Standards For Serum Gastric Function Tests were validated by BIOHIT

www.biohit.cn

1. GastroPanel® application history

2. In the 1990s, Sipponen, a Finnish scholar, pioneered the G-17 test and advocated the 4 in1 detection of serum PG I, PG II, G-17 and HP to comprehensively assess the function of the gastric mucosa. A number of countries around the world have been using the above-mentioned indicators to screen for gastric cancer and pre-cancerous diseases by "serological biopsy" of the gastric mucosa.

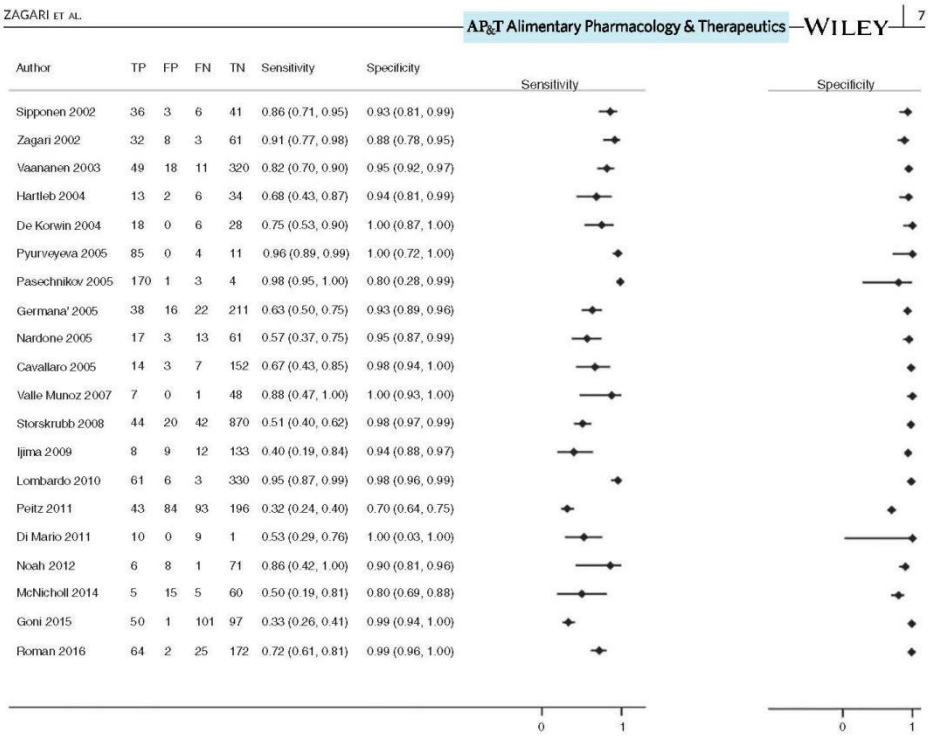


FIGURE 2 Forest plots of coupled sensitivity and specificity for atrophic gastritis regardless of the site. TP = true positive, FP = false positive, FN = false negative, TN = true negative

(95%CI, 22.5% to 65.4%) and 99.1% (95%CI,98.4% to 99.5%) for the diagnosis of both antrum and corpus atrophic gastritis (Figure S4), respectively.

4 | DISCUSSION

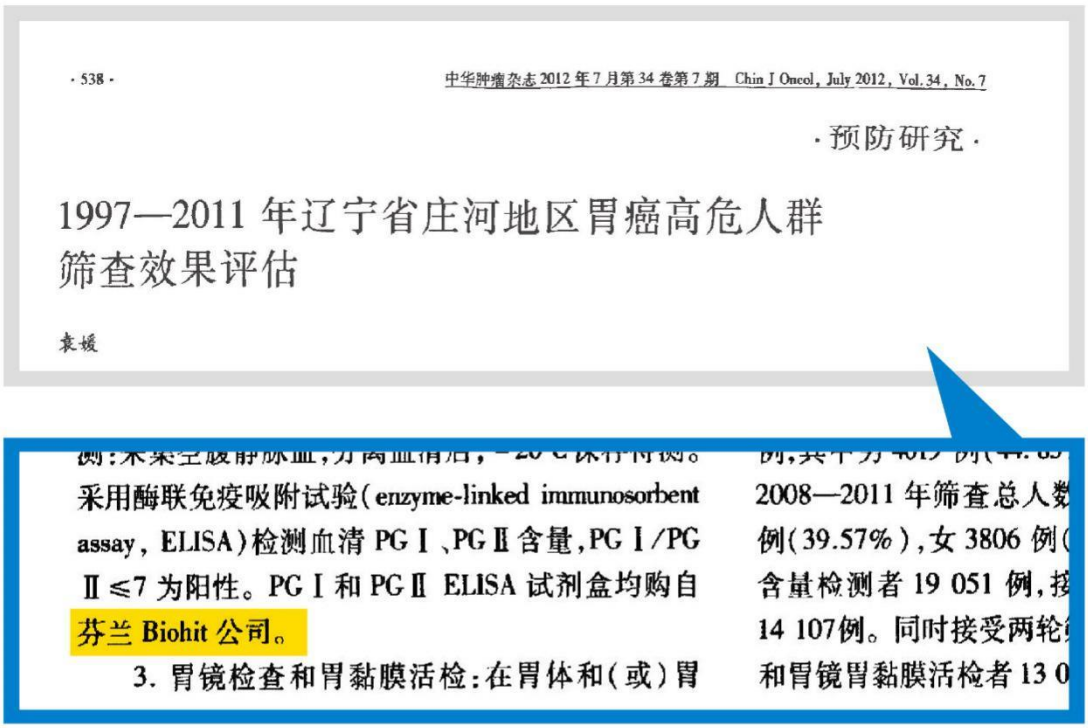
This meta-analysis included 20 studies assessing the accuracy of the combination of pepsinogens, gastrin-17 and anti-*H. pylori* antibodies serum assays for the diagnosis of atrophic gastritis, compared to histology; pooling data from these studies yielded a summary sensitivity of 74.7% (62.0% to 84.3%) and a summary specificity of 95.6% (92.6% to 97.4%). Based on the median prevalence of atrophic gastritis across the studies of 27%, which is very close to that estimated worldwide in the general population (around 30%),[54] the negative predictive value of the panel test was 91% and the positive predictive value was 86%; this implies that 91 of 100 subjects with a negative test will be true negative for the presence of atrophic gastritis, while 86 of 100 subjects with a positive test will be true positive. Using the pooled likelihood ratios, with a median pre-test probability of atrophic gastritis of 27%, the post-test probability was 9% for subjects with a negative test and 86% for subjects with a positive test result.

