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ACUTE TOXICITY STUDY OF VEDANĀSTHĀPANA GHANA VATI

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ABSTRACT

Vedanāsthāpana gana is mentioned in the fourth chapter of *Charaka samhita* and it is useful in alleviating the pain in pain predominant disorders. Present study was designed to examine the acute toxicity of *Vedanāsthāpana ghana vati*. *Vedanāsthāpana ghana vatis* were prepared according to classical method and used for the study. The acute toxicity study was carried out as per OECD guideline 425, on Swiss albino mice weighing 25 to 30 gm each. Minimum dose of 2000 mg/kg to maximum dose of 5000mg/kg was administered orally in the form of aqueous slurry. All groups were under continuous observation to check mortality and behavioral changes during first 24 hrs and then daily for fortnight. Changes observed in the parameters like body weight, food and water intake as well as cage side observations were reported. There was no abnormality observed or reported during the study in any of the Swiss albino mice. Result provides the evidence to state firmly that *Vedanāsthāpana ghana vati* is nontoxic and safe.

Keywords: *Charaka Samhita, Vedanāsthāpana Ghana vati* and acute toxicity

INTRODUCTION

Property of the drug which subsides pain in particular part of the body and which restores the normal state is known as *Vedanāsthāpana*[1]. *Vedana* (sense of pain) is generated by the touch of sense object with its respective sense organ in association with *Manas (mind)*. Mind and body together with the sense organs are considered as sites of manifestation of happiness and miseries[2]. Pain is the most common complaint which makes the patient to seek remedy. Pain is said to be one of the nature's earliest sign of morbidity. Miseries are mainly caused by pain and it can be relieved by the usage of *Vedanāsthāpana gana dravya*. Plants and its derivatives playing a key role in world health and have long been known to possess biological activity. At present it is easier to determine efficacy and safety of herbal remedies because the chemical compounds are known along with its side effects. Medicinal plants behave as authentic

medicines because the chemical substances of which they are formed can have a biological activity in humans. Determination of efficacy and safety of herbal drugs is necessary because many people using these agents as self medication.

Toxicity is the fundamental science of poisons. The Organization for economic co - operation and Development (OECD) mentioned acute toxicity as, the advance effect occurring within a short time of oral administration of a simple dose of a substance or a multiple doses given within 24 hours. Photo chemical interactions of poisons lead to injury or death of living tissues. Toxicology is a science and it is also an art like medicine. It includes observational data gathering and data utilization to predict outcome of exposure in humans and animals. Ancient humans are categorized some plants as harmful and some as safe[3].

Toxicologists usually divide the exposure of animals to toxic substances into four categories which are acute, sub acute, sub chronic and chronic[4-5]. Poisons are the agents capable of producing a deleterious response in a biological system, seriously injuring function or producing death. The aim of present work is to study the toxic effect of Vedanāsthāpana ghana vati.

Ayurvedic formulations contain multiple ingredients, for example *dashamoola gritha, amalaki rasayana* etc are used to cure many aliments and to prevent forthcoming diseases. Similarly *Vedanāsthāpanaghana vati* is one such formulation used to cure vedana of a particular disease. In a poly herbal preparation, as all the drugs have different properties by means of *rasa panchakas,* it is very difficult to predict the action of particular preparation and *Vedanāsthāpanaghana vati* is not an exception for this. Modern pharmacology speaks in terms of kinetics and dynamics; it is the need for Ayurvedic researchers to adopt some of the contemporary techniques in order to justify time tested principles of Ayurveda. So in the present study toxicity of the formulation i.e*., Vedanāsthāpanaghana vati* was carried out.

OBJECTIVE OF THE STUDY:

To study the toxic effect of *Vedanāsthāpana ghana vati.*

MATERIALS AND METHODS

Materials used for the study:

For the present study mainly two materials are used they are Swiss albino mice and *Vedanāsthāpanaghana vati.*

Selection and maintenance of the sample

Healthy mice were selected for the study, weighing in between 25 to 30 grams each. All mice were housed in polyurethane cages. Cages were provided with wheat husk bedding and were cleaned daily. Animals were provided with drinking water *ad libitum* and were fed on commercially available Mice feed supplied by Amrut Feed. The specifications of the feed are listed below in table no 1**.** The feed was enriched with stabilized vitamins such as Vit. A, Vit D3, Vit. B12, Thiamine, Riboflavin, Folic acid and supplemented with all minerals and micro elements. Measured quantity of water and feed were supplied daily in each cage. Consumption of water was recorded on the basis of amount of water left in the feeding bottles. In the same way amount of feed was assessed based on the quantity of feed left in the feed hopper.

