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A CLINICAL STUDY TO EVALUATE EFFICACY AND SAFETY OF AYULAX CAPSULE IN THE MANAGEMENT OF FUNCTIONAL CONSTIPATION

Dr. C.D. Jagdhane[1], Dr. Monica Shrestha[1] and Dr. Sanjay Tamoli[2]*

[1]R. A. Podar Ayurved Medical College and M. A. Podar Hospital, Dr. Annie Besant Road, Worli, Mumbai-400 018.
[2]*Target Institute of Medical Education and Research (TIMER), Dahisar (West), Mumbai, Maharashtra. India.

***Correspondence for Author: Dr. Sanjay Tamoli**
Target Institute of Medical Education and Research (TIMER), Dahisar (West), Mumbai, Maharashtra. India.

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ABSTRACT

Objectives: The objective of present study was to evaluate efficacy and safety of Ayulax capsule in the management of functional constipation. **Methods:** Total 34 subjects suffering from functional constipation were recruited in the study. All subjects were given Ayulax capsule in a dose of 2 capsules at bed time orally with water for 14 days. After baseline visit (day 0), all subjects were called for follow-up visits on day 7, 14 and 21. Patients were advised to stop taking Ayulax capsule from day 14 to day 21 to observe recurrence. Data describing quantitative measures were expressed as mean ± SD. Comparison of variables representing categorical data was performed using appropriate statistical methods. **Results**: Significant increase in bowel frequency was observed at the end of the study as compared to baseline visit. Statistically significant changes in stool form (on Bristol scale) were observed at the end of the study. Also, significant decrease in mean score of straining on defecation, sensation of anorectal blockage (on VAS), requirement of manual assistance to evacuate, time spent for bowel evacuation and other associated symptoms of constipation were observed at the end of study. There was slight increase in score of associated symptoms of constipation after observatory period. But the score of associated symptoms was less than that of baseline value. Most of the subjects showed excellent to good overall efficacy and tolerability to study drug. Very few patients had mild abdominal cramps which did not require any treatment. **Conclusion**: Ayulax capsule acts as an effective and safe laxative in treatment of functional constipation.

KEYWORDS: Ayulax capsule, Functional constipation, Bristol scale, VAS.

INTRODUCTION

Constipation is a condition in which patient experiences uncomfortable or infrequent bowel movements.[1] It is a troublesome symptom which can occur in all ages, both sexes, and in all educational and socioeconomic groups.[2] There is no single definition of constipation.[3] Most commonly, constipation is defined as complaints of one or more symptoms including hard stools, infrequent stools (typically fewer than three per week), a sense of incomplete bowel evacuation, defecation with excessive straining and excessive time spent on the toilet or in unsuccessful defecation.[3] Worldwide approximately 20% of individuals are suffering from this gastrointestinal tract complaint in which elder persons contribute more.[4-5] In India 8% of elderly population has been reported to suffer from this condition.[6]

Constipation is caused due to both chronic and acute etiologies. It may be common complaint of healthy individuals or may occur due to organic (anatomical cause) or functional causes. Also, it can result from serious diseases or medications.[7] History taking, rectal examination, lab investigations, etc., are primary and useful measures for diagnosis of constipation.[3] The 'Rome III criteria' is a widely accepted format for diagnosis of Functional constipation.[8]

Though constipation is not considered as life threatening illness yet it needs proper medical attention. It has been observed that many patients suffering from constipation live silently throughout their lives and some try self-medications. Very few patients seek medical help and treatments can be unsatisfactory.[4] Treatment of constipation is most often empirical. Simple, helpful measures include patient education, dietary fiber supplementation, adequate fluid intake and regular physical activity.[3] If these factors fail then drugs are recommended to treat constipation. Drugs commonly used include osmotic laxatives (magnesium or phosphate salts, lactulose, sorbitol, glycerin suppositories, and polyethylene glycol), bulk laxatives (polycarbophil and methylcellulose), stimulant laxatives (docusate, bile acids, phenolphthalein, bisacodyl, sodium picosulfate and ricinoleic acid), non-absorbable sugar, cholinergic agents and other prokinetic agents. Some drugs such as selective chloride channel activators can increase intestinal water secretion resulting in increased intestinal motility and facilitating the bowel movement.[8-9]

Though modern treatment modalities are well established and safe, they possess few side effects and do not provide satisfying improvement in many patients. Drugs such as stimulant, osmotic and saline laxatives of chemical origin are known to cause abdominal cramping, hypokalemia, flatulence, abdominal distension, and alteration in electrolyte transportation which limit their long-term use. There is shifting interest of patients in other therapeutic strategies.[8-9]

