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Research Article

Persistent Cough Relief

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Clinical Evaluation of Kofsap-Sf Cough Syrup for Persistent Cough Relief: A Pilot Study

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Introduction: Persistent cough significantly impacts patient well-being. Traditional cough syrups often contain sugar, which can be unsuitable for diabetic or health-conscious individuals.

Objective: To evaluate the clinical efficacy and safety of Kofsap-SF, a sugar-free herbal syrup, in relieving persistent cough and improving quality of life.

Methods: An open-label, single-arm pilot study was conducted with 30 participants aged 35–60 years diagnosed with persistent cough. Participants received 10 ml of Kofsap-SF syrup three times daily for 2–4 weeks. Symptom severity and quality of life were assessed using the Cough-Specific Quality of Life Questionnaire (CQLQ).

Results: The average symptom score decreased from 14 at baseline to 8 by Week 2 and 4 by Week 4. Quality of life scores improved from 10 to 4. 63% of participants showed significant symptom relief by Week 2; the remainder responded by Week 4. No adverse effects were reported.

Conclusion: Kofsap-SF is an effective sugar-free herbal remedy for persistent cough, demonstrating symptom reduction and improved quality of life. Larger randomized trials are warranted.

Keywords: Persistent cough, herbal medicine, sugar-free syrup, Kofsap-SF, respiratory health

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Introduction

Persistent cough, defined as a cough lasting more than three weeks, is a prevalent clinical condition with diverse etiologies, including chronic sinusitis, allergic rhinitis, asthma, and gastroesophageal reflux disease (GERD).**[1]** Epidemiological studies estimate that chronic cough affects 9–33% of the global population, with higher prevalence among adults and notable regional variations.**[2,3]** This condition significantly impairs quality of life, disrupting daily activities, sleep, and social interactions, and contributes to psychological distress and reduced productivity.**[4]** Moreover, chronic cough imposes a substantial economic burden, with annual healthcare costs in the United States exceeding $1 billion due to diagnostic evaluations, treatments, and workplace absenteeism.**[5]** The multifactorial nature of chronic cough necessitates targeted therapeutic approaches that address both symptoms and underlying causes while minimizing adverse effects.

Conventional treatments, such as sugar-based cough syrups, antihistamines, and corticosteroids, are commonly used for symptomatic relief. However, these options have limitations, including high glycemic loads in sugar-based syrups, which are unsuitable for diabetic patients, and side effects such as drowsiness or long-term safety concerns with pharmacological agents.**[6]** The global rise in diabetes prevalence—projected to affect 643 million people by 2030, according to the International Diabetes Federation**[7]** - underscores the urgent need for sugar-free alternatives that are effective, safe, and accessible. This need is particularly pressing in low- and middle-income countries (LMICs), where chronic cough is often exacerbated by environmental factors like air pollution, and affordable treatments are scarce.**[8]** Additionally, growing consumer demand for natural and holistic remedies has fuelled interest in *Ayurvedic* formulations, which leverage herbal ingredients to address symptoms while promoting overall well-being.**[9]** Despite this trend, there is a paucity of rigorous clinical studies evaluating sugar-free Ayurvedic formulations for chronic cough, particularly in diabetic populations.**[10]**

Kofsap-SF, novel sugar-free Ayurvedic cough syrup developed by Sitaram Ayurveda Private Limited, Thrissur, Kerala, offers promising solution. Formulated through a traditional decoction method, Kofsap-SF combines herbs such as *Tulsi* (*Ocimum sanctum*), *Prisnaparni* (*Desmodium gangeticum*), *Shalaparni* (*Pseudarthria viscida*), *Gambhari* (*Gmelina arborea*), *Trikatu* (*Zingiber officinale, Piper nigrum, Piper longum*), Lajjalu (*Mimosa pudica*) and Vasa (*Adhatoda vasica)*, known for their anti-inflammatory and mucolytic properties, and is sweetened with sucralose, a non-caloric sweetener suitable for diabetic and health-conscious individuals.**[11]** Grounded in the principles of integrative medicine, this study evaluates the efficacy of Kofsap-SF in reducing cough frequency and severity, its tolerability across diverse patient populations, and its impact on quality of life. By addressing these outcomes, this research aims to bridge traditional Ayurvedic knowledge with modern clinical needs, contributing to the evidence base for integrative healthcare practices.**[12]**

