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ORIGINAL

Comparison of clinical efficacy and dosing regimens between Nirsevimab and Palivizumab for prophylaxis against RSV in the pediatric population

Comparación de la eficacia clínica y esquemas de dosificación entre Nirsevimab y Palivizumab para la profilaxis contra el VSR en población pediátrica

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ABSTRACT

Background: Respiratory syncytial virus is a major cause of lower respiratory tract infections in infants, leading to significant hospitalization rates in Argentina. For decades, Palivizumab was the only effective prophylactic option, but its multiple-dose regimen and limited accessibility reduced its impact. Nirsevimab, a long-acting monoclonal antibody, emerges as an innovative alternative, providing sustained protection with a single seasonal dose. Methods: A systematic literature review was conducted using PubMed, MEDLINE, Embase, and SciELO, including systematic reviews, meta-analyses, observational studies, and pediatric society guidelines published up to April 2024. Results: Nirsevimab demonstrated a significant reduction in hospitalizations related to RSV, surpassing Palivizumab and improving adherence. When combined with maternal vaccination, its effectiveness and cost-efficiency were further enhanced across multiple clinical settings. Conclusion: Nirsevimab represents a highly effective, safe, and easy-to-implement strategy with the potential to transform infant RSV prevention policies. However, additional studies in local populations are essential to evaluate long-term effectiveness, feasibility, and sustainability.

Keywords: Respiratory Syncytial Virus Infections; Palivizumab; Nirsevimab; Infant, Newborn; Infant, Premature.

RESUMEN

Introducción: El virus sincicial respiratorio es una de las principales causas de infecciones respiratorias bajas en lactantes, con elevada carga hospitalaria en Argentina. Durante décadas, Palivizumab fue la única herramienta profiláctica eficaz, aunque su uso se ve limitado por la necesidad de múltiples dosis y barreras de acceso. Nirsevimab, un anticuerpo monoclonal de vida media prolongada, surge como una alternativa innovadora gracias a su aplicación única por temporada y protección sostenida. Métodos: Se realizó una revisión sistemática de la literatura en PubMed, MEDLINE, Embase y SciELO, incluyendo revisiones sistemáticas, metaanálisis, estudios observacionales y consensos pediátricos publicados hasta abril de 2024. Resultados: Nirsevimab mostró una reducción significativa de hospitalizaciones por VSR, superando a Palivizumab y mejorando la adherencia. La combinación con vacunación materna potenció la protección y optimizó la costo-efectividad en diversos escenarios clínicos. Conclusión: Nirsevimab representa una estrategia eficaz, segura y sencilla de implementar, con potencial para transformar las políticas de prevención de infecciones por VSR en lactantes. Sin embargo, se requieren estudios locales para evaluar su efectividad real y sostenibilidad a largo plazo.

Palabras clave: Respiratory Syncytial Virus Infections; Palivizumab; Nirsevimab; Infant, Newborn; Infant, Premature.

INTRODUCTION

According to the Argentine Ministry of Health, respiratory syncytial virus (RSV) is the leading cause of acute lower respiratory infections in infancy, particularly bronchiolitis and pneumonia. It is responsible for a high number of hospitalizations in infants under one year of age during the months of seasonal circulation, mainly between May and July in Argentina.

In this context, palivizumab, a humanized monoclonal antibody approved in the late 1990s, served for more than two decades as the primary prophylactic tool available for preventing severe manifestations of RSV infection. Its efficacy in reducing hospitalizations among high-risk infants—such as preterm infants, patients with bronchopulmonary dysplasia, or congenital heart disease—is well documented. However, its implementation has significant limitations: it requires multiple monthly doses throughout the epidemic season, leading to low adherence, high costs, and an indication restricted to very specific groups based on cost-benefit criteria.

In light of these challenges, the recent development of nirsevimab, a long-acting monoclonal antibody, has marked a paradigm shift in RSV immunoprophylaxis. Its main advantage lies in the administration of a single dose per season, which maintains sustained antibody levels. Clinical trials have also demonstrated that nirsevimab reduces hospitalizations, intensive care admissions, and the need for mechanical ventilation, both in healthy full-term infants and in high-risk infants.

Although Nirsevimab has already been approved in Argentina by ANMAT, it has not yet been incorporated into the national public health system's immunization schedule. Concurrently, since 2024, the country has adopted a maternal RSV vaccination strategy for pregnant women in their third trimester, to provide passive protection to newborns during their first months of life. This measure not only helps strengthen protection and antibody levels in infants but also establishes itself as a cost-effective strategy within RSV prevention policies.

