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ORIGINAL PAPER

Effect of Dietary Intervention in Paediatric Patients with Chronic Spontaneous Urticaria: Open Labelled Randomised Controlled Trial

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ABSTRACT

Objectives: *Chronic spontaneous urticaria (CSU) is a skin disorder characterized by itchy wheal, angioedema or both that persists for over six weeks. 'Pseudoallergens' in food induce hypersensitive reactions similar to true allergic reactions and are linked to CSU. These consist of food additives, vasoactive amines (histamine) and a few natural substances in fruits, vegetables and spices. This study aimed to investigate if dietary restriction (pseudoallergen-free and low histamine diet) can improve the clinical outcome in paediatric CSU patients.*

Materials and methods: *The present open-label randomized control trial was conducted in a paediatric tertiary care centre of Eastern India from September 2021 to August 2022. Paediatric CSU patients (n=140) attending the centre were randomly allocated to one of two treatment interventions: DR group (n=70, drug) or DRDI group (n=70, drugs and dietary intervention). Both groups were compared at baseline. The weekly urticaria activity score (UAS7) was calculated by trained parents. All data were entered in an Excel spreadsheet. T-test was used to compare the UAS7 of both groups at baseline, three and six weeks of treatment.*

Results: *There was no significant difference in demographic characteristics, clinical features, laboratory parameters and weekly urticaria activity score (UAS7) between groups at baseline. After six weeks of treatment, the UAS7 of patients in the DRDI group was lower as compared to those in the DR group (8.80±4.27 vs 10.19±4.66), though statistically insignificant (t=1.79, p=0.07).*

Conclusion: *Pseudoallergen-free diet is a safe and cost-effective measure to decrease CSU patients' symptoms*

Keywords: chronic urticaria, child, food additives, diet therapy, elimination diets, India.

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INTRODUCTION

Urticaria is a heterogeneous group of inflammatory skin disorders that affects 20% of individuals at some point in their life (1). The pathophysiology involves a cascade of reactions starting with activation and degranulation of mast cells of the skin, histamine release, activation of sensory nerves, vasodilatation, exudation of plasma and cellular recruitment (2, 3). The patient presents with itchy wheals or angioedema or both (1). Based on the duration of illness urticaria is classified into the acute and chronic types. When the duration of illness is up to six weeks, it is known as acute urticaria, and when it lasts for over six weeks, it is known as chronic urticaria (3).

Chronic urticaria has also been further subdivided into two forms – inducible and spontaneous – based on the triggering factor. In inducible urticaria, the disease appears after exposure to a definite trigger, while in spontaneous urticaria there are no definite triggering factors. However, the disease process in chronic spontaneous urticaria (CSU) can be increased by infection, stress or other aggravating factors (3-5). Chronic spontaneous urticaria affects 0.5–1.5% of children globally and it accounts for almost two-third of cases with chronic urticaria (6). The prevalence of CSU in the United Kingdom, Germany, France, Italy and Spain has been reported to be 0.81%, 0.58%, 0.80%, 0.86% and 0.72%, respectively (7). In developing countries, the exact prevalence of CSU in the paediatric population may be underestimated, as a significant number of paediatric CSU cases might not turn up for specialist consultation and are possibly treated by parents and caregivers using over-the-counter medications (7). The exact prevalence of the disease in India is not known (8). Chronic spontaneous urticaria has a major influence on the health-related quality of life (HRQoL) of paediatric patients compared to other childhood illnesses like diabetes and epilepsy (9). This condition may lead to absenteeism from school, thereby impacting the child's learning ability and increasing their parents' mental stress (10).

The international European Academy of Allergy & Clinical Immunology/Global Allergy and Asthma Excellence Network/European Academy of Dermatology and Venereology/World Allergy Organization guidelines have advocated a stepwise treatment approach for the management of paediatric CSU patients (3). The first line of treatment is second-generation non-sedating H1-antihistamines. If symptoms persist over two weeks, the drug dose is increased and adjusted as per the child's weight. Omalizumab, leukotriene-receptor antagonists (LTRAs), or ciclosporin are prescribed as an add-on therapy in patients who do not respond to H1-antihistamines. During periods of acute exacerbations, a short- course of systemic corticosteroids may be administered. Sedating H1-antihistamines is generally not prescribed, as children are likely to experience more adverse effects from a higher dose compared to adults (11).

