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Efficacy and Mucosal Inflammatory Safety of Eranda (ricinus communis l.) Beeja (seeds) taila (oil) in Chronic Constipation: A Prospective Open Label Pilot Study

Dr Sachin Rangrao Patil*[1], Dr Umesh Vamanrao Tekawade[2], Aniket Arun Joshi[3]

*[1]MD .Ph.D (Scholar), Associate Professor, Department of Rachana Sharira College of Ayurved Pune Satara-Road Pune – 43, Bharati Vidyapeeth Deemed to be University Pune, Email id: patil.sachin1@bharatividyapeeth.edu, Orcid ID 0009-0008-4928-9497
[2]MD .Ph.D (Scholar), Professor, Department of Rachana Sharira, College of Ayurved Pune Satara-Road Pune - 43, Bharati Vidyapeeth Deemed to be University Pune
Email id: umesh.tekawade@bharatividyapeeth.edu, Orcid ID 0000-0002-1265-5886
[3](Manager & Technical Lead, GastroLab India Pvt Ltd, 411045, CITY: Pune, STATE: Maharashtra, COUNTRY: India, MSc. In Virology, National Institute of Virology, Pune, BSc. Biotechnology, KET'S V. G. Vaze College Mumbai University)
Email id: joshianiket289@gmail.com

ABSTRACT

Background: In the ayurveda the Purishaja Udavarta (chronic constipation) is the disease condition of digestive system principally concerned with Purishavaha srotas (Large intestine and Rectum). Chronic constipation is functional gastrointestinal disorder associated with gut motility, staining, lumpy stools, neuromuscular coordination. Faecal calprotectin, a neutrophil-derived biomarker, is widely used to distinguish inflammatory bowel diseases from functional gastrointestinal disorders; however, its relevance in functional gastrointestinal disorder remains unclear. The current study evaluates the effect of Eranda taila in patients with Purishaja Udavarta on the basis of titrating the faecal calprotectin levels using the point- of -care (POC) test and reduction in the score of the PAC-SYM questionnaire. Materials and methods

An open-label prospective cohort of 15 patients received 2.5 mL of oral castor oil with 50 mL of lukewarm water once daily before dinner for 21 days. Clinical symptom burden was quantified using the Patient Assessment of Constipation Symptoms (PAC-SYM) instrument (Abdominal, Rectal, and Stool domains). Intestinal mucosal inflammation was assessed pre- and post-intervention via POC faecal calprotectin testing. Differences were analyzed using the Wilcoxon signed-rank test.

Results All 15 patients completed the protocol. Total PAC-SYM scores decreased significantly from 1.63 ± 0.72 at baseline to at Day 21 0.40 ± 0.26, with consistent improvements across abdominal (1.40 to .40), rectal (1.27 to.31) and stool domains (2.03 to .45). Faecal calprotectin decreased significantly from 189.45 ± 260.93 at baseline to at Day 21 63.01 ± 88.21. No treatment-emergent mucosal toxicity was observed.

Conclusion The 21 -day oral intervention of castor oil relives chronic constipation and reduction in range of faecal calprotectin demonstrates significantly attenuating stasis-associated subclinical intestinal mucosal inflammation, confirming both therapeutic efficacy and mucosal safety.

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Chronic Constipation, Faecal Calprotectin, Large Intestine, Castor Oil, FGID.

1. Introduction

The anatomical site of origin and manifestation of *Purishaja Udavarta* [1] (Chronic constipation) localize predominantly in the *Pakvashaya* [2] is belongs to the organ of Mahasrotas [3] (Gastrointestinal tract). Ayurvedic texts describe the roopa (symptoms) of *Purishaja Udavarta , Purisha sanga* (Retention of faeces), *Atopa* (Gurgling sound of the intestines/ borborygmus), *Udar Shoola* (Colicky pain in the abdomen), *Parikartika* (Cutting type of pain in the anal region*) Urdhavavata* (Belching), *Adhmana* (Abdominal distention/bloating)[4] .

