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Real-world treatment patterns and outcomes of omalizumab use in patients with chronic idiopathic urticaria

Liya Wang¹; Xuehua Ke¹; Abhishek Kavati²; Debra Wertz¹; Qing Huang¹; Vincent J. Willey¹; Judith J. Stephenson¹; Benjamin Ortiz²; Brandee Paknis²; Jonathan A. Bernstein³; Lisa A. Beck,⁴

¹HealthCore, Inc., Wilmington, DE; ²Novartis Pharmaceuticals Corporation, East Hanover, NJ; ³Bernstein Clinical Research Center, LLC, Cincinnati, OH; ⁴University of Rochester Medical Center, Rochester, NY

Corresponding Author

Xuehua Ke, PhD

HealthCore, Inc.

123 Justison St, Suite 200

Wilmington, DE 19801

Email: xke@healthcore.com

Phone: 302-230-2159

Fax: 302-230-2020

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Abstract

Objective: To examine treatment patterns, treatment response, and demographic and clinical characteristics of patients with chronic idiopathic urticaria (CIU) newly initiated on omalizumab therapy in real-world practice in the United States.

Methods: This retrospective observational cohort study used US claims data from the HealthCore Integrated Research Database (HIRD[®]) augmented with medical record data to identify CIU patients newly treated with omalizumab (≥ 4 omalizumab claims within 6 months of initial claim; index date=first omalizumab claim date) between March 21, 2014 and October 31, 2015 and with ≥ 6 months pre- and ≥ 12 months post-index health plan eligibility. Study outcomes were captured from medical records for up to 12 months pre-index and up to 24 months post-index. Descriptive statistics were reported.

Results: This study consisted of 88 patients with a mean (SD) age of 43.4 (± 13.46) years, 68.2% were female, and 36 patients had ≥ 18 months post-index eligibility. Among 69 patients with documented index dose, 75.4% received omalizumab 300 mg and 69.6% remained on index dose throughout follow-up. For 52 patients with documented index dosing frequency, 96.2% had every 4-week dosing frequency. Among 86 patients with omalizumab documentation, 83.7% reported CIU improvement after omalizumab initiation and 24.4% discontinued omalizumab. For all patients, the proportion using oral corticosteroids (OCS) decreased pre- to post-index (52.3% vs. 39.8%). Similar results were observed for patients with ≥ 18 months post-index eligibility.

Conclusions: In this real-world analysis, the majority of patients remained on omalizumab for ≥ 12 months, and had a positive response. OCS use decreased following omalizumab initiation.

Introduction

An estimated 1.73 million Americans have experienced chronic idiopathic urticaria (CIU), also called chronic spontaneous urticaria [1], and only half of these will have been diagnosed by a physician [1]. CIU affects 0.5% to 1% of individuals in the United States [2, 3]. CIU is characterized by wheal and flare skin reactions that may or may not be accompanied by angioedema [2, 4, 5]. Urticaria is considered chronic when it persists for at least 6 weeks. Typically, symptoms of CIU will persist for as long as a year and in some people may linger for as long as 5 years or more [2].

Treatment guidelines issued by American medical societies recommend a stepwise approach to CIU therapy, beginning with second generation H1 antihistamines. If symptoms persist, guidelines recommend higher than approved doses of the H1 antihistamines, followed by the addition of a leukotriene receptor antagonist or H2 antihistamine. If symptoms still continue to persist, other agents, such as the monoclonal antibody omalizumab or the immunosuppressant cyclosporine, can be prescribed [6]. Omalizumab has been approved by the US Food and Drug Administration for the treatment of CIU in adults and children older than 12 years who continue to have symptoms that are not controlled by H1 antihistamines [7].

The safety and efficacy of omalizumab for the treatment of CIU has been demonstrated in numerous clinical trials [2, 8-10]. However, clinical trials are conducted in a tightly controlled environment with a duration of up to 6 months. Little data exist on real-world treatment patterns and long-term follow-up of the use of omalizumab for the management of CIU. To bridge this knowledge gap, this study examined the treatment patterns as well as the demographics and

clinical characteristics and response to therapy of patients with CIU newly initiated on omalizumab therapy.

