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Asthma exacerbations and socio-economic status in French adults with persistent asthma: a prospective cohort study.

Running title: Asthma exacerbations and social deprivation in France.

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Abstract

Introduction:

Adults disadvantaged by poor socio-economic status (SES) are more severely affected by asthma compared to those with better SES. We aimed to determine whether the frequency of asthma exacerbations (AEx), as well as aspects related to AEx management, differed based on SES in patients treated with daily treatments.

Methods:

This study, part of the prospective observational cohort ASTRO-LAB, included French adult patients with persistent asthma. Patients were considered as low SES if they benefited from publicly funded special health insurance and/or were perceived as low SES by their general practitioner. AEx was defined as at least one of the following: asthma-related oral corticosteroid course, medical contact, hospitalization, and death. We examined associations between SES and AEx frequency, perceived triggering factors and type of medical contact after AEx.

Results:

In our sample of 255 patients, 11.40% were considered as low SES. Patients with low SES did not report significantly more AEx than medium/high SES patients during one-year follow-up (0.79 versus 0.55, $p=0.38$). The type of medical contact during AEx differed significantly between the two groups ($p=0.03$): patients with medium/high SES consulted their general practitioner more frequently (OR=2.23, 95% CI=0.91-5.50, $p=0.08$) and were less likely to visit an emergency department or be hospitalized (OR=0.27, 95% CI=0.09-0.84, $p=0.02$).

Conclusions:

AEx frequency did not differ significantly between low and medium/high SES patients, but differences were found in the management of AEx. Studies are needed to better understand the relation between precariousness and management of asthma.

Introduction

Asthma, a chronic inflammatory disease of the respiratory tract, currently affects 235 million people worldwide, and prevalence is estimated to increase [1]. Asthma affects about four million people in France (6-7% of the population), of which half suffer from persistent asthma [2]. Daily use of controller treatments aims to improve asthma control and reduce the risk of asthma exacerbations (AEx) [4, 5]. In Europe, 50% of adults with asthma are insufficiently controlled [5]. Multiple factors can lead to poor asthma control and the occurrence of asthma exacerbations (AEx), such as exposure to allergens and air pollutants, smoking, interruption of controller treatments, or emotional stress [6, 7, 8].

Despite the availability of effective treatments, AEx remain relatively common, particularly in persistent asthma. In a recent prospective cohort study in France and the United Kingdom, 32.4% of patients with persistent asthma and daily controller treatment experienced an AEx during a 12-month follow-up period [9]. AEx are responsible for about 50 000 hospitalizations per year in France [2]. The overall cost of asthma in France is estimated at 1.5 billion euros per year, of which half is spent on hospitalizations [10].

In adults, people disadvantaged by poor socio-economic backgrounds are the most severely affected by asthma: the prevalence of asthma is higher among people with publicly funded special health insurance (PFSHI, which is the French full social security coverage delivered to

people with very low incomes), low-income people and the unemployed [11, 12]. A low socioeconomic status (SES) is recognized as a risk factor for severe acute asthma, poor asthma control, and asthma-related death [13, 14, 15]. Although in France there is universal health coverage, this reimburses only a limited set of essential services and therefore paid complementary health insurance is needed for a more extensive coverage. Yet, four million people do not have complementary health insurance in France and 15% of the French population declares that they have abandoned healthcare for financial reasons [16]. France is one of the countries in Europe where social inequalities in health are most substantial, while life expectancy is among the highest [17]. Thus, at the age of 35 years, a manager can expect to live 7 years longer than a manual worker [18]. These social inequalities in health have widened in recent years [18]. Although many studies have shown increased morbidity in terms of cardiovascular disease, cancer or psychiatric diseases in low SES patients [19], few prospective studies have investigated AEx managed in primary care among socially-deprived adult populations in Europe. In the United States, an association between low SES and asthma related emergency department visits was demonstrated [20,21].

The primary objective of this study was to determine whether there was an association between a low SES and AEx in persistent asthma patients treated with inhaled long-acting β 2-agonists (LABAs) and/or corticosteroids (ICs); we hypothesized that low SES patients experience more AEx than medium/high SES patients. To better understand the role of SES and other patient characteristics in the occurrence of AEx in this group, we further examined perceived triggering factors and type of medical contact during AEx.

