Comparison of Asthma Control Test (ACT) with (GINA) guidelines in the Assessment of Asthma Control and determine if can use Asthmda Control Test ACT as alternative to Gina guidelines in control asthma.

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Abstract:

Background: The gold standard in assessing asthma control is the Global Initiative for Asthma (GINA) criteria. And because of the difficulties of access to pulmonary functions tests, The ACT has the added advantage that it does not require lung function assessment.

Objectives: The aim of this study is to assess asthma control through ACT score and GINA guideline, and to determine if the ACT can be as useful as the GINA-guidelines criteria in assessing asthma control in Iraq.

Patient and method: Cross sectional study with comparing ACT vs. GINA guideline in control of asthma level. This study was conducted at Respiratory consultation unit of the Iraqi National center of early detection of Cancer, Baghdad-Iraq, The study was conducted during the period from 1stNovember 2012 to 1stJuly 2013. A total of 71 adult asthmatic patients who were attended to the respiratory consultant unit were asked to participate and were enrolled in this study regardless their age or gender. Their asthma diagnosed and proved clinically by a combination of history, clinical finding In addition objective measurements using spirometry(FEV1) measured by the reversibility test which is defined as(an increment of>12% or 200 ml of FEV1 after 20 minutes of administration of inhaled short acting B2-agonist).

Result: There were 71 patients enrolled in this study, of them 66 (92.96%) had an ACT score of $\leq$ 19 ((26) (39.4%) are male),(40)(60.6%) are female ,and 5 patients (7.04%) had an ACT score of > 19 (only(1) (20.0%) is male and and(4)(80.0%) are female. It had been found the number of male is(27)and(26)(39.4%) out of them had an ACT<19and only(1)(20.0%) had ACT>19 and number of female is(44),(40)(60.6%)out of them had ACT<19 and(4)(80.0%)had ACT>19. No significant differences had been found in between those patients with $\leq$19 ACT score vs. those with > 19, regarding the age and gender, in both comparison P>0.05 it had been found that good agreement present between ACT and GINA, 92.9%.ACT agreed the GINA in (37 patients with uncontrolled asthma, 24 patients with partially controlled and 5 patients with controlled).

Conclusion: ACT can serve as an alternative diagnostic tool in assessing asthma control even without an aid of a spirometer or a peak flow meter. An ACT score of more than 19 can classify patient as controlled asthmatic while an ACT score < 19 can classify the patient as uncontrolled and partially controlled asthmatics.

Keyword: (ACT): Asthma Control Test.(GINA) Global initiative for asthma.

Introduction:

Asthma has defined as "a chronic inflammatory disorder of the airway(1), A simple 5-question test for asthma has been developed and validated in several studies.(2–4) The asthma control test(ACT) was initially developed in a study which looked at 25 of the most common questions that doctors ask when talking to patients about asthma control, with 5 questions standing out as being the most accurate predictors.2The 5 questions take less than a minute to answer and can be asked by the health care professional or the patient can complete the test themselves. There is a score of 1–5corresponding to a high level of symptoms. Studies have shown that the ACT score effectively discriminates between patients who differ in asthma control, is responsive to changes in control, and can discriminate between groups of patients in different lung function ranges. A score of 20–25 means that a patient's asthma is controlled. A score of 15-19 is partially control means that it may be possible to increase the level of asthma control and a full review of the treatment plan, including education on inhaler technique and the important of compliance with treatment, is warranted. A score of 14 or less indicates that asthma is poorly or not controlled and that an urgent review of

