Treatment with an Immune Stimulating Homeopathic Preparation - Results of a Drug-Monitoring Study

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Summary

In a drug-monitoring study of the homeopathic preparation Galium-Heel (drops or injection solution), 661 patients were treated for the indications *activation of the non-specific defense mechanisms in chronic diseases, general activation of the non-specific defense mechanisms,* and *other diagnoses.* The predominant underlying diseases were chronic diseases. In 81% of the patients, the duration of treatment ranged from 2 weeks to 3 months. In approximately 90% of the cases, first signs of a general improvement of the specific symptoms were observed within the first six weeks of therapy, the maximum of 30% being seen in weeks 2 to 4 of treatment. Relative to the total number of the patients, the efficacy of the treatment was assessed by the investigators as *very good, good,* and *moderate* in 31%, 47%, and 17% of patients, respectively. No improvement was observed in 4% of patients. The tolerability assessment of the remedy was positive (*excellent* and *good* in 77% and 22% of patients, respectively).

Introduction

Stimulation of the impaired immune system is a promising therapeutic concept in the causal treatment of chronic diseases. Activation of the nonspecific defense mechanisms leads to general strengthening of the body's resistance and self-healing capabilities. Thus, chronically recurring complaints can be reduced or even cured.[1] Within the general concept of antihomotoxic therapy, immune stimulation plays a significant role and is one of its fundamental sup-

Constituent/Potency	Pharmacological and Clinical Notes
Galium aparine 3X	Precancerous dermatitis, diuretic, edema, favors granulation of ulcers
Galium album 3X	Detoxifying agent
Sedum acre 3X	Precancerous dermatitis, hemorrhoidal disorders, anal fissures
Sempervivum tectorum 4X	Precancerous dermatitis, herpes zoster, hemorrhoids, nephritis
Clematis 4X	Hyperplastic, hard glandular swelling, urethral stricture, prostatitis; vesicular highly irritating eczema
Thuja 3X	Constitutional remedy, especially for diseases with a tendency towards proliferative processes
Caltha palustris 3X	Uterine carcinoma, bronchitis, pemphigus
Ononis spinosa 4X	Nephrosis, nasal hemorrhage
Juniperus communis 4X	Diuretic, glomerulonephritis
Hedera helix 4X	Acute and chronic nasal (sinus) catarrh
Betula alba 2X	Diuretic, choleretic remedy, mucosal catarrh and, in particular, also gastritis
Saponaria 4X	Eczema, diuretic, cholagogue, acute chills
Echinacea angustifolia 5X	To strengthen the defensive mechanism, inflammation of every kind and location, septic processes
Calcium fluoratum 8X	Glandular swellings (of stony hardness)
Phosphorus 8X	Remedy for affections of the parenchyma (lungs, heart, liver, kidneys), decalcification of bone
Aurum metallicum 10X	Remedy for affections of the tissues, arteriosclerosis, depression (tendency towards suicide)
Argentum 8X	Deficiency of memory, vertigo, angiospasms, coxitis
Apis mellifica 12X	Edema, exerts a channelling action on the connective tissues
Acidum nitricum 6X	Dyscrasia, eczema, dermatosis, chronic nephritis
Pyrogenium 6X	Infectious reaction phases, edema
Urtica 3X	Rheumatism, gout, eczema, dermatosis

Table 1: Potency and pharmacological/clinical notes of the single constituents of Galium-Heel.

	Patients' age (years)								
Fields of indications	<21	21-30	31-40	41-50	51-60	61-70	71-80	>80	*
Activation of the non-specific defense mechanisms in chronic diseases, n = 440	10.9	11.4	20.9	16.6	15.0	13.9	8.6	1.8	0.9
General activation of the non-specific defense mechanisms, n = 191	17.8	12.0	19.9	16.2	15.7	10.5	3.7	4.2	0.0
Other diagnoses, n = 46	6.5	19.6	23.9	17.4	21.7	4.4	6.5	0.0	0.0
All patients, n = 661	12.8	12.3	21.0	16.5	15.3	12.1	7.0	2.4	0.6

** no data available*

Table 2: Patients' age. Distribution in the different fields of indications (in percentage) and in the total patient population. Multiple assignment was possible.

ports. On its own or combined with other therapeutic approaches it enables the body to eliminate homotoxins.[2,3]

