Thermotherapy self-treatment for neck pain relief—A randomized controlled trial

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Received 9 January 2012; received in revised form 28 March 2012; accepted 10 April 2012

Abstract

Aim of the study: To evaluate the potential of thermotherapy self-treatment in relieving pain and improving sensory function in patients with chronic mechanical neck pain.

Materials and methods: Fifty patients (74% female; mean age 57.18 ± 12.3 years) with chronic mechanical neck pain were randomized to either treatment group (n = 25) or control group (n = 25). Treatment group used a mud heat pad once a day for 20 min over a period of 14 days while the control group was left untreated. Both groups were allowed to continue self-directed usual care. Primary outcome measure was neck pain intensity as assessed by a 100 mm visual analog scale (VAS) after 14 days. Secondary outcome measures included a pain diary (daily measure of pain intensity on a 100 mm VAS), functional disability (neck disability index; NDI) and health-related quality of life (short form-36; SF-36). Physiological measures included mechanical detection threshold (MDT), pressure pain threshold (PPT) and vibration detection threshold (VDT) at the site of maximal pain and in the adjacent region.

Results: Significant group differences occurred for pain intensity (mean difference = 16.00 mm; 95% confidence interval = 26.07; −5.92; P = 0.003) and pain diary (P = 0.013). Group differences for MDT and VDT occurred at the site of maximal pain (MDT: P < 0.001; VDT: P = 0.035) and in the adjacent region (MDT: P = 0.042; VDT: P = 0.008). No group differences were found in NDI, SF-36 or PPT.

Conclusions: Thermotherapy self-treatment seems to be effective in relieving pain and improving sensory functioning in patients with chronic mechanical neck pain. Further research is needed to underpin these preliminary results.

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Keywords: Thermotherapy; Self care; Complementary therapies; Randomized controlled trial; Neck pain; Sensory thresholds

Introduction

Neck pain is a common worldwide problem with a mean one-year prevalence of about 37% and a mean lifetime prevalence of 48.5% in the world population [1]. While most patients recover within three to six months, chronic neck pain occurs in approximately 14% of the population [2].

Chronic neck pain causes substantial personal suffering due to pain, functional impairments in daily life [3] and decreased health-related quality of life [4]. Moreover, muscle pain and increased muscle tonicity can restrict cervical range of motion [5] and impair somatosensory functioning [6].

Since neck pain is rarely attributable to serious causes [7], most patients are diagnosed with chronic mechanical neck pain. This non-specific neck pain is associated with psychological [8,9], social, and occupational factors [8,10]. Stress, anxiety, and postural deficits cause increased muscle tonicity and pain, which individuals sustain by adopting relieving postures [11]. Mechanical neck pain is commonly treated with analgesics,
chiropractic or rest [12,13]. However, treatments that involve active participation of the patient are highly recommended for neck pain relief [14].

Therapy – the therapeutic application of topical heat – is used since antiquity in the relief of musculoskeletal pain syndromes [15,16]. It provides an easy to apply self-treatment strategy for patients with chronic musculoskeletal pain and is widely used in classical natural medicine to provide neck pain relief [17]. Therapy self-treatment is also commonly recommended by general practitioners, which are most often consulted by patients suffering from chronic neck pain [12,13]. There is limited evidence of effectiveness of therapy in the treatment of rheumatoid arthritis [18] and low back pain [19,20]. However, despite the frequent use in clinical practice [13], there is no evidence of effectiveness in the relief of neck pain yet [21].

The aim of this study was to evaluate whether therapy self-treatment can provide pain relief and improve sensory function in patients suffering from chronic mechanical neck pain.

Materials and methods

Design

The study was conducted as a two-arm monocentric randomized controlled trial comparing therapy self-treatment with a waiting list group.

The study was planned and conducted in accordance with the principles of the World Medical Association’s declaration of Helsinki and was approved by the local ethics committee (approval number: 09-3953).

