

L'alimentazione del bambino...
sano, allergico, con malattia cronica
Una esigenza della famiglia a cui il pediatra risponde
con evidenze e... buon senso

VI Giornate Pediatriche "A. Laurinsich"
SIPPSAGGIORNA



Parma, 26 - 27 Ottobre 2012

Centro Congressi della Camera di Commercio di Parma
via Giuseppe Verdi n°2, Parma



**La desensibilizzazione:
immunoterapia
specifico o
assuefazione?**

Iride Dello Iacono

**Unità Operativa di Pediatria ed
Allergologia Pediatrica
Ospedale Fatebenefratelli
Benevento**

M. CALVANI¹, V. GIORGIO², S. MICELI SOPO²

Specific oral tolerance induction for food. A systematic review

On the contrary, specific oral tolerance induction (SOTI), proposed and carried out since about 20 years ago (7), seems to be weighted by fewer side effects and therefore is now put under new interest.

. Mc Ewen LM. Hyposensitization. In: Brostoff J and Challacombe SJ eds. Food Allergy and Intolerance. Baillier Tindall, 1988: 985-94.

Table 1

Results of recent prospective studies of OIT and SLIT for food allergy (excluding individual case reports)

Year	Author	Food Allergen	Type	Age	Blinded	Total Subjects	Completed Treatment	Completed Food Challenge	Immunoglobulin Changes
1984	Patriarca et al ²²	Milk, egg, other	OIT	—	No	19	15/19	14/15	n/a
2003	Patriarca et al ²⁵	Milk, egg, other	OIT	3–55	No	59	38/59	n/a	↓IgE, ↑IgG4
2004	Meglio ⁴⁰	Milk	OIT	5–10	No	21	15/21	n/a	IgE no change
2007	Buchanan et al ²⁶	Egg	OIT	1–7	No	7	7/7	4/7	↓IgE, ↑IgG
2007	Staden et al ²⁷	Milk, egg	OIT	1–13	No	25	16/25	9/16	↓IgE
2008	Longo et al ²⁸	Milk	OIT	5–17	No	30	27/30	11/27	↓IgE
2008	Skripak et al ²⁹	Milk	OIT	6–17	Yes	13	12/13	4/12	IgE no change, ↑IgG4
2008	Staden ⁴¹	Milk	OIT	3–14	No	9	6/9	n/a	n/a
2008	Zapatero ⁴²	Milk	OIT	4–8	No	18	16/18	n/a	IgE no change
2009	Clark et al ³⁰	Peanut	OIT	9–13	No	4	4/4	3/4	n/a
2009	Jones et al ³¹	Peanut	OIT	1–16	No	39	29/39	27/29	↓IgE, ↑IgG4
2010	Blumchen et al ³²	Peanut	OIT	3–14	No	23	14/23	3/14	IgE no change, ↑IgG4
2010	Itoh ⁴³	Egg	OIT	7–12	No	6	6/6	3/6	↓IgE, ↑IgG4
2005	Enrique et al ³⁶	Hazelnut	SLIT	19–53	Yes	12	11/12	5/11	IgE no change, ↑IgG4
2011	Kim et al ³⁷	Peanut	SLIT	1–11	Yes	11	11/11	0	↓IgE, ↑IgG4



Oral Immunotherapy



Specific oral tolerance induction in food allergic children: is oral desensitisation more effective than allergen avoidance?

A meta-analysis of published RCTs

H R Fisher, G du Toit, G Lack

Arch Dis Child 2011;**96**:259–264. doi:10.1136/adc.2009.172460



COCHRANE META-ANALYSIS IN ALLERGY

Oral immunotherapy for IgE-mediated cow's milk allergy: a systematic review and meta-analysis

J. L. Brožek¹, L. Terracciano², J. Hsu³, J. Kreis^{4,5}, E. Compalati⁶, N. Santesso⁵, A. Fiocchi² and H. J. Schünemann¹

Methods

Criteria for considering studies

We developed a protocol for the guideline and systematic assessment of the literature and determined *a priori* to include randomized trials and observational studies with an independent control group that enrolled patients – children and adults – with CMA as defined by the study authors. The intervention of interest was the oral immunotherapy with cow's milk.

