Oral Treatment of Traumatic, Inflammatory, and Degenerative Conditions with a Homeopathic Remedy

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Summary

A total of 138 practicing physicians took part in this prospective study documenting the usage indications, therapeutic efficacy, and tolerance of *Traumeel®S* tablets and drops. Of the 1359 patients involved in the study, one third were treated with the drops and two thirds with the tablet form of *Traumeel®S*.

The clinical pictures most frequently documented included various injuries such as bruises, sprains, and hematomas as well as degenerative and inflammatory conditions such as arthrosis, frozen shoulder, and carpal tunnel syndrome. One third of the patients were treated without any additional drug or non-drug therapy. In 83% of the cases, therapeutic results were rated as very good or good. No cases of adverse drug reactions were reported.

Introduction

Traumeel®S (manufactured by Biologische Heilmittel Heel GmbH of Baden-Baden, Germany) is a homeopathic combination remedy available as tablets, drops, injectable solution, and ointment. The medicinally active ingredients of *Traumeel®S* are prepared in accordance with the German homeopathic pharmacopeia (HAB) and are present in the final product in low to middle potencies. Along with various plant-derived ingredients such as Arnica montana, Calendula officinalis, and Hamamelis virginiana, the remedy also contains individual mineral remedies such as Hepar sulphuris. Usage indications of *Traumeel®S* range from acute post-traumatic conditions to inflammatory and rheumatic processes to degenerative joint disorders (arthroses). Table 1 illustrates the composition of *Traumeel®S*.

Several systematic studies on large groups of patients confirm the reliable therapeutic effect of *Traumeel®S* within the range of usage indications delineated above. In 1992 a multicentric prospective study was conducted on 3422 patients using the ointment [1]. In the context of this study, the emphasis was on the use of the ointment in treating sprains. The therapeutic efficacy of *Traumeel®S* ointment has also been confirmed in two placebo-controlled clinical studies [2,3]. The results of a multicentric prospective study on the injectable solution form of *Traumeel®S* were also published in 1992 [4]. This study emphasized the treatment of arthrosis. In spite of the fact that degenerative joint disorders are well known for being chronic and resistant to therapy, very good to good results were achieved in 60% of cases. Additional empirical reports and clinical studies also confirm the claimed efficacy of the injectable solution [5, 6].

Traumeel®S is available not only in the ointment and injectable solution forms whose usage indications, efficacy, and tolerance have been well researched, but also as tablets and drops. The purpose of the current study, the first to monitor the use of the tablet and drop forms in a large group of patients, was to complete the documentation for the entire spectrum of *Traumeel®S* products.

Methods

This multicentric prospective study was carried out in three different European countries. Parameters of the study are given in Table 2. Data were reported on standardized questionnaires that the authors of the study had made available to the participating physicians in sufficient quantities. There were no criteria for patient inclusion or exclusion.

The patients were to be admitted to the study at random rather than specially selected by the physician. The choice

Ingredient	Potency	Tablets (amount per tablet)	Drops (amount per 100g)
Arnica montana, radix	2x	15mg	5g
Calendula officinalis	2x	15mg	5g
Hamamelis virginiana	2x	15mg	5g
Millefolium	3x	15mg	5g
Belladonna	4x	75mg	25g
Aconitum napellus	3x	30mg	10g
Mercurius solubilis	8x	30mg	10g
Hepar sulphuris calcareum	8x	30mg	10g
Chamomilla	3x	24mg	8g
Symphytum officinale	8x	24mg	8g
Bellis perennis	2x	6mg	2g
Echinacea angustifolia	2x	6mg	2g
Echinacea purpurea	2x	6mg	2g
Hypericum perforatum	2x	3mg	1g

Tab. 1: Composition of Traumeel®S

• implementation:	August 1994-February 1995
• locations:	Germany, Italy, Portugal
• participating physicians (total):	138
specialties:	121 general practice
	10 orthopedics
	3 otolaryngology
	3 pediatrics
	1 sports medicine
• total number of questionnaires sent out:	2410
• total returned:	1359 (56.4%)
• duration of monitoring, per patient:	2 months maximum
• criteria for patient inclusion/exclusion:	none
• documentation:	standardized questionnaire
• number of patients per physician:	maximum 10

Tab.2: Parameters of the prospective study

of *Traumeel®S* tablets or drops, dosage, length of treatment, and whether or not to use concomitant therapies was left up to the individual physician. However, all data relevant to treatment had to be documented on the questionnaire. Desired results of therapy were evaluated on the following scale: very good = complete freedom from symptoms; good = noticeable improvement; satisfactory = slight improvement; no success = symptoms remained the same or worsened. Any adverse reactions were to be reported on a separate questionnaire. Treatment data were gathered on a total of 1359 patients. All of the questionnaires returned to the authors were suitable for statistical evaluation. The results of the questionnaires were tabulated with the help of a computer program (Report, Fa. IDV/Gauting) and then evaluated descriptively.