Pooling data from seven studies produced a summary sensitivity of the panel test of 65.4% for the diagnosis of antrum atrophic gastritis, 70.4% for the diagnosis of corpus atrophic gastritis and 42.6% for both antrum and corpus atrophic gastritis; the summary specificity was higher than 95% for any site of atrophic gastritis.

4.1 | Strengths and weaknesses of the study

A strength of this review is the comprehensive search of literature without restrictions on the language of publications; we also identified and included unpublished studies, which were reported as abstracts in international conferences proceedings, minimising the risk of missing relevant studies. As there is not a powerful method of testing for publication bias in a meta-analysis of diagnostic accuracy studies,[6] we are not able to assess the likely impact of unpublished studies on our results. However, the studies included in this systematic review are likely to be the majority on this topic and, in

3. From 1997 to 2011, Professor Yuan Yuan and others of First Affiliated Hospital of China Medical University used a two-round screening method of serum PG test and gastric mucosal biopsy to screen a total of 13,078 people in three large-scale population screening exercises in areas with a high incidence of gastric cancer in China. The risk cutoff for gastric cancer in China for PG testing was proposed: PG I concentration ≤70 μg/L and PGR ≤7 μg/L.



· 538 ·

中华肿瘤杂志 2012 年 7 月第 34 卷第 7 期 Chin J Oncol, July 2012, Vol. 34, No. 7

· 预防研究 ·

1997—2011 年辽宁省庄河地区胃癌高危人群筛查效果评估

袁媛

采用酶联免疫吸附试验(enzyme-linked immunosorbent assay, ELISA)检测血清 PG Ⅰ、PG Ⅱ 含量,PG Ⅰ/PG Ⅱ≤7 为阳性。PG Ⅰ 和 PG Ⅱ ELISA 试剂盒均购自芬兰 Biohit 公司。

3. 胃镜检查和胃黏膜活检:在胃体和(或)胃

2008—2011 年筛查总人数
例(39.57%),女 3806 例(
含量检测者 19 051 例,接
14 107例。同时接受两轮
和胃镜胃黏膜活检者 13 0

Online Submissions: wjg.wjgnet.com
www.wjgnet.com
wjg@wjgnet.com

World J Gastroenterol 2007 December 28; 13(48): 6562-6567
World Journal of Gastroenterology ISSN 1007-9327
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RAPID COMMUNICATION

Serum pepsinogen levels and their influencing factors: A population-based study in 6990 Chinese from North China

Li-Ping Sun, Yue-Hua Gong, Lan Wang, Yuan Yuan

parameters.Serum PG concentration was measured by enzyme-linked immunosorbent assay(ELISA) with PGI /PGII ELISA kits (Biohit Co., Ltd., Finland).

4. Consensus on Chronic Gastritis in China (2012)

中国慢性胃炎共识意见（2012 年，上海）

中华医学会消化病学分会
房静远，刘文忠，李兆申，杜亦奇，纪小龙，戈之铮，李延青，姚健敏，吕农华，吴开春，陈崇暄，萧树东

低。因此，血清胃泌素 G17 以及胃蛋白酶原 I 和 II 的检测有助于判断胃黏膜有无萎缩和萎缩的部位[58-60]。萎缩性胃体炎可由 *H. pylori* 感染或自身免疫

[58]

[58] Vă ă n ă nen H, Vauhkonen M, Helske T, et al. Nonendoscopic diagnosis of atrophic gastritis with a blood test. Correlation between gastric histology and serum levels of gastrin-17 and pepsinogen Ⅰ: a multicentre study[J]. Eur J Gastroenterol Hepatol, 2003, 15:885-891.

H Vāānānen　M Vauhkonen　T Helske　I Kāāriainen
J Koskenpato　M Sotka　M Turunen　R Sandström
P Sipponen
Eur J Gastroenterol Hepatol 2003 Aug:15(8):885-91
Medivire Medical Clinics, Helsinki,Finland.

[59]

[59] Wu KC, Li HT, QiaoTD, et al. Diagnosis of atrophic body gastritis in Chinese patients by measuring serum pepsinogen[J]. Chin J Dig Dis, 2004, 5:22-27.