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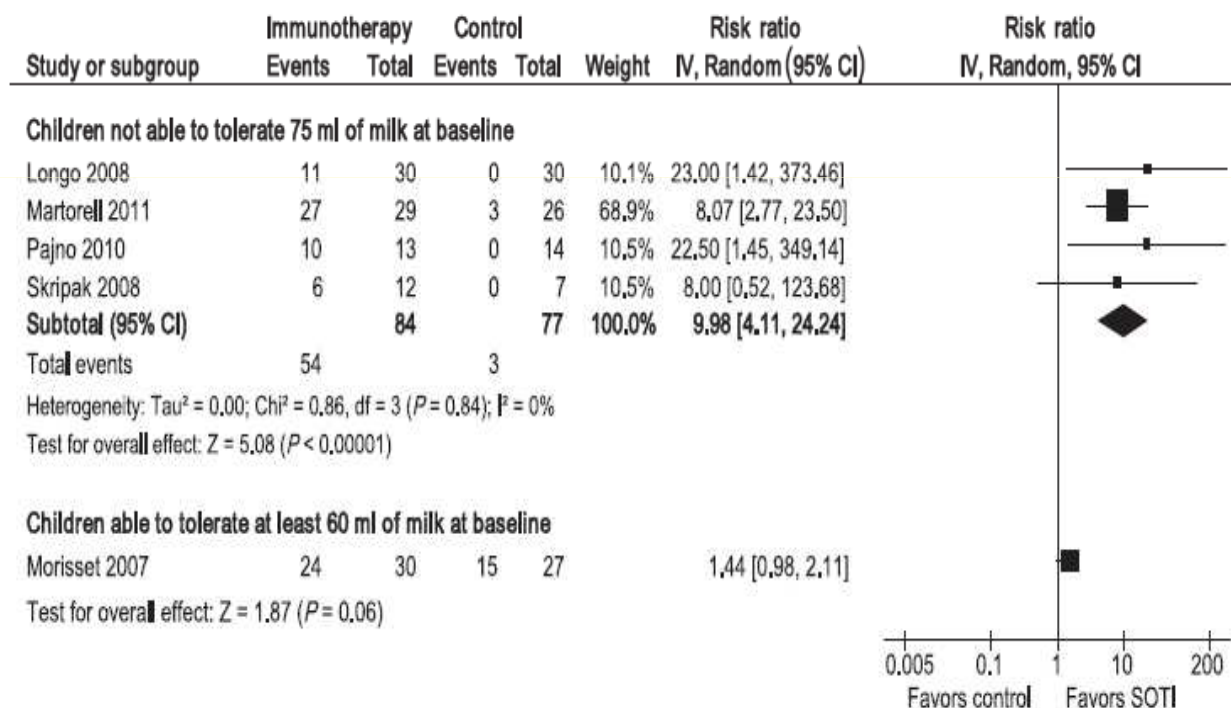


Fig. 2. Randomized controlled trials showing the probability of achieving full tolerance of cow's milk (i.e. being able to tolerate ≥ 150 mL of milk during a challenge and/or drink milk and eat dairy products with no problems) with oral immunotherapy, compared to placebo or elimination diet, in patients with CMA.

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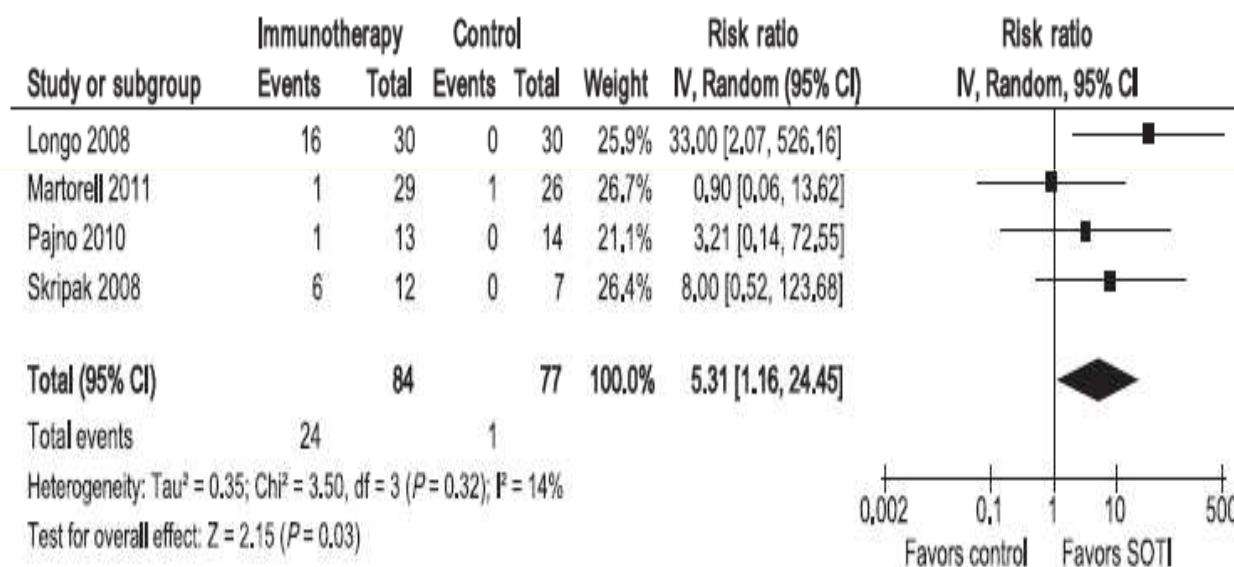


Fig. 3. Randomized controlled trials showing the probability of achieving partial tolerance of cow's milk (i.e. being able to tolerate 5–150 mL of milk during a challenge) with oral immunotherapy, compared to placebo or elimination diet, in patients with CMA.

