

Identifying Risk Factors for Non-Clinical Remission in Asthma in the Outpatient Department: A Retrospective Cohort Study

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Abstract

Objective: This study aimed to identify the clinical characteristics associated with the failure to achieve clinical remission in asthma. **Methods:** A retrospective 3-year cohort study was conducted in an outpatient chest department, with data recorded from National Health Insurance claims and the “Pay for Performance Program for Asthma” (P4P). **Results:** A total of 285 patients were screened between January 2021 and December 2023, of whom 143 were included in the analysis. The cohort had a mean age of 57.6 years; 62.2% were female, 14.0% were current smokers, and 17.5% had a baseline ACT score below 20. Clinical remission was defined as an ACT score ≥ 24 , FEV₁ $\geq 80\%$ of the predicted value, and no exacerbations for at least six months. After a minimum of six months of follow-up, 56.6% of patients failed to achieve remission. Non-remission was significantly associated with smoking (adjusted odds ratio [aOR] 4.944, $p=0.023$), ACT scores < 24 (aOR 4.669, $p=0.003$), FEV₁ $< 80\%$ (aOR 17.892, $p<0.001$), and recent exacerbations within three months before enrollment (aOR 3.441, $p=0.033$). Baseline differences in age, BMI, sex, comorbidities, and blood eosinophil counts were not statistically significant. **Conclusion:** These findings identified risk factors for non-clinical remission and provide practical insights for asthma management in community hospitals.

Key Words: Asthma, Remission, Pulmonary function tests, Asthma control test

Introduction

Asthma is a prevalent chronic disease globally, with the Global Initiative for Asthma (GINA) estimating approximately 300 million patients worldwide, which is projected to increase by 100 million by 2025^{1,2}. Similarly, in Taiwan, the prevalence of adult asthma increased from 7.57% in 2000 to 11.53% in 2011³.

Chronic asthma management aims to control symptoms and minimize future risks such as exacerbations, poor lung function, and medication side effects⁴. Advances in biologic agents have transformed treatment options, shifting goals from symptom control to sustained remission or halting disease progression^{5,6}. Clinical remission is defined by the absence of significant symptoms, no systemic corticosteroid use for exacerbations, no hospitalizations or unscheduled doctor visits, and optimized lung function with postbronchodilator forced expiratory volume in one second (FEV₁) \geq 80%. However, complete remission includes normalization of the underlying pathology⁷. The remission of asthma is not equivalent to a cure, while remission is stringent, it is achievable and assessable in routine practice⁵.

Studies on clinical remission have focused primarily on severe asthma patients using biologic agents, with remission rates ranging from 8-37%⁸⁻¹¹. Remission is more likely in patients with type 2 inflammation (T₂) with high biomarkers, shorter disease duration, better asthma control test scores, better lung function, lower maintenance oral corticosteroid use, lower rates of prior exacerbation, and fewer comorbidities⁹. Few studies have focused on patients without severe asthma or those not prescribed biologic agents. However, patients with infrequent symptoms or mild asthma are still at risk of exacerbations¹, with up to 30% of asthma exacerbations and deaths occurring in people with infrequent symptoms^{12,13}.

To improve asthma outcomes in Taiwan, the Bureau of National Health Insurance (NHI) launched a Pay for Performance (P4P) program in 2001. This program provides financial incentives to encourage physicians to adopt patient-centered care, improve monitoring and management quality, and achieve better clinical results, potentially reducing long-term medical costs¹⁴. This analysis aims to utilize this real-world registry cohort of well-documented asthma patients to investigate the clinical characteristics associated with achieving clinical remission.

Materials and methods

Study Design

This retrospective study was conducted at the specialized asthma outpatient clinic of Cheng-Ching General Hospital, Chung-Kang Branch. The study adhered to the Declaration of Helsinki principles and received approval from the Institutional Review Board of Cheng-Ching General Hospital (No. HP240009). We utilized NHI claim data and records from the P4P program for asthma to investigate factors associated with improved asthma control.¹⁴ Patients presenting with airway symptoms at the chest clinic undergo systematic evaluations, which include assessments of asthma risk factors, atopy history, and lung function variability. The final asthma diagnosis is determined by the attending chest physician.