Procedure

After enrollment (T1), patients completed questionnaires and tests measuring sensory thresholds. Afterwards, patients were randomized to either treatment or waiting list control group. After randomization, the treatment group was instructed how to apply the heat pad for home usage. After 14 days, the tests were repeated (T2). Patients were not allowed to apply the heat pad on the day of T2.

Due to organizational reasons, outcome assessors were not blinded to treatment allocation.

Patients

Since no prior trials on therapy for chronic neck pain were available for effect size estimation, this study was planned as a pilot study with a convenient sample size of N=50. Study patients were recruited by local newspaper advertisement. Patients were first screened by a telephone interview. Inclusion criteria were minimum age of 18 years and mechanical neck pain of insidious onset the last 3 months with a mean pain intensity of at least 4 on a 10-level numerical rating scale with “0” meaning “no pain” and “10” meaning “worst pain imaginable”. Patients were eligible only if specific causes for their neck pain had been excluded by an orthopedist or a neurologist. Exclusion criteria were radicular symptoms, congenital spine deformity, skin diseases in the painful area to be treated, pregnancy, insulin-dependent diabetes mellitus, rheumatic diseases, active oncologic diseases, steroid medication, anticoagulation medication and recent invasive or surgical treatment of the spine.

If patients met all inclusion criteria and did not meet any exclusion criteria they were referred to a physical examination carried out by a physician at an enrollment visit.

All patients gave written informed consent.

Randomization

Patients were randomized, one by one, to either treatment or waiting list control group by a non-stratified block randomization. Random order was established using a computerized random generator. Randomization was carried out by means of sequentially numbered, sealed opaque envelopes, prepared by the study coordinator, who was neither involved in treatment nor measurement. After baseline assessment, the study physician opened the lowest numbered envelope to reveal that patient’s assignment.

Interventions

At T1, the treatment group was instructed in the use of a moor mud filled heat pad (beinio® therm, bb med. product GmbH, Kalkar (Kehrum), Germany). The pad was chosen because it was ideally shaped to cover the neck and shoulder region. Patients were instructed to heat the pad to a hot, but tolerable temperature and to apply it over the painful area once a day for 20 min during a period of 14 days. During this period the waiting list group was left untreated. Both groups were instructed to continue their usual medication — including analgesic drugs — and physiotherapy during the study period. However, invasive treatments (i.e. injections, acupuncture, and surgery) and additional topical heat application besides the study intervention were not allowed. After the intervention, at T2, the waiting list patients received the same instructions as the treatment group and received the heat pad for self-application.

Patients in both groups were allowed to retain the heat pad after the trial.

Outcome measures

Self-report measures

The primary outcome measure was actual pain intensity as assessed on a 100 mm visual analog scale (VAS) with “0” mm meaning “no pain” and “100” mm meaning “worst pain imaginable” [22]. Secondary outcome measures included pain at motion on a 100 mm VAS, where patients had to rate the intensity of pain evoked by six cervical spine movements (flexion, extension, left/right rotation, left/right lateral flexion). The ratings were averaged over all six movement directions [23]. Patients kept a pain diary over the 14-days period, consisting of a 100 mm VAS to rate neck pain intensity each day and a question
regarding daily pain medication and physiotherapy. Neck pain specific disability was measured using the neck disability index (NDI) [24]. Health-related quality of life was measured using the short form-36 health survey questionnaire (SF-36) [25].

The safety of the intervention was assessed at T2. Patients were asked about occurrence of adverse events.

**Sensory thresholds**

To assess changes in somatosensory functioning, mechanical detection threshold (MDT), pressure pain threshold (PPT), and vibration detection threshold (VDT) were measured twice, at T1 and T2. Measurements were performed according to the quantitative sensory testing (QST) protocol [26].

