Current Medical Research

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Natural Family Planning

Diocesan Activity Report

SUPPLEMENT

Fall 1991

Mechanisms Behind Heterosexual Transmission of HIV Explored. From: *Research Reports from the NICHD* September 1991.

Deborah Anderson, Ph.D. from Harvard School of Medicine presented her studies on the presence of HIV (Human Immuno-deficiency Virus) in the semen of infected men. The more advanced the disease, the higher the prevalence of HIV in semen and also in white blood cells which are found in ejaculate. AZT reduces the concentration but does not abolish it. HIV has also been present in saline washings of the vagina from infected women even when they have no symptoms. These findings indicate that both men and women without symptoms can transmit the disease sexually. Other studies have shown that male AIDS patients have HIV positive cells in the testis, epididymis, and prostate. While Dr. Anderson did not find HIV in sperm, other researchers have reported it.

An animal model using Simian Immuno-deficiency Virus (SIV, the same type of virus as HIV in monkeys) has been found in genital transmission in monkeys without trauma or breaks in the genital skin. Some hysterectomized monkeys became infected through vaginal exposure alone, suggesting that sperm entry into the cervix and uterus are not necessary for infection. Exposing the male monkey's penis to the SIV is enough to produce infection. In female, viruses could be recovered from the vagina regardless of the menstrual cycle phase. Another researcher found that the spermicide Nonoxynol 9 was effective in reducing transmission of SIV by 50%, however, chronic use of Nonoxynol 9 may cause vaginal inflammation which in turn may facilitate viral transmission. These studies were reported at the 7th International AIDS Conference, June 16-21, 1991 in Florence, Italy.

New Female Intravaginal Barrier Contraceptive Device: Preliminary Clinical Trial. A.A. Shihata and J. Trussell, *Contraception* July 1991, 44:11-19.

The Fem Cap is a silicone rubber cervical cap shaped like a sailor's hat. It fits better, is less likely to disintegrate than its predecessor, the latex cervical cap, and is apparently better tolerated. In a trial of 106 women, there were 5 pregnancies: 2 due to dislogement of the cap during intercourse, 3 due to inconstant use. The cap was used together with Nonoxynol 9 which caused irritation in nine women. Two women whose pap smear went from Class I to Class II also had condylomas. Four converted from Class II to Class I. No one went beyond Class II. Three (3) women developed chlamydia; seven, yeast infections; and one, trichomonas. There were no reports of trauma nor any evidence of trauma on examination. Since the cap is reusable for two to three years and takes less time to learn to insert than the cervical cap currently in use, FDA approval is being sought.

Evaluation of the Effects of a Female Condom on the Female Lower Genital Tract. D.E. Soper, N.J. Brockwell, and H.P. Dalton. *Contraception* July 1991, 44:21-29.

Thirty (30) subjects were randomly assigned to use either the female condom or diaphragm during a study to ascertain whether either of these devices caused trauma to the cervix, vagina, and vulva or caused infections of the vaginal or urinary tracts. Initial and three follow-up visits over 7 days included colposcopy of the vagina, cervix, and vulva, and cultures for fungal, aerobic, and anaerobic infections of the vagina. Neither device elicited significant trauma nor did the vaginal flora change appreciably during the use of the female condom, while lactobacilli were less frequently found at the end of the diaphragm use and aerobic gram-negative rods were more frequently found. The polyurethane female condom is less likely to leak than the male (latex) condom and is impermeable to HIV and cytomegalovirus. All study subjects were using either oral contraceptives, IUDs, or were sterilized. The study lasted seven days. Each subject was required to have had a minimum of five acts of intercourse using their contraceptive device. The median number of acts was six. While the study concerned itself only with trauma and infection, the authors recommend continuing study of the device (Reality™) as a safe device for the "prevention of unwanted pregnancy and sexually transmitted diseases."

Physicians' Attitudes, Recommendations and Practice of Male and Female Sterilization in Sao Paulo. P.E. Bailey et al. *Contraception* August 1991, 44:191-207.

More than one-third of the women of child-bearing age have been sterilized by tubal ligation in Brazil. A random sample (660) who are one-fourth of the practicing physicians in major Sao Paulo hospitals were interviewed about attitudes towards Family Planning in general and towards voluntary sterilization in particular. While the medical community reported a high incidence of vasectomy - 1 in 10 - and recommend vasectomy and tubectomy equally often

to their patients; nevertheless, very few men elect vasectomy.