In Ayurveda, constipation is called as *Malavastshambha*. *Malavastshambha* mainly caused due to the predominance of the *Vata Dosha* (dry in nature). According to Ayurveda, several etiological factors such as wrong diet, less fiber supplementation, low fluid intake, less physical activity, diseases, etc., can cause the constipation.[1] In Ayurveda, several herbs and herbal combinations in the form of *Churna* (powders), *Vati* (tablets/pills), etc., are used to treat constipation. Herbs commonly used include *Sanai*, *Haritaki*, *Vibhitaki*, *Amalaki*, *Swarnapatri*, *Shatapushpa*, *Shunthi*, etc. Classical Ayurvedic medicines include *Gandharva Haritaki Churna*, *Tikshan Virechana churna*, *Triphala churna*, *Argvadha-Kapila Vati*, etc.[1,8-10]

Welex laboratories have developed a unique combination called Ayulax capsule for the management of constipation. All the ingredients of the formulation have laxative properties. The ingredients help to soften the stool, thus relive constipation and related discomfort. Most of the ingredients increase peristaltic movements of the colon and stimulate gastrointestinal motility. Ingredients of the formulation also reduce abdominal pain and flatulence. Ingredients of the formulation help to improve indigestion and promote appetite.

The present clinical study was conducted with an aim to evaluate the efficacy and safety of Ayulax capsule in the management of functional constipation.

MATERIALS AND METHODS

1.1 Study Design

It was an open label, single center, prospective, interventional phase II clinical study.

1.2 Study objectives

Primary objective of the study was to evaluate efficacy of Ayulax capsule in the management of functional constipation by assessing changes in frequency of bowel movements. Secondary objectives were to evaluate efficacy of Ayulax capsule by evaluating the changes in stool form (assessment using 'Bristol stool form scale), changes in symptoms of functional constipation [straining on defecation, sensation of incomplete evacuation, sensation of anorectal blockage, manual maneuvers required & average time spent for bowel evacuation], and changes in associated clinical symptoms. Also, the secondary objectives were to assess clinical global assessment for overall improvement by the physician and by the patient. The other secondary objectives were to evaluate safety of Ayulax capsule by assessing tolerability of study drugs and by assessing the adverse events and/or adverse drug reactions and changes in laboratory parameters at the end of the study.

1.3 Sample size

A total of 36 patients suffering from functional constipation were screened for recruitment in the study. Out of 36 screened patients, 34 patients were recruited in the study. Two patients were not recruited in the study as they did not meet inclusion/exclusion criteria. Out of 34 recruited subjects, 32 completed the study, while two subjects dropped out prematurely. The reason for drop out was lost to follow up because patient did not turn for follow up visit.

1.4 Subject selection

Healthy male and female subjects of age group of 18-70 (both inclusive) years, willing to follow study procedures mentioned in the protocol and voluntarily signed the informed consent forms were included in study. Subjects were presenting with two or more symptoms of functional constipation for last 3 months with onset at least 6 months prior to diagnosis. Functional constipation as per the Rome III diagnostic criteria including straining during at least 25% of defecations, lumpy or hard stools at least 25% of defecations, sensation of incomplete evacuation at least 25% of defecation, sensation of anorectal obstruction/blockage at least 25% of defecations, manual maneuvers to facilitate at least 25% of defecations (e.g., digital evacuation, support of the pelvic floor) and fewer than three defecations per week. Subjects in whom loose stools were rarely present without the use of laxatives, subjects not meeting Rome diagnostic criteria for IBS and having stool form between 1 to 3 on the 'Bristol Stool Form Scale' were selected for study. Pregnant, lactating women and women with child bearing age, who refused to use effective contraceptive methods, were excluded from the study. Subjects who had recently undergone abdominal surgery, subjects with history of anorectal surgery, subjects having other functional gastrointestinal disorders other than functional constipation [i.e. IBS, Belching disorders etc], structural abnormalities [like anorectal/rectal prolapse, rectocele, rectal intussusceptions, anorectal stricture, solitary rectal ulcer syndrome], perineal descent and colonic/rectal mass or tumor with obstruction [e.g. adenocarcinoma, colonic stricture, radiation, ischemia, diveticulosis, intestinal obstruction] were excluded from the study. Subjects with renal or liver dysfunction, uncontrolled DM and diagnosed with HIV, Tuberculosis, neurological problems [like Parkinson's disease, multiple sclerosis, sacral nerve damage (prior pelvic surgery, tumor), paraplegia & autonomic neuropathy] and colonic inertia were excluded from the study. Also, subjects allergic or atopic to any of the ingredients of the study medication and subjects on chronic medication (> 60 days) and/or who are on medications known to cause constipation were not included in the study. Subject was withdrawn

from the study in case of any life threatening illness or adverse event and/or noncompliance to the study medication and/or repeated protocol violation.

1.5 Investigational drug

The investigational product (Ayulax Capsule) was manufactured by the Sponsor i.e. Welex Laboratories Pvt Ltd., following GMP and all applicable regulatory guidelines. The composition of the Ayulax Capsule is given in (Table 1).