M. CALVANI¹, V. GIORGIO², S. MICELI SOPO²

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Table 4 - Main outcome of RCT's of oral desensitization for milk.

Author	Age	Popolation	Tolerance	Partial tolerance	Non responder	Tolerance in controls
Morisset, 2007	(mean age 2.2 yr)	Less sensitive patients	24/27 (89.9%)		3/27 (11.1%)	18/30 (60%)
Longo, 2008	(mean age 7.9 yrs)	Only severe cow's milk allergy	11/30 (46%)	16/30 (54%)	3/30 (10%)	0/30 (0%)
Skripak, 2008	(mean age) 10 yrs	Excluding severe Cow's milk allergy	4/13 (30,7%) (> 250 ml)	6/13 (46,1%) (> 70 ma < 250 ml)	3/13 (23%) (< 70 ml)	0/7 (0%)

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Allergy Unit, Department of Pediatrics, University of Messina, Messina, Italy.

Age	Popolation	Tolerance	Partial tolerance	Non responder	Tolerance in controls
9 yrs	Less and severe CMA (2)	10/13 (76,9%)	1/13 (7,69%)	2/13 (15,3%)	0/14

doi: 10.1111/j.1365-2222.2011.03749.x

Clinical & Experimental Allergy, 41, 1297–1304

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ORIGINAL ARTICLE Clinical Allergy

Oral desensitization as a useful treatment in 2-year-old children with cow's milk allergy

A. Martorell^{1*}, B. De la Hoz^{2*}, M. D. Ibáñez³, J. Bone⁴, M. S. Terrados², A. Michavila⁵, A. M. Plaza⁶, E. Alonso⁷, J. Garde⁸, S. Nevot⁹, L. Echeverria¹⁰, C. Santana¹¹, J. C. Cerdá¹, C. Escudero³, I. Guallar⁴, M. Piquer⁶, L. Zapatero⁷, L. Ferré⁹, T. Bracamonte¹⁰, A. Muriel¹², M. I. Martínez¹³ and R. Félix¹

Age	Popolation	Tolerance	Partial tolerance	Non responder	Tolerance in controls
25,75 m	Excluding severe CMA	27/30 (90%)	1/30 (3,3%)	2/30 (6,6%)	7/30 (23,3%)



Il bambino candidato alla DOPA



Pediatric Allergy and Immunology

ORIGINAL ARTICLE

Specific oral tolerance induction with raw hen's egg in children with very severe egg allergy: A randomized controlled trial

Iride Dello Iacono¹, Salvatore Tripodi², Mauro Calvani³, Valentina Panetta⁴, Maria Carmela Verga⁵ & Stefano Miceli Sopo⁶

¹Department of Paediatrics, Fatebenefratelli Hospital, Benevento, Italy; ²Paediatric Allergology Unit, Sandro Pertini Hospital, Rome, Italy;

³Department of Paediatrics, S. Camillo-Forlanini Hospital, Rome, Italy; ⁴L'altra statistica srl, Rome, Italy; ⁵Primary Care Paediatrics ASL Salerno, Italy; ⁶ Department of Paediatrics, Catholic University, Rome, Italy

