

Long-Term Efficacy and Side Effects of Tap Water Iontophoresis of Palmoplantar Hyperhidrosis - the Usefulness of Home Therapy

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Abstract. Treatment of palmoplantar hyperhidrosis was carried out with a conventional galvanic generator in 40 patients and with a newly developed iontophoresis apparatus, which is suited for home treatment, in 31 patients. The new apparatus is operated by a rechargeable energy source or by batteries and is disconnected from the electrical net during treatment. It conforms to most recent safety regulations as approved by Underwriter's Laboratory. Hyperhidrosis was completely controlled after 10-12 treatments as revealed by quantitative gravimetric measurements of sweat rates and semiquantitative estimation of starch iodine paper imprints. There was no apparent difference in efficacy between the two apparatuses. Not only hyperhidrosis was abolished, but associated symptoms such as lividity of palms or soles, acral hypothermia and edema of fingers or toes, also subsided. Skin temperature on palms rose from 29.7 ± 1.8 °C before treatment to 32.2 ± 1.4 °C thereafter. Maintenance treatment was continued on an average for 14 months, in 4 patients for more than 3 years. No loss of efficacy was found during that period. Side effects were minimal and depended upon ampereage used. Only slight discomfort during treatment and mild short-lasting skin irritation were observed. Long-term side effects did not occur.

Introduction

Localized idiopathic hyperhidrosis involves axillae, palms and soles. It represents a functional disorder of unknown origin with polygenic inheritance. Whereas relief from axillary hyperhidrosis is achieved by topical application of aluminum chloride hexahydrate in aqueous [1-3] or ethanolic

[4-6] solutions, this therapeutic approach proved little effective in hyperhidrosis of palms or soles [1, 2, 7]. In addition, surgical excision of axillary skin [8, 9] offers a practical way of permanent cure; in palmoplantar hyperhidrosis sympathectomy is the only means of surgical treatment. This measure, however, bears several severe risks. These include chronic neuralgia, injury of the plex-

nic nerve, Horner's syndrome, gustatory sweating and compensatory hyperhidrosis in noninvolved areas on the trunk [10, 11]. For this reason sympathectomy cannot be recommended as a routine treatment of idiopathic hyperhidrosis of palms or soles. It is rather to be considered as a last resort.

Currently, the only effective therapeutic alternative is offered by iontophoresis. The principle of tap water iontophoresis was first described by Japanese authors [12] and then adopted by physiotherapists [13] and dermatologists [14, 15] in the United States of America. The elaborate experimental studies of Bouman and Grunewald-Lentzer [13] showed that the use of two separate trays was more effective than placing both electrodes in one single vessel. Addition of sodium chloride or aluminum chloride failed to improve therapeutic efficacy. On the contrary, increased concentrations of electrolytes diminished the therapeutic effect. Levit [15] was the first to introduce tap water iontophoresis into practical dermatotherapy. Its efficacy has been proven in several studies [16-21], however, only limited numbers of patients have been observed for short periods of treatment. Little is known about long-term efficacy or long-term side effects.

The conduction of prolonged therapeutic studies recruiting large cohorts of patients is hindered by several factors. Treatment has to be carried out in clinics or laboratories due to the lack of inexpensive and safe equipment suited for home treatment. Multiple patient visits are required. Treatment is time-consuming for the clinical staff and patients. Since only transient relief is offered, maintenance treatment has to be continued for years; this alters the patient's life style. Resolution of these problems was sought by introducing a battery-operated



Fig. 1. Starch-iodine paper imprints: a Diffuse darkening, borders washed out (4+); b Dark print with distinct dermatoglyphics (3+); c Faint dots with clear outline of palm (2+); d Faint dots, outline of palm not discernible (1+).

apparatus designed for home use [22], which came to be known as the Dronic device. Its efficacy in the treatment of excessive palmoplantar hyperhidrosis, however, was found unsatisfying in the majority of our patients [23].

The present study was aiming at several goals. First, the effectiveness of tap water iontophoresis was demonstrated by quantitative assessment of sweat rates in a large group of severely hyperhidrotic patients. Second, the possibility of long-term side effects during continuous treatment over extended periods of time, up to more than 3 years, was evaluated. Third, the practical use of a newly developed iontophoresis apparatus which was designed for home treatment was tested.

