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Efficacy and safety of escitalopram: an observational study on major depressive disorder in Bangladesh

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Abstract

Background: *Major Depressive Disorder (MDD) is a mood disorder characterised by the occurrences of one or more major depressive episodes. Escitalopram is a selective serotonin reuptake inhibitor (SSRI) often used to treat it.* ***Objectives:*** *To find out the efficacy and safety of escitalopram in patients with MDD.* ***Materials and Methods:*** *This was a prospective, observational, 12 weeks follow-up study of patients with Major Depressive Disorder (MDD) conducted in the Department of Psychiatry, Rajshahi Medical College, for six months beginning in January 2022 and ending in June 2022. A sample of 84 participants (≥ 18 years of age) with MDD were recruited through systematic random sampling. Data were collected through face to face using a semi-structured questionnaire. The DSM-5 diagnostic criteria for MDD were used to identify depression. To determine the severity of depression, the Montgomery-Asberg Depression Rating Scale (MADRS) was employed.* ***Results:*** *The mean (±SD) MADRS total score at baseline was 21.74 (±6.15); which was decreased in subsequent follow-up, and at 12-week score was 9.71 (±5.22). A paired sample t-test was done to measure the level of significance. In terms of statistics, the difference was quite significant (p 0.001). In this study, 49 (58.3%) respondents experienced remission. The common adverse effects were dizziness 55(65.50%), headache 49 (58.30%), and nausea 25(29.80%).* ***Conclusion:*** *Escitalopram was efficacious as it reduced more than 50% of the baseline score, and the remission rate was 58.3% after 12 weeks of treatment. The remission rate was 58.3% after 12 weeks of treatment. Escitalopram also had high tolerability because adverse events related to escitalopram therapy were generally less. So, this study concluded that escitalopram could be used as an effective and well-tolerant antidepressant drug for treating major depressive disorder.*

Keywords: *Major depressive disorder, escitalopram, Bangladesh*

Introduction

Major Depressive Disorder (MDD) is a mood disorder characterised by the occurrences of one or more major depressive episodes and the absence of any history of manic, hypomanic, or mixed episodes. There are often feelings of low self-esteem, guilt, self-reproach, withdrawal from interpersonal contact, and somatic symptoms such as eating and sleep disturbances. Major depressive disorder has a prevalence of 10-15% worldwide (1). According to the National Mental Health Survey Bangladesh 2018-1019, the overall prevalence of depressive disorders in Bangladesh is 6.7% (5.8-7.6), and women (7.9%) suffer more from MDD than men (5.4%). The most often prescribed class of antidepressants is selective serotonin reuptake inhibitors (SSRIs). Among the SSRIs, escitalopram had a superior tolerability profile, with significantly fewer discontinuations of patients than other antidepressants. It has also been suggested that escitalopram has a better efficacy and safety profile than other SSRIs used in the treatment of MDD (2). The data regarding the efficacy and adverse effects of escitalopram was scarce in our Bangladeshi population. Therefore, the present study evaluated the efficacy of escitalopram by assessing clinical improvement. The adverse effects were also assessed during the treatment of MDD. So, the study might give an idea about the efficacy and adverse effects of escitalopram and might help psychiatrists and specialised physicians to select the proper drug for treating Major Depressive Disorder (MDD).

Materials and Methods

This was a prospective, observational, 12 weeks follow-up study of patients with Major Depressive Disorder (MDD) conducted in the Department of Psychiatry, Rajshahi Medical College, for six months from January 2022 to June 2022. The study had the following inclusion criteria: both genders aged ≥18 years, have sustained moderate-severe depression symptoms, meet DSM-5 criteria for a diagnosis of major depressive disorder, and Montgomery-Asberg Depression Rating Scale (MADRS) score: 7 or more. Patients with suicide risk, episodes of mania or hypomania, schizophrenia, bipolar disorder, substance abuse or dependence, cogitative impairment, hepatic impairment, pregnancy, taking anti-depressant drugs and lipid-lowering agents, and refusal to consent were excluded.

