

Allergen Immunotherapy



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Question: what do you do in Allergic patients

- ☐ **What happens to an allergic patient with an immune system that is already up-regulated in Th2 bias,(Increased total IgE & specific IgE) who becomes the recipient of chronic antibiotic usage and antihistamine ,corticosteroids?**
- ☐ **What are the therapeutic implications?**

Influence of Anti-Allergic Drugs

WHO Position Paper:



Allergen avoidance and immunotherapy are the only treatments that modify the course of an allergic disease either by preventing the development of new sensitivities or by altering the natural history of disease or disease progression.

Allergen contact

Effector cells of
allergic
responses

Mediators of
allergic
responses

Allergic
symptoms

Anti-IgE-antibodies

Antihistamines

Anticholinergics

LAMA

Mast-cell stabilizers

Leukotriene receptor
antagonists

Decongestive

LABA

Corticosteroids

ICS+OCS

Immunotherapy

These options only provide symptomatic treatment

No preventive effect on asthma by pharmacotherapy

- Allergic factors associated with the development of asthma and the influence of **cetirizine** in a double-blind, randomised, placebo-controlled trial: first results of ETAC. Early Treatment of the Atopic Child.
 - ▶ *Pediatr Allergy Immunol* 1998 Aug;9(3):116-24.
- Guilbert TW, Morgan WJ, Zeiger RS, Mauger DT, Boehmer SJ, Szeffler SJ, et al. Long-term **inhaled corticosteroids** in preschool children at high risk for asthma.
 - ▶ *N Engl J Med* 2006;354(19):1985-97.
- Bisgaard H, Hermansen MN, Loland L, Halkjaer LB, Buchvald F. Intermittent **inhaled corticosteroids** in infants with episodic wheezing.
 - ▶ *N Engl J Med* 2006;354(19):1998-2005.

Specific immunotherapy at its best

- decrease in symptoms
- decrease in use of medication
- Long-term effectiveness
- acting on basic immunological mechanisms
- anti-inflammatory treatment
- causal treatment
- preventive treatment

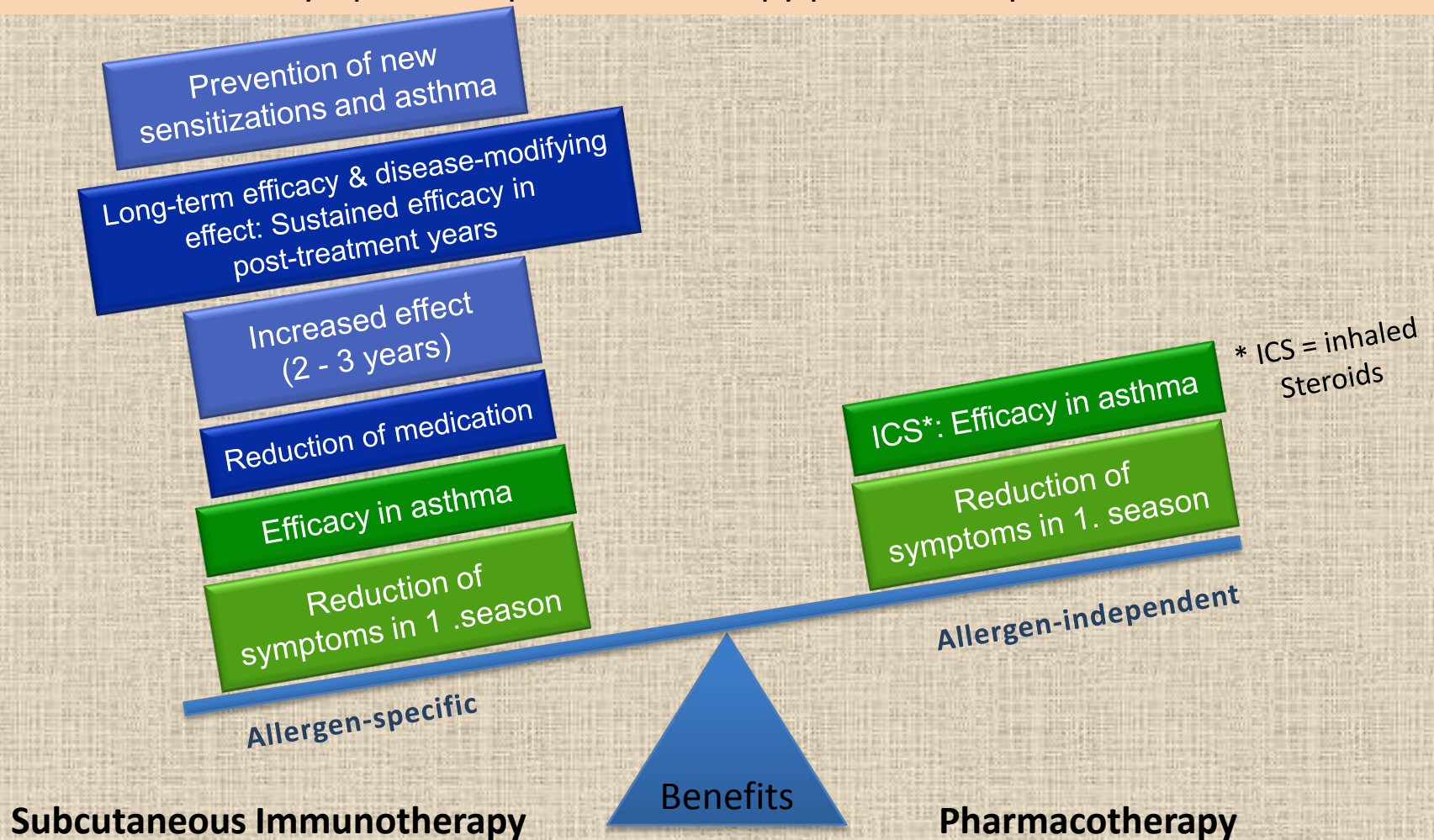
Immunotherapy is the only treatment that influence the basic course of the allergic diseases
WHO Position Paper



Recommended dosage
5-20 µg major allergen

Subcutaneous Immunotherapy vs. Pharmacotherapy

Subcutaneous Immunotherapy has demonstrated numerous benefits over and above the symptomatic pharmacotherapy provided to patients



Why do Allergists Love IT?

- *Subcutaneous immunotherapy (SCIT) has been used for over 100 years*
- *Well documented efficacy for AR and asthma secondary to pollens, HDM, and cat*
- *What are the benefits of SCIT / SLIT ?*
 - *Preventive effect(New sensitization)*
 - ↓ *Progressive effect (Rhinitis to Asthma)*
 - *Persistent effect(Has disease-modifying effects)*

Q. WHY IMMUNOTHERAPY?

Efficacy of specific immunotherapy

- **Early effect**
 - ▶ reduction in symptoms(60%)/need for medication(70%)
- **Progressive effect**
 - ▶ reduction in symptoms/need for medication
 - ▶ reduction in hyperresponsiveness/late phase response
- **Persistent effect**
 - ▶ long-term reduced symptoms/need for medication
 - ▶ long-term reduced hyperresponsiveness/late phase response
- **Preventive effect**
 - ▶ prevention of new sensitivities and exacerbation of disease (rhinitis into asthma)
- **Immunological effect**
 - ▶ immunomodulation

Vs PHARMOCOTHERAPY

-
- Treats the symptoms, not the underlying disease
 - After treatment symptoms usually re occur and there are no long term benefits
 - Continued life-long treatment

Q. WHY IMMUNOTHERAPY?

IT: prevention of new sensitizations

New sensitizations after 3 years:

55% SIT group vs 100% control group.

Des Roches et al, JACI 1997

New sensitizations after 3 years:

25% SIT group vs 67% control group.

Pajno et al, Clin Exp Allergy 2001

New sensitizations after 4 years

23% SIT group vs 68% control group.

Purello D'Ambrosio et al, Clin Exp Allergy 2001

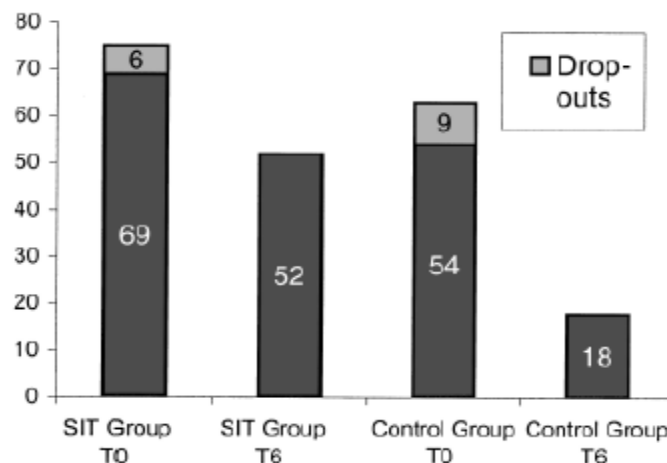
Q. WHY IMMUNOTHERAPY?

Prevention of new sensitizations in asthmatic children monosensitized to house dust mite by specific immunotherapy. A six-year follow-up study.

G. B. PAJNO*, G. BARBERIO*, Fr. DE LUCA*, L. MORABITO*, and S. PARMIANI†

| | Number of patients | |
|--|---|---|
| | SIT Group | Control Group |
| Sex: Female | 42 | 38 |
| Male | 33 | 25 |
| Mean age: yrs (range) | 7.14 (6–8) | 6.38 (5–7) |
| Mean duration of allergy before enrolment: yrs | 3.6 | 3.2 |
| Symptoms | Intermittent asthma/ intermittent asthma and rhinitis | Intermittent asthma/ intermittent asthma and rhinitis |
| Sensitization | house dust mite | house dust mite |

