In conclusion, serum TPA values obtained in order to evaluate tissue TPA concentrations in patients with various diseases of the digestive system. Serum TPA values obtained from 83 normal subjects were 52.3 ± 24.4 U/L (mean ± standard deviation) and cut off level was set at 100 U/L. Serum TPA was positive in 53% (21/40) for gastric cancer, 53% (16/30) for colorectal cancer, 64% (7/11) for esophageal cancer, 88% (38/43) for hepatocellular carcinoma, 80% (4/5) for gallbladder cancer, 67% (4/6) for bile duct cancer and 83% (35/42) for pancreatic cancer, respectively. In patients with some benign diseases such as gastric ulcer, acute hepatitis and liver cirrhosis, serum TPA concentrations were elevated. Preoperative serum TPA levels were closely related to the degree of the malignancy. Determination in gastric and colorectal cancers and serum TPA concentrations declined markedly after surgical treatment in 11 out of 13 patients with pancreatic cancer. There was no correlation between serum TPA and CEA values. In conclusion, serum TPA determination by using RIA would be useful in patients with malignancy of the digestive system.

Clinically, serum TPA can be used as a tumor marker for the detection and monitoring of malignancy in various organs. The sensitivity and specificity of serum TPA in various tumors were: gastric cancer, 71%; colorectal cancer, 64%; esophageal cancer, 88%; hepatocellular carcinoma, 80%; gallbladder cancer, 67%; bile duct cancer, 83%; and pancreatic cancer, 83%. Serum TPA was not elevated in normal volunteers, and the cut off level was determined to be 100 U/L. Serum TPA values in 81 patients with malignancy were significantly higher than those in normal persons.

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**E. In vitro, RIA**

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Serum concentrations of tissue polypeptide antigen (TPA) were measured using RIA kits provided through Santec Inc.-Dictichi RI research institute. The characteristics of the kit and clinical usefulness were evaluated.

Intra- and interassay variations assessed with 4 control sera ranged from 2.8 to 13.7% and from 3.1 to 10.3% in C.V., respectively. The mean recovery of added TPA was 115.2%. Linear correlation was observed in dilution tests. No significant cross reaction was observed with CEA, AFP, β2-microglobulin and PAP.

Serum TPA levels in 24 healthy volunteers were 54.3 ± 24.0 u/l (M ± 1 S.D.). In patients TPA over 100 u/l was regarded as positive. Serum TPA concentrations were measured in 241 patients with various cancers and in 122 patients with benign diseases. Positive ratio of TPA in cancer patients was 57% in average including hepatoma (86%), biliary tract ca (75%), lung ca (67%), pancreas ca (58%), colorectum ca (58) and gastric ca (46%). False positive ratio in benign diseases was 34% with the highest ratio in liver diseases (76%). Clinical usefulness of TPA when combined with CEA and ferritin was discussed.