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A STUDY OF EFFICACY AND TOLERABILITY OF AMITRIPTYLINE IN MAJOR DEPRESSIVE DISORDER.

Pharma

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ABSTRACT

Depression is a common but a serious mental illness. It affects an estimated one in 15 adults (6.7%) in any given year and one in six people (16.6%) will experience depression at some time in their life. Depression can be treated with psychotherapy, medications, or combination of both. Amitriptyline is most widely used TCA. SSRI's have now replaced TCA's in the treatment of depression. Here we aim to study the efficacy and tolerability of Amitriptyline in treatment of depression. An Observational, Prospective, Cross-sectional study was conducted for a duration of one year. Patients who were suffering from depression and who met the inclusion and exclusion criteria were registered for the study after taking their informed consent. Hamilton depression rating scale was used to measure the antidepressant effect. The efficacy was evaluated on the basis of HAMD score before and after the study. Amitriptyline was given to 30 patients.In the group, mean age was found to be 37.10 (with SD 12.61). The mean percentage reduction in HDRS score at day 30 and 60 was found to be 50.47% and 60% respectively.

KEYWORDS

Amitriptyline, Depression, Efficacy, HDRS score

INTRODUCTION

Depression is a common but a serious mental illness. It negatively affects a person's thinking, feelings and action. Depression affects an estimated one in 15 adults (6.7%) in any given year and one in six people (16.6%) will experience depression at some time in their life. Depression can occur at any age but it usually appears during the late teens to Mid-20s.Women are at higher risk of suffering from depression.

Depression is a disabling disorder associated with considerable comorbidity, risk of suicide and social consequences that is surpassed by ischemic heart disease as a major public health issue in industrialized countries. Fortunately, depression is the most treatable mental disorder. Depression can be treated with psychotherapy, medications or combination of both.

Tricyclic antidepressants (TCAs) formed mainstay of treatment for many decades.Amitriptyline is most widely used TCA and it is considered one of the reference standards against which new ADs are compared with respect to both efficacy and tolerability.

SSRI's have now replaced TCAs in the treatment of depression.

This study was therefore designed to evaluate the efficacy and tolerability of Amitriptyline, the reference standard TCA drug.

MATERIALAND METHODS

This study was conducted at Gandhi medical college and associated Hamidia Hospitals Bhopal, Madhya Pradesh in the Department of Psychiatry. It is a Tertiary care teaching Hospital. The study was Observational, Prospective, Cross-sectional and was conducted for a duration of one year. Approval from Institutional ethics committee was obtained before the study. Patients were diagnosed and treated by the clinicians and we observed their treatment responses. Data about patient's demographic details and clinical symptoms were obtained on case sheet by interviewing patients and Hamilton Rating Score sheet was filled according to their responses. Patients who were suffering from depression and who met the inclusion and exclusion criteria were registered for the study after taking their informed consent.

The Inclusion Criteria Were

- All patients aged between 18 to 60 years undergoing treatment of depression at Department of Psychiatry, Gandhi Medical College, Bhopal during the study period.
- Patient giving consent for the study.
- Patients receiving either Escitalopram or Amitriptyline for depressive disorder.
- Both Male and Females.

The Exclusion Criteria Were

- Patients who refuse to give consent.
- Pregnant Females.
- Lactating Females.
- Those with other co – morbid diseases.

All the patients completed the study. Hamilton depression rating scale was used to measure the antidepressant effect. The efficacy was evaluated on the basis of HDRS before and after the study. Patients were registered and interviewed for their details and HDRS score was recorded on day of starting the treatment which we refer as day one of study. Follow-up was done on day 15, 30 and 60 and HDRS score were recorded.

The collected data was then entered in Microsoft excel and analysed using Spss 23.0. The Qualitative data was expressed as percentage while the Quantitative data was expressed as mean and standard deviations were obtained.

The mean value of HDRS score were calculated for day 1, 15, 30 and 60. Then using paired t test, the p-value was obtained for various groups.

RESULT

During the study period a total of 30 patients were registered and monitored for a 60 days.

Demographic Characteristics

Age

The mean age of the patients was found to be 37.10 years with SD 12.62.

Table – 1 The Sample Distribution According To Age Is As Shown Below-

Age Group	No. of patients	Percent
18 – 20 yrs	1	3.3
21 – 30 yrs	10	33.3
31 – 40 yrs	8	26.7
41 – 50 yrs	4	13.3
51 – 60 yrs	7	23.3
Total	30	100.0

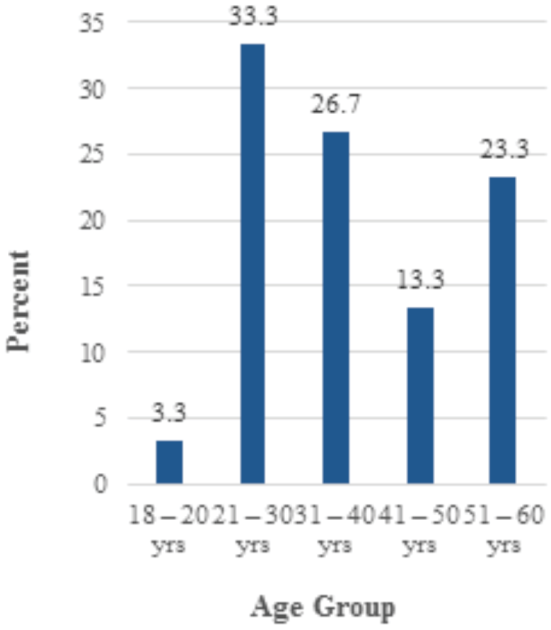

Fig – 1 The Age Wise Distribution Of Patients Is As Shown Below In Diagram-

Gender

There were 16 males (53.3%) and 14 females (46.7%).

