



The effect of special training for quinacrine sterilization (QS) in Faisalabad, Pakistan: a report on an 1833-women subset of 11,000 cases

A. Bashir*, M. Bashir, S. Afzal

Mother & Child Welfare Association, Faisalabad 38000, Pakistan

Abstract

Objective: To determine the impact of retrained clinicians on the efficacy of transcervical quinacrine sterilization. **Method:** Retraining of clinicians in the accepted insertion technique was conducted in 1996. From 1 January 1997 through 2001, they performed 1089 quinacrine sterilizations in 11 MCH clinics of the Mother & Child Welfare Association at Faisalabad, Pakistan. Of these, 885 women had a recorded follow-up visit (81.4%) by 31 December 2001. **Result:** Reported pregnancy failures declined after retraining from 5.4% (SE 2.3) for one year of use to 1.1% (SE 0.4) for 5 years of use. The rates at 4 years of use showed the expected increase in failures for women 30 years old or younger of 1.5% (SE 0.7) compared to 0.9% (SE 0.4) for those over 30; a lower rate of 0.8% (SE 0.4) for breastfeeding subjects and 2.2% (SE 1.1) for mothers not breastfeeding; but rates were similar for uterine length and post insertion traumatic bleeding. **Conclusion:** Quinacrine sterilization appears safe with acceptable efficacy.

© 2003 International Federation of Gynecology and Obstetrics. Published by Elsevier Science Ltd. All rights reserved.

Keywords: quinacrine sterilization, female sterilization, sterilization training

1. Introduction

Quinacrine sterilization (QS) was introduced in Faisalabad, Pakistan, by the late Professor Altaf Bashir in 1990 [1] at the Gulzar Colony MCH Centre of the Mother & Child Welfare Association. The preceding year, a survey of 993 married women in Faisalabad [2] revealed that only 12.1% were using a contraceptive, 3.2% of whom were sterilized. During 1990, a concerted effort was made to popularize family planning methods including the introduction of QS. A repeat survey [3] in January 1991 of 1005 married women

showed contraceptive prevalence at 41.7% including 18.1% using female sterilization, the largest increase of any method. Information about contraception was provided mainly by trained traditional birth attendants (TBAs) [4]. During 1990, 2100 QS procedures were performed, of which 79% were for women aged 31–40 years; 68% of these patients had parity of 5 to 8. In this group, 85 pregnancy failures (2.4%) were reported for that year. Popularity of QS was sustained with 1583 cases being performed in 1991, 1550 in 1992 [5], and a total of over 10,000 cases were reached by 1995.

During this early experience, the family planning promotion was integrated into a well-organized MCH effort to reduce maternal morbidity and mortality. It succeeded in bringing maternal mortality in Faisalabad significantly below the national average [6].

*Corresponding author. Tel.: 91-41-711550; Fax: 92-41-535261

E-mail address: macwafsd@yahoo.com

Correspondence address: Mother & Child Welfare Association, 18 Gulzar Colony (near Passport Office), Faisalabad 38000, Pakistan

QS was carried out in camps and cases were referred to MCH clinics, primarily by TBAs. In our first approach to this nonsurgical method of sterilization, QS procedures involved single transcervical insertions of seven quinacrine pellets each containing 36 mg for a total of 252 mg. These were performed in the proliferative phase of the menstrual cycle. A Copper T IUD inserter was used and we followed the Copper T insertion technique. With this approach under aseptic conditions, the sterile dry inserter was loaded with clean quinacrine pellets and, as with an IUD placement, the loaded inserter was advanced transcervically to the fundus where the inserter sleeve was withdrawn to release all pellets in a line from the fundus. No deaths were reported in this large experience and complications were rare. The safety of QS was well established. Faisalabad had gained the largest single insertion experience with QS.

Because reports suggested that a revised insertion technique [7,8] with multiple insertions [7] might improve efficacy, we then focused our attention on this new technique.

