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ORIGINAL ARTICLE

Use of extracorporeal shock wave therapy in patients with spasticity related to stroke: a pilot study

Utilização da terapia extracorpórea por ondas de choque em acidente vascular encefálico com espasticidade: estudo piloto

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Abstract

Introduction: This research aims to show the reduction of muscular tonus by using extracorporeal shock wave lithotripsy in order to recover normal movements. **Methods:** 10 patients over 50 and under 80 years of age presenting stroke with spasticity participated in this pilot study, which used three methods: 1) the Ashworth scale, 2) the digital goniometer and 3) the displacement of muscle belly, before and after the shock waves. To check the displacement of muscle belly, a current pulse was applied, measured by LTM 165 class 2 Laser. This approach is similar and consists of measuring the displacement on a laser sensor basis. The Ortho-lithotripsy equipment used was a Direx Integra. The dose/intensity was 1000 cps – 0.030 mJ/mm². **Results:** We also observed a better quality of muscle contraction (Scale Ashworth p=0.05). At digital goniometry, the shoulder abduction developed 35° in 7 of the patients and 15° in 3 of them (p<0.05). **Conclusion:** The muscles do not become hypotonic with the shock waves treatment, (they present an adequate tonus). The patients who presented micro-shortening and did not undergo to regular physiotherapy showed a minor improvement (15° goniometry).

Keywords: stroke, spasticity, lithotripsy.

Resumo

Introdução: O objetivo desta pesquisa é demonstrar a redução do tônus muscular utilizando a terapia extracorpórea por ondas de choque e promover o retorno dos movimentos normais. **Métodos:** Foram escolhidos 10 pacientes idosos que apresentavam espasticidade, faixa etária entre 50 e 80 anos. Este estudo piloto utilizou 3 métodos: a escala de Ashworth, goniometro digital e o deslocamento do ventre muscular, antes e após as aplicações das ondas de choque. Aplicou-se uma corrente de pulso para verificar o deslocamento do ventre muscular, por meio de um laser marca LTM 165 classe 2 Stanley. O deslocamento foi medido por um sensor a laser. O equipamento de ortolotripsia foi a Direx Integra, cuja dose/intensidade foi entre 1000 ciclos por segundo e 0,030 mJ/mm de energia em 12 gpm. **Resultados:** Na escala de Ashworth os resultados foram significativos (= 0,05). Na goniometria digital a abdução do ombro evoluiu em média 35° em 7 pacientes e 15° em 3 pacientes. (p > 0,05). **Conclusão:** Observa-se que as ondas de choque não deixam os músculos hipotônicos, mas com tônus adequado. Os pacientes que obtiveram pouca melhora (15° goniometria) apresentaram micro-encurtamentos e não apresentam história de participação regular nas sessões de fisioterapia.

Palavras-chave: acidente vascular cerebral, espasticidade, litotripsia.

Introduction

Spasticity is a motor disorder in which the dependence raises of the tonic strain reflexes (muscular tonus) combined with exaggerated tendinous reflexes, and results in an extreme excitability of the elongation reflexes as a component of the superior motor neuron syndrome [1]. An injury of the nervous system can cause spasticity and alterations in the supra-spinal inhibitory mechanism and stretch reflex [2].

The study of Amélio *et al.* [3] about ESWT on fingers and wrist in 20 patients, using the Modified Ashworth Scale and the digital goniometer, showed the decreasing of spasticity, persisting for 12 weeks. These 20 patients were compared with placebo group. In comparison with other study of Amelio *et al.* [4] on 20 patients, the results did not persist until the 12^a week [3]. The shock waves presented better results, decreasing the muscle hypertonia, in the performance of movements and on members which have not been treated. The ESWT reduces pain in spastic muscles for weeks [4].

It is known, accordingly to Manganotti *et al.* [5] and Lohse *et al.* [6], that shock waves reduces the spasticity and after the application of ESWT the muscle remains stable. The movement execution appears when the muscle tonus begins to increase. The quality of the movement increases with the physical therapy sessions.

