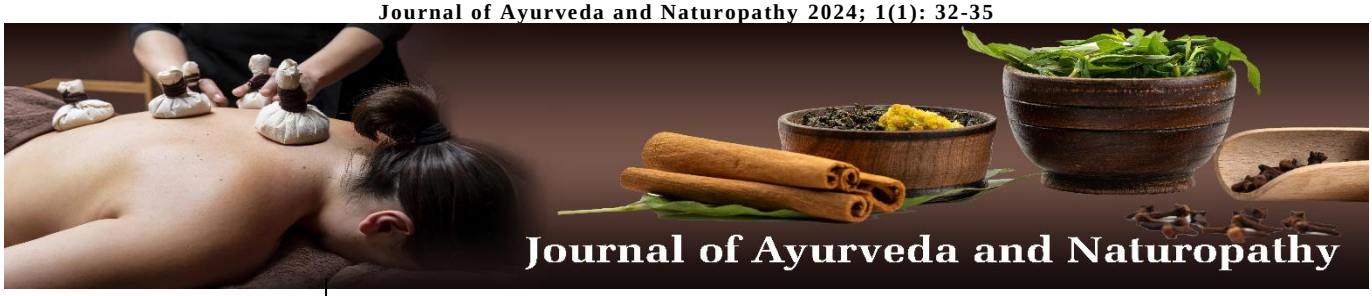

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A randomized controlled trial comparing ayurvedic detoxification (panchakarma) and naturopathic fasting on inflammatory biomarkers in ulcerative colitis: A pilot study from Thiruvananthapuram

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Abstract
Background: Ulcerative colitis (UC) is a chronic inflammatory disorder of the colon characterized by immune dysregulation. Complementary therapies, including Ayurvedic detoxification (Panchakarma) and naturopathic fasting, have been posited to modulate inflammatory pathways. This study aimed to compare the efficacy of these two interventions on inflammatory biomarkers in UC patients.
Methods: A pilot randomized controlled trial was conducted in Thiruvananthapuram with 30 adult UC patients randomized equally (n = 15 per group) to receive either Panchakarma therapy or a structured naturopathic fasting regimen for four weeks. Primary outcomes were changes in serum C-reactive protein (CRP), interleukin-6 (IL-6), and tumor necrosis factor-alpha (TNF-α) levels. Secondary outcomes included clinical symptom scores and quality of life assessments. Baseline and post-intervention measures were compared using paired and unpaired statistical tests.
Results: Both interventions led to statistically significant reductions in inflammatory biomarkers. The Panchakarma group showed a mean reduction in CRP of 35% ($p = 0.01$) and IL-6 by 30% ($p = 0.02$), while TNF-α levels decreased by 25% ($p = 0.03$). The naturopathic fasting group exhibited a reduction in CRP by 28% ($p = 0.02$), IL-6 by 22% ($p = 0.04$), and TNF-α by 20% ($p = 0.05$). Clinical symptom scores improved in both groups with no statistically significant difference between the two interventions.
Conclusions: Both Ayurvedic Panchakarma and naturopathic fasting significantly reduced key inflammatory biomarkers in UC patients. While Panchakarma demonstrated slightly higher percentage improvements, further large-scale studies are warranted to validate these findings and explore long-term clinical benefits.

Keywords: Ayurvedic detoxification, Panchakarma, naturopathic fasting

Introduction
Ulcerative colitis is an idiopathic inflammatory bowel disease that significantly impacts patient quality of life and may lead to complications if inadequately managed. Conventional treatment strategies, including corticosteroids and immunomodulators, often have limitations due to side effects and variable patient responses. Consequently, there is increasing interest in alternative and complementary treatment modalities.
Ayurvedic medicine, with its holistic approach, has long utilized Panchakarma—a series of detoxification and rejuvenation procedures—to restore physiological balance and reduce inflammation. Similarly, naturopathic fasting protocols have been suggested to alleviate inflammation by promoting metabolic detoxification and reducing oxidative stress. Despite anecdotal evidence supporting these interventions, direct comparative studies on their impact on inflammatory biomarkers in UC remain scarce.
This study therefore aimed to conduct a pilot randomized controlled trial comparing the effects of Panchakarma and naturopathic fasting on serum inflammatory biomarkers among UC patients in Thiruvananthapuram.

