



Quinacrine sterilization (QS) experience in The Philippines: a preliminary report

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Abstract

Objective: The first clinical trial of Quinacrine Sterilization (QS) in the Philippines was undertaken in Cebu City on January 10, 2000, to evaluate the acceptability, safety, effectiveness and side effects of this technology. We intend to recruit 500 patients to utilize this technique for limiting family size. For the purposes of this report, our cut-off date is April 11, 2003. **Methods:** Over more than two years, QS was performed on 36 volunteer patients. After careful explanation of the procedure and given the opportunity to ask questions, they had signed an informed consent. The trial involved transcervical insertion of 252 mg quinacrine in the form of pellets, and placed at the tip of the uterine fundus on two occasions, a month apart. Condoms were routinely provided to all patients except those on oral contraceptive pills and DMPA after the first insertion to be used for six weeks after the second one. As the numbers are small, no statistical evaluation was called for. **Results:** The accumulated experience was 515 woman-months. There were no pregnancies, neither ectopic nor intrauterine. Adverse events (AE) were mild. Some patients complained of a yellow discharge and itching. Fifty percent experienced mild abdominal discomfort which was easily managed with mefenamic acid. **Conclusions:** Although this is a small study, we believe that QS is both safe and effective and we are strongly encouraged to continue to offer this nonsurgical sterilization method to our patients.

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1. Introduction

The invention and development of quinacrine sterilization (QS) by Dr. Jaime Zipper opened a new epoch for women to control their reproductive function [1]. QS involves the insertion of quinacrine pellets transcervically into the uterine cavity causing scars to develop and block the fallopian tubes (oviducts). The drug itself has a 70-year history of safety. QS is a procedure that has been the subject of extensive research for over 30 years. The technique was introduced to the Philippines in Cebu City at the Southwestern

University Medical School, where a program was started on January 10, 2000. This paper describes our experience with this method of sterilization for more than two years, that is, until April 11, 2003.

2. Materials and methods

Before undertaking this trial of QS, the researchers familiarized themselves with the established world literature describing how to protect human subjects volunteering for clinical research. This included reading and applying such measures as are found in the Helsinki and International Accord Conventions. All of our subjects were volunteers, who received instruction in reproductive physiology.

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Quinacrine sterilization was carefully explained and patients observed a video describing the technique. They were instructed on alternative methods of birth control such as condom, diaphragms, birth control pills, etc. to assure that their free choice was an informed one. They were given opportunities to ask questions and the researchers responded with satisfactory answers in detail. Patients chose QS voluntarily as their best option. Each woman signed an informed consent.

Our intention was to enroll 500 patient volunteers who desired sterilization and to offer them transcervical chemical sterilization with quinacrine. Thirty-six patients have undergone QS. The profile of our patients reveals that their ages ranged from 26 to 43, with parity from 3 to 11. They had had at least three years of high school education. All were married women who felt they had completed their families with their desired number of children. The majority were Roman Catholic. Upon admission, a complete medical history was obtained and a thorough physical examination was performed. No patients were refused because of serious negative findings in the medical history or physical examination.

The quinacrine sterilization trial involved the transcervical insertion of 252 mg divided in seven pellets which were loaded into a modified Cu-T IUD inserter. QS was carried out in each case three to five days after menses ended. The seven pellets were carefully placed at the very top of the uterine fundus as described by Hieu [2]. Occasionally, a client was given mefenamic acid, 250 mg, one to two hours prior to the procedure. Afterwards, she was advised to lie flat on the examination table for at least 30 minutes before leaving for home. A second insertion was repeated four weeks later. Condoms were routinely given to all patients at the time of the first insertion of quinacrine and to continue to be used for six weeks after the second insertion. Our cut-off date for the purposes of this report was April 11, 2003.

Because this trial is small, statistical analysis is simple.

3. Results

There were no major adverse events (AE) reported. An immediate side effect was the loss of about 2 cc of blood following insertion. This was largely due to the

cervical injury sustained once the tenaculum applied to the anterior lip of the cervix was detached. One woman complained of fever for one or two days after her first insertion. However, follow-up on this patient revealed that she had an upper respiratory infection acquired that day which probably caused her fever.

The most commonly reported AE was a yellow discharge noticed for a few days after quinacrine insertion. The condition was explained to these women as something to be expected and was transient. They were all reassured. All patients were instructed that if the discharge persisted for several days, especially if it became purulent, they should return to the clinic and would be examined for a possible cervicitis or pelvic inflammatory disease. No such serious AE was reported. About 50% of the group experienced mild abdominal discomfort. Mefenamic acid was prescribed to be taken every four hours if needed.

The 36 patients accumulated 515 woman-months or 42.9 woman years of exposure. No pregnancies of any type, neither intrauterine nor ectopic occurred.

4. Discussion

In the past, sterilization has not been popular in our community for a variety of reasons: cost of the procedure; lack of ready availability; fear of complications; lack of information and knowledge about QS; myths and rumors about sterilization in general; questions about safety and efficacy of any type of sterilization; and religious and moral convictions.

The Reproductive Health (RH) Clinic of the Sacred Heart Hospital, the teaching facility of the College of Medicine of Southwestern University in Cebu City, Philippines, has served all reproductive health needs of the greater population in this area. These services include: reproductive health counseling; family planning; maternal and child nutrition and care; pre- and post-natal care, treatment of reproductive tract infections; male reproductive health care; and campus screening programs. Family planning services include a wide variety of options for natural and artificial methods of contraception, including the permanent methods.

QS has many advantages never heretofore seen with other methods of sterilization, especially surgical techniques, e.g., simplicity, no need for an anesthetic, no incision, few side effects and low cost.

QS was new to our institution. It provided us with the opportunity to introduce an innovative and unique technology to our community. It has been received enthusiastically and will be, and already is, a celebration of women's rights. This clinical trial constituted an introduction to the staff and patients of this method of limiting family size. Admittedly, this series was small. Yet with no pregnancies and only minor AEs noted, QS is gaining acceptance in our area. More clinical trials of QS are warranted. Our research indicates that QS will deservedly continue to be offered in the Philippines.

References

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