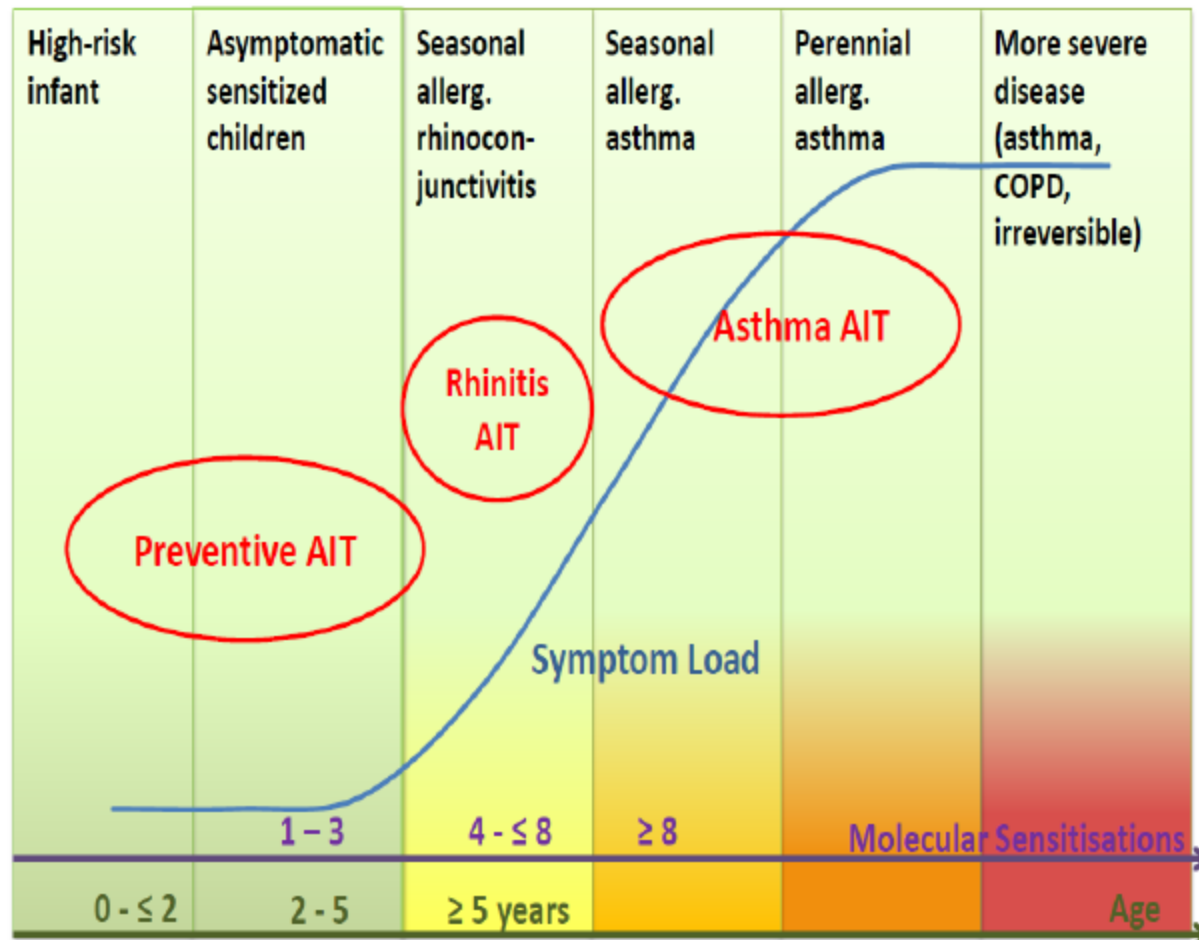
Evolution of monosensitization



Sensitization rates after 6 yrs: SIT: 24.6% ; CG : 66.7%

Allergy Prevention by AIT

Age-Dependent Windows of Opportunity



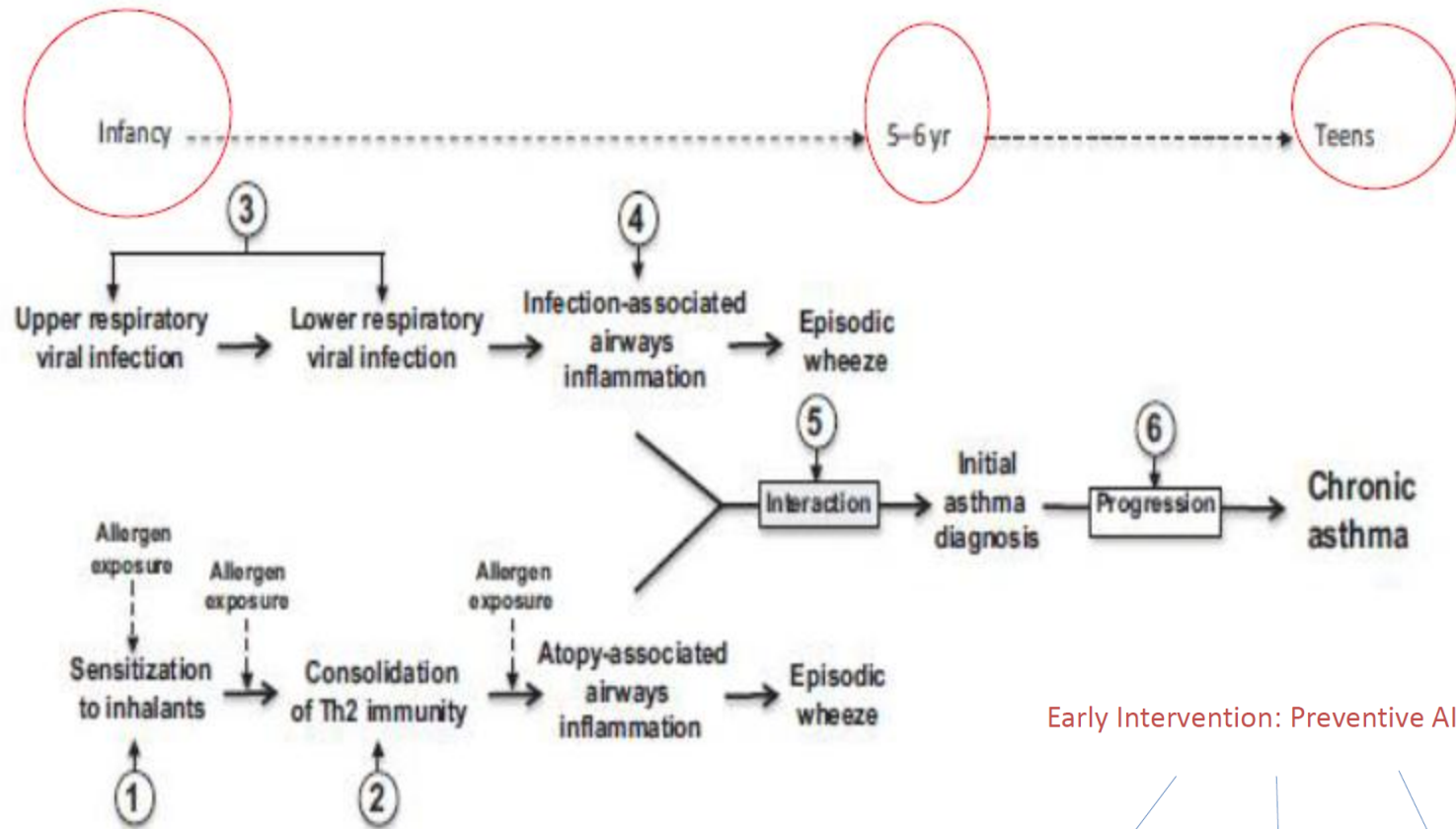
Q. WHY IMMUNOTHERAPY?

Prevention of allergic asthma

- **Primary prevention**
 - ▶ Allergen avoidance
 - prevention of allergic sensitisation and symptoms
 - ▶ Prevention by infant allergen vaccination (ITN)
- **Secondary prevention**
 - ▶ ETAC/EPAAC
 - prevention of asthma in AD children (antihistamines)
 - ▶ Immunotherapy
 - prevention of asthma in rhinitis (PAT)
 - prevention of new allergies
- **Tertiary prevention**
 - ▶ START
 - prevention of asthma exacerbations (steroids)

Prevention – what is the most promising approach?

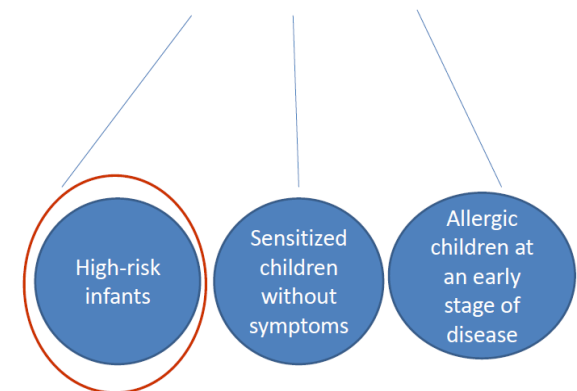
Patrick G. Holt



Early Intervention: Preventive AIT

Randomized controlled trial of primary prevention of atopy using house dust mite allergen oral immunotherapy in early childhood

Zaraquiza Zolkipli, MSc,^{a,*} Graham Roberts, DM,^{a,b,c,*} Victoria Cornelius, PhD,^{a,d} Bernie Clayton, RN,^e
 Sarah Pearson, RN,^a Louise Michaelis, MSc,^a Ratko Djukanovic, DM,^{a,b,e} Ramesh Kurukulaaratchy, DM,^{b,c,e} and
 S. Hasan Arshad, DM^{a,b,c,e} *Southampton, Isle of Wight, and London, United Kingdom*



■ Secondary prevention

▶ ETAC/EPAAC

- prevention of asthma in AD children (antihistamines)

▶ Immunotherapy

- prevention of asthma in rhinitis (PAT)
- prevention of new allergies

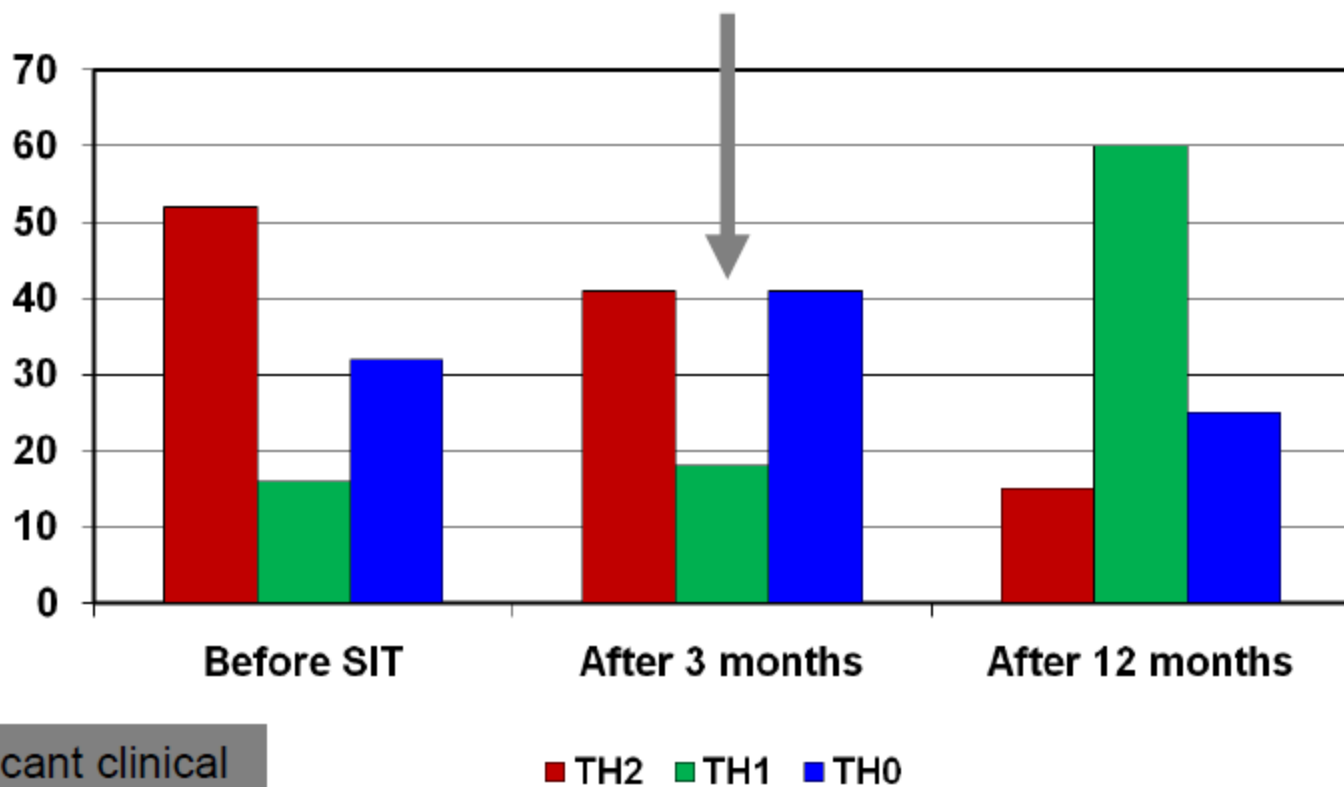
Long-lasting efficacy of IT: controlled studies

| AUTHOR | ALLERG | ROUTE | DISEASE | LONG - LASTING |
|----------------|---------|-------|-------------|-------------------|
| Mosbech 1988 | Grass | SCIT | Rhinitis | 6 yrs |
| Hedlin, 1995 | Cat/dog | SCIT | Rhin/Asthma | 3 yrs |
| Jacobsen, 1997 | Birch | SCIT | Rhin/Asthma | 6 yrs |
| Ariano, 1999 | Pariet | SCIT | Rhinitis | 4 yrs |
| Durham, 2000 | Grass | SCIT | Rhinitis | 5 yrs |
| Eng 2002 | Grass | SCIT | Rhinitis | 3 yrs |

