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Effects of interferential current on autonomic nervous system in healthy volunteers: randomized clinical trial

Efeitos da corrente interferencial no sistema nervoso autônomo em voluntários saudáveis: ensaio clínico randomizado

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ABSTRACT
To evaluate the effects of different amplitude-modulated frequency (AMF-100Hz and AMF-10Hz) of the interferential current (IC) on autonomic nervous system (ANS) in healthy volunteers. Thirty healthy volunteers (23.7 ±2.7 years old) were randomized into placebo interventions (turned off), IC with AMF-100Hz and IC with AMF-10Hz. Interventions ware applied in the paravertebral ganglionar region for 30 minutes. ANS evaluated by the heart rate variability before and immediately after the interventions. 10Hz intervention reduced the sympathetic activity in 6% and an increase in the parasympathetic in 6%. 100Hz intervention increased 12% to sympathetic activity and decreased 12% to parasympathetic activity. IC changes the autonomic balance in healthy volunteers. 10Hz reduces the sympathetic activity and increases parasympathetic, although the 100Hz has opposite results. The IC at 10Hz improves the autonomic balance and presents potential effects to be tested in hypertensive patients.

Keywords: Autonomic nervous system. Blood pressure. Electric stimulation therapy. Heart rate. Sympathetic nervous system.

RESUMO
Avaliar os efeitos de diferentes frequências moduladas em amplitude (AMF-100Hz e AMF-10Hz) da corrente interferencial (CI) sobre o sistema nervoso autônomo (SNA) de voluntários saudáveis. Trinta voluntários saudáveis (23,7±2,7 anos) foram randomizados em intervenções placebo (desligado), CI com AMF-100Hz e CI com AMF-10Hz. As intervenções foram aplicadas na região ganglionar paravertebral por 30 minutos. O SNA foi avaliado pela variabilidade da frequência cardíaca antes e imediatamente após as intervenções. A intervenção em 10Hz reduziu a atividade simpática em 6% e aumentou a parassimpática em 6%. A intervenção de 100Hz aumentou 12% para a atividade simpática e diminuiu 12% para a atividade parassimpática. A CI altera o equilíbrio autonômico em voluntários saudáveis. 10Hz reduz a atividade simpática e aumenta parassimpático, embora o 100Hz tenha resultados opostos. A CI a 10Hz melhora o equilíbrio autonômico e apresenta efeitos potenciais a serem testados em pacientes hipertensos.

Palavras-chave: Frequência cardíaca. Pressão sanguínea. Sistema nervoso autônomo. Sistema nervoso simpático. Terapia por estimulação elétrica.

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INTRODUCTION

The autonomic nervous system is divided into sympathetic and parasympathetic components[1], where activation of the sympathetic nervous system causes increases in heart rate, peripheral vascular resistance and venous return to the heart, favoring an increase in blood pressure[2]. On the other hand, the activation of the parasympathetic nervous system favors the reduction of blood pressure[1,2]. The autonomic imbalance, characterized by the hyperactive sympathetic system and the hypoactive parasympathetic system, is associated with cardiovascular diseases, such as hypertension and heart failure[3]. Therapeutic correction of this imbalance is associated with reduction in mortality from cardiovascular diseases[4].

Sensorial electrostimulation has been studied as a therapeutic alternative in the correction of this imbalance[5–7]. The application of transcutaneous electrical nerve stimulation (TENS), which is a low-frequency current (<1000Hz)[8], showed increased baroreflex sensitivity through a somatosensory impulse mediated by the fibers A-δ[9], increase the release of endogenous opioids[10], decrease levels of epinephrine and norepinephrine, altering the sensitivity of peripheral α1-adrenergic receptors[11], improving the blood flow and reducing peripheral vascular resistance[11,12]. However, the neuromodulation generated by this low frequency current may vary depending on the local of application and parameters used, especially on the frequency used[6,7,11].

