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Assessing Omalizumab for Food Allergy Treatment

Dr. Caudle:
Welcome to *Clinician's Roundtable* on ReachMD. I'm your host, Dr. Jennifer Caudle, and today, I'm speaking with Dr. Sayantani Sindher, who is a Clinical Associate Professor of Medicine and Pediatric Allergy and Clinical Immunology Physician at Stanford Healthcare and Stanford Medicine Children's Health. Together, we'll be discussing her research from an article, titled "Omalizumab for the Treatment of Multiple Food Allergies," which was published in *The New England Journal of Medicine* in 2024.

Dr. Sindher, thank you so much for joining us today.

Dr. Sindher:
Thank you so much, Dr. Caudle, for inviting me.

Dr. Caudle:
Of course, and congratulations on your article. Would love to dive right in with you. So what prompted your interest in doing this study?

Dr. Sindher:
Oh, yes. Thank you so much for that question. So currently, when it comes to food-allergic children, our main source of management and guidance in children and adults is avoidance. And yes, there is a peanut oral immunotherapy product that is FDA-approved. It really doesn't address the needs of the majority of our patient population. We see a lot of our folks who have multi-food allergies, so 45 percent of the patients we see in our research unit, as well as my outpatient clinic have not just peanut allergy but many other allergens that are not met with our current treatment options, and that's where—and many people before me have paved the way for this with initial pilot studies and phase I studies—where they have looked at the use of omalizumab in conjunction with oral immunotherapy to see if that can actually help us better meet the needs of our patients. So that's where it all started.

Dr. Caudle:
That's wonderful. And can you talk a little bit about the objective?

Dr. Sindher:
Exactly. Right. So the paper is based on just the initial stage 1 results of an ongoing study. So the ongoing OUtMATCH study is up to four years long, and it is still ongoing, so we shall have more publications to date, but the objective of the stage 1 was to assess whether omalizumab alone has the potential for preventing allergic reactions in the setting of accidental exposures.

Dr. Caudle:
Excellent. And which methods did you use? And who were the specific patient populations?

Dr. Sindher:
Right. So we wanted to look at children as young as one year of age all the way up to 55 years of age, so children and adults. And because this is a clinical trial, a lot of emphasis was based on safety. So when we assess for eligibility, those who had prior history of very severe reactions, we did not include them in the study because a lot of the endpoints that we were looking at to assess whether omalizumab is working is to give them doses of the food that they're allergic to and watch them react. So that is one subgroup of patients who likely will benefit the most from something like this that we were not able to incorporate into the study because of safety concerns. But outside of that, as I mentioned, children as young as one year of age all the way up—adults all the way up to 55 years of age—were included. We looked at folks who had positive skin prick testing to peanut and two other allergens, and then we did IgE testing, so blood work to see who would qualify. And if they met the criteria there, we performed what we called double-blind placebo-

controlled food challenges where we are blinded—the investigators, the participants are blinded—so we don't know what they're getting, the participants don't know what they're getting, and we have placebo in there as well. And we perform these food challenges to make sure that they reacted. So only those who reacted at a level of less than 100 milligrams of peanut protein are those that qualified for the study. And just to put it into perspective, one peanut is about 300 milligrams of protein, so folks had to be reacting at a rate where the peanut protein was one-third of the size of an actual peanut.

Dr. Caudle:
Okay. Thank you so much for that. And for those of you who are just tuning in, you're listening to *Clinician's Roundtable* on ReachMD. I'm your host, Dr. Jennifer Caudle, and I'm speaking today with Dr. Sayantani Sindher about her research on the use of omalizumab for the treatment of food allergies.

So now that we have some background on this study, Dr. Sindher, what were some key findings? And were there any adverse effects?

Dr. Sindher:
Yes. So the key findings were actually very exciting. The analysis was done in over 177 children and adults, and what we found is two-thirds of the participants who were treated with omalizumab for 16 to 20 weeks actually were able to eat the equivalent of two and a half peanuts at the end of that period, and these are folks who reacted at less than one-third of a peanut, so that was a huge jump and very exciting.

In terms of adverse events, omalizumab has actually been out there for over 20 years. It is already approved for asthma, as well as a few other allergic indications, such as those who have spontaneous hives and a few other medical indications, so it has been out there for a long time, so we've been able to really look at adverse events over time. But as part of the study, we saw that it was very well tolerated. The most common reactions we saw were injection site reactions that occurred in about three percent of the population, and then we also saw some pyrexia, or increased temperature, which we found in 16 percent of the population, who were treated with Xolair, but generally, they were very well-tolerated.

Just as a note, Xolair does come with a black box warning of anaphylaxis, and we did not note any cases of anaphylaxis in this study. We did not have to stop Xolair on any participant because of adverse reactions or poor outcomes.

Dr. Caudle:
Interesting. And are clinicians able to incorporate this data into practice?

Dr. Sindher:
Yeah. So what was also very exciting recently is middle of February, February 16th, the FDA actually approved the use of omalizumab in the setting of food allergy, and it was approved for children one all the way up into adulthood, no upper age limit, and it could be utilized for folks with single or multi-food allergy with avoidance. So yes, in many practices I think allergists may already be prescribing omalizumab for their food-allergic patients.

Dr. Caudle:
That's interesting and quite exciting. And looking ahead, Dr. Sindher, what further research needs to be done on omalizumab and other treatments for food allergies?

Dr. Sindher:
Oh yes, as excited as we are, it also brings up many, many questions. One important fact is that we saw the successful outcome in two-thirds of the patients, which means one-third did not have that benefit, and what we really would like to find out is why. How can we get this number up to 100 percent? How can we meet the needs of all our patients? And what is it that makes some patients more receptive to omalizumab versus those that don't have such a positive outcome? Because if we can identify that from the get-go, we can give appropriate guidance to the patients and manage them accordingly. So that is an area that is being explored right now, trying to understand why one-third of patients did not have that positive benefit that we saw in two-thirds of the patients.

And then the other element that we are looking into is the high IgE level. As part of the clinical trial, only patients who met an IgE value that was within the dosing algorithm for Xolair were included in the study, but in our outpatient clinics, we see patients with very high IgEs who were not assessed in this study, and it would be great to understand outcomes in those patients where their IgE values are outside the dosing algorithm for Xolair. So still a lot more work to be done, but a great step in the right direction.

Dr. Caudle:
With those forward-looking thoughts in mind, I'd like to thank my guest, Dr. Sayantani Sindher, for sharing her research and insights on the potential of treating food allergies with omalizumab.

Dr. Sindher, it was a pleasure speaking with you today.

Dr. Sindher:
And thank you so much for having me. Likewise, the pleasure was mine as well.

Dr. Caudle:
I'm your host, Dr. Jennifer Caudle. And to access this and other episodes in our series, visit *Clinician's Roundtable* on ReachMD.com, where you can Be Part of the Knowledge. Thank you so much for listening.