Data kindly provided by Canonica (2003)

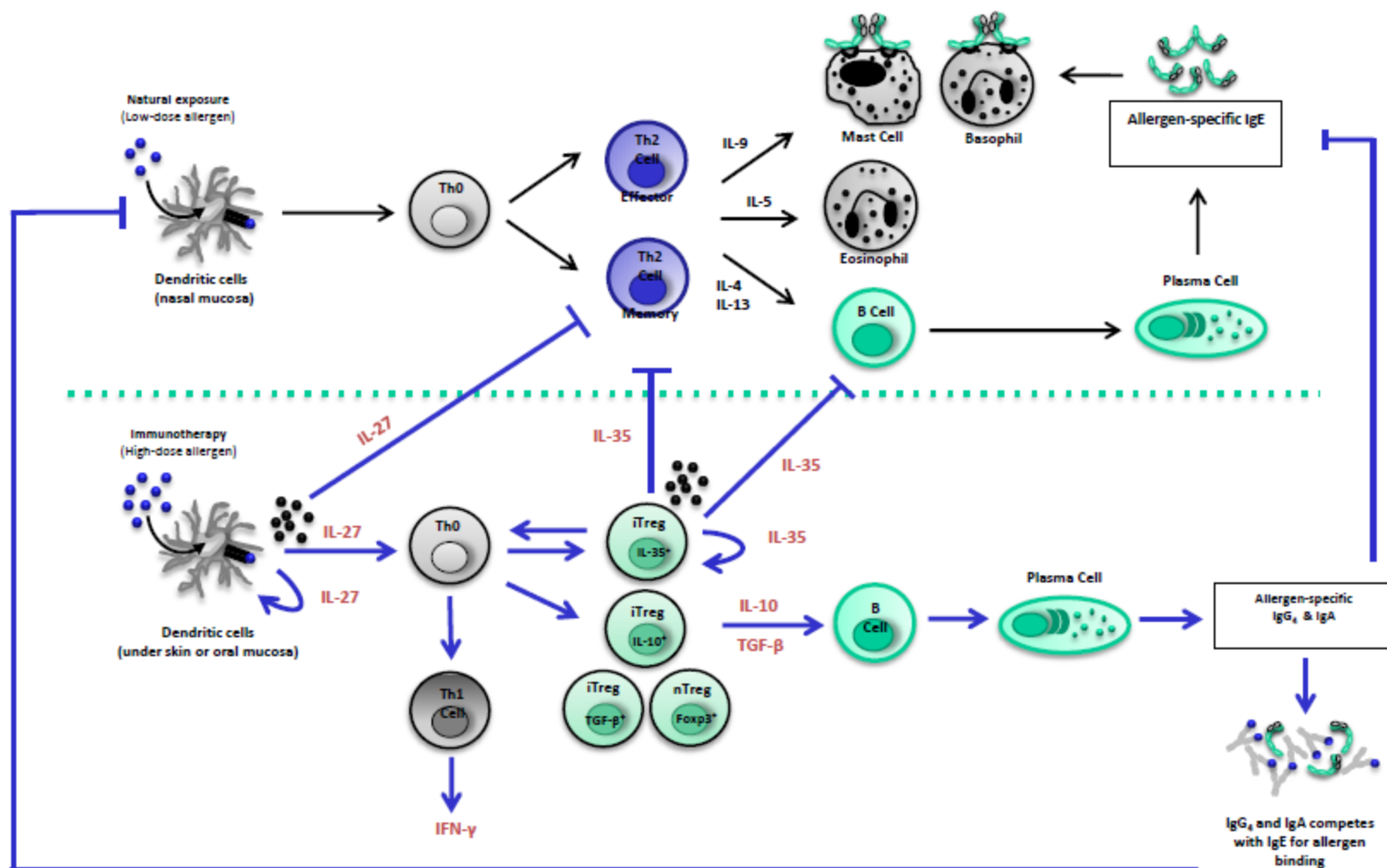
Shift from TH₂ to TH₁-like response following SIT for grass pollen allergy

(maintenance dose: 100,000 SQ-U, Alutard[®] SQ)

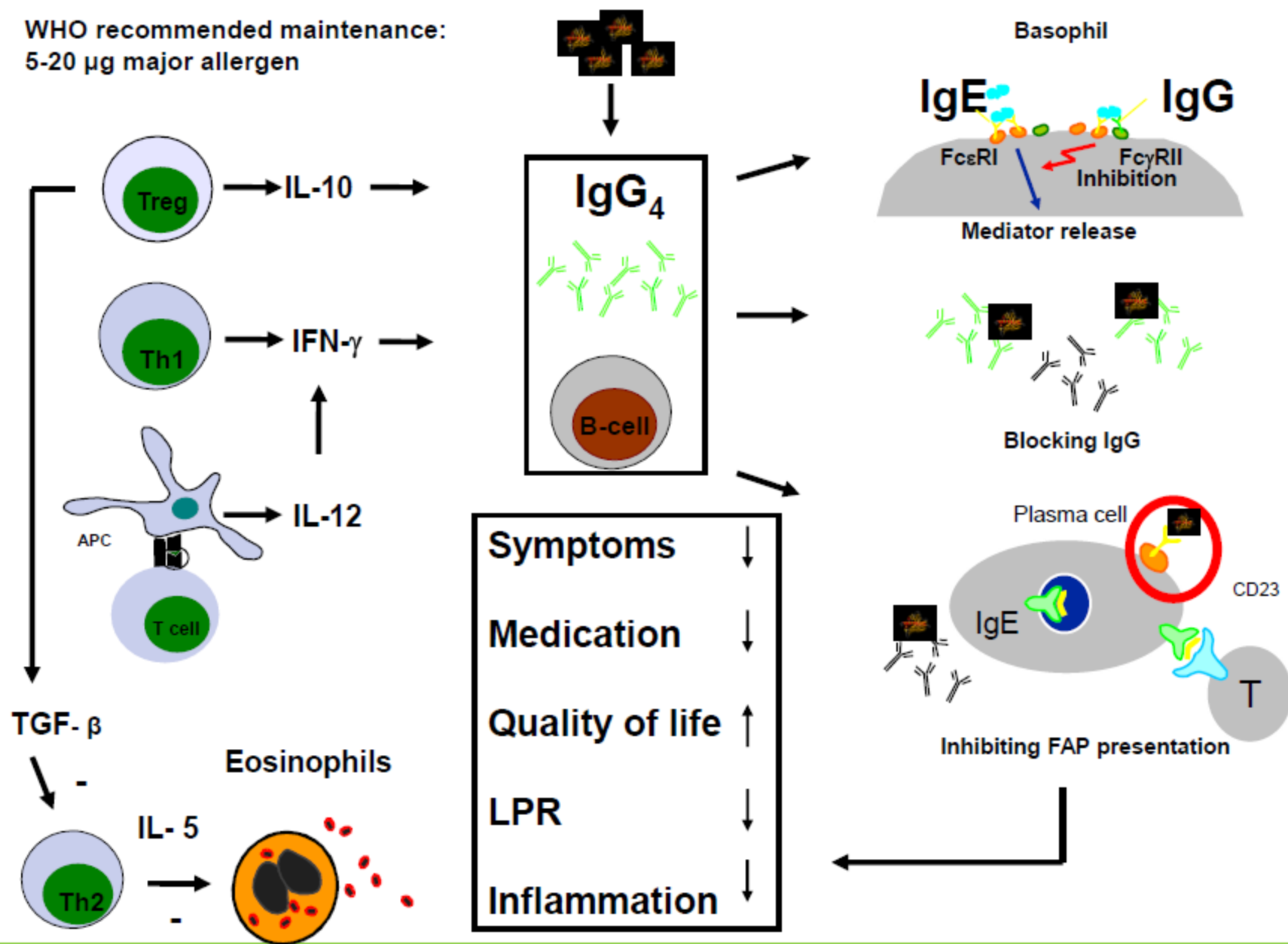


Significant clinical effect.

