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Breath Ammonium Test in Diagnostic of Helicobacter Pylori Infection

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Abstract

Breath ammonium test is an alternative method for diagnostic of H. pylori infection. For several years we work with this test. Our studies are showing high levels of sensitivity and specificity for this test. Also we see decreasing prevalence of H. pylori infection since 2009 to 2014. Breath ammonium test shows a high efficacy in comparison to histological method and polymerase chain reaction and can be recommended to use in diagnostic of H. pylori infection.

Keywords: *Helicobacter pylori, breath ammonium test, prevalence, diagnostic, dyspepsia*

Introduction

Helicobacter pylori infection is one of the most serious gastroenterology problems and is a Group I carcinogenenic factor. The urease breath test with 13C and the enzyme immunoassay of *H. pylori* in the faeces were approved as the recommended diagnostic methods for identification of *H. pylori* at the Maastricht Consensus III-V [1-3]. But the existence of a large number of different methods for diagnostics of the *H. pylori* infection supports the postulate that there is not yet a unique method, a so-called "gold standard" for the diagnostics of this microorganism [4]. Also, an urease breath test with C13 urea is not common in use in russian gastroenterological practice. It is important to make an alternative breath tests to diagnose *Helicobacter pylori* infection, for example,, breath ammonium tests [5-12].

For several years we work with breath ammonium test ("Helic-test", Association of Medicine and Analytic, St-Petersburg, Russian Federation) for verification of H. pylori infection. The mechanism of this test you can see at fig. 1-3.

