

Clinical Opinion

Sterilization needs in the 1990s: The case for quinacrine nonsurgical female sterilization

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Much evidence suggests that demand for sterilization is a function of supply of surgical sterilization services in less-developed countries. If such services were greatly expanded, the number of procedures performed would grow dramatically. While the prevalence of sterilization is estimated to increase from 23.5% to 28.8% of married women of reproductive age in the 1990s, there will actually be 106,432,000 more couples of reproductive age at the end of this decade than at its beginning who use either no method or a far less effective method with much lower continuation rates than sterilization—nearly a 20% increase. To achieve a mean sterilization prevalence of 47% of married women of reproductive age in the less-developed world, as now seen in the Republic of Korea and Puerto Rico, the number of sterilizations would need to be more than double the current projection for the 1990s: 328,429,000 rather than 159,000,000. The quinacrine pellet method for nonsurgical female sterilization offers hope that this enormous shortfall in sterilization services can be overcome in this decade. (AM J OBSTET GYNECOL 1992;167:1203-7.)

Key words: Female sterilization, nonsurgical, quinacrine

Sterilization is the only contraceptive method that is highly effective and has a continuation rate approaching 100%. For couples who are certain they want no more children, this is a desirable option. Sterilization has been widely accepted around the world. In the United States more than two thirds of the couples who desire no more children have been sterilized; if current trends continue, the proportion will soon approach 80%.¹ As discussed later, cohorts in several less-developed countries approach the current United States rate.

Ravenholt,² after 14 years of experience as the head of the United States Agency for International Development's Population Assistance Program, concluded that it is not possible to establish the level of demand

for a family-planning service unless that service is fully available to all who may desire it. Ravenholt's conclusion is intuitively reasonable.

Actual demand for sterilization has probably never been measured in any country. Indeed, it is unlikely that it can currently be done with accuracy. What has been measured in hundreds of regional and national surveys around the world is the demand for sterilization that has already been met by the supply of services, a more traditional definition, which, in spite of its limitations, we have used for the purposes of this article.

National family planning surveys since 1985 covered about 80% of the developing world's population and about 95% of all contraceptive users. Ross³ recently completed a study of sterilization prevalence and projections in less-developed countries for this decade as a part of the United Nations Fund for Population Activities Population Council Project on "Monitoring and Analysis of National Family Planning Programs." We have assessed the program implications of his data.

Past demand for sterilization

In the developing world as a whole, about 23% of all married women of reproductive age have been steril-

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Table I. Number and percent of married women of reproductive age using sterilization in selected countries (1990 estimate)

Country	Married women of reproductive age	
	No. (thousands)	%
China	82,519	36.8
India	52,511	31.3
Brazil	8,112	30.4
Korea, Republic of	3,639	47.6
Mexico	3,207	21.8
Thailand	2,796	30.4
Bangladesh	2,469	—
Indonesia	1,188	—
Philippines	1,135	—
Colombia	1,082	19.6
Korea, PDR	992	22.3
Taiwan	950	26.0
Argentina	917	19.9
Sri Lanka	830	31.4
Dominican Republic	407	36.5
Puerto Rico	—	46.8
Panama	—	37.7
El Salvador	—	36.1

Data from Ross JA. Sterilization: past, present, future. Stud Fam Plann [In press].

Table II. Proportion of couples using sterilization method in selected cohorts

74% at ages 35-39 for couples with three children in the Republic of Korea, 1988
62% at ages 35-39 in Panama, 1984
60% at ages 35-39 in China, 1988
57% at ages 35-39 in the Dominican Republic, 1986
54% at ages 35-39 in the Republic of Korea, 1988
5 1% at ages 35-39 and 40-44 in India, 1988
49% at ages 30-34 in El Salvador, 1985
43% at ages 35-39 in Brazil, 1986

Data from Ross JA. Sterilization: past, present, future. Stud Fam Plann [In press].

ized and about 50% of all contraceptive users are now protected by sterilization. Surgical sterilization is by far the most important contraceptive method used, preventing more unwanted pregnancies than all other methods combined. High rates of acceptance in many countries can be seen in Table I. According to a 1990 estimate, 49% of all contraceptors and 37% of all married women of reproductive age in China rely on sterilization. In India, 70% of all contraceptors and 3 1% of all married women of reproductive age use sterilization. These two countries account for 82% of all users of sterilization in the less-developed world.

