

## Review

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# The Past and Present Status of Clinical Hyperthermia in Japan : a Survey in 2004 using a Questionnaire

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**Abstract :** Clinical research in hyperthermic oncology began in 1978, when the research group chaired by Prof. T. Sugahara, supported by a grant from the Ministry of Education, played an important part. Six years later, the first annual meeting of the Japanese Society of Hyperthermic Oncology (JSHO) was held in Kyoto, and the 23rd meeting was held in Nara in 2006. Over this period, the number of members as well as the number of scientific papers presented have decreased. However, new technologies such as immuno-stimulation, high temperature ablation, and mild hyperthermia have been introduced into clinics. The health insurance control committee of the JSHO conducted a survey on the clinical applications of hyperthermia. Data obtained through the use of questionnaires have been used to present the state of hyperthermic treatment in the major hospitals in Japan. An outline of the patients and diseases treated with hyperthermia, heating conditions including combination therapy, and clinical outcomes were summarized in this study. From the viewpoint of fiscal responsibility at each hospital, the difference between income and expenses for hyperthermic therapy is something which cannot be ignored. Further analysis of survey data and additional survey studies might be essential to resolve this problem.

**Key Words :** hyperthermia, RF capacitive heating, questionnaire survey, local response

## Introduction

Clinical research in hyperthermic oncology was started by the Japanese Hyperthermic Study Group (JHSG) in 1978. A research group chaired by Prof. T. Sugahara, supported by a grant from the Ministry of Education, played an important part in the establishment of JHSG. The first scientific meeting was held in Osaka, and was attended by 50 researchers, and 17 papers were presented<sup>1)</sup>. The first presentations dealt mainly with problems dealing with heating of the human body and the biological effects obtained using various heating procedures. The little clinical data presented and discussed were

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in the field of hyperthermia using perfusion with hot water for the treatment of carcinoma of the urinary bladder. Six years later, in 1984, the Japanese Society of Hyperthermic Oncology (JSHO) was established<sup>1-3)</sup> (Table I). Since then, the JSHO has made substantial progress when compared to the North American Hyperthermia Society (NAHS) and the European Society for Hyperthermic Oncology

**Table I.** History of the annual meeting for the presentation of research in hyperthermia in Japan

No.	Year	Location	Chairman
Hyperthermic Study Group : Annual Meeting			
1	1978	Osaka	Sugahara T.
2	1979	Osaka	Sugahara T.
3	1980	Kyoto	Onoyama Y.
4	1981	Tokyo	Egawa S. & Saito M.
5	1982	Nagoya	Nakamura W. & Amemiya Y.
6	1983	Tokyo	Matsuda T. & Kikuchi M.
Japanese Society of Hyperthermic Oncology : Annual Meeting			
1	1984	Kyoto	Sugahara T. (JSHO established)
2	1985	Tokyo	Egawa S.
3	1986	Osaka	Onoyama Y.
4	1987	Yonago	Koga N.
5	1988	Kyoto	Sugahara T. (Joint Conference with the 5th ICHO)
6	1989	Tokyo	Saito M.
7	1990	Okayama	Sekiba K.
8	1991	Tokyo	Kamata R.
9	1992	Kanazawa	Hisazumi H.
10	1993	Osaka	Shimoyama T.
11	1994	Osaka	Tanaka Y.
12	1995	Tokyo	Kanai H.
13	1996	Fukuoka	Sugimachi K. (1st Congress of ASHO)
14	1997	Kyoto	Kondo M.
15	1998	Tokyo	Tanaka Y. (2nd Congress of ASHO)
16	1999	Osaka	Kano E.
17	2000*	Niigata	Tanaka R.
18	2001	Tokyo	Takahashi T.
19	2002**	Nagoya	Ueda K.
20	2003	Fukuoka	Masuda K.
21	2004	Kyoto	Yoshikawa T.
22	2005	Okayama	Kawasaki S.
23	2006	Nara	Ohnishi T. (4th Congress of ASHO)

\*The 8th ICHO was held in Kyon-ju, Korea, in 2000.

\*\*The 3rd ASHO was held in Zhengzhou, Henan, China, in 2002.

(ESHO). The JSHO was organized by Professor Tsutomu Sugahara, from Kyoto University, Kyoto. He was succeeded in 1991 by Tadayoshi Matsuda, of the Tama-Nambu Regional Hospital, Tokyo. In 1995, Professor Yoshiaki Tanaka, from Nihon University School of Medicine, Tokyo, became president, and he was succeeded by Professor Makoto Kikuchi, of the National Defense Medical College, from 1998 to 2002. The current president, Professor Takeo Ohnishi, of Nara Medical University, became president in 2003.

