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Research Article

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Acute toxicity assessment of the Siddha medication Vaalairasa Mezhugu

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Abstract

The increasing interest in traditional medicine, particularly Siddha formulations, necessitates a thorough understanding of their safety and potential toxicity. Vaalairasa mezhugu is a notable Siddha medicine mentioned in the Siddha text "Siddha marundhu perumuraigal,"(2) and it has various applications. However, there is currently no available information regarding the safety profile of Vaalairasa mezhugu (VRM). This study was conducted to assess the acute toxicity of VRM. The acute oral toxicity test was carried out in accordance with the OECD 423 guidelines for chemical testing. In conclusion, the study found no toxic effects at doses up to 2000 mg/kg of Vaalairasa mezhugu (VRM)

Keywords: Vaalairasa mezhugu, acute toxicity, Siddha, OECD 423 guidelines

Introduction

Siddha medicine, one of the ancient systems of traditional medicine originating from the Indian subcontinent, represents a profound and intricate healing tradition with a history spanning several millennia. Rooted primarily in Tamil Nadu and practiced by the Tamil-speaking communities, Siddha medicine is distinguished by its comprehensive approach to health, integrating spiritual, physical, and psychological dimensions into its therapeutic practices. The system is believed to have been developed by the Siddhars, revered sages who are credited with not only codifying the medical principles but also pioneering a range of medicinal preparations and practices that address various aspects of human well-being.

The significance of Siddha medicine lies not only in its long-standing cultural heritage but also in its holistic methodology, which emphasizes the balance between the body's three humors—Vata, Pitta, and Kapha—and their interaction with the environment.

Siddha medicine is classified into 32 types of internal medicines and 32 types of external medicines.Mezhugu is one among the 32 internal medicines and has shelf life of five years. Mezhugu is of two types,

o Araippu mezhugu [obtained by grinding drugs]
o Churukku mezhugu [obtained by heating them by adding oily substance](1).

One such Siddha herbomineral preparation " VAALAIRASA MEZHUGU", a type of araippu mezhugu mentioned in Siddha marundhusei perumuraigal consist of Purified Veeram (Hydragyrum perchloride), Purified Rasam (Hydragyrum), Purified Pooram (Hydragyrum subchloride), Elam (Elettaria cardamomum), Kirambu (Syzygium aromaticum), Varagarisi (Paspalum scrobiculatum). It has specific indication to arayappu(Inguinal bubo), pavuthiram (fistula), kandamalai (cervival lymphadenitis), mudakkuvatham (arthritis), soolai (Neuralgia) with adjuvant palm jaggery.

Siddhars are knowledgeable about the potential harmful effects of medications and the specific countermeasures to address them. The purpose of toxicity evaluation is to identify the adverse consequences of substances. In today's context, there is increasing concern about drug safety due to the lack of scientific validation and the focus on the relationship between dosage and its impact on the organism. Hence, ensuring the safety of herbomineral formulations is crucial for realizing their full benefits. Ingredients in Vaalairasa Mezhugu, such as Rasam, Veeram and Pooram are known for their anti-inflammatory, anti-pyretic, anti-microbial, and antioxidant properties. However, there has been no toxicity study conducted on Vaalairasa Mezhugu. Therefore, this study aims to investigate both acute toxicity of Vaalairasa Mezhugu using Wistar albino rats.

2. Materials and Methods

2.1.Animals

The study utilized albino Wistar rats weighing between 140 and 160 g, which were sourced from the animal house at The Tamil Nadu Veterinary and Animal Sciences University in Madhavaram Milk Colony, Chennai. These rats were housed individually in polypropylene cages within a ventilated environment (with air cycles at 15 per minute and a 70:30 exchange ratio) at a temperature of 22±3°C and 30-70% relative humidity, following a 12-hour light/dark artificial photoperiod. The rats had free access to RO water and were fed rodent pellets. They were acclimatized to the laboratory conditions for at least seven days before the experiments began. The study received prior approval (NIS/IAEC-24/R04/06122022/18).

2.2. Acute Toxicity study (OECD Guidelines – 423):

The acute oral toxicity test was conducted according to the OECD 423 guidelines for chemical testing.[3] The female rats were randomly divided into two groups (n=3). Group I served as the control, while Group II received Vaalairasa mezhugu at a fixed dose of 2000 mg/kg body

weight via oral gavage. The treated group was closely monitored for signs of toxicity at intervals of 30 minutes, 1 hour, 2 hours, 4 hours, 8 hours, 12 hours, and up to 24 hours. Observations included visual and behavioral changes related to the central nervous system (CNS), autonomic nervous system (ANS), cardiovascular system (CVS), as well as respiratory function, body weight, and muscle coordination over a period of 14 days. Specific attention was paid to changes in skin, fur, eyes, and mucous membranes, along with monitoring for tremors, convulsions, respiratory issues, cardiovascular collapse, sensitivity to stimuli, salivation, diarrhea, lethargy, sleep patterns, coma, and mortality. Data were systematically recorded throughout the study.[4][5] At the conclusion of the 14-day period, all animals underwent gross necropsy to assess any pathological changes.