Table II shows a high level of acceptance of sterilization in selected cohorts in very diverse cultures. For example, couples in which the wives or husbands have been sterilized are as follows: in Panama 62% of couples with wives aged 35 to 39 years; in China 60% of those

Table III. Percentage of women wanting no more children in selected countries in 1980s

Country	Women (%)
Peru	73
Colombia	69
Thailand	67
Ecuador	67
Egypt	64
Mexico	64
Dominican Republic	63
Tunisia	58
Trinidad and Tobago	57
Indonesia	51
Kenya	49
Morocco	48

Data from United Nations Fund for Population Activities. Population issues briefing kit. New York: United Nations, 1991.

aged 35 to 39; in India 5 1% of those aged 35 to 39 and 40 to 44; and in El Salvador 49% of those aged 30 to 34.

Ross³ concludes from these surveys that if current trends continue, 80% of couples in a number of developing countries will have been sterilized by the time the woman reaches age 50. Collectively, the data in Tables I and II confirm the broad acceptance of sterilization in different cultures where it has been widely offered. Furthermore, a high percentage of women in many countries want no more children (Table III). For example, surveys undertaken in the 1980s found that 73% of women in Peru want no more children, 69% in Colombia, 67% in Thailand, 64% in Egypt, and 51% in Indonesia. Sterilization is a realistic option for these couples, yet the majority of them do not have access to the method.

Unfortunately, less-developed countries have not been able to offer surgical sterilization to all who want it without significant barriers—a prerequisite for establishing true demand for this procedure.

Projected demand for sterilization in this decade

Three different estimates have been made for the number of new sterilizations that will be performed in this decade. Mauldin used the simplest approach by taking the United Nations medium projection of the total fertility rate and keeping the present method mix through time. He estimated that there will be 15 1,000,000 new sterilizations in the 1990s.³

Ross³ applied two approaches. In one he used the TARGET computer simulation program to make the projection. He started with the current method mix and prevalence level for all less-developed countries and assumed that the sterilization share will increase from 50% to 60% over the decade. An estimate of 164,000,000 was obtained.

In a second estimate he attempted to be more precise

Table IVA. Losing ground with program reliance on surgical sterilization in 1990s

728,170,000*	Couples in reproductive age pool in less-developed countries in 1990	(a)
931,783,000*	Couples in the reproductive age pool in less-developed countries at end of decade	(b)
203,613,000	Couple increase in reproductive age pool	(c)
$c = b - a$		
171,328,000*	Couples using sterilization in less-developed countries in 1990 for prevalence of 23.5%	(d)
Year 1990 prevalence = $d \div a \times 100$		
159,000,000*	New sterilizations in 1990s	(e)
61,819,000*	New sterilization that will simply be replacements for couples leaving pool because of aging	(f)
97,181,000	Increase in pool of sterilized couples of reproductive age during decade	(g)
$g = e - f$		
47,849,000	New sterilizations will be needed just to keep same prevalence because of growth of reproductive age pool	(h)
$h = c \times 0.235$		
49,332,000	Users remaining to raise prevalence	(i)
$i = g - h$		
Prevalence increases from 23.5% to 28.8% of couples during decade		
Year 2000 prevalence = $d + g \div b \times 100$		
106,432,000	Increase in number of couples during decade who will use either no method or methods that are far less effective and have much lower continuation rates than sterilization	(j)
$j = c - g$		
There will be nearly 20% increase in number of these couples during decade		
Percent increase = $j \div (a - d) \times 100 = 19.1\%$		

*Data from Ross JA. Sterilization: past, present, future. Stud Fam Plann [In press].

by using current trends in the growth of the sterilization acceptance rate. This yielded an estimate of 159,000,000 new sterilizations in the 1990s, which we have used in our analysis.

