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Study Of Safety And Efficacy Of Escitalopram Versus Sertraline In Major Depressive Disorder Patients: A Comparative Study.

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ABSTRACT

The study was aimed to study safety and efficacy of Escitalopram versus Sertraline in patients of major depressive disorder patients attending Psychiatric OPD of S.N.M.C , AGRA This study was conducted in the Department of Pharmacology and therapeutics in collaboration with the Department of Psychiatry of Sarojini Naidu Medical College, Agra The selected patients of Major Depressive Disorder were assigned randomly to receive either Escitalopram 10 mg or Sertraline 50 mg orally once daily and Anti-Anxiety medication like Alprazolam, Clonazepam, Etizolam, Lorazepam were added if required by the clinician. The highest number of study subjects were observed to be in the age group of 31- 40 years (38.57 %).The lowest number of study subjects were observed to be in the age group of 51-55 years (5.71%).The chi-square value is 0.02 , df=1, the p value is 0.88 and the difference were found to be statistically non-significant. Among 70 study subjects , total 92.8 % and 7.2 % were having mild and moderate HAM-D score at 12 weeks respectively and in group A study subjects 94.3 % and 5.7 % were having mild and moderate HAM-D score at 4 weeks respectively whereas group B study subjects 91.4 % and 8.6 % were having mild and moderate HAM-D score at 4 weeks respectively .Among total of 70 study subjects, no subject were found to have severe symptoms in group A and group B after 12 weeks of therapy. The chi-square value is 0.215 , df=1, the p value is 0.64 and the difference were found to be statistically non-significant. The occurrence of adverse effects in group B was found to be numerically higher than group A and this difference was found to be statistically non significant (p=0.4). The study confirms that both Escitalopram and Sertraline are efficacious as the treatment of depressive disorder. There was no toxicity or major adverse drug reaction was observed during the study period in the groups.

Keywords: Escitalopram, Sertraline, Safety, Efficacy , HDRS scale , UKU scale.

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INRODUCTION

Depressive disorder is a broad term encompassing major depressive disorder (MDD) (including major depressive episodes), persistent depressive disorder (dysthymia), disruptive mood dysregulation disorder, premenstrual dysphoric disorder, substance/medication-induced depressive disorder, depressive disorder due to another medical condition, other specified and unspecified depressive disorder. All forms of depressive disorders share common symptoms of mood changes i.e, irritable, sad, and empty along with cognitive and somatic features which can cause a significant impact on the individual's functional capability and capacity. The distinguishing part in the above spectrum of depressive disorders is the time of occurrence, duration of symptoms or episodes, and the diagnosed etiology [1, 2]. Selective serotonin reuptake inhibitors are the first choice of drugs for depression and are frequently prescribed. Still, it has not been possible to declare one particular drug in this class to be more efficacious than the other [3]. The purpose of this study is to compare two of the drugs from this class of SSRIs, namely Sertraline and Escitalopram, in terms of efficacy and safety among major depressive disorder patients, attending the psychiatric outpatient departments in S.N.Medical College and Hospital.

Ethical Clearance

Ethical Clearance Letter No. IEC/2022/124, was taken from Institutional Ethics Committee , S.N. Medical College , Agra

MATERIAL AND METHODS

This study was conducted in the Department of Pharmacology and therapeutics in collaboration with the Department of Psychiatry of Sarojini Naidu Medical College, Agra.

The selected patients of Major Depressive Disorder were assigned randomly to receive either Escitalopram 10 mg or Sertraline 50 mg orally once daily and Anti-Anxiety medication like Alprazolam, Clonazepam, Etizolam, Lorazepam were added if required by the clinician.

35 patients were included in the Escitalopram group and 35 patients in the Sertraline group. The primary efficacy outcome measure was change from the baseline in the values on the Hamilton Depression Rating Scale. Each item on the questionnaire is scored on a 3 or 4 point scale and depending on the item, the total score is calculated. A score of 10-13 is mild, scores 14-17 indicate mild to moderate depression, >17 moderate to severe depression. The scale was observed at baseline, 4 weeks, and 12 weeks in both groupsof patients in the study.

