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

Harald Vogelsang<sup>1</sup>, Franz Brenner<sup>2</sup>

## Abstracts

**Hintergrund:** Ein Fünftel der Bevölkerung der westlichen Welt leidet im Laufe ihres Lebens an einem Reizdarmsyndrom (IBS), das zwar keine medizinische Bedrohung darstellt, aber eine große Bedeutung für das Wohlbefinden und die Arbeitsfähigkeit der Patienten hat. Bis jetzt ist noch keine ursächliche Therapie des IBS bekannt. Da das IBS keine gefährliche Erkrankung ist, sollte eine Therapie frei von Nebenwirkungen sein. Caricol®\* ist eine Spezialzubereitung – gewonnen aus der Papayafrucht – und schien bei Obstipation wirksam zu sein. Da Patienten mit Reizdarmsyndrom (IBS) oft sowohl an Obstipation als auch Diarrhö leiden, führten wir eine prospektive Pilotstudie durch, um die mögliche Wirksamkeit dieser Präparation unter diesen Bedingungen zu untersuchen.

**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 Schmerzreduktion, 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

**Background:** One-fifth of the population in the Western world suffers from irritable bowel syndrome (IBS) during their life, which may not hold an increased risk for serious medical conditions but has a great impact on the patients' well-being and working ability. To date, no causal treatment is known. Since IBS represents no threatening condition, lack of adverse effects is mandatory for any treatment. Caricol®\*, a special preparation of papaya, seemed to be effective in constipation. As IBS-patients often suffer from both constipation and diarrhoea, we conducted a prospective pilot study in order to recognize a possible efficacy of the agent in this condition.

**Methods:** Fifteen patients with diarrhoea-dominated IBS received two Caricol® sticks per day for one month. The dosage could be increased or reduced according to the number of bowel movements. The treatment success was evaluated by questionnaires which referred to IBS-symptoms and psychological parameters like anxiety and depression (HAD).

**Results:** 87 % of patients reported about pain relief which ranged from slight to complete. Mood and anxiety were also improved ( $p=0.002$ ). However, the treatment did not exert any effect on depression.

**Discussion:** Caricol® can well be compared with other standard therapeutics for IBS. A positive effect on diarrhoea-dominated IBS may be achieved with two Caricol® sticks per day within four weeks, but further randomized controlled studies are necessary to confirm our preliminary results.

**Key words:** Irritable bowel syndrome, visceral hypersensitivity, diarrhoea, papaya, phytotherapy



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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).<sup>1,2,3,4</sup> 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.<sup>2,3,4</sup>

Nowadays diagnosis of the IBS is done by means of the Rome II criteria<sup>5</sup> – recently the Rome III criteria are already available – which have generally been accepted in the meantime<sup>6</sup> 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<sup>7,8,9</sup>:

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.\*

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.<sup>10</sup>

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.

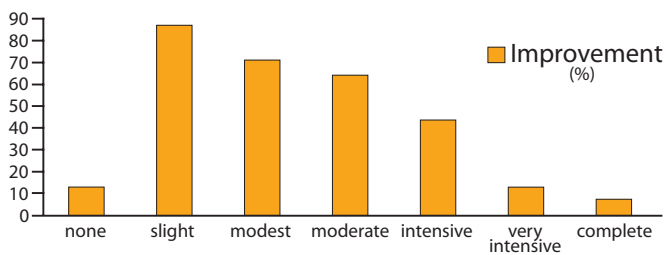
By definition, a change of investigated parameters was only acknowledged as significant if more than 80 % of patients experienced improvement after four weeks of continuous treatment, since placebo effects of up to 50 % (38 % to 46 %<sup>11</sup>) could be expected.

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-



**Figure 1:** 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® is assumed to have enzymatic power – as enzymatic activity has been found – improving digestion of the food components and thus reducing flatulence, pain and diarrhoea. In this way a rather quick response to the treatment can be expected.

- Because of its enzymatic activity, Caricol® promotes the splitting up of food antigens which might otherwise stimulate increased immune reactions e.g. IgG-antibodies and modified functioning of the intestine in individuals with some kind of allergic disposition. Such antigen reduced diets have shown to improve symptoms in IBS. Due to such an effect a slow response to treatment must be expected. Unfortunately such effects on IgG-antibodies could not be found in our patients (data not presented).

- There might be some adrenergic effects on smooth muscles of the intestine inducing relaxation and reduction of cramps. In vitro testing of these effects is in progress.

- 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.

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](http://www.bpi-fmb.com), [www.caricol.com](http://www.caricol.com).

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