Ross noted that at the beginning of the decade there were 728,170,000 couples in the reproductive age pool of less-developed countries; however, by the year 2000 there will be 931,783,000 for an increase of 203,613,000 couples. In 1990 there were 171,328,000 couples who relied on sterilization, and although 159,000,000 new procedures will have been performed this decade, 61,819,000 are needed just to replace those leaving the pool. In spite of the resulting 97,181,000 increase (159,000,000 - 61,819,000) in their number, 47,849,000 new sterilizations will be needed just to keep the prevalence the same, 23.5%. Only 49,332,000 users remain to raise the prevalence, which will increase to 28.8%. These findings are summarized in Table IVA.

Program implications

The Ross findings have alarming program implications. Through further calculations (Table IVA) it can be seen that there will be 106,432,000 more couples at the end of the decade than at its beginning who will be using either no method or a less effective one with

a much lower continuation rate than sterilization. This is nearly a 20% increase during the decade.

Our goal should be to make it possible for **the prevalence of sterilization to reach the level now seen in the Republic of Korea and Puerto Rico (recognizing that it took decades to reach this level in Puerto Rico). If sterilization were made fully available to all couples in less-developed countries, we assume the prevalence could resemble the Korean and Puerto Rican levels (47% of married women of reproductive age).** In the two largest less-developed countries the figures are already at 37% (in China) and 31% (in India). As noted earlier (Table I), some cohorts have already exceeded 47% in countries as diverse as Panama, China, the Dominican Republic, India, and El Salvador.

In the 1980s a majority of women (73% in Peru) in many different countries (Table III) said they wanted no more children, further evidence that 47% of married women of reproductive age is a reasonable goal. However, creating the possibility and realizing it are two different goals. We will not know if the two goals can be achieved until we try.

To increase the prevalence to 47% of married women of reproductive age throughout the less-developed countries during the 1990s, the number projected to be performed must be more than doubled from the

Table IVB. Unmet demand for sterilization in less-developed countries at end of 1990s with 1990 prevalence rate of Republic of Korea and Puerto Rico as standard (47% of married women of reproductive age)

437,938,000	Sterilizations needed to achieve 47% prevalence in less-developed countries by year 2000	(k)
	$k = b \times 0.47$	
109,509,000	Number sterile in 1990 who will remain in pool of sterilized couples in 2000	(l)
	$l = d - f$	
169,429,000	Deficit in number of sterilizations in year 2000 if surgical sterilization is relied on to achieve 47% prevalence of married women of reproductive age	(m)
	$m = k - (d - f) - e$	

159,000,000 estimated by Ross to 328,429,000, an increase of 169,429,000. This estimate is obtained with figures from Table IVB. A 47% prevalence among the 93 1,783,000 couples expected by the year 2000 would mean that 437,938,000 couples would be sterilized at that time. To achieve this prevalence we would add the number in 1990 who will remain in the pool of sterilized couples of reproductive age in the year 2000 (171,328,000 - 61,819,000 = 109,509,000), the number of sterilizations currently projected for the 1990s (159,000,000), and the 169,429,000 needed to arrive at 437,938,000 sterilizations.

Although sterilization is the method of choice for couples who are sure they desire no more children, clearly surgical sterilization cannot safely meet the needs of this population in less-developed countries in the 1990s. Almost half of all surgical sterilizations in the 1990s will occur in China alone. China accounts for approximately one fourth of the population in less-developed countries. Thus Chinese couples will be three times as likely as others in less-developed countries to use this method, strongly suggesting that there will be considerable unmet need in the other less-developed countries. While the prevalence of surgical sterilization will rise, there will be a remarkable increase in the absolute number of couples who would choose this method but would have no hope of getting it. It is unlikely that the availability of surgical sterilization could meet this need safely in this decade simply because of the limitations of surgical resources.