The physical therapy treatment is essential to demonstrate the possibilities of improvement. Through this evaluation, it was possible to know the abilities acquired after the application. For example: if the ESWT improves the balance, the balance practice must be done. If it will help the patient to grab an object, for example, it is necessary to practice the graduation of the movements to grab such object [1].

The works done in stroke with extracorporeal waves inspired the use of these methods [5]. In this article, the waves are irradiated on wrist and finger, in patients who shows flex pattern. This pattern lows down after the irradiation.

It is vital that this treatment is combined with a physical therapy treatment as well. Soft stretching, muscle stimulation and the incentive to active movements help the recuperation.

Shockwave therapy uses equipment that generates shockwaves external to the patient by means of an electrical sensor placed in a water-filled container. When excited, this sensor produces a compression wave that propagates inside this container [7]. The shock waves are applied in short breaks. Hundreds of microseconds raising the collapse energy. Lithotripsy was initially used to break renal calculus into fragments. With high energy and intensity, it possesses a great destructive power. With lower energy, it is possible to treat spasticity [8-10].

The Direx Integra Electro Magnetic Lithotripsy was chosen taking into consideration the size of its electrode and its relatively low maintenance cost. Extracorporeal shockwave therapy generally produces decreased spasticity. Extracorporeal Shock Wave Therapy (ESWT) releases nitric oxide (ON) which is located at the junction of neuronal synapses decreasing the impulses between synapses causing muscle relaxation.

The aim of this study was to obtain the reduction of spasticity using extracorporeal shock wave lithotripsy and to provide for the patient an increase of movements possibilities. According to literature reviewed, it is possible to achieve spasticity reduction using various dosages [3].

Methods

The ultrasonic lithotripter is equipment that has excellent molecular impact. It should work at low energy and intensity [11]. It makes shock waves in short breaks (hundreds of microseconds). It is also possible to utilize even lower doses, which can change chemical structures [7,12,13].

The Ethical Committee in research CAEE approved this research (4849511500000093). The volunteers authorized this study with an informed consent.

Selection

Ten patients were selected to do the lithotripsy applications to verifying the motor potential of the movements. The treatment duration was 10 sessions, 30 minutes each. At the end of the treatment, the volunteers did a new evaluation.

Ten patients composed the sample, with seven men and three women. Seven patients had severe spasticity and three moderate spasticity. The minimum age of the participants were 59 years old and the top age was 76 years old. The average age was 70.5 years old.

The patients included presented: 1) Moderate spasticity, 2) Severe spasticity, 3) Undergo to regular physical therapy. We excluded the patients with 1) Articular limitation, 2) Deformities, 3) Anticoagulant use.

The group can be compared with the one treated by physical therapy published by Figueiredo *et al.* [1]. The aim was to demonstrate that the shock waves (independent of the applied physiotherapy) can reduce the muscle tonus.

The evaluation and the treatment took place in a private physical therapy clinic. The applications occurred in Uopar – The Red Cross Hospital, associated to this research.

Measure instruments and technique

Three measurement methods were performed, the Ashworth scale, digital goniometry and muscle belly displacement.

Ashworth scale

The National Health Institute in CVA developed the Ashworth scale used as a comparison criterion. The patients were examined with the Modified Ashworth Scale (MAS), depicted by Bohannon *et al.* [14]. It consists in a subjective test to verify the levels of spasticity, before the shock waves applications. In this evaluation, it must be firstly applied the Modified Ashworth Scale (MAS), then the Aussie Current, to verifying the displacement of the muscle. A laser (Stanley) and a digital goniometer measure the displacement. Muscle belly displacement is measured by a class 2 laser and a digital goniometer.

Digital goniometer

We used a digital angle measure meter. The equipment parameters are: 10" Digital protractor rule 2-in-1, measurement 0 to 360 degrees, 0.05 resolutions, ± 0.3 accuracy. The study proposal is to verify the decrease of the extensor reflex by the digital goniometer, because of the flexor synergy of the articulations. These measurements are performed before and after the extracorporeal therapy applications (shock waves).

