Clinical significance of CA19-9 in diagnosis of digestive tract tumors

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INTRODUCTION

The CA19-9 antigen isolated by Koprowski and colleagues[1] in 1979 is a lacto-N-fucopentaose II-like substance and one of the tumor-associated antigens present in serum in the mucin fraction. Close attention has been paid to the role of CA19-9 in the diagnosis of digestive tract tumors[2,3]. After strictly inspecting the quality of a commercially available CA19-9 antigen kit, we assayed serum CA19-9 levels in 207 patients with gastrointestinal diseases and in 111 normal adults (for comparative analysis as healthy controls). These data was used to evaluate the clinical significance of CA19-9 in diagnosis of digestive tract tumors.

MATERIALS AND METHODS

Experimental equipment

The CA19-9 McAb solid phase IRMA kit (Tianjin SYTRON Biotech Inc.) and the FT-613 automatic counter of 125I radioimmunoassay (Beijing) were used.

Normal CA19-9 value

CA19-9 concentration was determined in the sera of 111 normal adults from the Guangzhou area (55 males, 50 females; mean age of 47.7 years) and used as the normal referential values for the study.

Patients

Serum samples were obtained from 207 patients with malignant and benign diseases of the digestive system. All diagnoses were confirmed by clinical, laboratory and pathological examinations. Of the 207 cases, 70 were gastric cancer, 90 were colorectal cancer, 7 were pancreatic cancer and 10 were esophageal cancer; a total of 30 of the cases were benign disorders, including 6 cases of chronic superficial gastritis, 7 of antral gastritis, 5 of gastric ulcers, 10 of duodenal ulcers, and 2 of acute appendicitis. The patients consisted of 148 males and 59 females, with age range of 22 years to 85 years (average age: 52.9 years).

RESULTS

The mean serum CA19-9 concentration in the 111 healthy controls from the Guangzhou area was 11.254 ± 6.006 kU/L. The differ-
en of CA19-9 value among the healthy controls was not statistically significant among groups divided by age or sex (P > 0.05). The demarcation value of CA19-9 between the negative and positive was < 31.0 kU/L in our laboratory. The serum CA19-9 concentrations in patients with malignant and benign diseases are listed in Table 1. Table 2 shows the evaluational indexes of CA19-9 for diagnosing some of the gastrointestinal tumors.

DISCUSSION

We have determined the normal referential value of CA19-9 (11.254 ± 6.006 kU/L) in 111 healthy controls from the Guangzhou area using the solid phase IRMA kit. This result was similar to the results obtained by testing with solid phase radioimmunoassay kits manufactured by the Abbott Company and ORIS Company (France). The demarcation value of CA19-9 between the negative and positive was < 31.0 kU/L. This value was slightly lower than that reported in the kit’s accompanying documentation (< 34.0 kU/L).

The results of our study showed that serum CA19-9 levels in patients with gastric cancer, colorectal cancer and some postoperatively recurrent cancers were significantly higher than those detected in the healthy controls. The sensitivity of CA19-9 in diagnosing gastric and colorectal cancers was 47.7% and 50.0%, and the specificity and positive predictive value were both 100% for all. None of the 30 patients with benign disorders of the gastrointestinal tract had a higher serum CA19-9 level than the normal referential value. The sensitivity and specificity of CA19-9 for benign disorders were 0% and 100%, respectively, indicating that CA19-9 is a highly specific tumor marker for diagnosing gastric and colorectal cancers and suggesting its potential to play an important role in the differentiation of benign and malignant diseases of digestive tract.

It is worth noting here that of the 39 patients with gastric cancer or colorectal cancer in this study who had no recurrent tumor postoperatively, none had a higher CA19-9 level than the normal referential value. The mean value of CA19-9 of the 39 patients was similar to the normal referential value. However, the serum levels of CA19-9 in the 9 patients with recurrent gastric cancer and in the 16 patients with recurrent colorectal cancer postoperatively were significantly higher than the normal referential value. The positive rate of CA19-9 in recurrent gastric and colorectal cancers was 77.8% and 68.7%, respectively. The CA19-9 level reached 2500 kU/L in a few of the patients with recurrent tumors. These collective results suggest that CA19-9 is a good index for evaluating the effect of treatment and predicting the prognosis of gastric and colorectal cancers postoperatively.

