

Medicolegal diagnosis of Occupational Asthma

Does the Medical Diagnosis of Occupational Asthma Coincide With the Legal Diagnosis?

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Abstract

Objective The incidence of occupational asthma(OA) is increasing worldwide. In this study, we first aimed to document the rate of diagnosis of OAamong patients who were referred to our clinic from Social Security Institution and factors that affected diagnosis, and secondly, we aimed to assess the consistency of the medical diagnosis and the legal diagnosis.

Methods The study involved 132 consecutive patients who were referred to our clinic for evaluation of OA between 2010 and 2015. Detailed workplace history,the tools used in the diagnosis such as peak expiratory flow(PEF) monitoring and bronchial provocation tests and final medical diagnosis were recorded from case files.

Results Asthma was diagnosed in 75% (n = 99) of the patients. Among them, 22.2% were diagnosed as having OA. The diagnosis was confirmed by serial PEF measurement (45.5%), non

specific bronchial hyperreactivity (NSBHR) assessment (22.7%) and both tests (27.2%) at work and off-work periods. OA diagnosis was mostly established in workers who were actively working (72.7%). The legal diagnosis period was completed in 54.5% of these 22 patients, and 50% (n = 11) were officially diagnosed as having OA with an 91.6% concordance with medical diagnosis.

Conclusion This study verifies the importance of correct diagnosis of asthma in the evaluation of OA as first step. Diagnostic tests other than specific provocation tests could be preferential in patients who still work in the same field. We believe that cooperation with the patient's occupational physician and adequate recognition of the work environment will improve the consistency of legal and medical diagnosis.

Key words

Occupational asthma, Compensation, Specific provocation testing, Medicolegal diagnosis

Introduction

Asthma is a common disease in the general population and can be caused or worsened in different environmental conditions. As an important part of environmental conditions, 10-15% of adult-onset asthma has been reported to be associated with occupational exposure.¹ In an epidemiologic study that involved almost 7000 participants in 13 European countries, the risk of occupational asthma among adults with new-onset disease was reported to be between 10-25%.² If work exposure causes or exacerbates asthma it is called work-related asthma (WRA),³ which consists of two categories. Asthma primarily caused by working conditions is called occupational asthma (OA), whereas asthma that worsens at work but is not initially caused by the workplace is defined as work-exacerbated asthma (WEA).^{3,4} Both OA and WEA share many characteristics and both can cause severe work related disability. Distinguishing among the differences may exist in diagnosis, treatment, prognosis and prevention^{3,5} Furthermore a certain diagnosis of OA is important for compensation issues as patients with WEA are not generally supported by compensation systems in many countries⁶ ~~To date, more than 400 agents have been reported to cause OA.^{4,5,6} Occupational sensitizers are commonly high-molecular-weight (HMW) agents, but low-molecular-weight (LMW) chemicals can also cause sensitization.⁷~~

The diagnosis of OA is a challenging area in which investigations are highly recommended to start as soon as possible once the diagnosis is suspected. Asthma should be diagnosed in accordance with the criteria described in the guidelines because under or over diagnosis of asthma is common.⁷⁻¹⁰ The next step should be to evaluate the relation of asthma to workplace conditions. The assessment of workplace exposure is an important step in the clinical

investigation of OA.^{3,4} Guidelines for occupational asthma state that the most reliable method for diagnosis is specific inhalation challenge (SIC) testing;^{4,11,12} however, it is not available in many centers. Until recently, SIC testing was not available in our country. Alternatively, potential combinations of other diagnostic tests such as serial peak expiratory flow (PEF) rate measures at work and rest, immunologic tests, and NSBHR assessment at the end of working and resting periods can be used.^{4,11,13} The major problem in the diagnosis is the referral of most patients after leaving work, which causes inaccuracy in the diagnostic steps of OA.

In another aspect, diagnosis of OA is a medico-legal issue that requires compensation to varying degrees, depending on the impairment level of the patient. Compensation procedures vary widely between countries in medically-confirmed cases of OA, according to differences in legal practice. Being a tertiary reference center for OA, many patients have been referred to our clinic for evaluation of OA as an initial step of legal diagnosis. Due to the implementation schedule for OA in our country, we are not notified about the final legal decision of patients who we diagnosed as having OA. Therefore, we primarily aimed to assess to what extent the medical and legal diagnosis coincided during the medico-legal procedure. In doing so, we additionally attempted to review the outcomes of the patients in terms of diagnosis and diagnostic steps used in patients with suspected OA.

