IMPROVED PROCESSING OF RADIOIMMUNOASSAY DATA APPROACHES FOR SELECTION OF REGRESSION MODELS AND FOR DISCRIMINATION OF DOSE RESPONSE CURVE WITH LARGE ABERRANCE

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Goodness-of-fit of 3 regression models, 4-parameter logistic, quadratic logit-log and linear logit-log models, were evaluated by analysis of variance (F-test) for data of 6 kinds of radioimmunoassays (RIA). Scatchard plot analyses were made with the representative data of these RIAs in order to find the best choice of regression model in relation to the characteristics of antigen-antibody reaction. It was concluded that RIA with linear pattern on Scatchard plot could be satisfactorily regressed with either of 3-regression models, RIA with linear with tail pattern regressed with either the logistic or quadratic logit-log model, and RIA with hyperbolic pattern regressed best with quadratic logit-log model.

An study was also made on statistical indises derived from regression analysis which enable quantitation of the scatter around the regression curve. It was found that among such indises normalised standard deviation of replicate means around regression curve (designated as NSL) were the most sensitive indicator of the aberrancy in dose-response curve.

QUALITY CONTROL PROGRAM ON RADIOIMMUNOASSAY AND ITS REALITY

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The necessity of quality control on RI in-vitro tests has been regarded as important due to its prompt development and generalization or mass sample treatment. There are,however, still incompletion of basic investigations on actual execution of quality control program,such as, assay standarization,non-specific interference,propriate selection of control and standard serum and practical difference among commercially available kits. In this circumstances, I would like to present the contents of our quality control program and ask for your constructive comments on it for establishment of the rough guideline of future improvement and advancement. We adopt the control chart which shows the simultaneous comparison between normality of standard curve and variation of pooled and control serum as the first check which is advocated by Rodbard. Then we adopt NBS/T% and values of bound% intercept at three different concentration levels as index of standard curve. We make pooled serum of different concentration levels by ourselves. At the same time we select optimal concentration levels for commercially available control serum. Since the indicated values of commercially available control serum are different from kit to kit, individual laboratory has to set up its own rigid values for them. Thus as far as the stability of control serum after reconstitution is closely checked, it is quite useful means to examine the quality of assay system. As second check, we control the reliability of data by measuring the differnce between indicated and actual values at each assay with double blind test. As final check, we totally verify the obtained data by refering the data by other assay methods and clinical observations. We adopt the 2-standard diviation(SD) of allowance range, 3SD for some specific items, for the variation of index as check point. We use Olivethi-P-6060 for data processing of quality control data in order to increase the reliability of Checker judgement and prevent the mistakes resulting from mass sample treatment. We still have many things to investigate and have to gather necessary data for statistical processing to complete the final program of automatic quality control. At the present situation, the quality control of RIA more heavily depended

upon the subjective checks of well experienced technician comparing with biochemical assay.
Thus, the issues pointed out above are summarized like follows:

1) Sources of error on Radioimmunoassay
2) Standarization/Computerization of Radioimmunoassay
3) Laboratory Grouping System on RIA Quality Control

QUAIITY CONTROL IN RADIOIMMUNOASSAY

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The quality of work performed in clinical laboratories was for many years the subject of much criticism and discussion. As a result of intensified supervision, several systems of quality control were born. With them came an increased emphasis on accuracy and an earnest effort to improve the reliability of analytic results by the use of known control samples. The purpose of this study is to re-emphasize the progress made in this direction, using both commercial reference standard and self-made control sera.

Method

In the clinical laboratory of the Hospital of Dokkyo University School of Medicine, serum TSH, T_3-RU, T_4, T_3, Insulin, gastrin, IH, FSH, cortisol and α-fetoprotein were measured by radioimmunoassay procedures. As control sera, self-made control sera and commercial reference standard were used. 1) The degree of variation in each radioimmunoassay procedure was determined by comparing an assayed value with the value of the mean. 2) The coefficent of variation (CV) for a certain control sera is not necessarily agree with that obtained by another control sera. The comparison between the value of the mean of each control sera and CV was made.

Result

1) CV of each assay was almost within 15% regardless of difference of the control sera. CV of TSH radioimmunoassay alone was over 40%. Although the reasons for this high CV remaines unclarified, it may be attributable to quality of antibody. 2) When one uses control sera which value of the mean was extremely high or low, CV in the assay was relatively high. 3) All the commercial reference standard was found to be acceptable as control sera in routine assay.

Conclusion

In our clinical chemical laboratories, it was found that the control of precision and accuracy in radioimmunoassay can be achieved