SUMMARY

Background: Herpes simplex virus (HSV) typically infect epithelial and nerve tissues. Acyclovir (ACY) is reported to be effective in the treatment of herpes labialis (HSV-1) and herpes genitalis (HSV-2) if given orally or intravenously with many systemic toxic effects. Role of acyclovir in treating the disease topically is limited due to poor drug penetration into the different layers of the skin. This investigation was undertaken to develop and evaluate clinically a novel topical gel to treat these infections at their initial stage by entrapping ACY in liposomes and incorporating it in HPMC K4M gel base to improve drug’s therapeutic index, reduce side effects like itching, burning, micturation etc., and possibly to reduce the cost by reducing the duration of therapy.

Material and Methods: Twenty-six patients suffering from HSV-1 and HSV-2 infections (HSV-1 4F, 6M, aging between 21-34 years; HSV-2 16M, aging between 24-40 years) were subjected to double blind clinical evaluation for the period of eight weeks. 1%w/w ACY plain gel (PAG) and liposomal ACY gel (LAG) were evaluated clinically by applying gel topically five times a day on ten patients of HSV-1 and sixteen patients of HSV-2. Patients were only on topical therapy; however anti-inflammatory drugs were given orally three times a day to control the severe pain and inflammation during therapy.

Results: A significant increase (p<0.05) in average percent improvement of healing of the lesions (AP1HL) of HSV-1 and HSV-2 was observed with LAG when compared to PAG. The local adverse effects like itching, burning in both HSV-1 and HSV-2, and micturation in HSV-2 infection were significantly (p<0.001) reduced when treated with LAG. No significant differences (p>0.05) were found in pain and inflammation on application of LAG and PAG, may due to simultaneous administration of anti-inflammatory drugs during the course of studies. A complete healing of lesions was observed after five weeks of treatment with LAG while complete healing of lesions was not observed with PAG even after eight weeks of treatment.

Conclusion: From the results, it may be concluded that topical LAG of this investigation significantly enhances the efficacy of the drug in the treatment of HSV-1 and HSV-2 infections. LAG may be used in treatment of patients suffering from herpes simplex at initial stages. However, in the severe cases, the topical therapy may be used as supplementary to oral or intravenous therapy. Topical supplementation with LAG is expected to reduce the dose or duration of therapy and thereby possibly the cost of therapy in these patients.

Key words: Acyclovir, Herpes simplex, Clinical studies, Liposomes.