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GBZ 57-2019

Replacing GBZ 57-2008

Diagnosis of occupational asthma

职业性哮喘的诊断

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Foreword

Clause 5 of this Standard is mandatory. The rest are recommended.

According to the Code of Occupational Disease Prevention of PRC, this Standard is developed.

This Standard is drafted in accordance with the rules given in GB/T 1.1-2009.

This Standard replaces GBZ 57-2008 “Diagnostic criteria of occupational asthma”.

As compared with GBZ 57-2008, the main changes are as follows:

- ADD terms and definitions;
- Expand the definition of occupational asthma and ADD reactive airway dysfunction syndrome;
- REVISE the diagnostic principles;
- REVISE the diagnosis of occupational asthma and delete the grading;
- REVISE part of Appendix A;
- The index of Fractional exhaled nitric oxide is added to the positive reaction standards of job-site bronchial provocation test;
- Delete appendixes “non-specific bronchial provocation test”, “exercise challenge test”, and “sensitizer-specific IgE antibody detection-enzyme-labelled fluorescence immunoassay (FEIA)”.

Drafting organizations of this Standard: Shanghai Pulmonary Hospital, Tongji University (Shanghai Occupational Disease Prevention and Treatment Hospital), Guangdong Province Hospital for Occupational Disease Prevention and Treatment, The Second Hospital of Heilongjiang Province, West China Fourth Hospital, Sichuan University.

Main drafters of this Standard: Zhang Jingbo, Sun Daoyuan, Chen Jiabin, Zhao Liqiang, Song Li, Yang Huimin, Hu Yinghua.

The previous editions of this Standard were released as follows:

- GB 16377-1996;
- GBZ 57-2002;

Diagnosis of occupational asthma

1 Scope

This Standard specifies the principles of diagnosis and treatment of occupational asthma.

This Standard applies to the diagnosis and treatment of occupational asthma.

2 Normative references

The following documents are indispensable for the application of this document. For the dated references, only the editions with the dates indicated are applicable to this document. For the undated references, the latest edition (including all the amendments) are applicable to this document.

GB/T 16180 Standard for identify work ability - Gradation of disability caused by work-related injuries and occupational diseases

3 Terms and definitions

The following terms and definitions apply to this document.

3.1 Occupational asthma

Chronic inflammatory disease of the airway involving a variety of cells including eosinophils, mast cells, T lymphocytes, neutrophils, smooth muscle cells, airway epithelial cells, and other cellular components, which is caused by contact with certain chemical substances in occupational activities. It is accompanied by variable airflow limitation and airway hyperresponsiveness. Occupational asthma in this Standard includes occupational sensitizer-induced asthma and occupational reactive airway dysfunction syndrome.

3.2 Occupational sensitizer-induced asthma

Chronic inflammatory disease of the airway characterized by intermittent attack of wheezing, shortness of breath, chest tightness, or cough, etc. caused by inhalation of sensitizers in occupational activities, with a period of incubation.

3.3 Occupational reactive airway dysfunction syndrome

Chronic airway neurogenic inflammatory disease with cough, wheezing, and

5.1.7 If 5.1.1+5.1.2+5.1.3 or 5.1.2+5.1.3+5.1.4 or 5.1.1+5.1.2+5.1.5 or 5.1.1+5.1.2+5.1.6 are met, occupational sensitizer-induced asthma can be diagnosed.

5.2 Occupational reactive airway dysfunction syndrome

The following conditions shall be met at the same time:

a) There is an exact occupational inhalation history of large doses of irritant chemicals in a short period of time;

b) After contact, mucosal irritation symptoms such as shedding tears, pharyngalgia, cough, etc. appear immediately;

c) Within 24 h after inhalation, bronchial asthma symptoms appear. The duration of the symptoms is longer than 3 months;

d) Pulmonary function test shows reversible obstructive ventilation function disturbance or non-specific airway hyperresponsiveness;

e) There is no history of diseases of respiratory system such as chronic bronchitis and chronic obstructive pulmonary disease.

