

## PILOT STUDY OF THE THERAPEUTIC EFFECT OF EXCIPIAL U LIPOLOTION EMULSION IN RADIOTHERAPY PATIENTS WITH INFLAMMATORY SKIN REACTION

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### Summary

During radiotherapy, inflammatory skin reaction develops to a lesser or greater extent in almost every patient. Transdermal moisture loss - skin dehydration, as one of the effects of irradiation, is favorable for the onset of inflammatory skin reactions, it enhances the symptoms and retards skin recovery. **Excipial U Lipolotion**, W/O emulsion with a 4% urea segment rehydrates the skin and decreases the transdermal moisture loss. In the past clinical studies, preparations with a 3-4% urea segment have proved to be efficient means of treating the inflammatory skin reactions.

Based on that, we have conducted a study applying the **Excipial U Lipolotion** preparation on the skin of radiotherapy patients with explicit inflammatory skin reactions. Patients with head and neck cancers as well as breast cancer were included. The preparation's efficiency was evaluated upon a clinical review of the skin condition's subjective parameters by the physician and by questioning the patient whether or not the preparation was useful. We came to a conclusion that **Excipial U Lipolotion** has a favorable effect on the inflammatory skin reactions with a very distinct effect on the dry inflammatory reactions. It also decreases subjective problems - irritation, burning, pain - to a greater extent in radiotherapy patients. Regarding the fact that the evaluation parameters were subjective, further research of the **Excipial U Lipolotion** effect is required, based on objective clinical indications - skin moisture degree during the preparation's application.

KEY WORDS: *inflammatory skin reactions, Excipial U Lipolotion, radiotherapy, transdermal moisture loss*

### ISPITIVANJE TERAPIJSKOG DJELOVANJA EXCIPIAL U LIPOLOTION EMULZIJE NA UPALNE REAKCIJE KOŽE U BOLESNIKA NA RADIOTERAPIJI

#### Sažetak

Tijekom radioterapije u gotovo svih bolesnika se u većoj ili manjoj mjeri pojavljuju upalne kožne reakcije. Transdermalni gubitak vlage – dehidracija kože kao jedna od posljedica iradijacije, pogoduje nastanku upalnih reakcija, pojačava simptome i usporava oporavak kože. Preparat **Excipial U Lipolotion**, V/U emulzija s 4%-tnim udjelom uree rehidrira kožu i smanjuje transdermalni gubitak vlage. Preparati s 3–4%-tnim udjelom uree u dosadašnjim su se kliničkim istraživanjima pokazali učinkovitim sredstvima u liječenju upalnih kožnih reakcija. Temeljem toga provedli smo istraživanje u kojem smo primijenili preparat **Excipial U Lipolotion** na kožu bolesnika na radioterapiji, koji su imali izražene upalne kožne reakcije. U istraživanje su bili uključeni bolesnici s tumorima glave i vrata te dojke. Procjena učinkovitosti preparata provedena je na temelju liječnikove kliničke prosudbe subjektivnih parametara stanja kože i pitanja upućenih bolesniku smatra li da mu preparat pomaže. Došli smo do zaključka da preparat **Excipial U Lipolotion** povoljno djeluje na upalne kožne reakcije, osobito na suhe upalne reakcije. U većine bolesnika na radioterapiji preparat brzo i znatno smanjuje i subjektivne tegobe – svrbež, pečenje, bolnost. Budući da su parametri procjene bili subjektivni, potrebno je daljnje istražiti učinak **Excipial U Lipolotiona** temeljem objektivnih kliničkih pokazatelja – mjerenja crvenila i stupnja vlažnosti kože tijekom primjene preparata.

KLJUČNE RIJEČI: *upalne kožne reakcije, Excipial U Lipolotion, radioterapija, transdermalni gubitak vlage*

