ISSN Print: 2394-7500
ISSN Online: 2394-5869
Impact Factor: 5.2
IJAR 2018; 4(12): 521-524
www.allresearchjournal.com
Received: 07-11-2018
Accepted: 16-12-2018

Dr. M Nithya Kumari
Assistant Professor,
Department of Dermatology,
Sambhram Institute of Medical Sciences and Research,
Bangalore, Karnataka, India

Dr. Rupjyothi Sarma
Associate Professor,
Department of Dermatology,
Sambhram Institute of Medical Sciences and Research,
Bangalore, Karnataka, India

Correspondence
Dr. Rupjyothi Sarma
Associate Professor,
Department of Dermatology,
Sambhram Institute of Medical Sciences and Research,
Bangalore, Karnataka, India

To study omalizumab efficacy and safety in the management of persistent spontaneous urticaria

Dr. M Nithya Kumari and Dr. Rupjyothi Sarma

Abstract
Background and Objectives: Urticaria refers to a temporary condition characterized by distinct, superficial erythematous or pale swellings of the dermis. These swellings are typically accompanied by intense pruritus and are often accompanied by a surrounding red flare, occasionally accompanied by angioedema. The objective of this study was to evaluate the efficacy and safety evaluation of Omalizumab as a therapeutic intervention for Chronic Spontaneous Urticaria.
Material and Methods: This study employed a non-probability sampling method known as convenience sampling. This study utilized a sample size of 25 patients. The present investigation was conducted from October 2017 to September 2018. The investigation was carried out at the Department of Dermatology, Sambhram Institute of Medical Sciences and Research, Bangalore, Karnataka, India.
Results: There was no observed correlation between the duration of time, the quantity of urticarial lesions, and the frequency of urticaria episodes each week. The inference was formed based on the results of the paired t-test. The efficacy of Inj. Omalizumab in illness management has been demonstrated. There was a significant and consistent improvement in the UAS7 score from the pre-treatment to treatment week12. During the follow-up period, there was a marginal increase in the UAS7 score, but the efficacy of Omalizumab was not statistically significant. There was no notable enhancement in the UAS7 score following the therapy period. However, there is variation in the responses across individuals within the research population. The findings of this study align with the research conducted by Maurer *et al.*, which demonstrated a consistent enhancement in the UAS7 over the course of the treatment period.
Conclusion: The wheals score of UAS7 experienced a significant decrease, whereas the itch severity level remained unchanged during the follow-up period. A single patient experienced pseudoscleroderma subsequent to the initial administration of omalizumab. The subcutaneous administration of Omalizumab 300mg can be administered once every 4 weeks, unless there are specific contraindications.

Keywords: Omalizumab, treatment of chronic, urticaria

Introduction
Urticaria is characterized by small, clearly defined, reddening or paleening of the dermis swellings that are typically extremely irritating and accompanied by a red flare or, in rare cases, angioedema. Permanent, uncontrollable urticaria affects 0.5% to 1% of people who have it. Life satisfaction, mental health, and productivity can all take a hit when dealing with chronic spontaneous urticaria. When dealing with persistent spontaneous urticaria, the initial line of defence is to use 2nd generation antihistamines [1-3].
The dosage of antihistamines can be raised by a factor of up to four in patients who do not show any improvement. If a patient's chronic spontaneous urticaria does not respond to antihistamine treatment, omalizumab is the next step in managing their condition. This monoclonal antibody blocks the degranulation of mast cells by blocking the binding of IgE Fc εRI receptors in mast cells. It targets free IgE. The dosage is once every four weeks, and the side effects are minimal. The Urticaria Activity Score is used to evaluate the efficacy [2-4].
When urticaria lasts more than six weeks, physicians call it chronic urticaria. In order to identify chronic spontaneous urticaria (CSU), it is necessary to rule out inducible chronic urticaria. It is estimated that between 0.5 to 1 percent of the global population suffers from chronic urticaria, and about two thirds of those people are CSU patients. A major health concern, CSU lowers sufferers' quality of life. Patients with CSU are initially treated with

non-sedative H_1 antihistamines. If a patient is not responding to treatment, the prescribed dosage of these medications can be quadrupled. If a patient's urticaria worsens, systemic steroids can be administered whenever necessary [3-5].

