

Pharmacoepidemiological analysis of drug therapy for chronic spontaneous urticaria in the Smolensk region

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Abstract

Introduction: Pharmacotherapy for patients with chronic spontaneous urticaria should follow the algorithm presented in the Federal Clinical Guidelines of Russia. Adherence to recommended therapy significantly improves treatment effectiveness and safety. However, routine clinical practice often shows deviations from the therapeutic algorithm, which requires prompt identification and correction. **Aim of the study:** To conduct a pharmacoepidemiological analysis of chronic spontaneous urticaria treatment in the Smolensk region to improve pharmacotherapy effectiveness and safety.

Materials and Methods: Retrospective analysis of 284 medical records of adult patients with chronic spontaneous urticaria hospitalized at the Smolensk Regional Center of Allergology and Immunology (2014–2024).

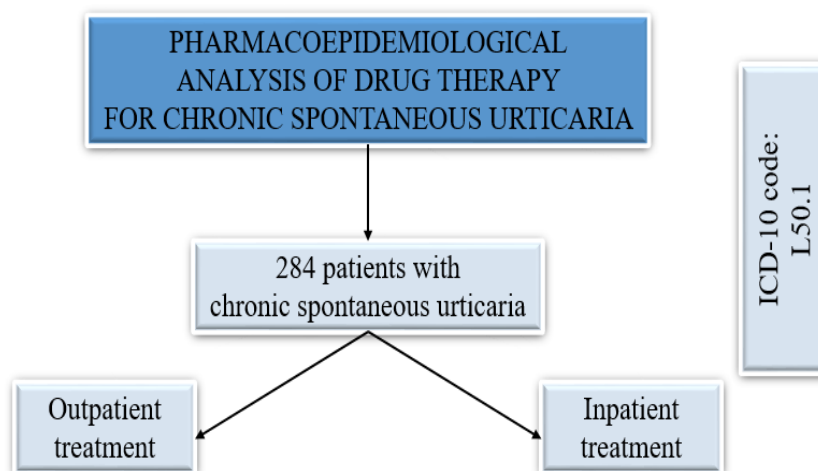
Results: At the outpatient stage, 247 patients (87.0%; 95% CI: 83.1–90.9%) used second-generation antihistamines at clinical guideline-permitted dosage, 63 patients (22.2%; 95% CI: 17.4–27.0%) – first-generation antihistamines, and 111 patients (39.1%; 95% CI: 33.4–44.8%) – systemic glucocorticoids. At the inpatient stage, all 284 patients received second-generation antihistamines, 12 (4.2%; 95% CI: 1.9–6.6%) first-generation antihistamines, and 35 patients (12.3%; 95% CI: 8.5–16.1%) systemic glucocorticoids. During the first hospitalization, 18 patients with chronic spontaneous urticaria received an initiating dose of omalizumab. Off-guideline drugs (sodium thiosulfate, ketotifen, calcium gluconate, histaglobulin) were used in isolated cases.

Conclusion: The analysis revealed good adherence to the therapeutic algorithm for chronic spontaneous urticaria treatment in the Smolensk region. Deviations from the recommended treatment algorithm (first-generation antihistamines and prolonged systemic glucocorticoids) identified during the study require individual analysis and further correction to optimize patient care.



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Graphical Abstract



Keywords

antihistamines; chronic spontaneous urticaria; **omalizumab**; pharmacotherapy; systemic glucocorticoids

Introduction

Chronic spontaneous urticaria (CSU) is an autoimmune/autoallergic disease characterized by recurrent itchy wheals and/or angioedema lasting more than 6 weeks (Warp et al. 2026). The unpredictable, often long-term course of the disease and symptoms appearance despite treatment significantly impair patients' quality of life, their mental and emotional well-being, and ability to work (Kolkhir et al. 2025). High expectations of patients from treatment, coupled with the unmanageable nature of CSU, leads to patient disappointment, further increasing disease burden (Sanchez-Borges et al. 2021). To optimize patient engagement and improve pharmacotherapy outcomes, clear understanding and adherence to the treatment algorithm, combined with an individualized pharmacotherapy for each patient, is essential.

