

# Axillary Hyperhidrosis HDSM-Ax-7 Patient-Reported Outcomes for Sofpironium Topical Gel, 12.45%: A Multicenter, Randomized, Controlled Double-Blind Study (NCT03836287)

**Authors:**  
Linda Stein Gold, MD<sup>a</sup>  
Michael H Gold, MD<sup>b</sup>  
Patricia S Walker MD, PhD<sup>c</sup>

<sup>a</sup>Henry Ford Health System, Detroit, MI,  
<sup>b</sup>Tennessee Clinical Research Center,  
Nashville, TN  
<sup>c</sup>Botanix Pharmaceuticals, Wayne, PA

## SYNOPSIS

**Introduction:** Primary axillary hyperhidrosis can impair quality of life. HDSM-Ax-7 is a validated patient-reported outcome measure that captures the concepts of most relevance to patients with primary axillary hyperhidrosis with respect to their condition. Each of the 7 questions is rated on a 5-point scale, with 2 questions focused on frequency of underarm sweating (0 = none of the time to 4 = all of the time), and 5 questions focused on severity of underarm sweating (0 = I did not experience this to 4 = very severe). A 1-point change was determined to be clinically meaningful.<sup>1</sup>

**Methods:** In this double-blind, randomized, controlled pivotal phase 3 study, subjects were randomized 1:1 to daily application of sofipironium topical gel, 12.45%, (SOFDRA) (n = 173) or vehicle gel (n = 177) to the axillae at bedtime for 6 weeks.

**Results:** Slightly more than half of subjects were female (56.6%), with a median age of 32 years (range, 11–71 years) and a median 13-year history of primary axillary hyperhidrosis. The treatment group was significantly better than control at achieving both a  $\geq 1$ -point (p = 0.0053) and  $\geq 2$ -point (p = 0.0004) HDSM-Ax-7 improvement from baseline at end of treatment. Analysis of  $\geq 2$ -point improvement for each of the individual HDSM-Ax questions showed that the treatment group was significantly better than control for 6 of the 7 questions: frequency of damp or wet clothing caused by underarm sweating (p = 0.0063); frequency of underarm sweating for no apparent reason (p = 0.0146); severity of underarm sweating when you felt nervous, stressed, or anxious (p = 0.0006); severity of damp or wet clothing caused by underarm sweating (p = 0.0116); severity of underarm sweating after little or no physical exercise (p = 0.0079); severity of underarm wetness (p = 0.0160); and severity of underarm sweating for no apparent reason (p = 0.0800).

**Conclusion:** The validated HDSM-Ax-7 questionnaire captures the bothersome symptoms of axillary hyperhidrosis from the patient perspective, and daily topical application of sofipironium topical gel, 12.45%, led to significant improvement on the overall HDSM-Ax-7 as well as 6 of its 7 questions.

## OBJECTIVE

To determine the impact on quality of life of daily topical application of sofipironium topical gel, 12.45%, as assessed on the HDSM-Ax-7 patient-reported outcome questionnaire.

## METHODS

- Double-blind, randomized, controlled pivotal phase 3 study
- Subjects randomized 1:1 to daily application of sofipironium topical gel, 12.45%, (n = 173) or vehicle gel (n = 177) to the axillae at bedtime for 6 weeks

### Hyperhidrosis Disease Severity Measure-Axillary (HDSM-Ax-7)

- Validated patient-reported outcome measure of axillary hyperhidrosis severity
- Captures concepts of most relevance to patients with respect to their condition
- 7 questions, 5-point scale:

**2 questions on frequency of underarm sweating**  
0 = none of the time  
1 = a little of the time  
2 = some of the time  
3 = most of the time  
4 = all of the time

**5 questions on severity of underarm sweating**  
0 = I did not experience this  
1 = mild  
2 = moderate  
3 = severe  
4 = very severe

- 1-point change is clinically meaningful

## RESULTS

Demographics and baseline characteristics are summarized in **Table 1**.