Purishaja Udavarta represents one of the distinct clinical manifestations of the Udavarta. *Udavarta* categorized into six types [5] by Charaka and thirteen types by Sushruta [6]. Due to *Nidansevan* (etiologic factors) *Apanavayu* gets vitiated in the *Pakvashaya* (large intestine) and obstructs the *Adhogami Srotas* (downwards transport channels of body) as result of which the movement of *Vita (*faeces), *Maruta* (flatus) and *Mutra* (urine) gets gradually obstructs [7]. Untreated or improperly treated *Udavarta vyadhi* become a causative factor

for other diseases e.g. *Hradaroga* (heart diseases) *Grahaniroga* (malabsorption disorder) [8]. *Purisha* (faeces) is the fundamental elements of the body which are basically products of metabolism and responsible for homeostasis, when present in the state of equilibrium [9] .*Purisha* (faeces) is considered as a waste product formed after digestion of food. Retention of faeces is a required phenomenon of metabolic activities. If the lower part of gastrointestinal tract fails in timely excretions of faeces regularly due to suppression of defaecation reflex, imbalance diet, mental stress then retention of faeces occurs and gets accumulated and acts as a primary trigger for disease development called as *Purishaja Udavarta*.

The three domains with their subscales of Patient Assessment of Constipation Symptoms Questionnaire (PAC-SYM questionnaire) [10] were used for the assessment of *Purishaja Udavarta*. The score of the PAC-SYM questionnaire was used for the evaluation of effect of the *Eranda Taila* in the management of the *Purishaja Udavarta.* The pathogenesis of chronic constipation is multifactorial. It involves dysfunction in the homeostasis of the neuro-gastro-intestinal-musculature that can lead to the development of the symptoms and disease condition.[11][12] Among the biomarkers investigated for the assessment of intestinal inflammation, faecal calprotectin has emerged as one of the most clinically valuable and extensively studied non-invasive markers [13][14]. Faecal calprotectin [15] is gut microbiome was used to monitoring the safety and evaluate clinical efficacy of *Eranda Taila* during the treatment of *Purishaja Udavarta* . Faecal calprotectin is useful for determining the cause of gastrointestinal symptoms, when it is difficult to differentiate between organic and functional causes by symptoms or clinical examination[16].Calprotectin, also known as MRP8/14 and S100A8/A9, is a calcium- and zinc-binding protein of the S-100 protein family first isolated from blood leucocyte[17].The genes for the calprotectin subunits are known as S100A8 and S100A9 and are located in chromosome 1q21[18]. MRP8 is considered as the active subunit while MRP14 prevents early degradation of MRP8.[19] .

The present study concentrations on *Eranda taila*, a classical Ayurvedic oil formulation mentioned in Charaka Samhita for the management of *Purishaja Udavarta* [8]. The Eranda taila is recognized for their *Kaphavatahara* (pacifies the actions *of Kapha* and *Vata*), *Vrushya* (eugenics/ aphrodisiacs), *Balakaraka* (increases physical endurance), *Agnidipaka* (increase in power of digestion), *Bhedaka* (drastic purgative), *and Pachaka* (enhancing digestion) and *Vedanasthapaka* (analgesic) effects.[20][21]

Hence, the present study was performed to evaluate the efficacy of *Eranda Taila* (castor oil) in patients with *Purishaja Udavarta* on the basis of improvement in the score of the subscale of PAC-SYM questionnaire. Additionally, baseline and post-intervention faecal calprotectin levels were measured to evaluate the therapeutic response of castor oil in Purishaja Udavarta (chronic constipation), to determine whether the condition manifests as a functional gastrointestinal disorder or a subclinical inflammatory disease and mucosal inflammatory safety of Eranda (Ricinus communis L.) beeja (seeds) taila (oil) in management of Chronic constipation

2. Materials and Methods

2.1 Research Design:

An open-label, single arm, pilot study was conducted at Bharti Vidyapeeth Ayurveda Hospital Pune. The three domains with their subscales of Patient Assessment of Constipation Symptoms Questionnaire (PAC-SYM questionnaire) were used for the assessment of *Purishaja Udavarta*. The patients were assigned with a specific number & the same were used to generate the patient information sheet with the help of QuantOnCal dashboard. At baseline and post intervention symptoms and severity of chronic constipation of patients was recorded as per guidelines of PAC SYM questionnaire and the QuantOnCal test was performed with the help of Faecal sample collected as per the procedure provided by the manufacturer. To evaluate patients overall progress at baseline and after treatment by analyse and interpretation of the Total PAC-SYM Score using validated Mean Score Method. The investigation range of faecal calprotectin were observed, recorded, and assessed for the intestinal mucosal integrity(homeostasis) of patients with chronic constipation at baseline and after the intervention.