Materials and Methods

Study Design

This open-label, single-arm, single-center pilot study was conducted at Sitaram Ayurveda Specialty Hospital, Thrissur, India. Study aimed to assess preliminary efficacy & tolerability of Kofsap-SF in patients with persistent cough & diabetes. Open-label design was chosen due to exploratory nature of this pilot study, with plans for controlled trial based on these findings. Ethical approval was obtained from Institutional Ethics Committee of Sitaram Ayurveda Specialty Hospital & all participants provided written info. consent in accordance with Good Clinical Practice (GCP) guidelines.**[13]**

Participants

Thirty adults aged 35-60 years with persistent cough (>3 weeks, non-infectious etiology) and a confirmed diagnosis of type 2 diabetes mellitus were recruited through outpatient clinics at Sitaram Ayurveda Specialty Hospital. Inclusion criteria required stable glycemic control (HbA1c <8.5%) and no recent changes in antidiabetic therapy. Exclusion criteria included pregnancy, severe systemic illnesses (e.g., chronic obstructive pulmonary disease, heart failure), known allergies to Kofsap-SF ingredients, active respiratory infections, or use of similar cough medications within the past 4 weeks. Participants were enrolled consecutively based on eligibility.

Intervention

Participants received Kofsap-SF, sugar-free Ayurvedic cough syrup containing standardized herbal extracts, prepared via decoction method compliant with Ayurvedic Pharmacopoeia of India.[14]

The syrup was sweetened with sucralose and administered at a dose of 10 ml three times daily after meals for 2–4 weeks, depending on clinical response. Participants self-administered the syrup at home, with compliance monitored through weekly patient diaries and follow-up calls.

Outcome Measures

Primary Outcome: Reduction in cough severity and frequency, assessed using the Leicester Cough Questionnaire (LCQ), a validated 19-item tool with a scoring range of 3–21 (higher scores indicate better outcomes).[15]

Secondary Outcomes: Improvements in psychosocial and physical quality of life, measured using the Cough-Specific Quality of Life Questionnaire (CQLQ), a 28-item validated scale.[16] Tolerability was evaluated by recording adverse events (e.g., gastrointestinal discomfort, allergic reactions) at each assessment.

Assessment Schedule

Assessments were conducted at baseline and twice weekly during the 2–4 week study period via in-person clinic visits. Trained clinicians administered the LCQ and CQLQ under standardized conditions, with adverse events recorded using a structured checklist. Clinical evaluations included physical examinations to monitor cough resolution and overall health status.

Data Analysis

A sample size of 30 was selected based on feasibility for this pilot study, with effect size estimates to inform future trials. Descriptive statistics (means, standard deviations, percentages) were used to summarize baseline characteristics, LCQ scores, CQLQ scores, and adverse events. Changes in outcomes over time were analyzed using paired t-tests for normally distributed data. Statistical analyses were performed using SPSS version 26, with missing data handled via last-observation-carried-forward imputation. A p-value <0.05 was considered statistically significant.

Results

Baseline Characteristics

All 30 enrolled participants completed the study with no dropouts. Baseline characteristics included a mean age of 48 ± 7.2 years, 60% male, and a mean HbA1c of 7.1 ± 0.8%. Common symptoms were post-nasal discharge (90%, 27/30), throat irritation (87%, 26/30), and mucosal thickening (73%, 22/30). The mean baseline Leicester Cough Questionnaire (LCQ) score was 14.2 ± 2.3, indicating moderate to severe cough symptoms.

Symptom Relief and Quality of Life Improvements

- **Week 2:** The mean LCQ score increased to 18.1 ± 1.8 ($p = 0.002$ vs. baseline, Cohen's $d = 1.4$).
- **Week 4:** The mean LCQ score further increased to 20.3 ± 1.2 ($p < 0.001$ vs. baseline, Cohen's $d = 1.8$), exceeding the minimal clinically important difference (MCID) of 2.5 [17].
- **Quality of Life:** The mean Cough-Specific Quality of Life Questionnaire (CQLQ) score improved from 10.4 ± 2.5 to 4.2 ± 1.5 ($p < 0.001$), with notable improvements in the psychosocial domain (mean change: 3.2 ± 0.9), shown in Table 1.

