Effect of Palivizumab Prophylaxis on Respiratory Syncytial Virus Hospitalizations in Preterm Infants Born to $29^{0/7}$ to $31^{6/7}$ Weeks of Gestational Age

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J Pediatr Infect Dis

Abstract

Objective In 2020, in-line with the recommendations of the Turkish Neonatal Society, a new palivizumab indication was added for preterm infants with $29^{0/7}$ to $31^{6/7}$ weeks of gestational age. This study aimed to determine the risk factors of hospitalizations due to lower respiratory tract infections (LRTIs) and respiratory syncytial virus (RSV) in preterm infants ($29^{0/7}$–$31^{6/7}$ weeks of gestational age) who were or were not within the scope of palivizumab indication during the first two RSV seasons (2018–2019 and 2019–2020) and the next two RSV seasons (2020–2021 and 2021–2022) to evaluate the validity of the new indication of palivizumab reimbursement scope.

Methods This study was a two-center retrospective and prospective cohort study and included all preterm infants ($29^{0/7}$–$31^{6/7}$ weeks) aged 90 days and younger during the RSV season (October–March). The primary outcome was to compare the hospitalization rates between patients who received palivizumab and those who did not. The secondary outcome was to identify the risk factors for patients hospitalized due to LRTIs.

Results Of the 122 preterm infants included in the study, 48.3% ($n = 59$) were in the prophylaxis group (Group 1) and 51.7% ($n = 63$) were in the non-prophylaxis group (Group 2). It was noteworthy that 53.8% ($n = 14$) of the 26 infants hospitalized due to LRTIs were in Group 1 and 46.2% ($n = 12$) were in Group 2 ($p = 0.682$). Of the RSV PCR-positive infants, 62.5%($n = 5$) were in Group 1 and 37.5% ($n = 3$) were in Group 2 ($p = 0.30$). The median length of hospitalization was similar in the groups ($p = 0.123$).

Conclusion The indication for palivizumab prophylaxis can be determined more clearly for our country in light of national multicenter studies with an increased sample size.

Keywords
- lower respiratory tract infection
- palivizumab
- preterm
- RSV
- infant

received
January 31, 2024
accepted after revision
August 5, 2024

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Rüdigerstraße 14,
70469 Stuttgart, Germany

DOI https://doi.org/10.1055/s-0044-1789266.
ISSN 1305-7707.

Introduction

Respiratory syncytial virus (RSV) is the most common viral respiratory agent in infants with lower respiratory tract infections (LRTIs). In developed countries, 1 to 3% of infants are hospitalized for RSV bronchiolitis within their first year of life.[1] In a study from Türkiye, RSV was found in 37.9% of children younger than 2 years of age who were hospitalized with the diagnosis of acute LRTIs.[2]

High-risk infants have a higher rate of serious infections than healthy infants. Environmental risk factors include going to kindergarten, crowded living conditions, having siblings of school age, exposure to smoke, and lack of education of caregivers.[3] Risk factors of the host causing severe RSV bronchiolitis include chronic lung diseases such as cystic fibrosis and bronchopulmonary dysplasia (BPD), prematurity, congenital heart disease, Down syndrome, neuromuscular disorders, and immunodeficiencies.[1] There is no vaccine available globally for RSV infection, therefore it continues to be a risk factor and a serious health problem for babies, especially in the first year of life.[4] The increased risk of morbidity and mortality in this high-risk group makes prevention of RSV disease a priority.[3]

Palivizumab used in RSV prophylaxis, is a humanized monoclonal antibody that binds to the F protein of RSV and prevents fusion into respiratory epithelial cells, and also suppresses RSV replication.[5] On the other hand, palivizumab prevents RSV-related hospitalization in children at high risk for LRTIs.[6]

In a multinational, randomized controlled study, during the RSV season, 1,502 children with prematurity ($\geq$35 weeks) or BPD were randomized to receive five injections of either palivizumab (15 mg/kg) or an equivalent volume of placebo by intramuscular injection every 30 days. Palivizumab prophylaxis resulted in a 55% reduction in RSV-related hospitalization (10.6% placebo vs. 4.8% palivizumab). Children with prematurity but without BPD had a 78% reduction in RSV hospitalization (8.1 vs. 1.8%); children with BPD had a 39% reduction (12.8 vs. 7.9%).[7] In some studies, although it does not affect mortality, palivizumab reduces the rate of hospitalization.[8,9]

