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Analysis of the Effective Dosage of Extracorporeal Shock Waves Therapy to Reduce Spasticity

Análise da Dosagem Eficaz da Terapia Extracorórea por Ondas de Choque para Redução da Espasticidade

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Abstract

The required dosages in shock waves are investigated for a safe and effective therapy in muscle spasticity. The objective was to analyze the shock waves application in spastic individuals considering their dosage, energy cycles, safety margin capable of reducing spasticity. Measurements were performed on 23 individuals in two different groups. The first group has 10 normal individuals (20-50 years old). Muscle resistance is verified against the shock waves application in high doses in which inspection is used for analysis. The second group consists of 13 individuals with moderate and severe spasticity (50-70 years), in which the application of lithotripsy will be performed to analyze the effectiveness of the equipment, using the inspection, Ashworth scale, digital goniometer and accelerometer with an electrical stimulator. The spasticity and muscular resistance reduction in relation to the equipment is proven, using high doses and intensities. (Dosage: 0.060 mJ / mm² at 1000 cycles / s). There was a reduction in the mean in the four measurements, for example, in elbow flexion the average dropped from 2.85 to 1.46 (p-value <0.001). In the Ashworth scale there was a difference of 2 points in the median. In accelerometry, there was significance for maximum acceleration (p <0.001), acceleration time (p = 0.128) and there was no significance for dilation time (p = 0.003). No skin irritation was found after using the equipment. High doses do not harm patients. Physiotherapy is important for the success of this equipment. Muscle preparation is proportional to the effectiveness of the method.

Keywords: Muscle Spasticity Lithotripsy. High-Energy Shock Waves. Walk Test.

Resumo

As dosagens necessárias em ondas de choque são investigadas para uma terapia segura e eficaz na espasticidade muscular. O objetivo foi analisar a aplicação das ondas de choque em indivíduos espásticos considerando sua dosagem, ciclos de energia, margem de segurança capaz de reduzir a espasticidade. As mensurações foram realizadas em 23 indivíduos em dois grupos diferentes. O primeiro grupo apresenta 10 indivíduos normais (20-50 anos). Verifica-se a resistência muscular frente a aplicação das ondas de choque em doses elevadas no qual utiliza-se a inspeção para análise. O segundo grupo compõe-se de 13 indivíduos com espasticidade moderada e severa (50-70 anos), no qual se efetuará a aplicação da litotripsia para analisar a eficácia do equipamento, utiliza-se a inspeção, escala de Ashworth, goniômetro digital e acelerômetro com um estimulador elétrico. Comprova-se a redução da espasticidade e a resistência muscular frente ao equipamento, utilizando doses e intensidades elevadas. (Dose: 0,060 mJ/mm² á 1000 ciclos/s). Houve redução da média nas quatro mensurações, como por exemplo, na flexão do cotovelo a média caiu de 2,85 para 1,46 (p-valor <0,001). Na escala de Ashworth houve diferença de 2 pontos na mediana. Na acelerometria houve significância para a aceleração máxima (p<0,001), tempo de aceleração (p=0,128) e não houve significância para o tempo de dilatação (p= 0,003). Não foram constatados nenhuma irritação na pele após a utilização do equipamento. As dosagens elevadas não causam danos aos pacientes. A fisioterapia é importante para o sucesso deste equipamento. O preparo muscular é proporcional à eficácia do método.

Palavras-chave*: Espasticidade Muscular. Litotripsia. Ondas de Choque de Alta Energia. Teste de Caminhada.*

1 Introduction

Extracorporeal Shock Waves Therapy (ESWT) is a non-invasive procedure that uses a potent ultrasound of a supersonic nature and represents a therapeutic concept whose results are evident in several areas of health, such as orthopedics, neurology, angiology and physiotherapy.

