



Research Article

A SINGLE CENTRIC, OPEN-LABEL, NON-RANDOMIZED POST- MARKETING SURVEILLANCE STUDY TO MEASURE THE EFFICACY AND SAFETY OF PETAFFA TABLETS IN SUBJECTS SUFFERING FROM CONSTIPATION, GAS AND ACIDITY

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ABSTRACT

Constipation, gas, and acidity are common gastrointestinal issues with a significant global prevalence. Traditional medicine systems like Ayurveda have long utilized medicinal plants to address these concerns. However, clinical validation of their efficacy in patients with constipation has been lacking. **Objectives:** This study aimed to assess the efficacy and safety of Petsaffa tablets, an Ayurvedic formulation containing various herbal ingredients, in relieving constipation, gas, and acidity. **Methods:** The study, conducted as a single-centric, open-label, non-randomized post-marketing surveillance study, involved 120 subjects with constipation. Subjects were evaluated using inclusion and exclusion criteria and provided Petsaffa tablets for a 14-day intervention. Various parameters, including bowel movement frequency, constipation scores, and subjective assessments, were measured. Vital signs, laboratory safety parameters, and adverse events were also monitored during the study period. **Results:** Petsaffa tablets significantly improved bowel movement frequency, constipation scores, and subjective symptoms related to constipation. Stool consistency and other associated symptoms such as acidity and gas were also reduced at the end of the study. None of the participants reported any adverse events, and safety parameters remained within normal limits during the study period. **Conclusion:** Petsaffa tablets offer a promising, safe, and effective alternative option for individuals with common gastrointestinal issues such as constipation, acidity, and gas.

INTRODUCTION

Constipation, gas, and acidity are the most common gastrointestinal issues that affect a significant number of populations worldwide. Constipation affects people of all ages and is characterized by, but not limited to, hard stools, excessive straining, infrequent bowel movements, bloating, and abdominal pain and difficulty passing stools.^[1,2] According to epidemiological studies, the prevalence of constipation ranges from 2% to 30% worldwide.^[3] Gas and acidity, often accompanied by bloating and discomfort, can

also be prevalent and bothersome. Constipation can result from various factors, including dietary habits (e.g., low fiber intake, poor food and fluid intakes), lifestyles, stress, certain medications, and underlying medical conditions such as depression or anxiety, diabetes, pregnancy, cancer, and thyroid disease.^[4,5] Non-pharmacological interventions, like lifestyle adjustments encompassing physical activity, a diet rich in fiber, and adequate hydration, often pose challenges for older individuals due to factors such as reduced mobility, multiple medication use, and underlying health issues.^[6] Depending on the severity and persistence of the condition, various pharmacological treatments, such as bulking agents, stimulants, stool softeners, and osmotic agents, are employed in clinical practice.^[7,8] Despite the established safety and efficacy of traditional treatments, many patients do not experience significant relief from their symptoms. ^[9]

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Laxatives are commonly prescribed to manage constipation; however, these medications can sometimes lead to undesirable side effects including diarrhea, abdominal cramping, electrolyte imbalances, bloating, and abdominal distention.^[10]

In recent times, there has been a growing interest in harnessing the power of herbal treatments rooted in traditional medical systems, such as Ayurveda, to address common gastrointestinal issues. Ayurveda, an age-old Indian medical system, heavily emphasizes the use of medicinal plants to promote and maintain bodily balance and harmony.^[11] A wide range of Ayurvedic ingredients including *Cassia angustifolia* (Swarnapatri), *Terminalia chebula* (Haritaki), *Terminalia bellirica* (Bibhitaki), *Embllica officinalis* (Amalaki), *Trachyspermum ammi* (Ajamoda), *Operculina turpethum* (Trivrit), *Foeniculum vulgare* (Saunf), *Piper nigrum* (Maricha), and *Glycyrrhiza glabra* (Yashtimadhu), known for their potential benefits in promoting digestive health and alleviating digestive discomforts such as constipation, gas, and acidity.^[12,13] These natural ingredients have been traditionally used to relieve constipation and digestive discomfort, and their effectiveness continues to be a subject of interest in modern healthcare.

