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Non-pharmacological approaches to chronic headaches: transcutaneous electrical nerve stimulation, lasertherapy and acupuncture in transformed migraine treatment

Abstract In an open, randomized trial, we evaluated transcutaneous electrical nerve stimulation (TENS), infrared lasertherapy and acupuncture in the treatment of transformed migraine, over a 4-month period free of prophylactic drugs. Sixty women suffering from transformed migraine were assigned, after a one month run-in period, to three different treatments: TENS (Group T; n=20), infrared lasertherapy (Group L; n=20) or acupuncture (Group A; n=20). In each group the patients underwent ten sessions of treatment and monthly control visits. In Group T patients were treated for two weeks (5 days/week) simultaneously with three TENS units with different stimulation parameters (I: pulse rate = 80 Hz, pulse width = 120 μs; II: 120 Hz, 90 μs; III: 4 Hz, 200 μs). In Group L an infrared diode laser (27 mW, 904 nm) was applied every other day on tender scalp spots. In Group A acupuncture was carried out twice a week in the first two weeks and weekly in the next 6 weeks. A basic formula (LR3, SP6, LI4, GB20, GV20 and Ex-HN5) was always employed; additional points were selected according to each patient's symptomatology. The number of days with headache per month significantly decreased during treatment in all groups. The response in the groups differed over time, probably due to the different timing of applications of the three methods. TENS, lasertherapy and acupuncture proved to be effective in reducing the frequency of headache attacks. Acupuncture showed the best effectiveness over time.

Key words Acupuncture • Lasertherapy • Randomized trial Transcutaneous electrical nerve stimulation • Transformed migraine

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Introduction

Frequent headache sufferers often overuse symptomatic medications. There are many drugs to choose from, but untoward reactions to even the simplest drugs often occur and chronic drug use increases the likelihood of toxic reactions. Moreover, drug overuse can lead to chronic daily headache (CDH) by a "rebound" or "drug-induced" mechanism [1]. Most patients with CDH have a history of episodic migraine which gradually evolved into what has been termed *transformed migraine* (TM).

Patients suffering from TM are difficult to treat, especially when they exhibit comorbid depression and physical and emotional dependency [2]. Besides, prophylactic medications, otherwise often effective, will rarely benefit these individuals [3]. Non-pharmacological therapies can probably offer a valid chance to these patients, successfully replacing the use of preventive drugs.

Among non-pharmacological approaches to headache, few can be signalled for their scientific validation: biofeedback-assisted relaxation training, acupuncture, transcutaneous electrical nerve stimulation (TENS) and lasertherapy. Biofeedback offers a fairly good number of scientific publications which value its application, also in the specific treatment of TM [2, 4]. Recent systematic reviews of randomized controlled trials on acupuncture in headache prophylaxis have underlined the evidence that acupuncture has an effective role in the treatment of migraine [5, 6]. Nevertheless

there is almost a total lack of trials on CDH. For TENS and lasertherapy [7–9], even if a common validation in painful syndromes and occasionally in headache exists, no study establishes their real effectiveness in TM.

Until now, no study has compared the results obtained by TENS, infrared lasertherapy and acupuncture in the prophylactic treatment of TM. Therefore, we evaluated the effectiveness of these techniques, applying them in different cutaneous zones, but always corresponding to acupuncture points.

Patients and methods

Sixty female patients of mean age 41.4 years (SD=10,3 years; range 21–60) suffering from TM, defined as proposed by Silberstein et al. [3], were enrolled in an open, randomized study comparing the effects of ten therapeutic sessions of three non-pharmacological methods: TENS, infrared lasertherapy and acupuncture. Criteria for admission to the study were: age ranging from 18 to 60 years; a minimum 1-year history of TM; more than 15 days with headache per month in the last six months; no past or present disease, and in particular no history of convulsive seizures; no pregnancy or lactation; no inadequate contraception; no cardiac pacemaker; no previous treatment with TENS, lasertherapy, acupuncture or other mind/body modalities. No migraine prophylaxis was allowed during the study. Patients were invited to limit the intake of rescue medications as much as possible, eventually preferring the long-acting non-steroidal anti-inflammatory drugs.

