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Pressure pain threshold and needle acupuncture in chronic tension-type headache – a double-blind placebo-controlled study

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Abstract

In order to examine the role of muscular mechanisms in chronic tension-type headache a study with needle acupuncture was performed. Needle acupuncture could be of therapeutic value because it has shown some positive effects in myofascial pain syndromes. We performed a double-blind, placebo-controlled study with 39 patients (mean age 49.0 years, SD = 14.8) fulfilling the International Headache Society criteria for chronic tension-type headaches. Participants were randomly assigned to verum or placebo condition. Six weeks after end of treatment no significant differences between placebo and verum could be observed with respect to visual analogue scale and frequency of headache attacks. Nevertheless, pressure pain thresholds significantly increased for the verum group. The findings of our study support the hypothesis that peripheral mechanisms – such as increased muscle tenderness – only play a minor role in the pathogenesis of chronic tension-type headache.

Keywords: Tension-type headache; Therapy; Acupuncture; Pressure pain threshold

1. Introduction

The pathophysiology of episodic and chronic tension-type headache (TTH) is not well understood including central and peripheral mechanisms – such as altered descending pain inhibitory system and increased muscle tenderness, respectively. Based on epidemiological (Schwartz et al., 1998) and other data (Jensen et al., 1993) it could be argued that episodic and chronic TTH are not the same.

Nociception from pericranial muscles may play a major role in the pathophysiology of TTH. Thus, it has been demonstrated that pericranial muscles are significantly more tender in patients with chronic TTH than in healthy controls, and that the degree of tenderness is strongly correlated to the frequency and intensity of TTH (Ashina et al., 1999). Therefore there have been some attempts to treat the muscle tenderness primarily, i.e. with botulinum toxin (Zwart et al., 1994; Relja, 1997; Wheeler, 1998; Rollnik et al., 2000). However, the results of these studies are conflicting. Whereas some earlier studies suggested that botulinum toxin could be of therapeutic value in TTH, one recent double-blind placebo-controlled study could not find any significant effect of this procedure (Rollnik et al., 2000). Needle acupuncture is also known as a possible procedure to deactivate myofascial trigger points besides segmental and heterosegmental effects (Filshie and White, 1998). In the treatment of TTH with needle acupuncture, results have been equally disappointing (Carlsson et al., 1990; Tavola et al., 1992), but the tenderness of muscles are reduced in some muscles after acupuncture (Carlsson et al., 1990). In a study of Loh et al. (1984) a beneficial response to acupuncture treatment for migraine and TTH was more likely when the patient had local tender muscular points. EMG studies show an average decrease in postural activity of the temporalis or frontalis muscles, although marked individual variations in muscular response are noted (Borglum Jensen et al., 1977; Ahonen et al., 1983). Those EMG changes are suggested to reflect an abnormal endogenous pain control system (Schepelmann et al., 1998).

We conducted our study to examine whether treatment with acupuncture on local and distal points is able to change pressure pain threshold (PPT) or improve other outcome parameters (such as visual analogue scale (VAS) values).

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2. Patients and methods

2.1. Patients

We included 39 subjects (mean age 49.0 years, SD = 14.8) with chronic TTH according to the (IHS) classification (Headache Classification Committee of the International Headache Society, 1988). Exclusion criteria were anticoagulation, predominantly operating factors (e.g. secondary gain, compensation, disability, and psychosocial factors), rebound analgesic headache syndrome, and symptomatic or other concomitant headaches. In particular, patients with migraine now or at any time in their lives were excluded. Concomitant medication was allowed (including analgesics and rescue medications) but patients were required to document carefully any pharmacotherapeutics in their home diary. In a double-blind placebo-controlled design, subjects were randomly assigned to placebo or verum condition. Both groups did not significantly differ with respect to sociodemographic data (Table 1). The patients gave written informed consent to participate in the study, as required by the local ethic committee.