### ***Membership and Organization of the JSHO***

In March, 1998 there were 918 members in the JSHO. This group was comprised of 697 clinical oncologists which included specialists in radiation oncology and radiology (281); surgery (169); internal medicine (85); urology (38); neurosurgery (36); oral and maxillo-facial surgery (27); gynecology (12); *etc.* Two hundred and twenty one members came from other disciplines; physics and engineering (94); biology (59); and associated medical and radiological technicians, nurses and others<sup>3)</sup> (68). In North America and Europe, radiation oncologists constitute more than 70% of the membership of the Hyperthermic Societies. Current JSHO membership has decreased, and includes 493 clinical oncologists (72%), 104 basic scientists (15%), and 89 members from other disciplines (13%) (Table II).

### ***Scientific papers presented at the Annual Meeting of the JSHO***

To analyze the effect of the JSHO's efforts, the numbers of scientific papers presented at the annual meetings was analyzed. This examination shows a gradual increase in the number of papers presented at each meeting from 1984 through 1988, when the 5th Congress of the International Society for

**Table II.** Number of JSHO members in different subspecialty fields in 2004

No.	Department	Number	Number (%)
1	Radiation Oncology & Radiology	205	493 (72)
2	Surgery	129	
3	Internal Medicine	54	
4	Urology	20	
5	Neurosurgery	18	
6	Oto-rhino-laryngology/Oral and maxillofacial Surgery/Dentistry	5/15/10	
7	Gynecology	7	
8	Clinics (Others)	30	
9	Physical Science and Engineering	68	104 (15)
10	Biology	14	
11	Other Basic Science in Medicine	22	
12	Radiological Technology	44	89 (13)
13	Others	45	
Total		686	(100)

Hyperthermic Oncology (ISHO) was held and 222 papers were presented<sup>4)</sup>. After that, the number decreased gradually to an average of 120 papers a year. The year of 1998 was special since the combined 2nd Congress of the Asian Society of Hyperthermia Oncology (ASHO) and the JSHO was held in Tokyo<sup>5)</sup> (Fig. 1).

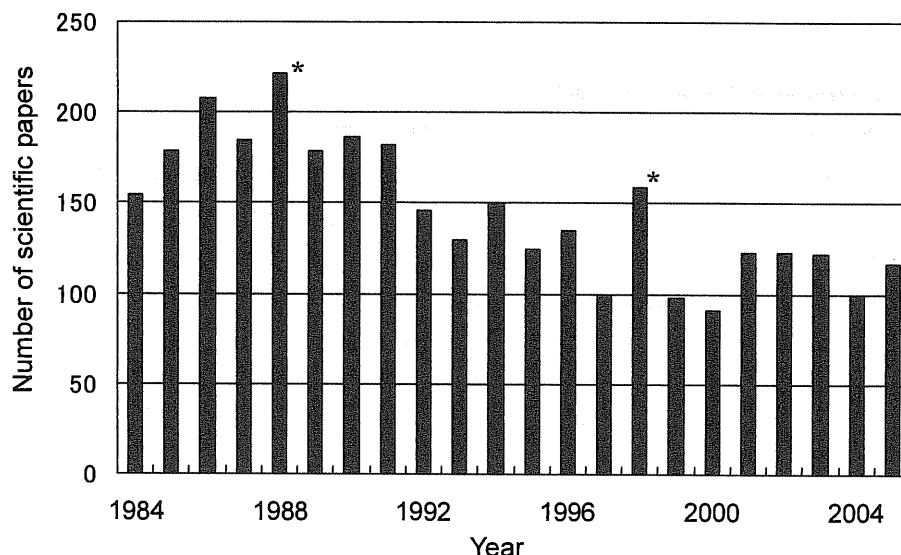


Fig. 1. Number of scientific papers presented at the annual meeting of the JSHO from the 1st Meeting in 1984 through the 22nd Meeting in 2005. (\*) The 5th meeting in 1988, Kyoto, and the 15th meeting in 1998, Tokyo, were held in conjunction with the 5th ICHO and the 2nd ASHO, respectively.

