Title

Pain Associated With Cervical Priming for First-Trimester Surgical Abortion: A Randomized Controlled Trial.

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Pain Associated With Cervical Priming for First-Trimester Surgical Abortion: A Randomized Controlled Trial

I was very interested in the comparison of cervical preparation with mifepristone or misoprostol before first-trimester vacuum aspiration reported by Hamdaoui et al in the June 2021 issue.[1] The single (surgeon)-blind, randomized trial was designed to evaluate their primary outcome, dilation pain, in persons having an office procedure with cervical anesthesia only; no other preoperative or intraoperative analgesia was provided. The investigators also reported aspiration and postoperative pain, all measured with a visual analog scale (VAS). The investigators claim superiority of mifepristone over misoprostol based on less dilation pain (35.6±21 vs 43.5±21, respectively, P=.04). Additionally, the authors report similar benefit based on mean VAS score during aspiration (34±24 vs 47.8±23, respectively, P=.003) and surgeon evaluation of ease of performing the procedure (88±16 vs 80±23, respectively, P=.04).

However, based on their sample size description, their primary outcome and surgeon ease of procedure fail to reach clinical significance. The investigators established sample size estimates to detect a difference of 13 mm on a 100-mm VAS. With pain studies, a relatively large sample allows investigators to calculate what they claim is a statistically significant finding that does not reach clinical significance,[2,3] as the authors have done here. Two other obvious issues with pain assessments are obvious based on their Figure 2, a boxplot of VAS scores. First, the scores do not appear normally distributed; thus, medians and not means were the appropriate values to compare, as is typical of most pain studies. Second, more than 10% of preoperative (baseline) pain scores were considered outliers. Thus, median change in individual pain score rather than population median at each time point may have been a more appropriate evaluation.

Visual analog scales are very effective for studying pain, but clinical as well as statistical difference must be demonstrated to differentiate outcomes. Unlike what the authors conclude, this study fails to show any benefit of mifepristone over misoprostol in this clinical situation.

Financial Disclosure: Dr. Creinin is a consultant for Danco. Off-label use: Mifepristone and misoprostol are unapproved for cervical preparation prior to suction aspiration.

Editor's Note: Hamdaoui et al declined to respond.

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Perinatal Outcomes of Two Screening Strategies for Gestational Diabetes Mellitus

In their recent randomized trial in the July 2021 issue, Davis et al[1] conclude that the gestational diabetes mellitus (GDM) testing approach from the International Association of Diabetes and Pregnancy Study Groups (IADPSG) resulted in more women diagnosed and treated for GDM than the Carpenter-Coustan approach without reducing the incidence of large-for-gestational age (LGA) birth weight or maternal or neonatal morbidity. The study design parallels a much larger (N=23,792 vs N=921) randomized controlled trial[2] that reported similar results and conclusions. In a clinical opinion,[3] we urged caution in interpreting the results of that study because of several questionable assumptions; the Davis study shares a number of those issues. The sample size calculations called for a 7% absolute risk reduction in LGA neonates in the group of women randomized to the IADPSG approach compared with the group randomized to the Carpenter-Coustan approach. To reduce the absolute number of LGA neonates by 7% among the 428 patients randomized to the IADPSG approach who completed visit 2, treatment of the 44 additional IADPSG GDM patients would have had to prevent 30 cases of LGA, meaning that at least 68% of IADPSG GDM patients would have LGA neonates if untreated. The authors previously reported[4] that 19% of untreated GDM patients by IADPSG criteria had LGA offspring, compared with 15% of treated Carpenter-Coustan GDM patients. It is not reasonable to expect that treating the additional 10% of patients diagnosed by IADPSG criteria would reduce the absolute risk of LGA by 7% in the entire group. The relative risk in the IADPSG group was 0.90, the amount of reduction we would predict[3] and similar to the outcome of the much larger randomized controlled trial by Hillier et al.[2] Although the risk reduction confidence interval crossed 1, the sample size was not powered to detect that size effect, similar to the Hillier et al randomized controlled trial.[2] Although it is useful to determine the benefits of a particular approach to the entire tested population, expectations should be reasonably based on valid data. We continue to urge caution in interpreting the results of these two similar studies.

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