A comparative study on efficacy, safety and cost effectiveness analysis between vortioxetine and escitalopram in major depressive disorder

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Abstract

Major depressive disorder (MDD) is a prevalent and debilitating mental health condition. This study aimed to compare the clinical efficacy, safety, and cost-effectiveness of vortioxetine and escitalopram in the treatment of MDD among outpatients at NRI General Hospital, Guntur, Andhra Pradesh. A non-randomised interventional trial was conducted over eight months involving 180 patients diagnosed with MDD based on Diagnostic and Statistical Manual of Mental Disorders (DSM-5) criteria. Participants were equally divided into two groups, one receiving vortioxetine and the other escitalopram monotherapy. Clinical outcomes were assessed using the Hamilton Depression Rating Scale (HAM-D), and safety was evaluated using the World Health Organization (WHO) causality assessment scale. A pharmacoeconomic analysis was conducted using the incremental cost-effectiveness ratio (ICER). Both groups showed significant improvement in HAM-D scores ($p < 0.0001$), with no statistically significant difference in efficacy between the two treatments, although escitalopram demonstrated slightly greater symptom reduction (mean score reduction: 14.37 vs. 12.7). Vortioxetine, however, was associated with fewer and less severe adverse drug reactions. Cost-effectiveness analysis revealed escitalopram to be more economical than vortioxetine (average cost of ₹2129.44 vs. ₹3448.20 per patient), with a negative ICER indicating it as the more cost-effective option. These findings suggest that escitalopram is the more cost-effective antidepressant for MDD treatment in this study setting, while vortioxetine's favourable safety profile may offer advantages for patients prioritising tolerability, highlighting the importance of individualised treatment selection based on both clinical and economic considerations.

Keywords: major depressive disorder, escitalopram, vortioxetine, clinical efficacy, incremental cost-effectiveness ratio

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Introduction

Major depressive disorder (MDD) is a common, chronic, and recurrent mental health condition. In 2008, the World Health Organization (WHO) ranked it as the third leading cause of the global disease burden.[1] In India, the national mental health survey 2015–16 reported that nearly 15% of Indian adults require active intervention for one or more mental health conditions, with one in 20 individuals experiencing depression.[2] MDD is a highly prevalent psychiatric disorder, with a lifetime prevalence of 5–17%, averaging around 12%. Women are nearly twice as likely to be affected as men, a difference attributed to hormonal factors, childbirth, psychosocial stressors, and behavioural patterns. While the mean age of onset is approximately 40 years, an increasing incidence in younger individuals has been observed, likely due to substance abuse, including alcohol and other drugs.

MDD is characterised by a persistent low mood, loss of interest or pleasure in activities, and significant impairment in social functioning. Treatment options include both pharmacological and non-pharmacological approaches. MDD is believed to have a multifactorial aetiology, involving biological, genetic, environmental, and psychosocial factors. Initially, it was thought to primarily result from neurotransmitter abnormalities, particularly serotonin, norepinephrine, and dopamine, as evidenced by the effectiveness of antidepressants targeting these systems. However, more recent theories suggest that MDD is associated with complex neuroregulatory systems and neural circuits, leading to secondary disturbances in neurotransmitter function.[3] Antidepressants are widely used for managing MDD and are available globally. However, ongoing debate and concerns persist regarding their efficacy and safety.[4,5]

MDD is managed through pharmacological, psychotherapeutic, interventional, and lifestyle approaches. The initial treatment typically includes medications, psychotherapy, or a combination of both, which has been found to be more effective than either treatment alone. Electroconvulsive therapy (ECT) is the most effective treatment for severe depression.[6,7] Commonly prescribed antidepressants include selective serotonin reuptake inhibitors (SSRIs) such as fluoxetine, sertraline, citalopram, escitalopram, paroxetine, and fluvoxamine, which are first-line treatments. Serotonin-norepinephrine reuptake inhibitors (SNRIs) like venlafaxine, duloxetine, desvenlafaxine, and milnacipran are often used in patients with comorbid pain conditions. Other antidepressant classes include serotonin modulators (trazodone, vilazodone, vortioxetine), atypical antidepressants (bupropion, mirtazapine), tricyclic antidepressants (TCAs), and monoamine oxidase inhibitors (MAOIs). While MAOIs and TCAs are less commonly used due to side effects and overdose risk, mood