TABLE NO 1: COMPOSITION OF FEED

Name	Percentage
Crude Protein.	20 - 21 % minimum
Ether Extractive	04 - 05 % minimum.
Crude Fiber	04 % maximum
Calcium	1.2%.
Phosphorus.	0.6 % minimum
NFE	54 %.
ME Kcal/Kg	3600.
Pallet Size	12 mm
Ash	08 % maximum.

Ingredients of Vedanāsthāpanaghana vati

Vedanāsthāpanaghana vati formulated by using ten drugs namely *Shāla, Kadamba, Katphala, Padmaka, Shireesha, Ashoka, Mocharasa, Elavāluka, Tumba* and *Vetasa*[6] Properties of individual drugs and its components are given in Table no 2 and 3.

TABLE NO 2. PROPERTIES OF INDIVIDUAL DRUGS PRESENT IN VEDANĀSTHĀPANAGHANA VATI

Sl no	Drugs	Rasa	Guna	Virya	Vipaka	Dosha karma
1	Shala	Kashaya(twak) Kashaya, Madhura (Rala)	Ruksha	Sheeta	Katu	Pitta Kapha Shamaka
2	Katphala	Kashaya Tikta Katu	Laghu Tikshna	Ushna	Katu	Kapha vata shamaka
3	Kadamba	Tiktha Kashaya	Ruksha	Sheeta	Katu	Tridosha Shamaka
4	Padmaka	Kashaya Tikta	Laghu	Sheeta	Katu	Kapha pitta Shamaka
5	Tumba	Katu Tikta	Laghu Ruksha	Ushna	Katu	Kapha vata shamaka
6	Mocha Rasa	Madhura	Laghu Snigdha Picchila	Sheeta	Madhura	Vata Pitta Shamaka
7	Shirisha	Kashaya Tikta Madhura	Laghu Ruksha Tikshna	Eshad Ushna Sheeta	Katu	Tridosha Shamaka
8	Vetasa	Kashaya Tikta	Laghu	Sheeta	Katu	Kapha Pitta Shamaka

9	Elavaluka	Kashaya	Sheeta	Sheeta	Katu	Pitta kapha shamaka
10	Ashoka	Kashaya Tikta	Laghu	Sheeta	Katu	Kapha Pitta shamaka

TABLE NO 3. COMPONENTS OF THE FORMULATION

No	Drug (Sanskrit name)	Botanical name	Family	Chemical constituents
1	Shala	Shorea robusta	Dipterocarpeaceaa	Sterols, Methyl sterols
2	Katphala	Myrica nagi	Myricaceae	Myricitrin, Myrisetin,Tanin
3	Kadamba	anthocephalus indicus	Rubiaceae	cinchotannic acid, Beta sitosterol
4	Padmaka	Prunus cerasoides	Rosaceae	Taxifolin Amygdaline
5	Tumba	Zanthoxylum aramatum	Rutaceae	Berberine Dictamnine
6	Mocha rasa	Salmalia malabarica	Bombacaceae	Tannin Saponin
7	Shirisha	Albizzia lebback	Leguminoseae	Teflitinin, Sayanitin, Saponin
8	Vetasa	Salix tetrasperma	Salicaceae	Hydrocyanic acid, Volatile oil, Salicylic acid
9	Ela valuka	Prunus avium	Rosaceae	Prunasin (D-mandelonitrile-β-glucoside), Quercetin-3-0-rutinosyl-7,
10	Ashoka	Sarraca ashoka	Lleguminoseae	Tannic acid, Gallic acid, Tannin and Catechin

Method of preparation of Vedanāsthāpanaghana vati

Vedanāsthāpana gana dravyas are collected and made into *Yavakuta churna (Coarse powder)*. That was subjected for boiling with 16 times of water and reduced to 1/4th. The resulting solution was sieved through a cloth and brewed until it becomes thick. The thick solution was dried in sunlight. The dried solution was made into *ghanavati* of proper size at S.N Pandit pharmacy, Mysore. The *ghanavati* was made into aqueous slurry by using tween 80 and administered orally.

