Background and Importance

Chronic graft versus host disease (cGVHD) associated oral mucositis is a complication after stem-cell transplantation. Corticosteroids are the standard treatment, but there is no consensus in case of refractory lesions. Platelet concentrates may be a safe treatment option.

Aim and Objective

- Design an sterile oral formulation able to release platelet lysate (PL) on oral cavity, and evaluate its effectiveness in a series of cases.

Materials and Methods

**ORAL GEL COMPOUNDING**

PL diluted 1:1 with sodium chloride 0,9%  
Carboximethylcelulose sodium base 5% gel 

Mixed 1:1 in ASEPTIC CONDITIONS

25% oral Platelet Lysate gel 

Packaged in 6mL syringes 

Stored in freezer

**EFFECTIVENESS EVALUATION**

Patients with cGVHD associated oral mucositis from November 2021 to August 2022.

Effectiveness was evaluated based on severity of the oral mucositis (NCI-CTCAE Grade 1-4).

1 - 10 Patient satisfaction was self-assessed in a visual scale according to the degree of pain/discomfort.

Adherence was assumed based on the number of syringes dispensed.

Results

**GEL CHARACTERISTICS**

- Slightly yellow, translucent, pH=6, with medium consistency that leads adequate bioadhesive characteristics.
- No changes of pH, color, weight, or microbial growth were observed during galenic validations.
- A beyond-use date of 45 days at -20ºC was given.
- **Instructions of use:** apply on the oral lesion 2 mL of the gel every 8 hours.

**Conclusion and Relevance**

- The formulation of a gel based on sodium carboximethylcelulose was adequate to administer PL on the oral cavity.
- Four patients with cGVHD associated oral mucositis refractory to standard treatment were successfully treated.

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