A Calibration Study of Therapeutic Ultrasound Equipment Output Intensity Accuracy

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Purpose: The principal objective of this study was to evaluate the power output of ultrasound in Korean clinics and compare the value with Korean and global standards.

Methods: A total of 69 units were measured for ultrasound power output. The normal range of power output level was ± 30% of the output set according to KFDA standards. Device model, manufacturer, ERA, and BNR were obtained via simple questionnaires. A portable ultrasound power meter was used for output measurement.

Results: 37 machines, with reported ERA values, were assessed for power output per unit area. Of these machines, 13 (37.14%) were considered to be compliant with US FDA standards at 0.5, 1.0, 1.5, 20 W/cm^2 and 18 (51.43%) were considered within KFDA standards. The remainder of the machines were outside the standard error and evidenced irregular output levels, even though most of them were the same model.

Conclusion: Appropriate ultrasound intensity is incredibly important for safety and effective use. Therefore, the KFDA standards regarding ultrasound may require revision in light of global standards, including BNR and ERA additionally, attention should be paid to regular calibration for safe use in clinical practice.

Keywords: Ultrasound, Calibration, Power output, BNR, ERA

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I. Introduction

Ultrasound is one of the most widely employed devices in physical therapy.[1-5] Ultrasound is a general term for sound waves above human hearing ability, which is a wave pass through a medium with a frequency of 20 kHz or more. In physiotherapy, the most regularly applied frequency is 0.7-3.3 MHz. When a medium is applied in human tissue, mechanical vibrations are generated which induce biological effects.[1,2] However, inappropriate intensity can potentially cause injury at the cellular or tissue level.[1,2,6]

Effective radiating area (ERA), beam nonuniformity ratio (BNR), total power, and spatial average intensity (SAI) should be confirmed for more stable ultrasound output.[7-9] ERA is the area that represents all areas producing more than 5 percent of the maximum power output of the transducer. It is required for calculating energy per 1 cm^2 and total delivered energy to body[7,9-11]. BNR is the ratio between the peak amplitude and the average amplitude of the ultrasound beam across the ERA. The lower the BNR is, the more uniform the intensity of the sound wave is; lower BNR minimizes the risk of "hot spots". Global standards limit BNR values to less than 8 and the generally acceptable BNR range is between 2 and 6.[7,9-11] Total power describes the amount of power generated by a unit.[9,10] SAI describes the amount of power per unit area of the sound head's ERA.[9,10] Depending on the SAI of ultrasound, the amount of energy delivered to the body is determined. Too low intensity has no effect on the body, and too high intensity creates tissue damage if users do not adequately understand the level of output intensity, patients are subjected to potential risk.[10,11] Thus, measurement of the output levels of therapeutic ultrasound is very important for safety and effective treatment.[10,11]

In the 1960's, the International Electrotechnical Commission (IEC) presented detailed criteria for the inspection of ultrasonic stimulators.[12] The WHO implemented a standard by which the maximum intensity of ultrasound is not to exceed 3W/cm^2 per unit the FDA also specified a maximum BNR for ultrasound.[10,13] Based on these standards, a safe and effective standard was created for ultrasound stimulators.[9] In the United States of America Food & Drug Administration (US FDA), the accuracy range of power output is within ±20% of the output setting and in the CANADA14 and IEC9 standards, it is ±30% of output setting. The Korea Food & Drug Administration (KFDA) implemented an electrical medical device standard that the accuracyrange of power output level should be within ±30% of the output setting in cases in which the output exceeds 10% of the rate current.[15]

However, most studies conducted prior to the 2000's demonstrated that many of the ultrasound output settings evidenced a high failure rate.[7,11,16] Treatment using these machines could fail as a result and the effects of therapeutic ultrasound could be reduced; additionally, other adverse effects could ensue when the delivery energy is too high.[8,14,17] Despite the importance of intensity accuracy in therapeutic ultrasound, to the best of our knowledge, there has been no research conducted into the measurement of therapeutic ultrasound output in Korea. The principal objective of this research was to measure the actual emitted output and compare the value with Korean and global standards, providing fundamental data for the safe and proper use of ultrasound in clinical practice.

