A Non-Randomized Single-Blind Clinical Study to Assess the Utility of *Strychnos Nux-Vomica* L. in the Management of Patients with Bowel Disorders

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Abstract: Purpose: Bowel disorders encompass a cluster of gastrointestinal conditions marked by persistent symptoms like abdominal discomfort, bloating, and changes in bowel patterns. They represent a significant public health concern necessitating increased awareness, diagnosis, and treatment efforts. This research sought to explore the potential of Nux Vomica as a treatment option for individuals suffering from bowel disorders, with the goal of reducing the frequency and intensity of their symptoms to provide optimal relief.

Materials and Methods: This research involved 30 individuals diagnosed with bowel disorders according to the Rome IV diagnostic criteria. They received treatment with the homoeopathic remedy Nux Vomica, selected based on a comprehensive assessment of their symptoms. To assess the treatment's effectiveness, the study monitored a reduction in the number of symptoms and quantified improvements using the Gastrointestinal Quality of Life Index questionnaire.

Results: Statistical analysis was carried out using the Student paired "t" test. Following the therapy, a significant reduction in the number of symptoms was observed, and no adverse effects were documented. On average, the GIQLI score exhibited an improvement of -38.23 ± 13.68 points (t-statistic value: 15.31), while the average decrease in the number of symptoms amounted to 4.03 ± 1.47 points (t-statistic value: 14.99). The resulting "p" value was 0.000, indicating an exceptionally low level of significance upon completion of the study.

Conclusion: The homoeopathic remedy Nux Vomica effectively addresses bowel disorders. These results open up new avenues for future research exploring the treatment of bowel disorders with homeopathic medicine.

Keywords: Bowel disorders, Rome IV Criteria, nux vomica, non-randomized study, Homoeopathy.

1. INTRODUCTION

Bowel Disorders

Bowel disorders are characterized by symptoms originating in the middle or lower gastrointestinal tract (GI). [1] These symptoms typically involve irregularities in bowel function, such as constipation, diarrhea, or a combination of both, along with primary indicators like abdominal pain, bloating, and distention. [2] Previously referred to as functional bowel disorders (FBD), the Rome Foundation categorizes them as a subset of functional gastrointestinal disorders (FGIDs). [3]

The Anna-Karenina-Principle, inspired by the opening line of Leo Tolstoy's novel "Anna Karenina" ("Happy families are all alike; every unhappy family is unhappy in its own way"), provides an apt analogy for understanding functional bowel disorders (FBD). While originally applied in microbiological research, in the context of FBD, it suggests that the intricate process of digestion remains in a state of balance (referred to as health) only when all its components function harmoniously. Conversely, any disruption in just one of these components among many can lead to the progression

of disease. In essence, there is only one path to health, but numerous paths to developing a disease, particularly within the realm of FBD. [4]

In 1977, George Engel's groundbreaking work marked a turning point in promoting a unified perspective on health and disease. He proposed that illness results from the interactions of biological, psychological, and social subsystems across multiple levels. The specific nature of an illness is determined by the interplay of these interacting subsystems. When considering bowel disorders, it becomes evident that they can be attributed to disturbances in various factors, including biological elements (such as genetic predisposition and past gastrointestinal infections), psychological factors (including parental behavior, life stressors, personal stress, and personality traits), and social factors. [3,5]

The clinician should be alerted to the presence of potential organic gastrointestinal diseases when encountering red-flag symptoms: [6,7]

- Individuals over the age of 50 experiencing symptoms for the first time
- Presence of blood in the stools
- Unintentional weight loss
- A family history of colon cancer
- Occurrence of symptoms during the night

Bowel disorders stand apart from other gastrointestinal disorders due to distinct characteristics [2]:

- Chronicity, with symptoms persisting for six months or more at the time of presentation
- Current activity, indicating symptoms that have emerged within the past three months
- Frequency, with symptoms occurring on at least one day per week on average
- Lack of apparent anatomic or physiologic abnormalities detectable during routine diagnostic examinations

