# Lansoprazole Found Safe for Infants With GERD

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SAN FRANCISCO — An investigational formulation of lansoprazole can safely treat gastroesophageal reflux disease in neonates and infants as old as 1 year of age, according to the results of a pair of phase I trials presented in a poster at the annual meeting of the Pediatric Academic Societies.

Dr. Margaret Ann Springer reported that the new formulation of lansoprazole (Prevacid), a proton pump inhibitor, relieved symptoms for most babies in the two studies. At the end of 5 days, the investigators saw improvement in 79% of 24 neonates and in 88% of 24 older infants.

Gastroesophageal reflux disease (GERD) did not worsen in any of the babies. Although four neonates and one older infant had adverse events related to the treatment, no baby had to be withdrawn from the trial because of side effects.

All the babies met judicious criteria for clinically evident GERD before being enrolled, said Dr. Springer, of Louisiana State University in Shreveport, in an interview at the meeting. These included feeding intolerance and refusing to eat; vomiting after feeding; irritability and/or crying while being fed; an arching back; impaired growth; and respiratory symptoms. "Babies can die of these pneumonias. Babies can slow their heart down enough to stop breathing. Babies don't gain weight and grow because every time they eat it hurts."

Lansoprazole is approved for short-term treatment of GERD in children aged 1-17 years. Dr. Springer said the Food and Drug Administration agreed to test it in infants and newborns because GERD is highly symptomatic in this population. She estimated a third to half of babies present with some GERD symptoms, and about 10% have serious cases requiring special care.

TAP Pharmaceutical Products Inc. of Lake Forest, Ill., maker of lansoprazole, sponsored the two open-label trials, which enrolled babies in the United States and Poland. The phase I neonate trial enrolled 24 term or postterm newborns. The average age was 3.7 weeks; mean weight, 3,015 g. The second phase I trial enrolled 24 infants aged 4 weeks to 1 year. Their average age was 24.1 weeks; mean weight, 6,379 g.

Clinicians reconstituted a prepackaged granular powder of lansoprazole in sterile water. For the neonates, they used a concentration of 1 mg/mL, which was delivered once daily in a 0.5-mg/kg or 1.0-mg/kg dose. The older infants were given a 2-mg/mL concentration in a daily 1.0-mg/kg or 2.0-mg/kg dose.

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Lansoprazole could be administered by syringe, intraorally, or via a gastronomy tube. An analysis of pharmacokinetics found infants 10 weeks or younger had "substantially higher exposures" to lansoprazole compared with the older infants.

Each trial included 24-hour pH profiles of six babies to determine changes in intragastric levels. Investigators used a pH level of 4 or greater as a goal to demonstrate the drug was indeed reducing stomach acid. The average percentage of time that pH levels were greater than 4 increased from 77% on day 1 to 97% by day 5 for neonates on 0.5 mg/kg per day of drug, and from 59% to 99% for those on the 1.0-mg/kg daily dose.

The older infants substantially increased the percentage of time their pH profiles reached the target, but the result was not as great. Their proportions went from 50% to 85% on the 1.0-mg/kg daily dose and from 52% to 84% on 2.0 mg/kg per day.

The treatment-related adverse events included two cases of flushing, one of anemia, and one increase in transaminase in the neonates plus one increase in hepatic enzyme in an older infant. Two serious adverse events, respiratory distress syndrome and viral pneumonia, occurred after the last day on lansoprazole, but neither was deemed study related.

Dr. Springer said the pharmaceutical company has initiated a longer safety and efficacy trial based on the results. The meeting was sponsored by the American Pediatric Society, Society for Pediatric Research, Ambulatory Pediatric Association, and American Academy of Pediatrics. ■