

CLINICAL EVALUATION OF A DOUBLE-PASS MICROWAVE DEVICE FOR TREATING AXILLARY HYPERHIDROSIS AND BROMHIDROSIS

Hien Thanh Le, MD¹, Quan Dinh Nguyen, MD.PhD¹, Quang Huu Nguyen, MD.PhD¹, Tuan Quoc Dinh, NR¹, Sau Huu Nguyen, MD.PhD^{1,2}, Son Hong Nguyen, MD.PhD^{1,*}

ABSTRACT

Objectives: Microwave thermolysis (MWT) is a permanent treatment for axillary hyperhidrosis and bromhidrosis/osmidrosis. The study aims to evaluate the effectiveness and safety of the miraDry system for axillary hyperhidrosis and bromhidrosis using a double-pass protocol. The results were assessed by using patient-reported outcome measures (PROMs).

Subjects and methods: 50 adults with primary axillary hyperhidrosis and/or bromhidrosis were enrolled in the study. All participants were treated using microwave devices with double-pass protocol. The efficacy of treatment for hyperhidrosis and bromhidrosis was evaluated using patient-reported outcome measures (PROMs) including Hyperhidrosis Disease Severity Scale (HDSS: 1 - 4), Odor Scale (OS: 1 - 10), respectively. Additionally, the overall Dermatology Life Quality Index (DLQI: 1 - 30) and patient satisfaction were assessed. Safety was evaluated by documenting early and late complications. Subjects were followed for up to six months post-treatment.

Results: At baseline, patients reported significant sweating and odor, both of which negatively impacted on their quality of life. At the 6-month follow-up 96% of patients had an HDSS score of 1 or 2 ($p < 0.001$). The DLQI score significantly decreased from a median of 21 to 2.5, with a median 11 points reduction ($p < 0.001$). The Odor Scale (OS) score was reduced from a median of 7 to 2 on both sides ($p < 0.001$). All patients experienced transient effects in the treatment area, such as swelling, hematoma and pain. No severe and/or permanent adverse events were seen after 6 months.

Conclusions: Microwave thermolysis using a double-pass protocol is an effective and safe treatment method for axillary hyperhidrosis and/or bromhidrosis.

Keywords: Axillary bromhidrosis, axillary hyperhidrosis, axillary osmidrosis, double-pass microwave, microwave thermolysis.

1. INTRODUCTION

Although a benign condition, axillary hyperhidrosis/bromhidrosis, characterized by excessive sweating and odor, significantly impact on the quality of life of affected individuals. These conditions interfere with daily activities, work, mental health, and social interactions. Hyperhidrosis can be classified into 2 main types:

¹National Hospital of Dermatology and Venereology

²Hanoi Medical University

Corresponding author: Son Hong Nguyen, MD.PhD

Email: tomsonnguyen@gmail.com

Received: 4 July 2024

Received: 21 August 2024

Accepted: 31 October 2024

DOI: <https://doi.org/10.56320/tcdlhn.49.273>



Primary and secondary. Primary hyperhidrosis primarily affects healthy individuals and is most observed in the face, axillae, soles, and palms, with axillary hyperhidrosis being the most prevalent. Secondary hyperhidrosis is caused by underlying medical condition or medications, such as pain relievers, antidepressants, and some diabetes and hormonal treatments, often resulting in generalized sweating across the body. Bromhidrosis, on the other hand, is characterized by offensive body odor due to hyperactive apocrine glands, often manifesting after puberty. Similar to hyperhidrosis, bromhidrosis can be localized or generalized, with axillary bromhidrosis (armpit odor) being the most ordinary form. The level of malodor considered to be excessive and sufficient to diagnose is inconstant in each patient. Sometimes, hyperhidrosis and/or bromhidrosis can lead to chromhidrosis.^{1,2}

In many years, the standard treatment for axillary hyperhidrosis consists of temporary solutions such as topical (antiperspirants and deodorants, botulinum toxin A injection, surgical interventions, sympathectomy) and alongside systemic treatment such as antihypertensives, psychoactive agents, oral anticholinergics.³ However, patients prefer non-invasive treatments with long-term efficacy as well as limited downtime and side effects.

