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Evaluation of Efficacy and Safety of miraDry® Procedure in the Treatment of Primary Axillary Hyperhidrosis

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Abstract

Introduction Primary axillary hyperhidrosis significantly impacts the quality of life of affected individuals. miraDry®, a non-invasive local precisely controlled thermal energy procedure, represents a promising treatment option. This retrospective analysis aimed to evaluate the treatment success and patient safety following miraDry® procedure in the treatment of primary axillary hyperhidrosis.

Material and Methods A total of 139 patients receiving miraDry® procedure from 2019 to 2023 with miraDry® fresh protocol for treatment of excessive axillary hyperhidrosis were analyzed. Subjective assessment was performed before and after treatment using hyperhidrosis disease severity scale (HDSS). Minor test (iodine starch test) was done before treatment and 6 months after treatment to objectively quantify sweat severity. Patients with subjective or objective unsatisfied results after first procedure were scheduled for a second treatment.

Results The majority of treated patients (84%) could effectively be treated with one single treatment, while only 16% ($n = 22$) required a secondary intervention. HDSS after treatment completion (single and double treatment) showed a significant improvement ($p < 0.001$) in subjective evaluation of the treatment success. Minor tests demonstrated a significant reduction in sweat severity ($p < 0.001$), with 95% of patients experiencing no or minimal sweating after treatment completion. The miraDry® procedure demonstrated a favorable safety profile with typical and transient treatment reactions that mostly resolved within 6 months (94.2%)

Conclusion Our data demonstrate that miraDry® procedure is an effective and safe treatment option for primary axillary hyperhidrosis, which results in an immense improvement in quality of life and high satisfaction of affected individuals.

Level of Evidence II This journal requires that authors assign a level of evidence to each article. For a full description of these Evidence-Based Medicine ratings, please refer to the Table of Contents or the online Instructions to Authors www.springer.com/00266.

Keywords Axillary hyperhidrosis · Hyperhidrosis severity scale · HDSS · Minor test · Iodine starch test · Microwave thermolysis · miraDry®

Introduction

miraDry® is a FDA-approved non-invasive, microwave-based device for permanent-targeted treatment of primary axillary hyperhidrosis and bromhidrosis. Primary axillary hyperhidrosis represents an idiopathic condition characterized by local excessive sweating persisting independently of heat or physical exertion for at least a period of 6 months in affected individuals. Diagnostic confirmation includes the following criteria: bilateral and nearly symmetric sweating, onset of symptoms before the age of 25,

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positive family history, impairment of daily activities, and absence of sweating during sleep. Primary axillary hyperhidrosis is confirmed when two of the above listed criteria are met. However, in primary hyperhidrosis axillae, palms, soles, and craniofacial region are mainly affected [1]. In contrast, secondary hyperhidrosis can manifest either locally or in a generalized manner and is associated with an underlying medical condition or medication intake [2]. Therefore, this group of patients benefit from treatment of the responsible underlying condition. More than 90% of individuals affected by hyperhidrosis are diagnosed with primary hyperhidrosis, predominantly affecting the axillae [2, 3]. According to previous studies, the overall prevalence of axillary hyperhidrosis is approximately 1.4% [3]. Affected locations as described before are characterized by a high concentration of eccrine sweat glands. The sympathetic division of the autonomic nervous system mediates stimulation of sweat glands, with acetylcholine serving as neurotransmitter. Previous studies hypothesized that irregular sympathetic activation of eccrine sweat glands is accountable for the higher sweat production in affected individuals [4, 5].

Treatment Options for Primary Axillary Hyperhidrosis

Treatment of primary axillary hyperhidrosis consists of non-surgical (anticholinergic agents, botulinum toxin type A) or surgical approaches. These therapeutic options are constrained by the limited duration of their effects as observed in topical antiperspirants [1] and botulinum toxin injections [6] or associated with complications, efficacy concerns, and increased downtime in the case of surgical interventions like suction-curettage [7, 8] and sympathectomy [9]. Prior research indicates that patients favor treatments for axillary hyperhidrosis that is less invasive with minimal downtime and favorable functional and cosmetic outcomes [10]. Through the introduction of the microwave-based device miraDry®, a non-surgical and non-invasive therapeutic option in the treatment of primary axillary hyperhidrosis has emerged.

miraDry®

miraDry® is a FDA-approved non-invasive, microwave-based device for targeted treatment of primary axillary hyperhidrosis, reducing sweat production, odor, and hair. The procedure promises a permanent reduction in sweat severity with a low-risk profile. The mechanism of action is a selective elevation of temperature at the interface between skin and subcutaneous adipose tissue, specifically addressing the location of sweat glands, inducing their irreversible thermolysis.