Results

Patients

The age and gender distribution of the 1359 patients included in the study makes it clear that more females than males were represented and that the distribution of ages was very broad (<21 to >80 years of age). The age group of 21-40 years was most strongly represented, with only slightly fewer patients falling into the 41-60 year old category (Figure 1). Given the range of usage indications of *Traumeel®S*, this age distribution can be considered typical, since most of the symptoms for which *Traumeel®S* is indicated occur more frequently among amateur and recreational athletes.

The preparation under observation, *Traumeel®S* (drops and tablets), is administered primarily in cases of traumatic, inflammatory or rheumatic, and degenerative disorders. It is most frequently used for injuries of various sorts (bruises, sprains, hematomas, and post-traumatic edema) and for conditions of arthrosis (primary gonarthrosis, polyarthrosis, and coxarthrosis). At least 100 cases of treatment for diagnosed carpal tunnel syndrome, frozen shoulder, and epicondylitis were documented. Mentioned under the category "Other Ailments" were, among others, a great variety of inflammatory diseases (e.g., arthritis, periodontal disease, pharyngitis, sinusitis, and tonsillitis) as well as disorders of the cervical and lumbar spine. (See Table 3.) On evaluating the diagnoses listed, it was evident that in most cases *Traumeel®S* had been used in areas of claimed efficacy.

Because of the broad range of usage indications of *Traumeel®S*, reported durations of illness often differed considerably. In addition to many acute illnesses, many cases of chronic illness were documented. For example, the duration of symptoms among patients diagnosed with bruises, sprains, hematomas, and concussion was less than one week in 80-90% of cases, while duration of the illness was documented as more than 6 months in 60% of the cases with a diagnosis of arthrosis. In general, it can be stated that approximately 1 patient out of 2 had been experiencing symptoms for less than a week, 1 out of 4 for 1-4 weeks, and 1 out of 10 for 1-12 months or longer.

In line with documentation that showed the majority of cases as having had symptoms for a relatively short time, the proportion of patients who had received treatment prior to being accepted into the study was relatively small—

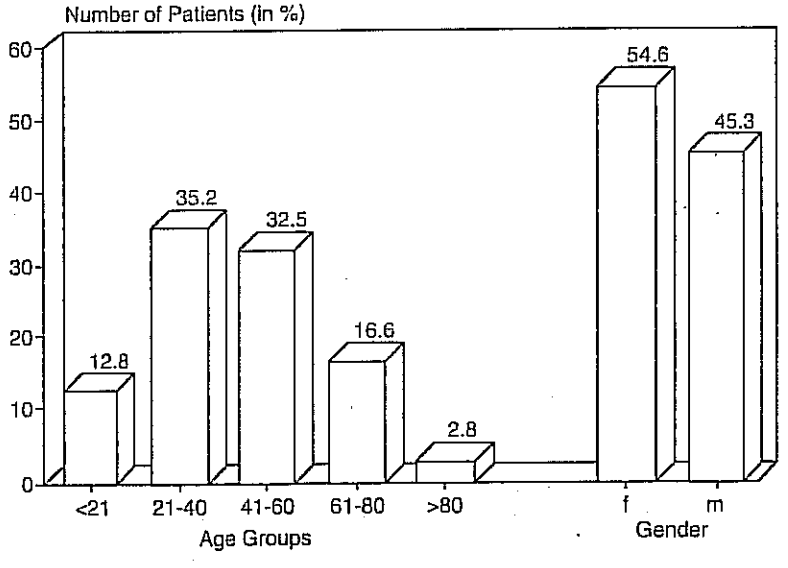

Fig. 1: Distribution of Age and Gender within the Patient Collective (n = 35g)

approximately 27%. In most instances prior treatment had consisted of medication, with analgesics, anti-inflammatories, and corticosteroids being prescribed most frequently. Non-drug therapies had been previously used in only a few cases, but included electrotherapy, physical therapy, bandaging, application of ice, and massage.

Dosage

The participating physicians had been given the choice of prescribing *Traumeel®S* in the form of drops or tablets, so it is noteworthy that 69% of the patients ended up taking the drops while only 29% used the tablets. The other 2% were treated with both forms of the medication. The reason for prescribing both of the oral forms for these patients may have lain in anticipated compliance difficulties, since there is no therapeutic difference between the two forms.

