RWD133

Palivizumab use in infants and children under 24 months in South Korea: Utilization patterns and demographic insights in real world

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Why did we perform this study?

- Respiratory syncytial virus (RSV) is a leading cause of severe lower respiratory tract infections in young children, particularly among vulnerable infants, resulting high healthcare utilization and increased mortality [1,2,3]. In South Korea, 76.3% of RSV-confirmed infants require hospitalization, and the economic burden for vulnerable infants is approximately ten times higher than for non-vulnerable populations [4].
- Currently, palivizumab is the standard of care for vulnerable children under two years old and is reimbursed in Korea. However, There is no universal or standardized definition of adherence to a course of palivizumab prophylaxis, making it difficult to determine how to best implement interventions and lack of real-world adherence studies especially within Asian or nationwide population-based contexts.
- **Objectives:** To examine real-world treatment patterns of palivizumab using population-representative data, with an emphasis on adherence to therapy among the study population. To identify and compare the characteristics of populations adherent to versus non-adherent to palivizumab prophylaxis.

Key takeaway *The real-world adherence rate to palivizumab was significantly lower than that observed in randomized clinical trials, and adherent patients differed significantly from non-adherent populations in terms of initiation time of palivizumab and health conditions in South Korea.*

How did we perform this study?

- **Study design**: Longitudinal retrospective cohort study
- **Data source and study**: Health Insurance Review and Assessment Service (HIRA) database covering the entire claims data of patients who had history of LRTIs when patients are under 2 years old in Korea from Jan 2019 to Apr 2022.
- **Study population:** Children < 2 years old with history of at least one injection of palivizumab from Jan 2019 to Apr 2022 the inclusion and exclusion criteria and population selection flow is presented in Figure 2.
- **Definition of adherent group of palivizumab:** Patients were categorized as adherent if they achieved at least 80% adherence to the expected number of palivizumab doses over one year follow-up [5].
- **Baseline characteristics:** Baseline characteristics of study population was assessed at the time of first injection of palivizumab.
- **Statistical analysis:**
  - Continuous variables were summarized using means with standard deviation (SD) and categorical variables were presented as counts and proportions.
  - Differences between groups were evaluated using t-tests for continuous variables and chi-square tests for categorical variables. Statistical significance was determined at $p < 0.05$.
  - Statistical analysis using SAS® Enterprise Guide 7.15 (SAS Institute Inc.)
- **The reimbursement criteria for palivizumab** in South Korea are multifaceted, encompassing infants with low gestational age (wGA), children with congenital heart disease (CHD) and bronchopulmonary dysplasia (BPD), as well as infants born during the RSV season who have at least one of older sibling with a wGA <36 (Figure 1).

Figure 1. Palivizumab reimbursement criteria in South Korea (Since Oct 2016)

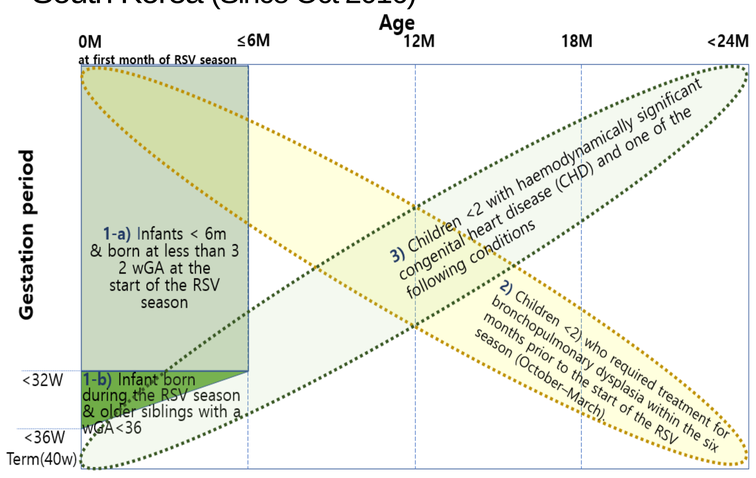
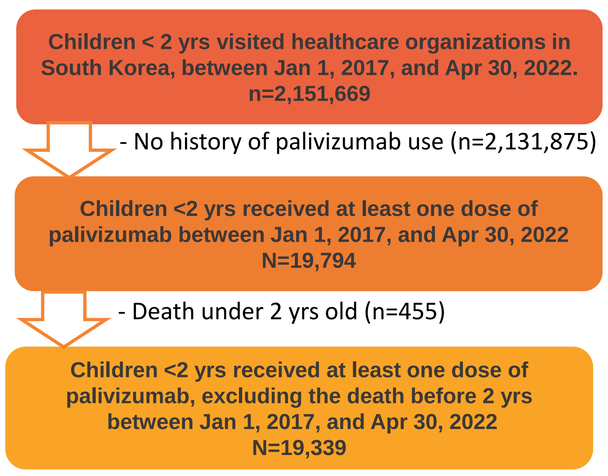


