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Relationship between the level of asthma control, lung function and bronchodilator response in asthmatic children on inhaled corticosteroids

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Abstract

This study evaluated tools for assessing asthma control in 149 children on inhaled corticosteroids, focusing on the Asthma Control Test (ACT) and the Global Initiative for Asthma criteria (GINAc). It also explored the role of lung function (LF) tests, including spirometry and bronchodilator response (BDR), in identifying uncontrolled asthma. The GINAc identified 65.8% of children as having uncontrolled asthma, compared to 29.5% by the ACT ($p<0.001$). Spirometry and BDR results did not differ significantly between controlled and uncontrolled asthma groups. However, abnormal LF was more frequent in children with uncontrolled asthma identified by GINAc (18.4%) than in those with controlled asthma (5.9%; $p = 0.038$). In ACT-identified uncontrolled cases, 18.2% had abnormal LF compared to 12.4% with controlled asthma ($p=0.360$). Similarly, BDR appeared in 17.3% of uncontrolled cases by GINAc and 11.8% in controlled cases, with 25% of ACT-identified uncontrolled cases showing BDR vs. 11.4% in controlled cases ($p=0.037$). Findings suggest GINAc detects more cases of uncontrolled asthma than ACT and highlights the potential value of including spirometry and BDR to complement asthma control questionnaires, mainly aiding in identifying controlled asthma cases with underlying abnormal LF or BDR.

Key words: pediatric asthma, asthma control test, GINA guidelines, lung function, bronchodilator response.

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Introduction

According to major asthma guidelines, one of the primary goals of asthma treatment is effective symptom control [1,2]. Among the various tools available to assess asthma control, the Asthma Control Test (ACT) for children aged 4-11 years and those 12 years or older, along with the asthma control criteria recommended by the Global Initiative for Asthma (GINA), are among the most used [3,4]. However, evidence indicates significant discrepancies between clinical, functional (*e.g.*, spirometry), and inflammatory criteria for evaluating asthma control [5]. Additionally, the level of agreement between different ACTs in children ranges from low to moderate [6].

Moreover, no clear advantage has been established for one method over another in terms of accurately assessing asthma control, particularly in children on inhaled corticosteroids (ICS), where asthma control can serve as an indicator of treatment effectiveness. Limited information exists regarding the applicability of the ACT and GINA criteria (GINAc) in children from underprivileged populations, where lower educational levels may increase the risk of misinterpreting questions, thereby reducing the reliability of responses. In such cases, administering questionnaires through a physician to both parents and children may result in a more reliable assessment of asthma control, further supported by lung function (LF) tests and the bronchodilator response (BDR) [7,8].

LF and BDR can enhance the assessment of asthma control based on ACT and GINAc, as BDR may indicate poorer asthma control even in patients with normal spirometry results [9]. Nevertheless, many children with asthma exhibit a weak or nonexistent correlation between asthma control, as assessed by questionnaires, and LF [10,11]. This study aimed to compare the asthma control levels obtained using the ACT and GINAc, administered by respiratory physicians to asthmatic children and their parents, and to evaluate the contribution of spirometry and BDR in identifying cases of uncontrolled asthma that may be overlooked by the ACT and GINAc.

Materials and Methods

This prospective study was conducted between January and September 2018 at the Department of Pediatric Respiratory Medicine, Hospital El Pino, located in a low-resource urban area of South Santiago, the capital of Chile. A total of 149 asthmatic children were consecutively scheduled for spirometry as part of their routine evaluation. All patients were receiving regular ICS therapy and on-demand salbutamol. Participants were included if they had no active tobacco smoke exposure, were free of acute lower respiratory infections, asthma exacerbations, hospital admissions for

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asthma, or treatment with systemic corticosteroids in the past 3 months and had no other associated diseases with potential respiratory implications.

