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The Efficacy and Safety of Fluoxetine Delayed-Release 90 mg/Weekly in Psychiatry: An Evidence-Based Mini-Review

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Abstract

Context: Fluoxetine, a selective serotonin reuptake inhibitor (SSRI), is widely used in the treatment of various psychiatric disorders. While the standard therapeutic dose of fluoxetine is typically 20 - 60 mg per day, slow-release higher doses, such as 90 mg/weekly and more recently 180 mg/weekly, have been explored to assess their potential benefits in certain psychiatric conditions. This mini-review aims to evaluate the evidence regarding the effects, efficacy, and safety profile of fluoxetine at a dosage of 90 mg in psychiatry.

Evidence Acquisition: A comprehensive literature search was conducted using electronic databases (PubMed and Embase) to identify relevant studies published until July 2023. Studies investigating the use of fluoxetine at a dosage of 90 mg/week in psychiatric conditions were included. The identified studies were critically appraised for their methodology and quality.

Results: Limited research has specifically examined the effects of fluoxetine at a dosage of 90 mg/week in psychiatry. However, some studies have investigated this dosage form and provided insights into its potential efficacy in treating certain psychiatric conditions, such as major depressive disorder (MDD), obsessive-compulsive disorder (OCD), premature ejaculation, and premenstrual dysphoric disorder. These studies have shown that compliance with weekly fluoxetine was better than with once-daily dosing.

Conclusions: Once-weekly dosing may be effective in psychiatry, improving compliance and enhancing psychological well-being.

Keywords: Efficacy, Fluoxetine, Once-Weekly, Safety

1. Context

Fluoxetine is a selective serotonin reuptake inhibitor (SSRI) with several indications for psychiatric disorders. It may reduce anxiety and improve sleep, mood, appetite, and energy levels (1). Fluoxetine and its active metabolite, norfluoxetine, have long elimination half-lives of 4 - 6 days and about 9 days, respectively, allowing for less frequent dosing. This relatively long half-life has enabled the development of a delayed-release (enteric-coated) formulation containing 90 mg of fluoxetine per capsule for once-weekly oral administration (2).

A once-weekly enteric-coated formulation of fluoxetine offers a new option for this drug, which has been found effective in treating various psychiatric disorders such as depression, panic disorder, obsessive-compulsive disorder (OCD), eating disorders, premenstrual dysphoric disorder, and premature ejaculation based on studies. This once-weekly treatment strategy has provided a convenient alternative for many patients during long-term treatment of psychiatric disorders. It might also improve the outcome of continuation treatment and medication adherence (3).

The purpose of this review is to comprehensively assess the efficacy and safety of fluoxetine 90 mg in psychiatric disorders.

2. Evidence Acquisition

For this narrative review, relevant articles published from 1998 to July 2023 were searched in the Web of Science, Embase, Google Scholar, and PubMed databases. The search was limited to studies published in the English language. The keywords used in titles and abstracts were "fluoxetine 90 mg," "once-weekly," "safety," "efficacy," and "psychiatric disorders." References cited in the articles were also used to find other relevant studies.

The inclusion criteria encompassed any type of study, including reviews, systematic reviews, clinical trials, and case reports that examined the efficacy and safety of fluoxetine 90 mg in psychiatry. Two reviewers independently reviewed the titles and abstracts of the articles for relevant information, and any discrepancies were resolved by consulting the first author. Duplicate records were then removed (Figure 1). Each of the selected articles was evaluated based on the 10 evaluation questions provided by Yang and Solomon (4).

3. Results

3.1. Studies

In total, 20 studies met the inclusion criteria (Table 1).

3.2. Psychiatric Disorders

3.2.1. Major Depressive Disorder (MDD)

Major depressive disorder (MDD) is often a relapsing and chronic disease that requires maintenance treatment. Daily pharmacotherapy can lead to reduced adherence to completing the course of treatment in some patients. A once-weekly formulation of fluoxetine has recently become an alternative approach (14).

