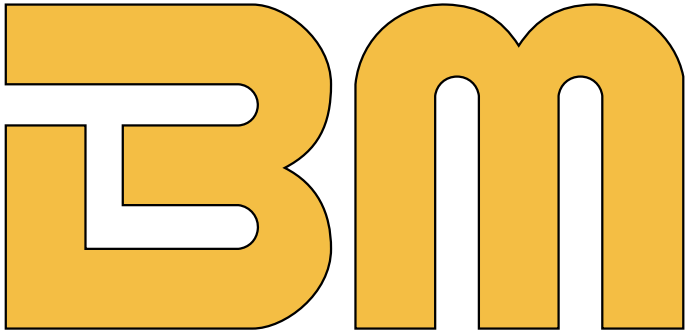


Internationale Zeitschrift für biomedizinische Forschung und Therapie

INTERNATIONAL JOURNAL FOR BIOMEDICAL RESEARCH AND THERAPY



BIOLOGISCHE MEDIZIN

Translated from *Biologische Medizin*
Vol. 29, No. 2, 2000, pp. 72–9

This Journal is regularly listed in EMBASE/Excerpta Medica
and Complementary Medicine Index (AMED/CATS)

Cralonin as Adjuvant Therapy in Heart Disease

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Abstract

Cralonin, a homeopathic compound remedy containing *Crataegus*, *Spigelia*, and *Kalium carbonicum*, was the subject of a prospective study that gathered data of practical relevance on a total of 665 patients. The study documented the symptoms for which Cralonin was prescribed as well as dosages and methods of administration.

Cralonin is prescribed either alone or as an adjuvant therapy for functional or organic heart disease and post-infection cardiac symptoms. Approximately 50% of the patients in this study took Cralonin as an adjuvant to standard therapy with antihypertensives or cardioactive drugs. The participating practitioners assessed patient tolerance of Cralonin as “excellent” or “good” in the great majority of cases. No side effects were reported. Therapeutic efficacy was rated “good” or “very good” in approximately 90% of patients. The medication was most effective and fast-acting in cases of functional cardiac symptoms and stabbing pains in the heart region.

Keywords: Antihomotoxic medicine, Cralonin, *Crataegus*, heart disease, homeopathy, prospective study.

Introduction

Crataegus (hawthorn) is a natural plant remedy that has long been used in treating cardiovascular disorders, especially arrhythmias and mild forms of coronary insufficiency (NYHA I and II). The therapeutic effect of extracts of hawthorn leaves and flowers is attributed to their content of flavonoids and oligomeric procyanidins, but the working mechanisms of *Crataegus* in phytotherapeutic preparations have not yet been definitively explained. *Crataegus* may directly inhibit sodium-potassium ATPase and indirectly influence intracellular processes by interacting with cardiac beta-1 receptors.^{1,2)} Known pharmacological effects of *Crataegus* extracts include:

- positive inotropism (by increasing intracellular Ca^{2+} concentration),
- increasing the supply of energy and oxygen to the myocardium (by dilating the coronary vessels),
- alleviating arrhythmia (by lengthening the refractory period).

Double-blind studies with placebo controls have conclusively verified the therapeutic efficacy of phytotherapeutic preparations of *Crataegus* in coronary insufficiency³⁾. The patients in these studies reported improvement in subjective symptoms and increased tolerance of exertion. Prospective studies have documented the success of *Crataegus* therapy in mild to moderate arrhythmias⁴⁾. Generally, no undesired effects of significant severity or frequency were reported. It has not yet been scientifically proved that homeopathic formulations of *Crataegus* also offer patients desirable, effective, low-risk alternatives to allopathic heart medications.

The preparation Cralonin (manufactured

by Biologische Heilmittel Heel GmbH, Baden-Baden, Germany) combines homeopathic *Crataegus* with *Spigelia* (worm grass) and *Kalium carbonicum* (potassium carbonate), whose homeopathic drug pictures also include cardiovascular effects (Table 1). This combination of ingredients makes Cralonin suitable for use either alone or as an adjuvant to standard therapy. It is indicated especially in cases of inadequate coronary circulation, angina pectoris, stabbing pains in the heart region, cardiodynia, and infectious-toxic myocardial insufficiency and postcoronary conditions.