We hypothesized that LF impairment and a positive BDR would be associated with poorer asthma control as detected by either of the two questionnaires. During a medical interview and prior to LF testing, the GINA asthma symptom control criteria and the ACT questionnaires (for children aged under and over 12 years) were administered randomly to children and parents to assess asthma control. Respiratory physicians explained the questions and were allowed to clarify any doubts that parents and children had regarding the meaning of the questions. This physician-administered approach was assumed to improve the accuracy of the questionnaires in detecting uncontrolled asthma by minimizing the potential bias introduced by question misinterpretation [7,8].

According to the GINAc for asthma symptom control, well-controlled asthma is defined as a negative response to all questions, partly controlled asthma as a positive response to one or two questions, and uncontrolled asthma as a positive response to three or four questions [2]. For this study, controlled asthma was defined as responding "no" to all questions, and uncontrolled asthma as responding "yes" to one or more questions [12]. In the ACT questionnaires, a score of ≤19 indicated uncontrolled asthma [4].

Spirometry was performed using a Medgraphics CPFS/D processing system (Medical Graphics Corp., St. Paul, Minnesota, USA). The observed values of forced vital capacity (FVC), forced expiratory volume in the first second (FEV1), FEV1/FVC, and forced expiratory flow at 25-75% of FVC (FEF25-75%) were converted to z-scores based on the Global Lung Initiative reference equations [13]. A z-score of <-1.64 was considered abnormal, while a BDR was defined as a 12% increase from baseline in FEV1 measured 15 minutes after inhaling 400 µg of salbutamol [14] *via* a metered-dose inhaler with a spacer. Salbutamol and long-acting β-2 agonists were discontinued 12 and 24 hours before testing, respectively, while ICS therapy was maintained as prescribed. This study was approved by the Scientific Ethics Committee of the Chilean Ministry of Health, Southern Metropolitan Area of Santiago de Chile. Fully informed, signed consent was obtained from all parents.

Statistical analysis

Groups of children with controlled or uncontrolled asthma, as determined by the ACT or GINAc , were compared using descriptive statistics, including the chi-square test, correlation analysis, and inter-rater agreement. Analysis of variance was used to compare LF (z-scores) and BDR after salbutamol (% change) between patients with controlled and uncontrolled asthma, as classified by each method. The correlation between dichotomous variables (*e.g.*, yes/no, controlled/uncontrolled, normal/abnormal) was assessed using the φ coefficient of correlation (or the mean square contingency coefficient). Inter-rater agreement was evaluated using the κ statistic. The sample size was estimated to be 137, using a two-sided α of 0.05, with 95% confidence intervals (CI) and 80% power. Statistical significance was set at $p<0.05$. All analyses were performed using MedCalc Software version 22.006 (Ostend, Belgium).

Results

A total of 149 children successfully completed both methods of asthma control assessment, spirometry, and the BDR test. There were no significant differences between boys and girls in terms of age, height, weight, LF, or BDR to salbutamol (Table 1). Therefore, data from boys and girls were pooled for further analysis. A significant difference was found in the proportion of patients identified with uncontrolled asthma by the GINAc (65.8%; 95% CI, 57.8-72.9) compared to the ACT (29.5%; 95% CI, 22.8-37.3), with $p<0.001$.

Correlations and agreement

A significant correlation was observed between ACT and GINAc, coded as controlled/uncontrolled asthma ($p<0.0001$). The FVC value expressed as z-score (zFVC) was normal in all the patients, so no correlation analysis was done for ACT and GINAc *vs.* zFVC. No significant correlations were observed between GINA-defined asthma control (GINAc) and FVC, FEV1, or FEF25-75%, all expressed as z-scores (zFVC, zFEV1, and zFEF25-75%, respectively). Similarly, there were no significant correlations between zFEV1, zFEV1/FVC, or zFEF25-75% (nor-

Table 1. Anthropometric and spirometry measurements (z-scores), by gender (n=149).

