

Contraceptive efficacy - still an unresolved dilemma aggravating birth control and family planning.

Kurt Kraetschmer*

Austrian American Medical Research Institute, Hermannng 4, A-2700 WrNeustadt, Austria

Abstract

Women interested in contraception are nowadays not content with information they receive in their doctor's office but search for additional information in various sources. Among these sources websites, publications by government agencies, and in fewer cases articles and books are the most preferred. The present paper highlights data presented in research publications and websites that are incomplete, inaccurate or misleading and suggests remedial strategies to ascertain the derivation of reliable data on the efficacy of contraceptive methods.

Keywords: Contraception, Family planning, Birth control

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Introduction

Numerous are the publications dealing with contraceptive efficacy, and even more numerous are statistical details. Such interest in efficacy does not come as a surprise as for most women and their care providers interested in birth control or family planning, efficacy of contraceptive methods together with safety are the primary concerns. Interestingly enough precisely this highly important issue of efficacy is embedded in obscurity, despite innumerable figures for failure rates, Pearl indices, etc.

The dilemma associated with research on contraceptive efficacy recently has come to the forefront in a 2016 publication on typical use failure rates in the developing world [1]. In this study, published not only in a specialized journal but also as a report of a Reproductive Health Institute [2], the authors find it necessary to draw attention to the fact there their estimates for periodic abstinence were “markedly lower than U.S. estimates” [2]. Apparently in their comparison of data, they had expected that periodic abstinence, which they identify as “calendar rhythm”, would be similar to the estimates for the U.S., namely 24. Thus, it came as a surprise that developing world users of the method performed significantly better, i.e., 13.9, than users in the U.S. In view of such a result, the question arises of how to explain a disparity of 13.9 versus 24 for the same methods.

Although the authors do not mention a search for a possible explanation, such an inquiry seems necessary for a correct interpretation of the data obtained. One possible explanation for the unexpected inferiority of the U.S. users would be that developing world users are more capable of using methods that involve, more than any other method, cognitive abilities and utmost compliance. In view of the illiteracy that goes rampant in some of the 43 countries included in the study, such an explanation seems difficult to substantiate. Another explanation however, would be that the estimates for the U.S. are simply incorrect. Support for this latter explanation comes from the authors themselves because at one point of their comments they admit that their estimates for the U.S. are not derived from a recent evidence-based investigation but are taken from an outdated source, i.e., “from 1995 and 2002 National Surveys of Family Growth” [2].

Interestingly enough, this assertion dovetails with the statement made by authors of contraceptive technology research affirming the use of outdated figures: “Estimates of the probability of pregnancy during the first year of typical use” are taken from the 1995 National Survey of Family Growth [3]. Not surprisingly, the same unverifiable figure appears also in a 2012 survey, which inappropriately groups several methods under one heading and assigns one common typical use failure rate to all of these methods instead of differentiating among their individual failure rates and mention also perfect use failure rates [4].

A similar incorrectness plagues a recent study published by the Guttmacher Institute, where fertility awareness-based methods are not distinguished from one other but indiscriminately assigned a failure rate of 0.4-5 for perfect use and 24 for typical use [5]. An additional problem in this publication is the introduction of a new taxonomy listing three groups of methods as belonging to the fertility awareness-based methods, i.e., “cervical mucus methods”, “body temperature methods”, and “periodic abstinence”. Besides the problem of a novel taxonomy, there arises the question of how a method with a remarkable failure rate of 0.4 (symptothermal) or 3.0 (ovulation) in case of perfect use can deteriorate to a disappointing failure rate of 24 in case of typical use; a question, alas, not answered by the authors.

Of course, unexplained data for failure rates can be found as early as 1999, when one of the most widely used reference-books saw the light in its 17th edition [6]. In this scholarly remarkable work of long standing, the symptothermal method is recognized as the most precise in determining the days where abstinence is mandatory. The failure rate of 10% attributed to this “periodic abstinence method” of family planning disagrees, however, with the 0.3 pregnancy rate established by international research [7].

Following a historical penchant one could investigate further into the history of medicine and draw attention to the 1982 Lancet publication on “effectiveness of frequently used contraceptive methods” [8]. In this publication which made its appearance in one of the world's leading medical journals, the unspecified terminus “rhythm” was used, and the rhythm method was ranked as the most ineffective (15.5 “failures per 100 women years”),

inferior even to diaphragm (1.9 failures per 100 women years), condom (3.6), withdrawal (6.7), spermicide (11.9).

In view of the numerous unverifiable data whose origin can be traced back to several decades into the last century, it is not surprising that in our days various agencies and academic institutions across the U.S. continue to disseminate error-prone data among millions of women seeking information on birth control and family planning. Thus, the most authoritative and most frequently consulted agency, the FDA provides information on contraceptive methods in the form of a consumer-friendly survey of FDA-approved contraceptive methods [9]. Yet, to the disappointment of the increasing number of women who seek alternatives to pills and devices, there is no mention, not even in a footnote, of such methods as symptothermal, ovulation, Two Day, and Standard Days. These methods have been included in research on contraceptive failure in the U.S. and assigned estimates for perfect use of 0.4 (symptothermal), 3.2 (ovulation), 3.5 (Two Day), and 4.8 (Standard Days), respectively [10], and this indicates that they are more efficacious than some of the methods included in the FDA survey. In the face of the incomplete FDA survey it has to be feared that numerous U.S. consumers are left with the impression that there are no other methods available than the 19 listed by the FDA.