The sample size was calculated using the formula below:

$$n = \frac{[P\ (100-P\ ) + P\ (100-P\ )] \times (Z\ + Z_{\beta}\ ^{2}}{(P\ -P\ )^{2}}$$

The sample size was determined by using hypothesis testing for the difference between two proportions and it was calculated from the findings of a previous study (13). Firstly, in the department of Psychiatry, all the attending patients with MDD were listed then, a sample of 84 participants (≥ 18 years of age) with MDD were recruited. Every 3rd patient was selected by systematic random sampling technique Data was collected through face to face using a semi-structured questionnaire. Escitalopram 10 mg once daily was started in patients with MDD. Clinical improvement and tolerability of escitalopram were evaluated at 6 weeks and 12 weeks. Participants were told of the study's objectives, and their written informed permission was obtained. The Rajshahi Medical College's (RMC) Ethical Review Committee (ERC) gave its approval (IRB no. RMC/IRB/2022/37) to the study. Collected data were subjected to appropriate descriptive statistics of different variables using frequency and

percentage, mean, and standard deviation. Paired samples t-test was used for quantitative data and a p-value of <0.05 was considered statistically significant. Statistical Package for the Social Sciences (SPSS) version 24 was applied to analyze the data.

Results

The highest number of respondents were in the age group 30 years, which occupied 42 (50.00%), and the lowest number of respondents were in the age group 30-40 years, which occupied 18 (21.43%). Females were 48 (57.1%) and males were 36 (42.9%). In this study, 42 (50.0 %) were married, and only 6 (7.1%) were divorced. Regarding educational status, 37 (44.0%) were graduates & above, 24 (28.6%) were HSC, 22 (26.4%) were SSC & 1 (1.2%) were educated through primary education (Table 1). 29 (34.5%) respondents had a positive smoking history (Figure 1). The study revealed a considerable number of respondents (29.00%) had a previous history of depression (Figure 2). However, in only 2.40% of cases had positive family history among them (Figure 3).

The mean MADRS baseline score was 21.74 (±6.15). At the first follow-up (at 6 weeks), the score was 17.57 (±5.72) and at the second follow-up (at 12 weeks), the score was 9.71 (±5.22). (Table 2). The significant t-test results found in the baseline score and 2nd follow-up score ($p < 0.001$) imply that the treatment with this drug is to be effective. It was observed that 49 (58.3%) respondents experienced remission (Table 3). The predominant adverse effect following treatment was dizziness 55(65.50%) followed by headache 49 (58.30%). Other adverse effect shows in Table 4.

Table 1: Socio-demographic characteristics of the study participants (n=84)

Variable	Frequency	Percent (%)
Age in years		
< 30 years	42	50.00
30-40 years	18	21.43
≥ 40 years	24	28.67
Mean ± SD	30.90 ±10.34	
Gender		
Male	36	42.90
Female	48	57.10
Marital status		
Married	42	50.00
Unmarried	36	42.90
Divorce	6	7.10
Occupational status		
Student	40	47.60
Housewife	23	27.40
Business	11	13.10
Service holder	4	4.80
Others	6	7.10
Educational status		
Graduate and	37	44.00

