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Seasonal Trends in Palivizumab Compliance in High-Risk Infants Before, During, and After COVID-19 Restrictions

COVID-19 Kısıtlamaları Öncesinde, Sırasında ve Sonrasında Yüksek Riskli Bebeklerde Palivizumab Uyumundaki Mevsimsel Eğilimler

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ABSTRACT

Aim: This study evaluated palivizumab prophylaxis compliance in high-risk infants across four consecutive RSV seasons—pre-pandemic, during COVID-19 restrictions, early post-restriction, and post-pandemic. Our central hypothesis was that compliance would decline after COVID-19 restrictions were lifted, resulting in increased RSV incidence.

Materials and Methods: This retrospective study included 626 high-risk infants who received at least one palivizumab dose at Ankara Bilkent City Hospital between October 2019 and April 2023. Compliance was defined in two ways: full prophylaxis—receipt of all scheduled doses within a season, and full compliance—administration at 30 ± 5-day intervals. In Türkiye, the RSV season spans October–April, with a maximum of five monthly doses. Data were obtained from hospital records and parental interviews. We compared seasonal rates of full prophylaxis, full compliance, and PCR-confirmed RSV infection using the chi-square test for trend.

Results: Of 626 infants, 548 (87.5%) received full prophylaxis, and 453 (72.3%) achieved full compliance. Full compliance declined significantly across seasons: 83.3% in Season 1, 82.2% in Season 2, 75.1% in Season 3, and 56.4% in Season 4 ($p < 0.001$). In parallel, PCRconfirmed RSV incidence increased: 0.0%, 1.9%, 8.3%, and 23.6% across Seasons 1–4 ($p < 0.001$). Partially compliant infants consistently had higher rates of PCR-confirmed RSV infection, non-RSV pneumonia, and bronchiolitis (all $p < 0.05$).

Conclusion: In line with our hypothesis, compliance decreased after the lifting of pandemic restrictions, coinciding with a marked rise in RSV incidence. Full compliance was associated with fewer RSV and non-RSV infections; however, causality cannot be inferred from this ob- servational study. These results emphasize the importance of sustaining high compliance in high-risk infants and call for targeted strategies to optimize prophylaxis adherence in the postpandemic era.

Keywords: COVID-19, palivizumab, RSV, prophylaxis, neonate

ÖZ

Amaç: Bu çalışma, palivizumab profilaksisi uyumunu dört ardışık RSV sezonu boyunca — pandemi öncesi, COVID-19 kısıtlamaları sırasında, kısıtlamaların erken kaldırıldığı dönem ve pandemi sonrası — yüksek riskli bebeklerde değerlendirmiştir. Ana hipotezimiz, COVID-19 kısıtlamaları kaldırıldıktan sonra uyumun azalacağı ve bunun sonucunda RSV insidansının artacağı yönündeydi.

Gereç ve Yöntemler: Retrospektif olarak tasarlanan çalışmaya, Ekim 2019–Nisan 2023 tarihleri arasında Ankara Bilkent Şehir Hastanesi'nde en az bir doz palivizumab alan 626 yüksek riskli bebek dahil edildi. Uyum; tam profilaksi (bir sezonda tüm dozların uygulanması) ve tam uyum (dozların 30±5 gün aralıklarla uygulanması) şeklinde tanımlandı. Türkiye'de RSV sezonu Ekim–Nisan arasında olup, en fazla beş doz uygulanmaktadır. Veriler dosya kayıtları ve ebeveyn görüşmelerinden elde edildi. Sezonlar arasında tam profilaksi, tam uyum ve PCR ile doğrulanmış RSV infeksiyonu oranları ki-kare trend testi ile karşılaştırıldı.