Interferential current is another form of sensory electrostimulation, is formed from two different medium-frequency currents, which interfere with each other, resulting in a new electric current, called amplitude-modulated frequency[13,14]. Recent study has shown that different amplitude-modulated frequency (100Hz and 5Hz) of interferential current applied in the paravertebral region modify the vessel diameter and blood flow of healthy volunteers[15], which suggests a therapeutic potential in reducing sympathetic activity and blood pressure, but such effects have not yet been investigated.

Medium-frequency currents (interferential current) pass more easily through the skin than low-frequency currents (TENS), due to their lower impedance, generating effects in the deeper tissues[16,17]. These differences in skin propagation and in the depth of the penetration of interferential current in relation to TENS[16,17] suggest that this electrical current may be more effective in the management of autonomic imbalance. However, there are no studies that have evaluated the effects of interferential current on the autonomic balance. The objective of this research was to evaluate the effects of the application of different frequencies (amplitude-modulated frequency 100Hz and 10Hz) of interferential current on the autonomic system in healthy volunteers.

METHODOLOGY

DESIGN OVERVIEW AND SETTINGS

The present double-blind, crossover, randomized clinical trial was approved by the institutional ethics committee (Protocol: 2.180.257) and was registered in Clinical Trial (Protocol: NCT03258489). Methodologic design was based on the determinations of the 2010 CONSORT statement. Volunteers were informed of the study protocol and provided written informed consent before participating. Data were collected between October 2017 and April 2018 at the Clinical Research Laboratory of Department of Physical Therapy and Rehabilitation of Federal University of Santa Maria (UFSM).

PARTICIPANTS

All enrolled volunteers were literate, both sexes, aged between 20 and 30 years-old, body mass index lower than 30 kg/m^2; non-smokers; and free of skeletal muscle, rheumatic, cardiovascular, metabolic, neurologic, oncologic, immune, hematologic, psychiatric or cognitive disorders. The enrolled volunteers were not taking any type of medication (except contraceptive).

Participants were instructed not to perform exhaustive exercises (48 hours before) and not to drink beverages containing caffeine or alcohol 12 hours before the exams. On the day of the examinations, volunteers who presented values of blood pressure above normal (SBP > 120mmHg and DBP > 80mmHg)[18] or reported stressful events that occurred in the last 48 hours, would be excluded from the study. From these criteria, three volunteers, who presented blood pressure values above normal, were excluded. The flowchart of the study design is shown in Figure 1.

