Original Article

Comparison of the Effect of Sertraline and Escitalopram on the Treatment of Major Depressive Disorder in Hemodialysis Patients: A Randomized Controlled Trial

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Abstract

Background: We decided to compare the effects of sertraline and escitalopram in the treatment of major depressive disorder in hemodialysis patients.

Materials and Methods: In this single-blind randomized clinical trial, 100 patients with End-Stage Renal Disease (ESRD) undergoing hemodialysis with a Beck Depression Inventory (BDI) score greater than 15 who were not using medication for depression were included in the study. Then randomly assigned to two groups: (one receiving sertraline and one receiving escitalopram). Both groups were monitored using the Beck questionnaire at the end of the first, second, and third months. Additionally, side effects, treatment compliance, and mortality were compared between the two groups.

Results: In total, 100 patients with ESRD were included in the study (48 in the sertraline treatment group and 52 in the escitalopram treatment group). The results indicate that in both treatment groups, depression rates significantly decreased over time with medication (P<0.001). Comparing the depression scores over time revealed that the effect of sertraline and escitalopram in reducing depression was not significantly different. However, the depression score in the sertraline group was slightly lower than that in the escitalopram group, although this difference was not statistically significant. Side effects, treatment compliance, and mortality were comparable between the two groups.

Conclusion: In general, both sertraline and escitalopram significantly reduced the score of depression in patients, but sertraline in reducing the depression score was greater than that of escitalopram, although this difference was not significant.

Keywords: Depression, Hemodialysis, Escitalopram**,** Sertraline

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Introduction

Improving the quality of life is paramount for hemodialysis (HD) patients. Major depressive disorder stands out as one of the most prevalent psychiatric disorders among individuals with end-stage renal disease (ESRD) HD treatment[1]. The prevalence of depression, depending on the methodology employed, ranges from 20% to 40%[2,3]. It is closely associated with diminished quality of life, heightened suicide risk, and increased mortality rates[4]. Furthermore, the commencement of hemodialysis represents a significant alteration in daily functioning, often exacerbating psychiatric symptoms.

Consequently, it is recommended to screen for depression and anxiety at the onset of treatment[5]. Depression has long been recognized as a prominent concern for the psychological well-being of ESRD patients. Characterized by feelings of helplessness, hopelessness, disability, and grief, these symptoms, though prevalent in depression, may also manifest in other psychiatric disorders or even in individuals without underlying mental health issues[6].

According to the Diagnostic and Statistical Manual of Mental Disorders, 5th edition (DSM-V), the diagnosis of major depressive disorder (MDD) requires the presence of a combination of mood and somatic symptoms persisting for at least two weeks[7]. It is important to note that the criteria outlined in DSM-V for MDD diagnosis often overlap with symptoms related to uremia[6,7]. Many studies employ various assessment tools, such as the Beck Depression Inventory (BDI), Children Depression Inventory (CDI), Hamilton Depression Score, Zung Self-rating Depression Scale, Short Form Survey (SF-36), and Kidney Disease Quality of Life Questionnaire (KDQOL), to evaluate depression in ESRD patients. A high prevalence of depression is observed when the BDI score is ten or higher, and a score of 15 or higher demonstrates high sensitivity and specificity for diagnosing depression.

Treatment options for depression can be categorized into drug and non-drug interventions. Selective serotonin reuptake inhibitors (SSRIs), including citalopram, fluoxetine, fluvoxamine, paroxetine, and sertraline, are recommended for depression treatment. However, further studies are required to assess the efficacy of these medications, specifically in HD patients[8-11]; non-drug treatments encompass psychotherapy, Cognitive and Behavioral Therapy (CBT), and repeated hemodialysis. SSRIs are generally considered the first-line drug treatment for HD patients with depression due to their liver-based clearance. Sertraline, in particular, is favored for its lower side effects and higher effectiveness compared to fluvoxamine[12]. A randomized clinical trial also mentioned the higher efficacy of treatment with sertraline than CBT[13]. Studies on citalopram and escitalopram are limited, with concerns arising about their use due to their potential to prolong the QT interval[14]. HD patients take many drugs, so minimal drug interaction is one of the important factors in drug selection. Escitalopram has lower drug interaction than other SSRIs. Considering the pharmacodynamics and pharmacokinetics of antidepressant drugs and the fact that sertraline and escitalopram do not require additional dosing adjustments after hemodialysis[15,16]. These two medications were chosen for our study.

