

International Journal of Gynecology and Obstetrics 83 Suppl. 2 (2003) S77-S85

International Journal of GYNECOLOGY & OBSTETRICS

www.elsevier.com/locate/ijgo

The acceptability, efficacy and safety of quinacrine non-surgical sterilization (QS), tubectomy and vasectomy in 5 provinces in the Red River Delta, Vietnam: a follow-up of 15,190 cases

D.T. Hieu^{a,*}, T.T. Luong^b, P.T. Anh^b, D.H. Ngoc^b, L.Q. Duong^b

^aDirector (retired), Department of Maternal and Child Health/Family Planning, Ministry of Health, Hanoi, Vietnam ^bDepartment of Maternal and Child Health/Family Planning, Ministry of Health, Hanoi, Vietnam

Abstract

Objectives: To compare the safety, efficacy and acceptability of quinacrine sterilization (QS), tubectomy and vasectomy in Vietnam. *Methods:* This study was initiated in January 1998 and completed in February 2000. A sample of 9 districts in 5 provinces, where the prevalence of QS was known to be high, was selected. Every person sterilized in these 9 districts between January 1, 1988 and March 31, 1998 was identified and systematically interviewed by family planning clinicians who had received special training for this project. *Results:* A total of 15,982 sterilization users were identified and 15,190 were interviewed and examined, including a gynecologic exam, if needed: a follow-up rate of 95%. Of those interviewed, 9,753 used tubectomy, 3,734 used QS and 1,703 used vasectomy. All three methods were found to be safe, although morbidity associated with tubectomy was more serious than with QS or vasectomy. No deaths were reported. After more than 5 years of follow-up, tubectomy had the lowest failure rate: 1.0%, followed by 4.1% with vasectomy. A pregnancy rate of 13.2% was reported with quinacrine, although only a small fraction of these failures were confirmed. A strong preference for QS was found. *Conclusion:* QS has an important role to play in sterilization services in Vietnam.

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

Keywords: surgical sterilization, quinacrine sterilization, female sterilization, vasectomy

1. Introduction

The use of contraception increased substantially in Vietnam during the decade of the 1990s, especially in the provinces of the Red River Delta (Table 1). This is a reflection of both the desires of couples for smaller families and the effort made by the government to make family planning services available. The crude birth rate (CBR) and the proportion of couples with more than 3 children fell precipitously during this decade (Table 2). By 1998, the total fertility rate (TFR) had

fallen to 2.48 nationally and to 1.91 in the province of Thai Binh (Table 3).

Until the late 1980s, family planning in Vietnam relied chiefly on IUD use with abortion or menstrual regulation (MR) as a back up. Until 1990, tubectomy was rarely performed and then only in association with cesarean section or surgical treatment in the abdomen or pelvis. Interval sterilization was rarely seen in Vietnam before 1990. This method accounted for less than 1% of the method mix. In 1989, quinacrine sterilization (QS) was introduced to the family planning program by the Ministry of Health. It was widely accepted until 1993 when the program was halted for re-evaluation following a letter from the World Health Organization claiming that quinacrine probably

^{*} Corresponding author. Tel./Fax: 84-4-943-3207.

E-mail address: ngaquan2000@yahoo.com

Correspondence address: 41 Tran Quoc Toan, Hanoi, Vietnam

^{0020-7292/03/\$ –} see front matter © 2003 International Federation of Gynecology and Obstetrics. Published by Elsevier Science Ltd. All rights reserved. PII: S0020-7292(03) 00000-0

Area	1992		1996		1998	
	All methods CPR	modern methods	All methods CPR	modern methods	All methods CPR	modern methods
Vietnam	53.8	41.3	68.3	52.9	71.9	57.9
Hai Duong	66.3	62.7	79.1	71.0	80.6	71.2
Hung Yen					78.9	72.4
Thai Binh	73.3	67.1	80.9	71.1	79.1	69.6
Nam Dinh	63.6	57.5	74.1	65.1	72.8	67.6
Ha Nam					77.4	72.8

Contraceptive prevalence rate (CPR) in Vietnam and in the 5 study provinces during the 1990s a,b

^a Data from the Vietnam Government Statistical Office.

^b Note: In late 1986, Hai Hung Province was divided into Hai Duong and Hung Yen Provinces. At the same time, Nam Ha Province was divided into Nam Dinh and Ha Nam Provinces. The data in the table for 1992 and 1996 are for the original larger provinces before subdivision.

