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Effectiveness of Individualized Homoeopathic Treatment in Patients with Persistent Gastrointestinal Symptoms After Cholecystectomy: An Observational Clinical Study

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Abstract

Background: Post-cholecystectomy syndrome (PCS) represents a significant clinical challenge, with many patients experiencing persistent gastrointestinal symptoms despite surgical intervention. Evidence regarding homoeopathic management of such conditions remains limited. **Objective:** To evaluate the effectiveness of individualized homoeopathic treatment in managing persistent gastrointestinal symptoms following cholecystectomy using validated outcome measures. **Methods:** An observational, open-label, non-randomized clinical study was conducted at the National Institute of Homoeopathy, Kolkata. Among 62 screened patients, 42 met eligibility criteria, and 30 completed the 6-month follow-up. Individualized homoeopathic prescriptions were administered based on detailed case-taking and repertorization. Outcomes were assessed using the Numerical Rating Scale (NRS) for abdominal pain and PROMIS-GI symptom scales. Statistical analysis was performed using paired t-test. **Results:** Significant reductions were observed in both PROMIS-GI scores (mean: 146.43 to 67.63) and NRS pain scores (mean: 4.8 to 1.3) after 6 months ($p < 0.05$). Large effect sizes (Cohen's $d > 3$) indicate substantial clinical improvement. **Conclusion:** Individualized homoeopathic treatment may be effective in managing persistent gastrointestinal symptoms post-cholecystectomy. However, controlled trials with larger sample sizes are necessary to validate these findings.

Keywords: Post-cholecystectomy syndrome, Homoeopathy, PROMIS-GI, NRS, Observational study, Gastrointestinal symptoms.

Introduction:

Gallbladder and biliary tract diseases are a significant health burden on the

world and the incidence is ever rising in the past decades(1,2). Epidemiological research shows that approximately 6 percent of the world population is infected with gallstone disease with women and the old forming a higher population. In India, the prevalence is between 0.5-10 percent, in case of regional, dietary and genetic differences. Cholecystectomy and especially laparoscopic cholecystectomy have become the gold standard form of treatment of the symptomatic gallstone disease because of its least invasive nature and positive postoperative results. Although it has become common, a large number of patients still report persistent or recurrent gastrointestinal symptoms after surgery (3).

In this case, the presence of biliary colic or the appearance of new gastrointestinal symptoms following the removal of the gallbladder is known as the existence of a well-established clinical phenomenon, post-cholecystectomy syndrome (PCS). Such symptoms are abdominal pain, bloating, dyspepsia, nausea, diarrhea, and altered bowel habits and may last months or even years (4). It has been reported that up to a third of patients develop such symptoms after surgery, which is a significant burden to the quality of life and raises healthcare use. Multifactorial etiology of PCS comprises both biliary and non-biliary etiology, such as retained stones, dysfunction of the sphincter of Oddi, a change in bile flow, dysbiosis in gut microbiota, and gastrointestinal motility (5).

Pathophysiologically, removal of the gallbladder interferes with the physiological functions of the gallbladder as a bile storage site and a controlled discharge site. This causes the flow of bile into the intestine to be constant, which causes the change in enterohepatic circulation, bile acid metabolism, and intestinal motility. The changes can be associated with such symptoms like bile reflux gastritis, diarrhea, and functional gastrointestinal disorders (6). Traditional approaches to the treatment of PCS consist mostly of symptomatic therapies and, in most cases, include drug treatment like antispasmodics, bile acid sequestrants, proton pump inhibitors and dietary changes. Nonetheless, such methods might not be sufficient to respond to individualized and multifactorial character of the condition. The presence of unresolved symptoms in spite of repeated visits to the medical

institution in most cases proves the necessity to adopt alternative or complementary therapeutic approaches (7).