2.2. Examination

The patients were carefully examined and then followed-up 6 weeks after the end of the treatment (two treatments per week and ten treatments in total). Patients were asked to keep a home diary throughout the study (starting 4 weeks prior to the study) recording daily consumption of analgesics, pain intensity (visual analogue scale: range 0–10 cm; 0 = no pain, 10 = strongest pain), site, and duration of headache attacks. Furthermore, patients were required to give a rating on the VAS and their impression of improvement on a clinical global impressions (CGI) scale (National Institute of Mental Health, 1976) when followed-up. In order to evaluate quality of life parameters and coping strategies, subjects were asked to complete a Nottingham Health Profile (Passchier et al., 1996), an Everyday-Life-Questionnaire (Holzner et al., 1998), a Freiburg Questionnaire of Coping with Illness (Muthny, 1989), and a von Zerssen Depression Scale (Krakow et al., 1999).

Table 1
Sample characteristics (baseline values)[a]

	Placebo	Verum
N	18	21
Mean age in years	47.3 (16.5)	50.4 (13.5)
Gender (f/m)	11/7	8/13
Mean headache frequency/month	27.2 (5.9)	26.9 (7.0)
VAS at consultation	6.3 (2.2)	6.2 (2.2)
Analgesics/month	10.2 (12.0)	8.3 (11.8)
D–S (range 0–48)	11.3 (5.5)	9.6 (7.7)
Depression subscale of FQCI (range 1–5)	2.6 (0.6)	2.1 (0.8)

[a] Standard deviation is indicated in parentheses. FQCI, Freiburg Questionnaire of Coping with Illness; D–S, von Zerssen Depression Scale.

2.3. Measurement of pressure pain thresholds

In addition, PPTs (Jensen et al., 1993) were measured at baseline and at the follow-ups. PPT was determined according to Jensen et al. (1992): the algometer (handle with a pressure-sensitive strain gauge situated at the tip and connected to a power supply and an amplifier, tip covered with a probe 0.5 cm^2 in area) was held perpendicular to the skin against the temporal region where palpation had shown the anterior part of the temporal muscle to be most prominent (usually 2 cm behind the lateral orbital margin and 2 cm above the temporal line). Subjects were instructed to push a button as soon as the pressure became painful. Then the pressure was immediately released. Always the same investigator assessed PPTs three times, then the median was computed. PPTs were expressed in k-pascals.

2.4. Treatment

2.4.1. Placebo needle

The tip of the needle is blunt, and when it touches the skin a pricking sensation is felt by the patients, simulating puncturing of the skin (Streitberger and Kleinhenz, 1998). To place the needle we used a cube-shaped elastic foam which we fixed upon the area of the acupoint. Therefore it is not visible that the blunt placebo needle is not inserted into deeper tissue layers, but the blunt tip upon the skin may be felt by the volunteers. Also because of the elasticity of the foam the needle appears to be shortened.

2.5. Protocols

After randomization the patients were needled over 5 weeks twice a week with acupuncture (Seirin B-type needle no. 8 (0.3×0.3 mm) and no. 3 (0.2×0.15 mm)) and placebo at acupoints GB20 (medial to the mastoid process), LI4 (first dorsal interosseus muscle of the upper limbs) and LR3 (first dorsal interosseus muscle of the lower limbs) and depending on symptoms and local tender muscular points at acupoints GB8 (above the tip of the ear), GB14 (above the middle of the eye-brow), GB21 (over the middle of upper border of the trapezius), GB41 (lateral to the tendon of the extensor digiti longus V), UB2 (medial end of the eye-brow), UB10 (insertion of the trapezius at the external protuberantia occipitalis), UB60 (middle between the external malleolus and the tendon of the gastrocnemius), LU7 (between the tendon of the extensor pollicis and the radius), TW5 (between radius and ulna proximal to the wrist), ST8 (in the angle of forehead and temple), ST36 (lateral to the tibia at level of the tuberositas tibiae), ST44 (between second and third toe in the fold), DU20 (middle of the skullpan), Extra1 (middle between the eye-brows). A maximum of 15 needles were inserted. The needles stayed in

place for 30 min. The exact localization of those acupoints is described in Cheng (1990).

