



AN EXPERIMENTAL STUDY TO ASSESS THE EFFECTIVENESS OF CONSTITUTIONAL HOMOEOPATHIC MEDICINE IN CHRONIC URTICARIA IN AGE GROUP 18 TO 60 YEARS

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ABSTRACT

Background- It is estimated that about 1 in 5 people will have urticaria once in their lifetime and this seems to be the case across all age groups. Up to 1% of the population suffers from chronic urticaria (CU) and all age groups appear to be affected, although the peak incidence is between 20 and 40 years of age. Till now there are lot of research done on urticaria but most of them have made comparison between the various physical causes and the effectiveness of anti allergidrug. In this we see how constitutional Homoeopathic medicine effective in cases of Chronic urticaria in age groups 18 to 60 years

Method- It is a informal Experimental, Non Randomised, Single Group, single blind study conducted at outpatient department of Bharati Vidyapeeth Deemed University Homoeopathic College & Research Centre, Katraj, Pune, Maharashtra. Total 30 patients (Male & Female) age group 18-60 years were enrolled in this study.

Result- The final outcome was decrease in intensity, frequency & severity of eruption & itching by help of UAS 7 Scoring after 10-12 weeks of outpatient care. Pre-test and posttest analysis was done by using Student paired t test. A significant reduction observed in before and after treatment & patients symptomatically relieved as well. The mean UAS7 score was 11.467 ± 2.501 , on final follow up mean UAS7 score was **decreased** to 2.367 ± 4.263 . Mostly used constitutional medicine was Phosphorus (16.67%) along with Pulsatilla (13.33%) & Natrum mur (13.33%).

Conclusion- Constitutional Homoeopathic Medicine produced significant effect in reduction of the frequency & intensity of eruption & itching in chronic urticaria. Further studies with control group can provide a greater resource for proving that Constitutional Homoeopathic approach is effective in treatment of Chronic Urticaria

KEYWORDS : Chronic urticaria, Constitutional, Homoeopathy

INTRODUCTION

Urticaria is a heterogeneous group of disorders characterized by itchy wheals, which develop dueto evanescent edema of dermis (and sometimes of subcutis)^[1]

Chronic urticaria (CU) is defined as the recurrence of wheals more than twice a week for a period of 6 weeks or longer. CU also has a number of other characteristics features such as wheals lasting more than 1 hour (unlike simple dermatographic urticaria) and less than 24-36 hours (unlike urticarial vasculitis). Lesions may be indurated and painful. The natural course of the disease varies greatly with outbreaks and remissions that can last from a few months to more than 20 years. Major repercussions on quality of life that are considered equivalent to those in severe coronary disease. No underlying food or drug allergies. Considering histopathological features, CU is characterized by a perivascular infiltrate, without vasculitis or immune deposits, constituted by CD4+ cells with mixed TH1/TH2 characteristics, monocytes, and variable quantities of polymorphonuclear cells, eosinophils, and basophils that form a late-phase infiltrate.^[2]

CU is divided into inducible urticaria (triggered by specific physical stimuli) and spontaneous (or idiopathic) urticaria. In at least one-third of idiopathic presentations, the aetiology is autoimmune and could be associated with thyroid autoimmunity, with or without clinical hypothyroidism, as well as presenting antithyroid antibodies more frequently than the general population, CU patients may have IgG antibodies targeting circulating IgE or (much more often) the α subunit of the IgE high-affinity receptor (Fc ϵ RI). These antibodies can be detected by skin testing with autologous serum although the results are poorly reproducible owing to high variability

depending on who performs the test or by demonstrating healthy basophil degranulation in vitro in serum. In addition, immune blotting with patient serum can reveal a 30 to 35kDa IgG-binding band corresponding to the α subunit of Fc ϵ RI. These antibodies may be present in other 4 autoimmune processes such as lupus or dermatomyositis, although in autoimmune CU they correspond to the IgG1 or IgG3 subclass, which is capable of activating complement and generating anaphylotoxins such as C5a. In other words, they are functional, a characteristic that is considered to be specific of autoimmune CU.^[3]

