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ORIGINAL PAPER

Pilot study for permanent resolution of axillary hyperhidrosis: elimination of sweat glands with intradermal microneedle radiofrequency

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Abstract

Background Hyperhidrosis is a disorder of the autonomic nervous system that creates severe social and work problems through the production of excess uncontrolled perspiration. This disease affects about 1 to 3% of the world's population. Essential or primary hyperhidrosis being most frequently seen. Treatment with a variety of surgical and non-surgical systems has been reported. Recently, intradermal microneedle radiofrequency has attracted favorable attention.

Methods Seventy-four armpits in 37 patients (9 males, 28 females, average age 28 years [range 15–68 years]) diagnosed as having axillary hyperhidrosis who were performed intradermal microneedling fractional radiofrequency (MRF) in three deeps 2 mm, 3 mm, and 3.5 mm. The study was performed from July 2014 until July 2016. All patients completed control and follow-up sessions for 6 months.

Results A permanent decrease in sweating of over 50% was achieved in 30 patients (80%); intermediate results in 2 (7%) and little or no results in 5 patients (13% of patients).

Conclusions results suggest that MFR is a novel, safe, effective, permanent, and minimally invasive method to treat AHH with tolerable side effects.

Level of Evidence: Level IV, therapeutic study.

Keywords Microneedle fractional radiofrequency · Thermoregulation · Primary hyperhidrosis · Joule heating

Introduction

The sweating allows thermoregulation of the body, through evaporation of moisture from the most zones of the skin surface.

Hyperhidrosis (HH) is a poorly understood pathogenesis, that is, characterized by excessive sweating in normal conditions in certain areas of the body, such as axilla, palm, and sole which will affect patient's daily activities.

HH is a disorder of the autonomic nervous system. This pathology affects about 1 to 3% of the world's population. The causes are multifaceted and complex, and one result is the body's inability to achieve thermoregulation [1]. Most of HH are of the primary or essential type and there is a family history. In general, HH begins in childhood or adolescence and occurs at least once a week, although in extreme cases, it may occur several times during a day [2].

Secondary HH might appear as a result of numerous pathologies such as, endocrine diseases (hypoglycemia, hyperthyroidism), neurological disorders (syringomyelia, focal lesions of the central nervous system), menopause, and neoplasia (Hodgkin's lymphoma, carcinoid tumor, pheochromocytoma) and it also could be associated with chronic infections [3].

Axillary Hiyperhidrosis (AHH) is the most frequent type of HH, as it occurs in 60% of cases. It develops through hyperactivity of the axillary sweat glands and this causes uncomfortable and embarrassing moments to the patient due social rejection (antihygienic appearance) [4]. Most cases of AHH are bilateral.

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Human skin contains two types of sweat glands: eccrine and apocrine. There are approximately 600 sweat glands per square centimeter of skin [1, 5, 6]. At the axillary level, most are between 2 and 4 mm in depth [2].

Eccrine glands comprise the majority of all sweat glands, with approximately 3 million throughout the skin. Although they are distributed throughout the skin of the body, there are a greater number in and around the axilla, palms of the hands, and soles of the feet. They drain through pores directly onto the skin. Their main function is thermoregulation. Eccrine glands are innervated by cholinergic fibers from the sympathetic nervous system [3, 6].

Found in lower quantities than the eccrine glands, the apocrine glands are activated at puberty. Most of the apocrine glands in the skin are found in the armpits, the groin, and the areolar area of the breast. Their secretions are thick and small in quantities which drain out to the surface of the skin via the sheath of the hair follicle.

This secretion comes in contact with saprophytic bacteria on the skin and releases a distinctive unpleasant odor under the combined action of oxygen in the air and the enzymes produced by the microflora commonly found in the armpit and the groin. When that smell becames unpleseant it is called Bromhidrosis [3, 6].

Numerous treatments have been reported for AHH, both invasive and non-invasive. Most of these treatments show poor and inconsistent results and are temporary and/or involve scarring. Specifically, local antiperspirants [3], iontophoresis [7], anticholinergics and propantheline bromide [8], sympathectomy [9], local radiotherapy, subdermal abrasion [10], subdermal liposuction [11, 12], cutaneous resection [13] subdermal laser [14, 25], botulinum toxin [15, 16], and, more recently, radiofrequency (RF) energy [2, 4, 17, 18, 24].