Methods

We performed a retrospective review of the case files of patients with suspected OA who were referred to the Ankara University School of Medicine Department of Chest Diseases, Division of Allergy and Immunology, Ankara, Turkey between August 2010 and December 2015.

Demographic features, occupational history, physical examination, results of spirometry tests, skin-prick tests, chest X-ray, and if available, NSBHR and SIC tests, serial PEF measurements, and specific IgE results were recorded for each patient.

This study was conducted in accordance with the amended Declaration of Helsinki. The study was approved by the Medical Ethics committee of Ankara University School of Medicine (date: 22/08/2014, approval number:13-593-14).

Diagnosis of asthma

Diagnosis of asthma was made using the clinical history and demonstration of objective measures of reversible airway obstruction [forced expiratory volume in 1 second (FEV_1) $<80\%$ and FEV_1 /forced vital capacity (FVC) $<70\%$ with an improvement in $FEV_1 \geq 12\%$ and ≥ 200 mL after 400 mcg salbutamol].¹⁴ In the absence of reversible airflow limitation, asthma was diagnosed based on a provocative concentration of methacholine that induced a 20% fall in $FEV_1 < 4\text{mg/mL}$.¹⁵

Following the initial evaluation, patients were divided into three groups: those diagnosed as having asthma (group 1), patients with unconfirmed asthma (group 2), and those lost to follow-up (group 3).

Evaluation for OA

Patients with a confirmed diagnosis of asthma were then assessed for the relation of asthma with workplace exposure. A detailed work history including occupation suspected or known exposures in the workplace, duration of asthma and employment and relationship between

asthma symptoms and workplace exposure was obtained. Subjects with asthma symptoms starting after getting the job were considered as suspected OA.

PEF recordings at work and off-work weeks

Using a portable peak flow meter, patients were asked to measure PEF rates in sets of three repetitions, four times per day (the best measurement for each was recorded on a chart) for 15 days at rest, and 15 days at work. Occurrence of 20% diurnal PEF variability in at least 2/3 of working days and maximum 1/7 of resting days. ~~more often on working days~~ and worsening in PEF values in work vs. off work periods were considered to favor OA(4).

Methacholine challenge following working and resting periods

We performed NSBHR assessment with methacholine at the end of two weeks in work and off-work periods in patients with FEV1 value >70%, and FEV1/FVC >70%. A threefold decrease in methacholine PC20 value at the end of the work vs. off-work periods was accepted as being compatible with OA.^{4,11}

Evaluation of atopy and occupational sensitization

Atopy was evaluated with a common panel of aeroallergens. In the presence of exposure to HMW/LMW agents in the workplace, skin-prick tests (SPT) and/or specific IgE measurements were performed with relevant allergens (ALK- Abello, Madrid, Spain). SPTs were performed with wheat flour, rye flour, and storage mites. Serologic testing for IgE specific to occupational allergens (isocyanates, ethylene dioxide, flour, α -amylase, and storage mites) were also measured by using a fluorescence immunoassay (Pharmacia CAP, Uppsala, Sweden).

SIC testing

Our SIC laboratory was only established in 2015; therefore, very few study patients underwent SIC testing. SIC testing was performed in a 7 m³ chamber that was impermeable to the passage of particles. The patients were exposed to a sham substance on the first day, and on subsequent days they were progressively exposed to the occupational agent that was suspected to have caused their asthma. If there was a 20% fall in FEV₁ from baseline, SIC testing was considered to be positive. A threefold reduction in PC20 value in the methacholine challenge between the control day and the last day of exposure was also considered as a positive result if the SIC testing was negative.

Following these steps, patients were classified into three groups: patients with OA (OA), patients with non-OA (non-OA), and those suspected but not accurately diagnosed as having OA (sOA); this group was officially reported as ‘having probable exposure to causative agents in the workplace, but inadequate objective data to make the final decision for OA.’

Evaluation of consistency of medical with legal diagnosis of OA

Legal decision procedures of occupational diseases include several predefined steps in our country. Patients with suspected OA are referred to chest departments of tertiary hospitals for the confirmation of the medical diagnosis by the Social Security Compensation Board. Majority of the referrals are directed to our clinic as a reference center. The committee makes the final decision for the legal OA diagnosis and rate of compensation by evaluating the medical diagnostic report along with the workplace inspectors’ document and occupational physicians’

opinion; this period takes approximately 1 to 2 years. In the final step, the disability rate is assessed and financial compensation is paid to patients with a disability rate higher than 10%.

