

A CLINICAL STUDY TO EVALUATE THE EFFICACY OF BILVA MAJJADI YOGA IN THE MANAGEMENT OF VATIKA PRAVAHIKA W.S.R. TO IRRITABLE BOWEL SYNDROME

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ABSTRACT

Vatika Pravahika is the disease mainly caused by the derangement of *Agni*. It has striking similarity to Irritable bowel syndrome. *Ama Pachana*, *Agni Deepana* and *Satvavajaya Chikitsa* are key treatments for *Vatika Pravahika*. Thirty patients were registered for this clinical study, out of which only 27 completed the trial. Patients were selected in the age group between 18-70 years under single group. "*Bilva Majjadi Yoga*" was selected for study. The signs and symptoms were studied before and after treatment. Result of the study indicates significant satisfactory results. No adverse effect of the trial drug came into light during the course of trial.

KEYWORDS: *Vatika Pravahika*, IBS, *Agni*.

INTRODUCTION

Irritable bowel syndrome (IBS) is a group of symptoms including abdominal pain and changes in the pattern of bowel movements without any evidence of underlying damage.^[1]

The primary symptoms of IBS are abdominal pain or discomfort in association with frequent diarrhea or constipation and a change in bowel habits.^[2] Women are around two to three times more likely to be diagnosed with IBS and four to five times more likely to seek specialty care for it than men.^[3] About 10 to 15% of people in the developed world are believed to be affected by IBS.^[4] It is estimated that IBS affects up to 15% of the world population with its symptoms of chronic abdominal pain and major disturbance of bowel functioning. Females are generally more affected than males and it is twice as common in women as men and typically occurs before age 45.^[5] IBS is considered a functional disorder, where no visible disease process or tissue damage is seen. In Ayurveda, *Vatika Pravahika* definitely have striking similarity with IBS.^[6,7,8] This disease is mainly caused by the derangement of *Agni*. Ayurveda has given prime importance to *Agni* as *Mandagni* is basic root of all the diseases. *Ama Pachana*, *Agni Deepana* and *Satvavajaya Chikitsa* are key treatments for *Vatika Pravahika*.

AIMS AND OBJECTIVES

To assess the efficacy of "*Bilva Majjadi yogaa*" in the management of "*Vatika Pravahika w.s.r to Irritable Bowel Syndrome*".

MATERIALS AND METHODS

The study was Randomized open trial study cleared by the institutional ethics committee on 15/5/2012 vide letter no. 8/2012. Informed consent was taken from all the patients before including them into the trial. 30 patients were registered for this clinical study, out of which only 27 completed the trial. Patients visiting the OPD/IPD of *Kayachikitsa*, Department of Rajiv Gandhi Govt. Post. Graduate Ayurvedic College and Hospital, Paprola, who were fulfilling the criteria, were selected in the age group between 18-70 years, irrespective of their sex, caste and religion.

Dose and Mode of Administration

The drug "*Bilva Majjadi yoga*" contains *Apakva bilva majja churna* (*Ch Chi. 19/115*), *Pakva bilva majja churna* (*Priya Nighantu 1/20*), *Isabgol husk* (*D.G.Vi.Part-2, Chapter-5 by P.V Sharma*) in the ratio of 2:2:1. Drug Dose was 20gm per day in three divided doses with lukewarm water (*samshitoshna jala*). Trial duration was 30 days with follow up of after every 7 days.

Dos & Don'ts- Patients were advised following points regarding their life style & dietary habits:

- i. Make a symptoms diary to record the time and severity of symptoms, food intake, and life events which aggravate the symptoms.
- ii. Include meditation, exercise & various *yogasana* in daily routine.
- iii. Eat slowly.
- iv. Don't take stress.
- v. Avoid junk food (like Pizzas, carbonated drinks etc.)
- vi. Do not inhibit natural reflexes especially defecation, micturition & flatus passage.
- vii. Do not strain to defecate.
- viii. Avoid flatogenic foods like beans, cabbage, onion, cauliflower, corn etc.

