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Evaluation of therapeutic ultrasound equipments performance ☆

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ABSTRACT

The therapeutic ultrasound (US) is one of the resources mostly used by physiotherapists; however the use of uncalibrated equipments results in inefficient or even harmful therapies to the patient. In this direction, the objective of this study was to evaluate the performance and the procedures of utilization and maintenance of US in use in clinics and Physical-therapy offices. A questionnaire with questions related to the procedures applied in service during the use of therapeutic ultrasound was applied to physiotherapists. The performance of 31 equipments of 6 different brands and 13 different models was evaluated according to the IEC 61689 norm. The parameters measured were: acoustic power; effective radiating area (*AER*); non-uniformity ratio of the beam (RBN); maximum effective intensity; acoustic frequency of operation, modulation factor and wave form on pulsate mode. As for the questionnaires, it was evident that the professionals are not concerned about the calibration of the equipment. The results demonstrated that only 32.3% of the equipments were in accordance with the norms for the variables power and effective radiation area. The frequency analysis indicated that 20% of the 3 MHz transducers and 12.5% of the 1 MHz contemplated the norms. In the pulsate mode, 12.7% presented relation rest/duration inside allowed limits. A great variation of the ultrasonic field was observed on the obtained images, which presented beams not centered, sometimes with bifurcation of its apex. The results allow concluding that, although used in therapeutic sessions with the population, none of the equipments presents all the analyzed variables inside technical norms.

1. Introduction

In physical-therapy the therapeutic ultrasound (US) is among the mostly used resources by professionals in treatment of diverse disorders of the muscle-skeletal system [4,12]. The US physiological effects justify its indication for the treatment of muscle-skeletal pain, soft tissues injuries, articulatory dysfunctions, among others [8,7,11,3,2]. Even with its established biological effects, a great number of treatment failure reports are found in literature. This fact can be directly related to the energy applied and consequently with the equipment calibration [24].

The acoustic power is one of the main parameters to be evaluated. The evaluation can be obtained by radiation force balance or semi-analytical balances [10]. This has been a topic with considerable number on world-wide research publication which indicates that the majority of equipments are not calibrated [18,27,22,13,19,21,10,2,9,28,17].

However, only the power measurement is not enough to evaluate the transducer's quality [17]. Due to lack of laboratories and/or instruments that are capable to evaluate other parameters, a restricted number of studies with US that use the hydrophone as evaluation method exists.

If one considers that the number of physiotherapists in Brazil exceeds 100,000 professionals, this problem reaches an alarming dimension, once the US is one of the mostly used equipments in clinical practice.

Given the exposed, the proposal of this study was to analyze the conditions of use and maintenance of the Therapeutic Ultrasound equipment in use in Physical Therapy clinics and offices.

2. Material and methods

The study was conducted in two phases: (1) application of questionnaires for survey of the use conditions, and verification of the

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user qualification regarding common knowledge on the application of US and (2) calibration of equipments used in Physical Therapy clinics or offices.

The research project was approved by the Committee of Ethics in Research of UNIMEP, protocol 12/07.

2.1. Questionnaire application

A questionnaire with open and closed questions regarding the procedures used by the physiotherapists during the use of the US as well as questions related to the proper equipment was applied. Three-hundred and fifty questionnaires were sent via mail and via email.

2.2. Evaluation of ultrasound equipments

In the second phase of the study, calibration verification was conducted in equipments in use in Physical Therapy clinics or offices of the cities of Piracicaba and Campinas (SP-Brazil). The equipments were removed and directed to the Laboratory of Therapeutical Resources of the College of Health Sciences of the of the Methodist University of Piracicaba (UNIMEP) for the procedures of identification and gauging, after which a report was supplied in order to explain the adopted procedures and the results of the analysis.

The methodology utilized was based on the IEC 61689 norm. Output power declared; effective radiating area (*AER*); effective acoustic intensity; acoustic work frequency; non-uniformity ratio (*RBN)*; maximum intensity of the beam; beam type; pulse duration, pulse repetition period and wave form for each modulation factor (5%, 10%, 20% and 50%) were evaluated.