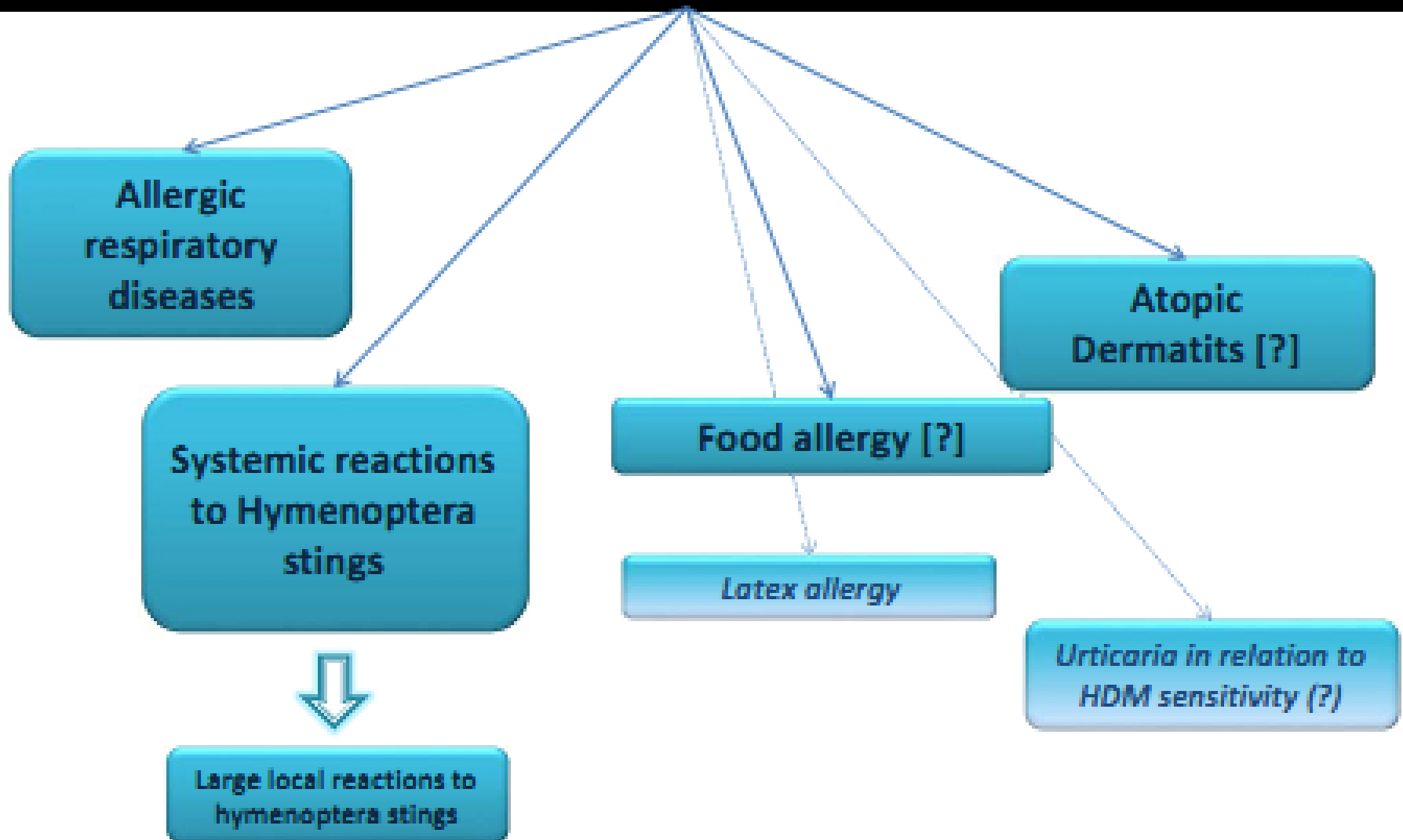
Proposed Mechanisms of AIT



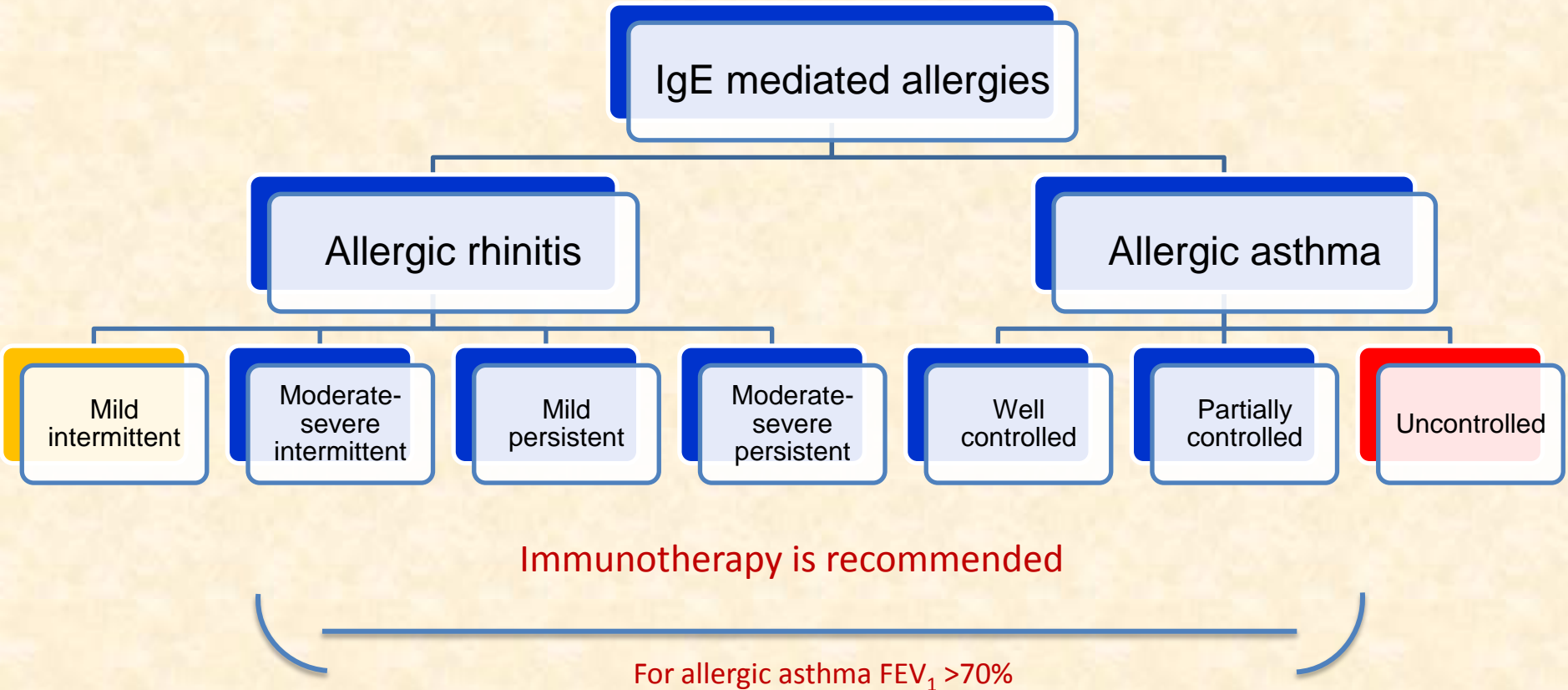
WHO recommended maintenance:
5-20 μg major allergen



Indications of Immunotherapy



Indications for Immunotherapy in Allergic Rhinitis & Allergic Asthma



Recent indications WAO-2013 . (Failure to drugs is not an essential perquisite)

- 1- Who Wish To Avoid Long -Term Pharmacotherapy ?**
- 2- Who Poorly Response To Drugs Or Intolerant ?**
- 3- Who Wish To Prevent Diseases Progration ?**

Diagnosis: Allergic rhinoconjunctivitis to House dust
Mite, suspicion of bronchial asthma

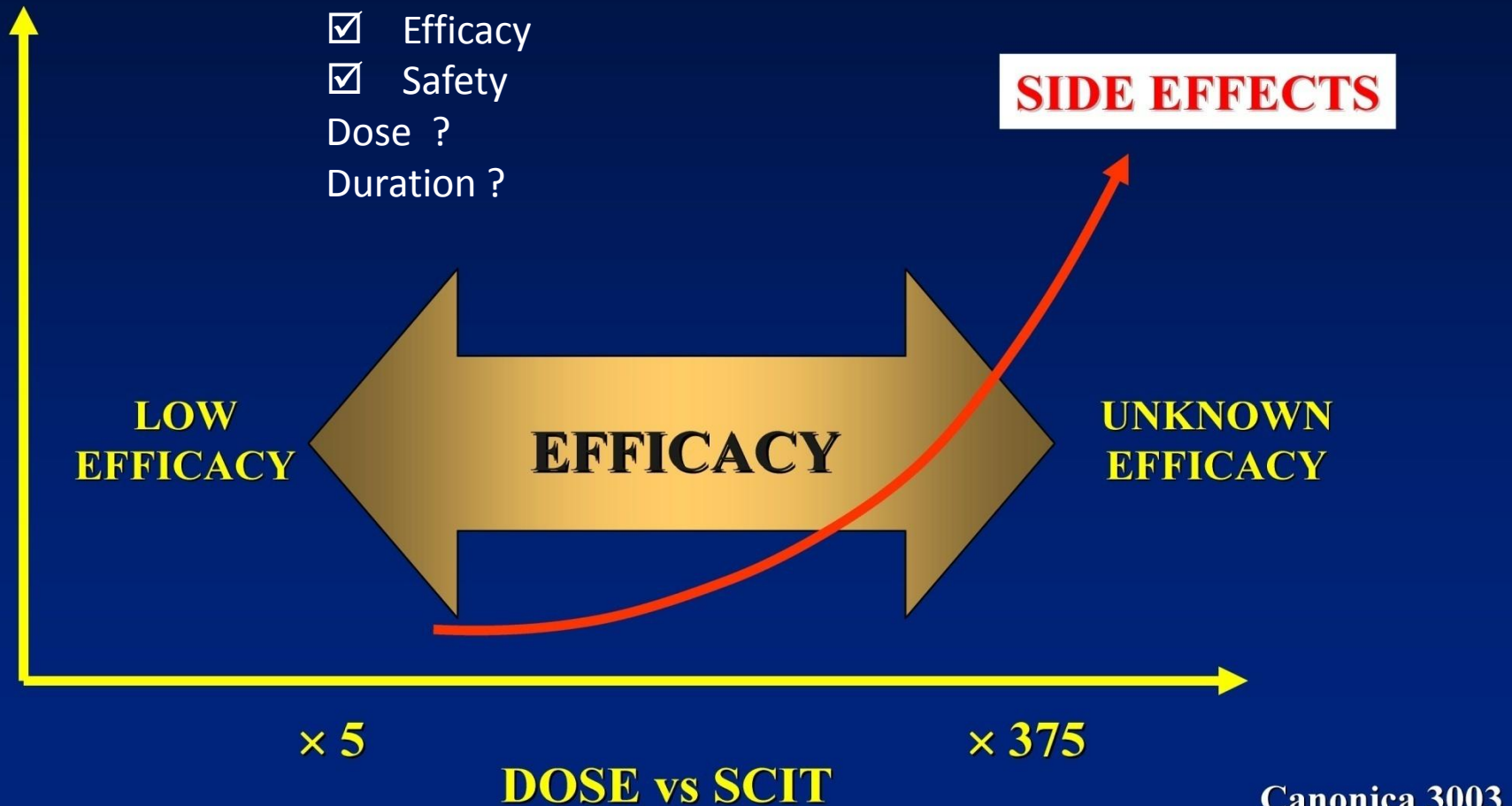
Case Report

- 5 year old boy is admitted to hospital in June with acute wheezy bronchitis and dyspnea
- Itchy eyes and runny nose since early June
- Wheezy bronchitis in March of same year treated with oral salbutamol
- Both parents allergic to grass pollen, father with seasonal asthma

