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Original Research Article

Therapeutic effects of Asafoetida (*Ferula foetida* oleo-gum-resin) on lung function tests, clinical symptoms, and blood parameters in asthmatic patients

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Abstract

Objective: Asthma is a common chronic disease with a wide global prevalence. In this disease, airway inflammation causes multiple attacks of wheezing. Treatment of asthma with chemical drugs has many complications. Therefore, researchers have recently focused on the use of medicinal plants for the treatment of asthma. So, the present study investigates the therapeutic effects of Asafoetida (*Ferula foetida* oleo-gum-resin) on asthma.

Materials and Methods: The present study was done in two groups of stable severe asthmatic patients: one group was treated with Asafoetida (n=39, 300 mg capsules daily, oral) and the other with placebo (n=35, 300 mg capsules daily, oral) for one month. Respiratory symptoms, pulmonary function tests (PFT), Asthma control test (ACT) score, total and differential blood cell counts, and blood biochemical factors, were examined before and at the end of the 30-day treatment with asafoetida or placebo consumption.

Results: The results indicated no statistically significant difference in the incidence of complications between the two groups. The mean ACT score in the both treated groups one month after initiation of the treatment was significantly increased compared to baseline ($p<0.001$ for both cases). The percent change of ACT score was significantly higher in the asafoetida group compared to the placebo group ($p<0.05$). Treatment with asafoetida also significantly improved wheezing ($p<0.001$) and decreased forced vital capacity (FVC) ($p<0.001$). Consumption of asafoetida did not affect serum lactate dehydrogenase (LDH) level or serum leukocyte level.

Conclusion: According to these results, treatment with asafoetida improved respiratory symptoms and ACT score in patients with stable severe asthma. However, further clinical studies are needed to investigate the therapeutic potential of this plant in the treatment of asthma.

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Introduction

Asthma is a chronic respiratory tract inflammation, and it is characterized by airway remodeling, and reversible airflow limitation. According to the World Health Organization Guidelines for the Diagnosis and Treatment of Asthma (GINA), this disease imposes a burden on patients, families, and society. Approximately 334 million people worldwide suffer from this disease. The highest prevalence of asthma in Iran is in Tehran at 35.4% and the lowest prevalence is in Kermanshah at 1% (Varmaghani et al. 2016; Zobeiri 2011). People with asthma may rarely experience asthma attacks under normal circumstances. These people often have asthma attacks during exercise, strenuous activity, and exposure to microbes, industrial products, and other environmental and occupational allergens (Fahy 2001). Symptoms of asthma vary from person to person but generally include shortness of breath, wheezing during exhalation, phlegm, chest tightness, sleep problems, and in severe cases, difficulty breathing (Asher et al. 2017). The main characteristic of respiratory tract involvement in asthmatic patients is inflammation (Zhang et al. 2019) which occurs due to the action of various inflammatory cells including leukocytes and inflammatory cytokines. Inflammatory changes in the respiratory tract lead to tissue damage, epithelial structural changes, and cell necrosis (Li et al. 2023; Wark et al. 2002). These structural changes include epithelial cell shedding and accumulation in the airway lumen, collagen deposition under the epithelium, thickening of the basement membrane, airway smooth muscle hyperplasia and hypertrophy, increased blood vessel number, and mucosal hyperplasia (Chanez 2005; Murdoch and Lloyd 2010; Zhang et al. 2019). In bronchial biopsies obtained from individuals with asthma, leukocyte infiltration and plasma-derived proteins, such as lactate dehydrogenase (LDH), were observed (Barnes 2008; Wark et al. 2002).