In this context, it is important to conduct a comparative analysis of the characteristics, efficacy, safety, and feasibility of Palivizumab and Nirsevimab to generate scientific evidence to inform public health policy decisions and optimize RSV prevention strategies for the Argentine pediatric population.

METHODS

A comprehensive review and analysis of the current scientific literature was conducted to evaluate respiratory syncytial virus (RSV) prophylaxis in the pediatric population, with an emphasis on comparing the monoclonal antibodies Palivizumab and Nirsevimab. To this end, a literature review was designed that integrates systematic reviews and meta-analyses with prospective and retrospective observational studies, as well as position statements issued by pediatric scientific societies. This strategy enabled the collection of both high-quality evidence from clinical trials and real-world data, providing a comprehensive and up-to-date view of the clinical and epidemiological impact of the interventions analyzed.

The literature search was conducted across internationally recognized electronic databases, including PubMed, MEDLINE, Embase, and SciELO. To optimize the specificity and sensitivity of the search, "MeSH" (Medical Subject Headings) terms were used, including: "Respiratory Syncytial Virus," "Palivizumab," "Nirsevimab," "Immunoprophylaxis," "Lower Respiratory Tract Infection," "Hospitalization," "Infant, Newborn," "Infant, Premature," "Child, Preschool," and combinations with Boolean operators AND and OR, to ensure the inclusion of relevant studies. The search covered articles published through April 2024, with no strict language restrictions, prioritizing texts in English and Spanish.

Additionally, information from official publicly accessible sources in Argentina was incorporated, including reports and press releases from the Ministry of Health, as well as regulatory documents and press releases from the National Administration of Medicines, Food, and Medical Technology (ANMAT), to contextualize the scientific evidence within the national regulatory and epidemiological framework.

The following criteria were established for the selection of studies:

Inclusion criteria.

Systematic reviews and meta-analyses evaluating the efficacy and safety of palivizumab and nirsevimab in the prevention of severe lower respiratory tract infections caused by RSV in infants and young children.

Prospective and retrospective observational studies analyzing the use, effectiveness, clinical outcomes, and cost-effectiveness of Palivizumab and Nirsevimab in high-risk pediatric populations.

Position statements, consensus documents, and clinical guidelines issued by national or international pediatric scientific societies.

Publications in Spanish or English, with no strict date restriction, emphasizing the most recent evidence (2022–2024).

Studies whose population includes preterm infants, children with bronchopulmonary dysplasia, hemodynamically significant congenital heart defects, healthy infants undergoing prophylaxis with monoclonal antibodies, and, where applicable, pregnant mothers vaccinated to confer passive protection to newborns.

Studies reporting comparative results between Palivizumab and Nirsevimab, or between immunoprophylaxis strategies and control groups.

Studies that include information on adherence, administration regimens, and the duration of protection conferred by monoclonal antibodies.

Exclusion criteria.

Studies that do not report relevant clinical, epidemiological, or cost-effectiveness results regarding RSV prophylaxis with the aforementioned monoclonal antibodies.

Studies focused on interventions other than Palivizumab and Nirsevimab.

Studies whose population does not consist of infants or children under 2 years of age, nor includes pregnant women when evaluating maternal immunization.

Narrative reviews lacking rigorous methodological support or adequate scientific evidence.

Duplicate articles or those with incomplete data that preclude adequate analysis.

Studies that do not provide information on the safety of monoclonal antibodies or relevant adverse events.

Publications with insufficient design or reporting to extract outcomes of interest, such as hospitalizations, ICU admissions, or the need for mechanical ventilation.

RESULTS

The following section presents the findings regarding the efficacy of Palivizumab, followed by those for Nirsevimab, direct comparisons between the two monoclonal antibodies, and their cost-effectiveness analysis. Finally, the results related to combined prophylaxis regimens that integrate maternal vaccination and antibody administration in infants will be examined.

Table 1. Comparison of the main studies on Palivizumab and Nirsevimab in the prevention of lower respiratory tract infections caused by respiratory syncytial virus (RSV), including study type, characteristics, population, and conclusions.

Autor / Referencia	Tipo de estudio	Característica principal	Población estudiada	Conclusiones
[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
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[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
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[illegible]	[illegible]	[illegible]	[illegible]	[illegible]

Clinical Efficacy of Palivizumab in the Prevention of RSV Respiratory Infections.

A multicenter observational study titled "Respiratory syncytial virus immunoprophylaxis with Palivizumab: 12-year observational study of usage and outcomes in Canada," describes the analysis of 12 consecutive seasons, which included 25,003 infants from 32 centers, demonstrating that the administration of palivizumab maintained an overall hospitalization rate for respiratory infection of 6.9% and a RSV-specific rate of 1.6%, figures notably lower than those historically reported in similar populations without prophylaxis. Among hospitalized children, only 21.9% required admission to a pediatric intensive care unit, 30.3% required respiratory support, and 9.6% required intubation, demonstrating significant control over the progression of clinical conditions. Adherence to the Palivizumab regimen was high: 83.8% of patients received all scheduled doses, and 64.7% achieved perfect adherence, enhancing its effectiveness, especially in those with multiple risk factors.

