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Levofloxacin-Induced Cutaneous Adverse Reactions: Characteristics and Rational Use Strategies

Authors' Contribution:
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Background: Levofloxacin is a fluoroquinolone antibiotic that can cause a range of dermatological adverse drug reactions (ADRs), including rashes, phototoxicity, and hyperpigmentation, as well as severe conditions such as Stevens-Johnson syndrome, toxic epidermal necrolysis, and drug reaction with eosinophilia and systemic symptoms. The China National Adverse Drug Reaction Monitoring System (CADRMS) is an online pharmacovigilance network that includes data from patient medical records. This study evaluated 35 patients with levofloxacin-induced cutaneous ADRs reported to CADRMS in 2021.

Material/Methods: Individual case safety reports involving levofloxacin-associated cutaneous ADRs in 2021 were retrieved from CADRMS. After excluding duplicates and cases with insufficient details or alternative causative drugs, 35 cases with probable/possible causality were included. Key variables (demographics, administration route/dose, comorbidities, polypharmacy, ADR manifestations, onset, severity, and outcomes) were descriptively analyzed.

Results: Among 35 patients (mean age 43.7±17.6 years; 60% male), 80% received intravenous levofloxacin (71% at 500 mg/day), primarily as inpatients (77%) for respiratory (43%) or urinary (37%) infections. Polypharmacy was common (89%), and all had comorbidities. Cutaneous manifestations were predominantly mild (89%), including maculopapular rash (37%), pruritus (20%), urticaria (14%), erythema (11%), and photosensitive dermatitis (9%). Onset was rapid (89% within 24 hours). One severe case (3%; exfoliative dermatitis) occurred. All reactions resolved fully after drug discontinuation and supportive therapy (antihistamines in 37%; corticosteroids in a few cases).

Conclusions: Levofloxacin-induced cutaneous ADRs are typically mild, immediate-onset, and reversible with prompt discontinuation and anti-allergic treatment. Rational prescribing should emphasize allergy history screening, close monitoring during initial intravenous administration, and cautious use in comorbid or polypharmacy settings to minimize risks while preserving clinical utility.

Keywords: Levofloxacin • Urticaria • Cutaneous Elimination • Dermatologic Agents • Estrogen Receptor Modulators • Drug-Related Side Effects and Adverse Reactions • Skin • |Clinical Nursing Research • Retrospective Studies

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Introduction

Levofloxacin, a third-generation fluoroquinolone antibiotic, is widely prescribed for urinary tract infections, community-acquired pneumonia, and other bacterial infections due to its broad-spectrum activity, tissue penetration, and near-complete oral bioavailability [1]. However, it is linked to cutaneous adverse drug reactions (ADRs), including common presentations such as erythema, pruritus, and urticaria, as well as less frequent ones like fixed drug eruptions and photosensitive dermatitis, and rare severe forms such as Stevens-Johnson syndrome or exfoliative dermatitis [2]. These reactions arise primarily from hypersensitivity mechanisms [3].

Fluoroquinolone-associated cutaneous hypersensitivity is uncommon but clinically significant globally, contributing to 1.8-2.3 events per million patient-days and accounting for about 4.5% of all drug-induced skin reactions [4]. In China, levofloxacin ranks among the top-prescribed antibiotics, with annual sales surpassing CNY 1 billion in 2020 despite a recent compound annual growth rate decline of -4.75% from 2016-2020 [5]. These global trends are particularly relevant in China, where levofloxacin remains widely used, increasing the likelihood of encountering ADRs. This high consumption amplifies risks, yet pharmacovigilance reporting in China remains limited due to underreporting of challenges [6]. Key risk factors include genetic predispositions like human leukocyte antigen (HLA) alleles for severe cutaneous ADRs, high doses, intravenous administration, and polypharmacy [3], with vulnerable groups encompassing the elderly, atopic patients, and those with comorbidities such as HIV or thyroid disorders [7,8]. Amid rising immune-mediated ADRs from quinolone use, local data gaps hinder tailored safety measures.

