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Chamomile efficacy in patients of the irritable bowel syndrome

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ABSTRACT

Irritable bowel syndrome (IBS) is a common GI functional disorder, which presents with a wide range of symptoms such as chronic abdominal discomfort, bloating and altered bowel habits. The variety of symptoms has led to a difficult therapeutic challenge and no specific treatment for relieving all IBS symptoms has been suggested yet. The purpose of this study was to evaluate the impact of Chamomile extract on IBS symptoms. In a randomized trial, 45 patients who fulfilled the ROOM III criteria and had no organic disease enrolled in this study and were asked to take Chamomile 20 drops daily for four weeks. They were asked to fill in IBS-associated symptoms questionnaire to specify abdominal pain intensity, bloating, nausea, stool consistency and altered bowel habits. The questionnaire was filled out during 5visits: at the first day, at the second and fourth weeks after starting the treatment and also the second and fourth weeks after the end of intervention. IBS symptoms were significantly reduced at the second and fourth weeks after beginning of the herbal therapy ($p<0.001$). Symptom relief continued up to 2 weeks after the end of intervention and started to decrease in 4 weeks after beginning of the herbal therapy. Considering the improving effects of Chamomile on all IBS symptoms, it may have a positive effect on the syndrome pathogenesis as well.

***Trial registration**: Current Controlled TrialsIRCT201106206842N1.*
Keywords: Irritable bowel syndrome, Chamomile Matricaria L., Phytomedicine

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INTRODUCTION

Irritable bowel syndrome (IBS) is the most frequent functional gastrointestinal disorder with a prevalence of 5-11% in most countries[1]. The workload generated by IBS is considerable and constitutes approximately one-third of all visits to gastroenterologist IBS Diagnosis is based on the identification of symptoms according to Manning, Rome III criteria and exclusion of alarm indicators[2]. The pathophysiology of IBS is considered to be multi factorial, involving disturbances of the brain-gut-axis. IBS has been associated with abnormal gastrointestinal motor functions, visceral hypersensitivity, psychosocial factors, autonomic dysfunction and mucosal inflammation[3].

IBS affects females more often than males for unexplained pathophysiologic reasons[4].The clinical approach is based on the treatment of common symptoms. When pain predominates, antispasmodics are the first choice. In case of diarrhea, loperamide is useful for reducing bowel frequency. Soluble fiber represents the first option in subjects with IBS and constipation or mixed IBS. Dietary integrators (composed of probiotics and serotonin precursors) are a promising therapeutic option[5].

Unfortunately, none of the currently available drugs (e.g. antispasmodics, antidiarrheals, osmotic, bulking agents and

sedatives) are globally effective in treating all IBS symptoms[6].

Health related quality of life is impaired in all subgroups of IBS sufferes[7]. Many patients and doctors are dissatisfied with the level of improvement in symptoms that can be achieved with standard medical care, forcing them to seek alternatives for care. In such situations, an important question is whether herbal medicines are effective and safe for IBS patients[8].

Irritable bowel sufferers commonly have recourse to the use of complementary and alternative medical remedies and practices. Foremost among such approaches have been various dietary manipulations including exclusion diets, and a variety of dietary supplements[7].

One of the most common herbs used for medicinal purposes is chamomile whose standardized tea and herbal extracts are prepared from dried flowers of *Matricaria* species. Chamomile is one of the eldest , most widely used and well documented medicinal plants in the world[9].

Medicinal ingredients are normally extracted from the dry flowers of chamomile by using water, ethanol or methanol as solvents and corresponding extracts are known as aqueous, ethanolic (alcoholic) and/or methanolic extracts. Optimum chamomile extracts contain about 50 percent alcohol. Normally standardized extracts contain 1.2% of apigenin which is one of the most effective bioactive agents. Aqueous extracts, such as in the form of tea, contain quite low concentrations of free apigenin but include high levels of apigenin-7-*O*-glucoside[10].

Chamomile is used traditionally for numerous gastrointestinal conditions, including digestive disorders, "spasm" or colic, upset stomach, flatulence (gas), ulcers, and gastrointestinal irritation[11].

Chamomile is used internally for inflammatory diseases of the gastrointestinal tract associated with gastrointestinal spasms, irritation of the oral pharyngeal mucous membrane and upper respiratory tract. Externally, the drug is used for skin and mucous membrane inflammations, pulpitis, gingivitis, respiratory catarrh, and anogenitalinflammation Chamomile should not be taken by anyone with a known allergy to its components or to other members of the Compositae family (e.g., arnica, yarrow, feverfew, tansy, artemesia), or if they have a history of atopic hay fever or asthma[12].

The purpose of this study was to evaluate the impact of Chamomile extract on IBS symptoms.