Bulgular: 626 bebekten 548'i (%87,5) tam profilaksi aldı ve 453'ü (%72,3) tam uyum sağladı. Tam uyum oranları sezonlar boyunca anlamlı olarak düştü: Sezon 1 %83,3, Sezon 2 %82,2, Sezon 3 %75,1 ve Sezon 4 %56,4 ($p < 0,001$). Paralel olarak PCR ile doğrulanmış RSV insidansı da arttı: Sezon 1–4 için sırasıyla %0,0, %1,9, %8,3 ve %23,6 ($p < 0,001$). Kısmi uyum gösteren bebeklerde PCR ile doğrulanmış RSV infeksiyonu, RSV dışı pnömoni ve bronşiolit oranları sürekli olarak daha yüksekti (tümünde $p < 0,05$).

Sonuç: Hipotezimizle uyumlu olarak, pandemi kısıtlamalarının kaldırılmasının ardından uyum azalmış ve bu durum belirgin bir RSV artışı ile eş zamanlı olmuştur. Tam uyum daha az RSV ve RSV dışı enfeksiyonla ilişkilendirilmiş olsa da nedensellik bu gözlemsel çalışmadan çıkarılamaz. Bulgular, yüksek riskli bebeklerde uyumun sürdürülmesinin önemini vurgulamakta ve post-pandemik dönemde profilaksiye uyumu artırmaya yönelik hedeflenmiş stratejiler gerektirdiğini göstermektedir.

Anahtar Kelimeler: COVID-19, palivizumab, RSV, profilaksi, yenidoğan

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INTRODUCTION

Respiratory syncytial virus (RSV) is one of the leading causes of lower respiratory tract infections in infants, especially in those born prematurely or with underlying chronic conditions such as bronchopulmonary dysplasia (BPD) or congenital heart disease (CHD) (1). Palivizumab, a monoclonal antibody, is used for immunoprophylaxis in high-risk infants during the RSV season, which in Türkiye typically spans from October to April. High adherence to the monthly dosing schedule is essential to ensure effective protection.

The COVID-19 pandemic and the associated public health measures—including lockdowns, reduced outpatient visits, and changes in health service utilization—may have significantly influenced adherence to prophylactic regimens. While some studies suggest that these restrictions temporarily reduced RSV circulation, the subsequent relaxation of measures may have contributed to an increased RSV burden (2,3). However, data on how these changes affected palivizumab adherence in high-risk infants remain limited, particularly in Türkiye.

The aim of this study was to evaluate adherence to palivizumab prophylaxis in high-risk infants across four consecutive RSV seasons: pre-pandemic, during COVID-19 restrictions, early post-restriction, and post-pandemic. The primary hypothesis was that the lifting of pandemic restrictions would be associated with a decline in adherence and a subsequent increase in RSV incidence.

MATERIAL AND METHOD

This retrospective, observational, single-center study was conducted at Ankara Bilkent City Hospital Neonatal Outpatient Clinic. The study protocol was approved by the local ethics committee (TABED 1-25-1082, Date: 12.03.2025). The study population included 825 high- risk infants who received at least one dose of palivizumab prophylaxis between October 2019 and April 2023.

A total of 825 high-risk infants who received at least one dose of palivizumab during this period were initially considered for inclusion. Eligibility was determined based on the 2018 guidelines of the Turkish Neonatology Association (4). These included:

- Preterm infants born at <32 weeks of gestation with a chronological age ≤3 months at the start of RSV season,
- Infants with birth weight <1000 grams,
- Infants under 1 year of age with bronchopulmonary dysplasia (BPD) or hemodynamically significant congenital heart disease (CHD),
- Infants under 2 years of age with a history of BPD requiring treatment in the past six months.

Study Population and Exclusion Criteria

A total of 825 high-risk infants who received at least one dose of palivizumab prophylaxis between October 2019 and April 2023 at Ankara Bilkent City Hospital Neonatal Outpatient Clinic were initially identified from hospital records. As our center is a quaternary referral hospital, many of the infants receiving palivizumab prophylaxis at our unit were born in other provinces and transferred to our care after discharge from other hospitals. Consequently, the denominator for calculating the proportion of eligible infants discharged from our own NICU who subsequently received prophylaxis would not accurately represent the total number of infants receiving prophylaxis at our center. For this reason, we reported the absolute number of infants receiving prophylaxis per RSV season, rather than the proportion relative to our NICU discharges.