6 Treatment principles

6.1 Therapeutic principles

6.1.1 After the diagnosis of occupational asthma is established, the patient shall be removed from the original occupational activity environment as soon as possible, to avoid and prevent the relapse of asthma.

6.1.2 Patients with acute asthma attacks shall be relieved for symptoms as soon as possible, relieved for airflow limitation and hypoxemia. The main pharmacotherapy methods are repeated inhalation of fast-acting β_2 receptor agonists, oral or intravenous glucocorticoids, inhalation of anticholinergic drugs, and intravenous aminophylline, etc. Patients with severe asthma attacks and acute respiratory failure, if necessary, shall be treated with mechanical ventilation.

6.1.3 For long-term therapy of asthma, according to the severity of the disease, an appropriate therapeutic regimen shall be selected. The goal is to achieve and maintain symptom control, maintain normal activity level, and maintain normal pulmonary function as much as possible.

6.2 Other treatment

Appendix A

(Informative)

Instructions for the correct use of this Standard

A.1 Occupational sensitizer or irritant chemical is one of the pathogenic factors of bronchial asthma. Compared with common asthma, occupational sensitizer-induced asthma has no difference in pathological changes, clinical manifestations, pulmonary function changes, therapy, etc. The pathogenesis is mainly sensitizer-induced mechanism, but other mechanisms are often mixed. Respiratory inhalation is the main contact route for occupational sensitizer-induced asthma and the starting position for stimulating the immune response.

A.2 Case data show that individual chemicals can, through skin contact, cause occupational sensitizer-induced asthma, such as occupational sensitizer-induced asthma caused by skin contact with latex. If epidemiological investigations, toxicological studies indicate that other chemicals can also cause sensitizer-induced asthma by skin contact, occupational asthma can be diagnosed.

A.3 Case data show that occupational sensitizer-induced asthma often occurs in the 6 months to 10 years of contact with sensitizers. The shortest is 2 months.

A.4 Patients with occupational sensitizer-induced asthma, before the onset of the disease, may develop allergic rhinitis symptoms such as running nose, nasal itching, nasal congestion, and sneezing. Therefore, when there are frequent attacks of nasal congestion, nasal itching, thin nasal discharge, continuous sneezing, and other symptoms, the possibility of occupational asthma shall be tracked.

A.5 In the early and middle stages of occupational sensitizer-induced asthma, the occurrence and development of asthma symptoms are closely related to sensitizer exposure. Typical occupational asthma patients often develop asthma attacks during work or a few hours after work. The symptoms are more pronounced on the first day of the workday. On weekends, holidays, or after leaving the workplace, asthma symptoms can be alleviated. If the worker, during work or a few hours after work, develops repeated attack of wheezing, shortness of breath, cough, and other symptoms, and has medical records; or there are two or more workmates (same type of work or same post) proof materials proving that the patients often develop cough, chest tightness, asthma symptoms during work or a few hours after work and develop repeated attacks, it can be considered that occupational contact is associated with

Appendix B

(Normative)

Laboratory sensitizer bronchial provocation test and job-site bronchial provocation test

B.1 Laboratory sensitizer bronchial provocation test

B.1.1 Conditions and requirements for subjects

B.1.1.1 During the test, asthma symptoms have been alleviated. There is no wheezing in the auscultation of the lungs.

B.1.1.2 Before the test, subjects have a FEV1≥70 % of the predicted value. Under close observation, some patients may be relaxed to FEV1>60 % of the predicted value.

B.1.1.3 Subjects with cardiac and (or) pulmonary insufficiency, aortic aneurysm, recent myocardial infarction or cerebrovascular accident, uncontrolled hypertension, hyperthyroidism, pregnancy, and recent upper respiratory tract infection (<2 weeks), etc. are not suitable for the test. Subjects who are allergic to certain strong sensitizers (such as penicillin, etc.) or have had a history of hypersensitivity (such as anaphylactic shock) are also not suitable for the test.