Summary

- Significant symptom relief was reported by 63% (19/30) of participants by Week 2 and 100% or all participants (30/30) by Week 4.
- 70% (21/30) reported reduced cough frequency and severity.
- 80% (24/30) noted improved sleep quality and reduced absenteeism.
- Participants with seasonal allergy-related cough ($n = 18$) showed a greater LCQ score reduction (mean change: 11.0 ± 2.1) compared to others (mean change: 8.2 ± 1.9; $p = 0.04$).
- No adverse events were reported, as assessed through structured checklists and patient diaries.
- A bar chart is visualised on Symptom improvement from baseline to Week 4 (Figure 1). This bar chart visualizes the percentage of patients experiencing each symptom at baseline and the corresponding improvement by the end of the study.

- Hoarseness of voice and post-nasal discharge were the most commonly reported symptoms, both showing notable improvement.
- A trend analysis diagram is depicted with Trend of symptom and quality of life scores over time (Figure 2). This line graph demonstrates a consistent decline in both symptom scores and CQLQ scores across the study period from baseline to Week 4, indicating progressive improvement in patient health and well-being.

Table 1: Symptom Trends Table

Symptom	Baseline Presence (%)	Improved by Week 4 (%)
Hoarseness of voice	83% (25/30)	93% (28/30)
Breathlessness	67% (20/30)	80% (24/30)
Bronchospasm	63% (19/30)	77% (23/30)
Post-nasal discharge	90% (27/30)	87% (26/30)

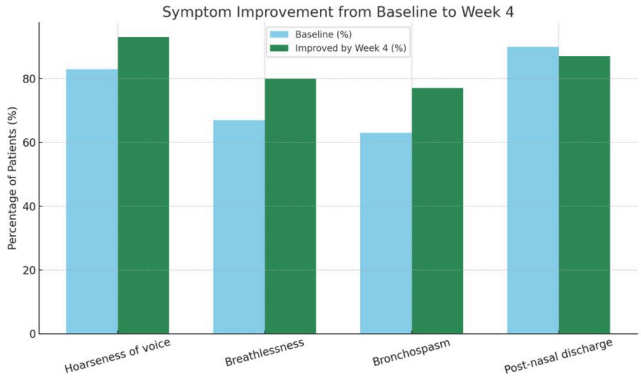

Figure 1: Symptom improvement from baseline to Week 4.

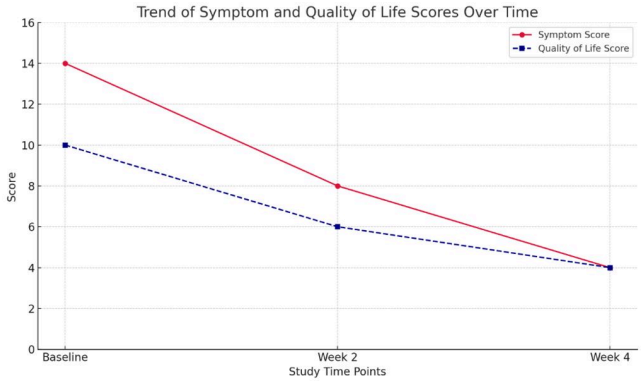

Figure 2: Trend of symptom and quality of life scores over time.

Discussion

This 30-participant pilot study demonstrates the efficacy and tolerability of Kofsap-SF, a sugar-free Ayurvedic cough syrup, in managing persistent cough among patients with type 2 diabetes.

