FOUNDATION AND FUTURE PROJECTS OF A NEW EUROPEAN HYPERTHERMIC SOCIETY: SOCIETÀ ITALIANA DI IPERTERMIA ONCOLOGICA (SIIO)

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Abstract

The Italian Society of Oncological Hyperthermia (Società Italiana di Ipertermia Oncologica) was founded in September 2023 to promote oncological hyperthermia in Italy to better cure and serve cancer patients and give correct data to the Italian Ministry of Health and Regional Health Departments to develop a real Health Technology Assessment in oncological hyperthermia, currently not existing. SIIO intends to operate in all areas of medical, biological and physical research and promote all activities of support for patients, to organize data base, protocols of assistance, and new phase II and III trials. More than three thousand patients were treated with hyperthermia every year in Italy, 86% in private clinics and 14% in public Hospitals, all patients are in the metastatic phase relapsing after chemotherapy and radiotherapy. SIIO wants to expand the therapeutic paradigm of hyperthermia through the increase the number of Centres and the training of new doctors, nurses and technicians dedicated to hyperthermia.

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Introduction

World Health Organization reported that the prevalence of cancer has increased worldwide in the last ten years (1,2). Hyperthermia is a generic term for different techniques using heat in cancer therapies. Temperatures of about 42° Celsius in combination with chemotherapy or radiotherapy may improve the effectiveness of those treatments.

Oncological hyperthermia is a well-known group of methods that overheat the malignant tissues locally or systematically. Nevertheless, hyperthermia is not widely accepted, primarily because although cancer cells are more sensitive to heat it has always been difficult to perform thermometry on deep tissue. Even if hyperthermia kills them, it should be theoretically possible that the temperature-triggered higher blood flow can increase both the useful arrival of chemotherapeutic drugs but also the nutrient supply to the tumour (3). Modulated electro-hyperthermia (mEHT) has been developed in the last two decades to overcome the risks of sustain cancer cells, it is a heating therapy that uses synergized thermal and nonthermal effects to heat and destroy malignant cells selectively without damaging healthy cells. The mEHT applies electromagnetic interactions to deliver energy to the cancer cells. This event is realized in the synergy of two effects. Thermal effects, as usual in hyperthermia, occur in the form of heat and temperature increase these are mostly unselective. The heat spreads all over the volume seeking thermal equilibrium. The temperature characterizes the homogeneous distribution as average energy of the heat-absorbers. Non thermal processes, mainly observed in mEHT, are electron excitations, generating chemical reactions. The non thermal impact may change the intercellular membrane, and intracellular processes select them by the dielectric and conductive heterogeneity of the target (5).The mEHT applies a precise, personalized theranostic selection and treatment of

malignancy, supporting natural homeostatic processes such as apoptosis, immune reactions, conditional effects, etc. (6).

Another deficiency is the lack of homogeneity of the hyperthermic treatments that the various public Hospitals and private centres adopt. Similarly, is the diversity of machines used and treatment protocols making it very difficult to compare the therapeutic results obtained (4).
Another important problem is who pays for hyperthermia. In some European countries such as Switzerland and the Netherlands, hyperthermia treatments for various cancers in well-defined stages are paid by the National Health Systems. In other countries there are insurances that cover the costs while in the United Kingdom the costs are paid by the citizens. Oncological hyperthermia had been present in Italy since 1991 and was removed from the National Health System's list of treatments paid by National Health System on December 31, 2024. To request a new inclusion in the services paid by the National Health System, the Italian Society of Oncological Hyperthermia (SIIO) was born. The President of SIIO, on behalf of the Society, went to the Ministry of Health in Rome in September and October 2024 to submit an official request for the reinstatement of the hyperthermia in the therapies offered by the National Health System.

In any case, there are different conditions in the various Italian Regions. In some Regions hyperthermia has been suspended while the Tuscany Region has maintained hyperthermia in the free services offered to cancer patients. On March 25, 2025, the Puglia Region resolved that at the John Paul II National Cancer Institute in Bari there is a package of services that includes hyperthermia in the care of cancer patients completely paid by the Puglia Region and without economic burden for patients.

To reintroduce hyperthermia into the National Health System and overcome these limits the Italian Society of Oncological Hyperthermia (Società Italiana di Ipertermia Oncologica - SIIO) was founded in September 2023 to promote oncological hyperthermia in Italy and develop it on the national territory to better cure and serve cancer patients and their families and give correct data to the Italian Ministry of Health and Regional Health Departments to develop a real Health Technology Assessment in hyperthermia, currently not existing. Currently the presence of a new medical society dedicated to hyperthermia as SIIO, appears to be significant in the fight against cancer in Italy because the two main medical societies dedicated to the treatment of cancer, the Italian Society of Radiotherapy (AIRO) and the Italian Society of Medical Oncology (AIOM) have accepted the European guidelines, based on greater evidence from randomized trials and included in their Guidelines the use of hyperthermia in thoracic recurrences from breast cancer and in not operable or borderline soft tissue sarcomas. This happened in 2022, and it seems essential to develop a network of hyperthermia centres in Italy where patients can be treated with competence in the context of shared decisions in multidisciplinary groups (7,8).

