

Associations of severity and adherence to inhaled glucocorticoid therapy with serum interleukin-5 among patients with asthma: a cross-sectional study in Indonesia

ZALEŻNOŚCI MIĘDZY NASILENIEM CHOROBY A PRZESTRZEGANIEM ZALECEŃ ODNOŚĄCYCH SIĘ DO TERAPII GLIKOKORTYKOIDAMI WZIEWNYMI A STĘŻENIEM INTERLEUKINY-5 W SUROWICY U PACJENTÓW Z ASTMĄ: BADANIE PRZEKROJOWE PRZEPROWADZONE W INDONEZJI

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Streszczenie

Stężenie Interleukiny-5 (IL-5) jest związane z zaostrzeniem astmy, a jego poziom w surowicy można obniżyć za pomocą inhalacyjnej terapii glikokortykoidami. Celem niniejszego badania była ocena związku między nasileniem astmy i przestrzeganiem zaleceń dotyczących terapii glikokortykoidami a stężeniem IL-5 w surowicy. To badanie przekrojowe przeprowadzono na pacjentach oddziału pulmonologicznego. W sumie zrekrutowano 40 dorosłych pacjentów z potwierdzoną klinicznie astmą, u których zmierzono poziom przestrzegania zaleceń terapeutycznych oraz stężenie IL-5. Przestrzeganie zaleceń dotyczących stosowania inhalatora mierzono za pomocą skali Medication Adherence Report Scale Asthma (MARS-A). Stężenie IL-5 mierzono za pomocą Testu immunoenzymatycznego. Wyniki wykazały, że większość pacjentów przestrzegała zaleceń dotyczących stosowania inhalatora (n=29, 72,5%). Ponad 50% (n=23, 57,5%) pacjentów otrzymało instruktaż dotyczący stosowania inhalatora. Tylko 37,5% wszystkich pacjentów (n=15) doświadczyło zaostrzeń, przy czym astma sporadyczna, łagodna przewlekła i umiarkowana przewlekła została odnotowana odpowiednio u 34% (n=18), 23% (n=12) i 19% (n=10) wszystkich pacjentów. W porównaniu z osobami cierpiącymi na astmę o umiarkowanej nasileniu, stężenie IL-5 było znacznie niższe w przypadku astmy sporadycznej i łagodnej (w obu przypadkach $p<0,001$). Nie stwierdziliśmy istotności statystycznej stężenia IL-5 w grupach przestrzegających i nieprzestrzegających zaleceń ($p=0,207$). IL-5 jest związana z nasileniem astmy, ale nie z przestrzeganiem zaleceń dotyczących terapii glikokortykoidami. Aby potwierdzić brak wpływu glikokortykoidów na stężenie IL-5, konieczne są dalsze badania z udziałem większej liczby uczestników i przy użyciu bardziej solidnej metodologii.

Słowa kluczowe: Astma, interleukina-5, przestrzeganie zaleceń, inhalator glikokortykoidowy, zaostrzenie

Summary

Objective(s)

Interleukin-5 (IL-5) concentration has been reported to be associated with asthma severity, where the serum concentration can be reduced with glucocorticoid inhaler therapy. This study aimed to assess the associations of asthma severity and glucocorticoid therapy adherence with serum IL-5 concentration.

Methods

This cross-sectional study was conducted on patients in the pulmonary department. A total of 40 clinically confirmed adult asthma patients were recruited and subjected to adherence and IL-5 measurements. Adherence to inhaler use was measured using the Medication Adherence Report Scale Asthma (MARS-A). IL-5 concentration was measured using the Enzyme-Linked Immunosorbent Assay.

Results

The results revealed that the majority of the patients adhered to inhaler use (n=29, 72.5%). More than 50% (n=23, 57.5%) received an inhaler use demonstration. There were only 37.5% of the total patients (n=15) experienced exacerbations, where intermittent, mildly persistent, and moderately persistent asthmas were recorded in 34% (n=18), 23% (n=12), and 19% (n=10) of the total patients, respectively. In comparison with individuals having moderately persistent asthma, the IL-5 concentrations were significantly lower in intermittent and mildly persistent asthma (both with $p<0.001$). We found no statistical significance in IL-5 concentrations in adherent versus non-adherent groups ($p=0.207$).

