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ARTICLE

 **Belgin Usta Guç**<sup>1</sup>  
 **Ozlem Yılmaz**<sup>2,3</sup>

<sup>1</sup> Adana City Training and Research Hospital, Department of Pediatrics, Division of Pediatric Allergy and Immunology, Adana, Türkiye

<sup>2</sup> Çanakkale Onsekiz Mart University, Department of Pediatrics, Division of Pediatric Allergy and Immunology, Çanakkale, Türkiye

<sup>3</sup> Mersin City Hospital, Department of Pediatrics, Division of Pediatric Allergy and Immunology, Mersin, Türkiye

**Corresponding Author:**  
*Belgin Usta Guç*  
mail: defneusta@hotmail.com

Received: 14.02.2023  
Acceptance: 12.03.2023  
DOI: 10.18521/kt.1251390

**Konuralp Medical Journal**  
e-ISSN1309-3878  
konuralptipdergi@duzce.edu.tr  
konuralptipdergisi@gmail.com  
www.konuralptipdergi.duzce.edu.tr

## Is It Time to Add Domains of Quality Of Life to the Childhood Asthma Control Test and the GINA Criteria?

### ABSTRACT

**Objective:** To measure the quality of life by using the Standardized Pediatric Asthma Quality of Life Questionnaire (PAQLQ(S)) in children with asthma and to determine the association of the Childhood Asthma Control Test(c-ACT) and Global Initiative for Asthma(GINA) criteria of asthma control with the PAQLQ(S) domains.

**Method:** This study was planned in a cross-sectional design. Parents of children between the ages of 7-11 who had been followed up at least  $\geq 1$  year with a diagnosis of asthma according to GINA in the Pediatric Allergy and Immunology Clinics of Mersin City and Adana City Research and Training Hospital were invited to participate in the study. Children who fulfilled inclusion criteria enrolled consecutively as they were administered to the clinics in the study period from January to June. Children filled out PAQLQ(S). The levels of asthma control were defined by c-ACT and GINA criteria of asthma control.

**Results:** Of the total 120 children, the median (%25-75) PAQLQ(S) and c-ACT scores were 4.90(1.3) and 17.9(4.8). All children had quality of life impairments except four. According to c-ACT, 41.7% of children were controlled; 58.3% of them were uncontrolled. PAQLQ(S) scores were found to be correlated with both c-ACT scores ( $p < 0.001$ ,  $r = 0.612$ ). The c-ACT score was more significantly correlated with the symptom domain of PAQLQ(S) ( $r = 0.667$ ,  $p < 0.001$ ). A more significant positive correlation was found between c-ACT and the duet score of activity and emotional function ( $r = 0.930$ ;  $p < 0.001$ ).

**Conclusion:** Asthma affects the quality of life in children. PAQLQ(S) scores decrease significantly when asthma is out of control. PAQLQ(S) is more significantly associated with c-ACT than GINA criteria. It would be useful in clinical practice if c-ACT or GINA criteria can be improved to cover quality of life, at least the part of the quality of life related to the symptoms or the activity limitations and emotional functions.

**Keywords:** Asthma Control, Asthma Control Test, Childhood's Asthma, Quality of Life.

## Çocukluk Astım Kontrol Testi ve GINA Kriterlerine, Yaşam Kalitesi Alanlarını Eklemenin Zamanı Geldi mi?

### ÖZET

**Amaç:** Astımlı çocuklarda Standart Pediatrik Astım Yaşam Kalitesi Anketi (PAQLQ(S)) kullanılarak yaşam kalitesini ölçmek; Çocukluk Çağı Astım Kontrol Testi (c-ACT) ile Global Initiative for Asthma (GINA) Testinin PAQLQ(S) alanları ile ilişkisini belirlemektir.

**Gereç ve Yöntem:** Bu çalışma kesitsel olarak planlandı. Mersin ve Adana Şehir Hastanesi Pediatrik Alerji ve İmmünoloji Kliniklerinde  $\geq 1$  yıldır astım tanısı ile izlenen 7-11 yaş arası tüm çocukların ebeveynleri çalışmaya davet edildi. Çalışma kriterlerini karşılayan çocuklara polikliniklere çalışma süresi Ocak-Haziran boyunca, polikliniğe başvurdukları sıraya göre ardosıra alındı. Çocuklar PAQLQ(S)'yi doldurdu. Astım kontrol seviyeleri, c-ACT ve GINA kriterleri ile aracılığıyla tanımlandı.

