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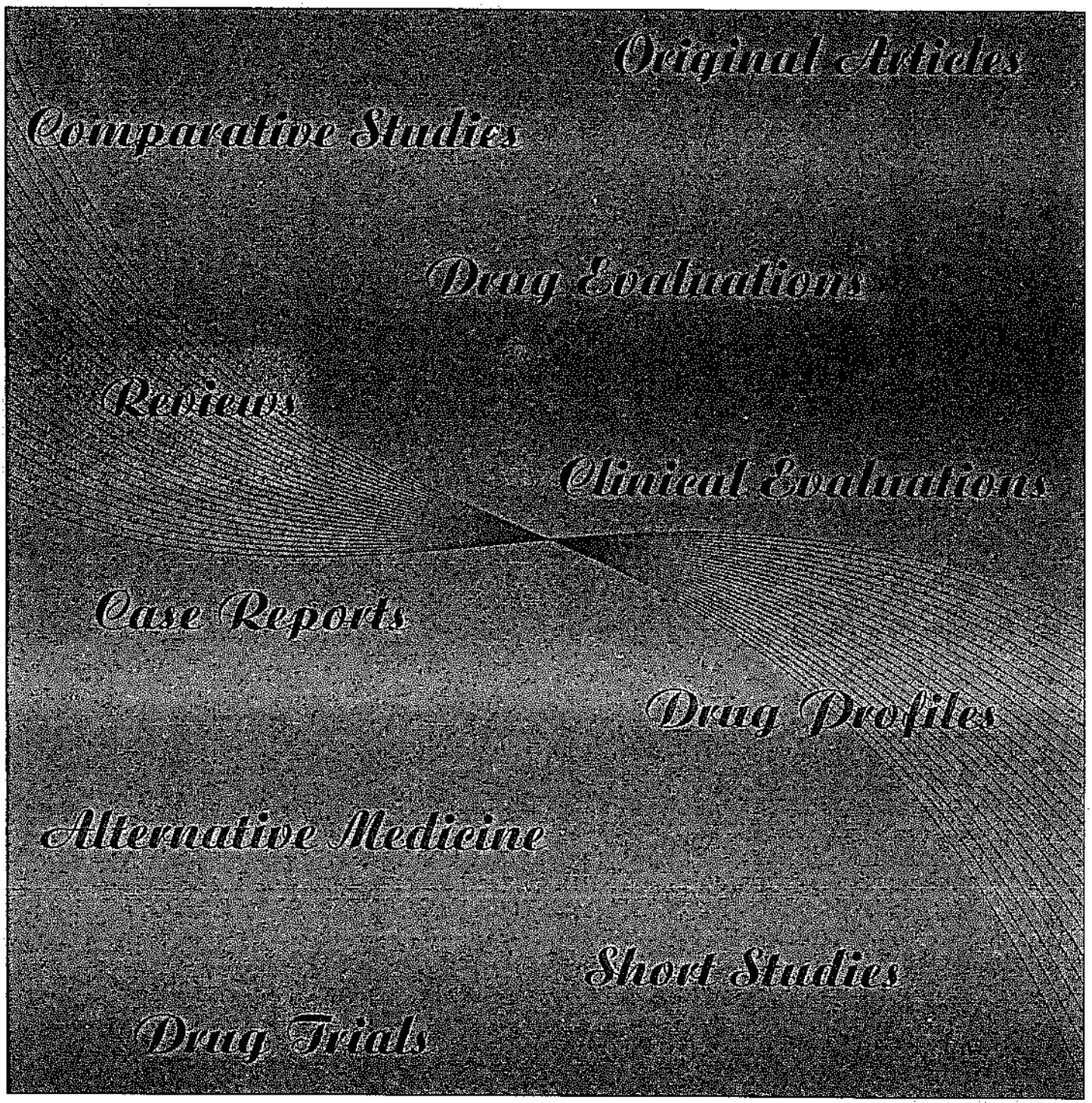

Clinical Evaluation

Clinical Study of Softovac — A Herbal Bowel Regulator for the Treatment of Constipation

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Introduction

Irregular bowel evacuation 'Constipation' is a very common lower gastrointestinal tract complaint. It is an area of concern since ages and considered responsible for producing various complaints and complications namely, headache, stress, distension of abdomen, disagreeable breath, furred tongue and even now frightened by autointoxication and cancer[1]. Its origin is of a multi-factorial nature, and, therefore deserves careful evaluation and measures for an effective relief.

The definition of constipation as per the Rome II criteria includes infrequent bowel movements (less than 3 bowel movements per week), difficulty / straining during evacuation of feces, inability to defecate at will and passing of hard feces.

It has been observed that normal storage, transport and evacuation mechanisms of the colon are deranged, due to which the normal bowel movements is hampered, progressing to passing of infrequent and hard stool with difficulty [2].

