Efficacy of Microcurrent Therapy in the Treatment of Chronic Nonspecific Back Pain

A Pilot Study

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Objectives: Microcurrent therapy (MCT) is a novel treatment for pain syndromes. The MCT patch is hypothesized to produce stimuli that promote tissue healing by facilitating physiologic currents. Solid evidence from randomized clinical trials is lacking. To evaluate the efficacy of MCT in treating aspecific, chronic low-back pain, we conducted a double-blind, randomized, crossover, pilot trial.

Methods: Ten succeeding patients presenting with nonspecific, chronic low-back pain in our university hospital were included. Patients started with two, 9-day baseline period followed by a 5-day treatment periods. During the treatment periods, either a placebo or MCT (verum) patch was randomly assigned. Mean and worst pain scores were evaluated daily by a visual analog scale (VAS). Furthermore, analgesic use, side effects, and quality of life were assessed after each period. Differences between the last 4 days of a treatment period and the baseline period were calculated. Differences between verum and placebo periods per patient were compared using paired *t* tests. A 20-mm VAS score reduction was considered clinically relevant.

Results: The VAS score was lower during verum treatment, with a reduction [95% confidence interval (CI) of −0.43 (−1.74; 0.89) in mean and −1.07 (−2.85; 0.71) in worst pain. Analgesic use decreased during verum treatment, except for nonsteroid anti-inflammatory drug use, which increased. Quality of life improved during verum treatment. However, note of the findings were statistically significant.

Discussion: A positive trend in MCT use for aspecific, chronic low-back pain is reported. Further investigations are required to evaluate the significance and relevance of this.

Key Words: microcurrent therapy, chronic low-back pain, randomized, controlled trial, placebo, crossover design

(*Clin J Pain* 2009;25:495–499)

Chronic low-back pain is a serious problem affecting approximately 20% of the general population, with no specific diagnosis being made in more than 90% of these cases.[1,2] Despite the many available therapies, treatment of chronic low-back pain can be difficult and disappointing.

Microcurrent therapy (MCT) is a novel treatment for different pain disorders and is defined as a low-intensity, direct current that delivers monophasic or biphasic pulsed microamperage currents across the skin.[3–8] Patients do not perceive MCT currents, and the putative mechanism of action differs from conventional transcutaneous electrical nerve stimulation (TENS). Conventional TENS delivers a 10 to 100 Hz frequency, 1 to 2 mA current, whereas our device delivers a microcurrent of 25 μA, with a frequency of approximately 71.5 kHz.[9] Conventional TENS is hypothesized to "close the gate" in the spinal cord, thus suppressing nociceptive pain and stimulating endogenous opioid release.[9–11] MCT is hypothesized to increase the synthesis of adenosine triphosphate, amino-acid transportation, and protein synthesis to decrease inflammation and to promote tissue healing.[4,12,13]

Once or twice weekly, intermittent MCT treatment for 20 to 40 minutes with a 100-μA device provided a significant (3.8-fold) reduction in pain intensity in an uncontrolled trial with patients with intractable, chronic low-back pain.[14] The present pilot study evaluates the efficacy of continuous (24-h daily) intervention with the MCT patch, delivering a monophasic current, for the treatment of chronic low-back pain, using a randomized, placebo-controlled, double-blind, crossover design.

PATIENTS AND METHODS

To investigate the efficacy of continuous MCT-patch treatment, we included 10 otherwise healthy adults with aspecific, chronic low-back pain of more than 3 months' duration and an average intensity on a 0 to 100 mm visual analog scale (VAS) of above 40. Furthermore, participants were required to be out-patients, between 18 and 65 years of age, of normal weight and height, and able to comprehend the study design and give informed consent. Patients participating in other trials, undergoing other pain treatment (except escape medication), pregnant women, or patients with circulatory defects of their extremities, any connective tissue disease, any disease with a predisposition for, or with, seizures, a pacemaker, a skin infection at the site where the patch will be placed, or a neurologic disease leading to sensory disturbances were excluded from the trial. Patients were referred to our academic pain clinic after unsuccessful treatment by general practitioners and secondary care. An anesthesiologist specialized in pain treatment confirmed the diagnosis. We used a Pain Away patch (Newmark Inc, Cheshire, CT) delivering a 25 μA microcurrent, with a frequency of approximately 71.5 kHz and 3 V.