2. Materials and methods

A preliminary study of a convenience sample of 948 QS cases in 11 MCH clinics of the Mother & Child Welfare Association extending from 1990 to 1995 showed a cumulative life-table pregnancy failure rate of 5.4% (SE 2.3) in 1990 which on a continuing basis did rise with time. In 1996, a retraining effort was initiated for all nurse-midwife inserting clinicians with particular attention to using the then recommended technique first described by Hieu [7]. This involved advancing the loaded inserter transcervically to the fundus, then withdrawing it 0.5 cm. Then, while holding the inserter sheath steady, the plunger was advanced to deposit all pellets at the very top of the uterine fundus. Although patients were advised to return for a second insertion in one month as recommended internationally [9], few did so because the single-insertion procedure had been so well established in the community. Following this training, a series of 1089 QS cases were performed by these trainees during the period 1 January 1997 through 2001. Several research questions were explored, including the impact

on efficacy of such things as patient's age, breastfeeding, length of uterus and evidence of traumatic bleeding. Each of these items was recorded on a register recommended by the International Federation for Family Health. Efficacy rates are based on use from last insertion to last patient contact. Cases at risk are limited to recorded data for each item evaluated. This may have amounted to less than 885 cases followed.

3. Results

In this series of 1089 QS procedures conducted after retraining in the 11 MCH clinics, 885 (81.4%) women had a recorded follow-up visit, of whom 158 (17.9%) received only a single insertion. There was no statistically significant difference in failure rates between single- and 2-insertion data, so these data were combined for the analysis. Efficacy, combining single- and 2-insertion cases, is shown in Table 1, with a pregnancy failure rate of 1.1% (SE 0.4) at 5 years of use.

The difference in efficacy by age can be seen in Table 2 with a failure rate of 0.9% (SE 0.4) for women older than 30 and 1.5% (SE 0.7) for those 30 or younger at 4 years of use.

The difference in failure rates for breastfeeding is evident in Table 3 with 0.8% (SE 0.4) for breastfeeding subjects and 2.2% (SE 1.1) for non-breastfeeding patients at 4 years of use.

The difference in efficacy by length of uterus is shown in Table 4 where uteri sounding over 6 cm had failure rates of 1.2% (SE 0.4) while those sounding 6 cm or under had 1.9% (SE 1.3). The difference in

Table 1
Cumulative life-table pregnancy failure rate for 885 followed quinacrine sterilization cases by months of use. Faisalabad, Pakistan, 1997–2001 ($N = 1089$)

Month	1 + 2 insertions, $N = 885$		
	At risk	Rate (%)	Standard error (SE)
12	878	0.3	0.2
24	751	1.0	0.3
36	479	1.1	0.4
48	217	1.1	0.4
60	48	1.1	0.4

Table 2

Cumulative life-table pregnancy failure rate by months of use for quinacrine sterilization by subject's age. Faisalabad, Pakistan, 1997–2001 ($N = 885$)

Month	>30 years ($N = 610$)			≤30 years ($N = 275$)		
	At risk	Rate (%)	Standard error (SE)	At risk	Rate (%)	Standard error (SE)
12	605	0.3	0.2	274	0.4	0.4
24	527	0.7	0.3	225	1.5	0.7
36	362	0.9	0.4	115	1.5	0.7
48	172	0.9	0.4	45	1.5	0.7
60	43	0.9	0.4			

Table 3

Cumulative life-table pregnancy failure rate by months of use by subject's breastfeeding status. Faisalabad, Pakistan, 1997–2001 ($N = 640$)

Month	Breastfeeding ($N = 449$)			Non-breastfeeding ($N = 191$)		
	At risk	Rate (%)	Standard error (SE)	At risk	Rate (%)	Standard error (SE)
12	447	0.2	0.2	191	0	
24	384	0.5	0.3	187	1.1	0.7
36	291	0.8	0.4	101	2.2	1.1
48	148	0.8	0.4	61	2.2	1.1
60	32	0.8	0.4			