	Boys (n=72)		Girls (n=77)		p[a]
	Mean	95% confidence interval	Mean	95% confidence interval	
Age (years)	10.9	10.1 to 11.6	10.4	9.7 to 11.1	0.352
Weight (k)	45.9	41.5 to 50.4	43.86	40.5 to 47.2	0.458
Height (cm)	144.6	140.2 to 148.9	139.5	136.0 to 143.0	0.068
BMI	21.08	20.1 to 22.1	21.97	21.01 to 22.94	0.208
zFVCbas	0.92	0.69 to 1.15	1.02	0.77 to 1.28	0.434
zFVCbd	0.94	0.74 to 1.15	1.08	0.82 to 1.34	0.403
zFEV1bas	0.48	0.21 to 0.74	0.72	0.43 to 1.01	0.542
zFEV1bd	1.07	0.85 to 1.30	1.23	0.94 to 1.52	0.211
zFEF25-75bas	-0.42	-0.67 to -0.16	-0.34	-0.58 to -0.10	0.694
zFEF25-75bd	0.58	0.33 to 0.84	0.55	0.30 to 0.81	0.870
zFEV1/FVCbas	-0.59	-0.82 to -0.37	-0.56	-0.78 to -0.35	0.841
zFEV1/FVCbd	0.12	-0.11 to 0.35	0.06	-0.18 to 0.29	0.639

[a]Comparison between boys and girls (analysis of variance); bas, baseline; bd, post-bronchodilator; BMI, body mass index; z, z score; FVC, forced vital capacity; FEV1, forced expiratory volume in the first second; FEF25-75, forced expiratory flow at 25-75% of FVC.

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mal/abnormal) and ACT (controlled/uncontrolled). Regarding BDR, there was a significant correlation with controlled/uncontrolled asthma according to ACT, but no significant correlation was found between GINAc and BDR.

Table 2. Correlations (φ) and agreement (κ) between Asthma Control Test, Global Initiative for Asthma criteria, lung function and bronchodilator response.

Correlations	φ coefficient	p
ACT *vs.* GINAc	0.4670	0.001
GINAc *vs.* zFEV1	0.0027	0.974
GINAc *vs.* zFEV1/zFVC	0.0351	0.668
GINAc *vs.* zFEF25-75	-0.008	0.078
ACT *vs.* zFEV1	0.0111	0.884
ACT *vs.* zFEV1/zFVC	0.1335	0.103
ACT *vs.* zFEF25-75	0.0916	0.263
Agreement	**κ value**	**p**
ACT *vs.* GINAc	0.358	0.001
ACT *vs.* BDR	0.158	0.036
GINAc *vs.* BDR	0.041	0.371

ACT, asthma control test; GINAc, Global Initiative for Asthma criteria; zFVC, forced vital capacity value expressed as z-score; zFEV, forced expiratory volume in the first second value expressed as z-score; zFEF25-75%, forced expiratory flow at 25-75% of FVC value expressed as z-score; BDR, bronchodilator response.

The level of agreement between ACT and GINAc was fair but statistically significant. The agreement between BDR and asthma control, as determined by ACT, was significant, but it was not significant between BDR and GINAc (Table 2).

Spirometry

Among the 149 patients, 21 (14.1%, 95% CI 9.41-20.59) had at least one abnormal spirometry parameter (z-score <-1.64): 2%, 11.4%, and 13.4% exhibited abnormal FEV1, FEF25-75%, and FEV1/FVC, respectively, while no patients had abnormal FVC. The BDR was present in 15.4% (95% CI 10.51-22.10) of the children. There were significant differences between baseline and post-bronchodilator mean values for FEV1 (p=0.001), FEF25-75% (p=0.001), and FEV1/FVC (p<0.001), but not for FVC (p=0.206).