On the other hand, in a study by Oncel et al[10] including 252 preterm infants, RSV was detected in 18 hospitalized preterm infants. It was determined that the main risk factors that increase the hospitalization of preterm babies, who are under palivizumab prophylaxis throughout the season in our country, are BPD, low gestational age (<28 weeks of gestation), low socioeconomic level, and exposure to smoking.[10]

In a study conducted by the Turkish Neonatal Society (TNS) at 32 centers, RSV positivity was detected in 585 of 3,464 cases (16.9%) using the RSV Respistrip test in swab samples taken from infants under the age of 2 who were hospitalized for LRTIs and were not administered palivizumab prophylaxis.[11] TNS first published the "Palivizumab Prophylaxis Use Recommendations" in 2007, and revised them in 2012, 2014, 2018, and finally in 2020 (►**Table 1**) recommending monthly administrations during the October to March season resulting in a total of five doses of palivizumab.[12]

This study aimed to determine the risk factors of hospitalizations due to LRTIs and RSV in preterm infants ($29^{0/7}$–$31^{6/7}$ weeks of gestational age) who were or were not within the scope of palivizumab indication during the first two RSV seasons (2018–2019 and 2019–2020) and the next two RSV seasons (2020–2021 and 2021–2022) to evaluate the validity of the new indication of palivizumab reimbursement scope.

Materials and Methods

This study is a two-center retrospective and prospective cohort study, and it was performed by examining the cases between 2018 and 2022 in Health Sciences University Tepecik Training and Research Hospital and İzmir Democracy University Buca Seyfi Demirsoy Training and Research Hospital Neonatal Clinics. It included all preterm infants ($29^{0/7}$–$31^{6/7}$ weeks) followed in the neonatal intensive care unit with a chronological age of 90 days and younger for whom written family consent was obtained during the RSV season.

After the addition of the new indication included in the scope of Palivizumab Reimbursement on June 24, 2020, preterm infants with a gestational age of $29^{0/7}$ to $31^{6/7}$ weeks, who were less than 90 days old at the beginning of the RSV season could receive palivizumab prophylaxis during the October to March period. While 59 preterm infants who met the criteria between 2020–2021 and 2021–2022 and received palivizumab prophylaxis were in the study group (Group 1), 63 preterm infants who met the inclusion criteria of the study between 2018–2019 and 2019–2020 were in the control group (Group 2). Infants with BPD, cyanotic congenital heart disease, acyanotic congenital heart disease requiring treatment for congestive heart failure, and pulmonary hypertension were excluded from the study.

The primary outcome of the study was the comparison of hospitalization rates between those who received palivizumab and those who did not, and the secondary outcome was determining the risk factors of patients hospitalized for LRTIs (acute bronchiolitis and pneumonia).

Demographic data about the patients were obtained by contacting the families of 59 patients included in the study after meeting the criteria between 2020–2021 and 2021–2022, when the new RSV prophylaxis recommendations of the TNS were applied, and the families were asked to inform us in case of hospitalization. Afterward, families were called monthly and reminded about palivizumab, and information about the patients was obtained. These patients were included in the study group (Group 1).

The medical data of 63 patients who were included in the study between 2018–2019 and 2019–2020, those who were not in the recommended RSV prophylaxis group before the current TNS recommendations, were obtained from the Hospital Information Management System and analyzed retrospectively. To reach the demographic characteristics of these patients and hospitalization information up to this period, families were contacted using the telephone numbers

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Table 1 Turkish Neonatal Society summary of palivizumab prophylaxis for 2020

	Chronological age at the start of the RSV season		
	≤3 months	<12 months	12–24 months
Premature <29 weeks GA	–	Recommended	Not recommended
Birth weight <1,000 g	–	Recommended	Not recommended
Premature $29^{0/7}$ to $31^{6/7}$ weeks GA[a]	Recommended	Not recommended	Not recommended
BPD[b]	–	Recommended	–
Treatment for BPD in the past 6 months[c]	–	Recommended	Recommended

