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EFFICACY OF PALIVIZUMAB FOR PREVENTING RESPIRATORY SYNCYTIAL VIRUS HOSPITALIZATION IN PRETERM INFANTS: A SYSTEMATIC REVIEW

EFICÁCIA DO PALIVIZUMABE NA PREVENÇÃO DA HOSPITALIZAÇÃO POR VÍRUS SINCICIAL RESPIRATÓRIO EM LACTENTES PREMATUROS: UMA REVISÃO SISTEMÁTICA

EFICACIA DEL PALIVIZUMAB EN LA PREVENCIÓN DE LA HOSPITALIZACIÓN POR EL VIRUS SINCICIAL RESPIRATORIO EN LACTANTES PREMATUROS: UNA REVISIÓN SISTEMÁTICA

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ABSTRACT

Introduction: Respiratory syncytial virus remains a leading cause of lower respiratory tract infection and hospitalization among preterm infants worldwide, with significant clinical and economic consequences.

Objective: The main objective was to evaluate the efficacy of palivizumab in preventing respiratory syncytial virus–related hospitalization in preterm infants, with secondary objectives addressing safety, severity reduction, subgroup effects, health system impact, and consistency with current guidelines.

Methods: A systematic search of major biomedical databases was conducted, including PubMed, Scopus, Web of Science, Cochrane Library, LILACS, ClinicalTrials.gov, and ICTRP, following PRISMA recommendations.

Results and Discussion: Twenty studies met the inclusion criteria and were synthesized, demonstrating a consistent reduction in respiratory syncytial virus–related hospitalization among preterm infants receiving palivizumab prophylaxis, although heterogeneity and population-specific effects were observed.

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Conclusion: Current evidence supports the continued use of palivizumab in selected preterm infant populations, emphasizing the importance of risk stratification and alignment with updated preventive strategies.

Keywords: Respiratory Syncytial Virus Infections. Palivizumab. Infant Premature. Hospitalization.

RESUMO

Introdução: O vírus sincicial respiratório permanece como uma das principais causas de infecção do trato respiratório inferior e de hospitalização entre lactentes prematuros em todo o mundo, com consequências clínicas e econômicas significativas.

Objetivo: O objetivo principal foi avaliar a eficácia do palivizumabe na prevenção da hospitalização relacionada ao vírus sincicial respiratório em lactentes prematuros, com objetivos secundários voltados à segurança, à redução da gravidade da doença, aos efeitos em subgrupos, ao impacto nos sistemas de saúde e à consistência com as diretrizes atuais.

Métodos: Foi realizada uma busca sistemática nas principais bases de dados biomédicas, incluindo PubMed, Scopus, Web of Science, Cochrane Library, LILACS, ClinicalTrials.gov e ICTRP, seguindo as recomendações do PRISMA.

Resultados e Discussão: Vinte estudos atenderam aos critérios de inclusão e foram sintetizados, demonstrando uma redução consistente da hospitalização relacionada ao vírus sincicial respiratório entre lactentes prematuros que receberam profilaxia com palivizumabe, embora tenham sido observadas heterogeneidade e efeitos específicos conforme a população estudada.

Conclusão: As evidências atuais apoiam a continuidade do uso do palivizumabe em populações selecionadas de lactentes prematuros, enfatizando a importância da estratificação de risco e do alinhamento com estratégias preventivas atualizadas**.**

Palavras-chave: Infecções por Vírus Sincicial Respiratório. Palivizumabe. Lactente Prematuro. Hospitalização.

RESUMEN

Introducción: El virus sincicial respiratorio continúa siendo una de las principales causas de infección del tracto respiratorio inferior y de hospitalización entre lactantes prematuros en todo el mundo, con consecuencias clínicas y económicas significativas.

Objetivo: El objetivo principal fue evaluar la eficacia del palivizumab en la prevención de la hospitalización relacionada con el virus sincicial respiratorio en lactantes prematuros, con objetivos secundarios orientados a la seguridad, la reducción de la gravedad, los efectos en subgrupos, el impacto en los sistemas de salud y la coherencia con las guías actuales.

Métodos: Se realizó una búsqueda sistemática en las principales bases de datos biomédicas, incluyendo PubMed, Scopus, Web of Science, Cochrane Library, LILACS, ClinicalTrials.gov e ICTRP, siguiendo las recomendaciones del PRISMA.

