White Paper for United States Senators and Representatives

Enzyme Potentiated Desensitization (EPD)

The American EPD Study: 1993–2000

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Abstract

Enzyme Potentiated Desensitization (EPD) is a unique method of immunotherapy, developed in the 1960s, which involves treating all types of allergy with combinations of a large variety of extremely low dose allergens. EPD is a cell-mediated type of immunotherapy. It has been employed to treat multiple conditions and appears to be a long lasting treatment option for allergy and autoimmune illnesses. It has also been employed for many conditions not generally thought to be due to any type of allergy or autoimmune disease.

This paper summarizes the results of treatment with EPD of 10,372 patients for various conditions from 1993 through 2000 by members of the American EPD Society (AEPDS). The AEPDS is a group of over 60 physicians specifically trained to administer EPD immunotherapy. From 1993 through 2000, the study was formally supervised by the institutional review board (IRB) of the Great Lakes College of Clinical Medicine (GLCCM).

Introduction

Enzyme Potentiated Desensitization (EPD) is a method of immunotherapy developed by the clinical and academic allergist, Leonard M. McEwen, M.D., in England in the mid 60's.[1-8] The method involves desensitization with combinations of a wide variety of extremely low dose allergens (10^{-14} to approximately 10^{-7}, or 1 part in 100 million to as low as 1 part in 1 quadrillion). These allergens are given with the enzyme, β-glucuronidase. The β-glucuronidase likely acts as a *lymphokine*, a substance which potentiates the immunizing ability of the allergens. EPD appears to specifically induce the production of "activated" T-suppressor cells. This is most likely by way of production of $CD8^+$ cytotoxic cells, or via "switching" Th2 to Th1 cells.

Conventional "escalating dose" (where the dose is started "low" – usually 1 to 10,000, and increased over time to as high as 1 to 10, 1 to 20 or 1 to 100) immunotherapy is employed in this country primarily to treat hay fever and cat and dust mite allergy, which are all IgE mediated. This type of therapy works primarily through by causing the patient to produce "blocking antibody" (specific IgG), which inhibits the histamine-releasing ability (which produces the allergy symptoms) of the mass cell. The higher the level of blocking antibody that can be produced, the more successful is the treatment. In order to produce adequate levels of blocking antibody it requires administration of very high doses of allergen. Therefore, treatment using this method can be dangerous due to the risk of severe reactions such as anaphylaxis, massive swelling, collapse and death

In fact, conventional escalating dose immunotherapy is banned in the United Kingdom, except when employed in a closely supervised hospital setting; 26 deaths had been reported there over a period of several years. In the United States, at least 60 deaths have been recorded as a result of conventional immunotherapy, but the number is likely closer to 100 since treatment began in the 1930s.

Deaths from conventional escalating dose immunotherapy are generally a result of anaphylaxis. This is due to the extremely high dose of antigen required to produce a significant clinical effect. EPD immunotherapy, however, is cell-mediated and extremely

low dose. The highest ending dose ("maintenance" dose) of EPD is at least 10 million times less than the standard maintenance dose for conventional immunotherapy. Likely as a direct result from this, no serious systemic reaction or death due to EPD immunotherapy has been recorded since use began in the 1960s. EPD immunotherapy is the only allergy immunotherapy permitted to be used in a physician's office (outside a hospital setting) in the United Kingdom.

The danger of fatal or life-threatening systemic reactions to EPD treatment is negligible. Well over 350,000 doses of EPD have been given worldwide, and – unlike other types of immunotherapy – life-threatening reactions to EPD *have not been reported* since use was begun in the late 60's.

In England, "conventional" (escalating dose) immunotherapy has now been banned by the Medicines Commission (26 deaths had been reported) and may now only be given in a hospital setting where emergency resuscitation equipment is immediately available. On the other hand, EPD is allowed to be administered in physicians' offices in England. Hence there has been a virtual demise of "traditional" high dose immunotherapy in England.

Conventional escalating dose immunotherapy generally does not offer long lasting benefit, and it cannot easily be stopped without the return of significant symptoms in 3 to 12 months. It has been suggested by several previous studies of EPD immunotherapy that this method of treatment can produce much longer lasting desensitization than does conventional immunotherapy, with treatments lasting as long as 1-5 years. Approximately half of patients who respond to EPD may stop permanently after between 10 and 20 treatments.