The prevalence of constipation increases with age and is more common among women than men in all age groups. It is more frequent with non-whites and in colder climates, poor and rural states. Constipation is a frequent problem in infants and children, which is mostly short-lived. In a study, 16% of 22 month old children in US, while in United Kingdom, 34% of 4 - 7 years old children and about 37% of Brazilian children of age ranging from birth to 12 years were reported to be constipated [3, 4].

Constipation is known to be of heterogeneous origin, such as intake of low fiber diet, lack of exercise, medications, changes in life style, old age, abuse of laxatives, ignoring the natural urge to have a bowel movement, pregnancy, specific diseases such as piles, fistula, irritable bowel syndrome, etc., problems with the colon and rectum, and problems with intestinal function. Constipation is classified as primary or secondary, which emphasizes the need to identify and treat underlying systemic disorders before proceeding with the gastrointestinal evaluation[5].

The gastrointestinal motility is essential for propagation of food, adequate absorption of fluids, electrolytes, nutrients and evacuation of excreta. The local neuronal reflexes and circulating enteric peptide hormones play an important role in regulating the neuro-humoral control of gastrointestinal smooth muscles. The nerve cells when stimulated release excitatory and inhibitory neurotransmitters, peptides and a complex interaction among these coordinate the intestinal motility. Since the central nervous system plays an important role in controlling the activity of gastrointestinal smooth

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muscles, the mental disturbances can increase gastro-intestinal transit time, which may lead to constipation [6,7]. Also, if an excessive amount of water is extracted, the stool can become hard and difficult to expel[8].

It often observed that changes in life style and dietary modifications are helpful for the relief of constipation. Patients whose constipation is not relieved by lifestyle and diet modification may benefit from judicious use of a laxative drugs.

Various classes of laxative drugs such as stimulant, saline, osmotic and bulk are used for treating constipation. Also enemas, suppositories, behavioral therapy and surgery are procedures used for treating constipation. The long-term use of stimulant laxatives, osmotic and saline laxatives are restricted as they are reported to cause abdominal cramps, hypokalemia, flatulence, abdominal distension and altered electrolyte transportation etc[8].

In therapeutics of Indian System of medicine (Ayurveda) constipation is described as Vibandh. The guidelines are described for its treatment. Many effective medicines are documented to bring about satisfactory evacuation of bowel, which could fill the gap for safe and effective treatment of constipation.

Softovac (herbal bowel regulator formulation) has been developed by Lupin Limited to provide effective relief of constipation. The formulation is in powder form, and consists of high fiber bulk formers with natural and non-synthetic mild laxatives that provides efficacious and safe treatment of constipation.

Objective of the Study

The objective of the study was to evaluate the efficacy and safety of Softovac treatment in patients with constipation.

Methods and Materials

It was an open and non-comparative clinical study. The trial was completed in 30 patients with constipation. The duration of treatment was 14 days.

Patients of either sex, and aged between 18-60 years, having bowel movements less than three per week and two or more associated symptoms such as straining at defecation, sense of incomplete evacuation and passing of hard stool, using synthetic laxatives / purgatives (oral, rectal) or enema were enrolled for the study. Patients suffering from any organic disorder of digestive tract (cancer, intestinal obstruction etc.) and patients with a history of any surgery of gastrointestinal tract were excluded from the study. Patients suffering from serious chronic systemic metabolic, cardiac, respiratory, neurological, and psychiatric illness were excluded. Also pregnant and lactating women were excluded from the study.

The patients satisfying the inclusion and exclusion criteria and who gave written informed consent were enrolled.

A detailed clinical history was taken at baseline. All the observations were recorded in the CRF at base line as well as at every follow up visit (Follow-up1/Day 7) till the completion of study (Follow-up 2/Day 14).

The clinical examination (general, systemic and local) had been carried out at baseline and every follow-up visit (once in seven days).

The safety blood investigations such as complete blood count (hemoglobin, red blood cell count, white blood cell count, neutrophils, eosinophils, basophils, lymphocytes, monocytes), erythrocyte sedimentation rate (ESR), serum glutamate pyruvic transaminase (SGPT), serum creatinine and fasting blood sugar (FBS) were also performed at baseline and at the end of study treatment.

After baseline assessment, the patients were initiated with the herbal bowel regulator formulation Softovac. The dose was 5-10 gm (1-2 teaspoon) at night daily with lukewarm water / fresh juice for 14 days duration.

The efficacy variables - normalization of bowel frequency /complete remission of constipation (that is more than 3 bowel movements/week), no straining at defecation, feeling of complete evacuation and passing of no hard / pallet stool, formed stool consistency, no use of synthetic laxatives / purgatives (oral, rectal) or no enema and absence of other symptoms were evaluated at baseline and at every follow-up visit and compared with baseline[4]. The efficacy variables were graded as follows:

1. Normalization of bowel frequency or remission of constipation 0 (No Response) = Less than 3 bowel

movements/week, Fair (1) = 3 bowel movements/ week, Good (2) = More than 3 bowel movements/ week and Excellent (3) = Daily passing of stool.