Adverse effects due to both drugs will be monitored using the Udvalg for Kliniske Undersogelser (UKU) scale, i.e. UKU Side Effect Rating Scale. It is a clinician-rated scale with well-defined items developed to provide a comprehensive rating of the side effects of psychopharmacological medications[5].

RESULTS

The data collected from the study were statistically analysed using SPSS software 21 version according to protocol analysis. 84 study subjects were enrolled for the study after taking their consent , and randomly assigned (lottery method) into two groups of 41 and 43 in group A and group B respectively . Out of them, 35 patients of each group A and group B successfully completed the 12 weeks study.

Table 1: Age-wise distribution

Age group	Total	
	No.	%
≤30 years	26	37.14
31-40 years	27	38.57
41-50 years	13	18.57
51-55 years	4	5.71
Total	70	100.00

Table 1. depicts the age distribution in the study group.

The highest number of study subjects were observed to be in the age group of 31- 40 years (38.57 %).The lowest number of study subjects were observed to be in the age group of 51-55 years (5.71%).

Table 2: Sex wise distribution

Sex	Total	
	No.	%
Male	42	60.00
Female	28	40.00
Total	70	100.00

Table 2. depicts the sex distribution in the study group.

The number of study subjects with depression were more common in males (60 %) than females (40 %) .

Table 3: Marital Status

Marital Status	Total	
	No.	%
Married	16	22.86
Unmarried	54	77.14
Total	70	100

Table 3. depicts the Marital Status distribution in the study group.

The number of study subjects with depression were more common among unmarried (77.14 %) than married subjects (22.86 %) .

Table 4: Monthly Income

Monthly Income (Rs.)	Total	
	No.	%
<10000	43	61.43
10000-20000	18	25.70
>20000	9	12.87
Total	70	100.00

Table 4. depicts the monthly income status in the study group.The number of study subjects with depression were highest seen in subjects earning less than Rs.10000 (61.43 %).The number of study subjects with depression were lowest seen in subjects earning was more .

Table 5: Profession

Profession	Total	
	No.	%
Unemployed	32	45.73
Unskilled	22	31.43
Semi-skilled	14	20
Professional	2	2.84
Total	70	100

Table 5. depicts the professional status in the study group.The number of study subjects with depression were highest among patients who were unemployed (45.73 %) and least were seen in subjects who were professional (2.84 %) .

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Table 6: Socioeconomic Status Class

SES Class	Total	
	No.	%
III	7	10
IV	61	87.15
V	2	2.85
Total	70	100

Table 6. depicts the Socioeconomic Status Class in the study groups. The number of study subjects with depression were highest in class IV socioeconomic status (87.15 %) and least were seen in class V socioeconomic class (2.85 %).

Table 7: Symptoms (at 0 week)

BASELINE HAM-D SCORE	GROUP A n(%)	GROUP B n(%)
Mild	16(39.9%)	23(53.5%)
Moderate	25(60.1%)	20(46.5%)
Severe	0	0
Total	41	43

Table 7. shows Baseline HAM-D score of study subjects with depression.

Table 8. Symptoms (at 4 weeks)

HAM-D SCORE at 4 weeks	Group A		Group B		Total	
	No.	%	No.	%	No.	%
Mild	32	78	33	77	65	77
Moderate	9	22	10	23	19	23
Severe	0	0	0	0	0	0
Total	41	100.00	43	100.00	84	100.00

Chi-square value=0.02, df 1, p-value=0.88

Table 8. depict HAM-D score between group A and group B at 4 weeks. Among 84 study subjects , total 77 % and 23 % were having mild and moderate HAM-D score at 4 weeks respectively and in group A study subjects 78 % and 22 % were having mild and moderate HAM-D score at 4 weeks respectively whereas group B study subjects 77 % and 23 % were having mild and moderate HAM-D score at 4 weeks respectively . Among total of 84 study subjects, no subject were found to have severe symptoms in group A and group B after 4 weeks of therapy. The chi-square value is 0.02 , df=1, the p value is 0.88 and the difference were found to be statistically non-significant.

