

CLINICAL EVALUATION OF BILVADI CHURAN IN THE MANAGEMENT OF GRAHANI ROG W.S.R. TO IBS (IRRITABLE BOWEL SYNDROME)

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ABSTRACT

IBS is probably the most common gastro-intestinal disorder encountered by primary care Physicians. Due to high prevalence and many times incapacitating symptoms; IBS is the cause of both individual suffering & considerable socio-economic costs. Grahani Rog is an Ayurvedic disease which represents similarities with IBS. Study was done to evaluate the efficacy of Bilvadi Churan containing Bilva, Mochras, Bhang, Shunthi, Dhataki, Dhanya and Sounf, in the management of Grahani Rog. Thirty one patients of either sex with age group of 15-45 years with uncomplicated cases of IBS are selected. The trial drug was administered to the patients in dose of 3gm B.D with Takra. All patients completed the full 40 days treatment except one. The outcome of medicinal preparation on 30 patients by various assessment criteria were gained after statistical analysis of data obtained. Study showed highly significant result in abdominal pain,

ati-srishtam, trishna, lohamgandhi udgar, gas & flatulence ($p < 0.001$). Arochak ($p < 0.005$) highly significant. Varasya ($p < 0.003$) highly significant. Prasaka ($p < 0.07$) significant. Asthiruk ($p < 0.004$) highly significant. 91.5% relief in symptoms was seen in maximum patients which is highly significant i.e. $p < 0.001$. Hence Bilvadi Churan is an excellent combination of deepan pachan drugs having appetizer, digestive, carminative, antispasmodic action. It is effective remedy in uncomplicated & new cases of Grahani Rog. Has produced

mild, moderate & maximum response without any serious complications and very cost effective treatment in the management of Grahani Rog.

KEYWORDS: Grahani, IBS, Arochak, Varasya.

INTRODUCTION

Healthy mind in a healthy body is the principle aim guiding all the prevailing system of Medicine. There is a popular saying that “*If you have your health, you have everything*”. Unfortunately, our health is something not appreciated until we are without it. *Acharya Charaka* mentions that a person can eat that much quantity of food which will be easily digested in a proper length of time and which will not cause any harm to body and health.^[1] He also mentions that a person should eat food which should be suitable for the *Rutu* i.e. season, which will help to gain *Bala* and *Varna*.^[2] *Acharya Sushruta* says that, Sign of healthy body is proper balance of *Dosh*, *Agni*, *Dhatu* and *Mala* with their right function in the body system. Along with the required function of *Indriyas* (Senses) and *Mana*. But out of these four *Agni* is most important in chain of creation and is having the capacity to digest and transform. Various metabolic activities of our body depend upon the status of *Agni* in our body.^[3] *Acharya Charaka*'s says that “Better health depends upon the increased and decreased functional capacities of *Pachakapitta*.”^[4] Because of this, *Kayachikitsa* is known as *Antaragni Chikitsa*. The seat of *Antaragni* (*Jatharagni*) is known as *Grahani*. The relation between *Grahani* and *Agni* is similar to the relation between structure and function^[5]. *Acharya Charaka* says that *Grahani* is the seat of *Agni* and is called so because of holding up the food. Normally, it holds up the food (till it is digested) and releases it from the side after it is digested. But when it is deranged due to weak digestive fire (*Manda Agni*) it releases the ingested material even in unripe condition. This condition or working of *Grahani* is called as *Grahani Rog*.^[6] *Grahani Rog* manifests in the form of irregular bowel habits with pain i.e. sometimes patient pass formed and sometimes semi solid stool or liquid stool. Other symptoms which appear in this disease include loss of weight, thirst, letharginess, indigestion, dyspepsia, vomiting, and nausea, swelling of limbs, fever, and weakness etc.^[7] Irritable Bowel Syndrome, which can be correlated with *Grahani Rog*, which is a GIT disorder characterized by altered bowel habits and abdominal pain in absence of detectable structural abnormalities. IBS affects up to 20% of the population in Western countries with a 2-3:1female predominance. In general, there is a clear female predominance among *IBS* patients. Among those seeking health care services, women lead men in *IBS* diagnoses by a

