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Correspondence

Letter to the editor re: "A noninferiority randomized controlled trial to compare transabdominal and transvaginal sonography for eligibility assessment prior to medical abortion"

To the Editor:

We read with great interest the manuscript entitled "A noninferiority randomized controlled trial to compare transabdominal and transvaginal sonography for eligibility assessment prior to medical abortion" by Dr. Fu and colleagues [1].

In Dr. Fu's study, the inferiority margin was set at a difference of 10%. The authors report that 19.9% of women in the transabdominal sonography (TAS) arm required additional testing (urine or serum HCG, additional ultrasound). They claim this is just within the upper bound of 10% more than their pre-specified acceptable difference, and invite the reader to draw their own conclusions. However, this appears to be the incorrect comparator. The difference between the measured point estimates of the two arms was 15.4%, with a 95% confidence interval (CI) of 10.4% to 20.4%. The CONSORT statement on noninferiority suggests that a figure showing confidence intervals and the noninferiority margin may be useful [2]. Referring to Fig. 1 we include here from the CONSORT statement, the noninferiority margin (in this case 10%) is indicated by the dotted line; treatment results whose confidence intervals are completely to the right of it (example "H") are considered inferior (in this case 10.4–20.4%).

This demonstrated inferiority is bolstered by the authors' report that the difference between the groups was significant at the $p<.01$ level. Ultimately, the authors have demonstrated inferiority of TAS for medication abortion eligibility determination given the current degree of comfort of both APNs and MDs with TAS for this indication. This is especially notable given the limited number of obese patients in the TAS arm. Given the many advantages of TAS outlined in this paper, if moving to this modality is to become reality, future work should focus on effective and economical transabdominal ultrasound training. We appreciate the authors including the complete data in Table 3, which allowed us to calculate the between groups difference and CIs [1].

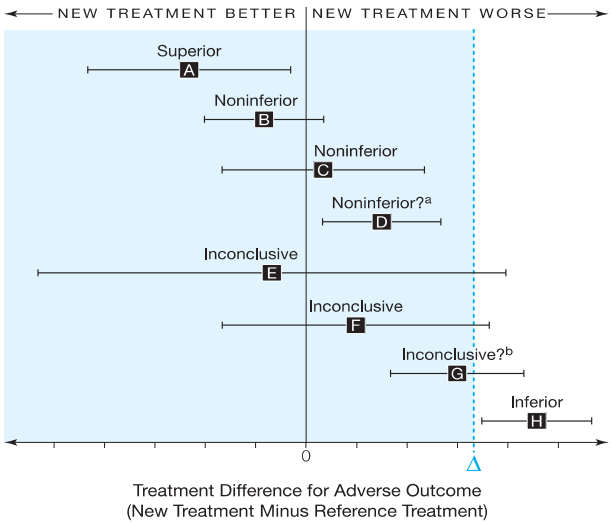

Fig. 1. Possible Scenarios of Observed Treatment Differences for Adverse Outcomes (Harms) in Noninferiority Trials.

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[2] Piaggo G, Elbourne DR, Pocock SJ, Evans SJW, Altman DG. Reporting of noninferiority and equivalence: randomized trials extension of the CONSORT 2010 statement. JAMA 2012;308:2594–604.