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Clinical Effects of Capacitive Electric Transfer Hyperthermia Therapy for Lumbago

KUNIYASU TAKAHASHI, MD, PhD[1)], TETSUO SUYAMA, MD, PhD[1)], MAKIKO ONODERA, PT[1)], SHIGERU HIRABAYASHI, MD, PhD[2)], NOBUYUKI TSUZUKI, MD, PhD[2)], LI ZHONG-SHI, MD, PhD[2)]

[1)]*Department of Rehabilitation, Saitama Medical Center, Saitama Medical School, Kamoda-Tsujidoumachi 1981, Kawagoe City, Saitama 350-8550, Japan. TEL +81 492-28-3690*
[2)]*Department of Orthopaedic Surgery, Saitama Medical Center, Saitama Medical School*

Abstract. We conducted physical therapy for patients suffering from lumbago (n=37) with high-frequency hyperthermia equipment by a capacitive electric transfer method, MD-303 (0.65 ± 0.05 MHz), which is employed in Europe and America. The 37 patients comprised 13 with lumbar spondylosis deformans, 7 with lumbar spinal canal stenosis, 5 with lumbar disc herniation, 4 with lumbar spondylolysis/spondylolisthesis, 4 with lumbar discopathy, and 4 with other diseases accompanied by lumbago. The electricity was used 10 times in total, for 20 minutes per time. A rise in skin temperature was observed even 15 minutes after treatment, with no occurrence of adverse reactions, and this therapy was highly effective in relieving pain, with an efficacy rate of 81.1%. This paper reports the results of the use of this therapy.
Key words: Lumbago, Physical therapy, Capacitive electric transfer.

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INTRODUCTION

Various types of physiotherapeutic equipment are used in Japan. However, little use is made of high-frequency-range hyperthermia equipment. We used hyperthermia equipment with a radio frequency, particularly the middle frequency range, for the treatment of various diseases involving lumbago. This paper mainly describes the results of use of this therapy, with an overview of relevant publications.

METHODS

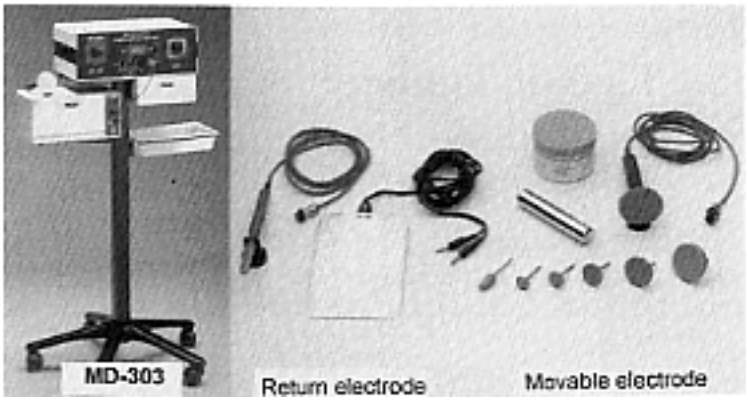
1. Subjects

Thirty-seven patients with lumbago for whom electrotherapy was not contraindicated were enrolled in this study. The 37 patients consisted of 27 females and 10 males, with a mean age of 60.9 years (range, 28 to 85 years old).

The patients suffered from the following diseases: lumbar spondylosis deformans (13), lumbar spinal canal stenosis (7), lumbar disc herniation (5), lumbar spondylolysis/spondylolisthesis (4), lumbar discopathy (4), "lumbago" (3), and lumbar spine sprain (1) (Table 1).

Table 1. Patients

	N.O
Lumbar spondylosis deformans	13
Lumbar spinal canal stenosis	7
Lumbar disc herniation	5
Lumbar spondylolysis/spondylolisthesis	4
Lumbar discopathy	4
"Lumbago"	3
Lumbar spine sprain	1
Total	37



General Characteristics

Frequency	0.65 ± 0.05 MHz
Output Power	140 W
Maximum Capacity of Electrode	400 pF
Required Voltage	100 V
Required Frequency	50/60 Hz
Required Input Power	320 W
Dimensions	602 × 430 × 170 mm
Weight	13.5 kg

Fig. 1. Hyperthermia equipment MD-303
Return electrode: A planar electrode was used for the abdomen of the patient with lumbago. Movable electrode: An electrode of 60 mm diameter was used for the patient with lumbago.