Table 9: Symptoms (at 12 weeks)

Symptoms	Group A		Group B		Total	
	No.	%	No.	%	No.	%
Mild	33	94.3	32	91.4	65	92.8
Moderate	2	5.7	3	8.6	5	7.2
Severe	0	0	0	0	0	0
Total	35	100.00	35	100.00	70	100.00

Chi-square value=0.21 , df 1, p-value=0.64

Table 9. depict HAM-D score between group A and group B at 12 weeks. Among 70 study subjects , total 92.8 % and 7.2 % were having mild and moderate HAM-D score at 12 weeks respectively and in group A study subjects 94.3 % and 5.7 % were having mild and moderate HAM-D score at 4 weeks respectively whereas group B study subjects 91.4 % and 8.6 % were having mild and moderate HAM-D score at 4 weeks respectively .

Among total of 70 study subjects, no subject were found to have severe symptoms in group A and group B after 12 weeks of therapy. The chi-square value is 0.215 , df=1, the p value is 0.64 and the difference were found to be statistically non-significant.

Table 10: Incidence Of Adverse Events In Group A And Group B

ADVERSE EVENTS	GROUP A (N = 35)	%	GROUP B (N=35)	%
HEADACHE	2	5.7	2	5.7
NAUSEA	1	2.8	1	2.8
DIARRHOEA	0	0	2	5.7
DRY MOUTH	1	2.8	2	2.8
LOSS OF APPETITE	1	2.8	2	5.7
INSOMNIA	1	2.8	1	2.8
SEXUAL DYSFUNCTION	0	0	0	0
TOTAL	7	16.9	10	28.5

Group	Adverse events	Adverse events not present	Total
A	7	28	35
B	10	25	35

Chi-Square Value: 0.69 , P-Value =0.40

DISCUSSION

This study was conducted in the Psychiatry department OPD of S. N. Medical college, Agra from December 2020 to march 2022. Total 84 subjects enrolled in the study after taking their consent, out of them 70 study subjects i.e, 83% of participants completed the study at 12 weeks. Intake and allotment of study subjects were randomly (lottery) assigned in group A and B. There drop outs of subjects due to lack of contact with them and some other unknown/ non specific reasons.

Study participants were divided as per standard recommendation into four age class intervals for the analysis of depression. The highest number of study subjects was observed in age group 31- 40 years, reason may be due to lack of skill and higher unemployment rates seen in these age group . Similar results was seen in study conducted by Kadam et al and Kudyar et al showed mean age 37 years having higher depression [5, 6].

Males outnumbered females in the current study as the ratio between males and females was 3:2. This may be due to more affordability of male patients to reach the tertiary center OPD even from far off places and may be due to more reluctant nature of females to take antidepressant therapy also due to social constraints with females which is less seen with males. In this study, the number of unmarried individuals were found to have more depression than married individuals, the difference may be due to loneliness and lack of spouse support. In this study the number of individuals who were educated till middle school were highest percentage of having depression and least percentage of individuals who had depression were among graduates. Unskilled professionals and study subjects who earn monthly income less than Rs.10000 were having more depression as compared to among all other study subjects who earned more. In this study individual who belonged to socioeconomic status class IV according to kuppuswamy classification were having more depression than seen with other classes that may be due to lack of literacy , unemployment , not skilled and low income , these results showed correlation and similarity seen with hasin et al [7].

