

Effects of shiatsu on pain in people with limb fractures: clinical trial

Efeito do shiatsu sobre a dor de pessoas com fraturas nos membros: ensaio clínico

Efecto del shiatsu sobre el dolor en personas con fracturas de extremidades: ensayo clínico

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ABSTRACT: The postoperative period for limbs fractures is characterized by different levels of pain intensity. *Shiatsu* is a therapy applied with the hands on meridians and *tsubos* (points similar to acupuncture) related to pain. **Objective:** To evaluate the effect of *shiatsu* on postoperative pain in men with arm and leg fractures. **Method:** Non-randomized and uncontrolled clinical trial, with assessment of pain levels using the Visual Numerical Scale (VNS) (0–10) and measurement of salivary cortisol. The R software and the Wilcoxon test and Fisher's exact test were used. **Results:** 41 people participated in the research; the initial mean value of salivary cortisol concentration was 0.39 $\mu\text{g}/\text{dl}$ and, after *shiatsu* intervention, it decreased to 0.32 $\mu\text{g}/\text{dl}$ ($p < 0.0001$). The Mean pain value was 4.93 (VNS) before the intervention and 3.90 ($p < 0.0001$) after. **Conclusion:** The application of *shiatsu* contributed to reducing pain and cortisol levels in people undergoing orthopedic surgery.

Keywords: Shiatsu. Bone fractures. Pain.

RESUMO: O pós-operatório de fraturas dos membros superiores e inferiores é caracterizado por diversos níveis de intensidade dolorosa. O *shiatsu* é uma terapia aplicada com as mãos nos meridianos e *tsubos* (pontos similares aos da acupuntura) relacionados à dor. **Objetivo:** Avaliar o efeito do *shiatsu* sobre a dor no pós-operatório de homens com fraturas dos braços e pernas. **Método:** Ensaio clínico não randomizado e não controlado, com avaliação dos níveis de dor por meio da Escala Numérica Visual (ENV) (0–10) e de mensuração do cortisol salivar. Foi utilizado o *software* R e o teste de Wilcoxon e o teste exato de Fisher. **Resultados:** 41 pessoas participaram da pesquisa; o valor médio inicial da concentração salivar de cortisol foi de 0,39 $\mu\text{g}/\text{dl}$ e, depois da intervenção com *shiatsu*, diminuiu para 0,32 $\mu\text{g}/\text{dl}$ ($p < 0,0001$). O valor médio da dor foi 4,93 (ENV) antes da intervenção e 3,90 ($p < 0,0001$) depois. **Conclusão:** A aplicação do *shiatsu* contribuiu para reduzir os níveis de dor e cortisol em pessoas submetidas a cirurgias ortopédicas.

Palavras-chave: *Shiatsu*. Fraturas. Dor.

RESUMEN: El postoperatorio de fracturas de miembros superiores e inferiores se caracteriza por diferentes niveles de intensidad del dolor. El *Shiatsu* es una terapia que se aplica con las manos sobre meridianos y *tsubos* (puntos similares a la acupuntura) relacionados con el dolor. **Objetivo:** Evaluar el efecto del *Shiatsu* sobre el dolor postoperatorio en hombres con fracturas de brazo y pierna. **Método:** ensayo clínico no aleatorizado y no controlado, con evaluación de los niveles de dolor mediante la Escala Numérica Visual (ENV) (0–10) y medición de cortisol salival. Se utilizó el *software* R, la prueba de Wilcoxon y la prueba exacta de Fisher. **Resultados:** Participaron de la investigación 41 personas y el valor medio inicial de la concentración de cortisol salival fue de 0,39 $\mu\text{g}/\text{dl}$ y después de la intervención de *Shiatsu* disminuyó a 0,32 $\mu\text{g}/\text{dl}$ ($p < 0,0001$). El valor promedio del dolor fue de 4,93 (ENV) antes de la intervención y de 3,90 ($p < 0,0001$) después de la intervención. **Conclusión:** La aplicación de *Shiatsu* contribuyó a reducir el dolor y los niveles de cortisol en personas sometidas a cirugía ortopédica.

Palabras clave: *Shiatsu*. Fracturas. Dolor.

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INTRODUCTION

Pain control is a challenge for healthcare professionals, and *shiatsu* has been used in several countries, effectively and safely, in a variety of clinical contexts¹.

Acute pain is an experience that can reach a prevalence of 34% in adults admitted to medical-surgical clinics and is often related to surgical procedures and trauma; it may be persistent, even after drug administration².

It is a common symptom in the orthopedic postoperative period, often related to the surgery itself, configuring the need to define its characteristics, especially the level of pain³.

In Western culture, pain is generally treated with drugs, but alternative treatments have been sought, among the best known, those derived from traditional Chinese medicine, which has several approaches, many already consolidated in European countries⁴.

Multimodal analgesia has been recommended in association with alternative therapies, including *shiatsu*, which is based on the idea of a flow of energy that flows through channels called meridians, that have entry doors called *tsubos* (points similar to those in acupuncture). Thus, it is possible to manipulate such structures for therapeutic purposes⁵.