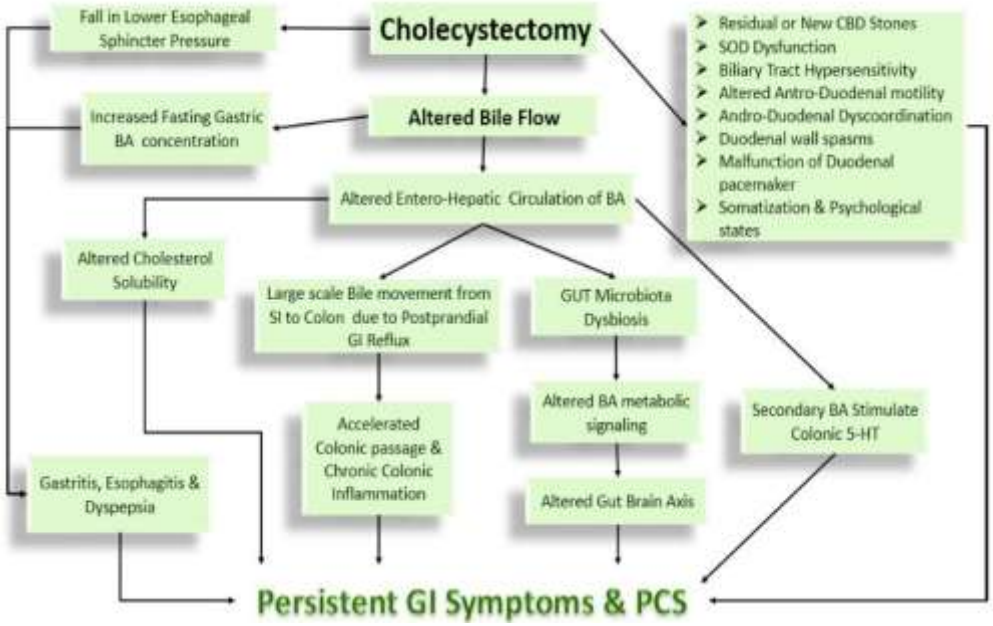

Figure 1. Schematic overview of mechanisms underlying persistent gastrointestinal symptoms and post-cholecystectomy syndrome (PCS), highlighting altered bile acid flow, gut microbiota dysbiosis, disrupted signaling pathways, and associated motility and functional disturbances.

Using the principles of individualization and holistic evaluation of patients, homoeopathy provides a unique treatment model in the treatment of chronic and functional diseases. Trying to take into account the totality of symptoms (physical, mental, and constitutional) homoeopathic treatment does not suppress symptoms but tries to restore the balance in the system. In specific disease states such as PCS where structural pathology can be insignificant or not, personalised homoeopathic treatment can offer a plausible method of symptom management. The vulnerability model of disease used in homoeopathy also contributes to its use in dealing with the unique responses of the patient to etiological determinants.

Although the theoretical relevance of homoeopathic treatment in patients who have undergone cholecystectomy is relevant, a dearth of clinical evidence to assess its efficacy is present. The literature available is mostly on

conventional management and little has been done on integrative/individualized therapeutic modalities. Thus, there is the obvious necessity of regular clinical research with evaluation of the role of homoeopathy in this respect by methods of valid outcome measures (8).

The current study was conducted in this background as an observational clinical study to determine the efficacy of personalized homoeopathic therapy in patients with chronic gastrointestinal symptoms after cholecystectomy. The research consists of the use of standardized and validated methods, i.e., Numerical Rating Scale (NRS) to evaluate the abdominal pain and the PROMIS Gastrointestinal Symptom Scale, which will be used to objectively measure the results of the treatment within six-month follow-up (9).

Materials and Methods:

Study Design and Setting:

This study was designed as an observational, open-label, non-randomized clinical investigation conducted at the National Institute of Homoeopathy, Kolkata, West Bengal. The study aimed to evaluate the effectiveness of individualized homoeopathic treatment in patients presenting with persistent gastrointestinal symptoms following cholecystectomy. Patients attending the outpatient department (OPD) were screened and recruited based on predefined eligibility criteria.

Study Population and Sample Size:

A total of 62 patients were initially screened for eligibility, of whom 42 met the inclusion and exclusion criteria and were enrolled in the study. During the follow-up period, 12 participants were lost to follow-up, resulting in a final sample size of 30 patients who completed the six-month study duration and were included in the statistical analysis. The study population included individuals aged between 18 and 60 years, irrespective of gender, religion, or socioeconomic status.

Inclusion and Exclusion Criteria:

Patients were included if they had a history of cholecystectomy and presented with persistent gastrointestinal symptoms such as abdominal pain, bloating, dyspepsia, or altered bowel habits. Only those willing to participate and provide informed consent were enrolled. Patients were excluded if they had undergone cholecystectomy within the previous

one year, had congenital hepatobiliary anomalies, were undergoing radiation therapy, had serious systemic illnesses or life-threatening infections, or were already receiving homoeopathic treatment for chronic conditions.

