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CONSENSUS DOCUMENT

Clinical guidelines for diagnosis and treatment of prolactinoma and hyperprolactinemia☆

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KEYWORDS
Prolactinoma;
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Abstract
Objective: To provide practical and up-to-date recommendations for evaluation, differential diagnosis, and treatment of prolactinoma and hyperprolactinemia in various clinical settings.
Participants: Members of the Neuroendocrinology Working Group of the Spanish Society of Endocrinology.
Methods: Recommendations were formulated according to the Grading of Recommendations, Assessment, Development, and Evaluation system (GRADE) to describe both the strength of recommendations and the quality of evidence. A systematic search was made in Medline (Pubmed) for each subject, and authors' considerations were added in areas where the literature provided scarce evidence. Finally, recommendations were jointly discussed by the Working Group.
Conclusions: The document provides evidence-based practical and updated recommendations for diagnosis and management of hyperprolactinemia and prolactinoma, including drug-induced hyperprolactinemia, treatment options for prolactinoma (drugs, surgery, and radiotherapy), prolactinoma in pregnancy, adverse effects of dopaminergic agents, and drug-resistant and malignant prolactinomas.
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PALABRAS CLAVE
Prolactinoma;
Hiperprolactinemia;
Guía clínica

Guía clínica de diagnóstico y tratamiento del prolactinoma y la hiperprolactinemia

Resumen
Objetivo: Proporcionar recomendaciones prácticas y actualizadas para la evaluación, diagnóstico diferencial y tratamiento del prolactinoma y la hiperprolactinemia en diversos contextos clínicos.

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Participantes: Miembros del Grupo de Neuroendocrinología de la Sociedad Española de Endocrinología y Nutrición.
Métodos: Las recomendaciones se formularon de acuerdo al sistema *Grading of Recommendations, Assessment, Development, and Evaluation* (GRADE) para establecer tanto la fuerza de las recomendaciones como el grado de evidencia. Se realizó una búsqueda sistemática en *Medline (Pubmed)* para cada apartado, y se añadieron consideraciones de los autores en los aspectos en los que la bibliografía ofrece escasa evidencia. Tras la formulación de las recomendaciones estas se discutieron de forma conjunta en el Grupo de Trabajo.
Conclusiones: El documento establece unas recomendaciones prácticas y actualizadas del diagnóstico y tratamiento de la hiperprolactinemia y el prolactinoma incluyendo la hiperprolactinemia inducida por fármacos, diversas modalidades del tratamiento de los prolactinomas (fármacos, cirugía y radioterapia), prolactinoma y gestación, efectos adversos de los fármacos dopaminérgicos, y prolactinomas resistentes a fármacos y malignos.
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Methodology to prepare these clinical guidelines

These guidelines were based on a literature review of original papers, meta-analyses, and clinical guidelines prepared by expert groups of recognized competence, supplemented by our views and personal experiences. Whenever possible, the available evidence on each subject has been categorized based on the grades of recommendation (GRADE system) used by the Endocrine Society in preparing its clinical guidelines. This system includes two grades of recommendation (1: strong, or 2: weak) and classifies the quality of evidence into one of four categories (⊕⊕⊕⊕: high, ⊕⊕⊕◯: moderate, ⊕⊕◯◯: low, or ⊕◯◯◯: very low). As with other subjects related to neuroendocrinology, it should be taken into account that little high-quality evidence is available in many aspects.

Introduction: prolactinoma and hyperprolactinemia

Prolactinoma is a pituitary adenoma that secretes prolactin (PRL). Prolactinomas account for 40% of all pituitary adenomas and occur more commonly in women. Based on size, they are classified as microprolactinoma (<10 mm) and macroprolactinoma (≥10 mm). Eighty percent of prolactinomas are intrasellar microadenomas which will not grow during follow-up.[1] Although they are rarely hereditary in nature, they may be part of multiple endocrine neoplasia (MEN1) and of the so-called familial isolated pituitary adenomas.[2] Malignant prolactinoma is uncommon.

PRL is subject to the inhibitory effect of dopamine. Hyperprolactinemia may therefore be not only due to tumor hypersecretion, but also because of various physiological and pathological conditions, and also due to multiple drugs which alter dopamine production, transport, or action.

Together, prolactinoma and hyperprolactinemia are a common cause of visits to endocrinology outpatient clinics.

Clinical signs

Regardless of its cause, hyperprolactinemia interferes with pulsatile GnRH secretion and inhibits LH and FSH secretion, thus causing hypogonadism in both sexes and infertility. In addition, the mass of a prolactinoma may cause compressive effects on parasellar structures and hypopituitarism.

In women, most prolactinomas are microadenomas and induce menstrual changes (oligoamenorrhea), galactorrhea, and infertility. In postmenopausal women, the clinical signs are mainly due to the mass effect of the adenoma. In men, 80% of prolactinomas are macroadenomas. Thus, clinical signs due to a mass effect (headache, vision loss) and/or the involvement of other pituitary axes usually occur. Hyperprolactinemia causes decreased libido, erectile dysfunction, oligospermia and infertility and, less frequently, gynecomastia and galactorrhea. Hypogonadism induced by hyperprolactinemia is associated with decreased mineral bone density in both sexes.[1]

Prolactinoma is rare in children and adolescents, and causes delayed puberty and/or clinical signs due to a mass effect.

Diagnosis of hyperprolactinemia

For most laboratories, normal serum PRL levels are less than 25 ng/mL in women and less than 20 ng/mL in men (1 ng/mL is equivalent to 21.2 mIU/L).

As recommended by the most recent clinical guidelines, the measurement of PRL in a single sample is sufficient for diagnosis if vein puncture has not been traumatic (1⊕⊕⊕⊕). When the results are doubtful (mild PRL elevations) or inconsistent with the clinical picture, the measurement may be repeated on samples taken at 15–20 min intervals to minimize the effect of pulsatility.[3,4]

Dynamic tests (TRH, L-dopa, domperidone, etc.) have no advantage over basal PRL measurement, and are therefore not recommended[3–5] (1⊕⊕⊕⊕).

PRL levels usually correlate to prolactinoma size. In large adenomas with only slightly elevated PRL levels, the ''hook effect''[6] should be ruled out, although this is

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