If a patient is diagnosed with asthma by the same chest physician on at least two occasions within a 90-day period, a specialized health education nurse responsible for case management and health education prompts the physician to evaluate the patient's eligibility for enrollment in the P4P program. Physicians are required to explain the treatment plan to patients and ensure their cooperation with regular follow-up visits. If a patient is lost to follow-up for more than 90 days, declines further

treatment, or is referred to another hospital, the case is closed and cannot be re-entered into the program at the same hospital within one year.

At each scheduled clinic visit, patients undergo a 10- to 15-minute assessment conducted by a specialized health education nurse. This nurse provides education on asthma prevention and management, assists with asthma control test (ACT) scores evaluations to support treatment adjustments by the physician, and uploads relevant records to the NHI for administrative purposes. Additionally, the nurse acts as a communication bridge between the physician and the patient. Asthma health education includes instruction on proper inhaler techniques to ensure correct usage, identification of critical errors, assessment of difficulties in using inhalers, documentation of exacerbation events and rescue medication use between visits. Evaluation of overall asthma control and decisions regarding follow-up lung function tests, medication adjustments, inhaler device selection, spirometry, blood tests, chest X-rays, and other diagnostic procedures are made at the discretion of the attending physician. The asthma education program and medication regimens adhere to Taiwanese asthma guidelines.

Enrollment criteria of this study

The study screened patients between January 1, 2021, and December 31, 2023. The inclusion criteria included participation in the P4P program for asthma, at least two follow-up visits, and a minimum follow-up duration of six months.

Exclusion criteria of this study

1. Age under 18 years.
2. Non-compliance with asthma diagnosis criteria per the GINA guidelines^{1,15}.
3. Failure to return for follow-up within three months or irregular follow-ups led to program exit within one year.

Study participants

The data collected included patient smoking history, ACT scores, lung function tests, exacerbation history within three months before entering the P4P program, blood eosinophil counts, significant comorbidities, and medication use. Exacerbation was defined as an unscheduled outpatient visit requiring systemic corticosteroids, an emergency department visit, or hospitalization due to asthma symptoms. Follow-up visits included ACT scores and FEV₁ measurements via spirometry. The ACT score, ranging from 5 to 25, assesses asthma control over four weeks, with scores below 20 indicating a need for treatment adjustment. Compared with the predicted values, the FEV₁ percentages were used to assess objective lung function. Clinical remission in our study was defined by an ACT score of 24 or more, an FEV₁ over 80% of the predicted value, and no exacerbations during at least six months of follow-up.

Statistical analysis

Continuous variables are expressed as the means (standard deviations, SDs) or medians (interquartile ranges, IQRs). Student's t test was used for normally distributed data, and the Mann-Whitney U test was used for skewed data. Categorical data are expressed as frequency distributions, with the chi-square test or Fisher's exact test identifying significant differences. Variables with $p \leq 0.2$ in univariate analysis and those of clinical importance were included in a multivariable logistic regression model to control for confounding factors. Statistical significance was defined as $p < 0.05$. Analyses were conducted via IBM SPSS Statistics version 19.0 (IBM Corp., Armonk, NY, USA).

Results

Between January 2021 and December 2023, 285 patients were screened for the study. Among these patients, 36 were excluded because they were

lost to follow-up or had insufficient follow-up duration, 103 had incomplete ACT or FEV₁ data, and 3 were diagnosed with chronic obstructive pulmonary disease (COPD) overlap. Consequently, 143 patients were included in the final analysis (Figure 1). Among those who did not achieve clinical remission, 21 experienced exacerbations, 66 had an ACT score less than 24, and 13 had an FEV₁ less than 80% at the end of follow-up.