ratio of 2-4:1, whereas the distribution seems 17 to be less than 2:1 in prevalence data based on community surveys.^[8] The present trial is taken from the text *Sidh Yog Sangrah*.^[9] It contains *Bilva*, *MochRas*, *Sontha*, *Bhang*, *Dhaya Flower*, *Dhaniya*, *Soonf*, which are herbo mineral in nature and is easily available and is an excellent combination of *Deepan Pachan* drugs having appetizer, digestive, carminative, antispasmodic action. It is effective remedy in uncomplicated & new cases of *Grahani Rog*. Has produced mild, moderate & maximum response without any serious complications and very cost effective treatment in the management of *Grahani Rog*.

MATERIAL AND METHOD

Selection of Patients

1. It was a single clinical study with a pre-test & post-test design, where a minimum of thirty patients of either sex with age group between 15 – 45 years suffering with *Grahani Rog* and fulfilling the inclusion criteria were selected from O.P.D. of Jammu Institute of Ayurveda & Research and Department of Medicine Community Health Center, R.S.Pura, Jammu. & put into a single group.
2. Diagnosis is made on the basis of special perform prepared in relation to *Grahani Rog*.
3. *Bilvadi Churana* is administered in the patients full filling the criteria of selection, in the dose of 3gm twice daily for 40 days.
4. Patients were monitored and observations were recorded before and after the drug schedule.

Criteria of selection

a) Inclusion criteria

- Belonging to age group 16-45 years
- Both sexes
- Chronicity less then 5yrs
- Uncomplicated cases of *IBS*

b) Exclusion criteria

- Below 16 yrs and persons above 45 yrs
- Any serious life threatening disease
- Pregnancy
- Patient having *IBD*, *T.B*, *Lactose intolerance*, *Celiac disease*, *Ca colon*, *diabetes*, *malignancy*

PLAN OF WORK

1. Detailed perform: A special Performa was prepared regarding the disease and the patient as a whole, as mentioned below.

a) Demographic Profile: Name, age, sex, father's name, occupation, religion, education, marital status, socio-economic status, date of registration, OPD/IPD no., research case no., scheduled initiation date, completion date and result are the points included in demographic profile.

b) Clinical Profile: Following are the points under the clinical profile.

c) Chief complaint with duration, History of present illness, past illness, Occupational history, Family history, Personal history, Treatment history, menstrual history, Obstetric history

d) General Examination: It includes General appearance, Pulse rate, and Respiratory rate, B.P, Temperature, Built (Height and Weight), Clubbing, Pallor, Koilonychias, Icterus, Cyanosis, Lymphadenopathy, Edema and Thyroid.

e) *Ashtavidha Pariksha*

f) *Dashvidha Pariksha*

g) Systemic Examination.

2. Laboratory Investigation

a) Haemogram – Blood for Hb%, Total Leucocytes Count (TLC), Erythrocytes Sedimentation Rate (ESR), Packed Cell Volume (PCV).

b) Urine- Routine and Microscopic examination was done.

c) Stool- Routine and Microscopic examination was done.

3. Test Drug & its schedule

The trial formulation, *Bilvadi Churana*^[9] from Sidh Yog Sangrah is a polyherbal preparation, containing following 7 indigenous drugs.

- | | |
|----------------|--------|
| 1. Bilva | 1 part |
| 2. Mochras | 1 part |
| 3. Sontha | 1 part |
| 4. Bhang | 1 part |
| 5. Dhaya Phool | 1 part |

6. Dhaniya 2 part
7. Soonf 4 part

The trial formulation was prepared in the pharmacy of Jammu Institute of Ayurveda and Research, Nardani, as per the Ayurvedic Sidhant.

It was given to patients for a period of 40 days at dose 3gm twice a day after food with *Takra* as *Anupana*.