Methods

Study design:

ASTRO-PREC (ASTRO-LAB and PRECariousness) was an ancillary study of ASTRO-LAB (Assessment of the safety of long-acting β 2-agonists in routine asthma care), a prospective cohort study conducted in primary care in France and the United Kingdom [22]. The ASTRO-LAB study has been approved by Ethics and Regulatory Boards in both countries.

The ASTRO-PREC cohort study recruited French patients of ASTROLAB cohort study, included from May 2013 to February 2015.

Participants:

Patients included in ASTRO-PREC were French patients aged from 18 to 40 years, suffering from persistent asthma (defined as having taken the same controller treatment for at least 6 months during 12 months before enrollment, consecutively or not). They had to have been followed by their general practitioners (GP) for at least 12 months before inclusion and have a medical history available for this period. Patients' prescriptions needed to include LABAs alone, ICs alone, and/or a fixed or free combination of LABA and ICs. Patients treated with chronic oral corticosteroids (OCs), for more than 15 continuous days in the previous three months, or with omalizumab were excluded. Patients with severe exacerbation in the 2 months preceding inclusion were not considered in the initial objectives of the ASTROLAB study. So, patients with OCs courses, unplanned visits to GP or a hospital emergency department, or hospitalizations related to asthma were excluded. Patients with respiratory comorbidities

(chronic obstructive pulmonary disease, cystic fibrosis, pulmonary fibrosis, tuberculosis, bronchiectasis) were not included in our study.

In France, participating GPs enrolled patients according to study criteria. Patients were then contacted by the study team for study consent and data collection. Those who refuse the computerization of their data, who were unable to be followed-up by phone, who had no regular internet access for the following 24 months or no mobile phone were excluded.

Data collection

Figure 1 summarizes the data collection process, which has already been published [22]. Patient reported data were collected by computer-assisted telephone interviews (CATIs) immediately after inclusion and every 4 months thereafter to assess asthma control, current asthma treatment, declared adherence and AEx [22]. Every month during the follow-up, patients were sent a phone text message asking whether new AEx occurred. In the event of a new AEx, additional questions were asked (via CATI) about its management and triggers. Socio-demographics (age, gender), medical history (infectious sinusitis, nasal polyps, intolerance to aspirin, intolerance to non-steroidal anti-inflammatory drugs, allergic rhinitis, gastroesophageal reflux, past history of obesity, anxiety disorder or depression) and treatment prescription data (SABA, LABA, IC) from GPs were collected by computerized questionnaires at enrollment, and in the twelfth, and twenty-fourth months [22].

Variables

AEx represented the primary endpoint and were defined as the occurrence of at least one of the following asthma-related events: OCs courses, unplanned medical visits to a GP or a hospital

emergency department, hospitalization, or death. These were computed based on patient-reported data.

In the event of an AEx, additional data were collected from patients, as followed: medical contact chosen for managing AEx (4 options: GP visit, hospitalization or emergency unit, OCs course); presence of any triggering factor (yes/no) and, if yes, type of perceived triggering factor among 11 categories pre-defined according to the literature (due to a contact with an animal, pollens exposure, home condition, sport, pollution, infection, emotion, weather, food, insufficient use of treatment, or strong use of treatment).

To assess SES, we used two SES-related data sources within the ASTRO-LAB study: the French National claims database [23] and the GPs computerized questionnaires. First, patients benefiting from publicly funded special health insurance (PFSHI) were identified from French National database. PFSHI is allocated, in France, to persons with an annual income below €8600. Second, GPs were asked to report if they considered their patients as low SES or medium/high SES, based on the following definition included in the survey (English translation): "Precariousness is the absence of one or more of the securities, in particular that of employment, enabling individuals and families to fulfil their professional, family and social obligations, and to enjoy their fundamental rights" [24]. This social assessment by the GP aimed to bring a more complete evaluation of the social status of the individual. Thus, patients were regarded as having a low SES if they had PFSHI and/or if they were assessed as 'low SES' by their GP. All the other patients were grouped in a second category of medium/high SES.

Franchise exemption for asthma was assessed from French National database. In France, patients with a long term severe diseases, based on medical criteria of severity, are fully refunded for

treatments. Behavioral and environmental data, such as level of study, type of occupation (skilled or unskilled), tobacco use, were collected on patients' online questionnaire. Pharmacotherapeutic group of anti-asthmatic treatment used by patients were self-reported by patients and categorized (ICs, LABAs, short acting β 2-agonists (SABA), fixed combination).

