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Significance of Autologous Serum Skin Test in Chronic Idiopathic Urticaria- Efficacy of Low Dose Methotrexate Vs Autologous Serum Therapy in Chronic Autoimmune Urticaria

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Conflict of interest: Nil

Abstract

Background/Introduction: Chronic spontaneous urticaria (CSU) is a persistent inflammatory skin condition characterized by recurrent wheals, pruritus, and occasional angioedema lasting longer than six weeks. Standard antihistamines are often insufficient, necessitating alternative immunomodulatory therapies. Low-dose methotrexate (LDMTX) and autologous serum therapy (AST) have both emerged as promising options, but head-to-head comparative data remains limited.

Aim/Objectives: To compare the clinical efficacy and safety of low-dose methotrexate versus autologous serum therapy in chronic urticaria patients who exhibit poor response to antihistamines.

Materials and Methods: A prospective comparative study was conducted involving 100 chronic urticaria patients at a tertiary care dermatology center from August 2022 to December 2023. Group A received weekly AST for 9 weeks, while Group B received weekly LDMTX (10mg) for 9 weeks. Total Symptom Score (TSS) was recorded at baseline, 4 weeks, 8 weeks, 12 weeks, 4 months, and 6 months. Statistical analysis was performed using SPSS v23.

Results: Both treatments demonstrated significant intra-group reduction in TSS ($p < 0.001$). At 6 months, TSS decreased from 13.28 to 1.84 in AST and from 12.96 to 1.70 in LDMTX. Inter-group comparison revealed no significant difference across evaluation intervals ($p > 0.05$). Adverse effects were minor and self-limited.

Conclusion: Both low-dose methotrexate and autologous serum therapy exhibit comparable efficacy and safety in managing chronic urticaria refractory to antihistamines. Either therapy may be chosen based on patient suitability, comorbidities, and clinician discretion.

Keywords: Chronic urticaria, Methotrexate, Autologous Serum Therapy, Immunomodulation, Total Symptom Score

Introduction

Chronic spontaneous urticaria (CSU) is defined as the presence of transient wheals, erythema, pruritus, and/or angioedema occurring daily or almost daily for longer than six weeks without an identifiable allergen[1]. It affects approximately 0.5–1% of the general population and significantly impairs quality of life due to persistent itching, sleep disturbance, psychosocial stress, and functional disability[2,3].

The pathophysiology of CSU is multifactorial, involving mast cell degranulation, histamine release, autoantibodies to IgE or its high-affinity receptor, complement activation, and neuro-immune interactions. Conventional therapy includes second-generation antihistamines and dose up-titration; however, 30–50% of patients remain symptomatic[4-6]

Autologous serum therapy (AST) is an inexpensive, minimally invasive intervention that neutralizes circulating histamine-releasing autoantibodies and modulates autoreactivity. Low-dose methotrexate (LDMTX), on the other hand, exerts systemic immunomodulatory effects, reducing cytokine-driven mast cell activation.

The present study compares these two interventions to identify which modality shows superior or equivalent efficacy in patients with chronic urticaria inadequately controlled by antihistamines.

Materials and Methods

Study Design: Prospective, comparative, observational study

Study Duration: August 2022 – December 2023.

Study Population: 100 patients meeting diagnostic criteria for chronic urticaria attending the Dermatology OPD at a tertiary care center.

Inclusion Criteria

- Age ≥ 18 years
- Symptoms persisting for >6 weeks
- Poor response to standard antihistamines
- Willing to participate and consent

Exclusion Criteria

- Pregnancy/lactation
- Hepatic/renal impairment
- Concurrent immunosuppressant therapy
- Malignancy
- Acute infections
- Uncontrolled medical illness

Sampling method

Simple random method using odd and even numbers was used to allocate the patients to A and B groups. All the odd number patients were assigned to group A (Autologous serum therapy)and even numbers to group B (Low dose Methotrexate)after satisfying inclusion criteria.

- Group A will comprise patients who will be treated with ASST (Autologous Serum Therapy) – 2 ml of autologous serum intramuscular injection once a week for 9 weeks.
- Group B will comprise patients who will be given oral Methotrexate 10 mg (in 4 divided doses at 12 hourly interval) per week for a period of 9 weeks.