CRITERIA FOR ASSESSMENT

Most of the signs and symptoms of *Grahani Rog* described in *Ayurveda* are subjective in nature, to give the results objectively and for statistical analysis scoring system have been adopted. The symptoms score is obtained before treatment, after 20 days of initiation of treatment and after 40 days of complete treatment. A statistical analysis and percentage relief was taken to know the efficacy of therapy. Criteria of assessment are divided into two headings.

- a) Subjective Criteria
- b) Objective Criteria

Subjective Criteria

The following criteria or variables were assessed before and after the drug administration^[7,8]–

1. Ati- Srishtam (Loose Stool)
2. Vibdham (Hard Stool)
3. Dravam (Watery Stool)
4. Trishna (Polydipsia)
5. Arochak (Anorexia)
6. Varasya (Tastelessness of Mouth)
7. Prasaka (Excessive Salivation)
8. Shoonpadha (Swelling of Feet)
9. Asthipar Ruk (Joint Pain)
10. Chardi (Vomiting)
11. Jawar (Fever)
12. Lohamgandhi Udgar (Sour Belching)
13. Abdominal pain/ discomfort
14. Constipation

15. Diarrhea
16. Constipation & Diarrhea
17. Mucus in stool
18. Gas & Flatulence

Objective Criteria: Based on various investigations like blood, urine and stool are done before and after treatment. The statistical analysis was done of these score before starting the treatment and after completion of 40 days course. The details of the scores adopted for the chief signs and symptoms in the present study were as follows.

Atishrishtam Mala Pravriti

Passing of normal consistency stool (1-2 times/day)	0
Passing of loose stool (2-3 times/ day)	1
Passing of loose stool (3-4 times/day)	2
Passing of loose stool (5-6 times/ day)	3
Passing of loose stool (>6 times/day)	4

Vibdhama Mala Pravriti

No Vibdhata, pass stool daily without difficulty	0
Difficulty in passing stool daily without Vedana	1
Difficulty, feeling of incomplete evacuation passing hard stool on alternate day with Vedana	2
Very difficulty in passing hard stool with pain on fourth day	3

Drava Mala Pravriti

No Drava Mala Pravriti	0
Passing of watery stool 2-4 times/day	1
Passing of watery stool 5-6 times/day	2
Passing of watery stool >6 times/ day	3

Trishna

Normal feeling of thirst	0
Frequent feeling of thirst but quench with normal amount of fluid intake	1
Satisfactory quench after increased intake of fluids but no awakening during nights	2
Satisfactory quench after increased intake of fluids with regular awakening during nights	3
No quench even after heavy intake of fluids	4

Arochak

Normal appetite and relish	0
Eating timely without much desire	1
Desire for food little late than normal time	2
Desire for food after long intervals	3
Totally unwilling to eat	4

Varsaya

No tastelessness of mouth	0
Mild tastelessness of mouth	1
Moderate tastelessness of mouth	2
Total tastelessness of mouth	3

Prasaka

No Prasaka at all	0
Increased frequency of salivation occasionally	1
Increased frequency of salivation everyday	2

Shoonpadha

No swelling	0
Slight swelling	1
Moderate swelling	2
Sever swelling	3

Asthiparvruk

No pain	0
Occasional but disappears	1
Often but disappears	2
Often persistent	3
Constantly persistent	4

Chardi

No vomiting at all	0
Feels sense of nausea and vomits occasionally	1
Frequency is not more than 2 to 3 per week	2
Frequency of vomiting is daily	3
Frequency of vomiting after every meal	4

Jwara

Normal	0
99.1°F - 100°F	1
100.1°F - 101°F	2
101.1°F - 102°F	3
>102°F	4

Lohamagandhi Udgara

No Udgara at all	0
Sometimes during day	1
Udgara of moderate intensity	2
Severe Udgara disturbing the patients	3
Small amount of fluid regurgitate to patients mouth	4