This study aims to address the local data gap and enhance understanding of ADRs related to levofloxacin. It analyzes 35 probable/confirmed levofloxacin-induced cutaneous ADR cases from China's National Adverse Drug Reaction Monitoring System (CNADRMS) in 2021 – the first such descriptive examination of national patterns. By delineating demographic, clinical, and management features, it guides rational prescribing and enhances pharmacovigilance in high-use settings.

Material and Methods

Data Source

Cases were retrieved from CNADRMS, the official national pharmacovigilance database administered by the National Center for Adverse Drug Reaction Monitoring under the National Medical Products Administration (NMPA; https://english.nmpa.gov.cn). CNADRMS collects spontaneous (voluntary) reports submitted by healthcare professionals, marketing authorization holders, and patients across mainland China. Although spontaneous reporting systems are subject to well-known limitations, including underreporting, reporting bias, and variable report quality [9,10], CNADRMS remains the most comprehensive source of real-world post-marketing safety data for China. The present analysis was restricted to reports received between January 1 and December 31, 2021, to provide a contemporary snapshot of levofloxacin-associated cutaneous ADRs during a single complete calendar year, capture recent reporting trends, and keep the dataset manageable for detailed manual review. This 1-year timeframe inevitably limits temporal trend analysis and generalizability to other periods, but it minimizes confounding from changes in prescribing patterns, formulation availability, or reporting practices over longer intervals.

As this study involved secondary analysis of fully anonymized individual case safety reports from a national pharmacovigilance database, with no identifiable patient information or direct patient involvement, ethical approval was not required per NMPA regulations and institutional guidelines. All data handling complied with national data protection and pharmacovigilance standards.

Search Strategy

A systematic search was conducted within the CNADRMS database in March 2022 by authorized personnel of the provincial ADR monitoring center. The search was performed manually (no automated batch export) using both Chinese and English terms to maximize retrieval. The primary Boolean query was: ("左氧氟沙星" OR "levofloxacin" OR "盐酸左氧氟沙星" OR "levofloxacin hydrochloride" OR related trade names) AND ("皮肤" OR "皮疹" OR "药疹" OR "荨麻疹" OR "红斑" OR "瘙痒" OR "光敏" OR "剥脱性皮炎" OR "cutaneous" OR "rash" OR "urticaria" OR "erythema" OR "pruritus" OR "photosensitive" OR "exfoliative dermatitis" OR "drug eruption") AND report year=2021. Filters applied: suspected drug=levofloxacin (or its salts); system organ class (MedDRA)="Skin and subcutaneous tissue disorders". Duplicate reports (identified by identical patient initials, age, sex, hospital, and event date) were removed. This process yielded 42 individual case safety reports.

Case identification, screening, and exclusion were performed independently by 2 pharmacovigilance specialists to ensure consistency. After exclusion of 7 cases – 4 with insufficient clinical details (lacking essential information on timing, manifestation description, or dechallenge outcome) and 3 in which an alternative concomitant drug was considered more likely to be the causative agent based on a stronger temporal association, known safety profile of the alternative drug, or positive dechallenge with the alternative drug alone – 35 cases with primary cutaneous adverse reactions (no significant mucosal involvement) were retained for analysis.

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Evaluation Criteria

Causality was assessed using the "Evaluation Criteria for ADRs of Skin and Mucous Membrane Injuries" outlined in the "Measures for the Reporting and Monitoring of ADRs" (NMPA, 2011) [11]and the "Technical Guidelines and Evaluation Criteria for Common Serious ADRs" (NMPA, 2017) [12]. These criteria classify causality as certain, probable, possible, unlikely, unassessable, or unrelated. All 35 cases were judged at least "possible"; of these, 29 (82.9%) were classified as "probable" and 6 (17.1%) as "possible". For transparency and international comparability, the World Health Organization-Uppsala Monitoring Centre (WHO-UMC) causality assessment system and the Naranjo algorithm were also applied retrospectively by 2 independent pharmacovigilance specialists [13,14]. Concordance was high: 100% of cases remained at least "possible" by WHO-UMC criteria, and Naranjo scores ranged from 3 to 8 (median 5, corresponding to "possible" or "probable").

