Treatment of irritable bowel syndrome symptoms and the role of compounded charcoal - A multicentre study

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Abstract

Aim: Inflammatory Bowel Syndrome (IBS) is characterised by recurrent abdominal pain, diarrhea, constipation or alternating constipation and diarrhea, as well as gassiness and meteorism. The aim of this multicentre study was to demonstrate the efficacy and tolerability of compounded charcoal tablets in a large number of patients with IBS treated over a period of 12 weeks.
Methods: 802 patients from three countries (Hungary, Morocco and Albania) participated in this study [543 patients (68.2%) were female and 253 patients (31.8%) were male]. IBS was diagnosed at the beginning of the study in 756 (95.5%) of 792 patients, of whom 488 patients (59.9%) were with constipation. Diarrhea was diagnosed in 90 patients (12.0%) and in 148 patients (19.8%) alternating constipation and diarrhea. IBS in patients was evident since 36.8±50.2 months. Daily dosage of six pills per day was adapted within the 12-week therapy step-by-step. The dosage was documented at the start of the trial, at week six and at the end of the trial (at week twelve).
Results: Evaluation of the efficacy by physicians and patients at the end of the study (week 12) shows a significant reduction of abdominal pain, significant improvement of symptoms, which are influencing also the quality of life, such as constipation, hard stool, modified bowel movement and abdominal press, abrupt impulse to defecate, sense of incomplete defecation, flatulencies, and abdominal distension.
Conclusion: This multicentre study showed that this highly significant and clinically relevant reduction of abdominal pain, as well as the significant improvement of most of the other symptoms, has a clear impact on the improvement of the quality of life in patients with IBS. The side-effects were few and not relevant. The efficacy and tolerability of this natural compounded charcoal tablets, composed of solely natural ingredients can, therefore, be described as very satisfactory.

Keywords: compounded charcoal tablets, IBS symptoms, quality of life, Rome III criteria.

Introduction

Irritable Bowel Syndrome (IBS) is a disorder characterized by the presence of chronic or recurrent symptoms of abdominal pain, diarrhea, constipation and/or abdominal distension (1). It is a complex disorder involving the brain-gut axis, the etiology of which is incompletely defined. Irritable bowel syndrome is a disorder that is generally underestimated, because it is not a life-threatening disorder, there is no need for surgery and it does not reduce the survival of patients. As a chronic disease, the most important outcome of IBS is the impairment of the quality of life of the patients (2).
Since more than 100 years, compounded charcoal is an efficient worldwide used drug for regulating the activity of the intestinal bowel function. It is a mild laxative and intestinal adsorbent, composed of solely natural ingredients like vegetable charcoal senna leaves, rhubarb root, purified sulfur, essential oils of mint and fennel.
It has a unique dual mode of action, which is depending on the dosage. At a dosage up to 3 pills per day there is mainly an adsorptive action and in a higher dosage the main mode of action is both laxative and carminative in a mild way.
The main symptom in patients with IBS is recurrent abdominal pain (3), which is very often improving after defecation, diarrhea, constipation or alternating constipation and diarrhea, as well as gassiness and meteorism (4).
Following the Rome-III-criteria, the definition of an Irritable Bowel Syndrome is recurrent abdominal pain or abdominal discomfort occurred for at least three days per month during the past three months in connection with at least two of the following symptoms:

- Improvement of the symptoms after defecation;
- Start of the symptoms in connection with changing of the frequency of stool;
- Start of the symptoms in connection with changing of the consistency of stool (5).

In order to demonstrate the efficacy of compounded charcoal tablets in patients with IBS, a large multicentre trial in 802 patients in three countries (Albania, Hungary and Morocco) was conducted between 2005 and 2009.
More specifically, the aim of this multicentre study was to demonstrate the efficacy and tolerability of compounded charcoal tablets in a large number of patients with IBS treated over a period of 12 weeks.

Methods

In total, 802 patients from three countries (Albania, Hungary and Morocco) participated in this study. There were 399 patients from Hungary, 349 patients from Morocco and 54 patients from Albania. Selected patients' data are presented in Table 1.
In 796 patients (99.3%) out of 802 patients data on gender were available. There were 543 (68.2%) female patients and 253 (31.8%) male patients. This allocation is correlating with the experience that the incidence of IBS in women is two to three times higher than in men (6).

Table 1. Patients' data

	Age	Weight at the beginning (kg)	Weight at the end (kg)	Height (cm)
Total Number	789	594		
Average	46.1	69.1	68.4	164.1
Median	45.0	70.0	68.0	166.0
Range	2.0 – 92.0	10.0 – 162.0	12.0 – 162.0	70.0 – 190.0

Diagnosis

In this study, we have evaluated the symptoms and signs in patients treated with eucarbon, whose final diagnosis was IBS. IBS was diagnosed at the

beginning of the study in 756 (95.5%) of 792 patients, of whom 488 patients (59.9%) reported constipation as a concomitant symptom. Diarrhea was diagnosed in 90 patients (12.0%) and in 148 patients (19.8%) alternating constipation and diarrhea was present. On average, IBS in patients was evident since 36.8 months (±50.2 months). Main concomitant diseases were cardiovascular conditions (high blood pressure, chronic heart disease), diabetes, depression, gastritis and duodenal ulcers. Three hundred and nine (40%) of 778 patients were on diet, 23.2% of the patients were smoking and 99 (12.7%) consumed alcohol regularly.

