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Assessment of axillary hyperhidrosis and bromhidrosis treatment with microwave technology

Mikrodalga teknolojisi ile aksiller hiperhidroz ve bromhidroz tedavisinin değerlendirilmesi

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Abstract

Aim: Hyperhidrosis and bromhidrosis are disorders related with generalized or local excessive sweating that can have a significant impact on the quality of life of patients who suffer from them. There are several treatments, both topical and invasive, with permanent or temporary effects. In recent years, microwave technology has emerged as a non-invasive procedure with permanent effects and few side effects. The study aim was to evaluate the efficacy, safety and satisfaction degree of patients with axillary hyperhidrosis and bromhidrosis treatment using microwave technology, and the primary outcome was to increase patient satisfaction about their sweating levels.

Methods: Retrospective cohort study is planned and included the patients underwent a single microwave session with miraWave® technology for hyperhidrosis or bromhidrosis. Efficacy and safety were assessed at one, three, six, and 12 months. Inclusion criteria were men or women between 18-65 years old, diagnosed with hyperhidrosis and an HDSS score of 2-4. Patients with pacemakers and expectant or lactating mothers were excluded. Before treatment, patients were diagnosed using the Hyperhidrosis Disease Severity Scale, and the Minor test. Satisfaction was assessed through a subjective assessment of the satisfaction level, using a questionnaire in which participants chose the sentence that best fitted with an assigned score of 0-10.

Results: A total of 46 patients participated in the study: 20 women (43.48%) and 26 men (56.52%) aged between 18-65 years old. Throughout the follow-up period, an average of 49.88% of patients reported a subjective improvement of hyperhidrosis and 95% reported the same about bromhidrosis. After comparing the results of their previous level of sweating with those after one year of treatment, 80.40% of patients showed themselves satisfied. All side effects were resolved in a time not exceeding 10 weeks.

Conclusion: Microwave technology proves to be an effective and lasting treatment after one single session for axillary hyperhidrosis and/or bromhidrosis.

Keywords: Axillary hyperhidrosis, Axillary bromhidrosis, Microwave technology, Axillary glands

Öz

Amaç: Hiperhidroz ve bromhidroz, bunlardan muzdarip olan hastaların yaşam kalitesini önemli ölçüde etkileyebilecek genelleştirilmiş veya lokal aşırı terleme ile ilgili bozukluklardır. Kalıcı veya geçici etkileri olan hem topikal hem de invaziv olan birkaç tedavi vardır. Son yıllarda, mikrodalga teknolojisi kalıcı etkiler ve az yan etki ile non-invaziv bir prosedür olarak ortaya çıkmıştır. Çalışma amacı, aksiller hiperhidroz ve bromhidroz tedavisi alan hastaların mikrodalga teknolojisi kullanılarak etkinlik, güvenlik ve memnuniyet derecelerini değerlendirmek ve birincil sonuç, terleme düzeyleriyle ilgili hasta memnuniyetini araştırmaktır.

Yöntemler: Retrospektif bir kohort çalışması planlandı ve hiperhidroz veya bromhidroz için miraWave® teknolojisi ile tek bir mikrodalga seansı geçiren hastalar dahil edildi. Etkinlik ve güvenlik bir, üç, altı ve 12 ayda değerlendirildi. Dahil edilme kriterleri, 18-65 yaşları arasında, hiperhidroz ve HDSS skoru 2-4 olan kadın veya erkeklerdir. Kalp pili ve hamile veya emziren anneleri olan hastalar çalışma dışı bırakıldı. Tedaviden önce hastalara Hiperhidroz Hastalığı Şiddet Ölçeği ve Minor testi ile tanı kondu. Memnuniyet, memnuniyet seviyesinin öznel bir değerlendirmesi ile değerlendirildi, katılımcıların en iyi 0-10 puan almış bir cümleyi seçtikleri bir anket kullanıldı.

Bulgular: Çalışmaya toplam 46 hasta katıldı: 20 kadın (%43.48) ve 18-65 yaşları arasındaki 26 erkek (%56.52). Takip süresi boyunca, hastaların ortalama %49.88'i hiperhidrozun subjektif bir iyileşmesini ve %95'i bromhidroz konusunda aynı olduğunu bildirdi. Önceki terleme seviyelerinin sonuçlarını bir yıllık tedavi sonrası durumla karşılaştırdıktan sonra, hastaların %80.40'ı kendilerinin tatmin olduğunu ifade etti. Tüm yan etkiler 10 haftayı geçmeyen bir sürede yok oldu.

