ISSN 2706-6819 Vol.5, Issue 9: 116-121, DOI: 10.25236/IJFM.2023.050919

Analysis of Clinical Application of C13-urea Breath Test for Detection of Helicobacter Pylori Infection

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Abstract: *The purpose of this paper is to investigate the clinical diagnostic value of the C13 urea breath test in the detection of Helicobacter pylori infection. The methodology of this study was to select 100 patients with epigastric discomfort who visited our hospital from January 2022 to July 2023. All patients underwent rapid urease test (RUT) and C13-urea breath test. Histological examination was used as the diagnostic gold standard to compare the diagnostic accuracy of the two methods for various diseases in patients, including the diagnostic positive rate. The diagnostic performance of the two methods (sensitivity, specificity, accuracy, negative predictive value, positive predictive value) was assessed. Results Of the 100 patients with epigastric discomfort is that 90 were diagnosed by pathologic examination. The C13-urea breath test had a higher diagnostic positive rate for duodenitis and peptic ulcers compared to RUT ($P<0.05$). There was no significant difference in the diagnostic positive rate between the two methods for gastric polyps, chronic gastritis, and gastric cancer ($P>0.05$). The C13-urea breath test had higher sensitivity, specificity, accuracy, positive predictive value, and negative predictive value compared to RUT. The specificity and accuracy of the two methods were significantly different ($P<0.05$), while the sensitivity, negative predictive value, and positive predictive value were not significantly different ($P>0.05$). This paper concludes that both the C13-urea breath test and the RUT are effective diagnostic methods for detecting H. pylori infection, but the C13-urea breath test has a higher diagnostic positivity rate and overall diagnostic performance. It provides a strong basis for clinical diagnosis and treatment, and has high clinical value. Therefore, it is worth promoting.*

Keywords: *C13-urea breath test. Helicobacter pylori infection. Diagnostic results*

1. Introduction

With the gradual improvement of socio-economic conditions, people's lifestyles, environments, and dietary habits have undergone significant changes. Helicobacter pylori (H. pylori) infection-related diseases are common in modern clinical practice. The relationship between H. pylori infection and gastrointestinal diseases is closely intertwined, and there is also a strong connection with other systemic diseases. In the early stages of H. pylori infection-related diseases, the clinical symptoms are often not obvious, typically manifesting as abdominal distension, upper abdominal pain, and so on. As the disease progresses, H. pylori colonizes the gastric antrum, leading to various digestive system diseases and even gastric cancer, severely affecting patients' normal life and physical health. To improve the prognosis of patients with this disease, early treatment is necessary, and early treatment relies on effective diagnostic measures. Currently, there are various methods for detecting H. pylori infection, including rapid urease test, bacterial culture, serological tests, urea breath test, histological techniques, and others. Histological techniques are considered the gold standard for diagnosing this disease, but they are invasive, cannot be repeated frequently, and may cause cross-infection if disinfection is inadequate, affecting patients' physiological and psychological well-being. The urea breath test is a widely used non-invasive detection method that observes the presence of H. pylori infection in a patient's body by analyzing isotopically labeled urea. It has high detection accuracy, specificity, and sensitivity, and can be repeated, making it easily accepted by patients. In this study, the author selected 100 patients with upper abdominal discomfort who visited our hospital from January 2022 to July 2023 to analyze the detection method of the C13-urea breath test. The following research was conducted.

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2. Information and Methodology

2.1. General information

The study included 100 patients with upper abdominal discomfort who visited our hospital from January 2022 to July 2023. Among them, there were 43 male patients and 57 female patients. The age range was 20-72 years, with an average age of (45.35±6.09) years. The duration of the disease ranged from 0.5 to 3 years, with an average duration of (1.85±0.53) years. The body mass index ranged from 22 to 27 kg/m2, with an average body mass index of (24.30±0.28) kg/m2.

