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A randomized, comparative, open clinical trial for evaluating the efficacy of PP/JLN/107/09-10 Syrup in the management of Functional Constipation

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ABSTRACT

Context: Functional constipation which has no underlying organic causes is difficult to be allopathic treatment for long term due to its side effects and undeniable effect, thus a natural balanced and compatible formulation needs to be validated. **Objectives:** Current study aimed to assess a poly-herbal formulation in management of functional constipation. **Material and Methods:** This study was 28 days, two armed, randomized, open labeled, prospective clinical study. 60 clinically confirmed cases of functional constipation patients randomized to receive orally either 2 teaspoonful of PP/JLN/107/09-10 Syrup or 1 teaspoonful of 5-6 gm of *Isabgol* powder. Results were analyzed as per Rome II criteria and other associated symptoms like headache, acidity, belching, barborgysmy, flatulence and abdominal distension or bloating which are recorded on VAS score. **Results:** PP/JLN/107/09-10 scored over *Isabgol* on four out of six parameters of Rome II Criteria viz., frequency of bowel movement, straining at defecation, lumpy I hardstool formation, feeling of incomplete evacuation, feeling of ano-rectal blockage and manual maneuvers ($p < 0.001$). Trial drugs showed comparable effects ($p > 0.05$) in reducing the mean scores of associated symptoms like headache, acidity, belching, borgorgysmy, flatulence and abdominal distension. However, trial drug was found to perform statistically significant result in more number of parameters in comparison to *Isabgol*. **Conclusion:** PP/JLN/107/09-10 was found to be effective and safe in reliving functional constipation.

Key words: *Functional Constipation, PP/JLN/107/09-10, Isabgol, Clinical Study, Rome II Criteria.*

Trial Registration: *Clinical Trail Registry of India vides Ref. CTRI/2018/02/012110 Dated 23/02/2018.*

INTRODUCTION

Constipation is a commonly encountered symptom in clinical practice, but uncertainty exists also the precise definition of the term, which has led to controversy concerning its incidence, pathogenesis and treatment. Constipation can be a result of primary motor disorders, other diseases, adverse effects of many drugs, chronic illnesses that lead to physical and mental impairment. However elderly women use laxatives more often and constipation is common in persons 65years and older. This may be because the elderly people often define constipation as need for strain to defecate rather than infrequency of bowel movements.

Most constipated patients have no obvious cause for their symptoms but are presumed to have an underlying disorder of colonic or ano-rectal motor function. The most common endocrine disorders that cause constipation are diabetes mellitus and hypothyroidism. Neurological diseases are associated with constipation because the colonic motor functions are co-ordinated by extrinsic sympathetic and parasympathetic nerves.

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Constipation is defined as having a bowel movement fewer than three times per week. With constipation stools are usually hard, dry, small in size, and difficult to eliminate. Constipation is a symptom, not a disease. Almost everyone experiences constipation at some point in their life, and a poor diet typically is the cause.

Universally constipation (functional constipation) has about 10-12% incidence rate. All forms of constipation together account for >20% incidence.

Constipation is one of the most common prevalent gastrointestinal symptoms, affecting approx. 14% of the population. There is no single definition of constipation and it can be defined by one or more symptoms: hard stool, infrequent stools (typically fewer than three per week), a sense of incomplete bowel evacuation, and excessive time spent on the toilet or in unsuccessful defecation.

Causes

Constipation is frequently multifactorial and can result from systemic or neurologic disorders or medications. Constipation may also be caused by conditions such as: Primary diseases of the colon (stricture, cancer, anal fissure, and proctitis) metabolic disturbances (hypercalcemia, hypothyroidism, and diabetes mellitus) Neurologic disorders (Parkinsonism, spinal cord lesions).

Management

The life style change and dietary modifications are helpful for the relief of mild to moderate constipation. Patients whose constipation is not relieved by lifestyle and diet change may benefit from judicious use of a laxative. Various classes of laxative drugs such as stimulant, saline, osmotic and bulk are used depending upon the chronicity and severity of the condition. Other treatment procedures such as enemas, suppositories, behavioural therapy and surgery also have a place in the management of constipation.

Pelvic Floor Retralning

Many constipated patients have pelvic function disorder. Surgical removal of the colon may not benefit patients with pelvic floor disorder.

Behaviour and Pain Management

Many patients with colonic dysmotility benefit from evaluation and therapy for stress and other psychosocial factors and for problems of chronic abdominal pain.