2. Consistency of stool 0 = Passing hard / pellet stool.1 = Passing watery stool, 2 = Not passing of hard or pellet stool or passing formed stool.

3. Straining at the defecation 0 = Straining at defecation, 1= No straining at defecation.

4. Feeling of complete evacuation of feces 0 (No Response) = No feeling of complete evacuation, 1 (Good) = Feeling of partial evacuation of feces, 2 (Excellent) = Complete evacuation of feces

5. Intake of other laxatives (Oral, rectal, enema) no/ week 0 = More than two times a week, 1 = Once a week, 2 = Does not require or not taken for a single day.

The severity of pain is evaluated for straining at defecation, passing stool, abdominal pain/discomfort, fullness of abdomen and borborgymi on the basis of Visual Analog Scale (VAS) from 0-4 score.

In addition to above, the clinical global impression (CGI) by the physician was also evaluated.

The patients were observed at every follow-up visit for adverse clinical events such as dry mouth, heart burn, vomiting, loss of taste, feeling of fullness, belching, abdominal pain, constipation, diarrhea, loss of appetite, fatigue, uneasiness, lethargy, headache, itching, rashes, weight loss, sweating, faintness, drowsiness, dizziness, sleepiness, disturbed sleep, anxiety, depression, stress, worry, emotional vulnerability, body ache, painful menstruation in women, loss of concentration etc. The blood investigations as in part were also evaluated for safety.

The study data were analyzed on computer using SPSS/ PC+ Statistical package. Based on the distribution of the variables appropriate Parametric and Non-parametric statistical methods were applied to the completed patients. Friedman tests, Analysis of repeated measures, unpaired t tests, paired t tests, Mann Whitney U tests, Wilcoxon Signed rank tests and Chi square tests were applied to the data wherever appropriate and accurate. Level of significance was taken as P = 0.05.

Softovac - A Herbal Bowel Regulator

It is an experiential and evidence based comprehensive Ayurvedic formulation for the treatment of constipation. The formulation is in the form of powder. The ingredients of the formulation are known for their inherent traditional pharmaco-therapeutic effects resulting in bowel regulation. It is safe and efficacious.

Each 5 gm of Softovac Contains:

S.No.	Medicinal Plant	Dose
01.	Isaphgol (*Plantago ovata*)	2.00 g
02.	Sonamukhi (*Senna*)#	0.75 g
03.	Harad (*Terminalia chebula*)#	0.50 g
04.	Amaltas (*Cassia fistula*)#	0.50 g
05.	Mulethi (*Licorice*)#	0.25 g
06.	Gulab Dal (*Rose petals*)	0.25 g
07.	Saunf (*Badi Saunf*) (*Fennel Seed*)	0.25 g
08.	Saunf Taila (*Fennel Oil*)	0.05 g
09.	Sharkara (*Sugar*)	QS

Water Extracts

Results and Observations

The study data analysis showed that out of total 30 subjects in whom the study was completed, there were 63% (19) males and 37% (11) female patients. The mean age of the study patients was 33.64 + 11.69 years (Range 19 –60 years) and all 30 patients (100%) were married. The detailed personal history profile of 30 patients is presented in the **Table 1.**

The treatment with Softovac (14 days dosing) has shown statistically significant improvement in all efficacy parameters during the study treatment period.

The bowel frequency was less than 3 bowel movements per week in 27 (90%) patients and 3 patients (10%) had 3 bowel movements per week at baseline. At the end of study treatment period with Softovac, 29 patients (97%) were

Table 1
Personal History Profile of Patients (n=30) with Constipation

Sl. No.	Variables	Values	
1.	Age (Mean ± SD)	33.64 ± 11.69 years (Aged between 19 - 60 Years)	
2.	Sex	Male	19 (63%)
		Female	11 (37%)
3.	Marital Status	Married	30 (100%)
4.	Diet	Vegetarian	13 (43%)
		Non Vegetarian	17 (57%)
5.	Smoking	Smokers	9 (30%)
		Non-Smokers	21 (70%)
6.	Alcohol	Yes	1 (3%)
		No	29 (97%)
7.	Appetite	Normal	30 (100%)
8.	Bowels	Irregular	30 (100%)

observed to have passed stool daily and one patient (3%) had more than 3 bowel movements per week. The administration of drug has shown statistically significant ($p<0.001$) improvement in normalizing frequency of bowel movement when compared between visit -1 & visit –3. The study treatment has shown normalization and regularization of bowel evacuation within a fortnight of dosing. The details are presented in the **Table 2**.

