

Gastrointestinal therapy with Nux vomica-Homaccord

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ABSTRACT

Nux vomica-Homaccord is a homeopathic combination medication used to treat a variety of diseases and functional disorders of the gastrointestinal (GI) tract as well as symptoms related to abuse of caffeine, nicotine or alcohol. The purpose of this drug monitoring study was to document the mode of application, therapeutic efficacy and tolerability of Nux vomica-Homaccord in a large number of patients. 1153 cases of treatment yielded data suitable for statistical analysis. Implementation of therapy (i.e., dosage, duration of treatment and use of adjunct pharmaceutical or naturopathic therapies) was left to the discretion of the participating physicians. No criteria for inclusion or exclusion of patients were defined. The results of the study demonstrate that Nux vomica-Homaccord, as used in everyday practice, is a safe and effective treatment for all indications specified by the manufacturer. In general, patient tolerance of the medication was good, although adverse drug reactions were reported in five individual cases.



Keywords: Nux vomica-Homaccord, drug monitoring, functional disorders of the gastrointestinal tract

INTRODUCTION

At some point in life, virtually everyone suffers from functional GI disorders. Diseases and malfunctions of this organ system appear in many different forms and degrees of severity. Gastritis is one frequent and often stubborn stomach complaint; it is more commonly diagnosed in smokers⁽¹⁾. Overconsumption of spicy foods, alcohol or coffee can also cause stomach symptoms. Approximately 15 percent of the general population develop a GI ulcer at least once in the course of a lifetime, with men affected three times as often as women⁽²⁾. Duodenal ulcers occur five to ten times as frequently as ulcers of the stomach mucosa⁽³⁾. Another frequent GI disorder is irritable bowel syndrome, which primarily affects the large intestine and causes a tendency to constipation and/or diarrhea⁽⁴⁾. Other important intestinal disorders include diverticulitis, Crohn's disease (regional enteritis), ulcerative colitis and colon cancer.

Today a plethora of medications is available for treating GI disorders. Under the heading "gastrointestinal medication," the "Red List" (the German counterpart of the PDR) lists many different types of products (such as acids and antacids, adsorbents, carminatives, ulcer medications and digestive enzymes), all of which can be incorporated into treatment protocols for definitively diagnosed ailments. It is worth noting, however, that no obvious organic changes are found in 40 to 60 percent of all patients who consult a physician for GI symptoms⁽⁶⁾. A broad-spectrum homeopathic regulation medication not only offers help in these cases but also supports self-healing in clearly diagnosable disorders.

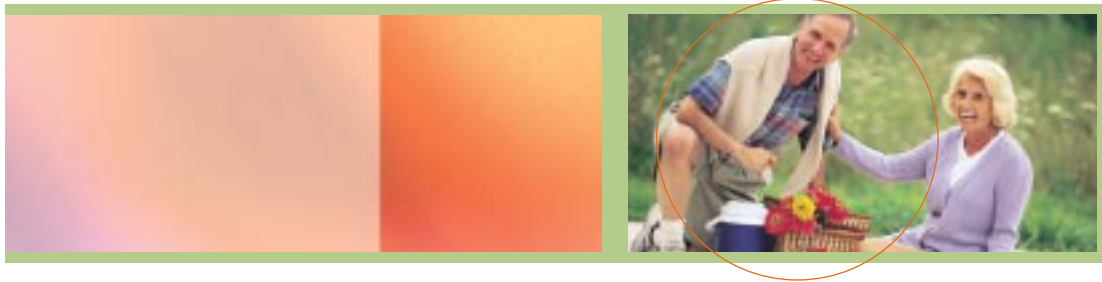
The homeopathic combination medication Nux vomica-Homaccord (manufactured by Biologische Heilmittel Heel GmbH of Baden-Baden, Germany) is able to effectively treat a wide variety of different GI diseases and malfunctions due to the interaction of its four individual remedies (nux vomica, bryonia, lycopodium and colocynthis). See also the Commission D's monographs for these remedies⁽⁷⁻¹⁰⁾.