Inclusion criteria

- Patients willing for trial.
- Patients in age group between 18-70 years of either sex.
- Patients fulfilling Rome III criteria for IBS:
 1. Pain is relieved by defecation.
 2. Onset associated with change of frequency of stools.
 3. Onset associated with a change in form (appearance) of stools.
- Presence of mucus in the macroscopic stool examination
- Patients not having any state mentioned in the exclusion criteria given below.

Exclusion criteria

- Patients with bleeding per rectum.
- Mixed infections with parasites like round worms, hook worms etc.
- Patients with evidence of malignancy.
- Patients with poorly controlled diabetes mellitus (FBS > 250 mg/dl)
- Patients with poorly controlled hypertension (> 160/100 mm of Hg)
- Patients on prolonged (6weeks) medication with corticosteroids etc. that may have an influence on the outcome of study.
- Patients suffering from major systemic illness necessitating long term drug treatment.
- Patients who have a past history of atrial fibrillation, MI, stroke in last 6 months.
- Symptomatic patients with clinical evidence of heart failure.
- Patients with concurrent serious hepatic disorder or renal disorder, severe pulmonary dysfunction or any other condition that may jeopardize the study.
- Pregnant and lactating women.
- Showing any allergy to trial drug.

Investigations: To rule out any other pathology or any other organic disorders, following baseline investigations were done:

Blood - Hb(gm%), TLC, DLC, ESR, FBS, B.Urea, S.Creatinine, S.Bilirubin (direct and indirect), SGOT, SGPT

Stool examination – for parasites, mucus, vegetative cells & occult blood.

Criteria of diagnosis:- The gradations for subjective symptoms used in the present clinical study consisted of four grades (0-3) scale and were defined by descriptive anchors, specified for each symptom. 0(zero) indicating complete absence of symptoms and 3 (three) indicating extreme degree of symptoms.

Table No. 1: Pain abdomen/Abdominal discomfort.

1.	Absent	0
2.	Occasional/Completely relieved after passage of stool or flatus	1
3.	Mild constant/Decreased after passage of stool or flatus	2
4.	Moderate constant/ Not at all relieved after passage of stool or flatus	3

Table No. 2: Increased stool frequency.

1.	0-3 times per day	0
2.	4-5 times per day	1
3.	5-6 times per day	2
4.	More than 6 times per day	3

Table No. 3: Decreased stool frequency.

1.	Up to thrice a week	0
2.	Twice a week	1
3.	Once per week	2
4.	Occurs after a gap of one week	3

Table No. 4: Loose consistency stools.

1.	Normal consistency	0
2.	Mildly loose (pasty) consistency	1
3.	Moderately loose (thick soup like) consistency	3
4.	Watery stools	4

Table No. 5: Hard consistency stools.

1.	Normal consistency	0
2.	Mildly hard stools	1
3.	Moderately hard (ribbon like) stools	2
4.	Extremely hard (pellet like) stools	3

Table No. 6: Mucoïd Stools.

1.	No visible mucus	0
2.	Occasionally found stickled to the stool	1
3.	Moderate amount & often	2
4.	Large amount & always	3

Table No. 7: Urgency of defecation.

1.	Absent	0
2.	Occasional	1
3.	Often	2
4.	Definite	3

Table No. 8: Abdominal bloating.

1.	Absent	0
2.	Occasional	1
3.	Often	2
4.	Always	3

Table No. 9: Postprandial defecation.

1.	Absent	0
2.	Mild & Occasional	1
3.	Moderate & frequent	2
4.	Moderate & definite	3

Table No. 10: Increased no. of visits to toilet per day.

1.	1-3 times per day	0
2.	4-5 times per day	1
3.	6-7 times per day	2
4.	More than 6 times per day	3

Table No. 11: Dissatisfaction after morning evacuation of stool.

1.	Absent	0
2.	Mild & occasional	1
3.	Moderate & often	2
4.	Always dissatisfied	3

Table No. 12: Straining during defecation.