Dosage

The dosage regime was set by the attending physicians referring to the recommended daily dosage of six pills per day and was adapted within the 12-week-therapy step-by-step. The dosage was documented at the start of the trial, at week six and at the end of the trial at week twelve (Table 2).

At the beginning patients took on average 3.7 tablets/day. Until week six the dosage could be reduced to 3.3 tablets/day and at the end of the therapy at week twelve the dosage was on average 3.1 tablets/day. Thirty one percent of the patients were changing the dosage at week six. In 52 patients (7.5%) the therapy was stopped at week six due to lack of symptoms.

Table 2. Dosage of compounded charcoal at the beginning, week 6 and week 12

	Start of the trial	Week 6	Week 12
Average	3.7 (2-6) Pills	3.3 (2-5) Pills	3.1 (2-5) Pills
Median	3	3	3

Results and Discussion

IBS is a common functional gastrointestinal disorder. About 10% of the population has IBS at any one time and about 200 people per 100,000 will receive an initial diagnosis of IBS over the course of a year (7). In the absence of any objective marker, the identification and classification of functional gastrointestinal disorders are based on symptoms (8,9).

The prevalence of IBS has a vide variation among countries and the socioeconomic status of the patients has not been well-described (10).

Nearly 80% of both the physicians and the patients at the end of the 12-week treatment were assessing the therapy as very well and well, while there were just minor differences between the assessment of medical doctors and patients (Table 3).

Table 3. Evaluation of the efficacy by physicians and patients at the end of the study (week 12)

Efficacy	Very well	Well	Medium	Ineffective	Total
Physicians	280	253	105	30	668
	41.9%	37.9%	15.7%	4.5%	100%
Patients	250	279	102	37	668
	37.4%	41.8%	15.3%	5.5%	100%

The efficacy was assessed as very well and well in 533 patients (79.8%) by physicians and in 529 cases (79.2%) by the patients. Also, the tolerability assessed by physicians and patients was very similar in 88% or 90% of the cases as very good or good (Table 4). Actually, there are a lot of studies on different treatments with encouraging results. Studies are directed on treatments with good tolerability and efficacy, acceptable for long-term treatment, as it should be in IBS patients. Recent studies are now focusing both on new therapeutic approaches and innovative adaptation of previously available treatments (11).

Table 4. Evaluation of the tolerability by physicians and patients

Tolerability	Very well	Well	Medium	Ineffective	Total
Physicians	265	337	59	7	668
	39.7%	50.4%	8.8%	1.1%	100%
Patients	243	347	65	13	668
	36.4%	51.9%	9.7%	2.0%	100%

The tolerability was assessed as very well and well in 602 cases (90.1%) by the physicians and in 590 cases (88.3%) by the patients.

Reduction of abdominal pain

The reduction in abdominal pain was highly significant. Only 86 of 790 patients (10.9%) reported non-existent pain at the beginning of the therapy. Already after six weeks of therapy with compounded charcoal, the number of patients without abdominal pain increased to 387 (53.9%) and at the end of the study (week 12) there were 511 (77.7%) without abdominal pain. This very clear reduction in abdominal pain was not only highly significant, but also of high clinical relevance (3,12). Before starting the therapy, 155 patients (22.7%) reported pain at abdominal percussion, whereas after 12 weeks of therapy only 20 patients (7.2%) reported pain at percussion. Without any doubt, such a very clear reduction of abdominal pain means a clear improvement of the quality of life for the patients suffering from IBS.

Pathological findings of the abdomen were reported in 87.5% of the patients at the beginning of the trial, whereas after 12 weeks of therapy only in 59% of the patients pathological findings occurred.

There was also a significant improvement in the severity of the illness, which was measured by the physicians. At the beginning only 63 patients (8.3%) were classified as not ill, whereas after 12 weeks of therapy with compounded charcoal 325 patients (49.9%) were classified as not ill.

The following symptoms, which also influence the quality of life, were measured at the beginning and at the end of the study, showing a significant improvement (P=0.0001), which is clinically relevant: constipation; hard stool; modified bowel movement and abdominal press; abrupt impulse to defecate; sense of incomplete defecation; flatulencies; abdominal distension; and pain.