Clinical conditions in which *shiatsu* may be applied include allergies, cancer, respiratory disorders, dysmenorrhea, stress, and sleep disorders. The authors searched the databases Ovid-MEDLINE, Ovid-EMBASE, the Cochrane Central Register of Controlled Trials (CENTRAL), the Cumulative Index to Nursing and Allied Health Literature (CINAHL), six electronic databases of Korea, China National Knowledge Infrastructure (CNKI) and Japan Science and Technology Information Aggregator (J-STAGE) and identified ten studies with favorable results for this therapy⁶.

The effectiveness of *shiatsu* in reducing pain and the impact on cortisol in people with limbs fractures is still unknown, and the present research aimed to answer the question: can *shiatsu* reduce pain in people with limbs fractures?

OBJECTIVE

To evaluate the effect of *shiatsu* on pain and salivary cortisol in the postoperative period of limbs fractures.

METHOD

A non-randomized and uncontrolled clinical trial modality (before and after an intervention) was developed. This option

is appropriate when a randomized clinical trial (RCT) would be ideal, but not possible. This modality is more practical than RCTs and is used when it is necessary to demonstrate the effectiveness of a therapy⁷.

The research took place in a teaching hospital in the countryside of the state of Minas Gerais and, due to the low demand for females in the same clinical context, the male sample was chosen. To determine sample size, the formula was used to compare the means, adopting the 95% confidence interval, the power of 80%, the standard deviation of 13.6, and the minimum difference to be detected on the verbal-numerical pain scale. To calculate sample size and precision for estimating the population proportion, Epidat version 3.1 was used.

Data collection and application of therapy to a sample of 42 men, within 48 hours of post-operative fractures in the arms and legs, took place between March 2016 and March 2017. Pain assessment and cortisol collect before and after the intervention were carried out between 8 and 11 a.m. All people invited to participate signed the informed consent.

The *tsubos* that underwent intervention were: IG4 (*Hegu*), located on the hands; C7 (*Shenmen*) and P6 (*Neiguan*), on the forearm; E36 (*Zusanli*), on the leg; and R1 (*Yongquan*), on the foot. The intervention lasted between 40 and 60 minutes and was applied bilaterally. Pain was measured using the Visual Numerical Scale and cortisol was collected with the Salivette[®] kit (Sarstedt, Nümbrecht, Germany 51.1534) and measured in the laboratory using the ultrasensitive electrochemiluminescent immunoassay (ECLIA). Data were entered into the Statistical Package for the Social Sciences — SPSS, version 22 (IBM Corp. Released 2013. IBM SPSS Statistics for Windows, Version 22.0. Armonk, NY: IBM Corp) and analyzed using the R software, version 3.2.4.

Qualitative variables were described using absolute and relative frequency, while for quantitative variables, measures of central tendency, position, and dispersion were used. Variations in cortisol and pain were evaluated using the Wilcoxon Paired test, since each person was evaluated at two distinct moments. To check whether there is an association between high cortisol values and pain, the Fisher test was used.

The project was approved by the Ethics Committee through Plataforma Brasil, under number 947.084 and CAAE: 38884414.0.0000.5108, in accordance with Resolution 466/12.

RESULTS

Laboratory data from one person were lost during cortisol analysis, leaving the sample with 41 people who underwent orthopedic surgery to correct fractures in their arms and legs. The majority of them (63.41%) came from other cities; 51.22% were single and 34.15% married; 9.76 lived in a stable union and 4.88 were separated. As for education, 53.66% reported having studied between five and nine years; 85.37% were hospitalized for treatment of lower limb fractures; 68.29% had no history of fractures; and 7.32% declared having hematological diseases.

Consumption of alcoholic beverages was reported by 65.85%, but 73.17% denied using tobacco. The use of opioid and non-opioid analgesic medications in the postoperative period was identified in 72.50% of people; prescriptions were for dipyron and tenoxicam (Chart 1). Median age was 28 years (from 18 to 58 years); mean cortisol value before the intervention and the standard deviation were 0.39 ± 0.32 $\mu\text{g}/\text{dl}$, and after, 0.32 ± 0.30 $\mu\text{g}/\text{dl}$, significantly reducing its levels through intervention ($p < 0.0001$).

Mean pain value was 4.93 ± 2.76 before the intervention and 3.90 ± 2.43 after, with a statistically significant difference ($p = 0.0001$), as shown in Chart 2.

The variables final cortisol, initial pain, and final pain were distributed homogeneously, while final pain presented an abnormal distribution, as shown in Chart 3.

Mean cortisol and standard deviation before the intervention were 0.39 ± 0.32 $\mu\text{g}/\text{dl}$, and after, 0.32 ± 0.30 $\mu\text{g}/\text{dl}$. There was a statistically significant reduction in cortisol levels post-intervention with *shiatsu* ($p < 0.0001$).

Mean value on the numeric pain scale was 4.93 ± 2.76 before the intervention and 3.90 ± 2.43 after. There was a statistically significant reduction in pain levels after *shiatsu* intervention ($p = 0.0001$).

People taking opioids combined with non-opioids had a mean pain level 73% higher than those taking opioids alone ($p = 0.008$).