Table 2. Symptom severity classification standards

Grade	Severity of symptoms
4	Daily life is extremely limited, with findings of intolerable symptoms (pain, numbness, limited movement, etc.)
3	Daily life is very limited, with findings of severe symptoms (pain, numbness, limited movement, etc.)
2	Daily life is moderately limited, with findings of moderate symptoms (pain, numbness, limited movement, etc.)
1	Daily life is slightly limited, with findings of slight symptoms (pain, numbness, limited movement, etc.)
0	No limit to daily life is observed, with no findings of symptoms (pain, numbness, limited movement, etc.)

2. Equipment used and manner of electricity usage

The appearance of and specifications for high-frequency hyperthermia equipment, MD-303, are shown in Fig. 1. Hyperthermia therapy was conducted for 20 min once daily, 10 times in total. Therapeutic efficacy was evaluated in terms of improvement in post-treatment symptoms from pretreatment symptoms. No other therapies that might affect the therapeutic efficacy judgment were conducted. It was decided not to change the medication the patients had been receiving before the study. Therapies and medication conducted for diseases other than the target diseases of the study were continued, unless they affected the present assessment.

A 60 mm movable electrode was used for the affected site, and a planar electrode was used as a return electrode for the abdomen.

The electricity was used in the following manner: Paste was applied to the site with the severest pain and its adjacent area, and the electricity output was raised by moving the movable electrode within the patient's tolerance level, while the skin temperature tolerable to the patient was checked.

3. Evaluation methods

Evaluation of symptoms, including the presence or absence of adverse reactions, was carried out before the start of treatment and after the end of the 10th treatment.

Symptom evaluation items included spontaneous pain, projected pain, motor pain, numbness, feeling of stiffness, limited motion, myotonia, and tenderness. These symptoms were evaluated according to the severity classification standards (Table 2) set in reference to the Pain and QOL Scale[6].

How symptoms following the 10th treatment changed from pretreatment symptoms was evaluated in terms of their severity (changes in grades).

A seven-grade ranking scale was used to evaluate the above-mentioned improvement of each symptom in accordance with the improvement evaluation standards (Table 3). For reference, skin temperature changes were observed before, immediately after, and 15 minutes after the third, fifth, and 10th treatment using thermography.

The therapeutic effectiveness of the hyperthermia equipment was judged in accordance with the effectiveness evaluation and judgment standards

Table 3. Symptom improvement evaluation standards

Improved	Details				
Marked improvement	Three-level or more improvement in symptoms and findings	4-0	4-1	3-0	
Improvement	Two-level or more improvement in symptoms and findings, or post-treatment disappearance of pretreatment symptoms, despite their grade being 1	4-2	3-1	2-0	
Slight improvement	One level or more improvement in symptoms and findings	4-3	3-2	2-1	1-0
Unchanged	No change in symptoms or findings	4-4	3-3	2-2	1-1
Slight exacerbation	One-level exacerbation of symptoms and findings				
Exacerbation	Two-level or more exacerbation of symptoms and findings				
Marked exacerbation	Two-level or more exacerbation of symptoms and findings				

Table 4. Effectiveness evaluation judgment standards

Effectiveness	Judgment standards	
Very effective	Marked improvement in four or more items	However, if slight or more exacerbation of even one item is observed, the case was judged as not applicable and treated as applicable to the following evaluation. However, if slight or more exacerbation of even one item is observed, the case was judged as not applicable and treated as applicable to the following evaluation.
Effective	Marked improvement, improvement, or slight improvement in three or more items	
Slightly effective	Marked improvement, improvement, or slight improvement in one or more items	
Ineffective	No change in four or more items, with no item showing slight or better improvement	
Slightly exacerbated	Slight exacerbation of even one item	
Exacerbated	Exacerbation or marked exacerbation of even one item	
Markedly exacerbated	Marked exacerbation of two or more items	

(Table 4), with reference to the symptom improvement evaluation standards.