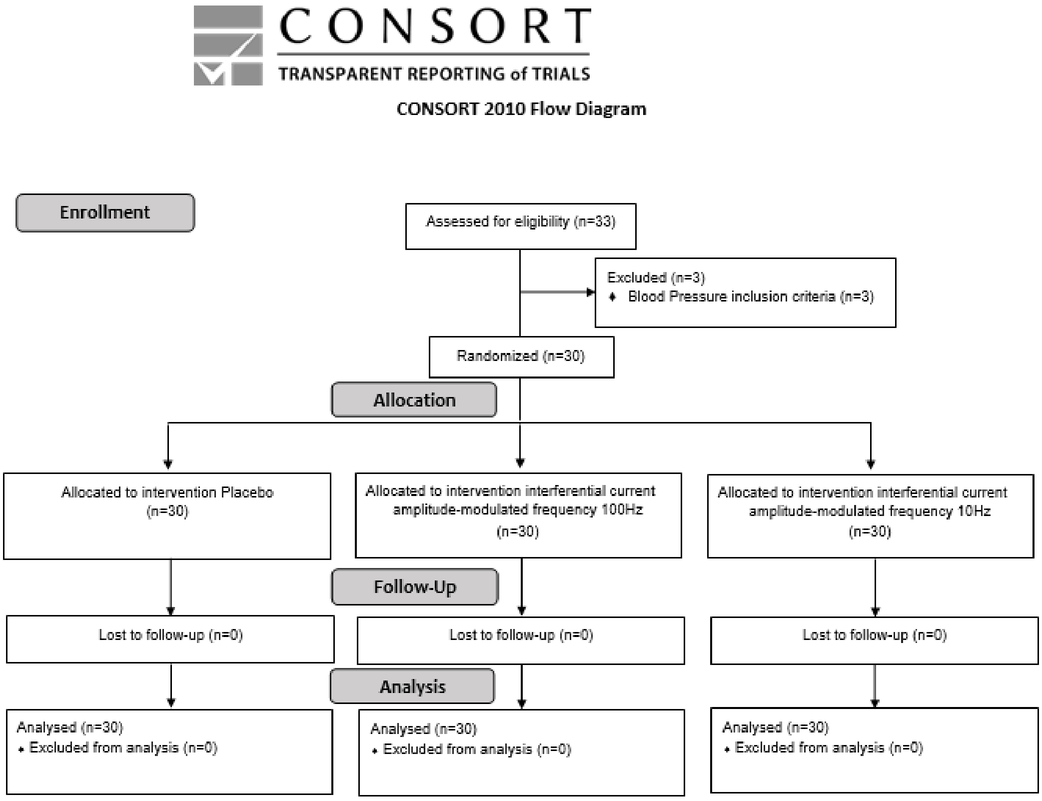


Figure 1. Flow Diagram of study.

INTERVENTIONS

All volunteers underwent the three interventions (Placebo, interferential current: amplitude-modulated frequency - AMF 100Hz and interferential current: amplitude-modulated frequency – AMF 10Hz), which were performed within the period of one week. Autonomic nervous system and blood pressure measurements were evaluated simultaneously before and immediately after the interventions. Interventions were previously randomized through the website www.random.org. The information was kept in a sealed brown envelope and was randomly chosen on the day of the exams, with the evaluator and the volunteers blinded about the interventions.

The volunteers were placed in the supine position and remained in this position for one hour and a half (rest: 20min, data collection: 20min, interventions: 30min and data collection: 20min). The temperature of the room was maintained between 21 to 24ºC. The skin was duly sanitized with 70% alcohol and the self-adhesive electrodes (5x5 area) were positioned in the tetrapolar form, in the paravertebral ganglionar region, between C7 and T4[16,19–21], according to Figure 2.

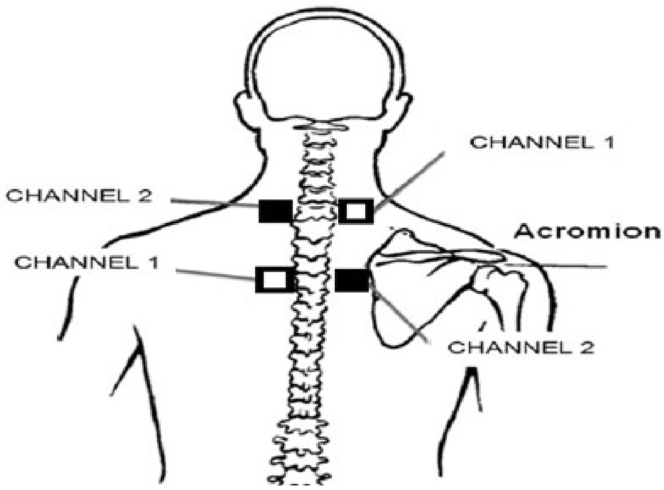


Figure 2. Local of electrodes (paravertebral ganglionar region - C7 and T4).

The interferential current (Dualpex 071® model, Quark Medical, São Paulo, Brazil) was applied for thirty minutes, in continuous flow, with biphasic pulses and a slope of 1/5/1. The interferential current with amplitude-modulated frequency 100Hz was used in the following parameters: the current was adjusted to 4000Hz, pulse width of 100μs and an amplitude-modulated frequency variation of 0Hz. Interferential current with amplitude-modulated frequency 10Hz: current was adjusted to 4000Hz, pulse width of 100μs and an amplitude-modulated frequency variation of 0Hz. Intensity in milliamperes (mA) was adjusted every 5 minutes at the sensorimotor threshold level, without muscle contraction or according to the tolerance to the stimulus informed by the volunteers[7]. The placebo intervention consisted in the repetition of the previous procedures, where the intensity was increased until the sensorial threshold and later the equipment was turned off, remaining in such way until the end of the data collections.