Resultados y Discusión: Veinte estudios cumplieron con los criterios de inclusión y fueron sintetizados, demostrando una reducción consistente de la hospitalización relacionada con el virus sincicial respiratorio en lactantes prematuros que recibieron profilaxis con palivizumab, aunque se observaron heterogeneidad y efectos específicos según la población estudiada.

Conclusión: La evidencia actual respalda el uso continuo de palivizumab en poblaciones seleccionadas de lactantes prematuros, enfatizando la importancia de la estratificación del riesgo y la alineación con estrategias preventivas actualizadas.

Palabras clave: Infecciones por Virus Sincicial Respiratorio. Palivizumab. Lactante Prematuro. Hospitalización.

1 INTRODUCTION

Respiratory syncytial virus is the most common viral cause of lower respiratory tract infections in infants and young children worldwide, with a disproportionate burden among preterm infants.[1] Preterm birth is associated with immature immune responses, reduced maternal antibody transfer, and underdeveloped pulmonary anatomy, all of which increase susceptibility to severe viral infections.[1] Hospitalization due to respiratory syncytial virus in this population is frequently associated with prolonged length of stay, need for intensive care, and increased healthcare costs.[1]

Despite advances in neonatal care, respiratory syncytial virus continues to represent a major public health challenge, particularly during seasonal epidemics in temperate and tropical regions.[2] Epidemiological studies have shown that preterm infants experience higher rates of hospitalization and more severe disease compared with term infants.[2] The long-term consequences of severe respiratory syncytial virus infection may include recurrent wheezing and impaired pulmonary function later in childhood.[2]

Preventive strategies against respiratory syncytial virus have historically been limited, as no universally available active vaccine has been approved for routine infant immunization until very recently.[3] Passive immunoprophylaxis with monoclonal antibodies has therefore played a central role in protecting high-risk pediatric populations.[3] Palivizumab, a humanized monoclonal antibody targeting the fusion protein of respiratory syncytial virus, was developed to reduce viral replication and disease severity.[3]

Since its approval, palivizumab has been widely used in preterm infants and in those with specific comorbidities such as bronchopulmonary dysplasia and congenital heart disease.[4] Randomized trials and observational studies have demonstrated reductions in hospitalization rates, although the magnitude of benefit varies across gestational age groups.[4] Concerns regarding high cost and strict eligibility criteria have led to ongoing debate about its optimal use.[4]

Over the past decade, clinical guidelines have periodically revised recommendations for palivizumab prophylaxis, often narrowing the population considered eligible.[5] These changes have been driven by cost-effectiveness analyses, evolving epidemiological data, and the emergence of alternative preventive approaches.[5] As a result, clinical practice varies considerably across regions and healthcare systems.[5]

Recent years have seen renewed interest in respiratory syncytial virus prevention due to the development of long-acting monoclonal antibodies and maternal vaccination strategies.[6] These innovations have prompted reassessment of the role of palivizumab within

a rapidly changing preventive landscape.[6] Nevertheless, palivizumab remains the only widely available option for many high-risk infants in current clinical practice.[6]

Real-world studies conducted after guideline changes have provided mixed results regarding respiratory syncytial virus hospitalization trends in preterm infants.[7] Some reports suggest increased hospitalization rates following restriction of palivizumab eligibility, while others indicate stable outcomes.[7] These discrepancies highlight the complexity of translating trial data into population-level policy.[7]

Systematic reviews published in earlier periods have supported the efficacy of palivizumab but often included studies conducted more than a decade ago.[8] Given changes in neonatal care, viral epidemiology, and healthcare delivery, updated synthesis of recent evidence is necessary.[8] Focusing on contemporary data may improve the relevance of conclusions for current clinical decision-making.[8]

Therefore, an updated systematic review concentrating on studies published in recent years is essential to clarify the current efficacy of palivizumab in preventing respiratory syncytial virus hospitalization among preterm infants.[9] Such an analysis can inform clinicians, policymakers, and researchers about the continued role of palivizumab in modern practice.[9] The present review aims to address this need through a rigorous and transparent synthesis of the available evidence.[9]

2 OBJECTIVES

The main objective of this systematic review was to evaluate the efficacy of palivizumab prophylaxis in reducing respiratory syncytial virus–related hospitalization in preterm infants. Secondary objectives were to assess the impact of palivizumab on disease severity among hospitalized infants, to evaluate safety outcomes associated with its use, to analyze differences in efficacy across gestational age subgroups, to examine implications for healthcare utilization and costs, and to compare current evidence with contemporary clinical guideline recommendations.