Galium-Heel drops or injection solution (manufactured by Biologische Heilmittel Heel GmbH, Baden-Baden, Germany) is a homeopathic complex medication with such effects and is therefore suitable for the treatment of chronic diseases with a great variety of different symptoms. The individual ingredients of Galium-Heel are listed in Table 1 along with their homeopathic potencies and pharmacological and clinical notes. By promoting detoxification and secretory reactions, the functions of the connecting tissues are strengthened and the homotoxic terrain is cleansed. Galium-Heel has been successfully used in the treatment of chronic bronchitis,[4] in geriatrics,[5] and other internal, neurological, urological, dermatological, ophthalmological, and ENT diseases for many years. Precancerous dermatitis and therapy-induced illness are further indications for this preparation. In dentistry, it is an essential medication that supports detoxification and elimination functions, both during and after amalgam removal[6] and is also used in the treatment of gingivitis.[7] Galium-Heel is often administered simultaneously with additional homeopathic remedies to ensure comprehensive basic and symptom-oriented therapy.

To obtain further data on the efficacy and tolerability of Galium-Heel treatment, a prospective drug-monitoring study was conducted with a large number of patients in Germany, Belgium, and the Netherlands. The participating physicians were allowed to continue their normal specific treatment procedures without having any study specific restrictions placed upon them. The intention was to obtain data that would reflect the results of therapy under conditions of daily routine treatment.

Methods

It was generally possible to include all patients into the drug monitoring study for whom treatment with Galium-Heel was appropriate. The respective data was ascertained during a screening and a termination visit of the patient, and entered into a specific patient form. Inclusion or exclusion criteria were not specified. No further restrictions were made, as to the duration of the treatment or the number of the patient's visits at the site. The following data was compiled to describe the participating patient population: demographic data, disease/diagnosis, duration and possible pre-treatment of the disease, dosage regimen, formulation and mode of application (in the case of injection solution), possible additional medications or other therapies, and duration of the therapy.

The disease or symptoms to be treated could be selected from the following fields of indications:

- activation of the non-specific defense mechanisms in chronic diseases (to be specified)
- general activation of the non-specific defense mechanisms
- other diagnoses (to be specified)

Assessment variables for therapeutic efficacy were:

- moment of first improvement of the symptoms
- assessment of the efficacy of the treatment by the investigator (according to the following scale: very good = no more complaints, good = significant improvement, moderate = slight improvement, without success = no change and deterioration).

Assessment variables for therapeutic tolerability were:

- determination of possible side effects
- assessment of the tolerability by the

investigator (according to the following scale: excellent, good, moderate, poor).

The statistical analysis of the data was performed exploratively by calculating absolute and relative frequencies.

Results

Patients

In total, 661 patients were treated in this drug-monitoring study (Germany: 627, Belgium: 24, the Netherlands: 10, by 75 physicians during a 5 month period. The physicians were general practitioners (72), complementary medical practitioners (7), pediatricians (2), ENT specialist (1). Sixty percent of the patients were female. The distribution of the patients by the different fields of indications were:

- activation of the non-specific defense mechanisms in chronic diseases, n= 440
- general activation of the non-specific defense mechanisms, n = 191
- other diagnoses, n = 46

The sum of the patients in the different indication fields was higher than the total number of patients, as multiple assignment was possible.

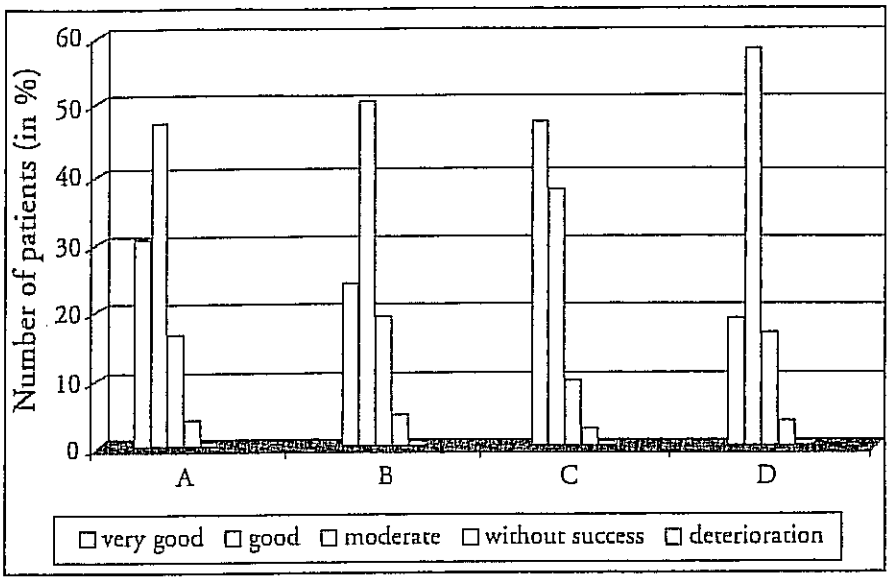

Fig. 1: Investigator's global assessment of the efficacy in the total patient population and in the different fields of indication. Treatment with Galium-Heel plus additional concomitant medication. A = total patient population (n = 661), B = activation of the non-specific defense mechanisms in chronic diseases (n = 440), C = general activation of the non-specific defense mechanisms (n = 191), D = Other diagnoses (n = 46) (Multiple assignment was possible).

