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Validation of the Asthma Control Test in pregnant asthmatic women

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Summary
Objective: To determine the validity of the Asthma Control Test (ACT) questionnaire for assessing pregnant asthmatic women.
Methods: The study involved 40 pregnant asthmatic women over a total of 113 medical visits. On each occasion the participants had a pulmonary function test and a clinical evaluation to assess the level of asthma control. In addition, the ACT was carried out with the obstetrician being blinded to its results.
Results: The most accurate cut-off point was 16, with a sensitivity of 95.4%, specificity of 68.8%, a negative predictive value of 91.7% and a positive predictive value of 80.5%. The positive and negative likelihood ratios were 3.052 and 0.067 respectively. The questionnaire was found to be highly effective for discriminating between controlled and uncontrolled asthma, with an area under the receiver operating characteristic (ROC) curve of 0.846 (95%CI: 0.748–0.92). Reliability assessed in patients with the same clinical classification resulted in an intra-class correlation coefficient of 0.86 (95%CI: 0.75–0.93). Improved clinical conditions corresponded to a significant increase in the ACT score ($p < 0.005$), indicating good responsiveness to changes in clinical status.

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Conclusions: The ACT proved to be reliable and could discriminate between levels of asthma control in pregnant women confirming its value as a useful tool for the management of asthma during pregnancy.

Introduction

Asthma is characterized by an increase in airway sensitivity and chronic inflammation leading to an obstruction that is partially or completely reversible [1]. It is the most common chronic disease in women of reproductive age [2], affecting up to 8% of pregnant women in the United States [3].

The course of asthma in pregnant woman is unpredictable. Improvement is observed in one-third of cases, deterioration in another third and no change in the remainder [4]. Pregnant asthmatic women are at an increased risk of experiencing preeclampsia, premature delivery, intrauterine growth restriction, and of being submitted for cesarean section [1,5]. Furthermore, asthmatic exacerbations during pregnancy are associated with an increased risk of congenital malformations [6]. However, when well-controlled, asthma is associated with a good fetal and maternal prognosis [7]. Therefore, keeping the disease under control is pivotal for an uneventful pregnancy and a healthy newborn infant [8].

A subjective evaluation of asthma control can be of no assistance in distinguishing between well-controlled and uncontrolled patients, leading either to insufficient treatment or to excessive medication [9,10]. In pregnant women, shortness of breath is the most common respiratory complaint. However, this physiological dyspnea is not associated with the other typical symptoms of asthma such as wheezing, coughing and chest tightness [11,12]. Thus obstetricians unfamiliar with the disease may find it difficult to evaluate the level of asthma control in pregnant women due to the numerous peculiarities and complaints produced by pregnancy itself.

The ACT questionnaire was developed in 2004 by Nathan et al. [13] and can be self-administered. It can be used for identifying patients with poorly controlled asthma and for monitoring treatment [14]. It has been validated in Spain [15], China [16], Korea [17], North Africa [18], Brazil [19], Greece [20], Vietnam [21] and Turkey [22]. Some authors have recommended its use to evaluate pregnant women [23].

However, to the best of our knowledge, no studies have assessed ACT's performance in pregnant asthmatic women and it is not known to what extent the presence of the breathlessness due to pregnancy itself may alter the value of the ACT score. Thus the objective of the present study was to assess the ability of the ACT questionnaire to distinguish between pregnant women with controlled asthma from those with poorly controlled disease and verify its reliability and responsiveness.

Patients and methods

A convenience sample of forty pregnant women was recruited from consecutive patients seeking care at the sub-specialty outpatient department for asthma in pregnancy located at the Hospital das Clínicas, the teaching hospital at the Federal University of Pernambuco (UFPE), Brazil, between December 2011 and October 2012. The women were 18 years of age or more, of more than 12 weeks in gestational age and had had a positive diagnosis for asthma. The study was approved by the institutional ethics committee and all patients signed an informed consent form.

A validation study was chosen as the most appropriate study design. Evaluations were conducted prior to delivery over a maximum of four visits scheduled at least four weeks apart. At each visit, the patients answered the Portuguese version of the ACT questionnaire [19], while a single obstetrician trained in the management of pregnant women with asthma performed a clinical evaluation and spirometry. Asthma diagnosis was confirmed by the clinical history and a previous increase of more than 12% in the one-second forced expiratory volume (FEV_1) after bronchodilation [24].

The first procedure at each visit was the pulmonary function test conducted using spirometry. The variable FEV_1, expressed as a percentage of the predicted value, was the parameter used to evaluate the degree of airway obstruction. Next, the ACT questionnaire was completed. Since there was no restriction in the study protocol on the inclusion of individuals with little or no schooling, the questionnaire was applied by interviewers, who had been instructed not to interpret the questions or influence the patients' answers. The pregnant women were asked to refer to their experiences with asthma during the previous four weeks and to answer the questions on the form.

At the end of each visit there was a clinical evaluation in accordance with the Global Initiative for Asthma (GINA) guidelines [24], which, in association with the pulmonary function test results, is considered the gold standard for asthma control. The obstetrician conducting these evaluations had specific training in asthma diagnosis during pregnancy and was blinded to the results of the ACT. At the first visit, clinical examination confirmed the diagnosis of asthma, evaluated its severity and classified the control level of the disease in accordance with the criteria proposed in the GINA guidelines [24]. At the following visits, the procedures consisted of evaluating the level of asthma control during the preceding four weeks.

Based on the GINA criteria, the patients were divided into controlled and uncontrolled asthma groups — the latter including partially controlled and uncontrolled cases. To evaluate the capacity of the ACT to distinguish between controlled and uncontrolled asthma, the patients were classified based on a score that ranged from 5 to 25. Validation measures were applied for each of the scores - sensitivity, specificity, positive and negative predictive