PATHOGENESIS -

Basic pathology is vasodilatation of vessels and leakage of fluid into the surrounding tissues. Though several mediators are involved, histamine released from mast cells plays a key role. Histamine is released from mast cells by several mechanisms like antigen-induced IgE mediated release, classical complement pathway induced, direct induced by drugs and chemicals.^[4]

CLINICAL FEATURE

1. Itching is prominent, especially if wheals are superficial. However, patients tend to rub rather than scratch their lesions, so scratch marks are not seen.
2. Morphology: Lesions begin as erythematous macules, which rapidly evolve into pale pink oedematous wheals with a surrounding flare. Larger lesions annular with paler centre.
3. Evolution: Wheals last a few hours and resolve within 24-48 h leaving behind normal skin. Wheals of cholinergic urticaria subside within a few minutes.
4. Shape: Shape can be circular, annular, serpiginous or bizarre. Dermographic urticaria is characterized by linear

wheals.

5. Angioedema: Half the patients with urticaria have associated episodes of angioedema in which pale pink swellings occur especially on the face affecting eyelids and lips. May also be associated with swelling of tongue, pharynx, and larynx (when the patient may present to the medical emergency). Itching is minimal and the swelling may last for several days.
6. Associated features: Urticaria may be associated with systemic symptoms in form of Malaise and fever, headache, abdominal pain, diarrhoea, and vomiting, arthralgia, dizziness and syncope, anaphylaxis (with severe acute urticaria).

METHODOLOGY

Theoretical study: Theoretical study of this topic was done from various books, Homoeopathic journals, research journals, researches and authentic internet search through websites, Google scholar, Pubmed, etc.

Clinical study: 30 patients with chronic urticaria of both sexes, of age group 18-60 years were enrolled in the study.

Case definition:

Those case of urticaria with the recurrence of wheals (also other urticaria symptoms) more than twice a week for a period of 6 weeks or longer will be taken for study in both 19 sexes and age group 18 to 60 years with no systemic disease (T₂DM) will be taken and cases fulfilling inclusion and exclusion criteria. The case taking will be done by standard case taking proforma as per Homoeopathic Principle.

Study setting: Bharti Vidyapeeth (Deemed to be) University, Homoeopathic hospital OPD, IPD and various Peripheral OPD attached to hospital.

- Design- Informal Experimental, pre & post design
- Allocation: Non-randomized
- End point classification: Effectiveness.
- Masking: Single blind
- Mode of intervention : Oral

Intervention: All the selected samples was prescribed the Constitutional Homoeopathic remedy. Medicine are being manufactured by standard Homoeopathic Pharmacy, which are GMP certified, as per norms of Homoeopathic Pharmacopoeia of India (HPI) will be used in required potencies. Dispensing was done in globule, powder and liquid form because medicine touches more number of nerves in liquid form. (Ref. Aph. No.272) Potency like 30, 200, 1M was administered in various potencies as per instruction given by Dr.Hahnemann in his Organon of medicine (5th edition) & according to the need of patient required Potency & Repetition of doses was done as per the need of the case Storage was according to standard homoeopathic pharmacy stored in BVDU pharmacy Katraj, Pune. Drug was stored as per the rules of homoeopathic pharmacopoeia.

Case taking was done according to the standard case taking proforma as per Homoeopathic principles. medical history, physical examination (including vital signs, systemic examination) was recorded on a case form.

Follow up: Each case was followed up for 3 months every weekly according to assessment score of UAS7 score

- All the patients were duly followed up and details of the symptomatic and clinical changes were recorded and prognoses were studied.
- Follow up differed from patient to patient.
- Standard Follow-up was prepared giving details.
- It was based on Homoeopathic principles.