The baseline characteristics of this cohort included a mean age of 57.6±16.3 years. Among the participants, 62.2% were female, 14.0% were current smokers, and 17.5% presented with an ACT score below 20 at baseline. Rhinitis was the most common comorbidity, affecting 83.9% of the participants. Blood eosinophil counts were available for 86 individuals, with 44.2% exceeding 2% of the white cell count, 41.9% more than 150 cells/μL, and 10.5% more than 400 cells/μL.

After a minimum of six months of follow-up, the 143 asthma patients were divided into two groups: the clinical remission group (43.4%) and the non-clinical remission group (56.6%). The baseline ACT scores and FEV₁ values were significantly

lower, whereas the percentage of current smokers and exacerbation history three months before P4P program enrollment were significantly higher in the non-clinical remission group (Table 1). Among those with eosinophil levels of at least 150 cells/μL and 400 cells/μL, 38.2% and 14.7%, respectively, achieved clinical remission. The baseline blood eosinophil counts and comorbidities were similar between the two groups. During the study period, the mean change in ACT score was 1.37±2.26 for patients who achieved clinical remission, whereas it was 0.99±2.44 for those who did not achieve remission ($p=0.339$). The FEV₁ percentage change from baseline to the end of the study was 4.48 ± 14.29% versus 5.09±13.41% ($p=0.798$), and in liters, it was -0.01±0.86L versus 0.08±0.35L ($p=0.415$). While differences in ACT scores and FEV₁ changes existed between groups, they were not statistically significant.

The multivariate analysis identified several independent risk factors (Table 2). Compared with the clinical remission group, the non-clinical remission group was associated with smoking (adjusted odds ratio [aOR] 4.944, 95% confidence interval [CI]

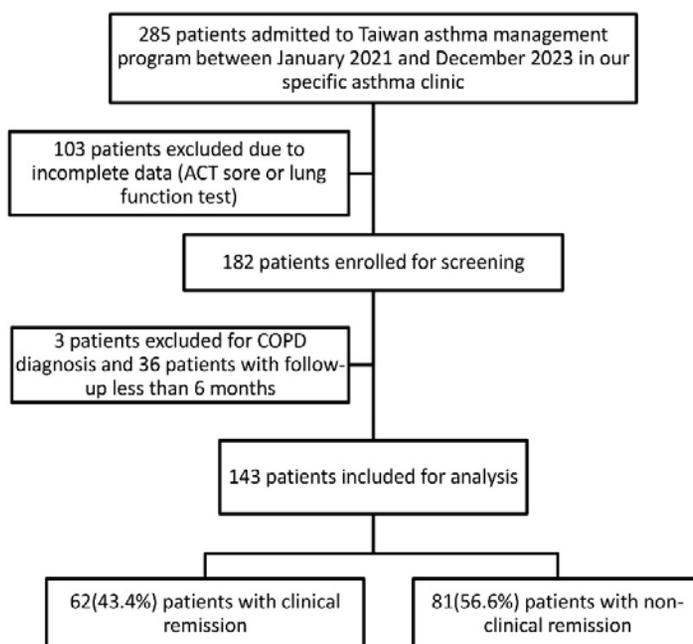


Figure 1. Study design algorithm.

Table 1. Patient demographics and clinical characteristics.