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## INTRODUCTION

Inflammatory skin reactions are frequent in radiotherapy patients. Such reactions usually develop 1-2 weeks after beginning irradiation, in the form of a dry or wet inflammatory reaction and erythema. The reaction is most distinct by the end and after the completion of irradiation. It is most unpleasant for the patient because of irritative burning sensation and tension, pain and skin blush. In addition, it represents a significant problem in the course of treatment because it is a frequent reason to stop radiotherapy, to make a recess, or to abort it completely due to a strong skin reaction. Inflammatory reactions occur more often and are more distinct in the areas where epidermal and subdermal tissue are thinner, for example the head and neck area and thoracic skin after ablation of the breast. As radiotherapy is usually conducted postoperatively, the skin in the radiation area is already irritated by the surgery performed, and therefore more prone to an inflammatory reaction. Poor general condition and cachexia, that are very common with oncology patients, also facilitate the development of inflammatory reactions, retard the damage recovery and lower skin's radiation tolerance. One of the significant consequences of irradiation is skin dehydration - transdermal moisture loss. Apart from enhancing pain, burning and skin tension, dehydration lowers skin's recovery capability which is especially the problem with the older patients who, due to their advanced age, have less hydrated skin. Preparations that rehydrate the skin and prevent its further dehydration should consequently soothe inflammatory skin reaction and accelerate its recovery as well as enhance skin's tolerance to radiation. A favorable effect of testing such a preparation, i.e. **Excipial U Lipolotion** on the irradiation-caused inflammatory skin reaction was the goal of our research.

During the three-month period at the Radiation Oncology Department, University Hospital for Tumors, Zagreb, Croatia, we were testing the efficiency of **Excipial U Lipolotion** in soothing of dry and wet inflammatory skin reactions in radiotherapy patients with head and neck, as well as with breast tumor. The goal was to reduce in-

flammatory reactions' signs and symptoms by 50% compared to those at the beginning. The **Excipial U Lipolotion** preparation is an emulsion of a water-in-oil type; it contains 36% lipids and 4% urea. It affects the skin in the way of adding lipids and moisture to the skin's natural protective layer, thus enhancing the skin's capability to recover. Clinical studies so far have shown that preparations containing 3-4% urea improve the skin's hydration and have a good effect in soothing the radiation-associated inflammatory skin reaction.

## MATERIAL AND METHODS

The study was carried out on 30 patients hospitalized at the Radiation Oncology Department: 25 patients with tumor of the head and neck region regardless of its primary location, and 5 female patients undergoing ablation or segmentectomy for breast cancer. Eligibility criteria were the application of radiotherapy and a distinct inflammatory skin reaction. The stage of local and system disease played no role in the selection of patients. Neither prior surgery for head and neck tumor nor any other adjuvant therapy (chemotherapy, hormonal therapy, immunotherapy) after breast surgery played a role in the selection of patients.

Table 1 shows the group of patients with head and neck tumors adjusted to the location of their primary tumor, and Table 2 shows the female patients related to the type of surgery performed:

Table 1.

Primary tumor location	Number of patients
Ca sublinguale	7
Ca laringys	5
Ca baseos linguae	3
Ca oropharingis	3
Ca maxillae	2
Ca tonsillae	1
Ca epiglottidis	1
Ca sinus piriformis	1
Ca metastaticum colli	2

Table 2.

Type of surgery	Number of patients
Breast ablation	3
Breast segmentectomy	2

In the case of patients with head and neck tumors, radiotherapy was conducted using the tele-cobalt therapy (TCT) by photons of 1.25 MV. Total tumor doses of 60 Gy in 30 fractions by 2 Gy (standard fractioning) were applied bilaterally to the facial and neck area with the exclusion of the spinal cord from the photon beam after 50 Gy, and 50 Gy doses were applied to the distal neck. The patients were irradiated using individually formed protection masks.

Patients with breast tumor were treated using beams of a linear accelerator (Linac, Mevatron). All the patients were delivered total tumor doses of 50 Gy in standard fractions. In the case of patients with ablation, the thoracic wall skin was irradiated by 9 MeV electron beams with the application of 1 cm bolus, while the combination of 6 MV photon beams and 20 MeV electronbeams were delivered to the supraclavicular region. The patients with segmentectomy were irradiated with 6 MV tangent photon beams to the breast after which the area of the surgical incision (scar) was radiated by a «boost» dose of 5 x 2.5 Gy. Supraclavicular and axillary regions were also irradiated depending on the stage of the disease.

**Excipial U Lipolotion** is a W/O emulsion of minor viscosity. It contains Triclosan and Chlorhexidin conservatives, 36% lipids, 4% urea, dermatology tested perfume and non-ionised emulor tolerable by the skin. It has the following cosmetic characteristics: it is quickly absorbed, it does not stick, it shines the skin to a very small extent, it is quickly applied to large skin surfaces, it is applicable to mildly hairy parts of the body and is waterproof. Its bio-pharmaceutics' qualities are as follows: it provokes a significant occlusion effect, it enhances and prolongs skin's capacity to retain water, it moistens dry skin, it lowers skin's roughness, it does not irritate mildly damaged skin (urea's concentration below irritation), and it does not increase the production of comedones.