Inclusion criteria: ① All patients were adults over 18 years of age who sought medical attention for upper abdominal discomfort. ② Patients did not receive any relevant medication treatment at the time of the visit. ③ After admission, patients had personal electronic medical records with complete clinical information [1-3].

Exclusion criteria: ① Presence of abnormal major organ function. ② Patients were pregnant or lactating at the time of the visit. ③ Presence of upper gastrointestinal bleeding. ④ History of gastric resection surgery.

2.2. Methodologies

Prior to testing, all patients should maintain fasting overnight for a minimum of three hours. They are required to swallow the C13 capsule without chewing it. Patients should be educated about the relevant knowledge of the test to ensure their cooperation.

① Rapid urease test (RUT) method: Patients should maintain fasting prior to the test. The examination is performed using gastroscopy, during which local anesthesia with 1% lidocaine is applied. The patient is positioned on the left side, and a diagnostic kit is used to obtain mucosal tissue lesions. After five minutes, the color change of the test strip is observed to determine the presence of H. pylori infection. A positive result is indicated by a color change to red.

② C13-urea breath test: Patients should maintain fasting and swallow a C13-urea breath test capsule with warm water. After sitting still for twenty minutes, they exhale into the provided gas collection card until the indicator color in the display window of the card turns colorless. The card is then inserted into the H. pylori detection device, and the test result is observed after two minutes. A C13 level of 100 dpm/mmol or above indicates a positive result, while a lower level indicates a negative result [4-6].

③ Live tissue testing: Detection using the hematoxylin-eosin staining method: H. pylori in positive specimens appears as short rod-shaped bacteria with a bright red color, mainly distributed in gland lumens and gastric pits. Immunohistochemical staining method: H. pylori in positive specimens appears as S-shaped or round granules with a brownish-brown color. If both staining results are negative, the live tissue test result is negative. If either of the two test results is positive, it is considered a positive result.

2.3. Observation Indicators

① Compare the positive diagnostic rates of the two methods for various diseases, including: duodenitis, peptic ulcer, gastric polyps, chronic gastritis, and gastric cancer.

② Compare the diagnostic performance of the two methods, including: sensitivity, specificity, accuracy, negative predictive value, and positive predictive value. Sensitivity is the ratio of true positive cases to the sum of true positive cases and false negative cases; specificity is the ratio of true negative cases to the sum of true negative cases and false positive cases; accuracy is the ratio of the sum of true positive cases and true negative cases to the total number of cases; positive predictive value is the ratio of true positive cases to the sum of true positive cases and false positive cases; negative predictive value is the ratio of true negative cases to the sum of true negative cases and false negative cases [7-9].

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2.4. Statistical Processing

Statistical analysis was conducted using SPSS 20.0 software. The mean + standard deviation ($\overline{x} \pm$ s) was used to represent quantitative data. T-test was performed, and percentages (%) were used to represent categorical data. Chi-square test was used to assess the differences between two groups of data, and when P<0.05, the differences were considered statistically significant [10-12].

3. Results

3.1. Comparison of the positive diagnostic rates of the two methods for various diseases

Among 100 patients with upper abdominal discomfort, 90 cases were confirmed by pathological examination. The C13-urea breath test showed a higher positive diagnostic rate for duodenitis and peptic ulcer compared to RUT (P<0.05). There was no significant difference in the positive diagnostic rates for gastric polyps, chronic gastritis, and gastric cancer between the two methods (P>0.05), as shown in Table 1.

Table 1. Comparison of the diagnostic positivity rate of the two methods for each disease [n (%)]

Methods	Duodenitis (n=27)	Peptic ulcer(n=30)	Gastric polyps(n=3)	Chronic gastritis(n=28)	Gastric cancer(n=2)	Total(n=90)
C13-urea breath test	26(96.3)	29(96.7)	2(66.7)	27(96.4)	2(100.0)	86(95.6)
RUT	21(77.8)	23(76.7)	2(66.7)	26(92.9)	2(100.0)	74(82.2)
X^2	4.103	5.192	0.000	0.352	0.000	8.100
P	0.043	0.023	1.000	0.553	1.000	0.004

3.2. Comparison of the diagnostic efficacy of the two methods

The diagnostic sensitivity, specificity, accuracy, positive predictive value, and negative predictive value of C13-urea breath test were higher than that of RUT, and the comparison of specificity and accuracy (P < 0.05), sensitivity, negative predictive value, and positive predictive value between the two groups (P > 0.05) is shown in Tables 2, 3, and 4.

