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Research Article

Comparative Efficacy of Celastrus paniculatus (Willd.) and Escitalopram, Alone and in Combination, in Major Depressive Disorder: A Prospective Interventional Study

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ABSTRACT
Background- Depression is rated as third leading cause of the burden of disease worldwide according to WHO in 2008. It often goes untreated. Conventional treatment approaches include antidepressant medications like Serotonin Reuptake Inhibitors (SSRIs) and properly modulated and planned psychotherapies. A shrub belonging from Celastraceae family called *Jyotishmati (Celastrus panniculatus* Willd.) contains a seed oil which is tranquilizer and sedative. Current study is an attempt to find out efficacy of this ayurvedic medication in treating depression
Aims and objectives- 1. To assess antidepressant efficacy of Jyotishmati (*Celastrus panniculatus* Willd.) in treating Major Depressive Disorder (MDD). 2. To compare its efficacy with Escitalopram 10mg alone and its combination with escitalopram.
Methodology- This study was conducted in department of Psychiatry of Government Medical College and Rajindra Hospital, Patiala from 28-12-2020 to 31-05-2023, 182 patients suffering from Major Depressive Disorder (MDD) were included in study. They were randomly divided into 3 groups using computer generated random numbers. Sociodemographic data was collected using sociodemographic proforma. Diagnosis of MDD was confirmed using International Classification of Diseases for mental health and behavioural disorders 10th edition (ICD-10). Hamilton Depression Rating Scale -17 was applied at baseline to know severity of depression and at 6 months of administering medications to know therapeutic response. Group A patients received 10mg of Escitalopram, Group B patients received *Jyotishmati* seed oil in capsule preparation and Group C subjects received both 10mg Escitalopram and *Jyotishmati*. Institutional Ethics committee permission was obtained before commencing the study. Written informed consent was obtained from all patients before including them into this project.
Observations- Out of 182 patients suffering from MDD, 14 patients dropped out during the course of study. 18 were excluded because of exclusion criteria. 150 subjects (50 in each group) were finally left behind. It was observed there was statistically significant reduction of HDRS-17 scores in subjects receiving *Jyotishmati* (Group B) (13.2±3.92 to 11.36± 4.66 in 6 months). This reduction was less than the group receiving escitalopram 10mg (Group A) and group receiving both escitalopram and Jyotishmati (Group C). Maximum reduction was seen in combination treatment group (13.46±3.84 to 7.16 ± 3.48 in 6 months)
Conclusion- This gives us scope of combining ayurvedic medications like *Jyotishmati* with conventional antidepressant medications for better results. For that more extensive research is needed.

Keywords- *Celastrus Paniculatus* Willd., *Jyotishmati*, Major Depressive Disorder, Integrated medicine.

Abbreviations- MDD= Major Depressive Disorder, HDRS-17= Hamilton Depression Rating Scale- 17 items, ICD-10= International Classification of Diseases for mental health and behavioural disorders 10th edition.

INTRODUCTION

Depression is a common psychiatric condition which often goes undiagnosed and untreated. However, currently it is being recognised more often than it used to be in past. It is clinically characterized by subjective sadness of mood, loss of interest in previously pleasurable activities, persistent fatigue or tiredness, low self-esteem, feelings of guilt, suicidal ideation, decreased attention and concentration, appetite changes, sleep changes and decreased psychomotor activity. It can cause the affected person to suffer greatly and function poorly at work, at school and in the family. At its worst, depression can lead to suicide. Over 700 000 people die due to suicide every year. Suicide is the fourth leading cause of death in 15-29-year-olds.[1]

It effects 3.8% of world population including 5.0% adults and 5.7% adults older than 60 years of age.[2] WHO reports prevalence of depression to be 0.8 % to 9.6% across all countries.[3]According to 2015 global estimates, depression was 3rd leading cause of disability.[4] If this condition prevails, unipolar depression will be 2nd leading cause of disability by 2030.[5]. According to national mental health survey 2015-16, prevalence of depressive disorders is 2.7%. Its prevalence was more in urban metro cities as compared to non metro urban cities and rural areas. Prevalence of depression was 3% among females, 3.5% among people having low income, 3.6% among illiterates and 5.2% among widowed and maritally separated people.[6]