2.3 Statistical analysis

ANOVA, or one-way analysis of variance, was used to conduct the statistical analysis. Mean ± SEM is used to express the results. Dunnet's multiple comparison test was used after ONE WAY ANOVA for statistical analysis of the data. P-values less than 0.05 were regarded as significant.

3.Results

3.1. Result Analysis of Acute Toxicity Study

3.1.1. Result Investigation of Acute Toxicity Profile of Vaalairasa mezhugu

Following the guidelines established by the Organization for Economic Co-operation and Development, a short-term acute toxicity study of the test drug VRM was conducted at a fixed dose of 2000 mg/kg body weight. The administration of VRM at this maximum dose did not result in any adverse effects among the treated animals, and no abnormalities were observed in any clinical signs. Throughout the study period, no instances of mortality or morbidity were recorded in the VRM-treated group.

Gross necropsy examinations showed no abnormal pathological findings in any of the treated animals. Additionally, there was no significant difference in body weight between the control and test groups. Similarly, behavioral activities related to the central nervous system (CNS), autonomic nervous system (ANS), and cardiovascular system (CVS) showed no significant changes in the drug-treated group. The results are summarized in Table 1. Furthermore, sensory responses in the drug-treated group remained unchanged, and no significant gross pathological differences were found in the vital organs of the treatment group compared to the control group, as detailed in Table 2.

3.1.2.Effect of VRM on Body weight of female rats in acute toxicity study

In accordance with OECD guidelines, an acute toxicity study of VRM was conducted at a dose of 2000 mg/kg body weight. Administration of the test drug VRM at this maximum dose did not show any abnormal clinical signs in the animals. All the rats survived, and there were no treatment-related fatalities during the 14-day observation period. Gross necropsy did not indicate any pathological abnormalities in any of the animals. There was no significant difference in body weight gain between the control and test groups, and no weight loss was noted in the groups receiving VRM. Additionally, there were no significant changes in behavioral activities related to the central nervous system (CNS), autonomic nervous system (ANS), or cardiovascular system (CVS) in the drug-treated group. The findings are summarized in Table 1.
Furthermore, the drug-treated group's sensory response has not changed significantly. When comparing the gross pathological observations of any of the treatment group's vitals to those of the control group, no discernible difference was discovered. The LD50 cut off is unclassified because no toxicity was seen up to 2000 mg/kg in the results, which were summarized in table 2.

Table 1: Effect of VRM on Clinical signs of rats in Acute Toxicity Study

Clinical signs	Control	Test group
Animal appearance	Normal	Normal
Lacrimation	Absent	Absent
Salaivation	Absent	Absent
Convulsion	Absent	Absent
Skin color	Normal	Normal
Diarrhea	Absent	Absent
Touch responsibility	Normal	Normal
Mortality	Nil	Nil
Behaviour	Normal	Normal

Table 2: Impact of EC on Female Rats' Body Weight in an Acute Toxicity Study

Treatment	1st day	7th day	14th day
Group I -Control	162.2±9.15	173±14.54	183±10.56
Group II-VRM 2000mg/kg	172.8±3.96	185.4±4.34	200.2±6.38

Values are mean ± SEM (n = 3), Statistical analysis carried out using One-way ANOVA followed by Dunnett's test.

Table 3: Effect of VRM on gross observation of vital organs of female rats in Acute Toxicity Study

Organs	Control	Test group
Brain	Normal	Normal
Heart	Normal	Normal
Lungs	Normal	Normal
Liver	Normal	Normal
Stomach	Normal	Normal
Spleen	Normal	Normal
Kidney	Normal	Normal
Uterus	Normal	Normal
Ovary	Normal	Normal

4. Discussion

Traditional medicines are often considered safer than chemical products, leading to less focus on toxicity studies for these formulations compared to their chemical counterparts. However, some herbal-based products can be toxic and pose risks to human health. Therefore, understanding the oral toxicity of Siddha formulations is essential; it helps identify safe dosing and potential clinical signs associated with the agents being studied. In an acute toxicity study, the Siddha formulation VRM was administered orally at a dose of 2000 mg/kg and monitored for 14 days. The results indicated that there were no fatalities among the rats, and treated animals showed no signs of toxicity. Additionally, no behavioral changes, neurotoxic effects, or cardiovascular issues were detected. There were no abnormalities in behavior, posture, gait

Conclusion

In conclusion, the acute toxicity study showed no toxic effects at doses up to 2000 mg/kg of Vaalairasa mezhugu (VRM). Therefore, it can be inferred that VRM is safe for therapeutic use in humans.

Conflict of interest: Nil

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