

Fertility Drug for Single Births

by Barbara J. Culliton

From famine to feast and back again, the story of a childless woman miraculously conceiving does not always have a happy ending. Chances are that if fertility drugs succeed in stimulating ovulation in a sterile woman, she will not only become pregnant, she will become too pregnant. Instead of having one child, or twins at best, she may have quadruplets, quintuplets or even sextuplets, and her joy at conceiving may be dimmed by the tragedy that so often attends multiple births.

One reason for sterility is that ovulation (the release of a ripe egg) never takes place. Fertility inducing drugs aimed at remedying this deficiency are generally so potent they trigger the release of several eggs from the ovaries; hence, multiple fertilization resulting in multiple births.

The solution, obviously, is a drug that stimulates the release of one, not several eggs, and that solution seems near at hand.

A few years ago, scientists looking for a compound to limit the size of animal litters, found one that had a beneficial effect on women as well.

For several years now doctors throughout the country have been conducting experimental tests with an offshoot of that drug. It is clomiphene citrate, a synthetic compound that resembles female hormones and is called Clomid by its manufacturer, the Wm. S. Merrell Company in Cincinnati. Results of these tests have been submitted to the Food and Drug Administration which is expected to approve Merrell's new drug application soon. A spokesman for the company said, however, that no date for commercial production has been set.

Clomid does its job by working through the pituitary gland where it synchronizes the production of gonadotrophins, sex hormones that stimulate ovulation. If the pituitary fails to release these hormones in the right amounts or at the right time, no ovulation occurs.

Scientists believe this is what happens, or doesn't happen as the case may be, in sterile women.

The reason Clomid is less prone to sparking multiple births than other compounds used for the same purpose is probably related to the fact that it does its work through the pituitary rather than directly on the ovaries. In

other words, it reminds the pituitary to release natural hormones in proper fashion, setting off a natural chain of events.

Clomid's leading opponent, so to speak, is Perganol, a natural hormone drug prepared by Cutter Laboratories of California. Perganol itself contains gonadotrophins, obtained from the urine of women who have passed menopause. Though they no longer have functioning ovaries to regulate the pituitary gland's production of the stimulating hormones, their glands continue to produce these hormones which are excreted in urine.

There is, as yet, no way to determine how much of the hormone a woman herself may be producing; therefore, it is hard to know how much of the potent Perganol to administer.

Too little, no ovulation; too much, multiple birth.

Consensus among experimenters is that Clomid—cheaper, less powerful, less risky—should be tried on an infertile woman before there is resort to Perganol.

One must remember, however, that not every barren woman can be helped by fertility drugs, no matter how potent.

Dr. Edward Tyler, an endocrinologist at Los Angeles Medical School, has been using Clomid in controlled studies since the end of 1959. He reports that of the 1,200 women given the drug, which comes in tablet form, 40 percent ovulated and one third of that group or 160 women became pregnant. Even though the number of pregnancies seems low, it is considered a good percentage by researchers in the field, Dr. Tyler says.

The number of pregnancies following Perganol therapy is higher, he commented, but so is the number of premature infant deaths reported for women taking this drug.

A woman usually takes Clomid three or four days in a row, Dr. Tyler reported, and will ordinarily ovulate within a week if she is going to. Since his patients are not ovulating otherwise, they generally have irregular menstrual cycles at best, so any three or four days in a month will do.

Among the undesirable side effects with both Perganol and Clomid is the growth of ovarian cysts, a noncancerous, liquid-filled sac on the ovary. Of Dr. Tyler's 1,200 patients, 15 to 20

percent developed cysts, but most of the cysts dissolved within a few weeks time. Only one woman required surgical removal.

Any physician treating a woman with fertility drugs must be alerted to this possibility, he said, so that if a cyst does develop, surgery is not performed immediately and perhaps unnecessarily.

Many investigators, Dr. Tyler among them, and many infertile women consider the risk of a cyst a small price to pay for becoming pregnant. This is among the points FDA authorities will consider in reaching a decision on whether or not to approve the drug for general use.

Drugs which carry risk—as most do—are often approved on the basis of a risk versus benefits ratio.

In another study, two doctors from New York's Mount Sinai Hospital recently reported treating 80 women with Clomid; nearly half became pregnant. So far, ten of the pregnant women have given birth to single infants, and there is no indication that the other women whose pregnancies have not yet reached full term will have anything but single births.

The doctors are Richard U. Hausknecht and Marvin Fogel, who agreed on the basis of their studies that Clomid is easier and safer to use than Perganol.

Clomid has also been suggested as a compound that can be used to regulate ovulation effectively so that a woman practicing birth control by the rhythm method could know almost precisely when she is fertile.

In this case, the woman would take the drug for three successive days beginning on the eleventh or twelfth day of her menstrual cycle. Ovulation usually takes place on the fourth day.

However, an element of doubt remains because no one knows exactly how long sperm can remain alive in the female reproductive tract, ready to fertilize an egg when it is released.

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