Many of these drugs are expensive and their use is associated with adverse effects. This propels many patients to look for safer alternatives like dietary management (12). Unlike the Western guidelines, the Asian ones recommend an exclusion diet for managing specific cases of CSU (13). The different dietary modification strategies which have been studied in CSU patients are: allergen-free diet, pseudoallergen-free diet, low histamine diet, personalized diet, vitamin D supplementation, diamine oxidase supplementation and probiotic supplementation. Out of these different strategies, pseudoallergen-free diet and low histamine diet has moderate recommendation in managing CSU patients (12). These two strategies do not involve any additional financial burden on the patient.

The majority of studies report the effect of dietary management in managing urticaria in adult patients. There is a paucity of data on the role of dietary management in paediatric CSU patients. This study aims to investigate if dietary restriction (pseudoallergen-free and low histamine diet) can improve the clinical outcome in paediatric CSU patients from Eastern India. ❑

METHODS

Study design

This was an open labelled randomised controlled trial conducted at Dr. B. C. Roy Post Graduate Institute of Paediatric Sciences, a tertiary care centre in Eastern India. The study was conducted over 12 months (September 2021 – August 2022). Ethical clearance was taken from the Institutional Review Committee before starting the study (Memo no. BCH/ME/PR/162). Trial re-

gistration was done under the Clinical Trials Registry of India with registration number CTRI/2021/08/035943. An information leaflet was provided and thereafter informed and written consent was taken from the parents of all children enrolled in this study. Patients' confidentiality was maintained throughout the study.

Study participants

We approached the parents of all children presenting with chronic spontaneous urticaria, who attended the Paediatric Dermatology outpatient department of our hospital. The inclusion criteria were paediatric patients (aged 2-12 years) experiencing chronic urticarial symptoms. All cases of inducible urticaria, autoimmune urticaria, urticarial vasculitis, those with a history of anaphylaxis, those with associated severe and moribund illness due to any causes and those unwilling to participate were excluded from the study. Patients fitting the inclusion and exclusion criteria were identified during consultation in the outpatient department and their parents were intimated about the research by the study team.

Sample size

A convenient sample size of 140 was taken, wherein a 1:1 allocation ratio was done among the two intervention arms was used. This was done mainly looking at the feasibility of the interventions in a hospital, in a resource-constrained setting.

Randomization

After enrollment, patients were randomly allocated to one of two intervention arms (DR group: treatment with drugs alone; DRDI group: treatment with drugs and dietary intervention) in a 1:1 ratio. The random sequence was computer-generated and block randomization was done with blocks of variable sizes. Sequentially numbered opaque sealed envelopes were used to hide this sequence. Only when written informed consent was obtained, the patients were informed about their allocation.

Intervention

Patients allocated to both DR and DRDI groups were provided with drugs as per guidelines. Subjects included in group DR were not given any information on dietary restrictions. Those allocated to DRDI group were advised to practice dietary restrictions on certain food in addition to taking their regular medications. The list of food items prohibited was prepared based on a previous study (14), keeping in mind the dietary patterns of people living in Eastern India. This list of food allowed and prohibited for patients in DRDI is mentioned in Table 1.

Outcome measures

The outcome measured in this study was the weekly urticaria activity score (UAS7). The UAS7 is a scoring system based on the evaluation of

TABLE 1. List of allowed and prohibited food items

Allowed food items	
Cereals	Rice, handmade Indian bread (chapati), wheat flour, rice cakes, unprocessed cereals (*e.g.*, pure cornflakes)
Meat	Fresh meat
Fish	Freshwater fish such as Rohu (*Labeo rohita*), Katla (*Labeo catla*), Indian torrent catfish *(Amblyceps mangois)*
Dairy products	Milk, buttermilk, natural yogurt, butter, ghee (clarified butter)
Vegetable oil	All types
Vegetables	Potatoes, lettuce, carrot, cabbage, onion, cauliflower, broccoli
Fruits	All fresh fruits
Others	Salt, sugar, honey, tea, coffee
Prohibited food items	
Processed food	Processed meat, noodles, potato chips, chocolates, candy, packaged fermented foods
Seafood	Hilsa fish, barb fish, seafood, prawns, crab
Eggs	Eggs including all food prepared with egg
Bakery products	Cake, biscuit
Dairy products	Margarine, mayonnaise, cheese
Vegetables	Peas, tomatoes, mushrooms, olives, garlic, chillis, spinach, sweet peppers
Fruits	All dry fruits
Others	Chewing gum, aerated drinks, herbal tea, artificial sweeteners, canned foods