**Bulgular:** Toplam 120 çocuğun medyan(%25-75) PAQLQ(S) ve c-ACT puanları 4.90(1.3) ve 17.9(4.8) idi. Dördü dışında tüm çocukların yaşam kalitesinde bozulma vardı. c-ACT'ye göre çocukların %41,7'si kontrol altındaydı. PAQLQ(S) skorları her iki c-ACT skoru ile korele bulundu ( $p < 0.001$ ,  $r = 0.612$ ). c-ACT skoru, PAQLQ(S)'nin semptom alanı ile daha anlamlı bir şekilde koreleydi ( $r = 0.667$ ,  $p < 0.001$ ). c-ACT ile aktivite ve emosyonel fonksiyon düet skoru arasında daha anlamlı bir pozitif korelasyon bulundu ( $r = 0.930$ ;  $p < 0.001$ ).

**Sonuç:** Astım çocuklarda yaşam kalitesini etkilemektedir. PAQLQ(S) puanları, astım kontrolden çıktığında önemli ölçüde düşer. PAQLQ(S), GINA kriterlerine kıyasla c-ACT ile daha anlamlı bir şekilde ilişkilidir. c-ACT veya GINA kriterleri, yaşam kalitesini kapsayacak şekilde iyileştirilmesi klinik uygulamada yararlı olacaktır.

**Anahtar Kelimeler:** Astım Kontrolü, Astım Kontrol Testi, Çocukluk Çağı Astımı, Yaşam Kalitesi

## INTRODUCTION

Asthma is one of the most common chronic diseases in children (1). The disease does not just place a burden on health care systems, but it also places a burden on people's social lives; causes physical, educational and emotional impairments(1,2). The asthma treatment's aim is to achieve and maintain clinical control and reduce future risk of adverse outcomes. Clinical control of asthma is assessed by symptoms and lung function measurements according to Global Initiative for Asthma (GINA) guideline(3). A validated and simple method for measuring asthma control in daily practice is to use composite control measures such as asthma control test, childhood asthma control test, and asthma control questionnaire(3,5).

Quality of life measurement increases in importance when children with their maturing physical and psychological potentials are considered. Children's emotions and reflections may be quite different from that of adults. Thus, the effect of asthma on emotions, behaviors or in a broader sense the quality of life should also be measured. For this purpose, asthma quality of life questionnaires was produced (3,6).

Our purpose was to measure the quality of life in children with asthma and to evaluate the association of the Standardized Pediatric Asthma Quality of Life Questionnaire (PAQLQ(S)) with the Childhood Asthma Control Test (c-ACT) and GINA criteria of asthma control. The secondary aim was to determine the association of c-ACT and GINA criteria of asthma control with the PAQLQ(S) domains.

## MATERIAL AND METHODS

We planned the study in a cross-sectional design in the Pediatric Allergy and Immunology Clinics of Mersin City and Adana City Research and Training Hospital in Turkey. Mersin and Adana are the cities on the south coast of Turkey, neighbouring the Mediterranean Sea. The population of these cities is about 3,5 million.

Parents of children between the ages of 7-11 who had been followed up at least one year with a diagnosis of asthma according to GINA in the Pediatric Allergy and Immunology Clinics of Mersin City and Adana City Research and Training Hospital were invited to participate in the study. Children whose parents gave informed consent and who fulfilled inclusion criteria enrolled consecutively as they were administered to the Pediatric Allergy and Immunology Clinics in the study period from January to June. Children who were not able to communicate due to language barriers and had chronic diseases other than asthma were excluded from the study. The xxxxx University Ethical Board approved the study (No:148/2015). Informed consent was obtained from both parents at enrollment.

In order to determine the sample size, the mean of the sum of the quality-of-life scores of

those who were controlled according to GINA was found to be 5.5(±2) in the literature. Accordingly, it was predicted that the quality-of-life scores of the uncontrolled subjects would be 25% lower than those of the controlled 4.1(±1.7) and the sample size was calculated accordingly, and it was calculated that there should be 40 patients in each group.

**Standardized Pediatric Asthma Quality of Life Questionnaire:** PAQLQ was developed for measuring the asthma-related quality of life impairment in children by Juniper et al. in 1996 (7). The activity domain PAQLQ had two generics and three child-specific questions. Because of the three child-specific activities, PAQLQ was not very practical(6). For that reason, PAQLQ(S) and The Mini Asthma Quality of Life Questionnaire-MiniPAQLQ were developed (8) and validated (9). All the activity questions in PAQLQ(S) were generic. The Turkish versions of PAQLQs were validated by Yuksel et al (10).