Analysis:

We used data from patients who had a complete follow-up of 12 consecutive months and were assessed for the occurrence of AEx.

The statistical analysis tested whether there was a difference between the two SES groups in terms of AEx frequency via non-parametric comparison of the means (Wilcoxon Mann-Whitney test). We examined differences in socio-demographic characteristics and medical history between the SES groups and between exacerbating and non-exacerbating patients (including differences in self-reported triggers). In order to compare distributions, Fisher's test (for patient group ≤ 5) or the Chi-squared test (patient group > 5) were used. Differences in SES regarding medical contacts after AEx were tested via logistic regression. The significance threshold for all statistical tests was set at 0.05.

Results

Patients' characteristics:

The ASTRO-PREC cohort included 416 patients. Two hundred and fifty-five asthma patients (61.30% of the cohort) had a complete follow-up of 12 consecutive months and were assessed for the occurrence of AEx (flowchart in figure 2). Among these, 29 patients (11.37%) of the study population, were regarded as having low SES. Women represented 57.25% of the sample. The mean age of the sample was 29.57 years (SD=6.86). In our sample, 36.67% reported being

active smokers. Patients' characteristics are summarized in Table 1. There was no significant difference between low SES and medium/high SES patients in terms of sex, age, body mass index (BMI) and smoking. The level of education was significantly lower in low SES patients than in medium/high SES patients (Odds Ratio (OR)=0.14, 95% Confidence Interval (CI) =0.04-0.44, $p<0.01$). Medium/high SES patients were significantly less likely to benefit from franchise exemption for asthma (OR=0.31, 95% CI= 0.10-0.94, $p<0.05$). Patient comorbidities did not differ significantly between the two groups except for obesity. The risk of obese patients was significantly lower among medium/high SES patients than among low SES patients (OR=0.38, 95% CI=0.15-0.98, $p=0.04$). There was no significant difference in the pharmaco-therapeutic group of anti-asthmatic treatment used between medium/high SES and low SES patients.

Asthma exacerbations:

In patients with 12 consecutive months of follow-up, 84 (32.94%) had at least one AEx: 11 (37.93%) in low SES patients, 73 (32.30%) in medium/high SES patients. In total, 148 AEx occurred: 125 in medium/high SES and 23 in low SES patients. The number of exacerbations ranged from 0 to 5 per patient over the 1-year follow-up in the medium/high SES group versus 0 to 4 in the low SES group. The mean number of AEx over the follow-up year in the medium/high SES group and low SES group was 0.55 (median = 0.00) and 0.79 (median = 0.00) respectively. There was no significant difference between the two groups (Wilcoxon Mann-Whitney test: $p=0.38$). No deaths were reported.

Comparison of characteristics of patients with AEx and those without:

Characteristics of patients with AEx are available in Table 2. Exacerbating patients were more females (chi squared test: 62 exacerbating female (73.81%) vs 84 non exacerbating female

(49.12%), $\chi^2(1, N=255)=14.03$, $p<0.01$). Several medical conditions were significantly associated with the occurrence of AEx: intolerance to non-steroidal anti-inflammatory drugs ($\chi^2(1, N=201)=4.81$, $p=0.02$), obesity ($\chi^2(1, N=201)=5.86$, $p=0.02$) and gastro esophageal reflux ($\chi^2(1, N=201)=4.11$, $p=0.04$).

Factors triggering AEx:

Regarding the triggering factors described by patients in Table 3, there was no significant difference between the two groups. Only meteorological factors were significantly more frequently reported by low SES patients (Chi-squared test: 39.13% vs 13.60%; $\chi^2(1, N=148)=8.74$, $p<0.01$). The most commonly reported triggering factors were: infections, climatic conditions, pollens, indoor environment and air pollution.

Type of medical contact after AEx:

The type of medical contact during the occurrence of an AEx differed significantly between the low SES group and the medium/high SES group. Medium/high SES patients went to the hospital significantly less frequently in the event of an AEx (OR=0.27, 95% CI=0.09-0.84, $p=0.02$) as reported in Table 4.

Discussion

Our study is the first to examine the relationship between SES and AEx in a routine primary care population, with patient-reported outcomes which ensure more precise information on AEx occurrence, and also possible triggers and healthcare utilization patterns. Our results suggest there were no significant differences in the frequency of AEx occurring over 12 months between low and medium/high SES patients. Yet, medical contact in response to AEx differed significantly between the two groups: medium/high SES patients went less frequently to hospital.