Materials and Methods

Patients

There were 36 male and 35 female patients referred to the Department of Dermatology for treatment of excessive hyperhidrosis of palms or soles during the years 1983-1986. Their ages ranged from 13 to 57 years (mean 38, median 25). 50.7% gave a family history with involvement of at least one first-degree relative. Most patients (84.3%) suffered from hyperhidrosis of palms and soles; in 11.3% only hands, in 4.2% only feet were involved. Many patients (46.5%) complained about additional excessive axillary sweating. In the majority of patients, hyperhidrosis of palms or soles started in childhood before puberty, sometimes even in infancy. Onset of palmo-plantar hyperhidrosis was rarely observed in adult life. Age of onset varied from 1 to 46 years (mean 10, median 5).

Control Subjects

Spontaneous palmar and plantar sweating was quantitatively assessed in 10 healthy control subjects. There were 5 males aged 22-39 and 5 females between 19 and 42 years.

Assessment of Sweat Rates

Two different methods were routinely employed in each patient. These were gravimetric assessment of sweat rate and semiquantitative estimation of degree of sweating by obtaining sweat prints using a colorimetric method. Measurements were performed before treatment, at least once weekly during the initial phase of therapy, at the time when inhibition of sweating was complete and at least once monthly during maintenance treatment.

Gravimetric Measurement. Secretion rates per minute of whole palms or soles were determined gravimetrically. Films or soles were blotted dry and then brought into contact with a thin sheet of soft preweighed paper for 1 min. The amount of sweat secreted during this collection period was determined as weight increase by laboratory scales (Precisa 30 M-300 C, Schönbach, Gießen, FRG).

Colorimetric Measurement. For semiquantitative estimation of hyperhidrosis sweat prints were recorded on sheets of typing paper using a modification of the starch-iodine technique [24]. The paper was pre-treated with iodine solution (iodine 0.5, castor oil 10.0, absolute ethanol ad 100.0) and air-dried. A print was

produced by placing the paper on the test site, which had been blotted dry prior to the test, for 1 min. Prints were rated on a 4-point scale: 0 = no print visible; 1+ = faint dots, outline not discernible; 2+ = faint print with clear outline of palm or sole; 3+ = dark print with distinct dermatoglyphics; 4+ = diffuse darkening, borders washed out (Fig. 1).

Measurement of Skin Temperature

Skin temperature was determined by a radiation thermometer (KT 41, Heilmann, Wiesbaden, FRG) in 22 patients during the initial treatment course. Measurements were carried out before each iontophoresis treatment on the tip of the third digit, then at hypothenar and center of palm.

Iontophoresis Apparatus

Two different apparatuses were employed in the study. First, a generator that is used in physiotherapy for galvanic stimulation (Galvanofor, Martin, Tuttingen, FRG) served as the current source. With this apparatus 40 patients were treated. Since 1985, a new apparatus was used, which had been specially designed for the purpose of treating palmo-plantar hyperhidrosis (Hilder, Gesellschaft für Medizin und Technik, Wuppertal, FRG). The new apparatus is operated by a rechargeable energy source or by batteries. It features safety equipment, automatic timing and remote control for amperage adjustment. Thus, it can be operated by the patient alone and is suitable for home treatment. It conforms with most recent safety regulations and is approved by Underwriter's Laboratory (Technischer Überwachungsverein). This apparatus was used by 31 patients; 26 patients carried out maintenance home therapy.

The electrodes of the current source were placed in two separated plastic trays, which are commonly used for developing photographs. The trays measured 30x40 cm; the rim was 4 cm wide. In conjunction with the Galvanofor apparatus custom-made squares of stainless steel measuring 1.5x1.5 cm were fixed to the inner side of the trays' rim by adhesive tape and served as electrodes. The Hilder apparatus was equipped with a stainless steel sheet covered with a silicone rubber screen. The electrode exactly fitted the bottom of the plastic tray and was connected with the current outlet. To prevent electric shock, by inadvertently touching the connecting cords, plugs or electrodes all parts of the electric wiring were kept insulated.

Treatment of Hyperhidrosis by Iontophoresis

Treatment

Hands or feet are placed flat on the bottom of the trays. All metal items, e.g., rings, bracelets, watch, have to be removed prior to treatment to prevent iontophoretic burns. The trays are filled with tap water until palms or soles are completely submerged including the dorsum of the distal phalanges of fingers or toes. Then, the current is switched on and the amperage is increased gradually until the patient experiences slight discomfort; it averages 15 mA on palms and 20 mA on soles. During the treatment amperage is maintained just below the threshold for discomfort. Adjustments can be made any time, if necessary. After 30 min, at the end of the treatment period, the current is slowly switched off. Although changes of amperage cause painful sensations in the extremities treated and have to be avoided, in the Hilder apparatus electronic control system automatically cut down voltage and limit amperage in the event of sudden current fluctuations. Thus, in case of emergency, the patient can remove hands or feet from the water baths during treatment without major discomfort. Defects in the anatum corneum barrier by fissures or erosion cause painful burning and itching even at low electrical currents. Covering these lesions with petroleum ointment abolishes pain.

