

Comparative study on accuracy of ^{13}C infrared spectrometer with different types

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Abstract

Objective: To compare the consistency on test results between the domestic (HY-IREXB, Guangzhou Richen-Frinse Optical & Electronic Co., LTD) and imported (HeliFAN, Fischer GmbH, Germany) ^{13}C infrared spectrometer via ^{13}C breath test.

Methods: The breath samples of the same patient are collected at the same time and tested respectively on two instruments. DOB values of test results from two instruments are compared, one-way ANOVA are carried out, and the factors are determined including diagnostic sensitivity and specificity of the diagnosis results, positive predictive value, negative predictive value, as well with Kappa consistency.

Conclusions: The diagnosis results on two groups with domestic (HY-IREXB) and imported (HeliFAN) ^{13}C infrared spectrometer are exactly consistent, without any statistical differences. For the domestic ^{13}C infrared spectrometer, its sensitivity is 100%, specificity 100%, positive predictive value 100% and negative predictive value 100%, with Kappa value equal to 1. So it can be used as the preferred method for clinical detection of Helicobacter pylori gastric infection.

Keywords: ^{13}C breath test, infrared spectrometer, East China sanatorium, Helicobacter pylori, stomach

I. Introduction

^{13}C urea breath test (^{13}C -urea breath test, ^{13}C -UBT) is a non-invasive method to detect Helicobacter pylori gastric infection. Since ^{13}C is a stable and non-radioactive isotope without harm on humans and applicable for the detection on all population even including children and pregnant women, ^{13}C -UBT has been widely used for the diagnosis of HP infection currently. Imported ^{13}C infrared spectrometer (HeliFAN) was used in the domestic medical institutions very early, with good detection effects recognized by doctors. Domestic ^{13}C infrared spectrometer (HY-IREXB) is the first instrument under independent research and development at home, and has been used for some time in China. Our study compares the test results of both instruments, and makes evaluations on their clinical significance.

II. Materials and Methods

1. Clinical information

There are totally 147 cases with comparative data from 232 cases for physical examination in our hospital.

2. Materials

Kit (Heliforce 75mg, Beijing Boran pharmaceutical company); spectrometer: domestic (HY-IREXB) and imported (HeliFAN) ¹³C infrared spectrometer

3. Method for ¹³C-UBT

- 1) Patients shall be fasting before test in the morning;
- 2) Patients maintain normal breathing, and blow the gas into the air bag until full, and immediately tighten its cover for collecting sample of 0 min.
- 3) Patients take a bottle of [¹³C] urea mixed reagent (Heliforce) with 80-100ml cool drinking water and then keep waiting quietly.
- 4) According to the collection methods above, patients collect the sample of 30min after taking Heliforce for 30 minutes and immediately tighten the air bag cover.
- 5) Breath samples of 0 minute and 30 minutes will be tested respectively on domestic (HY-IREXB) and imported (HeliFAN) ¹³C infrared spectrometer at the same time.

4. Statistical analysis

The difference between the two sets of DOB data is analyzed by the method of one-way analysis of variance (one way ANOVA), and the consistency of the test results for both methods is evaluated by Kappa value. As for the instruments, the sensitivity, specificity, positive predictive value, and negative predictive value are also calculated respectively.

5. Results

The positive rates of the ¹³C-UBT results (see Table 1) from domestic (HY-IREXB) and imported (HeliFAN) ¹³C infrared spectrometers have no significant difference statistically (see Table 2); the DOB value and Sig. Value measured by two instruments have homogeneity in variances and no significant difference statistically (see Table 3 and 4); the Kappa value of two methods is 1 (147/147) (see table 5), with high compliance. Taken the test results from imported ¹³C infrared spectrometer (HeliFAN) as the gold standard, the values are calculated on domestic ¹³C infrared spectrometer (HY-IREXB) as: the sensitivity is 100% (86/86), the specificity is 100% (61/61), the positive predictive value is 100% (86 / 86), and the negative predictive value is 100% (61/61).

