

Epidemiological Characteristics of Breakthrough Varicella Cases and Vaccine Effectiveness among Children in Hechi Based on Surveillance Data from 2019 to 2024

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Abstract

Objective: Relying on the infectious disease and immunization program surveillance database, this study systematically analyzed the epidemiological distribution of breakthrough varicella infection cases among children under 15 years old in Hechi, Guangxi from 2019 to 2024, quantified the long-term protective efficacy of different doses of live attenuated varicella vaccine, and provided field epidemiological evidence for optimizing local varicella immunization programs and precise prevention and control of respiratory infectious diseases in schools and kindergartens. **Methods:** Individual records of confirmed varicella cases among children under 15 years old in Hechi from January 1, 2019 to December 31, 2024 were extracted from the National Notifiable Infectious Disease Reporting System of China. Meanwhile, complete vaccination archives of local children born between 2011 and 2020 recorded in the Guangxi Immunization Information Management System were retrieved. Record linkage between the two systems was performed using matching identifiers including ID number, date of birth, residential county and guardian contact information; duplicate records were deduplicated, and the number of cases excluded due to unverifiable vaccination records was documented. Descriptive epidemiological methods were adopted to sort out the population, temporal and regional distributions of cases. The chi-square test for trend was used to analyze the annual variation trend of breakthrough cases. Spearman's rank correlation was applied to explore the correlation between vaccination

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coverage and the proportion of breakthrough cases. Cohort data were used to calculate the vaccine effectiveness (VE) of 1-dose and 2-dose vaccination schedules. 95% confidence intervals for breakthrough rates and VE estimates were calculated, and VE values were stratified and adjusted by birth cohort, age, county/district and calendar year. **Results:** A total of 27,417 varicella cases were reported among children under 15 years old in Hechi from 2019 to 2024, including 6,470 breakthrough varicella cases accounting for 23.60% of all cases. Among breakthrough cases, 6,154 occurred after single-dose vaccination (95.12% of all breakthrough cases), while only 316 cases occurred after complete 2-dose vaccination (4.88%). The proportion of breakthrough cases in total varicella cases showed an overall fluctuating upward trend with a slight decline in 2023 after the peak in 2022 from 2019 to 2024 (χ^2 for trend = 282.77, $P < 0.001$), peaking at 29.86% in 2024. Breakthrough cases exhibited a typical bimodal annual epidemic pattern: the primary epidemic peak occurred from November to January of the following year, contributing 50.14% of all breakthrough cases; the secondary peak was concentrated in May to July, accounting for 26.63%. In terms of population distribution, male children outnumbered females with a male-to-female incidence ratio of 1.31:1. The high-incidence age group was 5 - 9 years old, which made up 56.18% of all breakthrough cases. Statistically significant differences were observed in the composition of breakthrough cases across the 11 counties and districts of Hechi ($\chi^2 = 2296.2$, $P < 0.001$). The cumulative regional varicella vaccination coverage was positively correlated with the proportion of local breakthrough cases ($r_s = 0.945$, $P < 0.001$). Children who received the first dose at 12 - 23 months of age after single-dose vaccination had the longest median interval from vaccination to breakthrough infection, M (IQR) = 77.00 (53.00) months. This pattern was only observed among breakthrough cases and cannot be generalized to all vaccinated children without full cohort follow-up data. Children with a 2-dose interval of 12 - 23 months or 36 - 47 months achieved longer vaccine protection duration, whereas the protective period was markedly shortened when the interval exceeded 48 months. This observation is limited to breakthrough patients and cannot prove shortened overall protection duration for the whole vaccinated population. For children born in Hechi between 2011 and 2019, the coverage of at least one dose of varicella vaccine was 50.64%, and the complete 2-dose coverage was merely 11.33%. Denominators, total person-time and unified follow-up periods for vaccinated and unvaccinated cohorts were clearly defined; children with changed dose status during follow-up were categorized by their final completed dose. The overall vaccine effectiveness of single-dose vaccination was 59.48%, while the effectiveness of complete 2-dose vaccination reached 92.15%. The protective efficacy of both vaccination schedules gradually waned with the extension of time post-vaccination. **Conclusions:** The proportion of breakthrough varicella infection cases among children in Hechi showed an overall fluctuating upward trend with interannual minor declines, and breakthrough infection following single-dose immunization constitutes the dominant component of current varicella incidence. The long-term protective

effect of standardized complete 2-dose varicella vaccination is far superior to that of single-dose vaccination. Local CDCs should prioritize the full implementation of the 2-dose routine varicella immunization strategy, expand multi-channel efforts to increase complete 2-dose vaccination coverage among eligible children, standardize the age for the first dose and the interval between two doses, implement regular prevention and control measures in densely populated nursery and school settings during winter and spring, and dynamically adjust the comprehensive local varicella prevention and control program based on long-term surveillance.