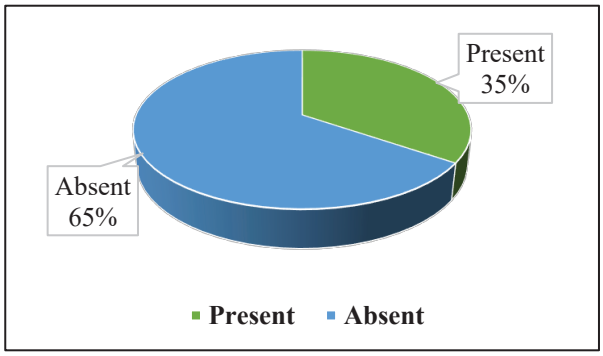

Fig 1. Pie chart showing the smoking history of the respondents

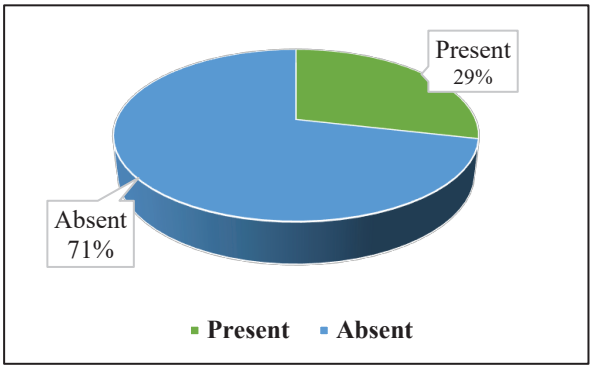

Fig 2. Pie chart showing the previous history of depression

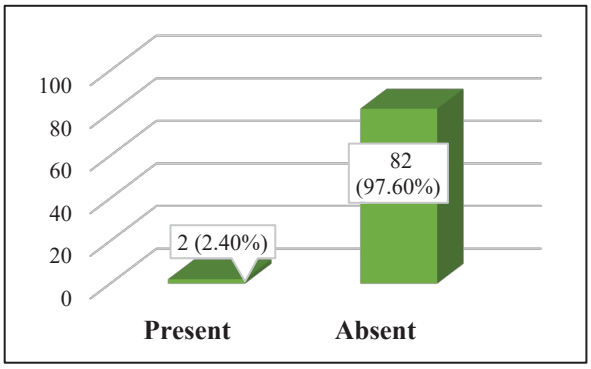

Fig 3. Bar diagram showing the family history of depression

Table 2: Montgomery Asberg Depression Rating Scale score at baseline, first follow-up (at 6 weeks), and second follow-up (at 12 weeks)

Montgomery Asberg Depression Rating Scale score	**Mean ± SD**	**P value**
Baseline score	21.74 ± 6.15	t =25.26
First follow up	17.57 ± 5.72	p <0.001
Second follow up	9.71± 5.22	

Table 3: Distribution of respondents by remission after 12 weeks of treatment (n=84)

Remission after 12 weeks of treatment	**Frequency**	**Percent (%)**
Remission occurred	49	58.30
Remission don't occurred	35	41.47
Total	84	100.00

Table 4: Adverse effects following treatment of the respondents (n=84)

Adverse effects	Present (%)	Absent (%)
Headache	49 (58.3%)	35 (41.7%)
Dizziness	55(65.5%)	29(34.5%)
Nausea	25(29.8%)	59(70.2%)
Weight gain	7(8.3%)	77(91.7%)
Sexual dysfunction	7(8.3%)	77(91.7%)
Diarrhea	1(1.2%)	83(98.8%)
Weakness	1(1.2%)	83(98.8%)
Restlessness	3(3. %)	81(96.4%)
Insomnia	9(10.7%)	75(89.3%)

Discussion

In this study, the majority of the patients were below 30 years of age. The mean age of the escitalopram-treated group was 30.90 (±10.34) with a range of 18-52 years. In a study in China reported that the mean age was 37.1 (±14.1) for the escitalopram-treated group & the minimum & maximum ages were 18 and 65 years respectively which was quite similar to the present study findings (3). In this study, more than half (57.1%) of the respondents were female. A study done by Huang (4) in 12 different countries found that females were 54.3% of escitalopram-treated group respondents, which was similar to our findings. This present study revealed that half (50%) of the respondents were married, just above two fifth (42.9%) were unmarried & some (7.1%) of them were divorced. In a study in Canada, exposure to depression doubled the proportion of transitions from married to separated or divorced status (5). In a study in Egypt found that 36.9% of married women had mild depression symptoms, and 1.9% had severe depression symptoms. The findings of these above-mentioned studies were not similar to our study findings (6).