### Board Certification

In order to promote the effectiveness, quality, and safety of hyperthermic treatment in clinical practice, the JSHO established a board certification for hyperthermic oncology in 1996 both for physicians and researchers, and for associated medical staff, including radiotherapy technicians and nurses. A certification was also established for institutions. The JSHO also founded educational refresher courses in conjunction with district scientific meetings for the management and establishment of board certification. This is an effective approach leading to the increase of quality assurance in hyperthermic treatment in clinical applications.

### Clinical applications

A nation-wide survey revealed that radiofrequency (RF) capacitive heating equipment was the most common choice for the treatment of deep-seated tumors, mainly using the Thermox 500/1000 (Omron Co., Ltd., Kyoto, Japan) and the Thermotron-RF8 (Yamamoto Vinita Co., Ltd., Osaka, Japan) instruments. Initially, hyperthermia was used in conjunction with radiation therapy in about 60% of the patients, with chemotherapy in 25%, and with chemo-radiotherapy in 15%. At this time, hyperthermia was usually applied to 1) locally advanced tumors, 2) radio-resistant tumors, 3) recurrent tumors, 4) accessible tumors which could be easily heated, and 5) others not suitable for management with radiation

alone<sup>6)</sup>. In April 1990, the Japanese Government approved the use of health insurance to cover the costs of treatment by hyperthermia when it was limited to the application of an electromagnetic field, provided that it be used in combination with radiotherapy. Since then, there has been a remarkable increase in the frequency of clinical applications of hyperthermia in cancer treatments. In April 1996, hyperthermia applied with equipment using an electromagnetic field was approved for clinical uses other than combination with radiotherapy. Since then, clinical applications have been expanded to cover any tumors treatable with hyperthermia. In the United States and Europe, most clinical trials used microwave heating of superficial tumors. In Japan, research in the field of hyperthermia has mainly focused on RF capacitive heating for the treatment of deep-seated tumors. Based on the findings published during the initial ten years, it is possible to chart the effectiveness and progress of treatment modalities involving hyperthermia for the following diseases: 1) thermo-radiotherapy for metastasis to the cervical lymphnode<sup>7)</sup>, locally advanced carcinoma and/or postoperative recurrent tumors of the breast<sup>8)</sup>, lung<sup>9-12)</sup> (especially treatments of superior sulcus tumors), rectum<sup>13,14)</sup>, uterine cervix<sup>15,16)</sup> and soft tissue sarcoma<sup>17,18)</sup>, 2) thermo-chemotherapy for lung cancer with carcinomatous dissemination to the pleura<sup>19)</sup>, peritonitis carcinomatosa<sup>20-22)</sup>, hepatocellular carcinoma<sup>23,24)</sup>, and vaginal carcinoma<sup>25)</sup>, and<sup>3)</sup> thermo-chemo-radiotherapy for locally advanced head and neck cancer<sup>26)</sup> and carcinoma of the breast<sup>8,27)</sup>, esophagus<sup>28,29)</sup>, malignant mesothelioma<sup>30,31)</sup>, extrahepatic biliary system<sup>32)</sup>, pancreas<sup>13,33)</sup>, uterine cervix<sup>16)</sup> and urinary bladder<sup>34)</sup>.

### ***Results of a questionnaire survey of clinical hyperthermia in Japan***

The health insurance control committee of the JSHO conducted a survey on the clinical applications of hyperthermia in Japan. Data were obtained from questionnaires distributed from January, 2003 through December, 2004 to major medical centers, in which hyperthermic equipment using an electromagnetic field was installed and used for the treatment of cancer patients. A total of 25 institutes were registered for this study. The hyperthermic equipment consisted of 23 units of the Thermotron-RF8, one unit of the Thermotron pro-eight, and one unit of the Thermox 500, all of which are radiofrequency (RF) capacitive heating devices. A total of 1,151 patients had been treated with hyperthermia each year in these 25 institutes. The number of patients treated per institute ranged from 5 to 205 patients per year (average 41.3 patients; median 18 patients) and the number of sessions per patient from 1.3 through 13.8 sessions (average of 10.4+/-9.5 sessions). The treatment period per patient ranged from less than one month to more than 6 months (average 2.1+/-1.2 months) with about half of the patients (48.4%) treated for less than one month with 4.0+/-2.2 hyperthermia sessions (Table III). The abdomen was the area most frequently treated with hyperthermia (37.3%) followed by the pelvic region (30.6%), thorax (19.7%), head & neck (7.3%), and bone & soft tissue (5.1%) (Table IV). Chemotherapy, radiotherapy, and chemo-radiotherapy were applied in combination with hyperthermia, where chemotherapy was the most frequent modality (33.9%) followed by radiotherapy (25.4%), chemo-radiotherapy (23.0%) and hyperthermia alone (17.6%) (Table V). Local responses were analyzed by groupings of combination therapy with chemotherapy and/or radiotherapy. The data were obtained from subjective impressions of physicians in which "excellent" meant that nearly all tumors and symptoms had disappeared, including discomfort and pain; "good" meant partial regression of the