The main feature of diagnosing inflammation in asthma is the identification of various inflammatory biomarkers, including white blood cells (WBC). Moderate to severe asthma may be associated with bacterial and viral infections (Asseri 2024). In addition, in advanced asthma, the symptoms are breathing difficulties, and severe wheezing during exhalation (Asher et al. 2017). Difficulty in breathing is determined by spirometry and lung function tests including forced vital capacity (FVC) and forced expiratory volume in the first second (FEV1). These two factors represent the percentage of lung size at expiration, and reduction of these parameters indicate airway obstruction (Sharifi et al. 2016). Wheezing during exhalation is caused by spasms of the respiratory tract (Asher et al. 2017). In asthma, inflammation is caused by damage to lung cells, and increasing their permeability causes edema. These factors cause cell necrosis and disruption of cell integrity, leading to elevated blood levels of LDH (Al Obaidi et al. 2009; Wark et al. 2002). The asthma control test (ACT) questionnaire is a validated Persian questionnaire used to assess the severity and type of asthma in individuals (Sharifi et al. 2016). By diagnosing the type and severity of asthma, individuals are placed under various care to control the disease. Two important principles in the asthma treatment are avoiding contact with antigens and timely use of medicines (Gross 2006). The use of chemical drugs in the treatment of asthma has numerous side effects including increased heart rate, osteoporosis, thinning of the skin, cataracts, glaucoma, hives, high blood pressure, and growth suppression in babies (Dahl 2006; Kaur and Singh 2018). Therefore, researchers are now focusing on using medicinal plants to treat various diseases including respiratory diseases (Yamauchi 2006).

The relationship between plant compounds and respiratory diseases based on inflammatory processes including

asthma, has been widely revealed. The effective compounds of these plants exert their inhibitory and self-regulatory effects on the modulation of the inflammatory process by affecting various inflammatory molecular pathways (Iranshahy and Iranshahi 2011). The genus *Ferula* includes medicinal plants that have strong therapeutic effects on inflammatory diseases (Chanez 2005). This genus belongs to the Apiaceae family. This family consists of 140 species with a wide distribution from the Mediterranean to east Asia. One of the most important species of this plant is *Ferula foetida* (*F. foetida*) which is native to Iran. A part of the *F. foetida* with potential therapeutic effects is a resin called asafoetida (Takeoka 2001). Asafoetida has antispasmodic, digestive, expectorant, sedative, analgesic, and antiseptic effects in Iranian traditional medicine (Farhood 2022; Iranshahy and Iranshahi 2011). This plant also has numerous therapeutic uses in the traditional medicine, including in the treatment of asthma, bronchitis, epilepsy, influenza, gastrointestinal disorders (Homer and Elias 2005), whooping cough, tuberculosis (Kavoosi and Rowshan 2013), and angina pectoris (Bagheri et al. 2016; Latifi et al. 2019; Tripathi et al. 2019).

At present, with the advancement of science, clinical studies on the therapeutic effects of various plants have received much attention. Given that no clinical trial has been conducted to date on the effect of *F. foetida* oleo-gum-resin on improving respiratory function in asthmatic patients, the present study examined the efficacy of gum of this plant on improving respiratory disorders in patients with stable severe asthma.

Materials and Methods

Study design

The present study was conducted as a double-blind clinical study on patients with stable severe asthma from May 4, 2024, to June 5, 2024, at the Dr. Majid Mirsadraei respiratory medicine Clinic in Mashhad. This study was approved by the Ethics Committee with the Research Trials Council (IRCT) of Damghan University of Medical Sciences with the code IRCT20210909052420N1. The study conditions were clearly explained to the patients, and informed consent was obtained from them.

Patients

In this study, a total 102 patients were randomized into two groups (45 patients in the placebo group and 57 patients in the Asafoetida group) after singing a consent form for participation in the study. Follow-up data were available for 37 patients in the placebo group and 46 patients in the Asafoetida group. The final analysis included 35 and 39 patients, respectively, based on available data. Participant flow is shown in Figure 1. During the study, some patients lost eligibility criteria and were withdrawn from the study. Moreover, some participants discontinued consumption of the treatments due to adverse events, while others declined to continue their participation.

