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Beyond Symptom Control: Treating the Root Cause of House Dust Mite Allergies

Dr. Caudle:
This is *Clinician's Roundtable* on ReachMD, and I'm your host, Dr. Jennifer Caudle. And joining me today to discuss ODACTRA®, a sublingual immunotherapy tablet for the treatment of allergic rhinitis due to house dust mites, is Dr. Jacqueline Eghrari-Sabet. She's an allergy and immunology specialist with the Kaufman Allergy Asthma and Immunology Center in Vienna, Virginia. She's also a Clinical Assistant Professor at the George Washington University School of Medicine and Health Sciences in Washington, DC.

Dr. Caudle:
Dr. Eghrari, welcome to the program.

Dr. Eghrari:
Thank you for having me today.

Dr. Caudle:
Of course. So Dr. Eghrari, to start out our discussion today, can you describe some of the challenges that patients with allergic rhinitis face in terms of symptom control and treatment effectiveness?

Dr. Eghrari:
Sure! Symptomatic medications, like antihistamines or nasal sprays, are commonly used to treat allergic rhinitis, and they're mostly available over the counter. The challenge is that they may not always completely control allergy symptoms. Even though patients are using these medications daily and frequently, their symptoms are still not well controlled, leaving them with the burden of managing these symptoms.[1]

The allergic rhinitis symptoms they experience may have an impact on sleep, school performance, and outside activities.[1] For example, as cited from Golbin et al in 1992, 88 percent of adolescents and children were estimated to experience sleep disturbances, leading to daytime drowsiness.[2] Additionally, 40 percent of parents reported that their child's allergies negatively affected their school performance.[1] Children with inadequately managed allergies are three to four times more likely to restrict outdoor activities.[1] For example, they may stay inside during recess or avoid playing on sports teams.

We're also seeing that for some patients, symptomatic treatments can fall short. More than half of the parents reported that their child's nasal spray lost effectiveness with increased use. In the same survey, the researchers found that 40 percent of parents requested a change in their child's prescription because the treatment was ineffective. When allergy symptoms like rhinitis or conjunctivitis aren't well controlled with over-the-counter symptomatic therapies, introducing allergy immunotherapy may be the next step in effectively managing these challenges.[1]

Dr. Caudle:
So, Dr. Eghrari, how does allergy immunotherapy differ from symptomatic medications in treating allergies?

Dr. Eghrari:
Well, allergy immunotherapy targets the root cause, rather than just alleviating symptoms.[3,4]

It works by desensitizing the immune system through repeated, controlled doses of allergens that trigger symptoms.[5] Using naturally derived ingredients, this type of treatment is for long-term use, typically spanning about three to five years.[5] Allergy immunotherapy

comes in two FDA-approved formulations. One is a subcutaneous immunotherapy, or SCIT, also known as allergy shots, and the second is sublingual immunotherapy tablets, or SLIT-tablets.[4,6]

Despite being on medication to help alleviate symptoms, some patients with allergies suffer with symptoms for as many as ten years before they're offered allergy immunotherapy.[7] So early initiation of allergy immunotherapy, when appropriate, may lead to earlier patient benefits.[5]

These benefits may include improved symptom control, reduced need for symptomatic medication, and a decrease in the development of new allergies. This can ultimately result in possible cost savings in terms of pharmacy, outpatient, and total health care costs, so I often introduce allergy immunotherapy within the first or second visit with the patient.[5]

Dr. Caudle:
Now, Dr. Eghrari, can you explain the differences between subcutaneous immunotherapy injections and sublingual immunotherapy tablets and how these differences may impact the choice of therapy for individual patients?

Dr. Eghrari:
Absolutely. They are distinct in several ways. To begin, after the first dose is taken under the supervision of a healthcare professional, sublingual immunotherapy is taken at home as a once-daily tablet with only occasional follow-up visits to monitor adverse events, adherence, and response.[8–10] Allergy shots, or SCIT, however, require the patient to come to the clinician's office weekly to monthly to receive injections. And over the course of three to five years of allergy shots, this can add up to 180 office visits due to sensitization build-up and maintenance treatments.[11]

Second, some patients with house dust mite allergies may notice an improvement in symptoms in about eight weeks when treated with sublingual immunotherapy because they are receiving the maintenance dose from the onset of therapy,[8,12] while it may take up to 12 months with allergy injections.[13]

Next, sublingual immunotherapy is available to treat common allergens like grass, ragweed, and house dust mites once the diagnosis is made by clinical history and confirmed with a serum IgE test.[14] With allergy shots on the other hand, the allergens are most often diagnosed with a skin prick test of multiple allergens or a serum IgE test to determine which ones to treat.[3]

