

Ojus Tablet in the Treatment of Irritable Bowel Syndrome

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Abstract

Irritable bowel syndrome (IBS) is one of the commonly occurring gastrointestinal disorders characterized by abdominal pain and altered bowel habits. Because the causes and mechanisms are unknown, a drug to cure this condition is still not available. Ojus Tablet, a herbal comprehensive single formulation is claimed to be effective in the treatment of IBS.

A study was conducted to evaluate the efficacy and safety of Ojus Tablet in 50 patients with established IBS. After a detailed history, clinical examination and relevant investigations, patients were administered Ojus Tablet 1 tablet twice a day half an hour after meals for 6 weeks, with a follow up every 2 weeks.

Forty-seven (94%) out of fifty patients responded to Ojus within 6 weeks of therapy, this was evident from statistically significant reduction in individual symptom scores ($P < 0.05$). Further the patient compliance was excellent and no adverse effects were reported.

Thus Ojus Tablet represents a useful first line treatment in established cases of IBS.

Introduction:

Irritable bowel syndrome (IBS) is one of the common gastrointestinal diseases having a broad clinical spectrum of severity. It has been reported that IBS sufferers worldwide seeking medical attention contribute 25 to 50% of referrals to gastroenterologists. The symptoms of IBS are best characterized by the criteria of Manning and coworkers, viz abdominal pain related to bowel movements, distension altered bowel habits, passage of mucus and a sense of incomplete evacuation after defecation. As the causes and mechanisms of IBS are unknown, the search for a rational. **It has been reported that IBS sufferers world-wide seeking medical attention contribute 25 to 50% of referrals to gastroenterologists.**

Therapy till date has been frustrating.

A part from dietary modification, the treatment of IBS is directed to the predominant symptom. With diarrhea-predominant IBS, an antidiarrhoeal is used. Prokinetics are used in patients with constipation-predominant IBS. For abdominal pain as the predominant symptom, antispasmodics or tricyclic antidepressants are administered. Anxiolytics are used when stress related exacerbations of symptoms are present. Most of these drugs especially the anxiolytic agents cannot be used on a long term basis because of risk of

habituation, withdrawal reactions and drug interactions. Tricyclic antidepressants often cause or aggravate constipation in IBS patients because of their anticholinergic side effects and are best avoided in the subgroup with pain and constipation. Again all the above

| Table I | |
|----------------------------------|------------------------|
| N | 50 |
| Males : Females | 31 : 19 |
| Mean age of patients | 32.24 \pm 1.76 years |
| Age range | 21 to 40 years |
| Treatment administered | Ojus Tablet |
| Dose | 1 tablet twice a day |
| Data expressed as Mean \pm S.E | |

Agents treat just one or the other symptom of the disorder and not IBS as a whole. In fact many drugs have found their way into practice through their impressive placebo effect. Till date, no single drug is available which combines all the desired actions required in the treatment of IBS.

In this context, indigenous drugs are undergoing extensive research. Today the WHO has acknowledged the contribution of ethnomedicine in the treatment of various diseases. The fact that about one third of patients with IBS resort to alternative system of medicine suggests that physicians and emotional needs of the patients.

In the current emerging scenario, Ojus Tablet represents an alternative medicine for IBS. Ojus is a comprehensive herbal formulation enriched with time tested ingredients of superior efficacy and high safety, beneficial in the treatment of IBS. Ojus Tablet contains 6 harmoniously blended ingredients possessing the actions desired in IBS prominent among these are Sonth (*Zingiber officinale*), Karanj (*Pongamia glabra*), Bael (*Aegle marmelos*) and Chitrak (*Plumbago zeylanica*) and Harde (*Terminalia chebula*).

| Sr. No. | Ingredients | Botanical Name | Qty./Tab |
|---|--------------|-----------------------------|----------|
| PART I: Extracts of the following: | | | |
| 1. | Harde | <i>Terminalia chebula</i> | 300 mg |
| 2. | Sonth | <i>Zingiber officinale</i> | 300 mg |
| 3. | Pippali Mool | Root of <i>Piper longum</i> | 300 mg |
| 4. | Karanj | <i>Pongamia glabra</i> | 300 mg |
| 5. | Bael | <i>Aegle marmelos</i> | 300 mg |
| 6. | Chitrak Mool | <i>Plumbago zeylanica</i> | 300 mg |