chief urticaria symptoms, viz., wheals and pruritus. It is suitable for the evaluation of disease activity in urticaria patients thereby helping in patient management. Applying this, the patient is advised to self-document his/her 24-hour self-evaluation scores daily over several days. The sum score of seven consecutive days is used to determine disease severity and response to treatment. In this system, a score of 0, 1, 2 or 3 is assigned to wheal and pruritus, with a higher score referring to a more severe disease. No wheal, mild wheal (<20 wheals/24 h), moderate wheal (20–50 wheals/24 h) and intense wheal (> 50 wheals/24 h) are assigned a score of 0, 1, 2 and 3, respectively. Similarly, no pruritus, mild pruritus (which is not annoying), moderate pruritus (which is troubling but does not interfere with normal daily activity or sleep) and intense pruritus (which is troublesome and interferes with normal daily activity or sleep) are assigned a score of 0, 1, 2 and 3, respectively. The daily UAS score is calculated by adding the wheal and pruritus scores. The UAS7 score is obtained by adding the daily UAS score of the last seven days (15). In this study, the UAS7 score was calculated at baseline and then at three and six weeks after initiating intervention.

Data collection

Baseline data was collected for all participants. This included demographic characteristics (age, sex and religious affiliation), clinical symptoms including examination findings (cough and cold, rhinitis, wheezing, angioedema, wheal, photosensitivity, blood pressure, heart rate, respiratory rate), family history of urticaria and laboratory parameters (eosinophil percentage in differential cell count, serum thyroid stimulating hormone (TSH), free thyroxine (FT4), anti-thyroid peroxidase (anti-TPO) antibodies, anti-thyroglobulin (anti-Tg) antibodies, urea and creatinine). The UAS7 was calculated at baseline. Patients in the DR group were provided with drugs while those in the DRDI group were provided with drugs and dietary advice. The parents of patients in the DRDI group were provided with a leaflet in local language (Bengali and Hindi) which enlisted the food items allowed and restricted for consumption. The baseline UAS7 score was calculated by the research team. The research team taught the parents of patients in both groups the technique of self-calculating UAS7. All parents were provided with a checklist in the local language to assist them in self-calculating the UAS7 of their child. The research team contacted the parents over the phone weekly, to check their compliance with the intervention and to know their UAS7 score. All collected data was entered into a Microsoft Excel sheet.

Statistical analysis

Strict confidentiality was maintained throughout the study regarding patient data utilized for the current study. The continuous data was checked for normality using the Kolmogorov-Smirnov test. The parametric data was presented as mean ± standard deviations, while the non-parametric data was presented as median and interquartile range. All the categorical data were presented as frequency and percentage. Data was analyzed using IBM SPSS version 25. ❑

RESULTS

A total of 147 patients were found eligible during the first 10 months of our study period. Out of these, seven parents declined consent for their child's participation. The remaining 140 patients were enrolled, with 70 patients being treated with drugs alone (DR group) and 70 sub-