In recent years, MWT has gained prominence as a treatment for axillary hyperhidrosis and bromhidrosis.⁴ The device offers a variable efficacy profile for axillary hyperhidrosis and/or bromhidrosis that may be permanent. According to the manufacturer, treating axillary hyperhidrosis and/or bromhidrosis by MWT has become a promising new method. MWT uses a non-invasive handheld device to deliver precisely controlled electromagnetic energy to the targeted area where sweat glands are found.

The treatment is considered to target both the eccrine and apocrine, so, the treatment is hoped to reduce both sweat and odor.^{5,6} However, there is not any unified protocol for treatment of hyperhidrosis and/or bromhidrosis by MWT. Normally, the patient needs to receive 2 times treatment on average with a higher price. This study was conducted to evaluate the effectiveness and safety of double-pass MWT treatment with the highest energy level (5/5 level) in only one session compared with standard protocol.

2. MATERIALS AND METHODS

2.1. Study subjects

50 patients with a diagnosis of primary axillary hyperhidrosis with/without bromhidrosis were enrolled in the study. Inclusion criteria were ≥ 18 years old who met the primary standard diagnostic criteria for hyperhidrosis with/without bromhidrosis at National Hospital of Dermatology and Venereology from 6/2022 to 6/2023 and agreed to be treated by microwave device (Miradry system) with modified protocol. Exclusion criteria were having swelling or inflammation on the armpits/having pacemakers or other electronic implants/patients with a history of allergic reactions to topical anesthetics (lidocaine or epinephrine). All patients signed an informed consent form that was approved by the Ethics Committee prior to the treatment.

2.2. Study methods

Study design

This is an uncontrolled clinical trial.

Materials

MiraDry system is the first and only FDA-cleared treatment for bothersome under sweat, hair and odor. The miraDry system's unique miraWave technology delivers precise microwave

energy at the derma-fat interface, to safely heat and destroy sweat and odor glands and hair follicles. The miraDry system is composed of console, hand piece and bioTip. The console play key role in displaying treatment options and guide implementation. The main role of the handpiece is to isolate the skin area to be treated by suction, then emit microwaves and cool the skin surface. BioTip is a replacement part of the handle that allows microwaves to pass through and ensures sterility. BioTip is used once per treatment. (*Figure 1*)

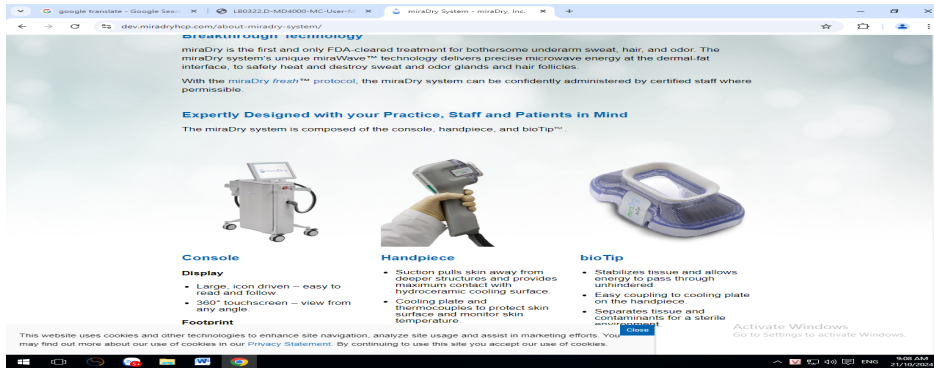


Figure 1. MiraDry system parts

Procedures

Patients were placed in the supine position and arms were abducted to about 90 degree. The treatment's area was marked by the special tools before the treatment after using Minor's test. The minor test⁷, or the iodine-starch test, is an important tool for clinical evaluation of hyperhidrosis based on starch reaction mechanism and follows the 4 steps as shown in *Figure 2*.