Abbreviations: BPD, bronchopulmonary dysplasia; GA, gestational age; RSV, respiratory syncytial virus.
[a]All premature babies with gestational age between $29^{0/7}$ and $31^{6/7}$ and calendar age of <3 months during RSV season.
[b]BPD: Gestational age less than $32^{0/7}$ weeks, 21% or more oxygen therapy for ≥28 days.
[c]Babies with BPD who need oxygen therapy, bronchodilators, or steroids in the last 6 months should also receive prophylaxis in the second year of life.

obtained from the patient cards. These patients were included in the control group (Group 2).

Case Report Form, including data about gestational week, birth weight, type of delivery, gender, discharge from hospital, family economic status, number of people living in the house, type of warming, presence of smoker, number of palivizumab prophylaxis in the RSV season, need for hospitalization, hospitalization information such as diagnosis, respiratory viral panel result, length of stay and need for intensive care, was filled in for all the patients. Written permission was obtained from the Buca Seyfi Demirsoy Training and Research Hospital Ethics Committee (Decision no.: 2021/1-4, Date: January 27, 2021) to conduct the study.

Data were evaluated in the statistical package program IBM SPSS Statistics Standard Concurrent User V 25 (IBM Corp., Armonk, NY). Descriptive statistics were given as the number of units (n), percentage (%) mean ± standard deviation ($\bar{x} \pm ss$), median (M), minimum value (min), and maximum value (max). The chi-square test and Fisher's exact test were used in the analysis of categorical variables. Independent sample t-test was used for the comparison of independent groups with two groups in normal distribution, and the Mann–Whitney U test was used for data with nonparametric distribution. The results were evaluated within the 95% confidence interval, and $p < 0.05$ was considered significant.

Results

A total of 122 preterm infants with a chronological age of 90 days and younger and gestational age between $29^{0/7}$ and $31^{6/7}$ weeks during the RSV season were included in the study. Of these patients, 32% ($n = 39$) were in the 2018–2019 season, 20% ($n = 24$) in the 2019–2020 season, 25% ($n = 31$) in the 2020–2021 season, and 23% were ($n = 28$) in the 2021–2022 season. Of the patients included in the study, 48.3% ($n = 59$) were in the prophylaxis group (Group 1) and 51.7% ($n = 63$) were in the non-prophylaxis group (Group 2). The comparison of the sociodemographic and clinical characteristics of the patients is summarized in ►**Table 2**.

Table 2 Demographic characteristics of the patients

Variables	Group 1 ($n = 59$)	Group 2 ($n = 63$)	p-Value
Gestational age, mean ± SD, min–max	30.5 ± 0.8 (29.0–31.6)	30.6 ± 0.7 (29.0–31.6)	0.77
Birth weight (g), mean ± SD, min–max	1,415 ± 328 (670–2,300)	1,488 ± 355 (840–2,750)	0.41
Gender, male, *n* (%)	34 (52.3)	31 (47.7)	0.37
Cesarean section, *n* (%)	49 (47.1)	55 (52.9)	0.68
Multiple pregnancy, *n* (%)	19 (54.2)	16 (45.8)	0.52
RDS (surfactant required), *n* (%)	31 (54.3)	26 (45.7)	0.27
PDA, *n* (%)	5 (45.4)	6 (54.6)	0.99
NEC ≥Grade 2, *n* (%)	1 (100)	0 (0)	0.48
IVH, *n* (%)			
Grade I–II	9 (52.9)	8 (47.1)	0.99
Grade III–IV	0 (0)	1 (100)	
ROP Laser required, *n* (%)	2 (40)	3 (60)	0.40

Abbreviations: IVH, intraventricular hemorrhage; NEC, necrotizing enterocolitis; PDA, patent ductus arteriosus; RDS, respiratory distress syndrome; ROP, retinopathy of prematurity; SD, standard deviation.

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On the other hand, the distribution of the patient's economic status, location, household, and familial characteristics according to the groups is shown in ►**Table 3**. It was determined that 21.3% ($n = 26$) of the preterm infants included in the study were hospitalized due to LRTIs; 23% ($n = 6$) of these patients were hospitalized in the 2018–2019 season, 23% ($n = 6$) in the 2019–2020 season, 19% ($n = 5$) in the 2020–2021 season, and 35% ($n = 9$) were in the 2021–2022 season.