Previous studies showed an association between low SES and asthma related emergency department visits [20,21]. These studies may differ from our study by several methodological aspects. They were conducted in the United States, had larger sample sizes, and assessed only asthma-related emergency department visits. Our primary endpoint was different, as it included ambulatory AEx management practices, with or without reliance on healthcare professionals, in addition to emergency department visits. Nevertheless, our findings are consistent: individuals with low SES use more the hospital for asthma care. We can assume that asthma exacerbations may be more severe in low SES patients. Another hypothesis should be that healthcare use may be different in low SES patients.

Many studies have already shown that populations with low SES tend to favour hospital visits and especially emergency department visits for healthcare because they are cheaper than primary care [3,24]. Prior studies indicate that hospitalization is not only motivated by perceived health status but also by psychological and socio-economic factors [25-27]. In 2009, a study found a higher rate of hospitalizations among PFSHI beneficiaries than among those without PFSHI (17.5% vs. 13.2%) [28]. In addition, long delays in seeking care [29], which are more commonly seen in patients with a low SES, may lead to more severe exacerbations justifying hospital management. Moreover, precarious populations describe themselves as being in poorer health and have more comorbidities than non-precarious populations [30,31]. Another reason that may explain the overconsumption of hospital care is the fact that hospital services are free in France (patients do not pay the fees, which are paid directly by insurance funds) [16]. In France, inequalities in access to ambulatory specialized healthcare are among the widest in Europe [32]. Difficulties in access to care and rights may be due to problems related to the patients themselves

(difficulties to afford travel, isolation, language barriers, etc.) or to the healthcare providers (differences in the dynamics of patient-provider interaction and health service provision) [33]. The resulting dropout from care may be a barrier renunciation (linked to budgetary problems) or a refusal-renunciation (linked to choice or mistrust of the care system) [34]. There is also a lack of preventive health behaviours in precarious populations, which may explain their difficulties in recognizing a health problem, and in perceiving the seriousness of their state of health and the need to access healthcare [29,30,35]. In our study, persons with a low SES were less well educated than those in the medium/high SES group. It is therefore possible that medium/high SES individuals are better able to navigate the health care system [36].

Low SES individuals with asthma have poorer control of their asthma due in particular to poorer adherence [37]. Since our ASTRO-PREC study found that low SES patients favoured hospital contact, their exacerbations may be more severe than those of medium/high SES counterparts or their asthma may be more severe. Unfortunately, for this study, no data were available on asthma severity based on criteria such as GINA (Global Initiative for Asthma), or on the severity of exacerbations (such as peak-flow measurement) [38]. In the literature, a low SES is associated with the occurrence of AEx, and precarious populations have less access to therapeutic education, which may partly explain the lesser control of asthma and delayed consultation [7]. In our study, low SES was associated with a higher risk of obesity which in turn was significantly associated with AEx occurrence. Obesity is a risk factor for unstable asthma [15,39,40]. Our study corroborated evidence that obesity is more prevalent in deprived populations [39,41]. Many studies have reported an association between asthma and obesity [37,40]. Obese asthma patients are more at risk of hospitalization in case of exacerbation [42].

In this study, low SES patients were significantly more frequently exempted from franchise for medical fees related to their asthma. This reimbursement is granted by the French health insurance agency on criteria of disease severity (the patient must have severe persistent asthma). A study conducted by the French Institute for Public Health Surveillance reported that the likelihood of exemption for the fixed charge for asthma was significantly higher among those without complementary private health insurance (this covered part or all of healthcare costs not covered by French health insurance, which is mandatory), those with low incomes, retired, or unemployed [42]. Moreover, people with lower income or standard of living are less likely to benefit from this exemption [43]. These findings show that GPs are responsive to the social problems of their patients, as they initiate exemption for asthma procedures more often in patients with low SES. In addition, asthma patients who meet the criteria for exemption are possibly more severely affected by the disease or less well controlled (frequent exacerbations), which is more common in precarious patients.

