Journal of Complementary and Alternative Medical Research

Volume 23, Issue 1, Page 46-51, 2023; Article no.JOCAMR.100086
ISSN: 2456-6276

Clinical Effectiveness of Hawthorn, Lemon Balm and Magnesium on Patients with Distress Disorders: Preliminary Data by a Survey of Italian Gastroenterologists

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Authors' contributions

This work was carried out in collaboration between both authors. Both authors read and approved the final manuscript.

Article Information

DOI: 10.9734/JOCAMR/2023/v23i1471

Open Peer Review History:
This journal follows the Advanced Open Peer Review policy. Identity of the Reviewers, Editor(s) and additional Reviewers, peer review comments, different versions of the manuscript, comments of the editors, etc are available here: https://www.sdiarticle5.com/review-history/100086

Original Research Article

Received: 01/05/2023
Accepted: 16/05/2023
Published: 15/07/2023

ABSTRACT

Aims: distress disorders (DD) include psychological symptoms such as sleep disorders, fatigue and psychophysical exhaustion that are common to many mental diseases. DD is often associated with somatic symptoms such as abdominal pain or bowel dysfunction. The aim of this study was to evaluate in patients with DD the effectiveness of a nutraceutical containing Hawthorn, Lemon Balm, and Magnesium (Vagostabil®) on psychological and abdominal symptoms. For this purpose, a clinical survey was conducted by 7 Italian gastroenterologists.
Methodology: 85 patients with DD (60 F, mean age 51,6 yrs), identified by a score > 18 based on the Hamilton Anxiety Rating Scale (HAM-A), were included in the study. All patients assumed

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Vagostabil®, three tablets a day for two months. The same HAM-A score and a VAS score for abdominal pain were used to measure clinical results.
Results: the mean score of the HAM-A scale decreased from 28.61 to 18.22 after 1 month and to 11.46 after 2 months of treatment respectively (P = .001 for all comparisons). An overall reduction of HAM-A score by 59.94 % was observed at the end of the treatment (P = .001). Similarly, VAS score for abdominal pain decreased from 7.59 to 4.86 after 1 month, and to 2.41 at the end of the treatment (P = .001 for both comparisons). A global reduction of 68.25% in the VAS score was observed at the end of the survey (P = .001).
Conclusion: this clinical survey showed that Vagostabil® can ameliorate psychological symptoms and associated abdominal pain in patients with DD. These preliminary data suggest that Vagostabil® could be utilized by gastroenterologists in functional gastrointestinal disorders. However, further studies are needed to confirm these data.

Keywords: Distress disorders; Irritable bowel disorders; hawthorn; lemon balm; magnesium.

1. INTRODUCTION

A universally accepted definition of distress is difficult to achieve and consequently, it remains a controversial clinical concept.

However, the definition of distress by the National Comprehensive Cancer Network (NCCN) describes a multifactorial unpleasant experience of a psychological (i.e., cognitive, behavioral, emotional), social, spiritual, and/or physical nature that may interfere with cancer management [1].

Generally speaking, distress disorders (DD) include a set of unpleasant sensations related to psychophysical exhaustion, such as chronic fatigue, interpersonal problems, sleep disorders, emotional disturbances, and psychosomatic disorders [2,3]. Among psychosomatic disorders, abdominal pain is one of the most frequently reported problems.

One of the most important diseases of the gastrointestinal tract that is linked to psychological distress is irritable bowel syndrome (IBS), which represents a common, and heterogeneous gastrointestinal disorder with a worldwide prevalence of 10-20% [4]. The pathogenesis of IBS is multifactorial but the dysregulation of the brain-gut axis with visceral hypersensitivity is a well-known mechanism. One of the major scientific challenges in the present day is understanding the interactions between the central nervous system and the enteric nervous system. Apart from bloating and evacuation problems, abdominal pain is the most significant symptom of this functional disorder. Also, there is a considerable overlap of the disorders of brain-gut interaction with other visceral and somatic “functional” pain syndromes (including urological pelvic pain syndromes, vulvodynia, fibromyalgia, and chronic back pain), and with psychiatric disorders, in particular, anxiety and depression.

