Summary of the La Crosse Method™ Practice Protocol

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Background

Since 1970, Allergy Associates of La Crosse has developed and refined what is today known as the La Crosse Method Protocol for sublingual immunotherapy. Since then, more than 200,000 patients across the country have been treated by Allergy Associates of La Crosse and other providers trained in the custom protocol to treat food and inhalant allergies.

We have observed a combination of clinical symptom improvements, reduced skin test reactivity, and decreases in specific IgE levels at low doses of sublingual antigen given three times daily. In 1986, Drs. Scadding and Brostoff published a dust mite study using threshold dosing four times daily. This double-blind, cross-over design study showed objective improvement in 72% of patients after only two weeks of treatment.

The past 20 years have produced studies using a variety of dosing regimens showing efficacy at 0.017 to 500 times the subcutaneous injection immunotherapy (SCIT) dose. Frequency of dosing has ranged from once per week to multiple daily administrations. An apparent paradox appeared — studies showed effectiveness at all dosing ranges. When giving single antigens on a once daily basis, there is a dose response for grass pollen. Durham has reported that at about 15-20 times the cumulative monthly dose of SCIT (equivalent to 150-200 mcg of major allergen), there appears to be a safe and effective dose for grass pollen (S. Durham, JACI Vol 117, No. 4 p 802-809.) When higher concentrations were used, side effects increased without much additional benefit. Several studies now suggest that more than one mechanism is affecting tolerance.

The study, *Multiple daily administrations of low dose SLIT in allergic rhinoconjunctivitis* by V. Bordignon (Ann Allergy Asthma Immunol, 2006 Aug; 97(2):158-63) helps in understanding why the La Crosse Method threshold dosing protocol has also been clinically effective. Bordignon and his colleagues reported:

"We found a direct correlation between the improvement of end points and the number of daily administrations."

"...with the extremely low doses we used, the impact of SLIT on skin reactivity to the relevant allergen and on the drug use scores was critically dependent on the number of daily assumptions."

"the allergen persistence in the oral mucosa may be a far more relevant factor for gaining efficacy than allergen concentration."

High-dose intermittent administration of antigen (in ranges similar to our Pre-seasonal option) produces clonal deletion and/or anergy. On the other hand, the low dose frequent administration of antigen sublingually leads to active suppression. (Omata, JACI April 2005; G. Ciprandi, Allergy 2006 61: 511 – 515).

Combining the threshold dosing with pre-seasonal rush protocols has clinically given us the ability to take advantage of both mechanisms to develop tolerance in a wide variety of cases.

Patient Selection

We have found SLIT to be useful for infants and children, including those with eczema and recurrent ear infections; severe asthmatics; patients with chronic sinusitis; patients with food and mold allergies; anaphylactic patients; patients with multiple severe allergies; and those who are averse to needles or would otherwise not comply with a regimen of SCIT.

Diagnostic Testing Options

The La Crosse Method Practice Protocol recommends the use of appropriate skin and or in vitro tests based on a thorough allergy history and physical examination.

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La Crosse Method Options

A combination of one or more protocol options may be offered to patients, with the selection of the appropriate dosing protocol depending on the patient's history, symptoms and the number and severity of sensitivities.

Multi-Allergen Inhalant Threshold Dosing

For patients with multiple moderate to severe allergies to pollens, mites and molds or a history of anaphylaxis. This preferred dosing protocol follows the multi-allergen U.S. tradition. The starting treatment level is intended to be therapeutic, and is based on the patient's skin test or specific IgE class results. Daily dose is 3 times daily. We recommend using a metered dispenser. Patients are re-evaluated every 3 months, and re-tested at 6 to 9 month intervals for evidence of reduced skin test or IgE class results. Treatment usually lasts 3 to 5 years, until the patient enjoys symptom relief and a reduced skin or in vitro response.

Pre-Seasonal Inhalant Dosing

This method is initiated 8 weeks prior to the onset of the allergen's season to serve as a "booster," and it is most appropriate for patients with strong seasonal symptoms to trees, grasses or ragweed. It is also used for mite prior to the heating season. This method provides short-term symptomatic relief and can be used in conjunction with Multi-Allergen Threshold Dosing.

Multi-Allergen Food Threshold Dosing

The starting treatment levels for this method are based on the patient's specific IgE concentrations. Treatment levels gradually increase as the specific IgE levels are reduced. Daily dose is 3 times per day, preferably using a metered dispenser. This is often prescribed with Multi-Allergen Inhalant Threshold Dosing for patients exhibiting both food and inhalant sensitivities.

SLIT Side Effects and Special Considerations

If mouth itching develops, use an antihistamine. Back down dose, or stay at the same concentration until itching subsides and tolerance increases.

Summary

The La Crosse Method Practice family of Protocols blends the strengths of U.S. and European SLIT traditions in testing and treatment. The underlying basis for the protocol relies upon careful testing and diagnosis in order to provide optimal treatment based on individual patient need. It is intended to offer practitioners with safe, effective options for the full spectrum of allergic patients — from those who are moderately sensitive, to those whose allergies have become debilitating and ultimately life-threatening.

When considering the appropriate protocol, special consideration should be given to ensure the method first and foremost minimizes safety risks for the specific patient given his or her history, exam and testing results. It is important to consider which will offer the maximum benefit with minimal risk. Based on clinical evidence and current scientific research, optimal dosing levels are based on what is therapeutically effective for each individual patient and adjusted accordingly throughout treatment.

Because our dose escalation is supported by retesting and monitoring patient response; it minimizes risks of unnecessarily high doses without incremental benefit or adverse events, while simultaneously avoiding a dosing scenario that becomes cost-prohibitive for patients.

Current and Future Research

Current research projects include the impact of SLIT in prevention of asthma and other comorbidities, and in the treatment of patients with specific food sensitivities. We welcome the opportunity to work with other investigators and researchers on the impact of SLIT in the treatment of patients suffering from allergic disease.

Bibliography

A complete copy of the La Crosse Method Practice Protocol and an updated sublingual immunotherapy research bibliography can be obtained from Allergychoices, Inc., 2731 National Drive, Onalaska, WI 54650.
Phone: 866-793-1680; email: info@allergychoices.com or visit allergychoices.com.

Validation

The La Crosse Method Protocol outcomes have been validated through the Care Innovations™ Validation Institute, an independent team of population health scientists and bio-statisticians who provide objective review to validate performance in healthcare. For more information, visit validationinstitute.com.