

Events	No.
<b>Immediate</b>	
Transient lower abdominal pain	3
Post-insertion bleeding	3
Vaginal discharge	13
Low backache	4
<b>Menstrual disturbances requiring treatment</b>	
Oligomenorrhea	21
Amenorrhea	6

The conditions and circumstances faced by these patients were many and varied. The following case reports serve as illustrations:

#### 3.1. Case 1: Anemia

B, a daily wage earner, was para 5 and had had 4 abortions by the village traditional birth attendant (TBA). She had tried the CuT-IUD, which had to be removed due to menorrhagia. She was refused surgical sterilization, as her hemoglobin was only 6.5 g/dl. We performed QS in December 1995 with no side effects.

#### 3.2. Case 2: Rheumatic heart disease and mitral stenosis

K, para 3, had rheumatic heart disease (RHD) with

mitral stenosis. In the preceding two pregnancies, she went into congestive heart failure (CHF) and had to be hospitalized. Her husband did not agree to vasectomy. Surgical sterilization was not feasible because of RHD and concomitant anemia. She underwent QS in February 1996 and is doing well on medical treatment for RHD.

#### 3.3. Case 3: Hypertension

HK, para 6, had 3 medical termination of pregnancy (MTP). She had intractable uncontrolled hypertension (BP = 180/100 mmHg). She was refused tubectomy. We performed QS in August 1996, and she is doing well on antihypertensive drug therapy.

#### 3.4. Case 4: Bronchial asthma

S, para 4, 2MTPs and had bronchial asthma. She had tried CuT-IUD, which caused menorrhagia, switched to oral contraceptives (OCs), but had to stop due to severe nausea. She was refused tubectomy because of bronchial asthma. We performed QS in September 1994 without problems.

#### 3.5. Case 5: Laparoligation failure

A, para 3, had one MTP. She presented for laparoscopic sterilization. During the procedure, the right fallopian tube was found to be thickened and adherent. The ring could not be applied on it. She refused minilap but readily agreed to QS, which was carried out in November 1996.

#### 3.6. Case 6: Fear of surgery

C, para 3, had displaced a CuT-IUD and had to undergo laparotomy for this. She was too frightened of any further surgery. She opted for QS, which was done in April 1994.

#### 3.7. Case 7: Laparoligation and minilap failure

SK, Para 6, conceived again after a failed laparoscopic sterilization when she was para 4. She went in for minilap just after the fifth full term normal delivery. Unfortunately, this too failed and she ended up with a sixth child. She became frustrated with surgical sterilization and opted for QS, which was performed in September 1995.

### 3.8. Case 8: Laparoligation failure

D, para 3, had 4 MTPs. She tried oral contraceptives (OCs) and a CuT-IUD but stopped both due to intolerable side effects. She opted for laparoligation. The procedure failed; the trocar did not reach the peritoneal cavity because of her marked obesity (weight 95 kg). She opted for QS, which was performed in May 1996.

## 4. Discussion

In our clinical practice, we find that a significant proportion of women are poor candidates for surgical sterilization. They need a non-surgical method of contraception. The QS experience in normal women exceeds 100,000 cases [3] and long-term concerns about the risks of ectopic pregnancy, birth defects and cancer appear to be similar to those for surgical sterilization [14]. There have been no failures in this trial of high-risk women, although failures are reported to be about twice those of surgical sterilization [14]. There were no major complications in this trial. However, more experience is needed in providing this option for such women.

We conclude that QS is a reasonable option, especially for women who are at high risk with the surgical procedure and for those where it is not technically feasible. Also, QS is a practical alternative for women who are apprehensive about surgery, but desire a permanent method of contraception. It is clinically efficacious and safe.

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