International Journal on Respiratory Care and Medicine

Advanced lung cancer patients: Palliative care efficacy trial using long-wave ultrasound stimulation / 7 cases (Is Dolphin Waves Effective for Patients with Lung Cancer?)

Research Article

Volume 1 Issue 1- 2023

Author Details

Yoshio Shimotori[1] and Meizo Kusaka[2]**

[1]*Research and Development Center, President of Kamiyama Limited, Japan*

[2]*Director of R&D, World brain, Co, Limited, Japan*

*Corresponding author

Yoshio Shimotori and Meizo Kusaka, Research and Development Center, President of Kamiyama Limited, Japan

Article History

Received: November 24, 2023 Accepted: November 28, 2023 Published: November 28, 2023

Abstract

A therapy that applied long-wave ultrasonic stimulation to the chest was applied to seven patients with lung cancer to alleviate symptoms, and the therapy was used as home therapy for 12weeks. We report the results of the home therapy and a summary including the patient questionnaire administered 1 year later.

Subjects: Patients with stage 3 to 4 lung cancer.

Research Design: Observational study, open study.

Equipment use: The test equipment is an ultrasonic stimulator lent to the test subject, which is used three times a day for 20minutes each time.

Evaluation Period: 12weeks.

Evaluation Items: NRS, KRS, subjective evaluation, tumor marker, X-ray CT evaluation.

Results: There was a significant improvement in subjective evaluation of respiratory pain (chest pain, breathing difficulty, etc.). Additionally, during the 3-month period of use, no worsening of symptoms was observed, and in some cases, the pain level of the NRS decreased, and some felt physically comfortable when using the Ultra-Ma.

Conclusion: Although no changes were observed in X-ray CT images, the patient's QOL improved with the use of the test device. There were no adverse events in this study, and there were no reports of device malfunctions, so it was thought that there was no problem with the safety of the test device. In addition, in a follow-up survey immediately after the clinical trial and one year later, multiple subjects reported that the cancer had disappeared in PET-CT images. It seems that accurate evaluation could not be made using X-ray CT images. It is considered necessary to perform PET-CT evaluation in future lung cancer examinations. This article was created based on the report of a clinical trial conducted by the Japan Clinical Trials Association (JACTA).

Keywords: Long-Wave Ultrasonic Stimulator, Advanced Lung Cancer, Home Treatment, Ct Images

Introduction

We have developed a low-frequency ultrasonic stimulation device that focuses on the frequency band emitted by dolphins in the ocean. This article summarizes the results of a clinical trial on palliative care for advanced lung cancer patients based on the concept of vibrating capillaries, nerve cells, and bones with weak long-wave ultrasonic stimulation. This device uses ultrasonic to stimulate the affected area of lung disease. The ultrasonic frequency is 30KHz (0.03MHz), which is a non-standard ultrasonic frequency for medical device. The wavelength inside the body (simulated in water) is approximately 5cm, and it is characterized by a low attenuation rate of propagation within the body and good penetration of acoustic vibrations. The speed of sound propagation in air is 340meters/second. The body is made up of 60% water, and the speed of sound is approximately 1,500meters/second, considering it to be propagated through water, while in bones it is 5,000meters/second, so acoustic vibrations are transmitted well. Motion stimulation to capillaries and nerve cells in the human body is thought to be obtained with vibration energy of several microwatts/cm^2. It is also often transmitted to the ribs that surround the lungs.

The acoustic intensity of this test equipment is less than 16mw/cm^2. Safety has been demonstrated in specific clinical trials conducted prior to this clinical trial targeting patients with temporo-mandibular joint disorders [1,2]. The intensity of this ultrasonic wave is about 1/10,000 or less of the intensity that causes cavitation. Furthermore, in preliminary clinical research, we confirmed that stimulating the capillaries and nerve cells in the brain with weak ultrasound waves for 20minutes increases cerebral blood flow [3,4]. Furthermore, clinical trials for cranial nerve diseases confirmed its safety and effectiveness [5-8].

We had received reports from patients with advanced lung cancer about the effectiveness of long-wave ultrasound therapy, a health device. Based on this report, we conducted this clinical study. In addition to the pain caused by the disease itself, lung cancer causes pain due to highly invasive treatments, leading to a decline in patients' QOL [9]. In addition to drug therapy, radiotherapy and nerve blocks are being considered to treat pain in patients with advanced cancer [10]. Furthermore, many patients and their families request various complementary and alternative therapies in hopes of alleviating their pain.

This device was developed by Kamiyama Ltd. and the clinical trial was commissioned to the Japan Clinical Trials Association (JACTA). We were briefly introduce the report of "Clinical research using this device on Seven patients with advanced lung cancer".

