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+15878858911
editorial-office@sciformat.ca

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NEW STRATEGIES FOR THE PREVENTION OF RSV INFECTIONS IN CHILDREN – A REVIEW ARTICLE

Oktawia Gwiaździńska *(Corresponding Author, Email: o.gwiazdzinska@gmail.com)*
Independent Researcher, Szczecin, Poland
ORCID ID: 0009-0001-1212-4276

Anita Strzykała
Independent Researcher, Szczecin, Poland
ORCID ID: 0009-0003-5392-2199

Jakub Lewandowski
Independent Researcher, Szczecin, Poland
ORCID ID: 0009-0006-2477-8660

Igor Szlegiel
Independent Researcher, Szczecin, Poland
ORCID ID: 0009-0000-8271-8945

Denis Myszak
Independent Researcher, Szczecin, Poland
ORCID ID: 0000-0001-5275-3141

ABSTRACT

Background: Respiratory syncytial virus (RSV) is a leading cause of lower respiratory tract infections in infants and young children worldwide, contributing substantially to hospitalizations, healthcare utilization, and long-term respiratory morbidity. Despite decades of preventive efforts, RSV remains a major public health burden, particularly in high-risk populations.
Objective: To review current and emerging strategies for the prevention of RSV infection in children, including traditional passive immunoprophylaxis, next-generation monoclonal antibodies, and maternal vaccination during pregnancy.
Methods: A narrative review of key clinical trials, systematic reviews, and guideline-based recommendations was conducted, focusing on evidence supporting palivizumab, nirsevimab, and maternal RSV vaccination. Data from pivotal randomized controlled trials and real-world studies were synthesized.
Results: Palivizumab, a monoclonal antibody targeting the RSV fusion (F) protein, has demonstrated a reduction in RSV-related hospitalizations of approximately 50–55% in high-risk infants, but its use is limited by cost and repeated dosing requirements. Nirsevimab, a long-acting monoclonal antibody, provides season-long protection after a single dose and has shown a reduction of up to 74.5% in medically attended RSV lower respiratory tract infections, with additional evidence from real-world studies confirming reduced hospitalization rates. Maternal RSV vaccination has been shown to confer passive immunity to infants through transplacental antibody transfer, significantly reducing severe RSV disease and hospitalization in early infancy, with a favorable safety profile.
Conclusions: Advances in RSV prevention have shifted clinical practice from targeted prophylaxis in high-risk infants toward broader population-based strategies. Long-acting monoclonal antibodies and maternal vaccination represent complementary and highly effective approaches with the potential to substantially reduce RSV-associated morbidity, hospitalizations, and healthcare burden globally.

KEYWORDS

RSV, Respiratory Syncytial Virus, Nirsevimab, Palivizumab, Pediatric Infections, Immunoprophylaxis, Maternal Vaccination, Pediatric Public Health

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1. Introduction

Respiratory syncytial virus (RSV) is a single-stranded RNA virus belonging to the Pneumoviridae family, one of the most common causes of lower respiratory tract infections in children worldwide (Hall et al., 2013; Kliegman & St. Geme, 2020; Murray et al., 2020; Shi et al., 2017). Infection occurs primarily through respiratory droplets and contact with respiratory secretions from an infected individual (Kliegman & St. Geme, 2020; Murray et al., 2020). The virus has a particular affinity for the respiratory tract epithelium, leading to its damage and the development of an inflammatory response (Collins & Graham, 2008; Murray et al., 2020; Openshaw & Chiu, 2013).

In pediatric practice, RSV is the leading etiological cause of bronchiolitis and one of the leading causes of pneumonia in infants (Hall et al., 2013; Shi et al., 2017). It is estimated that most children become infected with RSV within the first two years of life (Hall et al., 2013; Nair et al., 2010; Reeves et al., 2019). These infections pose a substantial clinical burden due to their high frequency and associated hospitalization rates (Nair et al., 2010; Shi et al., 2017; Stein et al., 2017).

The highest risk of severe infection occurs in premature infants, children with chronic lung disease, congenital heart defects, and immunodeficiencies (Shi et al., 2017; Stein et al., 2017). In these patients, RSV infection can lead to severe respiratory failure requiring hospitalization and, in some cases, long-term hospitalization (Shi et al., 2017; Stein et al., 2017). The clinical importance of RSV in pediatrics also lies in its potential long-term health consequences, such as an increased risk of developing bronchial obstruction later in life (Blanken et al., 2013; Hall et al., 2013; Murray et al., 2020).

