

## A Cross-Sectional study of Drug Prescription Pattern in Urticaria patients attending Dermatology & Venereology Department in a Rural Tertiary Care Teaching Hospital

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### Abstract

**Background:** Urticaria is a very common skin condition characterized by recurrent, pruritic (itchy), pink-to-red edematous (swollen) lesions that often have pale centers (wheals). Histamine is the main mediator of urticaria and H<sub>1</sub> antihistamines represent the initial and mainstay treatment of urticaria. The newer second generation H<sub>1</sub> antihistamines are preferred over the older first generation H<sub>1</sub> antihistamines as the initial choice of therapy due to its less sedating and less cholinergic side effects. Although numerous treatments are available for urticaria, there is little information about the prescription pattern for the treatment of urticaria. Hence this study was conducted.

**Methods:** This was a cross-sectional study conducted on 100 newly diagnosed and untreated patients of urticaria who attended Dermatology and Venereology outpatient department of a rural tertiary care teaching hospital. The prescriptions were collected for the duration of 18 months and details of prescription (particulars of the patient, diagnosis, name of the drugs, dose, route of administration, total duration etc.) were collected in case record forms.

**Results:** Majority of the patients (34) belonged to the age group of 21-35years. The mean age of the patients was 34.35±15.26 years. Most of the patients were treated with oral antihistamines. Among oral antihistamines, most of the patients received 2<sup>nd</sup> generation antihistamines either as monotherapy or in combination with 1<sup>st</sup> generation antihistamines and H<sub>2</sub> blockers. Among 2<sup>nd</sup> generation antihistamines, fexofenadine was prescribed highest either as monotherapy or in combination with levocetirizine and cetirizine. Patients with more severe form of disease were treated with combination of oral and parenteral therapy. Further long term study is required for proper assessment of prescription pattern in urticaria patients.

**Conclusion:** Most of the patients with urticaria can be effectively treated with Oral antihistaminic medication, and additional parenteral therapy may be required only for severe cases of acute on chronic urticaria.

**Keywords:** Urticaria, Oral medication, Parenteral therapy, Antihistamines.

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### Introduction

The term urticaria is defined as a transient eruption of circumscribed oedematous and usually itchy swelling of the dermis.<sup>[1]</sup> 15 to 20% of the general population will have urticaria at least once during their lifetime. Although most episodes of acute urticaria last for only a short duration, chronic urticaria can be quite distressing and even disabling for many patients. Degranulation of mast cells with release of histamine is the main mediator of urticaria and antihistamines are the initial and mainstay treatment of all urticaria.<sup>[2,3]</sup> An ideal antihistaminic drug should have a faster onset of action and fewer side effects. The new second generation H<sub>1</sub> antihistamines fulfil these criteria and these are the main stay of urticaria treatment at present.<sup>[1]</sup>

The treatment is usually started with a second generation non-sedating (or less sedating)

antihistamines like cetirizine, levocetirizine, loratadine, fexofenadine, etc.<sup>[2]</sup> Along with this, first-generation antihistamines, histamine H<sub>2</sub> blockers, leukotriene receptor antagonists, and brief corticosteroid bursts may be used as adjunctive treatment.<sup>[2]</sup>

Because of the variability in the severity and duration of the disease, availability of wide therapeutic options and their wide range of adverse effects the prevalent pattern of treatment may vary in different geographical regions, ethnic groups and also in different medical establishments. There are not much systematically analyzed data available in the Indian literature, regarding the pattern of drug use in urticaria patients. Hence, the present study was conducted to generate baseline data about prescription pattern in urticaria patients.

### Aims and Objectives

To assess the drug prescription pattern in urticaria patients attending Dermatology & Venereology Department in a Rural Tertiary Care Teaching Hospital.

### Materials and Methods

**Study design:** The present study was a Cross-Sectional study conducted in the Dermatology and Venereology

Out-patient Department (OPD) of a rural tertiary care teaching hospital to determine the drug prescription pattern in urticaria patients attending Dermatology & Venereology OPD.