Conventional immunotherapy must usually be administered twice weekly for the first four to six months of treatment. Once the very high maintenance dose is reached, the treatment interval may be extended to once every two weeks, but rarely less often. EPD immunotherapy, on the other hand, is only administered every two months or less often, according to previous published studies and our 7-year study.

Treatment is required only every two months initially for a period of approximately 12 months. After that time, the treatment interval may generally be extended to three months or longer. Most adults with significant problems require 16 of 18 treatments at intervals of three months or longer, at which time treatment may be discontinued or significantly reduced (intervals of a year or less often are common) for the majority of patients.

EPD includes mixtures of antigens developed by Dr. McEwen over the past 30 years which may act quite "universally." This means patients allergic or intolerant to *most substances* have responded to treatment. Available EPD mixtures include inhaled pollens, danders, dust and mites, a wide range of bacteria, fungi, yeast (including *candida* species), molds, all foods (except EPD will not desensitize to raw carrot and raw apple), many food additives, most common chemicals (except pesticides and herbicides), formaldehyde, detergents (for contact skin sensitivity), wood terpenes, and mosquito (which likely cross reacts with other non-venomous insects). EPD treatment for bee venom anaphylaxis is currently under investigation in England.

EPD has the distinct apparent advantage that it appears to effectively treat a very wide variety of immune and autoimmune disorders (and others not generally perceived to be immune-related), including illnesses which respond poorly -- or not at all -- to other methods of treatment of *any* kind. Some of the conditions being treated successfully with EPD include hay fever,[8,11,14,15,25] dust mite allergy,[16,20] perennial rhinitis,[6,14] asthma,[6,14,16,20] urticaria ("hives"),[14] eczema (dermatitis) of most all varieties,[14] angioedema (swelling of the face, lips, etc.),[6,14] anaphylactic reactions (life-threatening swelling, usually involving the airways) to

most known substances,[14] food (or food additive/preservative) allergy or intolerance,[7,12] adverse responses to chemicals ("multiple chemical sensitivity" or "MCS"),[14] ADHD (Attention Deficit Hyperactivity Disorder),[13,14] autism, Tourette's syndrome, irritable bowel disorders, Crohn's Disease, ulcerative colitis,[7] migraine and other headaches,[14,16,17,21] rheumatoid arthritis, ankylosing spondylitis and systemic lupus erythematosis[27], to name just a few.

The manufacturer of EPD (McEwen Laboratories, LTD) is in the process of submission of an IND (investigational new drug) protocol to the FDA in an attempt to obtain FDA approval. Currently the FDA has stopped EPD immunotherapy in United States, pending approval of the drug. Since approximately 2000 patients relied on EPD for their ability to function normally at the time the FDA halted it, they were left with no other options but to receive EPD outside the USA.

The American EPD Study

Method

73 physicians participated in the study at different centers (multi-center) in the USA and Canada. Patients were selected randomly for this study in many or most instances. However, although data was not collected to determine this variable, a quite significant number of patients were selected because they had previously failed on treatment with both medications and conventional immunotherapy.

EPD treatment was administered every two to three months, generally by one to five small (1/20 c.c.) intradermal (in the first layer of skin) injections which were generally administered in the skin of the inner aspect of the forearm. The "cup" method (the treatment mixture is placed in a specially designed cup over superficially abraded skin, and the treatment mixture absorbed slowly over a period of 12-24 hours) was used at first for anaphylactic patients (patients with potentially fatal systemic allergy, most often to a food or foods), but most physicians switched to the injection method except in very serious cases.

Patients were evaluated by the use of initial and interim questionnaires. These questionnaires were completed by the patients, usually checked by the physician and submitted to an independent organization (the EPD Study Office). Data from forms was then entered in a very large MS Access database. Any incomplete or incorrect forms were returned to the treating physician before data was entered.

The initial questionnaires were completed by patients prior to receiving EPD, and the interim questionnaires were completed immediately prior to receiving each subsequent treatment. Patients evaluated (see scale which follows) how they responded to EPD "overall" and how they responded to each specific condition recorded. Overall and individual categories were evaluated for both the improvement of the *frequency* of their symptoms and the effect upon *severity* of symptoms.

