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ORAL MEDICATION ADHERENCE IN AN NIH SPONSORED RANDOMIZED TRIAL

Hypothesis / aims of study

Adherence with oral medication is a challenge in the treatment of urgency urinary incontinence (UUI). There is scant information regarding the relationship of oral medication adherence and treatment outcomes for women affected by UUI, especially in studies without pharmaceutical support. In addition, the best methodology for assessment of adherence in research studies is uncertain. The NIH sponsored Anticholingeric and Botulinum Comparison (ABC) trial was a controlled randomized trial of treatment for women with idiopathic UUI and ≥5 UUI episodes per 3-day diary. The three aims of this planned secondary analysis were to describe the overall adherence to oral anticholinergic or placebo study treatment including comparing the 2 methods of adherence employed in ABC (pill counts and MEMSCAP®), identify factors associated with adherence and explore the relationship between adherence and study outcomes.

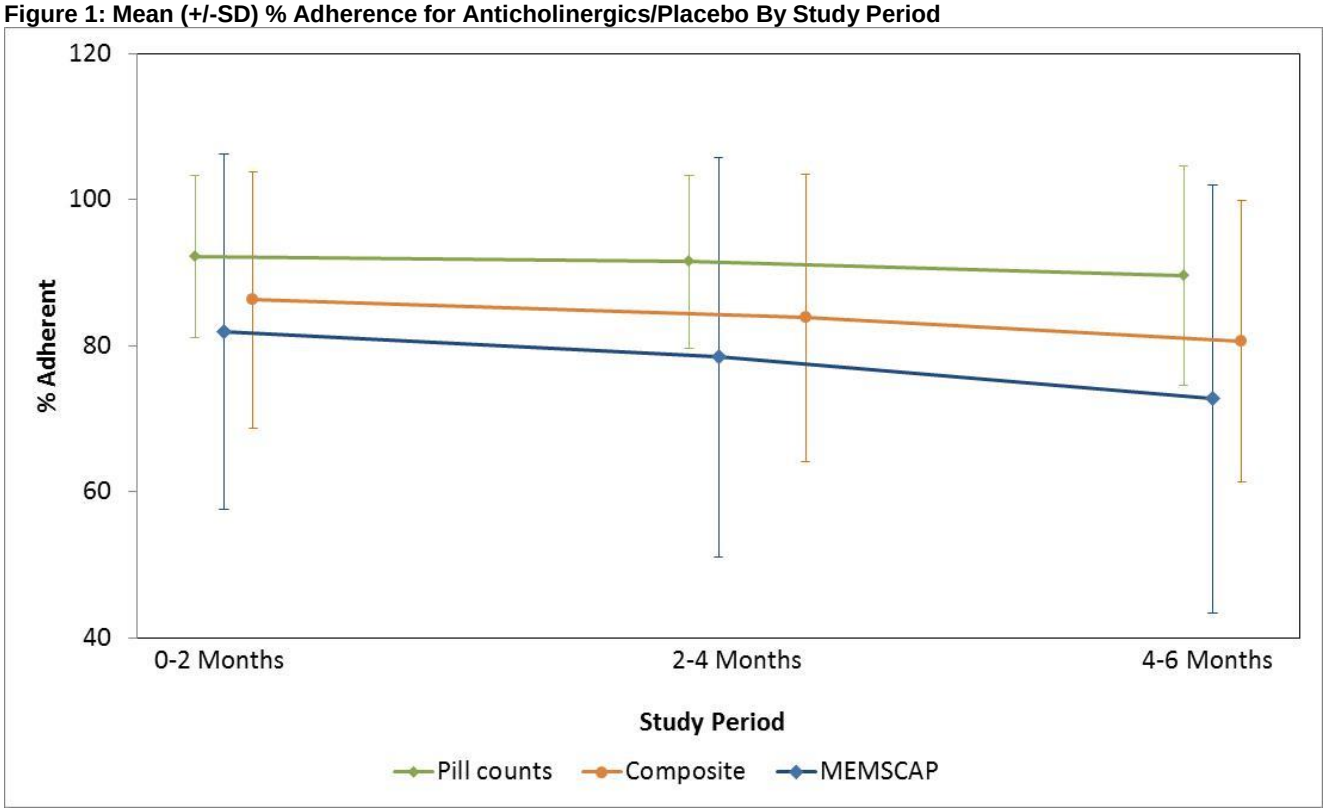
Study design, materials and methods

A total of 247 of 249 randomized ABC participants initiated study treatment [126 oral anticholinergic (AC)/placebo injection and 121 placebo (P) oral medication/active injection]. Of those, 243 provided adherence data [124 AC and 119 P]. Percent of time adherent to AC or P was calculated separately for pill count and MEMSCAP® data for 2 month study intervals during the 6 month treatment phase. An overall composite adherence estimate was created for each subject using the average adherence across all study intervals weighted by the duration of each interval. Primary efficacy analyses were repeated on the subset of treatment adherent subjects (defined as ≥80% adherent within each interval using the composite adherences measure) were used for secondary efficacy analyses.

Results

Treatment groups had similar overall anticholinergic or placebo oral medication dosing duration (p=0.76), without significant differences by drug/dosing regimen or study interval.

Figure 1: Mean (+/-SD) % Adherence for Anticholinergics/Placebo By Study Period



Overall adherence was similar in both treatment groups (AC: 83.3% ±16.8 vs. B: 84.8%±8), without differences by drug/dosing regimen or study period. The average adherence was > 80% in both treatment groups; only 53% over women met the criteria for treatment adherent. Correlation between adherence measured by pill counts versus MEMSCAP® decreased over the treatment period with adherence estimates obtained via pill counts tending to be higher than estimates obtained via MEMSCAP® (r^2= 0.53 0.50 and 0.36 for each 2 month interval). Factors associated with lower adherence included higher baseline incontinence severity (urgency incontinence episode frequency [UUIE]) and higher baseline OAB quality of life impact for the AC group, and current smoking status overall. Similar to the findings of the primary ITT analyses, we found no significant difference between treatment groups in the reduction of the frequency of episodes of urgency incontinence or improvements in quality of life within the subgroup of treatment adherent women.

Interpretation of results

In an NIH sponsored randomized trial, we found that adherence calculations using pill counts and MEMSCAP® were reasonably correlated. In the AC group, lower baseline severity as measured by UUIE was associated with higher adherence, whereas higher baseline OAB QOL scores were associated with decreased adherence. Current smokers were less adherent than those that never or previously smoked. Efficacy analyses in the treatment compliant population confirmed our efficacy findings from the main trial.

Concluding message

Oral medication adherence can be effectively recorded using pill counts or MEMSCAP® bottles, although combined use of both pill counts and MEMSCAP® may be best. Patient factors, including UUIE and OAB scores and smoking habits are associated with adherence. We found no significant difference between treatment groups in the reduction of the frequency of episodes of urgency incontinence or improvements in quality of life within the subgroup of treatment adherent women.

Disclosures

Funding: no **Clinical Trial:** Yes **Registration Number:** 204400 **RCT:** Yes **Subjects:** HUMAN **Ethics Committee:** IRB at all clinical and bioinformatic sites **Helsinki:** Yes **Informed Consent:** Yes