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and changes to the patient's management are needed. Although there are no randomized studies that demonstrate that use of the ACT translate into better asthma control, its use is highly likely to improve patient outcomes as asthma therapy can be confidently adjusted up if control is demonstrated to be poor. The (GINA)guidelines based on clinical symptoms including daytime symptom and limitation of activities and nocturnal shortness of breath, spirometric studies with FEV1,(GINA) guidelines classification of symptom control into control, partially control,uncontrol have promoted the progression and the improvement of asthma management.5-6To use these guidelines appropriately, it is extremely important to evaluate strategy essentially depends on the level of asthmacontrol.7,8 Studies of actual clinical care have indicated that there is poor use of pulmonary functiontests,6,9-10 including forced expiratory volume at 1 second , (PEF), which are require under most circumstances for proper evaluation of asthma control under these guidelines. The Asthma Control Test (ACT),11 developed in 2004, consisting of 5 questions. This tool is recognized as a superior for achieving asthma control.12-13One of the greatest benefits of ACT is that no respiratory function tests are required to evaluate asthma control. The ACT is thus suitable for administration using questionnaire surveys for asthmatic patient easy to use in the actual clinical care setting.

Patients and methods

Study design: This is a cross sectional study with comparing ACT vs. GINA guidelines in control of asthma level. This study was conducted at Respiratory consultation unit of the Iraqi National center of early detection of Cancer, Baghdad-Iraq.

The study was conducted during the period from 1stnovember 2012 to 1stJuly 2013.

Patients: A total of 71 adult asthmatic patients who were attended to the respiratory consultant unit were asked to participate and were enrolled in this study regardless their age or gender. Their asthma diagnosed and proved clinically by a combination of history and symptom: 1)cough which worsens at night, 2) wheeze, 3) difficulty of breathing, 4) chest tightness. In addition, objective measurements of airflow obstruction using spirometry(FEV1) measured by the reversibility test which is defined as(an increment of>12% or 200 ml of FEV1 after 20 minutes of administration of inhaled short acting B2-agonist) according to the British guidelines on the management of asthma.

Inclusion criteria:

1. Previously diagnosed asthmatic patients i.e. previously attend respiratory clinic and underwent spirometric test.

2. Patients who were aged 15 years and more were included.

3. Both genders were eligible able to underwent spirometer test.

Exclusion criteria:

Patient was excluded if he\she had one of the following criteria:

1. Had been hospitalized for Asthma.

2. Acute upper or lower respiratory tract infection within at least 4 weeks.

3. A known respiratory disorder other than asthma.

4. Smokers to exclude COPD.

5. Pregnancy.

Methods

Data collection: Data were collected via full medical history and complete clinical examination and the data were recorded in a pre-constructed data sheet which was included:

Socio-demographic data; age, gender, and clinical examination data   were included ,   Pulmonary Function Test Pre-bronchodilator FEV1 and FEV_1/FVC were measured using office spirometry in pulmonary function test outpatient clinic in Baghdad Teaching Hospital..

Assessment of Control of Asthma: All patients were assessed for their control of asthma by using ACT scoring   and GINA guideline as a golden standard, ACT scoring is a self administered 5 item questionnaire developed for assessing asthma control level. It evaluates the most recent 4 week time period. The Asthma Control Test (ACT) contains five items: the effect of asthma on daily activities, daytime and nocturnal symptoms, use of rescue inhaler medications and self assessment of asthma control, and dealing with asthma control during the previous 4weeks;each item is scored between 1 and 5, with the total-score ranging from 5 to 25. An ACT score of 25indicates that asthma is "controlled," whereas a score between15 and 19 shows partially controlled asthma and a score of <15 indicates "uncontrolled" asthma. And those with a score of <19 were re-grouped uncontrolled and partially control asthmatics. Then, the totally controlled patients were re-grouped as controlled patients (ACT>19). After the Asthma Control Test (ACT), patients had an interview wherein they were classified according to the GINA symptom severity,

The GINA classification of symptom control into control, partially control,uncontrol. This is based on clinical symptoms including daytime symptom and limitation of activities and nocturnal shortness of breath, spirometric studies with FEV1.

ASTHMA CONTROL TEST

1. In the past 4 weeks, how much of the time did your asthma keep you from getting as much done as usual at work, school, or at home?