Popu	lation (per	1000)	CH	CBR (per 1000) Over			Over 3 children		
1992	1996	1999	1992	1996	1999	1992	1996		
68,361	74,310	76,325	30.0	22.8	19.9	37.1	32.7		
2,614	2,780	1,650	24.5	18.2	18.8	21.3	18.5		
		1,069			19.8				
1,741	1,831	1,786	21.7	19.2	15.5	18.1	11.4		
2,538	2,721	1,888	26.6	20.9	18.5	33.8	28.9		
		792			18.2				
	Popu 1992 68,361 2,614 1,741 2,538	Population (per 1992 1996 68,361 74,310 2,614 2,780 1,741 1,831 2,538 2,721	Population (per 1000) 1992 1996 1999 68,361 74,310 76,325 2,614 2,780 1,650 1,741 1,831 1,786 2,538 2,721 1,888 792 792	Population (per 1000) CE 1992 1996 1999 1992 68,361 74,310 76,325 30.0 2,614 2,780 1,650 24.5 1,069 1,741 1,831 1,786 21.7 2,538 2,721 1,888 26.6 792	$\begin{tabular}{ c c c c c c c c c c c c c c c c c c c$	$\begin{tabular}{ c c c c c c c } \hline Population (per 1000) & CBR (per 1000) \\ \hline 1992 & 1996 & 1999 & 1992 & 1996 & 1999 \\ \hline 68,361 & 74,310 & 76,325 & 30.0 & 22.8 & 19.9 \\ 2,614 & 2,780 & 1,650 & 24.5 & 18.2 & 18.8 \\ & & 1,069 & & 19.8 \\ 1,741 & 1,831 & 1,786 & 21.7 & 19.2 & 15.5 \\ 2,538 & 2,721 & 1,888 & 26.6 & 20.9 & 18.5 \\ & & 792 & & 18.2 \\ \hline \end{array}$	$\begin{tabular}{ c c c c c c c c c c c c c c c c c c c$		

^a Vietnam Government Statistical Office surveys 1992, 1996, and 1999.

causes cancer [1]. The program has not resumed. In 1990, the no-scalpel vasectomy was actively introduced to Vietnam by the Ministry of Health. In 1992 and 1993, the Ministry undertook a major effort to promote the use of tubectomy and vasectomy. The number of sterilization procedures in Vietnam grew rapidly from 1990 to 1994. A part of this growth was due to QS, especially in the provinces of the Red River Delta. However, the bulk of the growth was due to surgical sterilization. The rapid growth in surgical sterilization can be attributed to the national government's incentive policies for three groups: providers, promoters and especially for users. In 1995, the number of surgical procedures declined rapidly (Table 4), including in the Red River Delta, and this decline continues.

One difficulty in evaluating QS has been the assessment of failure of this procedure. During the period Table 3 Population, crude birth rate (CBR) and total fertility rate (TFR) in Vietnam and in the 5 study provinces in 1998^a

Area	Population	CBR (1998 census)	TFR (1998 census)
Vietnam	76,324,753	19.89	2.48
Hai Duong	5,037,155	18.77	2.28
Hung Yen	1,047,040	19.77	2.42
Thai Binh	1,173,820	15.49	1.91
Nam Dinh	716,427	18.52	2.32
Ha Nam	965,240	18.15	2.30

^a Source: Vietnam 1998 population census, 1999.

QS was offered in Vietnam, pregnancy tests were unavailable. The price of a pregnancy test was US\$6

Table 1

Area				Number	of users				
Alca	1001	1002	1002	1004	1005	1007	1007	1000	
	1991	1992	1993	1994	1995	1996	1997	1998	
Vietnam	21,092	48,703	120,503	143,104	129,645	121,043	99,391	94,356	
Hai Duong		4,085	8,076	7,000	4,408	3,824	1,600	1,298	
Hung Yen							1,025	861	
Thai Binh	1,383	3,354	3,786	4,488	3,500	1,961	1,223	837	
Nam Dinh	3,405	4,503	5,692	4,217	2,888	2,669	1,740	1,317	
Ha Nam							577	466	

Table 4 Sterilization distribution by year in Vietnam and in the 5 study provinces during the 1990s.^a

^a Data from the Vietnam Government Statistical Office.

which the government could not afford. In comparison, the cost of a QS procedure was under US\$1. Thus, if a woman was late for her menstrual period and believed she was pregnant, she simply reported to the commune health clinic and requested a menstrual regulation (MR) procedure. There was never any confirmation of pregnancy. Pregnancy was assumed.