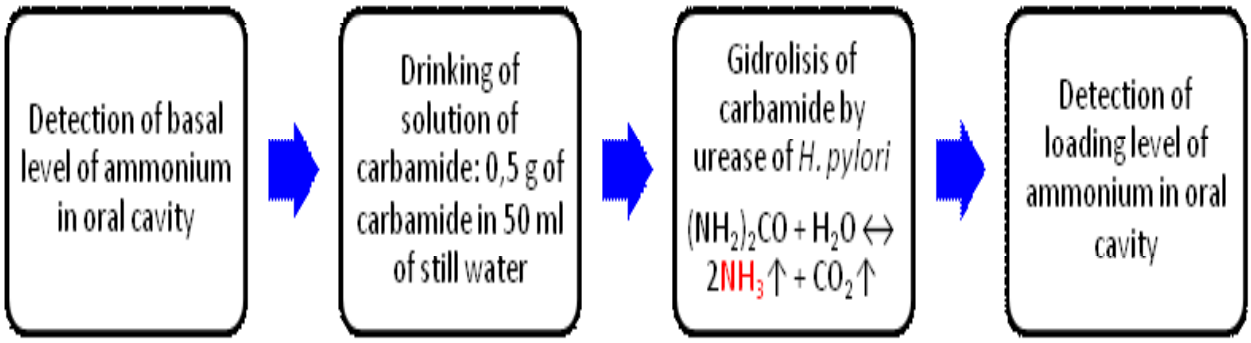

Fig 1. *Stages of breath ammonium test*

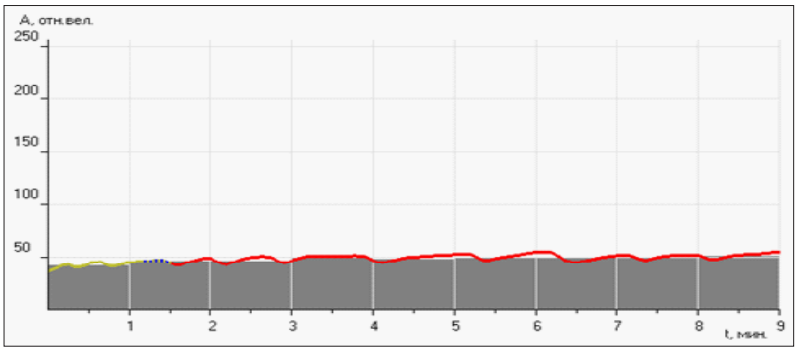

Fig 2. *Basal level (first stage of breath ammonium test)*

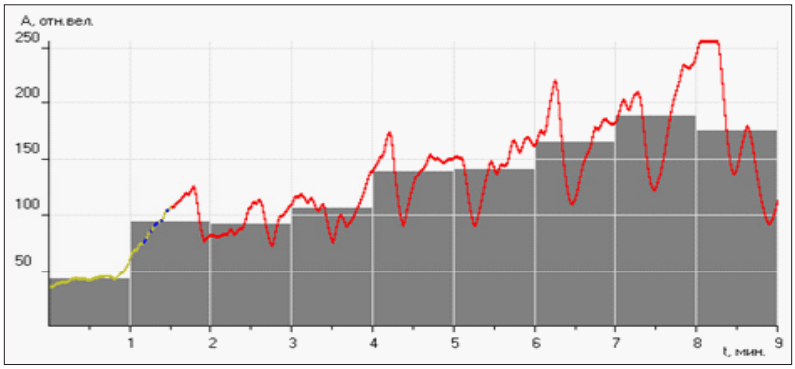

Fig 3. *Loading level 1 for H. pylori-positive patient (forth stage of breath ammonium test)*

Our studies are showing high levels of sensitivity and specificity for this test in different studies. Also we see decrease of prevalence of H. pylori infection in St-Petersburg, Russian Federation (5 million population region).

Study 1 (2007-2008)

The Aim

comparative evaluation of the results of different methods for identification of *H. pylori*

Material and Methods

135 patients with age between 17 and 72 years with the pathology of the upper part of the gastrointestinal tract were examined (37% of patients with peptic ulcer disease, 63% with chronic gastritis). Patients underwent a stomach endoscopy with a biopsy from the stomach body and antrum to verify *H. pylori* by following methods: rapid urease test, "Helic-test", histological examination, polymerase chain reaction (PCR) with detection of the *cagA* and *ureC H. pylori* pathogenicity island genes, bacteriological examination (seeding gastric mucosal biopsy materials for identification of the *H. pylori* growth).

When comparing the obtained results it was found that the maximum number of positive results was determined using the rapid urease test, and the minimum number - using the seeding of the gastric mucosal biopsy materials (Fig. 4).

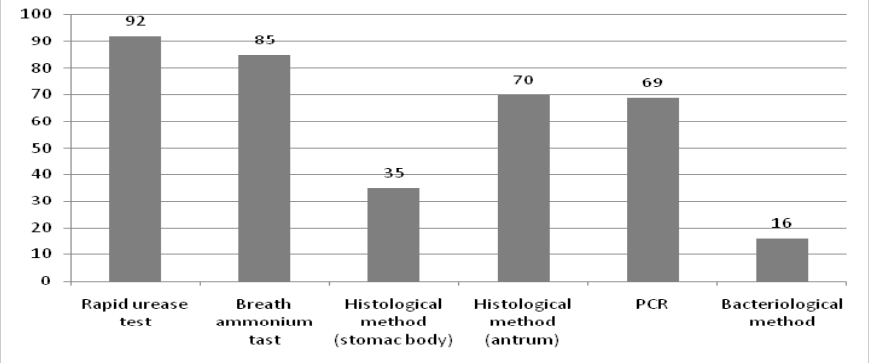

Fig 4. *Comparative characteristics of the results of various diagnostic methods for the identification of H. pylori*

Based on these data the following conclusions were drawn, and the following recommendations were developed:

1. Obtaining positive results of the urease test and the Helic-test combined with the negative results of the histological examination or PCR can be explained not as false positives, but the fact that the urease test and the Helic-test waste products of *H. pylori* are identified and not the microorganism itself, which may not get the biopsy sample analysed by the histological methods or the PCR.

2. The "Helic-test" is recommended as an accurate noninvasive method for evaluating the effectiveness of eradication therapy, especially in children.

Study 1a (2011-2013). The Comparative Analysis of Different Methods in Diagnostic of H. Pylori Infection

Objective

To compare results of different methods of diagnostics of *H. pylori* infection with estimation of efficacy of breath ammonium test.

Materials and Methods

42 patients with dyspepsia were under supervision. To all patients, the gastroscopy with a biopsy from stomach body and antrum and a complex of diagnostic methods for infection verification were made. Four diagnostic methods were used: breath ammonium test, histological method: one biosample from a stomach body, one biosample from stomach antrum, polymerase chain reaction (PCR): one biosample from a stomach body, one biosample from stomach antrum with detection of *ureC, ureI, cagA* genes, the breath test with C13 urea (the analysis of samples of exhaled air was made in Italy in "Spectra-2000" laboratory). Samples of exhaled air were transported to Italy one time a month.

