Innovative Research in Applied, Biological, and Chemical Sciences

ISSN: 3005-8449

INNOVATIVE RESEARCH JOURNALS

Research Article **IRABCS, vol. 3, issue 1, pp. 41-45, 2025**

Received: May 29, 2025
Revised: June 16, 2025
Accepted: June 16, 2025
https://doi.org/10.62497/irabcs.132

Efficacy of Ivy Leaf Extract Syrup in Managing Bronchial Asthma among Children: A Prospective Observational Study

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How to cite: Maqbool A, Khan MZ, Sania Begum SB, Kiran A. Efficacy of Ivy Leaf Extract Syrup in Managing Bronchial Asthma Among Children. IRABCS. 2025; 3(1):41-45. DOI: https://doi.org/10.62497/irabcs.132 Available from: https://irjpl.org/irabcs/article/view/132

Abstract

Introduction: Bronchial asthma is a common chronic respiratory disorder in children, and there is growing interest in exploring herbal therapies such as ivy leaf extract for symptom relief.

Objective: To evaluate the clinical efficacy and safety of dry extract of ivy leaves in children aged 7 to 12 years diagnosed with mild to moderate bronchial asthma.

Methodology: This prospective observational study was conducted at the Department of Pediatric Medicine, Pakistan Institute of Medical Science (PIMS), Islamabad, in collaboration with the International Islamic University, Islamabad, from August 2023 to July 2024. A total of 120 children with clinically stable bronchial asthma were enrolled using convenience sampling. All participants received a standardized dry ivy leaf extract syrup at a total daily dose of 105 mg, administered in age-appropriate doses for four weeks. Asthma symptoms were assessed using a standardized pediatric asthma control scoring tool at baseline and post-treatment. Adverse effects were monitored using structured checklists and open-ended questionnaires completed by caregivers. Statistical analysis was performed using SPSS version 26.0, with paired t-tests to assess symptom changes.

Results: The mean weekly frequency of daytime symptoms decreased from 4.58 ± 1.42 to 2.01 ± 1.18 ($p<0.001$), nocturnal awakenings reduced from 2.77 ± 1.11 to 1.05 ± 0.84 ($p<0.001$), and limitation in physical activity improved from 3.20 ± 1.03 to 1.35 ± 0.76 ($p<0.001$). Full compliance was observed in 108 (90.00%) patients. Adverse effects were minimal, with 101 patients (84.17%) reporting none; the most common were mild gastrointestinal discomfort in 10 patients (8.33%) and allergic rash in 5 patients (4.17%).

Conclusion: Dry ivy leaf extract syrup may be a well-tolerated and potentially effective adjunct for symptom relief in children with mild to moderate bronchial asthma. However, due to the observational design, causal inferences should be made cautiously, and further randomized controlled trials are recommended.

Keywords: Bronchial asthma, ivy leaf extract, children, herbal therapy, asthma control, pediatric respiratory care.

Introduction

One of the most common long-term respiratory conditions in children is bronchial asthma, which is characterised by frequent bouts of coughing, wheezing, chest tightness, and shortness of breath [1]. Paediatric healthcare is facing a major challenge as a result of its expanding worldwide prevalence, especially in low- and middle-income nations where access to specialised treatment is restricted, making illness management even more difficult [2]. Many children nevertheless suffer from chronic symptoms, adverse drug reactions, or poor compliance with long-term treatment plans, even with advances in pharmacotherapy, such as inhaled corticosteroids and bronchodilators [3].

Complementary and plant-based treatments have gained popularity in recent years as supplements to traditional asthma therapy [4]. Among them, the expectorant, bronchodilatory, and anti-inflammatory qualities of the dry extract of ivy leaves (Hedera helix) have garnered interest [5]. The plant's leaves are the main source of this herbal treatment, which is high in saponins, especially α-hederin, which are thought to increase the generation of surfactants and encourage the relaxing of bronchial smooth muscles [6]. Many European nations utilise the dry extract extensively to treat both acute and chronic bronchitis, and its safety profile in children is usually seen to be good [7].