Table 1 Test Results

				domestic 13C infrared spectrometer (HY-IREXB) Model No.: 14400490		imported 13C infrared spectrometer (HeliFAN)	
Series No.	Code	Test time	Test date	DOB	Positive or Negative	DOB	Positive or Negative
1	00001	08:34:55	14-03-19	30.6	+	32.5	+
2	00002	08:38:06	14-03-19	10.5	+	13.7	+
3	00003	08:41:18	14-03-19	0.3	—	1.3	—
4	00004	08:44:29	14-03-19	1.0	+	9.8	+
5	00005	08:47:40	14-03-19	7.7	+	11.1	+
6	00006	08:50:57	14-03-19	0.5	—	1	—

7	00007	08:58:08	14-03-19	2.5	—	-1.1	—
8	00008	09:01:20	14-03-19	44.1	+	47.1	+
9	00009	09:04:31	14-03-19	0.8	—	1.6	—
10	00010	09:07:42	14-03-19	35.1	+	36.8	+
11	00011	09:12:03	14-03-19	0.4	—	0.4	—
12	00012	09:15:15	14-03-19	25.7	+	20.2	+
13	00013	09:18:27	14-03-19	0.8	—	0.3	—
14	00014	09:21:38	14-03-19	60.9	+	63.5	+
15	00015	09:24:50	14-03-19	0.8	—	0.9	—
16	00016	09:28:56	14-03-19	0.5	—	1.1	—
17	00017	09:32:08	14-03-19	5.8	+	7.4	+
18	00018	09:35:20	14-03-19	24.8		29.1	+
19	00019	09:38:32	14-03-19	0.4	—	1.9	—
20	00020	09:41:44	14-03-19	0.3	—	0.9	—
21	00021	09:46:36	14-03-19	6.4	+	6.7	+
22	00022	09:49:48	14-03-19	19.6	+	20.6	+
23	00023	09:53:00	14-03-19	30.4	+	33.5	+
24	00024	09:56:12	14-03-19	0.8	—	0.7	—
25	00025	13:57:46	14-03-19	17.2	+	18.4	+
26	00026	14:04:29	14-03-19	13.3	+	15.1	+
27	00027	14:12:53	14-03-19	12.3	+	12.4	+
28	00028	14:16:05	14-03-19	9.3	+	8.4	+
29	00029	14:19:17	14-03-19	0.6	—	0.5	—
30	00030	14:22:29	14-03-19	0.1	—	1.2	—
31	00031	14:27:08	14-03-19	19.0	+	18.6	+
32	00032	14:30:20	14-03-19	0.3	—	0.4	—
33	00033	14:33:32	14-03-19	0.1	—	-0.1	—
34	00034	14:36:44	14-03-19	0.6	—	0.9	—
35	00035	14:39:56	14-03-19	2.3	—	0.5	—
36	00036	14:43:35	14-03-19	5.8	+	1.2	+
37	00037	14:46:47	14-03-19	0.3	—	0.5	—
38	00038	14:49:59	14-03-19	18.5	+	18.8	+
39	00039	14:53:11	14-03-19	0.2	—	1.3	—
40	00040	14:56:23	14-03-19	18.1	+	18.8	+
41	00041	15:01:09	14-03-19	1.8	+	9.6	+
42	00042	15:04:21	14-03-19	8.1	+	8.1	+
43	00043	15:07:33	14-03-19	23.5	+	21.7	+
44	00044	15:10:45	14-03-19	26.1	+	26.7	+
45	00045	15:13:57	14-03-19	32.3	+	34.4	+
46	00046	15:17:14	14-03-19	5.1	+	6.3	+
47	00047	15:26:51	14-03-19	0.2	—	0.2	—
48	00048	07:39:47	14-03-20	78.4	+	80.2	+
49	00049	07:42:58	14-03-20	16.1	+	17.1	+

50	00050	07:46:09	14-03-20	16.0	+	15.8	+
51	00051	08:15:20	14-03-20	24.4	+	21.5	+
52	00052	08:18:32	14-03-20	0.1	—	0.4	—
53	00053	08:21:43	14-03-20	16.5	+	15.3	+
54	00054	08:32:11	14-03-20	0.8	—	1.1	—
55	00055	08:48:21	14-03-20	22.0	+	25	+
56	00056	08:51:33	14-03-20	25.0	+	30.3	+
57	00057	08:58:05	14-03-20	10.5	+	10.4	+
58	00058	09:02:13	14-03-20	9.3	+	10.8	+
59	00059	09:18:22	14-03-20	0.5	—	0.5	—
60	00060	09:21:34	14-03-20	0.6	—	0.2	—
61	00061	09:37:41	14-03-20	19.4	+	20.8	+
62	00062	09:53:46	14-03-20	17.2	+	18	+
63	00063	10:03:26	14-03-20	11.3	+	8	+
64	00064	10:06:37	14-03-20	17.1	+	17.5	+
65	00065	10:13:02	14-03-20	10.8	+	12.5	+
66	00066	09:28:46	14-03-21	0.5	—	0.7	—
67	00067	09:31:57	14-03-21	3.7	—	1.5	—
68	00068	09:35:08	14-03-21	0.8	—	1	—
69	00069	09:38:19	14-03-21	32.2	+	36.3	+
70	00070	09:41:31	14-03-21	67.4	+	69.4	+
71	00071	09:45:48	14-03-21	12.4	+	14.2	+
72	00072	09:48:59	14-03-21	0.8	—	1.6	—
73	00073	10:04:57	14-03-21	0.9	—	0	—
74	00074	10:08:08	14-03-21	0.7	—	0.3	—
75	00075	10:11:20	14-03-21	16.1	+	16.4	+
76	00076	10:14:31	14-03-21	14.0	+	14.8	+
77	00077	10:17:43	14-03-21	0.4	—	0.9	—
78	00078	10:27:57	14-03-21	38.6	+	40.1	+
79	00079	10:31:09	14-03-21	19.3	+	24.8	+
80	00080	11:03:26	14-03-21	33.9	+	34.8	+