Lastly, both forms of immunotherapy can reduce symptoms and the need for symptomatic medication,[5,8–10] and allergy shots may provide lasting relief from multiple allergens including pollen, pet dander, and house dust mites.[6]

Ultimately, the choice between sublingual immunotherapy tablets and allergy shots should be based on multiple factors, such as the patient's specific allergies, treatment preferences, and lifestyle considerations.[4]

Dr. Caudle:
So now that we've talked about the differences between allergy immunotherapy options, Dr. Eghrari, let's turn our focus to house dust mites— a very common allergen—and ODACTRA®. Can you tell us about ODACTRA's efficacy as a sublingual immunotherapy for house dust mite allergies?

Dr. Eghrari:
I'd be happy to. First, I'd like to clarify something, as there's some confusion between house dust mites and bed bugs. Unlike bed bugs, house dust mites are microscopic creatures, invisible to the naked eye, that feed on dead skin cells. Unfortunately, some patients with a dust mite allergy may experience symptoms year-round, with the worst of it as soon as they wake up. And this is because one's bed provides the perfect feeding ground for dust mites with the combination of humidity and dead skin cells.[15]

The efficacy of ODACTRA was studied in patients with house dust mite-induced allergic rhinitis who were able to take traditional pharmacotherapy, such as antihistamines and nasal steroids, and also received either ODACTRA or placebo.[8]

The primary endpoint was the average total combined rhinitis score, also known as the TCRS, which is a score that combines daily rhinitis symptom scores and daily symptomatic medication use scores.[8]
As you can see here, the group treated with ODACTRA demonstrated a significant reduction versus placebo in the total combined rhinitis score, consistent with reduction in allergy symptoms as well as decreased use of symptomatic medications. These results were observed throughout 52 weeks of treatment, including through the pollen seasons, despite polysensitization in 67 percent of patients. In fact, in the last eight weeks of treatment, the ODACTRA group showed a 16.1 percent reduction in the total combined rhinitis score compared to placebo.[8,16]

Here you see data showing the efficacy of ODACTRA in adolescent patients aged 12 to 17 years. The patients taking ODACTRA had a 22 percent reduction in the average total combined rhinitis score compared to patients on placebo, as well as a 60 percent reduction in rhinitis daily medication use. As you can see here, the patients on ODACTRA also reported improvements in the daily symptom scores for rhinitis by 20 percent and conjunctivitis by 25 percent.[8,17]

Dr. Caudle:
Thanks for walking us through that efficacy data, Dr. Eghrari. And what can you tell us about the safety profile of ODACTRA?

Dr. Eghrari:
Well, whenever we consider allergy immunotherapy of any form, we need to talk about safety and tolerability. With sublingual immunotherapy, we're introducing something that the patient is allergic to, into their mouth. So we might expect a reaction of some sort in the local area. The adverse events that were most commonly reported with sublingual immunotherapy tablet treatment, in pooled analysis of safety data from phase II and III trials, included throat irritation, oral pruritis, ear pruritis, and mouth edema. These were usually mild and they resolved within 30 to 60 minutes after administration. And patients often no longer had these symptoms after the first two weeks of therapy.[8,18]

Now looking specifically at ODACTRA, patients aged 12 to 17 were asked to complete an adverse event report card to report symptoms experienced within 60 minutes of dosing every day for the first 28 days of treatment. The most common adverse events reported from this solicitation were itching in the mouth, throat irritation, and itching in the ear, and these occurred in at least 50 percent of adolescent patients in this study. To a lesser extent, tongue pain, stomach pain, swelling of the uvula or back of the mouth, and swelling lips were reported in 20 to 25 percent in the same patient population.[8]

In addition to the solicited adverse reactions collected over the first 28 days of daily treatment, investigators collected unsolicited adverse reactions reported over the entire trial period.

The most common unsolicited adverse reactions were oral paresthesia, oral pain, tongue pruritus, stomatitis, and chest discomfort, each reported in 2 to 5.3 percent of patients.[8]

You might be asking yourself, why is it important to know about both solicited adverse reactions during the first 28 days and unsolicited adverse reactions collected over the entire course of the clinical trials. Remember, we are administering a dose of allergen that the patient is allergic to, so it's important to understand what happens to a patient initially and over time. With this data, we can set expectations with patients when initiating therapy.[8]

The results with ODACTRA show that most patients will experience adverse reactions upon initiating therapy. But for the majority of patients who continue on therapy, these rates will decline.[8]

In addition to adverse reactions, I would like to share with you a few other important points from the clinical trials. First, there were no reports of adverse events requiring rescue epinephrine. Second, no other serious adverse events or treatment-related systemic allergic reactions were reported in the patients treated with ODACTRA. And finally, the discontinuation rate due to adverse events was 10 percent for ODACTRA and one percent for placebo.[8]

Dr. Caudle:
So, Dr. Eghrari, before we end our discussion today, could you please explain the process of evaluating a patient for sublingual immunotherapy and how healthcare providers can determine if ODACTRA may be an appropriate choice for their patients? For example, do pediatricians require a consultation with an allergist?

