INTERNATIONAL
AYURVEDIC
MEDICAL JOURNAL

IAMJ

Research Article ISSN: 2320 5091 Impact Factor: 4.018

A PROSPECTIVE OPEN LABEL INTERVENTIONAL CLINICAL STUDY TO EVALUATE THE EFFECTS OF CONSTALAX POWDER IN CONSTIPATION

Porwal Ashwin[1], Gandhi Paresh[2], Deepak Kulkarni[3],

[1]Consultant Colorectal Surgeon, Healing Hands clinic, [2]General Surgeon, Healing Hands Clinic,
[3]General Surgeon, Healing Hands Clinic;
4th floor, Millennium Star Extension, Above KFC, Adjacent to Ruby Hall Clinic,
Dhole Patil Road, Pune, Maharashtra, India

Email: drashwinporwal@healinghandsclinic.co.in

ABSTRACT

Constipation is a global problem found around the world, and affecting 2-27% of the population. It is been treated by its type using change in lifestyle, diet, exercise, drugs like laxative, stool softeners, stimulants. This causes many a time addiction, adverse events which gives the reason for the conduction of this study. Study was a open label prospective using Polyherbal Ayurvedic formulation in patients with chronic constipation (CC). In this study (n=600) adult patients who were visited at Healing hands clinic, Pune for their CC were enrolled and advised to take constalax powder for 60 days. Off 600 patients, 52 patients were the drop outs for various personal reasons. In this study total n= 548 patients were enrolled and Symptoms were observed using Longos ODS score system, Bristol stool form scale used to see the change stool form after using formulation, and change in quality of life using patient assessment of constipation –Quality of life (PAC- QOL) before and after enrollment in the study. In this study ($p<0.05$) after assessment from day 1 to day 60 it was found that during defecation reduction in pain Mean (SD) 2.76(1.04) to 60 day as 0.21(0.11), Straining Intensity 1.65(0.54) to 0.20(0.15), defecation frequency per week increased from 3.39(1.08) to 7.09(0.23), Extension of time in defecation 2.14(0.56) to 0.14(0.08), reduced in sensation of incomplete evacuation reduced from 2.1(1.14) to 0.09(0.21). Mean stool form was analyzed using Bristol stool form scale. It was found that score was increased significantly from baseline 2.62(0.58) to 4.20(0.69). Similarly mean PAC-QOL score, subscale including worries, concern, physical discomfort, and psychosocial discomfort, satisfaction score analyzed and found to be significantly improved from baseline. Non serious adverse events like feeling of diarrhea (15.88%) n=87, nausea (24.4%) n=134, weakness (33%) n=181 was also reported. All the participants n=548 who have completed this study showed good tolerability and formulation was found to be a good laxative, effective and safe formulation to be used in constipation.

Keywords: Constipation, Constalax Powder

INTRODUCTION

In normal Physiology intestines absorbs about 90% of water and large intestine or colon absorbs electrolytes, water from remaining in the colon[1, 2]. Delayed transit of stool through the colon leads to more and more absorption of water that will result in hardening of stool results in discomfort, infrequent hard and painful bowel movements. As per Rome III criteria fewer than three bowel movements per week is called as constipation[3]. Constipation affects physically, mentally and reduces the quality of life of an individual. It is affecting around 2% and 27% of the population[4, 5]. In two types of constipation functional, or primary, constipation further divided into three types: slow-transit constipation in this motility (gut movement) is decreased and increases the transit time, pelvic floor dysfunction, and normal-transit constipation. Secondary constipation can be caused by metabolic disturbances like hypothyroidism; neurological problems like Parkinson's disease, multiple sclerosis, and spinal cord injuries; celiac disease; and diseases of the large intestine such as colon cancer [6]. Constipation can be treated by changing unhealthy habits to healthy lifestyle that includes change in diet which includes fibers, take enough liquids in the form of water, juices etc, daily exercise[7,8,9,10]. For internal use laxatives, enema, bulk forming agents, stimulants, stool softeners, osmotic agents sometimes suggested[11,12,13]. But these internally used drugs results in adverse events like addiction to use, flatulence, abdominal cramps-distention, hypokalemia, alteration in electrolyte transportation. Hence there is a need of formulation to relieve the constipation without such adverse events. In Ayurveda literature many plants were suggested that could reduce the constipation[14]. Constalax is an Ayurvedic proprietary polyherbal formulation in which effects of used ingredients are already established and explained in Ayurvedic literatures hundreds of years before. In this open label interventional study effects of constalax powder in constipation was evaluated.