**Study subjects:** All new patients who were diagnosed to have urticaria attending Dermatology & Venereology out-patient Department (OPD) of a rural tertiary care teaching hospital during the study period were included in this study.

The patients were enrolled with prior written informed consent in English, Hindi and Marathi languages after fully explaining the study procedure to their satisfaction. Approval and clearance from the Institutional Ethics Committee was obtained before conducting the study. For collection of data from Dermatology & Venereology Department, permission had been taken for conducting the study.

**Study period:** This study was carried out from January 01, 2013 to June 30, 2014 (18 months).

**Sample size:** The present study was conducted in newly diagnosed urticaria patients attending Dermatology and Venereology OPD during the 18 months study period. During the study period, 113 new patients were diagnosed to have urticaria. Out of 113 newly diagnosed urticaria patients, 100 patients fulfilled the inclusion and exclusion criteria and were included in the study.

#### **Inclusion criteria**

1. Patients newly diagnosed as having urticaria attending Dermatology and Venereology OPD during the study period.
2. Patients who gave their written informed consent for participation in the study.

#### **Exclusion criteria**

1. Patient who were already under treatment for urticaria.
2. Drugs used for other reasons associated with these diseases.
3. Drug induced urticaria.
4. Lack of consent for participation in the study.

#### **Study procedure**

After signing the consent form, relevant data were collected from the prescriptions of the patients, immediately following consultation. Information about general particulars of the patients and the drugs prescribed to patients were noted. Collected data are as follows:

1. Particulars of the patients which included patient initials, age, sex, address and date of visit.
2. Diagnosis of the patients, and investigations advised.
3. Drug details noted were as follows:
  - A. Name of the drugs.
  - B. Dose and frequency of drug administration.
  - C. Route of drug administration.
  - D. Duration of drug use.
  - E. Total number of drugs used for each patient.

The above data was recorded using a Case Record Form.

#### **Statistical analysis**

Statistical analysis was done by using descriptive & inferential statistics using Chi-square test. The software used in the analysis was SPSS 17.0 version and Graph Pad Prism 5.0.  $p$ -value  $<0.05$  was considered as level of significance.

#### **Results**

The study was conducted in the Dermatology and Venereology out-patient Department (OPD) of a rural tertiary care teaching hospital to determine the prescription pattern in newly diagnosed urticaria patients.

**Table 1** shows age and gender distribution of the study patients. Out of the 100 patients, 39 were males and 61 were females. The mean age in urticaria patients was  $34.35 \pm 15.26$  years and majority of the patients ( $n=34$ ) were in the age group between 21-35 years. No significant difference ( $p=0.88$ ) in age was found between male and female patients.

