Behavioral Methods of Family Planning: A Comparative Study of Efficacy and Safety of Fertility Awareness Based Methods and Birth Control Pills

Ana Maria Dumitru,* Teresa Gilbride,**
Marguerite Duane, M.D., M.H.A.***

Background and Purpose

Published reports indicate that *over 100 million women worldwide* use the birth control pill (Oral Contraceptives, or OCPs).[1,2] However, in a national study conducted by the Battelle Centers for Public Health Research and Evaluation, rates of discontinuation of some birth control methods were as high as 90%, and had averages between 40-61% (depending on marital status) for women who were followed over a two-year period.[3] This suggests that women are searching for new methods, perhaps with fewer side effects or better effectiveness rates. Studies show up to *60% of women* would be interested in using Fertility Awareness Based Methods (FABMs) if given information.[4] Both FABMs and OCPs entail behavior modification on a daily basis, so the efficacy and side effects of FABMs and OCPs were chosen for comparison during this study.

Most commonly reported unintended pregnancy rates for FABMs and OCPs are based on low quality retrospective surveys. A popularly cited review from J. R. Trussell and colleagues report typical use failure rates of 24% for FABMs and 9% for OCPs.[5] These numbers are based on estimates of the probability of pregnancy drawn from the 1995 and 2002 National Surveys of Family Growth.[5,6] There are at least three major problems with these surveys. One is that these are lower quality retrospective surveys based primarily on patient recall, with the data collected via a series of phone surveys. Another major problem is that 86% of the purported FABM users surveyed identified the calendar rhythm method—a much older and less effective method—as their prima-

* Dartmouth Geisel School of Medicine.
** Uniformed Services University of the Health Sciences.
*** Georgetown University, Fertility Awareness Collaborative to Teach the Science.

ry form of contraception. Then, the rates for all types of FABMs were pooled together, including some methods which are not even classified as FABMs by trained providers. This "lumping together" of all FABMs including "rhythm" masks important differences in effectiveness among the variety of modern methods; a fact acknowledged by Trussell, the author of this estimate.[7,8,9] The third major issue with this review is that the rates of effectiveness were adjusted to account for the researchers' assumption of underreporting of abortion. As a result of the issues with these popularly cited statistics, we sought to design objective criteria with which to evaluate the primary literature available for FABMs and OCPs, in order to understand both the quality of the studies available as well as the true effectiveness rates.

Methods

In total, three major search engines (Medline, PubMed, and EMBASE) were used with keyword searches to identify relevant articles. For FABMs, 30 articles from 1980 on were included in the study.[6] For OCPs, 47 articles from 2000 on were included in the study. (The year 2000 was chosen in part because studies from earlier decades had used higher dose hormone formulations which were proven to be unsafe for women, and the trend in later years has been towards seeking lower dose hormonal formulations to provide the same efficacy with fewer side effects[1]). Strength of Recommendation Taxonomy (SORT) criteria[10] were established first for the FABM review[6] and then adapted for the OCP review (Adapted SORT). The adaptation was based on fundamental differences between FABMs and OCPs such as lack of a "learning phase" for OCPs. The purpose of the SORT and Adapted SORT criteria was to provide a framework to determine the level of evidence for individual studies.

Two independent reviewers scored each of the identified articles for the FABMs and the OCPs reviewed. Major discrepancies in scores were resolved by sending the articles in question to a third reviewer for a tie-break score.

Results

For the FABMs reviewed, there were 56 maximum possible points with the SORT criteria. The scores ranged from 31-55 points, and 10 of the 30 articles (30%) were found to earn a SORT Level 1 status (qualified by earning a positive score in all of the critical criteria).[6]

For the OCPs reviewed, there were 42 maximum possible points with the Adapted SORT criteria. The scores ranged from 18-41 points, and 5 of the 47 articles (11%) were found to earn a SORT Level 1 status.

The SORT criteria for the FABM articles included the following categories.[10]

1. Tracking of sexual activity
2. Prospective or retrospective status of the study
3. Sample size
4. Duration of follow-up
5. Survival analysis and statistical methods used

6. Detection and recording of pregnancy
7. Effectiveness rates for typical and correct use of method
8. IRB approval
9. Geographical location(s) of population studied
10. Diversity of population
11. Sexual behavior or other method use in conjunction with the method studied
12. Client profile and
13. Any counseling, learning phase, or instruction needed for the methods.

The Adapted SORT criteria used many of the same core criteria but excluded the categories of learning phase, counseling, and prospective pregnancy intentions (it was implied that women seeking OCPs had no intentions of pregnancy within the duration of the studies).

Of interest, it was found that every major FABM had at least one robust study which earned SORT Level 1 status in this review. These major methods are: Billings, Creighton, Two Day, SymptoThermal, Marquette, Standard Days, and Lactational Amenorrhea.

Of the OCP articles reviewed, the following five formulations earned SORT Level 1 status in this review: Triphasil, 21/7 Regimen, 24/4 Regimen, Extended Regimen, Ascending Dose Extended Regimen (ADER).[11-15]

Additional Findings

Over the course of the review, other findings of interest surfaced as observable patterns. Cited advantages for FABMs included sense of empowerment of the women in the studies, enhanced understanding of fertility, cost-effectiveness, environmental friendliness of methods, enhanced communication between couples, use of methods as a diagnostic tool, lack of medical side effects, and freedom from drugs and devices. Cited advantages for OCPs included improved cycle regularity and control, decreased dysmenorrhea, improvements in acne and seborrhea, improvement in mood and sense of well-being, reduction in bloating and water retention, and autonomy in managing cycles with flexible regimens.

A stark contrast was noted in the literature in regards to the reporting of adverse events associated with methods reviewed. For the FABMs, there were no adverse physical effects reported in the literature with any of the methods. For the OCPs, there were adverse events reported in every organ system in every article reviewed.

We also identified potential conflicts of interest. For the FABM articles, 43% of the articles had reported potential conflicts of interest, the majority of these (30%) were that one or more of the authors of the studies were trained in and/or developed the FABM that the article studied. For the OCP articles, 83% of the articles reported potential conflicts of interest, with the majority of these (68%) being that the pharmaceutical company manufacturing the OCP being studied directly funded the study.

Discontinuation rates were higher for the OCP studies than for the FABM studies. For the highest quality studies (Level 1), dropout rates were less than 20%. However only about 10% of the OCP studies were SORT Level 1; whereas one-third of the

FABM studies were SORT Level 1. The remaining OCP articles commonly report large drop-out rates. High discontinuation rates may skew statistical analysis of effectiveness rates, particularly when the reasons for discontinuation are not known (ie women are lost to follow-up). This is a point to keep in mind when discussing effectiveness rates for either of the methods.

In regards to effectiveness rates, another finding was that only 28% of the OCP articles included tracking of participants' use of barrier methods or other secondary contraceptive methods. In contrast, 73% of FABM articles included this tracking information.

Conclusions

We conclude that it is possible to make objective comparisons of effectiveness rates between FABMs and OCPs based on SORT and Adapted SORT criteria. There are reported advantages to the use of both FABMs and OCPs, with the major difference being that the OCPs also come with a significant number of reported adverse medical effects. We anticipate that this review will serve as a call for greater uniformity of approach to the study of the available methods of family planning, and for an elimination of the sources of bias currently evident in much of the primary literature.

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