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10-year follow-up of women who elected quinacrine sterilization (QS) in Wonosobo, Central Java, Indonesia

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Abstract

Objectives: To evaluate the safety and efficacy of quinacrine sterilization (QS) in Indonesia. *Methods*: During the period, August 1992 to October 1993, 200 women who had requested surgical sterilization volunteered for QS at the Wonosobo Regency Hospital, Central Java Province, Indonesia. The protocol called for transcervical insertion of 252 mg of quinacrine in the form of 7 cylindrical pellets and 55.5 mg of ibuprofen with a CuT-IUD (Kimia Farma) inserter during the proliferative phase of the menstrual cycle. A second procedure was done 4 weeks later. The technique used is essentially the same as inserting a CuT-IUD. Follow-up was scheduled at 6, 12, 24 and 48 months after the last insertion. In March 2003 additional monitoring was completed. *Results*: The 10-year cumulative pregnancy rate was 4.3 per 100 women with a follow-up rate of 93%. No pregnancies had occurred among these women since the 4-year follow-up. No long-term side effects or complications were reported. *Conclusions*: After 10 years of use, QS was found to be safe and reasonably effective.

Keywords: quinacrine sterilization, nonsurgical sterilization, female sterilization

1. Introduction

When this study was initiated 10 years ago, quinacrine sterilization (QS) was a promising method of nonsurgical female sterilization because of its safety, acceptability and effectiveness. Today, it is even more promising. The number of cases performed has tripled as has the number of countries where it has been offered. Yet no clinician has reported a bad experience with this method. This growing experience with QS is particularly important to Indonesia. When this study was initiated in 1992, Indonesia had a very low prevalence of female sterilization, 2.9% [1] and an unacceptably high maternal mortality of 390 per 100,000 live births [2]. These indicators have changed little in the last decade. Surgical sterilization requires trained personnel, adequate medical care facilities and acquisition and maintenance of sophisticated equipment. Most Indonesian women do not have access to these resources nor will they in the foreseeable future. This predicament is recognized by the National Family Planning Coordination Board (NFPCB) which consequently organized and conducted a QS clinical trial in 6 academic centers located throughout Indonesia in 1993–1995. The results of that study were recently published and contributed significantly to the growing body of evidence showing that this method is safe, reasonably effective and acceptable to women [3].

Research on the long-term effects of QS is also expanding and thus far, none have been identified. This report on a 10-year follow-up will add to the collective

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experience. Earlier results from this study are reported elsewhere [4,5].

2. Materials and methods

A prospective clinical study of QS was conducted at the Wonosobo Regency Hospital, Central Java Province, Indonesia, with the approval of the NFPCB of Wonosobo Regency, Central Java Province which served as the institutional review board. From August 1992 through October 1993, 200 women, who gave informed consent, received transcervically 252 mg of quinacrine hydrochloride in the form of 7 cylindrical pellets (Sipharm, Sisseln, Switzerland) followed by 55.5 mg ibuprofen in three pellets during the proliferative phase of the menstrual cycles. This process was repeated 4 weeks later. Pellets were provided by the Center for Research on Population and Security. All insertions were made by the senior author. The procedure was essentially the same as for inserting a CuT-IUD (Kimia Farma, Bandung, Indonesia).

Women seeking surgical sterilization were advised of the QS option and of the study in which they were invited to participate. Excluded were women who had pathologic pelvic conditions (except cervicitis), such as upper tract infection, or gross distortion of the uterine cavity or who appeared unusually nervous. Those who could not participate in the trial were offered a choice of surgical sterilization or other methods of contraception. Monitoring of the QS patients was scheduled at 6, 12, 24 and 48 months after the last insertion and at any time when complications or complaints occurred. In February and March 2002 we undertook an additional follow-up visit. Data were collected on standardized forms developed by the International Federation for Family Health. Life-table analysis was used to calculate efficacy.