The CSU treatment algorithm in the Russian Federation follows the Federal Clinical Guidelines (Clinical Guidelines – Urticaria, 2023). Federal clinical guidelines generally align with the international urticaria consensus (Zuberbier et al. 2021). Recommended treatments include: 1) second-generation antihistamines (AHs) at standard to 4-fold doses; 2) biological therapy (anti-IgE monoclonal antibodies – **omalizumab**); 3) **cyclosporine A**; 4) short course systemic glucocorticoids (sGCS) for severe exacerbations of CSU (Zuberbier et al. 2021). However, despite the recommended treatment options, achieving complete or partial CSU symptom control remains challenging in real-world clinical practice (Kocaturk et al. 2025). A significant number of patients (50–80%) report poorly controlled disease and suffer from recurrent symptoms of CSU (Bernstein et al. 2025). Only half (51%) of the surveyed physicians worldwide report complete control success (Weller et al. 2025). At the same time, up to 30% of dermatologists and allergists do not adhere to international recommendations and therapeutic protocols in their clinical practice (Weller et al. 2025).

Pharmacoepidemiological analysis of CSU treatment can enhance guideline adherence and continuity of pharmacotherapy across outpatient and inpatient stages. Identifying and correcting deviations from recommended disease treatment algorithms will ensure more effective and safer drug therapy results. These are essential conditions for the successful integration of clinical guidelines into routine medical practice.

Aim of the study: To conduct a pharmacoepidemiological analysis of chronic spontaneous urticaria treatment in the Smolensk region to improve pharmacotherapy effectiveness and safety.

Materials and Methods

Study design

A retrospective case series study analyzed 284 case histories of adult patients with CSU, selected using a continuous sampling method. All records were sourced from the archive of the Smolensk Regional Center of Allergology and Immunology, located at the Regional State Budgetary Healthcare Institution “Clinical Hospital No. 1”, Smolensk (retrospective period: 2014–2024).

Ethical review

The study design was unanimously approved by the Ethics Committee of Smolensk State Medical University of the Ministry of Health of the Russian Federation (extract from Minutes No. 2 of the Ethics Committee meeting dated September 19, 2025).

Statistical analysis

The case histories were selected using continuous sampling. The sample size was not pre-calculated.

Inclusion criteria:

- Patient has chronic spontaneous urticaria diagnosed by a physician.
- Patient is older than 18 years.

Exclusion criteria: not available.

Descriptive statistics were obtained based on the calculation of the mathematical expectation and its error. In the calculation, the confidence interval (CI) value was set to 0.95. The CI for proportions was calculated using the Wald test. Data were analyzed using StatTech v. 4.10.3 (developer – StatTech LLC, Russia).

Study limitations

The data analysis did not include results from validated disease tools instruments: Urticaria activity score (UAS-7), Urticaria Control Test (UCT), and Dermatology Life Quality Index (DLQI). This is due to the lack of results from these tools in the medical records of a large number of patients.

Results and Discussion

Brief description of the studied cohort of patients with CSU

Among 284 patients with CSU, 65 were men (22.9%; 95% CI: 18.0–27.8%) and 219 –women (77.1%; 95% CI: 72.2–82.0%). Mean age at CSU onset was 42.1 ± 1.0 years. At first hospitalization in the Smolensk Regional Center of Allergology and Immunology, mean disease duration was 26.7 ± 3.7 months, and the mean age of the patients – 44.2 ± 0.89 years. Hospitalization was planned (for in-depth evaluation and treatment tactics planning) for 261 patients (91.9%; 95% CI: 88.7–95.1%). Twenty-three patients (8.1%; 95% CI: 4.9–11.3%) were hospitalized for emergency reasons, of which: 18 were referred by outpatient physicians, 3 were delivered by ambulance, and 2 self-referred. Of these, 178 patients (62.7%; 95% CI: 57.1–68.3%) were admitted to the 24-hour hospital, and 106 (37.3%; 95% CI: 31.7–42.9%) – to the day hospital. Mean length of stay of a patient with CSU in the Smolensk Regional Center of Allergology and Immunology was 9.1 ± 0.17 days. The Smolensk Regional Center of Allergology and Immunology is the only medical institution in the Smolensk region that provides specialized allergology and immunology inpatient care. Therefore, the analysis of the center's archive data comprehensively reflects the pharmacoepidemiological situation regarding the disease in the Smolensk region.

Pharmacoepidemiological analysis of outpatient CSU therapy in the Smolensk region

The therapy that patients with CSC received throughout the outpatient stage of medical care is presented in Table 1.

As shown, the majority of patients (247 out of 284) used second-generation antihistamines (AHs) at guideline-permitted dosage during the outpatient stage. Second-generation AHs are first-line drugs for the treatment of CSU and are prescribed to most patients worldwide (Maurer et al. 2020). Off-label dosage increases of these drugs have a good safety profile (Maurer et al. 2025). However, off-label therapy requires an individual approach, especially in children, the elderly, and pregnant women.

