FEATURE ARTICLE
Biological Cardiac Therapy with Cralonin:
Results of a Study on Multicentric Application
with 2,178 Patients

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Abstract:
A multicentric study investigated the effectiveness, tolerance, and modes of application of the homeopathic combination preparation Cralonin (drops and injection solution). Case reports from 2,178 patients served by 317 physicians were available for the study. It was determined that these physicians primarily administered the preparation Cralonin for the following main indication groups: functional heart diseases, post-infection cardiac complaints, geriatric heart, coronary heart disease/angina pectoris, and hypertension/circulatory dysregulation. The study revealed good or very good therapeutic results for the great majority of patients in all these areas of indication. The tolerance of the preparation was very good.

1. Introduction

The administration of preparations taken from hawthorn (Crataegus) sources - i.e., the leaves, blossoms, and fruit - is widespread for minor forms of cardiac insufficiency (Stages I and II, according to the New York Heart Association), for geriatric heart not yet requiring cardiac glycosides, for sensations of pressure and constriction in the vicinity of the heart, and for minor forms of bradycardia [1]. Such a treatment is common among physicians practicing according to both phytotherapeutic as well as homeopathic principles [2, 3]. According to current insights, the therapeutic effects of Crataegus extracts are primarily the result of the oligomeric proanthocyanidines and the flavonoids which they contain. Pharmacological studies have accordingly documented an enhancement of coronary circulation, an increase in myocardial circulation, a higher level of myocardial tolerance to oxygen deprivation, and positive inotropic effects owing to the application of Crataegus. Authors have attributed these therapeutic effects to inhibition of c-AMP phosphodiesterase (which begins at low dosage levels) and to beneficial control of intracellular Ca²⁺ concentration [1, 4, 5, 6].

In the observation of therapeutic application described here, study was conducted of the possibilities of administration and the therapeutic effects of the homeopathic combination preparation Cralonin, with its primary active constituent Crataegus. The homeopathic spectrum of therapeutic functions for the active constituents of Cralonin include cardiac and circulatory disorders, cardiac insufficiency, geriatric heart, arrhythmia, angina pectoris, and blood-pressure disorders [2].

1.1 Therapeutic agent

Cralonin is a homeopathic combination preparation produced and distributed by the company Biologische Heilmittel Heel GmbH of Baden-Baden, Germany. It has been widely and effectively employed for decades as a cardiac medication in the form of drops and injection solution. It contains the agents Crataegus, Spigelia, anthelminth, and Potassium carbonate. A number of studies on its therapeutic results, in the form of empirical reports, have been published on Cralonin. G. Brückner has reported his experience with Cralonin in his practice of internal medicine, as employed for 146 patients suffering from the primary symptom of piercing cardiac pain [7].

Whereas previous publications have concentrated on the evaluation of therapeutic results for particular, mostly narrowly circumscribed individual indications, the study of observations which we would like to summarize here covered the entire indication range for the preparation Cralonin among an extensive patient population. The study further focused on the main areas of therapeutic possibilities associated with administration of Cralonin.

1.2 Methods employed and the patient population

During the period from 1 January 1988 to 31 December 1989, documentation within the context of a multicentric application study was prepared throughout the entire Federal Republic of Germany and West Berlin on the effectiveness, tolerance, and modes of application of the homeopathic combination preparation Cralonin (drops and solution for injection). Acquisition of data took place with the aid of standardized questionnaires which had been distributed to participating physicians. Each questionnaire contained requests in the form of specific questions for all relevant patient and therapy data for each individual case treated. The study did not feature criteria for accepting or rejecting patients in the study, since it was intended to depict a complete picture of all patients treated with Cralonin in a large number of practices. Each physician of course enjoyed complete freedom in his selection of form of administration, dosage, duration of treatment, as well as employment of adjuvant therapy. The only requirement was that the pertinent data be completely recorded on the questionnaire. A total of 317 physicians from various specialized fields took part in the study: primarily practical doctors, but also general practitioners and internists. These physicians returned a total of 2,202 filled-out questionnaires to the company Heel, of which 2,178 were suitable for evaluation of the data contained. The remaining questionnaires (24) were discarded owing to incomplete information: e.g., no diagnosis or lack of assessment of the therapy. Of the 2,178 patients included in data evaluation, 63% were female (1,371), and 35.9% (782) were male. For 25 patients (1.1%), the sex was not indicated. With only one exception,
the data included the ages of the patients: the average was 59.2 years. Fig. 1 graphically depicts the distribution of sex and age among those patients for whom complete data were provided (2,153 cases).