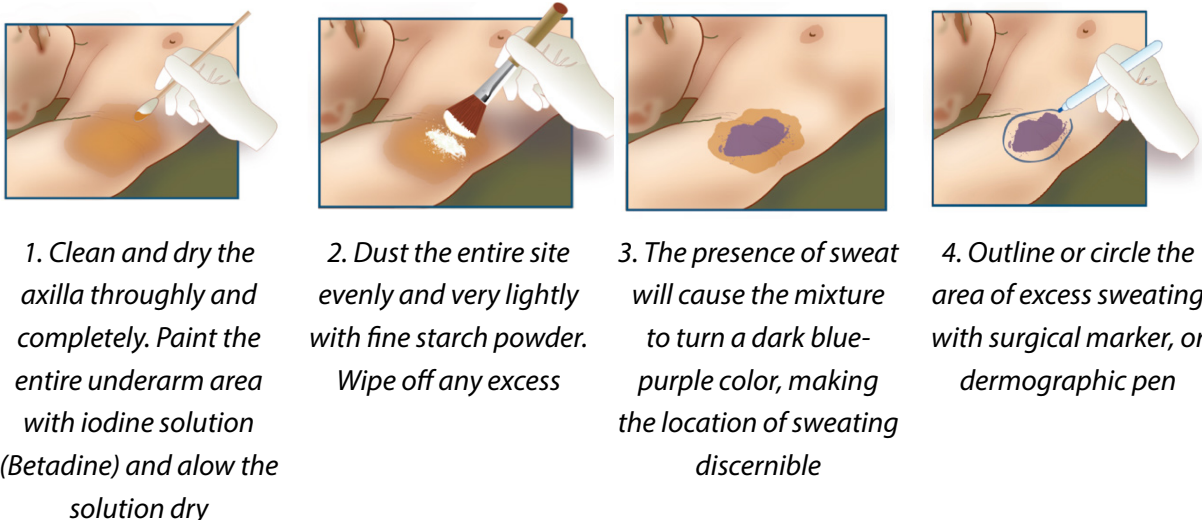


Figure 2. Minor's test procedure to determine the treatment area



After regular sterilization of the area, local anesthesia was given using 0.5% lidocaine with 1:200,000 epinephrine (tumescent solution). The amount of tumescent solution in the upper part was double.

Each armpit was treated by a miraDry system using the bioTyp two times (double-pass protocol) with highest energy level (5/5 level). The first pass, patients received standard procedures according to the manufacturer. Armpits were cooled

immediately after that. Next step was patients receiving a second pass with a half of points and the handpiece was rotated perpendicularly to the first pass (*Figure 3*). Cold compress was applied for both armpits in 15 minutes after finishing the procedure. All patients were given anti-inflammatory (ibuprofen 200 mg twice per day) and painkillers (paracetamol 500 mg in need) in 7 days. Patients were followed up 1 week, 1 month and 6 months after treatment.



The first pass according to the manufacturer's instructions



The second pass in the direction perpendicular to the first pass

Figure 3. Double-pass protocol for treatment of axillary hyperhidrosis and bromhidrosis
Axillary hyperhidrosis and bromhidrosis assessment (PROMs)

Axillary hyperhidrosis was assessed using the Hyperhidrosis Disease Severity Scale (HDSS) scale, which classifies severity into four levels: Mild, moderate, severe, and intolerable. The impact of hyperhidrosis symptoms on quality of life before and after treatment using Dermatologic Life Quality Index (DLQI) scale.^{1,8} The quality of life was assessed using the modified Dermatology Life Quality Index, which includes a 10-item questionnaire aiming to measure the effects of skin problems on usual life. There were four answers for every question: "not at all," "mild," "moderate," or "severe", with corresponding scores

of 0, 1, 2, and 3, respectively. Total scores ranged from 0 to 30, with higher scores showing a lower quality of life. Axillary bromhidrosis was assessed using the axillary odor severity grading VAS from 1 to 10 point,^{3,9} where 1 represents no odor at all and 10 represents very severe odor. The results of malodor elimination were graded by the patients as excellent, good, fair, and poor. Elimination of sweating was evaluated using the Hyperhidrosis Disease Severity Scale (HDSS).^{3,10} Overall patient satisfaction with treatment was assessed on a 3-statement Likert scale: "Satisfied", "Indecisive" or "Not satisfied".

