## RESEARCH LETTER

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# Asthma severity perception in Italian children: A nationwide cross-sectional study

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#### BACKGROUND 1

Symptom assessment is crucial in managing patients with asthma.<sup>1</sup> Asthma self-management is based on symptom severity.<sup>2</sup> However, the perception of respiratory symptoms may be approximate, mainly in children and adolescents.<sup>3</sup> Severe asthma symptoms may also be inconsistent with measured bronchial obstruction.<sup>4</sup> Therefore, there is a need to assess symptoms by reliable tools.<sup>5</sup> In this regard, the Visual Analog Scale (VAS) has been successfully used to investigate the breathlessness sensation.<sup>6,7</sup> A pediatric study showed that VAS scoring for breathlessness well correlated with lung function.<sup>8</sup> Meaningfully, a VAS cutoff <6 identified children with bronchial obstruction and reversibility.8,9

The Asthma Control Test (ACT) and the pediatric version (children-ACT, C-ACT) are reliable questionnaires for grading asthma control.<sup>10-12</sup> An adult study showed that low ACT values correlated well with VAS scores.<sup>13</sup> A recent pediatric study showed that VAS and C-ACT could identify children with exercise-induced asthma.<sup>14</sup> However, there is insufficient evidence about the VAS reliability in large populations of asthmatic children. Therefore, we tested the hypothesis that VAS scoring could identify children with uncontrolled asthma. So, the current nationwide study aimed at demonstrating the clinical relevance of VAS scoring in children with asthma.

#### **METHODS** 2

This cross-sectional study included a series of children and adolescents consecutively visited across 10 Italian pediatric third-level allergy clinics from January 2019 to December 2019. All patients were currently treated according to the GINA guidelines.<sup>1</sup>

The visit included careful history, comorbidities, clinical examination, lung function testing, ACT or C-ACT questionnaire self-administered, and GINA-based asthma control assessment.

The inclusion criterion was a documented asthma diagnosis, based on the history of intermittent wheezing, breathlessness, cough, and chest tightness combined with reversibility to bronchodilators and/or positive response to bronchial methacholine challenge. The exclusion criteria were lung disease other than asthma, recent asthma exacerbation, acute or chronic upper, and/or lower respiratory infections.

The Ethics Committee of the Istituto Giannina Gaslini of Genoa approved the study (22 253/2017). All the other Ethics Committees further approved the study.

Written informed consent was obtained from all parents. In addition, an electronic case report form recorded clinical data.

Spirometry was performed according to the ATS/ERS standards.<sup>15,16</sup> The diagnosis of allergy considered the consistency between sensitization and symptom occurrence. Rhinitis diagnosis considered the history of itching, sneezing, watery rhinorrhea, and nasal obstruction apart from a common cold.

VAS was a 10-cm vertical line on which 0 implied the perception of the most severe asthma, while 10 corresponded to no asthma

<sup>&</sup>lt;sup>†</sup> Member names are listed in the Appendix.

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problem. Patients, parents, and physicians were instructed to mark on the line their perception.

26, where 25 or 26 is the optimal asthma control, and <20 means uncontrolled asthma.

The ACT and cACT questionnaire consisted of five questions with five possible responses, exploring the patient's perception of his/her asthma control.<sup>17,18</sup> The result could range between 0 and 25 or

Baseline characteristics were described as mean with standard deviation (SD), median with interquartile ranges (IQR), or count and percentage (%), as appropriate. A univariate logistic regression model

# TABLE 1 Patient's characteristics

		Total	VAS < 6 54 subjects	VAS ≥6414 subjects	Univariate P-value	Multivariate OR (95%IC), P-value
Sex, males		325 (69.6)	38 (71.7)	287 (69.3)	.72	
Age, years		11.2 ± 3.07	10.6 ± 2.62	11.3 ± 3.12	.09*	1.17 (1.01-1.38); P = .047
BMI		19.7 ± 4.09	20.7 ± 5.47	19.6 ± 3.86	.18	
Presence of allergy		440 (95.0)	49 (92.5)	391 (95.4)	.36	
Presence of rhinitis		410 (87.8)	48 (90.6)	362 (87.4)	.51	
FVC (% of predicted)		99.1 ± 13.77	99.2 ± 13.81	99.0 ± 13.78	.64	
FEV <sub>1</sub> (% of predicted)		96.5 ± 15.28	93.1 ± 14.61	97.0 ± 15.33	.19	
Bronchial obstruction (FEV <sub>1</sub> < 80% of predicted)		55 (13.0)	11 (20.8)	44 (11.9)	.07*	
FEV <sub>1</sub> /FVC		97.7 ± 10.35	94.0 ± 10.00	98.2 ± 10.31	.006*	
FEF <sub>25-75</sub> (% of predicted)		85.3 ± 26.07	76.9 ± 21.59	86.4 ± 26.44	.020*	
Asthma control (GINA)	Well-controlled	259 (55.6)	21 (39.6)	238 (57.6)	.045*	
	Partly controlled	151 (32.4)	23 (43.4)	128 (31.0)		
	Uncontrolled	56 (12.0)	9 (17.0)	47 (11.4)		
VAS by physician (median and IQR)		8.0 (7.0-9.0)	6.0 (5.0-7.5)	8.0 (7.0-9.0)	<.001*	
VAS by parent (median and IQR)		8.0 (7.0-9.0)	6.0 (5.0-7.0)	8.0 (7.0-9.0)	<.001*	2.02 (1.56-2.62); P < .001
Childhood asthma control test (adjusted age) (median and IQR)		22.0 (19.0-24.0)	19.0 (15.0-21.0)	23.0 (19.0-25.0)	<.001*	1.17 (1.06-1.28); P = .002

Abbreviations: BMI, body mass index; FEV<sub>1</sub>, forced expiratory volume in one second; FVC, forced vital capacity; IQR, interquartile range; VAS, visual analogue scale.

