

Original Article

Serologic and stool antigen assay of *Helicobacter pylori* infection in hyperemesis gravidarum: Which test is useful during early pregnancy?

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Accepted 20 November 2009

Abstract

Objective: To investigate the relationship between *Helicobacter pylori* infection and hyperemesis gravidarum (HG) during early pregnancy by using serologic and stool antigen tests in developing South Anatolia region of Turkey.

Materials and Methods: A prospective cross-sectional study was performed on 40 pregnant women with HG and 40 asymptomatic controls without gastric problems at 7–12 weeks of gestation. The sociodemographic characteristics were recorded. The presence of *H pylori* was analyzed in the sera of the study-group patients by serology-specific IgG test in serum and by a stool antigen test in fecal samples.

Results: The rates of serology-specific *H pylori* IgG positivity were 80% (32 of 40) in patients with HG and 35% (14 of 40) in control group. The difference between the two groups was significant [odds ratio: 6.9 (confidence interval: 2.2–22.1); $p < 0.01$]. The rates of *H pylori* stool antigen test positivity were 87.5% (35 of 40) in patients with HG and 62.5% (25 of 40) in control groups. The difference between the two groups was significant (odds ratio: 4.5, confidence interval: 1.09–18.5); $p = 0.028$.

Conclusion: Both serology-specific IgG and stool antigen tests seem to be good screening methods to identify *H pylori* in our pregnant patient population with HG during early pregnancy.

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Keywords: Early pregnancy; *Helicobacter pylori*; Hyperemesis gravidarum; Serologic and stool antigen tests

Introduction

Nausea and vomiting affect up to 50% of pregnant women and diminish women's quality of life and social functions in early pregnancy [1]. In most women, these symptoms resolve by fluid and vitamin supplementation as well as dietary modifications. Hyperemesis gravidarum (HG) affects approximately 1% of pregnancies and causes severe and protracted vomiting that often results in dehydration, ketosis, and weight loss [1–3].

The onset of HG is always in the first trimester. The cause of HG, which still remains unknown, seems to be multifactorial and may be the end result of various unrelated conditions [3,4]. There is evidence indicating that, in HG, there are endocrine factors, such as elevated human chorionic gonadotropine, estradiol, and steroid hormone levels; gastrointestinal tract dysfunction; psychological causes; anatomical variations; genetic incompatibility; immunological factors; vitamin B6; and trace-element deficiency [2–4].

Helicobacter pylori is a spiral-shaped, gram-negative bacterium that is found in the gastric mucous layer or is adherent to the epithelial lining of the stomach. Most people who are infected by *H pylori* never suffer any symptoms related to the infection; however, *H pylori* is associated with chronic gastritis, gastroduodenal ulcers, duodenal structural and functional abnormalities, and gastric malignancies [5].

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Recently, the possible susceptibility to *H pylori* infection in pregnancy has been reported. Although there is an alteration for *H pylori* prevalence between different communities and considerable heterogeneity among studies, significant positive association between HG and *H pylori* infection has been demonstrated by a systematic review [2,6]. Indeed, endoscopic biopsy findings demonstrate that the severity of gastrointestinal symptoms in early pregnancy may be associated with the density of *H pylori* infection [7].

There is an increasing importance of treatment of *H. pylori* and a great need for simple, accurate, inexpensive, and noninvasive diagnostic methods. Serologic and stool antigen tests are the fast noninvasive techniques that should be recommended in the initial diagnosis of *H pylori* infection.

Serologic tests are based on the detection of specific anti-*H pylori* IgG antibodies in the patients' sera. These tests are not able to distinguish between active infection and a previous exposure to *H pylori*. Different commercial kits also have different levels of diagnostic accuracy (range, 68–82%) [8]. Stool antigen test is an enzyme immunoassay that detects the active presence of *H pylori* antigen in human feces. Stool test can be recommended for initial diagnosis in untreated patients with a pretreatment sensitivity and specificity of 63–100% [9].

The purpose of this study was to assess the clinical utility of noninvasive serologic and stool antigen tests for determining *H pylori* prevalence in patients with HG and to determine whether *H pylori* infection itself might contribute to hyperemesis during early pregnancy.