Intervention and Treatment Protocol

All enrolled patients received individualized homoeopathic treatment based on classical homoeopathic principles as outlined in the Organon of Medicine. Detailed case-taking was performed for each patient, including physical, mental, and general symptoms. Repertorization was carried out using homoeopathic software, followed by remedy selection based on Materia Medica correlation. The potency, dosage, and repetition of medicines were individualized according to patient response and susceptibility. In addition to homoeopathic treatment, patients were advised general lifestyle modifications, including a low-fat diet, increased dietary fiber intake, small frequent meals, and regular physical activity.

Data Collection and Outcome Measures:

Baseline data were collected using structured case-recording proformas, clinical examination, and relevant investigations where necessary. The primary outcome measures included the Numerical Rating Scale (NRS) for abdominal pain and the Patient-Reported Outcomes Measurement Information System Gastrointestinal (PROMIS-GI) symptom scale. These validated tools were used to assess symptom severity at baseline and after six months of treatment. Patients were followed up at monthly intervals or as clinically required to monitor symptom progression and treatment response.

Statistical Analysis

Data were compiled and analyzed using Microsoft Excel 2021 and SPSS version 27.0. Descriptive statistics were expressed as mean, standard deviation, frequencies, and percentages. Inferential analysis was performed using paired t-test to compare baseline and post-treatment scores for both NRS and PROMIS-GI scales. A p-value of less than 0.05 was considered statistically significant. Effect size measures, including Cohen's d and Hedges' g, were also calculated to determine the magnitude of treatment effect.

Ethical Considerations

The study protocol was reviewed and approved by the Institutional Ethical

Committee. As this was a non-invasive observational study, no experimental interventions were performed beyond standard homoeopathic care. Informed consent was obtained from all participants prior to enrolment. Patient confidentiality was strictly maintained throughout the study. Any adverse events or lack of response to treatment were managed appropriately, and patients requiring conventional medical intervention were referred accordingly.

Results:

A total of 62 patients were initially screened for eligibility, of whom 42 were enrolled based on the predefined inclusion and exclusion criteria. During the six-month follow-up period, 12 participants were lost to follow-up, resulting in a final sample size of 30 patients who completed the study and were included in the statistical analysis. The study population had a mean age of 41 ± 8 years, with the majority of participants belonging to the 29–39 years age group (47%), followed by 40–50 years (30%). A marked female predominance was observed (87%), with a female-to-male ratio of approximately 6.7:1. Most participants were from rural (43%) and semi-urban (40%) areas, and a significant proportion (60%) belonged to lower socioeconomic strata.

Clinical profiling revealed that 56% of patients had normal body mass index, while 37% were overweight and 7% were obese. Comorbid conditions included anemia (66%), hypertension (20%), and type 2 diabetes mellitus (14%). The majority of patients (70%) had undergone cholecystectomy within the past 1–5 years, with laparoscopic surgery being the predominant method (86%). At baseline, the most frequently reported symptom was gas bloating (28%), followed by abdominal pain (18%), heartburn (15%), constipation (14%), and nausea/vomiting (9%), whereas bowel incontinence and dysphagia were least reported.

Table 1: Comparison of PROMIS-GI Scores at Baseline and 6th Month

Time Point	Mean Score	Standard Deviation
Baseline	146.43	26.82
6th Month	67.63	16.24