There is twofold increased prevalence in major depression among females as compared to males across all cultures. The reasons hypothesized are hormonal differences, childbirth effects, psychosocial stressors and behavioural models of learned helplessness.[7] Mean age of onset of depression is about 40 years. Recent epidemiological data shows that prevalence of depression is increasing among people younger than 20 years. Reason behind this may be increased abuse of alcohol or drugs and increased career or academic related stress.[8] Major depressive disorder is more common among maritally separated people and divorcees as compared to married people. Good interpersonal relationship is considered as a protective factor.[9]

Depression has multifactorial causation. Bio-psycho-social etiological model has been proposed behind its occurrence. Genetic, neurological, hormonal, immunological, and neuroendocrinological mechanisms are main biological aetiologies which play a role in the development of major depression. Psychological vulnerabilities responsible are cognitive, interpersonal, and personality factors. Social aetiologies like acute life events, chronic stresses and childhood exposure to adversities also cause depression.[10]

Deficiency of biogenic monoamine neurotransmitters like serotonin, dopamine and norepinephrine has been implicated in pathophysiology of major depression.[11]

Nearly 60% of people with depression do not seek medical help. Many feel that the stigma of a mental health disorder is not acceptable in society and may hinder both personal and professional life. There is good evidence indicating that most antidepressants do work but the individual response to treatment may vary.[12] Selective serotonin reuptake inhibitors (SSRIs) are a class of medications that are most prescribed for the treatment of depression. They are often used as first-line pharmacotherapy for depression and numerous other psychiatric disorders due to their safety, efficacy, and tolerability. They are approved for use in both adult and paediatric patients. (13)

Ayurveda, the traditional Indian medicinal system remains the most ancient yet living traditions with sound philosophical and experimental basis. It is a science of life with a holistic approach to health and personalized medicine. It is known to be a complete medical system that comprised physical, psychological, philosophical, ethical, and spiritual health. (14)

Celastrus paniculatus Willd (*Jyotishmati*) is a woody scrambling or climbing polygamodioceous type of shrub. It belongs to family celastraceae. It is found in subtropical Himalayas. The seed oil and the fruit of the plant has tranquilizing and sedative properties. Leaf of plant is good emmenagogue and leafy sap is an antidote for opium poisoning. Seed is thermogenic, emollient, stimulant, intellect-promoting, digestive, laxative, emetic, expectorant, appetizer, aphrodisiac, cardiotonic, anti-inflammatory, diuretic, diaphoretic, febrifuge and tonic, and can treat abdominal disorders, leprosy, skin diseases,

paralysis, asthma, leucoderma, cardiac debility, inflammation, nephropathy, amenorrhea, dysmenorrhea.[15]

Celastrus Paniculatus is rich in many metabolites like β-Dihydroagarofuranoids sesquiterpenes, alkaloids (Celastrine, Celapanin, Celapagin, and paniculatin), flavonoids, terpenoid (β-amyrin, Lupeol, Pristimerin), sterols (β-sitosterol, campesterol, stigmasterol, α-tocopherol, γ-Tocopherol), fatty acid (palmitic, stearic, oleic, linoleic, linolenic acids) and non-fatty acids (Benzoic acid, Cinnamic acid). It also possesses nootropic properties. It has also been used in Alzheimer's disease, seizures/epislepsy, depression, psoriasis, malaria, pain and inflammation, wounds, bacterial infections, and several other debilitating conditions.[16]

Present study was conducted to know about its antidepressant properties and to compare it with conventional Selective Serotonin Reuptake Inhibitor (Escitalopram).