stabilisers and antipsychotics are sometimes added to enhance antidepressant effects. Psychotherapy, including cognitive-behavioural therapy (CBT) and interpersonal therapy, is beneficial, particularly when combined with medication.[8,9]

Comparing the efficacy and safety of antidepressants is essential due to the diverse treatment responses in MDD. With multiple drug classes available, including SSRIs, SNRIs, atypical antidepressants, and TCAs, understanding their relative effectiveness helps optimise treatment selection. Patients respond differently to medications, and some may require alternatives due to inadequate symptom relief or intolerable side effects. Comparative studies aid in identifying the most effective options while minimising trial-and-error prescribing, ultimately improving patient outcomes.[10-12]

Safety is equally important, as different antidepressants have distinct side-effect profiles, ranging from sexual dysfunction and weight gain to cardiovascular risks and overdose potential. Certain populations, such as the elderly or those with comorbidities, require careful drug selection to balance efficacy with safety. Comparative research, including meta-analyses and head-to-head trials, provides valuable evidence for clinicians, enabling personalised treatment plans that enhance adherence and improve overall quality of life for individuals with depressive disorders.[13-15]

Several comparative studies have evaluated antidepressant efficacy and tolerability across different populations, highlighting region-specific prescribing patterns and treatment outcomes.[16-18] In India, SSRIs, particularly escitalopram, are among the most commonly prescribed antidepressants due to their affordability, established efficacy, and favourable safety profile.[16,17] Newer agents such as vortioxetine have demonstrated comparable antidepressant efficacy to SSRIs, with potential advantages in tolerability and improvement of cognitive symptoms, although higher cost may limit their routine use in resource-constrained settings.[17] Indian clinical studies have also suggested improved treatment adherence with vortioxetine among patients experiencing fewer adverse effects.[16] Similarly, studies from other Asian populations, including China, report comparable efficacy of vortioxetine with additional benefits in cognitive and functional outcomes, while pharmacoeconomic factors continue to influence its broader adoption.[18] These findings emphasise the need for region-specific comparative and cost-effectiveness evaluations to guide optimal antidepressant selection.

In recent years, several antidepressants have been developed, including escitalopram, an SSRI introduced in 2002. It has been widely recognised for its efficacy and safety in treating patients with depressive disorders.[19,20] Vortioxetine, a newer multi-modal antidepressant, introduced in 2013, exerts its antidepressant effects by targeting six different pharmacological mechanisms. International studies have confirmed its effectiveness and favourable safety profile in the treatment of depressive disorders.[21,22]

Despite the widespread use of both escitalopram and vortioxetine in the treatment of depressive disorders, limited studies have directly compared their efficacy, safety and cost-effectiveness, particularly in the Indian population.[23,24] Given that pharmacokinetics and pharmacodynamics of drugs can vary across races and ethnicities, it is essential to generate region-specific clinical evidence to guide treatment decisions.

This study aims to address the gap in comparative research by evaluating the efficacy, safety and cost-effectiveness of escitalopram and vortioxetine in patients with depressive disorders from multiple perspectives. Understanding their effectiveness in the South Indian population will provide valuable insights into their therapeutic benefits, tolerability, and suitability for diverse patient groups. The findings will contribute to evidence-based treatment strategies, helping clinicians make informed decisions tailored to the specific needs of Indian patients with depression.

Methodology

Study design and objectives

This study was conducted on outpatients attending the Department of Psychiatry at NRI General Hospital, Guntur, Andhra Pradesh, India to compare the efficacy of vortioxetine and escitalopram in the management of MDD. The study design was a non-randomised interventional trial aimed at assessing both the clinical effectiveness, safety and pharmacoeconomic aspects of the selected antidepressant agents. The study spanned a duration of eight months, from November 2022 to June 2023.