Conclusion

IL-5 is associated with asthma severity but not with adherence to glucocorticoid therapy. To confirm the absence of glucocorticoid effect on IL-5 concentration, further studies employing larger participants and more robust methodology are warranted.

Key words: Asthma, interleukin-5, adherence, glucocorticoid inhaler, exacerbation

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Introduction

The Global Burden of Disease Study estimated that 262 million people had asthma in 2019, with asthma causing 461,069 deaths, mostly due to severe and uncontrolled asthma [1]. A survey in 2018 revealed that 1,017,290 Indonesians were diagnosed with asthma, with 2.3% being Acehnese [2]. Despite the significant burden of asthma in this region, localized data on the immune mechanisms driving disease severity remain limited. Asthma is a chronic inflammation of the airways with episodes of reversible obstruction, caused by increased airway responsiveness to various stimuli.

Asthma can be chronic and not totally curable, although it can be managed with adequate and consistent therapy. Guidelines from the Global Initiative for Asthma (GINA) in 2019, divided asthma into three categories based on the level of control (controlled, partially controlled, and uncontrolled asthma), daytime symptoms, nighttime symptoms, activity limitations, need for reliever medication, peak flow rate, and exacerbation events per year [3]. However, these classifications rely on general population data, with limited exploration of inflammatory profiles in Acehnese patients, whose asthma severity and immune responses may differ from other populations.

Inflammatory reaction in asthma is associated with T-helper type 2 (Th2), which promotes immunoglobulin E (IgE) production and recruitment of mast cells and eosinophils [4]. Interleukin (IL)-5 activates eosinophils, increasing their production. This can lead to airway narrowing, epithelial mucosal irritation, and airflow turbulence. If not properly addressed, these conditions can worsen clinical symptoms and may result in death. Allergic asthma has been reported to involve adaptive and innate immune responses, including antigen-independent mechanisms. In addition, Th2-type cytokines, such as interleukin-4 (IL-4), IL-5, and IL-13, are believed to be the drivers of disease pathology in patients with asthma and play a role in the development of many hallmarks of allergic inflammation [5]. In particular, IL-5 serves as a critical molecular switch that drives the development, migration, and recruitment of eosinophils to the lungs during allergic inflammation [6]. While allergic asthma has been extensively studied, much of the existing data stem from non-Indonesian populations, leaving a gap in understanding region-specific immunological patterns.

On the other hand, oral glucocorticoids have been proven to reduce serum IL-5 levels in patients experiencing acute asthma [7]. In addition, Visser and colleagues measured serum concentration in children receiving inhaled steroids, where the levels were undetectable in 45% of asthma patients [8]. A previous study also showed an increase among asthma patients with and without allergies, but the concentration became undetectable after receiving glucocorticoid therapy [9]. Another study stated that plasma soluble IL-2 receptor concentration in asthma patients dependent on oral glucocorticoids was higher compared to others [10]. This suggests that T lymphocyte cell activation is associated with severe chronic disease despite glucocorticoid therapy [10]. Low adherence is associated with increased airway inflammatory mediators and high rates of emergency room visits, hospitalization rates, and death rates [11]. Other than being affected by glucocorticoid administration, the serum level of IL-5 has also been reported to be associated with asthma severity

[12]. Given the lack of region-specific data, this study aimed to assess differences in IL-5 concentrations based on asthma severity and adherence to inhaled glucocorticoid therapy among Acehnese patients.

Methods

Study design

This study used a cross-sectional design and was performed in the Pulmonary Department of Zainoel Abidin Hospital, a referral hospital located in Aceh Province, Indonesia. This study included inpatients or outpatients who were diagnosed with asthma according to the GINA Guidelines (2019) and presented to the pulmonology department from April to July 2024. Each respondent was asked for informed consent before participating in this study. Consecutive eligible patients were included based on the total sampling approach. Ethical approval was obtained from the Zainoel Abidin Hospital Ethics Review Committee, No: 025 / ETIK-RSUDZA / 2024.

Participants

The study included all adult asthma patients (aged ≥ 18 years) who had been previously diagnosed with asthma by a pulmonologist and were undergoing at least one inhaler therapy such as a Metered Dose Inhaler (MDI) and/or Dry Powder Inhaler (DPI). While those with asthma overlapping with obstructive pulmonary disease, debilitating chronic conditions (such as carcinoma), and pregnant women were excluded.

