Retrospective Analysis of Successful Discontinuation of Long-Term Omalizumab Therapy in Patients with Chronic Urticaria

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Background

Omalizumab is a monoclonal antibody targeting unbound IgE which was approved for use in Chronic Urticaria (CU) in early 2013. Recent studies have highlighted biomarkers which predict patient response to omalizumab, such as D-dimer, IgE, and autologous serum skin testing. In terms of tapering however, there is currently no consensus amongst the experts guiding treatment duration once clinical efficacy has been established. Additionally, biomarkers and/or demographics attributed to success of treatment taper have not been identified.

Research Question

Are there biomarkers, or unique characteristics, among chronic urticaria patients who, after demonstrating clinical response to omalizumab, go on to fail tapering of omalizumab due to re-emergence of symptoms?

Methods and Materials

Retrospective chart review of 14 CU patients treated with omalizumab between June 2013 and December 2016. We analyzed factors specific to CU, including details obtained during clinic visits and any available allergy testing or lab data.

Results

Of the 14 patients, 6 successfully tapered off omalizumab and 8 were unable to taper due to refractory urticaria. Those able to taper off omalizumab remained symptom-free for at least 9 months (up to 24 months), until the completion of the study; these patients were on omalizumab for a duration of 11-23 months. Patients intolerant to omalizumab taper were on omalizumab for a duration of 13-37 months. We focused on descriptive frequencies due to our small sample size. Meanwhile, Wilcoxon test and Fisher's test were used to compare the two groups. Statistically significant differences between the two groups were the presence of angioedema in the "on omalizumab"/taper failure group and vitamin D supplementation in the "successful taper" group. Our study was limited by the fact that lab values were not obtained uniformly across all patients prior to or during therapy initiation.

Patient Demographics

	On omalizumab (n=8)	Successful omalizumab taper (n=6)
Age: mean (SD)	48.75 (13.26)	40.67 (13.99)
Female	4	4
Male	4	2
African American	2	1
Caucasian	6	5

Successful omalizumab tapering in treatment of chronic urticaria is associated with Vitamin D supplementation and lack of angioedema.

Categorical Variables	On omalizumab (n=8)	Successful omalizumab taper (n=6)	Odds ratio (95% CI)	Fisher's exact test p-value
Omalizumab Dose				
150 mg	5	2		0.27
300 mg	2	4		
375 mg	1	0		
Angioedema			0.08 (0.0013, 1.10)	**0.04**
yes	8	2		
no	0	4		
Asthma			1.36 (0.01, 125.24)	1
yes	1	1		
no	7	5		
Allergic Rhinoconjunctivitis			0.23 (0.004, 3.26)	0.31
yes	3	0		
no	5	6		
Former Smoker			0.36 (0.01, 6.48)	0.58
yes	3	1		
no	5	5		
CBC Abnormality on Omalizumab			1.46 (0.08, 28.60)	1
yes	2	2		
no	6	4		
CMP Abnormality on Omalizumab			1.90 (0.15, 33.34)	0.63
yes	4	4		
no	4	2		
Thyroid Autoantibodies			1.60 (0.08, 34.56)	1
yes	2	2		
no	5	3		
NA	1	1		
ANA +			3.33 (0.20, 75.60)	0.56
yes	2	3		
no	5	2		
NA	1	1		
Urticaria Index			1.40 (0.06, 100.83)	1.0
negative	1	0		
positive	6	4		
NA	1	2		
Vit D Supplementation			17.34 (1.15, 1165.33)	**0.03**
yes	0	4		
no	8	1		
NA	0	1		

Conclusion

Our preliminary results may be helpful by giving insight for planning larger studies for prediction of omalizumab discontinuation in the treatment of chronic urticaria. From our data, those with an angioedema component of their illness are more likely to require long-term therapy. Additionally, those on Vitamin D supplementation were more likely to tolerate omalizumab tapering and discontinuation. This could impact future recommendations towards Vitamin D supplementation during omalizumab treatment. Next steps are to expand our study to confirm our findings of angioedema and Vitamin D supplementation within a larger patient population.

References

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