Received for publication July 20, 2008; revised November 28, 2008; accepted December 7, 2008.

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The patches and the travel expenses of the participating patients were provided by the Benelux distributor of the patches TakeCare BV. The first and second authors have no conflicts of interest to declare, the third received compensation from the manufacturer. The first author is currently supported by an unrestricted grant from Pfizer for a totally unrelated research project.

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After obtaining informed consent and inclusion, a 9-day baseline period was started. Patients were randomly assigned to a 5-day treatment period with either verum (active MCT) patch or placebo followed by a 9-day wash-out period to eliminate any long-term effects of the MCT patch. During this 9-day period, no experimental intervention was given. Hereafter, patients crossed over to a second treatment period of 5 days with verum or placebo. The study design is further clarified in Figure 1. The patch was used continuously during both treatment periods. Patches were applied over the most painful spot with the positive electrode, marked by a LED light, closest to the spine (Fig. 2). Given the differences between TENS and MCT and the novelty of MCT, no uniform treatment regimen currently exists. We therefore chose to follow the manufacturer's recommendations. The placebo patch was indistinguishable from the active MCT patch in all aspects, owing to the fact that the microcurrent was below sensory threshold. Both patient and investigator were blinded to the assigned treatment.

The senior author numbered the placebo and verum patches from 1A and B to 10A and B. Each patient was given patch A during the first period and patch B during the second period by the first author, who was blinded to the treatment allocation. After the 2 treatment periods (1 active and 1 placebo), a 4-week open period began in which patients used an active MCT patch.

The primary end point was change in pain intensity between the treatment period and the placebo period. This was measured by daily VAS scores for average pain and for worst pain. Secondary end points were the use of analgesics in the treatment period, as compared with the placebo period, the scores on the short-form McGill Pain Questionnaire, Dutch Language Version (sf-MPQ-DLV), side effects, and global impression of the patients.[15] Quality of life was assessed by the European Quality of Life-5D (EQ-5D) at the end of each period.[16] These end points are all recommended as "core domains" by the Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials (IMMPACT).[17] The EQ-5D was specifically designed for a nonspecific evaluation of health status.[16] During the open phase, the VAS score and the use of additional medication were recorded on a weekly basis. Side effects and sf-MPQ-DLV and EQ-5D questionnaires were recorded once at the end. All data collection and analyses were carried out by the first author. This study was approved by the medical ethics commission of the University Medical Center Utrecht. Informed consent was obtained before participation.

Analyses

The baseline VAS score was defined as the mean of the last 4 days before a treatment period (baseline period or wash-out period 1 or 2, Fig. 1) to eliminate a carry-over effect of the before-treatment period. The mean VAS score at the end of a treatment period (blinded period 1 or 2, Fig. 1) was calculated as the mean of the last 4 days to provide a wash-in period of treatment. The mean change in primary and secondary end points during the verum and placebo treatment was measured. The differences between these changes were compared with a paired *t* test and the 95% CI was calculated. A 20-mm VAS score difference between placebo and verum was considered to be clinically relevant.

EQ-5D and sf-MPQ-DLV were scored using published procedures.[18,19] The use of analgesics was recorded daily, and the mean use per period was compared between the different treatment periods using a Student *t* test. *P* values were derived using the Wilcoxon paired-sample tests. Mean use was calculated by multiplying strength by daily dosage, and dividing this sum by the number of patients (n = 10).