**Table 1. Demographics and Baseline Characteristics**

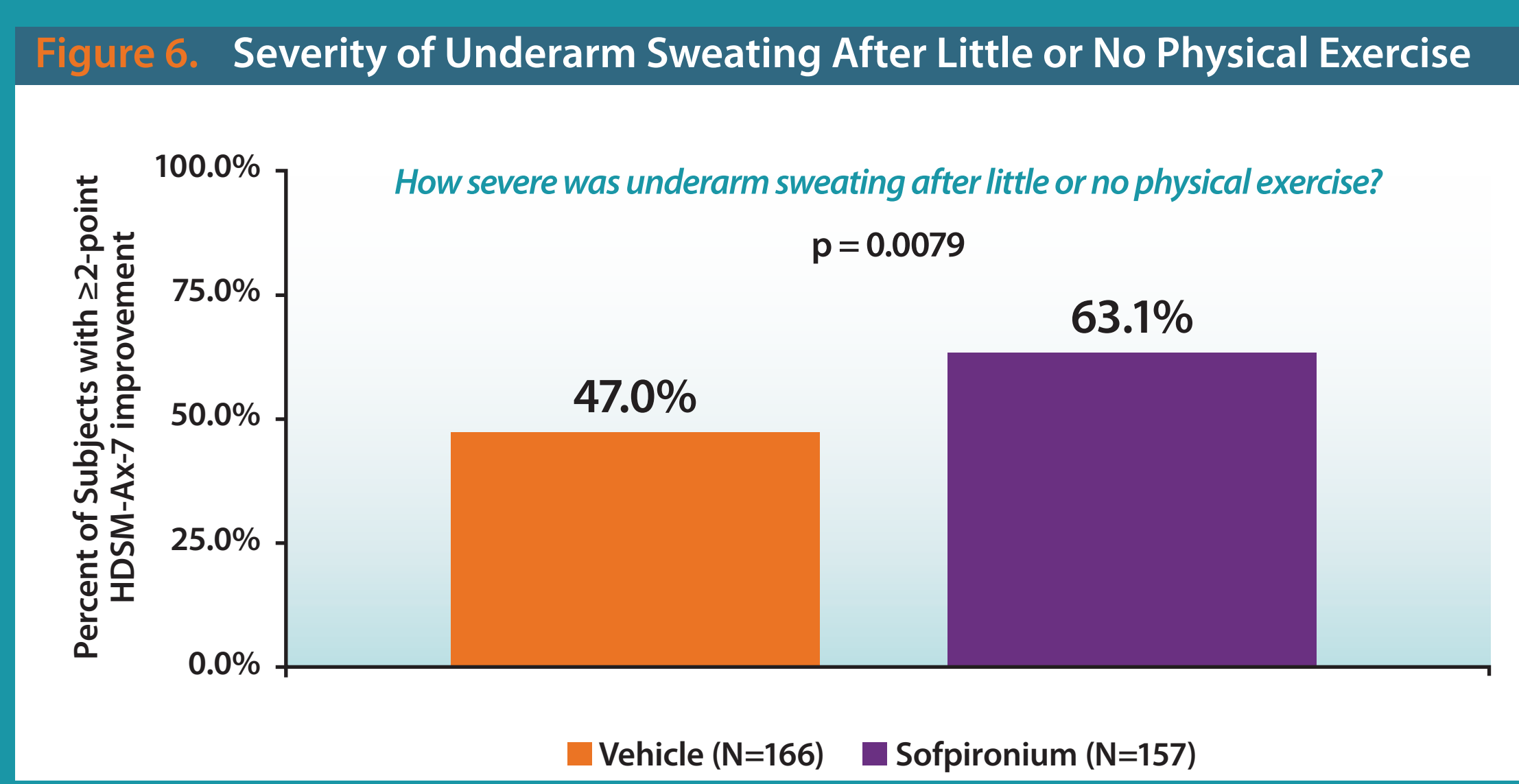
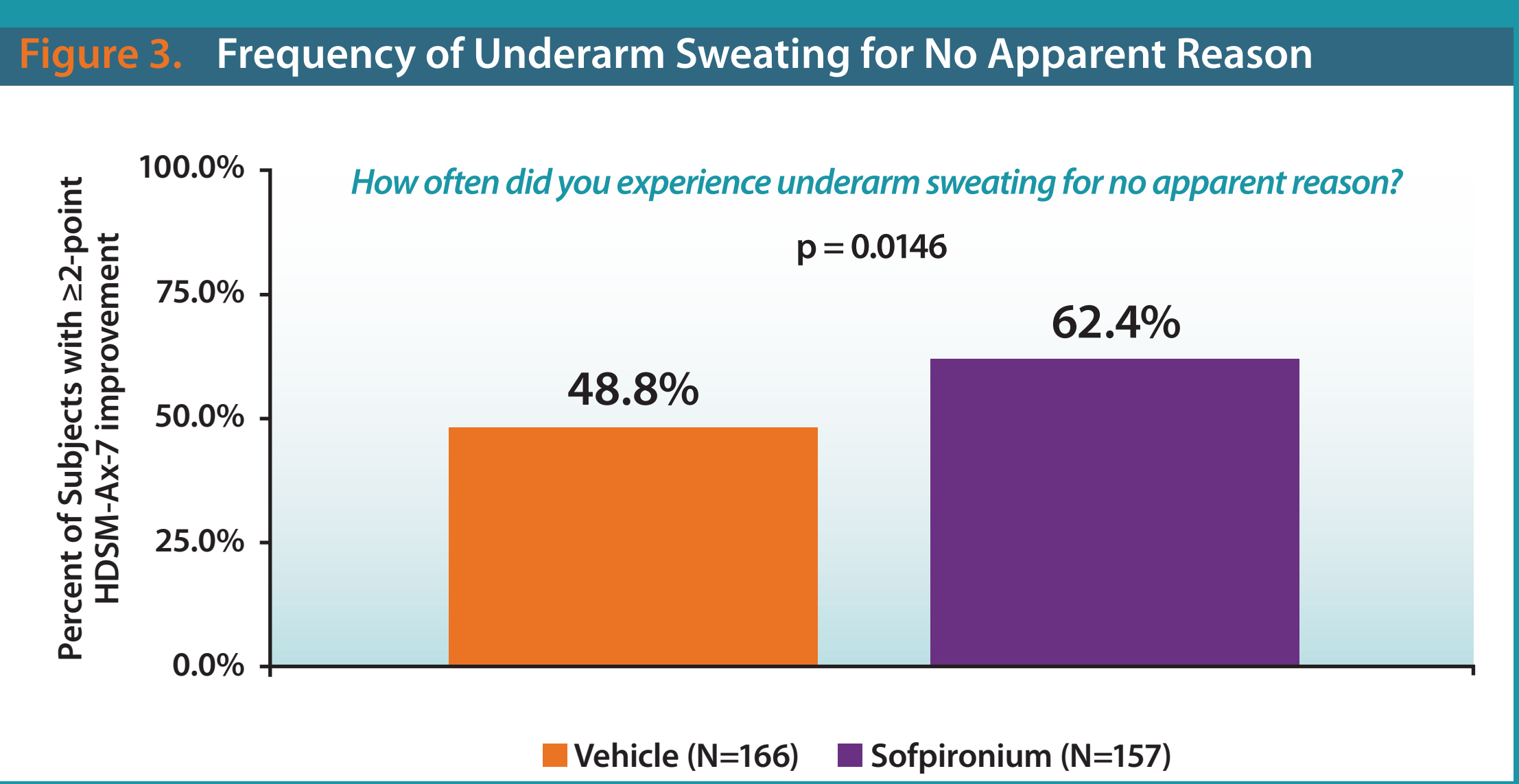
