Ampicillin Safety in Hospitalized Infants

Background

Ampicillin is the most commonly prescribed medication in the neonatal intensive care unit (NICU). Studies of ampicillin in infants provide limited safety data due to small study size and the Food and Drug Administration (FDA) label does not include adverse events (AE) for infants. We evaluated the safety of ampicillin in a large cohort of infants admitted to the NICU.

Methods

We included all infants discharged from 322 Pediatric NICUs from 1997–2010 exposed to ampicillin; gentamicin; vancomycin; or cefotaxime. We limited our analysis to infants not exposed to ipamprocidine, and without endotracheal or mechanical ventilation. We included the following covariates in all models: gentamicin and vancomycin exposure, gestational age, postnatal age, bacteremia, and NICU admission. We used multivariable logistic regression with generalizing estimating equations to account for clustering by NICU. We compared AEs between infant days of exposure against infant days on ampicillin (p<0.001).

Results

226,332/490,736 (46%) of infants exposed to ampicillin suffered at least one AE. The incidence of any AE was 15/16 (99%) infant days on ampicillin vs. 19/16/10 (99%) infant days on control antibiotics (p<0.001). The odds of any AEs combined were lower on ampicillin: odds ratio (OR)=0.97 (0.94, 1.01). The odds of all AEs combined were lower on ampicillin: odds ratio (95% CI)=0.93 (0.91, 0.95), while the odds of any SAE were not different, OR=0.97 (0.94, 1.01). Our study supports the overall safety of ampicillin, but highlights a number of adverse events of relevance to the clinician prescribing ampicillin.

Conclusions

Serum electrolyte abnormalities were the only laboratory AEs and SAEs more common while exposed to ampicillin. A number of clinical AEs were more common while exposed to ampicillin. Our study supports the overall safety of ampicillin, but highlights a number of adverse events of relevance to the clinician prescribing ampicillin to hospitalized infants.

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