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Case Report

In Painful Shoulder Disease, Inpatient Rehabilitation has Long Term Benefits with or without Therapeutic Nuclear Magnetic Resonance: A Randomized Controlled Clinical Trial

Abstract

Introduction: The aim of the presented study was to investigate the effect of an inpatient rehabilitation stay with application of therapeutical nuclear magnetic resonance therapy (NMRT) in 150 patients with painful shoulder diseases in a controlled trial.

Methods: In a double blinded placebo-controlled multicenter study during a three-week inpatient rehabilitation pain, sleep quality, shoulder function, respectively biomarkers for stress and pain by treatment series with therapeutical nuclear magnetic resonance (NMRT) applied as an additive treatment with a series of NMR on nine consecutive days (9 x 1h) was investigated.

Results: Virtually all (except sleep quality) investigated parameters, mainly pain (VAS) and function (Quick Dash) improved significantly during and after the rehabilitation programme in both study groups. We found no additional effect between the group that received rehabilitation without NMRT and the group with rehabilitation programme plus active NMRT at any time of the six month follow up.

Conclusion: In fact, a good outcome of the rehabilitation programme became obvious whereas, the NMR therapy did not result in a verifiable, additive effect. Therefore, one might consider that a possible positive effect by the NMRT on painful shoulder affections is masked by the obviously effective rehabilitation programme to treat the very complex shoulder joint.

Abbreviations

ACTH: Adrenocorticotropic Hormone / Corticotropin, CRP: C-Reactive Protein, DASH: Disability Of The Arm, Shoulder And Hand, ELISA: Enzyme Linked Immunoassay: MRI: Magnetic Resonance Imaging, NMRT: Nuclear Magnetic Resonance Therapy, NSAID: Oral Non-Steroidal Anti-Inflammatory Drug, OA: Osteoarthritis, POMC: Proopiomelanocortin, PSQI: Pittsburgh Sleep Quality Index, VAS: Visual Analogue Scale, WBC: White Blood Cells, 3M: 3 Months, 6M: 6 Months

Introduction

Chronic pain caused by musculoskeletal diseases can ultimately affect activity and participation. Shoulder pain as a common musculoskeletal affection often arises due to disorders in the complexity of the shoulder and its complex network of structures. Both in general enable great mobility.

Within the general population, 20 % of the patients who deal with complaints of the shoulder refer to shoulder pain accompanied by disability.

Most patients who suffer from shoulder pain recover with non-operative interventions. The goal of non-operative interventions as those used in rehabilitation programmes, in many respects, refer to: (i) pain reduction, (ii) help in recovery and maintain a passive range of motion, (iii) to strengthen the rotator cuff in a non-impingement range of motion, and (iv) to prevent the occurrence of progressive pathological changes.

Therapies for the management of musculoskeletal disorders of the shoulder are amongst others the manual therapy, the ultrasound therapy, low-level laser therapy, acupuncture and the pulsed or static electromagnetic field therapy, applied alone or in combination [1–3]. Kuhn summarized the outcome

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of eleven randomized, controlled trials to demonstrate that exercise (as applied in rehabilitation programmes) in the treatment of rotator cuff impingement has statistically and clinically best effects on pain reduction and improvement of function [4].

Conventional therapy within a rehabilitation centre is composed of exercise, physiotherapy, acupuncture, etc. By contrast, the pharmacological therapy of painful shoulder complaints includes corticosteroids or oral non-steroidal anti-inflammatory drugs (NSAID), topic NSAIDs or capsaicin. These Therapies reduce only the symptoms and usually do not prevent disease-progression accompanied by distinct risks in long-term application. Circumvention of joint surgery as a result of failed conventional therapy is of utmost urgency and therefore, there is an exceptional need of new treatment principles with long-lasting effects. For this reason, the evaluation of the efficiency of the nuclear magnetic resonance therapy (NMR) in painful rheumatic diseases as a new additive treatment appears to be of great interest.

Nuclear magnetic resonance (NMR) as a therapeutic form of treatment applied in rehabilitation medicine represents a therapeutical technology with the potential to activate cellular processes [5–7]. This easy-to-use therapeutic method that revives deregulated cell processes is directly based on the NMR imaging technology (= MRI). The nuclear magnetic resonance for therapeutic purpose is less intensive than the diagnostic MRI with its high fields; it is based on low fields with 1 - 2.3 mT and about 100 kHz.

