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Hearing Two Perspectives on CSU

Announcer:

Welcome to ReachMD.

This medical industry feature, titled “Hearing Two Perspectives on CSU” is sponsored by Genentech and Novartis. This program is intended for healthcare professionals.

Here’s your host, Dr Charles Turck.

Dr Turck:

Hello and welcome. Chronic spontaneous urticaria can come with daily or almost daily signs and symptoms, and some patients have described the itching associated with it as “unbearable.” For patients with H1 antihistamine-resistant chronic spontaneous urticaria, or CSU, how long is too long to wait for the possibility of relief? Approximately 50% of patients taking H1 antihistamines continue to experience CSU symptoms. In addition, patients with H1 antihistamine-resistant CSU spend an average of nearly a year and a half suffering with persistent itching and hives before they see a specialist.

This is ReachMD, and I’m Dr Charles Turck. Joining me today to talk about two different perspectives of CSU are my guests, Dr Jacqueline Eghrari-Sabet, who is board-certified in allergy and immunology and is an associate professor at the George Washington School of Medicine and Health Sciences, and practices in the Washington D.C. area.

Dr Eghrari-Sabet thanks so much for being here today.

Dr Eghrari-Sabet:

It’s a pleasure to be here!

Dr Turck:

We also have Jennifer, a patient who's been living with CSU. Jennifer, it’s great to have you with us.

Jennifer:

Thank you for having me!

Dr Turck:

Before we begin, let’s take a moment to review some Important Safety Information for XOLAIR.

Announcer:

INDICATION

XOLAIR® (omalizumab) is indicated for the treatment of chronic spontaneous urticaria (CSU) in adults and adolescents 12 years of age and older who remain symptomatic despite H1 antihistamine treatment.

Limitations of Use: XOLAIR is not indicated for treatment of other forms of urticaria.

IMPORTANT SAFETY INFORMATION

WARNING: Anaphylaxis

Anaphylaxis presenting as bronchospasm, hypotension, syncope, urticaria, and/or angioedema of the throat or tongue, has been reported to occur after administration of XOLAIR. Anaphylaxis has occurred as early as after the first dose of XOLAIR, but also has occurred beyond 1 year after beginning regularly administered treatment. Because of the risk of anaphylaxis, initiate XOLAIR therapy in a healthcare setting and closely observe patients for an appropriate period of time after XOLAIR administration. Health care providers administering XOLAIR should be prepared to manage anaphylaxis which can be life-threatening. Inform patients of the signs and symptoms of anaphylaxis and instruct them to seek immediate medical care should symptoms occur. Selection of patients for self-administration of XOLAIR should be based on criteria to mitigate risk from anaphylaxis.

Additional important safety information will be reviewed later. Jennifer is a real patient and individual results may vary.

Dr Turck:

Jennifer, does your experience feel similar to what I was just describing? Did you have to wait nearly a year and a half before you were diagnosed with CSU?

Jennifer:

Oh gosh yes. I didn't find answers about what was really happening to me for about 2 years. And they were a long two years.

Dr Turck:

How did CSU symptoms present for you?

Jennifer:

At first, I only noticed a spot on my chest that was perfectly round. I thought it was a heat rash. I had recently moved into a rental house and was constantly moving around because of my job, so I really didn't think much of it. But then a couple days later, that spot multiplied to 3 spots, then 5, and then more.

There were so many of them, and the itching got worse too. At one point I thought I might have lice because my scalp itched so bad—I even asked a good friend if she would check me for them. Sometimes the itching was so severe it would wake me up in the night.

Dr Turck:

Thank you for sharing your experience. And Dr Eghrari-Sabet, research has also shown that a lot of patients continue to be symptomatic despite taking H1 antihistamines. Do you encounter patients with CSU that are resistant to H1 antihistamines?

Dr Eghrari-Sabet:

I see a variety of patients, and they all have their unique situations. In general, when someone comes to me and they are presenting with symptoms of CSU, I start their treatment with H1 antihistamines. And while some patients may respond to the H1 antihistamines, I do encounter patients who just don't achieve optimal relief.

Dr Turck:

Do you find yourself seeing patients like Jennifer? People with individual specific needs for a treatment plan?

Dr Eghrari-Sabet:

Absolutely. Like I said, every patient is different. I believe it's important for us to work together as partners, so we can effectively customize a plan for treatment.

Jennifer:

I'm glad to hear you say that doctor, because that was not my experience at first. I saw numerous doctors, spent hours driving all over the country, and got misdiagnosed multiple times. Often I heard "you're just stressed out," but I couldn't accept that as an answer. So, I kept searching. I leaned on my mom a lot for support and would send her pictures. She could tell I was really struggling and was also looking into what it could be. We weren't going to stop until we found answers.

