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Prevention of Lower Respiratory Tract Diseases caused by RSV in Infants in Poland: A Review of Current Recommendations

Gabriela Mierzwa, Katarzyna Dąbek, Aleksandra Kajtel, Michał Ochwat, Martyna Piekarska, Anna Skowronek, Maria Sudoł

1. **Gabriela Mierzwa [GM]**
   Nowodworskie Medical Center, Miodowa 2, 05-100 Nowy Dwór Mazowiecki
   ORCID: https://orcid.org/0009-0000-5548-2316
   E-mail: gabrielamierzwa0@gmail.com

2. **Katarzyna Dąbek [KD]**
   Country Hospital in Strzyżów, 700-lecia 1, 38-100 Strzyżów
   ORCID: https://orcid.org/0009-0002-2592-0148
   E-mail: dabekkatarzyna63@gmail.com

3. **Aleksandra Kajtel [AK]**
   The University Hospital in Krakow, Macieja Jakubowskiego 2, 30-688 Kraków
   ORCID: https://orcid.org/0009-0004-2576-1209
   E-mail: akajtel@gmail.com

4. **Michał Ochwat [MO]**

Independent Public Health Care Facility No. 1 in Rzeszów,
Czackiego 3, 35-051 Rzeszów
ORCID: https://orcid.org/0009-0000-1225-5519
E-mail: michalochwat.michu@gmail.com

5. **Martyna Piekarska [MP]**

Independent Public Health Care Center of the Ministry of Internal Affairs and Administration in Krakow, Kronikarza Galla 25, 30-053 Kraków
ORCID: https://orcid.org/0009-0008-0698-3307
E-mail: piekarskamartyna@hotmail.com

6. **Anna Skowronek [AS]**

The University Hospital in Krakow, Macieja Jakubowskiego 2, 30-688 Kraków
ORCID: https://orcid.org/0009-0005-8567-6695
E-mail: aniasko99@gmail.com

7. **Maria Sudoł [MS]**

5 Military Clinical Hospital with Polyclinic SPZOZ, Wrocławska 1-3, 30-901 Kraków
ORCID: https://orcid.org/0009-0009-7204-3097
E-mail: sudol.m@o2.pl

Corresponding author:

Gabriela Mierzwa

Nowodworskie Medical Center, Miodowa 2, 05-100 Nowy Dwór Mazowiecki
E-mail: gabrielamierzwa0@gmail.com

Abstract

Introduction

Respiratory syncytial virus (RSV) is the frequent cause of severe lower respiratory tract infection (LRTD) in infants, with the most severe cases concentrated among infants.

Objectives

The aim of this study was to review the current recommendations, as well as the availability and options for prophylaxis of LRTD caused by RSV in infants in Poland.

Material and Methods

Databases such as PubMed, UpToDate and Google Scholar were used for research with the keywords included: vaccine, RSV, nirsevimab, palivizumab, Abrysvo, respiratory syncytial virus, maternal immunization, prevention. The review included studies evaluating the efficacy, safety, and comparison of immunization methods against RSV, along with new recommendations and guidelines from medical societies and organizations, especially in Poland.

Results

In Poland, RSV prevention in infants includes:

1. **Palivizumab**: Monthly injections during RSV season for high-risk infants, including preterm babies and those with serious health conditions.
2. **Nirsevimab**: A single-dose monoclonal antibody recommended for all infants under 1 year, though not yet available in Poland.
3. **RSV Vaccine (RSVpreF)**: For pregnant women (24–36 weeks), offering passive protection to newborns. Available in Poland from May 2024.

These strategies provide tailored protection based on individual needs and risks.

Conclusions

In Poland, effective LRTD caused by RSV prevention methods for infants are increasingly available, requiring healthcare providers and pregnant women to understand their benefits and limitations to make informed health decisions.

Keywords

RSV; Vaccination; Immunity; Infants

Introduction

Respiratory syncytial virus (RSV) is a leading cause of lower respiratory tract disease (LRTD) in infants. In the first months of life, 2-3% of infected children require hospitalization. The highest incidence of RSV-induced LRTD occurs within the first six months of life, although all infants are at risk of severe RSV infection. Approximately 80% of children under the age of two hospitalized with RSV have no chronic comorbidities or identifiable risk factors, making it difficult to predict which cases will have a severe course. In Poland, 94% of children hospitalized due to RSV infection are not considered at risk and were born full-term. Currently, no curative treatment exists for RSV, highlighting the critical importance of prevention[1-6].

In Poland, an official monitoring system for RSV infections has been in place since February 25, 2023. This system was established following the Minister of Health's regulation on February 23, 2023, which incorporated RSV under the provisions for preventing and combating infectious diseases. Clinically, this requires reporting confirmed RSV infections to the appropriate local sanitary-epidemiological station (PSSE). Reporting must be based on a positive rapid antigen test or laboratory confirmation, such as RSV isolation or nucleic acid detection via reverse transcription polymerase chain reaction (RT-PCR). Reports must be filed immediately, no later than 24 hours after diagnosis, using the ZLK-1 form or electronically via the Threat Monitoring System[7].

