Safety and Efficacy of High Intensity Focused Ultrasound for the Treatment of Primary Axillary Hyperhidrosis

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Abstract

Background

Hyperhidrosis is excessive perspiration and associated with negative impact on quality of life. Recently, High-intensity focused ultrasound(HIFU) has been used for the treatment of hyperhidrosis.

Objective

The present study focused on the clinical effectiveness and safety of V-RO 2.0(NEW DOUBLO 2.0) for the improvement of axillary hyperhidrosis.

Methods

Twelve patients with axillary hyperhidrosis were evaluated. Patients were treated with HIFU (V-RO 2.0(NEW DOUBLO 2.0), Hironic Co.), HIFU treatment procedure was performed on both armpits using a 4MHz transducer with a focal depth of 4.5mm at energy level of 1.20 J/cm^2 followed by a 7MHz transducer with a focal depth of 3mm at energy level of 0.45 J/cm^2. After the procedure, the subjects were conducted the subjective satisfaction assessment and iodine-starch test.

Results

After the treatment, Subjects who answered that the subjective satisfaction of the entire target group was Fair(25%) or higher showed high patient satisfaction at 83.3% (Excellent: 2 (13.6%), Good: 5 (50%), Fair: 3 (25%), Poor: 2 (13.6%)), and no specific side effects were observed.

KEYWORDS

bipolar radiofrequency, high intensity focused ultrasound, axillary hyperhidrosis

Introduction

Hyperhidrosis is characterized by perspiration in excess of the physiological amount necessary to maintain thermal homeostasis.[1] All forms of hyperhidrosis are associated with physical discomfort and social embarrassment and have an overall negative impact on quality of life.[2]

A large number of therapeutic options are used for the treatment of primary hyperhidrosis. These include application of topical agents, iontophoresis, sympathectomy and botulinum toxin injection.[3] High-intensity focused ultrasound (HIFU) has been used for the treatment of benign and malignant tumors for several years. And recently have been used for noninvasive correction of skin laxity and nonsurgical skin tightening with minimal downtime.[4]

HIFU induces vibration at the molecular level, which generates thermal energy and eventually forms

a thermal coagulation zone in the superficial muscular aponeurotic system (SMAS). It is different from other procedures in that the thermal lesion is found in the deep dermal tissue without damage to the superficial portion of the skin structure. The focused ultrasonic energy causes a contraction of the SMAS as well as a denaturation and remodeling of the targeted collagen fibers resulting in neocollagenesis, effects of which will result in significant skin tightening as well as a lifting of the targeted tissues.[5]

Recent study evaluated the safety, efficacy, and durability of treating axillary hyperhidrosis with High-intensity focused ultrasound (HIFU). Resulted in significant reductions in sweat production and patients reported high levels of satisfaction with the results they achieved with minor discomfort during treatment.[6]

Figure 1. V-RO LIFTING 2.0(NEW DOUBLO 2.0) (Hironic Corp., Ltd., South Korea)

V-RO LIFTING 2.0(NEW DOUBLO 2.0) is a newly developed combination device RF technology with HIFU equipment (Figure 1). HIFU, RF, and microneedle RF technology are installed in one device and up to 5 handpieces including two FL (Focused Linear) handpieces, two SD (Synergy Dotting) handpieces, and one RM (Microneedle RF) handpiece can be connected. The FL handpiece is linearly irradiated to a depth of 4.5mm, 3.0mm, 2.0mm, and 1.5mm of the target tissue as the thermal coagulation point of HIFU occurs sequentially. The present study focused on the clinical effectiveness and safety of V-RO 2.0 for the improvement of axillary hyperhidrosis.

Subjects and Methods

1. Subjects

From July to September 2023, the treatment was conducted on patients with primary hyperhidrosis who visited the Dr. Kim's Skin & Laser clinic (Suwon, South Korea). Through the detailed history taking, twelve subjects (7 males and 5 females) aged 22-45 1) exacerbated by emotional factors, 2) didn't have any other concomitant diseases, and 3) complained of social or occupational disabilities, years with primary hyperhidrosis were enrolled. All subjects provided written informed consent prior to the study. Subjects who are currently pregnant, breast feeding and patients with chronic illness were excluded.

2. Method

Patients suffering from axillary primary hyperhidrosis were treated with topical anesthetic cream (9.6% Lidocaine cream; Ostin Pharmaceutical Co., South Korea) 30 minutes before the HIFU procedure was performed on both armpits. Patients undergoing V-RO 2.0(NEW DOUBLO 2.0) were initially treated using a 4MHz transducer with a focal depth of 4.5mm at energy level of 1.20 J/cm2 followed by a 7MHz transducer with a focal depth of 3mm at energy level of 0.45 J/cm2.
Using the 4MHz transducer, each 25mm^2 square was exposed to 20 lines of V-RO 2.0(NEW DOUBLO 2.0) placed 2 to 3mm apart, each line requiring about two seconds to treat. The investigator continued treatment by making a second pass using the 7MHz transducer in the same manner.