OUTCOMES AND FOLLOW-UP

The primary outcome measure was autonomic nervous system, which was assessed by the heart rate variability in the time-domain and frequency-domain. Secondary outcome measure was blood pressure.

HEART RATE VARIABILITY

Autonomic nervous system was evaluated through the heart rate variability technique using a pulse frequency meter (Polar brand, model 810i, Kempele - Finland). The heart rate acquisition (sample rate – 1000Hz) was performed in time series of the RR intervals and acquired at continuous intervals (10 minutes) before and immediately after the interventions. The data were collected with controlled breathing (12 breaths per minute; I/E: 2/3) for 10 minutes[7]. In heart rate variability analysis, time and frequency domain were analyzed using an area corresponding to 5 minutes (containing at least 256 consecutive heart beats), which was moved over the visually more stable section of the 10-minute period before and immediately after the electrostimulation of interferential current.

The analysis was performed by spectral power density. This analysis decomposes the heart rate variability into fundamental oscillatory components, the main ones being: high frequency component (HF) of 0.15 to 0.4Hz, corresponding to respiratory modulation and to the indicator of the vagus nerve acting on the heart; low frequency component (LF) of 0.04 and 0.15Hz, which is due to the joint action of the vagal and sympathetic components on the heart, predominantly sympathetic. Normalized units (n.u.) were obtained by dividing the power of a given component by the total power (from which VLF has been subtracted) and multiplying it by 100 (LF or HF/(Total Power – VLF) x 100)[3]. The LF/HF ratio reflects the absolute and relative changes between the sympathetic and parasympathetic components of the autonomic nervous system, characterizing the sympatho-vagal balance on the heart[3]. The data were transferred to a computer and the R-R ranges processed to calculate the heart rate variability using the parameters of the Kubios program heart rate variability version 2.1 (Kuopio, Finland, 2012).

The variables in the time-domain were the heart rate (HR), standard deviation of all normal to normal R-R (NN) interval (SDNN), square root of the mean of the squares of successive R-R interval differences (rMSSD), percentage of intervals differing more than 50ms different from preceding interval (PNN50%) and Triangular Index. At the frequency-domain were total power (TP), low frequency (LF), high frequency (HF) and sympatho-vagal balance ratio (LF/HF).

BLOOD PRESSURE

Blood pressure (BP) monitoring (Systolic blood pressure - SBP, Diastolic Blood Pressure – DBP and Mean Blood Pressure - MBP) was performed using a multiparametric monitor (Dixtal, model 2021, Manaus, Brazil). The cuff was positioned on the right arm with the patient positioned in the supine position on the stretcher. Data were collected before and immediately after the interventions through three measurements, with a 10 minutes interval between them and the data expressed by means of measures.

SAMPLE SIZE

The sample size was calculated based on a previous study data[6]. It was estimated that a sample size of 30 volunteers in each group would have a power of 85% to detect a 11% difference between means (standard deviation 13%) for the sympathetic activity after electrical stimulation application, for $\alpha = 0.05$ (5%).

STATISTICAL ANALYSIS

Data are presented as mean and standard deviation (SD). The Kolmogorov-Smirnov normality test was used. Variables were compared by two-way ANOVA of repeated measures, followed by Bonferroni *post hoc*. Variations between interventions are reported as mean differences and 95% confidence intervals (95% CI). The α error rate of 5% ($p < 0.05$) was considered.

RESULTS

The sample was composed of thirty healthy volunteers (21 women; 13 using oral contraceptives), with 23.7 ± 2.7 years old, body mass index 23.2 ± 2.7 kg/m^2 and Waist/Hip relation 0.77 ± 0.04 cm.

Heart rate variability data in the time domain and frequency in response to different amplitude-modulated frequency of interferential current are shown in Table 1.