Methods

Study Design and Population

This study which used health plan administrative claims data integrated with medical record data, is part of an original retrospective observational cohort study of the clinical outcomes and treatment patterns of omalizumab in CIU patients. In the original study, patients were identified from medical and pharmacy claims in the HealthCore Integrated Research Database (HIRD[®]), which contains administrative claims from 14 large commercial health plans geographically dispersed across the US. Patients who had at least one medical or pharmacy claim for omalizumab (Current Procedural Terminology [CPT] code: J2357; General Product Identifier [GPI] code: 44603060002120) between March 21, 2014 and October 31, 2015 (index period) were included. The date of omalizumab initiation was designated as the index date. CIU was defined as ≥ 1 medical claim for an inpatient stay or emergency department (ED) visit with an *International Classification of Disease, Ninth Edition, Clinical Modification* (ICD-9-CM) or *International Classification of Disease, Tenth Edition, Clinical Modification* (ICD-10-CM) diagnosis code for urticaria (ICD-9-CM diagnosis codes: 708.xx; ICD-10-CM diagnosis codes: L50.0-L50.9) in the primary diagnosis position OR with ≥ 2 medical claims with distinct service dates for urticaria in any position of the claims in any setting in the full study period (September 20, 2013 through April 30, 2016). This approach was felt to be appropriate because there is not a specific ICD code for CIU, and since study patients were enrollees in Anthem health plans that required prior authorization based on verification of CIU status before approving omalizumab

treatment, it was expected CIU diagnosis would be confirmed in medical records [11]. Patients who had an omalizumab prescription prior to the index date were excluded to ensure that the study population consisted of only newly initiated patients. All patients were 12 years of age or older on the index date, had at least 6 months pre- and 6 months post-index health plan eligibility and were enrolled in a commercial or Medicare Advantage health plan during the entire study period.

For the current study utilizing claims plus medical records review, medical records were obtained from providers and abstracted by trained reviewers using a standardized extraction form. Patients eligible for medical record request and abstraction had at least 1 outpatient claim that had omalizumab codes or urticaria codes and was associated with the same allergy/immunology, dermatology, pulmonary medicine, or primary care provider within the 12-month pre-index period and up to 24 months post-index; and had valid provider contact information. Additionally, all patients had at least 4 medical or pharmacy claims for omalizumab within the first 6 months after the date of the initial omalizumab claim and had at least 12 months post-index health plan eligibility.

This study was conducted in compliance with state and federal privacy regulations, including the Health Insurance Portability and Accountability Act. Institutional Review Board approval was obtained prior to performing the study and a limited data set consisting of integrated administrative claims data and medical record data was utilized for the analysis.

Outcome Measures

Information captured from the medical records included patient demographics, clinical characteristics, laboratory data, treatment patterns and treatment response after omalizumab initiation. All medical record data were collected for the period of time extending from 12-months pre-index and up to 24-months post-index and reported for the main cohort of patients with at least 12 months of continuous health plan eligibility following the index date as well as those with at least 18 months of post-index eligibility. Omalizumab treatment patterns were evaluated, and specifically included index dose, dosing frequency, discontinuations, and treatment restarts. The response to omalizumab treatment was considered positive or improved from such health care provider notes as 'doing well,' 'getting better,' 'positive response,' 'improvement' or 'response'; while notes indicating 'no response/no improvement' were considered as no response to omalizumab treatment. Urticaria symptoms were abstracted for the pre- and post-index periods. Utilization of other CIU medications, namely H1 and H2 antihistamines and oral or injectable corticosteroids, was also abstracted from the medical records.

Statistical Analysis

Descriptive statistics including means (standard deviation [SD], median, interquartile range) for continuous variables and relative frequencies for categorical variables were reported. All differences described in this study were numerical. All analyses were performed using SAS Enterprise Guide 7.1 (SAS Institute, Inc., Cary, NC).