2.2 Setting and Participants

Participants were screened for the study from outpatient and inpatient department of Kayachikitsa, Bharati Vidyapeeth (Deemed to be University) College of Ayurved and Hospital, Pune, India. Eligible participants were adult men and women aged between 40 and 60 years with clinically features of chronic functional constipation fulfilling the Patient Assessment of Constipation Symptoms (PAC-SYM) diagnostic severity criteria and willingness to comply with the 21-day oral intervention protocol, provide paired stool specimens, and complete written informed consent. Exclusion criteria were clinical contraindications to therapeutic purgation (*Virechana* / cathartic therapy) or internal oleation (*Snehana*), secondary constipation attributable to pharmacological agents (including opioid-induced constipation), endocrine dysfunction, metabolic disorders, or underlying neurological conditions. Constipation secondary to prior gastrointestinal or pelvic surgery, structural organic disorders of the large intestine (such as colorectal malignancy, strictures, or inflammatory bowel disease), or megacolon. History of non-steroidal anti-inflammatory drug (NSAID) or systemic laxative administration within the seven days preceding

baseline evaluation and intervention initiation. Pregnant and lactating women. Exclusion criteria comprised clinical contraindications to therapeutic purgation (*Virechana* / cathartic therapy) or internal oleation (*Snehana*); secondary constipation attributable to pharmacological

Dose of *Eranda Taila*	Dose of *Anupana* (Adjuvant) *Kosnajal*	Root of drug administration	Time of Administration	Duration	Assessment
2.5 ml	**50 ml**	**Oral**	**Before food at night**	**21 Days**	**0-day: Before treatment 22-day: After treatment**

agents (including opioid-induced constipation), endocrine dysfunction, metabolic disorders, or underlying neurological conditions; constipation secondary to prior gastrointestinal or pelvic surgery, structural organic disorders of the large intestine (such as colorectal malignancy, strictures, or inflammatory bowel disease), or megacolon; administration of non-steroidal anti-inflammatory drugs (NSAIDs) or systemic laxatives within the seven days preceding baseline evaluation and intervention initiation; and pregnant or lactating women.

Data collection was conducted between February 2024 and June 2024. Participants were instructed to adhere to the treatment protocol and promptly report any adverse events to the research team. A total 18 subjects were screened, after screening 15 were enrolled as per approved inclusion and exclusion criteria in the study after providing written informed consent. Data from the 15 participants were included in final statistical analysis.

2.3 Ethics and registration

The study protocol was approved by the institutional ethics committee and registered with the clinical trial registry India.

Ethics Committee Approval Number: BVDUCOA/EC/-103(4)/2022-23

CTRI Registration Number: CTRI/2022/12/048079

Registration Date: 13 December 2022

2.4 Intervention

Eranda taila (Castor oil) of the seeds of *Rakta Eranda* **(***Ricinus communis* L.) extracted by cold pressed method from Bramha Ayurveda GMP-certified pharmacy, Pune and procured from Dhanwantari Aushadhalaya, Pune. Physicochemical analysis of Eranda taila done at In House Quality Control Laboratory.

Table 01: Details of intervention outline

Dietary and Lifestyle regimen:

Aahara (Diet and Fluids): Madhura, Amla, Lavana, Snigdha (unctuous), Laghu (easily digestible) Aahara and adequate fibre, lukewarm water was advice during and after treatment. **Apathya Aahara** (unwholesome): Etiological factors considered as Apathya, which should be avoided during and after treatment.

Vihara (Lifestyle)**:** Avoidance of *Vega-dharana* (suppression of natural urges, especially defecation), sedentary routine, Ratri-*jagarana* (night vigil).

2.4 Primary Outcome Measures

Intestinal mucosal inflammation was objectively evaluated at baseline (Day 0, pre-treatment) and at study completion (Day 21, post-treatment) using a rapid, quantitative point-of-care (POC) faecal calprotectin lateral flow immunochromatographic assay system (QuantOnCal).

Interpretation: Clinical cut-off thresholds were categorized as: Normal (negative mucosal inflammation): <50 µg/g, Borderline / Low-grade inflammation: 50-100 µg/g,Elevated mucosal inflammation: >100 µg/g.