Variables	Total n=143	Clinical remission n=62 (43.4%)	Non-clinical remission n=81(56.6%)	<i>p</i> value ^{ab}
Age, years	57.61 ± 16.32	57.16 ± 18.93	57.95 ± 14.11	0.784
Female, No. (%)	89 (62.2%)	40 (64.5%)	49 (60.5%)	0.623
Current smoker, No. (%)	20 (14.0%)	4 (6.5%)	16 (19.8%)	0.023
BMI (kg/m ²)	26.24 ± 4.77	25.59 ± 4.82	26.73 ± 4.7	0.158
ACT score	21.92 ± 2.46	22.53 ± 2.10	21.46 ± 2.61	0.009
Lung Function				
Pre-bronchodilator FEV ₁ (%predicted normal)	80.12 ± 22.88	95.08 ± 20.89	68.72 ± 17.09	< 0.001
Pre-bronchodilator FEV ₁ (L)	2.00 ± 0.95	2.35 ± 1.15	1.74 ± 0.65	<0.001
FEV ₁ /FVC (%)	74.37 ± 9.76	77.65 ± 8.18	71.87 ± 10.17	< 0.001
Laboratory Data				
Blood neutrophil percentage (%)	65.23 ± 13.97	66.86 ± 12.86	64.16 ± 14.68	0.384
ANC (cells/uL)	5482.09 ± 2870.51	5701.53 ± 2964.83	5338.62 ± 2827.04	0.57
Blood eosinophil percentage (%)	2.48 ± 2.50	2.76 ± 2.74	2.31 ± 2.34	0.416
BEC (cells/uL)	191.17 ± 226.06	207.85 ± 229.71	180.27 ± 225.21	0.583
Comorbidities, No. (%)				
Hypertension	55 (38.5%)	25 (40.3%)	30 (37.0%)	0.689
DM	16 (11.2%)	4 (6.5%)	12 (14.8%)	0.116
Rhinitis	120 (83.9%)	54 (87.1%)	66 (81.5%)	0.365
GERD	23 (16.1%)	9 (14.5%)	14 (17.3%)	0.655
Asthma related-medication on enrollment				
ICS-LABA	138 (96.5%)	61 (98.4%)	77 (95.1%)	0.389
ICS-LABA-LAMA	5 (3.5%)	1 (1.6%)	4 (4.9%)	
Exacerbation in 3 months before enrollment, No. (%)	33 (23.1%)	8 (12.9%)	25 (30.9%)	0.012
Follow-up (months)	14.97 ± 10.18	13.6 ± 9.11	16.02 ± 10.87	0.151

Abbreviations: ACT, Asthma Control Test; BMI, Body Mass Index; ICU, intensive care unit; ANC, absolute neutrophil count; BES, blood eosinophil count; DM, diabetes mellitus; FEV₁, forced expiratory volume in one second, FVC, forced volume capacity; GERD, gastroesophageal regurgitation disease; ICS-LABA-LAMA, inhaled corticosteroids, long-acting β-2 agonist, long-acting muscarinic antagonist.

^a *p* value stands for comparisons between the Clinical remission and non-clinical remission.

^b *p* values for the comparison of continuous variables using the t-test.

Table 2. Risk factors associated with non-clinical remission.

Variables	Univariable logistic regression			Multivariable logistic regression		
	OR	95% CI	<i>p</i> Value ^a	aOR	95% CI	<i>p</i> Value ^b
Gender						
Male		[Reference]				
Female	1.187	0.599-2.355	0.623			
Age						
<60		[Reference]				
≥60	1.128	0.581-2.189	0.723			
BMI (kg/m ²)						
<25		[Reference]				
≥25	1.346	0.689-2.627	0.384			
Smoking History						
Non-smoker		[Reference]			[Reference]	
Smoker	3.569	1.129-11.288	0.030	4.944	1.241-19.687	0.023
ACT score						
<24	2.566	1.214-5.424	0.014	4.669	1.670-13.053	0.003
≥24		[Reference]			[Reference]	
Lung Function (%)						
FEV ₁ <80	12.434	5.504-28.091	<0.001	17.892	6.881-46.527	<0.001
FEV ₁ ≥ 80		[Reference]			[Reference]	
Exacerbation in 3 months before entering P4P program						
Yes	3.013	1.250-7.262	0.014	3.441	1.102-10.744	0.033
No		[Reference]			[Reference]	

Abbreviations: ACT, Asthma Control Test; BMI, Body Mass Index; FEV₁, forced expiratory volume in one second; P4P, pay for performance program.

^a Univariate analysis.

^b All variables included in the multivariable analysis are reported in this Table.