There were limitations to our study, due to the fact that this was an ancillary study using information collected within the constraints of ASTRO-LAB cohort. Thus, difficulties of recruiting in primary care, strict inclusion criteria, extensive assessments, long follow-up with multiple measures, have limited the sample size, which might have led to a lack of power. Moreover, some patients with persistent asthma (using SABA), uncontrolled asthma (with severe exacerbations in the two months preceding inclusion), and those using omalizumab were not included. These exclusions of patients with poorly controlled asthma, at a high risk of AEx, may have led to a bias. Another possible source of bias could be that low SES patients were less likely to be included in this study due to study participation requirements, such as mobile phone

or internet access and availability for 24 months of follow-up. Furthermore, our study might have suffered from a classification bias. In case of missing value for one of the two criteria to assess SES conditions, the other available criterion was used. If patients did not meet the low SES conditions for that criterion, they were considered medium/high SES. It is therefore likely that some low SES patients were classified as medium/high SES on a single criterion.

This may have diminished disparities between the two groups and may explain the differences between our results and the literature. Moreover, as the allocation of PFSHI is based on economic criteria, it would be interesting to have another criterion to include more diverse group of patients with asthma (such as EPICES score, which is a global assessment of social deprivation validated in French health care centers) to classify patients as precarious or on-precarious [24].

Conclusions/key findings

Our study did not show a significant difference in AEx frequency between low and medium/high SES patients. However, we identified differences in the management of AEx, as medium/high SES patients went to hospital less frequently than did low SES patients. Further research needs to ascertain whether this behaviour indicates difficulties of accessing care in precarious populations or rather choices based on their representations of illness and health care services. The use of both qualitative analysis, to explore the relationship to healthcare and representation, and quantitative analysis.

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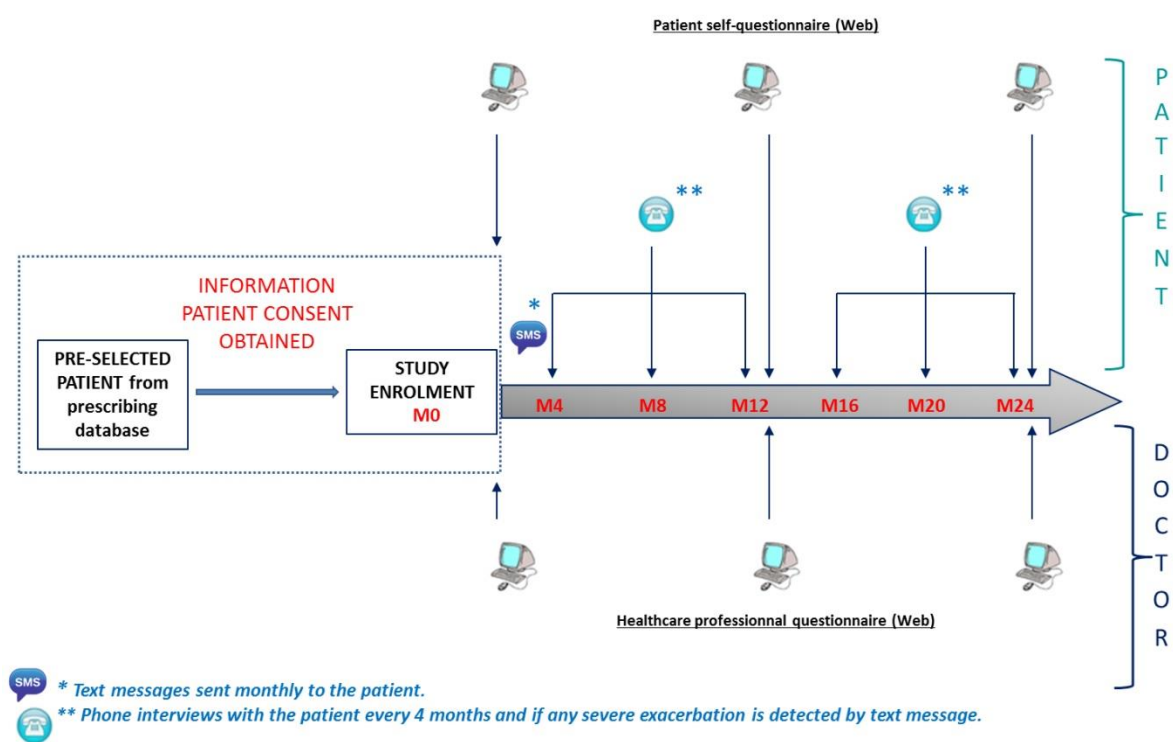


Figure 1: Data collection process for ASTRO-PREC study.