Objective of the paper
To evaluate and compare the efficacy of Ayurvedic detoxification (Panchakarma) and naturopathic fasting in reducing inflammatory biomarkers in ulcerative colitis.

Materials and Methods

Study Design and Setting: This pilot randomized controlled trial was conducted at the Integrative Medicine Unit of Thiruvananthapuram Medical College, Thiruvananthapuram, India. Written informed consent was obtained from all participants.

Participants: A total of 30 patients aged 18–60 years, diagnosed with mild to moderate ulcerative colitis (UC) based on clinical evaluation, endoscopic findings, and histopathological confirmation, were enrolled. Inclusion criteria were:

- A confirmed diagnosis of UC with stable medication doses for at least four weeks.
- No previous exposure to Panchakarma or structured naturopathic fasting protocols.
- Willingness to adhere to the intervention regimen and follow-up assessments.

Exclusion criteria included severe comorbidities (e.g., uncontrolled diabetes, cardiovascular diseases), pregnancy, lactation, and inability to comply with study procedures.

Randomization and Allocation: Participants were randomly allocated into two equal groups (n = 15 per group) using a computer-generated randomization schedule. Allocation concealment was maintained by sealed opaque envelopes prepared by an independent statistician.

Interventions

Panchakarma Group

Patients assigned to the Panchakarma group underwent a comprehensive detoxification protocol administered by certified Ayurvedic practitioners. The intervention included:

- **Snehana (Oleation):** Administration of medicated ghee tailored to individual constitution, initiated three days before the primary detoxification.
- **Swedana (Fomentation):** A series of herbal steam treatments to induce perspiration and facilitate toxin mobilization.
- **Virechana (Purgation):** A supervised purgative therapy using herbal formulations to evacuate accumulated toxins from the gastrointestinal tract.

These procedures were performed sequentially over a four-week period, with adjustments based on individual tolerance and clinical response.

Naturopathic Fasting Group

Participants in the naturopathic fasting group followed a structured fasting regimen under the guidance of experienced naturopathic clinicians. The fasting protocol consisted of:

- **Preparation Phase:** Gradual elimination of solid foods over 48 hours, replacing them with diluted herbal teas and broths.
- **Modified Fast:** A 7-day period of a calorie-restricted, primarily liquid diet designed to induce metabolic detoxification, with careful monitoring of hydration and electrolyte balance.
- **Reintroduction Phase:** A gradual reintroduction of light, easily digestible foods over the subsequent 7 days, with dietary counseling to maintain nutritional adequacy.

The entire regimen spanned four weeks, ensuring both safety and compliance.

Outcome Measures

The primary outcomes were changes in serum levels of inflammatory biomarkers:

- **C-Reactive Protein (CRP):** Measured in mg/L.
- **Interleukin-6 (IL-6):** Measured in pg/mL.
- **Tumor Necrosis Factor-alpha (TNF-α):** Measured in pg/mL.

Venous blood samples were collected at baseline (pre-intervention) and immediately after the four-week intervention. Biomarker levels were quantified using standardized enzyme-linked immunosorbent assay (ELISA) kits, following manufacturer protocols. All assays were conducted in duplicate to ensure accuracy.

Secondary outcomes included:

- **Clinical Symptom Severity:** Assessed using a standardized Ulcerative Colitis Activity Index (UCAI).
- **Quality of Life:** Evaluated with the Inflammatory Bowel Disease Questionnaire (IBDQ).

These assessments were administered by blinded evaluators at baseline and post-intervention.