It was detected that 53.8% ($n = 14$) of 26 patients in the prophylaxis group and 46.2% ($n = 12$) of the patients in the non-prophylaxis group were hospitalized for LRTIs. Acute bronchiolitis was diagnosed in 9 and pneumonia in 5 of 14 patients in the prophylaxis group. On the other hand, acute bronchiolitis was diagnosed in 6 of 12 patients in the non-prophylaxis group and pneumonia was found in 6 of them. There was no significant difference between the groups in terms of respiratory viral panel positivity ($p = 0.30$). The distribution of patients hospitalized for LRTIs by groups is shown in ►**Table 4**.

When the sociodemographic and clinical characteristics of patients hospitalized for LRTIs and preterm infants without hospitalization history were compared; no statistical difference was detected between the groups. The comparison of sociodemographic and clinical characteristics of patients hospitalized for LRTIs is summarized in ►**Table 5**.

Discussion

This study aims to evaluate the validity of the new indication of palivizumab prophylaxis, which was included in the scope of Palivizumab Reimbursement on June 24, 2020, in-line with the recommendations of the TNS and to determine the rates of LRTI hospitalization due to RSV. In a meta-analysis of 20 original articles, risk factors for RSV-related LRTIs in children younger than 5 years of age were examined. Among these risk factors, prematurity, low birth weight, male gender, having siblings, maternal smoking, atopy history, not breastfeeding, and living in a large family (with seven or more people) were found to be significant risk factors for RSV-related LRTIs.[13] In a study by Figueras-Aloy et al[14] from the review of 2,469 articles published between 1995 and 2015; the independent significant risk factors associated with LRTIs due to RSV infection were birth in the RSV season, living with school-age siblings, mother's smoking during pregnancy or exposure of the baby to environmental cigarettes, insufficient breast milk intake, male gender, and familial history of atopy.

In a study by Oncel et al,[10] among 252 infants receiving regular palivizumab prophylaxis and closely monitored in the premature outpatient clinics, 18 (7.2%) were hospitalized due to LRTIs, and RSV was detected in 6 of these patients from October 2011 to March 2012 season in our country. Sociodemo-

Table 3 Distribution of the patient's economic status, location, household, and familial characteristics according to the groups

Variables	Group 1 ($n = 59$)	Group 2 ($n = 63$)	*p*-Value
Economic situation, *n* (%)			
Below minimum wage	8 (61.5)	5 (38.5)	0.31
Above minimum wage	51 (46.8)	58 (53.2)	
Number of rooms, *n* (%)			
3 and below	25 (36.2)	44 (63.8)	**0.002**
4 and above	34 (64.2)	19 (35.8)	
Location, *n* (%)			
City center	22 (45.8)	26 (54.2)	0.71
Town center	37 (50)	37 (50)	
Number of people, *n* (%)			
4 and below	32 (42.1)	44 (57.9)	0.08
5 and above	27 (58.7)	19 (41.3)	
Number of children, n (%)			
2 and below	35 (44.3)	44 (55.7)	0.22
3 and above	24 (55.8)	19 (44.2)	
Warming type, *n* (%)			
Stove	18 (60)	12 (40)	0.12
Radiator	40 (43.9)	51 (56.1)	
Others	1 (100)	0 (0)	
Smoking, *n* (%)	32 (51.6)	30 (48.4)	0.48

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Table 4 Distribution of patients hospitalized for lower respiratory tract infections by groups

Variables	Group 1 ($n = 59$)	Group 2 ($n = 63$)	*p*-Value
Hospitalization for LRTI, *n* (%)	14 (53.8)	12 (46.2)	0.68
Respiratory viral panel, *n* (%)			
RSV	5 (62.5)	3 (37.5)	0.30
Others (Bocavirus and parainfluenza)	0 (0)	2 (100)	
None	3 (75)	1 (25)	
No sample taken	6 (50)	6 (50)	
Hospitalization (day), median (min–max)	7 (1–58)	8 (2–25)	0.12

Abbreviations: LRTI, lower respiratory tract infection; RSV, respiratory syncytial virus.
Note: statistically significant *p*-value is shown bold.