Subjects and Method

Subjects

The subjects were stage 3 to 4 lung cancer patients who did not receive or were unable to undergo surgery or radiotherapy, and who voluntarily consented to participate.

In addition, those who fall under the following were excluded.

a) Persons with mixed lung cancer of small cell cancer and non-small cell cancer

b) Persons with a history of allogeneic organ transplantation

c) Persons with a history of another primary malignant tumor

d) Persons with a history of active primary immunodeficiency

Clinical facility: After approval by the Clinical Trial Review Committee of Japan Clinical Trials Association, and it was conducted at the Koyasu Neurosurgery Clinic.

Clinical design: Since this study is an observational study of 7 cases, it is considered a case report.

Test device: The test device was an ultrasonic stimulator "Ultra-Ma Hp20" (hereinafter referred to as the "test equipment") that was lent to the subjects. They were used three times a day (110:00-12:00, 215:00-17:00, 319:00-21:00) for 20 minutes each. Specifications are shown in Table 1.

Table 1: Specification.

Items	Specifications
Rated voltage, current	AC 100v, 0.2A
Ultrasonic output (Body type)	30kHz, 0.01W/sec, Each vibrator (cell:2 parts)
Ultrasonic output (Head type)	30kHz, 0.002W/sec, Each vibrator (cell: 4 parts)
Type of treatment head	Pulse stimulation on left and right alternately, 10% pulse ratio
Timer	20 minutes

Method

Figure 1 shows how the test equipment was installed. Ultrasonic stimulation pads were attached to two locations: the head and the chest. The nervous system was stimulated directly to the head, and the respiratory system was stimulated directly to the lung cancer site in the chest. The device was used for 12weeks.

Clinical Schedule

The subjects were registered between December 2021 and Diagnosis was performed three times: before use, after 6 weeks, and after 12 weeks. During the study period, participants were required to continue their previous treatment and submit a diary in which they recorded their physical condition. The schedule is shown in Table 2.

Evaluation Item

NRS (Numeric Rating Scale): Evaluated respiratory pain (chest pain, dyspnea, etc.). Pain was divided into 11 levels, ranging from ``0: no pain" to ``10: the worst pain imaginable". A numerical value corresponding to the current pain was shown and evaluated as a score.

Figure 1: Installation status and controller of test device.

Table 2

Confirmation/ Test	Consent-Start	Before Starting Use	Start Using Test Device	6, 12 weeks Later
Obtaining consent	☒			
X-ray CT		☒	☒	☒
Blood sampling (tumor marker)		☒	☒	☒
NRS. KRS		☒	☒	☒
Use of test device		←	—	→
Patient diary			←	→

Subjective evaluation: Respiratory pain was comprehensively considered after 12 weeks, based on participants' diary entries and conversations with physicians on hospital visits (three times). The baseline was before use. Scores were given on a 5-point scale. ``3: Significantly improved," ``2: Improved," ``1: Slightly improved,"``0: No change," and ``-1: Worsening."

Karnofsy Performance Scale: The ability to carry out activities of daily living and the degree of dependence on assistance and nursing were evaluated by a physician using the KPS on an 11-point scale. The higher the value, the milder the symptoms.

Tumor marker: Blood was collected on the day of the test, and tumor markers were evaluated. The four items to be evaluated were CYFRA CK19 (NG/ML), CEA (CLEIA) (NG/ML), SLX-I antigen (U/ML), and SCC (NG/ML). The respective standard values are CYFRA: 3.5 or less, CEA: 5.0 or less, SlX: 38 or less, and SCC: 2.5 or less.

Evaluation of X-ray CT images (Figure 2-4)

It was conducted before using the test device, and at 6 and 12 weeks after using the test device.

Safety

The safety of the test device was evaluated based on a diary survey regarding lifestyle habits and adverse events during the test period, and a doctor's diagnosis on the day of observation.

Statistical Analysis

FAS was used for analysis. Measured values and scores were expressed as mean ± standard deviation, and a paired t-test was performed. In both cases, a significance rate of less than 5% ($p<0.05$) was determined to be a significant difference using a two-tailed test.

Evaluation of X-ray CT Images

It was conducted before using the test device, and at 6 and 12 weeks after using the test device.

