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# Disclosing the Capability of Biomarkers: Utilizing Precision Medicine to Evaluate Omalizumab Treatment Response in Chronic Urticaria

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#### Abstract

Chronic urticaria, characterized by recurrent and persistent hives and itching, poses significant challenges in terms of effective treatment options. Omalizumab, a monoclonal antibody targeting Immunoglobulin E (IgE), has shown promising results in managing chronic urticaria; however, not all patients respond equally to this therapy. The advent of precision medicine has opened up new avenues for tailoring treatment approaches based on individual patient characteristics and biomarker analysis. This review explores the capability of biomarkers in evaluating the treatment response to omalizumab in chronic urticaria. Several potential biomarkers, including serum levels of IgE, IgE autoantibodies, and various inflammatory mediators, have been investigated as indicators of treatment response. By analyzing these biomarkers, clinicians can gain valuable insights into the underlying mechanisms of chronic urticaria and predict the likelihood of response to omalizumab therapy.

Keywords: Omalizumab • Chronic urticaria • Treatment response • Biomarkers

# Introduction

Chronic Spontaneous Urticaria (CSU) is a skin disease characterized by the formation of wheals and/or angioedema for 6 weeks or more accompanied by itching, burning, and sometimes painful sensations in the skin. Wheals are edema in the upper dermis that only lasts a short time (less than 24 hours) and are typically surrounded by reflex erythema. CSU can cause severe distress in patients due to bothersome symptoms and the unpredictable nature thereof, potentially leading to anxiety in addition to other comorbidities. Angioedema is edema that is located in the lower part of the dermis and in the subcutis, frequently remaining there for more than 24 hours. Histamine release, along with other cytokines and neuropeptides, is the primary mediator of symptoms in CSU, which is caused by activation and degranulation of mast cells. The arrival of receptor from pole cells is an exemplary sort I prompt response in the Coombs and Gell's grouping, brought about by the cross restricting of two Immunoglobulin(Ig)E particles by an allergen, which thusly are bound to the Fc-receptor on the outer layer of the pole cells [1].

In recent years, precision medicine has emerged as a promising approach for the treatment of various diseases, including chronic urticaria. Chronic urticaria, characterized by recurrent and long-lasting hives, can significantly impact patients' quality of life. Omalizumab, a monoclonal antibody therapy, has shown efficacy in managing chronic urticaria; however, treatment response varies among individuals. Biomarkers play a crucial role in predicting and evaluating treatment response, enabling a more personalized and tailored approach. This study aims to explore the potential of biomarkers in assessing the response to omalizumab treatment in chronic urticaria, thereby improving patient outcomes [2].

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Received: 01 June, 2023, Manuscript No. jmbd-23-106343; Editor Assigned: 03 June, 2023, PreQC No. P-106343; Reviewed: 15 June, 2023, QC No. Q-106343; Revised: 21 June, 2023, Manuscript No. R-106343; Published: 28 June, 2023, DOI: 10.37421/2155-9929.2023.14.580

## **Literature Review**

Chronic urticaria is a common and distressing skin disorder characterized by the recurrent appearance of hives and angioedema for more than six weeks. Omalizumab, a monoclonal antibody targeting Immunoglobulin E (IgE), has emerged as an effective treatment option for chronic urticaria patients who do not respond to standard therapies. However, there is significant heterogeneity in treatment response among patients, necessitating the need for personalized approaches. Biomarkers have shown promise in predicting and evaluating omalizumab treatment response in chronic urticaria, enabling the application of precision medicine to enhance patient outcomes.

**Clinical biomarkers:** Clinical biomarkers encompass a range of measurable parameters associated with disease characteristics and treatment response. Disease severity, duration, and symptom patterns serve as initial indicators of treatment response in chronic urticaria patients. Studies have demonstrated that patients with more severe and longstanding disease may exhibit a better response to omalizumab. Additionally, the presence of specific symptoms, such as angioedema or delayed pressure urticaria, may correlate with treatment outcomes. However, clinical biomarkers alone do not provide a comprehensive understanding of individual response, necessitating the exploration of molecular and genetic markers [3].

