Outstanding Research Paper Award 2018
(For papers published in 2017)

Award Winner:

Peri-conceptional Progesterone Treatment in Women With Unexplained Recurrent Miscarriage: A Randomized Double-blind Placebo-controlled Trial.

Alaa M. Ismail, Ahmed M. Abbas, Mohammed K. Ali and Ahmed F. Amin;
The Journal of Maternal-Fetal & Neonatal Medicine, 31:3, 388-394

This randomized, double blind, placebo-controlled trial studied 700 women with a history of unexplained recurrent miscarriage (RM) to determine if progesterone started in the luteal phase would decrease the rate of miscarriage. Participants received either 400 mg of vaginal progesterone or placebo suppositories twice daily starting in the luteal phase and continuing through confirmation of pregnancy until 28 weeks of gestation. Ovulation was confirmed by ultrasound in the first cycle after enrollment and by urine luteinizing hormone kits in six consecutive subsequent cycles.

The miscarriage rate was significantly lower in progesterone group compared to placebo (12.4 versus 23.3% respectively, p.0.001) and there was significant improvement in the live birth rate in the progesterone group in comparison to placebo (91.6 versus 77.4%, respectively, p<0.05).

The authors concluded that progesterone is more effective than placebo in reducing the risk of miscarriage if administered in the luteal phase of the cycle, before confirmation of pregnancy in women with a history of unexplained RM.

Commentary: The recent large, randomized PROMISE study (NEJM 2016; 374:894) found no effect of progesterone started in the first trimester to prevent RM. Critics of this study question whether subgroups at risk for RM were excluded or not identified, such as those with subfertility or short luteal phases, or that progesterone was not started early enough (Carpentier, NEJM 2015). This study, and the two additional studies summarized below, strengthen the evidence promoting cooperative treatment with progesterone starting in the luteal phase and continuing beyond the first trimester for those at risk for RM. This is in addition to strong evidence for another indication for use of progesterone for short cervical length to reduce preterm birth (Conde-Agudelo, AJOG epub 2018; Romero, AmJ Obstet Gynecol 2012; Hassan, Ultrasound Obstet Gynecol 2011; Fonseca, NEJM 2007).

Other Papers Considered:

Effectiveness of an Online Natural Family Planning Program for Breastfeeding Women

Richard J. Fehring, Mary Schneider, and Thomas Bouchard
Journal of Obstetric, Gynecologic, & Neonatal Nursing 46, e129–e137; 2017

This was a longitudinal cohort study of the effectiveness of an online, nurse-managed natural family planning education program in 816 breastfeeding women. Participants tracked their fertile times with an electronic hormone fertility monitor (EHFM), cervical mucus monitoring (MM), or both.

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The overall correct use pregnancy rates were 3 per 100 users over 12 cycles of use, and typical rates were 14 per 100 at 12 cycles of use. At 12 cycles of use, total pregnancy rates were 16 per 100 for EHFM users (N 380), 81 per 100 MM (N 45), and 14 per 100 for EHFM + MM (N 391).

The authors concluded that the use of a nurse-managed online NFP program can be effective to help breastfeeding women avoid pregnancy, especially with correct and consistent use.

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Enrollment, Childbearing Motivations, and Intentions of Couples in the Creighton Model Effectiveness, Intentions, and Behaviors Assessment (CEIBA) Study
Joseph B. Stanford and Christina A. Porucznik
Frontiers in Medicine, 08 September 2017

This paper reports the enrollment baseline characteristics of the CEIBA study which was conducted to assess fertility motivations, intentions, fertility-related sexual behaviors, and their impact on effectiveness to avoid and to conceive among new users of the Creighton Model FertilityCare System (CrM) without a history of subfertility who were seeking to avoid pregnancy at enrollment. The study enrolled 305 women and 290 men (71% and 95% of those initially screened, respectively)

The majority of women were engaged (39%) or married (51%), college graduates (77%), Caucasian non-Hispanic (80%), and Roman Catholic (80%). The most common reasons for learning CrM (women) were to use a natural method for family planning (91%), for moral/ethical/religious reasons (70%), the lack of side effects (71%), or insight into the menstrual cycle and fertility (62%).

Women and men intended to have a mean of three and two additional children, respectively. Of women, 21% intended to have a child within a year and 60% between 1 and 3 years. The mean positive childbearing motivation score was 3.3 for both women and men (range 1–4, with 4 being most positive).

The authors note that previous studies of the effectiveness of CrM have used primarily behavioral measures. This study used prospective measures of desire, intentions and sexual/fertility behaviors, finding that couples beginning use of the CrM to avoid pregnancy have high levels of motivation, desire, and intention for future childbearing. These prospective measures will allow the authors to assess the impact of these factors on pregnancy rates among these couples.