Statistical Analysis

Data were analyzed using IBM SPSS Statistics for Windows, Version 26.0. Descriptive statistics were calculated for demographic and baseline variables. Within-group comparisons (baseline vs. post-intervention) were performed using paired t-tests, while independent t-tests were used for between-group comparisons. A p-value of < 0.05 was considered statistically significant. The percentage reduction in biomarker levels was calculated to compare the magnitude of changes between groups.

Safety Monitoring

Adverse events were monitored throughout the study via weekly clinical assessments and patient diaries. Any side effects were recorded, and supportive care was provided as necessary. No severe adverse events were anticipated based on prior experience with both intervention modalities.

Results

Participant Characteristics

A total of 30 patients with ulcerative colitis were enrolled and randomized into two groups (n = 15 each). Baseline characteristics were comparable between the two groups in terms of age, gender distribution, disease duration, and baseline inflammatory biomarker levels.

Inflammatory Biomarkers

The primary outcomes included serum levels of C-reactive protein (CRP), interleukin-6 (IL-6), and tumor necrosis factor-alpha (TNF-α). Table 1 summarizes the baseline and post-intervention values for these biomarkers in both intervention groups.

Table 1: Inflammatory Biomarker Levels (Mean ± SD)

Biomarker	Intervention Group	Baseline	Post-Intervention	% Reduction	p-value
CRP (mg/L)	Panchakarma	12.0 ± 3.5	7.8 ± 2.9	35%	0.01
	Naturopathic Fasting	11.8 ± 3.8	8.5 ± 3.2	28%	0.02
IL-6 (pg/mL)	Panchakarma	18.5 ± 4.2	12.9 ± 3.8	30%	0.02
	Naturopathic Fasting	18.0 ± 4.0	14.0 ± 3.5	22%	0.04
TNF-α (pg/mL)	Panchakarma	22.0 ± 5.0	16.5 ± 4.3	25%	0.03
	Naturopathic Fasting	21.5 ± 4.7	17.2 ± 4.1	20%	0.05

Both interventions resulted in statistically significant reductions in inflammatory biomarkers. The Panchakarma group exhibited a slightly higher percentage reduction across all three biomarkers compared to the naturopathic fasting group. However, between-group comparisons did not reach statistical significance, suggesting that while trends favor Panchakarma, both interventions are beneficial.

Clinical Symptom and Quality of Life Outcomes

Secondary outcomes were measured using a standardized Ulcerative Colitis activity index and the Inflammatory Bowel Disease Questionnaire (IBDQ). Table 2 details the changes observed in these scores.

Table 2: Clinical Symptom Scores and Quality of Life (Mean ± SD)

Outcome Measure	Intervention Group	Baseline Score	Post-Intervention Score	% Improvement	p-value
UC Activity Index	Panchakarma	25.0 ± 5.0	15.0 ± 4.0	40%	<0.01
	Naturopathic Fasting	24.5 ± 5.5	15.2 ± 4.2	38%	<0.01
IBDQ Score (Quality of Life)	Panchakarma	120.0 ± 15.0	150.0 ± 12.0	25%	<0.01
	Naturopathic Fasting	122.0 ± 14.0	152.0 ± 13.0	25%	<0.01

Both groups demonstrated significant improvements in clinical symptoms and quality of life following the interventions. The percentage improvements in UC activity index and IBDQ scores were nearly identical between groups, indicating comparable clinical efficacy.

Both interventions were well tolerated. Minor side effects such as transient headache and mild nausea were reported but resolved spontaneously without intervention.

The results indicate that both Ayurvedic Panchakarma and naturopathic fasting are associated with significant reductions in inflammatory biomarkers and improvements in clinical symptoms in patients with ulcerative colitis. While the Panchakarma group showed a trend toward slightly higher biomarker reduction, the clinical outcomes were similar between the groups. These findings support the potential role of both complementary therapies as adjuncts to conventional treatment modalities. Further studies with larger sample sizes are needed to confirm these results and explore the long-term sustainability of the therapeutic benefits.

