INTEREST OF A DERMO-COSMETIC PRODUCT IN THE MANAGEMENT OF RADIODERMATITIS IN BREAST CANCER

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INTRODUCTION

Radiodermatitis is the most common skin reaction induced by radiotherapy, which can be acute or chronic. The acute lesions are the most frequent and appear 2 to 3 weeks after treatment begins. They are characterized by dry skin, erythema, and desquamation. It constitutes a heavy burden affecting concerned patients, as these skin changes are often painful and debilitating, and can impair general activities of daily living. The aim of this study is to evaluate the skin barrier function and the interest of a dermo-cosmetic product in the management of dry radiodermatitis in breast cancer patients.

MATERIALS & METHODS

First, skin barrier function was evaluated using 2 methods: GC/LC-MS to measure the total lipids from swab samples on 20 healthy subjects with initial TEWL ≥12, and, by transepidermal water loss (TEWL) on 10 healthy subjects, with initial TEWL ≥10 g/m²/h. For both the product was applied twice daily from D0 and D28 on a treated zone (versus an untreated zone). Second, a prospective multicentric observational study was performed including 45 breast cancer patients who presented grade 1 radiodermatitis according to the National Cancer Institute's Common Terminology Criteria for Adverse Events (CTCAE) version 5.0. They applied the product once or twice daily for at least 4 weeks (2 weeks during and after radiotherapy). At each visit (inclusion visit followed by 4 weekly follow-up visits), the improvement of radiodermatitis and clinical symptoms (erythema, dryness, desquamation, edema, irritation, oozing, crust, hyperpigmentation, sign of infection) were assessed by 4 oncologists using a 4-point scale. The subjects evaluated functional symptoms such as pain, itching and burning sensation, using a 100 mm visual analogue scale, the product's efficacy, and the skin-related quality of life using the Dermatology Life Quality Index (DLQI). Finally, the safety was evaluated at each visit by the investigator.

RESULTS

The quantity of total lipids (cholesterol, free fatty acids, ceramides) increased significantly by 21% (**Fig. 1**), and the TEWL significantly decreased by 11.8% ($p<0.05$) after 4 weeks of product application compared to an untreated zone.

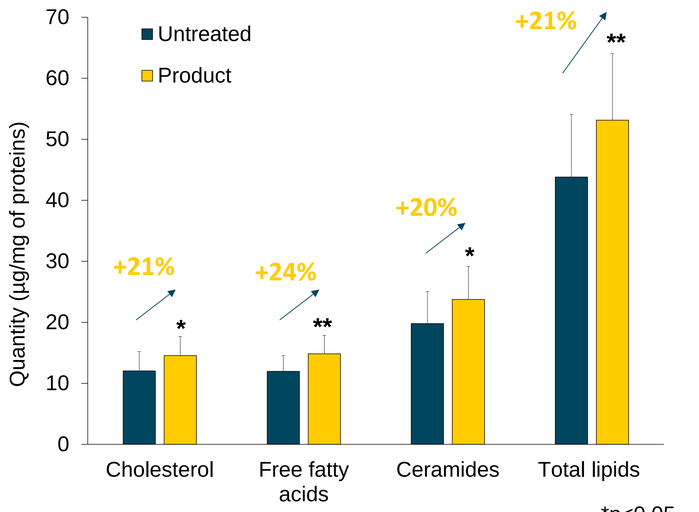

Figure 1: *Lipids dosages at D28*

*p<0.05
**p<0.01
Student test

In the clinical study, 45 women aged from 33 to 70 years (mean 54.9) with breast cancer and grade 1 radiodermatitis were included. After at least 4 weeks of product application, the lesions disappeared in 93.3% of the subjects. According to the investigators, erythema, dryness, and desquamation significantly decreased (**Fig. 2**) and the product was deemed good to very good as a supportive care during radiotherapy. The other clinical signs were weak or absent at inclusion or during the study. Results on pain and itching were not relevant, and the intensity of burning sensation significantly decreased (**Fig. 3**).

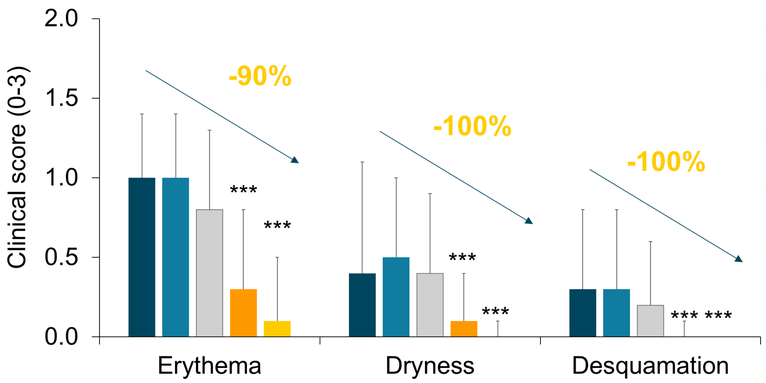

Figure 2: *Evolution of clinical signs at each visit*

*p<0.05
***p<0.001
Wilcoxon test

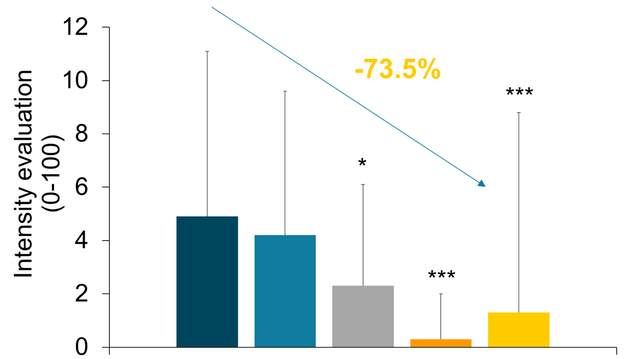

Figure 3: *Evolution of burning sensations at each visit*

The DLQI score remained below 1 in average all over the study, meaning that no negative effect was observed on subject's quality of life. Moreover, 82.2% to 93.3% of the subjects agreed that the product nourishes and restores the skin, reduces discomfort and protects the skin from radiotherapy**.** The product was very well tolerated by all subjects.

CONCLUSION

Skin care of the radiated area may avoid treatment interruptions, while preserving patient's overall quality of life. Topical application of a specific dermo-cosmetic product, with an appropriate protocol, improves skin barrier integrity, making this exhausting process less traumatic to patients, and easier to complete.

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