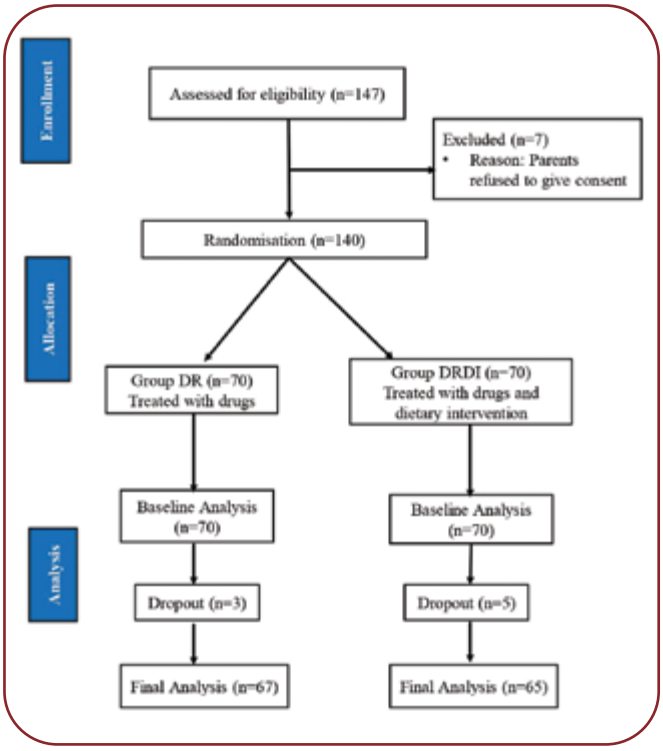

FIGURE 1. Study flow diagram

		Drug (DR) (n=70)	Drug + dietary intervention (DRDI) (n=70)	Pearson Chi-square	p-value
Age group	2 to 5 years	38 (54.3%)	44 (62.9%)	1.06	0.30
	6 to 12 years	32 (45.7%)	26 (37.1%)		
Sex	Male	37 (52.8%)	28 (40%)	2.33	0.13
	Female	33 (47.1%)	42 (60%)		
Religion	Hindu	37 (52.8%)	30 (42.9%)	1.40	0.24
	Muslim	33 (47.1%)	40 (57.1%)		

TABLE 2. Demographic characteristics of patients in both study groups

Symptoms		**Drug (DR) (n=70)**	**Drug + dietary intervention (DRDI) (n=70)**	**Pearson Chi-square**	**Unpaired t-test**	**p-value**
Cough and cold		41 (58.6%)	43 (61.4%)	0.119		0.73
Rhinitis		33 (47.1%)	38 (54.3%)	0.714		0.40
Wheezing		21 (30%)	26 (37.1%)	0.801		0.37
Family history of urticaria		0 (0%)	0 (0%)	-		-
Clinical findings						
Angioedema		21 (30%)	13 (18.6%)	2.486		0.12
Wheal		70 (100%)	70 (100%)	-		-
Photosensitivity		0 (0%)	0 (0%)	-		-
Blood pressure (in mm Hg)	systolic	102.54±9.74	101.23±8.63		0.85	0.40
	diastolic	66.46±5.76	66.14±5.45		0.33	0.74
Heart rate (per min)		98.99±9.87	100.22±8.83		- 0.75	0.45
Respiratory rate (per min)		23.28±1.95	23.29±2.04		- 0.03	0.98

TABLE 3. Clinical characteristics of patients in both study groups

jects with drugs and dietary intervention (DRDI group), as shown in Figure 1.

The baseline demographic characteristics of 70 patients enrolled in the study are presented in Table 2. There was no significant statistical difference in the age distribution, sex distribution and religious affiliation of patients in both groups, DR and DRDI.

When we analysed the presenting symptoms, we observed that, in the DR group, 41 subjects (58.6%) had cough and cold, 33 (47.1%) rhinitis and 21 (30%) wheezing. In the DRDI group, 43 (61.4%) patients had cough and cold, 38 (54.3%) rhinitis and 26 (37.6%) wheezing. No patient in either group had a family history of urticaria. There was no significant statistical difference in the presenting symptoms of patients in both groups. The presenting symptoms of patients in the two groups are summarised in Table 3.

On analysing the clinical findings, we observed that angioedema was present in 21 (30%) patients in the DR group and 13 (18.6%) subjects in the DRDI group. All patients included in both groups presented with wheal. No patient in either group reported photosensitivity. The systolic blood pressure of patients in the DR and DRDI groups was 102.54±9.74 mm Hg and 101.23±8.63 mm Hg, respectively (t=0.85, p=0.40). The diastolic blood pressure of patients in the DR and DRDI groups was 66.46±5.76 mm Hg and 66.14±5.45 mm Hg, respectively (t=0.33, p=0.74). The heart rate of patients in the DR and DRDI groups was 98.99±9.87/min and 100.22±8.83/min, respectively (t=-0.75, p=0.45). The respiratory rate of patients in the DR and DRDI groups was 23.28±1.95/min and 23.29±2.04/min, respectively (t=-0.03, p=0.98). These clinical examination findings presenting symptoms of patients in both groups are presented in Table 3. There was no significant statistical difference in these findings between patients in both groups.

