

Establishment of a monomer prolactin detection method and specific reference interval to enhance the ability to identify macroprolactinemia

Huashan Hospital Fudan University
Shanghai, China

KEY PARTNERS / STAKEHOLDERS

Ming Guan | Yao Hu | Hongying Ye | Zhaoyun Zhang | Yao Zhao

Hyperprolactinemia is a clinical condition characterized by continuously elevated serum prolactin levels above the normal range. While not life-threatening, hyperprolactinemia can lead to significant complications, including irregular menstruation, infertility, loss of sexual desire, breast hyperplasia, unwanted milk secretion and other problems in women. In men, it may cause infertility, loss of libido, breast enlargement, and more. Thus, prompt identification and treatment of hyperprolactinemia is crucial for patient quality of life.

Macroprolactin is a non-bioactive isoform of prolactin that interferes with immunological assays used in the detection of prolactin. Excessively high concentrations of macroprolactin, i.e., when >60% of circulating prolactin is composed of macroprolactin, while not harmful, can cause erroneous diagnoses of hyperprolactinemia, leading to potential unnecessary examinations and/or treatments. It is estimated that the global incidence of macroprolactinemia in hyperprolactinemia is 18.9% (95%CI 15.8%, 22.1%)¹, thus, early screening for macroprolactin can help avoid incorrect diagnosis and unnecessary treatment.

The Endocrinology Department of Huashan Hospital, composed of neuroendocrinology and the pituitary multidisciplinary team, sees a large number of patients with pituitary diseases, including hyperprolactinemia. Thus, in collaboration with Huashan Laboratory Department, case discussions helped identify clinical needs related to macroprolactin, including establishment of a macroprolactinemia screening initiative. Of importance, this involved a standardized laboratory procedure of polyethylene glycol precipitation. On the basis of chemiluminescence immunoassay, a prolactin monomer detection method was constructed with established reference intervals. The method was validated and verified through clinical samples for identification of macroprolactinemia.

From 2021 to 2023, a total of 14,950 patients at Huashan Hospital have undergone prolactin monomer testing, of which 3,238 patients have been diagnosed with macroprolactinemia. Early identification of macroprolactinemia has mitigated unnecessary medications and/or imaging tests every 6 months, thereby reducing anxiety for patients and their families, all while reducing overall healthcare costs.



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1. Che Soh, NAA; Yaacob, NM; Omar, J; et al. Global Prevalence of Macroprolactinemia among Patients with Hyperprolactinemia: A Systematic Review and Meta-Analysis. [J]. Int J Environ Res Public Health. 2020;17(21)