Methods

The purpose of this drug monitoring study was to compile data on mode of application, efficacy and tolerability of Nux vomica-Homaccord in a large number of patients. The product is available as an injection solution and as drops for oral administration. For purposes of this study, only the oral form was prescribed. A total of 125 licensed physicians from four European countries (Austria, Belgium, Germany and Portugal)

participated in this drug monitoring, which ran from April to September 1993 and was conducted as a prospective study. No criteria for inclusion or exclusion of patients were defined. All data on the patients' illnesses and details of therapy were recorded on standardized questionnaires. Upon conclusion of therapy, overall therapeutic outcome for each patient was rated on a five-point scale ("very good" = complete freedom from symptoms, "good" = significant improvement, "satisfactory" = slight improvement, "unsuccessful" = no change in symptoms, and "symptoms worsened"). Any incidence of adverse effects that occurred in conjunction with administration of Nux vomica-Homaccord were recorded on a separate questionnaire.

Although entries were missing from a few questionnaires, the quality of the data was high enough for all of the documented cases of treatment to be included in statistical analysis. Data were compiled with the help of a computer program and then analyzed using descriptive statistical procedures.



RESULTS

Patients and diagnosis

A total of 1153 patients were included in the study. At 54 percent, women accounted for a slightly larger percentage of the total patient population than men. Figure 1 shows the age and gender distribution of the patients.

For the sake of clarity, the diagnoses reported by the participating physicians were grouped together under four headings: 1) functional disorders of the stomach, 2) functional disorders of the intestines, 3) symptoms related to abuse of nicotine, alcohol or coffee and 4) other diagnoses. Multiple listings occurred, partly due to the close physiological relationship between the stomach and intestines and partly because abuse of the above-listed legal drugs was the cause of GI symptoms in many cases (see Figure 2).

Physicians reporting cases of stomach or intestinal disorders were asked to enter specific diagnoses and symptoms in the questionnaires. Table 1 lists diagnoses and symptoms that were reported for more than 2 percent of the patients. The heading "other diagnoses" includes such ailments as liver abnormalities, headache, migraine and diabetes.

Duration of illness

Duration of illness prior to beginning treatment varied considerably among patients and seemed unrelated to diagnosis, which suggests that the study included both patients with acute illnesses as well as those with chronic conditions. Within the patient population as a whole, duration of illness was less than one week for approximately 25% of patients and two to four weeks for 20%. 13% of the patients had been ill for five to eight weeks, 14% for two to six months, 9.8% for seven to twelve months and 18.7% for more than one year.

Prior treatment

Of the 1153 patients admitted to the drug monitoring study, 35.9% had taken medication for their illness in the six months prior to admission to the study. Within individual diagnostic groups, the percentage of pretreated patients ranged from 30.9% (symptoms related to abuse of caffeine, nicotine or alcohol) to 53.4% (other diagnoses). Categorizing prior therapies according to the Red List's main groups of pharmaceuticals revealed that GI medications (57.5%) and spasmolytics (7.5%) had been most frequently prescribed, while homeopathic medicines had been prescribed for only 6.5% of patients.

Dosage

According to the manufacturer's recommendations, Nux vomica-Homaccord can be used not only as intensive therapy for acute symptoms (10 drops every 15 minutes for up to two hours) but also in long-term treatment (standard dose = 10 drops three times a day). The dosage prescribed was reported for 1131 of the 1153 patients. Approximately 89% of these patients received long-term treatment with the recommended standard



dose; for the remainder, the dosage was slightly different, with the maximum daily dose being 30 drops three times a day. In 38% of these cases, treatment began with a period of intensive therapy.

In almost all cases (98.7%), the initially prescribed dosage of Nux vomica-Homaccord was maintained over the entire treatment period. In 1.3% of cases treated, the dose was reduced as therapy progressed. In no instance was the initially prescribed dose increased.