Abdominal Pain or Discomfort

No abdominal pain	0
Some time/ rarely abdominal pain intermittent crampy lower abdominal pain which is relived by passage of flatus & stool	1
Intermittent crampy lower abdominal pain which is relived by passage of flatus & stool	2
Continuous abdominal pain often over the Rt. Upper quadrant/ mid epigastria/ which is not relieved by passage of flatus & stool	3

Constipation

Stool with normal consistency	0
Defecation after physical exercise such as a brisk walk or after taking liquid	1
Difficult passage of stool with feeling of incomplete evacuation	2
Passes hard stool which is relived by increasing fiber diet or laxatives	3

Diarrhea

Stool with normal frequency & consistency	0
Diarrhea or pencil like stool passage inn morning upon arising or after breakfast	1
Passage of 3-4 loose stool occurring intermittently	2
Passage of 5-6 loose stools everyday	3
Watery diarrhea throughout the day	4

Presence of mucus in stool

No visible mucus in stool	0
Visible mucus stickled to the stool	1
Passage of mucus with frequent stool	2
Passage of large amount of mucus in stool	3

Gas or flatulence

No abnormal gas/ flatulence	0
Occasional abdominal distention	1
Frequently abdominal distention with increased flatulence & belching	2
Rumbling / gargling sound present in abdomen	3

On the basis of microscopic stool analysis

Ova absent	0
Ova present	1
Cyst absent	0
Cyst present	1

Monitoring of subjects

All the subjects consumed the formulation for prescribed duration i.e. for 40 days with follow up after every 20 days. 1 patient dropped out in between the course. So the effect of therapy was seen only in 30 patients.

Statistical analysis

The data was analyzed in form of Mean score before and after treatment, standard deviation and standard error. Student paired't test was carried out for statistical significance. Demographic profile, clinical features and haematological parameters of 30 patients was also observed.

OBSERVATION AND RESULTS**Demographic Profile of 31 subjects (Table no.1).**

Male to female ratio was 16:15. 69.35% of the patients were in the age range from 16-25 year and 54.83% were in age group 36-45 year. Religion wise 70.96% belong to Hindu community and rest 29.03% to Sikh. 67.74% are married in marital status class. Type of work distribution, contribution of people doing light work is 67.74%. 25.8% patients were educated up to middle school, 32.25% were educated up to high school level and 41.93% percentage patients were graduate. 80.64% subjects belong to above poverty line group. 61.29% patients take fast/ spicy food and 58.06% take non-vegetarian diet.

Total 41.93% patients were addicted to tea and 45.16% have no addiction. 38.70% have 5-6 times/day stool frequency. 51.61% patients have pittkapha prakrti. All patients have madhaya koshta. Patients have 67.74% madhaya samhanan, 61.29% madhaya abhavarana shakti, 61.74% madhaya jaranshakti and 51.61% madhaya vyayama shakti are involved respectively.

