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Natural Family Planning

Diocesan Activity Report

SUPPLEMENT

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Current Status of Natural Family Planning in Granada (Spain). E. Barranco, et al. *Advances in Contraception* March 1994:10:1:27-32.

Natural Family Planning is not widespread in Spain. CODIPLAN, an NFP Center in Granada, Spain, had offered NFP to clients but began to reach out to professionals in 1989. Among recruits were physicians, nurses, and teachers, including 43 students from the Medical School who participated in a 30-hour course in Natural Medicine. Most women who requested information about NFP were women who were not satisfied with artificial methods and those who were trying to achieve pregnancy. See the following abstract for results.

Fertility Control by Natural Methods. Analysis of 218 Cycles. M.D. Chica & E. Barranco. *Advances in Contraception* March 1994:10:1:33-36.

A pilot program of 14 women used the sympto-thermal method for 218 cycles to space pregnancies. The couples reported satisfaction and effectiveness. There was no report of pregnancies.

Association for Voluntary Surgical Contraception: A Technical Statement on Quinacrine Pellets for Nonsurgical Female Sterilization. A.E. Pollack & C.S. Carignan. *Advances in Contraception* March 1994:10:1:43-50.

An article in the July 24, 1993 *Lancet* reported nearly 32,000 cases of nonsurgical sterilization with quinacrine from Vietnam. Intrauterine insertion of Quinacrine (chloroquin) pellets had been used in Chile in the late seventies and eighties with an initial 12-month failure rate of 2-3.3% when pellets had been inserted three times at monthly intervals. At 24 months, the failure rate was 6.7%. The study was supported by Family Health International. In 1989, concern about an abnormal incidence of cancer (site unspecified) caused FHI to discontinue support pending studies. Later, an unpublished report found no association. The Vietnamese study reported lifetable pregnancy rates of 2.63 at one year and 4.31 at two years with two insertions and 5.15 for one year with one insertion of pellets. There were 8 major complications: severe bleeding (2), hysterectomy for pain and amenorrhea (1), premenstrual pain and dysmenorrhea (1), PID (1), allergic reaction (1), and synechiae of the cervical canal (2). There were no deaths in the study groups. There were also 19 ectopic pregnancies and 1 birth defect in a fetus conceived after the insertion. In addition to major inconsistencies between studies, the report only covers a subset of 11,686 cases of the 31,781. Altogether, the follow-up was inadequate and FHI is now doing a prospective study utilizing hysterosalpingography to study the occlusion of the tubes produced by quinacrine. At this time it is not possible to know whether or not quinacrine is safe as a nonsurgical method of female sterilization. Because of the low cost and ease of administration of quinacrine - it is inserted with an IUD inserter - usually 8 pellets into the fundus - the question of free and informed choice must be addressed "with a loud voice." [*WHO is also funding quinacrine pellet insertion in Pakistan. They reported approximately 10% failure rate. Note that this article came from the Association for Voluntary Surgical Contraception. Their concern about informed consent is noteworthy. Ed.*]

Changes in Ovarian Function After Tubal Sterilization. A.U. Hakverdi, et al. *Advances in Contraception* March 1994:10:1:51-56.

Forty-three (43) women who had undergone tubal ligation underwent studies for ovarian function with mid-luteal endocrine profiles and endometrial biopsies at 3, 6, and 12 months after surgery. Progesterone levels were diminished by 50%. Surgical tubal sterilization carries an increased risk of ovarian dysfunction, especially corpus luteum deficiency and anovulation, probably due to reduced ovarian circulation following damage to utero-ovarian vessels.

Comparative Contraceptive Efficacy of The Female Condom and Other Barrier Methods. J. Trussell, et al. *Family Planning Perspectives* March/April 1994 26:2:66-72.

The six-month lifetable probability of failure of the female condom was 15% — 12% in the U.S. vs. 22% in Latin America. Using historical controls of female barrier methods, Trussell et al. were able to conclude that the contraceptive efficacy of the female condom during typical use is not significantly different from that of the diaphragm, sponge, or cervical cap, and conclude that the 6-month probability of failure

during perfect use is 2.6%, similar to diaphragm and cap, but lower than the sponge. Comparison with male condom is not possible because there are no carefully controlled prospective clinical trials but extrapolations suggest that the perfect use of the female condom may reduce the annual risk of acquiring HIV by more than 90% among women who have intercourse twice weekly with an infected male.