All RF systems require an electrode, or electrodes, to deliver the current (delivery electrode) and an electrode (or electrodes) to return the current to the system.

A recent stage has been the development of the use of paired sets of delivery and return microneedles inserted intradermally with only the tips as the electrodes, the rest of the needle shaft being insulated: it is called microneedle RF system [18].

Patients and methods

Between July 2014 and July 2016, 114 armpits in 57 patients with AHH were enrolled in the study at the author's institution. Of that 57, 37 patients (74 armpits) completed all treatment sessions, all pre-and post-treatment surveys, and the required follow-up periods. These 37 patients therefore formed the study group. They comprised 9 males and 28 females, with an average age of 29 years (range, 15–68 years).

Inclusion criteria:

- Patients diagnosed as having AHH on the hyperhidrosis disease severity scale (HDSS, Table 1) of grades II, III, or IV.
- Patients who completed pre- and post-treatment surveys and fulfilled the minimum follow-up assessments at 1 week, and 1, 3, and 6 months post-treatment.

No distinction was made as to sex or age.

Exclusion criteria:

- Treatment with axillary botulinum toxin in the 6 months previous to the study, as it could interfere with the objective evaluation
- Patients with pacemakers
- Patients with axillary skin infections
- Pregnancy or lactation
- Patients with HDSS grade I AHH
- Patients enrolled in the study and treated, but who did not complete the minimum established assessments

All 37 patients received bilaterally treatment. Majority of patients receive only 1 treatment (23 patients), 10 patients went on to receive 2 treatments, and 4 patients required 3 treatments, giving a total of 55 treatment sessions: 62% of patients thus required only 1 treatment, with more than 1 treatment being required by 38%.

All patients received same protocol of treatment: 3 passes in different depth (2.5, 3.0, and 3.5 mm) treating to include the mayor quantity of eccrine glands.

Other parameters: the power level was set between level 10 and 18 (25 to 45 W). The most commonly used level was 16 (40 W). The exposure time or pulse duration was between 500 and 800 ms. The most commonly used pulse duration was 600 ms.

Table 1 Hyperhidrosis severity scale (HDSS) and the number (*N*) of respective patients in the present study

Grade	Criteria	*N*
I	My underarm sweat is unnoticeable and never interferes with my daily activities.	0
II	My underarm sweat is tolerable but sometimes interferes with my daily activities.	9
III	My underarm sweat is poorly tolerated and frequently interferes with my daily activities.	12
IV	My underarm sweat is intolerable and always interferes with my daily activities.	16

Microneedle RF system used

The equipment used was the Lutronic INFINI™ (Lutronic Corporation, Goyang, South Korea). This is a 1 MHz bipolar RF system using insulated microneedles mounted in a disposable single-use tip delivering microneedle fractional RF (MFR). Each tip contains a matrix of 49 needles (7 × 7) over an area of 1 cm^2 (1 cm × 1 cm). The surgical stainless steel needles are 200 μm in diameter with a 20-μm tip. The needles are coated with gold for conduction, and all of the needles with the exception of the first 300 μm are insulated with a silicon compound. Thus, only the very top of each needle comprises the electrode. The handpiece incorporates a dial whereby needle penetration depth can be preset, from 0.5 to 3.5 mm in 0.5 mm increments. The output power or level is adjustable from 1 to 20 at 2.5 W per setting, giving a maximum power of 50 W. The exposure time can be set between 100 and 1000 ms. In Figs. 1 and 2 we have an explanation of the MFR system.

Average treatment parameters

Following performance of starch-iodine test, minor test, bilaterally, local infiltration anesthesia was given (8–10 cc xylocaine 2% with epinephrine per axilla). Three passes were delivered to each underarm in three different depths (2.5, 3.0, and 3.5 mm).