Methods

In this double-blinded Randomized Clinical Trial (RCT), we selected 132 End-Stage Renal Disease (ESRD) patients who had undergone regular weekly hemodialysis for a minimum of three months at Imam-Hossein Hospital and Shohada Gomnam in Tehran between 2020 and 2022. Before the commencement of the study, we obtained ethical approval from the ethics committee of Shahid Beheshti Medical University in Tehran, Iran (IR.SBMU.MSP.REC.1399.554).

The inclusion criteria were as follows: a diagnosis of major depressive disorder according to DSM-V criteria in hemodialytic patients, willingness to participate in the study, and age above 21. Exclusion criteria included the presence of other psychiatric disorders, excluding substance dependency other than MDD, patients unable to tolerate treatment due to drug complications, incomplete data, patients receiving treatment for MDD

in the last three months, life expectancy less than 12 months, contraindicated medications such as warfarin, candidates for kidney transplant, and individuals with hepatic failure.

Initially, patients underwent a DSM-V interview conducted by a psychiatrist. Upon confirmation of the diagnosis, patients completed a BDI questionnaire, with a score of 15 or above being the threshold for inclusion in the study. Subsequently, we employed block randomization with stratification, dividing the patients into two groups: Group 1 received escitalopram treatment, while Group 2 received sertraline treatment.

Group 1 began with a dosage of escitalopram (Ezipam, Abidi) at 10 mg, which was later increased to 20 mg over three months unless lower dosages resulted in symptom improvement or complications arose. Similarly, Group 2 received sertraline (Asentra, actover). Starting at 25 mg, the dosage can be increased to 200 mg during the three months unless lower dosages lead to symptom improvement or complications occur.

Two groups compare the incidence of new arrhythmia and increased QT interval based on EKG cardiovascular mortality. EKG was done in pretreatment and after three months. QT corrected (QTc) based on Bezetts formula was calculated. The QTc is considered prolonged if greater than 450 ms in males and 470 ms in females. In addition, the two groups compare side effects such as gastrointestinal problems and sleep disorders. According to the inclusion and exclusion criteria mentioned, eventually, 100 patients completed this study, and 32 patients were excluded.

According to the European Renal Best Practice (ERBP) guidelines, the recommended duration for SSRI treatment is typically 8 to 12 weeks. In our study, we followed patients for three months(14). Both groups completed the BDI questionnaire at one, two, and three months after initiating treatment. Routine laboratory examinations were conducted, and we monitored the side effects of both drugs and assessed adherence monthly. The sample size was calculated as below:

$N= [P1 (1-P1)] + [P2 (1-P2)] \times (Z\ 1-\alpha/2+ Z\ 1-\beta)^2 \rightarrow$
$N= (0.75 \times 0.25) + (0.5 \times 0.5) \times 7.8\ (P1-P2)^2 \quad (0.25).$
$\rightarrow N= 55$

Alpha= 0.05 Beta = 0.2
P1 (Escitalopram)= 0.75, P2 (Citalopram)= 0.5

Statistical analysis: Data analysis was done using SPSS version 25, and the efficacy of drugs was evaluated using the Chi-squared test and Fisher test. Scores before and after treatment were evaluated using the paired T-test and ANOVA test, and a P-value lower than 0.05 was considered.