Figure 2. Study population selection flow



What did we find?

Our nationwide population-based retrospective study found that 34.7% of children remained adherent to palivizumab therapy for one year after their first injection, while 22.6% received only one prophylactic dose (Figure 3)

- Additionally, 98.6% of palivizumab administrations occurred during the RSV season in South Korea (Figure 4).
- Adherent children initiated palivizumab prophylaxis at a later age and had a higher prevalence of CHD or BPD compared to non-adherent children (49.8% vs. 26.9%).

Figure 3. Real-word palivizumab use over one-year follow up

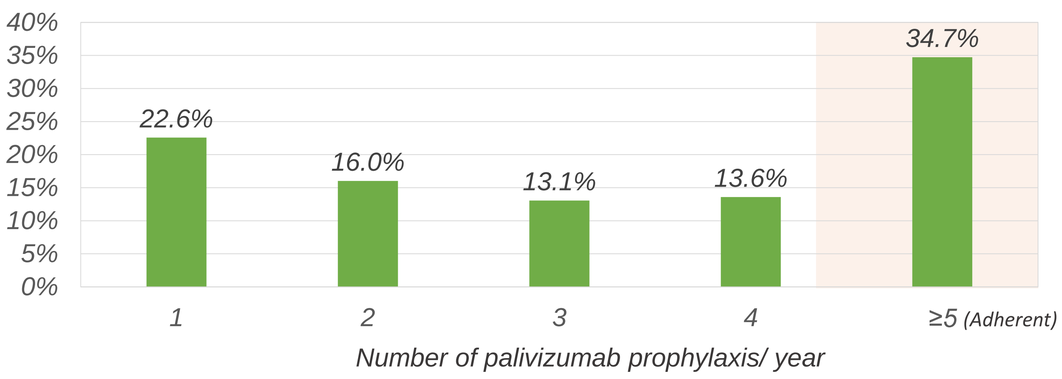


Figure 4. Palivizumab use according to RSV seasonality

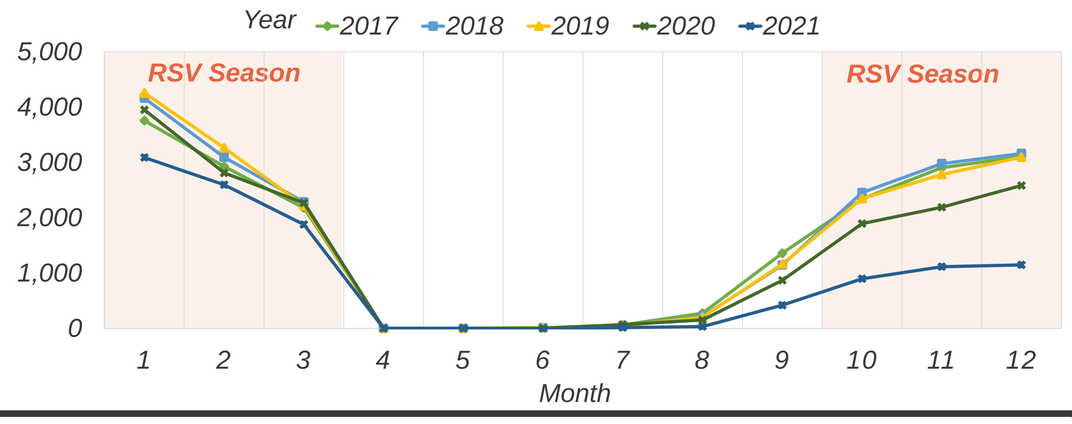


Table 1. Baseline characteristics of populations adherent to versus non-adherent to palivizumab prophylaxis