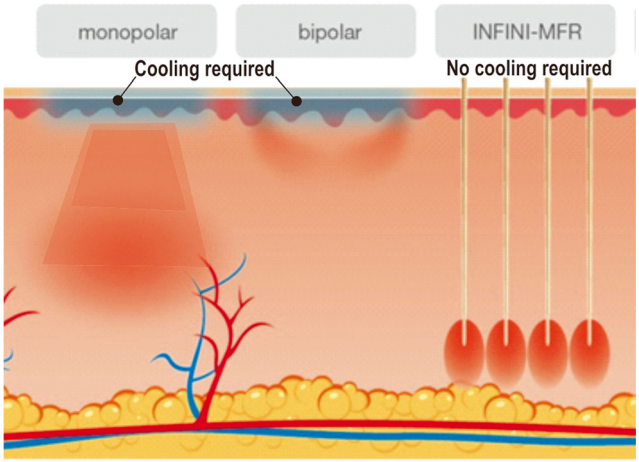

Fig. 1 Schematic image comparing the depth and degree of action and electrothermal dispersion of the RF energy emitted by monopolar and bipolar transepidermal RF and bipolar microneedle intradermal RF systems. The greater depth and better-controlled electrocoagulation of the RF energy through bipolar microneedles are evident, and the insulated needle shafts mean that cooling the epidermis is not required

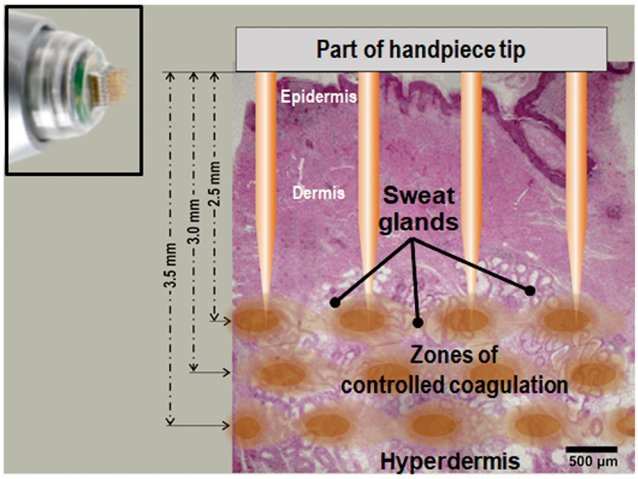

Fig. 2 (Inset, upper left) MFR tip with the needles extended. (Main illustration) Schematic overlay on a histological section of axillary skin with eccrine sweat glands showing how controlled and discrete areas of deep coagulation are achieved in the sweat glands in the hypodermis following multiple passes with MFR at different needle depths. Only four of the needles are shown, and the illustration is drawn to scale based on the original magnification of the hematoxylin- and eosin-stained specimen (× 10)

Efficacy assessments

We evaluated the treatment results both objectively and subjectively. The objective evaluation consisted of performing the minor test at baseline and at 6 months post-treatment, with digital photography (Sony 5000 camera 20.1 mega pixels) taken on both occasions and compared by an independent blinded evaluator to assess the decrease in the sweating pattern.

The subjective evaluation consisted of a post-treatment survey in which the patient evaluated their degree of improvement related to both perspiration and improved quality of life on a scale of 1 to 10. The result of the subjective assessment was graded as poor with little or no effect when the response was between 1 and 3, and successful when the response was between 5 and 10. Those responding with a grade 4 possibly indicated some degree of glandular destruction, so it was decided to score them as intermediate.

Results

As noted above, 74 armpits in 37 patients successfully completed all treatments and the assessment points at 1 week, 1, 3, and 6 months post-treatment. In all cases, the objective minor test comparison of the clinical photography showed a decreased sweating pattern at 6 months post-treatment compared with the baseline scoring. Figure 3 shows representative results of the typical minor test discoloration: the degree of change between baseline and post-treatment findings was

