

Expectant Management Effective for Some Couples

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For couples with unexplained subfertility and more than a 30% chance of pregnancy without treatment, the use of intrauterine insemination with controlled ovarian hyperstimulation offers little benefit, reported Dr. Pieter Steures, of the Academic Medical Center in Amsterdam, and colleagues.

Correctly identifying couples who are

unlikely to benefit from the use of these techniques can help prevent the misuse of facilities and resources, the researchers concluded (*Lancet* 2006;368:216-21).

The study compared the effectiveness of intrauterine insemination for 6 months with controlled ovarian hyperstimulation versus 6 months of expectant management in couples with unexplained subfertility who had a 30%-40% chance of a spontaneously ongoing pregnancy within a year. (The prognosis was calculated us-

ing a prediction model that incorporates factors such as the woman's age, duration of subfertility, and postcoital test results.)

The study protocol recommended the use of follicle-stimulating hormone for controlled ovarian hyperstimulation, but in 11% of cycles an antiestrogenic drug was used.

Couples were recruited from 26 fertility centers in the Netherlands and underwent a basic fertility assessment to determine their chances of conceiving

naturally within the next 12 months.

The researchers randomized 253 couples to receive either intrauterine insemination with controlled ovarian hyperstimulation or expectant management for 6 months. The primary end point of the study was ongoing pregnancy within 6 months.

The researchers assumed that the expectant management group would have a pregnancy rate of about 22% in 6 months based on the 30%-40% chance of ongoing pregnancy within 12 months. The intrauterine insemination plus ovarian hyperstimulation intervention would be considered beneficial only if the ongoing



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pregnancy rate after 6 months was at least 35%, the researchers wrote.

After 6 months, 42 (33%) pregnancies occurred in the intervention group and 29 (23%) were ongoing, compared with 40 (32%) pregnancies in the expectant management group, of which 34 (27%) were ongoing.

Of the 42 women who conceived in the intervention group, 6 had spontaneous pregnancies before treatment started and 7 had spontaneous pregnancies between treatment cycles. In the intervention group, 444 cycles of intrauterine insemination were started and 63 were canceled. There was a 6.5% total pregnancy rate per started cycle and a 4.1% ongoing pregnancy rate per started cycle, the researchers wrote.

Within the expectant management group, 25 (20%) couples started treatment with intrauterine insemination with controlled ovarian hyperstimulation before 6 months of expectant management, which resulted in 4 of the 34 total ongoing pregnancies in that group.

The study had some possible limitations, the researchers wrote. For example, while the study protocol called for the use of follicle-stimulating hormone to be used for controlled ovarian hyperstimulation, an antiestrogenic drug was used in 11% of cycles. There were also variations in the intrauterine insemination protocols at each of the centers involved in the study. Finally, the researchers noted that their study had a lower ongoing pregnancy rate per started cycle than the figures cited in previous studies.

Physicians need to appreciate that couples with an intermediate prognosis as described in the study can get pregnant without treatment, and patients should be told about those chances, Dr. William D. Schlaff, professor and chief of reproductive endocrinology at the University of Colorado Health Sciences Center in Denver, said in an interview. However, there are still some unanswered questions from the study, he said. ■



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