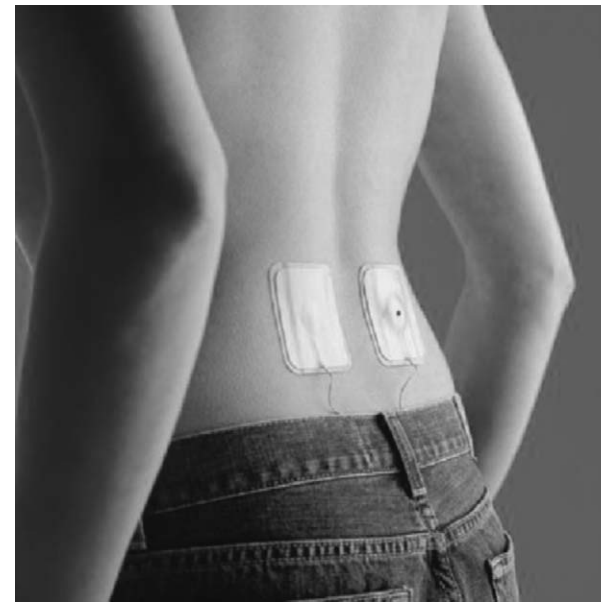

FIGURE 2. Disposable microcurrent therapy patch for continuous application.

RESULTS

Patient inclusion is displayed in Figure 3. During a 4-month period, 12 succeeding patients referred to our clinic with low-back pain were assessed for eligibility: 1 patient was excluded because she had a hip implantation; 1 patient refused informed consent; and 10 patients gave informed

Period 1: 9 days	Period 2: 5 days	Period 3: 9 days	Period 4: 5 days	Period 5: 9 days
Baseline period	Blinded period 1	Washout 1	Blinded period 2	Washout 2
V1	V2: randomization	V3	V4	V5
		Period 6		
Week 6	Week 7	Week 8	Week 9	Week 10
Open period				End of study
V6				V7

FIGURE 1. Study design. V1 to V7 denote data collection points 1 to 7. The last 4 days of the period before a "blinded period" were used to calculate baseline measures, whereas the last 4 days of the "blinded period" itself were used to calculate treatment effect.

consent. Patient characteristics are listed in Table 1. The mean and worst VAS scores during baseline, placebo, and verum treatment are described in Table 2. After treatment with an active patch, the VAS score was reduced by 0.09, in contrast to an increase of 0.34 during treatment with the placebo patch. The worst VAS score was decreased by 0.65 during verum treatment, whereas it increased by 0.41 during placebo treatment. The treatment effect of the verum patch can be described as small for the mean VAS score and as moderate for the worst VAS score, using the standardized nomenclature first introduced by Batterham and Hopkins.[20] The sf-MPQ-DLV and EQ-5D assessments and the use of additional pain medication improved during the use of the verum patch (Tables 2, 3). Paracetamol usage decreased during the verum period, whereas this increased during placebo treatment. Opioids were used less during treatment. Nonsteroid anti-inflammatory drug use increased during verum treatment, whereas this decreased during placebo treatment. The use of gabapentin remained constant.

The adverse events reported during this study were present in 6 patients during one or more of the treatment periods. These were pain (other than low-back pain), skin irritation, and itching (Table 4). None of the patients found these serious enough to withdraw from the study. All patients reported suboptimal adherence of verum and placebo patches at some time during the 3 treatment periods. Discontinuation of the continuous (24 h) application was prevented by the use of back-up patches. Back-up patches (either placebo or verum, depending on the allocated treatment) were available for use once the old patch had stopped adhering optimally.

