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Wirkung von Caricol® beim Reizdarmsyndrom –
Effect of Caricol® on the Irritable Bowel Syndrome

Harald Vogelsang¹, Franz Brenner²

Abstracts


Methoden: Fünfzehn Patienten mit Diarrhö-dominiertem IBS erhielten zwei Caricol®-Sticks pro Tag über einen Monat lang. Die Dosis konnte entsprechend der Anzahl der Stühle erhöht oder vermindert werden. Der Behandlungserfolg wurde mittels Fragebögen evaluiert, die sich auf IBS-Symptome und psychologische Parameter wie Angst und Depression (HAD) bezogen.

Ergebnisse: 87 % der Patienten berichteten über Schmerzreduction, die sich zwischen leicht bis vollständig bewegte. Stimmung und Angst wurden ebenfalls verbessert (p=0.002). Die Behandlung hatte jedoch keinen Effekt auf Depressivität.

Diskussion: Caricol® lässt sich gut mit anderen Standardtherapeutika für IBS vergleichen. Ein positive Wirkung beim Diarrhö-dominierten IBS kann mit Gabe von 2 Sticks pro Tag innerhalb von 4 Wochen erreicht werden, dies muss jedoch erst durch weitere placebokontrollierte Studien bestätigt werden.

Schlüsselwörter: Reizdarmsyndrom, viszerale Hypersensitivität, Diarrhö, Papaya, Phytotherapie

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INTRODUCTION

Functional gastrointestinal diseases are defined by symptoms which are not the consequence of structural organic intestinal changes. 10 % to 30 % of the Western population – depending on the used criteria and the underlying population – might suffer from irritable bowel syndrome (IBS). 1, 2, 3, 4 Approximately 50 % of the afflicted women are seeking medical attention for this matter. Medical help is desired because the patients have to cope with a substantially less quality of life and consequently with a restricted ability to work as well as a certain psychological strain. 2, 3, 4

Nowadays diagnosis of the IBS is done by means of the Rome II criteria 5 – recently the Rome III criteria are already available – which have generally been accepted in the meantime consisting of three main criteria: Abdominal pain or discomfort for twelve weeks (not necessarily consecutive) or longer during the previous twelve months with at least two of the following characteristics: 1. diminished after each defecation, 2. combined with a change of stool frequency, 3. combined with a change of stool consistency.

The IBS can be divided into three subgroups according to the predominant symptoms 7, 8, 9: 1. diarrhoea-dominated IBS (more than three defecations daily), 2. constipation-dominated IBS (less than three defecations weekly), 3. pain-dominated IBS.

It is not rare that all three forms can be observed in one person, however at different points of time. Although IBS is a functional and therefore harmless disease, it can lead to absenteeism from work and partially to disablement due to the agonizing, chronic disturbances. Unfortunately, no causal treatment has been identified so far. For every therapeutic option, the lack of adverse events is one of the most important conditions.

Due to the big therapeutic demand further harmless and cheap agents or therapeutic strategies are looked for all over the world. Dietetic interventions are desired especially from the patients because an association between food ingestion and exacerbation of the abdominal discomfort is often observed. Therefore, preparations like Caricol® – a special preparation of the papaya fruit – which forms a link between food supplement and enzymes are welcome. 8

According to previous unpublished observations, Caricol® seems to be effective in the field of constipation and possibly also in chronic diarrhoea. Due to the fact that many IBS-patients suffer alternately from constipation and diarrhoea, Caricol® could support recovery in both situations. Moreover, a reduction of flatulence and thus of pain/discomfort due to bowel extension might be feasible. Therefore we tried to investigate the possible benefits in patients with IBS in an observational pilot study.

PATIENTS AND METHODS

We examined the effects of Caricol® (ingredients of Caricol® are: pulp of ripe papayas (99.45 %), lemon juice concentrate (0.5 %), and natural papaya flavour (0.05 %), Manufacturer: Botanical Products International, F. M. Brenner GmbH, Hauptstraße 10, 2392 Wienerwald/Grub, Austria) in patients suffering from diarrhea-dominated IBS. 15 patients fulfilling the Rome II criteria were offered a treatment with Caricol® free of charge for the duration of one month. 12 women and 3 men (median age: 55 years, range: 23 – 65 years) were invited and took part and were evaluable for analysis. One woman got lost during the follow-up and thus could not be included in the evaluation. The study was conducted from April 2005 through February 2006.