The final decision and disability rate were recorded during the follow-up if the legal period was completed. The medical diagnosis was then compared with the legal decision for every patient and consistency was evaluated.

Statistical analyses

The statistical analysis was performed using the Statistical Package for the Social Sciences program version 20.0 (SPSS Inc., Chicago, IL, USA). Numeric values with normal dispersion are expressed as means $\pm$ SD, and abnormally dispersed variables are given as median values (min-max). Categorical variables values are given as n (percentage). The Chi-square test was used for the comparison of two independent groups for categorical data. The importance of the difference according to the means between groups was examined using ANOVA variance analyses. The Kruskal-Wallis test was used to determine the importance of the difference in medians between independent groups. All directional *P* values were two-tailed and significance was assigned to values lower than .05.

Results

Study population

A total of 132 patient files (M:121/ F:11) were reviewed. The mean age was 42.78 ± 7.9 years, the mean working period was 14.6 ± 8 years, and the mean time to onset of symptoms after starting work was 9.8 ± 7 years. Among the study group, 22 patients (29%) were still working in the same

job, 56.8% (n = 75) had quit, and 21.2% (n = 28) had changed their workplace. Fifty-seven percent (n = 76) of the patients had positive smoking history and 22.7% (n = 30) of them had positive reaction to aeroallergens in SPTs. The majority of the patients were painters and metal workers (Table 1).

Evaluation of asthma

Seventy-five percent (n = 99) of the patients were diagnosed as having asthma (Figure 1). Diagnosis was not confirmed in 20.5% (n = 27), and 4.5% (n = 6) of the patients were lost to follow-up in whom no diagnostic procedures were available. Furthermore, 59% (n = 16) of the patients with non-confirmed with asthma were referred to the pulmonology department to be evaluated for other pulmonary diseases (9 COPD, 5 pneumoconiosis, 1 interstitial pulmonary diseases and pneumoconiosis, and 1 COPD and pneumoconiosis).

Subjects with a certain asthma diagnosis were further evaluated for having occupational or work exacerbated asthma. All the patients (n = 99) reported asthma symptoms after starting the job with a latent period of 9.8 ± 6.99 years (min:3months- max:32 years).

Suspected but not accurately diagnosed as having (sOA) group

Among the patients with a diagnosis of asthma, 75.8% (n = 75) comprised the sOA group. These patients were not able to undergo methacholine challenge and serial PEF measurements during work and off-work periods because they were no longer working in the same workplace, but had a history compatible with OA.

Non-OA group

In two patients (1 carpenter, 1 baker), the diagnosis of OA was excluded. This decision was made based on the insignificant difference obtained in the comparison of PEF and PC20 values between the end of work and rest periods in both patients. Additionally, SIC testing with flour was found negative in the baker.

OA group

OA was diagnosed in 22.2% ($n = 22$) of the patients with asthma ($n = 99$) (Table 2). Among these patients, 72.7% ($n = 16$) were still working in the same job, 22.7% ($n = 5$) were working in different parts of the same workplace, and 4.5% ($n = 1$) had quit but could return to their jobs.

The diagnosis of OA was made through the determination of a 3-fold decrease in the patients' methacholine PC20 value at the end of the work vs. off-work period in 22.7% ($n = 5$), with the decrease in the PEF values during work weeks compared with weeks off-work in 45.5% ($n = 10$) of the patients (Figure 1). There was both a 3-fold difference in BPT and a difference in the serial PEF measurements at work and off-work periods in 27.2% ($n = 6$) of the patients and with SIC testing in one patient (Figure 1).

There was no prominent occupation among the group with a diagnosis of OA (Table 2). Even though we found no significant relation between the diagnosis of OA and the patients' profession, the highest rates in diagnosing OA were in the carpenters (37.5%, $n/T = 3/8$) followed by textile (28.6%, $n/T = 2/7$) and PVC-plastic workers (28.6%, $n/T = 2/7$), respectively.

