# Incidence, prevalence, clinical characteristics, and treatment patterns of patients with warm autoimmune hemolytic anemia: a nationwide population-based study in Taiwan, 2017–2022

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## Key Takeaways

- **This is the 1st population-based study investigating the prevalence and incidence of wAIHA patients in the Asia-Pacific region.**
- **Prevalence of wAIHA in Taiwan is increasing. The 5-year (2017-22) prevalence is between 8.61~10.69 per 100,000 population.**
- **The results highlight the significant unmet medical needs in the management of wAIHA.**
  - **52.5% used blood transfusion and 13.4% used >5 times in first year**
  - **Limited treatment options leads to reliance on corticosteroids, blood transfusions**
- **Further research is warranted to better understand clinical & economic burden of wAIHA and new treatment strategies in improving patient outcomes.**

## Background

Warm autoimmune hemolytic anemia (wAIHA) is a rare but serious autoimmune disorder characterized by autoantibody-mediated premature destruction of healthy red blood cells at body temperature.[1,2]

wAIHA is the most common type (70–80%) of AIHA.[3,4]

There is limited evidence on the epidemiology, treatment patterns, and clinical outcomes of wAIHA in the Asia-Pacific region.

## Objectives

This study aims to report the trend of incidence, prevalence, clinical characteristics, and treatment patterns of wAIHA in Taiwan.

## Methods

### Data Sources

- Data were collected from the National Health Insurance Research Database,[5] which covers more than 99% of Taiwan's population, linked with the Taiwan Cancer Registry and National Death Registry.

### Study Population

- Patients aged ≥18 years with ≥1 diagnosis codes of AIHA (ICD-10 codes starting with D59.1), ≥6 months pre-index enrolment, **and** with ≥1 record of wAIHA-related treatments such as corticosteroids or non-steroidal immunosuppressants on or after the index date (the date of the first observed diagnosis code of AIHA) between January 1, 2017, and December 31, 2022.
- Patients were categorized as **primary** or **secondary wAIHA** based on the presence of underlying diseases. Secondary wAIHA cases included patients with hematologic malignancies, solid tumour (ovarian cancer), immunodeficiencies, or autoimmune diseases within (±) 180 days of the index date; in infection, HIV, tuberculosis, brucellosis, or babesiosis ≤180 days before to ≤14 days after the index date; or Hepatitis B or C ≤28 days before to ≤14 days after the index date.

### Study Measures

- **Epidemiology:** Exposure-adjusted incidence rate and annual prevalence.
  - **Main analysis:** Patients with ≥1 record of wAIHA-related treatment and the diagnosis code on the same claim.
  - **Sensitivity analysis:** Patients with ≥1 record of wAIHA-related treatment regardless of diagnosis codes on the same claim
- **Treatment patterns:** A line of therapy started at the first observed treatment and ended at discontinuation, defined as a gap of at least 60 days between refills/re-administration of the index treatment at the class level, or a prescription filled for a therapy in another class.
- **Overall survival:** Defined as the time from the index date to the date of death by any cause. Patients without a death date were censored as of the end of follow-up or loss to follow-up.
- **Statistical analyses:** For continuous and count variables, means and standard deviations (SDs) were reported. For categorical variables, frequency (n) and proportion (%) were reported; Kaplan-Meier curves were used to describe time-to-event processes. Multi-Cox regression was further used to evaluate OS after adjusting for age, sex, and Charlson comorbidity index.

## Results

### Patient characteristics.

- A total of 1,503 patients with wAIHA were identified and patient characteristics were reported in **TABLE 1**. In secondary wAIHA cases, autoimmune disease was the most underlying disease (n=306, 76.88%) followed by infection (n=94, 23.62%), hematologic malignancy (n=3, 0.75%), solid tumor (n=3, 0.75%), and immunodeficiency (n=1, 0.25%).
- The exposure-adjusted incidence rate was 1.27 per 100,000 person-years with annual prevalence increasing from 3.87 in 2017 to 4.58 per 100,000 population in 2022. 5-year prevalence of 8.61 per 100,000 (2018-2022). In the sensitivity analysis, the exposure-adjusted incidence rate was 1.60 per 100,000 person-years. 5-year prevalence was 10.69 per 100,000, and annual prevalence ranged 4.50 in 2017 to 5.06 per 100,000 in 2022.

### Treatment use.

- Corticosteroids were the most frequently used therapy across all treatment lines either as monotherapy or combined with other treatment, including blood transfusions, and immunosuppressants (**TABLE 2 &3**).
- Emergency blood transfusion was used in 52.5% of the wAIHA patients in first year of wAIHA diagnosis, and 13.4% used >5 times a year. Patients using emergent blood transfusion decreased from 2nd year, however, there was still 7.4% of patients requiring emergent blood transfusion in the 3rd year (**FIGURE 1**).

### Overall survival.

- The 1-year, 3-year, and 5-year survival probabilities for patients with wAIHA were 85.0%, 73.3%, and 67.1%, respectively (FIGURE 2).
- There were no statistically significant difference in survival between primary and secondary wAIHA after adjusting for age, gender, and Charlson comorbidity index (adjusted HR: 1.08, p=0.5611; crude HR: 1.54, p=0.0007).

