REVIEW

Global impact of nirsevimab on respiratory syncytial virus: Valle d'Aosta and beyond

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ABSTRACT

Respiratory syncytial virus (RSV) is a leading cause of bronchiolitis and pneumonia in infants, with significant morbidity and mortality worldwide. Despite advancements in medical care, RSV continues to impose a substantial economic and emotional burden on families. Current preventive measures, such as the monoclonal antibody palivizumab, are limited to high-risk populations due to cost and administration frequency. Recently, a new prophylactic agent, nirsevimab, has become available for protection of all infants and children during their first RSV season. Nirsevimab is a humanized monoclonal antibody that targets the fusion (F) protein of RSV in its prefusion conformation, a critical structure for viral infectivity. Nirsevimab has shown an extended half-life and broad neutralizing activity against various RSV strains, including those resistant to other antibodies.

This review focuses on implementation of universal nirsevimab prophylaxis, including the pivotal Italian experience in the Valle d'Aosta region, during the 2023-2024 epidemic season. Data from the region indicates a significant reduction in RSV hospitalizations among infants who received nirsevimab, with no hospitalizations reported in this group compared to 9.7% hospitalization rate in the non-prophylaxis group. The side effects were mild and short-lived. The findings suggest that universal nirsevimab prophylaxis is an effective and safe strategy for reducing the burden of RSV in infants, aligning with successful programs in other countries, such as USA, Spain and France. Further research is needed to explore its long-term impact and cost-effectiveness. By addressing these questions, nirsevimab can play a crucial role in improving infant health outcomes and reducing the burden of RSV.

IMPACT STATEMENT: The review highlights the significant reduction in RSV hospitalizations among infants following the implementation of universal prophylaxis with nirsevimab, demonstrating its effectiveness and safety. This strategy has the potential to substantially alleviate the global burden of RSV, improving infant health outcomes.

KEY WORDS

RSV; nirsevimab; bronchiolitis; monoclonal antibody; universal immunization strategy.

INTRODUCTION

Respiratory syncytial virus (RSV) is the leading cause of bronchiolitis and pneumonia in infants worldwide, with infection rates peaking in the winter months. Beyond acute illness, RSV can lead to long-term respiratory problems like recur-

rent wheezing and asthma. There is a critical need for effective preventive strategies to reduce the impact of RSV on infant health. Despite advancements in medical care, RSV-related morbidity and mortality remain high, causing substantial economic and emotional strain on families (1).

GLOBAL IMPACT OF RSV

Globally, RSV causes about 33 million cases of lower respiratory tract infections requiring medical attention, 3.6 million hospitalizations and more than 100,000 deaths in children aged 0-5 years each year (**Figure 1**). In fact, RSV infection is the leading cause of hospitalization for respiratory infection among children under 1 year of age and is the second leading cause of child mortality after malaria (2).

Considering all infants and children in their first epidemic season, more than 20% require outpatient medical care (3, 4), and 4% are hospitalized (including nearly 1/5 in intensive care) (5).

If we consider the Italian cohort of nearly 400.000 new births (http://dati.istat.it/), >80.000 children will require outpatient medical care, 24.000 access emergency rooms, 16.000 will be hospitalized and 3.200 admitted to intensive care (6).

RSV not only causes an acute respiratory illness that requires medical attention, such as bronchiolitis, but also increases the risk of needing care in the medium and long term: in fact, 30-40% of children who do RSV bronchiolitis in the first year of life develop wheezing and/or asthma in early childhood (7, 8).

Most of the children hospitalized for RSV lower respiratory tract infection, such as bronchiolitis, were born at term and born healthy, for whom, therefore, there was still no possibility of prevention. In fact, in Italy 87% of RSV hospitalizations occur in children born healthy and/or at term (3), while 97% of children with bronchiolitis seen by the Family Pediatrician are healthy children and 92% are children born at term. The serious clinical burden of respiratory infections, such as bronchiolitis, is not only at the hospital level, but is also at ambulatory level (9).

Therefore, the main risk factors for developing a respiratory RSV infection requiring outpatient medical care and/or hospitalization are seasonality and age, two factors that affect all children (1).

Currently, the main preventive measure against RSV is the monoclonal antibody palivizumab. However, its use is limited to specific high-risk populations, such as preterm infants, those with significant heart disease, or infants with compromised immune systems (10). Palivizumab's high cost and need for frequent administration further restrict its widespread use. As a result, there is a pressing need for alternative prevention strategies that are both effective and accessible.