Aim and Objective:

1. Primary objective of this study was to evaluate the effect of constalax powder in chronic constipation.
2. Secondary objective of this study was to evaluate change in quality of life after using constalax powder.
3. Tertiary objective was to find out the adverse event caused by the constax powder.

Material and Methods:

Study Drug

Constalax is an Ayurvedic polyherbal formulation it contains *Sonamukhi* (*Cassia Angustifolia*), *Sunthi* (*Zingiber Officinale*), *Saunf* (*Foeniculum Vulgare*) , *Balhirada* (*Terminalia Chebula*), Ajwain (*Trachyspermum Ammi*), *Narikel Lavan* (*Cocus Nucifera with Rock Salt*), Permitted Excipients & Preservatives. Good manufacturing practices (GMP) approved plant was used while manufacturing the formulation.

Dose:

2 Tablespoon at Bed time(Approximately 8gm)

Anupan: Lukewarm water

Duration: 60 nights

Study Design:

1. Prospective observation, open label, single arm, single centre study conducted at Healing Hands Clinic, Pune India.

Inclusion Criteria:

1. Patient diagnosed with constipation as per Rome III criteria
2. Above 18 years Non vulnerable patients with all the ages
3. Patient agreed for voluntary informed consent and follow all standard instructions advised by the study physician

Exclusion Criteria:

1. All the patient with colorectal cancer, bed ridden, pregnant women, inflammatory bowel disease, alcoholic, drug of abuse.
2. Patient used other herbal formulation in last 1 month for constipation

Study Intervention

Adult patient with chronic constipation who is able to give voluntary written informed consent was included as per inclusion criteria. Constalax powder in a required amount was given to all the participants and asked to take 2tablespoon with lukewarm water before going to bed for sleep for 60 nights. Every patient was followed up in the interval of 15, 30, and 60 days after the baseline visit.

Statistical Analysis: Using MS Excel statistical analysis was done. Data with quantitative measure were expressed as Mean (SD).

Ethics committee approval and regulatory compliance

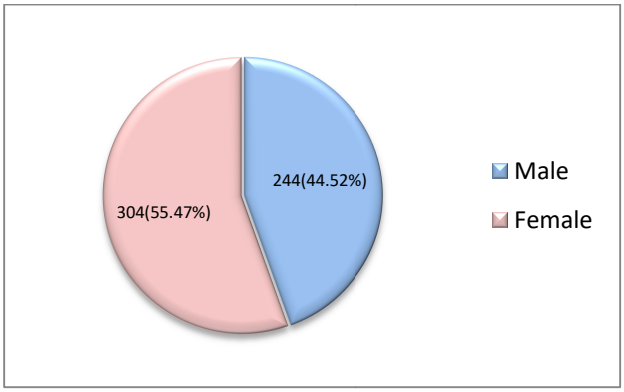
This study was conducted after getting approval from independent ethics committee and conducted as per schedule Y of drug and cosmetics rule 1945[15] , ICMR national ethical guidelines for biomedical and Health research involving human participants[16]. Every participant selected was carefully screened, informed about the study till the satisfaction of all arise queries. Written informed consent was obtained from each patient before enrolling as participant in the study.

Participant:

Rome III diagnostic criteria [17] were used to select the patient with constipation. Bristol stool form scale was used for feedback about stool form from every patient.

Results:

Total 600 patients were enrolled in this study, of which 548 continued till end of this study. Male (n=244) and female (n=304) participants both were included in this study as patient who came to visit at Healing hands clinic for their chronic constipation.