Ivy leaf extract may aid children with bronchial problems by reducing cough frequency, improving mucus clearance, and alleviating respiratory symptoms, according to a number of observational

studies and clinical trials [8]. However, little is known about the precise effectiveness of its dry extract formulation in treating paediatric bronchial asthma, particularly in varied populations where lifestyle, environmental, and genetic variables may affect treatment results [9]. Furthermore, standardised data on the best dose, length of therapy, and degree of symptom improvement when administered as a supplement to routine care in children with asthma are lacking [10].

It is crucial to investigate the therapeutic potential of ivy leaf extract via methodologically sound clinical research given the growing trend towards incorporating natural treatments into traditional paediatric respiratory care.

Research Objective

To evaluate the clinical efficacy of the dry extract of ivy leaves in reducing asthma symptoms in children diagnosed with bronchial asthma.

Materials and methods

Study Design and Setting

This prospective observational study was conducted at the Department of Pediatric Medicine, Pakistan Institute of Medical Science (PIMS), Islamabad, in collaboration with the International Islamic University, Islamabad, from August 2023 to July 2024.

Inclusion and Exclusion Criteria

According to the Global Initiative for Asthma (GINA) standards, children between the ages of 7 and 12 who had a clinical diagnosis of mild to moderate bronchial asthma were deemed eligible to participate. Participants were limited to individuals in stable clinical conditions with signed informed permission from their parents or legal guardians. Children who were enrolled in another clinical study at the time of recruitment, had severe or uncontrolled asthma that required hospitalisation, or had coexisting chronic respiratory or cardiac disorders were not allowed to participate.

Sampling and Sample Size

Convenience sampling was used to register 120 kids from the eligible outpatient population. The single-center design and the goal of including every consecutive patient who satisfied the inclusion criteria over the research period served as the justification for using convenience sampling. This approach, while practical for real-world settings, may introduce selection bias and is acknowledged as a limitation of the study. Nonetheless, the selected sample size was judged sufficient to detect any clinical changes and is in line with other observational studies looking at plant-based therapy in paediatric asthma [11].

Data Collection

Baseline clinical and demographic information, including age, sex, history of asthma, intensity of symptoms, and usage of concomitant medications, was gathered at enrolment. For four weeks, each child received 105 mg of dried ivy leaf extract syrup daily, divided into age-appropriate doses. The syrup used was a standardized commercial preparation of ivy leaf extract, produced by a GMP-certified pharmaceutical company in Pakistan. Asthma symptoms were assessed using the Childhood Asthma Control Test (C-ACT), a validated tool for children aged 4–11 years, to evaluate the frequency of symptoms, nocturnal awakenings, and physical activity limitations at baseline and post-treatment clinical evaluations. Parental reporting was used to track treatment compliance. At every follow-up visit, careers completed both an open-ended questionnaire and a standardized checklist to evaluate adverse effects. The attending pediatrician recorded and evaluated any reported adverse events—such as gastrointestinal distress, allergic reactions, or behavioral changes—to determine severity and causality.

Statistical Analysis

Data were analyzed using IBM SPSS version 26.0. Descriptive statistics were calculated for demographic and baseline clinical characteristics. Changes in symptom scores before and after treatment were assessed using paired t-tests. A p-value of less than 0.05 was considered statistically significant.

Ethical Approval

Ethical approval for this hospital-based study was obtained from the Institutional Review Board (IRB) of the International Islamic University, Islamabad, prior to data collection at the Department of Pediatric Medicine, Pakistan Institute of Medical Science (PIMS), Islamabad. All procedures were performed in accordance with the ethical standards of the Declaration of Helsinki. Written informed consent was obtained from the parents or legal guardians of all participants.