Treatments were carried out preferably once every day, at least 3 times a week. Few patients were treated twice daily. Polarity was kept constant in 40 patients or switched from one treatment to the next in 23 patients. In 6 patients polarity was changed after 15 min and the treatment then continued for another 15 min. Following this regimen the patients' tolerance was found to be improved during the second part of the treatment and the amperage had to be reduced rendering the treatment altogether less effective. Thus, this regimen was discontinued in the further course of the study.

When sweating was sufficiently reduced, maintenance therapy was carried out on an individual schedule. Sixty patients entered maintenance treatment, 26 of whom had switched to home therapy with the Hilder apparatus by the end of the study.

Results

Initial Treatment

Clinical Findings. The prominent clinical feature of palmo-plantar hyperhidrosis is ex-

cess moisture of palms and soles. On palms the affected area is sharply demarcated from the distal part of the forearm; the borderline follows approximately the distal flexor skin fold on the wrist. In severe hyperhidrosis sweat droplets appear and drip off. In these patients also the dorsal aspects of the fingers are involved. With increasing degree of hyperhidrosis sweating progressively involves the proximal dorsal parts of the fingers. Similar observations can be made in hyperhidrosis of the soles. There, with increasing severity, sweating spreads to the lateral and medial aspects of the foot in addition to involvement of dorsum of toes.

Besides accumulation of excess fluid on the skin surface causing maceration of the stratum corneum, palms and soles of hyperhidrotics are erythematous, often combined with Hividity. In extreme hyperhidrosis fingers and toes are edematous and swollen. As a result of acroasphyxia in combination with constant heat loss due to evaporation of sweat, hands and feet are not only soaking wet, but also cold.

Following the first few iontophoretic treatments, many patients experience an increase in intensity as well as in frequency of sweat outbursts. Then, after 3-5 treatments, sweat rates start to decline and bursts of excessive sweating occur less often. A reduction of sweating is first noticed on the ear and hypothenar and in the vault of the sole. Tips of fingers and soles are most resistant to treatment. Finally, hyperhidrosis is abolished. A satisfying therapeutic result was achieved after an average of 12 treatments of the hands and 10 treatments of the feet.

If polarity of the electrodes is kept constant during the treatment course, inhibition of sweating is first induced in that extremity



Fig. 2. Dry scaly skin on toes and lateral aspect of foot after 10 treatments with tap water iontophoresis.

Table I. Skin temperature prior to and after successful treatment by tap water iontophoresis.

Skin temperature, °C	
before treatment	after iontophoresis
32.5	33.9
28.6	34.7
30.8	33.3
30.9	31.4
28.3	34.3
28.8	32.6
31.4	33.0
26.4	30.0
28.5	33.5
31.0	34.5
Mean 29.7 ± 1.8	33.2 ± 1.4

Average values of measurements on both palms (finger tip, thenar, hypothenar, center of palm) are presented; n = 10.

treated in the tray connected with the anode. When treatment is continued, this side difference levels off. Complete inhibition of sweating resulted in dry skin with fine scaling (fig. 2). In addition, lividity of palms or soles and edematous swelling of fingers and toes subsided. Also skin temperature was found elevated and disagreeable clamminess was abolished.

Measurements of skin temperature before and after successful iontophoretic therapy revealed an average increase of 3.5 °C (table I). When polarity was kept constant during the complete treatment course, a transient side difference in skin temperature was noted. After 5-10 treatments, the hand treated by the anode was found warmer, since there sweating was suppressed more rapidly (table II).

Quantitative Assessment of Sweat Inhibition. Rates of spontaneous sweating in the 10 healthy control subjects were found to be between zero and 20 mg/min on palms

(mean 9 mg/min) and between zero and 15 mg/min on soles (mean 10 mg/min) when the gravimetric method was used. Semiquantitative evaluation of sweat prints on a 4-point scale revealed a score of 0.75 as an average degree of sweating in normal controls, individual scores ranging from zero to 1.5 (fig. 3, 4).