Material and Methods

In this retrospective study, a total of 139 patients receiving a local precisely controlled thermal energy procedure using miraDry® for the treatment of excessive primary axillary hyperhidrosis from 2019 to 2023 at the Plastic Surgery Department of the Academic Hospital Feldkirch were analyzed.

The investigation aimed to assess the efficacy and safety of a microwave-based ablation procedure for the treatment of primary axillary hyperhidrosis using miraDry® fresh.

Assessment of Treatment Success

Subjective Assessment

Assessment of treatment success was performed using hyperhidrosis disease severity scale (HDSS) for analysis of the subjective impairment of individual's life (Table 1). HDSS was evaluated before and upon treatment completion.

Objective Assessment

Minor´s test (iodine starch test) was performed to quantify sweating severity before treatment and 6 months after treatment. All results of the minor testing were photographical documented. Analysis of the minor test was done on the photodocumentation. Hereby, the hair bearing area of the axilla was divided in quarters to receive more precise results (Fig. 1).

Primary outcome measurement of this study was the objective assessment 6 months after first treatment. Patients who showed residual sweating in more than one quarter in the minor test 6 months after treatment or reported unsatisfying subjective results were scheduled for a second treatment. Treatment completion was defined as end of treatment, when satisfying objective and subjective results were evident. The endpoint of the study was defined as treatment completion after first or second treatment. Patient data were collected retrospectively and included analysis of photodocumentation of minor testing and enquiry of HDSS in the medical documentation. Missing HDSS grades in the medical documentation were gathered by telephone interview with patients.

Treatment Process

miraDry® provides a variety of standard energy settings (Levels 1–5), each delivering higher energy doses as the level increases. In this study, patients were treated with miraDry® Fresh, defined as the highest energy level (Level

Table 1 Hyperhidrosis disease severity scale (HDSS)

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

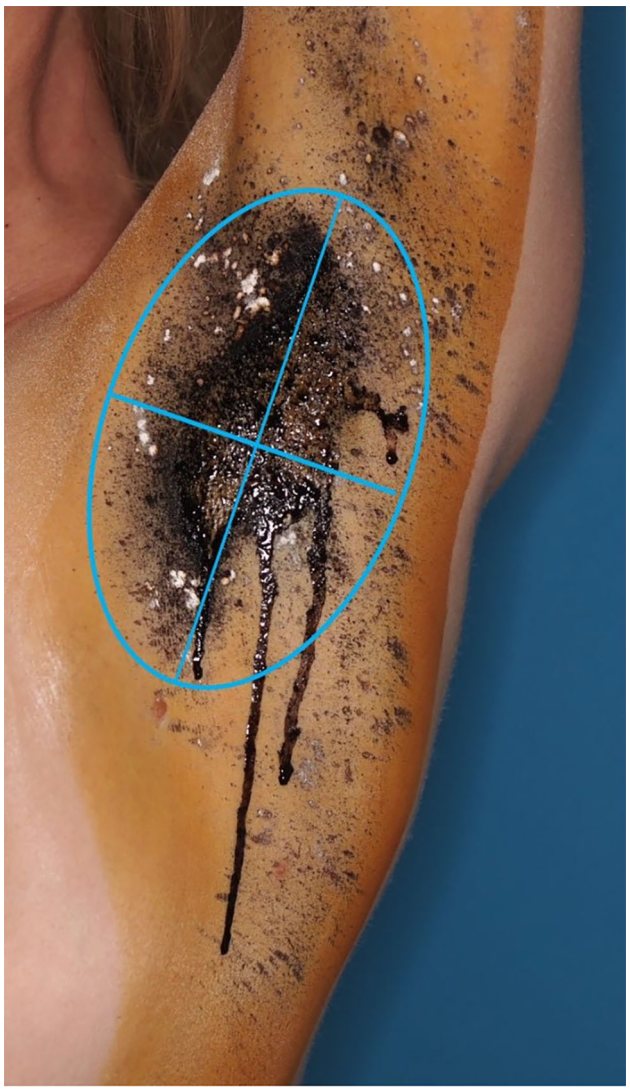

Fig. 1 Minor's test quantifying sweating severity before and 6 months after treatment, with axillary area divided into quarters for analysis

5 unlocked). Treatment was performed according to the standards and treatment process guidelines for miraDry® treatment in local anesthesia. Anti-inflammatory treatment consisted of Dexibuprofen 200 mg three times per day for 3 days after miraDry® procedure. Standard antibiotic treatment was not administered. Patients were instructed to not exercise, taking a swim or go to sauna for 1 week after treatment. In addition, shaving of the axilla was not allowed for 7-day post treatment.