The primary objective of this clinical study was to evaluate the effectiveness and safety of Petsaffa tablets, an Ayurvedic herbal formulation containing a blend of traditional ingredients, in the relief of constipation, gas, and acidity. Integrating ancient knowledge and Ayurvedic principles, Petsaffa Tablets target these common gastrointestinal issues. Through the execution of this non-randomized post-marketing surveillance study, our aim was to collect real-world data on the utilization of Petsaffa Tablets and their impact on individuals grappling with constipation, gas, and acidity. This initiative serves to enhance our comprehension within the domain of gastroenterology.

METHODS

Ethics

The study adhered to the ethical principles and guidelines outlined in the Declaration of Helsinki, as well as those set forth by the Indian Council of Medical Research (ICMR), International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use-Good Clinical Practice (ICH-GCP), Ayurveda, Siddha, and Unani - Good Clinical Practice (ASU-GCP), and other pertinent governmental regulations. Approval for the study protocol was obtained from the Care Multispecialty Hospital Institutional Ethics Committee under Protocol No. SBS/DIV/003/2022. Furthermore, the study was registered with the Clinical Trials Registry-India (CTRI Number: CTRI/2023/03/051058) on March 27, 2023,

in compliance with the necessary regulatory requirements.

Study Design

This was a single-center, open-label, non-randomized post-marketing surveillance study involving 120 eligible subjects. The study consisted of three in-person visits on days 0, 1, and 14, along with one telephonic follow-up on day 7. The research commenced with a screening visit on Day 0, during which subjects were evaluated against specific inclusion and exclusion criteria, and informed consent was obtained from each participant. Blood samples were collected for laboratory tests at this stage. Eligible subjects were enrolled during the baseline visit on day 1. All subjects were provided with Petsaffa tablets and instructed to take one or two tablets daily with lukewarm water from day 1 to day 14. The effectiveness of the product was assessed using the Investigator Assessment Scale and Self-Assessment Questionnaires on both day 0 and day 14. A telephonic follow-up was conducted on day 7 to monitor any adverse events.

Inclusion and Exclusion Criteria

Subjects were between 18 and 80 years old and experienced symptoms of constipation, gas, and acidity. All subjects willingly signed the Informed Consent Form and agreed to refrain from using similar medications during the study.

Subjects were excluded if they were pregnant, breastfeeding, recently underwent surgery, or participated in other clinical trials within 30 days from the day of screening. Those with serious medical conditions, abnormal lab values, known allergies to any ingredient of the investigational product, or necessitating long-term medications were also excluded. Furthermore, individuals with genetic or endocrinal disorders or those who did not provide consent were not included.

Study Intervention

The study intervention, Petsaffa tablets, is a carefully formulated blend of Ayurvedic ingredients designed for oral administration. It aims to alleviate common digestive issues, including constipation, gas, and acidity, providing natural relief and enhancing overall well-being. The composition of Petsaffa tablets includes Ayurvedic elements such as *Cassia angustifolia*, *Triphla* (a combination of *Terminalia chebula*, *Terminalia belerica*, and *Embllica officinalis*), *Foeniculum vulgare*, *Trachyspermum ammi*, *Piper nigrum*, *Glycyrrhiza glabra*, and *Operculina turpethum*. This intervention draws from the rich heritage of Ayurveda to offer a holistic approach to digestive health.

Primary Outcomes

The primary outcome measures of the study focused on the frequency of subjects exhibiting significant symptomatic reduction in constipation, as well as a reduction in gas and acidity. For constipation, the Investigator Assessment Scale was utilized, incorporating a comprehensive evaluation of various aspects, including the frequency and consistency of bowel movements, the severity of difficulty experienced during bowel movements, and a Constipation Scoring System to quantify the overall severity of the condition. Participants openly provided insights on pain, abdominal discomfort, incomplete evacuation, time spent on the toilet, the number of attempts required, and the need for assistance, facilitating tailored treatment plans and a holistic understanding of the impact on their quality of life. The cumulative Constipation Score, ranging from 0 to 30, provided a quantitative measure of the overall severity of constipation.

A subjective assessment of symptoms related to constipation, gas, and acidity was also conducted using a structured questionnaire, allowing participants to rate the severity of each symptom on a scale of 0 to 4 (0 = absent, 1 = mild, 2 = moderate, 3 = severe, and 4 = very severe). The study assessed a range of symptoms including gastrointestinal discomfort, abdominal discomfort, abdominal pain, abdominal bloating, stomach cramps, painful bowel movements, rectal burning during or after a bowel movement, rectal bleeding or tearing during or after a bowel movement, incomplete bowel movements, hard bowel movements, small bowel movements, straining or exertion during bowel movements, and a feeling of having to pass a bowel movement but being unable to do so.