From this initial cohort, 199 infants were excluded for the following predefined reasons:

- Incomplete or missing hospital records (n = 89)
- Inability to contact families for follow-up interviews (n = 64)
- Lack of parental consent for data use (n = 43)
- Duplicate or inconsistent records (n = 3)

After exclusions, the final analytic sample consisted of 626 infants, all of whom had complete data for analysis.

Definitions and Compliance Assessment:

Palivizumab was administered monthly during the RSV season (October to April), with a maximum of five doses per season depending on individual discharge dates and eligibility. In this study, palivizumab administration adherence was evaluated using two distinct metrics; Full prophylaxis : Receipt of all scheduled palivizumab doses within the same RSV season, regardless of the interval between doses. This definition measures dose coverage only. Full compliance : Receipt of all scheduled doses at regular intervals of 30 ± 5 days, in addition to fulfilling the full prophylaxis criterion. This definition measures both dose coverage and timing adherence. Partial prophylaxis : Missing one or more scheduled doses during the RSV season. Partial compliance : Receiving all scheduled doses but with one or more given outside the recommended 30 ± 5-day interval.

The study population was grouped according to four distinct RSV seasons for comparative analysis:

- Season 1: October 2019 – April 2020 (pre-pandemic),
- Season 2: October 2020 – April 2021 (during strict COVID-19 measures),

- Season 3: October 2021 – April 2022 (post-restriction),
- Season 4: October 2022 – April 2023 (RSV resurgence period).

Data Collection

Data on the total number of palivizumab doses received, history of pneumonia, hospitalizations for pneumonia and bronchiolitis, use of nebulizer treatment, and PCR nasopharyngeal swab results for respiratory viruses were extracted from patients' hospital records. Only infants who presented with respiratory symptoms or who required hospitalization underwent nasopharyngeal PCR testing; therefore, the denominators reported for PCR-confirmed RSV per season refer to the symptomatic/tested subset for that season rather than to all infants who received palivizumab that season.

Patients' parents or legal guardians were contacted face-to-face or by telephone to inquire about factors affecting their palivizumab compliance, such as whether there was a smoking household and a sibling attending daycare.

Statistical Analysis

Statistical analyses were performed using SPSS for Windows, version 27.0 (IBM Corp., Armonk, NY, USA, 2020). The assumption of normal distribution for continuous variables was assessed using the Shapiro–Wilk and Kolmogorov–Smirnov tests. Continuous variables with a normal distribution were reported as mean ± standard deviation, while those without a normal distribution were presented as median (minimum–maximum). Categorical variables were summarized as frequencies and percentages.

For comparisons between groups:

- The Mann–Whitney U test was used for continuous variables that did not follow a normal distribution,
- The Chi-square test was applied for categorical variables,
- Fisher's exact test was used when the assumptions of the Chi-square test were not met.

To evaluate temporal trends, the Chi-square test for trend was performed. A two-sided p-value ≤ 0.05 was considered statistically significant for all analyses.

RESULTS

Of the 626 infants included in the study, 285 (45.5%) were female and 341 (54.5%) were male. The mean gestational age was 28.9 weeks and the mean birth weight was 1305 grams. Among these infants, 127 (20.3%) were born before 29 weeks, 15 (2.4%) had a birth weight under 1000 grams, 216 (34.5%) had bronchopulmonary dysplasia, 16 (2.6%) had congenital heart disease, and 252 (40.3%) were born between 29 and 32 weeks of gestation. During the first year of life, 126 infants (20.1%) developed pneumonia, 236 (37.7%) developed bronchiolitis, and 32 (5.1%) had PCR-confirmed RSV infection. A total of 130 infants (20.8%) were hospitalized, 278 (44.4%) received inhaler therapy, 229 (36.6%) required short-term treatment, and 49 (7.8%) required long-term treatment (Table 1).

