血清胃功能检测项目
行业标准为必欧瀚证明

www.biouhan.com

1、GastroPanel®应用历程

- **1990** 芬兰学者首创 G-17 检查方法，并用于胃病诊断中
- **2009** 《内科学》-人民卫生出版社
- **2012** 中国慢性胃炎共识意见
- **2014** 中国早期胃癌筛查及内镜诊治共识意见
- **2015** 科技部十二五支持计划[早期胃癌多中心临床应用研究]
- **2017** 使用五种胃特异性循环生物标志物进行血清学检查以评估胃癌风险：一项多阶段研究
- **2018** 卫生部胃癌诊疗规范 2018 版
- **2018** 中国早期胃癌筛查流程专家共识意见

2、上世纪 90 年代，芬兰学者 Sipponen 首创 G-17 检测方法，倡导四位一体联合检测血清 PG、G-17、HP，全面评估胃黏膜功能状态。世界多个国家相继利用上述指标组成的胃黏膜“血清学活检”进行胃癌及癌前疾病筛查，取得一定成效。

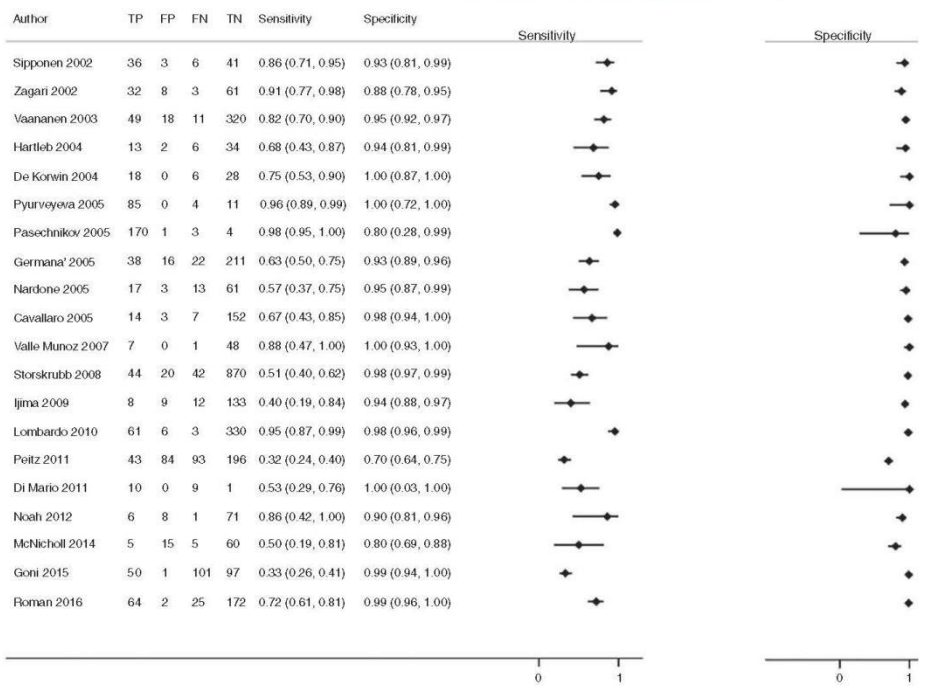


FIGURE 2 Forest plots of coupled sensitivity and specificity for atrophic gastritis regardless of the site. TP = true positive, FP = false positive, FN = false negative, TN = true negative