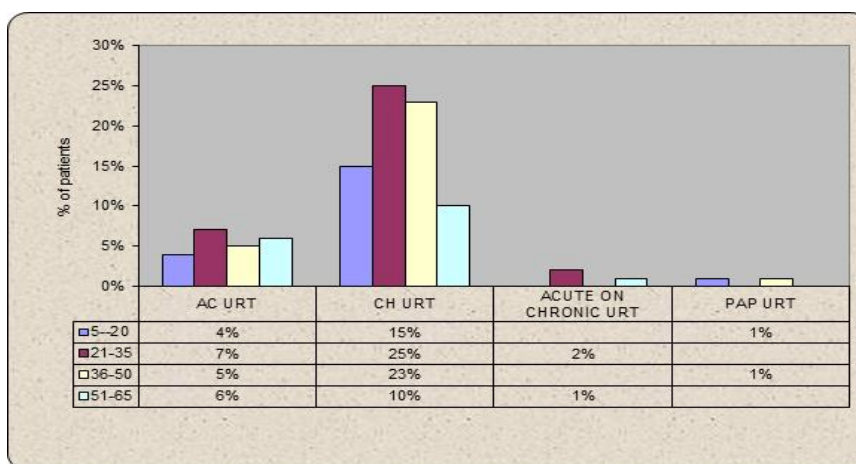
**Fig. 1** shows different clinical types of urticaria. Among different clinical types, 73 patients had chronic urticaria (CH URT), 22 patients had acute urticaria (AC URT), 3 patients had acute exacerbation of chronic urticaria (ACUTE ON CHRONIC URT) and 2 patients had papular urticaria (PAP URT). **Fig. 2** shows percentage of oral (O) and oral+parenteral (O+PT) therapy. Out of 100 patients, oral therapy was prescribed in 80 patients and parenteral therapy was prescribed in 20 patients. **Fig. 3** shows different types of oral therapy (O). Among oral therapy, 1<sup>st</sup> generation H<sub>1</sub> antihistamines (G1H1AH) alone ( $n=6$ ) was prescribed in 1 patient of acute urticaria and 5 patients of chronic urticaria, 2<sup>nd</sup> generation H<sub>1</sub> antihistamines (G2H1AH) alone ( $n=49$ ) was prescribed in 10 patients of acute urticaria, 38 patients of chronic urticaria and 1 patient of papular urticaria. Combination of 1<sup>st</sup> and 2<sup>nd</sup> generation H<sub>1</sub> antihistamines (G1H1AH + G2H1AH) ( $n=13$ ) was given in 4 patients of acute urticaria, 8 patients of chronic urticaria and 1 patient of papular urticaria. Combination of 2<sup>nd</sup> generation H<sub>1</sub> antihistamines and H<sub>2</sub> antihistamines (G2H1AH + H2AH) ( $n=12$ ) was prescribed in 3 patients of acute urticaria and 9 patients of chronic urticaria. No patient of acute on chronic urticaria received oral therapy. **Fig. 4** shows 2<sup>nd</sup> Generation antihistaminic (G2H1AH) therapy. Among patients receiving oral therapy alone ( $n=80$ ), 49 patients were treated with different types of 2<sup>nd</sup> generation antihistamines (G2H1AH). Among oral G2H1AH therapy, tab.fexofenadine (T.FFND) alone ( $n=15$ ) was prescribed in 2 patients of acute urticaria and 13 patients of chronic urticaria, tab.levocetirizine (T.LCET) ( $n=4$ ) was prescribed in 1 patient of acute urticaria, 3 patients of chronic urticaria.

T.FFND+T.LCET combination therapy (n=23) was given in 7 patients of acute urticaria, 15 patients of chronic urticaria and 1 patient of papular urticaria and T.FFND+T.CET combination therapy was prescribed in 7 patients of chronic urticaria. **Fig. 5** shows Oral +parenteral therapy (O+PT) Combination of oral+parenteral (O+PT) therapy was prescribed in 20 patients. Oral agents used along with parenteral therapy included GIH1AH, G2H1AH, H2AH, oral corticosteroid (prednisolone) either as monotherapy or combination therapy. Histaglobulin (human gamma globulin +histamine dihydrochloride) and Injection pheniramine maleate were used as parenteral therapy.

**Table 1: Age and gender distribution (n = 100)**

Age distributio n	Gender (%)		Total
	Male	Female	
5-20	9	11	20
21-35	12	22	34
36-50	12	17	29
51-65	6	11	17
Total	39	61	100
Mean ± SD	34.07±15.9	34.52±14.9	34.35±15.2
κ <sup>2</sup> -value	5	2	6
	0.66.p=0.88,NS,p>0.05		