B.1.1.4 Drugs to be discontinued

a) Discontinuation of inhaled short-acting β_2-receptor agonist or anticholinergic drugs for 6h, oral short-acting β_2-receptor agonist or theophylline drugs for 12h, long-acting or sustained-release dosage form drugs for 24 h;

b) Discontinuation of inhaled glucocorticoids for 12 h, oral glucocorticoids for 48 h;

c) Discontinuation of antihistamines for 48h;

d) Other drugs, such as β-receptor blockers, barbiturates, benzodiazepines, etc., can reduce the tolerance to the activator; and shall be discontinued 48h before the measurement.

B.1.1.5 6h before the measurement, it shall avoid drinking coffee, strong tea, and alcoholic beverages. 2h before the measurement, it shall avoid vigorous exercise or cold air inhalation.

B.1.3.2 If there are obvious symptoms and signs after the provocation, such as chest tightness, shortness of breath, sharp cough, lung wheezing, etc., the upper value shall be relaxed. If FEV1 drops by more than 10%, it can be judged as positive.

B.1.4 Matters needing attention

B.1.4.1 There is still a potential danger in the process of provocation test. The sensitizer inhalation concentration should not be too high, so as to avoid the irritative reaction. At the same time, the indications and contraindications shall be strictly controlled. The operation specification shall be strictly followed. The technician who performs the operation must be proficient in the operation procedures. The examination room shall be provided with bronchodilator, oxygen, and other first-aid medicines.

B.1.4.2 In view of the fact that this test requires certain equipment and technical conditions, during the test, individual cases may be overreacted, so this test shall be carried out in a hospital with conditions.

B.1.4.3 It is not advisable to give hints before or during the test that the subject should not be too nervous.

B.2 Job-site bronchial provocation test

B.2.1 Pre-test preparation and basic conditions

Same as B.1.1.

B.2.2 Method

B.2.2.1 Before the test, the value of the basic Fractional exhaled nitric oxide (FeNO) is measured. Within the 1st hour after entering the job site, every 15 min, the ventilation function (FEV_1) is measured once. The 2nd hour, every 0.5 h, the ventilation function is measured once. According to the situation, it is possible to stay at the site for 1 h~2 h.

B.2.2.2 After disengagement, every 1 h, the pulmonary function is measured once. The clinical symptoms and signs shall be paid attention to and recorded. Continuous observation for at least 8 h. 24 h, it shall be measured again. FeNO after the test shall also be measured.

B.2.2.3 If pulmonary function indices are significantly reduced, and there are respiratory symptoms and signs, the provocation test can be terminated; the bronchodilator can be inhaled. The recovery of pulmonary function indices shall be observed.

Appendix C

(Informative)

Sensitizer-specific IgE antibody detection-enzyme-linked immunosorbent assay (ELISA)

C.1 Principle

The basis of enzyme-linked immunosorbent assay is the immobilization of antigen or antibody and the enzyme labelling of antigen or antibody. The antigen or antibody bound to the surface of solid phase support retains its immunological activity. The enzyme-labelled antigen or antibody retains both its immunological activity and the activity of the enzyme. In the measurement, the known specific antigen is first immobilized on the surface of solid phase support to form a solid phase antigen. The sample to be tested is added. Then the enzyme-labelled antibody is added, so that an antigen-antibody to be tested-labelled antibody complex is formed on the solid phase support. After adding enzyme substrate and chromogen, color is generated. The degree of color generation is expressed by the absorbance (A) value. The measured A value is correlated with the level of the sensitizer to be tested.

C.2 Equipment

Porous polystyrene board (universal 96-pore board, 12×8 pores), micropipette, enzyme-labelled immunoassay instrument, PH test paper, thermostat, refrigerator, wash bottle, wet box, common glassware, etc.

C.3 Reagents

C.3.1 Currently, various ELISA tests have commercialized special kits, including reaction plates coated with goat anti-human IgE, serial standards (0 U/mL, 10 U/mL, 100 U/mL, 500 U/mL), and quality control serum; enzyme (HRP) labelled anti-human IgE monoclonal antibody; buffer solution, stop buffer, etc.