Inclusion and exclusion criteria

The inclusion criteria for the study are based on the diagnosis of asthma according to the GINA (Venkatesan 2023). Exclusion criteria included having systemic diseases, use of other medications with antioxidant properties, use of herbal medicine, intolerance to the side effects of Asafoetida (nausea, vomiting, diarrhea, etc.), having inflammatory, autoimmune, or liver diseases or immune system deficiencies, or pregnancy.

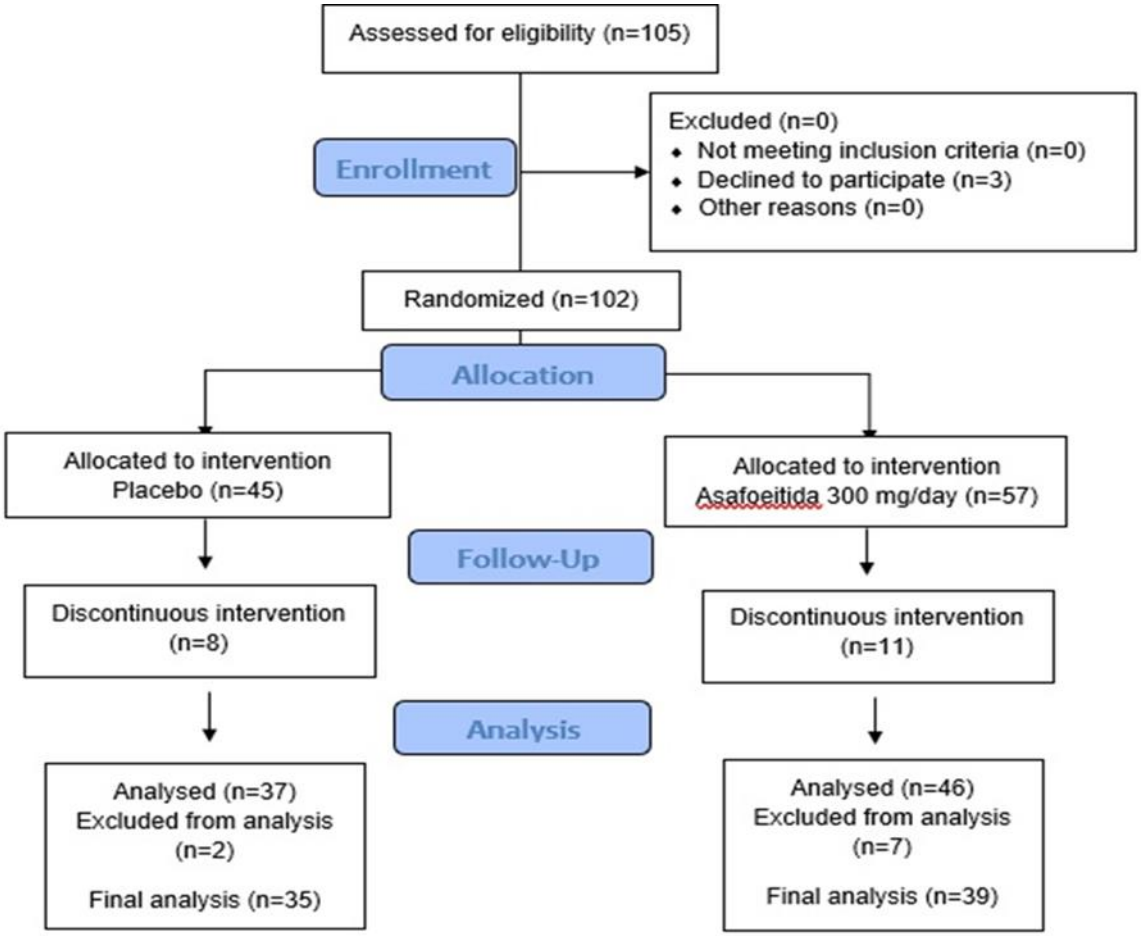


Figure 1. CONSORT flow diagram of the study

Randomization

The subjects in this study were enrolled using a block randomization method based on the inclusion criteria. The subjects were randomly assigned to two groups: placebo and asafoetida. Patient selection and randomization were performed by colleagues who were not familiar with the clinical issues and details of the present study. The results were analyzed by a statistical analyst without knowing the groups.