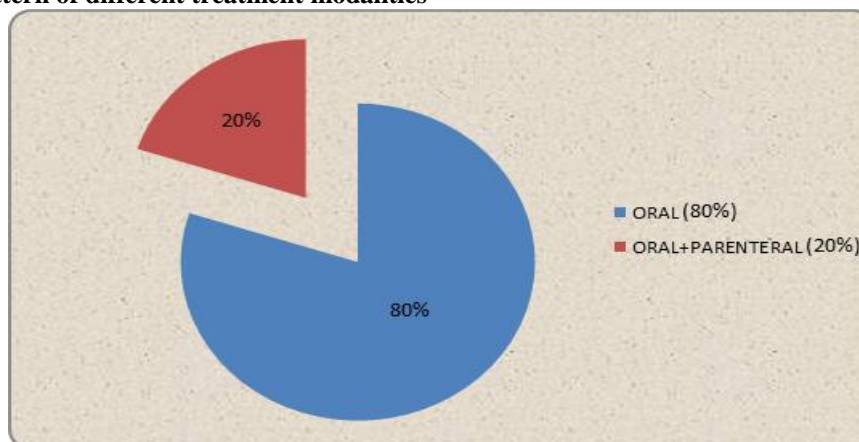
n- Number of patients, κ<sup>2</sup> -Chi-square, SD-Standard deviation, NS-Non-significant



**Fig. 1: Shows different clinical types of urticaria**

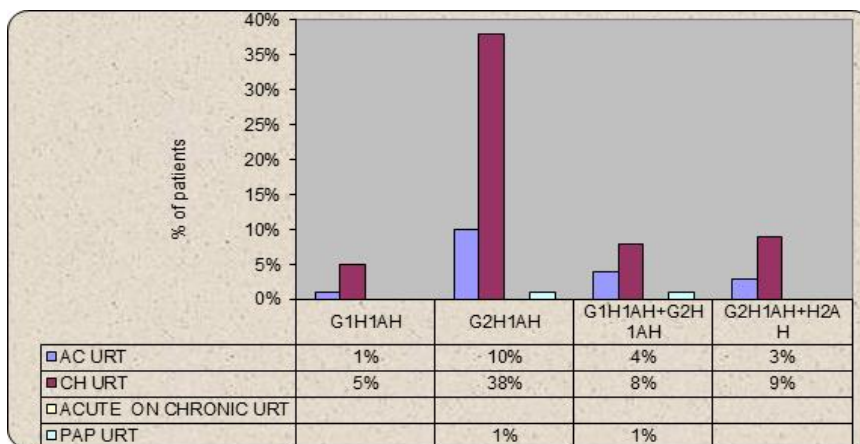
AC URT- Acute urticaria, CH URT- Chronic urticaria, ACUTE ON CHRONIC URT- Acute on chronic urticaria, PAP URT- Papular urticaria

**Prescription pattern of different treatment modalities**



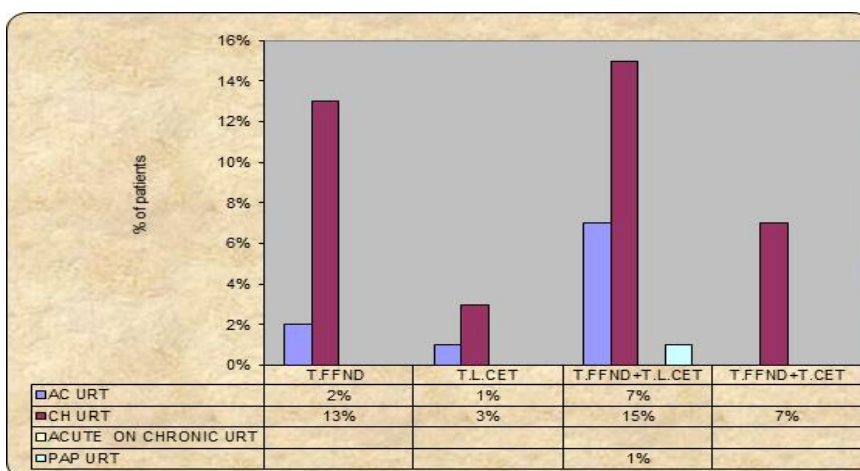
**Fig. 2: Oral (O) and Oral+Parenteral (O+PT) therapy**