Statistical Analysis

The current study aimed to identify treatment success and patient safety of locale and precisely controlled admission of thermal energy on axilla using miraDry® for the treatment of primary axillary hyperhidrosis. Data documentation and statistical analysis were performed using IBM SPSS Statistics for Windows 24.0 (IBM Corp., Armonk, NY). Descriptive statistics were calculated in the form of frequencies, mean with standard deviation (SD), or median with interquartile range (IQR, first and third quartile) as appropriate. Kendall's rank correlation was used to identify potential associations between subjective and objective evaluation of severity of preoperative sweating. To investigate treatment success, Wilcoxon signed-rank test was estimated. P-values < 0.05 were considered to indicate statistical significance.

Results

A total of 139 patients and 278 axillae receiving a local precisely controlled thermal energy procedure using miraDry® for treatment of primary axillary hyperhidrosis from 2019 to 2023 at the Plastic Surgery Department of the Academic Hospital Feldkirch were analyzed. About 43.9% (n = 61) of treated patients were male with a mean age of 41.5 years (SD, 15.5) and 56.1% (n = 78) were women with a mean age of 34.3 years (SD, 10.3). Almost 84% (n = 116) of treated patients could effectively be treated with a single treatment only. Twenty-two patients were scheduled for a second treatment, which on average was performed 14.2 months after first treatment (SD, 7.0). One patient was excluded in this study after first treatment as no follow-up data were available. This patient reported an insufficient result after miraDry® treatment and was undergone a surgical sweat gland removal in another institution.

Assessment of Treatment Success

Subjective Assessment

Before treatment patients, irrespective of gender complained about severe impairment in daily life due to increased axillary sweat production. All patients indicated high levels of HDSS (HDSS 4 $n = 90$, HDSS 3 $n = 49$) before treatment (Fig. 2). At the endpoint of this study HDSS could be reduced by 2 or 3 points in almost 60% of treated patients (Fig. 2). After treatment completion, 19.6% of treated individuals report a HDSS of 1, 63.8% HDSS of 2, and 16.7% HDSS of 3. The Wilcoxon signed-rank test showed a statistically significant difference with a smaller median of 2 (IQR, 2–2) after treatment completion in comparison with a median of 4 (IQR, 3–4) before treatment ($p < 0.001$). Therefore, a significant improvement in subjective evaluation of the treatment success and hence a symptom decrease post-treatment could be observed.

Objective Assessment

Almost 50% of individuals showed increased staining in three or more quarters in the minor test before treatment. However, the extent of sweating investigated in the preoperative minor test is not associated with the indicated HDSS before treatment (left axilla $r = -0.06$, $p = 0.41$; right axilla $r = 0.001$, $p = 0.99$).

Six months after first treatment, a statistically significant difference in the extend of axillary sweating area for both sides was found ($p < 0.001$). The post-treatment median for both sides of 0 (IQR, 0–1) indicates a meaningful reduction in the extend of axillary sweating area in comparison with the pretreatment median of 0 (IQR, 1–3).

Eighty-six percent of treated axillae showed no or minimal sweating in the minor testing 6 months after intervention (63% 0/4, 23% 1/4), as depicted in Fig. 3. Only one axilla showed heavy sweating in 4/4 areas. Sixteen percent ($n = 22$) of patients received a secondary intervention. However, only three patients presented with persisted sweating in three quarters or more. After treatment completion, significant reduction of sweating could be observed in the minor tests ($p < 0.001$), resulting in 95% of patient with no or minimal sweating and only 5% of patients having a sweating area of two quarters after treatment (Fig. 4).

