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ORIGINAL ARTICLE

Quality assurance protocol for superficial and deep hyperthermia systems established by the Hellenic Association of Medical Physicists (HAMP) in cooperation with the Hellenic Society of Oncologic Hyperthemia (HSOH): A study based on European Society for Hyperthermic Oncology (ESHO) quality assurance guidelines

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Summary

Purpose: *During the last years hyperthermia is a developing therapeutic modality in Greece. Quality assurance (QA) procedures are essential for ensuring the correct operation of the hyperthermia system and therefore the selective heating of the tumor with minimum toxicity to the surrounding healthy tissues. The European Society for Hyperthermic Oncology (ESHO) has proposed QA guidelines for superficial as well as deep hyperthermia systems. The purpose of this study was to describe the adapted QA protocol for superficial and deep hyperthermia systems established in Greece.*

Methods: *A working group was created by the Hellenic Association of Medical Physicists (HAMP) for the proposal of QA guidelines for superficial and deep hyperthermia systems. A review of the protocol proposed by ESHO, together with the existing protocols in other European and International centers, as well as protocols suggested by European or International organizations, was performed. Then, a protocol was suggested, describing procedures for QA according to the current technology and the existing equipment used in Greece.*

Results: *A protocol describing the procedures for QA of superficial and deep hyperthermia systems was proposed. These procedures aim to evaluate the correct operation of the device, the thermometric system, the generator, the incorporated power meter and the applicators. It will also ensure the electrical safety of the devices.*

Conclusions: *The proposed protocol, applied by medical physicists in Greece, will ensure an efficient treatment with safety and minimum adverse effects. This protocol has been approved by the Hellenic Society of Oncologic Hyperthermia and the Hellenic Association of Medical Physicists.*

Key words: *deep hyperthermia, performance evaluation procedures, quality assurance, superficial hyperthermia*

Introduction

Hyperthermia (HT) is an anticancer treatment modality that uses non ionizing radiation and can be performed in conjunction with radiotherapy and/or chemotherapy [1]. HT can be applied using different methods depending on the type and location of the tumor. Superficial HT is applied for tu-

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mors of depth less than 5cm from the body surface, while deep HT is applied for tumors deeper within the human body [2]. Its efficacy depends on the controlled temperature increase of the tumor cells at 40-44°C [3]. Correct operation of the HT system should ensure the selective heating of the tumor with minimum toxicity to the surrounding healthy tissues. Therefore, QA procedures are essential in order to provide an effective HT treatment. ESHO has proposed QA guidelines for superficial as well as deep HT systems [4,5]. During the last 15 years, HT is a developing therapeutic modality in Greece [6-11], and a Hellenic protocol for QA of superficial and deep HT equipment was established [12] by cooperation of the HSOH with the HAMP. The procedures proposed are based on the ESHO protocol, on National and International experience and on corresponding protocols of other National and International committees taking into account the equipment currently used in Greece. The purpose of this article was to describe the procedures of the Hellenic QA protocol.

Methods

A working group was created by the HAMP for the proposal of QA guidelines for superficial and deep HT systems. A critical analysis of English language literature was performed in order to identify the protocols suggested by other Centers. A review of the relevant protocols proposed either by ESHO or other investigators, together with relevant publications of QA was performed. The procedures described were divided according to the type of hyperthermia systems. Afterwards, for each hyperthemia system the procedures were further divided into the following sections: correct operation of the device, QA of the thermometric system, QA of the generator-power meter, dosimetric QA and electrical safety. These procedures were adapted to the current technology and hyperthemia equipment existing in our country. Finally, the necessary equipment for the implementation of the suggested protocol was also defined.

Results

Necessary equipment

The necessary equipment for the QA of superficial and deep HT consists of a calibrated thermometer, two waterbaths, a tissue equivalent phantom, an infrared (IR) camera, a calibrated digital frequency counter, a calibrated power meter, a 50-Ohm load and a calibrated isotropic radiation survey meter.