The safety of the equipment was judged based on the overall evaluation of the presence or absence of adverse reactions, the operation state of the equipment during usage, etc.

RESULTS

1. Therapeutic efficacy

The mean therapeutic effectiveness of all of the patients improved from grades before treatment, at 11.5 ± 4.9 (from 4 to 22 grades), to grades after the 10th treatment, at 6.2 ± 4.0 (from 0 to 16 marks) (Table 5). A statistically significant difference in this symptom improvement was observed between before and after treatment (Student's t-test, p=0.05).

The results of improvement evaluation of the eight symptom items in accordance with the improvement evaluation standards (Table 3) are shown in Table 6. Six patients exhibited slight exacerbations, including spontaneous pain, numbness, and feeling of stiffness (Tables 5 and 6).

2. Changes in skin temperature

The skin temperature of the affected site changed from 29.2–29.5°C before treatment to 30.2–30.5°C immediately after treatment, and rose further to 31.1–31.3°C 15 minutes after treatment. The skin temperature rose statistically significantly following every treatment, i.e. immediately and 15 minutes after treatment, compared with the pretreatment temperature (Student's t-test, p=0.05). It was particularly noted that the skin temperature rose even at 15 minutes after treatment (Fig. 2).

Figure 3 shows an effective case. The patient was a 61-year-old female suffering from lumbar discopathy. Twenty grades for pretreatment symptoms improved to 14 grades for symptoms after the 10th treatment. At the third treatment, the skin temperature of the affected site was 27.8°C before

treatment, 28.2°C immediately after treatment, and 30.5°C at 15 minutes after treatment. A marked rise of the skin temperature even after the end of treatment was observed.

3. Effectiveness rate

The effectiveness of the hyperthermia equipment was judged in accordance with the effectiveness evaluation judgment standards (Table 5). The rates of "very effective" patients, "effective" patients,