This kind of therapy is often compared badly – as there are clear physical differences –with diverse magnetic field applications which have as yet not resulted in verified effects. Effectiveness and tolerance of nuclear magnetic resonance fields were proven in therapy of various forms of musculoskeletal diseases mainly osteoarthritis (OA) in numerous in vitro and in vivo studies [7–10].

Within the broad field of therapeutic treatment options, research for more modern and innovative methods turned up with the nuclear magnetic resonance therapy as a new encouraging therapeutically intervention [9]. To our knowledge up to date there are no existing reports about the effect of NMRT on painful affections on the shoulder.

Therefore, our study comprising the treatment of shoulder pain during inpatient rehabilitative elaborates the following question:

Does NMRT enhance the patient's outcome of inpatient shoulder rehabilitation on pain? As a secondary objective: Can we describe the outcome of pain and functionality in shoulder affection by measurement of a biochemical parameter for stress and pain? The present study was designed to provide evidence of new treatment modalities like NMRT which requires to be proven in a controlled trial setting.

Methods

In a multicentre, double-blinded study 150 patients (82 male, 68 female, mean age: 56.5 ± 9.4 years) in four Austrian rehabilitation centres were recruited. The participating centres were: 1) state of Upper Austria: Special Hospital/Rehabilitation Centre of the PVA Bad Ischl, 2) State of Styria: Special Hospital/Rehabilitation Centre of the PVA a) Bad Aussee and b) Gröbming and 3) State of Salzburg: Special Hospital/Rehabilitation Centre of the PVA Saalfelden. All included patients suffered from painful shoulder problems. The inclusion criteria were painful affection of rotator cuff without rupture (tendinitis, impingement-syndrome), painful partial rupture, painful osteoarthritis of the shoulder, painful bursitis, and sonography of the shoulder, VAS ≥ 4, age between 30 and 75 years and sufficient knowledge of German language. Figure 1 shows the frequency spreading of the included disease specific diagnoses. 128 of them were evaluable per protocol. At the beginning of the study all three approvals of the ethical review committees of the different states were on hand.

The exclusion criteria were: fracture of the scapula and/or upper arm, systematic inflammatory rheumatic diseases, fracture of the clavicle and other periarticular fractures, fresh (non-operated) total rupture of the rotator cuff, rupture of biceps, frozen shoulder, cervical discopathy with radicular symptomatic, patients with acute infections, tumour, HIV, liver diseases, alcohol- or drug addiction, pregnancy and lactation period as well as implanted pacemaker, defibrillators, pain- or insulin pumps.

All included patients received a standardized rehabilitation programme during their three weeks lasting stay in one of the four participating rehabilitation centre. The rehabilitation programme contained individual physiotherapy with stretching, mobilisation, manual therapy, therapeutical training regarding coordination and force, medical gymnastic, underwater gymnastic, electrotherapy, sonography, massages and compresses. In addition to this standardized rehabilitation programme one group of the patients received a NMRT treatment for 1 hour per day on 9 consecutive days (NMRT: MBST – OpenSystem 700; Wetzlar, Germany). The assignment to the groups was made double-blind randomized (block-randomisation). The NMRT device was used with blinded programmed chip cards; therapeutic active cards for NMR treatment and non- activated cards for the placebo group

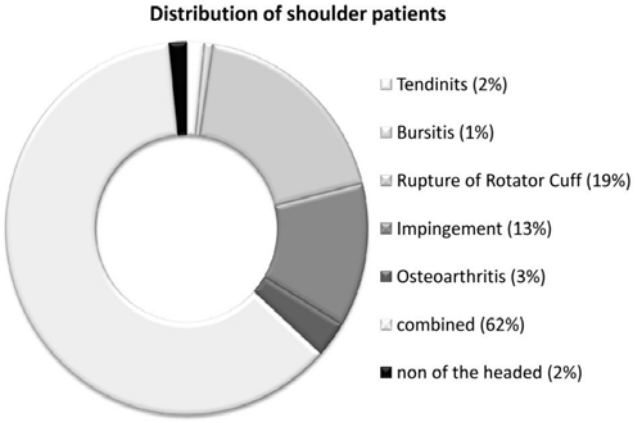

Figure 1: Distribution of shoulder patients. Percentual distribution of various shoulder disorders of the included study patients.

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(group 1: inactive NMRT, group 2: active NMRT). 67 patients were in the verum group (rehabilitation plus NMRT = group 2) and 61 patients to in the standardized shoulder rehabilitation solely (= group 1), where the NMRT device was not active.