In hyperhidrotic patients spontaneous sweating on palms and soles was found to be greatly increased. Palmar sweat rates averaged $52 \pm (\text{SD})26$ mg/min and plantar sweat rates $43 \pm (\text{SD})31$ mg/min. There was great individual variation. Maximum sweat rates reached 322 mg/min on palms and 345 mg/min on soles. Using the starch-iodine paper impregnated with the average degree of sweating was graded as 3.5 on palms and 3.25 on soles.

The reduction of sweating during the treatment course of tap water iontophoresis could be monitored by both quantitative gravimetric and semiquantitative colorimetric measurements. On palms as well as on soles a gradual inhibition of sweating was achieved which was detected after 3-5 treatments and finally reduced sweat rates to normal after 10-12 treatments (fig. 3, 4). Average posttreatment sweat rates in hyperhidrotics still remained slightly higher than average sweat rates in normal controls, but mean values of hyperhidrotics are found within the range of normals. At that stage of the treatment course, control of hyperhidrosis was considered complete by both patients and physician. Treatment schedule was switched to maintenance therapy.

Between the two iontophoretic devices used no apparent difference was observed, neither in efficacy nor in respect to side effects. At any time during initial-phase treatment, average sweat rates of palms or soles failed to differ significantly between the two

Table II. Skin temperature on thenar after 5-10 galvanic treatments (anode side vs. side treated by cathode; n = 22)

Skin temperature, °C			difference
anode	cathode		
31.2	28.2	3.0	
33.9	31.8	2.1	
34.5	30.7	3.7	
31.4	29.5	1.9	
30.5	27.5	3.0	
32.0	29.1	2.9	
27.0	25.0	2.0	
26.3	27.4	1.1	
36.0	35.2	0.8	
30.0	33.5	3.5	
28.8	25.5	3.3	
29.5	28.2	1.3	
34.5	32.2	2.3	
35.0	32.7	2.3	
33.0	31.5	2.0	
29.7	25.5	4.2	
34.8	31.0	3.8	
31.5	31.5	0.0	
34.0	32.5	1.5	
27.7	27.6	0.1	
32.5	27.0	5.5	
33.5	30.2	3.3	
Mean 31.7 ± 2.8	29.3 ± 2.8	2.4 ± 1.3	

treatment groups. Some patients, however, felt less discomfort while treated by the Hidrex apparatus, in which the sheet electrodes provided a current density evenly distributed over the treated skin area.

Maintenance Therapy

If iontophoretic treatments are discontinued, hyperhidrosis recurs gradually within several weeks. Complete inhibition of hyperhidrosis lasts only for 1-2 weeks.

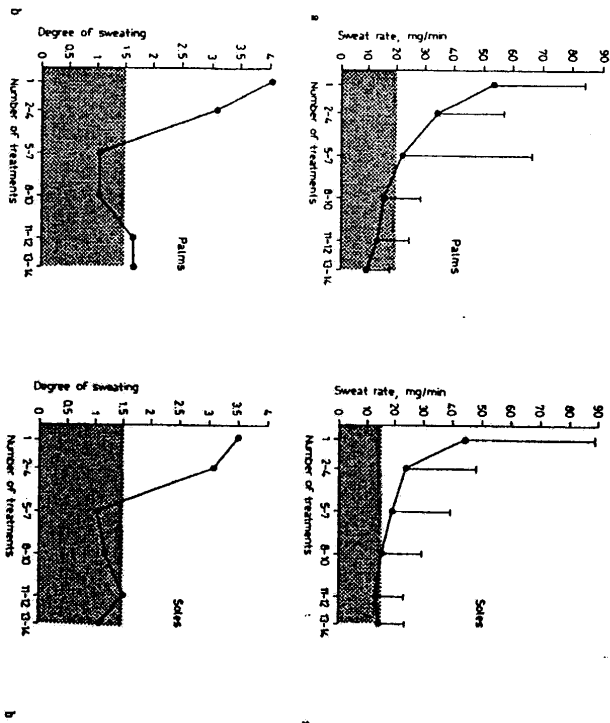


Fig. 3. Reduction of sweating by tap water iontophoresis in palmar hyperhidrosis. a Gravimetric measurement. b Semiquantitative estimation by starch iodine prints. Shaded areas represent normal range.

Fig. 4. Reduction of sweating by tap water iontophoresis in axillary hyperhidrosis. a Gravimetric measurement. b Semiquantitative estimation by starch iodine prints. Shaded areas represent normal range.

