Leukocyte Histamine Release Test

Medical Policy

Section: Medicine
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Description

The leukocyte histamine release test (LHRT) is designed to provide an in vitro correlate to an in vivo allergic response (i.e., skin prick testing). An allergen is added to the peripheral blood leukocytes of the individual being tested and the in vitro release of histamine from basophils in response to exposure to the allergen is measured. Histamine is normally released as a consequence of the interaction of allergen with cell-bound IgE antibodies. In contrast, the RAST test (radioallergosorbent test) attempts to correlate the presence of allergy to serum levels of antigen-specific IgE as an index of allergic reactivity. Initially, measurements of histamine release required isolation of leukocytes from whole blood followed by the isolation of the released histamine; the laboratory techniques were difficult and time consuming and thus LHRT was primarily used as a research tool only. Recently, a special type of glass fiber has been developed that binds histamine with high affinity and selectivity. These glass fibers can be used as a "solid phase" to absorb the histamine that is released directly into the blood. The recent commercial availability of simplified and automated methods of laboratory analysis (i.e., both ELISA and radioimmunoassays) have renewed interest in the clinical applications of LHRT in the evaluation of food, inhalant, and drug allergies.

Policy
The leukocyte histamine release test (LHRT) is considered investigational as a technique for the diagnosis and management of allergic disorders.

Policy Guidelines
No applicable information

Rationale
The published literature regarding LHRT is reviewed using the same criteria as used in the TEC Assessment of serial endpoint testing (See policy No. 2.01.23). For example, quality indicators for studies of diagnostic trials include:

- Prospective enrollment
- Representative patient population enrolled
- Appropriate spectrum of patients
- Unbiased enrollment (no referral bias)
- Few patients not enrolled that are eligible
- Appropriate accounting for all eligible patients
- All eligible patients receive both tests
- LHRT interpreted independently of alternative test (i.e., skin prick, RAST, or bronchial provocation test)
- Alternative tests interpreted independently of LHRT.

In assessing the diagnostic accuracy, the comparative reproducibility, sensitivity, and specificity of LHRT are the primary outcomes to be considered. In the absence of an accepted gold standard for the diagnosis of allergy, it is difficult to ascertain the comparative performance characteristics of available diagnostic tests. For this reason, the concordance, or correlation, of results from different tests is typically reported for LHRT. The published literature regarding the commercially available LHRTs suffers from the fact that alternative tests have not been performed in a blinded manner, or studies did not indicate whether or not there were blinded interpretations of the tests. (1, 2) Some studies included patients with known allergies, and thus these highly selective populations do not represent the same population with equivocal allergy histories that would undergo testing. (2-6) In some situations, results were compared with
bronchial provocation testing, considered the gold standard for inhalant allergies. However, bronchial provocation may only be performed on a subset of patients with a limited number of allergens. For example, bronchial provocation may only be performed when there are discordant results between RAST and skin prick testing. (7) Thus overall, these studies are potentially prone to spectrum bias, referral bias, and ascertainment bias, and are not sufficient to permit conclusions on the diagnostic accuracy of LHRT. It has been suggested that LHRT may be a valuable test in those patients with discordant results of skin prick testing and RAST testing, but studies focusing on this subgroup of patients were not identified in a literature search.

2005 Update

A search of the literature was performed for the period of 2003 through February 2005. No studies were identified that would prompt reconsideration of the policy statement, which remains unchanged.

2006 Update

A search of the MEDLINE database for the period of October 2004 through September 2006 found no studies that would prompt reconsideration of the policy statement; the policy is unchanged.

2007 Update

A search of the MEDLINE database for the period of October 2006 through January 2008 found no studies on the clinical use of the leukocyte histamine release test. The evidence is insufficient to permit conclusions concerning the effect of this test on health outcomes. Therefore, LHRT is considered investigational.

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