Parameter used: Weekly Urticaria Activity Score (UAS7)

Tab.1 – UAS 7 Score weekly sheet

Day	Daily no. Of wheals	+	Daily intensity of puritus	Daily UAS score
Day 1	0 1 2 3	+	0 1 2 3	
Day 2	0 1 2 3	+	0 1 2 3	
Day 3	0 1 2 3	+	0 1 2 3	
Day 4	0 1 2 3	+	0 1 2 3	
Day 5	0 1 2 3	+	0 1 2 3	
Day 6	0 1 2 3	+	0 1 2 3	
Day 7	0 1 2 3	+	0 1 2 3	

Tab.2- Assessment of disease activity in patients with CU (UAS scale)

SCORE	WHEELS	PRURITUS
0	None	None
1	Mild (less than 20 wheals/24 hours)	Mild (present but not annoying or troublesome)
2	Moderate (20-50 wheals/24 hours)	Moderate (troublesome but does not interfere with normal daily activity or sleep)
3	Intense (more than 50 wheals/24 hours or large confluent areas of wheals)	Intense (severe pruritus, which is sufficientlytroublesome to interfere with normal daily activity or sleep)

Criteria for Assessment of disease activity in patients with CU (UAS scale)

UAS 7 SCORE	HEALTH STATE	RATIONALE
0	urticaria free	Itch & hives free Considered a full treatment response
1-6	well-controlled	Well-controlled urticaria Indicates good response to treatment
7-15	mild urticaria	Indicates low response level
16-27	moderate urticaria	Moderate activity urticaria
28-42	severe urticaria	Severity activity urticaria

INCLUSION CRITERIA:

- Cases from the age group of 18 – 60yrs.
- Patients irrespective of ethnic group, socio-economic status and gender will be considered.
- Cases which fulfils the case definitions
- Diagnostic criteria is mainly on clinical presentation and local examination.

EXCLUSION CRITERIA:

- Patient who requires emergency medical treatment.
- Patients who not fulfilling the case definition.
- Patient not taking medicines as per direction or not co-operating for follow up.
- Systemic diseases with its complications.
- Patient suffering from life threatening diseases.
- Pregnant and lactating women.

Outcome Measures:- These were compared with the initial values, and the difference analyzed using statistical tests, to find the efficacy or otherwise of the treatment. Statistical analysis was done by using student paired t test, in which observation value before treatment, during treatment were compared. A mean statistical analysis was done by regression analysis.

OBSERVATION AND RESULTS

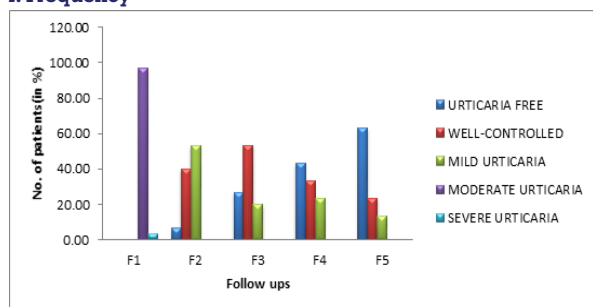
Total 30 patients (n=30) were selected based on the age group of 18-60 years. Out of which 9 were male (30%) & 21 were female (70%) according to sex wise distribution. It depicts that

only 3.33% of the patients belongs to age class below 20yrs, most(60%) belongs to age class 20-30yrs, 30% belongs to age class 30-40yrs and 6.67% belongs to age class 40 years and above. It depicts that only 3.33% of the patients belongs to age class below 20yrs, most(60%) belongs to age class 20-30yrs, 30% belongs to age class 30-40yrs and 6.67% belongs to age class 40 years and above.

Table 3: Distribution of the patients according to demographic variables, n=30

Demographic variables		f	%
Age	Below 20 years	1	3.33%
	20 - 30 years	18	60.00%
	30 -40 years	9	30.00%
	40 years and above	2	6.67%
Gender	Male	9	30%
	Female	21	70%

f: Frequency



Graph 1- Distribution of patients according to severity of Urticaria at each follow up

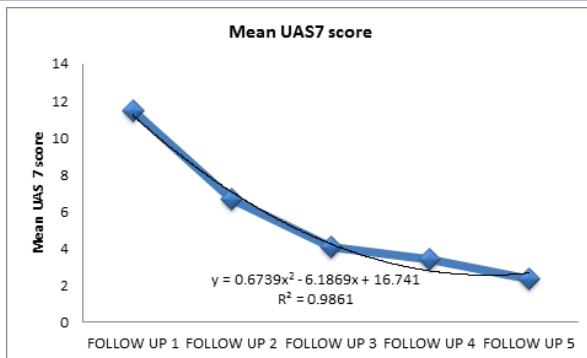
Table 5- Distribution of patients according to severity of Urticaria at each follow up

