

Editorial



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Prospects for Nonsurgical Female Sterilization

There has been a dramatic increase in couples controlling their fertility through sterilization over the past two decades, from an estimated 15 million to over 100 million [1,2]. Varying greatly from a high of 43% in Canada to less than 1% in most of the African continent [3], sterilization prevalence tends toward 30% in the United States, New Zealand, Panama and Korea, countries where the procedure is readily available [3]. And in China, despite heavy reliance on IUDs, it is still as much as 24.5% [3]. This increase in sterilization prevalence reflects the growth of relevant services and improvement in outpatient surgical methods that intensify demand for and facilitate delivery of those services.

Unmet need

Nevertheless, a considerable unmet need is all too apparent. The World Fertility Survey provides evidence that approximately half the fecund women in developing countries want no more children, but fewer than half of these women use effective methods of fertility control [4]. This is an estimate of unmet need for sterilization. In addition, many of them continue to use effective reversible methods of contraception for long periods after they desire no more children. This occurs when access to sterilization is limited or physicians are reluctant to refer to these services. But other factors are also at play, including religious proscriptions and fear of surgery.

For sterilization services to be freely available throughout the world (excluding China), they would have to increase fivefold to meet the need, with a projected average prevalence of 31.3% [5]. Such a prospect is unlikely in developing countries, where surgical female sterilization, for which the demand is greatest, could not be safely provided to this extent.

Nonsurgical female sterilization

A simple method of nonsurgical female sterilization has been developed by Dr. Jaime Zipper of Santiago, Chile [6]. It consists of two transcervical applications of 250 mg of quinacrine as pellets, using a Copper T IUD inserter. Insertions are made a month apart in the proliferative phase of the menstrual cycle. Techni-

cally, any health care provider trained in IUD insertions could deliver this sterilization method, which appears to be safe, with no serious complications reported in over 10,000 insertions. Its one drawback is a 5% lifetime failure rate [7] compared to a 0.5% failure rate in better studies of surgical female sterilization [8]. On the other hand, the quinacrine pellet nonsurgical method has no operative mortality or serious morbidity and does not have the increased risk for tubal pregnancy among its failures that surgical sterilization has.

It is obvious that the health risks of sterilization failures, including ectopic pregnancies, vary among countries. A comparative estimate of surgical and nonsurgical (quinacrine pellet) sterilization mortality per 100,000 sterilizations for Bangladesh and the United States gave results shown in Table I. Although little difference is seen between mortality risk for surgical and nonsurgical methods in a developing country like Bangladesh, with high **maternal** mortality estimated at 570 per 100,000 live births, a persuasive argument can be made for the nonsurgical intervention, to the extent that this method can increase availability of sterilization services and result in increased sterilizations performed for women desiring no more children.

The arithmetic behind this argument is simple. On average, each sterilization prevents two births (or abortions). With a maternal mortality of 570, the lives of 1140 women are saved per 100,000 sterilizations, at a cost of 30 deaths attributable to sterilization. The risk/benefit ratio is 30/1140, or 1 to 38. Few other health services for women in Bangladesh can claim this level of risk/benefit ratio.

The cost of materials for each completed quinacrine pellet sterilization is one dollar (US). Financial cost-effectiveness is also impressive. Let us use India as an example, with a maternal mortality similar to Bangladesh and a vast network of over 12,000

Table I Estimated deaths attributed to surgical female sterilization on nonsurgical quinacrine female sterilization in Bangladesh and the United States (per 100,000 procedures) [9].

	Estimated deaths			
	Surgical		Nonsurgical	
	Bangladesh	USA	Bangladesh	USA
Procedure	19.0	4.0	0.0*	0.0*
Ectopic pregnancy	10.7	0.2	1.7	< 0.1
Delivery/abortion	2.9	< 0.1	28.5	0.4
Attributable	32.6	4.2	30.2	0.4

*Based on limited published reports.

primary health centers, many of them already providing IUD insertions. I estimate that an additional million sterilizations would occur annually in India if the quinacrine pellet method were introduced into its national family planning program. Each million sterilizations would save over 10,000 women's lives, at a cost of one million dollars for needed supplies, or \$100 per life saved.

For countries with a lower maternal mortality than Bangladesh, the same arithmetic argues for substituting this nonsurgical approach for present surgical methods. In the United States, relatively few deaths would be avoided because of the low attributable risk of surgical sterilization. Notwithstanding, it is unfortunate that this option is not available to women in this and other industrialized countries.

To date, Phase I studies of the quinacrine pellet method have been completed to the satisfaction of the United States Food and Drug Administration with financing by the Agency for International Development (AID). But needed Phase II trials are proceeding very slowly, because AID judges only a single insertion method to be practical in the field [10]. The World Health Organization terminated support of the methyl-cyanoacrylate method of nonsurgical female sterilization for the same reason [11]. However, few women obtain surgical female sterilization with a single visit. Field experience with these nonsurgical methods shows very few women fail to return for a second insertion. In the case of the quinacrine pellet method, which has no increased risk of ectopic pregnancy among failures, women receiving only a single insertion will have a permanent method of fertility control about as effective as barrier methods without the inconvenience.

At this time there is little prospect for official approval of the quinacrine pellet method of nonsurgical female sterilization by the World Health Organization or the United States Food and Drug Administration. Developing countries should have the courage to initiate trials of this promising method of nonsurgical female sterilization as a high priority in fertility research. It could save the lives of **countless** women.

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