



## Clinical safety analysis of aminophylline injection: a retrospective cohort study based on electronic health records in China

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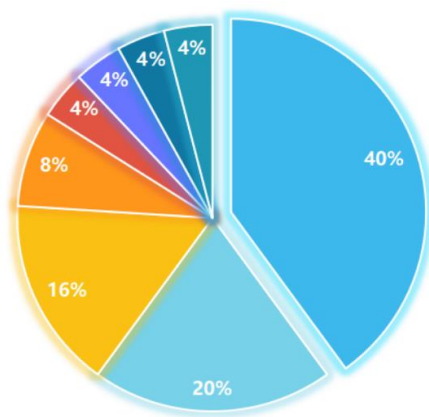


**OBJECTIVES:** Aminophylline is a widely used bronchodilator for acute bronchial asthma exacerbations, chronic obstructive pulmonary disease and cardiac asthma. However, its administration and dosage require strict control to minimize adverse reactions. This study aimed to evaluate the clinical safety of aminophylline injection in real-world practice and provide empirical support for promoting rational medication use.

**METHODS:** Data were collected from the China Hospital pharmacovigilance System (CHPs) across three national sentinel hospitals between January 2020 and December 2022. All patients who received aminophylline injections during the study period were included. Analysis focused on the incidence of adverse drug reactions (ADRs) and unexpected ADRs. Statistical analysis was performed using Microsoft Excel 2023 and SPSS 27.0.

**RESULTS:** A total of 13,442 patients were included. Nineteen valid adverse drug events (ADEs) were recorded, with an overall ADR incidence rate of 1.41%.

Based on drug labels, clinical guidelines, expert consensus, and hospital-approved off-label uses, five cases of unexpected ADRs were identified, including palpitations (n=4) and chest tightness (n=1), corresponding to an unexpected ADR incidence rate of 0.372%. According to ADR incidence classification standards, the overall incidence was categorized as "occasional".



### ACCUMULATED SYSTEM (A TOTAL OF 25 CASES)

- Neurological disorders
- Cardiovascular diseases
- Gastrointestinal diseases
- Respiratory diseases
- Diseases of the skin and skin appendages
- Mental illness
- Musculoskeletal disorders
- Systemic diseases of the whole body

**CONCLUSIONS:** Aminophylline injection demonstrated a generally acceptable safety profile for clinical use, though vigilance regarding unexpected adverse reactions remains necessary. Further prospective pragmatic controlled trials are warranted to better characterize and enhance the safety profile of aminophylline injection.

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