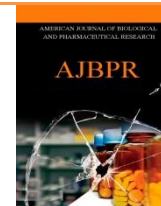




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ORAL TOXICITY STUDY OF ETHANOLIC EXTRACT OF *FICUS CARICA* IN FEMALE SWISS ALBINO MICE

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ABSTRACT

The plant *Ficus carica* Linn is traditionally used for in different disorders such as gastrointestinal, respiratory, metabolic and cardiovascular disorders. The present investigation was carried out to evaluate the safety of aqueous extract of *Ficus carica* (L.) (AEFC) and ethanol extract of *Ficus carica* (L.) (EEFC) by determining its potential toxicity after 28 days repeated administration in albino mice. During the study, body weight, general behaviors, morbidity and mortality were observed. On 28th day, Biochemical parameters and haematological parameters were estimated and also brain, heart, liver and kidney were processed for histopathology studies. EEFC and AEFC 200 and 400mg/kg/p.o treated groups did not show significant changes in body weight, general behaviors, biochemical parameters and haematological parameters when compared to control. Histopathological studies suggest that no pathological changes in EEFC and AEFC treated animals.

INTRODUCTION

Ayurveda, Siddha, Unani and Folk (tribal) medicines are the major systems of indigenous medicines. Among these systems traditional systems of medicine continue to be widely practiced on many accounts. Population rise, inadequate supply of drugs, prohibitive cost of treatments, side effects of several allopathic drugs and development of resistance to currently used drugs for infectious diseases have led to increased emphasis on the use of plant materials as a source of medicines for a wide variety of human ailments. Global estimates indicate that 80% of about 4 billion population can not afford the products of the Western Pharmaceutical Industry and have to rely upon the use of traditional medicines which are mainly derived from plant material.

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The Indian Government seeks the active and positive use of traditional medicine in national health programmes, family welfare programmes, and primary health care etc.

In Ayurveda, the distinction between food and medicine is not as clear as in Western medicine. Food and diet are important components of Ayurvedic practice, and so there is a heavy reliance on treatments based on herbs and plants, oils (such as sesame oil), common spices (such as turmeric), and other naturally occurring substances. Both the general consumer and health-care professionals need up-to-date, authoritative information on the safety and efficacy of medicinal plants [1].

Herbal therapy aims to support vital functions of human body. The application of herbs and their effect on the body are not always the same as usually understood for conventional medicines. Herbal medicines may be used



more to evoke healing responses in the body than to attack symptoms; this generates a different research question. As the common laboratory animal with a metabolism closest to the human beings, the rat or mouse would probably be the creature of choice for research. The rationale for herbal medicine is likely to be based on the activity of plant or its chemical constituents, to interact in the context of the gut and body tissues, to affect bioavailability [1].

From an analytical perspective, herbs and herbal preparations are particularly difficult to standardize. Pharmacological activity is established in many instances but there are also many situations in which claimed activity has not yet been scientifically proven [2].

European Agency for the Evaluation of Medical products discussed criteria for the pre-clinical assessment of herbal medicinal products and a guideline for Non-clinical testing of herbal drug preparations with long-term marketing experience – Guidance to facilitate mutual recognition and use of bibliographical data [3].

MATERIALS AND METHODS

The plant *Ficus carica* Linn is traditionally used for in different disorders such as gastrointestinal, respiratory, metabolic and cardiovascular disorders [4-6]. The claim for the utility of the plant in treating anxiety has not been scientifically evaluated.

Procedure

Female Swiss albino mice, 25-35 g, were kept in temperature-controlled environment ($23 \pm 2^\circ\text{C}$) with a 12 h light-dark cycle. Food and water were freely available and were acclimatized for a week. The animals were divided into five groups of six in each group. Group – I served as control group – II group III treated with EEFC 200 and 400 mg/kg./p.o, group IV and V treated with AEFC treated with the dose of 200 and 400 mg/kg./p.o by gavage for 28days (once a day). The animals were weighed every 3 days once, 1st and final day weights were tabulated (Table 1).

