

Non-Surgical Tubal Occlusion

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ABSTRACT

Out of 151 women provided with chemical female sterilization with three insertions of 250 mg. of quinacrine spaced one month apart, there were seven pregnancies in 3 years. If these pregnancies were a result of failure to occlude the entrance to one or both fallopian tubes, birth events should decrease exponentially with time. Unexpectedly, the low failure rate has not decreased significantly over the 5-year observation period.

INTRODUCTION

A non-surgical transcervical method of tubal occlusion, if perfected, would be particularly useful in countries where medical services are overstretched but the demand for voluntary sterilization high (3). Of the numerous transcervical methods of female sterilization under development (5), quinacrine hydrochloride in a tableted dosage is a leading contender. If chemical sterilization is to become generally available, it is important to determine the long-term effects.

METHODS

We reported on the results of 3 years of follow-up on 151 women who volunteered for intrauterine administration of quinacrine hydrochloride (2). Quinacrine tablets 3.2 mm in diameter containing 250 mg had been delivered to the uterus through an IUD-inserter tube. Each subject received three separate insertions of 250 mg tablets separated by an interval of 1 month. Three-year follow-up has now been completed. By the end of the 38th month of observation, seven pregnancies had occurred and were distributed evenly over the whole interval. The 36-month life-table pregnancy rates are reproduced in Table 1. This short report compares the expected exponentially distributed frequency of pregnancies with the observed frequency to illustrate the need for a better understanding of the mechanism of failure.

RESULTS

Figure 1 represents three different models to explain the observed spacing of the pregnancies. These data correspond to the life-table results presented in Table 1, by Guzman-Serani et al. (2). The solid curve assumes a constant pregnancy rate and assumes that the pregnancy rate for the women lost to

follow-up was the same as the rate for the women who were followed for 38 months. The broken curve assumes a constant pregnancy rate but also assumes all women who started the program and experienced an accidental pregnancy returned to the clinic. Both models fit the observed pregnancy distribution reasonably well. Quinacrine "sterilization" results in a constant low pregnancy rate of 1.5-2 per 100 women per year. One hypothesis concerning the action of tubal sclerosing agents is that method failure is more commonly unilateral than bilateral. One patent tube should give a fecundity one-half the normal, or conservatively 0.1 pregnancies per month for each subject with one tube patent. Given that seven pregnancies occurred and the pregnancy rate was 0.1 per month, then the most likely times for the pregnancies number 1, 2, . . . 7 are 1.27, 2.73, 4.46, 6.58, 9.31, 13.16 and 19.74 months, respectively. The broken curve in the figure is based on these times; it does not fit the observed pregnancies.

DISCUSSION

The uniform distribution of pregnancies is similar to that of a model for an effective contraceptive and does not support a hypothesis that sterilization method failure leave one or both tubes patent. Thus, the term "non-reversible chemical contraception" may be more accurate than chemical or non-surgical sterilization. These data, based on three insertions of quinacrine spaced 1 month apart, raise an interesting question about what the pregnancy distribution would be if only one insertion were used. Would the treatment act like a contraceptive with a low efficacy, a mixture of tubal occlusion and no occlusion, or some other combination? Is there a constant probability of tubal repair?

The quinacrine tablets used in this study had a nominal dissolution time of 10 min. Preliminary studies with 100 min dissolution time tablets indicate they may be associated with a greater probability of tubal occlusion than the 10 min tablets (4). If this suggestion is confirmed, we hope to compare a results with one, two and three insertions. These results may provide a basis for estimating the relative importance of failure to occlude and repair of occlusion as causes of method failure. It is intended to continue intensive follow-up of this group of women, together with parallel studies by Zipper (4) and Bhatt and Waszak (1) to maintain a cohort of women who have been treated with quinacrine pellets. We expect them to be increasingly valuable for studying the long-term event rates of tubal occlusion with quinacrine hydrochloride.

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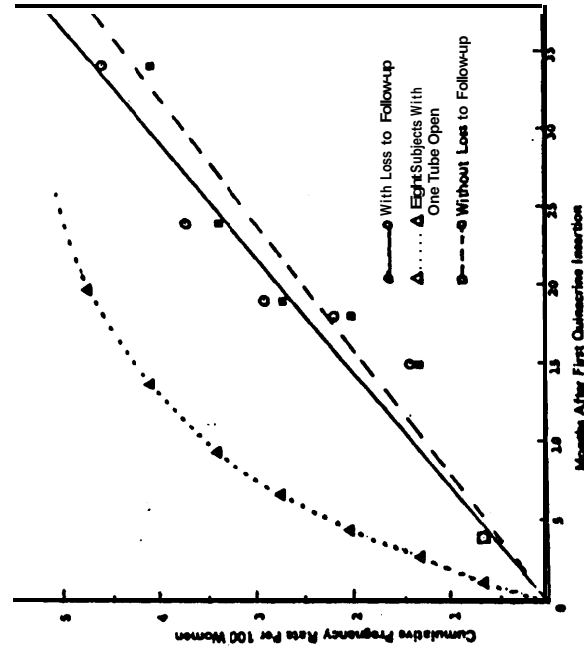


Figure 1. Time distribution of seven pregnancies occurring after 150 women were treated with three intrauterine doses of 250 mg quinacrine tablets at the beginning of months 1, 2 and 3. The ordinate is the cumulative risk of pregnancy conditional upon surviving to the beginning of the month without a pregnancy. The solid and broken lines represent a model in which the risk of pregnancy remains constant over time. The broken line assumes all pregnancy women come back to the clinic and the solid line is based on an observed follow-up rate of .09921 per month. In the dotted curve, the most likely distribution of pregnancies and cumulative hazard rate is illustrated assuming that eight of the 150 procedures failed to close one tube. This model does not fit the observations.

Table 1. Cumulative gross life-table pregnancy rates per 100 women who completed three insertions of quinacrine hydrochloride pellets.

Period of IUD use (month)	Pregnancy rate	Follow-up rate
6	0.7±0.7	100.0
12	0.7±0.7	99.3
24	3.4±1.5	97.2
36	4.3±1.7	81.1

N = 149

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