Bowel disorders result from dysregulation of the gut-brain axis, leading to susceptibility, provocation, and chronicity. This disruption in bidirectional neuronal communication can be triggered by centrally initiated risk factors (e.g., adverse early-life events, anxiety, depression, chronic or acute psychological stress) and peripheral signals (e.g., intestinal infection, dysbiosis, changes in luminal bile acids, short-chain fatty acids, serotonin [5-HT] release). [4,8–12] These disorders involve complex abnormalities in gut motility, mucosal and immune function, intestinal microbiota diversity, central nervous system processing, and visceral hypersensitivity. [6,13] They are generally considered medically non-harmful as they do not cause organic damage or reduce life expectancy but can interfere with daily activities to varying degrees. Patients may require regular medical leave or abstain from enjoyable activities like dining out or going on vacation. Inappropriately prescribed diagnostic tests, unnecessary treatments, and medical leave contribute to increased societal costs.

Bowel disorders are classified based on the Rome IV diagnostic criteria, encompassing irritable bowel syndrome, functional constipation, functional diarrhea, functional abdominal bloating/distension, unspecified functional bowel disorders, and opioid-induced constipation. (Figure 1) [3,7,14]

Figure 1:

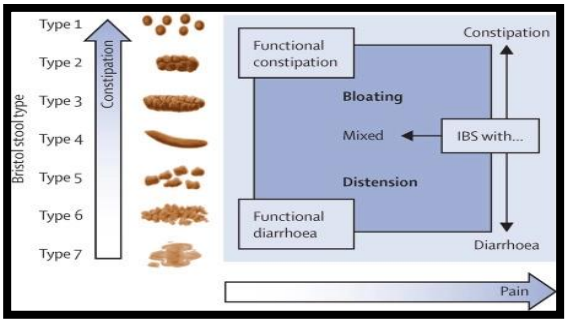

Figure 1: This figure illustrates the interconnected nature of bowel disorders and the Briston stool form scale. [14]

Additionally, bowel disorders may present with extra-gastrointestinal symptoms. Many patients experience symptoms unrelated to the gastrointestinal tract, including fatigue, insomnia, pain in other body parts (e.g., headaches and backaches), chronic pelvic pain, temporomandibular joint dysfunction, non-ulcer dyspepsia, dysmenorrhea, and symptoms affecting other organ systems (urogenital, cardiovascular). [5,15,16]

Treatment options for bowel disorders encompass dietary adjustments, pharmacotherapy, psychotherapeutic approaches, and complementary medicine. [5,11,16–18]

Dr. Hahnemann's explanation in Aphorism 72 of his Organon of Medicine suggests that chronic diseases stem from a healthy state disrupted by chronic miasms. These miasms have subtle beginnings, progress gradually, and persist within the afflicted individual until they pass away. The vital principle, responsible for defending and maintaining health, weakens as the illness advances. Administering the appropriate medication may stimulate the vital principle, aiding in ending the ailment and promoting healing. [19]

According to the principles of Homoeopathic Repertory, when symptoms of bowel disorders were cross-referenced with various repertories, Nux Vomica emerged as one of several medicines (including Sulphur, Nat-mur, Kali-c, Lycopodium, Phosphorus, and others) that covered these symptoms. (Figure 2) [20]

Figure 2:

