

**Application of <sup>13</sup>C-urea breath test in screening helicobacter pylori infection during health examination in Chengdu, Sichuan** YANG Yan-hua. LIU Yu-ping. CHENG You-fu, SHUAI Ping. LU Qiao. ZHENG Xiao-xia, HONG Min. WU Ya-ping. XIAO Xian (Health Management Centre. Sichuan Academy of Medical Sciences & Sichuan Provincial People's Hospital, Chengdu 610072, China)z

**【Abstract】 Objective** To compare the differences of Helicobacter pylori (Hp) infection rates among different age, sex and seasonal groups by using a <sup>13</sup>C breath test in health examination population in Chengdu area, and explore the distribution of Hp infection. **Methods** Two thousand and four hundred cases who underwent health examination were divided into different groups and detected Hp by the <sup>13</sup>C breath test in our physical examination center. **Results** The positive infection rate of Hp was 44.08%. Hp infection rates were significantly different between different age groups (P<0.05) However\* no significant difference was observed between men and women > as well as among the season groups. **Conclusions** The <sup>13</sup>C breath test is applicable to the general population in detection of Hp infection. The health education will improve people's knowledge level that may help to prevent and control stomach diseases.

**【Key words】** Helicobacter pylori; Infection; <sup>13</sup>C-Urea breath test

In recent years, with the rising of living standards for the people, the incidence of all kinds of stomach trouble is on the rise. Gastric helicobacter pylori (HP) has been proved to be one of causes for some stomach problems such as active gastritis, peptic ulcer, gastric mucosa associated lymphoid tissue lymphoma. Also, HP may be one of risk factors of gastric cancer [1]. Therefore, inspection on whether HP exists in the stomach has very important clinical value [2]. There are two methods for current diagnosis of HP infection in stomach: (1) invasive (e.g., histology, rapid urease test, bacterial culture and so forth) and (2) non-invasive (serology, urea breath test). In our hospital, the health management center carried out the breath test to detect HP for 2400 cases of physical examination people, where epidemiological characteristics (e.g., HP infection, gender, age and season) were observed. The details are as follows:

#### 1. Data and methods

1.1 General information: Subjects were 2400 people receiving the physical examination from June 2010 to June 2011, including 1510 people being males and 890 females and a range of ages 3-82. These subjects were

1.2 Testing method: Testing instrument was HG-IRIS200 as an IR spectrometer. Reagent used was <sup>13</sup>C-UBT diagnostic reagent from RICHEN FORCE HOLDINGS, Beijing. The testing procedures described in the manual were performed. Before a test, the subjects were subject to a fasting overnight or for more than 4 hours, so as to avoid an impact from the food on test results. The air bag was labeled and filled with the required information. The subject opened the air bag and immediately blew air into the bag. In other words, the zero-time air was collected. About 80 ml of warm drinking-water was used to dissolve 75 mg of urea reagent (<sup>13</sup>C) (concentration > 99%). After 30 minutes of sitting still, the air again collected by blowing. A labeling was made, and then a testing. A subject was tested using a testing agent for 3 minutes and 13 seconds. The result was automatically displayed in the instrument. When <sup>13</sup>C-UBT positive value is greater than or equal to 4.0 + / - 0.4, the the subject can be considered HP-positive.

1.3 Statistical method: SPSS17.0 statistical software was used for analysis. Counting data was subject to chi-square test, and alpha being equal to 0.05 acted as a testing criteria. At P < 0.05, the difference is

divided into child & youth group (0-29 years of age), middle-aged group (30 to 59) and elderly group (60 or above). All the people for 13C-Urea Breath Test (13C-UBT) met the following conditions: (1) denying HP infection in the past; (2) not taking antibiotics, bismuth agents and proton pump inhibitors in HP treatment in nearly a month.

statistically significant.

## 2. Results

2.1 HP infection rate and age distribution: Among 2400 subjects, 1058 subjects were HP- positive, and HP infection rate was 44.08%. The comparison between child & youth group, middle-aged group, and elderly group showed that HP infection rate differences were statistically significant ( $\chi^2 = 15.54$ , P less than 0.05). HP infection age distribution is shown in table 1.

Table 1. Distribution of ages for HP infection

Group	Age (Years)	HP Positive (n)	HP Negative (n)	Total (n)	HP Infection Rate (%)
Child & Youth Group	0-29	57	119	176	32.39
Middle-aged Group	30-59	911	1091	2002	45.5
Elderly Group	above 60	90	132	222	40.54

2.2 HP infection gender distribution. HP infection rate differences between males and females were not statistically significant ( $X^2 = 2.259$ ,  $P$  less than 0.05), as shown in table 2.

