



## Health-related quality of life in asthma patients - A comparison of two cohorts from 2005 and 2015



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### ABSTRACT

**Introduction:** The aim was to investigate temporal variation in Health-Related Quality of Life (HRQL) and factors influencing low HRQL, in patients with asthma.

**Material and methods:** Questionnaire data on patient characteristics and the mini-Asthma Quality of Life Questionnaire (mini-AQLQ) scores from two separate cohorts of randomly selected Swedish primary and secondary care asthma patients, in 2005 (n = 1034) and 2015 (n = 1126). Student's *t*-test and analysis of covariance with adjustment for confounders compared mini-AQLQ total and domain scores in 2005 and 2015. Multivariable linear regression analyzed associations with mini-AQLQ scores.

**Results:** The mean Mini-AQLQ scores were unchanged between 2005 and 2015 (adjusted means (95% CI) 2005: 5.39 (5.27–5.33) and in 2015: 5.44 (95% CI 5.32 to 5.38), *p* = 0.26).

Overweight (regression coefficient 95% CI) (0.21 (–0.36 to –0.07)), obesity (–0.34 (–0.50 to –0.18)), one or more exacerbations during the previous six months (–0.64 (–0.79 to –0.50)), self-rated moderate/severe disease (–1.02 (–1.15 to –0.89)), heart disease (–0.42 (–0.68 to –0.16)), anxiety/depression (–0.31 (–0.48 to –0.13)) and rhinitis (–0.25 (–0.42 to –0.08)) were associated with lower HRQL. Higher educational level (0.32 (0.19–0.46)) and self-reported knowledge of self-management of exacerbations (0.35 (0.19–0.51)) were associated with higher HRQL.

**Conclusions:** HRQL in Swedish patients with asthma is generally good and unchanged during the last decade. Overweight, obesity, exacerbations, self-rated moderate/severe disease, heart disease, depression/anxiety and rhinitis were associated with lower HRQL, and high educational level and knowledge on self-management with higher HRQL.

### 1. Introduction

Health related quality of life (HRQL) is an important patient outcome in asthma, and can be assessed by several instruments. The validated Asthma Quality of Life (AQLQ) instrument has 32 items distributed over the four domains of symptoms, activity limitation, emotional function and environmental stimuli, and has been used in many contexts [1,2]. The reduced 15 item form Mini-Asthma Quality of Life (mini-AQLQ) is also well validated [3], is convenient to use, and has been employed in several randomised controlled trials [4,5].

Previous studies have shown that female sex [6,7], older age [8], current smoking [6,9], lower level of education [8], subjective severity rating [10], previous exacerbations [11], higher body mass index [12–14], and comorbid conditions such as depression [6,13], chronic rhinosinusitis [12,15] and obstructive sleep apnoea syndrome [16] are associated with lower HRQL in asthma. However, the influence of comorbid conditions on HRQL in asthma, and the associations of different factors with HRQL as assessed by mini-AQLQ, are still understudied areas. Moreover, the Global Initiative for Asthma (GINA) recommendations for asthma management [17] has been updated several

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times during the last decade, with subsequent national implementation strategies [18]. Change in HRQL over time in specific asthma cohorts has been investigated [19,20], but repeated cross sectional studies of HRQL in different populations from the same area are missing.

The objectives of this study were to investigate whether the level of HRQL assessed by mini-AQLQ has changed in the asthma patient population from both primary and secondary care in Sweden between 2005 and 2015, and how different factors are associated with HRQL as assessed by a cross-sectional analysis of mini-AQLQ in 2015.

## 2. Material and methods

### 2.1. Data collection

In 2005, the first PRAXIS asthma study cohort was created, with primary and secondary care patients from seven county councils in central Sweden [21–24]. Each county council was represented by the department of respiratory medicine in their central hospital, the department of internal medicine from one randomly selected district hospital and eight randomly selected primary health care centres (PHCCs), in total 14 hospitals and 56 PHCCs. A list of all adult asthma patients with a doctor's diagnosis of asthma (ICD-10 code J45) in the medical records during the period of 2000–2003 was compiled for every participating center. After a centralised random selection, a questionnaire was sent to 1675 patients. The response rate was 71%, resulting in 1195 patients including 861 from PHCCs and 349 from hospital outpatient clinics. In 2015, a second cohort was created, with a new random selection of 2794 asthma patients from the same 14 hospitals and at 54 of the original 56 PHCCs. The response rate was 46%, recruiting 1291 patients (915 from primary care and 376 from hospitals). In both 2005 and 2015, data were collected using questionnaires about patients' characteristics. The 2015 version was somewhat extended compared with the 2005 version, but both questionnaires included the Swedish version of mini-AQLQ.