Patient enrolment and diagnostic criteria

A total of 180 outpatients diagnosed with MDD were enrolled in this study. The diagnosis was established based on the Diagnostic and Statistical Manual of Mental Disorders, fifth edition (DSM-5 criteria).[25] These criteria define MDD through symptoms such as persistent depressed mood, loss of interest in activities, significant weight changes, sleep disturbances, psychomotor changes, fatigue, excessive guilt, diminished concentration, and suicidal ideation. To ensure diagnostic accuracy, qualified psychiatrists conducted comprehensive assessments, and only patients meeting DSM-5 criteria for a current major depressive episode were included.

Treatment group allocation

A total of 180 participants were systematically allocated to one of the two treatment arms, with 90 patients receiving vortioxetine monotherapy and 90 patients receiving escitalopram monotherapy. This division allowed for a direct comparison of efficacy, safety, and pharmacoeconomic outcomes. The selection process ensured uniformity in baseline characteristics between both groups to minimise confounding variables.

Inclusion and exclusion criteria[26]

The inclusion criteria required participants to:

- Be aged between 18 and 70 years, covering both adult and elderly populations.
- Provide written informed consent after receiving detailed information about study objectives, procedures, benefits, and risks.
- Be experiencing an active depressive episode, as defined by DSM-5.
- Be clinically evaluated to confirm that antidepressant therapy was appropriate, based on symptom severity and absence of prior treatment failure with vortioxetine or escitalopram.

Exclusion criteria were established to reduce potential confounding factors. Patients were excluded if they:

- Had a prior diagnosis of dementia at any stage, as cognitive impairment could interfere with depression assessment and treatment response.
- Were diagnosed with schizophrenia, as its neurobiological mechanisms and treatment approaches differ significantly from MDD.
- Had comorbid medical conditions or pharmacological contraindications that could interfere with the administration of either vortioxetine or escitalopram. This included severe hepatic or renal impairment, hypersensitivity to study drugs, ongoing MAOI therapy, or concurrent use of psychotropic medications.

Ethical considerations and patient monitoring[27]

Following recruitment, written informed consent was obtained from all the participants to ensure compliance with ethical research protocols. Patient anonymity was strictly preserved, following the guidelines of the Institutional Human Ethical Committee. Participants underwent periodic clinical assessments to evaluate treatment efficacy and adverse drug reactions (ADRs). Data collection was conducted through a structured patient case report form (CRF), and scheduled follow-up visits were implemented for continuous clinical outcome monitoring.

Pharmacoeconomic evaluation: cost-effectiveness analysis[28]

A pharmacoeconomic evaluation was conducted to determine the cost-effectiveness of vortioxetine and escitalopram in MDD treatment. This was assessed using the ICER, a key economic measure that compares the additional cost of one treatment relative to another against the corresponding difference in clinical effectiveness.

ICER=C. Vortioxetine−C. Escitalopram/ E. Vortioxetine−E. Escitalopram

where:

- C represents total treatment costs, including medication expenses, physician consultations, monitoring, and management of ADRs.
- E represents treatment effectiveness, measured using standardised clinical scale, i.e., HAM-D score reduction from the baseline.

A lower ICER value indicates that a treatment provides greater clinical benefits at a lower cost with high effect, making it the preferred cost-effective option. This analysis helps to determine which antidepressant offers better long-term economic value in routine clinical practice.

Safety assessment: adverse drug reactions[29]

The safety assessment of vortioxetine and escitalopram was conducted by monitoring the occurrence of ADRs and evaluating their causality using the WHO causality assessment scale. This scale classifies ADRs into categories such as:

- Certain – Strong evidence confirming the ADR is drug-related.
- Probable – A likely but unconfirmed association with the drug.
- Possible – The ADR might be drug-related, but other factors cannot be ruled out.
- Unlikely – The ADR is unlikely to be linked to the drug.
- Unclassified/ Unassessable – Insufficient data to determine causality.