Table 2. Distribution of genders for HP infection

Genders	HP Positive (n)	HP Negative (n)	Total (n)	HP Infection Rate (%)
Male	648	862	1510	42.91
Female	410	480	890	46.07

2.3 HP infection time distribution. In the comparison between seasons concerning HP infection rates, there was no statistically significant difference ( $X^2 = 2.957$ ,  $P$  less than 0.05), as shown in table 3 and table 4.

Table 3. Distribution of months for HP infection

Time	HP Positive (n)	HP Infection Rate	HP Negative (n)	HP Negative (%)	Total (n)
June, 2010	27	35.53	49	64.47	76
July, 2010	69	48.25	74	51.75	143
August, 2010	62	42.47	84	57.53	146
September, 2010	53	37.32	89	62.68	142
October, 2010	22	40	33	60	55
November, 2010	11	32.35	23	67.65	34
December, 2010	16	57.14	12	42.86	28
January, 2011	3	42.86	4	57.14	7
February, 2011	14	33.33	28	66.67	42
March, 2011	114	47.5	126	52.5	240
April, 2011	171	46.59	196	53.41	367
May, 2011	182	41.6	256	58.51	438
June, 2011	314	46.04	368	53.96	682
Total	1058	44.08	1342	55.92	2400

Table 4. Distribution of Seasons for HP infection

Time	HP Positive (n)	HP Infection Rate (%)
June to August, 2010	158	43.3
September to December, 2010	102	39.4
January to March, 2011	131	45.3
April to June, 2011	667	44.9

### 3. Discussion

Foreign literature reported that HP infection rate was 67% and increased with the age, and that the incidence was higher in women than men. In our country and other developing countries, there is a high incidence of HP infection. From 2001 to 2004, a HP epidemiological survey among the natural population from 20 provinces and municipalities of China carried out by HP Group, Gastroenterology Branch, Chinese Medical Association showed that the HP infection rate was 40% - 90%, average 59% in our country. Our test results of 2400 people subject to physical examination showed that HP infection was higher (40.08%) with its difference in different age groups being statistically significant ( $P < 0.05$ ), and that HP positive infection rate was higher in middle-aged group (30 to 59 years of age) than other age groups. But the gender and seasonal differences were not statistically significant, and this was not consistent with that in Hunan Province. This might be related with the following factors: different folkways and diet customs, similar dietary structures among males and females around this region, adequate supplies of fruits and vegetables (no obvious seasonal differences), and no big seasonal change in eating habits.

HP infection has been recognized as an important risk factor causing a variety of gastric diseases and other system diseases [1].

In our country, gastric HP infection rate detected is high among people subject to physical examination, and there is a very lack of related prevention knowledge. To carry out the HP screening among healthy people targeted is one of the important work of prevention and control of gastric disorders. Through the HP testing, we can early find the infected people, actively adopt prevention measures, and give timely treatment. In addition, to strengthen relevant health propaganda and education and make return visits is very necessary among the people targeted, for this can improve their knowledge level and ability to prevent the stomach disease. In our hospital, the medical examination center in the prevention of HP infection mainly carries out the post-check consultation, advises the inspected person to see a doctor in the gastroenterology clinic, invites experts to do the propaganda and education about relevant prevention and control in some units, and pays a return visit by telephone and so forth, thus letting the people subject to the physical examination to have more knowledge about HP and effectively preventing a spread of HP [6].

In this test,  $^{13}C$  as a test reagent is a stable isotope suitable for all ages of the subjects, especially suitable for pregnant women and children. The test using  $^{13}C$ -UBT has the following advantages: high accuracy, real-time presentation of HP infection state in the entire stomach, more than 95% in both sensitiveness and specificity [7], simple and rapid operation, high degrees of automation, no wound, and no radiation pollution. Thus, it is a method being accurate, repeatable, safe and practical, and suitable for clinical diagnosis and treatment of HP infection, monitoring on anti-HP effectiveness, review, and follow-up visit. Disadvantages are that it may produce false positive or negative results due to the impact from food, drug, upper gastrointestinal bleeding, and other miscellaneous bacteria in the stomach, and that it needs more expensive apparatuses and reagents leading to a high test cost, thus greatly limiting epidemiological investigations inclusively in grass-roots hospitals. When compared with  $^{13}C$ -UBT,

non-invasive serological test has a result of positive PH showing had the HP infection previously. After HP infection is removed, serum antibodies still persist for months or even years, this serological test should not be used for the diagnosis of existing HP infection and the monitoring of drug effectiveness. On the other hand, <sup>13</sup>C-UBT can reflect the status of existing HP infection, so is more suitable for monitoring drug effectiveness as a non-invasive examination method of choice [9-10].

As infrared spectrometers and polarization laser scanners are successfully developed, the mass spectrometers can be replaced to reduce equipment cost. The breath test for HP detection has become a simple, accurate and effective method, which is suitable for conducting a HP screening among healthy people [11].

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