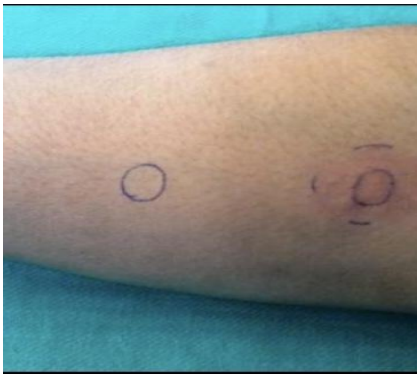

Figure 1: ASST positive

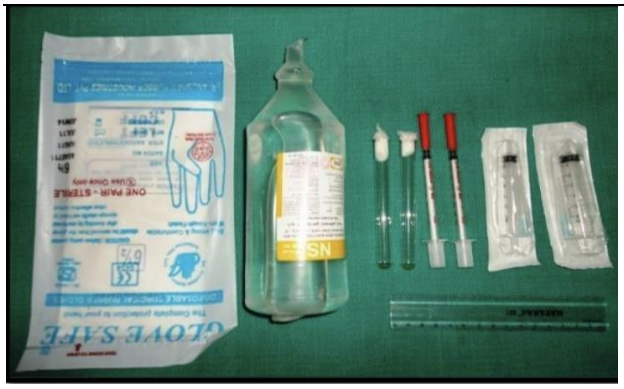

Figure 2: Materials required for AST preparation

Outcome Measure: Total Symptom Score (TSS)

Components:

Table 1: Number of wheals

Score	Number of wheals
0	none
1	<10
2	11-50
3	>50

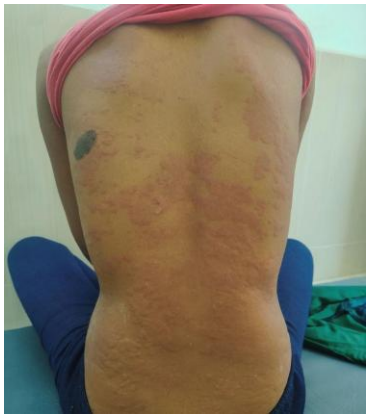

Figure 3: Wheals over the back

Table 2: Pruritus intensity

Score	Pruritus
0	Absent

1	Present but not disturbing sleep
2	Disturbing but not hampering the sleep/day time activity
3	Hampering the sleep/day time activities

Table 3: Duration of lesions

Score	Duration of wheals
0	none
1	<1hr
2	1-12hr
3	>12hrs

Table 4: Antihistamine requirement

Score	Frequency of antihistamines usage
0	none
1	<once/once a week
2	2-3times/week
3	almost daily

Table 5: Size of wheal score

Score	Size of wheal score
0	none
1	<1cm
2	1-3cms
3	>3cms

Follow up assessments:

TSS Score Grade

0 CLEAR

1-6 MILD

7-12 MODERATE

13-18 SEVERE

Evaluated at: baseline, 4 weeks, 8 weeks, 12 weeks, 4 months, 6 months.

Statistical Analysis

- Software: SPSS v23
- Mixed ANOVA for inter-group differences
- Paired t-test for intra-group changes
- $p < 0.05$ considered statistically significant

Results

Table 6: Results

Variable	Group A		Group B		P value
	N=50	%	N=50	%	
Age					
<20	10	20	2	4	0.005
21 – 30	11	22	6	12	
31 – 40	15	30	15	30	
41 – 50	5	10	19	38	
> 51	9	18	8	16	
Gender					
Male	20	40	23	46	0.545
Female	30	60	27	54	
Duration					
≤14 Months	27	54	26	52	0.776
≥15 Months	23	46	24	48	
Atopy					
Positive	12	24	16	32	0.373
Negative	38	76	34	68	
Comorbidities					
Diabetes Mellitus	2	4	7	14	
Hypertension	3	6	1	2	
DM + HTN	3	6	9	18	0.036
Asthma	1	2	5	10	
Hypothyroid	12	24	7	14	
Nil	29	58	21	42	
Dermatological examination					0.119