[According to a press report, the unusually high incidence of caesarian section among private patients in Sao Paulo is partly related to the physicians' fear of venturing out at night in view of a high rate of street crime. Most caesarian sections are scheduled electively and usually tubal ligation is performed at the time of the second or third section. While the authors present a sophisticated analysis, they acknowledge that at least 80% of the men in the general population either fear impotence from vasectomy or lack information. If information about the increase in prostatic cancer after vasectomy is disseminated, I doubt if these attitudes will be altered. Ed.]

Pregnancy Rates After Peritoneal Ovum-Sperm Transfer. C.B. Coulam et al. *American Journal of Obstetrics and Gynecology* June 1991, 164:1447-52.

Coulam and associates report 12 women with unexplained infertility who underwent 23 cycles of transvaginal peritoneal ovum-sperm transfer performed under local anesthesia with sedation as an office procedure. Ova are recovered by an ultra- sonographically directed needle inserted through the vagina and reinjected into the peritoneal cavity after being mixed with sperm, usually four ova were injected in one treatment. Six clinical pregnancies occurred for a rate of 26% per cycle. Of these, three terminated in spontaneous abortion before eight weeks gestation. Two of these had chromosome abnormalities. The three pregnancies produced six healthy infants, one singleton, one twin, and one triplet gestation. All of them survived and were healthy. This is compared to an overall pregnancy rate of 16% for in vitro fertilization and 27% for gamete intrafallopian transfer (GIFT). Since this technique is at least as successful as the in vitro route and is safer, since it requires no general anesthesia, as well as costing half as much as in vitro fertilization, it is suggested as a first line approach for couples with unexplained infertility. The discussion of the papers followed: After super ovulation, a procedure which is routine for ovum retrieval, the incidence of heterotopic pregnancy (pregnancy both within the uterus and outside) is 1:200. Normally it is 1:25,000. While Coulam et al did not find any sperm antibodies in response to their procedures, other authors have found these. *[Further, the rate of pregnancy in cases of unexplained infertility, even without any treatment is 30%. Ed.]*

Folic Acid to Prevent Recurrence of Spina Bifida and Anencephaly. *ACOG Newsletter* 35:9:8 September 1991. Interim Guidelines August 1991, Centers for Disease Control:

Women who have already had one birth with spina bifida or anencephaly are advised to take four milligrams (4 mg) of folic acid daily beginning at least four weeks before conception and continuing during the first three months of pregnancy. At this dosage, the recurrence rate is reduced to one percent from an expected rate of 3.5%. This represents a 71% reduction of the relative risk of recurrence. This dosage of folic acid must be prescribed by a physician. While ordinary prenatal vitamins contain 0.4 milligrams of folic acid, it would be highly dangerous to try to reach the required dosage by taking 10 such tablets a day because the women would be at considerable risk of Vitamin A and possibly Vitamin D toxicity. Long-term dosage with folic acid is not without risk; hence, it is a prescription item and should be respected as such.

A Controlled Study for Gender Selection. S.B. Jaffe, R. Jewelewicz, E. Wahl, and M.A. Khatamee, *Fertility and Sterility* August 1991, 56:254- 258.

Semen was obtained by masturbation and separated according to Ericsson's protocol for an albumin gradient technique separation to obtain Y-bearing sperm. Insemination was done once per cycle and timed according to basal temperatures and luteinizing hormone surge. For those desiring a male, insemination was performed when the follicle was very close to rupture - 18-22 mm. Patients who desired a female received 50 mgs. of clomiphene citrate on cycle days 5-9 and human chorionic gonadotropin when the follicle was 16-18 mm., i.e., earlier. Couples had been instructed to abstain 5 days prior to the fertile phase and 5 days afterwards. Forty-eight (48) study couples were compared to 46 controls. The success rate for males was 56.5% in the study group and 60.9% in the control group. Of those seeking females, 78.6% of the procedure group were successful versus 35.3% of the control group. The study debates the value of the Ericsson protocol for achieving male offspring. The majority of couples wanted a son because they had a number of daughters. Only 2.4% presented for genetic indications.

Pregnancy Outcome in an Active-Duty Population. E.F. Magann and T.E. Nolan. *Obstetrics and Gynecology, Part I* September 1991, 78:391-393.

Comparison of pregnant active-duty women with dependent wives showed a much higher incidence of cesarian section and operative vaginal delivery, newborns apgar scores of less than 7 at 5 minutes (less than optimal conditions for the baby), premature labor and rupture of the membranes requiring transfer to the tertiary care center, pregnancy-induced hypertension, intrauterine growth retardation, and other complications in the active-duty group compared with the dependent wives. Despite defined limitations of work and ready access to health care, active-duty women continue to represent a high risk population in their "high demand and low control" situation. *["Low control" indicates little control over the environment. Ed.]*

Ovulation-Inducing Drugs Versus Specific Mucus Therapy for Cervical Factor. J.H. Check et al. *International Journal of Fertility* March/April 1991 36:108-112.