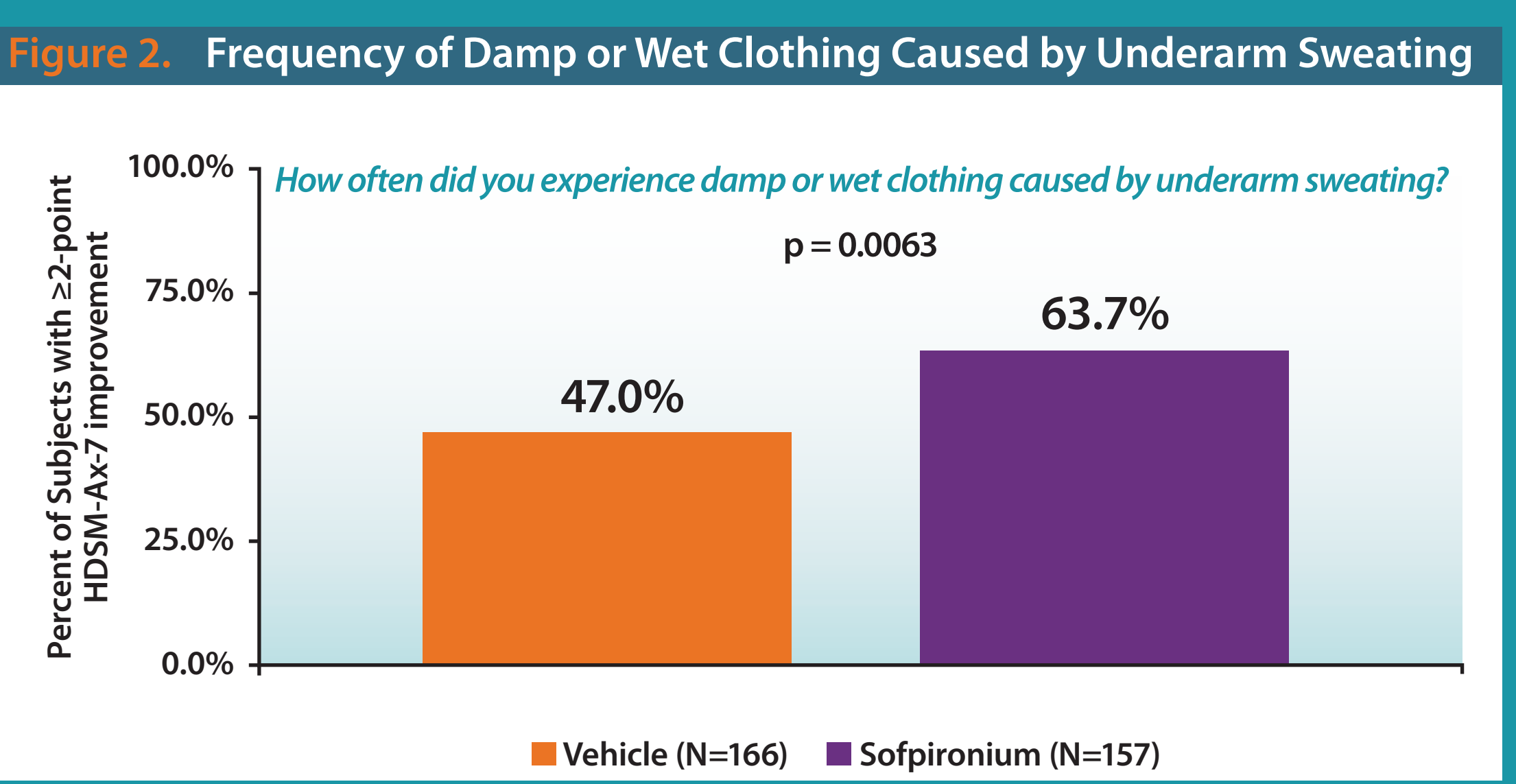
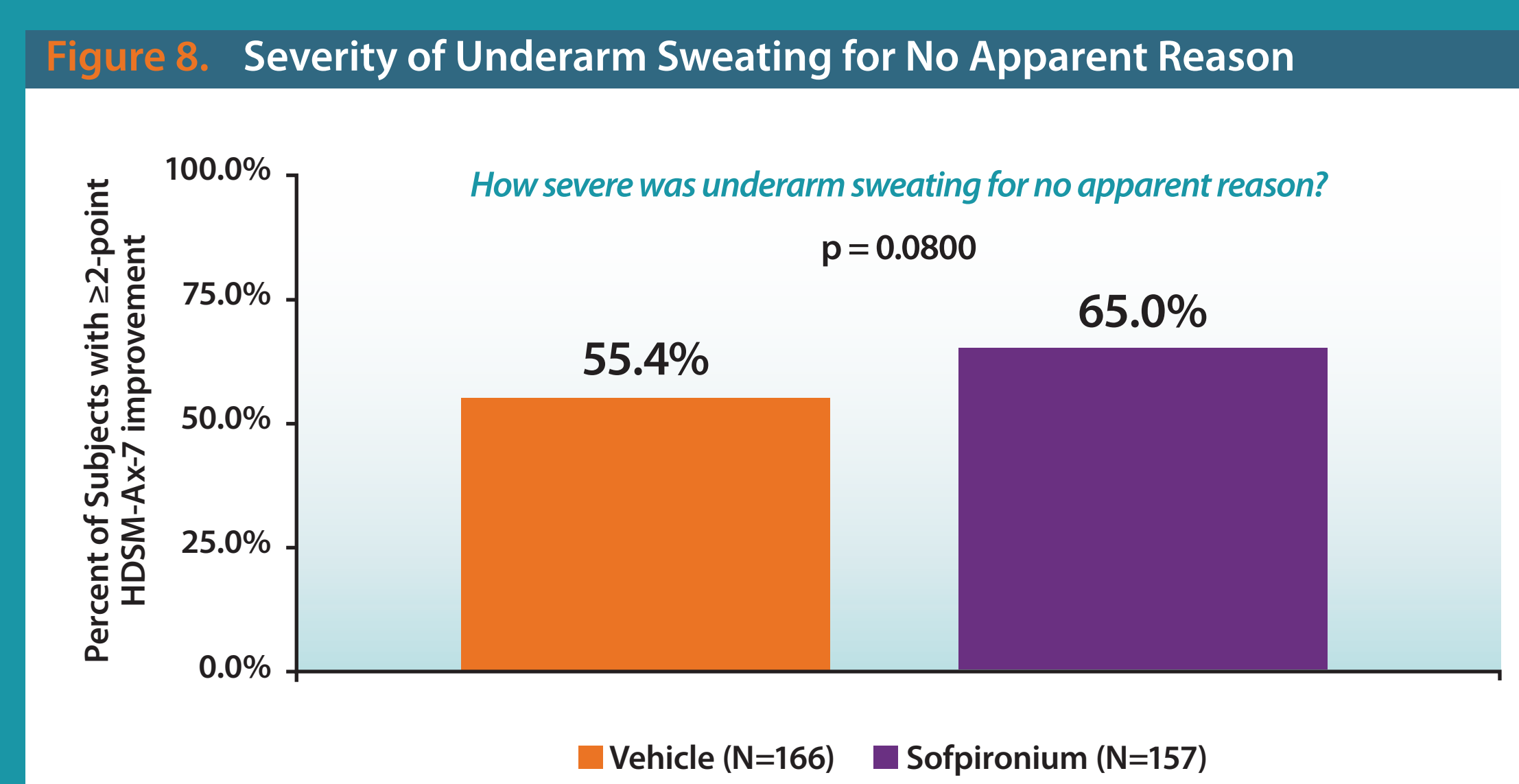
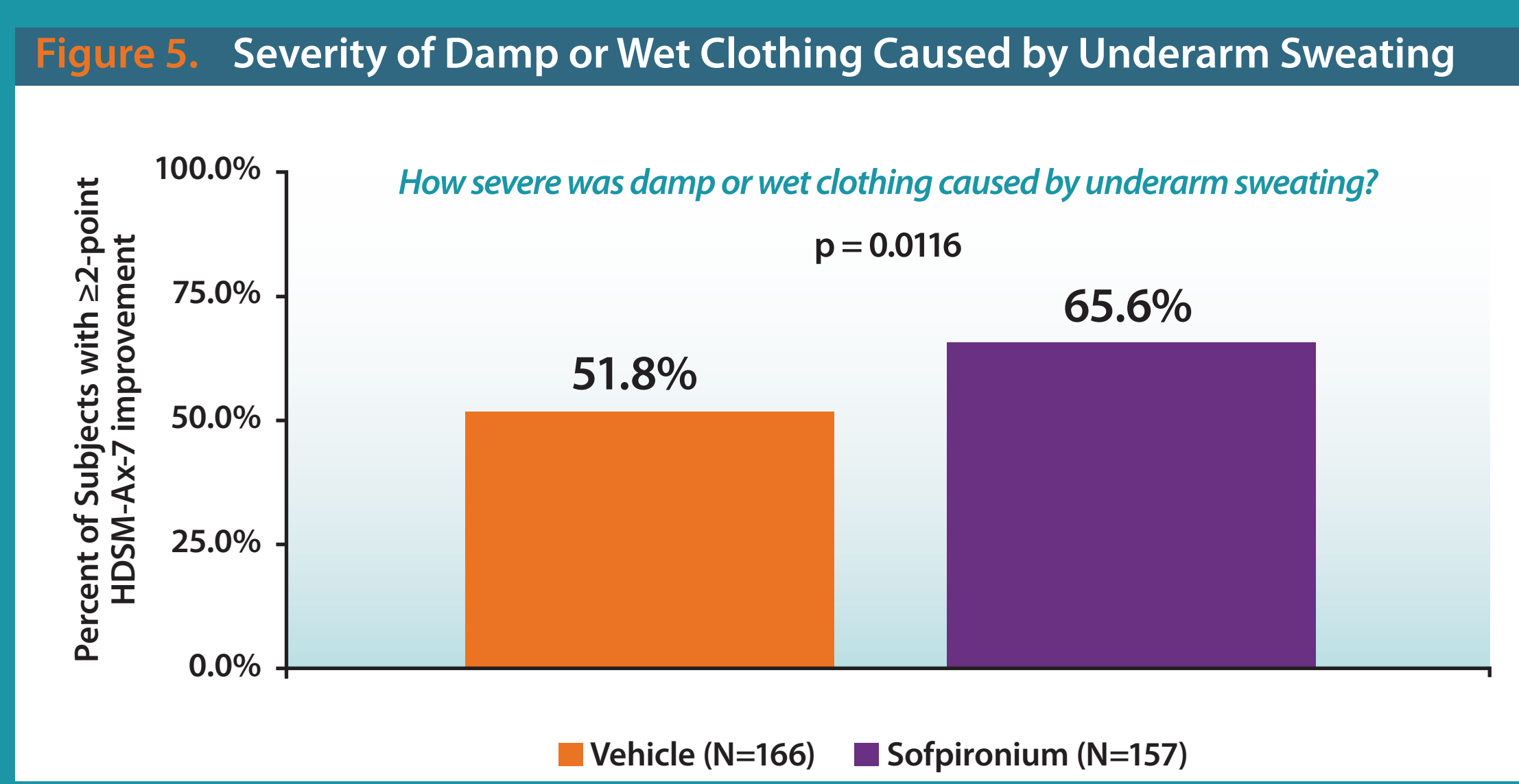
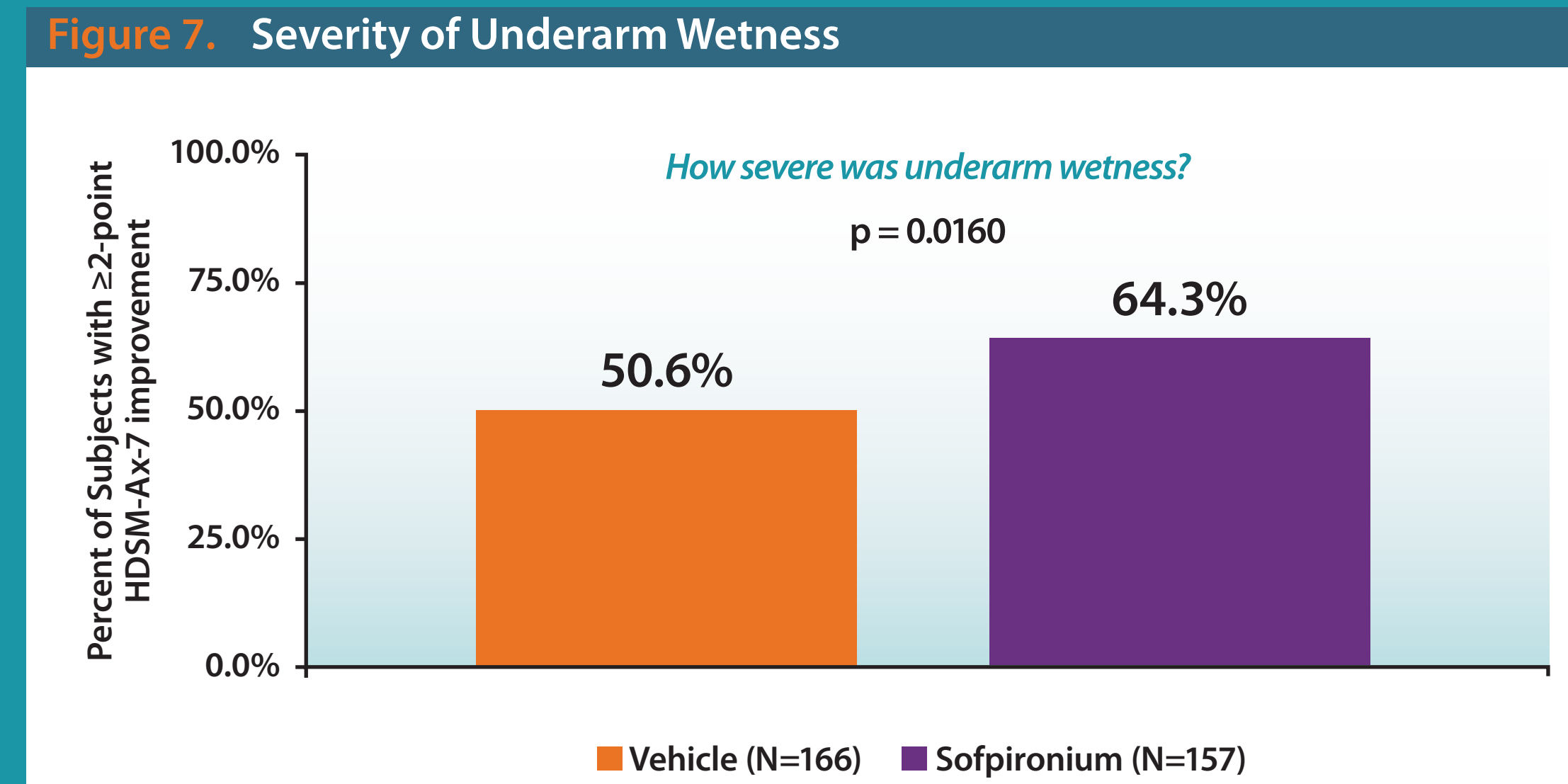