No significant differences were observed in the mean values of FVC, FEV1, FEF25-75%, and FEV1/FVC (Table 3) either at baseline or post-bronchodilator (Table 4) between patients with controlled or uncontrolled asthma, as determined by GINAc or ACT.

In children classified as having uncontrolled or controlled asthma according to GINAc, 18.4% (95% CI 11.96-27.17) and 5.9% (95% CI 2.02-15.92), respectively, had abnormal spirometry (p=0.038). Regarding ACT, abnormal spirometry was present in 18.2% (95% CI 9.51-31.96) of those classified as having uncontrolled asthma *vs.* 12.4% (95% CI 7.38-20.04) of those with controlled asthma (p=0.360).

When comparing the proportion of patients with BDR in the

Table 3. Lung function in asthmatic children with controlled or uncontrolled asthma according to Asthma Control Test or Global Initiative for Asthma criteria.

	Asthma control level	ACT Mean	ACT 95%CI	p[a]	GINAc Mean	GINAc 95%CI	p[a]
zFVC	Uncontrolled	0.67	0.44 to 0.9	0.294	0.58	0.22 to 0.94	0.86
	Controlled	0.44	0.08 to 0.81		0.62	0.38 to 0.85	
zFEV1	Uncontrolled	0.98	0.78 to 1.19	0.882	0.90	0.58 to 1.22	0.54
	Controlled	0.95	0.64 to 1.27		1.01	0.81 to 1.21	
zFVC	Uncontrolled	0.67	0.44 to 0.9	0.294	0.58	0.22 to 0.94	0.86
	Controlled	0.44	0.08 to 0.81		0.62	0.38 to 0.85	
zFEF25-75%	Uncontrolled	-0.27	-0.48 to -0.06	0.057	-0.31	-0.63 to 0.01	0.58
	Controlled	-0.63	-0.94 to -0.32		-0.41	-0.62 to -0.20	
zFEV1/FVC	Uncontrolled	-0.51	-0.69 to -0.33	0.193	-0.52	-0.78 to -0.25	0.58
	Controlled	-0.73	-1.03 to -0.44		-0.61	-0.8 to -0.42	

[a]Comparison between controlled and uncontrolled asthma (analysis of variance); ACT, asthma control test; GINAc, Global Initiative for Asthma criteria; CI, confidence interval; z, z-score. FVC, forced vital capacity; FEV1, forced expiratory volume in the first second; FEF25-75, forced expiratory flow at 25-75% of FVC.

Table 4. Bronchodilator response after 400 µg of salbutamol in asthmatic children with controlled or uncontrolled asthma according to Asthma Control Test or Global Initiative for Asthma criteria.

	Asthma control level	ACT Mean	GINAc 95%CI	p[a]	Mean	95% CI	p[a]
zFVCbd	Uncontrolled	1.03	0.82 to 1.24	0.762	0.96	0.63 to 1.28	0.626
	Controlled	0.97	0.69 to 1.25		1.04	0.85 to 1.23	
zFEV1bd	Uncontrolled	1.17	0.94 to 1.4	0.740	1.05	0.70 to 1.40	0.433
	Controlled	1.1	0.78 to 1.43		1.21	0.99 to 1.42	
zFEV1/FVCbd	Uncontrolled	0.1	-0.09 to 0.3	0.778	-0.01	-0.31 to 0.29	0.399
	Controlled	0.05	-0.26 to 0.36		0.14	-0.06 to 0.33	
zFEF25-75%bd	Uncontrolled	0.6	0.39 to 0.81	0.525	0.49	0.17 to 0.81	0.541
	Controlled	0.48	0.12 to 0.83		0.6	0.39 to 0.82	

[a]Comparison between controlled and uncontrolled asthma (analysis of variance); ACT, asthma control test; GINAc, Global Initiative for Asthma criteria; CI, confidence interval; z, z-score; bd, post-bronchodilator (salbutamol); FVC, forced vital capacity; FEV1, forced expiratory volume in the first second; FEF25-75, forced expiratory flow at 25-75% of FVC.