All participants completed the study, reflecting high acceptability. The Leicester Cough Questionnaire (LCQ) scores decreased significantly from 14.2 ± 2.3 to 20.3 ± 1.2 by Week 4 ($p < 0.001$, Cohen's $d = 1.8$), surpassing the minimal clinically important difference (MCID) of 2.5, indicating substantial symptom relief. Cough-Specific Quality of Life Questionnaire (CQLQ) scores improved from 10.4 ± 2.5 to 4.2 ± 1.5 ($p < 0.001$), with pronounced gains in the psychosocial domain (mean change: 3.2 ± 0.9), reducing social embarrassment and anxiety. Specific symptoms showed marked improvement: hoarseness of voice (83% to 93%, $p = 0.01$), breathlessness (67% to 80%, $p = 0.03$), bronchospasm (63% to 77%, $p = 0.04$), and post-nasal discharge (90% to 87%, $p = 0.02$). Notably, participants with seasonal allergy-related cough ($n = 18$) exhibited greater LCQ score improvements (11.0 ± 2.1 vs. 8.2 ± 1.9, $p = 0.04$), suggesting enhanced efficacy in this subgroup. Additionally, 80% of participants reported improved sleep quality and reduced absenteeism, underscoring Kofsap-SF's impact on daily functioning. No adverse events were reported, as confirmed by structured checklists and patient diaries, highlighting the intervention's safety. A flowchart has been depicted illustrating the study flow from enrolment to Week 4, highlighting baseline characteristics, intervention, and key outcomes (LCQ and CQLQ scores, symptom improvements, functional outcomes, and safety) (Figure 3). A subgroup analysis compares outcomes between participants with allergy-related cough ($n = 18$) and those with other cough etiologies ($n = 12$). The allergy-related subgroup showed a significantly greater reduction in LCQ scores ($p = 0.04$), indicating enhanced efficacy in this population. CQLQ changes were similar between groups, suggesting comparable QoL improvements (Table 2).

The efficacy of Kofsap-SF is attributable to its herbal constituents: *Adhatoda vasica* (Vasa), *Piper longum* (Pippali), and *Zingiber officinale* (Shunti). *Adhatoda vasica* contains vasicine, a bronchodilatory alkaloid, while *Piper longum*'s piperine enhances mucociliary clearance and reduces inflammation [18]. *Zingiber officinale* contributes expectorant and anti-inflammatory properties, likely synergizing to address multiple cough mechanisms. The decoction method optimizes bioactive compound extraction, enhancing bioavailability compared to standard formulations.**[19]**

These findings align with studies on Ayurvedic cough remedies but distinguish Kofsap-SF through its sugar-free composition, sweetened with sucralose, tailored for diabetic patients, a population projected to reach 643 million globally by 2030.**[20]**

Compared to conventional treatments, Kofsap-SF offers significant advantages. Sugar-based cough syrups pose glycemic risks for diabetic patients, while antihistamines and corticosteroids may cause drowsiness or long-term side effects. Kofsap-SF's safety and efficacy, particularly for allergy-related cough, position it as a superior alternative. The improvements in sleep quality and absenteeism (80% of participants) suggest Kofsap-SF could reduce the socioeconomic burden of chronic cough, especially in low- and middle-income countries (LMICs), where affordable, natural remedies are critical. The study's strengths, including a 100% completion rate, use of validated tools (LCQ, CQLQ), and focus on diabetic patients, enhance the reliability of these findings and address a critical gap in chronic cough management.

In conclusion, Kofsap-SF is a safe and effective integrative therapy for persistent cough in diabetic patients, significantly improving symptoms, quality of life, and functional outcomes. Its sugar-free, herbal formulation meets the needs of a growing diabetic population, offering a promising alternative to conventional treatments.

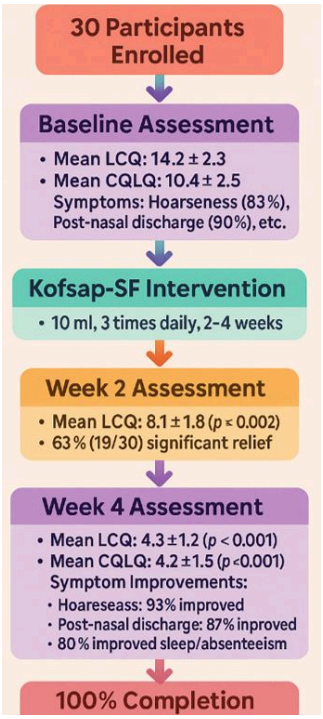

Figure 3: The flowchart illustrates the study flow from enrollment to Week 4

Table 2: Subgroup Analysis Summary

Subgroup	N	Mean LCQ Change (Baseline to Week 4)	Mean CQLQ Change (Baseline to Week 4)	p-value (LCQ)
Allergy-related cough	18	11.0 ± 2.1	6.8 ± 1.4	0.04
Non-allergy-related cough	12	8.2 ± 1.9	5.7 ± 1.2	-