Health state	UAS 7 score	Follow ups				
		F1	F2	F3	F4	F5
Urticaria free	0	f 0	2	8	13	19
	%	0.00%	6.67%	26.67%	43.33%	63.33%
Well-controlled	1-6	f 0	12	16	10	7
	%	0.00%	40.00%	53.33%	33.33%	23.33%
Mild urticaria	7-15	f 0	16	6	7	4
	%	0.00%	53.33%	20.00%	23.33%	13.33%
Moderate urticaria	16-27	f 29	0	0	0	0
	%	96.67%	0.00%	0.00%	0.00%	0.00%
Severe urticaria	28-42	f 1	0	0	0	0
	%	3.33%	0.00%	0.00%	0.00%	0.00%

Table 5 & graph 1 shows that at the time of first visit most (96.67%) of the patients had moderate urticarial while 3.33% had severe urticarial. On 2nd follow up maximum (53.33%) of the patients had mild urticarial, 40% had well controlled urticarial while 6.67% of the patients were urticarial free. On 3rd follow up, only 20% of the patients had mild urticarial, 53.33% had well controlled urticarial and 26.67% of the patients were urticarial free. On 4th follow up 23.33% of the patients had mild urticarial, 33.33% had well controlled urticarial and 43.33% of the patients were urticarial free. On last follow up only 13.33% of the patients had mild urticarial, 23.33% had well controlled urticarial and most (63.33%) of the patients were urticarial free. It shows that severity of urticarial is decreasing after every follow up that is treatment given is effective.

Table 6: Follow up wise descriptive statistics of UAS 7 score

Variable	Mean	SD
FOLLOW UP 1	11.467	2.501
FOLLOW UP 2	6.633	3.285
FOLLOW UP 3	4.1	4.088
FOLLOW UP 4	3.4	4.099
FOLLOW UP 5	2.367	4.263



Graph 2- showing mean value of UAS7 Score in each follow up

Table 6 and above graph 2 shows that on 1st visit mean UAS7 score was 11.467±2.501, on 2nd visit mean score was 6.633±3.285, on 3rd visit mean score was 4.1±4.088, on 4th visit mean score was 3.4±4.099 and on last visit mean score was 2.367±4.263. From the graph we can see that second degree polynomial equation fitted good as the coefficient of determination is 98.61% so we can say mean UAS7 score decreases after each follow up.

Table 7 shows that at the time of first follow up mean UAS7 score was 11.467± 2.501, on final follow up mean UAS7 score was decreased to 2.367±4.263. To check the effectiveness of treatment paired t-test was used. Test statistic value is 13.28 and p-value (0.000) is very small, it suggests that we reject H0 and accept H1 that is, there is significant effect of Constitution Homoeopathic Medicine in Chronic Urticaria.

Table 7: Descriptive statistics of UAS7 score at baseline and at final follow up

UAS7 score	Mean ± SD	T-value	p-value	Decision
Baseline	11.467± 2.501	13.28	0.000**	Reject H ₀
Final follow up	2.367±4.263			
Difference	9.100± 3.754	Difference is Highly Significant		

Test used: Paired t-test, **: Highly Significant Difference, T-value: Test Statistic value