Surgery Subtotal Colectomy (also called Total Abdominal Colectomy).

The surgeon removes the colon then joins the end of the small bowel to the top of the rectum. The Surgery does not cause loss of stool control because the anal sphincter remains intact. Following surgery, patients can expect to have from one to four bowel movements each day.

The procedure can be performed by open or laparoscopic surgery. The stimulant laxatives, osmotic and saline laxative are reported to cause abdominal cramping, hypokalemia, flatulence, abdominal distension and alters electrolyte transportation etc. which limits their use on long-term.

There are several laxative as well as purgative agents described under various categories. The main categories are: *Virechana*/purgatives Ex. *Danti* (*Baleospermum montanum*), *Sramsana*/laxatives Ex. *Aragvadha* (*Cassia fistula*), *Bhedana*/cholertics Ex. *Katuki* (*Picrorrhiza kurroa*), *Mrudurechana*/mild laxatives Ex. *Trivrit* (*Operculina turpethum*), *Tivrarechana*/ cathartics Ex. *Eranda* (*Ricinus communis*) and *Virechanopaga* /pro-drugs to purgatives Ex. *Yashtimadhu* (*Giycyrrhiza glabra*).

The ingredients of the formulation are known for their inherent traditional pharmaco-therapeutic effects on bowel regulation. Therefore the present study is planned to evaluate the efficacy of the JLN/PP/107/09-10 in comparison with marketed herbal laxative formulations like *Isabgol* etc.

OBJECTIVES OF THE STUDY

The study objectives were to evaluate the efficacy *JLNIPP/107* syrup in the management of functional Constipation and to compare the efficacy of *JLN/PP/107* with *Isabgol powder* in the management of functional Constipation.

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METHODOLOGY

This was an Open label, Comparative, Prospective, Randomized trial. A randomization chart given by the bio-statistician is followed to remove any bias in the enrolment of subjects. About 60 clinically confirmed Functional Constipation subjects between the age group of 20 -60 years belonging to both the sex were randomized and allocated into two groups viz., Group A and Group B wherein Group A is administered with the trial drug while Group B received the *Isabgol* powder.

Study Participants

Subjects presenting with either or all symptoms as mentioned in the inclusion criteria were provisionally included in the study from the outpatient department of *Kayachikitsa* (Internal Medicine), S.J.S. Ayurvedic College & Hospital, Nazratpettai, Chennai.

Subject selection Criteria

Subjects presenting with two or more of the following for at least 12 weeks (not necessarily consecutive) in the preceding 12 months. (The Rome II criteria) viz., Straining during > 25% of bowel movements, Lumpy or hard stools for> 25% of bowel movements, Sensation of incomplete evacuation for > 25% of bowel movements, Sensation of anorectal blockage for> 25% of bowel movements, Manual manoeuvres to facilitate> 25% of bowel movements (e.g. digital evacuation or support of the pelvic floor) and Less than 3 bowel movements per week were included in the study. Only the subjects in the age group 18-60 years who are willing to sign informed consent and to come for regular follow- up examinations as & when required were included.

Patients with diagnosed colonic inertia, anorectal surgery, structural abnormalities, like: rectal prolapse, rectocele, rectal intussuception, anorectal stricture, solitary rectal ulcer syndrome

Perineal descent, Colonic / rectal mass or tumor with obstruction e.g. adenocarcinoma, Colonic stricture: radiation, ischemia, diverticulosis, Hirschsprung's disease,Idiopathic megarectum, Intestinal obstruction were excluded. Patients with diagnosed neurological problems, Patients with serious systemic ailments, Pregnant or lactating females and those patients on chronic medication (>60 days) and/or who are on medications known to cause constipation were also excluded.

Study End Points

2 weeks of intervention with JLN/PP/107 Syrup in Group A and *Isabgol* powder in Group B was taken as therapeutic end point. Any improvement or relief from clinical symptoms related to constipation at the end of 2 weeks and 4 weeks or by the resolution of symptoms whichever stands early and the Clinical Global Response by Physician were considered as clinical end points.

Study interventions

PP/JLN/107/2009-10 has *Trivrit (Operculina turpethum)* 300 mg *Yashtimadhu (Glycyrrhiza glabra)* 75 mg with excipients qs. Subjects in group A were advised to take PP/JLN/107/2009-10 in a dose of 2 Teaspoonful (10ml) at Bed time and in Group B to take *Isabgol* powder, (5-6g) one teaspoonful at Bed time.