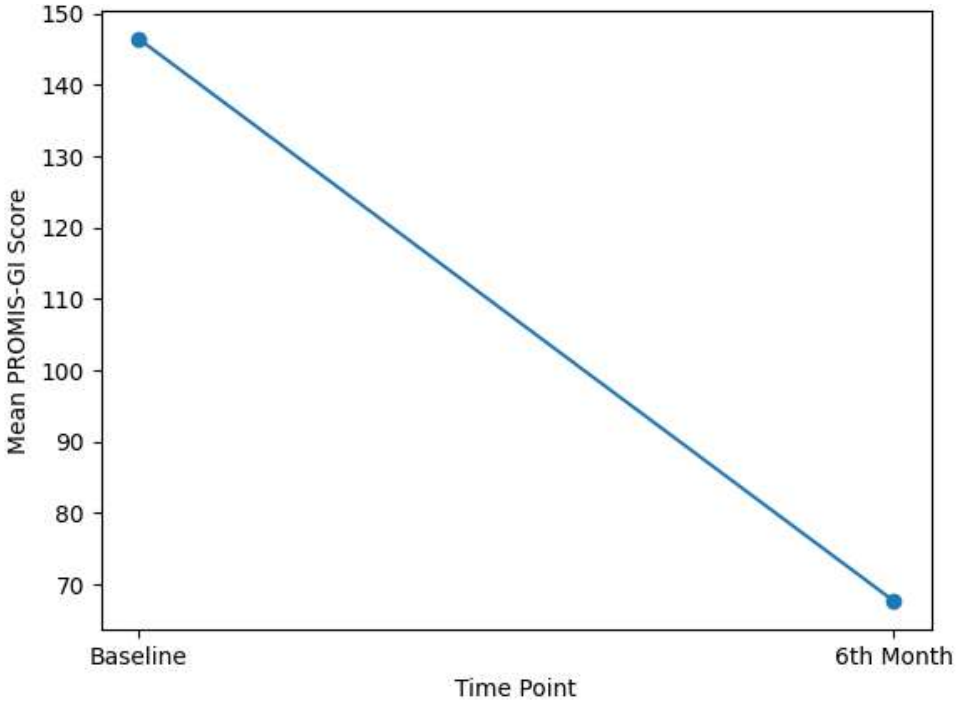

Figure 2: Reduction in PROMIS-GI Scores from Baseline to 6th Month

Following six months of individualized homoeopathic treatment, a marked improvement in symptom severity was observed across all measured parameters. The distribution of abdominal pain severity, assessed using the Numerical Rating Scale (NRS), demonstrated a significant shift from moderate and severe categories to mild or no pain. At baseline, 77% of patients reported moderate pain and 7% reported severe pain, whereas after treatment, 70% reported only mild pain and 30% reported no pain, with complete elimination of moderate and severe pain categories.

Table 2: Comparison of NRS Abdominal Pain Scores

Time Point	Mean Score	Standard Deviation
Baseline	4.8	1.44
6th Month	1.3	0.99

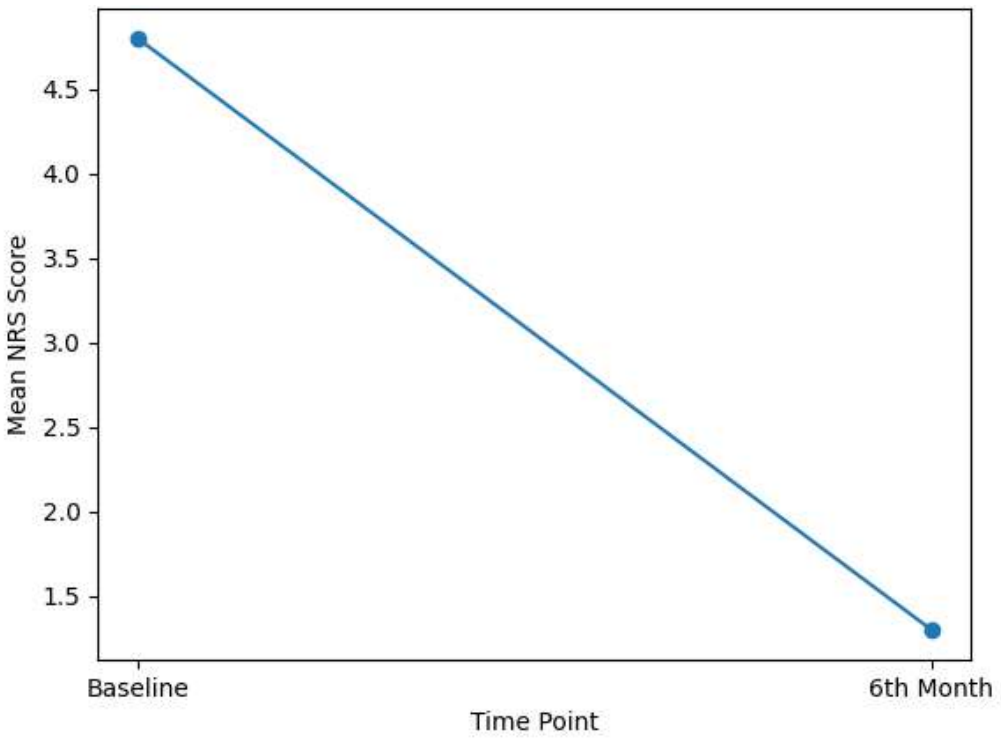

Figure 3: Reduction in NRS Abdominal Pain Scores

Quantitative analysis further supported these clinical observations. The mean PROMIS-GI symptom score decreased significantly from 146.43 ± 26.82 at baseline to 67.63 ± 16.24 after six months of treatment. The mean difference of 78.80 was statistically highly significant, with a calculated t-value of 20.58 and a p-value of 7.52×10^{-19} . Similarly, the mean NRS abdominal pain score showed a significant reduction from 4.8 ± 1.44 at baseline to 1.3 ± 0.99 post-treatment, with a mean difference of 3.46, a t-value of 18.84, and a p-value of 8.27×10^{-18}. These findings indicate a highly significant improvement in both gastrointestinal symptoms and pain severity following treatment.

