

5

Discussion: Feasibility and Acceptability of Transcervical Sterilization

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IN DEVELOPING COUNTRIES, WHERE PHYSICIANS ARE SCARCE, HOW FEASIBLE IS SURGICAL REVERSAL, AND HOW IMPORTANT IS REVERSIBILITY AS A CRITERION, IN EVALUATING A TRANSCERVICAL STERILIZATION METHOD FOR PROGRAMS?

There is considerable discussion of reversibility of sterilization procedures, but considering the physician/population ratios and the distribution of physicians in the developing world, a woman seeking reversal would have difficulty finding a gynecologist who is trained to do reversals. A few centers have been established around the world to offer reversal of currently used sterilization methods, but their capacity for reaching large numbers of people is limited. Relative to the number of sterilizations being done, the demand for reversal is very small.

Reversibility becomes important when it is a major advantage of a method, as with the silicone plug or the fimbrial hood. These techniques might have wide appeal and applicability, especially in countries where conventional procedures are often prohibited.

WHAT ARE THE MINIMUM REQUIREMENTS OF A TRANSCERVICAL METHOD, IN TERMS OF EFFICACY, FOR PROGRAMMATIC USE?

Opinions differ on this question. A conservative standard would be a rate of effectiveness fairly close to that achieved with the IUD, perhaps a 2% to 3% failure rate in terms of pregnancy, preferably with one application, or with some way of determining whether or not the closure has been successful.

In considering effectiveness standards, it is important to distinguish between tubal closure rates and pregnancy rates; the actual pregnancy rate may be lower than one would expect, on the basis of the tubal closure rate. With quinacrine, for example, an 85% bilateral tubal closure rate may not seem adequate, whereas the actual pregnancy rates achieved with the method may be low enough to meet program standards.

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Also, it is critical from a programmatic viewpoint not to consider failure rates for chemical sterilization procedures on the same basis as the rates for conventional surgical sterilization procedures. The generally accepted pregnancy rate for IUDs over a 5-year period is 9/100, and the usual rate for surgical sterilization is less than 0.5%, although in some instances, the rate is higher.

HOW ACCEPTABLE, CULTURALLY AND PROGRAMMATICALLY, IS A METHOD REQUIRING TWO OR EVEN THREE TREATMENTS (AND VISITS TO THE CLINIC) TO ACHIEVE REASONABLE EFFICACY?

A two-treatment procedure is reasonably acceptable, provided that the first visit is not an unpleasant one; however, much depends on the woman's experience during the first visit. The acceptability literature provides information on factors that might seem like frills to the investigator but are important determinators of acceptance, such as availability of child care, not keeping women waiting 6 or 8 hours for a procedure but treating them in perhaps half an hour, provision of good support from the staff, the relative ease with which the service is provided, the distance the woman has to travel to the site of the procedure, and other factors. If at the first visit the experience does not cost a woman a day's absence from her work and it is not humiliating or unduly painful, then she is likely to return for a second treatment. If it is difficult for her, then getting her to return will be difficult. There is an enormous variation in the quality of service provided in different programs around the world, and these factors can create an enormous variation in the success and acceptability of a procedure.

Another significant consideration is the availability of other contraceptive options. Assuming that for much of the population of the developing world, sterilization is unavailable, in terms of the physician/population ratios, then the choice is for the woman to become pregnant again and again using ineffective methods or no methods, or to have a lower pregnancy rate by using the more simply applied and cheaper method, which might be available through less highly trained physicians or paramedical personnel, or which might require several visits to a clinic.

One concept of program strategy is to offer a broad enough range of options, in a kind of family planning cafeteria, with methods varying in price, effectivity, and ease of delivery and permanence, so that almost everyone will like something on the menu.

WHAT PHARMACOLOGIC MEANS ARE AVAILABLE TO RELAX THE TUBAL OSTIA TO ENSURE ADEQUATE INSTILLATION OF AN AGENT?

Swedish investigators are having fairly good success in humans using β_2 -adrenergic agents for the relaxation of the intramural part of the oviduct. The relaxation effect lasts for 15 to 20 minutes.

ARE THERE ANY DATA INDICATING THAT PROGESTIN SIGNIFICANTLY INHIBITS TUBAL REPAIR AND THAT IT WOULD INCREASE THE EFFECTIVENESS OF ANY OF THE TRANSCERVICAL METHODS?

There does not seem to be any evidence that progestin would be useful for inhibiting repair. Some investigators have tried unsuccessfully to **accelerate** healing in laboratory animals by hormonal methods.