1.3 Diagnosis

The organizers of the study requested that each physician provide a precise clinical diagnosis for the questionnaire. In order to simplify the entries, the questionnaire already included the following diagnosis possibilities, as indications for which Cralonin has proven effective over many years:

1. Functional heart diseases.
2. Post-infection cardiac complaints.
3. Geriatric heart.

In addition, however, the physician was asked to provide further diagnosis in the form of self-composed text, in the space provided. Evaluation of data revealed that the physicians in 2,068 cases took advantage of the indication possibilities provided by the organizers on the form. On only 110 of the valid questionnaires did the diagnosis appear exclusively in the form of the physician's own text. On the other hand, a great number of doctors took advantage of the possibility of checking one of the diagnoses already printed on the form, and of entering their own diagnosis text. Consequently, multiple diagnosis entries were made for 492 patients: from 2 to a maximum of 5 indications. The following conclusions are therefore justified: that many of the patients treated with Cralonin in the practices covered suffer from an entire complex of cardiac complaints, and that the individual symptom complex cannot in many cases be characterized by a precise single diagnosis. Table I provides an overview of the diagnosis breakdown (the table includes only indications which appeared for more than 0.1% of the patients).

1.4 Forms of administration, types of application, and dosage of Cralonin

Within the context of this study, Cralonin was administered orally in the form of drops, injections from ampules, or a combination of these two. In a majority of the cases treated (87.3%), the participating physicians exclusively selected the oral form, with drops. In these cases, the great majority of prescriptions (91.3%) called for a dosage of 20 drops taken 3 times a day.

In 138 cases (6.3% of the evaluated patients), the patients exclusively received Cralonin in injection form (ampules). In 121 cases (5.6%), the physicians chose combination therapy of both forms of administration. For 0.9% of the patients, the doctors made no entry for the choice of application.

Of the 259 patients who received Cralonin by injection, or by injection together with drops, 98 (37.8%) obtained the preparation by intravenous means and 96 (37.1%), by intramuscular application. The physicians decided on subcutaneous injection in 41 cases (15.8%), and for intracutaneous injection in 13 cases (5.0%). On 11 questionnaires, the physicians failed to indicate the manner of administration for the ampule preparation. In 41.7% of the injection cases, patients received the Cralonin injection solution with a dosage of 2 ampules per week. In slightly more than 20% of cases, physicians administered a dosage of 1 ampule daily; they employed the dosage of 1 ampule weekly with approximately the same frequency; somewhat more than 20%. Other dosage amounts and frequencies were indicated on 6.2% of the forms, and for almost 7% of the cases there was no indication of Cralonin injection dosage. On the whole, it may be concluded that dosage in the great majority of cases was moderate in amount and frequency: extremely high or low dosages represented exceptions.

1.5 Adjuvant therapy

During the study, the participating physicians were free to employ any other medication or other therapeutic measures deemed helpful. Assessment of the data revealed that 1,069 patients (49.1%) received adjuvant medication; 477 of these patients also underwent therapy of non- medicamentous nature. For 466 patients (21.4%), the therapy involved strictly non-medicamentous measures in addition to administration of Cralonin. Patients who were treated only with Cralonin - i.e., without adjuvant therapy of any kind - represented 29.5% of the total population.
The most frequently prescribed medicamentous adjuvant therapy may be broken down as follows:

- Cardioactive agents: 129 cases.
- Medication for stimulation of blood circulation: 119 cases.
- Antihypertensives: 82 cases.

The following is a breakdown of adjuvant therapy from another standpoint:

1. Medication acting directly on the heart (e.g., cardioactive agents, coronary agents, antiarrhythmics, and the like): in 247 cases (11.3% of all patients).