☐1	☐2	☐3	☐4	☐5	☐
All of the time	Most of the time	Some of the time	A little of the time	None of the time	Score

2. During the past 4 weeks, how often have you had shortness of breath?

☐1	☐2	☐3	☐4	☐5	☐
More than once a day	Once a day	3 to 6 times a week	Once or twice a week	Not at all	Score

3. During the past 4 weeks, how often did your asthma symptoms (wheezing, coughing, shortness of breath, chest tightness, or pain) wake you up at night or earlier than usual in the morning?

☐1	☐2	☐3	☐4	☐5	☐
4 or more nights a week	2 to 3 nights a week	One night a week	One or two nights in the last 4 weeks	Not at all	Score

4. During the past 4 weeks, how often have you used your rescue inhaler or nebulizer medication (such as albuterol)?

☐1	☐2	☐3	☐4	☐5	☐
3 or more times per day	1 or 2 times per day	2 or 3 times per week	Once a week or less	Not at all	Score

5. How would you rate your asthma control during the past 4 weeks?

☐1	☐2	☐3	☐4	☐5	☐
Not controlled at all	Poorly controlled	Somewhat controlled	Well controlled	Completely controlled	Score

Total score:

Gina guideline classification asthma control:

	Controlled	Partly controlled (any present in any week)	Uncontrolled
Daytime symptoms	None (2 or less\week)	More than twice \week	Three or more features of partly controlled asthma present in any
Limitation of activities	None	Any	
Nocturnal symptoms / awakening	None	Any	
Need for rescue/ "reliever" treatment	None (2 or less\week)	More than twice/ week	
Lung function (PEF or FEV_1)	Normal	< 80% predicted or personal best (if known) on any day	

Statistical analysis: Data of all patients were entered and analyzed by using the statistical package for social sciences (SPSS) software for windows version 18. Descriptive statistics were presented as mean ± standard deviation (SD) for continuous variables and as frequencies and proportions (%) for categorical variables. Student's T test (independent 2 samples) was used to compare means of age, FEV1 in between two groups according to ACT level (≤ 19 or > 19). Chi square was used to assess the significance of association in between groups regarding the categorical variables. Agreement between ACT and GINA was calculated using percent agreement calculation and Kappa statistics.

Result:
There were 71 patients enrolled in this study, of them 66 (92.96%) had an ACT score of ≤ 19 and 5 patients (7.04%) had an ACT score of > 19, figure 1.
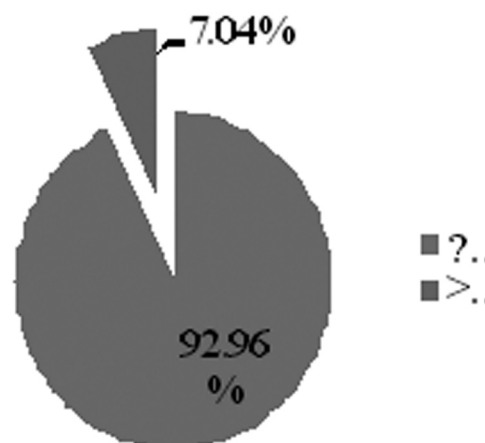

Figure 1. Distribution of Asthmatic patients according to ACT score

Table 1. summarizes the patients characteristics distributed by ACT score level, No significant differences had been found in between those patients with ≤ 19 ACT score vs. those with > 19, regarding the age and gender, in both comparison P>0.05. Regarding the distribution of ACT score vs. GINA classification, It had been found that out of the 66 patients with ACT≤19, 37 patients (56.1%) were labeled as uncontrolled on GINA, 29 (43.9%) labeled as partially controlled and none labeled as controlled, in contrast none of those with ACT score > 19 were labeled as uncontrolled or partially controlled on GINA, and 0nly the 5 patients with ACT score > 19 were labeled as controlled. On the other hand asthmatic patients with > 19 ACT score were significantly had higher FEV1 level 2 0f them (40%) had FEV1 of > 80 and 3 (60) of them had FEV1 of (60-80) while none of them had FEV1 < 60. Out of those patients with ≤ 19 Act level, none had FEV1 >80, 35 (53%) had 60-80 and 31 (47%) had FEV1 < 60. On comparison of mean FEV1 in between groups, those with ACT ≤ 19 had lower mean FEV1 as compared to those with >19 ACT, the mean FEV1 was 55.3 ± 15 and 74 ± 5.5 respectively, P=0.007.These finding indicating that FEV1 and ACT were directly correlated.