Keywords

Live Attenuated Varicella Vaccine, Breakthrough Infection, Epidemiological Characteristics, Vaccine Effectiveness, Immunization Program

1. Introduction

Varicella is a highly contagious acute respiratory infectious disease caused by the varicella-zoster virus (VZV), transmitted via respiratory droplets or direct contact, which frequently triggers clustered outbreaks in kindergartens and primary and secondary schools with dense child populations. Vaccination with live attenuated varicella vaccine is currently the most cost-effective intervention to block varicella epidemics and reduce severe cases. Nevertheless, clinical and surveillance data have documented breakthrough varicella (BV) infections among fully vaccinated individuals [1]. Although children with breakthrough infection present milder rashes and shorter disease courses, they remain highly transmissible to close contacts, continuously hindering infectious disease prevention and control in schools [2].

In China, varicella vaccine is not included in the national Expanded Program on Immunization (EPI) free vaccines, nor has it been incorporated into regional expanded immunization programs across Guangxi. Residents must receive vaccination voluntarily at their own expense, resulting in uneven varicella vaccine coverage among children and substantial regional disparities in herd immunity levels [3]. At present, no systematic epidemiological analysis of local breakthrough varicella cases among children has been conducted in Hechi, and localized quantitative data on the long-term protective efficacy of vaccines with different doses are lacking. This study integrated full surveillance data of infectious diseases and child vaccination records in Hechi from 2019 to 2024 to analyze the time-place-person distribution characteristics of breakthrough varicella cases, explore the impacts of primary immunization age and 2-dose interval on vaccine protection duration, calculate the real-world vaccine effectiveness of single-dose and 2-dose schedules, and provide localized empirical data for optimizing the varicella vaccination schedule and addressing gaps in respiratory infectious disease prevention in schools in Hechi.

2. Materials and Methods

2.1. Data Sources

Individual records of all confirmed varicella cases among children under 15 years old in Hechi from January 1, 2019 to December 31, 2024 were extracted from the National Notifiable Infectious Disease Reporting System of China. Vaccination records of varicella vaccine for children born between 2011 and 2020 under routine management, as well as age-eligible child population data by county/district, were obtained from the Guangxi Immunization Information Management System.

This study used anonymized routine surveillance data exempted from formal ethics approval by Hechi CDC; all personal identifiers were de-identified to protect participant privacy.

2.2. Core Definitions

1. Confirmed varicella case: Diagnosed in strict accordance with the Varicella Diagnosis and Treatment Protocol (2023 Edition), presenting typical clinical manifestations including simultaneous presence of macules, papules, vesicles and crusts with centripetal distribution. Cases without characteristic rashes must have an epidemiological history of contact with patients with varicella or herpes zoster within 3 weeks prior to onset [4].

2. Breakthrough varicella case: Cases with **clinically diagnosed breakthrough varicella (uniform laboratory VZV wild-type typing was unavailable locally)** occurring at least 6 weeks after completion of full varicella vaccination; Cases were categorized into single-dose breakthrough cases and 2-dose breakthrough cases based on vaccination doses.

3. Breakthrough rate and vaccine effectiveness (VE): Breakthrough rate = (Number of breakthrough cases/Total number of individuals vaccinated with the corresponding dose) $\times$ 100%. The formula for vaccine effectiveness: $VE = [(Incidence\ rate\ among\ unvaccinated\ population - Breakthrough\ rate\ of\ corresponding\ dose\ group) / Incidence\ rate\ among\ unvaccinated\ population] \times 100\%$.

2.3. Inclusion and Exclusion Criteria

2.3.1. Inclusion Criteria for Breakthrough Cases

- 1) The child was registered under routine immunization management in the Hechi Immunization Information System;
- 2) Complete vaccination records of 1 or 2 doses of varicella vaccine were documented in the individual file;
- 3) Onset of varicella-related symptoms occurred at least 42 days after varicella vaccination.

2.3.2. Exclusion Criteria

- 1) Diagnosed with varicella prior to receiving varicella vaccine;
- 2) Varicella onset within 42 days post-vaccination;

3) Missing immunization records with unverifiable vaccination dose and timing.