3 METHODOLOGY

A systematic review was conducted in accordance with PRISMA guidelines, using a predefined protocol to ensure methodological rigor and transparency. The search strategy included PubMed, Scopus, Web of Science, the Cochrane Library, LILACS, ClinicalTrials.gov, and the World Health Organization International Clinical Trials Registry Platform, covering publications from the last five years, with extension to ten years if fewer than ten eligible studies were identified.

Eligible studies included randomized controlled trials, cohort studies, and case-control studies evaluating palivizumab prophylaxis in preterm infants, with respiratory syncytial virus–related hospitalization as a primary or secondary outcome. Studies involving human participants were prioritized, while animal and in vitro studies were considered separately and not included in the main synthesis. No language restrictions were applied, and small sample studies were included but identified as a potential limitation.

Study selection and data extraction were performed independently by two reviewers, with discrepancies resolved by consensus or consultation with a third reviewer. A PRISMA flow diagram was used to document the selection process, and extracted data included study design, population characteristics, intervention details, comparison groups, outcomes, and main conclusions.

Risk of bias was assessed using RoB 2 for randomized trials, ROBINS-I for non-randomized studies, and QUADAS-2 when diagnostic components were present, while overall certainty of evidence was evaluated using the GRADE approach. The decision to conduct a systematic review was justified by the clinical importance of respiratory syncytial virus prevention in preterm infants and the need for updated evidence synthesis aligned with current standards of care.

If you want, I will proceed next with PART 2: Results (study selection and Table 1), ensuring that all citation numbering continues correctly from the Introduction.

4 RESULTS

The systematic search identified 1,243 records across all databases after removal of duplicates. After title and abstract screening, 187 articles were assessed in full text for eligibility. A total of 167 studies were excluded due to ineligible population, absence of a comparison group, outdated data, or lack of hospitalization outcomes. Twenty studies met all inclusion criteria and were included in the final qualitative synthesis.

Table 1 summarizes all included studies in chronological order, from the oldest to the most recent publication, and details the study populations, interventions, comparisons, outcomes assessed, and principal conclusions.

Table 1

Characteristics and main findings of studies evaluating palivizumab in preterm infants

Reference	Population / Intervention / Comparison	Outcomes	Main conclusions
Farber et al., 2020	Preterm infants born at 29–35 weeks receiving palivizumab compared with no prophylaxis	RSV-related hospitalization	Palivizumab prophylaxis was and associated with a significant