3. Results

Less than 2% of the women who opted for QS were excluded as a result of our criteria. Their mean age was 33.2 years (SD 9.75), and they were between 24 and 40 years old. The mean number of live births was 3.5 (SD 0.5) and ranged from 2 to 8. All 200 women completed the first insertion but 3 declined the second and were offered an alternative method. One month after the first insertion, 116 women (58%) reported that they had experienced lower abdominal pain. Two women complained of severe abdominal pain and required antibiotic and analgesic treatment, 26 (13.5%) had fever, 15 (7.5%) leukorrhea, 7 (3.5%) menorrhagia, and 2 (1.0%) amenorrhea. At the 1-year follow-up, two women informed us that they had had amenorrhea for 4 months and then resumed menstruation. More detailed results are provided in our two-year [4] and four-year reports [5].

Four women became pregnant during the 2-year follow-up period, at 4, 5, 14 and 18 months after the second insertion. Before the 4-year follow-up there were 4 additional pregnancies for a total of eight. No additional failures were documented and, thus, the 10-year cumulative pregnancy rate was 4.3 per 100 women. The follow-up rate was 93% at 10 years.

Two of the 8 pregnancies were terminated by vacuum aspiration; one aborted spontaneously. The other five ended in spontaneous full term deliveries. No major malformations were noted.

At the 10-year follow-up, 2 women had amenorrhea. No cancers or long-term side effects had occurred.

4. Discussion

The fact that less than 2% of the volunteers requesting QS were excluded from the study is in itself an important finding. All but a few women will be good candidates for this procedure. The side effects recorded are similar to those mentioned by other investigators. The two cases of amenorrhea during the 10-year follow-up could be anticipated. Ten years later, some of these women who had QS could be expected to be menopausal. When this study was initiated in 1992, there was some evidence that ibuprofen might enhance the effectiveness of QS. This has now been convincingly disproved [6] and is no longer recommended.

An accurate explanation for the distribution of failures over time may assist in improving the efficacy of QS. That all 8 failures would occur in the first 4 years is an observation of interest and may be of significance if substantiated by other studies. More investigators are needed to evaluate all aspects of the procedure and arrive at solutions. For example, after our study

was initiated, Hieu and his colleagues [7] made an important discovery in recognizing the importance of placing the pellets at the fundus and, in turn, lowering the failure rate. There will be other such advances. The failure rate of this study of 4.3 per 100 women at 10 years is most acceptable given the alternatives available to women in Indonesia and elsewhere. We found QS to be safe, indeed, much safer than surgical sterilization and there was no hint that QS might cause any long-term side effects, including cancer. We conclude that QS has great promise. It is safe, effective and acceptable.

References

[1] Central Bureau of Statistics (CBS) [Indonesia]; State Ministry of Population/National Family Planning Coordinating Board (NFPCB); Ministry of Health (MOH); Micro International, Inc. (MI). Indonesian Demographic and Health Survey 1994: Calverton, Maryland: CBS and MI: 1995:73.

[2] Central Bureau of Statistics (CBS) [Indonesia]; op. cit., p. 211.

[3] Agoestina T, Hoesni RHM, Purwara BH, Santoso BI, Siswanto P, Dasuki D, et al. Randomized trial of one vs two transcervical insertions of quinacrine pellets for sterilization. *Fertil Steril* 2002; 77:1065–1068.

[4] Suhadi A, Soejoenoes A. Quinacrine pellet nonsurgical female sterilization in Wonosobo, Indonesia. *Fertil Steril* 1997; 67:966–968.

[5] Suhadi A, Anwar M, Soejoenoes A. Four-year clinical evaluation of quinacrine pellets for non-surgical female sterilization. *Adv Contracept* 1998; 14:69–77.

[6] Randic L, Haller H, Sojat S. Nonsurgical female sterilization: comparison of intrauterine application of quinacrine alone or in combination with ibuprofen. *Fertil Steril* 2001; 75:830–831.

[7] Hieu DT, Tan TT, Tan DN, Nguyet PT, Than P, Vinh DQ. 31,781 cases of non-surgical female sterilization with quinacrine pellets in Vietnam. *Lancet* 1993; 342:213–217.