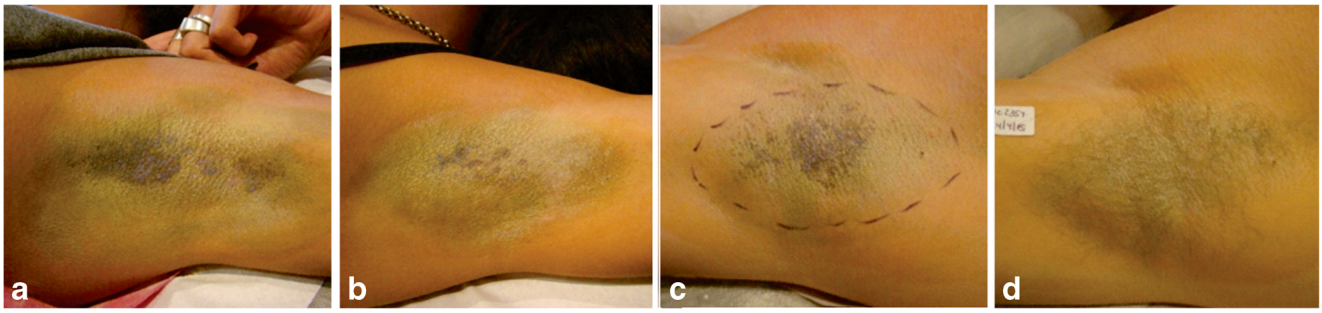

Fig. 3 Minor test photos before treatment (**a**, **c**) and 6 months after the final treatment (**b**, **d**). A reduction in the sweating pattern can be seen, more so in Fig. 4a, b. The degree of decreased sweating is directly proportional to the degree of destruction of the sweat glands

indicative of the degree of destruction achieved by MFR in the eccrine glands.

In the subjective assessment, 30 patients (80%) evaluated their result as successful (between 5 and 10), with 2 cases (7%) as intermediate with a score of 4, and 5 cases (13%) with a poor result, scoring between 1 and 3 (13%) (Fig. 4).

Complications and adverse effects

Immediately after each treatment, edema, inflammation, erythema, transudate, and epidermolysis were noted in the treated areas with spontaneous evolution of all sequelae in less than 7 days. The treated areas were dressed only with solid petroleum jelly (vaseline).

Type AB burns under the Benaim classification [19] were seen in all 57 of the originally enrolled patients, and of these, 4 of the 74 armpits of the 37 patients who were in the final study population (5.5% of the total armpits treatments) were left with small scarred areas and permanent dyschromia (evolution of type B burns under the Benaim classification) (Figs. 6 and 7).

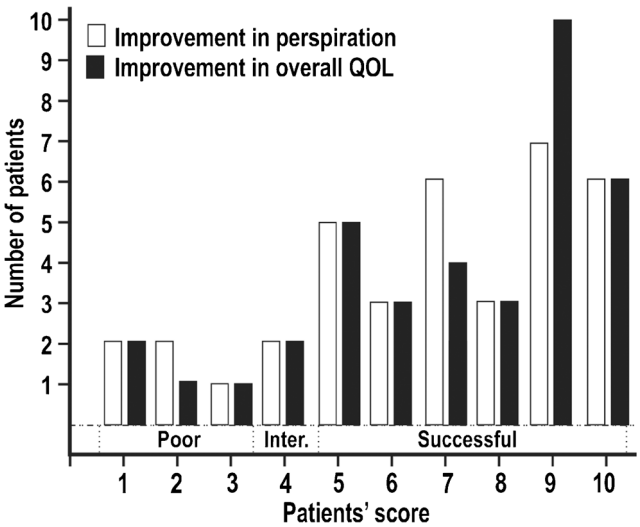

Fig. 4 Satisfaction rates subjectively scored by the 37 patients for improvement in both sweating and overall quality of life (inter = intermediate)

Discussion

HH is a condition that affects a large number of the world population (1 to 3% according to the various reports). Most of them undiagnosed and unaware that there is a solution to their problem.

Of the various forms of HH, AHH is the most frequent and, therefore, the one that has the greatest negative social and workplace effects for AHH patients, which is why all doctors should prioritize its treatment.

Frequently, a patient's initial consultation takes place with a dermatologist who will often prescribe palliative and/or temporary treatment (aluminum hydroxide solutions, iontophoresis, anticholinergics, botulinum toxin) which are not curative or permanent.