We preferred to use the self-administered format of PAQLQ(S) in the study (7,8). We used the validated Turkish version of PAQLQ(S) (9). PAQLQ(S) is composed of 23 questions in three domains: Symptoms (10 questions), Activity Limitations (5 questions) and Emotional Function (8 questions). Children recalled their experiences in the last week and responded to each question on a 7-point scale (1= severe impairment, 7= no impairment). The scores were calculated separately for each domain as the arithmetic mean. The total PAQLQ(S) score was calculated as the sum of the scores of the three domains divided by three (6).

**Childhood Asthma Control Test:** c-ACT is composed of two parts with seven questions in total. The first part—consisted of four questions which were answered on a scale using a boy's face with emotions to facilitate comprehension by children. The second part consisted of parents answering three questions. The highest score of c-ACT was 27. Children who scored ≤19 points were determined to have uncontrolled asthma, and those who scored >20 were assessed to have controlled asthma (4). A Turkish version of c-ACT was validated by Sekerel (11) et al in 2012.

Demographic data of children (age, sex, atopic sensitizations and the number of emergency visits or hospitalizations in the previous year) were recorded from their medical charts.

Firstly, a clinical nurse gave children the self-administered version of PAQLQ(S). Children were encouraged to complete all of the questions in the PAQLQ(S). Children completed PAQLQ(S) on their own while their parents were waiting in another room for not to distract their answers. After the completion of the questionnaire, the clinical nurse checked whether there were any missing answers. If there were any, she reminded the children to fill out the missing questions. When

children completed PAQLQ(S), she gave them c-ACT and reminded them to fill out the first four questions of c-ACT. After completion of c-ACT by children, parents were asked to answer the remaining three questions of c-ACT according to the symptom frequency of their children in the last four weeks.

After PAQLQ(S) and c-ACT had been completed, children’s asthma control was determined according to GINA criteria at the same clinical visit by the same physician.

**Statistical Analysis:** First of all, the descriptive properties of the variables (mean, median, number and percentage) were found. It was checked whether the numerical variables fit the normal distribution. When comparing the two groups, the student’s t-test was used for normally distributed numerical variables, and the Mann-Whitney U test was used for non-normally distributed numerical variables. In cases where more than two variables were compared, ANOVA was used for those with normal distribution, and the Kruskal Wallis test for those who were not normally distributed. Chi-square was used when comparing categorical variables and the Spearman correlation analysis method was used for correlation analysis. The “Statistical Package for Social Sciences” SPSS 25 (IBM Corp., Armonk, NY, USA) program was used to evaluate the results. A p-value <0.05 was considered significant.

**RESULT**

In total, 120 children participated in the study. The median age (%25-75) was 10.7(2.7) and 62.5% of the children were male. The other demographic and clinical data of the participants

and the median scores of each PAQLQ(S) domain were shown in Table 1.

**Table 1. Characteristics of children with asthma**

Variable	Value
Age, † y	10.7 ±2.7
Sex, male ‡	75 (62.5)
Aeroallergen sensitization, ‡	111 (92.5)
Exacerbations in the previous year, ‡	54 (45)
0	66 (55)
1	32 (26.9)
2	9 (7.5)
3-6	13 (10.8)
Hospitalizations in the previous year, ‡	
0	109 (90.8)
≥1	11 (9.17)
Childhood asthma control test, †	17.9(4.8)
<b>PAQLQ(S) § scores of the study population‡</b>	
Activity limitations	5.0(1.4)
Symptoms	4.6(1.5)
Emotional Function	5.2(1.4)
Total	4.9(1.3)

† median (%25-75), ‡, n(%),§ PAQLQ(S):The Standardised Paediatric Asthma Quality of Life Questionnaire

All children filled out a self-administered version of PAQLQ(S) on their own. The median total PAQLQ(S) scores of the study population were 4.90 (1.3). All children had quality-of-life impairments according to PAQLQ(S) scores except four children.

According to GINA criteria of asthma control, 33.3% of children were controlled (n=40), 33.3% of children were partly-controlled (n=40) and 33.3% of them were uncontrolled (n=40). The comparison of patients' data according to GINA control status was presented in Table 2.