Table II
Distribution of symptoms in IBS patients before and after treatment
with Ojus Tablet (n=50)

| Symptom | Number of patients Before Rx (%) | Number of patients After Rx (%) |
|-------------------------------------|-------------------------------------|------------------------------------|
| Abdormal pain | 47 (94%) | 4 (8%) |
| Nausea | 6 (12%) | 0 (0%) |
| Vomiting | 4 (8%) | 0 (0%) |
| Anorexia | 11 (22%) | 2 (4%) |
| Mucous in stools | 38 (76%) | 5 (10%) |
| Diarrhoea | 38 (76%) | 4 (8%) |
| Feeling of incomplete evacuation | 39 (78%) | 8 (16%) |
| Constipation | 22 (44%) | 5 (10%) |
| Fullness after meals | 32 (64%) | 3 (6%) |
| Belching | 43 (86%) | 4 (8%) |
| Flatulence | 38 (76%) | 3 (6%) |
| Heartburn | 26 (52%) | 5 (10%) |
| Anxiety | 43 (86%) | 3 (6%) |
| Insomnia | 29 (58%) | 2 (4%) |

Ojus Tablet is claimed to act by restoring the gastrointestinal motility. It reinforces the body's natural supply of digestive enzymes, assists in digestion, absorption and assimilation. Further, it relieves flatulence and treats constipation or diarrhea. In fact Ojus Tablet provided by other medications in the treatment of IBS.

The following study was undertaken to evaluate the efficacy and safety of Ojus Tablet in the treatment of patients with established IBS.

Table III
Symptoms scores in IBS patients before and
after treatment of Ojus Tablet

| Symptom | Score Before Rx | Score After Rx | P value |
|-------------------------------------|--------------------|-------------------|----------|
| Abdormal pain | 2.39 ± 0.10 | 0.08 ± 0.02 | p < 0.05 |
| Nausea | 0.28 ± 0.11 | 0.0 ± 0.00 | p < 0.05 |
| Vomiting | 0.14 ± 0.08 | 0.0 ± 0.00 | p < 0.05 |
| Anorexia | 0.40 ± 0.12 | 0.08 ± 0.01 | p < 0.05 |
| Mucous in stools | 2.13 ± 0.12 | 0.18 ± 0.11 | p < 0.05 |
| Diarrhoea | 2.17 ± 0.09 | 0.09 ± 0.02 | p < 0.05 |
| Feeling of incomplete evacuation | 2.21 ± 0.08 | 0.30 ± 0.02 | p < 0.05 |
| Constipation | 1.03 ± 0.05 | 0.10 ± 0.01 | p < 0.05 |
| Fullness after meals | 1.29 ± 0.07 | 0.08 ± 0.01 | p < 0.05 |
| Belching | 2.34 ± 0.05 | 0.08 ± 0.01 | p < 0.05 |

| | | | |
|------------|-------------|-------------|----------|
| Flatulence | 2.17 ± 0.05 | 0.06 ± 0.03 | p < 0.05 |
| Heartburn | 0.81 ± 0.04 | 0.12 ± 0.01 | p < 0.05 |
| Anxiety | 2.31 ± 0.10 | 0.08 ± 0.04 | p < 0.05 |
| Insomnia | 0.64 ± 0.06 | 0.06 ± 0.01 | p < 0.05 |

Wilcoxon's signed rank test was used for comparison.
Value < 0.05 - significant

Materials and Methods

Fifty patients of established IBS (as per the Manning criteria) attending the **Gastroenterology OPD of Methodist hospital, Mathura, INDIA**, satisfying the inclusion criteria were studied. The ethics committee of the hospital approved the study and a written informed consent was taken from each patient after explaining the treatment pattern and follow up schedule.

Patients with organic disorders of gastrointestinal tract (neoplasm, sigmoid volvulus, megacolon), history of abdominal surgery or depression, anxiety, panic disorders or patients with inflammatory bowel disease or intestinal malabsorption (which produce symptoms mimicking IBS) were excluded from the study. This was an open trial.

All the patients were thoroughly interviewed, their clinical examination done and symptoms recorded and scored. The scoring of symptoms was done as follows:

No symptoms = 0,
Mild = 1,
Moderate = 2,
Severe = 3.

