

Will American women want quinacrine?

As the number of American couples desiring permanent methods of birth control continues to rise, the time and money available to family planners to perform the procedures is shrinking, sources tell *Contraceptive Technology Update*. If a safe, effective, simple, and inexpensive method of sterilization were available, women would choose it over a tubal ligation, they say.

Such a method may be on the distant horizon if quinacrine, a chemical inserted into the uterus in pellet form in the same manner as an IUD, is made available in the United States. So far researchers can prove it is simple and inexpensive, but they have yet to convince some family planning experts it is completely safe and effective. (See related stories, pp. 41 and 45.)

If quinacrine can pass safety and efficacy standards in the United States, it will compare favorably with surgical sterilization.

In a large field trial in Vietnam,¹ the major complication rate was found to be 0.03% based on federal Centers for Disease Control and Prevention criteria.* No deaths have occurred among women using the method, and common side effects include lower abdominal pain, mild fever, headache, and menstrual changes that usually disappear in three months. Rare side effects include severe bleeding, pruritis, and synechiae, a treatable condition characterized by the opposing walls of the uterus sticking together.

Based on the same CDC criteria, laparoscopic sterilization is associated with a major complication rate of 1.7%. In a study conducted by the CDC of 3,500 women in the United States,² 37 women (1.1%) required unintended major surgery, 16 women (0.4%) required rehospitalization, and seven (0.2%) were treated for febrile morbidity. This study also specified women at higher risk for complications from surgical sterilization, including diabetic and obese women, and women who had previous abdominal or pelvic surgery, lung disease, or a history of pelvic inflammatory disease (PID).

Until recently, it seemed that surgical sterilization would be easier to reverse than the quinacrine method; opening tubes obstructed with quinacrine was thought to require expensive and time-consuming reimplantation of

unaffected parts of the tube. But in December 1993, an American radiologist successfully reversed two nonsurgical sterilizations in India by using a procedure much like the cardiac treatment called angioplasty. Using fluoroscopic guidance, a set of catheters in various sizes was used to ream out the blocked tube, taking about 45 minutes, says **Amy Thurmond**, MD, associate professor of obstetrics and gynecology at Oregon Health Sciences University in Portland. The two Indian women had lost their children and they wanted to try to get pregnant again, says Thurmond, who has been using the catheter technique on women whose tubes are blocked due to complications from sexually transmitted diseases.

Meeting demand for sterilization difficult

Female sterilization is chosen twice as often by couples than is male sterilization. In the United States in 1987, 640,000 female sterilizations were performed, compared to 336,000 vasectomies.³ And family planners say many more women would choose sterilization if they had access to it.

"I think there are a lot of women in America who cannot afford a surgical sterilization who would like to be sterilized," says **Stephen D. Mumford**, DrPH, president of the nonprofit Center for Research on Population and Security in Research Triangle Park, NC. "They either don't have medical insurance, their insurance doesn't pay, or they don't have access to a Medicaid-funded system."

There is an unmet need for sterilization in this country, says **Margie Rose**, MPH, JD, head of the women's preventive health branch of the State Department of Environment, Health, and Natural Resources in Raleigh, NC. Title X-funded programs such as hers have the added burden of limited resources — clinician time and money — that makes meeting the demand for services difficult.

"I think the cost consideration is looming very large around sterilization, particularly female sterilization, which is more expensive," she says.

If quinacrine proves to be safe and effective, and there were no sanction against using it by the Office of Population Affairs (which administers the Title X program), Rose says she can't imagine any family planning program not being interested in the new method.

“For those women who have completed their families and are quite certain that they don’t want additional children and don’t want to use long-acting methods for whatever reason, I would think those women would welcome any options available to them,” Rose says.

Whether American women will accept the concept of quinacrine — a chemical that works by scarring the fallopian tubes — remains to be seen, Rose says. Acceptability data was not measured in the recent Vietnamese study.

In the Namha Province of Vietnam, where part of the large quinacrine study was carried out, surgical sterilization was available at all district hospitals, but quinacrine was only available at several community health centers; the women still chose quinacrine in a ratio of 11:1 over surgical sterilization.⁴

Accepting data from another country is dangerous because lifestyles and cultures are different, warns **Gary K. Stewart**, MD, medical director of the Planned Parenthood Association of Sacramento (CA) Valley. In Vietnam, several lifestyle factors may affect the acceptability and the efficacy of quinacrine, such as a probable lower frequency of intercourse and perhaps an older population of women using the method, he says.

“If you take the same study and do it again, let’s say in Sacramento, things would be different,” Stewart says.

The unpleasant side effects that some women experience will probably make quinacrine unacceptable to American women, says **Judy Norsigian** of the Boston Women’s Health Book Collective.

“I suspect that only women with deep-seated fears about incisions would want to do something like this because it is a very caustic substance,” she says.

Nonsurgical method preferred

But fear of surgery and its aftermath can cause a great deal of dread and hesitation, clinicians say.