According to Mazela et al.[8], hospitalization rates per 1,000 residents during the 2022/2023 season were as follows:

- 44.9 for children under one month,
- 94.9 for children aged 2–3 months,
- 61.6 for children aged 4–6 months,
- 27.6 for children aged 7–12 months.

Methods

Databases such as PubMed, UpToDate and Google Scholar were used for research with the keywords included: vaccine, RSV, nirsevimab, palivizumab, Abrysvo, respiratory syncytial virus, maternal immunization, prevention. The review included studies evaluating the efficacy, safety, and comparison of immunization methods against RSV, along with new recommendations and guidelines from medical societies and organizations, especially in Poland.

Prophylactic options

Palivizumab

Since 2008, palivizumab, a monoclonal antibody against RSV, has been available in Poland. It is currently approved for use in:

- Infants born before 28 weeks of gestation,
- Children up to 2 years old with bronchopulmonary dysplasia or hemodynamically significant congenital heart defects,
- Infants up to 6 months old born between 29 and 32 weeks of gestation,
- Infants born before 35 weeks of gestation with a birth weight not exceeding 1500 g,
- Starting September 1, 2024, children up to 2 years old diagnosed with spinal muscular atrophy and those up to 1 year old with cystic fibrosis[9, 10].

Palivizumab is administered via intramuscular injection once a month throughout the RSV season (September 1 to April 30). Under Poland's drug program, a maximum of five doses per season is allowed.

Nirsevimab

In 2022, the European Medicines Agency (EMA) approved a new monoclonal antibody, nirsevimab, aimed at all newborns and infants during their first RSV season. The Polish Society of Vaccinology recommends that all infants under 1 year of age receive this single-dose passive immunization, regardless of comorbidities. For children at risk of severe RSV infection, the recommendation extends to those under 2 years old during their second RSV season. Nirsevimab can be administered alongside routine vaccinations[1, 11-14].

Despite its European approval, nirsevimab is not yet available in Poland. However, studies have demonstrated its high efficacy in reducing cases of RSV-induced bronchiolitis and hospitalizations due to RSV-related bronchiolitis or pneumonia (Tab. 1)[15-19]. Nirsevimab is given as a single intramuscular injection before or during the RSV season.

Tab. 1. Effectiveness of nirsevimab in countries that introduced it into routine use during the 2023/2024 season

France
-reduction of bronchiolitis cases by 70% during the 2022/2023 and 2023/2024 seasons
Spain
-significant decrease in RSV-related hospitalizations among infants under 6 months -87.6% reduction in hospitalizations due to bronchiolitis caused by RSV -90.1% decrease in ICU admissions related to RSV bronchiolitis -48.1% reduction in outpatient bronchiolitis cases -68.9% decrease in RSV-related infections -60.7% reduction in viral pneumonia cases -55% decrease in emergency room visits for bronchiolitis

Luxembourg
-38% reduction in RSV-related hospitalizations among children under 5 years -69% decrease in RSV-related hospitalizations among infants under 6 months
United States
-90% reduction in hospitalizations associated with RSV infections

RSV Vaccine (RSVpreF - Abrysvo®)

In August 2023, the U.S. Food and Drug Administration (FDA) approved the RSV vaccine RSVpreF (Abrysvo®) for use in pregnant women between the 32nd and 36th weeks of pregnancy. The Abrysvo vaccine is a bivalent RSV vaccine containing two recombinant F proteins (in their prefusion conformation) from RSV subgroups A and B. These proteins are essential for RSV infection and are the primary targets for antibodies generated following vaccination. The purpose is to provide passive protection against lower respiratory tract diseases (LRTD) caused by RSV during the first six months of an infant's life. In Poland, Abrysvo® is available from May 2024, and national guidelines are currently under development[20-23].

The vaccine works by transferring IgG-class antibodies from the mother to the fetus through the placenta and to the infant during breastfeeding, offering passive protection against RSV. This mechanism has been well-documented in vaccinations recommended during pregnancy, such as those against pertussis, influenza, and COVID-19. These vaccinations have proven to be effective and safe for both pregnant women and their children[24-26].

Currently, Poland has two registered vaccines for RSV prevention. However, only one is approved for use during pregnancy to provide passive protection against RSV-related lower respiratory tract diseases in infants from birth to six months of age. According to the product characteristics, this vaccine should be administered as a single dose between the 24th and 36th weeks of pregnancy[21].

Discussion

RSV infection remains a significant clinical and epidemiological challenge both in Poland and worldwide. Since 1958, efforts have been underway to develop effective prophylaxis against these infections. However, progress has been hindered by the virus's antigenic variability, ability to evade the host immune system, and lack of lasting immunity following infection. Currently, RSV prevention strategies include two monoclonal antibodies: palivizumab and nirsevimab, as well as vaccines for the adult population, including pregnant women.