2.5 Secondary Outcome Measures: Patient Assessment of Constipation Symptoms (PAC-SYM)

Subjective symptom burden was evaluated using the validated 12-item PAC-SYM questionnaire, graded on a 5-point Likert scale (0 = absence of symptoms to 4 = very severe symptoms). Evaluations were broken down into three sub-domains: Stool Symptoms (5 items), Abdominal Symptoms (4 items), and Rectal Symptoms (3 items), alongside the global overall mean score.

Spontaneous Bowel Movement (SBM) Frequency: Patients recorded the number of SBMs occurring per week in their validated symptom diaries.

Safety and Tolerability Monitoring: All treatment-emergent adverse events (TEAEs)such as abdominal cramps, nausea, flatulence, bloating, or excessive diarrhoea were documented at each scheduled contact with their severity, duration, and relationship to the study drug.

2.6 Statistical Analysis

Continuous variables were assessed for normality using the Shapiro-Wilk test. Continuous data are expressed as mean ± standard deviation (SD). Pre- and post-treatment differences in normally distributed symptom scores (PAC-SYM total and domain sub scores) were evaluated using the paired Student's t-test (reporting t-statistic, degrees of freedom, and p-values). For non-normally distributed and positively skewed variables (faecal calprotectin), both the paired Student's t-test and the non-parametric Wilcoxon signed-rank test were conducted. Statistical significance was established at an alpha threshold of α= 0.05. All analyses were executed in R software (v4.x).

A sample size of $N = 15$ was selected based on established pilot trial methodology (Julious, 2005; Whitehead et al., 2016), which recommends 12 to 15 participants to assess feasibility, evaluate parameter variance, and estimate effect sizes for future definitive trials.

3. Result

A total of 15 patients diagnosed with chronic constipation completed the study and were included in the final analysis. The therapeutic efficacy was evaluated using the Patient Assessment of Constipation Symptoms (PAC-SYM) questionnaire, while inflammatory flareup staging was assessed by quantitative measurement of faecal calprotectin concentrations before treatment (BT) and after 21 days of oral castor oil (Eranda Taila) therapy.

3.1 Cohort Characteristics: The cohort consisted of 8 males and 7 females with a mean age of 45.7 ± 7.8 years (range: 39–59 years).

3.2 Primary outcomes:

Baseline faecal calprotectin concentrations demonstrated considerable inter-individual variability, ranging from 14.8 µg/g to 920 µg/g. The mean faecal calprotectin concentration decreased from 189.45 ± 260.93 µg/g before treatment to 63.01 ± 88.21 µg/g after treatment, indicating an overall reduction in intestinal inflammatory activity following castor oil therapy (Table 02) (Figure 01: C).

Table 2: Comparison of clinical outcomes and faecal calprotectin levels before & after *Eranda Taila* therapy

Outcome Variable	Before Treatment (BT) Mean ± SD	After Treatment (AT) Mean ± SD	Mean Difference (Δ) ± SD	Paired -t test (t -value, d f =14)	p-value (t-test)	Wilcoxon Test (W-value)	p-value (Wilcoxon)
Total PAC Sym Score Abdominal Symptoms	1.63 ± 0.72	0.40 ± 0.26	1.23 ± 0.57	t = 8.368	p<0.0001	W=0.0	p<0.0001
Abdominal Domain (Q1–Q4)	1.40 ± 0.68	0.40 ± 0.28	1.00 ± 0.54	t = 7.135	p<0.0001	W=0.0	p<0.0001
Rectal Domain (Q5–Q7)	1.27 ± 0.75	0.31 ± 0.23	0.96 ± 0.65	t = 5.667	p<0.0001	W=0.0	p<0.0009
Stool Domain (Q8–Q12)	2.03 ± 0.80	0.45 ± 0.33	1.57 ± 0.64	t = 9.567	p<0.0001	W=0.0	p<0.0001

Faecal Calprotectin (µg/g)	189.45 ± 260.93	63.01 ± 88.21	126.43 ± 237.20	t =2.064	p=0.058	W=17.0	p=0.012

BT: Before treatment, AT: After treatment; SD: Standard deviation; µg/g: Micrograms per gram of stool; t: paired t-test

Based on baseline faecal calprotectin concentrations, three patients (20%) exhibited values >250 µg/g, suggestive of marked intestinal inflammatory activity. Five patients (33%) had concentrations between 50 and 250 µg/g, indicating mild to moderate inflammatory activity, while seven patients (47%) demonstrated faecal calprotectin concentrations within the normal reference range (<50 µg/g). Following treatment, the proportion of patients with faecal calprotectin concentrations within the normal range increased from 47% to 73%, whereas patients with concentrations >250 µg/g decreased from 20% to 7%, indicating an overall shift towards lower inflammatory activity (Table 03).