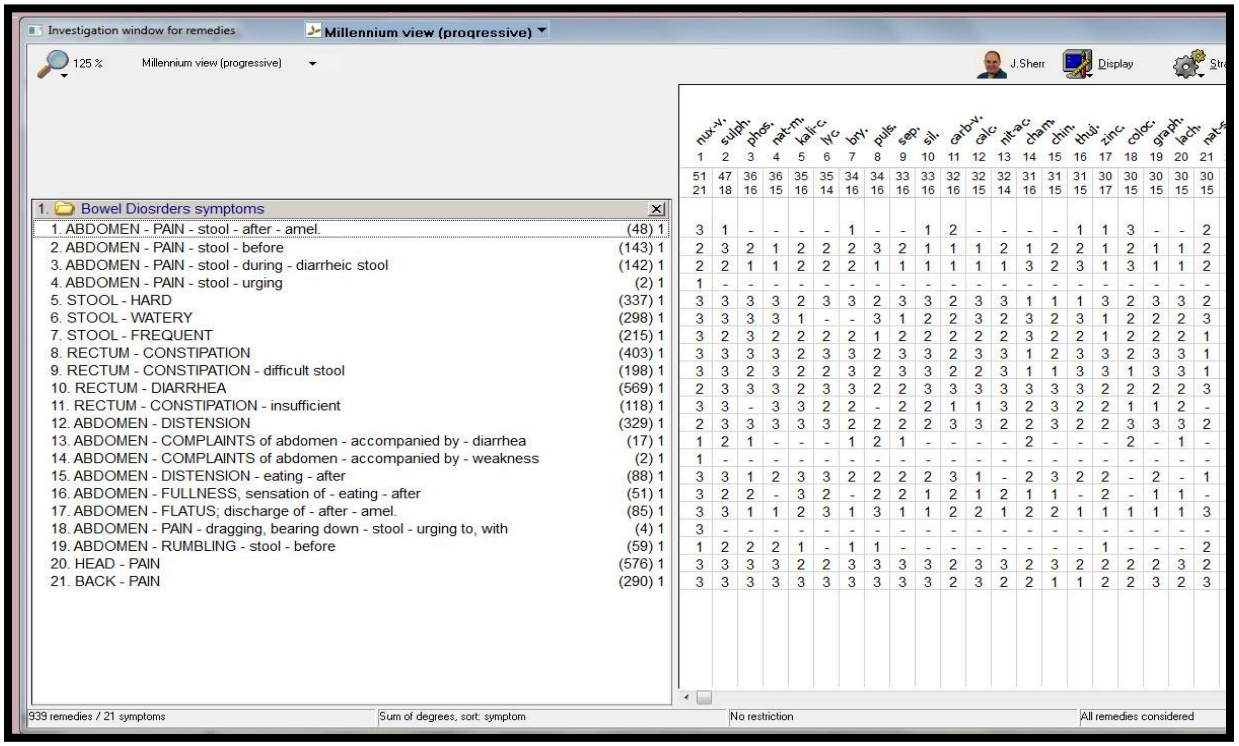

Figure 2: Repertorial totality of symptoms of bowel disorders using synthesis repertory in RADAR software.

***Strychnos Nux-Vomica* L.**

The term 'Nux Vomica' originates from the Latin words 'Nux,' meaning nut, and 'Vemere,' signifying vomiting. [21] Dr. M. L. Tyler advocated that "Every household should have a small homoeopathic medicine chest for common ailments, and every homoeopathic medicine chest should have Nux." [22] In the 18th century, Hahnemann's provings, published in 1805, expanded the medicinal use of Nux vomica, with assistance from Flaeming, Friedrich, and Wahle. [23]

Morphology: *Strychnos nux-vomica* is a deciduous tree native to Southeast Asia and India. Natural populations in the Eastern Ghats region exhibit profuse flowering from February to April, with the blossoms opening in the evening. It is a compact evergreen tree or shrub, reaching heights of 5-25m. [24,25]

Active Principles: Phytochemically, Nux vomica contains 2.6%-3% total alkaloids, with strychnine ($C_{21}H_{22}O_2N_2$) constituting 1.25%-2.5% and brucine ($C_{23}H_{26}N_2O_4$) accounting for 1.5%-1.7%. Triturations are prepared from the seeds. [24,26,27] Strychnine, a lethal indole-type alkaloid, was initially discovered in Saint Ignatius Bean in 1818 by French chemists Joseph-Bienaime Caenoiu and Pierre-Joseph Pelletier. [28] Brucine, a mild alkaline indole alkaloid, was first isolated from the bark of the *Strychnos nux-vomica* tree in 1819 by Pelletier and Caventou. [29]

Nux Vomica is considered the premier Polychrest remedy, with "Spasm" and "exaggerated sensitiveness" as its primary characteristics. [30,31] Its sphere of action includes the gastrointestinal tract, addressing symptoms of bowel disorders. Individuals with Nux vomica traits often exhibit a lean physique, quick movements, anxiety, hyperactivity, and irritability [31] Their anxieties, worries, and fears primarily revolve around work and business. [32] Factors such as mental stress, a sedentary lifestyle, extensive studying, and long office hours contribute to these traits. Nux vomica patients typically crave rich and spicy foods and may turn to alcohol and other indulgences to cope with their demanding schedules. [33]

Some medications used to treat bowel disorders may have various side effects. For example, bile acid binders can lead to bloating, loperamide may cause chest discomfort, and psyllium might result in breathing difficulties and skin issues. Consequently, studies have shown an increase in the use of complementary and alternative medicines (CAM).