Table 5. Therapeutic effectiveness

N.O.	Age (yr)	Gender	Clinical diagnosis	Sponta-neous pain	Pro-jected pain	Motor pain	Numbness	Feeling of stiffness	Limited motion	Myotonia	Tenderness	Total score before treatment	Total score after 10th treatment	Effectiveness
1	60	F	D	2–1	1–0	3–1	1–0	2–1	3–1	2–1	3–1	17	6	E
2	74	F	SD	3–1	2–1	2–1	2–1	0–0	1–1	3–1	3–1	16	7	E
3	66	M	SCS	2–1	3–1	3–0	2–1	2–1	2–0	2–1	2–0	18	5	E
4	54	M	DH	2–2	2–2	2–2	0–0	3–2	2–2	3–1	2–1	16	12	E
5	58	F	SCS	2–1	2–1	1–0	0–0	2–1	2–1	2–1	2–1	13	6	E
6	73	F	SCS	2–1	2–2	1–1	0–0	0–0	2–1	2–1	2–2	11	8	E
7	66	M	D	3–2	3–2	3–1	1–0	2–0	1–0	3–1	3–1	19	7	E
8	65	F	DH	2–0	0–0	2–0	0–0	0–0	1–0	2–0	2–0	9	0	E
9	51	M	SCS	2–0	1–0	1–0	0–0	1–0	2–0	2–0	2–0	11	0	E
10	74	F	SD	1–0	1–0	1–1	0–0	0–0	0–0	2–1	2–0	7	2	E
11	31	M	DH	3–1	3–1	3–1	3–1	3–2	3–2	2–0	2–1	22	9	E
12	50	F	SS	0–0	3–1	1–1	3–2	3–1	2–0	3–2	2–2	17	9	E
13	33	M	DH	0–0	0–0	2–1	2–2	1–1	2–2	2–2	2–1	11	9	SE
14	48	F	SS	2–2	1–1	2–1	3–1	2–2	2–2	2–1	1–0	15	10	E
15	51	F	SD	3–2	2–2	3–2	0–0	0–0	2–1	3–1	2–1	15	9	E
16	61	F	D	3–1	3–2	2–1	2–2	3–3	2–1	3–2	2–2	20	14	E
17	47	F	SP	3–1	1–1	1–0	0–0	0–0	0–0	3–1	2–1	10	4	E
18	75	F	SCS	2–2	3–3	2–2	0–1	3–2	2–2	2–2	2–2	16	16	SEX
19	28	F	L	2–1	0–0	3–2	0–1	0–0	0–0	1–1	2–1	8	6	SEX
20	54	F	SD	1–1	0–0	2–1	1–0	1–1	1–0	1–1	2–1	9	5	E
21	32	M	L	1–1	0–0	1–0	0–0	0–0	1–0	1–0	0–0	4	1	E
22	66	M	SD	2–1	1–1	2–1	0–0	0–0	1–1	1–1	1–0	8	5	E
23	58	F	DH	1–1	1–1	3–2	1–1	2–1	2–2	2–1	3–2	15	11	E
24	71	F	SS	0–1	0–0	2–1	0–0	1–0	1–1	1–1	1–1	6	5	SEX
25	71	F	SD	2–0	0–0	2–0	0–0	0–0	2–0	1–0	2–2	9	2	E
26	40	F	L	0–0	0–0	2–1	0–0	0–0	2–1	1–1	2–1	7	4	E
27	54	F	SD	2–0	0–0	2–1	0–0	0–0	2–1	2–1	1–0	9	3	E
28	64	F	SD	1–0	0–0	1–0	0–0	0–0	1–1	1–1	0–0	4	2	SE
29	72	F	SD	2–1	0–0	2–1	2–1	0–1	0–0	1–1	1–1	8	6	SEX
30	62	F	SS	0–1	1–1	1–0	0–0	1–0	1–1	1–1	1–0	6	4	SEX
31	72	M	SD	0–0	0–0	2–1	0–0	0–0	2–1	2–1	1–0	7	3	E
32	70	F	SD	0–0	0–0	2–0	0–0	0–0	1–0	1–0	1–0	5	0	E
33	78	F	SD	0–0	0–0	2–0	2–1	2–1	1–0	1–1	1–0	9	3	E
34	80	M	SD	1–2	0–0	1–1	0–0	0–0	1–1	1–1	2–2	6	7	SEX
35	85	F	D	3–2	3–2	2–0	3–2	3–2	1–0	2–1	2–0	17	9	E
36	82	F	SCS	1–1	1–1	2–2	3–3	0–0	2–2	2–2	1–1	12	12	IE
37	76	F	SCS	2–1	2–2	2–1	1–1	2–2	2–1	2–1	2–1	13	10	E

The greatest severity of each item was assessed as 4 grades, and no symptom as 0 grade. In [A–B] for each item, A shows grades before treatment, and B shows grades after the 10th treatment. The total of grades for symptom evaluation is 32 for the severest symptom and 0 for no symptom.

Clinical diagnosis: Lumbar spondylosis deformans (SD), Lumbar spinal canal stenosis (SCS), Lumbar disc herniation (DH), Lumbar spondylosis/ spondylolisthesis (SS), Lumbar discopathy (D), "Lumbago" (L), Lumbar spine sprain (SP). Effectiveness: Very effective (VE), Effective (E), Slightly effective (SE), Ineffective (IE), Slightly exacerbated (SEX), Exacerbrated (EX), Markedly exacerbated (MEX).

and “slightly effective” patients were 0.0%, 75.5%, and 5.4%, respectively. The total of “slightly effective” and better patients accounted for 81.1% (30/37 patients) (Table 6).

4. Safety

One patient exhibited increased pain of the affected site a few hours after the electricity was used. However, no adverse reactions due to the hyperthermia equipment were observed, and there were no safety problems.

Table 6. Effectiveness rate

	N.O	%	
Very effective	0	0.0	
Effective	28	75.7	81.1%
Slightly effective	2	5.4	
Ineffective	1	2.7	
Slightly exacerbated	6	16.2	
Exacerbated	0	0.0	
Markedly exacerbated	0	0.0	
Total	37	100.0	

“Slightly effective” and better patients were treated as effective cases.