Next, we analysed the laboratory findings, viz., differential cell counts, thyroid profile parameters and renal function parameters of patients from both groups, which we summarised in Table 4. The eosinophil percentage in differential count of leukocytes was 4.03±1.71% in the DR group and 3.57±1.66% in the DRDI group (t=1.60, p=0.11). Serum TSH level was 3.67±0.58 µIU/L in the DR group and 3.72±0.74 µIU/L in the DRDI group (t=-0.38, p=0.07), whereas serum FT4 level was 1.22±0.18 ng/dL in the DR group and 1.17±0.19 ng/dL in the DRDI group (t=1.79, p=0.08). Serum urea level was 25.74±4.65 mg/dL in the DR group and 25.14±4.85 mg/dL in the DRDI group (t=0.75,

Parameter	Drug (DR) (n=70)	Drug + dietary intervention (DRDI) (n=70)	Unpaired t-test	p-value
Eosinophil % (in differential count)	4.03±1.71	3.57±1.66	1.60	0.11
Serum TSH (in µIU/L)	3.67± 0.58	3.72±0.74	-0.38	0.70
Serum FT4 (in ng/dL)	1.22±0.18	1.17±0.19	1.79	0.08
Serum urea (in mg/dL)	25.74±4.65	25.14±4.85	0.75	0.46
Serum creatinine (in mg/dL)	0.43±0.11	0.44±0.11	-0.61	0.54

TABLE 4. Comparison of laboratory parameters of patients in both groups

Parameter		Drug (DR) (n=67)	Drug + dietary intervention (DRDI) (n=65)	Unpaired t-test	p-value
UAS7 score	At enrollment	19.25±5.57	19.05±5.42	0.22	0.83
	Three weeks	14.97±4.85	15.29±4.26	-0.41	0.69
	Six weeks	10.19±4.66	8.80±4.27	1.79	0.07

TABLE 5. Comparison of UAS7 score in patients of both groups

p=0.46), whereas serum creatinine level was 0.43±0.11 mg/dL in the DR group and 0.44±0.11 mg/dL in the DRDI group (t=-0.61, p=0.54).

We compared the UAS7 score of patients in both the groups at enrollment, three weeks and six weeks. At enrollment, the UAS7 score of patients in the DR and DRDI groups was 19.25±5.57 and 19.05±5.42, respectively. There was no significant difference in the UAS7 score between the two groups (t=0.22, p=0.83). We observed that after six weeks of treatment, the UAS7 score of patients in the DRDI group was lower as compared to those in the DR group (8.80±4.27 *vs* 10.19±4.66), though this was statistically insignificant (t=1.79, p=0.07), as shown in Table 5. ❑

DISCUSSION

In our study, 82 (58.6%) patients were 2.1-5 years of age and 58 (41.4%) subjects were >six years of age, with a mean age of 5.16 ± 2.35 years. The majority (75 out of 140, 53.6%) of our patients were females, as shown in Table 2. A European study reported that the prevalence of CSU was higher in older age groups (7-11 years) compared to the youngest age group (0-6 years) in Germany, France, Italy and Spain (7). A study conducted in Canada on paediatric population (0-17 years) reported that the mean age of disease onset was 6.7 ± 4.7 years (16). Studies conducted on the adult population have reported that females tend to suffer more from urticarial symptom compared to males (17-19). Kasperska-Zajac *et al* (20) highlighted that the fluctuations in the levels of sex hormone, viz., estrogen and progesterone were linked with a higher preponderance of urticaria in females.