ADRs were recorded through patient-reported symptoms, clinician observations, and objective clinical findings. The incidence rates of ADRs in both treatment groups were compared to determine which medication had a better safety profile. By employing the WHO causality assessment scale, the study ensured an objective, standardised approach to drug safety evaluation.

Statistical analysis[30]

Statistical analysis was performed using Student's t-test, a widely used parametric test for comparing the means of two independent groups. Data analysis was conducted using GraphPad statistical software, focusing on symptom severity reduction (specifically improvement in HAM-D scores), treatment response rates, and the incidence of ADRs between the vortioxetine and escitalopram groups. The null hypothesis (H_0) assumed no significant difference between the two treatments, while the alternative hypothesis (H_1) proposed a significant difference in efficacy and safety. A p-value < 0.05 was considered statistically significant, indicating a meaningful distinction between the two groups.

Results and discussion

A total of 180 participants diagnosed with MDD and meeting the inclusion criteria were enrolled in the study. Of these, 90 patients were assigned to receive vortioxetine, while the other 90 were treated with escitalopram. The age distribution of the study population revealed that the majority of participants, 75 individuals (41.66%), were in the 30–40-year age group, indicating that this age range may be particularly vulnerable to depressive disorders. This was followed by 42 participants (23.33%) aged 18–30 years, suggesting a notable prevalence of depression even among young adults. Additionally, 24 participants (13.33%) each were from the 40–50 and 50–60 age groups, while the smallest group, comprising 15 individuals (8.33%), belonged to the 60–70-year age range.

These findings are consistent with those of Kessler et al.[31] who identified a higher prevalence of depression in younger age groups, particularly those between 18–34, 35–49, and 50–64 years, with varying prevalence rates. This trend is similarly observed in the current study, where the majority of depressed individuals were below 50 years of age. Furthermore, the mean age of the participants was 39.73 ± 12.43 years, which closely matches the data reported by Shao et al.,[32] where the mean age was 40.76 ± 13.30 years, further reinforcing the reliability and representativeness of the current study population in comparison with existing literature.

With respect to gender distribution, the study revealed a slight predominance of female participants, accounting for 109 individuals (55%), while males comprised 71 individuals (45%), resulting in a female-to-male ratio of approximately 1.5:1. This trend is consistent with the findings of Albert who reported a higher prevalence of major depression among women compared to men.[33]

In the present study, the analysis of comorbid conditions among participants revealed that anxiety was the most prevalent coexisting disorder, affecting 70 individuals (38.8%). This was followed by hypertension observed in 29 participants (16.1%), and diabetes reported in 20 participants (11.1%). Notably, 61 individuals (33.8%) did not present with any comorbidities. These findings reflect the common clinical observation that depression frequently co-occurs with other medical and psychiatric conditions. When compared to previous research, such as the studies by Melartin et al.,[34] Li et al.,[35] and Hussain et al.,[36] the current results show a somewhat lower but still significant comorbidity rate. The referenced studies reported a higher prevalence of depression among individuals with anxiety (57%), hypertension (26.8%), and diabetes (38%). The variation in comorbidity rates may be attributed to differences in study populations, diagnostic criteria, and healthcare settings, but the overall trend underscores the importance of integrated care approaches for individuals with depression.

