CLOBETASOL PETROLATUM OINTMENT 0.015% FOR THE TREATMENT OF CUTANEOUS GRAFT-VERSUS-HOST DISEASE IN PEDIATRIC PATIENTS: A CASE REPORT

Castellana E., Soave G., Angiolillo M., Scaldaferri M., Chiappetta M.R., Cattel F.

BACKGROUND AND IMPORTANCE

Chronic graft-versus-host disease (cGVHD) is an important late complication in allogeneic hematopoietic stem cell transplant (HSCT) recipients. The skin is usually the first and most affected organ involved in cGVHD and topical steroids are one of the most commonly drugs used for this affection.

AIM AND OBJECTIVES

A 3-year-old boy was diagnosed with acute myeloid leukemia in 2019 and, after HSCT, manifested cutaneous cGVHD. The hospital pharmacy service was asked to develop a pediatric magistral formula of topical ointment based on clobetasol 0.015% in petrolatum.

MATERIAL AND METHODS

A topical magistral formula of clobetasol ointment 0.015% in petrolatum was developed, to be administered once daily on lesions. The efficacy of the formulation was evaluated by the physician. Skin therapy also included moisturizing lotion and almond oil.

RESULTS

The development was based on a case series of oral cGVHD in which a hydrophilic gel formulation was used successfully. Clobetasol has been shown to have higher potency and the highest level of evidence.

In contrast to the hydrophilic gel, the 0.015% clobetasol ointment preparation was formulated on petrolatum to allow for superior skin permanence, starting with low concentrations of clobetasol as the patient aged. Petrolatum forms an occlusive, hydrophobic layer on the skin, physically blocking transdermal water loss and creating increased skin hydration for more than 4 hours.

A shelf life of 30 days has been established, based on the critical skin injury in this pediatric patient.

Odor, color and phase separation remained stable during the month.

The patient well tolerated the treatment, and the doctor confirmed, after four months of treatment, the improvement of the skin lesion. The pediatric patient, after the described improvement, discontinued the clobetasol ointment.

CONCLUSION AND RELEVANCE

Clobetasol ointment 0.015% is a good therapeutic solution in pediatric patient with cGVHD, especially for its pharmaceutical formulation.