Within the rehabilitation stay, blood samples were taken at admission (= baseline) and discharge from the rehabilitation centre (after 3 weeks). Beside typical laboratory routine parameters (blood sedimentation rate, CRP, WBC, platelets) special parameters like ACTH (adrenocorticotropic hormone/ Corticotropin) and ß-Endorphin were examined. For the investigations, enzyme linked immunoassays (ELISA) from Cusabio Biotech (Great Britain) were used.

The study measurement points were day 0, 21 days, 3 months (3M), 6 months (6M). So after in-patient rehabilitation stay on the follow-ups 3M and 6M questionnaires were sent to the patients. The clinical parameters included the visual analogue scale (VAS) for pain intensity rating (0-10), in more detail pain at rest and pain on motion.

To ascertain the sleep quality, PSQI (Pittsburgh Sleep Quality Index) was used [11]. The index which consists of seven items was performed at admission, discharge and three and six months after discharge. The total score of the PSQI lasts from 0 points (good sleep quality) to 21 points (insomnia).

Quick-DASH (Disability of the Arm, Shoulder and Hand) was used to determine the function laesa of the shoulder. Like PSQI Quick-DASH was performed from baseline to follow up 6M.

Constant Score was performed at baseline and 3 weeks later. The Constant Score was not ascertained after the rehabilitation stay because this score has to be conducted under guidance of professional physical therapists.

Statistical analyses were done by Microsoft Excel 2007 and SigmaPlot 12.3 (Systat Software Inc., USA). For analyses of significance paired t-test or Wilcoxon Signed Rank Test was used.

Results

The results indicate that there is no difference in efficacy between rehabilitation group (group 1) and rehabilitation+NMRT (group 2).

Measurements of pain intensity (pain on motion and pain at rest) (Figure 2)

In both groups mean intensity of pain at rest which was moderate at admission (VAS 4.0 and 3.6) decreased. Pain intensity at admission was nearly the same in both groups. The biggest difference in the *rehabilitation-only* group 1 was between admission and discharge ($p < 0.001$). After three months the VAS value stayed ongoing at 2.1 ± 2.3 (mean ± SD). In the rehabilitation+NMRT group (group 2) the mean pain intensity decreased continuously from 3.5 to 1.4. There was a significant difference between admission and all other points of measurement ($p < 0.001$). Between the two study groups we found no significant difference.

The values of the VAS of pain on motion indicate similar results. The mean baseline levels of both groups were highest on baseline with VAS 6.1 ± 2.0 in group 1 and 6.0 ± 1.9 in group 2 (mean ± SD). Concerning the pain on motion again no detectable difference between the two groups could be determined.

Analysis of the serum samples for different biomarkers

ACTH and ß-Endorphin are POMC (Proopiomelanocortin)-derived peptides and were also be found in distinct cells of the synovial tissue and bone [12]. The both biomarkers were selected to measure differences of stress and pain in the study groups. ACTH served as biomarker for stress and ß-Endorphin for pain [13,14]. But there was no significant difference between the two study groups concerning the laboratory parameters ACTH and ß-Endorphin (Figure 3).

PSQI

There was no significant difference in sleep quality between the two treatment groups. The total score improved during the rehabilitation stay. After rehabilitation the sleep quality decreased but was still enhanced compared to baseline six months after rehabilitation. In group 2 a significant difference could be observed between admission and discharge. A significant distinction could be also detected in group 1 between admission and six months after rehabilitation.