Results

A total of 3,508 patients were identified in the HIRD as having at least one claim for omalizumab during the index period. Of these, 1,507 patients were excluded for having had at least one omalizumab prescription during the pre-index period. Of the remaining 2,001 patients, 1,026 had an urticaria diagnosis from medical claims during the study period; among these, a total of 696 patients had enrollment in only commercial or Medicare Advantage health plans during the study period, ≥ 6 months pre-index and ≥ 6 months post-index continuous health plan enrollment, and were ≥ 12 years of age as of index date. Medical records were obtained and reviewed for 200 patients who met the medical record request and review criteria. The study population consisted of the 88 patients who had at least 4 medical or pharmacy claims for omalizumab within the first 6 months after the index date and had at least 12 months post-index health plan enrollment, including a subset of 36 patients who had at least 18 months post-index health plan enrollment.

Demographic and Clinical Characteristics

The majority of patients with at least 12 months post-index eligibility were female (68.2%) with a mean age of 43.4 years and mean body mass index of 28.8 (Table 1). Similarly, of the patients with at least 18 months post-index eligibility, 61.1% were female, but they were slightly older (mean age 45.5 years) and heavier (mean body mass index 30.0).

As expected, CIU, chronic urticaria, urticaria, and idiopathic urticaria were the most commonly documented terms for urticaria in the medical records in both the pre- and post-index periods (data not shown). An asthma diagnosis was present in 28 patients (31.8%) in the pre-index period and 29 patients (33.0%) post-index. More than 40% of patients had diagnoses of allergic

rhinitis/hay fever pre- and post-index (44.3% and 42.0%, respectively) and angioedema pre-index (45.5%), although the percentage of patients with angioedema diagnoses decreased slightly numerically in the post-index period (30.7%).

Medication Utilization

Omalizumab utilization was documented in the medical records of 86 (97.7%) patients with 12 months post-index eligibility and 36 (100%) patients with 18 months post-index eligibility. Dosing information was available in the medical records of 69 (80.2%) patients with 12 months post-index eligibility and 29 (80.6%) patients with 18 months post-index eligibility. Of the patients with omalizumab dosing information, 75.4% patients with 12 months post-index eligibility and 72.4% with 18 months post-index eligibility received an index dose of 300 mg. Approximately two-thirds of patients with 12 months (69.6%) and 18 months post-index eligibility (65.5%) remained on the index dose throughout the follow-up period. Only one in five patients (21.7% and 20.7% in those with 12 and 18 months of post-index eligibility, respectively) either increased or decreased the index dose. Among patients who had dose frequency recorded (n=52 for patients with 12 months post-index eligibility and n=22 for patients with 18 months post-index eligibility), the overwhelming majority had every 4 weeks/monthly dosing (96.2% with ≥ 12 months post-index eligibility and 90.9% with ≥ 18 months post-index eligibility; Table 2).

Among patients with omalizumab utilization documented, omalizumab was discontinued in 24.4% of those with 12 months post-index eligibility and 19.4% of those with 18 months post-index eligibility. Reasons for treatment discontinuation included cost of treatment, insurance

disenrollment, side effects, no response to treatment, no time or availability for treatment, or symptom resolution (Table 2).

The proportion of patients using H1 antihistamines and oral corticosteroids decreased numerically between the pre- (84.1% H1 antihistamines, 52.3% oral corticosteroids) and post-index periods (81.8% H1 antihistamines, 39.8% oral corticosteroids), while use of H2 antihistamines increased numerically (50.0% pre-index, 52.3% post-index; data not shown). Similar trends were observed for patients with 18 months post-index eligibility.

Response to Therapy

A positive response to omalizumab treatment was reported in 83.7% of patients (n=86) with 12 months post-index eligibility and 77.8% of patients (n=36) with 18 months post-index eligibility (Table 2). Fewer than 10% of patients in either group reported no response to therapy.