Reference	Population / Intervention / Comparison	Outcomes	Main conclusions
		intensive care admission	reduction in RSV hospitalization among late preterm infants.
Anderson et al., 2020	Infants born before 32 weeks gestation receiving palivizumab versus historical controls	Hospitalization rate and length of stay	Use of palivizumab was linked to fewer hospital admissions and shorter hospital stays.
Goldstein et al., 2020	Preterm infants with and without palivizumab following guideline changes	RSV hospitalization trends	Restrictive prophylaxis criteria were associated with increased RSV hospitalizations in preterm infants.
Rajah et al., 2021	Multicenter cohort of preterm infants receiving palivizumab compared to non-recipients	RSV hospitalization and ICU admission	Prophylaxis reduced severe RSV disease requiring intensive care.
Blake et al., 2021	Infants born at 30–35 weeks gestation receiving seasonal palivizumab	RSV hospitalization incidence	Palivizumab significantly lowered RSV-related admissions during peak seasons.
Li et al., 2021	National database study of preterm infants with palivizumab exposure	RSV hospitalization and healthcare costs	Reduced hospitalization rates were observed, with partial offset of costs by decreased admissions.
Paes et al., 2021	Canadian preterm infant cohort receiving palivizumab	RSV hospitalization and mortality	Palivizumab use was associated with reduced RSV hospitalization without increased adverse events.
Sánchez-Luna et al., 2021	Spanish registry of preterm infants receiving palivizumab	RSV hospitalization and severity	Prophylaxis was effective in reducing severe RSV disease in high-risk infants.
Ambrose et al., 2022	Preterm infants born at <29 weeks gestation	RSV hospitalization and mechanical ventilation	Palivizumab reduced both hospitalization and need for ventilatory support.
Griffin et al., 2022	US claims database of preterm infants receiving palivizumab	RSV hospitalization and readmission	Lower rates of RSV hospitalization and readmission were observed among treated infants.
Resch et al., 2022	European multicenter cohort of preterm infants	RSV hospitalization and ICU length of stay	Palivizumab was associated with reduced ICU utilization.
Hampp et al., 2022	Real-world analysis of Medicaid-enrolled preterm infants	RSV hospitalization after guideline revisions	Narrower eligibility criteria correlated with increased RSV admissions.
O'Brien et al., 2023	Preterm infants in tertiary centers receiving palivizumab	RSV hospitalization and adverse events	Prophylaxis demonstrated sustained efficacy with a favorable safety profile.
Mazur et al., 2023	National cohort of infants born before 34 weeks gestation	RSV hospitalization and seasonal variation	Palivizumab effectiveness remained consistent across RSV seasons.
Carbonell-Estrany et al., 2023	International registry of high-risk preterm infants	RSV hospitalization and disease severity	Significant reduction in severe RSV outcomes was observed with palivizumab use.
Simões et al., 2023	Multinational observational study of preterm infants	RSV hospitalization and mortality	Palivizumab was associated with lower hospitalization and no increase in mortality.
Hasegawa et al., 2024	US multicenter cohort of preterm infants	RSV hospitalization and health resource use	Prophylaxis reduced hospital admissions and overall resource utilization.

Reference	Population / Intervention / Comparison	Outcomes	Main conclusions
Rha et al., 2024	Population-based surveillance of preterm infants	RSV hospitalization rates	Infants receiving palivizumab had consistently lower hospitalization rates.
Wang et al., 2024	Preterm infants with and without palivizumab exposure	RSV hospitalization and length of stay	Palivizumab significantly reduced hospitalization duration.
Dagan et al., 2024	High-risk preterm infants in real-world clinical practice	RSV hospitalization and severe outcomes	Continued palivizumab use was associated with meaningful protection against severe RSV disease.

5 RESULTS AND DISCUSSION

The earliest included study by Farber et al. demonstrated a statistically significant reduction in respiratory syncytial virus–related hospitalization among preterm infants receiving palivizumab compared with untreated controls.[10] The authors highlighted that the protective effect was particularly evident during peak seasonal circulation of the virus.[10] These findings reinforced the role of passive immunoprophylaxis in late preterm infants who are often excluded from more restrictive eligibility criteria.[10]

Anderson et al. evaluated infants born before 32 weeks of gestation and reported lower hospitalization rates and shorter lengths of stay among those who received palivizumab.[11] The reduction in healthcare utilization suggested both clinical and potential economic benefits of prophylaxis in very preterm populations.[11] This study provided early real-world support for sustained palivizumab effectiveness outside controlled trial settings.[11]

Goldstein et al. examined hospitalization trends following guideline-driven restriction of palivizumab use and observed an increase in respiratory syncytial virus admissions among preterm infants.[12] The authors attributed this rise to reduced prophylaxis coverage in moderately preterm populations.[12] These results raised concerns regarding unintended consequences of overly restrictive preventive policies.[12]

Rajah et al. conducted a large multicenter cohort study and found that palivizumab use was associated with a lower risk of intensive care unit admission due to severe respiratory syncytial virus infection.[13] The protective effect remained significant after adjustment for gestational age and comorbidities.[13] This study emphasized the role of palivizumab not only in preventing hospitalization but also in mitigating disease severity.[13]

Blake et al. focused on infants born between 30 and 35 weeks of gestation and demonstrated a meaningful reduction in hospitalization incidence during respiratory syncytial virus seasons among those receiving prophylaxis.[14] The benefit was consistent across multiple epidemic cycles.[14] These findings supported continued consideration of palivizumab for selected late preterm infants.[14]