In 2000, G Tougas explored how neural networks, immune systems, and endocrine systems communicate along the brain-gut axis. The autonomic nervous system's two branches, which integrate with visceral sensory pathways, play a critical role in regulating gut function. This system also mediates the visceral response to central influences such as psychological stress and other central factors. [8]

Dr. Gaurav Gupta et al. (2022) describe Irritable Bowel Syndrome (IBS) as a condition characterized by recurrent stomach pain, abnormal bowel patterns, and a negative impact on the quality of life, affecting approximately 20% of the global population. Treatment involves dietary modifications, psychological counseling, exercise, and more. IBS places a burden on both patients and healthcare systems, making homoeopathy a comprehensive approach that addresses not only the illness but also the patient's overall well-being. [34]

***Dr. Subhranshu Prabha Mishra et al. (2022*)** explain that the prevalence of IBS is highest in middle-aged individuals, especially those with primarily sedentary occupations. IBS-D is more prevalent than IBS-C and IBS-M. A significant improvement in 25 out of 30 cases was observed, with the severity of IBS shifting from severe to moderate or mild, indicating the effectiveness of the homeopathic similimum approach based on the Kentian evaluation technique. [35]

To effectively treat bowel disorders, more efficient treatment methods are needed, and homoeopathy can offer a safer, more cost-effective approach. Nux Vomica helps alleviate bothersome symptoms and prevent the emergence of new ones.

2. MATERIALS AND METHODS

This clinical investigation, conducted within the outpatient department of BVDTUHMC, formed a part of a post-graduate research project spanning from 2022 to 2023. It encompassed a well-documented collection of case histories along with their subsequent follow-ups involving 30 patients experiencing bowel disorders, comprising both males and females aged between 25 and 50 years. The patient assignment was non-randomized, and a single-blind masking approach was employed. Patients meeting the typical diagnostic criteria for bowel disorders, characterized by symptoms or signs such as abdominal pain, bloating, distention, and irregularities in bowel habits (including constipation, diarrhea, or mixed patterns), were eligible for inclusion based on the ROME IV diagnostic criteria. Nux Vomica was exclusively administered for cases displaying mild to moderate severity, as determined by the FBDSI score and symptom similarity.

To gauge the extent of improvement, the GIQLI score and the number of symptoms were recorded both before and after the intervention. This study comprehensively presents the outcomes of statistical significance tests and data analysis performed on meticulously collected data.

2.1. Inclusion Criteria

Patients meeting the ROME IV diagnostic criteria, irrespective of gender and within the age range of 25 to 50 years, were considered eligible. Patients with mild and moderate FBDSI scores were considered. Additionally, inclusion encompassed patients devoid of any concurrent systemic diseases and those who provided written consent.

2.2. Exclusion Criteria

Exclusion criteria comprised individuals not meeting the ROME IV diagnostic criteria, patients with severe FBDSI scores, patients grappling with severe complications arising from gastrointestinal disorders, pregnant and lactating women, immunocompromised individuals, patients with psychiatric diagnoses, and those who did not provide written consent.

2.3. Selection of the Remedy and Potency

The process of case-taking and subsequent follow-ups adhered to the principles of homoeopathy, with the selection of Nux Vomica based on symptom similarity. Potency selection followed the guidelines outlined in the 6th Edition of the Organon of Medicine and was approached in a rational manner.

2.4. Repetition Schedule

The frequency of medication repetition was contingent upon the presentation of symptoms. For cases involving bowel disorders, each patient was under observation for approximately three months. A meticulous record was maintained, tracking symptomatic and clinical changes, as well as prognosis. The follow-up schedule varied from one patient to another as per the need

2.5. Storage of Medications

Medications were stored in compliance with HPI guidelines and were maintained at the appropriate temperature within the pharmacy of Bharati Vidyapeeth Homoeopathic Hospital in Katraj, Pune. Batch and log numbers were meticulously documented. In instances where medication was not required, sugar of milk globules served as a placebo.

