Title of the abstract: Comparison of efficacy and safety of intranasal Midazolam with syrup Chloral hydrate for procedural sedation of children undergoing Auditory Brainstem evoked Response audiometry – a randomized, double-blinded, placebo controlled trial.

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Objective:

The objective of this study was to evaluate the efficacy and safety of intranasal Midazolam compared to syrup Chloral hydrate for procedural sedation in children undergoing Auditory Brainstem evoked Response audiometry (ABR).

Methods:

A prospective, randomized, double-blinded placebo controlled trial was carried out in the audiology lab of a tertiary care hospital over a period of 18 months. 82 children between the age group of 1 to 6 years (mean 2 years) irrespective of their developmental maturity, belonging to ASA class I and II who were referred for ABR testing were recruited. Children were randomized to receive either midazolam spray with oral placebo or syrup chloral hydrate with nasal placebo spray. The nasal spray was dosed at 0.5 mg/kg delivered as 100mcg per spray and oral syrup at a dose of 50 mg/kg. Those children who did not show onset of sedation at 30 minutes were administered the second dose at half the initial dose. Randomization was computer generated and allocation concealment was

achieved by opaque sequentially numbered sealed envelopes that were employed serially to the participating children. The primary outcome measured were safety which was measured in terms of heart rate, respiratory rate, oxygen saturation and efficacy was measured in terms of level of consciousness (uninterrupted sleep without movement) and successful completion of the procedure. The various secondary outcomes were time to onset of sedation, time to parental separation, nature of parental separation, duration of procedure, parental satisfaction, audiologist's satisfaction, time to recovery and number of attempts.

Results:

The trial was completed over a period of 18 months when 41 children were studied in each arm. Both the drugs were found to be safe with no major adverse events. One child who had received Midazolam developed transient hypoxia. It was corrected with appropriate head positioning. Minor side effects noted were sneezing, hiccups and crying.

Children on Chloral hydrate had an earlier onset of sedation (66% of children) at or less than 30 minutes as compared to only 33% from the Midazolam group. Developmentally delayed children had an earlier onset of sedation compared to developmentally normal group irrespective of the drug they received. Parental separation was earlier for chloral hydrate group at 20 minutes than for midazolam at 30 minutes. There was no statistically significant difference in the duration of procedure. There was a significant difference noted in the time to recovery (Chloral hydrate children (78 minutes) as compared to Midazolam children (105 minutes)). Parental and audiologists satisfaction were higher for Chloral hydrate (95 % and 75% respectively) than for Midazolam (49% and 29%). A larger number of patients (80%) slept with the first dose of Chloral hydrate as against Midazolam children who required a second dose. Overall, sedation was successful among 95% of children who received chloral hydrate compared to 51% of children who received

Midazolam. Once sedation was achieved, both the drugs were efficacious in maintaining sedation with no intra-procedural interruption in sedation.

Conclusion:

Intranasal Midazolam and oral Chloral hydrate are both safe and efficacious for pediatric procedural sedation in ABR. However, Chloral hydrate had a superior efficacy to intranasal Midazolam with an earlier time to onset of sedation, a faster recovery, better parental and audiologist's satisfaction and successful sedation even with the first attempt. There was no difference in the duration of the procedure. Developmentally delayed children showed an earlier onset of sedation and faster recovery compared to their normal counterparts irrespective of the drug regimen they received.