Aims and Objectives

1. To assess the efficacy of *Celastrus Paniculatus* Willd seed oil capsule as an antidepressant in Major depressive disorder.
2. To compare its antidepressant effect with that of escitalopram 10mg alone and its combination with escitalopram.

MATERIAL AND METHODS

This study was conducted in department of Psychiatry of Government Medical College and Rajindra Hospital, Patiala from 28-12-2020 to 31-05-2023, 182 patients suffering from Major Depressive Disorder (MDD) were included in study. They were randomly divided into 3 groups using computer generated random numbers. Sociodemographic data was collected using sociodemographic proforma. Diagnosis of MDD was confirmed using International Classification of Diseases for mental health and behavioural disorders 10th edition (ICD-10). Hamilton Depression Rating Scale -17 was applied at baseline to know severity of depression and at 6 months of administering medications to know therapeutic response. Group A patients received 10mg of Escitalopram, Group B patients received *Jyotishmati* seed oil in capsule preparation and Group C subjects received both 10mg Escitalopram and *Jyotishmati.* Institutional Ethics committee permission was obtained before commencing the study. Written informed consent was obtained from all patients before including them into this project.

Study design- Interventional, comparative, prospective study

Inclusive criteria- All consenting patients diagnosed with Major Depressive Disorder (mild to moderate severity) as per ICD-10

Exclusion Criteria- 1. Patients below 18 years and above 67 years of age. 2. Pregnant and lactating patients. 3. Patients having symptoms of psychosis. 3. Patients having severe MDD as per ICD-10. 4. Patients presenting with catatonic symptoms. 5. Patients having medical comorbidities. 6. Patients having other psychiatric comorbidities. 7. Patients having comorbid substance abuse. 8. Patients on other antidepressants or mood stabilisers.

Instruments used-

1. Sociodemographic proforma to record sociodemographic variables.
2. International Classification of diseases for mental health and behavioural disorders 10th edition (ICD-10) to confirm diagnosis of MDD.
3. 17 itemed Hamilton Depression Rating scale (HDRS-17)- This is one of the earliest scale devised to assess severity of depression. Original scale composed up of 21 items, but Hamilton pointed out that the last four items (diurnal variation, depersonalization/derealization, paranoid symptoms, and obsessive-compulsive symptoms) should not be counted toward the total score because these symptoms are either uncommon or do not reflect depression severity. A score of 0-7 is considered normal, 8-13 is mild depression, 14-18 is moderate depression, 19-22 is severe depression and a score of more than 23 is very severe depression. Internal consistency coefficients of the scale is 0.83 and Inter-rater reliability has been reported to be very high for HDRS-17 total scores (0.80–0.98). Validity of the scale ranges from 0.65 to 0.90.[17]

Statistical analysis of data- All the data collected was compiled and tabulated. It was statistically analysed using the software Statistical Package for Social Sciences (SPSS) version 21.

Observations

Due to time constraints researchers could approach only 182 patients of MDD. Out of which 14 patients dropped out on their own. 18 patients were excluded out due to exclusion criteria. 150 patients (50 in each group) were finally studied. Following observations were derived.

Table-1:- Age distribution of patients in Group A,B and C.

Age Group (Years)	Group A		Group B		Group C		Group A vs Group B	Group A vs Group C	Group B vs Group C
	Patients	Percentage	Patients	Percentage	Patients	Percentage			
18-27 Years	11	22%	13	26%	12	24%	0.949 (t=0.064)	0.977 (t=0.028)	0.972 (t=0.035)
28-37 Years	6	12%	4	8%	5	10%			
38-47 Years	6	12%	7	14%	7	14%			
48-57 Years	22	44%	19	38%	19	38%			
58-67 Years	5	10%	7	14%	7	14%			
Total	50	100%	50	100%	50	100%			
Mean± SD	43.04±14.00		42.86±14.16		42.96±14.16				
Median	48.50		48.50		48.50				
Range	18-64		18-64		18-64				
F value	0.002								
p value	0.998								