2.6. Route of Administration

All patients were administered the medication in the form of 30-sized globules. These globules were placed on the tongue orally, half an hour prior to their evening meal, and no water intake was allowed for a minimum of 15 to 20 minutes.

2.7. Assessment Criteria

Assessment of outcomes took place after completing five follow-up sessions. The evaluation was based on a comparison of the total number of symptoms present before and after the therapeutic intervention. Additionally, the GIQLI questionnaire was employed to measure the patient's quality of life, with scores assessed both before and upon the study's conclusion.

2.8. General Management

Several factors were taken into account for general patient management, including the administration of homoeopathic medication, necessary dietary adjustments, and the implementation of stress management techniques as needed.

3. RESULTS

A total of 30 patients (n=30) were selected from the age range of 25 to 50 years. Notably, the age group of 25 to 35 years exhibited the highest prevalence of patients, constituting 63.33%, while those above 45 years accounted for the lowest proportion at 6.66%. Among the participants, 17 were female (56.67%), and 13 were male (43.33%). Their occupational distribution revealed that 33% were employed, 27% were students, 20% were housewives, and 20% were businessmen. Concerning the type of bowel disorders experienced, 50% of patients had irritable bowel syndrome, 23% had functional constipation, 20% had functional diarrhea, and the remaining 7% were dealing with functional bloating. The assessment of FBDSI scores indicated that 47% of patients had moderate scores, while 53% exhibited mild FBDSI scores. (Table 1)

Table1: Distribution of the patients according to demographic variables (n=30)

• Demographic variable		• *f*	• *%*
• Age	• 25-35 years	• 19	• 63.33%
	• 35-45 years	• 9	• 30.00%
	• 45 years & above	• 2	• 6.66%
• Gender	• Male	• 13	• 43.33%
	• Female	• 17	• 56.67%
• Occupation	• Job	• 10	• 33.33%
	• Student	• 8	• 26.67%
	• Business	• 6	• 20.00%
	• Housewife	• 6	• 20.00%
• Type of bowel disorder	• Irritable Bowel Syndrome	• 15	• 50.00%
	• Functional Constipation	• 7	• 23.33%
	• Functional Diarrhea	• 6	• 20.00%
	• Functional Abdominal Bloating/ Distension	• 2	• 6.67%
• FBDSI Score	• Mild (<36)	• 16	• 53.33%
	• Moderate (37-110)	• 14	• 46.67%

Regarding symptomatology, prior to the intervention, patients with bowel disorders presented an average of 6.1 ± 1.6 symptoms (mean ± SD). After treatment, this number significantly reduced to 2.1 ± 1.4, resulting in a mean difference of 4.03 ± 1.47. The effectiveness of the treatment was evaluated using paired t-tests, yielding a highly significant p-value of 0.000, with a test statistic value of 14.99. This outcome supports the acceptance of H_1 and the rejection of H_0, indicating a substantial difference in the average number of symptoms before and after the homoeopathic treatment for bowel disorders using Nux Vomica (table 2).

Table 2: Paired t-test and Descriptive statistics of the Number of Symptoms before and after the intervention by Homoeopathic medicine Nux Vomica

Number of Symptoms	N	Mean±SD	Min	Max	T Statistic Value	P-Value	Decision
Before Treatment	30	6.1 ± 1.6	3	9	14.99	0.000**	Reject H_0
After Treatment	30	2.1 ± 1.4	0	5			
Mean difference		4.03 ± 1.47			The difference is highly significant		
95% CI for the mean difference		(3.48, 4.58)					

In the context of the Gastrointestinal Quality of Life Index (GIQLI) scores before and after treatment with homoeopathic medicine Nux Vomica, the pre-treatment score was 87.8 ± 16.9 (mean ± SD), which increased to 126.0 ± 7.2 post-treatment. A paired t-test assessed the treatment's efficacy, resulting in a test statistic value of -15.31 and an exceedingly low p-value of 0.000. This compelling evidence supports the rejection of H_0 and the acceptance of H_1, affirming that homoeopathic medicine Nux Vomica positively influences the treatment of bowel disorders by enhancing patients' gastrointestinal quality of life (Table 3).