The treatment of functional digestive disorders is multimodal, symptom-related, and includes pharmacological and non-pharmacological measures. An increasing number of gastroenterologists tend to use complementary and alternative medicine. Herbal preparations and nutraceuticals have also been the subject of several trials but the results were sometimes controversial [5].

In particular, Vagostabil® is a nutraceutical containing Hawthorn (Crataegus oxyacantha), Melissa (Melissa Officinalis), and Magnesium (Table 1), providing a potential benefit in states of stress, nervous tension, irritability, and agitation. Hawthorn is a fruit-bearing shrub with a long history as a medicinal substance. It has been also used for the treatment of digestive ailments, dyspnea, kidney stones, and cardiovascular disorders [6].

Table 1. Nutraceutical (Vagostabil®) composition

Components	Dosage	% VNR
Hawthorn:	690 mg:	
Crataegus oxyacantha	483 mg	
Crataegus monogyna	207 mg	
Flavonoids	10,35 mg	
Melissa officinalis	510 mg	
Rosemary acid	20,4 mg	
Magnesium	150 mg	40%

Based on this evidence, the aim of this clinical survey was to evaluate the effects of Vagostabil® in the treatment of psychological distress and abdominal pain in patients followed by gastroenterologists.

2. MATERIALS AND METHODS

2.1 Study Design

Consecutive patients with DD, followed by seven Italian gastroenterologists, were recruited. Inclusion criteria were age >18 years and basal score distress higher than 18 based on the Hamilton Anxiety Rating (HAM-A) Scale [7].

Patients with pregnancy, organic systemic disease, major psychological disorders, current alcohol or drug abuse or dependence, or concomitant anxiolytic and antidepressant therapy were excluded from the study. A potential intolerance to one or all components of nutraceuticals was excluded before the treatment.

In all recruited patients Vagostabil was orally administered three times a day for two months.

For each patient, the extent of distress was investigated using the HAM-A scale. The HAM-A scale was composed of 14 points, each defined by a series of symptoms, both psychic anxiety (mental agitation and psychological stress) and somatic anxiety (physical disorders related to anxiety). Each item was scored on a scale ranging from 0 (not present) to 4 (severe). The scale has a total score ranging from 0 to 56, where a score < 17 indicates mild generalized anxiety disorder, a score between 18 and 24 mild to moderate generalized anxiety disorder, a score of 25 to 30 moderate to severe generalized anxiety disorder, and a score greater than 30 very severe generalized anxiety disorder.

In addition, a VAS scale was also used to evaluate the level of abdominal pain. The VAS scale was scored from 0 to 10, where 0 indicates no pain, 1 to 3 mild pain, a score from 4 to 6 moderate pain, and a score from 7 to 10 severe pain.

Both scores were evaluated at baseline (T0), after one month (T1), and after two months (T2) of treatment, in order to demonstrate a clinical improvement.

Finally, any adverse events and possible dropout cases were recorded.

2.2 Statistical Methods

First of all, descriptive statistics of all the variables were calculated: for the qualitative variables, the numbers and percentages were reported, and for the quantitative ones, the main indices (mean, median, quartiles, minimum, maximum, and standard deviation).

The variables were almost all of the ordinal type, therefore non-parametric tests were conducted to verify the hypotheses.

As regards the VAS scale, measured at times T0, T1, and T2, the Friedman test was used to verify any significant difference. In the case of statistical significance, Dunn's post hoc tests were conducted to verify the achieved results.

With respect to HAM-A, measured at times T0, T1, and T2, the Friedman test was also used.

For all tests, the level of significance considered was p= .05. Statistical analyses were conducted with IBM SPSS v25 software.

3. RESULTS

The data of a total of 85 patients followed by gastroenterologists were collected. The sample was composed of 69 females and 16 males and the mean age was 51,6 years.

3.1 HAM-A Scale Score

The mean score of the HAM-A scale decreased from 28.61 at T0 to 18.22 at T1 and to 11.46 at T2. Considering the score reduction in percentage terms, the HAM-A score decreased by 36.21% from T0 to T1, by 37.10% from T1 to T2, and considering the total time treatment by 59.94% from T0 to T2 (p = .001 for all comparisons) (Fig. 1).