Dr Turck:

Thank you for sharing that experience. Let's pause on that note and take a quick break. For those just joining us, this is ReachMD.

I'm Dr Charles Turck, and today I'm speaking with Dr Jacqueline Eghrari-Sabet and Jennifer about chronic spontaneous urticaria, or

CSU. Dr Eghrari-Sabet is board-certified in allergy and immunology and is an associate professor at the George Washington School of Medicine and Health Sciences, and practices in the Washington D.C. area. And Jennifer is a patient who has personal experience facing CSU.

We've spoken a bit about what Jennifer's experience was like as a patient: how she experienced symptoms of CSU and what she went through before receiving a diagnosis. We've also heard from Dr Eghrari-Sabet about how frequently she see patients like this within her own practice. Now let's shift to discussing ways to treat CSU, even in cases where it appears to be resistant to H1 antihistamine options.

Jennifer, what was the turning point for you when it came to your experience with CSU?

Jennifer:

When I was diagnosed, that was definitely a powerful moment for me. After so much time spent getting all these different opinions, I took a chance. My friend recommended another doctor to me, a specialist, and when I went this doctor immediately diagnosed me with CSU. He talked to me about my condition and for the first time I felt heard.

Receiving that diagnosis led to such a mixed bag of emotions, but the strongest one I felt was a sense of empowerment—to know what it is that you're suffering with and know you're not the only one going through this. I immediately called my mom and told her I'd finally found an answer, and we had a plan to help me find relief.

Dr Eghrari-Sabet:

Jennifer, I'm so glad to hear you were able to have such a productive conversation with your doctor and finally receive a CSU diagnosis. Approaching this condition is a team effort, and I deeply value seeing my patients as partners in this process.

Dr Turck:

That's an interesting point you just brought up, Dr Eghrari-Sabet. How do you address the unique situations of each patient?

Dr Eghrari-Sabet:

Well, for one thing, I ask a lot of questions. A number of factors need to be considered. I want to know what their disease history is, how they're feeling in the moment compared to how they've felt before our appointment, any triggers or comorbidities they may have, and what their hopes are for treatment. I want my patients to get to a place where they really understand their condition and what may be available to them in terms of options.

Dr Turck:

You mentioned earlier that you tend to prescribe H1 antihistamines for patients with CSU. In the situations where you see that patients are still experiencing symptoms, what actions do you take next?

Dr Eghrari-Sabet:

Well, when I start my patients off on H1 antihistamines, I let them know that the goal with this treatment is to be almost completely itch- and hive-free. But I also let them know that sometimes symptoms may persist, even on a treatment like this. And if they don't get close to the goal of nearly complete relief, there is a biologic treatment that we can try in appropriate patients after the H1 antihistamines. So I make sure to assess my patients with CSU at every follow-up appointment for disease activity, control, and impact. That can look like administering a weekly Urticaria Activity Score, or UAS7, which is a validated, patient-reported outcome that offers a composite score for both itch severity and hive count. I find the daily scoring of the UAS7 very helpful.

Dr Turck:

What kind of treatment options are generally available to these patients with H1 antihistamine-resistant CSU?

Dr Eghrari-Sabet:

As I mentioned, during the very first conversation about treatment options, I let the patient know there is an additional option with XOLAIR. As the first biologic approved to treat CSU, XOLAIR has been prescribed to nearly 311,000 patients in the US since 2014. When patients learn that XOLAIR exists as an option if the H1 antihistamine is not working, we discuss this treatment as a potential option for them.

Dr Turck:

Jennifer, what has your experience been like in having these kinds of conversations with your doctor? Have they gone similarly to what Dr Eghrari-Sabet is describing?

Jennifer:

I have a very positive relationship with my doctor who gave me my diagnosis. When he prescribed me XOLAIR, he let me know about his years of experience in prescribing it to other patients and gave me some insight on patient experiences he had seen. He also gave me some background information on clinical trials and safety risks that are possible with XOLAIR.

Dr Turck:

How does it feel to be treated like a partner in the decision-making process when you're talking to your doctor?

Jennifer:

I value it so much, I almost can't put it into words. Feeling respected, feeling like my voice is heard, and feeling like I'm being treated as a person is everything.

Dr Eghrari-Sabet:

I'm so glad to hear that you finally found a situation that works, and I fully agree with you. It's critical that you feel heard throughout this entire process.

Dr Turck:

My last question for you Jennifer is this: if you had to go through this whole process again, would you change anything?

Jennifer:

I'll tell you what I wouldn't change. I would never stop advocating for myself. Being persistent, searching for answers until I found a doctor who listened to me and treated me as a partner. That's one thing I will never change. I only wish I had found my allergist, and XOLAIR, earlier.