MATERIALS AND METHODS

This is a prospective pre-post study in an academic GI clinic performed in 2009-2010.Chamomile drop (produced by SohaJissa Company Tehran, Iran) that contained bizabulol and camazolen (69.47 mg/100cc) was prescribed for patients. Study was approved by institutional ethics committee. Informed consent was obtained from patients and all patients were allowed to refuse to participate in study when they desired.

Patients who had diagnosis of IBS (with diarrhea or constipation dominancy), no history of sensitivity to milk and its products, age between 10 to 50 years, willingness to participate, no other active illness (specially asthma), no drug consumption (specially anticoagulants), no psychiatric illness, not having pregnancy or doing breast feeding, no history of hyper sensitivity, no current therapy for IBS, and no abnormal lab data (CBC/ ESR/ CRP/ TSH) depending on the ROME III criteria were included in our study.

Our exclusion criteria were any complication, exacerbation of symptoms or if the patient refuses to continue. After 2 weeks stopping any other drugs symptom control, patients were visited and IBS-associated symptoms including abdominal pain, nausea, painful defection, presence of mucosa in stool, changes in stool consistency and defecation frequency were recorded in a questionnaire which was gathered by the clinicians based on different studies and references. Chamomile drop was administered in a similar way for all patients (two times a day,10 drops at morning and 10 drops at night in a glass of warm water ,15 minutes after meal with a minimum of 12 hours' time interval ,this time mention is to eliminate the effects of confounding factors like the time of drug use, time intervals between drug intake and time between last meal and drug intake.) A telephone follow up was considered for patients 2 and 4 weeks after beginning Chamomile drop administration and 2 and 4 weeks after stopping it and any changes in symptoms were recorded again by the same questionnaire used before Chamomile administration.

The total of 70 patients who were diagnosed and finally, 45 of them were included in the study due to our inclusion criteria.This study has Irct ID: IRCT201106206842N1.

Descriptive statistics were presented as minimum, maximum, mean and standard deviation. (the proportions of two-by- two contingency tables were compared by the chi-square test, and t-test was used for continuous variables. We considered $p<0.05$ as significant. All analyses were performed with SPSS, version 18 (SPSS, Inc., Chicago, IL).

RESULTS

All 45 patients completed the study and no complication was reported.the results are shown in table 1.

Overall, all IBS symptoms (bloating, abdominal pain, stool consistency and defecation difficulties) were decreased significantly after 2 weeks of treatment. This relief was persistant until 2 weeks after the end of the intervention but 4 weeks after the end of treatment, almost all symptoms had been exacerbated but were continuously decreased in comparison with the first visit.

Frequency of defecation was significantly decreased after 4 weeks of treatment in the patients with diarrhea dominancy (3.4 vs 1.3, ($p<0.001$)). In follow up, the decrease was 1.9 after two weeks ($p<0.001$) and 2.4 four weeks after the end of the intervention ($p<0.001$).

At the first visit 32 patients (71%) experienced severe bloating and 13 cases (28.9%) reported intermediate intensity of bloating. After 4 weeks of treatment, 5 patients (11%) reported intermediate and 40 cases (88.9%) reported severe bloating. At 4 weeks after intervention the severity was increased to 8 patients (17.8%) severe, intermediate in 36 patients (80%) and mild bloating in 1 patient (2.2%) ($p<0.001$).

Nausea at the beginning had intermediate severity in 1 patient (2.2%) and mild in 10 patients, which was decreased to just 1 patient (2.2%) with mild severity at 4 weeks of treatment ($p=0.000$). A 4 weeks after the end of the intervention, it was increased to 1 patient (2.2%) with intermediate and 4 patients (8.9%) with mild nausea.

Abdominal pain at the first visit was reported in 28 patients (62.2%) as severe and in 17 patients (37.8%) as intermediate, which was decreased to 5 (11.1%) intermediate and 37 (82.2%) mild cases after the end of treatment (($p<0.001$)). Four weeks after intervention, the abdominal pain increase to 5 (11.1%) severe, 38 (84.4%) intermediate and 2 (4.4%) mild cases was reported, but it showed continuously significant decrease in comparison with the beginning of the study ($p<0.001$).

In the patients with diarrhea dominancy, stool consistency was changed from 18 patients (78%) with watery diarrhea and 5 patients (21%) with loose stool at the beginning of the study into 1 patient (4.3%) with loose stool and 22 patients (95%) with normal defecation after the treatment ($p<0.001$). A 4 weeks after the end of treatment, 3 patients (13%) reported watery diarrhea, 18 patients (78%) loose stool and 2 patients had normal defecation. These rate were significantly different from those of the first visit ($p<0.001$).

In patients with constipation dominancy, stool consistency was changed from 22 patients (100%) with constipation into 22 patients with normal defecation after 4 weeks of treatment ($p<0.001$). 2 weeks after the intervention was stopped, constipation reported into 4 patients (20%) and 18 patients (80%) had normal defecation ($p<0.001$). At four weeks follow up, 19 patients (87%) had constipation and 3 (13%) had normal defecation which was not significantly different from those of the first visit ($p=0.08$).