A randomized controlled trial (RCT) compared fluoxetine dosages ranging from 20 to 80 mg/day in patients with MDD. The results showed that the enteric-coated once-weekly formulation is safe, effective, and well-tolerated for the continuation treatment of depression in patients who responded to acute treatment with fluoxetine 20 mg/day. Higher doses (≥ 60 mg/day) were associated with greater improvement in depressive symptoms compared to lower doses (5).

Another study investigated the efficacy of enteric-coated fluoxetine 90 mg once weekly for maintenance treatment in patients whose depressive symptoms had responded to a daily dose of selective serotonin reuptake inhibitors (SSRIs) such as paroxetine, sertraline, citalopram, escitalopram, or fluoxetine. The results demonstrated that 79% of the patients tolerated and responded successfully, and 9.3% discontinued the medication due to ineffectiveness or relapse (6). One RCT was conducted to evaluate the effectiveness of once-weekly fluoxetine 90 mg on outpatients with MDD. Inclusion criteria were patients meeting DSM-IV criteria for nonpsychotic major depression, a modified 17-item Hamilton Rating Scale for Depression (HAM-D-17) score of ≥ 18, and a Clinical Global Impression-Severity of Illness scale (CGI-S) score of ≥ 4 for 13 weeks. Subsequently, 501 responders were randomized, double-blind, to treatment with once-weekly fluoxetine 90 mg, fluoxetine 20 mg daily, or placebo for 25 weeks. The results showed that 26% of patients using fluoxetine 20 mg daily experienced a relapse after 109 days, while relapse was seen in 37% of patients using fluoxetine 90 mg weekly after 105 days, and in 50% of placebo users after 86 days. This demonstrated the superior efficacy of weekly fluoxetine (with a significantly longer time to relapse of depressive symptoms) compared to placebo (7).

In the mentioned study, the observed side effects were not significantly different between the two groups. Impaired concentration and nervousness were the most observed adverse effects for the 90 mg dose compared to the 20 mg dose, occurring at rates of 8.9% vs. 1.6% and 13.7% vs. 6.3%, respectively (7).

According to a cohort study, enteric-coated fluoxetine 90 mg, administered in weekly or twice-weekly doses, is effective and well tolerated as a treatment strategy in the maintenance phase of MDD. It can be a suitable alternative for some patients during the long-term treatment of depression (15).

3.2.2. Obsessive-Compulsive Disorder (OCD)

Obsessive-compulsive disorder (OCD) is a chronic and long-term disorder characterized by repetitive, involuntary, and irrational thoughts or actions. The patient's resistance to these obsessions and compulsions causes anxiety (16).

In an open-label study, patients with treatment-resistant OCD received fluoxetine at dosages ranging from 40 to 100 mg/day. The results showed that higher doses (> 60 mg/day) led to significant reductions in OCD symptoms (17).

3.2.3. Panic Disorder

Panic disorder is a mental disorder characterized by mood and behavioral symptoms, accompanied by sudden episodes of intense anxiety, including palpitations, sweating, tremors, shortness of breath, and numbness (18). Previous studies have proven the