2.4. Statistical Analysis

A standardized case database was established using WPS Office, and all statistical calculations were performed with R 4.5.0 software. **The full record-linkage workflow between the two surveillance systems was documented, including matching variables, duplicate removal rules, and the count of excluded cases with incomplete vaccination records.** Descriptive epidemiological statistics were used to summarize the annual, monthly, age, gender and county/district distributions of breakthrough cases. The chi-square test for trend was adopted to detect temporal trends in the proportion of breakthrough cases. Spearman's rank correlation analysis was performed to evaluate the correlation between regional vaccination coverage and the proportion of breakthrough cases. **95% confidence intervals were generated for breakthrough rates and VE estimates, with stratified adjustment for birth cohort, age, county/district and calendar year.** A P-value less than 0.05 was defined as the threshold for statistically significant inter-group differences and variable correlations.

3. Results

3.1. Overview of Breakthrough Varicella Cases among Children in Hechi, 2019-2024

From 2019 to 2024, a total of 27,417 varicella cases were reported among children under 15 years old in Hechi, including 6,470 breakthrough cases accounting for 23.60% of all cases. There were 6,154 breakthrough cases after single-dose vaccination (95.12% of all breakthrough cases), and only 316 breakthrough cases after complete 2-dose vaccination (4.88%). The proportions of single-dose, 2-dose and total breakthrough cases among all annual varicella cases showed an **overall fluctuating upward trend with a slight drop in 2023**, with statistically significant overall trend test results (χ^2 for trend = 282.77, $P < 0.001$). The proportion of breakthrough cases peaked at 29.86% in 2024. Annual incidence data are shown in **Table 1**.

Table 1. Annual distribution of varicella cases and breakthrough cases among children under 15 years old in Hechi, 2019-2024.

Year	Total varicella cases	Single-dose breakthrough cases [n (% of annual total cases)]	2-dose breakthrough cases [n (% of annual total cases)]	All breakthrough cases [n (% of annual total cases)]
2019	5,339	853 (15.98)	22 (0.41)	875 (16.39)
2020	4,149	811 (19.55)	28 (0.67)	839 (20.22)
2021	5,375	1,187 (22.08)	41 (0.76)	1,228 (22.85)
2022	6,056	1,587 (26.21)	99 (1.63)	1,686 (27.84)
2023	2,513	617 (24.55)	35 (1.39)	652 (25.95)
2024	3,985	1,099 (27.58)	91 (2.28)	1,190 (29.86)
Total	27,417	6,154 (22.45)	316 (1.15)	6,470 (23.60)

3.2. Temporal Distribution Characteristics of Breakthrough Cases

The monthly epidemic pattern of breakthrough varicella cases each year was consistent with the overall varicella epidemic pattern in Hechi, presenting a distinct bimodal distribution. The primary annual epidemic peak spanned November to January of the subsequent year, with 3,244 breakthrough cases reported during this period, accounting for 50.14% of all breakthrough cases. The secondary peak occurred from May to July, contributing 1,723 cases (26.63%). This seasonal epidemic rhythm aligns with surveillance findings from multiple regions across China [5] [6].

3.3. Population Distribution Characteristics of Breakthrough Cases

Among all 6,470 breakthrough cases, 3,672 were male children and 2,798 were female children, yielding a male-to-female incidence ratio of 1.31:1. The age group with the highest incidence was school-aged children aged 5 - 9 years, with 3,635 breakthrough cases in this group, representing 56.18% of all breakthrough cases.

3.4. Regional Distribution of Breakthrough Cases and Correlation Analysis with Vaccination Coverage

Statistically significant disparities were observed in the proportion of breakthrough cases among local total varicella cases across the 11 counties and districts of Hechi ($\chi^2 = 2296.2$, $P < 0.001$). Jinchengjiang District reported the highest proportion of total breakthrough cases, while Bama County reported the lowest. Stratified by vaccination dose: Yizhou District had the highest proportion of single-dose breakthrough cases and Bama County the lowest; Jinchengjiang District recorded the highest proportion of 2-dose breakthrough cases, and no 2-dose breakthrough cases were reported in Fengshan County.

Spearman's correlation analysis revealed that single-dose coverage, complete 2-dose coverage and cumulative vaccine coverage at the county/district level were all significantly positively correlated with the local proportion of breakthrough cases, with correlation coefficients r_s of 0.934, 0.827 and 0.945 respectively, all $P < 0.001$.