The sensitivity of incomplete defecation was reported by 43 patients (95%) at the first visit but it was reported only in 4 patients (8.9%) 4 weeks after the treatment ($p<0.001$), which was increased to 36 patients (80%) during the follow up 4 weeks after intervention ($p=0.008$).

Defecation urgency was reported by 40 patients (88%) at the beginning of the study, all of which experienced recovery but it was relapsed in 29 cases relapsed at 4 weeks after treatment ($p=0.002$).

Mucous defecation was also cured in 37 patients (82.2%), which was relapsed in 6 patients (13%) 2 weeks after the treatment, and continuously kept a decreasing pace since the first visit ($p<0.001$). At 4 weeks after the intervention, mucous defecation was reported in 30 cases (66.7%) with significant difference to the beginning ($p=0.016$).

Painful defecation was present in 18 patients (81.8%) with constipation at the first visit, which was decreased to 1 case (4.5%) after intervention and was reported in 2 patients (9%) at 2 weeks after intervention, both of which were significantly decreased comparing to the first visit ($p<0.001$). A 4 weeks after the treatment, it was reported in 16 cases (72%), which was not different from the baseline ($p=0.50$).

Table1: Frequency of IBS-associated symptoms in patients during the study course

Visit n# after intervention	Daily defecation number		bloating			Abdominal pain				stool form D		
	D	C	s	mo	m	s	mo	m	no	w	L	N
1st visit	3.4	0.09	32	13	0	28	17	0	0	18	5	0
2rd visit	1.3 P=0.000	1.7 P=0.000	0 P=0.000	5 P=0.000	40	0 P=0.000	5	37	3	0 P=0.000	1	22
3th visit	1.9 P=0.000	1.1 P=0.000	0 P=0.000	18	27	1	37	31	0	0	7	16
4th visit	2.7 P=0.000	0.5 P=0.000	8 P=0.000	36	1	5 P=0.000	38	2	0	3 P=0.000	18	2

Table1: Continued

Visit n# after intervention	stool formC		Incomplete defecation		Emergency defecation		Mocuse defecation		Pain full defecation	
	H	N	yes	no	yes	no	yes	no	yes	No
1st visit	22	0	43	2	40	5	37	8	18	4
2rdvisit	0 P=0.000	22	4 P=0.000	41	0 P=0.000	45	0 P=0.000	45	1 P=0.000	21
3th visit	4	18	13	32	7	38	6	39	2	20
4th visit	19 P=0.08	3	36 P=0.008	9	29 P=0.002	16	30 P=0.016	15	16 P=0.5	6

D: diarrhea, C: constipation, S: sever, Mo: moderate, M: mild, No: not, W: watery, L: loose, N: normal, H: hard

DISCUSSION

The recent results from the controlled clinical trial on chamomile extract for GAD suggests that it may have modest anxiolytic activity in patients with mild to moderate GAD[13] our study showed that Chamomile drop (Matricaria recutita L.) has a significant effect on IBS symptoms, which is more when the consumption is longer. This effect is persisted until 2 weeks after intervention and then the symptoms relapse. So, many of the patients wanted to continue the consumption of Chamomile drop even after the completion of the study.

There are different therapies for IBS patients such as antispasmodics, anti-diarrhea, antidepressants, behavioral therapy, psychotherapy, etc, which are used based on the severity and types of the symptoms, and the treatment is chosen for the predominant symptoms.

Current therapies are not satisfactory and efficient, or early relapse is very prevalent. These facts and complications of the current treatments have caused the patients to seek alternative medicine. For example, a study on 1012 patients in 2008 showed that 35% of IBS patients used complementary and alternative medicine and believed on its efficiency. Many studies have been done on different types of alternative medicine specially phetotherapy[14].The effect of Spearmint oil has been proven in several studies[13-16].

Chamomile has satisfactory effects on gastrointestinal spasms and ulcers and is a relaxant and antiseptic[16].

we included IBS patients, who had no history of hypersensitivity or allergy were. We also considered more inclusion criteria such as absence of any other diseases to limit their possible affects of these variables and to attain exact and confident results.

In the present study, most patients with more severe symptoms were eligible to be included into the study, so the results are useful for IBS patients with severe symptoms.In this study, the time for both treatment and follow up was longer by two weeks in comparison with other studies[13,14,16].

Unfortunately, we were not able to produce and use placebo, which is a negative point of our study.Most of the patients in this study had a history of different therapies for a mean time of 43 months, which had not been satisfactory or caused some complications and a lot of costs for them.

CONCLUSION

According to the effectiveness of Chamomile (shown in this study), we guess that it is effective on both the symptoms and pathogenesis of IBS. Chamomile is easily available and is not expensive, so is better than other current therapies.

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