Severity was graded according to WHO recommendations [15]:

- Mild: symptoms self-limiting, no specific treatment required beyond drug discontinuation;
- Moderate: marked symptoms requiring specific pharmacological treatment and/or prolongation of hospitalization but not life-threatening;
- Severe: life-threatening or resulting in death, persistent disability, or requiring intensive care.

In the final dataset, 31 cases (88.6%; 95% CI 73.3-96.8%) were classified as mild, 3 cases (8.6%; 95% CI 1.8-23.3%) as moderate (significant pruritus or extensive rash requiring systemic corticosteroids and prolonged observation), and 1 case (2.9%; 95% CI 0.1-14.9%) as severe (exfoliative dermatitis with systemic involvement). The 3 moderate cases had initially been grouped under "mild" in the preliminary analysis; they were reclassified during peer review to better reflect treatment intensity and clinical impact.

Methods and Observed Indices

The following variables were extracted from each report when available:

1. Patient demographics (age, sex);
2. Clinical context:
   - Reporting department (the clinical specialty that submitted the ADR report, reflecting the primary indication for levofloxacin);
   - Inpatient or outpatient status;
   - History of drug allergy (explicitly documented as "yes," "no," or "unknown/not stated" in the original report);
   - Underlying diseases/comorbidities (primary diagnosis or reason for levofloxacin prescription, coded narratively and later grouped);
3. Drug administration details (route, daily dose, duration of therapy until reaction onset, concomitant medications);
4. ADR characteristics (clinical manifestations – limited to skin disorders; mucosal lesions were not considered primary in any included case – time to onset, severity, seriousness);
5. Management and outcome (dechallenge, rechallenge if performed, symptomatic treatments, resolution status, sequelae).

Allergy history and underlying diseases were not systematically solicited fields in 2021 CNADRMS reports; data reflect only what was voluntarily provided by the reporter. Missing data for key variables (eg, allergy history in 22.9% of cases) were reported as "unknown" and retained in descriptive analyses without imputation.

Statistical Analysis

Data were analyzed descriptively using IBM SPSS Statistics version 20.0. The distribution of continuous variables (primarily age in this dataset) was evaluated for normality using the Shapiro-Wilk test, supplemented by visual inspection of histograms and Q-Q plots. Continuous variables were presented as mean±standard deviation (SD) when approximately normally distributed or as median (range) otherwise; categorical variables were presented as frequencies (n) and percentages (%) with 95% confidence intervals (Wilson score interval with continuity correction) for key proportions to indicate precision of estimates. No inferential statistical tests were performed because of the small sample size (n=35), the exploratory and hypothesis-generating purpose of the study, the absence of a comparison group, and the known biases inherent in spontaneous reporting data, all of which render hypothesis testing inappropriate and potentially misleading. The dataset is intended for characterization of reported signals rather than estimation of incidence or broad generalization to all levofloxacin-associated cutaneous ADRs in China.

Results

Patient Demographics

As shown in **Table 1**, patients ranged from 23 to 89 years old (mean±SD: 43.66±17.61 years). Male patients predominated (21 cases, 60.0%). The majority were aged 20-40 years (20 cases, 57.1%) (**Table 1**).

Clinical Context and Administration

Reports originated predominantly from respiratory medicine (15 cases, 42.9%), urinary surgery (13 cases, 37.1%), orthopedics (3 cases, 8.6%), and other departments (4 cases, 11.4%).

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Table 1. Age and sex distribution of 35 cases of levofloxacin-induced cutaneous adverse drug reactions (ADRs).

Characteristic	Category	No. of cases	Proportion (%)
Sex	Male	21	60.0
	Female	14	40.0
Age (years)	20-40	20	57.1
	>40-60	10	28.6
	>60	5	14.3

Most patients were inpatients (27 cases, 77.1%). A documented history of drug allergy was present in 5 cases (14.3%), absent in 22 (62.9%), and unknown in 8 (22.9%). Underlying conditions were primarily urinary/reproductive tract disorders (22 cases, 62.9%), followed by respiratory diseases (8 cases, 22.9%).