Adverse events (Aes) and local skin reactions

AEs and local skin reactions were reported during the procedure, immediately after the procedure, on 1 week, 1-month follow-up (1M FU) and 6-months follow-up (6M FU).

Statistical analysis

Statistical analysis was performed using non-parametric tests, with statistical significance at the 95% confidence level ($p < 0.05$). The calculations were performed using the SPSS 20.0 and Excel 2019. Statistical comparisons for qualitative variables within the same group used the McNemar's test; comparisons between two groups used the Chi-square test, with Fisher's exact test applied if the expected value was less than 5. For quantitative variables, T-tests were used to compare means between two independent samples.

2.3. Ethics

Personal information of patients was kept confidential and used solely for the purpose of this study, in accordance with the 2013 Helsinki guidelines. This study was approved by the National Hospital of Dermatology and Venereology and was reviewed by the hospital's ethics committee.

3. RESULTS

3.1. Patients characteristics

A total of 50 patients with primary hyperhidrosis and concomitant bromhidrosis were included and demographic information is shown in *Table 1*.

Table 1. Demographic characteristics for the 50 subjects

Characteristic	Value
Age, median (range)	31.1 ± 8.8 (18 - 49)
Sex, n (%)	
Male	10 (20)
Female	40 (80)
Body mass index, average, kg/m2	21.23
Career	
Indoor jobs, n (%)	41 (82%)
Outdoor jobs, n (%)	9 (18%)

3.2. Bromhidrosis evaluation

At baseline, patients reported an OS score of median 7, ranging from 3 to 9 score. Baseline and follow-up OS scores are presented in detail in *Table 2*. At 1M FU, OS scores were decreased from 7 to 2 compared with baseline ($p < 0.001$). The delta reduction was a median of 5 points. At 6M FU, there was no difference with the outcome which was reported at 1M FU.

Table 2. Patient-reported odor and sweat reduction after 1M FU and 6M FU

Outcome assessment	Patient-reported odor OS (1-10)	Patient-reported sweat HDSS (1-4)
Baseline (n = 50)		
Baseline median score	7 (3 - 9)	4 (2 - 4)
1M FU (n = 50)		
1M FU median score	2 (1 - 6)	1 (1 - 3)
p*-value baseline vs 1M FU	< 0.001	< 0.001
Delta median reduction	5	2
6M FU (n = 50)		
6M FU median score	2 (1 - 6)	1 (1 - 3)
p*-value baseline vs 6M FU	< 0.001	< 0.001
Delta median reduction	5	2
*Fisher's extract test.		

The improving malodor level after treatment was presented in Table 3. After treatment (1M FU and 6M FU), there were 70% of patients had excellent and good improvement of malodor elimination; 28% of patients had fair result and only 1 patient had poor result

Table 3. Malodor elimination level after treatment

Improving malodor level after treatment	1-month follow-up		6-months follow-up	
	n	%	n	%
Excellent (neither patients nor close people are aware of malodor)	20	40.0	20	40.0
Good (very marked improvement and minimal malodor sometimes occurs during heavy activities)	15	30.0	15	30.0
Fair (marked improvement but can be aware of light malodor by patients/close people during daily activities)	14	28.0	14	28.0
Poor (limited improvement, patients and close people are easily aware of malodor)	1	2.0	1	2.0

3.3. Hyperhidrosis evaluation

At baseline, patients reported an HDSS score of median 4, ranging from 2 to 4 score. Baseline and follow-up OS scores are presented in detail in *Table 4*. At 1M FU, HDSS scores reduce significantly from 4 to 1 compared with baseline ($p < 0.001$). The delta reduction was a median of 2 points. At 6M FU, there was no difference with the outcome which was reported at 1M FU.