Dr Turck:

Excellent, that's a great point for us to think on as we come to the end of today's program. Thank you so much for sharing your experience with us, Jennifer, and to Dr Jacqueline Eghrari-Sabet for sharing her experience with CSU as a physician.

I want to thank my guests for helping us better understand some ways to identify and treat appropriate patients with chronic spontaneous urticaria, or CSU. To find more information on XOLAIR and how it can treat H1 antihistamine-resistant CSU, please visit xolairhcp.com. That's x-o-l-a-i-r-h-c-p-dot-com.

Jennifer and Dr Eghrari-Sabet, thank you both for this conversation. It was great speaking with you both today.

Jennifer:

Thank you for having me!

Dr Eghrari-Sabet:

Thank you for this opportunity!

Dr Turck:

I'm Dr Charles Turck. Let's take a moment to review some additional Important Safety Information related to XOLAIR.

Announcer:

CONTRAINDICATIONS

XOLAIR is contraindicated in patients with a severe hypersensitivity reaction to XOLAIR or to any ingredient of XOLAIR.

WARNINGS AND PRECAUTIONS

Anaphylaxis: Anaphylaxis has been reported to occur after administration of XOLAIR in premarketing clinical trials and in postmarketing spontaneous reports. In premarketing clinical trials in patients for a different indication, anaphylaxis was reported in 3 of 3507 (0.1%) patients. Anaphylaxis occurred with the first dose of XOLAIR in two patients and with the fourth dose in one patient. The time to onset of

anaphylaxis was 90 minutes after administration in two patients and 2 hours after administration in one patient.

A case-control study in asthma patients showed that, among XOLAIR users, patients with a history of anaphylaxis to foods, medications, or other causes were at increased risk of anaphylaxis associated with XOLAIR, compared to those with no prior history of anaphylaxis.

In postmarketing spontaneous reports, the frequency of anaphylaxis attributed to XOLAIR use was estimated to be at least 0.2% of patients based on an estimated exposure of about 57,300 patients from June 2003 through December 2006. Approximately 60% to 70% of anaphylaxis cases have been reported to occur within the first three doses of XOLAIR, with additional cases occurring sporadically beyond the third dose.

Initiate XOLAIR only in a healthcare setting equipped to manage anaphylaxis which can be life-threatening. Observe patients closely for an appropriate period of time after administration of XOLAIR, taking into account the time to onset of anaphylaxis seen in premarketing clinical trials and postmarketing spontaneous reports. Inform patients of the signs and symptoms of anaphylaxis, and instruct them to seek immediate medical care should signs or symptoms occur.

Once XOLAIR therapy has been established, administration of XOLAIR prefilled syringe or autoinjector outside of a healthcare setting by a patient or a caregiver may be appropriate for selected patients. Patient selection, determined by the healthcare provider in consultation with the patient, should take into account the pattern of anaphylaxis events seen in premarketing clinical trials and postmarketing spontaneous reports, as well as individual patient risk factors (e.g. prior history of anaphylaxis), ability to recognize signs and symptoms of anaphylaxis, and ability to perform subcutaneous injections with XOLAIR prefilled syringe or autoinjector with proper technique according to the prescribed dosing regimen and Instructions for Use.

Discontinue XOLAIR in patients who experience a severe hypersensitivity reaction.

Malignancy: Malignant neoplasms were observed in 20 of 4127 (0.5%) XOLAIR-treated patients compared with 5 of 2236 (0.2%) control patients in clinical studies of adults and adolescents (≥12 years of age) for a different indication and other allergic disorders. The observed malignancies in XOLAIR-treated patients were a variety of types, with breast, non-melanoma skin, prostate, melanoma, and parotid occurring more than once, and five other types occurring once each. The majority of patients were observed for less than 1 year. The impact of longer exposure to XOLAIR or use in patients at higher risk for malignancy (e.g., elderly, current smokers) is not known.

A subsequent 5-year observational study of 5007 XOLAIR-treated and 2829 non-XOLAIR-treated adolescent and adult patients for a different indication found that the incidence rates of primary malignancies (per 1000 patient years) were similar in both groups (12.3 vs 13.0, respectively). Study limitations which include the observational study design, the bias introduced by allowing enrollment of patients previously exposed to XOLAIR (88%), enrollment of patients (56%) while a history of cancer or a premalignant condition were study exclusion criteria, and the high study discontinuation rate (44%) preclude definitively ruling out a malignancy risk with XOLAIR.

Corticosteroid Reduction: In CSU patients, the use of XOLAIR in combination with corticosteroids has not been evaluated.