The evaluation of mean HAM-D scores before and after treatment offers critical insight into the clinical efficacy of vortioxetine and escitalopram in managing MDD. At baseline, both treatment groups exhibited mean HAM-D scores indicative of moderate to severe depressive symptoms, establishing a comparable starting point for therapeutic assessment. Clinical efficacy was assessed using the HAM-D score at baseline (prior to initiation of therapy) and subsequently at monthly intervals for six months, with the final follow-up score used for outcome analysis. As illustrated in Figure 1, a notable reduction in mean HAM-D scores was observed in both the vortioxetine and escitalopram groups at the end of the study. Statistical analysis demonstrated that this decrease was significant in both cohorts (95% confidence interval, $p < 0.0001$), underscoring the effectiveness of each medication in reducing depressive symptoms. These findings are consistent with the results reported by Shao et al.,[32] where both treatment arms showed a significant reduction in total HAM-D scores ($p < 0.05$). Furthermore, no statistically significant difference was found between the two groups post-treatment ($p > 0.05$), reinforcing the comparable therapeutic efficacy of vortioxetine and escitalopram in routine clinical practice.

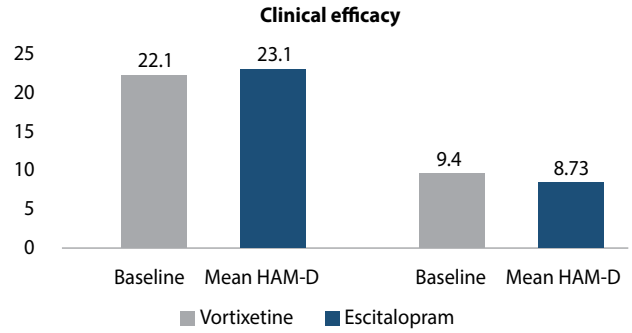

Figure 1: Baseline and post-intervention mean HAM-D scores

The comparative evaluation of ADRs between the escitalopram and vortioxetine treatment groups provided valuable insights into the safety profiles of these antidepressants. In the escitalopram group, the incidence and distribution of ADRs are illustrated in Figure 2. Among the reported side effects, headache emerged as the most frequently observed, affecting 24 participants (26.6%). This was followed by weight gain in 21 participants (23.3%), nausea in 15 (16.6%), insomnia in 12 (13.3%), and diarrhoea, dizziness, and fatigue, each reported by 9 participants (10%). Less

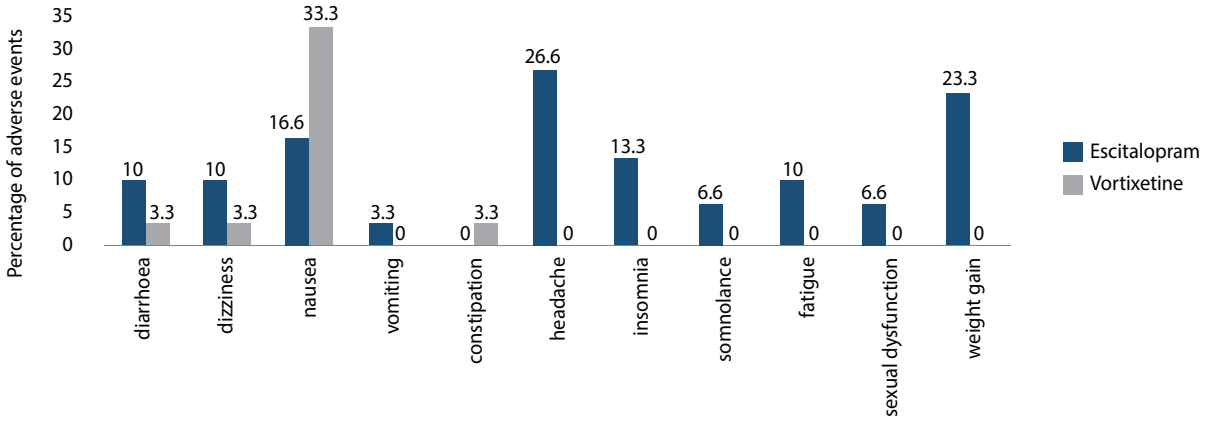

Figure 2: Comparison of adverse effects in escitalopram and vortioxetine groups

commonly, somnolence and sexual dysfunction were observed in 6 participants each (6.6%), while vomiting was reported in 3 participants (3.3%).