Intervention

In this study, the gum prepared from the *F. foetida* was formulated and, after the necessary controls, formulated into 300 mg capsules. The selected dose was chosen based on the clinical trial conducted by Hasanpour et al. (Hasanpour et al. 2022). The asafoetida and placebo groups were treated with a 300 mg asafoetida capsule or 300 mg placebo capsule once daily for one month, respectively. During the study, the patients also received their ordinary medications. The study was conducted under the supervision of a pulmonologist.

Disease symptoms and side effects

Asthma control was assessed using the Asthma control test (ACT) questionnaire, a validated, patient-completed questionnaire consisting of five items evaluating symptoms. Each item is scored from 1 to 5, with a total score 5 to 25. Higher scores indicate better asthma control. In addition to the total ACT score, asthma symptoms including the presence of wheezing were recoded. Possible side effects of the drug were checked by phone every other week, and patients with side effects and cases of asthma recurrence and exacerbation were excluded from the study.

Spirometry evaluation

In all patients participating in the study, pulmonary function tests including FVC and FEV1, were measured by a trained technician under the supervision of a pulmonologist physician using a spirometer device (Roma, Italy) before and at the after the end of the treatment.

Laboratory evaluation

In this study, 2 ml of blood were collected from the brachial vein of the subjects before and at the end of the trial. One milliliter of the blood sample was poured into a tube containing K3 EDTA to count the types of leukocytes including WBC, neutrophils, lymphocytes, eosinophils, and monocytes. Another 1 ml was transferred to a tube without anticoagulant to check the serum LDH level (U/L).

Data collection

All patient data, including age, gender, medical history, type of medication used, lung function tests, and symptoms, including wheezing were recorded in the patient's chart.

Statistical analysis

The data analysis was performed using SPSS version 26 software. Data is presented as means (±standard deviation) or frequencies (percentages). The normality of quantitative variables was determined by the Kolmogorov-Smirnov test. For categorical variables, the Pearson chi-squared test was applied. A comparison between the studied groups was performed for quantitative variables using Mann-Whitney test and independent sample t-test, depending on the normality of data distribution. According to the normality of the distribution, data were compared during two steps in each group using Wilcoxon test and paired sample t-test, respectively. Also, the proportion of patients with wheezing before and after treatment in each group was compared using McNemar test. A $p<0.05$ was considered significant for all statistical analyses.

The percent change in each parameter during treatment period was calculated as:

$$\text{Percent change} = \frac{(\text{value after treatment} - \text{value before treatment})}{\text{value before treatment}} \times 100$$

Results

Baseline demographic characteristics were presented in Table 1 for all randomized patients (n=102), as no dropouts had occurred at the time of randomization. However, outcome analyses were conducted on patients who completed treatment period (n=74). In the asafoetida group, there were 37 (64.9%) females and 20 (35.1%) males, and in the placebo group, 26 (57.8%) females and 19 (42.2%) males. The mean age of asthmatic patients in the asafoetida group was 55.56±14.91 years and in the placebo group 56.49±14.29 years. Measured variables were not significantly different between the two groups before starting treatment (Table 1).

Table 1. Demographic characteristics of the patients in studied groups

Variables		Groups		p-value
		Placebo group	Asafoetida group	
Sex, N(%)	Male	19 (42.2)	20 (35.1)	0.595[a]
	Female	26 (57.8)	37 (64.9)	
Age (year), Mean±SD		56.49±14.29	55.56±14.91	0.751 [b]

[a] Pearson Chi-Square. [b] Independent Samples Test

The effect of Asafoetida on clinical symptoms and adverse events

Number of patients with wheezing was significantly reduced in both groups at the end of the trial compared with before treatment ($p<0.001$ in both cases, Figure 2). The proportion of patients who experienced improvement in wheezing (i.e. who had wheezing at baseline but not after treatment) was significantly higher in the asafoetida group than the placebo group ($\chi^2= 4.257$, $p=0.039$).