The number of patients passing hard stool were 28 (93%) and there were 2 (7%) patients passing unformed watery stools at the basal visit. On first follow-up (visit -2), none of patients were passing hard stool, while only 8 (27%) patients reported passing of watery stool and 22 (73%) were passing formed stool. On the final visit (visit -3) it was observed that all the patients (100%) were passing formed stool. The change in consistency of stool was found to be statistically significant ($p<0.001$). The details are presented in the **Table 2**. The dosing with Softovac has helped to pass normal formed stool in study patients.

It was observed at baseline that all 30 patients (100%) complained about straining at defecation, which improved remarkably i.e. the passing of stools without straining at first follow-up visit and this effect was continued till the end of study treatment dosing. The change was statistically significant ($p<0.001$). This indicates that Softovac was found to provide relief from discomfort and pain in addition to normalization of bowel evacuation. The details are presented in the **Table 2**.

There was a history of feeling of incomplete evacuation observed in 15 (50%) patients and 15 (50%) patients reported to have partial evacuation of feces at baseline. In subsequent follow-up visit (visit -2) 17 (57%) patients had feeling of complete evacuation, while only 13 (43%) patients had feeling of partial evacuation. At third follow-up visit all 30 (100%) patients reported having a feeling of complete evacuation of bowel. This change has shown statistically significant response in the evacuation of stool ($p<0.001$). Interestingly the formulation has also demonstrated the efficacy by enhancing the feeling of complete evacuation in study patients. The details are presented in the **Table 2**.

During the study dosing with Softovac, the need for intake of other laxative medications did not arise in all patients, this indicates the desired benefit of Softovac in the study patients.

The relief in the severity of pain was evaluated on the basis of Visual Analog Scale (VAS) score, it has shown statistically significant reduction. At basal visit, VAS score (Mean ± SD) of severity of pain was reduced from 3.50 ± 0.51 to 2.17 ± 0.75 at first follow-up visit. The score was remarkably decreased to 0.33 ± 0.48 at second follow-up. The details are presented in the **Table 3** and **Fig. 1**.

The severity of pain recorded on VAS in straining at defecation was found to be 3.73 ± 0.45 at baseline that reduced to 2.07 ± 1.05 at first follow-up visit. The score was very significantly reduced to 0.47 ± 0.57 at the end of treatment. This indicates that Softovac has shown response in relieving straining at defecation. The details are presented in the **Table 3** and **Fig. 2**.

At baseline the severity of pain as scored on VAS during passing of stool was found to be 3.80 ± 0.48, which reduced to 1.83 ± 0.99 and reduced significantly 0.37 ± 0.49 when compared with basal score. The details are presented in the **Table 3** and **Fig. 3**.

Table 2
Improvement In Efficacy Parameters with Softovac Treatment in Patients (n=30) with Constipation

Sl. No.	Observations	Visit – 1 [0 Day]	Visit-2 [7 Days]	Visit-3 [14 Days]	Comparison among 3 Visits by Friedman , Sign., P value
1.	Normalization of bowel frequency or remission of constipation				Chi sq. = 54.6, S, P<0.001
	0 = Less than 3 bowel movements per week	27	0	0	
	1 = 3 bowel movements per week	3	5	0	
	2 = More than 3 bowel movements per week	0	20	1	
	3 = Daily passing of stool	0	5	29	
2.	Consistency of stool				Chi sq. = 46.1, S, P<0.001
	0 = Passing hard stool	28	0	0	
	1 = Passing watery stool	2	8	0	
	2 = Passing formed stool	0	22	30	
3.	Straining at defecation				Chi sq. = 45.0, S, P<0.001
	0 = Straining at defecation	30	0	0	
	1 = No straining at defecation	0	30	30	
4.	Feeling of complete evacuation of feces				Chi sq. = 46.2, S, P<0.001
	0 (No Response) = No feeling of complete evacuation	15	0	0	
	1 (Good) = Feeling of partial evacuation of feces	15	13	0	
	2 (Excellent) = Complete evacuation of feces	0	17	30	
5.	Intake of other laxatives (Oral, rectal, enema) no/week				Chi sq. = 0.1, S, P<0.001
	0 = More than two times a week	0	0	0	
	1 = Once a week	1	0	0	
	2 = Does not require or not taken for a single day	29	30	30	

The relief in the severity of abdominal pain/discomfort as scored on VAS was also found to be statistically significant. At basal visit the VAS score was observed to be 3.57 ± 0.82. There was statistically significant reduction observed in VAS score at follow-up visit 1 and 2, which were 1.57 ± 0.90 and 0.20 ± 0.48, respectively. The details are presented in the **Table 3** and **Fig. 4**.

The severity of pain as recorded on VAS in fullness of abdomen was observed to be 3.30 ± 0.99, 1.33 ± 0.61 and 0.03 ± 0.18 at basal, follow-up visit 1 and follow-up visit 2 respectively. This shows a statistical significant reduction in the VAS score. The details are presented in the **Table 3** and **Fig. 5**.

