

# Spasmocanulase in irritable bowel syndrome

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## ABSTRACT

**Objectives:** Irritable bowel syndrome, is a functional gastro intestinal disorder, with various symptomatology and difficult to treat using several medications. Spasmocanulase, which has an anti-spasmodic and anti-flatulence effect and contains several ingredients, was tried in patients with irritable bowel syndrome, who had been on other medications previously without improvement.

**Methods:** At the gastroenterology out-patient clinic, Armed Forces Hospital, Riyadh, Kingdom of Saudi Arabia, 21 patients who were diagnosed with irritable bowel syndrome for more than 2 years on treatment and did not benefit from these medications, received spasmocanulase one tablet 3 times a day and followed in the gastroenterology out-patient clinic, every 6 weeks for 6 months. Their previous medications were discontinued, and which had been used for different durations and in different combinations included Mebeverine, Colpermin, Normacol, Importal, Librax. The main symptoms were different types of abdominal pain, bloating, flatulence, diarrhea, constipation or both.

**Results:** There was improvement or disappearance of the symptoms in more than 50% of the patients who were not improved on previous medication used for more than 2 years. The overall improvement in symptoms ranged between 43-75% in these patients, when followed up in the clinic at 6 weeks and 3 months. Spasmocanulase caused improvement in abdominal pain, flatulence and bloating compared to their previous medications. Only 43% of patients with diarrhea, showed improvement on spasmocanulase.

**Conclusion:** Although the number of patients, we studied is small, this study has shown that spasmocanulase is beneficial in improving symptoms of irritable bowel syndrome.

**Keywords:** Irritable bowel syndrome, spasmocanulase, spastic colon.

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**F**unctional gastrointestinal disorders are the result of disordered gastrointestinal (GI) functions in the absence of known pathology of structure. Irritable bowel syndrome (IBS) is a chronic and at the same time complex syndrome, which frequently occurs. An estimated 40-60% of patients seen at the Gastroenterology clinic have IBS. Exact figures in this connection are lacking, because the diagnosis is not based on clear objective criteria, and because only some of the patients consult a doctor.<sup>1</sup> Irritable bowel syndrome is the consequence of a sensory, motor and secretory dysfunction occurring in the colon. The amount of gas collected in the colon is

important for symptomatology. The main symptoms are abdominal pain, a changed defecation pattern and hypersecretion of mucus in addition to various dyspeptic phenomena.<sup>2</sup> Irritable bowel syndrome is very varied in its symptomatology, which makes rapid and accurate diagnosis difficult. The diagnosis of spastic colon is actually always made by exclusion. Endoscopy or x-ray investigation of the colon can help in establishing the diagnosis. The pathogenesis of IBS is not entirely clear. Some authors believe that disorders of the autonomous, neuron or humeral regulation of motility play a part leading to accumulation of gasses and distension.<sup>3</sup> In

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a recent study on patients with IBS, frequently complaining of excessive gas where fasting volume of intestinal gas in normal, it was hypothesized that the pathophysiological mechanism involved may be impairment of intestinal gas transit.<sup>4</sup> The management of patients with IBS is challenging to the physician, because usually these patients have various symptoms and are anxious. Several drugs have been used in treating these patients but, they are usually not satisfied with the treatment and some may benefit from antidepressants or other psychiatric management. Spasmocanulase's active ingredient composes digestive enzymes, antifatulant and anti-spasmodic (Metixene Hydrochloride, Dimethyl Polysiloxane, Pepsin, Glutamic acid Hydrochloride). It has previously been tried in patients with IBS.<sup>5,6</sup> At the gastroenterology out-patient clinic, we studied the effect of Spasmocanulase on patients who have been on other medications without improvement.

