Short-term treatment with risperidone or haloperidol in first-episode schizophrenia: 8-week results of a randomized controlled trial within the German Research Network on Schizophrenia.


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Patients with first-episode schizophrenia appear to respond to lower doses of neuroleptics, and to be more sensitive to developing extrapyramidal side-effects. The authors therefore compared in such patients the efficacy and extrapyramidal tolerability of the atypical neuroleptic risperidone and of the conventional neuroleptic haloperidol. Risperidone was hypothesized to have better extrapyramidal tolerability and efficacy in treating negative symptoms. Patients were randomly assigned under double-blind conditions to receive risperidone (n=143) or haloperidol (n=146) for 8 wk. The primary efficacy criterion was the estimated difference in the mean change in the Positive and Negative Symptom Scale (PANSS) negative symptoms. Secondary efficacy criteria were the other extrapyramidal symptoms, measured with the Hillside Akathisia Scale (HAS) and the Abnormal Involuntary Movement Scale (AIMS). The primary tolerability criterion was the difference in baseline-adjusted occurrence rates of extrapyramidal side-effects measured with the Simpson-Angus Scale (SAS) compared between treatment groups. The main hypothesis was that risperidone would be superior in terms of improving negative symptoms and lowering the risk of extrapyramidal symptoms. Secondary tolerability criteria were the other extrapyramidal symptoms, measured with the Hillside Akathisia Scale (HAS) and the Abnormal Involuntary Movement Scale (AIMS). The average mean daily doses were 3.8 mg (s.d.=1.5) for risperidone and 3.7 mg (s.d.=1.5) for haloperidol. There were similar, significant improvements in both treatment groups in the primary and secondary efficacy criteria. At week 8 nearly all scores of extrapyramidal side-effects indicated a significantly higher prevalence of extrapyramidal side-effects with haloperidol than with risperidone [SAS: risperidone 36.5% of patients; haloperidol 51.5% of patients; likelihood ratio test, ch2(1)=7.8, p=0.005]. There were significantly fewer drop-outs [risperidone n=55, drop-out rate=38.5%; haloperidol n=79, drop-out rate=54.1%, ch2(1)=7.1, p=0.009] and a longer non-discontinuation time [risperidone: average of 50.8 d to drop-out; haloperidol: average of 44.0 d to drop-out; log rank test, ch2(1)=6.4, p=0.011] in the risperidone group. Risperidone and haloperidol appear to be equally effective in treating negative and other symptoms of first-episode schizophrenia. Risperidone has better extrapyramidal tolerability and treatment retention rate than the equivalent dose of haloperidol in these patients.

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