Cervical mucus abnormality may result from poor estrogen stimulation, inadequate endocervical cells, or poorly functioning endocervical cells. Treatment aimed at improving the mucus alone may fail if the cause of poor mucus has not been determined. The difficulty may be local or may be the result of inadequate follicular maturation. Thirty (30) couples who desired pregnancy were found to have an inadequate post-coital test. They were studied with ultrasonography and ovarian estrogen and progestin studies. Tubal patency had been established and the

male partners had a normal semen volume of at least 2 ml. with 60% normal sperm morphology and a sperm concentration of at least 20 million motile sperm per ml. with no less than grade 3 or 4 progressive forward motion. Initial treatment consisted of guaifenesin 400 mg. 3x a day from day 3 to ovulation. If unsuccessful, 20 micrograms of ethinyl estradiol was added from day 3 to ovulation. If this combination was unsuccessful, intrauterine insemination was performed. Fourteen (46.6%) patients with cervical mucus problems also had ovulatory disturbances. Of these, 7 improved with guaifenesin alone and 4 of those conceived. Low estrogen plus guaifenesin improved the mucus of 13 additional patients who achieved 5 more pregnancies. In the second phase of the study, induction of ovulation was added and 4 of 6 patients succeeded in achieving. Only one woman conceived with intrauterine insemination (IUI). It is concluded that quite often cervical dysfunction reflects ovulatory dysfunction. Conversely, the success of IUI may simply be the result of induction of ovulation, as shown in Patton's series which reported a 40% success with IUI but none in unstimulated cycles. *[Low dose estrogen may in fact stimulate ovulation. Ed]*

Routine Intrauterine Insemination, and the Effect of Spermatozoal Washing as Assessed by Computer-Assisted Semen Analyzer. M.J. Tucker et al. *International Journal of Fertility* March/April 1991 36:113-120.

Two hundred eighty-three (283) intrauterine insemination (IUI) cycles were performed on 237 patients who presented with cervical factor infertility, spermatozoa antibodies, infertility of unknown cause, poor post-coital tests, or low sperm counts. Twenty-eight (28) pregnancies were achieved with natural cycles and 17 from clomiphene citrate supplemented cycles. An additional 133 patients who had only cervical factor or unknown infertility were subject to computer-assisted semen analysis before and after spermatozoa washing for IUI. All factors in the spermatozoa profile changed significantly after the washing. Twelve (12) clinical pregnancies resulted from 144 cycles of IUI. Post-wash sperm concentration was slightly higher while velocity was significantly less. The authors reviewed the literature on "swim up" procedures in semen analysis and believe that the slower moving sperm has a better chance of penetrating the ovum. They discussed applying these procedures not only to IUI but to other forms of assisted reproduction. *[None of these procedures conform to the guidelines of Donum Vitae. Ed.]*

Direct Intrafollicular Insemination - A Case Report. E. Lucena et al. *The Journal of Reproductive Medicine* July 1991 36:525-526.

When a woman has at least one functioning ovary and an intact tube, a new variant of in vitro fertilization was used which was successful in 5 of 14 procedures: after ovarian hyperstimulation treated fresh donor sperm was injected into the follicle through an ultrasound guided transvaginal needle. This is a simpler outpatient procedure than in vitro fertilization (IVF/ET) or GIFT, the transfer of the egg and sperm into the tube. *[It is only a matter of time before ovarian pregnancies will be reported following these procedures. An ovarian pregnancy is a particularly dangerous form of ectopic pregnancy because it ruptures without warning symptoms and can hemorrhage very rapidly. Ed.]*

Gamete Intrafallopian Transfer by Hysteroscopy as an Alternative Treatment for infertility. G. Possati et al. *Fertility and Sterility* September 1991 56: 496-499.

Gamete intrafallopian transfer (GIFT) throughout patient hysteroscopy procedure was successful in 7 of 26 women, 5 of whom had live births. There were no ectopic pregnancies. Masturbated sperm was prepared as usual, ova retrieved after the usual hyperstimulation protocol through a transvaginal needle guided by ultrasound, ova were examined and between 2 and 5 ova reinjected with sperm and tubal fluid through a catheter which had been threaded into the tube through the hysteroscope. Infertilization was either unexplained or due to male factor, endometriosis, or damage to the open end of the tube through infection. There were no ectopic pregnancies in this initial series.

The Appropriate Upper Age Limit for Semen Donors: A Review of the Genetic Affects of Paternal Age. B.L. Bordson and V.S. Leonardo. *Fertility and Sterility* September 1991, 56:397-401.