Variables	Population total n (%)	Non-adherent population n (%)	Adherent population n (%)	P-value
Total	19,339	12,683 (65.6)	6,656 (34.4)	-
Age at first palivizumab injection				
≤30 days	10,219 (52.8)	7,384 (58.2)	2,835 (42.6)	<0.0001
1 month < age < 12 months	8,734 (45.2)	4,968 (39.2)	3,766 (56.6)	
12 month ≤ age < 24 months	386 (2.0)	331 (2.6)	55 (0.8)	
Sex				
Boys	10,568 (54.6)	6,928 (54.6)	3,640 (54.7)	0.9332
Preterm	16,694 (86.3)	10,779 (85.0)	5,915 (88.9)	<0.0001
wGA < 32	9,497 (49.1)	5,081 (40.1)	4,416 (66.3)	<0.0001
Disease				
Congenital heart disease (CHD)	5,849 (30.2)	2,715 (21.4)	3,135 (47.1)	<0.0001
Bronchopulmonary dysplasia (BPD)	1,343 (6.9)	887 (7.0)	456 (6.9)	0.7018
CHD or BPD	6,723 (34.8)	3,408 (26.9)	3,315 (49.8)	<0.0001
Health organization of first palivizumab injection				
Tertiary	13,458 (69.6)	8,441 (66.6)	5,017 (75.4)	<0.0001
Hospital	5,810 (30.0)	4,174 (32.9)	1,636 (24.6)	
Clinics or others	71 (0.4)	68 (0.5)	3 (0.0)	
Type of insurance				
National health insurance	19,178 (99.2)	12,559 (99.0)	6,619 (99.4)	0.0022
Medicaid	161 (6.0)	124 (1.0)	37 (0.6)	

Limitations

- Due to the nature of the claims database used in this study, it was difficult to identify sibling effects or parental characteristics that may contribute to adherence to palivizumab.
- Additionally, uninsured use of palivizumab was partially captured because uninsured items were not mandatory information for reimbursement claims.

Conclusions

Our findings on palivizumab adherence align with previous population-representative real-world studies in the US but are lower than those reported in clinical trials, registry studies, or small-sized population studies in Western countries or multinational contexts. However, most prior studies were conducted over a decade ago [6].

References

1. Li Y, XinBlau, Dianna MCaballero, Mauricio TFeikin, Daniel RGill, Christopher JMadhi, Shabir AOmer, Saad BSimões, Eric AFCampbell, Harry. Global, regional, and national disease burden es timates of acute lower respiratory infections due to respiratory syncytial virus in children younger than 5 years in 2019: a systematic analysis. The Lancet. 2022;399(10340):2047-64. **2.** Ratti C, Greca AD, Bertoncelli D, Rubini M, Tchana B. Prophylaxis protects infants with congenital heart disease from severe forms of RSV infection: an Italian observational retrospective study : Pal ivizumab prophylaxis in children with congenital heart disease. Ital J Pediatr. 2023;49(1):4. **3.** Mavunda K, Jiang X, Ambrose CS. Prevalence and clinical characteristics of perinatal chronic lung disease by infant gestational age. J Neonatal Perinatal Med. 2021;14(1):43-51. **4.** Han, Hyun Jin, et al. "Healthcare resource utilisation and costs in infants with confirmed respiratory syncytial virus infections: a national population cohort study." BMC Infectious Diseases 24.1 (2024): 1152. **5.** Baumgartner, Pascal C., et al. "A systematic review of medication adherence thresholds de pendent of clinical outcomes." Frontiers in pharmacology 9 (2018): 1290. **6.** Wong, Sophie K., et al. "Adherence and outcomes: a systematic review of palivizumab utilization." Expert review o f respiratory medicine 12.1 (2018): 27-42.

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