It was decided that the best approach to evaluate QS, given that no pregnancy tests were available, would be to determine the worst-case scenario. The worst case would be that every woman reporting to the clinic with a late period following QS was in fact pregnant. In other words, any woman who missed her period and obtained an MR was reported as a pregnancy failure of QS. This was the only approach available to us at the time and represented at best a crude estimate of the failure rate. Unfortunately, amenorrhea is a frequent side effect of QS compelling us to estimate a higher pregnancy rate. In a carefully conducted study of menstrual pattern changes following QS in Indonesia, Agoestina reported that among women who had regular cycles in the beginning, 26% had amenorrhea after the second insertion and 21% after the third [2]. She does not report on amenorrhea after the first insertion. In Chile, Guzman-Serani reported that 35.7% of his patients experienced amenorrhea after at least one of the three insertions [3]. In our paper on 31,781 cases of QS, we found amenorrhea in only 0.3% of the women following insertion of quinacrine [4]. Nearly all of these women, instead of reporting amenorrhea, said that they were pregnant and asked for and received an MR. Thus, the QS failure rates cited in previous publications [4,5] undoubtedly overstate

the true pregnancy rate, which will never be known. Further study is needed to refine previous estimates.

Sterilization is an important part of the contraceptive mix and is critical in reducing the need for abortion. The purpose of this study is to compare sterilization methods used in Vietnam and to determine why the practice declined so sharply in the 1990s. Such knowledge will enable us to plan a superior strategy to increase the use of sterilization.

2. Methods

This retrospective study included both an interview and a clinical examination. The study sample was chosen in the following manner:

Five provinces where QS, tubectomy and vasectomy were known to have been performed in significant numbers were selected. In each province, 2 districts were chosen except in Thai Binh where only one district was selected. Each had to meet the following criteria: All commune health centers must be accessible by car. The district leadership must express a readiness to participate and to agree to the need for such a study. This phase was initiated during the first quarter of 1998.

The name of the districts involved in this study were: Bink Luc and Ly Nhan in Ha Nam Province; Xuan Truong and Giao Thuy in Nam Dinh Province; Dong Hung in Thai Binh Province; Yen Mo and Nho Quan in Ninh Binh Province; and Chau Giang and Tien Lu in Hung Yen Province. Thus, there was a total of 9 districts involved. Investigators were chosen from among health workers at provincial Maternal and Child Health/Family Planning (MCH/FP) centers of the study provinces (2 physicians from each) and from district health centers (1 physician from each). A district team consisted of 2 physicians (1 provincial and 1 district) and 1 or 2 midwives/nurses. The team leader was the doctor from the provincial MCH/FP center. A 5-day training course was organized for the 10 doctors from the provincial MCH/FP centers. They, in turn, organized courses for their district colleagues. All training was conducted in the second quarter of 1998.

A list of users sterilized between January 1, 1988 and March 31, 1998, was completed by the local investigators in cooperation with health authorities. Then each user was invited to the commune health center (CHC) to be interviewed individually and have a clinical pelvic examination if needed. Interviewing was initiated in July 1998 and completed in March 1999.

In cases of illness or discomfort, the team leader provided the patient with appropriate management and treatment. She was monitored by the district investigator. Each woman who participated in the study was offered a small gift by the study team. Data collection was completed in March, 1999.

3. Results

Table 5 presents the number of sterilization users and the number of interviewees by method. The total number of users was 15,982 and the total number of interviewees was 15,190. The percent of followup ranged from 92.8% to 96.2%, exceedingly high given the numbers of years that had passed since sterilization.

Table 6 shows that the number of both female and male sterilizations procedures peaked in 1993, the year

Table 5

Number of users and interviewees by method who were sterilized between 1989 and 1998 in the 9 sample districts, Vietnam

Method	No. users	No. interviewees	Interview rate
Tubectomy	10,139	9,753	96.2
QS	4,008	3,734	93.2
Vasectomy	1,835	1,703	92.8
Total	15,982	15,190	95.0

the QS program was halted and the second year of the implementation of incentive policies for surgical sterilization. The number then decreased rapidly from 4,274 in 1993 to 861 in 1997. The experience in the study districts thus paralleled that of the country as a whole as shown in Table 4. Nearly all (99.3%) of the 13,487 women were farmers. Their mean age at the time of sterilization was 34.7 years and they had completed a mean of 6.6 years of school. When asked if they had experienced any pressure to undergo sterilization, either QS or tubectomy, 13,405 (99.4%) said no while 82 (0.6%) said yes. The latter had pressure from their husbands because their husbands did not want another child. 91.6% of the women had the approval of their husband to obtain the sterilization procedure while 8.4% did not.

