# Efficacy of the Drionic unit in the treatment of hyperhidrosis

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A portable iontophoretic device (the Drionic unit) has recently been introduced for the treatment of hyperhidrosis. Twenty-two patients with hyperhidrosis were treated at twenty-seven sites (axillae, palms, soles) with this unit. Sweat output was measured by use of Persprint paper and the data were quantified by an image analysis computer. The data clearly demonstrate the efficacy of the Drionic unit at all treatment locations in the great majority of subjects. One month posttreatment follow-up showed a statistically significant continued sweat inhibition at the palmar sites. Side effects were common, but none was severe enough to necessitate discontinuation of treatment. Based on the results of this study, we conclude that the Drionic unit appears to have a definite place in the treatment of hyperhidrosis. (J AM ACAD DERMATOL 1987;16:828-32.)

Hyperhidrosis of the palms, soles, and axillae is a common problem. Many treatments have been proposed, ranging from topical agents to surgical sympathectomy, but these methods have often produced variable results either because of lack of efficacy or serious side effects.[1,2]

The process of iontophoresis has long been known to inhibit sweat production.[3] Iontophoresis passes a direct current through the skin, which has been postulated to lead to hyperkeratinization and subsequent obstruction of the eccrine sweat duct unit.[4]

However, some investigators have disputed this and state that the actual mechanism of inhibition is unknown.[5,6] Whatever the mechanism, several studies have demonstrated the efficacy of iontophoresis in the treatment of hyperhidrosis.[7-9] These studies were usually conducted in a laboratory setting with large nonportable units. In 1984, a compact iontophoretic device designed for home use (the Drionic unit, General Medical Co., Los Angeles, CA) was introduced. Recent studies with this unit have produced variable results, possibly because of the small number of patients and the subjective assessment of sweat inhibition.[6,10] In the present study, the Drionic unit was used to treat the palms, soles, and axillae in twenty-two patients with hyperhidrosis.

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## MATERIALS AND METHOD

Twenty-two patients (9 women and 13 men) with a history of excessive sweating of the palms, soles, and/or axillae were entered into the study. Enrollment was limited to individuals demonstrating marked sweat output rates as measured by Persprint paper. The method utilizes paper impregnated with starch and an oxidizing agent. A colorless iodide solution is applied to the test site, which is then placed in contact with the paper. The starch-iodine reaction produces a permanent coloration, the intensity of which can be quantified by computerized image analysis.

**Treatment.** Twenty-seven treatment sites (10 palms, 9 soles, and 8 axillae) were selected. Hyperhidrotic

**Table I.** Pretreatment measurements (square inches)

| Treatment site | Soles | Palms | Axilla | Total group |
|---|---|---|---|---|
| Mean control | 9.32 | 9.67 | 5.23 | 8.70 |
| Mean treated | 9.01 | 9.71 | 5.90 | 8.78 |
| Mean difference | 0.31 | 0.04 | 0.67 | 0.08 |
| SD | 1.86 | 1.71 | 2.08 | 1.99 |
| Sample size | 8 | 10 | 9 | 24 |
| p value | NS | NS | NS | NS |

SD: Standard deviation; NS: no significant difference.

**Table II.** Final measurements (square inches)

| Treatment site | Soles | Palms | Axilla | Total group |
|---|---|---|---|---|
| Mean control | 7.06 | 9.34 | 4.93 | 7.48 |
| Mean treated | 3.06 | 2.26 | 1.70 | 2.39 |
| Mean difference | 4.00 | 7.08 | 3.23 | 5.09 |
| SD | 1.90 | 2.83 | 1.90 | 2.84 |
| Sample size | 8 | 10 | 6 | 24 |
| p value | <0.001 | <0.001 | <0.01 | <0.001 |

SD: Standard deviation.

regions were randomly divided into the right and left sides with the untreated site serving as a control. As recommended by the manufacturer, the treatment site was exposed to the Drionic unit for 30 minutes twice a day for 5 days followed by 30-minute daily treatments. Treatment was continued until a reduction in sweating was noted. Patients were instructed not to use antiperspirants or other topical agents during the study.