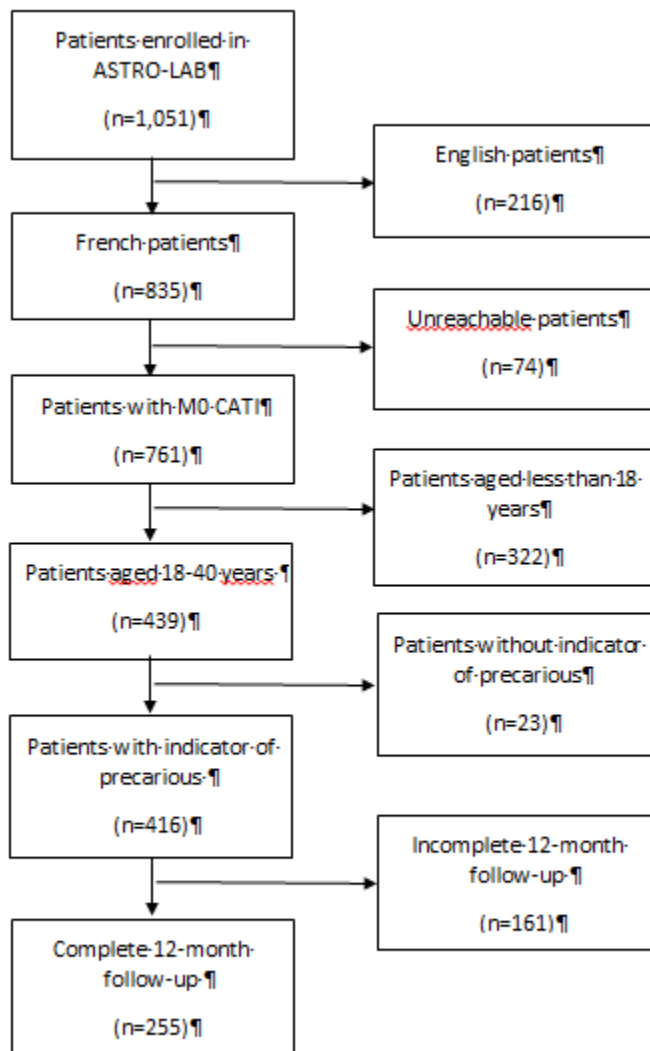


Figure 2: patients' inclusions' flow chart.

Table 1: Patients' characteristics.

		middle/high SES patients n=226 n (%)	low SES patients n=29 n (%)	p- valu e
Gender	male	101 (44.69)	8 (27.59)	0.08
	female	125 (55.31)	21 (72.41)	
Age	until 25 years	71 (31.42)	12 (41.38)	0.54
	from 26 to 33 years	70 (30.97)	7 (24.14)	
	over 34 years	85 (37.61)	10 (34.48)	
Body mass index*	until 25	120 (63.16)	11 (44.00)	0.12
	from 25 to 30	43 (22.63)	7 (28.00)	
	over 30	27 (14.21)	7 (28.00)	
Tobacco use*	active smoker	83 (61.03)	12 (85.71)	0.08
	non-smoker	53 (38.97)	2 (14.29)	
Level of study*	Less than bachelor's degree	15 (10.87)	7 (46.67)	< 0.05
	High than bachelor's degree	123 (89.13)	8 (53.33)	
Occupation*	unskilled	41 (54.67)	4 (57.14)	1
	skilled	34 (45.33)	3 (42.86)	
Franchise exemption for asthma*	No	186 (93.47)	22 (81.48)	< 0.05