Sonuç: Mikrodalga teknolojisi, aksiller hiperhidroz ve / veya bromhidroz için tek seanstan sonra etkili ve kalıcı bir tedavidir.

Anahtar kelimeler: Aksiller hiperhidroz, Aksiller bromhidroz, Mikrodalga teknolojisi, Aksiller bezler

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Introduction

Hyperhidrosis is a condition characterized by generalized or local excessive sweating. Primary hyperhidrosis is usually local and affects one or more areas of the body, generally in a symmetrical manner, especially the palms of the hands, the armpits, the soles of the feet, or the face [1]. Its origin is idiopathic, although it has been suggested that it may be the result of hyperactivity of the sympathetic system. It has an incidence of about 3% and usually appears between 25-64 years old [2]. Secondary hyperhidrosis is usually generalized, affecting the entire body, and its origin is an underlying cause, like an infectious, endocrine or neurological disorder [3].

On the other hand, bromhidrosis is characterized by body odor and is closely related with excessive sweating. Corynebacterium is believed to be significantly involved in the biotransformation of natural, odorless secretions in volatile, smelly molecules in the armpit [4].

These disorders may have a significant impact on the quality of life and professional, social and emotional burden of the people suffering from them [5]. This situation has prompted efficacy studies to be conducted with new treatments with minimum side effects. The options to treat hyperhidrosis include topical treatment with aluminum chloride and oral anticholinergic drugs, which in most mild-to-moderate cases are enough. Injections of botulinum toxin A [6], sympathectomy and local excision are also highly effective [7], but they are reserved for cases that are resistant to conservative therapy, although there still could be side effects, like compensatory sweating after an endoscopic transthoracic sympathectomy [8].

For some years, microwave-based technology has been added to these treatments [9], with good results reported in studies conducted for the treatment of underarm sweating [10-12]. It is a local, non-invasive procedure that uses non-ionizing energy with a frequency of 5.8 MHz. Its design enables it to deliver energy with precision at the depth of sweat glands (located 2-5 mm deep) [8], and produce thermolysis of the eccrine and apocrine glands, eliminating them permanently and, consequently, reducing sweat volume and bad odor.

Possible post-treatment side effects are edema and/or pain with some degree of intensity for three days after treatment, inflammation and occurrence of nodules in the armpit 7-15 days after treatment, hematomas in the anesthesia puncture site, redness due to the suction procedure, or permanent loss of underarm hair since it also acts on hair follicles [8], resolving after a few weeks. Compensatory sweating rarely occurs since axillary sweat glands make up 3% of the entire body and, with this technique, only about 66.6% of axillary sweat glands are eliminated.

The objective of this study was to use patients' subjective post-treatment assessments during a follow-up period of one year to evaluate the efficacy of axillary hyperhidrosis and bromhidrosis treatment using microwave technology.

Materials and methods

Study design

This was an observational, retrospective, cohort study, single-center, open study conducted at the Clínica Tufet (Barcelona, Spain). It included men and women between 18 and 65 years old, diagnosed with axillary hyperhidrosis and/or bromhidrosis based on the Hyperhidrosis Disease Severity Scale (HDSS).

The study was conducted in compliance with the principles laid down in the current revised version of the Declaration of Helsinki, Good Clinical Practices (GCPs), and all the relevant applicable laws and regulatory requirements for the use of medical devices in Spain. Individual material logs were kept in the investigator's source documents, and case report forms did not include any personal information.

Inclusion criteria: Men or women between 18-65 years old, diagnosed with hyperhidrosis and an HDSS score of 2-4.

Exclusion criteria: Patients with pacemakers, and expectant or lactating mothers.

The primary outcome was to increase patient satisfaction about their sweating levels.

Study protocol

After accepting to participate in the study, and if they met all inclusion criteria, patients were subjected to one single microwave session with the miraDry® device (Miramar Labs, Santa Clara, CA), which uses miraWave® technology.

The system is designed to be used by medical professionals in a properly prepared site. It applies precise amounts of microwaves on the soft tissue of the armpit with a frequency of 5.8 GHz to treat excessive sweating in a superficial, local and non-invasive way. While microwaves are applied, the device protects the surface of the tissue by means of an active contact cooling system. It has a console with a main body and a touch screen, a bioTip and a handpiece.