Results

A total of 100 patients with ESRD undergoing chronic hemodialysis and experiencing depression successfully completed this study. Among them, 62 were female, and 38 were male. The patients' ages had a mean (standard deviation) of 59.82 (±13.76) years, ranging from 30 to 80. Out of the total participants, 48 were assigned to the sertraline treatment group and 52 to the escitalopram treatment group. Demographic information is summarized in (Table 1).

Regarding the duration of dialysis, 53% of patients had undergone hemodialysis for 1-5 years, and diabetes mellitus was the cause of ESRD in 52% of patients. Information on the duration and causes of ESRD is provided (Table 2).

Scores from the BDI questionnaire were assessed at four-time points: before treatment, at one month, two months, and three months after treatment initiation. The results indicate a significant improvement in scores during the treatment period ($P < 0.001$). When comparing escitalopram and sertraline, no statistically significant differences were observed, although the sertraline group showed a slightly greater improvement in BDI scores (Table 3).

The results also reveal that the effect of escitalopram and sertraline in men during treatment did not significantly differ. However, in women, during months two and three, sertraline demonstrated significant efficacy compared to escitalopram (Table 4). Age did not emerge as a differentiating factor between the two groups, with both drugs exhibiting similar effectiveness in improving depression across all age groups (Table 5).

Table 1. Demographic information of patients.

Variable		Total (100) N (%)	Sertraline (48) N (%)	Escitalopram (52) N (%)	p-value
Gender	Female	38 (38)	19 (39.6)	19 (36.5)	0.91
	Male	62 (62)	29 (60.4)	33 (63.5)	0.47
Age	30-49	26 (26)	13 (27.1)	13 (25)	0.84
	50-69	50 (50)	22 (45.8)	28 (53.8)	0.06
	≥70	24 (24)	13 (27.1)	11 (21.2)	0.12
Education	Under diploma	55 (55)	27 (56.3)	28 (53.8)	0.65
	Diploma	38 (38)	18 (37.5)	20 (38.5)	0.22
	University	7 (7)	3 (6.2)	4 (7.7)	0.69
Marital status	Married	96 (96)	44 (91.7)	52 (100)	0.22
	Single	4 (4)	4 (8.3)	0	0.14

Table 2. Clinical characteristics of patients.

Variable		Total N (%)	Sertraline N (%)	Escitalopram N (%)	p-value
Time of ESRD	<1 year	7 (7)	5 (10.4)	2 (3.8)	0.06
	1-5 years	53 (53)	27 (56.3)	26 (50)	0.52
	>5 years	40 (40)	16 (33.3)	24 (46.2)	0.059
Cause of ESRD	Diabetes mellitus	52 (52)	23 (47.9)	29 (55.8)	0.12
	Hypertension	32 (32)	14 (29.2)	18 (34.6)	0.24
	Other	16 (16)	11 (22.9)	5 (9.6)	0.06

Table 3. Comparison of the mean BDI scores between two groups during follow-up.

BDI score	Sertraline Mean±SD	Escitalopram Mean±SD	p-value
Before treatment	20.18 (±5)	20.21 (±5.41)	0.98
1 month after treatment	19.16 (±4.46)	19.98 (±4.82)	0.38
2 months after treatment	17.39 (±4.34)	18.76 (±4.62)	0.13
3 months after treatment	15.87 (±4.39)	17.25 (±4.01)	0.10
Comparison during treatment	**P<0.001**	**P<0.001**	0.32

Table 4. Comparison mean BDI score between two groups according to gender.