Secondary Outcomes

The secondary outcomes of this study included assessments of stool consistency using the Bristol stool scale and evaluations of constipation questionnaires. Physiological impacts were evaluated through monitoring changes in vital signs from the screening to the end of the study. The study also closely monitored laboratory safety parameters throughout the study duration to ensure the safety of the intervention. Additionally, documentation of adverse events aimed to ensure the overall safety and tolerability of the study intervention.

Statistical Analysis

The study did not consider statistical implications when determining the sample size, ultimately enrolling 120 subjects out of 125 screened subjects. Descriptive statistics were used to describe the characteristics of the study subjects. Safety variables were summarized using mean, SD, percentages, minimum, and maximum values for quantitative variables, and frequencies for qualitative variables. A sample t-test was utilized to compare screening and end-of-study data, with results expressed as mean, standard deviation, 95% confidence interval, and p-value. A significance level of 0.05 was adopted for statistical significance.

RESULTS

Demographic Data

In this study, demographic data were analyzed using standard descriptive statistics, which included frequency counts and corresponding percentages, arithmetic means, standard deviations (SD), as well as minimum and maximum values. Out of the initial 125 individuals screened, 3 were ineligible due to not meeting the inclusion criteria, and 2 were lost to follow-up, resulting in a final enrolment of 120 subjects. The average age of participants was 50.23 ± 14.66 years, with ages ranging from 21 to 75 years. Among the participants, 73 (60.83%) were males, and 47 (39.17%) were females. The participants had an average weight of 62.19 ± 7.28 kg and an average height of 168.99 ± 5.79 cm.

Primary Outcome Measures

Frequency of bowel movement

The assessment of constipation in this clinical study was based on categorizing subjects according to the frequency of their bowel movements. At the screening visit, a significant percentage of subjects experienced infrequent bowel movements, with 61.67% having less than one bowel movement per week and 30.0% reporting 2 to 3 bowel movements per week. However, at the end of the study, notable improvements in bowel movement frequency were observed. There was a substantial increase in the number of subjects reporting bowel movements "2 to 3 times per day" (from 1.67% to 19.17%) and "once per day" (from 1.67% to 67.50%). Conversely, the number of subjects with infrequent bowel movements decreased, with "2 to 3 times per week" dropping to 0.83% and "less than once per week" to 5.83% (Table 1).

Table 1: Frequency of bowel movement at the screening and at the end of study (n=120)

Bowel movement frequency	Screening		End of Study	
	Number	Percentage (%)	Number	Percentage (%)
More than 3 times per day	6	5.00	8	6.67
2 to 3 times per day	2	1.67	23	19.17
Once per day	2	1.67	81	67.50
2 to 3 times per week	36	30.0	1	0.83
Less than once per week	74	61.67	7	5.83

Constipation Score

To assess changes in constipation scores, a comparison was made between the screening data at day 0 and the results obtained at the end of the study on day 14. The analysis, based on data from all 120 subjects, revealed a highly significant difference (p-value < 0.0001), indicating a substantial improvement in constipation (Figure 1). The mean difference between day 0 and day 14 constipation scores was found to be 10.62, with a 95% confidence interval ranging from 10.15 to 11.08, highlighting the remarkable magnitude of improvement.

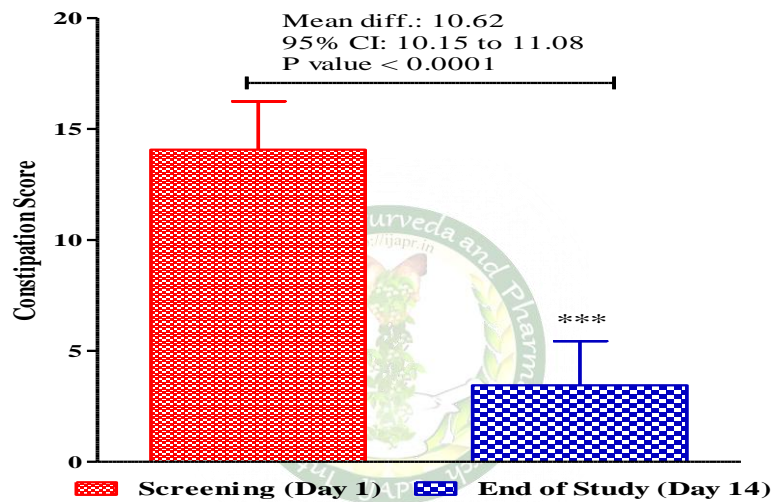


Figure 1: Change in constipation symptom scores before and after treatment. Statistical comparison screening vs end of the study data was done by t-test. *P<0.0001.**