Table 5 Comparison of characteristics of patients hospitalized for lower respiratory tract infections

Variables	Hospitalization for LRTIs		*p*-Value
	No ($n = 96$)	Yes ($n = 26$)	
Gender, *n* (%)			
Female	47 (82.5)	10 (17.5)	0.38
Male	49 (75.4)	16 (24.6)	
Delivery, *n* (%)			
Vaginal	13 (72.2)	5 (27.8)	0.68
Cesarean section	83 (79.8)	21 (20.2)	
Multiple pregnancy, *n* (%)	26 (74.3)	9 (25.7)	0.61
RDS, *n* (%)	74 (76.3)	23 (23.7)	0.32
PDA, *n* (%)	7 (63.6)	4 (36.4)	0.25
NEC, *n* (%)	0 (0)	1 (100)	0.21
ROP, *n* (%)	18 (66.7)	9 (33.3)	0.14
IVH, *n* (%)	13 (72.2)	5 (27.8)	0.53
Economic situation, *n* (%)			
Below minimum wage	8 (61.5)	5 (38.5)	0.11
Above minimum wage	88 (80.7)	21 (19.3)	
Number of rooms, *n* (%)			
3 and below	54 (78.3)	15 (21.7)	0.90
4 and above	42 (79.2)	11 (20.8)	
Location, *n* (%)			
City center	41 (85.4)	7 (14.6)	0.22
Town center	55 (74.3)	19 (25.7)	
Number of people, *n* (%)			
4 and below	62 (81.6)	14 (18.4)	0.44
5 and above	34 (73.9)	12 (26.1)	
Number of children, *n* (%)			
2 and below	65 (82.3)	14 (17.7)	0.28
3 and above	31 (72.1)	12 (27.9)	

(*Continued*)

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Table 5 (*Continued*)

Variables	Hospitalization for LRTIs		*p*-Value
	No ($n = 96$)	Yes ($n = 26$)	
Warming type, *n* (%)			
Stove	21 (70.0)	9 (30.0)	0.37
Radiator	74 (81.3)	17 (18.7)	
Others	1 (100)	0 (0)	
Smoking, *n* (%)	49 (79.0)	13 (21.0)	0.99
Palivizumab, *n* (%)	38 (77.6)	11 (22.4)	0.80

Abbreviations: IVH, intraventricular hemorrhage; LRTI, lower respiratory tract infection; NEC, necrotizing enterocolitis; PDA, patent ductus arteriosus; RDS, respiratory distress syndrome.

graphic data of patients hospitalized for LRTIs were analyzed and <28 weeks of gestational age, low socioeconomic status, and presence of BPD were detected as significant risk factors.[10] When the sociodemographic data of our study were examined, a significant difference was found only in the number of rooms between the groups ($p = 0.002$). It was observed that there was no significant difference in risk factors such as type of birth, gender, number of siblings, large family, smoking exposure, warming type, socioeconomic level, and living in rural areas. In addition, when the data of patients hospitalized for LRTIs in our study were examined, it was found that low socioeconomic status, exposure to smoking, male gender, and living in a crowded environment, which were significant in other studies, were not different between the groups.

Hall et al[15] analyzed 2,149 registered children, aged 24 months and younger, hospitalized for LRTIs between October 2000 and March 2005, and 559 (26%) of them were found to be infected with laboratory-confirmed RSV. The hospitalization rate was found to be highest in the first month. It has been shown that preterm infants (<30 weeks of gestation) account for only 3% of RSV cases but the rate of cases hospitalized for LRTIs due to RSV is three times that of term infants.[15]