Table-1. Demographic and Clinical Characteristics of High-Risk Infants

		n	%
Gender	Female	285	45.5
	Male	341	54.5
Nationality	Turkish	616	98.4
	Other	10	1.6
Gestational Age*		28.9 ± 2.3	
Birth Weight*		1305 ± 459	
Having a sibling attending daycare	(-)	491	78.4
	(+)	135	21.6
Living in a smoking household	(-)	402	64.2
	(+)	224	35.8
Pneumonia	(-)	500	79.9
	(+)	126	20.1
Bronchiolitis	(-)	390	62.3
	(+)	236	37.7
Indication	A gestational age of <29 weeks	127	20.3
	A gestational age between 29th and 32nd weeks	252	40.3
	A birth weight of <1000 g	15	2.4
	BPD diagnosis	216	34.5
	CHD diagnosis	16	2.6
Nebulizer treatment	(-)	348	55.6
	(+)	278	44.4
Ventolin Pulmicort treatment	Short-term	229	36.6
	Long-term	49	7.8

SD: Standard deviation, *Mean ±SD

Full prophylaxis vs partial prophylaxis

Among the 626 infants, 548 (87.5%) received full prophylaxis and 78 (12.5%) received partial prophylaxis.There were no significant differences between these two groups in sex, gestational age, or birth weight. However, nationality differed slightly, with other nationalities being more frequent in the partial prophylaxis group (5.1% vs 1.1%, p = 0.026) (Table 2).

Pneumonia occurred in 92 (16.8%) infants with full prophylaxis compared to 34 (43.6%) with partial prophylaxis (p = 0.001). Bronchiolitis occurred in 199 (36.3%) vs 37 (47.4%), respectively (p = 0.05). PCR-confirmed RSV pneumonia was observed in 25 (4.6%) full prophylaxis vs 7 (9.0%) partial prophylaxis (p = 0.09). Inhaler therapy was used in 229 (41.8%) full prophylaxis vs 44 (56.4%) partial prophylaxis (p = 0.015). Hospitalization was required in 101 (18.4%) vs 29 (37.2%), respectively (p < 0.001) (Table 3).

Of the 78 infants (12.5%) who received partial prophylaxis, the reasons were parental neglect or non-attendance at appointments in 56 cases (71.8%), hospitalization in 12 cases (15.4%), parental refusal in six cases (7.7%), language barriers due to foreign nationality in three cases (3.8%), and death in one case (1.3%). There was no statistically significant demographic difference between infants receiving full prophylaxis and those receiving partial prophylaxis.

Table-2. Demographic Characteristics Who Received Partial and Full Prophylaxis

		Full prophylaxis (n=548)	Partial prophylaxis (n=78)	
		n	n	p
Gender	Female	249 (45.4%)	36 (46.2%)	0.905
	Male	299 (54.6%)	42 (53.8%)	
Nationality	Turkish	542 (98.9%)	74 (94.9%)	0.026
	Other	6 (1.1%)	4 (5.1%)	
Gestational Age*		28.9 ± 2.3	29.2 ± 2.5	0.194
Birth Weight*		1294 ± 450	1387.0 ± 511.4	0.182
Living in a smoking household	(-)	357 (65.1%)	45 (57.7%)	0.199
	(+)	191 (34.9%)	33(42.3%)	
Having a sibling attending daycare	(-)	432 (78.8%)	59 (42.3%)	0.527
	(+)	116 (21.2%)	19 (24.4%)	

SD: Standard deviation,
***Mean ±SD**

Table-3. Clinical Characteristics Who Received Partial and Full Prophylaxis

		Full prophylaxis (n=548)	Partial prophylaxis (n=78)	
		n	n	p
Pneumonia	(-)	456 (83.2%)	44 (56.4%)	0.001
	(+)	92 (16.8%)	34 (43.6%)	
Bronchiolitis	(-)	349 (63.7%)	41 (52.6%)	0.05
	(+)	199 (36.3%)	37 (47.4%)	
RSV Pneumonia	(-)	523 (95.4%)	71 (91.0%)	0.09
	(+)	25 (4.6%)	7 (9.0%)	
Nebulizer treatment	(-)	319 (58.2%)	34 (43.6%)	0.015
	(+)	229 (41.8%)	44 (56.4%)	
Hospitalization	(-)	447 (81.6%)	49 (62.8%)	<0.001
	(+)	101 (18.4%)	29 (37.2%)	
Indication	A gestational age of <29 weeks	115 (21.0%)	12 (15.4%)	0.25
	A gestational age between 29th and 32nd weeks	221 (40.3%)	31 (39.7%)	0.92
	A birth weight of <1000 g	12 (2.2%)	3 (3.8%)	0.41
	BPD diagnosis	190 (34.7%)	26 (33.3%)	0.81
	CHD diagnosis	10 (1.8%)	6 (7.7%)	0.001