Concerning *activation of the non-specific defense mechanisms in chronic diseases*, the following diseases were specified most frequently:

- diseases of the respiratory tract (bronchitis = 68, sinusitis = 40, bronchial asthma = 20)
- dermatological diseases (neurodermatitis = 12, eczema = 10, acne vulgaris = 7, verrucae = 6)
- chronic and recurrent infections (general susceptibility to infections = 12, cystitis = 11, influenza = 11, sore throat = 11, tonsillitis = 8)
- rheumatological diseases (arthritis/arthrosis = 12)
- allergic diseases (allergic rhinitis = 4)
- metabolic diseases (diabetes mellitus = 10)
- gastro-intestinal diseases (Crohn's disease = 7)

Regarding the distribution of patients'

	Duration of treatment							
Fields of indications	<1 week	1-2 weeks	2-4 weeks	4-6 weeks	6-8 weeks	2-3 months	3-4 months	>4 months
Activation of the non-specific defense mechanisms in chronic diseases	0.2	3.9	15.0	21.6	22.0	19.1	9.3	8.9
General activation of the non-specific defense mechanisms	0.0	11.0	24.1	29.8	17.8	15.2	0.0	2.1
Other diagnoses	0.0	2.2	13.1	26.1	39.1	8.7	6.5	4.3
All patients	0.1	5.9	17.7	24.1	21.8	17.2	6.5	6.7

Table 3: Treatment duration. Percentage in the different fields of indications and in the total patient population. Multiple assignment was possible.

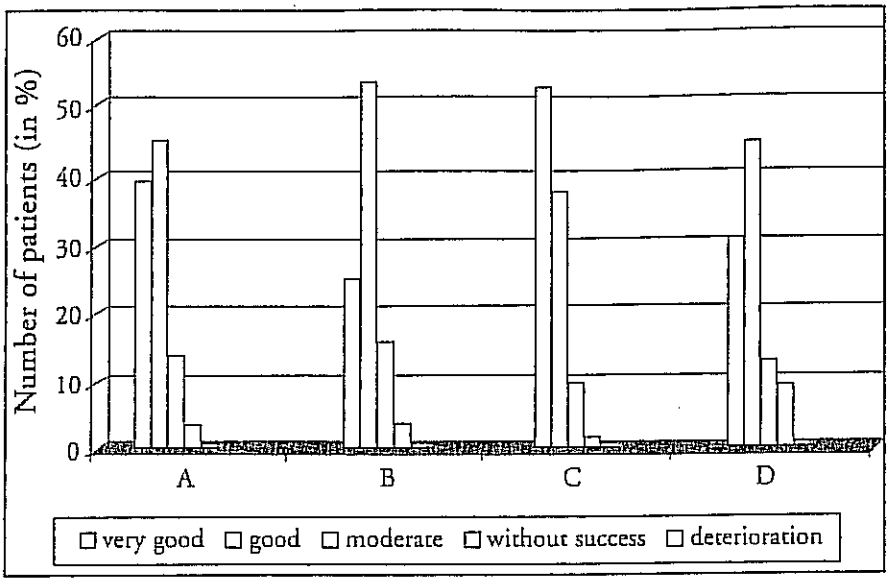

Fig. 2: Investigator's global assessment of the efficacy in the total patient population and in the different fields of indication. Treatment with Galium-Heel and without any additional concomitant medication. A = total patient population (n = 340), B = activation of the non-specific defense mechanisms in chronic diseases (n = 182), C = general activation of the non-specific defense mechanisms (n = 144), D = Other diagnoses (n = 22) (Multiple assignment was possible).

age, the greatest proportion was in the range of 31-40 (21%), followed by 41-50 (17%), and 51-60 (15%) years of age. Nevertheless, the distribution of patients was quite homogenous, as younger and older patient groups significantly contributed to the total number of patients treated (Table 2).