Diagnosis of atrophic body gastritis in Chinese patients by measuring serum pepsinogen

Kai Chun WU, Hong Tao LI, Tai Dong QIAO, Cai Ning LI, Wan Sheng JI, Feng Qi TIAN, Xin WANG, Biao Luo WANG, Ji Yan MIAO, Jie DING & Dai Ming FAN

Department of Gastroenterology, Xijing Hospital, Fourth Military Medical University, Xi'an, Shaanxi Province, China

...ommon in older ...intestinal hemor- ...w-up therapy, were ...nhibitory medica- ...mucosa protectant

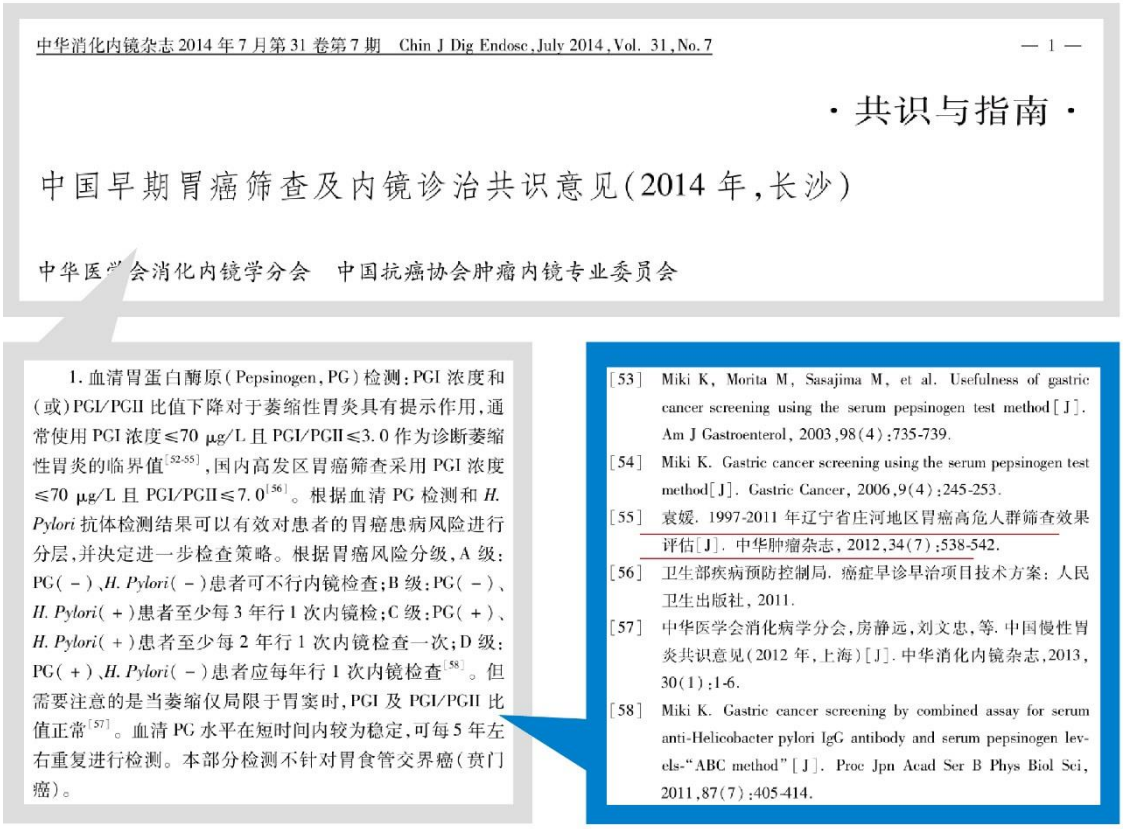
PGI, PGII and antibodies to *H. pylori* were determined using specific commercial ELISA kits[11] (Pepsinogen I, Pepsinogen II, *H. pylori* ELISA Kit, Biohit, Helsinki, Finland) in batches of 40 samples in a microwell plate, in accordance with the manufacturer's instructions.

[60]

[60]曹勤，冉志华，萧树东. 血清胃蛋白酶原胃泌素-17 和幽门螺杆菌IgG 抗体筛查萎缩性胃炎和胃癌[J]. 胃肠病学杂志，2006，11 ：388-394

以酶联免疫吸附测定(ELISA)定量检测血清 PGI、PGII 和 G-17。PGI、PGII 和 G-17 ELISA 试剂盒由芬兰 Biohit 公司，批号分别为 Cat No 601010、Cat No 601020、Cat No 601030。用于酶免疫测定实验的 PGI、PGII、G-17 单克隆抗体具有高度特异性。PGI 和 PGII 试剂之间无交叉反应。

5. Consensus on Early Gastric Cancer Screening and Endoscopic Management in China (2014)



中华消化内镜杂志 2014 年 7 月第 31 卷第 7 期　Chin J Dig Endosc, July 2014, Vol. 31, No. 7　— 1 —

·共识与指南·

中国早期胃癌筛查及内镜诊治共识意见(2014 年,长沙)

中华医学会消化内镜学分会　中国抗癌协会肿瘤内镜专业委员会

1. 血清胃蛋白酶原(Pepsinogen, PG)检测:PGI 浓度和(或)PGI/PGII 比值下降对于萎缩性胃炎具有提示作用,通常使用 PGI 浓度≤70 μg/L 且 PGI/PGII≤3.0 作为诊断萎缩性胃炎的临界值[52-55],国内高发区胃癌筛查采用 PGI 浓度≤70 μg/L 且 PGI/PGII≤7.0[56]。根据血清 PG 检测和 *H. Pylori* 抗体检测结果可以有效对患者的胃癌患病风险进行分层,并决定进一步检查策略。根据胃癌风险分级,A 级:PG(－)、*H. Pylori*(－)患者可不行内镜检查;B 级:PG(－)、*H. Pylori*(＋)患者至少每 3 年行 1 次内镜检;C 级:PG(＋)、*H. Pylori*(＋)患者至少每 2 年行 1 次内镜检查一次;D 级:PG(＋)、*H. Pylori*(－)患者应每年行 1 次内镜检查[58]。但需要注意的是当萎缩仅局限于胃窦时,PGI 及 PGI/PGII 比值正常[57]。血清 PG 水平在短时间内较为稳定,可每 5 年左右重复进行检测。本部分检测不针对胃食管交界癌(贲门癌)。

[53] Miki K, Morita M, Sasajima M, et al. Usefulness of gastric cancer screening using the serum pepsinogen test method[J]. Am J Gastroenterol, 2003, 98(4): 735-739.

