

WHO prompts *Helicobacter pylori* screening to prevent gastric cancer

Biohit Oyj Press Release October 1, 2014

Appendix

Acetium and GastroPanel inventions: The GastroPanel blood examination reveals, e.g., atrophic gastritis (anacidic stomach) with related risks, such as risk of stomach and oesophageal cancer. Acetium capsules may decrease the risk of these serious cancers.

The state-of-the-art, safe and economic GastroPanel examination for the diagnosis of *Helicobacter pylori* (*H.pylori*) infection and atrophic gastritis does not have any of the following serious medical problems

The 13C urea breath test (UBT), stool antigen test and antibody tests for *H. pylori* infection do not detect atrophic gastritis which is caused by *H. pylori* infection or an autoimmune disease. The early and reliable diagnosis of atrophic gastritis is important and often life-saving because of its several risks, including, e.g., unnecessary deaths due to stomach and oesophageal cancer.

In addition to the risks of gastric and oesophageal cancer, atrophic gastritis may cause malabsorption of vitamin B12, iron, magnesium, calcium and some drugs. Calcium deficiency causes osteoporosis, and vitamin B12 deficiency can cause Alzheimer's disease, dementia, depression and polyneuropathy, as well as high homocysteine content in the body, which in turn is thought to be an independent risk factor for atherosclerosis, heart attacks and strokes. The absorption of dipyridamole, some iron products and antifungals (fluconazole, itraconazole), thyroxine and atazanavir is considerably impaired in an anacidic stomach.

Atrophic gastritis in the gastric corpus and PPI therapy cause anacidity (achlorhydria) of the stomach. The risk of pneumonias and, in senior citizens, even the risk of fatal intestinal infections (such as giardiasis, malaria, *Clostridium difficile* and *E. coli* EHEC) may increase significantly in an anacidic stomach.

H. pylori gastritis may also develop into antral atrophic gastritis, which increases the risk of peptic ulcer disease and gastric cancer. If both antrum and corpus mucosa are atrophic, this condition is the highest risk for gastric cancer known to date.

Furthermore, none of the aforementioned three *H. pylori* tests provides any information on excessive gastric acid secretion (high acid output), which in patients with gastro-oesophageal reflux disease may cause complications of this disease in esophagus. Such complications are often asymptomatic and include ulcerative oesophagitis and Barrett's oesophagus, which may lead to oesophageal cancer if left untreated. In addition, the 13C urea breath test and stool antigen test may give up to 50 % false negative results if the patient has a) atrophic gastritis b) MALT lymphoma or c) bleeding peptic ulcer disease or d) if the patient is currently receiving antibiotics or PPIs.

The GastroPanel examination arguments for general practitioners – for huge unmet need (indications)

- GastroPanel should be one of the state-of-the-art, first-line diagnostic tests for the diagnosis of *H. pylori* infection (5-80% of the world population) and in examination of all patients with dyspepsia (20-40% of the western population).

- GastroPanel should be used to rule out or confirm the high acid output of reflux patients instead of the trial and error use of PPIs. The long term use of PPIs may increase the risk of stomach and oesophageal cancer.
- GastroPanel (Pepsinogen I, PGI, Pepsinogen II, PGII, Gastrin-17, G-17 and *H. pylori* antibodies) reveals: *H. pylori* infection and
 - subjects at increased risk for stomach- and oesophageal cancer, i.e. those with atrophic gastritis as well as those with a low risk of cancer; *H. pylori* gastritis with no atrophic gastritis in the antrum and/or corpus.
 - Early and reliable diagnosis of *H. pylori* infection and atrophic gastritis (AG) save costs and prevent many unnecessary diseases and deaths due to stomach and oesophageal cancer.
- GastroPanel is also indicated for special target patients, with autoimmune diseases (usually more than one at the same time), including, e.g.:
 - patients with autoimmune thyroiditis who may have autoimmune atrophic gastritis (AAG, 18%) in the corpus with related risks,
 - patients with type 1 diabetes who may have AAG and, e.g., also deficiency of B-12 vitamin (12%) with related risks,
 - patients with celiac disease who may have AAG with related risks, and
 - patients with rheumatoid arthritis who may have AAG with related risks
- In patients with AG or AAG, absorption of vitamin B-12 is reduced.
 - Due to vitamin B-12 deficiency, there is an increased risk of depression, Alzheimer's disease, dementia and polyneuropathy. Consequently, all patients with depression, Alzheimer's disease, dementia and polyneuropathy should be examined by GastroPanel to rule out or confirm those with AG or AAG in the corpus
 - Due to vitamin B-12 deficiency, increased homocysteine levels in the body may be related to:
 - Atherosclerosis – these patients should be examined by GastroPanel to rule out or confirm AG or AAG with related risks
 - Heart attacks – these patients should be examined by GastroPanel to rule out or confirm AG or AAG with related risks
 - Strokes – these patients should be examined by Gastro Panel to rule out or confirm AG or AAG with related risks
- Furthermore, in patients with AG or AAG of the corpus, absorption of Ca, Fe, Mg and Zn is reduced. Low Ca is associated with osteoporosis, while low serum Fe results in anemia.
- All osteoporosis and anemia patients should be examined by GastroPanel to rule out or confirm AG or AAG.
- The risk of pneumonia and, in senior citizens, also the risk of fatal intestinal infections (such as giardiasis, malaria, *Clostridium difficile* and *E. coli* EHEC) may increase significantly due to an anacidic stomach caused by AG, AAG or PPI's. All patients with such infections should be examined by GastroPanel for detection of AG and AAG.
- All subjects diagnosed with AG and AAG in GastroPanel examination need gastroscopic confirmation

Please note that the urea breath test (UBT), stool antigen test or *H. pylori* antibody test alone do not reveal AG or AAG. Furthermore, UBT and stool antigen test give 50% of false negative results in *H. pylori* patients, particularly if the patient has AG due to *H. pylori* infection or AAG, bleeding peptic ulcer, chronic use of PPIs, antibiotic treatment or MALT lymphoma due to *H. pylori* infection.

GastroPanel is also suitable for screening of healthy (asymptomatic) people, because *H. pylori* infection, AG or AAG with related risks are often asymptomatic.