**Treatment device.** The Drionic unit is a compact iontophoretic device that delivers a direct current to the skin. Battery-generated current is sent through two tap water–saturated wool pads, which are separated by a nonconducting barrier. The wool pads are placed on the treatment sites, thereby completing the circuit. Amperage is regulated by the patient with a control knob. Patients were instructed to use the unit at the maximum output tolerable. All units were tested prior to the study to assure uniformity of current output. Batteries were changed after every five treatments. All adverse reactions were recorded.

**Measurement of sweat output.** Sweat measurements were taken on day 0, day 6, and then weekly until a clinical response was noted. Treatment was then discontinued and a 1-month follow-up measurement was conducted. A positive clinical response was arbitrarily interpreted as a greater than 50% inhibition of sweat production on the treated side as estimated by two physicians. Patients were instructed to wash and dry test sites. Developer was then applied to control and selected treatment sites. Patients were stressed for 5 minutes using either initial interview stress or subsequent mental arithmetic with monetary reward (shown to enhance sweat output as demonstrated by Quatrale et al[11]). Test sites were then imprinted on Persprint paper for 30 seconds. Imprints were sent to an independent laboratory (Milton Roy Company, Analytical Products Division, Rochester, NY) where quantitative analysis by photodensitometry was performed using the Omnicon image analysis system.

This system produces quantitative readings of sweat prints in the following manner. The developed sweat print is viewed by a video camera that is part of the Omnicon system. This video image is converted to an electronic image. The data from this electronic image are entered into the computer, which then measures the developed regions of the print. Final readings are of the total developed area of the print. For this study all results are recorded in square inches.

**Statistical analysis.** The data were analyzed for statistical significance by means of Student's t test.

## RESULTS

Twenty-two patients (9 female and 13 male) with hyperhidrosis began this study with a total of

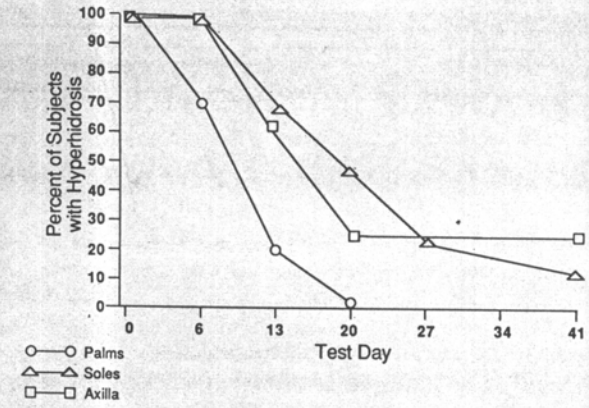


**Fig. 1.** Percent of subjects with hyperhidrosis versus time to clinical remission with Drionic treatment.

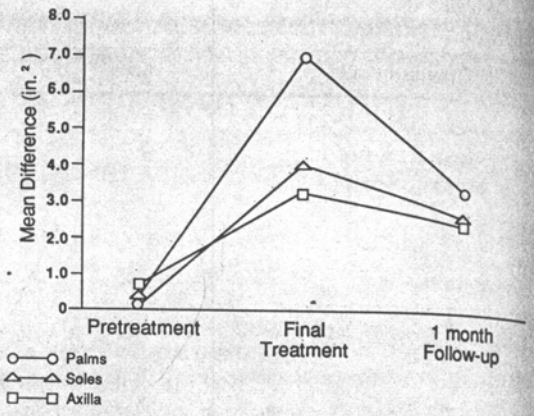


**Fig. 2.** Mean difference control versus treatment sites at pretreatment, final treatment, and 1 month follow-up.

twenty-seven different treatment sites. Of these sites, ten (five right, five left) were palms, nine (four right, five left) were soles, and eight (four right, four left) were axillae. Pretreatment measurements indicted no significant differences in the sweat rates in the control and treated sites (Table I).

Of the original twenty-seven treated sites, three did not respond clinically to the Drionic unit within 1 month and were dropped from the statistical analysis (2 axillae, 1 sole). An additional patient (axilla) moved after the final treatment and was unable to participate in the 1-month follow-up analysis. The twenty-four treated sites that showed at least 50% subjective clinical improvement were compared to control sites. The mean print values were significantly different at the palm and sole sites ($p < 0.001$), as well as the axilla site ($p < 0.01$), demonstrating a definite decrease in sweat production on the treated side (Table II).