[54] Miki K. Gastric cancer screening using the serum pepsinogen test method[J]. Gastric Cancer, 2006, 9(4): 245-253.

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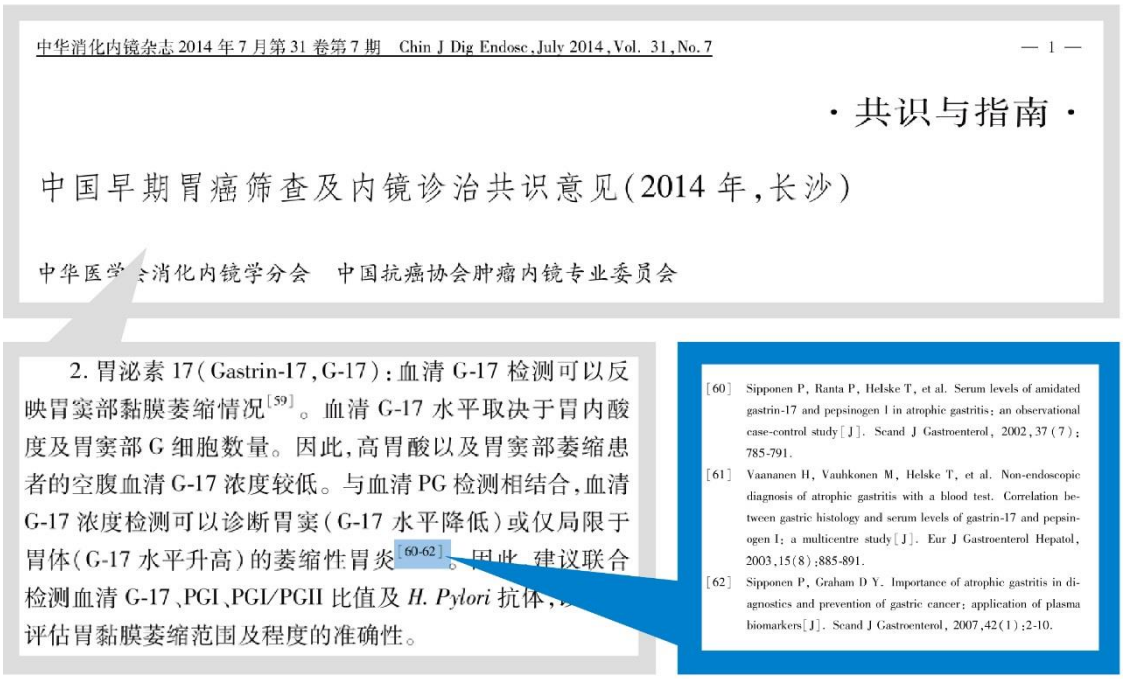
[56] 卫生部疾病预防控制局. 癌症早诊早治项目技术方案: 人民卫生出版社, 2011.

[57] 中华医学会消化病学分会, 房静远, 刘文忠, 等. 中国慢性胃炎共识意见(2012 年, 上海)[J]. 中华消化内镜杂志, 2013, 30(1): 1-6.

[58] Miki K. Gastric cancer screening by combined assay for serum anti-Helicobacter pylori IgG antibody and serum pepsinogen levels-"ABC method"[J]. Proc Jpn Acad Ser B Phys Biol Sci, 2011, 87(7): 405-414.



中华消化内镜杂志 2014 年 7 月第 31 卷第 7 期　Chin J Dig Endosc, July 2014, Vol. 31, No. 7　— 1 —

·共识与指南·

中国早期胃癌筛查及内镜诊治共识意见(2014 年,长沙)

中华医学会消化内镜学分会　中国抗癌协会肿瘤内镜专业委员会

2. 胃泌素 17(Gastrin-17, G-17):血清 G-17 检测可以反映胃窦部黏膜萎缩情况[59]。血清 G-17 水平取决于胃内酸度及胃窦部 G 细胞数量。因此,高胃酸以及胃窦部萎缩患者的空腹血清 G-17 浓度较低。与血清 PG 检测相结合,血清 G-17 浓度检测可以诊断胃窦(G-17 水平降低)或仅局限于胃体(G-17 水平升高)的萎缩性胃炎[60-62]。因此,建议联合检测血清 G-17、PGI、PGI/PGII 比值及 *H. Pylori* 抗体,评估胃黏膜萎缩范围及程度的准确性。

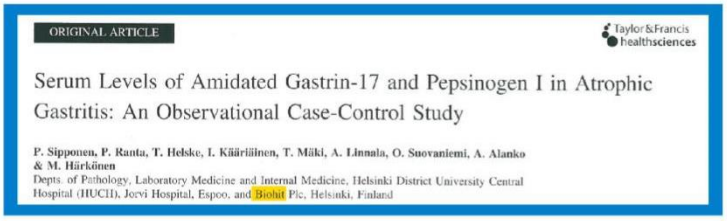
[60] Sipponen P, Ranta P, Helske T, et al. Serum levels of amidated gastrin-17 and pepsinogen I in atrophic gastritis: an observational case-control study[J]. Scand J Gastroenterol, 2002, 37(7): 785-791.