Sixty-three patients (22.2%; 95% CI: 17.4–27.0%) received first-generation AHs at the outpatient stage. Despite the absence of first-generation AHs in the treatment algorithms for

CSU, their use is reported in up to 50% of cases in retrospective studies (Bernstein et al. 2025). Violation of recommended approaches to disease treatment is also observed in relation to systemic glucocorticoids (sGCS). According to therapeutic guidelines, this group of drugs should be used in short courses to relieve severe exacerbations of CSU. However, literature data shows that they are often used in unjustified prolonged courses (Ledford et al. 2016). In our study, 17 patients with CSU (6.0%; 95% CI: 3.2–8.7%) used long-term courses of sGCS. Thus, the widely used practice of using first-generation AHs and sGCS requires correction in order to improve the efficacy and safety of pharmacotherapy in patients with CSU.

Table 1. Outpatient pharmacotherapy for chronic spontaneous urticaria before first hospitalization

Pharmacotherapy	Number of patients	Percentage from total patients included in the study (95% CI)
Second-generation antihistamines at standard dosage*	189	66.5 (61.1–72.0)
Second-generation antihistamines at a double increased standard dose	38	13.4 (9.4–17.4)
Second-generation antihistamines at a 4-fold increased standard dosage	20	7.0 (4.1–10.0)
Second-generation antihistamines at more than 4-fold increased standard dosage	2	0.7 (0–1.7)
First-generation antihistamines	63	22.2 (17.4–27.0)
Systemic glucocorticoids (less than 7 consecutive days)	94	33.1 (27.6–38.6)
Systemic glucocorticoids (over 7 consecutive days)	17	6.0 (3.2–8.7)
Sodium thiosulfate	5	1.8 (0.2–3.3)
Ketotifen	3	1.1 (0–2.2)
Montelukast	2	1.4 (0–2.8)
Calcium gluconate	2	0.7 (0–1.7)
Histaglobulin	1	0.4 (0–1.0)
Without treatment	8	2.8 (0.9–4.7)

Note: * – in case different dosages of second generation antihistamines were used, only the highest dose was taken for the calculation.

Pharmacotherapy at the outpatient stage in the Smolensk region rarely included such drugs as sodium thiosulfate, ketotifen (mast cell membrane stabilizer), calcium gluconate, histaglobulin, and montelukast (an antileukotriene drug). All of the listed medications are not included in the current recommendations for the treatment of CSU and should not be used for this disease.

Despite the high efficacy of omalizumab and cyclosporine A in achieving control over the symptoms of CSU, no cases of drug use at the outpatient stage were identified in the Smolensk region (2014–2024). The absence of omalizumab in outpatient pharmacotherapy is most likely due to its high cost. It is also possible that outpatient physicians hesitate due to the lack of comprehensive knowledge and limited practical experience in the use of monoclonal antibodies. Immunosuppressive therapy with cyclosporine A is, as evidenced by research, the least frequently used of the approved treatment options for CSU (Chu et al. 2025). This may be related to the safety profile of cyclosporine.

It should be noted that 8 patients with CSU (2.8%; 95% CI: 0.9–4.7%) received no outpatient treatment despite symptoms.

Next, we conducted a retrospective analysis of the effectiveness of outpatient therapy for patients with CSU (Table 2).

Retrospective analysis showed that only 102 patients out of 247 (41.3%; 95% CI: 35.2–47.4%) taking second-generation AHs in dosages permitted by clinical guidelines achieved complete control over disease symptoms. At the same time, the absence of a significant result of complete control with an increase in the dosage of 2nd generation AHs was indirectly noted. Thus, when using standard doses of 2nd generation antihistamines, complete control was achieved in 80 of 189 patients (42.3%; 95% CI: 35.3%–49.4%), and when using 4-fold increased doses – in 9 of 20 (45.0%; 95% CI: 23.2–66.8%). A large number of studies demonstrate this trend. Thus, inadequate disease control during therapy with 2nd generation antihistamines is observed in more than 60% of patients with CSU (Soong et al. 2023). An off-label increase in the dose of 2nd

generation AHs leads to a decrease in itching, but not in the number of rash elements (Iriarte Sotes et al. 2020). These data on the efficacy of second-generation AHs in CSU emphasize the need to adhere to the therapeutic algorithm. The disease guidelines note that the need to switch to biological therapy with **omalizumab** should be determined based on the results of achieving control after 2–4 weeks of daily administration of second-generation AHs. Long-term ineffective pharmacotherapy with 2nd generation AHs leads to delays in disease control. Regular assessment of disease activity and control is necessary for making decisions about further drug therapy and monitoring the response to treatment.