In a study of patients treated with methyl cyanoacrylate, the data were analyzed for differences in closure rates in patients using Depo-Provera or oral contraceptives versus closure rates in patients using condoms and diaphragms. No statistically significant difference was seen.

One observation may be pertinent: a study of the pregnancy rates of women who are operated on because they have true tubal occlusion and who undergo salpingostomy shows that a large proportion of pregnancies occurring in the first 6 months after the operation are ectopic, whereas nearly all the intrauterine pregnancies cluster in the third 6 months after the operation, with some intrauterine pregnancies in the middle 6 months. One possible, although weak, inference from this is that some type of regeneration has taken place over time; but what kind is not known.

WHAT IS THE INCIDENCE OF ECTOPIC PREGNANCIES WITH CHEMICAL STERILIZATION TECHNIQUES? HAVE ALL THE FAILURES BEEN INTRAUTERINE?

One of the major concerns with the nonsurgical or chemical methods of female sterilization has been failures resulting in intrauterine pregnancies, but, more importantly, perhaps, are those resulting in ectopic tubal pregnancies. A review of the literature of the chemical techniques used at present, as well as of those used in the past, does not reveal any cases of ectopic pregnancy with these methods. The numbers are very small, however, and the follow-up is limited.

DOES HYSTEROSCOPY AID IN IDENTIFYING THE TUBAL OSTIA?

In one center, where investigators are highly skilled in hysteroscopy, they have observed through the hysteroscope that the tubal orifice modifies its shape as pressure is increased and they have found that if the pressure inside the uterus is kept constant, whichever distending medium is used, that identification of the tubal orifices is easy. They use a special uterine insufflator for fluids that keeps the pressure constant at 180 mm Hg. Besides providing easy visualization of the tubal ostia, this approach avoids bleeding in the uterine cavity, even during training sessions lasting 10 or 15 minutes.

In a group of 1284 patients undergoing sterilization by electrocoagulation, the operators failed to identify the tubal orifices in only two patients. One woman had a polyp in the cornual region, and the other patient was in the wrong phase of the cycle. The mucus plugs were easily removed from the

tubal orifice through a Storz hysteroscope with a double surgical channel. Most tubes could be catheterized if no more than 1 cm to 1.5 cm of the catheter was introduced into the tube.

However, very few hysteroscopists have the skill and experience to visualize the tubal ostia almost every time. The procedure must be performed during the early proliferative stage of the cycle, and even then there is about a 10% failure to find both tubal ostia. This is an important consideration when hysteroscopy is evaluated for programmatic use.

WHAT EFFECT DOES THE LITERACY OF THE SUBJECTS HAVE IN THEIR ABILITY TO RESPOND TO THE ACCEPTABILITY QUESTIONNAIRE?

Obviously, in areas where literacy is very low, the woman herself does not fill out the questionnaire; an interviewer administers it. It is quite extensive, and a woman must be fairly literate to fill it out. However, with a population such as one in Los Angeles of newly arrived women from Mexico, use of an interviewer works very well and the data seem reliable. The investigators tested it for reliability in a poor Mexican-American clinic in San Antonio. If the woman filled out the questionnaire before she went in to see the physician, she was asked to repeat her answers to certain questions after she had finished her appointment, and the reliability was close to 97%.

IS PATIENT REFERRAL OF FRIENDS FOR PARTICIPATION IN A STUDY PROGRAM A RELIABLE INDEX OF ACCEPTABILITY OF A METHOD UNDER INVESTIGATION?

In various clinical trials over the years, one good measure of acceptability has been whether patients would subsequently refer their friends for treatment. In acceptability studies this is considered a reliable index of acceptability that the individual researcher might use. In one analysis of the results of a study looking at characteristics of women most affected by the attribute of reversibility, one of the variables having a strong impact on selection of sterilization, either a permanent or reversible method, was a friend's prior experience with sterilization. That fact overwhelmed almost all of the other variables.

WHAT NAME IS SUITABLE FOR THE PROCEDURES BEING DISCUSSED?

Chemical transcervical methods of sterilization are hopeful as another "dish on the menu," but providing a proper name for them that will be easily understandable and acceptable to consumers is a problem. These procedures probably should not be called nonsurgical sterilization because people associate sterilization with surgery, so it would sound to people like nonsurgical surgery. Logically, these are contraceptives with a low failure rate and a 100% continuation rate. However, that is difficult to explain to a lay audience, so a new name is needed.