Clinical Evaluation of Unani Formulation in Shara (Urticaria)

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Urticaria refers to an area of focal dermal oedema secondary to a transient increase in capillary permeability. Although persons in any age group may experience acute or chronic urticaria, these lesions increase in frequency after adolescence, with the highest incidence occurring in the third decade of life. In Unani texts, Urticaria has been mentioned as *Shara* or *pitti uchalna* as one of the clinical entities while in modern medicine it is considered as the sign, which is found in various diseases. Unani Scholars while describing its aetiology have emphasised mainly on the humoral basis and named certain foods and drugs which may be responsible for precipitating the clinical manifestation of Urticaria.

The main objective of this study was to scientifically evaluate the anti-allergic activity of our drugs in this commonly encountered clinical entity, referred as Urticaria. The study was open single group uncontrolled randomised clinical trial. In the present study thirty cases of 20 to 60 years of age who were clinically diagnosed were enrolled in the study for 45 days from the Department of Moalejat OPD, Aligarh Unani and Ayurvedic Medical College, Aligarh. The patients were treated with *Irasa* (*Iris ensata* Thunb.), *Zanjabeel* (*Zingiber officinalis* Rosc.), *Qaranfal* (*Eugenia caryophyllata* Thunb.) and *Maghz-e-Amaltas* (*Cassia fistula* Linn.) 6 grams, 3 grams, 3 grams and 4 grams, respectively, in the form of decoction 12 hourly for 45 days. All the patients were assessed for subjective parameters. Significant improvement in clinical presentation of the disease was observed. At the end of the study, it was concluded that the formulation was found effective in *Shara* (Urticaria).

Keywords: Urticaria, Eugenia caryophyllata, Iris ensata, Zingiber officinale, Cassia fistula.

Introduction

Urticaria refers to an area of focal dermal oedema secondary to a

transient increase in capillary permeability. The symptoms and signs of urticaria are due to large part mast cells degranulation with release of histamine and a variety of large vasoactive mediators^{1, 2}.

Urticaria involves only the superficial portion of the dermis, presenting as well-circumscribed wheals with erythematous raised serpiginous borders with blanched centres that may coalesce to become giant wheals. Although persons in any age group may experience acute or chronic urticaria, these lesions increase in frequency after adolescence, with the highest incidence occurring in the third decade of life^{3,4}.

Shara (Urticaria) has been described in the form of disease in Unani literature while in modern medicine it is considered as the sign, which is found in various diseases.

Shara (Urticaria) commonly known as *pitti uchalna*⁵. The causative agent of this disease is hot and acrid fluid which is produced as a result of disturbed metabolism. Indigestion, constipation, excessive ingestion of heavy foods, eruption of teeth in children and menstruation have been described as the predisposing factors for *Shara* (Urticaria)^{6,7}.

Hakeem Khursheed Ahmad in *Amrazul Atfal* has mentioned hot season and ingestion of fresh fruits as important etiological factors for *Shara* (Urticaria)⁸. While writing the causes of *Shara* (Urticaria), Hakeem Ghulam Jeelani (*Makhzanul Ilaj*) has listed heavy and delayed digested food, hot foods like brinjal, mango and meat⁹. In the book *Makhzan-e-Hikmat*, he has mentioned hot and dry foods like salty meat and fish, and some drugs like turpentine oil as well¹⁰.

The present study was carried out to see the efficacy of non-pharmacopoeial Unani compound formulation whose composition is given elsewhere in *Shara* (Urticaria) with regard to amelioration of symptoms and signs. Although several allopathic drugs are available to treat urticaria but their use is hindered by adverse effects of such drugs. Therefore, we felt the necessity to find an alternative treatment in Unani system of Medicine, which may be used over a prolong interval of time without any serious complications.

Material and Methods

The present study was conducted on randomly selected 30 patients presenting with clinical features of Urticaria from the outdoor patients of the Department of Moalijat, Aligarh Unani and Ayurvedic Medical College, Aligarh during the period extending from August, 2009 to December, 2010. The diagnosis was made on the basis of history and clinical examination. Once the diagnosis of Urticaria was made, the drugs *Irasa*, *Zanjabeel*, *Qaranfal*, and *Maghz-e-Amaltas* 6 grams,

3 grams, 3 grams and 4 grams, respectively, in the form of decoction 12 hourly for 45 days was administered orally.

Those suffering from diabetes mellitus, features of toxaemia and complications of urticaria or who had taken any form of treatment were excluded from this study. The patients were informed of the expected benefits and hazards. Clinical assessment of the patient was done fortnightly.