Specific laboratory investigations like flexible sigmoidoscopy and colonoscopy were done to rule out colonic neoplasm, inflammatory bowel disease and colitis. Additionally, complete blood count and ESR was done.

The patients were then put on Ojus Tablet in the dose of 1 tablet twice a day half and hour after meals for a period of 6 weeks. Patients did not receive any other drug for IBS apart from dietary advice. The data of the patients

| Response | Number of patients | Percentage |
|-----------------|---------------------------|-------------------|
| Complete | 43/50 | 86 |
| Satisfactory | 4/50 | 8 |
| No response | 2/50 | 4 |

Studied is shown in Table I

At each followup every 2 weeks, patients were examined, interviewed (for improvement and side effects of therapy if any). The results were analyzed and compared using appropriate statistical tests.

Statistical analysis

All the data are presented as Mean \pm S.E.

Wilcoxon's signed rank test was used to analyse the symptoms scores before and after the treatment with Ojus tablet . A value of $p < 0.05$ was considered as statistically significant.

Results

Fifty patients with established IBS were treated with Ojus Tablet for 6 weeks. The distribution of symptoms in IBS patients before and after treatment with Ojus Tablet is shown in Table II.

From Table II it is evident that the prominent symptoms in the studied patients were abdominal pain (94%), anxiety (86%), belching (86%), feeling of incomplete evacuation (78%), diarrhoea (76%), flatulence (76%), mucus in stools (76%), fullness in meals (64%), insomnia (58%), heartburn (52%), and constipation (44%). Symptoms of anorexia (22%) were less prominent in the patients studied.

The response to Ojus therapy is depicted in Table III. It can be seen that there is an improvement in the symptoms score ($p < 0.05$) in the patients. The same findings are depicted in Figure 1 to 3.

About the overall response to Ojus treatment, it can be said that a complete recovery was seen in 43/50 patients (86%) and a satisfactory recovery was seen in 4/50 (8%) patients after 6 weeks of therapy (Table IV). Two cases (4%) did not show any response. Thus, 47/50 (94%) patients responded to Ojus therapy.

The patients' compliance with Ojus Tablet was excellent and no side effect of the drug or a need to withdraw the drug any time was noted in any patient.

Discussion

IBS though a benign disease is a cause of great concern to the patients as it affects their daily life style. Infact, of the several reported studies, none offered convincing evidence that any therapy is effective in IBS. Further it is also reported that no single therapy is superior to placebo in any unselected cohort of IBS patients. In this context indigenous drugs have definitely proved their worth.

The results of the above study confirm that usefulness of Ojus Tablet in IBS. The mean age group in the studied population was 32.24 ± 1.76 years. So it can be said that IBS is more common in young people. Further 62% of patients were males. It has been

reported that amongst the IBS population in India, males outnumber females as compared to western countries.

In the present study most IBS patients presented with symptoms of abdominal pain (94%), anxiety (86%), belching (86%), feeling of incomplete evacuation (78%), diarrhoea (76%), flatulence (76%), mucus in stools (76%) , and treatment with Ojus was able to relieve most of these symptoms. A part from this other relatively uncommon symptoms like fullness in meals (64%), insomnia (58%), heartburn (52%), and constipation (44%) are also improved. An overall relief was seen in 47/50 (94%) patients. The onset of the response was quick as most of the patients reported an improvement within their first follow-up.

Among the ingredients in Ojus Tablet Harde regulate the gastrointestinal motility. IBS is associated with abnormal gastrointestinal motility (alternating constipation and diarrhoea) and normalizing the motility can itself relieve many associated symptoms. Bael acts as nervine sedatives and relieves anxiety and tension. Furthermore they relieve stress so commonly associated with IBS. Sonth, Pippalimool and Chitrak act as carminatives, relieve flatulence and abdominal distension. Apart from these Karanj and Chitrak act as appetizers. Bael and Sonth in additional take care of diarrhoea whereas Harde is beneficial in the treatment of constipation. All these actions are very much desirable in IBS. Thus Ojus Tablet is a compact formulation catering to the treatment of IBS.

Conclusion

From the above study, it can be concluded that Ojus Tablet represents a useful therapy in the management of IBS.

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