1.6 Ethical consideration

The study was carried out at Shalyatantra department at R. A. Podar Ayurved Medical College and M. A. Podar Hospital, Dr. Annie Besant Road, Worli, Mumbai-400 018. Before initiation of the study, the study protocol and related documents were reviewed and approved by IEC at R A Podar Medical College, Worli, Mumbai 400018 on 01.10.2014. The study was conducted in accordance with the ASU GCP guidelines for conducting clinical studies. The clinical trial was registered prospectively on the Clinical Trial Registry of India (CTRI), on 05/01/2015. The CTRI number for the trial is CTRI/2015/01/005349.

1.7 Study procedure

Subjects attending OPD of Shalyatantra department and presenting with symptoms of constipation were screened for the study. On screening visit (day -3), subject's voluntary written informed consent was taken. Subject's demographic data and *Dosha Prakriti* was noted. Subject's detailed medical history along with the current medications (if any) was noted. Subject's general and systemic examinations were done. Diagnosis of Functional constipation was made using Rome III criteria, Bristol stool form scale, assessment of patient, history, clinical symptoms and associated symptoms of constipation. A diary card was provided to the subjects to note down daily symptoms of functional constipation. Subject then underwent investigations i.e. fasting blood sugar, CBC, ESR, Hb%, Liver function tests, Renal function tests, lipid profile, urine routine and microscopic, stool routine and microscopic, urine pregnancy test (only if the subject is female of child bearing potential), HIV test (I& II), X- ray chest (PA View) and ECG.

A wash out period of 3 days was advised during which patients had to refrain from any medication (allopathic/Herbal /homeopathic etc.) that will have an effect on the constipation as well as digestive system. Patients were advised to come to hospital for baseline visit on third day after screening visit. All the subjects were advised to continue their routine diet and exercise regimen (which they had been following) during the entire study.

On baseline visit (day 0), subject was recruited in the study if he/she met all the inclusion criteria. On baseline visit and on every follow-up visit, subject was asked for any AE/SAE occurred and if subject had AE/SAE, the details of the incidence were documented in the source document and CRF. Also, SAE, if any, were reported to the IEC in SAE reporting form. Rescue medication used, if any, were recorded in the CRF.

On baseline visit and on every follow-up visit, subject's general and systemic examinations were done. Main clinical symptoms and associated symptoms (headache, acidity, belching, flatulence and abdominal bloating) of the functional constipation were assessed using respective clinical assessment scales. Stool form was assessed using Bristol Stool form scale for Functional constipation. On baseline visit and on every follow-up visit, subject's filled diary card was collected from the subject. The average of the three days readings of the type of stool on Bristol stool scale, noted in daily diary card was entered in the CRF. On every follow-up visit except last follow-up visit, a fresh diary was issued to the subject to note down daily changes in the symptoms of functional constipation.

On baseline visit and on 7^{th} day, 20 capsules of Ayulax were provided to the subject for next 7 days (14 capsules to be used for seven days and 6 additional capsules to be used if follow up is delayed maximum by three days). Subjects were advised to take medication in a dose of 2 capsules with water at bedtime for 14 days. On every follow-up visit except last visit, subjects were advised to return unused capsules after 7 days when they come for next follow up, to check drug compliance. Subject was asked to come for next follow up on 7^{th} day.

On every follow-up visit except last follow-up visit, the unused capsules were collected from subject and the unused capsules were counted. If 80% study medication was consumed over 80% time, the patient was considered compliant. If < 80% of study medication was consumed over 80% of time, the patient was considered as non-compliant.

On day 14 visit, tolerability of the trial medicine was also assessed on global assessment scale by patients and by the investigator. Subject's global assessment and investigator's global assessment for overall improvement was done. Subject then underwent investigations i.e. CBC, ESR, Hb%, liver function tests, renal function tests, lipid profile, urine routine and microscopic, stool routine and microscopic. Subjects were advised not to take the study medication for next 7 days, as the 14 days period of active treatment was over. Subjects were asked to come for next follow up on 21^{st} day.

On last follow-up visit (day 21), subject's global assessment and investigator's global assessment for overall improvement was done. If the symptoms of constipation persisted, subject was advised to take opinion of investigator for further course of treatment. If symptoms of constipation subsided, patient was told that the study is over and he/she needn't come for next visit

except in case of any illness. All the activities and findings were documented in the source document and CRF. Subjects were asked to stop the trial drug and were advised to meet physician for further course of treatment.

1.8 Statistical analysis

An in-house statistician performed the analysis using available version of statistical software SPSS 10.0. Data describing quantitative measures were expressed as mean ± SD. Qualitative variables were presented as counts and percentage. Comparison of variables representing categorical data was performed using appropriate statistical methods. Mean differences of continuous variables were examined by Student't' test and comparison between baseline and follow up visits was done. All p-values were reported based on two-sided significance test and all the statistical tests were interpreted at 5% significance level.