Evaluation of Treatment Safety

About 73.4% of patients showed treatment reactions 2 weeks after miraDry® procedure. As demonstrated in Table 2, more than half of primary-treated axillae developed palpable nodules (62.2%) in the area of treatment, 28.4% showed axillary hyposensitivity, 6.5% had local swelling, and 3.16% showed haematoma in the treated area. Post-treatment infection could be observed in 3 axillae (1.1%) and could be successfully treated with oral antibiotics in all cases. Three months after treatment only 28% of treated patients still showed local treatment reactions. Palpable nodules were evident in 15.1% of axillae, and hyposensitivity were indicated in 13.7%. However, 6 months after intervention, most treatment reactions were fully relieved. Only eight patients had persisting symptoms 6 months after treatment. In four patients, palpable nodules could be observed in the clinical examination and four patients still reported persisting hyposensitivity. A total of 7 axillae (2.5%) were affected of persisting hyposensitivity and another 7 axillae (2.5%) of locally palpable nodules 6 months after treatment. After second treatment, palpable

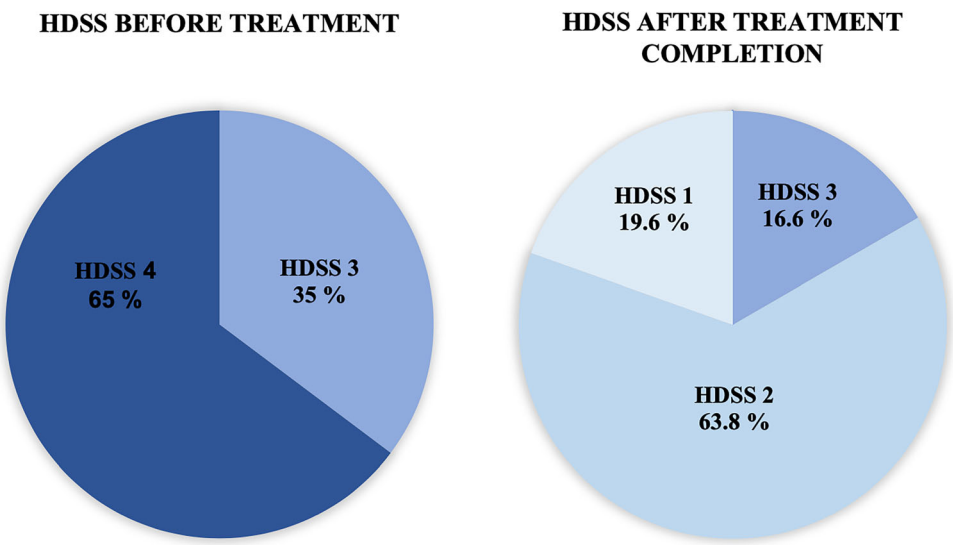

Fig. 2 HDSS before treatment and after treatment completion

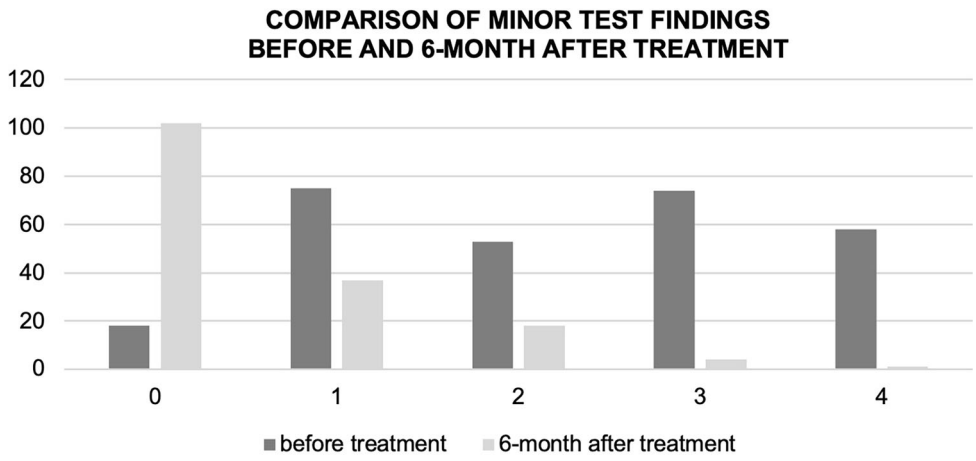

Fig. 3 Minor test findings before treatment and 6 months after treatment. Findings are documented in quarters (0 = 0/4, 1 = 1/4, 2 = 2/4, 3 = 3/4, and 4 = 4/4)