3.2 VAS Score

VAS scale score for abdominal pain dropped from 7.59 at T0 to 4.86 at T1, and to 2.41 at T2. Considering the score reduction in percentage terms, the VAS score decreased by 35.97% from T0 to T1 and by 50.41% from T1 to T2 (p = .001 for both). With respect to the global VAS score variation at the end of the treatment (T0 vs T2), a reduction of 68.25% (p= .001) was observed (Fig. 2).

Finally, neither adverse events nor dropout cases were recorded.

4. DISCUSSION

This study showed that a nutraceutical based on Hawthorn, Melissa, and Magnesium has

the potential to significantly reduce the degree of distress in 54% of patients after two months of treatment, without significant adverse events.

These data confirm the results of a previous real-life study conducted on patients followed by neurologists and neuropsychiatrists suffering from a generalized anxiety disorder [8,9].

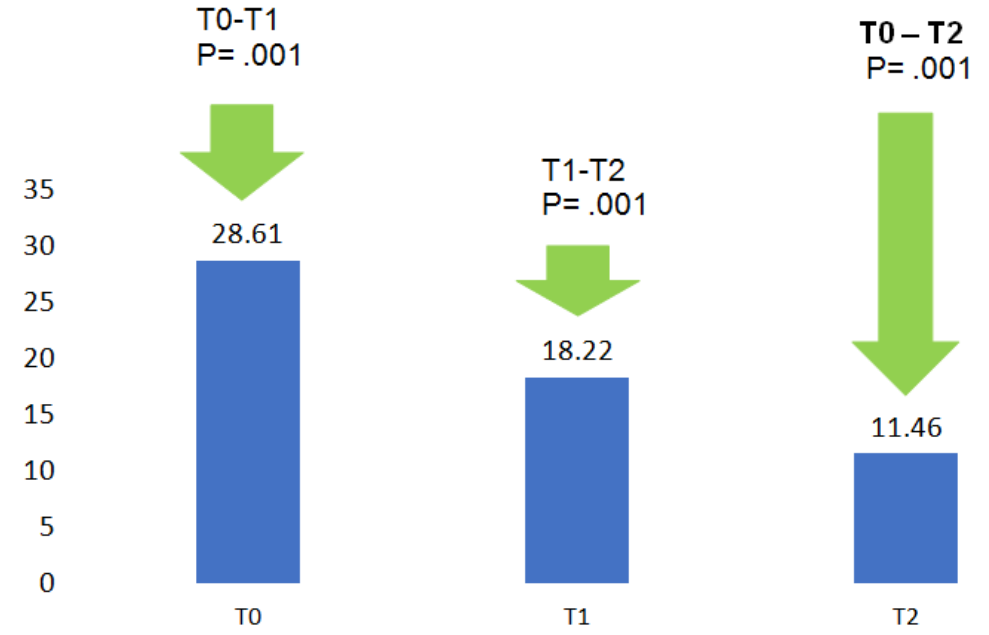

Fig. 1. HAM-A (Hamilton anxiety rating) scale score variation after treatment
T0, basal time; T1: 30 days; T2: 60 days