RESULTS

A total of 36 subjects were screened in the present study of which 2 subjects did not meet the inclusion criteria and therefore were not recruited in the study. Out of 34 subjects who were recruited in the study, 32 subjects completed the study while 2 subjects dropped out from the study. The reason for drop out was lost to follow up as patient did not turn for follow up visit. Out of 32 patients who completed the trial, there were 14 (43.75%) males and 18 (56.25%) females. Out of 32 patients, 6 (18.75%) patients were in the age group of 21 to 30 years; 10 (31.25%) patients were in the age group of 31 to 40 years; 14 (43.75%) patients were in the age group of 41 to 50 years; while remaining 5 (15.62%) patients were in the age group of 51 to 60 years. The *Prakriti*-wise distribution of patients is presented in graph 1.

No statistically significant changes in vital parameters (pulse, blood pressure, temperature and respiratory rate) and mean body weight were observed throughout the study. It was observed that the mean Hb % at the initial visit was 12.55 ± 1.25 which increased to 12.75 ± 1.75. This increase was not statistically significant. Other laboratory parameters and ECG did not show any significant change and remained in their normal limits, both at the initial visit and the final visit.

As a primary objective, the frequency of bowel movements was evaluated by the number of bowel movements on a daily basis which the subject recorded in the diary over the last week. It was observed that the mean frequency of bowel movements significantly increased on day 7 (13.21 ± 4.37) and day 14 (13 ± 3.44) visit as compared to baseline visit (5.32 ± 2.26). At the end of 21 days the frequency reduced (9.28 ± 2.09) but was still found to be statistically significant as compared to the baseline. The details on frequency of bowel movements are presented in table 2 and graph 2.

Assessment of the form of stool on every bowel movement or evacuation was done on Bristol scale. It was observed that the mean Bristol scale score significantly increased on day 7 (5.35 ± 0.85), day 14 (5.28 ± 0.76) and day 21 (4.57 ± 0.79) visit as compared to baseline visit (2.51 ± 0.95). This showed that the consistency of stool became soft. The details on mean Bristol scale score are presented in table 3 and graph 3.

Straining on defecation was evaluated by grading it on VAS scale of 0 to 100 (i.e. no straining to maximum straining). Significant decrease in mean VAS score for straining on defecation was observed on day 7 (16.42 ± 13.66), day 14 (7.14 ± 9.51) and day 21 (8.57 ± 12.14) as compared to baseline visit (41.78 ± 14.67). The details are presented in table 4 and graph 4.

Also, sensation of anorectal blockage was evaluated by grading it on VAS scale of 0 to 100 (i.e. no anorectal blockage to maximum anorectal blockage). Significant decrease in mean VAS score for anorectal blockage was observed on day 7 (15 ± 12.01) and day 14 (14.28 ± 25.72) as compared to baseline visit (40 ± 17.21). The score at the end of 21 days was (21.42 ± 27.34) also significant. The details are presented in table 5 and graph 5.

It was observed that 5 subjects complained that they required manual assistance to defecate. Of these 5 subjects 2 continued to require manual assistance at the end of 7 days while 3 were able to have bowel evacuation normally. At the end of 14 days and 21 days only one subject required manual assistance to evacuate.

Significant reduction in time spent in minutes for bowel evacuation was observed on day 7 (5.08 ± 4.08), day 14 (5.70 ± 3.62) and day 21 (7.72 ± 6.35) as compared to baseline visit (12.22 ± 7.12). The details are presented in table 6 and graph 6.

It was observed that a majority of subjects had other associated symptoms of constipation like headache, acidity, belching, flatulence, abdominal distension and bloating. Statistically significant reduction in symptoms such as headache, flatulence and abdominal distension and bloating were observed at all the follow up visits. Reduction in symptoms including acidity and belching was observed at the end of the study as compared to baseline visit, but the difference was not statistically significant. The details on other associated symptoms of constipation are presented in table 7 and graph 7.

As per physicians assessment for overall improvement/efficacy, 18 subjects showed excellent overall efficacy, 10 subjects showed good overall efficacy and 4 subjects showed satisfactory overall efficacy on day 14 visit whereas 14 subjects showed excellent overall efficacy, 12 subjects showed good overall efficacy, 4 subjects showed satisfactory overall efficacy and 2 subjects showed average overall efficacy on day 21 visit. None of the subjects showed poor overall efficacy on day 14 and day 21 visits. As per subjects

assessment for overall improvement/efficacy, 20 subjects showed excellent overall efficacy and 12 subjects showed good overall efficacy on day 14 visit whereas 18 subjects showed excellent overall efficacy, 10 subjects showed good overall efficacy and 4 subjects showed satisfactory overall efficacy on day 21 visit. None of the subjects showed average and poor overall efficacy on day 14 and day 21 visits. As per the physician's assessment, 15 subjects (46.87%) were reported to have excellent tolerability, 10 subjects (31.25%) to have good tolerability and 7 subjects (21.87%) reported to have fair tolerability to study drug. As per the subject's assessment, 16 subjects (50%) were reported to have excellent tolerability, 12 subjects (37.5%) to have good tolerability and 4 subjects (12.5%) reported to have fair tolerability to study drug.