Table 1. Results of heart rate variability data

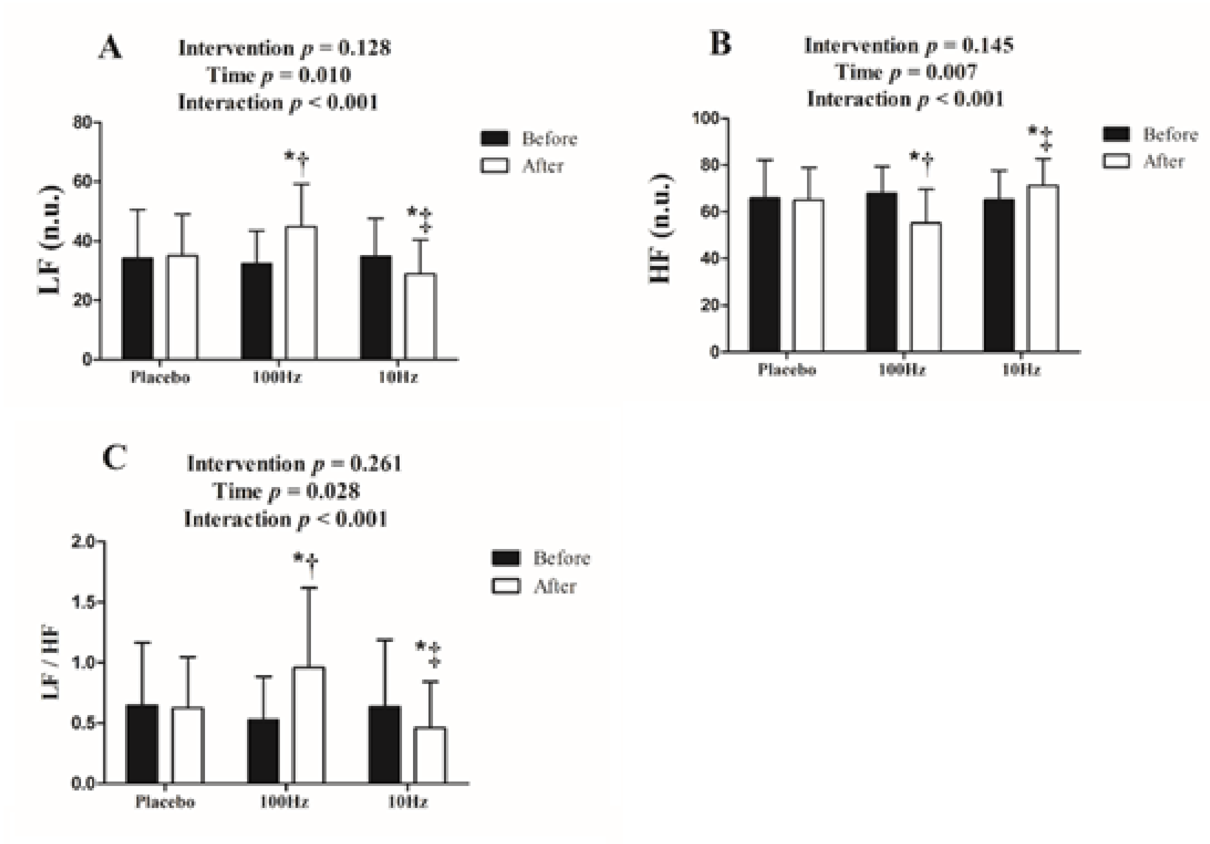
Variables		Placebo	AMF 100Hz	AMF 10Hz	*p*-Value		
					Intervention	Time	Interaction
Domínio do Tempo							
FC (bpm)	Before	69.6±11.0	67.8±11.4	70.1±12.4	0.828	<0.001	0.578
	After	65.4±10.0*	64.9±11.6*	65.7±8.9*			
SDNN (ms)	Before	76.7±32.4	73.7±28.0	75.1±27.6	0.997	<0.001	0.651
	After	86.0±31.5	89.1±31.3*	88.7±34.3*			
rMSSD (ms)	Before	64.7±27.6	71.1±39.3	65.6±35.9	0.937	<0.001	0.031
	After	78.0±39.2*	73.5±38.1	83.8±48.0*			
PNN50 (%)	Before	37.2±17.6	39.6±20.1	35.1±19.1	0.995	0.001	0.063
	After	43.7±18.3*	40.9±17.3	44.9±19.7*			
Índice Triangular	Before	16.9±5.6	15.2±4.1	14.9±5.3	0.446	0.020	0.411
	After	17.3±4.9	16.5±4.5	17.0±4.3			
Domínio da Frequência							
PT (ms²)	Before	6583±6329	5713±4969	5995±4469	0.966	0.002	0.437
	After	7762±5673	8340±5705*	8763±7326*			
LF (ms²)	Before	1349±1017	1290±1073	1305±986	0.641	<0.001	0.068
	After	1667±1348	2075±1600*	1520±1217			
HF (ms²)	Before	2592±2164	2950±3012	2467±2104	0.757	0.004	0.004
	After	3270±2949	2673±2733	4171±4274			