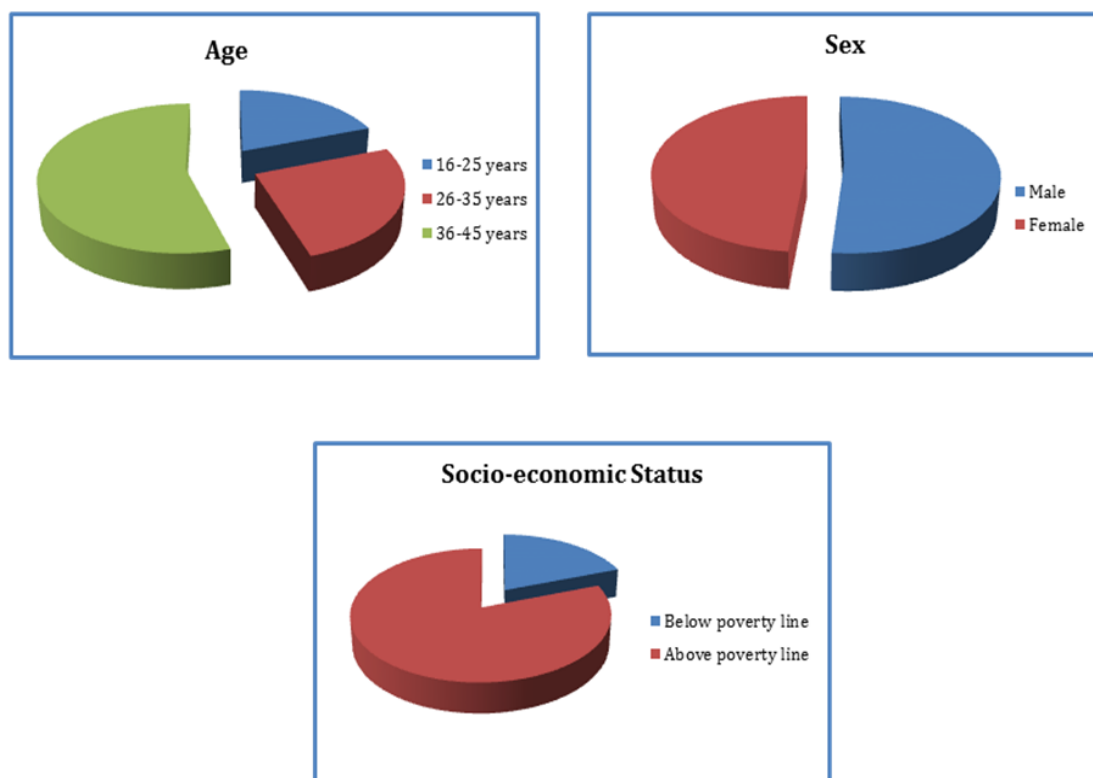


Fig.1

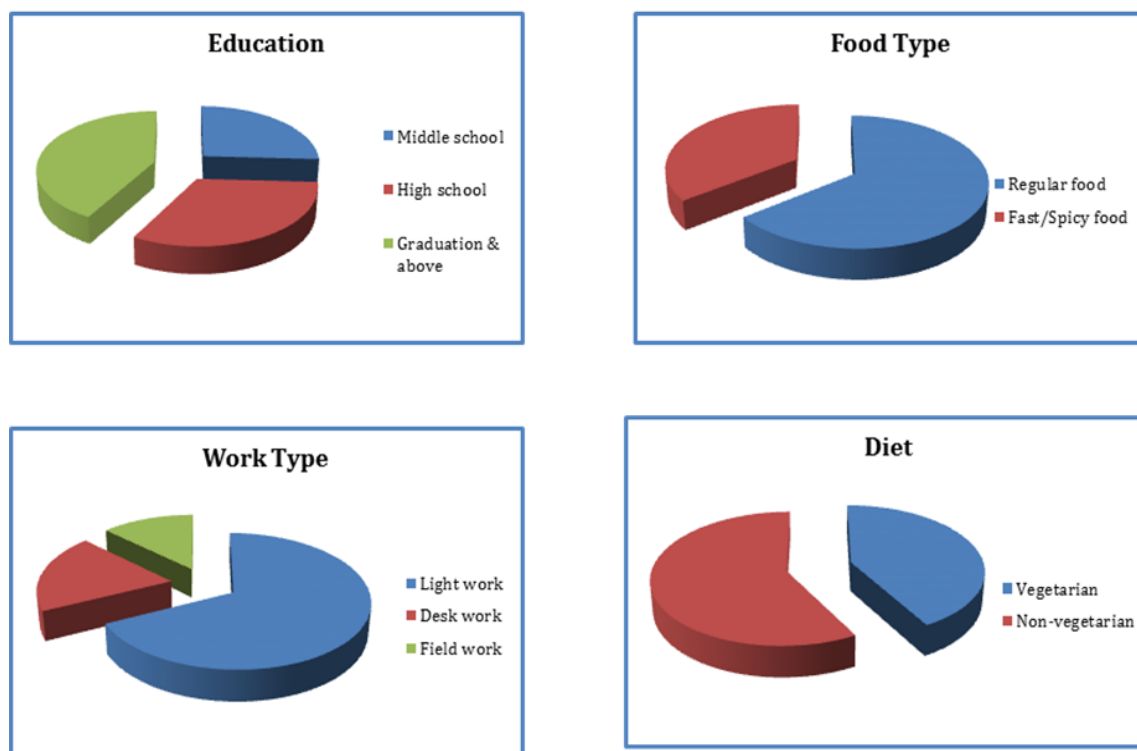