At the start of the drug-monitoring study, the intensity of the disease to be treated was characterized as mild in 10%, as moderate in 58%, and as severe in 19% of the cases (no data available: 13%). The pre-existence of the disease was, in accordance with its character, predominantly in the range of several months up to several years. A clear maximum was detectable for disease duration of longer than 2 years (32% of the total patient population). Duration of at least 4 months was ascertained for 67% of the patients. Corresponding to the therapeutic approach of the homeopathic treatment, the nature of the disease was chronic in most cases (chronic: 55%, acute: 11%, no data available: 34%). The majority of the patients had a pre-treatment before they entered the drug-monitoring study (63%). In almost all cases it was a medical (86%) or combined medical/physical (11%) treatment. An exclusively physical pre-treatment was listed for only 3% of the patients. The medications most frequently prescribed in the case of a medical pre-treatment were antibiotics, analgesic/antirheumatic drugs, antitussives, broncholytics, corticoids, rhinologics, therapeutics for the immune system, and additional homeopathic preparations, including Echinacea compositum®, Traumeel®, Lymphomyosot®, and Psorinoheel®.

Treatment

With regard to the pharmaceutical formulation, the application of Galium-Heel as drops (58%) was higher than the application as an injection solution (23%). 19% of the patients received both drops and ampules.

The preferred mode of application of the injection solution was intramuscular (44%), followed by intramuscular + auto-sanguis therapy (15%), subcutaneous (22%), intravenous (14%), oral (3%), intracutaneous (1%) and other

	Moment of first improvement of the symptoms							
Fields of indications	1-3 days	4-7 days	1-2 weeks	2-4 weeks	4-6 weeks	>6 weeks	No improvement	No data available
Activation of the non-specific defense mechanisms in chronic diseases	3.4	12.0	26.1	29.5	16.1	7.0	5.0	0.9
General activation of the non-specific defense mechanisms	5.8	24.6	28.8	29.3	6.8	2.1	2.6	0.0
Other diagnoses	0.0	17.4	21.7	43.5	10.9	2.2	4.3	0.0
All patients	3.9	15.9	26.5	30.4	12.9	5.4	4.4	0.6

Table 4: Moment of first improvement of the symptoms. Percentage in the different fields of indications and in the total patient population. Multiple assignment was possible.

methods (1%). In some cases more than one mode of parenteral application was used.

The preferred dosage of Galium-Heel drops was 10 drops three times daily (75%). Ten drops twice daily were prescribed for 16% of the patients and 9% received different dosages. Galium-Heel ampules were injected at the acute rate of once daily in 22% of the cases and in 78% at the standard dosage of once weekly. Thirty-nine percent received 2 ampules a week and 20% received 3 ampules a week. In some cases, different dosages were used.

The patients who were treated for *activation of the non-specific defense mechanisms in chronic diseases* and *other diagnoses (to be specified)*, predominantly obtained further medication in addition to Galium-Heel (monotherapy: 67% and 72%, respectively.) In contrast to that, most patients included for *general activation of the non-specific defense mechanisms* were treated only with Galium-Heel (66%). Additional medications were prescribed for 56% of the patients, 28% received additional medication together with physical therapy, and 16% received physical therapy exclusively. The most frequent additionally prescribed medications were further homeopathic preparations such as Engystol®, Lymphomyosot®, Traumeel® S, Echinacea compositum®, Psorinoheel®, as well as conventional drugs such as antitussives, analgesic/anti-rheumatic/anti-inflammatory drugs, broncholytics, and therapeutics for the immune system.

The duration of treatment mainly ranged from 2 weeks to 3 months (81% of the patients) with a maximum having 4 - 6 weeks treatment (24%) (Table 3). In most cases, a change in the dosage regimen during the treatment was not necessary (90%). When the dosage was changed, it was a dose reduction in 92%.

