A PHASE II, DOUBLE-BLIND, PLACEBO-CONTROLLED, RANDOMIZED, CROSSOVER PILOT STUDY OF THE SAFETY AND EFFICACY OF MULTIPLE DOSES OF INTRA-ORAL TROPICAMIDE FILMS FOR THE SHORT-TERM RELIEF OF SIALORRHEA SYMPTOMS IN PARKINSON'S DISEASE (PD) PATIENTS

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Introduction: Sialorrhea is a common non-motor symptom of PD. Short-acting antimuscarinic agents have potential to reduce saliva secretion without the side effects of long-acting antimuscarinics.

Aims: Explore the anti-sialorrhea effect of single doses of slow dissolving, muco-adhesive, intra-oral thin film tropicamide.

Methods: 19 non-demented, idiopathic PD patients (in the ON state) with SCS-PD documented sialorrhea randomly received 3 doses (0.3, 1, 3 mg) of tropicamide or placebo by muco-adhesive film, separated by 7 days. A visual-analog scale (VAS) was used at baseline, 15, 30, 45, 90 and 120 min after treatment to measure subjective assessment of saliva. For the last 7 patients, saliva volume was measured at baseline and 75 min by weighing cotton rolls placed into the buccal cavity for 5 minutes. Vital signs were monitored and ECGs were taken. Funding: by mean of a grant from the Michael J. Fox Foundation for Parkinson's Research.

Results: The mean age=67 years; 15 (78%) were male; median disease duration=8 years. VAS score differences (baseline-to-120 min) were -0.55±0.54, -1.08±0.54, -1.53±0.52 and -0.81±0.51 for placebo and 0.3, 1 and 3 mg tropicamide, respectively. While treatment effects were non-significant (F=0.6 p=0.6, ANOVA), the 1 mg tropicamide resulted in a significant decrease from 0 to 120 min in the VAS score. Saliva volume was reduced by 11-26% after tropicamide vs 5% with placebo (p=0.5, Friedman). No adverse events were detected.

Conclusion: This pilot study showed that intra-orally delivered tropicamide was safe and warrants further exploration as a possible treatment for sialorrhea in PD.