All women who had opted for tubectomy had received a cash incentive of 150,000 VND (approximately US\$25) from the authorities according to the regulations of the National Committee for Population and Family Planning. Among the QS users, 18.2% had received a small gift from local authorities. The incentives policies applied only to surgical methods of family planning and did not include QS.

During the three-year period, 1990 to 1992, most female sterilization procedures were QS (see Table 6). The national government never promoted QS and never funded any incentives for QS. Use of the method was halted by the government in December 1993 when a letter arrived from the World Health Organization (WHO) claiming that quinacrine probably causes cancer. However, the number of QS procedures performed had plummeted from 1,910 in 1992 to 244 in 1993 even before WHO intervention. Because the demand was so strong, a handful of QS cases were carried out after the program was officially halted. In 1992 the government began offering incentives for tubectomy and vasectomy and their number increased rapidly, peaking the next year, but then they declined rapidly.

Table 7 presents the outcomes of all pregnancies of all women interviewed prior to their sterilization procedures. Child loss was remarkably low. While the mean number of childbirths was 3.4, the mean number of living children was 3.3. The women had had an average of just over 1 induced abortion or menstrual regulation.

Table 8 is most telling. Women who had a single

Year	Tubec	tomy	Q	S	Vasect	omy	Tot	tal
	N	%	N	%	Ν	%	N	%
Before 1989	323	93.3	23	6.7	_	_	346	100.0
1990	112	21.9	399	78.1	_	_	511	100.0
1991	118	9.3	1,141	90.0	8 ^a	0.7	1,267	100.0
1992	235	10.3	1,910	83.8	134	5.9	2,279	100.0
1993	3,118	73.0	244	5.7	912	21.3	4,274	100.0
1994	2,229	89.3	10	0.4	256	10.3	2,495	100.0
1995	1,467	88.5	5	0.3	185	11.2	1,657	100.0
1996	1,156	89.1	1	0.1	140	10.8	1,297	100.0
1997	811	94.2	1	0.1	49	5.7	861	100.0
1998 Jan–Mar	184	90.6	0	0.0	19	9.4	203	100.0
Total	9,753	64.2	3,734	24.6	1,703	11.2	15,190	100.0

Table 6	
Number of sterilization users followed-up in sample districts by method and year, Viet	nam

^a Before 1992.

Table 7

Fertility status of female sterilization (QS and tubectomy) users, Vietnam, from January 1, 1988 to March 31, 1998

Parameter	Mean	Standard deviation (SD)
Pregnancies	4.6	1.82
Childbirth	3.4	1.22
Induced abortion	0.56	1.00
Spontaneous abortion	0.15	0.46
Menstrual regulation (MR)	0.51	1.17
Living children before sterilization	3.3	1.02
Current living children	3.3	1.02
Living sons	1.9	0.86
Living daughters	1.4	1.05

Table 9					
Tubectomy	failure rat	tes by ye	ar of tubed	ctomy, Vietnan	1

Tubectomy year	Tubectomies (N)	Pregnancies (N)	Failure rate (%)
Before 1990	323	7	2.2
1990	112	0	0.0
1991	118	2	1.7
1992	235	3	1.3
1993	3,118	36	1.2
1994	2,229	29	1.3
1995	1,467	11	0.7
1996	1,156	10	0.9
1997	811	3	0.4
1998	184	0	0.0
Total	9,753	101	1.0

Table 8

Failure rate for QS according to protocol used, Vietnam, 1989–1993

Protocol	No. QS users	No. pregnancy failures	Failure rate (%)
One insertion	472	127	26.9
Two insertions	3,068	360	11.7
Three insertions	81	1	1.2
One insertion & DMPA ^a	113	5	4.4
Total	3,734	493	

^a DMPA, depot medroxyprogesterone acetate.

insertion for QS reported a pregnancy 26.9% of the time. Women who had a depot medroxyprogesterone acetate (DMPA) injection with a single insertion reported a pregnancy 4.4% of the time. Two insertions led to women reporting pregnancy 11.7% and 3 insertions resulted in pregnancy 1.2% of the time. The women who had third insertions all had MRs after their second insertions because of a late period. We will return to these findings in the discussion.

