



Quinacrine sterilization in Libya: 200 cases

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Abstract

Objective: Document the safety, effectiveness and acceptability of quinacrine sterilization (QS) as an alternative to surgical sterilization in Libyan women. **Methods:** This study was initiated 1 October 1998 at the Misurata Central Hospital and Lamis Clinic. Patient intake was completed 30 September 2002. The cut-off date for this analysis was 31 December 2002. A total of 200 women were given 2 doses, each consisting of 252 mg of quinacrine hydrochloride in the form of 7 pellets inserted one month apart. They were placed at the uterine fundus during the proliferative phase of the menstrual cycle using a modified IUD inserter. Women were asked to report any unusual observations or side effects and instructed to use a barrier method or safe period for one month from the time of the first insertion. Follow-up was scheduled at 3, 6 and 12 months after the date of the second insertion and every 6 months thereafter. **Results:** Sixty-six women have been monitored for up to 3 years and follow-up of all patients continues. There has been no loss to follow-up. No side effects of any consequence have been reported. Thus far, no pregnancies have been reported for this protocol. **Conclusions:** Findings in this study are consistent with those seen in other countries. QS has been shown to be safe, effective and acceptable among Libyan women.

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1. Introduction

Family planning is essential to families all over the world, and female sterilization is the leading method of contraception among women who have decided not to have any more children. Although they remain fertile into their late 40s or early 50s, many have already had all the children they want during their 20s or 30s. Since the early 18th century, sterilization has been performed surgically. But in 1977, a nonsurgical method of sterilization using the drug quinacrine was developed by Zipper in Chile [1].

Quinacrine, also known as Atabrine or Mepacrine, is a drug that was originally introduced in 1931 to prevent

and cure malaria, and has subsequently been used by more than 100 million people. This included men, and even women who were pregnant as well as children. Today it continues to be prescribed for giardiasis, lupus, rheumatoid arthritis and tapeworm. After 70 years of use, its safety record remains unquestioned [2].

The QS method involves the transcervical intrauterine administration of quinacrine hydrochloride to nonpregnant women during the proliferative phase of the menstrual cycle (days 9–12). In the most commonly studied regimen, seven pellets, each containing 36 mg of quinacrine hydrochloride, are introduced into the uterus with a modified Cu–T IUD inserter. A second insertion is done one month later [2].

The local action of quinacrine is a partial necrosis of the endometrial lining of the uterus and the mucosal lining in the intramural segment of the fallopian tubes. Although the endometrium regenerates itself over a period of one or more menstrual cycles, inflammation

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of the tubes progresses into the inner muscular coat with sclerosis, preventing regeneration of tubal mucosa. Over the next 6–12 weeks, a small fibrous mass forms, joining the walls of the intramural tube and occluding or filling the lumen. After inflammation of the fallopian tubes subsides a plug of scar tissue remains [3].

Since 1977, clinical trials in numerous countries have found the method to be safe and effective. This includes research carried out in: Chile (Zipper et al., 1980 [1]), India (Bhatt and Wasak, 1985 [4]), Indonesia (Agoestina and Kusuma, 1992 [5]), Vietnam (Hieu et al., 1993 [6]), Pakistan (Bashir, 1993 [7]) and Iran (Soroodi-Maghaddam, 1996 [8]).

Quinacrine sterilization (QS) has the potential of being an inexpensive, safe and well-accepted procedure that would benefit women in both industrialized and developing countries.

2. Materials and methods

This 200-case clinical trial was initiated 1 October 1998 and patient enrollment was completed on 30 September 2002. Women seeking sterilization were recruited for the study. Anyone with a history of psychosis, psoriasis or hepatic disease was excluded. Postpartum women were required to wait until they had menstruated at least once before entering the study.

All patients were given two doses, each consisting of 252 mg of quinacrine hydrochloride in the form of pellets, one month apart. The pellets were placed at the very top of the uterine fundus during the proliferative phase of the menstrual cycle (between days 9 and 11 from the first day of menstruation) with a modified Cu-T IUD inserter. The authors performed all procedures. Patients were asked to use either a barrier method or the safe period between the two insertions and to report any unusual observation or side effect. Follow-up was scheduled at 3, 6 and 12 months after the second insertion and every 6 months thereafter. The cut-off date for data collection for this report was 31 December 2002.

3. Results

A total of 201 patients were recruited. One woman became pregnant between the first and second insertions.

This pregnancy was discovered by vaginal ultrasound during a routine examination just before the second insertion. Upon review of her medical history, it was learned that the patient was only 5–6 weeks postpartum and had not had a menses when she received her first dose of quinacrine. Since the research protocol had not been adhered to, she was excluded from the study. The woman went on to have a normal vaginal delivery of a male child. There were no signs of any congenital abnormalities.

The age of the women ranged from 34 to 45 years and the mean was 38 years. The number of children ranged from 5 to 13. The only side effect was a yellow discharge, which persisted for no more than 3 days from the time of the insertion. No other complications or side effects have been reported.

Follow-up has been 100% and we continue to monitor all patients. As of the cut-off date, of the 200 patients, 66 had completed their 3-year follow-up, 80 their 2-year follow-up and 54 the 1-year follow-up. There have been no pregnancy failures.

4. Discussion

Every patient was counseled that they might experience adverse events (AE) like headache, dizziness, backache, feeling hot, yellow vaginal discharge, itching, oligomenorrhea, amenorrhea, endometritis and possibly ectopic pregnancy. However, only yellow vaginal discharge was reported. Perhaps women did not report these other effects after having been forewarned that they are normal outcomes of this procedure. There were no uterine perforations, pelvic inflammatory disease or hematometra. Side effects simply were not a problem for our patients in this study.

Surgical sterilization is an invasive method that carries a significant risk of morbidity and a small risk of mortality. In a small percentage, reversal of sterilization is possible with the surgical methods. It is not known whether reversal of the quinacrine method can be done. Nevertheless, quinacrine is an acceptable alternative to surgical sterilization. Women preferred quinacrine over surgical methods. The demand for the procedure increased throughout our trial.

From this study and other research in different countries, we conclude that sterilization can be achieved safely and with high efficacy using QS.

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