Table 4

Cumulative life-table pregnancy failure rate by months of use for subject's uterine length. Faisalabad, Pakistan, 1997–2001 ($N = 760$)

Month	Uterine length ≤6 cm ($N = 128$)			Uterine length >6 cm ($N = 632$)		
	At risk	Rate (%)	Standard error (SE)	At risk	Rate (%)	Standard error (SE)
12	128	0		627	0.4	0.3
24	116	0.8	0.8	540	1.2	0.4
36	84	1.9	1.3	383	1.2	0.4
48	45	1.9	1.3	165	1.2	0.4
60				48	1.2	0.4

efficacy because of post-insertion bleeding over 1 ml (Table 5) showed a failure rate of 0.7% (SE 0.7) compared to 1.2% (SE 0.5) when there was no post insertion bleeding. Failure rates noted in Tables 4 and 5 were recorded after 4 years of use, and the differences were not statistically significant.

4. Discussion

The retraining effort appeared to be successful as pregnancy failure rates declined from 5.4% (SE 2.3)

to 0.3% (SE 0.2) at 12 months of use. This brings into question the need for a second insertion where the low failure rate for a single one may be acceptable in some localities. The higher failure rates reported by Hieu and his colleagues [7] may have been related to menstrual regulation (MR) procedures performed for delayed menstrual periods without a pregnancy test [10] and reported as pregnancy failures. Pregnancy tests were not available to Hieu or to the government at the time of this Vietnamese field trial. Amenorrhea lasting a month or more following insertion of quinacrine pellets affects

Table 5

Cumulative life-table pregnancy failure rate by months of use for quinacrine sterilization by report of post-insertion uterine bleeding. Faisalabad, Pakistan 1997–2001 ($N = 628$)

Month	Post-insertion bleeding ($N = 172$)			No post-insertion bleeding ($N = 456$)		
	At risk	Rate (%)	Standard error (SE)	At risk	Rate (%)	Standard error (SE)
12	171	0		453	0.4	0.3
24	134	0.7	0.7	407	0.9	0.4
36	94	0.7	0.7	306	1.2	0.5
48	49	0.7	0.7	167	1.2	0.5
60				44	1.2	0.5

30% of the women. This fact was not widely known by Vietnamese clinicians and therefore their patients were never forewarned. Experiencing amenorrhea, the woman would simply go to her local clinic, report a late period and request an MR without confirmation of pregnancy. She would receive an MR, and a pregnancy failure would be recorded following QS. It is understandable then that a significant proportion of the MR procedures may well have been done simply for a delayed menstrual period [11].

The difference in failure rates by age, while not statistically significant, is in the expected direction for younger women having a greater risk of pregnancy failure. In this case, a pregnancy rate of 0.9% (SE 0.4) was recorded for women over 30 and of 1.5% (SE 0.7) for women under 30 years of age.

Breastfeeding alone offers some protection against pregnancy. As expected, there is a marked difference in failures by breastfeeding status, with 0.8% (SE 0.4) for breastfeeding mothers and 2.2% (SE 1.1) for those who are not doing so.

There is little difference in pregnancy failures by length of uterus, being 1.2% (SE 0.4) for uteri over 6 cm and 1.9% (SE 1.3) for uteri 6 cm or less. This difference is, however, in the same direction as that found by El Kady and his associates [12].

The difference in pregnancy failures may vary because of post-insertion bleeding. When this amounted to over 1 ml the failure rate was 0.7% (SE 0.7) versus 1.2% (SE 0.5) when post-insertion bleeding was absent. While not statistically significant this difference is in the opposite direction of that reported by El Kady [12] whose study involved a smaller number of subjects. It is suggested that additional data from other centers is needed before reconsidering

present recommendations [9] to repeat procedures with post-insertion bleeding.