Failure of tubectomy was very low throughout the decade of the 1990s (see Table 9). This is a reflection

Table 10 Side effects/complications after QS, Vietnam, (N = 3,740). From 1989 to 1993

Table 12

Side effects/complications following 1,703 vasectomies, Vietnam. From 1991 to 1998

Side effect/complication	N	%
Yellow vaginal discharge	373	10
Mild pain lower abdomen	451	12.1
Others	289	7.7
Total	1,113	29.8

Table 11

Side effects/complications following tubectomy (N = 9,753), Vietnam. From January 1, 1988 to March 31, 1998

Side effect/complication	N	%
Bleeding at the incision	57	0.58
Hematoma at the abdominal wall	20	0.20
Fever (>38°C)	179	1.83
Suppuration at the incision	210	2.15
Pain at the surgical site	508	5.20
Others	182	1.86
Total	1,156	11.9

of good training and good program implementation, including monitoring. The failure rate at the time of the interview period was 1.0%. A lower rate is rarely reported.

Side effects and complications reported by QS users were mild and non-threatening. They are reported in Table 10. None required hospitalization. All were temporary, lasting from a few hours to a few days. Yellow vaginal discharge needed only genital washing, and pain was relieved by papaverine or paracetamol in one or two days. On the other hand, side effects and complications of tubectomy were more serious (Table 11) but not life-threatening, and none were severe. All tubectomy patients were hospitalized for a week or more and antibiotics were prescribed for them. Some required additional hospitalization for treatment of complications, which, in general, were more serious and more expensive to manage than those seen with QS.

Vasectomy was rare before 1992 as can be seen in Table 6. In the districts studied, the number quickly peaked at 912 in 1993 and then the number fell

Side effect/complication	Ν	%
Bleeding at scrotum	7	0.4
Hematomae	19	1.1
Infection	20	1.2
Fever	23	1.4
Pain	171	10.0
Others	55	3.2
Total	295	17.3

Table 13						
Reasons for choosing	vasectomy,	Vietnam.	From	1991	to	1998

Reason	Ν	%
Simple procedure, no major surgery	666	39.2
Want to terminate childbearing	1,409	82.9
Wife cannot be sterilized	207	12.2
Incentives will be given	91	5.4
Others	75	4.2
Total	1,703	143.8

precipitously to only 49 in 1997. All districts had a similar experience. As with female sterilization, most couples were relying on the IUD just prior to the vasectomy (83%). Interestingly, in 5% of the couples, the wife was currently using tubectomy. Vasectomy was accepted at an older age (a mean of 42.7 years) compared to QS and tubectomy but the number of years of school completed was identical (mean of 6.6 years). Table 12 lists the complications and side effects of vasectomy though none are major. They affected 17.3% of the men. Table 13 shows the reasons for choosing vasectomy. A full 83% said the finality of the procedure made it attractive. Its simplicity and that it was not major surgery appealed to 39%.

A total of 69 of 1,703 men who obtained a vasectomy experienced a failure of the method resulting in a pregnancy for a rate of 4.1%. The outcomes of these 71 pregnancies were as follows: childbirth 37.7%, induced abortion 53.6%, spontaneous abortion 7.3%, and ectopic pregnancy 1.4%.

4. Discussion

There were many important findings in this study. We can now discuss QS, tubectomy and vasectomy in Vietnam authoritatively and we can compare these methods to each other. Several reasons for the startling decline in the use of sterilization in Vietnam became apparent. Unfounded rumors regarding all methods abound. For example, many of the women believed vasectomy would impair sexual function and discouraged their husbands. OS declined rapidly in 1993 before the WHO letter claiming that guinacrine probably causes cancer [1]. This was mainly due to the large incentives paid to patients, promoters and clinicians for surgical sterilization which were never paid for QS. As a consequence of these promotions, many individuals sought sterilization before they were ready, and they eventually became very unhappy with their decision. These dissatisfied men and women are very poor ambassadors for sterilization and no doubt undermined the credibility of the program.