Table 2. C13-urea breath test results [n (%)]

C13-urea breath test	Pathological diagnosis		Total
	Positive	Negative	
Positive	78(78.0)	2(2.0)	80(80.0)
Negative	12(12.0)	8(8.0)	20(20.0)
-	90(90.0)	10(10.0)	100(100.0)

Table 3. Detection results of RUT [n (%)]

RUT	Pathological diagnosis		Total
	Positive	Negative	
Positive	71(71.0)	7(7.0)	78(78.0)
Negative	19(19.0)	3(3.0)	22(22.0)
-	90(90.0)	10(10.0)	100(100.0)

Table 4. Comparison of the diagnostic efficacy of the two methods [n (%)]

Methods	Sensitivity	Specificity	Accuracy	Negative predictive value	Positive predictive value
C13-urea breath test	78(86.7)	8(80.0)	86(86.0)	8(40.0)	78(97.5)
RUT	71(78.9)	3(30.0)	74(74.0)	3(13.6)	71(91.0)
X^2	1.910	5.051	4.500	3.767	3.082
P	0.167	0.025	0.034	0.052	0.079

ISSN 2706-6819 Vol.5, Issue 9: 116-121, DOI: 10.25236/IJFM.2023.050919

4. Conclusion

Helicobacter pylori infection is a commonly occurring infectious disease in modern clinical practice. The transmission routes generally include oral-oral transmission and fecal-oral transmission. The infection rate of this disease has significantly increased in recent years due to factors such as imbalanced diet structure, aging population, and misuse of medications. Helicobacter pylori infection is currently one of the main factors affecting the health of the Chinese population. It is infectious and can potentially threaten social security to a certain extent. When individuals are infected with Helicobacter pylori, immune reactions occur, and there is a high probability of gradual involvement of other organs, worsening the condition and significantly increasing the patient's treatment burden. In severe cases, it can lead to cancer and pose a serious threat to patient's life. Therefore, prevention and treatment of this infection need to be strengthened in clinical practice. The prevalence rate of Helicobacter pylori infection in our country is relatively low. In the early stages, most patients tend to neglect the disease due to nonspecific clinical symptoms and fail to seek timely medical attention. By the time the disease symptoms become apparent and the patient seeks medical consultation, the early intervention opportunity is often missed. Therefore, it is necessary to further screen high-risk individuals for Helicobacter pylori infection in clinical practice and then implement targeted measures for treatment [13-15].

In traditional clinical practice, the rapid urease test (RUT) is commonly used for detection. This is mainly because Helicobacter pylori can produce toxic factors such as urease, which hydrolyzes urea and changes the pH environment in the stomach, providing favorable conditions for the colonization of Helicobacter pylori. When using this method for detection, the change in color of the RUT reagent needs to be observed to confirm whether the patient has Helicobacter pylori infection. This detection method is relatively quick and relatively simple. However, this detection method requires the use of gastroscopy and rapid sampling to complete the test, making it an invasive type of detection method. The obtained test results are jointly influenced by various factors such as temperature, bacterial quantity in the tissue sample, and reaction time, which might reduce the accuracy of the test results. The urea breath test is capable of detecting the presence of urease, which decomposes and forms two substances. Carbon dioxide can be used to evaluate the infection status of Helicobacter pylori. When the test population takes isotopically labeled urea, if Helicobacter pylori infection occurs, the evaluation can be done by analyzing the peak value of carbon dioxide in the exhaled isotope, determining whether the patient has Helicobacter pylori infection. The urea breath test is mainly divided into C13 and C14 urea breath tests. The application of the C13-urea breath test method can improve the detection rate of Helicobacter pylori infection, and this method is relatively simple, quick, and can effectively diagnose Helicobacter pylori infection [16-18].

