China Clin Prac Med, Sep 2007, Vol.1, No. 9

• Article •

Clinic Research for HG-IRIS200 ^{13}C Infrared Spectrometer

(Translate Version)

FENG Lin-lin, YANG Hong-bo, LIU Yu-hong, et al.
Department of Examination, Xiaotangshan Hospital, Beijing 102211, China

[Abstract]
Objective: To verify the test veracity and stability of the HG-IRIS200 (^{13}C infrared spectrometer), by comparing the test result with ^{13}C mass spectrometry. They both use the ^{13}C-Urea breath test.
Methods: 283 outpatients did the ^{13}C-Urea breath test. The samples were all tested by the ^{13}C infrared spectrometer and the mass spectrometry separately. Then do the t relativity test and check the stability of the ^{13}C infrared spectrometer.
Results: The consistent rate of negative and positive results between the ^{13}C infrared spectrometer and the ^{13}C mass spectrometer was 100%. The DOB correlation coefficient between the 2 kinds of machines is 0.9998. The test result is t=-1.853 and P=0.074>0.05. So there was no statistical difference. The accuracy (δ_{sd}) of ^{13}C infrared spectrometer was less than 0.02%.
Conclusion: Both the stability and the accuracy of HG-IRIS200 (^{13}C infrared spectrometer) can satisfy the requirements of ^{13}C breath test.

[Key Words] ^{13}C-Urea breath test; H.pylori; ^{13}C infrared spectrometer; ^{13}C mass spectrometry

^{13}C-Urea breath test is a kind of ^{13}C breath test for diagnosis of H.pylori infection specifically in Human bodies, originally reported and used by two American Doctors, DY Graham and PD Klein [1] in 1986. By utilizing stable isotope and technologies such as mass spectrometry, both of the sensitivity and specificity of this method are around 95% [2]. It's non-invasive, non-radioactive and non-painful. So it's popular in clinical application.

^{13}C is a natural, stable isotope of carbon. It makes up about 1.1% of CO_2 in atmosphere. After taking 75mg ^{13}C-Urea in ^{13}C UBT, the increase of $^{13}CO_2$ exhaled is very tiny even if the patient has H.pylori infection. So in order to test the increase of abundance of ^{13}C (expressing by $\delta‰$) in breath samples accurately, Gas Isotope Ratio Mass Spectrometer (GIRMS)with high precision has ever been used. But it's difficult to be widely applied in general hospitals due to expensive price and high running cost. However, a new instrument with economical price and lower running cost for ^{13}C breath test appears in the market, which is HG-IRIS200 ^{13}C infrared spectrometer by testing the isotope abundance of ^{13}C in breath sample based on different infrared absorption wavelength between $^{13}CO_2$ and $^{12}CO_2$. Therefore, this article verifies the test veracity and stability of this instrument (HG-IRIS200) by comparing the test result with ^{13}C mass spectrometry during ^{13}C-Urea breath test.

1. Object and Method

1.1 Object of study

283 Outpatients: ages between 18-65, average age 45, 36 female patients, 71 patients with digestive disease symptom or medical history with gastritis or gastric ulcer.

1.2 Material/tool and Method

1.2.1 Instrument and Reagent: HG-IRIS200 ^{13}C Infrared Spectrometer (produced by Beijing Richen-force Science & Technology Co., Ltd), BreathMAT mass spectrometer (produced by US Finnigan), 75 mg ^{13}C-urea breath test kit.

1.2.2 Method to verify the veracity of ^{13}C infrared spectrometer

Calibrate the ^{13}C infrared spectrometer and mass spectrometry by 5% CO_2 as standard gas from the same source separately and debug instruments to make sure that they are in good condition and precision in default standard.

The patients should fast for 4 hours at least prior to the test [3]. Collect two pieces of breath samples with interval less than 30s before having ^{13}C-urea breath test kit (0-Minute), 10ml breath sample into glass tube for mass spectrometer (Insert the straw to the bottom of the tube and exhale for sample collection) and 120ml breath sample into sample collection bag for ^{13}C infrared spectrometer (Exhale into bag directly).