3. Assessment

After the procedure, the subjects were conducted following up at the hospital and asked to take the subjective satisfaction assessment. Subjective satisfaction assessment was analyzed with 5 levels, Excellent (=>75%), Good (50-75%), Fair (25-50%), Poor (=<25%), None (no improvement). Among them, an iodine-starch test(IST) was conducted with one of patients who was enrolled No.10. Measurements were taken at baseline, immediately after treatment, and 2weeks post-treatment to evaluate the efficacy with HIFU treatment were analyzed by using iodine-starch test. As an objective test useful for diagnosing hyperhidrosis, we can measure the degree of sweat secretion by applying a 2% iodine solution to the area of hyperhidrosis, spraying starch evenly five minutes after drying up, and observing the degree of discoloration to black. There is process of the iodine-starch test is subjective test. (Figure 2)

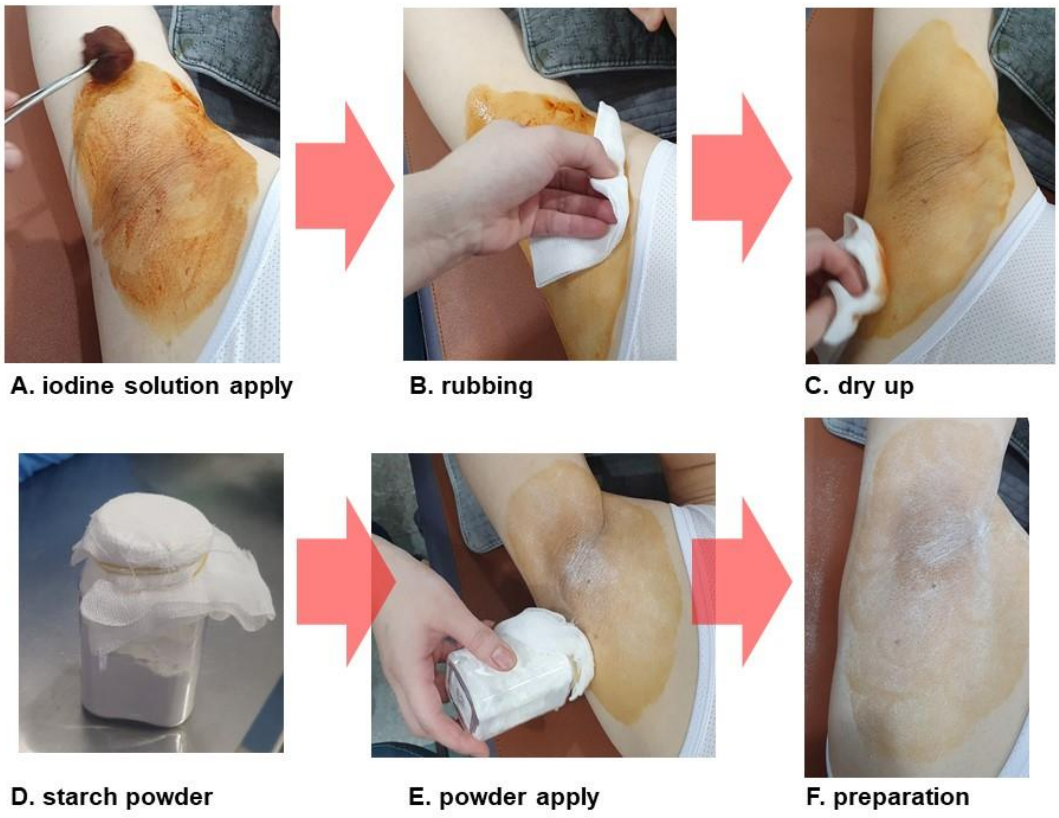

Figure 2. Iodine-starch test for primary axillary hyperhidrosis (Patient enrolled No.10, M/42)

Result

Twelve subjects (7 males and 5 females) aged 22-45 years (mean age: 32.58 years) with primary hyperhidrosis were finished the study. All 12 people performed the subjective assessment after 2 weeks post-treatment. One of subjects enrolled No.10 was asked to took IST. No specific side effects were observed for subjects, and no complained of discomfort other than slight pain during the procedure. (Table 1, 2)

