

Fact Sheet: Efficacy and Safety of Immunotherapy ('Allergy Shots')

Immunotherapy, or "allergy shots," 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 injections¹³ to 1 fatality per 7.5 million injections.¹⁴

Fatalities related to radiocontrast "dyes" used in intravascular radiologic studies in the early 1980s varied from 1 in 13,000 procedures¹⁵ 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}

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