1.241 to 19.687, $p=0.023$), an ACT score of 24 or less (aOR 4.669, 95% CI 1.670 to 13.053, $p=0.003$), and a reduced FEV₁ of less than 80% (aOR 17.892, 95% CI 6.881 to 46.527, $p<0.001$). Experiencing exacerbations three months prior to P4P enrollment was linked to a greater likelihood of non-clinical remission (aOR 3.441, 95% CI 1.102--10.744; $p=0.033$). Other variables, such as sex, age, and body mass

index, were not significantly associated with non-clinical remission in either the univariate or multivariate analyses.

The percentage of patients in non-clinical remission increased as the number of risk factors increased (Figure 2). For those without risk factors ($n=15$), this probability was 13.3%. It rose to 61.7% with one risk factor ($n=128$), such as current

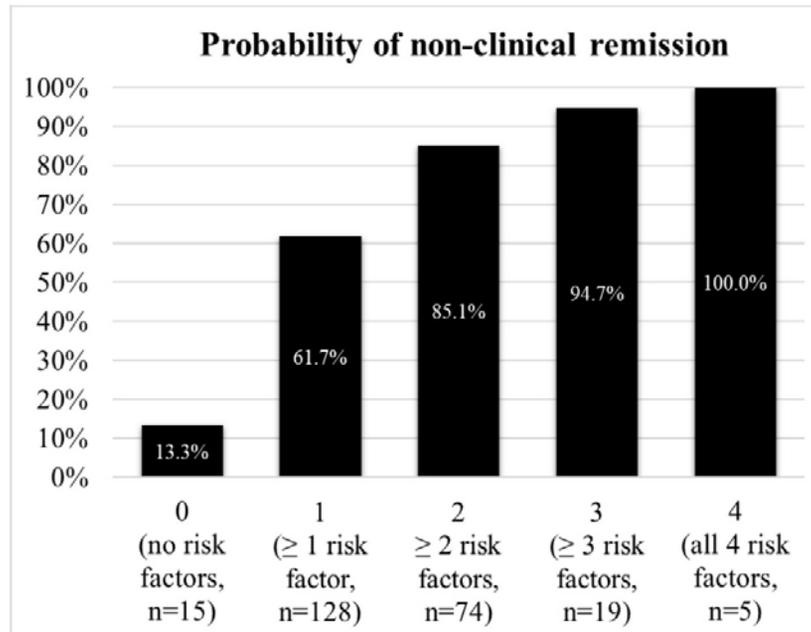


Figure 2. Probability of nonclinical remission on the basis of the number of risk factors. Risk factors, such as current smoking status, an ACT score less than 24, a reduced FEV₁ of less than 80%, and exacerbations three months prior to enrollment in the P4P program, are statistically significant.

smoking, an ACT score of 24 or less, an FEV₁ below 80%, or recent exacerbations within three months prior to P4P enrollment. The likelihood increased to 85.1% with two risk factors (n=74), 94.7% with three risk factors (n=19) and 100% with all four risk factors (n=5).

Discussion

In this study, we investigated a real-world registry cohort of well-documented asthma patients to identify the risk factors associated with failure to achieve clinical remission. Our findings revealed that among the 128 patients who presented with at least one risk factor, the probability of non-clinical remission was 61.7%. The identified risk factors for non-clinical remission include current smoking status, an ACT score less than 24, an FEV₁ less than 80%, and exacerbations occurring within three months prior to enrollment in the P4P program, each of which significantly impacts clinical outcomes.

Over 40% of participants achieved clinical remission in this study, a rate notably exceeding those reported in other studies, which range from 18% to 30%.^{8,9,16} This difference may be because other studies often include patients with severe, poorly controlled asthma requiring long-term oral corticosteroid therapy, whereas our cohort consisted of individuals with relatively milder asthma. Furthermore, a significant finding among patients enrolled in the P4P program was the reduction in exacerbation frequency. Before enrolling in the P4P program, 33 patients (23.1%) experienced exacerbations within the preceding three months. This number decreased to 21 patients (14.7%) reporting acute exacerbations six months post enrollment. While changes in ACT scores and FEV₁ from baseline to study conclusion were not statistically significant, the reduction in exacerbation rates might explain the higher remission rate observed in our study.