Case	Sex/Age	Results	Complications
Case 1	F/35	Good	None
Case 2	M/25	Fair	None
Case 3	F/26	Fair	None
Case 4	M/23	Good	None
Case 5	M/22	Poor	None
Case 6	F/42	Good	None
Case 7	M/33	Good	None
Case 8	F/45	Poor	None
Case 9	M/32	Fair	None
Case 10	M/42	Excellent	None
Case 11	M/36	Fair	None

Case 12	F/30	Good	None

Table 1. Results of the subjective assessment of axillary sweating

Result	No of patient
Excellent (=>75%)	2 (13.6%)
Good (50-75%)	5 (50%)
Fair (25-50%)	3 (25%)
Poor (=<25%)	2 (13.6%)
None (no improvement)	0 (0%)

Table 2. Axillary hyperhidrosis Patient satisfaction with V-Ro 2.0 treatment

After the treatment, Subjective satisfaction was shown and no improvement was observed. Excellent: 2 (13.6%), Good: 5 (50%), Fair: 3 (25%), Poor: 2 (13.6%). Subjects who answered that the subjective satisfaction of the entire target group was Fair(25%) or higher showed high patient satisfaction at 83.3%.

In Figure 3B, IST was conducted with primary axillary hyperhidrosis patient, enrolled No. 10 by using V-RO 2.0(NEW DOUBLO 2.0).(Figure 3) In Figure 3, there can be a partial increase in sweat is partially increased. With the IST findings performed after the V-RO treatment on the axillary hyperhidrosis area (Figure 3C), it can be seen that the sweat production decreased significantly after 2 weeks(Figure 3C) compared to the pre-procedure (Figure 3B).

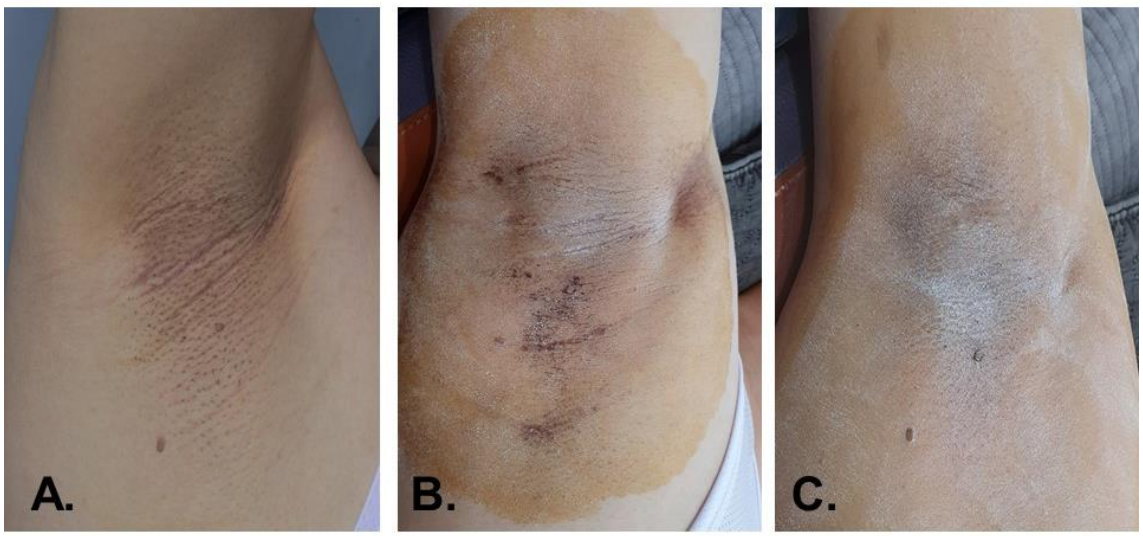

Figure 3. Iodine-Starch Test (IST), methods. A. Baseline (before V-RO 2.0 treatment). B. Baseline IST (before V-RO 2.0(NEW DOUBLO 2.0) treatment). C. IST, 2 weeks after V-RO 2.0(NEW DOUBLO 2.0) treatment

Discussion

primary hyperhidrosis has a prevalence rate of 0.6-1.0% among young adults and causes social atrophy and occupational disorders, including daily life. Among the various treatments for primary hyperhidrosis, except for topical applicants, electrical treatment using ion-phoresis passes ions or salts through the body using electric flow, and is known to have a good effect on the head and plantar hyperhidrosis, but it can cause difficulties in operation or unpleasant irritation. Surgical treatment, that is, chest sympathectomy using thoracic endoscopy, is performed only when it does not respond to other treatments and reports good postoperative treatment results, but side effects of pneumothorax, pneumonia, and compensory hyperhidrosis can occur, and rather, discomfort in daily life following infinity can occur.