Il bambino candidato alla DOPA



Tutti anafilattici

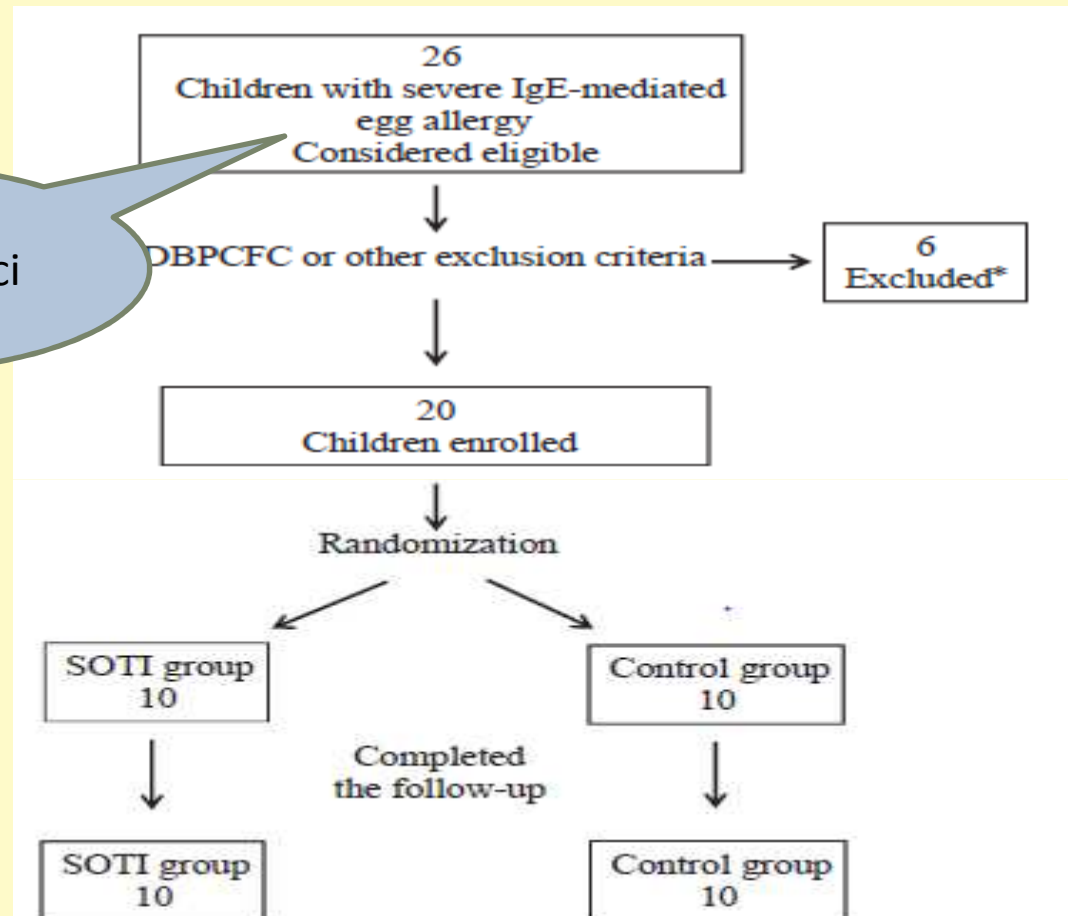


Figure 1 Flowchart of the enrolled population. *Six children (four boys and two girls) were excluded from the study: one child because the parents had a history of unreliable management of complications and treatments; two children because of poorly controlled asthma; and three children because of a positive Double-blind placebo-controlled food challenge at a dose of raw egg emulsion higher than 0.9 ml.

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To cite this article: Dello Iacono I, Tripodi S, Calvani M, Panetta V, Verga MC, Miceli Sopo S. Specific oral tolerance induction with raw hen's egg in children with very severe egg allergy: A randomized controlled trial. *Pediatr Allergy Immunol* 2012; **00**.

Table 4 Maximal tolerated dose for each patient before or after SOTI for an egg-free diet

SOTI Group				Control Group			
Patients	Maximal tolerated dose at first DBPCFC (ml)	Maximal tolerated dose after 6 months (ml)	Difference	Patients	Maximal tolerated dose at first DBPCFC (ml)	Maximal tolerated dose after 6 months (ml)	Difference
1	0.45	30	29.55	1	0.9	0.45	-0.45
2	0.45	30	29.55	2	0.45	0.9	0.45
3	0.9	20	19.1	3	0.45	0.9	0.45
4	0.45	10	9.55	4	0.225	0.225	0
5	0.225	5	4.775	5	0.45	0.225	-0.225
6	0.9	20	19.1	6	0.45	0.45	0
7	0.225	30	29.775	7	0.9	1.8	0.9
8	0.45	10	9.55	8	0.9	0.45	-0.45
9	0.9	10	9.1	9	0.225	0.45	0.225
10	0.9	30	29.1	10	0.9	0.9	0
Median (range)	0.45 (0.225–0.9)	20 (5–30)	19.1 (4.8–29.8)*	Median (range)	0.45 (0.225–0.9)	0.45 (0.225–1.8)	0 (-0.45–0.9)

DBPCFC, double-blind placebo-controlled food challenge; SOTI, specific oral tolerance induction.

* $p < 0.001$.

1/10 (10%)
non responder non
essendo riuscito a
superare i 5 ml

Future therapies for food allergies

Anna Nowak-Węgrzyn, MD, and Hugh A. Sampson, MD *New York, NY*

J Allergy Clin Immunol 2011

It is also unclear whether failure of desensitization is associated with the most severe and likely permanent food allergy phenotype, as opposed to the successful desensitization and tolerance induction that might be associated with a transient clinical phenotype and higher chances of spontaneous resolution of food allergy.

Io mi sono fatta quest'idea.....

