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Original Article

Comparison of Remission with Autologous Serum Therapy versus Fixed-Dose Levocetirizine in Chronic Urticaria: A Quasi-Experimental Study

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ABSTRACT

Chronic urticaria is a relapsing disorder characterized by recurrent wheals and pruritus for more than 6 weeks. Although second-generation H1-antihistamines remain first-line therapy, some patients show incomplete control, prompting interest in autologous serum therapy (AST). **Objectives:** To compare remission rates with AST versus fixed-dose levocetirizine in adults with chronic urticaria. **Methods:** This quasi-experimental study was conducted in the Department of Dermatology, Sheikh Zayed Hospital, Rahim Yar Khan, from March 21, 2024, to September 20, 2024. Eighty-eight adults with clinically diagnosed chronic urticaria were enrolled by non-probability consecutive sampling and allocated non-randomly to AST (n=44) or levocetirizine 5 mg daily (n=44). AST was prepared from autologous venous blood and administered as 2 mL intramuscular injections once weekly during the active treatment phase. Outcome assessment was not blinded. The primary endpoint was the complete absence of wheals and itching during the final 7 consecutive days of treatment. Chi-square testing was used for efficacy comparisons, and relative risk (RR) with 95% confidence interval (CI) was calculated. **Results:** Complete remission was observed in 34/44 patients (77.3%) receiving AST and 21/44 (47.7%) receiving levocetirizine (p=0.004; RR 1.62, 95% CI 1.14–2.29). Exploratory subgroup analyses showed higher remission with AST among patients aged 31–45 years (p=0.027) and among those with disease duration <6 months (p=0.006). No major adverse events were documented in the available study records; however, minor adverse events were not systematically assessed or reported. **Conclusions:** this non-randomized, unblinded study, AST showed higher short-term remission than fixed-dose levocetirizine, but findings remain hypothesis-generating and require confirmation through randomized controlled trials.

INTRODUCTION

Chronic urticaria is a painful and frequently chronic dermatologic condition, which is marked by recurrent wheals, angioedema, or both, lasting over 6 weeks [1]. It influences sleep, work efficiency, interpersonal communication, and general quality of life and is thus a significant therapeutic problem in everyday clinical practice [2,3]. The pathogenic mechanisms of the disease are believed to be complex, involving such processes as mast cell activation, histamine release, and, in certain patients, autoimmune or autoreactive. Due to its relapsing nature and intermittent severity, chronic urticaria often needs prolonged treatment and periodic clinical follow-up. Although it is a widespread disorder, in a significant percentage of patients, it is still hard to achieve complete and sustained control over symptoms. H1-antihistamines that are non-sedating and second-generation are the preferred choice of first-line treatment of chronic urticaria due to positive efficacy and safety profile [4]. The active enantiomer of cetirizine, levocetirizine, is common in this context and is the choice due to its relatively low sedative effect and excellent tolerability [5, 6]. Nevertheless, a significant number of patients still report persistent

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wheals and pruritus despite standard dose treatment, and this may prompt clinicians to contemplate dose escalation or alternative treatment options [7, 8]. Guideline-based escalation can offer further benefit, but it can be expensive and still might not lead to full remission in every case. Thus, the identification of efficient and cost-effective adjunctive therapies is still clinically important, especially in those environments that have limited resources. Autologous serum therapy (AST) has become an area of possible immunomodulatory therapy in patients with chronic urticaria, particularly in cases where autoimmune or autoreactive processes are suspected [9]. The treatment principle is the immunization of a patient with his own serum, and the goal is to change immune responses and decrease the disease activity in the long run. Past research has demonstrated that AST can alleviate the severity of symptoms, decrease the need to use antihistamines, and enhance control of the disease in both ASST-positive and ASST-negative patients [10-12]. Despite the encouraging evidence, published results remain heterogeneous in terms of study design, administration protocol, and outcome measurement. As a result, the comparative value of AST versus traditional antihistamine therapy is not sufficiently established.