Constipation

At the beginning there were 141 patients (18.3%) with severe constipation. At week six, only seven patients (1.0%) reported this symptom and at the end (week 12) only four patients (0.6%). Thus, there was nearly a complete recovery. Also, moderate constipation (371 patients, or 48.2% at the beginning) improved very clearly after six weeks of treatment with eucarbon (130 patients, or 18.5%). After 12 weeks, only 41 patients (6.3%) reported moderate constipation. Its mild laxative effect was impressively demonstrated by a clear reduction of the severity of the constipation from severe to moderate and mild. This development was underlined by an increase of mild constipation from 20.3% at the beginning to 34 after six weeks, and 4% after 12 weeks. The shift from severe to moderate and mild constipation can be considered as a clear improvement of the obstipative symptom among the patients concerned.

Three hundred and eighty two patients (58.8%) after 2 weeks of therapy compared with 102 patients (13.3%) at the beginning had no constipation. The improvement of constipation was highly significant. IBS with constipation predominating symptom imposes a substantial economic burden in terms of direct health care costs in a commercially insured population. Compared with matched controls, IBS patients incurred significantly higher total annual all-cause health care costs even after controlling for general and GI-related comorbidities. Incremental all-cause costs associated with IBS-C were mainly driven by costs related to more frequent use of

medical services as opposed to prescriptions (4,13,14).

Hard stool

Similarly, there was an improvement in the symptom "hard stool". Out of 138 patients (18.5%) at the beginning, only seven (1.0%) after six weeks and three (0.5%) after 12 weeks reported "hard stool". In a clear correlation, the number of patients with "normal stool" significantly increased from 112 (15.0%) at the beginning to 363 (59.0%) after 12 weeks of therapy. In both constipation and hard stool symptoms, already after six weeks could be considered a highly significant improvement.

Modified bowel movement and abdominal press

The severity of this symptom also showed a clear reduction after six weeks and a further reduction after 12 weeks. At the beginning of the study, 69 patients (9.5%) reported severe modified bowel movement and only one patient (0.2%) after 12 weeks of therapy. Also, the increasing number of patients from 203 (or, 27.9%) at the beginning to 377 (or, 61.1%) at the end of the study shows a clear correlation with the improvement of this symptom (15).

Flatulencies

Severe discomfort was mentioned by 91 patients (11.7%) at the beginning, but after 12 weeks just one patient (0.2%) was reporting severe flatulencies. Also, for this symptom there was a clear reduction of the severity already after six weeks (from severe to moderate to mild to non-existent). At the end of the therapy (week 12) there was a clear reduction in the discomfort for patients referring flatulencies. Health-related quality of life in irritable bowel syndrome patients is impaired to a degree comparable to other chronic disorders such as GERD and depression. A therapeutic response in irritable bowel syndrome-related pain and flatulence has a corresponding improvement in the quality of life (16-18). There was also a clear correlation between the improvement of the symptom and the increasing number of patients with non-existing flatulencies from 77 (9.9%) to 351 (53.7%).

Abdominal distension

Very similar was the improvement of abdominal distensions. Before starting the therapy, this symptom was reported by 62 patients (7.9%) as severe and by 341 patients (43.2%) as moderate. After 12 weeks there were only 3 (0.5%) patients reporting severe or moderate abdominal distension. The number of patients without this symptom increased from 86 (10.9%) at the beginning to 511 (77.7%) at the end of the therapy. Gas production and visceral hypersensitivity both contribute to digestive symptoms, especially bloating and borborygmi, in IBS patients after lactose ingestion (18,19). Therefore, it can be concluded that a therapy with compounded charcoal reduces both flatulencies and abdominal distension dramatically, which clearly underlines the carminative way of action of this medication.

Other symptoms

Only the diarrhea symptom, soft and liquid stool, did not improve in a significant way, but there was a clear tendency of improvement as shown in other studies (from severe to moderate and mild) (20,21).

Side-effects

Only a few side-effects were reported. There were 21 side-effects (2.6%); the most frequent were diarrhea (four cases) and headache (two cases) (22).

Conclusion

This multicentre study shows that in IBS, already after six weeks of therapy with compounded charcoal, there is a significant and clinically relevant reduction of abdominal pain. At the end of the therapy (week twelve) 77.7% of the patients had no abdominal pain compared with 10.9% at the beginning. Also, in most of the other symptoms like constipation, hard stool, modified bowel movement and abdominal press, flatulencies and abdominal

distensions there was a significant improvement after week six and especially week twelve due to the therapy with compounded charcoal. The severity of the illness was significantly reduced after week six and particularly week twelve and the pathological findings were reduced at week twelve.

As a conclusion, it can be postulated that this highly significant and clinically relevant reduction of abdominal pain, as well as the significant improvement of most of the other symptoms, has a clear impact on the improvement of the quality of life in patients with IBS, especially as the side-effects were few and not relevant. The efficacy and tolerability of compounded charcoal can, therefore, be described as very satisfactory.

Conflicts of interest: None declared.

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