Diagnostic Work- Up and Treatment Options

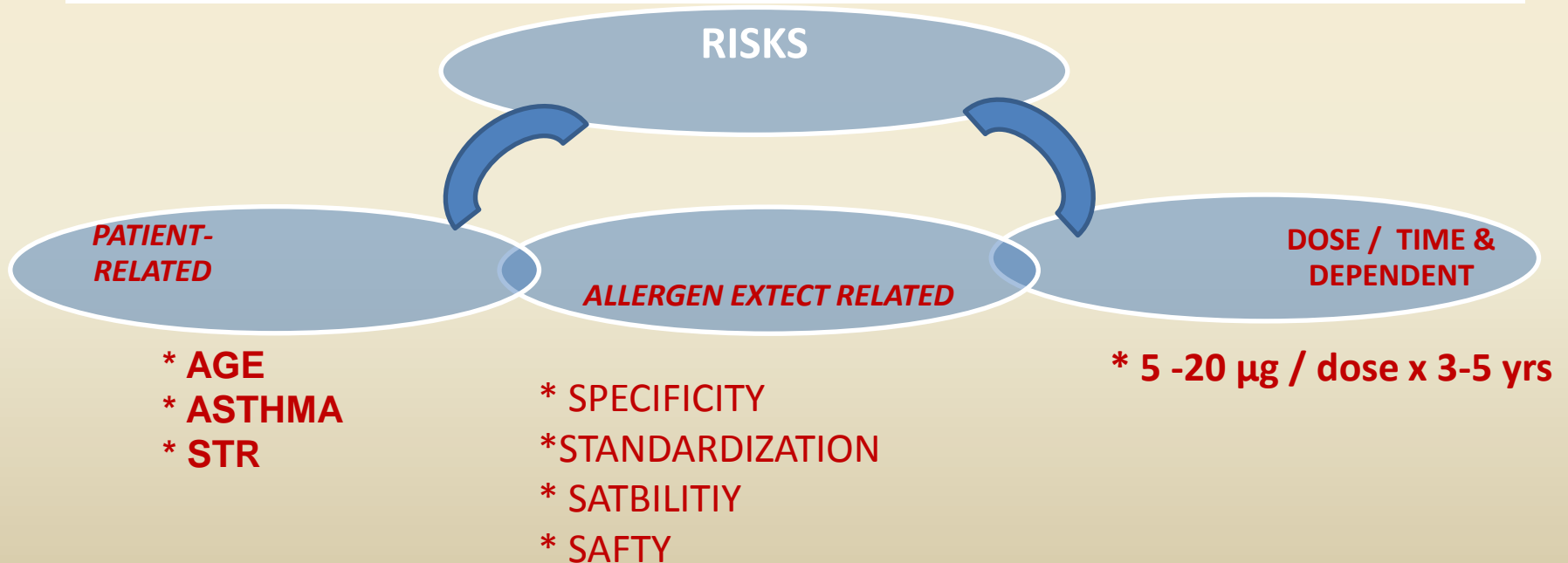
- Total IgE: 181kU/l; **Specific , IgE D.f** .9,9 KU/l;
 Specific IgE D.P 9.3 Ku/l
- **Diagnosis: Allergic rhinoconjunctivitis to** **House dust**
 Mite, suspicion of bronchial asthma
- Anti-asthmatic treatment incl. inhaled corticosteroids started for 3 months
- Clinical follow-up evaluation in 3 months incl. component-resolved allergy diagnosis
- **Initiation** **House dust Mite, allergen**
 immunotherapy?
 Administration route? **SCIT/SLIT Efficacy/ Risk /Dose/Duration**
 Age Issue?

Controversy in Immunotherapy



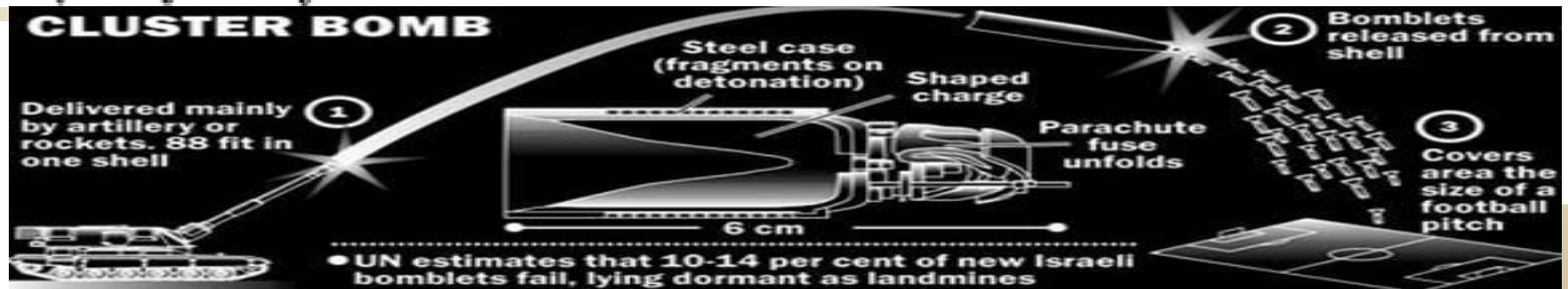
Why 15-25 % Receive Immunotherapy

Inconvenience due to the **time involved** in receiving allergen IT injections in a medically supervised setting is likely the reason for the low utilization of SCIT.



Why accelerate IT?

(1) A saving of time. Not only does the patient become desensitised in a shorter space but there is a saving of tiresome details, such as remembering to go for and getting the dose, and perhaps afterwards waiting for possible reactions. All this amounts to an unconscionable dislocation of affairs if repeated day by day.



CONVENTIONAL IMMUNOTHERAPY (7.5 month)30 inj/visits.

| January | | | | | | |
|---------|---|----|----|----|----|----|
| S | M | T | W | T | F | S |
| | | | | | 1 | 2 |
| 3 | 🟢 | 5 | 6 | 7 | 8 | 9 |
| 10 | 🟢 | 12 | 13 | 14 | 15 | 16 |
| 17 | 🟢 | 19 | 20 | 21 | 22 | 23 |
| 24 | 🟢 | 26 | 27 | 28 | 29 | 30 |
| 31 | | | | | | |

| February | | | | | | |
|----------|---|----|----|----|----|----|
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| 7 | 🟡 | 9 | 10 | 11 | 12 | 13 |
| 14 | 🟡 | 16 | 17 | 18 | 19 | 20 |
| 21 | 🟡 | 23 | 24 | 25 | 26 | 27 |
| 28 | | | | | | |

| March | | | | | | |
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| 7 | 🟡 | 9 | 10 | 11 | 12 | 13 |
| 14 | 🟡 | 16 | 17 | 18 | 19 | 20 |
| 21 | 🟡 | 23 | 24 | 25 | 26 | 27 |
| 28 | 🟡 | 30 | 31 | | | |

| April | | | | | | |
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| 11 | 🟡 | 13 | 14 | 15 | 16 | 17 |
| 18 | 🟡 | 20 | 21 | 22 | 23 | 24 |
| 25 | 🟡 | 27 | 28 | 29 | 30 | |

| May | | | | | | |
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| 2 | 🟡 | 4 | 5 | 6 | 7 | 8 |
| 9 | 🟡 | 11 | 12 | 13 | 14 | 15 |
| 16 | 🟡 | 18 | 19 | 20 | 21 | 22 |
| 23 | 🟡 | 25 | 26 | 27 | 28 | 29 |
| 30 | 🟡 | | | | | |

| June | | | | | | |
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| 13 | 🟡 | 15 | 16 | 17 | 18 | 19 |
| 20 | 🟡 | 22 | 23 | 24 | 25 | 26 |
| 27 | 🟡 | 29 | 30 | | | |

| July | | | | | | |
|------|---|----|----|----|----|----|
| S | M | T | W | T | F | S |
| | | | | 1 | 2 | 3 |
| 4 | 🟡 | 6 | 7 | 8 | 9 | 10 |
| 11 | 🟡 | 13 | 14 | 15 | 16 | 17 |
| 18 | 🟡 | 20 | 21 | 22 | 23 | 24 |
| 25 | 🟡 | 27 | 28 | 29 | 30 | 31 |

| Dilution from maintenance concentrate | | | |
|---------------------------------------|-----|--------|--|
| Vol/vol label | No. | Color | |
| Maintenance concentrate | 1 | Red | |
| 10-fold | 2 | Yellow | |
| 100-fold | 3 | Blue | |
| 1000-fold | 4 | Green | |
| 10,000-fold | 5 | Silver | |

Definition

Allergen immunotherapy: A practice param second update

| Visit Number | Volume (mL) | Dilution (v/v) | Vial Color | Dose (mg) | Cum D (mg) |
|--------------|-------------|----------------|------------|-----------|------------|
| 1 | 0.10 | 1:1000 | green | 0.1 | |
| | 0.40 | 1:1000 | green | 0.4 | |
| | 0.10 | 1:100 | blue | 1.0 | |
| 2 | 0.20 | 1:100 | blue | 2.0 | |
| | 0.40 | 1:100 | blue | 4.0 | |
| | 0.07 | 1:10 | yellow | 7.0 | |
| 3 | 0.10 | 1:10 | yellow | 10.0 | |
| | 0.15 | 1:10 | yellow | 15.0 | |
| | 0.25 | 1:10 | yellow | 25.0 | |
| 4 | 0.35 | 1:10 | yellow | 35.0 | |
| | 0.50 | 1:10 | yellow | 50.0 | 1 |
| 5 | 0.07 | 1:1 | red | 70.0 | 2 |
| | 0.10 | 1:1 | red | 100.0 | 3 |
| 6 | 0.15 | 1:1 | red | 150.0 | 4 |
| | 0.20 | 1:1 | red | 200.0 | 6 |
| 7 | 0.30 | 1:1 | red | 300.0 | 9 |
| | 0.40 | 1:1 | red | 400.0 | 1,3 |
| 8 | 0.50 | 1:1 | red | 500.0 | 1,8 |

APPENDIX 3. Example of a build-up schedule for weekly immunotherapy

| Dilution (vol/vol) | Volume (mL) |
|-------------------------|-------------|
| 1:1000 | 0.05 |
| | 0.10 |
| | 0.20 |
| | 0.40 |
| 1:100 | 0.05 |
| | 0.10 |
| | 0.20 |
| | 0.30 |
| 1:10 | 0.40 |
| | 0.50 |
| | 0.05 |
| | 0.07 |
| | 0.10 |
| | 0.15 |
| | 0.25 |
| | 0.35 |
| | 0.40 |
| | 0.45 |
| Maintenance concentrate | 0.50 |
| | 0.05 |
| | 0.07 |
| | 0.10 |
| | 0.15 |
| | 0.20 |
| | 0.25 |
| | 0.30 |
| | 0.35 |
| | 0.40 |
| | 0.45 |
| | 0.50 |

**Total
injections to
maintenance:
30**

Subcutaneous Cluster Schedule

- Cluster entails administering several injections at increasing doses (generally 2-3 per visit) sequentially in a single day of treatment on nonconsecutive days.
- Cluster schedule associated with the same or a slightly increased frequency of SRs compared with conventional schedules.
- Few studies compare safety and most used single allergen: *can safety be extrapolated to multiallergen?*


















APPENDIX 5. Example of a cluster immunotherapy schedule^{22,26}

| Visit | Dose (mL) | Concentration as dilution of maintenance vial |
|-------|-----------|---|
| 1 | 0.10 | 1:1000 vol/vol |
| | 0.40 | 1:1000 vol/vol |
| | 0.10 | 1:100 vol/vol |
| 2 | 0.20 | 1:100 vol/vol |
| | 0.40 | 1:100 vol/vol |
| | 0.07 | 1:10 vol/vol |
| 3 | 0.10 | 1:10 vol/vol |
| | 0.15 | 1:10 vol/vol |
| | 0.25 | 1:10 vol/vol |
| 4 | 0.35 | 1:10 vol/vol |
| | 0.50 | 1:10 vol/vol |
| 5 | 0.07 | 1:1 vol/vol |
| | 0.10 | 1:1 vol/vol |
| 6 | 0.15 | 1:1 vol/vol |
| | 0.20 | 1:1 vol/vol |
| 7 | 0.30 | 1:1 vol/vol |
| | 0.40 | 1:1 vol/vol |
| 8 | 0.50 | 1:1 vol/vol |


Example of a 8 visit 18 injection schedule in the 2nd and 3rd ITPP updates*

CLUSTER IMMUNOTHERAPY (5 weeks) 18inj / 8visits.