Patients were allowed to evaluate as few as one and as many as six conditions for which they were being treated. Patients were required to choose one of the following categories for both their "overall" response for each evaluation and their response to EPD treatment for each specific condition were evaluated:

Excellent
Very good
Good
Fair

Poor

Terrible (worse than the before starting treatment)

Patients also recorded their frequency of use of self-selected medications at the onset of treatment and for their evaluation after each treatment (over 600 medications were listed by patients).

Frequency of Treatment

EPD treatments were given every 2 to 3 months at first, then less often. Generally, patients with multiple problems were treated every two to three months for six to eight times. After that, treatments usually decreased to every four to six months and then less often. Once therapy reached once yearly, treatments were often stretched to as little as once every 6-12 months. 68,428 treatments were given to 10,372 patients. Since "treatments" consisted of 1 to as many as 7 injections, the total number of actual injections given is not known exactly, but is likely between 175,000 and 179,000.

Conditions treated with EPD

Over 60 conditions were treated with EPD in this study. The conditions treated are listed in Table I.

Complications and Adverse Reactions

There were 3 patients reported with possible complications to EPD to the IRB over the period of 1994-1999. None of these complications were serious or life-threatening.

Results

The study evaluated 10,372 patients over 7 years. Of those patients, 60% (6261) were female and 40% (4111) were male. Average age of females was 45, and the average for males was 33.

Of the 10,372 patients enrolled in the study, 6030 were evaluated as to overall response, response as to frequency (see Table II) and response as to severity (see Table III). Patients eliminated from the final evaluation are enumerated in Table IV. The "dropout" rate was 41% over the 7 year period of the study. This compares to 50% for much shorter term studies of escalating dose immunotherapy, where only very few conditions were studies (4 or less).

It has been established by previous study that it may take up to three treatments with EPD to determine whether the therapy may be effective. Considering this, the 1160 patients who stopped treatment were counted as dropouts, but cannot be counted as treatment failures.

Responses were scored numerically by computer. For specific conditions evaluated, for the purposes of this paper, patients who reported a response of "excellent", "very good" or "good" were grouped together. Patients who reported "fair" results were classified as "fair", and patients who reported "poor" or "terrible" were reported as "no change or "worse".

The "overall" response showed that 20% of patients reported excellent, 30% reported very good and 26% good, 14% reported fair and 8% reported no change. 2% of patients felt they were worse after receiving EPD than they had been prior to starting EPD; The investigators suspected that many of these patients worsened despite EPD, rather than as a result of EPD, though this could not be determined.

Discussion

The American EPD Society study is the largest outcome-based study ever undertaken of any type of immunotherapy, with well over 10,000 patients. [It should be noted that the FDA generally approves drugs based on studies which have *well under* a *total* of 1,000 patients.] We believe that this study demonstrates the significant clinical value of EPD as a treatment tool. We have listed a brief comparison of EPD immunotherapy to conventional immunotherapy in Table V. Discussion of some of the outcome results is indicated here.

Conventional escalating dose immunotherapy is the immunotherapy most widely used in the United States. This type of treatment in some form is employed by most classically trained allergists. It should be made clear, however, that this type of immunotherapy is effective for only a relatively few conditions. According to the medical literature, these conditions are fairly limited to seasonal hay fever, dust mite allergy, cat (and perhaps dog) allergy, and possibly seasonal asthma and some types of specific mold allergy.

Most studies done of patients treated with conventional immunotherapy for classical pollen allergy claim an overall success rate of between about 70 and 80 percent.

Although every condition evaluated in this study did not necessarily appear to respond dramatically to EPD immunotherapy, most responded quite favorably. Most importantly, a large number of conditions which do not respond at all to conventional immunotherapy – and many which do not respond well to *any* type of therapy – appear to have responded to EPD.

For example, there is no effective treatment (except for emergency drug treatment) for angioedema, which consists of facial swelling, swelling of the lips or eyes or swelling of other parts of the body, primarily as a result of acute food allergy. 78% of 180 patients reported satisfactory results with EPD immunotherapy.