Muscle displacement

The digital laser (Stanley TLM) is a portable distance measure equipment, with 1 mm resolution. The laser system makes it possible to measure with a 1.5 mm precision, and it reaches between 0.05 to 50 m, 0.3 lines display, associated to an electric current, which can give a method to determine some levels of hypertonia. The laser was put above the bed with a 50 cm high support system.

The equipment that produces the muscle contraction was the electric lbramed stimulator. The neurodim Aussie Sport was the electric stimulus applied, which is alike the Russian Current, utilized in lack of use atrophy. The electric current has the burst frequency lasting from 4ms to 15Hz. The ramp modulation has 1 second of climbing time and 9 seconds of resting time. It is important to emphasize the choice of the 15Hz frequency. It is the recommended frequency to stimulate the motor neurons of muscle fibers. It produces a strong contraction, which the laser can capture, before and after the lithotripsy applications. [13]

The study of MacAndrew *et al.* [13] inspired the muscle measurement. As well as the study of Krijaj *et al.* [15], it is possible to see that the electrical current produces a muscle displacement before and after the application of Extracorporeal Shock Wave Therapy (ESWT). The electrodes are positioned on the muscle, around the marked point and the intensity must be below of the tolerable motor threshold of the patient. The patient must be in dorsal decubitus on a stretcher, lower limbs flexed, and a pen mark made on the biceps.

A strong muscular contraction must be applied. Then, a laser will measure the displacement of the muscle before and after the lithotripsy application.

Orthopedic lithotripsy

The orthopedic lithotripsy equipment used is a Direx Integra. The choice of intensity is 1000 cycles per second and 0.030 mJ/mm² low energy in 12 turn for minutes with the aim of verifying the delay of hypertonia, the quality of movement and the decrease of the sensitivity disturbance.

The application of ESWT will respect the dose and intensity described. Then, the patients will pass for a new measure. The patient lay down on a stretcher in dorsal decubitus, with the lower limbs flexed. The biceps brachii is the chosen muscle. The physiotherapist positions four electrodes on the muscle. The current provides a muscular contracture.

Statistical analysis

The mean, median, 1^o and 3^o quartiles, minimum and maximum values and standard deviation measures describes the quantitative variables. We used the Wilcoxon signed-rank test to compare the two moments of the evaluation with the variables, which did not attend the normal condition. To the comparison of the variables that attended the normal condition, the Student test was considered for paired sample analysis, with P value < 0.05.

The null hypothesis of same results of the variables evaluated in the Ashworth scale were tested, in each moment, versus the alternative hypothesis of different means. In the table below the descriptive statics are presented so as the P-value.

In each one of the variables tested by the digital goniometry and on the displacement of the muscle belly, the null hypothesis of equal medias in the two moments were tested, also the alternative different means. The described statistic of each one of the variables, in each one of the moments, were tested (tables III, IV e V) (also the descriptive statistic for the difference between the results in the end and in the beginning). In addition, the p-values of the statistic tests are presented.

Results

The tables show the results of 10 patients in different stages of the treatment, before and after the applications. In the first table, it is possible to see the results of the muscle tonus measure on the compromised side. We evaluated four movements. According to the table I, in general, the muscle has moved 1 to 2 mm before the lithotripsy application and 3 mm after.

The muscle of the elderly dislocated 1 mm before the applications and 2 mm after the applications. It was possible to notice the relaxation and the improvement of the contraction quality.

Table I - Modified Ashworth Scale Application.

Variável	Moment	Mínimum value	1 ^o Quartile	Median	3 ^o Quartile	Maximum value	P value*
Arm flexion	Before/after	3	1 3,0	1,1 3,0	2,0 4,0	2,0 4	3 0,005
Arm Extensão	Before/after	2	1 2,0	1,0 3,0	1,0 3,0	1,4 4	3 0,005
Arm Abduction	Before/after	2	1 2,0	1,0 2,0	1,0 2,8	1,0 4	2 0,005
Elbow Flexion	Before/after	3	1 3,0	1,1 3,0	1,5 3,0	1,9 4	2 0,005

(*) Wilcoxon signed-rank test; p < 0.05; n = 10

The study of Figueiredo [1] demonstrated the increase of mobility and the decrease of spasticity after the physical therapy intervention. The tonus reduction was 1-2p on the Asworth scale. Nevertheless, on the other day the spasticity increases. The shock waves offer an effect that last 3 to 4 months [1].