Individual patient analysis demonstrated that all seven patients with baseline faecal calprotectin concentrations within the normal reference range remained within the normal range following treatment. Among the five patients with baseline concentrations between 50 and 250 µg/g, three patients demonstrated a reduction to normal concentrations after treatment, one patient showed a slight reduction without reaching the normal range, and one patient exhibited a slight increase in faecal calprotectin concentration. Three patients with baseline faecal calprotectin concentrations >250 µg/g, two patients demonstrated marked reductions into lower inflammatory categories, while one patient showed a substantial reduction but remained above the 250 µg/g threshold. Clinically 80% (12/15) of patients experienced a marked reduction in calprotectin. High baseline inflammation (>100 µg/g seen in 8 patients) was resolved in 6 patients, with 11 out of 15 patients (73.3%) normalizing to physiological normal (<50 µg/g). Statistical analysis using the Wilcoxon signed-rank test demonstrated a significant reduction in faecal calprotectin concentrations following treatment (V = 17, p = 0.012) (Table 02).

Table 3: Distribution of patients according to faecal calprotectin categories before and after *Eranda taila* therapy

FC Category	No. of patients BT	% BT	No. of patients AT	% AT
> 250 µg/g	3	20%	1	7%
50–250 µg/g	5	33%	3	20%
< 50 µg/g	7	47%	11	73%
Total	**15**	**100%**	**15**	**100%**

FC: Faecal calprotectin, BT: Before treatment, AT: after treatment, No: Number

3.3 Secondary Outcomes:

3.3.1. Patient Assessment of Constipation Symptoms (PAC-SYM)

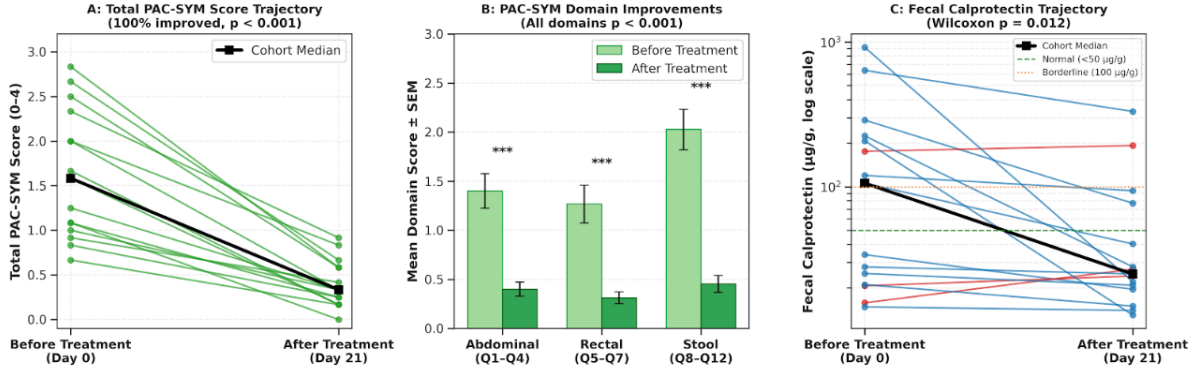
Comparison of PAC-SYM scores before and after treatment demonstrated a marked improvement across all symptom domains. The mean abdominal symptom score decreased from 1.40 ± 0.68 to 0.40 ± 0.28, rectal symptoms decreased from 1.27 ± 0.75 to 0.31 ± 0.23, and stool-related symptoms decreased from 2.03 ± 0.80 to 0.45 ± 0.33. Consequently, the overall PAC-SYM score was reduced from 1.63 ± 0.72 before treatment to 0.40 ± 0.26 after treatment, indicating substantial improvement in constipation-related symptoms (Table 02) (Figure 01: A and B).