The quinacrine pellet method

A recent review of ongoing research of nonsurgical method? suggests the quinacrine pellet method of nonsurgical female sterilization to be the only one ready for large-scale use. The quinacrine pellet method as developed by Zipper et al.⁶ involves transcervical intrauterine administration of 252 mg of quinacrine as pellets through a modified copper T intrauterine contraceptive device inserter. Two insertions a month apart are made in the proliferative phase of the menstrual cycle,⁷ resulting in occlusion of the fallopian tubes. Pre-

hysterectomy studies⁸⁻¹⁰ show this occlusion to be caused by inflammation and fibrosis, and it is limited primarily to the intramural segment of the tube.

Experience with this method is growing rapidly. At the First International Symposium on the Quinacrine Pellet Method of Nonsurgical Female Sterilization held in Bandung, Indonesia, on Sept. 15, 1991, the results of studies of >25,000 cases were reported. It is estimated that >50,000 procedures were performed worldwide by mid-1992. We project that current investigators alone will have completed 175,000 by the end of 1992.

The method is proving to be effective." With the addition of adjuvants, such as antiprostaglandins,¹² the failure rate has been markedly reduced when compared with results of studies that used quinacrine alone. With recent improvements the method is currently successful 98% to 99% of the time. Four studies have been reported that used a protocol of three insertions of 252 mg of quinacrine pellets alone. In 1980, Zipper et al.⁶ reported a 12-month cumulative gross life-table pregnancy rate of 3.1 per 100 women at 1 year. In 1984, Guzman-Serani et al.¹³ reported cumulative gross life-table rates per 100 women of 0.7 at 1 year and 4.3 at 3 years. The next year Bhatt and Waszak¹⁴ reported cumulative gross life-table pregnancy rates per 100 women of 0.0 at 12 months and 3.7 at 4 years. In 1987, Zipper et al.,⁷ reporting on another study, found cumulative gross life-table pregnancy rates per 100 women of 3.3 at 1 year and 6.7 at 2 years.

The method is proving to be safe. At the Bandung symposium reports were given on 2000 cases from Chile, 9300 from India, 10,000 from Vietnam, 2700 from Pakistan, and 1000 from other countries. Not a single serious complication was reported among these 25,000 cases. However, we would have expected 425 complications from 25,000 surgical sterilizations—a rate of 1.7%.^{15, 16}

Not a single death has been reported with the quinacrine pellet method. Two reports on deaths attributable to surgical sterilization in developing countries found rates of 19 deaths¹⁷ and 20 deaths¹⁸ per 100,000

procedures. However, for developing countries generally, the rate is thought to be six to nine deaths per 100,000 procedures compared with 1 or 2 in the United States.¹⁹ Thus we would have expected two deaths in 25,000 surgical sterilizations.

The quinacrine method has three other very important attributes. The pellets and inserters cost <25 cents (U.S.) per sterilization, affordable to the world's poorest women if it is made accessible. It is a procedure that anyone trained in intrauterine contraceptive device insertions and counseling can perform. Expansion of services can be very rapid. For example, in Vietnam, 200 procedures were performed in 1988 and 1989. In the month of September 1991 alone, the number had reached >7000. In 1991 and 1992, it is expected to exceed 100,000.

As a result of its ease of delivery, this method can save many lives by raising contraceptive prevalence among high-risk mothers who desire no more children in countries with high maternal mortality. Nearly 500,000 of these women lose their lives each year as a result of pregnancies that were mostly unwanted.²⁰ For example, in these countries, on average, a sterilization prevents two pregnancies. On the Indian subcontinent, maternal mortality is 500 per 100,000 live births. For each additional 100,000 procedures performed because of the ease of delivery of this method, the lives of twice the maternal mortality rate would be saved (1000 lives per 100,000 procedures). The 12,000 procedures performed in India and Pakistan that were reported at the Bandung symposium saved an estimated 120 lives, because they all were essentially additional procedures.

We know only too well that the requirements in providing safe surgical sterilization, the necessary surgical skills, the facilities, the equipment, and the supplies will seriously restrict the provision of these services. Reliance on surgical sterilization to meet world demand for sterilization services in this decade is certain to result in a serious shortfall. The quinacrine pellet method offers hope that this shortfall can be remedied.

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