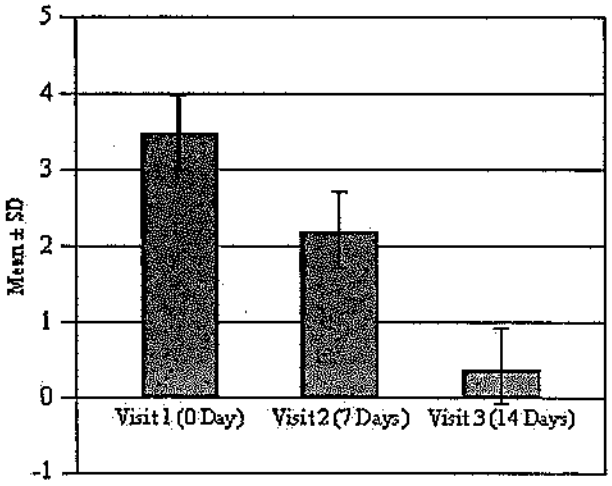
At baseline the evaluation of severity of pain in borborygmi as scored on VAS was found to be 2.70 ± 1.53, which significantly reduced to 1.33 ± 1.06 at follow-up 1 and further reduction to 0.23 ± 0.43 was observed at follow-up 2 (**Fig. 5**). The details are shown in the **Table 3** and **Fig. 6**.

In all above efficacy parameter there was comparative difference between each follow-up visit, the p value<0.001, which showed that Softovac has effectively contributed to relief from constipation and regularization of bowel movements, while correcting the associated complaints. This shows that the response is statistically significant.

Table 3
Reduction in the Severity of Pain Evaluated On Basis Of Visual Analog Scale (VAS) Score in Patients (n=30) with Constipation

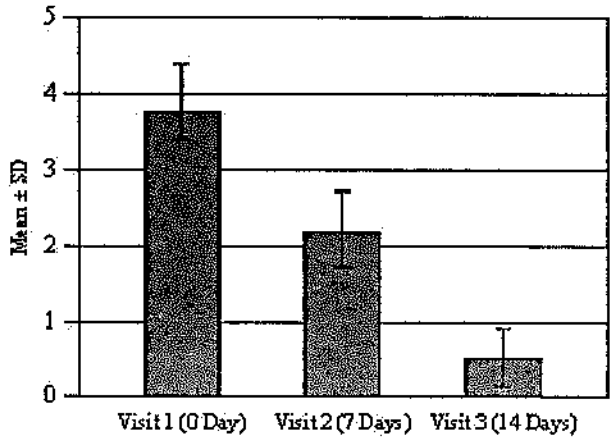
Observations	Visit – 1 [0 Day]) Mean ± SD	Visit-2 [7 Days] Mean ± SD	Visit-3 [14 Days] Mean ± SD	Comparison among 3 Visits by Friedman, Significance, P value
1. Severity of Pain	3.50 ± 0.51	2.17 ± 0.75	0.33 ± 0.48	Chi sq. = 56.3,S, P<0.001
2 Severity of Pain Straining at defecation	3.73 ± 0.45	2.07 ± 1.05	0.47 ± 0.57	Chi sq. = 55.2,S, P<0.001
3. Severity of Pain Passing stool	3.80 ± 0.48	1.83 ± 0.99	0.37 ± 0.49	Chi sq. = 56.1,S, P<0.001
4. Severity of Pain Abdominal Pain/Discomfort	3.57 ± 0.82	1.57 ± 0.90	0.20 ± 0.48	Chi sq. = 57.0,S, P<0.001
5. Severity of Pain Fullness of Abdomen	3.30 ± 0.99	1.33 ± 0.61	0.03 ± 0.18	Chi sq. = 56.1,S, P<0.001
6. Severity of Pain Borborgymi	2.70 ± 1.53	1.33 ± 1.06	0.23 ± 0.43	Chi sq. = 40.1,S, P<0.001
Level of significance = 0.05				

Fig. 1
Reduction in Mean ± SD Severity of Pain as Scored on VAS at Basal and Follow-up Visit 1 and Follow-up Visit 2 in Patients (n = 30) with Constipation



Conclusion : There was reduction in severity of pain as scored on VAS from Visit 2 onwards.

Fig. 2
Reduction in Mean ± SD Severity of Pain as Scored on VAS (Straining at defecation) at Basal And Follow-up Visit 1 and Follow-up Visit 2 in Patients (n = 30) with Constipation



Conclusion : There was reduction in severity of pain (straining at dedecation) as scored on VAS from Visit 2 onwards.

The safety blood investigations have shown no statistical difference in the counts from the baseline to the end of treatment. All the findings were within normal limits.