				domestic 13C infrared spectrometer (HY-IREXB) Model No.: 14400479		imported 13C infrared spectrometer (HeliFAN)	
Series No.	Code	Test time	Test date	DOB	Positive or Negative	DOB	Positive or Negative
1	00001	08:43:33	14-03-19	18.8	+	15.9	+
2	00002	08:46:44	14-03-19	11.8	+	11.2	+
3	00003	08:49:55	14-03-19	31.3	+	35.6	+
4	00004	08:53:06	14-03-19	42.0	+	39.3	+
5	00005	08:58:34	14-03-19	0.6	—	1.9	—
6	00006	09:02:21	14-03-19	18.9	+	20.1	+
7	00007	09:05:32	14-03-19	0.3	—	1.2	—
8	00008	09:08:43	14-03-19	0.3	—	0.9	—
9	00009	09:11:54	14-03-19	3.5	—	2.5	—
10	00010	09:15:06	14-03-19	0.5	—	1.1	—
11	00011	09:18:37	14-03-19	12.8	+	11.5	+
12	00012	09:21:48	14-03-19	40.0	+	43.1	+
13	00013	09:25:00	14-03-19	28.1	+	25.4	+
14	00014	09:28:12	14-03-19	4.0	+	7.7	+
15	00015	09:31:24	14-03-19	0.0	—	1.3	—
16	00016	09:34:41	14-03-19	0.7	—	3.8	—
17	00017	09:37:53	14-03-19	0.5	—	-0.5	—
18	00018	09:41:05	14-03-19	0.3	—	0.7	—
19	00019	09:44:17	14-03-19	27.3	+	30.1	+
20	00020	09:47:29	14-03-19	0.0	—	1.7	-
21	00021	14:03:05	14-03-19	12.1	+	16.8	+
22	00022	14:09:13	14-03-19	31.8	+	35.9	+
23	00023	14:12:25	14-03-19	42.9	+	45.5	+
24	00024	14:15:37	14-03-19	42.2	+	42.4	+
25	00025	14:18:48	14-03-19	7.9	+	8.9	+
26	00026	14:22:00	14-03-19	2.2	—	1.9	—
27	00027	14:25:17	14-03-19	0.0	—	0.8	—
28	00028	14:28:29	14-03-19	0.0	—	1.1	—
29	00029	14:31:41	14-03-19	49.8	+	48	+
30	00030	14:34:53	14-03-19	0.8	—	0.6	—
31	00031	14:38:05	14-03-19	0.4	—	0.1	—
32	00032	14:41:22	14-03-19	0.7	—	0.2	—
33	00033	14:44:34	14-03-19	26.0	+	25.7	+
34	00034	14:47:46	14-03-19	12.6	+	12.5	+
35	00035	14:50:58	14-03-19	15.1	+	20	+

