Editorial

Prevention strategies for Respiratory Syncytial Virus (RSV) Infections in the APAC region

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Introduction

Respiratory syncytial virus (RSV) infections are a leading cause of acute respiratory illness and bronchiolitis in infants, the elderly, and the immunosuppressed. All humans have been infected with RSV at least once by the age of three. RSV infection induces a wide range of clinical outcomes, from a mild cold to severe respiratory illness and long-term debilitating clinical consequences and death in the older adults and children[1,2,3], its' high prevalence, coupled with the high degree of severe morbidity, make this virus one of the critical public health concerns.

Epidemiology

Globally in young children, from data in latest study in 2019 estimated that there were 33.0 million RSV associated acute lower respiratory infection episodes (LRTI), 3.6 million RSV-associated acute LRTI hospital admission. 26 300 RSV-associated acute LRTI in-hospital deaths, and 101 400 RSV-attributable overall deaths in children aged 0–60 months[3], resulting in a substantial burden on healthcare services. About 45% of hospital admissions and in-hospital deaths due to RSV induced acute LRTI occur in children younger than 6 months.

In 2019, RSV infection accounted for an estimated 5.2 million cases of acute respiratory infection, 470,000 hospitalizations, and 33,000 in-hospital deaths among adults 60 years of age or older in industrialized countries4. In Hong Kong, RSV hospitalization incidence was 2 per 10,000 among adults aged 65-74 years and rose to 10 per 10,000 among 75 years and older (1998–2012)[5].

RSV Infections and Need for Prevention:

Apart from children born prematurely, with chronic pulmonary or congenital heart disease, children with neurological conditions or an immunodeficiency, the elderly age group are also vulnerable to RSV infections. The highest rates of RSV hospitalization are in infants ≤ 2months of age when the ability to elicit strong anti-

RSV responses may be compromised by the presence of maternal antibodies and the immaturity of the infant immune system. In fact, most hospitalizations happen in otherwise healthy infants, highlighting the need to protect all infants against RSV. RSV infections in infants have been associated with the development of asthma, wheezing, and other chronic lung diseases later in life, the risk of severe outcome increases with age with presence of comorbidities.

In the Post COVID-19 pandemic era, we are experiencing a changing epidemiology of RSV surge globally. The proposed mechanisms include: decreased viral immunity in vulnerable age groups caused by the prolonged lack of RSV circulation in the pandemic (immunity debt)[6], potential Severe Acute Respiratory Syndrome Corona Virus 2 (SARS-CoV-2)-induced immune dysregulation, viral interactions between SARS-CoV-2 and RSV, and modifications in health-seeking behaviors as well as heath systems factors.[7,8]

RSV infections are often associated with bacterial coinfection[9,10] One reason being the impaired innate immunity which extends beyond period of viral shedding. Bacterial coinfection in RSV infection was associated with significantly longer hospital stay, more need of ventilator support and higher needs of ICU care. Higher serum CRP level and hyponatremia were the most significant independent predictors of bacterial co-infection in children younger than one-year-old with RSV infection[9]. In adult, a study found that laboratory-confirmed viral-bacterial co-infection as a nonspecific group had a higher mortality, and among patients with viral infection alone, RSV and parainfluenza infection resulted in lower survival rate than influenza. The mortality difference persisted even in the subgroup of patients without chronic lung disease and congestive heart failure[10].

Virology

RSV an enveloped negative-sense single-stranded RNA virus of the family Paramyxoviridae. It encodes 11 proteins, including the fusion (F) and attachment (G) surface glycoproteins that are the targets for virus-neutralizing antibodies. The mature F protein is a trimer of heterodimers consisting of disulfide-linked F1 and F2 subunits. This highly conserved protein exists on the surface of virions in a prefusion conformation that drives an irreversible conformational change that brings the viral and host cell membranes together as it adopts a stable postfusion conformation. Most of the neutralizing activity detected in a human immunoglobulin (IgG) preparation is capable of protecting the at-risk infants from RSV disease and was found to be directed against the prefusion conformational change of RSV F[11] thus blocking the viral entry into the host cells.

Multiple elements of the innate and adaptive immune response[12] contribute to the control of RSV infection. Despite successful viral clearance, protective immunity against RSV is short lived and it is common to become re-infected throughout life[13,14,15]. This poor induction of long-lasting immunity has made the development of an effective vaccine a difficult task.

Preventive Strategies

Three approaches to the prevention of RSV have been pursued: i) passive immunization of infants through the

direct administration of antibodies; ii) maternal immunization during pregnancy with transplacental transfer of antibodies; or iii) active immunization of an individual[16].

During the development of preventive strategies to RSV infection, it is important to avoid the binding of non-neutralizing antibodies or antibodies binding to viral antigens at subneutralizing concentrations without adequately blocking or clearing the infection. This has the potential leading to the promotion of antibody-dependent enhancement of infection (ADE of infection) or enhanced disease severity (ADE of disease)[17,18].

The development of vaccine to RSV was difficult as a vaccine-enhanced RSV disease was observed with a formalin-inactivated vaccine candidate administered to seronegative infants in the 1960s. Infants who were seronegative to RSV before vaccination experienced RSV lower respiratory tract infection more frequently and with more severe disease upon subsequent natural RSV infection, with 80% of vaccine recipients requiring hospitalization (vs 5% of the control group) and 2 fatalities among vaccinated infants[19,20].