RSV infections also pose a significant burden on healthcare systems, resulting in substantial healthcare costs, including hospitalization and treatment expenses (Hodgson et al., 2021; Li et al., 2022). This issue remains particularly relevant due to the rapid development of new preventive strategies, including long-acting monoclonal antibodies (Hammitt et al., 2022; Zhu et al., 2017). The introduction of new preventive strategies offers the potential to reduce hospitalizations and the risk of severe infection in children (Hammitt et al., 2022; Mazur et al., 2023). Furthermore, epidemiological changes observed in recent years emphasize the need to update our knowledge about RSV infections (Shi et al., 2017).

The aim of this review is to summarize current and emerging strategies for the prevention of RSV infections in children, with particular emphasis on their clinical effectiveness and public health impact.

2. Methodology

This manuscript is a narrative review of the literature focusing on preventive strategies for RSV infections in children. A structured search was conducted in PubMed, Scopus, and Web of Science databases using keywords such as “RSV”, “nirsevimab”, “palivizumab”, and “maternal RSV vaccination”.

Peer-reviewed articles, randomized controlled trials, systematic reviews, and international guidelines published in English were included. Priority was given to high-quality clinical trials and meta-analyses. Studies focusing on pediatric populations and RSV prevention were selected.

Due to the narrative nature of the review, no formal statistical analysis was performed.

3. Epidemiology and Clinical Significance

Infections caused by respiratory syncytial virus (RSV) occur worldwide and constitute a significant public health problem. Studies indicate that children under 5 years of age are the most affected population (Borchers et al., 2013; Nair et al., 2010; Shi et al., 2017). RSV infections show marked seasonality, especially in temperate climates. The peak incidence occurs during the autumn and winter months, most often from November to March (Obando-Pacheco et al., 2018; PATH, 2023; Shi et al., 2017). However, it should be emphasized that in recent years, especially after the COVID-19 pandemic, changes in the seasonality of RSV infections have been observed, which may be related to previously implemented epidemic restrictions (Shi et al., 2017).

RSV is one of the most common causes of lower respiratory tract infections in children, accounting for a substantial proportion of cases of bronchiolitis and pneumonia (Kliegman & St. Geme, 2020; Nair et al., 2010; Shi et al., 2017). It is estimated that most children become infected with RSV within the first two years of life, and some develop severe disease requiring hospitalization (Hall et al., 2013; Nair et al., 2010). The highest incidence and risk of severe illness are observed in infants, particularly in their first months of life (Hall et al., 2013).

From an epidemiological perspective, RSV is a significant cause of infant hospitalization worldwide (Shi et al., 2017; Stein et al., 2017). Data indicate that RSV infections account for a significant proportion of hospital admissions due to lower respiratory tract infections, and in severe cases may require admission to an intensive care unit (Stein et al., 2017). The burden on the healthcare system associated with RSV includes not only hospitalizations but also frequent outpatient visits and the need to follow-up of patients after infection (Borchers et al., 2013; Hodgson et al., 2021; Li et al., 2022).

Groups particularly at risk of severe illness include premature infants, children with bronchopulmonary dysplasia, congenital heart defects, and immunocompromised patients. In these patients, RSV infection more often leads to complications such as severe respiratory failure requiring oxygen therapy or mechanical ventilation (Shi et al., 2017; Stein et al., 2017). However, it should be emphasized that a significant proportion of hospitalizations also occur in previously healthy children, indicating the broad impact of this pathogen.

4. Pathogenesis and Clinical Course

Respiratory syncytial virus (RSV) has a particular affinity for ciliated epithelial cells of the respiratory tract, particularly in the bronchioles (Collins & Graham, 2008; Murray et al., 2020). Infection occurs primarily through droplets or direct contact with respiratory secretions from an infected individual (Kliegman & St. Geme, 2020; Murray et al., 2020). After entering host cells, the virus replicates rapidly, leading to epithelial damage, loss of cilia, and shedding of cells into the respiratory tract (Collins & Graham, 2008; Murray et al., 2020). This process disrupts mucociliary clearance mechanisms and promotes secretion retention (Collins & Graham, 2008; Openshaw & Chiu, 2013).