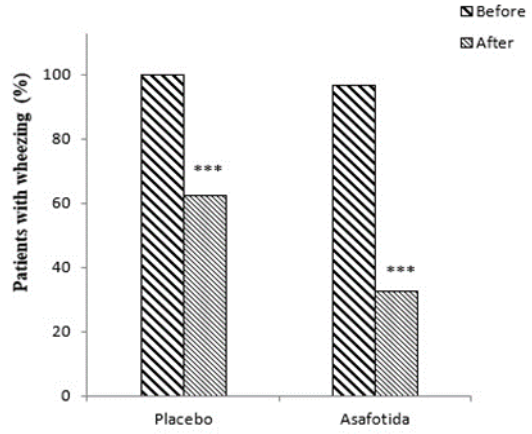


Figure 2. Number of patients with wheezing before and at the end of the trial in placebo and Asafoeitida groups. Values are presented as percent. Statistical analyses were performed using the McNemar Test. ***p<0.001, between the groups treatment compared to baseline.

The mean ACT score in the both treated groups at the end of the trial was significantly increased compared to baseline ($p<0.001$ in both cases, Figure 3). The percentage increase in ACT score after treatment relative to before treatment in the asafoetida group was significantly higher than the placebo group ($p<0.05$, Table 2).

Seven patients in the asafoetida group and 1 patient in the placebo group showed complications which were not statistically different between the two groups ($\chi^2=2.422$, $p=0.120$). The reported adverse events consisted mainly of gastrointestinal problems, including reflux, constipation and halitosis. Participants who developed these events were withdrawn from the trial.

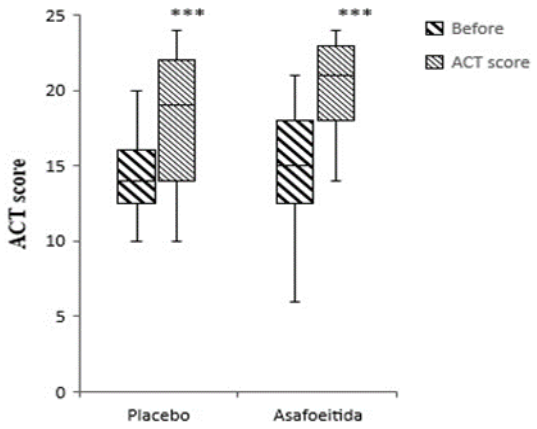


Figure 3. ACT score in placebo and Asafoeitida groups before and at the end of the trial. Values are presented as median (interquartile range). Statistical analyses were performed using the Wilcoxon signed ranks test. ***p<0.001, after treatment compared to baseline. ACT: Asthma Control Test.

The effect of Asafoetida on LDH

The LDH level after treatment, in the placebo group (340.889±53.315 (U/L)) was not significantly different with that of before treatment (336.814±79.691 (U/L)). Also, there was no significant difference in LDH level after treatment (336.455±68.436 (U/L)) compared to before treatment (337.518±80.851 (U/L)) in the Asafoetida group treatment (Figure 4). The percent changes of LDH in the Asafoetida group was higher than in the placebo group but was not statistically significant between the groups (Table 2).

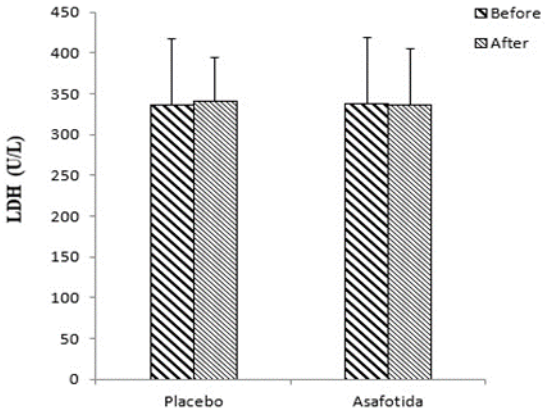


Figure 4. Lactate dehydrogenase (LDH) level before and 1 month after treatment in placebo and Asafoeitida groups. Values are presented as mean ± SD. Statistical analyses were performed using the paired samples T-test and Wilcoxon signed ranks test.