All sensory thresholds were determined at two sites at the neck: (1) at the site of maximal pain as indicated on a pain drawing [27] and verified by physical examination at T1 and (2) in the adjacent region, 1–2 cm outside the painful area. Furthermore, thresholds were measured at two control sites apart from the painful area, the right hand and foot, serving as measures of intra-observer reliability.

MDT was measured with a set of von Frey filaments (Somedic Sales AB, Hörby, Sweden) that exert forces between 0.26 and 1080 mN. The filaments were placed on the skin (on the neck, the back of the hand and the back of the foot) out of sight of the patient who was instructed to report each sensation of touch. The test series started with a 16 mN filament. The threshold was determined by the methods of limits whereby the stimulus intensity is decreased until the patient can no longer perceive the touch and then the stimulus intensity is increased until the patient first perceives the touch again. The final threshold was the geometric mean of five series of descending and ascending stimulus intensity.

PPT was measured using a pressure gauge algometer (Somedic Sales AB, Hörby, Sweden) with a probe size of 1 cm². Three ascending ramps of 50 kPa/s each were applied at the neck, over the thenar eminence and over the abductor hallucis muscle. The patients were instructed to indicate when the sensation changed from pressure alone to pressure and pain by depressing a switch. The test then was stopped and the strongest pressure applied indicated the pressure pain threshold. The mean threshold was calculated for each test site.

VDT was measured as a disappearance threshold. A Rydel–Seiffer graded tuning fork (64 Hz, 8/8 scale) was placed over a bony prominence (the spinal process next to the site of maximal pain or the adjacent region, respectively, the ulnar styloid process and the medial malleolus) and patients were instructed to report when the sensation of vibration stopped. The arithmetic mean of three repetitions of descending stimulus intensity was calculated.

**Statistical analysis**

All outcome measures were analyzed based on the intention-to-treat population. Missing data were replaced by carrying the last observation forward. To test the effect of data imputation, data were also analyzed per-protocol.

Since MDT and PPT have been shown to be normally distributed after logarithmic transformation in previous studies [26], they were log-transformed as recommended in the QST protocol [26].

Baseline group differences were tested using t-tests except for gender where a chi-square test was used.

To account for possible baseline differences between groups, parametric tests of outcome measures were performed with univariate analyses of covariance (ANCOVAs) [28] with the value at T2 as dependent variable, group as between-subject factor and the respective baseline value (T1) as linear covariate. The only exception was the pain diary, which was analyzed using a repeated measures ANCOVA with time as within-subject factor, group as between-subject factor and pain intensity at T1 as linear covariate.

ANCOVAs have been proposed as a way to minimize bias by baseline differences in clinical trials and to add power in comparison to unadjusted analyses of change scores [28]. Specifically, ANCOVAs have been shown to improve quality in clinical trials for chronic neck pain treatment [29].

Nonparametric tests – used to analyze the rating of perceived change in health status in the SF-36 – were performed with the Mann–Whitney U test.

A P-value of <0.05 was considered statistically significant for all statistical testing. Statistical analyses were performed with SPSS 17.0 statistical software (IBM Germany GmbH, Munich, Germany).

**Results**

**Patient characteristics**

After a first screening by telephone, 50 patients (74% women, mean age 57.18 ± 12.3 years) were invited for further examination. All invited patients fulfilled the inclusion criteria and agreed to participate.

There were no significant baseline differences in demographic characteristics between groups (Table 1). Differences occurred in actual neck pain intensity in VAS mm and in the SF-36 subscales “physical functioning”, “vitality”, “social functioning” and “mental health” (Table 1).

No differences were found in any of the sensory threshold baselines.

One patient in the treatment group and one patient in the control group were lost to follow up (Fig. 1). For these patients, missing data from T2 were replaced by carrying the data from T1 forward.

**Self-report measures**

At T2, the two groups showed significant differences in pain intensity (VAS) (mean difference −16.00 mm; 95% confidence interval −26.07; −5.92; P = 0.003) (Table 2).