(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

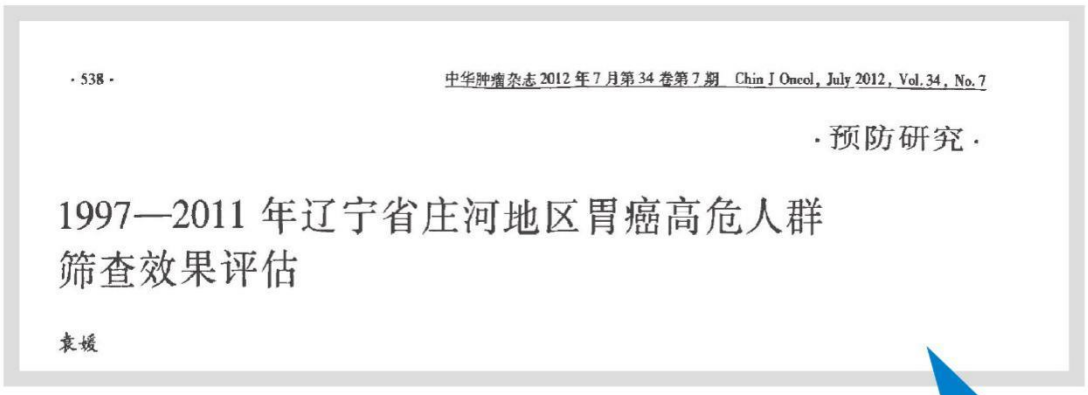
This meta-analysis included 20 studies assessing the accuracy of the combination of pepsinogens, gastrin-17 and anti-*H. pylori* antibodies serum assays for the diagnosis of atrophic gastritis, compared to histology; pooling data from these studies yielded a summary sensitivity of 74.7% (62.0% to 84.3%) 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

3.1997-2011 年，中国医科大学附属医院袁媛教授等采用血清 PG 检测和胃黏膜活检的两轮筛查法，在中国胃癌高发地区进行了 3 次大规模人群筛查，共计筛查 13078 人。提出了 PG 检测的中国胃癌风险判定界值：PG Ⅰ浓度≤70μg/L 且 PGR≤7。