Data collection and variables

Patient characteristics, including age, gender, and education history, were obtained from medical records. Clinical data, such as the prescribed inhaler type, history of exacerbations within the past year, history of allergies, and duration of asthma, were also extracted from medical records. Information on inhaler use, including whether patients received a demonstration of proper technique at the outpatient clinic or inpatient ward and any reported difficulties in using the inhaler, was collected through interviews. The effectiveness of inhaler use was assessed through interviews by asking patients about their perceived symptom control and any asthma-related exacerbations or hospital visits. Adherence to glucocorticoid inhalation was assessed using the Medication Adherence Report Scale Asthma (MARS-A) questionnaire, which consisted of 10 validated questions. This questionnaire exhibited a reliability of 0.65, sensitivity of 0.82, and specificity of 0.69 in the Indonesian population as previously reported [13]. Furthermore, each adherence-related behavior was scored on a five-point scale: 1 ("always"), 2 ("often"), 3 ("sometimes"), 4 ("rarely"), and 5 ("never"). Total scores ranged from 10 to 50, with a score of 26 or above indicating adherence and a score below 26 indicating non-adherence [14].

Lung function was assessed using spirometry (Fukuda Denshi, Spirosoft SP5000) when the patient could perform the spirometry maneuver or at subsequent visits. Spirometry measurements were used to assess airway obstruction in asthma including forced expiratory volume in the first second (FEV1), which was presented in liters. Peripheral blood was collected via venipuncture, processed to obtain the serum, and stored at -4°C before

IL-5 concentration measurement using Enzyme-Linked Immunosorbent Assay (ELISA).

Data collection and variables

Serum IL-5 concentrations were determined using the Human IL-5 ELISA Kit (BT-Laboratory, Cat No. E0091Hu) following the manufacturer's instructions. The assay employed a sandwich ELISA method. An IL-5 standard curve was generated by serially diluting the IL-5 standard stock solution (960 ng/L) to 480, 240, 120, 60, and 30 ng/L using the kit's standard diluent. The kit's minimum detectable concentration for IL-5 was 1.52 ng/L.

Statistical Analysis

The distribution of IL-5 concentrations for the normality test was assessed using the **Shapiro-Wilk test**. Univariable analysis was performed to present descriptive study characteristic data. Since IL-5 concentrations were not normally distributed, the Kruskal-Wallis test was applied to assess differences in IL-5 concentration based on asthma severity, while the Mann-Whitney test was used to evaluate differences in IL-5 concentration based on adherence to inhaled glucocorticoid use. Additionally, correlation analyses were conducted to assess relationships between IL-5 concentration and FEV1, allergy history, asthma duration, and the type of inhaler used. Statistical significance was set at $p < 0.05$ for a 95% confidence interval (CI). All statistical analyses were performed using SPSS version 16.0 (IBM Corp., Armonk, NY, USA).

Results

Characteristics

A total of 40 asthma patients were recruited in this study, with the majority being females ($n=28$, 70%) and having senior high school education certificates ($n=22$, 55%). Most participants were outpatients ($n=27$, 67.5%), while the rest were hospitalized ($n=13$, 32.5%). The majority of the respondents used glucocorticoid inhalers ($n=31$, 77.5%). Regarding the inhaler technique, 57.5% ($n=23$) of patients reported having a demonstration, while 42.5% ($n=17$) had never received one. Therapy adherence was observed in most of the patients ($n=29$, 72.5%). Only 37.5% ($n=15$) of the total participants experienced exacerbations regarding clinical conditions. Eighteen patients (24%) had intermittent asthma, 12 (23%) had mild persistent asthma, and 10 (19%) had moderate persistent asthma. The average serum concentration of IL-5 was 139.57 ± 99.89 mg/dL and the average FEV1 was 1970 ± 510 liters and 77.5 ± 13.849 for FEV1% indicating a mild degree of airway obstruction .

