Efficacy of multidimensional dynamic deep wave therapy in patients with chronic non-specific low back pain: a randomized, double-blind, stratified, placebo controlled clinical trial

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Introduction

Chronic non-specific low back pain (LBP) which persists for > 12 weeks and is not attributed to a recognisable pathology, affects more than 70% of individuals in developed countries at some time in their lives, and causes more disability than any other medical condition worldwide (1,2). A myriad of therapy strategies including drug treatment, injection therapies (e.g. epidural corticosteroid injections, local injections), back exercises, acupuncture, behavioural therapy, massage, biofeedback, and TENS have been described. Electrical muscle stimulation (EMS) for management of chronic non-specific low back pain has yet not been properly studied.

EMS leads to muscle contraction by activation of myelinated motor neurons before activation of pain fibres and so differs from TENS. Studies demonstrated that EMS improves lumbar spine function significantly in a low back pain population, improves back pain/disability scores and functional capacity, quality of life and muscle strength (3). It has been shown (4) that hot treatment reduces pain by vasodilatation effect and moves reflex arcs that inhibit pain by means of heat receptors. There are few secondary effects when applied regularly. A combination of heat therapy and medium frequency EMS may provide addition benefit for patients with chronic non-specific low back pain.

Our hypothesis was that electric muscle stimulation in combination with heat could provide better pain relief and improvement of subjective and objective data compared to standard treatment without electrotherapy.

Participants

Adult (>18 years) patients with a medical diagnosis of non-specific low back pain for > 6 months with a pain intensity of NRS ≥ 4/10 were enrolled. Patients with planned spinal surgery or previous spinal surgery less than 12 month ago, spinal disorders like e.g. tumors, fractures or disk herniation with nerve compression with neurological disorders and actual or previous treatment with electrical stimulation, including TENS were excluded. In addition, patients with concomitant illnesses (e.g. cardiopulmonary, inflammatory, malignancy, osteoporosis, epilepsy or neurological, psychiatric, rheumatologic disorders) or cardiac demand pacemakers, defibrillators, spinal stimulators or other implanted electronic devices, or with a history of alcohol abuse, substance abuse, or substance dependence were not eligible. Pregnant patients, patients who become pregnant during the study, patients who were not able to read and speak German or patients with pension process were also excluded.

StimaWell

In this clinical trial, a StimaWell 120 MTRS was used. This system administers a dynamic, wavelike stimulation, via 12 sequentially operating channels. Different effects can be achieved depending on the frequency used. In addition, the stimulation mattress with integrated electrodes heats up to 40°C and further integrates heat therapy effects.

Study design

Between March 2015 and January 2017, we conducted a 6 week randomized, double-blind, stratified, placebo controlled clinical trial, comparing two different forms of multidimensional dynamic deep wave therapy with placebo treatment with a follow-up 12 weeks after randomization. The local Ethics committee of Carinthia approved the study protocol and informed consent (protocol number A15/14). The study design included a screening day (baseline evaluation before randomization); a double-blind, placebo-controlled, randomized, stratified treatment phase (18 treatments in 6 weeks; 3 days a week); and a 12-week follow-up. Electrical stimulation was discontinued after the 18th treatment.

After randomization in one of 4 groups, patients get either one of the multidimensional dynamic deep wave therapy programs in combination with heat (40°C) (Group A and B), a sham electrotherapy with reducing electrical current output and reducing heat (Group C, placebo group), or standard treatment without electrotherapy (Group D, control group).

Results

In summary 100 patients, from 217 patient screened, were recruited. Most of the patients (60%) successfully completed the trial.

The most common causes of withdrawal were lack of efficacy (11%), increasing back pain during and after treatment (9%), protocol violations (3%), headache (1%), recognition of placebo treatment (1%), skin irritation (1%), and AEs (1% - increasing pain after improper use of dynamometer). 14% discontinued because they were randomized to the control group.

Discontinuation rates were 5 in Group A (20%), 7 in group B (26.9%), 16 in group C (64%), and 12 in group D (50%). Statistical analysis showed that patients in group C and D discontinue more likely (p = 0.005) than patients in groups A and B.

Demographic data were similar for the 100 patients who were randomized. Patient demographic characteristics were representative of a LBP population.

During and after treatment negligible side effects e.g. skin irritations were present and EMS was shown to be safe.

Primary endpoint

Our primary outcome was a change from baseline at 18 days in low back pain pain-intensity score (NRS). Actual pain-intensity scores showed no statistical difference between the 4 groups before treatment. Mean actual pain intensity score at baseline was 5.7 (SD 0.9). After 18 treatments mean actual average pain-intensity score was 2.6 (SD 2.1); in follow-up, mean actual average pain-intensity score was 3.8 (SD 2.4).

After 18 treatments there was a statistical significant pain reduction in group A (p = 0.000), which was also shown for follow-up (p = 0.001). A significant pain reduction (p = 0.000) after 18 treatments and in follow-up (p = 0.001) was also shown for the treatment group B. Also a placebo effect for group C (p = 0.006) has been shown after 18 treatments, but not in follow-up (p = 0.302). There was no significant change from baseline in the control group D.