Table 3: Paired t-test and Descriptive statistics of the Gastrointestinal quality of life Index (GIQLI) Score before and after the intervention.

GIQLI Score	N	Mean±SD	Min	Max	T Statistic Value	P-Value	Decision
Before Treatment	30	87.8±16.9	36	115	-15.31	0.000**	Reject H_0
After Treatment	30	126.0±7.2	109	140			
Mean difference		-38.23 ± 13.68			The difference is highly significant		
95% CI for the mean difference		(-43.34, -33.12)					

The distribution of patient (%) symptom improvement, categorized as marked (>75%), moderate (50–75%), and mild (<50%), following homoeopathic treatment for specific bowel disorders is depicted in (Figure 3). Notably, patients with functional abdominal bloating exhibited moderate improvement in 50% of cases and marked improvement in the remaining 50%. In the case of functional diarrhea, 50% of patients experienced mild improvement, while the other 50% showed marked improvement. For patients with functional constipation, improvement was distributed as follows: mild in 14.29%, moderate in 42.86%, and marked in another 42.86%. In the category of irritable bowel syndrome patients, 20% experienced mild improvement, 20% moderate improvement, and 60% marked improvement. When considering all patients (n=30), (Figure 4) illustrates that 13% observed minor improvement in their bowel disorders, 33% showed a moderate degree of improvement, and 54% achieved a remarkable level of improvement.

Figure 3:

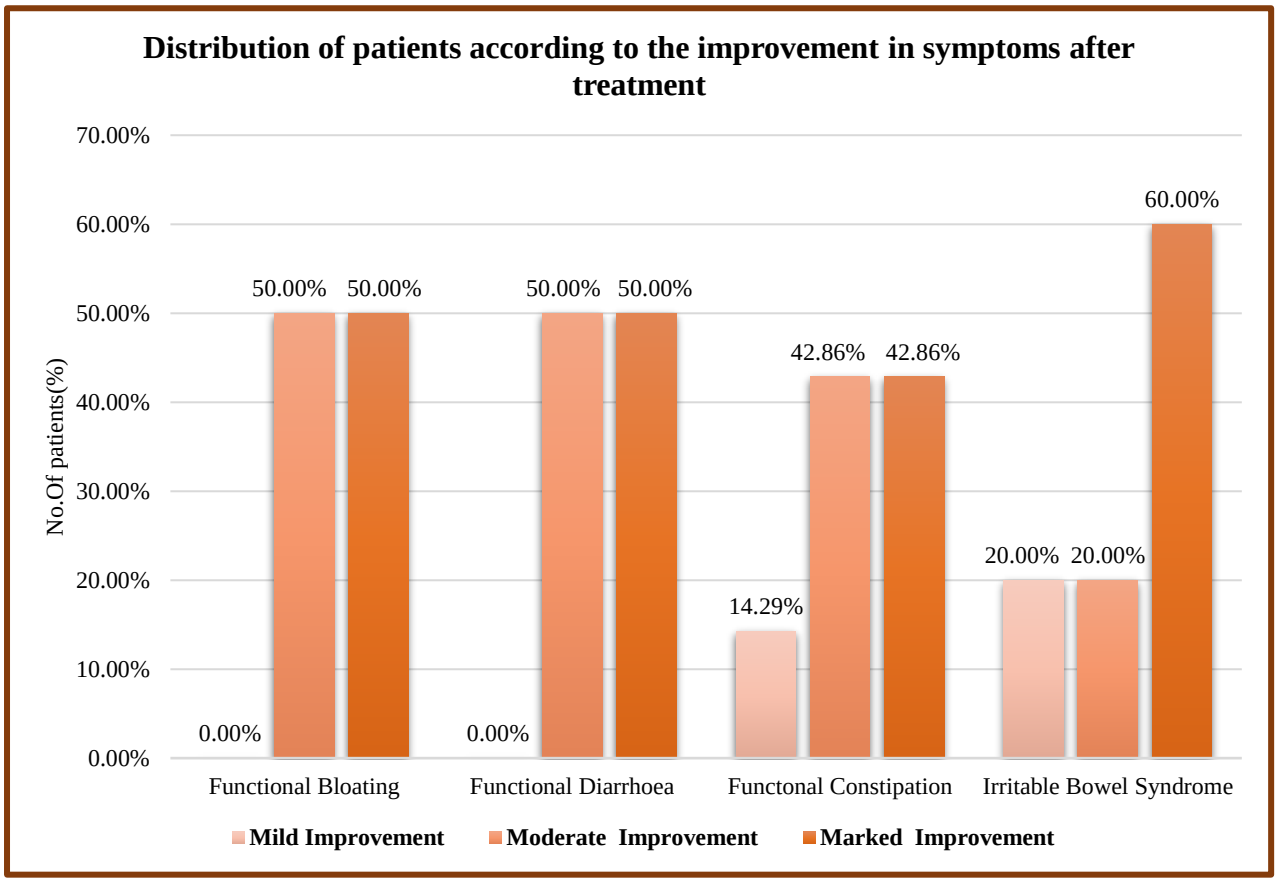

Figure 3: Bar diagram representing the distribution of patients according to the improvement in symptoms after treatment of the disease diagnosed by Nux Vomica.

Figure 4:

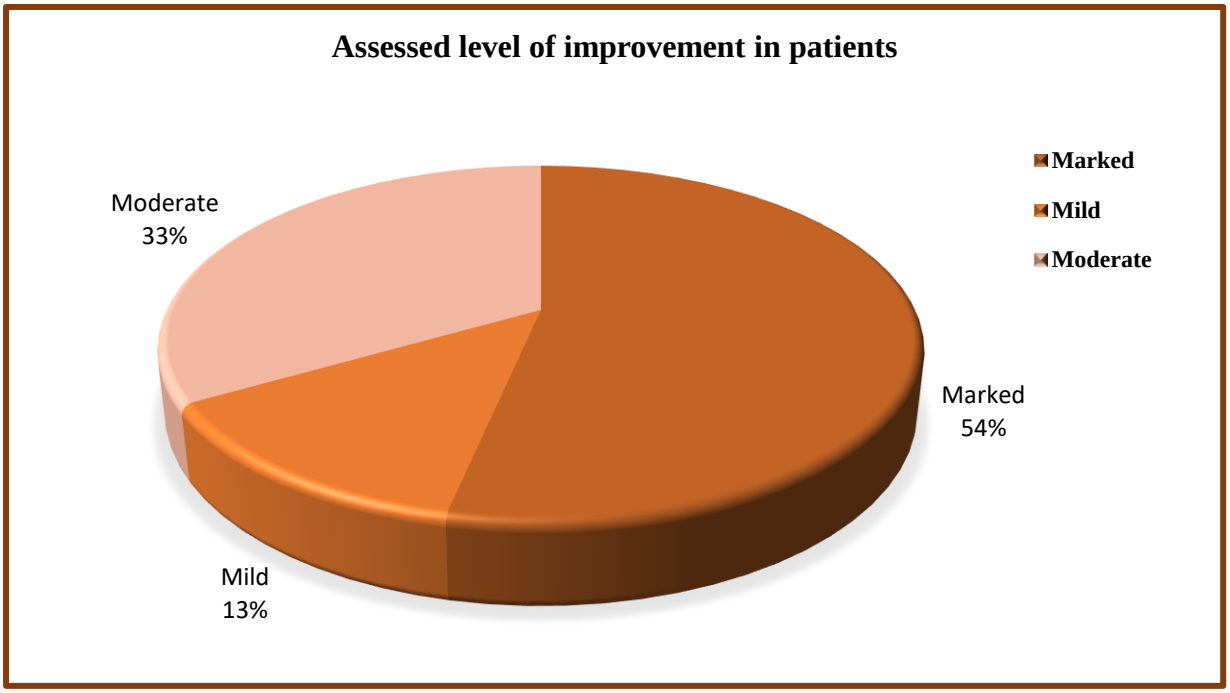

Figure 4: Pie diagram representing the distribution of patients according to the Assessed level of improvement in patients with bowel disorders by homoeopathic medicine Nux Vomica