Table 1. Weight of the mice

Groups	Initial weight(gms)	Final weight(gms)
Control	25.5±1.2	26.2±0.8
EEFC 200mg/kg/p.o	27.7 ± 1.2	28.4 ± 1.8
EEFC 400mg/kg/p.o	28.3 ± 0.9	27.4 ± 0.6
AEFC 200mg/kg/p.o	29.5 ± 0.8	28.3 ± 0.9
AEFC 400mg/kg/p.o	25.4 ± 1.7	25.4 ± 1.7

Table 2. Behavioral Observations of 28 Days Repeated Oral Toxicity Study for EEFC and AEFC

Observations	Group I Control	Group II EEFC 200mg/kg/p.o	Group III EEFC 400mg/kg/p.o	Group IV AEFC 200mg/kg/p.o	Group V AEFC 400mg/kg/p.o
Behavioral	Normal	Normal	Normal	Normal	Normal
Tremors	Nil	Nil	Nil	Nil	Nil
Salivation	Normal	Normal	Normal	Normal	Normal
Diarrhea	Nil	Nil	Nil	Nil	Nil
Lethargy	Nil	Nil	Nil	Nil	Nil
Sleep	Normal	Normal	Normal	Normal	Normal
Convulsion	Nil	Nil	Nil	Nil	Nil
Coma	Nil	Nil	Nil	Nil	Nil

Table 3. Haematological Parameters of 28 Days Repeated Oral Toxicity Study for EEFC and AEFC

Groups	Total WBC (per cu mm)	Lymphocytes (%)	Neutrophil(%)	Total RBC (million /cu mm)	Platelet count (lacs per cu mm)	Hb (g/dl)
Group I Control	5240 ±74.7	42.8 ± 1.2	54.4 ± 1.3	3.94 ± 0.1	1.8 ± 0.02	12.6 ± 0.2
Group II EEFC 200mg/kg/p.o	5280 ± 203.1	43 ± 1.5	54 ± 1.4	4 ± 0.03	1.9 ± 0.04	12.4 ± 0.1
Group III EEFC 400mg/kg/p.o	5340±105.4	36 ± 3.9	60 ± 3.9	3.7 ± 0.1	1.8 ± 0.1	12.2± 0.2
Group IV AEFC 200mg/kg/p.o	6060 ±103.4	38±1.75	58±1.9	3.5 ± 0.3	1.6 ± 0.1	12.9 ± 1.2
Group V AEFC 400mg/kg/p.o	5000 ± 109.3	42 ± 2.4	54.2 ± 1.9	4 ±0.2	1.62±0.05	11.55±0.5