A predetermined computer-made randomization list was generated; consecutively numbered, opaque envelopes containing a sheet with the allocation were prepared and opened after patients had been included in the study. The subjects had an equal probability of being assigned to each treatment group. All patients gave informed consent to participation in the study. The eligible patients were assigned, after a one month run-in period free of prophylactic therapy, to three treatments: TENS (Group T; n=20), infrared lasertherapy (Group L; n=20) or acupuncture (Group A; n=20). In each group the patients received ten sessions of treatment at our outpatient department and then were no more treated until the end of the study period.

Transcutaneous electrical nerve stimulation

Patients (Group T) were treated for 30 minutes every day, from Monday to Friday, for 2 weeks. Three TENS units, operating with different stimulation parameters, were employed together in each subject (Fig. 1). The first device (*conventional* TENS, pulse rate = 120 Hz, pulse width = 90 μs) was connected to tender head spots corresponding to Ex-HN5 *Taiyang* and BL2 *Zanzhu*, bilaterally. The second one (*conventional* TENS with modulation in amplitude, pulse rate = 80 Hz, pulse width = 120 μs) was applied on trigger points corresponding to GB20 *Fengchi* and GB21 *Jiangjing*, bilaterally. The third one (*acupuncture-like* TENS, pulse rate = 4 Hz, pulse width = 200 μs) treated the acupoints LI4 *Hegu* and SI3 *Houxi* only on the non-dominant hand. This lets the patients have one free hand to set the power knobs, to control the electrical sensation and to regulate the intensity of stimulation. The patients were instructed to gradually increase stimulation, at the start of each session, until a tingling sensation was felt, and to maintain this pleasant sensation during the treatment period. According to the position of the point stimulated, re-usable carbon-silicone pads or disposable sponge electrodes were applied. When carbon-silicone pads were utilized, they were taped to the skin after hypoallergenic electrotransmission gel was spread on their surface; when sponge electrodes were used (on points located on the head), they were inserted under a tubular elastic net bandage after being dampened with water. In all cases the electrodes were firmly connected to the TENS machine through an appropriate number of lead wires.

Infrared lasertheraphy

Patients (Group L) were treated on Mondays, Wednesdays and Fridays for ten sessions. Each treatment lasted about 25 minutes. A 27-mW, 904-nm, infrared diode laser was used. The laser pointer was placed directly over each point on the skin for 60 seconds of stimulation. The patients felt nothing from the infrared stimulation. Some points, corresponding to the acupoints GB20 *Fengchi,* GV20 *Baihui*, GB14 *Yangbai,* Ex-HN5 *Taiyang,* were always treated. Additional points (generally 10–12) were chosen among the so-called *Ashi* points (or trigger points) on the scalp. Using a *baton de*