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Evaluation of Effects of Artemether + Lumefantrine (Artemisinin-based Combination Therapy) on Women's Reproductive Cycle using Creighton Model FertilityCare System and NaProTECHNOLOGY.
Francis Achebe
Niger J Gen Pract 2017;15:31-41

Malaria is prevalent in Nigeria, and artemether + lumefantrine (artemisinin-based combination therapy [ACT]) is drug of choice in treatment of uncomplicated cases.

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This article describes a case series of a convenience sample of 3 women who used the Creighton Model FertilityCare System (CrM) who had normal ovulation as determined by ultrasound.

The use of ACT on cycle day 11-13 was associated with a decrease in the mean CrM mucus cycle score from 12.6 to 7.5 (p = 0.019) and was also associated with an ovulation defect of partial rupture syndrome as defined by a follicular rupture difference of less than 7.5 mm diameter. The mean follicular rupture difference before and after ACT was 14.6 and 2.8, respectively (p = 0.003). ACT was not associated with a significant difference in follicular estradiol. There was a significant increase in luteal estradiol (p = 0.01) and a significant decrease in luteal progesterone (p=0.01).

The author concluded that ACT is associated with significant decrease in CrM mucus cycle score and with the partial rupture syndrome ovulation defect and advocated that women exposed to ACT should be informed of a possible resulting reversible contraceptive effect.

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Implementation of Routine Postpartum Depression Screening and Care Initiation Across a Multispecialty Health Care Organization: An 18-Month Retrospective Analysis
April Lind, Sara Richter, Cheryl Craft, and Alice C. Shapiro
Matern Child Health J 2017; 21(6): 1234-1239

This article describes a retrospective analysis of the effect of the implementation of a quality improvement project aimed at postnatal postpartum depression (PPD) screening and the subsequent initiation of treatment of women presenting for routine postpartum care or for their children's well child visits.

The 18-month evaluation period began 6 months after an implementation effort in an integrated health system of a standardized screening and treatment guideline utilizing the Edinburgh Postnatal Depression Scale.

Query of the electronic medical record's data warehouse revealed that screening for PPD occurred at 88% of 28,389 eligible postpartum and well-child visits for approximately 5,000 unique women.

The authors concluded that screening for PPD can be successful in a large multispecialty health care organization with multiple community-based clinics.

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Luteal Start Vaginal Micronized Progesterone Improves Pregnancy Success in Women With Recurrent Pregnancy Loss
Mary Stephenson, Dana McQueen, Michelle Winter and Harvey Kliman
Fertil Steril 2017;107:684–90.

This was an observational cohort study of the initiation of vaginal progesterone in the luteal phase in 116 women with 2 or more unexplained pregnancy losses <10 weeks in size who were managed in a university program focused on recurrent pregnancy loss (RPL). Women were included if they had an endometrial biopsy performed 9-11 days after an LH surge and had one or more subsequent pregnany(ies).

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An elevated (>20%) expression of endometrial glandular epithelial nuclear cyclin E (nCyclinE), a cell cycle regulator, has been associated with infertility. This marker was elevated in the endometrial glands in 59 women who then received 100–200 mg vaginal micronized progesterone every 12 hours, starting 3 days after LH surge and continued through 10 weeks of gestation.

The main outcome was pregnancy success defined as an ongoing pregnancy >10 weeks in size on ultrasound. Pregnancy success in the 59 (51% initial cohort) women with elevated nCyclinE significantly improved after intervention: 6% (16/255) in prior pregnancies versus 69% (57/83) in subsequent pregnancies (p< .001). There was also significant improvement in pregnancy success in the 57 women with normal nCyclinE expression, (25 of whom had insisted on vaginal progesterone) from 11% to 60 %. Live birth rates were not reported.

The authors concluded that the use of luteal start vaginal micronized progesterone was associated with improved pregnancy success in a strictly defined cohort of women with RPL and expressed the urgent need for a randomized, placebo-controlled trial of the effect of luteal start progesterone on the live birth rate.

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Natural Conception Rates in Subfertile Couples Following Fertility Awareness Training
 P. Frank-Herrmann, C. Jacobs, E. Jenetzky, C. Gnoth, C. Pyper, S. Baur, G. Freundl, M. Goeckenjan, and T. Strowitzki

The purpose of this study was to determine the cumulative pregnancy rates of subfertile couples after fertility awareness training in the Sensiplan method. A prospective, observational cohort of 187 subfertile women (age 21-47) were observed for 8 months. They had attempted to achieve pregnancy for 3.5 years on average (range 1–8 years).

