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Pasireotide treatment significantly improves clinical signs and symptoms in patients with Cushing's disease: results from a Phase III study

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Résumé en anglais	**Objective** Signs and symptoms of Cushing's disease are associated with high burden of illness. In this analysis, we evaluated the effect of pasireotide treatment on signs and symptoms in patients with Cushing's disease. **Design** Phase III study with double-blind randomization of two pasireotide doses. **Methods** Patients (n = 162) with persistent/recurrent or de novo Cushing's disease and urinary free cortisol (UFC) levels ≥1·5× upper limit of normal (ULN) were randomized to receive subcutaneous pasireotide (600/900 µg bid). At month 3, patients with UFC ≤2 × ULN and not exceeding the baseline value continued their randomized dose; all others received 300 µg bid uptitration. At month 6, patients could enter an open-label phase until month 12 with a maximal dose of 1200 µg bid. Changes in signs and symptoms of hypercortisolism over 12 months' treatment in patients still enroled in the study and with evaluable measurements were assessed in relation to degree of UFC control. **Results** Reductions in blood pressure were observed even without full UFC control and were greatest in patients who did not receive antihypertensive medications during the study. Significant reductions in total cholesterol and low-density lipoprotein (LDL)-cholesterol were observed in patients who achieved UFC control. Reductions in BMI, weight and waist circumference occurred during the study even without full UFC control. Adverse effects were typical of somatostatin analogues except for hyperglycaemia-related events, which were experienced by 72·8% of patients. **Conclusions** In the largest Phase III study of medical therapy in Cushing's disease, significant improvements in signs and symptoms were seen during 12 months of pasireotide treatment, as UFC levels decreased.
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