Key questions remain about which RSV prophylaxis method is most advantageous for infants and under what circumstances. The recent approval of an RSV vaccine for pregnant women marks a breakthrough in protecting the youngest patients. Randomized studies have shown that a single dose of the RSV vaccine administered to pregnant women between 28+0 and 36+0 weeks of gestation reduced the risk of RSV-induced lower respiratory tract infections (LRTIs) in the first 90 days of life by 39.4% (95% CI 5.3–61.2%). For severe LRTIs with hypoxemia caused by RSV, the efficacy was 48.3% (95% CI -8.2–75.3%)[27].

Differences in vaccine registration by the FDA in the U.S. (32–36 weeks) and the EMA in the EU (24–36 weeks) highlight varying approaches to mitigating risks. The FDA's recommendation of vaccinating no earlier than 32 weeks may be more cautious, minimizing the risk of preterm birth and ensuring higher antibody levels in newborns, thus enhancing postnatal protection. However, this excludes infants born before 32 weeks from benefiting from maternal vaccination. These nuances are reflected in varying recommendations across countries (Tab. 2) [4,28-33] . There is no universal solution, which underscores the need for tailored guidelines that consider local population needs and risks.

Tab. 2. Recommendations for RSV Infection Prophylaxis in Infants through Maternal Vaccination

Country	Recommendation
Austria	A single dose of the vaccine administered between the 24th and 36th week of pregnancy shortly before the start of the RSV epidemic season
United Kingdom	A single dose of the vaccine administered between the 28th and 36th week of pregnancy shortly before the start of the RSV epidemic season
Belgium	A single dose of the vaccine administered between the 28th and 36th week of pregnancy shortly before the start of the RSV epidemic season
France	A single dose of the vaccine administered between the 32nd and 36th week of pregnancy shortly before the start of the RSV epidemic season
Argentina	A single dose of the vaccine administered between the 32nd and 36th week of pregnancy during the RSV epidemic season
United States	A single dose of the vaccine administered between the 32nd and 36th week of pregnancy, administered seasonally (September–January)

It is estimated that it takes at least 14 days for the mother to produce specific antibodies after vaccination, which is why the upper limit for the timing of vaccine administration is the 36th week of pregnancy.

The experts from the Advisory Committee on Immunization Practices (ACIP) have addressed the possibility of using both preventive methods — vaccination and monoclonal antibodies — simultaneously, though this approach is not routinely recommended. There are situations in which the administration of nirsewimab in infants born at least 14 days after the mother's vaccination during pregnancy may be considered, including:

- The risk of a weaker immune response to vaccination in the mother or limited transport of specific antibodies across the placenta.
- The risk of loss of maternal antibodies in the infant (e.g., due to the use of extracorporeal circulation or extracorporeal blood oxygenation).
- The infant is in a high-risk group for severe RSV infection.

The decision on which intervention is most beneficial should be made by the patient in consultation with their healthcare provider. Each preventive method has its advantages and disadvantages, and the choice may also be influenced by its availability or lack thereof (Tab. 3)[34].

Tab. 3. Advantages and disadvantages of RSV prevention methods in infants.

Prevention method	**Advantages**	**Disadvantages**
Vaccination of pregnant women against RSV	Protection immediately after birth No need for an injection in the infant	Potential risk of preterm birth Risk of adverse events (AE) Weaker protection if there is reduced antibody production by the mother or inefficient transplacental antibody transfer
Administration of nirsevimab to the infant	No risk of negative effects for the pregnant woman Antibodies are directly given to the infant Likely longer duration of protection for the	Currently unavailable Need for an injection in the infant

	child	
Administration of palivizumab to the infant	No risk of negative effects for the pregnant woman Antibodies are directly given to the infant Likely longer duration of protection for the child	Need for multiple injections in the infant Available free of charge only through the drug program

Conclusions

In Poland, there is an increasing availability of effective methods for preventing RSV-related diseases in infants. Each method has its advantages and disadvantages, which should be well understood by healthcare providers, particularly neonatologists, pediatricians, and obstetricians, as well as by pregnant women. This knowledge will empower patients to make informed decisions regarding their own health and the health of their children.

DISCLOSURE

Author`s contribution:

Conceptualization: Gabriela Mierzwa, Katarzyna Dąbek

Methodology: Gabriela Mierzwa, Martyna Piekarska

Software: Michał Ochwat, Aleksandra Kajtel

Check: Anna Skowronek, Maria Sudoł

Formal analysis: Gabriela Mierzwa, Martyna Piekarska

Investigation: Gabriela Mierzwa, Katarzyna Dąbek
Resources: Maria Sudoł, Michał Ochwat
Data curation: Anna Skowronek, Aleksandra Kajtel
Writing -rough preparation: Gabriela Mierzwa, Michał Ochwat, Katarzyna Dąbek
Writing -review and editing: Anna Skowronek, Aleksandra Kajtel
Visualization: Martyna Piekarska
Supervision: Maria Sudoł, Anna Skowronek
Project administration: Gabriela Mierzwa

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