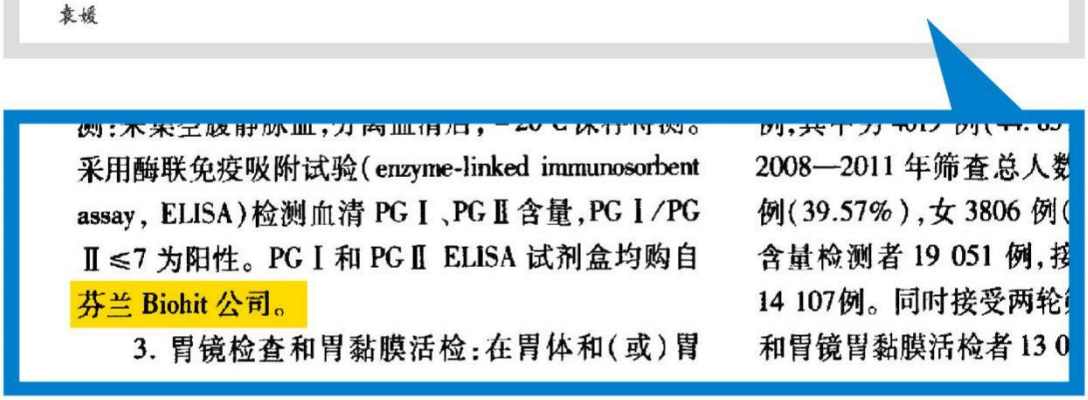


· 538 ·　　中华肿瘤杂志 2012 年 7 月第 34 卷第 7 期　Chin J Oncol, July 2012, Vol. 34, No. 7

· 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

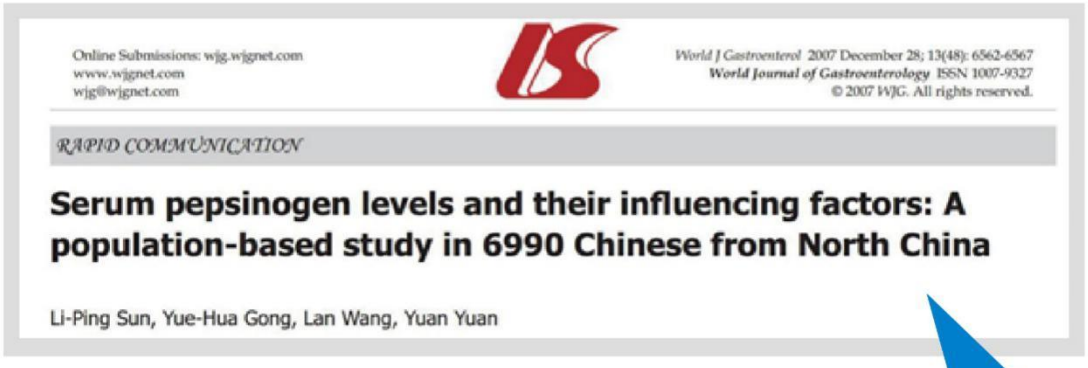
袁媛



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



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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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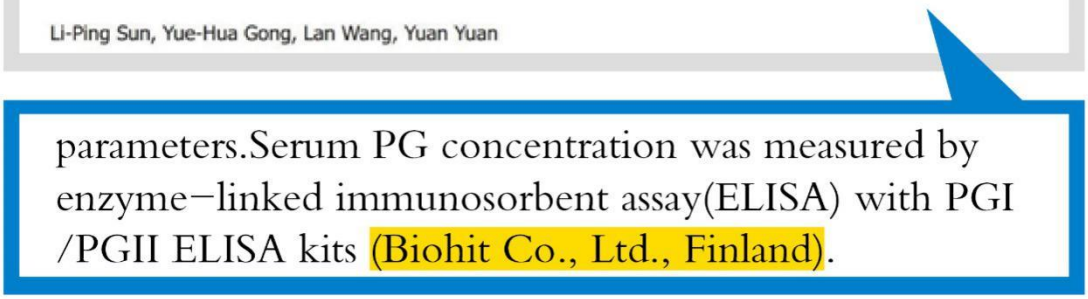
RAPID COMMUNICATION

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. 2012《中国慢性胃炎共识意见》

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，姒健敏，吕农华，吴开春，陈棠晅，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 Väänänen　M Vauhkonen　T Helske　I Kääriainen
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

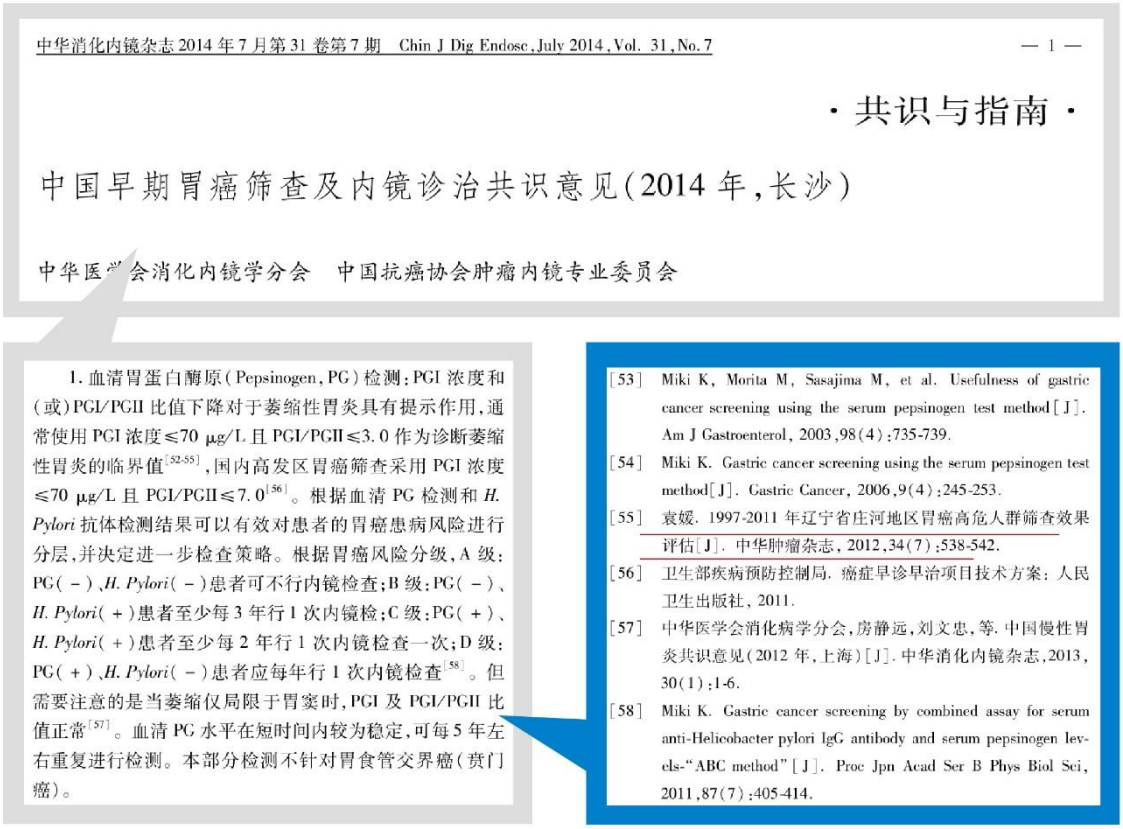
PGI, PGII and antibodies to *H. pylori* were determined using specific commercial ELISA kits[11] (Pepsinogen I, Pepsinogen II, *H. pylori* ELISA Kit, Biohit, Helsinki, Finland) in batches of 40 samples in a microwell plate, in accordance with the manufacturer's instructions.