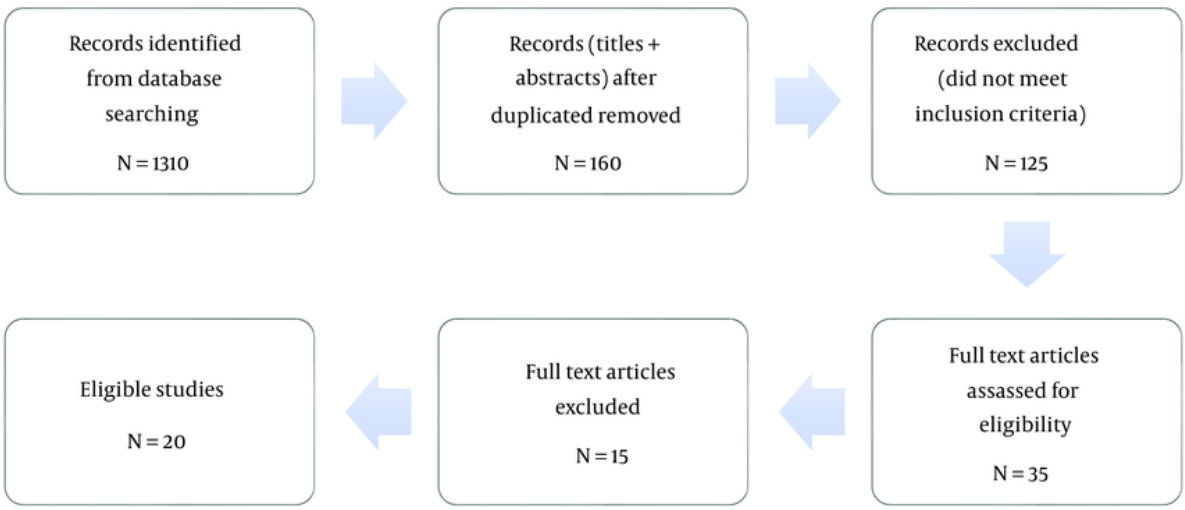

Figure 1. Flowchart of the article selection process

effectiveness of serotonin reuptake inhibitors in helping to treat the symptoms of panic disorder (18).

The results of a study revealed that patients with panic disorder who did not respond satisfactorily to a dose of 20 mg/day of fluoxetine may benefit from further dose increases (19).

According to one study, 10 patients who initially responded adequately to daily benzodiazepine and fluoxetine treatment for 1 month were then treated with a weekly dose of fluoxetine. The patients tolerated it well and remained symptom-free, with only one patient experiencing a recurrence of panic attacks after 18 months. This treatment regimen may save significant costs and serve as a suitable alternative method for treating panic disorder (9).

3.2.4. Binge Eating Disorder

Studies have demonstrated the effectiveness of fluoxetine in the acute management of bulimia nervosa (10, 20, 21).

A double-blind, flexible-dose study on sixty outpatients with a DSM-IV diagnosis of binge-eating disorder was conducted to assess the efficacy and safety of fluoxetine at doses ranging from 20 to 80 mg/day in the treatment of this disorder. The study evaluated binge-eating frequency, clinical global impressions-severity score, Hamilton Rating Scale for Depression, Body Mass Index, weight, and response categories. The results showed that after 6 weeks, there was a decrease in binge-eating frequency, severity of illness, and weight (10).

3.2.5. Sexual Effects

Serotonin reuptake inhibitor drugs are associated with sexual dysfunction, but the nature and frequency of such effects have not been systematically determined (8).

In one study, sexual performance was evaluated in depressed patients who responded well to a 13-week course of treatment with fluoxetine 20 mg daily in the acute phase of the disease. These patients then underwent maintenance treatment with fluoxetine 20 mg per day, fluoxetine 90 mg per week, or placebo for 25 weeks. The results showed that 51.6% of women and 40.6% of men recovered, 35.0% of women and 41.9% of men reported no change, and 13.4% of women and 17.4% of men experienced a decline in sexual performance. Data analysis revealed that worsening sexual function, often reported as difficulty achieving orgasm, was closely related to worsening depressive symptoms (8).

A study investigating the efficacy and safety of 90 mg of fluoxetine once weekly versus 20 mg daily in 80 patients with a mean age of 36 years who had premature ejaculation without obvious organic causes indicated that fluoxetine 90 mg per week may be considered a safe and effective treatment after a 4-month follow-up. Side effects such as insomnia, nausea, and headaches were

Table 1. Clinical Trial Studies With Once-Weekly Fluoxetine 90 mg in Psychiatry Disorders