Likewise, immediate food allergy, which includes anaphylaxis (a condition which is generally life-threatening) has no effective treatment except for emergency drug treatment and avoidance of the offending food or foods. This includes such severe problems as peanut and shrimp or shellfish allergy. In the group of 519 patients who had some type of immediate food allergy, EPD was effective in 72%. Conventional immunotherapy has no effect for anaphylaxis to foods or chemicals condition, and is in fact dangerous and contraindicated. The only exception is a type of immunotherapy (Rush desensitization) which has been employed for penicillin desensitization.

Several conditions which are difficult to treat, don't respond extremely well to drug therapy and cannot be treated with conventional immunotherapy appeared to respond well to EPD in this study. The quite successful response (in regards to severity) of such conditions as perennial asthma, (732 patients with 75% success), headaches (1186 patients with 75% success), food intolerance - or food reactions, which in most cases was moderate to moderately severe (2857 patients with 74% success), chronic perennial rhinitis (2258 patients with 74% success), hyperactivity/attention deficit disorder (578 patients with 70% success) and eczema or severe dermatitis (669 patients with 69% success), are just a few conditions, to *any* type of immunotherapy should be considered dramatic.

Although the results of treatment with EPD of some of the autoimmune diseases studied here may not appear to be dramatic, treatment of these conditions with any type of immunotherapy has previously not been considered or has been extremely disappointing.

Results for certain autoimmune conditions varied from center to center, primarily as a result of specific treatment protocols employed by physicians which were used in addition to the fundamental study protocol. For example, in this study, 14 patients with ankylosing spondylitis (severe, debilitating arthritis of the spinal column) had a modest success rate of 64%. However, in one treatment center, likely as a result of the specific protocol chosen by the physician, all four patients treated for ankylosing spondylitis with EPD did extremely well (basically a 100% success rate).

The same case can be made for rheumatoid arthritis. This is a typically debilitating and progressive disease for which the only available treatment is the employment of a specific regimen of drug therapy. For the 76 patients with rheumatoid arthritis in the study, most would consider a 57 percent rate of success – which means patients were satisfied with the results –remarkable. 79% of patients with rheumatoid arthritis in the study reported a decrease in the medications needed to treat symptoms.

Although the final statistics have not yet been calculated, the considerably large numbers of patients in fairly well-defined groups gives a strong indication that the conclusions are reliable. Also, the success rate of EPD (78%) for seasonal rhinitis (1361 patients) compares favorably to that of conventional immunotherapy. It also compares favorably those of previously published papers in regards to the treatment of seasonal rhinitis with EPD.

Conclusions

At the end of this 7-year study of 10,372 patients who received at least 175,000 injections of EPD, the physicians who participated in this study conclude that the healing and health potential of EPD for use to treat allergy and autoimmune disease is immense.

An empirical estimate of how many US citizens might benefit from EPD therapy is: 15-20% of the population, including the very young and the still-productive older segment. This EPD-benefit estimate would be – 52-million immune-injured Americans.

As a result of the findings of this study, and in comparison to conventional immunotherapy, we conclude that EPD:

- is extremely safe, without incidence of fatality or serious side effects
- is virtually the only option available to actually prevent the occurrence of life-threatening reactions or death as a result of acute food allergy
- is as successful as conventional immunotherapy for the very limited conditions for which conventional immunotherapy is used to treat.
- EPD can be used to successfully treat a vastly greater number of conditions, and is more convenient than conventional immunotherapy (i.e. treatment every 2 weeks)
- EPD reduces the amount and/or number of drugs required to be taken by patients by at least 50 percent on the average.
- has several major advantages over conventional escalating dose immunotherapy:
    - is 30-60% more cost-effective
    - is administered far less frequently with an earlier and more complete endpoint
    - can be discontinued without complete relapse of symptoms, or treatments can be extended to very long intervals of a year or more

Most critically, we strongly recommend that EPD be immediately re-released into use by the Government for use by trained practitioners, since:

a. The FDA has prohibited EPD treatment in this country, and patients now must travel outside the USA to receive it, and
b. many patients have been unable to travel to receive EPD and have suffered considerable or severe consequences. As a result,
c. many patients could come to severe harm or die without this treatment.

