European Journal of Physical and Rehabilitation Medicine 46 Suppl. 1 (2):42(2010)

Universität Rostock

Traditio et Innovatio

Treatment of patients with fibromyalgia syndrome with vibration massage by deep oscillations

Objective

Patients with fibromyalgia syndrome (FMS) estimate conventional massage to be convenient and effective.
The aim of the present study was to evaluate the safety and tolerability of the treatment with a new developed massage device in patients with FMS. Additionally, the effects on symptom severity, pain, and quality of life were studied.

Methods

In a prospective observational study patients (n = 70, (intention-to-treat, (ITT)) age: 57.3 ± 10.5 years, 97.1 % female) were assigned to receive 10 treatments with a 45 min deep oscillation massage by an electrical device (Fig. 1) within 5 weeks (2 / week).
Outcome parameters were adverse events, the fibromyalgia impact score (German version (FIQ-D)), the subjective pain (VAS), the quality of life (SF-36) and a validated German score for affective and sensitive pain (SES). Main data was collected at baseline (I1), after completion of treatment (I2) and again 2 months after I2 (I3).
Safety was evaluated by adverse event monitoring (open questions) at visit I2. At I2, also the tolerability of deep oscillation massage was rated by a 5-point Likert scale (from 1=very good to 5=very bad).
For statistics standard methods were used (SPSS version 17).
Principle of the therapy: A manual applicator (Fig. 2), controlled by an electronic device (Fig 1), is moved over the skin area to be treated. Due to a pulsating electrostatic field the attractive force between applicator and skin alternates, resulting in changes of static friction. Consequently rhythmic vibrations (f < 200 Hz) are generated locally, if the applicator is moved.

Fig. 1: Hand-held device DEEP OSCILLATION® PERSONAL

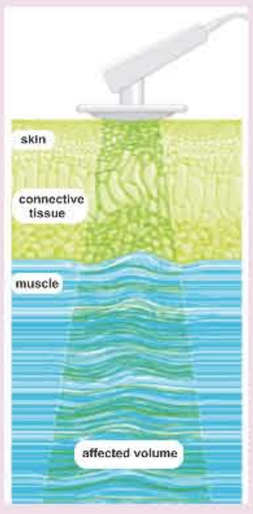

Fig. 2: Applicator and tissue to be treated

Results

Sixty-three patients finished the study per protocol. At I2, patients reported that adverse events related to treatment (r) were mild and short lasting and did not result in drop-outs (Tab. 1). Twenty-nine patients did not report any adverse events. Patients rated the tolerability of the treatment at I2 as 1.8 (95 % CI: 1.53;2.07).

Tab. 1: Adverse events in the ITT population (n=70): (r) related, (u) unrelated to treatment

Adverse events reported at I2	# of events	% of all events
Pain during or immediately after therapy (r)	18	36.0
Fatigue immediately after therapy (r)	13	26.0
Strangury/rectal tenesmus immediately after therapy (r)	6	12.0
Nausea immediately after therapy (r)	5	10.0
Adynamia immediately after therapy (r)	3	6.0
General tension immediately after therapy (r)	2	4.0
Pruritus immediately after therapy (r)	2	4.0
Metastasis of breast cancer (u: withdrawn)	1	2.0
Total	50	100.0

At I2 and I3, the FIQ-D and nearly all measures of pain and quality of life were improved clinically relevant (Fig. 3, Tab. 2).

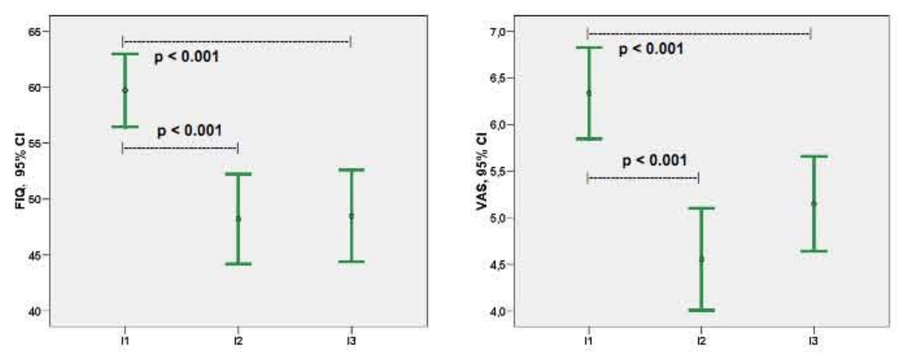

Fig. 3: FIQ-D and VAS at I1, I2 and I3 (mean; 95 % CI), n=70

Tab. 2: Outcome measures at I1, I2 and I3: mean (95% CI), n=70

Outcome measure	I1	I2	I3	P
FIQ-D	59.7 (56.5;63.0)	48.2 (44.2;52.2)	48.5 (44.4;52.6)	< 0.001#
VAS	6.34 (5.85;6.83)	4.55 (4.01;5.10)	5.15 (4.64;5.66)	< 0.001#
SF-36				
- Physical sumscale (ksc)	30.9 (29.1;32.7)	35.0 (33.0;37.0)	34.8 (32.7;37.0)	< 0.001#
- Psychic sumscale (psc)	40.5 (37.5;43.4)	44.1 (41.5;46.7)	41.7 (38.9;44.4)	< 0.02*
SES (T-values)				
- affective score	52.3 (50.0;54.7)	45.5 (43.2;47.7)	47.0 (44.4;49.7)	< 0.001#
- sensitive score	55.8 (53.2;58.4)	51.0 (48.3;53.7)	50.3 (47.8;52.8)	< 0.001#

#: significant difference between I1 and I2 and between I1 and I3, the lower P value is shown;
**: significant difference between I1 and I2 only*

Conclusions

The results of the study suggest that vibration massage by deep oscillation is well tolerated and safe in patients with FMS.
A series of 10 treatments within 5 weeks seems to have a long-lasting effect on symptom severity, pain and quality of life.
A controlled study should follow.

Janik, Hubert; Kanter, Susanne and Karin Kraft
Chair of Complementary Medicine,
Center for Internal Medicine, University of Rostock
Ernst-Heydemann-Str. 6, D-18057 Rostock, Germany
http://www.naturheilkunde.uni-rostock.de

Supported by Fa. PHYSIOMED ELEKTROMEDIZIN AG, Schnaittach/Laipersdorf, Germany