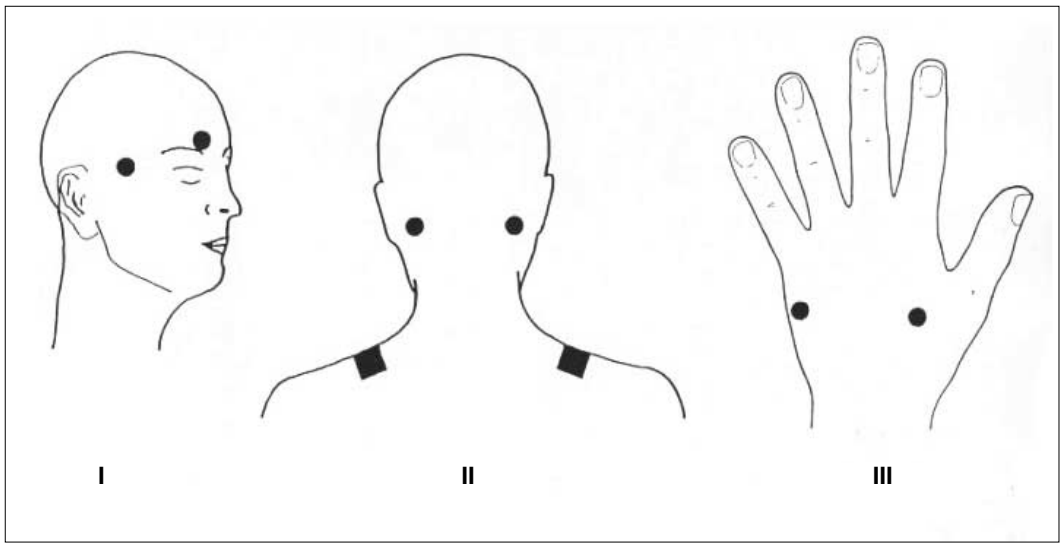

Fig. 1 TENS electrodes placement. Roman numbers (I, II, III) represent the three different TENS units

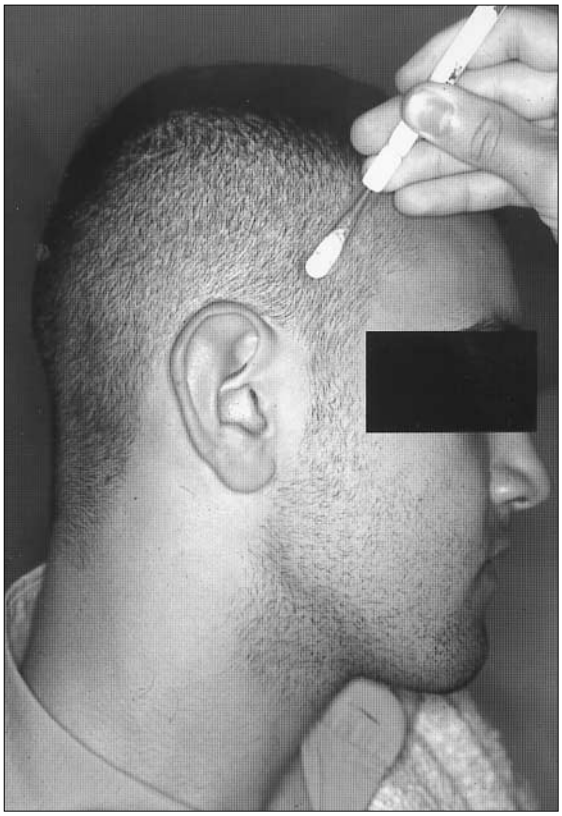

Fig. 2 The method used to exactly locate tender points of the scalp where laser beam has to be applied: a *baton de verre* is systematically rubbed horizontally over the scalp

verre (a small glass stick with smoothed ends), rubbed over the scalp horizontally, some spots of high scalp tenderness were elicitated (Fig. 2); the most painful ones were treated.

Acupuncture

Acupuncture in group A was carried out twice a week in the first 2 weeks and weekly in the next 6 weeks.

In order to standardize the treatment scheme, we always used a basic formula, consisting of the following acupoints: LR3 *Taichong,* SP6 *Sanyinjiao,* LI4 *Hegu,* GB20 *Fengchi,* GV20 *Baihui*, Ex-HN5 *Taiyang*. Moreover, additional points were used, if necessary, following pain location (GB14 *Yangbai*: frontal pain; BL10 *Tianzhu*: nuchal pain; GB21 *Jiangjing*: dorsal irradiation of pain) and accompanying symptomatology (ST36 *Zusanli*, CV12 *Zhongwan*: nausea and vomiting; HT 7 *Shenmen*: anxiety and insomnia). Unless for CV12 and GV20, located on the body median line, bilateral acupuncture was performed. All points were punctured with 0.3-mm diameter sterile disposable steel needles (length: 52 mm) that were inserted to a depth of 10–30 mm and manipulated until the patient reported the characteristic irradiating sensation, said to indicate effective needling, that is commonly called *De Qi* [10, 11]. Needles were inserted perpendicularly in all points (except GB14, Ex-HN5 and GV 20 that were punctured horizontally). For needle manipulation the so-called even (intermediate) method was always used. After obtaining the needle sensation the manipulation was stopped. Needles were left in situ for 20 minutes and they were not manually stimulated further on. Acupuncture was always performed with the same needle manipulation technique by three of the authors (G.A., P.E.Q., G.L.), who are experienced and qualified acupuncturists.