According to the manufacturer's recommendations, the drops should be administered in doses of 10 drops 3 times daily (or, in the case of soft-tissue edema, 30 drops 3 times daily). For 94% of the patients treated with the drops, the dosages prescribed fell between a minimum dosage of 5 drops 5 times daily and a maximum of 30 drops 6 times daily. For the tablets, the manufacturer recommends a standard dosage of 1 tablet 3 times a day. This recommendation was followed in 74% of cases treated with the tablets; other frequently prescribed dosages were 1-2 tablets 6 times a day, 2 tablets 3 times a day, and 1 tablet 2 times a day. (The minimum dosage was 1 tablet per day, while the maximum was 1 tablet 8 times a day.) Assessment of the dosages reported revealed that in approximately 95% of cases the initially prescribed dosage was maintained throughout treatment, while in the other 5% a reduction in the daily dosage took place. There were no cases in which the daily dosage was increased.

Concomitant therapies

Additional drug or non-drug therapies were prescribed for approximately two

Diagnoses	Number of patients	Percentage of total
Injuries		
Bruises	239	17.6
Sprains	170	12.5
Hematomas	164	12.1
Post-traumatic edema	113	8.3
Post-operative edema	88	6.5
Joint effusion	76	5.6
Dislocations	73	5.4
Concussion	25	1.8
Inflammatory and/or degenerative diseases		
Arthrosis	170	12.5
Carpal tunnel syndrome	130	9.6
Frozen shoulder	124	9.1
Epicondylitis	101	7.4
Bursitis	46	3.4
Other soft-tissue rheumatic rheumatic illnesses	40	2.9
Styloiditis	10	0.7
Additional indications	235	17.3

Tab.3: Types and frequencies of treated conditions

Treatment Groups	Results of Therapy				
	very good	good	satis-factory	no success	worse
Total group of patients (n=1359)	38.7	44.3	12.9	3.9	0.2
Patients receiving concomitant drug or non-drug therapy (n=904)	33.7	47.5	14.6	4.1	0.1
Patients not receiving concomitant therapy (n=455)	48.6	37.8	9.5	3.7	0.4
Patients receiving *Traumeel®S* (drops) (n=395)	40.3	45.6	10.6	3.3	0.2
Patients receiving *Traumeel®S* (tablets) (n=942)	38.6	43.7	13.1	4.4	0.2

Tab.4: Therapeutic results for various treatment groups

Usage Indication		Results of Therapy				
		very good	good	satis-factory	no success	worse
Injuries						
Bruises	(n=239)	54.4	40.6	5.0	-	-
Sprains	(n=170)	48.2	48.2	3.0	0.6	-
Hematomas	(n=164)	54.3	40.9	4.2	0.6	-
Post-traumatic edema	(n=113)	46.9	47.8	3.5	1.8	-
Post-operative edema	(n=88)	42.0	48.9	8.0	1.1	-
Joint effusion	(n=76)	39.5	43.4	14.5	2.6	-
Dislocations	(n=73)	41.1	46.6	12.3	-	-
Concussion	(n=25)	84.0	16.0	-	-	-
Inflammatory and/or degenerative diseases						
Arthrosis	(n=170)	5.9	48.2	36.5	9.4	-
Carpal tunnel syndrome	(n=130)	36.2	46.9	14.6	2.3	-
Frozen shoulder	(n=124)	21.0	51.6	20.2	7.2	-
Epicondylitis	(n=101)	24.8	53.5	17.7	4.0	-
Bursitis	(n=46)	26.1	63.0	8.7	2.2	-
Other soft-tissue rheumatic diseases	(n=40)	17.5	40.0	25.0	15.0	2.5
Styloiditis	(n=10)	50.0	40.0	-	-	10.0
Other Symptoms	(n=235)	36.6	46.0	10.6	6.4	0.4

Tab.5: Results of therapy within various usage indications

thirds of the patients. In the majority of cases, the patient's diagnosis was the deciding factor in choosing to implement a concomitant therapy. For example, among patients with concussion the proportion receiving concomitant therapy was only 36%, while among patients with symptoms of arthrosis or frozen shoulder this proportion was approximately 80%. The most frequent supplemental prescriptions were for analgesics, anti-inflammatories, and medications for circulatory disorders. In contrast to earlier treatment, additional homeopathic remedies were used more frequently during the study. Zeel® , in the form of tablets, ointment, and injectable solution, was the most frequent choice.

The most frequent non-drug supplemental therapies were application of ice, electrotherapy, and physical therapy. Other procedures that were each used in more than 30 cases were bandaging, iontophoresis, restraints, and pressure bandages.

Duration of therapy

Duration of therapy was left up to the individual physicians, with a maximum patient monitoring time of 2 months. Treatment duration of less than this amount of time was reported for about 92% of patients. Tabulating the responses to the questionnaires revealed that 23% of patients received *Traumeel®S* over a period of 1-7 days, 27% for 1-2 weeks, 22% for 2-3 weeks, and 14% for 4-5 weeks. Duration of therapy was 6-8 weeks for only 6% and more than 8 weeks for only 8%.