**Excipial U Lipolotion** has following clinical indications: intended for dry to very dry skin, for interval and degree therapy, for therapy of xerotic skin in the winter, Etat craquele, geriatric xerosis with pruritus, for damaged skin therapy - for instance, after psoriasis therapy, system retinoids usage, PUVA-therapy etc., for seborrhoeaic skin. Its clinical qualities are as follows: excellent clinical tolerance, no irritating potential, and it does not contain any potentially allergenic substances such as Kathon, Paraben, Lanolin, Propylenglykol etc.

During the research study, the emulsion was applied to the patients' skin in the field of radiation, twice a day. On weekdays, it was applied in the morning and evening, always after receiving a daily radiation dose. The emulsion was not applied prior to radiation sessions in order to prevent the "build-up" effect. On weekends during the regular radiation pause, the emulsion was also applied in the morning and evening, as well as in the case of possible therapy cessation on weekdays. If for any reason it was necessary to abort the therapy for a longer period (one week or more) and release the patient, the emulsion would be given to him with the application instructions on the same base. The emulsion was applied by nurses according to the instructions and under the physician's supervision. No other local anti-inflammatory therapy was applied to the patients at the same time.

The evaluation of inflammatory skin reaction therapy success was performed on each application day; depending on how many daily radiation fractions the patient was going to receive until the end of radiotherapy. The same physician performed evaluation by days according to the following criteria: skin redness, pain, itching, and desquamation. Patients used their own words to describe does the emulsion provides any relief, and for the purposes of this research their answers were deduced to 3 options: "it helps", "it does not help", "it makes it worse".

Radiotherapy was completed with all the 30 patients, with short radiation breaks (one week at the most) for 5 patients with head and neck tumors due to their moderate and severe inflammatory reaction. Female patients with breast tumor did not discontinue radiotherapy.

## RESULTS

Sixty-three percent of the patients (15 patients with head and neck tumor and 4 female patients with breast tumor) had a significant reduction of clinical parameters by the end of **Excipial** therapy. The most distinct improvements were reported with dry inflammatory reactions, somewhat less in the case of wet inflammatory reactions and erythema.

The rest of the patients did not show a significant reduction of clinical parameters, meaning that it was more or less equal to that of the patients who had not used **Excipial**. Not a single patient showed an aggravation of clinical signs of the inflammatory reaction.

Eighty-three percent of the studied patients (21 patients with head and neck tumour and 4 female patients with breast ablation) gave an affirmative answer to the question: "Do you think that **Excipial U Lipolotion** is helping you?" As a main effect of the emulsion the patients mentioned the skin's cooling sensation along with decreasing the itch, burning and skin tension. Others did not think they felt any better.

## CONCLUSION

**Excipial U Lipolotion** proved to be a very efficient therapeutic means of soothing the clinical signs of inflammatory skin reaction. Soothing of patient's subjective problems was especially distinct; tension, burning and itch in particular. The emulsion produced the most distinctive results with the dry inflammatory reactions. The majority of patients were of the opinion that **Excipial U Lipolotion** was helpful during the therapy and stated explicit relief of their problems. Not a single patient suffered from side effects during the emulsion application, and no increase in the existing inflammatory skin reaction was noted.

The results of the study relied solely on subjective evaluations: physician's evaluation of clinical parameters and patient's evaluation of the effect the emulsion had on his/hers problems. These results without a doubt point that **Excipial U Lipolotion** has a favorable effect on the inflammatory skin reaction. For a more complete and objective evaluation of the **Excipial U Lipolotion's** effect, however, further clinical research studies should be conducted; those in which the clinical score would be supplemented - and a new parameter introduced to the clinical parameters - moisture of skin, which would be measured by an apparatus. Objective measuring of skin moisture - transdermal moisture loss would show the emulsion's direct effect on the skin. Combined with subjective parameters (burning, itching, pain), these objective parameters could give a complete image of the clinical effect of **Excipial U Lipolotion** on inflammatory skin disorders.

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