Standards for freezing human spermatozoa have been established by the American Association of Tissue Banks. Among other items, the standards have limited the age of semen donors to 35 years or younger, yet the genetic evidence shows that increased paternal age has no effect on chromosomal anomalies. However, serious nonchromosomal birth defects, especially those arising from autosomal mutations increase with paternal age. These include ventricular septal and atrial septal defects (heart defects), skeletal defects, such as malformation of cartilage and situs inversus (180° rotation of thoracic and abdominal organs). While chromosomal changes could be detected by examining the sperm prior to insemination, nonchromosomal skeletal disorders, polycystic kidneys, multiple polyps of the colon, and premature aging (progeria) also occur. Even though the authors believe that age 40 is an adequate cut-off point to prevent donation of spermatozoa with potential genetic defects, the article gathers recommendations from the literature which suggest that men have their children before the age of 40.

Prevalence of Endometriosis in Asymptomatic Women. J.M.R. Rawson. *Journal of Reproductive Medicine* July 1991 36:513-515.

In order to evaluate the frequency of endometriosis which produced no symptoms, 86 consecutive laparoscopic patients were evaluated: 45.3% were found to have definitive evidence. Of these, one-third were in the earliest stage. Since earlier studies had shown that 90% of women with open tubes have backflow of menstrual blood into the peritoneal cavity, the finding of endometriosis confirms Sampson's theory. Clearly endometriosis is not only associated with infertility. *[Regretably,*

the paper did not report coital practices in relation to menstruation. Ed.]

Editorial: Hormonally-Based Male Contraceptives: Will They Ever be a Reality? *Journal of Clinical Endocrinology and Metabolism* September 1991, 73:464A-464B.

Editorial comment on the article by Bremner et al. ("Gonadotropin Releasing Hormone Antagonists plus Testosterone: A Potential Male Contraceptive" *Journal of Clnical Endocrinology and Metabolism* September 1991 73:465-469) in which suppression of sperm production was effected in 22 adult male macacus monkeys by giving the gonadotropin-releasing hormone agonist Deterelix. Deterelix suppressed stimulation of the testes and required concommitant testosterone injections to maintain the male libido. The editorial raises many questions about the applicability of this approach to humans. Safety issues, such as reactions of the local testosterone injection site and the possibility of allergies. Reversibility has not been determined, nor the appropriate level of testosterone, given the wide variation of testosterone levels among normal men. Are there adverse consequences if the normal daily rhythm of circulating testosterone would be absent for many years? Many body tissues are affected by supraphysiological doses of testosterone, such as increase in red blood cells, acne, weight gain, behavioral changes, and the potential for an increasing risk of prostatic hypertrophy and cancer. If circulating blood lipids are changed, the possibility of coronary artery disease [and stroke] would increase. Since testosterone is now a controlled substance in many parts of the United States, it could not be made available to the general public. Finally, the possibility for tumor development by prolonged suppression of sperm production must be carefully examined.

Network *(Family Health International)* September 1991 12:2:2.

Family Health International received $186 million grant to prevent AIDS from USAID. The money is to be used over five years to assist countries in Africa, Asia, Latin America, and the Caribbean to expand HIV prevention control programs. Strategies to slow the AIDS endemic are 1) reduction in the number of sexual partners, 2) widespread use of condoms, and 3) control of sexually transmitted diseases (presumably by treatment of those which are susceptible to treatment) according to Dr. Peter Lamptey, who will direct the new project. Dr. Lamptey directed the initial $40 million AIDSTECH Project which was also awarded to FHI by USAID and WHO.

Malcolm Potts, M.D., Ph.D., formerly President of FHI, has been replaced by Dr. Theodore M. King, formerly Vice President for Medical Affairs, Johns Hopkins University. While Dr. King was chairman of the Dept. of OB/GYN at Johns Hopkins, he also directed the PIEGO project, a program which trained physicians from the developing world in techniques of sterilization and abortion.

Questions?

Do you need further explanation 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 4th St., N.E., Washington, D.C. 20017. We look forward to hearing from you.

Erratum:

Current Medical Research Supplement Summer 1991, p. 2. Adult Sexual Behavior in 1989: Number of Partners, Frequency of Intercourse and Risk of AIDS. T.W. Smith. *Family Planning Perspectives* May/June 1991 23:102-107, stated "97% of adult Americans have had sexual intercourse *by* age 18." The correct statement is "...*since* age 18."

Current Medical Research, a supplement of the **NFP Diocesan Activity Report**, is published quarterly. Dr. 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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