Data analysis and statistical elaboration

Days with headache per month were recorded on a headache diary in all groups. Their variations with respect to the run-in period (T0) were calculated every month (T1, T2, T3, T4) as outcome measures. Analysis of diary data was conducted by operators blind to the assignment of patients to treatment groups. Patients in all groups underwent a control visit by these operators every month.

Statistical analyses were carried out on a monthly basis and compared to the corresponding values during the run-in period (intra-group analysis) and to the corresponding values of the other treatment (intergroup analysis). An ANOVA test for repeated measures was used; in order to localize the source of variance a post-hoc Bonferroni *t* test was then applied. Moreover, in order to evaluate the difference among groups, a one-way ANOVA test was always performed for each level of the variable "Time". Values in the text are reported as arithmetic means (±standard deviation).

Results

Seven patients failed to complete the course of treatment for perceived ineffectiveness (n=6; 2 in each group) or incomplete diary compilation (n=1 in Group L). The results are therefore based on the remaining 53 patients.

The three groups were homogeneous in terms of age, systolic and diastolic blood pressures, age at onset and clinical characteristics of the disease.

During the run-in period, no significant difference was detectable among the treatment groups as for days with headache ($T0_T$=21.72±4.39; $T0_L$=21.71±4.78; $T0_A$=21.33±4.26) (Fig. 3). Statistical evaluation suggests that in all groups there was a difference in headache activity among the various study times: the number of days with headache significantly decreased during the treatment (ANOVA for repeated measures, $p<0.0001$ in each group).

In Group T, a significant decrease in headache days was already reached after 1 month of therapy ($T1_T$=11.00±5.76; Bonferroni *t* test vs. $T0_T$, $p<0.05$), maintained at 2 and 3 months ($T2_T$=13.56±4.10 and $T3_T$=14.61±2.89: $p<0.05$ for both comparisons vs. $T0_T$). Data obtained in the fourth month ($T4_T$=19.17±3.73) were not different from those of the run-in period.

Also in Group L, days with migraine decreased significantly after 1 and 2 months ($T1_L$=10.82±5.89 and $T2_L$=13.41±4.09, $p<0.05$ for both comparisons vs. $T0_L$); they were still lower, even if no more significantly, after three months ($T3_L$=18.47±4.05) and increased furtherly in the fourth month ($T4_L$=20.06±4.04).