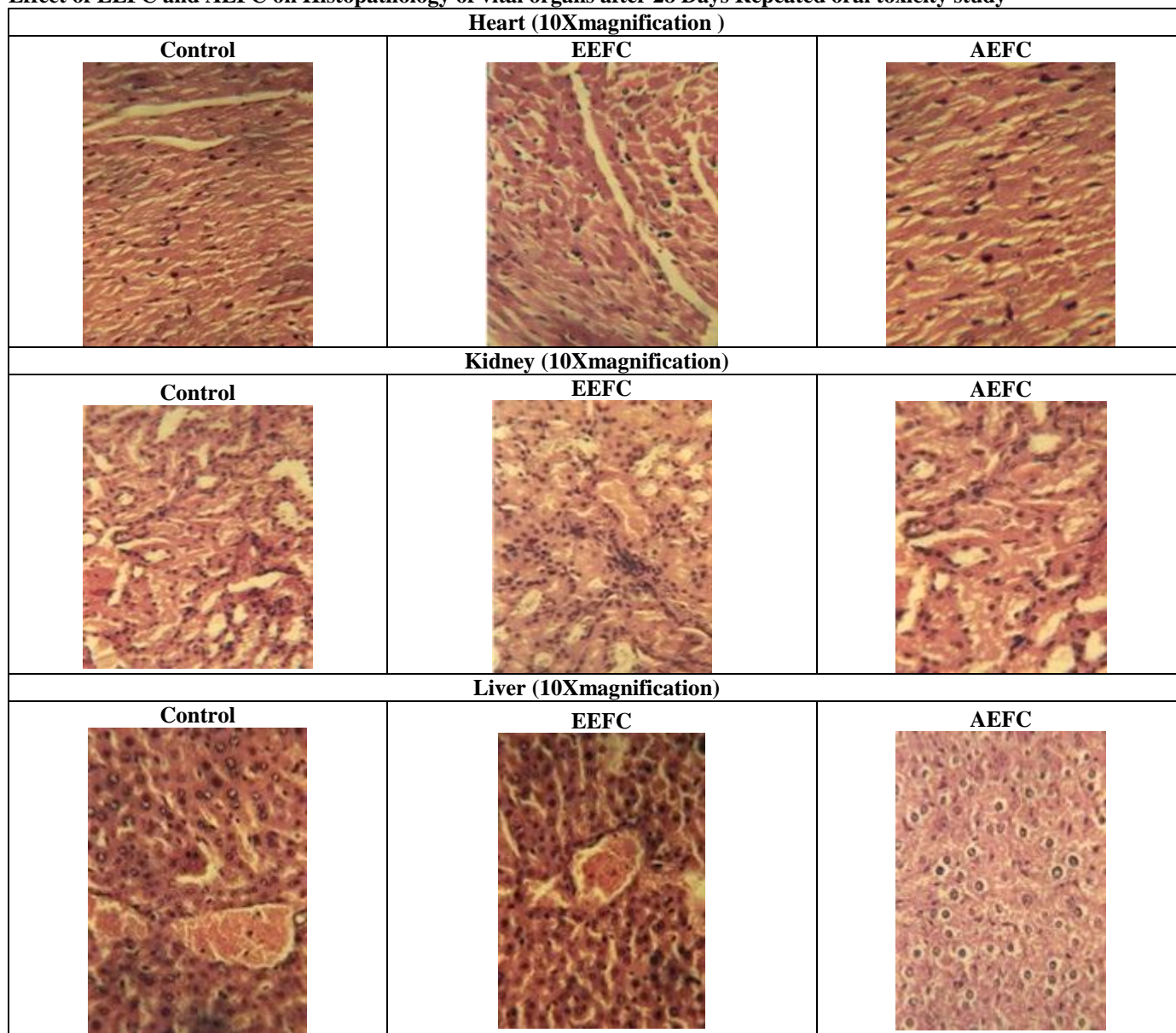


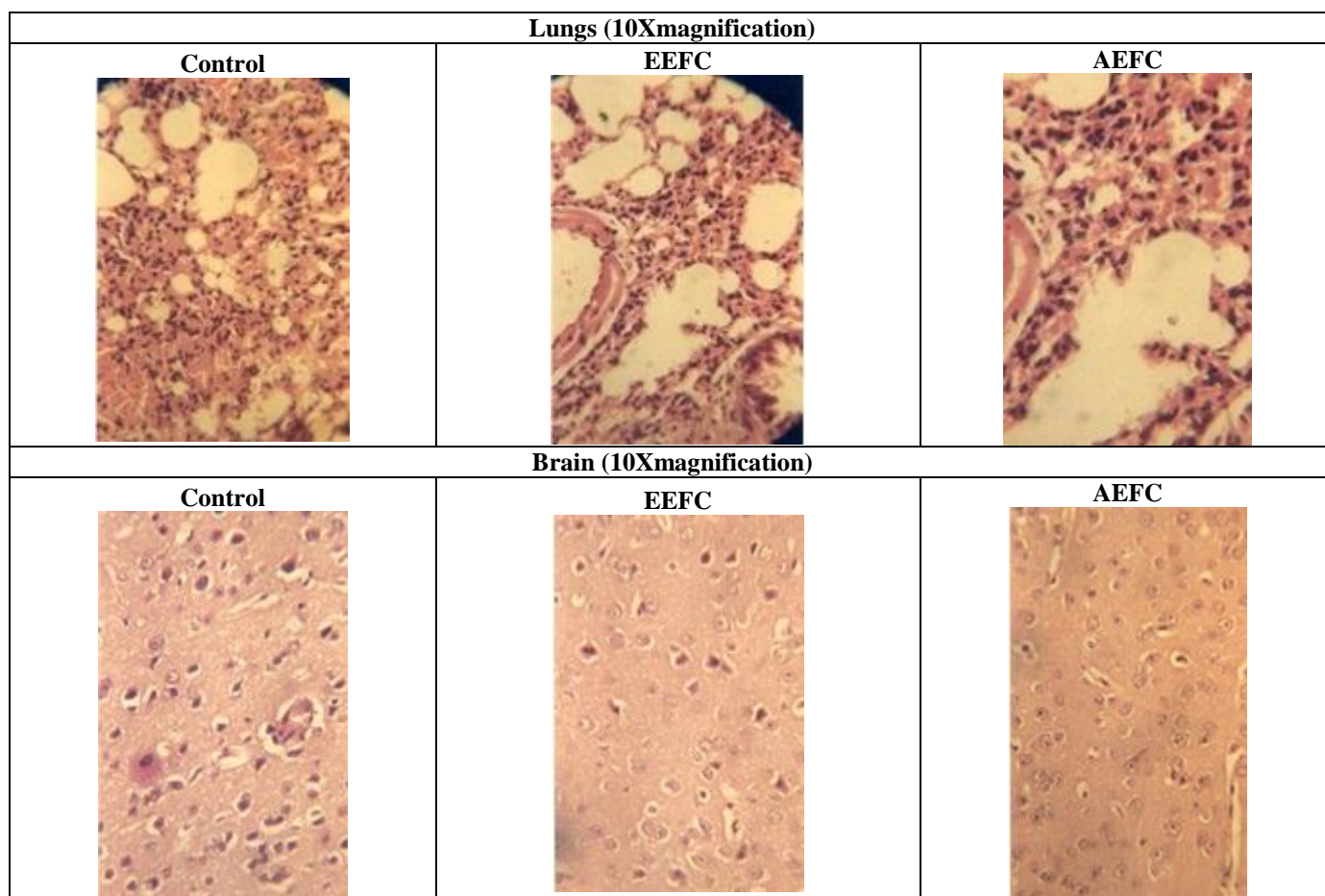
Table 4. Biochemical Parameters of 28 Days Repeated Oral Toxicity Study for EEFC and AEFC