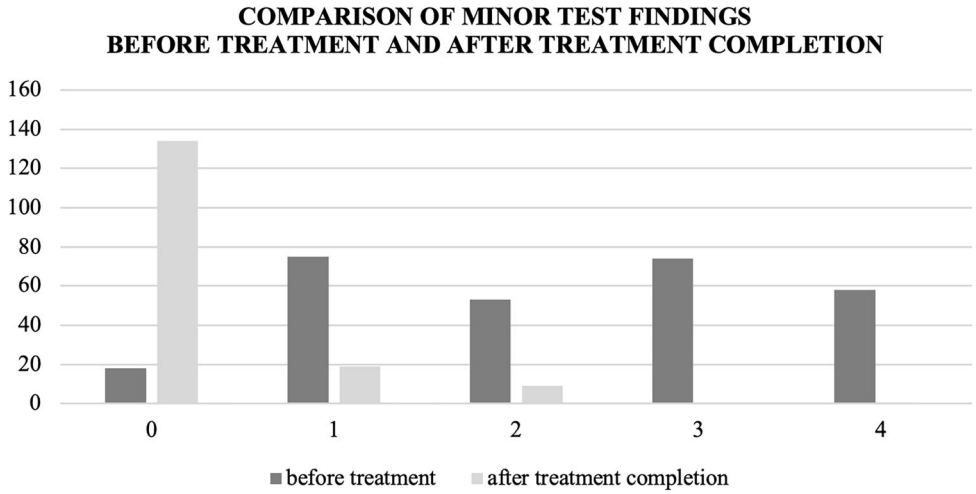

Fig. 4 Minor test findings before treatment and after treatment completion. Findings are documented in quarters (0 = 0/4, 1 = 1/4, 2 = 2/4, 3 = 3/4, and 4 = 4/4)

Table 2 Treatment reactions/complications after miraDry® procedure

Evaluation	Palpable nodules	Hyposensitivity	Swelling	Hematoma	Infection
Treatment 1 n = 278					
2-week pt* n = 278	173 (62.23%)	79 (28.42%)	18 (6.47%)	6 (2.16%)	3 (1.08%)
3-month pt n = 278	42 (15.11%)	38 (13.67%)	0	0	0
6-month pt n = 276	7 (2.52%)	7 (2.52%)	0	0	0
Treatment 2 n = 44					
2-week pt n = 44	11 (25%)	7 (15.91%)	0	0	0

* pt = post-treatment

nodules could be observed in 25% of treated axillae and hyposensitivity in 15.9% of treated axilla 2 weeks after procedure. In Table 2, treatment reactions are listed.

Discussion

Efficacy

Our data demonstrate a statistically significant difference in sweat severity with a reduction in both subjective and objective postinterventional evaluations. HDSS comparison before and after treatment completion showed a statistically significant improvement in patients' quality of life. This is consistent with the results of previous studies [11–13]. In concordance to our findings, Chih-Ho Hong et al. [14] reported that more than 90% of treated patients stated HDSS of 1 or 2 at the 12-month post-treatment assessment. Furthermore, several studies have stated a significant improvement in patients' quality of life after miraDry® for the treatment of axillary hyperhidrosis [8, 14]. Other studies have additionally integrated the 10-point Odor Scale (OS), documenting a

notable reduction in odor among participants following the microwave-based treatment [11, 15, 16].

In this study, minor test was performed to objectively evaluate sweating severity. A simplified evaluation method for physicians was applied to objectively assess outcomes by dividing the underarm area into quarters on the medical documentation. Remarkably, 6 months after first treatment, 86% of treated axillae demonstrated no or minimal sweating (63% showed no sweating = 0/4, and 23% showed minimal sweating = 1/4). This indicates that axillary hyperhidrosis can be effectively managed with a single miraDry® fresh treatment in the majority of cases. Only 22 out of 139 evaluated and treated patients required a second treatment. Overall, including these patients, 95% of treated axillae showed no or minimal sweating after the completion of the intervention, with the others having a lasting sweating area of two quarters only, resulting in a statistically significant reduction in sweat severity.

In a prospective, randomized, and blinded study conducted by Grove et al. [17], participants underwent treatment in one axilla with energy level 5 and in the other with level 3 to assess the differential outcomes associated with varying settings. Notably, treatment with the higher energy level demonstrated a statistically significant increase in efficacy for both sweat and odor reduction, as assessed by the HDSS and the OS. However, the gravimetric test which was used as objective measurement did not reveal a significant difference ($p = 0.53$) between the two energy levels at the 3-month follow-up. As reported by the authors, patients expressed a willingness to tolerate a higher incidence of temporary local skin reactions associated with the higher energy setting when experiencing greater reductions in odor and sweat. Although the study did not find more severe side effects with elevated energy levels, the small sample size ($n = 20$) may be a limitation in both.

