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DOUBLE-BLIND, RANDOMIZED, PLACEBO-CONTROLLED CLINICAL TRIAL

Treatment of tension-type headache with articulatory and suboccipital soft tissue therapy: A double-blind, randomized, placebo-controlled clinical trial

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Summary This study researches the effectiveness of two manual therapy treatments focused on the suboccipital region for tension-type headache.

A randomized double-blind clinical trial was conducted over a period of four weeks with a follow-up at one month. Eighty-four patients with a mean age of 39.7 years (SD 11.4) with tension-type headache were assigned to 4 groups which included the following manual therapy treatment: suboccipital soft tissue inhibition; occiput-atlas-axis global manipulation; combination of both techniques; and a control group.

The primary assessment consisted of collecting socio-demographic data and headache characteristics in a one-month base period, data such as age, gender, severity of pain, intensity and frequency of headache, among other. Outcome secondary assessment were: impact of headache, disability, ranges of motion of the craniocervical junction, frequency and intensity of headache, and pericranial tenderness.

In the month prior to the study, average pain intensity, was rated at 6.49 (SD 1.69), and 66.7% subjects suffered headaches of moderate intensity. After 8 weeks, statistically

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significant improvements were noted. OAA manipulative treatment and combined therapy treatments proved to be more effective than suboccipital soft tissue inhibition for tension-type headache. The treatment with suboccipital soft tissue inhibition, despite producing less significant results, also has positive effects on different aspects of headache.

Introduction

Tension-type headache (TTH) is the most common type of primary headache and it represents 47% of headache disorders in adult population worldwide (Jensen and Stovner, 2008). TTH was included in the group of primary headaches by the International Headache Society (IHS, 2004). The cause of TTH has not been established, whereas secondary headaches have a known cause. Most of the patients suffering from TTH are women, with ages around 40 years-old, with a mild to moderate average headache pain intensity (Espí and Gómez, 2010a,b). TTH has an enormous socio-economic impact in terms of hospital costs, medication, consultations with specialists, and laboratory tests (Stovner et al., 2006), and it affects patients' emotional, social and working lives (Holroyd et al., 2000).

The connection between TTH and craniocervical musculoskeletal disorders has already been described, as well as a higher frequency and intensity of pressure pain in suboccipital muscles (Couppe et al., 2007; Fernández-de-Las-Peñas et al., 2008) and variations in head position and neck mobility (Fernández-de-las-Peñas et al., 2006a,b) in patients with TTH. Regarding headache becoming chronic, Buchgreitz et al. (2008) argue that central sensitization caused by prolonged nociceptive input may lead to chronic headache.

Manual treatment reduces headache frequency and intensity (Moraska and Chandler, 2008) and cervical spine manipulation has been shown to be effective in reducing frequency, duration and intensity of headaches in patients with TTH (Fernández-de-las-Peñas et al., 2006a,b). However, although TTH is generally characterized by interparietal and occipital location of pain, the effectiveness of suboccipital soft tissue inhibition (SI) and occiput-atlas-axis (OAA) articulatory manipulation in the treatment of TTH has not been investigated to date. The hypothesis of this study is that both SI and OAA can be effective on their own, but will be even more effective when combined. The objective of SI is to release tension in the suboccipital muscles, reducing the muscular tension that may contribute to the onset of headache and OAA articulatory manipulation is aimed at restoring the range of motion and reducing suboccipital muscle spasm which we expect will reduce pericranial pain and will improve different aspects of headache.

Therefore, the purpose of this study is to evaluate the effectiveness of the use of OAA articulatory and SI soft tissue techniques in the treatment of TTH, assessing the effectiveness of each intervention both separately and combined (SI + OAA), on different parameters, such as age, sex, frequency and intensity of headache, severity of pain and pericranial tenderness, disability and impact of headache, and ranges of motion of the craniocervical junction.

Subjects and methods

Patient population

All patients in this study have been diagnosed TTH, they were recruited between January 2010 and December 2011 and fulfil the criteria defined by the International Headache Society (IHS, 2004), subsequently revised (IHS, 2006). Inclusion and exclusion criteria are shown in Table 1.

Eighty-four patients diagnosed with episodic tension-type headache (ETTH) and chronic tension-type headache (CTTH) participated in this study. A non-probability and convenience sampling was performed. Sixty-eight of participants were women (81%). Mean age was 39.7 years (SD 11.4) within an age range of 18—65 years. All patients were invited to participate in the study when seeking treatment for headache pain on their own initiative: 51.2% came from

Table 1 The study's inclusion and exclusion criteria.

Inclusion criteria	Exclusion criteria

- Be between 18 and 65 years
- ETTH or CTTH diagnosed
- Longer than three months of TTH
- More than 1 headache day per month
- Episodes of pain from 30 min to 7 days
- Fulfil 2 or more of the following characteristics:
  ○ Bilateral location of pain
  ○ Non-pulsatile pain pressure
  ○ Pain mild to moderate
  ○ The headache does not increase with physical activity
- The headache may be associated with pericranial tenderness
- Controlled pharmacologically
	- Patients with infrequent ETTH, or with probable frequent and infrequent forms of TTH or other primary or secondary type of headache
	- Pain aggravated by movement of the head
	- Metabolic or musculoskeletal problems with similar headache symptoms
	- Previous trauma to the cervical spine
	- Vertigo, dizziness, uncompensated tension
	- Joint stiffness, atherosclerosis, or advanced osteoarthritis
	- Patients undergoing pharmacological adaptation
	- Emotional stress
	- Patients with heart devices
	- Suffer from photophobia, phonophobia, nausea, or vomiting
	- Joint instability
	- Neurological disorders
	- Laxity of cervical soft tissues
	- Radiographic abnormalities
	- Generalized hyperlaxity or hypermobility
	- Pregnancy