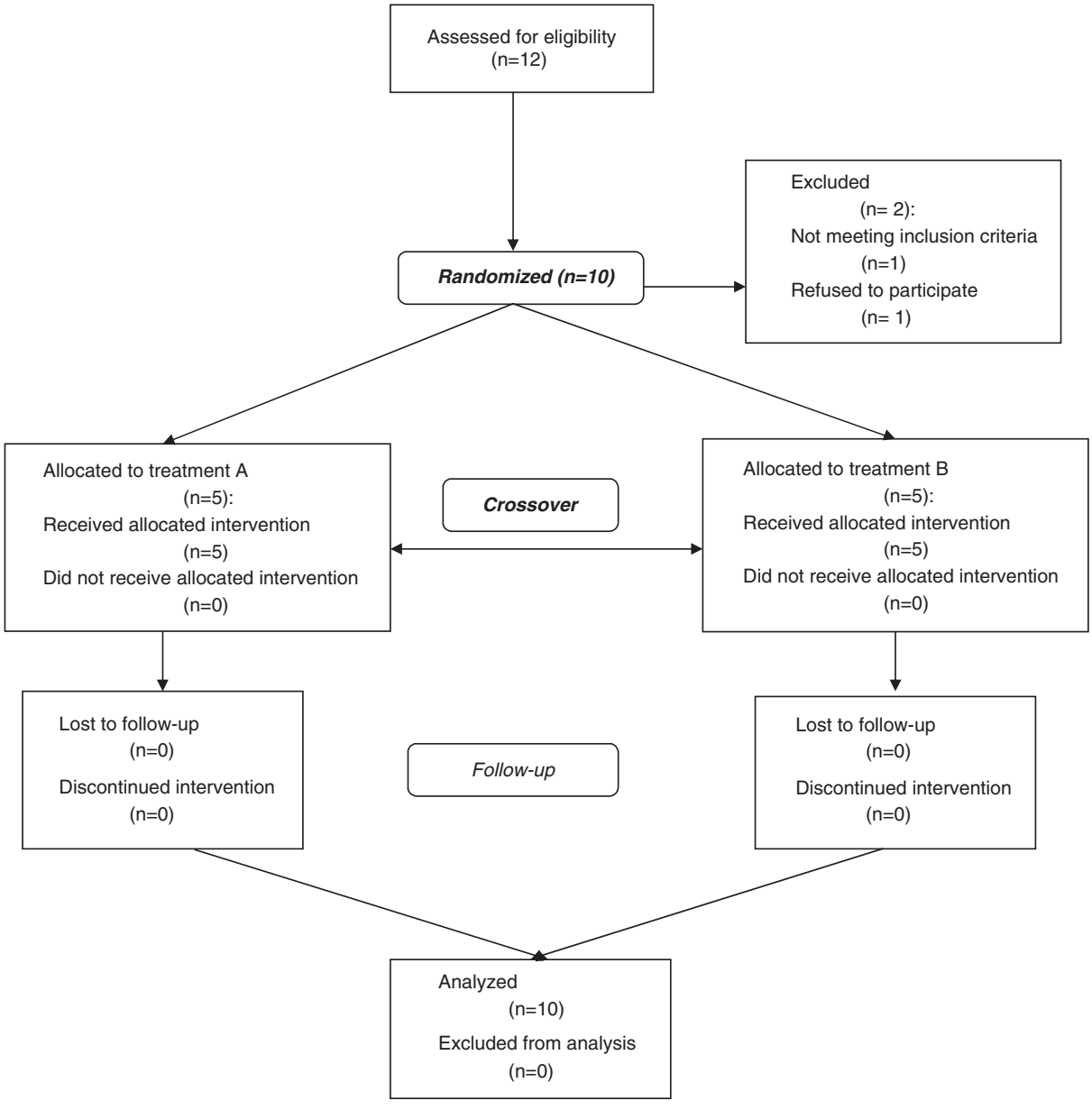

FIGURE 3. Consort diagram for patient inclusion.

TABLE 1. Baseline Characteristics of Patients

Patient	Sex	Age (y)	BMI (kg/m^2)	Previous Invasive Pain Treatment	Months of Pain
1	Male	45	29.17	Yes	32
2	Female	61	29.73	No	360
3	Male	35	25.83	Yes	132
4	Female	58	28.09	Yes	156
5	Male	46	30.99	No	96
6	Female	39	30.48	Yes	36
7	Female	50	20.68	Yes	46
8	Female	52	25.64	Yes	144
9	Female	59	26.30	Yes	36
10	Male	60	31.01	Yes	32
Mean	40% male	50 (9.2)	27.79 (3.25)	80% yes	107.0 (102.0)
Placebo first	60% male	52 (7.1)	27.63 (4.34)	80% yes	48.4 (27.2)
Verum first	20% male	49 (11.5)	27.95 (2.20)	80% yes	165.6 (118.6)

The SD is displayed between ( ). Verum first means the first treatment period was with a verum patch.

BMI indicates body mass index.