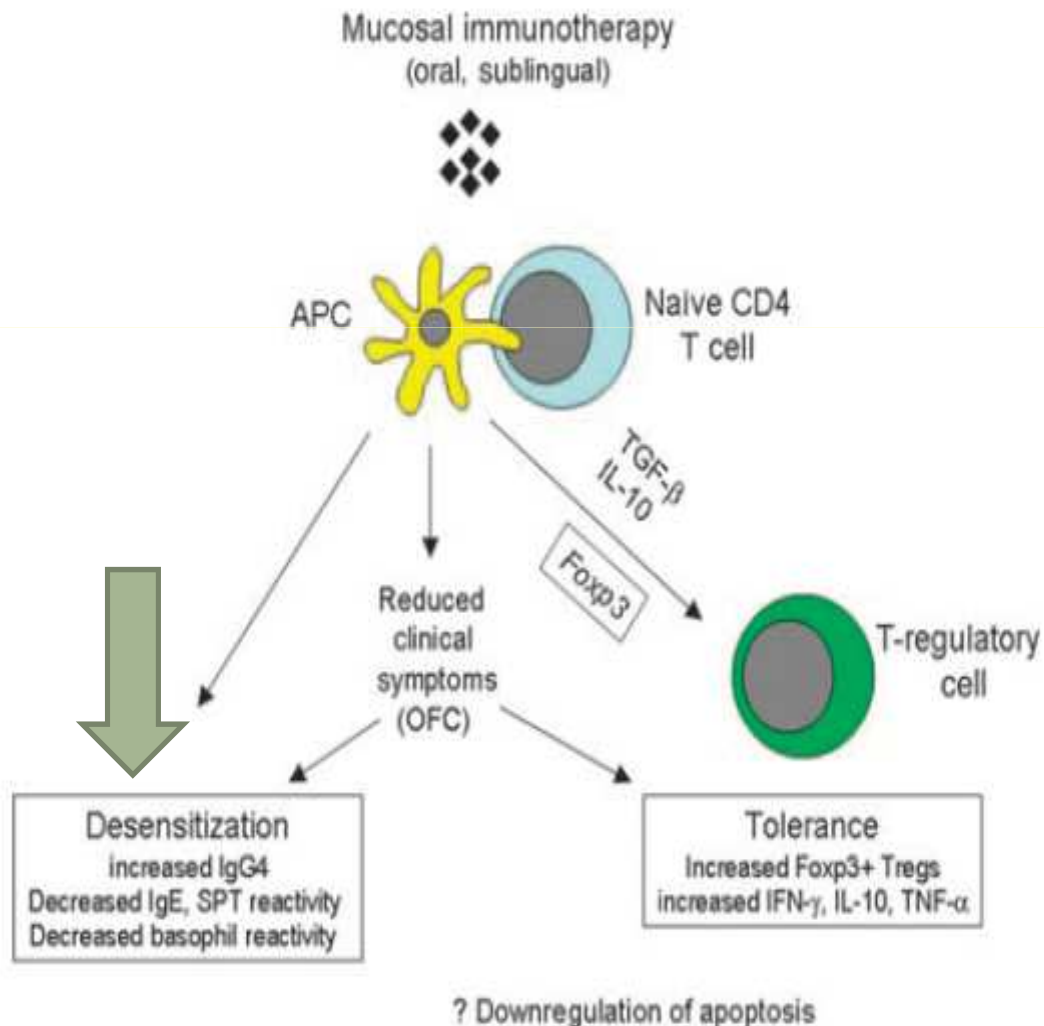
- CHE ESISTA UN NUOVO FENOTIPO DI AA:

IL SOGGETTO CON AA NON RESPONDER
ALLA DOPA

Mucosal Immunol. 2010 Jul;3(4):345-54. Epub 2010 May 26.

Pediatric food allergy and mucosal tolerance.

Scurlock AM, Vickery BP, Hourihane JO, Burks AW.



