Plan B May Not Be Effective at a Population Level

BY ROBERT FINN
San Francisco Bureau

SAN FRANCISCO — A review of 11 studies examining the impact of increased access to emergency contraceptive pills finds no evidence that this increased access reduces the number of pregnancies or the number of abortions at a population level, James Trussell, Ph.D., reported at a meeting on contraceptive technology sponsored by Contemporary Forums.

In an often-cited 1992 paper, Dr. Trussell of Family Health International, Research Triangle Park, N.C., used modeling to suggest that access to emergency contraception could prevent half of all unintended pregnancies and abortions in the United States (Fam. Plann. Perspect. 1992;24:269-73).

But in nine randomized trials and one cohort study in which a total of 11,830 women were enrolled, and in one demonstration project in which 17,831 women were given emergency contraceptive pills (ECPs), not one of the studies found clinically or statistically significant differences between intervention and control groups in pregnancy or abortion.

Dr. Trussell noted that although many of these studies had substantial flaws, including small sample size, huge losses to follow-up (up to 62%), weak interventions, good access to ECPs among the comparison group, a low baseline risk of pregnancy, and a lack of randomization, none of the studies had all of those problems and some were very good.

"The consistency of these findings is hard to ignore," Dr. Trussell said.

Dr. Trussell considered several other possible explanations for the failure of access to ECPs to reduce unintended pregnancies and abortions. Some have suggested that easy availability of emergency contraception would increase risk taking among women. But the studies found no evidence of an increase in unprotected sex or decrease in use of regular contraception with enhanced ECP access. Furthermore, two of the studies fail to find any increase in sexually transmitted infections with increased ECP access, also arguing against the increased-risk-taking hypothesis.

A third hypothesis is that emergency contraceptive pills have intrinsically low efficacy. The labeling on Plan B (two doses of levonorgestrel) quotes an 89% reduction in pregnancy risk after a single act of coitus, and estimates of risk reduction in the published literature range from 60% to 94%. But Dr. Trussell called all these estimates into question because it's difficult to accurately estimate the expected number of pregnancies that would have occurred without emergency contraception.

Expected pregnancies are calculated by determining the day of the menstrual cycle when the coital act occurred, and by using published charts listing probabilities of pregnancy by cycle day. But those charts might not apply in this population since they were constructed from data in women who wanted to become pregnant. Women using ECP don't want to become pregnant, and that could lead to possible differences in fecundity, the frequency of unprotected sex, and the accuracy of self-reports. Dr. Trussell concluded that the numbers of expected pregnancies reported by studies are probably too high and that most published efficacy figures are probably overestimates. Nevertheless, it's clear that emergency contraceptives produce physiologic effects that are incompatible with pregnancy and that at the very least they are more effective than nothing.

The fourth hypothesis is that even when they have easy access to ECPs, women don't use them sufficiently. The studies showed that repeated use of ECP was uncommon, that many unprotected acts remained uncovered by ECPs, and that no ECPs were used in most pregnancy cycles.

Women in the studies cited several reasons for non-use including a failure to perceive pregnancy risk, a lack of motivation to use emergency contraception, forgetfulness, and inconvenience. (Dr. Trussell expressed amazement that some women cited inconvenience as an excuse in view of the fact that they had free, study-supplied ECPs in their possession.)

Expense and side effects further reduce ECP use in the real world. Dr. Trussell concluded that insufficient use is definitely a problem and likely contributed to the failure of ECPs to reduce unintended pregnancies.

As for how physicians should respond to this new information, Dr. Trussell urged honesty. Physicians should not oversell emergency contraception by implying that Plan B will reduce unintended pregnancy at a population level, he said.

Contemporary Forums and this news organization are both wholly owned subsidiaries of Reed Elsevier. ■

Weight Loss Vital in Treatment Of Polycystic Ovary Syndrome

BY TIMOTHY F. KIRN
Sacramento Bureau

VAIL, COLO. — Weight loss can go a long way toward improving the effects of hyperandrogenism in the adolescent with polycystic ovary syndrome, Dr. Patricia S. Simmons said at a meeting sponsored by the American Academy of Pediatrics.

"In the obese patient, this can be all she needs," said Dr. Simmons, a past president of the North American Society for Pediatric and Adolescent Gynecology. "If their weight normalizes, usually their insulin levels and secondary hyperandrogenism will, too. It is certainly the most effective long-term treatment we have," she added.

