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European Double Check Sympto-Thermal Method of Natural Family Planning Highly Effective When Used Consistently and Correctly: Researchers Claim Efficacy Comparable to Modern Methods of Contraception, Including the Birth Control Pill

The European study group for natural family planning has been systematically investigating the efficacy of a double check Symptom-Thermal Method (STM) of Natural Family Planning (NFP) for over 20 years.<sup>1</sup> The European Double Check Method essentially entails using 2 natural biological markers for estimating the beginning and end of the fertile phase of the menstrual cycle. The markers for estimating the beginning of fertility are the presence of selfdetected cervical secretions and a calendar based determined day. The 2 biological markers, that indicate the end of the fertile phase, are the peak day of cervical mucus and the basal body temperature (BBT) shift (which ever comes last). The European study group now has enrolled a large sample of women who were taught the European STM at a number of centers throughout Europe and are now able to conduct a large efficacy study of the method to avoid pregnancy.

The purpose of the current study was to determine the overall perfect and total use-effectiveness of the European STM to avoid pregnancy. Other aims of the study were to determine if use of barriers during the fertile phase influenced the efficacy of the method and to determine the acceptability rate of the method. The researchers were able to enroll 1.599 women into the study between 1985 and 2005. Nine-hundred of the women met the inclusion criteria for the prospective study. These 900 women produced 17,638 cycles of data. The biggest sub-groups of women that were excluded from the study were those seeking pregnancy (N=356) and those who recently discontinued the hormonal birth control pill (N=125). To be included into the study, the women participants needed to be between the ages of 19-46, have cycle lengths between 22-35 days (of which only 20% could be outside of this range), have no known infertility problems, and were willing to avoid pregnancy for 12 months. All of the women participants were taught a standardize form of the European STM by certified NFP teachers.

Eighty-eight percent of the 900 participants were between the ages of 19-35, most (88.9%) had a secondary education or higher, 73.8% were Roman Catholic, 51.9% never were pregnant, and only 35.8% were married. The total unintended pregnancy rate for the entire 900 participants was 1.79 per 100 women over 13 months of use. The total unintended pregnancy rate for the sub-group of women participants whose partners used barriers during the fertile time was 1.62 per 100 women over 13 months of use, and the unintended pregnancy rate for those women who

used a mixed STM (i.e., used a mixture of abstinence and barriers during the estimated fertile phase) was 2.02. There were no significant statistical differences between these unintended pregnancy rates. Those women who followed the rules of the method correctly and consistently and avoided intercourse during the estimated fertile phase had a perfect (or method use) unintended pregnancy rate of only 0.43 per 100 women over 13 months of use. However, those women/couples who had intercourse during the fertile phase some of the time had a significantly higher unintended pregnancy rate of 7.47 per 100 women over 13 cycles of use. Finally, the overall discontinuation rate was only 9.2 per 100 women over 13 cycle of use. The most frequent reason for discontinuation was dissatisfaction or difficulty with the method.

The authors of the study concluded that the European double check method of STM was a highly effective method of family planning as long at the method is used consistently and the guidelines of the method are followed correctly. However, the authors also boldly stated that the method effectiveness of the European STM is as effective as modern methods of contraception, including the hormonal birth control pill.

## Comments

The European NFP study group was diligent in including the latest recommendations for quality efficacy studies for family planning methods. Some of the quality control features included: a large sample of participants, a longitudinal prospective cohort study design, a low rate of lost to follow-up, documentation of all sexual behaviors, and

documentation of intention of use before the beginning of each menstrual cycle. A negative assessment of these criteria could be that having couples declare their intentions before each menstrual cycle is an artificial situation. This is so, because couples' intentions to achieve a pregnancy are not always an "either or" proposition. In real life, a continuum of decision making is typical. The study group was also careful to use appropriate survival analysis statistical procedures and well defined perfect and imperfect use behaviors.

A concept of interest that the authors introduced was that of "intelligent risk takers." This was applied to woman participants who had intercourse during the fertile phase but still were intending to avoid pregnancy. The unintended pregnancy rate for this group was only 7.5% and much lower than the 15-20% found in other NFP efficacy studies. The authors speculate that these women intelligently decided to avoid the most fertile days during the estimated fertile window. Of note, is that the average length of the estimated fertile time for this study was 13 days. Besides the surprising low unintended pregnancy rate for the risk taker group was the very low unintended pregnancy rate for those women who used barriers during the fertile phase. The untested assumption among NFP users groups is that use of barriers during the fertile phase will decrease the efficacy of the NFP method. The authors do point out that use of barriers (rather than abstaining from intercourse) during the fertile phase is considered a fertility awareness based (FAB) method and not NFP.

The authors intimated that the European Double Check STM is probably more effective than the single indicator cervical secretion methods. They also claim that the women participants in this study would be comparable to NFP users in other modern Western countries. However, I wonder if this is so. According to the *United States 2002 National Survey of Family Growth* there were no un-married women between the ages of 15-44 who were users of cervical mucus or BBT (STM) based methods of NFP.<sup>2</sup> I am not sure that un-married sexually active couples in the US would have the discipline, commitment, and relational trust to use modern methods of NFP. I applaud the European NFP study group for their continued systematic study of NFP and related topics. (RJF)

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