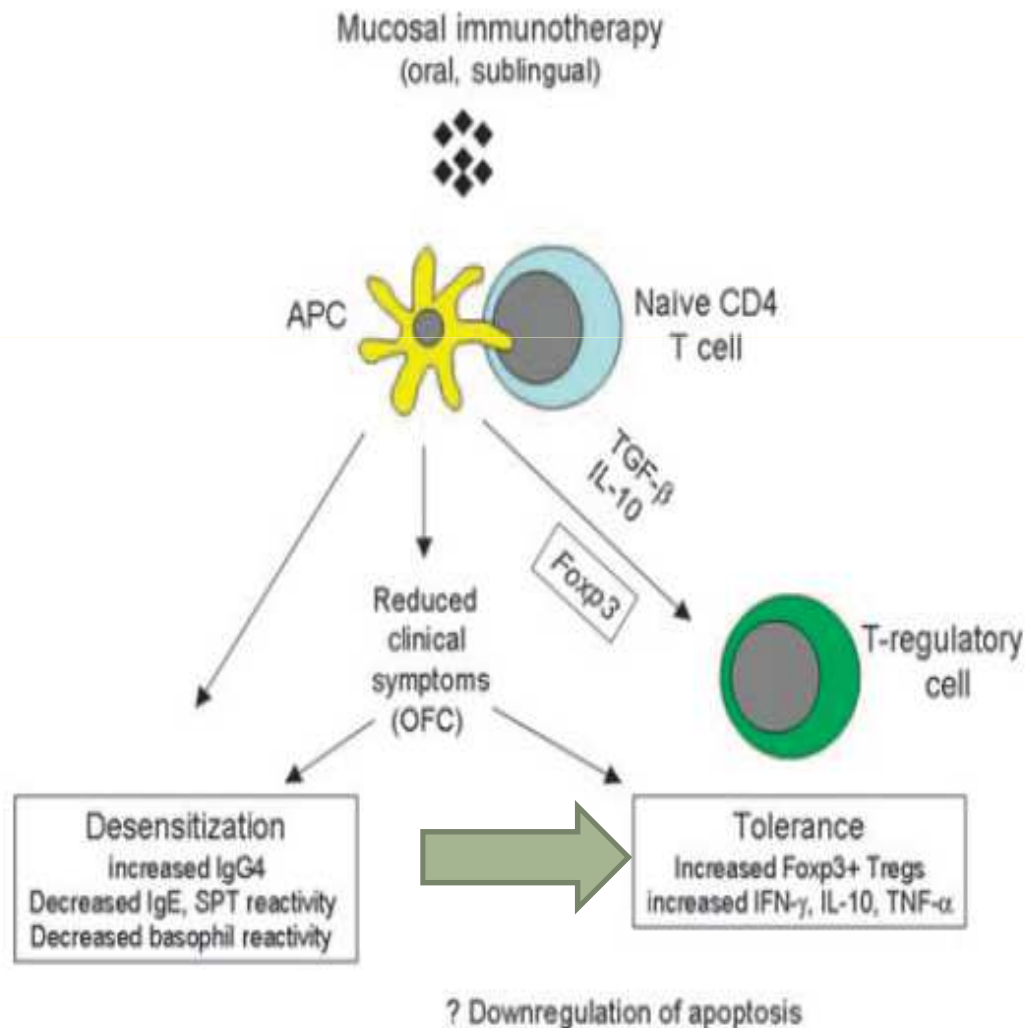
***Desensitization** is defined as a change in threshold dose of ingested food allergen necessary to cause allergic symptoms; this state is dependent on ongoing antigen exposure*

***Mechanistic markers of desensitization** include increase IgG4 and reduced IgE, as well as decreased activation and release of inflammatory mediators by mast cells and basophils*

Mucosal Immunol. 2010 Jul;3(4):345-54. Epub 2010 May 26.

Pediatric food allergy and mucosal tolerance.

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In contrast, tolerance is the induction of long-term immunologic changes associated with the ability to ingest a food without symptoms and without ongoing therapy.

Mechanism of tolerance induction include active modulation of the immune response to promote regulatory T-cell development and immunologic skewing away from a Th2 response.



Oral Immunotherapy



Association of allergen-specific regulatory T cells with the onset of clinical tolerance to milk protein

[Wayne G. Shreffler, MD, PhD](#) , [Niya Wanich, MD](#), [Maria Moloney, MD](#), [Anna Nowak-Wegrzyn, MD](#), [Hugh A. Sampson, MD](#)

The Journal of Allergy and Clinical Immunology
[Volume 123, Issue 1](#), Pages 43-52.e7, January 2009

Desensibilizzazione Orale: Immunoterapia specifica o assuefazione?

- *Lo scopo della DOPA, nei pazienti “anafilattici”, è, principalmente, l’evitare il rischio di reazioni severe per minime tracce di alimento offending nascoste nei cibi*

(DESENSIBILIZZARE)

- *Lo scopo della OIT, nei pazienti con una tolleranza intermedia, è quello di innalzare la dose soglia di reattività per poterlo condurre alla dieta libera*


(INDURRE LA TOLLERANZA)

Future therapies for food allergies

Anna Nowak-Węgrzyn, MD, and Hugh A. Sampson, MD *New York, NY*

Oral tolerance versus desensitization

The ultimate goal of food allergy therapy is permanent oral tolerance, which is established when the food can be ingested without allergic symptoms despite prolonged periods of avoidance. The mechanism of permanent oral tolerance likely involves the initial development of regulatory T cells and immune deviation away from the proallergic T_H2 response, for example, at later stages.⁴⁹ In contrast, in a “desensitized state,” protection depends on the regular ingestion of the food allergen; when dosing is interrupted or discontinued, the protective effect might be lost or significantly decreased. Immunologic changes accompanying oral desensitization include decreased activity of mast cells and basophils, increased food-specific IgG4 antibodies, and eventually decreased food-specific IgE antibodies. The permanence of protection can be tested with intentional interruption of dosing for at least 4 to 12 weeks followed by a supervised oral food challenge.^{38,50}



Interruzione
intenzionale per
almeno 4-12
settimane

Specific oral tolerance induction in food allergy in children: efficacy and clinical patterns of reaction.