Pre-Treatment procedures

HDSS scale adapted to Spanish: Patients will use this scale to classify their hyperhidrosis by choosing one of the following statements:

- Score 1: My sweating is never noticeable and never interferes with my daily activities.
- Score 2: My sweating is tolerable but sometimes interferes with my daily activities.
- Score 3: My sweating is barely tolerable and frequently interferes with my daily activities.
- Score 4: My sweating is intolerable and always interferes with my daily activities.

A score of 3-4 is for severe hyperhidrosis, a score of 2 is for moderate hyperhidrosis, and a score of 1 is for absence of hyperhidrosis.

Minor test: Most commonly used in clinical practice, it is based on the color that the skin assumes when the sweat of the study area touches certain chemical substances (iodine solution followed by corn starch). The solution turns blueish in those areas with more sweating, enabling to locate those areas of maximum perspiration, as well as to assess the result after treatment.

Subjective assessment of the satisfaction level: It is performed by choosing the best fitted sentence, which has an assigned score of 0-10:

- 0: I am not happy; the treatment did not work.
- 1-4: I am not very happy, the treatment barely worked.
- 4-6: I am moderately happy, the treatment moderately worked.
- 6-8: I am happy, the treatment worked.
- 9-10: I am very happy; the treatment has met all my expectations.

Treatment protocol

It was a local, non-invasive, long-acting procedure, not indicated for the treatment of hyperhidrosis in other areas of the body. First, the patient's armpit was measured to determine the grid pattern to be used, which conditioned the number and place of impact points. Then, tumescent anesthesia (Klein solution) was applied through four entry points. This type of anesthesia enabled to work with more efficacy and safety, and with less amount of anesthetic than necessary when the point-by-point technique was used. Volume ranges from 70-130 ml of solution per armpit, depending on its size.

Once the area was anesthetized, the handpiece was applied on those points predetermined by the grid pattern. The device had different types of intensity (1-5), being the maximum level (Level 5), the more successful, and the lowest was reserved for the upper area of the armpit to avoid accidentally damaging the brachial plexus. Based on the amount of subcutaneous fat, sensitivity, and the desired result, energy levels determine the volume and depth of the treatment, at the same time preserving most of the dermis. The handpiece acted over an area of 10 x 30 mm, so, depending on axillary size, the treatment was required between 30-45 minutes per armpit.

As a safety measure and to increase efficacy and protect the dermis, the device had a skin suction and cooling system. During the treatment cycle, cooling fluid flowed through a chamber in contact with the skin, protecting the epidermis and upper dermis from excess heating - this procedure allowed to protect structures that are deeper than sweat glands from heat injury. Furthermore, the frequency and structure of the antennae can be adapted to limit penetration, focusing the irradiated microwave energy on the dermal/hypodermal interface.

The energy was delivered for about 30 seconds, followed by a 20-second post-cooling period. Upon completion, the vacuum was released, and the cessation of the audio signal indicated the end of the treatment cycle. The operator then moved the handpiece to the next adjacent treatment area, and the process was repeated.

Post-Treatment

After treatment, patients were prescribed anti-inflammatory drugs, like dexamethasone or ibuprofen and local cold packs. They were also recommended to use antiseptic soap to wash the area, avoid going to pools, spa resorts, saunas or the beach, and do not exercise four days after treatment.

Patient follow-up

Treatment efficacy and safety was assessed 1, 3, 6 and 12 months after treatment. Post-treatment follow-up visits included patient subjective assessments of treatment efficacy; all adverse effects were recorded. At the end of 12 months, all patients were provided a satisfaction questionnaire.

Data assessment

Variables analyzed were gender, age, family history of hyperhidrosis, prior treatments, type of hyperhidrosis, patient subjective assessment of their treatment result, global satisfaction, secondary effects and duration of the treatment.

Statistical analysis

Unless otherwise noted, quantitative variables are described as mean and standard deviation (SD), whereas categorical variables are expressed as percentages.

Results

A total of 46 patients participated in the study: 20 women (43.48%) and 26 men (56.52%) aged between 18-65 years old.

Pre-Treatment evaluations

Forty-two (91.32%) patients were initially diagnosed with primary hyperhidrosis, of which 17 (40.47%) had concomitant bromhidrosis. One (2.17%) patient was diagnosed with secondary hyperhidrosis due to a surgery. Three (6.51%) were diagnosed with bromhidrosis without hyperhidrosis. Twelve (26.09%) patients had family history of hyperhidrosis.