II. Methods

1. Study period and data collection

This study was conducted as a cross-sectional measurement study. The objective and design of the study were posted on the website of the Daegu Physical Therapist Association to inform potential participants the participants were later contacted via phone to confirm participation and agreement with the consent form. Measurements were conducted at 29 hospitals and ultrasound power output was measured in a total of 69 units from Apr. 1 to Apr. 15, 2011. The normal range of power output level was ±30% of output set according to KFDA standards and ±20% of US FDA standards.

2. Procedure and equipment

Prior to data acquisition, the correlation coefficient (r) was 1.0 in test-retest reliability for zero adjustment calibration. Using a simple questionnaire, detailed ultrasound information was obtained, such as device model, manufacturer, ERA, and BNR.

For output measurement, a portable ultrasound power meter (PUP-50, Ohmic Instruments Company, USA) was used the apparatus was designed to measure the power output of transducers up to 30 watts with 0.05 watts of resolution and transducer operating frequencies in a range of 0.5~10 MHz (Figure 1). The measured value is displayed digitally and the accuracy is ±0.05%. The transmitter contained in the fluid is in the shape of a cone, and a linear variable differential transmitter (LVDT) was used to measure the output. The amount of energy applied to the cone was measured. As a customer operating

Figure 1. Illustration of the power output testing procedure.

procedure, the PUP-50 test tank was filled with de-grassed water at room temperature. By means of the positioning clamp, the researcher attachedthe transducer head and radiating face of the head at 3.15 mm below the water level. To reduce measurement error, one researcher fixed the transducer head and checked the transducer surface with no air or bubbles. In each measurement, the researcher checked the calibration with a zero point adjustment using a 1 gram weight. In each machine, four intensity settings (0.5, 1.0, 1.5, 2.0W/cm^2) with continued mode (1 MHz) were tested.

3. Calculations

To determine energy per 1 cm^2, the ERA was used as follows:

Measured output per 1 cm^2 = Measured power output/ERA. The difference between measured SAI through PUP-50 and output setting indicated the error of the device and expressed using the following formula:

Error of the device = (Measured SAI/Output setting) × 100

Table 1. List of manufacturers of the tested ultrasound units

Manufacturer	Model		BNR	ERA	No.
Chungwoo Medical	CWM 302	Korea	6.1	7	4
Daeyang Medical	DM 77	Korea	5.5	None	1
DMC	Lectron-200UD	Korea	8	4.5	1
Hanil Medical	HS-501	Korea	None	None	11
ITC	Cora-100	Korea	None	None	1
Kwang Sung Medical	KS-920	Korea	None	None	1
Mega Medical	PT-300	Korea	None	None	1
MI technology	DF-02	Korea	None	None	1
Saeik Medical	Super Sonic S-13	Korea	None	None	1
Samson med	Sm-250	Korea	None	5	1
Shinjin	SUS-2N	Korea	None	None	4
StraTek	LST-10A	Korea	8	2	4
Young In Medical	IN-5000	Korea	None	None	4
Fysiomed	Sonic 15	Belgium	None	5	1
Gymna	Pulson 200	Germany	4.5	4.1	3
	Pulson 320		5	5	2
Metrax	Primedic-sono	Germany	None	5	1
Nemectron	Nemectroson 110	Germany	4.5	3.6	1
Simens	Sonostaf 833	Germany	6	4	2
Eletrovica Pagani	NT10	Italy	None	None	1
ITO Physio-threapy	Ultrasound US-700	Japan	4	5.5	1
OG Giken	ES-1	Japan	None	None 10	5
	ES-2		4		1
Asahi-Denshi	Ultra Sound Therapy Unit	Japan	None	None	1
Enraf Nonius	SonoPlus 390	Netherlands	6	5	2
	SonoPlus 490		6	5	1
	SonoPlus 590		6	5	4
	SonoPlus 591		6	5	2
Chattanooga	Intelect Mobile Ultrasound 2776	USA	5	5	4
Medical Device Depot Inc.	Metron Accusonic Plus AP170	USA	6	5	2
Mean			5.83	5.03	
Total					69

*None means not presented value by manufacturer or physical therapist

III. Results

Sixty-nine machines were evaluated. The mean BNR value (range) was 5.83 (4.5~8.0). The mean ERA value (range) was 5.03 (2-7) (Table 1). Thirty-seven machines with known ERA values were calculated for power output per unit area. However, two machines were automatically transformed to pulsed mode from continued mode to reduce energy above 1 W/cm^2, and two machines did not display output. Of these machines, 18 (51.43%) were considered to be within KFDA standards and 13 (37.14%) were considered within US FDA standards at 0.5, 1.0, 1.5, 20 W/cm^2 (Table 2).

