

Reactie Dr. med. Petra Frank-Herrmann op de interpretatie van haar onderzoek (2007) in de NHG-Standaard Anticonceptie

Huidige informatie (29-3-2021) in de Richtlijn:

Sympto-thermale methode (blz.65 NHG-Standaard Anticonceptie)

In een prospectief observationeel onderzoek (n = 900, 17.638 cycli) van Frank-Herrmann et al. (2007) werd de effectiviteit van een sympto-thermale methode (sensiplan®) onderzocht. Vrouwen met een onregelmatige cyclus, of leeftijd > 45 jaar (premenopauze) werden uitgesloten. Van de 900 vrouwen gebruikten 509 een condoom in combinatie met de sympto-thermale methode, de overige vrouwen gebruikten geen condoom, maar deden wel aan periodieke onthouding. Na 13 cycli participeerden nog 434 vrouwen (waarvan 136 vrouwen alleen de sympto-thermale methode toepasten). Het zwangerschapscijfer bedroeg na 13 maanden $1,79 \pm 0,52$ per 100 vrouwen in het hele cohort. In het cohort dat een condoom gebruikte tijdens de vruchtbare dagen bedroeg het zwangerschapscijfer $1,62 \pm 0,89$ en in het cohort dat geen condoom gebruikte $2,02 \pm 0,72$. Bij vrouwen die onbeschermd coïtus hadden tijdens de vruchtbare periode bedroeg het zwangerschapscijfer na 13 maanden $7,47$ per 100 vrouwen. (56 10)

Onderstaand de Engelse vertaling en haar reactie hierop:

Symptothermal method

A prospective observational study (n = 900, 17,638 cycles) by Frank-Herrmann et al. (2007) examined the effectiveness of a symptothermal method (sensiplan®). Women with an irregular cycle, or age > 45 years (premenopause) were excluded. Of the 900 women, 509 used a condom in combination with the symptothermal method, while the remaining women did not use a condom, but did have periodic abstinence. After 13 cycles, 434 more women participated (of which 136 women applied only the symptothermal method). After 13 months, the pregnancy rate was 1.79 ± 0.52 per 100 women in the whole cohort. In the cohort that used a condom during the fertile days, the pregnancy rate was 1.62 ± 0.89 and in the cohort that did not use a condom was 2.02 ± 0.72 . In women who had unprotected coitus during the fertile period, the pregnancy rate after 13 months was 7.47 per 100 women.

Clarifications of Dr. med. Petra Frank-Herrmann

This discussion reflects a misreporting and misunderstanding of the cited effectiveness data on Sensiplan.

1. Every effectiveness study has to ensure a fertile study group, no matter which family planning method is being investigated (i.e. also for investigating the efficacy of condoms, intrauterine systems and all the others). Therefore, the study design, which is agreed internationally, requires a cycle length of 22-35 days. In our study, 20% of the cycles of each study participant were allowed to deviate outside this range. So, in fact, we did not exclude irregular cycles or women with a large variability of cycle length, however we excluded women with few ovulations per year. So, the reason for this criterion is to exclude infertility

and to ensure that the women could become pregnant (risk of exposure). This is a necessary scientific criterion that is commonly required for that type of study.

Of course, we studied women with irregular cycles or premenopausal women as well, in separate analyses.

2. The cited dropout does not mean that the participants left the Sensiplan method. Only 9,2% dropped out for dissatisfaction and/or change of the family planning method. Most of the participants dropping out of the effectiveness study merely changed their situation e.g. because they announced that they were going to try for pregnancy from the following cycle and other reasons. There was no minimum study duration required.
3. The following is cited wrong: „In the cohort that used a condom during the fertile days, the pregnancy rate was 1.62 ± 0.89 and in the cohort that did not use a condom was 2.02 ± 0.72 .“ It is the other way round: the cohort that used a condom from time to time during the fertile days, the pregnancy rate was 2.02 ± 0.72 and in the cohort that did not use a condom was 1.62 ± 0.89 . Both rates are use-effectiveness rates, this means they include inconsistent behaviour (e.g. occasionally unprotected intercourse in the fertile phase). The rates for consistent behaviour (method efficacy) are not cited at all in the above statement. Completely wrong is the following: „In women, who had unprotected coitus during the fertile period, the pregnancy rate after 13 months was 7.47 per 100 women.“ For this rate, only cycles with inconsistent behaviour were included (a woman may have 4 cycles with abstinence in the fertile phase, 2 cycles with condom use and another 3 with unprotected intercourse in the fertile phase). For that rate of 7,47, we took only those cycles of the whole study with inconsistent use. Thus, the calculated rate is **not** women-related. An analog example: studies on the oral contraceptive pill, include inconsistent cycles as well, e.g. cycles in which a woman forgets to take the pill for one or more days. If only those cycles are taken into the calculation, the calculated pregnancy rate is related to this inconsistent behaviour. However, the use-effectiveness (typical use) includes all types of behaviour (consistent and inconsistent use) and therefore is better than for inconsistent behaviour only.

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