QS is clearly safer than surgical sterilization, particularly in terms of early complications [13]. Long-term follow-up shows no increased risk of cancer [14]. Recent reports [8,15,16], including this paper, confirm that the efficacy with presently recommended insertion techniques approaches that of accepted methods of surgical sterilization [17]. QS is ready for use in service programs, especially in developing countries.

Acknowledgment

The authors are grateful to Mr. Hafeez Javed and Mrs. Razia Sultana for their assistance in this study, and wish to thank the staff of MCWA for their contribution to our program.

References

- [1] Bashir A, Cheema MA, Akram S, Naheed R. Quinacrine nonsurgical female sterilization. *The Gynaecologist* 1993; 3:129–136.
- [2] Bashir A, Cheema MA, Akram S, Mustansar M. Family planning in Pakistan: results from a survey in Faisalabad City. *The Gynaecologist* 1991; 1(2–3):94–98.
- [3] Bashir A, Cheema MA, Mustansar M, Naheed R, Akram S. Family planning practices in Pakistan: a step towards success. *Quarterly Specialist* 1991; 8:31–36.
- [4] Bashir A. Refresher courses of Traditional Birth Attendants. *JPMA* 1982; 32(7):168–169.
- [5] Bashir A, Mustansar M, Cheema MA, Choudhury MY. Nonsurgical female sterilization: 3 years' experience with quinacrine. *Gynaecol Bimonthly* 1992–3; 3(2,3):129–136.
- [6] Khalid S. The Faisalabad mother & child health programme. *Gynaecol Bimonthly* 1992–3; 3(2,3):116–118.

- [7] Hieu DT, Tan TT, Tan DN, Nguyet PT, Than P, Vinh DQ. 31 871 cases of non-surgical female sterilisation with quinacrine pellets in Vietnam. *Lancet* 1993; 342:213–217.
- [8] Bairagi NR, Mullick BC, Kessel E, Mumford SD. Comparison of the efficacy of intrauterine diclofenac and ibuprofen pellets as adjuvants to quinacrine nonsurgical female sterilization. *Adv Contracept* 1995; 11:303–308.
- [9] Institute for Development Training. Female voluntary non-surgical sterilization: the quinacrine method. Module 12 of Training Course in Women's Health. IDT, Chapel Hill, North Carolina, 1996.
- [10] Sokal DC, Weiner DH. What is the future of quinacrine sterilization? (letter) *Fertil Steril* 2001; 75:1244–1245.
- [11] Kessel E. Menstrual regulation. In: M Potts, P Bhiwandiwala, editors, *Birth Control: An International Assessment*. Baltimore: University Park Press, 1979, 187–200.
- [12] El Kady AA, Nagib HS, Kessel E. Efficacy and safety of repeated transcervical quinacrine pellet insertions for female sterilization. *Fertil Steril* 1993; 59:301–304.
- [13] Layde PM, Peterson AB, Dicker RC, DeStefano F, Rubin GL, Ory HW. Risk factors for complications of interval tubal sterilization by laparoscopy. *Obstet Gynecol* 1983; 62:180–184.
- [14] Sokal DC, Dabancens A, Guzman-Serani R, Zipper J. Cancer risk among women sterilized with transcervical quinacrine in Chile: an update through 1996. *Fertil Steril* 2000; 74:169–171.
- [15] Soroodi-Maghaddam S. Preliminary report on a clinical trial of the quinacrine pellet method for nonsurgical female sterilization in Iran. *Int Fam Plann Perspect* 1996; 22:122–123, 127.
- [16] Sarin AR. Quinacrine sterilization: experience among women at high risk for surgery. *Adv Contracept* 1999; 15:175–178.
- [17] Peterson HB, Xia Z, Hughes JM, Wilson LS, Tylar LR, Trussel J. The risk of pregnancy after tubal sterilization: Findings from the U.S. Collaborative Review of Sterilization. *Am J Obstet Gynecol* 1996; 174:1161–1170.