Burden of Axillary Hyperhidrosis Using a Patient-Reported Outcome Measure to Assess Impact on Activities and Bothersomeness

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INTRODUCTION

Hyperhidrosis, which is estimated to affect 4.8% of the US population or approximately 15.3 million people, is a chronic condition in which the reduction of excessive or abnormal perspiration is a challenging and unmet medical need. Specifically, axillary hyperhidrosis affects an estimated 1.4% of the US population or approximately 4.3 million people. The axillae of asymptomatic patients as a control group have been assessed in several studies. In 3 axial chambers, it was estimated that only 8.3% of the control population had axillary sweating exceeding 10 mg/min.3

METHODS

ATMOS-1 and ATMOS-2 Study Design

• ATMOS-1 (N=304) and ATMOS-2 (N=353) trials were parallel group, 4-week, double-blind, placebo-controlled trials in which patients with primary axillary hyperhidrosis (mean ± SD age 32.2 ± 12.4 years) were treated with placebo or a 10mg / ml solution of 99.7% aluminum chloride hexahydrate (AXD) solution, which was applied to the axillae by patients once daily for 7 days to assess the efficacy of treatment in reducing sweating and associated symptoms.

• Patients with primary axillary hyperhidrosis who met the inclusion criteria (aged >16 years and with axillary sweating severity grade 2 or higher) were randomized 2:1 to receive AXD or placebo in a double-blind manner.

• Grade 2 was defined as sweating at its worst, defined as scores of 7 or 8 on ASDD Item 2 and scores of 3 or 4 on ASDD Items 3 and 4, respectively.

• Grade 3 was defined as sweating at its worst, defined as scores of 9 or 10 on ASDD Item 2 and scores of 3 or 4 on ASDD Items 3 and 4, respectively.

• Baseline axillary sweating severity grade 3 or 4 was an inclusion criteria for the study; 1 subject entered ATMOS-2 with HDSS=2, which was a protocol violation.

• In each trial, more than half of all patients reported weekly average scores ≥7 before randomization, indicating considerable impairment in work productivity, social activities, emotional well-being, and personal life activities associated with considerable impairment in work productivity, social activities, emotional well-being, and personal life activities. In ATMOS-2, 80% of patients (95% CI 78.7, 81.3) reported weekly average scores ≥7 before randomization.

RESULTS

• Table 2: Baseline and Disease Characteristics (ITT Populations)

Table 3. Proportion of Patients Reporting Moderate-to-Severe Impact of Axillary Sweating at Baseline (ASDD/ASDD-C Item 5 Scores)

CONCLUSIONS

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REFERENCES

1. Fehnel, S. et al. Pariser et al. Poster presented at: 13th Annual Winter Clinical Dermatology Conference, Poster presented at: 13th Annual Winter Clinical Dermatology Conference, 2018. 2. Table 1. Baseline Disease Characteristics (ITT Populations). 3. Figure 2. Baseline axillary sweating severity grade 3 or 4 was an inclusion criteria for the study; 1 subject entered ATMOS-2 with HDSS=2, which was a protocol violation. 4. In each trial, more than half of all patients reported weekly average scores ≥7 before randomization, indicating considerable impairment in work productivity, social activities, emotional well-being, and personal life activities. In ATMOS-2, 80% of patients (95% CI 78.7, 81.3) reported weekly average scores ≥7 before randomization.

Figure 1. Diary: A patient-reported outcome measure to assess sweating severity.

Figure 2. Proportion of Patients Reporting Moderate-to-Severe Axillary Sweating at Baseline (ASDD/ASDD-C Item 5 Scores)

Figure 3. Proportion of Patients Reporting Moderate-to-Severe Impact of Axillary Sweating at Baseline (ASDD Item 5 Scores)

Figure 4. Proportion of Patients Reporting Moderate-to-Severe Bother of Axillary Sweating at Baseline (ASDD Item 5 Scores)

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Table 2. Axillary Hyperhidrosis Patient Measures (HPM)

Table 3. Proportion of Patients Reporting Moderate-to-Severe Impact of Axillary Sweating at Baseline (ASDD/ASDD-C Item 5 Scores)

Table 4. Proportion of Patients Reporting Moderate-to-Severe Bother of Axillary Sweating at Baseline (ASDD Item 5 Scores)

In conclusion, our study supports the use of a validated patient-reported outcome measure (Diary: A patient-reported outcome measure to assess sweating severity) to assess the impact of axillary hyperhidrosis on patients' daily lives. The results indicate that axillary hyperhidrosis significantly impacts daily activities and emotional well-being, highlighting the importance of addressing this unmet medical need with effective treatment options.