Relationship between duration of exposure, symptoms, occupation, and ratio of OA diagnosis

The mean time to the onset of symptoms was not found different in subjects with OA, sOA, and non-OA (10.3 ± 5.9 years, 10.3 ± 7.8 years, and 11.5 ± 9.1 years, respectively). There was also no significant relation between the occupations, mean duration of exposure, and mean time to onset of symptoms. Within the occupations, bakers (21.3 ± 10 years), carpenters (19.8 ± 10 years), and repairmen (19 ± 2.4 years) had the longest exposure durations. Textile workers had the shortest duration of exposure (11 ± 5 years) and had earliest onset of symptoms (7 ± 5.5 years).

Legal diagnosis

The legal diagnoses of the Social Security Institution Compensation Board were reviewed in all patients ($n = 132$) (Figure 2). No sufficient information on the legal decision was available in 15.2% ($n = 20$) of the patients. Forty-four percent (44%; $n = 58$) of the patients had not yet been given a decision and were waiting for the legal period to end. Seventeen percent (17.4%, $n = 23$) were confirmed as non-OA, 8.3% ($n = 11$) were reported as having no asthma, and 15.2% ($n = 20$) of the patients were adjudged to have OA. In total, 54 patients (43 asthma, 11 non-asthma) had received their final judgement from the Social Security Institution (Figure 2). The median judgement period was 10 months (range, 2-53 months).

Patients who were judged as having no asthma ($n = 11$) were those who also received a medical diagnosis of no asthma. The compensation board judged 9 patients to have OA among the sOA group ($n = 31$). Eleven patients had a legal diagnosis for OA among the 12 with a medical diagnosis of OA, thus the legal diagnoses were 91% concordant with the medical diagnoses of OA. The comparison between the medical and legal diagnoses of 37 patients with asthma is

shown in Table 3 ($P = .001$). The number of patients with a disability rate higher than 10% was 10; each was compensated by the Social Security Institution.

Discussion

The determinants of disability in occupational asthma is inadequately studied in our country. Our results showed that the ratio of medical diagnosis of OA was as low as of 22.2% among the patients referred for evaluation of OA in our clinic. The diagnostic rate seems to be related to the availability of in- and off-work assessments. Accordingly, a huge majority of patients are not able to receive a certain diagnosis of OA because they quit their job in the past, despite a history compatible with OA, which leads to lack of in- and off-work assessments. Contrary to this, the majority of OA diagnosis were made in subjects who were actively working at the same job, which made in-work assessment possible. From the other side of the issue, legal diagnosis was consistent with medical diagnosis in the majority of the patients (83%) with OA. To our knowledge, this is the first study to evaluate the consistency of medical and legal diagnoses of OA in a group of patients referred to a tertiary clinic in Turkey.

Being a tertiary reference center for OA, many patients have been referred to our clinic for evaluation of OA. In order to prevent misdiagnosis, the first step in evaluating patients for OA is to confirm the diagnosis of asthma. Even in people with work-related respiratory symptoms, diagnosis other than WRA should be considered and ruled out if clinically plausible.¹⁶ In a recent study it was reported that 35.3% of patients with a history of work-related symptoms had no diagnosis of asthma.¹⁷ In our study, a diagnosis asthma was excluded in 20.5% of the patients; the final diagnosis was COPD, pneumoconiosis, and interstitial lung diseases in some of these patients, and some were found to have no respiratory condition. Another important diagnostic

step is the differentiation of OA and work exacerbated asthma (WEA). As all the patients with a diagnosis of asthma reported that their symptoms began after getting the work, we excluded WEA and took all the patients into consideration for OA. The reason for compatible history with OA in all patients may be due to the pre-selection of patients before referral to our center as a tertiary clinic.

We believe that the establishment of a relation between asthma symptoms and workplace exposure in patients still at work was a big issue when compared with patients off-work. It has been reported that agreement of serial PEF monitoring with expert diagnosis has sensitivity and specificity of up to 75% and 94%, respectively, and a positive test result significantly influences expert opinion on the probability of OA.¹⁸ Additionally, worsening of the provocative concentration of methacholine at work vs. off-work beyond the test's normal variability (threefold or greater change in PC₂₀) has been stated to provide evidence to support the diagnosis of OA.¹⁸ In accordance with these data, through the use of objective measures (serial PEF monitoring, NSBHR test) during work and off-work periods, we were able to confirm or eliminate the diagnosis of OA in all patients who were still working. Thus, the rate of concordance between the medical and legal diagnosis of OA was found high in the group of still-at-work patients. One of the greatest challenges we faced was the patients who had already left their job at the time of diagnostic work-up. However Compensation Board needs an accurate diagnosis in this group of patients, which makes SIC testing mandatory for final decision.