Concomitant therapies

Somewhat more than half of the patients were treated exclusively with Nux vomica-Homaccord. In the remaining cases, additional pharmaceutical and/or nonpharmaceutical therapies were implemented. Although GI medications had been the most frequently prescribed type of prior medication, they figured less prominently (at 22.8%) in this study. In contrast, other homeopathic medicines (at 64.7%) were the most frequently prescribed concomitant medications. Among the nonpharmaceutical adjuvant therapies, dietary measures (at 82.7%) took first place, as expected.

Duration of treatment

Duration of treatment varied quite widely among patients and seemed unrelated to diagnosis. 40% of patients were treated for up to two weeks, another 40% for two to five weeks, while only 20% of the patients required treatment for longer than five weeks. As with duration of illness, discussed above, these differences in duration of treatment are explained by differences in severity of illness and by the fact that both acute and chronic cases were included in the study.

Results of therapy

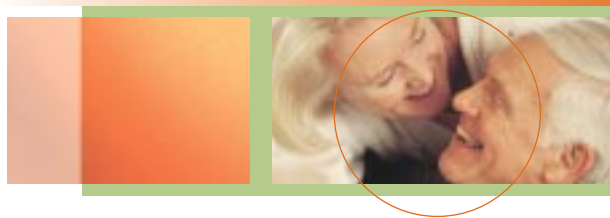
To assess the therapeutic efficacy of a medication, it is important to gather information about how quickly it takes effect. For this reason, each patient's physician was asked to record the approximate timing of the first improvement in symptoms. Out of the entire patient population, 17.3% reported improvement soon after first taking Nux vomica-Homaccord. Almost half of the patients reported improvement within the first week of treatment, 22.2% after two to three weeks, 5.4% after four to five weeks, and 1.4% after six to eight weeks of treatment. Only 0.5% reported improvement that began after more than eight weeks of therapy. Approximately 5% of patients completed the course of therapy without reporting any improvement.

These findings are also reflected in the therapeutic outcomes reported by the physicians upon conclusion of therapy. For more than 80% of the patients, efficacy of the therapy was rated "very good" or "good." Treatment was unsuccessful in only 5% of patients, and symptoms worsened in only 0.3% (see Figure 3). Therapy with Nux vomica-Homaccord was effective in all diagnostic groups and rated "very good" or "good" for over 80% of patients in each of the four categories.

To estimate the influence of concomitant therapies on outcomes, Figure 4 compares the results for all patients receiving adjuvant therapies to the results for all monotherapy patients; Table 2 compares results by diagnostic groups. The data make it clear that in all four diagnostic groups, Nux vomica-Homaccord was effective even as monotherapy. The percentage of "very good" or "good" therapeutic outcomes is slightly higher for the monotherapy group than for patients receiving adjuvant therapies, possibly because additional pharmaceutical or nonpharmaceutical treatment was more likely to be prescribed for patients with less favorable prognoses, i.e., those whose initial symptoms were more severe.

Tolerability

Since among the 1153 patients treated, only five reported adverse effects that were associated with administration of Nux vomica-Homaccord, the rate of adverse drug events (at 0.43%) must be considered low. After taking the medication, two patients experienced vertigo and one the beginning of a migraine; one patient reported heartburn and another vertigo, headache and heartburn. In the two latter cases, therapy was discontinued due to adverse effects. Only the patient who developed a migraine required treatment for side effects; she used a medication containing paracetamol (acetaminophen). In evaluating the symptoms reported as side effects, it is important to remember that vertigo and headache are part of the drug picture of nux vomica⁽⁷⁾. These symptoms may therefore be interpreted as initial reactions to the homeopathic medication's stimulating effects on the body's self-healing mechanisms. One case of heartburn may have been due either to the medication's alcohol content or to excessive coffee consumption, while the second may have been related to the patient's original complaint (nausea). On the whole, however, it must be noted that all adverse effects were temporary and reversible; in no case did they cause permanent damage.



