Fluoxetine prolonged time to relapse in bulimia nervosa


QUESTION: In patients with bulimia nervosa (BN), is fluoxetine effective and safe for preventing relapse after response to short term fluoxetine treatment?

Design
Randomised (allocation concealed*), blinded | participants, healthcare providers, data collectors, outcome assessors, and data analysts|†*, placebo controlled trial with 1 year of follow up.

Setting
16 sites in the US.

Patients
150 patients who were ≥18 years of age (mean age 30 y, 98% women); had a psychiatric diagnosis of BN, purging type (including self induced vomiting) according to DSM-IV criteria; and responded to 8 wks of fluoxetine, 60 mg/day (response was defined as ≥50% decrease in frequency of vomiting episodes during ≥1 of the preceding 2 wks). Exclusion criteria included previous treatment with fluoxetine, coexisting psychiatric diagnoses, and recent use of investigational drugs or psychoactive medications. 97% of patients had ≥1 assessment after randomisation.

Intervention
Patients were allocated to fluoxetine, 60 mg/day (n=76), or placebo (n=74) for up to 1 year.

Main outcome measures
Change in number of vomiting episodes per week and time to relapse (return to baseline frequency of vomiting for 2 consecutive weeks).

Main results
The fluoxetine group had a smaller increase in vomiting episodes per week than the placebo group at 1 year (mean increase 2.9 vs 4.8 episodes, p=0.001). Fluoxetine prolonged the time to relapse relative to placebo (p=0.02). The relapse rate was lower in the fluoxetine group than the placebo group during the first 3 months (table); the difference was not statistically significant at 6 and 12 months. The attrition rate was high, especially during the first 3 months (43% for fluoxetine vs 74% for placebo, [p<0.001]‡); the groups had similar attrition rates overall.

Conclusion
In patients with bulimia nervosa, fluoxetine prolonged time to relapse.

*See glossary.
†Information provided by author.
‡Value calculated from data in article.

COMMENTARY
Antidepressant drugs, especially fluoxetine, are widely used in the treatment of BN. In general, trials provide substantial evidence of real if modest beneficial effects in the short term. However, such trials do not reflect clinical practice precisely. Thus, there is much less evidence about long term drug treatment. Of course, longer term treatment is likely to make sense only if there has been benefit in the short term. The study by Romano et al provides relevant evidence by studying the effect of continuing drug treatment for those who have responded somewhat.

The study involved collaboration among 16 centres. It is not clear why so many investigators were required to study such a common clinical issue and whether cryptic selective factors were at work. On paper, the participants look like the usual patients presenting with BN. It is described as a study in relapse prevention, although the patients had to be improved rather than in remission at entry to the study. Separate study of the minority of patients (17% of the originally treated sample) who had become symptom free during the initial treatment phase would have been of interest, but these data were not provided.

The attrition rate was high, and this somewhat underestimates the utility of inferences that can be made. Nevertheless, the study provides fairly convincing evidence for the superiority of fluoxetine over placebo in preventing deterioration over a period of 1 year. This is useful to know. However, the study also confirms that, for most bulimic patients, such drug treatment alone with frequent contact was not associated with high remission rates or lasting major benefit, even among the small minority of patients who persisted for the full year. On average, patients deteriorated during follow up in both the fluoxetine and placebo groups. As the authors note, it seems that most patients with BN will need psychological treatment if they are to be helped to get better and remain better.

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Fluoxetine vs placebo for bulimia nervosa§

<table>
<thead>
<tr>
<th>Outcomes</th>
<th>Fluoxetine</th>
<th>Placebo</th>
<th>Absolute rate difference (95% CI)</th>
<th>NNT (CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Relapse rate at 3 months</td>
<td>19%</td>
<td>37%</td>
<td>18% (1 to 35)</td>
<td>6 (3 to 100)</td>
</tr>
<tr>
<td>Relapse rate at 6 months</td>
<td>29%</td>
<td>43%</td>
<td>14% (~7 to 35)</td>
<td>Not significant</td>
</tr>
<tr>
<td>Relapse rate at 12 months</td>
<td>33%</td>
<td>51%</td>
<td>18% (~8 to 42)</td>
<td>Not significant</td>
</tr>
</tbody>
</table>

§Abbreviations defined in glossary; NNT and CI calculated from relapse rate differences, which were derived from Kaplan Meier survival curves.
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