In this study, patients with suspected but not accurately diagnosed OA were defined as the sOA group, in which nearly one third of the patients had the legal diagnosis of OA. All of the patients in this group had left their job at the time of the evaluation. This was not a surprising outcome

because we could not use the objective diagnostic tools and could not reach an accurate diagnosis of OA. However, we think that we should focus on patients who had a legal diagnosis of OA in this group and analyze the factors leading to this decision. When this group was evaluated according to their occupations, painters were found in the majority, followed by textile workers. Among the painters, patients with a legal diagnosis of OA had longer working duration and later onset of symptoms. It was also observed that they had a history of improvement in their asthma after leaving the job. Taken together, working in areas with heavy exposure, longer working periods, and history of symptom relief after quitting seems to be effective for a favorable judgement of the Compensation Board.

It is reported that a detailed work exposure history that enables the determination of likely exposure to a known workplace sensitizer or irritant is mandatory for the accurate diagnosis of OA. However, patients may not know what agents were used at work; therefore, it is suggested more information should be obtained from management safety data sheets in the workplace.¹⁸ A recent study emphasized the importance of expert assessments, reporting that some potential sensitizing agents were detected by the occupational hygienist in the majority of patients with negative SIC testing.¹⁹ In this study, we obtained information related to exposure from the patients, and we had neither safety data sheets nor workplace inspection documents included in the referral files. On the other hand, the Compensation Board draws its final conclusion based on the medical report and work place inspectors' document. We believe the lack of workplace data was an important barrier for us in the evaluation of patients in the sOA group.

It is generally agreed that performing SIC with an occupational agent leads to a confirmed diagnosis of OA when other objective methods are not feasible, are less efficient, or have failed

to provide definitive results.²⁰ Most authors consider SIC as the reference test in OA diagnosis despite false positives and false negatives.²¹ A European task force reported that SIC testing could be performed in 24 centers from 12 countries in Europe.^{20,22} Occupational challenge is the usual practice for diagnosis in Canada, but this test is not clinically available in many centers in the world.²³ We were not able to perform SIC testing until recently. Thus, this test was only performed in two patients in the study group. We believe that if SIC testing had been available earlier in our clinic, the rate of OA diagnosis would be higher.

Our study has limitations that need to be considered. First, although the number of patients included in the study was satisfactory, the litigation procedures had been completed in few subjects. In this situation, we were not able to make a subgroup analysis in terms of the consistency of medical and legal diagnosis in different occupations. The second limitation of this study is that we were not able to perform SIC testing in the majority of the study period. The number of subjects with an accurate diagnosis of OA would be higher with the use of SIC testing, particularly among patients who had quit their job. If so, we would be able to make a stronger argument on the medico-legal relation of OA in our study population.

In summary, our results demonstrate that we had a favorable outcome in the diagnostic assessment of OA in patients still at work. However, it is evident that there is a clear need for additional diagnostic steps such as SIC testing and workplace exposure information in patients who have left their jobs. The collaborative work of physicians and workplace hygienists seems an important step in breaking through the barriers in the diagnosis and the medico-legal aspects of OA in our population.

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Table 1. Distribution of Patients According to Occupations

	n	%
Painters	26	19.7
Metal Workers	20	15.2
Welders	17	12.9
Textile workers	9	6,8
Carpenters	9	6,8
PVC-plastic workers	8	6,1
Mine workers	7	5,3
Bakers	6	4,5
Repairmen	5	3,8
Others *	25	18.9
Total	132	100

*Cleaner 4, Ceramic Worker 3, Cement-Tile Factory worker 3, Printing Sector 2, Plaster-Mold 2, Laboratory Equipment Production Worker 2, Hairdresser 1, Scavenger 1, Asphalt Worker 1, Dental Technician1, Nurse 1, Melamine Press Worker 1, Naphthalene Factory Worker 1, Detergent Factory Worker 1, Dishwasher 1