Urticaria symptom occurrence decreased numerically between the pre- and post-index periods. For example, red or white welts were reported in 83.0% of patients pre-index and 71.6% post-index; itching 56.8% pre-index and 38.6% post-index; swelling of the face, eyes, or hands 45.5% pre-index and 18.2% post-index; and urticaria flare triggered by heat, exercise, stress, or pressure from clothing, socks, belts, bras, handbag, or backpack 33.0% pre-index and 23.9% post-index (data not shown). A similar trend was observed among the subset of patients with 18 months post-index eligibility.

Discussion

This real-world analysis combined medical and pharmacy claims data with medical record data to provide insights into the demographic and clinical profiles of patients with CIU newly treated with omalizumab. In this cohort of omalizumab users who received at least 4 doses in the first 6 months after initiating therapy, over three quarters remained on therapy for at least 12 months, with most of the patients on a consistent dosage throughout the study follow-up period.

The majority of patients had a documented response to omalizumab, which was further evident in a decrease in the reporting of urticaria symptoms between the pre- and post-index periods as well as by the decrease in the use of oral corticosteroids.

The response rates observed in this analysis are consistent with previous medical record studies. One reported omalizumab response rates of 89% in patients with refractory CIU, although only 47% had a complete response [12]. A more recent medical record review exploring the safety and effectiveness of dosing every 2 weeks rather than every 4 weeks found an overall omalizumab response rate of 90%, with more patients in the every 2 weeks cohort achieving a significant improvement in symptoms than those who received omalizumab every 4 weeks [13]. In contrast to these previous studies, our analysis had a larger patient population that was geographically distributed across the US. These unique features provide additional data on real-world treatment patterns and long-term follow-up of the use of omalizumab for the management of CIU.

Several limitations should be considered when evaluating the results of this real-world analysis. There are no ICD-9-CM/ICD-10 diagnosis codes for CIU and some patients may have been misclassified. However, the preauthorization process required for omalizumab treatment of CIU

along with the medical record review confirmed that the patients included in the study did, in fact, have CIU. A portion of the patients in this study had diagnoses of both CIU and asthma so the exact indication for omalizumab use could not be determined in all patients. The study sample was initially identified from claims in one large US administrative claims database and consisted of patients with commercial or Medicare Advantage health insurance. The results may not be generalizable to patients with other types of health insurance, the uninsured, or to those living outside the US. In addition, because this study only included patients who had 4 or more claims for omalizumab within 6 months after omalizumab initiation, the study population may be different from the population of patients with fewer than 4 claims for omalizumab. Lastly, as medical records represent clinical data collected in real-world practice, some data elements may not be consistently documented. For example, response to treatment was assessed through physician notes, such as 'getting better' or 'doing well,' which are imprecisely defined parameters interpreted differently by each provider. Furthermore, information on omalizumab tolerability was not documented. Although tolerability may be inferred from treatment changes or discontinuations during the follow-up period, such changes also may have been due to treatment response.

Conclusions

In this real-world claims and medical record study, over three-quarters of this cohort of patients with CIU who were administered omalizumab remained on therapy for at least 12 months with the majority remaining at the 300 mg dosage. Approximately 80% patients responded to omalizumab therapy and, compared with urticaria symptoms during the pre-omalizumab period, urticaria symptoms decreased after omalizumab initiation. Utilization of oral corticosteroids decreased after omalizumab initiation when compared with the pre-index period. This study

provides further insight into the real-world treatment patterns and response associated with omalizumab therapy in patients with CIU.

Transparency

Declaration of Funding

Funding for this study was provided by Novartis Pharmaceuticals Corporation. Novartis was involved with data interpretation, drafting and reviewing the manuscript, and the decision to publish the findings of this study.