4. DISCUSSION

Bowel disorders represent a prevalent global health issue that affects individuals across diverse age groups, genders, and ethnic backgrounds. While prevalence rates may vary by region, the far-reaching consequences of bowel disorders on both quality of life and healthcare utilization remain substantial on a global scale. These disorders are associated with elevated healthcare expenditures, increased rates of work absenteeism, and reduced productivity. Furthermore, the psychological toll they exact on individuals is significant, often leading to conditions such as anxiety, depression, and social isolation. It is evident that bowel disorders constitute a substantial public health concern necessitating heightened awareness, improved diagnostics, and enhanced treatment strategies.

The treatment and management of bowel disorders exhibit regional variation but generally encompass a multidisciplinary approach primarily centered on symptom management. This approach commonly involves dietary and lifestyle adjustments, medications aimed at alleviating symptoms such as pain and bloating, pharmacological interventions, and psychological therapies. In some regions, complementary therapies like acupuncture and herbal remedies are also employed. However, there is a pressing need for additional evidence-based research to bolster the therapeutic efficacy of homoeopathy in addressing bowel disorders.

The principal objective of this study was to investigate the potential impact of the homoeopathic remedy Nux Vomica on the treatment of patients with bowel disorders. A cohort of thirty patients of varying genders, aged between 25 and 50 years, was recruited from the outpatient department for this inquiry. These patients were diagnosed with different bowel disorders in accordance with the Rome IV Diagnostic Criteria established by the Rome Foundation in 2016. The specific breakdown of diagnoses included 15 cases of irritable bowel syndrome, 7 cases of functional constipation, 6 cases of functional diarrhea, and 2 cases of Functional Abdominal Bloating/Distension. The choice of prescription was grounded in symptom similarities, leading to the administration of Nux Vomica to all thirty participants over a span of three months, with regular follow-ups occurring every 7-14 days. To ensure safety and mitigate potential complications, only mild and moderate cases, as determined by the FBDSI score, were included in the study. Improvement was assessed by analyzing patients' symptoms before and after the intervention, and changes in quality of life were tracked through GIQLI scores. The patients willingly agreed to participate following a comprehensive explanation of the study.

Each patient received Nux Vomica alongside dietary and stress management guidance. Among the thirty patients, 16 exhibited marked improvement, 10 displayed moderate improvement, and the remaining 4 demonstrated mild improvement. Given the limited sample size, statistical analysis was conducted utilizing the paired Student's t-test. Results indicated that patients across all diagnoses showed overall improvement, leading to the rejection of the null hypothesis (H_0) and the acceptance of the alternative hypothesis (H_1). This suggests that the homoeopathic remedy Nux Vomica is effective in treating patients with bowel disorders. Remarkably, the GIQLI score significantly improved following treatment, accompanied by reductions in the number, severity, and frequency of symptoms. Throughout the trial period, no individuals required emergency medical care, and no adverse treatment effects were observed.

5. CONCLUSION

Based on the evidence presented, it can be reasonably concluded that *Strychnos Nux Vomica*, a homoeopathic remedy, demonstrates efficacy in the treatment of individuals grappling with bowel disorders. The administration of Nux Vomica appears to mitigate the severity and frequency of symptoms associated with bowel disorders. By exerting its influence on the gut-brain axis, Nux Vomica contributes to regulating gastrointestinal system function, thereby aiding in managing conditions such as bloating, constipation, diarrhea, and abdominal pain. These findings suggest that the prescription of Nux Vomica guided by symptom similarity holds the potential to improve patient well-being, reduce symptom intensity and frequency, and elevate GIQLI scores.

Nevertheless, it is important to acknowledge the limitations of this study, including the relatively small sample size and the relatively brief duration of the investigation. Future research endeavors should incorporate larger sample sizes and extended study durations to bolster the robustness of these findings. Additional evidence-based studies are imperative to further validate the applicability of homoeopathic treatment for bowel disorders, offering a more comprehensive and efficacious approach to patient care.

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STATEMENT OF CONFLICT OF INTEREST

There is no conflict of interest, according to the authors.

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