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**Original research article**

# Evaluation of omalizumab's efficacy and safety in the management of persistent spontaneous urticarial

**[1]Dr. Sachin Ambirwar Pundlikrao, [2]Dr. Pinninti Srivalli**

[1]Assistant Professor, Department of Pharmacology, Madha Medical College, Chennai, Tamil Nadu, India

[2]Associate Professor, Department of Dermatology, Madha Medical College, Chennai, Tamil Nadu, India

**Corresponding Author:**
Dr. Pinninti Srivalli

**Abstract**

**Background:** One in five people will have urticaria, a common inflammatory skin condition. The presence of urticaria, angioedema, or both of these symptoms is indicative of it. Using the Urticaria activity score 7, we will determine whether Omalizumab is safe and effective in treating chronic spontaneous urticaria.

**Material and Methods:** This study is a prospective study that utilizes non-probability convenience sampling. The study employed a sample size of 20. This was the one year study conducted between the August 2016 to July 2017. This study was done at Department of Dermatology, Madha Medical College, Chennai, Tamil Nadu, India.

**Results:** The prevalence of CSU was highest among individuals aged 20-40 years, which aligns with the findings of Maurer *et al*., where the most prevalent age group affected was also 20-40 years. The female-to-male ratio was 3:1, indicating a modest increase compared to the ratio of 2:1. The majority of ladies were homemakers. Angioedema does not show any correlation with age, sex, serum IgE level, or absolute eosinophil count. In our study, the occurrence of ASST positivity was 6.7%, which is lower compared to the occurrence of ASST positivity in patients with chronic urticaria in other studies, ranging from 35% to 58%. There was no correlation observed between the duration of time, the quantity of urticarial lesions, and the frequency of urticaria episodes each week.

**Conclusion:** The study observed no association between angioedema, serum IgE levels, and absolute eosinophil count with age or sex. There was no correlation between the incidence, duration, and number of lesions per day in cases with urticaria. The treatment resulted in a notable enhancement of UAS7 after 12 weeks, but, no substantial progress was observed throughout the subsequent monitoring period.

**Keywords:** Omalizumab, persistent spontaneous urticaria, efficacy and safety

## Introduction

Urticaria refers to temporary, clearly defined, shallow red or pale swellings of the skin's dermis. These swellings are typically accompanied by intense itching and a red flare around them. In some cases, angioedema may also be present. Approximately 0.5 to 1% of individuals with urticaria experience persistent spontaneous urticaria [1, 2]. Chronic spontaneous urticaria significantly impacts the individual's quality of life, leading to depression and increased rates of work absenteeism. Second-generation antihistamines are the primary treatment option for chronic spontaneous urticaria. If patients do not respond to antihistamine treatment, their dosage is escalated by up to four times. Omalizumab is prescribed as a third option for those who do not respond to antihistamine treatment for persistent spontaneous urticaria [3, 4].

Urticaria is a prevalent condition that impacts approximately 20% of individuals at some stage in their lives. The defining features of this condition are the manifestation of urticaria, angioedema, or a combination of both. Urticaria is considered chronic when symptoms persist on a daily or practically daily basis for more than six weeks [5, 6]. The prevalence of chronic urticaria ranges from 0.5% to 1%, and it is more common in females. Most cases of chronic urticaria do not have a distinct trigger, however in certain individuals, the symptoms can be caused by clearly identifiable stimuli such as heat, cold, pressure, UV radiation, or elevated body temperature. The diagnosis of chronic spontaneous urticaria (CSU) relies solely on clinical evaluation, without the necessity of conducting normal diagnostic procedures. Specific provocative tests are employed to validate the diagnosis of induced urticaria for each distinct kind [7, 8].

While the exact cause of CSU is not completely understood, there is substantial evidence suggesting that mast cell activation occurs due to autoimmune processes. The release of pre- and neo-formed mediator mast cells, including histamine, which is primarily responsible for the symptoms of urticaria, is triggered by either IgE class antibodies against its proteins or antibodies of the IgG class against the high-affinity

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receptor for IgE or against IgE itself, once activated. CSU exerts a substantial influence on the patients' quality of life, markedly disrupting their everyday professional, academic, and social engagements. Research utilising a designated survey to evaluate the well-being of individuals with urticaria reveals that the condition detrimentally impacts various elements like anxiety, despair, sleep and self-esteem. Therefore, the main objective of treatment is to achieve symptom control [9, 10].

This is a monoclonal antibody that targets free IgE and stops it from attaching to IgE Fc RI receptors on mast cells. As a result, it blocks the release of granules from mast cells. The administration frequency is once every 4 weeks and there are minimal unwanted effects. The efficacy is evaluated through the utilisation of the Urticaria Activity Score. This study involves the subcutaneous administration of Inj Omalizumab at a dosage of 300mg once every 4 weeks for a total of 3 cycles. The patients will then be followed up for a period of 12 weeks to evaluate the effectiveness and safety of omalizumab in individuals with chronic spontaneous urticaria [9-11]. To evaluate the efficacy and safety of Omalizumab in managing Chronic Spontaneous Urticaria by employing the Urticaria Activity Score 7.

**Materials and Methods**

This study is a prospective study that utilizes non-probability convenience sampling. The study employed a sample size of 20. This was the one year study conducted between the b August 2016 to July 2017. This study was done at Department of Dermatology, Madha Medical College, Chennai, Tamil Nadu, India.

**Inclusion Criteria**

- Both genders.
- Age greater than 12 years.
- Patients who are willing to provide informed consent.
- Patients who are willing to participate in follow-up.

