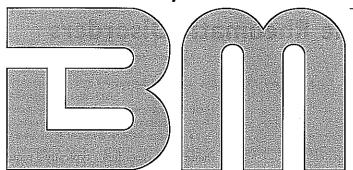


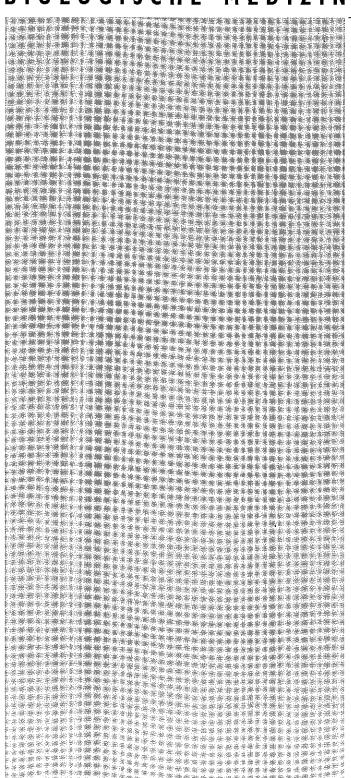
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Homeopathic Treatment of Soft Tissue Rheumatic Disorders

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Abstract:

This drug monitoring documents therapeutic efficacy and tolerance of Rheuma-Heel in the treatment of soft tissue rheumatic disorders. Treatment data were recorded on a total of 53 patients. The most frequent diagnoses were periarticular disorders and disorders of the bursae, tendons, or tendon sheaths. 43 of the patients rated the success of the therapy as either very good or good. Tolerance was rated very good in the majority of cases (n = 46) by both patients and physicians. No side effects were reported.

Keywords: antihomotoxic therapy, homeopathy, soft tissue rheumatic disorders, periarthritis, Rheuma-Heel.

Homeopathic Treatment of Soft Tissue Rheumatic Disorders

Introduction

Rheumatic diseases are endemic. Each year, several million people in Germany alone are treated for rheumatic disorders involving fibrous tissues (muscles, tendons, tendon sheaths, ligaments, connective tissues, bursae). Clearly, these illnesses constitute a major factor in public health costs (1). Soft tissue or nonarticular rheumatic disease encompasses a diverse group of fibrous-tissue pathologies, including tendinitis, carpal tunnel syndrome, and bursitis, to list a few examples (2). Characteristic clinical signs include hardening of the muscles and pain as a result of pressure, stretching, or movement. Frequent causes include overexertion, ergonomic injuries, and faulty pos-Extreme physical stress hyperextensions and strains (due to exercise, for example) can also trigger soft tissue rheumatic symptoms (3).

Although a number of nonsteroidal antiinflammatories (NSAIDs) are available to rheumatic patients, gastrointestinal side effects can be expected with long-term use (4). The biological school of therapy offers a number of alternative therapeutic possibilities (5, 6). Most rheumatic disorders respond well to natural therapies such as homeopathic remedies, whose low rate of side effects make them well suited for long-term use, either alone or as adjuvants to allopathic drugs — an especially important consideration since soft tissue rheumatic disorders typically require extended periods of treatment. Homeopathic combination remedies not only relieve the main symptoms of rheumatic disease (pain and inflammation) but also produce lasting results by stimulating endogenous forces of regeneration (7).

The goal of this study was to verify that the homeopathic combination remedy Rheuma-Heel (manufactured by Biologische Heilmittel Heel GmbH, Baden-Baden, Germany) is both effective and well tolerated when used to treat soft tissue rheumatic disorders. According to the drug pictures of its five ingredients, Rheuma-Heel is indicated for periarthritic and soft tissue rheumatic symptoms (Table 1).

Methods

This drug monitoring recorded treatment data on a total of 53 patients. The maximum observation period per patient was two months. Standardized questionnaires were used for recording data on the patients medical histories and treatment. Criteria for including and excluding patients were defined and applied (see Table 2). Patient examinations were mandatory on intake and on conclusion of therapy; the monitoring plan called for at least one interim examination. Parallel use of concomitant drug therapy for rheumatic symptoms was not permitted; that is, for the duration of the study all

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Tab.1: Ingredients of Rheuma-Heel and their drug pictures

Parameters (questionnaire) • demographic data on patients • Vital parameters 🍃 🛊 risk factors • diagnosis (severity, type, duration) • pathognomonic symptoms (type, severity) • prior treatment (type) · laboratory findings (rheumatoid factor, uric acid, ESR, CRP, immune status) dosage of Rheuma-Heel non-drug concomitant therapy (type, duration) • concomitant-diseases (type, treatment) duration of treatment with Rheuma-Heel therapeutic efficacy (general well-being, severity of pathognomonic symptoms, onset of improvement, overall rating by physician/patient) tolerance (side effects, termination of therapy, overall rating by physician/patient) criteria for inclusion diagnostic confirmation of soft tissue rheumatic disease criteria for exclusion known or suspected sensitivity to the ingredients of Rheuma-Heel (especially poison oak/ivy/sumac) patients requiring additional medication to treat their soft tissue rheumatic symptoms • positive rheumatoid factor (as indicated by later rheumatoid factor test or Rose-Waaler test) clinically relevant changes in CRP, ESR, or uric acid

Tab.2: Observation parameters and criteria for inclusion/exclusion

patients were treated only with Rheuma-Heel. The dosage of Rheuma-Heel, the duration of therapy, and the option of implementing non-drug adjuvant therapies were left up to the participating physicians. All data relevant to treatment had to be reported. The success of the therapy was assessed according to the following parameters:

- General condition, rated by the patients themselves on a scale of 1 to 4: good = 4, satisfactory = 3, unsatisfactory = 2, poor = 1.
- Ratings of three pathognomonic symptoms for each patient by the physician, on a scale of 0 to 4: symp-

tom-free = 0, mild = 1, moderate = 2, severe = 3, very severe = 4.