The time period until sweating decreased significantly (as approximated by a 50% decrease in treated versus control side), varied from 6 days (three hands) to more than 34 days (one foot). Eight of the ten hands (80%), three of the nine feet (33%), and three of the eight axillae (37.5%) responded by 2 weeks. By day 20, ten of ten (100%) hands and six of eight (75%) axillae had a significantly decreased sweat rate. By day 41, eight of nine (88.8%) feet had responded. A total of fourteen of twenty-seven sites responded by day 13 (52%) (Fig. 1) and twenty-five of twenty-seven (93%) sites responded by day 20 (Fig. 1).

The 1-month follow-up sites continued to show a statistically significant decreased sweat output as a group ($p < 0.01$), but when analyzed individually by location, only the hands showed a significant difference of 3.44 square inches ($p < 0.05$) at the 1-month follow-up, whereas the soles and axillae were lower, at 2.63 and 2.44 square inches, respectively (Table III). Fig. 2 demonstrates the greatest difference between control and treatment sites in the palms (7.08 square inches) as compared to soles (4.00 square inches) and axillae (3.23 square inches).

Side effects occurred in twenty of the twenty-seven treatment sites. They were minor and none required the patient to stop treatment. The most common side effect was discomfort during treatment, ranging from mild (11 sites) to moderate (5 sites) to severe (4 sites). Other side effects noted included vesicles, erythematous papules, and scaling (Table IV).

## DISCUSSION

The data clearly demonstrate the efficacy of the Drionic unit, regardless of treatment site. Unlike previous studies in which only subjective results were obtained,[6,10] this study objectively quantified the results by use of an image analysis computer. This study also evaluated more subjects and test sites than previous studies, allowing for statistical analysis of data at different treatment locations.

Although the Drionic unit can reduce sweat output, several treatment sites did not show inhibition and others were slow to respond. The manufac-

**Table III.** One month follow-up measurements (square inches)

| Treatment site | Soles | Palms | Axilla | Total group |
|---|---|---|---|---|
| Mean control | 6.70 | 9.90 | 6.70 | 8.03 |
| Mean treated | 4.07 | 6.46 | 4.26 | 5.07 |
| Mean difference | 2.63 | 3.44 | 2.44 | 2.96 |
| SD | 3.67 | 4.23 | 5.31 | 4.14 |
| Sample size | 7 | 10 | 5 | 22 |
| p value | NS | <0.05 | NS | <0.01 |

SD: Standard deviation; NS: no significant difference.

**Table IV.** Side effects

| | Vesicles | Erythematous papules | Scaling | Discomfort | | | |
|---|---|---|---|---|---|---|---|
| | | | | None | Mild | Moderate | Severe |
| Axilla (n = 8) | 2 | 4 | 3 | 1 | 4 | 2 | 1 |
| Palms (n = 10) | 4 | 2 | 6 | 1 | 3 | 3 | 3 |
| Soles (n = 9) | 0 | 0 | 0 | 5 | 4 | 0 | 0 |
| Total (n = 27) | 6 | 6 | 9 | 7 | 11 | 5 | 4 |

n: Number of treatment sites evaluated.

turer states that use of the Drionic unit to produce an initial reduction in sweating may require 14 days or longer. This was substantiated by our results, which indicated that 80% of the hand sites, 33% of the sole sites, and 37.5% of the axilla sites responded within 14 days. However, with additional treatments, 100% of the hands, 78% of the soles, and 75% of the axillae responded within 20 days.

As previously noted, the hand sites as a group showed the earliest response. Additionally, this site was the only location to show complete inhibition of sweating at the end of treatment, as well as a statistically significant sweat reduction at the 1-month postreatment follow-up. The reasons for these regional differences are not entirely clear, but several possibilities exist. It is conceivable that anatomic differences (number of sweat glands per unit area, thickness of stratum corneum) between sites may influence the efficacy of the unit. Design differences between units used for different locations may also have affected results. Several patients complained of the awkwardness of the axillary unit and difficulty in maintaining proper skin contact because of the bulk of the device. Additionally, several patients reported discomfort in the nonaxillary areas that came in contact with the unit (chest wall and arm). These side effects may have further impaired positioning. Plastic axillary guards were added to the units during the study. These reduced side effects, but the bulk of the units remained a problem for some patients.