BPD: Bronchopulmonary dysplasia, **CHD:** Congenital heart disease, **RSV:** Respiratory Syncytial Virus

Table-4. Clinical Characteristics Who Received İnjections Partial and Full Compliance				
		Full compliance(n=453)	Partial compliance (n=95)	
		n	n	p
Pneumonia	(-)	384 (84.8%)	72 (75.8%)	0.03
	(+)	69 (15.2%)	23 (24.2%)	
Bronchiolitis	(-)	299 (66%)	50 (52.6%)	0.01
	(+)	154 (34%)	45 (47.4%)	
RSV Pneumonia	(-)	437 (96.5%)	86 (90.5%)	0.01
	(+)	16 (3.5%)	9 (9.5%)	
Nebulizer treatment	(-)	275 (60.7%)	44 (46.3%)	0.01
	(+)	178 (39.3%)	51 (53.7%)	
Hospitalization	(-)	380 (83.9%)	67 (70.5%)	0.002
	(+)	73 (16.1%)	28 (29.5%)	
Indication	A gestational age of <29 weeks	104 (23%)	11 (11.6%)	0.013
	A gestational age between 29th and 32nd weeks	189 (41.7%)	32 (33.7%)	0.147
	A birth weight of <1000 g	12 (2.6%)	0 (0%)	0.237
	BPD diagnosis	138 (30.5%)	52 (54.7%)	<0.001
	CHD diagnosis	10 (2.2%)	0 (0%)	0.223

BPD: Bronchopulmonary dysplasia, **CHD:** Congenital heart disease, **RSV:** Respiratory Syncytial Virus

Full compliance vs partial compliance

Of the infants who received injections, 453 achieved full compliance and 95 had partial compliance. Pneumonia occurred in 69 (15.2%) of fully compliant infants versus 23 (24.2%) of partially compliant infants (p = 0.03). Bronchiolitis was recorded in 154 (34.0%) vs 45 (47.4%), respectively (p = 0.01). PCR-confirmed RSV pneumonia was significantly lower in the full compliance group — 16 of 453 (3.5%) — compared with 9 of 95 (9.5%) in the partial compliance group (p = 0.01). Nebulizer treatment was used in 178 (39.3%) of fully compliant infants vs 51 (53.7%) of partially compliant infants (p = 0.01). Hospitalization occurred in 73 (16.1%) of fully compliant infants compared with 28 (29.5%) of partially compliant infants (p = 0.002) (Table 4).

The number of infants receiving prophylaxis by season was 102 in Season 1, 152 in Season 2, 177 in Season 3, and 195 in Season 4. The proportion receiving full prophylaxis was 90.1% in Season 1, 85.5% in Season 2, 89.2% in Season 3, and 86.1% in Season 4, with no statistically significant difference across seasons (p = 0.64). In contrast, the rate of full compliance, defined as receiving all doses at 30 ± 5-day intervals, declined significantly from 83.3% in Season 1 to 56.4 % in Season 4 (p < 0.001) (Figure 1).

RSV infection was detected in 14 of 65 infants (21.6%) with a sibling attending daycare and in 18 of 83 infants (21.7%) without a sibling attending daycare, with no statistically significant difference between the groups (p>0.05). There was no significant association between having a sibling in daycare and vaccine compliance (p > 0.05). RSV infection occurred in 19 of 224 infants (8.5%) living in a smoking household compared with 13 of 402 infants (3.2%)

in non-smoking households, with a significantly higher infection rate in the smoking group (p = 0.008). No significant association was found between household smoking and vaccine compliance (p > 0.05).