Spasticity causes rigidity and much pain, several treatments are performed to minimize its effects. This situation may lead to joint deformities, in addition to intense pains caused by shortening. Lithotripsy is an ultra-high frequency sound, about 1000 times the power of a normal ultrasound. Lithotripsy is a device that reduces spasticity present in individuals who have suffered stroke to a significant degree. It is necessary to investigate the safe and effective dosage by comparing normal and pathological individuals, considering their dosage, energy cycles and safety margin capable of reducing spasticity. In severe spasticity, the patient is unable

to perform any movement, in the moderate one the patient is able to perform some movements, poor with difficulties[1,2].

Shock waves are generated by the displacement of a metal plate submerged in water inside a tube through a magnetic field. This displacement generates a shock wave toward the point where lithiasis is located.[3,4]

Spasticity is a neurological condition accompanied by rigidity that affects people who have suffered stroke or cerebral palsy, usually accompanied by diplegia or hemiplegia. A number of symptoms or signs of major importance occur. Regarding motor alterations, there are several motion disorders such as spasticity, ataxia, athetosis or a mixed type, mixing many of these alterations. A comprehensive assessment is urgently needed.[5]

In spasticity, muscle tone becomes high. Tonus is muscle resistance to continuous stretch. Normal tonus is a light and constant tension to the healthy muscle. There are elastic, viscous and plastic properties of muscle fibers. Viscosity is the speed of a muscle when being stretched, several types of treatments should be carried out to activate the muscles with the patient's voluntary effort, aiming to obtain intentional movements.[6,7]

Muscle tonus resists upon pulling away part of the body toward opposite direction the movement. Upon stretching a body segment, the antagonist muscles adapt to the new movement and interact with each other. Resistance varies from one individual to another. Spasticity, therefore, is an increased resistance to movement. Hypertonia is a release of the tonic reflex activities manifested in stereotyped patterns.[8,9]

It is important to clarify some doubts when applying extracorporeal shock waves therapy in spasticity of causing damage to patients in high dosages.[6,7]

The fundamental principle of this study is to investigate the safety margin capable of reducing muscle spasticity by shock waves, allowing an increase in movements.

2 Material and Methods

2.1 Procedure

This project was submitted to the Ethics and Research Committee of Positivo University of Paraná under the number CAAE 48495115.0.0000.0093. The participants were informed and made aware of the study and its objectives and procedures. The procedures were performed only for volunteers who agreed to participate in the study and to sign the free and informed consent terms.

The selected patients were evaluated in a private physiotherapy clinic in a large room, containing a stretcher, portable accelerometer and a digital goniometer. The clinic is fully adapted for wheelchair users. Evaluations were performed with patients lying on a stretcher in dorsal decubitus. Lithotripsy applications were at Clínica Uropar Clinic, a medical unit belonging to Hospital da Cruz Vermelha associated with the research, located in Curitiba/PR, at Batel neighborhood. During the shock wave applications, the patient remained lying in dorsal decubitus on the equipment. The transducer was positioned under the arm.

In this study, shock waves were applied in normal and pathological patients. High doses were applied in normal individuals with the objective of checking muscle resistance, that is, the skin surface impedance before supersonic current.

23 individuals were selected in 2 different groups. The first group presents 10 normal individuals aged between 20 and 50 years, where the inclusion criteria were: 1) Adequate health. 2) Absence of stroke and motor difficulties. The exclusion criteria are: 1) Inadequate health. 2) movement disorders.

The second group consists of 13 individuals aged between 50 and 70 years whose inclusion criteria are: 1) Mild hypertonia. 2) Severe hypertonia. The following individuals are excluded: 1) Light hypertonia. 2) Joint limitation. 3) Deformities.

The objectives were: Group 1: To verify the muscle resistance to high-dose shock waves. Group 2: To prove effective spasticity reduction and skin resistance against shock wave applications, the same high intensities doses of the first group are applied.