[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。

5.2014 年《中国早期胃癌筛查及内镜诊治共识意见》



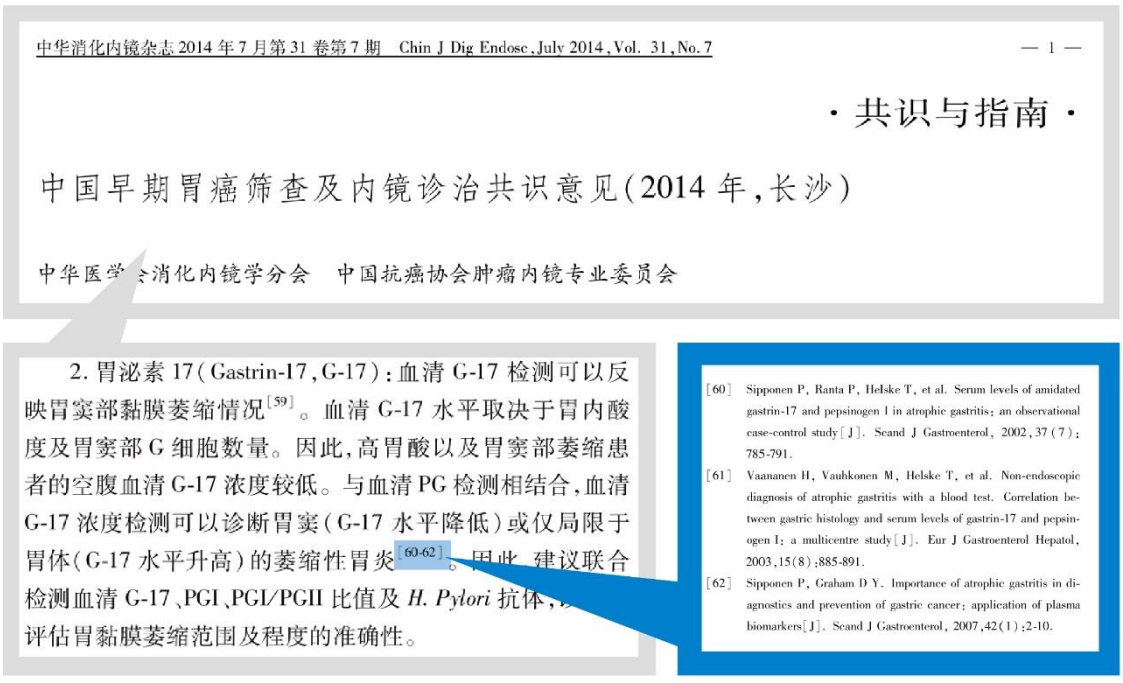
·共识与指南·

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.
[55] 袁媛. 1997-2011 年辽宁省庄河地区胃癌高危人群筛查效果评估[J]. 中华肿瘤杂志, 2012,34(7):538-542.
[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.



·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)

