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RADIORECEPTOR ASSAY OF ANTI-TSH RECEPTOR ANTIBODIES. Y. 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 m+SD 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 a conclusion, anti-TSH receptor antibodies have diversity in their binding sites on receptor molecule, and also in their biological activities.

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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 referrence samples and others applied in laboratory of clinical pathology. The first one is based on Response-Error-Relationship and therefrom derived a predicted precision profile. Since the goodness in fitting standard curve is important to get better predicted pre-cision, computor 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 outlieres in precision was introduced using precision profile. Three times of standard deviation was used for rejection limit in that case.

In referrence 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 the results could show the state of control in commercial kits. Precision and accuracy were examined in each kit using a computor pro-gram developed with modification of the method of A.Faure in our laboratory.

(com.prog.biomedicine 12:105,1980)
In AFP assay precision was controlled in 95 % and accuracy was controlled in 60 % of low value control serum and in 71 % of high value control serum. In IRI accuracy was controlled in 52 % of low value and in 59 % of high value. But precision was controlled in 93 % and 95 % respectively. In thyroxine assay accuacy was controlled in 82 % of low value and in 75 % of high value. The luck of control in precision was only 3 %. As for triiodothyronine accuracy was controlled in 73 % of low value and 66 % of high value. Precision was controlled in 94 % and in 89 %, respectively. TBG showed exellent precision, that means the lowest CV %. Accuracy was controlled in 71 % and precision was controlled in 80 %. Seventy four percent of low value and 71 % of high value were controlled in TSH assay. In this assay precision was controlled in 94 %.

In general, <u>PRECISION</u> was in good or exellent control. However <u>ACCURACY</u> was not well controlled. In order to improve accuracy of radioimmunoassay, we have to control the <u>BIAS</u> which is supposed to be mainly caused by Lot-to-Lot difference.