Subjective Assessment of Constipation Symptoms

In this clinical study, the influence of Petsaffa tablets on constipation symptoms was subjectively assessed. At the screening visit, subjects reported moderate to severe symptoms across various categories, including abdominal discomfort, pain, bloating, cramps, painful bowel movements, rectal burning or bleeding, incomplete bowel movements, hard and small stool, straining during bowel movements, and the sensation of needing to pass stools. Over the course of the study, a remarkable reduction in the mean scores for each symptom category was observed, with mean differences ranging from 2.0 to 2.358. These improvements were highly statistically significant (p<0.0001) based on the 95% confidence intervals (Table 2). These findings indicate that the treatment had a substantial and beneficial effect in alleviating constipation-related symptoms within the study population.

Table 2: Change in Subjective Assessment of Constipation Symptoms (n = 120)

Symptoms	Screening (Mean ± SD)	End of Study (Mean ± SD)	Mean diff.	95% CI	P value
Abdominal discomfort	2.72 ± 0.61	0.68 ± 0.75	2.042	1.889 - 2.194	< 0.0001
Abdominal pain	2.73 ± 0.77	0.71 ± 0.61	2.017	1.828 - 2.206	< 0.0001
Bloating	2.80 ± 0.77	0.50 ± 0.65	2.286	2.125 - 2.446	< 0.0001
Stomach cramp	2.88 ± 0.83	0.52 ± 0.67	2.358	2.163 - 2.554	< 0.0001
Painful bowel movement	2.81 ± 0.81	0.72 ± 0.76	2.092	1.896 - 2.288	< 0.0001
Rectal burning during/ after bowel	2.61 ± 0.74	0.61 ± 0.65	2.000	1.833 - 2.167	< 0.0001

movement					
Rectal bleeding/ tearing during/after bowel movement	2.69 ± 0.86	0.53 ± 0.69	2.167	1.961 - 2.373	< 0.0001
Incomplete bowel movement	2.88 ± 0.89	0.55 ± 0.63	2.319	2.116 - 2.523	< 0.0001
Too hard bowel movement	2.79 ± 0.82	0.51 ± 0.66	2.283	2.077 - 2.489	< 0.0001
Too small bowel movement	2.69 ± 0.75	0.66 ± 0.67	2.033	1.847 - 2.219	< 0.0001
Straining/squeezing to pass bowel movements	2.67 ± 0.87	0.55 ± 0.66	2.117	1.923 - 2.310	< 0.0001
Had to pass a bowel movement	2.54 ± 0.68	0.47 ± 0.67	2.075	1.896 - 2.254	< 0.0001

Secondary Outcome Measures

Bowel Movement Consistency

The assessment of bowel movement consistency during the trial demonstrated a significant improvement in subjects' gastrointestinal health. Initially, the majority of participants described their stool types as harder (type 1, 12.50%), lumpy (type 2, 42.50%), and with a surface resembling cracked sausages (type 3, 45.0%), with no occurrences of softer, smoother stool types (types 4-7). However, at the end of the study, a notable shift was observed, with no participants reporting harder stool types and a substantial proportion experiencing softer (type 5, 30.83%) and mushier stool (type 6, 55.0%) types, along with the presence of entirely liquid bowel movements (type 7, 14.17%) (Table 3). These findings suggest a positive change in bowel movement consistency over the course of the trial, which may be indicative of improved gastrointestinal health in the study subjects.