Time of BDI score evaluating	Gender	Sertraline Mean±SD	Escitalopram Mean±SD	p-value
One month	Male	18 (±3.92)	17.39 (±2.13)	0.94
	Female	20.94 (±4.74)	23.52 (±6.06)	0.15
Two months	Male	16.65 (±3.98)	16.87 (±2.45)	0.78
	Female	18.52 (±4.73)	22.05 (5.64)	**0.04**
Three months	Male	15.27 (±4.19)	15.63 (±2.4)	0.67
	Female	16.78 (±4.64)	20.05 (±4.71)	**0.03**

No significant differences were found between the two groups based on education levels, with depression showing similar improvement across all educational backgrounds. Additionally, no disparities were detected between the two groups based on the time of initiation of hemodialysis. However, in patients with a longer history of renal failure, the effect of sertraline appeared to increase, albeit not to a statistically significant degree. When analyzing patients with different causes of renal failure, no differences were found when diabetes mellitus was the cause. However, in patients where renal failure resulted from hypertension, sertraline yielded significantly better BDI scores after three months, and in patients with other

Table 5. Comparison mean BDI score between two groups according to age.

Time of BDI score evaluating	Age group	Sertraline Mean±SD	Escitalopram Mean±SD	p-value
One month	30-49	18.84 (±3.53)	19.30 (±2.89)	0.71
	50-69	18.42 (±4.46)	19.46 (±4.72)	0.44
	≥70	21.06 (±5)	22.09 (±6.47)	0.66
Two months	30-49	17.30 (±3.49)	18.23 (±3.41)	0.50
	50-69	16.76 (±4.63)	18.03 (±4.43)	0.33
	≥70	18.76 (±4.71)	21.27 (±5.74)	0.25
Three months	30-49	16 (±3.48)	16.92 (±3.04)	0.47
	50-69	15.52 (±4.94)	16.57 (±4.04)	0.41
	≥70	16.61 (±4.53)	19.36 (±4.54)	0.15

causes (e.g., systemic lupus erythematosus, trauma, congenital diseases), escitalopram demonstrated better BDI scores, though not statistically significant.

Regarding adverse drug reactions, no significant differences were observed between the two groups. While the sertraline group had a lower incidence of sleep disorders, this difference did not reach statistical significance. Importantly, there were no recorded mortalities during the study. Electrocardiograms were conducted both before treatment and after three months. The corrected QT interval (QTc), calculated using Bezetts formula, did not show any prolongation in either of the two groups, and the mean values in both groups were similar. Adherence to medications was also comparable.

Discussion

The results of our study involving 100 patients with End-Stage Renal Disease (ESRD) undergoing chronic hemodialysis and experiencing depression demonstrate a profound prevalence of depression, affecting 75% of the patient population. Figure 1 exceeds the rates reported in other studies[17]. This may relate to differences in study populations and socioeconomic status.

Analyzing the treatment outcomes, we observed significant improvements in depression scores across the entire cohort during the study (P<0.001). When comparing the two antidepressants, sertraline and escitalopram, while the sertraline group displayed slightly greater improvements in BDI scores, this difference did not reach statistical significance. However, when examining subgroups, we found that sertraline had notable efficacy in women during the second and third months of treatment. Furthermore, in patients whose renal failure was attributed to hypertension, sertraline led to significantly better BDI scores after three months.