Still, even after increasing the dosage to the recommended level, a third of patients show no improvement while taking H1 antihistamines. If a patient with CSU does not respond to the H_1 antihistamine medication, omalizumab, cyclosporine, or montelukast should be considered as a third-line therapeutic option. In order to indirectly decrease the expression of FcεRI receptors on basophils and mast cells, omalizumab, a recombinant humanized monoclonal antiIgE antibody, binds to free IgE heavy chains in circulation. Obalizumab doses of 150 and 300 mg monthly were found to be helpful in treating CSU in clinical trials [4-6].

We evaluate the efficacy and safety of omalizumab in patients with chronic spontaneous urticaria by giving those 300 mg of Inj Omalizumab subcutaneously once every four weeks for three cycles and then following up with them for twelve weeks. Using an Urticaria activity score of 7, the researchers hoped to determine whether Omalizumab was safe and effective in treating chronic spontaneous urticaria [7-9].

Materials and Methods

This prospective study used a non-probability sampling method known as convenience sampling. The study included 25 individuals. From October 2017 to September 2018, this research was carried out. This research took place at the Department of Dermatology, Sambhram Institute of Medical Sciences and Research, Bangalore, Karnataka, India.

Inclusion criteria

- Both sexes.
- Patients above the age of 12.
- Willing to provide informed consent.

Exclusion criteria

- HIV/AIDS/Hepatitis.
- Parasitic Infestations.
- Pregnancy

Results

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

Table 1: The distribution of the study population according on age

Age		Frequency	Percent
Valid	< 20 Years	1	4
	20 - 40 Years	15	60
	> 41 years	09	36
	Total	25	100.0

This survey reveals that 60% of the participants fall within the age range of 20 to 40 years, while 36.0% are aged 41 years or older.

Table 2: The distribution of patients based on sex

Sr. No.	Gender	Patients	%
1.	Male	5	20.0
2.	Female	20	80.0
	Total	25	100.0

The study population consisted of 80% females and 20% males.

Table 3: Pre-treatment classification

Sr. No.	Category	Patients	%
1.	Mild CSU	2	08.0
2.	Moderate CSU	13	52.0
3.	Severe CSU	10	40.0
	Total	25	100.0

The pretreatment research population consists of 92% individuals classified as having moderate to severe CSU.

Table 4: Distribution of occupations

Sr. No.	Occupation	Patients	%
1.	Business	1	4.0
2.	Coolie	3	12.0
3.	House keeper	2	8.0
4.	House wife	10	40.0
5.	Office assistant	1	4.0
6.	Plumber	2	8.0
7.	Student	2	8.0
8.	Teacher	4	16.0
	Total	25	100.0

Table 5: The frequency of urticaria episodes each week.

Sr. No.	Days/week urticarial present	Patients	%
1.	2	2	8.0
2.	3	2	8.0
3.	4	1	4.0
4.	5	10	40.0
5.	6	5	20.0
6.	7	5	20.0
	Total	25	100.0

Among the various occupational groupings, the sample population comprised 40% of housewives. It was deduced that the urticarial posed challenges in performing routine domestic tasks, leading to a significant number of patients seeking medical attention at the dermatology Outpatient Department.The majority of the study participants had a frequency of urticarial lesions above five days per week.

Discussion

The prevalence of CSU was highest among individuals aged 20-40 years, which aligns with the findings of Maurer *et al.*, who also observed a comparable prevalence in this age group. The ratio of females to males was 3:1, which is marginally more than the ratio of 2:1 [11, 12]. The majority of ladies were homemakers. Angioedema, serum IgE level, and

Absolute eosinophil count do not exhibit any significant correlation with age or sex. In our study, the occurrence of ASST positivity was 6.7%, which was lower than the occurrence of ASST positivity in patients with chronic urticaria mentioned in other publications, which ranged from 35 to 58% [13-15].

