双極性障害に対する有効な維持療法

長時間作用型リスペリドンは双極I型障害患者の再発までの時間を遅らせる

Maintenance therapy with long-acting risperidone delays time to relapse in patients with bipolar I disorder

2009年American Psychiatric Association学会で発表された新たなデータから、長時間作用型リスペリドンは双極I型障害患者の再発までの時間を有意に遅延させることが示された。無作為化二重盲検プラセボコントロール長期スタディが行われ、薬物療法で落ち着いているかまたは急性躁病エピソードか混合性エピソード発現中の双極I型障害のDSM-IVクライテリアに合致する患者における維持療法としてのリスペリドンの効果が評価された。スタディの第一段階で303人の患者がオープンラベルの長時間作用型リスペリドン26週間投与にて安定した。二重盲検の段階で患者は長時間作用型リスペリドンによる維持療法群（154人）またはプラセボ群（149人）に無作為に割り付けられた。治療期間中央値はリスペリドン群で9ヵ月であり、プラセボ群で5ヵ月であった。一次エンドポイントは何らかの気分エピソード（うつ病、躁病、または混合性）再発までの時間であった。再発までの時間はプラセボ群と比較しリスペリドン群で有意に長かった（p<0.001）。さらに、二重盲検段階の再発率はリスペリドン群（30%；42/140）でプラセボ群（56%；76/135）よりも低かった。リスペリドン投与量の中央値は25mgであった。

Full Text

New data presented at the 2009 American Psychiatric Association annual meeting demonstrates that maintenance therapy with long-acting risperidone significantly delays time to relapse in patients with bipolar I disorder.

Bipolar Disorder is often characterized by debilitating mood swings from extreme highs (mania) to extreme lows (depression). Type I Bipolar Disorder is characterized based on the occurrence of at least one manic episode, with or without the occurrence of a major depressive episode.

A randomized, double-blind, placebo-controlled, long-term study was conducted to evaluate the effect of long-acting risperidone as maintenance therapy in patients who met DSM-IV criteria for Bipolar I Disorder who were stable on medications or experiencing an acute manic or mixed episode. In the first phase of the study, 303 patients were stabilized on open-label risperidone for 26 weeks. In the double-blind phase, patients were randomized to either maintenance therapy with risperidone (N=154) or placebo (N=149). The median duration of treatment was nine months for patients in the risperidone group and five months for patients in the placebo group. The primary endpoint was time to relapse of any mood episode (depression, mania, or mixed).

Time to relapse was significantly longer in patients receiving risperidone monotherapy as compared to placebo (p<0.001). In addition, the rate of relapse during the double-blind treatment phase was lower among patients in the risperidone group (30 percent; 42/140) compared with the placebo group (56 percent; 76/135). The median dose of risperidone was 25 mg.

The most common adverse reactions in clinical trials in patients with bipolar disorder were weight increase (5% in monotherapy trial) and tremor and parkinsonism (greater than or equal to 10% in adjunctive therapy).

"This is the first randomized controlled study to demonstrate the efficacy of RLAT as a maintenance therapy in patients with Bipolar Disorder," said Joseph Palumbo, M.D., Franchise Medical Leader, Psychiatry, Central Nervous System and Pain Therapeutic Area, Johnson & Johnson Pharmaceutical Research & Development, L.L.C. (J&JPRD). "These findings are important because the clinical course of Bipolar Disorder is often unpredictable and relapses can be very debilitating."

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