Table – 2 The Sample Distribution According To Gender Is As Shown Below

Gender	No. of patients	Percent
Male	16	53.3
Female	14	46.7
Other	0	0
Total	30	100.0

Fig – 2 The Gender Distribution Of Patients Is As Shown Below-

Hamilton Depression Rating Scale Score

- The mean Hamilton rating scale score on day 0 i.e., the day of registration was found to be 21.20 with SD of 2.92.
- This score reduced to 16.93 with SD 3.08 and 10.50 with SD of 1.50 on day 14 and 28 respectively.
- So, the mean percentage reduction in Hamilton rating scale score at the end of 4 weeks was found to be 50.47%.
- This score reduced to 8.46 on day 60 of the treatment.
- So, the mean percentage reduction in Hamilton Depression Scale Score at the end of 60 days was found to be 60%.

Table – 3 Statistical Analysis Showing Mean Hdrs Score At Day 0, 15, 30 And 60

STATISTICAL ANALYSIS				
DRUG NAME = AMITRIPTYLINE				
Hamilton Rating Scale Score	N	Minimum	Maximum	Mean ± SD
Day 0	30	15.0	28.0	21.20 ± 2.92
Day 15	30	10.0	23.0	16.93 ± 3.08
Day 30	30	7.0	14.0	10.50 ± 1.50
Day 60	30	6	11	8.46 ± 1.33

Table – 4 Statistical Analysis Showing p Value

STATISTICAL ANALYSIS				
Drug name = Amitriptyline	Mean ± SD	t value	p value	Conclusion
Hamilton rating scale score on day 0	21.20 ± 2.92	19.93	0.001	Significant
Hamilton rating scale score on day 15	16.93 ± 3.08			
Hamilton rating scale score on day 0	21.20 ± 2.92	27.64	0.001	Significant
Hamilton rating scale score on day 30	10.50 ± 1.50			
Hamilton rating scale score on day 15	16.93 ± 3.08	18.84	0.001	Significant
Hamilton rating scale score on day 30	10.50 ± 1.50			
Hamilton rating scale score on day 15	16.93 ± 3.08	20.85	0.001	Significant
Hamilton rating scale score on day 60	8.46 ± 1.33.			
Hamilton rating scale score on day z 30	10.50 ± 1.50	13.098	0.001	Significa
Hamilton rating scale score on day 60	8.46 ± 1.33			

Tolerability

No major side effect was found among the patients during the course of the study.

Table – 5 Adverse Effects Of Amitriptyline

Adverse Effects		No of Patients	Percentage
CNS Adverse Effects	Dizziness	0	0
	Sedation	9	30
	Confusion	2	6.7
CVS Adverse Effects	Tachycardia	0	0
	Arrythmia	0	0
	Orthostatic Hypotension	0	0
Antichol-inergic Side Effects	Blurred Vision	0	0
	Dry Mouth	0	0
Others	Nausea	8	26.7
	LFT Abnormalities	0	0
	Suicidal Tendencies	0	0
Patients With No ADR		11	36.7
TOTAL		100	

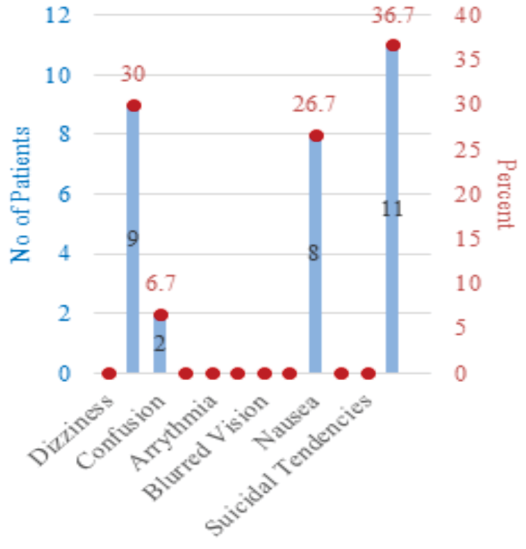

Fig – 3 The Distribution Of Patients And Their Percentage As Per Adverse Effects Is As Shown Below-

Severity Assessment

On evaluation of the severity of the ADR's by Hartwig et al., scale, it was evident that most of the ADR's reported in this study were of Mild severity.

Table – 6 Distribution Of Patients According To Severity Assessment Of ADRs

Type	No of patients with ADRs	Percentage
Mild	19	63.33%
Moderate	0	0%
Severe	0	0%
No ADR	11	36.6%
TOTAL	30	%

The above table shows that all the ADRs reported in this study were of mild severity. Patients treated with amitriptyline reported sedation(n=9), nausea(n=8) and confusion(n=2). Weight gain, constipation, xerostomia, dizziness, headache, and somnolence were not found in this study.

Causality Assessment

Causality assessment was done for individualized cases by using Naranjo's algorithm, and in most of the cases causality was found to be POSSIBLE.

Table – 7 Distribution Of Patients According To Causality Assessment-

Type	No of patients with ADRs	Percentage
Definite	0	0
Probable	0	0
Possible	19	63.33%
Doubtful	0	0
No ADR	11	36.66%
TOTAL	30	100

CONCLUSION

In this study we found that Amitriptyline brought significant reduction in Hamilton depression rating scale score in the treatment of depression at the end of 60 days.

The mean percentage reduction in HDRS scores was found to be Significant.

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