There was no observed correlation between the duration of time, the quantity of urticarial lesions, and the frequency of urticaria episodes each week. The inference was formed based on the results of the paired t-test. The efficacy of Inj. Omalizumab in illness management has been demonstrated. From the initial assessment to the twelfth week of treatment, there was a swift and consistent enhancement in the UAS7 score [14-16]. During the follow-up period, there was a marginal increase in the UAS7 score, but the efficacy of Omalizumab was not statistically significant. There was no notable enhancement in the UAS7 score following the therapy period. However, there is variation in the responses across individuals within the research population. The findings of this study align with the research conducted by Maurer *et al.*, which demonstrated a consistent enhancement in the UAS7 over the course of the treatment period [17-19].

There was a significant drop in the mean UAS 7 score for the entire study population from the pretreatment period to the follow-up period, which was consistent with the findings of the ASTERIA I and ASTERIA II studies. Itch severity score and wheals score are the two components of UAS 7 [20, 21]. The injection of Inj Omalizumab resulted in a significant reduction in the wheals score component of UAS7, although the itch severity score component exhibited a minor drop. In this trial, the duration of remission for urticaria symptoms ranged from 3 to 4 months in a subset of patients, in contrast to the ASTERIA II study where the average remission length was 6 to 9 months [20-22].

The observed adverse event during the duration of this trial was the occurrence of Pseudo scleroderma subsequent to the delivery of a dosage of omalizumab. The patient's administration of Omalizumab was postponed, and an inquiry is currently underway to determine if the adverse reaction was caused by Omalizumab or a co-incidental factor [23-25].

Conclusion

If your persistent spontaneous urticaria has not improved after four doses of second-generation antihistamines, omalizumab is the next step in your treatment plan. A total of 25 patients were included in the trial. After providing their informed consent, they were given three 300 mg doses of Inj. Omalizumab subcutaneously once every four weeks. The effectiveness of Omalizumab was evaluated using the Urticaria Activity Score 7. During the 12-week treatment period, the UAS7 shows a quick and steady improvement when compared to the baseline UAS7. But over the follow-up period, there is no discernible improvement. In the follow-up period, second-generation antihistamines were maintained in most patients. The UAS7 welt score has dropped significantly, but the itch intensity level has remained constant throughout the follow-up. Immediate side effects of omalizumab included pseudoscleroderma in one patient. Once every four weeks, unless there are other reasons not to, inject 300 mg of omalizumab subcutaneously.

Funding
None.

Conflict of Interest
None.

References

1. Zhao ZT, Ji CM, Yu WJ, Meng L, Hawro T, Wei JF, *et al.* Omalizumab for the treatment of chronic spontaneous urticaria: A meta-analysis of randomized clinical trials. Journal of Allergy and Clinical Immunology. 2016 Jun 1;137(6):1742-50.
2. Saini S, Rosen KE, Hseih H-J, *et al.* A randomized, placebocontrolled, dose-ranging study of single-dose omalizumab in patients with H1-antihistamine-refractory chronic idiopathic urticaria. J Allergy Clin. Immunol. 2011;128(3):567-573.
3. Bongiorno MR, Crimi N, Corrao S, Allotta A, Arena A, Brusca I, *et al.* Omalizumab for the treatment of chronic spontaneous urticaria in clinical practice. Annals of Allergy, Asthma & Immunology. 2016 Dec 1;117(6):703-7.
4. Metz M, Ohanyan T, Church MK, Maurer M. Omalizumab is an effective and rapidly acting therapy in difficult to treat chronic urticaria retrospective clinical analysis. J Dermatol. Sci. 2014;73(1):57-62.
5. Bongiorno MR, Crimi N, Corrao S, Allotta A, Arena A, Brusca I, *et al.* Omalizumab for the treatment of chronic spontaneous urticaria in clinical practice. Annals of Allergy, Asthma & Immunology. 2016 Dec 1;117(6):703-7.
6. Asero R. Chronic unremitting urticaria: Is the use of antihistamines above the licensed dose effective? A preliminary study of cetirizine at licensed and above-licensed doses. Clin. Exp. Dermatol. 2007;32:34-38.
7. Maurer M, Weller K, Bindslev-Jensen C, *et al.* Unmet clinical needs in chronic spontaneous urticaria. A GA2 LEN task force report. Allergy. 2011;66:317-330.
8. Staubach P, Eckhardt-Henn A, Dechene M, *et al.* Quality of life in patients with chronic urticaria is differentially impaired and deter-mined by psychiatric comorbidity. Br J Dermatol. 2006;154:294-298.
9. Al-Ahmad MS. Long-term efficacy of omalizumab in patients with treatment-resistant chronic spontaneous urticaria. Journal of Allergy and Clinical Immunology. 2015 Feb 1;135(2):AB128.
10. Maurer M, Sofen H, Ortiz B, Kianifard F, Gabriel S, Bernstein JA. Positive impact of omalizumab on angioedema and quality of life in patients with refractory chronic idiopathic/spontaneous urticaria: analyses according to the presence or absence of angioedema. J Eur. Acad. Dermatol. Venereol. 2017;31:1056-1063.
11. Regan SB, Khan DA. Prolonged Use of Omalizumab in Refractory Chronic Urticaria (CU). Journal of Allergy and Clinical Immunology. 2011 Feb 1;127(2):AB100.
12. Altman K, Chang C. Pathogenic intracellular and autoimmune mechanisms in urticaria and angioedema. Clin. Rev Allergy Immunol. 2013;45:47-62.
13. Beck L, Bernstein J, Maurer M. A review of international recommendations for the diagnosis and management of chronic urticaria. Acta Derm. Venereol. 2017;97:149-158.