Results

with the application of "Helic-test" the positive result was received in 50% of patients. With application of histological method *H. pylori* was defined in stomach body in 31%, in stomach antrum in 36%, in both parts of stomach – 24%, in common - 48% and by PCR – in stomach body in 12%, in stomach antrum in 50%, n both parts of stomach – 50%, in common - in 50% of patients. Unexpected there were results of breath urease test with C13 urea: 26% of positive results.

Conclusions

Breath ammonium test shows a high efficacy in comparison to histological method and PCR and can be recommended to use in diagnostic of *H. pylori* infection. The low percentage of positive results of breath urease test with C13 urea is probably connected with the long process of transportation. Therefore, it is necessary to avoid long storage of samples.

Study 2 (2013-2016). The Estimation of Efficacy of Breath Ammonium Test in Diagnostic of H. Pylori Infection

The aim

To investigate sensitivity and specificity of non-invasive breath ammonium "Helic-test" in the diagnosis of H. pylori.

Materials and methods

Two independent studies in Russia and Belarus were performed. In Russia 171 patients with dyspepsia and Belarus 98 patients with chronic gastritis were surveyed. H. pylori infection was confirmed by a histological examination of samples obtained from the antrum and corpus of the stomach during endoscopy. The choice of a histological method as reference method was dictated by that, using this method, J.R. Warren and B.J. Marshall described the existence of a elicoids bacterium in a mucous membrane of a stomach of patients with active chronic gastritis. For all patients, non-invasive breath ammonium Helic-test also was performed. Patients during at least four weeks before diagnostics did not take any medications (PPIs, antibiotics, antacids and bismuth), which could change the results of both invasive and non-invasive tests.

Results

Concordance of results of the histological method and ammonium HELIC-test were high: in 87,5% and 94,3% of cases in Russia and Belarus respectively. In Russia, the sensitivity of ammonium test was 92%, specificity – 93%. In Belarus, sensitivity and specificity of the test were 95%, and 96% respectively.

Conclusions

Breath ammonium Helic-test is a cost-effective non-invasive method for diagnosis of H. pylori infection. Sensitivity and specificity of Breath ammonium Helic-test are high enough. This method can be recommended as a non-invasive test for diagnosis of H. pylori infection.

Study 3 (2008-2009). The Analysis of Prevalence of H. Pylori Infection in St-Petersburg, Russian Federation

The Aim

To define the prevalence of *Helicobacter pylori* infection in St-Petersburg and to reveal the influence of age, sex and habitual intoxications on the microorganism invasion.

Materials and Methods

200 persons (119 employees and 81 students) without any gastroenterological complains (1st group), and 150 duodenal ulcer patients (2nd group) have been examined. For verification of *H. pylori, the* infection has been used noninvasive breath ammonium test - the "Helic-test".

Results

H. pylori have been revealed at 148 examinees (74 %) in 1st group and 117 patients (78%) in 2nd group (fig. 5).

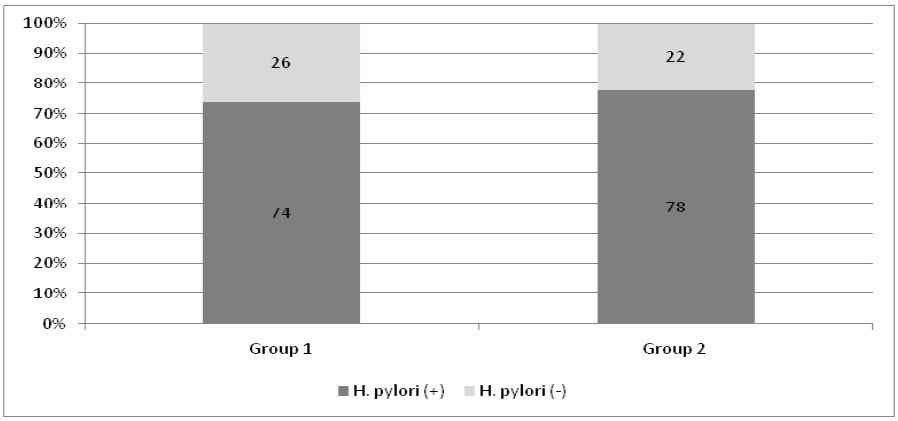

Fig 5. *Common prevalence of H. pylori infection (%)*

Microorganism has prevailed in age groups of 15-19 years, 30-39 years and 40-49 years. The prevalence of the infection in other groups of research was significantly lower (fig. 6).