The cumulative pregnancy rate after fertility awareness training was 38% (95% CI 27–49%; 58 pregnancies), which is significantly higher than the estimated basic pregnancy rate of 21.6% in untrained couples in the same cohort. Couples trying to achieve pregnancy for 1-2 years had pregnancy rate of 56%. This decreased to 17% for those trying for >2 years (p< 0.01). Female age above 35 had a pregnancy rate of 25% (p =0.06).

The authors concluded that training women to identify their fertile window in the menstrual cycle seems to be a reasonable first line intervention in the management of subfertility.

Comment: This is consistent with the results from the retrospective cohort study of a NaproTECHNOLOGY practice in Canada by Tham, et al, (Can Fam Physician 2012) where training in the Creighton Model FertilityCare System was the only intervention in 24% of those achieving pregnancy.   You go, FertilityCare Practitioners!!

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A Prospective Evaluation of Luteal Phase Length and Natural Fertility
Natalie M. Crawford, David A. Pritchard, Amy H. Herring and Anne Z. Steiner
Fertil Steril. 2017 March; 107(3): 749–755

 Prospective, community-based cohort study measuring the time to pregnancy of women age 30-44 years without known infertility who were trying to conceive, looking at the impact of a short

luteal phase on fecundability in the subsequent cycle. Luteal phase length was defined as the day after a positive ovulation predictor kit, through the day before the onset of the next menses.

A short luteal phase (length of 11 days or less including the day of ovulation) occurred in 18% of 1,635 cycles observed cycles from 284 women. Mean luteal phase length was 14 days. After adjustment for age, women with a short luteal phase had 0.82 times the odds of pregnancy (95% CI: 0.46–1.47) in the subsequent cycle immediately following the short luteal phase, which was not statistically significant. Women with a short luteal length in the first observed cycle had significantly lower fertility after the first 6 months of pregnancy attempt, but at 12 months, there was no significant difference in cumulative probability of pregnancy.

The authors concluded that an isolated cycle with a short luteal phase may negatively impact short-term fertility, but the incidence of infertility at 12 months was not significantly higher among these women.

Supplementation With Progestogens in the First Trimester of Pregnancy to Prevent Miscarriage in Women With Unexplained Recurrent Miscarriage: A Systematic Review and Meta-analysis of Randomized, Controlled Trials
Gabriele Saccone, Corina Schoen, Jason M. Franasiak, Richard T. Scott, Jr., Vincenzo Berghella
Fertil Steril 2017;107:430–8

This is a systematic review and meta-analysis of the preventive effect on the incidence of miscarriage, of progestins administered in the first trimester of pregnancy in women with unexplained recurrent miscarriage (2 or more).

Using standard methods of performing a valid meta-analysis, 10 trials were analyzed encompassing 1,586 women with recurrent miscarriage. Of these, 8 studies were double-blind, placebo-controlled. Two of the RCTs used natural progesterone, the recent Promise study (Coomarasamy 2015) and a small study published in 1953 using intramuscular progesterone pellets. Eight studies used progestins.

Pooled data from the 10 trials showed that women assigned to the progestins group had a lower risk of recurrent miscarriage (RR 0.72, 95% CI 0.53–0.97) and higher live birth rate (RR 1.07, 95% CI 1.02–1.15).

The authors concluded that supplementation with progestins may reduce the incidence of recurrent miscarriages in women with unexplained recurrent miscarriage. Limitations included moderate statistical homogeneity of the studies, the variety of progestins used, and seven of the studies having been published before 1990. The largest of the included trials (PROMISE) had a negative result and included more patients than all the others put together.

Use of Natural Family Planning (NFP) and Its Effect on Couple Relationships and Sexual Satisfaction: A Multi-Country Survey of NFP Users from US and Europe
Matthias Unseld, Elisabeth Rotzer, Roman Weigl, Eva K. Masel and Michael D. Manhart

Questionnaires for women and men with items on socioeconomic, health, gynecological, NFP, and sexual topics were developed in German and translated to English, Polish, Italian, Czech, and Slovak by native speakers. A total of 2,560 respondents from 2 large symptothermal (STM) NFP

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organizations completed the online questionnaire (37.4% response). Participants were married (89%) and well educated. 47% had previously used contraceptives.

95% of women and 55% of men said NFP has helped them to know their body better. 64% of women and 74% of men felt NFP helped to improve their relationship. Less than 10% felt NFP had harmed their relationship.

Most women (53%) and men (63%) felt NFP improved their sex life. 75% of women and 73% of men said they are either "satisfied" or "very satisfied" with their frequency of sexual intercourse.

The authors concluded that the STM of NFP is a well-accepted approach to family planning across several Western cultures that is consistently viewed as being beneficial to a couples' self-knowledge, their relationship, and satisfaction with frequency of sexual intercourse.

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