A key element in the pathogenesis of RSV infection is the host's inflammatory response. Activation of the immune system leads to the influx of inflammatory cells, including neutrophils, lymphocytes, and macrophages. This is accompanied by increased production of inflammatory mediators (Collins & Graham, 2008; Openshaw & Chiu, 2013). This leads to swelling of the bronchiole walls and overproduction of mucus. The accumulation of secretions, desquamated epithelial cells, and inflammatory infiltrate causes narrowing of the small airways, leading to increased airway resistance and impaired ventilation (Kliegman & St. Geme, 2020; Murray et al., 2020). These mechanisms underlie the development of bronchiolitis, the most common clinical manifestation of RSV infection in infants.

The clinical presentation of RSV infection varies and depends primarily on the patient's age and the presence of comorbidities (Stein et al., 2017). In older children, the infection is usually mild and limited to upper respiratory tract symptoms such as rhinorrhea, cough, and low-grade fever (Hall et al., 2013). However, in infants, especially in the first months of life, infection can lead to lower respiratory tract involvement in the form of bronchiolitis or pneumonia, significantly worsening the prognosis (Stein et al., 2017). The typical course of infection in the youngest patients begins with symptoms of upper respiratory tract infection, followed by disease progression within a few days (Stein et al., 2017). The clinical presentation is dominated by signs of airway obstruction, such as dyspnea, tachypnea, expiratory wheezing, and intercostal retraction (Stein et al., 2017). Physical examination often reveals crackles and a prolonged expiratory phase (Hall et al., 2013). In more severe cases, hypoxemia develops, requiring oxygen therapy and sometimes respiratory support (Hall et al., 2013; Shi et al., 2017; Stein et al., 2017).

A particularly severe course of infection is observed in at-risk children, in whom RSV can lead to acute respiratory failure requiring hospitalization or even treatment in an intensive care unit (Shi et al., 2017; Stein et al., 2017). In the youngest infants, especially those born prematurely, the infection may present atypically, manifesting as episodes of apnea (Hall et al., 2013).

The clinical significance of RSV infection is not limited to the acute phase of the disease. Severe RSV infections in early childhood have been shown to be associated with an increased risk of developing bronchial hyperresponsiveness and asthma later in life (Blanken et al., 2013; Hall et al., 2013; Murray et al., 2020). Furthermore, complications such as secondary bacterial superinfections and impaired lung ventilation are possible. Moreover, these infections can impact the quality of life of patients and their families, leading to absenteeism for caregivers and increased utilization of healthcare resources (Hodgson et al., 2021; Wang et al., 2008).

5. Current Methods of RSV Infection Prevention in Children

Until recently, options for preventing RSV infections were limited and focused primarily on passive immunoprophylaxis in children from high-risk groups. The most commonly used drug was palivizumab.

Palivizumab is a humanized monoclonal antibody directed against the RSV fusion protein (F), responsible for the pathogen's entry into host cells (American Academy of Pediatrics Committee on Infectious Diseases, 2009; Mejias & Ramilo, 2024). It was the first effective agent for specific RSV prophylaxis in children from high-risk groups (Mejias & Ramilo, 2024). Palivizumab's mechanism of action involves virus neutralization and inhibition of the fusion of the viral membrane with the host cell membrane (Mejias & Ramilo, 2024).

The clinical efficacy of palivizumab was confirmed in the randomized, double-blind IMpact-RSV clinical trial, which included 1,502 infants born prematurely or with bronchopulmonary dysplasia (Feltes et al., 2003). This study demonstrated a reduction in hospitalizations due to RSV infection by approximately 55% compared to the placebo group (Feltes et al., 2003). A particularly pronounced effect was observed in premature infants without bronchopulmonary dysplasia, where the reduction in hospitalizations reached up to 78% (Feltes et al., 2003; Simoes et al., 2007). Furthermore, the group receiving palivizumab had a shorter hospitalization period and a lower need for oxygen therapy and treatment in the intensive care unit (Feltes et al., 2003).

Subsequent studies and systematic analyses have confirmed the favorable efficacy and safety profile of palivizumab in high-risk populations (Andabaka et al., 2013; Simoes et al., 2007). Systematic reviews have shown that the use of this antibody leads to a significant reduction in the number of RSV-related hospitalizations and intensive care unit admissions (Andabaka et al., 2013). Meta-analyses also indicate a reduction in the risk of hospitalization by approximately 50% compared to placebo (Andabaka et al., 2013; Anderson et al., 2017; Wang et al., 2008).

