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WARUNEE HANPITHAKPONG : STUDIES ON SAFETY AND EFFICACY OF PHLAI  
GEL; THESIS ADVISORS: KRONGTONG YOOVATHAWORN, Ph. D., VERASING MUANGMAN,  
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Rhizome of Phlai (*Zingiber cassumunar* Roxb) has been used for a long time as an antiinflammatory component in Thai traditional medicine. In this study, the pharmacological effects of Phlai gel preparation containing 10% of Phlai extract developed by Thailand Institute of Scientific and Technological Research were studied. The drug in the form of gel was developed for external use in the treatment of inflammation.

Antiinflammatory activity of Phlai gel was studied in mouse ear edema and rat hind paw edema models. The maximal reduction of croton oil-induced edema of the ear by Phlai gel was equal to 46 % at 2 hours after application whereas the standard drug, diclofenac gel, was more potent in inhibiting edema formation than Phlai gel. A similar result in the antiinflammatory activity of Phlai gel was shown in rat hind paw edema model. Phlai gel inhibited the edema formation induced by carrageenan as effectively as piroxicam gel which was used as a standard drug (31 and 29 %, respectively, at 1 hour after application).

Phlai gel caused mild skin irritation when tested in rabbits (OECD method). The primary irritation index was 0.66. Repeated application under open condition on mouse ear (mouse ear irritation model) did not cause any irritant reactions. The preparation was also non-allergenic when tested for sensitization potential using Buchler's method in guinea pigs. It did not cause any subjective irritation reaction when tested by using the guinea pig model.

The antiinflammatory activity of Phlai gel applied topically to the affected site in trauma patients was not different from that of piroxicam gel with regard to reduction in swelling size, redness score and pain relief. In patients with pain at the affected site, Phlai gel could relieve pain as effectively and rapidly as piroxicam gel, i.e., about 20 – 40% at 1 hr after application. Itching as a result of Phlai gel application was reported by 9% of patients. It is concluded that Phlai gel containing 10% of Phlai extract is a promising preparation for use as an antiinflammatory drug. It is safe for external use since it causes neither skin irritation nor hypersensitivity reaction in experimental animal models. Overall results on safety and efficacy from this study indicated that Phlai gel can be used for the topical treatment of inflammation in patients with traumatic injury.