At each visit day 1, 15, 30, 60 vital signs including pulse, blood pressure, temperature, respiration rate were carefully noted.

Total n= 548 patient Symptoms were observed to see the effect of formulation using Longos ODS score system[18], Bristol stool form scale used to see the change stool form, and change in quality of life were assessed using patient assessment of constipation –Quality of life (PAC- QOL)[19,20,21,22,23] before and after enrollment in the study. In this study ($p<0.05$) after assessment from day 1 to day 60 it was found that during defecation reduction in pain Mean (SD) 2.76(1.04) to 60 day as 0.21(0.11), Straining Intensity 1.65(0.54) to 0.20(0.15), defecation frequency per week increased from 3.39(1.08) to 7.09(0.23), Extension of time in defecation 2.14(0.56) to 0.14(0.08), reduced in sensation of incomplete evacuation reduced from 2.1(1.14) to 0.09(0.21).

Table 1: Changes in mean score of chronic composition symptoms on Longo's ODS Score

Study Visit	Defection Frequency per week mean (SD)	Straining Intensity mean (SD)	Extension of time in defecation mean(SD)	Sensation of incomplete of evacuation mean(SD)	Recto/ Perineal pain/ Discomfort mean(SD)	Activity reduction per week mean(SD)	Digitations mean(SD)
Day 1	3.39 (1.08)	1.65 (0.54)	2.14 (0.56)	2.1 (1.14)	2.76 (1.04)	2.31 (1.84)	2.78 (2.45)
Day 15	6.45 (1.16)	0.58 (0.42)	1.06 (0.28)	1.34 (0.73)	1.19 (0.91)	1.98 (1.34)	1.87 (1.46)
Day 30	7.08 (0.22)	0.14 (0.34)	0.39 (0.16)	0.87 (0.73)	0.63 (0.51)	1.15 (1.03)	0.52 (0.71)
Day 60	7.09 (0.23)	0.20 (0.15)	0.14 (0.08)	0.09 (0.21)	0.21 (0.11)	0.42 (0.64)	0.24 (0.46)
*$p<0.05$, significant by student 't' test as compared to baseline (Day 1)							

Mean stool form was analyzed using Bristol stool form scale. It was found that score was increased significantly from baseline 2.62(0.58) to 4.20(0.69).

Table 2: Improvement in mean Score of stool from on Bristol stool from scale

Study Visit	**Mean (SD)**
Day 1	2.62 (0. 58)
Day15	4.58 (0.67)
Day30	4.13 (0.79)
Day60	4. 20 (0.69)
*p<0.05, significant by student 't' test as compared to baseline (Day 1)	

Similarly mean PAC-QOL score, subscale including worries, concern, physical discomfort, and psychosocial discomfort, satisfaction score analyzed and found to be significantly improved from baseline as below. Non serious adverse events like feeling of diarrhea (15.88%) n=87, nausea (24.4%) n=134, weakness (33%) n=181 was also reported.

Table 3: Changes in Mean Score of PAC – QOL Subscale Scores

Days	PAC-Q OL	Worries and concern	Physical discomfort	Psychosocial discomfort	Satisfaction
Study Visit	Mean(SD)	Mean(SD)	Mean(SD)	Mean(SD)	Mean(SD)
Day1	2.79 (0.62)	2.78 (0.98)	2.97 (1.18)	2.27(1.17)	1.45 (0.88)
Day15	1.85 (0.59)	1.56 (1.34)	1.62 (1.09)	1.86 (1.07)	1.32 (0.76)
Day30	0.56 (0.35)	0.98 (1.02)	0.91 (1.06)	1.02 (0.94)	1.05 (0.72)
Day60	0.39 (0.23)	0.49 (0.77)	0.70 (0.91)	0.73 (0.70)	0.58 (0.65)
*p<0.05, significant by student 't' test as compared to baseline (Day 1)					