### 2.2. Patient characteristics and measures

Information on sex, age, smoking habits, level of education, exacerbations, height, weight, self-rated severity of disease, written action plans and pharmacological treatment was provided by the patient questionnaires. The questionnaire in 2015 included additional items on self-reported knowledge of how to manage asthma exacerbations, and if any of the following comorbid conditions was present during the previous year; rhinitis, allergic rhino-conjunctivitis, heart disease, diabetes and anxiety or depression. Age was categorised as < 40, 40–59 and  $\geq 60$  years. The dichotomous educational variable identified the most highly educated group as those who had continued in full-time education for at least three years beyond the Swedish compulsory school period of nine years. Smoking history was categorised into current daily smoking or not. Obesity was defined as body mass index (BMI)  $\geq 30$ , normal weight as BMI < 25 and  $\geq 20$ , overweight as BMI < 30 and  $\geq 25$ , and underweight as BMI < 20 kg/m<sup>2</sup>. Exacerbations were defined as emergency visits during the last six months due to deterioration in lung disease and/or a course of oral steroids due to asthma worsening, and the number of exacerbations over the previous six months were grouped as 0 or  $\geq 1$ . The patient reported severity of disease was scored as very mild, mild, moderate, severe and very severe and dichotomized as very mild/mild or moderate to very severe. Self-knowledge about managing exacerbations was scored as yes; yes some, yes a little, and no, and dichotomized as yes or no. Treatment was reported as having 1; no treatment except short-acting bronchodilator rescue medication, 2; inhaled corticosteroids only, and 3; combinations of inhaled corticosteroids, long-acting beta-2-agonists or leukotriene antagonists. Asthma control was presented as control according to Global Initiative on Asthma (GINA) in 2005 and 2015, and using Asthma Control Test (ACT) in 2015. Controlled asthma

according to GINA was defined as no exacerbations previous 6 months, use of rescue medication no more than 2 times last week and no night awakenings last week. Controlled asthma according to ACT was defined as ACT score  $\geq 20$ .

### 2.3. Mini-AQLQ

The mini-AQLQ includes 15 items distributed over four domains; symptoms (5 items), activity limitation (4 items), emotional function (3 items) and environmental stimuli (3 items). Every item is assessed in a seven point scale from one to seven, where a higher value indicates better HRQL. The main outcome of the mini-AQLQ is the mean score calculated by the total score/the number of items, and the domain scores are calculated as the total score/the number of items for respective domain. The minimum difference considered clinically relevant is 0.5 [3]. Scores below six indicate that patients' asthma has an impact on their HRQL [25].

### 2.4. Statistical analysis

The analyses were performed using SPSS version 22.0 (SPSS Inc, Chicago). The total and domain mini-AQLQ mean scores were calculated for the two cohorts. The total mean score was dichotomized as low HRQL (< 6) or high HRQL ( $\geq 6$ ), where  $\geq 6$  indicates influence on HRQL hardly any or none of the time. Cross-tabulations and Chi-2 test examined differences in patient characteristics between high or low HRQL in 2005 and respectively 2015. Cross-tabulations and Chi-2-test were also used for an attrition analysis to investigate differences between the study populations and patients excluded due to not fully completed Mini-AQLQ items, for respective cohort.

Student's t-test was used to examine differences in mini-AQLQ between 2005 and 2015, and analysis of covariance with adjustment for confounders (ANCOVA) was used to compare adjusted mini-AQLQ mean scores for 2005 and 2015, for both total and domains scores.

In both cohorts, linear regression with mini-AQLQ score as the dependent variable was performed. Independent variables were sex, age (three groups), educational level, BMI (four groups), exacerbations during the previous six months (two groups), and self-rated severity (two groups). Sex and age groups were a priori confounders, and the remaining confounders chosen due to statistically significant associations in the unadjusted linear regression. To investigate differences in the patterns of factors influencing low HRQL between 2005 and 2015, interaction analysis used interaction terms for cohort year with each relevant variable with adjustment for the main effects and the potential confounding factors.

In the 2015 cohort, an extended multivariate linear regression was also performed, including previously used potential independent variables with additional adjustment for rhinitis, allergic rhino-conjunctivitis, heart disease, depression/anxiety and knowledge of self-management, all with statistically significant associations with low HRQL in unadjusted models. Finally, the multivariate linear regression model was repeated with the different domain mean scores as dependent variables. A p-value of  $p < 0.05$  was considered to be statistically significant.

### 2.5. Ethics

The study was approved by the Regional Ethical Review Board of Uppsala (DNr 2004: M-445 and 2011/318). Written consent was obtained from all participating patients.

## 3. Results

### 3.1. Patient characteristics

In total, the 2005 cohort comprised 1034 patients (734 from PHCCS

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