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CLINICAL SIGNIFICANCE OF SERUM β_2 -MICROGLOBULIN IN VARIOUS LIVER DISEASES. S. Fujiyama, Y. Tanggo, A. Tashiro, K. Sagara and T. Sato Third Department of Internal Medicine, Kumamoto University Medical School. Kumamoto

Using Phadebas β_2 -micro Test, serial determinations of serum β_2 -microglobulin (β_2 -m) levels were carried out in 460 patients with various liver diseases including 49 cases of hepatocellular carcinoma (HCC), and its clinical usefulness was evaluated. It considered that normal upper limit of serum β_2 -m level was 2.4 mg/l. High serum β_2 -m levels were found in patients with acute hepatitis (62.5%), chronic hepatitis (38.0%) and liver cirrhosis (56.6%). In general, serum β_2 -m levels in chronic liver diseases tended to increase with degree of impaired liver function, but in individual case it fluctuated with the clinical course. To compared with benign diseases, the incidence and serum levels of β_2 -m were considerably high in HCC (75.5%) and metastatic liver cancer (66.7%). The serum β_2 -m was not closely related to tumor growth or clinical evolution, and there was no significant correlation between serum β_2 -m and other tumor markers (AFP, CEA and ferritin) in these liver cancers. The ascitic/serum ratio of β_2 -m in the patients with HCC was significantly higher than that in liver cirrhosis. From these results, the presence of hepatic diseases must be considered in evaluating β_2 -m levels, and measurements of serum β_2 -m alone seem to be of limited values in the diagnosis and monitoring of liver cancer.

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EVALUATION OF NORMAL RANGE BY HOFFMANN'S METHOD--THE EFFECT OF THE POPULATION SIZE ON THE RESULT--. K. Imamura, F. Asaba, T. Takahashi, T. Sakaki, K. Hoshi, N. Sekita, Y. Sasaki, M. Fujii Department of Radiology, The Third Department of Internal Medicine, St. Marianna University School of Medicine, Division of Nuclear Medicine of University Hospital, Kawasaki

Hoffmann's method is a theory to calculate normal range of clinical examinations from patients' data. The effect of population size on the results was carefully examined.

T₄ RIA: Analysed population is of 2058 tests. Minor components are cause of uncertainty in the extraction of modal Gaussian distribution. Normal range was derived as 3~10 μ g/dl, and was stable if the analysed population is around 1000 or more. Iodine Uptake: Analysed was a population of 1268 tests of 7 years. Modal Gaussian distribution could not be extracted on the probability diagram of the population of all patients. We selected euthyroids (473 euthyroids out of 1268 tests) on the basis of plasma T₄ and T₃ levels, and analysed by Hoffmann's method. The results from the population of more than 300 euthyroids were in good accordance with the current normal range.

As a result, Hoffmann's method with the help of clinical information is effective to derive normal ranges from patients' data for clinical examinations in which normal ranges are difficult to decide.

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RESPONSE-ERROR-RELATIONSHIP IN RADIOIMMUNO-ASSAY. A. Kuroda, T. Yatabe, T. Inaba, K. Chiba, H. Murata & H. Yamada Tokyo Metropolitan Geriatric Hospital

Response-error-relationship (RER) can be used for reasonable weighting in regression of RIA standard curve and quality control. However some investigators have claimed there is no constant relationship between errors and response, such as counts, B/Y or B/Bo. The purpose of this presentation is to investigate relationship between response and error, and to find the most suitable models for RER, if any relationship is present.

In this study counts were used for response and standard deviation or variance was used for representing errors. Data from unknown samples were binned into 20 groups which were made by dividing the difference between the maximum and minimum counts in a certain assay with 20. Models used here for RER analysis were as follows, (1) $Y=bX$ (2) $Y=a + bX$ (3) $Y=bX + cX^2$ (4) $Y=a + bX + cX$ (5) $\text{Log}(s + 1) = \text{Log} A + J \text{Log} X$ and parameters were obtained by least square method. Sum of squares of residuals were used for comparison for the fitness among models. In every assay examined sum of squares of residuals was least in equation (4) and next in equation (3). However model (4) parameters showed the largest variation from assay to assay. In model (1) parameters were fairly constant but the sum of squares of residuals was largest. For the purpose of quality control equation (3) or (5) might be suitable.

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PRACTICAL QUALITY CONTROL OF RADIOIMMUNO-ASSAY (RIA) BY USE OF PATIENTS' TEST VALUES. K. Ichihara and K. Miyai Department of Laboratory Medicine, Osaka University, Osaka

The stability of distributions of patients' test values and performances of statistical parameters derived from them were evaluated in 8 RIAs performed routinely in our laboratory for the past one year. The parameters studied were Hoffmann's "average of normals" (nM), the "number plus" (%P) and a median of values that fall within the "normal" reference range (nMe). In T₃, TSH and GH RIAs, the patterns are constant and nM and nMe showed close correlations with values of "normal" quality-control sera. The degree of the correlations depended upon the extents of the reference ranges employed. In T₄, cortisol, IRI, LH and FSH RIAs, the patterns were not consistent and nM and nMe rarely correlated with values of the control sera. %P showed close correlations with values of control sera in only T₃ RIA and appeared affected by a disturbance in the distributions. In general, nM and nMe may be useful adjuncts to conventional quality-control of RIAs for the substances satisfying the following conditions: (1) the patterns of their distributions are almost constant, (2) their inter- and/or intra-individual variations are less prominent and (3) number of their test values that fall within the reference range in a run of assay are preferably more than 50, though frequency of abnormal data appears not to be critical.