Ethanol Pharmacokinetics in Neonates Secondary to Medication Administration

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Ethanol Pharmacokinetics in Neonates Secondary to Medication Administration

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Abstract

Purpose: Ethanol serves as a solvent and microbial preservative in oral liquid medications and is the second most commonly used solvent in liquid medications following water. Despite widespread use of ethanol in liquid medications in neonates, the pharmacokinetics and toxicity of ethanol in young children are not well described. The aim of the current study is to quantify blood ethanol levels in neonates secondary to oral ethanol containing medications.

Methods: Neonates who received either oral phenobarbital (15% ethanol) and/or oral desmethylase (30% ethanol) per standard of care were eligible for enrollment. A maximum of 6 blood samples per patient (±5 mL total) were taken over the study period. Blood samples were collected via heel stick at the time of clinical laboratory collections or following a specific collection for study purposes. All blood ethanol levels were below the American Academy of Pediatrics recommendation following a single dose of oral ethanol containing medication. All blood ethanol levels were below the American Academy of Pediatrics recommendation following a single dose of oral ethanol containing medication.

Sample Collection

- Approximately one third (1/3) of the blood alcohol levels were below the lower limit of quantitation.
- Blood ethanol levels ranged from below detection to 85 mg/dL.

Endogenous Ethanol Production

- Endogenous blood ethanol levels ranged from below the LLOQ to 1.00 mg/dL in neonates.

Concentrations-Time Profiles

- Ethanol is rapidly eliminated and does not accumulate with the current dosing regimens.

Conclusion & Future Directions

- Ethanol intake secondary to medication administration varied widely, but was generally low.
- Endogenous ethanol generation is present in non-ethanol treated infants (43% of samples ≥LLOQ).

Future Directions

- Develop a population pharmacokinetic model to describe ethanol pharmacokinetics.