The elimination of sweating after treatment was presented in *Table 4*. At baseline, 90% of patients were affected by increased sweating to daily activities (HDSS ≥ 2 points), among them, 52% were intolerable and always interfered with daily activities (4 points). After 1M FU and 6M FU, no patients felt intolerable (4 points) and 72% of patients were no longer affected by sweating.

Table 4. HDSS score at baseline, 1 month and 6 months follow-up (n = 50)

HDSS score	Patient's assessment	Baseline		1-month follow-up		6-months follow-up	
		n	%	n	%	n	%
1	Never noticeable and never interferes with daily activities	0	0	36	72	36	72
2	Tolerable but sometimes interferes with daily activities	5	10	12	24	12	24
3	Barely tolerable and frequently interferes with daily activities	19	38	2	4.0	2	4.0
4	Intolerable and always interferes with daily activities	26	52	0	0	0	0

3.4. Quality of life

The change in overall DLQI scores throughout the study is presented in *Figure 4*. Overall, patients reported a severe negative impact of axillary hyperhidrosis and bromhidrosis on their quality of life with a baseline DLQI score of median 21 and a range between 6 and 25, with moderate to extremely large effect on patient's life.

Following MWT treatment with double-pass protocol, the negative impact of axillary hyperhidrosis and bromhidrosis was significantly improved. After 1M FU, patients reported an improvement in QoL compared with baseline with DLQI score median 2.5 , ranging from 0 to 17 ($p < 0.001$). After 6M FU, QoL maintained the outcome after treatment similar to after 1M FU. The delta reduction was a median of 11 points.

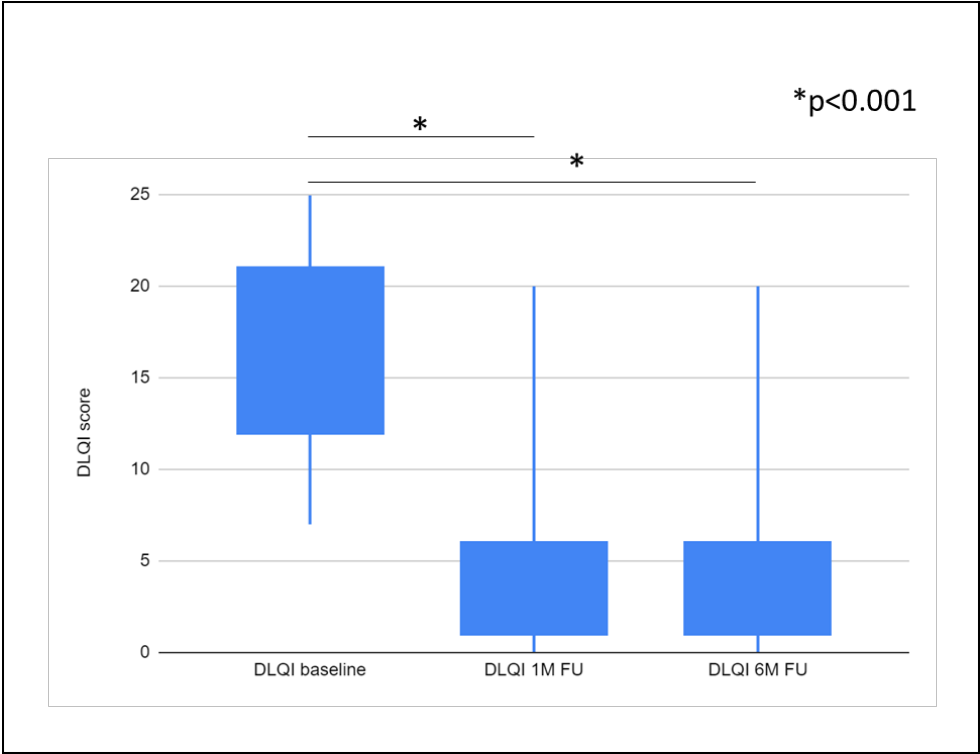


Figure 4. DLQI of patients at baseline, 1-month and 6-months follow-up

3.5. Adverse events

Pain is the most common side effect during the procedure caused by local anesthetic injection. Pain with the low to moderate level. There were no cases reported of more pain when carrying the second-pass. No patients complain about pain during microwave treatment after local anesthetic. Adverse events after procedure after 7 days, 1M FU and 6M FU were presented in Table 5. Seven days after the procedure, 100% patients reported swelling of armpit and area surroundings, 56% still complain about the pain with low levels. Dysesthesia was reported in 5 patients. 76% patients maintained the