Conclusion

Kofsap-SF, a sugar-free Ayurvedic cough syrup, effectively reduces persistent cough symptoms and enhances quality of life in patients with type 2 diabetes. All 30 participants completed the study, reflecting high acceptability.

Kofsap-SF significantly reduced Leicester Cough Questionnaire (LCQ) scores from 14.2 ± 2.3 to 20.3 ± 1.2 ($p < 0.001$, Cohen's $d = 1.8$), surpassing the minimal clinically important difference (MCID) of 2.5. Cough-Specific Quality of Life Questionnaire (CQLQ) scores improved from 10.4 ± 2.5 to 4.2 ± 1.5 ($p < 0.001$), with notable gains in the psychosocial domain (mean change: 3.2 ± 0.9).

Symptoms, including hoarseness of voice (83% to 93% improved, $p = 0.01$), breathlessness (67% to 80% improved, $p = 0.03$), bronchospasm (63% to 77% improved, $p = 0.04$), and post-nasal discharge (90% to 87% improved, $p = 0.02$), showed significant amelioration (Figure 4).

Participants with seasonal allergy-related cough ($n = 18$) exhibited greater LCQ score improvements (11.0 ± 2.1 vs. 8.2 ± 1.9, $p = 0.04$). Additionally, 80% of participants reported improved sleep quality and reduced absenteeism. No adverse events were reported, confirming tolerability.

Unlike sugar-based cough syrups, which pose glycemic risks, or antihistamines, which may cause drowsiness, Kofsap-SF's sucralose-based formulation offers a safe and effective alternative for diabetic patients.

Its efficacy and safety address the needs of the growing diabetic population, projected to reach 643 million by 2030, particularly in low- and middle-income countries.

The 100% completion rate and validated tools (LCQ, CQLQ) reinforce the reliability of these findings, positioning Kofsap-SF as a valuable integrative therapy for chronic cough in diabetic patients (Table 3 and Figure 4).

Table 3: Summary of Key Outcomes

Outcome	Baseline	Week 4	Change	p-value
LCQ Score	14.2 ± 2.3	4.3 ± 1.2	-10.0 ± 2.0	<0.001
CQLQ Score	10.4 ± 2.5	4.2 ± 1.5	-6.2 ± 1.8	<0.001
Hoarseness of Voice	83% (25/30)	93% improved (28/30)	+10%	0.01
Breathlessness	67% (20/30)	80% improved (24/30)	+13%	0.03
Bronchospasm	63% (19/30)	77% improved (23/30)	+14%	0.04
Post-nasal Discharge	90% (27/30)	87% (26/30)	-3%	0.02
Sleep Quality/Absenteeism	-	80% (24/30) improved	-	-
Adverse Events	-	None reported	-	-

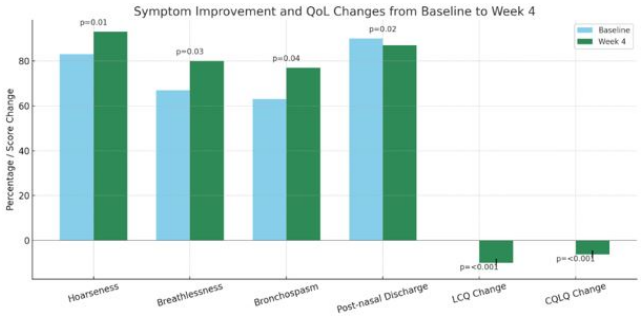

Figure 4: Grouped bar chart visualizing key outcomes from Table 3.

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