Regarding patients' prior treatments, the percentages were as follows: 16 (34.78%) were treated with topical antitranspirants, five (10.87%) with Botox injections, one (2.17%) with laser, one (2.17%) with sympathectomy, one (2.17%) with oral anticholinergics, and 22 (47.82%) had no prior treatments.

Evaluations after 12 months

Mean patient subjective assessments of treatment results using the scores obtained in follow-up visits were as follows:

- Of patients treated for hyperhidrosis, 20.93% (n=9) assessed the treatment result between 1-4 (“I am not very happy, the treatment barely worked”); 51.16% (n=22) between 4-6 (“I am moderately happy, the treatment moderately worked”); and 27.9% (n=12) between 6-8 (“I am happy, the treatment worked” (Figures 1 and 2). Therefore, 34 (79.06%) patients noticed a subjective improvement after treatment. The mean value of the subjective assessment was 4.99 (0.81) over 10.
- Regarding patients treated for bromhidrosis, 9.09% (n=2) assessed the treatment result between 6-8 (“I am happy, the treatment worked”), and 90.9% (n=20) between 9-10 (“I am very happy, the treatment has met all my expectations”) (Figures 3 and 4). Therefore, 22 (100%) patients noticed a subjective improvement after treatment. The mean value of the subjective assessment was 9.5 ±0.58 over 10.
- Mean response for both treatments was 89.53%.

Based on the satisfaction survey conducted at the end of the follow-up period (12 months), 79% of patients showed themselves very satisfied, 15% were satisfied, 6% were not too satisfied and no patients were unsatisfied (Figure 5).

Safety data

Regarding reported adverse effects, 100% (n=46) of patients showed edema, 95.65% (n=44) had hematoma in the anesthesia puncture sites, 69.56% (n=32) had subcutaneous nodules, 65.21% (n=30) had local alteration of sensitivity, and 2.17% (n=1) had axillary fibrous tissue. Side effects were resolved in an average of 1-10 weeks, depending on their severity (Table 1).

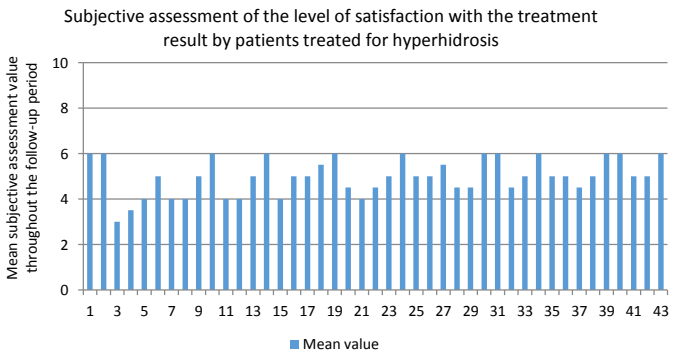

Figure 1: Mean subjective assessment of the level of satisfaction with the treatment result by patients treated for hyperhidrosis throughout the follow-up period (1, 3, 6 and 12 months)

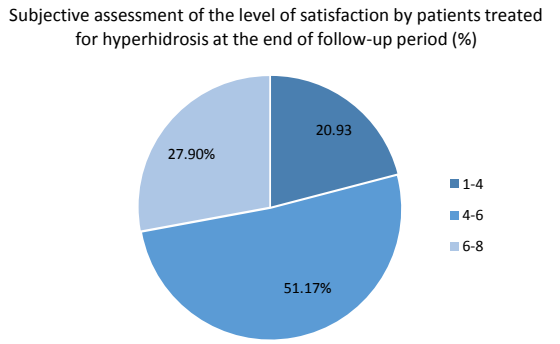

Figure 2: Subjective assessment by patients treated for hyperhidrosis upon completion of the follow-up period

Figure 3: Mean subjective assessment of the level of satisfaction with the treatment result by patients treated for bromhidrosis throughout the follow-up period (1, 3, 6 y 12 months)

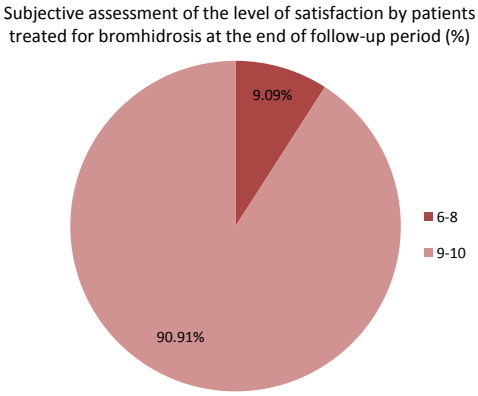

Figure 4: Subjective assessment by patients treated for bromhidrosis upon completion of the follow-up period