TABLE 3. Additional Medication

	Paracetamol	Nonsteroid Anti-inflammatory Drug	Opioids	Gabapentin
Baseline 1	879 (1189)	390 (645)	179 (180)	270 (854)
Verum	566 (1136)	540 (884)	175 (179)	270 (854
Verum-baseline 1	− 313	+ 150	− 5	0
Baseline 2	481 (911)	450 (700)	180 (197)	270 (854)
Placebo	1014 (1523)	420 (703)	171 (198)	270 (854)
Placebo-baseline 2	+ 534	− 30	− 9	0
Baseline 3	696 (1143)	338 (549)	174 (178)	270 (854)
Open period	979 (1597)	226 (470)	165 (162)	270 (854)
Open period-baseline 3	+ 283	− 112	− 9	0
Difference verum/ placebo	− 847 [− 2284; 591] $P = 0.50$	+ 180 [− 191; 551] $P = 0.18$	+ 4 [− 22; 31] $P = 0.79$	0 [0; 0] $P = 1.00$

The average daily dosage is given in milligrams, calculated by multiplying strength by dosage and dividing this sum by 10. The bold numbers represent the change in the measurements during one of the treatment periods. A negative number is, in general, an improvement whereas a positive number is a worsening. SDs are listed between ( ). The 95% confidence intervals are listed between [ ].

DISCUSSION

This is the first randomized trial to evaluate the efficacy of the continuous MCT patch and to find a reduction in mean and worst VAS scores in patients with nonspecific, chronic low-back pain. Our study has several limitations. First, the study population was small. Therefore, our parameters did not reach statistical significance and the results may not be robust. Second, we included patients in a tertiary pain clinic. These will be more complicated patients with larger medical histories including previously failed treatment, and thus harder to treat. Previous to this trial, 8 of 10 patients received unsuccessful invasive treatment. Therefore, treatment could, potentially, be more successful for patients presenting with nonspecific, chronic low-back pain in an earlier phase at a general practitioner's or a secondary pain clinic. The effect size might be larger in the latter patients as compared with our complicated study population. Thirdly, problem concerning the adherence of the patches was solved by providing multiple patches. Although this ensured continuous application, it lessened patient satisfaction and might influence quality of life.

Despite the above-mentioned points, we consider our results to be internally valid given our placebo-controlled, double-blind, randomized, crossover design and the absence of loss to follow-up.

TABLE 2. Primary and Secondary End Points

	VAS Score		EQ-5D		sf -MPQ-DLV				
	Mean	Worst	Question	VAS	NWC	Sum	Sen	Aff	Cog
Baseline 1	6.23 (1.45)	7.36 (0.68)	0.38 (0.34)	5.71 (2.19)	10 (3.16)	18.5 (7.23)	9.4 (4.84)	3.0 (2.26)	6.1 (2.23)
Verum	6.14 (1.42)	6.71 (1.58)	0.26 (0.35)	5.71 (1.82)	9.0 (3.27)	17.3 (7.78)	8.7 (4.76)	3.3 (2.87)	5.3 (2.11)
Verum-baseline 1	− 0.09	− 0.65	− 0.12	− 0.00	− 1.0	− 1.2	− 0.7	+ 0.3	− 0.8
Baseline 2	5.99 (1.37)	6.71 (1.48)	0.35 (0.39)	6.26 (1.97)	9.7 (3.59)	18.9 (8.06)	9.3 (4.83)	3.4 (2.95)	6.2 (1.40)
Placebo	6.33 (1.43)	7.12 (1.28)	0.33 (0.35)	5.42 (2.37)	10.6 (3.69)	20.8 (9.84)	10.7 (4.08)	3.8 (3.77)	6.3 (3.09)
Placebo-baseline 2	+ 0.34	+ 0.41	− 0.02	− 0.84	+ 0.9	+ 1.9	+ 1.4	+ 0.4	+ 0.1
Baseline 3	6.29 (1.30)	6.89 (1.18)	0.34 (0.37)	5.33 (1.73)	10 (3.23)	18.8 (6.53)	9.3 (3.65)	6.3 (2.26)	3.2 (2.53)
Open period	6.32 (1.26)	7.11 (0.79)	0.28 (0.33)	5.05 (1.51)	10.2 (2.94)	20.4 (6.04)	9.70 (4.79)	6.9 (2.33)	3.8 (2.39)
Open period-baseline 3	+ 0.03	+ 0.22	− 0.06	− 0.28	+ 0.2	+ 1.6	+ 0.4	+ 0.6	+ 0.6
Difference verum/ placebo	− 0.43 [− 1.74; 0.89] $P = 0.29$	− 1.07 [− 2.85; 0.71] $P = 0.39$	− 0.09 [− 0.50; 0.31] $P = 0.21$	− 0.85 [− 1.31; 3.00] $P = 0.28$	− 1.9 [− 4.22; 0.42] $P = 0.09$	− 3.1 [− 11.49; 5.29] $P = 0.67$	− 2.1 [− 5.31; 1.11] $P = 0.18$	− 0.1 [− 3.38; 3.18] $P = 0.40$	− 0.9 [− 3.65; 1.85] $P = 0.45$