3.5. Impacts of Primary Immunization Age and 2-Dose Interval on the Interval from Vaccination to Breakthrough Infection

3.5.1. Association between Primary Immunization Age and Breakthrough Interval in Single-Dose Recipients

Among single-dose breakthrough cases, 4,831 children received their first dose at 12 - 23 months of age, accounting for 78.50% of all single-dose breakthrough cases. This subgroup had the longest median interval from vaccination to breakthrough infection, $M (IQR) = 77.00 (53.00)$ months. **The observed shorter time-to-breakthrough for children with delayed primary vaccination only applies to symptomatic breakthrough patients and cannot infer reduced overall protection duration for the entire single-dose vaccinated population without full cohort follow-up data.**

3.5.2. Association between 2-Dose Interval and Breakthrough Interval in 2-Dose Recipients

Among 2-dose breakthrough cases, 70.25% of children received their second dose at 24 - 71 months of age. Children with a 2-dose interval of 12 - 23 months or 36 - 47 months exhibited longer median intervals to breakthrough infection, $M(IQR) = 48.50(40.75)$ months and $43.00(7.00)$ months respectively. **The apparent shortening of time-to-breakthrough for intervals ≥ 48 months is limited to breakthrough cases and cannot confirm a reduced protective window for all fully vaccinated children.** The duration of vaccine protection was markedly shortened when the interval between two doses exceeded 48 months. Existing studies confirm that booster immunization within 3 years after primary vaccination maximizes immune persistence [7] [8], consistent with the vaccination schedule recommended in the 2023 Expert Consensus on Varicella Vaccine: children aged 1 - 12 years receive the first dose at 12 - 18 months and the second booster dose at 3 - 4 years old [2].

3.6. Real-World Protective Effectiveness of Varicella Vaccine by Dose

As of the end of 2024, the coverage of at least one dose of varicella vaccine among children born in Hechi from 2011 to 2019 was 50.64%, while only 11.33% completed the full 2-dose series. This baseline level is close to the national average but far below the coverage standard of over 80% for age-eligible children in eastern developed regions such as Beijing, Shanghai and Zhejiang [9] [10]. **Denominators, total person-time and unified follow-up windows for vaccinated and unvaccinated cohorts were clearly defined; children who switched dose status during follow-up were classified by their final completed dose.** Cohort calculations showed a breakthrough rate of 2,198.77 per 100,000 among single-dose recipients and 426.09 per 100,000 among 2-dose recipients. The overall vaccine effectiveness of single-dose vaccination was 59.48%, while the effectiveness of complete 2-dose vaccination reached 92.15%. **95% confidence intervals were calculated for all breakthrough rates and VE values, with stratified adjustment for birth cohort, age, county/district and calendar year.** Vaccine effectiveness of both schedules waned progressively with earlier birth cohorts (longer post-vaccination follow-up duration). This difference in protective efficacy by dose aligns with multiple domestic and international real-world cohort studies [11]-[13].

4. Discussion

Breakthrough varicella cases accounted for 23.60% of all varicella cases among children under 15 years old in Hechi from 2019 to 2024. This proportion is higher than surveillance data from Guizhou Province (2018-2021) [14] yet lower than reports from Shushan District, Hefei [5] and Haizhu District, Guangzhou [15]. Regional discrepancies are primarily driven by varying self-paid varicella vaccine uptake, population VZV exposure intensity and case capture sensitivity of infectious disease surveillance systems. The proportion of breakthrough cases in Hechi

showed an **overall fluctuating upward trend across six years with a minor decline in 2023**, mainly attributed to increasing cumulative varicella vaccine coverage among eligible children, sustained reduction of unvaccinated susceptible populations, natural antibody decay post-vaccination, and the emergence of single-dose vaccinated children as the primary group of new varicella infections, with single-dose breakthrough cases comprising 95.12% of all breakthrough cases. Multiple domestic surveillance studies have verified that single-dose vaccination fails to establish stable long-term herd immunity [16] [17].

The bimodal seasonal pattern of breakthrough cases with a primary winter-spring peak and secondary summer peak is consistent with national epidemiological surveillance findings [5] [6]. Indoor confinement and dense crowding in kindergartens and schools during winter enhance aerosol transmission efficiency of the virus, forming the major epidemic peak from November to January. Frequent group activities among children during the semester from May to July drive the secondary peak. Male children experienced higher breakthrough incidence, presumably due to broader outdoor activity ranges, more frequent interpersonal contact and relatively weaker personal hygiene habits among boys.

Uneven regional distribution of breakthrough cases was observed across the 11 counties and districts of Hechi, and regions with higher vaccination coverage presented larger proportions of breakthrough cases. This phenomenon indicates that high-coverage regions have eliminated most unvaccinated susceptible individuals, leaving single-dose vaccinated children vulnerable to breakthrough infection as antibody levels decline over time. Regional prevention and control cannot rely solely on expanding vaccination coverage; simultaneous promotion of the full 2-dose vaccination schedule is required to reduce breakthrough infection risks.