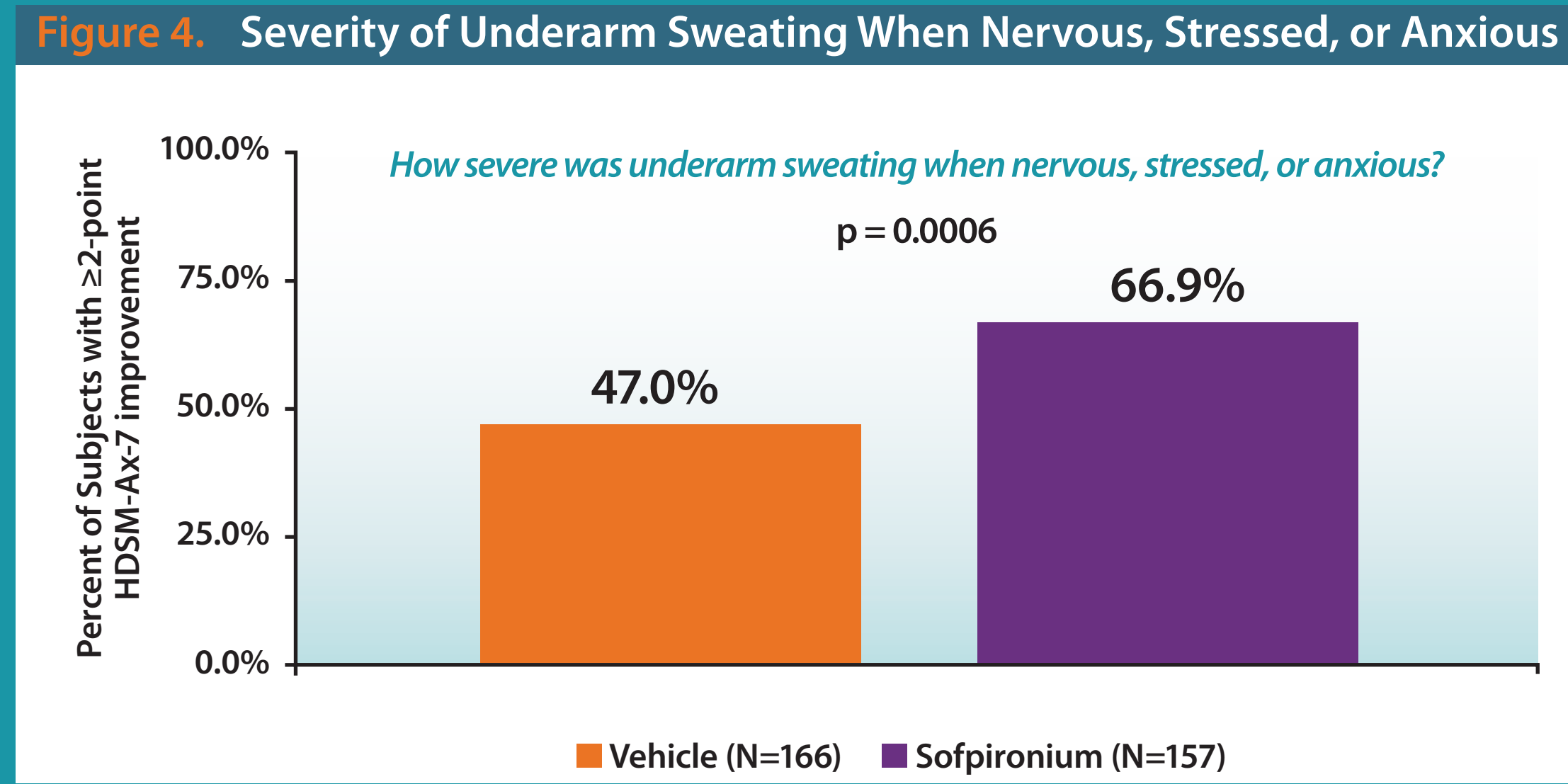
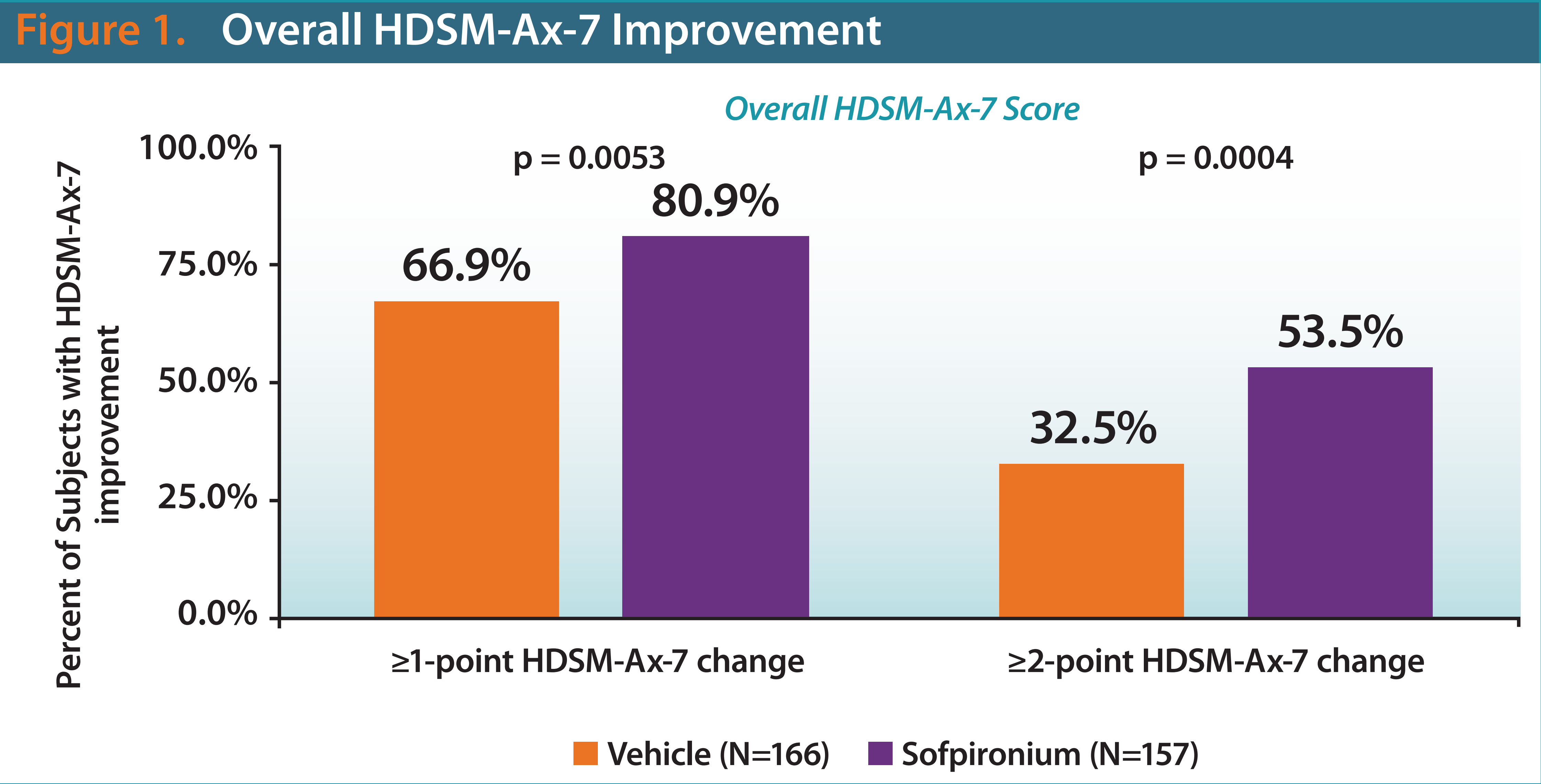
	Vehicle (N = 177) n (%)	Sofpironium (N = 173) n (%)
Female	99 (55.9)	98 (56.6)
Age, median (range)	32.0 (14 to 71)	32.0 (11 to 64)
Age $\geq 17$ years	168 (94.9)	164 (94.8)
Race		
White	130 (73.4)	140 (80.9)
Black or African American	43 (24.3)	31 (17.9)
Asian	3 (1.7)	1 (0.6)
Other/Unknown	1 (0.6)	1 (0.6)
Ethnicity: Hispanic or Latino	60 (33.9)	61 (35.3)
Time since start of hyperhidrosis symptoms, median months (range)	157.2 (19.9 to 588.6)	156.3 (6.5 to 564.7)