Currently, there is no universally accepted definition of clinical remission among medical societies, leading to variability in the criteria for asthma remission and consequently affecting the percentage of patients classified as being in remission^{10,11,17,18}. Previous studies have indicated that the inclusion of lung function criteria typically reduces remission by 1% to 7%^{8,9,16}. Fixed airflow limitation may not meet the remission criteria even when symptoms are well controlled and oral corticosteroids are completely discontinued. This underscores the importance of targeting remission through therapeutic interventions before patients experience permanent and irreversible loss of lung function¹⁹. Moreover, remission has been clearly defined in other chronic inflammatory conditions, such as rheumatoid arthritis, Crohn's disease, ulcerative colitis, and systemic lupus erythematosus²⁰. Similarly, greater emphasis should be placed on biomarkers in defining asthma remission rather than relying solely on symptom assessment and lung function measurement.

This study has several limitations, such as its small sample size, although it is statistically adequate, and the lack of more sensitive, specific, and laboratory tests during the follow-up period for quantitatively classifying blood eosinophil counts and FeNO¹⁸. However, these tests are primarily used in severe asthma cases to assist in phenotyping when control is inadequate¹⁷. On the basis of lung function data and medication and symptom scores, we estimate that less than 5% of our patients have severe asthma. Additionally, we did not conduct detailed analyses of inhaled corticosteroid use, including on-treatment or off-treatment strategies, or the exclusive use of maintenance and reliever therapy strategies. Our database revealed that all our patients were taking inhaled corticosteroids. We selected a six-month follow-up period based on several considerations. Previous literature indicates that the evaluation period for asthma remission ranges from six months to three years^{21,22},

while treatment guidelines recommend assessments at 12 months or longer, primarily derived from studies evaluating biologics in severe asthma patients^{6,7,11,23}. Some studies have adopted follow-up periods exceeding two years^{24,25}. A study on biologics in severe asthma reported that 15-23% of patients achieved clinical remission at six months, compared to 14-15% at 12 months,²⁶ suggesting that a six-month period can provide early remission evidence and allow comparisons with longer durations. Our study results may serve as a reference for future research with extended follow-up durations (>12 months). Further investigations could explore the potential for earlier remission evidence in patients with non-severe asthma. In our study, no statistically significant differences were observed in achieving non-clinical remission between the two groups based on the length of the follow-up period (Table 1).

Our study has several strengths. A notable strength is the real-world nature of our observations, providing valuable insights for clinical practice, particularly in community hospitals. This contrasts with multicenter, randomized controlled trials often conducted in highly controlled clinical settings with rigorous patient follow-up, which differ significantly from real-world clinical scenarios²⁷. Since we selected patients who were part of the P4P for asthma, regular follow-ups were performed. Patients who did not return for follow-up within six months were excluded from the program¹⁴. During visits, the specialized health education nurse assessed asthma control and inhaler technique, helping eliminate poor treatment adherence as a factor in our study. Since our patients were part of the P4P program, adherence to medication and medical advice was better.

Our study provides valuable insights for physicians in community hospitals and encourages greater participation in clinical research. In Taiwan, community hospitals function as intermediaries

between medical centers and local clinics, facing unique challenges in asthma management. Medical centers typically handle more severe cases, sometimes using biological agents, whereas local clinics often manage milder cases with diagnostic uncertainties. Our findings support the notion that each hospital, particularly regional community hospitals, should maintain its own data to address specific patient needs and improve care.