DISCUSSION

Gastrointestinal disorders are widespread and often difficult to treat due to their chronic or recurrent character. This study shows that many of the GI diseases and malfunctions observed in daily practice respond well to homeopathic treatment. In many cases, a homeopathic regulation medication such as Nux vomica-Homaccord is indicated to support self-healing. The advantages of this medication are especially relevant to patients who present with symptoms but with no detectable pathologies or whose symptoms change so rapidly that targeted therapy with allopathic “anti” medications cannot produce long-term success. Because of Nux vomica-Homaccord’s broad spectrum of activity, it can be expected to be reliably effective for a relatively broad array of symptoms in both acute and chronic conditions. This expectation is confirmed by the high rate of “very good” and “good” therapeutic outcomes achieved in all diagnostic groups. In assessing therapeutic outcomes, it is important to take into account that in GI conditions, in particular, successful treatment is heavily dependent on the patient’s cooperation – for example, in temporarily avoiding the caffeine, nicotine or alcohol that provoked symptoms in the first place.

This study also demonstrates that under certain circumstances, Nux vomica-Homaccord is effective even when used alone, as confirmed decisively by the high success rates for patients in monotherapy. The decision to use Nux vomica-Homaccord alone or in combination with other medications should be left to attending physicians who know their patients’ medical histories and are in a position to consider the severity of the patient’s illness and the presence or absence of concomitant illnesses when deciding on a course of treatment.

This drug monitoring study also confirms the findings of Hilsenitz, who investigated the therapeutic applications of Nux vomica-Homaccord in routine use⁽¹¹⁾. In a prospective study of 30 patients (average age 39.2 years), this medication was administered to 21 women and nine men suffering from acute or chronic gastritis. Dosage was 10 drops three times a day; no concomitant medications were prescribed. The design of the study included monitoring each patient’s progress once a week. Parameters documented were: pain when fasting, nocturnal pain, nausea and upper abdominal pain. Upon conclusion of therapy, outcomes were rated “good” for 83.3% of patients and “fair” for 6.7%. Therapy was unsuccessful in 10% of patients.

The present drug monitoring study also confirms that the use of Nux vomica-Homaccord makes it possible to eliminate or reduce allopathic drug therapy and its associated side effects. In contrast to prior treatments, conventional medications played a greatly reduced role during treatment with Nux vomica-Homaccord. The opposite was true of concomitant homeopathic medicines, prescribed relatively infrequently (in 6.5% of cases) as part of the patients’ prior treatment but in 64.7% of cases as adjuvants to therapy with Nux vomica-Homaccord.

Because drug-monitoring studies document large numbers of cases, they are better suited than clinical studies to determining how well a medication is tolerated. With five cases of adverse effects in 1153 patients, tolerability of Nux vomica-Homaccord can be described as good, confirming conclusions drawn from years of practical experience with this medication. Furthermore, it is important to note that some of the reported incidents of adverse effects can be interpreted as initial responses to the medication’s stimulating effects on endogenous self-healing mechanisms, while others may have been related to the patient’s original illness.

Tab. 1: Diagnoses listed for more than two percent of patients with functional gastrointestinal disorders.

| Diagnosis/symptoms (stomach) | N | Diagnosis/symptoms (intestines) | N |
|------------------------------|-----|---------------------------------|----|
| Gastritis | 182 | Typanites | 95 |
| Vomiting | 93 | Diarrhea | 70 |
| Nausea | 80 | Constipation | 50 |
| Gastralgia | 53 | Flatulence | 35 |
| Heartburn | 49 | Irritable bowel syndrome | 31 |
| Sensation of fullness | 48 | Intestinal spasms | 28 |
| Dyspepsia | 31 | Colitis | 23 |
| Belching | 20 | Spastic colon | 23 |
| Gastroenteritis | 18 | Enteritis | 14 |
| Irritable stomach | 17 | Colic | 12 |
| Typanites | 14 | Disorders of fecal elimination | 11 |

Tab. 2: Comparison of therapeutic outcomes in patients receiving concomitant therapies (left) and patients receiving monotherapy (right).