2. Medication with effects on blood flow/supply, blood pressure, blood vessels, circulation, and coagulation (e.g., antihypertensives, diuretics, anticoagulants, and the like): in 283 cases (13.0% of the total population).

3. Other medication, i.e., all preparations which were prescribed exclusively for treatment of accompanying diseases (e.g., antidiabetics and antirheumatics) – in addition to vitamins, mineral preparations, agents used for stimulation (reversal) therapy, as well as single and combination homeopathic remedies: together, in 539 cases (24.7% of the total population).

From these data, it is apparent that medicamentous agents specifically intended for therapy of cardio-circulatory disorders were prescribed for less than one-fourth of all patients (24.3%): the sum of Groups 1 and 2 from the above list. It may therefore be expected that the therapy results with Cralonin as described below would be significantly influenced by this relatively small share of agents with direct action on the organism.

### 1.6 Term of therapy

This study on the use of Cralonin also included clarification of how long the preparation is generally prescribed in actual practice. Physicians were asked to check one of the following possibilities for each patient:

1. Less than 1 week.
2. 1 week to 1 month.
3. Longer than 1 month.

Owing to the open-ended choice "longer than one month," it is of course not possible to calculate the average length of Cralonin therapy. The data revealed, however, that the majority of patients (69.6% of all cases) were treated with Cralonin for a period longer than one month. Physicians employed Cralonin less than a week in only 2.8% of the cases. As a result, it may be concluded that medical doctors administer this preparation primarily on a long-term basis.

It is interesting to note in this connection that the term of therapy tended to be shorter on the average when physicians exclusively administered the preparation in injection form. Of the patients who received Cralonin from ampules, the term of therapy for 61.2% of them was shorter than one month; the figure for drops, on the other hand, was only 27.3%. Apparently, physicians tend to use Cralonin injection solution chiefly for acute complaints, whereas they customarily prescribe the drops for long-term maintenance therapy.

### 2. Assessment of the results in the individual indication areas

Now, after presentation of the methods used in the study, and of the various influencing variables of significance for evaluation of the therapy results, the following report will concentrate on the main indication areas for Cralonin. In the decision as to which main indication areas would be assessed, the frequency of diagnosis possibilities as entered by the participating physicians played the primary role. The absolute number of diagnosed indications, however, was not the only criterion: just as important was the consideration as to whether the
respective single diagnosis actually held chief status among the complex of complaints for each individual patient - thereby justifying convincing grounds for Cralonin therapy - or whether it represented merely an accompanying disorder or complaint. For this reason, those cases of diagnosis were excluded from designation as main indications if they occurred only rarely, or not at all, as exclusive (single) diagnosis items. In assessment of the diagnosis „Coronary heart disease,” however, the procedure deviated from that just described, insofar as the diagnosis „Geriatric heart” was not evaluated as a supplementary diagnosis. This procedure seemed justified by the fact that coronary disorders in any case represent typical geriatric diseases, and that the indication „Geriatric heart” does not provide significant additional information. Consequently, the combined entry of coronary heart disease and geriatric heart was evaluated as a single diagnosis item. On the basis of this standpoint, the following five main indication areas were defined for Cralonin:

1. Functional heart diseases.
2. Post-infection cardiac complaints.
3. Geriatric heart.
5. Hypertension / circulatory dysregulation.

These five indication groups covered a total of 97.75% of all the patients included in this study. Certain overlap among these five groups, however, was inevitable owing to the many multiple diagnoses entered by the participating physicians. As a result, the total number of patients in the individual indication groups is not identical to the overall total of all patients included in the five groups.

The following is a detailed representation of the five main indication areas for administration of Cralonin, with special consideration of the therapy results obtained among the patients.

We would like to begin with a short elaboration on the method of acquiring and assessing the therapeutic results. In order to simplify acquisition of therapy results and assessment of treatment success for the relatively differentiated complexes of illnesses and complaints, we employed a five-stage rating scheme, as follows:

Results of therapy were:
1 = very good;
2 = good;
3 = satisfactory;
4 = unsuccessful;
5 = worse than before.

Although we fully realized the problems associated with such a simplified schematic evaluation, we decided after careful consideration to employ the method as outlined above.