2.2 Data Collection Instruments

Data collection instruments were directed to normal and pathological individuals. In normal individuals, the inspection and application of the shock waves were performed. In pathological individuals, four measurement methods were performed, the Ashworth scale, accelerometer, digital goniometer and the inspection before and after shock waves were applied.

The Ashworth scale, validated by the National Institute of Health in stroke (NIHSS), was used as a comparison criterion. People were examined by the modified Ashworth scale, described by Bohmann and Smith[10]; this is a subjective test to verify the spasticity levels. The Ashworth scale are clinical measures for spasticity being used by physiotherapists and researchers.[11] The Ashworth scale describes muscle evaluation at a ratio of 5 points. The modified Ashworth scale was elaborated by Bohannon and Smith[10], in which it modified the original scale, added degree 1+ and redefined degree 2 improving its accuracy.

The Ashworth scale was applied to flexion, extension, arm abduction and elbow flexion movements before and after shock wave applications.

It is possible to verify the decrease of the extensor reflex

by the digital goniometer because of the flexor synergy in the joints.[2,12] These measurements occurred before and after extracorporeal shock wave treatment and physiotherapeutic treatment[12]. The procedures for the goniometer application were: 1) To mark the anatomical points. 2) To capture data. 3) To record data.

The digital goniometer demonstrates better accuracy in angular measurements[2]. Marking the anatomical points of the joints and identify the bone mark is necessary, position in which the joints are evaluated. These markings were made with 10-mm diameter self-adhesive labels. The goniometer verified the different muscles lengths and their ability to perform the total movement range.

The digital goniometer was applied to flexion, extension, arm abduction and elbow flexion movements before and after the shock wave applications.

The accelerometer is a device that captures mechanical muscle vibrations, these vibrations are placed on the computer as a graph. This graph measures muscle contraction performance. It is a noninvasive technique that records vibrations of sounds produced by the muscles when contracting. These vibrations are also called oscillations. There is a relationship between the accelerometer signal and the tetanic contractions.[11] Accelerometry was used for several purposes: 1) To evaluate muscle fatigue. 2) To diagnose cardiac vibrations. 3) To analyze the evoked potential.

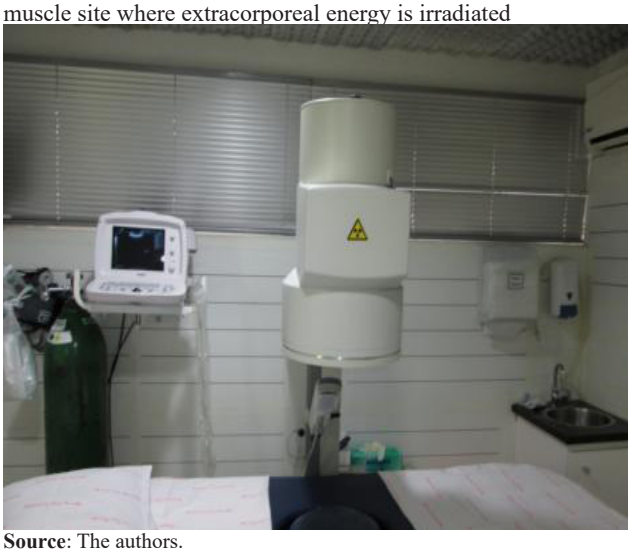
The accelerometer captures the muscle venter signals using the following variables: dilation time, maximum acceleration and acceleration time.

The equipment that will produce muscle contraction is the electrical stimulator of IBramed, neurodim Aussie Sport; the electric stimulus applied is Aussie in a time of 4 ms and a frequency of 15 hz. The ramp consists of 1 ms rise time and 9 ms rest time. Muscle fibers are resistant to fatigue, produced a strong contraction capable of being captured by the accelerometer before and after lithotripsy applications.