| Diagnostic group | very good in % | good | satisfactory | unsuccessful | symptoms worsened |
|---|----------------|-----------|--------------|--------------|-------------------|
| Functional disorders of the stomach (n = 327/357) | 33.6/50.1 | 48.9/39.5 | 8.9/5.9 | 8.3/3.9 | 0.3/0.6 |
| Functional disorders of the intestines (n = 269/188) | 36.4/45.2 | 45.0/38.8 | 11.5/10.1 | 7.1/5.9 | -/- |
| Discomfort after use of caffeine, nicotine, alcohol (n = 260/398) | 35.8/55.0 | 48.8/38.4 | 7.3/3.3 | 8.1/3.0 | -/0.3 |
| Other diagnoses (n = 81/35) | 32.1/37.1 | 44.4/60.0 | 17.3/2.9 | 6.2/- | -/- |

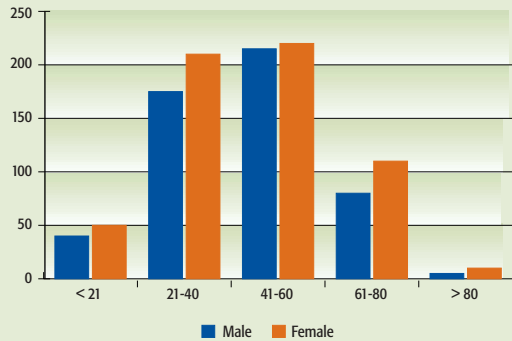


Fig. 1: Age and gender distribution in the patient population.

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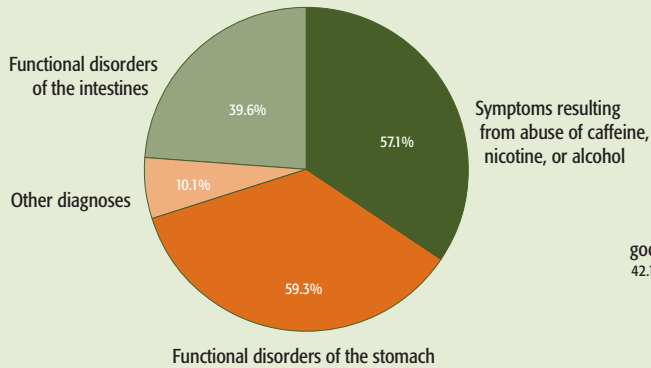


Fig. 2: Percentage of total patient population in each diagnostic group (multiple listings occurred, n=1153).

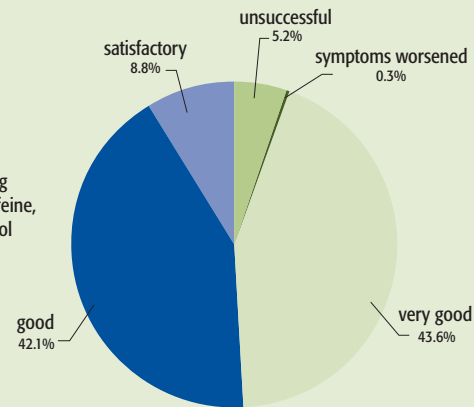


Fig. 3: Final ratings of therapeutic efficacy (n=1153).

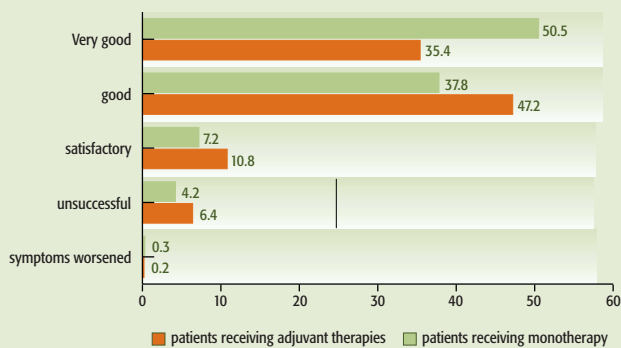


Fig. 4: Comparison in percentages of ratings of therapeutic efficacy between patients receiving adjuvant therapies (n = 528) and patients receiving monotherapy (n = 625)

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