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Comparative Study of Pregabalin, Desvenlafaxine, Escitalopram in Depressive Disorder

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ABSTRACT

Background: Depression is a chronic state of mood disorder that is characterized by anxiety, resulting in impaired function. This is a comparative study highlighting the efficacy, safety, and tolerability of escitalopram, desvenlafaxine, and pregabalin among patients suffering from major depressive disorder.

Methods: This is a prospective, randomized, and open-label study comparing 93 patients with major depressive disorder. Participants were allocated to three of the respective groups: escitalopram, desvenlafaxine, or pregabalin, respectively, for 6 weeks. The efficacy and safety were evaluated by the use of HAM-D, HAM-A, CGI, and UKU scales for statistical analysis.

Results: Comparative parameters were baseline age and gender. Pregabalin results in efficacy in physical, cognitive, or behavioural symptoms during follow-up, specifically parameters related to autonomy or anxiety. Post hoc analysis explained the reductions in the scores of HAM-D, HRS, CGI, and UKU, with comparison between Pregabalin, desvenlafaxine, and escitalopram. Pregabalin reduces the symptoms related to autonomic, cognitive, and behavioural patterns. Escitalopram resulted in effective control of thoughts, and Desvenlafaxine showed moderate efficacy with less efficacy.

Conclusion: The study concluded that Pregabalin is effective and provides rapid relief of symptoms, specifically for symptoms related to depression. This compares the desvenlafaxine and escitalopram for the effective use of managing the acute disorder of depression

Key-words: Depressive disorder; Pregabalin; Desvenlafaxine; Escitalopram; Comparative efficacy

INTRODUCTION

Depression is a mood disorder that leaves a person constantly depressed and uninterested. According to the Diagnostic Statistical Manual of Mental Disorders, Fifth Edition (DSM-5) of the American Psychiatric Association, the depressive disorders are categorized into:

1. Major depressive disorder (MDD)
2. Premenstrual dysphoric disorder
3. Disruptive mood disorder
4. Depressive disorder caused by a medical condition
5. Persistent depressive disorder

The common features between all the depressive disorders are irritable mood, emptiness, or sadness, along with somatic and cognitive alterations that have a profound influence on the ability of a person to perform. Due to wrong perceptions, approximately 60% of the depressed do not seek medical attention. The stigma surrounding a mental health condition does not seem to be acceptable to many people in society and can impair

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personal and professional life. There is evidence that most antidepressants are effective, but the reaction to the treatment may be different in different people [1].

Depression is a chronic process, and the associated anxiety symptoms are the co-morbidity. Symptoms of anxiety can lead to higher severity of symptoms, increased suicidal risk, and poor response to treatment as compared to depression and anxiety when used independently. There is a great overlap between the pathophysiologic aspects of depression and anxiety disorders using serotonergic, noradrenergic, and GABAergic systems of the brain, and how they are treated. The selective serotonin reuptake inhibitors (SSRI) and serotonin-norepinephrine reuptake inhibitors (SNRI) are reported to be useful in the treatment of anxiety disorders that are related to MDD [2, 3].

SSRIs are considered the first option of treatment of depression due to their overall effectiveness, higher safety, more acceptable side effects, and convenience of administration. The effectiveness and safety of desvenlafaxine in depression treatment are also well-determined. SSRIs have been reported, as well as selective norepinephrine reuptake inhibitors (SNRIs) have been reported to be effective in the treatment of anxiety that comes with depression [4].

Desvenlafaxine is an SNRI that was approved by the United States Food and Drug Administration (US FDA) in February 2008 to treat major depressive disorder (MDD), generalized anxiety disorder (GAD), panic disorder, and social anxiety disorder. The novelty of desvenlafaxine is that it inhibits the uptake of both norepinephrine and serotonin [4]. Escitalopram is an SSRI that is listed in both MDD and GAD in adults and children above the age of 12 years [5].