In most of the formative literature in the practice of plastic surgery, reports can be found dedicated to the surgical treatment of AHH with partial or totally curative solutions, but based on invasive surgical procedures with resulting scarring, which may require more time in surgery [13]. There are numerous articles on surgical procedures, which have been published in different journals within our specialty or associated specialties [10, 11, 20, 21].

Sympathectomy, which is performed by general or specialized thoracic surgeons as a solution to HH with good results at the palmar and plantar levels, does not present the same results for the resolution of AHH. Compounded by the fact that this practice is a thoracic surgical procedure under general anesthesia, it is not exempt from complications and adverse effects (pneumonia, bleeding, compensatory sweating, etc.) [3, 8, 22, 23]. As a point of interest, one of the patients in the present study population had their

AHH originally treated by a thoracic surgeon who performed a sympathectomy with a poor result and compensatory sweating. The surgeon followed up with surgical curettage with poor resulting evolution. With the MFR approach featured in the present study, the author achieved good improvement in this patient, both as documented by the minor test and evaluated by the patient, with a level of satisfaction of 8 points out of a maximum of 10, both in decreased sweating and improved quality of life.

However, in 2012, Fan et al. reported on the benefits of minimally invasive RF in the treatment of AHH [4], and since then RF for AHH has attracted growing attention.

More recently, in July 2018, a multi-centric study in the USA by Chilukuri et al. [24] also banned in the original work of Kim and collaborators of 2013 [2] obtains results similar to those obtained by Kim and our work.

The success of the proposed treatment with MFR is based on the following anatomical principle: the apocrine gland coil is mostly in the hypodermis, whereas the eccrine gland coil is located mostly in the dermis. When performing MFR at the depths used in the present study, the electrothermal damage in the form of controlled coagulation occurs at the dermal level and not in the hypodermis. Accordingly, a greater number of eccrine glands, responsible for a significant amount of the sweating-related problems in AHH, are destroyed. On the other hand, treatments for HH which are based on hypodermal resolution of the condition such as curettage, liposuction, and subdermal laser treatments would preferentially act on the apocrine glands which are responsible for the odor, but not the significant volume of sweating; this leads to the potential failure of the previously discussed treatments in patients with AHH, other than MFR.

Although in most of the reports consulted three standardized sessions were performed separated by 3 to 4 weeks, it was decided to modify the parameters of duration, depth, and intensity to be able to adapt the treatment from 1 to 2 sessions with a longer time separation; in fact, only 4 of the 37 patients required three sessions. This shortening of the treatment regimen corresponded to a problem with operating costs of the treatment both for the author and his patients, as the author's clinic is a private practice not currently covered by social security or health insurance reimbursement.

Regarding the optimum depths for MFR in treating AHH, reports published on AHH [17, 18, 24] in common with the study published by Kim et al. have placed the depth of the great majority of axillary sweat glands between 2 and 4 mm. Therefore, it was decided that the actionable depth for the MFR in the present study should be between 2.5 and 3.5 mm (the latter is the maximum penetration depth of the microneedles in the system used in the present study).

The length of the post-treatment evaluation of the results of MFR has varied among authors, from between 4 and 8 weeks to 6 and 12 months [2, 17, 18, 24]. From selected studies on the length of assessments for the same groups of patients, the authors of these studies found significant differences at the 1-month assessment, but saw little difference in the results between 6 and 12 months post-treatment. The final assessment in the present study was therefore set at 6 months as being sufficient time to see significant results, given that there would be no possibility of glandular compression due to edema or inflammation at that stage. This meant that decreased sweating noted at the 6-month assessment would be more or less directly proportional to the magnitude of destruction of the sweat glands.

The number of complications in the present study (4 armpits, 5.5% in total) comprised scarring and permanent dyschromia and was greater than in the publications consulted, but could be said to be inversely proportional to the acquisition of experience in the technique by the author; most were produced in patients treated during the first year after this study began and can therefore be attributed to the learning curve. The increased MFR parameters of power and duration used in the present study beyond the average of those reported in previous publications may also have led to the above complications. But, on the other enabled the shortening of the number of treatment sessions and a greater reduction in the magnitude of the sweating score. This is the goal of this protocol in compare with the regular three sessions in all treatments of previous publications [8, 15, 20, 22, 25]. Although there were 4 cases of scarring and dyschromia, only 2 were really dissatisfied with the treatment. The other 2 cases of complications valued the permanent decrease in sweating more than the complication. These are the 2 patients from Figs. 5 and 6. Compensatory sweating in 2 patients was reported as a complication in a previous study [8], but no patient in the present study suffered from this adverse effect.