Finally, we would encourage that further study be undertaken for the majority of the conditions discussed here under the supervision of an organization not regulated by the FDA.

Table I: Diagnoses and Conditions Treated with EPD, 1993-2000

1. Rhinitis, perennial (runny nose, nasal congestion, etc., year `round)
2. Rhinitis, seasonal, allergic (above but seasonal, hay fever, etc.)
3. Nasal polyps, *documented*
4. Allergic conjunctivitis (itchy/watery eyes) – *not* eczema of the eyelids
5. Asthma, year `round
6. Repeated chest infections
7. Chronic sinusitis, *documented* by X-ray
8. Chronic face ache/sinus pain, not proven by X-ray or negative X-rays
9. Secretory otitis media ("glue ear" -- an ENT diagnosis)
10. Repeated ear infections
11. Immediate food allergy (foods cause itching, swelling, collapse, shock) * *under revision, see #58, 59*
12. Food (or food chemical) allergy or intolerance/adverse response (not #11 above)
13. Chemical or fume intolerance (severe symptoms, when exposed by breathing)
14. Migraine/*severe* headaches
15. Headaches, other
16. Eczema, "dermatitis"
17. Contact dermatitis (from skin contact with a substance)
18. Urticaria (hives)
19. Swelling of the lips, face or tongue (angioedema)
20. Mental confusion (brain "fag," "fog," confusion, etc.)
21. Hyperactivity, ADD, ADHD, PDD * *under revision*
22. Epilepsy (any type)
23. Rheumatoid arthritis (RA), *documented*
24. ("osteo-") arthritis or joint pains: non-specific
25. Muscle pains, severe
26. Ulcerative colitis, *documented*
27. Crohn's disease, *documented*
28. "Irritable bowel", "spastic colon" or chronic diarrhea
29. Constipation (less than 1 bowel motion or movement on most days)
30. Gut "fermentation" (U.K., bloating after most meals, especially sugar)
31. Chronic anal irritation/itch (not caused by hemorrhoids)
32. Chronic vaginal symptoms
33. Urinary tract symptoms (not due to infection)
34. CFIDS, CFS or ME (U.K.) (history of *definite sudden viral onset*, healthy prior), *documented*
35. Chronic fatigue, not of sudden post-viral onset but of gradual onset
36. "Candida" (lay term) or fungal-related illness (patient's symptoms must respond clinically to antifungals)
37. Hyperventilation complex (medical diagnosis, U.K.)
38. Multiple complaints (patient has *more than 6 conditions to evaluate*, such as "E.I." (USA), "PIMS" (U.K.)
39. Plugged ears, moderately severe
40. Pruritis
41. Depression
42. Insomnia, moderately severe
43. Vulvadynia
44. Anosmia
45. Emotional/Behavior problems (not #21)
46. Interstitial cystitis (IC), *documented*
47. Post nasal drip, chronic, severe
48. Chronic cough
49. Asthma, seasonal only
50. Ankylosing spondylitis, *documented*
51. Dermatographia
52. Autism, *diagnosis must be documented*
53. Hypertension
54. Diabetes
55. Sjogren's Syndrome, *documented*
56. Meniere's Disease, *documented*
57. Psoriasis
58. Anaphylaxis due to ingested food or food substance
59. Anaphylaxis, cause unknown (idiopathic)
60. (Dx # 101) Tourette's, *documented*
61. (Dx # 102) Multiple sclerosis, *documented*
62. (Dx # 103) Cat-induced rhinitis only
63. (Dx # 104) Pre-menstrual syndrome (PMS)
64. (Dx # 105) Conjunctivitis, chronic, diagnosed as "non-allergic"
65. Raynaud's, *documented*
66. Reactive arthritis (autoimmune, non-RA), *documented*
67. Pharyngitis (Brazil)
68. Laryngitis (Brazil)