DISCUSSION

Chronic constipation can be treated by consuming fibrous diet, exercise[7,8,9,10], drugs like laxative, stool softener, stimulating agents[11,12,13] which tend to give unwanted adverse events to the individuals and sometime addiction also. In Ayurveda use of drugs from natural sources recommended which contains wide range of bioactives and comprises of rich source of medicine. In constalax powder a polyherbal contents were taken together as formulation using Ayurvedic literature that is helping in condition like constipation. Its content includes sonamukhi which is called as "*urdhva-adha kaya shodhini*" means to clean upper and rectal routes. *Sounf (faeniculum Vulgare)* is used in the treatment of mild digestive disorders due to its gastrointestinal tract stimulant effects mainly gut motility at higher concentration it shows antispasmodic actions. *Sunthi (Zingiber Officinale)* is appetizer, stomachic, thermogenic, carminative, laxative, digestive and is useful in many digestive problems such as colic, diarrhoea, flatulence, flatulence, hyperacidity, abdominal pain, vomiting etc. *Balhirada (Terminalia Chebula)* is a homeostatic laxative, antitussive, diuretic and a cardiotonic. Study conducted by seyyed AMd et all shows seed of *terminalia chebula* helps to reduce constipation, improves gastrointestinal transit ratio. *Ajwain (Trachyspermum Ammi)* in traditional Ayurvedic medicine primarily for stomach disorders such as indigestion, flatulence[24]. *Narikela Lavan* which is used to enhance the digestive power that helps to reduce constipation[25]. With the use all natural ingredients in balanced amount no serious adverse events were observed in this study. Non serious adverse events like feeling of diarrhea, nausea, weakness was reported.

CONCLUSION:

In this trial constalx a polyherbal Ayurvedic formulation found to be significantly safe and effective which could be useful in chronic constipation. As due to time limitations it was difficult for us to come to the conclusion this formulation also helps to improve digestion and gas problems. There is a need of separate studies with these objectives. The most difficult task found in this study was to convince the patient to continue use of constalax powder. This challenge results into dropout of 52 participants from the study. As we have tried this formula in pune at Healing Hands Clinic in the state of Maharashtra, India. We would like to overcome on this limitation and conduct the trial in all the other states in India and possibly in western countries as the constipation is common problem around the globe. As different countries with different biological, genetical, environmental conditions with different life styles may give us information on unknown adverse events. It will give the full safety and efficacy profile of constalx powder. We can conduct it in collaboration with government agencies around the world.