Levofloxacin was administered intravenously in 28 cases (80.0%) and orally in 7 (20.0%). Daily doses were 500 mg in 25 cases (71.4%), 750 mg in 6 (17.1%), and 200 mg in 4 (11.4%). Concomitant medications were recorded in 31 patients (88.6%).

ADR Characteristics

All 35 cases presented primary cutaneous manifestations without significant mucosal involvement. The most common were maculopapular rash (13 cases, 37.1%), pruritus alone or with rash (7 cases, 20.0%), urticaria (5 cases, 14.3%), erythema (4 cases, 11.4%), photosensitive dermatitis (3 cases, 8.6%), skin flushing (2 cases, 5.7%), and exfoliative dermatitis (1 case, 2.9%).

Time to onset was <2 hours in 3 cases (8.6%), 2-24 hours in 28 cases (80.0%), and >24 hours in 4 cases (11.4%). Using WHO severity criteria, 31 cases (88.6%; 95% CI 73.3-96.8%) were mild, 3 cases (8.6%; 95% CI 1.8-23.3%) were moderate, and 1 case (2.9%; 95% CI 0.1-14.9%) was severe.

Management and Outcomes

Levofloxacin was discontinued immediately in all 35 cases. Anti-allergic treatment was provided in most cases, including antihistamines in 32 cases and systemic glucocorticoids in 4 cases. Median time to symptom improvement was 2 days (range 1-5 days), and median time to complete resolution was 7 days (range 3-14 days). All 35 patients recovered fully with no sequelae (**Table 2**).

Discussion

The majority of levofloxacin-induced cutaneous ADRs in this cohort were mild (88.6%), immediate-onset (88.6% within 24 hours), and resolved rapidly after drug withdrawal. This profile is consistent with reported immune-mediated mechanisms, including mast cell degranulation that drives histamine release and manifests as urticaria, flushing, and pruritus [16,17]. Intravenous administration led to rapid onset signs and symptoms due to high peak plasma concentrations which promote direct mast cell activation or type I hypersensitivity in sensitized individuals. Photosensitive dermatitis (8.6%) matched established fluoroquinolone phototoxicity via UV-induced reactive oxygen species [18]. The single exfoliative dermatitis case (2.9%) underscored the possibility of rare progression to severe T-cell-mediated reactions in vulnerable patients [1].

Male patients predominated (60.0%), with a mean age of 43.7 years and only 14.3% aged >60 years. This differed from global pharmacovigilance data showing higher fluoroquinolone risk in female patients and the elderly [19]. The pattern likely stemmed from Chinese prescribing habits, rather than inherent sex- or age-based susceptibility; in China, levofloxacin is used to treat community-acquired respiratory and urinary infections mainly in working-age males. Reporting bias remains possible, as severe cases in elderly inpatients might be attributed to comorbidities instead of the antibiotic [9].

Immediate-onset reactions reached 88.6% in our cohort, surpassing most cohorts dominated by delayed T-cell-mediated reactions. The greater number of reactions seen with intravenous routes (80.0%) and 500-750 mg doses could be explained by the hastening of hypersensitivity in these conditions [17]. Chinese hospital polypharmacy with antimicrobials (51.4%) was common, but levofloxacin attribution was possible after confounder exclusion [9]. Recent HLA studies on severe cutaneous adverse reactions (SCARs) aligned with our low SCAR prevalence; routine screening lacks justification broadly but suits high-risk profiles (eg, prior reactions or ethnic factors) [19].

Strengths of this study included the featuring of national pharmacovigilance data with standardized causality assessment and multi-tool validation (WHO-UMC, Naranjo). Spontaneous reporting limitations included substantial underreporting (especially mild events) while over-representing serious cases in the literature [20]. Our mild-reaction dominance likely arose

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Table 2. Clinical characteristics, administration details, and features of levofloxacin-induced cutaneous adverse drug reactions (ADRs) in 35 patients.

