

OIT Maintenance Options

Richard L. Wasserman, MD, PhD



OIT Goals

- Cross contamination protection
- Bite proof
- Free eating
- Sustained unresponsiveness



Dallas Food Allergy Center

- **Original Protocol**
 - Dose twice a day during escalation and for 3 months on maintenance
 - After 3 months, dose daily indefinitely
- **Revised Protocol through 2019**
 - Dose daily during escalation
 - Dose daily indefinitely or until sustained unresponsiveness challenge
- **2019 further revisions after FAST meeting**

Dave Fitzhugh – Allergy Partners of Chapel Hill

- First 6 months maintenance daily
- After 6 months of daily maintenance measure sIgE
 - If the sIgE has decreased by $>50\%$ from pre-start, change to 3/7 days a week, typically on a Mon/Wed/Fri schedule
 - If the sIgE has decreased by 25-50% (i.e., 50-75% of prestart value), change to 5/7 days a week, usually Mon - Fri and weekends off.
 - If sIgE decrease is $<25\%$, continue daily dosing and recheck in 6 months.

Palforzia

- Current label
 - Daily dosing indefinitely
- Alternate maintenance regimens after 1 year of daily dosing
 - Daily dosing for 28 weeks
 - Daily dosing for another 56 weeks
 - Every other day for 4 weeks then twice weekly for 24 weeks
 - Daily for 4 weeks the every other day for 24 weeks then every other week for 24 weeks
 - Daily for 4 weeks the every other day for 24 weeks twice a week for 24 weeks

Palforzia Maintenance Frequency Reduction

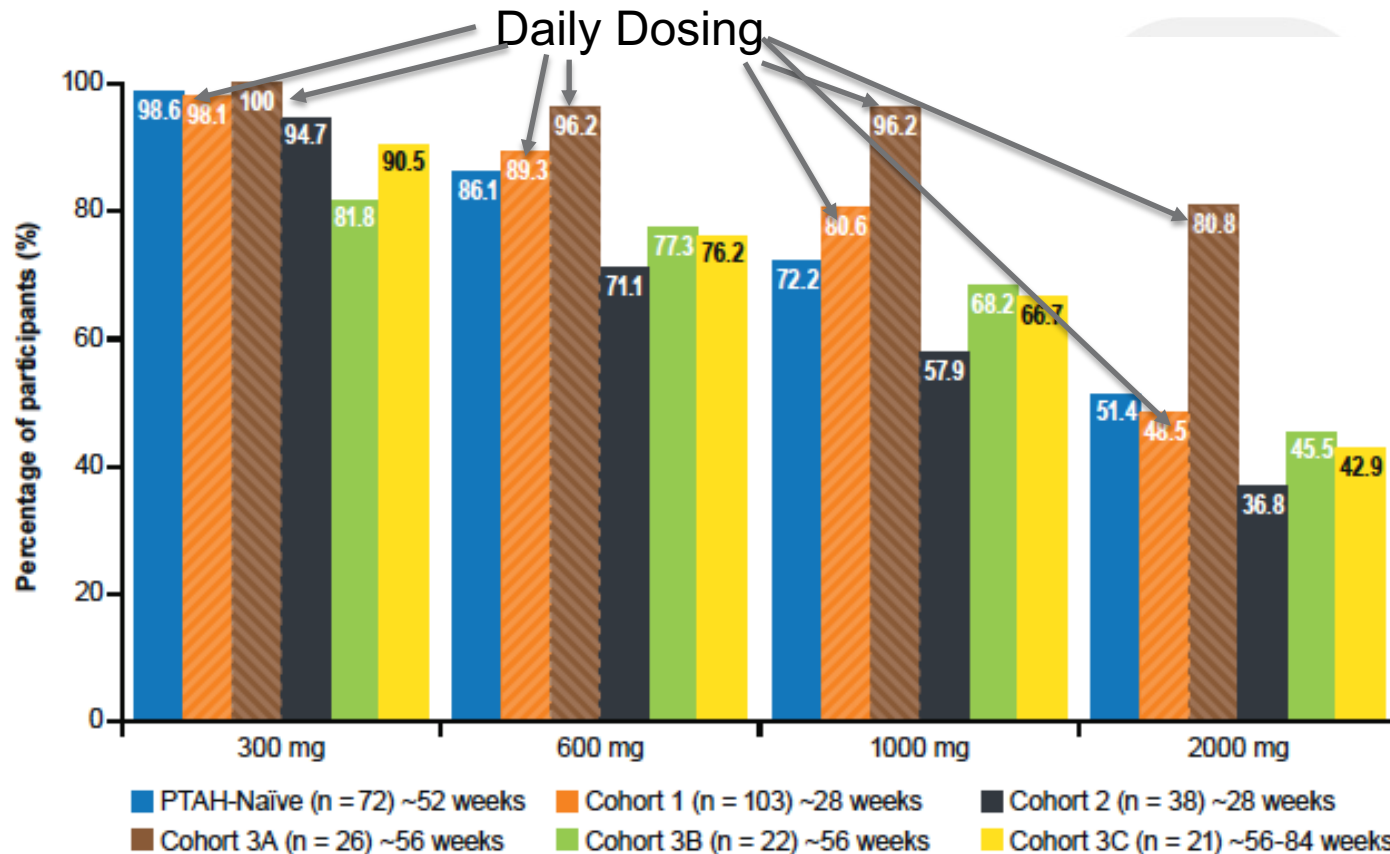


FIGURE 3. Desensitization rates based on the single highest tolerated dose at the exit DBPCFC (completer population; N = 282). Hatch marked bars indicate daily dosing cohorts.

Texas Children's – Carla Davis, et al

- 11/17 patients completed
- One year biweekly escalation
- Maintenance dose – 3,900mg peanut protein
- Maintenance schedule – daily for 2 years
- Maximum tolerated dose of 26,225mg peanut protein decreased significantly after 1 month avoidance
- Most patients had a dramatic fall in sIgE

POISED Study

- Treatment for 104 weeks – 4000mg
- 13 week avoidance or reduced dose (300mg) then challenge with 4000mg
 - 35% of the avoidance group passed
 - 54% of the 300mg group passed
- Interpretations
 - After two years only 35% maintained desensitization for 13 weeks
 - Reducing maintenance after two years reduces desensitization
- Conclusion
 - Higher maintenance is more effective

Sustained Unresponsiveness - DFAC

- Maintenance dosing for at least 3 years
- No significant reactions for at least 2 years
- If pre-OIT sIgE $>10\text{kU/mL}$ and sIgE $<2\text{kU/mL}$
- If pre-OIT sIgE $<10\text{kU/mL}$ and sIgE $<1\text{kU/mL}$
 - Significant reduction in SPT
- Challenge to 3x maintenance dose
- If the challenge is passed, recommend dosing once a week
- ~90% of DFAC patients meeting these criteria pass
- Many eligible patients decline the SU challenge

Is Sustained Unresponsiveness Important?

- SU ≠ never allergic ≠ naturally acquired ≠ tolerance
- What should be the avoidance period prior to SU challenge?
 - At least two weeks
 - One month? Three months? Longer?
- Common foods – Who cares?
- Foods not routinely eaten – How secure can one be?
- Is sustained unresponsiveness an artificial research endpoint with no practical clinical relevance?