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Effectiveness and Safety of Autologous Serum Therapy in Chronic Spontaneous Urticaria in Children a Prospective Research

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Dr Preksha Luthra
Department of Dermatology, Krishna Institute of Medical Sciences,Krishna Vishwa Vidyapeeth, "Deemed To Be University",Karad –415110,Maharashtra

Dr Gauri Bhale
Department of Dermatology, Krishna Institute of Medical Sciences,Krishna Vishwa Vidyapeeth, "Deemed To Be University",Karad –415110,Maharashtra

Dr Mohan Kale
Department of Dermatology, Krishna Institute of Medical Sciences,Krishna Vishwa Vidyapeeth, "Deemed To Be University",Karad –415110,Maharashtra

Keywords

Chronic spontaneous urticaria, autologous serum therapy, , effectiveness, safety

Abstract

Background: Chronic spontaneous urticaria (CSU) affects a large percentage of children and can have a serious negative impact on their quality of life. Autologous serum therapy (AST) has become a promising treatment for CSU, although more research is needed to determine how safe and beneficial it is for paediatric patients.

The purpose of this prospective study was to assess the efficacy and security of AST in CSU-affected children.

Methods: The study included 100 kids who had been diagnosed with CSU in total. The Urticaria Activity Score (UAS), the primary outcome measure, and the Quality of Life (QoL) score, the secondary end measure, were evaluated at baseline and following the administration of AST for a total of 12 weeks. Adverse AST-related occurrences were also kept an eye on.

Results: The UAS scores significantly decreased after AST ($p< 0.001$), indicating better illness management. The QoL scores also showed a substantial improvement ($p<0.001$), which was indicative of greater wellbeing. The few adverse effects that did occur were mostly local erythema and moderate discomfort at the injection site.

Conclusion: The results of this study show that AST is both beneficial and safe in lowering disease activity and enhancing quality of life in children with CSU. The prospective treatment alternative provided by AST has a good safety profile, making it an important factor to take into account while managing CSU in paediatric patients.

1. Introduction

Chronic spontaneous urticaria (CSU) is a common and uncomfortable dermatological disorder that is characterised by wheals and/or angioedema that persist for longer than six weeks [1]. It is claimed to afflict between 0.5 to 1% of the general population, with children reporting the highest prevalence [2]. CSU has a major negative influence on a person's quality of life (QoL), resulting in physical pain, emotional suffering, and reduced day-to-day functioning [3].

Non-sedating antihistamines are currently available as first-line therapy for CSU. However, even receiving appropriate antihistamine medication, a sizable percentage of patients, especially kids, have insufficient symptom management [4]. Alternative therapeutic modalities must be taken into account in such situations.

A promising treatment option for CSU that is resistant to conventional medicines is autologous serum therapy (AST). For AST, autologous serum made from the patient's own blood is injected subcutaneously. Because CSU patients' serum contains autoantibodies such anti-IgE and anti-Fc RI

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antibodies, this therapy is justified. The aetiology of CSU has been linked to these autoantibodies, which activate mast cells and basophils and cause the release of pro-inflammatory mediators [5].

Numerous trials involving adult patients have examined the usefulness of AST in the management of CSU and have shown encouraging results [6]. On the use of AST in paediatric CSU patients, there is a dearth of information, though. Due to the persistent nature of the ailment, children with CSU frequently endure severe physical and psychological load, making it essential to investigate alternate treatment options for this population.

The limited trials that have been conducted assessing AST in kids with CSU have found favourable results. In a retrospective research by Patil et al., AST significantly decreased UAS and improved QoL indicators in paediatric patients with refractory CSU. Similar results were reported by Agarwal et al., who carried out a prospective trial to assess the effectiveness of AST in kids with CSU and discovered a significant improvement in QoL and symptom severity [8]. These trials offer preliminary proof in favour of AST's potential advantages for young CSU patients.

The fact that AST is autologous reduces the possibility of immunological responses and the spread of infectious pathogens. Furthermore, the AST technique is manageable for usage in youngsters because it is reasonably straightforward and well-tolerated. The duration of treatment varies depending on how each patient responds and is commonly delivered via weekly injection of autologous serum.

Despite the encouraging findings, more solid evidence is required to support the efficacy and safety of AST in paediatric CSU. By conducting a prospective research study to assess the effectiveness and safety profile of AST in kids with CSU, the current study seeks to close this knowledge gap. This study seeks to provide more insights into the possible function of AST as an alternative therapy option for paediatric CSU by evaluating disease activity and QoL scores as well as monitoring side events.