Fig.2

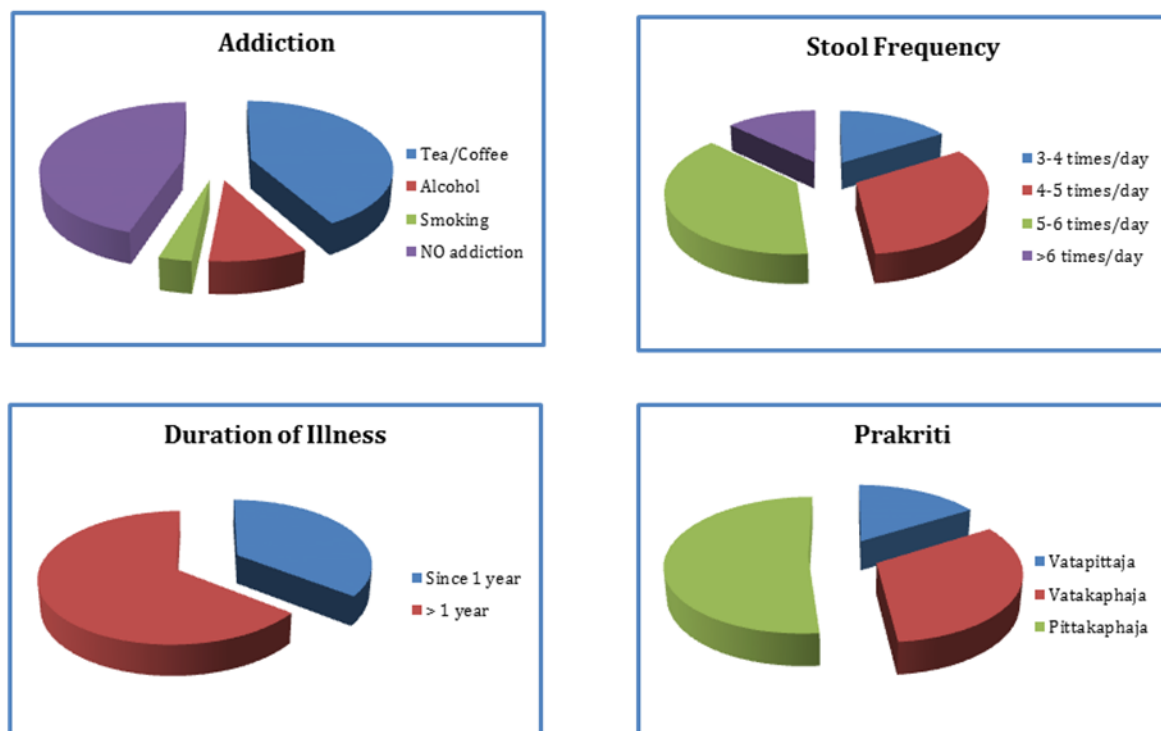


Fig.3.