Data are presented as mean ± standard deviation (SD). Variables were compared by two-way ANOVA of repeated measures. AMF: amplitude-modulated frequency; HR: Heart Rate (bpm min.-1); SDNN: standard deviation of all normal to normal R-R (NN) interval; rMSSD: Square root of the mean of the squares of successive R-R interval differences; pNN50: percentage of intervals differing more than 50 ms different from preceding interval; Total power (TP ms²): The variance of RR intervals over the temporal segment; LF (ms²): Power in low frequency range (0.04-0.15 Hz); HF (ms²): Power in high frequency range (0.15-0.4 Hz);
* $p < 0.05$ vs Before; † $p < 0.05$ vs Placebo; ‡ $p < 0.05$ vs 100Hz.

In the time domain, heart rate was within the limits of normality in all evaluations, but after interventions reduced 4 bpm (95% CI = -1 to -7) in the placebo intervention, 3 bpm (95% CI = 0.2 to -6) at amplitude-modulated frequency 100Hz and 4 beats per minute (95% CI = -0.2 to -7 bpm) at 10Hz. Standard deviation of all normal to normal R-R (NN) interval remained unchanged in placebo intervention, increased 15.4 ms (95% CI = 2.3 to 28.5) at 100Hz and 13.6 ms (95% CI = 20.1 to 26.7) at 10Hz. Square root of the mean of the squares of successive R-R interval differences increased 13.3 ms (95% CI = 1.8 to 24.9) after the placebo intervention and 18.2 ms (95% CI = 6.7 to 29.8) after 10Hz. Percentage of intervals differing more than 50 ms different from preceding interval (PNN50%) also increased 6.4% (95% CI = -0.4 to 13.3) in the placebo and 9.8% (95% CI = 2.9 to 16.7) at 10Hz. Triangular Index presented differences in time ($p = 0.020$), but was not confirmed Bonferroni posttest ($p > 0.05$) through confidence intervals (Placebo: 95% CI = -2.20 to 2.91; 100Hz: 95% CI = -1.18 to 3.93; 10Hz, 95% CI = -0.41 to 4.69).

In the frequency domain (Table 1), total power presented an increase of 2627 ms^2 (95% CI = 279 to 4975) at amplitude-modulated frequency 100Hz and 2768 ms^2 (95% CI = 419 to 5116) at 10Hz. The power in low frequency range (LF - ms^2) increased 784 ms^2 (95% CI = 340 to 1229) at 100Hz, while the power in high frequency range (HF - ms^2) increased 1705 ms^2 (95% CI = 716 to 2694) at 10Hz.