Study Procedure

Study period of 2 weeks with weekly follow up and a post treatment follow up for another 2 weeks after the therapy was planned. There were three visits apart from the baseline visit. Improvement in constipation on a Clinical Scoring system as per the Rome II criteria. Frequency of bowel movement (0 to 2 point scale), Straining at defecation (VAS scale), Lumpy or hard stools (VAS scale), Sensation of incomplete evacuation (VAS scale), Sensation of ano-rectal blockage (VAS scale), Manual maneuvers required per week (0 to 2 point scale where 2 is more than two manual maneuvers required per week while score of 1 is considered as 1 to 2 manual maneuvers per week. Score of 0 indicates subjects without manual manoeuvres) along with symptoms like headache, acidity, belching, borborgysmy, flatulence and abdominal distension or bloating are recorded on VAS scale.

VAS was taken as 0 to 33 considered free from symptoms or negligible symptoms of constipation.

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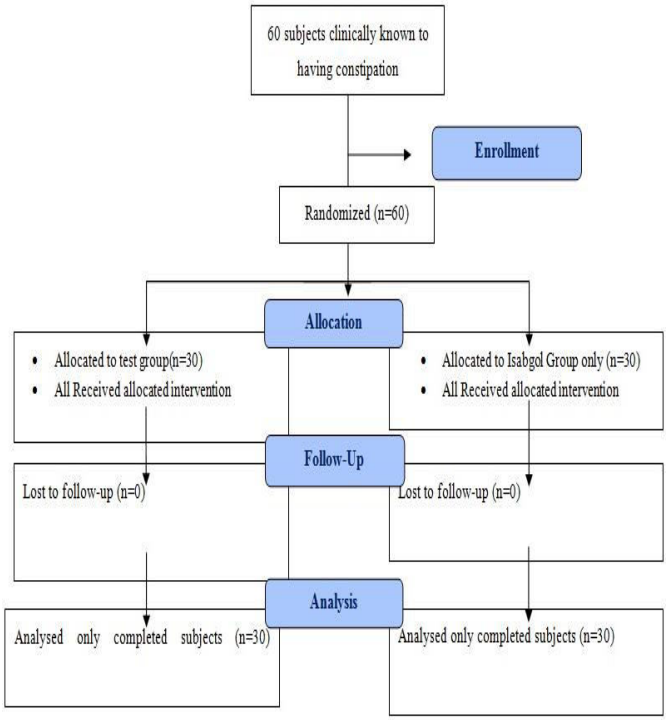
Scores from 34 to 67 is moderate constipation while 68 to 100 is severe constipation.

Complete Blood profile, Liver Function Test (SGOT, S. Bilirubin), Renal function Tests (B. urea, S. creatinine), Urine Analysis (R, M) were also carried out for safety assessment. USG of abdomen was also carried out while screening to rule out any structural anomalies.

Fig. 1: Patient enrollment flow chart: CONSORT 2010 flow diagram



OBSERVATIONS AND RESULTS

Total 60 subjects falling under the inclusion criteria were recruited and randomised equally to group A and group B. Among them, all were *clinically confirmed Functional Constipation* subjects, belonging to the age group of 20- 60 years. Demographic details are given in Table 1.

Table 1: Demographic details

Group	Male	Female	Mean Age in yrs
A (n=30)	10	20	37.67±18.10
B (n=30)	11	19	42.37±14.35

Effect on frequency of bowel movement

In group A, the mean score on *Rome II Scale* was 1.48 (out of 2 points) at the baseline which was reduced to 1.26 and 1.11 at the end of visit 1 and visit 2 respectively. The reduction was statistically significant ($p < 0.05$). The score was further reduced to 1.07 at the end of visit 3. In group B, the mean score on *Rome II Scale* was 1.33 (out of 2 points) at the baseline which was reducedto1.10 and 1.03 at the end of visit 1 and visit 2 respectively. The reduction was significant ($p < 0.05$.) The score was slightly increased to 1.13 at the end of visit 3.

Effect on Straining at Defecation

The baseline mean score was 85.33 while it was 13.33 after visit 2. The reduction was statistically highly significant $p < 0.001$. The score was decreased to 8.33 at the end of visit 3(i.e., after the follow up period of 2 weeks without medicine. In group B, The baseline mean score was 79.00 while it was 25.33 after visit 2. The reduction was statistically highly significant $p < 0.001$. The score was increased to 27.67 at the end of visit 3 (i.e., after the follow up period of 2 weeks without medicine).

