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Osteopathic manual therapy in heart failure patients: A randomized clinical trial

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ABSTRACT

Background: Heart Failure (HF) patients usually present with increased arterial resistance and reduced blood pressure (BP) leading to an impaired functional capacity. Osteopathic Manual Therapy (OMT) focused on myofascial release techniques (MRT) and in the balancing of diaphragmatic tensions, has been shown to improve blood flow in individuals using the resistive index (RI). However, its effects in HF patients have not been examined.
Purpose: To evaluate the acute response of selected osteopathic techniques on RI, heart rate (HR), and BP in patients with HF.
Methods: Randomized-controlled clinical trial of HF patients assigned to MRT (six different techniques with three aimed at the pelvis, two at the thorax, and one at the neck for 15 min) or Control group (subjects in supine position for 15 min without intervention). The RI of the femoral, brachial and carotid arteries was measured via doppler ultrasound while HR and BP were measured via sphygmomanometry before and after a single MRT or control intervention.
Results: Twenty-two HF patients equally distributed (50% male, mean age 53 years; range 32–69 years) (ejection fraction = 35.6%, VO_{2peak}: 12.9 mL/kg^{-1} min^{-1}) were evaluated. We found no intra or inter group differences in RI of the carotid (Δ_{MRT}: 0.07% vs $\Delta_{Control}$:11.8%), brachial (Δ_{MRT}:0.17% vs $\Delta_{Control}$: 2.9%), or femoral arteries (Δ_{MRT}:1.65% vs $\Delta_{Control}$: 0.97%) ($P > 0.05$) and no difference in HR or BP (Δ_{MRT}:0.6% vs $\Delta_{Control}$: 3%), ($P > 0.05$).
Conclusion: A single MRT session did not significantly change the RI, HR, or BP of HF patients.

1. Background

Heart failure (HF) affects the quality of life and functional capacity of individuals producing limitations in many aspects of their lives. The most common clinical manifestations of HF are early fatigue and dyspnea, which limits exercise tolerance in this population (Vogiatzis and Zakynthinos 2013). It has been suggested that muscle fatigue in HF during exercise may arise due to changes in oxygen supply (histological abnormalities of skeletal muscle, mitochondria oxidative enzyme activity and high phosphate handling energy) and muscle atrophy (Andrew et al., 1994).

Patients with chronic HF appear to have a significant reduction in microvascular density when compared with control subjects. Moreover, capillary density has been found to be significantly correlated with maximal VO_2 and total exercise time (Duscha et al., 1999; Downing and Balady, 2011) with greater capillary density associated with greater maximal VO_2. Thus, skeletal muscle blood flow (BF) appears to be an important factor associated with the pathophysiological manifestations of HF. Furthermore, increased sympathetic nervous system activity, plays an important role in the origin of the symptoms limiting exercise (Florea and Cohn, 2014; Olshansky et al., 2008; Sutton and Keane, 2007; Rogers, 2001).

All of the above changes likely contribute to the dyspnea and fatigue of HF patients, and there is no doubt that a combination of factors is found in some patients (Andrew et al., 1994). Thus, improving cardiac function alone may be insufficient to achieve symptom relief in patients with HF. Combined therapies targeting

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both an improvement in cardiac and skeletal muscle function are likely to improve quality of life and functional capacity in patients with HF (Witte and Clark, 2007).

Because of the role that reduced vascular flow appears to have in the pathophysiology of HF, adjuvant treatments aimed at improving vascular flow have the potential to produce important clinical outcomes in HF patients. One particular treatment that has been reported to improve vascular flow is the Osteopathic Manipulative Treatment. Taylor Still provided an osteopathic theory based on one of the principles that the rule of the artery is absolute. That is, any obstruction of blood flow has a possibility of generating diseases (Still, 1910). For this reason, it has been hypothesized that Osteopathic Treatment has the potential to improve BF even after one or more sessions due to an adjustment in the autonomic nervous system as well as a reduction of tension in the fascia in patients with peripheral arterial disease, hypertension or knee osteoarthritis (DiGiovanna et al., 1997; Lombardini et al., 2009; Queré et al., 2009; Jardine et al., 2012; Cerritelli et al., 2011).

Furthermore, although many osteopathic techniques exist, the current study will focus on osteopathic manual therapy (OMT) focused on releasing fascial restrictions and balancing tensions within the diaphragms.

An improvement in vascular flow via myofascial release techniques (MRT) is justified by the fact that cardiovascular structures, such as arteries and veins, pass through the fascia which if tight has the potential to constrict vascular structures. As well, an imbalanced intra-abdominal pressure gradient with altered tension in the diaphragms has the potential to decrease the fluids in the aortic hiatus, inguinal and adductor canals and to affect blood flow dynamics (Queré et al., 2009; Jardine et al., 2012). These factors are important to support the rationale in the choice of MRT and techniques focused in balance diaphragmatic tensions to improve blood flow dynamics in HF patients.