Table 3: Bowel movement consistency among the participants at the screening and at the end of study

Bowel movement consistency	Screening		End of Study	
	Number (n)	Percentage (%)	Number (n)	Percentage (%)
Type 1: Separate hard lumps, like nuts (hard to pass)	15	12.50	0	0
Type 2: Sausage shaped but lumpy	51	42.50	0	0
Type 3: Like a sausage but with cracks on its surface	54	45.0	0	0
Type 4: Like sausage or snake, smooth and soft	0	0	0	0
Type 5: Soft blobs with clear cut edges (passed easily)	0	0	37	30.83
Type 6: Fluffy pieces with ragged edges a mushy stool	0	0	66	55.0
Type 7: Watery, no solid pieces Entirely liquid	0	0	17	14.17

Constipation associated other symptoms

During the screening visit, a significant number of subjects reported a range of additional symptoms associated with constipation, including acidity (25.0%), gas (23.33%), indigestion (27.50%), stomach pain (4.17%), and a combination of two or more of these symptoms (20.0%) (Table 4). However, at the end of study, the prevalence of these reported symptoms had significantly decreased, with the vast majority (99.17%) of subjects indicating the absence of any of the aforementioned symptoms. This substantial reduction suggests a favourable outcome of Petsaffa tablets in addressing constipation-related concerns. It's worth noting that initially, 5 subjects depended on laxative medications to facilitate their bowel movements. However, at the end of study, none of the participants required the use of laxatives to support their bowel movements.

Table 4. Change in the frequency in constipation associated other symptoms

Symptoms	Screening		End of Study	
	Number (n)	Percentage (%)	Number (n)	Percentage (%)
Acidity	30	25.00	1	0.83
Gas	28	23.33	0	0
Indigestion	33	27.50	0	0
Stomach pain	5	4.17	0	0
Combination of two or more above symptoms	24	20.00	0	0
None of the above symptoms	0	0	119	99.17

Safety

Vital signs

Vital signs, including body temperature, pulse rate, respiratory rate, systolic, and diastolic blood pressure, were assessed at the screening visit (visit 1) and at the end of study (visit 4). A detailed analysis showed no significant differences in vital signs from screening to end of the study. Minimal changes were observed in body temperature from 36.79 ± 0.48 to $36.80 \pm 0.46^\circ\text{C}$, pulse rate from 74.38 ± 6.85 to 80.41 ± 6.70 BPM, respiratory rate from 16.12 ± 1.76 to 15.98 ± 1.82 bpm, systolic blood pressure from 117.97 ± 5.10 to 117.99 ± 5.17 mmHg, and diastolic blood pressure from 77.13 ± 4.79 to 77.38 ± 3.13 mmHg. Importantly, all vital signs remained within the normal range throughout the study, as shown in Figure 2.

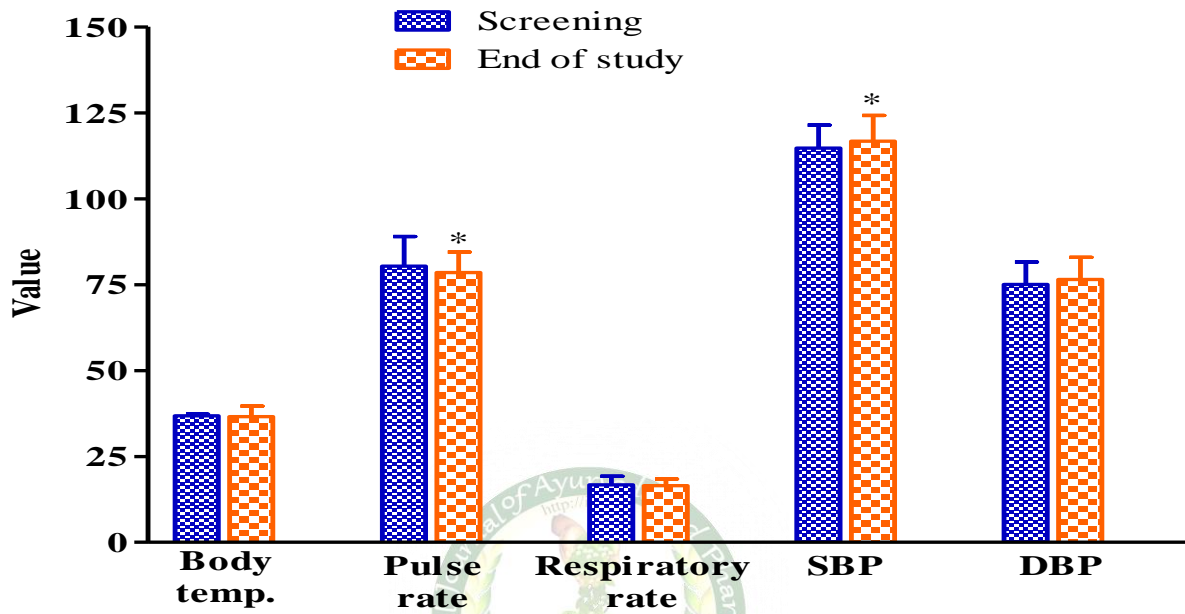


Figure 2: Mean change in vital signs from screening to end of the study (n = 120). A paired t-test was used to statistically compare the screening data with end of the study data (*P < 0.05). SBP, systolic blood pressure, and DBP, diastolic blood pressure.