No group differences occurred regarding pain at motion or NDI (Table 2).

The mean daily neck pain ratings in the pain diary exhibited a stronger decrease over the two-week period in the treatment
Table 1
Means (±SD) of baseline characteristics.

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Treatment (N=25)</th>
<th>Waiting list (N=25)</th>
<th>Group difference (95% CI)</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Demographic characteristics</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age</td>
<td>56.76 ± 14.10</td>
<td>57.60 ± 10.47</td>
<td>−0.84 (−7.90; 6.22)</td>
<td>0.812</td>
</tr>
<tr>
<td>Men/women</td>
<td>7/18</td>
<td>6/19</td>
<td>NA</td>
<td>0.747</td>
</tr>
<tr>
<td>Neck pain characteristics</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Duration in month</td>
<td>50.08 ± 47.91</td>
<td>68.80 ± 52.10</td>
<td>−18.72 (−47.10; 9.66)</td>
<td>0.191</td>
</tr>
<tr>
<td>Pain intensity on VAS</td>
<td>51.80 ± 22.17</td>
<td>38.32 ± 20.90</td>
<td>13.48 (1.23; 25.73)</td>
<td>0.032</td>
</tr>
<tr>
<td>NDI</td>
<td>30.40 ± 14.75</td>
<td>27.87 ± 15.49</td>
<td>−2.53 (−11.13; 6.07)</td>
<td>0.592</td>
</tr>
<tr>
<td>SF-36 subscales</td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Physical functioning</td>
<td>64.20 ± 24.61</td>
<td>80.00 ± 13.62</td>
<td>−15.80 (27.19; −4.41)</td>
<td>0.007</td>
</tr>
<tr>
<td>Role physical</td>
<td>44.00 ± 36.29</td>
<td>49.00 ± 41.13</td>
<td>−5.00 (−27.06; 17.06)</td>
<td>0.651</td>
</tr>
<tr>
<td>Bodily pain</td>
<td>42.36 ± 17.02</td>
<td>47.64 ± 15.95</td>
<td>−5.28 (−14.66; 4.10)</td>
<td>0.263</td>
</tr>
<tr>
<td>General health perceptions</td>
<td>59.00 ± 17.36</td>
<td>65.80 ± 13.81</td>
<td>−6.80 (−15.72; 2.12)</td>
<td>0.132</td>
</tr>
<tr>
<td>Vitality</td>
<td>53.20 ± 15.06</td>
<td>65.00 ± 17.32</td>
<td>−11.80 (−21.03; −2.57)</td>
<td>0.013</td>
</tr>
<tr>
<td>Social functioning</td>
<td>72.00 ± 18.14</td>
<td>89.00 ± 16.66</td>
<td>−17.00 (−26.91; −7.01)</td>
<td>0.001</td>
</tr>
<tr>
<td>Role emotional</td>
<td>72.00 ± 39.30</td>
<td>77.33 ± 39.35</td>
<td>−5.33 (−27.70; 17.03)</td>
<td>0.634</td>
</tr>
<tr>
<td>Mental health</td>
<td>64.80 ± 18.37</td>
<td>75.20 ± 14.09</td>
<td>−10.40 (−19.71; −1.09)</td>
<td>0.030</td>
</tr>
<tr>
<td>SF-36 component scores</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Physical</td>
<td>37.97 ± 9.26</td>
<td>41.49 ± 6.57</td>
<td>−3.52 (−10.80; 1.05)</td>
<td>0.128</td>
</tr>
<tr>
<td>Mental</td>
<td>48.66 ± 10.13</td>
<td>53.50 ± 9.47</td>
<td>−4.84 (−10.41; 0.74)</td>
<td>0.087</td>
</tr>
</tbody>
</table>

Bold P-values indicate significant group differences. VAS = visual analogue scale; NDI = neck disability index; SF-36 = short form-36 health survey questionnaire.

Fig. 1. Participant flow diagram.