Short acting antibodies

The ONLY preventive measures available for children at this moment is palivizumab, a humanized monoclonal antibody (mAb) directed against a neutralizing epitope found on both the pre- and post-fusion forms of the RSV F protein. A **monthly injection** of palivizumab is indicated in a small subset of preterm infants (<35 weeks gestational age) and up to 6 months of age at the start of the RSV season, and those with certain underlying conditions or those with comorbidities: infants with chronic lung diseases or airway abnormalities, haemodynamically significant congenital heart disease, or severe immunodeficiency. In Hong Kong, high risk infants are recommended to receive at least 2 monthly doses (up to maximum of 5 doses) of palivizumab during the RSV season[21]. RSV Prophylaxis with palivizumab is not available for use in healthy term infants.

Long-acting antibodies

Several long-acting mAbs which provide sustained protection are in development, Nirsevimab is one of these long-acting mAbs.

Nirsevimab, a recombinant human mAb that contain three amino acid YTE (M252Y/S254T/T256E) substitutions in the Fc region to give an a > 3-fold longer serum half-life than a typical monoclonal antibody of 11-30 days to approximately 63-73 days in healthy late preterm and term infants. This mAb binds the RSV prefusion (pre-F) protein at the highly conserved antigen site, locking it in the pre-F conformation to block viral entry into the host cell. The neutralising ability was of high potency, neutralizing both RSV-A and RSV-B strains >50-fold higher affinity than palivizumab[22,23].

In a recent Phase III study (MELODY) [24,25] , a single intramuscular dose protects infants with a significantly lower incidence of LRTI in the nirsevimab group compared with placebo group (efficacy 74.5%, p <0.0001) and demonstrated a favourable safety profile. The protection continues throughout two consecutive RSV seasons[26], the similar incidence of RSV LRTI among nirsevimab and placebo recipients in their second RSV

season suggests that prophylaxis with nirsevimab to protect against RSV disease in the first season does not result in a shift of the burden of disease to the second year of life. This is in keeping with evidence that nirsevimab does not inhibit an immune response to natural RSV infection[27]. A Phase II/III study (MEDLEY) demonstrated a similar safety and tolerability profile compared with palivizumab in preterm infants or those with chronic lung disease or chronic heart disease in their first second RSV season[28], the trial is ongoing to the second season[29]. Nirsevimab also demonstrated protective effect to healthy infants against RSV associated LRTI and hospitalization (HARMONIE)[30]. Preliminary early estimate results regarding nirsevimab effectiveness for prevention pf RSV associated hospitalization among infants also available in US a few European countries[31,32,33].

Vaccines

Maternal Immunization

Maternal immunization leads to transplacental transfer of increased levels of maternal antibodies to provide protection in infants immediately after birth and during the first months of life. This strategy is employed to protect infants from tetanus, pertussis, COVID-19, and influenza. The investigational bivalent RSVpreF vaccine used in maternal immunization contains stabilized preF glycoproteins[34] from the two main cocirculating antigenic subgroups (RSV A and RSV B). Phase III clinical study (MATISSE) demonstrated vaccine efficacy in infants after birth within 90 days (81.8%) and within 180 days (69.4%) in preventing severe LRTD[35,36]. Although maternal immunisation is effective in preventing severe RSV -associated lower respiratory tract disease among infants born to vaccinated mothers for up to 6 months after birth, clinical trial data showed a higher percentage of preterm births in the vaccinated group. Besides, in a US post-marketing study, maternal RSV vaccination did not show an increased risk for preterm birth but there was an observed increased risk of hypertensive disorders of pregnancy. Hence, pending additional safety data for using maternal RSV vaccination. Pregnant women may receive RSV vaccination to protect their newborn infants against RSV disease, as an individual decision under informed consent in consultation with their family doctor or doctor providing antenatal care37.

RSV vaccine for the adults 60 years of age or older

An AS01E-adjuvanted RSV prefusion F protein–based candidate vaccine for adults 60 years of age or older (RSVPreF3 OA) contains F protein stabilized in its prefusion conformation, which exposes epitopes targeted by neutralizing antibodies. Phase III clinical trial with 24,966 participants, RSVPreF3 OA showed season one efficacy against RSV LRTD: 94.6% in older adults with at least one underlying comorbidity and 82.6% overall (primary endpoint) and 94.1% against severe LRTD (secondary endpoint) regardless of RSV subtype and the presence of underlying coexisting conditions and with acceptable safety profile[38,39.] Also demonstrated a high vaccine efficacy, 74.5% against RSV LRTD over 2 full seasons and 74.5% in elderly with more than one comorbidity and 82.7% against severe LRTD with a median follow up of 17.8 months. Additional second dose before the next RSV season considered no added benefit[40]. Globally, this RSV vaccine

is licensed and recommended for use in thirteen countries.

International and Global Recommendations

- World Health Organization identified RSV as the most important cause of acute lower respiratory infections in infants and a significant burden in older adults and those with underlying conditions, calling for global surveillance and vaccine development[41].
- In a joint appeal published in The Lancet, The World Society for Pediatric Infectious Diseases (WSPID), The Asian Society for Pediatric Infectious Diseases (ASPID), The Asia Pacific Pediatric Association (APPA) and 41 leading scientific and social organisations from across the globe are calling on Gavi, the Vaccine Alliance, to take urgent action to save millions of young lives by protecting them against RSV[42, 43].
- GAVI is a global partnership that works to ensure access to life-saving vaccines for children in the poorest countries. In collaboration with the World Health Organization (WHO), Gavi has already saved millions of lives by vaccinating children against other major life-threatening diseases.[33]

Strategies in Prevention of RSV Infection

Prevention of RSV illness in the population is a major public health priority. Various regions and countries need to perform health economic studies regarding the health burden of RSV infection in babies, young children, adolescents and the elderly so as to assess the cost benefit ratio regarding the use of various preventive methods including maternal immunization, long acting mAbs for children and RSV vaccines for individuals in the community.

Parents should consider discussing with their healthcare professionals in choosing the most appropriate option to protect their infants against RSV lower respiratory tract infection.

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