Transcript Details
This is a transcript of an educational program. Details about the program and additional media formats for the program are accessible by visiting: https://reachmd.com/programs/medical-industry-feature/what-its-like-to-live-with-allergic-asthma/14919/

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What It's Like to Live With Allergic Asthma

Announcer:

Welcome to ReachMD. This medical industry feature, titled "What It's Like to Live With Allergic Asthma," is sponsored by Genentech and Novartis. This program is intended for healthcare professionals. Guests have been compensated for their participation. Here's your host, Dr Charles Turck.

Dr Turck:

In the United States, nearly 6 million children under the age of 18 have allergic asthma. And children with uncontrolled asthma have up to 8 times the risk of experiencing an asthma attack. So what lessons can we learn from those who have first-hand experiences living with and treating allergic asthma?

This is ReachMD, and I'm Dr Charles Turck. Joining me today to share their insights are Savanna, a 17-year-old patient who has been living with moderate to severe allergic asthma since she was around 6 years old, and Dr Sergei Belenky, who specializes in pediatric allergy and immunology. Dr Belenky has treated Savanna directly. Thank you both; we're very happy to have you here today.

Dr Belenky:

It's a pleasure to be here!

Savanna:

Thank you for having me!

Dr Turck:

Let's start our discussion with you, Savanna. Now allergic asthma has been a reality for you ever since you were a child. So do you remember when you first started experiencing symptoms?

Savanna:

To be honest, I think I was too young to remember the first moment I started having symptoms. I was just a baby. But when I was 4 or 5, I started to notice feeling short of breath. I'd wake up in the middle of the night and I wouldn't be able to talk. Also, my wheezing has always been really bad. That's always been a big symptom.

Dr Turck:

And how does it feel when you're going through a moment like that?

Savanna:

Terrible, definitely really scary. But I never fully understood how bad things were, or what was really going on, because I was so young. Cats were a big trigger and so was weather changes, which made me spend more time indoors.

Sometimes I would have to go into the hospital, and that would make me feel so anxious. My mom told me that at one point I was spending 3 weeks a year in the hospital. All I wanted to do was just get out of there and go back home. But coming home wasn't fun either because I'd have to be on bed rest for days at a time. When it was like that, I couldn't do anything. Not even get food for myself. It was awful.

Dr Belenky:

I'm so sorry to hear that you were having that experience when you were that young, Savanna.

Dr Turck:

Yes, that sounds so frustrating, especially to have to go through it as a child. And you mentioned that you had a few triggers for your allergic asthma. So if we turn to you now, Dr Belenky, do you see other patients with triggers like what Savanna is describing in your own practice?

Dr Belenky:

Oh, absolutely. Dust mites, pet dander, and cockroach debris are all important triggers of allergic asthma. Every patient is different, and that's why I really prioritize tailoring a treatment plan that can meet individual needs.

Dr Turck:

With that in mind, let's come back to you, Savanna. Do you remember when you got your diagnosis? How long did that take, and what was it like?

Savanna:

For me, from about the ages of 4 to 6, the same pattern would keep happening. My pediatrician gave several options for when my asthma flared up, and I still ended up back at the hospital sometimes. Then when I was 6, I had my first allergy test, and that's when I got the diagnosis. I'd still have to go through the same pattern, so it was very frustrating.

Dr Turck:

And let's pause on that note to take a quick break. For those just joining us, this is ReachMD. I'm Dr Charles Turck, and today I'm speaking with Savanna, who's a patient with allergic asthma, and Dr Sergei Belenky, who specializes in pediatric allergy and immunology.

Let's take a moment to review some Important Safety Information for XOLAIR.

Announcer:

INDICATION

XOLAIR® (omalizumab) is indicated for adults and pediatric patients 6 years of age and older with moderate to severe persistent asthma who have a positive skin test or in vitro reactivity to a perennial aeroallergen and whose symptoms are inadequately controlled with inhaled corticosteroids.

Limitations of Use: XOLAIR is not indicated for the relief of acute bronchospasm or status asthmaticus.

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 in this episode. Savanna is a real patient and individual results may vary.

Dr Turck:

Now before the break, Savanna, you mentioned being in a pattern with your allergic asthma, even after receiving a diagnosis. So how did that pattern begin to change?

Savanna:

I got prescribed XOLAIR when I was 13, and before that I was on several maintenance medicines. I trusted my doctor, so when he

suggested we try something different, my mom and I said yes. In the past, other doctors had made me feel like I didn't have a choice in the matter. But Dr Belenky made me feel more like a partner. I felt comfortable enough to talk to him and he listened to me when I had questions.

Dr Belenky:

Shared decision-making is the most effective way to reach treatment goals with a patient. And when I spoke with Savanna and her mom, we talked through all their questions and discussed the most common adverse reactions of XOLAIR, including nasopharyngitis, headache, pyrexia, and upper abdominal pain. Our conversation helped to establish trust and agreement that this was a good option to pursue.