Group than in the control group (F(13, 585) = 3.02; P = 0.013) (Fig. 2).

Regarding SF-36, 17 out of 24 patients in the treatment group rated their health to be better at T2 than at T1, compared to only two patients in the control group (U = 107.5; P < 0.001). No patient in either group reported a worsening of health.

No other group differences occurred in the SF-36 (Table 2).

Results did not differ substantially, when data were analyzed per-protocol.

Additional ongoing treatments

During the study period, mean days at which pain medication was used were 3.04 ± 4.89 for the treatment group and 1.54 ± 3.23 for the waiting list (group difference: 1.50, 95% CI −0.94 to 3.94; P = 0.221); physiotherapy was received at 1.17 ± 2.55 days by the treatment group and at 0.83 ± 2.68 days by the waiting list group (group difference: 0.33, 95% CI −1.19 to 1.85; P = 0.661).
Mainly, over-the-counter analgesics were used as pain medication; physiotherapy mainly consisted of therapeutic exercise and massage. No additional thermotherapy was used.

**Sensory thresholds**

The intra-observer reliability (Pearson’s r) for sensory thresholds was as follows: \( r_{\text{hand}} = 0.90 \) and \( r_{\text{foot}} = 0.85 \) for MDT; \( r_{\text{hand}} = 0.76 \) and \( r_{\text{foot}} = 0.76 \) for PPT; \( r_{\text{hand}} = 0.77 \) and \( r_{\text{foot}} = 0.84 \) for VDT.

MDT differed significantly between the two groups at T2, both at pain maximum and in the adjacent region (Table 3, Fig. 3). No differences between groups were found regarding PPT at pain maximum or in the adjacent area (Table 3). For VDT, there were significant group differences at pain maximum, as well as in the adjacent region (Table 3, Fig. 3).

**Safety**

There were no serious adverse events. One patient in the treatment group reported increased stiffness of the right shoulder. Another patient reported vertigo for a few minutes after treatment. Both patients continued to use the heat pad on their own wish, nevertheless.

**Discussion**

In this randomized controlled trial, we examined the effect of thermotherapy self-treatment on pain and functioning in patients...
suffering from chronic mechanical neck pain compared with a waiting list control group. The control group was however allowed to continue conventional medication and physiotherapy treatment. Thus, the control group in this study was similar to usual care.

Self-report measures

In this study, thermotherapy was more effective in relieving chronic neck pain, when compared to the control group. The mean group differences in self-rated pain intensity of 16 mm VAS is well inside the range of clinical relevance [30]. The steady decrease of pain ratings reported in the pain diaries seems to reflect an ongoing amelioration of pain, at least while the treatment continued. Nonetheless, since no follow-up data were recorded, it can only be speculated whether the effect lasts beyond treatment time.

Regarding agreements with previous studies, no trials on superficial heat for chronic neck pain were available. Thermotherapy has been included as a part of treatment interventions for neck pain in clinical studies [31], but the specific effect was not evaluable. However, a trial on heat or cold packs for acute back or neck strains found both interventions comparably effective [32]. A number of randomized trials on heat wrap applications for acute and subacute low back pain found evidence for short term pain relief [33,34].

In the current study, no group differences were found in NDI or in SF-36. While this might be interpreted as thermotherapy self-treatment not having any effects on neck pain specific disability or health-related quality of life, it might also mean that the study period of 2 weeks was too short to find substantial differences in these parameters.

Similar to previous studies, using thermotherapy in low back pain [33,34], there were only minor adverse events in this study.

The clear statistical and clinical significant changes in the primary outcome measure, the mean pain intensity on the VAS, along with the ratings of perceived positive health change and minor adverse events, indicates that home usage of thermotherapy seems to be a safe and effective method for short term relief of chronic insidious neck pain.

Sensory thresholds

The sensory testing protocols for MDT, PPT and VDT are likely to be less intuitive to the patients than more subjective measures. Therefore, these measures are less likely to be biased by patients’ expectations.

