

## HYDROGEN BREATH TEST AND OTHER ALTERNATIVES FOR DIAGNOSING LACTOSE INTOLERANCE.

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**Introduction:** Lactose intolerance is caused by a lack of the enzyme lactase, which is responsible for hydrolysing lactose into its monosaccharide components for quick absorption in the small intestine. The most frequent or primary cause of malabsorption is lactase non-persistence, also known as adult-type hypolactasia, and the secondary causes are due to diseases of the mucosa of the small intestine, such as celiac disease, gastroenteritis, or Crohn's disease, which may involve a transitory intolerance to lactase. The prevalence of hypolactasia is high and depends on the geographic area, ranging from percentages of 5% in north-west Europe, through to nearly 100% in some Asian countries.

Today, a variety of tests are available to detect lactase deficiency. However, in terms of diagnosing lactose intolerance itself, these tests are less precise, and require a simultaneous evaluation of poor lactose digestion, and the existence of gastrointestinal symptoms.

**Aims.** To locate scientific evidence on the sensitivity and specificity, use, indications, adverse effects, and costs of the H<sub>2</sub> breath test and other alternatives for diagnosing lactose intolerance.

**Methods.** An exhaustive search of the biomedical literature in March 2017, without any time limit, in the following databases specialising in systematic reviews: HTA (Health Technology Assessment), DARE (Database of Abstracts of Reviews of Effectiveness), NHS EED (Economic Evaluation Database del National Health Service) or the Cochrane Plus library; and general databases such as Medline, Embase, and the ISI database.

**Results and discussion.** A total of 22 studies were included from the 457 publications obtained from the literature search.

The intolerance tests are non-invasive, except for the gold standard, which consists of carrying out an intestinal biopsy, although this is not normally used in clinical practice, and other tests have been developed in order to avoid this invasive procedure. Amongst these, the H<sub>2</sub> breath test is the most widely used, although other tests are performed, such as the blood lactose tolerance test, the gaxilose test in urine and blood, the self-reported test, and genetic methods that are appearing in a growing number of studies, many of which are applied to clinical practice.

In general, the tests have a good degree of sensitivity and specificity for detecting lactose intolerance, except for the self-reported symptom detection test, which has a sensitivity and specificity that vary between 30-71% and 25-87% respectively. The test that provided the best results was the genetic test, with a sensitivity of 97%-100%, and a specificity of around 92%. In the case of the H<sub>2</sub> breath test, this provides good percentages for both sensitivity (78-98%) and specificity (76-100%).

Little information is available about the costs of the different tests in use, and no studies were found that refer to their cost effectiveness.

**Conclusions.** The available evidence differs depending on the test being evaluated. In the case of the H<sub>2</sub> breath test, genetic tests, and self-reported symptom tests, systematic reviews were found with a good level of scientific evidence. In the case of the gaxilose test, one RCT was found, while the rest of the studies included were observational in nature, and are therefore of a lower methodological quality.

- The H<sub>2</sub> breath test offers a good level of scientific evidence, and is considered to be a reliable, non-invasive test with good sensitivity and maximum specificity. Today it is considered as the method of choice for the diagnosis of malabsorption and intolerance to lactose, both in adults and in paediatric patients. However, it is not recommended for patients with irritable bowel syndrome.
- The analysis of the polymorphism for C/T13910 persistence or non-persistence is a genetic test with a good degree of sensitivity and specificity for the Caucasian population, which is simple to use and with good adherence.
- The lactose tolerance test, which involves measuring blood glucose levels, is carried out frequently, but offers less sensitivity and specificity than the H<sub>2</sub> breath test.
- The Gaxilose test in urine provides limited evidence, the data from an RCT indicated that it is a simple, non-invasive test, with good diagnostic validity.
- The self-reported symptoms test has very wide sensitivity and specificity intervals, and due to its inconsistency, it is not possible to arrive at a conclusion to recommend its use in clinical practice, without carrying out another objective test.

The adverse effects of the tests are due to the amount of lactose ingested in order to carry out the test, which are not serious. These include abdominal pain and swelling, distension, diarrhoea and vomiting, all associated with ingesting lactose. No adverse effects have been reported for the genetic test.