The results of this prospective study of Cralonin injectable solution supplement those of an earlier study that dealt primarily with Cralonin drops⁵⁾.

Methods

The goal of this multicentric prospective study, conducted in Germany, was to gather information of practical relevance on usage indications, methods of administration, therapeutic efficacy, and tolerance of Cralonin. With the help of a standardized questionnaire, the 68 participating physicians (primarily general practitioners) gathered demographic and anamnestic data on 665 patients as well as information on previous treatment; type and symptoms of the target illness and any accompanying disorders; concomitant therapies; and methods of administration, dosages, and durations of antihomotoxic therapy with Cralonin. The physicians also assessed the overall results of therapy on a five-point scale (“very good” = complete freedom from symptoms; “good” = obvious improvement; “satisfactory” = slight improvement; “no success” = symptoms remained the same; and “worse”) and

Ingredient	Selected Characteristics/Symptoms
Crataegus	Coronary insufficiency, geriatric heart disease, cardiac arrhythmias, angina pectoris, blood pressure disorders.
Spigelia	Acute cardiac inflammation, angina pectoris, neuralgia.
Kalium carbonicum	Cardiac disorders, anasarca (generalized edema with accumulation of serum in the connective tissue), degenerative disorders of the skeletal system (vertebrogenic angina pectoris), general weakness.

Tab.1: Ingredients of Cralonin and their characteristics/symptoms.

rated patient tolerance of Cralonin on a four point scale (“excellent,” “good,” “fair,” and “poor”). The physicians were also asked to record any undesired effects of treatment.

In order to include the broadest possible range of indications, the investigators did not specify methods of administration, dosages, and duration of therapy in advance or define any criteria for including or excluding patients. Data were summarized in frequency tables and converted into percentages.

Results

Patient Demographics

Treatment data were recorded for a total of 665 patients, of whom 60% were female. The age groups 51-60 years and 61-70 years were most frequently represented (at approximately 20% each), followed by the age groups 41-50 and 71-80 (slightly over 15% each).

Multiple diagnoses were listed for some patients, yielding a total of 747 individual indications. Cardiodynia was the most fre-

quent reason given for prescribing Cralonin (n = 168), followed by stabbing pains in the heart region (n = 156), inadequate coronary circulation (n = 144), angina pectoris (n = 124), postcoronary conditions (n = 37), and infectious-toxic myocardial insufficiency (n = 33). Other indications included cor nervosum (n = 13), age-related heart disease (n = 6), cardiac arrhythmia (n = 6), and inadequate cerebral circulation, coronary insufficiency, and hypotonia (each at n = 5) (Table 2).

The patients fell into two distinct diagnostic groups with regard to the duration of illnesses prior to the beginning of treatment. Cardiodynia or stabbing pains in the heart region had been present for no more than four weeks in 50% of cases, while more than half of the patients with inadequate coronary circulation or postcoronary conditions and nearly half of the those with angina pectoris had been symptomatic for at least six months. 12% of the patients had been prescribed other forms of therapy before using Cralonin for the first time. Least likely to have undergone previous treatment were patients with

stabbing heart pains (approximately 3%); most likely were patients with postcoronary conditions (approximately 24%). The most frequently prescribed previous medications were beta-blockers, calcium antagonists, ACE inhibitors, and unspecified cardioactive drugs; less frequently prescribed were nitrates, analgesics, psychopharmaceuticals and (in individual cases) homeopathic remedies. There was little correlation between the types of drugs prescribed and the patients’ individual diagnoses. The most frequent reasons listed for initiating Cralonin therapy (either alone or as an adjuvant to standard therapy) were inadequate efficacy and patient intolerance of previously prescribed medications.