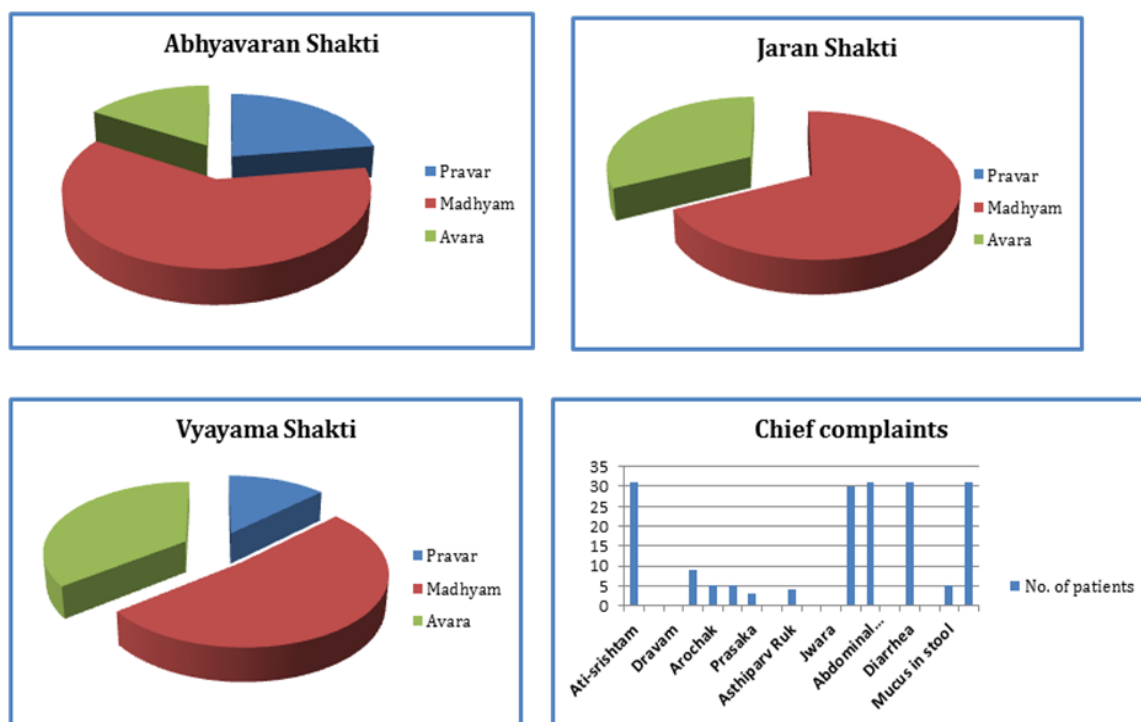


Fig.4

Efficacy outcomes in 31 patients

Grade score system was designed for assessing the improvement on subjective criteria in *grahani rog* patients. There was highly significant improvement in criteria of *Atisrishtam*, *Trishna* Lohamgandhi udgar, Abdominal pain and Gas & flatulence with $p < 0.001$ i.e. highly significant. Mucus in stool $p < 0.004$ that's also highly significant. Arochak, Varasaya, Prasaka and Asthiparv ruk have $p < 0.005$ (S), $p < 0.003$ (S), $p < 0.057$ (S), $p < 0.014$ (S) respectively. Hb % showed improvement by 3.29% significant at $p < 0.001$. TLC change by 2.13% at $p < 0.061$. ESR showed improvement by 21.9% significant at $p < 0.019$. PCV showed change by 1.98% which is statically significant at $p < 0.050$. No drug toxicity or severe side effect was observed during the course of trial.

Table No. 1.

Criteria	N*	Mean Score (BT ^x)	Mean score (AT ⁺)	%age relief	SD \pm	SE \pm	t	P
<i>Ati- srishtam</i>	30	3.1	0.33	89.24%	0.50	0.92	30.06	<0.001
<i>Trishna</i>	9	1.88	0.22	88.23%	0.50	0.16	10	<0.001
<i>Arochak</i>	5	1.60	0.20	87.5%	0.54	0.24	5.71	<0.005
<i>Varasaya</i>	5	1.80	0.20	88.89%	0.54	0.24	6.53	<0.003
<i>Prasaka</i>	3	1.33	0	100%	0.57	0.33	4.00	<0.057
<i>Asthiparv ruk</i>	4	1.50	0	83.33%	0.57	0.28	5.19	<0.014
<i>Lohamgandhi udgar</i>	29	2.72	0.13	94.93%	0.56	0.10	24.51	<0.001
<i>Abdominal pain</i>	30	2.13	0.16	92.42%	0.55	0.10	19.37	<0.001
<i>Mucus in stool</i>	5	1.40	0.20	85.71%	0.44	0.20	6.0	<0.004
<i>Gas & flatulence</i>	30	2.50	0.33	98.66	0.64	0.11	18.32	<0.001