The recently implemented Botulinum toxin intracellular injection acts on cholinergic nerve endings to inhibit the secretion of acetyl choline, and in hyperhidrosis, it is known to show the action by suppressing the pain of sympathetic nerves, pain during drug injection, discomfort to be performed periodically, and many other conditions should be considered each time.[8]

A microwave device has also been evaluated for treating axillary hyperhidrosis.[9] It has been reported to produce long-lasting results, but the incidence of adverse events is high.[10]

Recent study evaluated the safety, efficacy, and durability of treating axillary hyperhidrosis with High-intensity focused ultrasound (HIFU). Resulted in significant reductions in sweat production and patients reported high levels of satisfaction with the results they achieved with minor discomfort during treatment.[6]

V-RO LIFTING 2.0(NEW DOUBLO 2.0)) is a newly developed combination device RF technology with HIFU equipment. HIFU, RF, and microneedle RF technology are installed in one device and up to 5 handpieces including two FL (Focused Linear) handpieces, two SD(Synergy Dotting) handpieces, and one RM(Microneedle RF) handpiece can be connected. It is reducing the time for replacing consumables and enabling faster treatment.

The FL handpiece is linearly irradiated to a depth of 4.5mm, 3.0mm, 2.0mm, and 1.5mm of the target tissue as the thermal coagulation point of HIFU occurs sequentially. Cartridges according to each depth can be exchanged quickly and easily.

SD handpiece is different from general HIFU device. It is characterized in that HIFU and RF are combined in one handpiece. Bipolar RF is irradiated for a short time and HIFU follows immediately afterward.

The SD handpiece can obtain a synergistic effect simultaneously showing each effect by sequentially irradiating bipolar RF, which is known to be effective in skin regeneration, and HIFU, which forms thermal coagulation. (Figure 4)

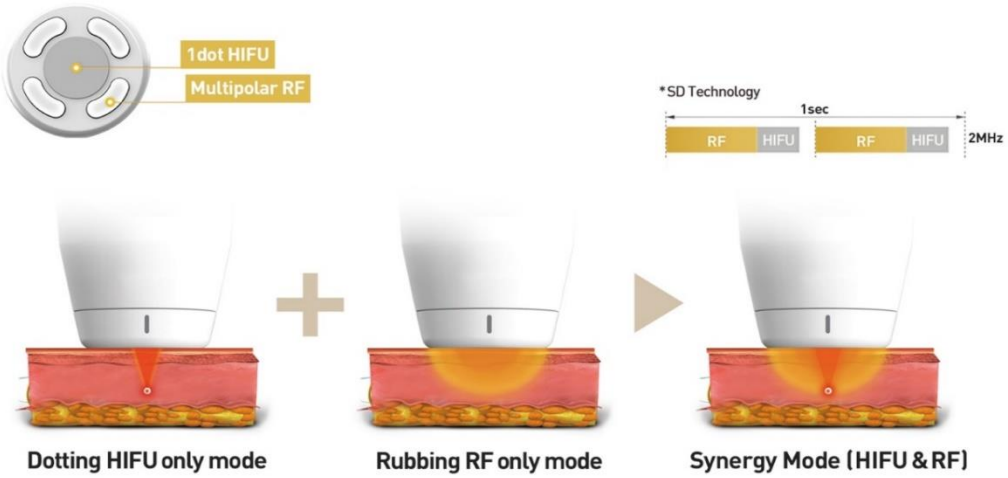

Figure 4. Schematic view of Synergy effect (single dot HIFU and RF). SD (Synergy Dotting) handpiece is composed with single dot HIFU and RF.

There is a report 'Efficacy of single dot ultrasound combined with radiofrequency for low eyelid laxity'.[11] Using the SD handpiece of V-RO 2.0(NEW DOUBLO 2.0) has the advantage of minimizing side effects and enabling precise treatment, resulted in improvement of low eyelid blepharoptosis.
In this study, the authors experienced that the primary axillary hyperhidrosis could be effectively treated using V-RO 2.0(NEW DOUBLO 2.0)'s FL(Focused Linear) handpiece. Pain during the treatment was sufficient to withstand with topical anesthetic cream, and no other general anesthesia was required.
Except for some pain during the procedure, no patients complained of any specific side effects even after the procedure.
Taken together, it is judged to be a safe, simple, and effective method compared to other existing treatment methods. In addition, significant positive satiation was obtained even with a single procedure, but it seems that maintenance treatment will have a better effect, and future research in needed.

Conclusion

The treatment of primary axillary hyperhidrosis using V-RO LIFTING 2.0(NEW DOUBLO 2.0) is a very simple, effective, and safe treatment method. A single procedure can have a significant effect.
Compared to other existing treatment methods, it is safe and has no significant side effects, and is expected to be widely used in primary axillary hyperhidrosis in the future.

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