[61] Vaananen H, Vauhkonen M, Helske T, et al. Non-endoscopic diagnosis of atrophic gastritis with a blood test. Correlation between gastric histology and serum levels of gastrin-17 and pepsinogen I: a multicentre study[J]. Eur J Gastroenterol Hepatol, 2003, 15(8): 885-891.

[62] Sipponen P, Graham D Y. Importance of atrophic gastritis in diagnostics and prevention of gastric cancer: application of plasma biomarkers[J]. Scand J Gastroenterol, 2007, 42(1): 2-10.

[60]

[60] Sipponen P,Ranta p,Helske T,et al.Serum levels of amindated gastrin-17 and pepsinogen I in atrophic gastritis:an observational case-control study[J].Scand J Gastroenterol,2002,37(7):785-791



ORIGINAL ARTICLE

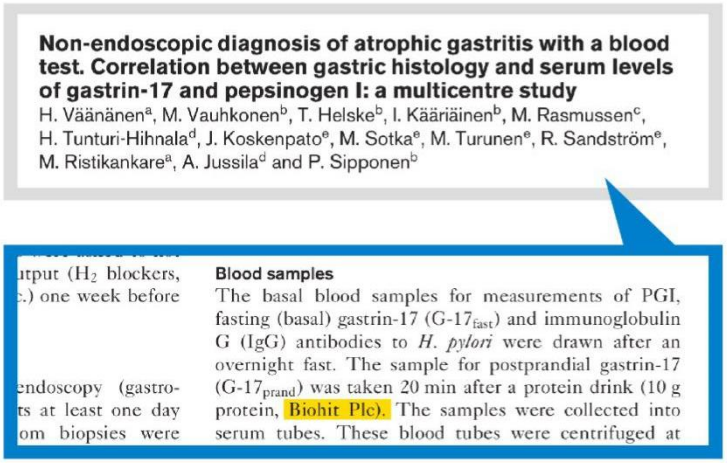
Taylor&Francis healthsciences

Serum Levels of Amidated Gastrin-17 and Pepsinogen I in Atrophic Gastritis: An Observational Case-Control Study

P. Sipponen, P. Ranta, T. Helske, I. Kääriäinen, T. Mäki, A. Linnala, O. Suovaniemi, A. Alanko & M. Härkönen
Depts. of Pathology, Laboratory Medicine and Internal Medicine, Helsinki District University Central Hospital (HUCH), Jorvi Hospital, Espoo, and Biohit Plc, Helsinki, Finland

[61]

[61] Vaananen H,Vauhkonen M,Helske T,et al.Non-endoscopic diagnosis of atrophic gastritis with a blood test. Correlation between gastric histology and serum levels of gastrin-17 and pepsinogen I:a multicentre study[J].Eur J Gastroenterol Hepatol,2003,15(8):885-891



Non-endoscopic diagnosis of atrophic gastritis with a blood test. Correlation between gastric histology and serum levels of gastrin-17 and pepsinogen I: a multicentre study

H. Väänänen[a], M. Vauhkonen[b], T. Helske[b], I. Kääriäinen[b], M. Rasmussen[c], H. Tunturi-Hihnala[d], J. Koskenpato[e], M. Sotka[e], M. Turunen[e], R. Sandström[e], M. Ristikankare[a], A. Jussila[d] and P. Sipponen[b]

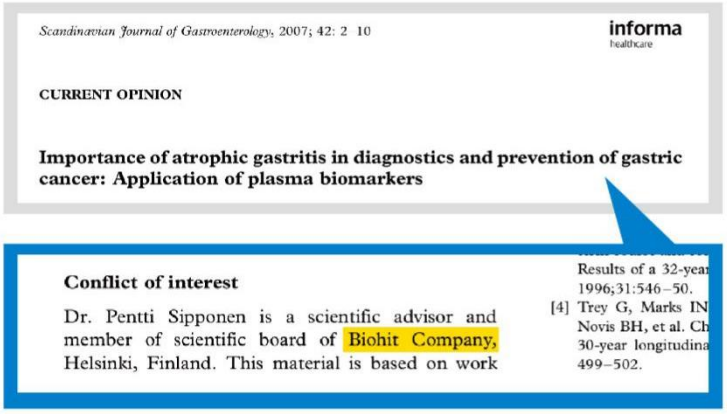
...itput (H_2 blockers, ...) one week before ...endoscopy (gastro- ...ts at least one day ...om biopsies were

Blood samples

The basal blood samples for measurements of PGI, fasting (basal) gastrin-17 ($G\text{-}17_{fast}$) and immunoglobulin G (IgG) antibodies to *H. pylori* were drawn after an overnight fast. The sample for postprandial gastrin-17 ($G\text{-}17_{prand}$) was taken 20 min after a protein drink (10 g protein, Biohit Plc). The samples were collected into serum tubes. These blood tubes were centrifuged at

[62]

[62] Sipponen P,Graham D Y. Importance of atrophic gastritis in diagnostics and prevention of gastric cancer:application of plasma biomarkers[J]. Scand J Gastroenterol,2007,42(1):2-10.



Scandinavian Journal of Gastroenterology, 2007; 42: 2–10

informa healthcare

CURRENT OPINION

Importance of atrophic gastritis in diagnostics and prevention of gastric cancer: Application of plasma biomarkers

Conflict of interest

Dr. Pentti Sipponen is a scientific advisor and member of scientific board of Biohit Company, Helsinki, Finland. This material is based on work

Results of a 32-year ...
1996;31:546–50.
[4] Trey G, Marks IN, Novis BH, et al. Ch... 30-year longitudina... 499–502.