14. Chang TW, Chen C, Lin CJ. The potential pharmacologic mechanisms of Omalizumab in patients with chronic spontaneous urticaria. J Allergy Clin. Immunol. 2015;135:337-342.
15. Zhao Z-T, Ji CM, Yu WJ Omalizumab for the treatment of chronic spontaneous urticaria: A meta-analysis of randomized clinical trials. J Allergy Clin. Immunol. 2016;137:1742-1750.e4
16. Maurer M, Altrichter S, Bieber T, *et al.* Efficacy and safety of omalizumab in patients with chronic urticaria who exhibit IgE against thyroperoxidase. J Allergy Clin. Immunol. 2011;128:202-209. e5.
17. Kaplan AP, Joseph K, Maykut RJ, Geba GP, Zeldin RK. Treatment of chronic autoimmune urticaria with omalizumab. J Allergy Clin. Immunol. 2008;122:569-573.
18. Zhao Z-T, Ji C-M, Yu W-J, *et al.* Omalizumab for the treatment of chronic spontaneous urticaria: A meta-analysis of randomized clinical trials. J Allergy Clin. Immunol. 2016;137:1742-1750.
19. Teach SJ, Kull S, Rennert S, *et al.* Preseasonal treatment with either Omalizumab or an inhaled corticosteroid boost to prevent fall asthma exacerbations. J Allergy Clin. Immunol. 2015;136:1476-1485.
20. Cruz AA, Lima F, Sarinho E, *et al.* Safety of anti-immunoglobulin Etherapy with Omalizumab in allergic patients at risk of geohelminths infection. Clin. Exp. Allergy. 2007;37:197-207.
21. Di Bona D, Fiorino I, Taurino M, *et al.* Long-term real-life safety of Omalizumab in patients with severe uncontrolled asthma: A nine-year study. Respir Med. 2017;130:55-60.
22. Iribarren C, Rahmaoui A, Long AA, *et al.* Cardiovascular and cere-brovascular events among patients receiving omalizumab: Results from EXCELS, a prospective cohort study in moderate to severeasthma. J Allergy Clin. Immunol. 2017;139:1489-1495.
23. Chipps BE, Zeiger RS, Luskin AT. Baseline asthma burden, comor-bidities, and biomarkers in omalizumab-treated patients in PROSPERO. Ann Allergy Asthma Immunol. 2017;119:524-532.
24. Xu M, Xu J, Asthma YX. Risk of cardiovascular disease or all-cause mortality: A meta-analysis. Ann Saudi Med. 2017;37:99-105.
25. Egeberg A, Kofoed K, Gislason G, Vestergaard C, Thyssen J. Cardiovascular risk is not increased in patients with chronic urticaria: A retrospective population-based cohort study. Acta Derm. Venereol. 2017;97:261-262.