Results

The study included 120 children aged 7 to 12 years with bronchial asthma (table 1). Most participants were in the 9–10-year age group (n = 44, 36.67%), followed by 11–12 years (n = 40, 33.33%) and 7–8 years (n = 36, 30.00%). Males constituted a slight majority (n = 68, 56.67%) compared to females (n = 52, 43.33%). Regarding asthma duration, over half had been diagnosed for 1–3 years (n = 67, 55.83%), while 32 children (26.67%) had asthma for more than 3 years and 21 (17.50%) for less than one year. In terms of asthma severity, 76 children (63.33%) had mild asthma, and 44 (36.67%) had moderate asthma. Concurrent medication use varied, with 50 patients (41.67%) using inhaled β2-agonists only, 35 (29.17%) using inhaled corticosteroids with or without long-acting β-agonists (LABA), and 35 (29.17%) not using any concurrent medication.

Table 1: Baseline Demographic and Clinical Characteristics of Participants (n = 120)

Characteristic	Category	Number of Patients (n;%)
Age Group (years)	7–8	36 (30.00)
	9–10	44 (36.67)
	11–12	40 (33.33)
Sex	Male	68 (56.67)
	Female	52 (43.33)
Asthma Duration (years)	<1 year	21 (17.50)
	1–3 years	67 (55.83)
	>3 years	32 (26.67)
Severity of Asthma	Mild	76 (63.33)
	Moderate	44 (36.67)
Concurrent Medication Use	None	35 (29.17)
	Inhaled β2-agonists only	50 (41.67)
	Inhaled corticosteroids ± LABA	35 (29.17)

After four weeks of treatment with dry ivy leaf extract syrup, significant improvements were observed across all measured symptom domains (table 2). The mean frequency of daytime asthma symptoms per week decreased from 4.58 ± 1.42 to 2.01 ± 1.18, showing a mean reduction of 2.57 episodes ($p < 0.001$). Nocturnal awakenings reduced from a mean of 2.77 ± 1.11 to 1.05 ± 0.84, a mean improvement of 1.72 awakenings per week ($p < 0.001$). Similarly, limitations in physical activity decreased from a mean score of 3.20 ± 1.03 at baseline to 1.35 ± 0.76 after treatment, reflecting a mean reduction of 1.85 points ($p < 0.001$). These findings indicate a statistically significant clinical benefit from the intervention.

Table 2: Changes in Pediatric Asthma Control Symptoms before and After 4-Week Treatment with Ivy Leaf Extract Syrup (n = 120)

Symptom Domain	Baseline Mean ± SD	Post-Treatment Mean ± SD	Mean Difference	95% CI	p-value
Daytime Symptom Frequency (per week)	4.58 ± 1.42	2.01 ± 1.18	-2.57	-2.82 to -2.32	<0.001
Nocturnal Awakenings (per week)	2.77 ± 1.11	1.05 ± 0.84	-1.72	-1.91 to -1.53	<0.001
Limitation in Physical Activity (score)*	3.20 ± 1.03	1.35 ± 0.76	-1.85	-2.04 to -1.66	<0.001

Abbreviations: SD = standard deviation; CI = confidence interval
p-values reflect results from paired t-tests comparing baseline and post-treatment scores.
Limitation in Physical Activity Score: Measured on a 5-point Likert scale (1 = no limitation; 5 = severe limitation).

Treatment compliance was high among the participants, with 108 children (90.00%) achieving full compliance and 12 (10.00%) reporting partial adherence over the 4-week treatment period (table 3). Adverse effects were minimal; the majority of children (n = 101, 84.17%) reported no side effects. Among the 19 children (15.83%) who did report adverse events, 10 (8.33%) experienced mild gastrointestinal upset, 5 (4.17%) developed an allergic rash, and 4 (3.33%) showed behavioral changes such as irritability. No severe or treatment-discontinuing adverse events were observed, indicating good tolerability of the dry ivy leaf extract syrup.

Table 3: Treatment Compliance and Reported Adverse Effects (n = 120)

Parameter	Category	n (%)
Compliance to Treatment	Full compliance	108 (90.00%)
	Partial compliance	12 (10.00%)
Reported Adverse Effects	None	101 (84.17%)
	Gastrointestinal upset	10 (8.33%)
	Allergic rash	5 (4.17%)
	Behavioral changes (e.g., irritability)	4 (3.33%)

Discussion

The clinical effectiveness and safety of dry ivy leaf extract syrup in children with mild to moderate bronchial asthma, ages 7 to 12, were the focus of this investigation. After a 4-week course of therapy, we found that asthma control metrics significantly improved, with few side effects and great treatment compliance.