In this study, all parameters showed satisfying intra-observer reliability.

Mechanical detection and vibration detection thresholds were decreased after the treatment period only for the treatment group.
Hypoesthesia to vibration and mechanical stimuli has recently been found in patients with chronic idiopathic neck pain and has been attributed to peripheral and/or central nerve malfunctions [6,35]. The nerves and their supplying microvessels are highly endangered by compression, tension or friction. Even mild compression, such as beginning entrapment of the median nerve in carpal tunnel syndrome, can affect nerve functioning [36]. Similar pathophysiology has been proposed for nerve malfunctions in chronic neck pain [6]: muscle spasm can cause local compression, microtrauma or inflammation of nerve tissue, influencing nerve function.

Topical heat treatment of moderate temperature applied directly on the skin increases temperature in the deep muscle tissue [37] and results in a two- to threefold increase of deep tissue blood flow [38,39]. This is accompanied by an increase of muscle extensibility, preventing further tissue damage [40]. These mechanisms have been shown to reduce muscle spasm and aid the healing of tissue damage and thus might reduce not only pain [16] but also nerve malfunction. Therefore, the observed changes in sensory thresholds following topical thermotherapy could be interpreted as a normalization of pathological hypoesthesia, at least temporarily.

No changes between groups occurred with regard to pressure pain threshold. This is remarkable, as hyperalgesia to pressure is the most common reported alteration in sensory thresholds in patients with chronic neck pain [41]. Hyperalgesia is often maintained by central sensitization [42], rather than peripheral nerve malfunctions. Therefore, the lack of a treatment effect on hyperalgesia fosters the assumption, that thermotherapy had no effect on central sensory processing. Therefore, the investigation of thermotherapy compared to other treatments for chronic neck pain, which have been shown to influence pressure pain threshold [23,43–46] would be an interesting topic for future research.

The study has several limitations. First, there were baseline differences between groups, with the control group reporting less pain and better quality of life. However, as randomization took place after the first measurement, baseline differences cannot be attributed to observer bias. Statistical analyses were performed by ANCOVAs to control for bias through baseline differences [28,29]. Another limitation is the low mean baseline pain intensity. Patients had to rate their pain intensity 4 or higher on a 10-level numerical rating scale to be included in the study. At T1, after study inclusion, actual pain was rated on a 100 mm VAS, whereas the mean pain rating was below 40 in the control group. This can be regarded as a possible source of bias, since patients might have exaggerated their complaints during screening to ensure inclusion into the study. As analyses were based on the intention-to-treat population, all patients were analyzed regardless of baseline pain intensity.

Due to the distinctive character of the thermotherapy treatment, no adequate placebo control was found. Therefore, instead of performing a pure observational study without any control or randomization, a waiting list control group appeared to be the most appropriate solution. Non-specific therapist effects can be ruled out due to self-treatment. Possible non-specific effects by applying a medical device cannot be ruled out. However, in clinical trials of conservative treatments for chronic non-specific neck pain, changes in pain scores normally are similar in wait-list control groups and placebo control groups [47].

Conclusions

Heat pad thermotherapy, self-applied during a period of 14 days, seems to effectively relieve pain and improve somatosensory function in patients suffering from chronic idiopathic neck pain. Thermotherapy thus might provide an effective and easy to apply self-help strategy for this patient population. Given the small sample size, short trial duration, concurrent physiotherapy use, and moderate baseline pain intensity, the results of this trial remain preliminary. Further research is needed to underpin these results, investigate the long-term effectiveness, and explore the effects of thermotherapy in more severely affected patients.

Financial support and conflict of interest

All authors disclose any commercial association that might create a conflict of interest in connection with the submitted manuscript. There is especially no competing financial interest for any of the authors.

Acknowledgement

This study was supported by a grant from the Karl and Veronika Carstens Foundation.

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