

Biological Therapy of Liver Disorders- Results of Drug Monitoring with 801 Patients

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Summary

The homeopathic liver remedy Hepar compositum (Heel) was tested in the context of drug monitoring with regard to its diagnostic application, mode of application, efficiency, and tolerance. The drug monitoring was based on 801 documented cases treated by 68 physicians. The conditions treated included hepatobiliary diseases, toxicogenic hepatic dysfunctions, as well as metabolic and cutaneous disorders. For 32% of the patients, the only medication administered was Hepar compositum. Findings revealed that 76% of the therapeutic results were rated either "very good" or "good." No adverse drug reactions were recorded. The patients' tolerance to Hepar compositum was good.

Introduction

Over the past 20 years, steadily worsening environmental pollution, changing social structures, and great increases in the consumption of alcohol and medication have contributed to a drastic rise in liver disease [1]. In many cases, furthermore, incidental laboratory findings originally obtained for diagnostic purposes have revealed an association between the liver and a variety of additional disorders such as skin diseases, autonomic dysfunction, or states of exhaustion. In a number of observed cases, however, subjective symptom complexes are completely lacking. Among many patients, the liver can no longer cope with the longterm burdens placed on it in its functions as an organ of detoxifica-

tion. The liver consequently suffers from gradual and increasing impairment of its metabolic functions. Accordingly, serious hepatic dysfunctions develop, followed not infrequently by associated secondary disorders [2].

The entire spectrum of medicinal products for liver disorders currently on the market is extremely extensive: it includes the entire range of immunomodulators, corticosteroids, antibiotics, and vitamin preparations especially intended for treatment of particular hepatic symptom complexes - as well as homeopathic remedies and phytomedicinal products [3].

Hepar compositum, produced by the company Heel, is a homeopathic preparation for hepatic disorders which contains a series of homeopathically prepared constituents. On the basis of its formulation, it is indicated for the following range of application: acute and chronic hepatobiliary diseases, toxicogenic hepatic dysfunction, as well as metabolic and cutaneous complaints.

Monitoring methodology

Characterization of the patients

During the period from March to August of 1993, 68 physicians (general practitioners and internists) in Germany and Austria conducted this drug monitoring survey on a total of 801 patients. The purpose of this survey was to document the application possibilities for Hepar compositum with respect to indica-

tions, dosage, mode of application, and adjuvant therapy. At the same time, the study was intended to assess the effectiveness of the preparation and its tolerance by the patients surveyed. Data acquisition took place through the medium of standardized questionnaires provided to the physicians for each of the patients included in the study. The questionnaires were used to record all relevant data on the patients and their therapy, in the form of answers to questions specifically directed to the physicians. No criteria were defined for including or excluding patients in the context of the survey. The following were left entirely to the discretion of the prescribing therapists: selection of the patients to be included in data collection, dosage of Hepar compositum, the period of administration, and accompanying therapeutic measures. The physicians rated the effectiveness of the therapy at the end of treatment by the following scale: very good (complete freedom from complaints), good (significant improvement), satisfactory (slight improvement), unsuccessful (patient's condition remains the same), and worsening.

Of the 801 patients, 55.2% were female and 44.4% were male (no data recorded for 0.4%). Fig. 1 shows the age distribution of the patients included in the survey.

No age data was recorded for 0.2%. Approximately every second patient was between 40 and 60 years of age.