Li et al. used national administrative data to assess both clinical outcomes and healthcare costs associated with palivizumab use.[15] Although prophylaxis was associated with reduced hospitalization rates, the authors noted that cost savings varied depending on baseline risk and hospitalization costs.[15] This analysis underscored the importance of targeted prophylaxis to optimize cost-effectiveness.[15]

Paes et al. reported outcomes from a large Canadian cohort and confirmed a reduction in respiratory syncytial virus–related hospitalizations without an increase in adverse events.[16] Safety findings were consistent with previous clinical trials.[16] This study strengthened confidence in the favorable risk–benefit profile of palivizumab.[16]

Sánchez-Luna et al. analyzed data from a national registry and observed lower rates of severe respiratory syncytial virus disease among preterm infants receiving prophylaxis.[17] The reduction was most pronounced in infants with additional risk factors such as chronic lung disease.[17] These results highlighted the importance of individualized risk stratification.[17]

Ambrose et al. evaluated extremely preterm infants and demonstrated reduced need for mechanical ventilation among those treated with palivizumab.[18] This finding suggested that prophylaxis may attenuate the clinical course even when infection occurs.[18] Such outcomes are particularly relevant for infants at highest risk of respiratory failure.[18]

Griffin et al. analyzed United States claims data and found lower rates of both initial hospitalization and readmission for respiratory syncytial virus among palivizumab recipients.[19] The consistency of findings across diverse healthcare settings supported external validity.[19] This study provided robust population-level evidence of effectiveness.[19]

More recent studies, including those by Resch, Hampp, and O'Brien, continued to demonstrate reduced hospitalization and intensive care utilization associated with palivizumab use.[20] However, these studies also reported substantial heterogeneity related to gestational age, comorbidities, and regional practice patterns.[20] Such variability contributed to moderate overall certainty of evidence according to GRADE assessments.[20]

Synthesizing all included studies, palivizumab consistently reduced respiratory syncytial virus–related hospitalization among preterm infants, although the magnitude of benefit varied.[21] Comparisons with recent guidelines revealed alignment for very preterm and high-risk infants but ongoing debate for late preterm populations.[21] These findings suggest that updated evidence should inform flexible, risk-based prophylaxis strategies.[21]

From a clinical perspective, the evidence supports continued palivizumab use in carefully selected preterm infants while acknowledging emerging alternatives such as long-acting monoclonal antibodies.[22] Future research should prioritize head-to-head comparisons

and long-term outcome assessment.[22] Until such data are available, palivizumab remains a clinically relevant preventive intervention.[22]

6 CONCLUSION

The present systematic review synthesized contemporary evidence demonstrating that palivizumab prophylaxis is consistently associated with a reduction in respiratory syncytial virus–related hospitalization among preterm infants. Across diverse study designs and healthcare settings, most investigations reported meaningful decreases in hospital admission rates and, in several cases, reduced disease severity. These findings reaffirm the clinical efficacy of palivizumab within high-risk neonatal populations.

From a clinical standpoint, the reduction in hospitalization and intensive care utilization observed in multiple cohorts highlights the relevance of palivizumab for protecting vulnerable preterm infants during respiratory syncytial virus seasons. The evidence suggests that benefits are most pronounced in infants of lower gestational age and in those with additional comorbidities, supporting targeted prophylaxis strategies. Integration of these findings into clinical decision-making may contribute to improved short-term respiratory outcomes.

The literature, however, is subject to important limitations that must be acknowledged. Many included studies were observational, introducing potential confounding and selection bias, while heterogeneity in eligibility criteria and outcome definitions limited direct comparability. Economic evaluations also varied substantially, reflecting differences in healthcare systems and baseline hospitalization risk.

Future research should focus on high-quality comparative studies evaluating palivizumab alongside emerging preventive options, including long-acting monoclonal antibodies and maternal immunization strategies. Longitudinal studies examining long-term respiratory outcomes and health economic impacts are also needed. Such efforts would help refine prophylaxis guidelines and optimize allocation of healthcare resources.

In conclusion, palivizumab remains an evidence-based and clinically valuable intervention for preventing severe respiratory syncytial virus disease in selected preterm infants. Its use should be guided by individualized risk assessment, multidisciplinary collaboration, and alignment with evolving preventive strategies. Continued appraisal of emerging evidence is essential to ensure that prophylactic approaches remain effective, equitable, and scientifically grounded.

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