The improvement in symptom severity was further confirmed by statistical analysis. Paired t-test analysis demonstrated significant reductions in abdominal symptoms ($t = 7.135$, $p < 0.0001$), rectal symptoms ($t = 5.667$, $p < 0.0001$), stool symptoms ($t = 9.567$, $p < 0.0001$), and total PAC-SYM score ($t = 8.368$, $p < 0.0001$), confirming the clinical efficacy of castor oil therapy in improving constipation-related symptoms (Table 02). (Figure 01: A and B) demonstrates the reduction in mean PAC-SYM subscale scores following treatment, with stool-related symptoms showing the greatest degree of improvement among all symptom domains.

3..3.2. Spontaneous Bowel Movements (SBMs): Weekly SBM frequency increased from 1.80 ± 0.56 evacuations per week at baseline to 4.87 ± 1.06 evacuations per week at Day 21 ($p < 0.0001$).

3.3.3. Tolerability: No severe adverse events or treatment withdrawals occurred. Transient abdominal cramping was observed in two patients during the initial 72 hours, resolving spontaneously.

Figure 01. Clinical symptom and mucosal inflammatory changes following a 21-day castor oil intervention (N = 15).



(A) Spaghetti plot of individual Total PAC-SYM scores before and after treatment, demonstrating symptom reduction across all 15 participants ($p < 0.001$).

(B) Mean PAC-SYM sub-domain scores (Abdominal, Rectal, Stool) before and after treatment (error bars indicate SEM (Standard error of mean) ***, $p < 0.001$).

(C) Individual paired trajectories of fecal calprotectin on a logarithmic scale; blue lines indicate reductions (n = 12) and red lines denote minor elevations (n = 3), with a decrease in cohort median from 106.0 µg/g to 25.0 µg/g ($p = 0.012$)

4. Discussion

4.1.1. Resolution of Stasis-Associated Inflammation

The high baseline calprotectin levels observed in over half the cohort (>100 µg/g) align with findings that severe faecal impaction and colonic dysbiosis induce localized mucosal micro-abrasion and neutrophil infiltration. Rather than worsening inflammation, castor oil facilitated bowel evacuation, reducing median calprotectin levels by 76.4 % ($p = 0.012$).

4.1.2. Receptor-Mediated Prokinetic Action

By acting through targeted EP_3 smooth-muscle prostanoid receptor stimulation rather than high-concentration chemical desquamation, low-dose ricinoleic acid restored colonic motility without triggering epithelial leakage or inflammatory shedding [22,23].

4.1.3. Multi-Domain Clinical Efficacy

The 74.7% drop in global PAC-SYM scores demonstrates that prokinetic evacuation translates into broad relief across stool consistency, straining, incomplete evacuation, and abdominal bloating.

4.1.4. *Eranda taila* is described as a *Kaphavatahara* (pacifies the actions of Kapha and Vata), *Bhedaka* (drastic purgative) and *Vedanasthapaka (*analgesic) in ayurvedic texts, which restores the downward movement of *Apana Vayu* in the lower part of gastrointestinal tract and relieves *Purisha sanga* (Retention of faeces) together with Atopa (Gurgling sound of the intestines), Adhmana (bloating), Udar Shoola (Colicky pain in the abdomen) and *Parikartika* (Cutting type of pain in anal canal).

4.2 Limitations of study

This pilot study was limited by an open-label, single-arm design and a small sample size ($N = 15$). Larger randomized controlled trials are warranted to corroborate long-term recurrence rates after treatment cessation.

4.3 Future Scope of study

These findings suggest that low-grade intestinal inflammation may contribute to symptom generation in a subset of patients and that faecal calprotectin can serve as a non-invasive biomarker for identifying such patients and monitoring treatment response. Randomised controlled trials, serial quantitative calprotectin measurement and mechanistic studies of transit, microbiota and mucosal

inflammation can build on these results and further define the therapeutic role of Eranda taila. As interest in evidence-based traditional therapies grows, combining validated symptom scores with objective biomarkers can help integrate Eranda taila into contemporary gastroenterological practice.

5. Conclusion

A 21-day course of low-dose oral castor oil (2.5 ml with 50 ml of lukewarm water) provides significant symptom relief across all PAC-SYM domains and significantly reduces elevated baseline faecal calprotectin levels in patients with chronic constipation. These findings support the mucosal safety and clinical utility of castor oil as an integrative short-term therapeutic option.

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Consent to participate: Written informed consent was obtained from all participants.

Consent for publication: Not applicable; no identifiable individual data are reported.

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