DISCUSSION

1. High-frequency hyperthermia equipment

The frequency used for high-frequency therapy in Japan is mainly ultra-short waves of 2,450 MHz, while little use is currently made of other frequencies[4, 5].

However, the hyperthermia equipment used in this study uses medium waves (0.65 ± 0.05 MHz), which induce few adverse reactions due to electromagnetic waves, with few contraindications, based on the capacitive electric transfer theory. The use of a small movable electrode (affected side) and a return electrode (stomach side) makes high-frequency current less likely to disperse. As a consequence, high-frequency current has been reported to heat the affected site efficiently by producing joule heat due to the resistance of the affected site tissue[7]. Because of the high electric resistance of the tissue immediately below the electrode, ordinary ultra-short wave therapeutic equipment has been reported to be liable to cause hot spots at this site. Because of the characteristics of the frequency used and the double electrode sys-

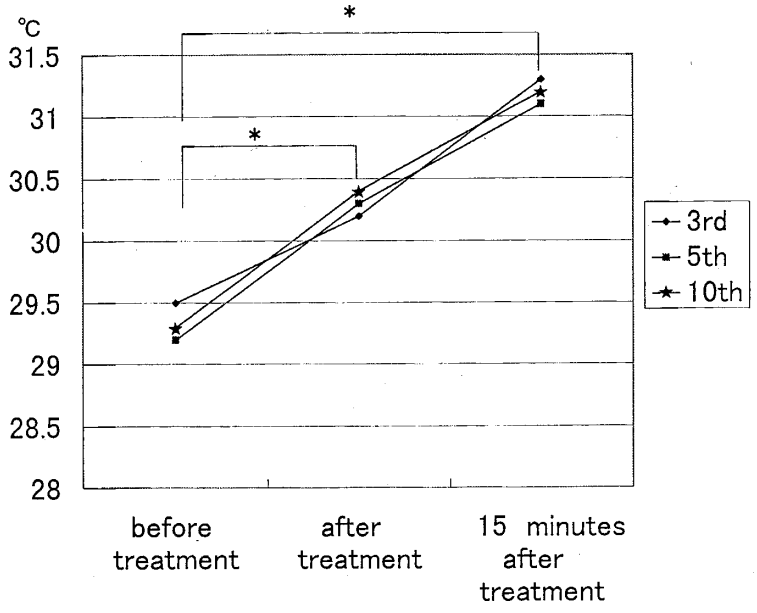


Fig. 2. Changes in skin temperature
The mean skin temperature rose immediately and remained elevated 15 min after treatment, with a significant difference from the mean skin temperature before treatment, with every treatment. Also, the raised skin temperature was maintained after the end of treatment. * p=0.05.

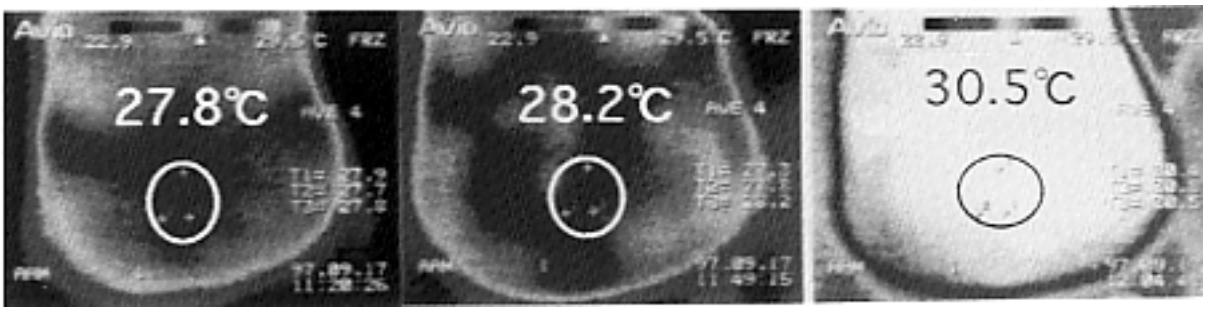


Fig. 3. A 61-year-old female patient with lumbar discopathy
The affected site is encircled. Skin temperature: 27.8°C before treatment; 28.2°C immediately after treatment; 30.5°C 15 min after treatment. Also, the skin temperature rose immediately and remained elevated 15 min after the end of treatment.

tem, however, the hyperthermia equipment has little likelihood of causing hot spots[6, 7]. Heating deep in the body was reported to produce a rise of 3 to 5°C at a depth of 5–10 cm after the electricity was used for 15 minutes. The temperature did not fall quickly, even after the end of the current; rather it was maintained for 3 to 4 hours. This has been reported to alleviate pain owing to various biological effects[7].

