

Original Research Article

Autologous serum therapy: a viable option for chronic spontaneous urticaria

Darshana Sundaresh*, S. Kumaravel, M. Anbumalar

Department of DVL, Meenakshi Medical College and Research Institute, Kancheepuram, Tamil Nadu, India

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***Correspondence:**

Dr. Darshana Sundaresh,

E-mail: drdarshana1012@gmail.com

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ABSTRACT

Background: Chronic urticaria (CU) is a common disorder causing decrease in quality of life of patients with associated morbidity, chronic dependence on medications and a huge pill burden. CU is multifactorial and a subset of patients have an autoimmune background for their condition which is confirmed by a positive skin reaction to ASST. This study compared the efficacy of Autologous serum therapy in both ASST positive and ASST negative patients by evaluating total severity score (TSS).

Methods: This quasi experimental study was conducted on fifty patients were selected randomly and withdrawn from antihistaminic use. ASST was done for all patients and AST was administered to all patients in both groups for 9 weeks. The patients were followed up at 4 weeks and 12 weeks after completion of AST. TSS measurements were used as baseline and recorded weekly after each injections till 9 weeks then 4th and 12th week after completion of therapy.

Results: 50 patients were the study population. The median age was 34.7 years with a female predominance. 23 patients were ASST positive and the rest were negative. Following treatment, ASST positive group had 69% improvement in TSS and ASST negative group had 61.5% improvement in TSS. There was statistically significant differences following treatment compared to baseline and between the two groups.

Conclusions: AST as an adjunctive treatment for chronic urticaria shows promise for patients irrespective of ASST positivity and is more effective for ASST positive patients.

Keywords: Chronic urticaria, Autologous serum skin test, Autologous serum therapy, Total severity score

INTRODUCTION

Chronic urticaria or the newer term, chronic spontaneous urticaria, is a common skin disorder with a point prevalence of 0.5 to 1% in the general population. Patients with chronic spontaneous urticaria suffer from recurrent episodes of wheal development with severe itching and may also be accompanied with angioedema, lasting for more than 6 weeks.¹ Pathogenesis of Chronic urticaria is unclear and possible causes may include, chronic infections, allergy to certain food or food additives,

anxiety, and autoantibody production against IgE receptor.² It remains a major problem in terms of investigation and management and causes significant morbidity to the patient with high pill burden.

Chronic urticaria significantly impacts the quality of life of affected patients both physically and psychologically. The symptoms are more in autoreactive urticaria which can be diagnosed using ASST. ASST is autologous serum skin test and is crucial for the diagnosis of autoreactive chronic urticaria. The clinical course of chronic urticaria is

unpredictable and treatment is continued till it goes into remission. The primary modality of treatment has so far been symptom control using antihistamines. For refractory cases immunosuppressive agents like corticosteroids, methotrexate, cyclosporine are used.² These second line drugs are associated with higher incidence of side effects, some even fatal. There is need for continuous patient monitoring and laboratory testing for patients on immunosuppression.

There has been a need for an alternative therapy with better efficacy and a lower side effect profile. This is where AST, autologous serum therapy, comes in. It is a relatively newer technique that has been found to significantly improve remission of symptoms, reduce antihistamine pill burden and improve the quality of life of patient with chronic urticaria.³

The objective of our study is to determine the reduction in symptoms using Urticaria total severity score in both ASST positive and ASST negative patients and compare the response to treatment between ASST positive and negative patients.

METHODS

This is quasi experimental study conducted in the Department of Dermatology, Venereology and Leprosy, Meenakshi Medical College, Kanchipuram. 50 patients were included in the study. Study was conducted from May 2019 to May 2020 after receiving approval from the institute ethical clearance committee. Enrolment was done on the basis of the inclusion criteria which were any sex, aged between 18 years and 60 years, recurrent wheal episodes daily for more than 6 weeks and people willing for the study. Patients who had a history of drug allergy, on steroids, pregnant and lactating women, immunocompromised patients, major systemic illness, substance usage, hereditary angioedema, connective tissue disorders were excluded. Data analysis was done using Statistical package for social sciences (SPSS) software version 21.

Details of the patients alongwith history of presenting illness, past history especially allergic history/ history of atopy were taken. Next, ASST was done for all patients who were willing for the study.

Method of ASST

Serum was prepared from patients own blood by withdrawing 5ml of venous blood, clotting it for 30 minutes and centrifuged for 10 minutes at 2500 rpm. 0.05 ml of the resultant serum was taken in an insulin syringe and 0.05 ml of sterile normal saline in another syringe and separate intradermal injections were given on the flexor aspect of forearm at 5 cm apart between the injection sites. The sites of injection were free from wheal for the past 24 hours. The wheal and flare response was recorded after 30 mins. A red wheal at the site of serum injection whose

diameter was 1.5 mm more than that caused by the sterile saline injection is considered positive.

The patients were divided into two groups, group A were ASST positive and group B were ASST negative. Both groups were given weekly autologous serum therapy (AST) for 9 weeks.

AST procedure

Autologous serum was prepared using 5 ml of patient’s venous blood as done for ASST. 2.5 ml of the prepared serum was injected intramuscularly in the gluteal region on alternate buttocks weekly. A total of 9 injections were given as part of the protocol. Patients were advised to take Levocetirizine 5 mg, a second generation H1 antihistamine as rescue therapy only. No other drugs were allowed.