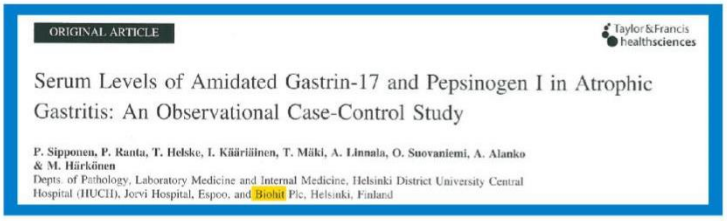
中华医学会消化内镜学分会 中国抗癌协会肿瘤内镜专业委员会

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

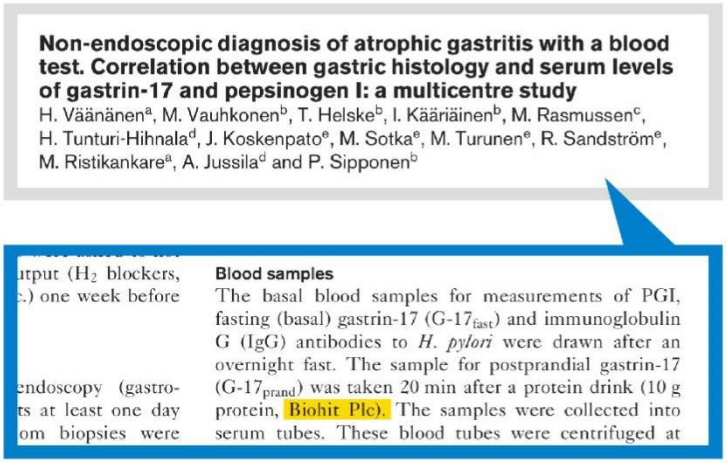
Taylor&Francis healthsciences

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]

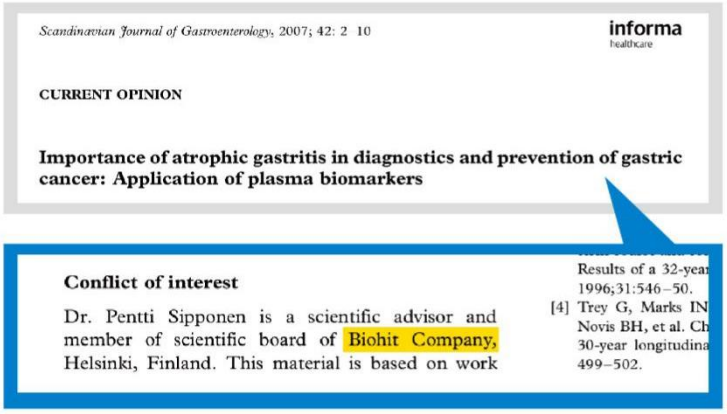
...itput (H_2 blockers, ...) one week before ...endoscopy (gastro- ...ts at least one day ...om biopsies were

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.

6.2015 年 1 月，国家十二五科技支撑计划 ——“消化病临床研究协同网络的建设及应用研究”（2015BAI13B08）

【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）

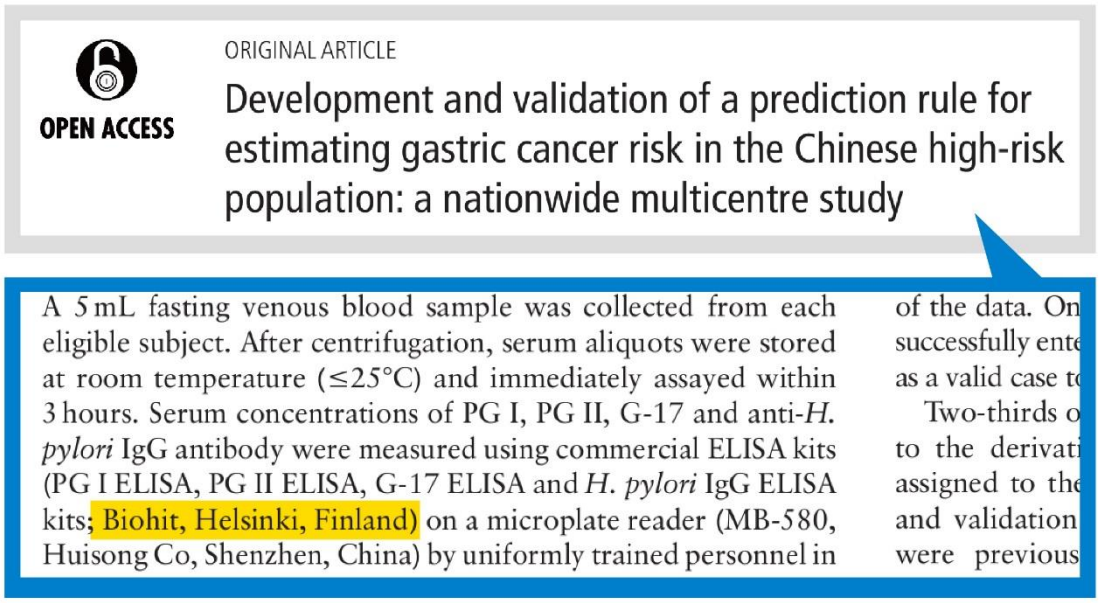
国家消化系疾病临床医学研究中心　中华医学会健康管理学分会　中国医师协会内镜医师分会消化内镜专业委员会　中国医师协会内镜医师分会消化内镜健康管理与体检专业委员会　国家消化内镜质控中心　中国抗癌协会肿瘤内镜专业委员会