Dr. Eghrari:
The short answer is that pediatricians can treat their dust mite-allergic patients appropriately with ODACTRA for patients 12 to 65 years of age.[8]

Really, I'm an advocate for empowering pediatricians and primary care providers to provide the care that they see fit for their patients. They know their patients best and have built relationships and trust with them and their caregivers. So they're in a great position to introduce shared decision-making around allergic immunotherapy to help address the root cause of allergic rhinitis.

We're trained to evaluate a patient with a history-first approach to identify the allergen. And so the first step is to consider the clues from a thorough patient history.

For example, a patient with a dust mite allergy may experience symptoms of allergic rhinitis with or without conjunctivitis year-round. But some patients may also experience seasonal exacerbations due to seasonal pollens.[19]

So a patient with a dust mite allergy who experiences seasonal exacerbations may be misdiagnosed for a seasonal pollen allergen alone. As a result, the underlying dust mite allergy can remain unaddressed. Treating the relevant allergen can help patients get below their allergen threshold.[20]

Once the history points us in the direction of house dust mite allergy, we can order a serum IgE test that includes Dermatophagoides farinae or Dermatophagoides pteronyssinus house dust mites.[8]

As you can see in this example IgE report, this patient tested positive for both species of house dust mite, Timothy grass, and short ragweed. Once you have a confirmatory test along with the patient history, you can consider ODACTRA for appropriate patients.[8]

Now, ODACTRA may not be appropriate for patients with severe, unstable or uncontrolled asthma, a history of any severe systemic allergic reaction or any severe local reaction after taking any sublingual allergen immunotherapy, a history of eosinophilic esophagitis or hypersensitivity to any of the product's inactive ingredients.[8]

Once you and the patient opt to treat their house dust mite allergy with ODACTRA, administer the initial dose in the office under clinician supervision. Patients will also receive medication counseling and education, including a review of potential adverse events. You'll also provide them a rescue epinephrine, instruct them on its proper use, and to seek immediate medical care if used. And finally, schedule regular check-ins to monitor adverse events, adherence, and response.[8]

Dr. Caudle:
Those are great practical key takeaways from our discussion.

And I'd like to thank my guest, Dr. Jacqueline Eghrari, for helping us better understand the allergy immunotherapy, its role and potential benefits, and how ODACTRA® can be used to treat appropriate patients with house dust mite allergic rhinitis.

Dr. Eghrari, it was great speaking with you today.

Dr. Eghrari:
My pleasure. If you'd like additional information on ODACTRA and other SLIT-Tablets, you can visit alktablets.com or email slittablets@alk.com.

Dr. Caudle:
For ReachMD, I'm your host Dr. Jennifer Caudle. Please stay tuned to hear some Important Safety Information.

ReachMD Announcer:
INDICATION:

- ODACTRA® is an allergen extract indicated as immunotherapy for the treatment of house dust mite (HDM)–induced allergic rhinitis, with or without conjunctivitis, confirmed by positive in vitro testing for IgE antibodies to *Dermatophagoides farinae* or *Dermatophagoides pteronyssinus* house dust mites, or by positive skin testing to licensed house dust mite allergen extracts.
- ODACTRA is approved for use in persons 12 through 65 years of age.
- ODACTRA is not indicated for the immediate relief of allergic symptoms

IMPORTANT SAFETY INFORMATION

WARNING: SEVERE ALLERGIC REACTIONS

ODACTRA can cause life-threatening allergic reactions such as anaphylaxis and severe laryngopharyngeal restriction. Do not administer ODACTRA to patients with severe, unstable or uncontrolled asthma. Observe patients in the office for at least 30 minutes following the initial dose. Prescribe auto-injectable epinephrine, instruct and train patients or parents/guardians on its appropriate use, and instruct patients or parents/guardians to seek immediate medical care upon its use. ODACTRA may not be suitable for patients with certain underlying medical conditions that may reduce their ability to survive a serious allergic reaction. ODACTRA may not be suitable for patients who may be unresponsive to epinephrine or inhaled bronchodilators, such as those taking beta-blockers.