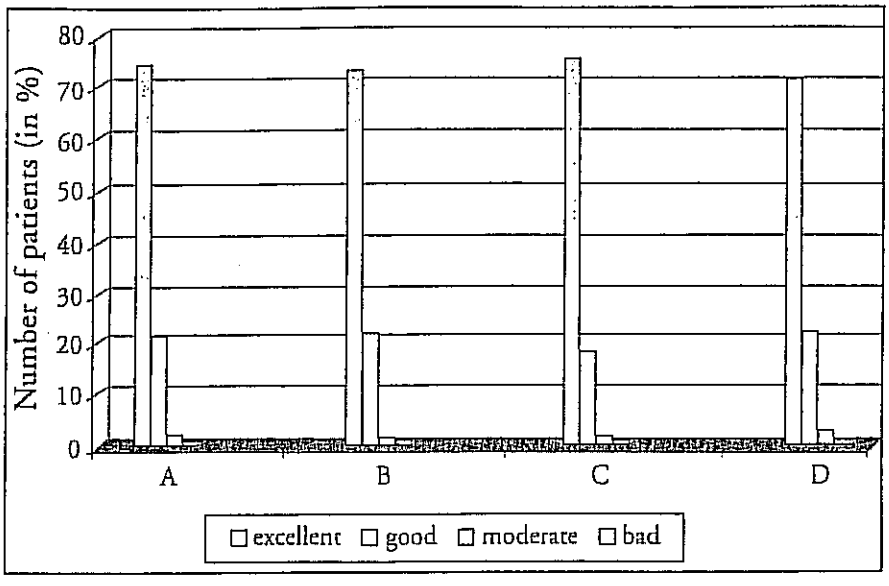

Fig. 3: Investigator's global assessment of the tolerability of Galium-Heel in the total patient population and in the different fields of indication. A = total patient population (n = 661), B = activation of the non-specific defense mechanisms in chronic diseases (n = 440), C = general activation of the non-specific defense mechanisms (n = 191), D = Other diagnoses (n = 46) (Multiple assignment was possible).

Efficacy parameters

The moment of first improvement of the symptoms was assessed as a parameter of efficacy. The analysis of the data revealed that for 90% of the patients a first improvement was noticed after six weeks of therapy; of these the largest proportion showed improvement after 2 - 4 weeks (Table 4).

The second parameter was the global assessment of efficacy on a five-point rating scale by the investigator and by the patient. The investigators assessed a therapy with Galium-Heel plus additional medication as *very good* (31%) or *good* (47%) in 78% of the cases. The result was *moderate* for 17% of the patients and *without success* for 4% (Figure 2). With regard to a monotherapy with Galium-Heel the respective values were as follows: *very good* (38%), *good* (45%), *moderate* (14%), *without success* (3%) (Figure 2). The patients' assessment of the efficacy of the therapy was similar. For the monotherapy the following data were ascertained: *very good* (40%), *good* (41%), *moderate* (8%), *without success* (3%), (no data available: 8%). The corresponding values for a therapy with additional medication were: *very good* (34%), *good* (43%), *moderate* (14%), *without success* (4%), (no data available: 5%).

Tolerability

The tolerability of a therapy with Galium-Heel was ascertained by means of a four-point rating scale. The tolerability was reported as *excellent* or *good* in almost all of the cases (99%). For 507 of the 661 patients the assessment was *excellent* (77%). Further assessments were as follows: *good* (148 patients = 22%), *moderate* (5 patients = 1%).

One case of a side effect was reported. A patient was being treated for conditions after febrile common cold. After an injection of Galium-Heel, itching started the following day and continued the next day with moderate intensity. As this patient was also taking antibiotics, broncholytics, and antitussives it is more likely that the allergic reaction was

caused by one of these medications. In any case, the complaints disappeared without any sequelae.

Discussion

Immune stimulation and discharge of homotoxins from the organism are basic concepts in antihomotoxic therapy.[2] Supporting the defense system of the body by improving deposition and drainage systems, pathological processes can be reversed, detoxification improved, and convalescence initiated.[3] The stimulation and regulation of the body's self-healing capabilities by mobilization of the defense functions is especially important in the treatment of chronic diseases, in order to reverse their continuing progress.

This drug-monitoring study was performed to examine the therapeutic efficacy of Galium-Heel under daily routine conditions in the physicians' practice.

Therefore, each patient selected for a therapy with Galium-Heel, in the physician's opinion, could be treated without any formal restrictions. With 661 patients, a considerable number of cases were evaluated to provide sufficient information on the efficacy and tolerability parameters to be examined. As was to be expected, the majority of the patients suffered from chronic diseases, predominantly of the respiratory tract, such as bronchitis, sinusitis, and asthma. In addition, chronic diseases from other indications significantly contributed to the spectrum of diseases to be treated. According to the character of the chronic diseases diagnosed, a short-term treatment was not to be expected. But considering the fact that 90% of the patients experienced initial improvement of their disease within six weeks of therapy, the positive effects of the homeopathic treatment become obvious. Obviously, a long-term therapy might be necessary in some cases, depending on the patient and the disease to be treated.

The success of the therapy was also reflected by the general efficacy assessments of the investigators and patients. Both assessed the efficacy of the treatment as *very good* or *good* in approximately 80% of the cases. Considering the chronic character of many of the underlying diseases, these results indicate the effectiveness of a therapy with Galium-Heel.

In total, it can be stated that Galium-Heel is an essential and safe preparation in a patient's homeopathic regulation therapy. Especially for patients with chronically recurring complaints, Galium-Heel is highly effective at helping detoxify the organism.

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