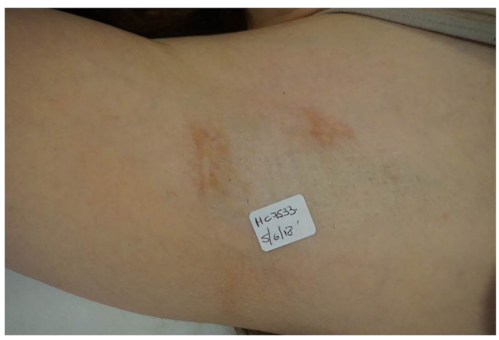

Fig. 5 Evolution of type B burn. Post-treatment follow-up at 6 months shows scarring

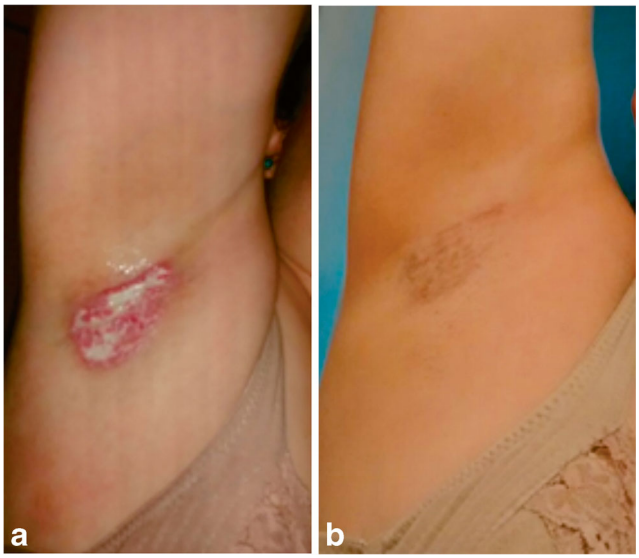

Fig. 6 Evolution of a type AB burn. **a** 1 month after treatment. **b** The findings at the 6-month follow-up show permanent dyschromia with acceptable cosmetic

One patient in the present study was a female, 57 years of age, who in addition to axillary sweating presented with facial sweating primarily on the forehead. It was decided to treat the two areas simultaneously. Quite surprisingly, although a successful level was achieved for the axillary sweating (score 7), the result for the forehead was greater (score 9), which led to the patient scoring her improvement in quality of life a 10.

Not included in the study, but noteworthy nonetheless, is a patient who came to the author's clinic exclusively to improve her axillary bromhidrosis, and achieved an apparent decrease after 2 treatments evaluated only by the patient. This bromhidrosis patient could be added to the 2 others included in this study who, at the final assessment, stated that in addition to the improvement achieved in their AHH, they experienced improvement in decreased underarm odor. This result is feasible, as not only are the eccrine sweat glands being destroyed, but also the apocrine glands which are responsible for underarm odor. A further study is required with a larger bromhidrosis population to confirm the optimistic results seen in these 3 patients.

As a final point, it can be seen that patients with grade I on the HDDS were excluded from the present study, even though MFR is an indication for such patients. This was simply to allow good quantification of changes in sweating amounts and QOL disruption between baseline and final assessments, as grade I AHH patients typically have minor disruptions to their QOL caused by sweating even though they may wish to be treated for social or work-related reasons.

A significant improvement in the present study was obtained regarding the permanent decrease in sweating, scored between 5 and 10 points (30 patients, 80%). However it is interesting to note that the evaluation of improvement in the overall QOL for the study subjects was also very high (range from 5 to 10, 32 patients, 87%). This highlights the importance that a pathological condition such as AHH can have in the normal social and workplace development of AHH patients. It is noteworthy that the results obtained in the present study were in accord with the results obtained in the literature consulted before putting MFR into practice [2, 18].

