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SKIN PROTECTION BY SUCRALFATE CREAM DURING ELECTRON BEAM THERAPY

ABDEL MAICHE, OLLI-PEKKA ISOKANGAS and PENTTI GRÖHN

Acute skin reactions, such as erythema and moist desquamation, constitute major problems during radiotherapy of superficially located tumours. There are no drugs available for the skin care. Sucralfate, a widely used anti-ulcer drug, has anti-inflammatory properties, and it activates cell proliferation. Based on these data and our previous experience of sucralfate cream on the aging skin we performed a double-blind randomized study to compare the efficacy of sucralfate cream to a base cream in 50 breast cancer patients receiving postoperative electron beam therapy to their chest wall. The acute radiation reaction of the skin was statistically significantly prevented by the sucralfate cream. The recovery of the skin was also significantly faster in the sucralfate cream group. Side-effects due to the cream were rare.

Acute radiation injury to the skin, ranging from redness to dry or wet desquamation is a common side-effect of radiotherapy. Most frequently it nowadays is seen during electron beam therapy. The severity of the reaction depends on the absorption characteristics of the energy, the type of irradiation, and the type of the skin (1). Concomitant chemotherapy can worsen the reaction. There is no effective means of alleviating or preventing this skin injury. Topical ointments (wax, paraffin, aloe, almond, olive and herb oils), chamomile cream or corticosteroids have been tried but mostly with poor success (2).

Sucralfate is widely used for the treatment of gastric ulcer. Its mode of action is not fully known but it has many interesting effects on the mucous membrane. Sucralfate stimulates cell growth by increasing the amount of prostaglandin E and epidermal growth factor (3, 4). It has a clear anti-inflammatory effect by inhibiting gamma-

interferon and interleukin-2 (K. Bendtzen, personal communication). It also increases the epithelial circulation, thus ameliorating the nutrition of the mucosa (5).

There is an increasing amount of data on the protective effect of sucralfate on the mucosal membranes during radiotherapy and even during systemic cytostatic chemotherapy. Large ingested daily doses of sucralfate suspension have been shown to prevent intestinal mucositis during radiotherapy to the abdomen and the pelvis (6–8). Its prophylactic intraoral use ameliorates the mucosal reaction of the mouth during both radio- and chemotherapy (9, 10). Our previous experiences of the skin caring effect of sucralfate cream on the aging skin warranted us to examine and evaluate the efficacy of the cream on the skin during radiotherapy.

Material and Methods

Fifty patients operated on for breast cancer and scheduled to receive electron beam therapy postoperatively were included in the present study. The mean age of the patients was 60 years (range 33–84 years).

Radiotherapy to the scar area was given as a non-split course using 6 MeV electron beam. The total dose was 50 Gy, 10 Gy weekly in 5 fractions. The surface area of the portals varied from 11 cm × 11 cm to 20 cm × 20 cm. The scar situated horizontally in the middle of the portal.

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The patients were randomized in a double-blind design to apply sucralfate cream containing 7% of micronized sucrose sulfate (BM Sucramed, Bukh Meditec A.S., Copenhagen, Denmark), or equivalent base cream on either side of the scar. Thus, every patient served as her own control. The creams were gently applied by the patient twice a day during the 5-week radiotherapy and for two weeks thereafter. The creams were identical as to the smell and appearance. The composition of the base cream is: PEG 400, PEG 400MS, arachis oil, isopropyl myristat, glycerine, lanoline and ion exchanged sterile water.

At the end of each week of treatment the skin reactions were evaluated by the responsible physician. The adverse effects of the radiotherapy were graded on a 5-point rating scale as follows: 0 = no reaction, 1 = light erythema, 2 = dark erythema, area painful, 3 = wet desquamation, 4 = necrosis of the skin. The areas were also photographed. The patients were asked about their preference and the cosmetic properties of the creams.

Results

Forty-four patients were included in the final analysis. Five patients were excluded because of a delay in the therapy due to one week's reparation of the linear accelerator, and one patient refused to continue her radiotherapy. The treated sites were evenly divided between the test creams.

The grade 1 and 2 reactions appeared significantly later on the areas treated with sucralfate cream. Grade 2 reactions were observed highly significantly more often at 4 weeks ($p=0.01$) and at 5 weeks ($p>0.01$ but <0.05 , two-tailed χ^2 -test and Wilcoxon-Pratt test) in favour of sucralfate. The weekly cumulative amounts of grade 1 and grade 2 reactions showed the same difference. The recovery of the skin lesions was faster on the areas treated with the sucralfate cream, and after finishing the radiotherapy the grade of skin reaction remained lower in the sucralfate than in the base cream treated areas ($p=0.05$, Figure).

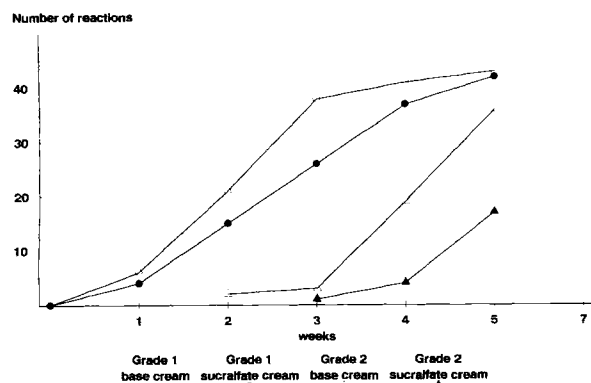


Figure. Cumulative appearance of grade 1 and 2 skin reactions during the electron beam therapy.

Itching was reported in 9 areas treated with sucralfate cream and in 12 areas with base cream. No allergic reactions were seen. The patients considered the cosmetic properties of the two creams excellent.

Discussion

A wide range of topical agents are used in the skin care of patients undergoing radiotherapy. Systemic studies of their efficacy are lacking. There is no scientifically established or accepted method, apart from the split, to prevent early or late radiation reaction of the skin.

In the present randomized double-blind study we have clearly shown that sucralfate cream prevent the acute radiation reaction of the skin. There is a statistically significant difference in the appearance and amount of grade 2 reactions, as well as in the recovery of the irradiated skin.

Sucralfate is a very interesting drug. Originally, it was thought to cover the gastric ulcer, thus allowing it to heal. Later investigations have revealed new features in its mechanism of action, mostly targeted on the lymphokines and growth factors of the superficial epithelial tissue. The mode of activity is highly similar to that of corticosteroids with the exception of the stimulative effect of sucralfate on the cell growth. Previous clinical studies have shown it to protect the intestinal and oral mucosa during radio- and chemotherapy (6–10). So far, no studies have been published on its protective activity on the irradiated skin. Our previous study showed that sucralfate cream accelerates cell proliferation in the superficial skin layers leading to a clear thickening of the epidermis and dermis (11). The findings suggested that sucralfate is active also on the skin. The same properties are assumed to alleviate the radiation reactions and to enhance the recovery of the skin.

The cosmetic properties of the cream were good. No adverse reactions were observed. There is a small risk of topical allergic reaction, since the base cream contains a small amount of pure lanolin. We recommend the use of sucralfate cream for the protection of skin during radiotherapy.

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