Dr Turck:

That's a great point, Dr Belenky. And you mentioned earlier that you value customizing treatment plans for your patients' individual needs. So how do you address your patients' unique situations?

Dr Belenky:

For starters, I'm a big believer in a home environmental assessment that asks about, and tests for, exposure to potential triggers like pet dander and dust mites. As an allergist, I want to better understand the patients' home and work or school environment to understand what, if anything, links their environment to their symptoms.

And then comes blood count, allergy testing, things like that. But the workup questions are very valuable to help me start thinking about individual triggers. That's one reason why it's so important for patients to see themselves as a partner with me in this process, so they can be open and honest and we can work together with that information.

Dr Turck:

And based on what Dr Belenky just said, Savanna, was that similar to your experience?

Savanna:

Yeah, I definitely felt I could be open with Dr Belenky, and I asked plenty of questions, too. My mom and I both liked that Dr Belenky had experience with XOLAIR and patients like me, and that he also discussed its safety. Being able to get all of that information from my doctor was really important.

Dr Turck:

That's great to hear, Savanna, and I have just one final question for you before we wrap up today. If you had to go through this process with allergic asthma again, is there anything you'd do differently?

Savanna:

Well, I wouldn't want to have to go through that repetitive cycle that went on for so long. I received care, but the care didn't control my asthma, and so I wish I hadn't waited so long to see an allergist that was able to help manage my uncontrolled allergic asthma.

Dr Turck:

Excellent. That's a great point for us to think on, and celebrate, as we come to the end of today's program.

Thank you so much for sharing your experience with us, Savanna, and a big thanks to you as well, Dr Belenky, for sharing your experience with treating allergic asthma. It was great speaking with you both today.

Dr Belenky:

Thank you for having me!

Savanna:

Thank you for this opportunity!

Dr Turck:

I'm Dr. Charles Turck. To find more information on XOLAIR and how it can treat patients with moderate to severe allergic asthma, please visit xolairhcp.com. That's x-o-l-a-i-r-h-c-p-dot-com. And let's take a moment to review some additional Important Safety Information related to XOLAIR.

Announcer:

Important Safety Information (cont'd)

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 with asthma, 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) with asthma 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 with moderate to severe persistent asthma and a positive skin test reaction or in vitro reactivity to a perennial aeroallergen 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.

Acute Asthma Symptoms and Deteriorating Disease: XOLAIR has not been shown to alleviate asthma exacerbations acutely. Do not use XOLAIR to treat acute bronchospasm or status asthmaticus. Patients should seek medical advice if their asthma remains uncontrolled or worsens after initiation of treatment with XOLAIR.

Corticosteroid Reduction: Do not discontinue systemic or inhaled corticosteroids abruptly upon initiation of XOLAIR therapy for asthma. Decrease corticosteroids gradually under the direct supervision of a physician.

Eosinophilic Conditions: In rare cases, patients with asthma on therapy with XOLAIR may present with serious systemic eosinophilia, sometimes presenting with clinical features of vasculitis consistent with Churg-Strauss syndrome. These events usually, but not always, have been associated with the reduction of oral corticosteroid therapy. Physicians should be alert to eosinophilia, vasculitic rash,

worsening pulmonary symptoms, cardiac complications, and/or neuropathy presenting in their patients. A causal association between XOLAIR and these underlying conditions has not been established.

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. Do not use serum total IgE levels obtained less than 1 year following discontinuation to reassess the dosing regimen for asthma patients, because these levels may not reflect steady state free IgE levels.

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 allergic reactions, including anaphylaxis, while avoiding food allergens.

ADVERSE REACTIONS

Asthma: In patients ≥12 years of age, the most common adverse reactions (≥1% more frequent in XOLAIR-treated patients) were: arthralgia (8%), pain (general) (7%), leg pain (4%), fatigue (3%), dizziness (3%), fracture (2%), arm pain (2%), pruritus (2%), dermatitis (2%), and earache (2%). In pediatric patients 6 to <12 years of age, the most commonly observed adverse reactions (≥3% more frequent in XOLAIR-treated pediatric patients) were: nasopharyngitis, headache, pyrexia, upper abdominal pain, pharyngitis streptococcal, otitis media, viral gastroenteritis, arthropod bite, and epistaxis.

Injection Site Reactions: In adults and adolescents with asthma, injection site reactions of any severity occurred at a rate of 45% in XOLAIR-treated patients compared with 43% in placebo-treated patients. Severe injection site reactions occurred more frequently in XOLAIR-treated patients compared with patients in the placebo group (12% vs 9%, respectively). The types of injection site reactions in asthma studies included: bruising, redness, warmth, burning, stinging, itching, hive formation, pain, indurations, mass, and inflammation.

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 in Patients with Asthma: A 5-year observational study was conducted in 5007 XOLAIR-treated and 2829 non-XOLAIR-treated patients ≥12 years of age with moderate to severe persistent asthma and a positive skin test reaction to a perennial aeroallergen 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 severe asthma (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.