

Comparison Between Esketamine and Alfentanil for Hysteroscopy: A Prospective, Double-Blind, Randomized Controlled Trial [Response to Letter]

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Dear editor

We appreciate Dr. Yang's thoughtful comments regarding the rigor of our recently published clinical trial.^{1,2} We agree that these issues deserve attention and discussion.

However, the goal of our study was to evaluate the safety and efficacy at the 95% effective dose (ED95) of these two drugs, rather than to compare the difference in success rates between esketamine and alfentanil. Because the ED95 dose was used during anesthesia with esketamine or alfentanil for hysteroscopy, it is expected that there would be minimal differences in anesthesia success rates between the two groups. Outcomes with small differences in incidence typically require a substantial sample size to achieve statistical significance. Hypotension, a major adverse event associated with alfentanil combined with propofol anesthesia, was the major outcome of this study.³ Therefore, we used the incidence of hypotension for our sample size calculation.

We then estimated the sample size based on previous studies that reported incidence rates of hypotension with esketamine or fentanyl combined with propofol of 6.2% and 35.2%, respectively.^{3,4} Using PASS software, we determined that 36 cases per group were needed to achieve a power of 0.9 and an α of 0.05. Considering a drop-out rate of 15%, we included 43 cases per group. After excluding one patient due to a change in surgical method, 85 patients were analyzed, 43 in the group E and 42 in the group A. This sample size was sufficient for the statistical analysis of our study. In addition, our results showed a statistically significant difference in the incidence of hypotension between group E and group A (4.7% vs 33.3%, $p = 0.001$). This also supports the conclusion of the current study.

Finally, we would like to thank Dr. Yang again for the valuable feedback on our research.

Disclosure

The authors report no conflicts of interest with respect to this communication.

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