BARRIER PROTECTIVE SKIN CARE FOR PROPHYLAXIS OF CHEMOTHERAPY-INDUCED CUTANEOUS SYMPTOMS

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ABSTRACT

Anti-tumour chemotherapeutic agents, as is known, cause toxic antiproliferative and antidifferentiating effects especially in the skin. Depending on the agent, the dosing regimen, and individual pathological factors the barrier function starts to decompensate, which is the main cause for clinical symptoms as pruritus and irritation and consequently reduces the quality of life of the patients. Niacinamide is a hydrophilic vitamin that, given a sufficient bioavailability, has antipruritic, antimicrobial, vasoactive and barrier protective effects, depending on concentration. Niacinamide is a well-tolerated and safe substance used in cosmetics.

In a prospective multicentre study, a niacinamide-containing, barrier protective preparation has been investigated in a cross over design in comparison with standard care (over 2 x 6 weeks, application twice a day) in patients with breast cancer undergoing chemotherapy. Primary target parameter was the weekly-collected dermatology life quality index (DLQI).

The results show that the prophylactic use of the test preparation stabilizes the quality of life and can effectively prevent the development of unwanted cutaneous effects.

INTRODUCTION

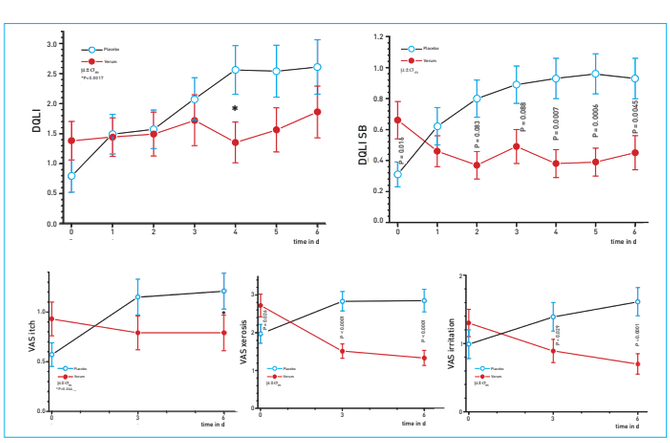
The number of new cases of cancer in Germany is about 470,000 per year with increasing tendency. Since 1980, the number of cancers diagnosed per year has been risen by 35% for women and by over 80% for men. This trend can also be observed in other industrial nations in the world. Several factors contribute to the increasing incidence: changes in the age structure of the population as well as the increasing burden of risk factors as tobacco and alcohol consumption, UV radiation and chronic infections are considered essential here. However, a significantly higher survival rate can be observed caused mainly by improvements in early diagnosis as well as by evidence based antineoplastic chemotherapies. Nearly all of antitumor pharmaceutical products used have specific or unspecific unwanted effects, often affecting the skin. Depending on the combination, doses and duration of the therapy up to 40% epidermal barrier disorders can be observed that become clinically apparent as dry, itching and finally irritated skin. This can seriously reduce the patient's quality of life. Depending on the intensity of the symptoms even discontinuation of the therapy might be required in single cases. Furthermore, depending on the pathogenetic pattern, symptom complexes dominated by inflammatory symptoms can be established, like the palmar-plantar erythrodysesthesia (hand-foot syndrome), the acne-like-rash, or phototoxic reactions. In order to maintain the patients quality of life, various strategies for supportive care are recommended. Their effectiveness has rarely been proven by clinical studies yet. Therefore, a randomized, open, controlled multicentre study has been carried out in order to prove the effectiveness of a niacinamide-containing preparation on quality of life in patients with breast cancer treated with antitumor chemotherapy.

STUDY DESIGN

- Prospective, open, randomized, controlled, crossover, multicentre (6 centres) interventional study
- DLQI (once weekly) as a standardized survey method, VAS pruritus, xerosis and irritability
- Test preparation (TP): Lipikar® Baume AP (containing 4% niacinamide)
- Standard care (SC): patients usual skin care as used before application twice daily, test preparation vs. standard care, start at the beginning of chemotherapy, crossover end of week 6, end after week 12
- Inclusion: adjuvant or neoadjuvant chemotherapy with anthracycline or taxane, accompanying antibody therapy using trastuzumab optional
- Exclusion: radiotherapy within 3 months prior to study; skin diseases with barrier disorders; use of retinoids, lipid lowering drugs (HMG-CoA-reductase inhibitors, fibrates, herbal lipid lowering drugs), and diuretics, unless it is used continuously for at least 2 weeks before study without doses changes; application of anti-inflammatory topic or systemic preparations: calcineurin inhibitors, glucocorticoids (except concomitant medication for chemotherapy), non-steroid antiphlogistics, DMARDs or herbal medicines, unless it is used continuously for at least 2 weeks bebore study without doses changes; use of vasoactive OTC drugs, i.e. antihistamines as well as OTC cold remedies containing antihistamines or phenylpropanolamine resp. phentolamine, that affects the barrier function of the skin.

RESULTS

Regarding the total DLQI, under treatment with TP it is slightly lower than under SC. Treatment showed significant influence on the DLQI after 4 weeks. However, sub-analysis of particular DLQI categories showed that the differences between TP and SC have been significantly higher in the category «symptoms and feelings», which, for this study setting, is the most decisive category. Already 2 weeks after treatment start, TP showed superiority over SC. After 6 weeks of treatment, decrease of pruritus, xerosis and irritability could be observed. *In summary it can be stated that the application of TP has considerable advantages regarding the relevant aspects of quality of life for patients with breast cancer undergoing chemotherapy.*



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