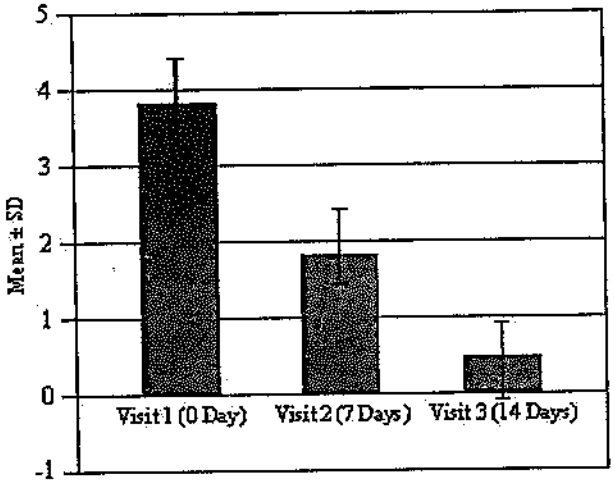
There were no serious adverse events (SAE) or side effects reported during the treatment with Softovac.

There was no change in body weight, physical appearance, pulse rate and blood pressure during the treatment with Softovac.

The routine clinical (physical, systemic and local) examination at baseline and at each follow-up visit has shown no significant difference during the study period. All clinical findings were within normal limits even after completion of treatment of 14 days dosing with Softovac.

Fig. 3

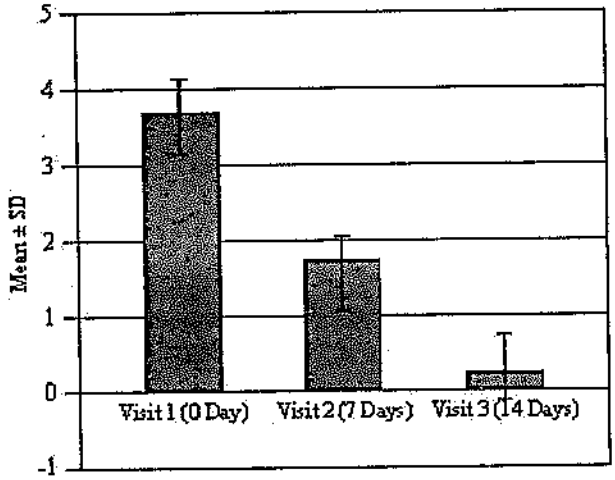
Reduction in Mean ± SD Severity of Pain as Scored on VAS (Passing of Stool) at Basal and Follow-up Visit 1 and Follow-up Visit 2 in Patients (n = 30) with Constipation



Conclusion : There was reduction in severity of pain (Passing of Stool) as scored on VAS from Visit 2 onwards.

Fig. 4

Reduction in Mean ± SD Severity of Pain as Scored on VAS (Abdominal Pain/Discomfort) at Basal and Follow-up Visit 1 and Follow-up Visit 2 in Patients (n = 30) with Constipation

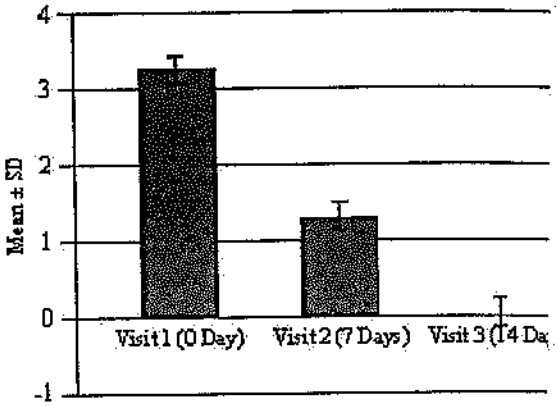


Conclusion : There was reduction in severity of pain (Abdominal Pain/Discomfort) as scored on VAS from Visit 2 onwards.

It was observed that during the entire study there were no dropouts.

Fig. 5

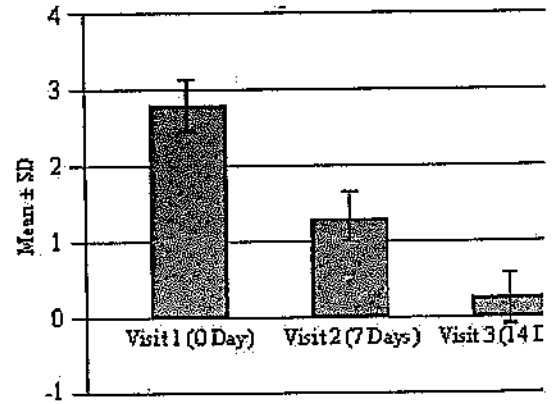
Reduction in Mean ± SD Severity of Pain as Scored o (Fullness of Abdomen) at Basal And Follow-up Visit Follow-up Visit 2 in Patients (n = 30) with Constipa



Conclusion : There was reduction in severity of p (Fullness of Abdomen) as scored on VAS from Visit 2 onwards.