Palivizumab is administered as an intramuscular injection at a dose of 15 mg/kg body weight every 30 days during the RSV season (American Academy of Pediatrics Committee on Infectious Diseases, 2009). However, the need for repeated administration is a significant limitation of this form of prophylaxis, affecting its cost and availability (Wang et al., 2008). Therefore, the drug is recommended primarily for children from high-risk groups, such as premature infants, children with chronic lung disease, and those with significant heart defects (American Academy of Pediatrics Committee on Infectious Diseases, 2009).

Despite its documented efficacy, the use of palivizumab has not led to the complete elimination of severe RSV infections, which is partly due to the limited population eligible for prophylaxis (Wang et al., 2008). Nevertheless, for over 25 years of use, palivizumab remained the standard of RSV prophylaxis, and its efficacy was confirmed both in clinical trials and real-world observations (Anderson et al., 2017; Mejias & Ramilo, 2024; Simoes et al., 2007). The introduction of this antibody represented a significant breakthrough in the prevention of severe RSV infections, setting the direction for the development of modern immunoprophylaxis strategies (Mejias & Ramilo, 2024).

6. New Prevention Strategies

6.1. Next-Generation Monoclonal Antibodies

Nirsevimab is a new generation of long-acting monoclonal antibodies developed for the effective prevention of RSV infection in infants (Hammitt et al., 2022; Zhu et al., 2017). Unlike previously used methods, this preparation provides long-lasting protection after a single dose, representing a major advancement in RSV prevention strategies (Domachowske et al., 2018; Griffin et al., 2020b; Hammitt et al., 2022).

Nirsevimab is a long-acting monoclonal antibody directed against the RSV fusion protein (F), which plays a key role in viral entry into host cells (Zhu et al., 2017). Unlike previous preparations such as palivizumab, nirsevimab has been modified to extend its half-life, allowing protection throughout the RSV infection season after a single dose (Griffin et al., 2020a; Hammitt et al., 2022). The mechanism of action involves virus neutralization by stabilizing the prefusion conformation of the F protein, which effectively prevents fusion of the virus with the host cell membrane (Zhu et al., 2017).

The clinical efficacy of nirsevimab was confirmed in the multicenter, randomized, phase III MELODY study, which included healthy infants born at term or late preterm (Hammitt et al., 2022). This study demonstrated that a single dose of nirsevimab reduced the risk of medically significant RSV lower respiratory tract infections by approximately 74.5% compared to placebo (Hammitt et al., 2022). Additionally, a reduction in RSV-related hospitalizations was observed, indicating the significant clinical significance of this intervention (Drysdale et al., 2023; Hammitt et al., 2022; Li et al., 2020).

A previous Phase IIb study by Mark P. Griffin et al., including premature infants, demonstrated a reduction in the incidence of RSV lower respiratory tract infections by approximately 70% (Griffin et al., 2020b). These results confirmed the high efficacy of nirsevimab also in high-risk populations. Importantly, the protective effect was maintained throughout the RSV season after a single dose of nirsevimab (Griffin et al., 2020b).

The safety of nirsevimab was assessed as favorable in clinical trials, and the incidence of adverse events was comparable to placebo (Griffin et al., 2020a & 2020b). The most frequently observed adverse events were mild and included injection site reactions and transient systemic symptoms (Griffin et al., 2020a, 2020b). The lack of the need for repeated administration of the drug represents a significant advantage over previous preventive strategies (Hammitt et al., 2022).

A significant breakthrough is the ability to use nirsevimab in a broad population of infants, rather than exclusively in high-risk groups (Domachowske et al., 2018; Hammitt et al., 2022). This approach allows for a substantial expansion of prophylactic coverage and a potential reduction in the global burden of RSV infections (Hammitt et al., 2022; Mazur et al., 2023). The results of the HARMONIE study, conducted in a real-world clinical setting, confirmed the efficacy of nirsevimab in reducing RSV-related hospitalizations in the general infant population (Drysdale et al., 2023).

The introduction of nirsevimab into clinical practice represents a significant step in the development of RSV infection prevention, shifting the approach from selective immunoprophylaxis to a population-based strategy (Hammitt et al., 2022; Mazur et al., 2023). This drug has the potential to significantly reduce hospitalizations, complications, and healthcare costs associated with RSV infections (Cromer et al., 2017; Hammitt et al., 2022; Li et al., 2022). Consequently, nirsevimab may play a key role in future preventive programs in pediatrics.

