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RESEARCH ARTICLE

EVALUATION OF ACUTE TOXICITY OF *MAHACHAITASA GHRITA*

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ABSTRACT

Mahachaitasa Ghrita is an Ayurvedic polyherbal ghee preparation mainly indicated for Sarvachetovikara (all disorders of mind), especially Unmada (Insanity) and Apasmara (Epilepsy) and it is an effective drug for this condition. Continuous administration of any medications may lead to some adverse effects on the body. So it is necessary to assess the toxicity of Ayurvedic formulations. Here in this study, 6 rats were administered Mahachaitasa Ghrita for 14 consecutive days and assessed in-life observation of rats, change in body weight, food intake, and water intake. Haematological and biochemical parameters were assessed before and after the study. The histopathology of the Liver and Kidneys were also analyzed. The in-life observation and other general observations showed no adverse effects after a 14-day pretreatment with Mahachaitasa Ghrita. Haematological and biochemical parameters had shown significant improvement in all parameters in the rats. The histopathology of the liver and kidney showed only mild changes. So we can suggest that Mahachaitasa Ghrita could be a safe drug for a 14-day administration at a dose of 4.93 g/kg in Wistar Albino rats.

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INTRODUCTION

Mahachaitasa Ghrita is an *Ayurvedic* formulation mentioned in *Bhavaprakasa Unmada Adhikara*. It is a *Ghrita* (Ghee) preparation with 42 drugs. It is indicated for a wide range of conditions, including *Unmada* (insanity), *Apasmara* (epilepsy), *Mandagni* (poor digestive fire), *Jvara* (fever), *Kasa* (cough), *Vatarakta* (rheumatoid arthritis), *Pratisyaya* (rhinitis), *Sosha* (desiccation), *Karsyam* (emaciation), *Tritiyaka Jwara* (tertian fever), *Mutrakrichra* (dysuria), *Katisula* (pain in the waist), *Visarpa* (herpes), *Panduroga* (anemia), *Kandu* (itching of the skin), *Visha* (poison), *Prameha* (polyurea), and *Gara Visha* (homicidal poison). It is also recommended in cases of possession by evil spirits, unconsciousness, and infertility in women. This remedy is considered auspicious and is believed to offer benefits such as longevity, increased strength, protection from witchcraft, relief from dizziness, intoxication, and fainting, as well as improvements in intelligence, memory, and creativity[1]. As it is a Ghrita preparation, there are so many doubts regarding its continuous use. Mahachaitasa Ghrita is an effective drug for Sarvacheto Vikara such as Apsmara and Unmada.

So it is necessary to evaluate the safety of this drug. Hence, the present study aims to evaluate the acute toxicity study of Mahachaitasa Ghrita in Wistar albino rats.

MATERIALS AND METHODS

Drug: *Mahachaitasa Ghrita* was prepared at Pankajakasthuri Herbals India (P) Ltd. Poovachal, Thiruvananthapuram by following standard guidelines as prescribed in ayurvedic classics. 192 g each of *Dasamoola*, *Rasna*, *Eranda*, *Trivrit*, *Bala, Murva*, and *Satavari* were made into Kashaya (decoction) and 12 g each of Vishala, Harithaki, Vibhithaki, Amalaki, Kaunthi, Devadaru, Elavaluka, Sthira, Ananta, Haridra, Daruharidra, Priyangu, Sariva, Krishna Sariva, Nilotpala, Ela, Manjishta, Danti, Dadima, Kesara, Vidanga, Agnipathri, Kushta, Chandana, Padmaka, Talisapatra, Brihati, and Malatikusuma were made to Kalka (paste). Then *Ghrita* (1536 ml) was prepared on mild fire along with the prepared *Kalka* and *Kashaya*[1].

Animals: Wistar strain albino male rats weighing 175 - 250 g, were used as per the guidelines of the Institutional Animal

Ethics Committee (IAEC). The animals were obtained from Animal House (Reg. No. 2093/PO/ReRcBi/S/20/CPCSEA) under Pankajakasthuri Herbal Research Foundation, Kattakkada, Thiruvananthapuram. The animals were maintained under ideal husbandry conditions in terms of standard conditions of temperature (23 ± 2° C), relative humidity (50–60%) and exposed to 12 h light and dark cycles. All animals were exposed to the same environmental conditions and were maintained on a standard diet and drinking water ad libitum. The experimental protocol was approved by the PKAMC/IAEC/NOC/02/2021 as per guideline of committee for the purpose of control and supervision of experiments on animals in India.