PCR-confirmed respiratory virus detection rates by season were 0.0% (0/42) in Season 1, 1.9% (1/54) in Season 2, 8.3% (9/108) in Season 3, and 23.6% (22/93) in Season 4, showing a significant increasing trend over time (p < 0.001) (Figure 2).

DISCUSSION

This study, evaluating palivizumab compliance among 626 high-risk infants over four consecutive RSV seasons (2019–2023),

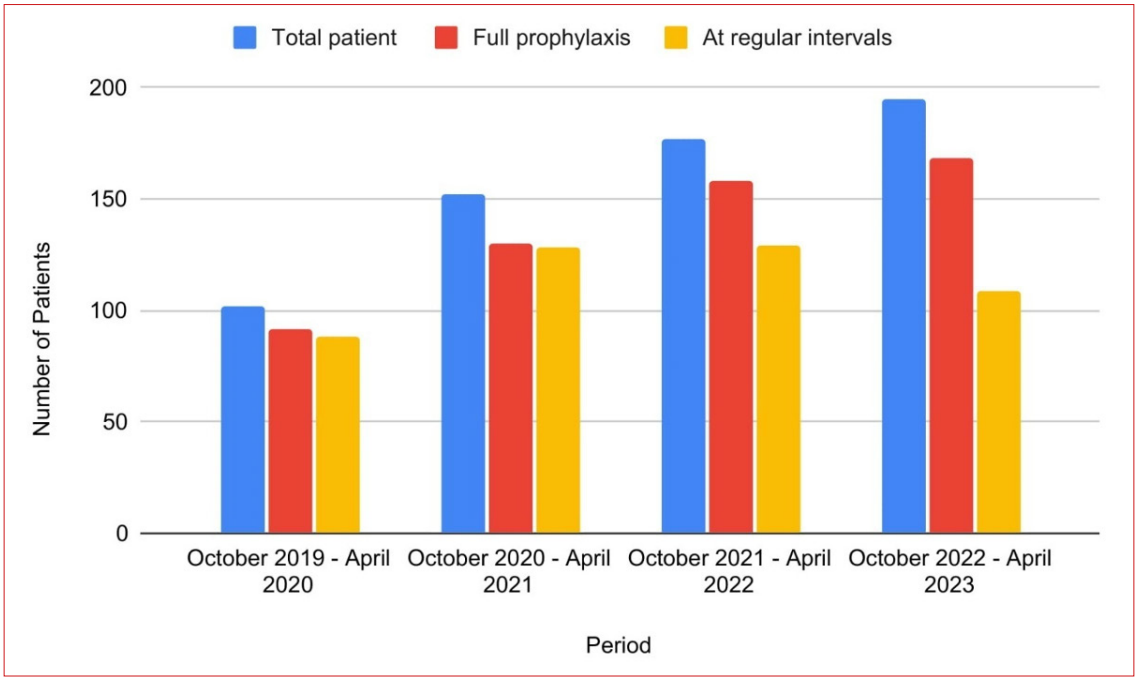

Figure 1. XXXXXXX

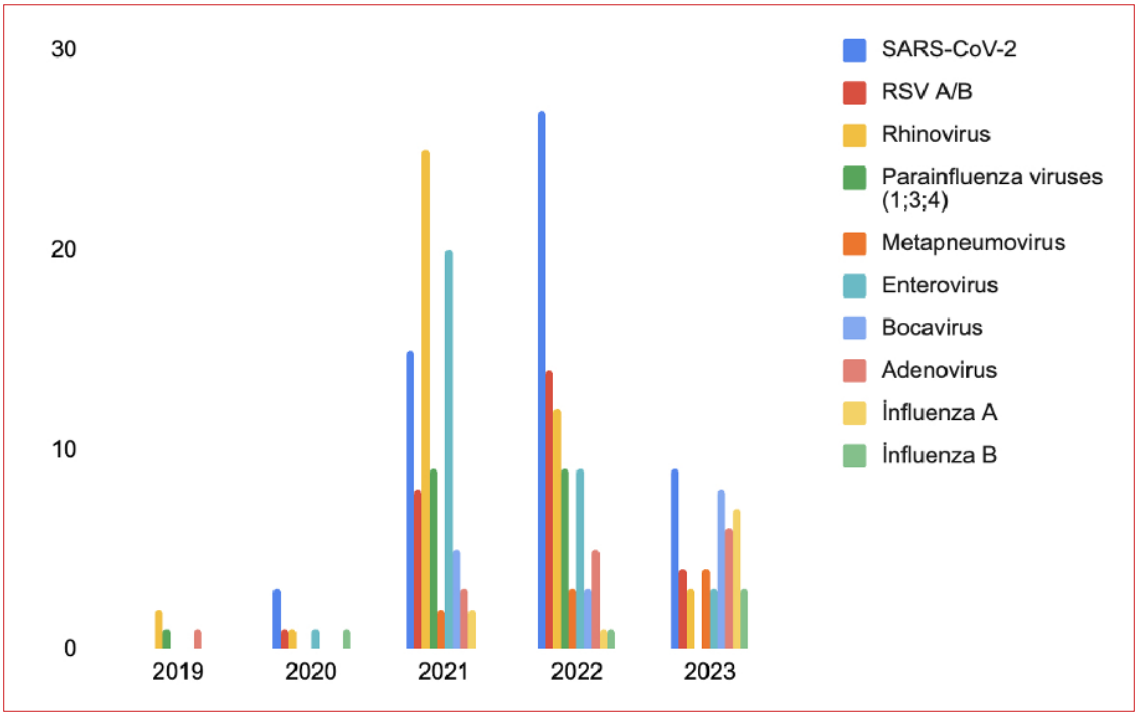

Figure 2. XXXXXXX

represents one of the most comprehensive analyses from Türkiye assessing adherence patterns and their temporal relationship with the COVID-19 pandemic. Overall, 87.5% of infants received full prophylaxis, but only 72.3% achieved full compliance, with rates declining significantly from 83.3% in Season 1 to 56.4% in Season 4 ($p < 0.001$). These compliance rates are broadly consistent with those reported in the literature. For instance, the Canadian Registry of Synagis (CARESS) reported that 81.2% of infants received all prescribed doses, with 60.9% fully compliant with the recommended dosing intervals, while a United Arab Emirates

study reported a higher compliance rate of 90.9% in 2019 (5,6). In parallel, PCR-confirmed RSV incidence rose sharply after the lifting of pandemic restrictions, from 0% in Season 1 to 23.6% in Season 4 ($p < 0.001$). These trends support our primary hypothesis that reduced adherence following the relaxation of COVID-19 measures contributed to increased RSV incidence.