Pregabalin is a GABA analog anticonvulsant (an analog of gamma-aminobutyric acid, GABA) approved to treat neuropathic pain but commonly used off-label to treat generalized anxiety disorder (GAD). It has a high affinity with the alpha2-delta subunit protein of voltage-gated calcium channels in CNS tissues and functions as a presynaptic modulator of excessive release in hyperexcited neurons of different excitatory neurotransmitters. Pregabalin is inactive at GABA-A, GABA-B, and benzodiazepine receptors, and contrary to SSRIs and SNRIs, does not occupy reuptake serotonin receptors or norepinephrine receptors [6].

The present study was analyzing the effectiveness, safety, and tolerability of pregabalin, desvenlafaxine, and escitalopram in patients with depressive disorder and present an insight into their relative therapeutic usefulness and informative evidence-based clinical decision-making

MATERIALS AND METHODS

Research Design- This study is designed as a prospective, randomised, open-label, comparative study aimed at assessing and comparing the efficacy and safety of Pregabalin, Desvenlafaxine, and Escitalopram among patients with Depressive disorders. The study was conducted in the Department of Pharmacology and the Department of Psychiatry at Santosh Medical College and Hospital, Ghaziabad, involving patients attending the Psychiatry Outpatient Department. The study population consisted of patients diagnosed with major depression accompanied by important Depressive symptoms. Randomisation minimized selection bias for the even distribution of variables across groups. Institutional Ethics Committee approval was obtained. Each participant was followed up for six weeks from baseline. Both verbal and written consent were taken from the participants.

Inclusion Criteria

1. Patients aged 18 to 55 years, of either sex.
2. Patients diagnosed with major depression accompanied by Depressive features as per DSM-5 criteria.
3. Hamilton Rating Scale for Depression score greater than 20 at baseline.

Exclusion Criteria

1. Patients using antidepressants, antipsychotics, or other medications along with the use of abusive substance, psychosis, or chronic medical illness were excluded.
2. Patients with hypersensitivity or intolerance and adverse reactions to medications.
3. Patients diagnosed with other psychiatric disorders such as schizophrenia, bipolar disorder, or delusional disorder.

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Sample Size Calculation- The sample size for this study was determined using the statistical formula $N=(Z\alpha/2)^2 \times 2s^2 / d^2$, where *N* represents the required sample size per group, *s* is the standard deviation derived from a previous study (0.4), *d* denotes the margin of error or accuracy of the estimate (0.2), and *Zα/2* corresponds to the critical value of 1.96 at a 5% level of significance for a two-tailed test.

$$N=(1.96)^2 \times 2 \times (0.4)^2 / (0.2)^2=30.84.$$

Accordingly, the minimum sample size per group is 31 participants out of a total of 93 participants, randomly allocated to each of the three treatment groups: Pregabalin, Desvenlafaxine, and Escitalopram.

Data Collection- After obtaining written informed consent, baseline data of the enrolled participants were recorded in a structured Case Record Form. The CRF captured complete information, including socio-demographic details and clinical characteristics like duration of illness, psychiatric and medical history, comorbid conditions, and prior treatment exposure. Hamilton Depression Rating Scale is used to assess the severity of depressive symptoms, to quantify the intensity of Depressive symptoms, and the Clinical Global Impression scale to assess the clinical status and improvement. Participants were followed up at Week 3 and Week 6 after initiation of therapy, and follow-up data were collected with treatment adherence, dose adjustments, and the occurrence of adverse events, which are recorded and graded using the Udvalg for Kliniske Undersøgelser Side Effect Rating Scale.

METHODOLOGY- Participants were randomly allocated in a 1:1:1 ratio into one of three treatment groups: Group A (Escitalopram), Group B (Desvenlafaxine), and Group C (Pregabalin). Patients in the Escitalopram group was receiving 10 mg/day for the first three weeks, titrated to 20 mg/day for the subsequent three weeks, Desvenlafaxine group was start with 50 mg/day, increased to 100 mg/day after three weeks, while Pregabalin group was receive 150–600 mg/day in divided doses. The total duration of treatment for each participant was six weeks. Clinical assessments, including HAM-D, HAM-A, and CGI scales, were conducted at baseline, week 3, and week 6. Udvalg for Kliniske Undersøgelser Side Effect Rating Scale ensured patient safety and tolerability profile. The primary outcomes include the change in Hamilton Depression Rating Scale and Hamilton Depressive Rating Scale scores from baseline to six weeks, as well as changes in Clinical Global Impression Improvement and Severity scores, and secondary outcomes was assess the proportion of patients achieving a ≥50% reduction in HAM-D scores, the incidence and nature of adverse drug reactions using the UKU Side Effect Rating Scale, and treatment adherence with therapy.