REFERENCES

1. Phillips SF, Giller J. The contribution of the colon to electrolyte and water conservation in man. J Lab Clin Med 1973; 81:733–46.
2. 2 Debongnie JC, Phillips SF. Capacity of the human colon to absorb fluid. Gastroenterology 1978;74:698–703.
3. Johanson JF, Sonnenberg A, Koch TR. Clinical epidemiology of chronic constipation. *J Clin Gastroenterol*. 1989;11(5):525-536.
4. Pare P, Ferrazzi S, Thompson WG, Irvine EJ, Rance L. An epidemiological survey of constipation in Canada: definitions, rates, demographics, and predictors of health care seeking. Am J Gastroenterol 2001; 96: 3130–7. 6
5. Stewart WF, Liberman JN, Sandler RS et al. Epidemiology of constipation (EPOC) study in the United States: relation of clinical subtypes to sociodemographic features. Am J Gastroenterol 1999; 94: 3530–40.
6. http://www.lifeextension.com/Protocols/Gastrointestinal/Constipation/Page-04
7. Marshall JB. Chronic constipation in adults: how far should evaluation and treatment go?. Postgraduate medicine. 1990 Sep 1;88(3):49-63.
8. Meshkinpour H, Selod S, Movahedi H, Nami N, James N, Wilson A. Effects of regular exercise in management of chronic idiopathic constipation. Digestive diseases and sciences. 1998 Nov 1;43(11):2379-83.
9. Young RJ, Beerman LE, Vanderhoof JA. Increasing oral fluids in chronic constipation in children. Gastroenterology nursing: the official journal of the Society of Gastroenterology Nurses and Associates. 1998;21(4):156-61.
10. Lingu I, Kulkarni PV, Tanna I, Chandola HM. EVALUATION OF DIET, LIFE STYLE AND STRESS IN THE ETIOPATHOGENESIS OF CONSTIPATION IN GERIATRIC PEOPLE. International Journal of Research in Ayurveda & Pharmacy. 2012 Nov 1;3(5).
11. Tramonte SM, Brand MB, Mulrow CD, Arnato MG, O'Keefe ME, Ramirez G. Treatment of chronic constipation: a systemic review. J Gen Intern Med 1997; 12:15–24.
12. Smith B. Effect of irritant purgatives on the myenteric plexus in man and the mouse. Gut 1968;9:139–143.
13. Smith B. Pathologic changes in the colon produced by anthraquinone laxatives. Dis Colon Rectum 1973;16:455–458
14. Pandey GS, Chunekar KC. Bhavprakash Nighantu (Indian Materia Medica). Revised and enlarged edition. 2010;527:58-9.
15. Schedule Y. Requirements and guidelines for permission to import and/or manufacture of new drugs for sale or to undertake clinical trials. Central Drug s Standard Control Organization website. New Delhi, India. 2013.
16. ICMR national ethical guidelines for biomedical and Health research involving human participants 2017
17. Rome F. Guidelines--Rome III Diagnostic Criteria for Functional Gastrointestinal Disorders. Journal of gastrointestinal and liver diseases: JGLD. 2006 Sep;15(3):307.
18. Longo A. Obstructed defecation because of rectal pathologies. Novel surgical treatment: stapled transanal rectal resection (STARR). InActs of 14th

international colorectal disease symposium. Fort Lauderdale, FL 2003 Feb 13.
19. Dubois D, Gilet H, Viala-Danten M, Tack J. Psychometric performance and clinical meaningfulness of the Patient Assessment of Constipation-Quality of Life questionnaire in prucalopride (RESOLOR) trials for chronic constipation. Neurogastroenterol Motil. 2010; 22:e54-63. doi: 10.1111/j.1365-2982.2009.01408.x. PubMed PMID: 19761492.
20. Nomura H, Agatsuma T, Mimura T. Validity and reliability of the Japanese version of the Patient Assessment of Constipation Quality of Life questionnaire. J Gastroenterol. 2014;49:667-73. doi: 10.1007/s00535-013- 0825-y. PubMed PMID: 23657607
21. Bengi G, Yalcin M, Akpinar H, Keskinoglu P, Ellidokuz H. Validity and reliability of the patient assessment of constipation quality of life questionnaire for the Turkish population. Turk J Gastroenterol. 2015;26:309-14. doi: 10.5152/tjg.2015.0185. PubMed PMID: 26039000.
22. Marquis P, De La Loge C, Dubois D, McDermott A, Chassany O. Development and validation of the Patient Assessment of Constipation Quality of Life questionnaire. Scand J Gastroenterol. 2005; 40:540-51. doi: 10.1080/00365520510012208. PubMed PMID: 16036506
23. Dennison C, Prasad M, Lloyd A Bhattacharyya SK, Dhawan R, Coyne K. The health-related quality of life and economic burden of constipation. Pharmacoeconomics. 2005;23:461-76. PubMed PMID: 15896098
24. Green A. Field guide to herbs & spices: How to identify, select, and use virtually every seasoning at the market. Quirk Books; 2006.
25. Kothari V, Kotecha K, Jain S, Kevalia J. SCIENTIFIC BASIS FOR ACTION OF NARIKELA LAVAN. Pharma Science Monitor. 2015 Jul 1;6(3).

Source of Support: Nil
Conflict Of Interest: None Declared

How to cite this URL: Porwal Ashwin et al: A Prospective Open Label Interventional Clinical Study To Evaluate The Effects Of Constalax Powder In Constipation. International Ayurvedic Medical Journal {online} 2018 {cited April, 2018} Available from: http://www.iamj.in/posts/images/upload/794_799.pdf