In this study, among the respondents, nearly half (47.6%) were students, nearly 1/4th (27.4%) were housewives & only 13.1%, 4.8% & 7.1% were involved in business, services & other occupations respectively. A study in India revealed that the majority (41.2%) of college students were found to be suffering from moderate followed by mild (26.6%) depression. The findings were similar to this study (7). In this study among the participants, more than 2/5th (44 %) were graduates & above. An almost similar proportion was up to HSC (28.6%) & SSC (26.4%) & one (1.2%) had PSC level education. A study in Sweden reported that there was a significant change in the level of depressive symptoms over time: an increase from the first to later years in education and a decrease to levels similar to baseline after graduation and a year in the profession (8). The study findings were quite similar to our findings.

This present study revealed that among the participants more than 1/4th (28.6%) of respondents had a previous history of depression and only two (2.4%) of the respondents had a family history of depression. In a study in England reported that family history had a significantly earlier age of onset with the largest estimate for MDD onset before age 20 years (HR=2.2), whereas family history is not associated with MDD for onset after age 50 years (9).

This present study showed that among the

respondents, just above 1/3rd (34.5%) had a smoking history. In a study in Malaysia revealed that depression and anxiety were significantly associated with smoking (OR = 1.347) which is different from our study findings (10). This present study showed the mean (±SD) MADRS baseline score was (21.74±6.15), the 1st follow-up (after 6 weeks) visit revealed that the mean MADRS score (17.57 ± 5.72) and the second follow-up (after 12 weeks) visit was (9.71 ± 5.22). In India found that the mean MADRS score for escitalopram decreased on subsequent follow-up from the baseline of 32.08 and, was 24.11 after 1st week, 20.22 after 2nd week, 16.92 after the 4th week, 13.86 after 6th week & 11.24 at the end of 8th week which were quite similar with the present study findings (11).

A study in China revealed that the mean MADRS baseline score was (30.1±5.4) and the 2nd follow-up (after 8 weeks from baseline) score was (9.2±7.4) for those treated with escitalopram (3). The findings were quite similar to our study findings. The present study revealed that remission after 12 weeks of treatment occurred more frequently among the respondents (58.3%). In a study in China (3) reported that at the end of 8 weeks of treatment, the remission rate was 82% for the escitalopram-treated group which was quite different from the present study findings. Another study done by Patel et al revealed that at the end of 8 weeks of treatment, the remission rate for the escitalopram-treated group was 64.9%, which was quite similar to the present study findings (11).

Another study in North America reported that clinical remission, no remission, and loss of follow-up among the escitalopram respondents were 54.9%, 15.8%, and 29.3% respectively(4). The remission rate was almost similar to the present study findings, In Chinese study found that the remission rate for escitalopram monotherapy was 46.4%, after 7 weeks of treatment, which was quite similar to the present study findings (12).

In our study, dizziness, headache, nausea, weakness, weight gain, and insomnia were the most common side effects. Escitalopram side effects were reported in a study to be modest, and manageable, and no one has experienced any serious negative effects. Constipation and nausea were the most frequent adverse effects, followed by dry mouth, yawning, headaches, and palpitations12. These findings were consistent with the multicenter study of escitalopram in patients with depression in China as well as the present study findings. Mao found that most adverse events were mild to moderate in severity and transient. Nausea, dizziness, drowsiness, dry mouth, and headache were the adverse events with an incidence greater than 5% and which were not similar to the present study findings.

Therefore, this study showed advantages in efficacy and tolerability profiles. So, the present study might postulate that escitalopram could help to reduce the depressive symptoms of patients with Major Depressive Disorder (MDD) more effectively.

Conclusion

Major Depressive Disorder (MDD) is a disabling disorder associated with considerable comorbidities, risk of suicide & societal consequences. The study provided an overview of escitalopram, focusing on their efficacy & adverse effects in the management of MDD. In terms of efficacy, escitalopram was efficacious as it reduced more than 50% of the baseline score after 12 weeks of treatment. The remission rate was 58.3% after 12 weeks of treatment. Escitalopram also had high tolerability because adverse events related to escitalopram therapy were generally less. So, this study concluded that escitalopram could be used as an effective

and well-tolerant antidepressant drug for the treatment of major depressive disorder.

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Conflict of Interest: Nil

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