In order to enhance the visual clarity and effectiveness of graphical representation in the following sections, we combined the ratings „very good” and „good,” and we reported the breakdown of patients among the rating categories in the form of percents. This technique facilitated comparison of therapy results, obtained as they were from patient subgroups of various sizes.

2.1 Functional heart diseases

Functional heart diseases and their complaints generally manifest themselves as attacks in the form of thoracic pain, tachycardia, and anxiety [8]. This diagnosis must be substantiated, however, by an extensive examination of the patient’s cardiocirculatory system which rules out significant pathological causes which would otherwise explain the complaints being suffered. In other words, findings for functional heart diseases always represent an exclusion diagnosis. The entry „functional heart disease” was made on a total of 1,097 of the questionnaires. The average age of this patient group was 51.9, with breakdown by sex approximately the same as for all the patients included in the study. For 46.6% of the patients, their physicians had already made the diagnosis „functional heart disease” more than one year before the study, for 14.2% of the cases, this diagnosis had been known for more than five years.

Exclusive diagnosis of functional heart disease was made for 883 of the patients covered; additional diagnoses were made for 214 further patients. Among these, geriatric heart (72 cases), hypertension (67 cases), and hypotension (41 cases) were the most frequent entered.

Upon comparison of the results of treatment for functional heart disease - i.e., with and without additional diagnoses, in Fig. 2 - it is apparent that the therapeutic success quota (at least a rating of „satisfactory”) lay in the same order of magnitude for both groups: 96.7% with and 98.6% without supplementary diagnoses. Among patients without additional diagnoses,
2.2 Post-infection cardiac complaints

Post-infection heart disease was diagnosed in 196 cases. The share of female patients here - 55.6% - is slightly less than the proportion of women in the entire patient population. The average age of the patients recorded here was 48.7, which indicates that Cralonin therapy for post-infection cardiac complaints was employed for a group of patients younger than those contained in the other diagnosis groups. Therapists entered additional diagnoses for 47 of these patients, with the following indications appearing the most frequently: geriatric heart in 19 cases, functional heart disease in 18 cases, and hypertension in 7. The length of time during which patients had suffered from post-infection heart complaints was comparatively short: only half of the patients had suffered for longer than 1 month. In 7% of cases, the complaints which led to Cralonin therapy had existed less than 1 week. This observation was to be expected, since the therapy involved here represents a reaction to the consequences of another acute disease.

Physicians' assessment of the therapy results as satisfactory or better was almost identical in the two patient groups: 97.9% at least satisfactory with additional diagnoses, and 97.3% satisfactory or better without additional diagnoses. Surprisingly, the share of patients with very good or good therapy results was somewhat higher in the group with additional diagnoses (91.5%) than for those with only single diagnoses (88.6%). Fig. 3 graphically represents these relationships.

2.3 Geriatric heart

First, a word of elaboration on definition of the diagnosis "geriatric heart". From the morphological standpoint, the human heart during old age becomes smaller and denser, and its walls become thicker. The increase in heart density correlates with the rise in arterial blood pressure. As a result of cardiac circulatory deficiencies, disturbances in energy metabolism develop, which are in turn responsible for the secondary structural alterations observed.

These structural alterations appear in the form of fibrosis, lipofuscinosis, proliferation of the interstitial connecting tissue, coronary arteriosclerosis, myolysis, heart-valve sclerosis, sclerosis of the cardiac skeleton, and structural dilatation of the heart (8).

This application study included 882 patients with geriatric heart. Their average age was 73.1. Of the total, 66.2% were female, 33.8% were male, and no sex was indicated for 1.6%. Participating physicians provided additional diagnoses for 308 patients (34.9%) with most frequent entry of functional heart diseases (72 cases) and coronary heart disorders (59 cases). Physicians had diagnosed geriatric heart for 84.1% of these patients for a period longer than one year. In 45.4% of the cases, this diagnosis had been known for more than 5 years, and even 13.6% of the patients had known of this diagnosis for longer than 10 years.