Staden U, Rolinck-Werninghaus C, Brewe F, Wahn U, Niggemann B, Beyer K.

SOTI group (Fig. 1)

Pattern I (responder): children who were tolerant in the follow-up DBPCFC after the secondary elimination diet.

Pattern II (responder – with regular intake): children who were tolerant with daily maintenance dose, but showed allergic symptoms after a period of avoidance.

Pattern III (partial responder): children tolerated a lower dosage of the allergen food than the planned full maintenance dosage. However, an increased dosage always resulted in clinical symptoms.

Pattern IV (non-responder): SOTI had to be stopped because the increasing titration steps of the respective SOTI protocol were repeatedly not tolerated by patients at the early steps of the protocol.

Specific oral tolerance induction in food allergy in children: efficacy and clinical patterns of reaction.

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Desensibilizzati e
non tolleranti

Table 3. Specific oral tolerance induction (SOTI) patterns and tolerance rates during SOTI or elimination diet

SOTI-group (<i>n</i> = 25)			Control-group (<i>n</i> = 20)	
Pattern		<i>n</i> (%)	Result	<i>n</i> (%)
I	Responder (natural course or SOTI?)	9 (36)	Tolerant	7 (35)
II	Responder (with regular daily intake)	3 (12)		
III	Partial responder	4 (16)		
IV	No responder	9 (36)	Allergic	13 [65%]

Egg oral immunotherapy in nonanaphylactic children with egg allergy

Ariana D. Buchanan, MD,^{a,*} Todd D. Green, MD,^{a,*} Stacie M. Jones, MD,^{b,c}
Amy M. Scurlock, MD,^{b,c} Lynn Christie, RD,^{b,c} Karen A. Althage, RN,^{b,c}
Pamela H. Steele, CPNP,^a Laurent Pons, PhD,^a Rick M. Helm, PhD,^d Laurie A. Lee, MD,^a
and A. Wesley Burks, MD^a *Duke*

2/4 desensibilizzati
e non tolleranti

Jaci 200

TABLE IV. Outcomes of DBPCFCs with cumulative ingested egg protein amount at reaction

Subject no.	First challenge* (24 mo, during OIT)	Second challenge† 3 mo after OIT)
001	Pass	Pass
002	2 g	NA
003	Pass	24 mg
004	Pass	Pass
005	Pass	2 g
006	14.7 g‡	NA
007	8 g	NA

NA, Not applicable.

*Each challenge consisted of 8 g of egg protein in the double-blind portion, followed by an open feeding 1 hour later of approximately 6.7 g of egg protein.

†Second challenges were performed 3 to 4 months after the first. Only subjects who passed the first challenge were challenged a second time.

‡Subject 006 successfully completed the double-blind portion of the challenge (8 g) but reacted during the open portion of this challenge after ingesting 6.7 g.

Oral peanut immunotherapy in children with peanut anaphylaxis

Katharina Blumchen, MD,^a Helen Ulbricht,^a Ute Staden, MD,^a Kerstin Dobberstein,^a John Beschoner,^a Lucila Camargo Lopes de Oliveira, MD,^a Wayne G. Shreffler, MD, PhD,^b Hugh A. Sampson, MD,^b Bodo Niggemann, MD,^a Ulrich Wahn, MD,^a and Kirsten Beyer, MD^a *Berlin, Germany, and New York, NY*

