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Resveratrol and Clobetasol-17-Propionate Co-administration to Manage Oral Lichen Planus: Embedding Actives-Loaded Lipid Microspheres Into a Patient-Friendly Buccal Patch

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Abstract : Oral lichen planus (OLP) is a chronic, non-infectious inflammatory disease of the oral cavity characterized by symmetrical and bilateral lesions or multiple lesions affecting the buccal mucosa, the tongue, and the gingiva, causing severe pain and impairing patients' quality of life. Due to its autoimmune nature, the conventional OLP treatment involves the topical administration of anti-inflammatory corticosteroids, and clobetasol-17-propionate (CLB) remains the primary therapeutic option, even if there are no commercially available pharmaceutical forms intended for the oral cavity. An aspect of OLP pathogenesis that has been underestimated till now is the role of oxidative stress. During inflammation, the generation of ROS is significantly enhanced. The latter can cause damage to several cellular components such as protein, membrane lipids, nucleic acids, etc, inducing genetic mutations and thus playing a critical role in the potential malignant degeneration. Consequently, a recent systematic review of over 1154 studies has demonstrated that antioxidants might not only effectively reduce pain but also increase the disease resolution rate and prevent potential malignant outcomes. Among natural antioxidants, resveratrol (RSV) is a polyphenol that was recently focused on by researchers due to its biological actions by, which it could be useful in the management of OLP in co-administration with conventional corticosteroids. However, both RSV and CLB suffer from several drawbacks related to their formulation and administration. Based on these considerations, the aim of this work was to develop novel, personalizable, and patient-friendly drug delivery systems for the loco-regional administration of CLB or co-administration of CLB and RSV to treat OLP lesions in order to clinically evaluate both i) the efficacy of stand-alone CLB when administered through a standardizable and innovative formulation instead of the conventionally used ones and ii) the efficacy of the co-administration of the two selected active molecules. To address this issue while also overcoming the limitations of the chosen drugs, a microcomposite patch was designed and characterized. Lipid-based microparticles (LMPs) as solid lipid microparticles (SLM) and microstructured lipid carriers (MLC) were then optimized to encapsulate CLB and RSV, respectively. The LMPs were prepared according to a patented technique [1, 2] and were accurately designed to be applied to the oral cavity. They thus resulted suitable in terms of melting temperature range (compliant with the oral temperature) and particle size (<450 µm). Moreover, in view of their next use for the preparation of the final dosage forms, they were further investigated as a pharmaceutical intermediate in terms of particle shape and flow properties. Subsequently, two different buccal patches were prepared by dispersing the LMPs into a mucoadhesive hydrophilic gel and then subjected to solvent casting: the CLB series patches were loaded only with the SLM-CLB, while the CLB+RSV series patches contained both SLM-CLB and MLC-RSV. Both formulations resulted in soft, deformable, homogeneous, reproducible, mucoadhesive, low swellable, and potentially comfortable for patients. Finally, their ex vivo ability to promote active entry into the buccal tissue was also demonstrated, making them promising drug delivery systems for a further clinical trial actually in progress (Oral Medicine Unit, Palermo University Hospital Policlinico "P. Giaccone").

Keywords : buccal patch, clobetasol-17-propionate, lipid microparticles, oral lichen planus, resveratrol
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