The effect of Asafoetida on pulmonary function test (PFT) values

The FVC value after treatment was significantly changed in both placebo and Asafoetida groups relative to before treatment ($p<0.001$ for both cases). In addition, FEV1 value in the placebo and Asafoetida groups at the end of the study was lower relative to baseline, but it was significant only in the placebo group ($p<0.05$, Figure 5). The percent change in FVC and FEV1 did not significantly differ between the Asafoetida group and the placebo group (Table 2).

Table 2. Percent change of ACT, FVC, FEV1, LDH, and total and differential WBC, at the end of the trial compared to before treatment in studied groups.

Parameters	Percent change		p-Value
	Placebo	Asafotida	
ACT	24.752±29.293	55.595±64.809	0.033
FVC	-11.818±22.736	-10.168±32.307	0.617
FEV1	-4.033±35.724	3.823±46.015	0.510
WBC	-2.694±28.785	-4.504±21.610	0.833
Neutrophils	-4.949±16.780	-0.444±11.802	0.188
Lymphocytes	17.289±38.377	9.019±43.816	0.208
Eosinophils	49.648±97.914	27.076±73.877	0.325
Monocytes	10.870±25.515	4.094±24.069	0.399
LDH	0.491±20.878	3.794±22.839	0.460

Data are presented as mean ± SD. Statistical comparisons were performed using the Mann-Whitney Test. ACT: Asthma control test; FVC: Forced vital capacity; FEV1: Forced expiratory volume in first second; LDH, Lactate dehydrogenase ; WBC: White blood cells.

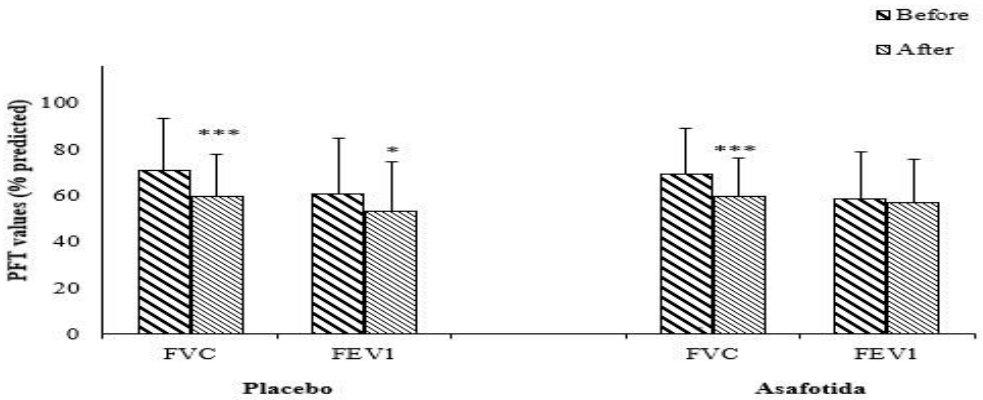
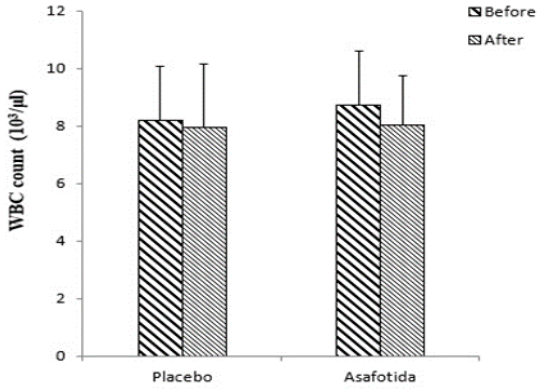


Figure 5. Pulmonary function tests values including FVC and FEV1 in the placebo and Asafoeitida groups before and 1 month after treatment. Values are presented as mean ± SD. Statistical analyses were performed using the paired samples T-test. *$p<0.05$ and ***$p<0.001$ after treatment compared to baseline. FVC: Forced vital capacity; FEV1: Forced expiratory volume in first second.