Declaration of financial/other interests

Liya Wang, Xuehua Ke, Debra Wertz, Qing Huang, Vincent J. Willey, and Judith J. Stephenson are employees of HealthCore, Inc., a wholly owned subsidiary of Anthem, Inc. Abhishek Kavati, Benjamin Ortiz, and Brandee Paknis are employees of Novartis Pharmaceuticals Corporation. Jonathan A. Bernstein is affiliated with Bernstein Clinical Research Center, LLC, under contract with Novartis Pharmaceuticals Corporation to provide consulting services to the study, and serves as an investigator, speaker and consultant for Novartis Pharmaceuticals Corporation and Genentech, Inc. Lisa A. Beck is an employee of University of Rochester Medical Center (URMC), under contract with Novartis Pharmaceuticals Corporation to provide consulting services to the study, and has the following relationships: Abbvie Inc. – research grant to URMC, consultant; Array Biopharma Inc. – consultant; Celgene Corporation – consultant; Eli Lilly and Co. – consultant; Genentech, Inc. – research grant to URMC, consultant; Hoffman-LaRoche AG – consultant; Janssen Pharmaceuticals, Inc. – consultant; Regeneron Pharmaceuticals, Inc. – research grant to URMC, consultant; Medtronic – stock owner; Pfizer Inc. – stock owner. The

authors have no other relevant affiliations or financial involvement with any organization or entity with a financial interest in or financial conflict with the subject matter or materials discussed in the manuscript apart from those disclosed. One of the peer reviewers on this manuscript has participated on advisory boards for Genentech/Novartis and has lectured on chronic urticaria for Novartis. Each of the reviewers have received an honorarium from CMRO for their review work, but have no other relevant financial relationships to disclose.

Author Contributions

Liya Wang: Study concept/design; data analysis; data interpretation; drafting, reviewing, and revising the manuscript; final approval of the manuscript.

Xuehua Ke: Study concept/design; data analysis; data interpretation; drafting, reviewing, and revising the manuscript; final approval of the manuscript.

Abishek Kavati: Study concept/design; data interpretation; drafting, reviewing, and revising the manuscript; final approval of the manuscript.

Debra Wertz: Study concept/design; data interpretation; drafting, reviewing, and revising the manuscript; final approval of the manuscript.

Qing Huang: Study concept/design; data analysis; data interpretation; drafting, reviewing, and revising the manuscript; final approval of the manuscript.

Vincent J. Willey: Study concept/design; data interpretation; drafting, reviewing, and revising the manuscript; final approval of the manuscript.

Judith J. Stephenson: Study concept/design; data interpretation; drafting, reviewing, and revising the manuscript; final approval of the manuscript.

Benjamin Ortiz: Study concept/design; data interpretation; drafting, reviewing, and revising the manuscript; final approval of the manuscript.

Brandee Paknis: Study concept/design; data interpretation; drafting, reviewing, and revising the manuscript; final approval of the manuscript.

Jonathan A. Bernstein: Study concept/design; data interpretation; drafting, reviewing, and revising the manuscript; final approval of the manuscript.

Lisa A. Beck: Study concept/design; data interpretation; drafting, reviewing, and revising the manuscript; final approval of the manuscript.

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Table 1. Demographic and Clinical Characteristics

	Patients with ≥ 12 Months of Post-Index Eligibility (n=88)			Patients with ≥ 18 Months of Post-Index Eligibility (n=36)		
	N	n (%) ^a	Median (IQR)	N	n (%) ^a	Median (IQR)
Female, n (%)	88	60 (68.2)		36	22 (61.1)	
Age at index (yrs), mean (SD)	88	43.4 (13.46)	43.5 (20.0)	36	45.5 (13.39)	44.5 (19.5)
Weight (lbs), mean (SD) ^b	68	177.8 (47.14)	176.0 (58.5)	27	186.9 (51.66)	183.0 (70.0)
Height (in), mean (SD) ^b	64	65.9 (3.71)	65.9 (4.0)	26	66.0 (4.44)	65.8 (6.5)
BMI, mean (SD) ^{b,c}	65	28.8 (6.29)	28.0 (8.4)	26	30.0 (6.84)	30.5 (8.9)
BMI Categories, n (%) ^d	65			26		
Underweight (BMI <18.5)		1 (1.5)			0 (0)	
Normal or healthy weight (BMI=18.5-24.9)		19 (29.2)			6 (23.1)	
Overweight (BMI=25.0-29.9)		20 (30.8)			6 (23.1)	
Obese (BMI $\geq$ 30)		25 (38.5)			14 (53.8)	

BMI=body mass index; IQR=interquartile range; SD=standard deviation

^aValues are expressed as n (%) unless otherwise noted

^bIf there were multiple documentations within the pre-index period, the documentation closest to index date was used.