The decrease in the frequency of daytime symptoms from a baseline mean of 4.58 ± 1.42 episodes per week to 2.01 ± 1.18 ($p < 0.001$) indicates that ivy leaf extract has a significant symptom-relieving and bronchodilatory impact. These findings are consistent with a previous research that found that children with respiratory disorders who received ivy

extract syrup saw a substantial decrease in the frequency and intensity of their coughs [12]. Similarly, while that research did not directly address asthma, another prospective investigation found that ivy leaf treatment improved symptoms in paediatric bronchitis patients [13]. Our results add to this body of data by demonstrating its effectiveness in treating paediatric asthma.

An essential measure of asthma management, nocturnal awakenings, dropped from a mean of 2.77 ± 1.11 to 1.05 ± 0.84 incidents per week ($p < 0.001$), confirming the extract's ability to enhance sleep and lessen bronchospasm at night. This result supports previous findings that α-hederin, a major active saponin in ivy extract, promotes bronchodilation and prevents airway spasms brought on by histamine [14]. Our findings point to a wider therapeutic utility in paediatric asthma, despite the fact that earlier research often focused on acute bronchitis or persistent cough.

There was a substantial improvement in physical activity restriction ratings, which decreased from 3.20 ± 1.03 to 1.35 ± 0.76 ($p < 0.001$), suggesting increased exercise tolerance and less exhaustion from asthma. These results are consistent with an observational research that showed children using ivy-based medications for respiratory problems had improved lung function and less activity limitation [15].

Ninety percent of subjects showed complete compliance with therapy, indicating good adherence. This good adherence was probably facilitated by the syrup composition and the regimented dosage. Furthermore, only 15.83% of patients had negative side effects, including minor and self-limiting gastrointestinal distress (8.33%), allergic rash (4.17%), and behavioural abnormalities (3.33%) recorded. Gastrointestinal symptoms may be attributed to the saponin content in ivy leaf extract, particularly α-hederin, which can mildly irritate the gastric mucosa in some children. Allergic skin reactions such as rash could result from hypersensitivity to herbal compounds or syrup preservatives. Behavioral changes may reflect mild discomfort or reporting variability, rather than a direct pharmacologic effect. Data from earlier research, which indicated that ivy leaf extract was well tolerated in paediatric populations, is in line with this safety profile [16,17].

Our results lend credence to the idea that dry ivy leaf extract is a safe and effective supplementary treatment for children with asthma. Additional randomized controlled studies are required to confirm these findings and investigate long-term effects.

Study Strengths and Limitations

This study's real-world, prospective design is one of its main advantages as it made it possible to gather data in a typical clinical situation, which improved the results' generalizability. Treatment response was measured objectively and quantitatively via the use of a standardized scoring method for paediatric asthma management. The safety evaluation is also given more legitimacy by the inclusion of a clearly defined paediatric age range (7–12 years) and thorough monitoring of adverse effects using both structured checklists and open-ended carer feedback. The lack of a control group, one of the study's shortcomings, limits the ability to draw conclusions about the effectiveness of ivy leaf extract. The single-center arrangement restricts wider application, and the convenience sampling approach may add selection bias. The absence of blinding may have introduced observer or participant bias, and reliance on parental reporting introduces the potential for recall or reporting bias. Additionally, normality testing for the paired t-test was not performed, which limits formal confirmation of statistical assumptions. The short follow-up duration also restricts the assessment of sustained treatment effects or long-term safety.

Conclusion

Children with mild to moderate bronchial asthma who take dry ivy leaf extract syrup for four weeks report significantly better asthma symptoms, including fewer nocturnal awakenings, decreased frequency of symptoms during the day, and increased tolerance to physical activity. With a high rate of compliance and few, mild side effects, the medication was well tolerated. According to these results, dried ivy leaf extract may be a safe and useful supplement to traditional asthma treatment in children, which calls for further research in randomized controlled study with longer follow-up periods.

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