The systematic review article titled: "Effectiveness and safety of Palivizumab for the prevention of serious lower respiratory tract infection caused by respiratory syncytial virus: a systematic review," which included 60 studies, ranging from phase III clinical trials to observational studies, confirmed that Palivizumab significantly reduces RSV-related hospitalizations in preterm infants, as well as in patients with bronchopulmonary dysplasia and hemodynamically significant congenital heart disease, compared to placebo or untreated groups. In addition, a reduction was observed in the length of hospital stay and in the need for respiratory support, including intensive care unit admissions and mechanical ventilation. Adverse events associated with palivizumab were infrequent and generally mild, confirming a favorable safety profile.

Taken together, these findings establish Palivizumab as an effective and safe preventive strategy against severe RSV respiratory infection in high-risk infants, optimizing clinical outcomes and limiting progression to severe y respiratory infection.

Clinical effectiveness of Palivizumab: impact of multiple doses, socioeconomic barriers, and lack of parental knowledge on adherence:

According to the article "A Systematic Review of Compliance with Palivizumab Administration for RSV Immunoprophylaxis," one point consistently highlighted is the impact of socioeconomic and logistical barriers on adherence to palivizumab prophylaxis. Factors such as enrollment in healthcare programs, difficulties with transportation or access to healthcare facilities, and parents' limited perceptions of the benefits of prophylaxis negatively influence caregivers' ability to complete the recommended regimen. Additionally, the need to administer multiple doses of palivizumab throughout the season contributes to lower vaccination rates, complicating treatment planning and implementation. These findings highlight that the clinical effectiveness of Palivizumab depends not only on its pharmacological properties but also on patients' ability to receive all doses as scheduled, underscoring the importance of designing interventions to overcome these challenges and improve adherence.

Clinical Efficacy of Nirsevimab in the Prevention of RSV Respiratory Infections.

First, the systematic review and meta-analysis titled "Impact of nirsevimab immunization on pediatric hospitalization rates: a systematic review and meta-analysis," which included 13 studies—5 randomized controlled trials (RCTs) and 7 real-world studies—assessed the impact of nirsevimab on the prevention of RSV-associated lower respiratory tract infections. The results showed a pooled hospitalization rate of 0.42% in immunized children, compared to 4.25% in unimmunized children, reflecting a combined efficacy of 88.4%. Efficacy was higher in real-world studies (90.5%) than in RCTs (81.0%), demonstrating good performance in both controlled conditions and everyday clinical settings. Furthermore, the estimated duration of protection provided by Nirsevimab allows coverage of an entire season with a single dose, eliminating the multiple administrations required by Palivizumab. Although some heterogeneity among studies and limitations in long-term follow-up were observed, the findings confirm the safety and effectiveness of Nirsevimab in reducing RSV-related hospitalization in infants.

Second, the observational study titled "Effectiveness of nirsevimab in preventing RSV-hospitalization among young children in Western Australia 2024" evaluated the effectiveness of a single dose of nirsevimab during the 2024 season in Western Australia in 284 eligible children, of whom 37.3% received the drug. The effectiveness against RSV-related hospitalization reached 88.2%, with a significant reduction in the need for oxygen or respiratory support (61.8%). These results, consistent with previous studies in other hemispheres, confirm the efficacy of Nirsevimab in real-world clinical practice and position this prophylaxis as a key tool for reducing hospital burden from RSV in infants.

The evidence therefore concludes that Nirsevimab offers high, sustained, and safe protection against RSV-related hospitalizations, representing an effective alternative to traditional strategies based on Palivizumab, particularly due to its seasonal coverage with a single dose and its applicability in real-world pediatric care settings.

Antibody duration: the basis for the single-dose administration of nirsevimab.

According to the article, "RSV Neutralizing Antibodies Following Nirsevimab and Palivizumab Dosing," a study was conducted to evaluate the efficacy and immune response of nirsevimab compared to palivizumab in infants. Both antibodies were observed to induce neutralizing responses against RSV. Still, Nirsevimab generates higher, more sustained levels with a single dose throughout the year, while Palivizumab requires monthly doses to maintain protective levels, and its effect diminishes more rapidly.

Analysis: Cost-effectiveness.