Jaci 2010

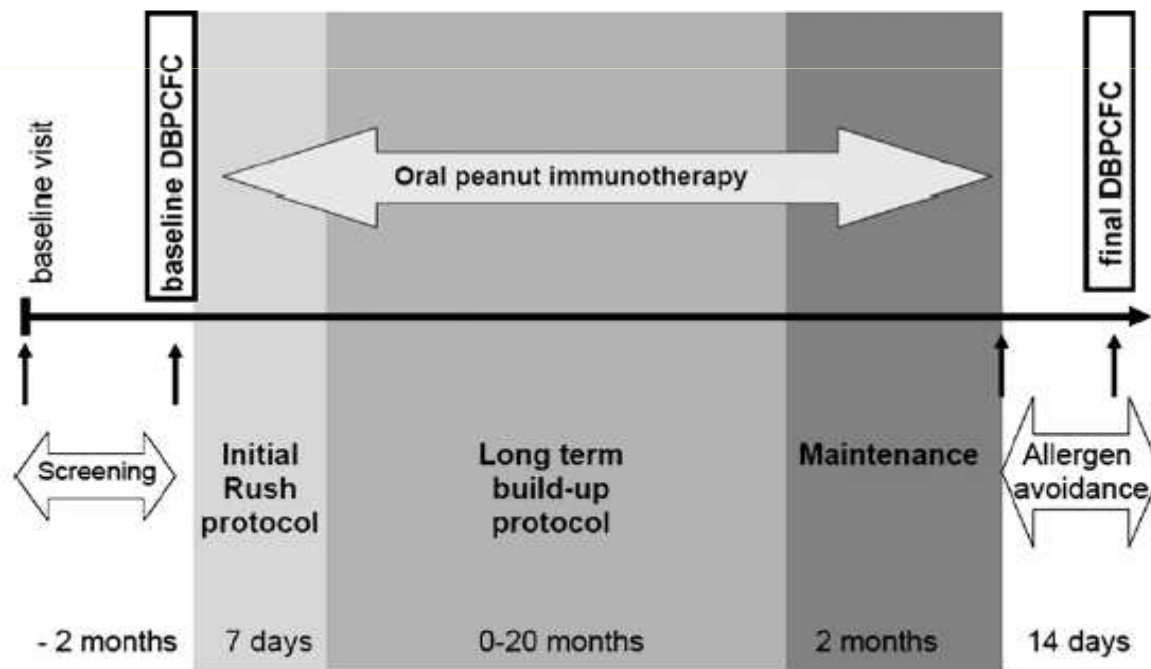


FIG 1. Study protocol. Black arrow, Visit (patient history/physical examination/blood drawing/SPT).

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Jaci 2010

14/14 hanno tollerato una dose di mantenimento 0.5-2 g e 3/14 la hanno incrementata

TABLE I. Comparison of the tolerated dose of peanut before OIT (at baseline DBPCFC), after the initial 7-day rush protocol, after the long-term buildup protocol, and after OIT (at final DBPCFC, after 2 weeks of peanut avoidance)

Patient no.	Maximum tolerated dose before OIT, at baseline DBPCFC (g)	Starting dose of OIT at rush phase (g)	Tolerated dose after the rush phase (g)	Daily tolerated dose after long-term buildup phase (g)*	Maximum tolerated dose after OIT, at final DBPCFC (g)†	Peanut dose during the long-term buildup (d)
4	0.13	0.0032	0.16	1.0	0.5	81
10	0.13	0.0032	0.08	0.5	0.25	334
7	0.5	0.012	0.16	0.5	1.0	158
12	0.25	0.006	0.9	1.0	1.0	47
14	0.06	0.0016	0.03	0.5	1.0	314
16	0.13	0.0032	0.14	0.5	1.0	251
21	1.0	0.024	3.0	2.0	2.0	88
23	0.25	0.006	0.4	1.0	4.0	230
25	0.015	0.0004	0.14	0.5	1.0	154
28	0.5	0.012	1.2	1.0	4.0	134
30	1.0	0.024	1.0	1.0	4.0	0
24	0.13	0.0032	0.05	0.5	1.0	389
22	0.25	0.006	0.4	0.5	0.5	476
18	0.06	0.0016	0.04	0.5	0.25	560
26	0.06	0.0016	0.14	0.2	No provocation	458
8	0.13	0.0032	0.16	Dropout	Dropout	Dropout
9	0.13	0.0032	0.024	Dropout†	Dropout†	Dropout†
13	0.13	0.0032	0.12	Dropout	Dropout	Dropout
15	0.03	0.0008	0.04	Dropout†	Dropout†	Dropout†
19	0.5	0.012	1.0	Dropout	Dropout	Dropout
20	0.13	0.0032	0.18	Dropout†	Dropout†	Dropout†
29	0.25	0.006	0.12	Dropout†	Dropout†	Dropout†

*Daily tolerated dose of peanut at maintenance after OIT using the long-term buildup protocol.

†Maximum tolerated dose of peanut at final DBPCFC (after OIT with the long-term buildup protocol and 2 weeks of peanut avoidance).

‡Dropout because of pulmonary adverse events.



IMMUNOTERAPIA SPECIFICA O ASSUEFAZIONE?

Allergy. 2007 Mar;62(3):335-6.

Food-exercise-induced anaphylaxis in a boy successfully desensitized to cow milk.

Caminiti L, Passalacqua G, Vita D, Ruggeri P, Barberio G, Paino GB.

IMMUNOTERAPIA SPECIFICA O ASSUEFAZIONE?

Allo stato attuale dobbiamo concludere:

**Oral immunotherapy has been shown
to consistently induce desensitization,
but its ability to induce long-term
tolerance appears limited**



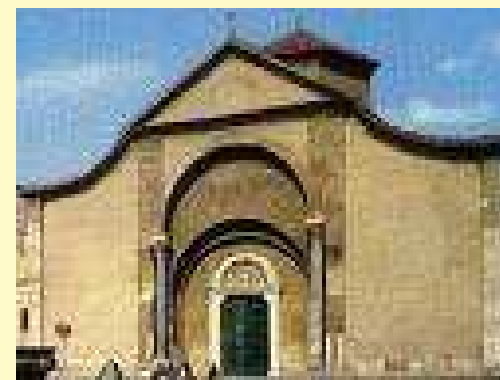
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