Observations and Results

There was significant improvement in the subjective parameters except in the swelling and rhonchi. The findings of demographic and subjective parameters were as follows:

During the course of study, patients were divided into four age groups viz. 20-30 years, 30-40 years, 40-50 years and 50-60 years. It was observed that maximum number of cases i.e. 17 cases (56.66%) belonging to age group of 20-30 years. 07 cases (23.33%) in the age group of 30-40 years, 05 cases (16.67%) in the age of group 40-50 years, 1 case (03.33%) in the age of group 50-60 years. Among the thirty patients, 14 cases (46.67%) were males, while 16 cases (53.33%) were females. This shows female predominance to develop Urticaria (Table 1) in this study.

TABLE 1
Showing Distribution of
Patients According to Age and Sex

Total No. of Cases = 30

Age group (in years)	Number and percentage of males	Number and percentage of females	Total Number and percentage	
20-30	07 (23.33)	10 (33.33)	17 (56.67)	
30-40	04 (13.33)	03 (10.00)	07 (23.33)	
40-50	02 (06.67)	03 (10.00)	05 (16.67)	
50-60	01 (03.33)	00 (00.00)	01 (03.33)	
Total	14 (46.67)	16 (53.33)	30 (100.00)	

Patients were divided into five categories according to their occupation as students, service, labour, business and housewife. The number of cases falling in each category was 05 (16.67%), 03 (10.00%), 09 (30.00%), 04 (13.33%) and 09 (30.00%), respectively. Thus it was observed that maximum number of patients belong to labourers and housewives (Table 2).

During the course of study the patients were also divided into two groups according to their food habits. It was observed that 20 (66.67%) belong to those who used mixed diet, while 10 cases (33.33%) were vegetarian (Table 3).

Our drugs had combined effect on all the clinical features of Urticaria. The significant effect was observed in patients with clinical feature of generalised itching (Table 4).

TABLE 2
Showing Distribution of
Patients According to their Occupation

Total	No.	of	Cases	=30

Occupation	Number of Patients	Percentage		
Students	5			
Service	3	10.00%		
Labour	9	30.00%		
Business	4	13.33%		
House wife	9	30.00%		
Total	30	100.00%		

TABLE 3
Showing Distribution of Patients According to Food Habits

Total No. of Cases = 30

Food Habits	Number of Patients	Percentage		
Vegetarian diet	10	33.33%		
Mixed diet	20	66.67%		
Total	30	100.00%		

TABLE 4
Showing Effect of Drugs on Clinical Features of Urticaria

Total No. of Cases = 30

	Follow-Up (in days)						
	Before treatment	After Treatment					
Clinical Features	0 day	15th day 30th day		45th day			
	Total No. of patients	No. of patients	Improved percentage	No. of patients	Improved percentage	No. of patients	Improved Percentage
Local Itching	30	19	36.67	09	70.00	07	76.67
Swelling	07	05	28.57	04	42.86	03	57.14
Generalized Itching	21	14	33.33	08	61.90	03	85.71
Rhonchi	03	03	00.00	02	33.33	01	66.67

Discussion

In the present study, the efficacy of *Irasa* (*Iris ensata* Thunb.), *Zanjabeel* (*Zingiber officinalis* Rosc.), *Qaranfal* (*Eugenia caryophyllata* Thunb.) and *Maghz-e-Amaltas* (*Cassia fistula* Linn.) was evaluated over a period of 45 days on the basis of improvement in the subjective parameters.

While analyzing the age group the patients were divided into four age groups. It was observed that maximum number of cases i.e. 17 (56.66%) belong to age group 20-30 years. It is well synchronized with the fact that highest incidence of Urticaria occurring in the persons of third decade of life⁴.

During the study, students and housewives were dominated. It may be due to the fact that labourers have risk for worm infestation and secondly they come in contact with various physical agents, which may trigger the urticarial reaction. Housewives get exposed to dust and various allergens while doing house hold work, which may be responsible for the development of Urticaria².

When the distribution of patients was done according to their clinical presentation, it was observed that the most consistent presentation was local itching in all the cases while generalised itching in 21 cases, swelling in 07 cases and rhonchi in 03 cases.

At the end of study, maximum benefit was observed in the generalised itching (85.71%) group followed by local itching (76.67%). Anti-allergic activity of *Zanjabeel*, anti pruritic and cooling properties of *Maghz-e-Amaltas* and blood purifying property of *Irasa* may be attributed to these effects of drugs¹¹⁻¹³.

There was 57.14% improvement in the patients of swelling, which may be due to the anti-inflammatory activity of *Maghz-e-Amaltas*, *Zanjabeel* and *Qaranfal*^{12,14}. The rhonchi were improved by 66.67% at the end of study. Expectorant property of *Irasa*, *Qaranfal* and *Zanjabeel* and antispasmodic activity of *Qaranfal* may be attributed also to the studied effect of drugs^{12, 13, 15, 16}.

Conclusion

This study shows the effect of coded Unani formulation to have an encouraging potential in Urticaria management with no major adverse effects and the patients tolerated this therapy well. Further long term studies to determine the relapse rate and the effect of Unani formulation on swelling and rhonchi along with standardization of active ingredients, purity and concentration needs to be done.

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