Table 1. Characteristics, adherence, and serum IL-5 of patients with asthma

Characteristics	Frequency (n)	Percent (%)
Setting		
Outpatient	27	67.5
Inpatient	13	32.5
Age		

Characteristics	Frequency (n)	Percent (%)
18- 35 years	21	51.4
35 – 45 years	13	37.1
>45 years	6	11.4
Gender		
Male	12	30
Female	28	70
Education		
Senior high school	22	55
University or higher	18	45
Type of Inhaler		
Inhaler corticosteroid	31	77.5
Inhaler corticosteroid-long acting beta agonist	9	22.5
Receiving inhaler demonstration		
Yes	23	57.5
No	17	42.5
Having difficulty in inhaler use		
Yes	15	37.5
No	25	62.5
Effectiveness of inhaler use		
Yes	25	62.5
No	15	37.5
Adherence Level		
Adherent	29	72.5
Non-adherent	11	27.5
History of exacerbation		
Yes	15	37.5
No	25	62.5
Asthma Severity		
Intermittent	18	34
Mildly persistent	12	23
Moderately persistent	10	19
History of allergies		
Yes	32	82.9
No	8	17.1
Asthma onset, mean \pm SD (years)	6.38 \pm 7.35	

Characteristics	Frequency (n)	Percent (%)
Forced expiratory volume 1 second (FEV1), mean±SD (liter)	1.97±0.51	
FEV1(%)	77.5±13.849	
Interleukin-5, mean±SD (ng/dL)	139.57±99.89	

Associations of asthma severity and therapy adherence with serum IL-5

Patients with moderate persistent asthma exhibited the highest average IL-5 concentration (239.75 ± 161.37), followed by patients with mild persistent (120.21 ± 36.4) and intermittent (96.8 ± 11.7) asthma (Figure 1a). A significant difference was observed in IL-5 concentration based on asthma severity ($p < 0.001$). However, there was no significant difference found in IL-5 concentration between the adherent (135.32 ± 98.5 ng/dL) and non-adherent (150.74 ± 107.28 ng/dL) groups ($p = 0.207$) (Figure 1b).

The summary of the associations between IL-5 and other variables is presented in **Table 2**. There were no statistically significant associations for gender ($p = 0.900$) or history of allergies ($p = 0.148$). Similarly, the type of inhaler used did not show a significant association with IL-5 concentration ($p = 0.825$). Furthermore, no significant difference in IL-5 concentration was observed between patients who experienced exacerbations (127.54 ± 95.05 ng/dL) and those who did not experience exacerbations (146.77 ± 103.90 ng/dL) with a p -value of 0.078.

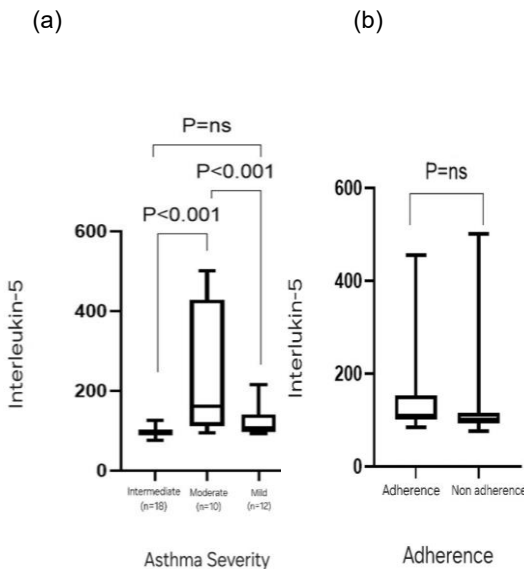


Figure 1. Serum IL-5 concentration according to asthma severity (a) and adherence to glucosteroid therapy (b).

Table 2. Relationship of IL-5 with the clinical profile of asthma patients

Clinical Profile	n	Mean Std. Deviation	±	p-value
Setting				
Outpatient	27	99.41	± 13.84	0.738
Inpatient	13	222.96	± 144.38	
Gender				
Male	12	111.03	± 31.58	0.900
Female	28	151.79	± 116.13	
Education				
Senior high school	15	136.04	± 106.02	0.914
University or higher	25	141.68	± 98.19	
History of allergies				
Yes	34	144.4	± 107.55	0.148
No	6	112.15	± 20.19	
Type of Inhaler				
Inhaler corticosteroid	38	141.61	± 102.10	0.825
Inhaler corticosteroid-long acting beta agonist	2	100.63	± 11.49	
Receiving inhaler demonstration				
Yes	23	136.74	± 106.12	0.207
No	25	139.42	± 105.83	
Having difficulty in inhaler use				
Yes	15	139.80	± 92.68	0.148
No	17	143.39	± 93.83	