Urticaria TSS

Disease assessment and response to therapy was done using TSS. TSS is calculated using number and size of wheals, duration of persistence of wheals, frequency of wheals, intensity of pruritus and frequency of antihistamine use. These parameters were recorded on a 0 to 3 points scale weekly from baseline to end of treatment at 9 weeks, then the score was recorded at follow up after 13 weeks and 21 weeks. TSS has a maximum score of 18 and minimum score of 0 and the disease severity was classified as mild (TSS 1-6), moderate (TSS 7-12) or severe (TSS 13-18).

Data were presented as frequency, percentage, mean and standard deviation. Independent sample t test was used to calculate the p value. P<0.05 is considered as significance. Statistical package for social sciences (SPSS) version 25 was used in the analysis.

Table 1: Urticaria TSS.

Parameter	Scores			
	0	1	2	3
Number of wheals	None	≤10	11-50	>50
Size of wheals	None	<1 cm	1-3 cm	>3 cm
Intensity of pruritus	None	Mild	Moderate	Severe
Duration of persistence	None	<1 hour	1-12 hours	>12 hours
Frequency of appearance	None	≤Once a week	2-3/ week	Daily/alm ost daily
Frequency of antihistamine use	None	≤Once a week	2-3/ week	Daily/alm ost daily

RESULTS

This study consisted of 50 patients. 20 were males and 30 were females. The youngest patient was 18 year and oldest patient was 59 years old. The median age was 34.7 years. ASST was done to divide them into ASST positive and ASST negative groups. 23 patients were ASST positive and the rest were negative. All the patients had history of urticaria for at least 6 weeks or more. History of atopy was present in 18 patients who were ASST positive and 14 patients in the ASST negative group.

Table 2: Age sex distribution.

Age (in years)	Males	Females
16-30	7	11
31-45	8	13
46-60	5	6

Table 3: ASST positivity distribution among males and females.

ASST	Males	Females	Total
Positive	9	14	23
Negative	11	16	27
Total	20	30	50

Table 4: Weekly TSS and % improvement in TSS.

Treatment duration	Mean TSS	Standard Deviation	% improvement in TSS
Baseline	13.4	1.1	0
1 st week	13.02	1.12	3
2 nd week	12.58	1.26	6
3 rd week	12.32	1.62	8
4 th week	11.90	2.053	11
5 th week	11.10	3.012	17
6 th week	9.36	4.03	30
7 th week	8.74	3.122	35
8 th week	6.42	1.991	52
9 th week	4.56	.993	64
13 th week	3.92	1.192	71
21 st week	3.60	1.28	73

Table 5: Difference in response ASST positive vs ASST negative patients.

Mean TSS at	ASST +ve	ASST -ve	P value
9 weeks	4.13	4.93	0.004
13 weeks	3.48	4.30	0.014
21 weeks	3.13	4.00	0.015

At 9th week, ASST positive group had 69% improvement in TSS and ASST negative group had 61.5% improvement in TSS. By the end of the follow up period there was 77%

percent improvement in TSS in ASST positive patients and 69% improvement in TSS in ASST negative patients. The difference between the two groups was statistically significant ($p < 0.05$).

DISCUSSION

Chronic spontaneous urticaria is a chronic disorder causing considerable annoyance to the patient and not uncommonly debilitating which negatively affects the social as well as work life of the patient. The disease causes a burdensome toll on the physical, emotional as well as financial aspect of the patient's life. Pharmacotherapy with H1 antihistaminic remain the primary modality of treatment where the target is symptom control. It acts by preventing degranulation of mast cells and neutralizing the granulation products. This remain an effective modality for treatment except in severe and refractory cases. Consequently there is a high pill burden as patients are required to take them on a daily basis, even twice a day. For severe and refractory cases, the line of treatment involves corticosteroids and immunosuppressants which have a significant side effect profile as well as high cost of therapy. A need has long been there to find an alternative sustainable therapy with good effectiveness and least side effects. AST has risen from such a need and multiple studies seem to prove the benefit of this modality, even though the mechanism of action remains unknown. The clinical course is unpredictable and treatment goes on till remission.

In our study population, female predominance is seen as expected. The mean age of the patients were 34.8 (± 10.2) years. This was consistent with findings by Debbeman et al.⁴

Of the 50 patients 46% of the patients were ASST positive, this was comparable with the findings of Bajaj et al² but higher than those reported by Godse et al.¹

The baseline TSS in ASST positive patients was 13.4 which was higher than the baseline TSS of the ASST negative group of 12.8. Vohra et al also reported an association of increased severity of urticaria with ASST positivity.⁵ Both groups have improvement in TSS with AST. There was a 69% improvement in the TSS in ASST positive patients at the end of 9 weeks which was comparable to the results of Bajaj et al, who reported 60% improvement in total severity score in ASST positive patients. There was 61.5% improvement in ASST negative patients in this study. The differences between response to treatment between ASST positive and ASST negative patients were also statistically significant ($p = 0.004$). Overall, there was marked improved in the symptoms of the patients in the study and autologous serum therapy was well tolerated among the study population.

Looking at the results of our study, we can consider AST can prove to be an extremely feasible adjuvant therapy for chronic spontaneous urticaria with very little side effects

and more studies on a larger scale should be done to prove its benefits beyond doubt.

CONCLUSION

The relatively recent modality of AST for treatment of chronic urticaria is an effective technique for treating chronic spontaneous urticaria. It can be used for both ASST positive and ASST negative patients. The effect for ASST positive patients in terms of severity reduction is greater than for ASST negative patients.

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Conflict of interest: None declared

Ethical approval: The study was approved by the institutional ethics committee

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