Correlation analysis revealed a moderate positive relationship between baseline and post-treatment scores (PROMIS-GI: r = 0.624; NRS: r = 0.719), suggesting consistency in patient response patterns. Furthermore, effect size calculations demonstrated a very large treatment effect, with Cohen's d values exceeding 3 for both PROMIS-GI and NRS outcomes, and Hedges' g values also indicating strong clinical significance. Overall, the results indicate that individualized homoeopathic treatment was associated with statistically significant and clinically meaningful

improvements in persistent gastrointestinal symptoms among post-cholecystectomy patients.

Table 3: Distribution of Pain Severity Before and After Treatment

Pain Category	Before Treatment	After Treatment
None	0	9
Mild	5	21
Moderate	23	0
Severe	2	0

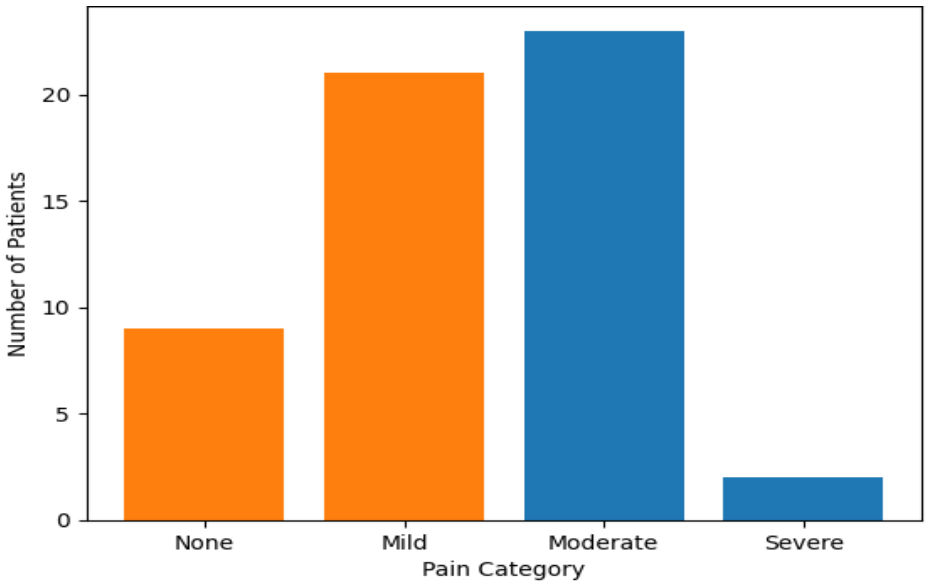

Figure 4: Distribution of Pain Severity Before and After Treatment

Discussion:

The present study demonstrated a statistically significant improvement in persistent gastrointestinal symptoms following individualized homoeopathic treatment, as evidenced by marked reductions in PROMIS-GI and NRS scores. These findings align with existing literature that recognizes post-cholecystectomy syndrome (PCS) as a multifactorial condition characterized by persistent abdominal pain, dyspepsia, bloating, and altered bowel habits (10).

Several studies have reported that a substantial proportion of patients continue to experience gastrointestinal symptoms even after cholecystectomy. According to a clinical review, PCS affects approximately 5–30% of patients, presenting with symptoms such as nausea, flatulence, diarrhea, and abdominal pain. Similarly, Saleem et al. reported that up to 40% of patients may develop PCS, highlighting the persistent burden of postoperative symptoms and the need for effective management strategies. The symptom distribution observed in the present study—particularly abdominal pain and bloating—correlates closely with these findings (11).

A cross-sectional study conducted in India reported bloating (60%), abdominal discomfort (56.6%), and dyspepsia (50%) as the most prevalent post-cholecystectomy symptoms. These findings are comparable to the present study, where gas bloating and abdominal pain were the most commonly reported symptoms at baseline. Furthermore, a meta-analysis of PCS symptoms indicated abdominal pain (~30%), dyspepsia (~20%), and diarrhea (15–25%) as dominant clinical features, reinforcing the consistency of symptom patterns across populations (12).