A total of 10 adverse events such as fever, headache and abdominal pain were observed. These events were however not related to the study drug. Eight subjects who participated in the study reported to have abdominal cramps which were attributed to the study medication. These were of mild nature and did not require any treatment and subsided normally. No statistically significant change in any of the laboratory parameter was observed after the treatment.

Table 1: Composition of Ayulax capsule
Each capsule contains

Sr. No.	Botanical name	Local name	Quantity
1	*Cassia angustifolia*	Sanai Patra	100 mg
2	*Operculina turpethum*	Trivruta	60 mg
3	*Terminalia chebula*	Haritaki	60 mg
4	*Trachyspermum ammi*	Yavani	50 mg
5	*Pimpinella anisum*	Shatapushpa	40 mg
6	*Zingiber officinale*	Shunthi	40 mg
7	*Helicteres isora*	Murud Shenga	40 mg
8	*Glycyrrhiza glabra*	Yastimadhu	30 mg
9	*Emblica officinalis*	Amalaki	30 mg

Table 2: Showing the frequency of bowel movements.

Sr. No	Baseline	Day 7	Day 14	Day 21
Mean ± SD	5.32 ± 2.26	13.21 ± 4.37	13 ± 3.44	9.28 ± 2.09
P value		t=6.68 (p<0.001)	t=5.49 (p<0.001)	t=3.98 (p<0.001)

Table 3: Showing the change in stool form on Bristol scale.

Sr. No	Baseline	Days 07	Day 14	Day 21
Mean ± SD	2.51 ± 0.95	5.35 ± 0.85	5.28 ± 0.76	4.57 ± 0.79
P value		t=7.32 p<0.001	t=5.29 p<0.001	t=3.99 p<0.001

Table 4: Showing the mean grade score of straining on defecation.

Sr. No.	Duration	Mean Grade Score ± SD	T Value (as compared to baseline visit)
1	Baseline Visit	41.78 ± 14.67	
2	7 days	16.42 ± 13.66	t=5.14 (p<0.001)
3	14 Days	7.14 ± 9.51	t=7.30 (p<0.001)
4	21 days	8.57 ± 12.14	t=4.61 (p<0.001)

Table 5: Showing the mean score of sensation of anorectal blockage.

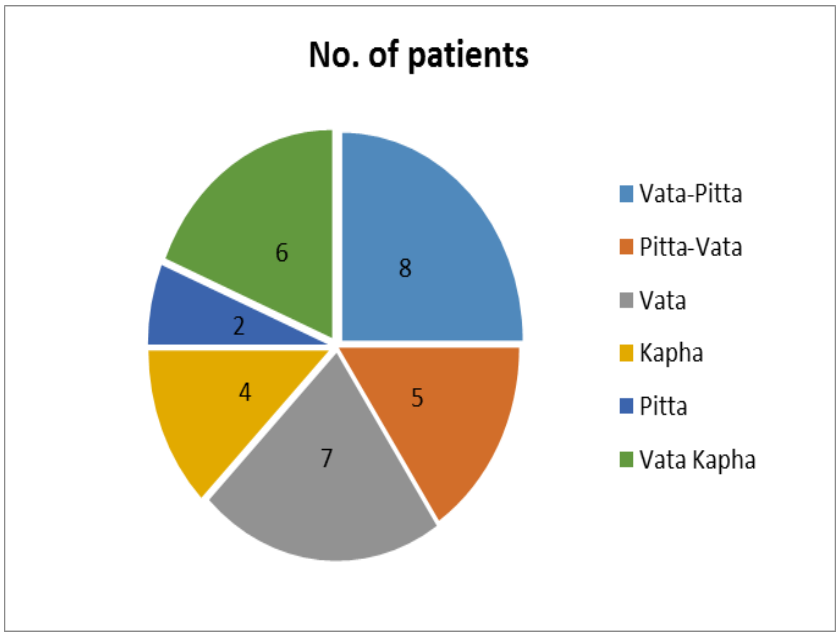
Sr. No.	Duration	Mean Grade Score ±SD	T Value (as compared to baseline visit)
1	Baseline Visit	40 ± 17.21	-
2	7 Days	15 ± 12.01	t=5.56 (p<0.001)
3	14 Days	14.28 ± 25.72	t=6.37 (p<0.001)
4	21 Days	21.42 ± 27.34	t=3.55 (p<0.001)

Table 6: Showing the average time spent for bowel evacuation on weekly basis.