DISCUSSION

The search for pain control leads health professionals to use other unconventional therapies, including *shiatsu*⁵. Such intervention has been shown to be effective in reducing pain⁸, despite cultural bias, previous experiences, and the ability to understand it determining its intensity^{9,10}; it can be considered a public health problem, and as such, requires planning and organization for professional use¹¹.

Results showed a significant difference ($p = 0.000$) in the mean post-intervention pain level, as well as in mean cortisol levels. The therapeutic efficacy to reduce postoperative pain is consistent with the study developed through meta-analysis applied to 33 controlled clinical trials that, regardless of the number of sessions and evaluation time (immediate or after six weeks), the best effects found were in heart surgeries and cesarean sections¹².

Chart 1. Descriptive analysis of people's characterization variables. Minas Gerais, Brazil, 2017.

Characteristics	N	%	
Origin	Diamantina	14	34.15
	Other cities	26	63.41
	Other states	1	2.44
Marital status	Single	21	51.22
	Married	14	34.15
	Stable union	4	9.76
	Separated	2	4.88
Education	4 years or less	4	9.76
	5 to 9 years	22	53.66
	10 years or more	15	36.59
Fracture site	Lower limbs	35	85.37
	Upper limbs	4	9.76
	Both	2	4.88
History	No	28	68.29
	Yes	13	31.71
Illnesses	None	28	68.29
	Hypertension	1	2.44
	Diabetes	1	2.44
	Obesity	1	2.44
	Hematological diseases	3	7.32
	Kidney diseases	2	4.88
	Liver diseases	1	2.44
	Diabetes and obesity	1	2.44
	Others	3	7.32
Smoking	No	30	73.17
	Yes	11	26.83
Alcohol	No	14	34.15
	Yes	27	65.85
Alcohol type	None	14	34.15
	Spirits	6	14.63
	Vodka	1	2.44
	Beer/wine	18	43.90
	Mixtures	1	2.44
	More than one type	1	2.44

Chart 2. Descriptive analysis of salivary cortisol ($\mu\text{g}/\text{dl}$) and pain levels before and after *shiatsu* intervention. Minas Gerais, Brazil, 2017.

Characteristics	Mean	SD	p-value*
Cortisol (before)	0.39	0.32	p<0.0001
Cortisol (after)	0.32	0.30	
Pain (before)	4.93	2.76	p<0.0001
Pain (after)	3.90	2.43	

SD: standard deviation. * Paired Wilcoxon test.

Chart 3. Normality test for cortisol and pain. Diamantina (MG), Brazil, 2017.

	Kolmogorov-Smirnov			Shapiro-Wilk		
	Statistical	G1	Sig.	Statistical	G1	Sig.
Initial cortisol	0.195	33	0.003	0.862	33	0.001
Final cortisol	0.117	33	0.200	0.918	33	0.017
Initial pain	0.155	33	0.042	0.935	33	0.048
Final pain	0.173	33	0.013	0.953	33	0.164

G1: Lilliefors significance correction to check normality; Sig.: significance.

Controlling pain may be related to increased levels of neurotransmitters, such as serotonin and dopamine, which contribute to reducing muscle tension, improving blood circulation and facilitating the removal of toxic metabolic waste, which, in turn, contributes to relieve pain¹³. These neurotransmitters are responsible for the feeling of well-being, pleasure and happiness, improving the quality of life of people with pain¹⁴.

These results are in line with those of other authors, who highlight that the use of alternative therapies helps to reduce stressful factors and, therefore, influences the reduction of cortisol levels^{15,16}.

Anti-inflammatory drugs increase cortisol levels, which may explain the findings of this research, in which people who used opioids and non-opioids in combination had higher cortisol levels compared to those who used opioids alone¹⁷.

A study similar to this, developed by Platzer et al.¹⁸, also obtained positive results in controlling pain and improving sleep quality, demonstrating that *shiatsu* therapy acts positively in stressful events for the person undergoing surgical treatment, whether immediately after application or after it¹⁹.

Shiatsu helped to balance cortisol levels, releasing dopamine and serotonin, responsible for the feeling of pleasure, happiness, and well-being. Reducing stress factors in people with fractures contributes to the physiological balance of cortisol levels, improving the quality of life of these people¹⁵.

Due to the lack of specific studies on the influence of the type of fracture on cortisol levels, it is important that new, well-designed research be carried out in order to outline the profile of the different types of fracture and their possible association with cortisol levels.

This study has methodological limitations in relation to the lack of randomization and in particular the small number of people participating, which translates into lower statistical power, as in other studies^{20,21}.

CONCLUSION

The results of the *shiatsu* intervention were favorable to its use in controlling postoperative pain in people with limbs fractures, supporting its adoption as clinical practice. Likewise, the therapy contributed to reducing cortisol levels, improving the quality of life of these people.

However, this research has methodological limitations, such as the small number of participants, lack of blinding, and the absence of a control group. However, the findings were positive and supported the professional's intervention to control pain and promote well-being. The literature indicated that there are few studies in the surgical context.

CONFLICT OF INTERESTS

The authors declare no conflicts of interest.

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