**Exclusion Criteria**

- Hypersensitive.
- Pregnancy.
- HIV.
- Tuberculosis.

**Screening Visit**

A comprehensive medical history of the patients was obtained. Patients were evaluated and chosen according to the specified criteria for inclusion and exclusion. Consent was acquired after providing written information. A comprehensive evaluation of the condition was conducted.

**Results**

Statistical techniques are widely employed in contemporary medical research. Statistical techniques such as descriptive statistics, correlation analysis, t-test, chi-square test, and ANOVA have become widely used in medical research.

**Table 1:** Distribution by age

| Age (Years) | | Number |
|---|---|---|
| | < 20 Years | 1 |
| Valid | 20 to 40 Years | 12 |
| | > 41 years | 7 |
| | Total | 20 |

In this study, 12 participants fall between the age ranges of 20 to 40 years, while 7 participants are older than 41 years.

**Table 2:** Gender wise distribution

| Sex | Patients | % |
|---|---|---|
| Male | 8 | 40.00 |
| Female | 12 | 60.00 |
| Total | 20 | 100.0 |

The study population consisted of 60.00% females and 40.00% males.

**Table 3:** Pre Treatment Category

| | Number | % |
|---|---|---|

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| | | |
|---|---|---|
| Mild CSU | 2 | 10.0 |
| Moderate CSU | 12 | 60.0 |
| Severe CSU | 6 | 30.0 |
| Total | 20 | 100.0 |

60% of the participants in the initial trial are classified as having moderate to severe chronic spontaneous urticaria (CSU).

**Table 4:** Frequency of urticaria per week

| Sr. No. | Days/week urticaria | Number | % |
|---|---|---|---|
| 1. | 2 | 2 | 10.0 |
| 2. | 3 | 2 | 10.0 |
| 3. | 4 | 3 | 15.0 |
| 4. | 5 | 5 | 25.0 |
| 5. | 6 | 4 | 20.0 |
| 6. | 7 | 4 | 20.0 |
| 7. | Total | 20 | 100.0 |

The majority of the study population experienced urticarial lesions with a frequency above 5 days per week.

**Table 5:** Angioedema

| Sr. No. | Angioedema | Number | % |
|---|---|---|---|
| 1. | No | 18 | 90.0 |
| 2. | Yes | 02 | 10.0 |
| 3. | Total | 20 | 100.0 |

Angioedema was observed in a mere 10% of the study population.

**Discussion**

The prevalence of CSU was highest among those aged 20-40 years, which aligns with the findings of Maurer *et al*., where the most prevalent age group was also 20-40 years. The ratio of females to males was 3:1, which is somewhat greater than the ratio of 2:1. The majority of ladies were homemakers. Angioedema does not show any correlation with age or sex, serum IgE level, or absolute eosinophil count. In our study, the occurrence of ASST positivity was 6.7%, which is lower compared to the occurrence of ASST positivity in patients with chronic urticaria in previous studies, ranging from 35% to 58%. There was no correlation observed between the duration of time, the quantity of urticarial lesions, and the frequency of urticaria episodes each week [11-13].

The following inference was derived from the paired t-test. Omalizumab is efficacious in managing the disease. During the period from pre-treatment to treatment week 12, there was a significant and consistent improvement in the UAS7 score [14]. During the follow-up period, there was a marginal increase in the UAS7 score, and the efficacy of Omalizumab was not statistically significant. Following the duration of the treatment, there was no notable enhancement in the UAS7 score. However, the response differs among individuals within the research population. This finding is reminiscent of the research conducted by Maurer *et al*., in which they observed a consistent enhancement in the UAS7 throughout the duration of the treatment period. The average UAS 7 score for the total study population significantly dropped from the pre-treatment period to the follow-up period, which was consistent with the findings of the ASTERIA I and ASTERIA II studies [15-17].

The UAS 7 consists of two components, namely the itch severity score and the wheals score. Following the administration of Inj Omalizumab, a significant reduction in the wheals score component of UAS7 was observed, whereas there was only a small drop in the itch severity score component [18, 19]. In this study, the remission length of urticaria symptoms ranges from 3 to 4 months for some patients, which is shorter than the average remission period of 6 to 9 months observed in the ASTERIA II study. The study period revealed an adverse effect of Pseudo scleroderma with the delivery of a single dosage of omalizumab. Omalizumab administration was postponed for the patient, who is currently being investigated to see whether the adverse event was directly caused by omalizumab or merely coincidental [20-22].

Omalizumab is used as a third option in the treatment of persistent spontaneous urticaria that does not respond to a four-fold increase in second-generation antihistamines. This study utilised a convenient sampling method to identify a study group consisting of 20 patients. After obtaining their informed consent, the patients were given 3 doses of Inj Omalizumab 300mg subcutaneously, with each dose provided once every four weeks. The effectiveness of Omalizumab was evaluated using the Urticaria Activity Score 7. The UAS7 does a 3-month follow-up of the patients and subsequently analyses the data

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[23-25].

**Conclusion**

The findings of this investigation are as follows: The predominant age range falls between 20 and 40 years, with a female-to-male ratio of 3 to 1. There is no correlation observed between angioedema, serum IgE levels, and absolute eosinophil count with respect to gender or age. There is no correlation between the frequency of urticaria per week, the duration of urticaria in years, and the number of urticarial lesions per day. During the 12-week therapy period, there is a significant and consistent improvement in the UAS7 compared to the initial baseline UAS7. However, there was no notable enhancement observed over the duration of the follow-up period.

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**Conflict of Interest:** None.

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