6. January 2015, National 12th Five-Year Plan for Science and Technology Support - "Construction and Application Research of Collaborative Network for Clinical Research on Digestive Diseases" (2015BAI13B08)

国家消化系疾病临床医学研究中心
National Clinical Research Center for Digestive Diseases
上海·长海医院

2016年8月28日 星期日 网站首页 | 新闻通知 | 中心简介 | 组织架构 | 协同网络 | 研究项目 | 项目进展 | 学术动态 | 下载中心 | 联系我们

研究项目
- 上消化道疾病
- 下消化道疾病
- 胰腺疾病

上消化道疾病

早期胃癌筛查研究

项目摘要

研究全称：	血清学 ABC 法联合内镜筛查早期胃癌多中心临床研究
研究简称：	早期胃癌筛查项目
适应症：	早期胃癌
研究类型：	观察性
研究设计：	多中心、诊断性试验临床研究
干预手段：	无
课题来源：	国家科技支撑计划（2015BAI13B08）
项目负责人：	李兆申 教授，上海长海医院消化内科主任

【关键词】胃肿瘤；诊断；多中心研究；胃蛋白酶原类；胃泌素 -17
基金项目：国家科技支撑计划(2015BAI13B08)

2. 血清 G-17 和 PG 的测定：血清样本采集前 2 周患者停服抑酸药，前 1d 停服胃黏膜保护剂，采集前 10h 保持空腹，禁烟酒。所有患者均晨起空腹采集静脉血 5mL。血清 G-17 和 PG 的测定均采用芬兰 Biohit 公司的 ELISA 试剂盒

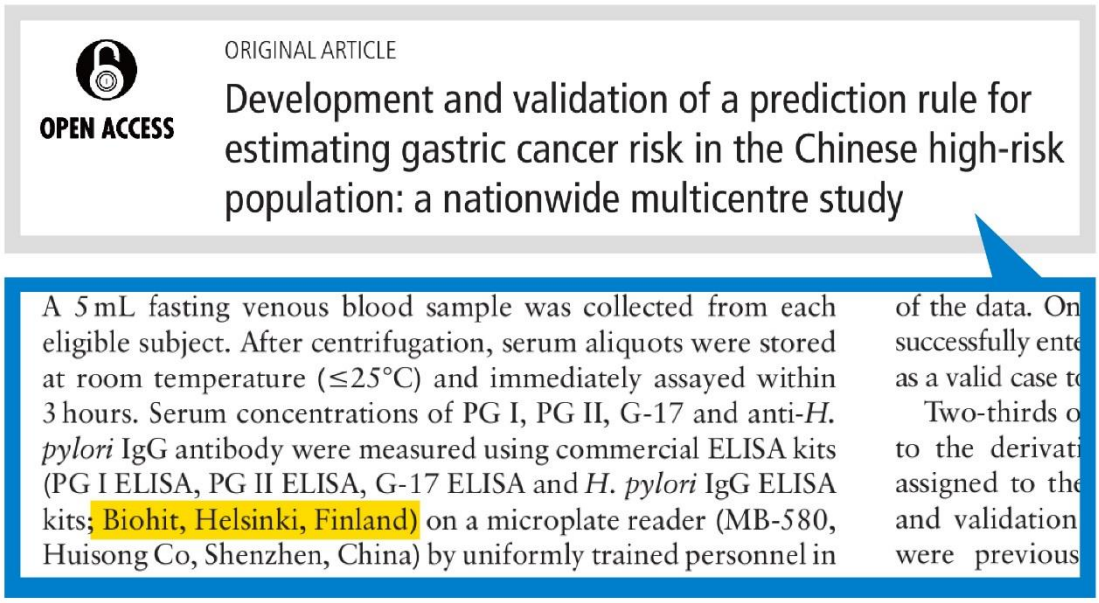
中国早期胃癌筛查流程专家共识意见
（草案 2017 年，上海）

国家消化系疾病临床医学研究中心　中华医学会健康管理学分会　中国医师协会内镜医师分会消化内镜专业委员会　中国医师协会内镜医师分会消化内镜健康管理与体检专业委员会　国家消化内镜质控中心　中国抗癌协会肿瘤内镜专业委员会

近期，国家消化病临床医学研究中心（上海）开展了一项全国 120 余家医院参加的大数据、多中心临床研究，对近 15 000 例的胃癌风险人群进行了血清 PG、G-17 和 *HP* 的检测，所有筛查对象接受了内镜检查。结果表明，当 PGR 低于 3.89，G-17 高于 1.50 pmol/L 时，胃癌的发生风险显著增高，这为建立新的胃癌风险人群筛查评分系统奠定了基础。经过统计学分析，在胃癌风险人群中，年龄、性别、*HP* 感染、PG、G-17 是与胃癌发生最相关的 5 个因素，分别予以不同的分值，可反映胃癌的发生风险。

（一）血清学筛查
血清 PGI 和（或）PGI 与 PGII 比值（PGI/PGII）水平降低。有研究认为，将“PGI≤70 μg/L 且 PGI/PGII≤3”（不同检测产品的参考值范围不同）作为针对无症状健康人群的胃癌筛查界限值，具有较好的时差结果。[16-19]

共识方案全部由必欧瀚提供的试剂获取的临床数据获得，其参考值具有产品标准性。



ORIGINAL ARTICLE

OPEN ACCESS

Development and validation of a prediction rule for estimating gastric cancer risk in the Chinese high-risk population: a nationwide multicentre study