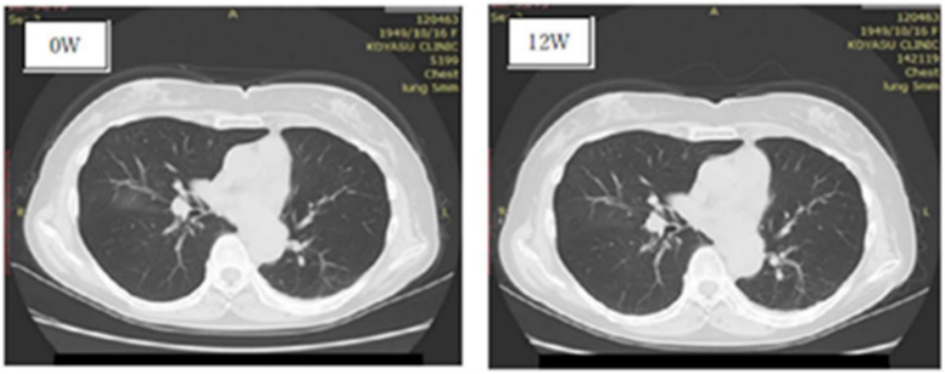

Figure 2: 72 years old, female, stage 4.

A. Diagnosis of the interpretation of radiogram: No progression, no change before and after ultrasonic stimulation.

B. Report from the subject (1 year later): I felt very well when I used the ultrasonic stimulator. The X-ray-CT images showed no changes, but the cancer was no longer visible on PET-CT images.

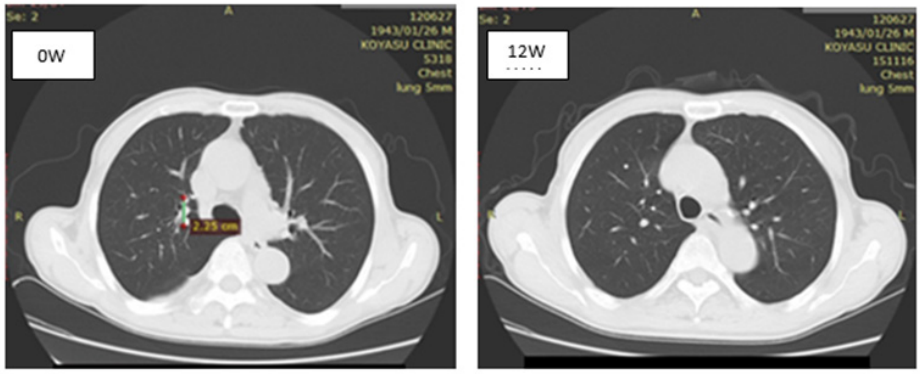

Figure 3: 78 years old, male, stage 4.

A. Diagnosis of the interpretation of radiogram

i. 0w: Right lower lobe lung cancer. There was a pleural effusion. Suspected of right clavicle metastasis. Cancer size 11.2cm

ii. 12w: Cancer size 9.6mm, no pleural effusion observed.

B. Report from the subject (1 year later): Although the size did not change in the X-ray/CT images, I feel that my immunity has improved.

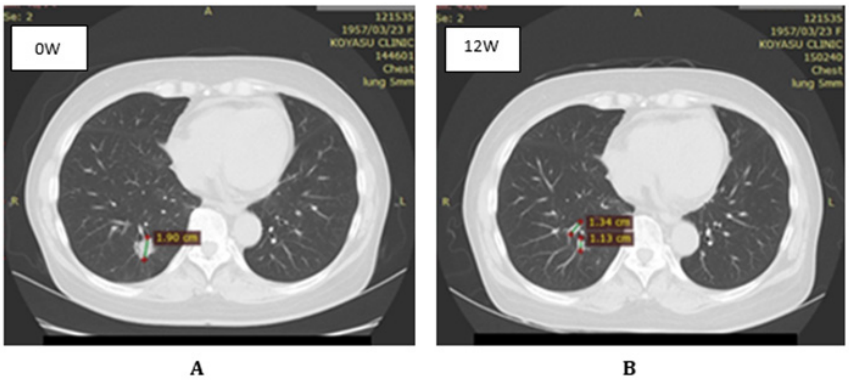

Figure 4: 64 years old, female, stage 4.

A. Diagnosis of the interpretation of radiogram: There was an irregular nodule in the right lower lobe. No pleural effusion was detected. No change from 0w to 12w.

B. Report from the subject (1 year later): During the regular medical checkup during the clinical trial, the marker values were low. Two months after the end of the clinical trial, PET-CT imaging at a clinic he visited showed that his lung cancer had become inactive. She was also diagnosed with no longer having metastasized to her bones. One year later, PET-CT images showed that the cancer in her back was no longer visible.

Result

Seven patients were analyzed (5 males, 2 females), with an average age of 69.6 ± 10.1years (52 to 78years). One of the patients was unable to visit the clinic on the observation day after 6 weeks due to personal reasons, and only visited the clinic before use and after 12weeks.

NRS-Subjective Evaluation-KPS

A significant increase (improvement) in subjective evaluation was seen when comparing before and after 12.

Tumor Marker

No significant changes were observed when compared to before use.