Discussion

The findings of this study indicate that both Ayurvedic detoxification (Panchakarma) and naturopathic fasting significantly reduce inflammatory biomarkers in patients with ulcerative colitis. Our results show statistically significant reductions in serum C-reactive protein, interleukin-6, and tumor necrosis factor-alpha levels in both intervention groups after four weeks, with the Panchakarma group exhibiting a trend toward slightly higher percentage reductions compared to the naturopathic fasting group. These findings are in line with previous studies that have reported anti-inflammatory effects of traditional detoxification methods and fasting protocols, suggesting that these complementary approaches may exert their benefits through modulation of immune and metabolic pathways. The reduction in inflammatory biomarkers observed in our study supports the hypothesis that traditional therapies can play a beneficial role in the management of inflammatory bowel diseases. Earlier research has demonstrated that Panchakarma techniques, which include oleation, fomentation, and purgation, help in reducing systemic inflammation by enhancing the body's detoxification processes and modulating the immune response. Similarly, fasting has been associated with metabolic shifts that reduce oxidative stress and inflammation, as evidenced by improvements in inflammatory markers in other chronic conditions. Although our study's sample size was modest, the significant improvements in both biomarker levels and clinical symptoms suggest that these interventions may serve as effective adjunct therapies to conventional treatment in ulcerative colitis. Our study also aligns with emerging literature that underscores the potential of integrative approaches in chronic inflammatory diseases. While conventional pharmacotherapy remains the cornerstone of ulcerative colitis management, the addition of complementary therapies such as Panchakarma and fasting could offer enhanced clinical benefits, particularly in patients who are refractory to or experience adverse effects from standard treatments. The similar improvements in clinical symptom scores and quality of life across both groups further support the potential of these non-pharmacological strategies to improve overall patient well-being. However, several limitations must be acknowledged. The small sample size and short duration of the intervention may limit the generalizability of the findings, and larger, multicenter trials with extended follow-up periods are needed to validate these preliminary observations and assess the sustainability of the benefits. Furthermore, while our study provides evidence of biomarker reduction, the exact mechanisms underlying these effects remain to be elucidated through more detailed biochemical and molecular investigations. In conclusion, the results of this pilot study suggest that both Panchakarma and naturopathic fasting can significantly ameliorate inflammatory processes in ulcerative colitis, warranting further exploration of these traditional therapeutic modalities as adjuncts to conventional treatment. Future research should aim to integrate mechanistic studies and long-term clinical outcomes to

better understand and optimize the use of these interventions in clinical practice

Conclusion

In conclusion, our pilot study demonstrates that both Ayurvedic detoxification (Panchakarma) and naturopathic fasting can significantly reduce key inflammatory biomarkers—C-reactive protein, interleukin-6, and tumor necrosis factor-alpha—in patients with ulcerative colitis. The data reveal that while both interventions lead to marked improvements in biomarker profiles and clinical symptomatology, Panchakarma showed a trend toward slightly greater reductions. These outcomes support the potential of integrating traditional therapeutic modalities with conventional medical treatments to manage inflammation and improve quality of life in ulcerative colitis patients.

The significant improvements observed in clinical indices and quality of life assessments further underscore the therapeutic benefits of these interventions. By modulating immune responses and facilitating metabolic detoxification, both Panchakarma and naturopathic fasting appear to offer complementary pathways to attenuate the inflammatory processes characteristic of ulcerative colitis. However, our study's limited sample size and short intervention duration necessitate cautious interpretation of the results.

Future studies with larger cohorts and longer follow-up periods are essential to validate these findings and to elucidate the underlying biological mechanisms driving the anti-inflammatory effects. Moreover, exploring the integration of these therapies with standard pharmacological approaches could potentially lead to more comprehensive and individualized treatment regimens for patients with chronic inflammatory conditions. Overall, our findings lay the groundwork for further research into the use of traditional and naturopathic interventions as adjuncts in the holistic management of ulcerative colitis.

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