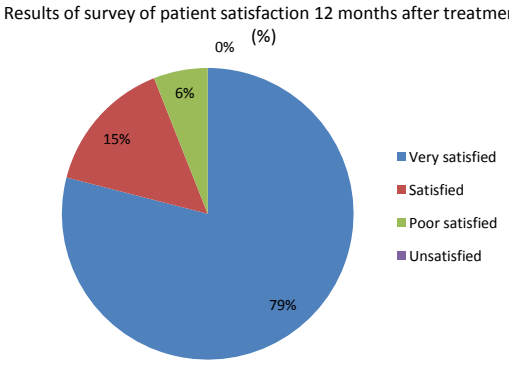

Figure 5: Result of patients' satisfaction survey conducted after 12 months of treatment

Table 1: Side effects and time of remission of symptoms

Side effects	Number of patients	%	Duration of symptoms (weeks)
Edema	46	100.00	1-1.4
Hematoma	44	95.65	1
Subcutaneous nodules	32	69.56	8-10
Local alteration of sensitivity	30	65.21	8-10
Axillary fibrous tissue	1	2.17	5
Eczema	0	0.00	-

Discussion

Microwave technology complies with the ideal requirements for the treatment of hyperhidrosis since it is focused, non-invasive, long acting and with minimum adverse effects. In our study, patients of both groups reported a mean response of 89.53%. Despite being a technology that has only been applied to the treatment of these disorders fairly recently, we already have results from randomized, long-term studies that ensure its efficacy and safety [10,11].

In the blind, randomized study by Glaser et al. [10], an active treatment group (n=81) was compared with a sham treatment group (n=39). The efficacy in the active treatment group, defined as a drop in HDSS to a 1 or 2 score after one year of follow-up, was of 74.75% (mean of all results obtained at follow-up visits). Likewise, the >50% reduction percentage, assessed with gravimetry, was 72.67% after 6 months. Adverse events were mild and resolved spontaneously.

In the first follow-up report from the long-term study by Lupin et al. [11], 26 patients showed 96.55% efficacy of treatment, defined as a drop in HDSS to a 1 or 2 score after 12 months, and 19 patients showed 98.19% efficacy after 24 months. This study also assessed patients' quality of life through the Dermatology Life Quality Index (DLQI), which was also used to evaluate the effect of the treatment as a higher or equal reduction to 5 score points. Results obtained had an average of 72.67% at 24 months. One year after treatment, all side effects (except underarm hair loss) had resolved. No patients showed new side effects during the second year. Differences concerning efficacy between both studies may be due to the difference in the number of patients.

In the study by Hong et al.[9], with 31 patients, of which 26 completed it, efficacy results between 74.3%-99.2% were obtained based on an HDSS score reduction to 1 or 2 after one year of follow-up, and a reduction percentage of DLQI that is higher or equal to 5 score points between 66.3%-99.9%. In this study, it was also observed that the treatment affected underarm odor. The percentage of patients that reported their body odor as not noticeable after 12 months of follow-up was 68.55%. Treatment efficacy didn't seem to vary with the number of procedures, and short-term adverse events related with therapy were usually minor. The most common were post-treatment edema, erythema and local discomfort, which resolved quickly after therapy.

In our study, the efficacy assessment was performed by patients at each follow-up visit using the subjective score provided by the results perceived after treatment. This information is important because patient's perception helps us improve the procedures, the explanation provided before starting the treatment, and expectations about results. Mean assessment of our patients was higher in the group treated for bromhidrosis, where 100% of patients perceived the treatment as positive, vs.

79.06% of patients treated for hyperhidrosis that perceived the treatment had provided them with some improvement. The differences may be due to the difference in the number of patients in each group.

Despite that the subjective assessments performed in our study don't use the same scale as those previously described, global results are similar and provide a guideline for the degree of satisfaction perceived by patients, which is translated in treatment effectiveness. If we average the data obtained from the studies by Glaser et al.[10], and Lupin et al. [11], at the same visits than our study (1, 3, 6 and 12 months), mean efficacy results were 74.75% for Glaser et al. and 96.55% for Lupin et al. If we compared them with the average of the subjective efficacy value obtained by patients in our study, which was 79.06%, we see that the number is similar to that obtained in the study with a larger number of patients.