Dissolve the ^{13}C-urea reagent with 50ml cold boiled water and drink it.

Collect the breath samples at 30 min after taking reagent by the same method as collecting 0-Minute samples. DOB data(Delta Over Baseline) is ^{13}C δ in 0-min samples subtracting ^{13}Cδ in 30-min samples. If DOB>=4, it's H.pylori infection positive. If DOB<4, it's negative.

1.2.3 Method to verify the stability of ^{13}C infrared spectrometer

Have the test at the frequency once per half an hour by 5% CO_2 as standard gas from the same source, lasting 10 hours.

1.3 Data Statistic Analysis

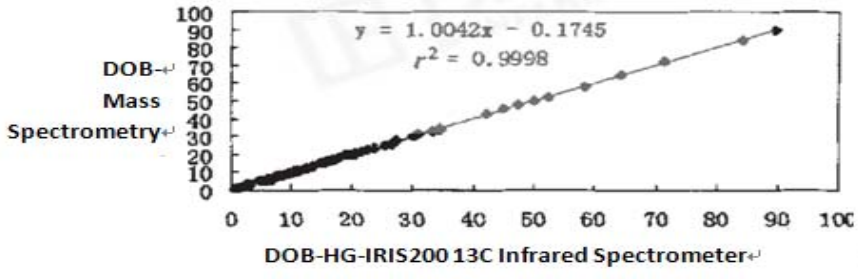
Analyze DOB correlation and t relativity between ^{13}C mass spectrometry and ^{13}C infrared spectrometer and calculate standard deviation of the test result.

2. Result

2.1 Test result from ^{13}C infrared spectrometer and ^{13}C mass spectrometry

Total patients: 283 Negative: 110 Positive: 173

The consistent rate of negative and positive results between the ^{13}C infrared spectrometer and the ^{13}C mass spectrometer was 100%. The DOB correlation coefficient between the 2 kinds of machines is 0.9998. (Refer to the Pic. 1)



Pic. 1

The test result is t=-1.853 and P=0.074>0.05. So there was no statistical difference.

2.2 Test result for stability of ^{13}C infrared spectrometer

^{13}C δ during 10 hours test by 5% CO_2 as standard gas from the same source is as follows (Table 1):

时间(h)	0.5	1	1.5	2	2.5	3	3.5	4	4.5
δ值	-22.30	-22.50	-22.32	-22.24	-22.16	-22.23	-22.35	-22.60	-22.41
时间(h)	5.5	6	6.5	7	7.5	8	8.5	9	9.5
δ值	-22.09	-22.43	-22.15	-22.20	-22.14	-22.31	-22.13	-22.50	-22.13

Table 1

S.D. of DOB is 0.146 and the accuracy (δ_{sd}) is within 0.02%.

3. Discussion

The establishment of 13C-UBT, relying on large isotope mass spectrometry initially, is golden standard for H.pylori test featured by being accurate, specific, rapid, non-invasive, non-painful and non-radioactive. But there are many obstacles from its establishment to clinic application, especially instrument cost and test accuracy as main factors.

^{13}C infrared spectrometer is used for ^{13}C breath test to detect H.pylori infection by testing the change of stable isotope ratio $^{13}C/^{12}C$ in exhaled CO_2. The ^{13}C infrared spectrometer used in this article has good correlation with mass spectrometry, with correlation coefficient 0.9998. The verification of stability shows that its accuracy δ_{sd} is less than 0.02%. So it can satisfy clinical requirement.

It's very known that in spite of high precision, mass spectrometry is expensive and must be operated and maintained by professional staff. However, ^{13}C infrared spectrometer is economical with low price, easy-operation and very accurate. So it can substitute ^{13}C mass spectrometer completely.

Reference:

[1] DY Graham, PD Klein, el al. Campylorbacter pylori detected noninvasively by the 13C-urea breath test. Lancet, 1987, 23:1174.
[2] Jiang Ji, 13C-urea breath test for H.pylori infection detection. China Internal Medicine Journal.
[3] Hu Fu-lian, Zhou Dian-yuan, The basis and clinic of H.pylori infection (revised edition). China Science and Technology Press

(The date of receiving article: 07-18-2007)