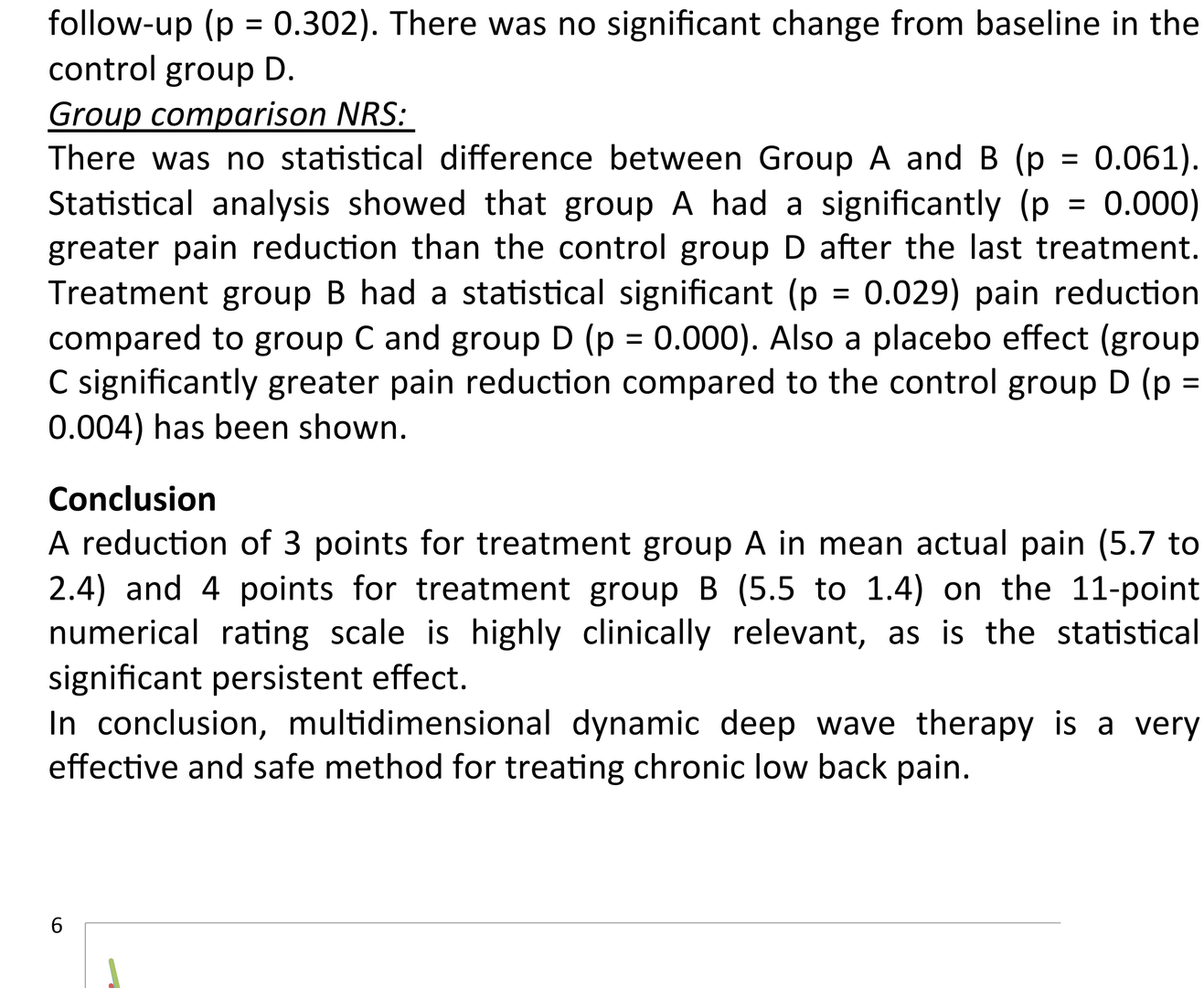
Group comparison NRS:

There was no statistical difference between Group A and B (p = 0.061). Statistical analysis showed that group A had a significantly (p = 0.000) greater pain reduction than the control group D after the last treatment. Treatment group B had a statistical significant (p = 0.029) pain reduction compared to group C and group D (p = 0.000). Also a placebo effect (group C significantly greater pain reduction compared to the control group D (p = 0.004) has been shown.

Conclusion

A reduction of 3 points for treatment group A in mean actual pain (5.7 to 2.4) and 4 points for treatment group B (5.5 to 1.4) on the 11-point numerical rating scale is highly clinically relevant, as is the statistical significant persistent effect.

In conclusion, multidimensional dynamic deep wave therapy is a very effective and safe method for treating chronic low back pain.



References

1. Chou R. Low back pain (chronic). BMJ Clin Evid. 2010; 2010: 1116.
2. Hoy D, March L, Brooks P, Blyth F, Woolf A, Bain C, Williams G, Smith E, Vos T, Barendregt J, Murray C, Burstein R, Buchbinder R. The global burden of low back pain: estimates from the Global Burden of Disease 2010 study. Ann Rheum Dis. 2014 Jun;73(6):968-74.
3. Durmus D, Akyol Y, Alayli G, Tander B, Zahiroglu Y, Canturk F. Effects of electrical stimulation program on trunk muscle strength, functional capacity, quality of life, and depression in the patients with low back pain: a randomized controlled trial. Rheumatol Int. 2009 Jun;29(8):947-54.
4. Demir Y. Non-Pharmacological Therapies in Pain Management. Pain Management - Current Issues and Opinions, Dr. Gabor Racz (Ed.), 2012. InTech, DOI: 10.5772/30050.

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