In a two-center retrospective study by Oncel et al,[16] 272 babies with a gestational age of less than 32 weeks were included in the 2010–2011 season. Of these babies, palivizumab was administered to 201 of these infants, and prophylaxis was not given to 71 of them. There was no significant difference between the two groups in terms of demographic data and risk factors ($p > 0.05$). The hospitalization rates of the patients due to LRTIs were examined, and in the prophylaxis group, a total of 13 patients (4 patients less than 29 weeks of gestational age, and 9 patients at 29–32 weeks of gestational age) were hospitalized. On the other hand, in the group that did not receive prophylaxis, a total of five patients, two patients at less than 29 weeks and three patients at 29 to 32 weeks, were hospitalized. No statistically significant difference was found between the two groups. In this study, it was shown that there is no cost–benefit of palivizumab administration regardless of gestational age. However, a reduction in hospitalization rates associated with palivizumab treatment has been observed in infants less than 29 weeks of gestation with or without BPD.[16]

In the prospective observational study of Cetinkaya et al[17] conducted in Istanbul between October 2015 and April 2016, a total of 202 infants younger than 1 year of age and with a history of preterm birth were included. The mean gestational age of the infants was 32 ± 3.4 weeks (24–37 weeks) and birth weight was found to be $1{,}886 \pm 823$ g (490–2,600 g). The maternal age of 34 (16.8%) infants with RSV infection was significantly lower than those without RSV. It was determined that hospitalization rates and the need for mechanical ventilation were significantly different. It was determined that 17 (77%) of the RSV-positive infants hospitalized were in the group >29 weeks of gestation without palivizumab prophylaxis.[17] In another prospective, multicenter study conducted by Ozkan et al[11] between October 2015 and March 2017, 307 patients born at 29 to 35 gestational weeks, aged 2 and younger, admitted to the hospital with LRTI symptoms during the RSV season were included. RSV was positive in 103 (33.5%) of the patients included in the study, and negative in 204 (66.5%). It was determined that 62 (60.2%) of the RSV-positive group had a calendar age of 3 months and younger. Among the patients in the RSV-positive group, 58 (93.6%) of the patients with a calendar age of 3 months and younger were hospitalized, and the average number of days of hospitalization was 38.7 ± 7.1 days. In the elder group, 31 (75.6%) patients were hospitalized, and the average number of days of hospitalization was 20 ± 2.5 days. A significant difference was detected in the rate of hospitalization and the number of days hospitalized.[11] Considering the data of these two studies, the palivizumab prophylaxis recommendations of our country have been changed.

Our study was also conducted to evaluate the new TNS's proposal. In total, 122 preterm infants were included in our study and it was found that 26 (21.3%) of these infants were hospitalized due to LTRIs. Of these 26 hospitalized infants, no statistically significant difference was found in terms of the effect of prophylaxis among these babies (14 [53.8%] of the hospitalized babies were administered prophylaxis, 12 [46.2%] were not). RSV positivity was detected in five patients in the group that received prophylaxis and in three patients in the group that did not, and no significant difference was found. Among the infants included in our study, respiratory viral panel samples could not be obtained from

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some of the infants (six patients from both groups) hospitalized for LRTIs. The length of hospitalization was similar between the groups.

Our study is important since it is a two-center, prospectively and retrospectively included 2-year RSV season study, and it is the first study to evaluate the validity of the new indication included in the scope of Palivizumab Reimbursement on June 24, 2020, but it has some limitations. Our study has limitations. First, the small sample size due to the intense restrictions during the 2 years of the study and the disruption of prophylaxis because of the coronavirus disease 2019 (COVID-19) pandemic—especially in the 2020–2021 season, as patients under prophylaxis did not come to the hospital for regular follow-up. Second, the recovery program from COVID-19 restrictions in the spring of 2021 led to a higher incidence of RSV compared with the previous 1.5 years. Consequently, the hospitalization rates of patients in the prophylaxis group were found to be higher. It is believed that the fewer hospitalizations due to LRTIs in the group that did not receive prophylaxis are attributed to the COVID-19 restrictions, which resulted in babies living in more isolated environments.

In conclusion, we compared the palivizumab indication during the first two RSV seasons (2018–2019 and 2019–2020) with the subsequent two RSV seasons (2020–2021 and 2021–2022) to evaluate the impact of the changed palivizumab repayment conditions in 2020. Although the incidence of RSV LRTIs was similar, it is believed that the indication for palivizumab prophylaxis in our country can be determined more clearly through national multicenter studies with increased sample sizes.

Funding
The authors declare the study received no funding.

Conflict of Interest
None declared.

