RADReceptor ASSay of ANTI-TSH RECEPTOR ANTIBODIES. T. Ichikawa. School of Medicine Keio University. Tokyo.

TSH receptor antibodies determined by inhibition of I-125 TSH binding to human thyroid membrane (TDA) were positive in 85% of untreated Graves' disease, while they were negative in most of patients with Hashimoto's thyroiditis, thyroid cancer or subacute thyroiditis. However, strongly positive TDA was also found in 5 patients with primary hypothyroidism without goiter. Four were female. One of them had 3 children, who all experienced transient neonatal hypothyroidism. The response of adenylate cyclase of human thyroid membrane to TSH was markedly decreased in the presence of IgG's of these patients.

Anti-receptor antibodies which does not inhibit TSH binding to receptor were also determined by immunoprecipitation method using solubilized membrane (Ip-Ab). Positive values (more than mSD of normal controls) were found in 75% of 22 patients with untreated Graves' disease. Statistically significant correlations were found between human thyroid adenylate cyclase stimulating activity (HTACS) and Ip-Ab (r=0.642, p<0.01), and between HTACS and TDA (r=0.461, p<0.05).

As anti-TSH receptor antibodies have diversity in their binding sites on receptor molecule, and also in their biological activities.

QUALITY CONTROL OF RADIOIMMUNOASSAY.

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Daily control of quality of assay is important to perform high quality assay. The methods of quality control can be classified into three categories. These include a method to use intrinsic nature of radioimmunoassay, to use reference samples and others applied in laboratory of clinical pathology. The first one is based on Response-Error-Relationship and therefore derived a predicted precision profile. Since the goodness in fitting standard curve is important to get better predicted precision, computer programs for Logistic, Loglogistic, Quadratic and Cubic Log-logit and Spline function was developed in our laboratory. Precision profiles of C-peptide showed good reproducibility in nine assays out of ten, that implicates the assay can be performed in similar degree of control in precision. The method to detect outliers in precision was introduced using precision profile. Three times of standard deviation was used for rejection limit in that case.

In reference sample methods six kinds of kit, that is, AFP, IRI, T-4, T-3, TBG and TSH were examined in successive lot numbers without any rejection. Thus, these results could show the state of control in commercial kits. Precision and accuracy were examined in each kit using a computer program developed with modification of the method of A.Paule in our laboratory.