Our findings align with global reports of an unprecedented decline in RSV during the restriction period, followed by a resurgence post-pandemic (7,8). For example, a UK study observed a 99.6% reduction in RSV incidence during 2020–2021 compared with pre-pandemic levels, with a rapid rebound thereafter (9). In our cohort, only four RSV cases were recorded in the first two seasons, increasing to 28 cases in the last two seasons. While causality cannot be confirmed due to the observational design, the temporal association and statistical trends are consistent with this global pattern. Moreover, our center observed a rise in rhinovirus and enterovirus infections post-pandemic, consistent with findings from Finland and Australia, where the incidence of these viruses decreased during restrictions and resurged afterward (10,11).

Partial prophylaxis was associated with higher rates of RSV and non-RSV pneumonia and bronchiolitis. Although the difference in RSV rates between full and partial prophylaxis groups (4.6% vs. 9%) did not reach statistical significance, the direction of the effect aligns with prior evidence showing increased RSV-related hospitalizations among noncompliant infants. The impact of palivizumab on non-RSV-related hospitalizations remains debated; however, in our study, infants who received partial prophylaxis had significantly higher rates of non-RSV pneumonia, bronchiolitis, and greater need for inhaled therapies such as salbutamol and budesonide ($p < 0.05$). These results are consistent with findings by Lacaze-Masmonteil et al., who reported markedly higher non-RSV hospitalization rates in infants who did not receive RSV prophylaxis (12), reinforcing the broader protective effect of timely prophylaxis.