Laboratory Safety Parameters

Laboratory safety parameters, including assessments of renal function, liver function, and haematological indicators, were conducted during the screening visit (visit 1) and at the end of the study (visit 4), as detailed in Table 5. Notably, all parameters remained within normal limits both at the initial screening and at the conclusion of the study. Statistically, there were no significant changes observed in the mean scores of these parameters between the two evaluation points, except for SGPT. These results indicate the overall safety and tolerability of Petsaffa tablets during the course of the study.

Table 5: Mean differences in renal function, liver function, and hematological parameters between screening visit and end of the study (n=120)

Parameters	Screening (mean ± SD)	End of the study (mean ± SD)	Mean diff.	p-value
SGPT, U/L	31.19 ± 7.29	28.77 ± 6.89	2.361	<0.0001***
Serum creatinine, mg/dl	1.10 ± 0.18	1.08 ± 0.18	0.021	0.249
Haemoglobin, g/dl	13.28 ± 0.98	13.28 ± 0.96	-0.010	0.837
RBC, million/mm ³	4.68 ± 0.40	4.72 ± 0.43	-0.050	0.055
Haematocrit (PCV)%	41.44 ± 3.82	41.65 ± 3.80	-0.244	0.138
Platelet count, lakhs/mm ³	2.34 ± 0.43	2.41 ± 0.45	-0.069	0.089
Total WBC, cell/mm ³	7866.67 ± 7729.77	7433.87 ± 1067.24	422.4	0.550
Lymphocytes, %	31.33 ± 6.10	31.32 ± 5.34	0.050	0.936
Eosinophils, %	2.43 ± 0.56	2.37 ± 0.55	0.059	0.264

Parameters	Screening (mean ± SD)	End of the study (mean ± SD)	Mean diff.	p-value
Monocytes, %	2.40 ± 0.51	2.45 ± 0.53	-0.059	0.276
Neutrophils, %	63.91 ± 6.01	63.90 ± 5.33	-0.034	0.958
Basophils, %	0.0 ± 0.0	0.0 ± 0.0	0.0	0.0

Note: Statistical comparison of screening data vs end of the study was performed by paired t-test. ***P < 0.0001.

Adverse effects

Following the completion of the study with 120 subjects, two individuals reported adverse symptoms that were not related to the study intervention. One subject reported experiencing abdominal pain and discomfort, while another reported nausea. It is important to note that these adverse events were not attributed to the study intervention. Despite these isolated instances, the overall data from the study strongly supports the safety of Petsaffa Tablets for human consumption. No additional adverse events were reported or observed among the remaining 118 subjects throughout the entire study period.

DISCUSSION

Ayurveda, an ancient Indian medical system is commonly utilized for the treatment of various gastrointestinal disorders, including constipation.¹² Within Ayurveda, a wide range of medicinal plants are recommended to address constipation, among them *Cassia angustifolia*, *Terminalia chebula*, *Terminalia bellerica*, *Emblica officinalis*, *Trachyspermum ammi*, *Operculina turpethum*, *Foeniculum vulgare*, *Piper nigrum*, and *Glycyrrhiza glabra*.^[12,14,15] These plant-based remedies aim to restore balance, particularly in rectifying Vata imbalances, and thus promote regular bowel movements.^[12] However, there has been a lack of clinical studies that validate the effectiveness and safety of these herbal plants and their formulations in individuals suffering from constipation. To address this gap, our study assessed the effectiveness and safety of an Ayurvedic formulation known as "Petsaffa" tablets. The Petsaffa tablets comprises a combination of ingredients, including *Cassia angustifolia*, *Terminalia chebula*, *Terminalia bellerica*, *Emblica officinalis*, *Trachyspermum ammi*, *Operculina turpethum*, *Foeniculum vulgare*, *Piper nigrum*, and *Glycyrrhiza glabra*. These ingredients, well-regarded in Ayurveda, are believed to offer a wide array of gastrointestinal benefits.^[12]