The elimination of eccrine sweat glands through intradermal microneedle radiofrequency with the system and at the parameters used in the present study could be recommended as a new, safe, successful, and permanent treatment of primary axillary hyperhidrosis.

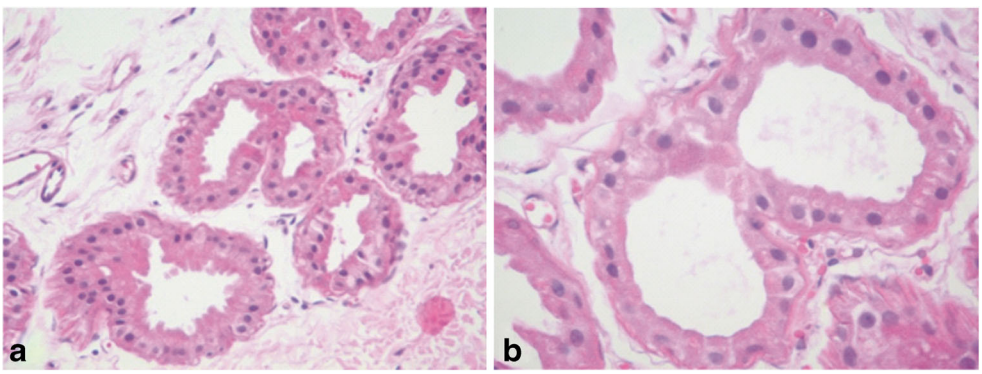

Fig. 7 Histological photomicrographs of the axilla from a volunteer patient. **a** Left axillary specimen at baseline showing normal eccrine gland structure. **b** Specimen from the left axilla of the same patient at 3 months after the final treatment (same magnification). Degenerative changes can be seen in the abnormal eccrine gland architecture. Some cells exhibit an absence of their nuclei, and the cytoplasm has undergone hydropic degeneration. Hematoxylin and eosin stain, × 10 original magnification

Because the RF energy was delivered and returned by multiple bipolar needle electrodes and was therefore fractionated among the electrodes, this approach became known as microneedle fractional RF, or MFR. The principles of monopolar and bipolar surface contact RF and intradermal MFR are illustrated in Fig. 1.

MFR has the advantage that epidermal cooling is not required because the needle shafts are insulated and no electrothermal damage occurs, except at the very tip of the needles. A second advantage is that the depth of the needles can be preset, allowing accurate placement of the controlled coagulation deep in the sweat glands. A third advantage is the fractional aspect of RF delivery, allowing areas of normal skin to exist between the electrothermal controlled coagulation to decrease post-treatment sequelae, and therefore patient downtime, and speed up the wound repair and remodeling process.

In the histological findings from biopsies taken from the volunteer patient (Fig. 7), normal eccrine gland architecture was seen at baseline (Fig. 7a). In the 3-month assessment, glandular destruction was apparent with absence of nuclei in some cells and hydropic degeneration of the cytoplasm (Fig. 7b).

In those two patients who in addition to suffering from hyperhidrosis had associated bromhidrosis, the latter symptoms were also notably improved.

One of the 37 patients agreed prior to treatment to authorize the performance of an axillary tissue biopsy before treatment and at 3 months post-treatment. A full-skin thickness punch biopsy (4 mm) was obtained; the specimen was routinely prepared for hematoxylin and eosin staining and examined under light microscopy (Fig. 7).

In addition, one patient (a 57-year-old female) had facial hyperhidrosis in the forehead area. She had 2 additional treatments on her forehead. Furthermore, 2 patients indicated that they also had bromhidrosis.In this case, in particular, a high level (level 16, 40 W) and maximum depth (3.5 mm) were used to achieve destruction of the apocrine glands, which are mostly in the hypodermis.

Conclusions

Our results suggests that MFR is a novel, safe, effective, permanent and minimally invasieve method to treat AHH with tolerable side effects.

Compliance with ethical standards

Conflict of interest Fabian Perez Rivera declares that he has no conflict of interest.

Ethical approval For this retrospective study formal consent from a local ethics committee is not required.

Informed consent All patients sign two different consents in which they accept to share their photos and information of the treatment for scientific purposes.

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