The effect of Asafoetida on total and differential WBC values

No significant reduction in total white blood cell count was observed at the end of the trial relative to baseline value in both placebo and Asafoetida groups (Figure 6). In addition, there was not a significant difference in percentage of total WBC between the Asafoetida and placebo group after the study period (Table 2).



placebo and Asafoeitida groups before and 1 month after treatment. Values are presented as mean ± SD. Statistical analyses were performed using the paired samples T-test.

In placebo group, neutrophil count was significantly decreased at the end of the trial compared to baseline ($p<0.05$, Figure 7). Additionally, a significant increase in lymphocyte count was observed at the end of the trial relative to baseline value in this group ($p<0.05$, Figure 7). There was no significant change in other differential WBCs in placebo group after treatment compared to before treatment (Figure 7). In the Asafoetida group, differential WBC counts were not considerably changed at the end of the trial in contrast to before treatment (Figure 7). There was also no significant difference in percent changes of differential WBCs in the Asafoetida group compared with the placebo group during the two steps of the study (Table 2).

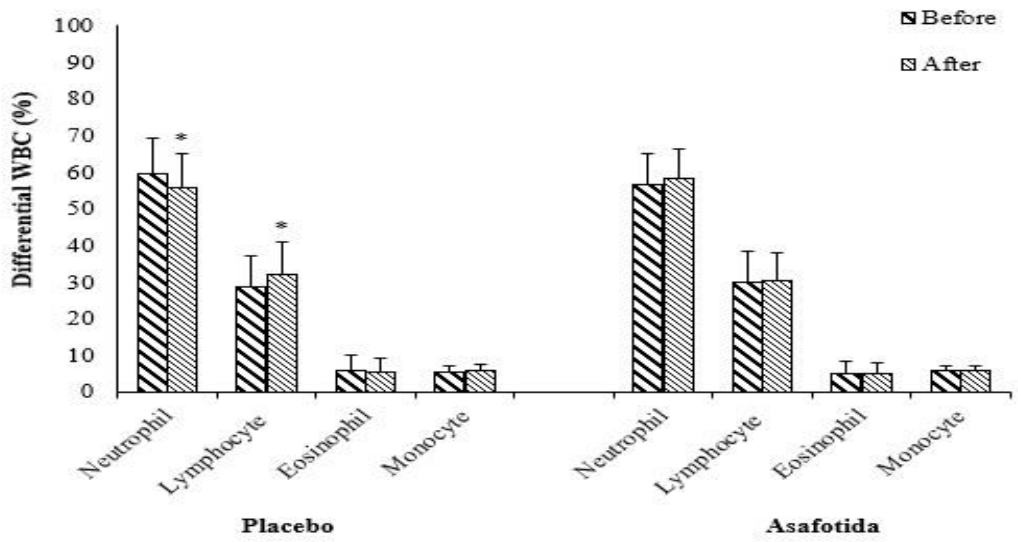


Figure 6. Differential white blood cell percent in the placebo and Asafoeitida groups before and 1 month after treatment. Values are presented as mean ± SD. Statistical analyses were performed using the paired samples T-test and Wilcoxon signed ranks test.

Discussion

This study was a double-blind, placebo-controlled clinical trial that evaluated the effects of one month treatment with Asafoetida on clinical symptoms (ACT score and wheeze), pulmonary function tests (FVC and FEV1), total and differential WBC, and LDH level in asthmatic patients.

For this end, patients received Asafoetida at a dose of 300 mg per day or placebo, in addition to standard therapy, for a period of one month. Clinical symptoms and other parameters were measured before and after the intervention.

