COMPOUNDING OF A VISCOUS ORAL, PRESERVATIVE- AND FLAVOR-FREE GEL FOR TREATING PAIN IN AN INFANT WITH EPIDERMOLYSIS BULLOSA

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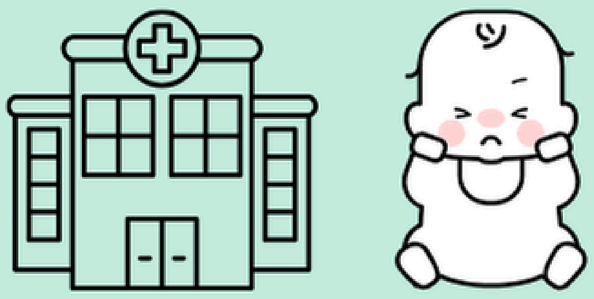
1 Why was it done?

In the postnatal period, a 37 week old infant presented with dysepithelialized lesions on the body, as well as involvement of the oral cavity, characterized by discoloration of the hard palate and gums.



The multidisciplinary team diagnosed EB and deemed it necessary to apply **LIDOCAINE GEL** because the infant was unable to feed due to pain from the sores.

Initially, several commercially available products were used, but their irritating excipients led to poor tolerance.

Consequently, it was necessary to prepare an extemporaneous formulation devoid of preservatives and flavorings.

2 What was done?

This intervention presents the development of an **extemporaneous preparation of lidocaine hydrochloride 0.5% w/w viscous oral topical gel**, free of preservatives and flavors. The gel was distributed to the neonatal intensive care unit staff in pre-filled syringes and applied to the oropharyngeal mucosa of a neonate diagnosed with EB.

3 How was it done?

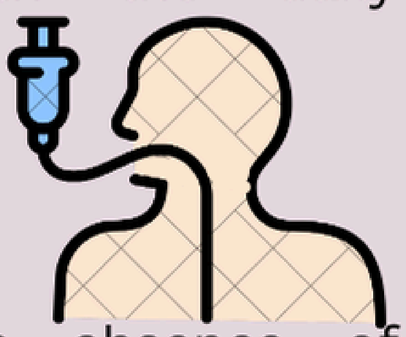
The components of the preparation included lidocaine hydrochloride, carboxymethylcellulose sodium (CMC), and sterile water. The gel was prepared using a high-shear magnetic stirrer, with increasing concentrations of CMC: (0.75%, 2.25%, 3%, and 4%). After discussions with the multidisciplinary team, the pharmacist recommended using the 4% gel, as its density allowed it to adhere well to the oropharyngeal mucosa. This adherence is crucial for preventing absorption and minimizing potential cardiac side effects of lidocaine.

4 What has been achieved?

The gel was successfully prepared with:

- 0.5% lidocaine
- 4% CMC

It was packaged in pre-filled syringes with the daily dosage.



Due to the absence of preservatives and stability data, the shelf life was established at 15 days when stored at 2-8°C. The viscous oral gel was administered three times a day, 20 minutes before feeding, to exert its anesthetic effect and facilitate breastfeeding

5 What is next?

The hospital pharmacist's extensive expertise was instrumental in determining the optimal concentration of CMC and customizing the formulation to meet the patient's unique requirements. This pivotal contribution led to a highly personalized therapy, ultimately resulting in the successful discontinuation of artificial nutrition in this critically ill patient.

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