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CLINICAL EVALUATION OF *BILVADI LEHA* IN THE MANAGEMENT OF *GRAHANI DOSHA*WITH SPECIAL REFERANCE IRRRITABLE BOWEL SYNDROME (IBS)

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ABSTRACT

IBS is chronic relapsing disorder of gastrointestinal function, the main features are abdominal pain associated with an altered bowel habit (may present with diarrhea or constipation or intermittently both) in the absence of any structural pathology. A careful review of the clinical picture of various GIT diseases, described in *Ayurveda* reveals that some of the disorders definitely have some clinical symptoms which observed in patients of IBS. So according to pathogenesis and sign & symptom, IBS can be a stage of *GrahaniDosha*. The present study was interventional, open label, prospective with time and single group. There was fifty two patients which clinically diagnosed case of IBS as per Rome III criteria were administered trial drugs *BilvadiLeha* 10 gm twice daily orally after taking meal with lukewarm water as a *Anupana* within duration of 12 weeks. For assessment of results, IBS severity score, WHO QOL score, *Ayurvedic* parameters, hematology and microscopic stool examination were used. The study was showed significant results in fifty one (one patient dropped) patients in management of IBS (*GrahaniDosha*) with safety profile as an important therapeutic agent.

Keyword: IBS (Irritable bowel syndrome), *GrahaniDosha*, *BilvadiLeha*

INTRODUCTION

Today, man is subjected to a major event of stress in modern fast way of life and the balance is frequently disturbed. The system is constantly kept under sympathetic stimulations without enough

time for the parasympathetic system to do its job. This repeated sympathetic stimulation in the body lead to intermittent upsurges of heart rate, poor digestion, elevated blood glucose etc. due to secretion of neurotransmitters i.e. serotonin etc[1]. The large bowel is very sensitive to nervous excitations. Diarrhea during examination is a common experience. In a person who is highly sensitive and tensed with much emotional suppressions, the colon cries by purging. IBS is a functional bowel disorder characterized by abdominal pain or discomfort and altered bowel habits in the absence of detectable structural abnormalities. Throughout the world, about 10-20 % of adults and adolescents have symptoms consistent with IBS, and most studies show a female predominance[2]. *GrahaniRoga* as described in *Ayurveda* is achronic bowel disease affecting the *MahaSrotasa*, means the GIT (Gastro Intestinal Tract). The cardinal symptom of *GrahaniRoga* is alternate constipation and diarrhoea with blood or mucous along with abdominal pain and progressive emaciation. *GrahaniRoga* is caused by *Mandagni.* Due to *Mandagni* all the *Dosha's* will vitiate, consequently it causes structural impairment of the *Grahani*, which in turn leads to malfunctioning of *Grahani*, resulting into infrequent evacuation of the bowel, which are hard or in liquid form[3]. The parameters of assessment were made more relevant to the purpose of study with emphasis on the improvement in the pattern of absorption from the gut, improvement of general health and relief from symptoms of *GrahaniRoga.* In presented study, *BilvadiLeha* was used in patients of *GrahaniRoga* for clinical evaluation of trial drug.

AIM AND OBJECTIVES:

The study was undertaken with the following specific objectives which divided-

- **Primary Objectives:** To assess the effect of *BilvadiLeha* on IBS Severity Score.
- **Secondary Objectives:**
- To study the conceptual basis of IBS in comparison with various similar *Ayurvedic* conditions described in literature.
- To assess the effect of *BilvadiLeha* on WHO-QOL BREF score.
- To assess the safety of *BilvadiLeha in patients of IBS.*

MATERIALS AND METHODS:

The study was an interventional, open label, not controlled, prospective, single group, clinical trial using pretest-posttest design and the study population was collected from the OPD and IPD of P.G. Department of *Kayachikitsa* at *Arogyashala*, National Institute of Ayurveda and SSBH, Jaipur (Raj.) and Department of Gastroenterology, SMS Medical College and Hospital, Jaipur (Raj.). Sample size was fifty twonumber of patients (1 patients dropped out and 51 completed) and who was diagnosed according to as per Rome III criteria.

Thetrial drug*BilvadiLeha* (API- Part II: Vol-1: Page no.7-9)[4]was given 10 mg per orally twice a day after food with lukewarm water for 12 consecutive weeks. Patients were guided regarding *Pathya/ Apathya* regimen. Patients were followed after every 14th days during treatment and after every 28th days after completed trial. The *bilvadiLeha*was provided by CCRAS and was prepared by ***Arya Vaidya Sala Kottakkal, Kerala.***

BilvadiLeha having following contents: *Bilva* in 128 Parts (*Aeglemarmelos*, *Root*)[5], *Musta* (*Cyperusrotundus, Root tuber*), *Dhanyaka* (*Coriandrumsativum, Fruit)*[6], *Jiraka* (*Cuminumcyminum, Fruit*), *Ella (Elettariacardamomum, Seed), Twaka (Cinnamomumzeylanicum, Stem bark), Nagkesera (Mesuaferrea, Stamens), Sunthi (Zingiberofficinale, Rhizome), Maricha (Piper nigrum, Fruits), Pippali (piper longum, Fruit),* in 12 part of each and *Jirnaguda (Old Jaggery)* in 64 Parts.

