

Allergy & Immunology, PLC's
Asthma and Allergy Center

Lynchburg
1715 Thomson Dr. Lynchburg, VA 24501
P. 434.846.2244 F. 434.846.0602

Roanoke
1505 Franklin Rd, SW, Roanoke, VA 24016
P. 540.343.7331 F. 540.343.7349

Salem
3529 Keagy Rd Salem, VA 24153
P. 540.343.7331 F. 540.725.1356

Dane McBride, M.D.

Luis Matos, M.D.

Saju Eapen, M.D.

Thomas Fame, M.D.

Larissa Norman, FNP

Pamela Price, FNP

Fact Sheet: Efficacy And Safety Of Immunotherapy

Immunotherapy, provided by qualified physicians, is an effective and safe treatment for asthma, allergic rhinitis and insect venom allergy.

Effective treatment for asthma

A meta-analysis of 20 published prospective studies showed that allergen immunotherapy is effective in the treatment of asthma.(1) The American College of Allergy, Asthma & Immunology (ACAAI) recently compiled an annotated bibliography of 59 articles from the medical literature indicating the value of expert care and immunotherapy for asthma.(2) A meta-analysis of 23 published studies involving 935 asthmatic patients with documented allergy indicated that immunotherapy is effective in a selected population of allergic asthmatic patients.(3)

Effective treatment for allergic rhinitis

An extensive review of immunotherapy for allergic rhinitis in children showed that the only treatment able to affect the natural cause of the disease is immunotherapy, and that immunotherapy may prevent the onset of asthma.(4) A meta-analysis of 18 published studies involving 789 patients concluded that immunotherapy is highly effective in the treatment of allergic rhinitis.(5)

Effective treatment for insect venom allergy

Immunization with insect venom is an extremely effective treatment for preventing future systemic reactions to insect stings in individuals with previously demonstrated susceptibility.(6) A meta-analysis of nine published studies indicated that a course of immunotherapy is highly effective in the management of insect sting hypersensitivity.(7)

Immunotherapy safety

A report from the Mayo Clinic on 79,593 immunotherapy injections over a 10-year period showed the incidence of adverse reactions to be less than two-tenths of 1 percent (0.137 percent). Most of the reactions were mild and responded to immediate medical treatment. There were no fatalities.(8)

More than 1 million injections were given without a fatality to 8,706 patients in allergy clinics at Roosevelt Hospital, New York City, between 1935 and 1955.(9)

Comparative risks of immunotherapy

Nevertheless, rare occurrences of fatal anaphylactic episodes related to immunotherapy

continue to be reported and studied. A total of 35 deaths following immunotherapy administration were reported for the years 1985 through 1993. It has been estimated that during that period there were 52.3 million immunotherapy procedures, making the incidence of fatality less than one per million (0.6692 per million).(10) Data recently compiled by the Allergen Products Manufacturers Association (APMA) estimated the incidence of fatalities to be about three per 190 million annual injections, or approximately one per 63 million injections.(11) Another study evaluating 13 international fatalities related to immunotherapy between 1992 and 1996 identified an elevated risk for patients with active asthma and being switched to high doses.(12)

For perspective, it is useful to compare these statistics with the incidence of fatalities related to other kinds of injections. Studies of fatal anaphylaxis reactions to injected penicillin have ranged from 0.4 fatalities per million injections(13), to 1 fatality per 7.5 million injections.(14)

Fatalities related to radio contrast "dyes" used in intravascular radiologic studies in the early 1980s varied from 1 in 13,000 procedures(15) to 1 in 75,000 procedures.(16) A more recent study showed a substantial improvement to about 1 fatality in 169,000 procedures.(17)

Guidelines for safe and effective immunotherapy

Any immunotherapy fatality, no matter how rare, is unacceptable. To promote immunotherapy safety, the American College of Allergy, Asthma & Immunology offers the following guidelines:

1. Immunotherapy should be prescribed only by an allergist-immunologist or other physician who is expertly trained in the therapy.
2. Immunotherapy should be administered under the supervision of an allergist-immunologist or other physician specifically trained in immunotherapy, the early signs and symptoms of anaphylaxis, and appropriate emergency procedures and medications.(18)
3. Patients must be suitably selected for immunotherapy.
4. Immunotherapy should be given only in facilities equipped to treat anaphylaxis.
5. The health status of the patient should be evaluated prior to every injection. Patients, who are acutely ill, especially with asthma or respiratory difficulties, should not receive immunotherapy until their disease is stabilized.
6. Patients should always be asked about current medications prior to immunotherapy, to avoid interactions with beta blockers and other conflicting medications.
7. Patients must wait at the health care facility a minimum of 20 minutes after an allergen injection. The time period may be extended for high-risk patients.(19, 20)

References

1. Abramson MJ, Puv RM, Weiner JM. Allergen immunotherapy effective in asthma? A meta-analysis of randomized controlled trials. *Am J Respir Crit Care Med* 1995;151:969-974.

2. Sullivan TJ, Selner JC, Patterson R, Portnoy J, Seligman M. Expert Care and Immunotherapy for Asthma. A review of published studies with emphasis on patient outcome and cost. ACAAI Monograph, Nov 1996,1-25.
3. Ross RR. Effectiveness of immunotherapy in the management of asthma: A meta-analysis of the literature. May 1997. Data on file with American Academy of Allergy, Asthma & Immunology (AAAAI) and American College of Allergy, Asthma and Immunology (ACAAI) and submitted for publication.
4. Bousquet J, Demoly P. Specific immunotherapy for allergic rhinitis in children. *Allergy Clin Immunol Inter* 1996; 8:145-150.
5. Ross RR. Effectiveness of immunotherapy in management of allergic rhinitis: A meta-analysis of the literature. May 1997. Data on file with AAAAI and ACAAI and submitted for publication.
6. Valentine MD. Anaphylaxis and stinging insect hypersensitivity. *JAMA* 1992; 268:2830-2833.
7. Ross RR. Effectiveness of immunotherapy in the management of insect venom hypersensitivity: A meta-analysis of the literature. May 1997. Data on file with AAAAI and ACAAI and submitted for publication.
8. Valyaservi MA, Yocum MW, Gosselin VA, Hunt LW. Systemic reactions to immunotherapy at the Mayo Clinic. *J Allergy Clin Immunol* 1997; 99:S66.
9. Van Arsdel PP, Sherman WB. The risk of inducing constitutional reactions in allergic patients. *J Allergy* 1957; 28:251-261.
10. Turkeltaub P. Deaths associated with allergenic extracts. *FDA Medical Bulletin* 24, May 1994.
11. Data on file with the Allergen Products Manufacturers Association. April 1997 Communication.
12. Kordash T, Miller J. Allergenic extracts used in immunotherapy fatalities. *J Allergy Clin Immunol* 1997; 99:S67.
13. Orange RP, Donsky GJ. Anaphylaxis. In Middleton E, Reed CE, Ellis EF, editors. *Allergy: principles and practice*. St. Louis 1978, Mosby.
14. Idsoe O, Gruthe T, Wilcox RR, et al. Nature and extent of penicillin side-reactions with particular references to fatalities from anaphylactic shock. *Bull WHO* 1968; 38:159.
15. Shehadi WH. Death following intravascular administration of contrast media. *Acta Radiol Diagn* 1982; 26:457-61.
16. Hartman GW, Hattery RR, Witten DM, Williamson B. Mortality during excretory urography: Mayo Clinic Experience. *AJR* 1982; 139:919-922.
17. Katayama H, Yamaguchi K, Kozuka T, et al. Reactions to ionic and nonionic contrast media: A report from the Japanese Committee on the Safety of Contrast Media. *Radiology* 1990; 175:621-628.
18. Joint task force on practice parameters representing the American Academy of Allergy, Asthma & Immunology and the American College of Allergy, Asthma & Immunology. Nicholas RA, Bernstein IL, Blessing-Moore J, Fineman S, editors. *J Allergy Clin Immunol* 1996; 98:1-11.

19. Executive Committee, American Academy of Allergy, Asthma & Immunology. The waiting period after allergen skin testing and immunotherapy. *J Allergy Clin Immunol* 1990; 85:526-527.

Board of Directors, American Academy of Allergy, Asthma & Immunology. Position Statement. Guidelines to minimize the risk from systemic reactions caused by immunotherapy with allergenic extracts. *J Allergy Clin Immunol* 1994; 93:811-812