Item	Category	No. of cases	Proportion (%)
Reporting department	Respiratory Medicine	15	42.9
	Urology Surgery	13	37.1
	Orthopedics	3	8.6
	Others	4	11.4
Patient type	Inpatient	27	77.1
	Outpatient	8	22.9
History of drug allergy	Yes	5	14.3
	No	22	62.9
	Unknown	8	22.9
Route of administration	Oral	7	20.0
	Intravenous	28	80.0
Daily dosage	200 mg	4	11.4
	500 mg	25	71.4
	750 mg	6	17.1
ADR characteristics			
Time to onset after administration	<2 h	3	8.6
	2-24 h	28	80.0
	>24 h	4	11.4
Severity	Mild	34	97.1
	Severe	1	2.9
Pre-existing conditions	Respiratory system disorders	8	22.9
	Gastrointestinal disorders	3	8.6
	Urinary/reproductive system disorders	22	62.9
	Others (Ear-Nose-Throat, soft tissue, etc.)	2	5.7
Concomitant drugs (main categories)	Antimicrobial agents	18	51.4
	Aminophylline	4	11.4
	Antitussive/expectorant agents	7	20.0
	Electrolyte solutions	4	11.4
	Compound vitamins	6	17.1
Clinical manifestations	Papules/maculopapules	13	37.1
	Pruritus	7	20.0
	Urticaria	5	14.3
	Erythema	4	11.4
	Skin flushing	2	5.7
	Photosensitive dermatitis	3	8.6
	Exfoliative dermatitis (severe case)*	1	2.9

* The single case of exfoliative dermatitis was the only severe ADR reported in this series, highlighting the rare potential for serious cutaneous reactions with levofloxacin.

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from inpatient intravenous settings enabling early rash detection. Small sample (n=35), single-year data, no controls, and absent genetic/immunological tests hindered risk factor analysis and generalizability. Voluntary reporting introduced indication and channeling biases.

Recommendations supported by evidence-based measures:

- Screen for prior drug allergy (documented in 14.3%) before levofloxacin prescription.
- Monitor intravenously infused patients ≥2 hours, given 88.6% reactions within 24 hours (often minutes) [17].
- Use lower doses (≤500 mg/day) and slower infusions in elderly or renally impaired patients, although this measure is unconfirmed statistically [20].
- Limit non-essential antimicrobial polypharmacy.
- Discontinue levofloxacin promptly and give antihistamines (plus short-course glucocorticoids for moderate/severe cases); in our cohort, full recovery occurred within 7-14 days.
- Limit HLA screening to high-risk groups (eg, Han Chinese with prior SCARs) pending larger studies [1].

In conclusion, levofloxacin-induced cutaneous ADRs in China during 2021 were predominantly mild, rapid in onset, and highly responsive to early discontinuation and supportive therapy. Targeted monitoring, particularly during intravenous administration, and individualized prescribing can further minimize risk while preserving the drug's clinical utility.

Conclusions

This study provides the first systematic characterization of levofloxacin-induced cutaneous ADRs based on 35 individual case safety reports from CNADRMS in 2021. Within this limited cohort, these reactions were predominantly mild (88.6%), rapid in onset (88.6% within 24 hours), and fully reversible upon prompt discontinuation of the drug and initiation of supportive therapy, with no sequelae observed.

The high proportion of immediate-type reactions, predominance of intravenous administration, and relatively young, male patient profile likely reflect local prescribing patterns for respiratory and urinary tract infections in China. Serious reactions were rare, with only 1 severe case identified.

These findings, derived from a small, single-year spontaneous reporting dataset, suggest that levofloxacin has a generally favorable cutaneous safety profile when used judiciously in similar clinical contexts. Clinicians should routinely inquire about allergy history, monitor patients closely (at least 2 hours) during the first intravenous infusion, use cautious dosing and infusion rates in elderly or renally impaired patients, avoid unnecessary antimicrobial polypharmacy, and withdraw the drug immediately with anti-allergic treatment if cutaneous signs appear. Genetic (HLA) screening should be reserved for high-risk subgroups until larger prospective studies support broader application.

In summary, targeted monitoring and individualized prescribing can help minimize cutaneous ADR risks while maintaining levofloxacin's utility for common bacterial infections in China. Larger, multi-year pharmacovigilance analyses are warranted to confirm these patterns and enhance generalizability.

Institution Where Work Was Done

Shanghai Neuromedical Centre, Shanghai, PR China.

Patient Permission/Consent Declarations

None declared.

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