Fig. 6

Reduction in Mean ± SD Severity of Pain as Scored (Borborgymi) at Basal And Follow-up Visit 1 and Fol Visit 2 in Patients (n = 30) with Constipation



Conclusion : There was reduction in severity of (Borborgymi) as scored on VAS from Visit 2 onw

There was an excellent compliance to the treatr Softovac in the study patients, which was evide follow-up and continued till the end of study per

The clinical global impression (CGI) was fo good in 9 (30%) and excellent in 21 patients (7

Table 4
Findings of Safety Blood Investigations In Patients (n=30) with Constipation

Sl. No.	Investigations	Basal (Visit 1) Mean ± SD	2-Follow Up (Visit 3) Mean ± SD	Comparison between Visit 1-3, t value, Significance, P value
01.	Hemoglobin (gm%)	14.30 ± 1.72	14.38 ± 1.66	3.04, S, P = .005
02.	R.B.C.count (ul)	5.31 ± 0.21	5.32 ± 0.18	1.0 , NS, P = 0.32
03	W.B.C.Count (cells/ul)	6790.0 ± 982.0	6610.0 ± 956.1	1.64 , NS, P = 0.11
04.	Neutrophils%	65.33 ± 2.89	67.00 ± 1.80	3.51, S, P = .002
05.	Eosinophils %	2.77 ± 1.17	1.80 ± 0.76	5.30, S, P < .001
06.	Basophils %	1.20 ± 0.81	0.93 ± 0.45	1.97, S, P = .058
07.	Lymphocytes %	28.83 ± 2.34	28.87 ± 1.17	0.07, NS, P = .94
08.	Monocytes %	1.87 ± 1.33	1.30 ± 0.70	2.54, S, P = .017
09.	E.S.R. (mm/hr)	12.17 ± 3.46	11.07 ± 2.42	2.35, S, P = .026
10.	S.G.P.T. (U/L)	16.43 ± 2.46	14.17 ± 2.04	3.97, S, P < .001
11.	Serum creatinine (mg/dl)	1.08 ± 0.12	1.07 ± 0.11	1.44, NS, P = .16
12.	Fasting Blood Sugar (mg/dl)	101.00 ± 5.00	101.00 ± 5.60	0, NS, P = 1

Level of significance = 0.05

Table 5
Findings of Clinical Examination in Patients (n=30) with Constipation

Sl. No.	Observations	Visit 1 (0 Day)	Visit 2 (7 Days)	Visit 3 (14 Days)
1	Physical Appearance	Normal = 30	Normal = 30	Normal = 30
		Abnormal = 0	Abnormal = 0	Abnormal = 0
2	Body Weight (Kg) (Mean ± SD)	61.6 ± 5.9	61.6 ± 5.9	61.6 ± 5.9
3	Temperature (Cm)	Normal = 30	Normal = 30	Normal = 30
		Abnormal = 0	Abnormal = 0	Abnormal = 0
4	Pulse Rate/Minute (Mean ± SD)	77.9 ± 4.6	78.2 ± 4.1	79.1 ± 3.7
5	Systolic BP [mm of Hg] (Mean ± SD)	122.0 ± 9.2	121.7 ± 7.0	119.7 ± 6.2
6	Diastolic BP [mm of Hg] (Mean ± SD)	76.7 ± 4.8	77.7 ± 5.0	77.0 ± 4.5

Softovac treatment and which was sustained further until the end of the therapy (**Table 7**).

Discussion

The irregular bowel evacuation "Constipation' is a very common compliant often seen worldwide in diverse clinical conditions. The continuous irregularity of bowel movement is known to have specific gastro intestinal tract as well as associated non-specific complaints, which may generate a concern of serious illness over a span of time and lower the quality of life (QOL).

It has been viewed that the reasons for constipation could be due to adversely increased transit time, in-coordination of gastro intestinal tract motility, and disturbed

Table 6
Compliance to Softovac Treatment in Patients (n=30) with constipation Values Are Expressed As Actual Number

Grade*	Visit-2 (Follow Up- 1 [7 Days])	Visit-3 (Follow up-2 [14 Days])
Poor (0)	0	0
Fair (1)	0	0
Good (2)	3 (10%)	1 (3%)
Excellent (3)	27 (90%)	29 (97%)

* Poor (0): Have not taken for 7 - 10 days (7 doses & above).
Fair (1): Have not taken for 3 - 6 days (3-6 doses).
Good (2): Have not taken for 1 - 2 days (1 – 2 doses).
Excellent (3): Have not missed any dose.

Table 7
Observation of Clinical Global Impression (CGI) with Softovac Treatment in Patients (n=30) with constipation

Grading	Study Intevestigator
Poor (0)	0
Fair (1)	0
Good (2)	9 (30%)
Excellent (3)	21 (70%)

transport, absorption, and storage mechanisms in the intestine.

For the treatment, the dietary modifications, and corrective life style measures are often helpful for the relief from constipation. The judicious use of laxative drugs is recommended to provide the desired benefits when above modifications are failed. However, lack of satisfactory feeling of bowel evacuation with current available measures / medication, their adverse effects, laxative abuse and high cost is the limitation.