(N*-no.of patients with specific subjective criterion, BT^x- before trial, AT⁺- after trial)

Table no. 2.

Parameters	n	Mean		D	%	SD	SE	t	P	Significance
		BT	AT							
Hb%	30	10.31	10.65	-0.34	-3.29	0.47	0.08	-3.9	<0.001	H.S
TLC	30	8.28	8.46	-1.76	-2.13	495.97	90.55	-1.95	>0.061	N.S
Polymorphs	30	60.86	61.20	-0.33	-0.54	2.41	0.44	-0.75	>0.455	N.S
Lymphocytes	30	33.70	34.06	-0.36	-1.08	2.44	0.44	-0.82	>0.418	N.S
Monocytes	30	2.50	2.20	0.30	12	0.79	0.14	2.06	<0.048	S
Eosinophils	30	2.33	2.33	0	-2.85	1.08	0.19	0	>1.00	N.S
ESR	30	6.73	5.33	1.40	21.9	3.09	0.56	2.48	<0.019	S
PCV	30	43.63	42.76	0.86	1.98	2.33	0.42	2.03	<0.050	S
Ova	0	0	0	0	0	0	0	0	—	—
Cyst	03	1.0	0	0	0	100	0	0	—	—

Table No. 3: Showing the pattern of clinical recovery in Grahani Rog.

Group	Single
Mean %	91.5%
t	10.72
p	<0.001

DISCUSSION

Every individual become victim to some gastrointestinal disorders during his life span. Among them majority of disorders are due to functional dearrangement of gastrointestinal tract. The main lacuna with the present available health practice (irrespective of the system) is that emphasis is always given on curative aspect of disease but not to the preventive aspect. *Ayurveda* is unique in its approach, where it clearly mentions its ultimate aim as nothing but to prevent the disease, and maintain the health of healthy individual.

Grahani Rog is a disease entity goes almost hand in hand with gastrointestinal disorders. *Grahani* is an important organ of *Maha-srotas* and is unanimously considered as organ of digestion by all ancient *Acharyas*. Since *Grahani* is an *Mandagni-janya* rog, so *Bilvadi churna*^[9] with *Takra* was given having *Tridoshshamka*, *deepana* and *pachana* properties. The drugs in combination form have appetizer, digestive, carminative, antispasmodic, stomachic antimicrobial, anti-ulcerogenic, immunomodulatory, mood improver, anti-anxiety and haematinic properties. The *Rasa* of the combination is predominantly *Katu* followed by *Tikta*, *Guna* is predominantly *Laghu* followed by *Ruksha*, *Veerya* is *Ushana* and *Vipaka* is predominantly *Katu*. The *Doshaghnata* is *Kapha-Pitta Shamaka* followed by *Kapha-Vata Shamaka*.

CONCLUSION

The following conclusion can be drawn from current research project.

- Bilvadi Churana* is an effective remedy in uncomplicated and new cases of *Grahani Rog* (IBS). But it has played a limited role in management of chronic cases of *Grahani Rog* (IBS).
- Administration of *Bilvadi Churana* has produced highly significant result.
- Patient of *Grahani Rog* (IBS) when treated with *Bilvadi Churana* produced mild, moderate and maximum response without any serious complications.

Therefore it can be concluded that *Bilvadi Churana*^[9] with *Takra* as *Anupana* is a very potent remedy for the management of *Grahani Rog* w.s.r. to IBS and Overall percentage of improvement was noticed in 91.5% of patients in the trial.

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