Constant-Murley Score

Constant-Murley Score improved in both groups from

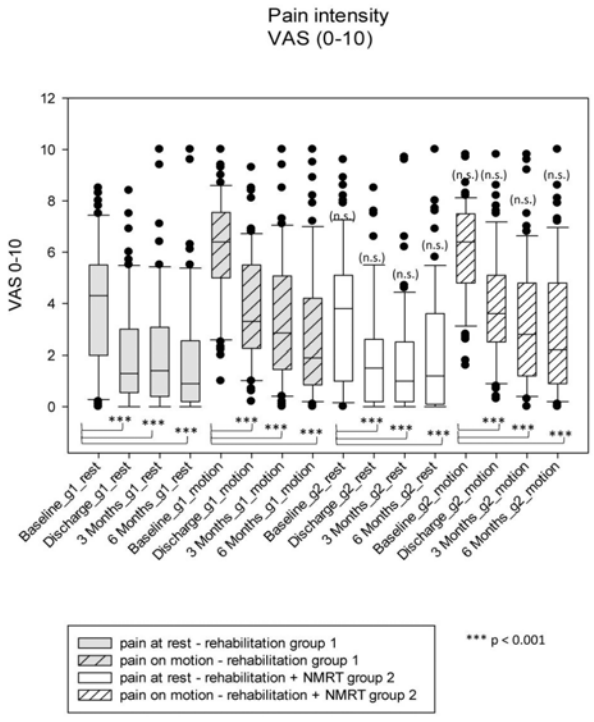

Figure 2: Pain intensity (VAS, visual analogue scale) of patients in group 1 (rehabilitation) and group 2 (rehabilitation+NMRT): Pain at rest and Pain on motion at baseline, discharge, 3 months and 6 months after rehabilitation. Significances within each group (beyond the boxes) and between the groups (above the boxes of group 2) are marked.

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44 points to 58 in group 1 and from 44 points to 59 in group 2. Again no difference could be seen between the groups. The observed change from admission to discharge from the rehabilitation centre was significant in both groups ($p < 0.001$).

Quick-DASH

In both groups, the Quick-DASH values changed significantly within the groups. There was a highly detectable improvement in shoulder disability from baseline to rehabilitation discharge. Three and six months after the inpatient rehabilitation stay the Quick-DASH shoulder function score was still improved considerately with best results after a half year. Between the two groups was no significant difference (Table 1).

Discussion

In the clinic investigations on painful shoulder disorders we found no significant differences between rehabilitation with and without therapeutic nuclear magnetic resonance therapy.

These results are somehow surprising although the NMRT (with a field strength ca. 1.0 – 2.3 mT, 10.000 times weaker than in the diagnostic MRI) seems to act positively in cell culture experiments, thus stimulating cell metabolism and regenerative processes [6,10,15].

In own studies concerning the influence of NMR on cellular mechanisms, differences in the regulation of transcription and translation in chondrocytes and osteocytes, respectively, could be observed [5,7].

In a clinical study, Froböse et al. demonstrated that patients afflicted with osteoarthritis of the knee, which underwent an NMR therapy, exhibited positive adaptations of the cartilaginous structures [16]. It is presumed that this

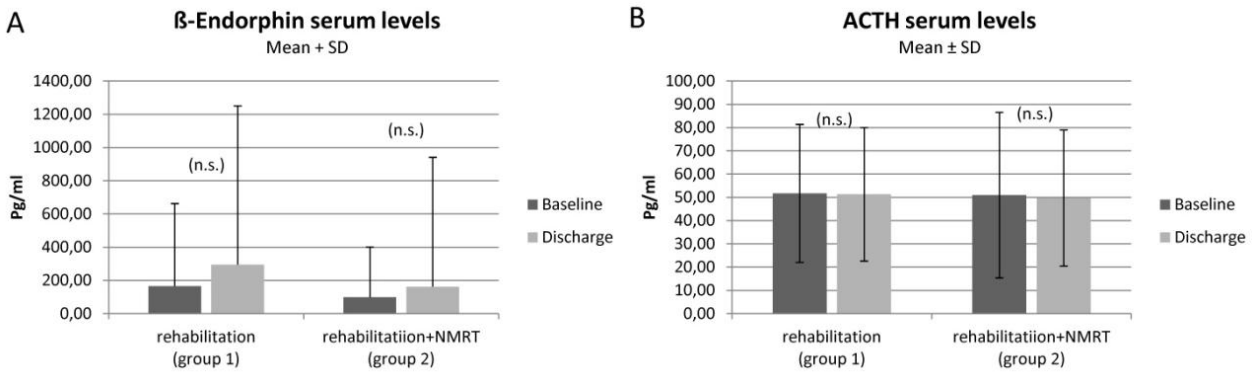

Figure 3: 3A: mean values of ß-Endorphin levels in group 1 and group 2. No significant difference between and within the groups. 3B: mean values of ACTH serum levels in group 1 and group 2. No significant difference between and within the groups.

Table 1: Outcome of sleep quality and shoulder function in the both study groups, p-value masks difference to baseline (Admission) and difference between the groups.