Wheal		17	34	12	24	
Plaque		14	28	24	48	
Dermographism		19	38	14	28	
ENT/Dental Infection(present)		14	28	9	18	0.235
CBP						
Normal		47	94	46	92	0.695
Eosinophilia		3	6	4	8	
Side effects						
Present		3	6	4	8	0.695
Absent		47	94	46	92	
	TSS at Baseline					
	Clear	0	0	0	0	
	Mild	0	0	0	0	0.418
	Moderate	19	38	23	46	
	Severe	31	62	27	54	
	TSS at 4 weeks					
	Clear	0	0	0	0	
	Mild	6	12	8	16	0.572
	Moderate	22	44	25	50	
	Severe	22	44	17	34	
	TSS at 8 weeks					
	Clear	0	0	0	0	
	Mild	17	34	16	32	0.976
	Moderate	28	56	29	58	
	Severe	5	10	5	10	
	TSS at 12 weeks					
	Clear	0	0	0	0	
	Mild	32	64	35	70	0.523
	Moderate	18	36	15	30	

	Severe	0	0	0	0	
	TSS at 4 months					
	Clear	4	8	5	10	0.921
	Mild	36	72	36	72	
	Moderate	10	20	9	18	
	Severe	0	0	0	0	
	TSS at 6 months					
	Clear	17	34	18	36	
	Mild	33	66	32	64	0.834
	Moderate	0	0	0	0	
	Severe	0	0	0	0	
	Mean TSS score	MEAN	SD	MEAN	SD	P value (t test)
	Baseline	13.28	3.52	12.96	3.43	0.596
	4 weeks	11.24	3.49	11.06	3.47	0.740
	8 weeks	8.26	3.59	8.04	3.61	0.698
	12 weeks	5.66	2.49	5.40	2.62	0.600
	4 months	3.62	2.67	3.48	2.58	0.821
	6 months	1.84	1.74	1.7	1.74	0.665

Table 7: Summary of results

Mean TSS score	MEAN	SD	MEAN	SD	MIXED ANOVA P value (Wilks' lambda) within the subjects	MIXED ANOVA P value (between the groups_
Baseline	13.28	3.52	12.96	3.43	<0.001	
4 weeks	11.24	3.49	11.06	3.47	<0.001	
8 weeks	8.26	3.59	8.04	3.61	<0.001	0.715
12 weeks	5.66	2.49	5.40	2.62	<0.001	
4 months	3.62	2.67	3.48	2.58	<0.001	
6 months	1.84	1.74	1.7	1.74	<0.001	

Discussion

The current study demonstrates that both low-dose methotrexate and autologous serum therapy significantly improve the clinical severity of chronic urticaria, with comparable efficacy at 6 months. LDMTX acts through suppression of T-cell function and pro-inflammatory

cytokine release, whereas AST is a targeted approach toward autoimmune urticaria mediated by functional IgG autoantibodies.

Our findings correlate with similar studies by Pandey et al. and Soni et al., which also demonstrated comparable efficacy between AST and methotrexate. Importantly, the safety profile in both groups was favorable, with no treatment discontinuation required.

The strengths of the study include prospective design, adequate sample size, use of validated scoring (TSS), and consistent monitoring. Limitations include single-center setting, short follow-up duration, lack of ASST-stratified subgroup analysis, and absence of comparison with omalizumab.

Future research should explore the long-term sustainability of response, patient-reported outcomes, cost-effectiveness, and biomarker correlation.

Conclusion

Both low-dose methotrexate and autologous serum therapy are effective, safe, and comparable therapeutic options in the management of chronic urticaria refractory to antihistamines. Treatment selection should be individualized based on patient preferences, comorbidities, and clinical judgement.

List of Abbreviations

- CSU – Chronic Spontaneous Urticaria
- AST – Autologous Serum Therapy
- LDMTX – Low-Dose Methotrexate
- TSS – Total Symptom Score
- ASST – Autologous Serum Skin Test

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