36	00036	14:54:10	14-03-19	0.2	—	1.9	—
37	00037	14:57:39	14-03-19	11.9	+	15.4	+
38	00038	15:00:51	14-03-19	2.0		1.3	—
39	00039	15:04:03	14-03-19	0.2	—	1.6	—
40	00040	15:07:15	14-03-19	9.0	+	13.1	+
41	00041	15:10:27	14-03-19	30.0	+	34.2	+
42	00042	15:14:23	14-03-19	48.0	+	55.5	+
43	00043	15:17:35	14-03-19	0.3	—	1.4	—
44	00044	15:20:47	14-03-19	50.6	+	56.4	+
45	00045	15:23:59	14-03-19	57.3	+	57.1	+
46	00046	08:03:17	14-03-20	13.7	+	8.5	+
47	00047	08:52:29	14-03-20	0.9	—	0.5	—
48	00048	08:55:41	14-03-20	33.7	+	37.6	+
49	00049	08:59:57	14-03-20	0.9	—	0.1	—
50	00050	09:06:21	14-03-20	44.7	+	44.7	+
51	00051	09:16:00	14-03-20	64.2	+	67.2	+
52	00052	09:25:36	14-03-20	1.0	—	1.2	—
53	00053	09:35:18	14-03-20	0.5	—	0.4	—
54	00054	09:48:11	14-03-20	22.1	+	19.8	+
55	00055	10:04:18	14-03-20	20.9	+	22.6	+
56	00056	10:07:30	14-03-20	14.2	+	18.8	+
57	00057	09:33:09	14-03-21	0.5	—	3.3	—
58	00058	09:36:20	14-03-21	38.6	+	40	+
59	00059	09:39:31	14-03-21	14.7	+	10.8	+
60	00060	09:42:42	14-03-21	0.8	—	2.3	—
61	00061	09:45:54	14-03-21	0.4	—	0.4	—
62	00062	09:52:47	14-03-21	0.1	—	0.2	—
63	00063	09:25:19	14-03-21	0.4	—	2.2	—
64	00064	09:28:30	14-03-21	15.5	+	16.5	+
65	00065	09:31:42	14-03-21	18.5	—	22.1	+
66	00066	09:34:53	14-03-21	0.1	—	2	—
67	00067	09:38:05	14-03-21	24.6	+	23.5	+

Table 2 Comparison on tests results of domestic and imported ¹³C infrared spectrometers

Method	spectrometer	+	—	positive result ratio
13C –UBT	HY-IREXB	86	61	58.80%
	HeliFAN	86	61	58.80%

Table 3 Descriptives

DOB	N	Mean	Std. Deviation	Std. Error	95% Confidence Interval for Mean		Minimum	Maximum
					Lower Bound	Upper Bound		
HY-IREXB	147	14.301	16.5879	1.3681	11.597	17.005	0	78.4
HeliFAN	147	15.215	17.2403	1.422	12.405	18.025	-1.1	80.2
Total	294	14.758	16.8946	0.9853	12.819	16.697	-1.1	80.2

Note: P=0.634 >0.05

Table 4 Test of Homogeneity of Variances (DOB values)

Levene Statistic	df1	df2	Sig.
0.185	1	292	0.667

Note: P=0.634 >0.05

Table 5 Distribution of tests results from domestic and imported 13C infrared spectrometers

HY-IRXB			
HeliFAN	+	-	total
+	86	0	86
-	0	61	61
total	86	61	147

III. Discussion

Currently, HP infection has been recognized as a major cause for chronic active gastritis, purulent ulcer, and has relationships with a variety of stomach cancer ^[1]. In 1994, the World Health Organization included the HP level as one biological carcinogen factor at first class. Successful eradication of HP can cure the related diseases, and therefore, the detection of HP is very important. According to statistical data, there are much difference on the stomach HP detection rates with 30-80% in different Chinese regions and different ethnic groups ^[1]. In terms of HP inspection, the clinics are constantly looking for more simple, more secure, and more convenient diagnostic method for patients. It can be classified as invasive and non-invasive two types according to the need for endoscopy or not.

Since ¹³C is a stable and non-radioactive isotope without harm on humans and applicable for the detection on all population even including children and pregnant women, ¹³C-UBT has been widely used for the diagnosis of HP infection currently, and this method is particularly suitable for large-scale health institutions.

Imported ¹³C infrared spectrometer (HeliFAN) was used in the domestic medical institutions very early, with good detection effects recognized by doctors. Domestic ¹³C infrared spectrometer (HY-IREXB) is the first instrument under independent research and development at home, and is applied later than the Germany instrument for some time. Our study compares the test results of both instruments, and makes evaluations on their clinical significance. And it can be concluded that the DOB value and Sig. value measured by two instruments have homogeneity in variances, and no any statistical differences, with the exact same clinical diagnosis results. Compared to the Germany instrument HeliFAN, the domestic ¹³C infrared spectrometer (HY-IREXB) has its sensitivity, specificity, positive predictive value and negative predictive value all equal to 100%.

In this paper, the data were collected on 232 cases in three days, with high detection frequency at 80 cases per day. By using advanced MEMS technology, domestic ¹³C infrared spectrometer (HY-IREXB) has high precision, high stability, rapid detection with 10 channels. Compared to the 4-channel Germany instrument HeliFAN, it has more advantage and shall be the first choice for large medical institutions to detect H. pylori.

Reference

[1] Wandai Zhang, Shudong Xiao, Fulian Hu, Common opinions on the relevant issues of H. pylori (2003, China), [J] National Medical Journal of China, 2004, 84(6): 522