Table 2. Demographics and Disease Characteristics of Patients with OA

Patient no	Age	Sex	Occupation	Duration of occupation (year)	Duration of asthma (year)	Atopic status	Diagnostic tools				Legal diagnosis
							Serial PEF* Measurement (mean value-ml)		BPT** (Pc20 - mg/ml)		
							Resting period	Working period	After resting period	After working period	
1	37	M	Baker	15	12	Flour mix spIgE:+5, pollen			0.74	0.38	Non-OA
2	48	M	Carpenter	37	15	nonatopic	350	250			OA
3	39	M	Welder	24	5	nonatopic	300	240			OA
4	50	M	Metal worker	19	5	nonatopic			1.32	0.39	OA
5	36	F	Labaratory Equipm ent Producti on worker	17	9	nonatopic			16	0.47	OA
6	39	M	Welder	17	3	nonatopic	350	250			OA
7	47	M	Metal	5	3	nonatopic	490	390	16	2.28	incomp

			worker								leted
8	32	M	Textile worker	9	7	nonatopic	470	280			incompleted
9	44	M	Mine worker	13	2	nonatopic	250	180	16	6.40	incompleted
10	51	M	PVC-plastic workers	12	7	nonatopic	140	125			OA
11	32	M	Welder	7	3	nonatopic	350	260			OA
12	40	M	Construction worker	10	3	nonatopic			4.53	1.68	incompleted
13	35	F	Hairdresser	27	5	nonatopic	160	140			OA
14	48	M	PVC-plastic workers	26	3	nonatopic	350	300	16	2,71	OA
15	29	M	Ceramic worker	6	1	nonatopic	400	200	2.79	1.61	incompleted
16	40	M	Carpenter	23	6	nonatopic	430	350	5.20	1.41	incompleted
17	39	M	Painter	23	17	pollen	600	300			incompleted
18	42	M	Ceramic worker	17	2	nonatopic	400	250	6.80	2.80	incompleted
19	36	M	Painter	16	7	nonatopic			2.07	0.38	incompleted
20	50	M	Carpenter	2	1	pollen	370	250			OA

21	46	F	Textile worker	11	6	nonatopic	440	330			OA
22	34	M	Painter	10	10	pollen	520	350			incompleted

*For 2 weeks

**End of the 2 weeks

Table 3. Comparison of the Study Patients' Medical and Legal Diagnosis

Legal diagnosis		Medical diagnosis			Total
Completed		OA	sOA	Non-OA	
	OA	11*	9**	-	20
	Asthma, non-OA	1*	22**	-	23
	<i>Total</i>	<i>12</i>	<i>31</i>	-	<i>43</i>
In completed		10	44	2	56
	Total	22	75	2	99

Difference between *- ** ($P = .001$)

