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Mifepristone With Buccal Misoprostol for Medical Abortion: A Systematic Review

I read with interest the systematic review on medical abortion by Chen and Creinin and was concerned by their conclusion that “more data are needed to evaluate clinical outcomes... beyond 63 days of gestation.” In fact, more data have been published since this review, but additional data should not be a prerequisite for offering the safe and effective regimen of mifepristone plus misoprostol between 64 and 70 days of gestational age.

To be sure, mifepristone is not a new drug with unknown properties: using it beyond 63 days of gestation is an addition to an established, proven procedure. The review authors indicate that the data from 332 patients identified between 64 and 70 days of gestation offer insufficient evidence to recommend clinical use, yet this sample provides a confidence interval (CI) of 89.6–95.5 in which even the lower limit represents a highly efficacious procedure that women should be allowed to choose. Doctors Chen and Creinin even note that the review demonstrates a higher efficacy through 63 days of gestation than the pivotal trial for U.S. Food and Drug Administration (FDA) approval. This statement is also true through 70 days of gestation. Indeed, the CIs are almost precisely the same (FDA approval to 49 days of gestation: 92% CI 90–94; 10 week review data: 93% CI 90–96%).

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Two substantial clinical trials have directly compared efficacy in the 9th and 10th weeks of gestation and find no statistically significant differences, and a new summary of the literature in the 10th week (more than 900 women) reaches the same conclusion. The caution advocated by Chen and Creinin in the 10th week of gestation should simply take the form of counseling. Women seeking medical abortion in the 10th week of gestation should know efficacy rates and then make their decisions Accordingly. Indeed, how much data do the authors feel would be enough to recommend this regimen in the 10th week of gestation? With what width of a CI? Let’s not allow excessive caution to distort our understanding of the evidence or inhibit us from providing the care our patients deserve.

Financial Disclosure: The author did not report any potential conflicts of interest.

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REFERENCES


In Reply:
Our systematic review focused on medical abortion outcomes with mifepristone and buccal misoprostol.

Dr. Blumenthal refers to a commentary that includes studies with regimens using vaginal and sublingual misoprostol, which we did not include in our review. The commentary compares outcomes between 57 and 63 days of gestation and 64 and 70 days of gestation for four studies with mifepristone and buccal misoprostol and reports no difference in outcomes. If this commentary had been approached as a systematic review of mifepristone and buccal misoprostol, the authors would have included more than 1,600 other women between 57 and 63 days of gestation; the success rates would be 94.8% (95% confidence interval [CI] 93.8–95.6%) and 92.5% (95% CI 89.7–94.6%) for women at 57–63 and 64–70 days of gestation, respectively ($P = 0.048$).

When evaluating efficacy, the type of failure is just as important as the overall failure rate. The limited data with mifepristone and buccal misoprostol show a continuing pregnancy rate in the 64–70 days of gestation range that is three times higher than the rate with mifepristone and oral misoprostol through 49 days of gestation. The implication of a lost-to-follow-up patient is more relevant with a higher rate of continuing pregnancy. We do not know as much about mifepristone and buccal misoprostol for women at more than 63 days of gestation as we do for earlier gestations. In our review, we found there are 100 times more women providing data on efficacy, side effects, and complications through 63 days of gestation ($n = 33,514$) compared with 64–70 days ($n = 332$). More studies are necessary to have comparable knowledge and confidence for use of mifepristone and buccal misoprostol beyond 63 days of gestation. We should not let our fervor for access compromise our judgment.

Financial Disclosure: Dr. Mitchell D. Creinin is a consultant for Danco. The author did not report any potential conflicts of interest.

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REFERENCES

1. Chen MJ, Creinin MD. Mifepristone with buccal misoprostol for medical abortion;
Feminism and the Moral Imperative for Contraception

In her Current Commentary article in the August 2015 issue, Dr. Espey makes a compelling case for the universal availability of family planning methods for all women and outlines many of the obstacles that stand in the way of reaching this goal. One major obstacle that should be considered is the continuing ban by the Catholic Church of any artificial methods of family planning.

The official position of the Church has been and still is that only the so-called natural methods of family planning are allowed. Pope Francis recently advocated that Catholics should limit their families to a manageable number of children. In the same interview the Pope reiterated the ban by the Church on all artificial methods. It seems to me that the Pope and the Church cannot have it both ways: on the one hand recommend limiting the size of families but on the other hand take away the effective means of doing so. That seems a bit unfair. In addition, Pope Francis very recently came out strongly for the equality of women. One can only hope this will better reflect (and summarize) the available data for a particular medication.

In 2011, about 10% of hospital beds in the country were in a Catholic-sponsored or Catholic-affiliated hospital, with resultant effects on access to reproductive health care for a large number of women. I agree with Dr. LeMaire that religious beliefs should not stand in the way of women’s health care.

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In Reply:

I appreciate Dr. LeMaire’s letter and wholeheartedly agree with his premise that women of the Catholic faith and all faiths should be sanctioned to use contraception. Not only does doctrine stand in the way of contraceptive choice, but hospital doctrine may pose a barrier as well. Catholic hospitals in particular follow the “Ethical and Religious Directives for Catholic Health Care Services.” which make a number of statements about appropriate care, including these two directives about contraception:

52. Catholic health institutions may not promote or condone contraceptive practices but should provide, for married couples and the medical staff who counsel them, instruction both about the Church’s teaching on responsible parenthood and in methods of natural family planning.

53. Direct sterilization of either men or women, whether permanent or temporary, is not permitted in a Catholic health care institution...

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