This study also established that we did a poor job of introducing QS, largely because of a serious shortfall in resources. It also confirmed that we did well technically with the introduction of surgical sterilization. The failure rate with tubectomy was a low 1% with an average follow-up of more than 4 years, an acceptable rate. The failure rate with vasectomy was 4% after a similar follow-up period. Part of this rate can be attributed to the learning curve and this rate is likely to fall with more experience. No life-threatening complications were reported in this study with any of the three methods.

However, OS had a clear advantage with regard to cost-effectiveness. QS costs only US\$1, while tubectomy costs US\$100 or more. By policy, 3-5 days' hospitalization were usually required with tubectomy, and after discharge, paid sick leave was always 7-10 days. Complications of surgical sterilization, though not lifethreatening, were more serious than with QS. They needed to be managed at health facilities and some of these patients had to be hospitalized. No deaths were reported in the provinces studied. However, one death from tubectomy was reported in a Central Highlands province. On the other hand, QS complications only needed to be treated at home with simple or no medications. Investment costs for surgical sterilization are much greater than for QS, involving expenses for personnel, training and facilities.

This study found that there was a strong preference for QS and many women interviewed and others encountered during the course of the study expressed their desire that QS be offered once more. During the course of this study, many representatives of local Women's Unions, speaking for their constituents, strongly urged the investigators to do everything possible to make QS available again.

Our research demonstrates that the stage is set for extensive use of sterilization in Vietnam as the method of choice among couples who want no more children. The rate of child loss among those who sought sterilization was found to be very low – an average of 0.1 children per couple. This is reflected nationally in the contraceptive prevalence data which reveal that couples in Vietnam strongly desire to limit the size of their families. Couples have realistic expectations that their children will survive. The high contraceptive prevalence level also indicates a strong commitment by the government to make good contraceptive methods available to everyone.

In the United States, nearly 80% of couples are sterilized before the wife reaches the end of her reproductive years. They are confident that their children will survive. This condition is now met in Vietnam, making sterilization more desirable. It is rightfully seen as the safest and most use-effective method. Because of its quantum leap in use-effectiveness, sterilization offers the opportunity to a family planning program to make a parallel transition in effectiveness. Family planning programs that offer only temporary methods reach a plateau where program effectiveness levels off well below the desired point. Both sterilization and abortion then create new potential plateaus. Abortion is currently easily accessible everywhere in Vietnam, but some couples choose not to use this service for religious or other reasons, and do not succeed in limiting their family size to the desired number of children. Sterilization can also sharply reduce the demand for abortion, making the family planning program more cost effective. For these reasons, accessibility to good sterilization services is an important goal for all reasonable family planning programs.

In this retrospective study, we have documented the failure of our attempt in the 1990s to make good sterilization services available in Vietnam. Our purpose was to shed light on the reasons for this failure and to identify the manner in which to achieve program success. Two separate and very different initiatives were undertaken in the 1990s to make safe and effective sterilization services available. We began with QS. The first study was undertaken in Nam Ha Province in 1989 (Nam Ha was later subdivided into Ha Nam and Nam Dinh Provinces) and results were very promising. Our second investigation was undertaken in 1990, again with good results. Then demand quickly soared. Before long, commune clinics were reporting that more than 100 women would line up in front of the building for QS on days it was offered. There were no government promotions or campaigns for QS. Unfortunately, there was no budget for training clinicians or other clinic staff, or for community information and education programs or educating counselors. Individuals only knew that they wanted their childbearing terminated and that QS would accomplish this safely. This demand for QS services was spontaneous and from the grass roots. It was apparent to them that QS did not harm women and that it usually worked. It was not clear early on that these critical program shortcomings could have serious negative effects on the program. It was clear that women found the OS method very attractive. For example, in one province, women were counseled both on QS and tubectomy and then given the choice of the two methods. For every woman choosing tubectomy, 11 chose QS. But by late 1992, it appeared that the failure rate with QS was much higher than expected. More and more pregnancies were being reported and this no doubt affected the credibility of QS with both clinicians and women. The reputation of the procedure became tainted. By then we recognized that perhaps there were serious shortcomings in the introduction of QS into our family planning program.

What was strongly discouraged was the use of a single insertion protocol for QS, as this usually reflected poor training and monitoring of clinicians. There was one exception. It was believed for a time that the addition of a single injection of DMPA at the time of the insertion may improve the efficacy of QS [6]. This was later disproved [7]. However, one trial of a single insertion plus DMPA was conducted in these provinces and some of these women appear in Table 8. This table also shows that a significant proportion of women received a single insertion without DMPA, documenting that our training and program monitoring were deficient. The 113 women who had 3 insertions returned to the clinic for a third insertion following an MR that was probably unnecessary.