Effect on Lumpy or Hard stools

The baseline mean score was 84.67 while it was 8.33 after visit 2. The reduction was statistically highly significant $p < 0.001$. The score was increased to 10.33 at the end of visit 3. In group B, the baseline mean score was 74.67 while it was 26.33 after visit 2. The reduction was statistically highly significant $p < 0.001$. The score was increased to 27.67 at the end of visit 3.

Effect on Feeling of Incomplete Evacuation

The baseline mean score was 81.00 while it was 15.67 after visit 2. The reduction was statistically highly significant $p < 0.001$. The score was increased to 14.00 at the end of **visit 3** (i.e., after the follow up" period of 2 weeks without medicine).The baseline mean score was 72.67 while it was 25.67 after visit 2. This reduction was statistically significant ($p<0.001$). The reduction was statistically highly significant $p < 0.001$. The score was increased t(l 27.33 at the end of visit 3.

Effect on Feeling of Anorectal Blockage

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The baseline mean score was 57.59 while it was 12.07 after visit 2. The reduction was statistically non-significant (p>0.05). The score was increased to 12.76 at the end of visit 3 (i.e., after the follow up period of 2 weeks without medicine).The baseline mean score was 47.00 while it was 24.67 after visit 2. This reduction was statistically non-significant (p>0.05). The score was almost the same (24.33) at the end of visit 3.

Effect on Manual Maneuvers

It is observed that 13 subjects out of 30 subjects in group A have reported with requirement of some manual maneuver for defecation at the base line. There were 1 subject, 9 subjects and 3 subjects respectively in the score range of 2, 1 and 0 in group A These were observed to be 0 subjects, 5 subject and 8 subjects respectively at visit 1;1 subject, 3 subject and 9 subjects respectively at visit 2; and 2 subjects, 6 subject and 5subjects respectively at visit 3. In group B, there were 1 subject, 7 subjects and 2 subjects respectively in the score range of 2, 1 and 0 at baseline. These were observed to be 1 subject, 4 subject and 4 subjects respectively at visit 1; 1 subject, 4 subject and 4 subjects respectively at visit 2; and 1 subjects, 6 subject and 2 subjects respectively at visit 3.

PP/JLN/107/09-10 scored over *Isabgol* on four out of six parameters of Rome II Criteria viz., frequency of bowel movement, straining at defecation, lumpy I hardstool formation, feeling of incomplete evacuation, feeling of ano-rectal blockage and manual maneuvers ($p < 0.001$).Trial drugs showed comparable effects ($p > 0.05$) in reducing the mean scores of associated symptoms like headache, acidity, belching, borgorgysmy, flatulence and abdominal distension. However, their inter-group mean score reduction on respective symptoms are statistically significant ($p<0.05$).

It is noticed that subjects in group A required less medical administration compared to group B. This is proved from the fact that number of subjects who achieved clinical end points before completion of 2 weeks in group Aare 11 against 02 in group B. The continued relief noted during follow-up period is more with group A when compared to group B.

Effect of study drug on various associated parameters is presented in Fig 2 and 3. **PP/JLN/107/09-10** showed clinically significant reduction in various associated parameters like headache, acidity, borborgymy, etc.