The thermometer must be of high accuracy within the therapeutic range. More specifically, the desirable accuracy must be ± 0.1°C within the range of 41 to 45°C. The waterbaths are two insulated containers filled with water of controllable temperature. The phantom must be of muscle-tissue equivalent material with 1 cm thick optional layer of fat tissue-equivalent material on top. Its shape has to be rectangular for superficial HT systems and cylindrical and symmetrical for deep heating systems. It must also have the capability to be vertically -along both axis- and horizontally split. The IR camera is needed for the temperature measurements, which are necessary for Specific Absorption Rate (SAR) calculations. The resolution of the readings of the camera must be 0.1°C and the relative accuracy 0.05°C.

Quality assurance protocol

The QA protocol consists of 5 different sections:

A. Correct operation of the device
B. QA of the thermometric system
C. QA of the generator- incorporated power meter
D. QA of the applicators / dosimetric measurements
E. Electrical safety

These sections will be further analyzed in different paragraphs below.

A. Correct operation of the device

Daily, prior to each treatment, a visual inspection of the system is necessary in order to ensure that the system is working properly. When energizing the device, the indicator lamps and the digital displays of temperature and output power must be functional. An inspection of the electrical cables is necessary for wear, breakage or exposed terminals. In case that there are loose connections, these should be tightened. In addition, the integrity of insulation and protective coatings of the applicator and the devices that come in contact with the patient, such as waterbolus, must be confirmed. Finally, it must be ensured that the temperature probes do not have bends, breaks or damage to the insulation. The exact position of the temperature sensors must be located and verified that it is correct [5,13,14].

B. QA of the thermometric system

For the QA of the thermometric system, the thermocouple is affixed to the calibrated thermometer and both of them are inserted into the waterbath, which contains water of stable temperature within the therapeutic range. The evaluation procedures are described in this paragraph and are shown along with their frequency and the acceptable limits in Table 1 [13-18].

Accuracy: This measurement verifies the accuracy of the thermocouple of the device. The

readings of the two thermometers are compared. This procedure is repeated for three different temperatures within the therapeutic range (41, 43 and 45°C).

Stability over time: This measurement verifies the stability of the thermocouple of the device. The reading of the thermocouple is recorded during the period of one hr at intervals of 15 min at water temperature of 42.5°C (±0.5°C). The reading of the thermocouple must be stable over time.

Interference of the EM fields of external devices with the thermometric system: The purpose of this measurement is to ensure that there is no interference of the EM fields of external devices with the thermometric system of the HT device, as such interference will influence the readings of the tumor temperature during therapy.

Devices near the treatment area are energized. Any deviance of the temperature readings will probably be due to interference of the EM of the external device with the thermometric system. This can be confirmed if the temperature readings return towards the baseline when the external devices are deactivated.

Interference of the EM fields of the HT device with the thermometric system: The purpose of this measurement is to ensure that there is no interference of the EM fields of the HT device itself with the thermometric system.

The HT device is turned on and if any immediate rapid increase in temperature occurs, this might be due to the interference of the EM fields of the HT device with the thermometric system. This can be confirmed if a similar rapid drop in the temperature indication occurs when turning off the HT device.

C. QA of the generator and incorporated power meter

For the QA of the generator and the incorporated power meter, the digital frequency counter is connected to one of the channels of the HT device (for the accuracy of frequency evaluation). The generator is then connected through a power meter to a 50-Ohm load. The evaluation procedures are described in this paragraph and are shown along with their frequency and the acceptable limits in Table 2 [13,14,16,19,20].

Accuracy of frequency: The device is turned on and the reading of the frequency on the counter is recorded and compared to the nominal frequency. This procedure is repeated for every channel of the apparatus and for all operating frequencies.

Accuracy of the output power of the generator: The output power is modified from zero to maximum value in a stepwise fashion. Each reading is compared to the nominal value of output power. This procedure is repeated for every channel of the apparatus. It is also important to ensure that the generator must provide the full output power specified by the manufacturer.

Long-term stability of the power level: A specific value of the output power is selected and the reading of the power is observed for a typical treatment period (eg 1 hr).