A 5 mL fasting venous blood sample was collected from each eligible subject. After centrifugation, serum aliquots were stored at room temperature (≤25°C) and immediately assayed within 3 hours. Serum concentrations of PG I, PG II, G-17 and anti-*H. pylori* IgG antibody were measured using commercial ELISA kits (PG I ELISA, PG II ELISA, G-17 ELISA and *H. pylori* IgG ELISA kits; Biohit, Helsinki, Finland) on a microplate reader (MB-580, Huisong Co, Shenzhen, China) by uniformly trained personnel in

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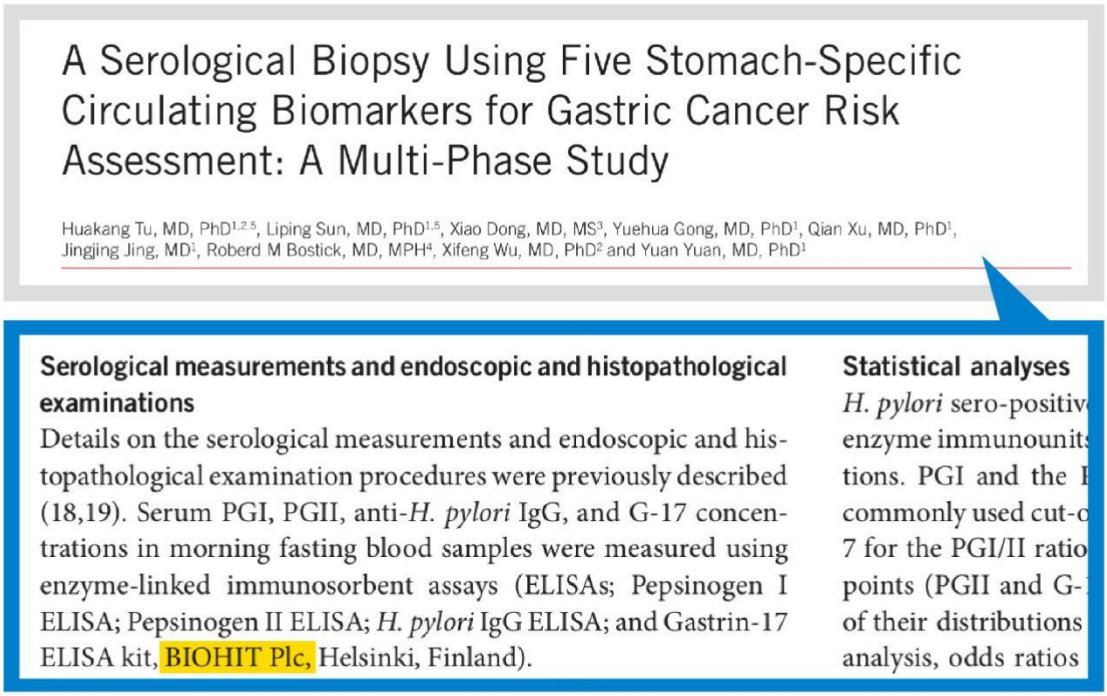


A Serological Biopsy Using Five Stomach-Specific Circulating Biomarkers for Gastric Cancer Risk Assessment: A Multi-Phase Study

Huakang Tu, MD, PhD[1,2,5], Liping Sun, MD, PhD[1,5], Xiao Dong, MD, MS[3], Yuehua Gong, MD, PhD[1], Qian Xu, MD, PhD[1], Jingjing Jing, MD[1], Roberd M Bostick, MD, MPH[4], Xifeng Wu, MD, PhD[2] and Yuan Yuan, MD, PhD[1]

Serological measurements and endoscopic and histopathological examinations

Details on the serological measurements and endoscopic and histopathological examination procedures were previously described (18,19). Serum PGI, PGII, anti-*H. pylori* IgG, and G-17 concentrations in morning fasting blood samples were measured using enzyme-linked immunosorbent assays (ELISAs; Pepsinogen I ELISA; Pepsinogen II ELISA; *H. pylori* IgG ELISA; and Gastrin-17 ELISA kit, BIOHIT Plc, Helsinki, Finland).

Statistical analyses

H. pylori sero-positiv
enzyme immunounit
tions. PGI and the
commonly used cut-o
7 for the PGI/II ratio
points (PGII and G-
of their distributions
analysis, odds ratios

8. On 13 December, 2018, the National Health Care Commission (NHC) issued the Notice on the Issuance of Diagnostic and Treatment Guidelines for 18 Tumours Including Primary Lung Cancer(2018 Edition) (NHC Medical Letter [2018] No. 1125) to the Health and Health Commissions (Health and Family Planning Commissions) of all provinces, autonomous regions, municipalities directly under the Central Government and Xinjiang Production and Construction Corps, in which the GastroPanel® (serum gastric function test) was incorporated into Chinese Guidelines for Diagnosis and Treatment of Gastric Cancer (2018) as diagnosis and treatment standard.