**Molecular biomarkers:** Molecular biomarkers offer deeper insights into the underlying mechanisms and pathways involved in chronic urticaria and omalizumab response. Cytokines, including Interleukin-6 (IL-6) and Tumor Necrosis Factor-Alpha (TNF- $\alpha$ ), have been investigated as potential biomarkers. Elevated baseline levels of IL-6 and TNF- $\alpha$  have been associated with reduced response to omalizumab therapy. Moreover, other biomarkers such as serum markers of basophil activation (e.g., histamine release assay) and autoantibodies against IgE or the high-affinity IgE receptor (Fc $\epsilon$ RI) have shown promise in predicting treatment response [4].

Genetic biomarkers: Genetic biomarkers, such as Single Nucleotide Polymorphisms (SNPs), have gained attention in identifying individuals likely to respond to omalizumab therapy. Polymorphisms in genes involved in the immune system, such as IL-4, IL-13, and IL-33, have been associated with treatment outcomes. Furthermore, SNPs in genes related to drug metabolism and pharmacokinetics, such as  $Fc_{\rm Y}$  receptors and cytochrome P450 enzymes, may influence omalizumab efficacy and adverse effects [5].

Research methodologies: To unveil the full potential of biomarkers in precision medicine for chronic urticaria, comprehensive research methodologies are essential. Prospective clinical trials involving large cohorts of patients receiving omalizumab therapy can validate the predictive value of identified biomarkers. Integration of various approaches, including gene expression analysis, proteomics, and next-generation sequencing, can aid in the discovery of novel biomarkers and elucidate the underlying molecular mechanisms.

## Discussion

Biomarkers offer a valuable tool for evaluating treatment response and predicting outcomes in chronic urticaria patients undergoing omalizumab therapy. These biomarkers can be categorized into different types, including clinical, histological, genetic, and molecular markers. Clinical markers such as disease severity, duration, and specific symptom patterns can provide initial insights into treatment response. However, to achieve precision medicine, it is crucial to delve deeper into the molecular and genetic biomarkers associated with chronic urticaria. Molecular biomarkers, including cytokines, immunoglobulins, and chemokines, have shown promise in predicting omalizumab response. Elevated levels of specific cytokines, such as Interleukin-6 (IL-6) and Tumor Necrosis Factor-Alpha (TNF- $\alpha$ ), have been associated with poor response to omalizumab therapy. Conversely, low baseline levels of IgE, the target of omalizumab, have been linked to a favorable response [6].

Furthermore, genetic biomarkers, such as Single Nucleotide Polymorphisms (SNPs) in genes related to the immune system and drug metabolism, may influence treatment outcomes. The identification and validation of these biomarkers require robust research methodologies, including prospective clinical trials and comprehensive molecular profiling. Utilizing techniques like gene expression analysis, proteomics, and next-generation sequencing can help identify novel biomarkers and decipher underlying molecular mechanisms involved in omalizumab response. Additionally, integrating biomarker analysis with clinical parameters and patient-reported outcomes can provide a holistic perspective on treatment response.

## Conclusion

Precision medicine holds significant potential in improving treatment outcomes for chronic urticaria patients receiving omalizumab therapy. Biomarkers, ranging from clinical to molecular and genetic markers, offer valuable insights into treatment response prediction and evaluation. By harnessing these biomarkers, clinicians can identify patients who are more likely to benefit from omalizumab and personalize treatment strategies accordingly. However, further research is needed to validate and standardize these biomarkers, enabling their integration into routine clinical practice. Ultimately, the integration of biomarker-guided precision medicine approaches in chronic urticaria management has the potential to optimize treatment outcomes and enhance the quality of life for patients.

# Acknowledgement

None.

# **Conflict of Interest**

There are no conflicts of interest by author.

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**How to cite this article:** Townley, Lara. "Disclosing the Capability of Biomarkers: Utilizing Precision Medicine to Evaluate Omalizumab Treatment Response in Chronic Urticaria." *J Mol Biomark Diagn* 14 (2023): 580.