Control system of generator – temperature: The applicator is coupled to a phantom and all the thermocouples of the device are inserted into a waterbath of temperature lower than a predominated temperature called the "target" temperature (eg 43°C). The apparatus is turned on and one of the thermocouples is inserted into a second waterbath of temperature higher than the target tempera-

Table 1. Perioperative use of fluids and medications

Evaluation procedure	*Acceptable limit*	*Frequency*
Accuracy	±0.3°C	1 M
Stability	±0.1°C	3 M
Interference of the EM fields of external devices with the thermometric system	±0.3°C	3 M
Interference of the EM fields of the HT device with the thermometric system	±1°C	3 M

QA: quality assurance, EM: electromagnetic, HT: hyperthermia, M: month

Table 2. QA of the generator and incorporated power meter: Evaluation procedure frequency and acceptable limits

Evaluation procedure	*Acceptable limit*	*Frequency*
Accuracy of frequency	±10%	3 M
Accuracy of the output power of the generator	±5%	3 M
Long-term stability of the power level	±10 %	3 M
Control system of generator– temperature	YES/NO	3 M
Accuracy of the incorporated power meter	±10 %	3 M

QA: quality assurance, M: month

ture. The power must be reduced or interrupted depending on the mechanism responsible for the regulation of temperature distribution. When the thermocouple is inserted into the first waterbath (of lower temperature), the power must be adjusted towards its original level or energized, depending once more on the mechanism responsible for the regulation of temperature distribution.

Accuracy of the incorporated power meter: The apparatus is connected through a power meter to a 50-Ohm load. The power is modified for a range of values and the readings of the power meter are compared to the nominal values.

D. Applicators

For the evaluation of the applicators, the apparatus is connected to the phantom, simulating a typical treatment. The temperature distribution will be measured with the use of the IR camera. In superficial HT systems the depth of interest is 1 cm, while in deep HT systems the depth of interest is in the center of the phantom. The procedures are described in this paragraph and are presented along with their frequency and the acceptable limits in Table 3 [4,13,15-17,21-27].

SAR-depth profile: The power is modified under standardized operating conditions and the temperature distribution is measured. The specific absorption rate (SAR) value is calculated at each depth using the equation:

$$SAR = c \frac{\Delta T}{\Delta t}$$

Where: SAR=Specific Absorption Rate in W/kg, ΔT/Δt=Temperature raise (°C) in time period of measurement (sec), c=specific heat of tissue or phantom material in $\frac{1}{J/kg*°C}$

The curve of SAR value as a function of depth is created along the central axis of the applicator.

In case that the maximum SAR value is not observed along the central axis, then an additional curve along this axis must be created. The curves are compared to the standard curves provided by the manufacturer. This procedure is repeated for all applicators. In case that a bolus is used in clinical practice, then the measurements must be repeated using the bolus since its use influences the energy deposition and distribution in tissue.

SAR profiles along x- and y central axis - Homogeneity and Symmetry: With the use of the IR camera, the SAR values are calculated along the x- and y- axis at 1 cm depth and at the center of the phantom for superficial and deep HT systems respectively. The procedure is repeated at a different depth within 5 – 10 cm.

It is important to inspect for the existence of hot spots. The homogeneity (F %) and the symmetry (S %) are calculated using the equations:

$$F = \frac{SAR_{max} - SAR_{min}}{SAR_{max} + SAR_{min}} *100$$

Where: SAR_{max}=maximum SAR value within the effective field size, EFS=FWHM, SAR_{min}=minimum SAR value within the effective field size

$$S = \frac{SAR\ (+x)}{SAR\ (-x)}$$

Where: SAR (±x) = SAR values of two symmetrical points over the central axis of the flattened area of the field.

Heating efficiency: The absolute SAR value per unit net input power is measured at a fixed depth in the central axis of the applicator. This value is then compared with the standard value provided by the manufacturer.

Calculation of the Useful Thermal Field Size (UFS) - Effective Field Size (EFS): The EFS is the area enclosed within the 50% SAR curve at 1 cm depth inside the tissue.

The UFS at a certain depth is the area enclosed by the curve delineating the 50% of the maximum SAR value at that depth.