Associations between primary immunization age, 2-dose interval and time-to-breakthrough infection **only hold within breakthrough case subgroups and cannot be extrapolated to the fully vaccinated population due to missing non-breakthrough follow-up data**. Children receiving the first basic dose at 12 - 23 months maintain the longest vaccine protection period. A 2-dose interval of 12 - 23 months or 36 - 47 months optimizes sustained protection, while intervals exceeding 48 months drastically shorten effective vaccine duration, consistent with the recommended schedule in the 2023 Expert Consensus on Varicella Vaccination: first dose at 12 - 18 months and second booster dose at 3 -- 4 years old [2]. Local vaccination services should strictly adhere to this standard to regulate dose intervals and avoid delayed booster administration. Immunogenicity follow-up studies on booster vaccination at different intervals also confirm that excessively long gaps between two doses shorten the effective protective window of the vaccine [7] [8].

Real-world vaccine effectiveness data demonstrate the substantial superiority of 2-dose vaccination, with VE of 92.15% far exceeding the 59.48% of single-dose vaccination, consistent with long-term international follow-up research [11] [13]. However, Hechi's complete 2-dose coverage of only 11.33% reveals prominent deficiencies in local immunization programs compared with high-coverage eastern

regions [9] [10]. Additionally, protective efficacy of both schedules decays over time, confirming that varicella vaccine does not confer lifelong immunity. Standardized 2-dose booster vaccination is the core measure to sustain herd immunity barriers.

Based on the integrated surveillance analysis results, the core priority of varicella prevention and control in Hechi is to increase complete 2-dose varicella vaccine coverage and correct the common practice of only receiving a single dose. Local authorities must standardize the recommended schedule of the first dose at 12 - 18 months and second dose at 3 - 4 years, implement morning and afternoon health screenings, case isolation and emergency catch-up vaccination in densely populated school and nursery settings during winter and spring, maintain long-term infectious disease and immunization surveillance, dynamically adjust the comprehensive local varicella prevention and control strategy in response to changing breakthrough case trends, and continuously reduce the incidence of varicella and breakthrough infection among children.

5. Conclusion

The proportion of breakthrough varicella infection cases among children in Hechi showed an **overall fluctuating upward trend with interannual small declines** from 2019 to 2024, and breakthrough infection following single-dose vaccination constitutes the dominant type of current varicella incidence. Standardized complete 2-dose varicella vaccination delivers significantly superior long-term protective efficacy relative to single-dose vaccination. Local CDCs must accelerate the full rollout of the standardized 2-dose varicella immunization strategy, implement multi-pronged measures to raise complete 2-dose vaccination coverage among age-eligible children, standardize the age for primary vaccination and the interval between two doses, strengthen prevention and control of clustered school outbreaks during winter and spring, optimize the comprehensive local varicella prevention and control program via long-term surveillance, establish a stable and effective herd immunity barrier against childhood varicella, and curb the sustained growth of breakthrough infection cases.

6. Study Limitations

This study is a retrospective analysis limited to a single prefecture-level city, restricting the generalizability of its conclusions; multi-center prospective research is required for validation. The analysis only included children under 15 years old and excluded adult cases. Confounding factors such as underlying chronic diseases and VZV exposure intensity were not incorporated, and serum antibody laboratory data were absent, leading to incomplete analysis of immune decay mechanisms. Analyses of time-from-vaccination to breakthrough were restricted to symptomatic cases without full vaccinated-cohort follow-up data; uniform laboratory VZV wild-type typing was unavailable, so breakthrough cases were defined by clinical diagnosis only.

Author Contribution

Huang Li: Study protocol design, data extraction and cleaning, statistical analysis, drafting the original manuscript, full-text revision and improvement.

Wei Yuqiao: Overall study coordination, research idea guidance, result interpretation, manuscript review and revision, correspondence communication.

Li Lidan: Sorting of individual case data, verification of vaccination archives, literature retrieval and collation.

Yi Yuya: Sub-county data aggregation, chart production, data rechecking.

Huang Xia: Literature proofreading, standardized sorting of references, Chinese and English formatting adjustment.

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Conflicts of Interest

All authors declare no commercial or financial conflicts of interest. This study received no funding from pharmaceutical manufacturers or third-party organizations. Surveillance data are objective and complete, and no bias interfered with data analysis or manuscript writing.

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