subcutaneous hemorrhage after 7 days but decreased gradually. No patients presented with systemic or local infection. After 1M FU, there were 3 cases reported dysesthesia at the inner arm, 1 case complaining about mild swelling armpit area with no impact on daily activities, 1 case presented with epithelial cyst and 1 case reported more sweating in the back. After 6M FU follow-up, there still 1 case reported about sweating more in the back. Besides, no severe side-effects of using drugs were noted and no serious or permanent adverse events of treatment were detected during the study.

Table 5. Adverse events reported at 7 days, 1M FU and 6M FU

AEs	7-days, n (%)	1M FU, n(%)	6M FU, n (%)
Pain	28 (56)	0 (0)	0 (0)
Swelling of armpit area	50 (100)	1(2)	0 (0)
Subcutaneous hemorrhage	38 (76)	0 (0)	0 (0)
Dysesthesia	5 (10%)	3(6)	0 (0)
More sweating in other parts of the body	0 (0)	1(2)	1(2)
Epithelial cyst	0 (0)	1(2)	0 (0)
Systemic/Local infection	0 (0)	0 (0)	0 (0)

3.6. Patient satisfaction

All 50 patients were asked about their satisfaction after 6 months of treatment. 84% of patients said that they were satisfied and indecisive with the treatment. There still 16% of patients were not satisfied with the treatment because of insignificant improvement (1 patient) and prolonged swelling (15 patients) (*Figure 5*).

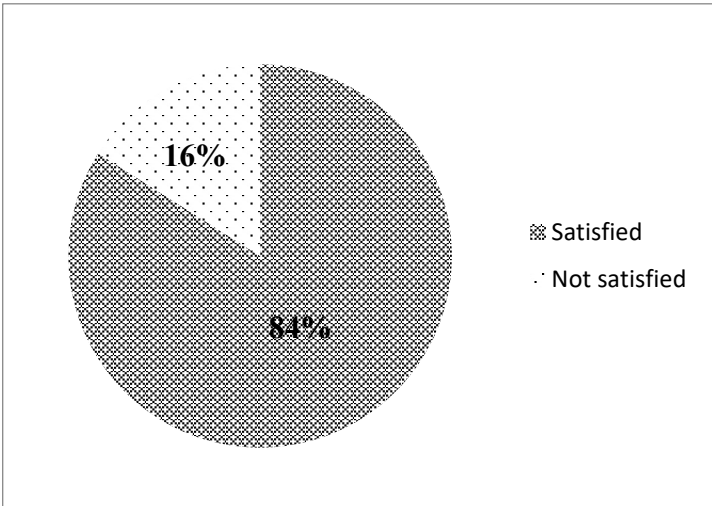


Figure 5. Patient satisfaction after double-pass microwave device (miraDry) for treating axillary hyperhidrosis and bromhidrosis



4. DISCUSSION

The clinical study shows differences in the symptoms before and after treatment of axillary hyperhidrosis and bromhidrosis using MWT (MiraDry system) by modified protocol (double-pass protocol), thus proving the effectiveness and safety of this treatment in reducing clinical symptoms.