The article "Cost-Effectiveness Analysis of Nirsevimab for Preventing Respiratory Syncytial Virus-Related Lower Respiratory Tract Disease in Dutch Infants: An Analysis Including All-Infant Protection" concludes that Nirsevimab has the potential to prevent a significant number of cases of RSV-related lower respiratory tract disease (LRTD) in all infants. An immunization strategy that protects all infants could prevent thousands of visits to primary care physicians, hospitalizations, and even admissions to pediatric ICUs. The analysis indicates that Nirsevimab may be cost-effective compared to the standard of care (Palivizumab for specific populations), depending on the administration strategy and the price per dose established by the relevant campaigns. The main advantage of this antibody is its ability to reduce the disease burden across the entire infant population, offering broad preventive effects and alleviating pressure on hospital services during the RSV season.

"Cost-effectiveness analysis of Nirsevimab and maternal RSVpreF vaccine strategies for prevention of Respiratory Syncytial Virus disease among infants in Canada: a simulation study" concludes that administering Nirsevimab to the entire birth cohort can significantly reduce outpatient care, RSV-related hospitalizations, and infant mortality. Programs that combine Nirsevimab with maternal vaccination yield the greatest reduction in disease and are the most cost-effective across a wide range of prices per dose, from both a health system and a societal perspective. The main feature of this study is the evaluation of multiple scenarios, which shows that combined programs are the most effective, offering a balance between high effectiveness and lower budgetary impact compared to programs using Nirsevimab alone.

According to "Cost-effectiveness of Nirsevimab and Palivizumab for respiratory syncytial virus prophylaxis in preterm infants at 29–34 6/7 weeks' gestation in the United States," it is concluded that Palivizumab is not cost-effective compared to standard care for preterm infants at 29–34 weeks' gestation without additional risk factors, due to its high cost. In contrast, nirsevimab has considerable cost-effectiveness potential if priced appropriately, offering protection with a single dose rather than the 5 required for palivizumab, thereby reducing direct medical costs.

DISCUSSION

The findings confirm that both Palivizumab and Nirsevimab are effective strategies for preventing severe lower respiratory tract infections caused by respiratory syncytial virus (RSV) in infants. However, they differ in their clinical applicability and population reach. Palivizumab reduces hospitalization and progression to severe illness in high-risk infants, supporting the results of multicenter studies and systematic reviews. However, its effectiveness is limited by the need for multiple doses, socioeconomic and logistical barriers, and a lack of parental knowledge, all of which hinder adherence to the prophylactic regimen.

In contrast, nirsevimab provides prolonged protection with a single dose, maintaining neutralizing antibody levels sufficient to cover the entire RSV season. This translates into a consistent reduction in hospitalizations, with efficacy exceeding 88% compared to unvaccinated infants. Its simplified regimen promotes adherence and improves clinical effectiveness, representing an innovation over traditional regimens.

From a cost-effectiveness perspective, nirsevimab also offers significant advantages, particularly when combined with maternal vaccination, successfully reducing outpatient visits, hospitalizations, and the need for intensive care unit admission.

Limitations of the reviewed evidence include heterogeneity in study designs, short-term follow-up in some studies, and variability across clinical contexts, all of which require special attention when extrapolating results. Although nirsevimab demonstrates prolonged protection, its long-term effectiveness and impact on population-level viral circulation need to be monitored.

The novelty of these findings lies in the possibility of achieving full-season prophylaxis with a single dose, combining high clinical effectiveness, safety, and improved cost-effectiveness. This allows for a rethinking of RSV prevention strategies for infants with a broader, more equitable approach, highlighting the need for future studies to evaluate its implementation at the national level and its impact on hospital morbidity and on the optimization of healthcare resources.

CONCLUSION

The analyzed evidence indicates that both Palivizumab and Nirsevimab are effective and safe antibodies for the prevention of severe lower respiratory tract infections caused by respiratory syncytial virus (RSV) in infants. However, they present significant differences in their clinical application, adherence to dosing schedules, and economic impact. Palivizumab remains useful in high-risk infants, but the need for multiple doses and socioeconomic barriers reduce its effectiveness in daily practice. In contrast, Nirsevimab provides seasonal protection with a single dose, simplifying adherence, consistently reducing hospitalizations, and offering cost-effectiveness advantages, especially when complemented by maternal vaccination. Based on the available literature, the importance of promoting its use among healthcare professionals and of encouraging research to evaluate its performance in local contexts is highlighted, as well as its impact on costs and long-term effects, to optimize its incorporation into health policies. However, given that Nirsevimab is a relatively recent strategy, it is essential to generate more evidence in populations comparable to Argentina, where the implementation of new prevention policies often faces structural and access challenges, to ensure its effectiveness and sustainability in practice.

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CONFLICT OF INTEREST

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