Material and Methods

The Italian Society of Oncological Hyperthermia (SIIO) was founded in September 2023 by fifty professionals belonging to 23 centres that administer hyperthermia to cancer patients. The first elective assembly took place in Rome on January 13, 2024. The President, the Vice-President, the Secretary and Treasurer and 4 members of the board were elected.

SIIO HAS AS STATUTORY PURPOSES THE FOLLOWING POINTS:

1. o promote oncological hyperthermia in Italy and develop it on the national territory to better cure and serve cancer patients (CP) and their families and give correct data to the Italian Ministry of Health and Regional Health Departments to develop a real Health Technology Assessment in hyperthermia, currently not existing (3).
2. To encourage the advancement of hyperthermia in all areas of medical sciences.
3. To organize a national database regarding tumours treated with hyperthermia: defining histology, genetics, stage, line of therapy, therapeutic results, calculation of the duration of OS and response, and toxicities.
4. To define new phase II and III protocols of chemo-hyperthermia, radio-hyperthermia, immuno-hyperthermia, magnetic hyperthermia, palliative medicine-hyperthermia.
5. To develop Health Technology Assessment (HTA) in hyperthermia as a multidisciplinary evaluation process that aims to determine the value of heath hyperthermia technologies and interventions to inform decision-making to promote an equitable, efficient and high-quality health system (9).

RESULTS

The collections of the preliminary data obtained are being processed. Approximately more than three thousand patients were treated with hyperthermia every year in Italy, 86% in private clinics and 14% in public Hospitals, all in the metastatic phase relapsing after chemotherapy and radiotherapy with a life expectancy ranging from 3 months to 24 months. It is estimated by default that at least 20,000 sessions of hyperthermia are administered every year in Italy.

No patients are currently enrolled in research phase III studies, the published papers have been significant retrospective comparative observational studies but never randomized. Actually, all patients are treated in a palliative way following experience and personalized protocols present in each individual centre and dictated by the experience of the physicians, expert in hyperthermia. Each patient received eleven hyperthermia sessions (range 3-28).

The median duration of hyperthermia session was 55 minutes (range 50 -110), 2-3 weekly sessions were administered on alternate days.

The patients treated with hyperthermia concurrently received single chemotherapy at personalized doses and 90% of them received integrative and supportive therapies Many treatments are based on papers recently published by Fiorentini G .and Szasz M. (11,12). Consideration and attention in SIIO centres were given to evaluate the improvement in patients' quality of life and compliance using the ESAS scale, ECOG performance status scale and electronic self-report assessment (10,11). Different brands of superficial and deep hyperthermia devices are currently adopted in Italy: Andromedic, Alba, BSD, Celsius, Oncotherm, Syncrotherm.

Conclusions

SIIO wants to expand the therapeutic paradigm of hyperthermia following the national and international guidelines and evidence more recognized (5-10) through the increase the number of centres and the training of new doctors, nurses and technicians dedicated to hyperthermia.

SIIO is open to the participation of groups of patients and their families and to all interested professionals and stakeholders. SIIO intends to collaborate with the Agency for Regional Healthcare Services (AGENAS), chapter of Italian Ministry of Health, with all Italian Regional Health Services (14) , with medical associations to provide truthful and real information on the use of hyperthermia to allow and obtain the best results by optimizing costs and facilitating the access of cancer patients to hyperthermic treatments on the Italian Territory.

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Author contribution

G.F, D.S, M.B, G.R, A.C, G.C, S.G, A.M, M.P conceived and designed the study. GF, DS, A. G, R. LD, and S.B drafting the manuscript. Critical revisions were performed by G.A, M.B, G.C, G.B, SB, CM, PD, PT,RC, and GL. Statistical analysis was performed by GF, DS, AM C, S.R. C, P.D, M.D,V.D, F.D.V.C, S.B. Administrative, technical, or material support were performed by DS, TS and SB. Supervision was carried out by GF, G.A,MB, GC, GR. V.C,S.C,G.C,F.G, F.D, L.G, S.M, C.M,R.N, M.N, F.P,N.P, EM. P, E.P, T.S, I.S, P.T, C.Z, A.B,
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Conflict of interest

The Authors have no conflicts of interest to report.

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