Methods of Administration

Cralonin therapy (sometimes including autohemotherapy) was administered in the form of intramuscular injections to approximately half of the patients, while intravenous injection was chosen in 27% of cases, subcutaneous injection in almost 15%, and oral administration in 8%. There was no clear preference for specific methods of administration in different diagnostic groups. In slightly less than 20% of the patient population, Cralonin was used exclusively for acute therapy at a dosage of one ampule per day. With few exceptions, the remaining patients were treated with the standard dosage of one to three ampules per week.

The acute dosage of Cralonin was prescribed disproportionately frequently as an adjuvant therapy in cases of infectious-

Diagnoses	Age (in years)							
	<21	21-30	31-40	41-50	51-60	61-70	71-80	>80
Total (n = 665)	1	3	10	17	21	20	16	12
Cardiodynia (n = 168)	1	4	12	20	29	15	11	8
Stabbing pains in the heart region (n = 156)	2	8	18	22	15	15	11	9
Inadequate coronary circulation (n = 144)	–	1	2	10	15	26	24	22
Angina pectoris (n = 124)	–	1	4	17	27	27	15	9
Postcoronary conditions (n = 37)	–	–	–	8	19	38	19	16
Infectious-toxic myocardial insufficiency (n = 33)	6	3	12	18	25	15	12	9
Other (n = 83)	2	4	13	16	19	18	16	12

Tab.2: Age distribution of patients among different diagnoses for which Cralonin was prescribed. (Multiple diagnoses occurred. Figures are given as percentages and rounded off.)

Diagnoses	Rating of therapy					
	very good	good	satisfactory	no success	worse	n/a
Total (n = 665/360)	39/50	49/41	9/ 8	3/1	-/-	-/-
Cardiodynia (n = 168/113)	44/50	47/40	8/ 9	1/1	-/-	1/-
Stabbing pains in the heart region (n = 156/116)	54/56	39/38	7/ 6	-/-	-/-	-/-
Inadequate coronary circulation (n = 144/54)	27/46	55/43	15/ 9	3/2	-/-	-/-
Angina pectoris (n = 124/56)	32/45	60/53	6/ 2	2/-	1/-	-/-
Postcoronary conditions (n = 37/12)	24/17	54/58	17/25	5/-	-/-	-/-
Infectious-toxic myocardial insufficiency (n = 33/20)	39/40	46/45	9/10	6/5	-/-	-/-
Other (n = 85/32)	40/59	46/32	8/ 3	6/6	-/-	-/-

Tab.3: Physicians' overall evaluation of therapeutic results (Total patient population/patients not receiving concomitant medication. Figures are given as percentages and rounded off.)

toxic myocardial insufficiency and cardiodynia and least frequently in angina pectoris. Duration of therapy was one to two months in one third of all cases and three to four weeks in approximately one quarter, while the two groups receiving treatment for less than two weeks or more than two months each accounted for approximately one fifth of the patient population. Stabbing pains in the heart region and cardiodynia were the diagnoses most frequently requiring only a short course of therapy, while the opposite was true of postcoronary conditions and infectious-toxic myocardial insufficiency.

Concomitant Therapies

In approximately 50% of cases, Cralonin was prescribed as an adjuvant to standard therapy. This occurred least frequently in cases of stabbing heart pains (approximately 30%), heart pain, and infectious-toxic myocardial insufficiency (approximately 40%), more frequently in angina pectoris and inadequate coronary circulation (approximately 60-65%) and most frequently in postcoronary conditions (approximately 84%). In most cases, the standard therapies in question were allopathic medications; the drugs most frequently prescribed were beta-blockers, calcium antagonists and/or ACE inhibitors and unspecified cardioactive drugs.

Tolerance

Overall, the physicians rated tolerance of Cralonin as "excellent" in approximately

70% of the patients and as "good" in nearly 30%. There were no apparent differences in tolerance among different diagnostic groups. No undesired effects were observed in conjunction with the use of Cralonin.