Dose fixation: As per classical guidelines, the therapeutic clinical dose of Mahachaitasa Ghrita is 48 g a day[2]. The suitable dose for rats was calculated as 4.93 g/kg body weight of rat[3]. The test drug was administered orally with the help of oral gavage.

Acute toxicity study: Wistar strain albino rats were selected and acclimatized for 7 days before the experiment. The test drug was orally administered at a dose of 4.93 g/kg to rats. The rats were observed closely for behavioral changes, signs and symptoms of toxicity, and mortality, if any continuously for the first 6 hours and thereafter periodically up to 14 days. The initial body weight of all animals was recorded. Blood samples were taken on the 0th day by taking blood from the lateral tail vein under mild anesthesia for analysis. Daily food and water intake were recorded for 14 days.

The general behavioral pattern was observed once a week by exposing each animal to an open arena. On the 14th day, animals were weighed again and euthanized by injecting Sodium pentobarbital at 200 mg/kg body weight dissolved with saline intraperitoneal and collected blood by cardiac puncture method. Then the abdomen was opened through a midline incision to record the autopsy changes followed by the dissection of the important organs. AST (Aspartate aminotransferase), ALT (Alanine Transaminase), ALP (Alkaline phosphatase), Total Protein, Albumin, Bilirubin Total, Direct Bilirubin, Total Cholesterol, Urea, Uric Acid, Creatinine, ESR (Erythrocyte Sedimentation Rate), HB (Hemoglobin), Total Count, Neutrophils, Lymphocytes, Monocytes, Eosinophils & Basophils were measured from the blood samples. The histopathology of the liver and kidneys was also done.

Statistical analysis: The data are expressed as mean ± standard deviation. The statistical test used was paired t-test and ANOVA method. p-value < 0.05 was considered statistically significant. The level of significance was noted and interpreted accordingly.

RESULTS

Throughout the entire study duration, rats were carefully observed for clinical signs. These observations occurred during handling and in an open field setting. Clinical signs included various sensory organ changes (e.g., skin, eyes, nose), alterations in body secretions, autonomous activities (respiratory rate, irregular breathing patterns, pupil size, piloerections), vocalizations, lacrimation, salivation, convulsions, tremors, response to handling, walking patterns, overall body language, reflexes, and changes in skin and fur texture, as well as muscle tremors and behaviors. These were observed daily, and it is worth noting that no noticeable abnormalities were detected in any of the rats during the entire study period. There were no abnormal changes in the Body weight, food intake, and water intake in test rats (Table 1-3).
The biochemical (Table 4a & 4b) and haematological parameters (Table 5) were checked before the administration of the test drug. Except for AST, Direct Bilirubin, Uric acid, and Urea, other parameters were within the normal range in all rats. The biochemical and haematological parameters were not increased further after 14 days of administration of test drug (Table 4a ,4b , 5). Histopathology of the Liver (Figure 1) and Kidney (Figure 2) showed mild changes.

Table 1. Change in Weight

	Mean	SD
0th day	240.83	10.685
14th day	265.00	9.487

Table 2: Change in Food intake

	Mean	SD
1st week	11.00	0.00
2nd week	12.33	1.21

Table 3: Change in Water intake

	Mean	SD
1st week	21.17	5.67
2nd week	19.00	0.63

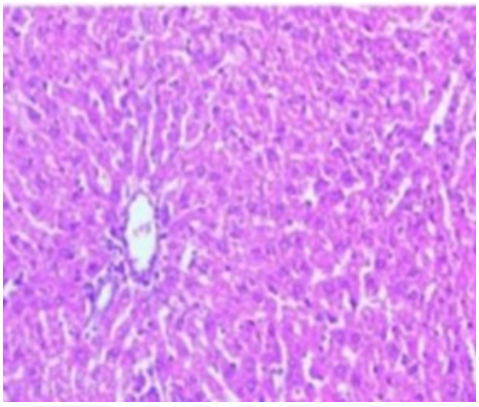

Figure 1. Histopathology of Liver tissue of experimental rats; a: *Mahachaitasa Ghrita* administered rat liver - Mild periportal mononuclear cell infiltration, mild hepatocyte degeneration and sinusoidal dilatation