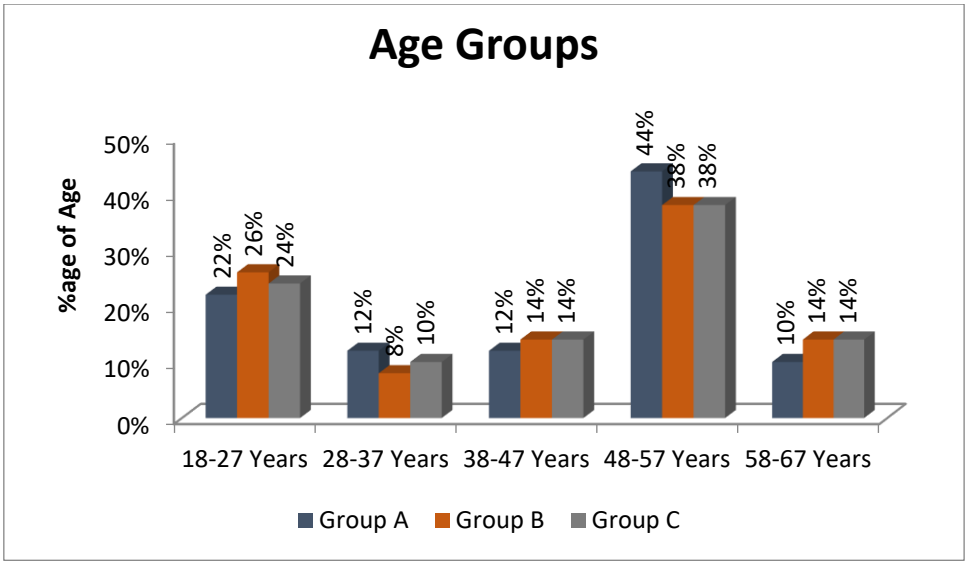


Table-2:- Gender distribution of patients in Group A,B and C.

Gender	Group A		Group B		Group C		Group A vs Group B	Group A vs Group C	Group B vs Group C
	Patients	Percentage	Patients	Percentage	Patients	Percentage			
Female	31	62%	31	62%	31	62%	0.837 (X^2=0.04)	0.837 (X^2=0.04)	0.837 (X^2=0.04)
Male	19	38%	19	38%	19	38%			
Total	50	100%	50	100%	50	100%			
X^2	2.42								
p value	0.119								