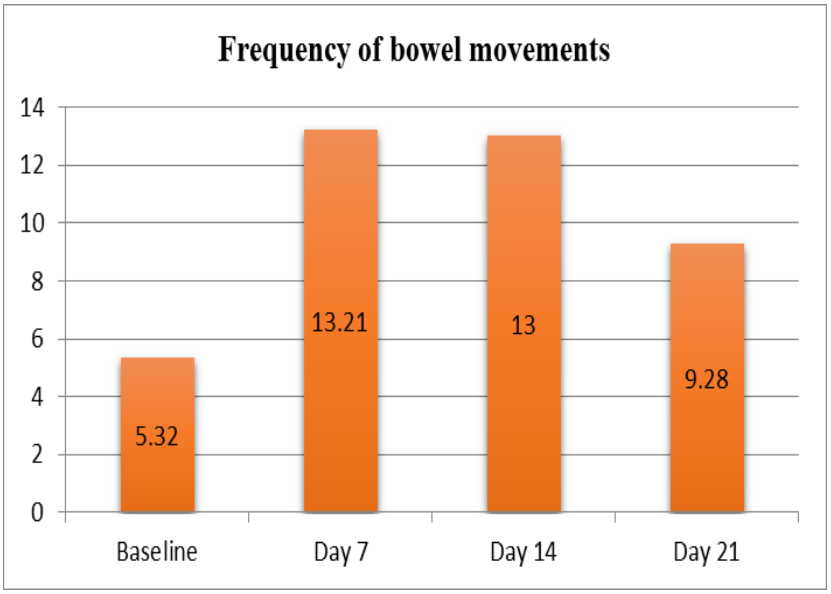
Sr. No	Duration	Mean Grade Score ±SD	t Value (as compared to baseline visit)
1	Baseline Visit	12.22 ± 7.12	
2	7 Days	5.08 ±4.08	t=5.13 p<0.001
3	14 Days	5.70 ±3.62	t=6.71 p<0.001
4	21 Days	7.72 ± 6.35	t=3.55 p<0.001

Table 7: Showing other associated symptoms of constipation.

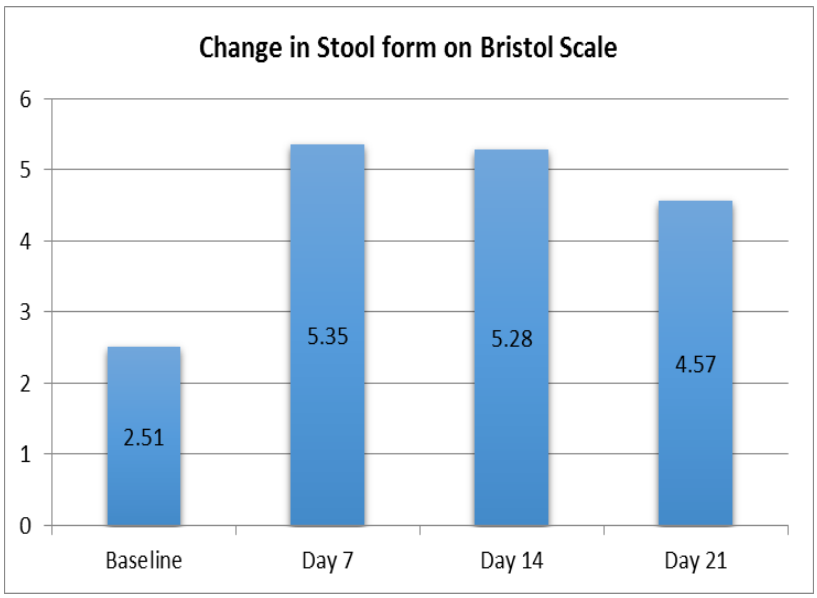
Associated symptom	Value	Baseline	7 Days	14 Days	21 Days
Headache	Mean ±SD	15.35 ±21.51	5.92 ±9.71	3.07 ±5.49	5 ±9.05
	t value p value	-	t=2.13 p<0.001	t=2.93 p<0.001	t=2.40 p<0.001
Acidity	Mean ±SD	20.35 ±23.95	14.44 ±22.07	12.69 ±20.89	16.53 ±21.89
	t value p value	-	t=1.03 p>0.05	t=1.41 p>0.05	t=0.80 p>0.05
Belching	Mean ±SD	15.71 ±16.19	8.14 ±9.62	10.38 ±20.29	12.30 ±21.22
	t value p value	-	t=2.14 p<0.05	t=1.23 p>0.05	t=0.84 p>0.05
Flatulence	Mean ±SD	23.92 ±15.23	11.11 ±10.12	10.76 ±9.34	14.23 ±13.31
	t value p value	-	t=3.83 p<0.001	t=4.11 p<0.001	t=2.85 p<0.05
Abdominal distension	Mean ±SD	23.57 ±10.95	11.48 ±7.18	12.30 ±8.62	14.23 ±12.05
	t value p value	-	t=4.45 p<0.001	t=4.09 p<0.001	t=3.07 p<0.05