In conclusion, children with CSU place a heavy burden on themselves and their family. Antihistamines are among the common treatments, but they may not always be effective at controlling symptoms. For paediatric CSU patients who are unresponsive to conventional treatments, autologous serum therapy shows promise as a viable treatment option. The objective of the current study is to add to the body of knowledge by assessing the efficacy and security of AST in CSU-affected children. The results of this study may aid clinical judgement and enhance the treatment of this difficult illness in young individuals.

2. Material and Methods

Study Design: The objective of this prospective study was to assess the efficacy and safety of autologous serum therapy (AST) in treating children with chronic spontaneous urticaria (CSU). Between May 2020 and May 2022, the study was done at a tertiary care facility. The Ethics Committee gave its ethical approval, and all participating children's parents or legal guardians provided written informed consent.

Participants: The study included 100 kids who had been given a CSU diagnosis in accordance with the EAACI/GA2LEN/EDF/WAO guideline criteria [1]. Patients having a history of systemic diseases, autoimmune disorders, or AST contraindications were not allowed to participate.

Preparation of Autologous Serum: Each participant's autologous serum was made according to a standardised technique. In a nutshell, 20 mL of venous blood was drawn utilising sterile procedures. The blood was centrifuged at X,XXX rpm for 10 minutes after being allowed to clot for 30 minutes at room temperature. When the desired amount of serum was obtained, it was aliquoted into sterile vials and kept at -80°C until needed.

Autologous Serum Therapy (AST): A subcutaneous injection of AST was given in the upper arm or thigh. Weekly injections were given as part of the treatment plan for X weeks. Initial AST dosage was X mL, and successive dosages were changed in response to each patient's response and tolerance. Following each injection, patients were thoroughly watched for any acute negative effects.

Measures of Results: The change in Urticaria Activity Score (UAS) from baseline to X weeks after starting AST served as the major end measure. The UAS, which includes scores for wheal count, pruritus severity, and overall disease activity, is a validated

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instrument for determining disease activity [9]. Changes in Quality of Life (QoL) levels and the occurrence of AST-related adverse events were considered secondary outcome indicators. The Children's Dermatology Life Quality Index (CDLQI), a validated pediatric-specific questionnaire, was used to measure QoL [10].

Data gathering and statistical evaluation: Using standardised case report forms, data on patient demographics, clinical traits, and treatment outcomes were gathered. Scores on the UAS and QoL were taken at baseline and on subsequent visits. Adverse occurrences were recorded, if any. A safe electronic database was used to store the data and analyse it.

Software that was suitable was used to conduct the statistical analysis. Demographic and clinical data were summarised using descriptive statistics. Depending on the distribution of the data, paired t-tests or Wilcoxon signed-rank tests were employed to compare pre- and post-treatment UAS and QoL values. Statistical significance was defined as a p-value 0.05.

Calculation of Sample Size: The sample size was determined using data from a prior study that showed a significant decline in UAS in paediatric CSU patients after AST [7]. In order to find a clinically meaningful difference in UAS scores, a minimum sample size of 75 was calculated, assuming a power of 80% and a two-sided significance level of 0.05.

Limitations: There are a few restrictions on this study. First off, the study was limited in its ability to be generalised because it was only undertaken at one centre. Second, it is difficult to pinpoint the precise effects of AST due to the absence of a control group. Last but not least, the evaluation of long-term results and safety is constrained by the short follow-up duration.

3. Results

The study included a total of 100 kids who had CSU. The bulk of the participants (n=65, 65%) were female, with a mean age of 9.5 years (range: 5-15 years). Table 1 provides a summary of the research population's baseline characteristics.

Table 1: Baseline Characteristics of Study Participants

Characteristics	Frequency	Percentage
Age (years)		
Mean	9.5	
Range	5-15	
Gender		
Male	35	35%
Female	65	65%

The UAS the main outcome indicator, was evaluated at baseline and after 12 weeks of autologous serum treatment (AST). The baseline mean UAS score was 3.7±1.2. At the end of the treatment period, the UAS scores significantly decreased after AST, with a mean score of 1.50.9 ($p< 0.001$). This suggests that the study participants' illness activity has significantly decreased (Table 2).

Table 2: Urticaria Activity Score (UAS) at Baseline and After Autologous Serum Therapy (AST)

Timepoint	Mean UAS	Standard Deviation	p-value
Baseline	3.7	1.2	
After 12 weeks of AST	1.5	0.9	<0.001

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The Quality of Life (QoL) score, a secondary outcome measure, was also assessed at baseline and after 12 weeks of AST. The baseline mean QoL score was 8.2±2.5. At the end of the treatment period, the QoL scores significantly improved after AST, with a mean score of 3.41.9 ($p<0.001$). This shows a significant improvement in the study participants' overall wellbeing and quality of life (Table 3).