	Rehabilitation + placebo (group 1)								*Rehabilitation + NMRT (group 2)*								p-value between groups
	n	Mean	SD	SEM	Max	Min	Median	p-value	n	Mean	SD	SEM	Max	Min	Median	p-value	
PSQI Admission	59	7.3	3.3	0.4	15.0	2.0	7.0		67	7.6	3.5	0.4	17.0	1.0	8.0		n.s.
PSQI Discharge	61	6.3	3.3	0.4	15.0	1.0	6.0	n.s.	66	6.2	3.2	0.4	14.0	1.0	5.5	p < 0.001	n.s.
PSQI 3 Months	61	6.7	3.3	0.4	15.0	2.0	6.0	n.s.	67	7.0	3.7	0.5	16.0	1.0	7.0	n.s.	n.s.
PSQI 6 Months	60	6.3	2.8	0.4	14.0	1.0	6.0	p < 0.05	65	7.0	3.6	0.5	15.0	1.0	7.0	n.s.	n.s.
Quick-DASH Admission	60	49.7	17.6	2.3	90.9	11.4	50.0		67	46.6	18.4	2.3	84.1	9.1	45.5		n.s.
Quick-DASH Discharge	61	31.5	16.8	2.2	75.0	2.3	31.8	p < 0.001	64	31.4	17.7	2.2	90.9	4.6	29.6	p < 0.001	n.s.
Quick-DASH 3 Months	61	32.4	22.6	2.9	90.9	0.0	27.3	p < 0.001	67	33.7	17.3	2.1	77.3	2.3	34.1	p < 0.001	n.s.
Quick-DASH 6 Months	60	29.9	22.2	2.9	90.9	0.0	30.7	p < 0.001	66	30.8	21.7	2.7	77.3	0.0	25.0	p < 0.001	n.s.
Constant Murley Admission	60	43.5	15.7	2.0	75.0	8.0	44.5		67	43.6	15.6	1.9	76.0	17.0	40.0		n.s.
Constant Murley Discharge	61	58.3	14.4	1.8	86.0	17.0	58.0	p < 0.001	67	59.2	14.9	1.8	98.0	21.0	58.0	p < 0.001	n.s.

Abbreviations: PSQI: Pittsburgh Sleep Quality Index. DASH: Disability of Arm. Shoulder and Hand.

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mechanism results from an activation of intact and/or partly functioning cartilaginous cells as well as from an increase of the synthesis of collagen. The outcome of NMR treatment on patients suffering from low back pain, additionally applied to standard therapeutic methods, implies further success in rehabilitation of spine related complaints [17]. Therapeutically effects of NMRT on osteoarthritis of the hand and finger joints were tested within a double-blind, controlled study [18]. NMR treatment resulted in significant improvement in the physical function of the hand (QUABA score) after 9 days of NMR treatment. Pain relieve persisted for 6 months.

Our results to the contrary indicate that patients with painful shoulder affections did not display particular measurable further benefit of a NMRT for nine days during an in-patient rehabilitation stay. All participating patients showed an improvement of function, disability and sleep quality during 3-weeks rehabilitation.

Peehal et al., investigated the effect of nuclear magnetic resonance therapy for knee joint osteoarthritis. This study was also double blinded with a treatment and non-treatment group. There was a significant difference in range of movement but not in pain, stiffness or in physical function. [19]

We found significant effects of the standardized 3-weeks in-patient rehabilitation programme with the same therapy units in all participating rehabilitation centres. Studies that consider physiotherapy for treating shoulder pain and function showed that active physiotherapy has a significant benefit to the patients in short- and long-term compared to non- or placebo-treatment. Physiotherapy intervention after surgical intervention results in a better outcome compared to physiotherapy alone [20] .

It is conceivable that the excellent effects of the applied rehabilitation programme strongly mask a possible additive effect of the NMRT. Therefore, our results point out that putative NMR-effects are too weak to overpower the implemented rehabilitative-programme consisting of a vast divergence of therapeutic application. From the results of this study we deduce retrying the investigations of NMRT effects in an ambulant setting of patients with painful shoulder diseases without the influence of inpatient rehabilitation. A current study of Tönük et al., investigated the effect of physical therapeutic agents on serum levels of stress hormones in patients with knee osteoarthritis [21]. There was no obvious effect on the hormone levels as well.

The shoulder joint as a very complex joint can be affected by different disorders. There are existing guidelines how to treat shoulder pain [22]. It can be assumed that the standard rehabilitation programme which consists of various therapies and aspects has a positive impact on shoulder disorders regarding biomarkers, pain, sleep quality and functionality which again influences life quality in a positive way.

Acknowledgment

We would like to thank Angela Schwaiger for her excellent help in the admission with sending out, timing and checking the follow ups

Conflict of interest

WK negotiated a grant for the Boltzmann department and the costless lending of the NMR-devices from MedTec Company Germany.

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