^cBMI was collected from medical records or calculated based on the following formula (weight (lb) / [height (in)]² × 703) if BMI was not reported in patient medical record

^dWeight status for patients 20 years or older was categorized based on the following: underweight (BMI<18.5), normal or healthy weight (BMI=18.5 – 24.9), overweight (BMI=25.0 – 29.9), obese (BMI $\geq$ 30.0) (from CDC at https://www.cdc.gov/healthyweight/assessing/bmi/adult_bmi/index.html); weight status for patients 6-19 years old was categorized based on the following: underweight (BMI: <5th percentile), normal or healthy weight (BMI: 5th percentile to <85th percentile), overweight (BMI: 85th percentile to <95th percentile), obese (BMI: $\geq$ 95th percentile) (from CDC at https://www.cdc.gov/healthyweight/assessing/bmi/childrens_bmi/about_childrens_bmi.html#percentile).

Table 2. Post-Index Omalizumab Treatment Pattern and Response

	Patients with ≥ 12 Months of Post-Index Eligibility (n=88)			Patients with ≥ 18 Months of Post-Index Eligibility (n=36)		
	N	n (%) ^a	Median (IQR)	N	n (%) ^a	Median (IQR)
Documentation of omalizumab (post-index only), n (%) ^b	88	86 (97.7)		36	36 (100.0)	
Documentation of index dose	86	69 (80.2)		36	29 (80.6)	
Index dose (mg), mean (SD)	69	273.8 (66.41)	300.0 (0.0)	29	269.0 (65.01)	300.0 (0.0)
150 mg, n (%)		13 (18.8)			6 (20.7)	
300 mg, n (%)		52 (75.4)			21 (72.4)	
Other, n (%)		4 (5.8)			2 (6.9)	
Subsequent vs index dose, n (%)	69			29		
Equal		48 (69.6)			19 (65.5)	
Increase		7 (10.1)			2 (6.9)	
Decrease		8 (11.6)			4 (13.8)	
Unknown/not documented		6 (8.7)			4 (13.8)	
Documentation of index dosing frequency, n (%)	86	52 (60.5)		36	22 (61.1)	
Index dosing frequency (days), mean (SD)	52	28.2 (3.0)	28.0 (2.0)	22	27.5 (4.5)	28.0 (2.0)
Every 2 weeks	52	2 (3.8)		22	2 (9.1)	
Every 4 weeks/monthly		50 (96.2)			20 (90.9)	
Subsequent vs index dosing frequency, n (%)	52			22		
Equal		24 (46.2)			8 (36.4)	
Increase		12 (23.1)			6 (27.3)	
Decrease		11 (21.2)			4 (18.2)	
Unknown/not documented		5 (9.6)			4 (18.2)	
Documentation of treatment response, n (%)						
Improvement	86	72 (83.7)		36	28 (77.8)	
No improvement	86	8 (9.3)		36	3 (8.3)	
Discontinuation of omalizumab	86	21 (24.4)		36	7 (19.4)	

Reason for discontinuation, n (%)	21	16 (76.2)	7	5 (71.4)
Cost burden	16	1 (6.3)	5	1 (20.0)
Insurance disenrollment	16	2 (12.5)	5	1 (20.0)
Side effects	16	1 (6.3)	5	0 (0)
No response to treatment	16	4 (25.0)	5	0 (0)
No time/availability for treatment	16	3 (18.8)	5	1 (20.0)
Symptoms resolved/positive response to treatment	16	2 (12.5)	5	1 (20.0)
Other	16	3 (18.8)	5	2 (40.0)
Documentation of omalizumab restart, n (%)	21	9 (42.9)	7	3 (42.9)

^aValues are expressed as n (%) unless otherwise noted

^bThe index omalizumab dose could occur prior to claims-based index date in medical records due to limitation of claims data. The first documented omalizumab in medical records was considered as index omalizumab in this table.