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Response to letter to the editor E08-5236A

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We appreciate the opportunity to address the concerns raised by Klein et al regarding the recently published randomized clinical trial of the Active Management of Risk in Pregnancy at Term (AMOR-IPAT).(1)

First, although it is true that the reductions in cesarean delivery rates were not statistically significant, they were clinically meaningful pointing towards the need for a larger trial. We powered the study based on our prior cohort findings and this study revealed a one-third reduction in cesarean delivery rather than the 50% reduction we had predicted. However, we did find statistically significant improvements in two composite assessments of birth health that are probably more important than the cesarean delivery rate alone. Uncomplicated vaginal birth reflects a theoretically ideal outcome, and the Adverse Outcomes Index is a benchmark of obstetric quality that is being used with increasing regularity.

Second, Klein et al suggest that the application of the Bonferroni correction would eliminate the finding of a statistically significant reduction in NICU admission rates in the AMOR-IPAT-exposed group. While this is technically correct, the Bonferroni correction is not routinely used to evaluate a limited number of primary and secondary outcomes in prospective randomized trials. Furthermore, it is not clear that the Bonferroni correction could be used to challenge the statistical significance of the differences of the two composite outcomes.

Third, of the eleven randomized subjects who were excluded, four had already delivered at the time of randomization, one withdrew consent for the study and her outcomes cannot ethically be reported, four underwent cesarean delivery due to persistent breech presentation, and one subject in each study group underwent cesarean delivery for active herpes labialis.

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Such exclusion criteria are a routine part of the study design of an RCT and with a trial such as this, some end up being post-randomization, by definition.

Finally, the statement by Klein et al that less desirable outcomes would occur if AMOR-IPAT were used in the “less highly controlled and committed conditions of usual practice” is an important consideration. Such translation of scientific studies to other practice settings needs to be studied as well. However, we are reassured that significant associations between the use of AMOR-IPAT and improved birth outcomes have already been reported from both non-academic settings (2) and Family Medicine settings (3). We remain optimistic that this thought provoking method of care may improve neonatal outcomes while also reducing the use of cesarean delivery.

References

1. Klein letter reference
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