Table II: American EPD Trial Outcome Results

*Improvement in **Frequency** of Symptoms (Nov., 1993 – Nov., 2000)*

Description	Patients	No response to question	Frequency	Excellent, Very Good, Good	%	Fair	%	No change or worse	%
Repeated Ear Infections	281	15	266	236	**89%**	16	**6%**	14	**5%**
Secretory Otitis Media	39	9	30	26	**87%**	2	**7%**	2	**7%**
Repeated Chest Infections	251	13	238	192	**81%**	24	**10%**	22	**9%**
Asthma, seasonal only	210	3	207	163	**79%**	19	**9%**	25	**12%**
Angioedema	180	18	162	127	**78%**	12	**7%**	23	**14%**
Rhinitis, Seasonal	1361	67	1294	1011	**78%**	152	**12%**	131	**10%**
Allergic Conjunctivitis	1017	48	969	746	**77%**	125	**13%**	98	**10%**
Chronic Cough, not asthma	303	8	295	228	**77%**	37	**13%**	30	**10%**
Chronic Face ache	484	39	445	336	**76%**	61	**14%**	48	**11%**
Asthma	732	46	686	512	**75%**	91	**13%**	83	**12%**
Contact Dermatitis	176	11	165	124	**75%**	23	**14%**	18	**11%**
Headaches, Other	1186	89	1097	818	**75%**	149	**14%**	130	**12%**
Nasal Polyps	112	10	102	75	**74%**	13	**13%**	14	**14%**
Rhinitis, Perennial	2258	128	2130	1570	**74%**	297	**14%**	263	**12%**
Food Allergy, Other	2857	140	2717	1958	**72%**	399	**15%**	360	**13%**
Immediate Food Allergy	519	38	481	348	**72%**	59	**12%**	74	**15%**
Plugged Ears, moderately severe	402	14	388	276	**71%**	53	**14%**	59	**15%**
Chronic Anal Irritation	132	4	128	89	**70%**	20	**16%**	19	**15%**
Chronic Sinusitis	352	21	331	233	**70%**	49	**15%**	49	**15%**
Eczema	669	29	640	444	**69%**	91	**14%**	105	**16%**
Emotional/behavioral problems	488	15	473	327	**69%**	65	**14%**	81	**17%**
Irritable Bowel	613	38	575	397	**69%**	88	**15%**	90	**16%**
Candida-Related Complex	940	59	881	598	**68%**	156	**18%**	127	**14%**
Hyperactivity	578	34	544	372	**68%**	81	**15%**	91	**17%**
Mental confusion (brain "fog")	1650	77	1573	1065	**68%**	263	**17%**	245	**16%**
Migraine/Severe Headache	691	36	655	448	**68%**	85	**13%**	122	**19%**
Chronic severe post-nasal drip	561	5	556	374	**67%**	102	**18%**	80	**14%**
Pruritis	177	4	173	116	**67%**	25	**14%**	32	**18%**
Chemical Intolerance	1413	83	1330	858	**65%**	252	**19%**	220	**17%**
Gut Fermentation	699	35	664	431	**65%**	124	**19%**	109	**16%**
Ankylosing spondylitis	14		11	9	**64%**	2	**14%**	3	**21%**
CFIDS	152	9	143	91	**64%**	24	**17%**	28	**20%**
Chronic Fatigue, Other	887	55	832	535	**64%**	163	**20%**	134	**16%**
Constipation	399	22	377	237	**63%**	68	**18%**	72	**19%**
Hypertension	109	6	103	65	**63%**	17	**17%**	21	**20%**
Depression, significant	452	8	444	276	**62%**	80	**18%**	88	**20%**
Epilepsy	45	3	40	26	**62%**	3	**7%**	13	**31%**
Psoriasis	65	4	61	38	**62%**	11	**18%**	12	**20%**
Arthritis, Non-Specific	689	43	646	393	**61%**	124	**19%**	129	**20%**
Chronic Vaginal Symptoms	179	8	171	103	**60%**	32	**19%**	36	**21%**
Muscle Pains	561	35	526	318	**60%**	117	**22%**	91	**17%**
Rheumatoid Arthritis	76	3	73	43	**59%**	13	**18%**	17	**23%**
Crohn's Disease	29	1	28	16	**57%**	6	**21%**	6	**21%**
Insomnia, moderately severe	423	9	414	225	**54%**	90	**22%**	99	**24%**
Autism	134	6	128	68	**53%**	31	**24%**	29	**23%**
Meniere's Disease	47		41	25	**53%**	11	**23%**	11	**23%**
Dermatographia, dermagraphia	17		12	8	**47%**	3	**18%**	6	**35%**
Sjogren's Syndrome	16		18	7	**44%**	4	**25%**	5	**31%**
Anosmia	116	5	111	48	**43%**	25	**23%**	38	**34%**
Multiple Sclerosis	5		4	1	**25%**	3	**50%**	1	**25%**