Table1.Patients characteristics and GINA classification distributed by ACT score

Variable		ACT score		P. value
		≤ 19 (n=66)	> 19 (n=5)	
Age (years)	Mean ± SD	41.6 ± 14.5	51.2 ± 15.4	0.137 [NS]
Gender n (%)	Male	26 (39.4)	1 (20.0)	0.39 [NS]
	Female	40 (60.6)	4 (80.0)	
GINA classification	Uncontrolled	37 (56.1)	0	
	Partially controlled	29 (43.9)	0	
	Controlled	0	5 (100.0)	
FEV1 No, (%)	> 80	0	2 (40.0)	
	60 - 80	**35 (53.0)**	**3 (60.0)**	
	< 60	31 (47.0)	0	
	Mean ± SD	55.3 ± 15	74 ± 5.5	0.007 [sig]

The distribution of ACT categories by the GINA classes is shown in table 2, it had been found that good agreement present between ACT and GINA, 92.9% and this percent is high due to small sample size.
ACT agreed the GINA in 37 patients with uncontrolled, 24 patients with partially controlled and 5 patients with controlled) and had been found the uncontrolled patients by Gina is (37) while uncontrolled patients by ACT is (42) and this indicate small difference between them.

Table 2.Distribution of ACT categories by GINA classification.

GINA classification n (%)	ACT			Total
	Uncontrolled	Partially controlled	Controlled	
Uncontrolled	37 (88.1)	0(0.0)	0(0.0)	37 (52.1)
Partially controlled	5 (11.9)	24 (100.0)	0 (0.0)	29 (40.9)
Controlled	0 (0.0)	0 (0.0)	5 (100.0)	5 (7.0)
Total	42 (100.0)	24 (100.0)	5 (100.0)	71(100.0)
Percent agreement = 92.9 %				

In table 3, the distribution of FEV1 according to the ACT categories of the patients shows a direct correlation between FEV1 and ACT, and compared as a means, found P<0.001.

Table 3.Correlation between FEV1 and ACT.

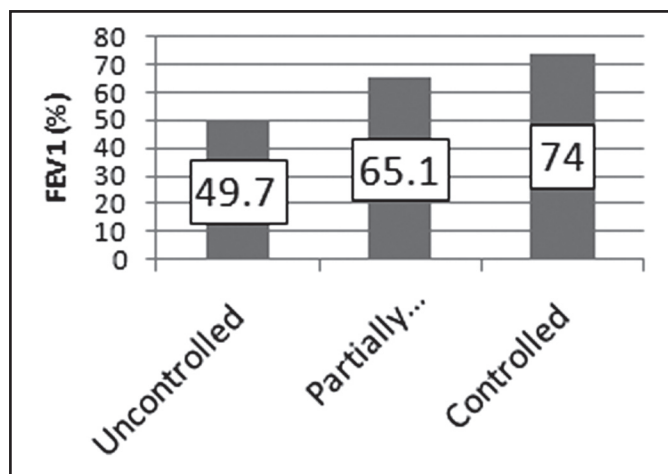| FEV1	ACT score level			P.value
	Uncontrolled	Partially controlled	Controlled	
> 80	0 (0.0)	0	2 (40.0)	
60 – 80	14 (33.3)	21 (87.5)	3 (60.0)	
< 60	28 (66.7)	3 (12.5)	0 (0.0)	
Mean ± SD	49.7 ± 15.1	65.1 ± 8.4	74 ± 5.47	< 0.001 [sig]

Figure 2. Comparison of mean FEV1 according to ACT level .

