Contraception

Contraception 94 (2016) 374 – 383

Letter to the Editor

The pitfalls of using selective data to represent the effectiveness, relevance and utility of the Standard Days Method (SDM) of contraception

Letter to the Editor,

The article, "Does the evidence support global promotion of the calendar-based Standard Days Method of contraception?" by Marston and Church claims to assess evidence about the effectiveness of the Standard Days Method (SDM) method of contraception. As readers and contributors to *Contraception*, we are concerned about the author's seeming disregard for accurate representation of data throughout this article. By referring to the method as calendar-based, the authors imply that SDM is no different from the rhythm method. SDM is a fertility awareness-based method, with a defined, biologically-based algorithm for use. SDM users may abstain from intercourse, use condoms or rely on emergency contraception during their fertile period. The paper misses the point that SDM offers a contraceptive option for a specific tranche of women who may not traditionally be reached with contraceptive methods, or who do not want to use other methods.

The SDM efficacy trial was conducted in three different settings to maximize relevance and utility. Marston and Church question the trial's methods and results, despite its following standard, rigorous, and adequately powered procedures to assess effectiveness. The 95% perfect and 88% typical use effectiveness rates demonstrated in the trial are aligned with Trussell's definition of these metrics; several studies show similar rates with typical use, despite Marston and Church's claims that there are no additional effectiveness data [1,2].

Marston and Church state that SDM is being marketed to users as being similarly effective as pills. They make this claim using the "perfect use" statistic. Counseling tools typically show either perfect *and* typical, or *only* typical use effectiveness. These tools do not make statements or claims that SDM provides typical use effectiveness similar to pills or other hormonal methods. Current best practice in counseling on contraceptive methods is to provide clients with full, free and informed choice using tiered effectiveness counseling. The authors' misrepresentation of how SDM is counseled on to clients suggests a lack of familiarity with real-world applications of contraceptive programming. The authors additionally claim to have found no independent assessment of SDM use in the general population. In fact, at least two independent studies on SDM integration are available in Nigeria and Ethiopia [3,4].

Marston and Church also repeatedly misquote evidence — they cite Che, Cleland and Ali, stating that "one…study showed periodic abstinence failure contributed to one sixth of all foetal losses". This paper actually states that periodic abstinence failure contributed to one sixth of all fetal losses among *contraceptive users*. The authors use these data to suggest that SDM may significantly contribute to illegal induced abortions, despite there being no evidence whatsoever to suggest that this is true.

Worldwide, women choosing SDM state concerns about side effects of other methods, not religion, as their primary motivation for selecting SDM [5]. Consistent evidence, including reviews completed by the World Health Organization, shows that SDM offers significant improvement over periodic abstinence or nonuse.

We agree that women and men have the right to accurate information about a range of methods. Marston and Church do readers a disservice with this review of SDM effectiveness which serves to diminish clients' right to informed choice.

Kelsey Q. Wright*
Karen Hardee
The Evidence Project, Population Council, 4301 Connecticut Ave., Suite 280, Washington, DC 20008, USA
*Corresponding author
E-mail addresses: kwright@popcouncil.org
khardee@popcouncil.org

John W. Townsend
Reproductive Health Program, Population Council, 4301 Connecticut Ave., Suite 280, Washington, DC 20008, USA
E-mail address: jtownsend@popcouncil.org

http://dx.doi.org/10.1016/j.contraception.2016.06.002

Referred to by: http://dx.doi.org/10.1016/j.contraception.2016.06.003

References

[1] Kalaca S, Cebeci D, Cali S, Sinai I, Karavus M, Jennings V. Expanding family planning options: offering the Standard Days Method to women in Istanbul. J Fam Plann Reprod Health Care 2005;31(2):123-7.

[2] Blair C, Sinai I, Mukabatsinda M, Muramutsa F. Introducing the Standard Days Method: expanding family planning options in Rwanda. Reprod Health 2007;11(2):60-8.

[3] Bekele B, Fantahun M. The Standard Days Method: an addition to the arsenal of family planning method choice in Ethiopia. J Fam Plann Reprod Health Care 2012;38(3):157-66 http://dx.doi.org/10.1136/jfprhc-2011-100116.

[4] Ujuju C, Anyanti J, Adebayo S, Muhammad F, Oluigbo O, Gofwan A. Religion, culture and male involvement in the use of the Standard Days Method: evidence from Enugu and Katsina states of Nigeria. Int Nurs Rev 2011;58(4):484-90.

