Study: Otherwise healthy premature infants 29 weeks gestation and over unlikely to benefit from palivizumab
by Melissa Jenco, News Content Editor

Prescribing palivizumab to certain premature infants won't significantly decrease their likelihood of being hospitalized, according to a new study.

Results of the study support the Academy's 2014 guidelines regarding the use of the drug for infants at risk of severe respiratory syncytial virus (RSV).

"We can feel more confident the AAP 2014 guidelines that were controversial when they were released was right on target and that the otherwise healthy 29-week gestation and above infant does not need and is not likely to benefit from palivizumab," said co-author Harold J. Farber, M.D., M.S.P.H., FAAP, assistant professor of pediatrics in the pulmonary section of Texas Children's Hospital and Baylor College of Medicine.


RSV is a common infection in infants and can lead to hospitalization, especially for those born very prematurely. The Food and Drug Administration licensed palivizumab in 1998 with the aim of lowering hospitalization rates for children who are at high risk of severe RSV.

Since that time, the Academy has continuously updated its guidance on use of the drug, and in 2014 advised against using it for infants born at or after 29 weeks' gestation who are otherwise healthy.

"Cost was considered during deliberations ... but the final guidance as presented here is driven by the limited clinical benefit derived from palivizumab prophylaxis," according to the policy statement.

The recommendation sparked debate among some health care professionals and parents, and a media campaign by the manufacturer pushed for its continued use.

Dr. Farber and his team set out to study the effectiveness of the drug by using data from nine Medicaid managed care programs in Texas. They looked at 14,097 premature infants born in 2012-’14 who were otherwise healthy. Of these, 9.1% had been prescribed palivizumab. That included 843 infants who were born at 29-32 weeks and whose prescriptions carried a retail value of $8.5 million, according to the study.

Researchers found hospitalization rates for RSV were higher (5%) among infants born at 29-32 weeks' gestation who did not receive palivizumab compared to those who did (3.1%). However, for those with bronchiolitis without RSV, the opposite was true. Hospitalization rates were 3.3% for those with a palivizumab prescription and 1.9% for those without one.

"So if you put the two together, it's a wash," Dr. Farber said.

The increased hospitalizations for bronchiolitis without RSV for infants born at 29-32 weeks' gestation taking palivizumab could be due to false-negative test results for RSV or children picking up infections during visits to their pediatrician's office to get their monthly dose, according to Dr. Farber.

"I think when we do administer the medication, we need to be very careful (about) infection control and bring
these kids in an area where they are much less likely to be exposed to other sick children," he said.

Researchers did not find an association between hospitalization rates and palivizumab dispensing for infants born at 33-36 weeks' gestation.

In a related commentary, Carrie L. Byington, M.D., FAAP, chair of the AAP Committee on Infectious Diseases, and Flor M. Munoz, M.D., FAAP, a member of the committee, said the data "provide a real life perspective on the utilization of palivizumab." They noted the high cost and limited impact for infants born at 29-36 weeks' gestation.

"Introduction of more restrictive guidelines in 2014 are likely to have had little impact in this population," they wrote. "In an era in which the overall rate of hospitalization for RSV bronchiolitis has decreased, the study by Farber et al. lends further support to the 2014 AAP guidelines for palivizumab prophylaxis."

**Resources**

- AAP News story "AAP updates guidance on use of palivizumab for RSV prophylaxis"
- AAP News Parent Plus article "RSV 101: Common virus can cause problems for some young infants"
- Information for parents on RSV