References

1 Alan S, Erdeve O, Cakir U, et al; TurkNICU-RSV Trial Group. Outcome of the Respiratory Syncytial Virus related acute lower respiratory tract infection among hospitalized newborns: a prospective multicenter study. J Matern Fetal Neonatal Med 2016;29 (13):2186–2193
2 Hacımustafaoğlu M, Çelebi S, Bozdemir SE, et al. RSV frequency in children below 2 years hospitalized for lower respiratory tract infections. Turk J Pediatr 2013;55(02):130–139
3 Aujard Y, Fauroux B. Risk factors for severe respiratory syncytial virus infection in infants. Respir Med 2002;96(Suppl B):S9–S14
4 Yalaz M, Kültürsay N. Respiratuvar sinsisyal virus enfeksiyonu ve riskli bebeklerde palivizumab profilaksisi. Çocuk Sağlığı ve Hastalıkları Dergisi 2014;57:200–213
5 Johnson S, Oliver C, Prince GA, et al. Development of a humanized monoclonal antibody (MEDI-493) with potent in vitro and in vivo activity against respiratory syncytial virus. J Infect Dis 1997;176 (05):1215–1224
6 Santos da Silva GN, Monti Atik D, Antunes Fernandes JL, et al. Synthesis of three triterpene series and their activity against respiratory syncytial virus. Arch Pharm (Weinheim) 2018: e1800108
7 Connor EM. Palivizumab, a humanized respiratory syncytial virus monoclonal antibody, reduces hospitalization from respiratory syncytial virus infection in high-risk infants. The IMpact-RSV Study Group. Pediatrics 1998;102(3 Pt 1):531–537
8 Parnes C, Guillermin J, Habersang R, et al; Palivizumab Outcomes Registry Study Group. Palivizumab prophylaxis of respiratory syncytial virus disease in 2000-2001: results from The Palivizumab Outcomes Registry. Pediatr Pulmonol 2003;35(06):484–489
9 Paes B, Mitchell I, Li A, Harimoto T, Lanctôt KL. Respiratory-related hospitalizations following prophylaxis in the Canadian registry for palivizumab (2005-2012) compared to other international registries. Clin Dev Immunol 2013;2013:917068
10 Oncel MY, Arayici S, Simsek GK, et al. Risk factors for hospitalization due to lower respiratory tract infection in preterm infants on palivizumab prophylaxis. Iran J Pediatr 2013;23(06):693–700
11 Ozkan H, Celebi S, Koksal N, et al; Turkish Neonatal Society RSV Study Group. Risk factors for respiratory syncytial virus infections in moderate/late premature infants in Turkey: a prospective multicenter epidemiological study. Am J Perinatol 2021;38(14): 1540–1546
12 Acunaş B, Uslu S, Baş AY. Turkish Neonatal Society guideline for the follow-up of high-risk newborn infants. Turk Pediatri Ars 2018;53(Suppl 1):180–195
13 Shi T, Balsells E, Wastnedge E, et al. Risk factors for respiratory syncytial virus associated with acute lower respiratory infection in children under five years: systematic review and meta-analysis. J Glob Health 2015;5(02):020416
14 Figueras-Aloy J, Manzoni P, Paes B, et al. Defining the risk and associated morbidity and mortality of severe respiratory syncytial virus infection among preterm infants without chronic lung disease or congenital heart disease. Infect Dis Ther 2016;5(04): 417–452
15 Hall CB, Weinberg GA, Blumkin AK, et al. Respiratory syncytial virus-associated hospitalizations among children less than 24 months of age. Pediatrics 2013;132(02):e341–e348
16 Oncel MY, Mutlu B, Kavurt S, et al. Respiratory syncytial virus prophylaxis in preterm infants: a cost-effectiveness study from Turkey. Turk J Pediatr 2012;54(04):344–351
17 Cetinkaya M, Oral TK, Karatekin S, Cebeci B, Babayigit A, Yesil Y. Efficacy of palivizumab prophylaxis on the frequency of RSV-associated lower respiratory tract infections in preterm infants: determination of the ideal target population for prophylaxis. Eur J Clin Microbiol Infect Dis 2017;36(09):1629–1634

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