The investigator performing PPT measurements and statistical procedures as well as the patients were blind to treatment condition (placebo vs. verum). Blinding the acupuncture practitioner was impossible due to methodological reasons. None of the patients was able to distinguish between verum and placebo acupuncture. This was controlled by a questionnaire (credibility of treatment).

2.6. Statistics

We used non-parametric tests (Wilcoxon- and Friedman-test) because of huge data variation. In addition, we computed bivariate Pearson correlations. Differences were regarded as significant with $P < 0.05$.

3. Results

At baseline (prior to treatment), placebo and verum group did not differ significantly with respect to VAS, headache frequency, sociodemographic data, and quality of life parameters (Table 1).

PPTs increased for the whole group from baseline to the second follow-up (Wilcoxon-test: PPT right side $Z = -2.526$, $P = 0.012$; PPT left side $Z = -1.268$, $P = 0.205$). Looking at the right side, PPTs remained relatively stable in the placebo group (no significant change), from 354.7 kPa (SD = 56.8) at baseline to 358.9 kPa (SD = 76.7) after treatment, but significantly increased in the verum group (Wilcoxon-test: $Z = -2.158$, $P = 0.031$), from 312.9 kPa (SD = 78.8) to 368.2 kPa (SD = 39.4) (Table 2). The situation was nearly the same for the left side: In the placebo group, there was no extensive change, from 373.2 kPa (SD = 28.6) at baseline to 366.6 kPa (SD = 57.1) after treatment, but PPTs tended to increase under verum condition (Wilcoxon-test: $Z = -1.329$, $P = 0.184$), from 329.1 kPa (SD = 70.5) to 360.0 kPa (SD = 41.3) (Table 2).

For the whole group, VAS scores significantly decreased (Friedman-test: $\chi^2 = 13.786$, d.f. = 2, $P = 0.001$) but without difference between placebo and verum group (Table 2): VAS of the placebo group before treatment was 6.3 (SD = 2.2) and 6 weeks after treatment (second follow-up) 3.9 (SD = 2.7). VAS of the verum group was 6.2 (SD = 2.2) before treatment and 6 weeks after treatment 4.0 (SD = 2.5). In addition, quality of life parameters did not differ between both groups at any follow-up.

4. Discussion

With acupuncture treatment, outcome is a composite of three factors: placebo effects, nonspecific physiological responses to piercing the skin, and specific responses to stimulation of the particular acupuncture points chosen for treatment. To assess placebo effects alone, a procedure must be devised that is both noninvasive and credible to the patients (Hammerschlag, 1998). When the placebo treatment involves mock needling it is virtually impossible to blind the acupuncturist. Blinding the patients is possible using the method of Streitberger and Kleinhenz (1998) even when the patients are acupuncture-experienced. The credibility of the placebo was assessed and showed similar results (data not shown) like in the study of Streitberger and Kleinhenz (1998). With respect to VAS and frequency of headache attacks there was a significant decrease immediately after treatment and 6 weeks later but there was no difference between placebo and verum treatment. There are similar results regarding effectiveness of needle acupuncture in TTH (Carlsson et al., 1990; Tavola et al., 1992) which are disappointing overall. A reason for this finding could be that the etiology of TTH is not clear yet. There are different pathological pathways involved in generating TTH in contrast to migraine which pathophysiological appearance is much more uniform (Ferrari, 1998). In addition, affective disorders are common in migraine (Breslau et al., 1994) and in primary headache as a comorbid illness. A lack of successful treatment especially for those patients has been mentioned several times (Tolksdorf et al., 1988; Tavola et al., 1992). The scores of the von Zerssen Depression scale (D–S) and the scores of the depression subscale of Freiburg's Questionnaire of Coping

Table 2
Measures of visual analogue scale (VAS), frequency of headache attacks (frequency), pressure pain thresholds (PPT), consumption of analgesics, and clinical global impressions (CGI) at baseline and follow-ups[a]