Fever, Arthralgia, and Rash: In post-approval use, some patients have experienced a constellation of signs and symptoms, including arthritis/arthralgia, rash, fever, and lymphadenopathy with an onset 1 to 5 days after the first or subsequent injections of XOLAIR. These signs and symptoms have recurred after additional doses in some patients. Physicians should stop XOLAIR if a patient develops this constellation of signs and symptoms.

Parasitic (Helminth) Infection: Monitor patients at high risk of geohelminth infection while on XOLAIR therapy. Insufficient data are available to determine the length of monitoring required for geohelminth infections after stopping XOLAIR treatment.

Laboratory Tests: Due to formation of XOLAIR:IgE complexes, serum total IgE levels increase following administration of XOLAIR and may remain elevated for up to 1 year following discontinuation of XOLAIR.

Potential Medication Error Related to Emergency Treatment of Anaphylaxis
XOLAIR should not be used for the emergency treatment of allergic reactions, including anaphylaxis. In studies to simulate use, some patients and caregivers did not understand that XOLAIR is not intended for the emergency treatment of allergic reactions, including anaphylaxis. The safety and effectiveness of XOLAIR for emergency treatment of allergic reactions, including anaphylaxis, have not been established. Instruct patients that XOLAIR is for maintenance use to reduce reactions, including anaphylaxis, while avoiding food allergens.

ADVERSE REACTIONS

Chronic Spontaneous Urticaria: The most common adverse reactions (≥2% incidence in XOLAIR-treated patients and more frequent than in placebo) for XOLAIR 150 mg and 300 mg, respectively, included: headache (12%, 6%), nasopharyngitis (9%, 7%), arthralgia

(3%, 3%), viral upper respiratory infection (2%, 1%), nausea (1%, 3%), sinusitis (1%, 5%), upper respiratory tract infection (1%, 3%), and cough (1%, 2%).

Injection Site Reactions: Injection site reactions of any severity occurred in more XOLAIR-treated patients (11 patients [2.7%] at 300 mg, 1 patient [0.6%] at 150 mg) compared with 2 placebo-treated patients (0.8%). The types of injection site reactions included: swelling, erythema, pain, bruising, itching, bleeding, and urticaria. None of the events resulted in study discontinuation or treatment interruption.

Injection Site Reactions in Healthy Adults: In an open label trial in healthy adults, in which the 300 mg/2 mL autoinjector was compared to the 300 mg/2 mL prefilled syringe, injection site reactions (e.g., induration, pain, erythema, hemorrhage, swelling, discomfort, bruising, hypoesthesia, edema, pruritus) were observed in 24% (16/66) of subjects treated with the autoinjector compared with 14% (9/64) of subjects treated with the prefilled syringe.

Cardiovascular and Cerebrovascular Events from Clinical Studies for a Different Indication: A 5-year observational study was conducted in 5007 XOLAIR-treated and 2829 non-XOLAIR-treated patients ≥12 years of age for a different indication to evaluate the long term safety of XOLAIR, including the risk of malignancy. Similar percentages of patients in both cohorts were current (5%) or former smokers (29%). Patients had a mean age of 45 years and were followed for a mean of 3.7 years. More XOLAIR-treated patients were diagnosed with a severe form of the condition studied (50%) compared to the non-XOLAIR-treated patients (23%). A higher incidence rate (per 1000 patient-years) of overall cardiovascular and cerebrovascular serious adverse events (SAEs) was observed in XOLAIR-treated patients (13.4) compared to non-XOLAIR-treated patients (8.1). Increases in rates were observed for transient ischemic attack (0.7 vs 0.1), myocardial infarction (2.1 vs 0.8), pulmonary hypertension (0.5 vs 0), pulmonary embolism/venous thrombosis (3.2 vs 1.5), and unstable angina (2.2 vs 1.4), while the rates observed for ischemic stroke and cardiovascular death were similar among both study cohorts. The results suggest a potential increased risk of serious cardiovascular and cerebrovascular events in patients treated with XOLAIR, however the observational study design, the inclusion of patients previously exposed to XOLAIR (88% for a mean of 8 months), baseline imbalances in cardiovascular risk factors between the treatment groups, an inability to adjust for unmeasured risk factors, and the high study discontinuation rate (44%) limit the ability to quantify the magnitude of the risk.

Pregnancy: Data with XOLAIR use in pregnant women are insufficient to inform on drug associated risk.

You may report side effects to the FDA at (800) FDA-1088 or www.fda.gov/medwatch. You may also report side effects to Genentech at (888) 835-2555 or Novartis Pharmaceuticals Corporation at (888) 669-6682.

Please see full Prescribing Information, including Boxed WARNING and Medication Guide, for additional Important Safety Information.

This program was sponsored by Genentech and Novartis. If you missed any part of this discussion, visit ReachMD dot com slash industry feature. This is ReachMD. Be Part of the Knowledge.