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controlled/uncontrolled asthma groups as determined by ACT or GINA, it was found that 25% (95% CI 14.57-39.44) of those with uncontrolled asthma according to ACT had BDR, compared to 11.4% (95% CI 6.66-18.92) in the controlled group (p=0.037). In contrast, according to GINA, 17.3% (95% CI 11.12-26.04) of those with uncontrolled asthma and 11.8% (95% CI 5.51-23.38) of those with controlled asthma had BDR (p=0.372).

Discussion

This study demonstrates substantial discrepancies between the two assessment methods, with the GINAc classifying two-thirds of patients as having uncontrolled asthma, compared to only one-third using the ACT. Our findings agree with previous studies, which have consistently reported that GINAc identifies a significantly higher proportion of asthmatic children as having uncontrolled asthma [3,6,12,15-17]. For instance, one study found that 66% of asthmatic children had uncontrolled asthma according to GINAc, compared to 18% using the ACT [15]. Other authors reported even higher rates [17], with 86% of children classified as having uncontrolled asthma by GINAc. In a study of 525 asthmatic children, the proportion of uncontrolled asthma was 76.5% using GINAc, compared to 29.5% with the ACT [16]. These findings are consistent across tools, as evidenced by studies evaluating the agreement between five commonly used asthma control questionnaires, where only modest agreement was found, and GINAc reported the highest percentage of uncontrolled asthma (71.7%) [6]. Despite the significant differences in the proportion of children identified with uncontrolled asthma by GINAc and ACT in the present study, both tests were strongly correlated, suggesting that they both achieve the primary objective of detecting uncontrolled asthma.

The discrepancies between tools assessing the same outcome (whether asthma is controlled or not) are likely due to several factors, including the ease of understanding and responding to the questionnaires. The number and clarity of the questions, as well as the number of possible response options, can influence the accuracy of results across different questionnaires. Consequently, misunderstanding even a single question can significantly impact asthma control scores [6-8].

Education level is a critical factor influencing how individuals respond to asthma control questionnaires, as it affects both symptom perception and perceived disease control. Patients with lower education levels tend to overestimate their symptoms [7]. As a result, some researchers suggest that the ACT should be administered by a physician in patients with lower education levels, as studies indicate no significant differences between self-administered and physician-administered ACT scores [8]. This approach is particularly relevant for populations from lower socioeconomic backgrounds, where educational disparities could affect the reliability of questionnaire responses.

However, regardless of the results obtained from different asthma control tools, in daily clinical practice, the final decision regarding treatment adjustments or management should primarily rely on the physician's evaluation. Nevertheless, efforts should be made to routinely incorporate tools for assessing asthma control into daily medical practice. In real-world settings, particularly in busy outpatient clinics, clinicians are likely to prefer simpler and shorter tests, especially when verifying responses from both children and their parents.

The latter is important because despite guidelines, many physicians remain hesitant to use asthma control questionnaires in practice due to several reasons, such as added time demands, reliance on clinical judgment, potential inaccuracies in parental input for young children, limited training on these tools, perceived lack of sensitivity in some questionnaires, and integration challenges with electronic health records, adding to documentation burdens. Our findings align with studies showing that functional markers do not [18] or only weakly [10, 11] correlate with reported asthma symptoms or control. This is consistent with reports indicating that current asthma tests have limited value in corroborating asthma diagnoses or evaluating asthma control levels [5,11,14,19], regardless of the tool used or regular ICS treatment. However, other authors have found that FEV1, FEF25-75%, and FEV1/FVC are higher, while fraction of exhaled nitric oxide (FENO) and BDR are lower, in patients with controlled asthma as assessed by the ACT [15,20]. Despite the variability in correlations between asthma control tools and LF, spirometry and BDR, when used alongside ACTs, provide valuable additional information for clinical decision-making, especially in children receiving ICS therapy. BDR may help assess asthma control and potentially predict future disease progression [8,21]. Furthermore, abnormal spirometry and BDR in patients on regular ICS therapy can predict poorer asthma control [8,9], and may indicate a pediatric asthma phenotype characterized by low LF and poor control [22].

