JOURNAL OF PHARMACEUTICAL SCIENCE AND BIOSCIENTIFIC RESEARCH (JPSBR)

(An International Peer Reviewed Pharmaceutical Journal that Encourages Innovation and Creativities)

Acute oral toxicity study of extract of Embelia basaal stem bark in rats: a safety study

Neha Palande

Research scholar: JJT University, Jhunjhunu, Rajasthan, India

ABSTRACT:

About twenty thousand deaths occur every year due to liver disorder which requires a lot of attention in management and treatment aspects. So designing of easy to administer, safe and effective liver protective and tonic option is one of the prime goal in alternative system of medicines. The current study was designed to study acute oral toxicity study of herbal extract of Embelia basaal stem bark as per the OECD 425 paragraph 22 guideline. For any new herbal preparation to arrive into market, it is required to perform stepwise testing approach for developing scientifically sound data on the safety of the formulation. The herbal extracts of Embelia basaal stem bark single oral dose supplemented to all laboratory screened rats selected for the study experiment. The assessment parameters like general appearance, behavior, body weight, mortality and necropsy were studied. No changes in general appearance and mortality was observed. The Embelia basaal stem bark extract was found to be safe at dose of 2000mg/kg. Still this is just a safety confirmation study so further studies like chronic toxicity study will be require to perform in future.

KEYWORDS: acute oral toxicity study, Embelia basaal stem, mortality, liver disorder

Article history:

Received 10 Oct 2015
Revised 22 Oct 2015
Accepted 30 Oct 2015
Available online 01 Nov 2015

Citation:

Palande N. Acute oral toxicity study of extract of Embelia basaal stem bark in rats: a safety study. **J Pharm Sci Bioscientific Res**. 2015 5(6):617-620

For Correspondence:

Neha Palande

Research scholar: JJT University, Jhunjhunu, Rajasthan, India

(www.jpsbr.org)

INTRODUCTION:

Liver disorder is one of the major causes of morbidity and mortality in public, affecting humans of all ages. About twenty thousand deaths occur every year due to liver disorders. Some of the commonly known disorders are viral hepatitis, non-alcoholic fatty liver disease, metabolic liver disease, alcohol liver disease, autoimmune liver disease, drug induced liver injury, gallstones, etc. carcinoma of liver cell is one of the ten most common tumors in the world with over 2, 50,000 new cases each year. As per the World Health Organisation estimates, globally 170 million people are chronically infected with hepatitis C only & every year 3–4 millions cases are newly added into the list. Also, there are more than 2 billion infected by hepatitis B virus (HBV) & over 5 million are getting infected with acute hepatitis B virus yearly.[1, 2]

Traditional system of medicine like ayurveda is comprehensively practiced in the prevention, diagnosis and treatment of various life threatening or incurable diseases and disorders.[3.4] Even though the extensive use of plants for treatment of several ailments there is tiny information known about their toxicity and safety aspects. The evaluation of the toxic action of the plant extracts or poly-herbal formulations is important in order to regard as safe before used as management options.[5, 8] A prime stage in ensuring the safety of drugs is to conduct toxicity tests in suitable animal models and as

per OECD guidelines.[6, 8] The acute oral toxicity test aims at establishing the therapeutic index, i.e. defined as the ratio LD50 and ED50. In common, the narrower this margin is, more likely it is that the drug might produce unwanted effects, and the greater is the index the safer the compound is for use. However, the term acute oral toxicity is most often used in lethal dose determinations.[7, 8] Embelia basal is highly valuable plant mention in various ayurvedic literature having Anthelmintic and antioxidant activity. The other antimicrobial activity was also attempted on it.

MATERIALS & METHOD:

Plant Materials

The species for the proposed study that *Embelia basaal* were collected from Dang and Ahva in the month of January 2013 and were authentified by Dr. S .B. Narkhede, department of Pharmacognosy, Smt.BNB. Swaminarayan Pharmacy College, Salvav.

Processing of plant samples

The stem of *Embelia basaal* were suitably washed in tap water and then rinsed with distilled water. The stems are kept for drying in an oven at a temperature of 34-40°C for 3 days. The dried stems of plant are pulverized, by using a sterile electric blender, to obtain a powered form of stem. The powdered form of these plants is stored in airtight glass containers, protected from sunlight until required for analysis of it.

Preparation of extracts of *Embelia basaal* stem:

The residue was successively extracted with petroleum ether, ethanol, and aqueous using hot percolation method (3 days). The extract obtained was filtered, concentrated and dried in a hot air oven.[9-10]

Acute oral toxicity study:

Healthy young adult wistar female rats, weighing 150-180 gm at the start of the experiment, were procured from animal house of the institute. The present study was approved by Institutional Animal Ethics Committee of SMTBNBSPC. Female rats were selected because literature review on conventional LD50 tests illustrate that usually there is slight difference in sensitivity between sexes, but in those cases where differences are observed, females are normally slightly more sensitive.[11] The animals were randomly screened and selected & kept in their cages for five days preceding to dosing to allow for acclimatization to the laboratory conditions. The animals were housed individually in clean polypropylene cages. The temperature of animal room and its humidity were maintained at 25°C (± 30°C) and 45-54% respectively with a light-dark cycle of 12 hours (light from 06:00 am to 06:00 pm). Clean husk bedding was provided to the experimental animals. The animals were fed with pellet chow and unlimited supply of drinking water.