After data normalization, the placebo intervention did not modify sympathetic (LF) and parasympathetic (HF) activities. The amplitude-modulated frequency 100Hz intervention increased 12% (95% CI = 8.5 to 16.3) to sympathetic activity (LF n.u.) and decreased 12% (95% CI = -8.8 to -16.6) to parasympathetic activity (HF n.u.) in relation to the period prior to application (Figure 3A). On the other hand, after the application of 10Hz, there were opposite effects, observing a reduction of sympathetic activity (LF n.u.) in 6% (95% CI = -2.2 to -9.9) and an increase in the parasympathetic (HF n.u.) in approximately 6 % (95% CI = 2.2 to 9.9) (Figure 3B). The amplitude-modulated frequency 100Hz and 10Hz presented different results after the application, where the 100Hz increased sympathetic activity in 16% and reduced parasympathetic activity 16% (95% CI = 6.6 to 25.3) in relation to 10Hz. Only the AMF-100Hz increased the LF (n.u.) in 9.7% (95% CI = 0.5 to 19.0) and reduced the HF (n.u.) in 9.7% (95% CI = -0.4 to -19.0) compared to placebo.



Data are presented as mean ± standard deviation (SD). Variables were compared by two-way ANOVA of repeated measures. A: Low frequency (LF n.u.), sympathetic activity: panels of spectral parameters of low frequency normalized component; B: High frequency (HF n.u.), parasympathetic activity: high frequency normalized component; C: LF/HF: sympathovagal balance ratio LF(ms²) / HF(ms²); * $p < 0.05$ vs Before; † $p < 0.05$ vs Placebo; ‡ $p < 0.05$ vs 100Hz.

Figure 3. The sympathetic-vagal balance results.

LF/HF ratio increased 0.4 (95% CI = 0.3 to 0.6) after application of amplitude-modulated frequency 100Hz and decreased 0.2 (95% CI = -0.02 to -0.3) after 10Hz (Figure 3C). LF/HF decreased 0.5 (95% CI = -0.2 to -0.8) between frequencies (100Hz vs 10Hz). 100Hz increased this ratio by 0.3 (95% CI = 0 to 0.7) compared to placebo.

Data of the blood pressure are shown in Table 2. Systolic, diastolic and mean blood pressure no differences were found between interventions, time and in the interaction in the study. During and after the interventions none of the participants reported any type of pain or discomfort or presented intercurrences.

Table 2. Results of Blood Pressure (BP)

Variables		Placebo	AMF 100Hz	AMF 10Hz	*p*-Value		
					Intervention	Time	Interaction
SBP (mmHg)	Before	109.3 ± 6.5	111.5 ± 7.1	109.4 ± 6.8	0.367	0.607	0.342
	After	110.6 ± 7.4	111.7 ± 8.9	108.7 ± 7.8			
DBP (mmHg)	Before	63.0 ± 5.4	63.5 ± 5.6	62.6 ± 5.0	0.514	0.126	0.998
	After	63.9 ± 5.6	64.6 ± 6.8	62.3 ± 4.9			
MBP (mmHg)	Before	78.5 ± 5.2	79.5 ± 5.3	78.2 ± 5.2	0.397	0.177	0.175
	After	79.4 ± 6.6	80.3 ± 6.7	77.8 ± 5.3			

Data are presented as mean ± standard deviation. Variables were compared by two-way ANOVA of repeated measures. AMF: amplitude-modulated frequency; SBP: Systolic Blood Pressure; DBP: Diastolic Blood Pressure; MBP: Mean Blood Pressure.

DISCUSSION

The results demonstrate that the different AMF of interferential current applied in the paravertebral ganglionar region (C7 to T4) modify the autonomic balance of healthy volunteers. Amplitude-modulated frequency 10Hz reduced sympathetic activity (LF) and increased parasympathetic (HF) of healthy volunteers. On the other hand, the 100Hz presented opposite results. Also, the different amplitude-modulated frequency of interferential current did not modify blood pressure.

Research on the interferential current effects on the cardiovascular system is scarce. Amplitude-modulated frequency is considered to be the effective component of interferential current, simulating low frequency currents such as TENS[22]. However, these currents differ in relation to the frequency of their currents (TENS is low-frequency and interferential current medium-frequency)[8] and the depth in which each of them reaches the tissues[16,17]. Although these currents are different studies have shown similar results when compared in analgesia[17,23]. In this sense, in part, we will refer to TENS in the discussion of the results of the present study.