O-Oral, O+PT-Oral+Parenteral



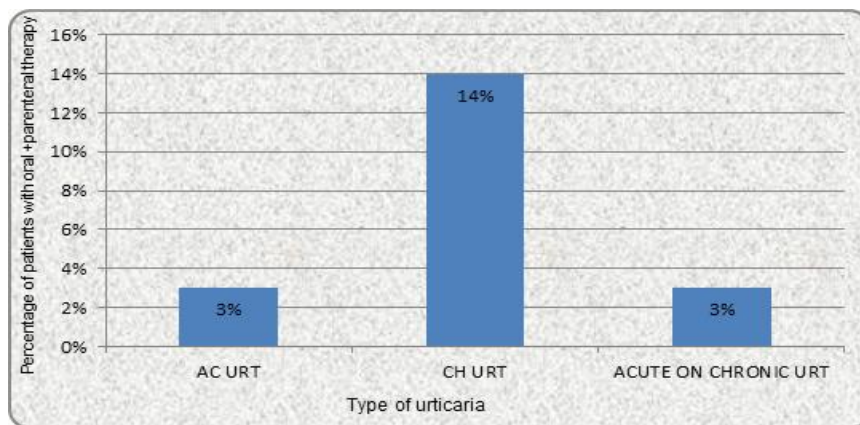
**Fig. 3: Graphical presentation of different types of oral therapy (O)**

G1H1AH-1<sup>st</sup> Generation H<sub>1</sub> antihistamines, G2H1AH-2<sup>nd</sup> Generation H<sub>1</sub> antihistamines, H2AH-H<sub>2</sub> antihistamines



**Fig. 4: Graphical presentation of 2<sup>nd</sup> Generation antihistaminic (G2HIAH) therapy**

T.FFND-Tablet Fexofenadine, T.LCET-Tablet Levocetirizine, T.CET-Tablet Cetirizine



**Fig. 5: Graphical presentation of Oral+Parenteral therapy (O+PT)**

**Discussion**

In the present study, the drug prescription pattern was assessed in newly diagnosed urticaria patients, who attended the Dermatology and Venereology out-patient Department (OPD) in a Rural Tertiary Care Teaching Hospital. During the study period 113 new patients diagnosed as having urticaria, were attended in

Dermatology and Venereology OPD. Among 113 new patients of urticaria, 100 patients fulfilled the inclusion and exclusion criteria and were available for follow up for 4 weeks and none of the patients dropped out of the study.

**Table 1** show the age and sex distribution in urticaria patients. The mean age of the patients was

34.35±15.26 years and majority of the study patients (34%) were in the age group of 21-35 years. Hayder R. Al-Hamamy et al<sup>[4]</sup> also found similar mean age of 32±11 in their clinical study.

61% were females and 31% were males, indicating higher prevalence in females. There was no significant difference in the mean age in male and female patients.

**Prescription pattern:** Clinical diagnosis was done by the treating Dermatologist mostly by taking detailed patient history and thorough physical examination. Laboratory investigations were done in selected cases (n=19) to confirm diagnosis.

**Fig. 1** shows the different clinical types of urticaria in our study. Chronic urticaria was the most common type, observed in 73% of the patients followed by acute urticaria observed in 22% of the patients. There were 2 patients with papular urticaria and 3 patients came with acute exacerbation of chronic urticaria. According to literature, acute urticaria is the most common type of urticaria patients. Acute urticaria can also occur as adverse drug reaction of various drugs due to hypersensitivity reaction to these drugs.<sup>[3]</sup> We have already excluded drug induced urticaria, which might be the cause of less number of patients of acute urticaria in our study.

The treatment modalities employed in the present study has been summarized in **Fig. 3, 4, 5 and 6**. The therapy for urticaria mainly involved various oral medications along with parenteral medications in selected cases. The oral therapy alone was considered in 80% of the patients while oral along with parenteral therapy was considered in rest 20% of the patients with more severe form of disease and in some patients in whom chance of recurrence is more.