Data on therapy results revealed very little difference between the two groups with and without additional diagnoses: 97.4% of the results were rated very good, good, or satisfactory for patients with additional indications, and 96.7% received one of these ratings with single diagnoses. The percent findings rated as very good or good also differed very little among these two groups. As was also the case with post-infection heart complaints, the Cralonin patients with additional diagnoses demonstrated a higher percent (83.1%) of very good or good results than patients with only single diagnoses - for whom the good or very good rating appeared in the smaller share of 80.3% of cases (see Fig. 4). Under consideration of the long case histories for the great majority of patients covered in this study, however, a share of more than four fifths with very good or good results must at any rate be regarded as highly respectable success.

2.4 Coronary heart disease

According to Pschyrembel's Clinical Dictionary (8), stenosing coronary sclerosis is the origin of coronary heart disease. Contrary to functional heart disorders, it is definitely therefore an organic disease of the heart. The diagnosis "coronary heart disease" was not listed on the printed questionnaire. It and its synonyms appeared so frequently in the freely composed handwritten text entries made by the physicians that we find it justified and useful to define it as another main indication for administration of Cralonin.
the percent of patients with very good or good therapy results in both groups (i.e., with and without additional diagnoses) was exceptionally high: considerably more than 80%. With respect to all patients suffering from coronary heart disease or angina pectoris, the quota of those for whom Cralonin therapy was unsuccessful was very small: only 4.6%. In this context, it may be assumed that the corresponding differences between the groups with and without additional diagnoses is probably the result of statistical deviations: especially since relatively small patient groups are being compared here.

### 2.5 Hypotension and circulatory dysregulation

Although the printed questionnaires did not contain the diagnosis possibility "hypotension," the participating physicians entered it 95 times, including 29 times as the only diagnosis. In 11 further cases, physicians entered "hypotonic dysregulation," without further additional diagnoses, on the questionnaire. For 66 of the patients, further diagnoses were made in addition to hypotension and circulatory disorders. On the basis of the total number of 106 patients with the complaint complex hypotension /circulatory dysregulation, it seemed logical to establish a further main

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**Fig. 4: Therapy results with Cralonin for patients with the diagnosis geriatric heart (n = 882).**

**Fig. 5: Therapy results with Cralonin for patients with coronary heart disease / angina pectoris (n = 106).**

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terms „coronary heart disease,“ its abbreviations, or „coronary insufficiency“ as diagnoses for 95 of the patients. In 5 of these cases, additional entry of angina pectoris or stenocardia was also made. Thirteen further patients, for whom the entries „angina pectoris,“ „stenocardia,“ or „anginose complaints“ were found, were also assigned to this group. According to Pshyrembel [8], the occurrence of angina pectoris attacks is due to an acute disproportion between the supply and the demand of oxygen in cases of coronary heart disease. In the patient group to be elaborated on in the following, it was possible to classify 108 therapy cases on this basis. If the indication „geriatric heart“ is disregarded as an additional diagnosis, additional diagnoses of other kinds occur in only 69 cases. Of these 69, in turn, hypertension was most common: 30 cases.

One may therefore assume that coronary heart disease in fact assumed central significance in the disease complexes of the patients included in this group, and that this central indication was decisively associated with the results of the Cralonin therapy.

The average age of the patients in this group is 68.1: somewhat younger than that for the group „geriatric heart.“ It is, on the other hand, definitely higher than the age of patients with functional heart diseases or post-infection cardiac complaints. In this group, 49 patients were male and 57 were female; in 2 cases there was no indication of sex. A noteworthy characteristic here was the long duration of the disease. The participating physicians indicated a term of illness longer than one year for 88.9%, longer than 5 years for no fewer than 44.4%, and longer than 10 years for 16.7%. As a result, the average term of illness exceeded that of the patient group with geriatric heart.

It is also worthy of mention here that
category of indication for Cralonin. Functional heart diseases (46 cases) and geriatric heart (17 cases) appeared most frequently as additional diagnoses. The average age of this entire patient group was 45.7; lower than in all other groups. Also noteworthy was the large share of female patients here: 81.1%. Data evidenced that young women relatively frequently suffer from hypotonic circulatory dysregulation. The complaints registered here had been diagnosed longer than 1 year for 54% of the patients, and longer than 5 years for 20.7%.