Statistical Analysis- All data collected was entered in Microsoft Excel and analysed using SPSS 27. Descriptive statistics were presented as mean±standard deviation for continuous variables and as frequency and percentage for categorical variables. Within-group comparisons were done using Repeated Measures ANOVA, while between-group comparisons were analysed using One-Way ANOVA, with post hoc Tukey's test applied. For categorical data, the Chi-square test or Fisher's exact test was employed, and Student's t-test was used for pairwise group comparisons. A p-value of <0.05 was considered statistically significant.

RESULTS

The analysis of the average age of patients in each group showed that there were no significant differences between the groups (F=0.80; p=0.45). The mean age for the Pregabalin group was 25.81 years, which was lower than that of the Desvenlafaxine (27.65 years) and Escitalopram (27.94 years) groups. Overall, the total mean age of the study population was 27.13 ± 7.14 years. These findings indicate that age was comparable across treatment groups and unlikely to influence the observed outcomes (Fig. 1).

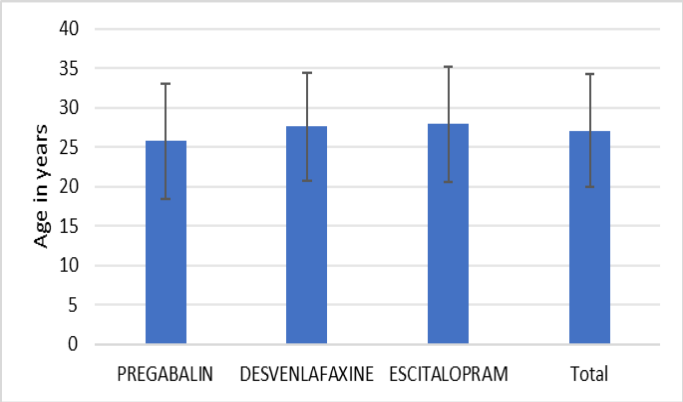

Fig. 1: Average age of the patients in each group and in the total sample

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The gender distribution across the three groups revealed no significant differences (Pearson Chi-Square=0.64, p=0.72). In the Pregabalin group, 36.2% were female and 28.6% were male. The Desvenlafaxine group consisted of 32.8% females and 34.3% males, while the Escitalopram group had 31% females and 37.1% males. Overall, 58 patients (62.4%) were female and 35 (37.6%) were male. Gender distribution did not influence the outcomes, ensures that any observed effects were not biased by gender differences (Fig. 2).