Retreatment levels of sweating are restored within 1-2 months. Duration of sweat inhibition shows some correlation to the degree of hyperhidrosis. In excessive hyperhidrosis sweating recurs rapidly, sometimes within several days, whereas in mild hyperhidrosis sweat suppression may last for many weeks. In our patients, who in the majority were

severely afflicted, maintenance treatments were required between once and twice weekly. On an average 1.3 treatments per week were necessary to maintain complete control of hyperhidrosis. Most of the patients who carried out galvanic therapy at home used the apparatus once weekly. Only during periods of thermal or psychological stress,

due to hot and humid weather or individual stress factors, treatment frequency had to be increased to twice or even thrice weekly by some patients.

Patients were treated for an average of 14 months. Four patients have been continuously treated for more than 3 years. The average frequency of treatments necessary to keep sweating suppressed remained constant in the same patient. Thus, the severity of hyperhidrosis remained unchanged. This is in contrast to treatment of axillary hyperhidrosis by aluminum chloride solution, in which the degree of hyperhidrosis decreases with the duration of treatment due to structural alterations of the glands [25]. On the other hand, efficacy of tap water iontophoresis was not found reduced; tolerance to galvanic therapy did not develop.

Side Effects

Side effects were minimal and restricted to slight discomfort during treatments and mild skin irritation. Depending on the patient's tolerance amperage reached on an average 15 mA on palms and 20 mA on soles. High amperage caused discomfortable sensations with burning and tingling on the submerged skin and pain in deeper tissue layers.

Apart from these immediate effects, skin irritation occurred in some patients, again predominantly at higher amperage. On the skin submerged and especially along the water surface, transient erythema and few small whitish vesicles measuring 1-2 mm appeared. This was associated with slight burning. Soreness lasted for no longer than several hours. The extremity treated by the cathode was found to be more prone to skin irritation. High amperage and short treatment intervals enhanced irritation. Adverse

effects of long-term maintenance therapy were not observed.

Discussion

The present study proves the efficacy of tap water iontophoresis for control of palmo-plantar hyperhidrosis in a large group of patients. Three aspects are noteworthy. Patients with extremely high sweat rates respond to the treatment, no adverse effects were noticed during long-term maintenance treatment, and tap water iontophoresis not only curbs sweating but also abates other discomfortable symptoms, such as lividity, edema and clamminess of palms and soles. Acute side effects were limited to skin irritation and some discomfort during the galvanic treatment. They are prevented by avoiding high current densities on the skin areas treated.

At present, tap water iontophoresis represents the most effective therapy in hyperhidrosis of palms or soles, besides sympathectomy. In our experience it also exceeds efficacy of devices employing wetted pads for iontophoresis [23]. With the use of an apparatus suitable for home treatment patients become independent of regular visits to the physician's office or the clinic. The apparatus has to conform with safety regulations to protect the patient from potentially deleterious electric shock. It is fortunate that such accidents evidently have not occurred so far. Not all devices marketed earlier meet the regulations recently introduced in Germany (Medizinische elektrische Geräte; begrenzte Festlegung für die Sicherheit von Reizstromgeräten für Nerven und Muskeln; DIN VDE 0750, Teil 219/1084, Entwurf, 1986; grundsätzliche

Aspekte der Sicherheit elektrischer Einrichtungen in medizinischen Anwendungen: VDE 0752, 1986). These safety rules for medical electrical appliances will probably also be adopted by the countries of the Common Market in the near future. Patients with cardiac arrhythmia or with electronic implants, e.g., pacemakers, should be excluded from iontophoresis. This is to be regarded as a prophylactic measure, since, from a theoretical point of view, severe complications in these patients are not to be expected.

The mechanism of action of iontophoresis is still elusive. Structural changes of the eccrine glands have not been found [26]. This was also confirmed by studies in our laboratory [27]. The authors of the former study as well as ourselves failed to reveal any mechanical obstruction of the eccrine ducts or a structural degeneration of acini in sweat glands unresponsive after tap water iontophoresis. Therefore, it is assumed that the cause of anhidrosis is not a structural defect, but a transient functional disturbance of the glands. It was further shown that galvanic treatment rendered sweat glands unresponsive to pharmacological stimuli. Intradermal injection of 0.1 ml 0.1% pilocarpine hydrochloride failed to elicit a secretory response in palmar skin treated by iontophoresis [27]. From these experiments it is concluded that blockage of neuroglandular transmission or inhibition of the secretory mechanism at the cellular level is involved in the therapeutic mechanism of iontophoresis.

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