Authors/Year	Country	Study Design	Objectives	Positive Findings	Quality Scores
Dinan ,2001 (5)	Ireland	RCT 90 mg enteric-coated fluoxetine versus 20 mg daily fluoxetine and placebo, during 25 weeks in 501 depressed patients who had responded to acute treatment with 20 mg daily fluoxetine.	Evaluating efficacy and safety of weekly treatment with enteric-coated fluoxetine in patients with major depressive disorder (MDD)	The once-weekly fluoxetine formulation provides an effective and tolerable treatment option for patients requiring extended depression therapy.	8
Miner et al., 2002 (6)	Ind	RCT once-weekly enteric-coated fluoxetine 90 mg for maintenance of treatment in 246 MDD patients for 12 weeks	Evaluating efficacy of once-weekly enteric-coated fluoxetine, 90 mg for maintenance of response in patients whose depressive symptoms have responded to daily dosing with selective serotonin reuptake inhibitors (SSRIs).	79% of these patients have successfully tolerated and responded.	7
Schmidt et al., 2000 (7)	Ind	RCT weekly regimen of fluoxetine 90 mg on 501 outpatients with MDD for 25 weeks	Evaluating the safety and effectiveness of a new formulation of once weekly enteric-coated fluoxetine (90 mg) during the continuation treatment of MDD	Superior efficacy of weekly fluoxetine (having a significantly longer time to relapse of depressive symptoms) compared with placebo was demonstrated.	8
Michelson et al., 2001 (8)	Ind	RCT fluoxetine 90 mg once weekly in 501 depressed patients for 25 weeks	Evaluating changes in sexual function during acute and six-month fluoxetine therapy	51.6% of women and 40.6% of men recovered and 35.0% of women and 41.9% of men reported no change.	7
Emmanuel et al.,1999 (9)	South Carolina	RCT fluoxetine at doses ranging from 10 to 60 mg administered once weekly in 10 panic patients for 26 months.	Evaluating the efficacy of once-weekly dosing of fluoxetine in the maintenance of remission in panic disorder	Patients tolerated the medicine well and were in a state of fear.	7
Arnold et al., 2002 (10)	USA	RCT fluoxetine 20 to 80 mg/day in the treatment of binge-eating disorder in 60 patients after 6 weeks	Assessing the efficacy and safety of Ffluoxetine in the treatment of binge-eating disorder	51.6% of women and 40.6% of men recovered.	9
Manasia et al., 2003 (11)	Spain	RCT 90 mg weekly versus 20 mg daily fluoxetine in the treatment of premature ejaculation without obvious organic causes in 80 patients after 7 months	Comparing the efficacy and side effects of 90 mg fluoxetine once weekly versus 20 mg fluoxetine as single oral therapy for patients complaining of premature ejaculation without evident organic causes.	Fluoxetine 90 mg once weekly may be considered as a safe and effective treatment after 4-month follow-up.	7
Mattos et al., 2008 (12)	Brazil	RCT fluoxetine 90 mg once weekly with tadalafil 20 mg in patients suffering from lifelong premature ejaculation in 60 patients after 3 months	Evaluating the association of a phosphodiesterase-5 inhibitor, tadalafil, and a selective serotonin reuptake inhibitor (SSRI), fluoxetine, in prolonging the intravaginal ejaculatory latency time (IELT) in men with lifelong premature ejaculation	Intravaginal ejaculation latency time in men with premature ejaculation was increased with fluoxetine plus tadalafil.	8
Miner et al., 2002 (13)	Ind	RCT fluoxetine 90 mg Enteric-coated, 14 and 7 days before menstruation during the luteal phase for 3 cycles in 257 patients	Evaluating the efficacy and tolerability of enteric-coated fluoxetine 90 mg given once or twice during the luteal phase for the treatment of PMDD.	Fluoxetine 90 mg Enteric-coated is well-tolerated and effective.	8

Abbreviation: RCT, randomized clinical trial.

reported, but no significant difference was observed between the two groups (11).

Another RCT was conducted on sixty patients suffering from lifelong premature ejaculation to investigate the effectiveness of tadalafil and fluoxetine in premature ejaculation. Fluoxetine 90 mg or placebo was given once weekly, and tadalafil 20 mg or placebo was administered 36 hours before intercourse with a fixed partner. Patients were followed up for 3 months. The combination of fluoxetine plus tadalafil significantly increased intravaginal ejaculation latency time in men with premature ejaculation compared to either drug alone or placebo (12).