Comparing before and 12weeks after use, an increase in markers was seen in 3 cases of CYFRA, 3 cases of CEA, 2 cases of SLX, and 5 cases of SCC, and a decrease was observed in 5 cases of CYFRA. : 1 case, CEA: 3 cases, SLX: 5 cases, SCC: 2 cases.

Adverse Events and Device Malfunctions

During the study period, there were no adverse events that appeared to be caused by the test device, and there were no reports of malfunctions due to the use of the test device. Based on the above, it was considered that there was no problem with the safety of the test device.

Conclusion

The ultrasonic stimulator ``Ultra-Ma Hp20" was lent for 12weeks to stage 3 to 4 lung cancer patients who would not or could not undergo surgery or radiation therapy. It was used three times a day (20minutes each, 60minutes in total). As a result, there was a significant improvement in subjective evaluation of respiratory pain (chest pain, breathing difficulty, etc.). Specifically, as a result of regular Checkups at the clinic where the patients regularly visit, three patients improved and one patient no longer felt pain while using the product. It is noteworthy that there was no worsening of symptoms during the 3-month test period, and that in individual cases, the level of pain on the NRS decreased, and some patients improved their QOL while using the drug. In addition to standard palliative care, Ultra-Ma Hp20 can be used as an adjunctive therapy to reduce pain in lung cancer patients. It would be of great significance if the patient himself or herself could face the treatment positively. Furthermore, during the study period, there were no adverse events thought to be related to the test device, and no adverse effects on the affected area were observed. There were no reports of any malfunctions during the use of the device, ,and it was safely used by patients with advanced lung cancer, indicating that this device is safe to use. On the other hand, no changes were observed in the X-ray CT image evaluation for lung cancer. Subjects who underwent PET-CT image diagnosis reported shrinkage and disappearance. However, subjects who underwent PET-CT imaging reported shrinkage and disappearance. This article was prepared based on the report [11] of a clinical trial conducted by the Japan Clinical Trials Association (JACTA).

References

1. Hiroki Morinaga, Takeshi Kaneko, Meizo Kusaka, Yoshio Shimotori, Yousuke Naito (2022) Effectiveness for temporomandibular joint disease masticatory muscle pain disorder by using ultrasonic stimulator "Ultra-Ma". Medical Consultation and New Remedies 59: 315-333.
2. Yoshio Shimotori, Meizo Kusaka (2023) Report on the effectiveness of long-wave ultrasonic stimulation for patients with temporomandibular joint disease and masticatory muscle pain disorder (Is dolphin waves effective for temporomandibular joint disease?). International Journal on Oral Health Volume 3 Issue 2.
3. Okano S, Shimotori Y (2015) Measurement of sound field of ultrasound massager for the head in skull model. The Japanese Journal of medical instrumentation 85(1): 14-21.
4. Okano S, Shimotori Y, Kazuo Uebaba, Yuta Manabe, Kazuhiro Shibata (2015) Changes of Cerebral Blood Flow by the Weak Trans-Cranial Ultrasound Irradiation in Healthy Adult Volunteers. Japanese Journal of Complementally and Alternative Medicine 12(2): 73-78.
5. Manabe Y, Shimotori Y (2023) A clinical study on the efficacy and safety of the head ultrasonic stimulator Ultra-Ma for patients with clinically diagnosed dementia with Lewy bodies. Clinical Study Report.
6. FujiiI H, Shimotori Y (2021) Reduction of dementia symptoms by weak transcranial ultrasound therapy. Japan Society for Dementia Prevention 11: 49-57.
7. FujiiI H, Shimotori Y, shukan Okano, Kenji Kosa (2022) Effects of Transcranial Weak Ultrasonic Stimulation on Parkinson's Symptoms - Consideration Focused on Cognitive Function Tests. Japanese Journal of Complementally and Alternative Medicine 19.
8. Yoshio Shimotori, Meizo Kusaka (2023) Efficacy and Safety of Low-Level Long-Wave Ultrasonic Stimulator for Dementia with Lewy Bodies and Parkinson's Disease (Is the Dolphin Wave Effective for Neurodegenerative Diseases in the Brain!). J Clin Res Med 6(2): 1-5.
9. Yoshinobu Matsuda, Akihiro Tokoro, Takako Kosugi, Hisa Takeda, Jun Naito, et al. (2018) Psychosomatic Medicine in Lung Cancer. Jpn J Psychosom Med 58: 44-48.
10. Mitsue Funato, Minako Okumura (2019) Enhancement of Palliative Care for Lung Cancer Patients in General Wards. Journal of Nursing of Adults Gifu College of Nursing 19 (1): 27-39.
11. Taro Shirakawa, Yoshio Shimotori Trial Use of Ultrasonic Stimulator "Ultra-Ma" in Palliative Care of Lung Cancer Patients Experience In 7 Case. Academy of JCAM 9(3).