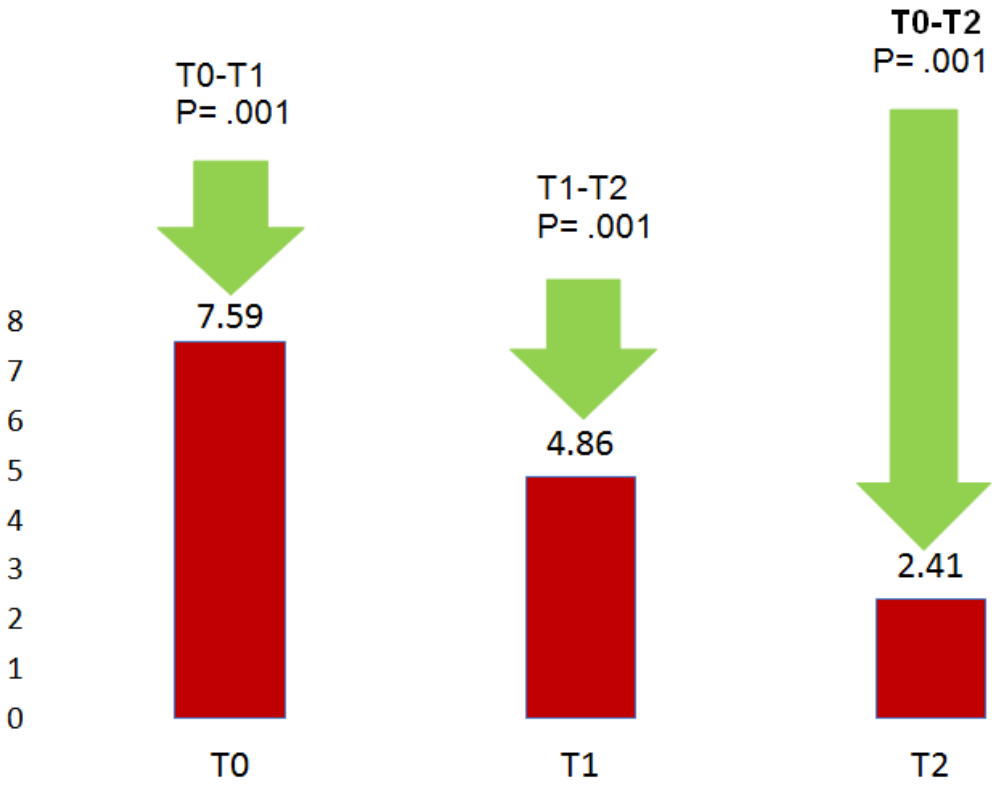

Fig. 2. VAS (Visual Analogue Scale) variation after treatment
T0, basal time; T1: 30 days; T2: 60 days

In addition, this nutraceutical achieved a significant reduction of abdominal pain as demonstrated by the significant reduction of VAS scale score by 68.25% compared to baseline values. Similar results were observed in a previous study in which Vagostabil® was administered for 28 days [10].

As regards the mechanisms by which this nutraceutical acts, its properties can be attributed to the synergic action of the various components. In particular, the hawthorn has a relaxing muscular activity, especially on the heart, and stabilizes the physiological nerve transmission [11,12]. On the other hand, Melissa officinalis has potential activity on the gastrointestinal tract, reducing gas production and exerting spasmolytic activity on the smooth muscles of the gut. This spasmolytic action is not a cholinergic effect, but it is due to a blocker action on calcium channels [13]. Finally, Magnesium is a fundamental element for the maintenance of normal neuromuscular and circulatory functions. It plays a primary role in maintaining the efficiency of the mechanisms of cellular energy production. Magnesium intake can, therefore, help in situations of stress and muscular tension. [14].

IBS is a common intestinal disorder causing abdominal pain but also bloating, diarrhea, and constipation and it is frequently associated with psychological problems [4,5,15]. The therapeutic options depend on the intensity of symptoms, IBS subtype, and the degree of psychosocial comorbidities. In case of failure of first level medical approach an alternative and complementary medical intervention can be proposed. Herbal preparations or nutraceuticals have the potential to improve both abdominal and psychological complaints. These preliminary data showed that this food supplement can be an alternative therapeutic resource for gastroenterologists although further randomized controlled studies are needed to confirm these promising data.

5. CONCLUSION

Vagostabil® can ameliorate psychological and abdominal complaints in patients with DD. Therefore these preliminary data suggest that this nutraceutical can be of help in the management of functional gastrointestinal diseases with psychosocial comorbidities in a gastroenterological clinical setting.

CONSENT

All authors declare that written informed consent was obtained from all patients

ETHICAL APPROVAL

As per international standard or university standard written ethical approval has been collected and preserved by the author(s).

COMPETING INTERESTS

Authors have declared that no competing interests exist.

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Peer-review history:
The peer review history for this paper can be accessed here:
https://www.sdiarticle5.com/review-history/100086