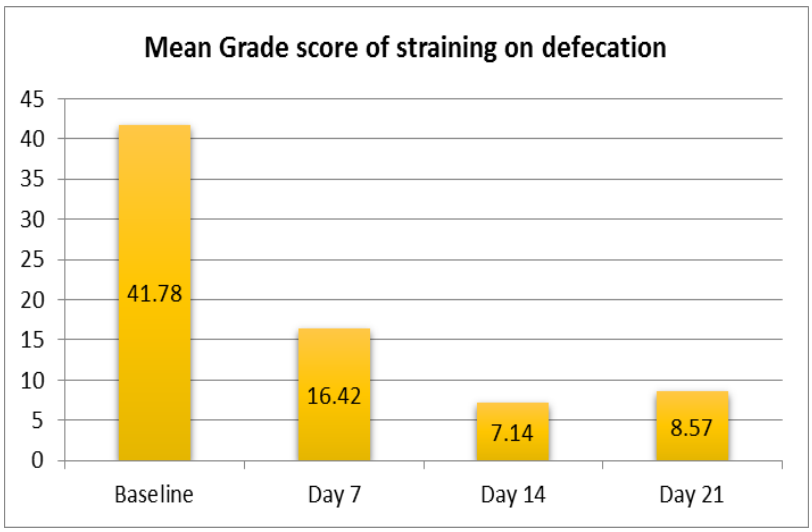
Graph 1: *Prakriti* wise distribution in patients.



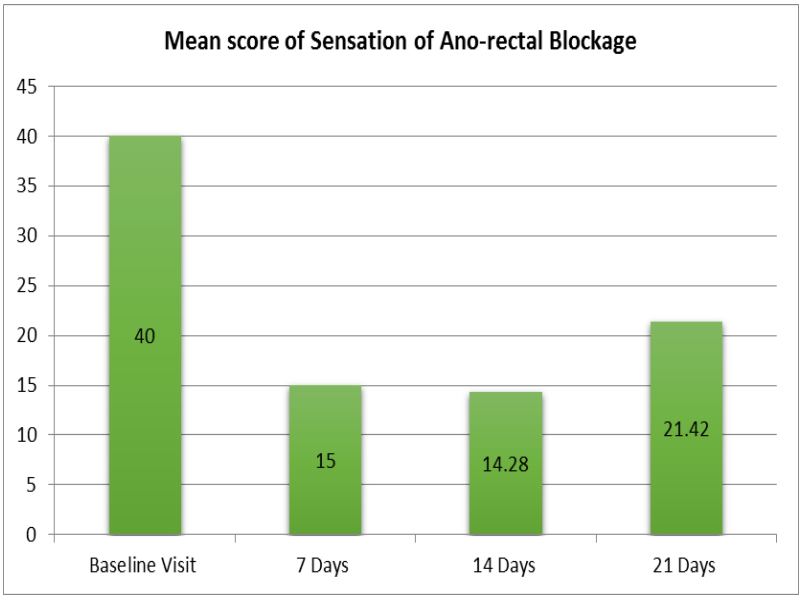
Graph 2: Showing the frequency of bowel movements.



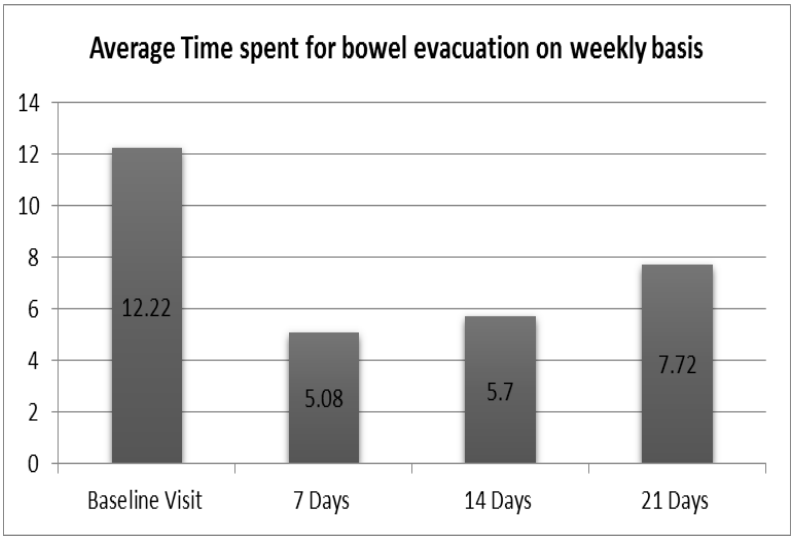
Graph 3: Showing the change in stool form on Bristol scale.