Thirty-five machines, comprising 13 models and 13 manufacturers, were domestic products, and 34 machines, comprised of 17 model and 12 manufacturers, were imported products. In domestic products, only nine machines--3 models and 3 manufacturers--displayed both BNR and ERA. Two machines--2 models and 2 manufacturers--displayed only BNR or ERA. The remaining 24 machines displayed neither BNR nor ERA. In the imported products, 25 machines--12 models and 12 manufacturers--displayed both BNR and ERA, and two machines--2 models and 2 manufacturers--displayed only ERA. The remaining seven machines displayed neither BNR nor ERA values.

The machines that did not display BNR and ERA values were outside the standard error and evidenced irregular measured output levels, althoughmost of them were the same model.

IV. Discussion

This is the first study conducted in the field of Korean physical therapy in which some of the issues relating to calibration and measurement of therapeutic ultrasound equipment are evaluated.

This study demonstrated 18 (51.43%) ultrasound machines were considered to be within KFDA standards and 13 (37.14%) were considered to be within US FDA standards. Pye and Milford[17] tested 85 therapeutic machines in the Lothian Region of Scotland, and determined that 81% of machines had power outputs more than ±20% in error, and 69% had power outputs more than ±30% in error. A large percentage of ultrasound machines in chiropractic physicians' offices deliver too much or too little dosage to the patient.[16] Forty-five ultrasound units for ultrasonic output and electrical safety were tested 44% failed either calibration or electrical safety inspection within ±20 standard error. Artho et al.11 determined that 32 (39%) of the tested ultrasound machines had variables outside the standard for at least one setting. Of these machines, 15 (18%) were above the ±20% standard and 17 (21%) were below the ±20% standard for at least one output setting. Ferrari et al.[7] measured 31 units from 6 different manufacturers and 13 different models in Brazil only 32.3% were within normal range of variable power and effective radiation area, and 20% of the 3 MHz transducers and 12.5% of the 1 MHz conformed to the norms. Kollmann et al18 asserted that a possible reason for this failure rate is the transducer condition, which can affect both the output power and the surface heating maximum. Transducersmay be damaged when the junction between the piezoceramic element and covering layer in transducer fails, which shortens the transducer life and induces output failure. Interestingly, many ultrasound devices being used are actually in failure conditions,and clinicians were unaware of the actual output. We suggest a careful use of ultrasound machines and transducers, as well as regular calibration, to reduce the failure rate.

We determined that BNR or ERA value weren't displayed on

Table 2. Evaluated output of equipments inside normal limits allowed by US FDA and KFDA

Evaluated parameters	n	Average value	Limits value		Number of equipments inside the norm (%)	
			Lowest	Highest	US FDA standard ±20%	KFDA standard ±30%
0.5 W/cm^2	35	0.50	0.06	5.14	18 (51.43%)	21 (60.00%)
1.0 W/cm^2	35	1.05	0.15	10.66	16 (45.71%)	20 (57.14%)
1.5 W/cm^2	33	1.66	0.45	15.84	15 (45.45%)	18 (54.55%)
2.0 W/cm^2	33	2.30	0.75	21.20	16 (48.48%)	19 (57.58%)
All†					13 (37.14%)	18 (51.43%)

All† indicate inside limits allowed by standards at all 0.5, 1.0, 1.5, 2.0 W/cm^2

most domestic products or on some old imported products. Although this study did not analyze the failure rate of these machines on which no BNR or ERA values were displayed, most of them evidenced inconsistent intensity at 0.5, 1.0, 1.5, and 2.0 W/cm^2. This phenomenon may be induced by the lack of essential regular requirements for ultrasound manufacture. According to KFDA standards 15, such displays are not required as a result, the manufacturer may not take BNR or ERA into consideration. However, according to IEC12 and US FDA standards, BNR and ERA should be expressed by the manufacturer to ensure safe use of ultrasound. In addition to BNR and ERA, the IEC 616899 protocols include output power, effective acoustic intensity, acoustic work frequency, maximum intensity of the beam, beam type, pulse duration, pulse repetition period, and wave form to ensure ultrasound safety. Therefore, the KFDA standards should be revisited and possibly revised to include BNR and ERA levels.