3.2.6. Premenstrual Dysphoric Disorder

Premenstrual symptoms in women can cause functional impairment. Over the past decade, a significant number of well-designed placebo-controlled studies have investigated the efficacy of several SSRIs as effective first-line treatments for this disorder (22).

Clinical trials have reported the efficacy of fluoxetine in diminishing symptoms during both the luteal and follicular phases of the menstrual cycle (13, 23, 24).

It has been demonstrated that many of the symptoms of premenstrual dysphoric disorder (PMDD) are limited to the luteal phase of the menstrual cycle. Therefore, a multicenter, randomized, double-blind, placebo-controlled, parallel-group trial was conducted to investigate the efficacy and tolerability of fluoxetine 90 mg, enteric-coated, administered 14 and 7 days before menstruation during the luteal phase for 3 cycles (13).

The findings of this study showed that the administration of fluoxetine 90 mg with enteric coating on days 7 and 14 of the luteal phase of the menstrual cycle for the treatment of PMDD is well-tolerated and effective (13).

3.3. Medication Adherence

Studies have shown that adherence to treatment in patients receiving daily fluoxetine for maintenance treatment decreased over time, whereas compliance with weekly fluoxetine was better than with once-daily fluoxetine (25). According to one study, the compliance rate for patients assigned to daily fluoxetine treatment was 85.4%, compared to 87.5% for those treated with weekly fluoxetine (24). This difference was not significant. Another study revealed that compliance with fluoxetine 90 mg once weekly was 99% at the onset and 96% at the end (26).

3.4. Safety Profile

Higher doses of fluoxetine may be associated with an increased risk of adverse effects. Common side effects include gastrointestinal disturbances, insomnia, and sexual dysfunction. However, the incidence and severity of adverse effects do not appear to differ significantly between standard doses and higher weekly doses (27).

One study showed that fluoxetine 90 mg once weekly generally has significant efficacy and tolerability. Side effects such as anxiety, headache, and insomnia were responsible for ten patients dropping out of the treatment (27.74%) (26).

A case report study showed that a new once-weekly formulation of fluoxetine caused a skin rash in a female patient with schizophrenia and depression, which improved well with a daily course of fluoxetine. Therefore, side effects should be considered when switching patients from daily to weekly fluoxetine treatment (28).

In the mentioned clinical trials, the incidence of side effects such as diarrhea, nervousness, and abnormal thoughts was observed with fluoxetine 90 mg weekly (3, 29).

A case series study described the use of fluoxetine at doses of 90 to 180 mg/week in hemodialysis patients. According to the study, weekly fluoxetine can be considered a reasonable therapeutic option for hemodialysis patients who have had a partial or insufficient antidepressant response. In this study, side effects such as restlessness, dry mouth, sedation, and lightheadedness were reported, which limited the tolerance of the 180 mg dose in some individuals (30).

4. Conclusions

Limited evidence suggests that fluoxetine at a dosage of 90 mg/week may have potential benefits in treating certain psychiatric conditions such as MDD, OCD, premature ejaculation, and premenstrual dysphoric disorder. Table 1 presents summaries of studies using fluoxetine 90 mg in psychiatric disorders. However, further well-designed studies are needed to establish its efficacy and safety profile at this specific dosage. Clinicians should carefully consider the risk-benefit ratio when prescribing higher doses of fluoxetine in psychiatric practice.

It is not entirely clear whether once-weekly fluoxetine protects against relapse as effectively as once-daily fluoxetine. Additionally, the effect of changes in gastrointestinal transit time on the pharmacokinetic properties of weekly fluoxetine is not known.

4.1. Disclaimer

This mini-review is based on available evidence up until July 2023 and should not replace clinical judgment or individualized treatment decisions.

Footnotes

Authors' Contribution: N.M., contributed to the study design; M.P. and N.M., contributed to the literature search; and writing the original manuscript with support from M.M. All of the authors reviewed the studies.

Conflict of Interests Statement: First and second authors are this journal's reviewers.

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