DISCUSSION

The worldwide incidence of chronic urticaria is 0.1% - 3% of the population with women affected twice more likely than men. It is estimated that about 1 in 5 people will have urticaria once in their lifetime and this seems to be the case across all age groups. Up to 1% of the population suffers from chronic urticaria (CU) and all age groups appear to be affected, although the peak incidence is between 20 and 40 years of age. The present study was primarily aimed to investigate the effectiveness of the Constitutional Homoeopathic Medicine in the management of cases of Chronic Urticaria between the age group 18-60 years. In this study 30 cases of chronic urticaria patients with age group 18-60 years of both sexes were selected. Two patients dropped out from this study after 1 or 2 follow up with rest 30 patients completed the study. They were subjected for 5-6 weeks of treatment with Homoeopathic Constitutional medicine after proper case taking. They were administered Constitutional Homoeopathic medicine & evaluation was done by seeing changes in urticarial symptoms (hives & itching) weekly in the patient during treatment & between the follow-up by UAS7 Score which showed a positive effect on the urticarial symptoms & its effects on their quality of life of the patients in the study sample. This effect was demonstrated by the result of the statistical analysis by using student paired t test which manifests that the first follow up UAS7 score & final follow up UAS7 score of urticarial symptoms which are indeed, different.

It proves that Constitutional homoeopathic remedies have good scope in treating chronic urticaria. Mostly used constitutional medicine was Phosphorus (16.67%) along with Pulsatilla (13.33%) & Natrum mur (13.33%). Least used medicine were Nux vomica (3.33%), Rhus tox (3.33%), Calcarea phos (3.33%). Finally this study data propose that constitutional Homoeopathic medicine has significantly favourable effect in patients who suffered from chronic urticaria & helps in improving their quality of life.

CONCLUSION

Urticaria is a relatively common & non dangerous, with a point prevalence of about 0.5- 1%, but it may affect your lifestyle, daily routine & quality of life which may further case you mental as well as physical damage which can be unknown for us without noticing. So by knowing it cause and work on its management we can help the patient for improving their quality of life. As data shows that most common age group affected was between 20-30 years which is very crucial age of our life-span, as most of them dealing with many mental stress & physical too, which can affect our biological clock, in other words circadian rhythm which may cause many known complication. The result showed that there is declined incidence of urticarial symptoms (eruption/itching) in cases of chronic urticaria. By using constitutional Homoeopathic approach & their medicine we can decrease the occurrence of chronic urticaria along with that we can decrease the intensity of urticaria symptoms too. Therefore constitutional Homoeopathic medicine has significant role & a good choice for treating the cases of chronic urticaria. As this study was done in small study group, research should be done in future considering large sample & extending the duration of the study also. Lastly, there is significant & effective role of Constitution Homoeopathic Medicine in Chronic Urticaria in age group 18 to 60 years

CONFLICT OF INTEREST

The authors have no conflict of interest among them regarding the research.

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REFERENCES

1. Khanna N. Illustrated Synopsis of Dermatology & Sexually Transmitted Diseases-E-book. Elsevier Health Sciences; 2014 Feb 10.
2. Chapel H, Haeney M, Misbah S, Snowden N. Essentials of clinical immunology. John Wiley & Sons; 2013 Dec 17.
3. Kasper D, Fauci A, Hauser S, Longo D, Jameson J, Loscalzo J. Harrison's principles of internal medicine, 19e. Mcgraw-hill; 2015.
4. Ralston SH, Penman ID, Strachan MW, Hobson R, editors. Davidson's Principles and Practice of Medicine E-Book. Elsevier Health Sciences; 2018 Feb 2.
5. Hahnemann CF Organon of Medicine; translated from the 5th ed. with an appendix by RE Dudgeon, with addition and alterations as per 6th ed. Translated by William Boericke, and introduction by James Krauss. Low Price ed. New Delhi: B. Jain Publishers (P) Ltd. 2002; 31:166-7.
6. Boericke W. Pocket manual of homoeopathic materia medica. Motilal Banarsidass Publ.; 1993.
7. Schroyens F. Radar. Synthesis.; 10(003).
8. Allen HC. Keynotes and characteristics with comparisons of some of the leading remedies of the materia medica with bowel nosodes. B. Jain Publishers; 2002.
9. Dhawale ML, Dhawale LD. Principles & Practice of Homoeopathy. Bombay, India: Institute of Clinical Research; 1985.
10. Vithoukias G. Essence of Materia Medica: A Textbook of Classical Homeopathy for the Professional. Paharganj. New Delhi, India: B. Jain Publishers, Ltd. 1995.