The second and third column displays the average (of all 10 patients) mean daily pain score and worst daily pain score per period. The bold numbers represent the change in the measurements during one of the treatment periods. A negative number is, in general, an improvement whereas a positive number is a worsening. An exception is the European Quality of life-5D (EQ-5D) Visual Analogue Scale (VAS) score, where a negative number means a worsened situation. The SD is between ( ).The 95% confidence intervals are listed between [ ]. sf-MPQ-DLV is the short form McGill Pain Questionnaire—Dutch Language Version.

Aff indicates focus on affinity of pain; Cog, focus on cognition of pain; NWC, net word count; Sen, focus on sensitivity of pain; Sum, summation.

TABLE 4. Adverse Events

	Verum Period			Placebo Period			Open Period		
Patient	**Pain***	**Skin†**	**Itching**	**Pain***	**Skin†**	**Itching**	**Pain***	**Skin†**	**Itching**
1	0	1	1	0	1	1	0	1	1
2	0	0	0	1	0	0	0	0	0
3	0	0	0	0	0	1	0	0	0
4	0	0	0	0	0	0	1	0	0
5	0	0	0	1	0	0	0	0	0
6	1	0	0	1	0	0	0	0	0

*This category constitutes pain other than low-back pain.
†Skin irritation/reaction to the patch.

A surprising finding was an increase in most end points during placebo treatment, especially as all patients participating in this study had low-back pain of long duration and could be considered stable. This increase cannot be explained by the traditional placebo effect, which would lead to a decrease in end points. An explanation can, however, be offered by a reverse placebo effect.[21,22] People are more hesitant to report positive effects knowing they could be treated with a placebo. This was likely an issue in the treatment phase as well, given our crossover design, so we analyzed our data using paired *t* tests. We found a slight improvement during verum treatment as opposed to placebo, although this was not significant (with the exception of paracetamol use).

This result cannot be extrapolated to conventional TENS, as the mechanism of action is different. Conventional TENS is hypothesized to "close the gate" in the spinal cord, thus suppressing nociceptive pain and stimulating endogenous opioid release.[9–11] MCT is hypothesized to increase adenosine triphosphate synthesis and decrease electrical resistance.[12,13] The findings of these studies and thus the potential working mechanism of MCT are speculative and were shown using a current range of 1 to 30,000 μA in vitro. Although these were interesting findings, no similar studies are available to compare these results. It must, furthermore, be noted that our device delivers a 25-μA microcurrent, compared with up to 30,000 μA in the studies by Cheng et al[12] and Mercola and Kirsch.[13]

As can be seen in Tables 2 and 3, none of our findings are statistically significant, with an α-value of 0.05. Despite this, a positive trend can be seen in almost all primary and secondary end points. Given our hypothesis that a reduction in the mean and worst VAS scores of 20% is clinically relevant and that the 95% CI of the reduction in the worst VAS score includes this, our findings could be clinically relevant. Our sample size was too small to make a definite conclusion about the relevance of our findings. In conclusion, our study finds a positive trend in the use of the MCT patch for the treatment of chronic low-back pain in patients attending a university hospital clinic. Larger sample sizes are required to establish the true effect of MCT in this patient population.

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