



Patient information

Clinical Studies - Hyperthermia

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Over the last 15 years, 34 clinical studies (17 phase I or II, 17 phase III) have been published regarding the effects of hyperthermia combined with radiation therapy and/or chemotherapy. The following studies are the most important studies from leading European and North American research centers.

Superficial tumors

In 1996, *Cancer*, the international journal of the American Cancer Society, reported a clinical study of 23 patients with head and neck tumors, breast carcinomas, and malignant melanomas, which was conducted by Mayer and Hallinan at Johns Hopkins Hospital (USA). The result showed complete remission in 89% of patients and demonstrated that 74% of patients were free of local recurrence after two years. All patients were treated with hyperthermia and brachytherapy. The authors concluded that “outpatient treatment of human neoplasia with interstitial thermoradiotherapy can be performed practically, and is safe and effective” (refer to 77/11, pp. 2363 – 2370)

In 2005, a randomized Phase III study on hyperthermia and radiation therapy for the treatment of superficial tumors, which was conducted by Ellen Jones et al., was published in the *Journal of Clinical Oncology* (vol. 23, no. 13, pp. 3079-3085). The majority of the 109 patients in the study has abreast wall recurrence. The other patients were suffering from head and neck tumors or melanomas. In patients who received hyperthermia combined with radiation, complete remission was observed in 66% of cases, compared to 42% of patients who received radiation alone. The effect was even greater among patients who had previously undergone radiation. In this case 68% of those who received hyperthermia and radiation experienced complete remission, compared to 24% who received radiation alone.

Head and neck tumors

In 1993, the *International Journal of Radiation Oncology, Biology, Physics* reported on the results of a phase III study by Valdagni and Amichelli at Ospedale S. Chiara in Trento, Italy, conducted on 41 patients with inoperable stage IV head and neck tumors. The result of the study showed that the combined treatment with hyperthermia and radiation therapy increase complete remission from 41% to 83% local recurrence-free survival from 24% to 68%, and the 5 year survival rate from 0% to 53%, compared with radiation therapy alone (refer to vol. 28, pp.163-169).

Malignant melanoma

In 1996, the results of a multi-centric Phase III study with recurrent or metastasizing malignant melanoma (performed by Overgaard, Aarhus, Denmark, et.al.) was published in the *International Journal of Hyperthermia*. The study showed that hyperthermia combined with radiation therapy increased the complete remission rate from 35% to 62% and recurrence-free survival after 5 years from 28% to 46% compared to radiation therapy alone. (refer to vol.12,no.1,pp.3-20).

Breast carcinoma

The results of a multi-centric clinical Phase III study that included 306 patients with superficial localized breast carcinoma were published in 1996 by Vernon, Hand, Field, et.al (London, Great Britain) in the *International Journal of Radiation Oncology, Biology, Physics*. The result showed that a rate of complete remission increased from 41% to 59%, and the recurrence free survival rate from 30% to 50%, when comparing the combined hyperthermia and radiation therapy treatment with radiation therapy alone (refer to vol.35,no.4,pp.731-744)

Glioblastoma

The results of a clinical Phase III study (performed by Sneed, Stauffer, McDermott et.al. at the University of California, San Francisco, USA) on 112 patients with glioblastoma multiforme was published in 1998 in the *International Journal of Radiation Oncology, Biology, Physics*. The study showed a doubling of the 2-year survival rate when combining hyperthermia and brachytherapy compared with brachytherapy alone (refer to vol.40,no.2,pp287-295).

Tumors in the pelvis

A clinical Phase III study by van der Zee, Gonzalez, van Rhoon et. al. (Rotterdam and Amsterdam, the Netherlands) on 358 patients with local, advanced tumors in the pelvis was published in *The Lancet* in 2000. The study showed that the combination of hyperthermia and radiation therapy increased the rate of complete remission for bladder carcinoma from 51% to 73% and for advanced cervical carcinoma from 57% to 83%. The 3-year survival rate in the hyperthermia and radiation therapy study group was 51% compared to 27% for the group with radiation therapy alone (refer to vol.355,pp.1119-1125).