The recommended starting dosage for the patients was two Caricol® sticks per day. The dosage was reduced to one stick per day if an increase of bowel movements was afflicting. If bowel movements were too scarce, the dosage was increased to two sticks b.i.d. Caricol® was generally taken according to the recommendations, along with lunch or dinner and mostly dissolved in water. As the empty sticks were to be returned to the investigator and counted there, the treatment adherence could be determined precisely.

The effect of the therapy was assessed by questionnaires completed by the patients before and after the treatment. The following details were evaluated at baseline and after 4 weeks: symptoms of the IBS like frequency of bowel movements, stool consistency, abdominal pain and flatulence by means of a VAS and the descriptive Likert-scale (the descriptive grading offers the following attributes: none, slight, modest, moderate, intense, very intensive, complete). Psychological parameters like anxiety and depression were evaluated by the HAD-scale. 10

The primary objective was the proportion of patients with improvement of discomfort/pain after four weeks. Secondary objectives included the proportion of patients with improvement of - flatulence, - stool consistency, - stomach ache and/or belching after four weeks.

By definition, a change of investigated parameters was only acknowledged as significant if more than 80 % of patients experienced improvement after four weeks of continuous treatment, since placebo effects of up to 50 % (38 % to 46 %) could be expected.

Parameters are given as median and range. SPSS and non-parametric tests were used for statistical analyses.

RESULTS

The median duration of treatment was 28 days (24 – 35 days). During this time, patients forgot to take Caricol® only in median twice (0 – 10 times), which indicates a good compliance. Prior to the start of the therapy, the participants experienced a median of three loose bowel movements per day concomitantly with increased abdominal pain which gradually disappeared after the bowel movement. 93 % of the patients also complained about feeling of incomplete defecation.

13 of the 15 enrolled patients (87 %) successfully completed the treatment in the sense of enjoying at least a slight improvement regarding abdominal pain (Fig.1). The indicated numbers in the figure refer to the proportions of patients who experienced at least a certain improvement. Among individual symptoms, according to a Likert scale of 0 (no improvement) to 6 (complete improvement) a particular response was noted regarding flatulence (median: 3), bowel movements (3), stomach ache (3), abdominal pain (3) and stool consistency (3). A rating of 3 is equivalent to a moderate improvement (rated by the patients). Furthermore, social and psychological parameters could be im-
Improvement of abdominal pain (by intensity of change) after 4 weeks therapy with Caricol®.

proved slightly. The self rated capacity to work again showed a moderate to intense improvement (4) as well as mood (3). Anxiety, which was also assessed by means of HAD-S, was significantly reduced from 8.9 to 6.6 (p=0.002) under therapy. Depression was not reduced. Besides, there was no correlation between improvement of anxiety and abdominal pain (p>0.10). Anxiety – at the beginning of the study – had a rather negative impact on the success of the Caricol®-therapy regarding pain (R=-0.5; p=0.02) and flatulence (R=-0.3; p=0.10).

**DISCUSSION**

With an overall response of 87 %, Caricol® is a symptomatic therapeutic aid which could be well compared with other standard therapeutics related to the IBS if this effect would be confirmed in a further randomized controlled study. The effect shown for diarrhoea-dominated IBS could be obtained within four weeks by taking two sticks per day. The best efficacy could be achieved concerning bowel movement, flatulence and pain, but also regarding the subjective working capacity of the participants.

Although the patients might have benefited from the special medical attention with improvement of anxiety during the study, the positive treatment effect cannot be explained solely by this fact, because particularly patients with a high level of anxiety did not respond well to the Caricol®-treatment. In this case, psychotherapy, hypnosis or antidepressant and anxiolytic medical therapy might be recommended earlier.

**SEVERAL MECHANISMS OF EFFECT MAY BE DISCUSSED:**

- Caricol® possesses a laxative effect (unpublished observations) which leads to more frequent bowel movements and a faster intestinal passage of gas and thus to a reduction of abdominal pain and discomfort. This might however induce an insufficient response in diarrhoea-dominated IBS.

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In conclusion, physiological studies of Caricol® have to be performed to elucidate the possible effects of this oral formulation and are currently done. To confirm the positive effects in IBS a double blind study should be initiated. However, already now Caricol® represents a harmless alternative to many other herbal preparations in the treatment of IBS with promising positive effects which would be desired in these patients mainly looking for “biological” therapeutics.

* The ingredients of Caricol® are: pulp of ripe papayas (99.45 %), lemon juice concentrate (0.5 %), and natural papaya flavour (0.05 %). Manufacturer: Botanical Products International, F. M. Brenner GmbH, Hauptstraße 10, 2392 Wienerwald/Grub, Austria, www.bpi-fmb.com, www.caricol.com.

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