In general, as was to be expected, the duration of therapy was dependent on the patient's diagnosis. For example, in 77% of the group diagnosed with bruises and 71% of those with sprains, therapy could be terminated within a maximum of two weeks, while this was the case in only 11% of patients with arthrosis. In that diagnostic group, 71% were treated for more than 4 weeks.

Results of therapy

The success of the therapy that had been selected was to be assessed by the physician on the basis of two criteria:

- The point in time at which the symptoms began to improve.
- An overall evaluation of the results of therapy, using a five-point scale (see Methods).

In round numbers, noticeable improvement in symptoms occurred within the first week of treatment in about half of the cases and in an additional 34% of patients within 1-3 weeks. Improvement set in only after more than 4 weeks in a mere 8% of the patients. No improvement was noted in about 4% of the patients. As was to be expected, the point in time when subjective improvement in symptoms was reported depended on both the symptoms in question and the severity of the illness or injury, among other things. For example, while symptomatic improvement occurred within the first week of treatment in approximately 80% of the patients with bruises, post-traumatic edema, and hematomas, only about 20% of the patients with symptoms of arthrosis or frozen shoulder reported improvement within this time frame.

The results of the overall assessment of this therapy show that very good or good results were achieved in 8 out of 10 cases, while treatment was rated "satisfactory" in 13% of cases. The treatment was unsuccessful in only 4% of the patients. It is very difficult to estimate what role the concomitant drug and non-drug therapies that were prescribed played in the success of the treatment. In some illnesses additional forms of therapy are certainly necessary. An across-the-board comparison of patients who received concomitant therapies with those who did not reveals that good to very good results can also be achieved when *Traumeel®S* drops or tablets are the only form of therapy administered. As was to be expected, there were no obvious differences in the results of treatment with the two different oral forms of the medication (Table 4).

The therapeutic efficacy of *Traumeel®S*(tablets/drops) encompasses all of the usage indications that appeared here. In almost all diagnostic groups, a rating of "very good" or "good" was achieved in over 80% of cases. As was to be expected, the success rates in patients with symptoms of arthrosis and frozen shoulder were lower, although even in these instances positive therapeutic results were achieved in the majority of cases (Table 5).

Tolerance

In the context of the present prospective study, no adverse reactions to either the drops or the tablets were observed. On the basis of the reported data on tolerance, both forms of *Traumeel®S* under observation here can be rated "very good" with regard to how well they are tolerated.

Discussion

Traumeel®S is a broad-spectrum homeopathic anti-inflammatory used in treating inflammation (and inflammation-related processes) as well as a great variety of injuries. Because of its composition, *Traumeel®S* has anti-inflammatory, antiexudative, and regenerative qualities. More precisely, it:

- stimulates wound healing
- relieves pain
- stops bleeding
- improves vascular tone
- eliminates venous stasis
- has anti-inflammatory and antiviral effects
- supports and improves cellular respiration and oxidative processes.

This prospective study of 1359 cases of therapy shows that many of the post-traumatic conditions that are encountered in daily practice, as well as a great percentage of musculoskeletal disorders that have inflammatory or degenerative components, respond to oral therapy with homeopathic remedies. The availability of two orally administered forms of *Traumeel®S* optimizes the possibilities of developing individualized treatment plans and makes it possible to deal with compliance difficulties in a timely manner. The drops have the advantage of individual dosage adjustments, while the

tablet form with its fixed quantities of medication are easier for patients to deal with and may therefore prove more advantageous for long-term treatment. Because of the alcohol content of the drops (35% by volume) the tablets are to be preferred for children and patients with pre-existing liver damage.

The treatment results presented here confirm that both of the orally administered forms of *Traumeel®S* are suitable for treating acute post-traumatic conditions, inflammatory and inflammation-related symptoms, and degenerative joint diseases. Depending on the type and severity of the illness, concomitant drug and/or non-drug forms of therapy may be indicated, although in the context of this prospective study treatment with *Traumeel®S* alone was sufficient in a great number of cases.

Along with the reliable efficacy of *Traumeel®S*, which encompasses its entire range of usage indications, this study confirms that both orally administered forms are well tolerated. No adverse drug reactions were observed in any of the total of 1359 documented cases of treatment. It is also advantageous that there are no restrictions on combining *Traumeel®S* with other medications, since no drug interactions are to be expected.

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NOTE: The formulas of *Traumeel®Tablets* and *Traumeel®Oral Drops*, as produced in the United States, contain the identical ingredients as *Traumeel®S*, used in this study. However, two ingredients, Arnica montana, radix and Hypericum perforatum, are at the 3X potency in the U.S. produced tablets and oral drops.

Traumeel®S tablets and drops are not available in the U.S.