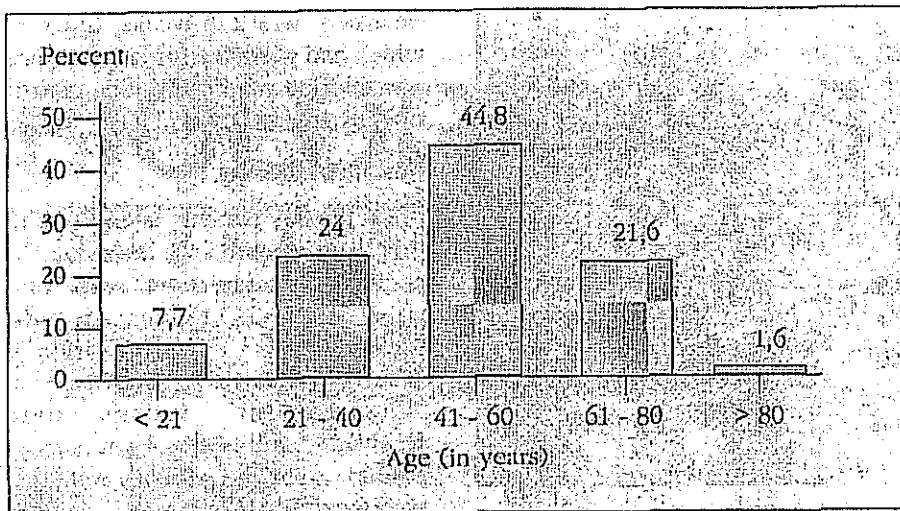


Figure 1: Age distribution of the patients.

Diagnoses, term of illness, and prior treatment

Due to the extremely great variety of problem complexes associated with illnesses in which the liver is involved, there was, as expected, a great number of different diagnoses rendered in this study. For this reason - and in accordance with the areas of application indicated by the manufacturer - six indication groups were established for this survey. Table 1 shows these classifications and the number of patients assigned to each.

Since most of the disorders covered

here had developed in an insidious manner and become chronic to a greater or lesser degree, the patients had generally suffered from these illnesses for considerable lengths of time: for the majority, more than one year. Only 14.5% had been ill for a period shorter than four weeks. See Table 2.

In accordance with the long term of disease experienced by the majority of these patients, the share who had received previous therapy was - as had been expected - correspondingly large: i.e., 55.6%. The groups of substances most frequently prescribed for these patients were as follows (as per the Rote Liste, the

German Physician's Desk Reference): liver medication (18.9%), dermatics (13.7%), and corticosteroids (13.5%).

Dosage and mode of application

The instructions for use for Hepar compositum provide the following dosage recommendation: in general, one ampule, 1- 3 times per week. Our data disclosed that the administering physicians adhered to these recommendations in 98% of cases. In our study, the dosage selected by the physician at the beginning of therapy was maintained in 9 of 10 cases throughout the entire term of treatment. For one patient in ten, it was possible to reduce the dose before conclusion of therapy.

With respect to route of administration, the manufacturer of Hepar compositum recommends IM, SC, IC, or if required IV application. This survey revealed that the physicians elected the IM route for the majority of patients (62%). The next-most-frequently employed means were SC (19%) and IV (10%) injection. It appears noteworthy, in addition, that 8.4% of the patients received Hepar compositum as orally administered ampule medication (i.e., an ampule is broken and emptied into a small glass of water, which the patient takes in small swallows throughout the course of a day).

Adjuvant therapy

It was left to the physicians' discretion to apply additional forms of therapy within the framework of this drug monitoring. Evaluation of data revealed that 67.8% of the patients in fact received concomitant therapy, broken down as follows: adjuvant medicamentous treatment (29.2%), adjuvant nonmedicamentous (e.g., physical) therapy (14.5%), and accompanying medicamentous plus nonmedicamentous treatment (24.1%). Monotherapy with Hepar compositum was administered to 32.2% of the patients.

Indication groups	No. of patients in each group
1. Acute hepatobiliary affections	79 (9.9%)
2. Toxicogenic hepatic dysfunctions	326 (40.7%)
3. Chronic hepatobiliary affections	157 (19.6%)
4. Inflammatory cutaneous illnesses	148 (18.5%)
5. Noninflammatory cutaneous illnesses	83 (10.4%)
6. Miscellaneous liver-related disorders	136 (17.0%)

Table 1: Indication groups (some patients were assigned to more than one group).

Term of illness before treatment	No. of patients
Less than one week	5.1%
2 - 4 weeks	9.4%
5 - 8 weeks	6.7%
3 - 6 months	13.0%
7 - 12 months	14.5%
Longer than one year	50.3%
No data on term of illness	1.0%

Table 2: Term of illness (n = 801).