The summary includes 6-month failure probabilities which range from 9.5% for U.S. women aged over 25 years who have never borne children to 26.2% for parous women under 25 years of age. Since there were no 12-month trials for contraceptive efficacy of the female condom, the authors then compare 6-month and 12-month rates for sponge-diaphragm, and cervical cap-diaphragm trials, and find that the ratio ranges from .47% for the nulliparous woman using sponge and diaphragm to 2.37% for the parous diaphragm user. Thus, we may assume that the 12-month trial for the female trial may involve either a doubling or perhaps a greater rise in rates. [*The title is misleading because the clinical trials did not include randomization with another method of contraception, hence did not compare the methods. This appears to be one of the more tortured analyses which Trussell has published. Ed.*]

IMPORTANT NOTICE

There was an error in the FACT Sheet entitled "Action, Effectiveness and Medical Side-effects of Common methods of Family Planning" of the Summer/Fall 1993 Supplement. Under the entry "Tubal Ligation" the number "04.2" should read ".04-2".

A corrected copy of this FACT SHEET has been enclosed with this issue of *Current Medical Research*.

We are sorry for this error.

Data from the National AIDS Behavioral Surveys. The 1990-1991 National AIDS Behavioral Surveys conducted by random telephone surveys was funded by grants from the National Institutes of Mental Health and is reported in the following four papers:

I. Sexual Risk for Human Immunodeficiency Virus Infection Among Women in High-Risk Cities. O.A. Grinstead, et al. *Family Planning Perspectives* November/December 1993 25:6:252-256, 277.

Approximately 15% of women aged 18-49 in 23 urban U.S. areas engaged in high-risk sexual behavior for HIV. Risks include multiple sexual partners, a risky main sexual partner, both multiple partners, and a risky main partner. When there were no other risk factors, 17% of women reported that they did not know their main partner's HIV status. Predictors of risk factors include: Single women are more likely than others to have multiple partners; among white women, those with more than 12 years of education were more likely to have multiple partners. Among Blacks and Hispanics, younger women are more likely than older women to have multiple partners, while among Hispanic women, married respondents and those with more than 12 years of education are more likely than others to have a risky main sexual partner: the inverse is found among white women. In general, women with a risky main partner are the least likely to use condoms consistently.

II. Multiple Sexual Partners Among Hispanics in High-Risk Cities. F. Sabogal, et al. *Family Planning Perspectives* November/December 1993 :25:6:257-262.

Among Hispanics, 17% of men and 4% of women have had multiple partners: 31% among unmarried Hispanic males, 28% Cuban males; 25% were aged 18-29, better educated 21%, lower-income 23%, and highly acculturated 20%. Highly acculturated Hispanic men with lower income are more likely to have multiple partners than less acculturated Hispanic men. Only 20% of Hispanics with multiple partners use a condom regularly with their primary partner and 29% with their secondary partner. As the number of partners increases, the use of condoms decreases. Among women, marital status (single), age (18-29), education, less than 12 years of age were predictors of multiple partners.

III. Multiple Sexual Partners Among Blacks in High-Risk Cities. J.L. Peterson, et al. *Family Planning Perspectives* November/December 1993 :25:6:263-267.

Thirty percent (30%) of men and 10% of women in the survey reported multiple partners. While respondents were more likely to use condoms with secondary than main sexual partners, 47% used no condoms with their main partner, and 35% used no condoms with their secondary partner.

IV. Multiple Sexual Partners Among Young Adults in High-Risk Cities. D. Binson, et al. *Family Planning Perspectives* November/ December 1993:25:6:268-272.

Analysis of a subset of 1,334 urban heterosexuals aged 18-25 found that 24% reported more than one sexual partner during the past year, young men were twice as likely as young women, and unmarried respondents eight times as likely as married respondents to have had multiple partners. Analysis of the interaction between race or ethnicity and education found that young white persons with 12 or more years of education were four times as likely to have multiple partners than those with less than a high school education, while educational level was not a significant factor among Hispanics and Blacks. Forty percent (40%) of individuals with multiple partners never use condoms with primary or secondary partners

while condom use decreases with increasing numbers of partners.

Diurnal and Gestational Patterns of Uterine Activity in Normal Human Pregnancy. T.R. Moore, et al. *Obstetrics & Gynecology* April 1994 83:4:517-523.

A 24-hour profile of uterine activity during normal pregnancy was undertaken to correlate contraction frequency with physical activity and emotional stress. One hundred sixty-nine (169) low-risk pregnant women who delivered at term recorded contractions for 24 hours twice weekly between 20 and 40 weeks using an ambulatory monitor and a diary of their physical activity and emotional stress. Analysis found that there were no contractions during 73% of the hours of record, and fewer than 4 contractions per hour occurred in 96% of women. Frequency increased with gestational age with two-thirds of contractions found at night.