Method of Preparation of Trial Drug: Firstly make *BilvaKwath*, added Jaggery and also added *PrakshepaDravya's* (*Musta* to *Pippali*, 9 drugs) continue heating till the preparation attains the consistency of *Leha* confirmed[7].

Inclusion Criteria: The following inclusion criteria was followed for selecting the patients-

- Patients of either sex with age between 18 and 65 years.
- Known case of IBS as per Rome III criteria.

(Symptoms of recurrent abdominal pain or discomfort and a marked change in bowel habit for atleast six months, with symptoms experienced on atleast 3 days/month in the last months associated with two or more of the following:-

- Pain is relieved by defecation.
- Onset associated with change of frequency of stools.
- Onset associated with a change in form (appearance) of stools.
- Willing and able to participate in the study.

Exclusion Criteria: The following was followed as exclusion criteria for selecting the patients-

- Patients with bleeding per rectum.
- Patients with evidence of malignancy.
- Alcoholic and/or drug abusers.
- Pregnant and lactating woman.
- Patients with Diabetes Mellitus, Hypertension, Mixed infection with intestinal parasites.
- Patients with prolonged (>6 weeks) medication such as corticosteroids, antidepressants etc.
- Patients suffering from major systemic illness necessitating long term drug treatment such as Rheumatoid arthritis, tuberculosis etc.
- Patients who have a past history of a trial fibrillation, MI, Stroke, severe arrhythmia in the last 6 months and with clinical evidence of Heart failure.
- Patients with concurrent serious hepatic disorders, renal disorders, severe pulmonary dysfunctions.
- Patients who have completed participation in any other clinical trial during the past six months and have a P/H/O hypersensivity.

Methods of Assessment:

- **Prior to selection (Screening):** Informed consent, Eligibility evaluation, and Physical examination and Laboratory investigation.
- **During selection (baseline):** General information, physical and systemic examination, Assessment of Ayurvedic parameters, IBS Severity Score, WHO QOL BREF Score.
- **During treatment i.e.14th, 28th days etc.:** Assessing drug compliance, physical and systemic examination, Assessment of Ayurvedic parameters, IBS Severity Score.
- **At the end of the treatment i.e. 84th days (at the end of 12 weeks):** Assessing drug compliance, physical and clinical examination, Assessment of Ayurvedic parameters, IBS Severity Score and laboratory investigations.
- **Assessment at the end of 16 weeks:** clinical assessments, Assessment of Ayurvedic parameters, IBS Severity Score and WHO QOL BREF Score.

Laboratory Parameters:

- Hemoglobin, Total Leucocyte Count (TLC), differential leucocyte count, Erythrocyte Sedimentation Rate (ESR), CBC.
- Biochemical investigations: FBS, PPBS, Liver function test (LFT), Renal function test(RFT).
- Stool for routine and microscopic examination.

Statistical Analysis: The quantitative data was assessed by using paired student t test when compared before and after study in a single group (intra group) and one- way analysis of variance (ANOVA) was applied to IBS Score and WHO QOLBREF Score.

- In IBS Score the comparison between BT and all follow ups was done with the help of ANOVA.
- In WHO QOLBREF Score the comparison between BT, AT and 4th weeks follow up after treatment was done with the help of ANOVA.

The P< 0.05 was considered as statistically significant, P>0.05 was considered as statistically not significant.

RESULTS AND OBSERVATIONS:

The observation made on 52 patients of IBS showed that maximum number of patients belonged to 18-30 years age group (53.84%), Male(84.61%), Married (65.38%), Literate (84.61%), above poverty line(75%), Urban habitant (67.3%), Hindu religion (88.46%), Vegetarian (67%), non- addicted (75%). 53.84% patients were having disturbed sleep pattern. A maximum patient belongs to *Vata-PittajaPrakriti* (60%), *Madhyama Samhanana* (67.3%), *Avara Aahara Shakti* (77%) and *Madhyama Vyayama Shakti* (75%).

In this study, recurrent abdominal discomfort or pain was presented in all patients and abdominal bloating was present in 46.15% patients, 23% of constipation and 78.84 % of having diarrhea. There was 46.15% of patients having urgency of bowel movements, 92.43% of patients were having feeling of incomplete evacuation and 15.38% patients were having mucous with stool.

There were significant improvements in chief complaints and *Ayurvedic* parameters. In IBS score % of improvement of symptoms was continuously increasing from 0 to 84th days. Percentage change in the improvement of symptoms from 0 to 16th weeks was reduced as comparative to 84th days depends on successive follow-ups there was variation of results. **[Table no. 1].** In WHO score, Domain 1(Physical health) and 2(Psychological health) were showed significant results from 0 to 84th days and 0 to 16 weeks where as insignificant results were showed from 84th days to 16th weeks. There was insignificant results in laboratory parameters after completion of trial also which showed that the safety profile of trial drugs.