The HAM-D scores calculated during the study were lowered by both Escitalopram and Sertraline as observed in a similar study by huang et al [8]. Among total study subjects , baseline (at 0 weeks) HAM-D score in group A subjects 15 (43%) were having mild and 20 (57%) study subject were having moderate whereas in group B study subjects 20 (57%) were having mild and 15 (43%) were having moderate HAM-D score . The chi-square statistical value is 1.42, df=2, the p-value is 0.23 and the difference is found to be statistically nonsignificant. Among total study subjects, HAM-D score at 4 weeks in group A subjects 20 (57.14%) were having mild and 15(42.85%) study subjects were having moderate HAM-D score where as in group B study subjects after taking 4 week treatment 19(54.28%) were having

mild and 16(45.72%)were having moderate HAM-D score. Comparison between both study groups, greater reduction in HAM-D score was found in group A study subjects as compared to group B study subjects at 4 weeks. The chi-square statistical value is 0.057, df=2, the p-value is 0.809 and the difference is found to be statistically nonsignificant.

Among total study subjects , HAM-D score at 12 weeks in group A subjects 23 (65.71%) were having mild and 12 (34.28%) study subjects were having moderate HAM-D score where as in group B study subjects after taking 12 week treatment 21(60%) were having mild and 14(40%)were having moderate HAM-D score. Comparison between both study groups, greater reduction in HAM-D score was found in group A study subjects as compared to group B study subjects at 12 weeks. The chi-square statistical value is 0.244, df=2, the p-value is 0.620 and the difference is found to be statistically nonsignificant. HAM-D score which is an indicator of depression has a significant role in assessing the improvement or deterioration of the disease. Both the drugs in the current study decreased the HAM-D score significantly in similar fashion. The following results were seen similar with the study by Vaya Lalit et al [4].

Escitalopram was given in a dose of 10 mg/day orally to patients in study group A. Sertraline was given in a dose of 50 mg/day orally to patients in study group B. Doses of escitalopram and sertraline were optimized during the course of the treatment. Hamilton Depression rating scale was used to assess the severity of depression at baseline and treatment response at monthly intervals. Hamilton depression rating score of 0-7 indicates no depression, a score between 8-16 denotes mild depression, 17-23 denotes moderate depression and a score more than or equal to 24 indicates severe depression similar with Vaya Lalit et al [4]. The distribution of patients with different grades of severity in both study groups was comparable. Assessment of response by HAM-D Scoring during follow up necessitated dose hikes in patients of groups A and B respectively. The rate of response within and between the treatment groups was assessed in terms of improvement in scores at subsequent visits at 4 and 12 weeks.

The above result indicates that the percentage of study subjects improved with the increase in the duration of treatment from baseline to 12 weeks proportionately to the concept that antidepressants take time to produce a clinical response by the mechanism of pharmacological action. Hence, in both the treatment groups there is a reduction in HAM-D score as assessed at 4 and 12 weeks in patients after the drug therapy was instituted, which implies that both escitalopram and sertraline are comparably efficacious in reducing the symptoms of depression as early as 4 weeks of treatment. The occurrence of adverse effects in group B was found to be numerically higher than group A and this difference was found to be statistically non-significant (p=0.4). There was no other treatment related adverse events in both groups and neither treatment emergent suicides in this study. No serious adverse events occurred during course of study. None of study participants in either group withdrew due to adverse effect, drop outs were due to other reasons, these results were similar with study by kudyar et al [5].

CONCLUSION

- The study confirms that both Escitalopram and Sertraline are efficacious as the treatment of depressive disorder.
- The efficacy profile in both the study groups was measured by using HAM-D scale , which we then found in this study done over 12 weeks that both the drugs reduced HAM-D scores during the course of the treatment and had no statistical difference.
- The assessment of safety, which was done by clinical parameters (UKU Side effects rating scale) showed that both the study groups were better tolerated and showed less number of adverse effects which was confirmed by statistically nonsignificant results . There was no toxicity or major adverse drug reaction was observed during the study period in the groups.

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