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A comparison of females and males for antiperspirant efficacy and sweat output

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INTRODUCTION

An antiperspirant product is an OTC (over-the-counter) drug and is regulated by the Food and Drug Administration (FDA). In order to be labeled an antiperspirant, a product must be formulated within the Category I guidelines of the *Antiperspirant Drug Products for Over-the-Counter Human Use* monograph (1) and must be tested according to these guidelines as well. The product must reduce axillary perspiration to a level that is statistically significantly greater than 20% reduction.

The primary aim of this research was to compare the antiperspirant efficacy achieved between male and female test subjects using the same test product within each study. The secondary objective was to compare the baseline sweat output of males and females who had been exposed to the same heat stimulus.

MATERIALS AND METHODS

Eight antiperspirant efficacy studies were included in this review. The FDA monograph procedure (1,2) was utilized in each study.

There were slight modifications in the specific designs of the individual studies; however, all study designs met monograph requirements. The test procedures for all studies are outlined as follows:

CONDITIONING PERIOD

Each subject was provided with a deodorant product to use for underarm odor protection, as needed, for a period of at least 17 days prior to enrollment. Use of axillary antiperspirant products was discontinued during this period.

BASELINE SWEAT COLLECTION

Gravimetric baseline sweat values were determined and used to compare the differences between the highest and lowest average rate of sweat output among the test subjects. The FDA monograph (2) requires that within a selected panel of test subjects, the difference between the subject with the highest rate of sweat and the subject with the lowest rate of sweat must exceed 600 mg of sweat/20 min/axilla during the baseline sweat collections. In addition, a subject must produce ≥ 100 mg of sweat/20 min/axilla during the baseline sweat.

SUPERVISED AXILLARY WASHES

A mild bar soap was used for all supervised axillary washes. Supervised axillary washes were conducted prior to each test article application.

TEST ARTICLE APPLICATION

Assignment of test articles and placebo was randomized to the right and left axilla. Subjects in each study received approximately four daily treatment applications (two studies required only two applications). The test articles were applied at a rate appropriate for the product form and were applied to uniformly cover approximately a 4×6-inch area centered in the axillary vault. No other axillary products were permitted to be used during the active treatment period.

SWEAT COLLECTION INTERVALS

Sweat collections were conducted at baseline and approximately one and 24 hr following application No.4 for six of the studies and approximately one hour after application No. 2 for two of the studies.

SWEAT STIMULATION

Sweating was induced by having the subject sit erect in a room maintained at 100°F ± 2°F, with the relative humidity in the range of 30% to 40%.

SWEAT COLLECTIONS

During the initial 40 minutes of the sweat stimulation period, the subject held unweighed pads of Webril (non-woven cotton padding fabric) in their axillae. This preliminary warm-up period was followed by two successive 20-min collection periods, during which the subjects held weighed Webril pads in the axillae. These pads were weighed in tightly capped polystyrene vials before and after use. The vials were labeled with the subject's number and axilla and collection designation. The first collection made with weighed pads was designated Collection B and the second Collection C.

STATISTICAL ANALYSIS

The source data were the milligrams of sweat output from the treated and placebo axillae at baseline and post-treatment. For the analysis comparing the efficacy, percent reductions were calculated for each test subject. The adjusted treated-to-control ratios for this analysis were calculated as follows (3,4):

$$\text{Percent reduction} = 100 \times \{1 - (PC \times T) / (PT \times C)\}$$

where PC is the pretreatment measure of moisture for the control axilla (placebo), PT is the pretreatment measure for the test axilla, T is the treated measure for the test axilla, and C is the corresponding quantity for the control axilla (placebo). For the analysis comparing the sweat output, the baseline average of the B and C collection milligram data across the right and left axillae were used.

The study results were analyzed using Student's *t*-test for independent data. The hypotheses for this test are shown below.

H_o: The means (output/percent reductions) of the males and females were identical.
H_a: The means differed.

Hypothesis testing was conducted at the 0.05 level of significance and no adjustments were made for the number of tests performed.

RESULTS

Table I indicates the number of subjects that participated in each study as well as the basic study design. The results of the statistical analyses indicate:

- There was no statistically significant difference between the mean percent reductions of the male and female test subjects in twelve of the fourteen time points analyzed from the eight studies. In the study where a statistically significant difference was indicated ($p < 0.5$), females had higher efficacy, and in the one study where a directional difference was seen ($p < 0.10$), males had higher efficacy. See Table I and Figure 1.

