

Evaluation of the female reproductive toxicity of aqueous extract of *Labisia pumila* var. *alata* in rats

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ABSTRACT

Objective: To detect potential adverse effects of aqueous extract of *Labisia pumila* var. *alata* (LPE) or 'Kacip Fatimah' on the estrous cycle, reproductive performance, post-natal growth and offspring survival of rats.

Materials and Methods: Forty eight (48) female Sprague Dawley rats with consecutive 4 to 6 days estrous cycle were given distilled water (as control) or LPE at 2, 20, 200, 400 or 800 mg/kg daily by gavaging ten days prior to mating, mating (a maximum period of ten days), gestation and lactation periods of seven days. Dams and fetuses were sacrificed on day seven postnatal.

Results: *Labisia pumila* extracts did not alter the estrous cycle and general health of all rats. All the animals proceed towards successful mating and pregnancies. There was no significant difference in the duration of pregnancy and all pregnant rats delivered normally. Statistically no test agent-related changes in the maternal body weight, number of implantations, litter size and pup body weights were observed. Other parameters measured include pup sex ratio, live birth index, pup viability index and percentage of implantation death which also showed no significant difference.

Conclusion: The present findings indicate that water based extracts of *Labisia pumila* var. *alata* do not pose any significant reproductive toxicity or complication in pregnancy and delivery in rats. The extract did not significantly alter the duration of pregnancy in rats, however the duration of delivery was not evaluated in this study.

KEY WORDS: Herb, adverse effect, estrous cycle, pregnancy, lactation.

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Labisia pumila var. *alata* (LPA) or popularly known in Malaysia as Kacip Fatimah (KF), is a very popular herb amongst the local womenfolk. Traditionally, the water decoction of the root or whole plant of KF are consumed by the Malay women for induction and facilitation of labour.^[1] Currently there are many commercial products containing this herb have emerged in Malaysian market for the purpose of enhancing vitality and libido, however, there is no scientific data on their quality, safety, and efficacy to substantiate claims. Studies supported by the Government of Malaysia, involving this herb conducted at various universities and institutes are in various stages, like extract preparation-standardization (undergoing patenting), authentication, and evaluation of safety and efficacy. Reports have shown that the LPA displayed a non-significant response to *in vitro* estrogen activity^[2] and had appreciable amount of iron.^[3] In addition, LPA root and leaves were found to contain two novel benzoquinoid compounds 1, 2 as major components.^[3] More information regarding this herb is expected to be available in the near future.

The objectives of the present study are to evaluate the female reproductive toxicity and potential effect of KF in inducing labor in rats. Standardized aqueous extract of *Labisia pumila* var. *alata* (LPE) at doses of 2-800 mg/kg/day were administered to determine the safety and efficacy of this herb. The general acute and sub-acute (28 days) toxicity studies of the same extract in rats were already performed by a team in Herbal Medicine Research Center of Institute for Medical Research, Kuala Lumpur, Malaysia. The results of the study revealed that the estimated LD₅₀ of the extract is more than 5 g/kg BW and the extract produced no significant adverse effects (personal communication). A chronic toxicity study is on going and at present, no deleterious effects is observed in rats. A phase 2 clinical trial conducted in post-menopausal women by a research team at School of Medical Sciences, Universiti Sains, Malaysia concluded that the therapeutic dose of the extract is 2.5 mg/kg/day (personal communication).

About 48 female Sprague Dawley rats were used in this Segment I (female reproductive toxicity) study. Rats with