An interesting aspect here was the fact that physicians almost exclusively prescribed Cralonin in the form of drops for this indication area. For patients who suffered from no additional indications besides hypotension and circulatory dysregulation, Cralonin was administered without exception as drops. For patients with additional indications, therapy in 64 of 66 cases also consisted exclusively of drops. In all of these cases, it appeared relatively frequently among dosage data that the physicians departed from the manufacturer's recommended levels (20 drops 3 times a day) and often prescribed 30 drops in the morning and 30 drops at noon. Fig. 6 provides therapeutic results for patients with hypotension or circulatory dysregulation, with and without additional diagnoses.

**3. Tolerance of the preparation Cralonin**

On the basis of this study, it is entirely justified to assess the tolerance of Cralonin drops and ampules as very good. The question on undesired side effects was answered in only 10 cases with yes: once for the ampules, and 9 times for the drops. There was one reaction after subcutaneous application in the form of local reddening of the skin, with itching, at the point of injection. One case of facial flush appeared after oral administration of Cralonin; this symptom also disappeared spontaneously, however. There was also one case of tachycardia and one case of transient high pulse frequency. In one of these cases, however, there was direct chronological connection with the side effects and the patient's immediately preceding termination of therapy with a beta blocker. One woman patient suffered from temporary development of an edema on her leg: it disappeared quickly after further Cralonin therapy and lymph drainage. There was also one case of each of the following: dizziness, nausea, and slight upset stomach. In two additional cases, patients demonstrated psychically associated rejection of the preparation. Of these two, one 32-year-old woman with functional heart disorder refused to take Cralonin on the grounds that she had not tolerated the preparation earlier: the more plausible reason, however, was the patient's fear of withdrawal symptoms in the event that she terminated the psychotropic medication which she had been taking. One 26-year old man who suffered from cardiac neurosis, on the other hand, said that he could not manage without Cralonin.

The relatively small number of patients who suffered from side effects, as compared to the overall number observed in the study, as well as the great variety of claimed side effects, did not enable in any single case a verified causal relationship with administration of Cralonin. As far as the severity of the described phenomena is concerned, it may be concluded that they in all cases involved minor subjective complaints. In no single case were we able to establish any degree of risk associated with Cralonin therapy. For 2,108 of the patients (more than 99.5%), the preparation was taken throughout the entire term of therapy without the slightest indication of discomfort.

**4. Assessment of results**

The results of observations made in this study revealed that there is in fact statistically verified justification for the use of biological medication such as Cralonin drops and solution for the therapy of cardiac disorders. The evidence produced by the study reveals that the preparation Cralonin, produced on the basis of Catecholus source material, can indeed provide reliable and effective therapeutic results, and can be recommended in addition to administration of the more conventional medications traditionally prescribed for cardiac disorders: i.e., digitalis glycosids, synthesized antiarrhythmics, and calcium antagonists. A study of therapy actually conducted on 2,178 heart patients revealed that the 317 physicians participating in this survey routinely prescribe Cralonin drops and injection solution for the following main indications: functional heart disease for patients of all ages, post-infection cardiac complaints, as well as all forms of geriatric heart. These physicians administered Cralonin with or without simultaneous application of digitalis, depending on the...
severity of cardiac insufficiency encountered. The share of patients with coronary heart disease who were successfully treated with Cralonin - no less than 5% of the entire patient population under study here - especially emphasizes the possibilities of successful use of Cralonin not only for what is termed heart disorders of neurovegetative nature, but also for organic heart diseases. Our data also documented the successful employment of Cralonin for hypotonic circulatory dysregulation.

In all these indication areas, the share of "good" and "very good" therapeutic results was over 80%, and the share of unsuccessful applications was 7.7% in the most unfavorable case.

In addition to the effectiveness of this preparation, the study also confirmed the good tolerance to therapy with Cralonin; serious side effects were registered in not one single case. The share of minor discomforts and other symptoms which arose at the time of Cralonin therapy was considerably less than 0.5% for both forms of administration.

As a result, Cralonin fulfills all requirements for the effective and extensively non-risk therapy of a variety of cardiac disorders and complaints.

References:


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