Treatment of Patients Suffering from Constipation with Eucarbon® Tablets

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Abstract:
In a drug-monitoring study efficacy and safety of Eucarbon® tablets, containing Carbo ligni (vegetable, non activated charcoal) 180 mg, Sennae leaves 105 mg, Sulfur depuratum 50 mg , Rhubarb extr. 25 mg, Aether oleum foeniculi 0.5 mg, and Aether oleum menthae pip.0.5 mg, were investigated in patients suffering from constipation, especially those with spasmodic complaints. After the 12-week treatment period, 61 patients were available for analyses, whereby the following questionnaires were used: global assessment for efficacy and safety/tolerance, modified Clinical Global Impressions Score (CGI) and modified Francis Score (IBS-Score). The majority of patients took 3x2 tablets daily. All major symptoms and complaints like abdominal pain, altered frequency of stool, flatulence, hyperperistalsis, tenderness on pressure, tympanitic resonance decreased during treatment. The medication was very well tolerated. In conclusion the efficacy and safety of the natural drug Eucarbon® in the indication constipation could be confirmed.

Keywords:
Carbo ligni, constipation, drug-monitoring study, Eucarbon®, non activated charcoal

Introduction
Chronic constipation, which has been defined as the delayed evacuation of dry, hard stools (Mutschler, 1996), is one of the most common complaints in clinical medicine, and has several possible causes. The most common ones are associated with nutritional factors such as the consumption of food with poor dietary fibre content, which results in the insufficient filling of the intestine, the intake of readily absorbed food with a reduced water-binding capacity or lack of exercise. Other causes include factors related to organ dysfunction or organ damage including gastro-intestinal disorders, changes in the intestinal wall (due to a tumour or chronic inflammation e.g.), metabolic and endocrine disorders (diabetes mellitus e.g.), functional and organic disturbances of the nervous system, such as Parkinson’s disease, or may be caused by the side-effects of drugs such as analgesics, antidepressants, antispasmodics or sedatives. Constipation per se is diagnosed if no bowel movements occur for three or more days and if this irregularity persists for longer than six days (Leuschner, 1996).
In addition to the adverse effect on the patients well-being, the following symptoms may also occur: sluggishness of the bowels, putrefaction, headache, fatigue, skin rashes and halitosis (Buchmann, 1997).

In many patients there is a smooth transition to other functional gastrointestinal disorders like irritable bowel syndrome (IBS) also known as spastic colon, which is a benign relapsing chronic disorder, characterized by recurrent abdominal pain and altered bowel function. Constipation and diarrhoea often alternate, and abdominal cramping, gassiness, and bloating are other common complaints.

It is a problem that occurs in only a small percentage of persons in the non-elderly population but affects as many as 26% of men and 34% of women over 65 years of age (Schaefer, 1998)

Constipation treatment considerations include dietary approaches (e.g. fibre supplementation), behavioural approaches (e.g. habit training), regeneration of healthy intestinal flora, physiotherapy, change of lifestyle, pharmacological approaches.

As constipation is unpleasant and the constant feeling of abdominal bloating combined with flatulence and pain that is reminiscent of colic, many patients look for short term relief which leads to the administration of laxatives.

Laxatives accelerate the bowel evacuation process mainly by increasing intraluminal volume. They subsequently induce peristaltic waves and stimulate local peristaltic activity (Farr 2002).

One widely used medicine in this indication, Eucarbon®, was already developed in 1909 by the pharmacist F. Trenka. It is a unique and well-balanced combination of plant components such as senna, rhubarb and carbo ligni, which are well-known agents used particularly in the treatment of constipation. These agents stimulate the accumulation of water and electrolytes in the colonic lumen and also enhance intestinal motility. Thus, due to its pharmacological and pharmacodynamic properties Eucarbon® is classified as a stimulant laxative, which has a mild laxative and spasmolytic effect and relieves gas pains.

As is not uncommon for most traditionally used medicines - especially for combination preparations – there is a lack of both scientific data or clinical trials on those medicines. The aim of this drug-monitoring study therefore was to gain further information on the application of Eucarbon® in daily practice, its efficacy and safety in patients suffering from chronic constipation.

Methods

The drug monitoring study was conducted by 7 General Practitioners in Vienna, Austria.