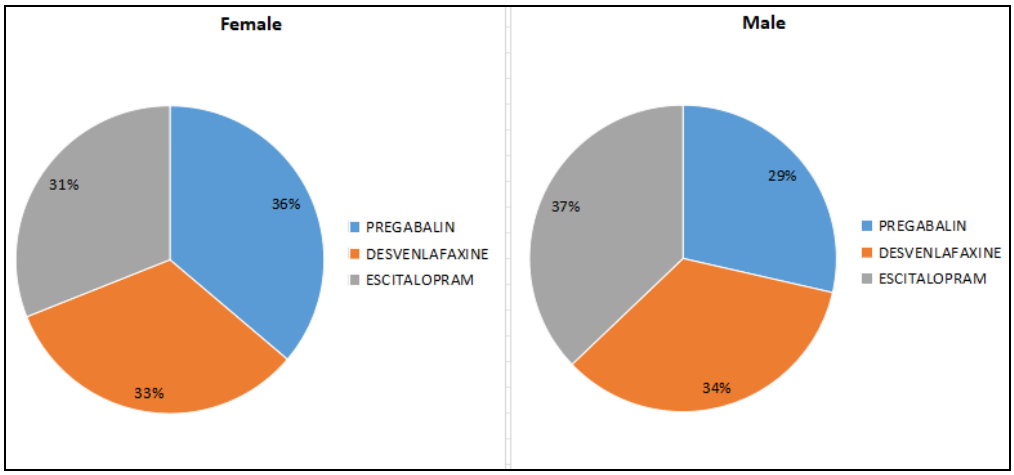

Fig. 2: Gender distribution of the patients in each group

Table 1 showed the analysis of baseline physical symptoms across the three groups revealed notable variations. For sweating, Pregabalin and Escitalopram groups exhibited a significantly higher prevalence compared to Desvenlafaxine (p=0.01). Nausea or abdominal distress was significantly more frequent in Escitalopram users (p=0.02). Restlessness showed high incidence in Pregabalin compared to Desvenlafaxine and Escitalopram (p=0.03). While palpitations, trembling, and dizziness showed no significant differences. Overall, minimal variation was observed, except for specific symptoms like sweating, restlessness, and nausea/abdominal distress.

Table 1: Baseline Physical Symptoms in patiesnts in each group and their analysis

Parameter	Total Patients	Pregabalin, N (%)	Desvenlafaxine, N (%)	Escitalopram, N (%)	Pearson χ^2	p-value
Palpitation	92	30 (96.8%)	31 (100%)	31 (100%)	2.02	0.36
Sweating	89	31 (100%)	27 (87.1%)	31 (100%)	8.36	0.01
Trembling	62	19 (61.3%)	23 (74.2%)	20 (64.5%)	1.25	0.53
SOB (Shortness of Breath)	42	13 (41.9%)	17 (54.8%)	12 (38.7%)	1.82	0.40
Chest Pain or Discomfort	32	12 (38.7%)	13 (41.9%)	7 (22.6%)	2.95	0.22
Dizziness or Lightheadedness	63	20 (64.5%)	21 (67.7%)	22 (71.0%)	0.29	0.86
Nausea or Abdominal Distress	54	15 (48.4%)	15 (48.4%)	24 (77.4%)	7.15	0.02
Muscle Tension	54	16 (51.6%)	16 (51.6%)	22 (71%)	3.17	0.20
Restlessness	73	29 (93.5%)	23 (74.2%)	21 (67.7%)	6.62	0.03
Sleep Disturbances	86	29 (93.5%)	30 (96.8%)	27 (87.1%)	2.16	0.33

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Table 2 showed that the cognitive and behavioral symptom analysis resulted in significant differences between the groups. Fear of losing control was present in all Pregabalin patients (p=0.002), whereas fewer Desvenlafaxine and Escitalopram users experienced it. Mental restlessness was notably more common in Pregabalin (p=0.02). Social withdrawal was significantly higher in Pregabalin (p=0). Persistent negative thoughts and repeated checking behaviors did not show major inter-group differences. Notably, the Pregabalin group exhibited high levels of fear of losing control and mental restlessness compared to the other groups. These differences underscore potential therapeutic implications and the varied response to different medications.

Table 2: Baseline Cognitive and Behavioral Symptoms in patients in each group and their analysis

Parameter	Total Patients	Pregabalin, N (%)	Desvenlafaxine, N (%)	Escitalopram, N (%)	Pearson χ^2	p-value
Difficulty Concentration	82	30 (96.8%)	25 (80.6%)	27 (87.1%)	3.91	0.141
Racing Thoughts	72	26 (83.9%)	25 (80.6%)	21 (67.7%)	2.58	0.27
Fear of Losing Control	81	31 (100%)	28 (90.3%)	22 (71.0%)	12.05	0.002
Persistent Negative Thoughts	77	26 (83.9%)	26 (83.9%)	25 (80.6%)	0.15	0.92
Avoidance of Situations that Cause Depressive	71	27 (87.1%)	22 (71.0%)	22 (71.0%)	2.97	0.22
Repeatedly Checking	83	28 (90.3%)	28 (90.3%)	27 (87.1%)	0.22	0.89
Social Withdrawal	70	29 (93.5%)	26 (83.9%)	15 (48.4%)	18.83	0
Mental Restlessness	76	30 (96.8%)	22 (71.0%)	24 (77.4%)	7.48	0.02
Irritability	75	26 (83.9%)	26 (83.9%)	23 (74.2%)	1.24	0.53
Hypervigilance	85	26 (83.9%)	29 (93.5%)	30 (96.8%)	3.556	0.16