Table III: American EPD Trial Outcome Results

*Improvement in **Severity** of Symptoms (Nov., 1993 – Nov., 2000)*

Description	Patients	No response to question	Severity	Excellent, Very Good, Good	%	Fair	%	No change or worse	%
Repeated Ear Infections	281	5	276	243	**88%**	18	**7%**	15	**5%**
Secretory Otitis Media	39	2	37	32	**86%**	3	**8%**	2	**5%**
Repeated Chest Infections	251	5	246	196	**80%**	22	**9%**	28	**11%**
Chronic Cough, not asthma	303	6	297	234	**79%**	33	**11%**	30	**10%**
Contact Dermatitis	176	3	173	135	**78%**	23	**13%**	13	**8%**
Rhinitis, Seasonal	1361	22	1339	1041	**78%**	162	**12%**	136	**10%**
Urticaria	230	6	224	175	**78%**	23	**10%**	26	**12%**
Allergic Conjunctivitis	1017	23	994	770	**77%**	126	**13%**	98	**10%**
Nasal Polyps	112	5	107	82	**77%**	11	**10%**	14	**13%**
Asthma, seasonal only	210	1	209	158	**76%**	22	**11%**	29	**14%**
Chronic Face ache	484	14	470	358	**76%**	61	**13%**	51	**11%**
Angioedema	180	9	171	128	**75%**	21	**12%**	22	**13%**
Asthma	732	17	715	539	**75%**	93	**13%**	83	**12%**
Headaches, Other	1186	24	1162	868	**75%**	154	**13%**	140	**12%**
Food Allergy, Other	2857	55	2802	2060	**74%**	385	**14%**	357	**13%**
Rhinitis, Perennial	2258	33	2225	1644	**74%**	307	**14%**	274	**12%**
Chronic Sinusitis	352	10	342	245	**72%**	47	**14%**	50	**15%**
Immediate Food Allergy	519	15	504	364	**72%**	65	**13%**	75	**15%**
Plugged Ears, moderately severe	402	7	395	281	**71%**	56	**14%**	58	**15%**
Hyperactivity	578	16	562	392	**70%**	84	**15%**	86	**15%**
Candida-Related Complex	940	30	910	630	**69%**	150	**16%**	130	**14%**
Eczema	669	10	659	457	**69%**	104	**16%**	98	**15%**
Emotional/behavioral problems	488	11	477	331	**69%**	61	**13%**	85	**18%**
Irritable Bowel	613	10	603	419	**69%**	96	**16%**	88	**15%**
Chronic Anal Irritation	132	3	129	88	**68%**	19	**15%**	22	**17%**
Migraine/Severe Headache	691	14	677	458	**68%**	83	**12%**	136	**20%**
Chronic severe post-nasal drip	561	6	555	370	**67%**	104	**19%**	81	**15%**
Mental confusion (brain "fog")	1650	27	1623	1095	**67%**	286	**18%**	242	**15%**
Chemical Intolerance	1413	28	1385	918	**66%**	240	**17%**	227	**16%**
Gut Fermentation	699	20	679	450	**66%**	116	**17%**	113	**17%**
Urinary Tract Symptoms	152	6	146	96	**66%**	20	**14%**	30	**21%**
Constipation	399	9	390	252	**65%**	62	**16%**	76	**19%**
Pruritis	177	2	175	114	**65%**	31	**18%**	30	**17%**
Ankylosing spondylitis	14		14	9	**64%**	1	**18%**	4	**36%**
Chronic Fatigue, Other	887	21	866	554	**64%**	168	**19%**	144	**17%**
Depression, significant	452	6	446	286	**64%**	67	**15%**	93	**21%**
Hypertension	109	3	106	67	**63%**	17	**16%**	22	**21%**
Arthritis, Non-Specific	689	21	668	413	**62%**	121	**18%**	134	**20%**
CFIDS	152	5	147	89	**61%**	29	**20%**	29	**20%**
Chronic Vaginal Symptoms	179	1	178	108	**61%**	34	**19%**	36	**20%**
Muscle Pains	561	10	551	333	**60%**	130	**24%**	88	**16%**
Crohn's Disease	29		29	17	**59%**	6	**21%**	5	**17%**
Psoriasis	65	5	60	35	**58%**	13	**22%**	12	**20%**
Ulcerative Colitis	40		40	23	**58%**	8	**20%**	9	**23%**
Meniere's Disease	47	1	46	26	**57%**	10	**17%**	10	**14%**
Rheumatoid Arthritis	76	2	74	42	**57%**	15	**20%**	17	**23%**
Insomnia, moderately severe	423	8	415	232	**56%**	89	**21%**	94	**23%**
Autism	134	7	127	70	**55%**	31	**24%**	26	**20%**
Epilepsy	45	6	39	21	**54%**	2	**4%**	16	**36%**
Dermatographia, dermagraphia	17		17	9	**53%**	3	**50%**	5	**29%**
Multiple Sclerosis	5		5	2	**40%**	1	**0%**	2	**100%**
Sjogren's Syndrome	16		16	6	**38%**	4	**33%**	4	**22%**