1.	Absent	0
2.	Mild & Occasional	1
3.	Moderate & Frequent	2
4.	Severe & Always	3

Table No. 13: Increased time spent in toilet per visit.

1.	0-5 min.	0
2.	5-10 min.	1
3.	10-15 min.	2
4.	15-20 min.	3

Table No. 14: Decreased bowel clearance in 1st attempt.

1.	76-100 %	0
2.	51-75 %	1
3.	26-50 %	2
4.	0-25 %	3

Table No. 15: Psychological features (anxiety /depression)

1.	Never	0
2.	Occasionally	1
3.	Often	2
4.	Always	3

Objective criterion

An IBS SSS (IBS Severity Scoring System) was adopted to assess the effect of the therapy. This scoring system uses a Visual analogue scale to measure severity of abdominal pain and includes an assessment of Pain frequency, Abdominal bloating, Dissatisfaction with life, Interference with life.

Statistical Analysis

The Information gathered regarding demographic data has been analyzed through percentage. The Scoring of Criteria of Assessment was analyzed statistically in term of B.T. (Before Treatment), A.T. (After Treatment), S.D. (Standard Deviation) and S.E. (Standard Error) with P value <0.0001(Extremely significant), P< 0.001(Highly significant), P<0.01(Moderate significant).

RESULTS AND OBSERVATIONS

The following data reveals that maximum no. of patients in this study were in the age group 31-40years (40.74%), males (66.67%), desk working (33.33%), literate (85.19%), middle class (77.78%), mixed diet (66.67%), having disturbed sleep (66.67%), not having any family history of IBS (92.60%), *Kaphavataja prakriti*(44.44%), *Rajasa prakriti* (55.56%), *medasaara* (37.03%), *madhyama samhanana*(55.55%), *madhyama satva* (81.48%), *madhyama aahara shakti*(55.56%), *madhyama vyayama shakti* (44.44%).

Effect of Therapy

Table No. 16: Effect of therapy on IBS symptomatology.

Sr.N	Symptom	N	B.T	A.T	% relief	S.D	S.E±	t	p	Remarks
1.	Pain Abdomen	27	1.56	0.41	73.72	0.36	0.07	16.48	0.000	H.S
2.	Increased stool frequency	11	0.78	0.30	61.54	0.75	0.15	3.32	0.003	M.S
3.	Decreased stool frequency	14	0.78	0.22	71.79	0.58	0.11	5.00	0.00	H.S
4.	Loose consistency stools	12	0.59	0.11	81.25	0.75	0.14	3.32	0.003	M.S
5.	Hard consistency stools	14	0.89	0.26	70.83	0.69	0.13	4.76	0.00	H.S
6.	Mucoid stools	16	0.70	0.15	78.95	0.51	0.10	5.70	0.00	H.S
7.	Abdominal bloating	6	0.63	0.07	88.89	0.51	0.10	5.70	0.00	H.S.
8.	Urgency of defecation	5	0.19	0.07	57.89	0.32	0.06	1.80	0.083	N.S
9.	Post Prandial defecation	8	0.37	0.04	89.19	0.62	0.12	2.79	0.01	S
10.	Increased no. of visits to toilet per day	16	0.93	0.30	67.74	0.63	0.12	5.20	0.00	H.S.
11.	Dissatisfaction after morning evacuation	19	1.00	0.26	74	0.53	0.10	7.32	0.00	H.S.
12.	Straining during defecation	14	0.78	0.22	71.43	0.58	0.11	5.00	0.00	H.S.
13.	Increased time spent in toilet per visit	17	0.93	0.22	75.27	0.61	0.12	6.01	0.00	H.S.
14.	Decreased bowel clearance in 1 st attempt	17	0.89	0.26	70.79	0.49	0.09	6.65	0.00	H.S.
15.	Psychological symptoms	25	1.41	0.52	63.12	0.32	0.06	14.42	0.00	H.S.

Table No. 16: Effect of the therapy on IBS Severity Score.

N	B.T.	A.T.	%age relief	S.D	S.E.±	t	p	Remarks
27	225.93	51.78	77.08	31.43	6.05	27.14	0.00	H.S.