As mentioned before, 16% of our cohort underwent a second treatment due to unsatisfying objective or subjective results 6 months after treatment. The second treatment was performed with a median time distance to the first treatment of 15 months. This indicates that results after first treatment will not improve over time. However, our rates of patients needing a secondary intervention are lower compared to findings from other studies [14, 17]. Grove et al. [17] suggest that conservative treatment with lower energy levels may increase the likelihood of requiring a second treatment, thus not reducing the overall risk of side effects.

Comparison to Botolinum Toxin Typ A and Liposuction Curettage in the Treatment of Axillary Hyperhidrosis

Botolinum Toxin Typ A (BoNT A) and Liposuction Curettage are both well-established treatment options in the treatment of axillary hyperhidrosis. The injection of BoNT A hinders the physiological process of sweating temporarily through inhibiting the release of acetylcholine from cholinergic neurons that innervate sweat glands. However, it is a well proven non-permanent treatment option for axillary hyperhidrosis resulting in a high patient satisfaction [18, 19] Following the initial treatment, the median duration of efficacy is approximately 6.7 months [6]. In contrast, microwave ablation therapy demonstrated consistent and commendable outcomes for patients extending after a 12-month period as mentioned above [14]. These data underline the superiority of miraDry® procedure regarding treatment durability.

However, studies have demonstrated a long-term effectiveness of liposuction curettage in treatment of axillary hyperhidrosis [20, 21]. Surgical removal of the axillary sweat glands is an invasive treatment option and is linked to surgery-associated side effects [22].

In a comparative study of liposuction curettage (LC) and microwave-based therapy for the treatment of osmidrosis, microwave therapy showed minimal downtime, low recurrence rates and was associated with fewer complications compared to LC, where hematoma and permanent subcutaneous contracture or scarring were the most common significant complications [8].

Safety

Our data showed that reactions immediately after treatment are typical but self-limiting over time. Typical reactions after treatment are palpable axillary nodules, swelling, and local hyposensitivity, which to a great extent dissolve within 3 to 6 months after treatment. In addition, no long-term complications requiring treatment could be observed in our study population. Another study applying the highest energy level reported only transient side effects after 6 months [13]. Hong HC et al. [14] and Glaser et al. [12] in concordance to our data report sensitivity disorders and palpable axillary nodules as predominant adverse effects. Notably, these side effects were observed to be mild and transient, resolving completely in each case within our study, aligning consistently with the outcomes documented in previous studies [11, 17].

Chang et al. [23] documented a rare case of a severely underweight female (BMI 15.2) treated at energy level 5 who did not fully recover after 6 months, experiencing motor and sensory nerve dysfunction of the brachial plexus. Kaminaka et al. [13] noted that skinny patients with lower fat tissue in the underarm areas are more prone to complications, regardless of gender. They recommend using a low energy level with high-volume fluid anesthesia for underweight patients.

Limitations: Our study reports data of a limited number of study participants and a limited follow-up timeframe. In addition, treatment results of a single center were revealed and data collection was performed retrospectively.

Further studies investigating treatment outcomes in a longer follow-up time will be needed.

Conclusion

The majority of patients were effectively treated with one single miraDry® procedure, with the remaining patients successfully treated with a second session. After treatment completion, a statistically significant reduction in sweating was observed in the Minor's test, with 95% of patients experiencing no or minimal sweating. HDSS evaluations indicated a significant improvement in the quality of life for treated patients. Mild, typical reactions occurred immediately after treatment but resolved over time, and no long-term complications requiring further treatment were observed. Therefore, we conclude that the miraDry® procedure is an effective and safe treatment option for axillary hyperhidrosis, resulting in substantial quality of life improvement for affected individuals and therefore a high patient satisfaction.

Declarations

Conflict of interest The authors declare that they have no conflict of interest to disclose.

Ethical Approval The study was conducted in accordance with the Ethical Standards of the Institutional and/or National Research Committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Informed Consent Participants gave informed consent for the treatment process. Data were collected retrospectively from medical documentation.

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