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**A CLINICAL EVALUATION OF UNMADAGAJAKESARI
RASA IN THE MANAGEMENT OF
KAPHAJA UNMADA WITH SPECIAL REFERENCE TO
MAJOR DEPRESSIVE DISORDER**



BY

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A clinical evaluation of Unmadagajakesari Rasa in the management of Kaphaja Unmada with special reference to Major Depressive Disorder.

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ABSTRACT

Depression, a significant contributor to the global burden of disease, affects more than 350 million of global population. World health organization stresses that this is the fourth most disabling health issue worldwide and is expected to be ranked second by 2020. Among depressive disorders, Major depressive disorder is one of the most prominent health problems affecting psychic and physical bodies. Kaphaja Unmada mentioned in Ayurveda is the disease that indicates a strong correlation with Major Depressive Disorder and Unmadagajakesari Rasa has been the broadly used herbomineral drug in ayurveda to manage mental disorders.

The present study focused on analyzing the components of pathogenic factors of Kaphaja Unmada and to present them in schematic forms in the light of Ayurvedic concepts, to evaluate the effectiveness of Unmadagajakesari Rasa in the management of Kaphaja Unmada in relation to clinical outcomes and biochemical changes and to evaluate the clinical safety profile of Unmadagajakesari Rasa.

The study was designed as a single-grouped pre-test, post-test, study and Consecutive sampling method was used. Patients who have Kaphaja Unmada were selected from the OPD of National Ayurveda Teaching Hospital, Borella and were enrolled in accordance with the exclusion and inclusion criteria. Patients were assessed using Hamilton Depression Rating Scale (HAM-D), Beck's Depression Inventory (BDI), Major Depression Inventory (MDI), Kaphaja Unmada Rating Scale (KURS), and Astavidha Manobhava Pareeksha (AMP) prior to the treatment. They were given Unmadagajakesari Rasa 250mg / once daily with ghee for eight weeks and were assessed again using the same assessment tools at the end of the treatment period.

The effectiveness of the trial drug in relation to clinical outcomes was found by comparing the percentage of relief and the severity level of depression of the patients before and after the intervention as indicated by the above mentioned assessment tools. The effectiveness of the trial drug in relation to biochemical changes was found by comparing the serum level of Dehydroepiandrosterone sulphate (DHEAS) of these patients before and after the intervention. The clinical safety profile of the trial drug was prepared by measuring vital parameters, and biochemical parameters of the Patients before and after the treatment. Basic statistics as well as paired sample *t* test was used to analyze the efficacy of the drug.

It was noted that the clinical features and severity levels of Kaphaja Unmada significantly declined from baseline to the end of the eight week acute treatment phase; accordingly, HAM-D, BDI, MDI, KURS and AMP found 68.97%, 75.17%, 69.25%, 71.04%, and 69.4% of overall improvements of Kaphaja Unmada, respectively. Moreover, HAM-D indicated that 12.5% and 87.5% of patients had moderate and severe levels of depression, respectively, prior to the treatment, whereas, 17.5% of them had mild depression after the treatment. BDI showed that 12.5% and 87.5% of patients had moderate and severe levels of depression, respectively, prior to the treatment, whereas 15% and 2.5% of them had mild and borderline depression after the treatment. MDI noted that 12.5%, and 87.5% of these patients had moderate and severe levels of depression, respectively, prior to the treatment, whereas, 17.5% of them had mild depression after the treatment. All the above assessment tools suggested that the majority of patients (82.5%) became free of symptoms after the treatment.

The mean scores of Heart Rate, Pulse Rate, Respiratory Rate, Blood Pressure, serum levels of SGPT, SGOT, BUN, SC, and FBS before the intervention were approximately as same as those after the intervention. Hence, it is obvious that the trial drug has not caused any significant change in vital and biochemical parameters of the patients after the treatment period compared to those before the treatment. The mean scores of DHEAS tests of the male patients before and after the treatment were found to be 3.93 and 2.92 respectively, giving the mean difference of (+) 1.015 and the change was statistically significant ($p < 0.000$). Moreover, it was evident that the elevated levels of serum DHEAS are associated with the pathophysiology of depression in males.

1. INTRODUCTION

In view of the above findings, it can be concluded that Unmadagajakesari Rasa is a highly effective and clinically safe drug in the management of Kaphaja Unmada and DHEAS is a distinct Biomarker for the diagnosis of Major depressive disorder in male patients.

It is recommended that Unmadagajakesari Rasa be used in Sri Lankan Ayurvedic hospitals in the management of Kaphaja Unmada; Moreover, clinical studies need to be carried out with a bigger number of patients in order to minimize the drawbacks of the research, and to find out the effectiveness of this medicine in the management of other types of mental disorders.