In results of this study, demonstrated significant improvements in the frequency of bowel movements, constipation scores, and constipation symptoms among the study participants after the administration of Petsaffa tablets. There was a notable increase in the frequency of bowel movements, with a shift from infrequent to more regular patterns. Constipation scores, based on various aspects of constipation severity, showed a highly significant

improvement at the end of the study, indicating a substantial reduction in constipation symptoms. Additionally, subjective assessments revealed marked reductions in symptoms related to abdominal discomfort, pain, bloating, cramps, and more. Furthermore, the improvement in stool consistency, reflected by the Bristol stool scale, suggested enhanced gastrointestinal health among the participants. The study also observed a substantial reduction in symptoms associated with constipation, such as acidity, gas, indigestion, and stomach pain. The prevalence of these symptoms decreased significantly, with the vast majority of subjects indicating the absence of any of these concerns at the end of the study.

The observed enhancements in the frequency of bowel movements, constipation scores, and constipation-related symptoms following the usage of Petsaffa tablets hold significant pharmacological and traditional significance in promoting regular and healthy bowel habits. This aligns with the traditional use of Ayurvedic components such as *Cassia angustifolia*, recognized for its laxative properties and historical use in relieving constipation.^[16] Similarly, *Triphala* (*Terminalia chebula*, *Terminalia bellerica*, *Emblica officinalis*) has long been employed for its digestive benefits, addressing gastrointestinal discomfort, and alleviating constipation.^[17] The improvement in stool consistency, as indicated by the Bristol stool scale, resonates with the traditional application of *Foeniculum vulgare* and *Piper nigrum*, known for their digestive and carminative properties.^[18,19] These ingredients are renowned in traditional medicine for their role in enhancing gastrointestinal well-being. Furthermore, the substantial reduction in symptoms related to constipation, including acidity, gas, indigestion, and stomach pain, highlights the holistic approach of Petsaffa tablets in addressing various digestive discomforts. In this context, *Glycyrrhiza glabra* and *Trachyspermum ammi* have been traditionally used for their digestive and anti-flatulent properties.^[20,21] Petsaffa tablets encompass a diverse array of bioactive elements sourced from these medicinal plants, including sennosides (*Cassia angustifolia*), chebulinic acid, gallic acid, and ellagic acid (*Triphala*), anisaldehyde, thymol, and estragole (*Foeniculum vulgare*), piperine (*Piper nigrum*), cymene, and pinene (*Trachyspermum ammi*), as well as glycyrrhizin and glycyrrhetic acid (*Glycyrrhiza glabra*).

Therefore, the effectiveness of Petsaffa tablets is likely attributed to the synergistic action of these key bioactive constituents.

The safety assessment of Petsaffa tablets included the monitoring of vital signs and laboratory safety parameters. Vital signs, including body temperature, pulse rate, respiratory rate, and blood pressure, remained within normal ranges throughout the study. Laboratory safety parameters, encompassing renal function, liver function, and haematological indicators, were also within normal limits. Most notably, no adverse events were reported or observed during the entire study period. These findings support the overall safety and tolerability of Petsaffa tablets for human consumption for individuals experiencing constipation, gas, and acidity.

CONCLUSION

In conclusion, the study findings strongly support the efficacy and safety of Petsaffa tablets in alleviating constipation, gas, and acidity. The treatment led to significant improvements in bowel movement and related symptoms, without the occurrence of adverse events. These findings suggest that Petsaffa tablets offer a promising treatment option for individuals suffering with common gastrointestinal issues, providing a natural and well-tolerated solution to enhance their digestive well-being. Further research with larger sample sizes and randomized controlled trials can further validate these positive outcomes.