The Ashworth scale presents an excellent p value in all parameters (0,005). The most significant values are the arm abduction and the elbow flexion.

Table II - Muscle contraction result, captured by the laser sensor, before and after the ESWT application.

Variable	Moment	Mean	Median	Minimum value	Maximum value	SD	p value*
Biceps	Before	534,8	538,5	510	545	11,4	<0,001
	After	537	541,0	512	548	11,6	
	After Before	2,2	2,5	2	3	0,2	

*Student t-test for paired samples; $p < 0.05$; $n = 10$.

Table III - Before and after ESWT measurement application, made with a digital goniometer.

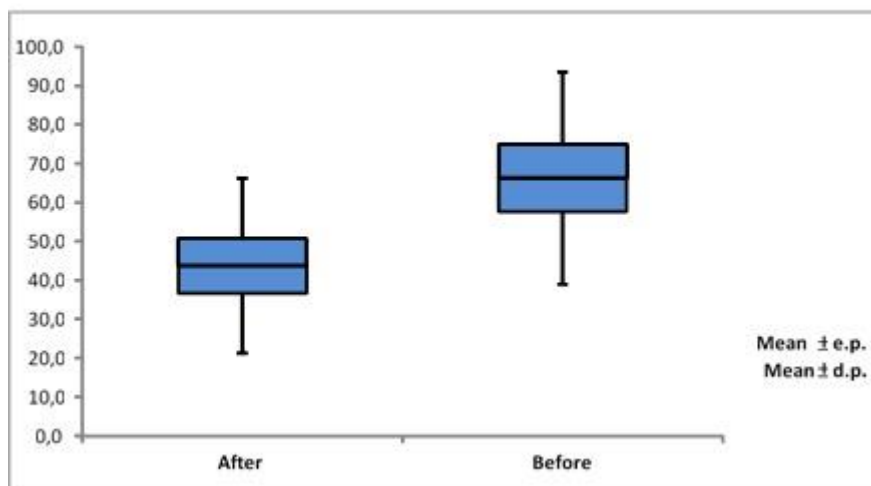
Variável	Moment	Mean	Median	Minimum value	Maximum value	SD	p value*
Shoulder flexion	Antes	43,70	52,28	15,80	75,40	22,11	0,002
	Depois	58,65	64,08	24,30	81,55	22,08	
	Depois Antes	14,95	11,90	3,60	31,20	10,53	
Shoulder extensão	Antes	21,98	17,05	9,25	44,20	12,80	0,014
	Depois	30,25	21,63	12,75	69,20	20,79	
	Depois Antes	8,24	4,53	0,85	25,00	8,56	
Shoulder abduction	Antes	43,73	51,75	14,10	76,85	22,41	<0,001
	Depois	66,28	66,93	36,30	105,15	27,24	
	Depois Antes	22,55	22,88	3,95	44,00	12,21	
Elbow flexion	Antes	39,45	52,40	13,00	65,30	21,65	0,011
	Depois	69,49	67,00	18,90	136,15	37,46	
	Depois Antes	30,04	15,30	3,30	82,00	29,80	

*Student t-test for paired samples; $p < 0.05$; $n = 10$.

The muscular displacement presents (2.2-2.0) values for mean and median. The minimum value of 1.0 shows the patients that did not had any improvement, only three of them <0.001. The best muscular displacement was 3.0.

The graphics represent the patients who presented a significant evolution from the ones that did not had any. These ones reinforce the selectivity of the equipment, which must be considered during the indication.

Seven patients showed a reduction of the tonus (shoulder abduction 44°), without losing the muscular resistance. The graphic presents the shoulder abduction (76.85 to 105.15 degrees). According to the graphics, the goniometry is the parameter which showed better evolution. The best improvements were observed in the shoulder and elbow flexion.