Besides incompleteness there is also inaccuracy that plagues publications by various agencies. In a website of the U.S. Department of Health and Human Services (Office on Women's Health) [11], reference is made to WHO data for the purpose of providing information on family planning. The so-called "fertility-awareness based methods" are assigned collectively 24% ("number out of every 100 women who experienced an unintended pregnancy within the first year of typical use") and considered as the least effective, just slightly superior to the "spermicide method" (28%). Such an assessment exclusively for typical use and not for perfect use, does not take into account that the nomenclature "fertility awareness" encompasses at least four different methods, each one with a failure rate of its own, ranging from 0.4 (symptothermal) to 4.8 (Standard Days). Interestingly enough these methods are described only in a different website with focus on fertility awareness, provided by the Office of Population Affairs [12]. Here again, a common failure rate of 25% is indicated for the four methods, as if all of them were equally effective - or rather ineffective. What is noteworthy in this website is the description of the "sympto-thermal" as a reliable method, combining basal body temperature and cervical mucus method. This description recognizes in contrast to the FDA survey the symptothermal method as a viable option, although it fails to mention one of the salient components of the method, which were mentioned already in 1999 where the symptothermal method was correctly described as combining observation of cervical mucus, basal body temperature and other symptoms associated with ovulation [6].

Besides incomplete and inaccurate information there are also misleading statements in various publications by authoritative agencies. The American Congress of obstetricians and gynecologists provides general information in one websites and states with reference to a statement of April 2015 that "fertility awareness, sometimes called natural family planning is not as effective as other methods of birth control" [13]. This

unfavorable assessment of the fertility awareness methods however, is contradicted in another website by ACOG [14] where the efficacy of fertility awareness /sic!/ is described as "fewer than 1-5 women out of 100" will get pregnant in case of perfect use and 12-24 in case of typical use. Such efficacy is of course superior to several other methods, especially to spermicide or diaphragm [3], so that the 2015 ACOG statement is led ad absurdum.

What is correct in this website is the acknowledgement of the advantages of fertility awareness methods and their usefulness for fertility treatments: "they cost very little Many women like the fact that fertility awareness is a form of birth control that does not involve the use of medications or devices" [14].

What should be mentioned also in discussions of advantages of natural methods is the problem of irregular menstrual cycles, recognized and analysed as early as 1995 by studies on human physiology [15] where the time of ovulation is described as "variable even from one menstrual cycle to another". Lack of attention to restrictions of the natural methods and to the difficulty of obtaining their perfect use estimates blemishes also some otherwise thorough publications of academic institutions [16].

In view of the present dilemma of contradictory data on the efficacy of contraceptive methods, the question arises of how a remedy can be found. Basically, two issues need amelioration: first, research methodology, and second taxonomy. Future research should refrain from quoting estimates from outdated sources, which in many cases are unverifiable and untrustworthy. In obtaining and evaluating reliable data attention must be paid to the special properties of the so called "natural fertility-awareness" or better simply "natural methods," whose efficacy depends more than all the other contraceptive methods on communication. While there is little need to instruct the woman, who receives implants or other LARCs, on details of the method, the opposite is true for the natural methods. Precise and comprehensive instruction on the part of the care provider and faithful compliance on the part of the user are a *conditio sine qua non* for successful use of the method. Obviously, in the past, failures attributed to the method were actually failures in communication processes rather than deficits in the method per se.

In conjunction with improvement of methodological procedures it seems also desirable that ambiguous nomenclature and taxonomy be avoided. This means that the recently observed changes in terminology should be circumvented, preferably by adhering to the the traditional historically evolved nomenclature, as it is still used in German and international research [17].

Actually, several of the nowadays used taxonomies could be easily adopted to ascertain comprehensibility and international communication among scholars, as for example the ACOG classification which uses the termini "Standard Days, Cervical Mucus, Basal Body Temperature, and Symptothermal" [14]. Similarly, minor adaptations would be possible for the classification used by contraceptive technology research which distinguishes among "symptothermal, Ovulation, Two Days and Standard Days" [3].

Conclusion

It must be underscored that the presently existing dilemma

caused by the uncritical use of obsolete data should be brought to a halt. Concerning estimates it is not mathematical precision that is expected by potential users of given methods but rather relative efficacy that is to say comparative estimates which allow to distinguish highly efficacious methods from less reliable ones. The possibility of a comparison of efficacy might motivate an additional number of women to actively practice birth control or family planning and thus reduce the number of unwanted pregnancies.

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*Correspondence to:

Kraetschmer K
 Austrian American Medical Research Institute
 Hermannng
 Austria
 Tel: (08441) 3335
 Fax: 0844171161
 E-mail: kurt.kraetschmer@aon.at