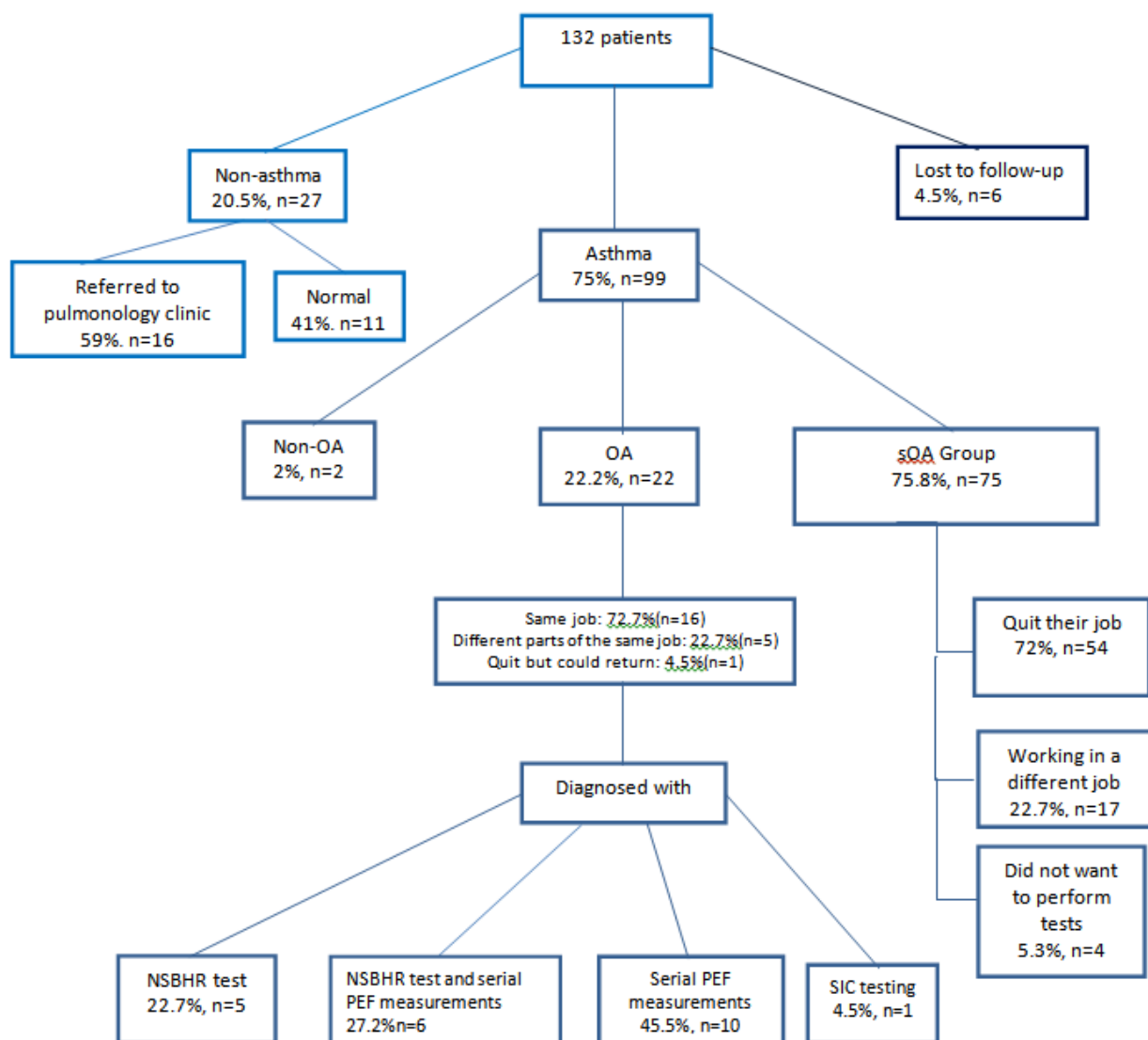


Figure1. Distrubition of the patients according to diagnosis

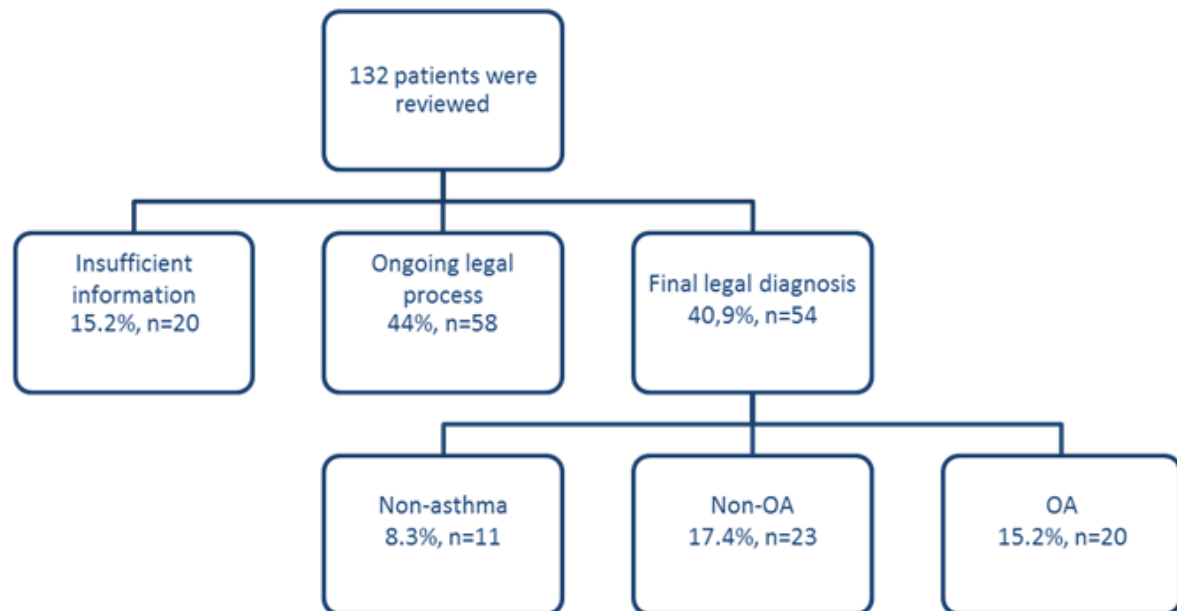


Figure2. Legal Period