A breakthrough in the implementation of Biohit GastroPanel® test into the national health service (NHS) of the UK. Results of the Homerton trial accepted for publication in a British journal.

Biohit Oyj Press Release 08.12.2024 at 10.00 local time (EEST)

The 2019 BSG (British Society of Gastroenterology) guidelines on the diagnosis and management of patients at risk of gastric cancer (GC) state that the key to early detection of GC and improved survival of the patients is to non-invasively identify those at risk before endoscopy (1). These guidelines recommend i) endoscopic surveillance every three years for the high-risk patients, i.e., those with extensive moderate to severe AG of the gastric corpus (AGC2+), as well as ii) endoscopic mucosal resection/endoscopic sub-mucosal dissection of visible gastric dysplasia and early GC (1). Until to date, however, identifying the patients with AGC2+ and its progressive carcinogenic lesions remains exclusively an endoscopic modality. Endoscopic diagnosis of AG is difficult and compromised by a low inter-observer agreement at both endoscopy and histology (2).

At present, UK endoscopy services are experiencing increased workload, the activity being predicted to increase by to 44% over the next five years (3). Accordingly, more than anything else, there is the need in the UK to distinguish the patients with functional dyspepsia but healthy stomach who are referred for endoscopy (1-3). On the other hand, there is a burning demand to avoid unnecessary endoscopy in patients already diagnosed with functional dyspepsia, even if symptomatic. This emphasizes the need for an objective, targeted and non-invasive diagnostic tool for the precise identification of the patients who are at high risk of developing GC, i.e. those with AGC2+.

To respond to this national demand, a clinical trial was designed at the Gastroenterology department of Homerton University Hospital, London (UK) to assess GastroPanel® performance in the identification of AGC2+ among patients with dyspepsia (4). GastroPanel® (Biohit Oyj; Helsinki, Finland) is a 4-biomarker ELISA test that measures 1) pepsinogen I (PGI); 2) pepsinogen II (PGII); 3) gastrin-17 (G-17); and 4) *Helicobacter pylori* IgG antibodies (*Hp* IgG) (5-7). In several large-scale clinical trials, the diagnostic accuracy (DA) of PGI and PGI/PGII ratio in detection of AGC2+ has been confirmed (8), and also verified in a recent meta-analysis (9).

In this single-centre, prospective diagnostic accuracy study at Homerton hospital (4), 324 patients (184 women and 140 men); median age 57 years (range 39-92 years) were originally referred for gastroscopy and biopsies, classified according to the updated Sydney System (USS). Blood (plasma) samples were collected for GastroPanel® analysis. Paired (GP, USS) samples were available from 268 patients (4). GastroPanel® samples were analyses at Biohit Oyj, interpreted using the GastroSoft® application as usual (5-8).

Panu Hendolin, Ph.D, Director of Research and Development, Biohit Oyj: “Overall agreement (OA) between GastroPanel® and the USS classification was 90% (95%CI=86.7-93.8%), with a weighted kappa (κ_w) of 0.828 (95%CI=0.781-0.865). In Receiver Operating Characteristics (ROC) curve analysis, using AGC2+ as the endpoint, AUC=0.840 (95% CI 0.630-1.000) and 0.960 (95% CI 0.907-1.000) for PGI and the PGI/PGII ratio, respectively (4). The results of the Homerton study implicate that GastroPanel® is a reliable triage test for dyspeptic patients distinguishing patients who can be safely treated conservatively from those with moderate to severe AGC who are at high-risk of developing GC.”

Jussi Hahtela, CEO, Biohit Oyj: “This is the first clinical validation study of GastroPanel® test in the UK, and as such represents an important breakthrough in the future implementation of this test in the UK national health service (NHS). This Homerton study has been set up and monitored by BIOHIT HealthCare Ltd, (London, UK). There are good prospects that the results of this successfully completed clinical trial can be exploited by the company in the future, hopefully by getting GastroPanel® test adopted as an integral part of the dyspepsia pathway in the updated BSG guidelines (1). Its use in clinical practice will produce a substantial financial and environmental impact

by avoiding unnecessary upper GI endoscopy procedures, and help keep the focus on patients with high-risk lesions of GC."

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Biohit in brief

Biohit Oyj is a globally operating Finnish biotechnology company. Biohit's mission is "Innovating for Health" – we produce innovative products and services to promote research and early diagnosis. Biohit is headquartered in Helsinki, Finland, and has subsidiaries in Italy and the UK. Biohit's Series B share (BIOBV) is quoted on NASDAQ OMX Helsinki in the Small cap/Healthcare group. www.biohithealthcare.com

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