Out of all 140 CSU patients in our study, 84 (60%) had cough and cold, 71 (50.71%) rhinitis and 47 (33.57%) wheezing (Table 3). Kulthanan *et al* (21) reported allergic rhinitis, asthma and allergic conjunctivitis in 20%, 4.4% and 1.3%, respectively, of paediatric urticaria patients in Thailand. Vito Buono *et al* (22) reported allergic diseases (rhinitis/conjunctivitis/asthma) in 37.84% of pediatric urticaria patients in Italy. Out of 140 patients in our study, 34 (20%) subjects had angioedema, all had wheal, while none had photosensitivity. No patient in our study had a family history of urticaria. Lee *et al* (23) reported that acute urticaria was associated with a family history of asthma, allergic rhinitis and atopic dermatitis. However, chronic urticaria was not associated with any history of allergic disease. Further, as digital record of past medical illnesses of patients is not kept in most public hospitals in India, it is sometimes difficult to assess the family history (24).

Thirty-seven patients in our study had an eosinophil percentage of five or above (which is more than normal), although there was no difference between both the groups, as shown in Table 4. Chang *et al* (25) reported that eosinophil count increases in acute stage of urticaria; however, during the chronic stage there are no such concrete findings. In our study, only six out of the total number of 140 patients had hypothyroidism. Out of those six patients, four subjects tested positive for anti-thyroid peroxidase antibody, one tested positive for anti-thyroglobulin antibody and one patient tested positive for both these antibodies. Kolkhir *et al* (26) conducted a

systematic review and reported that thyroid dysfunction was more prevalent in adult than paediatric CSU patients and treatment with levothyroxine (or other medications) improves the outcome in such patients.

Our study highlighted that patients who received both drugs and dietary intervention for six weeks had a better outcome (as per UAS7 score) than those treated with drugs alone, as shown in Table 5. However, we did not find this to be statistically significant (p=0.07). Cornillier *et al* (13) conducted a systematic review on 20 primary studies and analysed the findings of 1668 chronic urticaria patients with dietary restriction (pseudoallergen-free diet/low-histamine diet/fish restricted diet with standard antihistamine therapy). The team reported that this approach resulted in complete remission in 4.9% of patients and partial remission in 37.5% of subjects. However, most of the included studies were on the adult population. As it is difficult to control child feeding practices (27), the result of study outcome using restrictive diet in adults may not be extrapolated in children. Hence, we advocate further research on a large sample size to evaluate the role of dietary restriction on CSU patients.

The main advantage of our study was that it was the first trial assessing the effect of dietary intervention on paediatric CSU patients in the Indian population. One important implication of restricted diet was that those who did not respond to pseudoallergen-free diet could be reassured that food allergy was not the cause of their CSU.

Our study also had some limitations. We had a small sample size (n=140) and there was a drop out of eight (5.7%) patients during the study period. We did not assess the changes in patients' quality of life caused due to treatment response, but only focused on the UAS7. The UAS7 was calculated by the parent or caregiver and there were chances of subjective variation. During the study course we realized that dietary restriction was difficult among the paediatric population, and it needed a strict compliance and support from parents or caregivers. The previous literature does not highlight the duration for which dietary restriction must be continued for remission of urticarial symptoms. We did not look for symptom rebound in CSU patients in case they were put back on non-restrictive normal diet. The lack of information on rebound symptoms of CSU upon discontinuation of the pseudoallergen-free diet represents a limitation to practical application. Elimination diet for a prolonged period is presently advocated only when the food is confirmed to be a causative agent of CSU by food challenge test. It is not advocated for all CSU patients as it increases the risk of nutritional deficiencies and may impair the quality of life. ❑

CONCLUSION

Chronic spontaneous urticaria is a less known debilitating disease among paediatric population. However, it poses a significant negative impact on the child's physical and developmental well-being. In developing countries like India, the condition often goes unnoticed as patients do not turn up to the tertiary care centre. The existing literature suggests the role of pseudoallergen containing food behind urticaria. Based on the findings of our study, we recommend that a pseudoallergen-free diet along with standard drug treatment may be more beneficial in controlling the symptoms of CSU paediatric patients. Restricting diet containing pseudoallergens and using the UAS7 scoring system does not carry any extra financial burden on the patient and can be easily used in the developing nation settings. A personalized diet plan may be helpful in refractory CSU patients. ❑

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