Hydroxychloroquine niosomes: a new trend in topical management of oral lichen planus

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Abstract

The work aimed at studying a novel topical niosomal gel formulation of hydroxychloroquine for the management of oral lichen planus. Niosomes have been reported as conceivable vesicles to deliver drug molecules to the desired mucous membrane or skin layers. Hydroxychloroquine niosomes were designed using different methods of preparation. Tween 20 and cholesterol in molar ratio (1:0.5) were used. The prepared systems were characterized for entrapment efficiency, particle size and in vitro drug release. Different factors affecting the encapsulation of hydroxychloroquine in niosomes were studied vs. varying the type of surfactant, the cholesterol:surfactant molar ratio and the amount of the drug. The selected noisome formulation was dispersed in different gel formulations and evaluated according to the in vitro drug release and the physical stability. The results showed that the type of surfactant, cholesterol ratio and incorporated amount of drug altered the entrapment efficiency and the in vitro release of hydroxychloroquine from niosomes. The optimum formulation was prepared by reverse phase evaporation technique using Brij 98:cholesterol molar ratio (1:1.5) and containing 20 mg of hydroxychloroquine and incorporated in 20% w/v Pluronic F-127 gel. A double-blind, controlled clinical study was performed using two groups of patients. Group A (n = 11) who received hydroxychloroquine niosomal gel formulation, one application-a-day over 4 months showed 64.28% reduction in the size of lesions and the average score of pain was reduced from “4” to “1”. Compared to placebo group B (n = 5), who showed only 3.94% reduction in the lesion size and the average score of pain was remained “3”. Our results suggest that these niosomal formulations could constitute a promising approach for the topical treatment of oral lichen planus in short time with less side effects and no recurrence after stopping the treatment.

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