REFERENCES

1. Zhao Y, Yu YB. Intestinal microbiota and chronic constipation. *Springerplus*. 2016; 5(1): 1130.
2. Al Nou'mani J, Al Alawi AM, Al-Maqbali JS, Al Abri N, Al Sabbri M. Prevalence, Recognition, and Risk Factors of Constipation among Medically Hospitalized Patients: A Cohort Prospective Study. *Medicina*. 2023; 59(7): 1347.
3. Mugie SM, Benninga MA, Di Lorenzo C. Epidemiology of constipation in children and adults: a systematic review. *Best Practice & Research Clinical Gastroenterology*. 2011; 25(1): 3-18.
4. Ford AC, Quigley EM, Lacy BE, Lembo AJ, Saito YA, Schiller LR, et al. Efficacy of prebiotics, probiotics, and synbiotics in irritable bowel syndrome and chronic idiopathic constipation: systematic review and meta-analysis. *American Journal of Gastroenterology*. 2014; 109(10): 1547-1561.
5. Werth BL, Christopher SA. Potential risk factors for constipation in the community. *World Journal of Gastroenterology*. 2021; 27(21): 2795-2817.
6. Azimi M, Niayesh H, Raeiszadeh M, Khodabandeh-Shahraki S. Efficacy of the herbal formula of *Foeniculum vulgare* and *Rosa damascena* on elderly patients with functional constipation: A double-blind randomized controlled trial. *Journal of Integrative Medicine*. 2022; 20(3): 230-236.
7. Marshal JB. Chronic constipation in adults: How far should evaluation and treatment go? *Journal of Postgraduate Medicine*. 1990; 88(3): 49-63.
8. Rao SS. Constipation: Evaluation and treatment. *Gastroenterology Clinics of North America*. 2003; 32:659-683.
9. Johnson DA. Treating chronic constipation: How should we interpret the recommendations. *Clinical Drug Investigation*. 2006; 26: 547-557.
10. Eliasvandi P, Khodaie L, Mohammad Alizadeh CS, Mirghafourvand M. Effect of an herbal capsule on chronic constipation among menopausal women: A randomized controlled clinical trial. *Avicenna Journal of Phytomedicine*. 2019; 9(6): 517-529.
11. Tan N, Gwee KA, Tack J, Zhang M, Li Y, Chen M, Xiao Y. Herbal medicine in the treatment of functional gastrointestinal disorders: A systematic review with meta-analysis. *Journal of Gastroenterology and Hepatology*. 2020; 35(4): 544-556.
12. Malabadi RB, Kolkar KP, Acharya M, Chalannavar RK. Constipation-a major health disorder: role of herbal medicine treatment. *International Journal of Innovation Scientific Research and Review*. 2022; 4(4): 2634-2645.
13. Kimtata V, Gupta V, Singh L, Ahmed HA, Siddiqua Begum GA, Athar AM. The efficacy and safety of an ayurvedic petsaffa formulation in subjects with constipation: an open-label, non-randomized clinical study. *International Journal of Ayurveda and Pharma Research*. 2023; 11(3): 38-42.
14. Ashwin P, Paresh G, Jaya M, Kulkarni D. The effect of CONSTAC plus in the management of severe chronic constipation: a Pilot study. *International Journal of Ayurveda and Pharma Research*. 2016; 4: 15-18.
15. Peterson CT, Denniston K, Chopra D. Therapeutic Uses of Triphala in Ayurvedic Medicine. *Journal of Alternative and Complementary Medicine*. 2017; 23(8): 607-614.
16. Kumar A, Gupta AK, Siddiqui S, Siddiqui MH, Jnanesha AC, Lal RK. An assessment, prospects, and obstacles of industrially important medicinal crop Indian Senna (*Cassia angustifolia* Vahl.): A review. *Industrial Crops and Products*. 2022; 187: 115472.
17. Tarasiuk A, Mosińska P, Fichna J. Triphala: current applications and new perspectives on the treatment of functional gastrointestinal disorders. *Chinese Medicine*. 2018; 13: 39.
18. Badgujar SB, Patel VV, Bandivdekar AH. *Foeniculum vulgare* Mill: a review of its botany, phytochemistry, pharmacology, contemporary

- application, and toxicology. BioMed Research International. 2014; 2014: 842674.
19. Damanhoury ZA, Ahmad A. A Review on Therapeutic Potential of Piper nigrum L. (Black Pepper): The King of Spices. Medicinal & Aromatic Plants 2014; 3(3): 161.
20. Ranjan B, Manmohan S, Singh SR, Singh RB, Kumar TA. Medicinal uses of Trachyspermum ammi: a review. Pharmacologyonline. 2011; 2: 477-485.
21. Kaur R, Kaur H, Dhindsa AS. Glycyrrhiza glabra: a phytopharmacological review. International Journal of Pharmaceutical Sciences and Research. 2013; 4(7): 2470-2477.

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