At follow-up, significant differences emerged in several physical symptoms. Pregabalin demonstrated superior results in reducing palpitations, sweating, and sleep disturbances (p<0.001 for each), with near-complete resolution of sleep disturbances. Trembling showed a significant improvement in the Escitalopram group (p=0.001), while restlessness was substantially reduced in Pregabalin (p<0.001). Other symptoms, such as shortness of breath and chest pain, showed slight variation, with only chest pain significantly differing (p=0.03). These findings suggest that Pregabalin has a marked effect in alleviating certain physical symptoms, particularly those related to autonomic overactivity, while Escitalopram appears to be more effective in managing trembling (Table 3).

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Table 3: Follow-up Physical Symptoms in patients in each group and their analysis

Parameter	Total Patients	Pregabalin, N (%)	Desvenlafaxine, N (%)	Escitalopram, N (%)	Pearson χ^2	p-value
Palpitation	45	27 (87.1%)	0 (0%)	21 (67.7%)	51.92	<0.001
Sweating	49	26 (83.9%)	4 (12.9%)	14 (45.2%)	31.40	<0.001
Trembling	51	12 (38.7%)	8 (25.8%)	22 (71%)	13.54	0.001
SOB (Shortness of Breath)	38	18 (58.1%)	14 (45.2%)	8 (25.8%)	5.42	0.06
Chest Pain or Discomfort	28	20 (64.5%)	18 (58.1%)	27 (87.1%)	6.84	0.03
Dizziness or Lightheadedness	40	20 (64.5%)	10 (32.3%)	23 (74.2%)	12.19	0.002
Nausea or Abdominal Distress	33	28 (90.3%)	16 (51.6%)	16 (51.6%)	13.52	0.001
Muscle Tension	35	22 (71%)	15 (48.4%)	21 (67.7%)	3.94	0.13
Restlessness	29	28 (90.3%)	8 (25.8%)	28 (90.3%)	40.08	<0.001
Sleep Disturbances	40	31 (100%)	1 (3.2%)	21 (67.7%)	61.41	<0.001

Table 4 showed the follow-up cognitive and behavioral symptom analysis highlighted significant improvements in Pregabalin, especially regarding mental restlessness, hypervigilance, and irritability (p<0.001). Pregabalin provide reduction in fear of losing control and persistent negative thoughts. Social withdrawal showed a significant improvement in Pregabalin compared to other groups (p<0.001). Repeated checking and difficulty in concentration also demonstrated notable differences, favoring Pregabalin (p<0.001). Pregabalin was particularly effective in managing Depressive-related cognitive symptoms, while Escitalopram performed better in addressing racing thoughts and social withdrawal.

Table 4: Follow-up Cognitive and Behavioral Symptoms in patients in each group and their analysis

Parameter	Total Patients	Pregabalin, N (%)	Desvenlafaxine, N (%)	Escitalopram, N (%)	Pearson χ^2	p-value
Difficulty Concentration	49	21 (67.7%)	6 (19.4%)	17 (54.8%)	15.61	<0.001
Racing Thoughts	45	19 (61.3%)	6 (19.4%)	23 (74.2%)	20.40	<0.001
Fear of Losing Control	54	19 (61.3%)	3 (9.7%)	17 (54.8%)	20.13	<0.001
Persistent Negative Thoughts	56	16 (51.6%)	5 (16.1%)	16 (51.6%)	10.86	0.004
Avoidance of Situations that Cause Depressive	58	17 (54.8%)	9 (29.0%)	9 (29.0%)	5.86	0.053
Repeatedly Checking	56	18 (58.1%)	3 (9.7%)	16 (51.6%)	17.86	<0.001
Social Withdrawal	47	21 (67.7%)	5 (16.1%)	20 (64.5%)	20.73	<0.001
Mental Restlessness	45	31 (100%)	9 (29%)	8 (25.8%)	43.65	<0.001
Irritability	47	25 (80.6%)	5 (16.1%)	16 (51.6%)	25.89	<0.001
Hypervigilance	54	29 (93.5%)	2 (6.5%)	8 (25.8%)	53.25	<0.001