The findings of the present study indicated that treatment with Asafoetida led to significant reductions in wheezing 1 month after treatment compared with baseline value. The results also showed that Asafoetida resulted in significant increased ACT score after treatment compared with before treatment. However, it did not show a significant elevation on PFT values.

According to a previous clinical trial (Hasanpour et al. 2022), administration of Covexir® - a formulation derived from *Ferula foetida* oleo-gum- significantly improved respiratory symptoms such as cough and dyspnea in outpatients with COVID-19. Additional improvements were observed in myalgia, anorexia, anosmia, and sense of taste severity. These findings

are consistent with the results of our study in improving clinical symptoms.

No serious adverse events were observed in patients receiving Asafoetida. In line with this result, it has been shown that the consumption of herbal medicines including Asafoetida has been accompanied by no side effects or minimal side effects in the treatment of various respiratory diseases including asthma (Bahrami-Taghanaki et al. 2024; Salavatifar et al. 2023). Similarly, in the study by Hasanpour et al. (Hasanpour et al. 2022), no adverse effects were observed following the administration of *Ferula foetida* in patients with COVID-19, further supporting the safety profile of this herbal preparation .

The observed clinical improvements, particularly in respiratory symptoms, may be partly attributed to the anti-inflammatory properties of *Ferula* species. Previous studies have reported that components present in *Ferula szowitsiana* possess notable anti-inflammatory and immunomodulatory effects (Askari et al. 2021; Askari et al. 2020; Askari et al. 2018). In study conducted by Askari et al. (Askari et al. 2020), inflammatory cytokines including interleukin 6 (IL-6) and tumor necrosis factor alpha (TNF-α) significantly reduced after treatment with methanolic extract of *Ferula szowitsiana* (10–160 mg/ ml) in phytohemagglutinin (PHA)-stimulated isolated human lymphocyte. These findings align with the results of our study, where significant clinical improvements were observed, suggesting that the therapeutic effects of *F. foetida* may, at least in part, be mediated through its anti-inflammatory mechanisms.

Despite the well-documented anti-inflammatory and antioxidant properties of *Ferula* species, as well as prior evidence demonstrating clinical efficacy of *Ferula foetida* oleo-gum in improving respiratory symptoms in COVID-19 patients, our findings did not show significant improvements in objective outcomes such as pulmonary function tests or inflammatory and hematological markers. So far, no clinical trial has directly assessed the effects of asafoetida on asthma, and therefore, the findings of this study warrant further investigation. In the present study, although a reduction in clinical symptoms was observed, no significant improvements were noted in objective indices such as pulmonary function tests or inflammatory and hematologic markers. This may be due to limitations of the intervention protocol, particularly the relatively short, one-month treatment period. Existing evidence indicates that to achieve sustained changes resulting from plant-based therapies in respiratory indices and other related parameters, future clinical trials should employ longer treatment durations, repeated follow-ups, and optimized dosing regimens (Derakhshan et al. 2023).

The present study investigated the therapeutic effects of Asafoetida on improving ACT, lung function, and clinical symptoms including wheezing, and blood factors. The current study showed that Asafoetida, with its anti-inflammatory, antispasmodic, and bronchodilator effects, improved ACT, and reduced wheezing. However, lung function indices by examining FVC and FEV1 tests did not show significant improvement. Asafoetida did not affect blood leukocyte or LDH levels. The reason for this lack of effect could be the multifaceted nature of asthma. The long-term consumption of asafoetida and it higher dose should be examined on chronic obstructive pulmonary disease (COPD) patients in the future studies.

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Conflicts of interest

The authors have no conflicts of interest.

Funding

None

Ethical Considerations

This study was conducted under the supervision of the Ethics Committee and the Clinical Trials Council of Damghan University of Medical Sciences.

Code of Ethics

IRCT20210909052420N1

Authors' Contributions

SHGH: Literature search, Proposal writing, Data collection, Data Analysis, Data interpretation, Preparation Manuscript, Manuscript review. VH, SMM, MHB: Data interpretation, Manuscript review.

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