The results of this study indicate that there is a significant difference in the detection rates of duodenitis and peptic ulcer between the two methods ($P<0.05$). However, there is no significant difference in the diagnostic positivity rates of gastric polyps, chronic gastritis, and gastric cancer between the two methods ($P>0.05$). Therefore, the C13 urea breath test method can provide a better understanding of the actual Helicobacter pylori infection status of patients. Digestive system-related diseases such as peptic ulcer, duodenitis, chronic gastritis, and gastric cancer are all easily triggered by Helicobacter pylori infection, especially peptic ulcers being the most common. The formation of Helicobacter pylori not only damages the gastric epithelial cells to varying degrees, resulting in a reduced potential difference, but also increases the degree of mucosal damage as the disease progresses. This leads to an imbalance in the oxygen free mechanism and the production of a large amount of inflammatory factors, which disrupt the cellular balance and gradually increase the occurrence of complications such as peptic ulcers. It can be seen that this disease is a major factor in digestive tract diseases. However, the results of the RUT detection method are closely related to various factors and have uncertain outcomes. On the other hand, the C13 urea breath test method can avoid false-negative and false-positive reactions caused by uneven distribution of biopsy specimens. It can provide a better understanding of the actual Helicobacter pylori infection status throughout the entire gastric cavity, which is beneficial for timely detection of abnormalities and lesions by clinical doctors, enabling prompt treatment and effective control of the patient's condition, thereby improving prognosis. The study found that the C13 urea breath test has higher diagnostic sensitivity, specificity, accuracy, positive predictive value, and negative predictive value compared to RUT. The comparison between the two groups showed that there was a significant difference in specificity and accuracy ($P<0.05$), but no significant difference in sensitivity, negative predictive value, and positive predictive value ($P>0.05$). This indicates that the detection efficiency of the C13 urea breath test is higher than that of the RUT method. In addition, the application of the C13 urea breath test can accurately detect pathological

ISSN 2706-6819 Vol.5, Issue 9: 116-121, DOI: 10.25236/IJFM.2023.050919

tissues. It is relatively simple, safe, and reliable to use urea capsules for later labeling. It allows for repeatable testing and further improves diagnostic efficiency. Furthermore, the gradual development of C13 breath test-related products, including test kits, scintillation sampling bottles, and liquid scintillation test kits, provides more options. The card-style breath test kit is easy to store and transport, easy to use, has a high frequency of scintillation sampling, and is sensitive. The liquid scintillation test kit has high sensitivity and accuracy. The combination of these three testing methods greatly increases the accuracy and sensitivity of detecting Helicobacter pylori infection, providing a strong basis for formulating patient treatment plans. However, as clinical correlations research deepens, the results of the C13 urea breath test may be influenced by various factors, including past medical history and medication history, thereby increasing the false-negative rate. In addition, during the testing process, excessive exhalation force from the patient can also affect the final test results. Therefore, this highlights the importance of pre-test nursing intervention. Before the test, it is necessary to verify the patient's past medical history and medication history to ensure that the patient has not received effective treatment before the test. It is also important to educate the patient on fasting and drinking restrictions before the test and to instruct them not to chew the urea during ingestion. Proper guidance should be given on exhalation to prevent excessive exhalation force that could affect the final test results. Optimization of the testing process and the patient's understanding of the test method and cooperation are crucial for a successful test and to prevent a decrease in test accuracy due to human factors [19-21].

In summary, Helicobacter pylori infection can severely affect the patient's physical health and daily life. Timely diagnosis and treatment can improve the quality of life for patients. The C13 urea breath test can provide an effective diagnosis of Helicobacter pylori infection with good diagnostic efficacy. It can serve as a reliable basis for the formulation of follow-up treatment plans and deserves to be promoted in clinical practice.

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