When applying the modified protocol (double-pass) for treatment instead of the traditional way (single-pass), we were concerned about the increase of AEs and no change in the effectiveness. We were worried especially about permanent dysesthesia and longer swelling after treatment. However, no severe and permanent AEs were presented during the follow-up period. Compared with the previous study about AEs when using traditional protocol, our results have no differences. To prevent longer swelling after treatment, we applied a cool pack on the patient's armpit during, immediately and 1 week after the procedure. On the other hand, we described anti-inflammatory drugs (Ibuprofen 400 mg/day) for all patients in 1 week without any severe side effects of using drug. But there was one case that reported prolonged swelling of the armpit at 1M FU. To prevent permanent dysesthesia at the inner arm, we add more tumescent solution (double volume) at the upper part of the treatment's area which has the thinnest subcutaneous layer in order to avoid damaging medial brachial cutaneous nerves. There were 5 patients, and 3 patients reported dysesthesia at the inner arm after 1 week and 1 month, respectively. Fortunately, no patients maintain dysesthesia at 6M FU. In a report by Chang et al, numbness occurred in 4 of 7 patients irradiated at level 3, and neurological changes were observed during the histopathological assessment and this condition resolved in 1 - 3 months. In a majority of other reports on neuropathy after MWT, it took

a few months for the neuropathy to resolve.¹¹ So, neuropathy frequency in our study was familiar with previous studies using single pass. In a study by Tomoka et al, there was no histopathological damage to nerve tissue by MWT for both patient groups, one group applying double-pass and one group applying single-pass protocol if using tumescent technique instead of direct injection for local anesthesia. Because tumescent solution plays a key role in preventing nerves from microwave irradiation, especially using the highest level (5/5 level of energy) and double-pass treatment.¹²

About the effectiveness, overall, compared to baseline, a significant reduction of odor and sweat was detected which corresponds to the findings of other studies. In our study, we used PROMs to assess the treatment because this is the best way to assess the patient's satisfaction and the actual impact of the treatment on their life. Although PROMs cannot stand alone in the assessment of treatment of MWT, we only used positive gravimetric tests to locate treatment's area but did not use it to assess the effectiveness of MWT. Because patient satisfaction is still the best evaluation measure for treatment of hyperhidrosis and bromhidrosis which negatively impact on their daily life - cannot be assessed via only one test. 6 months after treatment, HDSS was reduced from a median of 4 to 1, with a median reduction of 2 points. OS was decreased from a median of 7 to 2, with a median reduction of 5 points. QoL was assessed and showed that there was a significant improvement in QoL similar to findings in previous studies. DLQI score reached a lower 5 point in median, which was a > 50% improvement from baseline median of 11. A total of 84% of patients were satisfied with the treatment. The results of treatment were still unchanged after 1 month and 6 months follow-up. These results were equivalent with the

findings of previous studies which use medium MWT two times separately.^{1,10,13}

Regarding the long-term effects of MWT, there have been studies showing the effect of changes on the histopathology of sweat glands after treatment¹⁴ and long-term results after 5 years follow-up.¹⁵ Besides, when compared with botulinum toxin (BTX) in treating sweating, the results show that MWT and BTX give equivalent results in terms of sweat reduction effectiveness, but MWT is superior in terms of odor reduction and hair removal.¹⁶

Limitations of our study include a small study sample, lack of a control group, and short follow-up period. Research with larger sample size and longer follow-up period is needed to compare the effectiveness with traditional procedures as well as other methods such as botulinum toxin injection or surgery.

5. CONCLUSIONS

The effectiveness of double-pass protocol MWT treatment (miraDry) at 1-month and 6-months follow-up was similar with the other studies which used medium two times and single-pass protocol without serious AEs reported. These things are very meaningful with patients who have low incomes. They have a higher opportunity of being cured after only one session treatment instead of having to do it twice with double price.