In the assessment, the inspection was carried out providing information that serves as a basis for a correct muscular analysis of the skin impedance, i.e., skin resistance before the equipment. Upon starting the muscle test, some factors capable of analyzing the muscles should be taken into account. The muscle test should be analyzed before 4 signs: presence of hematomas, presence of petechiae, local erythema and normal staining.

The lithotripsy equipment has an electromagnetic generator brand Direx, Integra®. The choice of dosage/ intensity was 1000 to 1500 cycles per second, 12 rotations per minute, at 0.060 mJ/mm² 1 energy in 12 gpm with the objective of observing the decrease in hypertonia and the quality of movement.

Figure 1 - Direx Integra®, lithotripsy and Orth lithotripsy equipment used by hospital da cruz vermelha at urology sector (uropar) coupled to ultrasound, being possible to visualize the muscle site where extracorporeal energy is irradiated



Source: The authors.

In normal individuals, the inspection was performed according to the same criteria described above and the lithotripsy application in the same dosages performed in pathological individuals.

2.3 Data Analysis

A 10° digital angle measurer Digital protractor rule 2-in-1, measurement from 0 to 360 degrees, resolution 0.05 is used. Accuracy +- 0.3 lowest display unit: 0.1 degree.[2,12]

The accelerometer has an electrical circuit for the range of the acceleromyographic signal through the triaxial, x, y and z sensors and gravity sensitivity adjustment (g) to calculate. The sensor response is set to 800 mV/V and 100 V/V amplification stage. The accelerometer used was BMA254, Bosch-brand sensor. Power consumption is 0.130 mA, resolution 0.019, range 39.227, minimum dilation of 10000 us and 14 hz speed.[13]

Parametric statistical tests were used, since normality of the quantitative variables of the main outcome was tested using the Kolmogorov-Smirnov test (KS) and normality distribution was verified. Parametric tests are more powerful in detecting significances. Therefore, the paired T-Student parametric test was selected.

3 Results and Discussion

During the inspection, no changes were found on the normal individuals' skin who were submitted to shock waves. Whereas for pathological individuals, two of them presented mild erythema due to high dosages, symptoms which disappeared after two days. The patients continued to participate in the research normally until the end. In pathological patient applications, the dosages-intensities were

the same used in normal individuals (0.0060mm/mj²), with the objective of observing the patients' tolerance to the equipment and the muscle spasticity reduction.

According to Table 1, the patients responded to the treatment significantly (<0.001 p-valor) the results were similar in all the variables, the patients preserved the muscle consistency. In the variables arm flexion, arm extension and arm abduction, the minimum and maximum values were significant. Overall, the results improve in all the movements. The standard deviation in relation to the mean showed homogeneity in the studies.

Table 1 - Statistical analysis of the modified Ashworth scale in pathological patients before and after shock wave applications at a dosage of approximately 0.0060mm/mj²

Modified Ashworth		Mean	Median	Standard Deviation	Min	Max	N	IC	P-value
Arm flexion	Before	3.15	3	0.69	2	4	13	0.37	<0.001
	After	1.77	1	1.01	1	4	13	0.55	
Arm extension	Before	2.92	3	0.76	2	4	13	0.41	<0.001
	After	1.46	1	0.88	1	4	13	0.48	
Arm abduction	Before	2.77	3	0.83	2	4	13	0.45	<0.001
	After	1.46	1	0.66	1	3	13	0.36	
Elbow flexion	Before	2.85	3	0.38	2	3	13	0.20	<0.001
	After	1.46	1	0.78	1	3	13	0.42	

Source: Research data.

So far ESWT has proven to be selective, or even intelligent, contributing to the future success of this treatment.[14,15] It reduces spasticity by preserving movements.[1] The planned objectives were met because the intention is to investigate the application criteria of shock waves that were not used in previous studies, whose purpose is to develop this technology, seeking better forms of treatment.[16]

In the digital goniometry contained in Table 2, elbow flexion improved its mean of (37.2-61.0). Followed by shoulder abduction (40,2-40.2). The worst performance was shoulder extension (21.8-27.4). The p-values were significant for all the variables.