January

| S | M | T | W | T | F | S |
|----|---|----|----|---|----|----|
| | | | | | 1 | 2 |
| 3 |    | 5 | 6 |    | 8 | 9 |
| 10 |    | 12 | 13 |   | 15 | 16 |
| 17 |   | 19 | 20 |   | 22 | 23 |
| 24 |   | 26 | 27 | 28 | 29 | 30 |
| 31 | | | | | | |





February

| S | M | T | W | T | F | S |
|----|---|----|----|----|----|----|
| |  | 2 | 3 | 4 | 5 | 6 |
| 7 | 8 | 9 | 10 | 11 | 12 | 13 |
| 14 | 15 | 16 | 17 | 18 | 19 | 20 |
| 21 | 22 | 23 | 24 | 25 | 26 | 27 |
| 28 | | | | | | |



March

| S | M | T | W | T | F | S |
|----|---|----|----|----|----|----|
| |  | 2 | 3 | 4 | 5 | 6 |
| 7 |  | 9 | 10 | 11 | 12 | 13 |
| 14 |  | 16 | 17 | 18 | 19 | 20 |
| 21 |  | 23 | 24 | 25 | 26 | 27 |
| 28 |  | 30 | 31 | | | |

April

| S | M | T | W | T | F | S |
|----|---|----|----|----|----|----|
| | | | | 1 | 2 | 3 |
| 4 |  | 6 | 7 | 8 | 9 | 10 |
| 11 |  | 13 | 14 | 15 | 16 | 17 |
| 18 |  | 20 | 21 | 22 | 23 | 24 |
| 25 |  | 27 | 28 | 29 | 30 | |


May

| S | M | T | W | T | F | S |
|----|---|----|----|----|----|----|
| | | | | | | 1 |
| 2 |  | 4 | 5 | 6 | 7 | 8 |
| 9 |  | 11 | 12 | 13 | 14 | 15 |
| 16 |  | 18 | 19 | 20 | 21 | 22 |
| 23 |  | 25 | 26 | 27 | 28 | 29 |
| 30 |  | | | | | |

June

| S | M | T | W | T | F | S |
|----|---|----|----|----|----|----|
| | | 1 | 2 | 3 | 4 | 5 |
| 6 |  | 8 | 9 | 10 | 11 | 12 |
| 13 |  | 15 | 16 | 17 | 18 | 19 |
| 20 |  | 22 | 23 | 24 | 25 | 26 |
| 27 |  | 29 | 30 | | | |

July

| S | M | T | W | T | F | S |
|----|---|----|----|----|----|----|
| | | | | 1 | 2 | 3 |
| 4 |  | 6 | 7 | 8 | 9 | 10 |
| 11 |  | 13 | 14 | 15 | 16 | 17 |
| 18 |  | 20 | 21 | 22 | 23 | 24 |
| 25 |  | 27 | 28 | 29 | 30 | 31 |

Dilution from

maintenance concentrate

Vol/vol label

No.

Color

Maintenance concentrate

1:1

1

Red

10-fold

1:10

2

Yellow

100-fold

1:100

3

Blue

1000-fold

1:1000

4

Green

10,000-fold

1:10,000

5

Silver

Result of Chemical Modification: Standardized Hypoallergenic Immunotherapy

Immunotherapy is a dose dependent therapy

- *Administering high doses of allergen yet keep chances of anaphylaxis to a minimum*
- *High dose administration allows faster up titration and attainment of immunological target sooner*
- *Lesser frequent dosage interval making treatment schedules more convenient*
- *Better compliance*

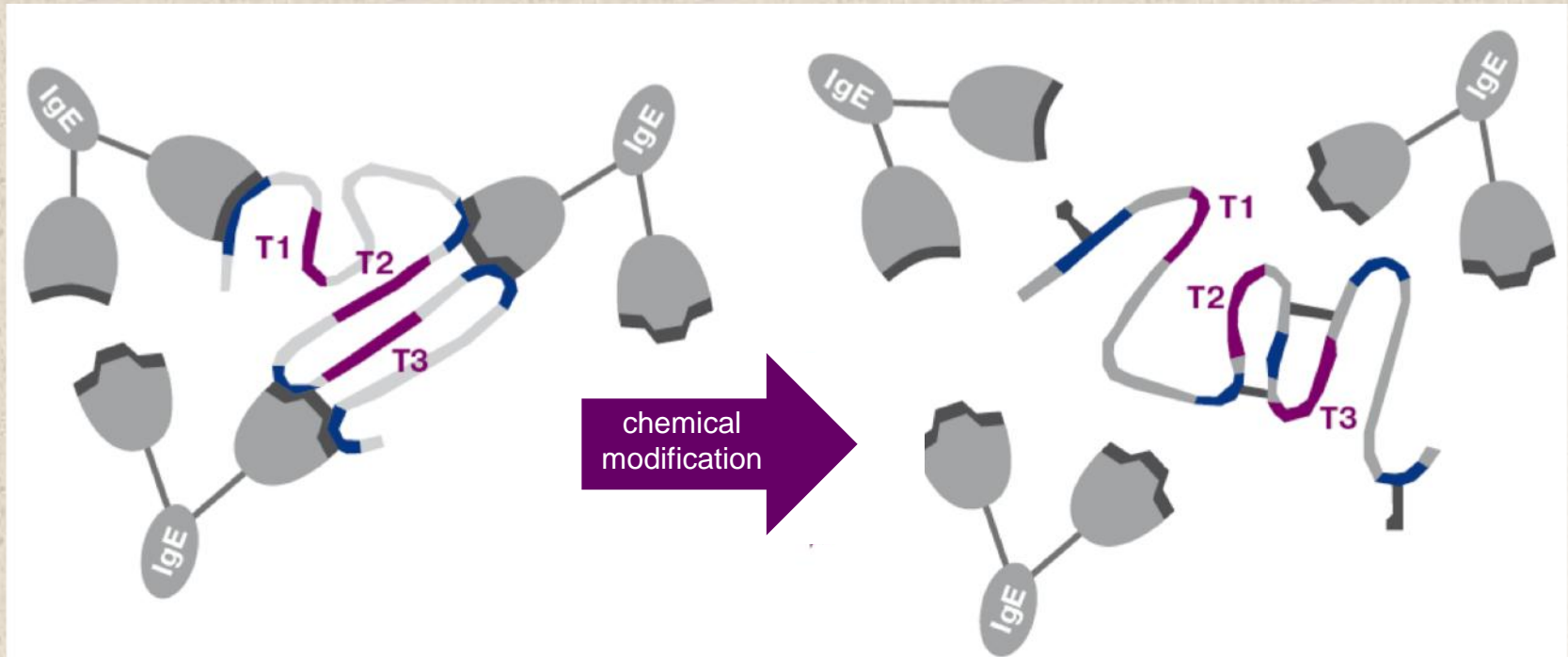
Allergoids are Standardized Hypoallergenic Allergens

Allergoids have:

- Reduced allergenicity &
- Retained immunogenicity

Hypoallergenic Allergen

- ■ ■ T-cell epitopes intact (→immunogenicity)
- ■ ■ IgE binding activity strongly reduced (→reduced allergenicity)



Standardized Hypoallergenic Immunotherapy – Recommended Schedule

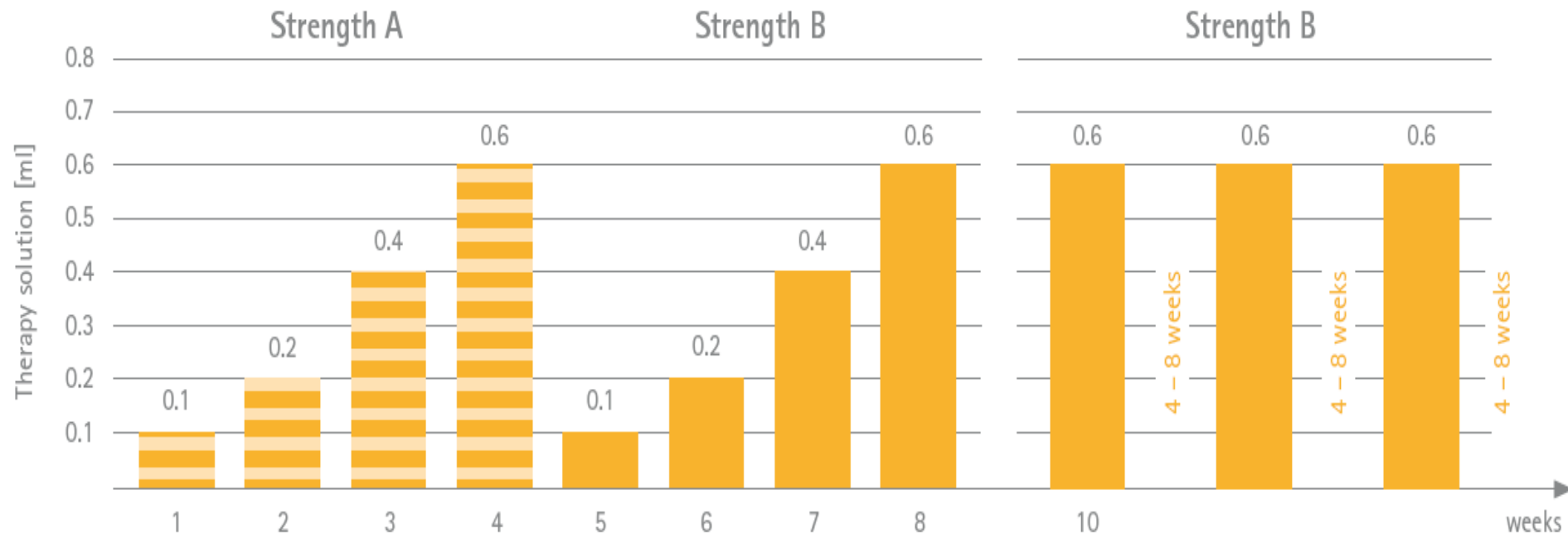
Recommended dosage schedule**

Initial therapy

Weekly increase up to peak dose

Maintenance therapy

Peak dose every 4 – 8 weeks



** Dosage will depend on individual patient tolerance

Allergens of Proven Efficacy

| Allergen | Level of Evidence | Availability of Data |
|--------------------|-------------------|----------------------|
| House Dust Mite | A | ++++ |
| Pollen | A | ++++ |
| Mould | A | ++ |
| Animal Epithelia | A | ++ |
| Hymenopteral venom | A | ++ |
| Cockroach | B | + |

++++ = Multiple long-term randomized controlled trials available;

++ = Few randomized controlled trials available

+ = Limited data; no placebo-controlled trials

AIT IN Mite-Allergic Patient

The prevalence of HDM respiratory allergic disease is a global challenge

Patients affected
by allergic rhinitis
worldwide^{1,2}

400-500
millions

Global
prevalence of
asthma^{3,4}

235-300
millions

>50%

allergic patients have
HDM allergy

Injection Allergen Immunotherapy for Asthma

- Eighty-eight trials were included (13 new trials)

42

house dust mite allergy

27

pollen allergy



10

animal dander allergy

2

cladosporium mould allergy

2

latex allergy

6

multiple allergens

AIT for House Dust Mite (HDM) Allergy: Why?