Indication groups	Very good	Good	Satisfactory	Unsuccessful
Acute hepatobiliary affections (n = 79)	34.2	45.6	9.0	1.2
Toxicogenic hepatic dysfunctions (n = 326)	29.5	50.4	13.9	6.2
Chronic hepatobiliary affections (n = 157)	18.5	50.3	22.3	9.0
Inflammatory cutaneous illnesses (n = 148)	17.0	62.4	16.4	4.2
Non-inflammatory cutaneous illnesses (n = 83)	22.9	55.4	16.9	4.8

Table 3: Therapy results for the individual indication groups.

The additionally prescribed medication primarily included not-identified homeopathic medication, as well as preparations for gastrointestinal disorders. Only 5.1% of the patients received an adjunct liver remedy. The physicians recommended dietary measures for 187 patients, and alcohol abstinence for 47.

Results

Term of therapy

This drug monitoring survey was furthermore intended to reveal the length of time necessary to administer Hepar compositum before the patient experienced an initial improvement in his or her condition,

as well as the total required period of treatment. These periods are also of considerable significance especially in the context of injection from ampules as a mode of application, since this form of administration demands a high degree of compliance from the patients.

Of the patients in the group of acute hepatobiliary affections, around one-third noticed initial improvement in their condition after only one week of treatment. In the other indication groups, first signs of success became apparent after 2-3 weeks; likewise for one-third of the patients. For the majority of persons who were acutely ill, the term of

treatment was 2-5 weeks. Illnesses which had persisted for lengthy periods of time required 4-8 weeks of therapy in most cases.

Results of therapy

Of the 801 patients taking part in this drug monitoring, three-fourths concluded their treatment with "very good" or "good" ratings. An additional 16.1% of the therapeutic results were rated "satisfactory." "Unsuccessful" ratings were received by only 7.5%. There was no case in which the patient's condition worsened. See Fig. 2.

Separate consideration of the results of treatment for each of the individual indication groups reveals that the total of "good" and "very good" results was approximately 80% - with the exception of chronic hepatobiliary diseases. Among those suffering from chronic hepatobiliary affections, "good" and "very good" therapy results were achieved for 68% of the patients; the share of "satisfactory" results, on the other hand, is around 8% higher in this group than in the other indication groups. The quota of unsuccessful results was lowest of all for the group with acute hepatobiliary affections: 1.2%. See Table 3.

Upon analysis of the sub-population composed of those patients treated exclusively with Hepar compositum (i.e., monotherapy), and after comparison of these treatment results with those of patients receiving combined forms of therapy, it is revealed that in both of these sub-groups, around three-fourths of the patients achieved "good" to "very good" treatment results. The "unsuccessful" share of results was 5.8% in the monotherapy group, and 8.3% in the combination therapy group. See Fig. 3.

Patient tolerance

Patient tolerance to Hepar compositum can without reservation be rated "very good," since this study disclosed no adverse drug reactions.

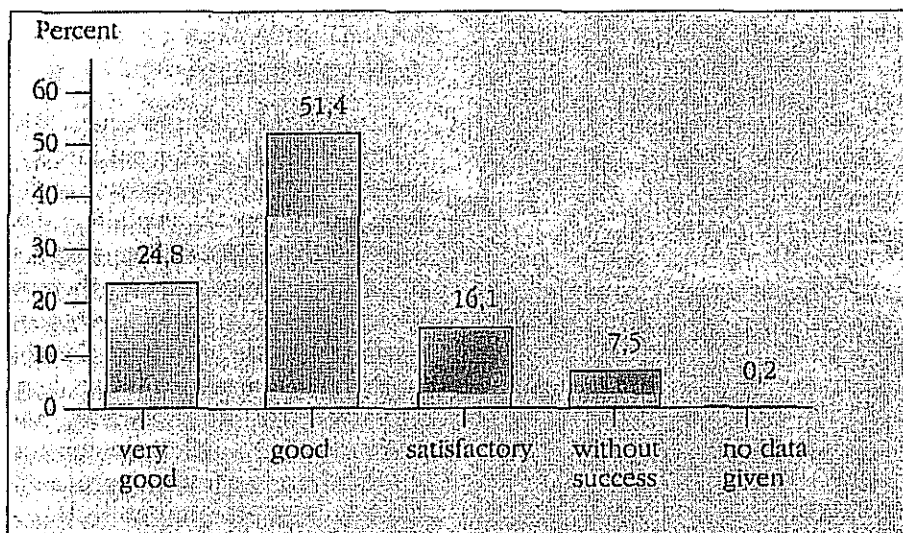


Figure 2: Results of therapy for the entire population (n=801).