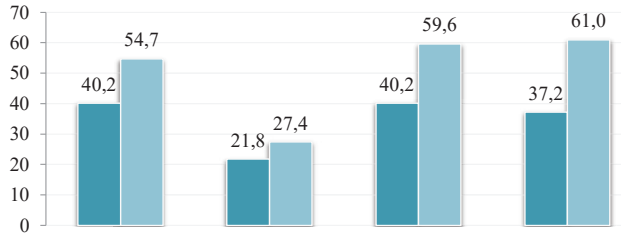
Table 2 - Statistical analysis using digital goniometer in pathological patients before and after shock wave applications at a dosage of approximately 0.060mm/mj²

Digital goniometer		Mean	Median	Standard Deviation	Min	Max	N	IC	P-value
Shoulder flexion	Before	40.2	42.7	21.6	15.1	77.2	13	11.8	<0.001
	After	54.7	60.3	20.6	24.0	79.1	13	11.2	
Shoulder extension	Before	21.8	20.0	10.8	10.2	43.3	13	5.8	0.034
	After	27.4	20.6	18.4	11.7	68.7	13	10.0	
Shoulder abduction	Before	40.2	35.0	21.3	15.2	77.9	13	11.6	<0.001
	After	59.6	57.5	26.6	25.7	103.1	13	14.5	
Elbow flexion	Before	37.2	45.2	21.0	13.2	68.5	13	11.4	0.005
	After	61.0	62.1	33.7	18.0	126.1	13	18.3	

Source: Research data.

The digital goniometer is also displayed in the graphic of Figure 2. There is an average difference in all measurements carried out, where it was observed that there was an increase in the mean. For example, the elbow Flexion measurement average raised from 37.2 to 61.0 (p-value =0.005).

Figure 2 - Comparison of moments in the digital goniometer



Source: Research data.

In accelerometry, as shown in Table 3, p-values were relevant for dilation time (0.003) and for maximum acceleration (<0.001), which did not show significance for acceleration time (0.128). It is concluded that there is a medium difference between the dilation time (mean fell from 0.22 to 0.08) and the maximum acceleration (mean raised from 0.97 to 1.27). The results of the accelerometer were uniform in all the patients. Improvement was observed in all the levels using 0.0060mm/mj² dosage, high dosage may have influenced the patients' evolution. In future studies, three applications with the same dosage/intensity placed in this study are recommended to reduce spasticity in a complete manner lasting from 4 to 6 months, followed by physiotherapy.

Table 3 - Statistical analysis using accelerometer in pathological patients before and after shock wave applications at a dosage of approximately 0.060mm/mj²
This table shows the dilation time, maximum acceleration, and acceleration time, in a curve, before and after the applications.

Accelerometer		Mean	Median	Standard Deviation	Min	Max	N	IC	P-value
Dilatation time	Before	0.22	0.2	0.15	0	0.5	13	0.08	0.003
	After	0.08	0	0.11	0	0.3	13	0.06	
Maximum acceleration	Before	0.97	0.9	0.43	0.4	1.7	13	0.24	<0.001
	After	1.27	1.2	0.54	0.5	2.1	13	0.29	
Acceleration time	Before	0.62	0.6	0.21	0.3	1	13	0.11	0.128
	After	0.53	0.5	0.18	0.2	0.8	13	0.10	

Source: Research data.

Another suggestion is the use of these criteria for lithotripsy applications in children performing the dosages demonstrated in this study, evidencing the possibility of using this protocol without the children's skin damage[2].

4 Conclusion

It is concluded that the high dosages presented in this Article do not cause damage to the patient, only mild erythema was observed. It effectively reduces muscle spasticity (Ashworth 3-1), being a therapy of choice for the treatment of cerebral palsy. This treatment method should be combined with physiotherapy to enable a functional improvement for the patient.

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