Optimal volume of administration of intranasal midazolam in children: A randomized clinical trial.

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Introduction: The optimal intranasal volume of administration (VOA) for achieving timely and effective sedation in children is unclear. We compared outcomes relevant to procedural sedation associated with using three different VOA to administer intranasal midazolam in children.

Methods: We conducted a randomized, single-blinded, three-arm, superiority clinical trial. Children 1 to 7 years old with simple lacerations requiring intranasal midazolam to facilitate the repair were block-randomized to receive midazolam using one of three VOA: 0.2mL, 0.5mL, or 1mL. We videotaped the procedures, with outcome assessors blinded to VOA. Primary outcome was time to onset of minimal sedation (i.e. score of 1 on the University of Michigan Sedation Scale). Secondary outcomes included procedural distress; time to procedure start; deepest level of sedation achieved; adverse events; and clinician and caregiver satisfaction.

Results: Ninety-nine children were enrolled; 96 were analyzed for the primary outcome and secondary outcomes, except for procedural distress (n=90). Time to onset of minimal sedation for each escalating VOA was 4.9 (95% CI 4.3, 5.6), 4.4 (95% CI 3.9, 4.8) and 5.5 (95% CI 4.8, 6.3) minutes, respectively (p=0.01 for VOA of 0.5mL compared to 1mL). There were no differences in secondary outcomes except for clinician satisfaction with ease of administration: fewer clinicians were satisfied when using a VOA of 0.2mL.

Conclusions: Although there was a shorter time to onset of minimal sedation when using a VOA of 0.5mL compared to 1mL, all three VOA produced comparable clinical outcomes. Clinicians were least satisfied with ease of administration using a VOA of 0.2mL.