GROUPS	SGPT (IU/ml)	SGOT (IU/ml)	Serum Total Protein (mg/dl)	Blood Urea (mg/dl)	Serum Creatinine (mg/dl)
Group I Control	24 ± 1.1	20.4 ± 0.8	4.7 ± 0.1	29.4 ± 1.3	1 ± 0.5
Group II EEFC 200mg/kg/p.o	25±1.2	22± 1.5	4.6 ± 0.2	31.6 ± 0.8	1 ± 0.5
Group III EEFC 400mg/kg/p.o	26 ± 1.1	23±1.6	4.9 ± 0.1	28 ± 1.7 60	1.04 ± 0.5
Group IV AEFC 200mg/kg/p.o	24 ±1.2	20± 1.7	4.6 ± 0.3	25.7± 1.38	1.5 ± 0.7
Group V AEFC 400mg/kg/p.o	27± 1.4	25±1.1	5.1 ± 0.2	30.6 ± 0.8	1.51±0.2

During the 28days repeated oral toxicity study, on 29th day after an overnight fast, the mice were anaesthetized with ether and blood sample were collected from the orbital sinus. The blood samples were used for different analysis.¹²⁷

Effect of EEFC and AEFC on Histopathology of vital organs after 28 Days Repeated oral toxicity study





The drugs were administered daily for 28 days the same time daily and observed at least twice daily for morbidity and mortality. Any changes in skin and eyes and mucous membrane (nasal), fur and also respiratory, circulatory, autonomic (salivation, lacrimation, perspiration, piloerection, urinary incontinence, and defecation) and central nervous system (drowsiness, gait, tremors and convulsion) motor activity. Behavioral changes like the signs of tremors, convulsion, salivation, diarrhoea, lethargy, sleep and coma were noted.

WBC, RBC, Neutrophil, platelet count, hemoglobin and lymphocytes were done by mindray hematological analyzer. SGPT, SGOT, serum total protein, urea and creatinine were estimated using standard procedures. Brain, heart, liver and kidney were processed for Histopathology studies.

The treatment with the extracts did not decrease the water and food consumption.

RESULTS AND DISCUSSION

In 28 days repeated oral toxicity, on the first day and final day Weight of the mice in EEFC and AEFC 200 and 400mg/kg/p.o treated groups did not show significant changes when compared to control. The Repeated oral

toxicity studies has also revealed that EEFC and AEFC 200 and 400mg/kg/p.o did not produce any changes in behaviour, tremors, salivation, lethargy, sleep, convulsion when compared to the control. In the hematological analysis RBC, WBC, lymphocytes, neutrophil, platelet count and Hb in EEFC and AEFC 200 and 400mg/kg/p.o treated groups did not show significant changes when compared to control. In biochemical analysis EEFC and AEFC 200 and 400mg/kg/p.o did not show any significant changes SGOT, SGPT, total protein, urea, creatinine and when compared with the control group.

CONCLUSION

The present study concluded the safety of *Ficus carica* Linn. In the macroscopic of the target organs of the treated animals (liver, lung, heart, and left kidney and brain) did not show significant changes in color and texture when compared with the control group. In histopathological examination of haematoxylin and Eosin stained section of the liver, lung, heart, left kidney and brain tissue showed no pathological damages and cellular architecture are intact in EEFC and AEFC 200 and 400mg/kg/p.o treated groups did not show significant changes when compared to control.



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