Study protocol (table no 4)

To assess the non toxic effect of *vedanāsthāpanaghana vati* following study design has been framed. Swiss albino mice are grouped in to two for the purpose of administration of the drug in minimum to maximum dose. Each group contains three Swiss albino mice. In the first group a minimum dose of 2000 *mg/kg* of drug is administered. On the other hand in second group maxi-

mum of 5000 *mg/kg* of drug is administered. Oral route of drug administration is followed. Drug is administered once in a day for 14 days (Table no 5 and 6). All these days' observations are done and the data is collected. Toxicity study done based on OECD guidelines 425[7].Present studies were carried out in Sarada Vilas College of pharmacy, Mysore, India. Institutional Animal ethical clearance obtained after ethical committee meeting in Sarada vilas college of Pharmacy. (No. SVCP/075/2014-15)

TABLE NO 4: STUDY PROTOCOL

Name of the study	Acute toxicity study
Test material	Vedanāsthāpana Ghana vati
Animal model	Albino Swiss Mice
Animals procured from	Shri Venkateshwara Agencies, Bangalore
Sex	Female
Weight range of animals	Between 25 to 30 grams
Route of administration	Oral
Vehicle	Water
No of administration	Single
Study duration	Acclimatization for 14 days, one day drug administration and 14 days observation period including holidays
Parameters observed	Cage side observations, daily food and water intake, daily body weight and daily mortality record etc.

TABLE NO 5: DOSES REGIME OF 2000MG/KG

Sl No	Sex	weight of the mice	Dose
1	Female	30 gm	60 mg(0.6 ml)
2	Female	26 gm	52 mg(0.52 ml)
3	Female	28 gm	56 mg (0.56 ml)

TABLE NO 6: DOSES REGIME OF 5000MG/KG

Sl No	Sex	weight of the mice	Dose
1	Female	26.62 gm	133.1 mg(1.33ml)
2	Female	28 gm	140. mg(1.4ml)
3	Female		150. mg (1.50ml)

Assessment tools

In the present study, data is obtained by using three tools, they are :

A. Cage side observations

B. Daily food and water intake

C. Daily body weight and daily mortality record

RESULT AND DISCUSSION

Cage side observations

The examination of the behavior of animals was reported by recording general

observations of each animal on a daily basis from the stage of dosing to the end of the study. Any changes or abnormalities recorded could be an indication of toxicity. The test animals at two different dose levels of *Vedanāsthāpana Ghana vati* showed no significant changes in behavior before and after the administration. (Table no 7)

TABLE NO 7: CAGE SIDE OBSERVATIONS FOR ALL ANIMALS

Parameters	Cage Side Observations
Condition of the fur	Normal
Skin	Normal
Subcutaneous swellings	Nil
Abdominal distension	Nil
Eyes- dullness	Nil
Eyes-opacities	Nil
Pupil diameter	Normal
Ptosis	Nil
Colour and consistency of the feces	Normal
Wetness or soiling of the perineum	Nil
Condition of the teeth	Normal
Breathing abnormalities	Nil
Gait	Normal

Body weight changes

Body weight is an important factor to monitor the health of an animal. Loss in body weight is frequently the first indicator of the onset of an adverse effect. A dose, which causes 10% or more reduction in the body weight, is considered to be a toxic dose. It is considered to be the dose, which produces minimum toxic effect, irrespective of whether it is accompanied by any other changes or not. All the animals from treated groups did not show any significant decrease in body weights for all the 14 days as compared with the zero day values. There was no significant change in food and water intake of the test animals at two different dose levels of *Vedanasthapana Ghana vati* for all days.

Mortality

Mortality is the main criteria in assessing the acute toxicity (LD50) of any drug. There was no mortality recorded even at the highest dose level i.e. 5000 mg/kg body weight, of *Vedanāsthāpana Ghana vati*. (Table no 8)

TABLE NO 8; MORTALITY RECORD FOR VEDANĀSTHĀPANA GHANA VATI

SEX	Female (mortality record)
Hr. 1	Nil
Hr. 2	Nil
Hr. 3	Nil
Hr. 4	Nil
Day 1	Nil

Day 2	Nil
Day 3	Nil
Day 4	Nil
Day 5	Nil
Day 6	Nil
Day 7	Nil
Day 8	Nil
Day 9	Nil
Day 10	Nil
Day 11	Nil
Day 12	Nil
Day 13	Nil
Day 14	Nil
Mortality	0

CONCLUSION

From the results of this study, it is observed that there is no change in body weight, food and water consumption by the Swiss albino mice in both the dose groups. There was no mortality recorded even at the highest dose level 5000 mg/kg body weight, which proves that *Vedanāsthāpana Ghana vati* have no any significant toxic effect in Swiss albino mice.

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