Taking sGCS for more than 7 days showed the highest frequency of complete control over disease symptoms: it was achieved in 64.7% (95% CI: 42.0– 87.4%) of patients. However, long-term treatment with steroids is associated with frequent side effects and, according to some data, may prolong the duration of CSU. As described previously (Table 1), 94 patients used short-course steroids. Symptomatic administration of short-term sGCS to relieve severe exacerbations produced a temporary positive effect in 90 out of 94 patients (95.7%; 95% CI: 91.7–99.8%). These data confirm the possibility of using short courses of sGCS as “emergency” drugs. However, such drug therapy does not provide long-term control and sustainable reduction of symptoms.

Table 2. Effectiveness of outpatient pharmacotherapy of patients with chronic spontaneous urticaria before first hospitalization

Pharmacotherapy	Total patients	Complete control of CSU symptoms was achieved**		Complete control of CSU symptoms was not achieved***	
		N, number of patients	% of patients (95% CI)	N, number of patients	% of patients (95% CI)
Second-generation antihistamines at standard dosage*	189	80	42.3 (35.3–49.4)	109	57.7 (50.6–64.7)
Second-generation antihistamines at a double increased standard dose	38	13	34.2 (19.1–49.3)	25	65.8 (50.7–80.9)
Second-generation antihistamines at a 4-fold increased standard dosage	20	9	45.0 (23.2–66.8)	11	55.0 (33.2–76.8)
Second-generation antihistamines at more than 4-fold increased standard dosage	2	0	0	2	100
First-generation antihistamines	63	4	6.3 (0.3–12.4)	59	93.7 (87.6–99.7)
Systemic glucocorticoid drugs (over 7 consecutive days)	17	11	64.7 (42.0–87.4)	6	35.3 (12.6–58.0)
Sodium thiosulfate	5	0	0	5	100
Ketotifen	3	0	0	3	100
Montelukast	2	0	0	2	100
Calcium gluconate	2	0	0	2	100
Histaglobulin	1	1	100	0	0

Note: * – in case different dosages of 2nd generation antihistamines are used, only the highest dose was taken for the calculation; ** – if the patient did not report symptoms of CSU (complete absence of weals / angioedema / itching) during at least a 2-week course of treatment with the drug, and the rash was not recorded by the attending physician during hospitalization, then the effect of the therapy was considered “achieved”; *** – if the patient noted symptoms of CSU (the appearance of weals / angioedema / itching) during at least a 2-week course of drug administration, and the rash was recorded by the attending physician during hospitalization, then the effect of the therapy was considered “not achieved”.

The use of drugs not included in clinical recommendations (**sodium thiosulfate**, **ketotifen**, **calcium gluconate**, histaglobulin, **montelukast**) was effective only in isolated cases. Of all 13 cases of pharmacotherapy with the indicated drugs, complete control was achieved in only 1 case (7.7%; 95% CI: 0–22.2%). This underscores the need to adhere to clinical guidelines in routine practice.

Pharmacoepidemiological analysis of inpatient therapy for patients with CSU in the Smolensk region

The therapy of patients with CSU during their first hospitalization in the Smolensk Regional Center of Allergology and Immunology is presented in Table 3.

Table 3. Inpatient pharmacotherapy of patients with chronic spontaneous urticaria during first hospitalization

Pharmacotherapy	Number of patients	Percentage from total patients included in the study (95% CI)
Second-generation antihistamines at standard dosage	114	40.1 (34.4–45.8)
Second-generation antihistamines at a double increased standard dose	42	14.8 (10.7–18.9)
Second-generation antihistamines at a 4-fold increased standard dosage	128	45.1 (39.3–50.9)
First-generation antihistamines	12	4.2 (1.9–6.6)
Systemic glucocorticoid drugs	35	12.3 (8.5–16.1)
Omalizumab	18	6.3 (3.5–9.1)
Montelukast	23	8.1 (4.9–11.3)
Sodium thiosulfate	23	8.1 (4.9–11.3)

In the hospital of the Smolensk Regional Center of Allergology and Immunology, all 284 patients with CSU received second-generation AHs. The number of patients taking second-generation AHs at increased doses was 170 (59.9% of the total number of patients; 95% CI: 54.2–65.6%), whereas at the outpatient stage there were 58 such patients (20.4% of the total number of patients; 95% CI: 15.7–25.1%). A nearly threefold increase in the number of patients receiving antihistamines at increased dosages may indicate escalation of dose in the hospital due to the ineffectiveness of the outpatient stage of treatment.