For the treatment of bromhidrosis, in the study by Hong et al. [9], 68.55% of patients assessed their odor after treatment as imperceptible vs. 90.9% of patients in our study that assessed treatment as having fulfilled their expectations.

One limitation of the study was that HDSS was not assessed throughout the study, only in the baseline. This fact has made it not possible to compare this parameter with other investigations.

After assessing the study results, we considered that the treatment of hyperhidrosis and/or bromhidrosis with microwave technology is efficient and has lasting effects. Patient satisfaction with the procedure is high, and adverse events are usually temporary and well tolerated. This technology provides an alternative, lasting, non-invasive therapeutic modality. Despite the good results obtained - clinical as well as concerning patients' level of satisfaction - more studies should be conducted to assess the duration of the treatment effects in time in order to design the best protocol for the maintenance of said results.

Likewise, given our experience with both treatments and considering the results, we believe that the microwave treatment may be the most appropriate due to its durability and cost-benefit ratio compared with axillary botulinum toxin.

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References

1. Atkins JL, Butler PEM. Hyperhidrosis: A review of current management. Vol. 110, Plastic and Reconstructive Surgery. 2002. p. 222–8. Doi: 10.1097/00006534-200207000-00039.
2. Haider A, Solish N. Focal hyperhidrosis: Diagnosis and management. Vol. 172, CMAJ. Canadian Medical Association; 2005. p. 69–75. Doi: 10.1503/cmaj.1040708.
3. Stolman LP. Hyperhidrosis: medical and surgical treatment. Eplasty. 2008 Apr 18;8:e22.
4. James AG, Austin CJ, Cox DS, Taylor D, Calvert R. Microbiological and biochemical origins of human axillary odour. Vol. 83, FEMS Microbiology Ecology. Oxford University Press; 2013. p. 527–40. Doi: 10.1111/1574-6941.12054.
5. Strutton DR, Kowalski JW, PharmD, Glaser DA, Stang PE. US prevalence of hyperhidrosis and impact on individuals with axillary hyperhidrosis: Results from a national survey. J Am Acad Dermatol. 2004;51(2):241–8. Doi: 10.1016/j.jaad.2003.12.040.
6. Hasson NA, Kam CS, Cataldo CK. Toxina botulínica en el tratamiento de la hiperhidrosis focal primaria. Dermatologia Rev Mex. 2014;58(4):331–8.
7. Kapıcıbaşı HO. Bilateral endoscopic thoracic sympathectomy via single incision for the treatment of palmar and axillar hyperhidrosis. J Surg Med. 2019 May 24;3(5):393–6. Doi: 10.28982/josam.518325.
8. Jacob CI. Treatment of hyperhidrosis with microwave technology. Semin Cutan Med Surg. 2013;32(1):2-8.
9. Hong HC, Lupin M, O'Shaughnessy KF. Clinical evaluation of a microwave device for treating axillary hyperhidrosis. Dermatol Surg. 2012 May;38(5):728–35. Doi: 10.1111/j.1524-4725.2012.02375.x.
10. Glaser DA, Coleman WP, Fan LK, Kaminer MS, Kilmer SL, Nossa R, et al. A randomized, blinded clinical evaluation of a novel microwave device for treating axillary hyperhidrosis: The dermatologic reduction in underarm perspiration study. Dermatologic Surg. 2012;38(2):185–91. Doi: 10.1111/j.1524-4725.2011.02250.x.
11. Lupin M, Hong HC, O'Shaughnessy KF. Long-term efficacy and quality of life assessment for treatment of axillary hyperhidrosis with a microwave device. Dermatol Surg. 2014;40(7):805–7. Doi: 10.1111/dsu.0000000000000041.
12. Sánchez-Carpintero I, Martín-Gorgojo A, Ruiz-Rodríguez R. Microwave Treatment for Axillary Hyperhidrosis and Bromhidrosis. Actas Dermosifiliogr. 2017;108(5):418–22. Doi: 10.1016/j.ad.2016.12.011.

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Suggested citation: Patrias K. Citing medicine: the NLM style guide for authors, editors, and publishers [Internet]. 2nd ed. Wendling DL, technical editor. Bethesda (MD): National Library of Medicine (US); 2007-[updated 2015 Oct 2; cited Year Month Day]. Available from: http://www.nlm.nih.gov/citingmedicine