This study had several limitations; the first was that it was performed only in Daegu, and the second was that the causes of the observed equipment failures were not confirmed, such as problems with the machine itself, or problems with the transducer. Additionally, our study did not consider other factors that can contribute to power output, such as yearof manufacture, hours of use, and periods of calibration. In the future, studies should be conducted with a larger sample and should use an updated questionnaire that takes these factors into consideration.

A great deal of research has been conducted to assess the biological effectsof ultrasound, data regarding which may be inappropriate due to machine defects.[2,19] These defective ultrasound machines continue to be used in actual clinics, thus affecting the resultant therapeutic effects and safety. Therefore, device calibration should be regularly performed every six months, or once per year. Additionally, if the ultrasound machine power output is found not to be within the ±20% or ±30% standard error, the machine should be calibrated by the technician or sent back to the manufacturer for calibration. This study provides scientific evidence suggesting that proper calibration would be beneficial for physical therapists using therapeutic ultrasound, helping to assure proper treatment and maximal safety.

Author Contributions

Research design: Yuk GC
Acquisition of data: Yuk GC
Analysis and interpretation of data: Yuk GC
Drafting of the manuscript: Yuk GC Park SH
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References

1. Baker KG, Robertson VJ, Duck FA. A review of therapeutic ultrasound: Biophysical effects. Phys Ther. 2001;81(7): 1351-8.
2. Robertson VJ, Baker KG. A review of therapeutic ultrasound: Effectiveness studies. Phys Ther. 2001;81(7):1339-50.
3. Park DJ. The effect of real-time ultrasound imaging feedback during abdominal hollowing in four point kneeling to healthy men. J Kor Soc Phys Ther 2010;22(6):1-6.
4. Park DJ. Changes of thickness in abdominal muscles between crook lying and wall support standing during abdominal hollowing in healthy men. J Kor Soc Phys Ther. 2010; 22(6):7-12.
5. Griffin XL, Costello I, Costa ML. The role of low intensity pulsed ultrasound therapy in the management of acute fractures: A systematic review. J Trauma. 2008;65(6):1446-52.
6. ter Haar G. Therapeutic applications of ultrasound. Prog Biophys Mol Biol. 2007;93(1-3):111-29.
7. Ferrari CB, Andrade MA, Adamowski JC et al. Evaluation of therapeutic ultrasound equipment performance. Ultrasonics. 2010;50(7):704-9.
8. Straub SJ, Johns LD, Howard SM. Variability in effective radiating area at 1 mhz affects ultrasound treatment intensity. Phys Ther. 2008;88(1):50-7.
9. IEC 61689. Ultrasonics - physiotherapy systems - performance requirements and methods of measurement in the frequency range 0.5 to 5 mhz. 1996.
10. Shaw A, Hodnett M. Calibration and measurement issues for therapeutic ultrasound. Ultrasonics. 2008;48(4):234-52.
11. Artho PA, Thyne JG, Warring BP et al. A calibration study of therapeutic ultrasound units. Phys Ther. 2002;82(3):257-63.

12. IEC. Testing and calibration of ultrasonic therapeutic equipment. 1963.
13. USFDA. Radiation safety performance standard. Ultrasound therapy products. Title 21, Part 1050.10. 1979.
14. Branch HP. Radiation emitting device regulations amendment pc 1981-908. 1981:1121-6.
15. KFDA. Electrical medical device standard. 2009.
16. Daniel DM, Rupert RL. Calibration and electrical safety status of therapeutic ultrasound used by chiropractic physicians. J Manipulative Physiol Ther. 2003;26(3):171-5.
17. Pye SD, Milford C. The performance of ultrasound physiotherapy machines in lothian region, scotland, 1992. Ultrasound Med Biol. 1994;20(4):347-59.
18. Kollmann C, Vacariu G, Schuhfried O et al. Variations in the output power and surface heating effects of transducers in therapeutic ultrasound. Arch Phys Med Rehabil. 2005; 86(7):1318-24.
19. Alexander LD, Gilman DR, Brown DR et al. Exposure to low amounts of ultrasound energy does not improve soft tissue shoulder pathology: A systematic review. Phys Ther. 2009; 90(1):14-25.