The influence of the order of food challenge days on DBPCFC outcomes in children

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Background: The double-blind placebo-controlled food challenge (DBPCFC) is the most reliable diagnostic test in food allergy for several reasons including reduction of patient and operator or observer bias, thus decreasing the chance of false-positive outcomes. In DBPCFC, the order of the challenges with verum or placebo food are randomized. It is currently unknown whether there is a significant difference when initiating the DBPCFC with a placebo challenge or with an active food challenge.

Aims of the Study: The study aims to explore whether there is a significant difference when initiating the DBPCFC with a placebo challenge or with an active challenge DBPCFC in children

Methods: In this study, a total of 1680 patients who underwent DBPCFC were analyzed. Differences between test day reaction frequencies were assessed with the Mcnemar test. Subjective and objective reactions were considered together and separately. Events occurring on placebo days were also assessed separately.

Results: There was no significant difference between the frequency of reactions on test day 1 and day 2 (p-value = 0.160). This was also the case for subjective and objective reactions considered separately (p = 0.640 and 0.193, respectively). When considering only placebo challenges, 58 patients experienced events on the first day and 47 patients on the second day. This difference was significant (p = 0.000).

Conclusion: Patients tend to experience spurious events more often during the first challenge day than the second challenge day, perhaps because of pre-conceived notions about the test and greater anxiety. However, this has no significant impact on the overall diagnostic accuracy of the test, even in patients where the diagnosis is made on the basis of subjective reactions.