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Table 5 highlighted that post hoc analysis showed significant pairwise differences between the groups. Pregabalin demonstrated superior improvements compared to both Desvenlafaxine and Escitalopram in UKU, HAM-D, and HRS (p<0.001 for each comparison). Pregabalin's improvement in UKU and HRS was significantly greater than that of Desvenlafaxine and Escitalopram, with mean differences of 1.54 and 2.87, respectively. Escitalopram showed the least improvement across the parameters, particularly in comparison to Pregabalin (p<0.001). In terms of the CGIS, Pregabalin's improvement over Desvenlafaxine was also significant (p<0.001). These results indicate that Pregabalin leads to superior symptom improvement compared to both Desvenlafaxine and Escitalopram in all assessed outcomes.

Table 5: Post hoc analysis of the outcome assessment parameters between the groups

Dependent Variable	(I) Group	(J) Group	Mean Difference (I-J)	Std. Error	p-value
UKU	Pregabalin	Desvenlafaxine	1.54*	0.29	<0.001
		Escitalopram	3.87*	0.29	<0.001
	Desvenlafaxine	Pregabalin	-1.54*	0.29	<0.001
		Escitalopram	2.32*	0.29	<0.001
	Escitalopram	Pregabalin	-3.87*	0.29	<0.001
		Desvenlafaxine	-2.32*	0.29	<0.001
Diff_HAMD*	Pregabalin	Desvenlafaxine	2.83*	0.41	<0.001
		Escitalopram	1.93*	0.41	<0.001
	Desvenlafaxine	Pregabalin	-2.83*	0.41	<0.001
		Escitalopram	-0.90	0.41	0.08
	Escitalopram	Pregabalin	-1.93*	0.41	<0.001
		Desvenlafaxine	0.90	0.41	0.084
Diff_HRS*	Pregabalin	Desvenlafaxine	2.87*	0.27	<0.001
		Escitalopram	1.61*	0.27	<0.001
	Desvenlafaxine	Pregabalin	-2.87*	0.27	<0.001
		Escitalopram	-1.25*	0.27	<0.001
	Escitalopram	Pregabalin	-1.61*	0.27	<0.001
		Desvenlafaxine	1.25*	0.27	<0.001
Diff_CGIS*	Pregabalin	Desvenlafaxine	.77*	0.18	<0.001
		Escitalopram	.51*	0.18	0.019
	Desvenlafaxine	Pregabalin	-.77*	0.18	<0.001
		Escitalopram	-0.25	0.18	0.35
	Escitalopram	Pregabalin	-.51*	0.18	0.01
		Desvenlafaxine	0.25	0.18	0.35

**difference of scoring between follow-up and baseline*

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DISCUSSION

A study was conducted to compare the effectiveness and safety of escitalopram and those of desvenlafaxine in depressed and anxious postmenopausal women. They found that Escitalopram would seem to perform better in short-term depression treatment, and as to the treatment of anxiety, both drugs would seem equally viable. Also, they seem to be as safe and tolerated in postmenopausal depressed and anxious women [7].

Comparison of the efficacy and safety of escitalopram and desvenlafaxine was conducted in a major depression treatment. The study established the same level of efficacy and safety in the reduction of depression and anxiety with escitalopram and desvenlafaxine, but clinical superiority of either of the drugs over the other cannot be drawn as a result of the small sample size [8].