**Table 2. The comparison of patients' data according to GINA† control status**

	Uncontrolled (n=40)	Partly-controlled (n=40)	Controlled (n=40)	P
Age, ‡ years	10.6 (2.9)	11.4(2.8)	10.1 (2.3)	0.029
Sex, male §	25 (62.5)	22 (55)	28 (70)	0.490
Childhood asthma control test’s scores‡	13.5 (4.3)	18.4 (2.6)	21.9 (3.1)	<0.001
Childhood asthma control test§				
Uncontrolled	39 (97.5)	25 (62.5)	6 (15)	<0.001
Controlled	1 (2.5)	15 (37.5)	34 (85)	
PAQLQ(S) ‡,¶				
Symptoms	3.5 (1.4)	5.2 (0.9)	5.2 (1.3)	0.363
Activity limitations	4 (1.3)	5.6(1.2)	5.3 (1.2)	0.226
Emotional Function	4.4 (1.5)	5.5(0.9)	5.5 (1.4)	0.603
Total	4 (1.2)	5.4(0.9)	5.3 (1.2)	0.965
Exacerbation in the previous year §	15(71.4)	17(50)	4 (19)	0.001

†GINA: Global initiative for asthma, ‡median (%25-75), §, n (%), ¶ PAQLQ(S): The Standardised Paediatric Asthma Quality of Life Questionnaire

In order to better interpret the difference between the groups, according to the GINA criteria, we included uncontrolled and partially controlled patients as one group, and controlled patients as the other group, and made the comparison between

these two groups. When patients with uncontrolled and partly controlled and those with controlled according to the GINA were compared, there were significant differences between the groups (Table 3).

**Table 3.** The comparison of patients' data according to the revised GINA† control status

	Uncontrolled + Partly-controlled (n=80)	Controlled (n=40)	P
Age, ‡ years	11 (2.9)	10.1 (2.3)	0.095
Sex, male §	47 (58.8)	28 (70)	0.317
Childhood asthma control test's scores ‡	16 (4.3)	21.9 (3.1)	<0.001
Childhood asthma control test §			
Uncontrolled	64 (80)	6 (15)	<0.001
Controlled	16 (20)	34 (85)	
PAQLQ(S) ‡,¶			
Symptoms	4.3(1.5)	5.2 (1.3)	0.001
Activity limitations	4.8 (1.5)	5.3 (1.2)	0.05
Emotional Function	5 (1.4)	5.5 (1.4)	0.025
Total	4.7 (1.3)	5.3 (1.2)	0.008
Exacerbation in the previous year §	32 (58.2)	4 (19)	0.005

†GINA: Global initiative for asthma, ‡median (%25-75), §, n(%),¶ PAQLQ(S): The Standardised Paediatric Asthma Quality of Life Questionnaire

All of the study population and their parents performed c-ACT. According to c-ACT, 41.7% of children (n=50) had 20-27 points and therefore, were controlled; 58.3% of them (n=70) had <19

points and were addressed to be uncontrolled. The median c-ACT score was 17.9(4.8). The comparison of patients' data according to c-ACT status was presented in Table 4.

**Table 4.** The comparison of patients' data according to the Childhood asthma control test status

The Childhood asthma control test	Uncontrolled (n=70)	Controlled (n=50)	P
Age, † years	10.7 (2.9)	10.7 (2.5)	0.850
Sex, male ‡	42 (60)	33 (66)	0.633
Childhood asthma control test's scores†	15.1 (4.1)	21.9 (2.3)	<0.001
Global initiative for asthma control status‡			
Uncontrolled	39 (55.7)	1 (2)	<0.001
Partly controlled	25 (35.7)	15 (30)	
Controlled	6 (8.6)	34 (68)	
PAQLQ(S) †,§			
Symptoms	4.1(1.5)	5.3(1.1)	<0,001
Activity limitations	4.6 (1.4)	5.6 (1.2)	<0.001
Emotional Function	4.8(1.5)	5.6 (1.2)	0.004
Total	4.5(1.3)	5.5(1.0)	<0.001
Exacerbation in the previous year ‡	26 (57.8)	10 (32.3)	0,05

†,median (%25-75); ‡, n (%); §, PAQLQ(S): The Standardised Paediatric Asthma Quality of Life Questionnaire

A positive significant correlation was found between the symptom score of PAQLQ(S) and c-ACT (r=0.667; p<0.001). Therefore, it was observed that the c-ACT score increased as the symptom score increased. A positive significant correlation between PAQLQ(S)'s activity score and c-ACT (r=0.494; p<0.001), a positive significant correlation between PAQLQ(S)'s emotional function score and c-ACT (r=0.518; p<0.001), a positive significant correlation (r=0.612; p<0.001) was found between the total score of PAQLQ(S) and c-ACT. A positive significant correlation between symptom score and activity score of PAQLQ(S) (r=0.745; p<0.001), a positive significant correlation between symptom score and emotional score (r=0.797; p<0.001), a positive significant correlation between activity score and emotional score (r=0.930; p<0.001).