	Placebo			Verum		
Follow-up	0	1	2	0	1	2
VAS (range 0–10 cm)	6.3 (2.2)	4.7 (2.4)	3.9 (2.7)	6.2 (2.2)	4.3 (2.6)	4.0 (2.5)
CGI (range −4 to +4)	–	0.8 (1.5)	1.1 (1.7)	–	1.6 (1.5)	1.3 (1.4)
Frequency per month	27.2 (5.9)	22.8 (10.0)	22.0 (9.9)	26.9 (7.0)	17.5 (12.6)	22.1 (10.6)
PPT left (kPa)	373.2 (28.6)	–	366.6 (57.1)	329.1 (70.5)	–	360.0 (41.3)
PPT right (kPa)	354.7 (56.8)	–	358.9 (76.6)	312.9 (78.8)	–	368.2 (39.4)
Analgesics per month	10.2 (12.0)	4.3 (5.7)	21.2 (27.6)	8.3 (11.8)	6.4 (11.2)	13.7 (17.2)

[a] Mean and standard deviation is indicated. Follow-up 1: last day of treatment; follow-up 2: 6 weeks after treatment.

with Illness (FQCI) of the study groups were little above normal limits (Table 1).

The finding of increased pain thresholds following acupuncture was significant. Raising pain threshold values immediately or several hours after manual or electroacupuncture were found earlier (Ha and Tan, 1982; Leong and Chernow, 1988; Lundeberg et al., 1989; List et al., 1993; McMillan and Blasberg, 1994; Farber et al., 1997; McMillan et al., 1997). Faber et al. (1997) showed increased pain thresholds after electroacupuncture at non acupuncture points but predominant in those points lying along the acupuncture meridians. The site of PPT measurement in our study meets not exactly an acupoint. McMillan et al. (1997) found slightly elevated PPT in both placebo and verum groups. List et al. (1993) showed elevated PPT following acupuncture treatment for craniomandibular disorders in contrast to placebo which were not found any more at the 6 month follow-up.

In our study the increased PPT following needle acupuncture was observed even 6 weeks after treatment in the verum group but not in the placebo group. Lundeberg et al. (1989) found significantly increased pain threshold values intrasegmentally in six healthy subjects after manual or electrical stimulation in contrast to superficial acupuncture. There were no elevated levels of beta-endorphin, ACTH or prolactin.

Although several studies have shown that temporal PPTs are less sensitive in TTH than tenderness scores assessed by manual palpation (Sandrini et al., 1994; Schoenen and Bendtsen, 1999) to avoid bias by the fact that palpation is not carried out by a 'blind' observer we conducted the determinations of PPT with the more objective measure of a pressure algometer. Furthermore, there is evidence that pressure pain thresholds in episodic TTH are constant even during a headache (Bove and Nilsson, 1999). This is supported by the findings of Ashina et al. (1999): the muscle hardness measured in patients with chronic TTH on days with headache did not differ significantly from the muscle hardness recorded on days without headache. In our study group with more than 26 days headache per month we expected at each consultation the presence of an actual headache.

The results of our study support the hypothesis that chronic TTH is rather caused by abnormal endogenous pain control systems than myofascial problems of the pericranial muscles which may exist independently in patients with chronic TTH and which are more frequent than in control groups. Like in other myofascial diseases (NIH Consensus Conference, 1998) acupuncture shows a benefit for the muscle tenderness because of segmental and local effects. The question why heterosegmental mechanisms of acupuncture do not cause any positive effect in chronic TTH patients in the present and other studies cannot be answered. One reason could be that the endogenous pain control system of patients with TTH is impaired in a way which makes it impossible for acupuncture treatment to compensate the malfunctioning. This hypothesis is not novel (Schoenen et al., 1991) and may be supported by the finding of Mazzotta et al. (1997) which found altered beta-endorphin levels in blood mononuclear cells and substance P levels in platelets in TTH-patients.

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