Clinical Profile	n	Mean Std. Deviation	±	p-value
Effectiveness of inhaler use				
Yes	25	141.74	± 105.01	0.825
No	15	135.93	± 94.14	
Adherence				
Yes	29	135.32	± 107.29	0.207
No	11	150.74	± 103.90	
History of exacerbation				
Yes	15	127.54	± 95.06	0.078
No	25	146.78	± 98.57	
Asthma severity				
Intermittent	18	96.81	± 11.72	0.002*
Mildly persistent	12	120.21	± 36.41	
Moderately persistent	10	239.75	± 161.37	

*Significant at $p < 0.001$

Discussion

The present study demonstrated a direct association between asthma severity and serum IL-5 concentration, distinguishing it from studies that rely solely on clinical endpoints or general inflammatory markers. However, other factors, including adherence to therapy, exacerbation history, and inhaler type, showed no significant associations with IL-5 levels. IL-5 is involved as a mediating cytokine in airway inflammation contributing to the severity of asthma in both atopic and non-atopic cases [15]. Findings from the present study are in line with those reported previously, where the concentration of serum IL-5 was elevated in moderate and severe cases [15]. The present study revealed the novel finding that the IL-5 concentration is significantly higher in moderately persistent asthma as compared to intermittent asthma. This detail is rarely emphasized in the existing literature and suggests that systemic IL-5 levels may increase progressively with asthma severity. According to a previous study, systemic IL-5 levels increase in acute asthma and significantly decrease after treatment with oral glucocorticoids [16, 17]. Though decreased, serum IL-5 concentration remained elevated as compared to healthy controls [16].

Another key aspect of this study is the assessment of IL-5 levels in relation to adherence to inhaled glucocorticoid therapy. While no significant association was found, this finding serves as an important starting point for future research. Such observations were consistent with the analysis discussed in a published report [17]. The lack of response of peripheral blood monocytes to IL-5 production under inhaled corticosteroid therapy was witnessed among asthmatic children [17]. However, it remains unclear whether other underlying factors contribute to IL-5 persistence despite glucocorticoid use. This gap highlights the need for further studies exploring additional determinants of IL-5 regulation, particularly in different asthma phenotypes and treatment regimens. On the other hand, it is worth noting that patients with severe eosinophilic asthma generally respond well to IL-5 inhibitor therapy, even though cumulative oral corticosteroid use increases the risk of adverse effects [18]. The detection of IL-5 in both atopic and non-atopic asthma across varying severity levels corroborates its central role in eosinophilic inflammation, reinforcing its relevance as a therapeutic target [18].

There are several limitations in this study that should be acknowledged. First, serum IL-5 levels were measured from peripheral blood samples, whereas the cytokine is most abundantly produced in the bronchial mucosa, which might better reflect asthma pathogenesis [19]. This study's cross-sectional design limits the ability to determine whether patients were also taking oral steroids alongside inhaled glucocorticoids—an issue better addressed through a longitudinal design. Third, the absence of an association between adherence to inhaled glucocorticoid therapy and serum IL-5 concentration might be influenced by allergic reactions or other uncontrolled factors. Due to the limited number of participants, we were unable to stratify them based on their history of allergies. These findings emphasize the need for future research with larger cohorts and alternative study designs to refine our understanding of IL-5 regulation in asthma.

Conclusion

Adherence to inhaled glucocorticoid therapy in asthma patients did not affect serum IL-5 concentration. IL-5 was detected in serum at all levels of asthma severity, with higher concentrations observed in patients with moderately persistent asthma. IL-5 may serve as a potential marker for monitoring disease progression. However, its relationship to inhaled glucocorticoid therapy requires further investigation.

Authors' Contribution

The experiments were planned by BY, executed by MA and HS, who also gathered data; the results were analyzed and interpreted by BY and WS. The study was managed, coordinated, and supervised by BY and MA. The final version was accepted for publication by BY, MA, and WS.

Conflict of Interest

The authors affirm that they have no competing interests.

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