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。



OPEN ACCESS

ORIGINAL ARTICLE

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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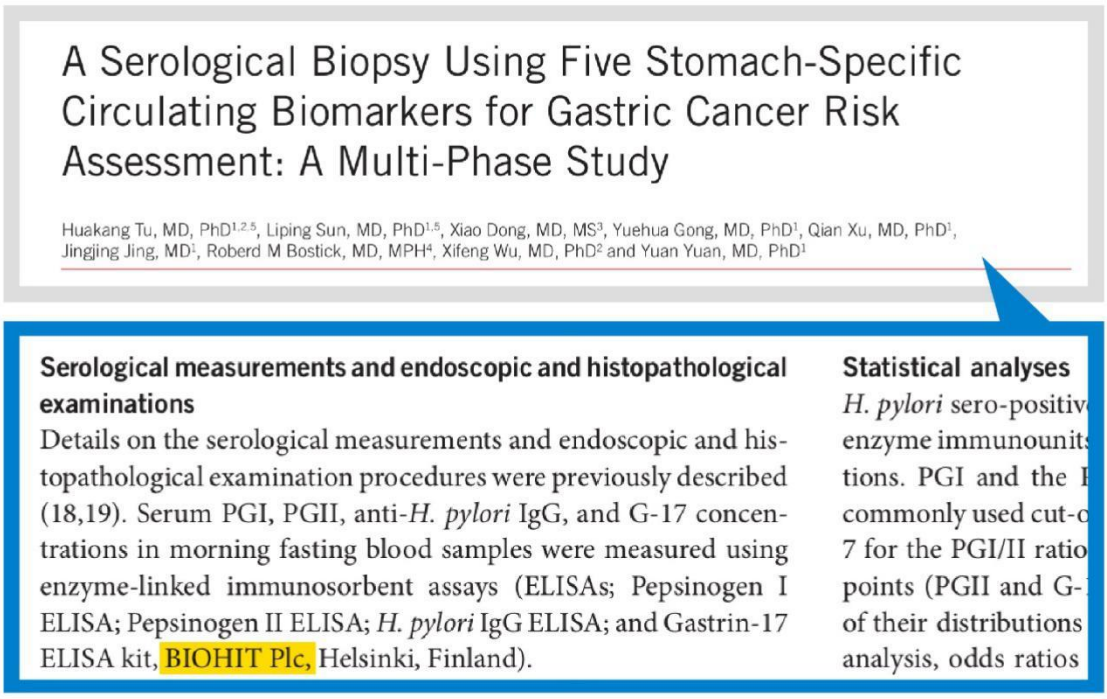
7.



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

8.2018 年 12 月 13 日，国家卫健委向各省、自治区、直辖市及新疆生产建设兵团卫生健康委（卫生计生委）下发了《关于印发原发性肺癌等 18 个肿瘤诊疗规范（2018 年版）的通知》（国卫办医函〔2018〕1125 号），其中《胃癌诊疗规范（2018 年版）》将 GastroPanel®（血清胃功能检测）纳入诊疗规范流程。

中华人民共和国国家卫生健康委员会
National Health Commission of the People's Republic of China

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索 引 号	00001361C/2018-00328	主 题 词	
主题分类		文　　号	国卫办医函〔2018〕1125号
发布机构	医政医管局	发布日期	

关于印发原发性肺癌等18个肿瘤诊疗规范（2018年版）的通知

国卫办医函〔2018〕1125号

各省、自治区、直辖市及新疆生产建设兵团卫生健康委（卫生计生委）：

为进一步提高相关肿瘤诊疗规范化水平，保障医疗质量与安全，我们组织对原发性肺癌等18个肿瘤病种诊疗规范进行了制修订，形成了相关肿瘤诊疗规范（2018年版）。现印发给你们（可在国家卫生健康委网站医政医管栏目下载），请遵照执行。