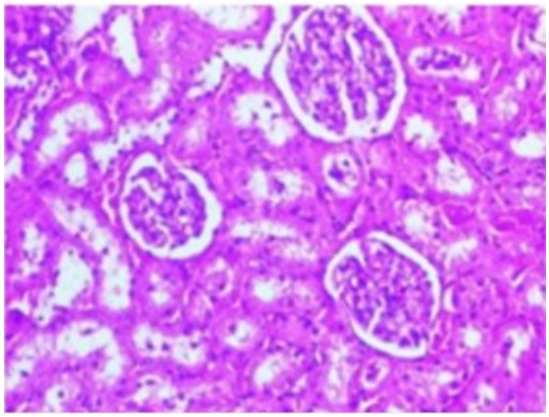

Figure 2. Histopathology of Kidney tissue of experimental rats: *Mahachaitasa Ghrita* administered rat kidney - Mild renal tubular degeneration and intertubular hemorrhage and mild widening of Bowman's space

Table 4a: Change in Biochemical Parameters

	AST		ALT		ALP		TOTAL PROTEIN		ALBUMIN		TOTAL BILIRUBIN		DIRECT BILIRUBIN	
	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD
0th Day	188.57	33.57	56.55	8.37	213.37	64.52	7.63	0.47	4.07	0.40	0.25	0.08	0.12	0.08
14th Day	140.33	27.89	43.32	8.05	180.63	61.29	7.22	0.52	3.98	0.25	0.20	0.09	0.12	0.08

Table 4b. Change in Biochemical Parameters

	URIC ACID		UREA		CREATININE	
	Mean	SD	Mean	SD	Mean	SD
0th Day	3.73	0.29	39.70	6.51	0.28	0.07
14th Day	2.45	0.61	32.40	5.25	0.27	0.02

Table 5. Change in Haematological Parameters

	ESR		HB		TOTAL COUNT		NEUTROPHIL		LYMPHOCYTES		MONOCYTES, EOSINOPHILS & BASOPHILS	
	Mean	**SD**	**Mean**	**SD**	**Mean**	**SD**	**Mean**	**SD**	**Mean**	**SD**	**Mean**	**SD**
0th Day	3.83	0.75	14.63	1.71	11167	1415	21.33	4.55	65.67	4.76	13	3.22
14th Day	3.50	0.55	15.30	1.26	10150	1328	23.50	3.51	68	3.46	8.50	2.35

DISCUSSION

The mean of ALT, ALP, Total Protein, Albumin, and Total Bilirubin were within the normal range throughout the study. The mean of AST was more than the normal range before the study (188.6) and it was markedly reduced to 140.3 after 14 days. The mean of Direct Bilirubin was more than the normal range throughout the study and the value remained the same (0.1) before and after the study. The antioxidant property of Go Ghrita (cow's ghee)[4] has already been proven and the Samskaryasyanuvarthana property (ability to carry the properties of herbs and other substances that are processed with it) of Go Ghrita[5] enhances the antioxidant and hepatoprotective properties of drugs in Mahachaitasa Ghrita. From these results, we can assume that the Mahachaitasa Ghrita has a hepatoprotective property. The mean of Creatinine was within the normal range throughout the study. The mean of Uric acid (3.7) and Urea (39.7) was not within the normal range before the study. After 14 days of drug administration, Uric acid and Urea decreased to 2.4 and 32.4 respectively. These results suggest that the Mahachaitasa Ghrita exhibits a renal protective property. All haematological parameters were within the normal range throughout the study. While analyzing the histopathological study results with biochemical & haematological parameters, mild structural changes were observed. However, no significant functional changes or general observation changes were observed in the rats after a 14-day administration of Mahachaitasa Ghrita. So, we can interpret this as the structural changes were not because of the effect of *Mahachaitasa Ghrita* and it may be the changes in the organs even before the study.

CONCLUSION

From the present study, it is concluded that Mahachaitasa Ghrita at a dose of 4.93 g/kg, orally did not produce any observable toxic effects and mortality for a period of 14 days in wistar albino rats. Hence, it can be inferred that Mahachaitasa Ghrita is a safe drug for different conditions.

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