NIRSEVIMAB: A PROMISING PREVENTIVE STRATEGY

One promising development is nirsevimab, a humanized monoclonal antibody targeting the RSV fusion (F) protein in its pre-fusion state, crucial for the virus's infectivity. Nirsevimab has shown an extended half-life and

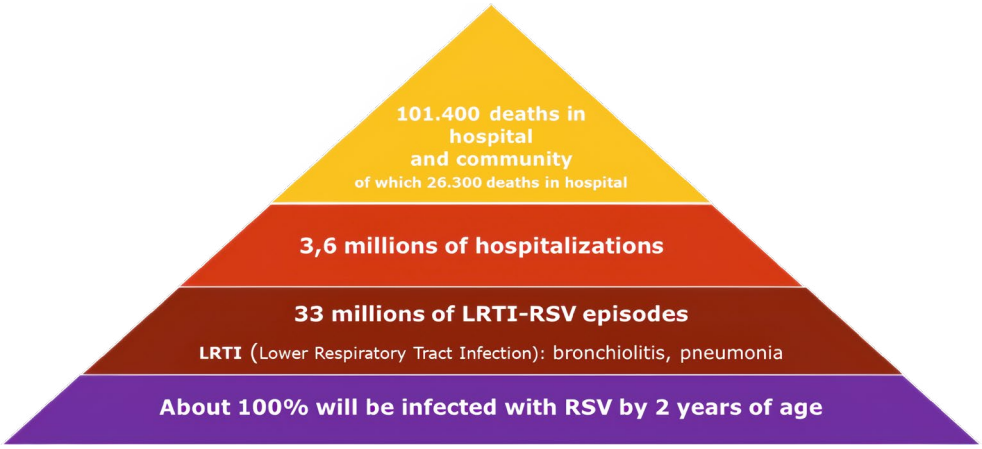

***Figure 1**. Annual worldwide RSV burden among children 0-5 years of age.*

broad neutralizing activity against various RSV strains, including those resistant to other antibodies (11). Clinical trials have demonstrated its efficacy in reducing medically attended RSV lower respiratory tract infections (LRTIs) and hospitalizations, with a favorable safety profile (11-15). Following its approval by the European Medical Agency (EMA) (16), several countries have implemented the immunization campaign with nirsevimab: USA, Spain, France, Luxembourg, Chile and Australia, aiming to reduce the burden of RSV among infants (17-22).

This is a paradigm shift in prevention because it is the first time that a monoclonal antibody has been used as a preventive tool, like a vaccine, for instance, and not as a therapy (23).

Implementation of nirsevimab in Valle d'Aosta

Many other countries, including Italy are poised to start the immunization campaign in the 2024/2025 season (24-28). In Italy, there is only one region that has started the immunization campaign as early as the 2023-2024 season: Valle d'Aosta (29).

In Valle d'Aosta, RSV infections have surged in recent epidemic seasons, with hospitalization rates exceeding the national average. To address this, Valle d'Aosta pioneered universal nirsevimab prophylaxis for newborns during the 2023-2024 epidemic season. Data and results of the immunization campaign were published in the journal Vaccines and presented at the ESPID 2024 (The 42nd Annual Meeting European Society for Pediatric Infectious Diseases) congress (29, 30).

In this article we report results from our prospective observational cohort study, comparing the incidence of hospitalization for RSV bronchiolitis or pneumonia in infants who received nirsevimab prophylaxis against those who did not. The study also monitors the safety of nirsevimab by tracking short-term adverse effects.

Infants born between 1 May 2023 and 31 March 2024 were included, excluding those with existing risk factors already receiving palivizumab because, in consideration of the late availability of nirsevimab (from 20 December), we decided to continue the immunization with palivizumab. Extensive training sessions for healthcare workers were conducted to ensure program adherence. Nirsevimab was imported from France, and parents were informed and summoned through postal services. Prophylaxis was administered at the Aosta hospital for the *in-season* babies (born from 12/19/2023 to 03/31/2024) and at the Hygiene and Public Health Services (SISP) for the 'catch-up' babies (born from 05/01/2023 to 12/18/2023) and monitored through follow-up telephone interviews and local health unit data. Out of 615 eligible neonates, 71.5% adhered to nirsevimab prophylaxis.

Hospitalizations for RSV bronchiolitis significantly decreased in the prophylaxis group compared to previous seasons. Among those who received nirsevimab, none were hospitalized for RSV bronchiolitis, while the non-prophylaxis group saw a 9.7% hospitalization rate (**Figure 2**). Side effects were generally mild and short-lived, including fever and local reactions at the injection site.