The average half-life of palivizumab is approximately 20 days. The American Academy of Pediatrics recommends administration at intervals of 25 to 35 days to maintain effective serum concentrations of ≥40 µg/mL (13). Our data reinforce this guidance: in the 2019–2020 season, full compliance was 83.3% and only one infant was hospitalized for RSV-related pneumonia. By contrast, in 2022–2023, full compliance dropped to 56.4%, with 22 RSV-related hospitalizations recorded. These findings suggest that reduced compliance may have contributed to the post-pandemic rise in RSV incidence, alongside the easing of COVID-19 restrictions.

Barriers to full compliance in our cohort included parental neglect or misinformation, hospitalization interruptions, vaccine hesitancy, and language barriers. Prior studies support these findings. For instance, Chan et al. identified maternal education level as a key factor in compliance (14), while Pignotti et al. found that language barriers led to lower compliance rates among non-native families (15). These observations highlight the importance of socioeconomic and cultural determinants in vaccine adherence. Our data did not show a statistically significant difference in RSV infection rates between infants with a sibling attending daycare and those without, despite previous studies such as Hui et al. (16) reporting a higher risk in such infants. There was also no association between having a sibling in daycare and vaccine compliance. In contrast, infants living in smoking households had a significantly higher RSV incidence compared to those in non-smoking households ($p = 0.008$), although smoking exposure did not significantly affect compliance. Previous research has suggested that non-smoking households are associated with better prophylaxis adherence (17); in our cohort, however, household smoking status did not influence adherence, indicating that its primary effect was on RSV incidence rather than compliance.

One of the major strengths of this study is that it was conducted at one of the largest neonatal intensive care units in Türkiye, with a high annual volume of palivizumab administration. However, several limitations must be acknowledged. First, the retrospective design limited our ability to collect some data and to ensure complete follow-up, especially after discharge. Second, as a single-center study, the findings may not be generalizable to all healthcare settings. Third, being a quaternary referral center that accepts patients from diverse geographic regions poses challenges in longitudinal monitoring. Fourth, limited access to the medical records and vaccination schedules of families who could not be contacted may have affected our ability to assess certain factors influencing compliance. Lastly, the evolving nature of pandemic measures during the study period likely introduced multiple overlapping confounders, making it challenging to isolate the direct effects of COVID-19 restrictions on both RSV incidence and prophylaxis adherence.

CONCLUSION

This study evaluated the effect of palivizumab prophylaxis on infections and vaccination compliance in high-risk infants in the post-COVID-19 pandemic period. Consequently, we found that infants receiving full palivizumab prophylaxis had lower rates of both RSV- and non-RSV-related respiratory tract infections. While these findings suggest a protective association between full compliance and reduced infection rates, they represent an association and not a demonstration of causality. The significant increase in RSV

infections observed with the lifting of COVID-19 measures highlights the effects of the pandemic on RSV incidence. Additionally, this study showed that family dynamics and environmental factors should be taken into account in preventing infections in addition to vaccination. Our study reaffirmed the efficacy of palivizumab prophylaxis in preventing RSV and non-RSV infections, showing that ensuring vaccination compliance can significantly reduce associated hospitalization rates.

However, causal inference cannot be drawn from these observational data.

Author Contributions: B.Y. was responsible for conceptualization, data collection, formal analysis, and drafting of the manuscript. G.Ç. contributed to data acquisition, statistical analysis, and critical revision of the manuscript. C.B. was involved in study design, supervision, interpretation of results, and critical editing. M.B. conducted patient follow-up, data verification, and literature review. M.Ş.A. oversaw the ethics approval process, contributed to data interpretation, and reviewed the manuscript. G.K.Ş. managed project administration, developed the methodology, and provided final approval of the manuscript. All authors read and approved the final version of the manuscript and agreed to be accountable for all aspects of the work.

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