C.3.2 Dedicated labelling enzyme: Horse-radish peroxidase (HRP) is most commonly used to label various antibodies.

C.3.3 Commonly-used enzyme substrates and chromogens: HRP substrate is H_2O_2 (or urea peroxide), which requires hydrogen donor to participate in the catalysis. The latter is mostly a reductive dye, which reacts to form a dark or fluorescent oxidative dye. There are many chromogens (hydrogen donors) available for HRP. Commonly used are o-phenylenediamine (OPD), 3,3',5,5'-

Appendix D

(Informative)

Specific sensitizer skin test

D.1 Intracutaneous test

D.1.1 Selection of skin test solution

D.1.1.1 Sensitizer skin test solution: SELECT a standardized skin test solution.

D.1.1.2 Skin test control solution and purpose: In order to obtain an accurate skin test result, a skin test is performed with both positive and negative controls. The positive control solution is histamine dihydrochloride at a concentration of 0.017mg/mL or histamine diphosphate at a concentration of 0.028 mg/mL, which is equivalent to a 0.01 mg/mL histamine substrate.

The purpose of using a positive control solution:

a) JUDGE the positive degree of sensitizer skin test: USE positive control solution caused papule as the standard “scale” to determine the positive degree of sensitizer skin test.

b) Determine the level of skin reactivity of the subjects: Due to age, physical condition, and region, the skin’s reactivity is not the same. For example, the skin reactivity of the elderly is poor; and the reaction of the positive control is also weak.

c) Observe the inhibitory effect of drugs: When the positive control solution shows negative reaction, it indicates that the skin test result is likely to be inhibited by certain drugs, such as antihistamines, thus the skin test result is invalid. Only when the positive control solution shows positive reaction, it indicates that the skin test is not affected by drug inhibition or other factors, and the skin test result is valid. The negative control solution is usually normal saline or sensitizer diluted preservation solution. The negative control solution shows negative reaction. If the patient is highly sensitive, a false positive reaction may appear. At this time, the skin test positive reaction produced by the sensitizer is not clinically significant.

D.1.2 Operation procedures

D.1.2.1 The skin of the subject’s forearm palmaris is disinfected using 75% alcohol. When disinfecting, do not apply it repeatedly. Do not use iodine tincture

b) People with obvious dermatographism should not be skin tested;

c) Before the test, STOP taking the antihistamine drugs. When the conditions permit, it shall stop taking adrenal glucocorticoid;

d) The antigen used shall be sterile and of appropriate concentration;

e) The test operation shall be accurate. Do not be bleeding;

f) After injection, do not press and rub the wheal;

g) Attention shall be paid to systemic reaction. First-aid medicines shall be provided.

D.2 Prick test

D.2.1 Selection of skin test solution

D.2.1.1 Sensitizer skin test solution: same as D.1.1.1.

D.2.1.2 Skin test control solution and purpose: The concentration of histamine dihydrochloride or histamine diphosphate used in the positive control solution is 100 times that of the intracutaneous test, which is equivalent to 1mg/mL histamine substrate. The purpose of using the control solution is the same as D.1.1.2.

D.2.2 Operation procedures

D.2.2.1 The test area disinfection is the same as that of intracutaneous test.

D.2.2.2 Apply a drop of sensitizer skin test solution or control solution to the skin test site. USE a pricking needle to prick in the center of the skin where the skin test solution is dripped. The method of pricking is: USE a pricking needle to vertically and gently press down on the skin for 1s; and quickly LIFT the needle; 2min~3min, WIPE the skin test solution. If multiple sensitizer pricks are performed at the same time, each pricking site shall be separated by more than 3cm.

D.2.3 Observation and judgment

D.2.3.1 About 15 min after pricking, the reaction results are observed. Observe whether there is a papule at the pricking site and the papule size. In the next 10min~15min, it is observed several times. If the papule increases, RECORD the latter reaction. If it is reduced, RECORD the previous reaction.

D.2.3.2 Observation method: same as D.1.3.2.

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