“The real reason this is going to take off in America is, getting a surgical sterilization is no fun,” Mumford contends. “Even with laparoscopic sterilization, you’re incapacitated for a week. You can still do things but there’s a lot of pain and a lot of serious complications, including death, which is rare but it happens. American women are going to take advantage of this

method if it is made available.”

Women will do almost anything to avoid surgery, says **Diane Lescher**, sterilization program manager at the Planned Parenthood of San Diego and Riverside (CA) counties. The easier a procedure is, the more accepting of it a woman will be, she says.

Surgery is a lot to go through, agrees Joseph **Feldman**, MA, manager of surgical and counseling services at Planned Parenthood of Central and Northern Arizona in Phoenix. If both options are available and the risks of each are about the same on balance, people will choose the nonsurgical method every time, he says.

Feldman says he thinks quinacrine will be popular if it is approved by the U.S. Food and Drug Administration. Experts interviewed by CTU say that will be a long time coming.

Drugs unapproved by the FDA can still be given to American women by a physician prescribing off label, but they are not provided to developing countries through the U.S. Agency for International Development (USAID). USAID’s policy is to only provide FDA-approved drugs in its family planning programs overseas, says **James Shelton**, MD, head of the research division in the Office of Population, USAID, in Arlington, VA. Of quinacrine he says, “a nonsurgical approach to female sterilization would be a wonderful method to offer women, and a lot of women would benefit from having that kind of option available.”

Should quinacrine be available now?

Proponents of quinacrine are calling for its limited use in America starting now. Women desiring surgical sterilization but who are at high risk for complications should be informed of this option, says **Elton Kessel**, MD, secretary general of the International Federation for Family Health in Carlton, OR. Once the women fully understand that quinacrine has a higher failure rate but a lower complication rate than the surgical method, they could then be provided with the quinacrine pellets and given three months worth of reliable contraception. At the end of three months, they could be tested with dye to see if their tubes were occluded, and if they weren’t, a surgical procedure could be done, he explains.

Some family planning providers say they agree to such a limited use, but only for certain women who understand the conditions.

“I certainly would not use this method at this

stage for someone who wanted surgical sterilization and was able to get it," says **Pouru Bhiwandi**, MD, MPH, a gynecologist in private practice in Raleigh, NC. "But there is a group of women who are afraid of surgery, or for whatever reasons do not want to have a surgical procedure. This would be a good alternative option if they clearly understood this had a higher failure rate."

Bhiwandi, formerly the medical director of Family Health International, took part in several small Asian clinical trials involving quinacrine. FHI is a reproductive health research organization in Research Triangle Park, NC.

Since we believe in the "cafeteria plan" of birth control in America, the role for quinacrine to play in this country is to be one more option, Bhiwandi says.

"I don't in any way see this as replacing surgical sterilization, but I do see it as one more option offered to women," she says.

References

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Target community foundations to fund family planning

What can clinicians do to improve service delivery in the face of shrinking federal dollars? How can family planners get a much-needed community intervention project under way? The answer might be right in your own back yard, say funding experts interviewed by *Contraceptive Technology Update*.

Administrators at several foundations that have funded family planning say the best way to get funding for your projects is to approach a

relevant community foundation.

"Obviously, the community foundations are far more directly involved with social-service delivery in their immediate area," says **Ruth Hennig**, administrator for The John Merck Fund in Boston, an independent trust fund with a focus on reproductive rights issues. A recent example of its funding efforts include grants made to promote the availability of the abortifacient RU 486 in the United States, Hennig says.

Peter Beilenson, MD, city health commissioner in Baltimore, found a local foundation to sponsor the purchase of Norplant kits by approaching the Association of Baltimore Area Grant Makers. That led to a grant of about \$70,000 from the local Abel Foundation, a group that funds many health-related activities with money originally donated by the founders of the city newspaper, the *Baltimore Sun*, Beilenson says.

The grant money was used not only to buy Norplant implant kits, but also to create a video on the method. The video is now being offered for sale. (See related article on p. 52.)

If you don't know where to begin and how to identify local foundations, Beilenson suggests contacting your local health department. You may even want to propose a grant in conjunction with the health department to improve your chances of success, he says.

Additionally, the health department may be able to pull together other providers in the area — creating a type of consortium — and you could apply for grants as a group, he explains.

For additional information on foundations, the Foundation Center in New York can be helpful. (See related article on p. 51.)

How to apply for funds

Your first step in the proposal process is to contact the foundation to determine its guidelines, says **Suzanne Holland**, a program assistant for The David and Lucille Packard Foundation in Los Altos, CA. This foundation has made grants for family planning in its surrounding four-county area, primarily in San Francisco and Monterey Bay.

Most foundations have written guidelines that are available to anyone searching for grant funding, Holland tells CTU. It is important to start your proposal process knowing what each foundation's guidelines are, because some foundations have strict proposal requirements, she explains. For instance, some may want your format to