- ODACTRA is contraindicated in patients with:

  - Severe, unstable or uncontrolled asthma
  - A history of any severe systemic allergic reaction
  - A history of any severe local reaction after taking any sublingual allergen immunotherapy
  - A history of eosinophilic esophagitis
  - Hypersensitivity to any of the inactive ingredients [gelatin, mannitol and sodium hydroxide] contained in this product

- Before prescribing ODACTRA, please read the Boxed WARNING, full Prescribing Information, and Medication Guide, for additional Important Safety Information.

- ODACTRA can cause systemic allergic reactions including anaphylaxis which may be life-threatening. In addition, ODACTRA can cause severe local reactions, including laryngopharyngeal swelling, which can compromise breathing and be life-threatening.

- Prescribe auto-injectable epinephrine to patients receiving ODACTRA. Instruct patients (or parents/guardians) to recognize the signs and symptoms of a severe allergic reaction and in the proper use of emergency auto-injectable epinephrine. Instruct patients (or parents/guardians) to seek immediate medical care upon use of auto-injectable epinephrine and to stop treatment with ODACTRA. See the auto-injectable epinephrine package insert for complete information.

- Administer the initial dose of ODACTRA in a healthcare setting under the supervision of a physician with experience in the diagnosis and treatment of allergic diseases and prepared to manage a life-threatening systemic or local allergic reaction. Observe patients in the office for at least 30 minutes following the initial dose of ODACTRA.

- Patients who have persistent and escalating adverse reactions in the mouth or throat should be considered for discontinuation of ODACTRA.

- Eosinophilic esophagitis has been reported in association with sublingual tablet immunotherapy. Discontinue ODACTRA and consider a diagnosis of eosinophilic esophagitis in patients who experience severe or persistent gastro-esophageal symptoms including dysphagia or chest pain.

- Withhold immunotherapy with ODACTRA if the patient is experiencing an acute asthma exacerbation. Re-evaluate patients who have recurrent asthma exacerbations and consider discontinuation of ODACTRA.

- ODACTRA has not been studied in subjects who are receiving concomitant allergen immunotherapy. Concomitant dosing with other allergen immunotherapy may increase the likelihood of local or systemic adverse reactions to either subcutaneous or sublingual allergen immunotherapy.

- Stop treatment with ODACTRA to allow complete healing of the oral cavity in patients with oral inflammation (e.g., oral lichen planus, mouth ulcers, or thrush) or oral wounds, such as those following oral surgery or dental extraction.

- The most common solicited adverse reactions reported in clinical studies for subjects 18 through 65 years of age treated with ODACTRA vs. placebo included throat irritation/tickle (67.0% vs. 20.8% placebo), itching in the mouth (61.3% vs. 14.1%), itching in the ear (51.7% vs. 11.7%), swelling of the uvula/back of the mouth (19.8% vs. 2.4%), swelling of the lips (17.7% vs. 2.7%), swelling of the tongue (15.8% vs. 2.1%).

- The most common unsolicited adverse reactions reported in clinical studies for subjects 18 through 65 years of age treated with ODACTRA vs. placebo included paresthesia oral (9.2% vs. 3.2%), tongue pruritus (4.7% vs. 1.1%), oral pain (2.7% vs. 0.6%), stomatitis (2.5% vs. 1.1%), dyspepsia (2.2% vs. 0.0%).

- The most common solicited adverse reactions reported in clinical studies for adolescents 12 through 17 years of age treated with ODACTRA or placebo included throat irritation/tickle (73.4% vs. 35.8% placebo), itching in the mouth (73.4% vs. 14.7%), itching in the ear (50.0% vs. 11.6%), tongue pain (24.5% vs. 4.2%), stomach pain (23.4% vs. 15.8%), swelling of the uvula/back of the mouth (20.2% vs. 3.2%), swelling of the lips (20.2% vs. 1.1%), swelling of the tongue (19.1% vs. 3.2%), throat swelling (18.1% vs. 8.4%), nausea (17.0% vs. 9.5%).

- The most common unsolicited adverse reactions reported in clinical studies for adolescents 12 through 17 years of age treated

with ODACTRA vs placebo included paraesthesia oral (5.3% vs. 0.0%), oral pain (4.3% vs. 0.0%), tongue pruritus (3.2% vs. 0.0%), pruritus (2.1% vs. 1.1%), stomatitis (2.1% vs. 1.1%), and chest discomfort (2.1% vs. 0.0%).

- All pregnancies have a risk of birth defect, loss, or other adverse outcomes. Available data on ODACTRA administered to pregnant women are insufficient to inform associated risks in pregnancy.

Before prescribing ODACTRA, please read the Boxed WARNING, full Prescribing Information, and Medication Guide, for additional Important Safety Information.

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