HDM allergens play a major part of allergic disease

45 to 85%

of asthmatics are sensitized to mites

In the Copenhagen Allergy Trial

50%

of HDM-induced rhinitis patients had HDM induced asthma

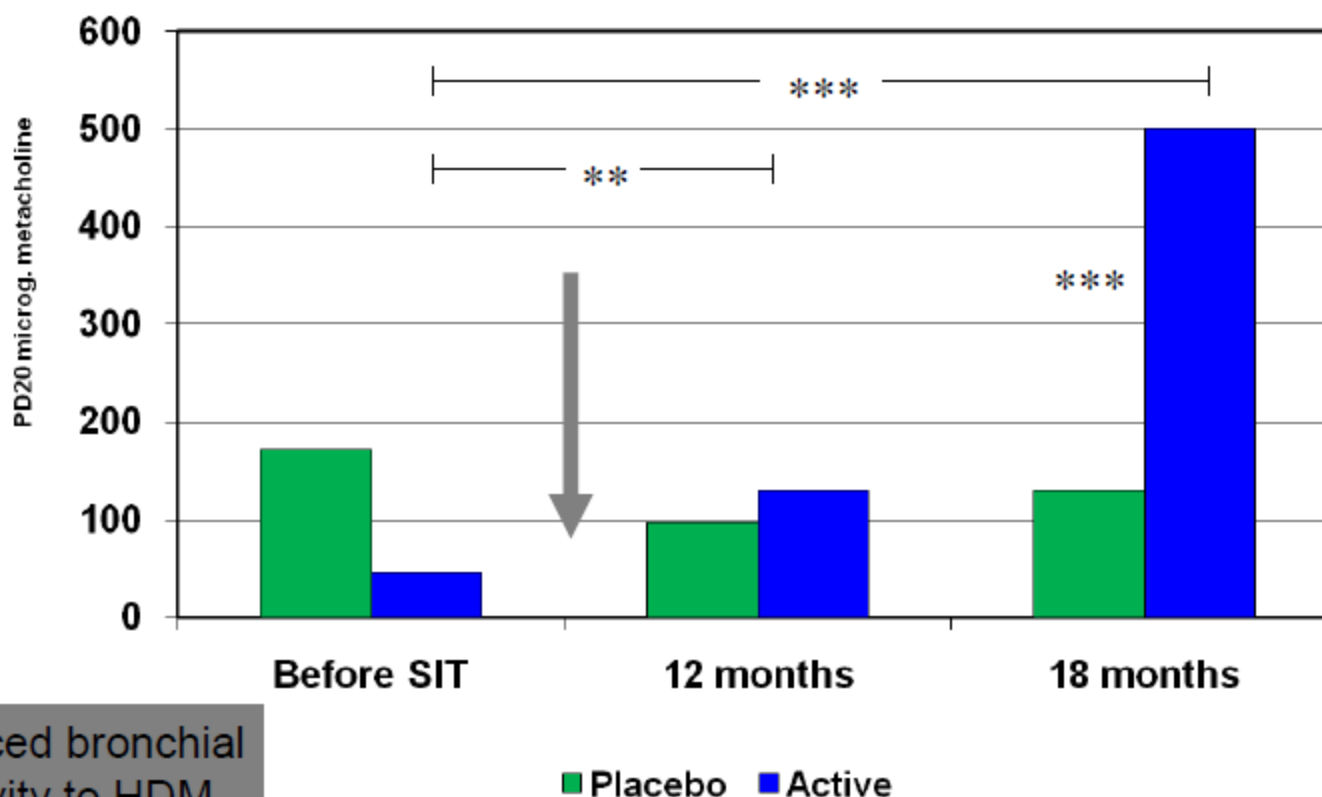
95%

of HDM-induced asthma patients also had HDM-induced rhinitis



Bronchial hyperresponsiveness after SIT with house dust mites.

(maintenance dose: 100,000 SQ-U, Alutard SQ)