Infectious sinusitis (reported by GP)*	Yes	13 (6.53)	5 (18.52)	0.7
	No	163 (91.57)	22 (95.65)	
Nasal polyps (reported by GP)*	Yes	15 (8.43)	1 (4.35)	0.6
	No	169 (94.94)	23 (100)	
Intolerance to aspirin (reported by GP)*	Yes	9 (5.06)	0 (0.00)	1
	No	168 (94.38)	22 (95.65)	
Intolerance to non-steroidal anti-inflammatory drugs (reported by GP)*	Yes	10 (5.62)	1 (4.35)	1
	No	168 (94.38)	22 (95.65)	
Allergic rhinitis (reported by GP)*	Yes	10 (5.62)	1 (4.35)	0.34
	No	82 (46.07)	13 (56.52)	
Gastroesophageal reflux (reported by GP)*	Yes	96 (53.93)	10 (43.48)	0.09
	No	166 (93.26)	19 (82.61)	
Past history of obesity (reported by GP)*	Yes	12 (6.74)	4 (17.39)	< 0.05
	No	148 (83.15)	15 (65.22)	
Anxiety disorder or depression (reported by GP)*	Yes	30 (16.85)	8 (34.78)	1
	No	152 (85.39)	20 (86.96)	
	Yes	26 (14.61)	3 (13.04)	

*: missing value for this variable

Table 2: Characteristics of patients with and without exacerbations.

	Non-exacerbating patients n=171 n (%)	Exacerbating patients n=84 n (%)	p (χ^2)
Sexe (male)	87 (50.88)	22 (26.19)	<0.05
Age			
until 25 years	55 (32.16)	28 (33.33)	
from 26 to 33 years	56 (32.75)	21 (25.00)	0.41
over 34 years	60 (35.09)	35 (41.67)	
Body mass index*			
until 25	97 (66.90)	34 (48.57)	
from 25 to 30	30 (20.69)	20 (28.57)	<0.05
over 30	18 (12.41)	16 (22.86)	
Active smoker*	61 (62.89)	34 (64.15)	0.88
Higher level of study than bachelor's degree*	82 (82.83)	49 (90.74)	0.23
Skilled occupation*	22 (40.00)	15 (55.56)	0.18
Franchise exemption for asthma*	8 (5.30)	10 (13.33)	<0.05
Infectious sinusitis (reported by GP)*	11 (8.21)	5 (7.46)	1
Nasal polyps (reported by GP)*	4 (2.99)	5 (7.46)	0.16
Intolerance to aspirin (reported by GP)*	7 (5.22)	4 (5.97)	1
Intolerance to non-steroidal anti- inflammatory drugs (reported by GP)*	4 (2.99)	7 (10.45)	<0.05
Allergic rhinitis (reported by GP)*	67 (50)	39 (58.21)	0.27
Gastroesophageal reflux (reported by GP)*	7 (5.22)	9 (13.43)	<0.05
Past history of obesity (reported by GP)*	19 (14.18)	19 (28.36)	<0.05
Anxiety disorder or depression (reported by GP)*	20 (14.93)	9 (13.43)	0.78

*: missing value for this variable

Table 3: Triggering factors of Aex.

		low SES patients n=23 n (%)	middle/high SES patients n=125 n (%)	p-value
Presence of trigger				
	No	4 (17.39)	18 (14.4)	0.75
	Yes	19 (82.61)	107 (85.6)	
Animal				
	No	22 (95.65)	118 (94.4)	1
	Yes	1 (4.35)	7 (5.6)	
Pollen				
	No	19 (82.61)	109 (87.2)	0.52
	Yes	4 (17.39)	16 (12.8)	
Home				
	No	20 (86.96)	106 (84.8)	1
	Yes	3 (13.04)	19 (15.2)	
Sport				
	No	23 (100)	123 (98.40)	1
	Yes	0 (0)	2 (1.60)	
Pollution				
	No	18 (78.26)	108 (86.4)	0.34
	Yes	5 (21.74)	17 (13.6)	
Infection				
	No	16 (69.57)	69 (55.2)	0.2
	Yes	7 (30.43)	56 (44.8)	
Emotion				
	No	20 (86.96)	111 (88.8)	0.73
	Yes	3 (13.04)	14 (11.2)	
Weather				
	No	14 (60.87)	108 (86.4)	<0.05
	Yes	9 (39.13)	17 (13.6)	
Food				
	No	23 (100)	125 (100)	
	Yes			
Insufficient use of treatment				
	No	22 (95.65)	122 (97.60)	0.5
	Yes	1 (4.35)	3 (2.40)	
Strong use of treatment				
	No	23 (100)	125 (100)	
	Yes			

Table 4: Medical contact after AEx according to SES using logistic regression.

	Odds Ratio (ref=low SES patients)	CI 95%	p-value
General practitioner	2.23	0.91-5.50	0.08
Hospitalization	0.27	0.09-0.83	0.02
Oral corticosteroid use	0.59	0.19-1.85	0.36