附件：1. 原发性肺癌诊疗规范（2018年版）
2. 甲状腺癌诊疗规范（2018年版）
3. 食管癌诊疗规范（2018年版）
4. 胃癌诊疗规范（2018年版）
5. 胰腺癌诊疗规范（2018年版）

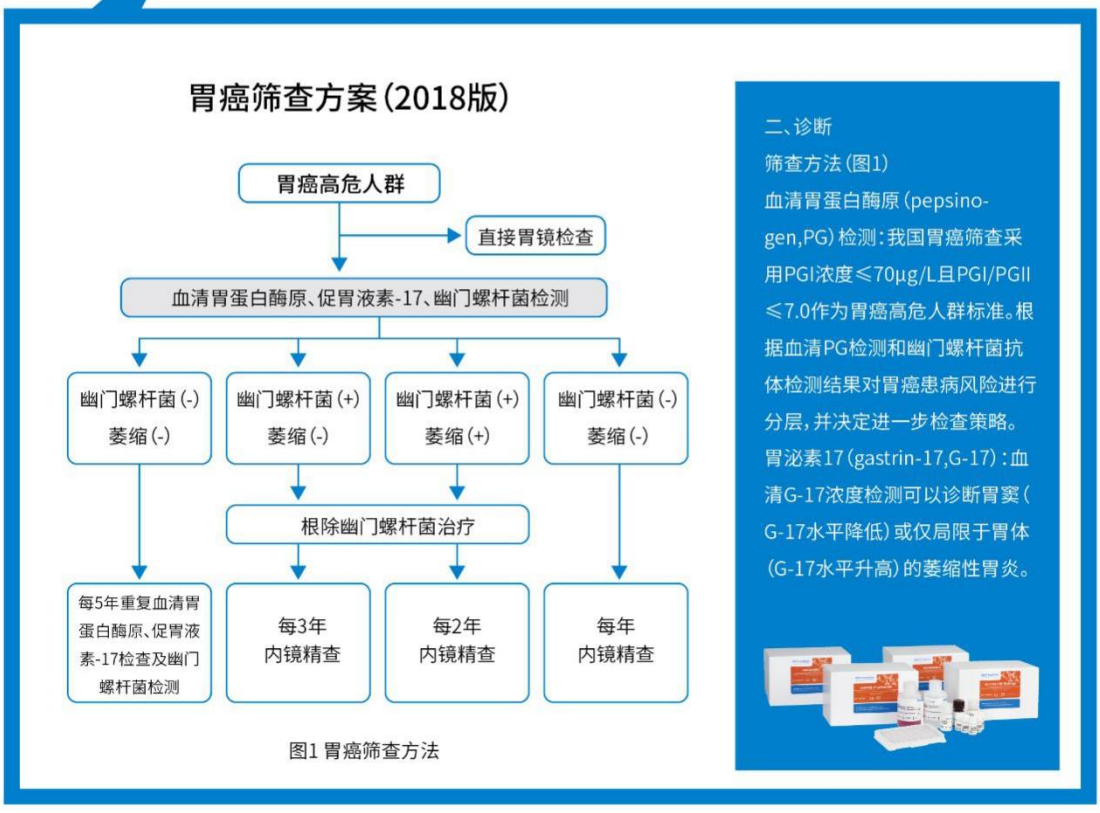
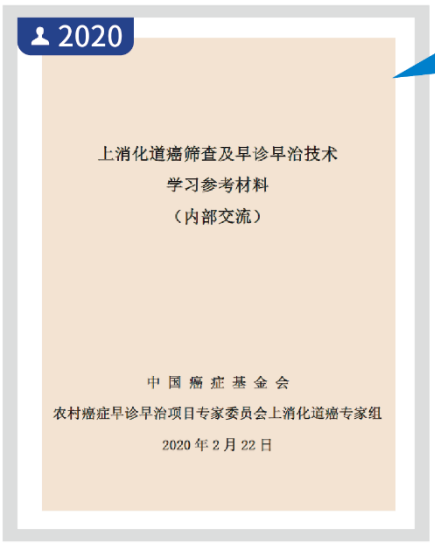


图1 胃癌筛查方法

9.



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