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Guest Editorial

New Approach to RSV-Bronchiolitis Prophylaxis: We have a Chance

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Bronchiolitis is an acute, highly contagious, viral lower respiratory tract infection and the leading cause of hospitalization and death in infants less than twelve months of age.

The most common causative agent is respiratory syncytial virus (RSV), although other virus can produce similar clinical presentation, such as rhinovirus, adenovirus, influenza virus, parainfluenza virus, metapneumovirus, alone or in the form of co-infection, have also been reported.

But RSV is the most common cause of hospitalizations for respiratory illness among infants and young children, resulting in largely predictable annual epidemics worldwide, it occurs every year in the winter months. It has been estimated that RSV infects more than 60% of all children during the first year of life, and that RSV infects nearly all children by the time they are 2 years old.

The estimated global impact of RSV-caused infections in infants younger than 5 years of age was reported being approximately 33 million (range: 21.6 - 50.3 million), with 3.2 million hospitalizations (range: 2.7 - 3.8 million), and 120,000 deaths (range: 94,000 - 149,000) annually. A rising intensity of care for children with bronchiolitis with increased intensive care admissions has been observed worldwide in the last years. RSV is a leading cause of infant deaths, primarily in low-income and middle-income countries.

During the first year of life, infants with a primary RSV infection are at risk for a severe lower respiratory tract infection. Preterm infants, as well as young children with chronic lung disease of prematurity or congenital heart disease, are at particularly high risk. Viral bronchiolitis in early life predisposes asthma development later in childhood.

Bronchiolitis is a clinical diagnosis, based on typical history and examination findings. Bronchiolitis typically begins with a coryzal prodrome followed by onset of one or more of cough, fever, difficulty feeding, apnoeic episodes, unsettledness/irritability. In the physical examination we can find tachypnoea, use of accessory muscles, bilateral wheeze and/or fine crepitations or hypoxia.

The main treatment of bronchiolitis is supportive. This involves ensuring appropriate oxygenation and fluid intake, and minimal handling. Cochrane evidence-based reviews have been performed on most treatment modalities for RSV bronchiolitis. No current pharmacologic treatment or novel therapy has been proven to improve outcomes compared to supportive treatment.

To address this, since a specific etiological treatment is not available, pharmacological prophylaxis is recommended based on the prevention of RSV infection. Reducing the global burden of RSV-related illness is considered a global health priority, and is a key priority for the World Health Organization.

But despite more than 50 years of attempts at vaccine development and extensive ongoing clinical research, there is no safe and effective RSV vaccine.

Passive RSV antibody approaches have been effective in clinical studies. The first licensed immunoprophylaxis for RSV was the monoclonal antibody (mAb) palivizumab produced by recombinant DNA technology and targeting the fusion (F) protein of the virus. Evidence has shown that palivizumab, approved in 1999 by European Medicines Agency, effectively reduced hospitalization and prevented lower respiratory tract infections in preterm infants. But Palivizumab was indicated and recommended only for the highest-risk infants: infants born preterm or with chronic disease, usually haemodynamically significant heart disease and chronic respiratory disease. Palivizumab was administered via intramuscular injection once each month during the RSV season for five doses (i.e. 15 mg/kg).

In October 2022, the European Medicines Agency approved nirsevimab a new mAb for the prevention of RSV-associated bronchiolitis in both preterm and full-term infants during their first RSV season. Nirsevimab is a recombinant human immune globulin G1 kappa monoclonal antibody, binds the highly conserved site 0 epitope present on the prefusion conformation of the RSV fusion protein. Nirsevimab is effective at neutralizing both RSV A and RSV B subtypes.

Nirsevimab has greater neutralizing activity and a longer serum half-life than palivizumab. One single intramuscular dose of nirsevimab provides protection for a typical RSV season, whereas monthly injections of palivizumab are required to provide sustained protection during the RSV season. Nirsevimab has a favorable safety profile, with no notable hypersensitivity reactions.

The recommended dose is a single dose of 50 mg administered intramuscularly for infants with body weight < 5 kg and a single dose of 100 mg administered intramuscularly for infants with body weight ≥ 5 kg.

Routine administration of nirsevimab to all infants born during the RSV season or aged less than 6 months at the start of the winter season is recommended to reduce the burden of disease and the rate of hospitalization due to bronchiolitis.

We have a chance with this new approach to RSV-bronchiolitis prophylaxis.

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