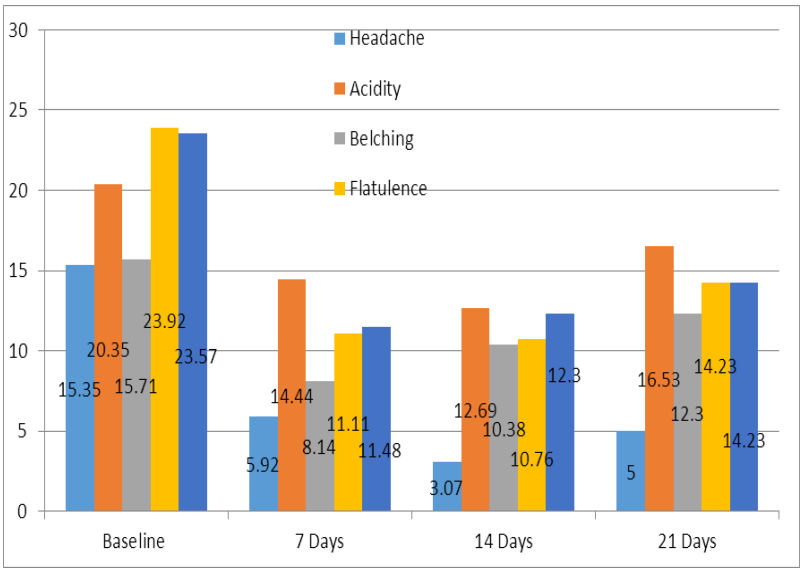
Graph 4: Showing the mean grade score of straining on defecation.



Graph 5: Showing the mean score of sensation of anorectal blockage.



Graph 6: Showing the average time spent for bowel evacuation on weekly basis.



Graph 7: Showing other associated symptoms of constipation.

DISCUSSION

In the present clinical study, the efficacy and safety of Ayulax capsule in subjects suffering from functional constipation was observed. This study confirms the beneficial effects of Ayulax capsule in functional constipation.

Fourteen days of treatment with Ayulax capsule showed significant increase in frequency of bowel movements on day 14. Also, the increase in mean bowel frequency after 'no laxative observatory period' of seven days (i.e. on day 21) was statistically significant than baseline visit. Stool form was significantly improved on all the three follow up visits ($p < 0.001$). Improvement in straining during defecation, sensation of anorectal blockage and sensation of incomplete evacuation was statistically significant ($p < 0.001$) even after discontinuation of laxative treatment with Ayulax capsule. Improvement in average time spent for bowel evacuation on weekly basis was statistically significant ($p < 0.001$) on every follow-up visit and even after stopping the medication the subject required less time for bowel evacuation as compared to its initial readings. Also, significant improvement in the scores of associated symptoms like headache, flatulence, abdominal distension and bloating were observed at all the three follow up visits while symptoms like acidity and belching did not show significant improvement. No relapse/recurrence was observed in most of the symptoms of the functional constipation even after discontinuation of study medication for 7 days.

The overall evaluation of efficacy and safety revealed excellent to good efficacy and safety by both the physician and subject. Laboratory parameters for safety evaluation showed no significant change in the values. Assessment of adverse events showed that 13% of the subjects complained of abdominal cramps which were attributed to the study medication. However, these symptoms subsided and did not require any treatment.

The results of present study are encouraging. Though the exact mechanism of action of Ayulax capsule is not clearly understood, the outcomes of present study may be because of synergistic activity of 9 herbs i.e. Amalaki (*Emblica officinalis*), Haritaki (*Terminalia chebula*), Yashtimadhuka (*Glycyrrhiza glabra*), Murud Shenga (*Helicteres isora*), Shunthi (*Zingiber officinale*), Shatapushpa (*Pimpinella anisum*), Yavani (*Trachyspermum ammi*), Trivruta (*Operculina turpethum*) and Sanai (*Cassia angustifolia*) present in the Ayulax capsule.[10] The herbs like Amalaki and Haritaki gently cleanse the colon and relives symptoms like anorectal blockage, sensation of incomplete evacuation, flatulence, and bloating.[11] Murud Shenga helps to reduce abdominal spasm whereas Shunthi is useful as an appetizer and digestive.[12-13] Sanai Patra and Trivutta are stimulant laxatives which increase the motility of the gastrointestinal tract and in turn the bowel frequency.[1]

The population on which the drug has been tested though enough to show statistically significant effect, but a randomized, double blind, multi-centric clinical study with large sample size to evaluate the efficacy and safety of 'Ayulax capsule' is indicated.

CONCLUSION

The present study provides evidence in support of the potential efficacy and safety of Ayulax capsule in a dose of 2 capsules at night in the treatment of functional constipation. Two weeks of treatment with the drug have prevented the relapse of most of the symptoms of functional constipation. Hence, the study concludes that Ayulax capsule is an effective, safe and non habit forming herbal laxative formulation for the management of constipation.

REFERENCE

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