A study by Jardine et al. found that treatment focused on releasing fascial restrictions and balancing tensions within the diaphragms performed acutely in patients with osteoarthritis (OA) of the knee were observed to have an improvement in the femoral artery resistive index (RI) obtained via Doppler echocardiography. The OMT performed in the Jardine et al. study consisted of six different techniques (cranial, visceral and fascial) aimed to improve femoral artery blood flow (Jardine et al., 2012).

No study of OMT in patients with HF appears to have been performed. Based on the artery is absolute principle, an improvement in vascular flow in patients with HF could reduce muscle fatigue and result in better cardiorespiratory fitness. The specific aim of this study was to reproduce the Jardine's study and evaluate the acute response of the same techniques in patients with HF.

2. Materials and methods

2.1. Subject

Twenty-two patients with HF (11 male and 11 female) between 32 and 69 years of age were studied. The subjects were recruited from the Program for the Rehabilitation and Prevention of Cardiovascular and Metabolic Disease from University of Brasilia. The study was performed in Physiologic laboratory of University of Brasília. The individuals were diagnosed with HF and received optimized drug therapy before the study. The inclusion criteria were: 1) diagnosis of HF (Mant et al., 2011) documented in the last 6 months; 2) left ventricular systolic dysfunction <45% demonstrated by echocardiography; 3) New York Heart Association classification (NYHA) class II and III: and 4) No participation in aerobic or resistance training programs in the last three months before the study protocol. Exclusion criteria were: individuals previously diagnosed with moderate or severe chronic obstructive pulmonary disease, recent heart surgery (last 3 months), morbid obesity (BMI $\geq$ 40 kg m^{-2}) or peripheral vascular disease.

2.1.1. Pharmacological treatment

Antihypertensive treatment was administered on the day of research. All subjects were administered ACE-inhibitors (ACE) and beta-blockers (BB) and 75% of the intervention group and 60% of the control group received digoxin for atrial fibrillation. Both groups received the diuretic Furosemide and 100% of the intervention group and 50% of the control group received lipid-lowering medication (Statins).

2.2. Experimental procedure

2.2.1. Overview of the study

The study was a controlled, randomized clinical trial using a sample of convenience. Randomization was done through the website: https://www.random.org/.

Initially all volunteers underwent a clinical assessment by the medical cardiologist (A.G.), after which subjects provided informed consent. The study was approved by the Ethics Committee and Research to Humans at the University of Brasilia. (CAAE: 39564614.3.0000.0030).

On the same day, the patients were divided randomly into two groups (intervention and control) to assess the acute effect of the MRT on vascular function. All subjects underwent an assessment of blood pressure (BP), heart rate (HR) and of BF in the carotid, brachial and femoral arteries before and after the intervention/control (Fig. 1). This assessment was performed by an experienced professional with this type of evaluation equipment who also was blinded as to the group that the volunteer was randomized.

2.2.2. Assessment of blood pressure and flow - Doppler

All tests were performed between 8 and 10 in the morning in a room with controlled temperature (24 °C) after 15 min of acclimatization to the room. Participants fasted for at least 12 h and did not perform physical exercise, ingest substances such as caffeine, high fat foods or vitamin C and did not smoke at least 4–6 h before the study (Corretti et al., 2002). A Digital sphygmomanometer (OMROM M3I, Series 5, Illions, United States) was used to measure blood pressure and heart rate. A high resolution ultrasound was used with a linear transducer of 11.0 MHz (model PHILIPS HD 11XE Select) to measure BF of the carotid, brachial and femoral arteries. The ultrasound exam included pulsed color Doppler sonography to evaluate the RI.

Five continuous spectral waveforms were recorded with automatic trace which allowed system software to calculate RI. The RI was calculated by dividing the peak systolic velocity (PSV) minus the end diastolic velocity by the peak systolic velocity. Doppler recordings were obtained using the Doppler pattern at an angle of 60°. Peripheral vascular assessment instrument controls were optimized for each exam. This follows the procedure cited frequently in the literature for measuring hemodynamics of peripheral vessels (Jardine et al., 2012; Ikee et al., 2005; Toprak et al., 2011; Terslev et al., 2008).

Participants were placed in the supine position comfortably on a stretcher. After which, a basal longitudinal image of the femoral artery was achieved at 2–10 cm medial from the anterior superior iliac spine toward the symphysis pubis. The carotid artery assessment was achieved between the sternocleido-mastoid muscle and the trachea with the head in midline position and rotation to the oppose side of the examiner. The brachial artery assessment was performed under the biceps muscle in the internal portion of the arm with the patient shoulder in 60° abduction and external