**Figure 1** - Before and after the ESWT applications with a digital goniometer graphic. Value of $p < 0.001$.

In the first figure, the mean and the medians of the shoulder abduction are the same (22.55-22.88). It shows a consistent improvement in these indicators. Its minimum value is 3.95. It is a uniform improvement in these parameters. The elbow flexion and the shoulder abduction demonstrated a better evolution on the digital goniometry $p < 0.001$, following their SD, as it is possible to see in figure number 2.

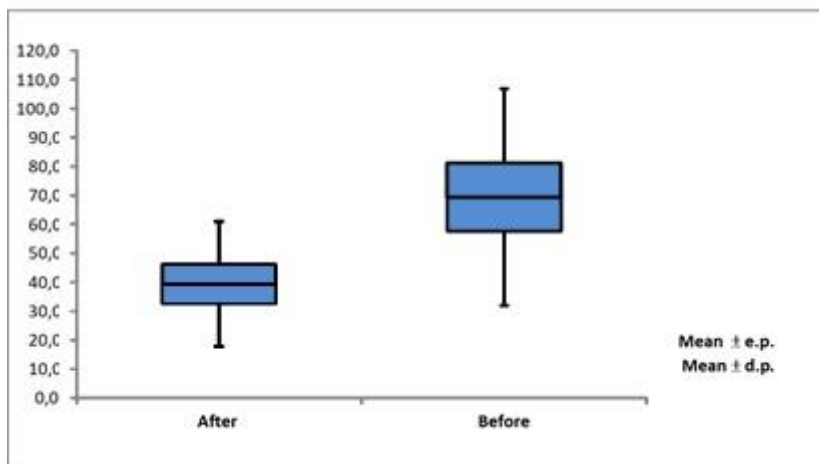


Figure 2 - Elbow flexion, before and after the ESWT applications with a digital goniometer graphic. P value = 0.011.

In the digital goniometry, there is a significant value. The value of the elbow flexion was 0.011. The maximum value was 82.00. The elbow flexion was 0.011. There was a great improvement for all the patients (30.04 mean).

Discussion

During the evolution of this research, it was possible to verify the increase of the movement amplitude. The movement became more selective. The intensity dosage used was lower if compared to the literature. Wu et al. [16] used 3.200 cycles and the applied energy was 0,030 mJ/mm² [16]. However, in the current study, 1000 cycles per second were used, 12 gpm with an energy of 0,030 mJ/mm², that is lower energy and cycles than other studies. The objective of the previous researches was to prove the efficacy of the reduction of the spasticity (that is the reason why the dosage was higher).

Some patients did not evolve as expected. In a deeper investigation of the patients who did not showed any improvement, it is possible that they already presented muscle contractures and the ESWT only can be successful in spastic healthy muscles, without any deformities [4].

The volunteers that did not show any improvement do not have a history of undergoing to regular physical therapy. The shortening muscles are better treated with the A Botulinum toxin.

The reduction of the muscular tonus, after the applications of ESWT reinforces the vibrational effect as a possible theory of the effects of ESWT in the human body [7,17].

Until now, the ESWT demonstrate selectiveness or even some intelligence, what helps the future success of the treatment.

Some suggestions are important in this line of work. It is important to think about lower intensity e higher frequency of the applications and to verify the time that the reduction of spasticity lasts. Currently, the effect of the extracorporeal waves lasts 4 to 6 months, when the decrease happens by the ESWT application and, by consequence, the liberation of the movements. The hypertonia limits the muscle potential. The application of ESWT helps to decrease the spasticity and the liberation of the movement hypertonia limits the muscle potential. As a result, the activities of the daily life can be made with more efficiency.

Conclusion

This study suggests that the reduction of the spasticity is possible. Elderly people were tolerant to the equipment and the intensity dose made it possible for the utilization of these criteria for other treatments.

The pilot study had some limitations. These limitations include the small sample size and the lack of a control group. However, at all stages of treatment there was seriousness in patient selection and measurements before and after shockwaves.

For a future work, it is interesting to verify the effects of lithotripsy in the gastrocnemius, in order to help the capacity of walk. The patient will respond positively to the application, because, as demonstrated, the shock waves does not make the muscle flaccid, but with the right tonus.

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