The inclusion criterion was constipation, especially in combination with spasmodic complaints, the approved indication for Eucarbon® tablets in Austria. A total of three visits was planned per patient: baseline (visit 1), control after 6 weeks (visit 2) and after 12 weeks of therapy (visit 3). Because of the non-interventional character of a post-marketing surveillance study, no application scheme or any other limitations concerning treatment were given. The participating physicians were asked to follow the recommendations of the Product Information and the Patient Information Leaflet for Eucarbon® tablets.

All data and observations were (written down) documented in prepared report forms. At the beginning of the monitoring study, after 6 and after 12 weeks the patients were assessed for severity of complaints and general well-being using the following questionnaires: global assessment for efficacy and safety/tolerance, modified Clinical Global Impressions Score (CGI) and modified Francis Score (IBS-Score, Francis, 1997), which summarises the actual complaints, incorporating pain, distension, bowel dysfunction, classified as mild, moderate or severe. Adverse events were assessed at each visit and had to be graded using common criteria.

Each patient received Eucarbon® tablets, a registered product, produced and distributed by F. TRENKA GMBH*. Tablets have the following composition: Carbo ligni (vegetable, non-activated charcoal) 180 mg, Sennae leaves 105 mg, Sulfur depotatum 50 mg, Rhubarb extr. 25 mg, Aether oleum foeniculi 0.5 mg, and Aether oleum menthae pip.0.5 mg.

The recommended dosage for Eucarbon® tablets in this indication is 1 to 2 tablets at or after meals with some liquid depending on patient symptoms, with the possibility to change the dose according to the symptoms and complaints.

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Because of the non-interventional character of this post-marketing surveillance study the evaluation was performed by descriptive statistical procedures.
This drug monitoring study was conducted in compliance with the Austrian regulatory requirements.

**Results**

Between the 3rd of April 2002 and the 9th of December 2003 a total of 61 patients were monitored by 7 General Practitioners in Vienna, Austria, who treated between 1 and 15 out-patients with Eucarbon® tablets.

50 patients suffered from chronic constipation with spasmodic complaints, 4 from irregular bowel movements, 2 each from diarrhoea, irritable bowel syndrome, constipation without further complaints, and 1 each from meteorism, gastritis and intermittent diarrhoea and constipation, respectively.

44 patients were female (72.1%), 17 male (27.9%), which reflects the already known male-to-female ratio of 1 : 3. The duration of complaints ranged from less than 1 week in 8.2%, 1 week to 1 month in 13.1%, 1 to 3 months in 29.5%, 3 to 12 months in 23.0%, 1 to 2 years in 4.9% and more than 2 years in 21.3%. About one third of the patients (37.7%) got a pre-treatment with various drugs, mostly laxatives. 14 patients were smokers, 22 drank alcohol and 22 were on different kinds of diets.

The most frequent concomitant diseases reported, and treated with according medication, were cardiovascular disorders in 31, metabolism and nutrition disorders in 16, and musculoskeletal and connective tissue disorders in 10 cases. Only in one patient was the concomitant medication changed, which had no connection or influence concerning the indication or treatment with Eucarbon®.

There was only a minimal decrease in the mean body weight (about 1% during the treatment period).

Most patients got 3x2 tablets (70.5%) at the beginning, 13.1% each got 3x1 and 2x1 tablet/day, respectively. The dosage was reduced in 11 patients at visit 2 due to improvement of their complaints.

The mean time to visit 2 (recommended after 6 weeks) was 51.8 days and to visit 3 (recommended after 12 weeks) was 96.6 days.

At the beginning of the treatment 77% of the patients showed pathological findings during the physical examination (tenderness on pressure, hyperperistalsis, tympanic resonance), at the end of treatment, (visit 3) after 12 weeks, only 13.1% (Fig.1).

In the modified Clinical Global Impressions Score (CGI) the attending physician had to judge the severity of the patient’s illness as a global assessment in five categories from “normal/not ill” to “severely ill”. During the treatment, the number of normal/not ill patients increased (as expected) and the number of ill patients diminished accordingly (Fig. 3), a highly significant result (p< 0.0004, Signed Rank Test).