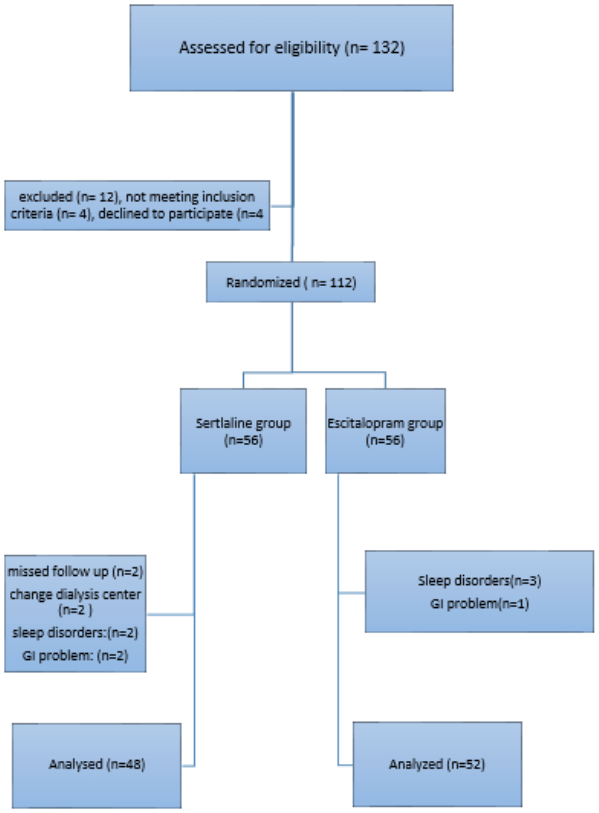

Figure 1. CONSORT flow diagram.

Our findings are consistent with previous research. Bhavyashree Laxman Naik and colleagues reported that escitalopram was effective in reducing depressive symptoms in hemodialytic patients, mirroring our study's outcomes[18]. Alicja Kubanek's study in 2021 confirmed the safety of sertraline in hemodialytic

patients, which aligns with our findings of sertraline's safety and efficacy[19]. Rajnish Mehorta and colleagues compared sertraline and cognitive-behavioral therapy (CBT) in hemodialytic patients and found that sertraline had a significant effect in treating MDD, similar to our results, although our study specifically aimed to compare sertraline and escitalopram[20].

There are few pieces of research available specifically on ESRD patients, however, in a new metanalysis by Yin et al. which concluded 30 studies, comparing escitalopram with other antidepressant drugs including sertraline the results showed that escitalopram was significantly more effective in terms of acute response and remission compared to sertraline in MDD[21]. Notably, Karin Friedli and colleagues found no difference between sertraline and placebo in treating depressive hemodialytic patients, contrasting with our results demonstrating sertraline's effectiveness[17]. Suetonia C Palmer and colleagues studied various antidepressant drugs, including sertraline, and concluded that these treatments improved depression scores but had no impact on the quality of life of depressive hemodialytic patients[2]. In contrast, our study found that BDI scores improved, and symptoms were better than the study's outset. Nagler EV and colleagues reported that escitalopram had no significant effect compared to a placebo, which diverged from our findings evaluating the impact of escitalopram[22]. Hosseini SH conducted a study on citalopram and psychotherapy, both of which reduced HADS and anxiety scores[23]. This contrasts our study, which specifically compares sertraline and escitalopram. Atalay H found that sertraline improved the health-related quality of life (HRQoL) and BDI scores in peritoneal dialysis patients, mirroring our study's outcomes[24]. Turk S treated depressive hemodialysis patients with sertraline and reported improved quality of life, aligning with our study's findings[25]. In a study by Assimon et al. on 30932 ESRD patients, it was concluded that higher QT-prolonging potential SSRIs like escitalopram and citalopram, compared to lower QT-prolonging potential drugs such as sertraline, were associated with higher sudden cardiac deaths[26].

Our study has some limitations. First of all, due to financial and human resources limitations, we were unable to conduct a double-masked study. Second, we had difficulties following the participants therefore there are some missing data. However, this study has also strengths, we compared two popular antidepressant medications in ESRD patients.

Conclusion

Our study involving patients with ESRD undergoing chronic hemodialysis and experiencing Major depressive disorder revealed that both sertraline and escitalopram significantly reduced the mean depression scores in all comparison groups. While, in most cases, sertraline exhibited a greater reduction in depression scores compared to escitalopram, this difference did not reach statistical significance. Notably, sertraline showed significant efficacy in women during the second and third months of treatment and led to significantly better BDI scores in patients with hypertension-induced renal failure after three months. These results highlight the potential benefits of sertraline and escitalopram in managing depression among hemodialysis patients. Further research is warranted to validate these findings and explore the nuances of antidepressant efficacy in this patient population.

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Conflict of interest

The authors further declare that they have no conflict of interest.

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