Discussion

In our study There were 71 patients enrolled in this study, of them 66 (92.96%) had an ACT score of ≤ 19 and 5 patients (7.04%) had an ACT score of > 19,it had been found the number of male is(27)and(26)out of them had an ACT<19and only(1) had ACT>19 and number of female is(44),(40)out of them had ACT<19 and(4) had ACT>19. In general characteristic of this study both male and female distributed according to ACT score level, found no significant differences between those patients with ≤19 ACT score vs. those with > 19, Regarding the age and gender, in both comparison found P>0.05 in table (1) and this have similar report in Kurdistan-Iran by sigarin,et al[35]. And consistent with results of USA study (2006) [36] and Philippines study (2007) [37]. This finding confirms the usefulness of ACT as a valid test in different populations. The present study revealed that 92.96% of studied asthmatic patients had ACT scores ≤ 19 and 7.04% of them had ACT scores > 19. This finding regarding proportion of uncontrolled asthmatic patients measured by ACT is higher than that reported by Philippine study in 2007[37] (72%) and close to results of USA study (2004) in which, most of asthmatic patients were uncontrolled. This high proportion of uncontrolled asthma showed that in our country, still asthma is not totally contained. And a full review of the treatment plan, including education on inhaler technique and the important of compliance with treatment is warranted. Our study revealed that 56.1% of uncontrolled asthmatic patients assessed by ACT were categorized as uncontrolled by GINA classification and 43.9% of them were categorized by GINA classification as partially controlled. This finding is consistent with that reported by Spanish study (2006) that found 57% of uncontrolled asthmatic patients were labeled as uncontrolled with GINA. All the asthmatic patients categorized as controlled by ACT were categorized by GINA classification as controlled (p < 0.001). This finding is consistent with results of USA study (2005) [37]on 522 subjects that showed ACT may serve as a useful screening tool in the community to determine whether patients have controlled or uncontrolled asthma. On the other hand asthmatic patients were the distribution of ACT categories according to the GINA classes is shown in table (2), in the present study percent agreement between ACT and GINA was 92.9%. This finding is consistent with results of Cross-sectional survey (2008) comparing ACT score and GINA classification of asthma control among 2949 patients attending primary care physicians and specialists

in France, Germany, Italy, UK, Spain and USA [37]. In this study we observed a stronger correlation between the ACT scores and mean FEV 1 (p < 0.001), and is consistent with the findings observed in other studies [42, 43] this have similar result with Kurdistan-Iran by sigarin,et al[35] al. These results confirm that asthma control cannot be inferred from the clinical measure of airway function alone. In this study, the ACT was useful in predicting GINA-defined asthma control categories and was particularly useful in confirming patients whose asthma was not controlled according to the GINA classification. We found that an ACT score of < 19 correctly predicted GINA 'partly controlled' or 'uncontrolled' asthma 100%. Stempel, et al[34], also in other study showed that ACT may serve as a useful screening tool in the community to determine whether patients have controlled or uncontrolled asthma Consequently, this makes it an excellent diagnostic tool for screening asthma severity.

Conclusion:

Asthma control test (ACT) can served as an alternative diagnostic tool in assessing asthma control even without an aid of a spirometer or a peak flow meter in an out-patient basis or as home based easily and quickly completed by patients. It can serve as a guide in the case management of asthmatic patients by step up and step down   adjustments in asthma therapy. The ACT may promote communication and partnership between patients and physicians, which helps the patients to establish confidence in asthma management, and improves physicians' performance and treatment outcome.

Recommendation

Asthma control questionnaire test should be applied routinely in our daily practice (especially respiratory clinics) to assist in future studying and planning for proper asthma management. Encouraging patients for using ACT score questionnaire in home and in work which is easily attend respiratory clinic. ACT score is a simple, inexpensive tool that can be used especially in our country Iraq where financial resources are limited and disabling our patient to do the standard diagnostic test such as spirometry.

Author contribution:
Study conception& design by Prof.Kassim.M.Sultan.
Acquisition of data analysis by Dr, Ahamed hassen.
Interpretation of data & Critical revision by Ass.Prof:
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