Using the SAR profile (at depth within 5-10 cm) that was created above, the value of the useful thermal field size is calculated by the equation:

$$UFS = FWHM_{(SAR)}$$

Table 3. QA of the applicators: Evaluation procedure frequency and acceptable limits

Evaluation procedure	*Acceptable limit*	*Frequency*
SAR- Depth profile	±10%	6 M
SAR profile (x and y axis) Homogeneity and symmetry	±35%	6 M
Heating efficiency	±10%	3 M
UFS - EFS	±10%	6 M
Ec parameter	±10%	6 M
Penetration depth	±10%	6 M

QA: quality assurance, M: month, SAR: specific absorption rate, UFS: useful field size, EFS: effective field size, Ec: electrical calculated

Using the SAR profile in 1 cm depth, the value of the EFS is calculated using the equation:

$$EFS = FWHM_{(SAR)}$$

The calculation of UFS and EFS is repeated for all applicators. Then, these values are compared to the standard values provided by the manufacturer.

Calculation of the Ec parameter: The Ec parameter is the ratio of the area of the useful thermal field of the applicator to the area of the applicator aperture. It is an indicator of the applicator clinical utility. Therefore, it is calculated by the following equation:

$$Ec = \frac{Useful\ Field\ of\ the\ Applicator}{Total\ Field\ of\ the\ Applicator}$$

This parameter is calculated for all applicators and then it is compared with the standard value provided by the manufacturer.

Calculation of Penetration depth (PD): PD is the distance below 1 cm at which the SAR value is reduced to 50% of its maximum value at 1cm depth.

This value is calculated from the curves of SAR as a function of depth and it is compared by the standard value provided by the manufacturer.

E. Electrical safety – Protection from EM energy

The procedures for the electrical safety are described in this paragraph [13-16, 28]. They must be repeated semi-annually and the acceptable limits for the leakage radiation are dependent on the operating frequency.

Electrical Leakage Currents: It must be ensured that there are no electrical leakage currents for AC 220V/50 – 60Hz.

Protection from EM energy: Leakage radiation is monitored with an isotropic survey meter in a distance less than 5 cm from the applicators' surface. This procedure must be performed not only with the use of phantoms but also during patient treatment, as leakage radiation depends on the patient load as well as on environmental conditions.

For patient protection, special attention must be paid to sensitive areas such as the eyes, face or groin area. Treatment conditions should be reconfigured in case that leakage exceeds the permissible limit.

For staff protection, leakage radiation must be monitored in all places where staff is standing during treatment. Special attention is needed as reflections of the EM energy from shielded objects and other surfaces might lead to high levels of leakage radiation in unexpected areas.

Discussion

The HAMP in cooperation with the HSOH established a QA protocol for superficial and deep HT systems in Greece based on the protocols developed by ESHO [4,5]. The main difference between the ESHO and the Hellenic protocol is that, in our protocol, dosimetric measurements are realized in terms of SAR values instead of "temperature rise" measurements.

In addition, the ESHO protocol proposes a measurement for the appropriateness of the heating device. More specifically the device must be capable to produce a temperature rise of 6°C in 6 min at depth of 1 cm inside the phantom. As the superficial HT device in Greece has been created in the National Technical University of Athens, it is considered a device of low requirements and it is probable that more time is needed in order to reach the temperature of 43°C. Therefore, this procedure is not included in our protocol.

For the efficiency evaluation of the system we used a slightly different method than the one proposed by the ESHO protocol. Though the proposal is to measure the temperature increase by heating the phantom for 10 min, in our protocol the efficiency is evaluated by using the absolute SAR value per unit net input power at a fixed depth in the central axis of the applicator. However the proposed procedure by ESHO will be taken into account in the revised version of our protocol.

Concluding, this is the first time in our country that a protocol for QA of HT systems has been proposed. The procedures are based on the ESHO protocol established for Superficial and Deep HT systems. Correct operation of the HT device will lead to the selective heating of the tumor with the minimum toxicity to the surrounding healthy tissues. These procedures should be followed by Medical Physicists in Greece in order to ensure an efficient treatment with patient and personnel safety.

Conflict of interests

The authors declare no conflict of interests.

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