An assessment of open-label desvenlafaxine therapy (as desvenlafaxine succinate) in postmenopausal women who failed to respond clinically to acute, double-blind desvenlafaxine or escitalopram treatment was conducted. Postmenopausal women with major depressive disorder not responding to acute, double-blind therapy with escitalopram or desvenlafaxine tapped a small, sustained response upon long-term, open-label therapy with desvenlafaxine [9].

The study compared the effectiveness of escitalopram versus pregabalin in the treatment of generalized anxiety disorders. The participants in group A were administered the 20 mg dose of escitalopram at the rate of one daily dose, whereas those in group B were administered the dose of 150-200mg at the same rate, and the level of anxiety before and after the experiment was determined using the Hamilton Anxiety Baseline. Escitalopram is superior and effective in the treatment of psychological conditions such as depression, bipolar disorder, and other affective disorders, despite the side effects that are minimal compared to Pregabalin [10].

The effectiveness of escitalopram and Desvenlafaxine in depression treatment was studied. Desvenlafaxine and Escitalopram are equally effective in alleviating the symptoms of depression, the somatic symptoms of which are significantly decreased using Desvenlafaxine [11].

A study was conducted to evaluate the effectiveness, safety, and tolerability of desvenlafaxine (given as desvenlafaxine succinate 50 and 100mg/day) in major depressive disorder (MDD). Both doses of desvenlafaxine were mostly well tolerated. Treatment-emerging adverse events were most common, and they included nausea, dizziness, insomnia, constipation, fatigue, anxiety, and loss of appetite. Desvenlafaxine 50 and 100mg/day are safe and mostly well-tolerated in fixed doses, and effective at a clinically relevant level to treat MDD [12].

A study investigated the effectiveness of maintenance treatment with escitalopram as a way of averting depression relapse in patients who had responded to acute treatment using SSRI medicines. Escitalopram maintenance treatment was tolerable and significantly decreased the chances of recurring depression. The rate of depression recurrence when patients who had low levels of residual symptoms after continuation treatment with escitalopram were switched to placebo showed that maintenance therapy of recurrent major depressive disorder was necessary, lasting beyond 4 or 6 months of initial symptom resolution, regardless of residual symptom levels [13].

There is epidemiological support of comorbidity between generalized anxiety disorder (GAD) and major depressive disorder (MDD) or dysthymia, as well as its comorbidity with major disability. Since the new 2-delta anxiolytic treatment of GAD, pregabalin, unlike the vast majority of other approved treatments of GAD, has not been studied in patients with MDD, one study tested its effects on depressive symptoms related to GAD by conducting a post-hoc analysis of the existing clinical trial database. Finally, the alternative treatment intervention, pregabalin, which has a different mechanism of action, also proved effective in the treatment of the depressive symptoms that are commonly experienced by patients with GAD [14].

A study was done to evaluate the anxiolytic effect of pregabalin in patients with generalized anxiety disorder. Pregabalin proved to be much more effective compared to placebo in the treatment of psychic and somatic symptoms of generalized anxiety disorder and was easily tolerated by the majority of the patients in the study [15].

CONCLUSIONS

This study demonstrates that pregabalin exhibits superior efficacy relative to desvenlafaxine and escitalopram in the treatment of Depressive disorders, providing rapid alleviation of symptoms, particularly somatic manifestations of Depressive. Pregabalin outperformed both desvenlafaxine and escitalopram

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across multiple clinical outcome measures, including the UKU, HAM-D, and HRS scales. While all three pharmacological agents showed therapeutic benefits, pregabalin's expedited onset of action and comprehensive symptom relief, especially in somatic depression, make it a preferred option for acute symptom management. Escitalopram, although effective, is characterized by a slower therapeutic onset and a more gradual improvement, making it suitable as a first-line treatment, particularly in patients with primarily psychological symptoms. Desvenlafaxine demonstrated moderate efficacy, with particular benefit in cases of comorbid depression and anxiety. These results provide valuable guidance for clinicians in selecting the most appropriate therapeutic intervention based on patient symptomatology and treatment goals.

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