6.2. Maternal Vaccination for the Prevention of RSV Infections in Infants

Vaccination of pregnant women is a promising strategy for the prevention of RSV infection in infants, based on the mechanism of passive transfer of antibodies from mother to child across the placenta (Munoz & Jamieson, 2018; Swamy & Heine, 2015; Welliver, 2003). The aim of this intervention is to protect the child during the first months of life, when the risk of severe RSV infection is highest (Madhi et al., 2020; Swamy & Heine, 2015). IgG antibodies produced by the mother cross the placental barrier, reaching high concentrations in the fetal circulation before birth (Swamy & Heine, 2015; Welliver, 2003).

RSV vaccines used in pregnant women contain the fusion protein (F) antigen in a stable pre-fused form, enabling the induction of a strong immune response (Munoz & Jamieson, 2018). Their mechanism of action involves the production of high levels of neutralizing antibodies in the mother, which then provide passive protection to the newborn after birth (Mazur et al., 2023; Munoz & Jamieson, 2018; Swamy & Heine, 2015). This strategy is particularly important because the immune system of infants in the first months of life is immature and less effective in fighting viral infections.

The effectiveness of maternal vaccination during pregnancy was assessed in a randomized, double-blind, phase III clinical trial conducted by Kampmann and colleagues (2023). This study demonstrated a significant reduction in the incidence of severe RSV lower respiratory tract infections in infants in the first months of life. A reduction in RSV-related hospitalizations was also observed, underscoring the clinical importance of this strategy (Kampmann et al., 2023).

The safety profile of vaccines administered during pregnancy was assessed as favorable, and the incidence of adverse events was comparable to the control group (Kampmann et al., 2023; Madhi et al. 2020). The most commonly observed symptoms were mild and included local reactions and transient systemic symptoms. No significant increase in the risk of complications for either the mother or the fetus was observed (Madhi et al. 2020).

A key advantage of maternal vaccination is its ability to protect a broad population of newborns without the need for direct administration of vaccines to the child (Munoz & Jamieson, 2018; Swamy & Heine, 2015). This strategy may be particularly useful in countries with limited access to healthcare, where implementation of other forms of prophylaxis may be difficult. However, the effectiveness of this method depends on the timing of vaccine administration and the antibody level achieved before delivery.

Vaccination during pregnancy is an important complement to available RSV prevention methods, such as monoclonal antibodies, and may play a key role in reducing the global burden of these infections (Mazur et al., 2023; Swamy & Heine, 2015). Implementing this strategy in clinical practice could significantly reduce the number of severe cases and hospitalizations in the youngest patients.

Key differences between available preventive strategies are summarized in Table 1.

Table 1. Comparison of palivizumab, nirsevimab, and maternal vaccination for the prevention of RSV infections in children

Feature	Palivizumab	Nirsevimab	Maternal vaccination during pregnancy
Type	Monoclonal antibody	Monoclonal antibody (long-acting)	Vaccine (maternal active immunization)
Mechanism of action	RSV virus neutralization (F protein)	RSV neutralization (pre-fusion F protein)	Transplacental transfer of IgG antibodies
Number of doses	Every 30 days per season	Once per season	Once during pregnancy
Target population	Children from high-risk groups	All infants	Neonates (indirectly through the mother)
Efficacy	↓ hospitalizations ~55%	↓ LRTI ~74.5% (MELODY)	↓ severe RSV infections
Key studies	IMpact-RSV	MELODY, HARMONIE	Kampmann 2023, Madhi 2020
Adverse reactions	Injection site reactions, rarely hypersensitivity	Mild local reactions, systemic symptoms	Mild local and systemic symptoms in the mother
Limitations	High cost, multiple doses	Availability, cost	Dependence on timing of vaccination

RSV - respiratory syncytial virus
LRTI - lower respiratory tract infection

7. Discussion

The introduction of new methods for preventing RSV infections is significantly impacting the current clinical approach and the organization of pediatric care. Previously, the use of palivizumab was limited to selected patient groups due to its high cost and the need for repeated administration (Wang et al., 2008). The current availability of nirsevimab and the development of maternal vaccinations offer the opportunity to extend prophylaxis to the general infant population, representing a major shift in RSV prevention strategies (Hammitt et al., 2022; Mazur et al., 2023; Swamy & Heine, 2015).