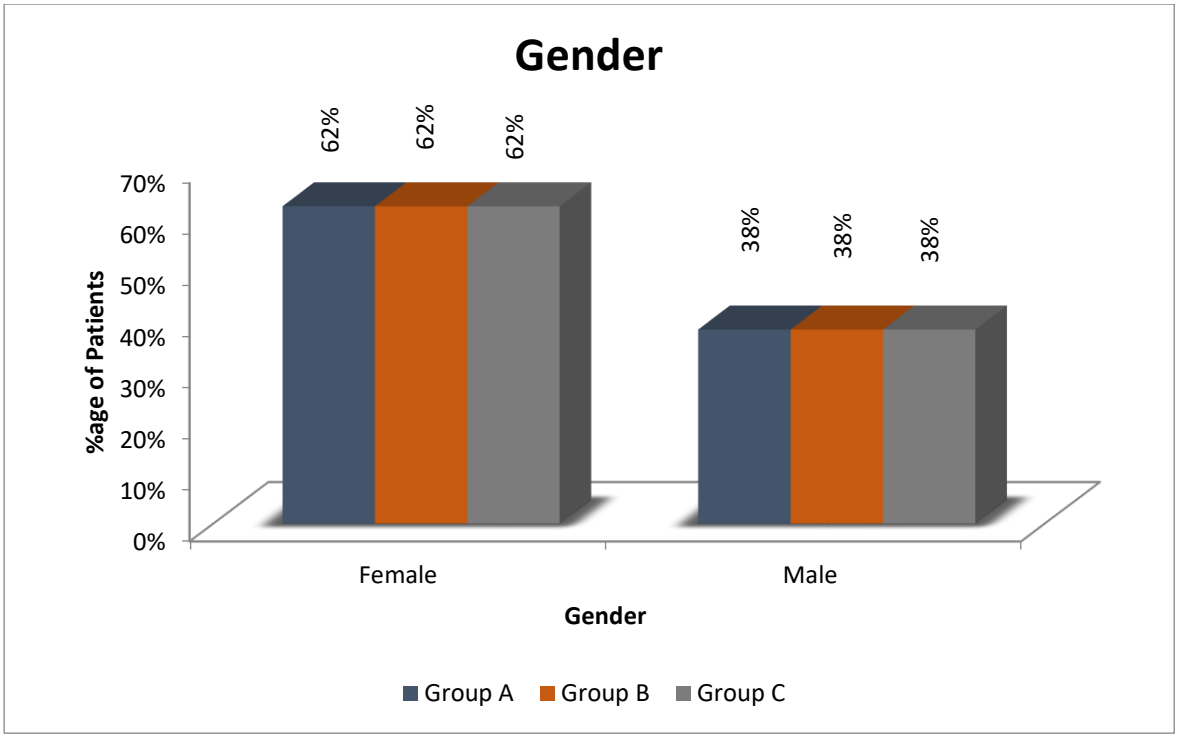
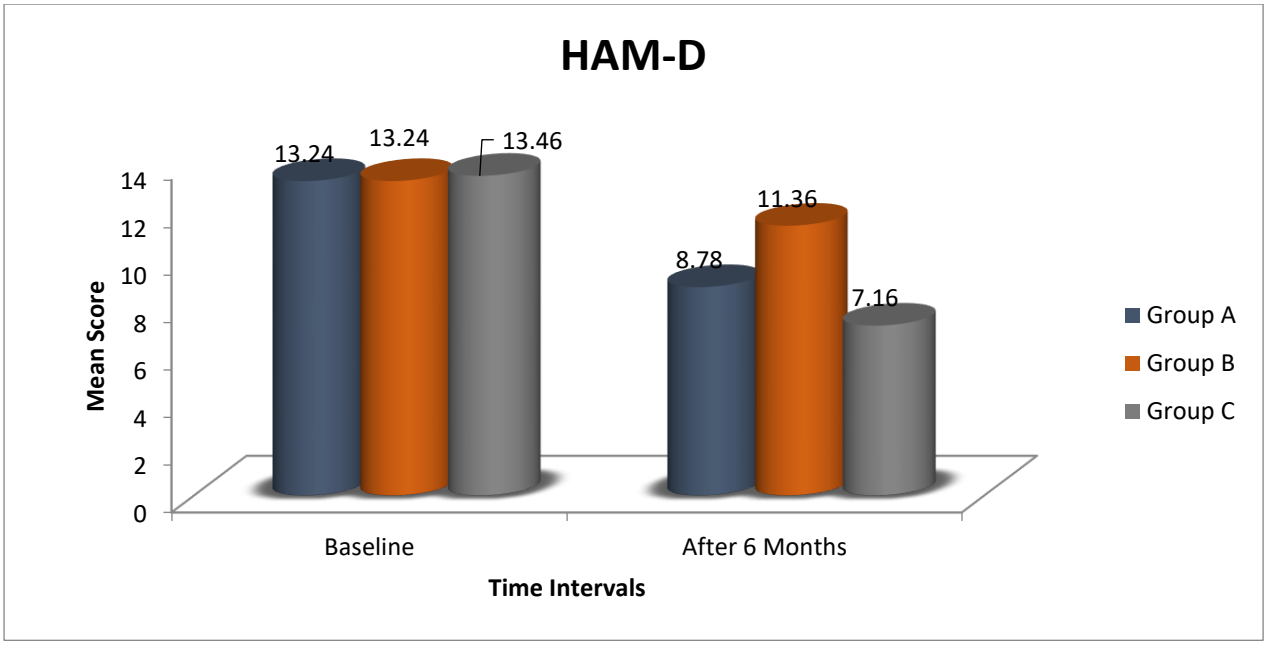


Table-3:- HDRS-17 scores at baseline and after 6 months of treatment of patients of Group A,B and C.