## RESULTS, Cont.

Treatment group was significantly better than control at achieving HDSM-Ax-7 improvement from baseline at end of treatment:

- Overall score  $\geq 1$ -point (p = 0.0053) and  $\geq 2$ -point (p = 0.0004) change (**Figure 1**)
- Frequency of damp or wet clothing caused by underarm sweating (p = 0.0063) (**Figure 2**)
- Frequency of underarm sweating for no apparent reason (p = 0.0146) (**Figure 3**)
- Severity of underarm sweating when nervous, stressed, or anxious (p = 0.0006) (**Figure 4**)
- Severity of damp or wet clothing caused by underarm sweating (p = 0.0116) (**Figure 5**)
- Severity of underarm sweating after little or no physical exercise (p = 0.0079) (**Figure 6**)
- Severity of underarm wetness (p = 0.0160) (**Figure 7**)

Severity of underarm sweating for no apparent reason was not significant between the groups (p = 0.0800) (**Figure 8**)



## DISCLOSURES

Funding provided by Botanix Pharmaceuticals for poster development, and medical writing services provided by Diane Murphy, MBA. Dr. Walker is the Chief Medical Advisor at Botanix Pharmaceuticals. Dr. Stein Gold is an advisor and speaker for Botanix Pharmaceuticals. Dr. Gold was an investigator for this study, which was conducted by Brickell Biotech, Inc.

## CONCLUSION

The validated HDSM-Ax-7 questionnaire captures the bothersome symptoms of axillary hyperhidrosis from the patient perspective, and daily topical application of Sofpironium topical gel, 12.45%, led to significant improvement on the overall HDSM-Ax-7 as well as 6 of its 7 questions.