"Natural Family Planning": Effective Birth Control Supported by the Catholic Church. REJ Ryder. *Br Med J* 307:723-726, 1993. Abstract in *ACOG Current Journal Review* 1994:7:2:53.

The abstract of the article by Dr. Ryder is reproduced in toto as is customary in this Review. There was no editorial comment. [*The article and subsequent correspondence was reviewed in a previous issue of* Current Medical Research. *Ed.*]

Early Diagnosis and Treatment of Cervical Pregnancy in an In Vitro Fertilization Program. E.S. Ginsburg, et al. *Fertility and Sterility* May 1994 61:5:966-969.

Cervical pregnancy is unusual. It occurs between 1/100-6/1000 of spontaneous conceptions, and in 0.15% of ectopic pregnancies. (Ectopic pregnancies are normally encountered in 1:80 pregnancies.) Cervical ectopic pregnancies comprise 3.7% of in vitro fertilization (IVF) ectopic pregnancies. This paper reports three cases of cervical pregnancy after IVF-ET (embryo transfer), including the first case of a triplet pregnancy with one embryo in the uterine fundus and two in the cervix. After careful preparation to prevent hemorrhage, the woman underwent dilatation and evacuation of the two gestational sacs within the cervix, and one from the fundus. By the time of evacuation, all embryos had died. The patient recovered and six months later, was able to support another IVF pregnancy to term.

The second cervical pregnancy was diagnosed by transvaginal sonography. She was initially treated with intravenous methotrexate, but her hCG continued to rise and repeat sonography showed an enlarging gestational sac within the cervix which contained a yolk sac and fetal cardiac activity. The pregnancy was therefore "resolved" with an injection of 2 ml to potassium chloride into the sac after which fetal cardiac activity ceased and the gestational sac gradually absorbed. Normal menses returned 39 days after the potassium chloride injection. The subsequent IVF attempt was unsuccessful.

The third patient had many difficulties, including a short cervix, hyperangdrogenism, oligo-ovulation, Stage I endometriosis, and asymptomatic recurrent chlamydial cervicitis. She suffered cervical stenosis secondary to a previous cauterization, had been exposed to diethylstilbestrol in utero, although she had normal uterine contour on hysteroscopy. She was also allergic to contrast medium. In spite of all of these obstacles IVF-ET was ultimately successful. Thirty days later, transvaginal ultrasound showed poor image quality, but noted cardiac activity in a fetus compatible to be 6.3 gestational weeks old. (Fetal age is still dated from the last menstrual period, even when the evidence for time of conception is incontrovertible.) After careful preparation to prevent potential blood loss, the patient's pregnancy was terminated with a dilatation and evacuation. Blood loss was minimal and she recovered. Six months later, she developed a left ampullary ectopic pregnancy from another IVF-ET cycle. (Ampullary ectopic pregnancies are life-threatening from intrauterine hemorrhage. Hence surgery or other treatment is imperative.)

The authors comment on their seemingly much higher rate of cervical pregnancy than other IVF Centers. They surmise that the higher cervical pregnancy rate could be due to previous pathology which had precluded naturally occurring conception or could be due to chance, but suggest that larger studies are necessary.

Mishaps and Misfortunes: Complications that Occur in Oocyte Donation. M.V. Sauer & R.J. Paulson. *Fertility and Sterility* May 1994 61:5:963-965.

Since 1987, the University of Southern California, Los Angeles has operated a program for oocyte donation. Of young working mothers, three-fourths are not aware of the recipients' identity while one-fourth are recruited by the potential recipient. Oocyte donation requires preparation similar to IVF, namely down regulation (shutting down) of the normal pituitary gonadotropins with leuprolide, followed by daily stimulations of hMG, followed by an injection of hCG. Donors are instructed carefully in the requirements and receive financial compensation. Since the protocol requires repeated injections, seven cases with problems are reported which either failed to take their injections as scheduled or omitted them. Another complication were eight unintended pregnancies. The donors had previously used oral contraceptives, but had to discontinue them during their participation. Despite the use of barrier methods, eight became pregnant, half of whom chose to abort. Seven of the eight pregnancies occurred between donation cycles while one had "unprotected" intercourse 72 hours before follicle aspiration. At that time, the clinical impression was that all the follicles had been aspirated successfully; nevertheless, the donor conceived and

had a viable intrauterine pregnancy. No incidences of hemorrhage, anesthetic accidents, or infections were experienced.