\*Variables included in the multivariate analysis.



**FIGURE 1** Correlation between visual analogue scale (VAS) scoring assessed by children with asthma and by their parents

identified all possible factors associated with pathological VAS scores. Variables with P < .10 in the univariate analysis were imputed in the subsequent multivariate analysis. The grade of correlation between patient VAS and parent VAS was explored with Spearman's rho. Two-sided *P*-values  $\le .05$  were considered statistically significant. The analyses were computed using SPSS Statistics version 21.0 (IBM Corp., Armonk, New York).

# 3 | RESULTS

The clinical and demographic characteristics of the sample are shown in Table 1. There were 468 patients with asthma, 325 (69.6%) males and 143 (30.4%) females; the mean age was 11.2 years; 268 were children, and 200 were adolescents. Fifty-five (13%) patients had bronchial obstruction, documented by forced expiratory volume in one second (FEV<sub>1</sub>) < 80% of predicted. Considering the GINA control grading, 259 (55.6%) had controlled asthma, 151 (32.4%) partially controlled, and 56 (12%) uncontrolled.

Stratifying patients by VAS cutoff, 54 (11.5%) subjects had VAS score < 6 and 414 (88.5%) had VAS  $\geq$  6. At univariate analysis, subjects with VAS <6 had lower FEV<sub>1</sub>/forced vital capacity (FVC) and FEF<sub>25-75</sub> (P = .006 and .02, respectively), more frequent partly/uncontrolled asthma (P = .045), lower C-ACT score (P < .001), and lower VAS by parents and physicians (P < .001 for both) than subjects with VAS score  $\geq$  6. The multivariate analysis confirmed an association between VAS <6 scores and parents' VAS (OR = 2.02, 95% CI: 1.56-2.62; P < .001), C-ACT (OR = 1.17, 95% CI: 1.06-1.28; P < .001), and age (1.17 [1.01-1.38]; P = .047). The comparison between children and adolescents did not show any difference.

Moreover, there was a strong association (r = 0.72; P < .001) between patient and parent VAS scores (Figure 1).

# 4 | DISCUSSION

The current nationwide study, promoted by the Italian Society of Pediatric Allergy and Immunology, explored the possibility of using VAS scoring to identify clinical differences, mainly concerning asthma control.

The outcomes confirmed that VAS scoring could also be a reliable tool to identify subjects with nonoptimal asthma management in children and adolescents with asthma. In particular, a VAS cutoff <6 was associated with impaired lung function, mainly concerning bronchial obstruction, documented by impaired FEV<sub>1</sub> value, FEV<sub>1</sub>/FVC, and FEF<sub>25-75</sub>. FEV<sub>1</sub>/FVC is the best marker of bronchial obstruction,<sup>16</sup> and FEF<sub>25-75</sub> is a reliable predictor of early bronchial airflow impairment when FEV<sub>1</sub> is still normal.<sup>19</sup> Remarkably, VAS <6 was significantly associated with a C-ACT low score, consistent with uncontrolled/partly controlled asthma interpretation, such as median C-ACT values 19 with an interquartile range between 15 and 21. This finding had a clinically relevant value as a low VAS score (<6) could predict nonoptimal asthma control (OR = 1.17).

There was a strong correlation between children's perception and parents' one concerning the asthma disease perception. This relevant correlation was confirmed by the significant association with VAS <6 (OR = 2.02). In other words, the parent perception correctly interpreted the children's feeling of asthma disease. This result was consistent with a recent study investigating the true-positive recall of parent-reported wheeze at 1 year of age, its determinants, and its implications for asthma and lung function at 6 years.<sup>20</sup> The study showed that a correct parental recall of wheezing episodes could mirror the clinical relevance of early wheeze and its impact on subsequent asthma and lung function impairment.

Therefore, VAS could be a reliable tool to obtain relevant information about asthma control, ideally also at home involving both children with asthma and their parents.

However, the current study had some limitations, including the cross-sectional design, the lack of biomarker evaluation, and the performance in a clinical setting and not at home. Further studies should address these unmet needs. On the other hand, the study's strength was the nationwide size that provides generalizability.

# 5 | CONCLUSIONS

VAS scoring of asthma disease perception could be a reliable tool to achieve clinically relevant information about asthma control. Moreover, the parent's perception of their children's asthma disease properly intercepts their feelings of current asthma.

#### FUNDING

The study had no funding.

### **CONFLIC OF INTEREST**

The authors declare no potential conflict of interests.

### AUTHOR CONTRIBUTIONS

Conceptualization: Maria Angela Tosca.

Formal Analysis Irene Schiavetti Writing: Giorgio Ciprandi.

The member of the ControL'Asma Study Group collected the clinical data.

All authors have read and approved the final version of the manuscript.

The corresponding author had full access to all of the data in this study and takes complete responsibility for the integrity of the data and the accuracy of the data analysis.

#### **TRANSPARENCY STATEMENT**

Giorgio Ciprandi affirms that this manuscript is an honest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as planned (and, if relevant, registered) have been explained.

# DATA AVAILABILITY STATEMENT

The authors confirm that the data supporting the findings of this study are available within the article.

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### APPENDIX

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