There are effective non-habit forming remedies / formulations to provide satisfactory evacuation of bowel, which could fill the gap by virtue of their traditional pharamaco-therapeutic benefits of each ingredient. These are safe and efficacious, hence their use is wider in the Indian System of Medicine (Ayurveda) for relief of constipation and associated complaints.

Therefore, a synergistic herbal bowel regulator 'Softovac' was developed and it has been evaluated scientifically to record its efficacy and safety in a designed proof of concept study.

Softovac, has shown an excellent response by providing relief from constipation and regularization of normal bowel evacuation in study patients, which are evident from the results and observations of the efficacy variables.

The essential variable that is normalization of bowel frequency (passing bowels more than three a week) was effectively achieved in the study with short course of treatment for the chronic problem of constipation.

The other associated complaints such as straining at defecation were corrected, and remarkable improvement in complete evacuation was noted. It was observed that the consistency of stool was changed from unformed (hard) to formed, as a result of which difficulty or straining at defecation was no longer experienced by the study patients

Usually in such chronic situations the use of synthetic laxatives or purgatives (oral, rectal suppositories) is a necessity to have the desired relief from constipation and sense of satisfaction. In this study there was no need for use of any concomitant/similar medication intended for relief from constipation. The reason is appears to be that the study medication Softovac has shown normalization and regularization of bowel evacuation due to its excellent composition. Therefore, the dependence on synthetic purgatives or / laxatives or enema etc was not noticed in study patients. The better compliance to study medication also co-relates.

The associated discomfort / pain in constipation was valuated on the basis of visual analog scale (VAS), the everity of complaints were recorded on a 0 – 4 score. he factors such as straining at defecation discomfort of assing of hard stool, abdominal discomfort, fullness of bdomen and borborygmi were evaluated at every follow-p visit. Since, the study outcome has demonstrated ffective normalization of bowel evacuation by which the ssociated level of severity is remarkably reduced and helped a improving the quality of life (QOL).

In addition to the above efficacy, the study has shown ormal blood (complete red blood and white blood cells ount, hemoglobin, ESR, liver, renal and metabolic) nvestigations. All variables are with in normal limits with oftovac dosing.

This has demonstrated excellent compliance and oleration to Softovac treatment without any side effects diarrhea, abdominal fullness etc.).

The possible mechanism of action of Softovac ormulation can be explained on the basis of pharmaco-herapeutic properties of the ingredients.

Isaphgol (*Plantago ovata*) is a bulk-forming laxative igh in both fiber and mucilage. The laxative properties of Plantago ovata are due to the swelling of the husk when it omes in contact with water. It passes through the small ntestine undigested, with demulsifying and lubricating ffects [9, 10, 11, 12, 13, 14, 15].

Sonamukhi (*Cassia angustifolia*) act as a lubricating, ulk and mild stimulant agent and aids in normal intestinal eristalsis. Senna possesses anti-absorptive and hydragogue roperties. They inhibit the absorption of electrolytes and ater from the large intestine. This increases the volume f luminal contents and raises the filling pressure in the ntestine thus stimulating bowel motility [14,16].

Harad (*Terminalia chebula*) increases the frequency of tools and has got the property of evacuating the bowel ompletely [16,17,18].

Amaltas (*Cassia fistula*) is a mild, safe laxative and so an be given safely to those persons possessing a delicate onstitution [19].

Mulethi (*Glycrrhiza glabra*) is a demulcent, possessing gentle laxative, spasmolytic, and promotes ulcer healing, anti-inflammatory actions. It helps in alleviates the colonic ulceration [20,21,22,23]. It likely checks minimally possible irritant effect of Senna due to its demulcent action.

Gulab (Rose petals) known to have demulcent action, mild laxative and flavoring agent [24,25].

Saunf and saunf taila is a carminative, anti-flatulent, spasmolytic, laxative [26,27].

Fennel oil disintegrates the faecolith, thereby helping in normalizing the consistency of stool and checks flatulence and griping pain.

Softovac is a comprehensive herbal formulation having bulk forming, mild stimulant, laxative, demulcent and lubricating properties. Softovac regulates normal peristalsis, and possesses carminative anti-flatulent and spasmolytic actions. The synergism of the above properties could be the contributing factor for normalization and regularization of bowel evacuation and relief from associated complaints of constipation. It can also improve the quality of life (QOL).

Therefore, Softovac in short course of use has provided potential therapeutic option for effective relief of constipation and the regularization of normal bowel evacuation.

Conclusion

Softovac is a synergistic herbal bowel regulator, which has shown highly significant response in patients with constipation, by helping to regularize the normal bowel evacuation effectively and providing relief from associated symptoms.

Softovac is found to be safe and no adverse events are reported at recommended dose. It has got excellent patient compliance in study patients.

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