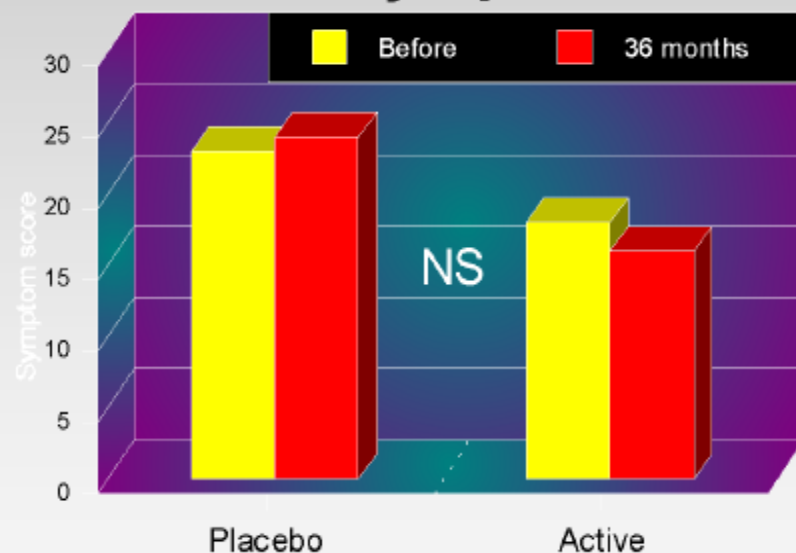


Reduced bronchial reactivity to HDM after 6 months

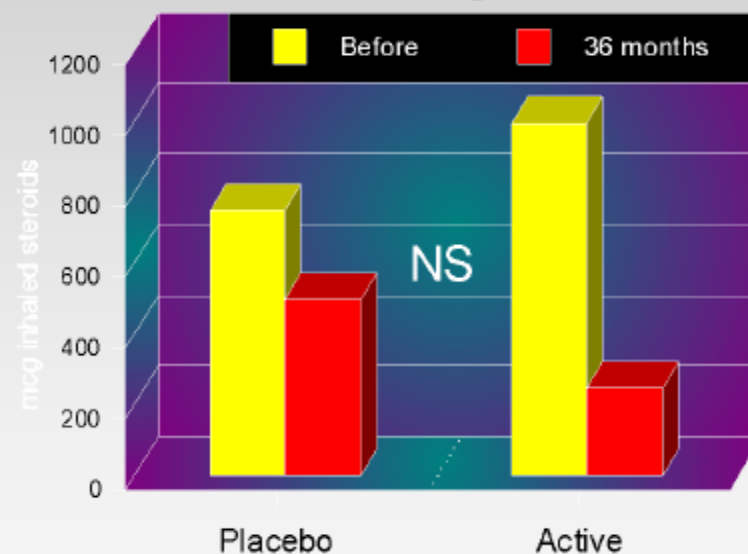
Efficacy of mite immunotherapy

Blumberga et al. Allergy 2006;61:843

Symptoms



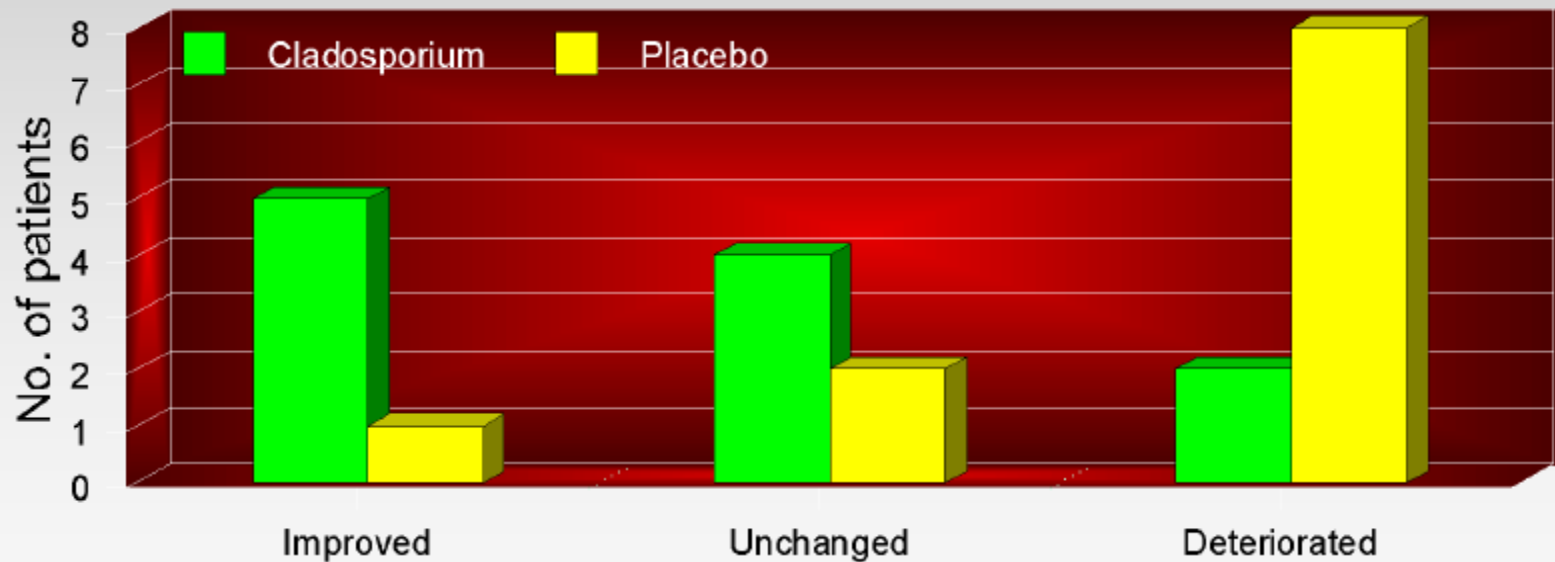
Drugs



Efficacy of mould immunotherapy

Change in disease severity from baseline

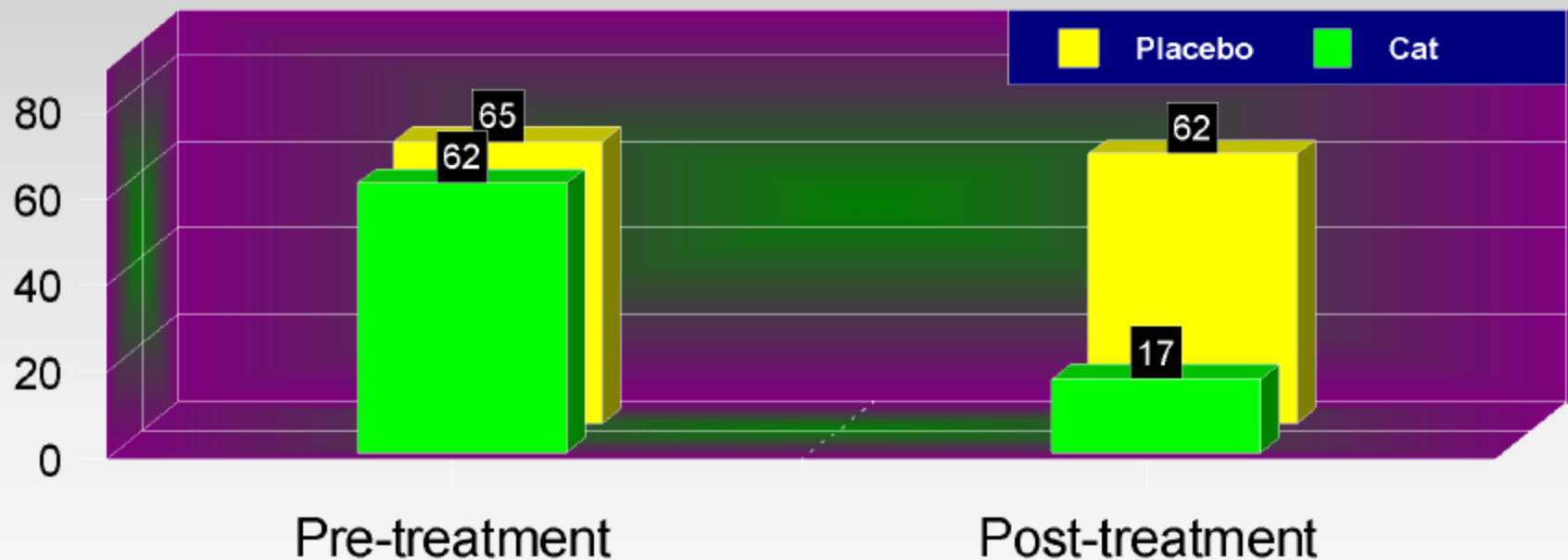
Malling et al. Allergy 1986;41:507



Efficacy of cat immunotherapy

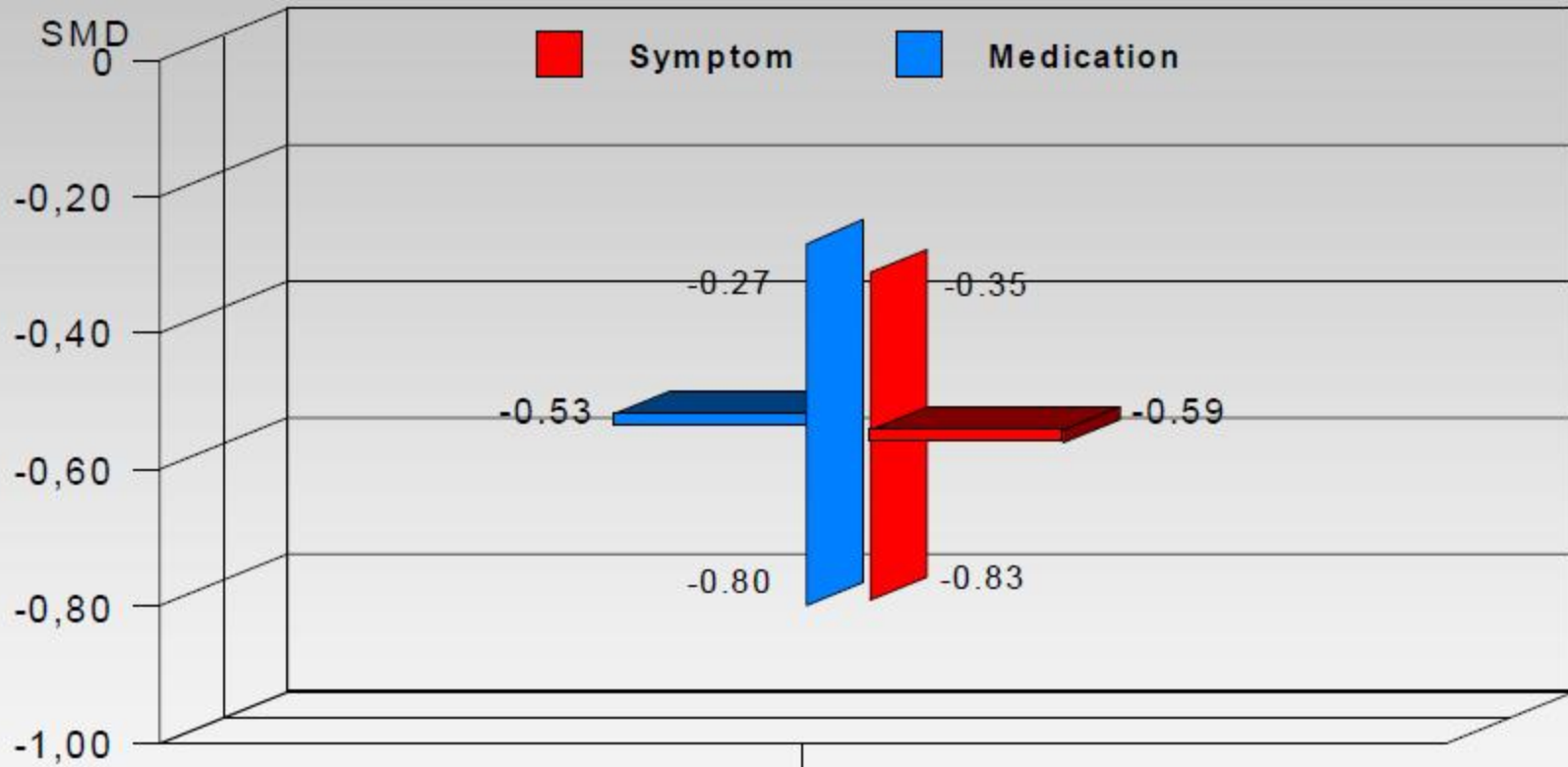
Cat exposure symptom score

Varney et al. Clin Exp Allergy 1997



Meta-analysis of SCIT in allergic asthma

Abramson et al. 2010



The effect size is considered trivial for SMD between 0.0 and 0.2, small for 0.2 to 0.5, moderate for 0.5 to 0.8, and large for greater than 0.8.

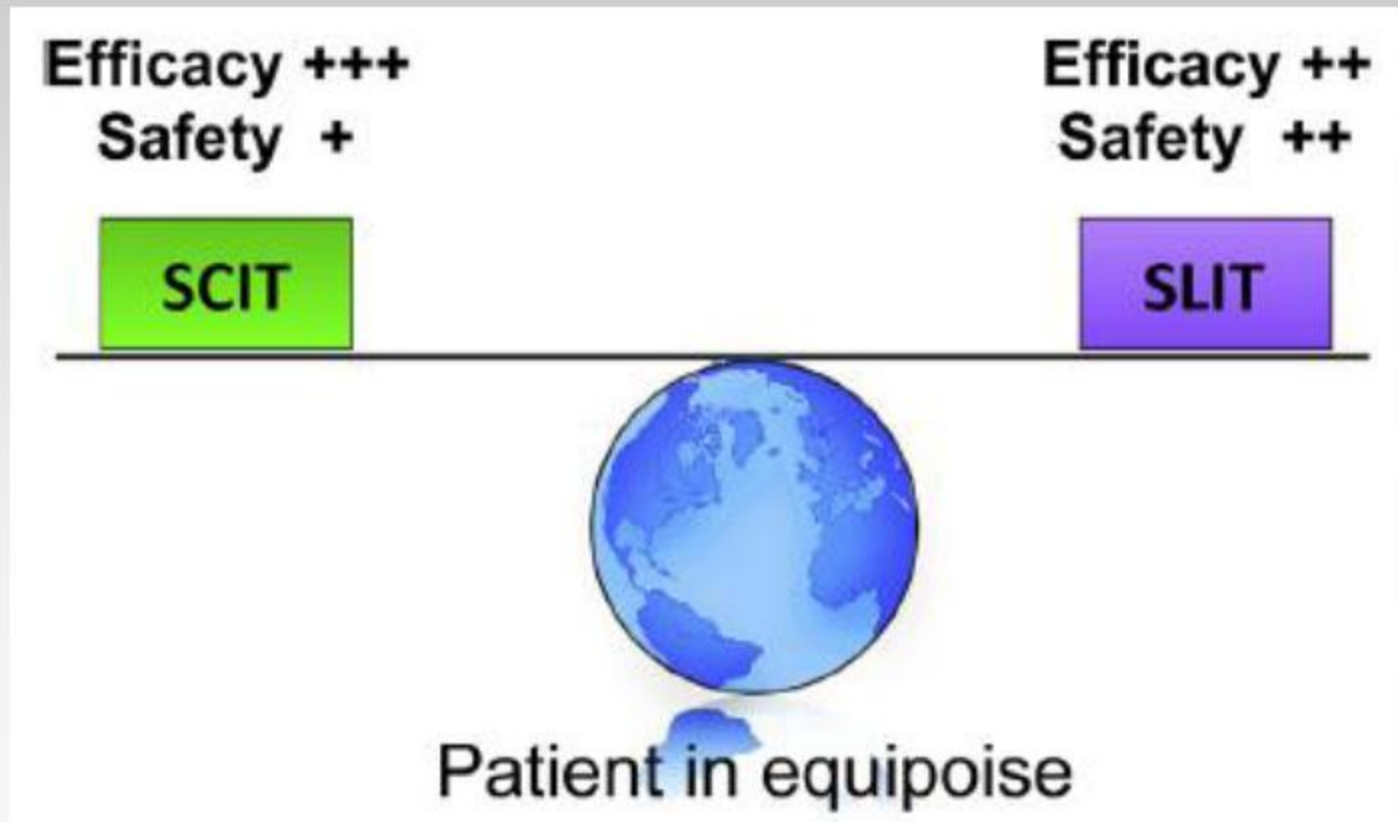
Sublingual Allergen Immunotherapy

- SLIT -



Efficacy vs safety

- Is a safe but ineffective intervention an option?



Recommendations for Allergy Prevention by AIT in 2016

- Early recognition of allergic sensitization in children by provision of appropriate allergy tests (molecular spreading)
- Early identification of the high risk child who may benefit most from allergen immunotherapy
- Early introduction of AIT – below age 5 yrs ?

Thanks

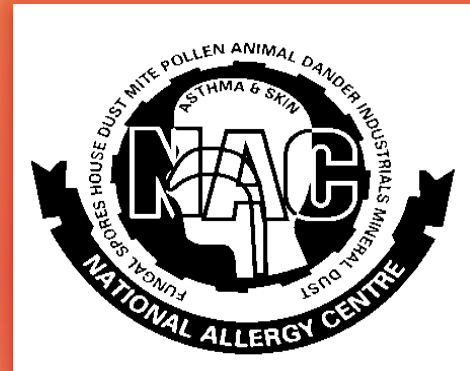
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