Complications of Assisted Reproductive Techniques. J.G. Schenker & Y. Ezra. *Fertility and Sterility* March 1994:61:3:411-422.

When women suffer from infertility due to ovulatory failure, 40% are treated with induction of ovulation. Extracorporeal (in vitro) fertilization methods are also used for mechnical problems, male factor, and unexplained infertility. This review of the relevant data from programs all over the world highlights the debate concerning efficacy, cost effectiveness, induction of ovulation with drugs, principally clomiphene citrate, human menopausal gonadotropin (hMG), purified FSH, and gonadotropin releasing hormone analogs (GnRH-a) can lead to varying degrees of hyperstimulation, known as ovarian hyper-stimulation syndrome (OHSS).

Ovarian hyperstimulation syndrome: 3-4% moderate OHHS, 0.1-0.2% severe.

Complications of severe OHSS

Tension ascites

Ovarian torsion

Adult respiratory distress syndrome

Thromboembolism: venous & arterial

Liver dysfunction

Renal disorders

Death *(occasional)*

Pituitary complications

Adenoma overgrowth
(few case reports)

Pituitary hemorrhage
(few case reports)

Endometriotic bloody ascites
(a case report)

Cancer

Ovary *(few cases)*

Endometrial stromal sarcoma
(a case report)

Breast *(not fully established)*

About 100,000 hyper-stimulated cycles occur annually: of these, 100-200 women will suffer severe OHSS as a result and encounter life-threatening situations. Recognition of the early stages is imperative to prevent progression. The persistent stimulation of the ovaries resulting in multiple follicular growth and high estrogen levels has been considered as a possible risk factor for the development of epithelial ovarian cancers. These drugs may also have direct carcinogenic effects. While few cases of ovarian carcinoma have been reported in association with ovulation induction, sporadic cases have been found, warranting a retrospective control survey. Similarly, the high progesterone levels produced by ovulation induction, coupled with high estradiol levels may produce an environment favorable for the development of breast cancer. So far the numbers of breast cancers found in women who had had ovulation induction is no greater than their age peers'. This should continue to be evaluated.

Retrieval of the ova with the laparoscope leads to 2-3/1000 complications. Regional anesthesia complications 2-4/1000. Abdominal injury ranges from injuries due to trocar or needle insertion into the peritoneum has damaged abdominal wall, blood vessels, intestine, uterus, bladder, and produced the occasional death. Emergency laparotomies range 1.8%-4.2/1000. An occasional death has also been reported from transvaginal oocyte retrieval injury, also infections from culture medium, especially hepatitis and AIDS have been reported.

Pregnancies: Spontaneous abortions - 25%; ectopic pregnancies - 3-5%; heterotopic pregnancies (combination of intrauterine and ectopic implantation of different embryos - 0.5-1.2%, found more frequently with induction of ovulation without IVF. Normally this occurs in 1/5000-15,000 pregnancies. Multi-fetal pregnancies - 18-24%. (Very often fetal reduction is then practiced, most commonly by injecting potassium chloride into the "excess" embryos or fetuses.) Premature deliveries: Singletons - 8-10%; Twins - 33-55%; Triplets - 83-95%. Maternal toxemia, bleeding, pregnancy-induced hypertension, gestational diabetes mellitus, anemia, fetal intrauterine growth restriction and low birth babies are more frequently encountered. Perinatal morbidity and mortality for: singletons - 7-23/1000, Twins - 38-72/1000, Triplets - 70-170/1000.

The reviewer found no increase in congenital malformations with IVF-ET, but hence more embryos are studied prior to implantation. This is still an open question.

The medical complications are an even more serious consideration than the cost when ART is considered.

Questions? *Do you need further information regarding research reported in this Supplement? Have you a specific question which you'd like to ask the Editor? Please direct your letter to the Editor,* ***Current Medical Research,*** *DDP/NFP, 3211 Fourth St., N.E., Washington, D.C. 20017. We look forward to hearing from you.*

Current Medical Research, a supplement of the **NFP Diocesan Activity Report,** is published quarterly. Hanna Klaus, M.D. is the editor. The purpose of the supplement is to serve the Roman Catholic diocesan NFP programs of the United States through providing them with up-to-date information on research within the field of fertility, family planning, and related issues. The Diocesan NFP teacher should be equipped to understand the various methods of contraception and be able to explain their incompatibility with the practice of the natural methods of family planning.

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