Table I
Percent Reductions for Females and Males

Study	Post-treatment sweat collection time point	Mean percent reduction: females	Mean percent reduction: males	*t*-test *p*-value
1	1 Hr after application 2	27%	23%	>0.5000
2	1 Hr after application 2	33%	43%	0.2924
3	1 Hr after application 4	40%	29%	0.0451*
3	24 Hr after application 4	36%	37%	>0.5000
4	1 Hr after application 4	42%	40%	>0.5000
4	24 Hr after application 4	35%	28%	0.2799
5	1 Hr after application 4	35%	40%	0.0844**
5	24 Hr after application 4	27%	28%	>0.5000
6	1 Hr after application 4	34%	38%	>0.5000
6	24 Hr after application 4	29%	30%	>0.5000
7	1 Hr after application 4	23%	28%	0.4150
7	24 Hr after application 4	20%	20%	>0.5000
8	1 Hr after application 4	43%	31%	0.2385
8	24 Hr after application 4	42%	32%	0.1064

*Significant difference (females higher).
**Directional difference (males higher).

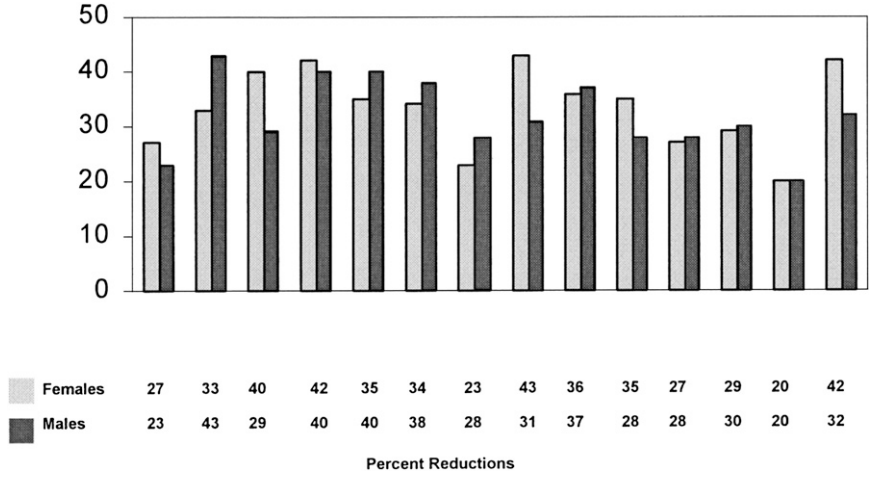

Figure 1. Percent reduction (females–males).

- The overall mean sweat output from the males was significantly higher than that for females ($p = 0.0001$). This result was also seen individually in five of the eight studies reviewed for sweat output ($p < 0.05$). See Table II and Figure 2.

DISCUSSION

The FDA has mandated that when testing antiperspirant products that will be marketed to males, manufacturers should test the product utilizing male panels, and that when testing products marketed to females, manufacturers should use female panels (5). The data available in the literature does not indicate a physiological difference between male and female axillae. Our data indicate that in some female/male panels the male test subjects sweat more than the females; however, we have shown that efficacy is not related to sweat output (6). Historically, in the testing industry, female test panels have been easier to recruit and maintain than male test panels. Our results, while not conclusive, do not indicate a difference between the efficacy achieved from male and female test subjects. We

Table II
Baseline Sweat Output for Females and Males.

	Females		Males		
Study	n	Mean baseline sweat output	n	Mean baseline sweat output	*t*-test *p*-value
1	32	405	11	657	0.0035*
2	24	476	18	478	>0.5000
3	20	384	20	453	0.1864
4	21	451	20	605	0.0957
5	30	388	30	633	0.0006*
6	20	393	19	539	0.0411*
7	23	431	27	522	0.0442*
8	22	421	20	585	0.0217*
Overall	192	407	165	559	0.0001*

*Significant difference (males higher in sweat output).

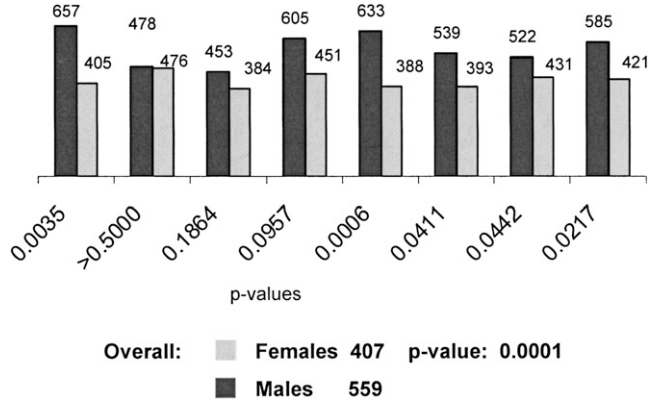

Figure 2. Sweat output (milligram output, females–males).

therefore believe it appropriate that female test panels can be used in the development of all antiperspirant products. However, when final claims are being defined, testing should be done as directed by the regulatory agency.

CONCLUSIONS

Data from eight antiperspirant efficacy studies indicated no significant difference between the efficacy achieved from males versus females. This paper indicates that gender does not have a significant impact on antiperspirant efficacy.

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