The study highlights the substantial reduction in RSV-related hospitalizations due to universal nirsevimab prophylaxis. The findings align with similar successful programs in other countries, such as USA, Spain, France and Luxembourg, demonstrating the efficacy and safety of nirsevimab. The cost-effectiveness of nirsevimab, considering reduced hospital admissions and social care costs, makes it a viable preventive strategy. The program's success in Valle d'Aosta underscores the importance of collaborative healthcare efforts and proactive policies in implementing innovative health measures.

Evidence from Spain and other countries

Valle d'Aosta data fits with other evidence that has been generated in countries that have implemented the universal immunization campaign in the 2023/2024 season (29).

In Galicia, coverage and hospitalization rates recorded throughout the immunization campaign were monitored weekly in the NIRSE-GAL study (31). It was achieved:

- 95.4% coverage in children born during the RSV season (October 2023-March 2024). who were immunized in the hospital at birth;
- 89.9% of coverage in children born out of season (born between April-September 2023) who were recalled for in-hospital immunization before the start of the RSV season (almost all of whom were already immunized in October 2023);
- 97% coverage in the highest risk infants (preterm <29 gw, CHD, CLD).

Recorded nirsevimab effectiveness in reducing RSV-related LRTI hospitalizations was 82%.

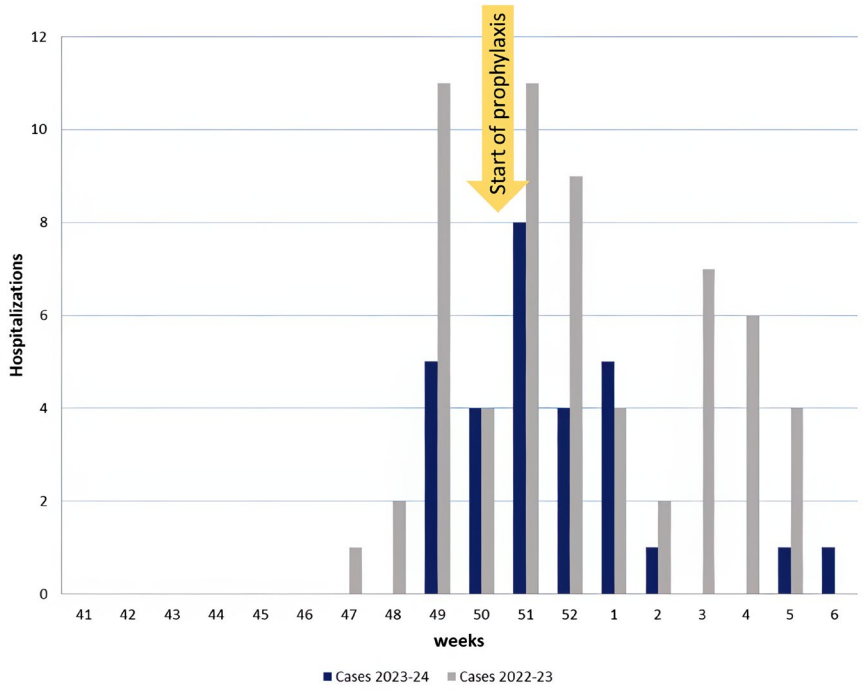

***Figure 2**. Hospitalizations for RSV bronchiolitis in Valle d'Aosta in the last two epidemic seasons.*

The effectiveness of nirsevimab in preventing hospitalizations for confirmed RSV infection and the impact of a birth immunization strategy were also evaluated in other regions of Spain.

In Navarre, of the 1177 infants analyzed in the cohort study, 1083 (92.0%) received nirsevimab, 95.6% of whom were immunized within seven days of birth.

The risk of RSV hospitalization was 8.5% (8/94) among non-immunized infants and 0.7% (8/1083) among immunized infants. The risks of ICU admission were 2.1% (2/94) and 0.3% (3/1083), respectively. The estimated effectiveness of immunoprophylaxis in preventing hospitalization for lower respiratory tract infection due to RSV was 88.7% (95% CI, 69.6-95.8). Efficacy estimates were similarly high in preventing emergency department visits (87.9%; 95% CI, 70.3-95.1) or cases requiring ICU admission (85.9%; 95% CI, 13.2-97.7) (32).

A multicenter active surveillance study was conducted in nine hospitals in three Spain regions: Valencia, Murcia, Valladolid.

A total of 166 infants admitted to one of the enrolled hospitals were included. Of the admitted infants, 95 were RSV positive, 56 of whom (59%) had been immunized.

The study used two methodological approaches: the screening method and the test-negative design. The screening method compared the proportion of infants immunized with nirsevimab among those hospitalized for RSV-positive LRTIs with the proportion immunized in the catchment area. The test-negative design compared the odds of being immunized with nirsevimab among infants hospitalized for RSV-positive versus RSV-negative LRTIs.