Materials and methods

A prospective cross-sectional study was designed and performed between January 2004 and June 2006 at Kahramanmaraş Sutcu Imam University Hospital, Department of Obstetrics and Gynecology, in a developing South Anatolia region of Turkey. Institutional review board had approved the study. Forty women who were hospitalized with the diagnosis of HG and 40 healthy pregnant women without any gastrointestinal symptoms, attending the antenatal unit of the university, were included in the study. In total, 80 pregnant women with gestational age between 7–12 weeks confirmed by ultrasonographic measurement were recruited.

Severe nausea and vomiting in the first trimester with a frequency of more than three times per day, weight loss greater than 5% of pre-pregnancy weight, ketonuria and dehydration that require hospital admission, and intravenous fluid therapy were the criteria for the diagnosis of HG. The exclusion criteria of the study participants were uncertain gestational age; multiple pregnancy; urinary tract infections; previous treatment with *H pylori* eradication therapy; and endocrine, hepatic, gastrointestinal, and psychological disorders. Controls were those who had singleton uncomplicated pregnancies without HG symptoms.

After obtaining informed consent, sociodemographic data, such as educational level, working status, monthly family income, were recorded by a detailed questionnaire at first

trimester. Maternal blood collected by venipuncture and stool samples from each patient were collected in clean cups. Blood samples were taken from 80 patients between 7 weeks and 12 weeks of gestation (study and control groups) and were kept at room temperature for 30 minutes till they coagulated. Then, they were centrifuged at 3,000 rpm for 10 minutes, and serums were obtained. These serum samples were stored at -20°C until studied. *Helicobacter pylori* IgG antibodies were investigated by enzyme-linked immunosorbent assay (ELISA) kit (Euroimmun Lübeck, Germany). Serum specimens were analyzed as described by the kit procedure. Adsorbance was read at 450 nm by the threshold value of optic density. A threshold value greater than or equal to 20% was interpreted as a positive result, and a value less than 20% was interpreted as a negative result.

Helicobacter pylori antigens were investigated by ELISA (Connex GmbH, Martinsried, Germany) method in stool specimens that were stored at -80°C . The results were analyzed spectrophotometrically. Absorbance was read at 450/650 nm within 15 minutes of adding stop solution. The results were considered positive if the OD was greater than 0.12 and negative if it was less than 0.10.

Data were stored and analyzed using SPSS 11.0 statistical package (SPSS Inc., Chicago, IL, USA) and expressed as mean \pm standard deviation or n (%). Demographic findings and clinical measures were compared with Mann–Whitney U test and t test. Comparison of serologic results for *H pylori* IgG antibody and stool antigen were assessed by Chi-square test. A p value less than 0.05 was considered statistically significant.

Results

A total of 80 patients were enrolled into the study. The sociodemographic data of these are presented in Table 1. There were no significant differences in gravidity, parity, body mass index, educational–working status, and family income, in women with HG and the controls. The maternal characteristics of age and smoking were associated with hyperemesis (Table 1). The mean age was 25.8 years in the study group and

Table 1
Sociodemographic characteristics of the study and control groups

Sociodemographic characteristics	Hyperemesis ($n = 40$)	Control ($n = 40$)	p
Age (yr)	25.8 \pm 4.72	28.4 \pm 4.21	0.025
Gravidity	1.9 \pm 1.2	2.2 \pm 1.2	0.14
Parity	0.5 \pm 0.7	0.7 \pm 0.9	0.17
Gestational age (wk)	10.2 \pm 1.7	10.4 \pm 1.7	0.84
Body mass index (kg/m^2)	23.8 \pm 3.88	25.6 \pm 3.54	0.066
Education ≤ 8 yr	21 (52.5)	18 (45)	0.22
Worker/student	4 (10)	6 (15)	0.28
Family income (TL/month)	648 \pm 329	873 \pm 956	0.16
Smoking	10 (25)	5 (12.5)	0.03

Data are presented as mean \pm standard deviation or n (%).

1 TL = \$0.66 and €0.46.

t test and Mann–Whitney U test were used for comparison.

TL = Turkish Lira.

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