Table No. 16: Effect of the therapy on Mucus in Stool examination.

N	B.T.	A.T.	%age relief	S.D	S.E.±	t	p	Remarks
19	0.70	0.22	68.43	0.51	0.10	4.914	0.00	H.S.

Table No. 17: Overall effect of the therapy.

Assessment	No. of patients	Percentage (%)
Cured	1	3.70
Markedly improved	23	85.19
Mildly Improved	3	11.11
Unimproved	00	00

DISCUSSION

Summing up all the features of IBS & *Vatika Pravahika*, they can be correlated on the following basis. Pain abdomen related with altered bowel habits is the key symptom of IBS. Similarly in case of *Pravahika*, when "Shoola" is the main symptom. *Vata Dosha (Vayu Pravridhho)* is the most important factor whose vitiation occurs in this disease. Apart from *Vata dosha*, *Kapha Sanchaya (Nichitam Balasam)* is also the contributory factor in the pathogenesis of *Pravahika*. Vitiation of both these *Doshas* is attributed to faulty dietary habits and improper life style. *Pakwashaya* (large intestine) and *Sihool Guda* (rectum) are the seat of *Pravahika*. Large intestine (especially colon) is involved in IBS chiefly. Vitiation of *Sharirika Dosha* start affecting *Manasika Dosha (Parasparam Anuvartamanam)*, thereby explaining the psychosomatic aspect of IBS. *Bilva* fruit is used in treating peptic ulcer as it forms a mucilaginous layer on the gastric mucosa & thus prevents interaction of acid with mucosal layer. Fruit pulp powder was found effective on Intestinal parasites particularly on

Ankylostoma. (Ayu. Pharma. Therapeutic uses of Med. Plants). Both ripe and unripe fruits are useful for prevention in Cholera. (D.G.Vi) (Ayu. Pharma. Therapeutic uses of Med. Plants). Ripe fruit keeps mind & body cool, helps to sharpen intellect & mind concentration. (Parichha S. Bael, Nature's most natural medicinal fruit). It acts as a mild laxative as it promotes peristaltic movements & thus helpful in removal of faecal matter. (Roy SK Singh et al, 1980). Unripe fruit is an appetizer, digestant and astringent. It is useful in loss of appetite, diarrhoea, dysentery, sprue & pain over abdomen. Unripe fruits ground to paste and cooked with sugar is very beneficial in bleeding piles. It also helps in healing of ulcerated intestinal surfaces. (D.G.Vi) (Ayu. Pharma. Therapeutic uses of Med. Plants). British Pharmacopoeia does not differ much with Ayurvedic observations in the utility of this plant in various disorders. *Bel* is an invaluable remedy in abstinent cases of chronic diarrhoea and dysentery, where there is no fever. It appears to have little or no effect in acute dysentery when there is definite tenesmus, blood & mucus discharge and no fever. The beneficial effects of fruit however are most evident when the condition has become sub acute or chronic. It is very useful in patients suffering from alternate diarrhoea and constipation. It has also been shown to be useful in chronic gastrointestinal catarrh and sprue. In the after treatment of Bacillary dysentery where constipation is the problem leading to the delayed healing of the ulcer surfaces, *Bilva* is said to be highly useful.

CONCLUSION

During this clinical study 30 patients were registered out of which 27 patients completed the trial. On the basis of the observations of this study it can be concluded that the trial drug *Bilva Majjadi yoga* administered orally have definite role in the management of *Vatika Pravahika* i.e. Irritable Bowel Syndrome. This research work was carried out over a very small sample of patients and requires further study on the large sample of subjects to establish its efficacy and observe the other adverse effects if any. The present trial work was based on *Shamana Chikitsa* only. Better results can be obtained by incorporating *Shodhan Chikitsa* like '*Piccha Basti*' & *Satvavjaya Chikitsa* with *Shaman Chikitsa* in IBS (*Vatika Pravahika*). Therefore in future, further studies can be done in this direction.

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