In view of the chronic nature of urticaria, the limitations of standard-dose antihistamine therapy, and the potential utility of AST as a low-cost treatment option, further local comparative evidence is needed. This is particularly important in routine tertiary care practice, where patients often present with prolonged symptoms and limited access to advanced therapies. This study aimed to compare the remission rates of autologous serum therapy and fixed-dose levocetirizine in adult patients with chronic urticaria treated at a tertiary care hospital.

METHODS

This quasi-experimental study was conducted in the Department of Dermatology, Sheikh Zayed Hospital, Rahim Yar Khan, after approval from the institutional ethical committee (Ref. No. 47/IRB/SZMC/SZH, dated 21st March 2024). The study period extended from March 21, 2024, to September 20, 2024. Adults aged 18–60 years of either sex with clinically diagnosed chronic urticaria were eligible. The diagnosis was established clinically by a dermatologist based on the presence of spontaneous wheals, with or without angioedema, occurring for at least 6 weeks. Written informed consent was taken. Patients with physical urticaria, autoimmune disease, thyroid disorders, systemic infection, pregnancy, lactation, current systemic steroid or immunosuppressant use, or known hypersensitivity to injection procedures were excluded. Participants were recruited by non-probability consecutive sampling. The specific sequence used for allocation was not prospectively randomized or concealed. After enrollment, patients were assigned to one of two active treatment groups through non-random quasi-experimental allocation; no formal random sequence generation, allocation concealment, or placebo arm was used. Because of this design, the risk of selection bias and confounding was recognized a priori. The revised manuscript has been reorganized to report the non-randomized design, allocation process, outcomes, and limitations more transparently. The sample size was calculated using efficacy proportions from the study by Naz *et al.* [13], who reported an efficacy of 76.92% in the autologous serum group and 48.08% in the antihistamine group. Using a 95% confidence level, 80% power, and equal allocation of participants to the two treatment arms, the required sample size was 44 patients per group, giving a total sample of 88 participants. Group A received AST. Five milliliters of venous blood were drawn aseptically, allowed to clot, and centrifuged to obtain serum; 2 mL of autologous serum was administered intramuscularly once weekly during the active treatment phase. The active treatment phase lasted 6 weeks, during which AST was administered once weekly and levocetirizine was administered daily. Intramuscular administration was the departmental protocol used during the study period. Group B received levocetirizine 5 mg orally once daily during the same treatment phase. Levocetirizine up-dosing was not permitted because the study protocol compared AST with a fixed-dose standard antihistamine regimen rather than guideline-based step-up care. No placebo or sham injection was used, and no additional antihistamines or adjunctive therapies were routinely allowed unless clinically essential. Baseline variables included age, gender, and duration of disease. Symptom outcome was recorded clinically on a structured proforma rather than with daily diaries or validated UAS7/DLQI instruments. ASST status was not assessed. Outcome assessment was not blinded to treatment allocation.

Data were analyzed in SPSS version 26.0. Continuous variables are presented as mean ± SD, and categorical variables as frequency (%). Independent-samples testing was used for baseline comparison of continuous variables, whereas chi-square testing was used for categorical baseline and efficacy comparisons. Relative risk (RR) with 95% CI was calculated for the primary comparison. Stratified analyses by age, gender, and disease duration were exploratory and unadjusted for multiple testing; therefore, subgroup findings were interpreted cautiously.

RESULTS

A total of 88 participants were enrolled, with 44 allocated to each treatment group. All enrolled participants completed the active treatment phase and were included in the final

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analysis; no withdrawals or losses to follow-up were reported. Baseline comparison showed comparable gender distribution between groups (male: 20/44 [45.5%] vs 19/44 [43.2%]; female: 24/44 [54.5%] vs 25/44 [56.8%]; p=0.830). Among continuous variables, the AST group was younger than the levocetirizine group (32.57 ± 7.40 vs 35.95 ± 8.36 years; p=0.048), whereas disease duration was similar between groups (10.23 ± 6.74 vs 10.93 ± 7.24 months; p=0.640). This age imbalance should be considered when interpreting comparative efficacy (Table 1).