**Table III.** Distribution of hyperthermic treatments (HT) : treatment period, number of patients, and treatment sessions

	Treatment period (months)					
	<1	1= $\leq$ , <2	2= $\leq$ , <3	3= $\leq$ , <6	6= $\leq$ , <12	12= $\leq$
Number of patients (%)	477 (48.4)	192 (19.5)	103 (10.4)	114 (11.6)	75 (7.6)	25 (2.5)
Number of HT sessions (S.D.)	4.0 (2.2)	8.7 (5.5)	13.5 (8.5)	19.4 (12.4)	42.5 (39.7)	47.3 (21.5)

**Table IV.** Distribution of patients treated with hyperthermia (HT) : site of treatment lesions

	Head & neck	Thorax	Abdomen	Pelvic region	Bone & soft tissue
Total number of patients	84 (7.3%)	225 (19.7%)	427 (37.3%)	350 (30.6%)	58 (5.1%)
Average number of HT sessions	10.7 $\pm$ 8.2	11.1 $\pm$ 12.4	11.7 $\pm$ 10.3	8.3 $\pm$ 4.7	7.4 $\pm$ 4.8
Average HT treatment period (months)	2.3 $\pm$ 2.0	2.1 $\pm$ 1.3	3.5 $\pm$ 5.7	1.9 $\pm$ 1.5	1.9 $\pm$ 1.8

**Table V.** Distribution of treatment modalities combined with hyperthermia (HT)

	CT	CT+RT	RT	HT alone
Number of patients	360 (33.9%)	244 (23.0%)	270 (25.4%)	187 (17.6%)
Number of HT sessions	13.4 $\pm$ 11.8	11.9 $\pm$ 12.6	6.2 $\pm$ 5.4	10.1 $\pm$ 6.6
Treatment period (months)	2.6 $\pm$ 1.6	3.5 $\pm$ 4.2	1.2 $\pm$ 0.6	2.2 $\pm$ 1.5

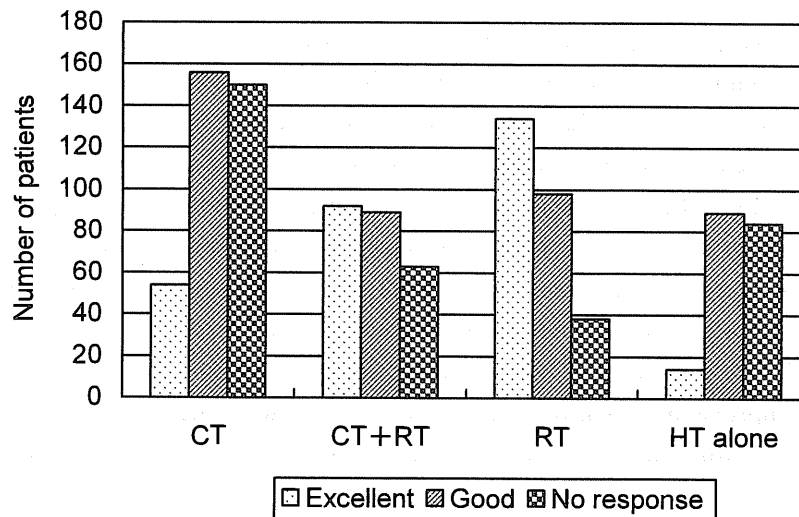
CT : chemotherapy, RT : radiotherapy

**Table VI.** Local responses of different treatment modalities in combination with hyperthermia (HT)

	CT	CT+RT	RT	HT alone	Total
Excellent	54 (15.0)	92 (37.6)	134 (49.5)	14 (7.5)	294 (27.7)
Good	156 (43.4)	89 (36.5)	98 (36.5)	89 (47.6)	432 (40.7)
No response	150 (41.6)	63 (25.9)	38 (14.0)	84 (44.9)	335 (31.6)
Total	360	244	270	187	1,061

( ) : %, CT : chemotherapy, RT : radiotherapy

tumors or clinical symptoms ; and “no response” meant non- or minimal regression and no substantial changes. The best effects were obtained with hyperthermia combined with radiotherapy in 134 out of 270 cases (49.6%) followed by chemo-radiotherapy in 92 out of 244 cases (37.7%), chemotherapy in 54 out of 360 cases (15.0%) and hyperthermia alone in 14 out of 187 cases (7.5%) (Fig. 2).



