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Novel TSH assays display improved correlation with clinical signs in hypothyroid patients as well as in patients under levothyroxine therapy

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Work over the past decades has assigned changes in TSH glycosylation to the onset of hypothyroidism. However, most current assays fail to accurately measure such diseased forms of TSH and more than often, TSH level does not correlate with clinical signs of hypothyroidism. To achieve a better assessment of TSH level, we developed a glycoengineered calibrator mimicking highly sialylated TSH and screened antibodies accordingly to construct new assays. All assays showed harmonized TSH measurements (84 patients with TSH 2.1-22.4 mIU/L). Clinical validation of 4 of these new assays was carried out on a cohort of 1363 patients (18-85y) with TSH between 0.1 -63mIU/L without TRAK or anti-TPO antibodies. FT3, FT4 and 11 clinical signs of hypothyroidism were also recorded. New assays showed a positive correlation between TSH level and clinical signs in 797 healthy subjects according to gender (M/F) and age (<60y and >60y). Moreover, in a cohort of 253 patients under T4 treatment, 26.3% of the patients did not present normal TSH values in contrast to the reference assay. 5 major hypothyroid signs as a therapy test to identify subclinical hypothyroidism, initiate and adjust hormonal treatment.TSH new assays may therefore serve as a therapy test to identify subclinical hypothyroidism, initiate and adjust hormonal treatment.

Biography

Catherine Ronin carried out a full academic career as Professor at Aix-Marseille University (France) and founded SiaMed'Xpress in 2010. She has published more than 35 papers related to TSH biological and immunological polymorphism in reputed journals and has been serving as expert, Vice Chair and Chair in Marie Curie ITN and JDP programs at the European, Research Agency over 12 years.