Table IV: EPD Immunotherapy: Patients Eliminated, 1993-1999

	Number	Percent
Starting Number of Patients	**10372**	
Dropped out with 3 treatments or less	1160	**11%**
Dropped out, considered treatment failures	834	**8%**
Dropped out, finances/other	1154	**11%**
Dropped out, EPD program too Difficult	396	**4%**
Lost Contact	670	**6%**
Dropped out, Insurance won't cover treatment	31	**0.3%**
Total Eliminated	4245	**41%**
Died as a result of condition being treated with EPD	5	**0.05%**
Died as a result of condition not being treated with EPD	24	**0.23%**
Patient doing well, no longer needs injections	765	**7.4%**
No injection in over 6 months, doing poorly at last eval.	56	**0.5%**
No injection in over 6 months, doing well at last eval.	105	**1.0%**
Death directly attributed to an injection of EPD	0	
Data irretrievable as determined by treating physician and/or is part of Phase I of the study	30	**0.3%**
Eliminated for Errors:	54	**0.5%**
Checking Errors, not yet defined	97	**1%**
Remaining:	6030	**58%**
Final Number Evaluated:	6030	**58%**

Table V: Comparison of EPD Immunotherapy to Conventional Immunotherapy

	Conventional Immunotherapy	**EPD Immunotherapy**
Strength (dosage) at start of therapy	1:10,000	1:1,000,000,000,000,000 (quadrillion) to 1:100,000,000
Strength (dosage) at maintenance (highest)	1:10	1:100,000,000
Conditions treatable	limited	Diverse
Autoimmune disease	Not treatable	Often treatable
Life-threatening food allergy (peanut, shellfish, others)	Not treatable, and immunization is contraindicated	Treatable (success rate of 72% of 519 patients)
Frequency of treatment	Twice weekly, usually for 6 months, then once every 1-2 weeks	Every 2 months for 12 months, then every 2-24 months
Ability to stop therapy	Often not possible	Half of all patients can stop after 10-20 treatments
Drug Usage	Very little changed	Considerably decreased, 50% of patients were able to stop medications
Cost	Moderate – long term	30-60% less than conventional
Safety	Fatalities recorded due to high dosages needed	safe; no fatalities ever recorded
Efficacy	Proven for certain pollen and other limited types of allergy. Not satisfactory for patients with allergy to multiple inhalants. Ineffective for patients with autoimmune diseases, food allergy and intolerance and most others. Efficacy said to be approx. 80% for *treatable* allergy.	Effective for all types of allergy and intolerance to inhalants, foods and chemicals. Effective for some types of autoimmune diseases. The *only* immunotherapy available for treatment of anaphylaxis to foods. Virtually all patients with allergy treatable. Overall efficacy for *all conditions treated* (approx. 60 diverse conditions, American EPD Study) was 75%.

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