**Fig. 2.** Local responses analyzed by treatment modalities in combination with hyperthermia (HT). The evaluations were categorized using a scale described in the text. CT : chemotherapy, RT : radiotherapy.

## Discussion

In Japan, research work with hyperthermia began in 1978 with the establishment of the Japanese Hyperthermia Study Group (JHSG). Six years later, in 1984, the JSHO was established with 650 members<sup>1,3)</sup>. Since then the JSHO has made remarkable progress in both, the fields of basic science, and in clinical practice<sup>35)</sup>. At the same time, RF capacitive heating devices such as the Thermotron-RF8 which is effective for heating over wide regions of the human body became available. In 1990, the Japanese Government approved the use of health insurance to cover hyperthermia treatment limited to the application of an electromagnetic field and in combination with radiotherapy, and these conditions were later changed to either combination with chemotherapy or hyperthermia alone. JSHO membership increased markedly during the initial years, but decreased and has stabilized at a number of about 660<sup>3)</sup>.

Based on the material presented here, treatment is available for the following malignancies : (1) Locally advanced carcinoma and/or postoperative recurrent tumors of the breast, lung (superior sulcus tumor), rectum, and soft tissue sarcoma in RT-HT. (2) Carcinoma of the esophagus, pancreas, and extrahepatic biliary system in CT-RT-HT. Initially, more than two hundred heating units were installed, but many institutions withdrew from clinical applications of their equipment because of problems encountered during the clinical uses of heating procedures, or because of economic considerations. These problems will probably be manageable in the near future as more scientific data becomes available concerning the clinical benefits of HT in cancer treatments.

In order to develop measures to cope with the problem of low reimbursement costs for the application of hyperthermia, the health insurance control committee of the JSHO conducted a survey of the clinical applications of hyperthermia. Data obtained with questionnaires have shown that the treatment period per patient averaged 2.1 months. The abdomen was most frequently treated with hyperthermia, followed by the pelvic region and the thorax. Chemotherapy, radiotherapy, and chemo-radiotherapy were used frequently in combination with hyperthermia, and the best effects were obtained in combined therapy with radiation, followed by combination therapy with chemo-radiotherapy, combination therapy with chemotherapy, and with hyperthermia alone.

The financial situation of individual hospitals is important, and the difference between the income received and expenses incurred for the application of hyperthermia is something which cannot be ignored. For example, three staff members, or a team involving a doctor, a technician and a nurse are required for the clinical application of hyperthermia with an average duration of about 2 hours for a treatment. In considering personnel expenditures, and the costs of the equipment and expendables used in the application of hyperthermia, it is clear that under the present situation, the hospitals can not recover their costs from the health care system in Japan. Further promotion or education concerning hyperthermia may be necessary to improve this situation, and also to increase the frequency of clinical applications, and improve clinical results from the use of hyperthermia in the treatment of cancer patients.

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## Abstract in Japanese

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# わが国における温熱療法のあゆみと現状： 2004 年のアンケート調査

田中良明<sup>1</sup>・今田 肇<sup>2</sup>・平木嘉幸<sup>3</sup>・小野誠治<sup>4</sup>  
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**要 旨：**わが国におけるハイパーサーミアの研究は、文部省科学研究費・菅原班を母体にして発足した第 1 回の研究会 (1978 年, 大阪) から始まる。その後、理工学, 生物学, 臨床の各分野の研究者の関心が高まり, 1984 年にハイパーサーミア学会としての第 1 回大会が京都で開催され, 以後, 本年 (2006 年) の第 23 回大会に至っている。この間に, 会員数, 発表演題数では若干の減少傾向にあるが, 最近では, 温熱療法による癌治療以外に, 免疫増強作用, 高温度壊死療法, 緩温度療法など, その臨床応用は多彩である。学会の健保委員会において診療報酬点数の改定要望が懸案事項となり, 臨時部会が中心となってわが国における RF 波誘電型加温装置による温熱療法の実態を調査した。その結果, 温熱療法の対象部位, 疾患, 加温実施状況, 併用療法, 臨床効果についての概略が明らかとなり, いっぽう医療経済的に見て問題のあることがわかった。今後も引き続き学会活動の一環として定期的に調査を行っていきたい。