In order to test the efficacy of the unit in the home environment, for which it is designed, all treatments were performed outside of the laboratory setting and therefore compliance could not be assessed. However, all patients claimed to have followed treatment instructions explicitly.

The manufacturer states that sweating may be inhibited for up to 6 weeks. In this study, the 6-week status was not evaluated, but 1-month follow-up studies were performed instead. At 1 month, the total group showed a statistically significant decreased sweat production, but when analyzed by location only the hands showed a statistically significant sweat reduction. Whether the hands would continue to show sweat reduction at 6 weeks is unknown.

Many patients complained of side effects associated with the use of the Drionic unit, but none was severe enough to necessitate discontinuation

of treatment. The most frequent complaint was described as a "pins and needles" sensation. In addition, several patients experienced visible changes, most commonly scaling. Possibly these side effects may be secondary to the minimal quantities of hydrochloric acid produced at the site of the positive electrode. It was suggested by the manufacturer that the unit be rotated every 10 minutes in order to decrease irritation. Rotation was attempted with some of the axillary patients, but no difference in irritation was noted. Recent suggestions by the manufacturer to reduce side effects by presoaking the positive pad with baking soda solution, followed by rinsing the same pad every 10 minutes during treatment, were not attempted in this study. Decreasing the twice-daily treatments to once daily may also reduce side effects but may change efficacy as well.

## CONCLUSION

The Drionic unit appears to have a place in the treatment of hyperhidrosis. However, for some patients it may take several daily treatment sessions for more than 2 weeks before results are seen. Posttreatment sweat inhibition may persist for several weeks, after which retreatment should be resumed.

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## ABSTRACTS

### Case report: toxic shock syndrome associated with TSST-1 producing coagulase-negative staphylococci

Kahler RC, Boyce JM, Bergdoll MS, Lockwood WR, Taylor MR. Am J Med Sci 1986;292:310-1

More than 95% of cases of toxic shock syndrome are associated with coagulase-positive staphylococci, with toxic shock syndrome toxin 1 produced in more than 90% of cases. A case of recurrent toxic shock syndrome is reported in which coagulase-negative staphylococci were isolated from the vagina and produced toxic shock syndrome toxin 1. No coagulase-positive staphylococci were isolated.

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### Clearance of psoriasis with low dose cyclosporin

Brookes DB. Br Med J 1986;293:1098-9

Six patients, 60 years of age or older, with classic plaque-type psoriasis showed rapid response to 1 mg cyclosporin A/kg body weight/day during the first month of therapy, although the cyclosporin dose had to be raised to 3 mg/kg/day in some patients. Psoriasis cleared rapidly but relapsed equally rapidly when treatment was stopped. No effect on blood pressure was observed; however, all patients developed increases in blood urea and serum creatinine.

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### Azidothymidine for AIDS

Abramowicz M. Med Lett 1986;28:107

In a double-blind study of acquired immunodeficiency syndrome (AIDS) and AIDS-related complex patients treated with azidothymidine, after 3 to 6 months of treatment sixteen of 137 taking placebo and only one of 145 taking azidothymidine (AZT) had died. Dosage is 200 mg orally every 4 hours and may have to be decreased to 100 mg every 4 hours or less if anemia develops. However, the effectiveness of lower dosages has not been determined. For adult patients with AIDS who have *Pneumocystis carinii* pneumonia, the drug is available on an investigational basis at no cost from the "AZT Treatment and Coordinating Center" (1-800-843-9388). Twenty-five percent of all patients taking AZT and 50% of those with AIDS developed severe anemia due to bone marrow depression, which improves when the drug is stopped or the dosage is lowered. Even with lower dosages many patients require repeated transfusions, with severe granulocytopenia or thrombocytopenia requiring interruption of therapy in about 5%, mainly patients with AIDS. Headache is also a common side effect. Some patients taking doses higher than those currently recommended developed severe agitation, restlessness, and insomnia. The drug may be better tolerated in patients with AIDS-related complex.

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