These results are in general agreement with those reported by Wade et al.[37] who identified headache (35%), nausea (35%), diarrhoea (25%), fatigue (16%), dizziness (16%), and vomiting (13%) as prevalent ADRs associated with escitalopram. According to the WHO causality assessment scale, all observed ADRs in the escitalopram group were categorised as possible, indicating a reasonable temporal association with the drug administration.

In comparison, the vortioxetine group reported a distinct ADR profile. The most frequently observed adverse event was nausea, reported by 30 participants (33.3%). Other side effects, including diarrhoea, dizziness, and constipation, were reported at a significantly lower incidence of 3.3% each (3 participant per symptom). These observations are consistent with findings from the study by Boulanger et al.,[38] which identified nausea, headache, diarrhoea, dry mouth, and dizziness as the most common ADRs (≥ 5% incidence) associated with vortioxetine. Similar to the escitalopram group, all ADRs in the vortioxetine group were also classified as possible based on the WHO causality assessment criteria. Overall, while both medications were generally well-tolerated, vortioxetine was associated with a lower incidence and diversity of ADRs, suggesting a potentially more favourable tolerability profile in the study population.

A cost-effectiveness analysis was conducted to compare the economic and clinical value of vortioxetine and escitalopram in the treatment of MDD. The analysis revealed that the average total cost of treatment per patient in the vortioxetine group was ₹3448.20, while the escitalopram group incurred a lower average cost of ₹2129.44. This substantial difference underscores the higher economic burden associated with vortioxetine. In terms of clinical effectiveness measured by the reduction in HAM-D scores from baseline to the end of the study, escitalopram demonstrated a greater improvement, with an average score reduction of 14.37, compared to 12.7 in the vortioxetine group. This outcome indicates that escitalopram not only reduced depressive symptoms more effectively but at a lower cost. The ICER was calculated to be -789.67, signifying that vortioxetine is both more expensive and less effective than escitalopram under the conditions of this study. A negative ICER in this context supports the conclusion that escitalopram is the dominant strategy in terms of cost-effectiveness. The vortioxetine group reported a lower incidence and severity of adverse effects compared to the escitalopram group. While this does not directly translate into greater clinical efficacy, it may have a significant impact on patient adherence, quality of life, and long-term treatment satisfaction, particularly in patients who are sensitive to side effects. It is evident that, although escitalopram demonstrates higher cost-effectiveness based on direct economic and clinical outcomes, the favourable safety and tolerability profile of vortioxetine may support its preferential use in select patient populations where minimising adverse effects is a key consideration.

Conclusion

This comparative clinical study evaluated the efficacy, safety, and cost-effectiveness of vortioxetine and escitalopram in the MDD over an eight-month treatment period. The demographic analysis revealed a higher prevalence of depression among individuals aged 30–40 years and a predominance among females, aligning with existing epidemiological data. Comorbid anxiety was the most frequent coexisting condition, highlighting the need for integrated treatment approaches in clinical practice.

Both vortioxetine and escitalopram demonstrated statistically significant reductions in HAM-D scores, confirming their effectiveness in alleviating depressive symptoms. No significant difference in post-treatment HAM-D scores was observed between the two groups, indicating comparable therapeutic efficacy.

In terms of tolerability, vortioxetine was associated with fewer and less diverse adverse effects compared to escitalopram, suggesting a superior safety profile. However, cost-effectiveness analysis favoured escitalopram due to its greater symptom reduction and lower treatment cost. The negative ICER value reinforces escitalopram as the economically dominant option in this study context.

Together, these findings support the clinical utility of both agents in treating MDD, with escitalopram offering better cost-effectiveness, while vortioxetine may be more suitable for patients who prioritise tolerability and minimal side effects.

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Conflict of interest

The authors report no conflict of interest.

Ethical approval

Following recruitment, written informed consent was obtained from all the participants to ensure compliance with ethical research protocols. Patient anonymity was strictly preserved, following the guidelines of the Institutional Human Ethical Committee.

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