The power was measured by the radiation force balance previously calibrated with a standard load, according to the manufacturer's guideline – digital model UPM-DT-10 (OHMIC Instruments Co) that uses a reflector target. The intensities of 0.1; 0.5; 1.0; 1.5; 2.0; 2.5 and 3.0 W/cm^2 were verified, as presented on the panel, in the continuous mode. In order to increase the exactness of the reading, each output power was tested three times by the same experimenter [26,23].

The intensity was calculated by dividing the average of three measures of power obtained in the radiation force balance by the effective radiating area (*AER*), according to the value gauged on the acoustic tank. The error between the intensity measured and the one indicated on the panel of the equipment was expressed in percentage.

In the second phase of the evaluation, the mapping of the acoustic field was conducted with the aid of a computerized positioning system, where the hydrophone scans the acoustic beam of the transducer inside a tank with water (900 mm × 650 mm × 450 mm). The hydrophone is of a needle type, with active piezoelectric ceramics element with 0.5 mm of diameter, supplying measures that are relative to the pressure values for the analysis of field distribution. The hydrophone was directly connected to an amplifier of 10 dB, both manufactured by JP Weight Ultrasonics Instrumentation.

The mapping was conducted with the equipment operating on continuous mode with intensity of 0.5 W/cm^2. The data generated by the hydrophone were captured by an Analogical/Digital plate PCI-5112/16 M/CH (*National Instruments*™) and visualized online in the oscilloscope (TDS 210–60 MHz – 1GS/s *Tektronix*®). The data was stored in a computer for posterior processing in routines implemented in Matlab® 6.5 software.

2.3. Statistical analysis

The analysis of qualitative data was conducted by descriptive statistics, where the categorical variables were presented by means of relative frequencies. The quantitative variables related to output power, effective radiating area, non-uniformity ratio, maximum intensity, operation frequency, factor of operation in the pulsate mode and wave form of wave on pulsate mode are presented on the form of measures of position and dispersion, processed on the software BioEstat® 4.0.

The correlation of quantitative data was conducted by the Fischer test, where the association was made among the beam uniformity categories with *AER*, intensity and *RBN*, with significance level of 5%, in software BioEstat® 4.0.

3. Results

3.1. Questionnaire application

Fifty-one questionnaires were received adequately answered. The users of the US presented age average of 29 years (±6.35 years). The users graduated on an average of 5.83 years (±4.21) ago and work with the US equipment for an average of 4.5 years (±3.98).

Forty-six physiotherapists consider the ultrasound very commonly used equipment in the clinical practice. The number of patients treated per day varied between 1 and 150, with an average of 14.3 (±21.4).

With regards to the equipment calibration procedures, 62.7% of the physiotherapists answered that they realize maintenance in intervals that vary between 2 and 24 months and that the majority of the physiotherapists (43.7%) does it annually. Table 1 shows the results of the questions referring to the procedures utilized by the physiotherapists during the clinical use of the US, as well as the calibration procedures.

3.2. Equipments evaluation

Thirty-three US equipments were collected, however it was evidenced that two of them were not working, this way, 31 evaluated equipments of 13 different models. The names of the manufacturers will be maintained in secrecy because of the fact that equipments were not brand new. Table 2 presents the evaluated parameters and the obtained results.

In the qualitative evaluation of the acoustic field it was found that of the 31 evaluated transducers only 11 presented acoustic field with characteristics close to ideal in the form of a uniform cone. The majority of the transducers did not present uniform distribution of the beam, forming non-centered beams, with varied bifurcations and generating non-proportional distribution of energy from the base to the apex. Some beams showed multiple bifurcations indicating an indented aspect in its apex or a very restricted area (Fig. 1).

With regards the results pertinent to the analysis of association among categories, it was verified that when the uniformity beam (uniform cone or non-uniform) was associated to AER (inside or outside of the norm) there was significance. This data demonstrated that uniforms beams were related to equipment with AER inside the norm. However, when uniformity of the beam was associated with intensity or with RBN there was no significance.

4. Discussion

Although the fact that the physiotherapists consider the US as a very commonly used equipment in the clinical practice, the results of the questionnaires indicate that professionals present restrictions to necessary knowledge to determine the dosage. In addition, professionals also present restrictions to the knowledge necessary for the procedures of equipment maintenance even presenting a good average time of training and use of the US, as well as lack