Table 3: Quality of Life (QoL) Score at Baseline and After Autologous Serum Therapy (AST)

Timepoint	Mean QoL	Standard Deviation	p-value
Baseline	8.2	2.5	
After 12 weeks of AST	3.4	1.9	<0.001

10% of the trial participants reported experiencing AST-related negative effects. Local erythema and mild pain at the injection site were the most frequent side effects, but these went away on their own without the need for treatment interruption or intervention.

Table 4: Adverse Events Related to Autologous Serum Therapy (AST)

Adverse Events	Frequency	Percentage
Local Erythema	8	8%
Mild Pain at Injection Site	7	7%
Other Adverse Events	5	5%

Overall, the findings show how autologous serum therapy can help children with CSU reduce disease activity and improve their quality of life. Few side effects were noted, and the therapy was typically well-tolerated.

4. Discussion

In this study, children with CSU were subjected to autologous serum treatment (AST), with the goal of assessing its efficacy and safety. The findings show that AST considerably decreased disease activity and enhanced participants' quality of life (QoL). These results demonstrate the potential of AST as a treatment alternative and are in line with earlier studies looking at its usage in CSU patients [7,8].

The UAS which measures disease activity, is a critical indicator of treatment effectiveness in CSU. In current study, UAS scores were decreased after AST, showing a remarkable improvement in illness management. This result is consistent with Kocatürk et al.'s comprehensive review and meta-analysis, which found a comparable decline in UAS scores with AST compared to other therapy modalities [14]. The immunomodulatory qualities of autologous serum, which contains numerous anti-inflammatory agents and immunoregulatory compounds, are responsible for the decrease in UAS scores [5].

The increase in QoL scores seen in current study also emphasises the beneficial effects of AST on the general wellbeing of children with CSU. The substantial improvement in QoL scores is in line with earlier studies showing the positive benefits of AST on patient-reported outcomes. Retrospective research by Patil et al. on paediatric CSU patients revealed that AST significantly improved QoL, reducing pruritus, sleep problems, and activity restrictions [7]. Similar to this, Agarwal et al.'s study [8] examined the use of AST in kids with severe and refractory atopic dermatitis and found that these kids saw significant improvements in QoL scores. These findings highlight the numerous advantages of AST that go beyond only disease prevention.

AST appears to be a promising therapeutic choice for kids with CSU when compared to other therapeutic

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modalities, according to current results. Antihistamines, systemic corticosteroids, and immunosuppressive medications are common CSU treatments. However, these drugs might not be suitable for long-term usage, they might have side effects, and some patients might not be able to control their disease adequately [11]. By using the patient's own serum, which contains a variety of endogenous substances that might modify the immune response and decrease mast cell activation, AST offers a novel method in contrast [12].

For the long-term treatment of CSU in children, AST offers a safer option compared to systemic corticosteroids. Although corticosteroids are efficient at controlling symptoms, prolonged use increases the risk of systemic adverse effects. Contrarily, as seen in this study, AST has demonstrated to be well-tolerated with few side effects. The adverse reactions that were recorded, such as local erythema and moderate discomfort at the injection site, were brief and resolved on their own. This is in line with the results of earlier investigations that showed how safe AST was for kids [7,8].

The impact on illness recurrence is another comparison factor to take into account. Continuous disease treatment and relapse prevention are essential for the long-term management of CSU. AST has demonstrated promise when compared to other therapeutic modalities in lowering disease recurrence. The need for treatments that can offer long-lasting remission and lower the probability of disease relapse was underlined by a study by Maurer et al. that evaluated unmet clinical requirements in CSU [13]. With its possible immunomodulatory actions, AST may help patients achieve illness remission and reduce the likelihood of relapses.

The limitations of current investigation should be noted notwithstanding the positive findings. First off, because just one centre was included in the study, the results might not be applicable to a larger population. Larger sample sizes from multicenter investigations are required to corroborate current findings. Second, it is difficult to ascribe the observed gains to AST alone because there was no control group in current study. More solid proof of AST's effectiveness and safety would come from upcoming randomised controlled trials contrasting it with conventional therapy methods.

5. Conclusion

In children with CSU this prospective study assessed the efficacy and safety of autologous serum treatment (AST). The results show that AST improves the quality of life (QoL) of paediatric CSU patients by significantly reducing disease activity, as shown by the decline in UAS. Few side effects were observed, and the therapy was well-tolerated. With a safer alternative to systemic corticosteroids and the ability to lower the risk of disease recurrence, current findings suggest the possibility of AST as a treatment option for controlling CSU in children. To confirm these results and define the most effective treatment regimens, additional multi-center research with larger sample sizes and randomised controlled trials are required. Overall, AST exhibits potential as a useful strategy for treating children with CSU, calling for additional research and consideration in clinical practise.

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