Aripiprazole is effective for relapse prevention in people with chronic stable schizophrenia


Q Does maintenance aripiprazole prevent relapse in people with chronic schizophrenia with residual symptomatology?

**METHODS**

- **Design:** Randomised controlled trial.
- **Allocation:** Unclear.
- **Blinding:** Double blinded.
- **Follow up period:** 26 weeks; participants monitored daily.
- **Setting:** 31 centres in the USA, Czech Republic, Poland, Russia, and Ukraine; 2000–01.
- **Patients:** 310 adults with confirmed schizophrenia (DSM-IV) of at least 2 years’ duration with residual symptomatology despite antipsychotic treatment. Main inclusion criteria: ongoing antipsychotic treatment to which they had shown some response; Positive and Negative Syndrome Scale (PANSS) score of ≥60 with score <4 on the hostility or uncooperativeness subscales; Clinical Global Impressions-Severity of illness scale (CGI-S) score <4. Exclusions: acute relapse; psychiatric comorbidity; resistant to antipsychotics; alcohol or substance abuse or benzodiazepine dependency; recent use ofloxetine, long acting antipsychotics, or electroconvulsive therapy; suicidality; pregnant or at risk of pregnancy; cognitive disorders such as dementia, delirium, or amnesia. Participants discontinued antipsychotic and psychotropic medication and underwent a three day washout period before randomisation.
- **Intervention:** Aripiprazole (15 mg/day) or placebo.
- **Outcomes:** Time to relapse (defined as an impairing decompensation based on at least one of the following: CGI- Global Improvement (CGI-I) score >5; PANSS score >5 on the hostility or uncooperativeness subscales on two successive days; or PANSS total score increase ≥20%); symptom scores and incidence of adverse effects.
- **Patient follow up:** 96% for efficacy outcome.

**MAIN RESULTS**

Aripiprazole significantly decreased relapse rate compared with placebo (Kaplan-Meier survival rates at week 26: 62.6% with aripiprazole × 39.4% with placebo; p<0.001; RR for relapse 0.50, 95% CI 0.35 to 0.71). Aripiprazole significantly improved schizophrenic symptoms compared with placebo at 26 weeks (PANSS total score, CGI-S and CGI-I scales; see table). Both groups had a similar incidence of adverse effects (79.7% with aripiprazole × 77.1% with placebo).

**CONCLUSIONS**

Aripiprazole is effective for preventing relapse in people with chronic schizophrenia and residual symptomatology over a six month period.

**Table**

|                      | Aripiprazole | Placebo | p Value |<|<|<|
|----------------------|--------------|---------|---------|<|<|<|
| PANSS total          | −2.08        | +4.50   | <0.01   |
| PANSS positive subscale | +0.12        | +2.27   | <0.01   |
| PANSS negative subscale | −1.40        | −0.54   | NS      |
| PANSS derived BPRS    | −0.21        | +1.17   | <0.01   |
| CGI-S                | +0.15        | +0.40   | <0.05   |
| CGI-I                | +3.74        | +4.47   | <0.01   |

BPRS, brief psychiatric rating scale; NS, not significant.
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Evid Based Mental Health 2004 7: 41
doi: 10.1136/ebmh.7.2.41

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