Table 1: Baseline Characteristics of the Study Groups

Variables	AST (n=44), (Mean ± SD)	Levocetirizine (n=44), (Mean ± SD)	p-value
Age, Years	32.57 ± 7.40	35.95 ± 8.36	0.048
Disease Duration, Months	10.23 ± 6.74	10.93 ± 7.24	0.640
Male, n (%)	20 (45.5%)	19 (43.2%)	0.830
Female, n (%)	24 (54.5%)	25 (56.8%)	

Independent-samples testing was applied to continuous baseline variables, whereas chi-square testing was used for gender distribution

Overall treatment efficacy differed significantly between groups. Complete remission occurred in 34 of 44 patients (77.3%) in the AST group and in 21 of 44 patients (47.7%) in the levocetirizine group (p=0.004), corresponding to a relative risk of 1.62 (95% CI 1.14–2.29) for remission with AST (Table 2).

Table 2: Comparison of Treatment Efficacy Between the Two Groups (n=88)

Groups	Not Efficacious, n (%)	Efficacious, n (%)	p-value
Autologous Serum Therapy	10 (22.7%)	34 (77.3%)	0.004*
Levocetirizine	23 (52.3%)	21 (47.7%)	

*Pearson chi-square test; RR for remission with AST = 1.62 (95% CI 1.14–2.29)

In exploratory age-stratified analysis, AST showed higher remission rates across all age groups. This difference reached statistical significance only in patients aged 31–45 years (77.3% vs 46.4%, p=0.027), whereas the differences in the 18–30 years and 46–60 years strata were not statistically significant (Table 3).

Table 3: Age-Stratified Comparison of Efficacy Between AST And Levocetirizine

Age Group	Group	Not Efficacious, n (%)	Efficacious, n (%)	Total	p-value
18–30 Years	Autologous Serum Therapy	5 (27.8%)	13 (72.2%)	18	0.149
	Levocetirizine	6 (54.5%)	5 (45.5%)	11	
31–45 Years	Autologous Serum Therapy	5 (22.7%)	17 (77.3%)	22	0.027*
	Levocetirizine	15 (53.6%)	13 (46.4%)	28	
46–60 Years	Autologous Serum Therapy	0 (0.0%)	4 (100.0%)	4	0.151
	Levocetirizine	2 (40.0%)	3 (60.0%)	5	

*Statistically significant. Chi-square test used within each stratum

In exploratory gender-stratified analysis, AST showed higher remission rates in both genders. Among male patients, remission occurred in 16/20 (80.0%) in the AST group compared with 9/19 (47.4%) in the levocetirizine group (p=0.034). Among female patients, remission occurred in 18/24 (75.0%) and 12/25 (48.0%), respectively; this numerical difference did not reach statistical significance (p=0.052) (Table 4).

Table 4: Gender-Stratified Comparison of Efficacy Between AST and Levocetirizine

Gender	Group	Not Efficacious, n (%)	Efficacious, n (%)	Total	p-value
Male	Autologous Serum Therapy	4 (20.0%)	16 (80.0%)	20	0.034*
	Levocetirizine	10 (52.6%)	9 (47.4%)	19	
Female	Autologous Serum Therapy	6 (25.0%)	18 (75.0%)	24	0.052
	Levocetirizine	13 (52.0%)	12 (48.0%)	25	

*Statistically significant. Chi-square test used within each gender stratum

In exploratory analysis by disease duration, AST showed the greatest advantage among patients with disease duration of less than 6 months (78.6% vs 29.4%, p=0.006). Differences in the 6–12 months and more than 12 months strata also numerically favored AST, but these comparisons were not statistically significant (Table 5).

Table 5: Duration-Stratified Comparison of Efficacy Between AST and Levocetirizine

Disease Duration	Group	Not Efficacious, n (%)	Efficacious, n (%)	Total	p-value
< 6 Months	Autologous Serum Therapy	3 (21.4%)	11 (78.6%)	14	0.006*
	Levocetirizine	12 (70.6%)	5 (29.4%)	17	
6–12 Months	Autologous Serum Therapy	5 (27.8%)	13 (72.2%)	18	0.507
	Levocetirizine	4 (40.0%)	6 (60.0%)	10	
> 12 Months	Autologous Serum Therapy	2 (16.7%)	10 (83.3%)	12	0.160
	Levocetirizine	7 (41.2%)	10 (58.8%)	17	