Had we defined uncontrolled asthma in our patients on ICS therapy as a 12% increase in FEV1 after salbutamol inhalation [9,14], most of the children studied would have been considered well-controlled, as 84.6% did not exhibit BDR. Previously, we reported that only 16.4% of clinically diagnosed asthmatic children showed BDR, while 24.9% had abnormal FENO levels [14]. Similarly, in children with current asthma (by epidemiological definition) not receiving ICS, only 7% had positive results for spirometry, BDR, and FENO [19]. Nevertheless, when abnormal, LF and BDR play a crucial role in establishing asthma diagnoses, improving treatment decisions, estimating asthma control levels, and predicting both short- and long-term outcomes.

In the present study, we found that 12.4% of patients with controlled asthma according to the ACT and 5.9% according to GINA had abnormal spirometry. This contrasts with other studies where 54% of children who reported reasonable asthma control exhibited abnormal spirometry results [9]. Additionally, 11.5% of patients classified as having controlled asthma by both GINAc and ACT had a positive BDR. Although the proportion of patients with controlled asthma who also had abnormal LF or BDR was relatively low, these children remain at an increased risk of future asthma exacerbations [21]. They should therefore be closely monitored for therapy adherence, inhaler technique, and exposure to harmful inhalants.

The variable relationship between asthma control tools and measures such as spirometry or BDR suggests that GINAc and ACT may be differently associated with asthma symptoms, LF, BDR, and inflammatory markers [5]. This aligns with our findings, where uncontrolled asthma detected by GINAc was linked to abnormal LF, while uncontrolled asthma identified by ACT was associated with BDR. Thus, regardless of the tool used to assess asthma control in children, incorporating LF tests, BDR, and potentially inflammatory markers such as FENO [14] into the assessment provides a more comprehensive understanding of disease control, as no single measure is sufficient to accurately determine asthma control on its own [9].

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Limitations

The potential incomparability of tools that assess different types of symptoms, severity, and control domains may limit the certainty of these results. Nonetheless, similar studies have conducted similar comparisons and reported consistent findings [6,12,15]. Although our relatively small sample size may limit the interpretation of our findings, systematic reviews, including studies with larger samples, have yielded similar results, further challenging the comparability of different questionnaires for evaluating asthma control in children [23].

The ACT questionnaire may be more effective in detecting moderate-to-severe symptoms compared to GINAc, especially when GINAc is used with only two of its three categories (controlled, partially controlled, and uncontrolled), as was done in this study (controlled and uncontrolled) and in similar studies. However, several other studies have consistently reported that GINAc detects a significantly higher proportion of patients with uncontrolled asthma, even when all three categories are used. Any validated method for accurately determining asthma control in children is valuable for clinical purposes, as poorly controlled asthma poses multiple risks, including reduced exercise performance, obesity, learning difficulties, impaired growth, diminished quality of life, school absenteeism, increased risk of exacerbations, and long-term pulmonary damage [1,23,24]. However, changes in the treatment of pediatric asthmatic patients, regardless of the results of pulmonary function tests or other complementary tools, should primarily be based on clinical evaluation and physician judgment.

Conclusions

The discrepancies between GINAc and ACT in this group of asthmatic children receiving ICS highlight the challenges in comparing these tools for evaluating asthma control. GINAc identified nearly two and a half times more cases of uncontrolled asthma than ACT. While abnormal spirometry and BDR were differently associated with uncontrolled asthma as defined by GINAc and ACT, they helped identify a subgroup of children with controlled asthma but abnormal LF and BDR, who may be at increased risk for future asthma exacerbations.

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