**Methods.** Twenty-one patients known with IBS (14 males + 7 females), age 24-62 years were included in the study. These patients were given one tablet of Spasmocanulase 3 times a day before meals. In 6 patients who have severe constipation, Importal (Lactitol) was also used. The main symptoms were: abdominal pain, bloating, flatulence, diarrhea, constipation or both. These 21 patients had been diagnosed with IBS for at least 2 years (had normal upper and lower endoscopy or normal barium studies, normal ultrasound, normal blood tests) and had been using other medication for IBS without improvement for at least one year. The previous medications used are shown in **Table 1**. **Table 1** shows that these patients were given different types of medication, which have been changed on different occasions to improve the patients symptoms during 2 years follow-up in the clinic, before using spasmocanulase. The patients were not put on a special diet and were asked to continue with the same dietary habits that they followed while on the other

**Table 1** - Medication used by 21 patients on different occasions during 2 years with no improvement.

Single Medication	n	2/3 Medications	n
Colefac (Mebeverine)	6	Colefac + Normacol	12
Colpermin	4	Colpermin + Normacol	10
Normacol	5	Colefac + Importal	8
Librax	4	Librax + Above	3
Buscopan	2	ImmodiemPRN+Colefac/ Colpermin	6
n - number, PRN - pro re nata (as required)			

previous medication or had been advised to follow during the last 2 years. Patients excluded from the study were those who were seen by a psychiatrist or on antidepressants, those who received different medications for 2 years or more but showed improvement and those who are under previous treatment for less than 2 years. None of the patients had been seen by a psychiatrist, nor had any psychotherapy. Patients were followed up in the clinic every 6 weeks for the first 6 months. Patients were asked about any improvement in their symptoms as well as if there were any side effects from spasmocanulase. By end of the 6 months, evaluation of each patient was carried out. Symptoms were graded as worse, static, improved or disappeared (cured). Spasmocanulase has an anti-spasmodic and anti-flatulence effect, and contains several ingredients as follows: Metixene: anti-cholinergic, which inhibits excessive GI motility. Dimethyl Polysiloxane: anti-foaming agent, which reduces the surface tension of gastric juice. Pepsin: Proteolytic enzyme, which assists in the digestion of protein in the stomach. Glutamic acid: acid buffering agent, which provides a favorable environment for pepsin to work. Pancreatin: Mixture of digestive enzymes, which help in the digestion of fat, starch and protein. Cellulase: cellulose-digesting enzyme, which inhibits gas formation as the bacterial action on cellulose leads to gas formation. Sodium dehydrocholate: fat emulsifying agent, which helps in the digestion of fat.

**Results.** Fifteen patients were started on spasmocanulase alone, one tablet 3 times daily, and 6 patients on spasmocanulase and Importal. All 21 patients attended for follow-up after 6 weeks, 16 patients came after 3 months and 14 patients were followed up for 6 months. These 21 patients can also be considered as the control group, as they had previously been on different medications without improvement before starting on spasmocanulase. Nineteen patients had abdominal pain and improvement was noted in 7 patients after 6 weeks and at 6 months 4 patients had no pain and 7 reported improvement. Eighteen patients had flatulence and 17 patients had bloating. At 6 weeks and 3 months 6 and 7 patients improved and 5 patients had no flatulence or bloating. Seven patients had diarrhea and 8 patients had constipation. After 6 weeks and 3 months of treatment 3 patients improved from diarrhea. Constipation improved in 5 patients after 3 months of treatment. **Table 2** shows the improvement of the severity of the symptoms in most of the patients as well as disappearance of the symptoms (cured) in few patients during follow-up of 6 weeks, 3 months and 6 months. There was improvement or disappearance of the symptoms in more than 50% of the patients (improvement 50-75% in most symptoms). Improvement was noted in only 43% of

**Table 2** - Follow-up symptoms for patients with IBS on spasmocanulase.

Indications	n	Worse	Static	Improved	Cured	Improvement %
Pain	19	3	6	7	6	68
Bloating	17	2	4	5	7	71
Flatulence	18	2	5	6	6	67
Diarrhea	7	2	3	1	2	43
Constipation	10	3	3	2	3	50
Alternating diarrhea+constipation	4	--	2	2	1	75

n - number, IBS - irritable bowel syndrome

**Table 3** - Medications and follow-up during 6 months.

Follow-up		6 Weeks	3 Months	6 Months
Spasmocanulase 15 patients	Improve	10	9	7
	No follow-up	0	2	5
	Same	5	4	3
Spasmocanulase + Importal 6 patients	Improve	5	4	3
	No follow-up	0	1	2
	Same	1	1	1

patients with diarrhea. **Table 3** shows the drugs used and follow-up of these patients during 6 months. There were no significant side-effects from spasmocanulase in all patients. There were no side-effects from Metixene, to stop medications in any of these patients.