Results of Therapy

Total duration of treatment was shorter for patients who reported initial improvement earlier. Of the total patient population, nearly 90% reported successful results within the first four weeks of treatment. No improvement was observed in only 3%. Approximately two thirds of the patients with stabbing heart pains and cardiodynia responded to Cralonin within the first week of treatment, often after the first injection. Improvement was most frequently noted in patients with inadequate coronary circulation and angina pectoris during the second week of therapy (ca. 30%), but only after four weeks at the earliest in approximately 20% of the patients with postcoronary conditions.

Because it is illegal to require physicians participating in a prospective study to conduct objective assessments such as stress tests, overall ratings of the results achieved were used evaluate the efficacy of the treatment protocols the physicians had selected. In most cases, the physicians rated the results as "very good" or "good" (Table 3).

When the results are evaluated by diagno-

sis, two distinct groupings become apparent. Cralonin was most effective (either alone or as an adjuvant to standard therapy) in cases of stabbing heart pains, cardiodynia, and angina pectoris. Results were rated "good" or "very good" in 90% of the cases in this group, but in only about 80% of patients with inadequate coronary circulation or infectious-toxic myocardial insufficiency.

Conclusions

The results of this prospective study confirm that physicians regularly prescribe Cralonin for many different forms of heart disease, but most frequently as an adjuvant to standard therapy. The best and most rapid results were achieved in treating functional disorders; in such cases, improvement in clinical symptoms was often noted after the first injection. The study also shows, however, that clinical syndromes of suspected or confirmed organic or postinfection origin also respond relatively quickly and well to therapy with Cralonin.

Approximately 50% of the patients received no other treatment in addition to Cralonin. Although it can be assumed that these patients represent the less severe cases, the results nonetheless demonstrate that under certain circumstances Cralonin merits independent status in the spectrum of cardiovascular medications, especially in the treatment of functional and postinfection complaints. For symptoms of or-

ganic origin, Cralonin was often prescribed in combination with allopathic medications, most frequently beta-blockers, calcium antagonists, and ACE inhibitors.

In conclusion, this study demonstrates that the homeopathic remedy Cralonin is well established in the practice of general medicine, where it is prescribed either alone or as an adjuvant to allopathic standard therapy for many different forms of heart disease. Because of its broad range of therapeutic efficacy, Cralonin is often combined with other medications. It has failed

to induce side effects even when used in this manner and/or for extended periods of time, so it is safe to assume that the benefits of Cralonin therapy significantly outweigh any risks.

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Cralonin®

Drops, Injection Solution

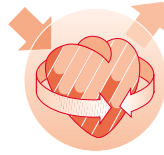
Composition: Drops: 100 ml cont.: Crataegus 0.70 ml; Spigelia anhelmia D2, Kalium carbonicum D3 1 ml each. Contains 45 vol.-% alcohol. Injection solution: 1.1 ml cont.: Crataegus D2 8.8 µl; Spigelia anhelmia D1, Kalium carbonicum D2 1.1 µl each. **Indications:** Drops: Geriatric heart, sequelae of myocardial damage, nervous cardiac disorders, piercing cardiac pain, and cardiac pain of other types (e.g., anginous complaints). Injection solution: Coronary insufficiency, angina pectoris, piercing cardiac pain, cardiac pain of other types, infectious-toxic myocardial insufficiency, status following myocardial infarction. **Dosage:** The physician should determine dosage in accordance with the individual needs of the patient. Drops: Typical dosage for longterm therapy: 10-20 drops, 3 times a day; in case of acute symptoms, 10 drops every 15 minutes at the beginning of severe complaints (Caution: the patient should not take the medication in this dosage over lengthy periods of time without control by a physician). Injection solution: In case of acute symptoms, 1 ampoule daily (possibly even every 6-8 hours), otherwise 1 ampoule 3-1 times weekly i.m., s.c., i.d., i.v. **Package sizes:** Drops: Drop bottles containing 30 and 100 ml. Injection solution: Packs containing 5, 10, 50 and 100 ampoules of 1.1 ml.



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