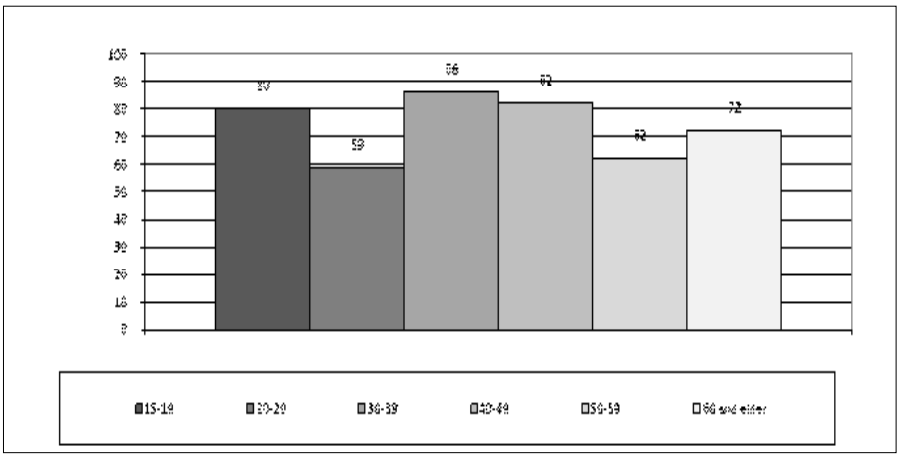

Fig 6. Prevalence *of H. pylori infection – age groups differences (%)*

In this work the research group revealed that to infection *H. pylori* smokers (77 %), than non-smoking (73 %) people are more subject. Estimating prevalence *H. pylori* among the persons who are using and not taking alcohol, a significant difference was not revealed - 73 % and 74 % accordingly.

Conclusions

smoking students, teenagers and people (especially men) of 30-49 years are in the basic group of risk on *H. pylori* invasion. It dictates the necessity of screening of these groups of people for timely administrates of eradication therapy for *H. pylori*-positive persons. In ulcer disease patients prevalence of H. pylori almost the same that in all population. So it is important to investigate the genetic features of a microorganism to divide ulcerogenic and non-ulcerogenic strains.

Study 3a (2012-2014). The dynamic analysis of prevalence of H. pylori infection in St-Petersburg, Russian Federation

The Aim

To define the dynamic prevalence of Helicobacter pylori infection in St-Petersburg. Russian Federation in 2008-2009 and 2012-2014.

Materials and methods

200 persons in 2008-2009 (1st group) and 128 persons in 2012-2014 (2nd group) without any gastroenterological complaints were have been examined. For verification of H. pylori, the infection has been used noninvasive breath ammonium test - the "Helic-test".

Results

H. pylori have been revealed at 148 examinees (74 %) in 1st group and 72 patients (56%) in 2nd group (fig. 7).

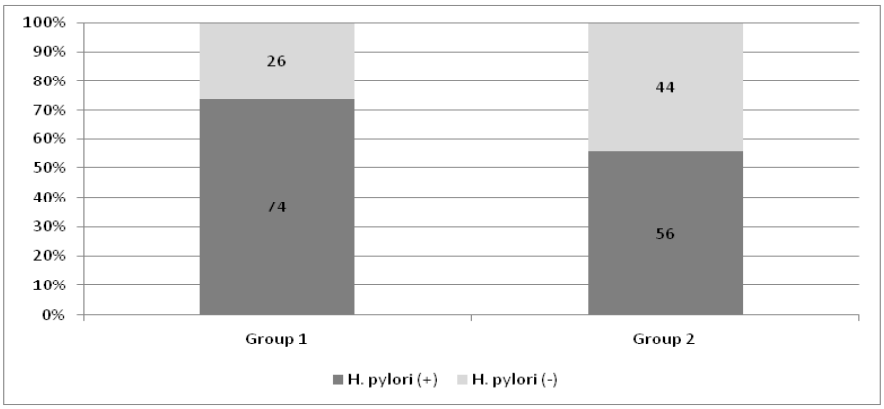

Fig 7. *Common prevalence of H. pylori infection (%)*

So we can see that prevalence of H. pylori infection is decreased in St-Petersburg, Russian Federation. It can be associated with common usage of eradication therapy.

Conclusion

Breath ammonium Helic-test is simple to perform a cost-effective non-invasive method for diagnosis of H. pylori infection. Efficacy this test is high enough. So breath ammonium test can be recommended as a non-invasive test for population screening, primary diagnosis of H. pylori infection and estimation of eradication therapy results. But of course, future studies are needed to have more evidence about its sensitivity and specificity.

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