It is noted that this hyperthermia equipment has characteristics different from those that have been used in Japan.

2. Evaluation of effectiveness

Since no control group was included in the present study, we compared the therapeutic efficacy of the present hyperthermia equipment and other similar equipment. Fisher's exact test ($p=0.05$) was used to compare with each of a semiconductor laser irradiation group[3], a group of patients who underwent treatment using a high-frequency pulse electromagnetic field[1], and a group of patients for whom high-frequency therapy was effective[3], each of which served as control groups.

The effectiveness rate of the present hyperthermia equipment was 81.1%, and no statistically significant difference was observed from the laser therapy group (effectiveness rate, 73.5%) or the high-frequency therapeutic equipment group (effectiveness rate, 78.0%). However, the effectiveness rate (90.0%) of the high-frequency pulse group was significantly higher than that of the present equipment group.

The above results demonstrated that the effectiveness of the hyperthermia equipment was nearly equivalent to that of the conventional physiotherapeutic equipment (Table 6).

3. Assessment of patients exhibiting symptom exacerbation

Some patients exhibited exacerbations, mainly of symptoms at sites other than the electrification site, but no lower back symptoms due to the use of the electricity. All patients who exhibited exacerbations of spontaneous pain were in the spondylolysis/spondylolisthesis patient group.

4. Clinical application

It is not thought that there will be many patients with various types of lumbago in the orthopedic surgery field for which treatment with hyperthermia equipment will be mainly used. However, therapy using this equipment was considered to be simple and effective enough as supportive therapy to relieve pain in patients with various diseases involving lumbago.

CONCLUSIONS

(1) Hyperthermia equipment MD-303 was used for patients suffering from various diseases involving lumbago in the orthopedic surgery field, and its effectiveness in relieving pain was evaluated.

(2) Post-treatment symptoms were improved, with statistical significance from pretreatment symptoms, and the effectiveness of this hyperthermia therapy was demonstrated.

(3) No occurrence of adverse reactions was observed. From these findings, it is concluded that hyperthermia therapy using this equipment is useful in the treatment of various painful orthopedic diseases.

REFERENCES

1) Ashida K: Clinical evaluation of high-frequency pulsed electromagnetic field on alleviating lumbar pain. Research of New Medical Devices 1 (1): 115–122, 1992 (in Japanese).
2) Harada T, et al: A clinical application of the 1W Ga-Al-As diode laser -double blind study-. J. Physical Medicine 9 (2): 99–103, 1998 (in Japanese).
3) Hashida T, et al: Clinical evaluation of lumbar pain treatment with a rechargeable high-frequency therapeutic device. Research of New Medical Devices 1 (1): 123–131, 1992 (in Japanese).
4) Kikuchi M, et al: RF-ha-no-ohyo(application of radio frequency waves): The institute of Electrical Engineers of Japan (IEEJ), Biological Effects of Electromagnetic Fields and Measurement, 1st ed. Corona Publishing Co., Ltd. Tokyo, 200–203, 1995 (in Japanese).
5) Kotsuka Y: Hyperthermia: The institute of Electrical Engineers of Japan (IEEJ), Biological Effects of Electromagnetic Fields and Measurement, 1st ed. Corona Publishing Co., Ltd. Tokyo, 215–239, 1995 (in Japanese).
6) Totoki T, et al: Evaluation of the pain and QOL. Sogo-Rinshou 41 (1): 74–78, 1992 (in Japanese).
7) Zauner Gutmann A: Recientes avances en fisioterapia. 1st ed., Editorial JIMS, Barcelona, 1993, pp 143–160 (in Spanish).