- Physicians = assessments of the point in time when improvement in symptoms was first observed.
- Overall assessment by physician and patient of the final results of therapy.
 Scale: very good = completely symptom-free, good = obvious improvement, satisfactory = slight improvement, no success = symptoms remained the same and condition worse, worse = worsening of symptoms.

Upon conclusion of therapy, both patients and physicians assessed patient tolerance of Rheuma-Heel on the following scale:

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Tab.3: Type and frequency of reported usage indications of Rheuma-Heel and age distribution within each diagnostic group of Rheuma-Heel (in number of patients)

very good, good, fair, and poor. Any side effects were to be reported on a separate questionnaire.

Explorative procedures involving calculation and display of absolute and relative frequencies were used in the statistical analysis of the data.

Results Patients

Of the 53 patients accepted into the study, 31 were female and 22 male. The emphasis in age distribution fell between 40 and 60 years of age (58% of patients). 29 patients were subject to risk factors such as obesity or smoking. The most frequent diagnoses appearing in the patients case histories were periarticular disorders and disorders of the bursae, tendons, or tendon sheaths (Table 3). The physicians rated the severity of the illness as moderate in approximately 75% of the patients and as severe in 19%. Approximately 53% of the patients suffered from chronic conditions. The most frequently reported pathognomonic symptoms in the diagnostic groups listed above were pain (in response to movement, exertion, or pressure), restricted motion, and swelling. Duration of symptoms prior to admission to the study ranged from a few days to 23 years. Approximately one third of the patients had received prior treatment for soft tissue rheumatic complaints. Previous therapies included both drugs (such as analgesics and antirheumatics) and physical means of treatment (such as massage and ultrasound).

One third of the patients were found to suffer from other conditions (primarily hypertension, heart disease, and diabetes mellitus) and were prescribed individually appropriate medications (antihypertensives, beta blockers, calcium antagonists, ACE inhibitors, antidiabetic drugs) in addition to Rheuma-Heel.

Therapy

The standard dosage of Rheuma-Heel, as recommended by the manufacturer, is one tablet three times a day. This standard dosage was prescribed by the participating physicians in approximately 83% of the cases. (The maximum dosage prescribed was two tablets three times a day). With regard to dosage, there was no notable difference among the diagnostic groups. Nondrug therapies (ultrasound, cryotherapy, iontophoresis) were prescribed in only ten

cases. Duration of treatment with Rheuma-Heel varied from patient to patient, depending on the nature and severity of the illness. Therapy was continued for 4-8 weeks in the majority of cases (74%).

Efficacy/ Effect on the Course of the Illness In the total patient population, the patients'

rating of their general condition improved from an average of 2.08 at the admission examination to 3.55 upon conclusion of therapy (scale: good = 4, satisfactory = 3, unsatisfactory = 2, poor = 1). This increase corresponds to a 71% improvement in general health. During therapy, the average severity of pathognomonic symptoms decreased significantly (Mantel-Haenszel test: p<0.0001) by approximately 80%, from 2.4 to 0.5 (scale: symptom-free = 0, mild = 1, moderate = 2, severe = 3). The ratings are also significant (p < 0.0001) when broken down into the main diagnostic groups (periarticular disorders, disorders of the bursae, tendons, and tendon sheaths) (Figure).

With regard to the third criterion listed above, half of the patients reported symptomatic improvement within two weeks. Given the character and chronicity of the majority of illnesses in question, this result must be considered positive.

Results of Therapy

Assessments of overall outcome of therapy reveal positive results in the great majority of cases regardless of diagnosis, although comparisons of results are difficult due to widely varying numbers of cases in different diagnostic groups. In four cases, therapy with Rheuma-Heel was terminated

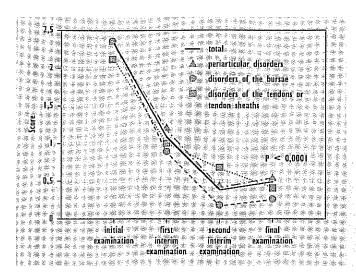


Figure: Change in degree of severity of pathognomonic symptons in the total patient group and in the 3 main diagnostic groups (Scale: symptomfree = 0, mild = 1, moderate = 2, severe = 3; statistics: Mantel-Haenszel test)

prematurely because the treatment failed to relieve symptoms. Overall, however, 79% of the patients (43 out of 53) achieved very good or good results (Table 4).

Tolerance

Both the physicians and the patients rated tolerance of Rheuma-Heel positively (very good: n = 46; good: n = 7). None of the patients reported side effects.

Conclusions

This drug monitoring of 53 patients with various soft tissue rheumatic disorders documents significant reductions in the severity of pathognomonic symptoms and equally significant improvements in the patients' general condition over the course of therapy. The overall success of therapy was rated positively, thus confirming that Rheuma-Heel can be used safely and successfully for all soft tissue rheumatic symptoms. Since no concomitant drug therapy

was permitted, the positive results must be attributed to the use of Rheuma-Heel in the great majority of cases. The treatment periods reported are appropriate to the degree of severity and chronicity of the various soft tissue rheumatic disorders considered in this study. The investigation confirms that Rheuma-Heel is both effective and well tolerated, and no side effects were reported. We can therefore postulate that Rheuma-Heel has a favorable risk-benefit profile when used in the treatment of soft tissue rheumatic disease.

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Tab.4: Overall assessment of results of therapy (rating by physician/patient)