**DISCUSSION**

The present study measured the quality of life in children with asthma by using a self-

administered version of PAQLQ(S) and showed that loss of asthma control resulted in significant quality-of-life impairments in children. PAQLQ(S) scores were found to be correlated with both c-ACT scores and GINA criteria of asthma control. However, the association of c-ACT with PAQLQ(S) was stronger than that of c-ACT with GINA criteria of asthma control. Additionally, c-ACT was more significantly associated with the symptom domain of PAQLQ(S) than the other domains.

The present study found that quality of life was significantly impaired in children with asthma. Asthma control was obviously associated with quality of life in children. Quality of life impairment was found to be especially related to the symptoms of asthma. In this study, asthma control was measured separately by using two objective methods. Between those objective methods measuring asthma control, c-ACT seemed to be more significantly associated with quality of

life impairments than GINA criteria in children. This finding may be related that actually c-ACT was also related to emotions in addition to the symptoms. Children answer the first part of c-ACT while looking at a boy's face with emotions. Consideration of emotions by this was may also be the reason for the high correlation between c-ACT and PAQLQ(S) (4).

Quality of life measurement in asthma is important for all age groups, but it should be considered, especially in children (2). Because children cannot express all of the symptoms and emotions related to asthma as well as adults. It is a high probability that activity limitations may frustrate children easily. Children cannot establish cause-and-effect relationships in contrast with adults. That may be the reason for the marked difference in PAQLQ(S) scores between the children with controlled and uncontrolled asthma.

It is very important to control the symptoms of asthma. Poor symptom control is a significant risk factor for future exacerbations, emergency department admissions and hospitalizations(1,12,13). In 2004, GINA executive committee recommended that asthma management should be based on symptom control (14). Control-based management defined by GINA has two domains; symptom control and future risk of adverse outcomes. Symptom control is based on the frequency of daytime and nocturnal symptoms, limitation of activities and use of rescue medications(3). Asthma control may also be determined by using composite scores. c-ACT is a simple and user-friendly tool measuring asthma control in children between the ages 4-11 (4). c-ACT also correlates with the GINA classification of symptom control (3).

The present study exemplified that asthma control either defined by GINA criteria or c-ACT is highly associated with quality of life in children with asthma. This finding also showed that loss of asthma control may significantly impair the quality of life of children by causing symptoms, limiting activities and disturbing emotions. It also emphasizes that we can improve the quality of life of children by controlling their asthma. The association of asthma control with quality of life has been examined in both adults (15,16) and children (17). To our knowledge, there is only one study evaluating the relationship of quality of life and quality of life measurement domains with asthma control using both c-ACT and GINA criteria (18).

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c-ACT was also more significantly associated with the symptom domain of PAQLQ(S) than the other domains. This is logical because both c-ACT and GINA criteria were related mostly to the symptoms. The addition of either the activity ( $r=0.74$ ) or emotion ( $r=0.79$ ) domain to the symptoms increased the correlation. However, both activity and emotion domains further increased the correlation to a high level ( $r=0.93$ ). Furthermore, the total PAQLQ(S) score had a less strong correlation than the duet domains. The feelings related to activity limitation in the PAQLQ(S) score and the symptom control in the c-ACT or GINA are essentially different. Actually, asthma control, symptoms, activity limitations and emotions are also concepts related to each other in asthma.

Although both c-ACT and GINA criteria of asthma control were correlated with PAQLQ(S), these control measures cannot be used instead of quality-of-life instruments. The present study showed that controlled children according to GINA criteria or c-ACT may also have some impairment in quality-of-life scores. In other words, quality of life measurement may cover the other impacts of asthma on life that are not measured by GINA criteria and c-ACT. Quality-of-life questionnaires are too time-consuming to be part of the routine (19). Therefore, both c-ACT and GINA criteria of asthma control may be improved to cover quality of life, at least the part of the quality of life related to activity limitations and emotional functions in addition to measuring asthma control in children.

One of the strengths of the present study is the use of validated tools. The other strength may be the comparison of each domain of PAQLQ(S) with c-ACT and GINA criteria. We suggest subsequent studies with larger sample sizes in older age groups in children.

## CONCLUSION

Asthma affected the quality of life in children. PAQLQ(S) scores decreased significantly when asthma was out of control. We found that both c-ACT and GINA criteria were associated with PAQLQ(S). However; PAQLQ(S) was more significantly associated with c-ACT than GINA criteria. Controlling asthma may improve quality of life. It would be useful in clinical practice if c-ACT or GINA criteria can be improved to cover quality of life, at least the part of the quality of life-related to the symptoms or the duet score of activity limitations and emotional functions.

**Acknowledgement:** We thank Ersoy Civelek who did the statistical analysis.

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