Time Intervals	Group A	Group B	Group C	p value	Group A vs Group B	Group A vs Group C	Group B vs Group C
Baseline	13.24±3.94	13.24±3.92	13.46±3.89	0.949 (F=0.053)	1.000 (t=0.000)	0.779 (t=0.281)	0.779 (0.282)
After 6 Months	8.78±4.01	11.36±4.66	7.16±3.48	0.001 (F=13.489)	0.004 (t=2.969)	0.033 (2.158)	0.001 (5.105)
*p value	0.001 (T=14.480)	0.001 (T=6.800)	0.001 (T=18.233)				

*p = Within Comparison & p = Between Comparison & t= Unpaired t-test & T= Paired t-test



DISCUSSION

In present study, age wise distribution shows that maximum cases of depression were of age group of above 45 years followed by age group of 18-27 years. This findings are similar to the findings of the study by Yosef Zenebe et al in 2021.[18]

It was seen in this study that sex wise distribution showed that more than half of females were found to be depressive. Which implies that females suffer from psychiatric illnesses like depression more than males. Possible reason behind this could be that females usually get mood changes and depressed feelings with frequent change in their hormone levels. Hence, women are nearly twice as likely as men to be diagnosed with depression. Similar results were found by Paul R. Albert in 2015.[19]

This study revealed that there was statistically significant reduction of HDRS-17 scores in subjects receiving *Jyotishmati* seed oil capsule(Group B) (13.2±3.92 to 11.36± 4.66 in 6 months). This reduction was less than the group receiving escitalopram 10mg (Group A) and group receiving both escitalopram and *Jyotishmati* seed oil capsule(Group C). Maximum reduction was seen in combination treatment group (13.46±3.84 to 7.16 ± 3.48 in 6 months). These findings are concordant with study conducted by Rekha Valecha et al.,(2016).[20]

In Ayurveda, it is believed that depression arises out of imbalance of kapha dosha. *Celastrus Paniculatus* Willd. (*Jyotishmati*) being a Medha Dravya (memory booster/neuronal regenerator) shows antidepressant efficacy. This might be because *Jyotishmati* interacts with dopamine D2 receptors, serotonergic and GABA B receptors. It increases the levels of brain dopamine & serotonin and decreases the levels of GABA. *Celastrus Paniculatus* seed oil also significantly inhibits MAO-A activity indicating that decreased metabolism of monoamines like serotonin, dopamine & noradrenaline. This also further contributes to antidepressant effect.

This study is a few of its kind that compares an ayurvedic product *Celastrus Paniculatus* seed oil capsule with conventional drug escitalopram. We comprehend that it may not be as effective as escitalopram but its combination is more beneficial. This hints us towards the path of integrated medicine where in allopathic experts and ayurvedic experts both can contribute their combined efforts in treating debilitating mental health ailments like depression. However larger scale studies are required in future.

CONCLUSION

This study concludes that combination of escitalopram and *Celastrus Paniculatus* Willd. (*Jyotishmati*) is more efficacious than escitalopram or Jyotishmati alone. *Jyotishmati* is not as effective as escitalopram. This motivates us to research traditional ayurvedic medications more and to study their mechanisms of action in treating mental health ailments. Through the practice of integrated medicine, we can use these resources for the benefit of mankind. Allopathic and Ayurvedic clinicians both should provide their expertise in this endeavour.

Limitations

1. Sample size was small in the study
2. It was a hospital-based study.

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