**Discussion.** Spasmocanulase has been used by physicians for over 40 years (since 1961). Though it has been used in patients with IBS, there are not enough publications in the recent literature on this subject. Most publications were reported between the 1960's and 1970's. There are several reports on metixene hydrochloride (an antispasmodic and constituent of spasmocanulase) and IBS, which showed that it is beneficial.<sup>7</sup> Barbezat from South Africa in 1974, studied the effect of spasmocanulase in 19 patients with spastic colon and found that 13 out of the 19 patients felt generally better and only 3 patients developed side effect for the first time on treatment (2 dry mouth and 1 somnolence).<sup>5</sup> Yannakouris studied the effect of spasmocanulase on 40 patients from Greece and found improvement in 80-90% of these patients.<sup>8</sup> In a large clinical study in 1965, Britener compared the effects of spasmocanulase, metixene hydrochloride or placebo

in therapeutic management of irritable bowel and found that there is symptomatic improvement from both spasmocanulase and metixene hydrochloride compared to placebo.<sup>9</sup>

Treatment of IBS is complex and difficult due to the nature of the functional disorder and different symptoms of the patient. A recent meta-analysis reported in Gut<sup>10</sup> showed that Pittler and Ernst<sup>11</sup> reported that the role of peppermint oil in the symptomatic treatment of IBS has not been established and carefully executed studies are needed to clarify the issue. In a review of anticholinergics, all 8 studies were judged to be flawed and with conflicting results.<sup>12</sup> A meta-analysis of 26 selected double blind, randomized trials were performed by Poynard and colleagues, which included 8 drugs: cimetropium bromide, dicyclomine hydrochloride, mebeverine, hyoscine butyle bromide, octylonium bromide, peppermint oil, pinaverium bromide, and trimebutine. Only 5 drugs (cimetropium bromide, mebeverine, octylonium bromide, pinaverium bromide, and trimebutine) have been shown to be clinically effective in patients with IBS without adverse reactions.<sup>13</sup> Our study showed that our patients had been using several drugs prior to spasmocanulase without significant improvement. There was considerable improvement (cure) or clear improvement in our patient's symptoms with spasmocanulase. There was no significant side effect from spasmocanulase. Our study also showed that there is improvement in symptoms in most of these 21 patients during the follow-up period (**Tables 2 & 3**). Some patients showed improvement in symptoms at 6 weeks, 3 months and 6 months. Six patients with severe or moderate constipation were given also Importal, 5 of them improved and one had no more constipation. This effect might not only be due to Importal but also spasmocanulase contains digestive enzymes such as pepsin, pancreatin and cellulose which inhibits gas formation produced by bacterial action on cellulose.

Meta analysis of different studies from different countries, compared (a) spasmocanulase, (b) spasmocanulase intent metixene (c) metexine and (d) placebo. Abdominal pain improved in: group (a) 83%; compared to 69% in group (b); 74% in group (c); and 37% in group (d) (placebo group). Similar results have been noted in disorders due to fullness and flatulence.<sup>14</sup> The number of patients entered into the study was small, because the study period was only for 6 months and also there were several patients with IBS who were not entered in the study or excluded as discussed under the methods section. In our hospital, primary care physicians usually see the majority of patients with IBS and refer to the gastroenterology clinic only those on long term medication or psychotherapy without improvement. Although the number of patients studied is small, this study has shown that spasmocanulase is beneficial in IBS as shown in previous studies.<sup>4,7,8,14</sup>

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