Fig 2: Associated symptoms in Group A

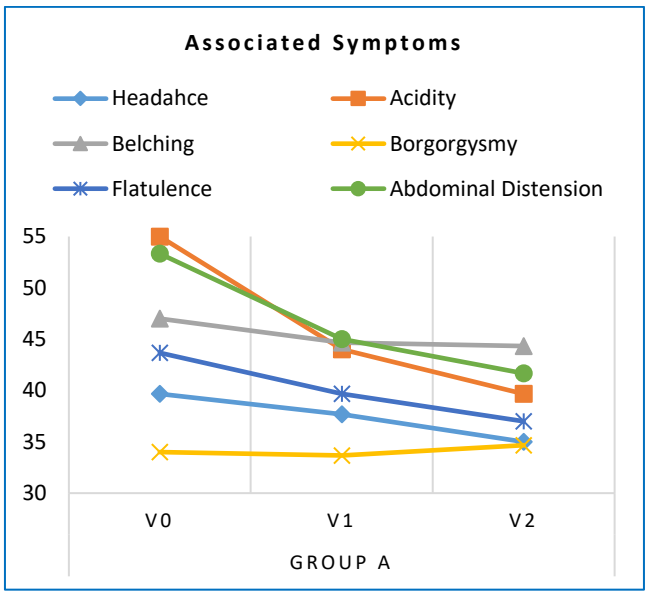
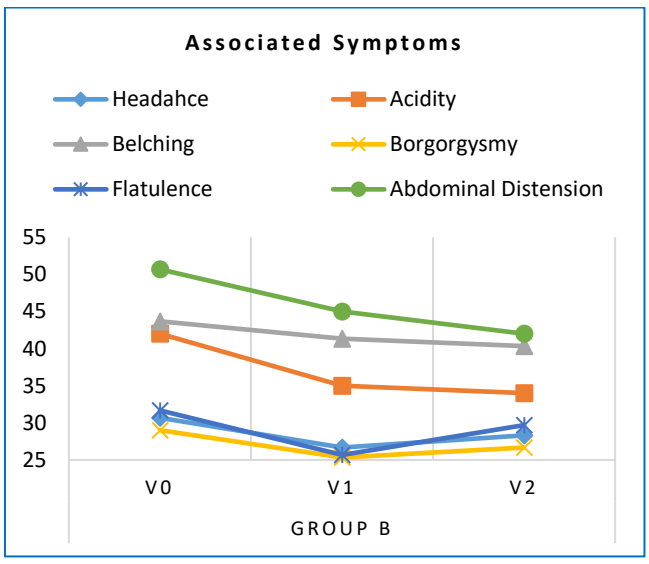


Fig 3: Associated symptoms in Group A



Discussion

Constipation can be classified into three broad categories: normal-transit constipation, slow transit constipation, and disorders of defecatory or rectal evacuation. More than one mechanism may contribute to constipation in a patient. "The Rome II

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criteria" is the widely accepted format for diagnosis of constipation.

"Functional" constipation or Normal-transit constipation is the most common form of constipation in which stool traverses at a normal rate through the colon and the stool frequency is normal, yet with a subjective feeling of constipation. The patients may experience bloating and abdominal pain or discomfort, and they may exhibit increased psychosocial distress; some may have increased rectal compliance, reduced rectal sensation, or both.

According to *Ayurveda*, *Vibandha* (constipation) may occur in *Ama-Avastha*, *Vata-vriddhi*, *Lakshana* in various diseases *Udavarta*, *Pureeksha-kshya*, *Vata-Vriddhi* in old age etc. Patients suffering from constipation who are having *Amalakshanas* like *Balabramsa*, *Gourava*, *Alasya*, *Apakti*, *Aruchi* etc. should not be given laxatives. For those *Deepana*, *Pachana* and *Amahara* drugs will relieve constipation as well as other symptoms.

Operculina turpethum (Linn.) is a stout twiner with qudrangular stem. In Vedic literature, it is quoted by *Sounaka* (*Sou*. 19/27/3). Though *Syama* is described in *Kousikasutra* (103/7), it is considered as the synonym of *Bhringaraja* or *Nili*. *Syamaka* is also found in the Vedic literature. *Acharya Caraka* emphasized *Trivrit* as the best herbs for *'Sukhavirecana'* (laxative). He described elaborately the different formulation of *Trivrit* for *Virecana* (purgation) in one chapter in *Kalpasthana* entitled *'SyamaTrivritKalpam'*. He further explained that it is of two kind's viz., *Aruna* and *Syama*. The second variety is considered to relieve even severe constipation. *Bhavamisra* while quoting two varieties of *Trivrit* (*Sveta* and *Syama*), explained that both are drastic purgatives but the black variety is inferior variety. In the market we come across the samples of *Marsedenia tenasissima* root being sold as *Trivrit*. *Trivrit* is indicated in *Sotha, Udara, Arsas, Pandu, Kamala, Jvara, Vibandha, Pliharoga, Krimi*. *Trivrit* Root *I* Root bark is used in *Ayurvedic* practice for *Vatarakta* (B.P. & V.S.) *Stanyasodhana* (C.S.Ci.30, *Vishamajvara* V.M., *Netraroga* (S.S.Ut. 10) in a dose of powder 1-3 g.