Future research could explore the need for blood eosinophil count, FeNO, and lung function tracking for all patients enrolled in the P4P program. The definition of remission should evolve over time and exclude patients with chronic oral corticosteroid use and those who overuse short-acting bronchodilators, as indicated by Taiwanese data^{28,29}. Our study uses symptoms, lung function, medication use, and past exacerbation history for convenient outpatient assessment. To reduce the further risk of asthma exacerbation, as suggested by the GINA guidelines¹, anti-inflammatory agents should not be reduced or discontinued solely on the basis of symptom improvement if patients do not meet remission criteria. Evaluations every three months provide a basis for treatment adjustments. Addition-

ally, long-term tracking of asthma patients is necessary⁸, although in our study, some patients were followed for less than 12 months. An expert consensus framework for asthma remission as a treatment goal recommended follow-up for at least 12 months⁵.

Conclusion

In conclusion, our real-world asthma cohort study identified key risk factors for failure to achieve clinical remission, such as current smoking status, an ACT score less than 24, an FEV₁ less than 80%, and recent exacerbations. Despite constraints such as a small sample size and limited follow-up tests, this study provides practical insights for community hospitals. Future research should focus on comprehensive biomarker tracking to refine remission criteria and guide treatment strategies effectively.

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List of abbreviations

Term	Definition
ACT	Asthma Control Test
BMI	Body Mass Index
ICU	Intensive care unit
PFT	pulmonary function test
COPD	Chronic Obstruction Pulmonary Disease
GINA	Global Initiative for Asthma
FEV ₁	Forced expiratory volume in one second
SD	Standard deviation
IQR	Interquartile range
OR	Adjusted odds ratio
CI	Confidence interval

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Ethics approval and consent to participate

This study was approved by the institutional review board of Cheng-Ching General Hospital with waiver of the requirement for patients' informed consent. (Approval No. HP240009)

Competing interests

The authors declare that they have no competing interests.

Authors' contributions

Conception and design of the study: C Hui, MC Chan

Acquisition of data: C Hui, MC Chan

Analysis and/or interpretation of data: C Hui, MC Chan

Drafting the manuscript: C Hui, MC Chan

Revising the manuscript critically for important intellectual content: C Hui, MC Chan

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門診氣喘病人緩解因素分析

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摘要

氣喘的治療已從單純控制症狀轉變為達到持續緩解，並預防疾病惡化。因此，本研究目的在評估未達緩解的臨床特徵。這項回顧性的研究納入在門診治療的氣喘病人，主要資料是來自參加中央健康保險署氣喘論質計酬 (pay for performance, P4P) 計畫的病人，以分析影響氣喘緩解相關的因素。在我們的研究中，氣喘的臨床緩解定義為：氣喘控制試驗 (asthma control test, ACT)，得分為 24 或以上，一秒鐘用力呼氣量 (forced expiratory volume in one second, FEV₁) 超過預測值的 80%，且在加入計畫後至少六個月內，無需要使用類固醇、急診就醫或因為氣喘需要住院等惡化情形。結果顯示，從 2021 年 1 月至 2023 年 12 月的資料中，篩選了 285 名病人，最終納入 143 名進行分析。這些病人的平均年齡 57.6 歲，62.2% 為女性，14.0% 為現吸菸者，17.5% 的初始 ACT 得分低於 20。追蹤六個月後，56.6% 未達臨床緩解標準。未達緩解的因素與吸菸 (adjusted odds ratio, aOR 4.944, $p=0.023$)、ACT 得分小於 24 (aOR 4.669, $p=0.003$)、FEV₁ 低於預估值值的 80% (aOR 17.892, $p<0.001$) 及近期曾發生惡化 (aOR 3.441, $p=0.033$) 顯著相關。年齡、體重指數 (body mass index)、性別、慢性共病及血液中嗜酸白血性球數量則無顯著統計差異。總結，本研究指出影響氣喘病人未達臨床緩解的重要因素，為門診診治提供參考。然而研究仍有不足之處，未來應該收集更多數據，探究疾病相關生物指標 (biomarker) 變化，以提供具體治療建議。