Initiating administration of **omalizumab** during the first hospitalization at the Smolensk Regional Center of Allergology and Immunology was performed in 18 patients. This number of patients demonstrates the availability of biological therapy for CSU in the Smolensk region. Furthermore, switching patients who are not symptom-controlled on antihistamine drug therapy to **omalizumab** demonstrates continuity in care for patients with CSU.

The administration of **montelukast** (an antileukotriene drug) in the hospital of the Smolensk Regional Center of Allergology and Immunology cannot be considered a violation of the therapeutic algorithm. This drug, along with **omalizumab** and **cyclosporine A**, had been included in the third line of treatment for CSU until 2018 (Zuberbier et al. 2014). Its use in inpatients during the period 2014–2018 at the Smolensk Regional Center of Allergology and Immunology is an indicator of compliance with clinical recommendations.

Compliance with clinical recommendations was also noted in regard to the use of sGCS. In hospital settings, 35 patients (12.3%; 95% CI: 8.5–16.1%) received sGCS. Among these patients, 31 (88.6%; 95% CI: 78.0–99.1%) required their use due to the development of a severe exacerbation of CSU. Moreover, the average duration of the course of sGCS was only 2.5 ± 0.23 days. In the remaining 4 patients (11.4%; 95% CI: 0.9–22.0%), gradual discontinuation of sGCS was performed in a hospital setting after long-term outpatient use of these drugs.

As shown above, in the Smolensk region, in general, adherence to the therapeutic algorithm of the CSU is observed. Moreover, cases of deviation from recommendations for drug therapy for the disease identified during the study require individual analysis in order to optimize treatment. Thus, in 23 patients (8.1%; 95% CI: 4.9–11.3%), **sodium thiosulfate** was used in therapy, with an average number of intravenous administrations of 7.2 ± 0.47 per patient; in 12 patients (4.2%; 95% CI: 1.9–6.6%), first-generation AHs were used in therapy, with an average duration of administration of 4.5 ± 0.77 days per patient.

It is impossible to reliably assess the effectiveness of inpatient therapy for patients with CSU based on a retrospective analysis of data from only one hospitalization. As follows from the therapeutic recommendations, a full determination of the result of achieving control over disease symptoms should be carried out after 2–4 weeks of daily administration of AHs at a stable dosage or after 6 consecutive injections of **omalizumab** with an interval of 4 weeks between injections. The average duration of hospitalization of patients was 9.1 ± 0.17 days. And in most cases, it was associated with the need for a detailed laboratory and instrumental examination of the patient and a meeting of the medical commission to decide on an off-label increase in the dosage of second-generation AHs or a switch to **omalizumab** therapy. Thus, only further observation of patients with long-term pharmacotherapy results recording can provide an answer to the question of the success of primary hospitalization.

Conclusion

A pharmacoepidemiological analysis of drug therapy for CSU in the Smolensk region demonstrated good adherence to the recommended therapeutic algorithm.

However, some discrepancies in the recommended treatment of CSU were identified, requiring correction in order to optimize patient care. Thus, at the outpatient stage of medical care, first-generation AHs were used, long-term sGCS were prescribed, and in the case of antihistamine-resistant form of CSU, there was no therapy with **omalizumab** and **cyclosporine A**. At the inpatient stage of medical care, first-generation AHs and **sodium thiosulfate** were used.

The results of the analysis confirm the low efficacy of second-generation AHs (first-line therapy for CSU), regardless of the dosages used. Efficacy indicators reveal the need for a rapid switch to biological therapy with **omalizumab** in patients with antihistamine-resistant disease. Good availability of **omalizumab** was noted in the inpatient setting of the Smolensk Regional Center of Allergology and Immunology.

The use of off-guideline medications demonstrated no meaningful effectiveness.

Additional Information

Conflict of interest

The authors declare that they have no conflicts of interest.

Funding

The authors have no funding to report.

Ethics statement

The study design was unanimously approved by the Ethics Committee of Smolensk State Medical University of the Ministry of Health of the Russian Federation (extract from Minutes No. 2 of the Ethics Committee meeting dated September 19, 2025).

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Data availability

All relevant data generated and analyzed during this study are included in this article.

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