The data reported in Table 8 offer new evidence on what was responsible for the high QS failure rate seen in our program. It now appears that women who missed a menstrual period returned to the clinic and reported that they were pregnant. They then requested an MR which they received. A failure of QS was then recorded in their record. Given that this method was so new and there was no education about QS offered by the government, women understandably were not confident in its results. Most of these women were rather desperate to avoid another child. The surest treatment was an MR. As previously mentioned, no pregnancy test was available.

The data in Table 8 support this explanation. The reported failure rate for women having only one insertion is 26.9%. However, in a smaller series undertaken to evaluate a possible potentiating effect of DMPA, the failure rate was only 4.4% after more than 6 years. Women were made aware that DMPA caused amenorrhea and were not concerned that it might be a sign of pregnancy and apparently usually ignored this condition. The rate of 4.4% is close to that reported for single insertion in some other countries, but is a small fraction of 26.9%. The DMPA was shown in other studies not to have a potentiating effect and has been abandoned for this purpose [7]. Also, Table 8 reports on the results of a three-insertion protocol. These 81 women had received a third insertion after they had undergone an MR following 2 insertions of quinacrine pellets. Their failure rate of 1.2% after more than 6 years is in line with experiences with this threeinsertion protocol in other countries.

This is compelling evidence that the numbers cited by Sokal and his colleagues in 2000 [5] grossly overstate the true failure rate of QS. The true rates of pregnancy in our program are likely much closer to those seen in other countries than the rates of 12.9% at 5 years after two insertions and 27.3% after one insertion that he reported. We believe that the training preparation for QS was inadequate and that the QS program was permitted to grow much too quickly, allowing our monitoring of the program to be overwhelmed. There was too little evaluation and what was undertaken was done too slowly. We also recognize that there should have been community information and education (I&E) programs developed and implemented. There should have been much more attention given to counseling, with an emphasis on the side effects of QS, including amenorrhea.

For obvious reasons, QS is viewed in Vietnam among providers, patients and the public in general, as failing far more often than it actually does. There are tens of thousands of Vietnamese women who are very happy with their QS who will be supportive of the reintroduction of the method. But before doing so, the practice of QS must be improved by retraining our family planning staff. Much has been learned both from our program and from others and should be incorporated into our retraining efforts. There were serious negative consequences of payment of incentives for surgical sterilization. Too often individuals elected sterilization for the wrong reasons and were unhappy with their decision or treatment. They expressed their discontentment in ways that served to undermine the sterilization program. The payment of incentives has been counter-productive in the long run and should be discouraged.

Given the findings of this research, a survey is needed to determine current perceptions of QS, tubectomy and vasectomy. Misperceptions must be addressed in any I&E program and in subsequent counseling. All methods should be made available and every couple counseled on all three so that they can then make an informed choice with which they will be happy. We have learned that satisfied users of a service are the most effective promoters.

References

- [1] The Editors. Death of a study: WHO, what, and why. Lancet 1994; 343:987-988.
- [2] Agoestina T, Kusuma I. Clinical evaluation of quinacrine pellets for chemical female sterilization. *Adv Contracept* 1992; 8:141–151.
- [3] Guzman-Serani R, Bernales A, Cole LP. Clinical report: quinacrine-fused pellets. In: Zatuchni GI, Shelton JD, Goldsmith A, Sciarra JJ, editors, Female Transcervical Sterilization. Philadelphia: Harper & Row. 1983: 100–104.
- [4] 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.
- [5] Sokal D, Hieu DT, Weiner DH, Vinh DQ, Vach TH, Hanenberg R. Long-term follow-up after quinacrine sterilization in Vietnam. Part I: interim efficacy analysis. *Fertil Steril* 2000; 74:1084–1091.
- [6] Mullick BC, Kessel E, Mumford SD. A potential single insertion protocol for quinacrine pellet non-surgical female sterilization. *Adv Contracept* 1995; 11:239–244.
- [7] Randic L, Haller H, Sojat S. Non-surgical female sterilization: comparison of intrauterine application of quinacrine alone or in combination with ibuprofen. *Fertil Steril* 2001; 75:830–831.