REFERENCES

1. Hornberger J, Grimes K, Naumann M, et al. Recognition, diagnosis, and treatment of primary focal hyperhidrosis. *J Am Acad Dermatol*. 2004;51(2):274-286. doi:10.1016/j.jaad.2003.12.029.
2. Nawrocki S, Cha J. The etiology, diagnosis, and management of hyperhidrosis: A comprehensive review: Etiology and clinical work-up. *J Am Acad Dermatol*. 2019;81(3):657-666. doi:10.1016/j.jaad.2018.12.071.
3. Grove GL, Togsverd-Bo K, Schwensen JFB, Andersson NW, Nissen CV, Zachariae C, Haedersdal M. Impact of microwave thermolysis energy levels on patient-reported outcomes for axillary hyperhidrosis and osmidrosis. *Lasers Surg Med*. 2023 Jan;55(1):105-115. doi: 10.1002/lsm.23610.
4. 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.
5. Lee SJ, Chang KY, Suh DH, Song KY, Ryu HJ. The efficacy of a microwave device for treating axillary hyperhidrosis and osmidrosis in Asians: A preliminary study. *J Cosmet Laser Ther*. 2013;15(5):255-259. doi:10.3109/14764172.2013.807114.
6. Johnson JE, O'Shaughnessy KF, Kim S. Microwave thermolysis of sweat glands. *Lasers Surg Med*. 2012;44(1):20-25. doi:10.1002/lsm.21142.
7. Hexsel D, Rodrigues TC, Soirefmann M, Zechmeister-Prado D. Recommendations for performing and evaluating the results of the minor test according to a sweating intensity visual scale. *Dermatol Surg*. 2010;36(1):120-2. doi: 10.1111/j.1524-4725.2009.01364.x.
8. Du H, Ding S, Gao L, Zeng J, Lu J. Microecological investigation and comparison of two clinical methods to evaluate axillary osmidrosis. *Mol Med Rep*. 2020 Nov;22(5):4207-4212. doi: 10.3892/mmr.2020.11528.
9. Şener S, Karakoç Y. Effects of Direct Current Administration on Hyperhidrosis Disease Severity Scale in Patients with Axillary Hyperhidrosis. *Biomed Res Int*. 2019 Oct 31;2019:3232015. doi: 10.1155/2019/3232015.



10. Yang HH, Miao Y, Chen YT, Hu ZQ. Minimally invasive approaches to axillary osmidrosis treatment: A comparison between superficial liposuction with automatic shaver curettage, subcutaneous laser treatment, and microwave-based therapy with a modified technique. *J Cosmet Dermatol*. 2019;18(2):594-601. doi: 10.1111/jocd.12731.
11. Chang YY, Chen CH, Chung-Yee Hui R, Jung SM, Yang CH. A prospective clinical and histologic study of axillary osmidrosis treated with the microwave-based device. *Dermatologica Sinica* 2015;33(3):134-141.
12. Tomoka H., Nei F. Et al. Pathological changes in axillary hyperhidrosis and axillary osmidrosis induced by microwave treatment: Comparison of single- and double- pass irradiation. *Laser in Surgery and Medicine*. 2021. 53(9): 1220-1226. doi: 10.1002/lsm.23412.
13. Nasr MW, Jabbour SF, Haber RN, Kechichian EG, El Hachem L. Comparison of microwave ablation, botulinum toxin injection, and liposuction-curettage in the treatment of axillary hyperhidrosis: A systematic review. *J Cosmet Laser Ther*. 2017;19(1):36-42. doi: 10.1080/14764172.2016.1248438.
14. Tan Y, Huang W, Liu J, Duan Z, He X, Li Q, Yang Z. The application of microwaves in axillary hyperhidrosis: Curative effect observation of a pathological examination over 1 year. *J Cosmet Dermatol*. 2024 Jan;23(1):134-140. doi: 10.1111/jocd.15909.
15. Lin MJ, Dubin DP, Genece J, Younessi S, Rai S, Khorasani H. A survey of long-term results with microwave energy device for treating axillary hyperhidrosis. *J Cosmet Laser Ther*. 2021 May 19;23(3-4):49-51. doi: 10.1080/14764172.2021.1957115.
16. Grove GL, Togsverd-Bo K, Zachariae C, Haedersdal M. Botulinum toxin A versus microwave thermolysis for primary axillary hyperhidrosis: A randomized controlled trial. *JAAD Int*. 2024 Jan 23;15:91-99. doi: 10.1016/j.jdin.2023.12.011.