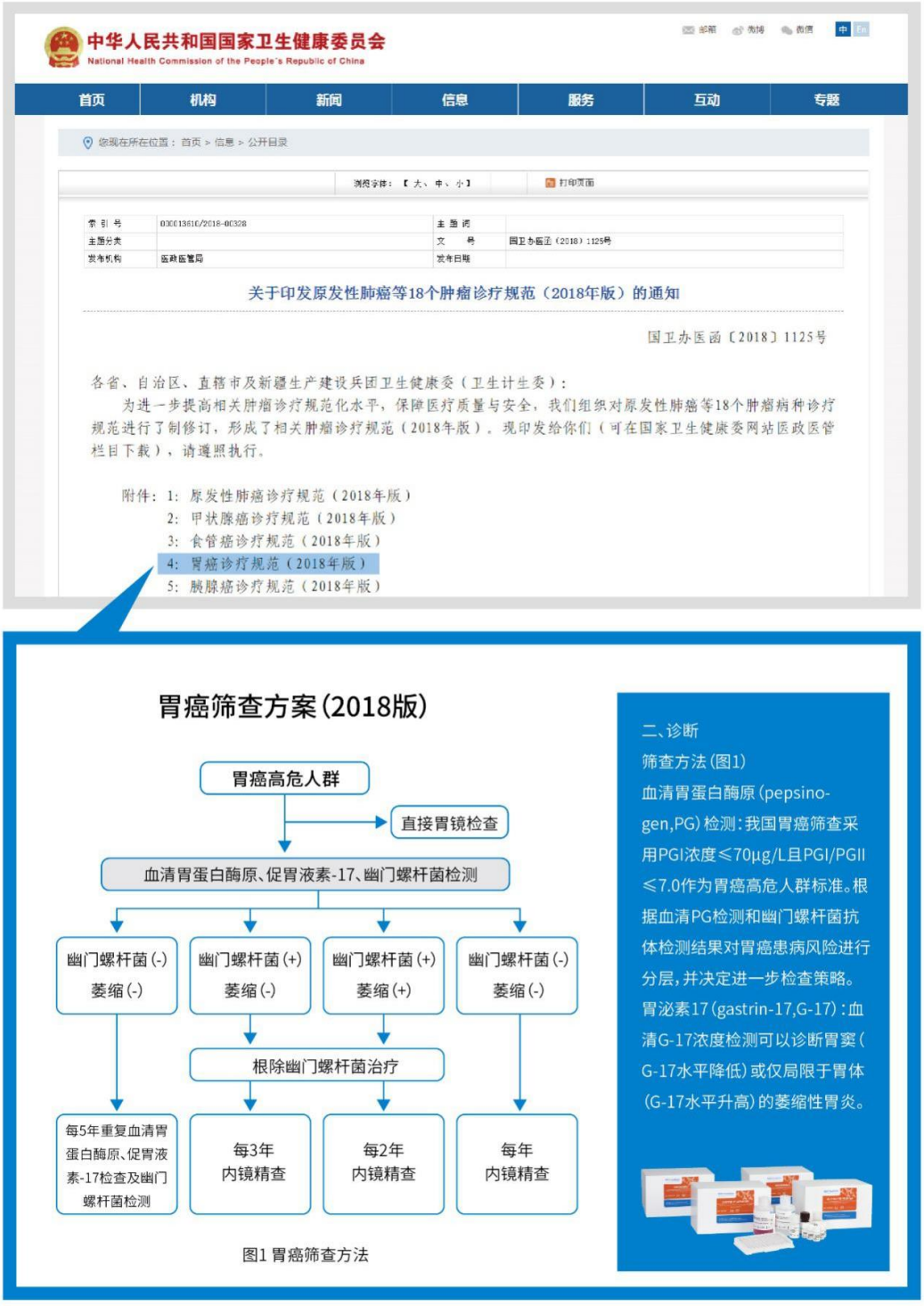
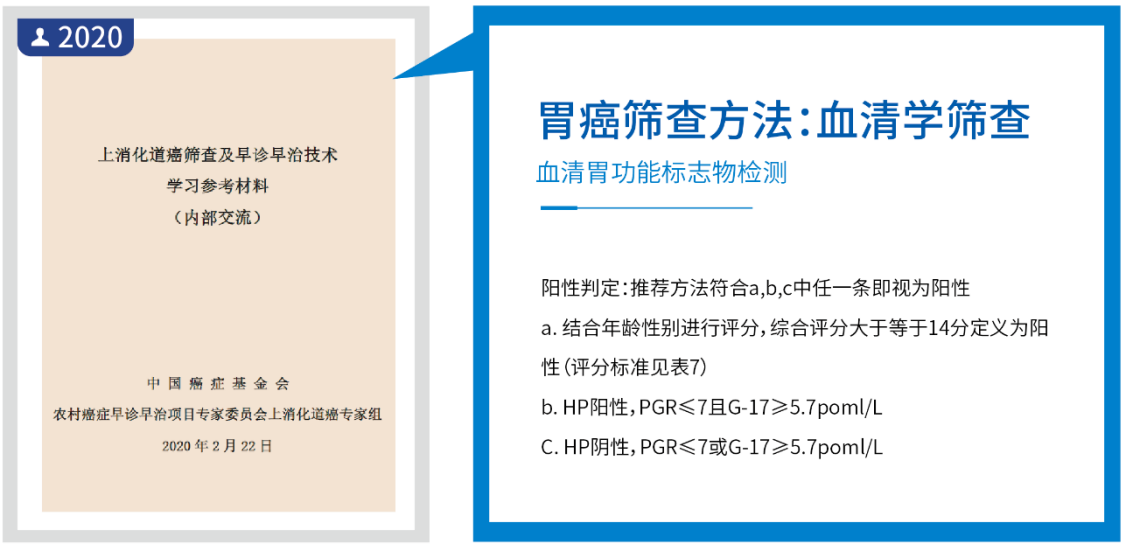


图1 胃癌筛查方法

9.


2020
上消化道癌筛查及早诊早治技术
学习参考材料
（内部交流）
中国癌症基金会
农村癌症早诊早治项目专家委员会上消化道癌专家组
2020年2月22日
胃癌筛查方法：血清学筛查
血清胃功能标志物检测
阳性判定：推荐方法符合a,b,c中任一条即视为阳性
a. 结合年龄性别进行评分，综合评分大于等于14分定义为阳性（评分标准见表7）
b. HP阳性，PGR≤7且G-17≥5.7poml/L
C. HP阴性，PGR≤7或G-17≥5.7poml/L