Both methods indicated that nirsevimab provided a high level of protection, with a reduction of at least 70%, against hospitalizations for RSV-positive LRTIs in immunized infants (33).

A study was conducted in Catalogna in which 26.525 infants were included. By the end of the study period, 23,127 infants (87.2%) had been immunized against RSV. The control group showed higher incidence rates for all outcomes, particularly for severe cases, including RSV-specific and all-cause outcomes, in both outpatient and hospital settings (34).

In the universal immunization campaign that began in the 2023-2024 season, nirsevimab administration demonstrated a good safety profile in line with that reported in the authorization.

In fact, of the more than 200,000 children who received nirsevimab in Spain, no new risks were identified beyond those listed in the data sheet: rash, pyrexia, and injection site reactions (19).

In the USA, the Centers for Disease Control and Prevention (CDC) estimated that in the US nirsevimab was 90% effective in preventing and reducing RSV-associated hospitalizations in all infants and children in their first season of RSV. In this multicenter analysis in which 699 infants hospitalized with ARI during their first RSV season were included, nirsevimab treatment was shown to be 90% effective against RSV-associated hospitalization. This early efficacy estimate supports existing recommendations for the prevention of severe VRS disease in infants in their first season of RSV (35).

A prospective, multicenter, case-control study was also conducted in France that analyzed the efficacy of nirsevimab against hospitalization for RSV-associated bronchiolitis in infants younger than 12 months of age in a real-world setting (36).

The study included 1035 infants, including 690 cases and 345 controls:

– cases were infants younger than 12 months of age who were hospitalized for RSV-associated bronchiolitis between October 15 and December 10, 2023;
– controls were infants with clinic visits to the same hospitals for conditions unrelated to RSV infection.

Infants at higher risk of severe RSV disease, such as: premature infants <6 months of age, infants with chronic lung disease of the premature, and congenital heart disease, were also included in the study.

A total of 60 case patients (8.7%) and 97 control patients (28.1%) were immunized with nirsevimab. Nirsevimab demonstrated an efficacy against hospitalization for RSV-associated bronchiolitis of 83.0%.

In addition, nirsevimab demonstrated efficacy of:

– 69.6% in the reduction of RSV-associated bronchiolitis that required ICU hospitalization;
– 67.2% in the reduction of RSV-associated bronchiolitis that involved ventilatory support.

Given the excellent results obtained (**Table 1**) and the good safety profile also confirmed in real-world, the International Health Authorities recommended nirsevimab in all infants and children at the first season of RSV.

Spanish Health Minister confirmed the use of nirsevimab for next season as well. In Germany, STIKO recommend the use of nirsevimab in all infants and children during their first RSV season, regardless of the presence of risk factors (24).

GLOBAL RECOMMENDATIONS AND

Table 1. *Reduction of hospitalization and coverage upon nirsevimab implementation during the 2023/204 RSV season in Spain, USA and France.*

Countries	Coverage	Reduction of hospitalization
Galicia	91%	82%
Navarre	92%	85.9%
Valencia, Murcia, Valladolid	59%	70%
Catalogna	87.2%	87.6%
USA	68%	90%
France	16%	83%

FUTURE DIRECTIONS

These studies provide compelling evidence for the universal use of nirsevimab in preventing RSV bronchiolitis in children, demonstrating its effectiveness and safety. Results from regions like Galicia are promising, and achieving similar outcomes will require substantial organizational efforts to ensure high levels of immunization adherence. This is crucial for replicating the efficacy observed in clinical trials and early implementation studies.

Ongoing surveillance will be necessary to comprehensively assess RSV circulation and detect any shifts in RSV epidemiology following widespread nirsevimab use. Additional data, including long-term effects and epidemiological trends, are essential to confirm and complement the already proven effectiveness of the product. To comprehensively evaluate nirsevimab, continuous research and surveillance in diverse settings are imperative.

Further research is needed to explore its long-term impact, cost-effectiveness, and performance in different clinical contexts. By addressing these questions, nirsevimab can play a crucial role in improving infant health outcomes and reducing the global burden of RSV-related illnesses.

COMPLIANCE WITH ETHICAL STANDARDS

Conflicts of interests

The Authors declare no conflicts of interest.

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Ethical approval

Human studies and subjects

N/A.

Data sharing and data accessibility

Data are available upon motivated request to the Corresponding Author.

Publication ethics

Plagiarism

Authors declare no potentially overlapping publications with the content of this manuscript and all original studies are cited as appropriate.

Data falsification and fabrication

All the data correspond to the real.

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