CLINICAL EVALUATION OF THYROXINE RADIOIMMUNOASSAY BASED ON THE SOLID PHASE TECHNIQUE

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Rapid method of the determination of serum thyroxine was developed recently based on the solid phase technique for preparation of bound(B) and free(F). This paper presents the results of clinical evaluation on the solid phase radioimmunoassay system for thyroxine using SPAC T_4 and GammaCoat T_4 kits in 99 normal subjects and 201 patients with various thyroid diseases.

Multiple dilutions of patients sera resulted in curves parallel to that obtained by standard T_4 in both kits. The intraassay reproducibility(C.V.) of serum T_4 assays was 6.54% in SPAC T_4 kit, and 2.05% in GammaCoat T_4 kit. The interassay reproducibility (C.V.) of serum T_4 assays was 6.40% in SPAC T_4 kit, and 4.05% in GammaCoat T_4 kit. The B % of standard curves and serum samples was increased significantly correlated to the incubation times. Good correlation was found between assay results of SPAC T_4 kit and GammaCoat T_4 kit - the correlation coefficient was $r = +0.94$, $y = 1.05x + 0.48$.

Serum T_4 levels of normal subjects was ranged from 4.6 to 12.1 μg/dl with SPAC T_4 kit, and from 5.3 to 11.3 μg/dl with GammaCoat T_4 kit. The assay results of hyperthyroid sera and hypothyroid sera was significantly different from euthyroid sera in both kits.

The accuracy and specificity of these systems is thought to be very useful for routine clinical determinations of thyroxine.

EVALUATION AND CLINICAL USE OF SOLID PHASE RADIOIMMUNOASSAY FOR THYROXINE

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Two types of solid phase radioimmunoassay of thyroxine (T_4) using Gammacoat T_4 (G) and Spac T_4 (S) Kits were evaluated for clinical application. and the following results were obtained, (1) Standard curves were compared when incubation was carried out at various temperatures (4, 26, 37°C) for 45 min. B/T ratio increased at the low level of T_4 when the incubation temperature was elevated, but T_4 values in three kinds of pooled serums determined at the same temperature were constant. (2) When the incubation time was varied from 15 min to 3 hours at constant room temperature, again, B/T ratio increased at the low level but serum value of T_4 determined at the same condition was constant. (3) Dilution of serum resulted in the parallel curve with that of standard T_4. (4) When ^{125}I-T_4 was reduced to 2/5, B/T ratio was increased but values of serum T_4 determined at the same condition were constant. (5) The recoveries of standard T_4 added to the pooled serum were 106 ± 3.3% (G) and 100 ± 2.9% (S) respectively. (6) Coefficients of variation within assay were 3.2 - 4.7% (G), 2.4 - 5.6% (S) and those between assay were 2.6 - 4.1% (G) and 3.4 - 6.5% (S) respectively. (7) Serum with slight hemolysis had no significant effect on T_4 value. (8) Serum concentrations of T_4 determined by means of these methods were 8.1 ± 1.57 μg/dl in 69 normal subjects (G) and increased in hyperthyroid and decreased in hypothyroid patients. (9) T_4 values determined by the double antibody method of Eiken (χ) was well correlated with those determined by the solid phase methods (Y , Y) as follows: $Y = 0.99\chi + 0.94$ ($r=0.98$) $Y = 1.05\chi + 0.17$ ($r=0.97$). In conclusion, the solid phase radioimmunoassay of T_4 was useful for clinical test.