Oral antihistamines were prescribed in all the patients (n=80) who received oral medication. No patient has received H<sub>2</sub> antihistaminic as monotherapy. Zaraq I et al in their study found that all 233 chronic urticaria patients were treated with oral antihistamines.<sup>[5]</sup>

Among oral antihistamines, second generation H<sub>1</sub> antihistamines monotherapy was prescribed highest in 49 patients which is in accordance with literature that second generation antihistamines have faster onset of action and less side effects and they are the mainstay of treatment in urticaria.<sup>[1]</sup>

Among H<sub>1</sub> antihistamines first generation antihistamines were used as monotherapy in 6 patients. Second generation antihistamines were used as monotherapy in 49 patients, as combination with first generation antihistamines in 13 patients and as combination with H<sub>2</sub>antihistaminics in 12patients. First generation antihistaminic monotherapy was given only for short duration maximum up to 7 days before sleep in patients whose sleep was disturbed due to itching. Among first generation antihistamines, hydroxyzine and pheniramine maleate were used. Hydroxyzine was

used in a dose of 25mg tid which was in accordance with literature.<sup>[6]</sup>

In 13 patients, 1<sup>st</sup> generation antihistamines were prescribed at night and second generation H<sub>1</sub> antihistamines were prescribed during day time. This pattern is similar to other studies.<sup>[7]</sup> This combination therapy does not disturb sleep and day time activities are not hampered.

Both H<sub>1</sub> antihistaminic and H<sub>2</sub>antihistaminic combination therapy was given in 6 patients. Since 15% of histamine receptors in the skin are H<sub>2</sub>-type receptors, H<sub>2</sub> antihistamines may also be helpful in some patients with urticaria but not be used as monotherapy.<sup>[3]</sup> **Mrs. Manjusha Sajith et al** found use of H<sub>2</sub> antihistaminic ranitidine in combination with other antihistamines in the treatment of urticaria.<sup>[8]</sup>

Maximum number of patients were treated with second generation H<sub>1</sub> antihistamines only which is similar to another study.<sup>[8]</sup> In our study, among the second generation H<sub>1</sub> antihistaminic, fexofenadine was prescribed highest as monotherapy (n=15) or in combination with levocetirizine (23) and cetirizine (7). Levocetirizine monotherapy was given in 4 patients.

In addition to oral antihistamines, other adjuvant oral medication were given which included oral corticosteroid prednisolone in four patients and antiparasitic drugs albendazole alone or in combination with ivermectin was prescribed in six patients and leukotriene antagonist montelukast in two patients. Patients with severe urticaria, a brief course of oral corticosteroids can be given.<sup>[3]</sup> Various gastro-intestinal parasites rarely may be responsible for causing urticaria for which antiparasitic drug may be helpful.<sup>[1]</sup>

Topical medication including emollient, calamine lotion and topical corticosteroid were also used in some patients as adjuvant therapy.

Oral and parenteral therapy was given in 20patients.Parenteral therapy included injection human gamma globulin 12mg with histamine dihydrochloride 0.15mg and Inj.pheniramine maleate. Pheniramine maleate IM injection alone was given in three patients of acute urticaria and three patients of acute on chronic urticaria to reduce the acute severe itching. Human gamma globulin with histamine dihydrochloride injection was prescribed in 14 patients of chronic urticaria in weekly dose for six weeks because in about one-third of patients with chronic urticaria, histamine releasing auto antibodies play a central role in the pathogenesis of chronic urticaria.<sup>[9,10]</sup>

## Conclusion

Most of the urticaria patients were treated with oral medications. Oral antihistamines formed the main stay of oral medications which included 1<sup>st</sup> and 2<sup>nd</sup> generation antihistamines and H<sub>2</sub> blockers. Among oral antihistamines, most of the patients received 2<sup>nd</sup> generation antihistamines either as monotherapy or in combination with 1<sup>st</sup> generation antihistamines and H<sub>2</sub>

blockers. Among 2<sup>nd</sup> generation antihistamines, fexofenadine was prescribed highest either as monotherapy or in combination with levocetirizine and cetirizine. Oral + parenteral therapy was reserved mostly for severe cases of urticaria and in some cases of chronic urticaria where there is chance of recurrence. As urticaria may have recurrent attacks, so study including longer duration will be helpful in assessing the prescription pattern in psoriasis patients further.

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