Elevated serum CA19-9 levels have been observed in many different malignant diseases. The test seems especially promising for detection of pancreatic cancer, as more than 80% of these patients have been reported to show increased serum CA19-9 value[5,6]; therefore, CA19-9 may be a good tumor marker for diagnosing pancreatic cancer and monitoring patients treated surgically[6]. Here, we assayed the CA19-9 levels in patients with pancreatic cancer, and the serum CA19-9 concentration was found to be > 85 kU/L in 6 of the patients, > 110 kU/L in 5, > 1900 kU/L in 3, and 3200 kU/L in 1. The sensitivity, specificity, accuracy, positive predictive value and negative predictive value were 83.3%, 100%, 97.3%, 100% and 96.8%, respectively.

The incidence of pancreatic cancer is increasing worldwide. In 1987, the Japanese Cancer Registries reported the 5-year survival rates for 177 resected cases of T1 stage, 783 resected cases of T2 stage, 463 resected cases of T3 stage and 304 resected cases of T4 stage cancer as being 39.8%, 21.7%, 14.3% and 13.4%, respectively[7]. These results indicate that it is important to diagnose early stage pancreatic cancer, so as to improve prognosis. However, using the current diagnostic methods, it is difficult to diagnose pancreatic cancer in the early stage and to distinguish it from benign conditions that resemble pancreatic cancer in many aspects. Although only 7 patients with pancreatic cancer received the CA19-9 test in the current study, the results still showed that the CA19-9 test seems to be a useful additional tool in the diagnosis of pancreatic cancer.

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**Table 1** Serum CA19-9 concentration in patients and healthy controls

| Disease                          | n  | x ± s | Range          | P, % |
|----------------------------------|----|------|----------------|------|
| Gastric cancer                   | 1266.58 ± 521.31 | 14.15 ± 2.25 | 111 | 0.2-3261.0 |
| Postoperative stability          | 47.6 | 68.7 | 30 | 100.0 |
| Postoperative recurrence         | 78.9 | 100.0 | 0 | 0.0 |
| Colorectal cancer                | 100.0 | 787 | 2 | 393.17 ± 3.804 |
| Preoperation                     | 97.3 | 68.7 | 30 | 100.0 |
| Postoperative recurrence         | 0.2-31.0 | 33 | 10 | 20.0 |
| Pancreatic cancer                | 0.0-31.0 | 33 | 10 | 20.0 |
| Esophageal cancer                | 100.0 | 787 | 2 | 393.17 ± 3.804 |
| Postoperative stability          | 97.3 | 68.7 | 30 | 100.0 |
| Postoperative recurrence         | 0.2-31.0 | 33 | 10 | 20.0 |
| Pancreatic cancer                | 0.0-31.0 | 33 | 10 | 20.0 |
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| Postoperative recurrence         | 0.2-31.0 | 33 | 10 | 20.0 |
| Pancreatic cancer                | 0.0-31.0 | 33 | 10 | 20.0 |

**Table 2** Evaluational indexes for CA19-9-based diagnosis of gastrointestinal benign and malignant diseases

| Disease                          | n  | Positive | Se, % | Sp, % | Ac, % | +PV, % | -PV, % |
|----------------------------------|----|----------|------|------|------|--------|--------|
| Gastric cancer                   | 55 | 26 | 47.3 | 100.0 | 65.9 | 100.0 | 50.8 |
| Postoperation and recurrence     | | | | | | | |
| Colorectal cancer                | 66 | 33 | 50.0 | 100.0 | 65.6 | 100.0 | 47.6 |
| Postoperation and recurrence     | | | | | | | |
| Pancreatic cancer                | 7 | 6 | 83.3 | 100.0 | 97.5 | 100.0 | 96.8 |
| Esophageal cancer                | 10 | 2 | 20.0 | 100.0 | 80.0 | 100.0 | 78.9 |
| Postoperative recurrence         | | | | | | | |
| Pancreatic cancer                | 11 | 8 | 72.7 | 100.0 | 97.5 | 100.0 | 96.8 |
| Esophageal cancer                | 10 | 2 | 20.0 | 100.0 | 80.0 | 100.0 | 78.9 |
| Postoperative recurrence         | | | | | | | |