Polycystic ovary syndrome (PCOS) can be associated with a different pathophysiology in different individuals, said Dr. Simmons, a professor of pediatrics at the Mayo Clinic, Rochester, Minn. About 2%-3% of the general female population has PCOS, and it is present in about 53% of adolescents with chronic anovulation and amenorrhea.

One of the condition's hallmarks, hyperinsulinemia, is present in about 20% of adolescents with PCOS. Those individuals are more often obese, but that is not always the case. And in those individuals, the hyperinsulinemia helps drive the hyperandrogenism, which is why weight loss and improving insulin sensitivity can help, Dr. Simmons said.

Though in overweight individuals, weight loss alone may be treatment enough, others may also require drug therapy. The first-line drug for adolescents is an estrogen/progestin oral contraceptive, she said. The progestin inhibits luteinizing hormone, which leads to decreased androgen production by the ovaries, and the inhibition of adrenal androgen production. The estrogen elevates serum hormone-binding globulin, which further inhibits the effects of androgen.

Over the long term, this therapy protects the endometrium from the dysplasia and cancer associated with PCOS.

The oral contraceptive that many experts recommend is Yasmin, with ethinyl estradiol and drospirenone, because that progestin is actually an antiandrogen structurally similar to spironolactone, which itself is used as a treatment for PCOS in conjunction with an oral contraceptive, Dr. Simmons said.

However, there are no data to say that Yasmin is any better than other oral contraceptives in the management of PCOS, she noted.

Patients tend to appreciate oral contraceptive therapy because it improves their acne, makes their menstruation more regular, and stops the progression of their hirsutism.

"The health of adolescents with PCOS who are on oral contraceptives is better than that of their counterparts who are not on them, so it's an easy thing to prescribe with great confidence," she added.

The diagnosis of PCOS in the adolescent can be difficult, especially since one would like to identify it early and begin addressing some of the long-term health impacts.

Oral contraceptives do not influence insulin levels, hence the necessity for weight loss in overweight PCOS patients. The use of oral glycemic agents in children and adolescents has not been rigorously studied and is recommended for use only in selective cases, she said.

Dr. Simmons had no conflicts of interest to report. ■

Treatment Deemed Unnecessary for Most Pediatric Labial Agglutination

BY KATE JOHNSON
Montreal Bureau

HOUSTON — Labial agglutination resolves spontaneously at puberty in up to 80% of girls and has a 40% recurrence rate after treatment, whether medical or surgical, making nontreatment the best option when patients are asymptomatic, according to Dr. Abbey B. Berenson, professor of obstetrics and gynecology at the University of Texas at Galveston.

"There is only one case report of this leading to urinary retention," she said at a conference on vulvovaginal diseases jointly sponsored by Baylor College of Medicine and the Methodist Hospital. "That's why I don't start treatment when they're asymptomatic. You could end up taking them to the OR just so they look normal, and you don't want to do that."

Extensive labial agglutination is present in 5% of prepubertal girls and up to 10% of girls aged 12 months or under, she said. Patients are usually referred with the chief complaint of "absent vagina" because there may be only a small opening visible below the clitoris. Although the majority of patients are asymptomatic, some may have urinary symptoms. "The vagina can form a sort of pocket in which urine gathers and then dribbles out. These are the ones you want to treat because you don't want to see kidney damage due to repeat urinary tract infections or urethritis," she said.

Dr. Berenson recommends topical estrogen cream as first-line treatment.

"I really think it's important to try and avoid surgery," she said in an interview. "It is such a big deal to take these children to the operating room, and so often the problem recurs anyway."

The success rates for estrogen medical therapy range from 50% to 100%, she said. "This works for thin adhesions but not thick or recurrent ones." Parents should be instructed to use a finger to apply the estrogen cream over the gray fusion line using some pressure. This should be done twice a day for 2-4 weeks but stopped if breast budding occurs.

It's important to try and avoid surgery. It is such a big deal to take these children to the OR.

DR. BERENSON

The risk of recurrence can be lowered with good hygiene and reduced irritation, because the condition is believed to develop as a result of low estrogen levels and local irritation, which injures tissue and results in adherence of the labia minora.

Surgical treatment should be reserved for those who fail medical therapy, Dr. Berenson said. ■