[5] Gribble JN, Lundgren RI, Velasquez C, Anastasi EE. Being strategic about contraceptive introduction: the experience of the Standard Days Method®. Contraception 2008;77(3):147-54.

Standard Days Method effectiveness: opinion disguised as scientific review

I am writing in response to "Does the evidence support global promotion of the abstinence-based Standard Days Method of contraception?" by Marston and Church [1]. I was involved in Standard Days Method (SDM) research and was an author of the effectiveness study [2] that the authors cite extensively. Their article is misleading and does a disservice to SDM and to the many researchers who have contributed to the growing body of literature about it.

The authors correctly say that SDM has been promoted in low- and middle-income countries by a wide range of large international organizations, most with seasoned researchers and strict procedures for reviewing evidence before adding a method to the contraceptive mix. The authors presume to understand the facts better than all these experts, yet the "evidence" they share in support of their views is partial.

An effectiveness study in which participants are instructed to avoid unprotected intercourse on fertile days (rather than abstain) [2] would be helpful. However, it would not inform a more typical-use failure rate. Effectiveness studies of user-directed methods, users of which continue to menstruate, require at least monthly interaction with health providers or researchers to rule out pregnancy, which results in bias. That is a weakness of all effectiveness studies of all such methods. Yet there is significant evidence that SDM is indeed effective when used with current guidelines. As Marston and Church said, implementation studies of SDM had a small sample size. However, these studies were standardized so data could be jointly analyzed. Study results provide "real" typical-use figures as they did not include the intensive follow-up inherent to effectiveness studies. When looked at together (n=1646), the typical-use failure rate was 14.1—better than other user-directed methods, such as condoms. These women (in 14 studies, 6 countries) were typical users. They came to the facility seeking family planning and, in the context of informed choice, selected SDM. Only then were they invited to join these studies [3]. A similar process was undertaken in the 5 study sites (3 countries) of the effectiveness study, so users were typical of women in these communities, and data were not as biased as Marston and Church claim.

The methodology section suggests a comprehensive literature review, but the authors ignored at least eight relevant articles, omitting references with results opposing their views. They say that they reviewed evidence only about effectiveness and used only promotional materials with respect to other method characteristics. However, several studies support claims about these characteristics that the authors overlooked [3–10].

SDM was never designed to replace other methods but rather to be offered in the context of informed choice. Studies show that adding SDM to the method mix increases overall contraceptive prevalence without reducing use of hormonal and long-acting methods [9]. Marston and Church do a disservice to millions of women around the world who use SDM effectively.

Irit Sinai
Palladium, Washington, DC 20004, United States
Tel.: +1 240 4826 170
*E-mail address:*irit.sinai@thepalladiumgroup.com

http://dx.doi.org/10.1016/j.contraception.2016.04.020

Referred to by: http://dx.doi.org/10.1016/j.contraception.2016.06.003

References

[1] Marston CA, Church K. Does the evidence support global promotion of the calendar-based Standard Days Method of contraception? Contraception 2016;93:492-7.

[2] Arévalo M, Jennings V, Sinai I. Efficacy of a new method of family planning: the Standard Days Method. Contraception 2002;65:333-8.

[3] Gribble JN, Lundgren RI, Velasquez C, Anastasi EE. Being strategic about contraceptive introduction: the experience of the Standard Days Method. Contraception 2008;77:147-54.

[4] Arévalo M, Yeager B, Sinai I, Panfichi R, Jennings V. Adding to the method mix: does it make a difference in a high-prevalence setting? Reprod Health 2010;28(2):80-5.

[5] Biruhtesfa B, Mesganaw F. The Standard Days Method: an addition to the arsenal of family planning method choice in Ethiopia. J Fam Plann Reprod Health Care 2012;38:157-66.

[6] Blair C, Sinai I, Mukabatsinda M, Muramutsa F. Introducing the Standard Days Method: expanding family planning options in Rwanda. Reprod Health 2007;11(2):60-8.

[7] Kalaca S, Cebeci D, Cali S, Sinai I, Karavus M, Jennings V. Expanding family planning options: offering the Standard Days Method to women in Istanbul. J Fam Plann Reprod Health Care 2005;31(2):123-7.

[8] Lundgren RI, Gribble JN, Greene ME, Emrick GE, de Monroy M. Cultivating men's interest in family planning in rural El Salvador. Stud Fam Plann 2005;36(3):173-88.