These changes are reflected in the updated recommendations of scientific societies, which increasingly recommend the use of long-acting monoclonal antibodies for all infants during the first RSV infection season. This approach can significantly reduce the number of hospitalizations and severe disease, particularly in the most vulnerable age group (American Academy of Pediatrics, 2024; Centers for Disease Control and Prevention, 2024; European Centre for Disease Prevention and Control, 2022; World Health Organization, 2023).

The results of clinical trials such as MELODY and HARMONIE indicate that the widespread use of nirsevimab can significantly reduce the number of hospitalizations and the burden on the healthcare system (Drysdale et al., 2023; Hammitt et al., 2022). A similar effect is observed with maternal vaccination during pregnancy, which reduces the risk of severe RSV infections in newborns and infants in the first months of life (Kampmann et al., 2023; Madhi et al., 2020).

From a clinical practice perspective, the availability of these interventions and their feasibility of implementing them in various healthcare systems are also crucial. Maternal vaccination may be easier to implement at the population level, while the use of nirsevimab requires appropriately organized prevention programs. However, implementing these strategies may contribute to reducing hospitalizations, shortening treatment duration, and reducing healthcare costs (Li et al., 2020). Future RSV prevention strategies will likely focus on expanding universal immunoprophylaxis, improving global access to preventive interventions, and optimizing integration of maternal vaccination programs into routine prenatal care.

8. Conclusions

RSV infections are a significant public health problem, being one of the leading causes of infant hospitalization worldwide (Shi et al., 2017; Stein et al., 2017). Their significance lies in both their high incidence and potentially severe clinical course, particularly in the first months of life and in at-risk groups (Hall et al., 2013; Shi et al., 2017; Stein et al., 2017).

Previous preventive strategies, primarily based on the use of palivizumab, although effective, are limited to selected populations due to cost and the need for repeated administration (Wang et al., 2008). The introduction of new methods, such as nirsevimab and maternal vaccination during pregnancy, represents a significant breakthrough in the prevention of RSV infections (Hammitt et al., 2022; Swamy & Heine, 2015).

Modern approaches enable protection of a much larger population of infants, which could lead to a significant reduction in hospitalizations and severe disease (Drysdale et al., 2023; Hammitt et al., 2022; Madhi et al., 2020). The results of clinical trials, including MELODY and HARMONIE, confirm the high effectiveness of these new preventive strategies and their potential impact on reducing the burden on the healthcare system (Drysdale et al., 2023; Hammitt et al., 2022).

Maternal vaccination during pregnancy is an additional, complementary preventive tool, providing protection to newborns during their most vulnerable period of life (Madhi et al., 2020; Swamy & Heine, 2015). Their use may be particularly important in the context of population-based interventions (Hammitt et al., 2022; Mazur et al., 2023). In summary, the development of RSV infection prevention is leading to a paradigm shift from selective protection of high-risk groups to broad-based population-based interventions. Implementing these strategies in clinical practice has the potential to significantly reduce the global burden of RSV infections and improve health outcomes for the youngest patients (Borchers et al., 2013; Mazur et al., 2023; Shi et al., 2017; Stein et al., 2017). These advances have important implications for global child health and healthcare resource utilization.

Author Contributions:
Conceptualization: Oktawia Gwiaździńska [OG], Jakub Lewandowski [JL], Anita Strzykała [AS],
Methodology: Oktawia Gwiaździńska [OG], Anita Strzykała [AS], Igor Szlegiel [IS], Denis Myszak [DM]
Check: Oktawia Gwiaździńska [OG], Jakub Lewandowski [JL], Anita Strzykała [AS], Igor Szlegiel [IS]
Formal analysis: Jakub Lewandowski [JL], Anita Strzykała [AS], Denis Myszak [DM]
Data curation: Jakub Lewandowski [JL], Anita Strzykała [AS], Denis Myszak, Igor Szlegiel [IS],
Writing –rough preparation: Oktawia Gwiaździńska [OG], Jakub Lewandowski [JL], Anita Strzykała [AS],
Writing –review and editing: Anita Strzykała [AS], Denis Myszak, Igor Szlegiel [IS],
Visualization: Oktawia Gwiaździńska [OG], Jakub Lewandowski [JL], Denis Myszak,
Supervision: Oktawia Gwiaździńska [OG], Igor Szlegiel [IS], Anita Strzykała [AS]
Project administration: Oktawia Gwiaździńska [OG].

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