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Customized Probability of Vaginal Delivery With Induction of Labor and Expectant Management in Nulliparous Women at 39 Weeks of Gestation

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In Reply:

We appreciate the comments of Drs. Peleg and Warsof regarding our secondary analysis of the A Randomized Trial of Induction Versus Expectant Management (ARRIVE) trial describing prediction of vaginal delivery after induction in nulliparous low-risk women at 39 weeks of gestation, which appeared in the October 2020 issue.¹ They wonder about differences in the number of participants included in the primary analysis² and the secondary analysis,¹ as well as the intention-to-treat analysis.

Women were randomized during week 38 to elective induction of labor between 39 0/7 and 39 4/7 or to expectant management. The expectant management group was asked to forego elective delivery before 40 5/7 weeks and to have delivery initiated no later than 42 2/7 weeks. It was expected that some would deliver before 39 0/7, due to spontaneous labor or for a medical indication, or experience a medical indication for delivery prior to an assigned elective induction after 39 0/7 weeks. It is a misunderstanding to believe these are protocol violations; rather, they were expected possibilities, beyond control of research procedures, and incorporated into the analytical planning of the trial. Because its specific aim was different than that of the primary trial, the secondary analysis was restricted to a specific subpopulation of the trial's population.

If we understand it correctly, the authors also suggest that exclusion of women in the secondary analysis somehow invalidates the primary trial's intention-to-treat analysis. We disagree. First, the ARRIVE trial was a randomized controlled trial, and an intention-to-treat analysis is widely accepted as the most appropriate way to analyze a randomized controlled trial.³ Second, the current secondary analysis reinforces the results and conclusions of the

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primary analysis. Our results regarding cesarean delivery were virtually identical (across a variety of conditions) in the actual treatment groups and the intention-to-treat groups.

Although the authors speculate that delivery at 42 weeks of gestation may have skewed the results in favor of the induction group, only 8 (0.3%) in the expectant management group delivered 42 0/7 to 42 2/7 weeks of gestation; none delivered after 42 2/7. Lastly, while the authors state that they still believe that expectant management most effectively lowers the cesarean rate, this belief ignores not just data from the ARRIVE trial, but the many other trials and observational studies that have explored this question.⁴

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REFERENCES

1. Silver RM, Rice MM, Grobman WA, Reddy UM, Tita ATN, Mallett G, et al. Customized probability of vaginal delivery with induction of labor and expectant management in nulliparous women at 39 weeks of gestation. *Obstet Gynecol* 2020;136:698–705. doi: 10.1097/AOG.0000000000004046 [PubMed: 32925634]
2. Grobman WA, Rice MM, Reddy UM, Tita ATN, Silver RM, Mallett G, et al. Labor induction versus expectant management in low-risk nulliparous women. *N Engl J Med* 2018;379:513–23. doi: 10.1097/AOG.0000000000004046.1056/NEJMoa1800566 [PubMed: 30089070]
3. Gupta SK. Intention to treat concept: A review. *Perspect Clin Res* 2011;2:109–12. doi: 10.4103/2229-3485.83221 [PubMed: 21897887]
4. Grobman WA, Caughey AB. Elective induction of labor at 39 weeks compared with expectant management: a meta-analysis of cohort studies. *Am J Obstet Gynecol* 2019;221:304–10. 10.1016/j.ajog.2019.02.046 [PubMed: 30817905]