Root contains resin in varying amounts (9-10%- Bhattacharya, 1961; 10-12%- Prasad et al, 1961; 12-13% Shah et al, 1961). The resin contained the glycosides, turpethin, a-turpetheinand 13-turpethein (Wealth of India, 1966). It also contained a coumarin, scopoletin, glucose, rhamnose and fuctose '(Shah et al., 1972). Turpenthinic acids A, B, C, D and E isolated from resin (Pianta Med. 1978, 33, 144). Betulin, lupeol and 13-sitosterol isolated from stem (ActaCienc.Indica, Chem. 1987,13, 171; Chem. Abstr. 1989,111,36646 r). The LD50 of the 50% ethanolic extract of 0. turpethum (whole plantexcluding roots) was> 1000 mg/kg i.p. in mice (Aswal et al., 1984). The cathartic effect of *Trivrit* is reported in a clinical study (n=30). The root powder of O.turpethum was administered at a dose of 5 g with water at bed time (Tripathi, 1989).

Madhuka or *Madhuyashtika* are known to the physicians, since vedic period. *Atharva Parisista* described *Madhuka* and is considered as *Dourbhagyanasana* and *Garbhabamhana*. Commentators like *Sayana* identified it with *Yastiimadhu*. It was used in the treatment of animal poisons (*Jangamavisha*). *Madhuyastika* is quoted in the context of "*Mulavidhi*" (Pa.Gr.1/21). *Brhat Trayi* used this herb extensively in therapeutics but *Caraka* included it in many of *Hiskashayavargas*. He also emphasized its utility among *Rasayana* drugs. It is indicated in *Vranasotha, Chardi, Trshna, Visharoga, Kshaya, Daha, Raktapitta, Hrdroga, Vrana, Vibandha, Bhagandara (S.S.Ci.8), Arthavabhedaka (S.S.Ut.26)* and *Hrdroga (C.S.Ci.26). Satapakamadhukataila; Madhuyashtyaditaila; Yashtyadichurna* etc. Important Preparations of *Yashtimadhu.*

Glycyrrhizin (principal sweetening agent), glycyrrhizic acid, glycyrrhetinic acid, liquirtin, isoliquiritin, neoisoliquiritin, liquiritogenin, isoliquiritogenin, glabrine, glabranine, licuraside, licochalcones A & B, hispagla-bridin A & B licoricidin, glabrene, liquiritic acid, glabrolide etc. are some of active ingredients of *Yashtimadhu*. In vivo study onisoliquiritigenin, a flavonoid isolated from the roots of *Glycyrrhiza glabra,* isoliquiritigenin produced a dual dose-related effect on the charcoal meal travel, inhibitory at the

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low doses, while prokinetic at the high doses. In vitro, isoliquiritigenin showed an atropine-sensitive concentration-dependent spasmogenic effect in isolated rat stomach fungus. However, a spasmolytic effect was observed in isolated rabbit jejunums, guinea pig ileums and atropinizedrat stomach fungus, either as non competitive inhibition of agonist concentration-response curves, inhibition of high K(+) (80 mM)-induced contractions, or displacement of Ca(2+) concentration-response curves to the right, indicating a calcium antagonist effect. Pretreatment with N (omega)-nitro-L-arginine methyl ester (L-NAME; 30 microM), indomethacin (10 microM), methylene blue (10 microM), tetraethylammonium chloride (0.5mM), glibenclamide (1 microM), 4-aminopyridine (0.1 mM), or clotrimazole (1 microM) did not inhibit the spasmolytic effect.

These results indicate that isoliquiritigenin plays a dual role in regulating gastrointestinal motility, both spasmogenic and spasmolytic. The spasmogenic effect may involve the activating of muscarinic receptors, 'while the spasmolytic effect is predominantly due to blockade of the calcium channels (Chen G. et al., 2009).

Thus, our study findings and various other research findings on ingredients suggest that a combination of *Trivrit* as *Sukhavirechaka* drug with *Yashtimadhu* as *Virechanopaga* drug in the management of functional constipation can be beneficial in terms of efficacy and safety.

CONCLUSION

From the above findings it is concluded that the trial drug PP/JLN/107/09-10 is both clinically and statistically significant ($p < 0.001$) compared to Isabgol in the management of functional constipation. The trial drug did not produce any side-effects. PP/JLN/107/09-10 exhibited clinically as well as statistically significant ($p < 0.05$) relief from constipation. Trial drug PP/JLN/107/09-10 syrup showed a better relief in subjects suffering from functional constipation in comparison to the *Isabgol*.

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