Observations:

Animals were observed continuously during the first 30 minutes after dosing and observed periodically (with special consideration given during the first 4 hours of dosing) for the next 24 hours and then daily thereafter, up to fourteen days. All observations were scientifically recorded with individual records being maintained for each animal. Observations included changes in skin, eyes and mucous membranes and behavioral pattern. Attention was given for observations of convulsions, tremors, salivation, lethargy, diarrhea mortality. Changes in wellness parameters were compared with control.

Body weight:

Individual weights of animals were recorded before the administration of drug on 1st day of the study and thereafter on the seventh and fourteenth day of the experiment. Changes in the weight of individual experimental animals were calculated & compared with that of the control animals.

Statistical Analysis:

Changes in body weights were expressed as mean [M] ± Standard Deviation [SD] and their statistical significance was calculated using student t-test. LD50 value of study was determined by using Acute Oral Toxicity (Guideline 425)

RESULTS AND DISCUSSION:

The behavioral patterns of animals were observed first 4 hours & followed by 14 days after the administration. No significant changes were observed in observational parameters used for assessment of toxicity. Skin, eyes, behavioral pattern and sleep pattern parameters of the treated animals were found to be normal. No somatic changes were observed in any animal. No mortality was

observed in any animal. All treated animals lived up to 14 days after the administration of herbal extracts.

Table 1: result of % yield of extracts of *Embelia basaal* stem

Sr no	Type of extract	% yield
1	Ethanol	15.50
2	Aqueous	15.38
3	Pet. Ether	1.49

Body Weight Statistical Analysis

The body weights of the animals were calculated and are recorded in Table 2. There were no significant changes in body weight. However, all animals exhibited a normal increment in body weight without drastic difference between both control and treated groups. Although, the body weights of all the rats were increased after the oral administration of extracts. But, the changes of the body weights were found to be statistically insignificant in Table 2. Insignificant increase in body weight of test animals indicates that the administration of the extracts does not affect the growth of the animals.

Table 2: Result of changes in body weight of study animals at end of study

Group	Treatment	Body weight in gm		T value	Observation
		Bf (m+ SD)	AF(m+ SD)		
Control	Gum acacia	155.34±2.05	163±3.87	3.64	No significant
Test	2,000 mg/kg of pet. ether extract of stem	174.00± 2.65	178.33 ± 4.16	3.506	No significant
	2,000 mg/kg of Aqueous extract of stem	171.24±2.36	174±2.45	3.207	No significant
	2,000 mg/kg of ethanol extract of stem	163.22±3.04	167.13±1.13	3.46	No significant

(m= mean, SD= standard deviation)

CONCLUSION:

The present results show that different stem extracts of *Embelia basaal* does not cause any apparent in toxicity of an animal included in the study. No death or any signs of toxicity were observed in rat treated with extracts at dose 2000 mg/kg thus establishing its safety in use. Hence, can be a fruitful option as ingredients or herbal component in various life threatening complications where no safe alternatives are not available in market. But still this is just a safety study so detailed experimental analysis of its chronic toxicity is essential for further support of this herbal drug in future.

ACKNOWLEDGEMENT:

Author would like to represent their sincere thanks to Dr. Anil Jadhav principal of swaminarayan Pharmacy College, Dr. S.B. Narkhede department of Pharmacognosy for their support in conducting the research in smooth way.

REFERENCE:

1. WHO fact sheet No. 164 and 204, October 2000
2. NIDDK/NIH. An action plan for liver disease research http://liverplan.niddk.nih.gov.
3. Humber JM. The role of complementary and alternative medicine: Accommodating pluralism. J Am Med Association; 2002; 288: 1655-56.
4. Dorai AA. Wound care with traditional, complementary and alternative medicine. Indian Journal of Plastic Surgery; 2012; 45(2): 418-24.
5. Nordeng H, Diallo D, Al-Zayadi W, Ballo N, Berit Smestad Paulsen. Traditional medicine practitioners' knowledge & views on treatment of pregnant women in three regions of Mali. Journal of Ethno-biology, Ethno-medicine; 2013; 9: 67.
6. Sari LM, Suyatna Fd, Utami S, Chairul C, Subita GP, Whulandhary YS, Auerkauri EI. Acute oral toxicity study of *areca catechu* linn. Aqueous

extract in sprague-dawley rats. Asian Journal of Pharmaceutical Clinical Research; 2014; 7(5): 20-2.

7. Ghosh MN. Fundamentals of Experimental Pharmacology, 3rd Edition. S.K. Ghosh & others publications; 2005; 190-7.

8. Gatne MM, Adarsh and Ravikanth. Acute oral toxicity study of poly-herbal formulation AV/KPC/10, IJBAR; 2015; 6 (03): 281-283

9. Vinod D Rangari. Pharmacognosy and phytochemistry: Part 1. 1st ed. Pune: Published by Career Publication; 2002; 129-139.

10. Pulok K Mokherjee. Quality control of crude drugs. 1st Ed. New Delhi: Published by Business Horizones Pharmaceutical Publishers; 2002; 403-405.

11. Lipnick RL, Cotruvo JA, Hill RN, Bruce RD, Stitzel KA, Walker AP, Chu I, Goddard M, Segal L, Springer JA, Myers RC. Comparison of the Up-and- Down, Conventional LD50 and Fixed dose Acute Toxicity Procedures. Fd Chem Toxicology; 1995; 33: 223-231.