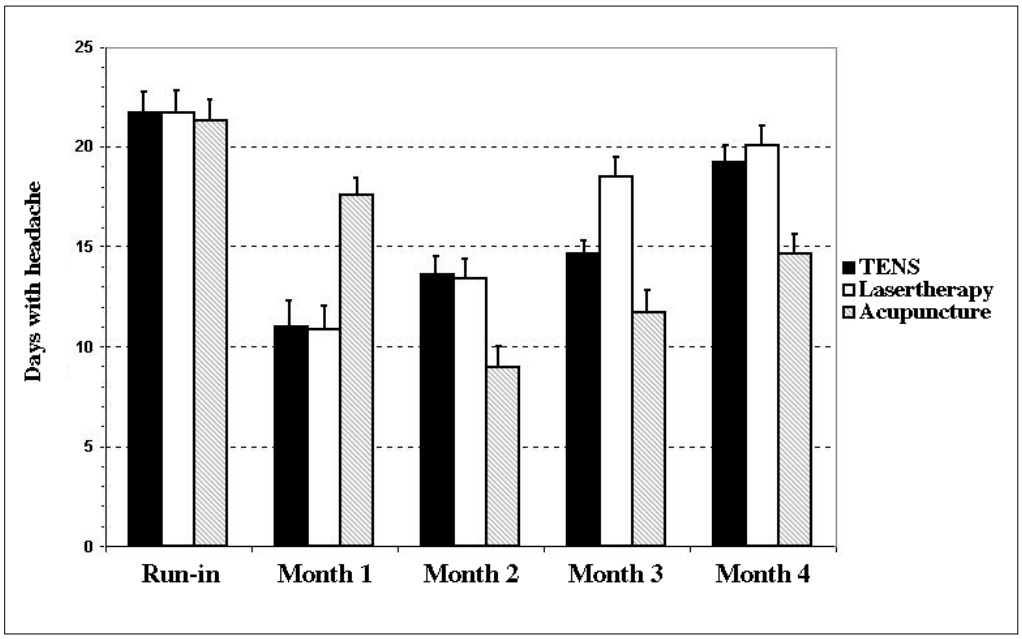

Fig. 3 Days with headache per month (x±s.e.m.) during run-in period and after 1, 2, 3 and 4 months in Group T (*black columns*), Group L (*white columns*) and in Group A (*gray columns*). ANOVA for repeated measures: Group T, $p<0.0001$; Group L, $p<0.0001$; Group A, $p<0.0001$. Bonferroni *t* test for intra-group analysis: Group T: T_0 vs. T_1 and T_2 and T_3 ; T_1 vs. T_3 and T_4; T_2 vs. T_4; T_3 vs. T_4, $p<0.05$; Group L: T_0 vs. T_1 and T_2; T_1 vs. T_3 and T_4; T_2 vs. T_3 and T_4, $p<0.05$; Group A: T_0 vs. T_1 and T_2 and T_3 and T_4; T_1 vs. T_2 and T_3 and T_4 ; T_2 vs.T_3 and T_4; T_3 vs. T_4, $p<0.05$

In Group A, the number of migraine days was always significantly lower at any study time compared to run-in period ($T1_A$=17.61±3.47, $T2_A$=8.94±4.48, $T3_A$=11.72±4.76, $T4_A$=14.67±3.80; $p<0.05$ for all comparisons vs. $T0_A$). A further statistical significance was achieved comparing the results obtained after 2 and 3 months of therapy with those obtained after 1 month.

The best results were achived by TENS and lasertherapy during the first month. At this time, headache days had been decreased by more than 50% in 10 of 18 patients (55.5%) in Group T and in 9 of 17 patients (52.9%) in Group L. The lowest number of headache days was present after two months in Group A, when days with headache decreased by more than 50% in 13 of 18 patients (72.2%). Moreover, the number of headache days significantly decreased in Groups T and L than in Group A in the first month, but this parameter became significantly lower in Group A than in Groups T and L at T3 and T4.

No serious side effects occurred in any group during the study.

Discussion

The present study demonstrates the efficacy of all studied techniques in the prophylactic treatment of TM. The number of days with headache significantly decreased in Groups T, L and A. These findings confirm the validity of acupuncture [5, 6, 12] and TENS [7] also in TM treatment and highlight the possibility that lasertherapy is effective in this painful condition too. Although all three methods showed good therapeutic results, acupuncture proved to be the most effective as it produced a significant decrease of days with headache at each study time, showing the best long-lasting beneficial effects.

Since in all treatments the stimulated points always corresponded to acupoints (it is well known that most musculoskeletal trigger points coincide with acupuncture points [13]), the local anti-inflammatory effect and the segmental antinociceptive role mainly played at trigeminal level exhibited, beyond the nature of the stimulus, a great efficacy in reducing headache attacks, at least at short and middle terms. Probably, the better results obtained in Group A are due to the peculiar acupuncture effect of harmonizing the physiologic functions of human body [14]. It has been demonstrated that the stimulation of distal points (i.e. LR3, SP6 and LI4), which have pronounced analgesic, sedative, tonifying or homeostatic effects, can primarily control the analgesic mechanism and promote the release of opiods. It is possible that an increased activity of the antinociceptive system helps to reduce both head pain and analgesic overuse.

In any case TENS, lasertherapy and acupuncture were used in a quite reductive way, limiting the treatment time only to ten sessions and without scheduling maintenance treatments. Probably TM patients could benefit from a prolonged series of these methods, eventually performed in conjunction with other pharmacological and non-pharmacological modalities. Further studies are necessary to answer to this issue.

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