**See figure 3 on next page**

Concerning the actual specific complaints - like abdominal pain, abdominal distension, flatulence, altered stool frequency, altered stool consistency, altered stool passage - the number of patients decreased (as anticipated) to less than 10% for each symptom at the end of the treatment period.
The modified IBS Score, reflecting the 6 above mentioned actual complaints in a score system (0 – nonexistent, 1 – mild, 2 – moderate, 3 – severe) improved from a mean of 10.6 to 2.7 under the treatment with Eucarbon® (p< 0.0001, Signed Rank Test) (Fig.4).

Discussion
Chronic constipation is one of the most common complaints in clinical medicine. It is a rising problem in modern society. Approximately one-fifth of all adults in industrialized countries suffer from chronic constipation (Rantis, 1997). It not only affects personal well-being, but may lead to symptoms such as intestinal sluggishness, sensations of bloating, headaches and fatigue. Constipation has a varied aetiology. The main causes include organ damage, metabolic and endocrine disorders, neurogenic disorders, disorders of extrinsic innervation, disorders of the enteric nervous system and medication-induced side effects.

Although self-medication with a variety of medicines with different mode of action is very common, it should be limited to mild forms and short duration of constipation. We should be aware that most cases of constipation are unpleasant but harmless and have a good prognosis. But medical consultation and diagnosis is absolutely essential in patients with blood and phlegm in the stools, abdominal pains of unknown aetiology, chronic constipation, nausea, suspected laxative abuse (Farr, 2002).
Most active patients do well with medical management and first of all patient education should take place emphasizing the importance of a high-fibre diet, adequate fluid intake, regular exercise and a behaviour-modification program enabling the patients to become more aware of and responsive to normal urges to defecate.

On the other hand the use of plant laxatives for self-medication of constipation has a long tradition because of its known and accepted efficacy and tolerance. As the aetiology of constipation is varied and often not precisely known, combination preparations are widely used and very often efficacious. One of those preparations, Eucarbon®, with its unique combination of senna leaves, rhubarb extract and plant charcoal has been used traditionally for about one hundred years. For decades its use was based on experience and tradition as a mild laxative, digestive and carminative agent, but in the last years its value could also be proven in radiology, urology, internal medicine, and surgery.

In order to gain further valid information on the application of Eucarbon® in the daily practice in patients with constipation this drug monitoring study has been conducted. And in fact the results from daily practice could be verified.

Most patients started with the recommended dosage of 3x2 tablets and reported improvement of their complaints within some weeks, in some case even in some days. Interestingly all major symptoms of chronic constipation could be improved and independently of the duration of intake, no side effects or drug-drug interactions were observed.

From long lasting experience with Eucarbon® it is known that at low doses (1-3 tablets daily) it has an adsorbent effect and at higher doses (4-6 tablets) an adsorbent and laxative effect. Therefore it seemed appropriate to investigate its application in further indications. Thus, in 2001, a double blind, controlled clinical trial was conducted in 145 patients with irritable bowel syndrome (IBS) with a slightly modified preparation, Eucarbon® herbal (containing the same ingredients like Eucarbon® but without sulphur depur.), which showed that the main symptoms of IBS decreased under 12 weeks treatment by about 60%. Especially the subgroup of patients suffering from constipation gained remarkable benefits. The medication was well tolerated. In the few cases with side effects it was not possible to distinguish the event from symptoms of IBS (Hübner, 2002). Meanwhile Machavariani and co-workers (Machavariani, 2003) published their experience with Eucarbon® in 15 patients with IBS, 10 patients each with atonic constipation and with spastic constipation, who received 2x3 tablets for 12 weeks. They came to the conclusion, that Eucarbon® is an active remedy for the treatment of colon dysfunction. It works equally effectively in all forms of constipation in colonic diseases. The atonic constipation treatment is especially effective. The IBS and spastic constipation is also influenced by Eucarbon®, but an optimum result was achieved after the addition of sedative and spasmylic drugs. This is in line with the long tradition of Eucarbon® in self-medication, but limited in more severe diseases, which need medical care.

**Conclusion**

Based on the unique combination of herbal and mineral components, Eucarbon® is a natural intestinal regulator, which again could prove its efficacy impressively in patients with constipation, especially with spasmodic complaints. Because of its good tolerance and lack of drug-drug interactions it seems to be especially appropriate for the elderly and for long-term treatment. For further information: [www.eucarbon.at](http://www.eucarbon.at)

**References**