Session 9

CLINICAL RESEARCH (PART II)

INTERCEPTION: FAILURE OF MIFEPRISTONE (RU486) AS A MONTHLY CONTRAGESTIVE, "LUNARETTE"

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The new antiprogestin, Mifepristone (RU486), was studied as a contragestive for continuous fertility control in 24 menstrual cycles. Two pregnancies out of three conceptions continued in spite of antiprogestin treatment. To date, Mifepristone at the doses used appears to be inadequate for monthly use.

A CLINICIAN'S EXPERIENCE WITH POSTCOITAL CONTRACEPTION AT A UNIVERSITY HEALTH SERVICE

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Over a span of eleven years a variety of postcoital contraceptive regimens have been offered. High doses of diethylstilbestrol for five days was the original method. For a period of time students were given a choice between different regimens and chose high-dose estrogen 9% of the time, copper IUDs 2%, and ethinylestradiol/dl-norgestrel combined 89% of the time.

Among the 1,071 patients who used postcoital contraception (PCC) who had satisfactory follow-up, there were 18 pregnancies (1.68%). Side effects were minimal and limited to nausea and/or vomiting. Two thirds of the patients reported "no problems".

On the basis of our experience and on published reports ethinylestradiol/dl-norgestrel combined appears to be as effective as any other available PCC agent, and simpler. This, along with one 10 mg capsule of prochlorperazine, is the only regimen currently being offered at the University.

A survey of 437 students coming to our clinic in 1984 revealed that 41% had had a therapeutic abortion. 85% of the females who had had an abortion were unaware of the existence of PCC at the time of their unintended conception. To help increase awareness of the existence of

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PCC we now routinely counsel all patients about PCC when we discuss contraception in general.

Providing PCC also affords an opportunity to discuss traditional contraception with a high-risk group of females to attempt to decrease the incidence of future unintended pregnancies.

64 THE EFFECTS OF MIFEPRISTONE (RU486) ON DILATATION OF THE CERVIX

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90 pregnant patients, 19 to 36 years old (mean ± SEM; 26.5 ± 0.86), with an amenorrhea of 7-12 weeks (mean ± SEM: 9.5 ± 0.16) requesting a therapeutic abortion were selected according to a general good health condition and gave their informed consent to the study. Prior to the study, dilatation of the cervix, plasma βHCG, prostaglandins $F_{2\alpha}$, E_2 and thromboxane levels were measured. Mifepristone (RU486) antiprogestin steroid was administered at random either at 0, 50, 100, 200 or 400 mg. The same variables were measured at 24 and 48 hours, at which time the aspiration was done. Data were analyzed according to a 2 x 5 factorial design (<10, ≥10 weeks of gestation and 5 doses of pharmacological treatment). In addition, a similar analysis was done using parity instead of gestational age. The results indicate a greater dilatation of the cervix in multiparas and in patients with a gestation ≥10 weeks. RU486 induced, in contrast to placebo, a significant increase in cervical dilatation from 100 mg on. Plasma βHCG levels showed a significant increase in patients under 10 weeks of gestation and in nulliparas; however, the 5 doses of Mifepristone did not differ one from the other. A significant induction of abdominal cramps and fatigue was observed with the high doses of the drug using the binomial probability test. The administration of an antiprogestin compound increases dilatation of the cervix, which might reduce the risk of cervical laceration with mechanical dilatation or the occurrence of cervical incompetent os.

65 THE SIPPR VALVED CERVICAL CAP

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The characteristic feature of the newly designed SIPPR valved cervical cap is that it can be closed tightly by itself to cut off the mucus pathway between the vagina and the cervical channel. The valve has a solely "open" or "closed" stable state, with a short transitional period. The shifting of the states is triggered by mucus pressure and body motion.

By regulating certain parameters, such as opening degree, closing degree and switch frequency, the properties of the valve can be easily controlled.

Clinical observations demonstrated that under pressure the shape of the cervix could be actively adapted to the shape of the internal cavity of cervical caps, and that the SIPPR valved cap made in standard sizes is ready for use. The body of the SIPPR cap is composed of two rubber layers, with the external layer receiving the forces from the vaginal wall and the soft internal layer transforming the forces into very small evenly distributed pressure on the surface of the cervix. Therefore, the SIPPR cap can not only be attached on the cervix for longer periods of time, but also decreases greatly the thickness of mucus film between the cervix and the cap. Preliminary clinical trials showed that the design of SIPPR valved cervical cap is successful.

INFLUENCE OF FOUR COPPER IUDS ON ENDOMETRIAL STEROIDAL RECEPTORS: TWO-YEAR FOLLOW-UP

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A comparative study was designed using four types of IUDs with different copper surface areas, Nova-T200, MLCu250 short, MLCu375 and TCu380. Several endometrial biopsies were performed on each subject on the 25th day of the menstrual cycle; prior to insertion of the device; in the first month of use and then each 6 months during two years.

The estrogen and progesterone receptors behaved differently, depending upon the amount of copper on the IUD. After 2 years of use, with the MLCu375, there was no progesterone-binding capacity in the material studied. These results are similar to findings in our prior studies. We observed significant differences in bleeding and pregnancy rates in favor of the MLCu375.