Interpretation of results of drug monitoring

Now as before, considerable controversy prevails in discussions of the medicamentous therapy of hepatic disorders. An essential topic in such deliberations concerns the self-regeneration capability of the liver [3]. The actual objective of liver therapy is the support and enhancement of healing processes, as well as elimination or

advantageous, especially in cases involving impairment of hepatic detoxification functions. A preparation such as Hepar compositum can prove particularly essential in such a context, since the spectrum of therapeutic activity offered by its constituents covers numerous symptom pictures. The predominantly good treatment results obtained for all indication groups of this survey verify this effectiveness. Especially noteworthy

this study, one salient aspect is that the application of Hepar compositum enables considerable reduction in the number of preparations employed - or their replacement by medication with fewer adverse side effects. For example: the number of corticosteroids prescribed fell from 60 to 5; the dermatics, from 61 to 24; and the other liver remedies, from 84 to 41. On the other hand, the number of patients who received adjuvant homeopathic medication rose from 62 to 252. In addition to its reliable effectiveness, these drug monitoring results verify good patient tolerance of Hepar compositum. No adverse drug reactions were recorded in any cases. Hepar compositum therefore satisfies all prerequisites for effective as well as safe therapy for a variety of hepatic dysfunctions.

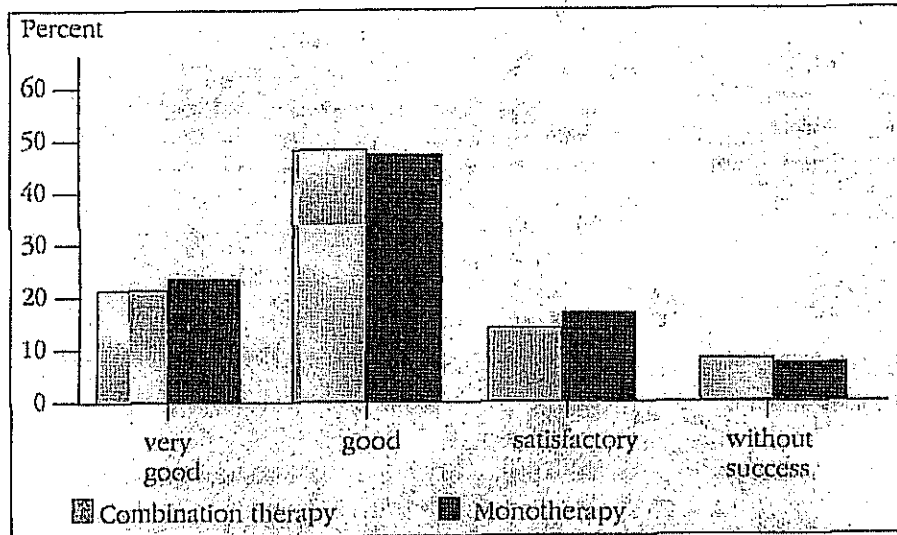


Figure 3: Therapy results: Combination therapy vs. monotherapy (n=543 and 258, respectively).

alleviation of the symptoms of disease. Such treatment should accelerate the self-regeneration of the hepatic parenchyma, and should reduce the alteration of tissue taking place as a result of accumulation of toxins in connective tissue. Effective liver therapy will lead to elimination of pathogenetic infiltration of fat, in favor of increased formation of glycogen and achievement of a positive energy balance - with the goal of fully restoring normal metabolic and detoxification functions [5].

The drug monitoring survey presented here has demonstrated that such liver therapy can well prove

thy in this connection are the facts that, even in the indication group for chronic hepatobiliary diseases, therapy results of "good" or "very good" were possible for 68% of the patients, and that the share of unsuccessfully treated cases was only 9%. These results are all the more significant in light of the severity of this indication: a symptom picture associated with difficult and protracted therapy, as any experienced therapist can verify.

Upon comparison of the extent of medicamentous treatment previously received by these patients with the adjuvant medication retained by the physicians for therapy covered by

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