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CHIROPRACTIC TREATMENT VS SELF-MANAGEMENT IN PATIENTS WITH ACUTE CHEST PAIN: A RANDOMIZED CONTROLLED TRIAL OF PATIENTS WITHOUT ACUTE CORONARY SYNDROME

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ABSTRACT

Objective: The musculoskeletal system is a common but often overlooked cause of chest pain. The purpose of the present study is to evaluate the relative effectiveness of 2 treatment approaches for acute musculoskeletal chest pain: (1) chiropractic treatment that included spinal manipulation and (2) self-management as an example of minimal intervention.

Methods: In a nonblinded, randomized, controlled trial set at an emergency cardiology department and 4 outpatient chiropractic clinics, 115 consecutive patients with acute chest pain and no clear medical diagnosis at initial presentation were included. After a baseline evaluation, patients with musculoskeletal chest pain were randomized to 4 weeks of chiropractic treatment or self-management, with posttreatment questionnaire follow-up 4 and 12 weeks later. Primary outcome measures were numeric change in pain intensity (11-point box numerical rating scale) and self-perceived change in pain (7-point ordinal scale).

Results: Both groups experienced decreases in pain, self-perceived positive changes, and increases in Medical Outcomes Study Short Form 36-Item Health Survey scores. Observed between-group significant differences were in favor of chiropractic treatment at 4 weeks regarding the primary outcome of self-perceived change in chest pain and at 12 weeks with respect to the primary outcome of numeric change in pain intensity.

Conclusions: To the best of our knowledge, this is the first randomized trial assessing chiropractic treatment vs minimal intervention in patients without acute coronary syndrome but with musculoskeletal chest pain. Results suggest that chiropractic treatment might be useful; but further research in relation to patient selection, standardization of interventions, and identification of potentially active ingredients is needed. (*J Manipulative Physiol Ther* 2012;35:7-17)

Key Indexing Terms: *Chiropractic; Manipulation, Spinal; Chest Pain; Randomized Clinical Trial*

Acute chest pain is the hallmark of acute coronary syndrome (ACS) and accounts for 5% to 6% of all admissions to emergency departments in Europe and the United States; however, only 20% to 25% of these admissions turn out to be caused by

ACS.^{1,2} Between 1990 and 2000, most hospitals observed an increase in the overall number of admissions for suspected ACS, caused primarily by a doubling of patients with angina pectoris or undifferentiated chest pain.³

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Patients with undifferentiated chest pain account for approximately 20% of admissions for suspected ACS.²⁻⁴ Commonly, they leave emergency departments without a definite diagnosis or a plausible explanation for their pain.⁵ Despite thorough diagnostic assessment, many continue to have recurrent episodes of chest pain, leading to anxiety, reduced quality of life, and frequent contacts with the health care system.⁶⁻⁹ In the United States, it has been estimated that it costs approximately \$8 billion for the initial care of patients suspected of having ACS, but who are subsequently found not to have coronary artery disease,¹⁰ whereas the long-term economic cost of undiagnosed chest pain is unknown.⁴

In patients with undifferentiated chest pain, musculoskeletal dysfunction may be an overlooked source of pain,^{11,12} for which chiropractic treatment has been suggested as being beneficial in case reports.^{13,14} In 2004, our research group developed a standardized evaluation protocol to identify patients with musculoskeletal chest pain among patients with known or suspected stable angina pectoris, and treated them with chiropractic therapy in a nonrandomized clinical trial.^{15,16} The results suggested that patients did benefit from the chiropractic treatment; but the study did not allow us to fully elucidate the value of chiropractic treatment in this category of patients, nor did it consider patients with acute chest pain.

The purpose of this randomized controlled trial was to evaluate the relative effectiveness of 2 conservative treatment approaches in patients with an acute episode of musculoskeletal chest pain: (1) chiropractic treatment that included spinal manipulation and (2) self-management as an example of minimal intervention. Effectiveness was assessed by questionnaires 4 and 12 weeks after randomization.

METHODS

Settings and Participants

This study was carried out in an emergency cardiology department at a 1000-bed, urban, university hospital in Denmark and at 4 local chiropractic clinics from 6 August 2006 to 31 March 2008. The study was approved by the regional ethics committee of Vejle and Funen counties, Denmark (approval no. #VF 20060002), and registered at ClinicalTrials.gov (identification no. NCT00462241).

All patients presenting at the emergency unit with an episode of acute chest pain underwent the routine diagnostic procedures performed by specialist cardiology nurses under cardiologist supervision. They covered rapid diagnostic assessment for ACS using electrocardiogram and biochemical cardiac marker testing, that is, creatine kinase MB (mass) levels on admission and 6 to 9 hours later, and troponin T levels at least 6 hours after the worst symptoms. When a patient was discharged from the unit, the study clinician (MJS) screened the patient's records to identify his/her eligibility for our study. Participants should

not have had a diagnosis of ACS or another definite cardiac or medical diagnosis, should be aged 18 to 75 years, should have had a primary complaint of acute chest pain for less than 7 days' duration, should be a resident of the local county, and should be able to read and understand Danish. In addition, participants should have undergone diagnostic procedures to rule out ACS and should not have shown significant comorbidity or contraindications for spinal manipulative therapy. Exclusion criteria comprised previous ACS, prior percutaneous coronary intervention or coronary artery bypass grafting, inflammatory joint disease, insulin-dependent diabetes, fibromyalgia, malignant disease, major osseous anomaly, osteoporosis, apoplexy or dementia, inability to cooperate, and pregnancy. In each case, the cause for exclusion was noted.

Trial Procedures

After providing written informed consent, the participants were assessed at baseline by the study clinician using a standardized and previously validated study protocol.^{15,17} The protocol involves a case history and a clinical health examination, including manual examination of the spine and chest wall, to diagnose possible musculoskeletal chest pain. Demographic and clinical information was collected through patient self-report questionnaires and checklists used by the study clinician. Detailed trial procedures are described elsewhere.¹⁸

Randomization and Blinding

Only patients with a positive diagnosis of musculoskeletal chest pain were eligible for randomization. The randomization schedule was computer generated by a researcher not involved in the study and concealed from the study team. Consecutively numbered opaque and sealed envelopes with treatment assignment cards were created using a 1:1 ratio with balanced blocks of randomly varying size. As patients became eligible, the envelopes were opened in consecutive order in the presence of the patient.

Description of Interventions

Two typical usual care management strategies for patients with musculoskeletal chest pain were chosen for this study: chiropractic treatment that included spinal manipulation and self-management as an example of minimal intervention.

Chiropractic Treatment Program. Participants in the chiropractic treatment group were assigned to 1 of 8 experienced chiropractors in their local community. Based on a combination of case history, clinical findings, and pragmatic, daily clinical practice, each chiropractor chose an individual treatment strategy accommodating the age and physical condition of each patient. However, treatment had to include high-velocity, low-amplitude manipulation

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