



ORIGINAL ARTICLE

One-year observational study of palivizumab prophylaxis on infants at risk for respiratory syncytial virus infection in Latin America[☆]

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KEYWORDS

Palivizumab;
Prophylaxis;
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Abstract

Objective: This study aims to describe real world palivizumab use and effectiveness in high-risk Latin American infants and young children.

Method: Prospective, multicenter observational study with infants at risk for severe RSV infection who received palivizumab according to routine clinical practice. Subjects were followed for one year with monthly visits after the first dose of palivizumab. An infant was considered adherent if receiving all the expected injections or five or fewer injections within appropriate inter-dose intervals. Annual incidence rates and risk factors of lower respiratory tract infection (LRTI) hospitalization were determined through Poisson regression models ($\alpha = 0.05$).

Results: The study enrolled 458 children from seven countries in Latin America, from February 2011 to September 2012. The majority (98%) were born <36 weeks gestation. Overall, patients received 83.7% of their expected injections and 86.7% completed one year of follow-up. Of the 61 LRTI hospitalizations, 12 episodes were due to RSV infection. The RSV-associated hospitalization rate was 2.9 per 100 patient-years. Bronchopulmonary dysplasia was identified as an

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independent risk factor for LRTI hospitalization. A total of 1165 adverse events were recorded during one year of follow-up. One hundred and two patients (22.3%) had a total of 135 serious adverse events, but no events were considered to be related to palivizumab.

Conclusions: The rate of RSV hospitalization in high-risk infants in Latin America was low and aligned with those observed in randomized control trials and observational studies. Palivizumab prophylaxis appeared effective and had a good safety profile in this population.

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PALAVRAS-CHAVE
Palivizumabe;
Profilaxia;
Vírus sincicial
respiratório;
Infecção do trato
respiratório inferior;
América Latina

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Estudo observacional de um ano da profilaxia com palivizumabe em neonatos com risco para infecção por vírus sincicial respiratório na América Latina

Resumo

Objetivo: Este estudo visa descrever o uso e a eficácia do palivizumabe no mundo real em neonatos e jovens crianças de alto risco latino-americanas.

Método: Estudo observacional prospectivo multicêntrico com neonatos em risco devido a infecção grave por VSR que receberam palivizumabe de acordo com a prática clínica de rotina. Os indivíduos foram acompanhados por um ano, com visitas mensais após a primeira dose de palivizumabe. Um neonato foi considerado adepto se recebeu todas as injeções esperadas ou ≤ 5 injeções nos intervalos entre doses adequados. As taxas de incidência anuais e os fatores de risco de internação por infecção do trato respiratório inferior (ITRI) foram determinados por meio dos modelos de regressão de Poisson ($\alpha = 0,05$).

Resultados: O estudo inscreveu 458 crianças de sete países da América Latina, de fevereiro de 2011 a setembro de 2012. A maioria (98%) nasceu com < 36 semanas. Em geral, os pacientes receberam 83,7% de suas injeções esperadas, e 86,7% completaram um ano de acompanhamento. Das 61 internações por ITRI, 12 episódios foram devidos a infecção por VSR. A taxa de internação associada ao VSR foi de 2,9 em cada 100 pacientes-anos. A displasia broncopulmonar foi identificada como um fator de risco independente da internação por ITRI. Foram registrados 1165 eventos adversos no total durante um ano de acompanhamento. 122 pacientes (22,3%) apresentaram um total de 135 eventos adversos graves, porém nenhum deles foi considerado relacionado ao palivizumabe.

Conclusões: A taxa de internação por VSR em neonatos de alto risco na América Latina foi baixa e em linha com as observadas em ensaios clínicos controlados randomizados e estudos observacionais. A profilaxia com palivizumabe pareceu eficaz e com bom perfil de segurança nessa população.

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Introduction

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Lower respiratory tract infections (LRTIs) are a leading cause of acute illnesses and mortality in infants and children < 5 years of age, accounting for approximately 1.4 million deaths in 2010 worldwide.¹ Respiratory syncytial virus (RSV) is the most frequent etiology of severe respiratory illness, such as bronchiolitis and/or pneumonia.^{2,3} One meta-analysis estimated that at least 33.8 million episodes of LRTI and 66,000–199,000 deaths in children < 5 years of age were caused by RSV infection in 2005.² Nearly 99% of RSV deaths occurred in developing countries, where the incidence of RSV-associated LRTI seems to be more than twice that observed in industrialized countries.²

In Latin America, a recent meta-analysis estimated a 41.5% (95% CI, 32.0–41.4) prevalence of RSV in infants aged 0–11 months with LRTI, and that RSV was responsible for 36.5% (95% CI, 28.5–44.9) of hospital admissions

due to LRTI among infants aged 0–11 months.⁴ Moreover, a prospective epidemiological cohort of patients aged < 18 years hospitalized due to LRTIs from 2000 to 2013 in Buenos Aires registered a RSV associated fatality rate of 1.9% (74 deaths/3888 cases).⁵ Although these estimates may imply an urgency for health-related interventions, more studies are needed to quantify the disease burden due to RSV and risk factors associated to LRTI hospitalizations in Latin American countries.^{2,4}

Several host- and social-related factors have been associated with an increased risk of RSV infection, namely age < 6 months at the beginning of the RSV season, male sex, multiple birth, household crowding, low socioeconomic status, and parental education, daycare attendance, exposure to indoor tobacco smoke, and abbreviated breastfeeding.^{6,7} In addition, some clinical conditions are associated with severe RSV disease and hospitalization, including prematurity (infants born at ≤ 35 weeks of gestational age),

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