Response re: A non-inferiority randomized controlled trial to compare transabdominal and transvaginal sonography for eligibility assessment prior to medical abortion

To whom it may concern,

Thank you for your thoughtful comments. We greatly appreciate your suggestions.

We hypothesized at the initiation of our project that women undergoing transabdominal sonography (TAS) would need further evaluation compared to transvaginal sonography (TVS). We did not design our study to assess the difference between the point estimates of each modality. Rather, our goal was to assess whether TAS results would fall within a range that would be clinically useful. We did not expect TAS results to be equal to TVS results.

We hypothesized there might be an underlying 10% difference between the TAS and TVS arms, such that the TAS participants would receive more additional testing. As we noted in our study, the lower bound of those who received additional testing in the TAS group was 15.6%, which did fall within the 95% confidence interval of the a priori non-inferiority margin. In re-assessing our data to address your letter, we agree that our results do not fall in line with conclusive non-inferiority; our results are more consistent with an inconclusive determination (G in Fig. 1) rather than inferiority.

One explanation for this inconclusive determination would be the heterogeneity of our results. Our study showed that there were marked, unexpected differences in the amount of testing ordered for TAS participants when we stratified by provider type. The amount of testing ordered by physicians was notably consistent with our hypothesized values (13.4% after TAS and 3% after TVS); results achieved by physicians alone would lead one to conclude that TAS was non-inferior. In contrast, advanced practice clinicians ordered more testing after TAS than after TVS (27.6% and 6.2%, respectively), a much larger than expected difference. Notably, the advanced practice clinicians ordered more testing overall, even for those participants randomized to TVS.

Therefore, we agree that future work should focus on effective training. These results suggest that advanced practice clinicians may have the most to gain from additional training in using TAS effectively before medication abortion. Of course, another important clinical direction is training for provision of medication abortion without using routine sonography.

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