*Statistically significant. Chi-square test applied within each stratum

DISCUSSION

This study found a higher short-term remission rate with AST than with fixed-dose levocetirizine in adults with chronic urticaria. The magnitude of difference was similar to that reported in a local comparative study by Naz *et al.* [13] and is also in line with the comparative findings reported by Pandey *et al.* [14]. Collectively, these data provide some supportive, but not conclusive, evidence that AST can be used to aid some patients in clearing their symptoms in the short term compared to standard-dose

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antihistamine therapy. The current results are also generally in line with the broader AST literature. A recent systematic review and meta-analysis by Suherman previously indicated that there could be a positive change in the outcome of disease activity with AST, but the heterogeneity of studies is a limitation [15]. The potential role of AST in chronic urticaria has also been reported in a recent clinical study, although treatment protocols and outcome measures have varied [16]. These observations can be consistent with the clinical improvement observed in our cohort, but protocol, route of administration, and outcome assessment are different, so they cannot be compared directly. Levocetirizine, however, is a proven first-line treatment of chronic urticaria. Zhang *et al.* observed symptomatic and inflammatory improvement with levocetirizine [17], and an overall therapeutic review still places antihistamines at the center of chronic urticaria treatment [18]. There is also some evidence that second-generation antihistamines used in up-dose may be beneficial in refractory disease [19]. Further cohort data by Wannous *et al.* [12] and route-comparison data by Abolnezhadian *et al.* [20] indicate that AST is safe and could have clinically meaningful effects, but protocols vary. The clinical usefulness of levocetirizine in the treatment of urticaria is also supported by pediatric evidence [21]. The purposeful maintenance of the levocetirizine dose at 5 mg daily in the current research was done to maintain a simple comparative protocol, which, however, might not fully capture the potential of optimized guideline-based antihistamine therapies.

There are a few limitations that are to be noted. The method employed in the study is non-probability consecutive sampling, non-random allocation, absent placebo control, and the absence of blinding, all of which make it more vulnerable to selection bias, confounding, and detection bias. There was a difference in baseline age between groups, and no validated scales were used to measure disease severity, like UAS7 or DLQI. The original study records did not systematically document the centrifugation speed/time, needle gauge, or exact injection site. The number of weekly injections completed by each participant was also not systematically recorded. Symptoms were recorded as a binary remission endpoint on a structured proforma, not as a diary-based score. ASST status, group-wise sex distribution to test post hoc comparability, the number of weekly AST injections was not systematically measured, adherence percentages and injection completion, and frequency of rescue medication were not reported. Adverse events were not assessed using a standardized adverse-event reporting instrument; therefore, minor adverse events could not be systematically quantified.Remission post-treatment and relapse after discontinuation were not fully evaluated, and subgroup analyses were not corrected and were exploratory. Future randomized controlled trials should compare AST with optimized guideline-based antihistamine therapy, incorporate validated symptom and quality-of-life measures, document safety and adherence rigorously, and include longer follow-up to determine sustained remission.

CONCLUSIONS

In this non-randomized, unblinded quasi-experimental study, a higher proportion of patients receiving autologous serum therapy achieved the predefined short-term remission endpoint than those receiving fixed-dose levocetirizine. However, this observed difference should be interpreted cautiously because of the non-randomized design, baseline age imbalance, lack of blinding and placebo control, and use of a non-validated outcome measure. The findings are therefore hypothesis-generating and do not establish the comparative effectiveness or superiority of AST. Randomized controlled trials using validated symptom and quality-of-life measures, standardized AST protocols, appropriate control groups, systematic safety monitoring, and longer follow-up are needed before AST can be recommended as an alternative to guideline-based therapy for chronic urticaria.

Authors' Contribution

Conceptualization: FH
Methodology: FH
Formal analysis: FH, NR
Writing and Drafting: FH, TH, MU, MKS, NR, ER
Review and Editing: FH, TH, MU, MKS, NR, ER

All authors approved the final manuscript and take responsibility for the integrity of the work

Conflict of Interest

All the authors declare no conflict of interest.

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