The site of application was chosen according to previous studies with the use of TENS[19–21] and interferential current[16]. In this place, the anatomical organization of the autonomic nervous system occurs with the presence of the ganglia that store the cellular bodies of the postganglionic sympathetic neurons, from which the axons forming the cardiac nerves to the periphery leave[1]. Due to this anatomical location, sensory stimulation in this region favors changes in the autonomic nervous system[5] and repercussions on peripheral blood flow[12].

In the present study, the interferential current with amplitude-modulated frequency 10Hz improved the autonomic balance, as it reduced sympathetic activity and increased parasympathetic activity. Previous studies have shown that the stimulation of interferential current with amplitude-modulated frequency 5Hz (bipolar application in T1-T4)[15] and 10-20Hz (applied in the quadriceps)[24] increased blood flow, reinforcing the findings of the present study. TENS (10Hz) applied on the paravertebral ganglionar region presented similar results to this research[7] and meta-analysis showed that the TENS (<50Hz) reduces SBP in healthy volunteers[25], showing that lower frequencies present better results on the balance autonomic and BP in these sensory stimuli. In addition, TENS (<4Hz) demonstrated to reduce sympathetic activity by increasing the release of endogenous opioids in the autonomic nervous system[10]. We believe that increasing of endogenous opioids also occur with the 10Hz interferential current.

The amplitude-modulated frequency 100Hz increased sympathetic activity and reduced parasympathetic, which was demonstrated in the present study. Previous study has shown that the 100Hz of interferential current decreased vessel diameter and increased blood flow (bipolar form application in T1-T4), which is due to the increase in sympathetic activity[15]. Our results also agree with a previous study using TENS 100Hz, applied to the paravertebral ganglionar region, that demonstrated the increase of the sympathetic activity and reduction of the parasympathetic evaluated by the heart rate variability technique[7]. Wong and Jette[26] suggest that increased sympathetic activity may be related to vasoconstricting of superficial blood vessels, generated by increased blood flow demand by the muscles contracting, producing pain relief[26].

The different amplitude-modulated frequency (100Hz and 10Hz) of the interferential current had opposite results, which also have been demonstrated with the different frequencies and sites of TENS application[6,7,11]. Such results reinforce that the cardiovascular effects, induced by sensorial electro stimulation, depend on the parameters used (frequency, place of application of electrodes, duration of the stimulus) and on the population studied[6,11,15,25].

The BP in relation to the different frequencies of interferential current remained unchanged. These results have already been demonstrated in studies that applied TENS electrical nerve stimulation (<4Hz) and did not identify alterations in BP in healthy subjects[27] and hypertensive patients[5,28]. However, the TENS (<50Hz) reduced BP in healthy volunteers[25] and 80Hz reduced SBP in young healthy volunteers[21]. These studies suggest that is more effective than interferential current in the reduction of BP in healthy volunteers and hypertensive patients, but studies comparing these different sensorial stimuli have not yet been performed in these populations.

LIMITATIONS

The absence of evaluation of plasma catecholamines and the duration of these effects on the autonomic balance and the method of assessing blood pressure through the casual measure are presented as limitations of the study. Among the clinical implications, the effects of interferential current with amplitude-modulated frequency 10Hz, in the paravertebral ganglionar region, become a potential non-invasive and non-pharmacological approach to be tested to improve the autonomic balance of patients with sympathetic hyperactivity, such as resistant hypertensive and patients with heart failure.

CONCLUSIONS

In conclusion, the application of interferential current applied in the paravertebral ganglionar region modifies the autonomic nervous system of healthy volunteers. The amplitude-modulated frequency of 10Hz reduces the sympathetic activity and increases parasympathetic, although the 100Hz has opposite results. The interferential current with amplitude-modulated frequency of 10Hz improves the autonomic balance and presents potential effects to be tested in the non-pharmacological management of hypertension patients.

DECLARATION OF INTEREST

The authors declare no conflicts of interests.

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