Table 1: ANOVA for IBS Score (Kruskal Wallis Test {non parametric test}.

S. no.	Comparison	Mean Diff.	% Change	S.D.±	S.E. ±	p- value	Remarks
1	0 & 14th day	67.33	27.06	75.038	10.507	<0.05	S.
2	0 & 28th day	102.33	41.14	78.797	11.034	<0.001	H.S.
3	0 & 42th day	120.8	48.64	83.505	11.693	<0.001	H.S.
4	0 & 56th day	142.76	57.39	76.2	10.67	<0.001	H.S.
5	0 & 70th day	151.0	60.70	73.083	10.234	<0.001	H.S.
6	0 & 84th day	150.61	60.54	73.224	10.253	<0.001	H.S.
7	0th D & 16th week	78.64	31.617	77.489	10.851	<0.001	H.S.
8	14th& 28th day	35.0	19.293	46.087	6.4535	<0.05	N.S.
9	14th& 42th day	53.47	29.47	63.722	8.9229	<0.05	N.S.
10	14th& 56th day	75.43	41.58	59.767	8.3404	<0.001	H.S.
11	14th& 70th day	83.66	46.12	68.803	8.6263	<0.001	H.S.
12	14th& 84th day	83.27	45.904	53.707	8.369	<0.001	H.S.
13	14th D& 16th week	11.31	6.236	51.271	9.6343	<0.05	N.S.
14	28th& 42th day	18.47	12.616	54.37	7.5206	<0.05	N.S.
15	28th& 56th day	40.43	27.615	51.271	7.1793	<0.05	N.S.
16	28th& 70th day	48.66	33.24	54.37	7.6133	<0.05	N.S.
17	28th& 84th day	48.27	32.97	51.866	7.2626	<0.05	N.S.
18	28th D& 16th week	-23.68	-16.18	73.742	10.326	<0.05	N.S.
19	42th& 56th day	21.96	17.165	38.106	5.3359	<0.05	N.S.
20	42th& 70th day	30.19	23.602	41.94	5.8728	<0.05	N.S.
21	42th& 84th day	29.80	23.295	41.352	5.7904	<0.05	N.S.
22	42th D& 16th week	-42.17	-32.95	68.966	9.6571	<0.05	N.S.
23	56th& 70th day	8.235	7.77	24.755	3.4664	<0.05	N.S.
24	56th& 84th day	7.843	7.400	23.071	3.2305	<0.05	N.S.
25	56thD & 16th week	-64.11	-60.5	59.705	8.3604	<0.05	S.

26	70^{th}& 84^{th} day	-0.392	-0.401	16.699	2.3383	<0.05	N.S.
27	70^{th}D & 16^{th} week	-72.35	-74.02	55.384	7.7553	<0.001	H.S.
28	84^{th}D & 16^{th} week	-71.96	-73.33	55.804	7.8141	<0.001	H.S.

DISCUSSION

In *Ayurveda,* the action of drugs is determined on Pharmaco dynamics factors as *Rasa, Guna, Veerya* and *Vipaka* along with certain specific properties called *Prabhava (Karma),* which cannot be explained on these principles inherited by the drugs. ***GrahaniDosha*** (IBS) is the disease of *Agnivikriti* and *ManshikaDoshaVikriti*. Formation of *AmaDosha* at different levels is the main *Samprapti* responsible for the disease. So for the *Samprapti-Vighatana* of the disease, the drug should remove *AmaDosha* at various levels, correct the *Agni* and cleanses the *Srotasa as well as equilibrium of Manshika and Sharirika Dosha's.* The main ingredient of *BilvadiLeha* is *Bilva* which acts as *Agnideepana, Amapachana* and having *Grahi* properties. The ingredients of *BilvadiLeha* were having maximum of *Katu Rasa* followed by *Tikta Rasa* and *KatuVipaka* and *UshanaVeerya* which act as *Deepana, Pachana, Ruchikara, Shodhana, Krimihara* and *Kaphaghna* properties. *UshanaVeerya* helps in cleanses the *Srotasa* (*Srotoshodhaka*) and *Kaphaghna* properties. *Sunthi, Pippali, Musta* etc. are maintaining the equilibrium of *Manshika* and *SharirikaDosha's* on the basis of previous researches.

CONCLUSION

The Observations and Results obtained in a series of patients of IBS treated with *BilvadiLeha* had showed good recovery in clinical manifestation of the diseases and well tolerated by all patients and no unwanted effects was seen. There was significant results showed in IBS score and WHOQOL BREF score (Physical and psychological as well as Physical and mental health). Thus it can be concluded that *BilvadiLeha* can be used as a safe and "important Therapeutic agent" in the management of Irritable Bowel Syndrome (IBS).

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