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Mifepristone vs. osmotic dilator insertion for cervical preparation prior to surgical abortion at 14–16 weeks: a randomized trial

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ATE are relatively rare events in younger women, even with the risk elevations that are present for COCs. Because of this, any excess fatal VTE and ATE events that might potentially be attributed to DRSP would contribute little to total mortality, so there is no reason to expect that total mortality is associated with DRSP.

In conclusion, while we agree that the conclusions of our study are open for interpretation, we do not agree with the critiques that Dr. Szarewski presented in her letter.

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## Mifepristone vs. osmotic dilator insertion for cervical preparation prior to surgical abortion at 14–16 weeks: a randomized trial

To the Editor:

I read with great interest the manuscript by Dr. Borgatta and colleagues regarding mifepristone versus osmotic dilators in women 14–16 weeks gestation [1]. Unfortunately, I believe the study was designed poorly to provide any clinically relevant data. The authors conclude that mifepristone is potentially preferred to osmotic dilation when used

for a 24-h period prior to abortion at 14–16 weeks because women experienced more pain with osmotic dilators. The authors feel they proved that women were more comfortable after mifepristone and because women had a marked preference for mifepristone that this option would be desirable to other women.

The primary flaw is the design of the study in which significantly more dilators were placed than needed. Wilson et al. [2] have shown that one Dilapan provides enough cervical softening and dilation effect to allow for an abortion to be completed after just 4 h of placement in women 16–18 weeks gestation. In this study of women between 14–16 weeks gestation, Borgatta and colleagues stuffed 3–6 dilators in women's cervixes. I would expect these women to experience significant pain in a 24-h period given the amount of dilators used. The authors were successful at demonstrating that using more osmotic dilators than necessary can result in increased complaints of pain from patients.

Secondly, as the authors point out, there was no blinding for the study. However, the surgeon certainly could have been blinded by having a different person place the speculum and remove the dilators prior to the surgeon starting the procedure. In that way, the surgeon would not have known if the subject had mifepristone or dilators. Accordingly, the authors statement that "(s)everal of the physicians volunteered that, after mifepristone use, mechanical dilation was easy in most women as the cervix was soft," has no validity.

Lastly, there is no mention in the Discussion section of cost-effectiveness of such an approach. Mifepristone retails for \$80–90 per tablet and osmotic dilators cost less than \$10 each. If one (or even two) dilators are used for a procedure at this gestational age, mifepristone would still be significantly more expensive. Moreover, misoprostol has been shown to be an effective agent for cervical preparation at this gestational age range in doses that would cost no more than a few dollars [2,3].

This small non-blinded, randomized trial of 50 women fails to provide convincing evidence that using mifepristone 200 mg orally 24 h before an abortion at 14–16 weeks has any advantages over osmotic dilators or misoprostol. This study, at best, is a pilot study. Because of design flaws and inherent biases, the authors overstate the certainty of their conclusions.

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## Response to Letter to the Editor

To the Editor:

We thank Dr. Creinin for his comments, and we are happy to respond. However, he has criticized us for a number of things that we did not say. This was a non-inferiority design, and the primary outcome of procedure time was not inferior within the specified margin. The word “preferable” does not appear in the manuscript. We stated our findings, which showed that we found that, in this study, women were more comfortable after mifepristone and had a preference for mifepristone. We did not use the word “proved” in the manuscript either.

Dr. Creinin has criticized our choice of control group, in which three to six osmotic dilators were used. The method picked for the control group was the one in use at the time of study; this method is described as a standard method in a comprehensive abortion textbook [1]. Dr. Creinin prefers another method, which is described in a retrospective study [2]. There are several methods of cervical preparation in use currently; each has advocates, and there are ongoing comparison studies.

As stated in the article, the appearance of the cervix after mifepristone (normal, closed external os) is different than the appearance after osmotic dilators (cervix enlarged, external os open, endocervix exposed). The operator can tell which method of preparation was performed by looking at the cervix. Therefore, attempts at blinding would have been unproductive. Inclusion of comments from investigators may be of interest to readers and may suggest future investigation. Comments are not conclusions and were not presented as such.

Cost analysis of the various methods of cervical preparation is complex. Mifepristone, indeed costing \$80–90,

requires counseling and a cup of water. Osmotic dilators require counseling, a procedure room with set-up and cleaning, patient gown, sterile instruments, supplies, local anesthetic if used, analgesia if used, antibiotics if used, and clinician time, etc. in addition to the cost of the dilator(s). Depending on the location, setting of care, and clinical practice, the cost of using osmotic dilators varies widely. In this hospital, both charges and costs for osmotic dilators are higher than for use of mifepristone.

We concluded “we believe that this option would be desirable to other women.” We do believe this. In one other study comparing medical and mechanical cervical preparation, quoted by Dr. Creinin [3], women preferred medical preparation, so this finding is not implausible. This is not a one-size-fits-all situation. The selection of the method of cervical preparation in second trimester is based on local facilities, time constraints, cost structure, and clinician preference. Perhaps there is a role for women’s preferences as well.

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