From a pathophysiological perspective, recent studies emphasize the role of altered bile acid metabolism, gut microbiota imbalance, and gut–brain axis dysregulation in the development of PCS. Chang *et al.,* (2023) demonstrated that cholecystectomy is associated with an increased incidence of functional gastrointestinal disorders, including dyspepsia and chronic abdominal pain, due to bile acid dysregulation and visceral hypersensitivity (13). Similarly, contemporary reviews suggest that disruption of bile flow and microbial composition significantly contributes to persistent gastrointestinal symptoms after surgery. These mechanisms support the rationale for individualized therapeutic approaches targeting functional disturbances rather than structural pathology alone (14).

In contrast to conventional studies that primarily focus on symptom prevalence and pathophysiology, the present study uniquely evaluates a therapeutic intervention—individualized homoeopathic treatment. While conventional management of PCS largely involves symptomatic pharmacotherapy (e.g., proton pump

inhibitors, bile acid sequestrants), evidence suggests that such approaches may not fully address the multifactorial and functional nature of the disorder. The significant improvement observed in this study, with large effect sizes (Cohen's d > 3), indicates a potentially meaningful clinical benefit of individualized treatment strategies (15).

Furthermore, previous observational and longitudinal studies have highlighted that patients with underlying functional gastrointestinal disorders (FGIDs) often experience persistent symptoms even after surgery. Shabanzadeh *et al.,* (2023) reported that patients with pre-existing functional disorders are less likely to achieve complete symptom resolution post-cholecystectomy, emphasizing the need for alternative or adjunctive therapies. The improvement observed in the present study suggests that homoeopathic treatment may play a role in addressing such functional components (16).

However, unlike controlled trials in conventional medicine, the current study lacks a control group, limiting direct comparison with standard treatments. Additionally, while existing studies focus on epidemiology and mechanism, there is a notable scarcity of clinical trials evaluating complementary or integrative therapies in PCS. Therefore, this study contributes novel preliminary evidence supporting the role of individualized homoeopathy in managing persistent gastrointestinal symptoms.

Overall, the findings of the present study are consistent with existing literature regarding symptom prevalence and pathophysiology of PCS, while offering new insights into therapeutic possibilities. The observed clinical improvements underscore the importance of individualized, patient-centered approaches in managing complex functional gastrointestinal disorders (17).

Conclusion:

The present observational clinical study demonstrates that individualized homoeopathic treatment is associated with significant improvement in persistent gastrointestinal symptoms following cholecystectomy. Statistically significant reductions in PROMIS-GI scores and NRS abdominal pain scores, along with very large effect sizes, indicate both clinical and practical relevance of the intervention. The shift in pain severity from moderate

and severe categories to mild or no pain further substantiates the therapeutic benefit observed over the six-month follow-up period.

These findings suggest that individualized homoeopathy may offer a promising complementary approach in the management of post-cholecystectomy syndrome, particularly in patients with functional gastrointestinal disturbances where conventional treatments may provide limited relief. The holistic and patient-centered nature of homoeopathic prescribing may contribute to addressing the multifactorial etiology of persistent symptoms.

However, the interpretation of these results should be made with caution due to methodological limitations, including the absence of a control group, small sample size, non-randomized design, and single-center setting. Therefore, while the outcomes are encouraging, they cannot establish definitive causality.

Future research should focus on well-designed randomized controlled trials with larger sample sizes, longer follow-up durations, and incorporation of objective biochemical and diagnostic parameters to validate and extend these findings. Integrating homoeopathy within a multidisciplinary framework may further enhance patient outcomes in post-cholecystectomy care.

Patient Consent

Written informed consent was obtained from all participants prior to their inclusion in the study. The purpose, procedures, potential benefits, and any possible risks associated with the study were clearly explained to each participant in a language they understood. Participants were informed of their right to withdraw from the study at any stage without any impact on their ongoing treatment. All efforts were made to ensure confidentiality and privacy of patient information. Personal identifiers were removed, and data were anonymized before analysis and reporting. The study was conducted in accordance with ethical principles and guidelines for biomedical research involving human participants.

Conflict of Interest:

The authors declare that there are no conflicts of interest regarding the publication of this study. The research was conducted in the absence of any commercial or financial relationships

that could be construed as a potential conflict of interest.

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Author Contributions (CRediT Statement)

Dr. Bhavya Lakshmi V S:

Conceptualization, Methodology, Investigation, Data Curation, Formal Analysis, Writing – Original Draft Preparation, Writing – Review & Editing, Visualization, and Project Administration.

Dr. Gautam Pal:

Methodology, Investigation, Data Curation, Formal Analysis, Writing – Review & Editing, and Project Administration.

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