**TABLE 1. Characteristics of patients with wAIHA**

| Parameter | Overall wAIHA | Primary wAIHA | Secondary wAIHA | p-value |
|---|---|---|---|---|
| N, % | 1,503 | 1,105 (73.52%) | 398 (26.48%) | |
| Sex, female, n (%) | 953 (63.41%) | 641 (58.01%) | 312 (78.39%) | <0.0001 |
| Age, mean (SD), years | 57.41 (17.95) | 59.73 (17.57) | 50.99 (17.44) | 0.0006 |
| Charlson Comorbidity Index, mean (SD) | 0.92 (1.36) | 0.87 (1.41) | 1.08 (1.20) | <0.0001 |
| Comorbidities, n (%) – during 12 month pre-index period | | | | |
| Anaemia | 856 (56.95%) | 668 (60.45%) | 188 (47.24%) | 0.0001 |
| Anxiety | 154 (10.25%) | 115 (10.41%) | 39 (9.80%) | 0.7315 |
| Diabetes | 291 (19.36%) | 240 (21.72%) | 51 (12.81%) | 0.0001 |
| Gastroesophageal reflux disease | 268 (17.83%) | 203 (18.37%) | 65 (16.33%) | 0.3621 |
| Hyperlipidaemia | 307 (20.43%) | 241 (21.81%) | 66 (16.58%) | 0.0266 |
| Hypertension | 441 (29.34%) | 345 (31.22%) | 96 (24.12%) | 0.0076 |
| Heart failure | 161 (10.71%) | 127 (11.49%) | 34 (8.54%) | 0.1027 |
| Rheumatoid arthritis | 67 (4.46%) | 28 (2.53%) | 39 (9.80%) | 0.0001 |
| Sjogren's syndrome | 173 (11.51%) | 80 (7.24%) | 93 (23.37%) | 0.0001 |
| Systemic lupus erythematosus | 281 (18.70%) | 60 (5.43%) | 221 (55.53%) | 0.0001 |

**TABLE 2. Treatment use in patients with wAIHA**

| | 1st line | 2nd line | 3rd line | ≥4th line |
|---|---|---|---|---|
| N | 1,503 | 505 | 232 | 126 |
| Corticosteroids | 1,440 (95.81%) | 413 (81.78%) | 198 (85.34%) | 97 (76.98%) |
| Immunosuppressants | 590 (39.25%) | 217 (42.97%) | 97 (41.81%) | 55 (43.65%) |
| Blood transfusion | 761 (50.63%) | 192 (38.02%) | 74 (31.90%) | 35 (27.78%) |
| Rituximab | 42 (2.79%) | 14 (2.77%) | 5 (2.16%) | 3 (2.38%) |
| Splenectomy | 13 (0.86%) | 4 (0.79%) | 1 (0.43%) | 0 (0%) |

**TABLE 3. Treatment regimens used in patients with wAIHA**

| | 1st line | 2nd line | 3rd line | ≥4th line |
|---|---|---|---|---|
| N | 1,503 | 505 | 232 | 126 |
| Corticosteroids only | 456 (30.34%) | 156 (30.89%) | 87 (37.50%) | 46 (36.51%) |
| Corticosteroids + immunosuppressant | 231 (15.37%) | 103 (20.40%) | 48 (20.69%) | 29 (23.02%) |
| Corticosteroids + blood transfusion | 412 (27.41%) | 81 (16.04%) | 32 (13.79%) | 11 (8.73%) |
| Corticosteroids + immunosuppressant + blood transfusion | 256 (17.03%) | 54 (10.69%) | 22 (9.48%) | 8 (6.35%) |
| Immunosuppressant only | 44 (2.93%) | 48 (9.5%) | 20 (8.62%) | 15 (11.90%) |
| Blood transfusion only | 15 (1%) | 43 (8.51%) | 12 (5.17%) | 13 (10.32%) |

**FIGURE 1. Emergency blood transfusions for patients with wAIHA**

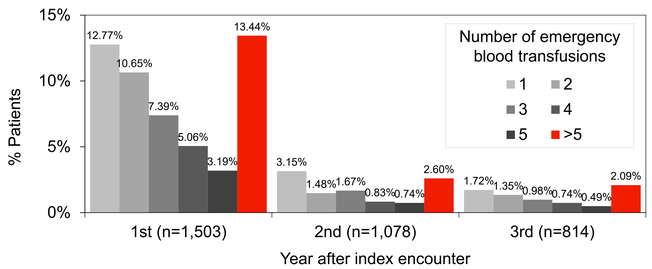
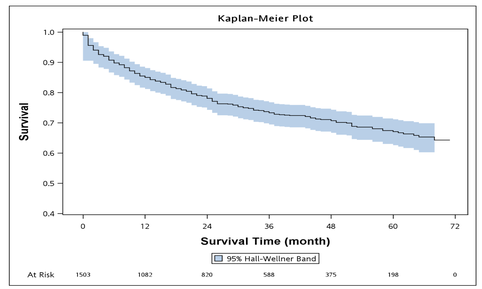



**FIGURE 2. Overall survival from diagnosis date in patients with wAIHA**




| | Total wAIHA | Primary wAIHA | Secondary wAIHA |
|---|---|---|---|
| 1-year(12-month) survival probabilities | 85.0% | 83.3% | 89.7% |
| 3-year(36-month) survival probabilities | 73.3% | 70.8% | 80.0% |
| 5-year(60-month) survival probabilities | 67.1% | 63.9% | 74.3% |

## Strengths & Limitations

- The national population-based claims database enables robust estimation of the prevalence, incidence, treatment patterns, and overall survival of wAIHA patients with minimal selection bias.
- The present study utilized reimbursement claims data, which did not include laboratory results (for wAIHA diagnosis confirmation), physical examination findings, nor captured off-label medication usage. In addition, the dedicated diagnostic code for warm autoimmune hemolytic anemia (wAIHA) was not used in clinical practice. The algorithm were developed and clinically validated to identify wAIHA patients and different algorithm was applied in sensitivity analysis.

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